7.3 Priority medicines for the elderly

See Background Paper 7.3 (BP7_3Elderly.pdf)

People aged 60 years and older are a growing part of both European and global communities (see also Chapter 5 Figures 5.2.1 and 5.2.2). The proportion of the global population aged 60 years and over is projected to increase from 11% in 2010 to more than 16% in 2030. In Europe, the growth of the elderly population is more pronounced, with an estimated proportion of 29% aged 60 and over by 2030. This rise poses challenges to health and social care systems. The incidence of diseases such as dementia, cancer and osteoporosis is increasing and the use of multiple medicines (polypharmacy) is common, often leading to medicine-related problems. In addition, the elderly reside in different care settings depending on the level of care needed – a trend that underlines the need for integration of care and for better self-management of medication. As with children, many medicines are prescribed off-label to the elderly. All of these issues require careful attention and analysis to guide future decision-making.

It is clear that the elderly often have difficulties with taking their medication, including opening packages, swallowing oral medication and/or reading leaflet information. For example, approximately 9% of people aged 65 years and up to 28% of people aged 85 years or over have problems with swallowing. Since many of the difficulties that the elderly have with medicine formulations are similar to the problems seen in children (e.g. swallowing medication), alignment is needed with the development of formulations for children, taking into account the differences between the two populations. When adapted formulations are developed in the near future, it will be necessary to evaluate these to determine whether these products have indeed led to better health in the elderly.

The elderly are still underrepresented in randomized clinical trials (RCTs), with age and (perceived) frailty being the predominant reasons for exclusion. A recent systematic review showed that in 38.5% of RCTs, people aged 65 years and over were excluded and in 81.3% of the RCTs people with comorbidities were also excluded. Furthermore, age and comorbidities were frequently categorized as poorly justified exclusion criteria (78.4% and 64.8%, respectively). There is a need to develop a consensus definition for frailty and tools to evaluate frailty, because these may enable the selection and inclusion of the elderly in RCTs as well as guide therapeutic decisions. Novel initiatives to increase the participation of the elderly in RCTs include the EU-funded development of a Charter in order to promote participation, and the launch by the European Medicines Agency (EMA) of a geriatric medicines strategy and the establishment of a Geriatric Expert Group. The geriatric medicines strategy promotes discussion concerning the anticipated effects of a medicine in geriatric patients, based on pharmacokinetics and other characteristics of the medicine. Investigation of population pharmacokinetics or specific pharmacokinetic studies (including those involving the very elderly) should be performed in order to recommend dose regimens.
and identify patients at risk. For these studies, modelling and simulation might be useful methods. The strategy recognizes the elderly as the main users of medicines and seeks to ensure that the development and evaluation of new medicines take into account specific safety and efficacy aspects related to ageing. In line with the recommendations for children and women, new approaches such as better use of electronic health records may be valuable in obtaining better data on medicine safety and effectiveness in the elderly (see also Chapter 8.4).

In addition, the strategy acknowledges the need to improve the availability of information for patients and prescribers on the use of medicines in the elderly. A recent study demonstrated that, while important information is often available in the European Public Assessment Reports (EPARs), this information is not sufficiently reflected in the Summary of Product Characteristics (SPC). For 53 new medicines, a maximum of 19 items derived from the ICH E7 guideline for studies involving geriatric populations were scored per new medicine. Of these items, 79% were included in the EPAR compared with only 56% in the SPC. Treatment guidelines appear to be more disease-driven than patient-centered, and specific guidance on the treatment of elderly patients is frequently lacking. This may not only cause overuse but also underuse of medicines in this population. Approaches to translate age-specific information on the benefits and risks of medicines into practical recommendations, in the SPC and/or treatment guidelines, should be further explored. Research should also focus on how physicians obtain the information needed to adequately treat elderly in daily practice, and how this information is updated on a regular basis.

Polypharmacy is very common in the elderly and inappropriate prescribing is often related to this. Medication reviewing, e.g. by pharmacists, is a structured evaluation and reconciliation of a patient’s medication and has become common practice in some countries. Although interventions to improve the appropriate use of polypharmacy lead to more appropriate prescribing and fewer medication-related problems, observed effects on important clinical outcomes such as hospital admissions or mortality are conflicting. This may at least partly be explained by methodological challenges. Due to a lack of robust research in this area, the cost-effectiveness of medication reviewing has not yet been established.

In order to facilitate appropriate prescribing and conduct medication reviewing more efficiently, there is a need to improve the supporting role of electronic health records. A computerized decision support system (CDSS) can be incorporated into a computerized physician order entry. When combined with other data such as laboratory values, this system can generate more advanced advice to provide clinical guidance that is based on clinical rules and aligned with treatment guidelines. These electronic solutions could make reviewing less time-consuming and help the reviewer to systematically select those patients who might benefit most from a review. In a hospital pharmacy in the Netherlands, the implementation of an alert system for adverse events involving medicines, with about 121 clinical rules, resulted in the selection of different patients and additional interventions performed by the pharmacist, compared with those of the conventional medication surveillance
method. The hospital setting, with more shared data between health care professionals, could serve as an example for primary care. In addition, the added value of fast and extensive data sharing with the aid of computerized systems needs to be established.

Finally, the integration and continuity of care in elderly patients is essential, especially when an elderly patient is living with several co-existing diseases, as many are. A Cochrane Review of follow-up studies involving older patients admitted to hospital who underwent a comprehensive geriatric assessment (a multidimensional interdisciplinary approach), indicated that they were more likely to be alive and to live at home, and less likely to live in residential care, to experience deterioration or to die. Similar approaches in other settings should be further explored. The elderly live in different care settings and each transfer introduces potential risks, such as the unintentional discontinuation of medicines or the re-prescribing of medication that was recently stopped. More extensive sharing of data could play a crucial role in preventing such errors. In addition, while effort is put into ensuring accurate medication taking (for example, through medication reviews), little effort is invested in ensuring effective communication between first and second-line care. Better interface management, both at a policy level and the health care professional level, is therefore needed.

There is a current trend for the elderly to live independently for a longer period of time. However, medication management becomes more complex as they age. Many elderly people have cognitive, physical and/or visual difficulties that may hamper accurate medication management. Tools have been developed to assess their ability to manage their medication at home, but further evaluation of these is needed.

In summary, improvement in the development and use of medicines in the elderly needs investments in:

- The development and evaluation of adapted formulations and packaging for the elderly and alignment with formulations for children where appropriate;
- Better use of electronic health records to obtain data on safety and effectiveness in the elderly, and approaches to translate age-specific information on the benefits and risks of medicines into practical age-specific recommendations;
- Evaluation of the (cost-)effectiveness of interventions to increase appropriate prescribing and use with a focus on important clinical outcomes;
- Approaches that support further integration of care, sharing of information and communication between health care professionals, and the role of electronic solutions, and other tools to assess and improve medication self-management among elderly people living independently in the community.
References


