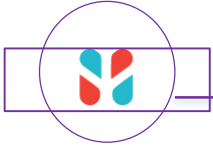


Farmacovigilância e Medicação Potencialmente Inapropriada em Idosos

Fátima Roque

froque@ipg.pt



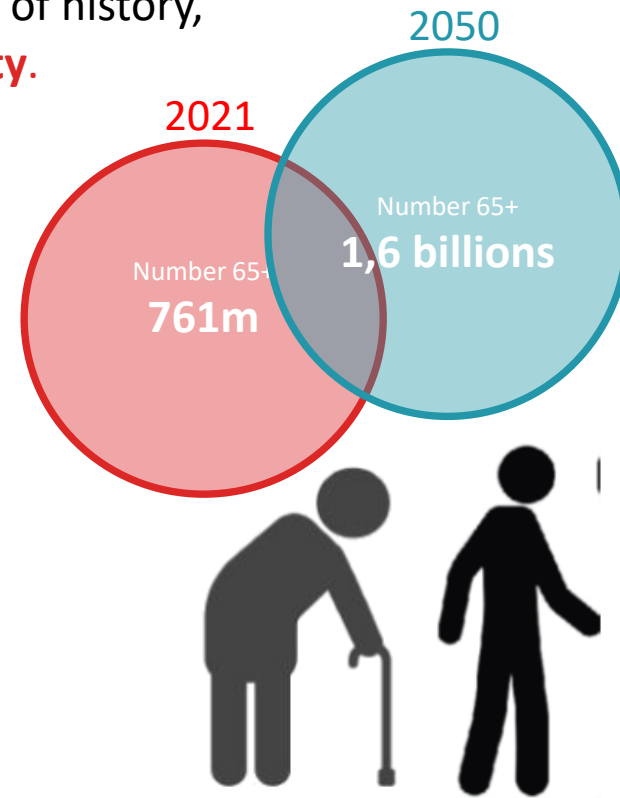
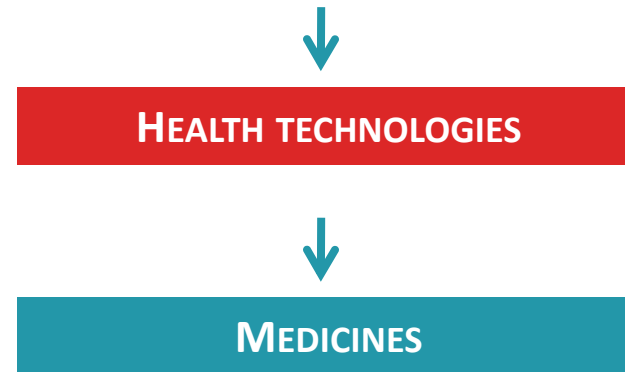
OVERVIEW

- **WORLD POPULATION AGEING**
 - AGEING AND HEALTH
- **POTENTIALLY INAPPROPRIATE MEDICATIONS FOR OLDER PATIENTS**
 - APLICAÇÃO API MED OLDER
 - ADRs AND POTENTIALLY INAPPROPRIATE MEDICATIONS IN OLDER PATIENTS
- **POLYPHARMACY AND FUNCTIONAL ABILITY AND COGNITIVE CAPACITY**
 - MEDICINES AND INTRINSIC CAPACITIES OF OLDER PERSONS



WORLD POPULATION AGEING

Population ageing is in many ways a demographic success of history, driven by the declines of fertility and **increase of longevity**.

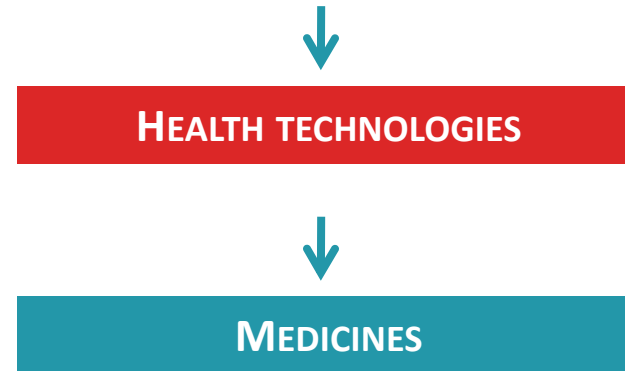


The number of persons aged 80 years or over is projected to triple, from 143 million in 2019 to 426 million in 2050.



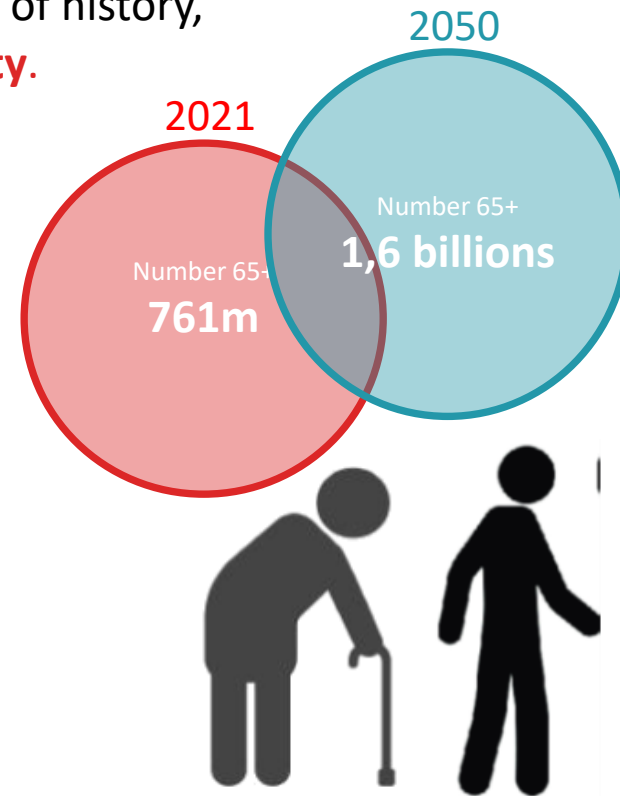
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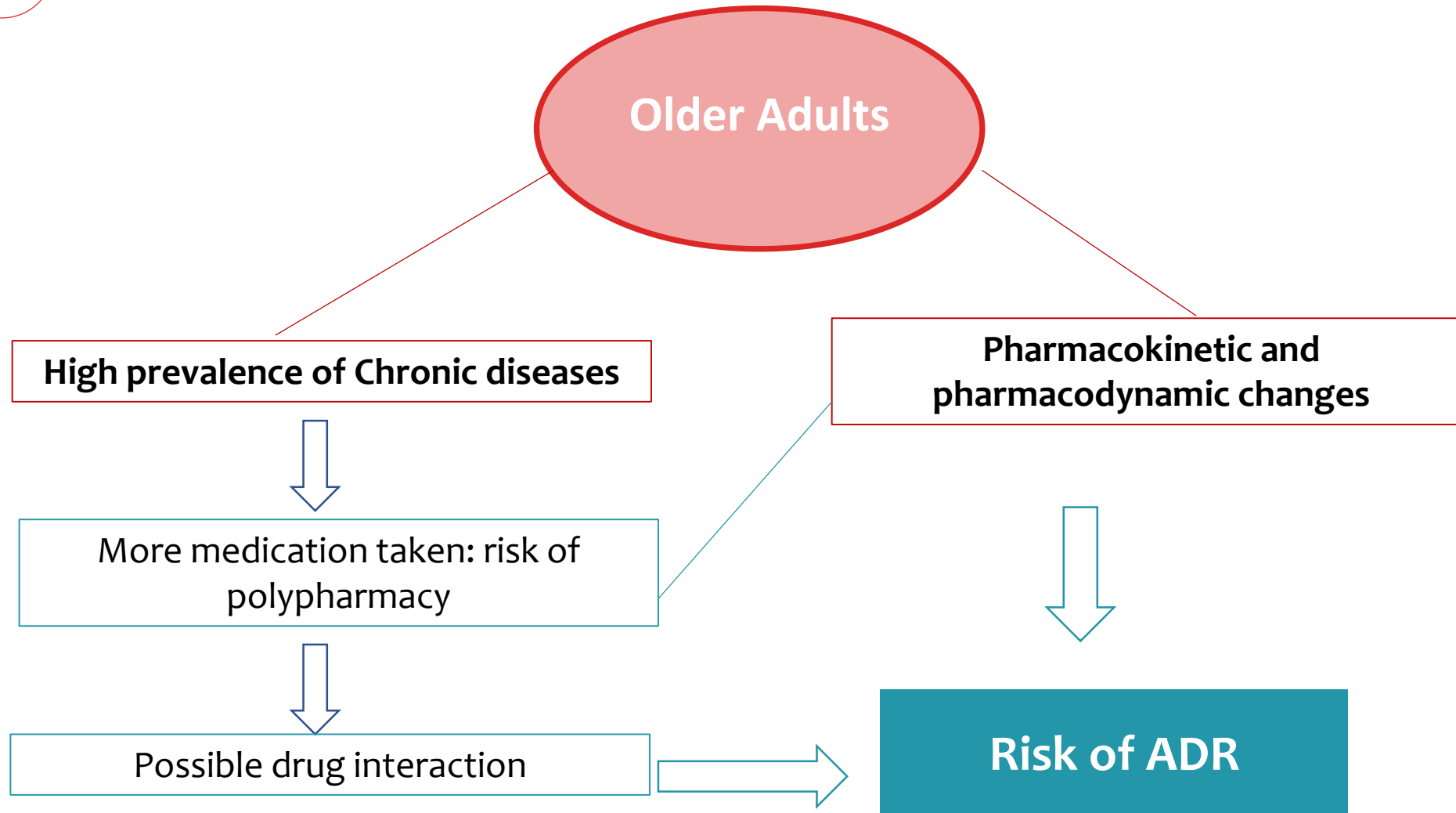


One in ten hospital admissions in older patients are due to ADRs.

*Identified risk factors are particular **medication classes** and polymedication. In most of the cases (~70%), ADRs are potentially **avoidable**.*

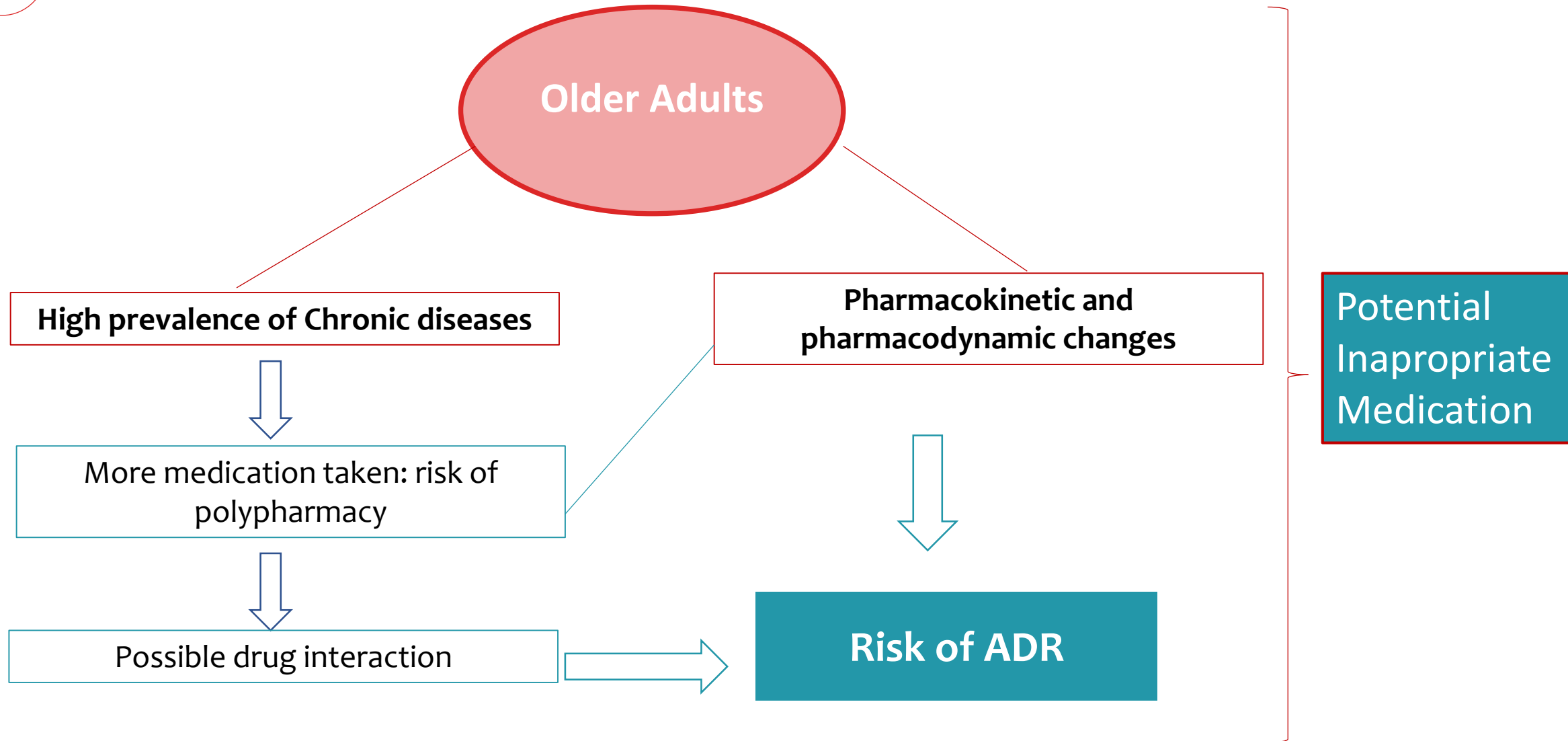


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AGEING AND HEALTH





POTENTIALLY INAPPROPRIATE MEDICATIONS FOR OLDER PATIENTS

*“Drugs that **should not be prescribed to the older population** since the **risk of adverse events outweighs the clinical benefit**, particularly when there is evidence in favour of a safer or more effective alternative therapy for the same condition”*



POTENTIALLY INAPPROPRIATE MEDICATIONS FOR OLDER PEOPLE

CLINICAL INVESTIGATIONS

Beers

American Geriatrics Society 2019 Updated AGS Beers Criteria[®] for Potentially Inappropriate Medication Use in Older Adults

*By the 2019 American Geriatrics Society Beers Criteria[®] Update Expert Panel**

*“Drugs that **should not be prescribed to the older population** since the **risk of adverse events outweighs the clinical benefit**, particularly when there is evidence in favour of a safer or more effective alternative therapy for the same condition”*



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Beers

CLINICAL INVESTIGATIONS

American Geriatrics Society 201
for Potentially Inappropriate Me

By the 2019 American Geriatrics Society Beers Cr.

Acta Med Port 2008; 21: 441-452

OPERACIONALIZAÇÃO PARA PORTUGAL
Critérios de Beers de Medicamentos
Inapropriados nos Doentes Idosos

Maria Augusta SOARES, Fernando FERNANDEZ-LLIMÓS, Carmen LANÇA,
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CLINICAL INVESTIGATIONS

American Geriatrics Society 2011 for Potentially Inappropriate Medications

By the 2019 American Geriatrics Society Beers Criteria

OPERACIONALIZAÇÃO PARA PORTUGAL Critérios de Beers de Medicamentos Inapropriados nos Doentes Idosos

Maria Augusta SOARES, Fernando FERNANDEZ-LLIMÓS, Carmen LANÇA,
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Age and Ageing 2015; 44: 213–218
doi: 10.1093/ageing/afu145
Published electronically 16 October 2014

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STOPP/START

**STOPP/START criteria for potentially
inappropriate prescribing in older people:
version 2**



POTENTIALLY INAPPROPRIATE MEDICATIONS FOR OLDER PEOPLE

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International Journal of
Environmental Research
and Public Health



STOPP/START

STOPP/START version 2: inappropriate prescriptions in older people—Translation and Adaptation to Portuguese of the STOPP/START Screening Tool

Luís Monteiro ^{1,2,*}, Matilde Monteiro-Soares ^{1,3,4}, Cristiano Matos ^{5,6}, Inês Ribeiro-Vaz ^{1,3,7}, Andreia Teixeira ^{1,3,8} and Carlos Martins ^{1,3}

Eur J Clin Pharmacol (2015) 71:861–875
DOI 10.1007/s00228-015-1860-9

PHARMACOEPIDEMIOLOGY AND PRESCRIPTION

The EU(7)-PIM list: a list of potentially inappropriate medications for older people consented by experts from seven European countries

Anna Renom-Guiteras ^{1,2,4} • Gabriele Meyer ^{3,4} • Petra A. Thürmann ^{5,6}

EU (7)-
PIM List



POTENTIALLY INAPPROPRIATE MEDICATIONS FOR OLDER PEOPLE

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Operationalisation for Portugal of the EU(7)-PIM List for Identification of Potentially Inappropriate Medicines in Older Adults

Operacionalização para Portugal da Lista EU(7)-PIM para Identificação de Medicamentos Potencialmente Inapropriados nos Idosos

Daniela A. RODRIGUES¹, Maria T. HERDEIRO², Petra A. THURMANN³, Adolfo FIGUEIRAS⁴, Paula COUTINHO^{1,5}, Fátima ROQUE^{1,5}
Acta Med Port 2021 Mar;34(3):194-200 • <https://doi.org/10.20344/amp.13618>



EU (7)-
PIM List



Medicamento Potencialmente Inapropriado

Operacionalização para Portugal da Lista EU(7) - PIM para Identificação de
Medicamentos Potencialmente Inapropriados nos Idosos

DESCOBRIR MAIS



APLICAÇÃO APIMedOlder









ADRs AND POTENTIALLY INAPPROPRIATE MEDICATIONS IN OLDER PATIENTS



Journal of
Clinical Medicine

Article

Adverse Drug Reactions and Potentially Inappropriate Medication in Older Patients: Analysis of the Portuguese Pharmacovigilance Database

Daniel Gomes ^{1,2,*} , Maria Teresa Herdeiro ^{3,*} , Inês Ribeiro-Vaz ^{4,5}, Pedro Lopes Ferreira ^{2,6} 
and Fátima Roque ^{1,7,*} 

➤ 2337 Reports

- ✓ 6617 ADRs
- ✓ 3170 Suspected Drugs

48,7% physician

17,1% pharmacists

4,9 % nurses

21,1 % other healthcare professionals

14,4 % Users and non-health professionals







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Table 1. Descriptive statistics of the ADR reported according with SOC of MedDRA terminology.

ADR ¹ According to MedDRA ² SOC ³ Terminology (>15%)	N Reports Identified	%
General Disorders and administration site conditions	671	28.7%
Skin and subcutaneous tissue disorders	512	21.9%
Gastrointestinal disorders	475	20.3%
Nervous system disorders	375	16.0%

¹ Adverse Drug Reaction; ² Medical Dictionary for Regulatory Activities; ³ Systems Organ Classes.



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Table 2. Descriptive statistics of the ATC groups reported as suspected medicines.

Pharmacological ATC ¹ Subgroup (>3%)	N ATC ¹ Identified	%
A10A—Insulin and analogues	94	3.0%
A10B—Blood glucose lowering drugs, excl. insulins	160	5.0%
B01A—Antithrombotic agents	193	6.1%
C10A—Lipid Modifying agents	95	3.0%
L01X—Other antineoplastic agents	275	8.7%
L04A—Immunosuppressants	117	3.7%
M01A—Anti-inflammatory and antirheumatic products, non-steroids	84	2.7%
N06A—Antidepressants	91	3.0%

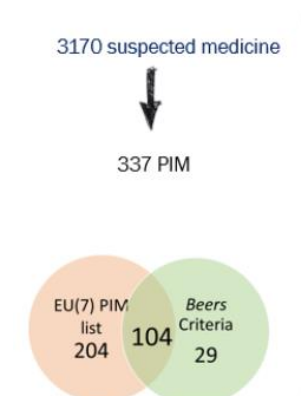
¹ Anatomical Therapeutic Classification.



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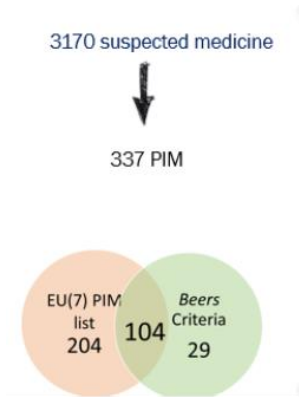


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Differences between reports including PIM and without PIM, regarding seriousness, respective sub-classifications, and notifiers.

	Reports Including PIM ¹ (n = 299)	Reports without PIM ¹ (n = 2038)	p Value
Serious ADR ² report	215 (71.9%)	1297 (63.6%)	0.005
Life risk	23 (7.7%)	136 (6.7%)	0.513
Hospitalization	105 (35.1%)	495 (24.3%)	<0.001
Death	8 (2.7%)	106 (5.2%)	0.058
Clinically relevant	96 (32.1%)	685 (33.6%)	0.607
Incapacity	13 (4.3%)	72 (3.5%)	0.482
Reported by physician	135 (45.2%)	1002 (49.2%)	0.195
Reported by pharmacist	43 (14.4%)	356 (17.5%)	0.185
Reported by nurse	6 (2.0%)	108 (5.3%)	0.014
Reported by patient or non-health professional	78 (26.1%)	415 (20.4%)	0.014

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3170 suspected medicine



337 PIM



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Differences between the number of reports including PIM and without PIM, regarding most frequent SOC identified.

	Reports Including PIM ¹ (n = 299)	Reports without PIM ¹ (n = 2038)	p Value
Nervous System Disorders	82 (27.4%)	293 (14.4%)	<0.001
General disorders and administration site conditions	72 (24.1%)	599 (29.4%)	0.411
Skin and subcutaneous tissue disorders	67 (22.4%)	445 (21.8%)	0.823
Respiratory, thoracic, and mediastinal disorders	52 (17.4%)	230 (11.3%)	0.002
Gastrointestinal disorders	58 (19.4%)	417 (20.5%)	0.670
Psychiatric disorders	32 (10.7%)	83 (4.1%)	<0.001
Vascular disorders	41 (13.7%)	159 (7.8%)	<0.001

¹ Potentially Inappropriate Medication



POLYPHARMACY AND FUNCTIONAL ABILITY AND COGNITIVE CAPACITY

PHARMACOEPIDEMIOLOGY AND DRUG SAFETY 2011; 20: 514–522
Published online 9 February 2011 in Wiley Online Library (wileyonlinelibrary.com) DOI: 10.1002/pds.2116

ORIGINAL REPORT

Association of polypharmacy with nutritional status, functional ability and cognitive capacity over a three-year period in an elderly population

Johanna Jyrkkä^{1,2*}, Hannes Enlund³, Piia Lavikainen¹, Raimo Sulkava^{4,5} and Sirpa Hartikainen^{1,6,7}

- ✓ Excessive polypharmacy is strongly associated with decline in nutritional status, functional ability and cognitive capacity in elderly persons aged 75 years and older.
- ✓ Associations between polypharmacy (more specifically for those using 10 drugs or more) and nutrition, physical functionality.
- ✓ Medication may also increase the possibility that the elderly person suffers from dry mouth (e.g. anticholinergics) or nausea (e.g. acetylcholine esterase inhibitors) which can lead to difficulties in eating increasing the risk of malnutrition



MEDICINES AND INTRINSIC CAPACITIES OF OLDER PERSONS



World Health Organization

Limited mobility



Malnutrition

Depressive symptoms



Visual impairment

Cognitive decline



Hearing loss

ICOPE



MEDICINES AND INTRINSIC CAPACITIES OF OLDER PERSONS



J Nutr Health Aging.2022;26(10):918-925
Published online October 3, 2022, <https://doi.org/10.1007/s12603-022-1847-z>

Original Research

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Intrinsic Capacity Impairment Patterns and their Associations with Unfavorable Medication Utilization: A Nationwide Population-Based Study of 37,993 Community-Dwelling Older Adults

L.-C. Meng^{1,*}, F.-Y. Hsiao^{1,2,3,*}, S.-T. Huang¹, W.-H. Lu^{4,5}, L.-N. Peng^{6,7}, L.-K. Chen^{6,7,8}

Table 4. The association between IC impairment subgroups and medication use

	OR	95% CI	p-value	aOR	95% CI	p-value
Excess polypharmacy						
Robust	ref	-	-	ref	-	-
Visual impairment	2.53	2.13-3.01	<0.01	2.42	2.03-2.88	<0.01
PCD with sensory impairment	4.87	4.09-5.79	<0.01	3.97	3.29-4.78	<0.01
Depression with cognitive impairment	4.36	3.53-5.39	<0.01	4.35	3.52-5.39	<0.01
Impairments in all domains	10.96	8.80-13.66	<0.01	9.02	7.16-11.37	<0.01
Potentially inappropriate medications						
Robust	ref	-	-	ref	-	-
Visual impairment	1.91	1.78-2.04	<0.01	1.79	1.67-1.92	<0.01
PCD with sensory impairment	2.04	1.87-2.23	<0.01	1.94	1.77-2.12	<0.01
Depression with cognitive impairment	2.82	2.55-3.11	<0.01	2.73	2.46-3.02	<0.01
Impairments in all domains	4.08	3.54-4.70	<0.01	3.75	3.24-4.34	<0.01
Adverse drug reactions						
Robust	ref	-	-	ref	-	-
Visual impairment	2.91	2.56-3.32	<0.01	2.69	2.36-3.06	<0.01
PCD with sensory impairment	3.22	2.77-3.78	<0.01	2.96	2.52-3.49	<0.01
Depression with cognitive impairment	6.26	5.39-7.28	<0.01	6.00	5.16-6.98	<0.01
Impairments in all domains	10.53	8.77-12.65	<0.01	9.45	7.81-11.44	<0.01

aOR= adjusted odds ratio from the multivariate logistic regression with adjustment for age, sex, and institution receiving IC assessment; IC, intrinsic capacity; PCD, physio-cognitive impairment



FINAL REMARKS AND THE ROLE OF PHARMACOVIGILANCE

Population ageing is one of the most significant social transformations of the twenty-first century, and globally, the increasing number of people aged 80 years or over, is faster than the number of older persons overall.

These increase in average life expectancy was a successfully challenge achieved in the modern world. However, nowadays a new challenge arise for all the society: achieving a better quality of life for increasing people's life.

Drug-related problems in older patients, have been reported to account for a large percentage of emergency treatment and hospitalizations, increasing the costs with health in the most aged regions.

United Nations, World Population Prospects. Key findings and Advance tables: The 2015 Revision.

Mjörndal, T., et al. Pharmacoepidemiology and drug safety, 2002. 11(1): p. 65-72.



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**Active Pharmacovigilance
Programmes in Geriatrics**

FARMACOVIGILÂNCIA: ENVOLVER O CIDADÃO

COMEMORAÇÃO DOS 30 ANOS
DO INFARMED, I.P.

Muito Obrigada
Thank You!

Fátima Roque

froque@ipg.pt