

The hospital pharmacist: your stakeholder for in-hospital medication safety!



Jacqueline Surugue Professor AG Vulto

Patient safety is suddenly high on the political and public agenda. The safety of patients in hospital is a small part of a developing scenario of increased perception and reduced acceptance of risk, but the part to which hospital pharmacists are called upon to respond. The reasons for today's increased vulnerability of patients can be described by 3 Cs:

- Complexity
- Cost-effectiveness
- Cooperation and communication

Treatment in hospital is **more complex** than it used to be. Doctors are treating more complicated diseases with more complex interventions. Think of open heart surgery, solid organ and bone marrow transplantation, and intensive cancer treatment. In addition, technological advances mean that specialist skills are required to operate a wide range of new devices and interpret their readings.

More competition in medical care between providers, hospitals, and third party payers, cost-consciousness and **pressure on efficiency** has resulted in reduced staff, shorter hospital stays and more intensive treatment.

As a result, medical care in hospitals is increasingly dependent on **seamless cooperation** between medical specialists and other professionals. Many studies have indicated that shortcomings

in communication and management may lead to unsafe practices.

Hospital pharmacists are experts in most aspects of safe medication practice. From drug selection by means of the hospital formulary; support for physicians regarding dosing / individual dose adjustments, interactions and therapeutic drug monitoring; to acquisition of high quality drugs, either by purchasing or in-house production and quality control, logistics; and finally drug distribution to the patient. Only the pharmacist is equipped to overview this whole process and in the EAHP's opinion the hospital pharmacist is the key stakeholder.

To address safety issues in hospital, hospital pharmacists call upon a fourth "C": the need to make the public and policy makers / politicians **conscious** of the ideal position they occupy as experts on medicines. The EAHP was surprised to see "Patient Safety – Making it Happen" organised by the European Union Presidency in April 2005 lacking a single pharmacist among the speakers. In this special issue we report on this meeting, which resulted in the Luxembourg Declaration on Patient Safety (summarised on page 20). The EAHP is one of the signatories of that declaration.

In May 2006 the Council of Europe issued a document on Patient Safety that says "medication errors are the most common single preventable cause of adverse events and European health authorities should consider them as an important public health issue." Nonetheless, the word pharmacist occurs only once in the 15-page document. Again: our message is that where medicines are concerned, hospital pharmacists play a pivotal role.

The European Association of Hospital Pharmacists – representing more than 20,000 pharmacists in 26 European countries – strongly supports Patient Safety and medication safety: it was the theme of our 1,700-delegate annual congress this year. Patient safety features

prominently in our official journal, the European Journal of Hospital Pharmacy, distributed to all our members.

Safe medication practice requires sufficient staff. Based on an EAHP survey and OECD data, we have estimated the average workforce involved in pharmaceutical care (see page 4-6). In the opinion of the EAHP, medication safety programmes may be under pressure in countries with a below-average number of pharmacists (ie. under 0.9 hospital pharmacists / 100 beds), unless related staffing levels are sufficient to compensate. Clearly patients are more at risk in some countries than in others and the European Commission and the national health authorities should be concerned to provide a sufficient number of fully trained hospital pharmacists to achieve what has been promised in European policy documents. Or, in the words of the Council of Europe ministers: "the safety of medication and interventions is the essential feature of healthcare provision and its cost should be included in the general budget.....".

We hope this special issue will convince you that improvements in medication safety cannot be taken for granted and that the EAHP is committed to ensuring the best achievable safe medicines practice. We welcome your feedback to our president, Mrs Jacqueline Surugue (president@eahponline.org) or our executive director, Mrs Catherine Hartmann (ed@eahponline.org).

Please visit our website (www.eahp.eu) for more information on our association, our members and the EJHP, our official journal.

On behalf of the Board of the European Association of Hospital Pharmacists,
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Patient safety: the new challenge



Wim Schellekens
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The issue of patient safety is now recognised as a serious problem in many countries. Health care is about curing, helping and supporting people and their relatives, and the successes in this area are many. But health care can also have unexpected and unwanted side effects, sometimes causing harm to the patient instead of the planned benefit. Baseline epidemiological research in many countries shows that patient safety is a serious and, until now, mostly hidden problem.

Patient safety is an umbrella term under which reside many categories of (potential) harm to patients: errors, medication problems, post-surgery wound infections, falls, bedsores, technical failures, communication issues, etc.

Research and many successful programmes show that we can do something about it. The main barrier to change is the culture around patient safety: the naming-blaming-shaming culture around errors and adverse events prevents us from recognising the problem, from learning from what goes wrong and to applying what we have learned. This is the reason we need leadership for change—clinical and managerial leadership at all levels of health care.

Building the will to change

Patient safety is a big and, until recently, hidden problem in our healthcare systems. The report “To Err is Human” from the Institute of Medicine in the US (1999) was the first that not only revealed the unpopular facts of human error but also treated the issue in a constructive, educational and challenging way. One

of the main conclusions was that harm to patients in almost all cases is a system problem and that naming, blaming and shaming is counterproductive for learning and improvement.

Baseline epidemiological studies in many countries show the same results: the rate of adverse events in hospitals is about 10% of all admitted patients (USA, Australia, UK, Denmark, New Zealand, Canada). Three per cent of all admitted patients experience some kind of moderate or serious harm, and in about 10% of these 3% this harm is so serious that the patient dies. This means 45,000–95,000 deaths in the US or 3,000–6,000 deaths in The Netherlands; estimates are that with our current knowledge about 50% of these deaths could be preventable. These data are only from admitted patients in hospitals. We still have almost no data from outpatient clinics, primary care facilities or nursing homes.

Reliability studies show that in only 60% of cases do patients receive the necessary beta-blockers and aspirin after a myocardial infarction (error rate around 1:10); wound infection after surgery, bed sore and death in high risk

surgery rates are about 1:100; neonatal mortality and general surgery death rates are about 1:1,000; the death rate in routine anaesthesia is about 1:10,000; and the blood bank error rate is 1:10,000. To compare: error rates in the airplane industry, nuclear power plants and the petrol chemical industry are from 1:1,000,000 to 1:10,000,000—an almost error-free environment.

Apart from these data, we now know that there is also unacceptable variations among doctors and hospitals: post surgery wound infection rates vary from between 2 and 9%, bed sore rates between 5 and 25%, etc. This shows the difference between best practices and many other instances. What a great opportunity to improve!

Vision for change

There is good news: we can do something about it. Breakthrough collaborations in the US, UK, Sweden, Australia and The Netherlands show that we can reduce medication errors to almost zero, that unnecessary pain after surgery can be eradicated, that bedsores in hospitals can be reduced to under 5%. Introduction of blame-free reporting at the departmental level increases the number of reported

incidents four to 10 times—a wealth for learning and improvement!

In many countries, patient safety has become the main strategy for improvement in healthcare systems. The World Health Organization has launched the very promising programme “World Alliance for Patient Safety”, under the leadership of Liam Donaldson, England’s Chief Medical Officer. The EU started the “Simpatie” project [1], a collaboration of organisations and knowledge institutes in the EU to bring together all we know around patient safety and translate this knowledge to patients and providers (coordinated by the Dutch Institute for Healthcare Improvement CBO). Under the presidency of Luxembourg, 2005 saw the first conference dedicated to

priority, the leadership has to take action to reformulate the “safety first” goal (mission), to decide what aims have to be reached five years from now (vision) and what has to be done by next year (strategy).

Systematic measurement, analysis of data and actions toward improvement must be introduced, as well as sustaining and increasing positive results. A real emphasis should be on applying what we already know.

It is also a leadership task to introduce a “blame-free reporting system” to learn from adverse events. This is the most important effort to change the culture from within.

On the national level



The Dutch Institute for Healthcare Improvement coordinates the SIMPATIE Project, a collaboration of EU institutions formed to share information around patient safety.

patient safety, which will ensure that this issue is high on the EU-agenda.

Strategy for change

Patient safety is a real, but hidden, problem. There is a vision and a willingness to do something about it, but what should be done? What should be put on the agenda?

On the institutional level

Patient safety is everybody’s task: doctors, nurses, managers. Anybody can take initiative and make a difference. But to make it an institutional

Change for improvement has to be implemented in the working environment. How can systems support and stimulate the desired actions? What might governments do?

- Make patient safety a national priority. Every country needs its own data to create a much-needed sense of urgency.
- Apply what we already know: discover best practices and develop a nationwide strategy for adopting them.
- Create incentives that stimulate learning and improvement.
- Build/support a national centre of

expertise on patient safety, improvement and implementation.

- Introduce measurement, analysis, improvement and control on a national level.
- Develop a research agenda for patient safety.

On the European level

How can the European Union work to promote patient safety?

- Anchor political commitment to create a common sense of urgency and a vision for change.
- Collaborate in designing and implementing systems.
- Take shared action on high priority topics: i.e. medication safety, post surgery wound infections, blame-free reporting, eHealth.
- Organise shared learning: build networks of experts, support centres.
- Build a common research agenda.
- Combine efforts to support the new EU countries.

Conclusion

Patient safety is a big hidden problem in our health care. We unintentionally harm patients. We have discovered the problem. We know what we can do about it. It is now time for action.

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1. A collaboration of the Council of Europe, CPME (European Doctors), HOPE (Hospitals of the European Union), ESQH (European Society for Quality in Healthcare), HAS (Haute Autorité de Santé, for accreditation), LMCA (Long Term Medical Conditions Alliance, for patient involvement) and CBO (Dutch Institute for Healthcare Improvement). This project is funded by the European Union. 213.177.130.12:591/database/Simpatie.pdf.

Workforce of EU hospitals and pharmacy services: a direct patient safety issue

Jacqueline Surugue, EAHP President

Professor Arnold G Vulto, EAHP Director of Education, Science and Research

There are many factors that contribute to a hospital’s ability to provide quality of care, but one of the most basic is the “number of hands on the bed.” Patient and medication safety cannot be addressed without a serious consideration of human resources [1]. In a hospital setting, this includes an adequate number of doctors and nurses, of course, but also with regards to medicines, to pharmacists and pharmacy technicians.

Hospital pharmacists play a key role in the “healthcare team” (a term which will be used throughout this article to refer to pharmacists, pharmacy technicians, nurses and doctors), when it comes to medication safety, but any comparison of adequate staff must consider the other healthcare team members, as well as the country’s healthcare system.

When looking at populations across the 26 EAHP member countries, six – Spain, Poland, Germany, Italy, the UK and France – represent 75% of the total population but account for 85% of the total number of hospital pharmacists, while the remaining 15% represent the 20 countries that make up 25% of the population. So it appears that there is no equal distribution of hospital pharmacy workforce over Europe. This warrants some further analysis.

According to the data published in the 10th Anniversary issue of EJHP 2004;10 (6):106-7 on Development of EAHP [2], the average number of practising hospital pharmacists per 1,000 inhabitants across Member States is 0.047, but there are

major discrepancies in the ratio of hospital pharmacists per 1,000 inhabitants by country—from 0.020 in Germany to 0.090 in Finland (see Figure 1). Per

Figure 1: Practising hospital pharmacists per 1,000 population (Average: 0.047)

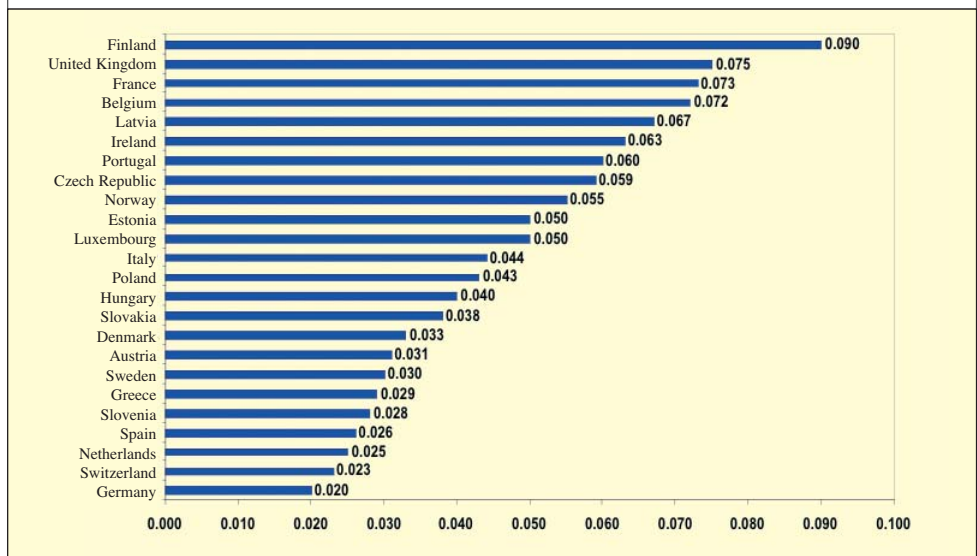
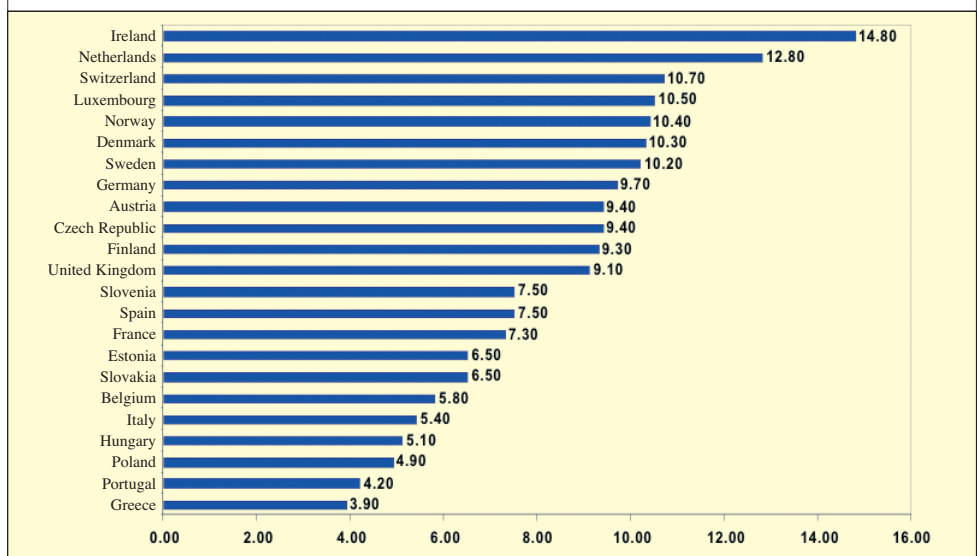


Figure 2: Practising nurses per 1,000 population (Average: 8.31)



hospital bed (see Figure 5), Estonia has the highest concentration of hospital pharmacists with nearly two per 100 beds, followed by Norway with 1.75. Switzerland and Germany have the lowest ratios at one-third hospital pharmacist manpower per 100 beds. This means that in Switzerland, each hospital pharmacist is responsible for 305 beds and in Germany, 319 beds. The average number of hospital pharmacists per 100 beds across Member States is around 1 (exact: 0.93). This makes it understandable that the role the hospital pharmacy can play in the healthcare team will vary also considerably across Europe.

Some of these discrepancies are due to the structure of health systems in various countries, including the respective roles of hospital and community pharmacists and the roles of other members of the hospital healthcare team. The roles played by members of the healthcare team can depend on healthcare culture or simply on the total number of each group available in any given country, which must be taken into account when assessing a country's or hospital's ability to invest in quality care, including the implementation of successful patient safety programmes with root cause analyses of adverse events.

When looking at the three main activities involved in drug treatment – prescribing, distributing and administering – it is easy to ascribe each area to one set of professionals – doctors, pharmacists and nurses, respectively. However, in many countries, nurses are largely responsible for both distributing and administering drugs. Therefore, in a country with a high ratio of nurses per bed, a lower ratio of pharmacists might be expected, and this does not necessarily lead to a lapse in the ability to provide sound patient safety due to lack of staff.

If we look at the UK as an example, we see that the number of hospital pharmacists per 1,000 residents and per hospital bed is high. However, as Figure 3 shows, the number of practising doctors per 1,000 residents in the UK is the lowest in Europe. Therefore, in regards to patient and medication safety, a shortage of doc-

tors is made up for by an influx of pharmacists. Similarly, while the number of beds per hospital pharmacist in Germany and Switzerland, as noted above, is very high, nursing and physician numbers in both countries are well above the European average. This means there may be adequate overall staff support to ensure a basic level of safety.

Although an adequate number of total staff may exist to ensure some standard of patient safety, the role and competencies of healthcare team members must also be taken into consideration. In Czech

Republic, for example, an above-average number of nurses per 1,000 residents could be due to pharmacists not practising clinical pharmacy; nurses are responsible for preparing ward stock and for full administration of drugs to patients. Although total number of healthcare workers are adequate in hospitals in the country, the lack of pharmacist involvement in the wards is a patient safety concern that is not shared by the UK.

Total numbers of each group of the healthcare team lead to certain kinds of practice, which is why hospital phar-

Figure 3: Practising doctors per 1,000 population (Average: 3.18)

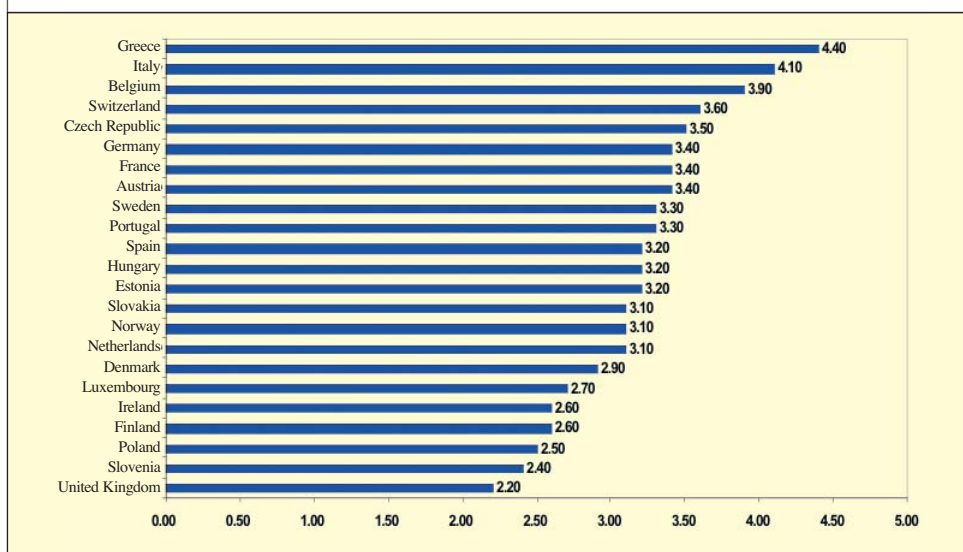
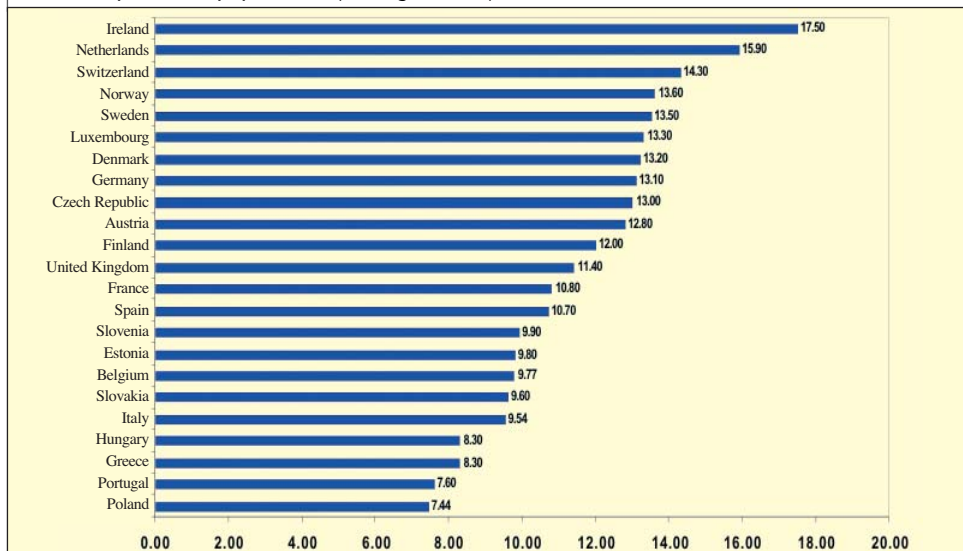


Figure 4: Practising total healthcare team members (doctors, nurses, hospital pharmacists) per 1,000 population (Average: 11.54)



macy in the UK differs from the rest of Europe, with pharmacists not only practising clinical pharmacy on the wards but doing so on a daily basis. This also helps explain the country’s movement toward supplementary pharmacist prescribing – a trend directly due to a shortage of available doctors.

Although the total number of healthcare workers per 1,000 people in the UK is average and comparable to several other countries (see Figure 4), the high ratio of pharmacists enables them to apply their specific technical skills to activities best performed by medication experts. A recent study in The Netherlands showed that the error rate at a decentralised pharmacy intravenous admixture unit (satellite pharmacy) was 2%, while the error rate when nurses made preparations on the ward was an eye-opening 71% [3]. But because The Netherlands’ ratio of pharmacists to nurses is quite low (0.75 pharmacists per 100 beds compared to 1.28 nurses), nurses may perform tasks better left to trained pharmacy technicians. Still, the high overall number of care staff in The Netherlands, which is 15.9 per 1,000 residents, ensures that nurses are not overworked, which is one of the leading causes of medication safety errors.

Data published in the 10th Anniversary issue of EJHP 2004;10(6):106-7 showed Estonia and Norway have the lowest number of beds to hospital pharmacist. The lower the ratio of beds to total hands, the lower the incidence of accidents and adverse effects [1, 4, 5]. Thus, even though Estonia has a below-average total number of healthcare team members, its very low ratio of beds to hospital pharmacists and its average number of hospital pharmacists per 1,000 population puts hospital pharmacists at an advantage to contribute to overall safety measures in hospitals, particularly in regards to clinical pharmacy. Norway is, as we can further see in Figures 1 and 4, at an even greater advantage to ensure patient and medication safety.

When comparing statistics across European countries, all this data must be taken into consideration because statistics can be misleading. France, for example, at 1.5 pharmacists per hospital is more than six times less than in the UK, despite a similar total number of hospital pharmacists. This is because France has a higher total number of hospitals. Also, as data from the Organisation for Economic Co-operation and Development (OECD) confirms, there are large differences in the number of hospitals in OECD member

countries with no apparent correlation with population. It is understandable that a hospital pharmacy needs a certain critical mass for proper management and back-office activities to allow for patient-oriented tasks. This can be better organised in larger institutions, and this is exactly what one sees happening in the UK and some other countries where hospitals are merging.

When assessing adequate needs for patient safety procedures and outcomes and the role a hospital pharmacist can play here, we must take into consideration the number of pharmacists per hospital, the number of beds per pharmacist and the role of the pharmacist in the healthcare team (“total number of hands on the bed”). With the background data provided in this paper, every hospital can benchmark its own staff availability to ensure safe medication practices and to develop a policy in case it needs improvement.

Acknowledgement

Figures 2, 3 and 4 data are from Health at a Glance, OECD Indicators 2005, ©OECD.

Figure 4 data is also based on results published in EJHP 2004 [2].

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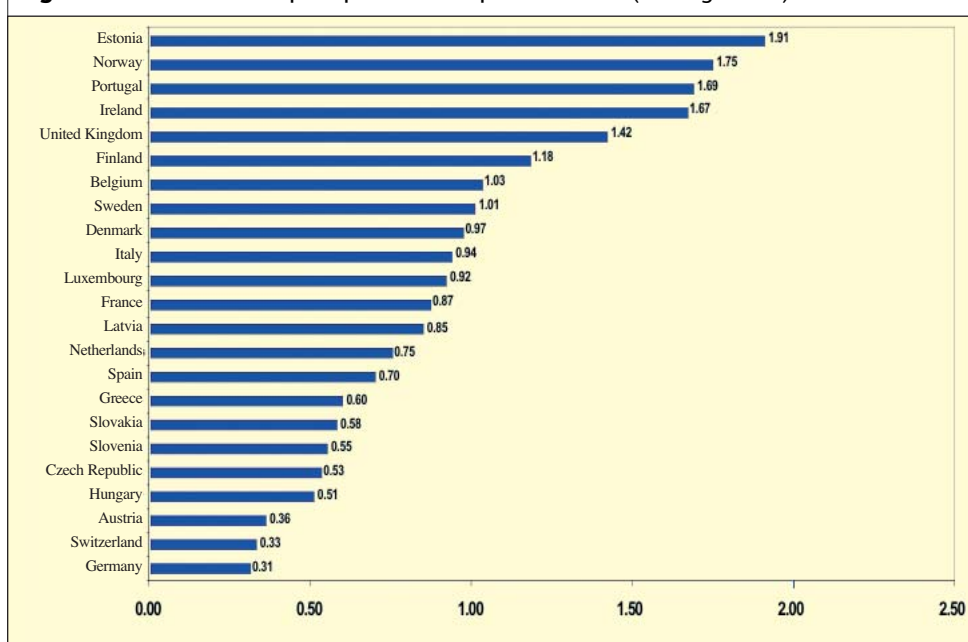
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Figure 5: Number of hospital pharmacists per 100 beds (Average 0.93)



Risk analysis and assessment: a tool for pharmacy practice



Extrinsic risks of treatment in a hospital include failures of the medical system and practitioners. The Bow Tie method can be used to identify where control over a process is lost and whether it is proactive (maintaining control) or mitigating (attempting to minimise consequences). Analysis of the medication process has identified at least 120 different threats and a number of systematic weaknesses.

Professor Dr PTW Hudson

The medical profession has always paid attention to the risks of procedures and drugs when treating patients. We can distinguish between intrinsic risks, which are inherent in treatments, and a different class of risks that cover failures or inappropriate procedures and medicines. For instance, there are a number of dangers intrinsic to nephrectomy; the risks are well known and involve the individual characteristics of the patient, the anatomy and physiology of the systems under consideration and the necessary elements of the procedure, such as anaesthesia. What is *not* included are a number of risks of medical failures, such as removing the wrong kidney, performing the operation poorly or connecting the wrong lines for the anaesthesia.

Similarly, significant risks are recognised with respect to medications that are intrinsic to the pharmacological processes and individual characteristics of patients. These recognised risks do not, however, include incorrect dosage, administration of the wrong medication or the fact that a patient may have been given an incorrect diagnosis.

We can label this second class of risks “extrinsic.” The famous 1999 study by the US Institute of Medicine [1] estimated that in the US between 44,000 and 98,000 people may die yearly as a result of medical errors. There are no indications that the EU is significantly different in this respect, which implies an EU mortality rate from medical error between 68,000 and 152,000. All of these incidences are the result of failures of the medical system to provide what is agreed to be the best care. This is quite different from mortality or morbidity resulting from problems where the risks were well known and those risks were taken, even if the consequences were unfortunate.

“As the medication system relies primarily on people rather than hardware, opportunities for failure are much less clear.”

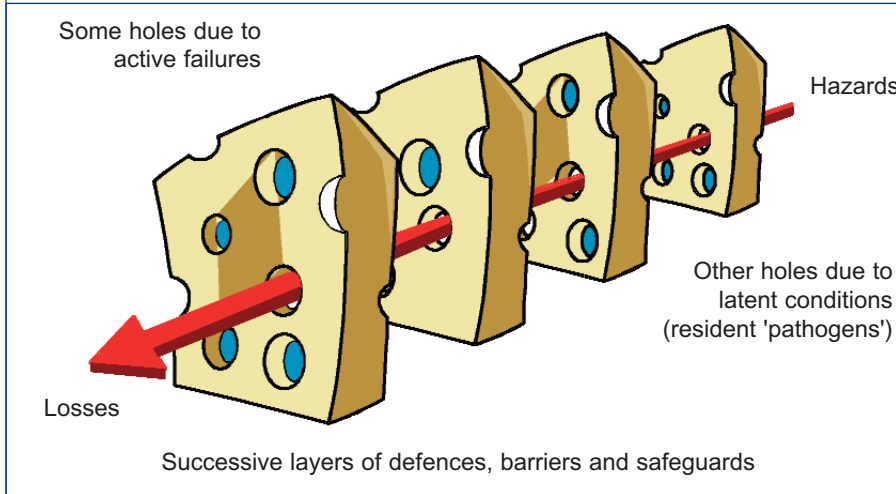
Medical systems are not well prepared to manage extrinsic risks, as shown by these high failure rates. Most approaches to managing medical errors have concentrated on

developing incident reporting systems – for example, the UK NHS report *An organisation with a memory* [2]. These are pitched as a way of flushing out problems that can then be solved, and incident reports currently form the main source of information available on such failures. A major problem with this is that members of the medical professions find it difficult, and often threatening, to report adverse events and near misses, whether they involve themselves or their colleagues. An alternative approach, one used in highly hazardous operations such as the nuclear power and oil and gas industries, involves the systematic analysis of hazards and

risks associated with the organisation’s activities and environment [3].

Risk assessment forms the core of any safety management system. Without a

Figure 1: The Swiss Cheese Model (Courtesy J Reason)



systematic identification and evaluation of the hazards, any approach to the management of extrinsic risks will be essentially ad hoc. The system needs to know how hazards can occur, how they can be controlled and consequences mitigated and how these controls themselves might fail. So, how can we analyse the extrinsic risks of medication and assess whether they are significant for patients? The current approach is heavily biased towards collecting information

from reports of adverse events and near misses. It is essentially reactive: 1) waiting for something to go wrong, and then 2) relying upon the issue being recognised as an incident/error, as many failures may produce no clinical effects, and finally 3) the practitioner(s) involved considering it to be worth reporting.

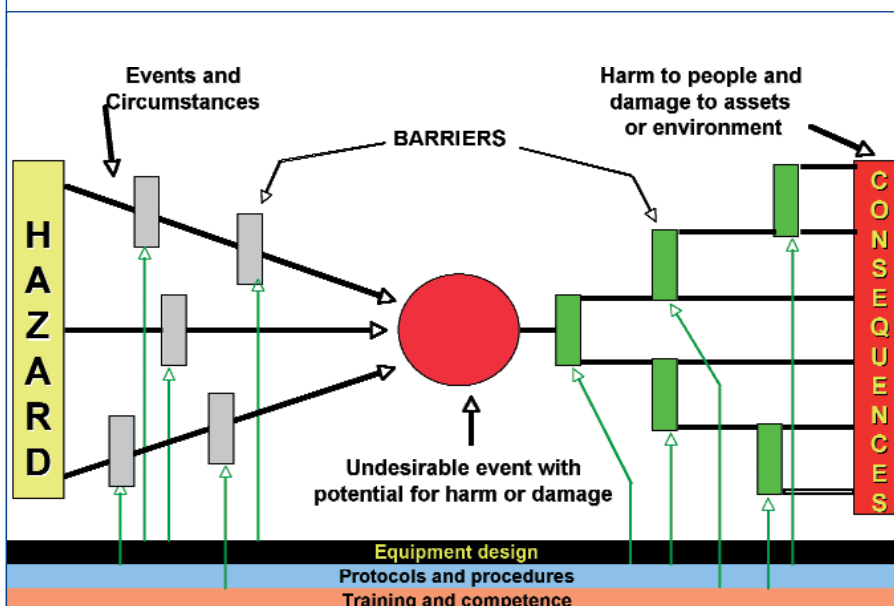
In terms of J Reason’s Swiss Cheese model (Figure 1) [4], this system provides us with information about

which barriers have holes and how large they are. When a failure reflects badly on the individual, especially if there has been no clinically significant consequence that must be reported, it is hard to persuade people to own up. When reporting does take place, it is often used simply to achieve other ends rather than to learn about system failures by having an unbiased sample of reported failures. For example, people may selectively report incidents to highlight a specific problem they experience, such as understaffing.

Industrial risk assessment

So how is risk analysis and assessment performed elsewhere? There are two basic approaches. One uses incidents and uncovers root causes by working backward from consequence to cause. The other, Failure Mode and Effect Analysis, moves from possible causes towards potential incidents by systematically varying every element or component in a system and seeing what failures result. The latter approach, while proactive, is labour intensive and is usually only applied to engineering problems with a concentration on “hard” component failures. As the medication system relies primarily on people rather than hardware, opportunities for failure and assessing how failures propagate are much less clear [5].

Figure 2: Bow Tie Risk Analysis Model



A risk analysis method called the Bow Tie model provides a way of combining these two approaches while significantly reducing the complexity (see Figure 2). Bow ties are based around a “top event,” the event or situation at which no adverse consequences have yet occurred, but where control over the process has been lost. There are a number of “threats,” ways in which the “hazards” can be released leading to a “top event” and on to the undesirable “consequences.” To prevent hazards

being released and the consequences happening, we can place barriers on the “threat pathway.” These barriers may depend on hard controls, such as infusion pumps that can only deliver a fixed rate, on protocols, such as requiring the presence of two people to administer medicines, a mixture, such as requiring the use of bar codes for drugs and patients, and training and competence, such as when vigilance is required to check the difference between NaCl and KCl.

A full bow tie represents a risk analysis with all the threat pathways and barriers identified. If the frequencies of threats and the effectiveness of the barriers are quantified, then we have a risk assessment. In the case of medication, we can simplify our task by assuming that medicines are always hazardous, as may be their absence.

Medication risk analysis

Generally, in the case of medication error, there are five undesirable situations that can be represented by distinct “top events” [6]. These are: 1) the Wrong Patient, 2) the Wrong Diagnosis, 3) the Wrong Drug, 4) the Wrong Dose and 5) the Wrong Delivery Route. The left side of the bow tie takes the hazards of medicines and shows how they can be unleashed. The right side shows how the undesired consequences can occur, including harm to patients, reputation and other losses for a hospital or for health professionals. There are a number of routes to and from the “top event.” Along each pathway, we can identify possible barriers (the slices of Swiss cheese) that can prevent the threat from becoming actualised.

On the left-hand side of the bow tie, the barriers represent preventative controls. Each of these barriers is unlikely to be perfect, and we can further identify what factors can reduce the effectiveness of any barrier. On

the right-hand side of the “top event,” we have the pathways to different consequences, which may range from no clinically observable effect to death of the patient, as well as reputation damage to the healthcare professional(s) and the hospital. On this side, the barriers represent mitigation measures, ranging from an antidote, if one is available, to procedures for talking to patients or relatives to reduce the chance of legal action. Antidotes, or palliative measures, require timely detection of problems after the event; sincere apologies go a long way to reducing legal consequences. When dealing with a “top event,” the measures required on the right-hand side are usually independent of what threat created the problem in the first place. For instance, an incorrect dosage has to be remedied, if this is possible, regardless of how it came to be incorrect.

So far we have identified about 120 different threat pathways. For instance, the mere presence of twins raises the possibility of a wrong patient event, so the next question is, what can we do to raise the chance of getting the right patient above 50% in the case of twins? Neonate twins may not even have names, so we can use bar-coding, which can be highly effective – provided that the documentation is itself correct and the barcode printer and readers are functional. We have also learned that the diagnosis step, often excluded from definitions of medical error, is both critical and poorly defended from error/failure. An incorrect diagnosis, once made, is hard to overturn. Many of the barriers require vigilance by members of the nursing staff, a commodity easily pressured by other demands.

Conclusion

The bow tie approach allows us to provide a systematic analysis of the ways hazards can lead to conse-

quences, in this case the risks associated with medication. The technique for developing bow ties is non-threatening, in fact often energising, as all involved in the process can use their knowledge of what *might* go wrong and what can prevent it [6]. For a patient, the risk picture actually includes both intrinsic and extrinsic risks; they do not distinguish the causes if something goes wrong.

Fortunately, the approach described here need not be restricted to extrinsic risks, where the medical system and individuals may have failed. We can and must ask the same questions and collect similar data when we attempt to understand the intrinsic risks. If a specific substance is both potentially effective and hazardous (as all medicines are at some level), then we ought to be able to identify the threat pathways and the controls that can be applied to minimise the risks to patients while maximising therapeutic efficacy.

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Drug-related problems: definitions and classification



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When reviewing literature on drug-related problems, most studies are difficult to compare because of variations in definitions and classification. A uniform definition and classification system for drug-related problems would solve this. A proposal for such a system is described in this article.

Drugs are a dualistic therapeutic tool. They are intended to cure, prevent or diagnose diseases, signs or symptoms, but the shadow side is that improper use can be the cause of patient morbidity and even mortality. While in the 1960s the interest in adverse drug reactions increased greatly after the thalidomide disaster (which can be considered as the final trigger for the establishment of formal programmes of drug approval and subsequent surveillance), only in recent years has attention shifted toward the problem of medication errors [1]. Literature is now expanding rapidly for both adverse drug reactions and medication errors.

In general, problems related to the use of approved drugs can be summarised with the term “drug-related problems” [2]. When reviewing the literature on drug-related problems (DRPs), one quickly discovers that most studies are difficult to compare because of variations in definitions and classification of DRPs [3, 4]. A uniform definition and classification system for drug-related problems would solve these difficulties.

Definitions

DRPs can be divided into intrinsic and

extrinsic toxicity. Intrinsic toxicity is caused by the interaction of the pharmaceutical, chemical and/or pharmacological characteristics of the drug itself and the human biosystem. Intrinsic toxicity is therefore synonymous with adverse drug reactions (ADRs). An ADR is defined by the World Health Organization (WHO) as “any response to a drug which is noxious and unintended and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of disease, or for the modification of physiological function” [5]. Previously unknown drug-drug interactions and lack of therapeutic effect [6] are included in this definition. Mechanistically there are two types of ADRs: Type A and Type B [2].

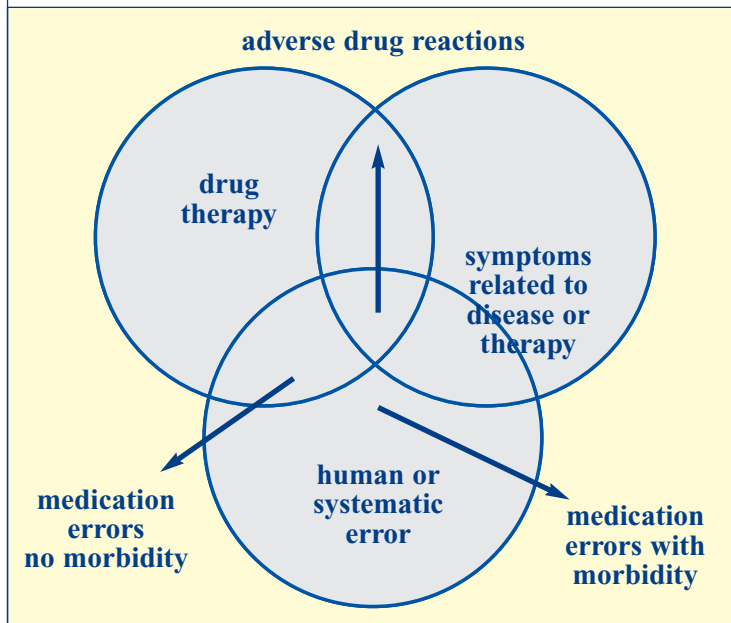
Type A reactions are pharmacological effects as much as therapeutic actions are, the essential difference being that they are unintended. Examples are constipation during the use of morphine and peptic ulcer induced by NSAIDs. Type A effects are by far the most prevalent. As a rule, there is a dose-response relationship: Type A ADRs are more frequent and more severe when higher doses are taken.

Type B reactions, in contrast, refer to the

phenomenon that a medicine is well tolerated by the (vast) majority of users but elicits an idiosyncratic reaction in predisposed patients. Type B effects are often unexpected (ie from pharmacology), rare and severe. Type B reactions have historically been the major reason for the withdrawal of medicines from the market. Characteristically there is no dose-response relationship. Type B effects are either immunological or non-immunological forms of hypersensitivity and occur in patients with a predisposing condition, which is often unknown or unrecognised. Stevens-Johnson Syndrome and anaphylactic shock are two examples of Type B reactions.

Extrinsic toxicity refers to the problems caused by the handling of the drug either by the healthcare professional or by the patient. The drug is not used in the proper way: a medication error has been made. A medication error is defined as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient or consumer [7]. Therefore, medication errors do not necessarily need to result in harm to the patient. In contrast, ADRs always involve some form of harm. Known drug-drug

Figure 1: Relations between definitions



both ADRs and medication errors [8-10]. The relationship between the various definitions is depicted in Figure 1.

Classification of intrinsic toxicity

ADRs can be classified using the WHO adverse reaction terminology [11]. According to this, ADRs are divided into 32 system-organ classes (e.g. skin). The class forms the first part of the code (e.g. 0100 for skin). The second part is formed by the so-called “preferred term,” a code that describes the ADR more specifically (e.g. 0001 for acne). Together both codes form the exact classification of the ADR, so 0100-0001 would refer to the skin reaction acne. A classification of seriousness is also often necessary. This can be achieved by applying the WHO Critical Terms List [12], which are ADR-codes related to possibly serious conditions. In practice, this classification is more useful than the more legal definition of serious: death, invalidity or (a longer duration of) hospitalisation. Finally, it is important to do a causality assessment of ADRs, for which various systems exist [13].

Table 1: Classification of prescribing errors

Administrative and procedural errors

- general (e.g. readability)
- patient data (e.g. patient mix-up)
- ward data and prescriber data
- drug name
- dosage form and route of administration

Dosage errors

- strength
- frequency
- dosage too high/low
- no maximum dosage in “at need” prescription
- length of therapy
- directions for use

Therapeutic errors

- indication
- contra-indication
- monitoring
- drug-drug interaction
- incorrect monotherapy
- (pseudo) duplicate therapy (duplicate therapy would be e.g. inderal [contains propranolol] and propranolol; pseudo duplicate therapy would be e.g. omeprazol and pantoprazol [two drugs from same therapeutic category])

Another ADR terminology coding system, the Coding Symbols for a Thesaurus of Adverse Reaction Terms (COSTART), was used together with the WHO coding system and the International Classification of Diseases (ICD) to create the Medical Dictionary for Drug Regulatory Affairs (MedDRA). This terminology is increasingly being used in the pre- and post-marketing phases of the medicines regulatory process [14].

Classification of extrinsic toxicity

Medication errors can be divided into five main classes: prescribing, transcription, dispensing, administration (including non-compliance) and “across settings” (errors occurring on the interface between different healthcare settings – for example, between hospital and ambulatory care) [3, 7, 15].

Prescribing errors are those occurring in the process of selecting and prescribing a drug and on monitoring of therapy. Table 1 shows a subclassification of types of prescribing errors [16].

Transcription errors occur when transcribing or interpreting a medication order of the physician. In literature, no subclassification of transcription errors can be found: an order is either transcribed correctly or not.

interactions can be seen as medication errors because the drugs were prescribed not taking into account the interaction.

Finally, the term “adverse drug events” is frequently encountered in literature. These are defined as injuries occurring during drug therapy, but this association may not necessarily be causal. They comprise

When the pharmacy makes an error, it is called a dispensing error. For example, the wrong drug or strength can be dispensed or a preparation error may occur [17]. A subclassification of dispensing errors can be found in Table 2. Errors made in the last stage of the drug distribution

process are administration errors. These errors are made by nurses or doctors in hospital or by the patient in the ambulatory setting (non-compliance). Table 3 shows the subclassification [18].

A bit of an exotic class of medication errors are the “across settings” errors, which are not mentioned as such in international literature. Yet studies have been performed on this class of errors, which occur, for example, when patients are admitted to or discharged from hospital. As in transcription errors, no subclassification is made.

As is the case with ADRs, medication errors can be classified in classes of seriousness. This can be done by using a modified version of the classification of the National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP) [7, 19]. This classification is illustrated in Table 4.

Conclusion

By choosing uniform definitions and classification of DRPs, results of studies can be communicated unambiguously. The same goes for reports in medication error reporting systems. The classification system presented in this article is not definite. Although it has proven value in Dutch studies on drug safety [20], it is subject to further improvement. Nevertheless, it may certainly constitute a firm basis for a uniform classification system. The authors welcome reactions to this proposal.

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Table 2: Classification of dispensing errors

- for wrong patient or for wrong ward
- wrong drug
- wrong dosage form
- wrong strength
- wrong time

Table 3: Classification of administration errors

- omission (drug not administered)
- unordered
- wrong preparation
- wrong dosage form
- wrong route of administration
- wrong administration technique
- wrong dosage
- wrong time (at least 60 minutes early/late)
- compliance/adherence

Table 4: Classification of medication errors in classes of seriousness

- A**
An error has been made, but the medication did not reach the patient
- B**
An error has been made, and the medication reaches the patient, but no harm is done
 - B1**
medication not administered
 - B2**
medication administered but no harm
- C**
An error has been made which results in an increased frequency of monitoring, but no harm is done
- D**
An error has been made, and harm is done
 - D1**
temporary damage necessitating treatment
 - D2**
temporary damage resulting in an increased length of hospital stay
 - D3**
permanent damage
 - D4**
patient nearly dies
- E**
An error has been made which results in the death of the patient

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Patient safety across the EU: minimizing the variations

Commissioner Markos Kyprianou

The topic of patient safety across Europe is of vital importance. Healthcare interventions are, of course, intended to benefit patients, but they may in some cases cause harm.

Modern health care puts into daily practice some of the most advanced technology and techniques of any field of human endeavour. We all benefit from this constant striving to do more. But, as with any complex set of processes and choices, mistakes will happen.

Research from around the globe suggests that a considerable percentage—perhaps 10% of hospital admissions may involve some kind of patient safety incident. Some studies estimate that up to half of these errors may be avoidable.

Even if clear figures on patient safety incidents are difficult to come by, the large variations in techniques and outcomes across Europe themselves tell the story. For example, five-year survival rates for breast cancer range from 81% in Sweden to 58% in Slovakia and Poland. Or take skin cancer—for malignant melanoma, five-year survival rates vary from 89% in Sweden and 86% in The Netherlands, to 62% in Estonia, 64% in Poland and 68% in Italy.

These variations have both a negative and a positive side. On the one hand, they show how far we have to go before we have a consistent high standard of care for everyone in the European Union. On the other hand, they underline the potential of benefiting from best practices to raise standards throughout Europe. As these statistics show, this is not just a matter of resources.

Of course, more money is important, and we are working to improve the resources available at the European level, but what resources are available still need to be used in the most effective way. Sharing expertise at the European level can help to achieve this.

Health systems across Europe face increasingly common challenges. We also

share common goals of providing high-quality care on the basis of medical need and financed through collective solidarity. Together with the enormous potential for greater collaboration to help improve the effectiveness and efficiency of all health systems, this provides a solid foundation for the need to develop European cooperation in the area of patient safety.

To do this, we have established a framework for policy exchanges through the open method of cooperation, as well as a High Level Group on health services and medical care to take forward practical coordination. In addition to issues such as health technology assessment and a European system of centres of reference, this High Level Group is also addressing today's topic of patient safety.

As set out in the 2004 report of the High Level Group, several member states have established their own patient safety programmes and systems for reporting and learning from incidents, including Sweden, Denmark, The Netherlands, Ireland, Czech Republic and the United Kingdom. The World Health Organization has also established a World Alliance for Patient Safety, providing a global framework for activities. Work is also taking place within the Council of Europe to develop recommendations.

With this wide range of increasing activity, it is important to bring different groups together to ensure that we share a common vision and that we focus energy and resources so as to achieve the best possible results. Creating an organisation such as an EU patient safety network could help to share information on different activities and to ensure a coherent approach among these many different initiatives.

However we organise our work, it is vital that we make progress on patient safety. Not only because of the importance for patients themselves but also because when we put the systems in place to ensure patient safety, we will also be making a major contribution to ensuring overall quality in health systems. If we can take concrete steps to reduce the statistical

variations and to raise standards across the EU to those of the most successful, we will be making a very significant contribution to health and health care.

I would like to see European collaboration on patient safety as being a driver for change. As a benchmark for success. As a source of ideas, knowledge and inspiration. Working collaboratively, we can turn the variations between our systems into a shared resource from which we all can learn.

Of course, however good the ideas are, they need to be backed with resources. We are already financing some projects under the existing public health programme. However, I hope to be able to announce significant new funds to support work in this area. You can expect to see a new proposal for an integrated and expanded health and consumer protection programme, which will include support of cooperation on health systems, including patient safety, and providing essential new resources to support work on these issues into the future. I hope that these new resources will help to turn at least some of your ideas into action in the coming years—and action into results.

This will not be easy, but it will be worth it. Improving patient safety will bring benefits in driving up standards and quality throughout Europe. It will also help to improve the confidence of patients in health care wherever they are across the EU.

Note: This article is the narrative form of a speech presented at the Luxembourg Conference on Patient Safety held on 4-5 April 2005.

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European strategy for health and patient safety



Fernand Sauer
Honorary Director General, European Commission

Citizens across the EU, whether they seek care in other Member States or remain in their own, expect the care they receive to be of high quality. Systemic approaches to improving patient safety are key toward improving overall quality in health care, and collaboration across Member States is crucial.

Efficacy, quality and safety of health care must be addressed in professional practices in consultation with patients and patient groups. Improving patient safety is important for all health systems across the world, and the World Health Organization has addressed the issue in recent years, including the launch of the World Alliance for Patient safety in 2004. The European Commission, which founded the European Centre for Disease Prevention and Control (ECDC) also in 2004, is keen to co-operate with this project, which raises awareness and increases political commitment in the area of patient safety. On the basis of experience gained with initiatives on tobacco control and on the quality of blood, tissues and cells, the Commission is proposing a new health programme for the coming years.

Patient mobility

In 2003, the Commission invited all EU Health Ministers, a representative of the European Parliament and six European Non-Governmental Organisations (NGOs), including doctors and patients, to discuss patient mobility and healthcare developments in the European Union. This led to the establishment of the High Level Group on health services and medical care, which has the commitment of all Member States and the support of European NGOs and successive EU Presidencies, for comparing, benchmarking and sharing data, experience and guidelines.

Detailed figures for adverse events are still difficult to obtain for Europe as a whole, but every national survey confirms the trend shown in the US – a 10% incidence of serious mistakes. The Commission has introduced provisions to encourage pan-European projects on quality assurance of health systems, covering in particular patient safety:

- SIMPATIE: Safety Improvement for Patients in Europe, led by the Dutch Institute for Healthcare Improvement (www.cbo.nl)
- EUHORIC: EU Public Health Outcome Research and Indicators Collection, led by Istituto Superiore di Sanità (www.iss.it)
- EARSS: European Antimicrobial Resistance Surveillance System (www.rivm.nl/earss)
- ABS: appropriate use of antibiotics in EU hospitals (www.antibiotika-strategien.at)
- IPSE: Improving Patient Safety in Europe (helics.univ-lyon1.fr)

Under the 2006 work plan of the public health programme, it states that in order to improve and maintain a high level of patient safety, we must support networking and the work of stakeholders – namely set up a “forum” or task force for stakeholders and fund research on patient safety.

Safety of health products

The Standing Committee for European Doctors (CPME) organised in April 2005 a major conference on patient safety, co-sponsored by the European Commission

and the Luxembourg presidency. The conference produced an official statement, the “Luxembourg Declaration on Patient Safety” (see page 20), which all delegates signed, including the European Association of Hospital Pharmacists.

The Luxembourg Declaration calls for patient safety to be taken into greater account when designing regulations on medical devices and pharmaceuticals. Europe already has an extensive structure of regulation regarding the quality, safety and efficacy of medicinal products. Further improvements to pharmacovigilance were introduced as a consequence of the recent revision of pharmaceutical legislation, with an increasing role for the European Medicines Agency (EMA).

The EU has recently adopted rules on the quality and safety of blood and blood products, as well as cells and tissues of human origin. This includes provisions to minimise errors at the bedside, such as providing the wrong blood to the wrong patient, and notification of serious adverse events and reactions.

European agencies for the protection of health and safety

Europe must act to protect its people against major health threats such as HIV/AIDS, SARS or pandemics, which do not stop at national borders. The ECDC began operations in Stockholm in May 2005 and works in close partnership with the World Health Organization and

with the Center for Disease Control in Atlanta.

While the ECDC is finding its feet, the progress made since 1995 by the EMEA in London is spectacular and of major importance for public health. These organisations are two examples of effective mechanisms available for transforming policy objectives into concrete activities, which benefit more directly the health and safety of European citizens and may have a significant impact on health professionals and economic operators.

“The ECDC provides a structured approach for co-operation between experts in the EU, the US and Canada.”

The ECDC strengthens Europe's disease and early warning systems by providing a structured approach for scientific co-operation between experts in the public health institutes of the EU, the US, Canada and other parts of the world. An area of high sensitivity is influenza and, in particular, the threat of the emergence of a lethal strain. The ECDC is helping Member States build up their defences against influenza and update their preparedness plans. In the fall of 2005, an exercise was conducted to test and evaluate coordination between the national plans. Moreover, the Commission is pushing for partnerships between the pharmaceutical industry and Member States with a view to accelerating pandemic flu vaccine development and the availability of antiviral drugs.

But while influenza might appear to be a likely source of a future global health crisis, threats might arise from unknown or unexpected sources. The ECDC enables us to be ever more vigilant against new or deliberate disease outbreaks by pooling expertise and knowledge to rapidly assess whatever health threats are in store.

EU co-operation

The Commission welcomed the call in the Luxembourg Declaration for greater EU collaboration on these issues and to work in alliance with the World Health Organization. The Commission is developing structures for collaborating

on these issues through the High Level Group on Health Services and Medical Care. The High Level Group has agreed to involve civil society participants in relevant working groups, and there is clearly a valuable contribution that health organisations can make.

The World Alliance for Patient Safety, chaired by Sir Liam Donaldson, Chief Medical Officer for Britain's Department of Health, is also looking at how to develop collaboration on these issues. In November 2005 in London, the UK Presidency organised, in partnership

with the European Commission, a major “Patient Safety Summit.” The EU Health Forum, which groups some 50 European representative NGOs in the health sector, has also created a special working group on patient safety.

The Commission has launched a network for health technology assessment across Europe, following the recommendations of the High Level Group. The Commission is also working on healthcare-associated infection control in the context of the Council Recommendation on the prudent use of antimicrobials.

A new public health strategy for Europe

Currently, health systems still focus on combating health threats and providing treatments. Europe needs to do more to encourage precautionary measures – for example, tackling tobacco use now so as to reduce the need for lung cancer treatment in the future. The Commission has launched a massive “Help” anti-smoking campaign with TV spots across Europe.

The health gap across the EU is widening. Far too much depends on where you live, what work you do and how much you earn. There is also a new tendency for health professionals and patients to travel across Europe in order to find a better situation, better service or a shorter waiting list in another Member State. The recent enlargement of the EU has exacerbated such variations.

European citizens need reliable and user-friendly information about what to do to stay in good health. And when they fall ill, people want clear information about their condition and treatment options. In April 2005, the Commission proposed a new health strategy for Europe together with funding plans under the new financial perspectives (2007-2013) and the further development of the ECDC. That development would include a new department dedicated to cooperation on healthcare systems, including patient safety, and on essential new resources, such as:

- Surveillance and early warning system against infectious diseases
- Centres of excellence and recognised expertise shared between Member States on key healthcare system issues
- Information campaigns to address some of the main health problems faced by the EU, such as the resurgence of HIV/AIDS
- Informational activities for citizens to learn about healthcare entitlements when visiting another Member State

Patient safety was an important topic on the agenda of the annual meeting of the European Association of Hospital Pharmacists in Paris in June 2005 and was the theme of its 11th Congress this year in Geneva. It is an area where European collaboration between health professions and patient organisations can help to achieve important national aims. The Commission looks forward to working together with all interested partners and European organisations, including European pharmacists and hospital pharmacists.

For more information, please visit europa.eu.int/comm/health/index.html.

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Patient safety - Making it Happen

In response to the growing concern over patient and medication safety, Luxembourg played host to “Patient Safety - Making it Happen!” EAHP President, Jacqueline Surugue gives her overall impression of the conference and its key speakers.

Jacqueline Surugue, EAHP President

European patients have the right to expect a high standard of safety in their healthcare environment. Solid documentation on reported accidents and adverse events in the healthcare setting make it impossible to ignore the facts: it is time for Europe to take action to prevent accidents and to enhance patient safety.

This was the focus of the conference “Patient Safety - Making it Happen!”, which was organised in Luxembourg on 4-5 April 2005 under the auspices of the Luxembourg EU Presidency and the European Commission by the Standing Committee of European Doctors and health partners committed to making patient safety a priority.

The venerable and still completely relevant Hippocratic oath “First do no harm” was immediately stressed in the first speech of the conference by Luxembourg Minister of Health and Social Security, Mars Di Bartolomeo, who said that risk management should be a routine part of hospital management and that hospitals should avoid general acceptance of routine incidents. In his well-documented presentation, Dr James Bagian, Director of the US Veterans Affairs National Centre for Patient Safety, called this the “normalisation of deviance”. He concluded that cultural change is needed to ensure the analysis of errors, action and feedback that are key in leading to safety.

Meanwhile, Markos Kyprianou, European Commissioner for Health and Consumer Protection, insisted on the need for European cooperation and discussed the programme of the High Level Group on health services and patient care (see page 13). Dr Wim Schellekens, CEO of the Dutch Institute for Healthcare Improvement, identified steps to be taken at the EU level and at the national level—as he said, it is all about mission, vision and strategy—

and insisted on collaboration of all involved partners (see page 2).

Professor Angela Coulter, CEO of Picker Institute Europe, stressed crucial aspects of communication between patients and health professionals, while Dr Jesper Poulsen, Vice President of the Standing Committee of European Doctors and President of the board of the Danish Medical Association, presented the “Danish Patient Safety Act” for improvement of patient safety in the healthcare sector. This intriguing presentation highlighted the obligation for health professionals to report adverse events. According to Dr Poulsen, reports under the act are made under confidentiality, do not lead to disciplinary measures (“no blame policy”) and result in prophylactic action. It is worth mentioning that in its first year, 50% of reports were related to medication errors.

As we heard from Dr Michel, representative of the World Health Organization’s World Alliance for Patient Safety and Medical Director of the French CCECQA, a coordination unit for clinical evaluation, risk management and quality improvement, France has already developed an integrated risk management system for healthcare products and some at-risk activities. We also heard from him the six action areas targeted by the World Alliance programme.

Dr Adamos Adamou, a Medical Oncologist from Cyprus and member of the European Parliament, gave his view on patient safety, stressing that illness should be an accident not an expected part of our lives, while Sir Liam Donaldson, Chairman of the WHO World Alliance for Patient Safety and Chief Medical Officer for England, led a vivid presentation on “Tackling the patient safety agenda in Europe” with poignant examples of what errors in the field of health care can lead to. Professor Donaldson has also been appointed to lead the special project on patient safety of the High Level Group of EU Health Directors,

which provides an appropriate platform to address hospital pharmacists’ concerns regarding patient safety.

Parallel sessions held on the conference’s second day offered practical examples of possible risks: from an increase of error due to fatigue and stress to misrepresentative communication with immigrants to the lack of EU regulations for expressing the concentration of injectable drugs to too similar drug packaging. All participants agreed that error reporting should be made with a “non-naming non-blaming non-shaming” attitude and under confidentiality.

At the end of the conference, participants supported the “Luxembourg Declaration on Patient Safety”, which is reproduced here on page 20.

Despite no system ever being able to completely remove all risk of possible harm to patients, it is of prime importance to establish a culture of openness and trust in the European healthcare sector in which it is expected—indeed an obligation—for healthcare providers to participate in learning from adverse events. This is the right way for all health professionals to take the first steps toward a new road to improved patient safety.

We as hospital pharmacists have to take up the challenge that is expected from us: to create a medical environment in the hospital that minimises risk and maximises the benefit for the patient. The EAHP wishes to play an active role in promoting this goal. We will keep you posted!

Note: Please visit www.cpme.be for more information regarding this challenging conference.

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Recommendation of the Council of Europe to Member States on patient safety

Acknowledging that access to safe health care is a basic right, the Committee of Ministers of the Council of Europe [1] adopted recommendation R(2006)7 in May 2006. Welcoming this, the EJHP presents the recommendation and the main opinions held by the Council.

Although error is inherent in all human activity, it is possible to learn from mistakes and to prevent their reoccurrence. Healthcare providers and organisations that have achieved a high level of safety have the capacity to acknowledge errors and learn from them. The methodology for the development and implementation of patient-safety policies crosses national boundaries; as their evaluation requires substantial resources and expertise it should be shared.

Patient safety is the philosophy underpinning quality improvement and all possible measures should therefore be taken to organise and promote patient-safety education and quality of healthcare education. There is also a need to promote open co-ordination of national and international regulations concerning research on patient safety.

Appendix to Recommendation R(2006)7

The appendix to the recommendation sets out a number of factors, attention to which will assist in the smooth running of healthcare systems. As a **prerequisite** to developing patient-safety strategies, governments should take a proactive, preventive and systematic attitude: admit that errors happen, identify and manage risk points in processes. The multi-factorial requirements if we are to achieve safety (sufficient levels of resources, financing, staff, connections between processes, information systems, documentation, communication, etc.) are clearly set out.

A system-based approach presupposes the systematic design of safe structures, procedures and processes, together with corrective reactions in response to safety incidents. It should be accepted that errors are a consequence of normal human fallibility and/or deficiencies of the system; these could be prevented by improving the conditions in which humans work. The aim is a system designed with built-in defences.

The best way of supporting patient safety within a healthcare system is to develop a **safety culture**. A safety culture is one in which everyone is actively aware of her/his role and contribution to the organisation, and of the potential for things to go wrong. It is an open and fair culture, where people are able to learn about what is going wrong and then put things right. Developing a safety culture in an organisation needs strong leadership and careful planning and monitoring. It also requires changes and commitment to safety at all levels of the system, from government to clinical teams and supporting staff. Commitment to safety should be backed up by policies and the allocation of resources.

Effective risk management requires understanding of human behaviour, human error, and the conditions likely to cause such error. It must be accepted that under specific circumstances and for various reasons individuals can make errors and that processes and equipment will sometimes fail. A systems-based approach moves the investigator away from focusing blame on individuals and looks at what was

wrong with the system in which the individuals were working. The system should be consistent with already established quality-management systems. Quality and risk management should be led by the highest level of the organisation and translated into shared values, norms and behaviour at all levels. The Council makes several recommendations about aspects of good communication.

There is a need to **assess** patient safety on an ongoing basis. Prior to embarking on actual patient-safety assessment activities, a systematic strategy should be established at an institutional or regional level to measure and report, using information about the most common services associated with a high probability of error. A qualitative approach to patient-safety indicators maps the activities that exist in the routine delivery of services. A quantitative approach uses indicators and epidemiological methods to systematically quantify distinct aspects of processes.

The Organisation for Economic Co-operation and Development report on patient-safety indicators is recommended (OECD health technical paper DELSA/ELSA/WD/HTP (2004) 18, www.oecd.org/els/health/technical-papers). It selects a total of 21 patient-safety indicators which address hospital patient-safety incidents and include only measures that focus on specific clinical outcomes.

The primary objective of an **incident reporting system** is the enhancement of patient safety, by learning from adverse

Recommendation R(2006)7 on management of patient safety and prevention of adverse events in health care [2]

- The Council of Europe recommends that governments of Member States, according to their competencies:
1. ensure that patient safety is the cornerstone of all relevant health policies, in particular policies to improve quality;
 2. develop a coherent and comprehensive patient-safety policy framework which:
 - a. promotes a culture of safety at all levels of health care;
 - b. takes a proactive and preventive approach in designing health systems for patient safety;
 - c. makes patient safety a leadership and management priority;
 - d. emphasises the importance of learning from patient-safety incidents;
 3. promote the development of a reporting system for patient-safety incidents in order to enhance patient safety by learning from such incidents; this system should:
 - a. be non-punitive and fair in purpose;
 - b. be independent of other regulatory processes;
 - c. be designed in such a way as to encourage healthcare providers and healthcare personnel to report safety incidents (for instance, wherever possible, reporting should be voluntary, anonymous and confidential);
 - d. set out a system for collecting and analysing reports of adverse events locally and, when the need arises, aggregated at a regional or national level, with the aim of improving patient safety; for this purpose, resources must be specifically allocated;
 - e. involve both private and public sectors;
 - f. facilitate the involvement of patients, their relatives and all other informal caregivers in all aspects of activities relating to patient safety, including reporting of patient-safety incidents;
 4. review the role of other existing data sources, such as patient complaints and compensation systems, clinical databases and monitoring systems as a complementary source of information on patient safety;
 5. promote the development of educational programmes for all relevant healthcare personnel, including managers, to improve the understanding of clinical decision making, safety, risk management and appropriate approaches in the case of a patient-safety incident;
 6. develop reliable and valid indicators of patient safety for various healthcare settings that can be used to identify safety problems, evaluate the effectiveness of interventions aimed at improving safety, and facilitate international comparisons;
 7. co-operate internationally to build a platform for the mutual exchange of experience and knowledge of all aspects of healthcare safety, including:
 - a. the proactive design of safe healthcare systems;
 - b. the reporting of patient-safety incidents, and learning from the incidents and from the reporting;
 - c. methods to standardise healthcare processes;
 - d. methods of risk identification and management;
 - e. the development of standardised patient-safety indicators;
 - f. the development of a standard nomenclature/taxonomy for patient safety and safety of care processes;
 - g. methods of involving patients and caregivers in order to improve safety;
 - h. the content of training programmes and methods to implement a safety culture to influence people's attitudes (both patients and personnel);
 8. promote research on patient safety;
 9. produce regular reports on actions taken nationally to improve patient safety;
 10. to this end, whenever feasible, carry out the measures presented in the appendix to this recommendation;
 11. translate this document and develop adequate local implementation strategies; healthcare organisations, professional bodies and educational institutions should be made aware of the existence of this recommendation and be encouraged to follow the methods suggested so that the key elements can be put into everyday practice.

events and mistakes made. Reporting and collection of incident data is meaningful only if the data is analysed and evaluated and if feedback is given to the professionals involved in the incident, and to all others who could learn from the incident.

Incidents may be reported by health professionals, patients and relatives, or by other informal caregivers and suppliers.

An incident reporting system should be voluntary; confidential (however, if the event is to be analysed in order to learn from it, the names of the personnel involved may need to be known inside the actual institution); anonymous, at least at regional and national levels; be non-punitive with regard to those who report, but provide no immunity because of the consequences to the patient.

The reports should also be objective and incentives should possibly be given to encourage reporting (for example, express recognition). The reporting system should be independent of regulatory or accrediting processes. A common format should be used to report all incidents.

Use of data: reporting and collection of patient-safety data is meaningful only if

the data is intelligently analysed and information is, where appropriate, fed back to healthcare professionals, managers and patients. There needs to be a clear understanding and agreement with healthcare institutions and professionals on how the data collected will be put to use.

Effective data collection depends on the willingness of frontline clinical staff. Several barriers to reporting exist, which should be removed through appropriate policies: fear of blame, resulting from a lack of open and fair culture; fear of the reports being used out of context by the media and others; lack of feedback as to what has changed as a result of the report; lack of time to report; lack of support from the management.

Patient-safety incident reporting systems can be established as “stand-alone” systems or can be integrated with **other systems** for recording complaints and compensation claims or applications for benefits (the sources of information will differ for each country). Each organisation should develop systems to analyse this information and to learn from it. Complaints, criticism and suggestions may contribute to patient safety and should be taken seriously and handled appropriately. Clear procedures should be implemented for recording and analysing complaints, which should be handled in a fair, transparent, flexible and conciliatory manner, whether they come from patients or their representatives.

Medication safety is a specific strategy to promote patient safety. Medication errors are the most common single preventable cause of adverse events and European health authorities should consider them as an important public health issue. Medication safety comprises both adverse drug reactions and medication errors. A clear distinction has to be made between them. The WHO links

adverse drug reactions (pharmacovigilance) to product safety, whereas medication errors are linked to the safety of healthcare services.

A medication error is defined as follows: “Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, healthcare products, procedures, and systems, including prescribing; order communication; product labelling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use.”

The following key dimensions in the provision of care should be taken into account in order to prevent medication errors:

- the organisation and structures used within health care that govern the prescription, dispensing, administration, and monitoring of medication use;
- a patient-safety culture in health care that promotes the understanding of activities that may have a high risk of undesirable outcomes with the use of medication, in the overall care process;
- the use of indicators that can establish a baseline for the actual incidence of undesirable events;
- a level of understanding among staff of the necessary and ongoing observations that need to be made to prevent or minimise the likelihood of errors in medication use.

Improvements in the system of medication use require continuing, specific strategies to promote patient safety at every stage of the medication process.

Human factors in error and **patient empowerment** are discussed. For example, health professionals should be given the opportunity to learn how to handle guilt and be supported to avoid becoming “the second victim” of the

safety incident. Education and training curricula for all health professions should include basic knowledge of the principles of clinical decision making; risk awareness; risk communication; risk prevention; individual and collective attitudes and behaviour in the case of adverse events (medical, legal, financial and ethical aspects).

Patients using health services must have adequate information available, allowing them to include safety considerations when making decisions. This information should allow patients to understand and balance the risks and benefits of different treatment options, in which they are considered a partner. Patients must feel able to speak up when they feel that something could go, or has gone, wrong during the course of their treatment.

The report concludes that the successful **implementation of a patient-safety policy** requires concerted action by all stakeholders and makes further useful suggestions, including patient safety education programmes, research and country-specific legislation. The safety of medication and interventions is the essential feature of healthcare provision and its cost should be included in the general budget.

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References

1. The Council of Europe is an organisation comprising 46 democratic European countries. It was set up to promote democracy and protect human rights and the rule of law in Europe. The Committee of Ministers, the Council's decision-making body, comprises the Foreign Affairs Ministers of all the Member States, or their permanent diplomatic representatives in Strasbourg. It is a forum where national approaches to problems facing European society can be discussed on an equal footing, and where Europe-wide responses to such challenges are formulated. www.coe.int
2. wcd.coe.int/ViewDoc.jsp?id=1005439&

2005 Luxembourg Declaration on Patient Safety (Summary)

Access to high quality health care is a key human right recognised 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. EAHP is one of the signatories of this Declaration.

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 healthcare 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 healthcare sector.

The conference recommends to 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 healthcare 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 treatments. 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 healthcare sector.

- To optimise the use of new technologies—for example, by introducing electronic patient records. Such records would include the personal medical profile and decision-making support programmes 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 healthcare professions and to ensure that policies on recruitment and retention are linked to patient safety.
- To recognise and support the user training provided by medical devices, tools and appliance 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 healthcare 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 healthcare providers:

- To facilitate a collaborative care approach between health professionals and healthcare providers aimed at enhancing patient safety.
- To implement workplace 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 healthcare professionals in order to inform patients/relatives of near misses and adverse events.