

Policy Recommendation

Special Interest Group Working Towards Eliminating Avoidable Harm

The Special Interest Group (SIG) Working Towards Eliminating Avoidable Harm set up by the European Association of Hospital Pharmacists (EAHP) has developed a set of recommendations calling for change at the European, national, regional and local levels to improve patient outcomes and minimise risks for both patients and healthcare professionals. Emphasis should be put on improving the processes and environments rather than the performance of individuals.

Discrepancies between legal requirements and delayed implementation in hospitals need to be troubleshooted by improved governance. Current critical incidents in hospitals rarely arise from central hospital pharmacies but from system errors leading to circumstances favouring medication errors on the ward. Thus, coping strategies require system-reengineering and designing robust GMP (Good Manufacturing Practice) compliance in ward environments. A straight line of subordination of all medicinal products handled under the license-holding hospital pharmacist is the fastest and most effective way of reducing medication errors and harm to patients. This requires a task shifting from exhausted health professionals to GMP-proven pharmaceutical professionals.

EAHP's SIG recommends putting in place binding guidance, and where necessary legislative measures, that ensures the involvement of hospital pharmacists in the medication use process.

The analysis of the critical incident and the organisational analysis of specific cases have shown the complexity of the chain of events that can lead to an unfavourable outcome. More attention must be paid to human and psychological factors, even more, if it is considered that the responsibility for the error is strongly conditioned by the context and by the working conditions. An error-minimising effect could be achieved by reengineering latent system errors. System thinking (i.e. governance and human and technical resource allocation) is even suitable to minimise so-called "inevitable" active individual failures of schematic and attentional behaviour. A broad automation of the supply chain, along with improvements at the men-machine interfaces, has been demonstrated to present promising

approaches for avoiding harm to patients. It is obvious the harmonisation and standardisation of patient safety doctrines in Europe will need funding and grants for some EU Member States.

EAHP's SIG urges both European institutions and national governments to make available financial resources to improve governance as well as human and technical resource allocation in European hospitals.

Human errors are inevitable. However, system errors – like latent errors and errors of planning can be minimised through investments. In order to identify avoidable harm both retrospective methods of analysing errors (e.g. root cause analysis) and prospective methods (e.g. FMEA etc.) should be used. Also, ICH-GMP (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use) and PIC/S (Pharmaceutical Inspection Co-operation Scheme) guidelines provide a number of risk management coping approaches.

EAHP's SIG stresses the importance of applying existing risk management coping approaches in hospitals.

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EAHP's SIG asks hospital managers to reorganise the handling of medicines on wards with the help of clinical pharmacy service introduction.

Also, harmonisation is key for working towards eliminating avoidable harm. Different initiatives have been carried out to achieve European-wide harmonisation, but these have failed for different reasons. Compliance with PIC/S pushed for by the Council of Europe is supportable but has so far not been achieved due to the lack of mandatory requirements.

EAHP's SIG calls on national governments to mandate PIC/S compliance across Europe.

Barriers to change identified include the lack of enforceability of existing quality management aspects, the lack of governance (e.g. the lack of individuals taking the lead on addressing harm in institutions) and the fact that some measures cannot be implemented at the national level and thus would require standard setting by a higher instance, e.g. at the EU level.

EAHP's SIG advocates for stronger patient safety measures adopted by both European institutions and national governments.

Inspiration for eliminating avoidable harm could also be drawn from primary care. As outlined in the comparison of the national minimum quality requirements, hospital pharmacists are not a mandatory group of professionals working in hospitals. When comparing this to the primary care sector, the picture looks different. In primary care, a pharmacist is always necessary for dispensing/receiving medication.

EAHP's SIG underlines that the management of medication is the responsibility of the hospital pharmacist.