

Active and Healthy Ageing: the European Innovation Partnership

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Steering Committee EIP on AHA



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NINTH WORLD CONFERENCE ON THE FUTURE OF SCIENCE

Secrets of Longevity

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Italian Medicines Agency



Università degli Studi di Brescia



Agenzia Italiana del Farmaco
AIFA

Ageing Headlines!

- Life expectancy in most European countries is increasing now by five hours a day. It is clear that within the next fifty years the population of Europe will contain a much greater share of older people, but what is less clear is whether people will age in good health or in poor health
- **"Population ageing will fundamentally change the lives of Europeans"**
- **From an economic standpoint, preventive strategies are considered the most cost-effective solution to the problem of disability in the elderly**

Promote active and healthy ageing: the help of innovation

- Research and community make efforts to point out **ways to transform unsuccessful aging**, a complex mixture of morbidity, social isolation, poverty, and invisibility **into a successful period of life**
- **Innovative approaches able to improve quality of life** are needed in order to prevent development of chronic diseases and to optimize opportunities for health, delaying the onset of frailty and dependency of elderly
- **The EU is taking innovative steps to promote quality of life in elderly, engaging public and private partners to support promotion of healthy lifestyles**



Europe 2020

Europe 2020 is the EU's growth strategy for the coming decade. The Union has set five ambitious objectives - on employment, innovation, education, social inclusion and climate/energy - to be reached by 2020.

Innovation
union

The Innovation Union aims to improve conditions and access to finance for research and innovation in Europe to keep up with ageing population and strong competitive pressures from globalisation.

European Innovation
Partnership (EIP) on
Active and Healthy
Ageing (AHA)

European Innovation Partnerships (EIPs) are a new approach to EU research and innovation, challenge-driven and focusing on societal benefits

Strategic Implementation Plan

Action Plan A1
Prescription and
adherence action
at regional level

Action Plan A2
Falls Prevention

Action Plan A3
Prevention of
functional decline
and frailty

Action Plan B3
Integrated Care

Action Plan C2
Independent Living

Action Plan D4
Age-friendly
Environments



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European Innovation Partnership on Active and Healthy Ageing



Headline target by 2020:

increasing the number of healthy life years (HLYs) by 2 in the EU on average

European Innovation Partnership on Active and Healthy Ageing (EIP on AHA)

A triple win for Europe

- Enabling EU citizens to **lead healthy, active and independent lives until old age**
- Improving the sustainability and efficiency of **social and health care systems**
- Developing and deploying **innovative solutions**, thus enhancing the competitiveness of EU industry through an improved business environment providing the foundations for growth and expansion of new markets, networking with partners worldwide (particularly with the U.S.)



Thematic priority 1

Innovation in support of

AWARNESS, PREVENTION & EARLY DIAGNOSIS

Thematic scope for actions

- Disease prevention - primary & secondary prevention (lifestyles, early diagnosis, screening, nutrition, physical exercise)
- Health literacy
- Medication compliance/adherence
- Older people's functionality including loss of cognitive functions and frailty

Thematic priority 2

Innovation in support of CARE & CURE

Thematic scope for actions

- Continuum of care
- Multimorbidity
- Chronic disease management
- Business models for more collaborative care systems
- E-health and tele-medicine
- HTA and evidence
- Clinical guidelines

Thematic priority 3

Innovation in support of INDEPENDENT LIVING

Thematic scope for actions

- ICT enabled products, services and devices for active and independent living
- European or global standards and interoperability
- Innovative use of public procurement schemes (inc. pre-commercial procurement)
- Involvement of users across the entire innovation process

Six agreed Actions

1. **"Prescription adherence action at regional level"** - within the "Health literacy, patient empowerment, ethics and adherence"
2. **"Program for falls prevention and early diagnosis"** - within the "Innovation-enabled personal guidance systems"
3. **"Early diagnosis and intervention action on frailty and malnutrition to prevent functional decline among older people"** - within the "Disease prevention, early diagnosis of functional decline"
4. **"Replicating and tutoring integrated care for chronic diseases, including remote monitoring in at least 50 regions and available to at least 1 million patients"** - within the "Capacity building for successful integrated care systems"
5. **"Global standards development, guidelines for business models and financing for independent living"** - within the "Flexible and interoperable ICT solutions for active and independent living"
6. **"Creation of age-friendly environments for older persons"**



Italian Areas of interest

- Italy has interest in all areas of the 6 agreed actions
- Many Italian Regions, Institutions and Companies are already working at numerous projects
- The Italian Ministry of Health, in September 2011 chose 3 areas of interest:
 - 1. Prescription adherence action at regional level**
 - 2. Early diagnosis and intervention action on frailty and malnutrition to prevent functional decline among older people**
 - 3. Global standards development, guidelines for business models and financing for independent living**



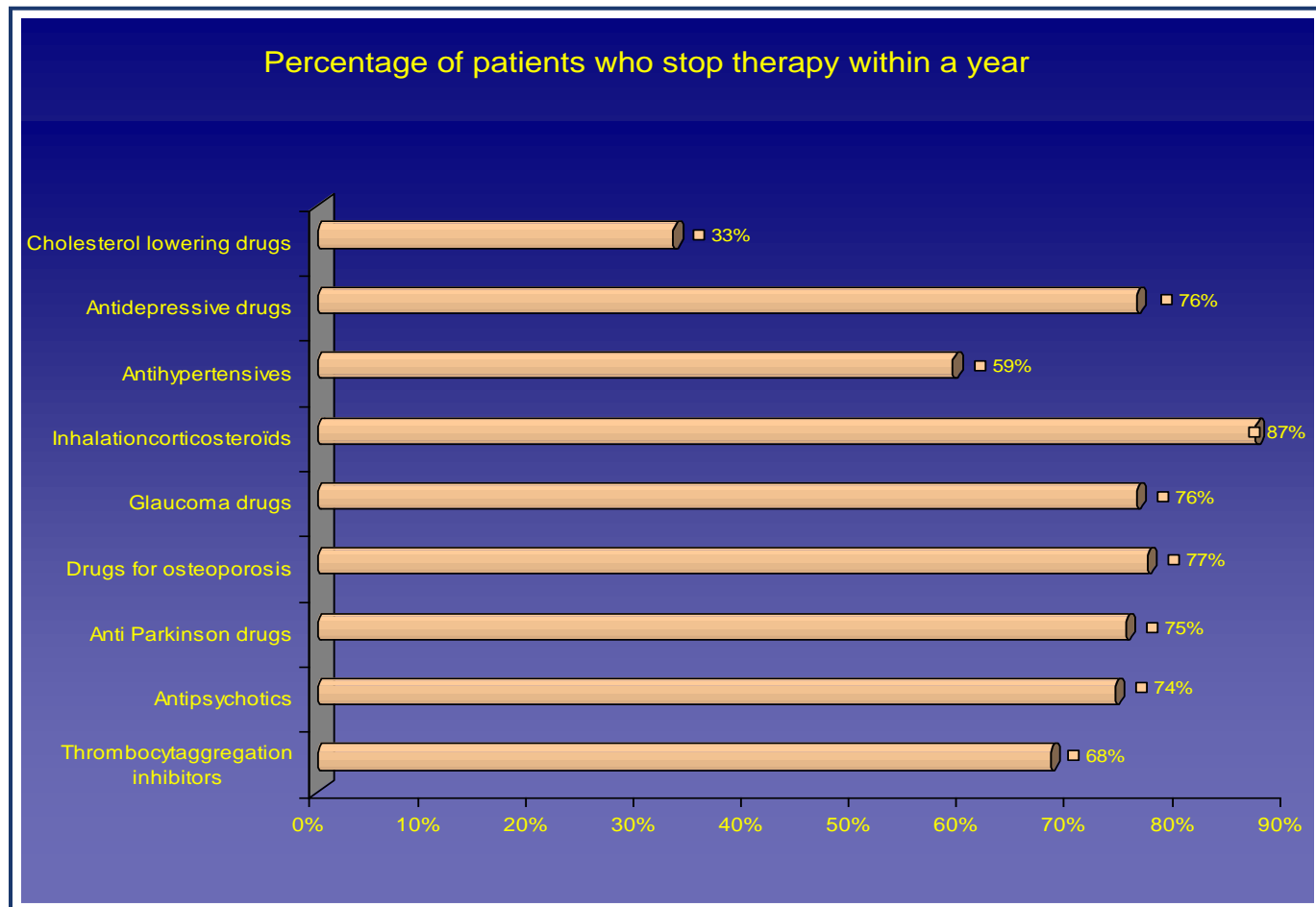
Adherence to treatment

- Poor adherence has been identified by the WHO as a **growing global problem** which **could severely compromise the effectiveness** of treatment
- The achievement of an adequate level of adherence means more than just following physician instructions but also it depends on the adoption of a range of **virtuous behaviors at individual and social level**
- In older people a poor adherence to pharmacological treatment has been reported in 26 - 59% of cases and is associated with a decline in clinical outcome, with consequent increase of health expenditures
- Non-adherence negatively impacts individual quality of life and healthcare systems sustainability



And it is an almost universal problem....

Different categories of drugs and Adherence



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Herings et al. On Chronic Pharmacotherapy. Report 2002

Better compliance to antihypertensive medications reduces cardiovascular risk

- 242,594 pts newly treated for hypertension in 2000-2001 followed until 2007
- 27% of the patients began therapy with a combination of two or more antihypertensive medicines
- During follow-up almost one-half of the patients experienced therapy with at least three antihypertensive medicines
- Co-treatments with lipid-lowering agents were experienced by more than one out of four patients and in more than 10% of the population other cardiovascular medicines were prescribed
- About 13% of the patients had at least one sign of comorbidity
- **190,977 (79%) experienced at least one episode of treatment discontinuation (discontinuers)**
- **Persistent patients had a 37% reduction in risk compared with discontinuers**

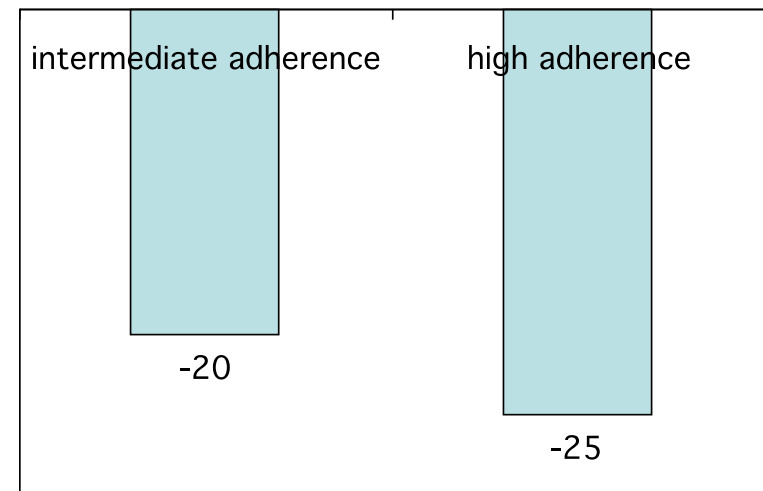
Discontinuation and very low or low levels of coverage with antihypertensive therapy were more common in:

- **women**
- **younger patients**
- **patients who began therapy with a combination of 2 or more antihypertensive agents**
- **patients who did not concomitantly use lipid-lowering agents, antidiabetic or other cardiovascular medicines**

Better compliance to antihypertensive medications reduces cardiovascular risk

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- About 13% of the patients had at least one sign of comorbidity
- 12,016 pts experienced the outcome (CV event)
- **20%-25% reduced risk of cardiovascular events in pts with intermediate and high adherence compared to those with low adherence**

Reduction in risk of CV events in pts with intermediate and high adherence compared to those with low adherence



Source: Corrao et al, Journal of Hypertension, 2011

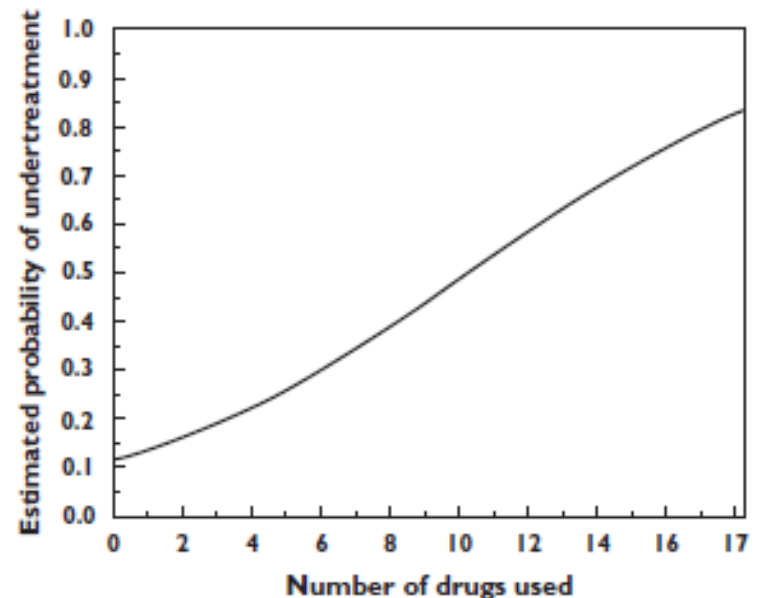
Adherence: a benchmark for Active and Healthy Ageing

- Demographic and epidemiological changes have produced a society with a growing share of elderly people
- Chronic diseases are the leading cause of mortality and morbidity in Europe, an even larger burden in the future is expected
- It's been estimated that about 39% of elderly population may be exposed to polypharmacy at least once in their life
- Polypharmacy increases the risk of adverse drug reactions and poor health outcomes such as falls, hospitalization and death



Relationship between polypharmacy and underprescribing

- Polypharmacy is common among the elderly
- Underprescribing is also frequent
- Optimizing polypharmacy included avoiding underprescription
- 43% of patients who used five or more medicines are undertreated
- In undertreated patients a mean of 1.4 medicines were lacking
- The probability of underprescription increases with the number of drugs used



PIM, Under-prescribing and Polypharmacy

To obtain optimal prescription, it is necessary for physicians to have a good understanding of the pathophysiology of the disease, the changes in pharmacology with increasing age.

- A study from 2012 with frail elderly persons (above 75 years of age) admitted acutely to a hospital were screened for potentially inappropriate medications (PIM). **PIM** was significantly associated with polypharmacy (more than five daily medications; OR 1.9, 95% CI 1.1-3.5 and $p = 0.026$).*
- Another study showed a relationship between under-prescribing and polypharmacy. Patients with five or more medications were more likely to be under-treated than patients with four medications or less (OR 4.8, 95% CI 2.0-11.2).**

*Dalleur O, Spinewine A, Henrard S, Losseau C, Speybroeck N, Boland B. Inappropriate prescribing and related hospital admissions in frail older persons according to the STOPP and START criteria. *Drugs Aging* 2012 Oct;29(10):829-37.

**Kuijpers MA, van Marum RJ, Egberts AC, Jansen PA. Relationship between polypharmacy and underprescribing. *Br J Clin Pharmacol* 2008 Jan;65(1):130-3.



Number and Type of Reports on Packaging

Some medicine users experience considerable difficulties with the packaging of their drugs: one of the major issues is opening a blister package.

Packaging of pharmaceuticals needs more attention: issues need to be addressed by the pharmaceutical manufacturers, registration authorities and community pharmacists.

Type	n (%)
Difficulty opening the package	359 (59.9)
blister packs	277 (46.2)
tablet container or bottle	29 (4.8)
suppositories, ovules, rectioles, eye drops, granules, tube	44 (7.3)
package form unknown	9 (1.5)
Other problems with use	188 (31.4)
package too large or too few doses per package	78 (13.0)
preference for different packaging	51 (8.5)
perforation of the blister pack	22 (3.7)
package unit does not match use	18 (3.0)
quality/vulnerability of package	11 (1.8)
tablet dosage does not match use	8 (1.3)
Problems with appearance (printed text and information leaflet)	52 (8.7)
printed text unclear	34 (5.7)
appearance of package/dosage confusing	14 (2.3)
package leaflet	4 (0.7)

The Italian Medicines Agency

The Italian Medicines Agency (AIFA), as national authority responsible for drugs regulation in Italy, is continuously committed to promote good health through medicines and to manage the value of medicinal treatments.

AIFA focused its interest on the first area “**Prescription adherence action at regional level**” and submitted its **Commitment** on 31st May 2012



High Prevalence of Poor Quality Drug Prescribing in Older Individuals: A Nationwide Report From the Italian Medicines Agency (AIFA)

Graziano Onder,¹ Stefano Bonassi,² Angela M. Abbatecola,³ Pietro Folino-Gallo,⁴ Francesco Lapi,⁵ Niccolò Marchionni,⁶ Luca Pani,⁴ Sergio Pecorelli,⁴ Daniele Sancarlo,⁷ Angelo Scuteri,⁸ Gianluca Trifirò,⁹ Cristiana Vitale,² Stefano Maria Zuccaro,¹⁰ Roberto Bernabei,¹ and Massimo Fini²; on behalf of the Geriatrics Working Group of the Italian Medicines Agency (AIFA)

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²Scientific Direction, IRCCS San Raffaele Pisana, Rome, Italy.

³Scientific Direction, Italian National Research Center on Aging (INRCA), Ancona, Italy.

⁴Agenzia Italiana del Farmaco (AIFA), Rome, Italy.

⁵Department of Preclinical and Clinical Pharmacology, University of Florence, Italy.

⁶Unit of Gerontology and Geriatric Medicine, University of Florence, Italy.

⁷Department of Medical Sciences, IRCCS Casa Sollievo della Sofferenza, San Giovanni Rotondo, Foggia, Italy.

⁸UOC Geriatria, Italian National Research Center on Aging (INRCA), Rome, Italy.

⁹Department of Clinical and Experimental Medicine, University of Messina, Italy.

¹⁰UOC Geriatria, Ospedale Israelitico, Rome, Italy.



The OsMed (AIFA) Study on Drug Quality Prescribing in the Older Population in Italy

- Aim: to assess the quality of drug prescriptions to the older (65+) Italian population.
- AIFA database of more than 1 billion drugs dispensed in year 2011, from a population of 11,593,989 individuals aged 65 years or older, representing 94.2% of the Italian residents of this age group, was used
- The information provided by 13 Quality Indicators, selected from a preliminary list of 74, allows the identification of critical issues concerning drug prescribing in Italy.



The OsMed (AIFA) Study on Drug Quality Prescribing in the Older Population in Italy

- Six major domains (polypharmacy, adherence, prescribing cascade, undertreatment, potential drug–drug interaction, drugs to be avoided), were assessed, identifying the occurrence of erroneous or risky prescriptions and suboptimal prescribing.
- Highly prevalent quality indicators, including polypharmacy and poor adherence, might be addressed by particular interventions.
- Such interventions will be developed in the context of the Action Group A1 of the European Innovation Partnership on Active and Healthy Ageing supported by the European Commission



The OsMed (AIFA) Study on Drug Quality Prescribing in the Older Population in Italy

This approach highlighted the huge dimension of suboptimal drug prescribing in older adults, a finding demanding the urgent implementation of national educational programs, targeted at increasing an appropriate use of medicines.



Action Plan A1 - Prescription and adherence action at regional level

The three coordinators of the partners involved in the A1 are:

LST Madrid

NHS Scotland Third
Sector Organization

AIFA Consortium

IRCCS San Raffaele Pisana, Rome, Italy

The Division of Geriatric Medicine and Cardiology,
the University of Florence, Italy

University Medical Center Groningen, The
Netherlands

Università Cattolica del Sacro Cuore at Policlinico
Gemelli of Rome

Gestione Sistemi per l'Informatica (GESI), Rome,
Italy

The Department of Neurological Sciences and DEIS
University of Bologna, Italy

Merck Serono Rome, Italy and Merck Serono
Geneva, Switzerland

National Centre for Scientific Research-NCSR,
Greece

Philips Research, Eindhoven, The Netherlands

European Generic medicines Association - EGA

European Patients' Forum – EPF

GlaxoSmithKline-GSK, European Office, Brussels,
Belgium

ASL Brescia

Pfizer Italy

GIRP-European Association of Pharmaceutical Full-
line Wholesalers, Brussels, Belgium

CIRFF, University of Naples/Campania Region, Italy



Action Plan on "Prescription and adherence action at regional level", the AIFA Consortium Partners

Monitoring adherence by the use of observational data in order to have a complete picture of the state of play of adherence in the older population, the AIFA Consortium is going to track adherence through databases.

The specific aims of the Consortium coordinated by AIFA:

- Monitoring adherence through administrative observatories and databases
- Monitoring adherence through cohort data and randomized clinical trials (RCT)
- Monitoring adherence in specific chronic diseases
- Monitoring appropriateness and polypharmacy
- Evaluation of poor adherence and inappropriate prescribing
- Investigation of the correlation of adherence with specific clinical outcomes
- Empower patients and their careers
- Development and implementation of education programs
- Implementation of determinant number of SMS reminders or specific devices
- Implementation of older persons friendly packaging, formulations or containers
- Follow-up of implemented strategies through identification of indicators, progress monitoring, identification of key gaps and difficulties
- Data analysis, results presentation and reports

AIFA Consortium: step-wise approach

Steps	Strategies	Partners	Time frame
First – Monitoring / Observational data	<p>1) Monitoring adherence through the utilization of observatories and databases. Collecting all prescription data, data regarding drugs dispensed by pharmacies, monitoring further prescriptions of the same patient and disease, admissions of these patients to hospital and diagnosis, registration of negative clinical outcome.</p> <p>2) Identification of causes of poor adherence- establish risk definitions to tailor interventions</p> <p>3) Evaluation of adherence-patients clinical outcome correlation</p>	<p>e.g. SeBA study</p> <p>IRCCS S. Raffaele Pisana Universities :Florence, Groningen, UCSC , Bologna, Napoli. GESI- Rome Merk Serono NCSR-Greece Philips Research Eindhoven EGA EPF GSK ASL Brescia Pfizer Italy GIRP Bruxelles Belgium</p>	2013-2014
Second – Development and implementation of interventions	<p>1) Implementation of Interventions addressed to improve poor adherence</p> <p>a)Empower patients and their careers b)Development and implementation of education programs c)Implementation of determinant number of SMS reminders, GESI Health KIT devices or other specific device d) Implementation of older persons friendly packaging, formulations or containers (with or without reminders)</p> <p>2) Follow-up of implemented strategies</p> <p>a)identification of indicators b)progress monitoring c)identification of key gaps and difficulties</p>		2014-2015
Third – Data analysis	1)Data analysis, results presentation and final report		2014-2015

AIFA Consortium: step-wise approach

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Assessment of Adherence and Polypharmacy in real practice (ASAP project)

ASsessment of Adherence and Polypharmacy in real practice (ASAP project)

AIMS:

- 1.To design analytical methods for assessing the appropriateness of drug prescription to older population in Italy
- 2.To determine the impact of appropriateness of drug prescription on clinical outcomes in older populations in Italy

Participants: AIFA, UCSC, University of Florence, University of Brescia, IRCCS S. Raffaele Pisana

AIFA Consortium: step-wise approach

Steps	Strategies	Partners	Time frame
First – Monitoring / Observational data	<p>1)Monitoring adherence through the utilization of observatories and databases. Collecting all prescription data, data regarding drugs dispensed by pharmacies, monitoring further prescriptions of the same patient and disease, admissions of these patients to hospital and diagnosis, registration of negative clinical outcome.</p> <p>2)Identification of causes of poor adherence- establish risk definitions to tailor interventions</p> <p>3) Evaluation of adherence-patients clinical outcome correlation</p>	IRCCS S. Raffaele Pisana Universities :Florence, Genova, Udine, Bari	2013-2014
Second – Development and implementation of interventions	<p>1) Implementation of Interventions to improve poor adherence</p> <p>a) Empower patients and their caregivers</p> <p>b) Development and implementation of educational materials</p> <p>c) Identification of barriers to adherence</p> <p>d) Identification of facilitators to adherence</p> <p>2) Follow-up of implementation</p> <p>a) identification of indicators</p> <p>b) progress monitoring</p> <p>c) identification of key gaps and needs</p>	Multidisciplinary and Comprehensive Approach based on Case management in community care (MY COACH project)	
Third – Data analysis	<p>1)Data analysis, results presentation and final report</p>		2014-2015

Case Multidisciplinary and COmprehensive Approach based on Case management in community care (MY COACH project)

Objective:

to develop, validate and implement **case management programs combined with comprehensive geriatric assessment** to improve quality of care in older adults with complex clinical conditions.

This approach will be combined with prescription support systems (i.e. Computerized Prescription Support Systems), to improve appropriateness of prescribing and adherence.

Funding: Application to EU grant
(second programme of community action 2008-2013)



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Data source

Integration of administrative archive databases

LOCAL HEALTH UNITS BENEFICIARIES' AND MORTALITY

- date of birth
- gender

PHARMACY CLAIMS

- prescribed drug
- date of prescription
- drug price
- nr. of packages
- dose

HOSPITAL DISCHARGE

- main diagnosis
- secondary diagnosis
- type of hospitalization
- date of admission
- DRG payment

OUTPATIENTS DIAGNOSTIC TESTS

- type of service
- date of service
- cost of service

patient's code

patient's code

patient's code

patient's code

patient's code



POPULATION DATABASE

patient's code

structural characteristics
trend of prescriptions
admissions to hospitals
lab tests results



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Expected results

- Improvement of adherence to treatment of chronic diseases and drug consumption rationalization
- Market opportunities for old and new companies in partnership with the health system
- Spread of the results at national and international level with the possibility to "export" our experience to other European areas, which can adopt this model adjust to their needs



Novel initiatives to increase the participation of the elderly in RCTs

- The EU-funded development of a Charter in order to promote participation
- Geriatric medicines strategy of European Medicines Agency (EMA)
- Geriatric Expert Group of European Medicines Agency (EMA)



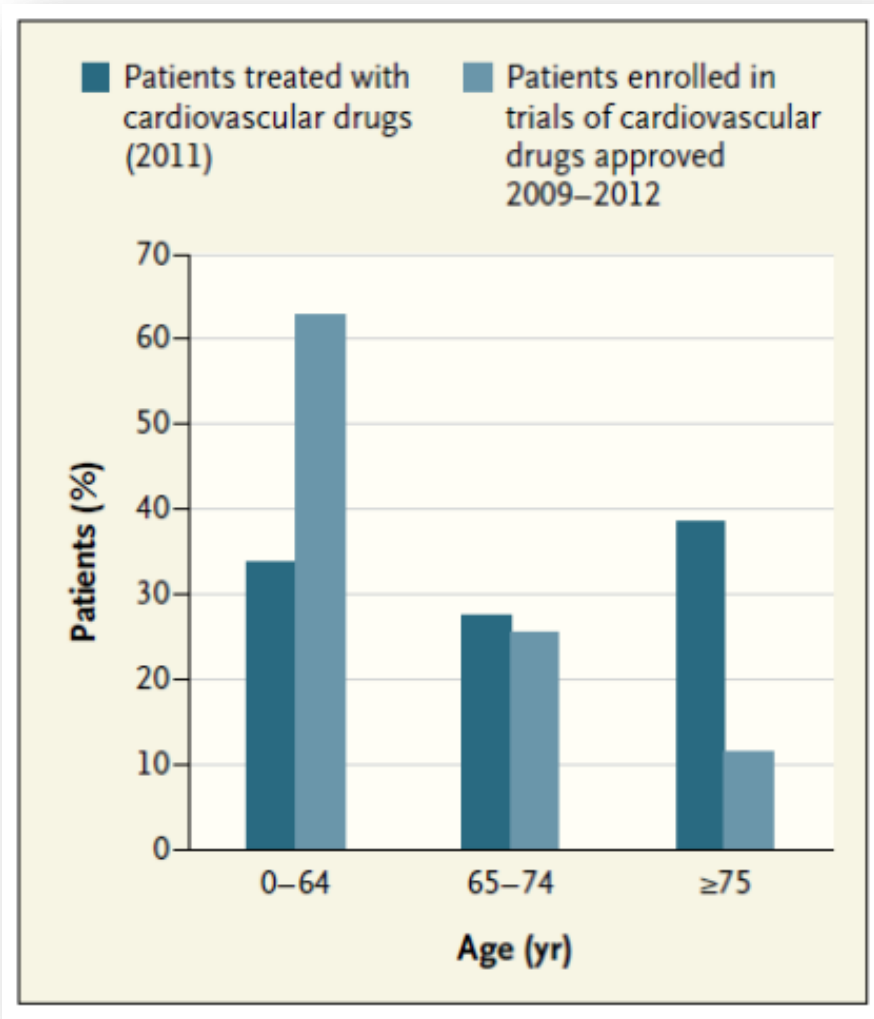
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Participation of elderly in clinical trials

Despite their large consumption of medicines and the fact that up to almost half of the total pharmaceutical expenditures is spent on the elderly, they are still underrepresented in clinical trials.

The figure represents the percentage of patients enrolled in clinical trials of cardiovascular drugs compared to the percentage of patients treated with this medicines.



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).

Exclusion Criteria	No. (%) of Trials*
Inability to give informed consent	242 (85.5)
Age, y	204 (72.1)
<16	170 (60.1)
>65	109 (38.5)
Sex	133 (47.0)
Related to female sex	111 (39.2)
Female sex	19 (6.7)
Pregnancy	90 (31.9)
Lactation	41 (14.5)
Lack of contraception use	25 (8.8)
Menopausal status	11 (3.9)
Related to male sex	22 (7.8)
Medical comorbidities	230 (81.3)
Unspecified medical condition	87 (30.9)
Nephrological	74 (26.1)
Infectious	69 (24.4)
Cardiac	69 (24.4)
Hepatic	63 (22.3)
Hematological	59 (20.8)
Malignancy	46 (16.3)
Neurological	43 (15.2)
Endocrine	43 (15.2)
Psychiatric	42 (14.8)
Substance abuse	37 (13.1)
Cerebrovascular	35 (12.4)
Decreased life expectancy	34 (12.1)
Poorly controlled hypertension	28 (9.9)
Physical disability or functional status	31 (11.0)
Pulmonary	29 (10.2)
HIV or AIDS	25 (8.9)
Rheumatological	22 (7.8)
Cognitive impairment	22 (7.8)
Musculoskeletal	13 (4.6)
Peripheral vascular	12 (4.2)
Dermatological	11 (3.9)
Medication-related	153 (54.1)
Socioeconomic status	39 (13.8)
Communication or language barrier	30 (10.6)
Participation in other trials	20 (7.1)
Ethnicity	6 (2.1)

Abbreviation: HIV, human immunodeficiency virus.
*Denominator is category-specific.

	No. (%) of Trials*
Grading of individual exclusion criteria	
Total number of exclusions	2709 (100.0)
Strongly justified	1275 (47.2)
Potentially justified	430 (15.9)
Poorly justified	1004 (37.1)
At least 1 poorly justified exclusion criterion	238 (84.1)
Category with poor justification	
Age	160 (78.4)
Medical comorbidity	149 (64.8)
Sex	70 (52.6)
Females	69 (62.2)
Males	1 (4.5)
Medication-related	56 (36.6)
Socioeconomic status	31 (79.5)
Percentage of poorly justified exclusion criteria	
≥10	228 (80.6)
≥25	174 (61.5)
≥50	83 (29.3)
≥75	24 (8.5)
Exclusions per trial, mean (SD)	9.5 (6.1)

*Unless otherwise indicated.



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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



Civil society's challenge



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