

# EHMA ROUNDTABLE DEBATE ON PATIENT SAFETY

22 January 2009, 12:15 – 14:30

## REPORT

**Jeni Bremner** (Director EHMA) opened the meeting, welcoming participants and introducing the aim of the Roundtable, i.e.

- informing key stakeholders on EU policy development impacting on health outcomes and health care delivery
- facilitating dialogue and debate between key stakeholders and engaging them in EU policy development

She underlined that patient safety is a core issue in health service delivery and that the experience of patients and all those receiving care is at the essence of health care.

Jeni then gave the floor to **Robert Madelin** (Director General DG SANCO), who presented the Commission Communication and proposal for a Council Recommendation on patient safety.

Patient safety is defined by the WHO as 'freedom for a patient from unnecessary harm or potential harm associated with healthcare'. An adverse event is 'an incident which results in harm to a patient'.

National studies from the UK, Spain and France suggest that as many as one in ten patients suffer from harm when in hospital. The problem may be even larger - for many countries data are not available. The Commission's own impact assessment concludes that, in EU Member States, between 8 and 12% of patients admitted to hospitals suffer an adverse event whilst receiving healthcare. Some of these are linked to the intrinsic risks of necessary interventions or treatments. Others, however, are caused by potentially avoidable medical errors, such as errors in diagnosis; failure to act on the results of tests, medication errors; failure of medical equipment and healthcare associated infections (HCAIs). The latter affect an estimated 4.1 million hospitalised patients (1 in 20 patients). HCAIs cause avoidable physical suffering and deaths as well as a huge financial burden (at least € 5.48 billion per annum).

Prior to coming forward with the proposal on 15 December 2008, the EU has been involved with patient safety in a number of ways until now, more specifically by means of the Patient Safety Working Group of the High Level Group on Health Services and Medical Care (running between 2005-2008), and co-funded patient safety projects.

The Commission proposal for a Council Recommendation addresses patient safety as well as HCAs in one single document and focuses on the following issues:

At Member State level:

- Support the development of national patient safety policies and programmes.
- Empower and inform citizens and patients.
- Establish or strengthen reporting and learning systems on adverse events.
- Include patient safety in the education and training of health professionals.
- Develop and promote research on patient safety.
- Classify, codify and measure patient safety.

At EU level:

- Develop and promote research on patient safety.
- Classify, codify and measure patient safety.
- Share knowledge, experience and best practice at European level.

The proposal was transmitted to the Council for discussion in December, and, once adopted, Member States will need to report to the Commission within 2 years on how the Recommendation has been implemented. In relation to HCAI, the ECDC will assist Member States, e.g. by developing guidance, and by helping to set up or further strengthen surveillance systems.

Interestingly, patient safety did not feature on the EU agenda until the recent past. This has changed, largely due to the adoption of an overarching EU strategy for health, which is based on and advocates a patient centred approach. There is an increasing willingness to talk about common health care issues at EU level, not in order to harmonise legislation and approaches, but rather to address common challenges. The Common Values, adopted by the Council in June 2006, make it possible to cooperate on local political and sensitive issues. However, there seems to be a contrast between Member States' willingness to embrace patient safety and quality of care initiatives on the one hand side and a reluctance to do the same in relation to the proposed Directive on the Application of Patients' Rights in Cross-Border Healthcare. If this reluctance is based on the 'fear' that EU legislation would be the vehicle for change to improve health safety and quality at Member State level, it could be solved. However, if this reluctance stems from a more general unwillingness to actually address patient safety and quality issues, it might prove more problematic. It will be interesting to monitor how both initiatives will be discussed and debated, and to see whether the Council will be able to present its conclusions on both initiatives within a similar timeframe. Robert Madelin concluded by saying that despite these apparent paradoxes, there are clear moves towards Europe developing health actions together for the greater good of citizens.

The second speaker, **Nicola Bedlington** (Director, European Patients Forum) provided an overview of her organisation's comments on the Commission proposals. EPF's vision is one of high quality, patient-centred, equitable healthcare for all patients across the EU, and it is clear that patient safety is central to this. Therefore, EPF welcomes the Communication and Proposal for a Council Recommendation as a significant step forward. EPF particularly welcomes the fact that Member States are recommended to embed patient safety in their health policy and programmes as well as designate a competent authority responsible for patient safety. In addition, the proposal explicitly acknowledges the role of patients' organizations in contributing to the development of policies and programmes on patients' safety. The fact that Member States are recommended to set up or improve blame-free reporting and learning systems, in a constructive, rather than punitive way also reflects the spirit of the EUNetPaS project in which EPF is involved. Education and training of healthcare workers in patient safety is strongly promoted and Member States are encouraged to

consider the development of core competences in patient safety (core knowledge, attitudes and skills) for patients. This is an important move forward, not least within the context of health literacy.

EPF will work with its member organisations and patients allies to make the Recommendation known and understood at national level, with the EPF Patients' Manifesto Campaign '150 million reasons to act' as an integral pillar to the work carried out on this issue. The EPF also works with the IAPO to promote their Patient Safety Toolkit.

Apart from welcoming the initiative, the EPF also has some questions. These relate to how the Commission will support Member States sharing best practice and experience in relation to patient safety programmes in practical terms.

A second question pertains to patients' involvement in reporting adverse events. Many patients offer a rich resource of information related to medical errors - many have witnessed every detail of systems failures from the beginning to end. Effective pathways to report are needed.

A third issue relates to Member States working with the Commission to develop common definitions and terminology and a set of comparable indicators and the mechanisms that will be set in place to achieve this. EPF also wonders whether the Commission is planning to set up an independent body that could be responsible for setting and monitoring performance against safety standards. Lastly, EPF would like to have information on the next steps in terms of legislative developments.

### **Audience debate**

During the audience debate that followed, the following issues were raised and addressed by either Robert Madelin or Lee McGill, also from DG SANCO:

#### *Importance and scope of patient safety*

Many participants expressed their interest in issues relating to patient safety, which was being described by many as a top priority. However, the proposals seem to mainly address clinical behaviours. While of course important, it was pointed out that management issues also play a role in determining the success of patient safety initiatives (or failures). Patient safety involves everybody related to health care. Systemic failures and health management are also part of the system, even if the proposal does not address these aspects more explicitly.

Questions were also raised about whether there are differences in terms of adverse events between the various health care settings and sectors. The Commission representatives informed the meeting that, while the use of the word 'patient' may suggest to some that the focus is on hospitals only, it should be interpreted as meaning 'a person receiving a health care service'. In other words, the proposal is holistic and encompasses all settings where health care is provided. It would be interesting to have more data on eventual differences between care settings.

Lastly, it was remarked that, in this time of economic insecurity, we have to remain vigilant and be more proactive to ensure that health budgets should not be sidelined.

#### *Reporting adverse events...*

A recent survey by WHICH? (UK) showed that 84 % of interviewed patients were not asked for their views about their hospital stay and care received. Even more telling was the fact that they also felt that their opinion would not have mattered, even if they had been asked – it was generally felt that patients' views do not really come into play. From this, it is clear that patients and carers have to be enabled to report errors.

Reporting adverse events might well depend on the care situation. In an intermittent or short term care situation, it may be easier to report adverse events than in a chronic care setting, where the person will depend on the person providing care for a longer period of time.

*...and the 'no blame' approach:*

Questions were raised about the validity and efficacy of the 'no blame' approach in relation to reporting. Would a 'blame' approach not be more effective? The Commission has opted for a 'no blame' approach as, in their opinion, this will be more conducive to prompt reporting and generalized learning. It needs to be highlighted that 'no blame' does not mean no responsibility or appropriate disciplinary measures. A 'blame' system would lead to maximum concealment and no learning – in other words, zero sum gain. To get the full picture in adverse events, a 'no blame' system would work better.

There should be areas where channels are created to provide feedback without the risk of retribution from the person providing the care. Ways need to be found to make reporting systems appear acceptable to individual caregivers, in other words make these systems more equitable as well as more efficient. Care providers should be included in the debate to provide information on what would make reporting systems acceptable to them, and develop unthreatening reporting systems which empower patients while being acceptable to care providers.

In terms of reporting and learning systems for patient safety, it needs to be underlined that reporting as such is not the most important element; it is the learning that can come from this that counts most. Learning from adverse events and developing solutions and interventions which will help prevent them happening again is the key.

*The patient's role in reporting adverse events:*

In relation to the patient's role, it was pointed out that – obviously - patients are not always there to report adverse events. In addition, not everybody who has suffered from adverse events is equally objective in their reporting. The question is how to capture the rich experience of patients in an objective way, about empowering patients while avoiding direct conflict around the adverse event in question.

*Monitoring patient safety:*

In relation to independent monitoring of patient safety, it is clear that there is a long way to go. The degree of ambition encompasses two levels. At one level, monitoring is definitely needed, and preferably this should be done by an independent body (this would be the second level). However, it is unlikely that decisions on such a mechanism at the EU level will be held before 2010, when EUNetPaS will complete its work. Then in 2011 things should be clearer when the first results of the implementation of the Recommendation will be assessed.

*Funding good practice exchange:*

Questions were raised in relation to the possibilities of EU funding for good practice (e.g. the NHS initiative in relation to MRSA, which has led to a 57 % reduction in 4 years). In terms of budget, it needs to be underlined that none of the Member States has yet taken up the possibilities offered by the EU Structural Funds for professional training and continuous development to its full extent. There are real opportunities here. EUNetPaS is currently playing a key role. However, this project will stop in 2010. It would be useful to start thinking about the longer term to keep sharing best practice, and therefore, it might be worthwhile to what extent the EU Health Portal can be put to use as this is a shared platform where experience can be exchanged.

*Patient safety in other EU initiatives:*

Questions were asked in relation to the link between the EU initiatives regarding safety of medicines and medical devices and the current patient safety proposal. The meeting was informed of DG SANCO's active participation in the Commission's Inter-service steering groups, aiming to put the patient safety messages on the agenda wherever possible.

*Time line:*

In relation to the Council response, it is by no means guaranteed that the Commission proposal will be the final text. A first discussion in the Council working party earlier on the same day focused on the rationale and general content of the proposal. The structure, and level of detail and substance of the content, will be addressed at later meetings and the content is certain to be changed. Hopefully the proposals will be adopted during the term of office of the Czech Presidency.

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