STAKEHOLDERS' POSITION PAPER ON PATIENT SAFETY

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1. Executive outline

This paper is a call for action for all parties concerned with the issue of patient safety at European level, the level of national authorities as well as at the level of local/individual healthcare providers. It is important to start acting now and continue working with all stakeholders involved.

Patient safety has gained its place on the political agenda.[1] However, knowledge of the best ways to improve patient safety is still evolving. Focusing on patient safety is essential in order to establish a culture of safety throughout the entire health system, so that all actors in the system become aware of where, when and how to avoid errors and adverse events.

European countries are at different stages of implementing patient safety in their health care systems, which often face the same type of problems and the adverse events being reported often demand the same type of solutions. Methodology for the development and implementation of patient safety systems and solutions crosses national borders and requires substantial expertise, resources, research and information exchange among European countries.

It is for these reasons that this paper calls for action to Europe and its national members to tackle the issue of patient safety by continuously working together and in joined efforts, building upon the Luxembourg Declaration for Patient Safety (See Annex 1), the work of the High Level Group Working Group on Patient Safety, the Council of Europe, the WHO Alliance for Patient Safety, and a few European projects on patient safety that started earlier this year.

Patient safety is an important tool to improve both quality of treatment and the financial sustainability of the health care sector: The actions proposed in this paper and the examples given need to be used to achieve the goals set in this document.

The health related stakeholders recommend the European Commission in cooperation with the High Level Group to set up a Task Force on Patient Safety responsible for the implementation of the above-mentioned activities. They also call upon the national authorities and all national member organizations to promote patient safety in their countries and they urge healthcare organizations to implement specific safety measures.

2. Introduction

Patient safety has gained its place on the political agenda[1,2] However knowledge of the best ways to improve patient safety is still evolving. Focusing on patient safety is essential in order to establish a culture of safety throughout the entire health system, so that all actors in the system become aware of where, when and how to avoid errors and adverse events.

European countries are at different stages of implementing patient safety in their health care systems, which often report similar adverse events and often demand the same type of solutions. A sound methodology for the development and implementation of patient safety systems and solutions crosses national borders and requires substantial expertise, resources, research and information exchange among European countries.

It is for these reasons that this paper calls the European Union and the Member States to action in order to tackle the issue of patient safety by continuously working together and in joined efforts, building upon the Luxembourg Declaration for Patient Safety (See Annex 1), the work of the High Level Group Working Group on Patient Safety, the Council of Europe, the WHO Alliance for Patient Safety, and European projects on Patient Safety like the SImPatIE[3] and the MARQuIS[4] projects.

3. Action to be taken at European level

With the aim of raising patient safety by sharing knowledge and integrating safety concerns in all decisions and actions taken in the field of Health Care, we recommend that the European Commission sets up a **Task Force** linked to European Health Policy Forum with participation from relevant healthcare stakeholders to discuss European activities and exchange experiences regarding patient safety.

Mission of the Task Force:

- To support national governments in creating and developing safer healthcare systems within the framework of EU policy
- To **set SMART goals** for patient safety at EU level: Specific, Measurable, Attainable, Reasonable and Time-bound., like the example of US JCAHO[5] annual National Patient Safety Goals (NPSGs)
- To sustain momentum for continuous development of the patient safety agenda
- To encourage concrete action in a coordinated way
- To encourage research actions on Patient Safety between EU countries
- To encourage concrete action by all players, including industry and other stakeholders in healthcare, to develop solutions to improve Patient Safety
- To enable knowledge sharing, exchange of experiences
- To help set the agenda of important issues relating to Patient Safety

In order to accomplish these goals, the Task Force needs to develop the following actions. However these actions are to be seen as the basis for further debate:

ACTION ❶ To work together **with WHO Alliance for Patient Safety** towards a common understanding on patient safety issues

The Task Force should join forces with the WHO Alliance for Patient Safety[6] to attain their goals: to empower patients, to establish patient safety taxonomy, to perform research, to look for solutions and to foster reporting and learning.

ACTION ❷ To establish an "**EU solution bank**" with "best practice" examples[7] and standards

- Build upon existing research, e.g. SImPatIE and the MARQuIS projects.

- Transform the Simpatie-database into a sustainable web-based resource
- Build a common database for sentinel indicators of iatrogenic error and violation

ACTION ❸ To ensure that **EU regulations** with regard to medical goods and related services are designed **with patient safety in mind**

Focusing on:

- Developing a method to assess the Patient Safety Implication of proposed regulations, to ensure that Patient Safety is tackled in a systematic way. The European Commission and more specifically DG Health and Consumer protection should take patient safety into consideration as part of the newly introduced impact assessment of proposals developed by DG Health and Consumer Protection
- Developing best practice guidance in the delivery and administration of medicines in hospitals. This will include analyzing where potential errors arise, and identifying how mistakes could be avoided.
- The need to undertake all the necessary measures to make freedom of movement of the health professionals fully compatible with patient safety. The need for a Workforce Monitoring Forum to be set up at EU level, which could perform an important role in capturing information about the movement of health professionals within Europe in order to make predictions for future trends.
- For medical technology products:
    1) Auto-identification technology that can be used to trace devices from shelf to patient
    2) The instructions for use provided by the manufacturer to be strictly followed
    3) Warnings on medical devices and medication to be easily radable and clear in meaning.
    4) Instructions for use to be made available also in electronic format
- Consultation of the involved stakeholders, e.g. patients, professionals, institutions, purchasers, etc., in the above

ACTION ❹ To ensure that the European regulatory framework protects the privacy and **confidentiality of patient records** in the best interests of the patient, while at the same time ensuring that relevant patient information is **readily available** to appropriate health care professionals. The task force on Patient Safety could:

- Provide input on the issues and conclusions of the eHealth Conferences and more specifically on:

    - Networked electronic patient files: Electronic Healthcare Record System (EHRS) with Secure IAS Services[8] were said to be preferable over European Health Card for political and financial reasons.
    - European Health Insurance Card (EHIC) and Smartcard with health data
- Coordinate consultation with patient/citizens representatives on the confidentiality/convenience trade-off
- Coordinate consultation with CPME /doctor associations, nurses and other healthcare professionals as to what information they need.
- To use the Electronic Medical Record (and the Information and Communication Technology) as a tool to foster the best practices and to monitor the clinical pathways.

ACTION ❺ To initiate and stimulate the organization of **International Patient Safety Conferences**

- To ensure follow-up to the UK Presidency Summit on Patient Safety
- To ensure continuity on Patient Safety activities and events
- To ensure that patient safety is considered and forms part of all conferences for healthcare professionals

ACTION ❻ To collect and update information regarding Patient Safety to be published on the EU website

- A database with Patient Safety activities from the Simpatie project can be linked to the EU Commission's webpage
- Data on Patient Safety can also be included on the ECHI-project[9] website and on EU Health Portal

ACTION ❼ To promote instant sharing of Alerts to all Health Care systems[10].

4. Actions to promote activities by national authorities

The responsibility of national patient safety regimes lies with national (or regional) authorities. There is also a need for national authorities to promote "safety culture" since this is the main prerequisite for implementing incident reporting systems, to establish co-operation between professionals and patients, to develop effective patient complaints and patient compensation systems and generally implement patient safety measures.

However, the EU and European healthcare organizations can play a role in the activities of national authorities by giving these authorities directions for policies based on the knowledge available at the aggregated European level.

In order to be able to give proper direction, the legislation frameworks in the different countries should be compared at EU level. Mapping of these legislative frameworks is being performed by the Simpatie and Marquis projects, which are referred to in this text.

The areas where directions and advice can be given to national authorities and relevant actions can be planned are:

ACTION ❶ For patients to have access to their personal health information in an accessible format

The action should be focusing on:

- Providing guidelines based on existing patients' rights charters[11,12,13]
- Encouraging countries to adopt the WHO Alliance Patients for Patient Safety SPEAK UP campaign[14] and actively work to further develop this program
- Promoting the patient access or citizen access to their personal health information by Health Portal (eHealth)

ACTION ❷ To support national reporting systems of adverse events and near misses

Focusing on:

- identifying prerequisites for successful reporting system by comparing existing systems, e.g. the confidential system Danish Act on Patient Safety[15] and National Reporting and Learning System (NRLS) [16]
- exploring and demonstrating the complementarities of other information sources like reporting systems
  - of patient safety incidents in general[17]
  - of Adverse Drug Events[18,19]
  - Patient Complaints system

ACTION ❸ To establish patient risk management routines

The EU in cooperation with other relevant European organizations can provide the framework for an overall integrated system for managing risks. The Council of Europe highlighted that this requires:

- incident reporting system
- patient complaint system
- patient compensation system
- and a supervisory body for healthcare professionals [20]

ACTION ❹ To optimize the use of new technologies by healthcare professionals

- Since new developments are expected in the coming years , as discussed in the e-health Conference in Tromso[21] , the EU must proceed in research of the practicality and implementation of the new developments in the fields of :
  - Medication management
  - ePrescribing
  - Decision support systems
  - Electronic Medical Records
  - Telemonitoring
- Promote Tele-medicine applications with the support of satellite communication for remote areas
- Promote e-learning environments, such as the NPSA e-learning for staff[22]

ACTION ❺ To establish and develop national fora for patient safety

- Countries should be encouraged to set up national for a on patient safety issues
- Cooperation between these national fora must be advanced and facilitated by the EU and European organizations

ACTION ❻ To safeguard working conditions for all health care professions for the safety of patients

The EU and European organizations should work together on order to provide recommendations and directions to national authorities such as:

- The Directive on Professional Qualifications[23] is a tool to safeguard working conditions throughout Europe:

- The Working Time Directive to regulate residency training work hour limitations
- The Mastalka report[24] ‘Promoting health and safety at the workplace’

ACTION ❼ To ensure adequate user training for new medical technology and surgical techniques

To recognize and support the user training provided by medical devices, tools and appliances manufacturers thereby ensuring the safe use of new medical technology and surgical techniques.

ACTION ❽ To include patient safety in regular curricula[25] and continuous training programs for health professionals

- Council of Europe Recommendations emphasize education for Patient Safety at all levels within health care systems. European institutions can provide guidance on successful educational programs and help in translating those to different national contexts.
- Appropriate funding and facilities for CPD are a pre-requisite for a successful Patient Safety outcome[26].

ACTION ❾ To educate and empower patients on Patient Safety

- Awareness campaigns on patient's role in creating safety
- National surveys on patients' experiences with patient safety
- Collaboration with representatives of mass media to build patients'/ providers' partnership on safety matters.

ACTION ❿ To create the possibility of support mechanisms for national initiatives regarding patient safety projects

- Encourage development of national Patient Safety centers[27],
- Provide the possibility for European funding of pilot initiatives at national level

5. Action to be taken by health care providers

Although the stakeholder group's major focus is on European level, it is evident that changes on the level of local/individual health care settings and health care professionals have to be triggered. In the case of patient safety, it is necessary that actions and initiatives on the level of health workers and healthcare institutes have to be planned, and more specifically:

ACTION ❶ To implement work place projects focusing on patient safety and to establish an open culture to deal with errors and omissions more effectively.[28]

ACTION ❷ To initiate a co-operation between patients/ carers and health care professionals in order that patients/carers are aware of near misses and adverse events.[29]

ACTION ❸ To establish incident reporting systems within the organizations.

- To be used by all persons involved in delivering health care at all levels to gain insights in adverse events[30]
- Data from this reporting system should be used in addition to information from other sources like patient complaint system, patient compensation system and a supervisory body for healthcare professionals

6. Conclusion

Patient safety is an important tool to improve both quality of treatment and the financial sustainability of the health care sector. It is important to start acting now and continue working with all stakeholders involved: at the European, national and organizational level, by developing this working paper further and making efforts to achieve the goals set in this document.

The health related stakeholders recommend the European Commission to set up a Task Force on Patient Safety responsible for the implementation of the above mentioned activities. They also call upon the national authorities and all national member organizations to promote patient safety in their countries and they urge healthcare organizations to implement specific safety measures.

[1] See e.g. World Health Assembly Resolution 55.18, (http://www.who.int/gb/ebwha/pdf_files/WHA55/ewha5518.pdf,), WMA Declaration October 2002 (http://www.wma.net/e/policy/p6.htm), and the Luxembourg Declaration on Patient Safety (http://www.cpme.be/content.php?c=patient_safety , See also Annex 1)
[2]

[3] Safety Improvement for Patients in Europe http://www.simpatie.org
[4] Methods of Assessing Response to Quality Improvement Strategies http://www.marquis.be
[5] http://www.jcipatientsafety.org/show.asp?durki=9726&site=164&return=9335
[6] http://www.who.int/patientsafety/en/
[7] *Best practices resources examples:*

- The US Agency for Healthcare Research and Quality (AHRQ) report 'Making healthcare safer: A critical analysis of Patient Safety Practices' identifies 11 best practices with solid scientific basis. (http://www.premierinc.com/all/safety/resources/patient_safety/downloads/23_AHRQ_evidence_report_43.pdf)
- The US National Quality Forum report 'Safe practices for Better Care' provides a consensus-based list of 30 best practices based on the AHRQ publication. (http://www.qualityforum.org/txsafeexecsumm+order6-8-03PUBLIC.pdf)
- The NHS guide 'Seven steps to patient safety – A guide for NHS staff'. (Taken from: NPSA (2004), Seven steps to patient safety – A guide for NHS Staff, http://www.npsa.nhs.uk/health/resources/7steps .)
- Use the US '100.000 lives campaign' (http://www.ihi.org/IHI/Programs/Campaign)and the US JCAHO Sentinel Event Resource Index (http://www.jcaho.org/accredited+organizations/sentinel+event/se_index.htm)
- In the Netherlands the 100.000 lives campaign inspired a hospital and primary care improvement project called the 'Better Faster Programme' (http://www.snellerbeter.nl/index.php?english)
- The 10 steps programme in Australia which was used as the basis for the Lets Talk program in Ireland, advocating patient empowerment and supporting a rebalancing of healthcare interactions

[8] Secure eIdentification, eAuthorization, and eSignature Services.
[9] European Community Health Indicators (ECHI), http://europa.eu.int/comm/health/ph_information/dissemination/echi/echi_en.htm
[10] *Examples:*

- the alerts and advice section on the website of the NPSA (http://www.npsa.nhs.uk/health/alerts)
- the US ECRI Alerts Tracker (http://www.ecri.org/tracker/default.asp)
- European reporting system for medical device (EUDAMED) (http://europa.eu.int:80/idabc/en/document/2256)
- EMEA: Adverse Drug Events reporting system, EUdraVigilance (http://www.eudravigilance.org/human/index.asp)
- AFSSAPS : Agence française de sécurité sanitaire des produits de santé (www.afssaps.sante.fr)

[11] Patient Mobility Resolution, http://www.europarl.eu.int/oeil/file.jsp?id=5199322
[12] EU Charter on patient rights, http://www.activecitizenship.net/projects/project_europe_chart.htm
[13] World Medical Association Declaration on the Rights of the Patient, http://www.wma.net/e/policy/l4.htm
[14] See Forward Program 2005, p.13, www.who.int/patientsafety/en/
[15] http://www.patientsikkerhed.dk/admin/media/pdf/133907d0940e4d5f751852ec8f6b1795.pdf
[16] http://www.npsa.nhs.uk/health/reporting
[17] http://www.npsa.nhs.uk/ppr
[18] Sweden: http://www.kilen.org/indexe.htm
Netherlands: http://www.lareb.nl/home/index.asp
Denmark http://www.dkma.dk/1024/visUKLSArtikel.asp?artikelID=1565
UK http://www.yellowcard.gov.uk/

[19] Sweden: http://www.kilen.org/indexe.htm
Netherlands: http://www.lareb.nl/home/index.asp

Denmark http://www.dkma.dk/1024/visUKLSArtikel.asp?artikelID=1565
UK http://www.yellowcard.gov.uk/

[20] NHS presentation at CoE Conference in Warsaw
http://www.czd.waw.pl/patient/conference%20program.htm
[21] http://www.ehealth2005.no/
[22] http://www.npsa.nhs.uk/health/resources/ipsel
[23] http://www.europarl.eu.int/oeil/file.jsp?id=220062
[24] http://www.europarl.eu.int/oeil/file.jsp?id=5209222
[25] Universities should include patient safety in their curricula. UK new educational program[25] is very much an example of a 'curriculum for patient safety'
(http://www.dh.gov.uk/AboutUs/MinistersAndDepartmentLeaders/ChiefMedicalOfficer/CMOGeneralArticle/fs/en?CONTENT_ID=4107830&chk=/L1BHd)
[26] http://www.aemh.org/navigation/section6/CONFERENCE.html
[27] such as the UK NPSA (www.npsa.nhs.uk) and the Danish Selskab for Patientsikkerhed (www.patientsikkerhed.dk/)

[28] Some examples here are the Danish Act on Patient Safety and the US examples from the '100.000 lives campaign'(http://www.ihi.org/IHI/Programs/Campaign)

[29] An example of such an action is the Danish Society for Patient Safety 'Ten tips for patients' which were formulated to enhance the patient/doctor-partnership

(http://www.patientsikkerhed.dk/admin/media/pdf/e0d3baa17291d2923b8e4a644286cd75.pdf)
[30] Example can be found at NPSA (http://www.npsa.nhs.uk)

(Annex 1: Luxembourg Declaration on Patient Safety)

European Commission
DG Health and Consumer Protection

Présidence luxembourgeoise
du Conseil de l'Union européenne

Patient Safety – Making it Happen!

Luxembourg Declaration on Patient Safety

LUXEMBOURG DECLARATION

Access to high quality healthcare is a key human right recognized and valued by the European Union, its Institutions and the citizens of Europe. Accordingly, patients have a right to expect that every effort is made to ensure their safety as users of all health services.

Background:

The health sector is a high-risk area because adverse events, arising from treatment rather than disease, can lead to death, serious damage, complications and patient suffering. Although many hospitals and healthcare settings have procedures in place to ensure patient safety, the health care sector still lags behind other industries and services that have introduced systematic safety processes.

A number of investigations from all over the world have underlined the need for and the possibility of reducing the number of adverse events in the health sector. Current data show that almost half of all preventable adverse events are a consequence of medication errors.

Accordingly, tools must be introduced aimed at reducing the number and consequences of adverse events. The health sector should be designed in a way that errors and adverse events are prevented, detected or contained so that serious errors are avoided and compliance with safety procedures is enhanced.

As a result of the work done in this field by many players and institutions and the evidence gathered, it is now clear that the first step that needs to be taken should be to establish a culture of patient safety throughout the entire health system. Risk management must be introduced as a routine instrument within the running of the entire health sector. A precondition for risk management is an open and trusting working environment with a culture that focuses on learning from near misses and adverse events as opposed to concentrating on "blame and shame" and subsequent punishment.

Health sector induced harm to patients imposes a heavy burden on society. Investment in patient safety therefore has the potential to generate savings in expenditure coupled with an obvious benefit to patients.

Focus on patient safety leads to savings in treating patients exposed to adverse events and the consequential improved use of financial resources. In addition, savings are achieved in administration costs associated with complaints and applications for compensation. Most importantly, patient safety contributes to an increase in quality of life. In order to achieve this, the culture of safety can be improved significantly in various ways.

In light of the above, the conference recommends that "Patient Safety" has a significant place high on the political agenda of the EU, nationally in the EU Member States and locally in the health care sector.

LUXEMBOURG DECLARATION

The conference recommends the EU Institutions:

- To establish an EU forum with participation by relevant stakeholders to discuss European and national activities regarding patient safety.
- To work in alliance with WHO Alliance towards a common understanding on patient safety issues, and to establish an "EU solution bank" with "best practice" examples and standards.
- To create the possibility of support mechanisms for national initiatives regarding patient safety projects, acknowledging that patient safety is in the programme of DG Health and Consumer Protection
- To ensure that EU regulations with regard to medical goods and related services are designed with patient safety in mind.
- To encourage the development of international standards for the safety and performance of medical technology.
- To ensure that the European regulatory framework protects the privacy and confidentiality of patient records in the best interests of the patient, while at the same time ensuring that relevant patient information is readily available to health care professionals.

The conference recommends to the National Authorities:

- To provide patients with full and free access to their personal health information whilst ensuring data accuracy and that patients fully understand their treatment. It is acknowledged that "informed patients" are well positioned to safeguard their own health.
- To consider the benefits of a national voluntary confidential reporting systems of adverse events and near misses.
- To work towards the introduction of risk management routines, for example, by developing guidelines and indicators as a part of a quality assessment system in the health care sector.
- To optimize the use of new technologies, for example, by introducing electronic patient records. Such records would include the personal medical profile and decision-making support programs for health professionals with a view to reducing medication errors and increasing compliance rates.
- To establish national fora, with participation by relevant stakeholders, to discuss patient safety and national activities.
- To safeguard working conditions for all health care professions and to ensure that policies on recruitment and retention are linked to patient safety.
- To recognize and support the user training provided by medical devices, tools and appliances manufacturers thereby ensuring the safe use of new medical technology and surgical techniques.
- To include patient safety in the standard training of health professionals combined with integrated methods and procedures that are embedded in a culture of continuous learning and improvement.
- To ensure that national regulatory framework protects the privacy and confidentiality of patient records in the best interests of the patient, while at the same time ensuring that relevant patient information is readily available to health care professionals.
- To create a culture that focuses on learning from near misses and adverse events as opposed to concentrating on "blame and shame" and subsequent punishment.

The conference recommends to health care providers:

- To facilitate a collaborative care approach between health professionals and health care providers, aimed at enhancing patient safety.
- To implement work place projects focusing on patient safety and to establish an open culture to deal with errors and omissions more effectively.
- To initiate a co-operation between patients/relatives and health care professionals in order that patients/relatives are aware of near misses and adverse events.

Annex 2: Background on Patient Safety – magnitude and consequences

Authors: CPME/Danish Society for Patient Safety, 20 July 2005

Several studies have found different rates of adverse events among hospitalized patients, but all are alarming: 16.6%[31], 11.7%[32], 9.0%[33], 3.8%[34 35]. The least pessimistic study that found adverse events occurring in 3.8% of the hospitalizations also shows that 16.6% of these lead to death of the patients concerned.

Although no accurate figures for Europe exist, recent rough estimates based on the best available research[36]suggest that the numbers of hospital inpatient episodes every year in Europe which may result in some form of unintended harm is likely to be in the order of millions of cases. Around half of those incidents may be preventable.

Data from the USA show that 4% of national health expenditure is caused by adverse events.

The effects that adverse events can have on patients, health care personnel and society at large are significant. Patients may suffer both physically and psychologically from sufferings created by the injury itself, but also by the way the incident is handled. Health care personnel on the other hand may experience shame, guilt and depression, with litigations and complaints imposing an additional burden. Society at large suffers from a lower quality of life of its members, with associated extra health care costs but also costs caused by a lower productivity of the society.

Retrospective research shows that 40%[37] to 48%[38] of adverse events are preventable. Furthermore a recent study showed that the prospective design assesses 25% more of the adverse events as preventable compared to the retrospective assessment.[39] This indicates that an even greater proportion of adverse events may be preventable. Seeing the above conclusion is that a lot of human and financial costs can be foregone by giving Patient Safety the attention it deserves by focusing on creating cultures of safety throughout our health care systems.

Annex 3: OECD Indicators

The OECD report[40] presents the consensus recommendations of an international expert panel on indicators for patient safety. Using a structured review process, the panel set out to select indicators to cover the five key areas: areas hospital-acquired infections, sentinel events, operative and postoperative complications, obstetrics, and other care related adverse events. This report proposes 21 indicators as follows:

Area	Indicator Name
Hospital-acquired infections	Ventilator pneumonia
	Wound infection
	Infection due to medical care
	Decubitus ulcer
Operative and post-operative complications	Complications of anaesthesia
	Postoperative hip fracture
	Postoperative pulmonary embolism (PE) or deep vein thrombosis (DVT)
	Postoperative sepsis
	Technical difficulty with procedure
Sentinel events	Transfusion reaction
	Wrong blood type
	Wrong-site surgery
	Foreign body left in during procedure
	Medical equipment-related adverse events
	Medication errors
Obstetrics	Birth trauma - injury to neonate
	Obstetric trauma – vaginal delivery
	Obstetric trauma - caesarean section
	Problems with childbirth
Other care-related adverse events	Patient falls
	In-hospital hip fracture or fall

Notes

[31] Wilson RM, Runciman WB, Gibberd RW et al. The Quality in Australian Health Care Study. *Medical Journalm of Australia,* 1995, 163:458-71.

[32] Vincent C, Neale G, Woloshynowych M (2001) Adverse events in British hospitals: preliminary retrospective record review, Clinical Risk Unit Department of Psychology University College London, BMJ 2001;322:517-519 (3 March)

[33] Schioler T, Lipezak H, Pedersen BL et al. Danish Adverse Event Study. Incidence of adverse events in hospitals. A retrospective study of medical records, *Ugeskr laeger*, 2001, 163 (39):5370-8.

[34] Brennan TA, Leape LL, Laird N et al. Incidence of adverse events and negligence in hospitalised patients: results of the Harvard Medical Practice Study. *New England Journal of Medicine*, 1991, 324 (6):370-7

[35] Leape LL, Brennan TA, Laird N et al. The nature of adverse events in hospitalized patients. Results of the Harvard Medical Practice Study II. *New England Journal of Medicine*, 1991, 324 (6):377-84.

[36] OECD Health Data 2002. The data includes: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Hungary, Ireland, Italy, Luxembourg, Netherlands, Portugal, Slovak Republic, Spain, Sweden, United Kingdom and excludes the following countries: Greece, Poland, Cyprus, Estonia, Latvia, Lithuania, Malta and Slovenia. For these countries OECD data show 74932746 hospital discharges for somatic diseases only. The AE rate of 3,8% results in: 0,038*74932746=2847444, so almost 3 million AEs for somatic diseases only.

[37] Schioler T, Lipezak H, Pedersen BL et al. Danish Adverse Event Study. Incidence of adverse events in hospitals. A retrospective study of medical records, *Ugeskr laeger*, 2001, 163 (39):5370-8.

[38] Vincent C, Neale G, Woloshynowych M (2001) Adverse events in British hospitals: preliminary retrospective record review, Clinical Risk Unit Department of Psychology University College London, BMJ 2001;322:517-519 (3 March)

[39] Michel P, Quenon JL, Sarasqueta AM, Scemama O (2004) Comparison of three methods of preventable adverse events in acute care hospitals, BMJ 2004; 328:199 (24 January)

[40] Selecting Indicators for Patient Safety at the Health Systems Level in OECD Countries, http://www.oecd.org/dataoecd/53/26/33878001.pdf