these data the authors of the IOM report estimated the death tool in the USA due to medical error-conditioned reaches to approximately 50,000 to 100,000 per year which in reality is several times higher than the overall road traffic accidents, breast cancer or HIV/AIDS in the USA.

The financial consequences of these avoidable medical errors in the US-American health system cost extra around 20 to 35 billion EURO per year. Another example in this regard is the third large Australian Health Care Study which overtly declared that malpractice/ medical errors cause annually 3.3 million unnecessary hospital days. The consequences in 1.7 million are (approximately 8% of all hospital days) simply said to be avoidable. The increasing trends of malpractice or errors in the health care are now widely known which obviously lead to the development of significant health related complications.

Epidemiological data showing the magnitude of problem in Germany is not yet available however studies are underway to address these issue as malpractices or medical errors induced complications are observed in every setting and reported in every country. The results of the above mentioned studies make the health authorities in Germany more conscious to give extra efforts to calculate with its high future casts and to put actions in vigorous momentum to arrest the problem as its universal trends declare it to be rapidly emerging global problem.

Based on the ***leading causes*** medical errors are classified in various categories for example: 1)illness related factors; unnoticeable and uncontrollable progression of an illness, 2)therapy related factors/ induced complications; for example side effects of a tumor therapy, 3)errors due to organizational inadequacies for example in the procedure, institution, interfaces, flow of communication etc, 4)technical inadequacies basically of diagnostic procedures and devices etc., 5)professional insufficiency or lack of appropriate attention of physicians/ health care provider on the part of patient.

Errors due to diagnostic methodology used, prescribed therapy along with surgical interventions are simplest to be identified.(see table.1)

Table. 1 Summary of avoidable and unexpected events (Leape, 1994 [8])

Type of unexpected medical errors	Number	Frequency (%)	Avoidable errors (%)
- Conservative or palliative Care			
- Pharmacological related errors	19.130	19,4	45,2
- Diagnostics related errors	7.987	8,1	98,8
- Therapy related errors	7.396	7,5	91,3
- Procedure dependent related errors	6.903	7,0	52,8
- System related errors	1.362	1,4	85,5
- Falls/accidents related errors	2.662	2,7	92,2
- Others	6.100	6,2	54,3
All conservative Care	51.540	52,3	65,5
Operative Care			
- Wound infection	13.411	13,6	71,9
- Technical complications	12.721	12,9	86,7

-	Complications due to delay	10.453	10,6	67,2
-	Not-technical Complications	6.903	7,0	54,5
-	Errors in the Intervention	3.550	3,6	94,0
	All operative Care	47.038	47,7	74,0
	Total	98.578	100	69,6

Cases explicitly representing avoidable errors are mostly related to the delivery and regulations of *medicines or pharmaceutical agents* used in the prescription[9] (see table 1). Among such cases majority of errors are attributed to the toxic/ harmful drug-drug interaction or in two or more than two regimens. In spite of their well known clinical interactions, health care provider or physician frequently ignores these aspects which lead to complications.

Patient usually develops some sort of allergic reactions in an already known cases to physicians but is not adequately considered. Based on weight, sex and age, errors in the proper dose adjustment are one of the potential causes[10].

The study of Bates et al was less successful in identifying patient related risk factors through which errors can be erased[11]. But the conclusion drawn by the authors does claim that errors can be effectively avoided or reduced as early as by fine tuning the health care system and optimising (*The procedure or procedures used to make a system or design as effective or functional as possible)* the medicinal regulations (see also system oriented errors).

Besides, lack of experience in dealing with the technically complex diagnostic procedures influence the accuracy of the results which in turn leads to further errors especially in establishing appropriate curative or preventive therapy. This was evident in the study of Gordon and his co-workers that medical doctors who perform 100 colposcopy per year gave more accurate results than the doctors who perform it less frequently[12].

In 1992, 54 % of all *surgical complications* in Colorado and Utah and 1 of 8 deaths in the hospital were the consequences of already applied medical interventions[6]. In the context and vision of the study frequent operations could be identified with high incidence of avoidable complications: e.g. bypass operation of the lower extremities (11%), operation with abdominal Aorta aneurysm(8.1 %), Colon resection (5,9%). Technical complications, post operative infections and post operative bleedings contribute thereby to approx. half of the surgical associated complications (see table. 1).

Although errors committed in the context of prescriptions, surgical interventions and diagnostics are the easiest to be identified but also have underlying causes related to the ***health care system*** (see table 2). Similarly Leape and his coworkers[10] identified errors related to primary system to be the prime cause of the three quarters of all identified unexpected cases. Inadequacies in the dissemination of pharmaceutical information (medicinal side effects) existing at various level are considered to have a significant role in the system related medical errors.

It ranges from the strict control on drug regimens to appropriate dosages, from drug regulations to pharmacies and to the proper education of patient which make half of all the system related cases (UAW related). A typical example of system related errors and its correlation with the state of personal training skills is observed directly. The related phenomenon was vividly noticed in the occurrence a of series of complications in post operative urinary tract infections, pneumonias, thrombosis etc[13].

Table 2: The frequency of avoidable System related medical errors (Laepe, 1994 [8])

Types of Medical errors	Number	Frequency (%)	Avoidable events (%)
Diagnostics			
Errors in diagnostics / diagnostics delay	11.731	17,1	71,1
Omission of an indicated test	782	1,1	91,4
Application of an absolute test or therapy	944	1,4	56.4
Negligence in interpreting tests results	1.579	2,3	55,2
Care			
Technical errors	30.373	44,4	19,8
Errors in implementation of an intervention	776	1,1	9,1
Error in dose adjustment	6.988	10,2	37,1
Delay in the commencement of therapy	3.154	4,6	69,4
Inappropriate counseling	141	0,2	0,0
Prevention			
Interruption in the preventive care	7.943	11,6	50,3
Inadequate diagnostic/follow-up	3.172	4.6	36,9
Others			
Omission in communication	244	0,4	52,6
Configuration errors	422	0,6	77,2
Others System related errors	136	0,2	0,0
Not classified errors	260		
Total	68.645	100	39,7

B. Action by Stakeholders

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

Is there a governmental policy especially for medical accidents? If there is, please describe the policy including the historical development of the policy.

There is not, mainly because the situation in Germany as compared to many other countries is different insofar as the federal structure of the "Laender" and the legal autonomy of the medical profession on the one hand and the growing integration into the European framework on the other do not leave much space for federal policy and in consequence also impair the availability of comparable and centralised information.

2. Action by other stakeholders

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

The arbitration board (AB) is a committee of an impartial individuals or group appointed by mutual consent or statutory provision which provide their expert assistance and counseling services for a dispute or controversial matters for clients or parties. The AB careful judges their differences, arguments submitted and try to find a settlement or possible solution before they get involved in any judiciary process.

The Hanover Arbitration Board is responsible locally for the cases of assumed medical errors which take place in the areas of the Medical Chambers in Berlin, Brandenburg, Bremen, Hamburg, Mecklenburg-Vorpommern, Niedersachsen, Sachsen-Anhalt, Schleswig-Holstein or Thüringen. It is particularly responsible for those cases in which the patient has a clear evidence of medical errors committed by the physician.

However AB Hanover is not responsible for any general complaints of patients about physicians or health care providers. Patients and their concerned physicians, hospitals and ensuring agencies are equally entitled and dealt in the process. As usual the cost free process runs through written informal application. Willingness for the procedure and acceptance of the formalities are essentially expected from all the participants.
The arbitration board assesses the circumstances in its own terms of references and releases a final statement after thorough exploratory process of papers of the concerned patient before and after the treatment given as well as the physician responsible for the provision of medical care. Besides insurers, health insurance companies and other authorities are also included if necessary with available findings etc.
If the desired documents essential for the appraisal are available, the assigned physician and lawyer in the AB who work on the case write a final recommendation and design a catalogue/checklist of relevant questions. All participants have the right to contribute before it is finally announced.
It is always intended to obtain an external expert opinion. There are exceptionally complex cases where it is crucial to add an external appraisal for more multidimensional judgment in specific medical problems. On the other hand involving several consultants will add significantly to the precision and an efficiently issuing of the final statement. As soon as the external appraisal is available at the AB, it is actively disseminated further to the concerned participants.
The medical and the lawyer or judiciary members of the arbitration board check the external appraisal from medical and legal perspectives whereby the arbitration board is not bound to change the evaluation report of the consultants. Coupled with this, any statement of the parties involved is also considered important to this appraisal.
It is possible that the arbitration board meets a decision on the basis of internal medically oriented estimations and asks its member for another aspect of medical evaluation. On the other hand it can lead to a diverging evaluation results which possibly relate to the considerations of lawyers and physicians due to the diverse approach.
The activity of the arbitration board ends with a statement to those who are considered liable for the act. Following the conciliation procedure and with affirmation adjustment negotiations are carried out directly between the patient and liability insurer for the possible payment of alleged damage or medical errors.
If new facts supporting the case are discovered, the arbitration board reconsiders the application in the view of a possible external expert. This is certainly considered the end of the possible role of arbitration board in this regard. Therefore arbitration board emphasizes at the same time that it has no further obligations for prosecution where ways are open for any legal or judiciary assistance any time.

The medical arbitration boards aim primarily to formulate and promote strategies for disputes and controversial issues in order to convince and clarify all participants to avoid any judiciary assistance or involvement for resolving matters between physicians and patients on medical errors or malpractice. It has been commonly experienced that the judicial processes normally take several years to resolve a conflict which brings unnecessary delay to them for their solutions.

1). Main Responsibility of the Arbitration Board: The AB is responsible for resolving and clarifying issues and disputes with out the assistance of court or judiciary involvement for cases which have suffered an alleged damage due to medical errors/malpractice of physicians on patients.

2). Responsibility for Area Coverage: The AB will be serving only those cases of medical

errors/malpractice which come from areas of medical syndicate/council of Berlin, Brandenburg, Bremen, Hamburg, Mecklenburg-Vorpommern, Sachsen-Anhalt, Schleswig-Holstein or Thüringen

3). Participation Eligibility:

a. Patients with their legal counterparts, hereditary belongings and lawyers.
b. The concerned physician and insuring agency or insurer.
c. The liability insurer of the physician or the hospital.

4). AB Procedure:

a. The procedure starts from a written application by the applicant who expresses all his/her concerns.
b. The participation in the AB procedures is free of cost and is on voluntary basis.
c. The AB can become actively involved only after getting the agreement of all the participants.

Filling out questionnaires and the assertion of professional secrecy by the patient is carried out. The agreement of the concerned physician or hospital and the liability insurance is obtained. The process starts as soon as the prerequisites are submitted which is further undertaken by the relevant experts. The documents are requested from the physician about the concerned patient before and after subsequent treatment.

5). Appraisal of the Documents: After the process of document appraisal/evaluation a demand letter is usually send to the participants to provide additional documents in case there is any ambiguity or deficiency found in the credentials.

6). Final Statement: After four weeks of duration when the appraisal process is completed and all the additional documents are in hand it is sent further to the consultants for final evaluation. In the final assessment every critical aspect of both sides for justification and non justification is thoroughly considered. Tools for appropriate judgment of cases are applied where professional instructions and ethics are not properly followed by both the participants. Objection against the final statement is possible only within the period of 4 weeks if sound supporting facts for reconsideration are available. No participant must accept the decision of the arbitration board. Further pursuing the course of law is not excluded by the activity of the arbitration board and is open for every individual.

7). Duration of the Procedure: The average duration of procedure is about 13 months. Strong upward or downward fluctuations can not be ruled out during the process which can significantly curtail or extend the time period. This usually depends upon the circumstances on which normally AB have little influence e.g. the time taken by the consultants in the process of evaluation or clients providing the supporting documents.

8). Cost of AB Procedure: The AB procedure is free of cost for clients. The cost of assigned representative and any loss of wages as well as relevant costs of food and other formalities on the spot which are made for further investigations for the hired consultants is organized by the patient himself.

9). Validity of the Process: The AB procedures restrain their validity as long as the party's participation who is liable to pay the damage is included "

10). Team at Service:
4 Lawyer with capability to the justiceship
33 Medical doctors
17 Special assistants
Chairman: Prof. Dr. med. Heinrich Vinz
Managing directors: Rechtsanwalt Johann Neu
Address: Schlichtungsstelle für Arzthaftpflichtfragen der norddeutschen Ärztekammern
Berliner Allee 20, D-30175 Hannover
Telefon: 0511/380-2416 / 2420.

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?
Very limited but slowly rising.

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 organization in your country?
Guidelines for implementing ISO 9000 quality management systems in the health care sector were published by ISO (International Organization for Standardization) on 20 September 2001 as its first "International Workshop Agreement" (IWA) [56] (www.iso.org and www.iso.ch/iso/en/; Ref. 802, 10 October 2001, ISO 9000 guidelines for health care sector). The guidelines are based on ISO 9004:2000, Quality management systems - Guidelines for performance improvements. IWA 1 contains much of the text of ISO 9004:2000, supplemented by specific guidance for its implementation in the health care sector. It provides a framework for the design and improvement of process-based quality management systems by health care organizations. The guidelines are voluntary and they are not intended for certification or accreditation. The generalized implementation of ISO 9000 quality management systems by health care establishments is seen as a means of rationalizing client-supplier relationships and an opportunity to improve the quality of health care while reducing the costs.

Another important actor in this field is the "Gesellschaft für QualitätsManagement in der Gesundheitsversorgung" (www.gqmg.de):

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It claims (together with Association of Salaried Employees Sickness Funds / Association of Wage-Earners Sickness Funds (VdAK/AEV) and the German Medical Association (BÄK)) the necessity of a hospital-specific accreditation procedure, which sensibly integrates the proven principles and methods of other procedures. In the course of the preliminary work, the German

Medical Association elaborated and published a Guide to Quality Management in Hospitals (1997), while the VdAK/AEV developed "Certificate A: Procedures for preparing quality assurance reports for hospitals" (1996). In June 1997, the German Medical Association and the VdAK/AEV resolved to jointly investigate possibilities for quality management in hospitals and to develop a procedure for
hospital accreditation based on international models. Within the development work, the results of the "Quality management in hospitals" pilot project conducted simultaneously by the Federal Ministry of Health are to be incorporated as far as possible. The partners have initiated the "Cooperation for Transparency and Quality in Hospitals" (KTQ) and established an office.

In order to arrive at a widely accepted procedure, an effort is being made to involve all the partners of the health care system in the project. Since the beginning of 1999 the German Hospital Federation joined the work of the KTQ, since the end of 1999 as an equally accepted third negotiating partner. The German Nursing Council (the umbrella organisation of the nursing associations) and representatives of a federation of church-run hospitals participate in the meetings of the KTQ. The other umbrella associations of the statutory health insurers will also be getting involved in the near future.

An assessment manual is to be designed for measuring performance within the framework of accreditation. Recognised experts assigned to working groups have defined criteria relating to the quality of hospital structures and processes in general, as well as to the quality of the results of the specialist departments in particular. These experts have extensive knowledge and experience in quality management as well as in hospital practice. In addition to the KTQ with its steering function, the working groups cover the areas of hospital management, patient surveys and the discipline-specific groups of surgery, gynaecology, urology, orthopaedics, anaesthesia and intensive medicine/care, internal medicine and nursing. In accordance with the available resources, other medical disciplines are also included according to the modular approach. The same applies to the functional sectors and the medical technology departments. In this context, consideration will also be given to criteria, standards and indicators used in the processes of external quality assurance.

Accreditation is to be handled by independent organisations. The accreditation is awarded for a limited time only and must be renewed at a defined time. An accreditation period of three to five years is considered standard in international practice. The German Association of Scientific Medical Societies (AWMF) is involved in the development work of the project. The Institute for Medical Information Processing of Tübingen University Hospital is responsible for the scientific support of the project and handles the following tasks: provision of advice on method-related issues, evaluation of the test phases and support in concept design.

The direct costs of accreditation will encompass the following items:

Costs of the surveys,
Costs for award of the accreditation, and
A percentage of the overheads for all hospitals which participate in accreditation.

These costs must be borne by the hospitals interested. There are also indirect costs resulting from self-assessment and the working hours spent on the surveys.

C. Information System

E. Concept of Quality and Safety

F. Risk Management at Hospital or Clinic level

The areas C. – F. are not really developed in Germany, however, the following gives a summarizing overview on what is under development:

A general consensus is found among the analysis of international research which concludes that medical errors occur due to system related factors and predominantly due to the failure of organizational harmony. In contrary to the situation the individual negligence or errors made by the experts/specialists in their medical practice are less important quantitatively.

These results put the conclusion more close to the idea that efforts can be particularly successful for the effective anti-bugging (errors detection) in health services or avoiding medical errors in health services if modifications are accomplished on the various level system. Improving the flow process of adopted procedures or sufficient financial and technical resources allocation, trained personal at the key positions are the steps which need to be taken. As described in the international research it is still to be verified whether the rate of system related errors in certain areas of the German health infrastructure are more than to be expected. In a comparative study conducted by Taxis and his co-workers explained that medical errors among the admitted patients in Germany are approximately 2.5 to 5% lower than the 8% of British hospitals[14].

Table. 3 Action plan of US Authorities for avoiding medical errors[15]

Mission with specific targets
- Establishing a center for the quality improvement and patient safety measures with a budget of 20 million US $ in the year 2000. The center will finance research projects which will focus to develop national plans for patient's security with an yearly published progress report, implementation of study results, information for educating patients, services for counseling on patient safety,
- Development of efficiently functioning registration system for the detection of death and complications caused by medical errors,
- Modeling the development of national documentation and registration for medicinal errors,
- Measures for improving behavioral change,
- Measures for improving data communication on medical errors,
- Analyses of the effectiveness/ efficiency of existing surveillance/signaling systems,
- The implementation of a reporting system and training for the veterans administration,
- Measures for the optimization of medicinal security in the clinical care,
- The implementation of screening programs in the 6000 supervised Medicare hospitals, automatic advanced measures for the optimization of medicament security,
- Improving standards for the medicinal security in the FDA.

How should patient security be assured ?
Responding to the recent research on health consequences induced by medical errors in USA and Australia, suggestions were made for launching a national campaign for the optimization of the system in order to secure patient's safety.(see table 3) But on the other side the core focus of the American concepts was to test and simultaneously implement possible technological measures which foster identifying incidents of malpractice more efficiently than before and to avoid all fatal complications.

The project gave high priority to the responsibilities of national health care administration (Medicare and veterans). On the other hand the Australian program in this regard had more broader and universal aspects which is illustrated in the following: strengthening capacities in quality improvement and quality management in the health care system and to organize general action plans for identifying and avoiding medical errors[table 4].

Table. 4: Australian action plan for strengthening quality & improving patient security [16]

Mission with specific targets

1. strengthening participation of consumers in the health care system,
2. Implementation of evidence based health care system,
3. improving information outflow between all participating institutions for the quality assuring activities and detection of complications/health damages caused by medical errors,
4. legislative measures for the surveillance of events leading to medical errors and maintaining a register for the results of applied diagnostics,
5. consent over uniform methods of analysis and entry for incidents, error-caused events and complaints in the medicine,
6. a national plan outlining evaluation procedures and statement of quality criteria in the health service,
7. optimization of common accreditation procedures regarding the consideration of security and quality on the system orientation,
8. improvement of the interface problems for the advantage of the consumer,
9. research to generate better clinical, systems and administrative information,
10. generalized consensus for qualification and training measures for service providers in the area of the quality management.

According to the content of both programs there are numerous questions regarding the medical errors and their hazards in the health care system which are still to be answered. The situation therefore demands for an extensive research efforts to explore all overt and covert realities lying behind the problem. This implies some crucial steps in this regard like the development of electronically monitored software system which can provide a multidimensional outlook[17].

Due to its important role it is considered a vital element applied in the American program for detecting errors. The program costs 75/12 million US$ for the clinical and veterans administrator as well as in the US army. The usefulness of such (EDV) system in the patient care has been proved by Morris in 1993[20]. An extensive international research are currently studying the influence of EDV supported system and its role in decision making and have shown its positive indication[21-25].

Main focus & specification for Germany?

Strengthening Qualitative oriented health care, consumers and information management in public health. Various action plans described in the Australian research can prove fruitful for the possible implementation in Germany specially in terms of quality promotion, aversion of errors and assuring more patient's security. This was demanded both in the conference of health minister[26,27] as well as expressed in the periodicals of various autonomous agencies in Germany as follows [28,29],

1. Strengthen the community and patient participation in health care services
2. Implementing evidence based health care provision
3. Efficient communication exchanges among all stake holders and participants
4. Scientifically sound and assuring pragmatic quality measures which are recommended for both in patient and outpatient of the health care system
5. Improvement of the interface problems for the advantage of the patient

Individual components of the action plan are already introduced and implemented in Germany so the consumer information centres e.g. the consumer federations, health insurance companies, physician chambers, checkout-medical unions are worth mentioning here. Patient complaint offices and organizations for clarifying claims for damages exist since 1975 in the form of the panels of experts / arbitration boards of the physician chambers which can be navigated under www.schlichtungsstelle.de as well as counseling or legal advices through authorized institutions (e.g. consumer centres) and specialized lawyers are currently in practice.

Meanwhile many professional organizations on local and federal level have created forums or adviser committee for briefing and advising the patients/ consumers (e.g. the patient forum of the Federal Medical council) etc. Since 1999 the internet news services can be reached under www.patienten-information.de which is the centre for the information on quality assurance in the medical and public health field.

This is the first facility providing German-language medical or health related expert opinions and information for lay men to the federation of self help organization at the federal level. Under the framework of public health reforms by the health insurance companies it was redefined and operationalised in 1999[30]. Further developmental aspects are included in the following,

- uniform and federally administered quality assurance program as well as instructions supported indicators for the ambulatory and stationary health care
- fee based quality oriented system
- integrated concepts of public health
- pertinent counseling cells for patients
- launching a public health opinion-forum for the quality control at the federal level (a working committee for the promotion and ensuring medical care under: www.aqs.de) and producing periodicals on the emerging issues related to patient safety.

This demands:

- general consent over the training measures for service providers in the area of the quality management and co-operation.
- Optimisation of general accreditation procedures regarding the consideration of security and

quality on the various echelon of the health system.

In Germany this is fulfilled at least in sections by the training programs and "curriculum on quality assurance/ physicians quality management"[31] as well as the certification program of KTQ® [32] arranged by autonomy bodies in the health service.

Identification of medical errors and their risks factors:
Contrary to the situation, Germany is still far behind in establishing country wide measures for the identification and prevention of medical errors so far. As already stated more extensive research is required in order to refine the fundamental tenets for the priority areas and identify potential gaps in the German health system.

Here appropriate epidemiological investigations are the only source of scientifically credible facts which are unfortunately missing till now. The results of international studies permit only tendentious conclusions which are country specific and needs more precise knowledge for implication in Germany. Though it refers to several bias but the data bank from the legal health insurance companies can be quickly utilized in Germany.

According to an estimate of snow white in1999 - only few countries including Germany posses universal database on quantitative medicinal consumption across the nation. Coupled with the already existing large deficits in the qualitative vision and its correlation with individual utilization of medicines, less up to date knowledge is available on physician's performances and on their diagnosis. This needs prompt attention here in future interventions. The personal linkage and analysis referring to errors in the medical field can utilize the data of GKV for the quality improvement programs and related initiatives. Based on this conception studies are underway in the province of Hessen [33].

Additionally the data of the liability insurers as well as the panels of experts and the arbitration boards of the physician chambers offers willingness for the analysis of medical error. After Hansis and Hansis approx. 30,000-40,000 cases of liability claims/ year are documented by the insurance companies, approx. 9000 cases by the panels of experts along with the rising tendency for cases of damage and damage expenditures or only acknowledging the damage[34].

The incorporation and integration of these findings into the national health report would be useful for the identification and quantification of error rates, types and also risk factors in particular for the designation of prioritizing fields in the future. Further the advancement of the quality assurance measures should consider the aspect of the error identifier in the context of the legal health insurance more strongly than before. By the analysis of these data errors and risk factors the following various levels of the health care system must have to be addressed :

- at the system level [35,36],
- at the örganizational level [37,38],
- at the interfaces of the health care [39],
- with special individuals[40],
- population groups[41] & occupational groups [42,43]
- for certain diagnostic procedures [44,45,46]

A broad consent over uniform analysis methods and entry for incidents, as well as error-induced events and significant medical complaints. For example the possible introduction of a uniform model and/or an obligatory registration system or surveillance system to capture case of deaths and cases with heavy health damage as well as conducting a study aiming at the development of clinical and administrative system information for a widespread system application by using

modern technology.

Besides all legal ways and means have to be brought in action to trace out all cases with recent error-based relevance and to maintain an up to date register containing data on the examination and diagnostic reports. Recently an attempt has been made by Hp. Kuhn who described " that systematic research on etiological errors does not exist in Switzerland. It is mainly the legislator who decides and defines which cases should be registered and which should remain without any sanctions?. In other words it means that consultants, judges, health managers and insurers are not supposed to submit any report" [48].

Prevention of medical errors and their risks factors:

When planning security is achieved and priorities of error problem are set, the next step is to figure out special risk constellation and then to develop a program for avoiding errors in the system should be implemented. Needless to say here that measures addressing behavioural trainings and improving skills have to be largely adopted to facilitate active errors detection including those from specialists and experts but also from consumers and patients. Special value has to be given to such projects which broadly analyses non-standard and non specific factors among those with insufficient error consciousness, complex and covertly applied minute errors[49,50]. Table. 5 in the following contain suggestions for an appropriate catalogue of guidelines which can add significantly to the challenge of errors detection.

Table.5 : Synopsis of Guidelines for Errors Awareness among Physicians

- Professional obligation to report medical errors
- Individual Aspects: moral consciousness and capability to deal with and advocate error induced circumstances
- Reveal relevant errors publicly- halt further consequences
- Typology of errors- collection and entry into the local registry
- Avoiding errors with appropriate strategies and techniques
- Quality and Risk Management

However such indicated measures alone will not lead to the modification in behavior. They must be accompanied by incentives for the participants in the programs and for the error identification as well as for avoidance. Schneeweiss discussed for example that the unwanted medicinal effects given in the catalog can be reimbursed for the physician's incapability (Schneeweiss 99).

In the discussion of errors-identification with scientific tools and its possible avoidance in the health care services is rarely documented[51]. Knowing the fact of extremely less attention given the lay press voluntarily dedicated themselves for this issue[51]. The report of the institutes of Medicine "To err is human" and later the analysis and comments given by the British Medical journal which particularly emphasized " Reducing errors- improve safety" has incredibly sensitized the public opinion. Through the recent amendments in the German public health insurance companies, Germany offers wide opportunities and an ideal setting for the development and implementation of various measures for the fine tuning of the system in detecting and avoiding medical errors.

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Appendix 1:

Appendix to Recommendation No. R (2000) 5

I. *Citizen and patient participation as a democratic process*

1. The right of citizens and patients to participate in the decision-making process affecting health care, if they wish to do so, must be viewed as a fundamental and integral part of any democratic society.

2. Governments should develop policies and strategies, which promote patients' rights and citizens' participation in the decision-making in health care, and provide for their dissemination, monitoring and updating.

3. Patient/citizen participation should be an integral part of health care systems and, as such, an indispensable component in current health care reforms.

4. Decision-making should be made more democratic by ensuring:

- a clear distribution of responsibilities for decision-making in health care;

- appropriate influence of all interest groups, including civic associations active in health-related matters, and not only of some stakeholders (professionals, insurers, etc.);

- public access to political debates on such issues;

- wherever possible, citizens' participation at the problem identification and policy development stages; participation should not be confined to resolving problems and simply choosing between solutions, which have already been drawn up.

5. Public debates should be more widely used to strengthen participatory

mechanisms.

II. *Information*

6. Information on health care and on the mechanisms of the decision-making process should be widely disseminated in order to facilitate participation. It should be easily accessible, timely, easy to understand and relevant.

7. Governments should improve and strengthen their communication and information strategies should be adapted to the population group they address.

8. Regular information campaigns and other methods such as information through telephone hotlines should be used to heighten the public's awareness of patients' rights. Adequate referral systems should be put in place for patients who would like additional information (with regard to their rights and existing enforcement mechanisms).

III. *Supportive policies for active participation*

9. Governments should create an environment, which is supportive of people's participation and responsibility in decision-making in health care.

This implies:

- instituting or strengthening mechanisms and/or structures for such participation; listening to patients and citizens should become a constant concern for the whole health care system at all administrative levels and in all regional, federal or national branches of health authorities;

- supporting democratic procedures for nominating and selecting citizens' representatives including membership in ethics committees, health boards and advisory bodies or any other structure in charge of taking health-oriented decisions;

- involving citizens and health care users in the management of different structures of the health care system;

- introducing ongoing evaluation of the dynamic participatory processes, in which citizens and patients take part;

- ensuring that all relevant population groups are able to participate on an equal basis;

- eliminating financial, geographical and/or cultural and linguistic restrictions to participation;

- promoting additional assistance to vulnerable groups to facilitate their participation;

- endorsing education and training facilities for citizens in order to develop democratic participation.

10. Governments should adopt policies that create a supportive environment for the growth in membership, orientation and tasks of civic organisations of health

care "users" by:

- creating a legal basis for participation of citizens in the management of health care facilities and insurance companies;

- creating favourable conditions, both in the legal and fiscal system, for the founding and operating of such organisations; the health budget, as far as possible, should include allocations to support such organisations;

- creating favourable legal conditions to support financing of such organisations by the industry while avoiding conflicts of interests;

- stimulating co-operation, whenever possible, between organisations, while respecting their diversity. Citizens associations dealing with health matters should work together towards achieving alliance strategies;

- facilitating the provision of services and support by these organisations to as many people as possible;

- granting these organisations a role in providing information to their members and the general public on specific questions and/or general health information;

- allowing such organisations their place among other interest groups in health care (organisations of professionals, insurers, etc.);

- encouraging democratic and ethical debates in these associations;

- developing transparent and open relationships between public authorities and associations.

11. The following complementary measures should be envisaged:

- publishing an annual report on the progress in citizens' participation in the decision-making process affecting health care;

- ensuring that every contract concluded with the public authorities or between key operators in the health care system should include a commitment to develop citizen/patient participation;

- training health professionals in communication and in participation practices;

- developing, in consultation with the NGO's, research programmes on patient/citizen participation in the process of health research and the most effective mechanisms for ensuring participation in the decision-making processes relating to health

care.

IV. *Participation mechanisms*

12. Citizens should participate throughout the legislative process in health care: in the drafting of laws, in their implementation and follow-up, including future modification procedures. This can be achieved through participation in commissions and public debates, whenever appropriate.

13. Citizens/patients should have the possibility of participating in setting priorities in health care.

For this purpose, the various different aspects of priority setting should be clearly explained to ensure responsible and informed participation by citizens. Aims, outcomes and responsibilities attached to these choices must be clearly set out, as well as implications of these choices as regards the allocation of resources, reorganisation of the health system and relations between the different components of the health care system.

14. Patients' viewpoints and expectations should be taken into account when assessing the quality of health care. Patients should have a say in internal evaluation and should also be involved in external evaluation via patients' associations. Contracts with service providers should contain a binding clause to this effect.

15. Patients and their organisations should be granted access to adequate mechanisms for enforcement of their rights in individual cases, which could be complemented by a supervision mechanism by an independent body.

In order to be effective these mechanisms should have a broad range, providing for forms of conciliation and mediation. Formal complaints procedures should be straightforward and easily accessible. Financial barriers to equal access to these mechanisms should be removed, either by making access free of charge or by subsidising people with low incomes who wish to use them.

16. Systematic collection and analysis of patients' complaints should be used to gather information on the quality of health care and as an indication for areas and aspects that need improvement.

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

Respondent: Christine Olthoff

A Survey of Medical Accident Prevention Policy

The Dutch Situation

Christine Oltho_

18 January 2002

Contents

1

1 Information on Medical Error

1.1 Studies and research activities on medical accidents / errors

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

There are no epidemiological studies concerning the occurrence of medical errors in the Netherlands. The frequency of medical errors is not well known. Available data are derived from the reporting system of the Inspectorate for Health Care. However, these data are believed to be just the tip of the iceberg (Inspectie voor de Gezondheidszorg, 2000).

1. Accidents in curative care:

kind of accident 1993 1994 1995 1996 1997 1998 1999 total
fatal 19 42 34 57 51 65 25 293
unreparable damage 8 9 8 5 4 5 3 42
temporary damage 7 16 16 37 24 29 18 147
total 34 67 58 99 79 99 46 482