REACTION FROM DENMARK, DPSA:

Dear Anna Edwards and Victoria Howes,

I work for the Danish Patient Safety Authority Division (DPSA) of Knowledge and Learning, which handles the Danish reporting system for adverse events, and I have been asked to participate in the working group session on effectiveness in relation to the upcoming EPSO conference in Copenhagen. I apologize for the late response to the questions you have provided in preparation for the session, but I have compiled brief answers that I hope can provide an overview of the Danish approach to reporting adverse events:

- 1. Adverse events are defined as preventable errors. They are ranged on the following scale:
 - a. No harm
 - b. Mild harm
 - c. Moderate harm
 - d. Serious harm
 - e. Death
- 2. DPSA communicates safety guidance to hospitals in various forms, e.g. patient safety warnings concerning specific medicines. For some safety guidance measures, compliance is ensured to some degree through supervision, but this is not the case for all measures.
- 3. We receive approximately 180.000 reports annually. Approximately 80.000 reports come from hospitals. This number has been stable for the past five years.
- 4. When an adverse event is reported, the local organisation has an obligation to analyse the event and consider local measures to prevent future incidents. Root cause analysis is one possible method to apply, but other methods can be used. Once a local report is finalised, all identifiers of involved persons, institutions etc. are removed and the report is transferred to the central database where all reports are included in aggregated analyses. Furthermore, all serious and deadly events as well as moderate medication related events are analysed individually at a central level as part of the DPSA's analysis of high risk areas.

I look forward to participating in the working group meeting.

Med venlig hilsen

Nina Jagd Andersen Projektrådgiver

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