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Medication safety in vulnerable patient groups - Elderly patients -

20th Congress of EAHP
25-27 March, 2015, Hamburg, Germany

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Conflict of interest: nothing to disclose.



Control questions

1. Should all medicines be started with the same initial dose in a 40-year-old and an 80-year-old?
2. Is creatinine a reliable indicator of glomerular filtration rate in the elderly subject?
3. Use of PIM is rarely appropriate in elderly patients – correct?



Learning Objectives



parameters, that influence pharmacokinetics and pharmacodynamics in elderly patients



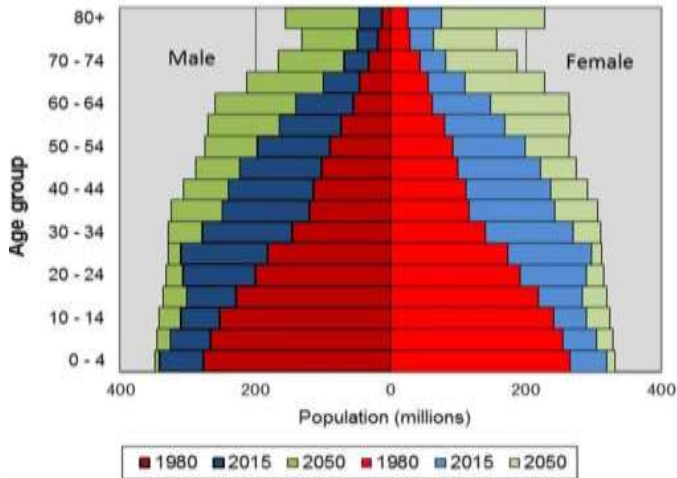
different classification systems for PIM (Potentially Inappropriate Medication)



problems with the application of drugs in elderly patients



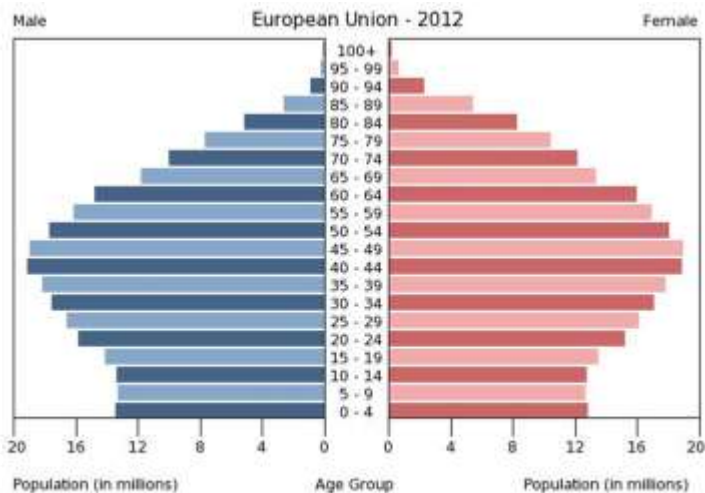
Global Demographics:
From pyramid (1980) to bell (2015) to barrel (2050)



Source: Calculations by Emi Suzuki based on WDI 2014 and UN World Population Prospects 2012 Revision

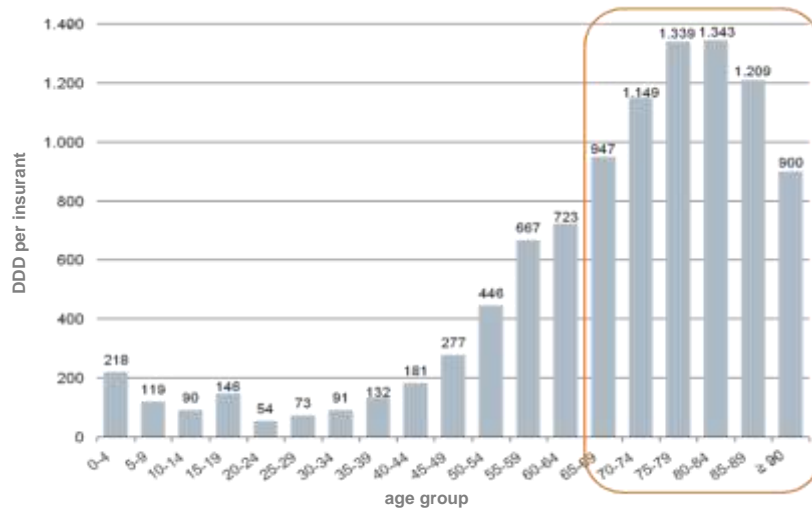


The situation in Europe



Source: The World Factbook 2012. Washington, DC: Central Intelligence Agency (CIA), 2012

Elderly patients are the most important target group of pharmacotherapy.



Schwabe U, Paffrath D. Arzneiverordnungs-Report, Aktuelle Daten, Kosten, Trends und Kommentare. Springer; 2008.

Multiple co-morbidities → polypharmacy

Beware of:

- drugs that are suboptimal or lacking an indication
- therapeutic duplication
- multiple prescribing doctors
- drug interactions
- vicious cycle of polypharmacy
- complementary medicines



nursing.advanceweb.com

A non-uniform group



www.apotheken-umschau.de

„Go-go-patients“



www.abendblatt.de

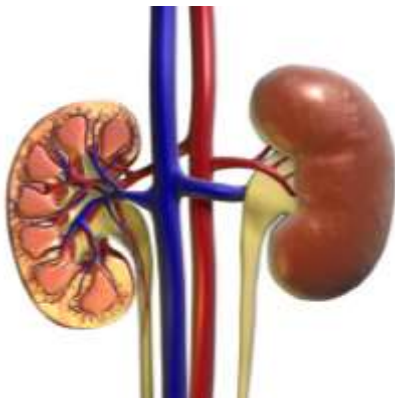
„Slow-go-patient“



www.allgemeinarzt-online.de

„No-go-patient“

Alterations in pharmacokinetics



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- **reduction in renal clearance**
- drug absorption changes little
- altered volume of drug distribution
- loss of first pass metabolism

Alterations in pharmacodynamics

- increased central nervous system sensitivity
- increased sensitivity for anticholinergic effects



Therapy based on guidelines?



- patients > 65 rarely enrolled in clinical trials
- patients on polypharmacy often excluded from clinical trials

→ only a few guidelines adequately address the elderly



Case example

83-year-old woman



PIM = Potentially Inappropriate Medication



- unfavourable balance of risks and benefits
- limited effectiveness in older adults
- carry an increased risk of adverse drug events
- with certain diseases or syndromes

International PIM-lists

author	country	year
Beers et al.	USA	1991
McLeod et al.	Canada	1997
Fick et al.	USA	2003 (update Beers-list)
Laroche et al.	France	2007
Gallagher, O'Mahony et al.: STOPP	Ireland	2008
Rognstad et al.	Norway	2009
Holt et al.: PRISCUS	Germany	2010
Wehling et al.: FORTA	Germany	2011 (validation 2014)
American Geriatrics Society: Beers Criteria 2012	USA	2012 (2 nd update Beers-list)
O'Mahony et al.: STOPP/START	Ireland	2014 (version 2)

2012 AGS Beers Criteria

53 medications or medication classes divided into three categories

1) PIM

Organ System or Therapeutic Category or Drug	Rationale	Recommendation	Quality of Evidence	Strength of Recommendation
Digoxin > 0.125 mg/d	In heart failure, higher dosages associated with no additional benefit and may increase risk of toxicity; slow renal clearance may lead to risk of toxic effects	Avoid	Moderate	Strong
Nitroglycerin, immediate release*	Potential for hypotension; risk of precipitating myocardial ischemia	Avoid	High	Strong

2) PIM with certain diseases and syndromes

Disease or Syndrome	Drug	Rationale	Recommendation	Quality of Evidence	Strength of Recommendation
Cardiovascular					
Heart failure	NSAIDs and COX-2 inhibitors Non-dihydropyridine CCBs (avoid only for systolic heart failure) Clonidine Verapamil Fingibronolol, nifedipine Cilostazol Dronedronolol	Potential to promote fluid retention and exacerbate heart failure	Avoid	NSAIDs: moderate CCBs: moderate Trandolapril (lurasidone): high Clonidine: low Dronedronolol: moderate	Strong

3) PIM to be used with caution in older adults

Drug	Rationale	Recommendation	Quality of Evidence	Strength of Recommendation
Aspirin for primary prevention of cardiac events	Lack of evidence of benefit versus risk in individuals aged ≥ 80	Use with caution in adults aged ≥ 80	Low	Weak

AGS 2012 Beers Criteria Update Expert Panel. American Geriatrics Society updated Beers Criteria for potentially inappropriate medication use in older adults. J Am Geriatr Soc. 2012 60(4):616-31.

FORTA - Fit for the aged

4 categories: **A – Absolutely**, **B – Beneficial**, **C – Careful**, **D – Don't**
190 items

BPSD: SLEEP DISORDERS	FORTA Class (original FORTA class in parentheses if different from consensus results)	Nr. of raters	Consensus coefficient, Round 1 (cutoff 0.800)	Expert ratings on a numerical scale A=1, B=2, C=3, D=4 Mean; Mode	Selection of pertinent comments given by participating experts during the consensus procedure
Substance/group					
Slow-release melatonin (2-4 mg)	C	18	0.833	3.1; 3	
Zopiclone (3.75-7.5 mg)	C	18	1.000	3.0; 3	Caution: not for long-term use
Tetracyclic antidepressant Mirtazapine (15-30mg)	C	20 (R1) 20 (R2)	0.775	3.0; 3 (R1) 3.0; 3 (R2)	Recommendation: lowest possible dosages recommended
Tricyclic antidepressant Doxepine (25-50mg)	C	18	0.801	3.4; 3	Recommendation: other substances should be favored when symptoms of depression are not present Caution: anticholinergic side effects

Beers Criteria versus STOPP



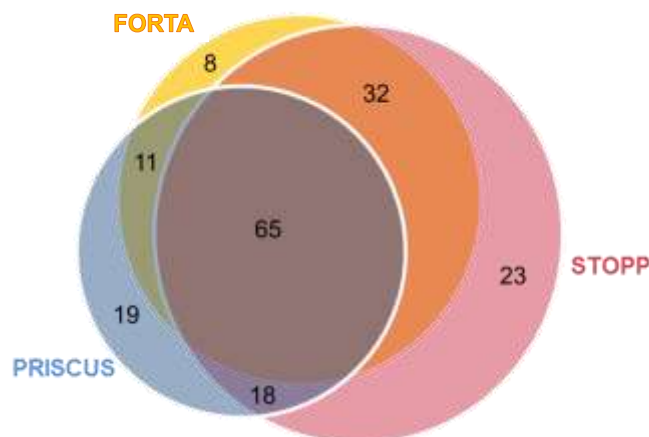
PIM prevalence

STOPP: 51.3%
Beers': 30.4%

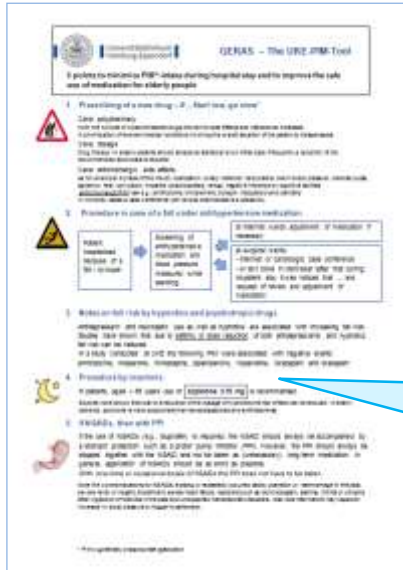
- Prevalence of potentially inappropriate prescribing in an acutely ill population of older patients admitted to six European hospitals.
Gallagher P et al. (Eur J Clin Pharmacol. 2011 Nov;67(11):1175-88.)
- Prevalence of potentially inappropriate medications and risk of adverse clinical outcome in a cohort of hospitalized elderly patients: results from the REPOSI Study.
Pasina L et al. (J Clin Pharm Ther. 2014 Oct;39(5):511-5.)
- **STOPP better than Beers' in Europe?**
- **Is there a European PIM-Tool?**

Beers' 2003: 20.1%
Beers' 2012: 23.5%

PIM-lists are variable in form and content -
Results from a study conducted at UKE (Germany)



GERAS – The UKE-PIM-Tool



GERAS – The UKE-PIM-Tool

If patients receive PIM-Intake during hospital stay and to improve the safety of medication for elderly people

1. Processing of a new drug – PIM-Intake, go now!

2. Procedure in case of fall under pathophysiologic condition:

3. Medication risk by hypoxia and apnoeic drugs:

4. Procedure by insomnia:

5. Medication, from oral PIM:

6. Medication, from oral PIM:

4. Procedure by insomnia

In patients aged > 65 years use of **zopiclone 3.75 mg** is recommended.

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Compliance – specific barriers

- polypharmacy
- cognitive impairment
 - forgetfulness
 - lack of understanding
- handling of medicines
 - problems opening packaging due to loss of fine motor skills
 - swallowing problems
 - vision loss
 - ...



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Sensible prescribing in older patients

- Is it needed?
- Start low, go slow!
- Keep it simple.
- Review regularly.
- Work in teams.



Take home messages



Prescribing of a new drug – if:
„Start low, go slow!“



PIM should be avoided in the elderly



Handling of medicines can be a problem in
the elderly → non-compliance



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