



CPME/AD/consultation/300408/105/EN

At the CPME Executive Committee, Brussels, 30 April 2008, CPME adopted the following document: "**CPME answer to the European Commission's consultation document on patient safety**" (CPME 2008/105 EN)

CPME¹ answer to the European Commission's consultation document on patient safety

Dear Mr McGill,

CPME would like to thank you for opening the opportunity for all European stakeholders to provide their views on how patient safety should be addressed on the European level, and therefore, to participate in the development of a future Commission's proposal on general patient safety issues.

We have today replied to the Open Consultation online, focusing on the matters where CPME could provide useful input, taking into consideration the nature of the organisation. Moreover, we would like to highlight the following points.

Question number 11, where the respondent is asked to prioritise types of events and rank them in order according to the urgency and the attention they deserve. We would like to suggest that high priority is given to **system analysis**.

When analysing medical failures, for instance through the procedure of a root cause analysis, it becomes clear that most serious adverse events are not simply the result of a communication problem, an error of diagnosis, a device related event or some other single type of event. Adverse events are nearly always a result of a whole system breakdown, where a combination of several types of adverse events leads to harm to the patient. For example: a communication error that leads to a medication error which is not addressed as the patient is moved to another department where they use a different type of IT support for medication.

Jim Reasons Swiss cheese model of adverse events, clearly illustrates how errors are the results of the failure of several systems and the way they interact. Breaking

¹ *The Standing Committee of European Doctors (CPME) is the representative body of about 2 million physicians in Europe. Its aims are: a) to promote the highest standards of medical training and medical practice, through advocating public health, the relationship between patients and doctors, and the free movement of doctors and patients within the European Union; b) to achieve the highest quality of health care in Europe.*

It is composed of the most representative non-governmental national medical organisations in EU/EEA countries, that is to say 30 National Medical Associations. It also unites associated members, observers and associated organisations (specialised European medical organisations).

down the patient safety issue into its single components will usually not show the full picture of a serious adverse event.

The CPME therefore stresses the importance of system analysis, when studying adverse events, in an effort to understand how human factors, medical devices, organisations, pharmaceutical products, etc., all interact in creating unsafe conditions in the health sector.

Questions number 13-15: the CPME ranks EU supporting resources as being very important.

Questions number 31-34: the CPME ranks all these as very important.

Questions number 50-51: an EU Patient Safety Agency should hold centrally information on device related incidents, medication incidents, best practices and use of IT solutions to patient safety problems.

Finally, CPME welcomes once more the European Commission's initiative to make a proposal on general patient safety issues before the end of 2008, and would like to offer its expertise whenever necessary.

Yours sincerely,



Lisette Tiddens-Engwirda
CPME Secretary General

AN OPEN CONSULTATION ON PATIENT SAFETY IN THE EUROPEAN UNION

Meta Informations
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intro
THE QUESTIONNAIRE
Name of the Organisation (if applicable) Standing Committee of European Doctors (CPME)
Stakeholder Group NGO
Country EU
Address 15 rue Guimard - 1040 Brussels
Contact Person
Name: Laura Rius
Role in organisation
Size of Your organisation
Number of employees
Annual turnover (in millions EUR)
Your organisation's geographical area of activities European
Are European citizens receiving the safest possible care?
1. Personal Experiences
QUESTION 1
Personally
Family Member

QUESTION 2
If you answered 'yes' to either option at Question 1, how would you describe that experience?

QUESTION 3
If you answered 'yes' to either option at Question 1, was that harm :

QUESTION 4

Personally

Family Member

QUESTION 5
If you answered 'yes' to either option at Question 4, how would you describe that experience?

QUESTION 6
If you answered yes to either options in Question 4, was that harm :

QUESTION 7

In general, how do you view the measures Not adequate
being taken to reduce harm to patients in
healthcare settings in your country?

2. National Political Support for Patient Safety

QUESTIONS 8-10

8. How important would a national Very Important
commitment to improving patient safety
in your country be?

9. How important would a national patient Very Important
safety strategy in your country, (perhaps
as part of a general healthcare quality
strategy) be?

10. How important is it to have an EU Very Important
strategy for patient safety ?

QUESTION 11

Medication-related event 1

Medical device or equipment-related 2
event

Healthcare-associated infection 3

Error in diagnosis 5

Surgery-related event 4

Communication problems 6

Other (Please specify)

Other, Please specify

system analysis should be given high priority	
QUESTION 12	
Political leadership and financial support?	1
A reporting and learning system	2
Patient involvement in policy development	7
Health professional involvement in policy development	3
Patient safety education for health professionals	4
Standards and/or external assessment for patient safety	9
Patient safety indicators	8
A dedicated patient safety research agenda and budget	6
A compensation system for those harmed by healthcare (or their families)	5
Other (please specify)	
Other, please specify	
3. Budgetary Commitment to Safety	
QUESTIONS 13-15	
13. How important is it to have a dedicated national resource commitment for patient safety initiatives in your country?	Very Important
14. How important is it to have resources identified at the healthcare organisation level for patient safety initiatives in your country?	Not particularly important
15. How important is it to have dedicated resources at the EU level to support Member States in addressing patient safety concerns?	Very Important
4. Patient and Public Involvement in Patient Safety Improvements	
QUESTIONS 16-20	
16. How important is it that patients should be seen as experts on patient safety in your country?	Important
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?	Important

18. How important is it to have systems in place at national and local level to involve patient groups?	Important
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?	Very Important
20. How important is it that patients (and/or their families) should be suitably supported in the aftermath of a patient safety incident?	Very Important
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?	
5. Local Healthcare Management and Leadership	
QUESTIONS 22-24	
22. How important is it that patient safety is treated seriously by the management of healthcare organisations in your country?	Very Important
23. How important is it for healthcare providers to have effective and comprehensive communications systems on patient safety issues and concerns in place?	Very Important
24. How important is it for every healthcare provider to have a senior person responsible for the safety of patients?	Important
6. Health Professionals	
QUESTIONS 25-29	
25. How important would further educating health professionals in your country in the area of patient safety be in reducing adverse events?	Important
26. How important would including patient safety in the continuing professional development of health professionals in your country be in reducing adverse events?	Important
27. How important are systems regulating health professionals, including disciplinary procedures, in efforts to minimise unsafe care in your country?	Not at all important
28. How important are professional standards and codes of practice for health professionals in efforts to minimise unsafe	Not important

care in your country?

29. How important is it for health professionals to be suitably supported in the aftermath of a patient safety incident? Important

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?

7. Reporting and Learning Systems

QUESTIONS 31-34

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? Very Important

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? Very Important

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? Very Important

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? Very Important

8. Other Patient Safety Information and the Sharing of Information

QUESTIONS 35-38

35. How important is it for there to be a common patient safety classification or terminology system in your country? Important

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

37. How important is it for a common set of patient safety indicators to exist in your country? Not particularly important

38. How important is it for a common set of patient safety indicators to be developed and used throughout the European Union? Not particularly important

9. Standards and/or External Assessment

QUESTIONS 39-42

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

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? Important

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? Not particularly important

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? Not particularly important

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?
National Board of Health

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 carrying out such an assessment in your country?

10. Research and Development around Patient Safety

QUESTIONS 45-48

45. How important is it for resources to be allocated to patient safety research in your country? Very Important

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? Very Important

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? Very Important

48. How important are I.T tools aimed at providing health professionals with relevant, timely 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? Very Important

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.	
QUESTION 50	
If you answered positively to Question 47, what type of information should be held centrally?	
Information on device related incidents, medication incidents, best practices, use of IT solutions to patient safety problems.	
QUESTION 51	
Again, if you answered positively to question 47, who or which organisation should be responsible for maintaining the central mechanism?	
EU Patient Safety Agency	
11. Complaints and Redress	
QUESTIONS 52-57	
52. How important is for there to be an arbitration system for settling complaints without going to court in your country?	Important
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?	Important
54. How important is it for the system of redress in your country to be based on the ability of the patient to prove an error was made by one or more healthcare professionals?	Not at all important
55. How important is it for there to be a national-wide system for calculating compensation payments in your country?	Important
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?	Not important
57. How important would it be to have an EU-wide system of redress?	Not particularly important
12. General Issues	
QUESTIONS 58-59	
58. Adequate steps are being taken in your country to tackle the problem of patient safety.	Disagree
59. The European Community can play a role in supporting Member States in their efforts to address patient safety concerns.	Strongly Agree
QUESTION 60	

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

Training of health professionals in systems thinking. Systematic use of IT such as electronic patient records, EPM's, etc. Regulation of medical devices i.e. banning those not designed for safety.

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?