Information for rational prescribing to older patients in European and American drug formularies

J.L. Boer¹, E. Beers¹, A.C.G. Egberts²,³, H.G.M. Leufkens²,⁴, P.A.F. Jansen¹,⁴

¹ Expertise Centre Pharmacotherapy in Old Persons (EPHOR) and Geriatric Department; ² Dept of Clinical Pharmacy, University Medical Center Utrecht; ³ Utrecht Institute for Pharmaceutical Sciences, Faculty of Science, Utrecht University; ⁴ Dutch Medicines Evaluation Board, The Hague, the Netherlands

Introduction

Drug formularies extract information from:
- The official product information:
  - Europe: the summary of product characteristics
  - US: the product label
- Other handbooks and literature.

Healthcare professionals in daily practice use drug formularies for rational prescribing of medicines.

Aim

To investigate the availability and clinical applicability of information about older people for rational drug prescribing in European and American drug formularies.

Methods

Included drug formularies: Belgian Repertorium, British National Formulary (BNF), German Rote Liste (RL), Dutch Farmacotherapeutisch Kompas (FK), American Physician’s Desk Reference (PDR).


A 19-items checklist based on the ICH E7 guideline was used to investigate whether information was available (See table).

Results

- 5 drug formularies and 35 medicines were included.
- See Figure for the proportion of available and clinically applicable information and information that was not needed, based on pharmacokinetic properties of the medicines.
- Information about the number and characteristics of older people investigated during clinical trials was absent in the European handbooks. The PDR provided this information in about 40% of the medicines.

Conclusions

- The availability and clinical applicability of information about older people for rational prescribing of medicines is incomplete in the investigated European and American drug formularies.
- In the American PDR more information was found than in the European formularies, since the entire product label is available.
- Since drug formularies are the primary documents that guide prescribing in actual clinical practice, the availability and clinical applicability of the information on older individuals should be improved, especially in the European formularies.

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Nature of the studied population (4 items)

Investigated participants ≥65 years and ≥75 years – Exclusions based on an upper age cut-off and on co-morbidity probably present in people ≥65 years.

Clinical experience in older people (4 items)

The number of participants ≥65 years – Age-related differences in efficacy, adverse events and dose response.

Pharmacokinetic (PK) properties (8 items)


Drug–drug interactions (DDI) (3 items)


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Applicability of available information (Systematic Information for Monitoring score): at least information about what to monitor, a critical value and how to respond.