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, 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.

Question

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? Don't know any.

b. Is the number of medical accidents increasing? Yes.

c. How much is the budged for those studies and research activities? No research funding of government budget.

d. Is the status of medical errors understood well in your country? Taiwanese did not have a good understanding of medical accidents.

2. Public concern for medical accidents/errors

a. To what extent are medical accidents/errors getting public concern in your country? Quite a few cases reported by mass media, particularly when the family members of the patient experienced medical errors protest violently at the front of hospital.

b. Is the number of lawsuit against medical accident increasing? Yes, according to statistics.

c. Is the industry interested in patient safety? Probably yes.

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?

Some health officers and a few in the industry knew it. However, no particular influence so far.

B. Action by Stakeholders

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

Is there a governmental policy especially for medical accidents? Law (Medication Harm Compensation Act) passed and a fund set up in 2000 to compensate drug accidents. Under the law, patient will be paid by the fund if a drug is in good quality and appropriately prescript, nevertheless, adverse results occurred. A draft of law (Malpractice Handling Act) on resolving dispute on medical accidents/errors between patients and providers has been proposed by National Department of Health in 2000 but not able to be approved by the congress.

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

- At the very beginning, the Taiwan Medical Association was responsible for the appraisal of medical affairs. Then, this task was taken over by the Medical Affairs Deliberation Committee of Department of Health since 1987.
- The government has instituted policies related to medical accidents both directly and indirectly, for example, Medical Act (1986), Medication Harm Compensation Act (2000). In particular, Malpractice Handling Act was proposed by National Department of Health in 2000 but not been approved by the congress.
- The Taiwan Joint Commission on Hospital Accreditation, the third party organization,

financed by both Department of Health and Hospital Association, was responsible for hospital accreditation, quality indicators and improvement activities including education and training in hospitals, and physician-patient relationship projects. And the results of the accreditation are made available for public.

2.Action by other stakeholders Is there a policy by provider association, medical doctor, nurse, or hospital?

- The Taiwan Medical Association established a Medical Ethics Committee to spontaneously review its members' behavior and practice.

No other policy ever been proposed by provider associations.

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?

The first patient group established in 1998, i.e., the Association for the Advancement of Patients' Rights of the Republic of China. There was a "Physician X-file" collecting all malpractice litigation information established by the Association for the Advancement of Patients' Right of ROC. As the pressure of Department of Health and medical groups, due to lacks a mechanism to verify, this file just showed on the web for a day and then was forced to close up.

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. The Taiwan Joint Commission on Hospital Accreditation, the third party organization, financed by both Department of Health and Hospital Association, is responsible for hospital accreditation,

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?

Officially, no reporting system of medical accident is taken place.

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?

One or two studies ever published of this regard. There is no formal and/or systematic collection in Taiwan.

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. However, compensation is given for adverse effects of vaccination.

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

No, as mentioned above.

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?

Quality is the top issue of National Health Insurance. Various tools and indicators were adopted by the Join Commission on Hospital Accreditation in order to improve quality of care. However, not much attention paid to medical errors.

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?

Not much.

F. Risk Management at Hospital or Clinic level

1. Risk Manager

a. Is there an organization to train a risk manager in your country? No.

b. Is there any post taking charge of medical error prevention such as risk manager in a hospital? No.

2. CQI (Continuous Quality Improvement) / Patient Safety

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

Yes. Hospitals are required to form such unit. The function of the unit is an important part of accreditation.

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? Individual hospital develops its own system.

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? Most hospitals develop their own measures.

5. Risk Analysis Method

What methods are generally employed to analyze risks associated with medical errors at health care institutions? Don't know.

6. Education and Training for Employee

a. Is there any training course for employees in a hospital? Most hospitals provide continue education and training for their employees. A certain number of credits required for extension of specialty license for MD's and skills to deal with National Health Insurance for various staff make education/training programs quite popular in and among hospitals.
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? Yes, however, mainly focus on quality but not on medical errors.

An exploratory study of the medical accident prevention policy in Taiwan

Chih-Liang Yuang and Yahui Sophie Hsieh

Summary

Objective:

The main objective of this study was to investigate medical accident prevention policy in Taiwan.

Methods:

There were some researches related to malpractice and dispute claim but no studies about medical accident prevention policy in Taiwan.

The open-ended questionnaire was originally developed by the National Institute of Health Services Management in Japan. For the purpose of this study, we translated it in Chinese and then revised it in a feasible form. Moreover, the in-depth interview was undertaken, from 13th to 28th December 2001, to explore current issues related to medical accident such as action by stakeholders, legislation and judicial involvement, risk management, and so forth.

The sample was purposefully selected. There were nine interviewees selected in this study. Three of them were task-related from government organizations, i.e., National Department of Health, Central Taiwan Office of Department of Health, and Taichung County Health Bureau. Other six of them were representatives of non-government organizations (NGOs). They are the Consumers' Union, Taiwan Medical Association, Taiwan Joint Commission on Hospital Accreditation, Taiwan Healthcare Reform Foundation, and the Association for the Advancement of Patients' Rights of the Republic of China.

Results:

Information on medical accident

- Regarding the incidence of medical accident or medical error, there was no official statistics and surveys. However, most of interviewees agreed that the incidence of medical accident was increasing.
- Most of interviewees recognized that most Taiwanese didn't have a good understanding of medical accident. Normally, when people suffered from malpractice , they will have a profound

experience of what happened and then take some actions such as ask for help from social workers or legislators

- How much lay people were concerned about the issue of medical accident was, mainly, affected by the mass media.
- Generally, there was no research funding for medical error or patient safety issues in terms of government budget.
- One interviewee pointed out that most health care organizations were concerned about the issue of patient safety but they did not have relevant skills or capacities, i.e., know-how, to implement.

Information system

- Officially, no reporting system of medical accident was taken place.
- There was a "Physician X-file" collecting all malpractice litigation information established by the Association for the Advancement of Patients' Rights of the Republic of China. As the pressure from Department of Health and medical groups, due to lacks a mechanism to verify, this file just showed on the web for a day and then was forced to close up.
- In viewpoint of patient complaints, nationally, there were no official organizations to be in charge of data collection and analysis. Most interviewees agreed that when patient complaints happen, the hospitals should simultaneously figure out the problems or concerns of patients.

Legislation and judicial involvement

- With regard to the legal system, if a doctor reports a case whose error is not caused by her/his negligence or system error, there was the system to protect the reporter from legal liability.
- If the medication harms occurred, however, the prescription is proper and the drug is in good quality, not due to human error or negligence, there will be some compensation for patients. That is no fault compensation scheme for side effects of drugs but not for medical accident or medical error.

Action by stakeholders

- At the very beginning, the Taiwan Medical Association was responsible for the appraisal of medical errors. Then, this task was taken over by the Medical Affairs Deliberation Committee of Department of Health since 1987.
- The government has instituted policies related to medical accidents both directly and indirectly, for example, Medical Act (1986), Medication Harm Compensation Act (2000), and Exceptional Diseases Prevention and Cure and Drugs Act (2000). In particular, Malpractice Handling Act

will be instituted in the very near future.

- The Taiwan Medical Association established a Medical Ethics Committee to spontaneously review its members' behaviour and practice.
- The first patient group on patients' rights, the Association for the Advancement of Patients' Rights of the Republic of China, established in 1998.
- The Taiwan Joint Commission on Hospital Accreditation, the third party organization, was responsible for hospital accreditation, quality indicators and improvement activities including education and training in hospitals, and physician-patient relationship projects. And the results of the accreditation are made available for public in terms of accreditation levels of hospitals.

Safety and quality

- There were no specific organizations to train risk managers. But some business consultants organized general risk management courses.
- In the medium and large hospitals, they had integrated managing units which in charge of quality improvement or medical accidents.
- Regarding the patient safety system, most hospitals adopted a task force to deal with. That is, in the organization chart, they probably had some committees such as medical ethics committee or medical quality improvement committee to prevent errors.
- The Taiwan Joint Commission on Hospital Accreditation had developed some educational tools and training materials for prevention of patient falls.
- Regarding the peer review, it was more "insurance-oriented". The National Health Insurance Bureau invites members of Medical Association to review claims for insurance payment. No in advance peer review was taken place, unless more and more hospitals adopt clinical trials due to NHI DRG payment.

Conclusions

Generally speaking, the medical accident prevention policy is much more conservative as the culture of physicians. Briefly, there are some issues arising in this study as follows.

First, patient education needs to be enhanced and organized more systematically. Then, lay people will have the right or good understanding of basic medical knowledge or medical accidents.

Second, more researches related to medical accidents or patient safety in Taiwan are needed and

should be encouraged both quantitative and qualitative or both epidemiological and analytical.

Third, although there are certain mechanisms related to patient safety in the Hospital Accreditation Standards, it is not strong enough to encourage health care organizations to do more efforts on the issue of patient safety.

Forth, most interviewees agreed that when patient complaints occurred in the hospital, the hospital should handle these complaints at once. However, this method of handling patient complaints is not 'independent' enough. In the future, it is better to set up a "third body" to handling patient complaints.

Finally, no reporting system of medical accidents was taken place in Taiwan. That is, in the policy level, it is fragmenting, not comprehensive and integrated, in terms of patient safety.

Response to the international comparative survey of medical Accident prevention and patient safety policy
The New Zealand situation

Respondent: Laurence Malcolm

Medical Accident Prevention Policy and Quality Promotion in New Zealand

Response to a questionnaire on international comparison of medical accident prevention policy from Toshihiko Hasegawa, M.D., M.P.H., Director, Department of Health Care Policy, National Institute of Health Services Management, Japan

Prepared by Laurence Malcolm

Professor Emeritus and Consultant
Aotearoa Health
Lyttelton RD1
New Zealand

July 2002

CONTENTS

1. Executive Summary

New Zealand is one of many countries now giving special attention to building a quality culture in its health system. Medical error and adverse events have been important political and media influences but the main drivers in building this quality culture are internal largely driven by clinical leadership.

Addressing medical error as an important feature of this quality culture but the emphasis is now on a broader systems approach and on building a culture of safety rather than blame.

This safety culture is being built by clinical leaders and others in a new partnership with management within all provider organisations. The new district health boards (DHBs), integrating all services, primary and secondary, hospital and community, disability and public health are proving to be important structures for developing an integrated quality culture.

Recent studies of medical error and adverse events in New Zealand have shown that such events were associated with nearly 13% of hospital admissions, similar to other international studies. A third of these events were found to be highly preventable.

A wide range of organisations are involved in promoting and contributing to the building of a quality culture including;

- Ministry of Health with an overall leadership role
- National Health Committee with a key independent advisory role to the Minister of Health
- New Zealand Medical Council responsible for medical registration and standards
- Clinical Colleges responsible for specialist accreditation and professional development
- Quality Health New Zealand/Standards New Zealand for accreditation of health services
- Accident Compensation Corporation for providing a government no-fault insurance system compensating patients for the consequences of medical misadventure
- Health and Disability Commissioner for responding to patient complaints and taking appropriate action
- Clinical Leaders Association of New Zealand exercising a key role in promoting clinical leadership as a critical factor in building a quality culture.

A range of information systems and projects have been developed to promote quality and safety.

The Ministry of Health has developed a system of reportable events classifying these as reportable, serious and sentinel depending on severity.

The Ministry of Health has also taken a leadership role in developing systems for developing clinical excellence through credentialling of senior medical staff in hospitals, clinical audit and related activities.

A wide range of legislation supports quality initiatives. However legislation has been a relatively minor factor in driving the activities and achievements reported.

Studies of quality improvement, including leadership in district health boards, has demonstrated that accountability for clinical quality is located within clinical divisions with clinical leaders occupying a a key role in promoting quality. Of particular importance is that resource management is now seen to be an integral part of the management of quality. Clinical leaders are taking a key role in determining resource priorities.

Many quality initiatives and achievements were reported including developing greater openness in building a culture of safety, a growing partnership between clinicians and management and the integration of quality efforts into a coherent system.

Important developments have also occurred in primary care organisations (PCOs) now representing the professional interests of some 90% of general practitioners. All PCOs have developed arrangements for quality. Many quality achievements were reported including high levels of immunisation, disease management and screening programmes supported by training and information systems.

The key lessons from the New Zealand experience in building a quality culture are that;

- it should be based upon a comprehensive systems approach with medical error being addressed as part of the total system

- provider organisations have a central role in building and delivering a quality culture

- clinical leadership is the critical factor in achieving this within provider organisations.

The role of national agencies in the building of this culture is the valuing and supporting of the key role of clinical leaders and of provider organisations.

2. Background

2.1 Building a quality culture

New Zealand, along with many other countries, has been giving special attention in recent years to building a quality culture in its health system (National Health Committee, 2002). Key drivers in this development have been, as for other countries, increasing awareness of adverse events Davis et al, 2001), clinical failings (Paul, 2000), increasing consumer expectations with events and action fuelled by often hostile media coverage (Wright et al, 2001; Malcolm et al. 2002). To an increasing extent the term clinical governance, similar in its definition and application in Britain, is being applied as a label to a wide range of quality initiatives being implemented (Wright et al, 2001; Malcolm et al. 2002a; Malcolm et al, 2002b).

One of the most important events which may have contributed to the sensitisation of New Zealand doctors to safety and quality was the Cartwright inquiry into the issues surrounding cervical screening in Auckland. This may be seen as New Zealand's equivalent of Bristol but at a much earlier stage. This inquiry and subsequent events had a profound effect on medical culture. Associated with these changes has been the struggle to recover from the damage done to clinical quality by the commercial experiment with the New Zealand health system of the 1990s, possibly more harmful than the experience in Britain (Hornblow, 1997; Health and Disability Commissioner, 1998). Another factor is what may be unaffordable consumer and professional demands for international clinical standards with a national per capita income some 20% below the OECD mean.

Significant progress is now being made in building a quality culture. Although external political, consumer and media pressures have been important the main drivers have been internal. Of critical importance has been the role of clinical leadership in building this quality culture. As a consequence New Zealand's clinical quality developments appear to be more significant than other comparable countries, as commented upon by key observers such Berwick.

Medical error and adverse events, from a political and professional perspective, have been important driving factors in action to build a quality culture. However approaches are now focussing on a wider systems framework, including building a culture of safety rather than blame. Four categories of quality issues are now being addressed (Wright et al, 2001). These are;

- the few but highly publicised 'bad apples'
- adverse events, the main driving force behind international clinical improvement initiatives the key feature of these categories being patient harm
- best practice' clinical issues, in which there may not be patient harm but significant

inefficiencies and access problems
- wider system issues affecting quality, eg building a culture of safety rather than blame as a key strategy to address quality issues.

This paper will seek to address the issue of medical error and clinical safety within this broader systems framework.

2.2 New Zealand background: recent health reform

The Labour-Alliance government, elected in 1999, introduced sweeping health system changes, largely abolishing the previous government's commercial model which had failed in achieving its goals of better access and cost containment. Now established are 21 decentralised and fully integrated district health boards (DHBs). These bring together the funding and provision of primary and secondary, hospital and community care and public health services with a requirement that they achieve specified population health and clinical outcomes as set out in the New Zealand Health Strategy (Minister of Health, 2000) and the Primary Health Care Strategy (Minister of Health, 2001). There is a strong emphasis on quality as a key factor in achieving better health outcomes.

However organisational change has also complicated the implementation of quality initiatives. There are major and continuing stresses associated with the radical restructuring implemented in 2000. These are placing major demands on the system generally and especially those in managerial and clinical leadership positions seeking to promote safety and quality.

2.3 National quality developments

Significant recent progress has been made by the Ministry of Health at the national level in building a quality driven system. A national framework for credentialling of senior medical officers has been developed along with a system of reportable sentinel events and other clinical practice improvement activities (Ministry of Health, 2001a&b). Quality Health New Zealand,(2001) as an independent agency with the support of Standards New Zealand, has developed a new and broadly focused system of accreditation of health services, now being widely implemented by DHBs.

The National Health Committee (2002) has taken a recent lead role in promoting clinical quality. However, as will be described, the main thrust for the delivery of quality has been developed at the local clinical level. The contribution of each of these developments to the building of a high quality culture will be discussed further below.

3. SOURCES OF INFORMATION

This report has sought to draw upon all available sources of information relating to the issue of medical error, clinical safety and quality generally. These include a wide range of documents published and unpublished, web sites of key organisations and three major studies of quality and safety commissioned by the Ministry of Health through the Clinical Leaders Association of New Zealand (CLANZ). These are as follows.

Wright et al (2001) Clinical leadership and clinical governance: a review of developments in New Zealand and internationally

This is an extensive literature, document and experience review on the issues leading to the international quality movement. It addresses questions such as what is quality, is quality an investment and the development of clinical leadership.

Malcolm et al (2002a) Clinical leadership and quality in primary care organisations in New Zealand

This is a study of clinical leadership, and progress in improving clinical quality, in 12 primary care organisations (PCOs). The study shows that a wide range of quality initiatives have been established, with significant achievements..

Malcolm et al (2002b) Clinical leadership and quality in district health boards in New Zealand

This is a study of clinical leadership and progress in improving clinical quality in 10 DHBs, six providing tertiary level services. Perhaps the most significant achievement from a quality perspective is the convergence of governance/management and clinical cultures in building a new partnership focusing upon health outcomes.

This report has been organised, as far as possible, around the format of the questionnaire from the Principal Investigator

4. MEDICAL ERROR IN NEW ZEALAND

4.1 Historical background

As indicated above awareness of medical errors and the serious adverse consequences was drawn to professional, political and media attention during the extended Cartwright enquiry in 1988. What became known as the Cartwright Enquiry exposed the failings of a gynaecologist and his

colleagues in 1988 and led directly to the subsequent establishment of the Office of the Health and Disability Commissioner (HDC). This Office has the statutory power to receive and to enquire into medical complaints, as will be discussed below. Ethics committees became wide ranging in their power and scope with a majority of non-health professionals to address not only research but also clinical issues.

The important consequence of the Enquiry and subsequent developments did much to sensitise New Zealand doctors and the health system generally to the need for a much more open approach to adverse events. It also reduced the power and dominance of medical professional control over these events.

Reports from the HDC have played an important part in generating ongoing concern and action about quality in the New Zealand Health system. These include the report on Canterbury Health Limited (Health and Disability Commissioner, 1998, 1998), focussing on Christchurch Hospital, Gisborne Hospital 1999-2000 (Health and Disability Commissioner, 2001) and others. These reports found organisations that were under considerable stress with serious conflict between clinical staff and management. These system problems were responsible for, or were likely to lead to, the adverse events reported which led to in the initiation of the investigations.

4.2 New Zealand studies of medical error/adverse events

New Zealand is one of few countries which has undertaken a comprehensive study of a adverse events relating to hospital admissions. In 1998 Davis et al (2001) studied the occurrence, impact and preventability of adverse events in public hospitals. A two-stage retrospective review was carried out on 6,579 medical records. These were selected by systematic list sample from admissions for 1998 occurring in 13 public hospitals
throughout New Zealand providing acute care and with over 100 beds. Following initial screening, medical records were subject to structured implicit review by a team of trained medical officers using a standardised protocol.

Analysis of the 850 adverse events (which may have occurred either within or outside public hospitals) were associated with 12.9 percent of admissions, comparable with other international studies. Approximately 35 percent of adverse events were classified as highly preventable. Although less than 15 percent of adverse events resulted in permanent disability or death, an average of over nine days per event was added to hospital stay. Nearly a fifth of events originated from outside public hospitals, only a quarter of which arose in another institutional context. Patient age was an important risk factor for an adverse event. Systems errors featured prominently in the analysis of areas for the prevention of recurrence.