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accompanying the

**COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN
PARLIAMENT AND THE COUNCIL**

**on patient safety, including the prevention and control of healthcare-associated
infections**

and the

Proposal for a

COUNCIL RECOMMENDATION

**on patient safety, including the prevention and control of healthcare associated
infections**

IMPACT ASSESSMENT

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{ COM(2008) 837 final}
{ SEC(2008) 3005 }

IMPACT ASSESSMENT¹

on a proposal for a Council Recommendation on patient safety and quality of health services, including the prevention and control of healthcare-associated infections

¹ On the basis of the Impact Assessment Guidelines of 15 June 2005 (SEC(2005) 791)

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EXECUTIVE SUMMARY

*The goal of this paper is to present the **impact assessment on a proposal for a Communication and a Council Recommendation on patient safety and quality of health services, including the prevention and control of healthcare-associated infections.***

Patient safety is a growing issue across Europe. It is estimated that between 6.7 and 15 million hospital admissions and over 37 million consultations in the primary care setting result in an adverse event for the patient as a result of receiving that healthcare.

*However, Member States have **varying levels of awareness** of the extent and type of adverse events occurring in their health systems and dedicate varying levels of resources and expertise to counter the problem. Due to the varying levels of policy commitments it is currently not possible to obtain and compare incidence rates across Europe, as reporting does not yet take place everywhere and, where it does, not on the basis of the same criteria and definitions. That also implies that **not enough information** is available on safety levels in healthcare systems or on the help available for those harmed by healthcare. Current **research findings**, learning, experiences and expertise available in the EU **are not sufficiently benefiting patients**. Not enough authoritative guidance is available to support patient safety efforts, such as agreed case definitions, guidance on best practice and requirements for infrastructure and processes.*

Although the problem of patient safety is primarily the responsibility of Member States, the European Union can support their efforts by taking actions where it has competence and - more broadly - in facilitating the exchange of good practice. Action by the EU is underpinned by the need to address the consequences of: 1. cross-border provision of healthcare resulting from mobility of patients and professionals, 2. trans-border spread of infections, and 3. the lack of EU-wide data collection and monitoring.

The general objective of the Recommendation is to prevent and reduce human illness and diseases and to obviate sources of danger to human health (as stipulated in Article 152 of the Treaty), through 1. protecting EU citizens from preventable² harm in healthcare, 2. supporting the Member States to put in place adequate strategies to prevent and control adverse events in healthcare, including healthcare-associated infections and 3. improving EU citizens' confidence that they have sufficient and comprehensible information on levels of safety and available redress in EU health systems.

Four policy options were identified and analysed in terms of their possible social, economic and environmental impact: I. No additional EU action but ongoing research and projects continue – the status quo, II. Strengthened cooperation with the Member States and other bodies, supported by technical guidance, III. Strengthened cooperation with the Member States and other bodies, supported by soft law instruments, such as a Commission Communication and Council Recommendation, and IV. Strengthened cooperation with the Member States and other bodies, supported by a regulatory instrument, such as a Commission Decision.

²

"Preventable" was, in our scenarios defined as what is considered avoidable with current state of the art knowledge and policies, but it should be noted that preventability also evolves over time when more experience and knowledge about patient safety is being gathered.

Based on this impact assessment, the policy option of a proposal for a Commission Communication and a Council Recommendation on patient safety and quality of health services, including the prevention and control of healthcare associated infections, is preferred. In a quantitative simulation - that used as a base, incidence rates reported in the literature and an evaluation of MS current policies against what is considered best practice in the relevant literature– we tried to give an idea about the potential for reduction in adverse events. It was estimated that a reduction of 750.000 preventable³ adverse events across EU could be reaped with the preferred option – if all MS established a patient safety policy (above all reporting and learning systems) that performed as good as countries currently listed in the second best out of five categories (with a 10 % incidence rate).

The cost savings and health benefits of patient safety policies would not come for free - as healthcare institutions will have to redeploy personnel from healthcare to patient safety monitoring and reporting. To e g reap a 20% reduction in healthcare associated infections, dedicated infection control staff will be needed. Secondly, also government spending for patient safety will be necessary to allow for upfront investment and supporting action at national level. However there is solid evidence and agreement about the cost effectiveness of such policies in the long term with cost savings between 50.000 – 1.5 million Euros for a 300 bed hospital.

1. PROCEDURAL ISSUES AND CONSULTATION OF THIRD PARTIES

1.1. Organisation and timing

1. In October 2004, the World Health Organization (WHO) launched the World Alliance for Patient Safety in response to a World Health Assembly Resolution (2002) urging countries to pay the closest possible attention to the problem of patient safety.
2. A topic chosen by the European Commission for the first Global Patient Safety Challenge covering 2005 and 2006 was healthcare-associated infections (HCAIs.)
3. The focus on HCAIs followed the Commission's report to the Council (COM (2005) 0684) on the implementation of Council Recommendation (2002/77/EC) on the prudent use of antimicrobial agents in human medicine. The report outlined a variety of measures already taken by Member States in line with the Council Recommendation; it also highlighted the areas of the Council Recommendation needing further attention, one of which was infection control to reduce the spread of resistant organisms.
4. Not only emergence (under selective pressure of antimicrobials) but also spread is an important driver of the problem of resistance and therefore the Commission decided to take an initiative in the area of infection control by developing recommendations on the prevention and control of HCAIs.
5. More generally, on patient safety, a conference organised by Luxembourg, as Council Presidency, adopted in April 2005 the Luxembourg Declaration on Patient Safety⁴.
6. Following this, the patient safety working group of the High Level Group on Health Services and Medical Care was set up to identify areas where European collaboration and coordination of activities could bring added value.
7. In 2007, the Working Group agreed on some recommended actions, which were subsequently endorsed by Member States, through the High Level Group
8. Against this background, patient safety, including the prevention and control of HCAIs, was made a strategic item under the Commission's legislative and work programme 2008. The intention is to adopt a proposal in late 2008.

1.2. Consultation and expertise

1.2.1. External consultation and expertise

High Level Group on Health Services and Medical Care

The patient safety working group of the High Level Group on Health Services and Medical Care has met regularly since 2005. As well as representatives from the Members States, it includes pan-European organisations representing doctors, nurses, patients,

⁴ http://europa.eu.int/comm/health/ph_overview/Documents/ev_20050405_rd01_en.pdf

hospitals, pharmacists and dentists as well as the Organisation for Economic Co-operation and Development (OECD), the Council of Europe (CoE) and WHO. This working group has played a key role in defining the issues described in this impact assessment, as well as refining the options for action.

Other stakeholder mechanisms such as the EU Health Policy Forum, the European Consumers Consultative Group, the Health Systems Working Party and the EU Social Dialogue Group on Hospitals have also had presentations on the issues.

Network on communicable diseases and the European Centre for Disease Prevention and Control (ECDC)

In the field of infection control, a document on 'Strategies for improving patient safety by prevention and control of healthcare-associated infections' was drafted with the help of a panel of experts. This incorporated comments from the surveillance authorities of the Community network on communicable disease established by Decision No 2119/98/EC of the European Parliament and the Council⁵. The strategies in this document form the basis for recommendations on the prevention and control of HCAs.

Expertise and data were also obtained from the ECDC.

EC funded projects

Projects funded by the Public Health Programme⁶ and by the Research Framework Programmes⁷ have also addressed aspects of the problem of patient safety and HCAs. Details of some of these are in section 3 and/or in Annex 1.

Public consultation – preliminary results

A web-based public consultation on actions on patient safety was launched on 25 March 2008 and closed on 20 May 2008. 184 responses were received.

The participants can be divided into eight categories, as in the table below.

Table 1: Overview of the responses received

Group	Number of responses
NGO's	36
Competent authorities total	32
<i>CA's at national level</i>	17 (CY; CZ; FI; IE; LV; SE; UK; MT, ES)
<i>CA's at regional level</i>	10

⁵ OJ L 268/1 Decision No 2119/98/EC of the European Parliament and of the Council of 24 September 1998 setting up a network for the epidemiological surveillance and control of communicable diseases in the Community

⁶ http://ec.europa.eu/health/ph_projects/project_en.htm

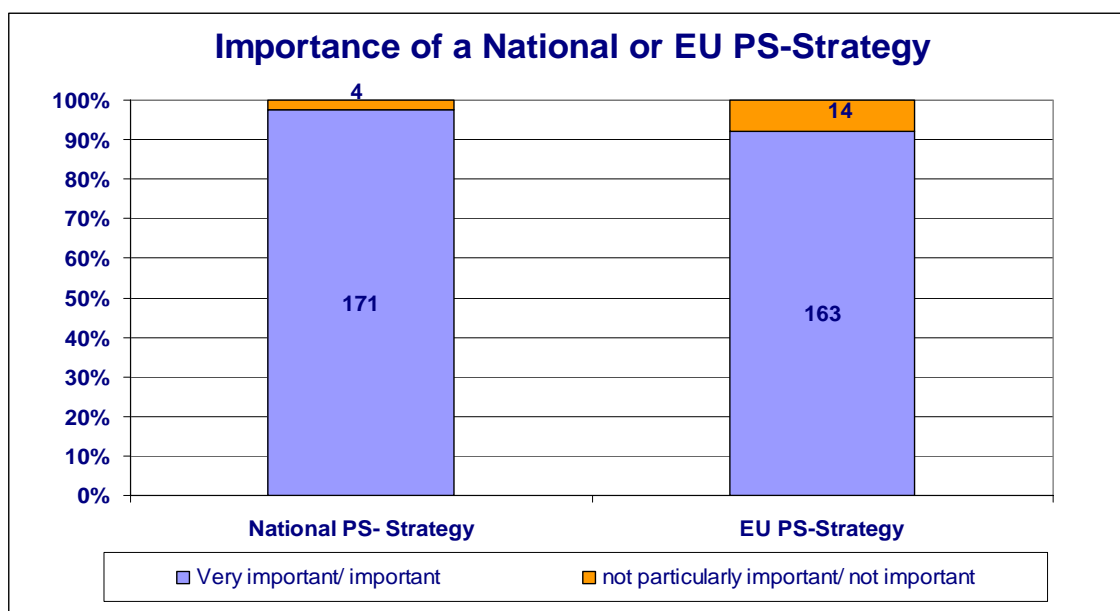
⁷ <http://ec.europa.eu/research/index.cfm>

<i>CA's at local level</i>	5
Health professional associations	25
Hospitals	21
Patient and Consumer organisations	12
Industry	8
Academia	6
Anonymous responses and others	44
Participants total	184

As shown in the table above, the NGO's represented the biggest group with 19% of the total responses, followed by the competent authorities with 17%, health professionals with 14%, hospitals with 11%, patient and consumer organisations with 6%, industry 4%, with and academia with 3%. Twenty-four percent of the responses were anonymous or could not be categorised in any of the groups mentioned. In addition, 19 replies were received outside of the on-line system.

From a preliminary analysis, the responses indicated strong support for both national and Community action on patient safety, as illustrated in the chart below.

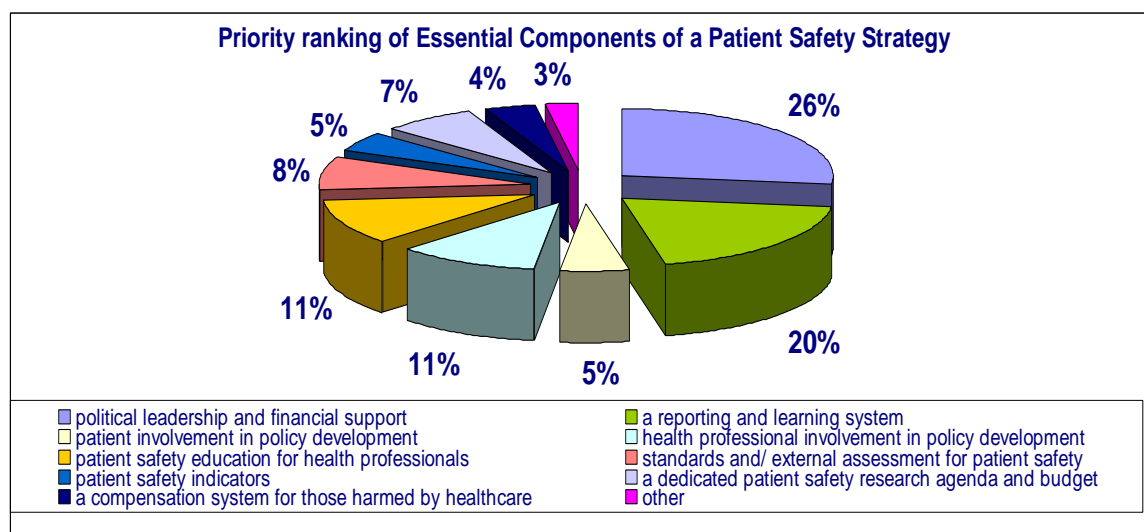
Figure 1: Importance of a national or EU Patient Safety (PS) Strategy



In the questionnaire, the Commission put forward nine possible areas of action. All of these received strong support from an overwhelming majority of participants. The chart below shows how the areas were ranked. In fact, *political leadership and financial support* (26%) and *a reporting and learning system* (20%) were viewed as the most

essential components followed by *health professional involvement in policy development* (11%) and *patient safety education for health professionals* (11%) (Figure 2).

Figure 2: Priority ranking of essential components of a patient safety strategy



A summary report of the consultation containing a detailed analysis of the contributions received is being drafted and will be published shortly.

On the specific topic of HCAIs, a separate consultation on the document 'Strategies for improving patient safety by prevention and control of healthcare-associated infections' was held from 28 November 2005 to 20 January 2006. Contributions were received from national and regional health authorities, hospital and professional organisations, networks on prevention and control of HCAIs, research institutes and patient associations. The Commission has evaluated the replies. The results of the consultation will be published in the near future.

External expert support to the impact assessment

The IA was supported by an external project to inform this impact assessment, with focus on the impact (and potential impacts) of three key areas of possible action on patient safety – the introduction of reporting and learning systems, redress mechanisms and developing and using knowledge and evidence. The project included a thorough review of peer-reviewed and grey literature, conducted preliminary data extraction and interviewed over thirty patient safety policy-makers and experts.

The ECDC and the panel of experts in the field of infection control also provided scientific input to the impact assessment.

On 4-5 June 2008, the Commission met hospital managers and infection control managers from EU hospitals and with a representative of the European Federation of Nurses to discuss the validity of the various assumptions made on the prevention and control of HCAIs in this impact assessment.

1.2.2. Internal consultation and expertise

Other activities of the Commission or its agencies addressing specific aspects of patient safety

There are a number of other ongoing or planned activities co-ordinated by the European Commission or its agencies aiming to address specific patient safety issues. These are described in more detail in section 3.

Inter-service coordination

An inter-service steering group was established in autumn 2007. DGs EMPL, ENTR, MARKT, RTD, SG, INFSO and EAC attended either or both of its two meetings on 14 November 2007 and 2 June 2008.

1.3. The Impact Assessment Board

The draft Impact Assessment was submitted to the Board on 11 June 2008. The present version of the IA takes account of the recommendations given by the Board in its opinion of 14 July. The key amendments made to the impact assessment following the issuing of the Board opinion are:

- Clarification of the baseline scenario, including identification of existing policies and the problems of the current situation, as well as best practice in Member States, now included in the problem section (section 3).
- Clarification on the EU dimension of the identified problems and finally
- Clarification of the objectives at general, specific and operational level

We therefore streamlined the 'problems still to be addressed' section and reduced issues from nine to seven and focussed in particular on those with a clear EU component such as the need for homogenous patient safety data to be able to compare safety levels across the EU. Also the objectives were streamlined as to allow for a more transparent comparison of options.

We inserted a new section into the description of the baseline scenario to better link it with the projects listed in Annex I and described in more detail current best practice, as well as levels of meticillin-resistant *Staphylococcus aureus* (MRSA) as an example of the problem of HCAs in the Member States.

2. TERMINOLOGY

Patient safety is defined as freedom for a patient from unnecessary harm or potential harm associated with healthcare. A patient safety incident is an event or circumstance which could have resulted, or did result, in unnecessary harm to a patient. An adverse event is an incident which results in harm to a patient. Harm implies impairment of structure or function of the body and/or any deleterious effect arising there from. Harm includes disease, injury, suffering, disability and death and may thus be physical, social or psychological⁸.

HCAs are defined as any disease or pathology (illness, inflammation) related to the presence of an infectious micro-organism (bacteria, fungi, viruses, parasites and other

⁸ The International classification for patient safety: Version 1.0 for use in field testing 2007 - 2008 (ICPS). Geneva: WHO World Alliance for Patient Safety; 2007.

transmissible agents) or its products as a result of exposure to healthcare facilities or healthcare procedures.

3. THE PROBLEM AND ITS CAUSES

3.1. Adverse Events: The Size of the Problem

There is a limited but growing body of evidence concerning the prevalence and incidence of adverse events in health systems in EU Member States. National studies from the UK, Spain and France provide the bulk of current evidence in Europe on in-patient adverse event prevalence and its implications. From these studies and from Key Informant Interviews conducted for an external project informing the impact assessment, it is estimated that in EU Member States between 8% and 12% of patients admitted to hospitals suffer from adverse effects whilst receiving healthcare.

In the UK, a National Health Service (NHS) report in 2000, *An Organisation with a Memory*, revealed that poor patient safety was a major problem: data showed that at least **400 patients died or were seriously injured in adverse events** involving medical devices in 1999 and that **nearly 10,000 people had experienced serious adverse reactions to drugs**. According to the 2006 Spanish National Study on Hospitalisation-Related Adverse Events (ENEAS), 9.3% of hospital patients in Spain in 2005 suffered **adverse events** and **42.8% of these were deemed preventable**. A recent French national survey of in-patient adverse events (Michel, 2007), found that in the course of the 7 days' observation per unit **at least one adverse event was observed in 55% of surgical units and 40% of medical units. 35.4% of the adverse events were considered to have been preventable**. More detail on these studies is in Annex 2.

Data from OECD on the prevalence of adverse event mortality in the table below show that adverse events occurred in many Member States, but also indicate that there are large gaps in the data about patient safety. Comparability of incidence data is also limited as low prevalence rates might simply mean low reporting and apparently higher prevalence rates may indicate better data capture through more advanced reporting systems.

Table 2: Prevalence and burden of adverse event mortality

	Adverse care events			Adverse drug events		
	Total deaths	Deaths per 100,000	Years lost /100,000	Total deaths	Deaths per 100,000	Years lost /100,000
EU-27						
Austria	99	1.0	16	4	0.0	1
Czech Republic	5	0.0	0	3	0.0	0
Denmark	6	0.1	1	-	-	-
France	492	0.5	2	848	0.9	3
Germany	635	0.5	5	72	0.1	1
Greece	128	0.9	11	2	0.0	0
Hungary	30	0.2	4	4	0.0	1
Ireland	17	0.4	8	3	0.1	2
Italy ⁴	347	0.4	4	11	0.0	0
Luxembourg	1	0.2	1	2	0.4	3

Netherlands	17	0.1	0	3	0.0	0
Poland	232	0.5	5	22	0.1	1
Portugal	23	0.2	1	13	0.1	1
Slovakia	4	0.1	0	1	0.0	0
Spain	255	0.5	5	264	0.4	2
Sweden	120	0.6	1	9	0.1	0
UK	413	0.5	3	36	0.0	1

No data available for: Belgium, Bulgaria, Cyprus, Estonia, Finland, Latvia, Lithuania, Malta, Romania, Slovenia

International

USA	2460	0.7	6	317	0.1	2
Australia	176	0.7	2	47	0.2	2
New Zealand	8	0.2	4	5	0.1	3
Canada	197	0.5	4	22	0.1	0
Japan	424	0.2	3	76	0.0	1

Source: OECD Health Data 2007

Despite the gaps in data, what is available, and the results of research studies, reveal similar patterns, and suggest substantial health costs and economic costs (and hence substantial potential savings) due to adverse events.

The sources of adverse events and harm in healthcare settings are many. The Spanish ENEAS study indicates the main causes of adverse events in Spain. As shown in table 3, medication related adverse events account for 37% of the total, followed by nosocomial infection-related (25%) and procedure-related adverse events (25%). A complete overview of the scale of the patient safety problem can be found in chapter 3.3 of the external study supporting this impact assessment.

Table 3: Type of adverse events

Adverse events	AE's	%
Related to the care provided	50	7.63
Medication-related	245	37.4
Nosocomial infection-related	166	25.34
Procedure-related	164	25.04
Diagnosis-related	18	2.75
Others	12	1.83
TOTAL	655	100.00

Source: ENEAS 2006

The results of the public consultation on patient safety confirmed the diversity of experienced adverse events (examples cited included medication-related, error in diagnosis, communication problems, surgery-related events, medical device or equipment related events and HCAIs). Medication-related events and errors in diagnosis

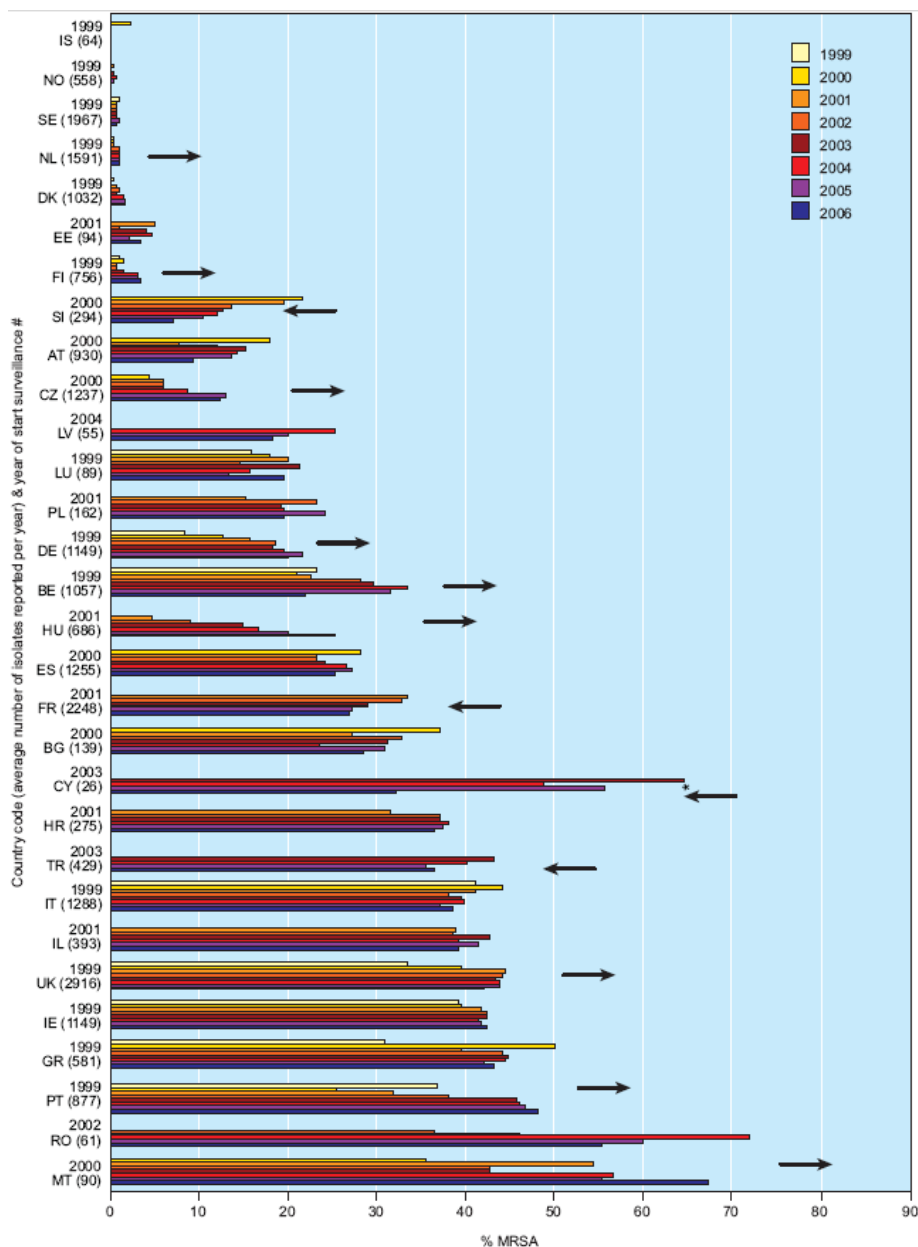
were the most frequently experienced in respondents' own country and in other Member States.

HCAIs, a key focus of the current initiative, are among the most important causes of unintended harm. Incidence figures for all types of HCAIs are not available for all EU Member States. However, on the basis of recent national HCAI prevalence surveys and the results of hospital-wide surveillance programmes of nosocomial bacteraemia in EU Member States, it can be calculated that HCAIs affect 5% of hospital patients on average and the total number of hospital patients acquiring at least one HCAI in the EU every year can be estimated at 4.1 million. Approximately 37,000 deaths are estimated to occur every year from these infections (see Annex 3).

For MRSA, a well-known micro-organism causing HCAIs, data for all EU Member States are available; significant differences in levels of MRSA rates can be seen as illustrated in Figure 3.

Figure 3: *Staphylococcus aureus*: trends of meticillin-resistance by country 1999-2006 (EARSS Annual Report 2006⁹)

⁹ The European Antimicrobial Resistance Surveillance System (EARSS) is a project co-funded by the Public Health Programme. The 2006 annual report can be found at http://www.rivm.nl/earss/Images/EARSS%202006%20Def_tcm61-44176.pdf



Southern European countries, the United Kingdom and Ireland report the highest MRSA-rates, whereas northern European countries still have proportions of MRSA in bacteraemia patients below 5%.

HCAIs mostly occur during or after hospitalisation but can also develop in the context of ambulatory care. Patients who acquire HCAIs may be acutely ill and more likely suffer co-morbidities and/or chronic disease. Thus elderly people are often concerned - an increasing proportion of the patient population. Individuals receiving antimicrobial chemotherapy (changing the composition of the host flora), patients with systemic or local immune defects, or with devices such as intravenous lines and urinary catheters in places that by-pass their natural immune defences, are also at particular risk.

Moreover, the infectious micro-organisms have frequently acquired resistance to antimicrobial agent(s), normally effective in the treatment of non-HCAIs. Consequently, infections and colonisations caused by these micro-organisms are often difficult to treat and to eradicate from the healthcare environment. Owing to the ability of infectious micro-organisms that can cause HCAIs to colonise patients for prolonged periods, these

patients may disseminate the micro-organisms both during and after their hospital stay. In this way the entire healthcare system, as well as the society as a whole, is carrying the burden of the increasing numbers of individuals infected or colonised with healthcare-associated pathogens.

HCAIs thereby pose a considerable, and tangible, threat to public health.

The main drivers relating to the incidence of HCAIs are depicted in the flow chart in Annex 4.

3.2. The Public Perception of Adverse Events

The 2005 Eurobarometer survey on perception of medical errors

Whilst estimating the extent of adverse events in our health systems is essential, it is also important to understand patients' perception of how safe they think EU health systems are. The challenge is not only to ensure the safety of those systems, but also convince citizens who are potential patients, or the friends and family of patients, that they are safe. Patient confidence is crucial. Therefore, in 2005, the European Commission carried out a Eurobarometer survey on the perception of medical errors in the EU. The poll also covered the then pre-accession and candidate countries and the Turkish Cypriot Community. The Commission published the results in 2006¹⁰.

Almost 4 in 5 EU citizens (78%) classified medical errors as an important problem in their country. 38% ranked the issue as very important and 40% saw the topic as fairly important. 23% said they or their family had been the victim of a medical error; 18% said this was in a hospital, while 11% said they had been prescribed the wrong medication. Over half of Europeans believed they cannot avoid serious medical errors in hospitals. The perception of citizens, therefore, is that this is a significant problem.

3.3. Current Member State Actions

Best Practice

Best practice in EU MS has been identified using as a reference the World Alliance for Patient Safety's definition of the core components of best practice in patient safety, especially in relation to the existence of reporting and learning systems, and MS have then be classified accordingly. Characteristics of best practice in MSs, or 'exemplary' systems according to RAND's definitions, more details of which are included at Annex 5, include a well-developed, blame-free national reporting and learning system (in addition to local systems to support this), which covers *all* adverse events, an established redress system that includes alternatives to going to court (e.g. a 'no fault' liability system), the MS being active in initiatives to develop and use knowledge and evidence on patient safety and an established national institute or other 'competent authority' dedicated to patient safety.

RAND found that four MSs – Belgium, Denmark, the Netherlands and the UK – currently carry out best practice when their systems were evaluated against these characteristics, categorising them as having 'exemplary' systems, including a mature, blame-free reporting system and an institute dedicated to patient safety. Three countries

¹⁰ http://ec.europa.eu/health/ph_publication/eurobarometers_en.htm

(Germany, Czech Republic, Slovak Republic) were categorised as ‘very good’; they had well-established and functioning reporting systems but these were not fully blame-free. Eight Member States (Sweden, Republic of Ireland, Spain, Bulgaria, France, Finland, Portugal, Austria) were classified as ‘good’ as they had only partial reporting systems which did not cover all types of adverse events. Five countries (Hungary, Lithuania, Latvia, Poland, Italy) were classified as ‘fair’ as their reporting systems were not at a national level. Finally, three countries (Slovenia, Greece, Cyprus) were considered to have ‘poor’ patient safety systems in that they had no patient safety reporting and learning system.

Of course, whilst it is logical to assume that there will be a positive direct causal relationship between the preferable characteristics of a patient safety system in Member States, as defined by RAND, and patient safety outcomes, the immaturity of patient safety research and evaluation means that we can not prove this for sure at this point in time. Further research, monitoring and evaluation should make this link clearer in future.

In the area of HCAs, strategies to prevent and control HCAs have been developed in different Member States and show positive results where a strong commitment for effective implementation exists. Best practice examples include entry screening of patients for colonisation with resistant micro-organisms, isolation of patients colonised with resistant micro-organisms, screening of healthcare staff, decolonisation of patients and healthcare staff, strict hygiene practices, surveillance and restrictive antibiotic use. For example, the uncompromising “search-and-destroy” policy (based on the above-mentioned best practices) in the Netherlands and in Nordic countries is thought to play an important role in the low prevalence of MRSA in these countries.

Therefore, for patient safety efforts in general and specific measures to prevent and control HCAs, there is clearly much to be gained by sharing knowledge and best practice;

3.4. Current EU Actions

3.4.1. European Commission Activities

Medication errors are already the focus of current EU legislation and initiatives. For example, the Commission is responsible for legislation in the areas of pharmacovigilance, which it is in the process of revising. The European Medicines Agency is currently developing new requirements for the naming of centrally-authorised medicines to try to reduce medication errors due to look-alike and sound-alike medicines.

The Commission has also recently revised its legislation on the safety of medical devices. Within the Open Method of Coordination, the Commission adopted in June 2006 a set of common indicators for the social protection and social inclusion process including health and long-term care.

In addition, the Commission is developing e-health systems at the European level (e.g. through the lead market initiative). Using new technology to improve patient safety in healthcare setting is one key element of this. Patient safety research is also included in the Commission’s 7th Framework Programme, which also covers eHealth patient safety solutions.

The Commission also continues the follow-up of Council Recommendation (2002/77/EC) on the prudent use of antimicrobial agents in human medicine. Indeed, the growing levels of resistance in micro-organisms causing HCAs due to inappropriate use of antibiotics is of concern. Therefore, the Commission is planning a second report to the Council on the implementation of Council Recommendation (2002/77/EC), outlining the progress made and the issues needing further attention.

3.4.2. Projects Co-Funded by the European Community

A number of European Community co-funded projects on patient safety, including HCAs, have either been completed or are currently still carrying out their work. A full list can be found at Annex 1 but two of the most important are described below.

EUNetPaS (European Union Network for Patient Safety) was launched in February 2008. It aims to establish an umbrella network of Member States and EU stakeholders to encourage and enhance collaboration in the field of Patient Safety by evaluating, validating and diffusing new knowledge and good practices.

The IPSE project (Improving Patient Safety in Europe) aims to reduce the burden of HCAs and their related threats of antimicrobial resistance (AMR) by providing evidence-based guidance and educational tools, strengthening the status of infection control professionals, strengthening surveillance and developing indicators.

3.5. Problems still to be addressed

The Health Strategy White Paper¹¹ adopted last year demonstrates how much has already been achieved in health policy at the EU level in a range of areas, based on different parts of the Treaty, for example in health and safety at work, pharmaceuticals, public health, food safety, research and environment. Following the introduction of specific public health provisions into the EU Treaties¹², in the 1990s a large number of individual issues have been addressed such as cancer, communicable diseases, rare diseases, health promotion and most recently alcohol related harm and healthy diets. All these initiatives were intended to co-ordinate and stimulate a wide range of activities in the specific health policy field.

The patient safety policy area is no different. As described in Section 1.1, EU involvement in patient safety policy dates back to the World Health Assembly resolution of 2002 and led to the recommendations by the High Level Group on Health Services and Medical Care in 2005. Alongside policy discussions; several focused initiatives developed, including the work of the Network on Communicable Diseases and of ECDC, as well as a number of EU-funded projects (see Annex 1) and initiatives in related areas of R&D and technological development.

However, despite current best practice in MSs and the measures already being taken at the EU level in specific patient safety areas already described, there is still a need for further action on patient safety at the EU level. The measures currently being taken in some MSs or at the EU level are not in themselves sufficient due to: (i) the absence of a clear and firm political commitment to action on patient safety from all MSs; (ii) the

¹¹ White Paper "Together for Health: A Strategic Approach for the EU 2008-2013", COM(2007) 630
¹² Initially in Article 129 of the Maastricht Treaty and then in a strengthened form in Article 152 of the Treaty of Amsterdam

limited time-span of EU co-funded projects, meaning there could be no guaranteed longer-term action on patient safety at the EU level; (iii) failure of current initiatives to optimise the safety of cross-border patients. The current initiative is built on a number of diverse actions as described, and is intended to create a framework to stimulate policy development and future action in, and between, Member States, to address the key remaining patient safety issues and problems confronting the EU, which are set out in more detail below.

1. Member States have varying levels of awareness of the human and economic costs of adverse events occurring in their health systems and we see, therefore, varying levels of political commitment to make patient safety a priority in national public health objectives.

Evidence suggests that EU Member States are at different levels of political awareness and priority-setting and, therefore, at different stages in the development and implementation of effective, comprehensive patient safety systems.

The prevention and control of HCAs is important for healthcare institutions as well as for national healthcare budgets and society at large. In the absence of political commitment, healthcare institutions will not always be motivated to invest adequately in the prevention and control of HCAs.

The variability of the existence of patient safety policies, systems, processes and cultures among EU Member States was identified by the SIMPATIE project. RAND Europe reviewed its findings categorised the 23 EU Member States involved according to their patient safety systems, policies, structures and processes. Best practice has already been explained earlier. Currently only four EU MS meet that best practice.

The EU could play a role in ensuring the communication of the core components of 'best practice' patient safety systems to all MSs. To achieve the necessary political commitment at national level, a 'push' from the EU level will support Member States to make patient safety a priority in national public health objectives.

2. No comparable data on incidence rates across EU and hence no possibility to compare patient safety levels and policies

Closely linked to the fact that not all MS have patient safety policies in place is the uneven picture on adverse events incidence in all EU MS, as shown in table 2. It is currently not possible to obtain and compare data on patient safety levels for all EU MS. Therefore, comparable and aggregate data on the level of adverse events in healthcare settings, and on how many of these were realistically preventable, should be collected.

When there is not enough information available to MS authorities or the public on the extent and type of adverse events in healthcare systems it is difficult for those authorities to decide where to best dedicate scarce resources to improve patient safety or for patients to make an informed judgment. An additional consideration is that the cross-border mobility of patients means that some patients may face a choice or decision to access healthcare in a Member State

other than their own. Others may have no choice but to do so. How do those patients know whether those health systems are as safe, safer or less safe than their own and what types of harm are they at particular risk from if accessing health systems at home or in another MS?

Also, when a patient is harmed or even dies as a result of an adverse event, what support can that patient or their family expect from the healthcare system or authorities? Patients accessing healthcare, either in their home country or another Member State, need to know how to make a formal complaint, what help, support and redress is available to them if they are harmed by that healthcare and how to access it. There is clearly a case to have data in all Member States which will help people to make informed choices or decisions about their care in terms of safety, support and possible redress, as well as to inform the relevant authorities.

Hence the need to develop a common 'language' or taxonomy' for patient safety within the EU - to make comparisons and learning easier and to be used to drive up performance. It is evident that such a common taxonomy can only be achieved jointly at the EU level.

The incidence of HCAIs is often underestimated because of inadequate surveillance. Insufficient data on the incidence of HCAIs in healthcare institutions makes it difficult to guide and evaluate the implementation of infection control measures and to compare rates between institutions as a measure of performance. At national level, insufficient surveillance data make it difficult to compare healthcare institutions in terms of HCAI incidence rates and hamper the follow up of the epidemiology of HCAIs in order to detect trends and emerging resistant micro-organisms. In addition, agreed structure and process indicators are lacking to evaluate the performance of healthcare institutions in a comparable way.

A comprehensive set of common indicators to monitor healthcare safety in Member States, including HCAI levels, is necessary.

3. Current research findings, learning, experiences and expertise available in the EU do not sufficiently benefit patients because dissemination of effective patient safety interventions and solutions is not coordinated or routinely carried out at the EU level.

When patients access healthcare in their own country, or in another Member State, they expect to receive the safest possible care – that is healthcare that has minimised the possibility of adverse events and preventable harm occurring. Patients would benefit from those reporting and learning systems that do exist in MSs being mined, and research findings being analysed, to inform the development of effective solutions and interventions which would then be shared *throughout* the EU. The EU can play a role in ensuring this dissemination of solutions and interventions.

4. Senior management in healthcare institutions does not have enough commitment towards the prevention and control of adverse incidents, above all HCAIs. Not enough research on the cost-effectiveness of prevention and control of HCAIs.

Experience shows that, in most Member States, healthcare institutions approach HCAs in a reactive instead of a proactive way. The prevention and control of HCAs is often perceived by the senior management of healthcare institutions as a net cost factor and often measures are only put in place after the healthcare institution has been confronted with an outbreak of HCAs.

Although evidence is available, there is not enough research on the cost-effectiveness of prevention and control in healthcare institutions and at the level of national healthcare budgets and for society at large. In addition, there is not enough dissemination of best practices in healthcare institutions that have been shown to be cost-effective.

This part of the action to improve patient safety is best addressed at the local/regional level, but political ownership and stewardship at national and EU level is essential to support the cultural change necessary. In addition, tools such as the Public Health Programme are useful to stimulate research on cost-effectiveness of public health interventions and to disseminate these results throughout the EU.

5. Not enough awareness among healthcare staff on the issue of HCAs and insufficient training on ways to prevent and control HCAs. Not enough authoritative guidance is available to support infection control staff, such as EU agreed case definitions, guidance on best practice and minimum requirements for infrastructure.

To bring about the necessary changes, a first step is that all staff in healthcare institutions need to be informed about the problem of HCAs. In addition, healthcare staff are often insufficiently trained on ways to prevent and control HCAs. The lack of awareness and training results for example in poor compliance with hygiene practices which is an important driver in the incidence of HCAs. This is a fundamental problem in the majority of healthcare institutions throughout the EU.

Although HCAs are a multifaceted problem, ways to prevent and control it are well understood. Nevertheless, the information is rather fragmented and authoritative guidance pooling the best expertise available is lacking.

At EU level, the ECDC can play an important role in pooling the best expertise to develop training and guidance, and assist Member States in implementing training and curricula for all healthcare staff and for infection control staff¹³.

6. Antimicrobial resistance

A particularly important problem is that of the growing levels of resistance in the micro-organisms involved in HCAI. This means that infections and colonisations caused by them are often difficult to treat and difficult to eradicate from the healthcare environment. The inappropriate use of antibiotics is a key

¹³ A European Core curriculum for training for infection control staff has been developed by the IPSE project and can be found at: <http://helics.univ-lyon1.fr/Working%20packages/WP1/Core%20Curriculum%20Report.pdf>. After the end of the IPSE project, many of the IPSE activities will be taken over by ECDC.

driver in the problem of antimicrobial resistance. A Council Recommendation 2002/77/EC, based also on the provisions of Article 152, dealt with the prudent use of antimicrobial agents in human medicine, and outlined clear-cut measures to be taken at national and EU level to reduce antimicrobial resistance. In 2005, the Commission issued a report to Council (COM (2005) 0684) on the measures taken and the areas needing further attention. The Commission is following up this important issue and plans a second report to Council in 2009.

7. Spread of micro-organisms causing HCAs

Throughout the EU, there is an increased movement of patients and healthcare staff within healthcare institutions. There is also an increased movement of patients and healthcare staff between healthcare institutions (nationally and internationally) These increased movements contribute to the spread of micro-organisms causing HCAs. Budgetary constraints in healthcare institutions can not only lead to high bed occupancy rates and poor staff to patient ratios but also to insufficient infrastructure (such as isolation facilities) to control the spread of micro-organisms.

Although there is no evidence available at this time to suggest that the cross-border movement of patients in itself presents a specific additional risk to patient safety, the fact that patients are increasingly making use of their rights to access healthcare in other MSs (as set out in the Directive on the Application of Patients' Rights in Cross-Border Healthcare), means that the problems described above can be detrimental to citizens of other MSs too, making the EU a valid participant in actions to attempt to solve these problems. Surveillance at EU level, based on data gathered by the Member States, can detect emerging threats quickly and can coordinate a quick and effective response to these micro-organisms that are not constrained by national borders.

4. THE RIGHT OF THE UNION TO ACT – SUBSIDIARITY TEST

The problem of patient safety is primarily the responsibility of Member States. The European Union can support their efforts by taking actions where it has competence and - more broadly - in facilitating the exchange of good practices. As far as specific work on patient safety is concerned, the following areas of competence are relevant:

- **Article 152 (public health)** states that “Community action, which shall complement national policies, shall be directed towards [...] preventing human illness and diseases, and obviating sources of danger to human health. [...] The Community shall encourage cooperation between the Member States in the areas referred to in this Article and, if necessary, lend support to their action”. This supports work on systemic patient safety as well as that on HCAs.
- **Article 153 (consumer protection)** provides an additional aspect especially linked to people's right to information. Both articles fall under shared Community and Member State competence.

- Besides the Treaty basis, Annex I of Commission Decision 2000/96/EC¹⁴ identifies nosocomial infections (or hospital acquired infections) as one of the health issues to be progressively covered by the Community network established under Decision No 2119/98/EC.
- The High Level Group on Health Services and Medical Care has endorsed a number of recommended actions in the area of patient safety where European level collaboration and coordination of activities could bring added value.

In areas closely related to patient safety, Member States have previously agreed on the right and the added value of the Union to act:

- Council Recommendation (2002/77/EC) of 15 November 2001 on the prudent use of antimicrobial agents in human medicine.
- Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC.
- Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells

The legal base exists to take action at EU level; this is however not enough to justify EU involvement. The subsidiarity test assesses whether EU action is necessary, in other words whether action by a Member State or a group of Member States cannot sufficiently solve the problem. The test then evaluates whether action at EU-level adds value to the work done by Member States (the 'added-value test'), and it asks if the measures chosen are proportionate to the objectives (the 'boundary test'). This section looks at the first two elements of the test.

Necessity Test

The arguments justifying the necessity of EU action on patient safety focus on 3 elements:

- Trans-boundary spread of infections
- Cross-border provision of healthcare resulting from mobility of patients and professionals
- Need for EU-wide data collection and monitoring.

Firstly, HCAIs can easily be transmitted from one Member State to another because of the mobility of patients. Micro-organisms are not constrained by national boundaries and can rapidly spread between countries as evidenced by the international spread of MRSA and *Clostridium difficile* PCR ribotype 027. In this area, it is therefore crucial that all MS

¹⁴ Commission Decision (2000/96/EC) of 22 December 1999 on the communicable diseases to be progressively covered by the Community network under Decision No 2119/98/EC of the European Parliament and of the Council. O.J. No L 28, 3.2.2000

are actively engaged and cooperation and coordination at EU will assist Member States in their actions.

As regards the cross border movements of patients and healthcare professionals, they are currently still low, with only an estimated 1% of patients receiving treatment in another Member States in any year, but this is greater in border regions and is likely to increase with general population mobility.

For many, concerns about the safety or quality of healthcare systems in other Member States are the main factors impeding their use of services elsewhere. In addition, some patients crossing borders to receive healthcare will also not be guaranteed the same level of redress (or any at all) that they would be entitled to in their own health system, if something does go wrong.

Finally, the European Commission as an international institution is well placed to collect comparable data from the EU-27. Analysis at EU level allows aggregation of data and more effective analysis of trends and developments as well as identification of best practice and solutions. This is all the more important as there is little co-operation between Member States to provide comparable data. Even though some Member States have well-developed data systems, these are not always compatible, and some Member States have very limited data.

The other benefits of this activity will be discussed under the added-value test.

Added-value test

The added-value of EU activity in the area of patient safety concentrates around three main factors:

- EU providing political weight and visibility, thus putting patient safety at the centre of MSs health priorities
- Economies of scale – benefits of community wide collection of data, filling in the gaps in research.
- Effective knowledge sharing through exchange of best practice.

Ensuring patient safety should be a very high priority – perhaps the highest priority – for Member States' healthcare systems. The EU's focus on this issue can help to improve knowledge and awareness, to suggest cost-effective solutions and thus persuade Member States to make more efforts towards keeping patients safe. Current evidence suggests that EU Member States are at different levels of political awareness about the patient safety issue and therefore also as regards development of effective, comprehensive patient safety systems.

On the other hand, available evidence from some MSs and non EU countries such as the US and New Zealand suggests that incidence rates, types of errors and potential effectiveness gains are similar in all health systems. At the moment, however, with reporting of adverse events not done everywhere, there are still significant data gaps as regards the patient safety levels and policies in the EU, which is why common definitions and data collection at EU level are needed. A broad list of indicators on patient safety will be needed in light of the systemic nature of the patient safety issue, as well as the

multitude of causes. The Member States can thus also benefit from economies of scale linked to EU involvement.

Finally, cooperation at European level using the best available evidence and expertise has great potential to bring added value both to individual patients and to health systems overall. By tackling common problems at the EU level, European expertise can be pooled, inequalities stemming from unsafe care reduced, and duplication of effort and resources avoided. One aspect where EU level action provides added-value is the effective use of ICT systems for patient safety purposes where cross-border issues such as inter-operability arise. Another aspect would be to agree upon case definitions for HCAIs and common indicators to measure the implementation and performance of measures to prevent and control HCAIs.

Similarly, Member States may implement – to different degrees – rules and incentives for the prevention and control of HCAIs, and professional groups and key stakeholders may continue to provide non-statutory guidance. However, in most Member States, these actions have so far not achieved the necessary organisational and behavioural changes needed to bring down the incidence of HCAIs.

5. OBJECTIVES

5.1. General objective

The general objective is to prevent and reduce human illness and diseases and to obviate sources of danger to human health, as stipulated in Article 152 of the Treaty.

5.2. Specific objectives

1. to protect EU citizens from preventable harm in healthcare, including from HCAIs.
2. to support the Member States to put in place the proper and adequate strategies to prevent and control adverse events in healthcare, including HCAIs, by pooling the best available evidence and expertise in the EU.
3. to improve EU citizens' confidence that they have sufficient and comprehensible information available on levels of safety and available redress in EU health systems, including healthcare providers in their own country and in other Member States.
4. These objectives should result in fewer preventable deaths and illnesses and in a reduction in costs treating unnecessarily sick patients.

5.3. Operational objectives

1. Increase political awareness on the scale and size of the patient safety issue, as well as promoting adequate Member States' political commitment and acceptance.
2. Gather homogenous and comparable data and information on patient safety systems, initiatives and safety outcomes at EU level.

3. Share best practice and experience of MS efforts to establish efficient and transparent patient safety systems, structures and policies, including reporting and learning systems, education and training developments, use of indicators and/or standards and efforts to improve culture, on adverse events in healthcare. To share at the EU level, experiences of successful (as well as less successful) patient safety interventions and solutions *at the healthcare setting level*, for example the introduction of a new patient identification system or efforts to reduce mistakes from look-alike medicines, implemented in one or more Member State and evaluate the transferability of those solutions, and also share major patient safety alerts among all MSs.
4. In the area of HCAs, foster with the European Centre for Disease Prevention and Control (ECDC) the establishment of surveillance methods, indicators to allow evaluation of the implementation and effectiveness of measures to prevent and control HCAs, guidance on best practices and minimum infrastructure requirements, as well as training curricula for healthcare staff.
5. Develop common definitions and terminology for patient safety at the European Union level, including case definitions for HCAs.
6. Explore indicators for safety and quality of care.
7. Consider other existing data sources, such as patient complaints, compensation systems, clinical databases, monitoring systems and other adverse incident reporting systems (such as those in the areas of medical device vigilance and pharmacovigilance) as complementary sources of information on patient safety. The compatibility of the data sources and the different reporting systems should be regularly reviewed.
8. Develop and promote the research agenda on patient safety, at both MS and EU levels, particularly focusing on filling the current research gaps, including further research on the cost-effectiveness of prevention and control of HCAs.
9. Promote the availability of information for patients and their families on how to complain, and what redress is available and how to access that redress, when patients are harmed by healthcare.
10. Promote collaboration on patient safety issues between Member States, ECDC, EU institutions and key European and international organizations such as the WHO, OECD and CoE to ensure an integrated and consistent approach towards safer patient care.

6. POLICY OPTIONS

Option I: No additional EU action –status quo

The baseline scenario has been extensively described in section 3.

Under this option, the Member States, stakeholders and international organisations would pursue their activities on patient safety without any further co-ordination or incentives from the Commission.

Member States' representatives would come together with stakeholders on a voluntary basis as now to discuss patient safety issues and possible EU activities such as EU funded projects. Similarly, Member States would implement – to different degrees – rules and incentives to increase patient safety including the prevention and control of HCAs; networks, professional groups and key stakeholders will continue to provide guidance¹⁵.

The Commission would continue co-funding projects on patient safety including HCAs via the Public Health Programme and the Framework Programme for research and technological development. Community actions trying to improve specific aspects of patient safety such as pharmacovigilance or medical device safety would also be carried forward.

The baseline scenario reflects the current situation and, therefore, includes the effects of the existing policies and projects as listed in section 3 and in Annex I. That means that this option also includes estimated effects of the EUNetPaS project that would continue to exist regardless of further action at EU level.

Option II: Strengthened cooperation with the Member States and other bodies, supported by technical guidance

Under this option, the Commission would strengthen cooperation with Member States and other bodies by making increased use of the instruments described under option I. For example, the Commission could increase the focus on patient safety including HCAs in the Health Programme and the Framework Programme for research and technological development. The Commission could also step up its efforts in stimulating Member States to cooperate on the issue of HCAs and to develop technical guidance through the ECDC and the network of surveillance bodies.

Article 5 of Regulation (EC) No 851/2004 of the European Parliament and of the Council establishing a European centre for disease prevention and control¹⁶ stipulates that "*The Centre, through the operation of the dedicated surveillance networks and the provision of technical and scientific expertise to the Commission and Member States, shall support the networking activities of the competent bodies recognised by the Member States.*" Member States have designated such bodies under Commission Decision 2003/542/EC¹⁷ and ECDC could coordinate these bodies to:

- identify main problems at European level and facilitate mutual information, consultation, cooperation, and action through the Community network (Decision No 2119/98/EC)
- establish / strengthen EU-wide surveillance on HCAs and develop a strategy for access to data from surveillance systems for HCAs, risk factors and indicators
- establish guidance on best practice on the prevention and control of HCAs, and minimum infrastructure requirements

¹⁵ e.g. guidance developed by 'Improving Patient Safety in Europe (IPSE)', a project funded by the Public Health Programme.

¹⁶ Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 April 2004 establishing a European centre for disease prevention and control. O.J. No L 142, 30.4.2004

¹⁷ Commission Decision 2003/542/EC of 17 July 2003 amending Decision 2000/96/EC as regards the operation of dedicated surveillance networks. O.J. No L 185, 24.7.2003

- foster training and education initiatives
- A comparable structure within which guidance on general patient safety issues could be developed is missing – with the exception of the newly established network for patient safety, EUNetPaS. However, as previously mentioned, this is a time-limited pilot network funded under the Public Health Programme which will work only in limited areas of patient safety.

Option III: Strengthened cooperation with the Member States and other bodies, supported by soft law instruments, such as a Commission Communication and a Council Recommendation

Under this option, the Commission would strengthen cooperation with Member States and other bodies by making increased use of the instruments described under option I. In addition, the Commission would develop a Communication and seek a political commitment from the Member States via a Council Recommendation on patient safety and quality of health services, including the prevention and control of HCAs.

The Communication would describe the broader context of patient safety, highlight the need for and types of action in the area and outline the Commission's strategy on improving patient safety.

The Council Recommendation would include general recommendations on patient safety and provide specific recommendations on the prevention and control of HCAs. The recommendations in the proposed Council Recommendation would be complementary to Council Recommendation 2002/77/EC based on Article 152 of the Treaty and would be consistent with the findings of its implementation report.

Option IV: Strengthened cooperation with the Member States and other bodies, supported by a regulatory instrument, such as a Commission Decision

This option would involve extension of Option II with a legislative proposal building on Decision No 2119/98/EC by adopting Commission Decisions covering aspects on the prevention and control of HCAs in accordance with Article 7 of Decision No 2119/98/EC, i.e. by comitology. Decision No 2119/98/EC established a Network for the epidemiological surveillance and control of communicable diseases in the Community, and Commission Decision 2000/96/EC already provided that nosocomial infections (i.e. HCAs) are a special health issue to be progressively covered by the Community network under Decision No 2119/98/EC.

For example, Article 3 c) of Decision No 2119/98/EC would allow the Commission adoption of a Decision covering case definitions for HCAs; Article 3 d) – e) would allow the adoption of a Commission Decision covering the nature and type of data and information to be collected and transmitted in the field of epidemiological surveillance on HCAs and the ways in which such data are to be made comparable and compatible, including epidemiological and microbiological surveillance methods.

Under this option, general patient safety issues could not be addressed in the Decision due to the lack of an appropriate legal basis which is limited to infection control and prevention.

Discarded options

Legislation, including a Regulation or a Directive on patient safety was ruled out as it would be extremely difficult to justify a specific and detailed legislative action covering all the aspects of the proposal on the grounds of subsidiarity and proportionality, in particular as this is an area where primary responsibility lies with the Member States and there is no explicit legal basis for legislative action in this area in the Treaty. Owing to the legal unfeasibility of this option, no screening for effectiveness, efficiency and consistency and no analysis of impacts is included.

7. ANALYSIS OF IMPACTS

In order to assess the possible health and economic impacts of the different policy options, quantitative simulation scenarios have been developed to support the present IA. These scenarios use only data for hospital settings, not for outpatient care, as the former is much better documented than the latter and is also the main setting for HCAI. It has to be stated that the scenarios constitute only a rough approximation of the policy options at stake. It was not the intention to overstate the impacts, but rather to present a simulation of effects of co-ordinated and comprehensive policies to reduce health burden due to patient safety incidents with fairly accepted degree of plausibility. The scenario analysis is meant to highlight in particular the extent to which more political ownership and leadership would improve patient safety outcomes.

Our scenario for general patient safety policies starts from the assumption that patient safety outcomes in various MS groups differ according to the systems in place and consequently are spread along the range of prevalence estimates for hospital-related incidents found in the literature range from 7 % to 16.6 % with a median of 10 %¹⁸.

¹⁸ To note: Prevalence rates in outpatient care are significantly lower than in hospital settings and are, according to national experience available from one country Spain in the range of less than 2 % and mainly caused by mismedication.

Table 4: Alternative scenarios used in simulations

	<i>Baseline</i>	<i>Scenario 1</i>	<i>Scenario 2</i>	<i>Scenario 3</i>	<i>Scenario 4</i>
	prevalence of adverse events related to hospitalisations	'poor' countries become 'fair'	'poor' and 'fair' countries become 'good'	'poor', 'fair', and 'good' countries become 'very good'	All countries become 'exemplary'
Country Category					
'exemplary'	7	7	7	7	7
'very good'	10	10	10	10	7
'good'	12	12	12	10	7
'fair'	14	14	12	10	7
'poor'	17	14	12	10	7

SOURCE: RAND Europe

Table 5: In-patient care: estimated number of adverse events

	<i>Baseline</i>	<i>Scenario 1</i>	<i>Scenario 2</i>	<i>Scenario 3</i>	<i>Scenario 4</i>
Simulated outcome	prevalence of adverse events related to hospitalisations	'poor' countries become 'fair'	'poor' and 'fair' countries become 'good'	'poor', 'fair', and 'good' countries become 'very good'	All countries become 'exemplary'
Adverse events	10,274,289	10,074,578	9,577,161	8,499,351	6,311,945
Permanent disability	1,562,411	1,532,041	1,456,399	1,292,496	959,857
Death	558,819	547,956	520,902	462,280	343,307
Preventable adverse events	4,397,396	4,311,919	4,099,025	3,637,722	2,701,512
Preventable length-of-stay (person-years)	50,845	49,857	47,395	42,061	31,236

SOURCE: RAND Europe

Table 6: In-patient care: estimated potential health benefits relative to baseline

	<i>Baseline</i>	<i>Scenario 1</i>	<i>Scenario 2</i>	<i>Scenario 3</i>	<i>Scenario 4</i>
Simulated	prevalence of 'poor'	'poor' and	'poor', 'fair', All countries		

Outcome	adverse related hospitalisations	events to	countries become 'fair'	'fair' countries become 'good'	and countries become 'very good'	'good' 'become 'exemplary'
Avoided Adverse events		0	199,711	497,417	1,077,810	2,187,406
Avoided Permanent disability		0	30,370	75,642	163,903	332,639
Avoided Death		0	10,863	27,054	58,622	118,973
Avoided Preventable adverse events		0	85,476	298,371	759,673	1,695,883
Avoided Preventable length-of-stay (person-years)		0	988	3,450	8,784	19,609

SOURCE: RAND Europe

As of now, data gaps for the EU do not allow us to establish a direct causal relationship between good patient safety policies, systems and structures, and patient safety outcomes. Our estimates were therefore based on how close the MS patient safety system is to what is generally considered best practice in the literature. We took as a reference the World Alliance for Patient Safety's definition of best practice, especially in relation to the existence of reporting and learning systems and classified MS accordingly.

The non-binding character of almost all of the options at stake limits the significance of this exercise, however the assumptions reflect experiences in the past with similar health policy initiatives where e.g. Council or Commission Recommendations - though legally non binding - triggered quite substantial improvements due to quick implementation at MS level. (see example of cancer screening recommendation). We have assumed that for a health issue as dependent on leadership as patient safety, similar effects can be envisaged.

We reviewed the above mentioned overall scenario by developing, with the help of infection control experts from ECDC etc. also a separate potential reduction scenario for HCAI-related events only. The figures we obtained were even higher in that case, which is because the overall adverse event scenario applies an average rate of 42% preventability. That reflects the fact that not every medical error will be easily avoidable, some errors e.g. those related to processes and communication will be much more difficult to rectify as they probably require considerable changes in the way medical staff communicate and coordinate. Nosocomial infection-related adverse events usually score much better on preventability (60% and higher) so that their reduction potential is underweighted in the overall reduction scenario.

7.1. Policy option I: No additional EU action – status quo

1. Economic impacts (direct and indirect costs of adverse events, costs of patient safety policies)

Current economic burden due to patient safety adverse events

Preventable medical errors prolong the suffering of patients, increase healthcare costs and have other direct and indirect economic implications, such as loss of productivity and disability. With adverse events ranging from 7.5% to 16.6 % of all hospital admissions, and with as much as half of those being preventable events, (in particular infected-related events are very often preventable by appropriate measures and therefore also the focus of this initiative), the potential cost savings for health care systems in all MS are apparent.

National experience from Spain suggests that adverse events **resulted in a prolongation of 2.2 days of avoidable stays per patient - a high number**. Furthermore, there are additional costs resulting also from additional procedures and treatments which are necessary after adverse events (this is the case in around two thirds of adverse events). In France it was observed that a longer hospitalisation period was associated with 40,5 % of all adverse events and the French study furthermore revealed that every hospital, regardless of size is affected, and that in the course of a 7 day observation of each unit at least one adverse events was observed in 55 % of surgical and 40 % of medical units.

The cost effectiveness of patient safety projects is furthermore documented by the fact that there are already today, e. g. in Germany, around 400 hospitals involved voluntarily in such projects – which they would probably not undertake if there was not a net benefit to be reaped.

The economic impacts are particularly well documented in the specific case of HCAI:

The **UK National Audit Office estimated the cost of hospital-acquired infections to be at £1 billion per year for the UK¹⁹ in the late 1990s (equivalent to £1.6b now)**. This was in fact an under-estimate in that it did not include infections in high-risk or specialised units such as renal dialysis or those occurring in tertiary referral centres. Costs will be different for other countries and will change with time; however the relative magnitudes will be similar.

Overall in the European Union, it has been estimated that there are around 4.1 million hospital patients suffering from at least one HCAI in the EU per year and that, based on an average excess hospital stay of 4 days²⁰, **HCAIs generate approximately 16.4 million extra hospital days per year**. Assuming an average EU hospital cost of 334 € (not including post-hospital costs²¹), the resulting healthcare cost for the EU27 can be estimated conservatively at €5.48 billion.

In addition, it has been estimated that patients that acquired a HCAI take on average 6 more days to return to work²². If we assume that 1/3 of the patients acquiring an HCAI

¹⁹ Action on healthcare associated infections (HCAI) in England: Regulatory Impact Assessment. Department of Health, UK
(http://www.dh.gov.uk/prod_consum_dh/idcplg?IdcService=GET_FILE&dID=246&Rendition=Web)

²⁰ Emori TG, Gaynes RP. An overview of nosocomial infections, including the role of the microbiology laboratory. Clin Microbiol Rev 1993; 6(4):428-442.

²¹ Hospitals in Europe Link for Infection Control through Surveillance. C. Suetens. ESQH Workshop, Brussels, 30 November 2001

²² Plowman R, Graves N, Griffin M, Roberts JA, Swan A, Cookson B, et al. The socio-economic burden of hospital acquired infection. London: PHLS, 2000 and Plowman R, Graves N, Griffin MAS, Roberts JA, Swan AV, Cookson B, Taylor T. The rate and cost of hospital-acquired infections occurring in patients admitted to selected specialties of a district general hospital in England and the national burden imposed. J Hosp Infect 2001; 47:198-209.

are productive, this represents a total loss of 8.2 million working days in the EU per year, resulting in a productivity loss of €1.37 billion (at an average EU labour productivity of €67.20/day²³ (see Annex 6)). This figure does not yet take into account the productivity loss due to people staying away from work to take care of relatives having acquired a HCAI. The costs of 37,000 attributable deaths annually have also not been taken into account.

Investment costs for a general framework for patient safety

Most administrative and compliance costs are related to the setting up and maintenance of a reporting and learning system which is at the core of any patient safety system and policy. Such systems already (at least partially or locally) exist in 20 MS. A new system would have to be set up in seven MS and adaptations and extensions of coverage would need to be made in up to 16 MS. There are costs to be expected at both the national and healthcare setting levels, and moreover the costs of setting up the systems will basically occur in the short term while the cost savings will come only in the longer-term.

Healthcare institutions will have to respond to additional reporting and surveillance duties in cases where more efforts are needed. In our scenarios for the different policy options, we made the following assumptions on investments in human resources: a 5-10 % reduction of HCAI across the EU with a staffing level of one infection control nurse per 600 beds; a 20-30 % reduction for one infection control nurse per 250 beds²⁴. One can assume an EU average annual cost of €42,000/infection control nurse²⁵ and a total of 2.88 million beds (see Annex 7) and a current staffing level of one infection control nurse per 1000 beds which would mean employing an additional 1,920 nurses in scenario one, 8640 in scenario two for the EU. Costs for other surveillance and improved infrastructure could not be obtained.

Government-spending will also increase in most cases. As a general indication, the per capita spending on patient safety investments in the UK and the US, both with advanced patient safety systems, can be used: 0,86 £ per capita in UK ; 0,22 US \$ per capita in US.

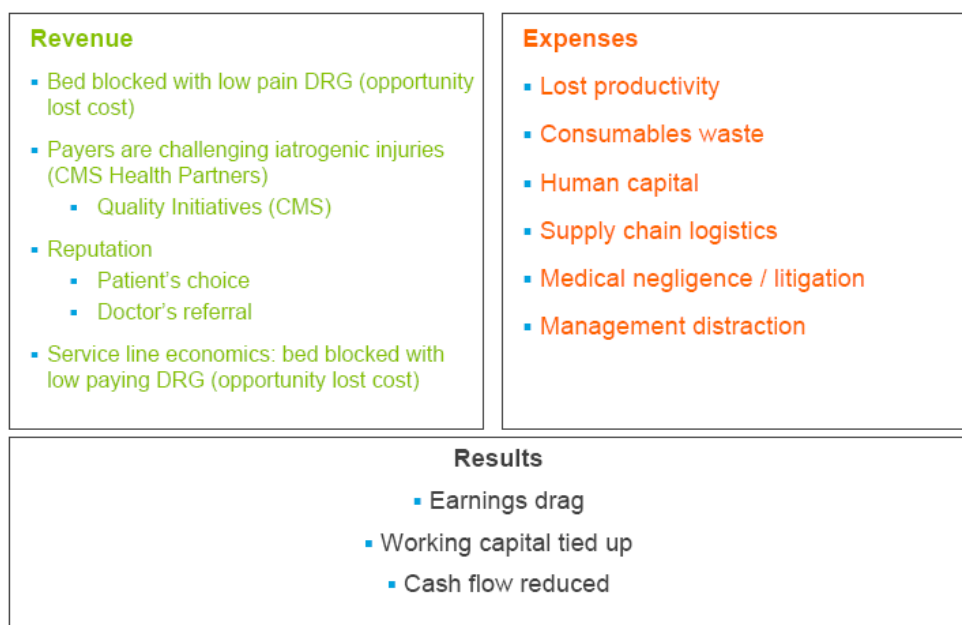
Cost-effectiveness of patient safety (including HCAI policies)

Although the upgrading of organisational structures for patient safety will result in additional costs in some MS, recent literature and national experience on the issue suggests that benefits from system-level patient safety improving strategies can well exceed costs, leading to net financial gains and reduce prevalence of adverse events.

²³ The figure of €67.20 per day is based on an average EU GDP output of €20.9/hour

²⁴ Recommended levels of infection control nurses of 1 per 100 – 250 beds have been cited in the literature (see section 7.3.2)

²⁵ The breakdown is as follows: gross salary: €30,000; benefits (15%): €4,500.00; computer and equipment: €3,500.00; training: €4,000.00



SOURCE: Wendin (2008)

Figure 4: Key financial impacts of adverse events

A cost benefit analysis in the US on interventions addressing adverse events with obstetric trauma, bedsores, surgical site infections, catheter-related bloodstream infections, MRSA and drugs suggests that the implementation of patient safety strategies can lead to **between 50% and 96% reduction in medical error rates and net savings from 50 thousand to 1.5 million € for a 300-bed hospital**. For HCAI in particular, a UK study from 2000 indicated that a 10% reduction in the number of hospital acquired infections in the UK could result in a saving of £93 million per year²⁶.

2. Health impacts (*mortality and morbidity*)

Health gains from better prevention in healthcare settings will also be significant.

The supporting study for this IA suggests that under the 'no policy change' option, i.e. no increased action on patient safety at the EU level, the EU is likely to see around 10 million adverse events related to hospitalisations (including those infection-related) of which almost 4.4 million would be preventable²⁷, resulting in more than 50.000 preventable person-years additional hospitalisation time. The US Institute of Medicine estimated that preventable adverse patient events, including hospital-acquired infections, are responsible for 44,000-98,000 deaths annually in the US at a cost of \$17-\$29 billion²⁸.

²⁶ Plowman R, Graves N, Griffin M, Roberts JA, Swan A, Cookson B, et al. The socio-economic burden of hospital acquired infection. London: PHLS, 2000.

²⁷ This reflects the share of preventability in all adverse events used in the Spanish ENAS study of 2005. This is only an average, in some cases e.g. for infections preventability will be much higher, in others, e.g. process related medial errors lower.

²⁸ To Err Is Human: Building a Safer Health System (2000). Institute of medicine. Committee on quality of health care in America. National academy press. Washington, D.C.

For HCAI in particular, on the basis of recent national HCAI prevalence surveys in Europe and the results of hospital-wide surveillance programmes of nosocomial bacteraemia in different Member States, it can be calculated that HCAs affect an estimated 5% of hospital patients on average and the total number of hospital patients acquiring at least one HCAI in the EU every year can be estimated at 4.1 million (with a total incidence of 4.5 million HCAs per year). Approximately 37,000 deaths are estimated to occur every year as a consequence of infection (see Annex 3).

The most frequent infections are urinary tract infections (UTIs, on average 28% (i.e. 1.26 million UTIs in the E27 per year) in the national prevalence surveys), followed by respiratory tract infections (25%, i.e. 1.13 million respiratory infections in the EU27 per year), surgical site infections (SSIs; 17%, i.e. 765,000 SSIs in the EU27 per year), bacteraemia (10%, i.e. 450,000 cases of bacteraemia in the EU27 per year) and others (including diarrhoea, with increasing importance due to *Clostridium difficile* (especially ribotype 027)). MRSA is isolated in approximately 5% of all HCAs.

Based on surveillance data (period 2004-2005) on patients staying more than 2 days in intensive care units (ICUs) in European hospitals, 7.2% developed pneumonia (mainly due to intubation), 3.1% developed blood stream infections (mainly catheter-associated)²⁹. Similar ICU surveillance data for the period 2000-2003 showed that 4.9% developed urinary tract infections³⁰. The EPIC (European Prevalence of Infection in Intensive Care) 1-day-prevalence study in 1992 found an ICU related infection in 20.6% of intensive care patients³¹.

Health equity

Patient safety events and in particular HCAI affect in particular vulnerable citizens such as the elderly, acutely ill people, people with impaired immune systems (e.g. transplant patients receiving immunosuppressive therapy, cancer patients receiving chemo- or radiotherapy, HIV positive people), who represent an important and growing share of the EU population: The elderly (65y or older) represent 16.5% (80 million) of the EU population³². Around 4.5 million people in the EU suffer from cancer³³ and there are estimated to be about 700,000 people with HIV in the EU at³⁴.

For policy option I, the baseline, we would assume that some progress in avoiding adverse events will be made in MS where patient safety is already on the political agenda and efforts would continue even without an additional EU initiative to frame patient-safety efforts.

We assume this because there are some EU projects ongoing (see Annex 1) that address some aspects of patient safety, but these projects are also time-limited and will therefore

²⁹ The IPSE (Improving Patient Safety in Europe) Annual Report 2006 (http://helics.univ-lyon1.fr/Documents/IPSE_Annual_Report_2006.pdf)

³⁰ HELICS Implementation Phase II, final report March 2005

³¹ The prevalence of nosocomial infection in intensive care units in Europe. Results of the European Prevalence of Infection in Intensive Care (EPIC) Study. EPIC International Advisory Committee. Vincent JL et al. JAMA. (1996) 275(5):362

³² Europe in figures — Eurostat yearbook 2006-07

³³ Research in the behavioural and social sciences to improve cancer control and care: a strategy for development. Eur. J. Cancer 40 (2004) 316-325

³⁴ The European Communicable Disease Epidemiological Report 2007, ECDC (http://www.ecdc.eu.int/pdf/Epi_report_2007.pdf)

not always deliver continued decreases in adverse events. However, there would be a substantial number of MS without a general patient safety policy in place at all - which implies that patients and/or healthcare practitioners will still not be able to report adverse events and near misses in their countries. Without systematic reporting there will be no solid basis for monitoring or launching a national patient safety policy. In some MS patients also do not have the possibility to seek redress after medical errors.

We assume that the gaps between advanced MS with a developed policy agenda for patient safety and those that have not would continue to exist under the baseline scenario. – given the importance of political commitment and senior staff stewardship. Hence substantial differences in the disease burden due to patient safety will continue to exist between Member States, which is discriminatory and affects equal access to high quality healthcare services.

Given the root causes of HCAI, the figures are not expected to decline either, despite the efforts of some Member States and funding through the Public Health and the Research Programmes. Moreover, in regard to HCAI it is not only patients, but also health professionals who are at risk: Their job quality and safety is affected if the necessary measures are not in place to protect them. This is in conflict with Article 13 of the Charter of Fundamental Rights of the European Union³⁵.

7.2. Policy option II: Strengthened cooperation with the Member States and other bodies, supported by technical guidance

As regards general policy frameworks for patient safety, we can assume under this option, which would require a strengthened cooperation of MS and other bodies, that increased knowledge sharing will help MS improve their patient safety systems and hence their performance in prevention of medical errors. It is not yet clear whether this policy option could also include some technical guidance for general patient safety issues, but this could certainly be done for HCAI based on the Commission Decision. Establishing common indicators and monitoring could be developed under this option, too, but only in technical subgroup the High Level Group that does not have political weight or a formal basis for its work.

1. Health and economic impacts

For this policy option, we assumed more progress would occur, in particular through knowledge sharing - so that in our simulation scenario all EU MS with 'poor' and 'fair' patient safety reporting and learning systems would be able to advance and experience similar adverse event rates as countries classified as having already 'good' patient safety reporting and learning systems. That would mean that instead of having an average of 14 % adverse events in hospital admissions, those countries would come closer to the performance of average countries which is in our scenario given with 12 %. In concrete terms that would mean that adverse preventable events would be reduced by 298.371 cases as compared to the baseline scenario resulting also in a reduction of 3450 prevented personal years of hospitalisation. However, the differences in Member States with their varying levels of political commitment to make patient safety a priority in national public health objectives will only be partly remedied under this option.

³⁵ Charter of Fundamental Rights of the European Union (2000/C 364/01). O.J. No C 364, 18.12.2000

In our specific scenario on nosocomial infections we assume that strengthened cooperation with the Member States and other bodies, supported by technical guidance would reap an overall 5% decrease of HCAI, a quarter of the potential for reduction in infection-related incidents reported in the literature. In the absence of a political commitment to bring about the needed organisational and behavioural changes, reaching the achievable 20-30% decrease of HCAs^{36, 37} (requiring an intensive prevention and control programme including surveillance and training of healthcare staff) is unlikely. We assume HIA reduction successes are applicable across the board, given that some infection-related safety policies are in place in all EU 27..

A projected 5% decrease would in our HCAI-scenario result in 225,000 HCAs fewer every year. As explained above, the higher numbers are due to the fact that HCAI cases are the easiest and quickest to prevent. 225,000 cases imply a considerable decrease of the HCAI morbidity and mortality burden. A 5% decrease would also save €274 million in health expenditure and represent a gain of €68.5 million in productivity. A UK study from 2000 indicated that a 10% reduction in the number of hospital acquired infections in the UK could result in a saving of £93 million per year³⁸.

Considering the above, it becomes clear that prevention and control of HCAs, even at suboptimal levels of 5%, is already highly cost-effective.

2. Employment effects

In all options (exception status quo) slightly positive employment effects can be expected due to the need for more resources for reporting and surveillance as well as infection control in health-care institutions.

Projected on the EU27 situation with a total of 2.88 million beds (see Annex 7), employing one infection control nurse per 600 beds³⁹ and assuming a current staffing level of one infection control nurse per 1000 beds would mean employing an additional 1,920 nurses. Assuming an EU average annual cost of €42,000/infection control nurse⁴⁰, this would mean an additional annual expenditure of about €80 million for policy option II. Costs for surveillance and improved infrastructure have not been obtained.

3. Environmental Impacts

Environmental impacts seem to be confined to the specific area of healthcare-associated infections, to a lesser extent be linked of other causes of medical errors. Under policy option II, minor environmental impacts are likely to occur due to an increased use of disposable medical products and disinfectant chemicals, but it is very difficult to estimate those.

³⁶ Harbarth S, et al. The preventable proportion of nosocomial infections: an overview of published reports. J Hosp Infect 2003; 54:258-266

³⁷ Haley RW, Culver DH, White JW, et al. The efficacy of infection surveillance and control programs in preventing nosocomial infections in U.S. hospitals. Am J Epidemiol 1985;121:182-205.

³⁸ Plowman R, Graves N, Griffin M, Roberts JA, Swan A, Cookson B, et al. The socio-economic burden of hospital acquired infection. London: PHLS, 2000.

³⁹ Recommended levels of infection control nurses of 1 per 100 – 250 beds have been cited in the literature (see section 7.3.2)

⁴⁰ The breakdown is as follows: gross salary: €30,000; benefits (15%): €4,500.00; computer and equipment: €3,500.00; training: €4,000.00

7.3. Policy option III: Strengthened cooperation with the Member States and other bodies, supported by soft law instruments, such as a Commission Communication and a Council Recommendation

The option would not only bring together various fragmented and specific patient safety initiatives at EU level (e.g. in the area of research, innovation policy and pharmacovigilance) under one framework, but would above all provide a high level political commitment from MS to take action on patient safety. It could address the overall cultural leadership systemic communication and process barriers and could integrate HCAI as part of an overall patient safety policy. As explained above, success for patient safety depends on leadership and cultural change which is why we assume substantial benefits for this option, where MS's ownership is greatest. In particular we assume that some MS that have no patient safety reporting system would start developing such systems and launch development of general patient safety policies. The more advanced MS would benefit from increased knowledge sharing and data gathering, including technical guidance for both systemic and infection-related issues. We therefore assumed in our general scenario a larger impact of EU-level action under policy option 3, with the result of all EU countries advancing to the relatively better levels of adverse events reported by the literature. That means that we assume the exemplary countries remain as efficient as they are and all other MS move towards the reported average of 10% adverse events ('very good'). This is still a conservative estimate (given the average preventability rate) but even so we could avoid more than 750.000 preventable adverse events and reduce by more than 8000 additional person-years of hospitalisation.

For our HCAI-only reduction scenario we came up with even better successes given that for infections, the ways to control them are well understood, and quick to implement, and above all they are highly preventable.

1. Health and economic impacts

According to the literature, a 20% (Harbarth *et al.*⁴¹) to 32% (Haley *et al.*⁴²) reduction in hospital acquired infections can be achieved using an intensive infection prevention and control programme including surveillance. Indeed, the SENIC (Study on the Efficiency of Nosocomial Infection Control) study, performed by Haley *et al.* in US hospitals from 1970-1976, found that an intensive infection prevention and control programme including surveillance reduced hospitals' infection rates by 32%⁴³.

Essential components of such programs included conducting organized surveillance and control activities and having a trained, effectual infection control physician, an infection control nurse per 250 beds, and a system for reporting infection rates to practicing surgeons. The same study estimated that the cost of infection control teams was only 7% of the infection costs. Therefore, if infection control programmes were effective in preventing only 7% of HCAs, the costs of the programmes would already be covered.

⁴¹ Harbarth S, et al. The preventable proportion of nosocomial infections: an overview of published reports. *J Hosp Infect* 2003; 54:258-266

⁴² Haley RW, Culver DH, White JW, et al. The efficacy of infection surveillance and control programs in preventing nosocomial infections in U.S. hospitals. *Am J Epidemiol* 1985;121:182-205.

⁴³ Haley RW, Culver DH, White JW, et al. The efficacy of infection surveillance and control programs in preventing nosocomial infections in U.S. hospitals. *Am J Epidemiol* 1985;121:182-205.

We assume now that under this policy option all EU MS would implement most of that so that the estimated reduction could actually reap the possible 20% decrease. A 20% decrease would mean up to 900.000 HCAs less every year, resulting in a major decrease of the HCAI morbidity and mortality burden which would save €1.10 billion in public health expenditure and represent a gain of €274 million in productivity.

2. Employment effects

In all options (except the status quo) slightly positive employment effects can be expected as more resources are needed for reporting and surveillance as well as infection control in healthcare institutions. Haley *et al.*⁴⁴ mentions the need for 1 infection control nurse per 250 beds as part of an intensive infection prevention and control programme. The Aucoin report⁴⁵ proposes 1 infection control nurse per 100 specialised care beds, 1 infection control nurse per 133 normal care beds and 1 infection control nurse per 250 long-term care beds. The EU has a total of 2.88 million beds. Employing one infection control nurse per 250 beds and assuming a current staffing level of one infection control nurse per 1000 beds would mean employing an additional 8,640 nurses. Assuming an EU average annual cost of €42,000 per nurse, this would mean an additional annual expenditure of about €363 million for policy option III. Costs for surveillance and improved infrastructure have not been obtained.

Considering the above, it becomes clear that successful prevention and control strategies are highly cost-effective.

3. Environmental Impacts

Environmental impacts seem to be mainly confined to the specific area of HCAs. Under option III, minor environmental impacts are likely to occur because of increased use of disposable medical products and disinfectant chemicals, but it is very difficult to estimate those.

7.4. Policy option IV: Strengthened cooperation with the Member States and other bodies, supported by a regulatory instrument, such as a Commission Decision

As stated, a Commission Decision could only address infection-related, and not general and systemic patient safety issues given the lack of a legal base for this. That would mean that this policy option would only reap benefits comparable to those of policy option III if it is accompanied by a Recommendation. If not, we assume the general patient safety benefits to be in the range of those identified under policy option II.

As regards HCAI, we do not assume, however, that the benefits would be much bigger than those identified in policy option III. That is because Article 3 of Decision No 2119/98/EC does not provide a legal basis to address all the operational objectives of the proposal, and therefore essential parts (e.g. creation of infection prevention and control

⁴⁴ Haley RW, Culver DH, White JW, et al. The efficacy of infection surveillance and control programs in preventing nosocomial infections in U.S. hospitals. *Am J Epidemiol* 1985;121:182-205.

⁴⁵ Aucoin et al. 'D'abord, ne pas nuire...Les infections nosocomiales au Québec, un problème majeur de santé, une priorité. Rapport du Comité d'examen sur la prévention et le contrôle des infections nosocomiales.' La Direction des communications du ministère de la Santé et des Services sociaux, Quebec, Canada (2005).

programmes in hospitals or developing specific training) of the integrated strategy to combat HCAs would have to be left out. Whereas it would be feasible to use Commission Decisions to reinforce certain aspects of the integrated strategy after it has been put in place via e.g. a Council Recommendation, it is expected that this option without an integrated strategy will not perform much better than the option of strengthened cooperation with the Member States. In particular, there would be no additional push resulting from an overarching patient safety policy.

A synoptic overview of the different policy options and the extent to which they could achieve the identified specific objectives is presented in Table 7. Figures were rounded.

	Policy option I	Policy option II	Policy option III	Policy option IV
Specific objective 1 Protect EU citizens from harm	Little progress, which would occur basically in countries where patient safety is a political priority O with slight improvements	Reduction of 300.000 preventable adverse events in total +	Reduction of 750.000 preventable adverse events in total ++	+ to ++
Specific objective 2 Support MS to put in place patient safety strategies	No additional EU level support O	Some additional EU level support through technical guidance on HCAI +	Political ownership and leadership of all MS, exchange of best practice Quick implementation possible ++	Political ownership if accompanied by a Recommendation, Decision addresses some aspects of HCAI which would be legally binding. + to ++
Specific objective 3 Improve EU citizens confidence	O	+	++	+ to ++

8. COMPARING THE OPTIONS

8.1. Advantages and disadvantages of the policy options identified in section 6

Option I No EU action – the status quo

Advantages	Disadvantages
The patient safety working group of the high level working group on healthcare is the main platform for patient safety information-sharing and learning at the European level, bringing together Member States, stakeholders and international organisations. The involvement of the key players has helped to ensure that synergies are developed and that overlap of efforts can be avoided.	The patient safety working group is, as the name suggests, a technical subgroup of another Committee and does not have political weight. It will not necessarily continue to exist as there is no formal basis of its work. While organisations like the WHO's World Alliance for patient safety have launched some patient safety

	<p>programmes and campaigns on particular aspects of patient safety such as clean hand policy, there has been no attempt to approach the patient safety problem comprehensively, addressing all the factors that could improve patient safety outcomes.</p> <p>It is clear that there are still big gaps in the data in most EU Member States on the extent and causes of adverse events. Without increased action at EU level these gaps are likely to continue to exist in many Member States.</p>
<p>Projects funded by the Commission have proved a valuable tool to progress towards a better understanding of the problems and finding possible solutions.</p> <p>These initiatives involve the professionals in the field and offer flexibility for Member States to tailor the results to their national situations.</p>	<p>Coordination of these projects under different Community programmes is quite difficult.</p> <p>The projects do not always include all Member States. In many instances those involved in the best systems are leading the projects and the results are not likely to benefit the whole EU.</p> <p>The projects have a limited time frame and limited resources so that there is a risk of losing continuity once the project is finished. The projects do not always have the financial capacity to transfer their results to the political level in order to make them more widely operatives.</p>
<p>Community initiatives aimed at improving patient safety in areas such as pharmacovigilance and medical device safety and technology already exist.</p>	<p>These actions do not fully meet the demands of the current situation or the needs of patients or governments to tackle this major public health concern.</p> <p>These initiatives only focus on specific patient safety concerns, such as in the area of product safety, and do not seek to address the overall cultural, leadership, systemic, communication and process barriers to improved safety.</p>
<p>The OMC for healthcare and long-term care may be useful in the future to monitor and compare Member States' performance in the area of patient safety against a number of indicators that could be developed.</p>	<p>Poor performance against such indicators in individual countries may prompt Member States to try to improve their performance in patient safety but would not provide adequate guidance on what actions could work best in their settings.</p> <p>As such, the OMC initiative could complement a proposal on patient safety, but would not be sufficient to address this important issue in itself.</p>
<p>No extra resources needed for the prevention and control of HCAIs</p>	<p>The non-statutory guidance on the prevention and control of HCAIs has up till now not been able to address the problems related to HCAIs as listed in section 3.</p> <p>This option fails to profit from Community added value by pooling the best expertise and identifying best practices on HCAIs as described in section 4.</p>
<p>The EUNetPaS project would continue to September 2010.</p>	<p>The EUNetPaS project is largely an operational mechanism and does not bring with it the full <i>political</i> commitment to improving patient safety from MS governments which we are seeking.</p>

	<p>EUNetPaS is also a time-limited project, (30 months running from February 2008 to August 2010) co-funded under the Public Health Programme, there will be doubts as to its long-term sustainability once its funding runs out. The project will not fully address the objectives of the Commission's initiative, even in the short-term.</p> <p>For example, the project is not seeking to establish and implement a common taxonomy and EU-wide patient safety indicators. The sharing of effective patient safety interventions is limited to medication safety whereas the Commission's initiative aims to share best practice and effective solutions in <i>all</i> areas of harm. EUNetPaS will be, in the short-term at least, a useful operational tool for Member States to add EU value on patient safety. However, it is a time-limited, specific project and should not be regarded as having either the same purpose or effect as a broad- ranging political initiative.</p>
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Option II) Strengthened cooperation with the Member States and other bodies, supported by technical guidance

Advantages	Disadvantages
The advantages listed under option I would be further underlined by a more active involvement of the Commission in current activities.	<p>Guidelines are not legally binding on Member States so this option presents a real risk that Member States could ignore them.</p> <p>Coordination between Member States has sometimes proved to be ineffective I without any legal instrument supporting the actions.</p>
Mechanisms to fund projects addressing HCAIs are in place (under the Public Health and Research Framework Programmes) and the focus on patient safety and HCAIs could be increased.	Although time-limited projects can increase understanding of problems, they cannot overcome structural differences among Member States nor assure political commitment.
ECDC could provide added value in coordinating the Member States' activities and providing guidance on the prevention and control of HCAIs.	Coordination between MS by itself may not be sufficient to control HCAIs since many Member States have varying levels of political commitment to taking action. Therefore, strengthened coordination supported by technical guidance may not be sufficient to bring about the needed organisational and behavioural changes.

Option III) Strengthened cooperation with the Member States and other bodies, supported by soft law instruments, such as a Commission Communication and Council Recommendation

Advantages	Disadvantages
A Communication would provide an overarching structure for the Community's diverse initiatives on	Neither a Commission Communication nor a Council Recommendation is legally binding.

<p>patient safety.</p> <p>It could address the overall cultural, leadership, systemic, communication and process barriers to improved patient safety. In consequence, morbidity and mortality due to patient safety issues could decrease substantially.</p> <p>It would present findings and good practice principles on patient safety to be applied in the EU and highlight the need for actions.</p> <p>A Council Recommendation could include recommendations on patient safety and specific recommendations on the prevention and control of HCAIs.</p> <p>A Council Recommendation would represent a strong political commitment to address patient safety and HCAIs.</p> <p>The literature and this impact assessment show that improved prevention and control of HCAIs is highly cost-effective.</p> <p>A Council Recommendation allows for monitoring and evaluation of the recommended measures.</p> <p>This option corresponds to what is indicated in the Commission's Legislative and Work programme as a strategic initiative for 2008.</p>	<p>This option would require detailed negotiations in the Council in order to achieve consensus.</p> <p>Investments are necessary to bring about the needed organisational and behavioural changes.</p>
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Option IV) Strengthened cooperation with the Member States and other bodies, supported by a regulatory instrument, such as a Commission Decision

Advantages	Disadvantages
<p>The legal basis exists to put in place via a Commission Decision some of the elements needed to improve the prevention and control of HCAIs.</p> <p>A Commission Decision is a legally binding instrument which would promote a strong political commitment to address the issues covered.</p>	<p>With a Decision only some of the elements to improve prevention and control of HCAIs can be put in place, but not all. Moreover, general patient safety issues, could not be addressed.</p> <p>Essential parts of the integrated strategy to combat HCAIs (e.g. creation of infection prevention and control programmes in hospitals or developing specific training on HCAIs prevention and control) would have to be left out.</p> <p>It would be feasible to use Commission Decisions to reinforce certain aspects of an integrated strategy on HCAIs after it has been put in place via e.g. a Council Recommendation. However it is expected that this option without an integrated strategy will not perform much better than the option of strengthened cooperation with the Member States.</p>

8.2. Conclusions

Based on the above, the policy option of a proposal for a Commission Communication and a Council Recommendation on patient safety and quality of health services, including the prevention and control of HCAs is preferred.

9. MONITORING AND EVALUATION

9.1. Progress indicators and surveillance

Problem definition			
<i>Issues to be monitored</i>	<i>Indicators</i>	<i>Source of info</i>	<i>How often data gathered and analysed?</i>
Level of awareness of extent and type of adverse events among Member States	Quality and harmonization of the level of awareness of MS	Data from the EUNetPaS project	Once a year from 2010
Availability of information for patients on safety levels and help available in case of harm in different healthcare systems	Patients' awareness of differences in safety levels and overall satisfaction	Reporting and learning system within the EUNetPaS project	Once a year from 2010
Objectives			
Creation of homogenous and comparable data and information on patient safety systems, initiatives and safety outcomes at EU level.	Access and level of use of up-to-date and comprehensive information system.	Competent authorities	Yearly report
Develop common definitions and terminology for patient safety at the EU level	Unified terminology in use.	An external evaluation.	Within a future evaluation of proposed SANCO health related initiatives
Develop case definitions for HCAs, in accordance with Decision 2119/98/EC	Commission Decision covering case definitions for HCAs	ECDC, external expertise	Continuous follow-up
Creation of European reference data for comparisons between countries and hospitals	Existence of functional surveillance systems	An external evaluation. Existing European surveillance systems, ECDC (for communicable diseases).	Within a future evaluation of proposed SANCO health related initiatives
Foster with ECDC the establishment of surveillance methods and indicators to allow evaluation of the implementation	Availability of surveillance methods, indicators, guidance on best	ECDC	Continuous follow-up.

and effectiveness of measures to prevent and control HCAs, guidance on best practices and minimum infrastructure requirements, as well as training curricula for healthcare staff.	practices and minimum infrastructure requirements, as well as training curricula for healthcare staff agreed at EU level.		
Monitor the implementation and effectiveness of the recommendations on the prevention and control of HCAs.	Process (e.g. standard operating procedures on hand hygiene) and structure (number of infection control personnel) indicators to be developed by ECDC, building on the work of the IPSE project.	ECDC	In reports to the Council at the interval specified in the Council Recommendation.
Decrease of level of HCAs in Member States.	Prevalence and incidence of HCAs in Member States.	National competent authorities, ECDC	The annual ECDC epidemiological report on communicable diseases in Europe.
Develop and promote the research agenda on patient safety, including the use of information and communication technology (ICT), new tools for the diagnosis, prophylaxis and treatment of HCAs, as well as further research on the cost-effectiveness of prevention and control of HCAs.	Number of accepted applications on patient safety.	Public Health Programme DG RTD	Yearly statistics

9.2. Evaluation

It is envisaged to evaluate the overall patient safety initiative, including implementation of the Recommendation, using external experts to assess its relevance, effectiveness and efficiency. This evaluation could be part of a comprehensive evaluation project for different health related initiatives. In relation to HCAI, Member States will also submit reports on implementation of the Recommendation. The proposed indicators and data to be collected in the future should enable the measurement of the economic and social impact of initiative.

ANNEX 1: EU-FUNDED PATIENT SAFETY / HCAIs PROJECTS

The **MARQuIS** research project ("**Methods of Assessing Response to Quality Improvement Strategies**") was designed to help assess the value of different quality strategies and to provide information for countries contracting care for patients moving across borders and for individual hospitals reviewing the design of their quality strategies. The results also provided evidence-based advice for developing quality approaches at EU level for healthcare institutions.

The **SIMPATIE** project ("**Safety Improvement for Patients in Europe**") aimed to facilitate free movement of people and services by developing EU-wide commonality and transparency in methodology on patient safety in healthcare institutions. The project used Europe-wide networks to establish a common set of vocabulary, indicators, internal and external instruments for improvement in safety in healthcare.

The, **EUNetPaS** ("**European Union Network for Patient Safety**") was launched in February 2008. It aims to establish an umbrella network of Member States and EU stakeholders to encourage and enhance collaboration in the field of Patient Safety by evaluating, validating and diffusing new knowledge and good practices.

The **HELICS implementation phase I** project (**Hospital in Europe Link for Infection Control through Surveillance**) aimed to lay the practical foundations for a European Network on hospital acquired infections by the creation and analysis of two databases (on surgical and intensive care unit (ICU) infections); developing consensus for prevalence surveys and surveillance of emerging infections in immuno-compromised patients; validating a European methodology to create evidence-based scientific advice, recommendations or standards; and setting up an inventory of training and fellowships on infection control.

The **HELICS implementation phase II** project (**Hospital in Europe Link for Infection Control through Surveillance**) aimed to create a robust and validated surveillance system and establish reference data sets for surveillance of Surgical Site Infections (SSIs) and infections in ICUs. Data on SSIs and infections in ICUs were collected on a pilot basis and a database was established to collect regular data on these infections.

The **IPSE** project ("**Improving Patient Safety in Europe**") aims to reduce the burden of HCAIs and their related threats of antimicrobial resistance (AMR) by providing evidence-based guidance and educational tools, strengthening the status of infection control professionals, strengthening surveillance and developing indicators.

PSIP (Patient safety through intelligent procedures in medication) is an ICT project under the 7th Framework Programme aiming at producing systematic epidemiological knowledge on adverse drug events and improving the medical cycle in a hospital environment through innovative data mining and semantic mining techniques using available hospital data.

ANNEX 2: EVIDENCE OF THE SCALE OF THE PATIENT SAFETY PROBLEM

Studies from the UK, Spain and France provide the bulk of current evidence in Europe on in-patient adverse event prevalence and its implications. The UK studies demonstrate the scope and universal nature of the problem, the costs of compensation claims and most common incident types. Spain's study also covers the scope of the problem, the proportion of incident types by severity, the root causes and consequences in extended hospital stays. The French study also shows the universality of the problem of patient safety and the root causes.

The **UK**, a National Health Service (NHS) report in 2000, *An Organisation with a Memory*, revealed a big problem of poor patient safety: existing data (admittedly poor) showed that at least 400 patients died or were seriously injured in adverse events involving medical devices in 1999 and that nearly 10,000 people had experienced serious adverse reactions to drugs.

Compared to the UK, there is a slightly lower nation-wide incidence of adverse events in **Spain**. According to the 2006 Spanish National Study on Hospitalisation-Related Adverse Events (ENEAS)⁴⁶, **adverse events among all hospital patients in Spain in 2005 was 9.3%**⁴⁷ **and 42.8% of these were deemed preventable**. More specifically, the incidence of patients with adverse events directly related to their hospital care (excluding primary care, out-patient treatment and those caused at another hospital) was 8.4% (473/5,624). A total of 17.7% of these patients had more than one adverse event related to their hospital care.

The Spanish study found that adverse events not only result in an extended hospital stay (31.4%), but also in re-admission to a hospital (24.4%), with some patients having more than one adverse event which caused their re-admission. Adverse events extended hospital stays by an average of 4 days and by 7 days where re-admission was needed. A total of 3,200 additional days (6.1 per patient) were caused by adverse events, 1,157 of which were avoidable.

The third European national study is a recent **French** national survey of in-patient adverse events (Michel, 2007). This, prospectively assessed with ward staff, found that in the course of the 7 days' observation per unit **at least one adverse event was observed in 55% of surgical units and in 40% of medical units**.⁴⁸ The investigators and the ward staff considered **35.4% of the adverse events to have been preventable** (39.6% in medicine and 32.1% in surgery). This result indicated that every type of hospital and unit is affected by adverse events, and hence substantiates the classification of in-patient

⁴⁶ ENEAS was a retrospective cohort study. A sample of 24 hospitals was random layered by hospital size, in which the hospitals to take part in the study were chosen at random according to the sample size required to compiling all of the discharges for the study period which met the criteria for inclusion. 6 small-sized (under 200 beds), 13 medium-sized (200-499 beds) and 5 large-sized (500 beds or more) were included, with a total of 5,624 case records.

⁴⁷ A total of 1,755 (32%) of the 5,624 patients were screened as possible AE's, 3,869 of whom were ruled out due to their not meeting the requirements of any of the screening guide alerts. On reviewing the patients screened as positive, 501 false positives and 191 patients showing solely incidents were found. A total of 1,063 patients with AE's during hospitalisation were detected, the incidence of patients with healthcare-related AS's being 9.3% (525/5,624).

⁴⁸ Excluding obstetric wards, but including public, private and teaching hospitals. Total participation rate was 40%. The 8754 patients included in the study were followed up on average over 4 days, giving a total of 35 234 days of observation (17 105 in medicine and 18 129 in surgery).

adverse events as a public health problem. A longer period of hospitalisation was associated with 40.5% of all adverse events.

ANNEX 3: THE BURDEN OF HEALTHCARE-ASSOCIATED INFECTIONS IN EUROPE: AN ESTIMATE FROM MULTICENTRE PREVALENCE SURVEYS OF NOSOCOMIAL INFECTIONS⁴⁹

Hospital-wide incidence figures for all types of nosocomial infections are not available from European countries. The type of surveillance generating these figures, hospital-wide surveillance of all nosocomial infection types, was abandoned worldwide in the early nineties because of poor cost-effectiveness in terms of prevention of nosocomial infections(1).

Given this lack of hospital-wide figures, the total annual number of nosocomial infections occurring on a yearly basis in the EU can be estimated by converting the mean prevalence of national or multicentre prevalence surveys to incidence figures according to the method described by Freeman et al. (2) and applied by Gastmeier et al. (3).

A review of recent prevalence surveys in industrialized countries showed that the mean prevalence of nosocomial infections in acute care hospitals is approximately 7.1%, ranging from 3.5% to 10.5% (table 1).

Table 1. Overview of recent prevalence surveys of nosocomial infections in industrialised countries

	<i>NI Prevalence</i>	Ref	N hospitals	N patients
Spain, 96-99	8.9%	(4;5)	233	210985
UK, 1996	9.0%	(6;7)	157	37111
Germany, 1997	3.5%	(8)	72	14996
France, 2001 (1996)	6.6%	(9;10)	1533	162220
Norway, 2003	5.1%	(11;12)	71	12257
Suisse, 2002	8.1%	(13;14)	60	7540
Italy, INF-NOS, 2002	7.5%	(15)	15	2165
Greece, 2000	9.3%	(16)	14	3925
Italy, Lombardy, 2000	4.9%	(17)	88	18667
Slovenia, 2001	4.6%	(18)	19	6695
Canada, 2002	10.5%	(19)	25	5750
UK & IE, 2006	7.6%	(20;21)	273	75763
France, 2006	5.0%	(22)	2337	358353
Scotland, 2007	9.5%	(23)	45	11608

⁴⁹ Calculation by ECDC, unpublished results

The Netherlands, 2007	6.9%	(24)	30	8424
Total, mean	7.1%			

Assuming an overall average length of hospital stay of 10 days (LA), a mean length of stay of 22 days in patients who acquire one or more nosocomial infections (LN) and a mean interval between admission to onset of first infection (INT) of 8 days (figures corroborated by ref.(3)), this prevalence figure of 7.1% converts to an incidence figure of approximately 5.1% according to the formula $I = P \cdot LA / (LN - INT)$ with a 95% confidence interval ranging from 4.3% to 5.9%. The figure of 5% compares relatively well to best nationwide figure of 5.7 per 100 admissions yet available from the US (25).

According to Eurostat figures, in the EU (2005 figures completed by earlier years if missing, ref. <http://epp.eurostat.ec.europa.eu/> and Health in Europe 2005 pocketbook edition), the number of hospital admissions is approximately 81 million per year (on average 16247 admissions/100 000 inhabitants/year). The yearly number of patients with at least one nosocomial infection in the EU can thus be estimated at 4,131,000 patients (95% CI 3483000-4779000). Since several patients acquire more than one infection during the same hospitalisation (average from the national prevalence surveys review 1.1 infections per infected patient) the yearly number of nosocomial infections can be estimated at 4,544,100 (95% CI 3831300-5256900).

The impact of nosocomial infections on the excess length of stay in the hospital and mortality (attributable morbidity and mortality) depends on the type of infection (highest for pneumonia and bloodstream infections) and estimates vary considerably in scientific literature. Based on overall estimates of attributable mortality in nosocomial infections by the CDC (26;27), approximately 37,179 deaths (0.9%; 95%CI 31347-43011) directly caused by nosocomial infections occur every year in the EU and an additional 111,537 (95%CI 94041-129033) deaths occur to which infections contributed. Nosocomial infections also generate approximately 16 million extra days of hospital stay per year (average of 4 days per infection (26)).

Reference List

- (1) Haley RW. Surveillance by objective: a new priority-directed approach to the control of nosocomial infections. The National Foundation for Infectious Diseases lecture. Am J Infect Control 1985; 13(2):78-89.
- (2) Freeman J, Hutchison GB. Prevalence, incidence and duration. Am J Epidemiol 1980; 112(5):707-723.
- (3) Gastmeier P, Brauer H, Sohr D, Geffers C, Forster DH, Daschner F et al. Converting incidence and prevalence data of nosocomial infections: results from eight hospitals. Infect Control Hosp Epidemiol 2001; 22(1): 31-34.
- (4) Vaque J, Rossello J, Trilla A, Monge V, Garcia-Caballero J, Arribas JL et al. Nosocomial infections in Spain: results of five nationwide serial prevalence surveys (EPINE Project, 1990 to 1994). Nosocomial Infections Prevalence Study in Spain. Infect Control Hosp Epidemiol 1996; 17(5):293-297.

- (5) Vaque J, Rossello J, Grupo de Trabajo EPINE. Evolución de la Prevalencia de las infecciones nosocomiales en los hospitales Españoles, Proyecto EPINE 10 años, 1990-1999. 1999.
- (6) Emmerson AM, Enstone JE, Griffin M, Kelsey MC, Smyth ET. The Second National Prevalence Survey of infection in hospitals - overview of the results. *J Hosp Infect* 1996; 32(3):175-190.
- (7) Plowman R, Graves N, Griffin MA, Roberts JA, Swan AV, Cookson B et al. The rate and cost of hospital-acquired infections occurring in patients admitted to selected specialties of a district general hospital in England and the national burden imposed. *J Hosp Infect* 47[3], 198-209. 2001.
- (8) Gastmeier P, Kampf G, Wischnewski N, Hauer T, Schulgen G, Schumacher M et al. Prevalence of nosocomial infections in representative German hospitals. *J Hosp Infect* 1998; 38(1):37-49.
- (9) Réseau d'alerte, d'investigations et de surveillance des infections nosocomiales (RAISIN). Enquête de prévalence nationale 2001 - Résultats. 2001.
- (10) Prevalence of nosocomial infections in France: results of the nationwide survey in 1996. The French Prevalence Survey Study Group. *J Hosp Infect* 2000; 46(3):186-193.
- (11) Eriksen HM, Iversen BG, Aavitsland P. Prevalence of nosocomial infections in hospitals in Norway, 2002 and 2003. *J Hosp Infect* 60[1], 40-45. 2005.
- (12) Bruun T, Loewer HL. Prevalence surveillance system of nosocomial infections in Norway. *Euro Surveill* 2007; 12(8):E070830.
- (13) Sax H, Ruef C, Pittet D. Résultats de l'enquête nationale de prévalence des infections nosocomiales de 2003 (snip03). *Swiss-Noso* 11, 1-5. 2004.
- (14) Sax H, Pittet D. Surveillance des infections nosocomiales en Suisse: méthodologie et résultats des enquêtes de prévalence 1999 et 2002. *Swiss-Noso* 10, 1-5. 2003.
- (15) Nicastrì E, Petrosillo N, Martini L, Larosa M, Gesu GPIG. INF-NOS Study Group. Prevalence of nosocomial infections in 15 Italian hospitals: first point prevalence study for the INF-NOS project. *Infection* 31[Suppl 2], 10-15. 2003.
- (16) Gikas A, Pediaditis J, Papadakis JA, Starakis J, Levidiotou S, Nikolaides P et al. Greek Infection Control Network. Prevalence study of hospital-acquired infections in 14 Greek hospitals: planning from the local to the national surveillance level. *J Hosp Infect* 50[4], 269-275. 2002.
- (17) Lizioli A, Privitera G, Alliata E, Antonietta Banfi EM, Boselli L, Panceri ML et al. Prevalence of nosocomial infections in Italy: result from the Lombardy survey in 2000. *J Hosp Infect* 54[2], 141-148. 2003.
- (18) Klavs I, Bufon LT, Skerl M, Grgic-Vitek M, Lejko ZT, Dolinsek M et al. Prevalence of and risk factors for hospital-acquired infections in Slovenia-results of the first national survey, 2001. *J Hosp Infect* 2003; 54(2):149-157.

- (19) Gravel D, Taylor G, Ofner M, Johnston L, Loeb M, Roth VR et al. Point prevalence survey for healthcare-associated infections within Canadian adult acute-care hospitals. *J Hosp Infect* 2007; 66(3):243-248.
- (20) Hospital Infection Society, Infection Control Nurses Association. The Third Prevalence Survey of Healthcare-associated Infections in Acute Hospitals 2006. England. Summary of Preliminary Results. http://www.his.org.uk/db/documents/Summary_of_preliminary_results_for_England.pdf, 1-7. 2007.
- (21) Hospital Infection Society. The Third Prevalence Survey of Healthcare-associated Infections in Acute Hospitals. Press release. http://www.his.org.uk/db/documents/Press_information.doc. 2006.
- (22) Réseau d'alerte, d'investigations et de surveillance des infections nosocomiales (RAISIN). Enquête nationale de prévalence des infections nosocomiales, juin 2006. Résultats préliminaires, janvier 2007. http://www.invs.sante.fr/publications/2007/enp2006_resultats_preliminaires/enp_2006_resultats_preliminaires.pdf. 2007.
- (23) Reilly J, Stewart S, Allardice G, Noone A, Robertson C, Walker A et al. NHS Scotland National HAI Prevalence Survey. Final Report 2007. Health Protection Scotland. <http://www.documents.hps.scot.nhs.uk/hai/sshaip/publications/national-prevalence-study/report/full-report.pdf>, 1-240. 2007.
- (24) PREZIES. PREZIES landelijk surveillance netwerk ziekenhuisinfecties. Resultaten prevalentiestudie maart 2007. <http://www.prezies.nl/prev/index.html>. 20-12-2007.
- (25) Haley RW, Culver DH, White JW, Morgan WM, Emori TG. The nationwide nosocomial infection rate. A new need for vital statistics. *Am J Epidemiol* 1985; 121(2):159-167.
- (26) Emori TG, Gaynes RP. An overview of nosocomial infections, including the role of the microbiology laboratory. *Clin Microbiol Rev* 1993; 6(4):428-442.
- (27) Martone WJ, Jarvis WR, Culver DH, Haley RW. Incidence and nature of endemic and epidemic nosocomial infections. In: Bennett JV, Brachman PS, editors. *Hospital Infections*, 3rd ed. Little, Brown and co. , Boston, 1992: 577-596.

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ANNEX 5: PATIENT SAFETY SYTEM CATEGORIZATION BY RAND

A. ‘Exemplary’ category

Among the twenty three countries studied, four Member States can be grouped as ‘exemplary’ countries in relation to patient safety.

Criteria:

The country in this rank has a ‘mature’ system for patient safety reporting and learning at national and local levels. But, the system may or may not include *patient* reporting;

The country has an established redress mechanism (e.g. a no-fault liability system, Tribunals of Inquiry and Compensation and/or litigation);

The country is very active in participating and/or leading EU-level and international-level initiatives to develop and use knowledge and evidence on patient safety (e.g. OECD patient safety indicator study, World Alliance on Patient Safety, High Level Working Group, SIMPATIE project, EU NetPaS);

The country has an institute dedicated to patient safety;

Some of these countries are reviewing and evaluating their Patient Safety systems for further improvements;

Some countries have already conducted their own country-specific studies of the extent of the problem of patient safety; *and*,

Nomination by other expert-respondents from other countries who confirm the exemplary nature of the countries in the Top Rank.

B. ‘Very good’ category

Three countries were categorised as ‘very good’, This group was a distinct category because the reporting and learning systems included patient reporting.

Criteria:

The country has a well-established and functioning reporting and learning system at national level for patient safety exists in the country AND patients can report to the system. But, the system may not be fully blame-free;

There is a redress mechanism;

The country may have a (new) institute dedicated to patient safety;

The country may be evaluating and/or implementing changes to the existing Patient Safety systems;

The country may have conducted its own study on the extent of the problem; *and*,

The country is actively participating in EU-level and/or international-level initiatives to develop and use knowledge and evidence on patient safety (e.g. OECD patient safety indicator study, World Alliance on Patient Safety, High Level Working Group, SIMPATIE project, EU NetPaS).

C. ‘Good’ category

The ‘good’ grouping was the largest one with 8 EU Member States included.

Criteria:

The country has a well-established and functioning reporting and learning system at national and local levels for patient safety exists in the country, but the system may not be fully blame-free and/or may be limited to some adverse events;

There is a redress mechanism;
 The country may have a (new) institute dedicated to patient safety;
 The country may be evaluating and/or implementing changes to the existing Patient Safety systems;
 The country may have conducted its own study on the extent of the problem; and,
 The country is actively participating in EU-level and/or international-level initiatives to develop and use knowledge and evidence on patient safety (e.g. OECD patient safety indicator study, World Alliance on Patient Safety, High Level Working Group, SIMPATIE project, EU NetPaS).

D. ‘Fair’ category

The ‘fair’ group included 5 countries

Criteria:

A reporting and learning system for patient safety exists in the country but may not be at the national level, or may not be fully developed at national level because it lacks the learning dimension or is not yet electronic (user-friendly);
 There may or may not be a redress mechanism in place and what is in place, is only court-based compensation;
 The country may have an institute for healthcare quality and safety but may not be dedicated only to patient safety; and,
 The country is actively participating in EU-level and/or international-level initiatives to develop and use knowledge and evidence on patient safety (e.g. OECD patient safety indicator study, World Alliance on Patient Safety, High Level Working Group, SIMPATIE project, EU NetPaS).

E. ‘Poor’ category

Three countries belonged to the ‘poor’ group

Criteria:

There is currently no national patient safety reporting and learning mechanism in the country, but there may be partial systems at local level;
 There is no redress mechanism that is fair to both patients and professionals in the country;
 As a minimum, the country is a member of the High Level Working Group and may also be active in developing and using knowledge and evidence at EU level through participation in, for example, World Alliance, OECD, SIMPATIE, IPSE, EU NetPaS etc;
 The country may have an institute for quality and safety in healthcare, but it is not dedicated to patient safety; and,
 Nomination by peers or self as being an example of a country having poor patient safety activities.

These criteria are summarised in the table below.

Taxonomy of selected EU countries working on Patient Safety Improvement Strategies

‘Objective’ criteria for country taxonomy	Star category				
	exemplary	very good	good	fair	poor
The country has a well-developed national reporting and learning system (RLS) in addition to local systems	✓	✓	✓	≈	✗
The country’s RLS is blame-free	✓	✗	✗	✗	✗
The country’s RLS includes both reporting and learning components	✓	✓	✓	✗	✗
The country’s RLS is not restricted to specific adverse events (i.e. includes the full range of incidents)	✓	✓	✗	✗	✗
Patients can participate in reporting to the country’s reporting and learning system	✗	✓	✗	✗	✗
The country has an established (<i>de jure</i>) redress system that includes more than going to court (e.g. a no-fault liability system, Tribunals of Inquiry and Compensation and/or litigation/tort-based)	✓	✓†	✓	✗	✗
The country is active in initiatives to develop and use knowledge and evidence on patient safety. Examples include, but are not limited to: OECD patient safety indicator study, World Alliance on Patient Safety, High Level Working Group, SIMPATIE project, EU NetPaS	✓	✓	✓	✓	≈
The country is active in leading initiatives to develop and use knowledge and evidence at either EU or international levels	✓	✓	✗	✗	✗
The country has an established national institute, or other Competent Authority and it is dedicated to patient safety	✓	✓	≈	≈	≈
There is currently, or there has been, an evaluation of the existing patient safety system(s) of the country in question for further improvements	≈	≈	≈	✗	✗
The scope of the national problem of patient safety has been, or is currently being, empirically investigated to some degree (either at national or local level) in the country in question	≈	≈	≈	✗	✗

SOURCE: RAND Europe

LEGEND: ✓ (full fulfilment of criteria); ≈ (partial fulfilment, at least in progress or planned); ✗ (not fulfilled).

NOTE: † One country in this 4-star category did not fulfil this criteria at all (i.e. has only a de facto tort-based redress mechanism), but it was included among the other countries in this category because it fulfilled all other criteria and was therefore not deemed to warrant being placed in the lower category.

ANNEX 6: CALCULATION OF LABOUR PRODUCTIVITY⁵⁰

	Population (million)	Male (million)	Female (million)	Employed men (million)	Employed women (million)	Hours worked by men (million)	Hours worked by women (million)	GDP (€ million)	GDP per hour worked (€)
Austria	8,2	4,0	4,2	3,0	2,6			245.000	
Belgium	10,4	5,1	5,3	3,5	2,9			298.000	
Bulgaria	7,8	3,8	4,0	2,3	2,1			21.000	
Cyprus	0,7	0,3	0,4	0,2	0,2			13.000	
Czech Rep	10,2	5,0	5,2	3,7	2,9			98.000	
Denmark	5,4	2,7	2,7	2,2	1,9			208.000	
Estonia	1,3	0,6	0,7	0,4	0,4			11.000	
Finland	5,2	2,5	2,7	1,8	1,8			155.000	
France	60,6	29,4	31,2	20,2	18,0			1.710.000	
Germany	82,5	40,4	42,1	28,8	25,1			2.247.000	
Greece	11,1	5,5	5,6	4,1	2,6			181.000	
Hungary	10,1	4,8	5,3	3,0	2,7			88.000	
Ireland	4,1	2,0	2,1	1,5	1,2			160.000	
Italy	58,5	28,4	30,1	19,9	13,6			1.417.000	
Latvia	2,3	1,1	1,2	0,7	0,7			13.000	
Lithuania	3,4	1,6	1,8	1,1	1,1			21.000	
Luxembourg	0,5	0,2	0,3	0,1	0,2			29.000	
Malta	0,4	0,2	0,2	0,1	0,1			4.000	
Netherlands	16,3	8,1	8,2	6,5	5,4			502.000	
Poland	38,2	18,5	19,7	10,9	9,2			243.000	
Portugal	10,5	5,1	5,4	3,7	3,3			147.000	
Romania	21,7	10,6	11,1	6,8	5,7			79.000	
Slovakia	5,4	2,6	2,8	1,7	1,4			38.000	
Slovenia	2,0	1,0	1,0	0,7	0,6			27.000	
Spain	43,0	21,2	21,8	15,9	11,2			904.000	
Sweden	9,0	4,5	4,5	3,3	3,2			288.000	
UK	60,0	29,4	30,6	22,8	20,2			1.791.000	
EU27	488,8	238,6	250,2	168,9	140,3	306.418,4	217.605,3	10.938.000	20,9

⁵⁰ Eurostat (2005 data). Hours worked based on Eurostat data with: an EU average of 93% and 66% of employed men and women respectively working full-time, with an EU average of 40 and 20 hours respectively for a full-time job and a part-time job; an EU average of 5 weeks of holidays. Days off sick from work have not been taken into account.

ANNEX 7: CALCULATION OF INPATIENT DAY COST⁵¹

	Beds per 100,000 inhabitants								inhabitants		cost/bed	cost/bed/	
	1998	1999	2000	2001	2002	2003	2004	2005	(million)	#beds	/day	day corr	cost/day
Austria	723,9	878,4	698,7	853,6	845,8	835,7	776,5	770,9	8,20	63.213,80	319,00	319,00	20.165.202,20
Belgium	787,5	782,3	777,8	767,4	759,2	752,3	749,1	744,8	10,40	77.459,20	501,00	350,70	27.164.941,44
Bulgaria	838,1	747,7	739,3	699,2	646,6	626,7	611,6	593,3	7,80	46.277,40	38,00	54,29	2.512.201,71
Cyprus	412,5	408,8	416,9	404,2	438,2	431,1	421,0	380,0	0,70	2.660,00	255,00	255,00	678.300,00
Czech Rep	876,0	860,2	867,5	867,0	872,5	868,0	859,3	850,3	10,20	86.730,60	110,00	157,14	13.629.094,29
Denmark	449,5	434,4	425,1	417,7	412,8	398,0	389,8	380,0	5,40	20.517,30	773,00	541,10	11.101.911,03
Estonia	722,8	716,5	682,9	681,8	605,9	591,2	581,0	548,4	1,30	7.129,20	73,00	104,29	743.473,71
Finland	776,3	759,7	753,4	745,2	735,9	723,6	705,6	704,2	5,20	36.618,40	267,00	267,00	9.777.112,80
France	847,7	832,6	817,1	794,3	783,5	768,4	749,6	734,8	60,60	445.288,80	524,00	366,80	163.331.931,84
Germany	929,3	920,2	912,2	901,9	887,8	874,4	857,6	846,4	82,50	698.280,00	625,00	437,50	305.497.500,00
Greece	508,0	496,6	495,2	478,2	472,1	470,3	469,8	473,8	11,10	52.591,80	389,00	389,00	20.458.210,20
Hungary	831,1	836,8	839,1	784,8	783,8	782,5	782,0	786,2	10,10	79.406,20	41,00	58,57	4.650.934,57
Ireland	654,2	639,7	628,9	606,0	593,0	581,6	574,4	559,6	4,10	22.943,60	349,00	349,00	8.007.316,40
Italy	548,7	486,8	470,9	461,4	444,6	417,9	400,6	400,9	58,50	234.526,50	541,00	378,70	88.815.185,55
Latvia	922,2	885,2	855,1	809,5	773,4	779,3		766,4	2,30	17.627,20	51,00	72,86	1.284.267,43
Lithuania	961,5	938,0	923,2	869,4	892,8	866,1	840,8	814,7	3,40	27.699,80	42,00	60,00	1.661.988,00
Luxembourg	1055,1	712,5	657,1	651,7	644,3	638,2	631,8	625,4	0,50	3.127,17	761,00	532,70	1.665.841,68
Malta	562,8	547,1	544,2	759,8	745,8	750,3	755,2	743,7	0,40	2.974,80	217,00	217,00	645.531,60
Netherlands	512,3	505,7	492,1	464,7	459,1	440,5	438,2	437,2	16,30	71.263,60	400,00	400,00	28.505.440,00
Poland	744,0	735,1	718,7	717,5	709,9	644,7		652,2	38,20	249.140,40	91,00	130,00	32.388.252,00
Portugal	387,6	385,8	381,6	374,9	365,1	366,2	365,1	365,5	10,50	38.374,00	296,00	296,00	11.358.704,00
Romania	749,7	749,6	762,7	769,2	747,1	657,4	658,3	661,8	21,70	143.610,60	40,00	57,14	8.206.320,00
Slovakia	804,4	796,3	785,5	765,4	755,5	722,5	689,0	677,1	5,40	36.563,40	66,00	94,29	3.447.406,29
Slovenia	559,1	554,0	540,6	516,9	508,9	496,0	480,1	483,9	2,00	9.678,00	240,00	240,00	2.322.720,00
Spain	380,9	376,0	372,7	362,5	356,7	347,8	344,5	339,0	43,00	145.770,00	321,00	321,00	46.792.170,00
Sweden	380,4	373,8	358,5	349,0	338,1	327,1	316,2	305,2	9,00	27.468,00	610,00	427,00	11.728.836,00
UK	424,7	415,7	413,1	408,5	405,3	404,6	398,3	388,7	60,00	233.220,00	830,00	581,00	135.500.820,00
EU27	679,8	661,9	652,6	640,9	628,6	607,5	595,9	590,4	488,80	2.880.159,77		334,02	962.041.612,74

⁵¹ Hospital beds: Eurostat (2005 data); shaded cells for number of beds were calculated by linear regression. Cost/bed/day: based on healthcare unit cost for inpatient day for patients with cardiovascular disease (J. Leal et al. Eur. Heart J. (2006) 27, 1610-1619); shaded cells for cost/bed/day are estimates extrapolated from healthcare unit costs in countries with similar comparative price levels (comparative price levels: Eurostat 2005 data). The estimates on cost/bed/day for the individual Member States are debatable as they were collected for treating cardiovascular disease (usually very expensive treatment) and not HCAs for which figures for all Member States are not available; in addition, these costs may not reflect the situation for 2008. When checking these figures with hospital representatives from different Member States, it was felt that the figures for the 'old' Member States represented an overestimation and the figures for the new Member States represented an underestimation. Therefore, the following correction factors were applied: figures in bracket 0-200 euro were divided by 0.70; figures in 200-400 bracket were not adapted; figures in excess of 400 euros were multiplied by 0.70.