

AN OPEN CONSULTATION ON PATIENT SAFETY IN THE EUROPEAN UNION

THE QUESTIONNAIRE

It would help us greatly in our analysis of responses if you could please complete as much of the personal information requested below as you feel comfortable providing.

Privacy statement

Purpose of personal data processing:

Your personal data are recorded and further processed to the extent that they are necessary for the follow-up of your answer to a public consultation.

Your data are processed according to Regulation (EC) N° 45/2001 on the protection of individuals with regard to the processing of personal data by Community institutions and bodies and on the free movement of such data.

Period for which data are kept:

Your data are recorded and stored as long as follow-up actions are needed in the context of your answer.

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Should you require further information concerning the processing of your personal data or exercise your rights (e.g. access or rectify any inaccurate or incomplete data) please contact the responsible person in the Unit via: Lee.mcgill@ec.europa.eu

You have the right of recourse at any time to the European Data Protection Supervisor at edsp@edsp.europa.eu

Name of the Organisation (if applicable) (optional)

Stakeholder Group (optional)



Member States authority



NGO



Industry



Other

Country (optional)

Address (optional)

Contact Person

Name: (optional)

Paul De Raeve

Role in organisation (optional)



senior management



management



strategy/policy function



specialist/expert



other

Size of Your organisation

Number of employees (optional)



1 - 9



10 - 24



24 - 99



100 - 249



250 -

Annual turnover (in millions EUR) (optional)



0 - 10



10 - 25



25 - 50



50 - 100



100 - 250



250 -

Your organisation's geographical area of activities (optional)



local



regional



national



European



International

Are European citizens receiving the safest possible care?

When patients access healthcare in their own country (or indeed in another EU Member State) they expect to receive safe care - that is healthcare that has reduced as much as possible the likelihood of those patients suffering an adverse event or preventable harm.

There are a number of areas of patient safety in which action can be taken within EU Member States, either at local, regional or national level, supported by Community action, to help to improve the safety of EU citizens using healthcare systems. Those areas have been split into eleven broad headings below.

We would like to find out more about your perceptions concerning the kind of policies, strategies, systems and processes already in place in your home country and what action on patient safety you would like to see both within your country but also at the EU level.

Please note that many of the questions are in the form of statements. For those questions, please indicate which of the five options best reflects your opinion of each statement.

1. Personal Experiences

QUESTION 1

Have you or a member of your family had first-hand experience of an adverse event or experienced harm in a healthcare setting *in your country*?

	Yes	No
Personally (optional)	<input type="radio"/>	<input type="radio"/>
Family Member (optional)	<input type="radio"/>	<input type="radio"/>

QUESTION 2

If you answered 'yes' to either option at Question 1, how would you describe that experience? (optional)

- Medication-related event
- Medical device or equipment-related event
- Healthcare-associated infection
- Error in diagnosis
- Surgery-related event
- Communication problems
- Other (Please specify)

QUESTION 3

If you answered 'yes' to either option at Question 1, was that harm : (optional)

- treatable over time irreversible

QUESTION 4

Have you or a member of your family had first-hand experience of an adverse event or experienced harm in a healthcare setting *in another EU Member State*?

	Yes	No
Personally (optional)	<input type="radio"/>	<input type="radio"/>
Family Member (optional)	<input type="radio"/>	<input type="radio"/>

QUESTION 5

If you answered 'yes' to either option at Question 4, how would you describe that experience? (optional)

- Medication-related event
- Medical device or equipment-related event
- Healthcare-associated infection
- Error in diagnosis
- Surgery-related event
- Communication problems
- Other (Please specify)

QUESTION 6

If you answered yes to either options in Question 4, was that harm : (optional)

- treatable over time
- irreversible

QUESTION 7

	More than adequate	Adequate	Neither adequate nor inadequate	Not adequate	Not at all adequate
In general, how do you view the measures being taken to reduce harm to patients in healthcare settings in your country? (optional)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

2. National Political Support for Patient Safety

If patient safety is to be improved in EU Member States, a culture of patient safety is surely desirable at all levels. A clear political desire to reduce the level of harm to patients will hopefully positively influence patient safety cultures and actions throughout the healthcare system by sending the right signals as to its importance to the delivery of good quality healthcare.

QUESTIONS 8-10

	Very Important	Important	Not particularly important	Not important	Not at all important
8. How important would a national commitment to improving patient safety in your country be? (optional)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. How important would a national patient safety strategy in your country, (perhaps as part of a general healthcare quality strategy) be? (optional)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. How important is it to have an EU strategy for patient safety strategy?. (optional)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

QUESTION 11

What types of adverse events do you think competent authorities in your country should be prioritising in their efforts to reduce? In order of importance, please rank the following from 1-7, 1 being the highest priority in your opinion:

	1	2	3	4	5	6	7
Medication-related event (optional)	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Medical device or equipment-related event (optional)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Healthcare-associated infection (optional)	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Error in diagnosis (optional)	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>				
Surgery-related event (optional)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Communication problems (optional)	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Other (Please specify) (optional)	<input type="radio"/>	<input type="radio"/>					

Other, Please specify (optional)

QUESTION 12

What do you think should be the essential components of a patient safety strategy in your country or the patient safety elements of a healthcare quality strategy? Please rank the following from 1-10, 1 being the most important in your opinion:

	1	2	3	4	5	6	7	8	9	10
Political leadership and financial support? (optional)	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
A reporting and learning system (optional)	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Patient involvement in policy development (optional)	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Health professional involvement in policy development (optional)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Patient safety education for health professionals (optional)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Standards and/or external assessment for patient safety (optional)	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>				
Patient safety indicators (optional)	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>					
A dedicated patient safety research agenda and budget (optional)	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>						
A compensation system for those harmed by healthcare (or their families) (optional)	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>					
Other (please specify) (optional)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>							

Other, please specify (optional)

3. Budgetary Commitment to Safety

Whilst high level political support to improve the safety of patients is desirable, many patient safety policies, strategies and systems will also incur a financial cost. It is, therefore, perhaps important that dedicated financial resources are identified at the national and local levels to support patient safety initiatives.

QUESTIONS 13-15

13. How important is it to have a dedicated national resource commitment for patient safety initiatives in your country? (optional)
14. How important is it to have resources identified at the healthcare organisation level for patient safety initiatives in your country? (optional)
15. How important is it to have dedicated resources at the EU level to support Member States in addressing patient safety concerns? (optional)

	Very Important	Important	Not particularly important	Not important	Not at all important
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

4. Patient and Public Involvement in Patient Safety Improvements

When things go wrong in healthcare systems, it is the patients and consumers of that system who are the primary sufferers from any harm caused, including physical injury, psychological damage, or financial damages. Some may feel that it is important that the experiences and perspectives of these groups are taken into account to efforts to improve the safety of patients.

Patients can often provide a personal and unique insight into safety issues in healthcare systems. Those experiences can be used to reduce the levels of unsafe care and handle situations where patients have suffered harm from healthcare much more satisfactorily. Patient and public involvement in the area of patient safety could be an important part of better patient-centered care.

QUESTIONS 16-20

16. How important is it that patients should be seen as experts on patient safety in your country? (optional)
17. How important is it that patients should not just informed but also empowered to take part in patient safety and quality programmes in your country? (optional)
18. How important is it to have systems in place at national and local level to involve patient

	Very Important	Important	Not particularly important	Not important	Not at all important
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

groups? (optional)

19. How important is it that patients and the public should be informed about potential and actual patient safety incidents and adverse events in your country? (optional)

<input type="radio"/>				
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20. How important is it that patients (and/or their families) should be suitably supported in the aftermath of a patient safety incident? (optional)

<input type="radio"/>				
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QUESTION 21

What further action, if any, would you like to see in your country to improve the involvement of the patient or public in patient safety policies and programmes? (optional)

5. Local Healthcare Management and Leadership

At the local level, it may be desirable that all individual healthcare organisations - i.e. the providers of care - place safety at the centre of their organisational cultures and quality of care strategies and communicate its importance to staff and patients. A positive safety culture might possibly enable health professionals to be more open, accept errors as part of the process of delivering healthcare and allow investigation of error without blame.

QUESTIONS 22-24

Very Important Important Not particularly important Not important Not at all important

22. How important is it that patient safety is treated seriously by the management of healthcare organisations in your country? (optional)

<input type="radio"/>				
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23. How important is it for healthcare providers to have effective and comprehensive communications systems on patient safety issues and concerns in place? (optional)

<input type="radio"/>				
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24. How important is it for every healthcare provider to have a senior person responsible for the safety of patients? (optional)

<input type="radio"/>				
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6. Health Professionals

Even if good national and healthcare provider patient safety cultures exist, some may argue that the safety of patients will not be optimised unless individual healthcare professionals are aware of the importance of the safety of their patients and steps they can take in their everyday practice to reduce the risk of harm to those patients. Whether

patient safety is adequately embedded into the education, training and continuing professional development of those health professionals will vary from organisation to organisation and from country to country. It is also important that health professionals are appropriately regulated and competent to practise if patients are to be safe-guarded. Health professionals achieving fitness to practise status would suggest that patient safety is not being unduly compromised by their actions and behaviours. Good systems of professional regulation should hopefully pick up 'high' risk practice, behaviours or attitudes.

QUESTIONS 25-29

	Very Important	Important	Not particularly important	Not important	Not at all important
25. How important would further educating health professionals in your country in the area of patient safety be in reducing adverse events? (optional)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
26. How important would including patient safety in the continuing professional development of health professionals in your country be in reducing adverse events? (optional)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
27. How important are systems regulating health professionals, including disciplinary procedures, in efforts to minimise unsafe care in your country? (optional)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
28. How important are professional standards and codes of practice for health professionals in efforts to minimise unsafe care in your country? (optional)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
29. How important is it for health professionals to be suitably supported in the aftermath of a patient safety incident? (optional)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

QUESTION 30

What further action, if any, do you think needs to be taken to improve the knowledge and awareness of patient safety issues and increase the application of safer practice actions among health professionals in your country? (optional)

CPD - STRUCTURAL FUNDS

7. Reporting and Learning Systems

The primary objective of patient safety reporting systems is to enhance patient safety by learning from failures of the healthcare system. It could be argued that reporting in itself is of limited value. The information gathered through such systems, however, could be analysed, disseminated and used to implement changes that might lead to safer care in the future. It is important that those reporting problems using such systems do not suffer in any way as a result of that reporting.

QUESTIONS 31-34

	Very Important	Important	Not particularly important	Not important	Not at all important
31. How important is it for there to be a national reporting and learning system that collects, analyses and monitors information on adverse events and patient safety incidents in your country? (optional)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
32. How important is it for incident and adverse event data and the results of analyses to be evaluated and shared nationally in your country, without being used to discipline individuals? (optional)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
33. How important is it for there to be a national (or regional) organisation (institute, agency etc) that actively seeks out and tries to spread best practice and learning in your country? (optional)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
34. How important is it for the data from national (or regional) reporting and learning systems to be pooled at the EU level as a common resource for learning? (optional)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

8. Other Patient Safety Information and the Sharing of Information

As highlighted in Section 6, it may be considered by some that the number, types, causes and consequences of errors and adverse events should be shared. Currently, however, intra- and inter-country comparisons could possibly be being hindered by the lack of a common patient safety classification or terminology. A common classification system could elicit, capture and analyse factors relevant to patient safety in a manner conducive to learning and system improvement, in an adaptable yet consistent way. Currently, there is a multiplicity of terms and definitions in use in the EU for the key aspects of patient safety including, for example, 'harm', a 'patient safety incident', an 'adverse event' and 'medical error'. Language difficulties may exacerbate this problem.

Patient safety indicators - administrative data-based indicators which identify potential safety events - may be a useful tool in identifying the extent and type of some of the major patient safety incidents as well as for examining trends over time. However, again both intra- and inter-country comparisons may suffer from the absence of a standard set of patient safety indicators. It may also be more difficult to evaluate the impact of actions on patient safety without a standard set of indicators.

QUESTIONS 35-38

	Very Important	Important	Not particularly important	Not important	Not at all important
35. How important is it for there to be a common patient safety classification or terminology system in your country? (optional)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

36. How important is it for common classification or terminology system to be developed and used throughout the European Union? (optional)

37. How important is it for a common set of patient safety indicators to exist in your country? (optional)

38. How important is it for a common set of patient safety indicators to be developed and used throughout the European Union? (optional)

<input type="radio"/>				
<input type="radio"/>				
<input type="radio"/>				

9. Standards and/or External Assessment

It could be argued that the use of a set of minimum standards for patient safety would help to drive up patient safety levels in all healthcare organisations. Compliance with such standards could support performance improvement in healthcare.

Some people working in the area of patient safety advocate the use of a system of external assessment for patient safety, which could be used to certify that healthcare organisations have complied with a set of patient safety criteria, perhaps in the form of required minimum standards for patient safety, as a key risk reduction tool.

Systems of external assessment and standards could operate in isolation or with one underpinning the other and may or may not involve some form of accreditation.

QUESTIONS 39-42

Very Important Important Not particularly important Not important Not at all important

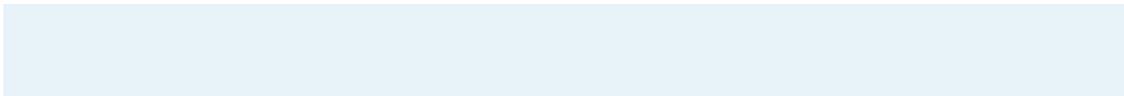
39. How important is it for there to be a system of minimum patient safety standards for healthcare organisations in place in your country? (optional)

40. How important is it for there to be a common set of minimum standards for patient safety for all healthcare organisations within the EU? (optional)

41. How important is it for there to be a system of external assessment of healthcare organisations in respect of patient safety in your country? (optional)

42. How important is it for there to be a common system of external assessment for all healthcare organisations in the EU in respect of patient safety? (optional)

<input type="radio"/>				
<input type="radio"/>				
<input type="radio"/>				
<input type="radio"/>				



QUESTION 43

If your response to Question 39 is in favour of a system of minimum patient safety standards, which organisation(s) do you think should be responsible for setting and monitoring performance against these standards in your country? (optional)

National Accrediation Centre	<input type="checkbox"/>
	<input type="checkbox"/>
	<input type="checkbox"/>

QUESTION 44

If your response to Question 40 is in favour of a system of external assessment for patient safety, which organisation(s) do you think should be responsible for carry out such an assessment in your country? (optional)

National Accrediation Centere Netw ork at EU Level - simunlar to Taiex Mission - Peer Review)	<input type="checkbox"/>
	<input type="checkbox"/>
	<input type="checkbox"/>

10. Research and Development around Patient Safety

Patient safety research (basic and applied) is taking place in the European Union and elsewhere in the world on the nature, number and causes of patient safety incidents, as well as into possible patient safety solutions and interventions. The results of that research may be vital to inform the policy-makers and those involved in the delivery of healthcare, especially research which identifies the causes of incidents and harm and effective solutions.

However, some argue that there are still many gaps in the research, and that results of patient safety research are not always disseminated widely, either within countries or among other EU countries.

QUESTIONS 45-48

	Very Important	Important	Not particularly important	Not important	Not at all important
45. How important is it for resources to be allocated to patient safety research in your country? (optional)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
46. How important is increased co-operation between EU Member States, supported by the European Community, on the priority-setting, and the commissioning, of patient safety research? (optional)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
47. How important would a database at the EU level be, which would bring together results of patient safety research and other learning and experiences, to be used as a common European resource? (optional)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
48. How important are I.T tools aimed at providing health professionals with relevant, timely	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

and up-to-date information, such as comprehensive electronic health records, decision support systems, e-prescription support and IT-based surgery training, to efforts to reduce harm? (optional)

QUESTION 49

In which areas of patient safety do you think more research needs to take place, if any? Possible areas include research on the extent of harm, the type of harm, on patient safety interventions, on the economic costs of harm, on harm outside the hospital setting and any others you feel are currently under-researched. (optional)

Communication between Health Care Settings - Hospitals & Primary care	
EUNetPass will provide methodology to create network between Member States and NGOs - firstly focussing on medication errors, but if successful outcomes, this methodology can be used for other areas related to patient safety	

QUESTION 50

If you answered positively to Question 47, what type of information should be held centrally? (optional)

What good practices exist in Member States	
	

QUESTION 51

Again, if you answered positively to question 47, who or which organisation should be responsible for maintaining the central mechanism? (optional)

DG Sanco	
	

11. Complaints and Redress

Whilst many measures can be taken to reduce the number of patient safety incidents and harm to patients in EU Member States' healthcare systems, it should be acknowledged that because the science of medicine carries with it a degree of risk, and healthcare is delivered in a complex environment, some patients will inevitably be harmed through the process of healthcare.

It could be argued that systems should be in place at the local and national levels to deal with these cases where things have gone wrong and patients have been harmed. Redress can be through financial (payment to compensate for harm, to pay for rehabilitation, loss of earnings etc) or non-financial (acknowledgments of error, explanations, apologies, reassurances that systems and processes will be changed to prevent re-occurrence and that fair and objective regulatory and/or disciplinary action will be taken etc) mechanisms or a combination of the two.

QUESTIONS 52-57

	Very Important	Important	Not particularly important	Not important	Not at all important
52. How important is for there to be an arbitration system for settling complaints without going to court in your country? (optional)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
53. How important is it for patients to have access to available information on the redress available to them if they (or their families) are harmed by healthcare in your country or in other EU countries? (optional)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
54. How important is it for the system of redress in my country to be based on the ability of the patient to prove an error was made by one or more healthcare professionals? (optional)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
55. How important is it for there to be a national-wide system for calculating compensation payments in your country? (optional)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
56. How important is it for compensation systems in your country to cover not only physical harm but other factors such as loss of income? (optional)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
57. How important would it be to have an EU-wide system of redress? (optional)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

12. General Issues

QUESTIONS 58-59

	Strongly Agree	Agree	Not particularly important	Disagree	Strongly Disagree
58. Adequate steps are being taken in your country to tackle the problem of patient safety. (optional)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
59. The European Community can play a role in supporting Member States in their efforts to address patient safety concerns. (optional)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

QUESTION 60

What (further) action needs to take place in your country at the national, regional and/or local levels to improve patient safety? (optional)

political will to put Patient Safety high on the agenda and to communicate with Health Care Professionals and Patients to start dialog.

Involve the media



QUESTION 61

In which areas of patient safety should the European Community play a role in supporting Member States in their efforts to address patient safety concerns and how should this support work in practice? (optional)

Providing a framework for Patient Safety

Identifying good practices

