



CPME response to the consultation with the members of the Patient Safety and Quality of Care Expert Group

Presentations of the Study on “Costs of unsafe care and cost-effectiveness of patient safety programmes”

CPME would like to thank the European Commission and the partners of the tender on the costs of unsafe care for the opportunity to submit comments. Please see below the CPME response to the presentation on unsafe care as well as general comments on the study progress presented by the Austrian Institute of Health.

Concerning OBJECTIVE 1. To provide a comprehensive picture of the financial impact of poor patient safety on the European Union’s health systems;

CPME promotes a culture of patient safety across healthcare systems. At EU level, CPME encourages a system analysis approach in an effort to understand how human factors, medical devices, organisations, pharmaceutical products, etc., all interact to create safe conditions in the health sector.

Reference: CPME response to the Commission proposal for a Council Recommendation on Patient Safety ([CPME 2009/108](#)).

➤ Suggested amendment of OBJECTIVE 1. To provide a comprehensive as possible picture of the financial impact of poor patient safety on the European Union’s health systems that takes into account the interaction between human factors, medical devices, organisations, pharmaceutical products, etc.;

Concerning OBJECTIVE 2. To identify cost-effective patient safety programmes implemented in the EU/EEA Member States and develop an analysis identifying their success factors;

Suggested amendment of OBJECTIVE 2. To identify transferable cost-effective patient safety programmes implemented in the EU/EEA Member States and develop an analysis that evidences their transferability and identifying-identifies their success factors;

Mis en forme : Justifié



General comments on the preliminary findings from the Study of Unsafe Care as presented on 28 September during the PSQC Expert Group meeting in Brussels



Main Objectives

- » 1. Aggregate level of adverse events
 - » Findings – Expert Panel
 - » Not complete
 - » No/Little information on prevalence/cost – or same as literature
 - » Information on share of adverse events
 - » Clinical/anecdotal evidence
 - » Main finding Expert Panel (so far):
 - » Quality of literature is overall very poor
 - » Add "decubitus ulcers" to "acute care adverse events"?!

Clinical evidence has to be differentiated from anecdotal evidence. In medicine, oftentimes clinical guidelines are more grounded in evidence than peer reviewed literature. As such, we suggest a strict selection criteria when doing a literature review, to include only systematic literature reviews from peer reviewed journals and we suggest to contact EU/EEA member states and medical professional representatives to include clinical guidelines when looking at the aggregate level of adverse events. Proceeding this way may also overcome the barrier that the quality of the literature is overall very poor.

The first results presented confirm the above-mentioned recommendation. A typical literature review method may not be adequate first because of the lack of systematic literature reviews and second because a more refined method needs to be applied that includes a database and translations of all the clinical guidelines that are relevant. Including evidence only from Anglo-Saxon countries would pose a problem of transferability for the other healthcare systems and possibly result in erroneous recommendations creating further costs.



First Results

- » Evidence on adverse events & unsafe care
 - » Evidence regarding prevalence of adverse events in non-Anglo-Saxon countries is sparse.
 - » Reported **incidence rates** of adverse events **vary considerably**, even within countries.
 - » As there are no national databases on adverse events, country-specific or even worldwide prevalence of AE rates are based on extrapolations from single facilities, which may feature non-average incidence rates.
 - » **Definitions** of unsafe care adverse events may **vary**; thus incidence rates may refer to different types of adverse events.
 - » Adverse events may be **quantified** in per admission, per bed-day, per operation or per patient;
 - » the optimal base unit may vary between types of adverse events, but institutional factors that differ between countries may complicate comparisons
 - » E.g. different hospital LOS prior/post operation affects incidence rate of (surgical site) infection

Furthermore, the proportion of adverse events due to surgical errors and acute care adverse events should not be grouped under the same section. Please include separate rows for acute care adverse events and surgical medical errors. Also, under surgical errors there is a need for further clarification. Should this include by definition all errors a patient may encounter during surgery or just the medical surgery errors?

The same should be the case for medication errors and adverse drug events. The reliability of this study and its methodological justification should represent a first priority.



First Results

» Proportion of Adverse Events

Adverse Event Group	Proportion Calculated	EP Estimation
acute care adverse events/ adverse events due to surgical errors	40%	30%
healthcare associated infections	25%	35%
adverse drug events/medication error	15%	15%
errors in diagnosis	10%	10%
adverse events due to falls	3%	3%
medical devices adverse events	2%	2%
adverse events due to unsafe blood products	1%	1%
adverse events due to unsafe biological products	1%	1%
Decubitus ulcers/pressure sores	3%	3%
errors in monitoring	?	?
	100%	100%