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

UMC Utrecht

J.L.Boer[1], E. Beers[1], A.C.G. Egberts[2,3], H.G.M. Leufkens[2,4], P.A.F. Jansen[1,4]

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

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.**

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.

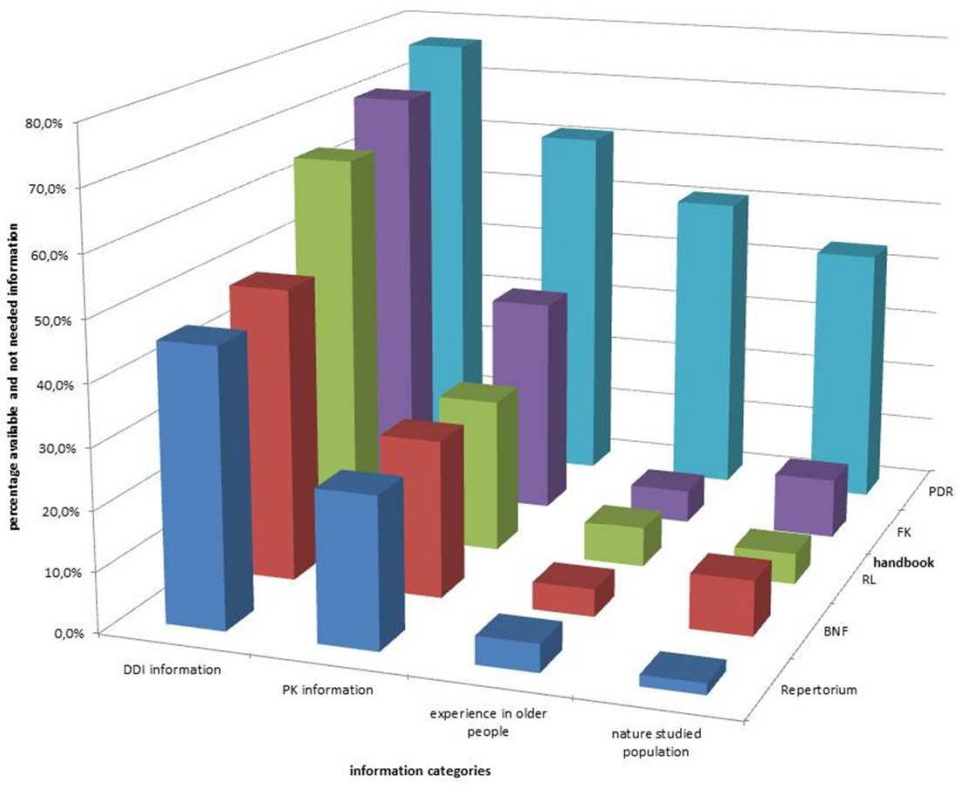

Figure. The proportion of available and not needed information

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.

Table. The 19 items extracted from the ICH E7 guideline

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)
PK behaviour of the drug – PK behaviour in older people – Influence of demographic and physiologic factors on the PK – Extent of renal and hepatic excretion of active substance – Renally and hepatically impaired patients
Drug–drug interactions (DDI) (3 items)
Therapeutic range – Relevant CYP450 metabolism – Drug–drug interactions

Methods

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

Included medicines: Indicated for diseases frequent in older people, first European centralised approval between 2008 and 2011, and FDA approval before October 2012.

A 19-items checklist based on the ICH E7 guideline was used to investigate whether information was available (See table). Applicability of available information (Systematic Information for Monitoring score): at least information about what to monitor, a critical value and how to respond.

Conflicts of interest
No conflicts of interest declared.

Contact information
Erna Beers MD PhD student
@ e.beers@umcutrecht.nl
☎ +31-88-7558280

Erna Beers has received a grant from:

The Expertise Centre Pharmacotherapy in Old Persons is financially supported by: