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Improving Patient Safety in the EU

Assessing the expected effects of three policy areas for future action

Annalijn Conklin, Anna-Marie Vilamovska, Han de Vries, Evi Hatzianandreu

Prepared for the European Commission
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Preface

This report presents our findings of a study in which we assess the expected effects of three policy areas for future action towards improving patient safety in the EU-27. Our study was informed by (1) existing European and international studies and evaluations on patient safety and related initiatives around the globe; and (2) primary qualitative data based on 32 interviews with members of the High Level Working Group on Patient Safety.

The main purpose of this report is to support the Commission’s Impact Assessment of the Patient Safety and Quality Legislative proposal for 2008. Following a brief introductory chapter, Chapter 2 defines the problem of patient safety in Europe and, where unknown, internationally. Chapter 3 describes our methodology for the Key Informant Interviews and presents the main results of the interview process. Chapter 4 provides our analysis of the expected impacts of three policy areas that the Commission would like to introduce to improve patient safety. This impact analysis chapter is divided into two sections according to our qualitative and quantitative data sources. Finally, Chapter 5 offers RAND Europe’s discussion before some concluding remarks in Chapter 6.

The report was prepared for, and funded by, the Health and Consumer Protection Directorate General of the European Commission (DG SANCO). It will allow patient safety experts, DG SANCO and other interested stakeholders to understand the extent to which it is possible to provide a clear and compelling account of the expected impacts of (1) establishing effective reporting and learning systems, (2) redress mechanisms, and (3) developing and using knowledge and evidence at EU level – three policy areas for future actions to improve patient safety.

This Impact Assessment has been peer-reviewed in accordance with RAND’s quality assurance standards (see http://www.rand.org/about/standards/) and therefore may be represented as a RAND Europe product. For more information about RAND Europe or this document, please contact the first author:

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This study assesses the extent of the current problem of poor patient safety in Europe as well as the expected impacts of proposed policy areas for future mitigating action.

DG SANCO identified three policy areas for future action to improve patient safety in Europe.

A variety of methods were used to assess possible impacts of the proposed policy areas for future action.

There is strong potential for great return on investment in improving patient safety, but the evidence base is under-developed.

Many stakeholders will benefit substantially in multiple ways from actions to improve patient safety, ranging from greater trust, better performance and lives saved.

There is considerable potential to improve patient safety in Europe and all actions areas are likely to reap the potential benefits of greater knowledge for improved patient safety.

The expected social and economic impacts of the three Action Areas are driven by common underlying factors: culture, priority-setting and media.

Acknowledgements

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Executive Summary

This study assesses the extent of the current problem of poor patient safety in Europe as well as the expected impacts of proposed policy areas for future mitigating action

There is converging evidence that patient safety incidents such as medical errors and adverse events in delivering healthcare are far more widespread and more harmful to patients than was previously realised, or acknowledged. In fact, it is now indisputable that patient safety is a “most important common issue in healthcare internationally”. The aim of this study is to support the Commission’s Impact assessment on the Patient Safety initiative by establishing the scope of the problem in Europe and also assessing the potential impacts of three policy areas for action.

In defining the problem of patient safety in Europe, we know that adverse events and near misses exist at high rates at a systemic and an individual level in healthcare systems in Europe as well as globally. The existing body of literature, increasingly with European contributions, reinforces the now well-known fact that patient safety is (1) a grave public health problem with significant and even deadly health consequences for affected patients, and their families; and (2) a high economic burden on limited health resources.

We also know that there are efforts being made in many countries in Europe and elsewhere to implement mitigating strategies to improve patient safety, such as national reporting and learning systems (RLS). However, we found that most of these are yet to be evaluated for their social and economic impacts on key stakeholder groups. Hence, our report provides an initial attempt to offer such evidence based on key informant interviews with experts on Patient Safety in Europe. We support our qualitative findings by discussing at the end of the report the growing body of literature on the positive impact of interventions like RFID (radio frequency identification) in healthcare, in terms of a demonstrated better quality of care including better patient safety.

DG SANCO identified three policy areas for future action to improve patient safety in Europe

The European Commission for Health and Consumer Protection wishes to improve patient safety in Europe and has proposed three policy areas for future action on this important issue. The policy areas for action (henceforth referred to as action areas)
considered include the following: (1) the establishment of “an effective reporting and learning mechanisms” (Action Area 1); (2) the establishment of “redress mechanisms” for fair compensation to injured patients (Action Area 2); and, (3) the “development and use of knowledge and evidence” (Action Area 3).

**A variety of methods were used to assess possible impacts of the proposed policy areas for future action**

This report reviews both the European and international literature; examines the scope of the problem as it applies to the EU-27; and assesses the potential health benefits that could be realised under the assumption that comprehensive patient safety actions will materialise and will also improve patient health outcomes. We employed both qualitative and quantitative methodologies. First, we conducted semi-structured in-depth interviews with members of the High Level Working Group on Patient Safety to complement the rather sparse relevant epidemiological data at the EU level. Second, we performed a grouping exercise to facilitate our understanding of the interview results and to obtain some overview measure of how countries can be classified in terms of their patient safety activities. The purpose of our development of a taxonomy (classification) was twofold: (1) to reveal the clustering of patient safety actions around certain characteristics that became apparent from our data (literature and interviews), and (2) to create a meaningful frame of reference for the subsequent quantitative analysis. Third, we extrapolated country-specific estimates on adverse events and their consequences, as reported in the literature, to the entire EU-27. Fourth and finally, we constructed scenarios to estimate the potential health benefits (i.e. safety events, deaths and disability avoided, and additional hospital days prevented) that could be expected if improvements in the proposed policy areas were made by the EU member states.

**There is strong potential for great return on investment in improving patient safety, but the evidence base is under-developed**

There was strong consensus among experts that action areas to improve patient safety have a strong potential for a great return on investment. In particular, the economic impact of effective reporting and learning systems was believed to be moderate to quite large in the short term but will save money in the long term from avoided costs of adverse events. The economic impact of redress mechanisms were unclear as they will depend on the type of mechanism in place and the threshold of severity established by a particular member state. Similarly, experts contested whether the economic impact of developing and using knowledge and evidence at the EU level will be positive or negative, and by how much.

The evidence base for the expected economic impacts of the three proposed policy areas is under-developed in Europe. Our interview respondents consistently noted the fact that no one in Europe has conducted a health economics (cost-effectiveness) study of any of the three proposed action areas for policy to improve patient safety. Our own review of the literature supports this expert consensus, as such evidence appears only to be available from international sources. It is clear that an empirical assessment of the economic impacts of
the proposed policy areas for future action, demonstrating the strong potential for a great return on investment, will require a longitudinal, cross-national study for future comparisons and learning.

**Many stakeholders will benefit substantially in multiple ways from actions to improve patient safety, ranging from greater trust, better performance and lives saved**

While the evidence base evaluating the economic impact of actions to improve patient safety is apparently under-developed in Europe, we found that, in some countries, there are both pilot and new studies beginning to investigate the social impact of the proposed action areas, such as reporting and learning systems. But, ultimately, any concrete social impacts arising from any of the three action areas will require developing future research and evaluation, particularly on the differences between and within the stakeholder groups we identified.

Nonetheless, our interview data suggests that there will be multiple benefits to patients, care providers and also healthcare systems from establishing effective reporting and learning systems. Benefits accrue to patients in the form of increased participation and empowerment (i.e. health literacy), honesty in the doctor–patient relationship, better managed expectations and lives saved. Benefits to care providers come from better culture and working environment, continuous knowledge exchange (education, awareness and skills) and accountability. Similarly, healthcare systems benefit from greater civic trust, better care provision and, consequently, avoided costs. The social impact of redress mechanisms is also significant: fair compensation undeniably benefits all injured patients; the benefit is primarily as moral compensation; fair redress mechanisms benefit health professionals through a greater sense of security (i.e. less fear) and a new blame-free culture that fosters transparency and trust; and, healthcare systems benefit from fair redress mechanisms in terms of fulfilling moral and legal obligations to citizens through greater safety vigilance and possibly cost savings. Finally, the social impact of Action Area 3 seemed overwhelmingly positive, but most directly for health professionals.

**There is considerable potential to improve patient safety in Europe and all actions areas are likely to reap the potential benefits of greater knowledge for improved patient safety**

Our study clearly revealed the need to know more about the effectiveness and impact of reporting and learning systems, redress mechanisms and the use and the development of knowledge and evidence at the EU level. We also found that in gaining such knowledge, particularly from an evaluation perspective, there is indeed a large potential for improvements in patient safety processes and, more critically, outcomes. Our exploratory quantitative analysis of health benefits showed there is great potential for below-average EU countries to improve to the level of above-average countries, revealing a large reduction in adverse events, associated readmissions and additional lengths-of-stay. For example, by extrapolating the additional length of stay due to adverse events found in the Spanish
national study of hospitals to the EU-27, we found that EU citizens may spend an additional 140,626 person-years in hospital as a result of adverse events, of which 50,845 person-years could have been prevented.

The expected social and economic impacts of the three Action Areas are driven by common underlying factors: culture, priority-setting and media

Our interview data revealed a number of emerging themes common to the experts’ assessments of all three Action Areas. First, the majority of respondents remarked on the issue of changing culture: culture change was described as being not only a pre-condition for future action to improve patient safety, but also an integral component of patient safety action as well as being a possible policy outcome. We identified six different kinds of culture implicated in actions to improve patient safety. Second, one of the underlying factors driving the expected impacts of the different Action Areas, as described by the expert respondents, was the timing of patient safety on the political agenda in terms of priority-setting. Our analysis revealed that while patient safety is now a high priority on the political agenda of a majority of European countries, but the political nature of the issue can present barriers to assessing action impacts. Finally, the third underlying factor driving the expected impacts of the proposed Action Areas was the media: the social and economic impacts of actions will positive if the media is a strong supporter of the proposed Action Areas (e.g. publicising mitigation strategies and other actions to improve patient safety), or the impacts will be negative if the media is an adversary to proposed actions (e.g. publicising high numbers of death and disability from adverse events).
Acknowledgements

Our sincere thanks and appreciation go to all the 32 participants in our study who gave their unpaid time (usually an hour) to respond to our Key Informant Interview questions. We are grateful to each of these Patient Safety Experts for the information they provided, which has greatly contributed to a richer description and understanding of the economic and social impacts we sought to analyse for the EU Commission.
## Abbreviations and Short Glossary of Terms

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>adverse event (AE)</td>
<td>An incident that results in harm to a patient which implies impairment of structure or function of the body and/or any deleterious effect arising therefrom</td>
</tr>
<tr>
<td>adverse drug events (ADE)</td>
<td>Injuries to patients caused by errors in administering drugs</td>
</tr>
<tr>
<td>adverse reaction</td>
<td>A term commonly used in relation to medication incidents, and is defined as ‘unexpected harm arising from a justified action where the correct process was followed for the context in which the event occurred’. An example would be unexpectedly getting neutropenia when that particular drug is not known to have this effect</td>
</tr>
<tr>
<td>AHRQ</td>
<td>Agency for Healthcare Research and Quality (in the US Department of Health and Human Services)</td>
</tr>
<tr>
<td>AIMS</td>
<td>Advanced Incident Management System</td>
</tr>
<tr>
<td>CIRS</td>
<td>Critical Incident Reporting System</td>
</tr>
<tr>
<td>error</td>
<td>Unintentional acts that constitute a failure to carry out a planned action as intended, or the application of an incorrect plan, and may manifest by doing the wrong thing (error of commission), or by failing to do the right thing (error of omission), at either the planning or execution phase. Even if an incident does not actually occur, errors increase the risk that an incident will occur</td>
</tr>
<tr>
<td>event</td>
<td>Something that happens to or involves a patient</td>
</tr>
<tr>
<td>EUNet PaS</td>
<td>European Union Network on Patient Safety</td>
</tr>
<tr>
<td>FTE</td>
<td>Full-time employee</td>
</tr>
<tr>
<td>HAI</td>
<td>Hospital acquired infection, or nosocomial-related infection (e.g. pneumonia, MRSA, C. difficile, etc)</td>
</tr>
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1 WHO (2007c).
<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Definition</th>
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<tbody>
<tr>
<td>HCAI</td>
<td>Healthcare-associated infection</td>
</tr>
<tr>
<td>HCUP</td>
<td>Healthcare Cost &amp; Utilization Project</td>
</tr>
<tr>
<td>HIQA</td>
<td>Health Information and Quality Authority</td>
</tr>
<tr>
<td>ICD-10</td>
<td>International Classification of Disease, Tenth Revision</td>
</tr>
<tr>
<td>ICD-9-CM</td>
<td>International Classification of Diseases, Ninth Revision, Clinical Modification</td>
</tr>
<tr>
<td>ICSP</td>
<td>International Classification for Patient Safety</td>
</tr>
<tr>
<td>ICT</td>
<td>Information and communication technology</td>
</tr>
<tr>
<td>ICU</td>
<td>Intensive care unit</td>
</tr>
<tr>
<td>incident</td>
<td>An event or circumstance which could have resulted (potential), or did result (actual), in <em>unnecessary</em> harm to a patient. Incidents may arise from both unintended and intended acts</td>
</tr>
<tr>
<td>incident type</td>
<td>A descriptive term for a category made up of incidents of a common nature grouped because of shared, agreed features; for example, medication incident type, healthcare-associated infections, documentation problems, problems with a clinical administration process, etc</td>
</tr>
<tr>
<td>IOM</td>
<td>Institute of Medicine</td>
</tr>
<tr>
<td>IPSE</td>
<td>Improving Patient Safety in Europe project</td>
</tr>
<tr>
<td>JCAHO</td>
<td>Joint Commission on Accreditation of Healthcare Organizations</td>
</tr>
<tr>
<td>MARQuIS</td>
<td>Methods of Assessing Response to Quality Improvement Strategies project</td>
</tr>
<tr>
<td>MoH</td>
<td>Ministry of Health</td>
</tr>
<tr>
<td>near miss</td>
<td>An incident that did not cause harm (i.e. a close call)</td>
</tr>
<tr>
<td>NHS</td>
<td>National Health Service</td>
</tr>
<tr>
<td>NRLS</td>
<td>UK’s National Reporting and Learning System</td>
</tr>
<tr>
<td>ONIAM</td>
<td>Office National d’Indemnisation des Accidents Médicaux</td>
</tr>
<tr>
<td>patient</td>
<td>A person who is a recipient of healthcare (i.e. services received by individuals or communities to promote, maintain, monitor or restore health)</td>
</tr>
<tr>
<td>patient safety (PS)</td>
<td>Freedom for a patient from a hazard – a circumstance, agent or action that can lead to or increase risk that an incident will occur</td>
</tr>
</tbody>
</table>
preventable

A preventable incident has been defined as ‘being accepted by the community as avoidable in the particular set of circumstances’

QAHCS

Quality in Australian Healthcare Study

RLS

Reporting and learning system

safety

Freedom for a patient from unnecessary harm or potential harm associated with healthcare that can lead to or increase risk

sentinel event²

An unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof

side effect

A known effect, other than that primarily intended, relating to the pharmacological properties of a medication. For example, a side effect would be when nausea, pruritis or urinary retention are encountered when morphine has been given to alleviate pain

system failure

A fault, breakdown or dysfunction that occurs within an organisation’s operational methods, processes or infrastructure. Factors contributing to system failure can be latent (hidden or apt to elude notice) or apparent, and can be related to the system, the organisation or a patient

unnecessary

Errors, violations, patient abuse and deliberately unsafe acts occur in healthcare and are unnecessary incidents, whereas certain forms of harm, such as an incision for a laparotomy, are necessary. The former are incidents but the latter are not regarded as such

WSPEs

Wrong side(site), wrong procedure and wrong patient adverse events, a term used to describe an event-specific type of adverse event

There is converging evidence that medical errors and adverse events in delivering healthcare are far more widespread and more harmful to patients than was previously realised, or acknowledged. In fact, it is now indisputable that patient safety is a “most important common issue in healthcare internationally”. This well acknowledged fact was once highly contested – most notably when Ivan Ilich first introduced the concept of ‘iatrogenic harm’ in the 1970’s in his classical work, Limits to Medicine.

Experience in the US demonstrates that “lapses in patient safety are a major healthcare quality problem and a leading cause of morbidity and mortality”. According to Patient Safety International, the new International Classification for Patient Safety (ICPS) from the World Health Organization (WHO) is an important step in addressing this serious public health problem. In addition, the Advanced Incident Management System (AIMS) of Patient Safety International is another promising step in the direction of addressing the crucial and contemporary challenge of improving patient safety. The promise of AIMS lies in the use of this tool to facilitate benchmarking to improve patient safety because (1) it includes a standardised classification recognised by WHO and the Institute of Medicine (IOM) and (2) it “collects and aggregates de-identified incident data into local, state, national and international databases”.

The WHO World Alliance for Patient Safety defines patient safety as “freedom for a patient from unnecessary harm or potential harm associated with healthcare”, whereby “healthcare-associated harm is harm arising from or associated with plans or actions taken during the provision of healthcare, rather than an underlying disease or injury”. In this framework, the term “patient safety event” is traditionally used to denote the existence of adverse and near miss events that negatively affect both patients (through either increased morbidity or mortality) and healthcare systems (through increased costs used to rectify inflicted harm, and reduced effectiveness of care).

\(^5\) NAO (2005).
\(^4\) Michaels (2007).
\(^8\) WHO (2007c).
Unfortunately, detailed, valid and reliable data on the number of adverse medical events, their causes and consequences are hardly reported at the individual member state level throughout the EU. If available at all, such data typically comes from ad hoc research studies, often limited to a single country, making EU-wide comparisons and extrapolations vulnerable to (inevitable) assumptions. Still, we have attempted to augment our qualitative findings in this Impact Assessment with some quantitative analysis, using the limited amount of data that is available to the fullest extent possible. In doing so, we have carefully stated our assumptions and the limitations of this approach. In addition, we have supplemented the patchy European epidemiology with international data from the US, Australia and elsewhere. We note that some of our data limitations are also related to publication bias insofar as we examined mostly English, and some French, language studies and reviews.

By putting all these different data types and sources together, we constructed a kaleidoscope of information in order to offer a better understanding of the magnitude of the problem of patient safety in Europe. Furthermore, we are sufficiently confident that the US experience, for example, can be repeated in the EU as Charles Vincent in the UK has already succeeded in doing so with similar results. Furthermore, we know from our interview data that other European countries, particularly the Scandinavian member states, are also currently replicating the same studies in their own countries, providing preliminary findings that are consistent with the well-known international experience.

Finally, we hope that one outcome of our mixed methods will be an increased awareness of how important it is to have reliable and detailed data on patient safety, not only at the local level but throughout the EU. In support of expert opinion, we consider such increased awareness to perhaps be a justification in itself for EU-level action to address this grave public health problem and improve patient safety.
CHAPTER 2  
Policy Areas for Action to Improve Patient Safety in Europe

The Commission wishes to introduce three ‘policy areas for action’ which are different from ‘policy options’ in that the former are much broader.9 The three policy areas for action (to be referred to henceforth as Action Areas) are the following: (1) ‘establish effective reporting and learning mechanisms’ (2) establish ‘redress mechanisms’ for fair compensation to injured patients; and (3) ‘develop and use knowledge and evidence’. The policy areas for action are described in more detail below.

2.1 Action Area 1: Establish effective reporting and learning systems

The purpose of this action area is to establish effective reporting and learning systems (RLS) on adverse events in healthcare in order to establish the extent of error and adverse events; monitor trends; develop effective interventions; observe changes following the introduction of those interventions; and share learning on which interventions are effective (as well as on those that are not). This action needs to work alongside and complement other adverse incident reporting systems, such as the pharmacovigilance and medical device vigilance systems, already in operation in the areas of medication and medical device safety respectively. Periodic analysis of the effectiveness and appropriateness of these various systems should take place.

The action will also establish a transparent, open and honest patient safety culture in healthcare by clarifying legal issues around health professionals’ liability and by creating an environment where it is easy and safe to report and learn from mistakes through blame-free reporting. This type of reporting needs to be differentiated from member states’ disciplinary systems and procedures for healthcare professionals; for example, in cases of negligence. Patient safety reporting systems themselves should not be linked to punitive measures, including the withholding of remuneration from healthcare.

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9 A key element of European policy towards improving patient safety has been the establishment of a Working Group on Patient Safety, in line with recommendations from the WHO World Alliance for Patient Safety, the first and second Global Patient Safety Challenge, and the 2005 Luxembourg Declaration on Patient Safety.
2.2 **Action Area 2: Redress mechanisms**

The driving question behind this action area is: ‘If something goes wrong, can it be put right?’ That is, the purpose of this action is to establish fair compensation and/or redress systems as appropriate for patients (or families of victims) affected by healthcare-related harm, including those from other member states. Such systems should also be fair to healthcare professionals and provide value-for-money for healthcare funders. Furthermore, the action involves informing patients and their families how those systems can be accessed by them; monitoring the effectiveness and efficiency of those systems; and aligning national systems for dealing with healthcare-related negligence with the broader patient safety and risk approach.

2.3 **Action Area 3: Developing and using knowledge and evidence**

This area comprises the following actions.

- Working towards common definitions and terminology at the European Union level; and contributing to the development of, and taking into account, international standardisation activities on risk taxonomy, such as the *International Classification for Patient Safety* being developed by WHO and the Council of Europe’s (CoE) work in this area.

- Mapping and reviewing national patient safety policies and initiatives to provide a basis for mutual sharing of information and knowledge.

- Reviewing and comparing existing indicator systems according to their feasibility and relevance to safer healthcare.

- Developing and considering a minimum set of common core and valid indicators at a European level; and building on the recommendations of work undertaken in this area by international organisations such as the OECD (Organization for Economic Co-operation and Development).

- Developing and promoting a research agenda on patient safety, in particular at the European level under the Health Theme of the 7th Framework Programme for Research, including in the very important areas of effective interventions and assessments of the economic impact of unsafe services on healthcare systems and member states’ economies more generally.

- Reviewing the results of relevant research projects at the European level and integrating their findings as a basis for refining the research agenda.

- Promoting the use of research and other evidence-gathering to develop efficient interventions and communicate solutions across the EU.

- Pooling data, information and expertise on patient safety and wider quality strategies to share good practice, through various mechanisms, including electronic forums, conferences and seminars, and the sharing of patient safety alerts.

- Using information and communications technology (ICT) to support information collection, processing and sharing, in order to support the integration of services and continuity of care.
• Encouraging investment in design for patient safety, particularly in the pharmaceutical and medical devices sectors, including measures to address the problem of look-alike and sound-alike medicines.
The objective of this chapter is to delineate the epidemiology and main implications of patient safety issues across the EU-27 member states, and internationally. The chapter begins with an overview of the framework within which the problem of patient safety unfolds, and the main drivers behind it (Section 3.1). Section 3.2 looks into the stakeholders and key actors involved in any patient safety improving actions, and their potential stakes in such activities. The epidemiology and implications of patient safety problems, both in the inpatient and outpatient settings, as described in the literature, are presented in Section 3.3. Available data on effective patient safety measures is also presented and a brief comparison of other public-health risks and initiatives is discussed.

3.1 Problem framing and drivers

During the past 40 years, the complexity of healthcare services has been increasing, both in terms of models of care, treatment regimens, technological advances and care organisation and financing. This complexity has lead to rising time pressures on healthcare providers (see Figure 3.1 below); with unclear and potentially detrimental effects on the effectiveness of the care they provide.\(^\text{10}\) It has also lead to rising fiscal pressures on member state healthcare systems, which are further aggravated by a variety of factors: Europe’s changing demographic profile; the increased longevity and inverted age pyramid, leading to more chronically ill patients; rising standards of care; and finite healthcare resources. Finally, these high demands on systems and providers have triggered policy initiatives aimed at improving care quality, effectiveness, accessibility and affordability. However, as these initiatives are developed and implemented on different schedules, and occasionally in a piecemeal way, they can potentially further strain both providers and the systems within which they operate.

In this context of dynamic interaction between providers, patients and policy initiatives, “system failures” and medical errors occur. As several studies have shown,\(^\text{11}\) one of the main manifestations of system failures is the unacceptably high level of preventable adverse patient safety incidents documented in healthcare systems today\(^\text{12}\) – events lying above and

\(^{10}\) Weingart (2000).

\(^{11}\) Leape (1997); IOM (2000); Reason (2000).

\(^{12}\) Bates et al. (1995).
beyond the inherent margin of acceptable error/side effects that are deemed unavoidable by providers when best practice care is taken. The distribution, prevalence and concrete costs of adverse patient safety events across Europe are discussed in Section 3.3.

The European, as well as international experiences, of advanced patient safety monitoring, learning and redress systems suggest that the existence of well-aligned and systematic efforts to monitor and learn from adverse, near miss and sentinel events can help minimise the number and severity of preventable patient safety incidents. It can also positively affect the broader objective of achieving a wider paradigm shift in healthcare provision culture and patient involvement, which the separate policy interventions mentioned above strive to support. This paradigm shift is conceptualised to bear directly on the effectiveness of care and overall system performance.13

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**Figure 3.1 Patient safety problem tree**

The careful implementation of patient safety policies in tandem with other ongoing quality, effectiveness and cost initiatives, holds the potential to strengthen each of the policies in question too, due to their interlinked and nested nature. Yet, systems and humans which lack awareness of the adverse events taking place within, or by them, do not invest in analysing such incidents. Moreover, healthcare systems which do not facilitate the sharing of clinicians’ knowledge about the nature of patient safety incidents and their solutions, face the real risk of not making healthcare safer.

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This risk is expected to become particularly problematic as the movement of patients across providers and systems within Europe increases. Factors underlying the expected rise in cross-border healthcare include increased mobility of Europe’s populations, an ageing population and/or the increasing complexity of care provision. In addition, the emerging tendency for healthcare providers to also move within and across national healthcare systems in Europe further complicates and potentially aggravates the status quo, especially if the current discrepancy in patient safety standards across Europe persists.

3.2 Stakeholders and key actors

Two key stakeholders in the problem of patient safety can be easily identified: patients and healthcare providers. There are also a multitude of actors at the international, European and national levels who are involved either directly or indirectly, or both, in the patient safety movement. The roles and implications for the two main stakeholders, to the extent known, are discussed below.

As outlined above, sub-optimal patient safety is viewed as a systemic and a human-based problem, and to a lesser degree related to individual negligence and intentional harm. In this context, actions taken to improve patient safety either at the EU or member state level should be viewed as empowering, directly, both patients and healthcare providers. Patients will benefit from safer, more efficient care (achieved primarily via monitoring and learning systems), and increased participation in their medical treatment (via the pro-patient cultural shift and better health literacy in care provision – a component of the patient safety improvement process). Healthcare providers will gain the ability to learn and prevent near miss and adverse events (again utilising the monitoring and learning systems), and hence to improve the quality of the care they provide to their patients, with the potential added benefit of greater workplace satisfaction and productivity.14

From the physician and other healthcare provider perspective, there are two key issues at stake in efforts to improve patient safety in Europe. First and foremost, physicians and nurses want to provide their patients with high quality healthcare, a professional motivation enshrined in the Hippocratic Oath. When healthcare systems are better designed to improve patient safety, this will impact on providers in terms of satisfaction in providing higher quality care. Moreover when blame-free RLSs are in place, along with no-fault liability mechanisms, practitioners can benefit from more open dialogue and discussion about the existence of adverse events in healthcare. Healthcare providers are often considered the “second victims” in adverse events among their patients as they, too, suffer, from the knowledge of having harmed their patient. In other words, improving patient safety will allow physicians and nurses to openly disclose adverse events and near misses during their care delivery. Transparency and openness are recognised as a benefit to this stakeholder group. A second issue at stake for healthcare provisions in improving patient safety relates to the recent ‘pay-for-performance’ movement in the US and the UK, which is based on quality indicators of which patient safety is the cornerstone. Thus, there

14 Wu (2000).
is a real, tangible moral and monetary incentive for this stakeholder group to improve patient safety as they will be monitored and held to account for such quality indicators.

Given that human resources form the largest single cost element in any health system (as much as 60-80% of total recurrent expenditure) and that health services have a considerable impact on a country’s economy (providing employment for about 10% of the workforce in Europe), the authors emphasise the importance of policy actions to be taken to improve patient safety for this key stakeholder group and, by extension, the health system more broadly. To demonstrate the fact that the healthcare workforce in the European Union is a key stakeholder in policy actions to improve patient safety in the region, we present the figures for the European Union from a 2007 WHO document on *Health Workforce Policies in the European Region* (Table 3.1). As the WHO notes, there is considerable heterogeneity in the geographical distribution and composition (skill mix) of health workers between and within countries in the European Region: for example, the ratio of nurses to doctors ranges from nearly 7.2 to 1 in Ireland and 0.7 to 1 in Italy and Greece. Nonetheless, the WHO estimates a total of over 16.6m workers in healthcare, an average of 18.9 per 1,000 population. Of this total, health service providers account for 69% (11.5m), and health management and support workers represent 31% (5.1m) of the total health workforce.

The number of physicians, as calculated in the statistics published by the WHO, includes generalists and specialists. The average value, for the 29 considered countries (EU-27 + Norway and Switzerland), is 3.32 doctors per 1,000 inhabitants. This means that there are nine countries (Hungary, France, Germany, Austria, Portugal, the Czech Republic, Bulgaria, Switzerland and Lithuania) that have a value bigger than the average but smaller than 4 per 1,000 population. The country with the smallest number of physicians per 1,000 people is Romania, with a density of 1.0, while Belgium has the highest value: 4.49 physicians per 1,000 population. The data provided by WHO on nurse density includes professional nurses, auxiliary nurses, enrolled nurses and other nurses, such as dental and primary care nurses. As there are significant differences across member states, it is very difficult to analyse comparatively the nurse numbers: the average value is 8.22 nurses per 1,000 people, but there is a wide range of values from 3.75 (Bulgaria) to 15.2 (Ireland). Only eight countries have a density of more than 10 nurses per 1,000 inhabitants, and they are located, with the exception of Switzerland (10.75), in the northern part of the continent: Sweden (10.24), Denmark (10.36), the UK (12.2), Netherlands (13.73), Finland (14.33), Norway (14.84), and Ireland (15.2).

Table 3.1 Health workers per 100,000 population in the European Union, 2002

<table>
<thead>
<tr>
<th></th>
<th>Physicians</th>
<th>Nurses</th>
<th>Midwives</th>
<th>Pharmacists</th>
</tr>
</thead>
<tbody>
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<td>351.22</td>
<td>669.02</td>
<td>45.07</td>
<td>50.93</td>
</tr>
</tbody>
</table>

SOURCE: WHO Regional Committee for Europe [2007], EUR/RC57/9

15 WHO Regional Committee for Europe (2007).
16 Key Health Data (2007).
Although no evidence exists on the social and distributional implications of improving patient safety, it has been argued that the impact of this effort will be larger when patients can contribute to safety improvement initiatives. Moreover, the extent to which patients can contribute to safety improvement will depend on various factors including demographic characteristics, perceived vulnerability to harm, and confidence in challenging health professionals.17 These influencing factors will be distributed unevenly and will differ across societies in Europe: Populations that are more vulnerable will have a higher risk of exclusion from participation in actions to improve patient safety. Thus, it is likely that the impact of the proposed policy areas for action will vary across Europe.

Patient characteristics are indeed recognised as one of the seven major causes of adverse events in an explanatory framework proposed by Vincent et al. (1998). In it, contributory factors that place patients at an increased risk of suffering an adverse event include: complexity and seriousness of a medical condition, language and communication barriers, personality and social factors (e.g. distress, increased vulnerability, poverty).18 This UK framework is supported by 1998 data from New Zealand’s blame-free compensation systems: among the 0.4% adverse events identified by the New Zealand Quality of Healthcare Study, the odds of complaining was significantly lower for patients who were elderly, of Pacific ethnicity, or lived in the most deprived areas. The 2005 and 2007 Commonwealth Fund health surveys further suggest that patient groups that would particularly benefit from improved patient safety, both in hospitals and in outpatient facilities, are those suffering from chronic conditions or those who do not have a trusting and open relationship with their primary care provider. Thus, as a key stakeholder group, the largest impact of measures to improve patient safety will depend critically upon an adequate assessment of differences in patient characteristics.

In addition to the two key stakeholders discussed above (patients and care providers), we identified a number of other key actors, based on our interviews with Expert Working Group respondents and our review of the literature. Although the list is not exhaustive, the diversity of other relevant stakeholders should be considered when preparing and implementing patient safety initiatives in EU-27 member states. For example, the Department of Foreign Affairs (or International Relations) in some European countries (e.g. Slovak Republic) are involved in initiatives to improve patient safety (see generally, members of the High Level Working Group on Patient Safety), which is most relevant to member states in the context of cross-border healthcare with identified implications for patient safety in Europe.19

In alphabetical order, we offer the following list of stakeholders that are active in the area of patient safety so as to provide insight into the range and diversity of key players.

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18 Bismark et al. (2006); Michel et al. (2007).

19 Wismar et al. (2006).
**International-level actors:**

- International Alliance of Patients’ Organizations
- OECD

**EU-level actors:**

- Alliance of UK Health Regulators on Europe (AURE)
- European Information System on the Outcomes of Care for very-low-birth-weight infants
- EU 27 and future member states
- EUNetPaS (European Union network for patient safety) members
- High Level Group on Health Services and Medical Care Working Group on Patients Safety members
- Improving Patient Safety in Europe (IPSE) project
- Medical Technologies Industry in Europe
- SIMPATIE project members.

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20 Members of this Alliance include: Alzheimer’s Disease International; Association for Prevention, Help and Action Against Viral Hepatitis (Croatia); Association of Kidney Transplanted and Friends (Bulgaria); Cancer Advocacy Coalition of Canada; CHEN Patient Fertility Association (Israel); Consumers Advancing Patient Safety (USA); Diabetic Association of Adamawa, Maco Clinic (Nigeria); Foundation for Patients’ Safety (Poland); Global Alliance of Mental Illness Advocacy Networks – Europe; Iatrogenic Europe Uni-Alliance Foundation (Netherlands); International Thalassaemia Federation (Cyprus); Joyce Fertility Support Clinic (Uganda); National Concern for Healthcare Infections (NCHI-UK); Public Personalities Against Aids Trust (Zimbabwe); Serbian Association for Patients’ Protection; and the Spanish Heart Patients Association.

21 We included AURE among other EU-level stakeholders because, event though AURE is a network of 10 UK health and social care regulators, it explicitly exists to respond to European Union developments relevant to health and social care regulation and patient and public safety. Members of this group include: General Medical Council; General Dental Council; General Optical Council; General Osteopathic Council; General Chiropractic Council; Health Professions Council; Nursing and Midwifery Council; Royal Pharmaceutical Society of Great Britain; General Social Care Council; and the Pharmaceutical Society of Republic of Ireland.

22 Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, United Kingdom.

23 26 EU member states (without Belgium); Council of European Dentists; Council of Europe; CPME (Standing Committee of European Doctors); EFN (European Federation of Nurses Associations); European Commission (DG Health and Consumer Protection; DG Enterprise and Industry; DG Employment, Social Affairs and Equal Opportunities; DG Research); EPIs (European Patients Forum); HOPE (European Hospital and Healthcare Federation); PGEU (Pharmaceutical Group of the European Union); and WHO European Regional Office.

24 EU-27; Turkey; Croatia; European Union; and, Norway.

25 Council of Europe; Standing Committee of European Doctors; European Hospital and Healthcare Federation; European Society for Quality in Healthcare; Haut Autorité de Santé; Long-Term Medical Conditions Alliance; Action Against Medical Accidents; and the Dutch Institute for Healthcare Improvement, lead partner.
Member state level actors:

- Academic institutions and researchers
  - Departments/Institutes of Public Health, of Infectious diseases and/or of Healthcare Management
  - Schools/Faculties of Medicine
  - Schools/Faculties of Nursing
  - Centres of Excellence on Patient Safety and/or Quality Improvement
- Biomedical laboratories (organisations and personnel)
- Consumer protection advocacy groups or associations, etc
- Healthcare financing agencies
- Healthcare professionals (nurses, doctors, healthcare administrators and managers)
- Local health institutions/organisations (hospitals, primary care, ambulatory care, long-term care, e.g. nursing homes, and community care facilities)
- National (and Regional) Authorities for Health: Ministries of Health/ National Boards of Health/National Public Health Authorities (internal and external)
  - Department of Health in Ministries of Social Affairs
  - Healthcare inspectorates and/or other healthcare surveillance authorities
  - Central Administration, including Healthcare Quality and Safety Accreditation (qualification) Units
  - National Centres for Disease Surveillance and Infection Control (CDC), or Health Protection Agencies
  - National centres/authorities or departments for quality, health information and/or patient safety
  - Departments of Patient Safety Rights
  - Ministerial advisers in Legal Affairs
  - Departments of International Relations (Permanent Representatives to the EU and/or Delegates (liaison officers) for European and International Affairs)
- National patient safety agencies, foundations, or coalitions on patient safety
- Patients’ protection advocacy groups (or associations, etc)
- Patient rights and other human rights organisations
- Professional bodies in law and medicine (e.g. Society of Hospital Infections)
- Private Sector Players
  - eHealth and other ICT industries
  - Insurance companies
  - Law firms and advisers.

The broad scope of interests and outcomes targeted by the stakeholders listed above, along with their sheer number, suggests that although organising coordinated patient safety initiatives at the member state and EU levels can be testing, the benefits of such coordination (in terms of effort effectiveness) could be significant. At the present
moment, however, the potential effects of patient safety initiatives for each of the noted stakeholders have not been explored adequately – an objective that lies outside the scope of this project.

3.3 **Problem epidemiology, and health implications**

This section describes what is known about patient safety in Europe and internationally. The epidemiology, root causes and implications of adverse events are first explored in the **hospital setting**, with attention given first to overall and then event-specific incidents. Next, we explore the prevalence and implications of adverse care events in the **primary care setting**. A discussion of known benefits and costs of strategies to improve patient safety concludes the section.

3.3.1 **Patient safety in the hospital setting**

**A. Data issues and limitations**

Despite the fact that patient safety epidemiologic research dates back at least two decades, it is important to remember that all currently available data suffer from significant limitations, mainly in terms of reliability and quality of reporting. Furthermore, most of the knowledge about patient safety events today relates to adverse events, rather than near miss, sentinel or negligence events. We provide raw data from WHO to demonstrate some of these quantitative issues (Appendix A).

Three main factors underlie the fact that available data on adverse events remains fragmented, incomplete and generally does not lend itself to comparisons across studies. First, there are persistent philosophical differences among and between researchers and healthcare providers on the issues of what constitutes a patient safety incident, an adverse or a near miss event. Second, studies differ methodologically; and third, there is an absence of denominator data, meaning that accurate estimates of incidence cannot be determined without mandatory reporting of the true incidence of annual medical procedures that affect patient safety. Moreover, as better reporting systems will tend to report more accurately (hence, higher numbers of events) than less sophisticated or non-existent formal systems, comparison between and among countries is by no means appropriate.

For example, a recent WHO investigation into the international classification of patient safety events found and considered 16 definitions for “error” and 14 for “adverse event” before arriving at agreed definitions for these concepts. The study also documented an unacceptable level of confusion regarding the relationships between and among the classes of patient safety events; and between contributing factors, preventive factors, recovery factors and mitigating factors. The European SIMPATIE project – which had the

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26 Thomas et al. (2000b); Runciman et al. (2000).
27 WHO (2007a). The International Classification of Disease, Tenth Revision (ICD-10) codes; these are used both in national and international population health reporting.
28 SIMPATIE (2005).
objective of establishing a common set of vocabulary, indicators, and internal and external instruments for improvement of safety in healthcare – reported similar diversity across European healthcare systems.\textsuperscript{29}

Compounding the effects of this conceptual confusion, the reliability of collected data is also uncertain insofar as under-reporting is generally considered substantial. Moreover, the quality of reporting is also considered unsatisfactory, with better systems more prone to report a higher frequency and different typology of adverse events. These concerns apply to both the aggregate and per-index data on adverse events in the hospital setting discussed below. The results are likely to be misleading since countries with more advanced systems may appear to have a higher incidence and burden of adverse events simply because they measure and report them.

These data issues and limitations adversely affect the scope and depth of empirical analysis of the types, causes and impacts of adverse (including near miss) events. \textbf{They also outline the vast gains that can be achieved in all of the areas listed, if uniform agreement and implementation of data collection strategies are achieved in Europe.}

In this imperfect data landscape, two classes of data can be outlined: first, cross-national studies which typically do not suffer from methodological discrepancies across locations but are affected by under-reporting and the denominator problem outlined above (examples include the OECD Health Data, and the Commonwealth Fund Health System surveys); and, second, single-country studies which are either nationally representative (by methodology) or not. We draw upon both data sources to provide the best possible comprehensive picture of the problem.

\textit{Existing OECD data on patient safety indices}

Table 3.2 below presents existing OECD data on mortality due to adverse care and drug events, as well as estimates of their cost in years lost per 100,000 citizens (the scale at which OECD data is presented in addition to total deaths per country).\textsuperscript{30} As emphasised above, the main drawback of these figures is that they are hard to interpret, beyond noting the under-reporting of the prevalence of the problem. Moreover, they only capture the mortality due to adverse patient safety events, omitting the far more prevalent morbidity and near miss cases which comprise the bulk of patient safety events. Nevertheless, the data presented in Table 3.2 is very valuable for two reasons: (1) it suggests that such events occurred in almost all member states that report to the WHO, and (2) it shows us actually how little we know about the burden and cost of inadequate patient safety.

\textsuperscript{29} Addressing these discrepancies became one of the main objectives of the IPSE project (funded by DG SANCO).

\textsuperscript{30} The OECD data on mortality due to adverse care events, and that due to adverse drug events, are additive measures based on the ICD-10 indexes.
Table 3.2 2003 Prevalence and burden of adverse event mortality, OECD data

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<td>Deaths per 100,000</td>
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<tr>
<td><strong>International</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>USA</td>
<td>2,460</td>
<td>0.7</td>
<td>6</td>
<td>317</td>
<td>0.1</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Australia</td>
<td>176</td>
<td>0.7</td>
<td>2</td>
<td>47</td>
<td>0.2</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>New Zealand</td>
<td>8</td>
<td>0.2</td>
<td>4</td>
<td>5</td>
<td>0.1</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Canada</td>
<td>197</td>
<td>0.5</td>
<td>4</td>
<td>22</td>
<td>0.1</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Japan</td>
<td>424</td>
<td>0.2</td>
<td>3</td>
<td>76</td>
<td>0.0</td>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>
As Table 3.2 indicates, adverse care events in 2003 resulted in at most one and at least zero deaths per 100,000 people, which equalled between 16 and zero potential years lost per 100,000 people annually. Similarly, adverse drug events resulted in at most 0.9 and at least zero deaths per 100,000 citizens, equalling between 3 and no potential years lost per 100,000 annually. Since 2003 is the latest year most countries submitted data, we treated this as base year. For some countries, more recent OECD data is also available, but it was felt that allowing for more than 3 years of lag would affect the comparability of information. The 0.0 figure means that, given the reported rate of adverse events, no single person per 100,000 died. This figure is likely to reflect that fact that nothing is being reported, as many RLSs in Europe are very new or non-existent, and compliance is very difficult to measure. International evidence and expert consensus clearly demonstrate that it is not possible to have zero patient safety events as there are always some events (e.g. side effects) that occur in healthcare provision. Some of these events are not possible to avoid as they are statistically expected (i.e. random error happens everywhere, especially with medication and other clinical procedures with side effects or complications). In a recent French national study, hospital staff expected a large proportion (41%) of adverse events due to the patients’ disease(s) itself, and which could have occurred in the absence of the related medical management.31

B. Hospital setting overview
The inpatient rate of adverse events has been documented to vary between 7.5% and 16.6%. Figure 3.2 gives an overview of these global estimates. In brief, these levels of adverse events has been shown to result in deaths among hospitalised patients, ranging from a few thousand (2,181) to a hundred thousand annually (100,000). Most extensive evidence on adverse event mortality, as well as the implications and root causes of adverse events, come from the US, Australia and New Zealand. First, however, we will present the limited European data available from the UK, Spain and France.

31 Michel et al. (2007).
Figure 3.2 Patient safety is a global problem

European evidence

The adult patient population
Studies from the UK (4), Spain (1) and France (1) provide the bulk of current evidence in Europe on inpatient 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 type. Spain’s study also gives the scope of the problem, proportion of incident types by severity, root causes and the consequences in extended hospital stays. The French study also shows the universality of the problem of patient safety and the root causes. We discuss each study, in turn, in more detail below.

In the UK, a seminal Department of Health 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 (not all of which are preventable). Since the report’s publication, Vincent et al. have published a pilot study of adverse events in two acute care hospitals in London using methods similar to those used in the Australian and US studies.32 The researchers found that 10.8% of patients in these hospitals experienced an adverse event during their hospital stays, with an overall rate of 11.7% when multiple adverse events were included. About half of these events were judged to be preventable with ordinary standards of care. A third of inpatient adverse events led to moderate or greater disability or death. The authors state that these results suggest that adverse events are a serious source of harm to patients and a large drain on NHS resources: while some events are major, many others are frequent, minor events that go unnoticed in routine clinical care but together have large economic consequences.

32 Vincent et al. (2001).
More specific data analysis of the UK study showed that less than 20% of preventable adverse events were directly related to surgical operations or invasive procedures and less than 10% were related to misdiagnoses. Fifty-three per cent of preventable adverse events occurred in general ward care (including initial assessment and the use of drugs and intravenous fluids) and 18% in care at the time of discharge. Vincent et al. (2001) suggest that probable contributory factors in these errors included dependence on diagnoses made by in-experienced clinicians, poor records, poor communication between professional caregivers, inadequate input by consultants into day-to-day care, and lack of detailed assessment of patients before discharge.

A third and more recent source of prevalence data comes from the UK National Audit Office. In 2003-04, roughly 885,832 adverse and near miss events occurred in 256 NHS acute, ambulance and mental health trusts (96% of the NHS); and, in 2004-5, there were 974,000 adverse and near miss events. More specifically, an average of 1,216 events per 1,000 staff occurred in acute settings; 114 in ambulances; and 1,610 in mental health trusts. In a repeat survey, 169 trusts provided data on the number of deaths resulting from patient safety incidents and indicated that there were at least 2,181 deaths but possibly as many as 34,000 deaths in 2004-05 – the wide range of figures takes into account the existing significant under-reporting of deaths and serious incidents, which affects 22% of incidents on average. Among the reported adverse and near miss events, the most common incidents were patient injury from slips, trips and falls, followed by medication errors, equipment-related incidents, record documentation errors and communication failures. The social impact of poor patient safety is clearly high but there is also a large economic impact: the cost of settled clinical negligence claims in 2003-04 was £423m, with provisions for outstanding clinical negligence claims in excess of £2 billion.

The fourth and most recent data collection and analysis of incidents in the UK’s National Reporting and Learning System (NRLS) can be found in quarterly summary reports by the UK’s National Patient Safety Agency, which feeds the information back to the NHS Trusts and other interested parties. The latest report covers the period of October to December 2007 with 264,706 incident reports submitted. Among the 427 NHS organisations in England and Wales, 89% reported at least one patient safety incident and 43% reported at least one per month. In the time period of October 2006 to September 2007, an overwhelming majority of reported patient safety incidents to the UK’s NRLS occurred in acute trusts/general hospitals (73%). The second most common care setting for reported incidents was mental health services (14%, or 114,295 reports). Patient accidents were consistently the most commonly reported incident type in care settings taking inpatients, ranging from 34% in acute/general hospitals to 51% in community services, including community hospitals. Following patient accidents, the next most commonly reported incident types were treatment/procedure and medication (both 9%).

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33 NAO (2005).
34 Taylor (2006).
35 NAO (2005).
More specifically, in mental health and learning disability services, the pattern of incident types differed compared to other care settings in this time period, although patient accidents still accounted for the largest proportion of incidents (35%). Interestingly, 10% of incidents were categorised as access / admission / transfer / discharge, whereas medication accounted for 5% of all incidents. The three main issues for patient safety that focus on mental health are: absconding and missing persons; sexual safety; and ligature points.

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)\(^\text{37}\), adverse events among all hospital patients in Spain in 2005 was 9.3% (95% CI: 8.6%-10.1%)\(^\text{38}\) and 42.8% of these were deemed preventable. More specifically, the incidence of patients with adverse events directly related to their hospital care (excluding those from primary care, outpatient treatment and those caused at another hospital) was 8.4% (473/5,624) with a tight 95% confidence interval (CI) of 7.7% to 9.1%. A total of 17.7% of these patients had more than one adverse event related to their hospital care, and for 22.2% of them, the adverse event was a cause for re-hospitalisation. Table 3.3 below shows adverse event incidence by hospital size and hospital unit type.

| Table 3.3 Adverse event incidence rate by hospital size and unit type |
|-------------------------------|----------------|---------------|
| **Layers**                     | **Patients**  | **Incidence rate** | **95% CI**     |
| **Hospital size:**             |               |                |                |
| Large hospitals                | 221           | 9.7%           | 8.45-10.9      |
| Medium-sized hospitals         | 206           | 7.1%           | 6.20-8.08      |
| Small hospitals                | 46            | 10.2%          | 7.41-13.0      |
| **Unit type:**                 |               |                |                |
| Medical units                  | 217           | 8.9%           | 7.73-10.0      |
| Surgical units                 | 256           | 8.1%           | 7.12-9.01      |

**SOURCE:** ENEAS (2006)

The Spanish study evaluated the relationship between patient characteristics and the risk of adverse events. The odds of suffering a hospital-related adverse event in Spain is 1.6 times for patients with intrinsic risk factors – invasive devices, such as peripheral venous catheter or urinary drainage system. Moreover, patients who are both over the age of 65 and have these intrinsic risk factors were at 2.5 times greater risk than those under age 65 without these factors.

\(^{\text{37}}\) 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 for compiling all of the discharges for the study period which met the criteria for inclusion. Six small (under 200 beds), 13 medium-sized (200-499 beds) and 5 large (500 beds or more) hospitals were included, with a total of 5,624 case records.

\(^{\text{38}}\) A total of 1,755 (32%) of the 5,624 patients were screened for possible AEs, 3,869 of whom were ruled out due to 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 AEs during hospitalisation were detected, the incidence of patients with healthcare-related AEs being 9.3% (525/5,624).
Figure 3.3 below illustrates the proportion of identified adverse events by level of severity. The incidence density of minor adverse events was 1.4 per 100 days’ hospital stay per patient (95% CI: 1.3-1.5). The incidence density of moderate or major adverse events was 7.3 for every 1000 days of hospital stay (95% CI: 6.5-8.1). As can be seen in Table 3.4 below, the degree of severity of the adverse events was largely unrelated to their preventability, but significantly related to the source-type (see Table 3.5).

![Proportion of adverse events identified by level of severity](chart.png)

**Figure 3.3 Proportion of adverse events identified by level of severity**

**Table 3.4 Degree of severity and preventability of adverse events**

<table>
<thead>
<tr>
<th></th>
<th>Unpreventable</th>
<th>Preventable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Slight</td>
<td>55.8</td>
<td>43.8</td>
</tr>
<tr>
<td>Moderate</td>
<td>58.0</td>
<td>42.0</td>
</tr>
<tr>
<td>Severe</td>
<td>58.1</td>
<td>41.9</td>
</tr>
</tbody>
</table>

**SOURCE:** ENEAS (2006)
Table 3.5 Adverse event source and preventability

<table>
<thead>
<tr>
<th>Type</th>
<th>Med.</th>
<th>Surg.</th>
<th>Total</th>
<th>Preventable (as a share of the Total)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Procedure-related</td>
<td>11.2</td>
<td>37.6</td>
<td>25</td>
<td>31.7</td>
</tr>
<tr>
<td>Nosocomial infection-related</td>
<td>21.2</td>
<td>29.2</td>
<td>25.3</td>
<td>56.6</td>
</tr>
<tr>
<td>Medication-related</td>
<td>53.8</td>
<td>22.2</td>
<td>37.4</td>
<td>34.8</td>
</tr>
<tr>
<td>Healthcare-related</td>
<td>8.7</td>
<td>6.7</td>
<td>7.6</td>
<td>56</td>
</tr>
<tr>
<td>Diagnosis-related</td>
<td>2.9</td>
<td>2.9</td>
<td>2.7</td>
<td>84.2</td>
</tr>
<tr>
<td>Other</td>
<td>2.2</td>
<td>1.5</td>
<td>1.8</td>
<td>33.3</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td>312</td>
<td>343</td>
<td>655</td>
<td>278 (42.6%)</td>
</tr>
</tbody>
</table>


With respect to the root causes of the identified adverse events, 37.4% were medication-related, 25.3% originated from nosocomial infections (or HAI) of any type, and 25% were related to technical problems during a procedure. Table 3.6 shows the causal distribution of adverse events in the Spanish national study, and Table 3.7 gives a more detailed break down of the types of adverse events per hospital type.

Table 3.6 ENEAS adverse events cause distribution

<table>
<thead>
<tr>
<th>Causes</th>
<th>No.</th>
<th>%</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Illness-related</td>
<td>276</td>
<td>26%</td>
<td>23.3%-28.6%</td>
</tr>
<tr>
<td>Linked to the care provided</td>
<td>787</td>
<td>74%</td>
<td>71.4%-76.7%</td>
</tr>
<tr>
<td>Minimal or slight probability</td>
<td>262</td>
<td>25%</td>
<td>22.1%-27.2</td>
</tr>
<tr>
<td>Moderate or high probability</td>
<td>525</td>
<td>49%</td>
<td>46.4%-52.4</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td>1,063</td>
<td>100%</td>
<td></td>
</tr>
</tbody>
</table>

Table 3.7 Types of adverse events by hospital size, taken from ENEAS 2006

<table>
<thead>
<tr>
<th>Types of AE's by hospital size</th>
<th>Large-sized</th>
<th>Percentage</th>
<th>Medium-sized</th>
<th>Percentage</th>
<th>Small-sized</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Healthcare-related</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pressure ulcer</td>
<td>28</td>
<td>8.78%</td>
<td>14</td>
<td>5.28%</td>
<td>8</td>
<td>11.27%</td>
</tr>
<tr>
<td>Burns, scrapes and confusions (including resulting fractures)</td>
<td>11</td>
<td>3.46%</td>
<td>6</td>
<td>3.02%</td>
<td>6</td>
<td>7.04%</td>
</tr>
<tr>
<td>Acute Pulmonary Edema and respiratory failure</td>
<td>3</td>
<td>0.94%</td>
<td>1</td>
<td>0.38%</td>
<td>0</td>
<td>0.00%</td>
</tr>
<tr>
<td>Other consequences of long-term immobilisation</td>
<td>3</td>
<td>0.94%</td>
<td>0</td>
<td>0.00%</td>
<td>0</td>
<td>0.00%</td>
</tr>
<tr>
<td>Medication-related</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nausea, vomiting or diarrhoea secondary to medication</td>
<td>18</td>
<td>5.64%</td>
<td>6</td>
<td>2.26%</td>
<td>8</td>
<td>11.27%</td>
</tr>
<tr>
<td>Pruritus, rash or skin lesions reactive to drugs or dressings</td>
<td>12</td>
<td>3.76%</td>
<td>18</td>
<td>6.79%</td>
<td>2</td>
<td>2.82%</td>
</tr>
<tr>
<td>Other secondary effects of drugs</td>
<td>16</td>
<td>5.02%</td>
<td>11</td>
<td>4.15%</td>
<td>2</td>
<td>2.82%</td>
</tr>
<tr>
<td>Poorly controlled glycaemia</td>
<td>11</td>
<td>3.45%</td>
<td>6</td>
<td>2.26%</td>
<td>2</td>
<td>2.82%</td>
</tr>
<tr>
<td>Haemorrhage due to anticoagulation</td>
<td>13</td>
<td>4.08%</td>
<td>4</td>
<td>1.51%</td>
<td>1</td>
<td>1.41%</td>
</tr>
<tr>
<td>Worsening of renal function</td>
<td>6</td>
<td>1.88%</td>
<td>6</td>
<td>2.26%</td>
<td>1</td>
<td>1.41%</td>
</tr>
<tr>
<td>Upper digestive tract haemorrhage</td>
<td>5</td>
<td>1.57%</td>
<td>6</td>
<td>2.26%</td>
<td>2</td>
<td>2.82%</td>
</tr>
<tr>
<td>Delay in treatment</td>
<td>5</td>
<td>1.57%</td>
<td>4</td>
<td>1.51%</td>
<td>1</td>
<td>1.41%</td>
</tr>
<tr>
<td>Heart failure and shock</td>
<td>5</td>
<td>1.57%</td>
<td>4</td>
<td>1.51%</td>
<td>1</td>
<td>1.41%</td>
</tr>
<tr>
<td>AMI, CVA, PTE</td>
<td>6</td>
<td>1.88%</td>
<td>2</td>
<td>0.75%</td>
<td>1</td>
<td>1.41%</td>
</tr>
<tr>
<td>Neutropenia</td>
<td>3</td>
<td>0.94%</td>
<td>6</td>
<td>2.26%</td>
<td>0</td>
<td>0.00%</td>
</tr>
<tr>
<td>Drug-related neurological alterations</td>
<td>4</td>
<td>1.25%</td>
<td>5</td>
<td>1.89%</td>
<td>0</td>
<td>0.00%</td>
</tr>
<tr>
<td>Drug-related alteration in heart rate or electrical activity</td>
<td>2</td>
<td>0.63%</td>
<td>5</td>
<td>1.89%</td>
<td>2</td>
<td>2.82%</td>
</tr>
<tr>
<td>Drug-related hypotension</td>
<td>3</td>
<td>0.94%</td>
<td>1</td>
<td>0.38%</td>
<td>3</td>
<td>4.23%</td>
</tr>
<tr>
<td>Opportunistic infection due to immunosuppressing treatment</td>
<td>1</td>
<td>0.31%</td>
<td>2</td>
<td>0.75%</td>
<td>3</td>
<td>4.23%</td>
</tr>
<tr>
<td>Electrolyte imbalance</td>
<td>1</td>
<td>0.31%</td>
<td>3</td>
<td>1.13%</td>
<td>2</td>
<td>2.82%</td>
</tr>
<tr>
<td>Drug-related headache</td>
<td>5</td>
<td>1.57%</td>
<td>0</td>
<td>0.00%</td>
<td>0</td>
<td>0.00%</td>
</tr>
<tr>
<td>Ineffective medical treatment</td>
<td>2</td>
<td>0.63%</td>
<td>2</td>
<td>0.75%</td>
<td>1</td>
<td>1.41%</td>
</tr>
<tr>
<td>Adverse reactions to anaesthetic agents</td>
<td>1</td>
<td>0.31%</td>
<td>2</td>
<td>0.75%</td>
<td>0</td>
<td>0.00%</td>
</tr>
<tr>
<td>Nosocomial infection-related</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surgical wound infection</td>
<td>19</td>
<td>5.96%</td>
<td>28</td>
<td>10.57%</td>
<td>3</td>
<td>4.23%</td>
</tr>
<tr>
<td>Nosocomial UTI</td>
<td>17</td>
<td>5.33%</td>
<td>20</td>
<td>7.55%</td>
<td>8</td>
<td>11.27%</td>
</tr>
<tr>
<td>Other type of nosocomial infection or unspecified nosocomial infection</td>
<td>10</td>
<td>3.13%</td>
<td>8</td>
<td>3.02%</td>
<td>4</td>
<td>5.53%</td>
</tr>
<tr>
<td>Sepsis and septic shock</td>
<td>10</td>
<td>3.13%</td>
<td>7</td>
<td>2.64%</td>
<td>2</td>
<td>2.82%</td>
</tr>
<tr>
<td>Nosocomial pneumonia</td>
<td>5</td>
<td>1.57%</td>
<td>10</td>
<td>3.77%</td>
<td>2</td>
<td>2.82%</td>
</tr>
<tr>
<td>Device-related bloodstream infection</td>
<td>2</td>
<td>0.63%</td>
<td>10</td>
<td>3.77%</td>
<td>1</td>
<td>1.41%</td>
</tr>
<tr>
<td>Procedure-related</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Haemorrhage or hematoma related to surgical operation or procedure</td>
<td>31</td>
<td>9.72%</td>
<td>24</td>
<td>9.06%</td>
<td>6</td>
<td>8.45%</td>
</tr>
<tr>
<td>Injury to an organ during a procedure</td>
<td>10</td>
<td>3.13%</td>
<td>10</td>
<td>3.77%</td>
<td>0</td>
<td>0.00%</td>
</tr>
</tbody>
</table>
The Spanish study found that adverse events not only result in an extended hospital stay (31.4%); but also in readmission to a hospital (24.4%), with some patients having more than one adverse event which caused their readmission. Most importantly, this load entailed an average 4-day stay for those adverse events that extended the hospital stay; and an average 7-day stay for those having led to a readmission. Thus, a total of 3,200 additional stays (6.1 additional stays per patient) were caused by adverse events, 1,157 of which were avoidable. That is, adverse events in Spain cause 2.2 additional avoidable stays per patient – a high number indeed. In addition, a total of 66.3% of all adverse events required additional procedures to be performed (e.g. radiodiagnosis testing), and 69.9% required additional treatments (e.g. medication, rehabilitation or surgery). Table 3.8 below presents the per-layer distribution of adverse events leading to readmission.

<table>
<thead>
<tr>
<th>Table 3.8 Adverse events leading to readmission by layer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Layers</td>
</tr>
<tr>
<td>--------</td>
</tr>
<tr>
<td>Hospital size:</td>
</tr>
<tr>
<td>Large hospitals</td>
</tr>
<tr>
<td>Medium-sized hospitals</td>
</tr>
<tr>
<td>Small hospitals</td>
</tr>
<tr>
<td>Unit type:</td>
</tr>
<tr>
<td>Medical units</td>
</tr>
<tr>
<td>Surgical units</td>
</tr>
</tbody>
</table>

The third European national study we identified through our interviews is a recent French national survey of inpatient adverse events (Michel, 2007). The French study 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.\(^{39}\) 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 clearly indicates that every type of hospital and unit is affected by adverse events, and hence substantiates the classification of inpatient adverse events as a public health problem. A longer period of hospitalisation was associated with 40.5% of all adverse events.

In France, the highest incidence density of adverse events was observed in geriatric units, and the lowest in internal medicine. In surgery, the highest density was observed in cardiothoracic surgery, gynaecology and urology. Invasive procedures formed the main exposure situation for adverse events occurring during hospitalisation: in particular, perioperative care was related to 42% of adverse events whereas adverse drug events represented 20% – nearly as high as healthcare-associated infections (HCAIs) found in the Spanish study. The preventability of adverse drug events was 42%, whereas that of perioperative adverse events was 31%. In 14.5% of the adverse events, inadequate care was found to be the main human error related to occurrence of adverse events: failure to choose the appropriate care in 5.9% and failure to administer care at the right moment in 8.8%. No human error was identified in 52.7% of adverse events.

Lastly, as suggested above, another main source of information on the problem of patient safety across EU-27 countries is the Key Informant Interviews we conducted as part of this project work. Our qualitative data also corroborate the prevalence figures identified by previous studies as they range from 8% to 12%, on average, with a few exceptions. In Latvia, depending upon the healthcare provision setting (delivery services, surgery, psychiatry, dentistry, necrology, primary care, emergency, etc), the prevalence of adverse events (i.e. the scope of the problem of patient safety) can reach up to 20%. However, as our respondent remarked, the total number of reports that were analysed nationally are low and originate predominantly from patients in the prison population (e.g. n=22, or n=46 per provision type) and may explain the high prevalence figure for this country.

### The paediatric patient population

Although there is patchy knowledge about inpatient safety problems among adults, even less is known about the epidemiology of patient safety among children. One of the few exceptions here is Selbst et al. (1999) who report that the prevalence of adverse drug events in a paediatric emergency department in which nurses and physicians were involved was 39%, many of which were preventable. Notably, in a third of adverse drug events, families of paediatric patients did not receive notification of the event. Kaushal et al. (2001) also suggest that potential medication errors are three times more common in children than in adults. This hypothesis has been confirmed by Barber (2006): paediatric

\(^{39}\) These figures exclude obstetric wards, but include public, private and teaching hospitals. Total participation rate was 40%. The 8,754 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).
prescribing errors are estimated to reach 10% in the general medical setting and 12% in intensive care units (i.e. per 100 prescriptions).

**International evidence**

As noted previously, the scope for comparing results on adverse event epidemiology is generally limited. However, the results of the 2007 *International Health Policy Survey of the Commonwealth Fund*\(^{40}\) paints a picture largely similar to the one reported above. Table 3.9 below presents the adverse event incidence in the seven countries included in the analysis.

<table>
<thead>
<tr>
<th>AEs reported in past 2 years</th>
<th>UK (%)</th>
<th>Germany (%)</th>
<th>Netherlands (%)</th>
<th>New Zealand (%)</th>
<th>Australia (%)</th>
<th>USA (%)</th>
<th>Canada (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Experienced medical or medication error</td>
<td>9</td>
<td>9</td>
<td>9</td>
<td>11</td>
<td>15</td>
<td>13</td>
<td>10</td>
</tr>
<tr>
<td>Experienced lab or diagnostic test error</td>
<td>10</td>
<td>4</td>
<td>8</td>
<td>9</td>
<td>11</td>
<td>14</td>
<td>12</td>
</tr>
<tr>
<td>Experienced any medical, medication, or lab error</td>
<td>13</td>
<td>12</td>
<td>14</td>
<td>16</td>
<td>20</td>
<td>20</td>
<td>17</td>
</tr>
</tbody>
</table>

SOURCE: Commonwealth Fund (2007)

Risk factors identified included visiting three or more providers; having two or more chronic conditions; and not having a medical provider that knows you, is easy to contact, and coordinates your care (i.e. the patient has no “medical home”). Evidence from the UK, Netherlands and Germany in this international study showed, for example, that 26%, 22% and 19% of all chronically ill patients without a medical home reported to have experienced at least one adverse event during the past two years, respectively. Similarly, 29%, 27% and 16% of patients in the same countries visiting three or more physicians in the past two years reported to suffer an adverse event.

In the U.S, *To Err is Human* (Institute of Medicine 2000) was the seminal study that identified healthcare error as a major public health issue both domestically and internationally. According to the report and concurrent studies (Weingart 2000), adverse events accounted for the death of at least 44,000 and perhaps as many as 98,000 Americans each year in US hospitals, and for 1m excess injuries annually – a higher death rate than for car accidents, breast cancer or AIDS. The report estimated that the total national costs of preventable adverse events in terms of lost income, lost household production, disability, and healthcare costs are between $17 billion and $29 billion each year,\(^{41}\) with more than half attributable to direct healthcare costs.

\(^{40}\) The survey used representative samples of adults aged 18 and older in Australia, Canada, Germany, the Netherlands, New Zealand, the United Kingdom, and the United States. Final samples were as follows: 1,009 Australia; 3,003 Canada; 1,407 Germany; 1,557 the Netherlands; 1,000 New Zealand; 1,434 United Kingdom; and 2,500 United States. Core topics included: Access, Coordination, Patient-Centred Care, Chronic Care, and Safety.

\(^{41}\) These figures would be approximately equal to between €18.45 billion and €31.47 billion a year (RAND Europe calculation using average historical exchange rate of US$1 to €1.085 for the year 2000 (www.oanda.com)).
More recently, Romano et al. (2003) identified about 1.12 million potential safety-related events that occurred in 1.07 million hospitalisations at non-federal acute care facilities in the US (see Table 3.10 below). And Robeznieks (2006) highlighted the existence of 1.24 million “patient safety incidents” among Medicare patients at hospitals from 2002-2004, an increase of about 5% from the 2001-2003 study period.

Table 3.10 Number of cases and rates of potential patient safety events among surgical, medical, and obstetric patients in US non-federal acute care hospitals, 2000

| Patient safety indicator | Total (95% CI) | Rate | Surgical | Rate | Medical/obstetric
|--------------------------|---------------|------|----------|------|------------------|
| Anesthesia reactions and complications | 5,306 (±1,455) | 0.056% | 5,306 | 0.056% | 4,835 (±0.066)
| Death in low-mortality DRGs | 5,912 (±1,433) | 0.043 | 1,075 | 0.040 | 1,875 (±0.065)
| Decubitus ulcer | 201,459 (±10,104) | 2.130 | 55,139 | 1.755 | 148,321 (±2.316)
| Failure to rescue | 267,541 (±5,066) | 17.424 | 68,671 | 17.497 | 198,873 (±17.579)
| Foreign body left during procedure | 2,710 (±204) | 0.008 | 2,284 | 0.024 | 431 (±0.002)
| Intravascular catheter perforation | 19,397 (±1,025) | 0.067 | 8,847 | 0.017 | 10,547 (±0.050)
| Infection due to medical care | 54,490 (±2,658) | 0.193 | 24,898 | 0.037 | 29,592 (±0.147)
| Postop hip fracture | 5,207 (±1,327) | 0.080 | 5,207 | 0.080 | 5,207 (±0.080)
| Postop hemorrhage/hematoma | 17,014 (±1,968) | 0.206 | 17,014 | 0.206 | 17,014 (±0.206)
| Postop pancreatic injury | 4,003 (±419) | 0.089 | 4,003 | 0.089 | 4,003 (±0.089)
| Postop respiratory failure | 12,842 (±938) | 0.359 | 12,842 | 0.359 | 12,842 (±0.359)
| Postop thoracic emboisolism | 75,811 (±4,156) | 0.919 | 75,811 | 0.919 | 75,811 (±0.919)
| Postop sepsis | 14,065 (±1,060) | 1.091 | 14,065 | 1.091 | 14,065 (±1.091)
| Postop abdominal pelvic wound dehiscence | 3,858 (±289) | 0.193 | 3,858 | 0.193 | 3,858 (±0.193)
| Accidental puncture or laceration during transfusion or injection | 89,348 (±5,669) | 0.324 | 8,931 | 0.002 | 6,417 (±0.003)
| Transfusion reaction | 138 (±145) | 0.0004 | 65 | 0.0000 | 65 (±0.0002)
| Birth trauma | 27,035 (±5,674) | 0.067 | 27,035 | 0.067 | 27,035 (±0.067)
| Obstetric trauma—vaginal with instrumentation | 60,622 (±3,104) | 24.048 | 60,622 | 24.048 | 60,622 (±24.048)
| Obstetric trauma—vaginal without instrumentation | 249,243 (±512,570) | 8.559 | 249,243 | 8.559 | 249,243 (±8.559)
| Obstetric trauma—cesarean | 5,523 (±597) | 0.593 | 5,523 | 0.593 | 5,523 (±0.593)

SOURCE: HCUP Nationwide In-Patient Sample, as featured in Romano et al (2003)

NOTE: Surgical, medical and obstetric categories are based on diagnosis-related group assignment. "Number" is the estimated total number of events nationwide.

For indicative purposes and for a broad comparison, we present a graphic comparison of the risk of death due to different activities, including receiving healthcare (Figure 3.4). Figure 3.4 illustrates the fact that the activity of receiving healthcare in the US is the riskiest one surpassing risky activities that are regulated such as driving as well as ultra-safe activities such as scheduled airlines.42 We offer this comparison with caution because the alternatives to mountain climbing (a dangerous activity) are much less risky than the

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42 Young (2005).
alternative to receiving care (i.e. receiving healthcare is risky but the absence of healthcare may be even riskier).

In Australia, the Quality in Australian Healthcare study (QAHCS) published in 1995 showed that 16.6% of all patients whose hospital charts were reviewed suffered an adverse event (14,000 admissions to 28 hospitals in New South Wales and South Australia). Half (51%) of these adverse events were considered preventable. The health consequences of this problem were also evaluated: disability related to adverse events was resolved within 12 months in 77.1% of them, but in 13.7% the disability was permanent and in 4.9% the patient died.

The QAHCS study data revealed a much higher level of adverse events than that found in the famous Harvard study of hospital adverse events in New York state, published several years earlier. Part of the reason is that the Australian study focussed on prevention and quality of care, rather than negligence and malpractice concerns that were key to the US Harvard study.

The Australian data clearly demonstrated that morbidity in healthcare was a major public health problem. More recent analyses have revealed that over 70% of the adverse events identified were the result of failures in technical performance; failures to decide or act appropriately based on available information; failures to investigate or consult; and a lack

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43 AHRQ, Commission on Systemic Interoperability, USA, 2005
45 Vincent et al. (1998).
46 Vincent et al. (2001); Wilson et al. (1995).
of care or failure to attend, all of which are potentially preventable. In New Zealand, Davis et al. (2001) report lower adverse event prevalence (19.7%), in a study of three Auckland hospitals, of which 40% were considered preventable. Moreover, care management was implicated as one of the main causes for more than half of all adverse events. For example, 24% of reported events were due to inadequate reporting or communication; 15% to a delay in services; and 11% to a lack of, or an inability to implement, medical protocol. Over half of all events resulted in disability that was resolved within a month. And, an average of 6.7 days extra stay in hospital were attributable to adverse events – a finding recently replicated in Spain.

All of these European and international findings demonstrably indicate the great potential and vast scope for systemic (or "structural") intervention and improvement in patient safety and positive health outcomes from healthcare provision. According to Wilson (2005) in New Zealand, adverse events in in-hospital healthcare ranks number 11 in the top 20 risk factors that account for 75% of deaths annually; ahead of air pollution, alcohol and drugs, violence and traffic road injuries, and equal to a third of the size of tobacco-related deaths.

Other international studies on the prevalence, preventability and root causes of adverse medical events are largely in line with the range estimates cited above. Wilson (2005), for example, reports that adverse events occur in 7.5% and 10% of all hospitalizations in Canada and Singapore, respectively; half of which health professionals regarded as easily avoidable. In the case of Canada, almost all adverse events occurred as a consequence of surgery, and adverse drug events accounted for another 24% of the total.

C. Event-specific epidemiology

While there is a growing international literature on the general epidemiology of in-hospital patient safety events, substantially less is known about in-hospital event-specific mortality and morbidity due to unsafe care. Much of this gap in knowledge is due to the data limitations we discussed earlier, which becomes particularly apparent when we present our summary tables at the end of this sub-section. Of all in-hospital events, the three categories on which more substantial evidence is gathered are general surgery adverse events, wrong side/patient/part surgery, and medication errors. Wrong side/site, wrong procedure, and wrong patient adverse events (WSPEs) are one of the best researched types of adverse events, along with medication errors. However, as is generally the case, the exact incidence and prevalence of WSPEs remains unknown as accurate estimates of incidence cannot be determined without mandatory reporting of the true incidence of annual surgical procedures. Below, we cover the peer-reviewed literature on what is known about event-specific adverse events.

Similarly, very little is known about the prevalence, morbidity and mortality associated with the inappropriate administration of patient records, failure to take sterile precautions during surgery, and blood-type mismatch during surgery, among other incidents. We present a very fragmented picture of this set of indicators in the latter part of the sub-section. Finally, we show event-specific epidemiologic and cost data based on the only existing cross-national data systems at present: the OECD Health Data, and the WHO Mortality Data (the source for the OECD data). We did this for indicative purposes only, since no concrete conclusions can be made due to the data limitations discussed earlier. It
shows, however, the potential for significant impact of coordinated data collection activities at the EU level.

Wrong side/site/patient/part surgery

The high prevalence (up to 40%) of general surgery-associated adverse events is frequently commented on. Several studies and databases document hundreds of cases. Some Swedish cases were reported as early as the 1970s, and other case reports have appeared sporadically. The majority of what is known and published about this event-specific problem of patient safety originates from international data which we discuss here.

From 1995 to 2005, the Joint Commission on Accreditation of Healthcare Organizations’ (JCAHO) sentinel event statistics database ranked wrong side surgery as the second most frequently reported event, with 455 instances accounting for 12.8% of 3,548 events reported since January 1995. Seiden and Barach (2006) document that WSPEs occur across all specialties, with high numbers noted in orthopaedic and dental surgery. They estimate that there are 1,300 to 2,700 WSPEs annually in America. The authors note that, despite these numbers of cases, reporting of WSPEs is “virtually non-existent”, with reports in the lay press far more common than reports in the medical literature. Kwaan et al. (2006) studied wrong site surgery cases reported to a large malpractice insurer between 1985 and 2004, identifying an incidence of 1 in 112,994 adverse patient events during this period. The authors suggest that under optimal conditions JCAHO’s Universal Protocol might have prevented 62% of the cases in the later study.

Wanzel et al. (2000) estimate that 39% of all general surgery inpatients suffered one or more adverse events: 1% of these were fatal, 7% were life-threatening, 63% were of moderate severity and 29% were trivial. Of all adverse events, 18% were deemed potentially attributable to error and yet, 80% were not presented at weekly morbidity and mortality rounds, and 66% were not documented on the face sheet of the patients’ final medical records. This suggests that general surgery adverse events are common and are under-reported by traditional methods, and that strategies to improve the recording and reporting of surgical complications must be developed. Later studies give similar conclusions. Based on Australian data, Wilson (2005) reports that 39.3% of all in-hospital adverse events were associated with general surgery. Baker et al. (2004) give a similar estimate in their Canadian adverse events study in which 34% of all detected adverse events occurred in general surgery.

Clarke et al. (2007) sought to identify factors contributing to wrongside(site)/patient/part surgery and examined all reports from all hospitals and ambulatory surgical centres — in a state that requires reporting of wrong site surgery — from June 2004 to December 2006. The authors reviewed 433,528 reports: 427 of these pertained to wrong side surgery and 56% were near misses. Wrong side surgery was the dominant form of error, occurring in 70% of all cases. The wrong procedure was a cause of 9% and the wrong patient was a cause of 8% of the reported incidents. Most wrong side surgeries involved symmetrical anatomic structures. The main causes of this event-specific incident type include lack of patient involvement, lack of knowledge about the procedure being performed, and failure of safety mechanisms to prevent the error from occurring. Other common contributions to errors resulting in the initiation of wrong site surgery involved carrying out patient positioning and anaesthesia interventions before any planned time-out process, not
verifying consents or site markings, and not doing a proper time-out process. Currently, the patient, family, and preoperative nurse provide the most protection against wrong site surgery.

Additional risk factors for this group of adverse events found by Michaels (2007) included several surgeons involved in the same operation, or multiple procedures for one operation, time pressure, emergency surgery, abnormal patient anatomy, and morbid obesity. Finally, an American Academy of Orthopaedic Surgeons’ (AAOS) task force reviewed malpractice insurance claims from 22 insurers and found that 68% were related to orthopaedic surgery cases.

**Adverse drug events (ADEs)**

From the peer-reviewed literature we know that adverse drug events account for substantial increases in lengths of stay and hospitalisation costs among hospitalised patients (Classen et al. 1997). Adverse drug events were also associated with an almost doubling of the risk of death, making them one of the most dangerous types of adverse events.

In the Netherlands, over 5% of all emergency admissions are related to adverse drug events, and 4% of all the United Kingdom’s hospital beds are filled with patients who experience similar circumstances. The risk of such an adverse event occurring in a hospital seems to be higher, even considerably higher. The biggest risk arising from such an episode is of death or severe long-term impairment.

A US study in two tertiary care hospitals reported rates of actual and potential adverse drug events of 6.5% and 5.5%, respectively (Bates et al. 1995). A high proportion of serious (28%) and life-threatening (42%) adverse drug events were judged to have been preventable. The prevalence rate reported for Australia is 6.7%47 and for Canada (when combined with fluid mixture) is 23.6%.48

In Canada, Orser et al. (2001) examined whether anesthesiologists had experienced a medication error and, if so, the causal factors linked to these errors. Survey results from 687 anesthesiologists from the Canadian Anesthesiologists’ Society (a 30% response rate) revealed that 85% of the participants had experienced at least one drug error or “near miss”. Although most errors were of minor consequence (98%), four deaths were reported. The most common error involved the administration of muscle relaxants instead of a reversal agent. “Syringe swaps” (70.4%) and the misidentification of the label (46.8%) were common contributing factors. Anesthesiologists (97.9%) reported that they read the ampoule label “most of the time” although the label colour was an important secondary cue. Approximately half of the participants would report the error if a reporting programme existed and 84% agreed that improved standards for drug labels would reduce the incidence of error. It is recognised that adverse drug events can also occur, and be perpetuated, as a result of patients’ non-compliance with medication recommendations.49

**Other incident types**

48 Baker et al. (2004).
With respect to the prevalence and effects of other types of event-specific in-hospital patient safety incidents, relatively little has been written. For example, according to Baker et al. (2004), 10.5% of all in-hospital adverse events are in actual diagnostic errors, 11.9% are clinical mixes, and 7.2% are medical misadventures. According to Wilson (2005), 10.6% of all in-hospital adverse events occurred due to improper administration of patient records, 9.3% were diagnostic errors, 8.4% were therapeutic errors, and 4.3% were procedural errors.

The scarcity of event-specific data on inpatient adverse events is particularly lamentable as such data provides the critical basis for the selection of patient safety improvement strategies and interventions. It is also particularly regrettable because the majority of these events, including others on which we do not comment here for lack of literature, are featured as codes in the International Classification of Disease, Tenth Revision (ICD-10); codes that are used both in national and international population health reporting.

3.3.2 Patient safety in the primary care setting

The main source of information on European incident epidemiology in the primary care setting that is currently available comes from the Spanish APEAS (Ministero de Salidad y Consumo 2005) study of adverse and near miss events in primary care. The study covered 48 health centres in 16 Spanish regions, and a total sample of 96,047 patient visits among 251 GPs, 49 paediatricians and 152 nurses. Another source of information on adverse patient incidents in outpatient settings is the UK’s National Patient Safety Agency data summary of incident reports in the NHS (2008).

APEAS data

In Spain, the prevalence rate of patient safety incidents was 1.863% (95% CI: 1.778-1.949). Of these, near misses occurred in 0.745% of all patient visits, and adverse events occurred in 1.118% of them (see Figure 3.5). Among all patients, 6.7% experienced more than one adverse event.

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50 CI95%: 0.691–0.80
51 CI95%: 1.052–1.185
Women accounted for 57.4% of the total patient population. The median age was 59, and the mean age was 53 for both sexes. Of those affected by adverse events, 58% presented one or more risk factors, as previously identified (including factors connected with the use of drugs, communication, handling and care practices).

Figure 3.6 illustrates the types of identified adverse events according to severity and the proportion of adverse events that were deemed preventable. Of the adverse events identified, 6.7% were considered totally unavoidable (n=74), 23.1% were difficult to prevent (n=256) and 70.2% were clearly preventable (n=778). In terms of preventability relative to their degree of severity, 65.3% of minor adverse events, 75.3% of moderately serious adverse events and 80.2% of serious adverse events were preventable. This is a statistically significant difference (value of p <0.001).

In 23.6% of cases, the consequences of the adverse events had no effect on healthcare; whilst in 33.1% they implied a higher level of observation and monitoring; in 7.5% they implied the need for further tests; and in 17.1%, additional surgical or medical treatment was provided at the primary healthcare level. In 24.9% of cases the consequences of the adverse events implied a need for consultation or referral to specialist care (without hospital admission) and in 5.8% they implied a need for life-saving hospitalisation.
Consistent with inpatient populations, the authors note that the causal factors of the adverse events were connected with medication in 48.2% of cases (of the less than 2% total adverse events), in 25.7% they were care-related, in 24.6% they were associated with communication, in 13.1% with the diagnosis, in 8.9% with handling and in 14.4% with other causes (see Figure 3.7).

These results show that the existence of adverse events in primary care is relatively low compared to inpatient settings (specifically hospitals), and that such adverse events are not too severe since only a quarter of the adverse events required referral to specialist services. Nevertheless, patient safety is important at the primary care level given the high number of patients visiting the primary healthcare centres, meaning that the absolute number of
patients affected is significant. If we were to extrapolate the results to the entire Spanish population, these results suggest that an average of seven out of every 100 patients could be affected in one year.\footnote{APEAS (2005).} Furthermore, the number of cases of care-related (nosocomial) infections at primary healthcare level cannot be deemed insignificant. In most cases, an adverse event will have a negative impact on the evolution of the patient’s original disease or complaint.

Prevention of adverse events at the primary healthcare level should therefore be a priority in any strategy to improve patient safety, given that 70\% of all adverse events, and 80\% of all serious adverse events, are preventable.

**NHS Summary Data**

In the quarterly summary report by the UK’s National Patient Safety Agency for the period of October to December 2007, the vast majority of reported incidents in community pharmacies related to medication (98\%), with a negligible proportion for the remaining incident types. Less than 1\% of reported incidents occurred in general practice (2,600 incidents of a total number of 791,429). For general practice, the top five most commonly reported incident types were: medication (29\%); documentation (14\%); access / admission / transfer / discharge (11\%); consent / communication / confidentiality (10\%); and treatment / procedure (8\%). By contrast, very few reported incidents were received in community optometry / optician services, so no conclusions could be drawn on incident patterns in the UK in this care setting.

As of 27 January 2008, there were 11,700 incidents in the NRLS reported to have occurred in primary care settings during the period above and, of these, 4,071 were related to medication errors (29\%). The four most common themes identified by the National Patient Safety Agency from medication errors in primary care were: vaccination; prescribing (including administration errors at production of prescribing); repeat prescribing; and dispensing.

Vaccination errors occur because of the complexity of the setting – providing care to the community with many patients in the same room attending as families. In addition, vaccination schedules have changed over time and demonstrate the need for repeated education and training of providers. In England, 659.7m prescription items were dispensed in community pharmacies between 1 April 2005 and 31 March 2006. Although modern computerised prescribing systems have reduced much of the burden of individually-written prescriptions, the National Patient Safety Agency’s review of the data suggests that some problems occur at the point of initiating and generating prescriptions.

Over 80\% of all prescriptions are generated as part of a repeat prescribing system and, whilst the system generally works well, the NRLS data highlights a number of problems that might be associated with the administrative side and the risks of medicines being wrongly changed or re-issued. Finally, the dispensing incidents reported to the NRLS from primary care show that medicines management arrangements in primary care offer many points of safety check. But, the National Patient Safety Agency report notes that
“empowering the patient to understand their medication is as important as a final safety check”.

The proportion of incidents between October 2006 and September 2007 reported as causing either severe harm or death was highest in general practice (2%), followed by mental health services (1.8%) and community services (including community hospitals) (1.5%). In general practice, there were 30 reported incidents resulting in severe harm (1.2%) and 21 reported incidents resulting in death (0.8%). In mental health services, there were 681 reported incidents resulting in severe harm and 1,349 reported incidents resulting in death (including suicides\(^53\)). In Community nursing, medical and therapy services, there were 709 reported incidents resulting in severe harm and 270 reported incidents resulting in death. As the National Patient Safety Agency report suggests, it is likely that the relatively high proportion of incidents reported as resulting in severe harm or death in general practices may reflect a “different reporting culture” compared to other care settings whereby fewer incidents are reported overall, but incidents with the greatest negative impact are most likely to be reported.

### 3.4 Strategies to improve patient safety

Among the previously discussed results of the root cause analysis, the particularly striking findings of the Utah-Colorado Study\(^54\) in America showed that 75% of the adverse drug events were attributable to system failures. Overall, system-related root causes of adverse events are featured in 10% to 70% of all occurrences\(^55\) and most adverse events are documented to result not out of negligence or lack of training but out of latent causes within systems\(^56\).

In this context, the use of information and computer technology (ICT) can help prevent medical errors and adverse events; initiate rapid responses to any event; enable the tracking of events, if they occur, and provide feedback on them to learn from. National norms on patient safety and quality standards, and the use of information technology (focused on incident reporting, medication, prescribing and patient identification) have also been shown to be associated at a statistically significant level with good working practices (including evidence-based guidelines implementation), safe medical care and use of pharmaceuticals\(^57\). For example, Colpaert et al. (2006) report that the incidence of medication prescription errors in the computerised intensive care units is significantly lower than the one in paper-based units: 3.4% vs. 27% respectively. In addition, clinical

\(^{53}\) Suicide, as an extreme act of self-harm, is generally viewed by the medical community as an adverse event in mental health services which are intended to provide the necessary psycho-social care to prevent harm to mentally ill patients, whether or not the harm is self-inflicted.

\(^{54}\) Thomas et al. (1999).

\(^{55}\) Nagel (2007).

\(^{56}\) World Health Professions Alliance Fact Sheet at http://www.whpa.org/factptsafety.htm.

\(^{57}\) WHO (2007b); Stroetmann et al. (2006).
studies in the US suggest that Bar Code Medication Administration might prevent up to 58% of adverse drug events. However, the 2007 European Commission report on the impact of communication technologies (ICT) on patient safety and risk management underscores that, like in other industrial sectors, strong evidence suggests that it is not ICT in isolation that leads to benefits like improved quality of care, reduced errors and, at the same time, significant cost savings. Rather, the “right” combination with complementary investment in working practices, human capital, and healthcare process restructuring will result in better quality of care and ultimately improved patient safety.

The experience of the Leapfrog Patient Safety Group in the US to improve patient safety by linking the demand for healthcare to its quality and safety has also proved successful. The Leapfrog group is an initiative driven by organisations that buy healthcare who are working to initiate breakthroughs in the safety, quality and affordability of healthcare.

According to root cause analyses, the cost of actions to prevent adverse events is frequently small. Mitigating interventions – such as proper administration of records, elevation of patients’ pillows during intubation, and hand hygiene – can drastically diminish adverse events incidence. Furthermore, to these we can add improved communication between medical team members, better continuity of care and more patient-centred healthcare. Nolan (2000) further explores system changes to improve patient safety and concludes that designing systems to detect or prevent predictable errors is feasible. According to him, useful tactics include reducing complexity, optimising information processing, using automation and constraints, and reducing the undesirable effects of change.

Pietro et al. (2000) also highlight the fact that how errors are perceived and handled can strongly impact on their outcomes, which suggests that the fears and practical problems associated with error detection need to be properly addressed via systems for blame-free reporting of adverse and near miss events, and learning from them and their resolution (i.e. no-fault compensation mechanisms). Indeed, several studies suggest that patients would also like to see functioning patient safety monitoring, learning and redress systems. Surveys reveal that patients want more openness about, and disclosure of, medical errors.

Furthermore, a survey conducted by the UK Department of Health Expert Group (2000) found that, of patients who had been affected by medical injury, 34% wanted an apology or explanation, 23% wanted an enquiry into the causes, 17% wanted support in coping with the consequences, 11% wanted financial compensation, and 6% wanted disciplinary action. In other words, the issue of patient safety implicates the principles of transparency and moral accountability more so than a demand for economic resolution.

Finally, according to a recent study by Mazor et al. (2004), when medical errors occur patients seek not only to be told about the incident but also to receive information on what happened, why it happened, how its consequences can be mitigated and how recurrences can be prevented. Honest disclosure of such information has been found to increase patient satisfaction and trust, and reduce the likelihood of legal action being commenced.

58 Patterson et al. (2002); Jensen et al. (2004); Anderson et al. (2002, 2003).

59 Hobgood et al. (2002); Witman et al. (1996).
In the Mazor et al. study, the basic requirements for effective national reporting and learning were also outlined. These include clear objectives; clarity about who should report; clarity about what gets reported; mechanisms for receiving reports and managing the data; expertise for analysis; capacity to respond to reports; a method for classifying and making sense of reported events; the capacity to disseminate findings; and technical infrastructure and data security. Many of these elements are reflected in the 2005 WHO draft guidelines on RLSs to enhance patient safety. The WHO draft guidelines highlight the following characteristics of successful RLSs that contribute to patient safety: (1) reporting is safe for the individuals who report; (2) reporting leads to a constructive response; (3) expertise and adequate financial resources are available to allow for meaningful analysis of reports; and (4) the reporting system must be capable of disseminating information on hazards and recommendations for changes.

At present, there are few national reporting, learning and redress systems, other than those in the UK, Denmark, the Netherlands, Belgium, and in New Zealand and Australia. The separate RLSs which exist in the US should also be mentioned here, with the caveat that we are aware of only State level and not national level indicators (e.g. Leapfrog has hospital ratings only). However, comprehensive evaluations of these systems are not yet available, with the exception of the US, New Zealand and Australian systems. Overall, little evidence is available on the costs these systems entail, and their potential benefits in terms of either decreased adverse event incidence and/or savings. Below we look at the available evidence for the US, Australian and UK systems. A 2008 RAND study\(^6\) on the patient safety initiatives of AHRQ (Agency for Healthcare Research and Quality, of the US Department of Health and Human Services) highlighted the “necessary but not sufficient” factors for successful implementation of safe practices (see Table 3.11).

**Table 3.11 Key factors for successful implementation of safety improvements**

<table>
<thead>
<tr>
<th>Factor category</th>
<th>Specific factors</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Organisational infrastructure</strong></td>
<td></td>
</tr>
<tr>
<td>Patient safety culture</td>
<td>Blame-free culture</td>
</tr>
<tr>
<td></td>
<td>Safety standards and guidelines</td>
</tr>
<tr>
<td></td>
<td>Incentives and recognition for safety</td>
</tr>
<tr>
<td></td>
<td>Data system for reporting</td>
</tr>
<tr>
<td>Corporate culture of excellence</td>
<td>(one factor)</td>
</tr>
<tr>
<td>Organisational leadership involvement</td>
<td>Support for the initiative</td>
</tr>
<tr>
<td></td>
<td>Support for the team</td>
</tr>
<tr>
<td>Staff training</td>
<td>(one factor)</td>
</tr>
<tr>
<td><strong>Implementation process</strong></td>
<td></td>
</tr>
<tr>
<td>Project implementation team</td>
<td>Team members</td>
</tr>
<tr>
<td></td>
<td>Team qualities and performance</td>
</tr>
<tr>
<td></td>
<td>Stakeholders’ involvement in project plan</td>
</tr>
</tbody>
</table>

\(^6\) Farley et al. (2008).
The RAND authors have argued elsewhere, however, that even with these factors completely in place, effective implementation could fail due to poor implementation techniques, insurmountable barriers, or otherwise unforeseen events. Other RAND researchers have emphasised particularly the following important administrative dimensions: (1) whether the reporting systems were mandatory or voluntary; (2) whether the states aggregated their report information in an electronic database format; and (3) whether states had formal data dictionaries or code books to standardise the way that report information is collected.

Beckett et al. (2006) found that, for each data element that IOM recommended be incorporated into event reporting systems, a wide array of informatics standards exists that could potentially be applied. Yet, with the exception of several states that made use of the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) diagnostic and procedure codes, as of 2005, none of the informatics standards suggested by the IOM had been widely adopted by the states. State reporting systems were also far removed from using a shared set of definitions for adverse outcomes, and therefore, the data coming from these systems will not easily lend themselves to aggregation at the national level. Moreover, as Cullen et al. (1995) suggest, over-reliance on incidence reporting data can result in a drastic under-estimate of adverse event rates, with 94% of adverse drug events being identified by record review and confidential reports only, and not by being reported in incident reports.

Still, the 2008 RAND report concluded that state-level adverse event reporting systems provide a potentially important resource for tracking trends in patient safety outcomes, although their effectiveness is currently limited by the lack of a common event taxonomy, inconsistent compliance by medical providers and facilities with reporting requirements, and limited feedback mechanisms with regard to reported data.

### 3.4.1 Evidence on cost of systemic interventions

The key documents which provide insight into the administrative costs of the RLS mechanisms in the US are Leape (2002), Rosenthal et al. (2001), Woolf et al. (2003), and Runciman (2002). According to them, for the 20 state reporting systems in place in 2002 annual funding ranged from $200,000 to $1,500,000 (with only three having more than

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61 Farley et al. (2007).
62 Beckett et al. (2006).
63 Beckett et al. (2006).
64 Beckett et al. (2006).
65 Beckett et al. (2006); Marchev et al. (2003).
four full-time staff members). Table 3.12 below shows the 2001 cost estimates of the key components of the mandatory reporting systems in New York and Florida. However, as the authors point out, segregating the costs of each component of a mandatory reporting system is instructive for establishing budgets, but may be misleading because other less tangible factors have been shown to lead directly from the financial commitment required to create and sustain reporting systems.

Table 3.12 Cost ranges for reporting programme activities in Florida and New York, 2001

<table>
<thead>
<tr>
<th>Function</th>
<th>In-house FTE</th>
<th>Estimated costs for in-house or contractual work</th>
</tr>
</thead>
<tbody>
<tr>
<td>Administration</td>
<td>0.5-0.75 FTE</td>
<td>$50,000-$275,000 (€55,845.5-€307,150.25)³</td>
</tr>
<tr>
<td>Systems design and maintenance</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Investigation</td>
<td>5-6 (1 FTE per 100-200 investigations)</td>
<td>$200,000-$675,000 (€223,382.00-€753,914.25)³</td>
</tr>
<tr>
<td>Data analysis and validation</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

SOURCE: Rosenthal et al. (2001)

Notes: ¹FTE = full time employee; ²assumes underlying system is in place; ³RAND Europe calculations using historical exchange rate of US$1 to €1.11691 on average for the year 2001 (www.oanda.com)

More recently, the Pennsylvania approach to developing a comprehensive, inter-agency approach to address patient safety – including a breadth of patient safety activities, and considering patient safety’s impact on a broad healthcare agenda of access, cost, and quality – showed that patient safety improvement efforts backed by stable financing can be effective. In 2004, Pennsylvania became the first state to require reporting of near misses, in addition to actual errors. Pennsylvania hospitals and other healthcare facilities must report “serious events” and “incidents” (i.e. near misses) to the Pennsylvania Patient Safety Authority on a monthly basis, using a confidential Web-based data collection system. Pennsylvania Patient Safety Authority receives almost 17,000 reports each month from over 400 facilities, and the numbers are rising. The vast majority of reports (over 96%) are “near misses” which provide crucial insights into how to avoid errors. Authorities believe this indicates better compliance and a greater desire to learn from the data, rather than an actual increase in near misses or adverse events. It is funded through an assessment on facilities, with a budget of about US$4m a year – a significant commitment compared with most other states.

66 These figures would be approximately equal to between €212,212.00 and €1.60m (RAND Europe calculation using average historical exchange rate of US$1 to €1.06106 for the year 2002 (www.oanda.com)).

67 These costs are incurred by the state administration, and not by healthcare providers.

68 The Pennsylvania Patient Safety Authority (PSA) is an independent, non-regulatory agency charged with identifying patient safety problems and implementing solutions to improve safety and reduce harm from medical errors.

69 This figure would translate to approximately €3.22m a year (RAND Europe calculation), based on the historical exchange rate of US$1 to €0.80510 on average for the year 2004 (www.oanda.com).

70 Hanlon and Rosenthal (2007).
The Pennsylvania Patient Safety Authority’s **Patient Safety Reporting System** (PA-PRS) is a safety education and learning resource that analyses a large number of reported events (approximately 200,000 in 2006), with an average cost of US$17 per report. PA-PRS provides feedback to providers via safety advisories and an annual report. So far, they have published about 140 articles with recommendations on how to avoid specific types of harmful events. An outside contractor identifies trends in the adverse event and near miss data submitted electronically to Pennsylvania Patient Safety Authority by hospitals, ambulatory surgical facilities, birthing centres, and certain abortion facilities. For the Pennsylvania Patient Safety Authority, narratives are critically important to initiating change in systems and providers’ behaviour.

Pennsylvania Patient Safety Authority does not have the authority to regulate healthcare organisations. Instead, the authority provides detailed reports on adverse events to individual facilities and aggregates information into regional and state-wide reports. It also develops tool-kits and other educational materials on patient safety principles and root cause analysis, including a CD-based training course. It communicates both through its website and presentations at hospitals, state and national conferences, and patient safety organisations. It is working with the Health and Hospital Association of Pennsylvania to develop curricula to inform hospital board members about the importance of patient safety. Finally, Pennsylvania Patient Safety Authority distributes a “Speak Up” brochure using information developed by the Joint Commission that encourages patients to ask questions to help ensure their safety.

Pennsylvania’s experience highlights **five** important lessons.

- By converting preventable errors and hospitalisations into avoidable costs, states can make a business case for patient safety.
- State officials can elevate patient safety on state agendas by integrating it into other policy initiatives.
- Demonstrating the impact of patient safety initiatives continues to pose a challenge.
- Patient safety initiatives need to be tailored to reflect the unique circumstances of each state.
- It is important to note that, as the authors of the Pennsylvania Report state: “it may be necessary to have fully developed incident reporting systems in place for several years before results can be evaluated”.

Other US examples for the cost of maintaining reporting systems come from the Medication Error Reporting Program and the Toxic Exposure Surveillance System. According to the **Medication Error Reporting Program** and the MedMARx program (receiving 7,000 reports annually) the establishment of a national system is expected to require a very large financial, technical and expert manpower commitment: reporting only 10% of the 5m serious and close-call error-related adverse events estimated to occur annually in the US is 15 times the number of errors processed by the Aviation Safety Reporting System (with current cost of US$70 per case).

By contrast, the **Toxic Exposure Surveillance System** (TESS, sponsored by the American Association of Poison Control Centres) is a more affordable example of how patient safety
can be improved. It serves 98.9% of the US population (based on information from 64 centres). Of 2,267,979 reports filed in 2001 in TESS, 167,014 (7.4%) were therapeutic errors, and 35,646 (1.6%) were adverse reactions to drugs. Reporting is non-punitive, confidential, and independent. A single nationwide toll-free number serves as the point of access; data are uploaded in real time, permitting immediate surveillance of sentinel events and unanticipated trends or clusters of cases. Clinical guidance provides a reporting incentive. TESS is used by regulatory agencies to assess product safety but has not realised its potential usefulness for post hoc expert analysis of adverse events and systems-oriented recommendations.

For comparison, the Australian Safety and Quality Council, directly funded by the Commonwealth Government, received the following budget in 2001 (see Table 3.13), allocating A$22m over four years to the institution (approximately €12.73m).\(^1\) To these, state and territorial governments committed a further A$33m over the same five-year period (approximately €19.09m).

### Table 3.13 Australia’s Quality and Safety Council’s five-year budget

<table>
<thead>
<tr>
<th></th>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
<th>Year 4</th>
<th>Year 5</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data and information</td>
<td>1,350</td>
<td>3,900</td>
<td>3,750</td>
<td>2,550</td>
<td>2,050</td>
<td>13,600</td>
</tr>
<tr>
<td>Standards and accreditation</td>
<td>360</td>
<td>1,500</td>
<td>3,800</td>
<td>3,200</td>
<td>2,700</td>
<td>11,560</td>
</tr>
<tr>
<td>Consumer feedback and participation</td>
<td>490</td>
<td>900</td>
<td>1,350</td>
<td>1,000</td>
<td>750</td>
<td>4,490</td>
</tr>
<tr>
<td>Cultural change</td>
<td>2,600</td>
<td>8,650</td>
<td>6,300</td>
<td>4,900</td>
<td>3,900</td>
<td>26,350</td>
</tr>
<tr>
<td>TOTAL</td>
<td>4,800</td>
<td>14,950</td>
<td>15,200</td>
<td>11,650</td>
<td>9,400</td>
<td>56,000</td>
</tr>
</tbody>
</table>

SOURCE: Gardner et al. (2002)

Although slightly out of date, the study by Garner et al. (2002) of the patient safety policies, institutional frameworks and initiatives in the UK, US and Australia reports the following data on patient safety improvement expenditures (see Tables 3.15 and 3.16).

### Table 3.14 Incident costs and government patient safety investments

<table>
<thead>
<tr>
<th></th>
<th>Cost estimate of preventable incidents</th>
<th>Estimated annual deaths –range</th>
<th>Patient safety investment</th>
<th>Canadian dollars</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>A$867m</td>
<td>10-14,000</td>
<td>A$141m</td>
<td>C$120m (€81.1m)</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>£2,000m</td>
<td>25,000</td>
<td>£47m</td>
<td>C$117m (£79.08m)(^1)</td>
</tr>
<tr>
<td>United States</td>
<td>US$17,000m</td>
<td>44-100,000</td>
<td>US$60m</td>
<td>C$95m (£64.2m)(^1)</td>
</tr>
</tbody>
</table>

SOURCE: Gardner et al. (2002)

NOTE: 1These are approximate figures using the historical conversion rate of C$1 to €0.67587 on average for the publication year 2002 (www.oanda.com).

\(^1\) (RAND Europe calculation based on the historical conversion rate of A$1 to €0.57856 on average for the year 2001 (www.oanda.com).
### Table 3.15 Government’s per capita patient safety investments

<table>
<thead>
<tr>
<th></th>
<th>Annual investment</th>
<th>Population</th>
<th>Per capita</th>
<th>Canadian $ per capita</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>A$141</td>
<td>19m</td>
<td>$7.42</td>
<td>C$6.38 (€4.312)</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>£47m</td>
<td>59m</td>
<td>£0.86</td>
<td>C$2.13 (€1.44)</td>
</tr>
<tr>
<td>United States</td>
<td>US$60m</td>
<td>273m</td>
<td>$0.22</td>
<td>C$0.35 (€0.24)</td>
</tr>
<tr>
<td>US with private</td>
<td>US$119.7</td>
<td>273m</td>
<td>$0.44</td>
<td>C$0.70 (€0.47)</td>
</tr>
</tbody>
</table>

SOURCE: Gardner et al. [2002]

NOTE: ¹These are approximate figures using the historical conversion rate of C$1 to €0.67587 on average for the publication year 2002 (www.oanda.com).

### 3.4.2 Evidence on economic benefits of systemic interventions

Although these costs are substantial, Wendin (2008) suggests that the benefits anticipated from system-level patient safety-improving strategies can exceed them, leading to net financial gains and reduced prevalence of adverse events. Wendin conceptualises the financial implications of patient-safety improvement strategies as occurring both on the revenue and expense side of health facilities’ budgets (see Figure 3.8).

![Figure 3.8 Key financial impacts of adverse events](image)

Wendin’s cost-benefit analysis on the merit of investing in interventions addressing adverse events associated with obstetric trauma, bedsores, surgical site infections, catheter-related bloodstream infections, MRSA and drugs (discussed in more length in Chapter 4 Projections) suggests that the implementation of strategies to improve patient safety can lead to a reduction in medical error rates of between 50% and 96%, and a net savings €50,078 to €1,544,594 for a 300-bed hospital (or from €116,849 to €3,861,458 for a 700-bed hospital).
Although a simulation exercise, Wendin’s work is the strongest evidence of the benefits of implementing patient-safety improving mechanisms, given that the number of surgical procedures needed to show a statistically significant difference between two incidences of rare events is enormous, as Clarke (2007) points out. However, the coherent inclusion of these diverse strategies in a national patient-safety framework can be expected to be the key bottleneck for achieving such results.

Other benefits that have not been, and are hard to be, quantified, from establishing national systems, include: the alignment of terminology, tools and classification systems internationally; and the rapid dissemination of successful strategies (see Figure 3.9). Moreover, many of the functions inherent in a mandatory reporting system are parallel to current state functions in licensure and certification units (e.g. complaints, desk reviews, and investigations), so the introduction of a reporting system does not require a sizeable influx of new positions, but depends on adjusting existing workloads and roles and responsibilities.

Mandatory reporting programmes also offer an opportunity to enhance the effectiveness (and cost efficiency) of a state’s overall quality oversight programme. Integral to the design of such a system can be its capacity to automate data collection and transfer processes, allowing concurrent review by central and regional office staff; a direct interface with hospitals for receipt of supporting information and root-cause analysis; and the capacity to interface with other functions. Hence, the reporting system improves the functionality of other oversight activities while satisfying regulatory requirements for incident reporting, and streamlining the flow and analysis of information, even if little is known about the impact of mandatory reporting programmes on patient safety.

Figure 3.9 An example of an integrated safety, quality and risk information and incident management system
CHAPTER 4  Key Stakeholder Interviews – Methodology and Results

4.1 Overview and research setting
To complement the rather sparse relevant data at the EU level, our assessment of the impacts relied partially on data collected through qualitative techniques, primarily using semi-structured in-depth interviews with a ‘non-probabilistic purposive’ (i.e. not random) sample of key experts in the area of Patient Safety. The research focused on the geographical area of Europe.

4.1.1 Study sample: The participants
All members of the High Level Working Group on Patient Safety (n=48) were emailed to invite their participation in our study. The list of members was made available to us by the EU Commission. Among these members, covering all EU-27 countries except Belgium as well as supra-national organisations, we interviewed 32 individuals in total. Twenty-four interviews covered 16 different member states; and eight interviews covered 8 different organisations. More specifically, for 5 different European countries, we interviewed two different respondents and for 1 member state, we interviewed three different respondents. In addition, we interviewed two individuals from a second list of four individuals not already on the original list provided by the Commission. One individual was suggested to us from a participant but we were unsuccessful in securing their participation through this snowballing method. Although our response rate was near 63%, we were unable to interview individuals from the following EU-27 countries: Austria, Czech Republic, Estonia, Italy, Luxembourg, Malta, Poland, Romania, and the Slovak Republic. A league table of experts interviewed, and their respective institutional affiliations, is included in Appendix B. (For full names to match the initials of the experts and organisations quoted below, see Appendix B.)

4.1.2 Data collection: Semi-structured in-depth interviews
Data was collected through individual, audio-taped interviews with all consenting participants. There was one exception to consent to record the interview, in which case we

72 The main initials of experts used in the following text are as follows: HBL; SO; BB; GJ; RN; IS; IC; EC; JV; TT; PF; NE; and KH. The abbreviations of organisations used include: WHO; PGEU; OECD; HOPE; EPF; EFN; CoE; SIMPATIE.
handwritten notes were taken to capture the participant’s responses. Interviews were conducted in a private, self-enclosed room, by telephone. As per our verbal (but recorded) consent agreement, all recordings will be destroyed upon completion of the study.

Each interview lasted between 40 minutes and an hour, depending on participant availability. The in-depth interviews were scripted (i.e. semi-structured) but also allowed for the adoption of appropriate probes. Questions were directed at two aspects of patient safety: the scope of the problem and the social and economic impacts of all three Areas for Action that the Commission wishes to introduce. That is to say, we employed two types of questions: namely, ‘informational’ questions to facilitate participants’ description of the level and types of adverse events in their country (if known); and ‘reflective’ questions to investigate the meaning (or impact) of, and factors driving, these impacts from the perspective of the expert participants.

The interviewees received the interview template protocol (which is included in Appendix C) at least one week before the scheduled date of the interview, and sometimes longer. The members of the High Level Working Group on Patient Safety were already familiar with the proposed policy areas for action in Europe as the proposal is the result of the Group’s work. We therefore only provided a brief summary (one paragraph) of the relevant proposal to introduce each policy area for action preceding our interview questions.

### 4.1.3 Data analysis

Discourse, or content, analysis will be performed on the qualitative data from the Key Informant Interviews. This analytic method accepts the interpretation that occurs between the narrator and listener. However, unlike narrative analysis, the presence of the researcher in the research ‘interaction’ will not be explicitly reflected upon and interpreted as part of the data analysis process. More specifically, the data will be analysed broadly, paying attention to emerging themes, patterns and issues that are content-specific and/or cross-cutting. The data will be explored for both similarities and differences in opinion among the Expert Participants. In light of the short project time-line, we have chosen not to employ the more rigorous ‘constant comparative model’ of more standard modes of qualitative data analysis such as coding and categorising based on either Glaser’s Grounded Theory Method,73 or Giorgi’s phenomenological analysis method.74

### 4.2 Summary of key issues and cross-cutting themes

Here we present the main findings of our Key Informant Interviews, grouping the qualitative data around two main dimensions: first, the scope of the problem and second, issues that cut across all three policy areas to improve patient safety. In terms of the scope of the problem: we found four common issues and themes and they are as follows: (1) patient safety is difficult to measure, especially the costs; (2) patient safety for cross-border healthcare is unknown and not formally supervised; (3) the problem of patient safety is

73 Glaser and Strauss (1967).
74 Giorgi A (1985) (pp. 8-22).
event-specific and multi-levelled in nature; and, (4) the problem of patients’ safety in a country in Europe is no better and no worse than in others.

In terms of the cross-cutting issues and themes that emerged, we found that there were 3 main points that many respondents emphasised in their assessment of the effects of the three policy areas to improve patient safety – usually in response to the underlying factors driving the social and/or economic impact. First, a (positive) ‘safety culture’ is a precondition for action, an integral component of patient safety action and a driver of action impacts. Second, patient safety policies, actions and their impacts are driven by the political context, in terms of timing of the topic on the political agenda. And third, media is an underlying factor driving the social and economic impacts of RLS and redress mechanisms because negative media can hinder a better patient safety culture and positive media can support achieving a better patient safety culture. That is, what information is communicated to the public and how (e.g. the high number of incidents versus the implementation of strategies used to mitigate harm) will be a driver of the impact of policy actions to improve patient safety.

Although the findings we present reflect, overall, a general consensus among the 32 Experts in the field of patient safety, and we chose the most useful and relevant quotes in support of the emerging issues and themes shared by the majority, we end this chapter by presenting the unique responses of three of the 32 interview participants who raised an issue that was not discussed by another respondent. The main reason for including these three distinct issues, as opposed to themes raised by a minority of experts in the High Level Working Group on Patient Safety, is to demonstrate that unique voices existed within the group which might be expected to produce similar answers based on shared values and beliefs about the proposed actions to improve patient safety. In so doing, the authors seek to shed light on the multiple perspectives and variability of expert opinion with a view to challenging hidden assumptions and also provoking questions for further debate and research.

4.2.1 Emerging issues and themes – Scope of the problem

A. Patient safety is difficult to measure, especially the costs

There is strong consensus among most respondents (Germany, PGEU, OECD, EFN) that the question of the scope of the problem is very difficult to answer for three reasons. First, it is difficult to actually count the number and especially the cost of adverse events, in part because there are “a lot of methodological hurdles” (Germany) and an “accumulation of assumptions” (OECD) that are not very scientific. One respondent summed up the situation well with the statement: we “don’t know the zero point” (EFN). This statement was made by respondents irrespective of whether their country had conducted its own original study on patient safety. The respondent from WHO confirmed that the full cost of the adverse events is only calculated for 5% of the 42 member states in the European region, and partially calculated for 8%. In addition, of the few national level studies that

75 Historically, the concept of ‘iatrogenic harm’ (i.e. healthcare-related injury) originates in the critical work of Ivan Illich in 1976. At that time, Illich’s comprehensive review of the ‘limits of medicine’ was highly contested and refuted by the American Medical Association, in part because of its highly political implications.
do exist, it is difficult to compare the data because of differences in indicators such as hospital days versus hospital stays (France).

Second, research on patient safety is “highly hospital driven” (OECD), which misses errors in other settings such as community care and ambulatory settings (PGEU, EPF). As the Dutch respondent explained, while the HARM study did look at adverse events outside of the hospital, it investigated only medication errors in primary care and not other causes of adverse events. Spain, however, is one exception: in addition to the national study of adverse events in a sample of 24 hospitals, a similar study was performed in primary care with results recently published (and reviewed in Section 3.3.2). The problem with such a heavy focus on the hospital setting is that the focus artificially narrows the full scope for understanding what patient safety really is: that, “it’s a public health issue” (EPF). Patient safety is more than just medical treatment, it “relates to correct product information and labelling of food products” since, for example, food allergies can be a matter of life and death for some individuals (EPF). The hospital-driven focus of research is reinforced by mandatory reporting policies that obligate a duty to report adverse events in hospitals only, such as in Denmark (HBL), or in Portugal where monitored notification of HAIs centre around only five areas of hospital care (intensive care unit (ICU) infections, surgery infections, antibiotic resistance, haemodialysis, bloodstream infections, and neonatology). We note the discussion in the literature regarding the role of voluntary vs. mandatory reporting which some of the respondents also noted, but which we will not discuss in detail here76.

Nevertheless, while many respondents acknowledged or criticised this issue, only one respondent from the UK articulated clearly the main reasons and justification for hospital-focused patient safety initiatives: namely, (1) the culture of managing risk is older and more established in hospitals and (2) there is a higher potential for risks in patient safety and the consequences of adverse events are more severe because of the critical nature of healthcare provided in hospital settings where the health of individuals requires more technical or potent therapies.

And (3), it is very difficult to make a fair economic impact assessment “because the real economic impact is not just an extrapolation of ‘let’s get rid of all the adverse events’,,” as one respondent stated. That is to say, the existing literature and work done on patient safety makes “very gross assumptions about the overall impact in terms of death that will be avoided” but rather should look at “the potential of reducing them” and then “benchmark impacts based on the country with the lowest [complication rate, or wrong site surgery rate]”. Unfortunately, “there is very little work done or literature published on what are the most risky areas of patient safety where investments would come up with the best results” (OECD).

In general, our qualitative data revealed that the extent of the problem of adverse events and near misses was understood, or indirectly assessed, either by the number of incident reports that were received by the various Competent Authorities, such as hospitals, health insurance companies, Ministries of Health and even patient advocacy groups; or by the number of complaints registered in the country’s redress system(s). That is to say, many

76 Billings (1998); Cohen (2000).
RAND Europe

51

respondents (e.g. UK, Denmark, Latvia) answered this question by providing concrete data on the numbers of reports or claims that had been submitted as a proxy for knowing the incidence of adverse events. Ultimately, whether or not different countries across the EU vary in the extent of the problem of adverse events and near misses, “people agree that there is a problem” and hence patient safety has become a targeted issue over the last 4 to 5 years in the majority of countries, for example in France, Germany, Denmark, Slovenia and Bulgaria.

B. Patient safety for cross-border healthcare is unknown and not supervised

In general, exact data on cross-border healthcare is unknown, or at least very difficult to estimate, but respondents believed that the numbers were quite low (a few thousand) (Sweden, Netherlands, Finland, UK, Denmark). Our Swedish respondent estimated that about 2,000 Swedish patients receive care abroad each year but there was no mechanism in place to monitor this activity. Lithuania estimates that less than 1% of the population receive healthcare abroad, as the majority of Lithuanians face a significant economic barrier to doing so. Nevertheless, respondents were unable to provide any data on the scope of the problem of patient safety incidents for this sub-population of mobile (cross-border) patients.

Indeed, the SIMPATIE project leader agreed that there is only “a few figures on cross-border” healthcare and that the numbers are “insignificant”. More specifically, 0.01% of global expenditures in healthcare are spent on cross-border services. But, as our respondent noted, these numbers may change with an ageing population contributing to the growing numbers of retired individuals spending more of their time in countries other than their own, particularly North–South European migration. According to one UK respondent, patient mobility involves some private health tourism, namely for those services not covered by the NHS (e.g. dentists, cosmetic surgery etc). And, as he explained, most ‘cross-border’ care (estimated to be 50,000 per year) is limited to the borders of the component countries. There is very little outward patient movement from the UK to the European continent (NE). By contrast, workforce mobility is higher and the UK does employ a large number of medical professionals from the EU (in the 1,000s). This changing workforce demographic could put patient safety at higher risk with the increasing potential for medical error due to miscommunication between non-UK health professionals and UK patients.

More importantly, it appears that there are no established mechanisms for (1) supervising when a country’s patients are treated abroad and (2) monitoring the extent of adverse events among this sub-population of mobile patients in order to understand any differences in treatment quality for foreign-born patients. Indeed, as one respondent from OECD claimed, there is no clear policy either for member states or for the EU Commission itself on cross-border care and patient safety. Thus, it was suggested by the respondent that one area of cross-border patient safety where the Commission could provide more added value above individual member state action is to provide better information on issues such as different prescriptions for the same illness across different European countries. By comparison, the Health Services Directive is an example of how EU action can be taken on an important public health area (although its impact is as yet unclear and has not been analysed). However, as a respondent remarked on the issue of EU
work to improve cross-border patient safety, there is a risk that further attention on patient safety in this proportionately small area of healthcare might create an imbalance away from national-focussed patient safety with broader public health benefit.

Some respondents referred to the results of the MARQUIS project, which provides qualitative evidence on the factors that could contribute to a higher risk of adverse events among this sub-population of cross-border patients. When we probed these experts on the question of how much greater risk to patient safety does cross-border healthcare present, one respondent from Denmark replied that there is “not much greater risk”. Again, this comment reflects the fact that there is currently no systematic method for providing quantitative data in this specific area relevant to patient safety.

C. The problem is event-specific and multi-levelled

The difficulty of accurately measuring the extent of the problem of patient-safety incidents is related to the issue of adverse event specificity. Two respondents repeatedly emphasised the need to “focus on very specific safety risks” and that, to accurately understand the extent of the problem, it is “important to separate which type of error” or adverse event is in question. For example, in the case of medication safety, there are errors at the prescription level, the dispensing level and the administration level, and the percentage of ‘medication errors’ will differ between these levels of medication provision. Interestingly, both of these respondents belonged to supra-national organisations: namely, the OECD and the Pharmaceutical Group of the European Union. As one respondent pointed out, while there may not be much research done on patient safety per se, there is sufficient evidence in the medical literature on the number and cost of particular kinds of “concrete” adverse events: for example, bed sores, post-operative infections or wrong site surgery.

The key point raised here by the need for specificity in patient safety research and the associated need for “more in-depth analysis of the level of error” is the apparent disconnection between the medical literature and political rhetoric. As some of our respondents noted, patient safety in the former case is highly specific according to type of adverse event (e.g. bed sore, wrong site surgery); whereas in the latter, the political rhetoric of patient safety is a conglomerate of adverse events. The OECD respondent emphasises that, in reality, patient safety is “a heterogeneous basket of adverse events”. Importantly, this disconnect has implications for conducting comprehensive impact assessments of actions to improve patient safety because, as some interviewees suggested, there is a real risk that the inherent heterogeneity of adverse events is lost at the political level where it matters most in terms of understanding the real economic impact.

Finally the evident complexity of patient safety, in terms of its multiple levels and multiple types, also has implications for cross-national comparisons of member state actions to improve patient safety through the three proposed policy areas, as per our grouping exercise (see Section 4.3 below). For example, the concept of patient safety in France is separated into different sub-components and, even though France has “lots of data and reporting on infections”, it is “not good on other parts and overall” (HOPE). The multi-levelled, highly event-specific problem of patient safety underscores the inherent limitations of applying a standard scoring scheme to all countries in the European Community.
D. The problem in one country is no better and no worse than in others

The extent of the problem of poor patient safety – how often adverse events occur and what kinds – is often viewed by country experts as being similar to that of other countries in Europe and internationally. A number of respondents claimed that the number of adverse events would be “no better and no worse than these other countries” where studies have been conducted (SO). For countries that have not yet conducted their own national-level study on patient safety (e.g. Republic of Ireland, Slovenia, Finland), or for those countries where studies are in progress (e.g. Germany, Denmark, Sweden), respondents felt that their number of adverse events was the same as for other healthcare systems. That is, in the words of our Slovenia respondent, “near the average of the EU”, or at least not very different from “other international experiences”.

And yet, ironically, we know that, at the level of implementation, there is “a variety of different things in place”. And, perhaps more problematically, “everybody thinks they have the best system and when they want to talk to each other, it seems that everyone has a different language when it comes to patient safety” (Raeve, EFN). Although it is clear from the interview data that patient safety is, for the most part, not being neglected and almost every EU-27 country is taking care of the problem, as one respondent noted, actions taken are done “not in a coordinated way”. The authors would suggest that one main reason for this apparent expert observation may be due to the recent emergence of the area of patient safety in the political domain, where only a few member states have voluntarily taken on leading roles in the key policy areas proposed by the Commission. The Commission, we suggest, could provide a suitable platform upon which such leadership can be more clearly coordinated across all member states.

Table 4.1 summarises the interview data revealing the extent of empirical knowledge among countries or organisations in Europe on the scope of the national problem of adverse events and near misses.
Table 4.1 Mapping of the extent of empirical knowledge and evidence on patient safety by country or organisation based on interview data

<table>
<thead>
<tr>
<th>No original study on patient safety</th>
<th>Original study on patient safety in progress</th>
<th>Original study on patient safety completed</th>
<th>Other studies or measurements relevant to PS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Republic of Ireland</td>
<td>Germany (end 2008)</td>
<td>PGEU (medication safety)</td>
<td>Germany (cross-national comparison of healthcare systems, end 2008)</td>
</tr>
<tr>
<td>Slovenia</td>
<td>Sweden (national survey, summer 2008)</td>
<td>Netherlands (HARM and Engo-Nivel)</td>
<td>Hungary (healthcare system survey)</td>
</tr>
<tr>
<td>Lithuania</td>
<td></td>
<td>UK (Vincent et al., 2001)</td>
<td>Latvia (national analysis of claims from patients, mostly prison data)</td>
</tr>
<tr>
<td>Finland</td>
<td>Denmark (T Schöler 2000)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Greece</td>
<td>OECD (comparing administrative databases on PS indicators)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bulgaria</td>
<td>Spain (ENEAS 2006 and APEAS 2005)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cyprus</td>
<td>France (prospective national survey of in-patient adverse events in 71 hospitals)</td>
<td></td>
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</tbody>
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SOURCE: RAND Europe

4.2.2 Emerging issues and themes – Cross-cutting the policy areas

A. Culture change is a pre-condition for action, an integral component of patient safety action and also a policy outcome

A resounding common theme that emerged among the majority of respondents was the issue of changing culture. The concept of culture, particularly the change of it, was invoked by many respondents in the following ways: (1) as a pre-condition for policy action to establish effective reporting and learning or to establish fair redress mechanisms; (2) as an integral feature of patient safety as a policy-relevant issue; and, (3) as a positive outcome (or social impact) of implementing a particular policy area to improve patient safety. In other words, ‘culture’ is a prominent social factor that drives the expected benefits of policy action to improve patient safety, and it also creates the capacity to act at the political level.

Changing culture was seen by several respondents to be a necessary first step towards, a precondition for, taking any policy action to improve patient safety. As one respondent from the Netherlands articulated, culture change is fundamental to the uptake of any form of healthcare innovation which can be divided into three groups: the ‘early adapters’; ‘the followers’; and the ‘lags’ and culture change is needed most for the latter group to get some physicians who are “stuck in their ways” “to get up to speed on more transparency” through patient safety RLSs (BvB). Similarly, culture change is a pre-requisite for establishing no-fault liability systems of patient safety redress (BvB). Indeed, as one of the

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Republic of Ireland respondents suggested, culture is an underlying factor driving the negative economic impact of the country’s redress mechanism because “culture means you always favour the system you are familiar with” and so a move away from litigation to more disclosure in a no-fault liability system is a threat to the stability of the current culture of Irish healthcare professionals.

Culture was also described as being an integral component of patient safety as a political issue. For example, a respondent from the Netherlands said that “patient safety has much to do with culture” insofar as the culture of patient safety allows people to speak about incidents. The respondent suggested, moreover, that “reporting is a good tool to change culture”. Similarly, when asked about the extent of the problem of incidents and adverse events in her country, a respondent from Hungary claimed at the outset of the interview that “culture is the most important element in policy” on improving patient safety. Further evidence of this theme was provided by a number of respondents who highlighted the fact that their country’s policy on establishing an effective RLS included activities oriented to changing culture, or rather, to establishing a ‘patient safety culture’ as part and parcel of the first action area (establishing an effective RLS), such as was the case in Germany. Indeed, a respondent suggested that the positive social impact of Action Area 1 is driven by the much needed culture change “in the political understanding of the RLS”. In terms of the relative rank of the three action areas in relation to the greatest economic and, separately, social impact, one respondent ranked ‘culture’ at the top (even though culture is not a proposed policy area for action). When probed further about the three specific areas of action in the interview protocol, the respondent associated culture with the first area of action, reinforcing the inseparability of culture from a policy action to improve patient safety.

Finally, culture change was not only an underlying driver of impacts, but was also viewed as a primary benefit of policy action to improve patient safety. The positive social impact of establishing a RLS in Denmark is, in large part, both driven by culture and leads to culture change. According to this Danish respondent, “the change in culture is visible”. When asked for possible evidence of this policy impact, the respondent suggested that anecdotal evidence shows that, in hospitals where there are few reports of adverse events, there are divisions among staff and that these divisions have been attributed to poor leadership. By contrast, established RLSs in other hospitals have had the noticeable impact of a new culture among hospital staff, marked by fewer divisions.

We note here that the importance of culture change, or culture shift, raised by our respondents can be found in the literature among the seven identified strategies for reducing hospital errors in the US healthcare system78.

B. There are 6 different kinds of culture implicated in actions to improve patient safety

Our interview respondents described in more detail the different types of ‘culture’ that they felt need to be changed to improve patient safety, or at least need to be considered in any action at the policy level to this end. Generally, respondents suggested that both the culture of professionals and the culture of senior healthcare and hospital managers needed

78 McFadden et al. (2006).
changing in order to facilitate the creation of a new blame-free culture which would be more conducive to professionals reporting, and learning from, adverse events. Such culture changes ultimately aim to embed an overarching safety culture. The corollary to changing the culture of professionals is the integration of a more patient-centred culture, one which focuses not only on the rights of patients but also on their responsibilities to their own healthcare delivery. Finally, it was suggested that the culture of individual patients is one social factor that will determine, and underlies, the distributional effects of policy actions to improve patient safety as it is known that the cultural background of a particular patient underlies that person’s relationship with medicine and clinical practice.

First, many respondents felt strongly that the culture of professionals (of doctors and nurses) needed to be changed to improve patient safety. More specifically, culture change is needed “in the trust between professionals and patients” in terms of professionals’ attitudes and beliefs about care delivery and how to share the responsibility of care. But, in order to have a culture of “trust-based partnership”, like in the Nordic countries, the EPF respondent emphasised the importance of providing information and training support to all stakeholders, including patient advocacy groups. This point was also repeated by our respondent from Slovenia, where clear information was considered critical to creating “fair relations between doctors and patients” and “better understanding of each others’ expectations”. As a result, this culture change (mediated by information) “will be a great benefit to society”.

Second, a few respondents also felt strongly that the culture of senior healthcare and hospital managers (i.e. leaders) must be changed to improve patient safety. More specifically, one respondent argued that culture makes it easier to move to a patient-safety RLS from a product-oriented parallel system of pharmacovigilance and this “means changing management culture” (CoE). Indeed, our respondent from the Netherlands claimed that the main problem for reporting adverse events is the current culture of the Board of Directors of Hospitals, stating that “despite the fact that reporting and learning is the responsibility of the Directors of Hospitals, they believe the responsibility for patient safety is an issue for doctors who are not true employees of hospitals but rather function like free enterprises with little cooperation [between hospital management and care providers]”. In the Dutch context, such a false belief held by managers with respect to their divested responsibility presents a barrier to improving patient safety in Holland.

Embedded within the concept of culture change among senior healthcare and hospital managers is the important role of both managerial and clinical leadership in improving patient safety. This point is confirmed by another respondent’s comment that the relative benefits of a RLS to healthcare systems in general depend on the existing “culture of professional protectionism” (CoE). More specifically, leadership was highlighted by the two respondents from the Republic of Ireland as an important concern for the current review of the country’s RLS.

A third type of culture was mentioned: namely, the need for creating a “blame-free culture”. As the respondent from Portugal suggested, the costs of implementing an effective RLS will “not be so much if you can ensure that professionals know they will not be blamed [for reporting]”. Conversely a “litigious culture”, such as in the Republic of Ireland and the UK, is understood to have contributed to the great negative economic
impact of the countries’ redress mechanisms, and much of this impact has been attributed to the fact that tort-based (litigious) redress is antithetical to creating a ‘blame-free culture’.

The above culture changes implicate a fourth type of culture that was viewed by the majority of respondents to be the culture most at stake in actions to improve patient safety: namely, it is critically important to embed a “safety culture” within and between member states of the EU. Our respondent from Finland, for example, felt that it is only by entrenching a safety culture that the positive economic and social impacts of patient safety action areas will be ensured both in the near and far futures. In the words of a German respondent, “the patient safety culture creates trust and confidence and these factors will create a decrease in costs”.

Repeated descriptions of patient engagement and transparency in the doctor–patient relationship would arguably constitute another, fifth, “culture” related to health literacy in patient-centred care. Respondents suggested that such a culture was needed alongside a change in care providers’ culture in order to maximise the positive social and economic impacts of patient safety action, especially establishing a RLS. Although not explicitly referred to as a specific “culture,” the respondent from Lithuania, like others, argued that “public awareness and understanding of their rights and responsibilities in the healthcare process” (emphasis in the original) is one of the underlying factors driving the impacts of the RLS as well as the redress mechanism in the country.

Finally, the social impact of policy actions to improve patient safety will be influenced to some degree by individual patient cultures. That is, the anticipated benefits of establishing RLSs, in particular, will vary according to the different cultures of various patient populations. As the expert from WHO explained: “Reporting can importantly contribute to health literacy, but it may also increase discrimination, when related to culture and social structures, if inappropriately addressed.” A more specific example was given by the Council of Europe respondent who suggested that in some cultures, like among the Roma, complaining is seen as ‘unfair’ and so, as the respondent suggested, some Roma might be ashamed by honour from according ‘blame [to] someone’ like a doctor using a RLS that is intended to improve patient safety. Thus, unless specific “culture-adjusted language” is integral to Action Area 1, RLSs could have some unintended consequences of negative social impact on particular groups, rather than be “especially protective of them”.

C. Patient safety is a high priority on the political agenda for most countries, but the political nature of the issue can present barriers to assessing action impacts

It is clear from many of the respondents that patient “safety is a highly political policy-driven agenda”. According to our respondent from WHO, patient safety is indicated as being “high on the agenda” for 97% of the 42 member states in the WHO European Region.

Our results show that the reasons for patient safety becoming a political priority can be quite dichotomous, which the authors note may reflect vastly different political backgrounds of healthcare services in the different member states. More specifically, our respondent from the Republic of Ireland confirmed that patient safety has also been a “very high political priority” there for the past few years (EC). However, the reason for this was not a positive one: as the respondent further explained, “this has been mainly due to a few cases of high profile system failures in recent times and these have raised the
political issue of the need to improve patient safety”. By contrast, positive action has been taken in other countries to deliberately “put patient safety on the political agenda” (G), such as in Germany. Since 2002, there have been several events in Germany (e.g. congresses and annual meetings of German doctors) leading towards the creation of the German Coalition for Patient Safety in 2005. The respondent described the German Coalition as constituting the “last political step” and further explained that these political events “were the first part of establishing reporting and learning mechanisms”.

The Danish Patient Safety Society is another concrete example of the results of patient safety coming onto the political agenda in 1999 which, as our respondent explained, followed a conference related to the British Medical Journal coverage of a crashed aeroplane. The respondent suggested that the setting of patient safety as a political priority had a positive effect: “By bringing together all the key stakeholders (doctors, politicians, civil society, etc) into a prolonged and formalised collaboration [ie the Danish Patient Safety Society], collaborations could be maintained and concrete actions carried forward.”

The inherently political nature of patient safety rhetoric has implications for understanding the full economic impact of actions to improve patient safety, such as establishing effective RLSs, for three main reasons. First, the political agenda of safety “results in new forms of institutions that in some countries seem to be emerging without attention to existing data sources and existing institutions”, as our OECD respondent noted. The implication of this statement is that resources are sometimes being unwisely allocated due to a lack of coherence in policy and institutional arrangements and hence the economic impact may be greater than it ought to be. However, not all countries create new institutions for patient safety when the issue is raised on the political agenda. For example, there is no specific authority for patient safety in Finland, rather there are several different public authorities working across sector on the same aim of improving patient safety.

Second, the problem of policy and organisational incoherence is compounded by the fact that the terms ‘safety’ and ‘adverse events’ are “largely ambiguous in interpretation” at the political level, according to the same respondent. The authors suggest this ambiguity might explain the inter-country variability in type of action taken and extent of implementation to improve patient safety in Europe and, hence, the difficulty of accurately assessing in a comparable way the economic impact of policy actions.

Apart from policy coherence and conceptual issues, the unwise allocation of resources is also a symptom of very limited attention to “real risk assessment” from a macro perspective of policy-making. That is to say, “there is [currently] a very high emphasis on hospital safety” despite the fact that, as several respondents highlighted, “healthcare is far more than just the hospital industry”. Such a narrow focus on the hospital industry will also determine a country’s assessment of the economic impacts of actions to improve patient safety. Indeed, as the OECD respondent lamented, a country’s “[consideration of] whether the investments made now in the hospital industry are worthwhile when compared to other sectors in healthcare is a highly political rationale that is regrettably not in the policy process”. Reflecting this concern, another respondent remarked that the “knowledge and evidence that are needed for administrative decisions in member states is ultimately a matter of ‘politics’”.
Given the strong role of politics in developing and implementing actions to improve patient safety, several respondents identified added value in EU-level policy action, particularly in developing and using knowledge and evidence at EU level. It was felt by some respondents that ‘politics’ is an arena where EU work can add value specifically “to coordinate cooperation and decision-making on patient safety” such that the impact of actions to improve patient safety will be less affected by the local politics of a country.

Finally, while it was recognised that the social impact of a RLS depends on the “political support” it receives at the national level, our respondent from Denmark claimed that the social impact also relies on the general professional standards and motivation of healthcare workers to continuously improve the standards of patient care.

D. Media: strong support or deadly enemy?
The role of the media is seen by many of the respondents as a key social factor that both drives patient safety onto the political agenda and underlies the economic and social impacts of different action areas to improve patient safety. In particular, as the SIMPATIE project leader noted, media is an underlying factor that drives the negative social impact RLSs and the negative economic impact of litigious redress mechanisms. Moreover, our respondent from OECD commented that the media also plays a role in shaping empirical investigations of adverse events and incidents. In his words, “because we only have a first impression [of the problem of patient safety] and we get this from the media, what is expressed in the media therefore determines the kinds of things that are measured”. The authors would suggest that this perhaps explains the “very high emphasis on hospital safety” given all the recent media attention in many countries to MRSA, C. difficile and other hospital-acquired infections (HAIs).

In the Republic of Ireland, our respondent explained that, in general, “healthcare is the second focus of the media in the country and the highest political agenda in terms of public calls for political change”. Since patient safety is a high priority on the political agenda, as noted above, this remark implies that the impacts of policy actions to improve patient safety will be significantly influenced by the Irish media. As noted above, media in the UK and Republic of Ireland has contributed to the negative social impact of the countries’ tort (litigious)-based redress mechanisms for injured patients.

For most respondents, the media plays an inhibiting role underlying the social impact of RLSs to the degree that media can “create a lack of trust in the healthcare system” when reports on adverse events are “seen as a problem rather than a mechanism for learning from mistakes”, as our respondent from Denmark indicated. Indeed, while redress is acknowledged as being necessary for injured patients in Latvia, the social impact on the public of publishing the numbers of adverse events in the press is “overall a negative process”. Similarly, the respondent from Slovenia commented that ‘bad publicity’ follows when adverse events are made public via the media and this disclosure has negative consequences for the social impact of RLSs.

Unlike most member states, France seems to have a unique relationship with the media in this regard: public dissemination of the reporting of all hospital-acquired infections is done through the national newspaper. As one French respondent noted, the impact of public perception on patient safety is not productive when you communicate a lot of information
on the global data of adverse events, which tends to increase the number of litigation cases for compensation like in the UK. Rather, public communication must be on the implementation of solutions for increasing the quality of care.

The authors here highlight the front page article on Thursday 28 May, 2008, in the Guardian: “Hospital surgery death rates to be made public” which explains that the UK will be the first in the world to publish death rates of patients undergoing major surgery at NHS hospitals in England. While the “desire for openness” is a laudable incentive for public disclosure of surgery-related adverse events in the UK, the authors stress the importance of also publishing the mitigating strategies the government will pursue to improve patient safety. Otherwise, it is clear from expert consensus that such good intentions to create more transparency can have the devastating effect on the public of a ‘crise de confiance’ in the NHS.

Therefore, member states must not only be aware of, but also properly manage, what type of information about patient safety will be communicated to the public through national newspapers in order to ensure that all stakeholders reap the expected benefits from actions to improve patient safety.

4.2.3 Unique responses

A. It is unclear to what extent RLSs will improve patient safety

One of the two respondents from the UK was highly critical of the relationship between RLSs on the one hand and real improvement in patient safety in terms of concrete reductions in adverse events on the other. In response to the question on the economic impact of Action Area 1, the respondent strongly questioned the underlying assumption shared by most experts regarding the long-term cost-savings from the initial investments in this area of action. To support this position, the respondent referred to a 2007 article in the British Medical Journal on the “Sensitivity of routine system for reporting patient safety incidents in an NHS hospital” by Baba-Akbari Sari et al.

The respondent’s critical view of the true effectiveness of RLSs for patient safety was shared by one other respondent, the leader of the EUNetPaS initiative, who commented that “reporting systems in general have been shown to reveal at best only 10% of the reports declaring incidents as ‘adverse events’”. Such critical questioning by only two respondents further highlights the great difficulty in assessing the efficiency and true value of Action Area 1 in terms of its economic and social impacts.

B. The added value from developing and using knowledge and evidence at EU level is questionable

One of the first interviews revealed an opinion that later proved to be distinct from the rest of the responses. In brief, one of the respondents expressed deep uncertainty about the added value of EU level action on all three areas of patient safety. Although some of the other respondents expressed a similar concern and uncertainty about the role of the EU in establishing either effective RLSs or fair redress mechanisms, no other respondent felt

79 Some respondents expressed uncertainty about the value of EU action in Action Areas 1 and 2. However, this concern reflected a misunderstanding of the proposed policy actions and this was clarified for participants by re-stating the purpose of the first two policy areas with the qualification ‘at the national level’ and that only
that rather than developing and using knowledge and evidence at the EU level, “it is better to consider national level, perhaps information could be given from one member state to another, not with European regulation but with exchange between experts”. Intriguingly, the respondent was “not sure if there is a necessity for pooled data at EU level; may be better to communicate with ICT”. In sum, only one of 32 respondents interviewed took such an extreme position in disfavour of EU-level action on patient safety.

C. Gender is an underlying driver of the impact of policy actions to improve patient safety

In response to the question on the social impact of both the RLS and redress mechanisms, a respondent from an EU-level organisation remarked that “it’s a gender issue” and there is a “need to look at the balance” between the male-dominated physicians and the mainly female nursing profession. The importance of gender balance in the healthcare workforce has implications for patient safety to the degree that it is well known that nurses are more likely to report adverse events than doctors who more easily hide adverse event incidents, either because of culture or male attitudes or both. In either case, the respondent felt that gender might be a contributing factor to the low level of incident reporting among male physicians.

The underlying factors driving the social impact of redress mechanisms is “also a gender issue” because “the salaries of females and the [associated] working conditions are much lower” than for males; and this is especially vivid in countries like Romania or Moldavia with poverty-level working conditions for nurses. The consequence of this gender-based working environment has implications for patient safety in two ways: (1) nurses working in poverty situations and needing three jobs to make a living wage are at an increased risk of making more mistakes in the last shift; and, (2) poverty drives frontline healthcare workers away from the healthcare sector, which puts further workforce pressures on the remaining staff with an increased risk to patient safety. Thus, gender and women’s issues is “something that Europe needs to deal with simultaneously” and, despite it being a “difficult issue”, it “needs to be taken into account” that reporting systems and other patient safety mechanisms “need to be built on equality” between the genders in the healthcare workforce, both within member states and between the EU-27. The authors note that this male respondent was affiliated with the European Federation of Nurses which would likely contribute to him having such a unique response on the gender dimension of the healthcare workforce.

4.3 Taxonomy of EU countries working on patient safety, based on interview data

To further facilitate our understanding of the interview results and to obtain some overview measure of how countries can be classified in terms of their patient safety activities, we performed a grouping exercise. The main purpose of the taxonomy (classification) was to create a meaningful frame of reference for the subsequent quantitative analysis, and reveal the clustering of patient safety actions around certain
characteristics that became apparent from our data (literature and interviews). It is not the purpose of the taxonomy to create a European ‘league table’ of patient safety structures and actions. Such a table could be easily misinterpreted, and would cause undue controversy, hence we have removed the names of the countries that fall into each category.

As noted above, we interviewed 32 individuals from 17 different countries and 8 supranational organisations. Based on our interview data, we have grouped a total of 24 EU countries according to criteria that seemed most relevant to the three areas for action that the EU Commission wishes to introduce. Our grouping also includes 7 countries that we did not interview directly but for which we obtained sufficient information from the SIMPATIE project using our criteria, or from several interviews (three or more) in one case. Based primarily on interview data, we have identified five distinct clusters of countries that could be classified into a particular group based on their level of fulfilment of 11 objective criteria. To facilitate comparison across categories by criteria, we use RAG-coloured (red, amber, green) symbols, as follows: a green check mark to indicate full fulfilment of the criteria; an amber wavy double line to indicate partial fulfilment (because the action is, at a minimum, in progress or planned); and a red letter ‘x’ to show that the criteria is not fulfilled. Categories with the amber symbol include countries that are at this level of fulfilment of the criteria, or above.

In using the data from the SIMPATIE project for our purposes here, we wish to emphasise that we encountered three problems. First, the information in the mapping exercise of the SIMPATIE was, in some cases, out-dated as many countries have made notable progress in key action areas since the publication of the SIMPATIE findings. Second, not all EU-27 countries were included in the report of the mapping exercise. And third, we found our criteria to be incompatible with the information provided in the mapping exercise. More specifically, for some countries, the SIMPATIE mapping exercise provided information on some but not all of the different components of the three areas for action, making their inclusion in our grouping difficult with incomplete data on, for example, the existence and nature of the redress mechanisms in a particular country. Conversely, for some countries that we did not interview, the SIMPATIE project provided information on the RLSs and redress mechanisms but not the third area for action: namely, developing and using knowledge and evidence at EU level.

In the top category, we classified 4 countries precisely because they have (1) a national RLS that is blame-free, and (2) the system covers all adverse events rather than only hospital-acquired infections (HAIs), or other event-specific incidence, as in some other member states. In addition, in this top category, all countries are at least in the process of conducting a national study of the problem of patient safety and one of these 4 has already completed such a study. There are 11 other member states that have some type of RLS for improving patient safety either at the national, regional or local levels. Five others have a partial RLS (i.e. not at national level and/or does not include a learning component). Finally, the authors note that the top and bottom groups can be further distinguished from the rest by peer nomination – by experts in this area from other countries who identified the country as an example of the top, or bottom, category.
Table 4.2 Taxonomy of selected EU countries working on Patient Safety Improvement Strategies

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<th>‘Objective’ criteria for country taxonomy</th>
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<td></td>
<td>****</td>
</tr>
<tr>
<td>The country has a well-developed national reporting and learning system (RLS) in addition to local systems</td>
<td>✓</td>
</tr>
<tr>
<td>The country’s RLS is blame-free</td>
<td>✓</td>
</tr>
<tr>
<td>The country’s RLS includes both reporting and learning components</td>
<td>✓</td>
</tr>
<tr>
<td>The country’s RLS is not restricted to specific adverse events (i.e. includes the full range of incidents)</td>
<td>✓</td>
</tr>
<tr>
<td>Patients can participate in reporting to the country’s reporting and learning system</td>
<td>✗</td>
</tr>
<tr>
<td>The country has an established (de jure) 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)</td>
<td>✓</td>
</tr>
<tr>
<td>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</td>
<td>✓</td>
</tr>
<tr>
<td>The country is active in leading initiatives to develop and use knowledge and evidence at either EU or international levels</td>
<td>✓</td>
</tr>
<tr>
<td>The country has an established national institute, or other Competent Authority and it is dedicated to patient safety</td>
<td>✓</td>
</tr>
<tr>
<td>There is currently, or there has been, an evaluation of the existing patient safety system(s) of the country in question for further improvements</td>
<td>✓</td>
</tr>
<tr>
<td>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</td>
<td>✓</td>
</tr>
</tbody>
</table>

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 criterion 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.
Table 4.2 above illustrates the clear differences between the five clusters of countries for which we had sufficient data to include in this grouping exercise. In brief, the main differences between the five- and four-star categories are (1) the five-star category countries have a national RLS that is blame-free, as highlighted in the Commission’s proposed Action Area 1, and (2) the four-star category is the only group of countries that include patient participation in the reporting of incidents.

Similarly, the last two categories can be differentiated by the fact that the two-star category includes countries that are minimally in the process of implementing, or at least have a plan, to establish a national RLS, whereas one-star countries have not fulfilled this criterion. Moreover, the one-star category of countries have only partially fulfilled the criteria of being active in initiatives to develop and use evidence and knowledge at the EU level, compared to the two-star group of countries which are not only members of the High Level Working Group but also participate in one or more of the other known European or international initiatives to improve patient safety.

A. Five-star category
Among the 16 countries, 4 member states can be grouped together as exemplary countries working on patient safety. One of these countries was included based on interview data provided by three or more experts from other countries.

B. Four-star category
Three countries were grouped together as four-star, 2 of which were there on the basis of SIMPATIE project data. This group of European countries was a distinct category because the RLSs included patient reporting.

C. Three-star category
The three-star grouping was the largest one with 8 EU-27 member states included. One of the countries included in this group was assessed as belonging to this category on the basis of SIMPATIE data.

D. Two-star category
The two-star group included 5 countries, of which 2 were grouped according to data from the SIMPATIE mapping exercise.

E. One-star category
Three countries we interviewed belonged to the one-star group as examples of poor country work on patient safety. A fourth country was included in this group because it was mentioned twice by respondents from other countries as an example of poor work on patient safety, but the country was not interviewed for our study.
This chapter presents the assessment of impacts based on qualitative data from our Expert Interviews. The potential economic and social impacts are presented for each of the three policy areas for action, followed by a summary of the relative ranking of these impacts according to our European Patient Safety Experts.

In brief, our interview data revealed the following key impacts.

1. The economic impact of Action Area 1 can be moderate to quite large in the short term but will save money in the long term.

2. There will be multiple benefits to patients, care providers and health systems from establishing effective RLSs, ranging from civic trust, better performance and work environments, saved lives and even money.

3. Fair redress mechanisms reinforce many of the benefits of RLSs for the key stakeholders, but the economic impacts are more unclear as they depend on the type of mechanism in place and the threshold of severity established by a particular member state.

4. Developing and using knowledge and evidence is overwhelmingly positive in terms of the social impact on health professionals primarily, but also on patients and the wider society. However, the economic impacts, either positive or negative, were contested among experts.

5. At present, no expert was aware of any existing European cost-effectiveness/health economics study on the economic impacts of Action Areas 1, 2 or 3.

The authors remind the reader that any figures provided by the respondents are reported in this chapter strictly for indicative purposes and we do not purport to provide any economic evaluation of the available data, as doing so goes beyond the scope of this project.
5.1 Potential impacts of establishing effective RLSs (Action Area 1)

5.1.1 Economic impacts

The economic impact can be moderate to quite large in the short term but over time money will be saved

In general, every respondent found this question very difficult to answer. For many, the answer was simply: “no one really knows” (Lithuania) or “I can’t give an exact figure for this.” In Germany, there have been “no calculations of the effort yet”; and this would be a difficult task because “there are many different smaller actions on this issue and no-one has collected all the costs” to determine the impact in terms of administrative and compliance costs or any macroeconomic effect. A major problem for such health economics studies, apart from data collection problems in decentralised healthcare systems, is the fact that most of the current effort put into healthcare systems on patient safety is voluntary with “no special fund to pay for patient safety” (GJ/RN).

For some respondents, there was difficulty in providing even qualitative data on the magnitude of the impact (low, moderate or high) and, in a few cases, the direction of the impact was also difficult to assess (positive or negative). The difficulty and sometimes scepticism of the question is not unfounded. From the UK perspective, a more key question is: “how to define cost? Especially the cost of cultural change, which is the predominant driver of the economic impact of RLSs, which is more about the providers’ understanding of professional accountability through culture across the NHS.” With further probing, however, most respondents answered our question in two distinct ways: short-term costs and long-term gains (returns on investments).

In the short term, there was disparity among the respondents regarding the level of negative economic impact with respect to the amount of ‘start up’ costs. For some respondents, there was an impression that the initial investment is moderate but reasonable, especially when “compared to molecular genetics or medical engineering” or compared with the “richness” of a country like Germany. However, a few respondents (e.g. Denmark) felt that it is, indeed, very costly to establish an effective reporting and learning mechanism and thus the economic impact in the short term will be quite large.

A key issue that emerges regarding the short-term economic impact of establishing an effective reporting and learning mechanism is “to consider to what extent you need to set up new data collection efforts and new forms of institutionalisation in a constituency to get relevant patient safety information” (OECD). For some countries, there is a need not only to establish effective RLSs, but also to create whole new institutions that, in the OECD view, “are sometimes doubling or repeating the work done by national quality institutes”. For those member states lacking any system for patient safety, the greatest initial cost would be ICT (e.g. Lithuania, Slovenia and Portugal). Experience in Denmark demonstrates how high the initial costs of establishing an electronic RLS could be; in the range of 6-8m Danish kroner (DKr), which is approximately €804,436.00 to €1.07m.80

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80 RAND Europe calculation based on the exchange rate of 1 DKr to €0.13406 as of 29 May 2008 (www.oanda.com).
Another important issue relevant to the short-term economic impact of RLSs is whether it is voluntary. As a German respondent explained, public authorities will not get any output for their money when they “spend a lot of money if you force people to report and they don’t do it”. Compared to a compulsory system where a lot of money will need to be spent on enforcing compliance, one will need “less investment” if the system is voluntary because you can have “a central electronic database” (GJ). Although no specific figures were provided, the respondent from France noted that a direct economic impact of the regulation in 1996, creating France’s national RLSs, was on the hospitals who had to pay for new risk managers (SO).

In the long term, however, there appeared to be strong agreement among the respondents on the positive economic impact of establishing effective RLSs in terms of the cost-savings to the health sector. Savings would be made in the future from preventing the high number of adverse events with their incumbent costs. One respondent from Sweden stated that “we know from the literature that 7 hospital days\(^{81}\) are saved for each patient injury avoided and that’s quite a lot of money”. Although there seem to be no other measures of economic impact apart from hospital days, all but one respondent accepted the assumption that RLSs, as a primary means of prevention of adverse events, would yield a large future return on the initial investment. Hence, any initial costs to establish and maintain the system were considered reasonable and justified in the long-term view. Whereas this unspoken assumption about the future cost-savings was held by the majority, it was less clear to some respondents whether the future cost-savings would be greater than the initial investment, or whether in fact the economic impact on balance would be “cost-neutral”, as suggested by a respondent from the Republic of Ireland. Nevertheless, a respondent from the Netherlands spoke adamantly that “when you have good safety, you save”.

One caveat provided by a respondent from Germany is the tension between the potential for great savings from decreasing the risk of adverse events through a CIRS (Critical Incident Reporting System), and the consequent potential increase in risky procedures as healthcare becomes safer. Intriguingly, the opposite view was taken by another respondent who felt that RLSs might have an unintended negative impact on care providers who may be less inclined to carry out risky procedures as awareness of patient safety increases. We have not explored the reasons for these dichotomous perspectives, but would suggest that such a conflict in expert views may be worth considering further as the Commission moves forward with improving patient safety in Europe.

We present in Table 5.1 a summary of all the concrete data on potentially relevant costs in terms of administrative burden and amount of human resources that was provided by our interview respondents. The purpose of the table is only to indicate the potential range of costs to public authorities in the different member states for different actions related to establishing an effective RLS.

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\(^{81}\) Although we did not probe the respondent further, this figure can be found in recent evidence from France (Michel et al. (2007) and from Spain (ENEAS 2006) as described above in the Problem Definition chapter.
<table>
<thead>
<tr>
<th>Country</th>
<th>Financial Resources</th>
<th>Human Resources</th>
<th>No. of incident reports</th>
</tr>
</thead>
<tbody>
<tr>
<td>Republic of Ireland,</td>
<td>€0.5 million – start up</td>
<td></td>
<td>Over 80,000 in last 2.5 years</td>
</tr>
<tr>
<td>Reporting and learning system</td>
<td>€100,000 annually</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Total: €1.3 million</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hungary, new quality</td>
<td>150 million Forint per year (approx. €615,750.00)³</td>
<td>50 employees</td>
<td>8,000 per year</td>
</tr>
<tr>
<td>and safety institute</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sweden, reporting and</td>
<td>€24 million</td>
<td></td>
<td></td>
</tr>
<tr>
<td>learning in 900 pharmacies</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Netherlands</td>
<td>A few €1,000 for software per hospital</td>
<td>e.g. 1 nurse per hospital department 1 day/wk (0.2 FTE)</td>
<td>[MoH goal to reduce adverse events by 50%</td>
</tr>
<tr>
<td></td>
<td>By 2011: €8 million for all hospitals to have R&amp;L system;</td>
<td></td>
<td>within 5 years]</td>
</tr>
<tr>
<td></td>
<td>€8 million for home and nursing care</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>2007: government pays 5 million DKK (approx. €670,300.00)²</td>
<td>4-5 academic employees in Board of Health national</td>
<td>10 to 20,000 reports per year</td>
</tr>
<tr>
<td></td>
<td>for all costs (compliance, training, culture change etc)</td>
<td>reporting system, of which 2-3 FTE for analysis of reports</td>
<td>In 2007: 20,368 reports⁵²</td>
</tr>
<tr>
<td></td>
<td>Analysis of reports costs approx. 2 to 3 million per year</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>(€268,120.00 to €402,180.00)²</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Belgium</td>
<td>€25 million for pilot reporting and learning projects in 5</td>
<td>1.5 FTE in largest hospital for its R&amp;L system</td>
<td></td>
</tr>
<tr>
<td></td>
<td>hospitals only (Belgium has 500 total)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Slovenia</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>1,400 reports to National Board of Health; 10,000 to patient</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>insurance companies (45% of complaints to insurance lead to</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>compensation)</td>
<td></td>
</tr>
<tr>
<td>Sweden</td>
<td>New database = 5 to 6 million SEK (initial cost of system</td>
<td></td>
<td>733,089 reports⁵³</td>
</tr>
<tr>
<td></td>
<td>upgrade) (approx. €536,500.00 to €643,800.00)⁷</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Germany</td>
<td>&gt; €5 million per year for administrative costs and</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>resources (approx. less than 0.5% of hospital budget for</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>R&amp;L) &lt;€1 million/year from MoH to cover all costs of</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Coalition for Patient Safety</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Over 4 years, €5 to 6 million for nursing home R&amp;L</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>systems</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Finland</td>
<td>Min. of 1 FTE for reports and 1 FTE for analysis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>UK</td>
<td>Significant, but not</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

⁵² Reports from Denmark in 2007 revealed the following event-specific distribution: 35% were related to medication; 5% to operations/surgeries; 14% events of falling; 1% suicide; 2% anaesthesia; 14% miscommunication (either insufficient information or wrong information or confusion of patients); 9% lack of continuity of care; 1% heart attacks/unexpected deaths; 19% other.

⁵³ The NPSA Data Summary Report (2008) indicates that between October 2003, when the NRLS was first set up, and December 2007, the NPSA has received 2,145,606 incident reports (based on date of submission). Between October 2006 and September 2007, a total of 791,429 patient safety incidents occurred and were reported to the NRLS.
### Social impacts

The social impact of a RLS is substantial when it is local and when learning leads to concrete action

A number of respondents highlighted two critical aspects of patient safety RLSs that are fundamental to their social impact which was felt by the majority of respondents to be substantial and in the positive direction, although not yet quantified or evidenced.

There was a repeating message from the respondents that reporting will have little social impact unless there is systematic and ongoing analysis of the reports; in other words, there must be learning from the reports. Although this might seem like an obvious statement, this was a strong feeling shared and expressed by several of the respondents which suggested that it needed to be flagged up in our report. A respondent from Germany explained “it is one thing to have a reporting system, but it must also be used and accepted by the doctors and nurses. It is accepted when the message of the doctor or the nurse will have a direct and concrete impact on creating better healthcare. So, the leader of the hospital must take notice and take concrete action.” The importance of feeding back surveillance data to prevent HAIs, for example, has also been highlighted in the literature. 84

A corollary component of an effective RLS with the expected positive social impacts on patients and care providers is that it must operate at the local level. In order for frontline care providers and staff to see the direct impacts of their reports, concrete action at the hospital level can only occur when the RLS “is as close to the patient as possible” (GJ & RN). The respondents from France reinforced this German sentiment that it is less important to have a central system than local-hospital-level RLSs. Thus, learning is key to the corrective action that underpins the success of this action area, and corrective action is dependent on the system being local.

While it is clearly important to have local RLSs as an action priority, it was also acknowledged that the heads of different reporting systems must come together to “decide on a common set of data” for comparing the results and impressions of reports, and, again,

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84 Gaynes et al. (2001).
to learn from the analysis of trends at the aggregate level. Importantly, such a linking of people for knowledge exchange depends on having trust among those coming together.

Benefits accrue to patients in the form of increased participation and empowerment (i.e. health literacy), honesty in the doctor–patient relationship, better managed expectations and lives saved

A majority of respondents felt that, through establishing an effective RLS, health literacy will increase because patients benefit from becoming “much better informed than in the past” (JV) about the delivery of their healthcare. In addition, as our Latvian respondent urged, this action area will benefit patients by creating: (1) more open communication; (2) more comfort and more trust [in the doctor-patient relationship]; and, (3) more involvement/participation of the patient in their own treatment; all of which will lead to greater health literacy. In raising patients’ awareness and health literacy, patients were felt to benefit from increased participation and associated empowerment in the doctor–patient relationship. Indeed, a respondent from Hungary suggested that the main benefit of this action area to patients as a key stakeholder group will be an “increase in patient satisfaction”.

Some evidence exists to support the expert consensus that patients will benefit in different ways from Action Area 1. First, patients themselves agree that establishing a RLS “could be a great benefit to them” – evidence provided by our respondent from Spain based on a survey of patients. Second, our respondent from the European Patients Forum offered evidence from a recent ‘involve’ study on the social impact of patient involvement in research and other patient participation initiatives. Finally, and perhaps most critically, our respondents from the Netherlands provided anecdotal evidence of the success of hospitals in the Dutch system “really saving lives” from the country’s action in this policy area. We also highlight here the evidence from a US survey of faculty and resident physicians in the Midwest, mid-Atlantic, and northeast regions of the US which showed that most respondents (84.3%) agreed that reporting errors improves the quality of care for future patients.

Benefits to care providers come from better culture and working environment, continuous knowledge exchange (education, awareness and skills) and accountability

When describing the strong social impact of establishing a RLS for healthcare professionals in Finland, our respondent said that it “means a lot for culture and for the working environment if you can reach more transparency and more honesty” through RLSs. The clear benefit to health professionals and care providers comes from the possibility, through culture change, to “talk freely and work in a blame-free and safe setting”. Indeed, a

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85 Although not described by the respondent, the authors note the results of the involve research – involve is a Participation Organisation funded by the UK Department of Health. The involve study found that there are benefits to allowing participation activities to be defined from the bottom up, to ensure that they reflect the characters and needs of the community in question (in the healthcare context, patients are the main beneficiaries of empowerment through authentic participation).

86 Kaldijan et al. (2008). Notably, the study concluded that most faculty and resident physicians are inclined to report harm-causing hypothetical errors, but only a minority have actually reported an error, suggesting that even in the countries with a longer history of attention to improving patient safety, much more can be done to improve quality of care for future patients.
respondent from the Netherlands suggested that this action area offers “more possibility to
discuss [work-related] uncertainty with others and this discussion will contribute to a safer
system”.

At least two respondents commented that patient safety is “as old as medicine itself” – a
“re-discovery of doctors’ primary virtues on systematic ground” – the only new thing is
that there are new ways to approach the old goal and issue of First Do No Harm. Several
other respondents spoke more generally about the motivation of professionals to provide
the best standards of care to patients, which the authors interpret as implicitly referring to
the Hippocratic Oath. In this context, RLSs benefit healthcare professionals, as well as
primarily patients, from performing safer care.

Many respondents discussed the benefit to health professionals of being able to avoid
mistakes in the future as a result of effective RLSs. A respondent from Slovenia speculated
that the benefits to health professionals of this action area would be twofold: (1) the level
of knowledge and skill will be augmented and stimulated by the RLS, and (2) the level of
awareness of patient safety will be increased. A respondent from Latvia echoed the benefit
of improved professional skills and added that RLSs help to create a better working
environment in which professionals know that they will not be punished for reporting
incidents.

There is some evidence from Spain that patient safety education, as part of establishing
effective RLSs, is a benefit to health professionals. Our respondent from Spain noted that a
local study had investigated the impact of a teaching programme for patient safety and
showed the utility of knowledge in terms of a change in skill, better clinical performance,
and reduced errors. In addition, the National Patient Safety Agency in the UK has
conducted a staff survey and found that there is more awareness of errors because of
reporting systems in the NHS. The UK respondent suggested that these findings serve as a
proxy for the positive impact of cultural change among health professionals in favour of
patient safety. Finally, there is anecdotal evidence in Germany that “hospitals with a good
running patient safety management system provides better satisfaction from doctors and
nurses and also lower costs from patient complaints than in problem hospitals”.

Healthcare systems benefit from civic trust, better care provision and avoided costs
A number of respondents suggested that healthcare systems benefit from RLSs by not
losing public “credibility and confidence”. A respondent from Slovenia suggested that
Action Area 1 might have “a general social effect in terms of augmenting trust in the health
system and the relation between the lay public and the health system”. From the British
perspective, culture change in the NHS is seen as the main benefit (social impact) of
establishing a RLS, given that the current legislation acts as a disincentive to making
reports because clinicians who do so could still be penalised for it.

Another benefit of this action area for healthcare systems that has macroeconomic
implications was described by our respondent from Finland; RLSs benefit the Finnish
healthcare system because more transparency and a more open climate will “bring more
innovative and productive workers”. A respondent from Spain also confirmed that, in
addition to knowing what is happening, a national RLS would benefit health systems as it
is “a way to monitor trends, and the national health system could save money for [payment
of] bad practices”. Indeed, the health system in Hungary was felt by our respondent to benefit from “the better use of resources” through “improved efficiency” as a result of a national RLS. The same would be true in the Netherlands: the benefits of this action area for the Dutch health system are in terms of cost. As a Dutch respondent stated: “When [the national RLS] works well and there are less adverse events, then the cost of healthcare will be lower and this is a benefit for the system”.

There is some anecdotal evidence that Action Area 1 has a greater impact on social inclusion and protection of vulnerable patient populations than on the general patient population, but a small group of experts expressed an absence of any special impact

The vast majority of respondents answered this question resoundingly with the fact that there is “no strong data”, or little evidence, on whether establishing a RLS will have a greater impact on the social inclusion and protection of particular groups than on patients generally. However, a small number of respondents provided anecdotal evidence from single institutions that a RLS will have a greater benefit for those people in groups “that already have problems in society and in healthcare” (GJ & RN). For example, an institution in Germany handling complaints of appendectomies found that “more migrants suffer from problems after surgery, so there might be special instances with special social groups” benefiting more from a RLS that can detect when these incidents occur in disproportionate numbers to certain groups of patients.

Several other respondents articulated more generally that they anticipated a distinct benefit for particular groups of patients (e.g. the elderly, those with low socio-economic status, ethnic minorities, people with disabilities) because it is known that certain social groups “have problems taking care of their own rights” despite the fact that European healthcare systems are, in principle, available to all of society. As a respondent from Hungary argued, establishing a RLS is “very important for elderly and minority groups” who are not given more attention by healthcare professionals, yet these groups “need special attention and need a lot of information about the system and the opportunities for them”. The respondent felt that RLSs “will improve the situation for these groups”.

In general, the social impact of RLSs “is related to the kind of groups at risk for certain events, so it’s obvious that when you concentrate on hospitals that [the] elderly are at risk for certain kinds of adverse events,” according to the OECD respondent. Although social impact depends on the indicator in question (e.g. distributional effects), this respondent confirmed that there is no existing European literature that has looked systematically at whether risks are higher for various socio-economic groups. Nevertheless, we know that the negative impact of safety issues is big: the damage is large and has a high negative social impact on those affected.

At the other extreme, however, there was a small group of respondents (e.g. Bulgaria, Slovenia, Portugal, the Netherlands) indicating that this action area would have no impact on, or specific benefit for, particular groups. The main reason given for this view was the fact that the respondent’s healthcare system “includes all members of society” and so a RLS would, in general, benefit all patients equally. Notably, experts sometimes qualified their responses by referring to the lack of data to support this opinion which was shared by a smaller group of respondents.
5.2 Potential impacts of redress mechanisms (Action Area 2)

5.2.1 Economic impacts

In general, the economic impact of redress mechanisms will depend on the legal systems and the cultures of the different member states as there are at least three distinct types of redress mechanisms possible. Table 5.2 briefly explains these three different types of redress mechanisms. One example of 'administrative compensation' is the Republic of Ireland’s Clinical Indemnity Scheme based upon “enterprise liability” to cover claims and incidents arising out of the performance of health professional duties under their contract of employment to provide clinical services to eligible patients. According to the Department of Health and Children, claims are investigated and managed by the State Claims Agency, using Agency staff or lawyers appointed to the Agency, and the Scheme encourages the use of mediation and other dispute resolution procedures to dispose of claims with the intention that they be resolved as speedily as possible to the satisfaction of all parties concerned.87

Table 5.2 Description of three types of redress mechanism for patients seeking fair compensation for adverse events and near misses

<table>
<thead>
<tr>
<th>Types of Redress Mechanism</th>
<th>Brief Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tort (court)-based compensation</td>
<td>Similar to worker’s compensation, patients who are injured due to medical treatment are only able to pursue any form of compensation (financial or other) from the individual physician and/or the hospital/medical institution through civil, or tort, law. In tort law, 'strict liability' is the legal doctrine that makes a person responsible for the damage/injury and loss caused by her/his acts and omissions regardless of culpability (or fault in criminal terms). This type of redress mechanism often requires substantial amounts of financial investment in legal representation on both sides, can be lengthy (as much as 10-20 years), and places the quite heavy 'burden of proof' of liability (through establishing causation) rests on the injured patient.</td>
</tr>
<tr>
<td>'No-fault’ compensation</td>
<td>Even though tort-based systems may be described as 'no-fault', there is still a need to establish some element of causation i.e. that patients have suffered some loss as a result of something which has happened to them, which should not have happened (which is the case for Sweden, but not Denmark). No-fault redress systems are often described as helping health providers to move away from the “blame culture’, towards a more open culture in which health professionals may find it easier to admit to errors or near-misses.</td>
</tr>
<tr>
<td>Administrative compensation (e.g. Arbitration Boards; 'Health Courts'; Clinical Indemnity Scheme)</td>
<td>A less burdensome form of civil compensation where injured patients bring their claims for redress under regulatory schemes or voluntary arrangements among medical institutions and professions. In other words, civil claims are administered by a decision-making body/panel of either health professionals or hospital associations rather than by a judge in a court room and, as a result, are significantly less lengthy and costly. However, the burden of proof usually still befalls the injured patient who risks not receiving any compensation.</td>
</tr>
</tbody>
</table>

SOURCE: RAND Europe

As some respondents suggested, proponents of tort (litigious)-based schemes argue that the threat of litigation (going to court) acts as a driver for better standards of care; the involvement of lawyers ensures that cases are fully tested; and the level of compensation is affordable, whereas a no-fault scheme might lead to a significant increase in the number of...

claims and so to much higher costs for the public purse. By contrast, other respondents explained that the British Medical Association and the Danish Patient Safety Society have argued that no-fault redress mechanisms will lead to greater frankness and encourage accountability of health professionals to patients, contributing to a more trusting relationship and, ultimately, to safer care with its associated cost-savings (in the long term).

All of these redress mechanisms could be considered ‘fair,’ according to a German respondent. Indeed, any assessment of economic impact in terms of overall compensation costs was difficult to answer because of a concern about “what is fair?” For example, experts from member states with no-fault liability redress do not consider tort-based systems to be ‘fair’ mainly because the number of injured patients who can afford to seek compensation through the courts is very limited, and the process is both lengthy and extremely expensive for all parties involved in the legal case. Moreover, for several respondents, the term ‘redress’ is too wide in meaning to be useful – redress can mean no-fault liability schemes (France, Denmark, Norway), or tort-based patient injury compensation schemes (Germany, Republic of Ireland, UK). The main difference between tort (or litigation)-based systems and no-fault systems is that there is no need for the claimant to prove negligence in the latter. In New Zealand, for example, the 2005 reforms mean that the scheme for compensation and complaints is “truly no-fault with no requirement to establish any error or negligence on the part of the healthcare provider.”

To add to the lack of conceptual clarity about ‘fairness’ as the basis for any redress mechanism, in whatever form it may take, new alternatives to the litigious system have been developed and introduced in several member states (Germany, France and the Netherlands). The move away from the current tort system of litigation for these member states, and also for the US, is known as ‘administrative compensation.’ As our German respondent explained about the new Arbitration Boards in the Chamber of Physicians, such administrative compensation serves as a special way of giving compensation to patients without them having to go to court because it allows patients to exercise their right to a second medical opinion at no cost to them, with the prospect of faster compensation.

In this context, the German respondent stated that the litigious redress mechanism in Germany is considered to be fair, though imperfect, and that the main issue about compensation in this type of tort-based redress mechanism is how stakeholders (patients and care providers) are treated in the system and who has the “burden of proof”. But,

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88 In many cases where a patient suffers some injury, it will not necessarily have been an individual clinician who has been negligent. It might be a failure on the part of a wider health team, or it might be the result of poor facilities, processes or poor communication between staff. According to the Scottish National Party (Scottish Consumer Council 2006), a move away from a system in which the focus is on individual negligence probably reflects the current reality in the NHS, although there will clearly still be cases where it is the fault of a particular clinician that has led to the injury.

89 Bismark (2006).

90 Mello et al. (2006).
unlike the US proposal for “Health Courts”, Germany has recently shifted the burden of proof in its administrative scheme away from the patient’s side to the doctor’s side.

In some European countries, like Hungary and Bulgaria, there is no de jure redress mechanism in place for patients when they experience an adverse event. In Bulgaria, the de facto redress mechanism exists in three variable forms: (1) if there is a complication due to mistakes made in a medical establishment, then that establishment will carry out the treatment of the complication; (2) financial compensation is only provided through the courts; and, (3) the general system for disability has a provision for social and financial benefits for those having had complications due to medical treatment. In the current system in Slovenia, healthcare professionals “can be sued as a person and not just as an employee of the institution” and, as our respondent noted, “this is dangerous for the professional’s economic position”. Hence, it was felt that if compensation can be established where there is no blame placed on the care providers as individuals, then such a system would “reassure the healthcare worker” thereby creating a beneficial solution for both parties: the injured patient and the health professional. However, establishing a fair redress mechanism, as proposed by the Commission, in transitional countries like Slovenia confronts both “the problem of funding” and the “problem of establishing a working system that will really compensate what has to be compensated” (BB). For Hungary, the most expensive part of any future redress mechanism will be the costs of “raising a lot of awareness” about the system being fair and blame-free (IS).

Overall, it was felt by most respondents that tort-based redress mechanisms have a high negative economic impact. In Germany, for example, the most expensive cases are more than €1m over a lifetime after obstetric-related injury and the highest sanction was €250,000 paid by the state after an adverse event from compulsory vaccination. Yet, while the cost of the German redress mechanism is high, the respondent noted that it is “not as expensive of the US health system and [Germans] don’t want to become like that”. Notably, the tort-based redress mechanism in the Republic of Ireland has made the country the most expensive litigious system outside the US, as our Irish respondent remarked.

By contrast, expert consensus appeared to suggest that the non-court-based redress mechanisms, like the Danish no-fault compensation system, would create significantly less economic impact on a member state than Irish- and American-type redress based on litigation. Indeed, there is preliminary evidence in a report of a Danish, Swedish and American survey suggesting that Nordic examples of redress mechanism will result in quite a positive economic impact of redress mechanisms in general (KH/HOPE). Although there is a high level of uncertainty and there are no exact figures, it is possible that similar systems in other non-Nordic countries may result in higher economic impact than that observed in the survey.

Alternatively, some evidence from the Netherlands suggests that there would be no difference in the administrative costs and resources between tort-based and no-fault redress mechanisms. According to the Chief Inspector, the Dutch Healthcare Inspectorate investigated the consequences of replacing the current system in the Netherlands with the

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91 Mello et al. (2006).
no-fault system of Denmark and “they found that it would not make a difference because you would have to pay more patients although the amount would be lower. So, there was no advantage seen to making a change in the system.” It was also suggested that evidence of the economic impact of redress mechanisms in Europe may be available in a 2004 Commission of Inquiry report on the Patient Injury Act in Sweden. (In Sweden, the redress system for medical injury is not regulated, according to our respondent, and it is a voluntary responsibility of insurance companies; hence, the Commission investigated the possibility of changing the legislation.)

Administrative costs of redress mechanisms are generally unknown ‘in numbers’ and are often a burden on private health insurance companies

Cost data on the administrative burden of a member state’s redress mechanism was generally unknown, or even unimaginable, to our experts. For Slovenia, for example, government representatives “don’t know in financial terms, but they know from other countries that this action would be a substantial cost to the country”. Despite the fact that Spain’s public health system can pay injured patients for damage after they make a complaint to the hospital or to a lawyer, the economic impact of the country’s redress mechanism “has not been worked on and [the respondent] had not asked about this issue [for the purpose of the interview] which is sensitive”.

Additionally, for several member states with private health insurance companies, such cost data would not be publicly available but would be accessible only to the lawyers and insurance companies, such as in Spain. In Sweden, the redress mechanism is not a state-funded system, rather it is “financed by the care-givers. They have an insurance together and the insurance companies pay the compensation” (PF). Hence, the administrative burden was unknown to the Swedish Ministry of Health and Social Affairs, Health Care Division as it is “private sector information”.92

Table 5.3 below presents a summary of the cost data we obtained from our expert interviews as an indication of the potential economic impact of this second action area.

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92 The Swedish respondent explained further that the County Councils are responsible for providing healthcare and, together, they have a private insurance company called the ‘County Council Mutual Insurance Company’ (Löf) which handles over 90% of all claims in Sweden and a few others deal with dental care insurance and private care.
Table 5.3 Summary of Interview data on the economic impact of Action Area 2 in terms of administrative burden

<table>
<thead>
<tr>
<th>Country, Institution</th>
<th>Financial resources</th>
<th>Human Resources</th>
<th>No. of cases (i.e. complaints)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Germany, Arbitration Board of the Chamber of Physicians</td>
<td>Approx. €5 million (½ paid by insurance and ½ by doctors) NOTE: only a small portion spent to deal with patient safety concerns</td>
<td>100 FTEs on the Boards</td>
<td>12,000 per year</td>
</tr>
<tr>
<td>France, ONIAM</td>
<td>€70 million (2004)</td>
<td>50 FTE (internal) Secretariat = President, 11 State representatives, 9 members of the MoH, 2 ONIAM representatives</td>
<td>1,813 registered requests of indemnity (January-June 2007) 735 case files in total (2006) - 529 files come from insurance companies, 27 from the L'Assistance publique - hôpitaux de Paris (AP-HP) which is its own insurance, and 178 from ONIAM</td>
</tr>
<tr>
<td>Lithuania</td>
<td>Hospitals pay €200,000 per year for insurance</td>
<td></td>
<td></td>
</tr>
<tr>
<td>UK, NHS</td>
<td>Cost of litigation to NHS is £2-4 billion for serious harm or death (approx. £2.52b to €5.05b)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Latvia</td>
<td></td>
<td>1,500 complaints in 2006</td>
<td></td>
</tr>
</tbody>
</table>

SOURCE: RAND Europe
NOTE: These figures are RAND calculations based on the conversion rate of £1 to €1.26142 as of 29 May 2008 (www.oanda.com)

The cost of compensation is difficult to quantify because it depends on decisions about the severity of patient injury and the type of member state redress mechanism in place

Many respondents found it difficult to quantify the direct costs of redress in terms of the amount of compensation paid to injured patients. The main reason that was repeated by the respondents is the fact that the cost will “depend on the threshold for getting compensation which can be quite high or low [depending on the type of redress mechanism in place] and it is very difficult to define this threshold [in any type of redress system]” (BB). As the respondent from Slovenia went on to explain about her country’s tort-based redress mechanism, “the threshold is about the severity of the event as well as the causative relationship between a medical error that has to be admitted and the actual patient outcome. It is sometimes hard to really know this causal link.” The latter point reminds the authors of the arguments in favour of no-fault compensation as in the Danish example.

95 There were 46 complaints in delivery services system, of which 20% were incorrect treatment; 18% of complaints in surgery were mistakes; 15% in psychiatry were mistakes; 28% in dentistry were real mistakes; 30% in primary care (n=50) were real mistakes; 32% in emergency care were mistakes (n=22).
The economic impact will vary according to the level of public financing of compensation, which depends upon the type and severity of adverse events included in the compensation system. As some respondents from countries which use either type of redress mechanisms argued, compensation costs may be too low for some patients when the redress system has to compensate all patients for every adverse event/damage in the healthcare process. Additionally, there was a concern among some of the respondents that, with greater awareness among patients as a result of various actions to improve patient safety, the associated “change in attitude” could lead to “increased compensation costs” as there may be more patients affected by adverse events seeking redress. For one of our French respondents, it was thought that the cost of compensation “could be important for hospitals but not so much because the mechanism is national” (SO).

Although creating a ‘fair’ redress mechanism in member states may create a win-win situation for patients and providers, with an associated positive impact, the cost to public authorities might increase, depending on the compensation threshold that is established (Slovenia). The balance between the potential rise in costs of establishing a fair redress mechanism and the likely benefits to stakeholders will depend upon how one sees the system. If, as the respondent suggested, the system is seen as a whole, then the balance could be neutral. But, if you look at the providers, then the balance is more positive (and, by implication, justifies the associated increased costs). An indication of the range of costs for different member states is summarised in Table 5.4.
<table>
<thead>
<tr>
<th>Country, Institution</th>
<th>Range of Compensation costs</th>
<th>Average, or minimal level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Germany, Arbitration Board of the Chamber of Physicians</td>
<td>€1 million over lifetime (obstetric adverse incident)</td>
<td>Expenditures are for the lump sum and the monthly rent. It is dangerous to give any numbers for average; depends on severity of the problem</td>
</tr>
<tr>
<td>Hungary</td>
<td>Approx. €1 million per year (estimate given based on other countries)</td>
<td>£1,000 to £2,000 (approx. €1,264.42 to €2,522.8)¹</td>
</tr>
<tr>
<td>Denmark</td>
<td>From €10,000 to 20,000 (only a fraction of potential costs, 5-10% compared to # of adverse events) (approx. €12,614.20 to €25,228.40)²</td>
<td>£1,000 to £2,000 (approx. €1,264.42 to €2,522.8)¹</td>
</tr>
<tr>
<td>France, ONIAM (2006): 175 files are concerned for a total sum of €13M; 17% of files range between €15,000 and €50,000 and 30% are between €100,000 and €200,000</td>
<td>(2006): the minimal total sum of indemnity is superior or equal to €15 000, and no file, even brought back to 100%, would have exceeded €500 000</td>
<td></td>
</tr>
<tr>
<td>Sweden, CC Mutual Insurance Company</td>
<td>Between 1,000 to several million SEK (approx. €107.3 to several €100,000 )² &gt; €1 million (obstetric delivery error), or €250,000 paid by state for AE from vaccination</td>
<td>Majority are &lt;50,000 SEK (less than €5,365, approx)²</td>
</tr>
<tr>
<td>Lithuania</td>
<td>Can be 30% of hospital’s budget (€3 million) Maximum that can be paid is LT $50,000 (approx. = €13-14,000)</td>
<td></td>
</tr>
<tr>
<td>Finland</td>
<td>Can be several 10,000 Euros for life-long damage</td>
<td></td>
</tr>
</tbody>
</table>

SOURCE: RAND Europe

NOTE: ¹These figures are RAND calculations based on the conversion rate of £1 to €1.26142 as of 29 May 2008 (www.oanda.com); ²This RAND calculation is based on the exchange rate of 1 SEK to €0.10730 as of 29 May 2008 (www.oanda.com)

There is little consensus on whether, if any, macroeconomic impacts can be expected from redress mechanisms

In general, the question of whether Action Area 2 would have a macroeconomic impact in terms of productivity, or efficiency, was difficult to answer for all respondents and was resisted by many. A German respondent remarked how “patient safety is not a job machine but it is absolutely necessary to keep the confidence of the healthcare system at a high level”. A respondent from Sweden was unable to assess whether redress mechanisms in his country would affect productivity or efficiency, but he speculated that the system “should lead to less costs totally for society in terms of compensation costs; the [redress] system gives lower costs to the whole [healthcare] system and so it is macro in one way”. For Slovenia, there would not be any macroeconomic impact in terms of productivity or efficiency because the impact of the country’s redress mechanism “would just be additional costs to the healthcare system”. But, for Hungary, the respondent felt that establishing a redress mechanism “would be better for the country, more efficient, and redress is good business”. The authors might interpret the latter remark as reflecting a litigious type redress mechanism which involves the business of lawyers in this particular member state.
### 5.2.2 Social impacts

**Fair compensation undeniably benefits all injured patients; the benefit is primarily as moral compensation**

For most respondents, there is a large positive social impact from redress mechanisms for injured patients because “in any case of patient complaints, you can offer the person a way to solve a problem on a fair basis” (GJ). In other words, “redress would be good for patients because they need it” (IS). In the German case, the process of seeking compensation through an Arbitration Board is free to patients and this is a big benefit to them. Intriguingly, unlike the RLSs, the same respondent could not tell whether “there are any social groups that would get a special benefit from this”. This answer may reflect the German context of a liability-based redress scheme which might present a barrier to vulnerable social groups rather than provide them special protection. The German redress mechanism was seen as being part of social protection for patients more generally as it is written in the Social Code that patients have a right to ask their insurance company for help and advice and obtain a free second opinion on whether a maltreatment was really a mistake or not, according to our respondent. Similarly, neither the Danish nor one of the Dutch respondents felt that redress mechanisms would impact the social inclusion and protection of vulnerable groups: from the Dutch perspective, redress mechanisms would “not especially [have] an impact to particular groups because every Dutch citizen has access to compensation when there has been damage”.

By contrast, even though redress mechanisms in Sweden benefit society as a whole insofar as it is “part of all the other social protection systems that they have [in the country]” (PF), our Swedish respondent also felt that redress mechanisms might offer a ‘special benefit’ to some groups of patients in the same way that RLSs would be a greater benefit to them than to the ‘general’ patient. Many of the respondents who felt that RLSs would be a ‘special benefit’ for some vulnerable groups in the patient population also felt that this would be the case for redress mechanisms. In the case of Hungary, for example, establishing a fair redress mechanism in her country would have a “greater benefit” to “the low educated, elderly and minority groups” because “these groups don’t have lawyers as others do now”. Although it was not clear whether establishing fair redress mechanisms, as proposed by the Commission, would offer a greater benefit to vulnerable groups of patients (e.g. the elderly, lower educated, disabled, etc), our interview data revealed a recurring comment that redress mechanisms offer all injured patients the benefit of “moral compensation”. A number of respondents raised the fact that the majority of injured patients seek redress in the form of explanation for the incident and information on how the harm will be prevented to help the care of future patients. According to some respondents, it is only a minority of injured patients who seek redress to obtain financial compensation. Thus, the authors would argue that the financial constraints of limited healthcare budgets, particularly in new or small member states, do not warrant the refusal in any European country to establish fair redress mechanisms as patients have a civil and political right to information about the root causes of their injury and about the measures taken by the appropriate authorities, at all levels, both to mitigate resulting harm and to prevent harm in the future. Indeed, a few respondents used the language of rights to describe the benefits to patients of this policy area to improve patient safety in Europe.
Fair redress mechanisms benefit health professionals through a greater sense of security (i.e. less fear) and a new blame-free culture that fosters transparency and trust

As a means of conflict resolution, redress mechanisms for patient injury or damage benefit healthcare providers by maintaining trust in the doctor-patient relationship which was believed to lead to better care. Our respondent from Spain suggested that the social impact on health professionals of fair redress mechanisms is “very positive” in terms of “open communication” which she contrasted with “the effects in the US”. Indeed, the respondent from the European Federation of Nurses felt that blame-free redress “would be an absolute benefit to health professionals” as the fear of redress can lead to health professionals refusing to perform high-risk treatments or procedures which may be the better care option for a particular patient. Similarly, a respondent from the Netherlands argued that, since all professionals are insured themselves, the impact of fair redress mechanisms is “more a mental process” and that the benefit “comes from a greater sense of security”. In Denmark’s case, the no-fault compensation system assumes that the health professional “gave the best possible care and hence this has generated a more open and honest relationship between providers and patients” which the respondent deemed to “definitely be a benefit to health professionals”. More specifically, as a Swedish respondent argued, in a blame-free redress system, “it is easier for [professionals] to inform and help patients make a claim because it doesn’t affect them personally and so it would be positive for them to know that patients can get compensation”. That is, the benefit to health professionals comes from the satisfaction of knowing that they can communicate openly and honestly with their patients and even help them in seeking redress (predominantly moral).

Yet, it is possible for redress to be both “better and worse for health professionals” (IS). While a blame-free system is good and this would be better for health professionals, the respondent from Hungary suggested that it would be worse because “some special services [would] decrease due to being blame-free”. The respondent speculated that, in the blame system, doctors ask for a lot of explanation and diagnosis, but there could be less explanation and less diagnosis if the system is blame-free.

Healthcare systems benefit from fair redress mechanisms in terms of fulfilling moral and legal obligations to citizens through greater safety vigilance and possibly cost savings

Several EU member states currently have laws in place, such as Quality Acts, that mandate redress to all injured patients. In Finland, a law on Patient Insurance is currently being prepared which will provide everyone with compensation for the “realistic costs of having extra treatment” as a consequence of adverse events. Thus, in the Finnish case, the social impact of the redress mechanism is “a matter of culture”, according to our respondent, in terms of “maintaining a basic healthcare system that is democratic and with a large scale public healthcare system not bound by money”. Similarly, each hospital in the Netherlands is responsible for compensating patients when an error occurs, as a respondent explained, and so, the effect of redress mechanisms in hospitals is such that “they have a duty to pay attention to making improvements on areas that have had repeated claims made”. Thus, in fulfilling a legal obligation, it is likely that the benefit of a fair redress mechanism to health systems comes from helping “to keep public trust and confidence in the system” (PF), as suggested by our Swedish respondent.

Our respondent from Spain suggested that a fair redress mechanism, such as the Nordic no-fault type, might benefit the country’s health system in terms of reducing “the budget
from all the legal procedures”. A similar argument was given by one of the Swedish respondents, with the qualification that “there is no proof of this” (TT). The respondent from Denmark also confirmed that the country’s “no-fault liability has kept away the US-style of having to prove the involvement of malpractice, in turn this has kept the pressure off the system for very high compensations”.

Another respondent, however, was unable to articulate what the benefit of this action area would be for Hungary’s healthcare system. The authors would suggest that this view might reflect the absence of a de jure redress mechanism in the respondent’s country, making it difficult to assess the unknown.

5.3 Potential impacts of developing and using knowledge and evidence at EU level (Action Area 3)

5.3.1 Economic impacts

The administrative burden and costs of compliance of Action Area 3 are generally unknown: the magnitude (large or small) and direction (positive or negative) was contested among experts

For many respondents (e.g. PGEU, Netherlands, Hungary, Sweden), the potential economic impact of this Area of Action in terms of administrative costs to healthcare systems or public authorities, and costs of compliance was unknown. One respondent from Denmark expected that “most of the costs will be more about adapting or changing the system”. And, there will also be administrative costs for developing and promoting a research agenda at EU level. But, true costs will be difficult to assess since “administrative costs will be linked to the research project which depends on who is doing it, the scope of the project etc” (WHO). Consistent with this view from Denmark, our WHO respondent stated that the “costs of compliance will depend on what the evidence proves. If the research is to develop solutions, then the costs will be for implementing the solutions”. In Denmark, developing and using knowledge and evidence “was an important impact on compliance” because this action area focuses on all adverse events. By contrast, the Finnish system is less expensive, because “they focus only on life-saving issues concerning patient safety”, according to the respondent from HOPE.

A German respondent mentioned that 90% of all patient safety activities are related to “distributing knowledge and taking care of the right culture to take action” (i.e. addressing and establishing a positive ‘safety culture’), and this does not require high expenditures (unlike, e.g., for equipment or laboratories). But, you do need to “invest in the right people”. A respondent from Sweden confirmed that administrative costs of this action area for European national public authorities are mainly in the contribution of personnel hours, and Spain noted that “the number of people is very important”. Like any small country, workforce is a major cost issue in Slovenia in relation to this action area. In Hungary, both human resources and translation would be the biggest resources needed to fulfil its policy to participate in this Area of Action. Hungary would need a new administration, IT, translation services, and to organise conferences – the overall costs are expected to be “very high” for Hungary (IS). Nevertheless, it was suggested that if several member states work together at EU level in developing and using knowledge and evidence, or in setting up a
database, then this activity would give “added value” for those personnel doing the same thing at national level.

Assuming that it is true that 90% of all patient safety activity is developing and using knowledge and evidence, there are two types of evidence to suggest that patient safety initiatives have positive economic impacts. First, there is the high number (n=1,000) of patient safety projects in 400 hospitals in Germany, and elsewhere, and these hospitals would not develop and use knowledge and evidence on patient safety “just to spend money”. Second, there are studies in the US and Canada that show “it is really worthwhile to invest in patient safety”. In addition, our respondent from HOPE offered evidence from Sweden on the “huge impact with clear figures that the investment in patient safety in this area [small-scale research on brain damaged babies] was less expensive than the consequences of caring for brain damaged babies”. The respondent from Slovenia speculated that research on patient safety will have a “positive economic impact when the results of research provide data on how to do things better and that’s a kind of return on investment in the long-term, similar to other interventions in the quality area”.

Similar to EU-level action in this area, some member states already have national-level ‘networks’ on Patient Safety (as in Germany) with small administrative costs for network offices. But most of the normal work to distribute knowledge and evidence is paid for by the institutions that are part of the network. So, since participating institutions absorb the majority of the expenditures from human capital costs (e.g. travel or phone interviews), any existing cost data will underestimate the full expenditures that member states may incur from activities related to this EU-level action area. Nevertheless, there was a shared sentiment that the costs of having a small office in each Member State for developing and using knowledge and evidence at the EU level (i.e. for linking experts and exchanging knowledge across the EU) would be minimal, or “only peanuts”, especially when compared to other monetary investments in health such as molecular research. It was therefore suggested that, for countries with low healthcare budgets and underdeveloped patient safety infrastructure, “the best the EU can do is pay for an office for regular meetings for the important relevant people” in those member state healthcare systems.

In the Republic of Ireland, however, the recently developed Health Information and Quality Authority (HIQA) has had a significant economic impact at the national level in terms of administrative costs on public authorities. HIQA is specifically tasked with using, disseminating and managing knowledge and performance standards in relation to healthcare. But, as the respondent also stated, the impact is “no more so than healthcare inflation, technological inflation or medical demand – these would outstrip the cost of managing and implementing such a system” of developing and using knowledge and evidence across different nations in the UK. In addition, the cost of compliance “has been increasing exponentially within healthcare” but, in parallel with industry, “we are in a catch up situation” where the rise in compliance costs relates to the opportunity cost of being in transition from voluntary compliance in developing and using knowledge and evidence, to it being mandatory in policy and practice. Once this transition is complete and the structures set up to do so, “it will be a short-lived cost” (IC). The respondent went further to suggest that the cost of compliance will “probably touch on 10% of the expenditure of any budget, but much of that will be a redirecting of resources within an organisation” from potential cost savings gained in productivity and fewer adverse events
and better performance which the literature suggests “is between 1% and 50%”. In similar vain, an EU-level respondent (CoE) suggested that “less than 1% of global costs would be the investment needed” for developing and using knowledge and evidence at EU level.

For one of the Danish respondents, the concern was less about the costs of promoting research on patient safety at EU level, but the potential for high costs from more core issues like how care is delivered in European countries and what are made the national obligations of countries to make healthcare safer in a country. Table 5.5 summarises the limited cost data and associated human resources information that were provided by respondents as an estimate of the economic impact of Action Area 3.

Table 5.5 Summary of Interview data on the economic impact of Action Area 3 in terms of administrative burden to public authorities

<table>
<thead>
<tr>
<th>Country, Institution</th>
<th>Administrative costs</th>
<th>Other resources</th>
</tr>
</thead>
<tbody>
<tr>
<td>Germany, Coalition for PS</td>
<td>MoH pays €100,000 per year for the Coalition</td>
<td>150,000 to 200,000 per year for Members of the Board, paid by institutions</td>
</tr>
<tr>
<td>Sweden, EU NetPaS</td>
<td>Costs may range from €2,000 to €80,000 for an NGO to work at EU level on research and evidence building for PS</td>
<td>2 people (not FTE) in database building, shared with Denmark</td>
</tr>
<tr>
<td>Patient Safety Organisations</td>
<td>€5-6,000 per year (of €15,000 total cost of project)</td>
<td>2 specialist for the project from Lithuania</td>
</tr>
<tr>
<td>Lithuania, SOROS project based in Ukraine on PS</td>
<td>€5-6,000 per year (of €15,000 total cost of project)</td>
<td>6 working groups of 10 people, plus large network of 100 people from the health and social care field (person-time inseparable from other Ministry costs)</td>
</tr>
<tr>
<td>Finland, national network for patient safety</td>
<td>6 working groups of 10 people, plus a large network of 100 people from the health and social care field (person-time inseparable from other Ministry costs)</td>
<td>2 civil servants and several doctors involved in activities to develop and use knowledge and evidence at EU and international levels</td>
</tr>
<tr>
<td>UK, Patient Safety High Level Working Group</td>
<td>£80,000 budget for this action (approx. €100,913.6)</td>
<td>1 FTE (L. McGill) as chair and support takes 0.1 to 0.2 FTE plus 0.5 FTE for international work</td>
</tr>
<tr>
<td>Spain</td>
<td>€8 to 9 million for research at national level</td>
<td>2 FTE</td>
</tr>
<tr>
<td>Latvia</td>
<td>€1,000 per month</td>
<td>Staffing scheduled to move from approx. 50 to 280 within the year</td>
</tr>
<tr>
<td>Republic of Ireland, HIQA—a network of 5 nations for licensing based on knowledge and evidence (akin to the Healthcare Commission).</td>
<td>€20 million per year (start up in May 2007)</td>
<td>5 FTE, plus 2 secretaries and 3 technical personnel helping at national level</td>
</tr>
<tr>
<td>Netherlands, EU NetPaS, OECD indicator project, and national patient safety program as national network of hospitals sharing knowledge and evidence</td>
<td>€45-48 million (for entire PS strategy, not specified by area of action), estimated that €8-9 million was for research</td>
<td>5 FTE, plus 2 secretaries and 3 technical personnel helping at national level</td>
</tr>
</tbody>
</table>

SOURCE: RAND Europe

NOTE: 1This estimate is a RAND calculation based on the conversion rate of £1 to €1.26142 as of 29 May 2008 (www.oanda.com).

There will be some new jobs, but no job losses

The question of macroeconomic impact of this action area was contested. Many respondents saw little value in making any assessment of this relationship as it could only be speculative and would not be supported by any hard evidence. However, a few
respondents felt that developing and using knowledge and evidence at the EU level would create a few new jobs, such as experts on patient safety in institutions and also educators to train doctors and nurses about patient safety. For Hungary, this action would have macroeconomic benefit in the long term as there would be new jobs and the action is “a good future for Hungary”. But, in Germany, the macroeconomic benefit may be negligible or unquantifiable as this action would lead to only a small number of jobs.

Consistent with a comment above about the redirecting of resources, our WHO respondent said that the macroeconomic effects of Action Area 3 on the health system are more about a “re-orienting of costs and may not be necessarily an increase in costs”. The impact will be a “redistribution of resources to research and then to targeted outcomes and this will be a positive impact because of improvement actions”. By contrast, a respondent from Sweden believed that “there is at least cost reduction for the government in the long term” as a main benefit of developing and using knowledge and evidence at EU level. The reasoning behind this comment was that, because the healthcare sector is a large proportion of the total economic burden for most countries, increasing patient safety and reducing costs from this action area should have some macroeconomic effects. However, as another respondent remarked, this analytic assessment assumes that knowledge and evidence at EU level will improve patient safety when really this action is a means to this end (via RLSs, for example).

Although developing and using knowledge and evidence can have a positive impact on the macroeconomic environment through improving efficiency, a negative impact of this action area “could be a decrease in attractiveness of the healthcare sector for a profession” because, through greater awareness of data on patient safety, “people may perceive [healthcare work] as too risky” (KH/HOPE). Because risky care may be avoided, knowledge and evidence may inadvertently prevent professionals from doing something, providing care, that may work and so more knowledge and evidence on patient safety would be a negative economic and social impact on the health system.

An EU-level respondent from PGEU suggested that since there appears to be no data on the macroeconomic impact of this (and other Actions) to improve patient safety in the EU, the need for more research – perhaps funded at the EU level in terms of public health programmes or the Framework for Research – might in itself have a macroeconomic impact in terms of financing more needed research. The respondent went further to suggest that research needs to take “an overarching view over the whole system and not just focus on the impact of policies in the hospitals” because “many errors happen at the interface”. The latter comment reflects back on one of the emerging themes described in the chapter above.

5.3.2 Social impacts

The social impact of Action Area 3 seemed overwhelmingly positive, most directly for health professionals

For many respondents, the social impact of this action area on patients, care providers and healthcare systems reflected and reinforced the expected social impacts of the other two action areas as it was envisaged to be “more or less the same”. For example, if an EU-level knowledge and evidence network contributes to one member state establishing a RLS, then the social impact would come from the latter more than the former. In the context of
interlinked actions, the social impact of Action Area 3 was felt to be greater than redress mechanisms at national level and closely linked to the impact of RLSs from which evidence and knowledge could be developed and used at the EU level. Since much of what is done and needed for patient safety is knowledge and evidence, this third action area, like RLSs, will contribute to greater patient awareness of patient safety issues and the systematic response from hospitals and healthcare professionals. And, when this is done well, “confidence will improve, or at least not decrease”. Greater patient confidence in health professionals was also viewed by a respondent from HOPE as a main benefit of this action area to health professionals.

Most respondents (e.g. Hungary, PGEU, Netherlands, HOPE, Sweden, Slovenia, Bulgaria, Spain) felt that the social impact of this third action area would cut across patients and care providers and, by extension, the health system – knowledge and evidence “benefits everyone” (JV). For Hungary, among these stakeholders, the clear benefit of knowledge and evidence at EU level comes from the change in methodology and subsequent culture change in the minds of doctors and in medical education. The respondent from HOPE also felt that this third action area would have a “strong impact on initial education and continuing education in terms of the way evidence is delivered and what’s missing today”; it is in medical education that there will be “big changes as well as in the culture of the profession”. A respondent from Spain felt that if the county could design a curriculum at EU level through EUNetPaS, they can “improve the knowledge on patient safety among professionals and the skills and the attitudes with patients”. At a local level, the positive impact of a pilot teaching programme in Spain was evident in terms of high participant satisfaction and the utility of the knowledge and the skill in the performance of clinicians (as described above).

The sharing of knowledge and evidence, according to our respondent from PGEU, actually “builds a relationship between different healthcare professionals which is essential if you want to put any type of Patient Safety strategy in place. Collaborative care, understanding the importance of each other and the need to work together would be a very important benefit” to care providers from this action area. As a consequence of working towards the same goal, collaborative care “means you are working in a more streamlined way” and, importantly, “gaining productivity” – not from being pushed by productivity pressures but rather by being pushed to be more aware of the effects of providers’ activities, to find efficiency and to work together. Although unquantifiable, the social impact of this Area of Action was believed to be “very positive” by our respondent from the Republic of Ireland who felt that “knowledge is never negative” and so, if this action area gives you “greater awareness of safety and of risks, it will only drive improvements ultimately in terms of delivery of service and of care” which is a benefit to healthcare professionals.

In a similar way, “anything that impresses upon patients’ empowerment and improving their utilisation of healthcare, and therefore society’s utilisation of healthcare, through greater awareness” should provide a benefit to society. One caveat to this benefit was raised by a respondent from the Netherlands who stated that, while “information can be good for patients,” the publication of the amount of deaths in hospitals, for example, can have the “unintended consequence of raising people’s level of fear of the healthcare system”. How “knowledge and evidence is communicated will determine the impact” of this action area (HOPE), and this point ties back to the themes of culture, communication and the role of
the media such that knowledge and evidence empowers patients rather than the reverse. This Dutch respondent stressed that “if there is patient engagement” in reporting incidents, then the “benefits outweigh the potential dis-benefits”. Similarly, the WHO respondent felt that, as “an awareness-raising tool”, developing and using knowledge and evidence at EU level is “an extremely important action” because it will “support the health literacy campaign, patient empowerment and engagement as well as constructive dialogue between the doctor and patient, with overall benefit at the health system level”.

Another unintended consequence of this action area was expressed by the Republic of Ireland respondent in relation to the impact on education systems. On the one hand, the positive social impact described above is mainly driven by the globalisation of knowledge in terms of sharing information and learning from systems abroad, and ready access of knowledge both for providers and purchasers/patients. On the other hand, this same driving force can perversely impact educational systems in a negative way in the Republic of Ireland insofar as making educational systems “more process and performance indicator-led might actually take away benefit to the individual pupil or scholar” (in terms of innovative and creative thinking).

Two respondents (WHO and Bulgaria) gave a unique social impact of this action area in terms of individual countries being able to “measure [themselves] against other countries” (Bulgaria) and that, in benchmarking, countries can get a “reality check” on how well they are doing to improve patient safety in reality, and “being evidence-based it’s indisputable”. Finally, one respondent from Spain mentioned that this third action area will give Spain more information about specific groups that have problems with the healthcare system and who are more exposed to errors. Currently, there is some information that certain immigrants in Spain, especially from the South (e.g. Morocco), are more exposed to errors than national people, because they lack the knowledge or the language ability to question the delivery of their healthcare. EU level action in developing and using knowledge and evidence, disaggregated by various social factors, could lead to member state improvements in health inequalities.

5.4 Summary of respondents’ relative ranking of social and economic impacts of patient safety actions

During the interviews, we asked respondents to give a relative ranking to each of the three areas for action on patient safety according to (1) the greatest economic impact, and (2) the greatest social impact. We had 26 responses to this question and many respondents found this ‘hidden’ question very difficult to answer, in part because of a lack of scientific method in their intuitive answers. One respondent did not provide a relative ranking and four respondents were not asked the question either due to time pressures on limiting the interview or because the question was implemented after two interviews had already been completed.

Redress (Action Area 2) would have the greatest negative economic impact but the least positive economic impact in terms of lower adverse event costs. One respondent ranked Action Areas 1 and 2 as having the same level of economic impact (High). When a mixed rank of 1/2 or 2/3 was given for two action areas, we counted both actions for the higher
level rank. For example, one respondent ranked Action Areas 1 and 2 as the same (high economic impact), so they were counted as each having a ‘high’ level. The following tables summarise our results (Table 5.6 and Table 5.7). Action Area 1 refers to establishing effective RLSs; Action Area 2 refers to redress mechanisms and Action Area 3 pertains to developing and using knowledge and evidence at EU level.

Table 5.6 Ranking of the three action areas according to greatest economic impact

<table>
<thead>
<tr>
<th>Impact level</th>
<th>Action Area 1</th>
<th>Action Area 2</th>
<th>Action Area 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>14*</td>
<td>11</td>
<td>4</td>
</tr>
<tr>
<td>Middle</td>
<td>8</td>
<td>7</td>
<td>11*</td>
</tr>
<tr>
<td>Low</td>
<td>4*</td>
<td>8</td>
<td>11</td>
</tr>
</tbody>
</table>

SOURCE: RAND Europe

NOTE: *Two respondents ranked the three action areas in terms of greatest cost input (the rest ranked according to greatest return on investment)

Table 5.7 Ranking of the three action areas according to greatest social impact

<table>
<thead>
<tr>
<th>Impact level*</th>
<th>Action Area 1</th>
<th>Action Area 2</th>
<th>Action Area 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>13</td>
<td>6</td>
<td>10</td>
</tr>
<tr>
<td>Middle</td>
<td>10</td>
<td>11</td>
<td>8</td>
</tr>
<tr>
<td>Low</td>
<td>2</td>
<td>9</td>
<td>6</td>
</tr>
</tbody>
</table>

SOURCE: RAND Europe

NOTE: *Three respondents gave the same rank (1/2) to Actions 1 and 2; one respondent gave the same rank (1/2) to Actions 1 and 3; and four respondents gave the same rank (2/3) to Actions 2 and 3.
Chapter 6  
Quantitative Simulation of Health Impacts

This Chapter presents our approach in estimating in a quantitative way the potential health impacts that activities for improving patient safety could have on inpatient and outpatient populations in Europe. However, the authors wish to stress the fact that our quantitative analysis is strictly exploratory, as we have made a number of different assumptions, some of which cannot be directly validated by empirical evidence.

6.1 Status quo: Possible impacts from no policy change

6.1.1 Analysis of inpatient (hospital) data

In this section we estimate the current number of adverse events across the EU-27, and their causes and consequences in terms of disability and mortality. Because very little data are available on the exact prevalence of adverse events for each member state, our research should be regarded as exploratory. The purpose is merely to provide guidance for subsequent testing of hypotheses, and give an overview of the estimated magnitude of the problem.

We first estimated the prevalence of adverse events across the EU-27 by applying a range of prevalence rates for inpatient hospitalisations reported in the literature to the total number of discharges in each country. The latter was obtained from publicly available Eurostat data. The estimates we found in the literature on the prevalence of adverse events related to hospitalisations ranges from 7.5% to 16.6%, with median of 10%, depending on country, year and specific study. In absence of more country-specific estimates, we assumed these prevalence rates to be constant across all countries. Applying these rates to the total number of discharges and summing over all EU countries gives the estimates shown in Table 6.1. The table shows that across the entire EU-27 between 6.7 and 15m hospital discharges are associated with an adverse event.

96 Eurostat (2005).

97 We compared the range of prevalence figures (7.5% to 16.6%) to recent data from the UK NRLS. The most recent patient safety incident rate available is 576,919 incidents in acute/general hospitals. On a total of 14.7m discharges, this estimate comes out at about 4%, substantially lower than the 7.5% reported in the literature. A possible explanation for the difference could be under-reporting in NRLS and differences in coding.
To further explore the consequences of adverse events in the hospitals setting, we applied findings from other studies, in particular the Quality in Australian Healthcare study (QAHCS) and the Spanish National Study on Hospitalisation-Related Adverse Events (ENEAS). Based on the QAHCS published in 1995, we hypothesised that 13.7% of these events would result in permanent disability, and 4.9% in death. The resulting extrapolations from these assumptions are shown in Table 6.2. This table suggests as much as 1.1m hospitalisations across the EU-27 result in permanent disabilities due to an adverse event, and as much as 404,000 hospitalisations result in death due to an adverse event.

We used two additional studies as a sensitivity analysis to obtain additional estimates. The study by Vincent et al. (2001) found quite similar figures for the prevalence of adverse events (11.7%) in the UK, although the breakdown by adverse events resulting in permanent disability (6%) and death (8%) were slightly different from the QAHCS study. The ENEAS investigators estimated a prevalence of inpatient adverse effects of 8.4%, with a 95% confidence interval ranging from 7.7% to 9.1%. Finally, Baba-Akbari Sari (2007) estimated in a separate UK study a prevalence rate of 8.7%, of which 15% “led to impairment or disability which lasted more than 6 months and another 10% contributed to death”. Table 6.2 shows that our simulations can be very sensitive to the inputs/assumptions. Thus, they confirm the need to treat these extrapolations in this section cautiously.

The authors recognise that it is possible, and perhaps even quite likely, that multiple adverse events contribute to death within a single patient. Ergo, we cannot interpret these simulated estimates as the number of people dying due to adverse events. This fact becomes apparent when we compare these estimates to those given by the Institute of Medicine in their report ‘To Err is human,’ for example. The US report estimated a range of 44,000 to 98,000 annual deaths caused by adverse events in a 1997 US population of 269 million. If we extrapolate these figures to the 2008 EU-27 population of 497m, we would find an estimate ranging from 81,306 to 181,090 deaths annually, which is a much lower figure than the estimated annual number of inpatient adverse events resulting in death shown in our table below.

**Table 6.1 Estimated annual number of discharges associated with an adverse event**

<table>
<thead>
<tr>
<th></th>
<th>Low bound (7.5%)</th>
<th>Median (10%)</th>
<th>High bound 16.6%</th>
</tr>
</thead>
<tbody>
<tr>
<td>EU-27</td>
<td>6,765,735</td>
<td>9,020,979</td>
<td>14,974,826</td>
</tr>
</tbody>
</table>

SOURCE: RAND Europe
Table 6.2 Estimated annual number of inpatient adverse events resulting in permanent disabilities and death

<table>
<thead>
<tr>
<th>AE prevalence assumption (Source):</th>
<th>Estimated annual number of inpatient adverse events resulting in permanent disability (13.7%)</th>
<th>Estimated annual number of inpatient adverse events resulting in death (4.9%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Low bound (7.5%)</td>
<td>Median (10%)</td>
</tr>
<tr>
<td>EU-27 (QAHCS)</td>
<td>850,057</td>
<td>1,133,409</td>
</tr>
<tr>
<td>EU-27 (Vincent et al., 2001)</td>
<td>372,288</td>
<td>496,383</td>
</tr>
<tr>
<td>EU-27 (Baba-Akbari Sari et al., 2007)</td>
<td>930,719</td>
<td>1,240,959</td>
</tr>
</tbody>
</table>

SOURCE: RAND Europe

Table 6.3 below is a replication of the results shown above in Table 6.1, but using estimates from the ENEAS 2006 study from Spain. The ENEAS study reports that 42.8% of these adverse events could have been prevented, which would be equal to a total of 3,590,711 preventable adverse events at the EU-27 level. In a population of 5,624 patients, the ENEAS investigators found 151 patients had to be readmitted to the hospital due to the adverse event, which would equal to 2.4m readmissions across the EU-27. By extrapolating the additional length of stay due to adverse events found in the ENEAS study to the EU-27, we found that EU citizens may spend an additional 140,626 person-years in hospital as a result of adverse events, of which 50,845 person-years could have been prevented.

Table 6.3 Estimated annual number of discharges associated with an adverse event using Spanish data

<table>
<thead>
<tr>
<th>Estimated annual number of discharges associated with adverse event</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low bound (8.6%)</td>
</tr>
<tr>
<td>Adverse events EU-27</td>
</tr>
</tbody>
</table>

SOURCE: RAND Europe

6.1.2 Analysis of primary care data

We used findings from the APEAS (2005) study reported for Spain regarding adverse events related to consultations, and made extrapolations for the entire EU-27, assuming the other countries would experience similar adverse event rates related to consultations as Spain (i.e. for every 1.86% of consultations a patient safety incident occurs, for 0.75% this
is a ‘near miss’ and for 1.12% this is an adverse event). Since Eurostat data do not include the number of consultations per patient, we used OECD Health Data (the latter does include this information). Unfortunately the OECD data encompasses a smaller set of EU countries, and hence we had to extrapolate the results for this smaller set (representing about 90% of the EU-27 population) to the entire EU-27 which we recognise is not as accurate as the preferred alternative of using country-specific data.

Table 6.4 shows for each country the estimated number of consultations leading to a patient safety incident, a ‘near miss’, or an adverse event. The number of patient safety incidents is calculated for each country by multiplying the number of consultations per person per year by the population size and applying the prevalence percentage. The EU-27 estimate is then obtained by summing across all countries. Under these assumptions, the total annual number of consultations resulting in an adverse event would exceed 37m across the EU-27, as Table 6.4 shows.

| Estimated annual number of patient safety incidents related to a consultation |
|-----------------------------------------------|---------------------|---------------------|
| Total                                         | Near miss (NM)      | Adverse event (AE)  |
| 1.86%                                         | 0.75%               | 1.12%               |
| EU-27                                         | 61,770,414          | 24,701,534          | 37,068,880          |

SOURCE: RAND Europe

Further utilising the results from the Spanish study, we estimated a breakdown of the adverse events (right-hand column in Table 6.4) according to preventability (Table 6.5), causes (Table 6.6) and consequences (Table 6.7). Overall, as it can be seen in Table 6.5, there is a great potential for prevention, as more than 26m adverse events relating to consultations could be prevented. Table 6.6 shows that the magnitude of events are due to medications errors which would contribute to nearly 18m adverse events across the EU, and Table 6.7 indicates a total of over 2m life-saving hospitalisations per year due to adverse events across the EU.

<table>
<thead>
<tr>
<th>Preventability of estimated annual number of patient safety incidents related to a consultation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preventability</td>
</tr>
<tr>
<td>EU-27</td>
</tr>
</tbody>
</table>

SOURCE: RAND Europe

<table>
<thead>
<tr>
<th>Causes of estimated annual number of patient safety incidents related to a consultation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medication</td>
</tr>
<tr>
<td>48.20%</td>
</tr>
</tbody>
</table>
In this section, we attempt to simulate the effects that coordinated and comprehensive policies could have in reducing the health burden due to patient safety incidents. To do this, we make further assumptions on the prevalence rates of adverse events in the EU countries. Specifically, we assume that the prevalence of adverse events depends on the sophistication of a country’s patient safety activities as a composite whole. We assume the following simplified hypothetical breakdown of prevalence rates across the five groups of countries identified in Section 4.3:

- ‘Five Star’ countries have an adverse event prevalence rate of 7
- ‘Four Star’ countries have an adverse event prevalence rate of 10
- ‘Three Star’ countries have an adverse event prevalence rate of 12
- ‘Two Star’ countries have an adverse event prevalence rate of 14
- ‘One Star’ countries have an adverse event prevalence rate of 17.

Note that this distribution covers the prevalence range reported in the literature. Thus, although the true rates are unknown, the rates should have face-validity to some degree. We then simulate four alternative scenarios, as shown in Table 6.8.
Table 6.8 Alternative scenarios used in simulations

<table>
<thead>
<tr>
<th>Country category</th>
<th>Prevalence of AEs related to hospitalisations</th>
<th>Scenario 1</th>
<th>Scenario 2</th>
<th>Scenario 3</th>
<th>Scenario 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>'Five Star'</td>
<td>7</td>
<td>7</td>
<td>7</td>
<td>7</td>
<td>7</td>
</tr>
<tr>
<td>'Four Star'</td>
<td>10</td>
<td>10</td>
<td>10</td>
<td>10</td>
<td>7</td>
</tr>
<tr>
<td>'Three Star'</td>
<td>12</td>
<td>12</td>
<td>12</td>
<td>10</td>
<td>7</td>
</tr>
<tr>
<td>'Two Star'</td>
<td>14</td>
<td>14</td>
<td>12</td>
<td>10</td>
<td>7</td>
</tr>
<tr>
<td>'One Star'</td>
<td>17</td>
<td>14</td>
<td>12</td>
<td>10</td>
<td>7</td>
</tr>
</tbody>
</table>

SOURCE: RAND Europe

In Scenario 1, we assume EU-level patient safety policies would allow countries classified in our taxonomy as being ‘one star’ to advance and experience equal adverse event prevalence rates as countries classified as ‘Two Star’. In Scenario 2, we assume ‘one star’ and ‘two star’ countries would be able to advance and experience similar adverse event rates as countries classified as being ‘Three Star’ due to more effective EU regulation in the proposed policy areas. In Scenario 3, we assume EU-level regulation has a large impact with the result that all EU countries advance to the relatively most favourable levels of adverse events reported by the literature. Finally, Scenario 4 takes figures from the best anchoring/benchmarks and simulates the impact of all countries becoming exemplary (Five Star).

The authors emphasise again that the following exploratory scenarios depend upon the assumption that the countries which perform better in terms of the different processes for improving patient safety will also have better health outcomes. We acknowledge that our analysis is limited by that fact that we cannot directly evaluate the validity of this assumption. We therefore show what could happen, if our assumption were true. Nevertheless, our assumption seems sound in light of other empirical evaluations done by the UK’s National Audit Office which have demonstrated, in comparative studies, the causal link between better processes (reorganisation, wiser use of existing care services, improved system quality) and better health outcomes.98

Table 6.9 shows the simulated EU-wide number of adverse events associated with inpatient hospitalisations, and resulting permanent disabilities and deaths, based on all the assumptions stated before. Thus, we replicated the estimation underlying Table 6.2 for each of the alternative scenarios. The difference between each scenario and the baseline predictions are shown in Table 6.10. For the estimation of preventable adverse events, we applied the ratio of 42.8% preventable adverse events, reported by the ENEAS study, to the adverse event estimates under each scenario, and assumed that the preventable length-of-stay would be proportional to the number of adverse events. Under the assumptions

98 See, for example, Hudson et al. (2007); and, also, NAO (2007).
stated above, these could be considered the potential benefits of additional EU regulation to improve patient safety systems.

**Table 6.9 In-patient care: estimated number of adverse events**

<table>
<thead>
<tr>
<th>Simulated outcome</th>
<th>Baseline</th>
<th>Scenario 1</th>
<th>Scenario 2</th>
<th>Scenario 3</th>
<th>Scenario 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prevalence of AEs related to hospitalisations 'One Star' countries become 'Two Star'</td>
<td>10,274,289</td>
<td>10,074,578</td>
<td>9,577,161</td>
<td>8,499,351</td>
<td>6,311,945</td>
</tr>
<tr>
<td>Permanent disability</td>
<td>1,562,411</td>
<td>1,532,041</td>
<td>1,456,399</td>
<td>1,292,496</td>
<td>959,857</td>
</tr>
<tr>
<td>Death</td>
<td>558,819</td>
<td>547,956</td>
<td>520,902</td>
<td>462,280</td>
<td>343,307</td>
</tr>
<tr>
<td>Preventable AEs</td>
<td>4,397,396</td>
<td>4,311,919</td>
<td>4,099,025</td>
<td>3,637,722</td>
<td>2,701,512</td>
</tr>
<tr>
<td>Preventable length-of-stay (person-years)</td>
<td>50,845</td>
<td>49,857</td>
<td>47,395</td>
<td>42,061</td>
<td>31,236</td>
</tr>
</tbody>
</table>

**SOURCE:** RAND Europe

**Table 6.10 In-patient care: estimated potential health benefits relative to baseline**

<table>
<thead>
<tr>
<th>Simulated Outcome</th>
<th>Baseline</th>
<th>Scenario 1</th>
<th>Scenario 2</th>
<th>Scenario 3</th>
<th>Scenario 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prevalence of adverse events related to hospitalisations 'One Star' countries become 'Two Star'</td>
<td>0</td>
<td>199,711</td>
<td>497,417</td>
<td>1,077,810</td>
<td>2,187,406</td>
</tr>
<tr>
<td>Permanent disability</td>
<td>0</td>
<td>30,370</td>
<td>75,642</td>
<td>163,903</td>
<td>332,639</td>
</tr>
<tr>
<td>Death</td>
<td>0</td>
<td>10,863</td>
<td>27,054</td>
<td>58,622</td>
<td>118,973</td>
</tr>
<tr>
<td>Preventable adverse events</td>
<td>0</td>
<td>85,476</td>
<td>298,371</td>
<td>759,673</td>
<td>1,695,883</td>
</tr>
<tr>
<td>Preventable length-of-stay (person-years)</td>
<td>0</td>
<td>988</td>
<td>3,450</td>
<td>8,784</td>
<td>19,609</td>
</tr>
</tbody>
</table>

**SOURCE:** RAND Europe
On a final note, we were unable to obtain data on consultations from the OECD for many of the countries grouped in the ‘One Star’ and ‘Two Star’ category, hence we did seek to simulate the potential benefits related to reduction in adverse events during primary care consultations. In addition, we did not include life-years lost as a health outcome in our quantitative simulation primarily because little is known about the effect of adverse events on life-years lost.
7.1 Brief review of general findings

This Report, supported by the European Commission, examined the scope of the problem of adverse events and near misses among patients in Europe, as well as internationally, using both quantitative and qualitative methodologies. We reviewed the evidence base in the literature and conducted in-depth, semi-structured interviews with 32 experts from the High Level Working Group on Patient Safety in Europe. In support of the Commission’s Impact Assessment of the Patient Safety and Quality Legislative proposal for 2008, the purpose of our Report is to provide the Commission with a comprehensive piece of research mapping the current landscape of patient safety improvement activities, knowledge, evidence and the expected impacts of three policy areas the Commission would like to introduce to improve patient safety in Europe.

Overall, our Report confirms that patient safety is an important public health problem as adverse events affect between 7.5% and 16.6% of hospital patients, and between 1% and 2% of patients in the primary care setting. Moreover, if extrapolated to the EU-27, these prevalence rates have the potential for adverse events to be associated with 6.7-15m hospital discharges. In the primary care setting, the total annual number of consultations resulting in adverse events would exceed 37m across the EU-27.

In reviewing the root causes and implications of adverse events it becomes clear that, while not all near misses and adverse events are preventable, a large fraction of them are preventable both in the hospital and primary care sectors. In particular we identified the main causes of preventable injury, which include invasive procedures and medication errors. A second observation which emerges is that systemic factors appear to account for a majority of adverse events at least in countries with developed systems in place to assess and measure incidents.

7.2 In-depth discussion of specific findings

1. There is a notable absence of economic evaluations relating to health for assessing the impact of the three policy action areas

The results of our qualitative interviews have shown that it is indeed difficult to quantify the impact of patient safety initiatives, such as the three policy action areas the Commission would like to introduce. In particular, regarding the third area of action, none
of the experts were able to provide any concrete assessment of the economic impact and any indicators provided served only as proxy measures, such as a general budget for institutions or organisations performing work akin to Action Area 3. For example, a German respondent provided the budget of the Coalition for Patient Safety. In Germany’s care, he felt that developing and using knowledge at the EU level would have minimal effect financially since work like it was already being done by the Coalition at national level. Therefore the cost data for the German Coalition was provided in this report as one example of what such actions, related to expert linking and knowledge exchange, might cost to other member states that as yet have no action in this area.

Currently, there are no economic evaluations in Europe of any of the action areas, especially not for an action area containing multiple actions such as in the case of developing knowledge and evidence at the EU level – an action which would likely involve collaborative research, personal networking and multi-organisational events to link stakeholders (researchers, politicians, patients etc) for knowledge exchange. This finding is consistent with a summary report of Pennsylvania’s Patient Safety Authority indicating how hard it is to “assign numbers and a value” to the state’s RLSs in terms of the number of lives saved in the past year. Moreover, an international review confirms our European expert consensus on the notable absence of health economic studies on the extent of anticipated cost-savings from RLSs, redress mechanisms or knowledge and evidence building at EU level. As Kilpatrick et al. (2005) conclude “scant attention is currently paid in the quality-of-care literature to the cost of implementing quality-enhancing interventions” based on their key finding that only 15 of 1,968 articles identified contained sufficient information on both the costs of implementing quality-enhancing interventions and the resultant changes in costs of care or revenues to permit the calculation of a return on investment.

In a recent review of a specific quality improvement initiative – the Quality Improvement Collaborative developed by the US Health Resources and Services Administration – Brian Mittman also found that there is only a modest quantity and quality of published evidence that supports its effectiveness. Despite the absence of a sufficient evidence base, there is widespread acceptance and application of this method. Our findings from the Expert Interviews parallel this general sentiment that collaboration on patient safety – at national and international levels – will lead to improved quality of care, or ‘better care.’ In the light of the absence of impact evaluations of quality improvement methods and patient safety strategies – in terms of developing and using knowledge and evidence in Europe – it

99 Hanlon and Rosenthal (2007). It is worth noting that PSA receives almost 17,000 reports each month from over 400 facilities and the numbers are rising. Authorities believe this indicates better compliance and greater desire to learn from the data, rather than an actual increase in near misses or adverse events according to its annual survey. PSA has a budget of about US$4m a year. (The Commonwealth Fund Health Policy, Health Reform and Performance Improvement. Patient Safety Initiatives; 24 December 2007. [Online] Available at http://www.commonwealthfund.org/innovations/innovations_show.htm?doc_id=675757 (Accessed: 2 April 2008)).

100 Kilpatrick et al. (2005).

is perhaps not surprising that there was little evidence offered by the respondents on the social and economic impacts of this Third Area of Action.

In other areas of healthcare policy research, there is sufficient evidence that strategies and initiatives to link health research and policy-making by formal and frequent exchanges at local and national levels are effective.\footnote{Conklin et al. (In press).} One could conceive that, through linkage and exchange-type networking strategies among key stakeholders in Europe, Action Area 3 – developing and using knowledge and evidence at EU level to improve patient safety – could produce similarly positive short-term and long-term impacts. Moreover, we know from international experience that other quality improvement initiatives, such as for depression, can offer societal cost-effectiveness comparable to that of accepted medical interventions, having effects on employment.\footnote{Schoenbaum et al. (2001).}

2. There is some international data on the social impact of the use of ICT to improve patient safety, but there are no impact assessments of the three policy areas for action proposed by the Commission

Like the impact assessment for Action Area 3, few respondents could provide data sources for evidence on the social impact of Action Area 1 and no known assessment of the economic consequences. The need to improve the assessment of the consequences/impacts of risk-reduction programmes (such as a RLS) led to a recent comparative study of methods for estimating rates of adverse events and rates of preventable adverse events in acute hospitals.\footnote{Michel et al. (2004).} Michel et al. (2004) concluded that the preferred method for studying organisational and human mishaps (especially for better effectiveness in identifying preventable adverse events) is to use a \textit{prospective} assessment. This finding supports the fact that few European member states with active patient safety programmes have benefited from enough time to study the real impacts of their risk-reduction strategies.

Looking internationally, new approaches to delivering quality healthcare are beginning to massively improve the benefit that health professionals and care delivery can offer to patients. For example, the Intermountain Healthcare system in Salt Lake City, America, has produced system-wide improvements through an organised system of care while significantly reducing costs.\footnote{James (2008).} Also at a macro level, an assessment of AHRQ’s (Agency for Healthcare Research and Quality in the US Department of Health and Human Services) has demonstrated its strong contributions to building patient safety culture, information systems, adverse event reporting systems, and multi-institutional collaborations.\footnote{AHRQ (2001).} In the field of critical analysis of patient safety practices, Stanford University’s Evidence-based Practice Center demonstrated the value of bringing together groups of diverse stakeholders and of providing them with intense patient-safety training in the first two years of AHRQ’s Patient Safety Improvement Corps.\footnote{AHRQ (2001).}
Although there is a movement towards eHealth and introducing other technology, such as RFID, into healthcare delivery to improve patient care quality and outcomes, studies in the US, UK and Australia have also found evidence of the potential danger of using computerised physician order entry systems (CPOE) as a key technology to help realise the goal of reducing medical errors. For example, a case study of a near miss by McDonald (2006) shows that computer systems, although having the potential to improve safety, may create new kinds of errors if not accompanied by well-designed, well-implemented crosscheck processes and a culture of safety. Moreover, computer systems may have the pernicious effect of weakening human vigilance, thereby removing an important safety protection.

Nevertheless, assuming that an integrated medication system that included unit dosing and bar-coding of medications can reduce errors in medication administration, for example, in the order of 40% and 30% respectively; the potential cost savings that could be expected would be over US$820,000 with lower rates, ranging up to US$1.4m. As Anderson et al. (2003) note, these estimated potential savings are “a significant impact of these [information technology] interventions” and when combined with other prevention strategies to reduce adverse drug events even further (e.g. better reporting of medical errors and inclusion of a clinical pharmacist on the ICU), information systems that prevent adverse drug events “are potentially cost effective”.

3. Action is being taken at the international level towards developing the necessary policy evaluations of current activities to improve patient safety

In this context, it is particularly salient for member states in Europe to know how they can learn from their reporting systems (both local and national ones). Given the known need to understand the anticipated impacts as well as unintended consequences of risk reduction programmes like patient safety RLSs, we note the importance of a recent Round Table discussion on ‘How do we learn from reporting systems?’ at the British Medical Journal International Forum on Thursday 24 April 2008. The discussion was chaired by the Director of the Danish Patient Safety Society and the Chief Executive of the UK’s National Patient Safety Agency. Similarly, there is currently a four-year project to evaluate the impact of New Zealand’s new legislation which eliminates the fault element of its redress mechanism (the Accident Compensation Corporation). The legislation, in force on 1 July 2005, is meant to replace the redress mechanism with an entitlement based on a direct causal link between a personal injury and treatment by a health professional and to simplify the criteria and claims processes for patient injuries. Finally, with respect

108 European Commission (2006); Haller et al. (2007); Turtle et al. (2004).
109 Sini, Locatelli and Restifo (2008); McFadden et al. (2006); RFID (2008); and, see, more generally, health-related articles in the RFID journal.
110 European Commission (2006); see also, Bates, Cohen, Leape et al. (2001); and, Patterson, Cook and Render (2002).
111 Anderson et al. (2003).
113 Australian Patient Safety Foundation (2007).
to event-specific patient safety incidents, the authors highlight recent action in the UK – a Westminster Health Forum keynote seminar on 20 May 2008 – on “Healthcare Associated Infections, Patient Safety and Innovation”. The seminar sought to discuss how HAIs can be minimised, how this might be implemented across the NHS, and the next steps in improving patient safety.

4. The existing information gap can be bridged using existing institutional structures

The importance of having evaluations of patient safety mitigation strategies underscores the comments, made by our OECD respondent, that it may not always be necessary to establish a new Patient Safety Institute at a member state level; these comments contrast with the typical response to recent political attention on the problem of patient safety. Rather it may be that existing quality institutions, in those member states that have them, could be in a position to provide sufficient administrative data for the purpose of reporting and learning of adverse events. Indeed, OECD has shown that it is not necessary to create a whole new database or institutional structure to this end.

Evidence from the patient safety literature in the US supports the emphasis from our OECD respondent that there is a need to evaluate whether existing administrative databases can be mined for patient safety indicators and whether EU-level action can help a member state to achieve what the literature suggests is important. In other words, “to assess the extent to which existing standards for reporting health information in other contexts – that is, outside the context of patient safety – could be used to code the information in adverse medical event reports […] Many of the detailed standards already exist for particular data elements, such as patient and product information.” And where there are discrepancies or a lack of standardised action and standards, EU-level action can help bridge these crucial information gaps by providing a comprehensive framework for the exchange, integration, sharing and development of patient safety health information.

Although there does not appear to be consensus among our Key Informants on best practice for redress mechanisms (as noted above regarding the difficulty of defining the concept of ‘fair’), the WHO has developed best practice guidelines on RLSs and how to implement them (as discussed in Chapter 3). It is worth noting, moreover, that the best practice guidelines presume that blame-free RLSs are correlated with a no-fault compensation system.

5. Patient engagement in RLSs varies across Europe and the benefits of this intervention are greater when patients can participate in reporting

In terms of ‘best practice’ and evaluations of patient safety improvement strategies, it is interesting to note the variation, among European member states with national RLSs, in the extent of participation of patients in the reporting process. Patient participation in RLSs was one of the criteria that distinguished the top two categories of European countries in the design of our taxonomy proposed in Section 4.3. This variation is relevant from an evidence-informed policy-making perspective because policymakers and health workers increasingly believe that encouraging patients to play a more active role in their healthcare could improve quality, efficiency and health outcomes. Yet, patient-focused

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114 Beckett et al. (2006).
quality interventions have often been criticised by sceptics as only political correctness. Although this debate was not raised directly in the interviews, several interview respondents assessed the social impact of RLSs for patients in terms of improved health literacy and greater patient engagement in their own care. This shared sentiment among some of the experts is indeed supported by evidence from Europe\(^\text{115}\) and elsewhere\(^\text{116}\) on the effectiveness of strategies for informing, educating and involving patients to improve patient safety. Indeed, patients could help select treatments, manage long-term conditions, and increase safety in relation to drug use and infection. Consistent with the literature, the positive benefits of engaging patients in RLSs for some of our respondents accrue because such interventions can improve patients’ knowledge and experience, use of health services, health behaviours, and health status.

6. The social impact of actions to improve patient safety are expected to be greater for vulnerable patient groups who are known to be disadvantaged in healthcare service access and delivery

Finally, while Coulter and Ellins (2007) found that a substantial evidence base exists in support of building strategies to strengthen patient engagement, they also conclude that “any strategy to reduce health inequalities must promote health literacy and engagement”. This key summary point highlights two key issues that have been raised by our work. First, a number of expert respondents suggested that the social impact of the proposed action areas, especially the first one, may be greater for some vulnerable patient populations – such as the elderly, those with disabilities, on low incomes or belonging to an ethnic minority – given the fact that these vulnerable groups are known to be disadvantaged in healthcare settings due to, among other reasons, language and cultural barriers. And second, the importance of embedding monitoring and evaluation research on patient safety improvement programmes is critical to addressing health inequalities and disparities among sub-populations in the relative risk of adverse events and near misses given that some groups of patients are more at risk than others (e.g. patients over 65 with intrinsic risk factors).

In the literature on health inequalities and social determinants of health, there are a number of recognised social factors that determine differences in health outcomes and experiences among sub-groups within a population, such as gender.\(^\text{117}\) Despite the fact that

\(^{115}\) Coulter and Ellins (2007).

\(^{116}\) Health Canada (2003).

\(^{117}\) In particular, gender is an important social factor that not only drives some of the social impacts of reporting and learning systems – as one respondent strongly emphasized – but gender also contributes to health inequalities among men and women in terms of women’s greater risk of experiencing an adverse event or near miss. For example, women in North America have greater contact with the health system and are more frequently hospitalised for both physical and mental health reasons (Secker 1999), putting them at greater risk of medical errors and adverse events in acute care. More specifically, black and white women of all classes, particularly unmarried women, comprise the largest group of psychiatrically hospitalised and “treated” Americans (Chesler 1971). In Stockholm, women make up 71% of psychiatric patients being treated (Hällström 2001). Moreover, even though the distribution of psychoses is the same between the sexes, prescriptions for psychosis, tranquilisers and sleeping pills are given to women at twice the frequency of male patients (Hällström 2001). The latter highlights the greater risk of medication error among women compared to men. “Sex differences” are also evidenced in patterns of diagnostic change after one year. Chaves et al. (2006)
only one of the 32 interviewees stated that gender was an issue for patient safety from a health workforce perspective,\textsuperscript{118} and that this statement cannot serve as the basis to make an empirical generalisation, a vast body of literature on Gender and Health (Bird and Rieker, 2008), examining the effects of constrained choice and social policies, suggests that there may be a series of research questions that need to be addressed, for example:

- What is the gender difference in the incidence of adverse events?
- What are the gender-based health outcomes of incidents?
- What is the impact of patient safety improvement strategies on women compared to men?

If the research were to indicate that women as patients are more likely to be exposed to healthcare services and medical interventions, and that women as nurses are more likely to report adverse events and near misses, as suggested by the literature and by the respondent from the European Nursing Federation, respectively, then we still need to know what is the relationship between gender and adverse events in a policy context of improving patient safety through three different action areas.

\textbf{7.3 Concluding comments}

The problem of adverse events for patient safety is twofold. First, it is abundantly clear that having data is essential, especially disaggregated data based on key social determinants of health. Two, patient safety as such is a relatively new and not well-addressed issue in Europe at present and hence the degree of maturity in society of the problem of adverse events suggests that the problem may not yet have reached critical mass for legal action at the EU level. It is important to remember that patient safety is not only a physician issue, but rather a whole healthcare delivery concern which includes settings other than hospitals, such as ambulatory care.

investigated patients diagnosed with first episode non-affective disorder and found that 22% of women diagnosed with schizophrenia spectrum disorder were later diagnosed with a mood disorder compared to only 1.7% of men. There are also gender differences in the diagnosis of schizophrenia as well as other psychotic disorders in general (Grossman et al. 2006). The fact that women and men have the same risk and yet there are gender differences in the experience of schizophrenia (Hällström 2001; Grossman et al. 2006), for example, further supports the case that gender must be seen as a critical aspect of patient safety improvement programmes to reduce health inequalities.

\textsuperscript{118} Gender also impacts on adverse events that affect patient safety through the healthcare workforce and nurse staffing policies (Canadian Health Services Research Foundation 2005). Numerous studies have demonstrated that reduced nurse staffing levels were correlated with increased patient mortality as well as increased adverse patient outcomes excluding mortality (ibid.). A number of different international studies, as described in a recent Canadian evaluation, provide empirical evidence to support one of our interviewee’s claim that “practice environments” negatively impact on the relationship between patient safety and nurse staffing. Our ‘outlying’ respondent accurately suggested that this ‘system factor’ is fundamentally a gender issue that must also be addressed if the European community wants to successfully reduce the many risks to patient safety. By implication, since gender cuts across issues of both patient safety and healthcare workforce policies and initiatives, it will be necessary for the EU to provide an overarching framework to properly manage healthcare workforce policies in the context of a broader patient safety agenda (WHO Regional Committee for Europe 2007).
Notwithstanding these limitations, the three policy areas for action constitute major cornerstones in moving forward to improve patient safety and health outcomes. Indeed, current work and activities in Europe to improve patient safety point to the importance of political commitment to cultural change among various stakeholders (e.g. providers and health managers). Most notably, patient safety is an important policy area that supports a more global movement of patient-centeredness and patient engagement in healthcare. Thus, patient participation in RLSs, for example, can function as a trust-building exercise as an added benefit to health systems more generally.

Patient safety-targeted actions cannot be fully and comprehensively evaluated in terms of their effectiveness and impacts on health outcomes (such as reducing the actual incidence of events and their consequences, i.e. death and disability). Part of the problem is that few systems have been in place, fully and appropriately implemented and for sufficient time, for outcomes to be demonstrated. The experience from the US strongly suggests that these systems need to be in place for several years and even then, study design and measurement challenges exist when attempting to document health outcome improvements. Thus, the first step is to focus and assess patient safety actions and initiatives by looking at context, input, and process measures.

We highlight the fundamental prerequisite for addressing any health policy issue as being the awareness and understanding of the problem at hand along with sufficient maturity in the collective “consciousness” of both the problem’s importance and the associated opportunity cost of inaction. From this vantage point, it would appear that ‘patient safety’ may not have reached this awareness level in the collective “consciousness” of the EU-27 member states. Thus, within the EU context, the Open Method of Coordination may be a crucial way to improve patient safety in Europe, both in mature and in burgeoning health systems, by a) building momentum and b) enabling formal and frequent exchanges among healthcare systems to set up common goals, research methodology, and continuous monitoring and learning.

Our quantitative exploratory analysis provides an example of how such learning might take place, and demonstrates the large potential in terms of reductions in adverse events, associated readmissions and additional lengths-of-stay, if below-average countries could improve to the level of above-average countries.
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SIMPATIE Project and reports [online] http://www.simpatie.org/Main


## Appendix A: Event-specific causes of adverse event morbidity, 2003 WHO raw country mortality files

<table>
<thead>
<tr>
<th>Country</th>
<th>Surgical operation</th>
<th>Foreign object left in surgery</th>
<th>Inadequate sterilisation</th>
<th>Drug dosage in surgery</th>
<th>Wrong fluid infusion in surgery</th>
<th>Endotractal tube placement</th>
<th>Blood mismatch in surgery</th>
<th>Patient record admin</th>
<th>Other misadventures</th>
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**Total** 201 100% 2 100% 6 100% 6 100% 1% 100% 4 100% 3 100% 2 100% 27 100%

Note: Blood mismatch in surgery, wrong fluid infusion in surgery, and wrong endotractal tube placement are sub-categories of events generally classified under “other misadventures during surgical/medical care.”
Appendix B: List of interview respondents from the Expert Working Group on Patient Safety

<table>
<thead>
<tr>
<th>Country/Institution</th>
<th>Organisational affiliation</th>
<th>Respondents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bulgaria</td>
<td>Department “National Health Policy”, Ministry of Health</td>
<td>Svetlana Spasova</td>
</tr>
<tr>
<td></td>
<td>General Coordinator, European Coordination Sector, Ministry of Health</td>
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<tr>
<td>Cyprus</td>
<td>General Coordinator, European Coordination Sector, Ministry of Health</td>
<td>Skevoula Evi</td>
</tr>
<tr>
<td>Denmark</td>
<td>The Ministry of Interior and Health</td>
<td>Helle Borg Larsen</td>
</tr>
<tr>
<td>Finland</td>
<td>Medical Counsellor, National Authority for Medico-legal Affairs</td>
<td>Pirjo Pennanen</td>
</tr>
<tr>
<td>France</td>
<td>Ministry of Health, Youth and Sport</td>
<td>Sandrine Odoul</td>
</tr>
<tr>
<td></td>
<td>Haute Autorité de santé, project lead for the EUNetPaS project</td>
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<td></td>
<td>German Coalition for Patient Safety</td>
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<tr>
<td>Germany</td>
<td>Senior Advisor Quality and e-Health Officer of the Deputy Minister</td>
<td>Zoi Kolitsi</td>
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<tr>
<td></td>
<td>Health Policy Department, Ministry of Health</td>
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<tr>
<td></td>
<td>Board Member, Health Information and Quality Authority</td>
<td>Ildiko Szy</td>
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<tr>
<td></td>
<td>Deputy Chief Medical Officer, Department of Health and Children</td>
<td>Jan Callanan</td>
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<tr>
<td></td>
<td>Ministry of Health, Deputy Head of</td>
<td>Eibhlin Connolly</td>
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<td></td>
<td>Division of Health Care Resources</td>
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<tr>
<td></td>
<td>Director, State Health Care Accreditation Agency under the Ministry of Health of the Republic of Lithuania</td>
<td>Kristine Klavina</td>
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<tr>
<td>Lithuania</td>
<td>Senior Advisor, Ministry of Health</td>
<td>Juozas Galdikas</td>
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<td></td>
<td>Welfare and Sport</td>
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<td></td>
<td>Senior advisor, Dutch Institute for Healthcare Improvement, project lead for the SIMPATIE project</td>
<td>Goef Buijs</td>
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<td></td>
<td>Chief Inspector, Dutch Health Care Inspectorate</td>
<td>Benno van Beek</td>
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<tr>
<td>Portugal</td>
<td>Directorate-General of Health</td>
<td>Jan Vesseur</td>
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<td></td>
<td>Department of Infectious Diseases,</td>
<td>José Robalo</td>
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<tr>
<td>Slovenia</td>
<td>University Medical Centre, Ljubljana</td>
<td>Bojana Beovic</td>
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<td></td>
<td>Specialist of Occupational Health, Head of the Department of Quality, Ministry of Health</td>
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<tr>
<td></td>
<td>Metka Terzan</td>
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<tr>
<td>Country</td>
<td>Position</td>
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<tr>
<td>Spain</td>
<td>Ministry of Health Yolanda Agra Varela</td>
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<td></td>
<td>Director, Medical Advisor, The Unit for Qualifications and Patient Safety</td>
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<td></td>
<td>Thomas Tegenfeldt</td>
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<td></td>
<td>National Board of Health and Welfare</td>
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<td></td>
<td>Ministry of Health and Social Affairs, Health Care Division</td>
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<td></td>
<td>Petra Ferngren</td>
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<td></td>
<td>Head of Patient Safety and</td>
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<td></td>
<td>Investigations, Department of Health</td>
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<td></td>
<td>Wendy Harris</td>
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<td></td>
<td>Director of Policy for the NHS</td>
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<td></td>
<td>Nigel Edwards</td>
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<td></td>
<td>Council of Europe Piotr Mierzewski</td>
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<tr>
<td>Other organisations</td>
<td>CPME (Standing Committee of European Doctors) Jesper Poulsen</td>
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<td></td>
<td>EFN (European Federation of Nurses Associations) Paul de Raeve</td>
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<td>EFN (European Federation of Nurses Associations)</td>
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<td></td>
<td>EPF (European Patients Forum) Roxana Radulescu</td>
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<td>HOPE (European Hospital and Healthcare) Karolina Hanslik</td>
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<td></td>
<td>OECD (Organization for Economic Cooperation and Development) Niek Klazinga</td>
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<td></td>
<td>PGEU (Pharmaceutical Group of the European Union) Ivana Silva</td>
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<td></td>
<td>WHO (World Health Organization) Valentina Hafner</td>
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</tbody>
</table>
Appendix C: Sample Interview Protocol

Respondent:
Date:

Introduction
- Purpose of interview = to bridge gaps in data, especially on economic and social impacts, and to capitalise on the knowledge of leading international experts and policy makers in this area
- Consent to record interview (all records will be destroyed when research has ended)
- The Commission wish to introduce 3 ‘areas for action’ and these are: Establishing effective reporting and learning mechanisms; Redress mechanisms; and Developing and using knowledge and evidence.
- These areas for action are different from ‘policy options’ in that they are much broader.

Section A – Extent of the problem
A1. Can you please give a short overview of patient safety in your country?
   Probe 1: Statistics on number and cost of adverse events; on Cross-Border healthcare
   Probe 2: Sources
   Probe 3: Policies

Section B – Establish effective reporting and learning mechanisms
Complementing other adverse incident reporting such as pharmacovigilance and medical device vigilance systems, this action seeks to establish the extent of error and adverse events, monitor trends, develop effective interventions, observe changes after introducing those interventions and share learning on what interventions are effective (as well as those that are not). Reporting should be blame-free and not linked to punitive measures (i.e. should be different from disciplinary systems and procedures for professional negligence). Effective reporting and learning mechanisms also means that there should be periodic analysis of the effectiveness and appropriateness of these various systems. Ultimately, these mechanisms aim to establish a transparent, open and honest patient safety culture in healthcare.

B1. Do you have any examples of such policies from your own country, or are you aware of other countries having any policies on this action?
B2. What do you think would be the likely economic impact of establishing a reporting and learning mechanism?

Probe 1. In terms of administrative costs and/or resources used (type and frequency) for public funds, a/o for other sectors?
Probe 2. In terms of overall cost of compliance?
Probe 3. In terms of the macroeconomic environment (eg productivity, efficiency)?
Probe 4. What underlying factors do you think are driving these economic impacts?
Probe 5. What kind of evidence is there for this? Can you point us to any relevant sources?

B3. What do you think would be the likely social impacts of establishing a reporting and learning mechanism?

Probe 1. In terms of social inclusion and protection of particular groups (eg low income, elderly, ethnic minorities, people with disabilities, women)?
Probe 2. In terms of benefits to patients?
Probe 3. In terms of benefits to health professionals?
Probe 4. In terms of benefits to health systems?
Probe 5. In terms of access to, and effects on, social protection (i.e. public protection such as giving accurate information, managing risks and diseases, ensuring the right standards are in place etc)?
Probe 6. In terms of access to, and effects on, health systems?
Probe 7. In terms of access to, and effects on, educational systems?
Probe 8. What underlying factors do you think are driving these social impacts?
Probe 9. What kind of evidence is there for this? Can you point us to any relevant sources?

Section C – Redress mechanisms

This action would establish fair compensation appropriate for patients (or families of victims) affected by adverse events, including those from other MSs. Redress systems should also be fair to healthcare professionals and provide value-for-money for healthcare funders. The action on redress mechanisms would include informing patients and their families on how to access redress mechanisms, as well as monitoring system effectiveness and efficiency and aligning national systems for medical negligence with the broader patient safety and risk approach.

C1. Do you have any examples of such policies from your own country, or are you aware of other countries having any policy on this action?

C2. What do you think would be the likely economic impact of establishing a redress mechanism?

Probe 1. In terms of administrative costs and/or resources used (type and frequency) for public funds, a/o for other sectors?
Probe 2. In terms of compensation costs?
Probe 3. In terms of the macroeconomic environment (eg productivity, efficiency)?
Probe 4. What underlying factors do you think are driving these economic impacts?
Probe 5. What kind of evidence is there for this? Can you point us to any relevant sources?

C3. What do you think would be the likely social impacts of establishing redress mechanisms?
Probe 1. In terms of social inclusion and protection of particular groups (eg low income, elderly, ethnic minorities, people with disabilities, women)?
Probe 2. In terms of benefits to patients?
Probe 3. In terms of benefits to health professionals?
Probe 4. In terms of benefits to health systems?
Probe 5. In terms of access to, and effects on, social protection (i.e. public protection such as giving accurate information, managing risks and diseases, ensuring the rights standards are in place etc)?
Probe 6. In terms of access to, and effects on, health systems?
Probe 7. In terms of access to, and effects on, educational systems?
Probe 8. What underlying factors do you think are driving these social impacts?
Probe 9. What kind of evidence is there for this? Can you point us to any relevant sources?

Section D – Developing and using knowledge and evidence

This action has a number of different but related goals, some of which include working towards common definitions and terminology at EU level, mapping the current landscape for mutual information and knowledge sharing, comparing existing indicator systems and considering a minimum set of core and valid indicators at EU level. The purpose of the action is also to develop and promote a research agenda on patient safety at EU level, to integrate research results for refining the research agenda, to pool data and expertise to share good practice through the use of ICT, etc.

D1. Do you have any examples of such policies from your own country, or are you aware of other countries having any policy on this action?

D2. What do you think would be the likely economic impact of developing and using knowledge and evidence on patient safety?
Probe 1. In terms of administrative costs on healthcare systems and/or resources used (type and frequency) for public funds, a/o for other sectors?
Probe 2. In terms of administrative costs on public authorities more generally?
Probe 3. In terms of overall cost of compliance in developing and using evidence?
Probe 4. In terms of the macroeconomic environment (eg productivity, efficiency)?
Probe 5. What underlying factors do you think are driving these economic impacts?
Probe 6. What kind of evidence is there for this? Can you point us to any relevant sources?

D3. What do you think would be the likely social impacts of developing and using knowledge and evidence on patient safety?

Probe 1. In terms of social inclusion and protection of particular groups (eg low income, elderly, ethnic minorities, people with disabilities, women)?
Probe 2. In terms of benefits to patients
Probe 3. In terms of benefits to health professionals
Probe 4. In terms of benefits to health systems?
Probe 5. In terms of access to, and effects on, social protection (i.e. ‘public protection’ such as giving accurate information, managing risks and diseases, ensuring the rights standards are in place etc)?
Probe 6. In terms of access to, and effects on, health systems?
Probe 7. In terms of access to, and effects on, educational systems?
Probe 8. What underlying factors do you think are driving this?
Probe 9. What kind of evidence is there for this? Can you point us to any relevant sources?

Hidden Question on Relative Ranking:

a) Which action will have the greater economic impact?

b) Which action will have the greatest social impact? (Most plausibility for Action)