

13. An Analysis of the Exclusion Criteria Used in Observational Pharmacoepidemiological Studies

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Background: The application of exclusion criteria in pharmacoepidemiological studies could have a major impact on the findings but there appears to have been no previous research to examine the types of exclusion criteria applied.

Objectives: To evaluate the exclusion criteria found in observational pharmacoepidemiological studies, and to determine any differences in research practice between investigators.

Methods: Ten senior pharmacoepidemiologists who had published five or more relevant papers between 1999 and 2004 were identified from an initial search of general medical, epidemiological and pharmacology journals. A further search using Medline and Embase was used to identify all their English-language observational pharmacoepidemiological studies for this period. Each article was evaluated independently by two authors using a classification system with 5 categories and 11 sub-categories to describe the exclusion criteria. The categories were: (1) data quality and validation (2) disease-related (3) exposure-related (4) patient characteristics (5) miscellaneous reasons. Within each sub-category, only the first exclusion criterion identified for that study was counted.

Results: We identified 200 studies, from which a total of 752 exclusion criteria sub-categories had been applied (mean 3.8 per study; between-author range of means 2.8–5.1). At the category level, exclusion criteria relating to data quality and validation were the most commonly applied (87% of publications), followed by patient characteristics (75%), disease-related (69%), exposure-related (38%) and miscellaneous (3%). The main categories for which research practice appeared to differ were those relating to diseases and exposures. The sub-category "risk factors and alternative causes" was applied in 35% of publications and the variation between authors was 0–81% of studies. 32% of publications excluded individuals due to the "medication of interest" and the range between authors was 5–93% of studies.

Conclusions: There are important differences between investigators in the application of exclusion criteria in pharmacoepidemiological studies. It is likely that a substantial part of the observed variation reflects different research practices of investigators.

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