EXISTING HEALTH ECOSYSTEMS AND PROJECTS IN HEALTHY LIVING AND ACTIVE AGEING

Alessandro Monaco - Project Chief Executive

15 October 2015, Valencia

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Interests in pharmaceutical industry	NO	Currently	Last 2 years	More than 2 years but less than 5 years ago	More than 5 years ago (optional)
Direct interests:					
Employment with a company	X				
Consultancy for a company	X				
Strategic advisory role for a company	X				
Financial interests	X				
Ownership of a patent	X				
Indirect interests:					
Principal investigator	X				
Investigator	X				
Individual's Institution/Organisation receives a grant or other funding	X				

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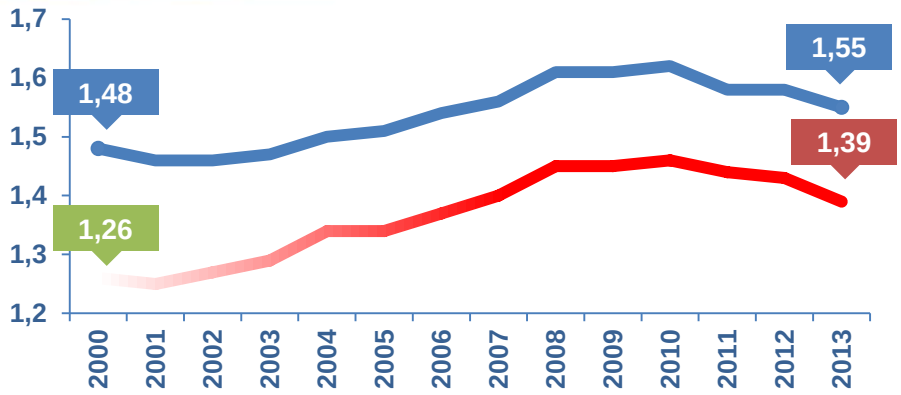
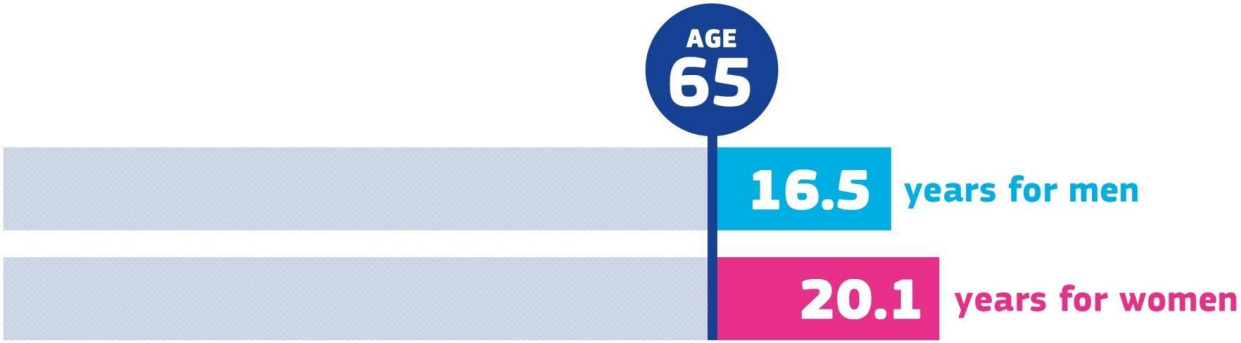
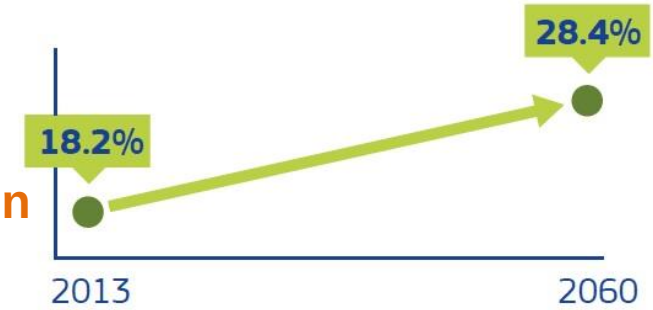


Total Fertility Rate: a european 13 years perspective



Life expectancy at age 65 has increased substantially in European countries

Share of population over 65 is increasing in OECD countries:



Courtesy of the European Commission

Challenges of medicines regulation

Limited resources

Unsustainable healthcare costs

(Highly innovative therapies…)

Challenging assessment of cost/effective ness

(Lack of objective evidences, increasing complexity…)

Conflicting social expectations and demands

"Balancing early market access to new drugs with the need for benefit/risk data: a mounting dilemma"

Hans-George Eichler
Nature Reviews Drug Discovery. Oct 2008; 818.

The strategy of the Italian Medicines Agency

- Efficient resources allocation
- No cross cuts
- Drive of society to reduce uncertainty and increase value in healthcare
- Strategic research of prioritary area of intervention

Adherence to medical treatment: a benchmark for Active and Healthy Ageing?

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

Polypharmacy is one of the main cause of **non-adherence** to medical prescription

Dimension of non-adherence…

Only 50%

of patients typically take their medications as prescribed

Nearly 200.000

premature deaths per year among Europeans are related to non adherence

…and impact on society

Patient health

- Potential harm from sub-optimal management of clinical condition
- Worsening of functional abilities

Health Services Use/Spending

- Cost of medicines dispensed but not used
- Higher medical spending
- Higher inpatient hospital days
- Higher Emergency Dpt visits

Social Engagement/ Productivity

- Reduced social activity and more days away from work derived from poorly managed long-term conditions

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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 Fini[2]; on behalf of the Geriatrics Working Group of the Italian Medicines Agency (AIFA)

Quality Indicator	All Age Groups (≥65 y), n = 12,301,537 (%)	65–74 y, n = 6,154,421 (%)	75–84 y, n = 4,474,887 (%)	≥85 y, n = 1,672,229 (%)
1. Polypharmacy				
5–9 drugs	6,024,383 (49.0)	2,681,639 (43.6)	2,462,378 (55.0)	880,366 (52.6)
≥10 drugs	1,389,591 (11.3)	529,506 (8.6)	629,043 (14.1)	231,042 (13.8)
2. Low adherence to antidepressant drug treatment*	201,290 (63.9)	83,110 (62.6)	82,623 (63.0)	35,557 (69.6)
3. Low adherence to antihypertensive drug treatment*	179,975 (46.4)	84,983 (43.2)	65,450 (47.2)	29,542 (56.1)
4. Low adherence to hypoglycemic drug treatment*	92,017 (63.0)	44,227 (63.0)	35,497 (64.7)	12,293 (70.1)
5. Low adherence to antiosteoporotic drug treatment*	56,621 (52.4)	24,424 (48.7)	24,351 (53.4)	7,846 (64.0)
6. Use of anti-Parkinson and antipsychotic drugs	25,949 (0.2)	10,200 (0.2)	10,625 (0.2)	5,124 (0.3)

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High frequency of suboptimal drug prescribing in older adults

ELSEVIER

JAMDA

journal homepage: www.jamda.com

Brief Report

Advanced Age and Medication Prescription: More Years, Less Medications? A Nationwide Report From the Italian Medicines Agency

Graziano Onder MD, PhD [a,*], Alessandra Marengoni MD, PhD [b], Pierluigi Russo MD, PhD [c], Luca Degli Esposti Econ D, PhD [d], Massimo Fini MD [e], Alessandro Monaco PhD [c], Stefano Bonassi Biol D [e], Katie Palmer PhD [c], Walter Marrocco MD [c], Giuseppe Pozzi MD [f], Diego Sangiorgi MStat [d], Stefano Buda MD [d], Niccolò Marchionni MD [g], Federica Mammarella MD, PhD [a,c], Roberto Bernabei MD [a], Luca Pani MD [c], Sergio Pecorelli MD [c] on behalf of the Geriatrics Working Group of the Italian Medicines Agency (Agenzia Italiana del Farmaco, AIFA) on behalf of the Medicines Utilization Monitoring Center Health Database Network[†]

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The mean number of prescribed medications progressively rise from 1.9 in the age group <65 years to 7.4 in the age group 80-84 years and then declined, with a more marked reduction in the age group 95 years or older with a mean number of 2.8 medications.

EIP on AHA - Action Group A1

63 Main partners/68 Multi-stakeholder commitments/31 Different Countries

	Objectives	Actions	Deliverables
1	Improve patient adherence to care plans, including medication and healthy habits.	Decision support tools (including mobile devices); Dispensing and Prescribing; Interventions; Monitoring	Sms alert, warning signals, sensor prototype, software programmes, lifestyle intervention plans, tele-monitoring electonic device tools, friendly packaging.
2	Empower the patients and caregivers to take care of their health and to be independent	Counselling; Education/Information; Online services; Social networks	«Let me decide» programme for and of life care, Expert Patient programme, public lectures, round table discussions, patient personal health folder, health literacy tool for self-management, combined cultural and physical fitness , PhD programme on ageing for health professionals.
3	Deliver improvements in the health care system to promote adherence	Electronic prescription; Best-practices; Service models; Training	Medicine reconciliation,reshaping care, electronic prescription, poly-pharmacy demonstrator pilots, roll out of emergency care and chronic medication services, advanced care plans for, training programmes for involved professionals, ICT based programs for remote monitoring and multi-disciplinar programmes
4	Contribute to the research and methodology on ageing and adherence	Evidence; Guidelines	Monitoring adherence through databases and observatories, algorithm to identify risk factors for non-adherence, reproducible model for patient centered care, HTA analysis, new guidelines for clinical trials in older people, assessment tools for poor adherence in polypharmacy…
5	Foster communication between different partners/actors in the healing and caring process to improve adherence	Data repository; Networking	European Network supporting clinical trials, web application about adherence levels, web-based social and stakeholder network, ICT and portal communication.

EIP on AHA - Action Group A1

Working Group on adherence to medical plans

Objective	Task
1. To produce/identify a set of indicators to be used for assessing adherence in the older population (independently of the clinical setting)	1.1 Review of literature
	1.1.1 Delphi exercise
	1.2 Collection of databases
	1.3 Assessment of the prevalence of the preliminary set of indicators in different databases
	1.4 Assessment of the association between the identified indicators and clinical outcomes in older adults
	1.5 To produce a final set of indicators to assess polypharmacy and adherence in the older population
2. To produce/identify available tools useful to improve adherence in intervention studies	2.1 Systematic review of the literature
	2.2 Assessment of the usefulness of different interventions aimed at improving adherence on clinical outcomes (including hospitalization, mortality, resources consumption, quality of life, independence) in older adults;
	2.3 To produce/ identify a final set of tools able to improve adherence in the older population

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EU Innovation Partnership on
Active and Healthy Ageing

International Strategic Advisory Board on Adherence (SABA)

	Definition	Target population	Health Professionals	How	Time
Intervention 1	**Comprehensive geriatric assessment (including adherence behaviour)**	All older adults applying to the program	GP+Health care assistant	InterRai + MARS?	Entry (minimum 1/year)
Intervention 2	**Optimize treatment (reduce polypharmacy)**	All older adults applying to the program	GP+Health care assistant	Software + clinical judgement	Entry and as needed (minimum 2/year)
Intervention 3	**Use of adherence aids**	Those with cognitive impairment; disability; social isolation; polypharmacy; unintended non-adherence; those who wish to have it;	Pharmacist, ICT company, Pharma company	Pillboxes, reminders, blistering by the pharmacy	continuosly
Intervention 4	**Patient (and caregiver if needed) education to improve patient empowerment**	Patients and caregivers or all older adults applying to the program and willing to receive the intervention	GP+Health care assistant, Pharmacist, healthcare system, Patients associations	Health Beliefs Model (HBM), training, multilevel interventions	continuosly
Intervention 5	**Physician and other Healthcare professional education**	Physician and other Healthcare professional	Educational professional and professional associations	Cascade model; circle meetings (both focused on improved medication knowledge and communication skill)	continuosly
Intervention 6	**Adherence assessment**	All older adults applying to the program	GP+Healthcare assistant; pharmacist	Objective (drug refill; drug count; clinical assays) and subjective (MARS/communication) evaluation	continuosly
Intervention 7	**Facilitating access to medicine by service**	All older adults applying to the program	GP and pharmacists	ICT, medication delivery, GP-Pharmacist bidirectional	continuosly

The national initiative

SABA

European experts assessing most effective interventions

Institutional workshop

Contextualization of interventions within the national framework

Integration model

Development of a coherent model to integrate specific actions within the NHS

National Strategic plan for Adherence

Agenzia Italiana del Farmaco AIFA

UNIVERSITY OF BRESCIA - HEALTH & WELFARE - UNIVERSITAS STUDIORUM BRIXIAE

FEDERANZIANI SENIOR ITALIA

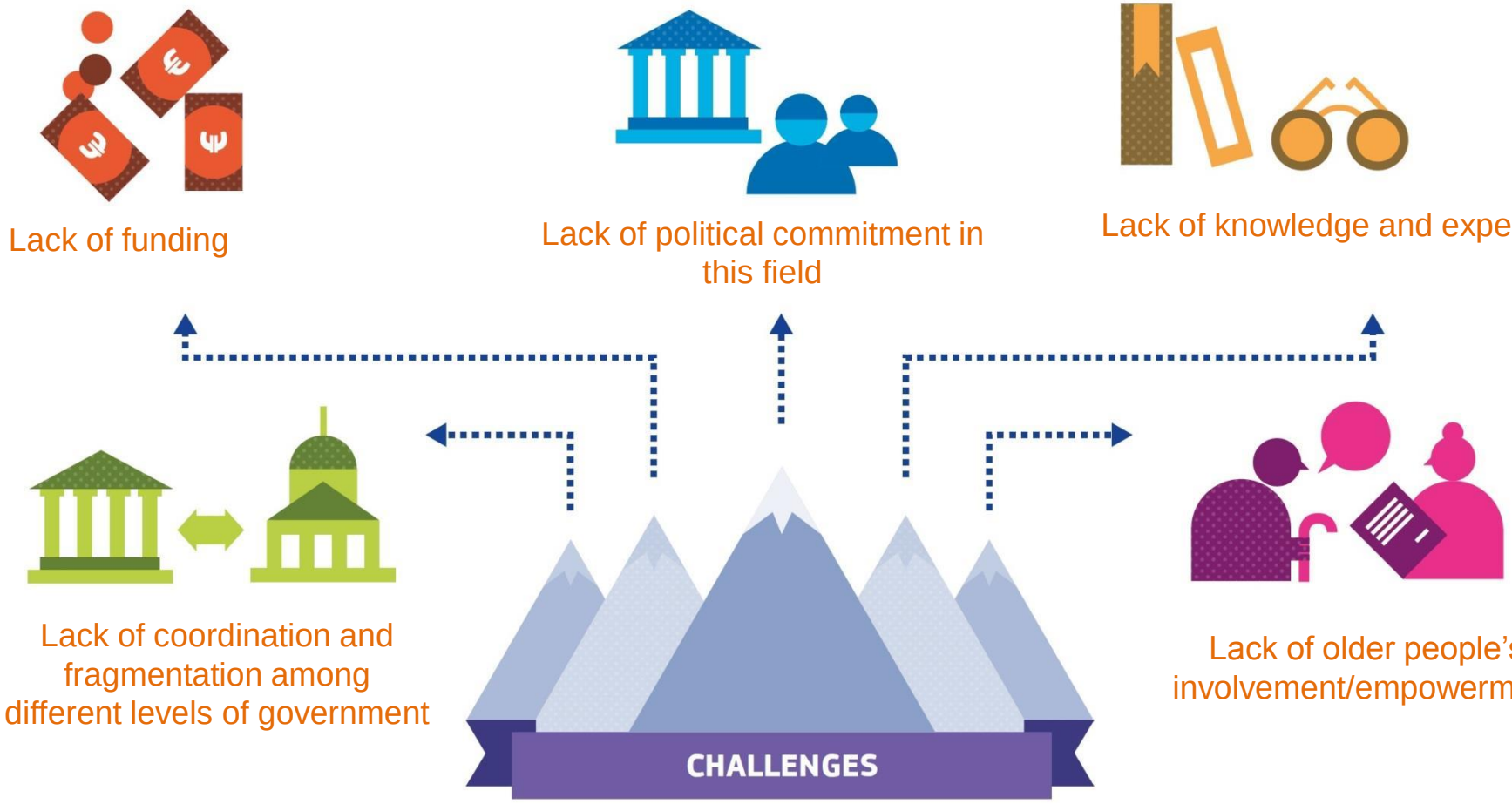
Ministero della Salute

Adherence in Health Policy

- Prescription and Adherence is becoming a **priority included in the political agenda**
  - e.g. Adherence implementation plan in Italy with clinical/economic impact

- In the European Commission, **adherence** has been highlighted as a **priority present in EU funding schemes**
  - e.g. IMI2 (2014-2020)

Challenges to address



Courtesy of the European Commission

Take home messages

1

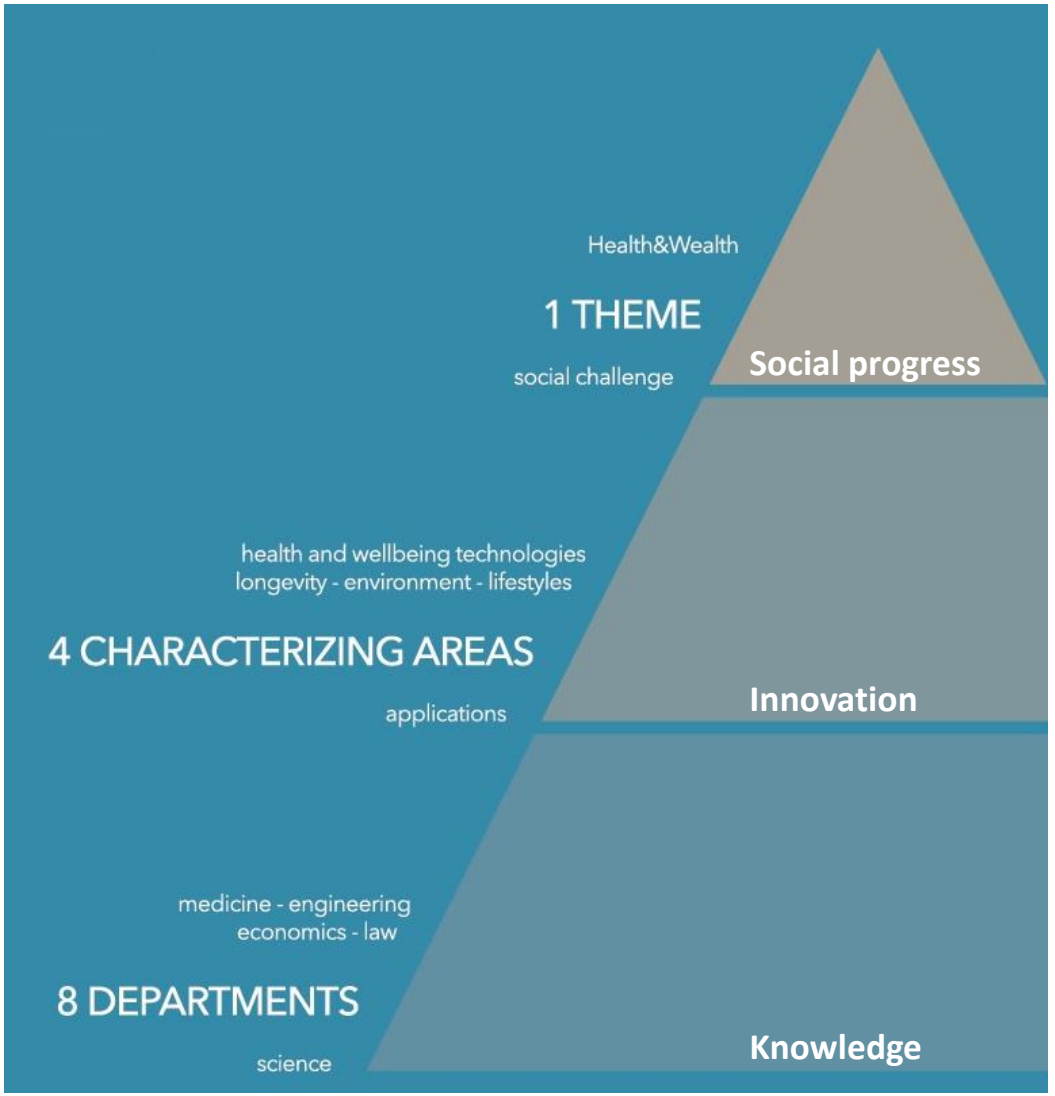
At institutional level there is the pressing need to gurantee access to safe and effective therapies while ensuring system sustainability through innovative models of care and reshaping of healthcare provision

University of Brescia: Health and Wealth

15.000 Students

600 Professors

1st of italian universities' for employment rates



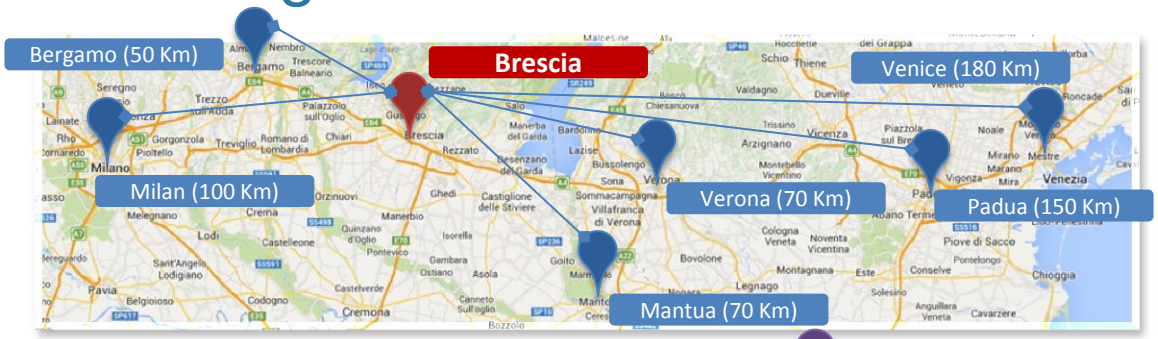
Brescia: a strategic location

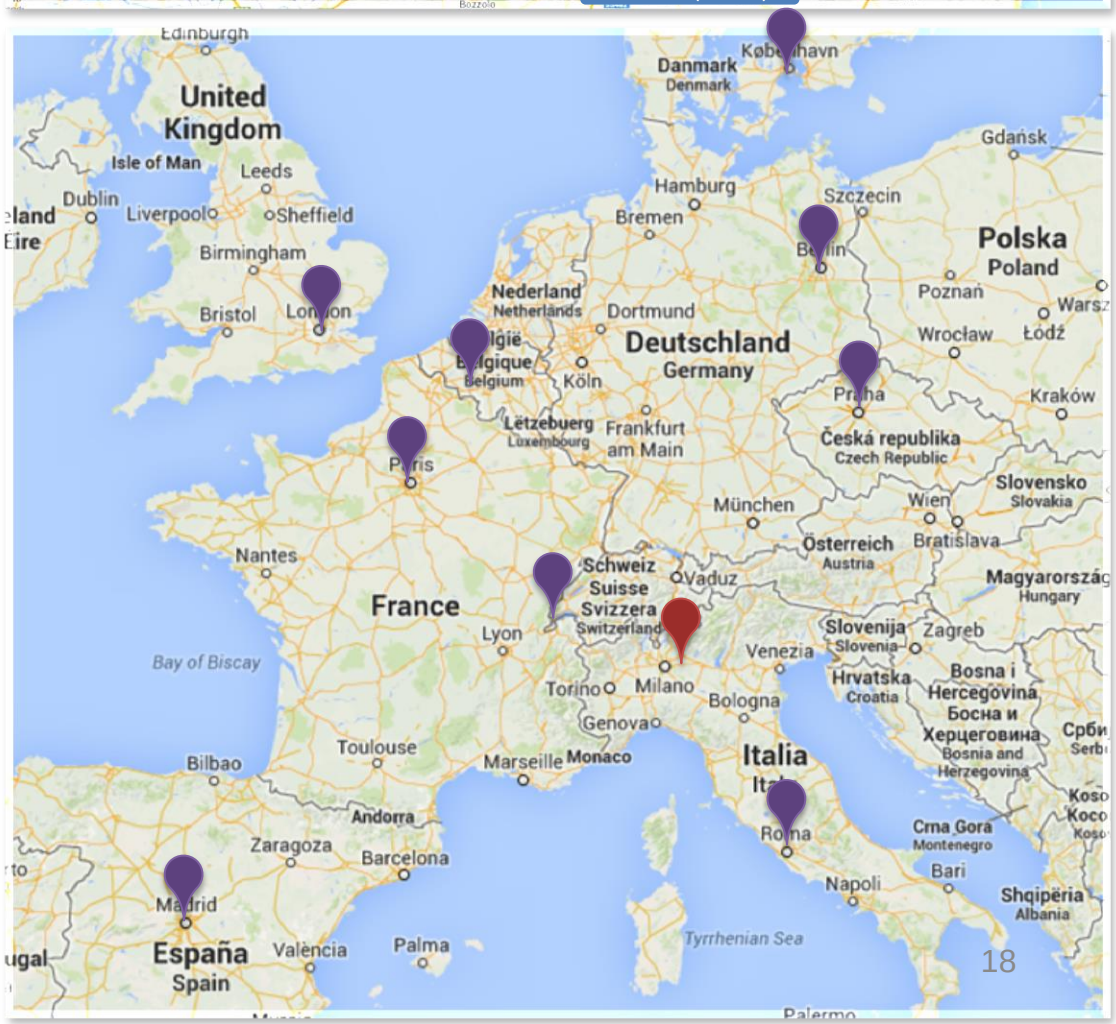
Lombardy region:

- 10 Millions inhabitants
- Highest pro-capite GDP of italy
- Representing 25% of italian GDP

Brescia province:

- Among the highest ranking in Healthcare services
- Among the highest ranking in quality of life
- Highest density of manufacturing industries
- Right in the heart of the european productive system





Project layout

Longevity | Environment | Lifestyle | Technology

Education

Tech transfer

Internationalization

Existing assets:
- Labs
- Projects
- Know how

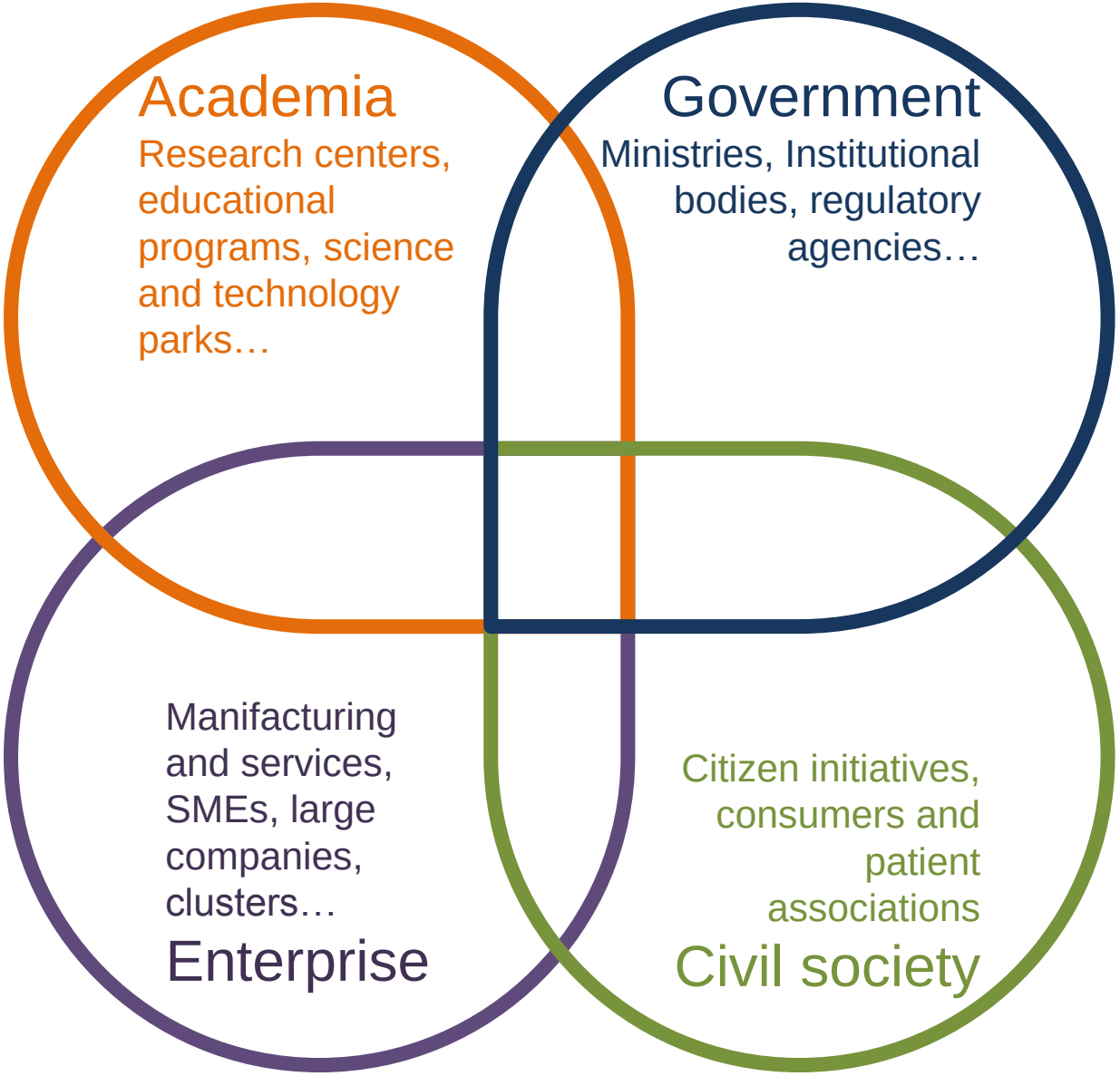
Cutting edge infrastructures

New thematic labs

Prototipal experimental models

Enabling themes

Quadruple Helix Model



Elderly network project (Anziani IN-RETE)

Phase I: Baseline

- Assess global health condition of elderly population in Brescia
- Map the social networks among elderly
- Evaluate the impact of the social network on the health status

Phase II: Follow up

- Impact of the social network on the variation of health status
- Impact of the social network on the adverse event occurred
- Policy indication to improve social network and health services for elderly
- Indicators to measure the economic impact of social inititative

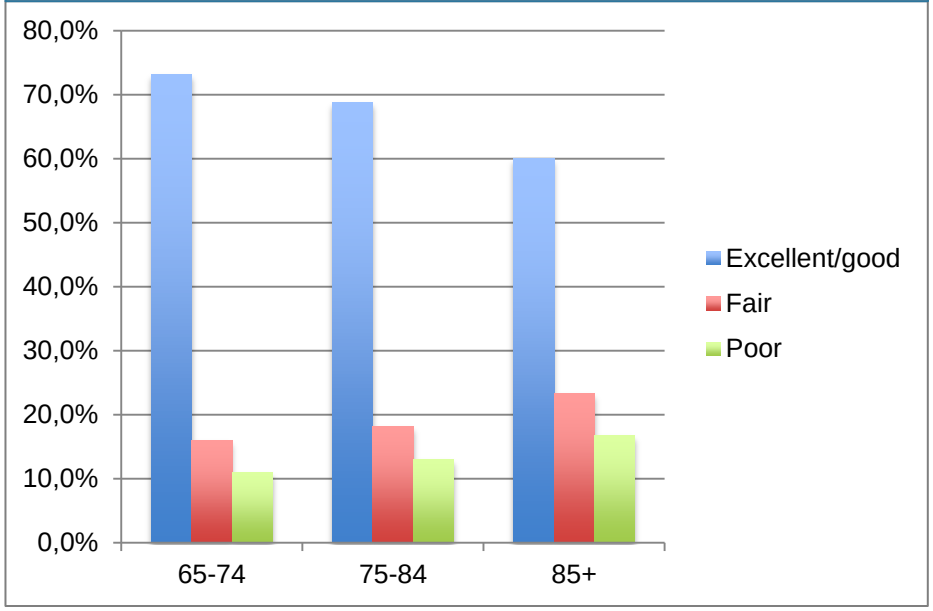
Courtesy of Prof. Alessandra Marengoni, University of Brescia

Elderly network project (Anziani IN-RETE)

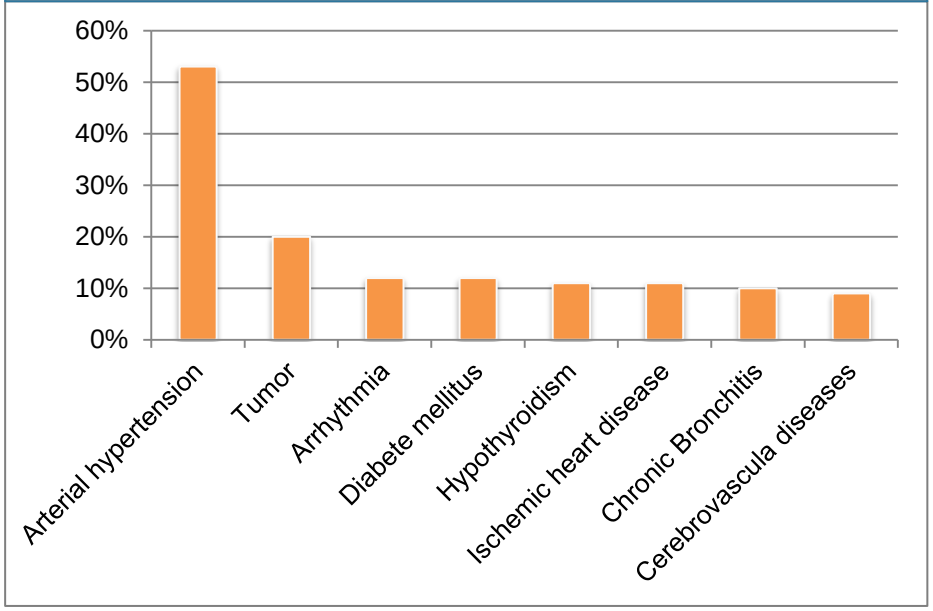
- Participants: 200
- Average age: 77 yrs (65-101)
- 59% Women
- Interview with comprehensive evaluation:
  - Medical condition and drugs
  - Vital parameters
  - Nutritional, functional, cognitive and affective status
  - Geriatric Syndromes, pain
  - Lifestyles Misure di prevenzione
  - Preventive intereventions
  - Formal or informal
  - Social network
- Blood and saliva withdraw

Courtesy of Prof. Alessandra Marengoni, University of Brescia

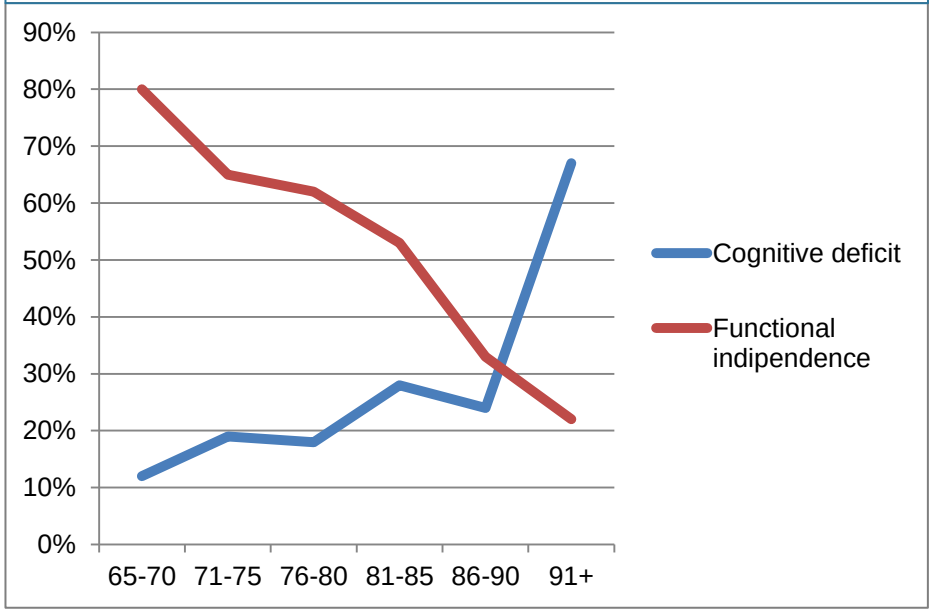
Own perception of health status



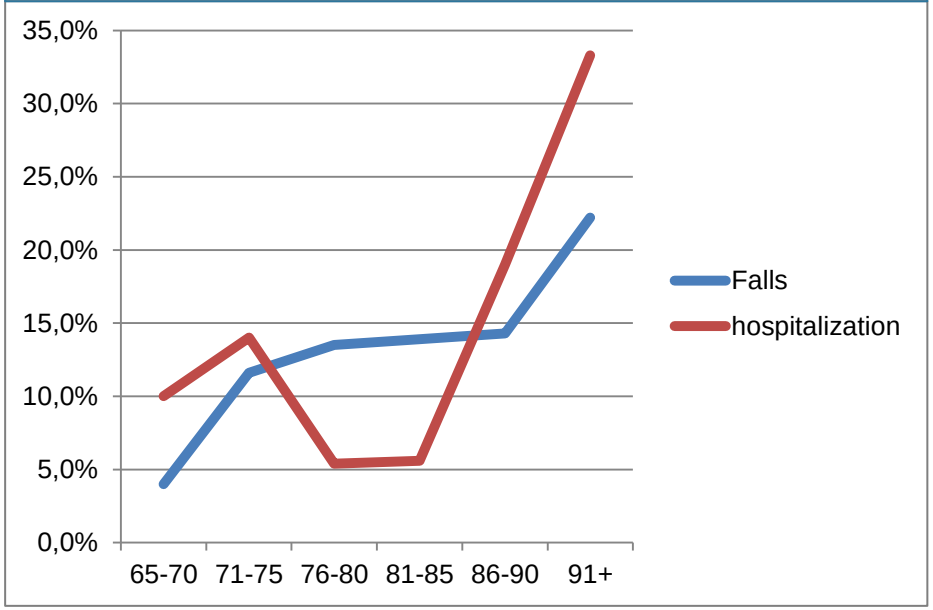
Chronic diseases



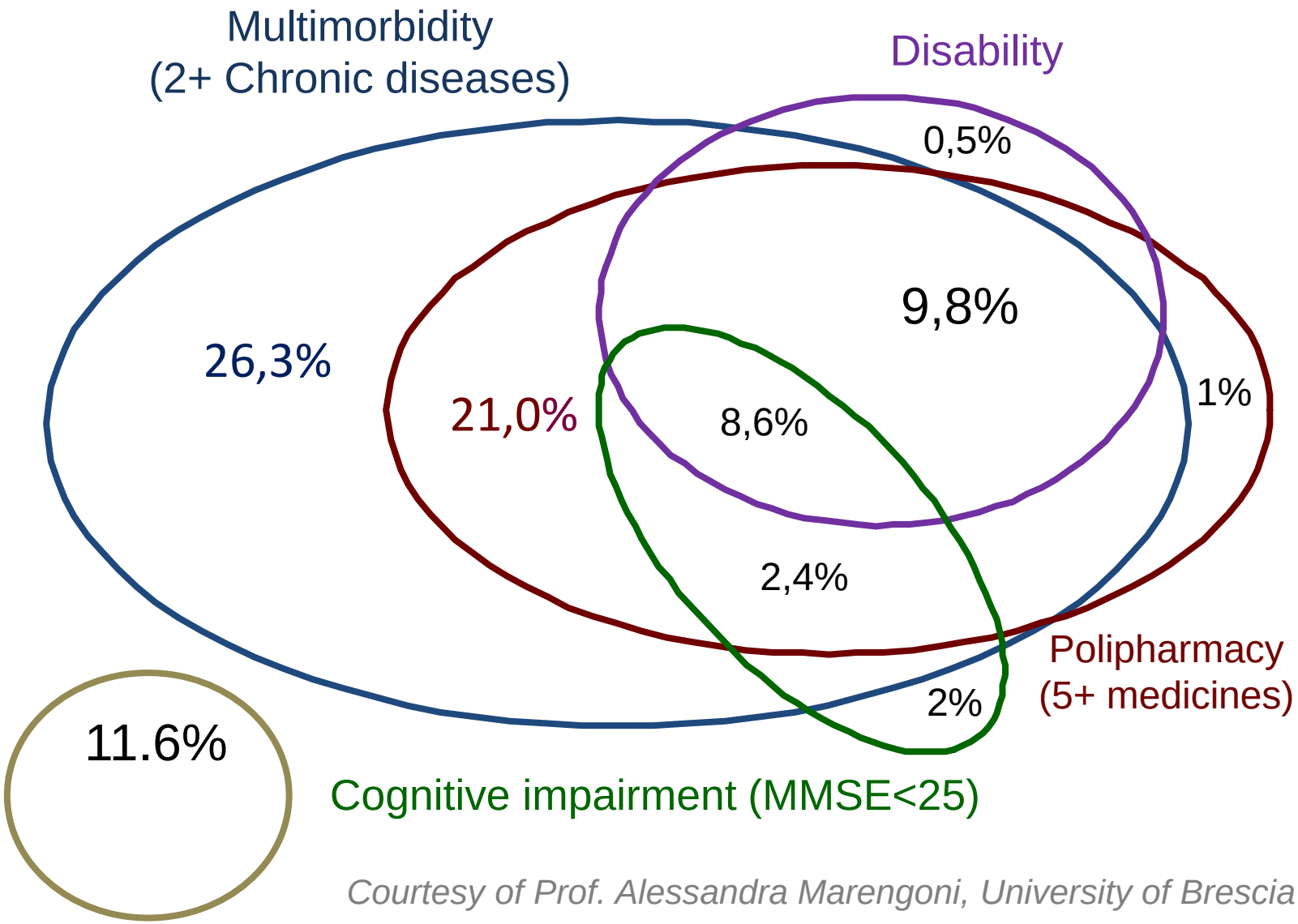
Disability and cognitive deficit



Adverse events



Clusters of medical conditions



Courtesy of Prof. Alessandra Marengoni, University of Brescia

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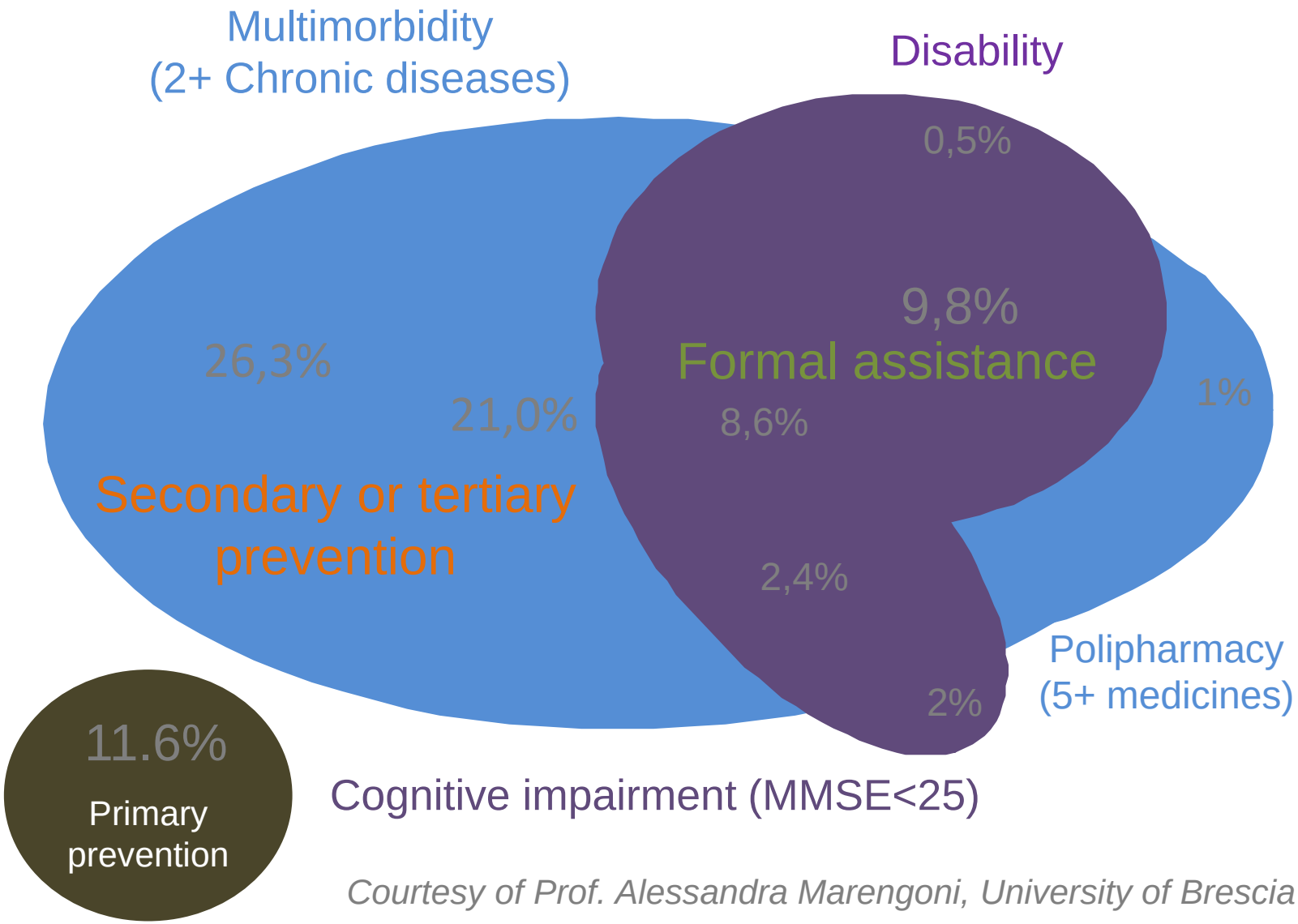

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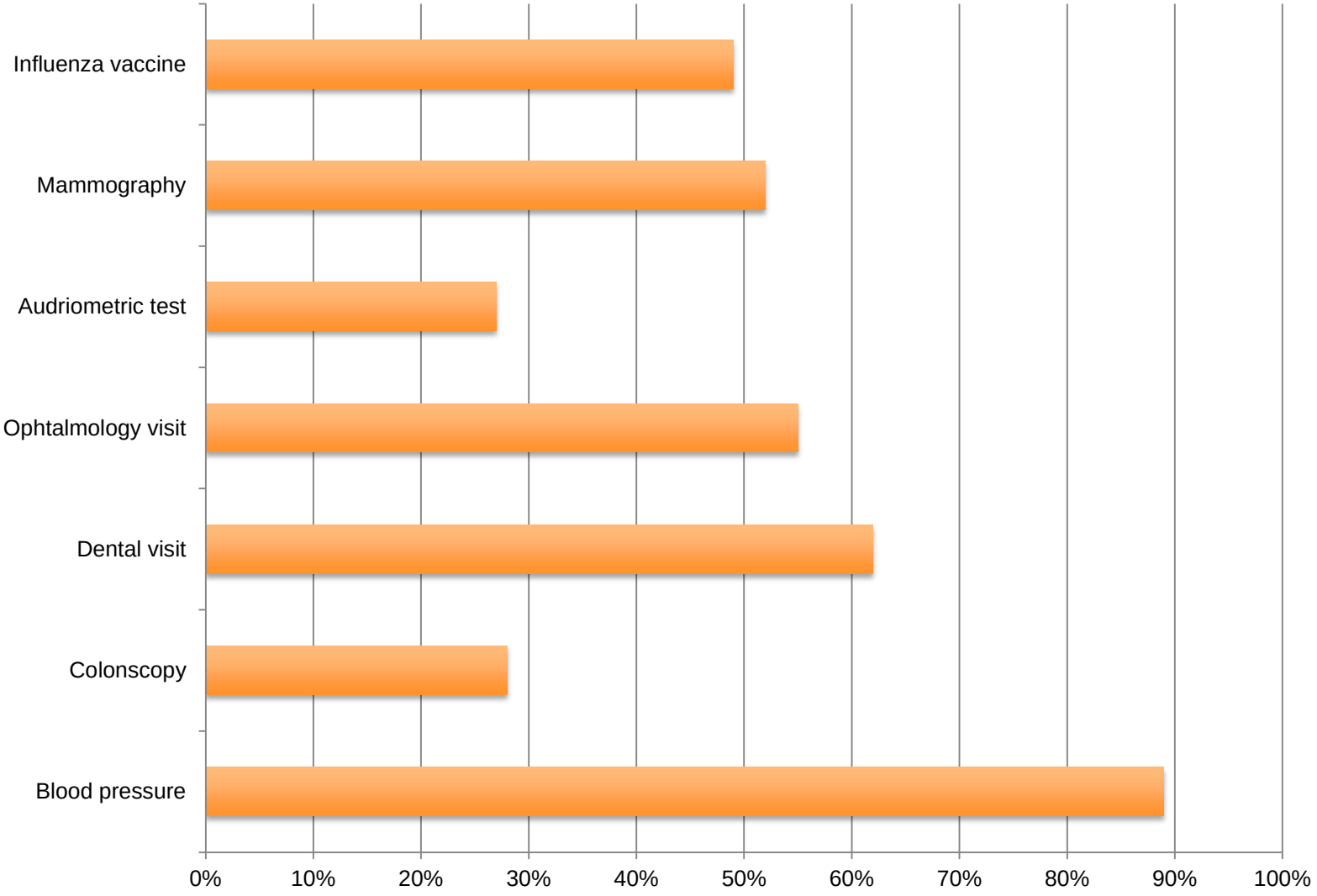
Preventive measures



Courtesy of Prof. Alessandra Marengoni, University of Brescia

Take home messages

1

At institutional level there is the pressing need to gurantee access to safe and effective therapies while ensuring system sustainability through innovative models of care and reshaping of healthcare provision

2

Detailed analysis of the population's health status (such as risk stratification) may provide critical insights and objective information for what concern health interventions planning (at regional level) and policy making (at national level)

Identification of clinically translationable Omics technology

Objective 1

Define a prototype model of partnership (public-private) able to develop an effective ecosystem to translate Omics technology in clinically actionable procedures

Objective 2

Develop a computational method that integrates large sets of experimental results to identify the best therapeutic intervention strategy

Main goal

Support the Italian Ministry of Health in strategic planning for disease prevention (Prevention National Plan) in different therapeutic areas

Precision Medicine – Paradigm Shift

	Yesterday	Today	Tomorrow
Data	Symptom based	Cohort based	Big Data/ Algorithm based
Actions	Intuition medicine	Evidence-based Medicine	Precision Medicine

Bridging the gap between research and clinical diagnostics

Clinical research

Translational research

Diagnostics

1 Bioinformatic method approach

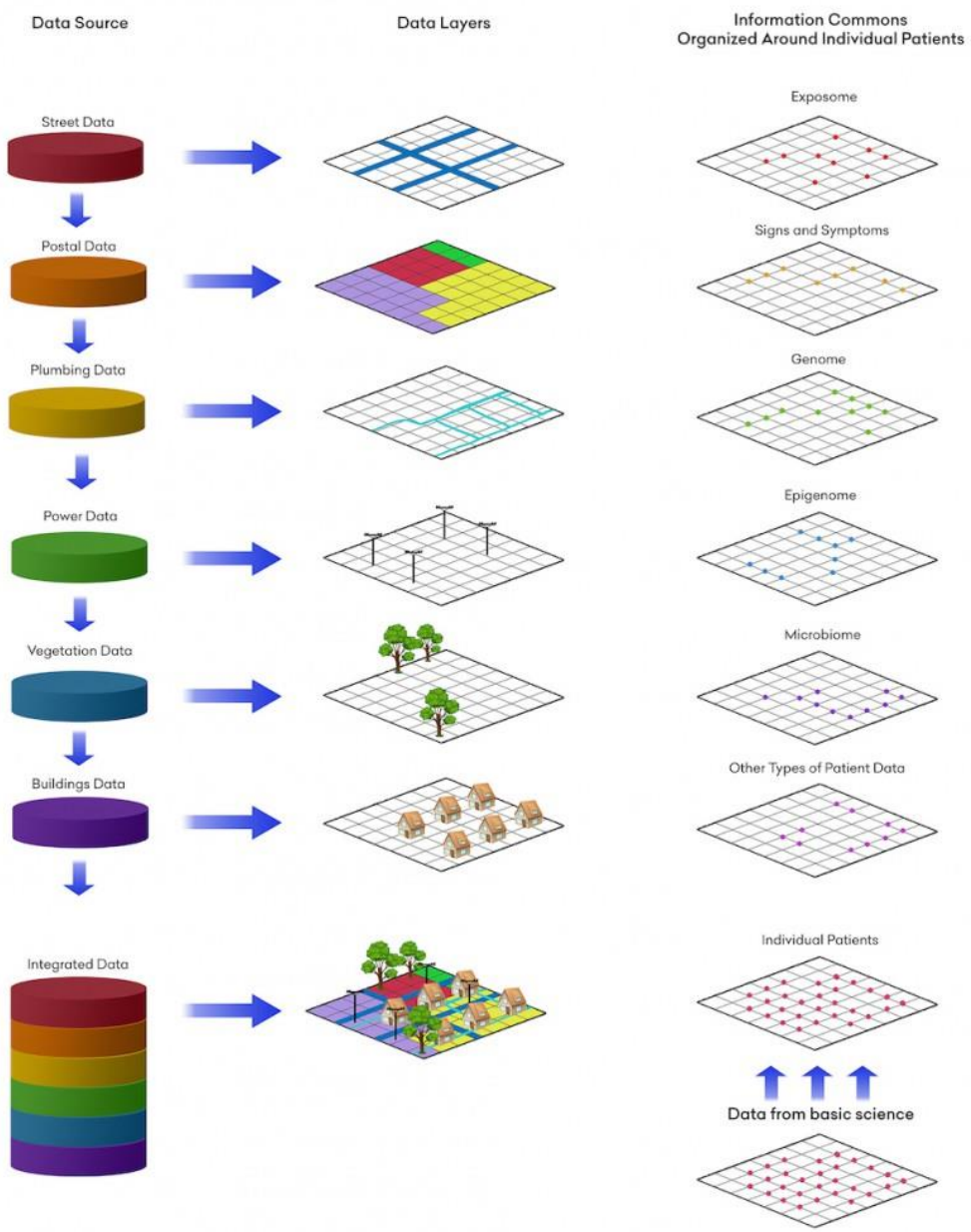
2 Proof of principle

3 Clinical utility evaluation

4 Integration into healthcare service

Main goal: Pushing forwards translational approaches of Genomics data clinical use through Computational Medicine

A computational medicine approach



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Detailed analysis of the population's health status (such as risk stratification) may provide critical insights and objective information for what concern health interventions **planning** (at regional level) and policy making (at national level)

3

Multidisciplinary inter-institutional efforts are needed to develop an health ecosystems able to adopt cutting-edge technologies mature enough to provide clinically actionable insights and tangible impact on patient health

Thank you!

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