

training materials designed to alter behaviors to prevent errors and increase safety?

Trust developed tools and training materials included

- those utilized in the induction/refresher courses mentioned in 6. above;
- Risk Management Computer Systems;
- an Internal Safety Notice system which informs staff of current safety related issues/problems. These are disseminated throughout their Risk Management network and provides regular feedback to local Risk Officers on all risk issues through the same network;
- education on clarity as to exactly what staff are required to do in order to look at their practice, review their service in accordance with the CNST standards and make absolutely clear what the Trust means by 'fair blame' and 'accountability'.

The Medical Defence Union has training materials that they supply to their members. They are currently focusing on the primary care sector, but their training materials are available to all members.

There are national training centres where surgeons and doctors can get skill certification, i.e., surgeons can get laparoscopic accreditation, the Resuscitation Council offers Advanced Life Support Courses and certification. Many of these certifications are required by private providers, such as BUPA and BPP who, for example, require surgeons to be properly accredited before they are allowed to operate. The NHS does not currently require specialist certification, but one would assume that certification would play a part in the hiring process. The GMC has a specialist register.

ALARM state that there is a real dearth of this sort of material and that currently risk managers must create their own. They state that this is a daunting task that is beyond the abilities of any one organisation or individual. The implication is that this is an area of need and where more work must be done.

BIBLIOGRAPHY

Government Papers

Building a Safer NHS for Patients
Department of Health 2001

An Organisation with a memory
Department of Health 2000

Supporting Doctors, Protecting Patients
Department of Health 1999

A First Class Service: Quality in the new NHS

Department of Health 1998

The new NHS: Modern, Dependable.

Department of Health 1997

Original Research

Adverse events in British hospitals: preliminary retrospective record review

Charles Vincent, Graham Neale, and Maria Woloshynowych

BMJ 2001; 322: 517-519

Incidence and types of preventable adverse events in elderly patients: population based review of medical records

Eric J Thomas and Troyen A Brennan

BMJ 2000; 320: 741-744

Current cost of medical negligence in NHS hospitals: analysis of claims database

Paul Fenn, Stephen Diacon, Alastair Gray, Ron Hodges, and Neil Rickman

BMJ 2000; 320: 1567-1571

Review Papers

Reporting and preventing medical mishaps: lessons from non-medical near miss reporting systems

Paul Barach and Stephen D Small

BMJ 2000; 320: 759-763

Detecting and reporting medical errors: why the dilemma?

Daniel A Pietro, Linda J Shyavitz, Richard A Smith, and Bruce S Auerbach

BMJ 2000; 320: 794-796

System changes to improve patient safety

Thomas W Nolan

BMJ 2000; 320: 771-773

Epidemiology of medical error

Saul N Weingart, Ross McL Wilson, Robert W Gibberd, and Bernadette Harrison

BMJ 2000; 320: 774-777

On error management: lessons from aviation

Robert L Helmreich

BMJ 2000; 320: 781-785

Anaesthesiology as a model for patient safety in health care

David M Gaba

BMJ 2000; 320: 785-788

Human error: models and management

James Reason

BMJ 2000; 320: 768-770

News Items

Adverse events may cost NHS £1bn a year

BMJ 2001; 322:

NHS faces medical negligence bill of £2.6bn

Annabel Ferriman

BMJ 2001; 322: 1081

Cost of medical negligence in NHS rose by 7% a year in 1990s

BMJ 2000; 320

NHS faces rise in negligence payments

Clare Dyer

BMJ 2001; 323: 11

Estimate of 98 000 deaths from medical errors is too low, says specialist

BMJ 2000; 320: 1362

Opinion

Not again!

Philip J Bickford Smith, J R C Seale, Saad M B Rassam, Tim Wilson, Anmol Malhotra, Mathew Matson, Otto Chan, and Roger M Goss

BMJ 2001; 322: 548

Medical errors: a common problem

K G M M Alberti

BMJ 2001; 322: 501-502

Safe health care: are we up to it?

Lucian L Leape, Donald M Berwick

BMJ 2000; 320: 726-7

Adverse events in British hospitals

Tuan V Nguyen, Ken M Hillman, Michael D Buist, S Chakraverty, J Wright, Rosalind Plowman, Jennifer A Roberts, Nicholas Graves, Mark A S Griffin, Barry Cookson, Lynda Taylor, Brian T Collopy, I G McDonald, David Griffith, Paul Diggory, Anand Mehta, Charles Vincent, Graham Neale, Maria Woloshynowych, R E Ferner, J K Aronson, and Stephen Bezruchka

BMJ 2001; 322: 1425

Medical errors

M H Gough, Paul Buss, Tim Wilson, Charles Turton, John Nottingham, Greg Rubin, Richard Horton, Nicola J Maran, Ronnie J Glavin, Richard A Grunewald, Carina J Mack, Tim Root, Angela Stefanou, Jim Siderov, Mario de Lemos, N J Langford, U Martin, M J Kendall, R E Ferner, Natalie Smith, Nick Burns-Cox, Lemke Solomon, and Simon Holmes
BMJ 2001; 322: 1421

Explaining about possible adverse events may reduce problems

Ron Behrens
BMJ 1996; 313: 1553-1554.

An ethical dilemma: Medical errors and medical culture • An error of omission • Commentary: Learning to love mistakes • Commentary: Doctors are obliged to be honest with their patients • Commentary: A climate of secrecy undermines public trust

Peter A Singer, Albert W Wu, Seena Fazel, and John McMillan
BMJ 2001; 322: 1236-1240

Reducing error, improving safety

Victor Barley, Graham Neale, Christopher Burns-Cox, Paul Savage, Sam Machin, Adel El-Sobky, Anne Savage, Aziz Sheikh, Brian Hurwitz, C K Connolly, Pia Maria Jonsson, Göran Tomson, Lars Räf, Ken McCune, Ron Law, Roger M Goss, Anonymous, Carlos A Estrada, James Carter, Clyde Brooks, Ann C Jobe, Jonathan Aldridge, Peter Freeland, Brenda Ashcroft, Max Eistein, Nicholas Boreham, Peter J Shirley, Leo Strunin, Maldwyn Morgan, Paul Cartwright, and Robert P Coffey
BMJ 2000; 321: 505

Press: Blunders will never cease • How the media report medical errors • A risky business

Trevor Jackson and Alison Harper
BMJ 2001; 322: 562.

Accreditation's role in reducing medical errors

Dennis S O'Leary
BMJ 2000; 320: 727-728

Medical error: the second victim

Albert W Wu
BMJ 2000; 320: 726-727

Let's talk about error

James L Reinertsen
BMJ 2000; 320: 730

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

Respondent: Bama Frits

Belgium

Answers to the survey of medical accident prevention policy in Belgium:

A. Information on medical error

1. Studies and research activities on medical accidents/errors:

- a. There are no studies, epidemiological or otherwise concerning medical accidents/errors. Seperate insurers have seperate databases concerning medical accidents/errors but these are not linked nor are there any analytical studies performed on them. The main insurers are CM and De Voorzorg (public health insurers) who respectively insure 60% and 30% of the Flemish population and Fortis AG and KBC (medical liability insurers) who insure almost the entire medical community. Within several hospitals throughout the country information on medical accidents/errors seems to be available but for internal use only.
- b. Though the number of complaints in connection with medical accidents/errors is increasing, it is assessed that the number of medical accidents/errors remains roughly status quo.
- c. There's no information available on this subject.
- d. Although it is understood by the medical community, the insurers and the general public that medical accidents/errors are a serious reason for concern, and each group is working out its own guidelines for prevention, but there is little or no open communication between the partners involved.

2. Public concern about medical accidents/errors

- a. There's great public concern in Belgium concerning medical accidents/errors, which is very well expressed by the huge media interest each time a 'therapeutic error' (as medical accidents/errors are called in Belgium) is brought forward by a member of the public in a lawsuit or otherwise.
- b. In Belgium the number of lawsuits concerning medical accidents/errors are increasing but no statistics are available on this subject. Of the record though some of the insurers say that some 80% are due to complications in a medical act or poor communication between patient and doctor, evoking frustration and anger with the patient.
- c. The industry is interested in patient safety which is clearly shown by the diverse protocols and safety guidelines in hospitals, clinics and surgeries throughout the country, but there's no clear and bounding guidelines provided by the federal government on this issue.

3. Impact of IOM report

It's impossible for me to assess the influence of this report because it wasn't issued to me.

B. Action by stakeholders

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

There are no government policies concerning medical accidents.

2. Action by stakeholders

There are clear ethical and professional guidelines for medical doctors and nurses and each hospital has its own set of protocols and guidelines. These different groups are controlled by the local and national medical boards plus in case of a hospital connected accident by the medical and ethical board of the hospital concerned.

3. Action by patients, patient groups or representatives

In Belgium there's only one patient representatives group which is called 'Erreur Medical' but its influence is minor.

4. Third party accreditation

Though hospitals have to meet minimum general criteria, there's no evaluation/accreditation organisation in Belgium.

C. Information systems

1. Reporting/information system

There's a voluntary adverse event system where concerning pharmaceutical products, its data is collected by the pharmaceutical industry. Concerning medical accidents/errors there's also an voluntary system and the data is collected by the hospital itself and analysed by the medical and ethical board of that hospital. In Belgium legal protection exists in form of 'het medisch geheim' (the medical confidentiality act) which can be overruled by a appointed court.

2. Complaints from patients or their families

Patient data is collected by the hospital, by the local medical board and by the public health insurer of that particular patient. Its data are assessed in a closed-session medical board which are covered by the medical confidentiality act and by the public insurers medical board. This medical board acts as an intermedium between patient and doctor or hospital.

3. Public availability of medical outcome information

There is no such information available at the moment.

D. Legislation and judicial involvement

- a. There is no such system in Belgium, liability is assessed by the local medical board, and in case of a lawsuit by the correctional court.
- b. To the extent of my knowledge there is no such compensation scheme available in Belgium.

E. Concept of quality and safety

Due to the fact that I haven't received this IOM report it's relatively difficult to assess its impact.

F. Risk management at hospital or clinic level

1. Risk managers

- a. In Belgium risk management forms part of the curriculum of 'Verpleeg –en Ziekenhuiswetenschappen', a program to form hospital management staff provided by most belgian universities, but there are no independant organisations training staff in risk management.
- b. In most belgian hospitals the head of the medical board, a practising medical doctor, is charged the communication and cooperation between the medical doctors of his hospital and as such also responsible for the prevention of medical accidents/errors.

2. CQI/patient safety

In most hospitals there is regular contact between the medical board and hospital management staff but there's a huge inter-hospital difference to the effectiveness and manner of this feedback.

3. Fail proof and fail safe fault system

Most high risk areas in hospitals have fixed protocols and procedures to maximise patient safety. These protocols are usually self-constituted by hospital staff.

4. Specific measures for high frequency risk procedures

In most belgian hospitals fixed protocols and procedures involving a.o. double checks are used to prevent common accidents.

5. Risk analysis methods

There is little or no analysis on epidemiological basis.

6. Education and training for employees

- a. Regular training courses are required to update employees especially in high risk areas in hospitals, these are mostly provided by the medical doctor or headnurse of the unit involved. They get most of there knowledge in peer training or peer reviews.
- b. These tools are recently put into use in the education of student-nurses and medical doctor students.

G. Peer review

In Belgium each medical practising doctor who is accredited by the gouvernement is required to obtain at least 200 Nascholings Eenheden (training units) within one year to remain accredited. Within this training package at least 30 units have to be on an ethical or economic topic, another minimum of 40 units and maximum of 80 units can be obtained by peer review and meetings with fellow medical doctors on diverse topics.

A special accreditation committee is responsible for this accreditation of the medical corps.

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

Respondent: Philippe R. Mosse and Francois Eisinger

France

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:, 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

Forewarning:

1 From our point of view if what is an error is sometime obvious, (blood transfusion with ABO incompatibility), more often the boundaries among, errors, imprudence, and adverse reactions following standard practice are fuzzy. External judgment had to be done (of which the golden standard is judicial).

2 Many surveys, statements, formations, information and statistics are gathering heterogeneous situations and are more or less focus on "unwelcome outcomes" which classification is based on background, causality and/or seriousness rather than on imputation/responsability/liability.

3 Guidelines, regulation statistics are mainly limited to hospitalized-based care, really few actions are targeted to both hospitalized and ambulatory care.

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?

Yes but mainly (is not solely) for accidents i.e. side effects of care. Few focus on learning curve (experience). No specific survey for error per se. Non-epidemiological analytical studies?

Not in the professional press but some reporting/debriefing are available in "top" institution which harbour quality control unit (or equivalent) for example I've got an analytic report on a

ABO incompatibility Please give references if available.

(Cf. appendix)

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

What is known is that the number of reported (registered) cases are increasing for the majority of accident under scrutiny. However for some of them, blood transfusion there is an observed decrease (fall of attention and/or overall decrease of transfusion)

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

The main call for grant in health research is "The PHRC" from the minister of Health and for the last years no specific topic was related to medical error. I think few research grants are allocate to that topic. The sole private insurance in charge of hospital risk allow annually a research fund for safety of 5000\$!

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

?

2. Public concern about medical accidents/errors

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

Lay press may be found of typical medical error (when they are informed about it) and use to disclose it with the name of the institution but not the name of the physician. More serious lay press favor expected or unexpected side effects of treatment (Uterine cancer following treatment with Tamoxifen: a well known side effect describe as a "scoop"). From time to times nosocomial infections are put forward.

France is not a country for which consumers supportive groups are not yet structured neither powerful (may be but for HIV/AIDS). In the official directory of health supportive group it could be however mentioned:

- A group dedicated to victims of blood transfusion
- A group dedicated to victims of mycobacteria xenopi
- A group dedicated to the protection of ill persons
- A group dedicated to victims medical accidents

It could be said that in France the concern of persons are not organized through "consumerist organization", however, our position is that there is a trend toward increasing worries about health safety grounded on some mediated crisis (of which contaminated blood and mad cow).

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

Looking at the statistics between 1976 and 1990 based on the main professional insurance company (more than 60% of practitioners and probably more than of 80% of insured physicians) it could be said that

1 there was an increasing in the reported serious accidents.

2 the rate of increasing is higher for complaint from patients, than for report by physicians and lastly for faulty accidents (that are increasing). Our comment to that point is that the faulty label is given after a judicial process and may not reflect a biomedical risk analysis (cf. breast prosthesis and silicone...)

3 the rate of increasing differs widely according to specialty (very slight increasing for general practitioners and high for surgery and gynecology-obstetrics)

We should have in a few days from now statistics between 1995 and 2000.

c. Is the industry interested in patient safety?

The industry is deeply involved in patient safety as far as their products are under the "vigilance" legal system of control (for example prosthesis pacemaker) and above all drug company. They comply to standardization (ISO) and industrial quality control process which should include the patients' safety dimension.

It is important to mention that health-related industry in France is still an important economic

sector (drug company, imaging devices,...)

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."

Among the 120 articles that quoted the IOM report and/or the related article in the New England none is in French.

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.

(See .PPT)

There is no specific organization (see .ppt) but a group of Agency of Sections of the Health minister in charge of different dimensions of risk management. For example a new organization was set in 1998 of which two main agencies could be identified:

1 The National Institute for Public Health Surveillance (NIPHS) is a public technical agency which was created (by law) in order to reinforce and coordinate the public health surveillance system in France. The general aim of the National Institute for Public Health Surveillance is to monitor, continually, the health of the population and its evolution. The specific activities that relate to this aim include epidemiological surveillance, risk evaluation and observation of health.

The objectives of NIPHS are to: detect all threats for the public health and to alert the Minister of Health of such threats, collect, analyze and disseminate information on health problems, their trends and determinants, carry out or support all action (investigation, study, expertise...) necessary to comply with its aims.

These missions apply to all the fields of Public Health such as:

Infectious Diseases (AIDS, viral hepatitis, vaccine preventable diseases, foodborne diseases, Creutzfeldt-Jakob Disease, etc), Environmental Health (health risks related to air pollution, exposure to chemicals, radioactive emissions, etc), Occupational Risks (health risks of a professional origin),

Chronic Diseases (surveillance of cancer, of nutritional health problems, etc).

2 The French Agency for Sanitary Safety of Health Products is in charge of Vigilance and statistics

about accidents related to Drugs, Reagent, Devices, Cosmetics products and Blood transfusion. This organization got some regulatory power such as the option to take off some products out of the market.

2. Action by other stakeholders

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

Some associations of physicians (specialized scientific society) based on voluntary are involved in the definition of "Good practice" mainly focus on best therapeutic options according to medical status but also on safety procedures or diseases prevention (For example: Standards, Options and Recommendations (SOR) for the surveillance and the prevention of cross infections in oncology. Federation Nationale des Centres de Lutte Contre le Cancer or Evaluation of the microbicidal efficacy of Steris System I for digestive endoscopes using GERMANDE and ASTM validation protocols.). These guidelines are released in the medical scientific press. It should be also a lot of local initiative in hospital with local procedures and/or formation.

Every ad-hoc committee in charge of official guidelines include some physicians expert of the topic under scrutiny. The statements are released in official journal and in the medical scientific

press (For example: Circular DGS/VS2-DH/EM1/E01/97-627 from 20 October 1997 relating to sterilization of medical instruments in health facilities)

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.

To the best of our knowledge few if any impact could be put down to patients or patient groups.

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?

In France there is only one financial organization (National Health Insurance) and only one governmental agency for accreditation (National Agency

for Accreditation and Health Assessment). There is a formal document specifications for accreditation. In that official document there is 10 sections of which 3 are related to safety:

1 about quality control and risk management as a whole

1 about the vigilance system and blood transfusion vigilance/safety

1 about nosocomial infection

Every hospital private or public have to undergone systematic assessment according to the specifications before 2003. Latter on regular on basis of 5 years new control will be carried out by the Agency.

An accreditation report is written by the agency for every hospital, a summary of which is available (even for lay people) on the ministry web site.

C. Information Systems

1. Reporting system/ information system

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?

If there is,

a. Is it obligatory or voluntary?_

It is obligatory for specific accidents (see .ppt) and not done for the other. For example there is no report for surgical mistake like the intervention on the wrong side or on the wrong patients.

b. Who collects the data?

There is usually two level one at the administrative level (Prefecture) then at the national level (The National Institute for Public Health Surveillance or The French Agency for Sanitary Safety of Health Products is in charge of Vigilance and statistics)

c. Who analyzes the data?

The same agency that collected the data, analyses them.

d. Is there any legal protection for the information reported, so that it cannot be used in lawsuits?

No.

The process for reporting could be described as precluding lawsuits, since it is done anonymously with regard to the patients' identification

2. Complaints from patients or their families

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

In France there is two de facto monopolistic situation for insurance. One for physicians (Le Sou Medical) and one for hospital (SHAM). The former releases statistics the latter not. The Minster

of Justice also collects some statistics

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?

There is no official statistics related to quality. Lay press recently release a kind of classification but the aggregate are under a lot of critics. No real transparency exists and it could be expected unless a cultural revolution will not be in the comings. For example in a lecture an insurer shown statistics related to the rate of reintervention fir hip surgery with hospital having more than 4 fold rate than the highest quality one. It state that it 'll be useless to disclose who is who due to their aim to improve quality on a "quiet negotiation basis" in rather than on a market-like regulation.

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?

No

b. 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?

Not yet, but in few month there 'll be in France a new law. Following the organization set in order to solve the contaminated blood crisis with a national fund for victim indemization and a trends for juridical casuistic positions. The victim of medical interventions without fault under the criteria of "seriousness" will be indemized. The funding will come from the National health Insurance System (i.e. tax-based like) and not with an individual (private-based) insurance. The ideological background is therefore solidarity.

For faulty (or error) accident the compensation will be carried out by the private insurance. This new law is designed for no-fault accident.

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?

Obviously, since there is no specific actions for errors, it could be said that quality care covers error but I'm not sure that it is because explicitly decision makers think that they have the same root.

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?

I think (but may be it's beacuse I'm a physisician) that risk management as a whole is seen by physiicians as a strain or may be a needless burden but mainly they think that is patient-oriented not a protection against litigation. However managers in Hospital may have a different view.

F. Risk Management at Hospital or Clinic level

1. Risk Managers

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

Not as such there is some specific training for specific conditions: like blood transfusion on radioactive safety/protection. The persons who usually went to these training formation are nurses or physicians that still practice their basic profession.

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

No it is split according to the kind of accident without transversal management.

In most hospital, there is a blood transfusion safety manager, a specialist of nosocomial infection prevention, both working in the same hospital using the same intellectual tool but ignoring each other...

2. CQI (Continuous Quality Improvement) / Patient Safety

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

Recently (due to the specification of the national agency for accreditation) new working team had been developed with focus on collection, analyze, and feed back of accident. There is not formal rule but mainly this task force assembled physicians, nurse, manager and technical personnel. The report are not disclose to outside professional for external reviewing neither to patient or patients' group. Post accident are follow by intervention for correction. This is a not yet stabilized working organization.

The national agency for accreditation which has been the momentum for the creation of such unit, is allowed to check the existence of these unit not their efficacy (control of the process not of the outcome)

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.

Only based on voluntary involvement. There should be huge difference among different hospital.

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.

For transfusion (a very sensitive topic in France) there is a multi level risk prevention management:

Initial training

Written procedures

Regular monitoring

Regular upgrading or even new training on a regular basis.

Specific measures come from the "sensitiveness" of the topic rather than on actual prevalence.

5. Risk Analysis Methods

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

There is two models both used (but not at a large scale)

Scientific benchmarking (guidelines,...) a kind of top-down regulation

Analyze and debriefing of reported accident (bottom-up management)

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?

There is no unfocused training formation but specialized on specific risk mainly: nosocomial, blood transfusion, and radioprotection

Peer Review

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

If you mean (external) peer reviewing of accident, there is no such organization at least formal one.

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

Respondent: Ulrich Laaser

Questionnaire on international comparison of medical accident prevention policy

Investigator: Toshihiko Hasegawa, MD, MPH, Director, Department of Health Care Policy, National Institute of Health Services Management, Japan

Contact: Junko Yamada, MA, Research Associate, Email: junkoyam@nih.go.jp

Response Author: Prof. Dr. med. U. Laaser DTM&H, MPH, Head, Section of International Public Health, Faculty of Health Sciences, University of Bielefeld, Germany, e-mail: ulrich.laaser@uni-bielefeld.de

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 medical accidents/errors

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

No, a comprehensive publication under the title "Medizinische Behandlungsfehler" has been announced by the Robert Koch Institute in the framework of the Federal Health Reporting System for the coming year (www.rki.de/GBE/THEMEN.HTM).

Figure 1 shows the development of applications to the North German Medical Arbitration Board of the consortium of northern German medical chambers: The number of applications i.e. formal complaints went up from 500 in 1976 to a level of about 1500 up to 1990 and since unification increased continuously up to 3750 at the end of the century.

b. Is the number of medical accidents increasing?

This cannot be ascertained in Germany, however, the level of awareness is certainly increasing very rapidly as can be seen from the data in figure 1 which are very likely to constitute a representative trend for the entire country.

c. How much is the budget for those studies and research activities?

There is no separate budget in any of the concerned institutions rather they decide to allocate some manpower within their overall capacity.

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

Rising awareness in the public goes parallel with the availability of patient information in the Internet (www.discern.de and www.patienten-information.de, for the translation of the opening page of the latter see [figure 2](#)). The increased interest in patient information and education is also apparent from the recommendation no: R (2000) 5 of the Committee of Ministers to member states on the development of structures for citizen and patient participation in the decision-making process affecting health care, adopted by the Committee of Ministers on 24 February 2000 at the 699th meeting of the Ministers' Deputies of the Council of Europe (<http://cm.coe.int/site2/ref/dynamic/recommendations.asp>). Its central message is as follows:

- ensure that citizens' participation should apply to all aspects of health care systems, at national, regional and local levels and should be observed by all health care system operators, including professionals, insurers and the authorities;
- take steps to reflect in their law the guidelines contained in the appendix to this recommendation;
- create legal structures and policies that support the promotion of citizens' participation and patients' rights, if these do not already exist;
- adopt policies that create a supportive environment for the growth, in membership, orientation and tasks, of civic organisations of health care "users", if these do not already exist;
- support the widest possible dissemination of the recommendation and its explanatory memorandum, paying special attention to all individuals and organisations aiming at involvement in decision-making in health care.

The full text is available in [appendix 1](#).

2. Public concern for medical accidents/errors

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

As indicated above, awareness is rising, however general satisfaction with the delivery of health care in Germany is still great. In Germany only 2% demand a complete restructuring of the health care system [54] as compared to e.g. Italy (33%) or Spain (14%), countries which are ranked in the recent WHO World Health Report 2000 [55], much better than Germany. Therefore the pressure on politicians and medical representatives is considerably less.

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

As the evaluation of liability in many cases may take years, the decisions taken by the North German Arbitration Board in 1992 may serve for the indication of trends: Among 1200 finalized cases around 870 cases had been evaluated as unjustified and 330 cases (27,5%) as justified. The liability insurers of the physicians/hospitals were asked in addition which brought about almost identical results: Among 1097 responses the insurers classified 781 cases as unjustified and 316 cases (28,8%) as properly justified. Out of these only 94 cases led to court proceedings, i.e. the process avoidance ration was 91,4% . [Figure 3](#) shows, however, an increasing proportion of justified cases rising up to almost 50% in the year 2000.

c. Is the industry interested in patient safety ?

No information provided.

3. Impact of IOM Report

Influence in Germany of the report from the Institute of Medicine in the US "To Err is Human"

The following is a synopsis of the state of information on the issue in Germany: Research has revealed that 4-100 cases admitted to the hospitals are due to allegedly committed medical errors in the medical institutes of the United States in which more than a half are easily avoidable. These are mainly attributed to errors or existing deficiencies in the health care and organizational system. Here individual human errors are noticed very often in the routine services of health care delivery. Due to lack of appropriate data it is not yet completely clear whether or not similar incidences can be expected in the German health system. However studies in the USA and Australia speculate that there is a greater tendency to declare the associated concerns about the fact of " medical errors " which is a global problem and is expected in any health system.

As revealed in several epidemiological researches in USA and Australia particular attempts are given in terms of relevant national action plans to identify and to *avoid medical errors* in the health system. The recommendations appear to be the most practicable for applying on the health services in Germany, to strengthen quality promotion or quality management and by direct measures of the error identifiers as well as its avoidance in the general care. Moreover this in other words means concretely:

- Identifying the extent of the problem by sources of error-referred use of existing data for example, from the liability insurer companies, arbitration boards (*the process by which the disputed parties submit their differences to the judgment of an impartial person or group appointed by mutual consent or statutory provision*), quality control boards (Qualitaetsicherungsprogramme GKV) and/or implementation of routine obligatory documentation and information centers as well as surveillance systems.
- Development of the legal bases for reporting sanction-protected procedures, measures for behavior-oriented training to recognize and avoid errors as well as incentive systems for error identification and avoidance by participation in the programs.
- Implementation of advance automatic measures for anti-bugging (e.g. by electronically (EDV) supported monitoring of unwanted pharmacological effects, or EDV-generated memory programs on the basis of prior set guidelines.

These measures can be implemented only with sufficient financing: The Clinton administration planned to donate a grant of more than 200 million US \$ annually to overcome this particular issue. Since the publication of the report "To Err is human" by the institutes of Medicine in the US-American National Academy of Sciences in the year 1999, the issues of medical risks, error and patient security have attained an increasing attention in the international research efforts and literature.

The report refers to the Harvard Medical Practice Study in which patient documents from over 30000 cases from 51 hospitals of New York city were analysed for the consequences brought about by medical errors. It was therefore revealed in the year 1984 that 3.7 of 100 cases were due to malpractice and more surprisingly 69 % among these cases were health complications induced by medical errors.

The results of this analysis was also acknowledged recently by another retrospective study on 15000 surgical patients from Utah and Colorado which showed that 3 % of the complications or damages were associated with medical or surgical induced errors. The study further documented that 54 % of complications/ damages were simply avoidable. On the basis of