DSEN ABSTRACT

Preventable Adverse Drug Reactions as a Proportion of Adverse Drug Reactions

Summary

- No primary study has been published with the aim of estimating in-hospital PADR incidence in Canada.
- Internationally, PADR incidence ranged from 0.006 to 13.3 PADRs per 100 patients in 37 primary studies.
- The method of event detection influenced PADR incidence, with prospective methods having the highest and most accurate reported PADR rate. This finding is in agreement with other literature.
- The least-biased pooled estimate of PADR incidence was 3.13 PADRs per 100 patients, taken from 13 studies that used prospective event detection methods.
- Considerable heterogeneity amongst primary studies using prospective event detection methods limited the validity of the overall PADR incidence.
- Subgroup meta-analyses found that PADR incidence varied with event detection method (prospective > retrospective > voluntary reporting), setting in hospital (ICU > wards), and clinical specialty (medical > surgical).

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What is the issue?

 Preventable adverse drug reactions (PADRs) in inpatients are linked with harms, including increased length of stay and potential loss of life, and result in elevated costs of care. The incidence of inpatient PADRs in Canada and internationally is unclear.

What was the aim of the study?

The following research questions were addressed:

- What is the incidence of PADRs in acute and continuing/long-term care hospitals/institutions (including both academic and community hospitals)?
- What is the incidence of PADRs within different age groups, settings (e.g., acute, continuing, and long-term care; academic vs community hospitals; wards vs ICUs), and clinical specialities (e.g., medicine vs surgery)?
- What are the causes of PADRs (including relationships to stages of the medication process and system level causes such as lack of training and lack of quality control)?
- What is the severity of patient outcomes associated with the occurrence of PADRs?
- What drugs and drug classes are commonly reported to be associated with PADRs?

How was the study conducted?

• A protocol was developed a priori for an overview of systematic reviews. We searched MEDLINE, Embase and the Cochrane Library. We included published systematic reviews that reported quantitative data on the incidence of PADRs in patients receiving acute or ambulatory care in a hospital setting. The full texts of all primary studies for which PADR data were reported in the included reviews were obtained and data relevant to review objectives were extracted. Quality of the included reviews was assessed using the AMSTAR-2 tool. Both narrative summaries of findings and meta-analyses of primary study data were undertaken.

What did the study find?

- Thirteen systematic reviews encompassing 37 unique primary studies were included. No primary studies were conducted in Canada.
- There was variability in primary objectives, methods and characteristics noted across both the sets of 13 reviews and 37 studies, including hospital setting, clinical specialty, age range, outcome definition and other factors.
- There was considerable variability across studies in PADR incidence, ranging between 0.006 and 13.3 PADRs per 100 patients. Extremely low PADR reporting rates in studies with extremely large sample sizes biased the pooled incidence estimate, which should be interpreted with caution (0.59 PADRs per 100 patients).
- Amongst 13 studies using prospective event detection methods (i.e., not chart review or voluntary/stimulated reporting), the pooled estimate of PADR incidence was 3.13 PADRs per 100 patients (95% CI 2.87–3.38). This estimate is likely less biased than the overall pooled estimate; however, heterogeneity remained high and the estimate should be interpreted with caution.
- Subgroup meta-analyses found that the incidence of PADRs varied greatly with event detection method (prospective > retrospective > voluntary reporting methods), setting in hospital (ICU > wards), and clinical specialty (medical > surgical). Within these subgroups, statistical heterogeneity between studies was high (I² > 50%) and results should be interpreted with caution. Patient age categories reported in primary papers overlapped and could not be quantitatively analyzed with validity; however, one included primary study found that PADR incidence was significantly higher in patients >65 years of age than in patients 18–64 years of age.

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