

# Providing value for medicines in older people

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## Abstract

The global population is ageing, but inequalities remain in older people's access to treatment, especially people 75 years of age and older. These people receive less frequent interventions and lower quality medical treatment than their younger counterparts. Explanations for these inequalities include ageism, a lack of testing of medicines in older people, unclear diagnoses resulting in hesitancy to institute treatment, polypharmacy, and a general lack of concordance and compliance. In Europe, responsibility for improving this situation lies with the pharmaceutical industry, the European Medicines Agency, national regulatory agencies, prescribers, dispensing pharmacists, and the patients or consumers themselves. Clinical trial and health economic data are needed to assure the effective and safe treatment of older people.

**Keywords:** Elderly, Ageism, Special populations, Pharmacovigilance, Safety

Owing to declining global birth rates and increased longevity, the global population is ageing. In 2000, one in nine people was 60 years or over, but by 2050, this figure is expected to rise to one in five.<sup>1</sup> This has and will continue to have an large impact on healthcare.

The European Review on the Social Determinants of Health and the Health Divide, Older People 2012 indicates that although the needs for healthcare services increase with age, older people – especially those aged 75 years and over – receive less and lower quality treatment.<sup>2</sup> They also receive less expensive treatments than younger people for the same illness. Some studies indicate that the number of prescriptions of recently introduced, non-substitutable pharmaceuticals tend to be proportionally lower in the younger part of the oldest age groups. Also, diagnostic procedures are often less intensively used among older people than

younger adults. Mammography is an example, partly because this diagnostic procedure has not been adequately tested in older women.

Furthermore, the review indicates that older people are less likely to be prescribed and receive target doses of relevant medications. For example, several country-specific studies have shown that older people were less likely to receive antihypertensive drugs. The number of prescriptions of angiotensin-converting enzyme inhibitors, angiotensin receptor blockers, and anticoagulants declined sharply in the 75- to 85-year age group. In addition, some studies have shown that older people are less likely to receive statins, angiotensin-converting enzyme inhibitors, and calcium channel blockers. In general, the review showed that for women with breast cancer, less treatment was administered to older women than to younger women.

Finally, treatment of older people has been shown to be symptom-based rather than diagnosis-based.<sup>3</sup>

## Factors accounting for inadequate or inappropriate drug treatment of older people

Many factors contribute to inadequate or inappropriate drug treatment of older people, including ageism; a lack of clinical data, proper diagnosis as a basis for treatment, concordance, and compliance; and polypharmacy.

### Ageism

Ageism was defined in 1969 by Larkin and Butler as a type of discrimination that involves prejudice against people based upon their age.<sup>4</sup> Similar to racism and sexism, ageism involves holding negative stereotypes about people. This is not limited to older people; adolescents and children can also be discriminated against because of their age.

Ageism, like racism and sexism, is difficult to combat. One step towards improving the situation is the approval of the proposed 2008 EU Directive

against age discrimination,<sup>5</sup> which not only covers work and education but also access to goods and services, healthcare, and social welfare. Approving the EU Directive will convey the message that it is not acceptable to deny older people the healthcare they need because of their chronological age and that the importance of the benefit of a treatment must be weighed against the risks for the individual patient in all people, regardless of age. The proposed directive is currently being considered by the Council of the EU.

On an individual level, people should also react and act when encountering ageism in all its forms. It is unacceptable to be denied a treatment, a subscription for a mobile phone, or a bank loan just because of chronological age.

#### *Lack of clinical data in older people*

Unlike medicines for children,<sup>6</sup> specific legal requirements do not exist for the development of medicines for use by older patients. The EMA has reacted to this and has prepared a document on quality aspects of medicines for older people.<sup>7</sup> Older people represent a heterogeneous population who react to medicines in different ways. Some may have difficulties in taking their medicines, for example, difficulties swallowing tablets, opening packages, or reading the patient information leaflet. In addition, many older patients have comorbidities, and physical changes such as renal or hepatic impairment or altered gastrointestinal motility are important when evaluating the benefit-risk profile of a medicine. The fact that many older patients use several medicines at the same time makes it difficult to design clinical trials where resulting data will not be confounded by polypharmacy. Ethical aspects must also be considered, including how to best obtain informed consent from persons who suffer from dementia and how to test new medicines in fragile individuals.

#### *Lack of a proper diagnosis as a basis for treatment*

Lack of a proper diagnosis as a basis for treatment contributes to inappropriate treatment of older people. For example, a survey by Boëthius and Westerholm<sup>8</sup> found that one-fifth of patients treated with hypnotics for insomnia were inappropriately receiving the medication because they had originally asked for it to treat feelings of loneliness even though they did not articulate this to the prescribing physician.

#### *Lack of concordance*

Concordance is defined as an agreement reached by negotiation between a patient and a healthcare

professional that respects the beliefs and wishes of the patient regarding whether, when and how medicines are to be taken.<sup>9</sup> This term and its practical effects have been questioned. Some patients want clear straightforward advice, while others want to discuss the pros and cons of a treatment. However, concordance should be sought for patients who show a need and want such discussions.

#### *Lack of compliance*

Lack of compliance is very common. It can be remedied by using various compliance aids such as tablet dosing boxes, watch alarms, and medication reminder charts.

#### *Polypharmacy*

Polypharmacy means that a patient is being treated with many different medicines. In Sweden, in 2011, people 75 years and over were treated with an average of five medicines at the same time, which is regarded as polypharmacy.<sup>10</sup> In the same year, 11% of all people 75 years and older were treated with 10 or more medicines at the same time, and 10% were being prescribed medicines that should be avoided in older persons.<sup>11</sup> Polypharmacy is known to be the main risks for adverse drug reactions in older people.<sup>10,12,13</sup> This might be due to the patient having many health problems that require medication. Other contributing factors include multiple prescribers for the same patient, different platforms for maintaining medical records, multiple names for the same medicine, and lack of consultation time for the patient.

## **Improving the treatment of older people**

The responsibility for improving the treatment of older people with medicines lies with the pharmaceutical industry and, in Europe, the EMA, as well as prescribers, pharmacists, and even patients themselves.

#### *The pharmaceutical industry*

The pharmaceutical industry plays an important role in that all medicines, old and new, should be tested in the age groups in which the medicines will be prescribed. The overall cost of medicines is increasing, and as more new expensive medicines enter the market, both the economic and clinical value of medications need to be documented. In addition, to help elderly patients, comprehensive patient information leaflets should be produced in large print, and advertising should follow the codes of ethics set out by the WHO and national

rules. Additionally, during the life cycle of medicines, the benefit–risk ratio in elderly patients should be re-evaluated.

#### *The EMA*

In Europe, the EMA is responsible for following the development of emerging medicines via clinical trials and through the on-going evaluation of licensed medicines. This includes evaluation of whether the medicine can be safely and effectively used in the patient groups to which the medicine is thought to be prescribed – in this instance, older people. The EMA has developed a geriatric medicines strategy<sup>7</sup> and established an expert group for the evaluation of medicines for older people (The Committee for Medical Products for Human Use Advisory Group on Geriatrics). Via this body, the EMA will ensure that medicines used by geriatric patients are of high quality and appropriately researched and evaluated throughout their life cycles. The EMA is also working on improving the availability of information on the use of medicines for older people, thereby assisting with informed prescribing (Product Information and European Public Assessment Reports). The EMA also interacts with stakeholders via the Patients and Consumers Working Party. Finally, the EMA is responsible for the Pharmacovigilance Programme, which includes reporting adverse reactions and medication errors.<sup>14</sup>

Medication errors are the single most common preventable cause of adverse events in medical practice. Thus, reporting of medication errors is a new and very important task in evaluating the safety of medicines because. The World Alliance for Patient Safety has estimated the annual cost of medication errors to be between €4.5 and 21.8 billion per year.<sup>13</sup> An estimated 19–56% of all adverse drug events among hospital patients are caused by medication errors that could have been prevented. New pharmacovigilance legislation that came into force in July 2012 acknowledges medication errors as a major public health burden. The legislation explicitly foresees reporting of suspected adverse reactions associated with medication errors.

#### *Prescribers*

Prescribers must base their prescribing on knowledge about the causes of the patient's health problems, the benefit–risk profile of the medicine, and the other medicines that the patient is prescribed. To avoid errors, one physician should be responsible for the medication of the patient and should coordinate prescriptions given by other physicians. The physician needs the time to inform the patient about the diagnosis and to discuss the medication

with them. Finally, the physician should assess the patient's reactions to treatment, evaluate them, and if necessary, adapt therapy, also known as 'therapeutic auditing'.

#### *Pharmacists*

Pharmacists are responsible for checking that the correct medicine is delivered. They should signal the prescriber when medicines not to be used by older people have been prescribed and when interactions might occur. Moreover, the pharmacist should allow time for the patient to ask questions.

#### *Patients: The Swedish example*

In Sweden, a project was started in 1999 that has now developed into the 'Master your drugs' campaign. The two major organisations for older people, the National Pensioners' Organisation and the Swedish Association for Senior Citizens, comprising some 700 000 members, are responsible for this activity.

Seminars and study circles about medicines are organised for the members in which they are shown how to weigh benefits and risks. The members are given a list of questions to ask their doctor, including:

- Why are you prescribing this medicine for me?
- For how long should I take it?
- What are the most common adverse effects?
- Can I use it together with other medicines and herbal products that I take?
- Is it good for me to take this medicine, bearing in mind how old I am?
- Has this medicine been tested in older people?

The members are also provided with a list of medicines contraindicated in older people, and if prescribed any of these, they are recommended to ask their doctor: 'The information on the list I have here says it is contraindicated in older people. Why are you prescribing it for me?'

This campaign was originally funded by the National Pensioners' Organisation and the Swedish Association for Senior Citizens, but the Swedish government found it so interesting that it is now financing the project. The programme is being assessed on an on-going basis, and the results will be presented in 2015.

Effective medicines are currently lacking in some indications such as rare diseases, Alzheimer's and Parkinson's disease, and osteoporosis, and new antibiotics are needed for infectious diseases for which bacterial resistance has become a problem. Such issues present challenges for the pharmaceutical industry.

In addition, re-evaluation of preventive medicine is needed. The lack of effective health economic evaluation is a problem that must be addressed to allow changes to current practice to be monitored. Data on number needed to treat to save one life are needed for different age groups. The question of whether it is right to treat large populations with medicines that may cause adverse effects to save one life is difficult to answer.

## Conclusion

Older people receive less and lower quality treatment than younger people. This is due to several reasons, and the responsibility for improving the treatment of older people lies with the pharmaceutical industry and, in Europe, the EMA, as well as prescribers, pharmacists, and even patients themselves. Medicines need to be not only clinically effective but also cost effective, bearing in mind the increasing number of older people needing medical treatment.

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## Author information

**Barbro Westerholm** is a medical doctor and pharmacologist. She is a long-standing member of the Swedish Parliament and former Professor of Drug Epidemiology; Head of the Division for Approval of New Medicines in Sweden; Director General of the Swedish National Board of Health and Welfare; and Vice President of the Executive Board of the World Health Organisation (WHO). Professor Westerholm established adverse drug reaction monitoring in Sweden; built up the national prescription register and organised postgraduate education for doctors on the rational use of medicines. A prolific publisher in the fields of clinical pharmacology, health care, politics, and ethics, she addressed EMWA in May 2013 on the subject of providing value for medicines in older people.