

DRUG PRESCRIPTION REGULATIONS


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EAMA VII/3






INTRODUCTION


- Elderly account for 1/3 of prescription drug use,
 - Ambulatory elderly fill between 9-13 prescriptions a year (new and refills)
 - One survey: Average of 5.7 prescription medicines per patient
 - Average nursing home patient on 7 medicines
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- Elderly persons use drugs at a higher rate than younger persons.


 - Elderly persons, those aged 65 and older are also more likely than younger adults to experience complications when taking some prescription drugs
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- In Tunisia, there is not legislative support specific for elderly

 - In Europe, both policy and legislation are in general inadequate, and inhomogeneous across nations, to support an efficacious practice of Geriatric Medicine.
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- Inappropriate medication use exist between European countries and might be a consequence of different regulatory measures, clinical practices, or inequalities in socio economic backgrounds

Daniela F and al. Potentially inappropriate medication use among elderly home care patients in Europe
JAMA 2005, 29: 1348-1358

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- Policy approaches
 - United Kingdom :
 - National services frameworks
 - New UK general practice
 - Regulatory approaches in USA
 - Nursing home Reform Act
 - Clinical justification of prescribing of psychotics medications
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NON-PRESCRIPTION DRUGS

- Surveys indicate that elders take average of 2-4 nonprescription drugs *daily*
 - Laxatives used in about 1/3-1/2 of elders - many who are not constipated
 - Non-steroidal anti-inflammatory medicines, sedating antihistamines, sedatives, and H2 blockers are all available without a prescription, and all may cause major side effects
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TOPICS TO BE DISCUSSED

- Drug trials in the elderly
 - Legal restrictions
 - Guidelines
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FDA / Drug trials in the elderly

- The food and drug administration (FDA) has noted that is important that drugs be studied for use by elderly persons during the clinical drug trials.
- The FDA approve new drugs for marketing in the United States. This responsibility includes determining if drugs are safe and effective for the people expected to use them, including elderly persons.

Kennedy EM, Waxman HA. Elderly persons in clinical drug trials.
United States Government Accountability office. September 2007



FDA/ Drug trials in the elderly

- So that the FDA guidance recommends that drug sponsors include elderly persons in clinical drug trials and FDA regulations require that the drug sponsors report clinical drug trial data by age.

Kennedy EM, Waxman HA. Elderly persons in clinical drug trials.
United States Government Accountability office. September 2007



LEGAL RETRICTIONS

- The art of prescribing for the elderly people is balancing :
 - the potentially conflicting demands of research evidence
 - practical considerations
 - patient's wishes.

Jackson SHD, Mangoni AA, Batty GM .
Optimization of drug prescribing. Br J Clin Pharmacol 2003; 57 (3) : 231-6.



LEGAL RETRICTIONS

- In the United Kingdom, adults are presumed to be capable of giving and withholding consent to medical treatment and such consent must be obtained before treatment is given.

- To treat a person without their consent is to commit the civil wrong of trespass to the person and may constitute a crime.

Jackson SHD, Mangoni AA, Batty GM .
Optimization of drug prescribing. Br J Clin Pharmacol 2003; 57 (3) : 231-6.



LEGAL RETRICTIONS

- A patient's capacity may be impaired temporarily or permanently for a variety of reasons.

- A patient who lacks capacity can neither consent to nor refuse treatment.

- If a patient wholly lacks capacity the doctor has a duty to act in the patient's best interests.

Jackson SHD, Mangoni AA, Batty GM .
Optimization of drug prescribing. Br J Clin Pharmacol 2003; 57 (3) : 231-6.



LEGAL RETRICTIONS

- In order to test for capacity it must be established that:
 - the patient understands the information given
 - can retain the information and
 - believes it.

- If a patient is suffering from a mental disorder, consideration must be given to the use of the Mental Health Act although whether this covers patients with dementia is not yet clear.

Jackson SHD, Mangoni AA, Batty GM .
Optimization of drug prescribing. Br J Clin Pharmacol 2003; 57 (3) : 231-6.



SOME EXAMPLES ABOUT RESTRICTIONS

- In dementia, drug has to be prescribed by a specialist under certain conditions
 - Prescription of opiates : it is very difficult to prescribe morphine and other opiates, you need to fullfill special forms that a lot of GPs does not have
 - European Medicine Agency warned physianscs and patients of the risk associated with second generation antipsychotic drugs
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GUIDELINES FOR ELDERLY

- Clinical Guidelines for Type 2 Diabetes Mellitus. endorsed by the European Union Geriatric Medical Society and the International Academy of Nutrition and Aging.
 - Guidelines for diagnosis and treatment of Syncope published by the European Society of Cardiology – ESC - in 2001. The 2004 Update has been prepared jointly with EUGMS and acknowledges the specific issues of syncope in the elderly.
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TAKE HOME MESSAGES

- The elderly take more medications than any other age group
 - Pharmacokinetics and pharmacodynamics are altered
 - Adverse drug reactions are common
 - Risks go up with the number of drugs used
 - Nonprescription and herbal therapies are common
 - With care and common sense, we can probably do a better job
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TAKE HOME MESSAGES

- Drug trials must include elderly people

 - Quite apart of the legal requirements, it is important to provide all patients with information appropriate to their needs prior to prescribing treatments and to provide a balanced view of the advantages and disadvantages of any particular course of action.
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