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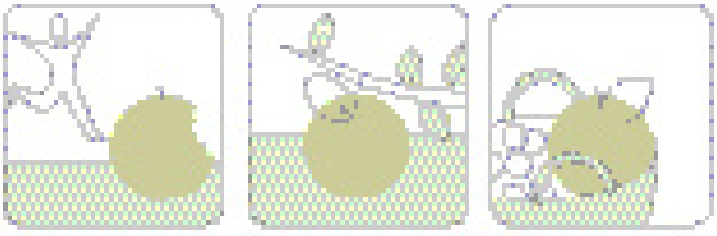
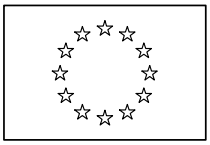
Report on the open consultation on Patient Safety in the European Union





COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 10.12.2008

Report

on the open consultation on Patient Safety in the European Union

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1. INTRODUCTION

The European Commission ran an open consultation on patient safety in the European Union between 25 March and 20 May 2008. The purpose of this public consultation was to gather information about general patient safety issues and concerns throughout the European Union which would be taken into account in the development of the Commission's Communication and proposal for a Council Recommendation at the end of 2008.

The Council Recommendation will address not only over-arching patient safety concerns, but also the prevention and control of a common cause of adverse events in healthcare, healthcare-associated infections on which separate public consultations have already been held. The Commission has evaluated the replies and will publish the results in the near future.

The Commission sought views on patient safety of all those involved in this field, including patients and consumers, national competent authorities, health professionals and healthcare managers. The public consultation provided an opportunity for all interested parties to report their experiences of adverse events in healthcare and to give their views and comments on possible areas of action on patient safety at the EU and Member State level.

This summary document aims to provide an overview of the main opinions expressed by the respondents to the consultation. It also looks into the responses of different stakeholder groups, with a particular focus on Member States' competent authorities.

2. TERMINOLOGY

Patient safety-related terminology varies greatly so we are using the following definitions as a guide to some of the key terms used in this document:

Patient safety is defined as freedom for a patient from unnecessary harm or potential harm associated with healthcare.

A ***patient safety incident*** is an event or circumstance which could have resulted, or did result, in unnecessary harm to a patient. An ***adverse event*** is an incident which results in harm to a patient. ***Harm*** implies impairment of structure or function of the body and/or any deleterious effect arising from that..

3. THE QUESTIONNAIRE

The consultation questionnaire consisted of 61 questions. A first set of questions addressed personal or family experiences of adverse events in healthcare settings. The main section of the questionnaire, consisting of ten different sub-sections, covered areas of possible Member State or EU level action in the field of patient safety: national political support for patient safety; budgetary commitment to safety; patient and public involvement in patient safety improvements; local healthcare management and leadership; health professionals; reporting and learning systems; other patient safety information and the sharing of information; standards and/or external assessment; research and development around patient safety; and complaints and redress. The final section of the questionnaire addressed general issues such as

the adequacy of the steps to tackle patient safety at national level and the role of European Union.

4. THE RESPONSES

4.1. Overview of all responses

We received 184 contributions in total that we divided into the following groups:

Table 1: Overview of the responses received

Group	Number of responses
NGO's	**36**
Competent authorities	**32**
CA's at national level	17 (from 9 Member States[1]) (CY; CZ; FI; IE; LV; SE; UK; MT; ES)
CA's at regional level	10
CA's at local level	5
Health professionals' associations	**25**
Hospitals	**21**
Patient and Consumer organisations	**12**
Industry	**8**
Academia	**6**
Anonymous responses and Others[2]	**44**
Participants total	**184**

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

[1] For some Member States, other competent authorities than the Ministries of Health responded.

[2] Either no name of an individual or of an institution was given or no classification in the groups above was possible.

No correspondents indicated they did not wish to have the replies posted. Accordingly, all contributions have been posted, together with this report, on the health section of the European Commission's *Europa* website,:

http://ec.europa.eu/health/ph_consultations/consultations_en.htm

In addition, 19 replies were received outside of the on-line system. They are not included in this report but they are as well available on the website mentioned above.

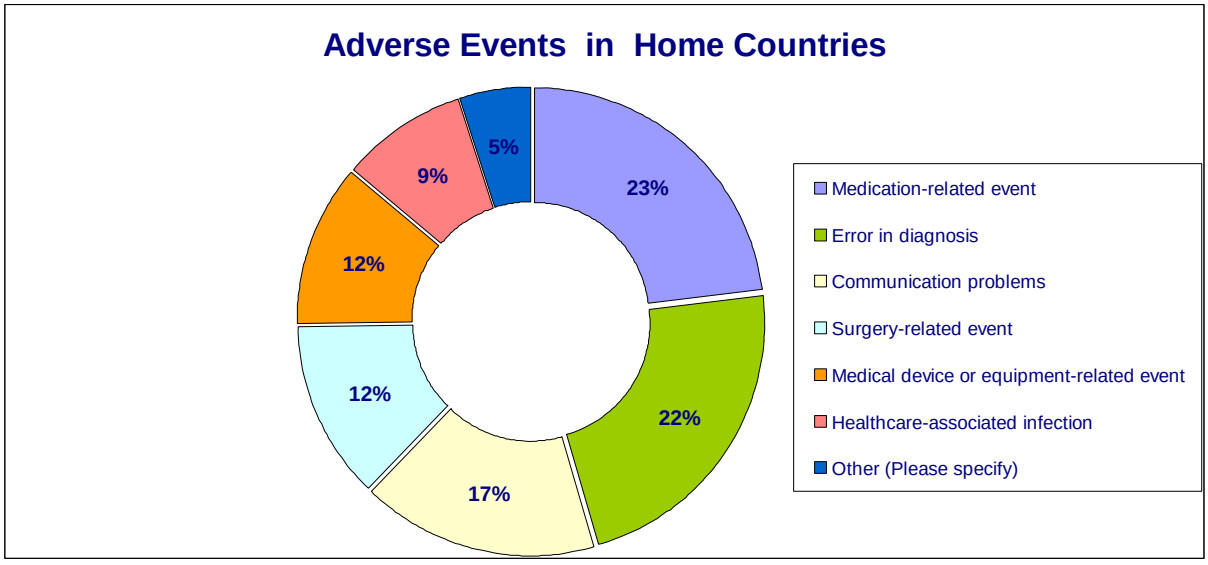
4.2. Analysis of the replies to the different sections of the questionnaire

4.2.1. Personal experiences of adverse events

When asked whether they or a family member had experienced an adverse event, 25% of respondents indicated that they had experienced an adverse event in their home country and 3% in another Member State. Regarding the experiences of family members, 50% of respondents had a family member who had experienced an adverse event in their own country, and 10% in another EU Member State.

The most frequently mentioned types of adverse events experienced in home countries were: ***medication-related events*** *(23%)****, errors in diagnoses*** *(22%) and* ***communication problems*** *(17%)* followed by surgery or medical device related event with 12% each. (Chart 1). Due to the low number of adverse event experienced in another Member State we did not categorise these events further.

Chart 1: Adverse events in Home Countries



When asked to specify other adverse events, delayed delivery of required healthcare was mentioned by 5% of respondents when referring to their home country and by 4% in relation to another Member State.

The adverse events were considered by the respondents to be irreversible for 34% of those experienced in the home country and for 31% of those experienced in another Member State.

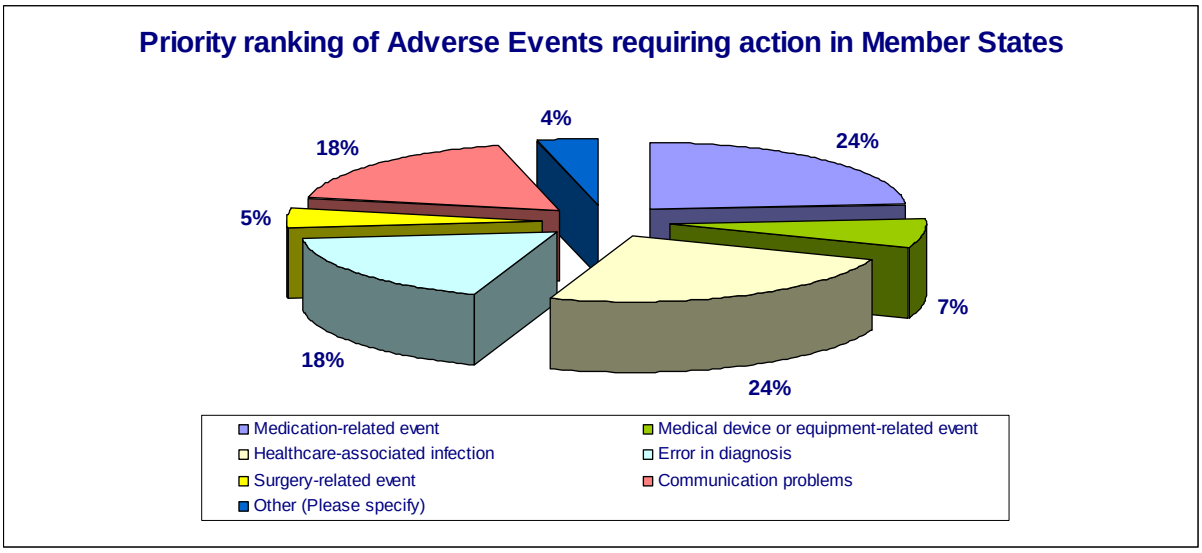
4.2.2. Possible areas of action on patient safety at the EU and Member State level

National Political Support for Patient Safety

When asked about how important a national commitment to improve patient safety was, almost all respondents felt that this is of high importance (98%) and that there is also a need for an EU strategy in this field (92%).

According to the respondents, Member States' competent authorities should prioritise their efforts to reduce the following types of adverse events, ranked in order of importance (Chart 2). Healthcare associated infections were jointly ranked first together with medication related events (24% each) followed by errors in diagnosis and communication problems (18% each), whereas medical device or equipment-related events and surgery-related events were considered not as important to tackle.

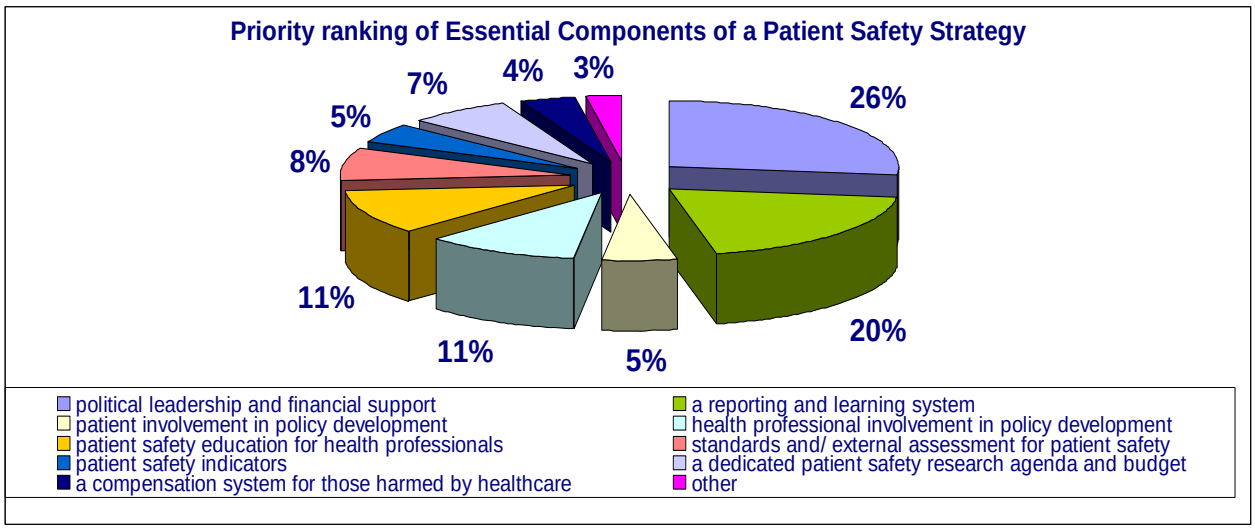
Chart 2: Priority ranking of Adverse Events



When asked to rank **other types of adverse events** (4% of total responses), incidents related to the physical environment (e.g. patient falls, suicides) and to herbal and homeopathic remedies were mentioned. As means to avoid adverse events the need for clinical documentation and the accessibility of good healthcare without delays were recommended. As factors that may lead to adverse events funding inadequacies; present trends towards a more market-oriented healthcare and the lack of time given per consultation in healthcare settings (e.g. doctors/ patients) were listed.

With regard to what respondents thought should be prioritised within a patient safety strategy, ***political leadership and financial support*** *(26%) and* ***a reporting and learning system*** *(20%)* were viewed as the most essential components followed by ***health professional involvement in policy development*** *(11%) and* ***patient safety education for health professionals*** *(11%)* (Chart 3).

Chart 3: Priority ranking of Essential Components of a Patient Safety Strategy



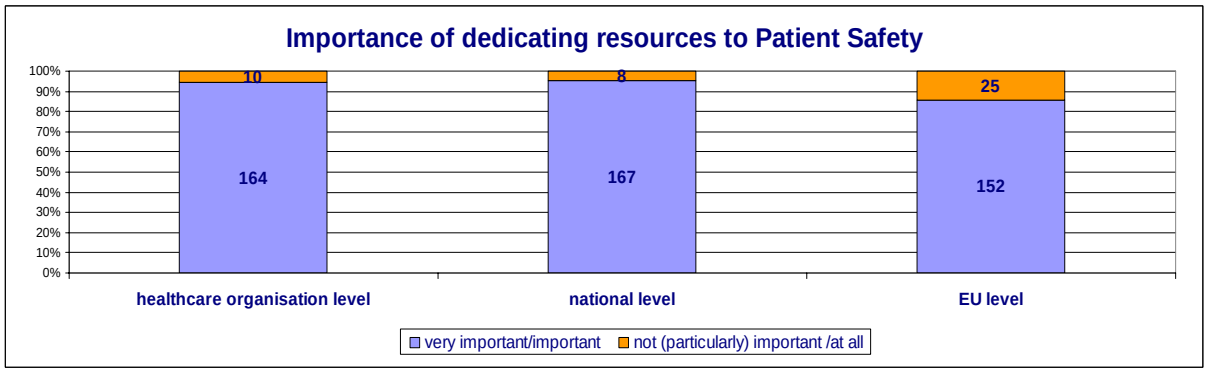
Other essential components of a patient safety strategy mentioned were: a more holistic approach to patient care involving prevention and complementary and alternative medicine approaches; a sampling system to find true incidence, not a passive reporting system; better evidence based on "real life" research i.e. in primary care; limiting randomised controlled trials that exclude the population seen in primary care e.g. asthma; a dedicated patient safety professional in every healthcare organisation; the development of a patient safety-related knowledge base; research into maintenance of effective competency assurance systems; quality control of patient satisfaction/service provided; and a broad-based public education about adverse event reporting.

It should be noted that many participants stated that a whole range of factors were really crucial, which made ranking them in order very difficult for them.

Budgetary Commitment to Safety

Participants were asked about the importance of dedicated financial resources for a patient safety strategy as it was clear that this would incur financial costs at different levels of policy-making and delivery, including at the healthcare organisation level, the national level and possibly the EU level. Again, the vast majority (95% in relation to national level budgetary commitment, 94% for the healthcare organisation level and 88% for the EU level) agreed that it is essential to reserve financial resources for improved patient safety policies and strategies (Chart 4).

Chart 4: Importance of dedicating resources to Patient Safety.

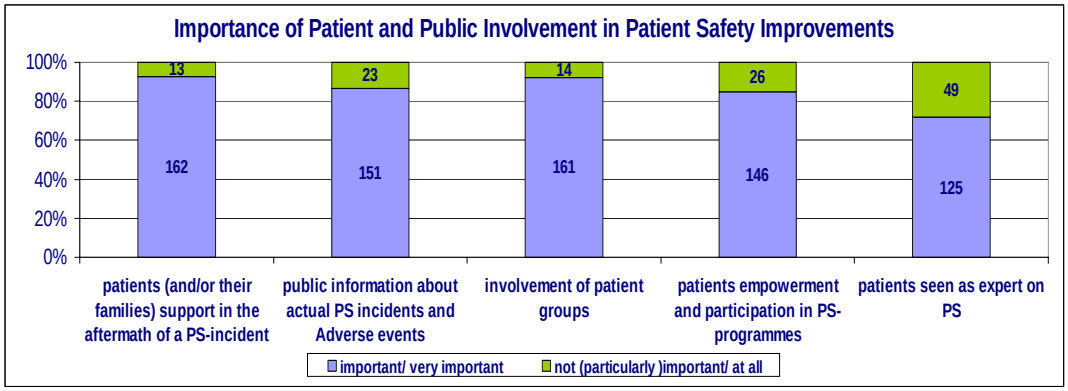


Patient and Public Involvement in Patient Safety Improvements

Respondents were asked whether they felt it important that the experiences and perspectives of patients are taken into account to efforts to improve the safety of patients.

In this context the majority of respondents (93%) were of the opinion that ***patients and/or their families should be supported in the aftermath of a patient safety incident*** and that ***patient groups should be involved*** in this process (85%). However, respondents were generally of the view that it was not as important that ***patients were seen as experts on patient safety*** (72%).

Chart 5: Importance of Patient and Public Involvement in Patient Safety Improvements.



An open question asked stakeholders about possible further actions they would like to improve patient safety in their countries. Some respondents suggested that there should be an improvement in patient access to patient safety information (through internet, leaflets and databases of adverse events) as well as patient education and training on patient safety issues. The need for transparency of information was also mentioned. It was important to respondents that patient groups are involved in policy decisions and supported by the authorities who should increase patients' participation and empowerment. In general, it was felt that patients' views have to be taken into account.

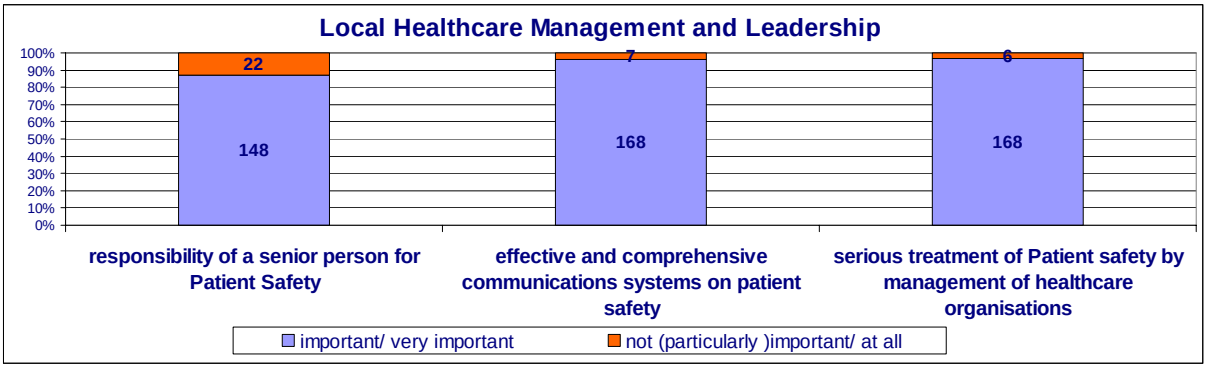
Respondents also considered that the media need to provide coverage of adverse events in a supportive way. There was a need for close cooperation between health professionals and patients and for an improvement in communications between those groups and better patient-centred healthcare.

Local Healthcare Management and Leadership

Respondents were asked about the importance of placing patient safety at the centre of organisational cultures and quality of care strategies of healthcare providers at the local level.

In this context, ***serious treatment of this topic by the management of healthcare organisations*** *(97%)* and ***effective and comprehensive communication systems on patient safety*** *(96%)* were considered to be more important than ***having a senior person responsible for patient safety*** in each healthcare setting (87%) (Chart 6).

Chart 6: Local Healthcare Management and Leadership



Health Professionals

In this section we asked for the opinions of respondents about the importance of the awareness of health professionals of the safety of their patients and the steps they can take in their everyday practice to reduce the risk of harm to those patients.

In this context, the majority of respondents (97%) agreed on the importance of ***continuing professional development of health professionals*** *and* ***further education in patient safety*** *(97%)* as the two main components of a good patient safety culture. ***Professional codes and standards of practice*** and ***support to healthcare professionals in the aftermath of a patient safety incident*** were also supported***.*** Respondents viewed ***regulation systems for health professionals including disciplinary procedures*** (67%) as not as important as the previous four components.

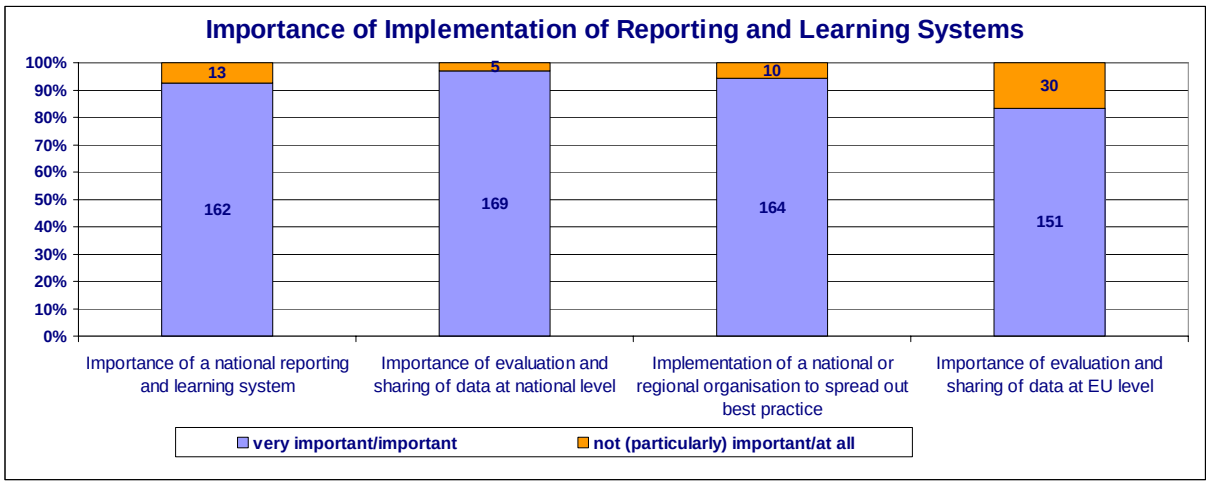
In response to the open question asking **which further actions are needed to improve the knowledge and awareness of patient safety and increase the application of safer practice among health professionals in Member States**, respondents' answers included stress on patient safety in health professionals' education and training, special education programmes, blame-free incident reporting, national guidelines and a designated body or person responsible for patient safety and quality in healthcare organisations.

Reporting and Learning Systems

In this section we asked for opinions on the information that should be available for health professionals and healthcare organisations.

When asked whether the implementation of reporting and learning systems at different levels could contribute towards an improvement in patient safety, the majority of the participants stressed the ***importance of the evaluation and sharing of data at the national level*** followed by the importance of ***implementing a national reporting and learning system*** and the ***implementation of a national or regional organisation to disseminate best practice***. There was slightly weaker, but still fairly strong support for the ***evaluation and sharing of data at the EU level*** (Chart 7).

Chart 7: Importance of Implementation of Reporting and Learning Systems

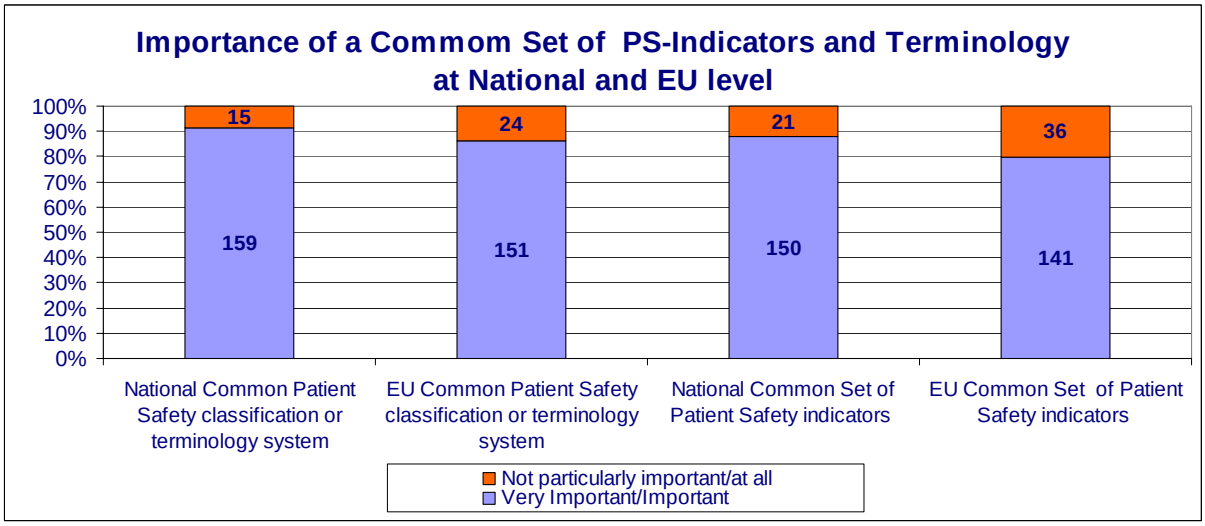


Other Patient Safety Information and the sharing of information

In this section we asked respondents about the importance of developing a common patient safety terminology and indicators in order to facilitate comparison between countries and mutual learning.

The data showed that between 80-90% of respondents agreed with the importance of setting up a common terminology and a common set of patient indicators at national, and also at EU, level (Chart 8).

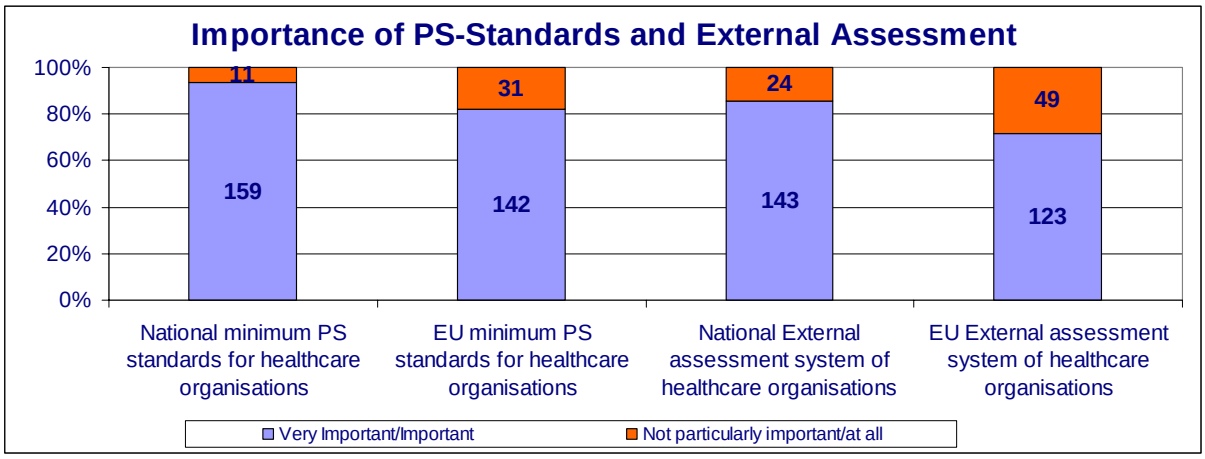
Chart 8: Importance of a Common Set of Indicators and Terminology at National or EU level.



Standards and/ or External Assessment

When asked whether the use of a set of minimum standards for patient safety would help to drive up patient safety levels in healthcare organisations, respondents agreed (Chart 9).

Chart 9: Importance of PS-Standards and External Assessment



Respondents were asked **which organisation should be responsible for setting and monitoring performance** (open question)**.** Those from countries where no such organisation existed thought that an independent body such as a national authority or board should be responsible, and stressed that it should be done in a way that ensures independency and impartiality. Participants from countries where such bodies already exist suggested those bodies, unsurprisingly, but also stressed that a distinction should be made between the setting of safety standards, which the majority thought should be done by relevant expert groups, and the monitoring of performance, which the majority thought should be done by national health ministries.

Respondents were asked **which organisation should be responsible for carrying out that external assessment.** Most favoured existing bodies, such as, the Healthcare Commission in the UK. Others favoured the establishment of a new organisation such as an EU network or national accreditation centres.

Research and Development on Patient Safety

The questionnaire aimed to identify respondents' priorities with regard to patient safety research. Nearly all respondents (96%) ranked the ***use of IT tools to improve patient safety efforts***, and the ***allocation of resources for patient safety research*** at a national level of most importance (95%). Also of great importance was ***an increased cooperation between Member States on priority-setting and commissioning of patient safety research***, coordinated by the EU (91%). Of slightly less importance (86%) was the ***implementation of a database of patient safety research findings at the EU level.***

In response to an open question asking **which areas of research on patient safety needed to take place**, some of the respondents pointed to the need for research on adverse events outside hospitals (including primary care, home care, mental health care) and also in other settings like long term care. Some mentioned the need to research the causes and types of adverse events in Member States. Other research fields mentioned were healthcare-associated infections, re-use of single-use medical devices, patient safety indicators, medication related events and drug safety, patient safety in the care of the elderly, research on the extent of harm (short-term and long-term effects of harm), economic costs (social and individual costs), communication and co-operation between different healthcare settings, extent of avoidable harm, patient safety standards and evidence-based medical practice.

In response to another open question in relation to **the type of information that should be held centrally,** respondents listed statistics on patient injury, infection, misdiagnosis, misuse

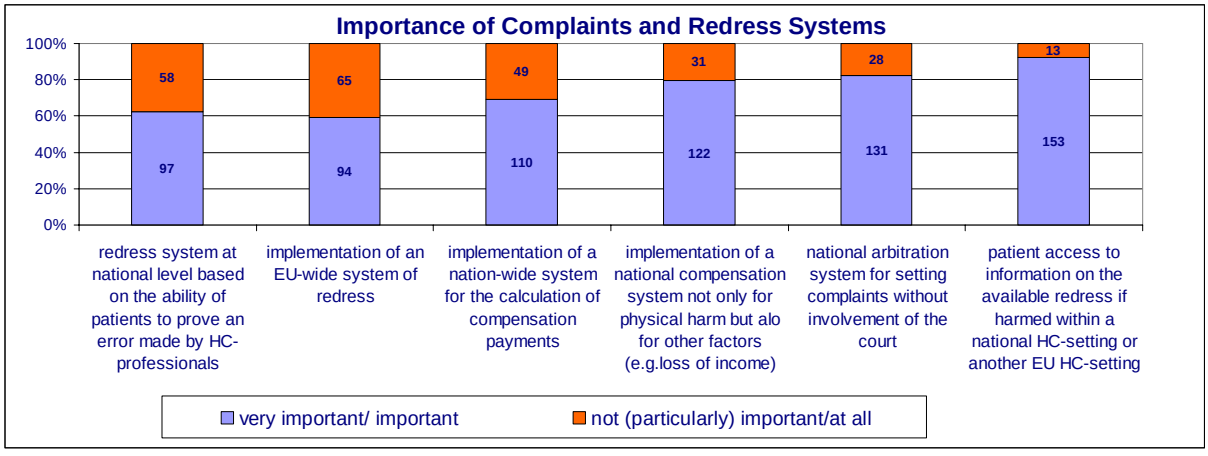
of medical devices, and medicine dosage errors. This should enable patients in Europe to access full and transparent data simply, and healthcare professionals/healthcare management to use it as a tool for exchanging best practice with other countries and striving to improve the situation in their own Member State. On the other hand, many participants argued that collecting data without using it properly could cause tremendous problems especially for the most vulnerable groups of people in our societies. A balance should be maintained between data protection issues - i.e. what information is collected by whom and for what purpose - and the need to improve patient safety.

When asked **which organisation should be responsible for maintaining the central mechanism,** those who favoured a centralised EU mechanism for collating and disseminating data on patient safety thought that the European Commission could assume this responsibility. Respondents considered that patient safety is an area where the EU can make a difference for Member States and their citizens, as co-ordination and sharing of experience are significant factors in improving patient safety. The EU should set a broad patient safety agenda and then monitor Member States' progress in tackling the problems they face. For this to happen, comparable data is essential. The European Medicines Agency (EMEA), DG SANCO, or even a new EU Patient Safety Agency were the favoured options to undertake this role.

Complaints and Redress

The majority of respondents supported, in descending order of importance: ***patient access to information on the available redress if harmed within a national healthcare setting or in another Member healthcare setting***; ***a national arbitration system for setting complaints without involvement of the court***; ***implementation of an national compensation system*** not only for physical harm but also for other factors e.g. loss of income, ***and implementation of a national-wide system for the calculation of compensation payments*** (Chart 10). An *EU-wide system of redress* and a *redress system at national level which is based on the ability of patients to prove an error was made by one or more health professionals* (85 participants pro versus 58 against) were less favoured by respondents, though both suggestions had more in favour than against.

Chart 10: Importance of Complaints and Redress Systems

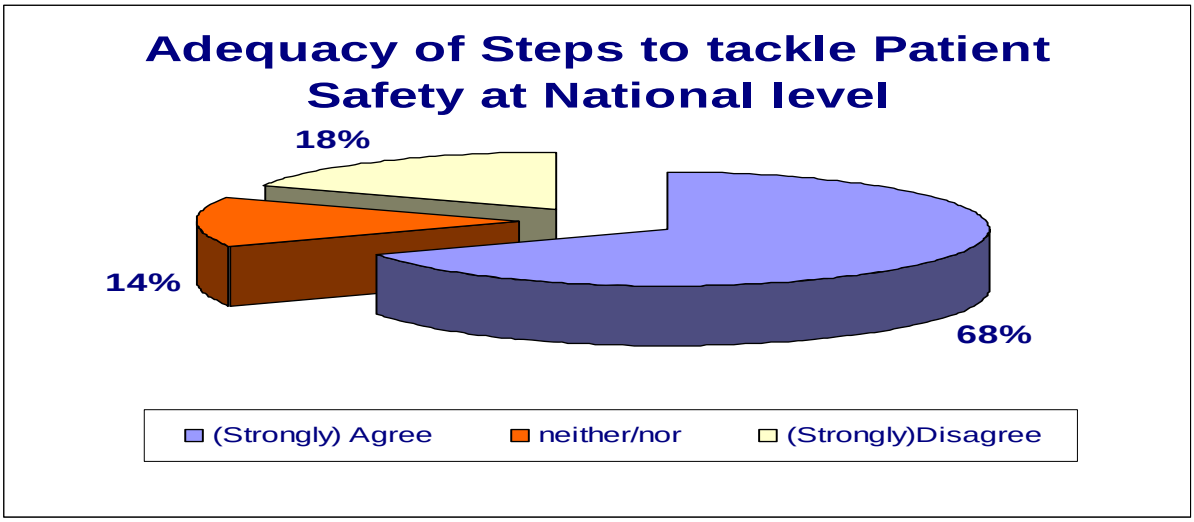


4.2.3. General Issues

The final section of the questionnaire addressed some more general patient safety issues. Although 68% shared the opinion that patient safety is being tackled by adequate or more than

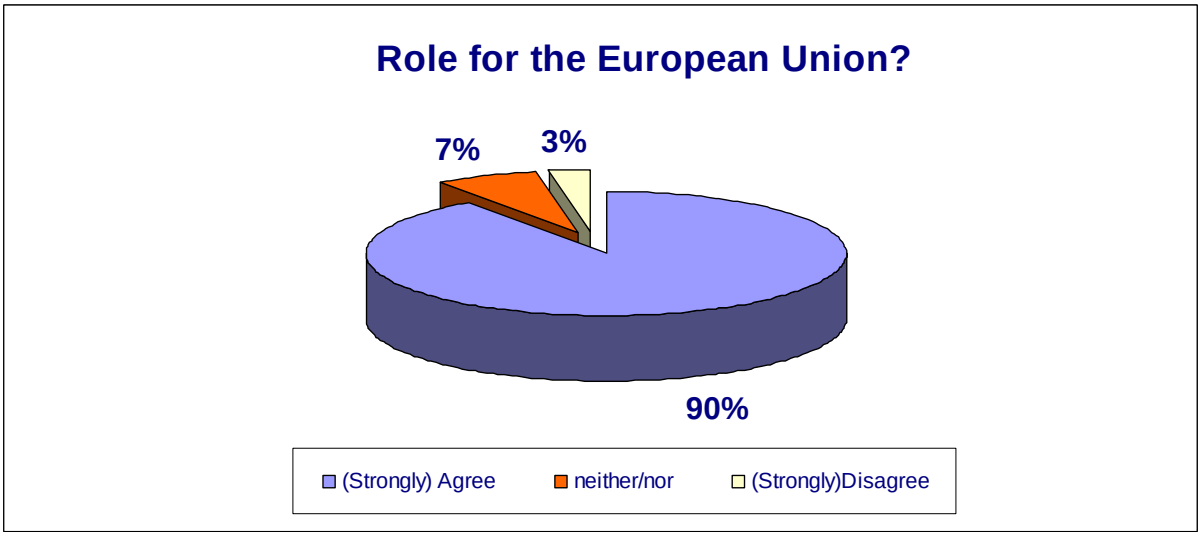
adequate measures at the national level, 90% still welcomed a coordinating role for the EU, to complement and support Member States' actions on patient safety (Charts 11and 12).

Chart 11: Adequacy of Steps taken to tackle Patient Safety



In response to an open question asking **what action needs to take place at the national, regional or local level to improve patient safety**, respondents answers included: putting patient safety needs high on the agenda of competent authorities; developing a 'no blame' culture; more education and training of healthcare professionals and patients; developing patient safety strategies: more research; better reporting systems; more awareness concerning patient safety between health professionals; pay for performance systems based on quality and safety data; more support to some specific diseases (chronic diseases like asthma); better communication between professionals and patients; better systems for collecting and analysing data; establishing national patient safety standards; IT support to prevent adverse events (personal access to medical records, IT tools to reduce medication errors); greater financial support; systems to share patient safety information with all stakeholders, including patients; patient safety committees in healthcare institutions; and legislative development.

Chart 12: Can the European Union play a role in supporting Member States in their efforts to address patient safety concerns?



When asked about the **areas of patient safety in which the European Union could play a role in supporting Member States**, respondents had the following suggestions: setting patient safety standards; recommending patient safety indicators, guidelines and reporting systems; identifying best practice; regulating health professionals' education and qualifications; promoting research; establishing a EU-wide network on patient safety; controlling tests of medicines by industry; increasing awareness of patient safety issues; establishing a patient safety data system and communication systems; recommending standardisation protocols and guidelines; financial support and other support for Member States.

4.3. Responses by specific groups of stakeholders

As well as reviewing and summarising the responses from all respondents, we also thought that it might be useful to look at responses of specific groups of stakeholder respondents to ascertain if particular stakeholder groups responded in a way which differed from the overall views.

For most stakeholder groups, the responses mapped very closely to the overall responses in terms of preferences for possible actions and the importance they attributed to those actions. However, when looking at the responses from Member States' competent authorities (including at national, regional or local level), there was enough of a divergence from the overall responses to warrant a separate specific section on their views.

4.3.1. Views of Member States' competent authorities

We received 32 on-line responses from Member States' competent authorities, representing 10 countries (United Kingdom, Germany, Sweden, Cyprus, Finland, Ireland, Malta, Spain, Latvia and the Czech Republic), 17% of the total respondents. Seventeen of these competent authorities were at national level, 10 at regional level and 5 were local.

In addition, we received 3 off-line responses (the Ministries of Health of France, Greece and Germany). These responses could not be included in the analysis provided in this report, but they are available on the website of DG Health and Consumers together with the other contributions to this consultation.

We cannot assume that the results presented below are representative of all the 27 Member States. However, they do give us an idea of Member States' views and priorities.

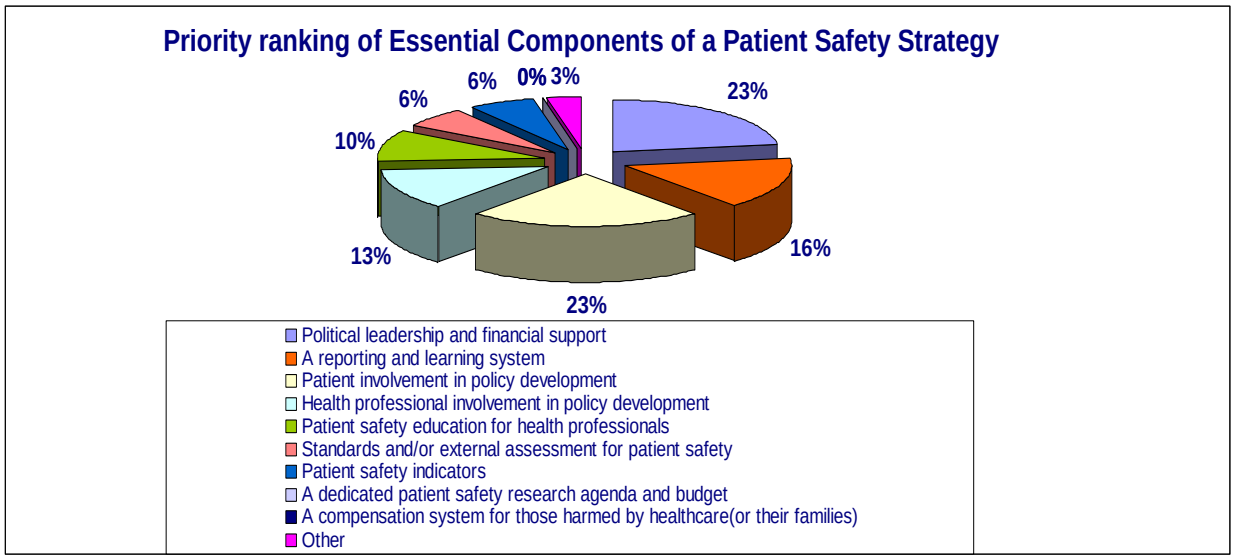
National support for Patient Safety

Reflecting the opinions of respondents as a whole, the Member States' competent authorities indicated very strong support (97%) for a ***national commitment to efforts to improve patient safety*** and also support for an ***EU strategy for patient safety (87%).***

Regarding the priority ranking of adverse events requiring action in Member States, this group reflected the overall views, ranking ***Healthcare-associated infections*** (33%) and ***Medication-related event*** (27%) at the top of the list, followed by *Communication problems(15%), Surgery-related event (9%), Error diagnosis (7%), other (5%) and Medical device or equipment- related event (4%).* Other areas that Member States' competent authorities thought need to be improved were health documentation, identification of patients and staff; lack of supervision of new personnel; time necessary for each patient in

consultations; unnecessary variation of healthcare procedures; and absence of local routines or neglecting to follow existing routines (Chart 13).

Chart 13: Priority ranking of Essential Components of a Patient Safety Strategy



With regard to the essential components of a Patient Safety strategy, this group prioritised ***political leadership and financial support*** and ***patient involvement in policy development*** (with 23% each), in contrast to the overall respondents who didn't consider it as important to have patient involvement in policy development .The third most important component for this group was ***a reporting and learning system*** (16%), similar to the opinions of the total respondents as a whole.

Other essential components mentioned by Member States' competent authorities included: distribution of more information for patients about quality and safety of healthcare and increased publication of best practices for staff; involvement in the development of initiatives and indicators, and a sense of ownership and responsibility for patient safety issues for all involved, from senior managers to clinical staff and patients.

Budgetary commitment to patient safety

The vast majority of the competent authorities thought it is essential to reserve financial resources at all levels of healthcare for patient safety policies. This group ranked ***Healthcare organisation resources*** as more important than ***National level resources*** in contrast to the total respondents who ranked these ***the other way around.***

Patient and public involvement

The most important issue for this group is the ***support to patients in the aftermath of a patient safety incident*** and ***systems in place at national and local level***. The least important issue for them was ***patients as experts on patient safety***, coinciding with the overall results.

Local Healthcare Management and Leadership

In contrast to the overall results of the questionnaire's section about local healthcare management and leadership, ***having a senior person responsible for patient safety*** in every healthcare setting was considered by this group to be as important as ***effective and***

comprehensive communication systems on patient safety and ***serious treatment of this topic by the management of healthcare organisations***.

Healthcare professionals

Reflecting the overall results relating to the issue of the health professionals' role and contribution to better patient safety culture, the majority of Member States' competent authorities considered ***continuing professional development of health professionals*** and ***further education in patient safety*** to be the two main components of a good patient safety culture. Other key elements were *support for health professionals in the aftermath of a patient safety incident* and the *implementation of professional codes and standards*. Competent authorities viewed *regulation systems for health professionals, including disciplinary procedures* as less important than the other four components.

Reporting and Learning Systems

Although the views of this group of stakeholders were similar to the results of the overall analysis, there was slightly weaker support for ***the evaluation and sharing of data at the EU level***.

Other Patient Safety Information

There was consensus that a common patient safety classification or terminology system could simplify intra- and inter-country comparisons as to the number, types, causes and consequences of adverse events within a common system to capture and analyse factors relevant to patient safety.

So, reflecting the overall results, a classification system should, therefore, be supported by a common set of patient safety indicators, not only at national level, but also at EU level.

Regarding ***standards and/or external assessment*** as well as ***research and development around patient safety,*** all results for this group corresponded to the overall findings.

Complaints and Redress

There were mixed views about an ***EU-wide system of redress*** (14 pro versus 11 against) and ***a redress system at national level which is based on the ability of patients to prove an error made by one or more health professionals*** (16 participants pro versus 5 against), though more were in favour of national systems. The majority of Member States' competent authorities supported the remaining four options, namely, in descending order, ***patient access to information on the available redress if harmed within a national healthcare setting or in another Member State healthcare setting*** followed by ***a national arbitration system for setting complaints without involvement of the cou*****rt** and ***an implementation of an national compensation system not only for physical*** **harm but also for other factors e.g. loss of income** and finally ***an implementation of a national-wide system for the calculation of compensation payments*** reflecting the overall response.

General Issues

In the final section of the questionnaire, 90% of Member States' competent authorities agreed or strongly agreed that the EU should play a role to support Member States in their efforts to

address patient safety concerns. Only 10% provided no opinion on this issue, and there were no respondents who disagreed with that statement.

5. CONCLUSIONS

The open consultation showed an overwhelming support for all areas of potential action to improve patient safety identified by the European Commission in its questions: national political support for patient safety; budgetary commitment to safety; patient and public involvement in patient safety improvements; local healthcare management and leadership; health professionals' reporting and learning systems; more patient safety information and the sharing of information; standards and/or external assessment; research and development around patient safety; and complaints and redress.

National political support for patient safety and implementation of reporting and learning systems in particular received a great deal of support from respondents, while compensation systems for those harmed by healthcare ranked as the least important among the proposed action areas.

The respondents confirmed the importance of tackling patient safety at the Member State level, but clearly also indicated their belief that there was added value in a European strategy. The opinions of Member States' competent authorities were, in general, more or less in line with the views of all respondents.

The results of this open consultation will support the development of the European Commission's proposal for a Council Recommendation on patient safety.