

# **SIMPATIE:**

Safety Improvement for Patients in Europe



Final report of the mapping exercise, work package 2 of the project



**Please note the companion document ‘Good practice in Europe in Patient Safety, a Compendium (plus Annexes)’**

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## **Preliminary ‘health warning’**

This report summarises a mapping exercise made predominantly through the use of questionnaires, although there are some additional documents which can be found on the accompanying database (see Simpatie website: [www.simpatie.org/mappingeurope](http://www.simpatie.org/mappingeurope) ) in which all the questionnaire data is entered. Mapping is complemented by the Good Practice Compendium ([www.simpatie.org/goodpracticecompendium](http://www.simpatie.org/goodpracticecompendium) ). It is not a piece of scientific research but is meant as a tool which can serve as the foundation for further, more sophisticated enquiry.

We have data from 23 of 25 EU countries (regarding United Kingdom, see note below (p.5) and approximately 80% of these responses are already independently validated. The missing countries are Latvia and Malta. To clarify what is meant by validation; Belgium, Lithuania, Luxembourg, Slovenia and the Slovak republic have so far provided uncorroborated data, albeit some from Health Ministries. Of the remaining 18 countries, data has been obtained from two or more sources in 12 cases, but in the other six, Cyprus, France, Greece, Ireland, Netherlands and Sweden, some effort had been made to validate the original data using a consensus approach, rather than simply providing an alternative set of responses (hence, in the database, only results from a ‘Master’ questionnaire will be entered for these six).

It is a given that this exercise represents a ‘first cut’, that is, the best approximation of the data available, working within the resource constraints of the present project. As a result there will inevitably be some inconsistencies, resulting particularly from; lack of adequate validation, disagreements between respondents, difficulties with vocabulary and the fact that this is a ‘snapshot’ of what is a continuously evolving picture. Where possible, in the text that follows, inconsistencies and possible explanations for them will be identified. Inevitably, not every inconsistency will be dealt with. Nevertheless, we are satisfied that the main objective, to obtain a crude but useable overview of patient safety activity in Europe as of December 31<sup>st</sup>. 2006, has been achieved.

To acknowledge the above factors, the text will normally present results in the form “ the country reports that...” as a short hand for “the available data from the one or more respondents (including data from the Best Practice Compendium) allows us to summarise the position in this country as...”. In

other words, some assumptions are being made, for the sake of practicality, although those interested in exploring responses in more depth can pull out the individual items from the database and draw their own conclusions.

### **A note on legislation:**

Legislation was not dealt with by a specific question in the final version of the questionnaire, the development of which is described below. However, we have sufficient data to provide a brief, although not necessarily complete, summary. The report for WHO (Europe) on national quality systems by Charles Shaw and Isuf Kalo (2002) assisted in this regard.

As far as formal legislation on health quality is concerned, current data indicates that Denmark has unique although fairly recent legislation on Patient Safety (June 2003) but a few other countries have specific legislation on Healthcare Quality. Czech Republic (resolution N458/2000), Lithuania (Law on patients rights and compensation for damage to health 1996), Netherlands (Individual Health Care Professions Act 1997), and Sweden (Health and Medical Services Act 1997) have what appear to be legislation directed at a comprehensive national approach to health quality, while Austria, France, Germany, Hungary, Italy, Spain and England and Wales have legislation but perhaps with a less comprehensive scope.

### **A note on the United Kingdom contribution**

England and Wales comprises a population of approximately 54 million of the total population of the UK (approx. 60.6 M). The term NHS, commonly used as a synonym for 'National Health Service' in reality relates primarily to England and Wales (and NHS Wales is partly devolved). Northern Ireland and Scotland have their own systems (see Wikipedia entry, 'NHS: disambiguation').

Sir Liam Donaldson, Chief Medical Officer for the NHS is indeed the UK government's principal medical advisor and represents the UK in European meetings, but is professional head of all medical staff in England only and there are separate CMO's for Scotland, Wales and Northern Ireland.

The National Patient Safety Agency only deals with England and Wales. For this study, to try to minimize confusion, data was only collected from England and Wales, as Scotland and Northern Ireland have different patient safety arrangements (and in Scotland, a separate legal system), but are not separate European entities.

# Developing the approach to mapping

## Setting the scene

Within the European Union it appears to have been under the Austrian Presidency in 1998 that there was first an agreement between Health Ministers to collaborate on quality in health care. The next major development was the Commission's new Public Health strategy, published in 2000, which included in the main subsection 'improving information for the development of public health' (para. 48), the concept of actively spreading good practice in health care (which would include quality assurance and improvement activities).

However, in 2002, with the initiation of the High Level Reflection Process on Health (HLRP) while David Byrne was Health Commissioner, more focussed interest on health quality became possible.

Previously Article 152 of the Treaty had been seen as proscribing any common approach to health policy matters other than those within a narrowly defined area. Pressure of events began to undermine this imperative. For example, the implications of citizens (albeit a minority) crossing state frontiers to seek health care outside of their country of origin led to an interest in finding ways of comparing outcomes in a meaningful way. Within the HLRP there were a number of subgroups including one related to patient mobility and one to health quality. Overlapping issues for these two subgroups were – do we know what is going on health quality-wise in member states, do we have a common vocabulary to allow us to make realistic comparisons and what expert consensus is there on the tools that are deemed effective to measure quality?

Following the report of the HLRP (end 2003) and the Commission's response in April 2004, this project on Patient Safety (acronym SIMPatIE) was one of the first quality related multinational projects part-funded by DG SANCO under the ongoing Programme of Community Action in the Field of Public health (2003-2008).

That Patient Safety should be chosen as the topic for such a collaborative project was no coincidence. The concept had been promoted in the USA increasingly since the Institute of Medicine's publication in 1999 'To err is

human' and particularly in the UK (led by the Chief Medical Officer, Dr. Liam Donaldson) with the publication in 2000 of 'An organisation with a memory'. This led to the setting up in late 2001 of a National Agency for Patient Safety (NPSA) in the UK, with Denmark (where the CMO Dr Jens Kristian Gotrik was also influential) following shortly with the establishment of the Danish Society for Patient Safety (DSFP). Patient Safety in Europe had become an area which stimulated considerable interest because successful improvements would result in both substantial cost savings as well as reducing the harm done to patients in the course of their treatment.

### **Work package development**

The Simpatie European mapping exercise was initiated in February 2005 as the first phase of the set of work packages that comprise the programme. The main phases of activity have been:

February – April 2005

background research and developing an understanding of allied programmes, recruiting to the experts' and reference groups and running initial reference group workshop to develop the first draft of the research framework.

April – September 2005

collaboration with WHO Europe leading to a joint symposium in Copenhagen in September 2005, input into development of the Simpatie website and pilot testing the instrument (the questionnaire).

September – November 2005

refinement of the survey instrument and collection of data against the first five areas of enquiry.

November 2005 – July 2006

collection of data for the remaining sixteen areas of enquiry.

July 2006 – November 2006

further collection of data in the interests of ensuring a comprehensive coverage together with verification/validation of the data and start of data analysis. Preliminary consideration of mapping data alongside results of work packages 3-6 (Council of Europe recommendations and toolbox results i.e. vocabulary, indicators and tools).

November 2006- December 2006

collection of good practice examples and entry of data from mapping and good practice exercise onto the Simpatie database.

### **Compatibility of Simpatie activities with other European initiatives**

A specific aspect of the brief from DGSANCO was to ensure compatibility and minimum overlap with other international initiatives (as well as relevant projects within DG Research). In this regard it was helpful that there had been involvement by representatives from the project consortium in the OECD patient safety indicator project which was completed in 2003 and that the Council of Europe (whose Committee of Experts on the Management of Safety and Quality in Healthcare had finally reported in early 2005) was also represented on the Simpatie consortium.

In considering the work undertaken by other international programmes, the WHO World Alliance work was seen as very different in nature to the others. It had a truly international focus and included participants from all parts of the World. The WHO European office on the other hand had already completed specific work on patient safety in Europe, such as their programmes on blood products. Their officers indicated that they were about to embark on a survey of health ministries to identify the readiness of member states in terms of setting up national patient safety programmes. Colleagues from Simpatie and WHO Europe agreed therefore to mount a joint symposium in September 2005, which was held in Copenhagen at WHO Europe's headquarters.

The event included details of the WHO Europe work, the Simpatie programme and various case studies of innovation in patient safety practice. There were workshops to examine particular aspects of both programmes, and the event was a highly useful networking opportunity for the forty colleagues from around twelve countries who attended this symposium, which was written up by WHO Europe as reference material to inform future international and national programmes.

# Methodology

## Initiating the work package

Two international groups were set up, the experts' network and the reference group. The experts' group constituted individuals who acted as contact points in each country and who agreed to help with collection of data via their in-country contacts. Through this arrangement, taking into account the identification of country experts within Question 5 of the survey instrument, it has been possible to create a network of more than 100 experts (nominated by their peers) across 23 countries. This group provided the basis for rapid collection of good practice examples during November and December of 2006 and it is obvious that this network has the potential for further development if a second phase of the project were subsequently to be initiated (see Discussion and Conclusions, below). CPME and HOPE, two of the consortium partners, were particularly helpful in supplementing country data with information from colleagues within their own networks. Peter Walsh of AvMA, was delegated by LMCA and advised on all patient issues.

The experts' group was therefore to an extent drawn together by serendipity, and because one agreed aim was to mobilise both networks and opinions outside those already involved and researched, a reference group was set up in parallel. This group consisted of colleagues from different countries, but more importantly who were representative of the different professional and special interest stakeholders that the data was to be of service to. Therefore this group was recruited from patient safety experts, academics, healthcare policy makers and managers, clinicians, those representing the interest of patients, professional organisations, specialist healthcare risk managers, lawyers, commentators, quality improvement specialists, regulators and educationalists. The group maintained contact and had occasional face-to-face meetings throughout the duration of the project.

The initial meeting of this group was hosted by one of the reference group members in Luxembourg. This meeting came up with an initial framework for the data collection (see Appendix A, p.37, below). It catalogued the potential interest areas for the different parties who might utilise the end product of the Simpatie mapping exercise once the project was completed. As the survey instrument developed it was shared between the Simpatie

partners and the reference group and pilot tested to check clarity, usability, completeness and fitness for purpose. This included the input of experienced social scientists practiced in the use of survey instruments, and healthcare experts from different countries to check on the use of terms and definitions. The instrument was in English and invited responses in English only, although attached documents in the language of the particular country were welcomed.

Although based on principles derived from previous quality mapping, e.g. the CASPE/BIOMED2 survey of External peer review in Europe (ExPeRT project), it is evident that the format of the questionnaire stems primarily from consensus between selected experts, rather than from scientific research. Nevertheless feedback from respondents suggests no major omissions in the span of the questions (potential sources of variance are identified on p.4, above). Future mapping exercises might incorporate into survey design both lessons learnt from projects such as this one and those from review of research literature.

As for the Good Practice Compendium, a ‘health warning’ is posted on p.2 of its final report, which will be repeated here, namely that examples for inclusion in the Compendium were nomination by other experts. Therefore there is no formal evidence base for these examples being good practice, nor validation of content other than the expert opinion of the nominating person.

### **The data to be collected**

The data to be collected was thus summarised in question form into a survey instrument with twenty-one different questions, and within these in excess of one hundred different data items to be collected. Most were questions of fact, but some were of opinion. Some sought further information on resources, or to steer towards the direction of further work covering a particular issue. In all, the survey instrument aimed to establish a comprehensive and wide-ranging insight into progress with patient safety initiatives in the respondent countries.

The survey instrument divides into various parts, and the twenty-one questions have the following themes and rationale for being worthy of investigation:

<b>Question number</b>	<b>Theme</b>	<b>Reason for interest</b>
1	Standard use of an in country definition for patient safety	As a first step it was felt important that countries had addressed the issue of what was meant by patient safety, and whether they were using a definition that was drawn from existing international work (in particular, the Council of Europe work)
2	National bodies or institutions active in patient safety work	The existence of national bodies specialising in patient safety, or programmes of work in national bodies (such as regulators) that had been specifically designed to promote patient safety initiatives. This would provide a guide to coordinated investment of effort in patient safety nationally
3	Taxonomy to classify patient safety reports	Whether there was an agreed national taxonomy for patient safety and incident reporting. Agreement of a national taxonomy would make initiatives such as benchmarking feasible
4	The use of standards or guidelines to control and minimise harm to patients	This would help identify whether commonly used methods for quality assurance and improvement (standards and guidelines) were specifically being used as a tool for contributing to patient safety efforts
5	In country experts in the field of patient safety	This would establish both that there were local patient safety

		experts, and also provide the Simpatie programme with contacts for further enquiry.
6	Any national incident reporting system	Developing a national reporting system has been seen as a useful first step in raising patient safety as an issue within countries.
7	Requirements for or existence of local incident reporting systems	As an alternative or supplementary stage to the existence of a national reporting system, the requirement for or existence of systems to collect local patient safety data has been a useful step to engineering improvement efforts
8	No fault/ no blame compensation schemes (for definition and comments, see below, p.20)	No fault compensation schemes have helped to reduce professional and organisational concern around collecting patient safety data. They can be seen as a way of helping to manage public interest concerns in relation to patient safety
9	Requirements to legally disclose information principally collected to support patient safety activities (adverse incident data)	The protection of patient safety information from potential use in compensation cases is seen as a constructive step in creating an appropriate blame free culture, and in having access to information about incidents and near misses in a manner that protects institutions and clinicians from litigation
10	The public availability of information relating to patient safety incidents	The broad availability of data relating to patient safety incidents is seen as a way of

		helping to build a local and in country awareness of patient safety problems. It provides benchmarks to establish progress in reducing errors and near misses over time. It helps build comparisons, and provides information about the likely effectiveness of reporting systems in terms of the completeness of reported incidents
11	Professional liability arrangements	This helps build an understanding of the way in which different countries have sought to ensure that professionals have access to professional liability cover, and that patients can be compensated when clinical errors which cause harm occur
12	Whistle-blowing policies (definition, see p.25, below)	A blame free culture depends on professionals being able to openly discuss service problems and report incidents and near misses. A whistle blowing policy and methods of protecting members of the team when discussing the performance issues of others is seen as a constructive step in bringing this about.
13	Professional patient safety membership organisations	The organisation of a working group of colleagues from healthcare interested in patient safety is seen as a useful tool in developing patient safety skills, and developing a national movement to tackle the issue over time.

14	Healthcare risk management qualifications	Training specifically relating to risk management in healthcare is seen as an essential step to building national capacity to address patient safety problems.
15	Professional support for patient safety or healthcare risk managers	The development of a patient safety discipline and networking opportunities for those with this task as their principal work is seen as a useful building block for local resolution of patient safety issues.
16	Patient safety training opportunities and requirements for healthcare staff	Specifically training clinicians and healthcare managers in patient safety awareness and techniques is seen as an essential step to tackling the problem and reducing the likelihood and consequences of patient safety incidents.
17	Specialist patient safety patient organisations	Specialist patient organisations with an interest in patient safety provide a means whereby patients can understand their rights, gain support, be provided with information and participate in becoming guardians of their own safety within a healthcare system.
18	National patient safety campaigns and public relations exercises	The existence of national campaigns and public relations interventions to address patient safety matters is an important step in helping to build a culture where patient safety is understood, taken seriously and makes progress in

		implementing improvements more possible. Examples of interventions and campaigns would include issues such as hand washing, communication with patients or the importance of completing antibiotic regimes.
19	Professional peer review schemes with patient safety content	This question looks at whether routine professional quality improvement activities are inclusive of patient safety issues and patient interests.
20	The role of European bodies in patient safety	This question aimed to gain an insight from participants into ways in which pan-European bodies could be useful to promoting patient safety campaigns or initiatives.
21	The usefulness of patient safety resources	Patient safety initiatives seem to spread much more rapidly through Anglophone countries than other countries. Also it was noted that some of the principal drivers were the early studies which helped provide evidence of the extent and nature of the patient safety problem. This question asks whether the availability of these resources, translated into other languages, would be seen as a useful and helpful step to supporting patient safety developments.

**A blank copy of the full questionnaire is attached as Appendix G, p.67, below.**

# Analysis of data

## Question 1 (Standard definition)

As to there being a recognised definition of patient safety, there are positive responses from 10 countries, Austria, England and Wales, Finland, Greece, Italy, Lithuania, Netherlands, Slovak Republic, Slovenia and Sweden. In four countries, Czech Republic, Denmark, Portugal and Spain different respondents could not agree (suggesting that there was certainly a current definition but not one totally accepted).

The remaining eight countries did not have a recognized definition. Of those that had a definition, five (plus obviously England and Wales) had it translated in English. These were Austria, Denmark, Netherlands, Slovenia and Sweden.

Of the fourteen that had acknowledged a definition, only two countries, Netherlands and Sweden, argued that theirs differed in certain respects from that of the Council of Europe study.

## Question 2 (National Agencies/Bodies and/or Institutions)

Given the answers from some countries e.g. Austria, Czech republic, Germany, Ireland and Netherlands, where seven or more national agencies were cited, one might well conclude with the advantage of hindsight that the original question was not specific enough.

To make a rough summary across the 22 respondent countries, in only five countries were agencies identified which had a role exclusively in patient safety, namely: the German Coalition for patient safety (APeV), the Danish Society for Patient Safety (DSFP), the National Patient Safety Agency (NPSA) in England and Wales, the National Platform for Patient Safety (PPV) in the Netherlands and the SMHCA in Spain (a specialist agency within the Ministry).

Certainly, the Ministry of Health (or equivalent) was quoted as a principal agent in promoting patient safety in eight countries, Belgium, Cyprus, Czech Republic, Estonia, France, Hungary, Italy and Slovenia.

Sometimes e.g. with the Joint Accreditation Committee of the Czech Republic or the Finnish National Authority for Medico-Legal affairs, or the Irish Clinical Indemnity Scheme and finally, the Polish Centre for Monitoring Healthcare Quality (CMJ) a significant role was perceived for an agency not apparently directly part of the Health Ministry.

Equally there are inevitably statutory bodies dealing with safety of medicines, medical devices, infection control and so forth that are cited by at least half of the respondents.

Patient organizations are mentioned by respondents from Czech Republic, Hungary, Ireland and Netherlands. Medical associations are quoted for Austria, Czech Republic, Germany and Netherlands.

Two final observations; responses from both Spain and Sweden suggest some tension between activities at a national and at a regional level and secondly, the proliferation of agencies perceived as playing some role in patient safety in Austria and the Netherlands (ten or more) is difficult to understand or interpret.

### **Question 3 (Taxonomy)**

Nine countries report the availability of a nationally agreed taxonomy for incidents or adverse events, Czech Republic, Denmark, Finland, Germany, Italy, Netherlands, Slovak Republic, Slovenia and Spain. Austria reports taxonomy related to pharmacovigilance. Others report ongoing work to develop agreement. The response from Estonia is equivocal.

In the three cases, Slovak Republic, Slovenia and Spain where there is an English version available this is because these countries are in fact using the taxonomy developed by the Council of Europe.

#### Question 4 (Standards/guidelines)

Only two countries answered 'no' to this question, others giving a wide range of examples, between one (in fact a weblink to a pdf containing dozens of examples from the Danish Patient Safety Office) to 'numerous'. With the advantage of hindsight, the question, despite appearing to probe a number of areas, is still ambiguous. The two 'no' answers are quoted below and explain the difficulty...

##### Estonia

"Master questionnaire response: Comments re: Question 4: There are no official guidelines of patient safety"

"Validation response: I would disagree. Because there are guidelines on medications, on blood (transfusion), on infection, on medical devices and even clinical guidelines. Some of them are even laws. And all of them are done because of patient safety."

##### Finland

"Comments re: Question 4:

*Finland does not have specific patient safety guidelines, but of course patient safety is the aim in e.g. national legislation regarding medication, blood transfusions and medical devices as well as health care personnel. Finnish legislation can be found at [www.finlex.fi](http://www.finlex.fi).*

*The Finnish Medical Society Duodecim ([www.duodecim.fi](http://www.duodecim.fi)) has produced a large variety of clinical guidelines to improve the quality of care and reduce variations in care practices. They are available through an internet portal and actively used in the whole country."*

Nevertheless, although it is time-consuming, detailed scrutiny of this data does reveal some interesting guidelines e.g. on safe transfer of patients (in Hungarian only), on effective hand hygiene (in Danish only) and protecting patients who are neck breathers (a safety notice issued by the NPSA for the care of patients with long term tracheostomy).

In addition, as one would expect, most countries give examples of guidelines or standards related to blood products, infection control, medical devices and medication safety.

### Question 5 (National experts)

There are variable reports, from only one nominated expert to more than ten. For the purposes of the call for good practice examples, a maximum of six were identified per country, but the list for all twenty three respondent countries still exceeded 100. The details by country can be obtained from the mapping database. In addition, where experts nominated others who had initiated good practices, the contact details of the latter are available on the good practice database.

### Question 6 (National Reporting Systems).

Seven countries claim to have a national reporting system. These are Czech Republic, Denmark, England and Wales, Germany, Ireland, Slovak Republic and Sweden. Some detail is given about potential differences in systems. For example, the English NHS system is fairly comprehensive (for detailed information see <http://www.npsa.nhs.uk> and enter NLRs, national reporting and learning system, into the search box at the top of the field. Also see Appendix B, below, p.40). The Swedish system collects data from healthcare organizations but does not include patient complaints. The Slovak Republic on the other hand collects patient complaints and ‘reports based on non-compliance between clinical diagnosis and necropsy’.

In relation to Q6 sub-sections c) to i), all but the Slovak Republic report ‘yes’ to c) near misses, d) data protection and g) analysis systems and ‘no’ to e) connection to litigation. In Sweden apparently in exceptional cases, the National board for Health and Welfare (NBHW) will refer information to a disciplinary board for assessment. Most respondents answered f) how is the data used, along similar lines to the Danish response, namely **‘1. For learning purposes; news letters, thematic risk reviews and case studies, based on root cause analysis, are issued. 2. To elaborate regulations that aim to reduce risks and to avoid adverse events in health care services. 3. To prioritise supervisory actions.’**

The Irish response refers in addition to early identification of possible claims.

In relation to the systematic approaches used i.e. Q6 h), four countries, Denmark, Germany, Ireland and Sweden refer specifically to RCA (root cause analysis). Czech Republic and Slovak Republic don’t answer. The English response is very detailed and is given below in Appendix B.

Finally, in four countries, Czech Republic, England and Wales, Germany and the Slovak Republic patients can report directly to the system (Q6 i)). In Denmark this facility is being prepared.

Six countries reported an unequivocal 'no', namely Estonia, Finland, Greece, Hungary, Lithuania and Poland. Although other responders from Spain report 'no', the Health Ministry reports that their Quality department has designed a national reporting system which they are currently piloting (as does Hungary in the Good Practice compendium).

The following countries; Austria, Belgium, Cyprus, France, Italy, Netherlands, Portugal and Slovenia report partial systems. These responses are pasted in Appendix C (see below, p.42).

#### **Question 7** (Local Incident Reporting Systems).

Here fewer countries report affirmatively i.e. England and Wales, Ireland and Sweden.

These responses are quoted in full in Appendix D, p.56, below, as they reflect how local legislation, policy direction and health system culture all influence the approach taken in a particular country.

Eight countries report 'no', namely Cyprus, Denmark, Estonia, Finland, Germany, Greece, Italy and the Slovak Republic.

The other 11 countries; Austria, Belgium, Czech Republic, France, Hungary, Lithuania, Netherlands, Poland, Portugal, Slovenia and Spain report very patchy activity at local level. However, the Netherlands report a system due to come into force in 2008, which will be more comprehensive and no longer voluntary, Portugal identifies incident reporting as part of a national accreditation project involving 23 hospitals and similarly Lithuania and Hungary see incidents as evidence of non-compliance within their ISO based approach to health quality systems.

#### **Question 8** (No-Fault/No Blame Compensation Systems).

A helpful editorial from the BMJ on no-fault compensation systems and their definition can be accessed via Google (BMJ 2003;[326:997-998](#)). The

principle is that claimants must show that a medical error was a causative factor in the resultant injury, irrespective of who is to blame. This allows more rapid investigation of claims without the restriction of communication typical of the adversarial process. Such a system is deemed by many, more equitable and more efficient.

Five countries report the existence of such a system. They are Austria, Denmark, Finland, France and Sweden. The response from Spain is equivocal. There appears to be no national system but the Spanish Medical Association and the Spanish Association of Health Risk Managers report that such a system operates in 'Autonomous Communities', supported by legislation, presumably an example where local government has taken a step in advance of national policy. The response from Estonia is also difficult to interpret. It does seem that more work is needed on researching which alternatives to litigation in clinical negligence cases exist and what constitutes good practice.

There is no such system reported to be in place in the other 15 countries.

**Question 9** (legal disclosure of adverse incident information).

This is a very difficult question to summarize. Logically, responses could be (for parts a) clinical information protected from disclosure and b) legal requirement to inform affected patients), Yes/Yes, Yes/No, No/Yes or No/No. In part this relates to legislation or good practice guides on confidentiality which vary from country to country and the degree of anonymising of data which is routinely employed locally or nationally.

One might conclude that Yes/No implies maximum exclusion of patients from knowledge, for whatever reason and No/Yes the opposite. Both No/No and Yes/Yes appear somewhat ambiguous and therefore explanatory information is provided, if available, from the responses.

No/Yes to a)/b): Cyprus, Estonia, France, Hungary, Slovenia and Sweden. Finland and Greece both qualify the 'Yes' to 9b) by stating that there is a legal requirement to give patients information about their treatment but not specifically about adverse events if they occur.

Yes/No: Belgium only.

No/No: Austria, England and Wales, Germany, Netherlands and Spain. These countries all indicate that although there is no legal protection, data generally is available in an anonymised form. Usually individual data can be required by a court if there are claim proceedings. As to informing patients, in these countries it is seen as part of the ethical code under which professionals practice. In Germany their solution to the lack of protection of incident data is to house their voluntary CIRS (critical incident reporting system) in Switzerland (what they call a 'workaround solution'!) Ireland, Italy, Lithuania, Poland, Portugal and Slovak Republic all respond similarly but with no explanation.

Yes/Yes: Czech Republic offers no explanation. For Denmark it appears that professionals are protected by having their data legally secured but patients are also safeguarded by there being a legal requirement under the Safety Law to inform patients both of incidents and of the existence of the No-Fault Compensation scheme.

**Question 10** (public availability of patient safety incident data).

Analysis so far done on this complex data indicates that, as far as the responses to the survey are concerned (given a degree of uncertainty about validity) there is little available public data on the performance of individual clinicians. One respondent in Belgium claims that such data is available publicly but this might be checked e.g. via the Belgian National Mortality Databank and the public health data at [www.iph.fgov.be](http://www.iph.fgov.be).

Certainly if one looks at the column 'By Department' a handful of countries report data and this is similar for the column 'By Healthcare Organisation'. There is least data in these categories for Falls, Deaths in restraint, Deaths following trauma, Suicide in care settings and within one month of seeking advice. In all cases there are three countries or less per cell in the matrix except that Austria claims comprehensive data based on both autonomous data from the nine Austrian provinces and from the operation of an IQIP (International Quality Indicator project).

Mortality data by Department is available in addition from Denmark, Germany (some), Portugal and Slovak Republic and by Healthcare organisation from Denmark, Greece, Slovak Republic and Spain. Deaths in Accident and Emergency and on intensive care units are available by Department apparently from Belgium, Cyprus, Czech Republic, Portugal and Spain (some). The data is also available for A and E (ER) by Healthcare organisation for a similar number of countries (i.e. four or five).

Healthcare acquired infection data and on Peri-operative deaths is available in about six countries per cell in the 'Department' and 'Healthcare organisation' columns the exception being acquired infection by healthcare organisation which has 11 entries, Belgium, Czech Republic, Denmark, England and Wales, France, Greece, Ireland, Slovak Republic and Spain, with Germany and Finland reporting 'some' data. Obstetric data in these columns has about six entries per cell.

Turning to National data, there are five entries or less in the categories, Falls, Deaths in restraint, Deaths in A and E and for the two Suicide categories.

The remaining eight categories will be listed by country:

Mortality: (all – save Finland and Portugal).

Deaths in ICU: Cyprus, England and Wales, Estonia, Portugal, Slovak Republic and Spain.

Deaths following trauma: Cyprus, Czech Republic, England and Wales, Estonia, Germany, Ireland, Lithuania, Slovak Republic and Spain.

Acquired infections: Austria, Belgium, Czech Republic, Denmark, England and Wales, Estonia, Finland, France, Greece, Ireland, Lithuania, Netherlands, Slovenia and Spain

Maternal deaths: (all – save Austria, Hungary and Netherlands).

Peri-operative deaths: Belgium, Cyprus, Czech Republic, Denmark, England and Wales, Estonia, Lithuania, Slovak Republic and Spain.

Still births: (all – save Austria, France and Netherlands).

Infant deaths in hospital: (all- save Austria, Czech Republic, France, Netherlands and Slovenia).

**Question 11** (liability arrangements).

There are affirmative answers to Q11a) existence of medical defence organisation, from seven countries, Belgium, Czech Republic, England and Wales, Germany, Ireland, Slovak Republic and Spain. A helpful definition of the term ‘medical defence organisation’ is given on the website of the UK General Medical Council (GMC) [http://www.gmc-uk.org/doctors/information\\_for\\_doctors/medical\\_defense\\_organisations.asp](http://www.gmc-uk.org/doctors/information_for_doctors/medical_defense_organisations.asp)

A point of interest is whether there is a pattern in the liability arrangements associated with the existence or otherwise of no-fault compensation schemes. This appears not to be the case. Although it is true that none of the five countries in Q. 8 has a large medical defence organisation, essentially private practitioners in Austria, Denmark, France and Finland use indemnity insurance. In Sweden claims tend to be made against the healthcare organization (as in Denmark).

Only three countries respond affirmatively to Q11b). In France a limited number of physicians engaged in high risk activities use such medical defence organisations based in other countries. In Ireland, their Clinical Indemnity Scheme does not cover private practice in private hospitals and clinicians obtain indemnity for this work from the Medical Defence Union or the Medical Protection Society in the UK. In Belgium it seems that clinicians use private insurance schemes either in Belgium or elsewhere in the EU. Q11c) (other malpractice schemes) provided no significant data. There is a slightly ambiguous response from Poland, where the Chamber of Physicians is apparently asked to investigate certain cases.

Finally, in relation to who pays premiums, in countries where there is a large medical defence organisation, there tends to be nevertheless a situation that although clinicians pay premiums, there is also a state indemnity scheme or the equivalent. This is the case in England, Ireland and Spain and to some extent in Belgium. In the Czech Republic, the employer pays and to some extent this is also the case in Slovenia and the Slovak Republic.

In Greece, Hungary, Italy, Lithuania, Netherlands and Poland, employers cover the cost of indemnity insurance. In Portugal it is paid by the clinician.

There are four countries, Austria, Cyprus, Estonia and France where arrangements are slightly more complex (see Appendix E, p.60, below). In Cyprus examination of the response suggests that neither patients nor

clinicians may be well served. In Estonia clinicians are automatically insured by paying their union dues but there are also some voluntary malpractice insurance schemes for employers but it not made clear how much these are subscribed to. France is mentioned because it appears to be the only country where doctors in private practice are given an incentive to join accreditation schemes by having part of their liability insurance paid for by the State.

### **Question 12** (Whistle-blowing)

Although six countries report that such a system exists, only two, England and Wales and Greece appear to have understood the question. Their replies are pasted in Appendix F, p. 65, below. This appears to be an issue of vocabulary (see also peer review, Q.19, another source of misunderstanding). Interestingly, the term whistle-blowing is not among the 24 items selected by the expert group in Work package 4 of this project. Neither does the term feature in the glossary prepared by the expert subgroup on medication safety within the Council of Europe recommendations.

Whistle-blowing, the ability of an employee to report to higher management an example of malpractice, without fear of reprisals, was a major concern in the National Health Service of England and Wales, following the public enquiry at the Bristol Royal Infirmary. It is seen as one of the important elements that contribute to a 'safety culture'. A committee, headed by Lord Nolan, provided a now widely accepted description of the components of a whistle-blowing policy and this is also pasted in Appendix F.

Of the four other 'yes' responses, those of Belgium and Sweden in fact refer to alerts, that of one of the Hungarian respondents to a proposed National programme on patient safety generally and the response from one of the Czechs is ambiguous.

Although all other countries report 'no' Austria and Ireland qualify this by reporting that such a scheme is currently under consideration. From telephone conversations with a few other respondents, one could reasonably conclude that some of those who answered 'no' also misunderstood the question. The term should probably have been defined in the questionnaire. However, it seems unlikely that whistle-blowing policies under another name would exist in those countries where the English label was not understood.

### Q.13 (Professional patient safety membership organisations)

Eight countries report professional organisations, but only four appear to meet the criteria implied in the question. France reports two small, relatively new risk manager associations, AFGRIS and SOGFRES. Ireland has an established Healthcare Risk managers Forum.

In Spain there are four organisations reported which exemplify the complexity of inter-relationships. The first is FAD, the prestigious Foundation Avedis Donabedian. This is a health quality research institute, but since 2002 has run CISP, a patient safety department. Although contributing to education and research, it is not a membership organisation like those quoted above. Similarly, both AEGRIS and SECA (the latter, part of the Spanish Society for Quality in healthcare) are multi-professional organisations supporting patient safety activity but are certainly not exclusively for patient safety specialists. Finally, ISMP (Spain) is dedicated to safe medication practices, but not to a comprehensive approach to risk or safety.

The German examples reflect this also. The German Coalition for Patient Safety (Aktionsbündnis Patientsicherheit.e.V) was in fact initiated by QMG, the Society for Quality Management in Healthcare and is a multi-professional platform, of which Patient Safety specialists are but part.

Four countries who answer 'yes' to this question, Czech Republic, Greece, Italy and Lithuania on closer examination cite member organizations interested in health quality, but not exclusively in patient safety.

Although no organisation is reported for England and Wales, the authors are aware of ALARM (the association of litigation and risk management), reference [www.alarmhealthcare.org](http://www.alarmhealthcare.org) This simply confirms that the questionnaire data can only provide an approximation of what goes on in each country.

Three countries answer 'no' but give information about relevant activity. Finland reports a network and meetings set up by the Ministry of Social Affairs and Health for organisations involved in patient safety. Netherlands sees its National Platform for Patient Safety where various patient safety experts share experiences as 'not official' and therefore answers 'no'. It, like

the four countries mentioned previously, also cites their national health quality membership organisation (in Netherlands, NVKZ). Similarly Poland refers to its health quality society as actively involved in teaching and other activities related to patient safety.

#### **Q.14 (Risk management qualifications)**

Eleven countries give examples of various trainings which more or less fit with what the question asks. For example, one respondent from Austria describes quality assurance commissioners (verificators), but these quality trained doctors in fact have the task of auditing the performance of health staff, not clinical risk management per se. In Cyprus 'some healthcare risk management initiatives are currently being developed by the National Quality Assurance and Risk Management Committee'. In France, Germany and Spain, courses are available as modules in University courses, although in France these are only non-medical risk qualifications.

It is therefore only in five countries that clinical risk management qualifications can be identified, Czech Republic (at the postgraduate institute of education in Public Health, IPVZ), Denmark (at the Danish Society for Patient Safety), England and Wales (run by the NHS and the London Deanery), Italy (a Masters at the University of Padova), Ireland (the HDipHRM at University College, Dublin) and Portugal (as in the Czech republic, at the National school for Public Health, ENSP).

#### **Question 15 (risk or patient safety managers required)**

Five countries answer 'yes'. Risk or safety managers are required in the Czech Republic, England and Wales, Germany and Sweden. In Portugal it is the case for hospitals working with Joint Commission International or involved in the IQS accreditation scheme.

Although the question was answered 'no', in Hungary, quality managers or quality specialists are required, who then do risk or patient safety work within their overall remit. In Netherlands, there will be a requirement for risk assessment as part of an overall safety system from January 2008. In five other countries, Finland, France, Ireland, Italy and Spain, risk managers

are strongly recommended, but their employment by organisations is voluntary, not mandatory.

**Question 16** (training in patient safety)

Eleven countries answered ‘yes’ to this question. Scrutiny of the results for Q.13, 14 and 15 shows a strong overlap between those identified as active in those areas. Here, Austria, Cyprus, the Czech Republic, Denmark, England and Wales, Estonia, Finland, Ireland, Netherlands, Portugal and Spain indicate training in two or more of the five categories (medical under- and post-graduate, nursing, other clinical staff and managers).

For Germany and Sweden there is an unequivocal ‘no’ to all categories. In France, it is indicated that training courses are on the way, but not so far required.

**Question 17** (specialist patient organisations for patient safety)

Eight countries answer ‘yes’. However, in most cases the names suggest that these are generic patients’ rights organisations. The exceptions are: England and Wales (Action against Medical Accidents, AvMA; although generics, the Patients Association and the Patients Forum are also quoted ), Spain (Asociacion El DEfensor del PAciente, ADEPA, plus two patients rights organisations, CECU and FEP), France (a small organization, LIEN, for patients acquiring nosocomial infections, within the Collectif Interassociatif Sur la Sante, CISS, another generic being Federation des Associations AVIAM) and Germany, where there is the German Coalition for Patient Safety (see Q 13) and a number of generics, e.g. DPSB and NGM-Bayern.

There are four countries that answered ‘yes’ and four that answered ‘no’ that have patient organisations involved in patient safety activity: Cyprus (PRAG), Estonia (EPAA), Ireland (IPA and Patient Focus), Slovak Republic (ANOPP), Czech Republic (Paziendi), Denmark (part of DSFP) Poland (Polish Patients Association Primum Non Nocere) and Netherlands (National Platform for Patient Safety, see Q2 and Q13. Note also, Ne Ve Me Dis, the Dutch Society of Medical Dissidents).

It has been pointed out by Peter Walsh (q.v. p.9. above) that there may be a difficulty in identifying patient organizations specifically concerned with

patient safety, particularly those formed by the ‘victims’ of medical accidents. They may not be recognized by those in the patient safety ‘establishment’ because they are seen as too informal, too outspoken or their messages are simply too uncomfortable. This area needs further examination.

**Question 18** (National patient safety campaigns)

Only six countries answered ‘no’ to this question, Austria, Estonia, Greece, Hungary, Lithuania and the Slovak Republic.

However, of the remaining, careful scrutiny suggests that only nine countries have genuinely had national patient safety campaigns aimed at two or more of the four categories, professionals, managers, purchasers or patients and the public. These are Belgium, the Czech Republic, Denmark, England and Wales, France, Ireland, Netherlands, Spain and Sweden.

Cyprus and Portugal report narrowly focused campaigns, on blood safety and medication safety respectively. Italy reports activity on a regional level, but not on a national one.

There are four countries that answered ‘yes’ where in fact the ‘campaigns’ were one-off national conferences, usually for doctors or some other form of medical education (Finland, Germany, Poland and Slovenia).

Some respondents confused general public health education campaigns (e.g. on AIDS or early detection of breast cancer) with patient safety campaigns.

**Question 19** (Peer review schemes with the aim of reducing medical error).

Peer review is used in many industry sectors to delineate the use of people who are peers within an industry or an organisation who review and judge a person’s performance, work product or other behaviour. Unfortunately, in health, there are nuances to the term, related to ‘peer review’ as a verb (relating mainly to publications), internal versus external peer review etc.

As with Q.12, vocabulary problems arise in part because, with the advantage of hindsight, it appears that the question should have been articulated more

clearly. The wording of the question, because it specifies peer review involving an aspect of patient safety, may result in some countries having answered 'no' because the classical internal clinical peer review using a 'case conference' or similar style was not seen as related directly enough to patient safety. So there may be false negatives. Cyprus, the Czech Republic, Denmark, Finland, Greece, Italy, Lithuania and Portugal constitute this group.

Equally, following the analysis of external audit methods in the introduction to Work package 5 of this project, accreditation does not equate with external peer review, despite the argument put by more than one respondent, that because trained assessors are in fact of the same peer group as those they are assessing, this is peer review (e.g. Ireland and Poland). Four countries among their responses offer external review for the purpose of re-certification as a form of external peer review arguing that working knowledge of patient safety is part of the expertise audited. Estonia, Germany, Netherlands and Poland fall into this category. Slovenia cites involvement of the Slovenian medical chamber in peer review of patient complaints as a form of external peer review. Certainly the 'visitatie' carried out via the NIAZ in the Netherlands, according to the experts from Work package 5, does qualify as external peer review. The comprehensive external peer review carried out in France via HAS certainly meets that criterion.

This leaves only seven countries that offer internal peer review, as described in the second paragraph, above, as a basis for their 'yes' answer; Austria, Belgium, England and Wales, France (to some extent), Germany (to some extent), Hungary and Spain (patchy implementation).

### **Question 20** (The role of European Bodies in patient safety)

As this was a question seeking opinions rather than facts and because analysis of a matrix answer can be complex (see Q.10) it was decided to omit this question from the final analysis.

**Question 21** (Learning about patient safety)

One country, Austria, gives an ambiguous answer. England and Wales and Ireland have English as a native tongue and interestingly Denmark and Finland, but not Sweden state that health professionals are assumed to be bilingual. Finland comments that the documents referred to are not widely disseminated. Netherlands also sees itself as more or less bilingual.

Only two countries claim to have translated versions of the documents, Italy and Spain (although not all the documents are available in Spanish).

There are therefore fourteen remaining countries that confirm that native translations of key patient safety documents would be helpful.

# Discussion and Conclusions

## Overview

The data described above represents a broad brush representation of current patient safety activities within Europe. If one takes the group of questions which could be interpreted as reflecting overall national involvement, Q1, 2, 3, 6, 7, 14 and 16, it is apparent that these key elements are present in a half or more of the countries for which data was collected (90% of the EU states prior to the entry of Bulgaria and Romania).

The approximate proportions for Q.1, having an agreed definition, are two-thirds, for Q.2, having a national agency, about half, Q.3, existence of a taxonomy of terms, about half. Q.6, a national reporting system, about two thirds (this reflects either an established system or systems in development and the same applies to the next question). For Q.7, local reporting, the proportion is about two-thirds (even if patchy), for Q.14, risk management training, about half, and similarly, about half for Q.16, more general training on patient safety.

The other group of questions, which would represent a wider commitment to patient safety activities nationally, is Q8, 12, 13, 15, 17, 18 and 19. With a certain amount of interpretation (using also the responses within the Compendium as a guide) these elements are present for roughly a quarter to one half of all respondent countries. Thus, no fault/no blame compensation systems (Q.8), about one third. There is a national policy on whistle-blowing (Q.12) in about one quarter of respondent countries. There are both professional patient safety (Q.13) and patient-led patient safety organisations (Q.17) in about one third. Finally, in about half the respondent countries there are risk or safety managers (Q.15, even if not mandatory), national patient safety campaigns of some kind or another (Q.18) and local peer review schemes (Q.19, even if not specifically focusing on patient safety).

Three questions produce data which is too complicated to allow a simple summary. These are Q.9 (legal disclosure of patient safety information); basically a very diverse range of responses! The same applies to Q.11, on liability arrangements. Q.10, public availability of patient safety data, simply shows that data on clinicians performance is least available, that of organisations more so and national data the most accessible.

The responses from Q.4, 5, 20 and 21, although interesting, were not felt to be helpful in summarised form.

**Conclusion (1): while patient safety is recognised as a health quality priority across Europe, inevitably there is wide variation in the level of implementation of appropriate mechanisms for improvement.**

## **General observations**

The ‘health warning’ at the beginning of this document (p.4) underlines the point that, although useful, the results are not of a quality to justify any detailed level of analysis. The misunderstandings of language or terminology highlighted in the discussion of results above, under Q.2, Q.12, Q.13, and Q.17-19 make this plain. In some cases the questions were probably not put clearly enough, in other cases, availability of validating data or data from the Compendium allowed determination that some respondents were making errors. Nevertheless, these problems do not undermine the validity of the general overview and indeed, what were just now referred to as ‘errors’ often serve as learning points (as in quality improvement generally).

The overview allows us to stand back from the inherent complexity of the information collected and conclude that certainly the degree of involvement around Europe in the patient safety field that this survey identifies says something for the enthusiasm that patient safety evokes as a healthcare quality priority. This helps explain the relatively high response level to the project enquiry tools, with not only the questionnaire response rates referred to above, but 18 out of 25 countries i.e. 75%, providing good practice examples and these also demonstrate a wide deployment of patient safety activity.

Inevitably the degree of investment both financially and in institutional engagement will vary and will mirror to some extent the overall development of healthcare services in the country. The lack of convincing examples of good practice in patient safety elicited from Estonia, Poland, Lithuania or Greece compared to responses from Netherlands, Ireland, Austria and the Czech republic (putting on one side the ‘market leaders’ Denmark and England and Wales) presumably also reflects the national

commitment to healthcare quality, which is relatively well-developed in the latter group of countries but at a much earlier stage in the former. Spain, Sweden, Italy and to a lesser extent France and Germany are countries where regional development of healthcare services appears to be much more influential than national initiatives. In some countries other geographical differences (e.g. the North/South dichotomy in Italy) are well documented. Evidence of these expected variations can be detected in the information so far collected in this study also, even at this 'first cut' stage (see p.4, above).

**Conclusion (2): there was a positive response to the mapping exercise from the majority of those approached and overall there is evidence of substantial expertise and good practice, scattered across Europe.**

### **Direction of future work**

This last observation raises the question, what next? One possible answer is that the model of mapping activity, gaining consensus on vocabulary, and expert consensus on tools such as indicators, could well be applied to other aspects of healthcare quality across Europe. The evolving public health agenda for the EU would be a guide to this.

Another alternative might be that investment in a particular topic, once made, needs to be capitalised upon. Indeed, if the momentum that has been gained through the Simpatie project is effectively mobilised, further fruitful activity could in itself help mould policy. What implications for future work arise if one follows the logic of the latter argument?

There has been some discussion in recent years around the notion, both at a national level and at the level of the individual healthcare organisation, of a 'culture of safety' as a critical factor in the successful implementation and sustainability of patient safety initiatives. The exploration of this concept might be seen as being partly elaborated by the questions in this study on no fault/no blame compensation schemes, public availability of clinical safety data, whistle-blowing, patient safety campaigns and use of patient safety tools. A further study could allow 'drilling down' to determine in more detail how the understanding of the concept and steps to implement the relevant elements to promote and sustain it, are reflected in activity within European healthcare services. An underlying assumption of this and similar

projects is that of the virtue or benefit of sharing information across country borders, of learning together and from each other, which in itself however is an act of faith until there is more robust evidence for its value.

A second option would involve maintaining and enlarging the databases established in the course of the Simpatie project and further work, for example on the indicator element of the project (work package 4), but the latter no doubt will be dealt with in the concluding report of that work package. The innovative element would be to manage these activities through a network arrangement that drew in representatives of all EU countries, thus enhancing opportunities for information exchange and learning. This idea was discussed at the first EUNetPaS meeting in Paris on 18.12.06, which was enabled by the Commission.

Thirdly, colleagues from Greece have already put forward a very preliminary proposal, focusing on education in quality (using patient safety as a model) thereby taking up the strands of both public education (including patient participation) and the better education of healthcare professionals in this area. Again, certain questions within the present survey touch on topics relevant to education, but a further, targeted study could lead to much greater understanding and agreement across Europe on effective mechanisms to achieve improvement using this approach.

**Conclusion (3): unless some funding is found to allow sustainability of the databases they will rapidly become obsolete. Equally, the network of contacts having now been set up (with potential for further expansion), the cost of refining survey tools and managing the databases in the medium term is relatively small compared to the initial outlay. This then offers excellent value for money as an investment and would actively support the policy direction associated with a European network for patient safety. For example, the network of contacts set in place includes competent authorities for some countries but also provides a means to establish competent authorities for some countries that have not yet identified them.**

## **Final remarks**

The targets of the mapping exercise have been met and options for further work identified. However rough and ready they may be, these results can

reasonably be seen to represent a potential baseline with which future developments in patient safety across Europe can be compared.

The putting together of the Good Practice Compendium has unexpectedly proved to be probably at least as valuable as the mapping exercise and resultant database. The Compendium's examples can provide help to other professionals in other countries to avoid re-inventing the wheel. Equally, data from the mapping and the Compendium together can be used in a synergistic way to clarify what is happening in a particular country but also to explore the range of approaches available with which to implement similar initiatives. Following the comment in the previous section, there does nevertheless need to be evidence that assistance is not only available, but that it is actually used. A culture of learning from each other may prove to be as difficult to establish as a culture of safety. What matters is that there are tools to measure whether it is happening or not.

Similarly these results represent very much a first stage in identifying what can happen to the individual citizen when they become a patient in a particular health service. A report that patient safety activity is taking place or is intended does not necessarily imply that patients suffer less harm as a result, any more than an organisation signing up to a patient safety protocol necessarily means that lives will be saved.

Although other work packages of this project systematically review quality tools that can measure the outcomes of patient safety activity, few of the examples that this work package has accumulated involve the use of such tools. Evidence in the future that such measurement routinely takes place (i.e. that a quality system is really operating) would be an obvious indicator that major progress is being made.

**Conclusion (4): the completion of the mapping exercise and good practice compendium provides a foundation for more focused investigation of specific elements within the general overview. The discussion above highlights two particular issues which could form the basis for further study; whether there is transfer of expertise across country boundaries as a result of collaborative projects and whether direct benefit to citizens, as customers of healthcare services, can be identified as an outcome of such collaborative efforts.**

# Appendix A

## Framework for data collection

National bodies concerned with healthcare:

- Politicians
- Regulators
- Stakeholders
- Insurers
- Alliances for professionals
- Consumer platforms
- .....
- 

Specialist patient safety organisations:

- Researchers/academics
- Educational institutes
- National agencies
- Patient safety specialised organisations
- Quality for healthcare organisations
- Alliances for patients
- .....

Local healthcare organisations:

- Healthcare organisations
- Chief executives & Managers
- Professionals
- Quality & Risk managers
- Patients
- .....

The combination of product and actors results in a 2-dimensional framework or matrix with nine compartments of activities.

Level of targets ↓	Level of actors →	<b>NATIONAL BODIES CONCERNED WITH HEALTHCARE</b>	<b>SPECIALIST PATIENT SAFETY ORGANISATIONS</b>	<b>LOCAL HEALTHCARE ORGANISATIONS</b>
		<ul style="list-style-type: none"> <li>- Politicians</li> <li>- Regulators</li> <li>- Stakeholders</li> <li>- Insurers</li> <li>- Alliances for professionals</li> <li>- Consumer platforms</li> <li>- .....</li> </ul>	<ul style="list-style-type: none"> <li>- Researchers/ academics</li> <li>- Educational institutes</li> <li>- National agencies</li> <li>- Patient safety specialised organisations</li> <li>- Quality for healthcare organisations</li> <li>- Alliances for patients</li> <li>- .....</li> </ul>	<ul style="list-style-type: none"> <li>- Healthcare organisations</li> <li>- Chief executives &amp; Managers</li> <li>- Professionals</li> <li>- Quality &amp; Risk managers</li> <li>- Patients</li> <li>- .....</li> </ul>
<b>SYSTEM DESIGN</b>		<p><b>Activities</b> at <u>national</u> level that contribute the <u>design</u> of safer patient care systems</p>	<p><b>Activities</b> in <u>specialist</u> organisations that contribute the <u>design</u> of safer patient care systems</p>	<p><b>Activities</b> at <u>local</u> level that contribute the <u>design</u> of safer patient care systems</p>
<b>IMPROVE</b>		<p><b>Activities</b> at <u>national</u> level that contribute the <u>improvement</u> of safer patient care systems</p>	<p><b>Activities</b> in <u>specialist</u> organisations that contribute the <u>improvement</u> of safer patient care systems</p>	<p><b>Activities</b> at <u>local</u> level that contribute the <u>improvement</u> of safer patient care systems</p>

<b>CONTROL</b>	<b>Activities</b> <i>at <u>national</u> level that contribute the <u>control</u> of safer patient care systems</i>	<b>Activities</b> <i>in <u>specialist</u> organisations that contribute the <u>control</u> of safer patient care systems</i>	<b>Activities</b> <i>at <u>local</u> level that contribute the <u>control</u> of safer patient care systems</i>

### FOR EXAMPLE

Below is a first draft framework based on the brainstorm of the reference group on the 3<sup>rd</sup> of April 2005. If one attempts to fit the areas tackled in the questionnaire into the cells below, they mostly fit into the first two rows of cells. Tools (WP 4,5,6) fit into the third row.

Level of targets ↓	Level of actors →	<b>NATIONAL BODIES CONCERNED WITH HEALTHCARE</b>	<b>SPECIALIST PATIENT SAFETY ORGANISATIONS</b>	<b>LOCAL HEALTHCARE ORGANISATIONS</b>
<b>SYSTEM DESIGN</b>		<ul style="list-style-type: none"> <li>▪ Laws &amp; regulations</li> <li>▪ Taxonomy / Classification</li> <li>▪ Communication</li> <li>▪ Surveys</li> <li>▪ Campaigns</li> <li>▪</li> </ul>	<ul style="list-style-type: none"> <li>▪ Education</li> <li>▪ Agencies / bodies</li> <li>▪ Literature</li> <li>▪</li> </ul>	<ul style="list-style-type: none"> <li>▪ Taxonomy &amp; Classification</li> <li>▪ Culture</li> <li>▪ Incentive system</li> <li>▪ Confidentiality</li> <li>▪ Communication between professional</li> <li>▪ Communication patient ↔ professional</li> <li>▪</li> </ul>
<b>IMPROVE</b>		<ul style="list-style-type: none"> <li>▪ Standards &amp; guidelines</li> <li>▪ Reporting systems</li> <li>▪ Analyzing systems</li> <li>▪ Solutions</li> <li>▪ Patient information</li> <li>▪ Research</li> <li>▪</li> </ul>	<ul style="list-style-type: none"> <li>▪ ICT-system</li> <li>▪ Quality methods, a.o. peer review systems, breakthrough)</li> <li>▪ Tools</li> <li>▪ Innovations</li> <li>▪ Patient education</li> <li>▪ Research</li> <li>▪</li> </ul>	<ul style="list-style-type: none"> <li>▪ Reporting systems</li> <li>▪ Analyzing systems</li> <li>▪ Quality methods, a.o. peer review systems, breakthrough)</li> <li>▪ Improvement actions</li> <li>▪ Discussions points</li> <li>▪ Safety officers &amp; Risk managers</li> <li>▪ Patient information</li> <li>▪ Patient involvement</li> <li>▪ Research</li> <li>▪</li> </ul>

<p><b>CONTROL</b></p>	<ul style="list-style-type: none"> <li>▪ Patient information</li> <li>▪ Networks</li> <li>▪ Experts</li> <li>▪ Priorities on national health agenda</li> <li>▪ Rating systems</li> <li>▪ Indicators</li> <li>▪ Accreditations systems</li> <li>▪</li> </ul>	<ul style="list-style-type: none"> <li>▪ Topics, e.g. infections, pharmaceuticals, .....</li> <li>▪ Benchmark system</li> <li>▪ Topics</li> <li>▪ Examples</li> <li>▪ Specialised professionals</li> <li>▪ Empowerment issues</li> <li>▪</li> </ul>	<ul style="list-style-type: none"> <li>▪ Best practices</li> <li>▪ Control systems</li> <li>▪ Indicators</li> <li>▪ Data</li> <li>▪ Complaint systems</li> <li>▪</li> </ul>
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## Appendix B

### Q.6 National reporting systems : England and Wales response

6a) Is there a <b>national</b> incident reporting system? <b>Yes</b> If yes, please answer points b) to i)
b) Please provide contact details:  <b>National Patient Safety Agency</b>  <b>4-8 Maple Street</b> <b>London</b> <b>W1T 5HD</b>  General enquiries tel:020 7927 9500  <a href="http://www.npsa.nhs.uk">http://www.npsa.nhs.uk</a>
c) Does the system collect information on near misses? <b>Yes</b>
d) Is the data protected from legal inquiry? <b>Yes</b>
e) Is the system connected in any way to litigation? <b>No</b>
f) How is the data collected used?  The data is held anonymously and is used to identify patterns and trends. It is hoped that by analysing the data they will be able to find solutions to specific issues. It is also fed back to the Health Service.
g) Is there a system for analysing reported events? <b>Yes</b>

h) what systematic approaches are used? (eg, root cause analysis, process mapping).

A National Reporting and Learning System (NRLS) is currently being evaluated by the NPSA and will use standard definitions of adverse events and near misses to determine the causes behind them. Evaluations have been aimed at testing the new centralised system for recording, coding, classifying, analysing and providing feedback on adverse events.

The information on incidents received by the NPSA, through the national reporting system, will already have been managed by the relevant NHS trust, organisation or accountability body. Through the national reporting the NPSA will be able to develop an accurate picture of the extent of adverse incidents taking place in healthcare and have a baseline against which to measure improvements in patient safety. By working with the organisations involved, NPSA will also be able to understand and tackle the "root causes" behind incidents and by sharing that learning help prevent the same incidents and errors occurring again. Through their work they will also be able to identify trends in the occurrence of, and reasons for, incidents and will produce guidance and patient safety alerts where needed to improve patient safety. Recognising the scale of the problems and the key fact that as many as half the adverse events and errors that occur are preventable, it is hoped that improvements and changes can be identified and delivered across the NHS in order to achieve better quality and ultimately safer journey for patients using the service. It has been implemented in stages since the end of 2003.

i) Can patients report incidents directly to the national reporting system? **Yes**

**This is possible through the NPSA website via the Please ask system**  
**<http://www.npsa.nhs.uk/pleaseask>**

## Appendix C

### Q.6. Country responses where national reporting systems are partial

#### Question 6 – NATIONAL REPORTING SYSTEM: Austria

6a) Is there a **national** incident reporting system?

Yes

In Austria, we have an extensive system of pharmacovigilance, clinical studies, a recall system for pharmaceuticals, regulations for medicinal products etc.

For detailed information please contact:

Federal Ministry of Health and Women

department III/6

Radetzkystrasse 2

1030 Vienna

Austria

Tel. +43-1/711 00-0

Fax +43-1/711 00-14300

<http://www.bmgf.gv.at>

No

But at present, there is no systematic national recording of “errors“ that occur in the health care system, although awareness of the existence of errors within the Austrian health care system is constantly on the rise.

For future plans please see Question 2

If yes, please answer points b) to i)

b) Please provide contact details:

Address:

Postcode:

Country:

Telephone number(s):

Email:

Website:

c) Does the system collect information on near misses? Yes/No
d) Is the data protected from legal inquiry? Yes/No
e) Is the system connected in any way to litigation? Yes/No
f) How is the data collected used? (Please briefly describe)
g) Is there a system for analysing reported events? Yes/No
h) If yes to question 6f, what systematic approaches are used? (eg, root cause analysis, process mapping). Please list - - - -
i) Can patients report incidents directly to the national reporting system Yes/No

**Question 6 – NATIONAL REPORTING SYSTEM: Belgium**

6a) Is there a <b>national</b> incident reporting system? Yes/No PARTLY If yes, please answer points b) to i) Administrative Data available Voluntary Claim Reporting
b) Please provide contact details:  Address: see above Federal Service of Health  Postcode:  Country:  Telephone number(s):

Email:
Website:
d) Is the data protected from legal inquiry? NA
e) Is the system connected in any way to litigation? NA
f) How is the data collected used? (Please briefly describe) To inform hospitals on AE detected
g) Is there a system for analysing reported events? Yes/
h) If yes to question 6f, what systematic approaches are used? (eg, root cause analysis, process mapping). Please list  -Depend on the hospitals methodology  -No systematic Methodology  -  -
i) Can patients report incidents directly to the national reporting system /No

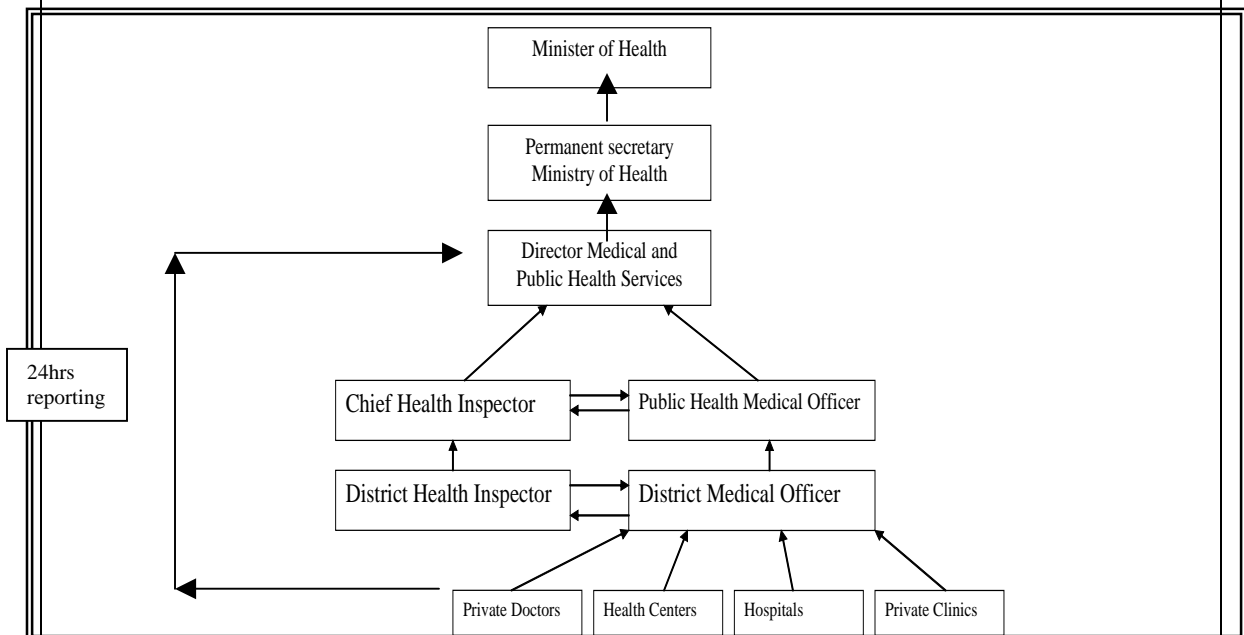
**Question 6 – NATIONAL REPORTING SYSTEM: Cyprus**

6a) Is there a <b>national</b> incident reporting system? ✓ Yes /No
<b><u>NETWORK FOR THE SURVEILLANCE AND CONTROL OF COMMUNICABLE DISEASES</u></b> <b><u>MEDICAL AND PUBLIC HEALTH SERVICES</u></b> <b><u>MINISTRY OF HEALTH</u></b>

## CYPRUS

A Network for the Surveillance and Control of Communicable Diseases has been developed under the Medical and Public Health Services of the Ministry of Health of Cyprus. Following a relevant amendment of the legislation, four systems for Surveillance of Communicable Diseases have been introduced:

1. *Mandatory Notified Communicable Diseases Network*, a System for reporting the Mandatory Notified Communicable Diseases, currently 57 in number. The notification procedure is described in the following diagram:



Apart from the timely notification of all these cases, for a number of them of special Public Health importance for Cyprus, there is a direct within 24hrs notification to the central level:

Through detailed Notification Forms, information of epidemiological importance is collected for all reported cases. Special notification forms were developed for a number of these diseases (i.e. viral meningitis, meningococcal disease/ bacterial meningitis, poliomyelitis, foodborne diseases, HIV e.t.c.) . The recommended by EU *Case Definitions* (categorizing as probable, possible or confirmed) are used for all 57 diseases.

2. *Sentinel Network*, it is a system for reporting 11 diseases/syndromes based on clinical diagnosis. Reporting is voluntary, mainly by primary health care physicians (GPs and Pediatricians) of Private and Public Sector, from all over Cyprus.
3. *Laboratory Network*, a voluntary System for reporting isolation of microorganisms/ positive serology results. Reporting is voluntary by Microbiology Laboratories of Private and Public Sector, from all over Cyprus.
4. *Sexually Transmitted Diseases Network*, a voluntary System for reporting a number of STDs. Reporting is voluntary by Gynecologists and Dermatologists of Private and Public Sector, from all over Cyprus.

All data are entered on EPI Info 2000 database which apart from statistical analysis provides geographic distribution information.

The system is going to provide feedback to the periphery through a 6monthly newsletter and will facilitate flow of information, related to Communicable Diseases, to EU.

If yes, please answer points b) to i)

b) Please provide contact details:

Address: Dr. Chrystala Hadjianastassiou, Chief Medical Officer, 10, Marcou Drakou Street, Pallouriotissa, Nicosia

Postcode: 1449

Country: Cyprus

Telephone number(s): +357 22 400146

Email: cycomnet@cytanet.com.cy

Website:

c) Does the system collect information on near misses? Yes/ No- **Non Applicable**

d) Is the data protected from legal inquiry? **√ Yes/No**

e) Is the system connected in any way to litigation? Yes/√ No
f) How is the data collected used? (Please briefly describe). For the surveillance of communicable diseases and for early detection of outbreaks
g) Is there a system for analysing reported events? √ Yes/No
h) If yes to question 6f, what systematic approaches are used? (eg, root cause analysis, process mapping). Please list  - Routine analysis on a weekly, monthly, six monthly and yearly basis which aim to assess the incidents of the communicable diseases.
i) Can patients report incidents directly to the national reporting system Yes/ √ No

#### Question 6 – NATIONAL REPORTING SYSTEM: France

6a) Is there a <b>national</b> incident reporting system? Yes/No If yes, please answer points b) to i)
<p>b) Please provide contact details:</p> <p>in France there are several national reporting systems. Some are mandatory :</p> <ul style="list-style-type: none"> <li>- mandatory reporting systems to AFSSAPS on failures with health products ( "vigilances"),</li> <li>- mandatory reporting system on associated health care infections that are to be declared to INVS (since 2001) on unusual and gravity criteria</li> <li>- a mandatory reporting system for all health care professionals will soon concern severe adverse events. The first step is an experimentation and is in progress</li> </ul> <p>Others are voluntary : like the one on the "near miss" events, linked to the doctors and health care teams accreditation process. Adverse events related to high risk interventional activities are going to be declared to HAS . A "decree" has just been published in July 2006</p> <p>Corrective measures are taken by the different agencies. For nosocomial infections the reports are gathered at the national level which draws conclusion about best practices, gives recommendations and develops national guidelines</p> <p>In conclusion the reporting system in the fields of drug, blood, medical devices and other healthcare products, along with nosocomial infections is highly structured, at national, regional, and local levels.</p>

Concerning nosocomial infections, the Ministry of Health is directly in charge of the definition of a risk reduction program and of its different action areas. As an example, the 2005-2008 program focuses on training, research, improvement of health care organisation and clinical practice .A national audit programme for nosocomial infections is carried out with a focus on hand hygiene is being carried out

Concerning other adverse events, reporting systems are in progress

Postcode:

Country:

Telephone number(s):

Email:

Website:

Does the system collect information on near misses? **Yes X/No**  
Near misses related to high risk interventional activities will be reported by physicians to the HAS on a voluntary basis and in exchange the physicians will receive an accreditation and a reduction in the cost of their insurance premium

Is the data protected from legal inquiry? **Yes/No X**  
The HAS and the Ministry of Health are conducting work to consider if solutions to protect data from legal inquiries can be adopted in regard to French law

e) Is the system connected in any way to litigation? **Yes/No X**

f) How is the data collected used? (Please briefly describe)

g) Is there a system for analysing reported events? **Yes/X /No**  
the national strategy is being defined and one of the aims will be to adopt more systematic rigorous approaches

h) If yes to question 6f, what systematic approaches are used? (eg, root cause analysis, process mapping). Please list

-

i) Can patients report incidents directly to the national reporting system

j) **Yes/No**

**Question 6 – NATIONAL REPORTING SYSTEM: Italy**

6a) Is there a <b>national</b> incident reporting system? Yes/No <b>NO</b> At the present time trust are requested by Ministry to report sentinel events (a list is provided) If yes, please answer points b) to i)
b) Please provide contact details:  Address:  Postcode:  Country:  Telephone number(s):  Email:  Website:
c) Does the system collect information on near misses? Yes/No
d) Is the data protected from legal inquiry? Yes/No
e) Is the system connected in any way to litigation? Yes/No
f) How is the data collected used? (Please briefly describe)
g) Is there a system for analysing reported events? Yes/No

h) If yes to question 6f, what systematic approaches are used? (eg, root cause analysis, process mapping). Please list

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-

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i) Can patients report incidents directly to the national reporting system Yes/No

## Question 6 – NATIONAL REPORTING SYSTEM: Netherlands

<p>6a) Is there a <b>national</b> incident reporting system? Yes/No</p> <p>The reporting of incidents is only obligatory for a very limited amount of incidents, only for the serious adverse events ('calamiteiten'). Calamiteiten or serious adverse events need to be reported to the management of a hospital, who is obliged by law to report to the Healthcare Inspectorate. This obligation is led down in the Law on Quality of Healthcare Organisations (Kwaliteitswet Zorginstellingen 2005)</p> <p>If yes, please answer points b) to i)</p>
<p>b) Please provide contact details:</p> <p>Address:</p> <p>Postcode:</p> <p>Country:</p> <p>Telephone number(s):</p> <p>Email:</p> <p>Website: <a href="http://www.igz.nl">www.igz.nl</a></p>
<p>c) Does the system collect information on near misses? Yes/No</p>
<p>d) Is the data protected from legal inquiry? Yes/No, only to a certain extent. Based on the Law on Public Openness (Wet Openbaarheid van Bestuur WOB) incident reports can be made public (after anonimisation) under specific circumstances.</p>
<p>e) Is the system connected in any way to litigation? Yes/No</p>
<p>f) How is the data collected used? (Please briefly describe)</p> <p>Hospital management can start an internal investigation in case of a serious adverse event. They always have to report this incident and the actions taken to the Inspectorate. The Inspectorate can be satisfied with this reaction of the hospital itself, but always has the right to start to conduct their own research.</p>
<p>g) Is there a system for analysing reported events? Yes/No</p>
<p>h) If yes to question 6f, what systematic approaches are used? (eg, root cause analysis, process mapping). Please list</p>

-

- i) Can patients report incidents directly to the national reporting system  
Yes/No

Other relevant information in this respect:

- **PREZIES network:** <http://www.prezies.nl/>

PREZIES stands for Prevention of Hospital infections by surveillance (= *PREventie van ZIEkenhuisinfecties door Surveillant*) The PREZIES network is a collaboration of participating hospitals, the Dutch Institute for Healthcare Improvement CBO and the National Institute for Public Health and Environment (RIVM). Results of PREZIES show that the risk on nosocomial (or hospital) infections indeed decrease by surveillance. PREZIES collaborates with national surveillance systems for nosocomial infections in other EU countries in the HELICS-project (<http://helics.univ-lyon1.fr/>).

- **Performance Indicators of Dutch Healthcare Inspectorate (IGZ)**

The Dutch Healthcare Inspectorate (IGZ) in 2004 for the first time started to ask hospitals to provide them with information on certain quality performance indicators. These results are made public and are a method for hospitals to be transparent on their quality and safety performance. This enables the IGZ to prioritise in governing the healthcare sector by focusing on high risk areas and to work more efficient and effective. This method is meant to fasten the application of best practices by hospitals. Of course the overall aim is to improve quality and safety for patients. The report of the Inspectorate on performance indicators 2005 is available on [http://www.igz.nl/15451/17873/Rapport\\_2005-05\\_Het\\_resulta1.pdf](http://www.igz.nl/15451/17873/Rapport_2005-05_Het_resulta1.pdf)

- **Complaint procedure within hospitals**

On 1 August 1995 the Law on Rights to Complain for Patients in Healthcare Organisations (Wet Klachtrecht Cliënten Zorginstellingen) came into force. Furthermore in December 2004 a standard on complaints was issued (Klachtenrichtlijn: <http://www.cbo.nl/product/richtlijnen/folder20021023121843/klacht-rl-2004.pdf>) The Law from 1995 aims to create complaint procedures that are easy accessible and that facilitate quality improvement. Healthcare organisation are obliged by law to have rules on complaint procedures, to have a complaint commission with an independent chairman, to annually report to the Inspectorate and to report serious adverse events to the Inspectorate. The complaint procedure system should by law be easy accessible, have expertise, objective, react quickly and inform the complainer on the actions that are taken.

- **Central Medication Registration (Centrale Medicatie Registratie, CMR)**

The Dutch Association of Hospital Pharmacists has developed a national database for uniform classification and registration of medical errors, Central Medication Registration (Centrale Medicatie Registratie, CMR). This database was piloted in the period starting 1 July 2004.

At this moment all hospitals can subscribe to the CMR. The CMR:

- i. national uniform classification and registration of medication related incident reports
- ii. Feedback on reported data to participating hospitals
- iii. Spreading alerts on alarming medication errors

More information can be found on: [http://www.nvza.nl/kr\\_nvza/default.asp](http://www.nvza.nl/kr_nvza/default.asp)

#### Question 6 – NATIONAL REPORTING SYSTEM: Portugal

6a) Is there a <b>national</b> incident reporting system? <b>Yes</b> If yes, please answer points b) to i) <b>only for medicines and medical devices</b>
b) Please provide contact details: <b>INFARMED see Question 2</b>  Address:  Postcode:  Country:  Telephone number(s):  Email:  Website:
c) Does the system collect information on near misses? <b>Yes</b>
d) Is the data protected from legal inquiry? <b>NO</b>
e) Is the system connected in any way to litigation? <b>NO</b>
f) How is the data collected used? (Please briefly describe)  <b>For statistical purposes and notice to public and professionals; to suspend or redraw products from the market.</b>
g) Is there a system for analysing reported events? <b>Yes</b>
h) If yes to question 6f, what systematic approaches are used? (eg, root cause analysis, process mapping). Please list

<ul style="list-style-type: none"> <li>- none of the above</li> <li>- analyse of concurrent medication and/or use of medical devices</li> <li>-</li> <li>-</li> </ul>
i) Can patients report incidents directly to the national reporting system <b>Yes</b>

**Question 6 – NATIONAL REPORTING SYSTEM : Slovenia**

6a) Is there a <b>national</b> incident reporting system? Yes If yes, please answer points b) to i)
b) Please provide contact details  Address: Ministry of Health, Štefanova 5, LJUBLJANA  Postcode:1000  Country:Slovenia  Telephone number(s): T:+3861 478 6061 F:+3861 478 6058  Email: e-mail:andrej.robida@gov.si Website: www.mz.gov.si
c) Does the system collect information on near misses? No
d) Is the data protected from legal inquiry? Yes
e) Is the system connected in any way to litigation? No
f) How is the data collected used? (Please briefly describe)  For feedback information and alerts

g) Is there a system for analysing reported events? Yes, by providers with the help of MoH

h) If yes to question 6f, what systematic approaches are used? (eg, root cause analysis, process mapping). Please list

Only sentinel events as defined by JCAHO are anonymously and confidentially collected on voluntary basis.

-RCA

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## Appendix D

### Q.7 Countries that report details of local reporting systems.

#### Question 7 – LOCAL INCIDENT REPORTING SYSTEMS : England and Wales

<p>7a) Are healthcare organisations required to have a local incident reporting system?</p> <p><b>Yes</b></p> <p>If yes, please answer points b) to h)</p>
<p>b) Please provide details of the requirement to have such a system (eg, is it a national standard, legal requirement, good practice, etc)</p> <p><b>At a local level, every NHS organisation must have in place a system for ‘clinical governance’. This is a clear and formal reporting process which allows organisations to safeguard high standards of care as well as continually improve the quality of their services.</b></p>
<p>c) Are systems required to collect information on near misses? <b>Yes</b></p>
<p>d) Is the data protected from legal inquiry? <b>No</b></p>
<p>e) Are the systems connected in any way to litigation?</p>
<p>f) How is the data collected used?</p> <p><b>A single overall database for analysing and sharing lessons from incidents and near misses, as well as litigation and complaints data is used to identify common factors and consider specific action necessary in order to reduce risks to patients in the future.</b></p>
<p>g) If yes to question 7e, what systematic approaches are used? (eg, root cause analysis, process mapping). Please list</p>

-
<p>h) Can patients report incidents directly to such local reporting systems <b>Always</b></p> <p>In England, you can contact the Patient Advice and Liaison Service PALS for the NHS organisation that your concern relates to. There is a PALS for each area who works directly with the NHS to help patients sort out any problems with their care. PALS can also explain to patients how they can make a formal complaint or report an incident directly to the NHS organisation that the concern relates to.</p> <p>It is also possible to complain about the NHS through the Independent Complaints Advocacy Service (ICAS).</p>

**QUESTION 7 – LOCAL INCIDENT REPORTING SYSTEM : Ireland**

Are healthcare organisations required to have a local incident reporting system? Yes	<b>Yes</b> (please answer 7a-7g) <b>No</b> – go to question 8
<p>a) Please provide details of the requirement to have such a system (eg, is it a national standard, legal requirement, good practice, etc)</p> <p>Required internally by the Department of Health and Children and the Health Services Executive as part of the requirements for the management of risk and safety. It is also required by indemnity organisations and other external regulatory bodies e.g. Irish Health Services Accreditation Board, Health and Safety Authority, Irish Medicines Board, Mental Health Commission, Social Services Inspectorate etc</p>	
b) Are systems required to collect information on near misses?	<b>Yes</b> <b>No</b>
c) Is the data protected from legal inquiry?	<b>Yes</b> <b>No</b>
d) Are the systems connected in any way to litigation?	<b>Yes</b> <b>No</b>

<p>e) How is the data collected used?          Currently there is no uniform way in which data is used and there is a degree of variance nationally. In the main it is used to make decisions regarding the level and type of review required and to identify trends and patterns so that targeted quality improvement strategies can be planned.</p>	
<p>f) If yes to question 7e, what systematic approaches are used? (eg, root cause analysis, process mapping). Please list.....          Root cause analysis, data and process mapping, facilitated team reviews, aggregated reporting to services and management,</p>	
<p>g) Can patients report incidents directly to such local reporting systems</p>	<p>Yes          No  <i><b>Depends on local arrangements</b></i></p>

**Question 7 – LOCAL INCIDENT REPORTING SYSTEMS : Sweden**

<p>7a) Are healthcare organisations required to have a local incident reporting system?   <b>Yes/No</b>           If yes, please answer points b) to h)</p>
<p>b) Please provide details of the requirement to have such a system (eg, is it a national standard, legal requirement, good practice, etc)   <u><b>The Regulation SOSFS 2005:12 (see question 4 Guideline 1) requires local systems for reporting and management of adverse events, near misses and risks.</b></u></p>

c) Are systems required to collect information on near misses? <b>Yes/No</b>
d) Is the data protected from legal inquiry? <b>Yes/No</b>
e) Are the systems connected in any way to litigation? <b>Yes/No</b> <i><b>There is a mandatory obligation for healthcare organisations to report adverse events entailing severe patient injury or risk for severe patient injury to the NBHW. The NBHW in turn is under certain circumstances obliged to refer information to the disciplinary board.</b></i>
f) How is the data collected used? Please briefly explain  <b>Data is more and more used to take measures that are aimed to improve patient safety.</b>
g) If yes to question 7e, what systematic approaches are used? (eg, root cause analysis and risk, process mapping). Please list <b>Referring to question 7f. A national educational material covering analysis of adverse events (Root Cause Analysis) and risk analysis of processes (Healthcare Failure Mode Effect Analysis) has enhanced the use of these methods within healthcare services</b>  -  -  -  -
h) Can patients report incidents directly to such local reporting systems  <b>Always/Never/Sometimes</b> <i><b>There are other specific reporting systems for patients</b></i>

## Appendix E

### Liability arrangements that have special features, from four countries .

#### Question 11 – LIABILITY ARRANGEMENTS: Austria

11a) Is there a medical defence organisation based in your country?

X No

Comment:

In Austria, most hospitals and doctors have concluded a professional liability insurance. However, they are not legally obliged to do so and there are no regulations governing further details of this insurance. This decision as well as the costs involved, are up to the hospitals' and doctors' own responsibility. This system works very well in practice.

If there is no insurance, the hospital or doctor who is liable for a medical error has to come up for the costs himself. In addition, there are public funds which will financially support patients who have suffered harm.

If a hospital had to pay damages to a patient who was harmed by one of its employees, the hospital can sue the guilty person for a refund of the damages paid. This is done in the form of civil proceedings at court. If the health professional is found to have acted grossly negligent, he is condemned to pay damages to the hospital. If his fault is less major, the damages he has to pay can be reduced by the court down to nothing at all, depending on the situation.

In serious cases, a doctor who has harmed a patient has to undergo criminal proceedings at court, which can result in high fines or even imprisonment. In such cases the competent Provincial Governor can ban him from working as a doctor for the duration of the proceedings.

In addition, if a medical doctor has infringed professional law, the Medical Chamber initiates disciplinary proceedings against him. For disciplinary proceedings and sanctions, see §§ 136-139 Doctors Act.

a) Do clinicians use medical defence organisations based in other countries?

b) Are there any other malpractice protection schemes used in your country?  
Please provide some brief details:

There are two institutions dealing with the majority of cases of **extrajudicial settlement of disputes**.

1. Patient advocacies / Patient representation bodies:

These bodies instituted in all nine provinces are supposed to allow professional legal action and protection of patient interests free of cost. They are no authorities, and as such are not taking legal coercive measures, but service

bodies which are not bound by instructions for the purpose of qualified and specialised patient representation.

Depending on the provincial legislation, their scope of competence may cover the entire health care and social system (hospitals, nursing homes, self-employed doctors, emergency medical services, convalescent homes, home care, pharmacies) or only specific areas (according to the Federal Hospital Law, hospitals have to be covered anyway).

Besides this, there are patient advocates (although the denomination is the same), representing and assisting exclusively patients in psychiatric hospitals.

## 2. Arbitration bodies:

Based on different models, these bodies are run in the provinces by the regional medical chamber, or with the contribution of the latter. It is their main purpose to achieve an out-of-court settlement of disputes between the patient and the doctor in the case of alleged misconduct due to a medical error.

Patient-compensation fund: This new form of out-of-court settlement of disputes has been instituted, in order to optimize civil liability law. This fund serve as "reserve" for special damage events (in case of difficulties in providing evidence or for uncompensable events which have lead to considerable damage for the patient).

c) Who are the premiums usually paid by?

Premiums for the professional liability insurance are usually paid by:

- i) **Individual clinicians** X Yes (self established physicians)
- ii) **Employer** X Yes (hospitals in case of employed physicians)
- iii) **The State** X No

Any other comments:

## **Question 11 – LIABILITY ARRANGEMENTS: Cyprus**

11a) Is there a medical defence organisation based in your country? Yes/  No

d) Do clinicians use medical defence organisations based in other countries?

Yes/

No

Please provide some brief details:

e) Are there any other malpractice protection schemes used in your country?

Yes/

√ No

Please provide some brief details:

In case of litigation, health professionals seek the assistance of lawyers. If they win the case in Court, then their expenses are reimbursed.

#### Question 11 – LIABILITY ARRANGEMENTS: Estonia

11a) Is there a medical defence organisation based in your country? Yes/**No**

b) Do clinicians use medical defence organisations based in other countries?

Yes/**No**

Please provide some brief details:

f) Are there any other malpractice protection schemes used in your country?

Yes/**No**

Please provide some brief details:

1. Some hospitals have voluntary insurance contracts against malpractice cases

2. Estonian Union of Doctors has the voluntary insurance contract against malpractice cases for the members.

**Question 11 – LIABILITY ARRANGEMENTS: France**

11a) Is there a medical defence organisation based in your country? Yes/No  
apart from specific insurance policies with legal support ,there is no special organisation  
but is an insurance policy with legal medical support considered as a medical defense organisation

b) Do clinicians use medical defence organisations based in other countries? Yes/No

Please provide some brief details:

A limited number of physicians engaged in high risk activities use medical defence organisations based in other countries

g) Are there any other malpractice protection schemes used in your country?  
Yes/No

Please provide some brief details:

h) Who are the premiums usually paid by?

j) **Individual clinicians** Yes/No

ii) **Employer** /No  
Yes : in part in public hospitals

iii) **The State** Yes/No  
yes for physicians who are engaged in accreditation, a part of their premium is paid by the " Assurance Maladie" social security

Any other comments:

## Appendix F

### Whistle-blowing policy

#### **Nolan and Audit Commission recommendations (UK)**

In late 1997 the second Nolan Report was published which included its full recommendations on whistleblowing. The specific points were that an effective whistleblowing system should include:

- a clear statement that malpractice is taken seriously in the organisation and an indication of the sorts of matters regarded as malpractice
- respect for the confidentiality of staff raising concerns if they wish, and the opportunity to raise concerns outside the line management structure
- penalties for making false and malicious allegations
- an indication of the proper way in which concerns may be raised outside the organisation if necessary.

#### **Question 12 – WHISTLE-BLOWING POLICY England and Wales**

Is there a national whistle-blowing policy? **Yes**

**Following the introduction of The Public Interest Disclosure Act (1998), the NHS Executive issued guidance that stated that all Trusts should implement whistle blowing policies. There is evidence to suggest however, that many staff are not aware of these policies.**

**A whistle blowing charity called Public Concern at Work ([www.pcaw.co.uk](http://www.pcaw.co.uk)) have a legal helpline which is free of charge and available to people concerned about wrongdoing at work but who are not sure whether or how to raise the concern.**

#### **Question 12 – WHISTLE-BLOWING POLICY Greece**

Is there a national whistle-blowing policy? YES

Please could you provide the details:

There is a national whistle-blowing policy that facilitates the written and verbal communication to a Person or Organization, to expose and/or inform upon, alleged wrongdoing or discrimination or other type of adverse occurrence that violates a law, or a regulation, or a policy, or ethics.

Under existing rules, staff already has an obligation to report concerns about potential wrongdoing to their hierarchy or directly to OLAF. Among the improvements made through Reform is the provision that, if the Commission or OLAF have not taken appropriate action within a reasonable period, the 'whistleblower' can bring the complaint to the attention of the Presidents of either the Council or Parliament or Court of Auditors, or to the Ombudsman.



by the Council of Europe?

F. Remarks and additional information

**Question 2 - NATIONAL AGENCIES / BODIES and/or INSTITUTIONS**

- A. Which national agencies/institutions in your country specialise in patient safety or are responsible for reducing the number of patient safety incidents?  
Could you give us their contact details?
- B. Is their role principally or only partly related to patient safety?
- C. In which areas of patient safety do they operate? eg, adverse events data collection, the environment of care, medical devices, etc

*In this question we ask you to provide us with the contact details of the organisations and your view on their areas of expertise. You can use the framework below. Please explain any abbreviations you may use.*

*In particular, please comment on the format of this question – for example, would additional categories for expertise be useful? If so, what would be useful to add?*

<p><b>Organisation name:</b></p> <p>Website:</p>	<input type="checkbox"/> Principal role is patient safety <input type="checkbox"/> Patient safety accounts for only part of their role
<p>Address, postcode, place, telephone number etc.</p>	<p><b>Expertise:</b></p> <input type="checkbox"/> infection control <input type="checkbox"/> medicines management <input type="checkbox"/> adverse events/near miss reporting <input type="checkbox"/> adverse events reduction <input type="checkbox"/> issuing risk alerts <input type="checkbox"/> environment of care <input type="checkbox"/> safe medical devices use <input type="checkbox"/> implementing standards relating to patient safety <input type="checkbox"/> training for better patient safety <input type="checkbox"/> mobilising patient/consumer input to safer care <input type="checkbox"/> awareness raising on patient safety <input type="checkbox"/> others (please state) ..... <input type="checkbox"/> ALL OF THE ABOVE

Any further remarks or information you feel useful to add



**Question 3 - TAXONOMY FOR PATIENT SAFETY**

Does your country have a taxonomy to classify incidents or adverse events relating to patient safety?	
B. In your native language?	<input type="checkbox"/> Yes → <input type="checkbox"/> please attach <input type="checkbox"/> No
C. Translated into another language?	<input type="checkbox"/> Yes → <input type="checkbox"/> please attachment <input type="radio"/> French <input type="radio"/> Spanish <input type="radio"/> German <input type="radio"/> Other: .....
<input type="checkbox"/> No	
Comments re: Question 3:	

**Question 4 - STANDARDS AND/OR GUIDELINES**

Does your country have patient safety standards and/or guidelines? If so, can you supply us with copies of them?

- A. Which subjects are covered by the standards/guidelines? For example: medication, blood, infection, medical devices, clinical etc.
- B. If the standards/guidelines are written in your own native language, do you also have translations into other languages?
- C. At what level are the guidelines developed? For example: national, local, by specialised institutions, by groups of professionals, by patient organisations.

*In this question we would like you to give information for each standard/guideline, which your country wants to share. For the internet site we could consider to translate guidelines from the native language to the English language.*

*To some questions you have the possibility of more answers.*

<b>Guideline 1</b> → <input type="checkbox"/> please attach .....		
<b>Relating to:</b> <input type="checkbox"/> Medication <input type="checkbox"/> Blood <input type="checkbox"/> Infection <input type="checkbox"/> Medical devices <input type="checkbox"/> Clinical <input type="checkbox"/> Other: .....	<b>Language:</b> <input type="checkbox"/> Native language <input type="checkbox"/> Translated into: .....	<b>Developed:</b> <input type="checkbox"/> At national level <input type="checkbox"/> At local level <input type="checkbox"/> By specialised institutions <input type="checkbox"/> By groups of professionals <input type="checkbox"/> By patient organisations

<b>Guideline 2</b> → <input type="checkbox"/> please attach .....		
<b>Relating to:</b> <input type="checkbox"/> Medication <input type="checkbox"/> Blood <input type="checkbox"/> Infection <input type="checkbox"/> Medical devices <input type="checkbox"/> Clinical <input type="checkbox"/> Other: .....	<b>Language:</b> <input type="checkbox"/> Native language <input type="checkbox"/> Translated into: .....	<b>Developed:</b> <input type="checkbox"/> At national level <input type="checkbox"/> At local level <input type="checkbox"/> By specialised institutions <input type="checkbox"/> By groups of professionals <input type="checkbox"/> By patient organisations

**Guideline 3** →  please attach

.....

<b>Relating to:</b> <input type="checkbox"/> Medication <input type="checkbox"/> Blood <input type="checkbox"/> Infection <input type="checkbox"/> Medical devices <input type="checkbox"/> Clinical <input type="checkbox"/> Other: .....	<b>Language:</b> <input type="checkbox"/> Native language <input type="checkbox"/> Translated into: .....	<b>Developed:</b> <input type="checkbox"/> At national level <input type="checkbox"/> At local level <input type="checkbox"/> By specialised institutions <input type="checkbox"/> By groups of professionals <input type="checkbox"/> By patient organisations
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**Guideline 4** →  please attach

.....

<b>Relating to:</b> <input type="checkbox"/> Medication <input type="checkbox"/> Blood <input type="checkbox"/> Infection <input type="checkbox"/> Medical devices <input type="checkbox"/> Clinical <input type="checkbox"/> Other: .....	<b>Language:</b> <input type="checkbox"/> Native language <input type="checkbox"/> Translated into: .....	<b>Developed:</b> <input type="checkbox"/> At national level <input type="checkbox"/> At local level <input type="checkbox"/> By specialised institutions <input type="checkbox"/> By groups of professionals <input type="checkbox"/> By patient organisations
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Comments re: Question 4:

## Question 5 - EXPERTS

Could you provide us with the names, contact details and additional information of experts in the field of patient safety in your country?

*Within national health services there are often a number of professionals with a high level of expertise in their field. Some of these individuals promote the need to improve quality of services and reduce risks associated with treatment. We are interested in learning more from these experts and from their published work.*

**After you have given us the names and contact details of experts, we will approach them to ask further information, amongst others their publications and their permission to add the information on the SIMPATIE website.**

<b>Expert Name 1:</b>
Area of expertise:
Address:  Postcode:  Country:  Telephone number(s):  Email:  Website:
Additional info:

**Expert Name 2:**

Area of expertise:

Address:

Postcode:

Country:

Telephone number(s):

Email:

Website:

Additional info:

**Expert Name 3:**

Area of expertise:

Address:

Postcode:

Country:

Telephone number(s):

Email:

Website:

Additional info:

**Expert Name 4:**

Area of expertise:

Address:

Postcode:

Country:

Telephone number(s):

Email:

Website:

Additional info:

**Expert Name 5:**

Area of expertise:

Address:

Postcode:

Country:

Telephone number(s):

Email:

Website:

Additional info:

## Question 6 – NATIONAL REPORTING SYSTEM

6a) Is there a <b>national</b> incident reporting system? Yes/No If yes, please answer points b) to i)
b) Please provide contact details:  Address:  Postcode:  Country:  Telephone number(s):  Email:  Website:
c) Does the system collect information on near misses? Yes/No
d) Is the data protected from legal inquiry? Yes/No
e) Is the system connected in any way to litigation? Yes/No
f) How is the data collected used? (Please briefly describe)
g) Is there a system for analysing reported events? Yes/No
h) If yes to question 6f, what systematic approaches are used? (eg, root cause analysis, process mapping). Please list  -  -  -  -

i) Can patients report incidents directly to the national reporting system Yes/No

**Question 7 – LOCAL INCIDENT REPORTING SYSTEMS**

<p>7a) Are healthcare organisations required to have a local incident reporting system?</p> <p>Yes/No</p> <p>If yes, please answer points b) to h)</p>
<p>b) Please provide details of the requirement to have such a system (eg, is it a national standard, legal requirement, good practice, etc)</p>
<p>c) Are systems required to collect information on near misses? Yes/No</p>
<p>d) Is the data protected from legal inquiry? Yes/No</p>
<p>e) Are the systems connected in any way to litigation? Yes/No</p>
<p>f) How is the data collected used? Please briefly explain</p>
<p>g) If yes to question 7e, what systematic approaches are used? (eg, root cause analysis, process mapping). Please list</p> <ul style="list-style-type: none"><li>-</li><li>-</li><li>-</li><li>-</li></ul>
<p>h) Can patients report incidents directly to such local reporting systems</p> <p>Always/Never/Sometimes</p>



**Question 8 – NO FAULT COMPENSATION**

a) Is there a no fault compensation system? Yes/No

Comments:

b) If yes, what are the contact details of the organisation co-ordinating the no fault compensation system?

Comments:

**Question 9 – LEGAL DISCLOSURE OF PATIENT SAFETY INFORMATION**

9a) Is information collected on clinical incidents protected from legal discovery/disclosure? Yes/No

Comments:

9b) Is there any legal requirement to inform the patient of any adverse event that has effected them during their course of care? Yes/No

Comments:

### Question 10 – PUBLIC AVAILABILITY OF PATIENT SAFETY DATA

Is data on the following publicly available?

Type of information	By individual clinician	By department	By healthcare organisation	Nationally
Mortality data				
Falls in care settings				
Deaths while in restraint				
Deaths in accident and emergency department				
Deaths while on intensive care unit				
Deaths following trauma				
Healthcare acquired infections				
Suicide in care settings				
Suicide within one month of seeking professional advice				
Maternal deaths				
Peri-operative deaths				
Still births				
Infant deaths within hospitals				

## Question 11 – LIABILITY ARRANGEMENTS

11a) Is there a medical defence organisation based in your country? Yes/No
b) Do clinicians use medical defence organisations based in other countries? Yes/No  Please provide some brief details:
c) Are there any other malpractice protection schemes used in your country? Yes/No  Please provide some brief details:
d) Who are the premiums usually paid by?  k) <b>Individual clinicians</b> Yes/No  ii) <b>Employer</b> Yes/No  iii) <b>The State</b> Yes/No  Any other comments:



**Question 12 – WHISTLE-BLOWING POLICY**

Is there a national whistle-blowing policy? Yes/No

Please could you provide the details:

**Question 13 - PROFESSIONAL PATIENT SAFETY MEMBERSHIP ORGANISATIONS**

13a) Does your country have a professional/membership society for healthcare risk/patient safety managers/specialists? Yes/No

b) If yes, please provide the contact details:

Organisation:

Contact name:

Address:

Postcode:

Country:

Telephone number(s):

Email:

Website:

c) If yes, are there any entry requirements? Yes/No

Please could you provide the details:

## Question 14 - HEALTHCARE RISK MANAGEMENT QUALIFICATIONS

14a) Are there professional healthcare risk management qualifications available in your country? Yes/No

b) If yes, please provide examples and the contact details of the providing organisations

Organisation:

Contact name:

Address:

Postcode:

Country:

Telephone number(s):

Email:

Website:

Organisation:

Contact name:

Address:

Postcode:

Country:

Telephone number(s):

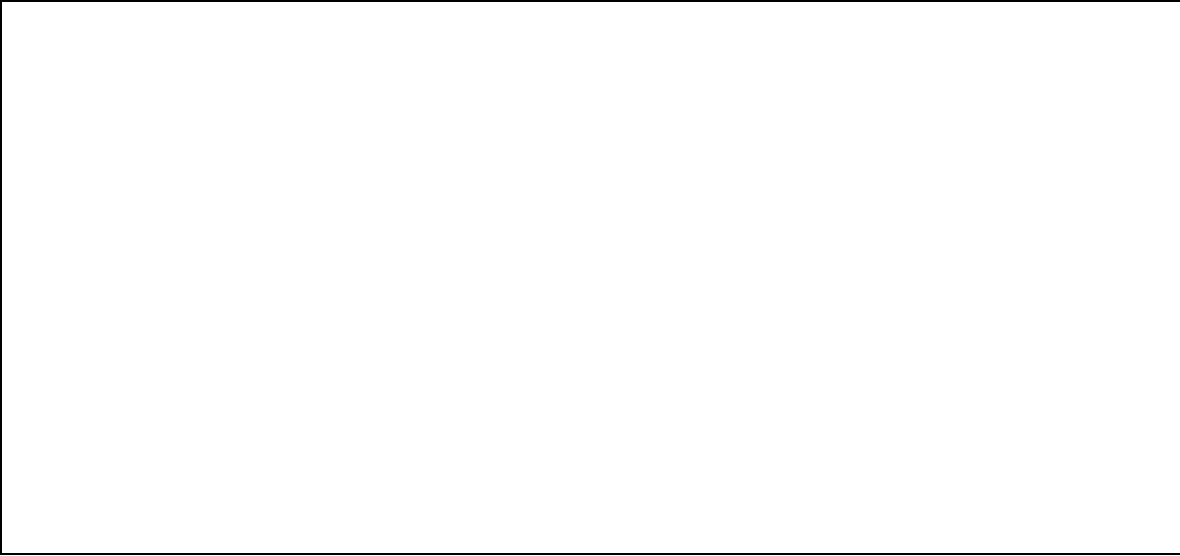
Email:

Website:

**Question 15 – RISK MANAGEMENT OR PATIENT SAFETY MANAGERS**

15. Are healthcare organisations required to have a risk management or patient safety manager? Yes/No

If yes, please provide details:



**Question 16 – PATIENT SAFETY TRAINING FOR HEALTHCARE STAFF**

16. Is patient safety training a required part of training in respect of:
a) Medical undergraduates? Yes/No  If yes, please provide details:
b) Medical postgraduates? Yes/No  If yes, please provide details:
c) Qualified nursing staff? Yes/No  If yes, please provide details:
d) Other clinical staff? Yes/No  If yes, please provide details:
d) Healthcare Managers? Yes/No  If yes, please provide details:



**Question 17 – SPECIALIST PATIENT SAFETY PATIENT ORGANISATIONS**

17. Are there any patient organisations the main focus of whose mission is patient safety? Yes/No

If yes, please provide contact details:

Organisation:

Contact name:

Address:

Postcode:

Country:

Telephone number(s):

Email:

Website:

Organisation:

Contact name:

Address:

Postcode:

Country:

Telephone number(s):

Email:

Website:

**Question 18 – NATIONAL PATIENT SAFETY CAMPAIGNS**

18. Within the past three years, have there been any national patient safety campaigns?
a) Addressed to healthcare professionals? Yes/No If yes, please provide details:
b) Addressed to healthcare managers Yes/No If yes, please provide details:
c) Addressed to healthcare purchasers Yes/No If yes, please provide details:
d) Addressed to patients or the public Yes/No If yes, please provide details:

**Question 19 – PEER REVIEW SCHEMES**

19a. Are there any professional peer review systems with the aim of reducing healthcare mishaps? Yes/No

b) If yes, please could you provide details?

c) Please could you provide contact details for the scheme?

Organisation:

Contact name:

Address:

Postcode:

Country:

Telephone number(s):

Email:

Website:

## Question 20 – THE ROLE OF EUROPEAN BODIES IN PATIENT SAFETY

In your opinion, is there a role for European bodies in respect of the following?

Issue	Yes	No	If yes, which body	What should that body be doing?
a) Patient safety generally				
b) Reduction of medication errors				
c) Wrong site surgery				
d) Sharing information about incompetent/dis missed clinicians				
e) Setting patient safety standards				
f) Improving patient safety information to professionals				
g) Improving patient safety information to the patients or the public				
h) Reducing blood borne infections				
i) Reducing hospital acquired infections				
j) Suicide prevention in care settings				
k) Reducing falls in care settings				
l) Reducing falls in the				

<b>community</b>				
<b>m) Other – please state</b>				

**Question 21 – LEARNING ABOUT PATIENT SAFETY**

Are the following resources freely available in the native language for healthcare professionals, managers and policy makers?

<b>Resource</b>	<b>Yes</b>	<b>If no, would this be helpful?</b>
a) Institute of Medicine Report “To err is human”		
b) Building a Safer NHS		
c) Seven steps to patient safety		
d)NPSA Risk Alerts		
e) Joint Commission Risk Alerts		
f) Details of the IHI “Saving 100,000 lives” campaign		
g) Danish Patient Safety Law		
a) Examples of patient safety standards from other countries? (give examples)		
b) Any other resources? Please provide examples		