Active and Healthy Ageing Innovation Partnership

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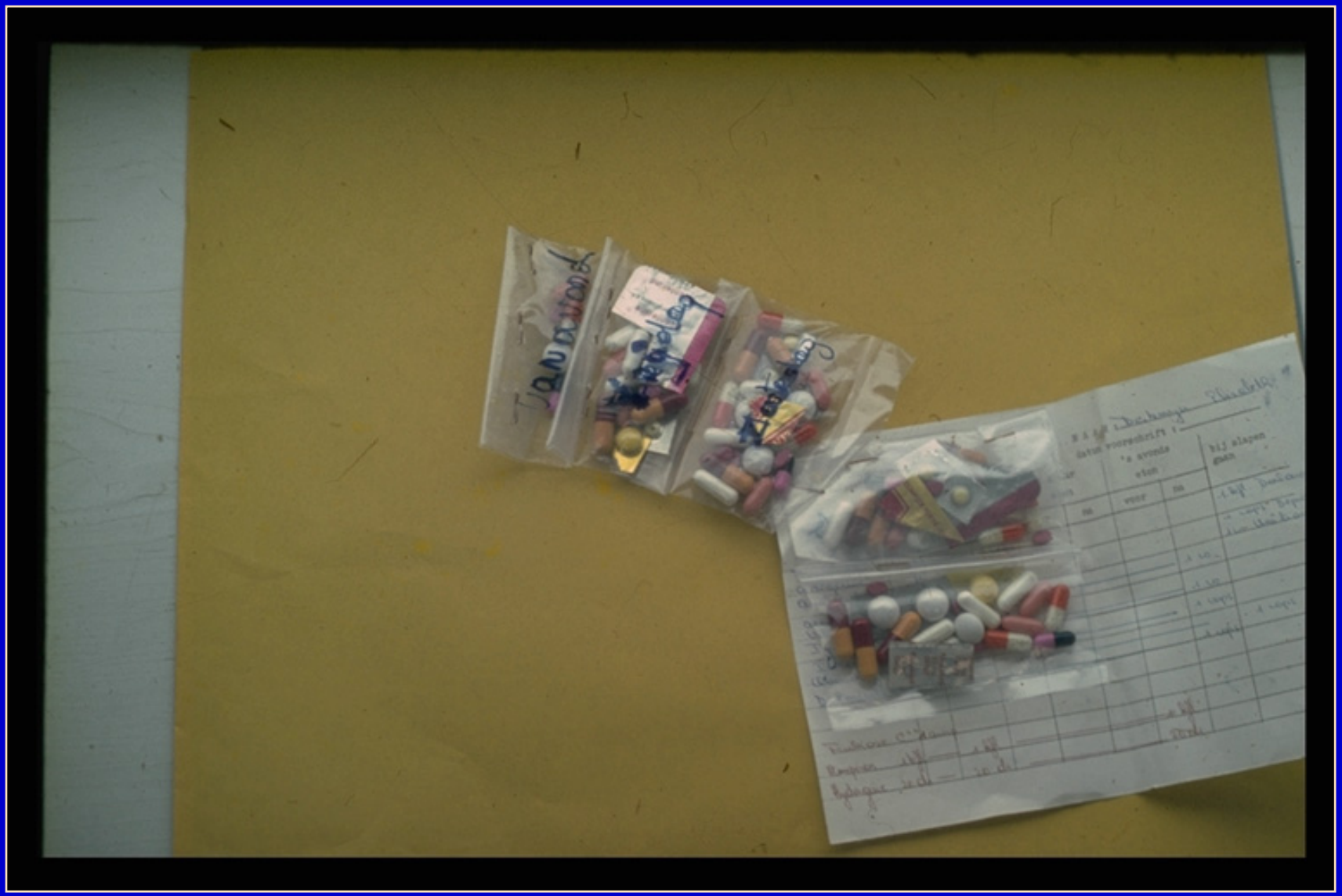
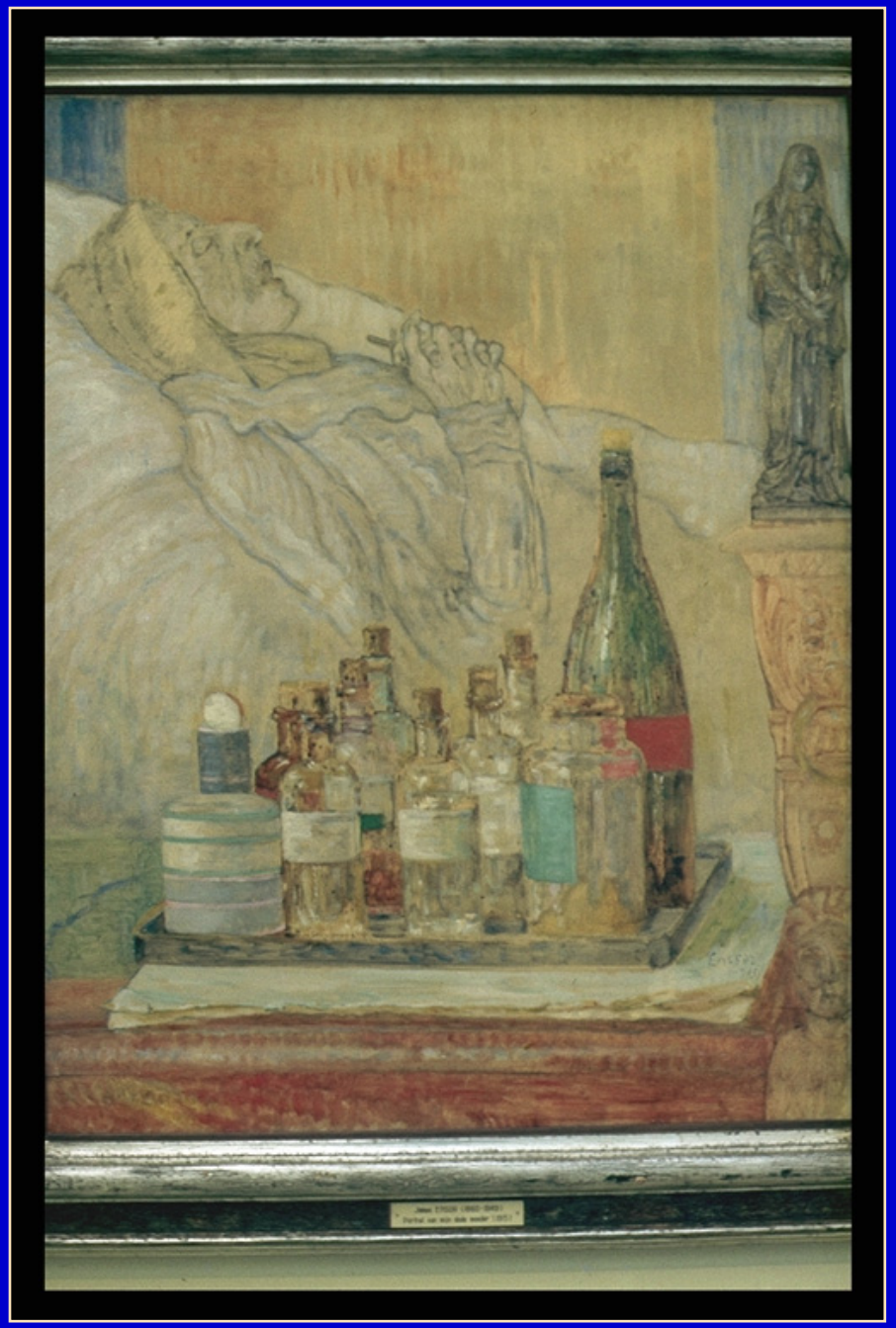
EMA London 16 June 2011





We are living in a period of great contradictions

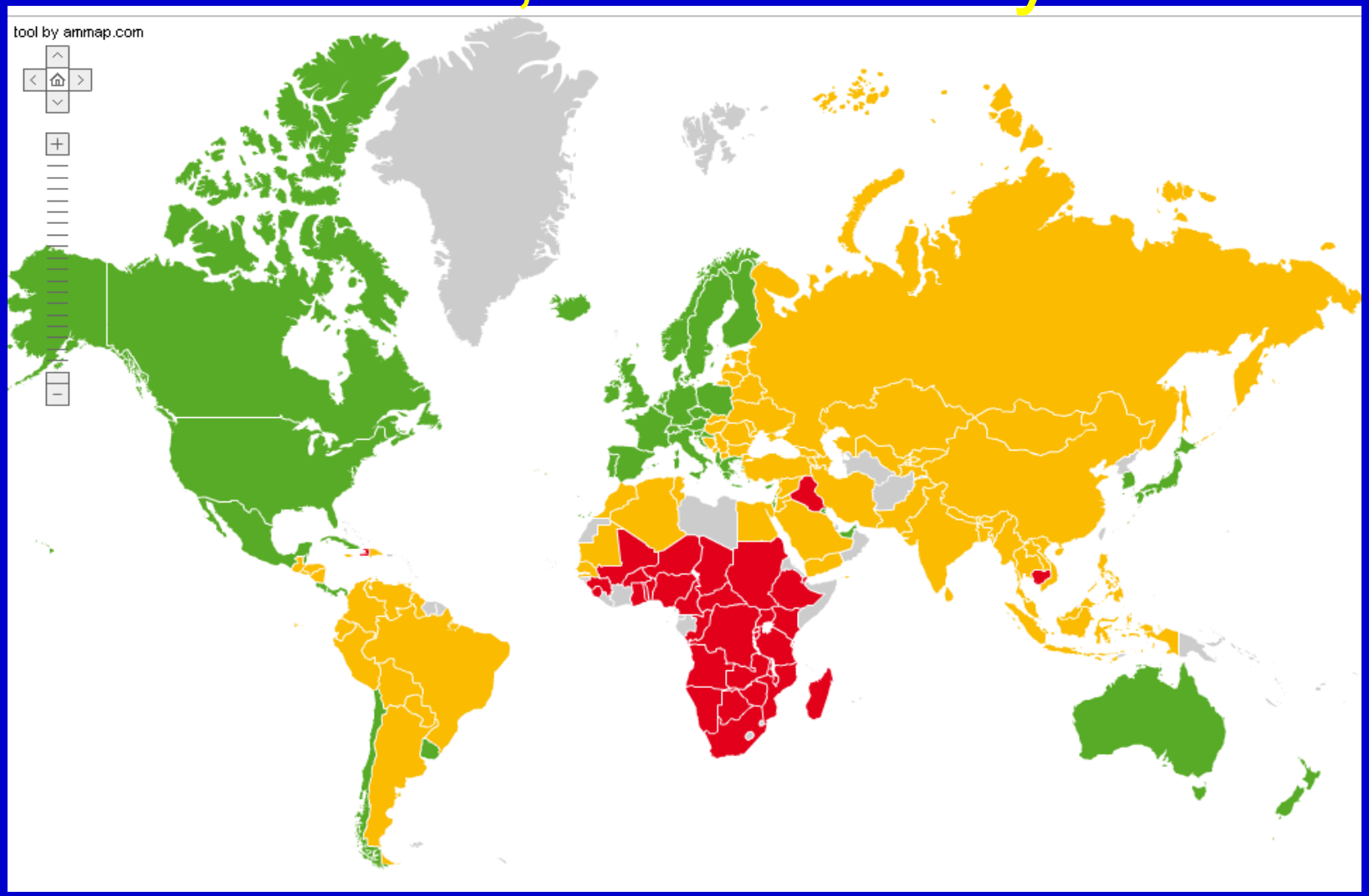
Old dream of mankind now fulfilled: most people reaches very old age

ANTI-ageing society !!!

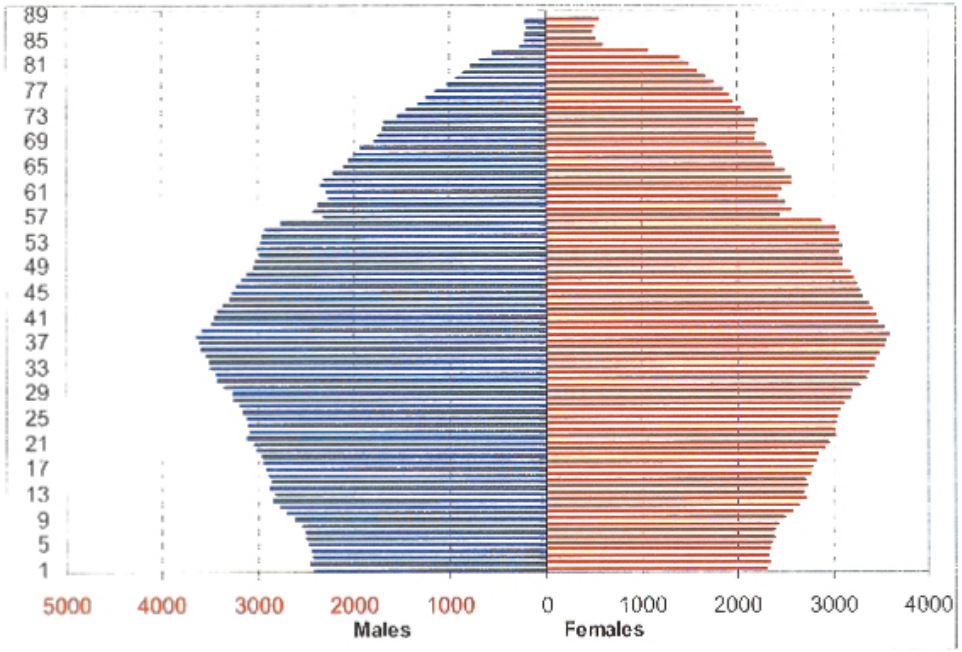
Longevity is increasing

- From 1960 till today in Western Europe, North America and Australia: increase of longevity with 3 months every year.
- (A gain of 5 hours every 24 hours living…)

Life expectancy from birth: Red: <60yr
Yellow: 60-75; Green: >75yr



2004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85
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69
65
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25
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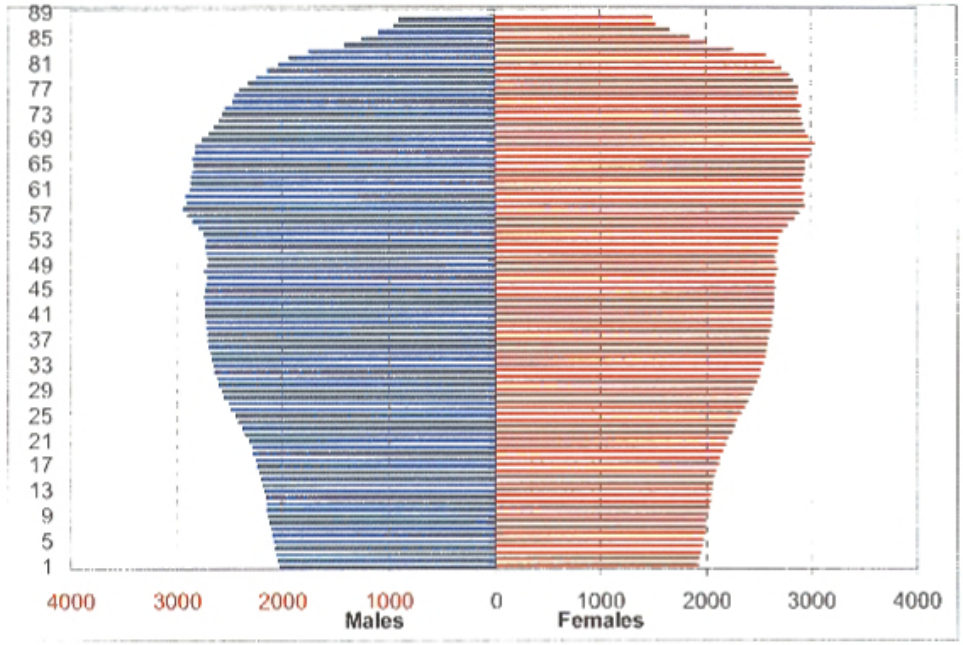
9
5
1
5000
4000
3000
2000
1000
0
1000
2000
3000
4000
Males
Females

2050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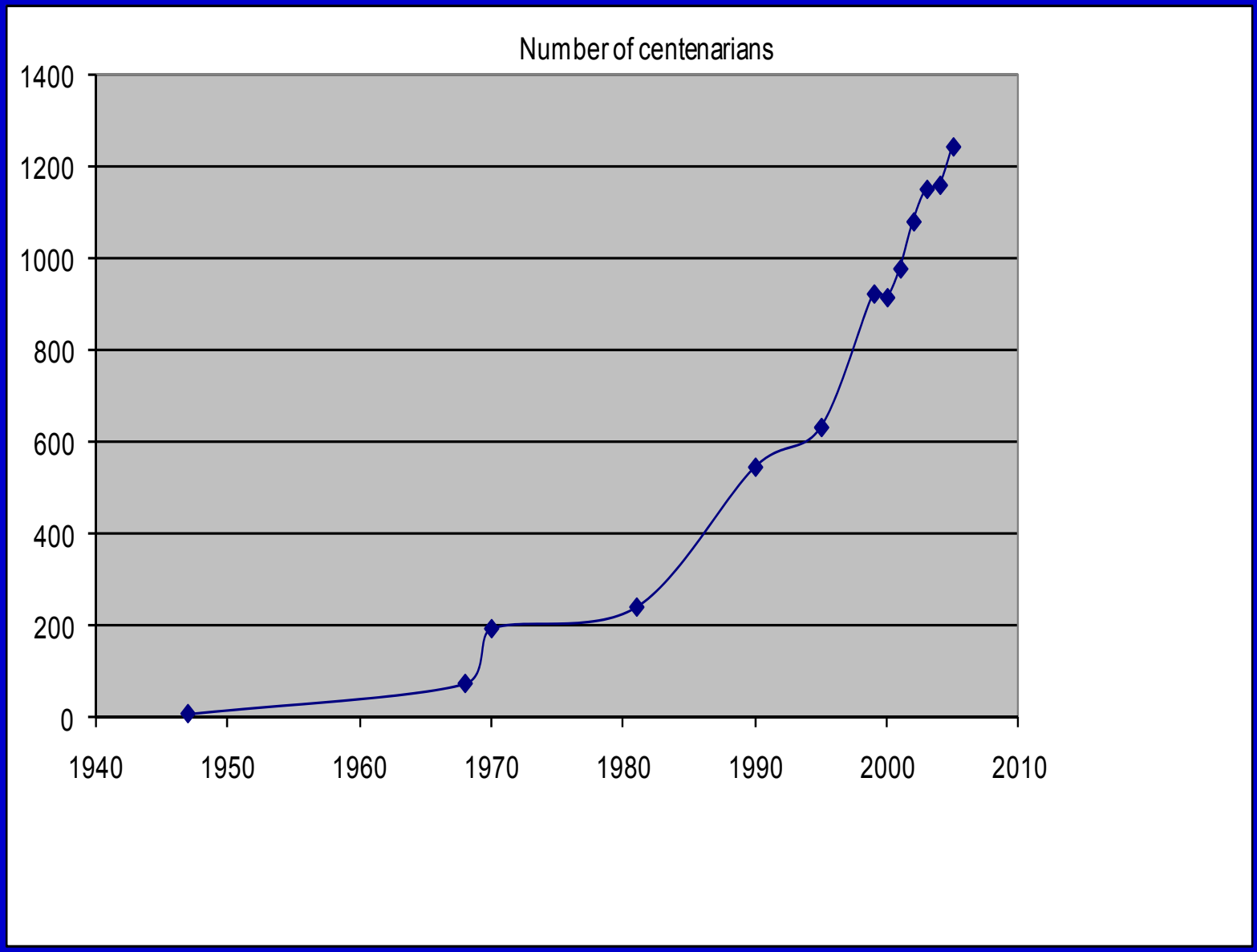
Males
Females


Number of centenarians
1400
1200
1000
800
600
400
200
0
1940
1950
1960
1970
1980
1990
2000
2010

We are living in a period of great contradictions

- People are living always longer (and in better health),

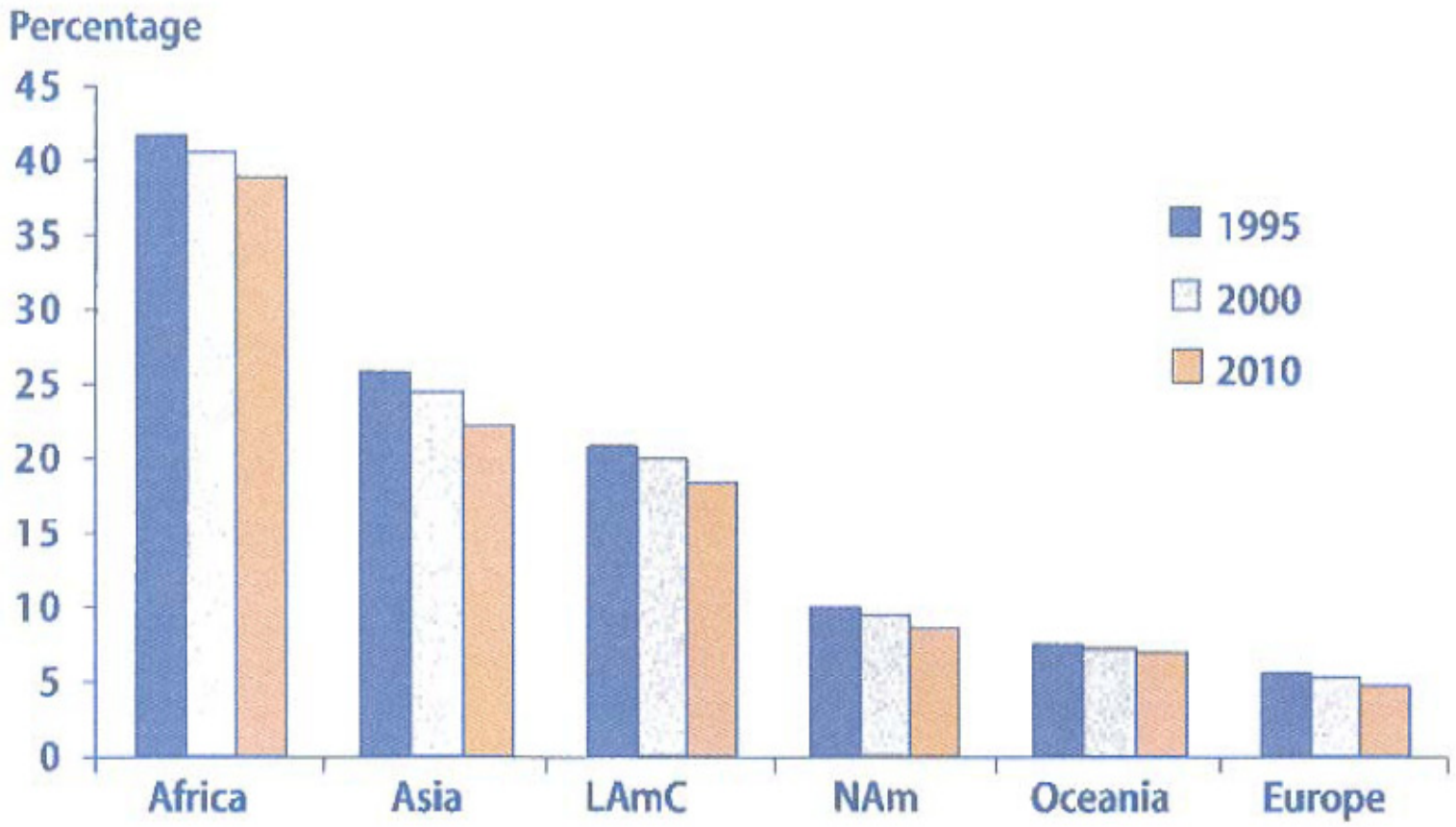
- but they are retiring always earlier…

120 years ago...

- Retirement age was fixed at 65 years by Mr Krupp in Germany...; life expectancy from birth was 46 years...

...only a few reached the age of 65 years...

Figure 9. Percentage of labour force participation by people 65 and older, by region



LAmC: Latin America and the Caribbean
NAm: North America

Source: ILO, 2000

We are living in a period of great contradictions

The gender differences are more and more pronounced !

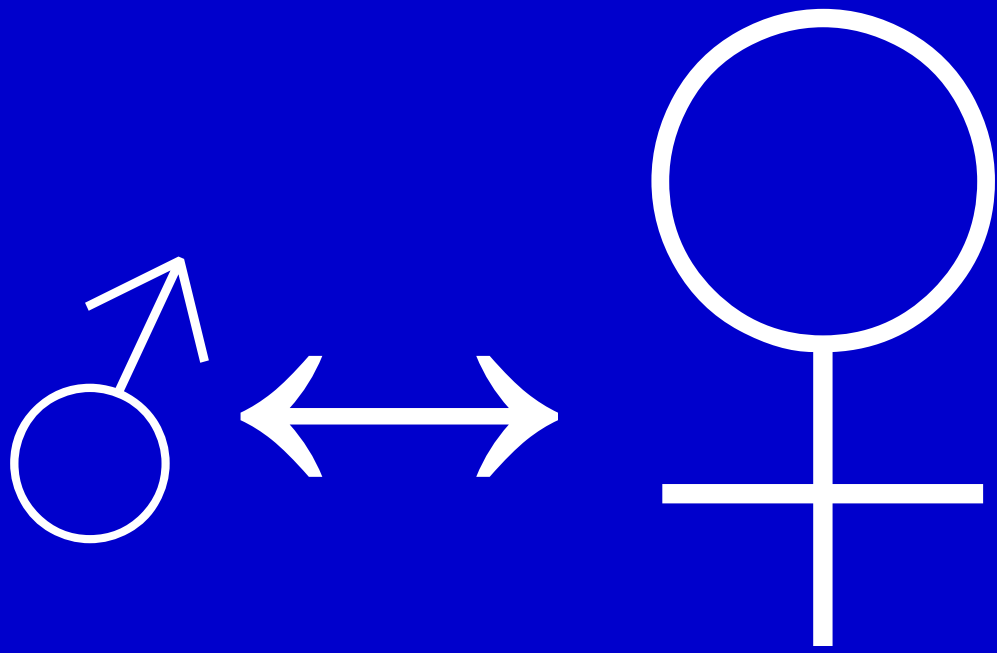
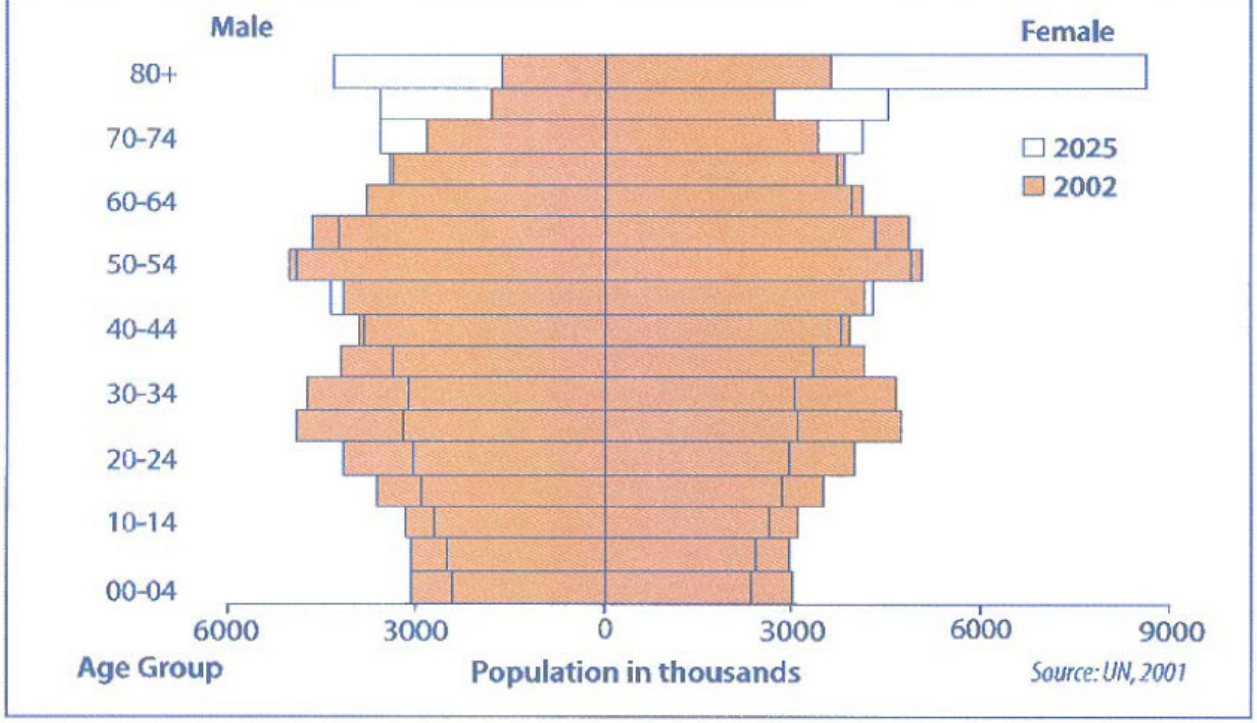


Figure 13. Population pyramid for Japan in 2002 and 2025

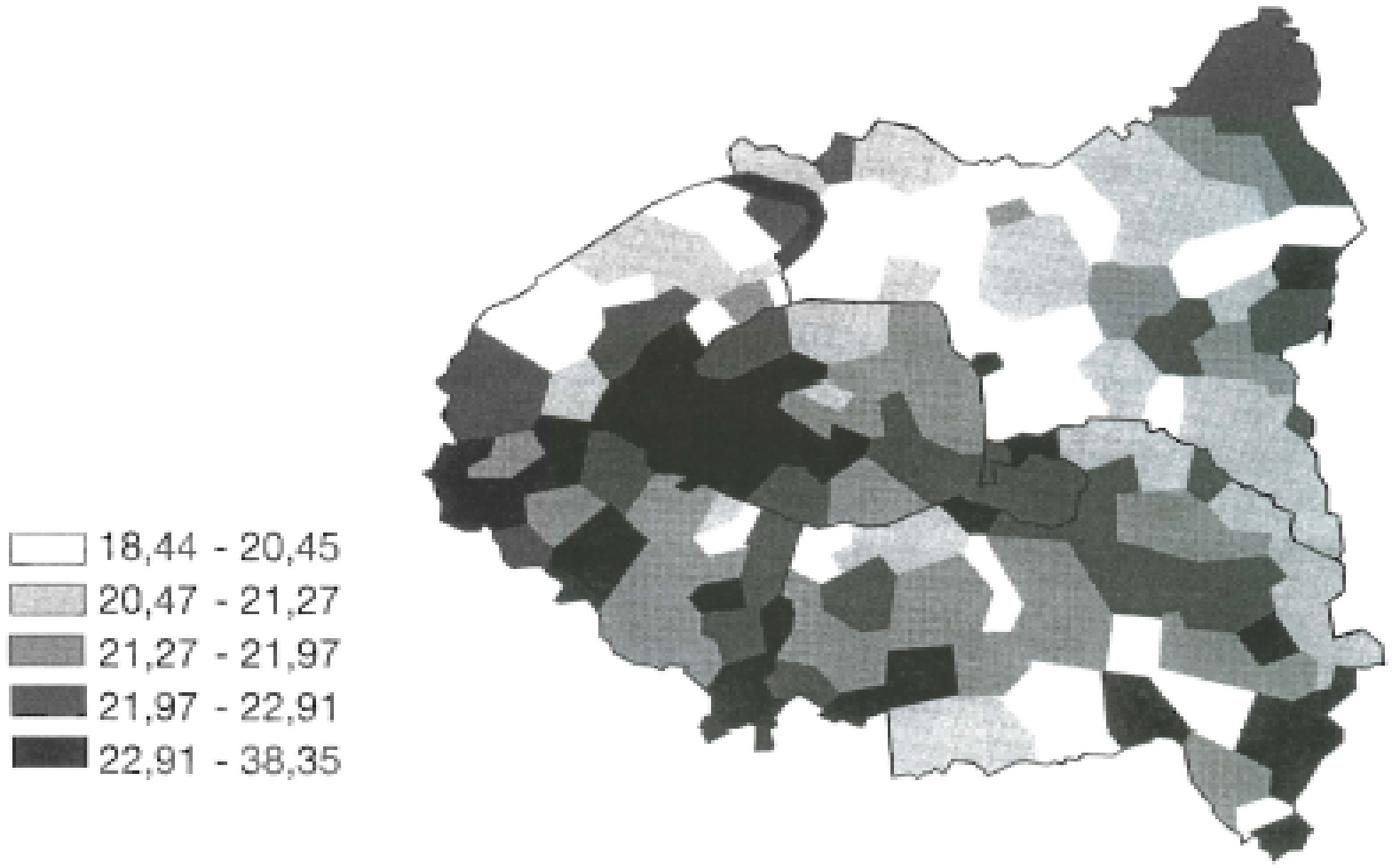


In contrast to the pyramid form, the Japanese population structure has changed due to population ageing towards a cone shape. By 2025, the shape will be similar to an up-side-down pyramid, with persons age 80 and over accounting for the larg-

We are living in a period of great contradictions

In the same city, life expectancy can differ 20 years between the rich and the poor suburbs.

Espérance de vie à 60 ans (hommes) sur Paris et la première couronne (communes et arrondissements)



Source : INSEE, ORSIF, 1999.

We are living in a period of great contradictions

Hospitals full with geriatric patients:

Treated NOT by geriatricians, but by organ specialist, NOT competent in Geriatric medicine.

We are living in a period of great contradictions

Research in Gerontology and Research in Geriatrics more and more separated…

Geriatric medicine is a multidisciplinary activity….

Gerontology is a multidisciplinary activity….

- Multidisciplinary research is urgently needed.

We are living in a period of great contradictions

Medications:

Tested in young adults : mean 50 years

Used in very old adults : mean 80 years

- 33% hospital admissions are related to medications…

We are living in a period of great contradictions

Evaluation of treatments is generally evaluated on the survival rate after 5 years.

In people of 85years: what means 5 years survival??: not relevant, not asked by this very old patients:

OTHER PRIORITY: QUALITY of Life.

Changes are urgently needed!

Who is old??

United Nations' Definitions

	United Nation's definition 1963	Situation now
3rd Age	60-74	70-84
4th Age	≥75	≥85

Definition of Geriatric Medicine (Malta 03-05-2008)

- Geriatric Medicine is a specialty of medicine concerned with physical, mental, functional and social conditions occurring in the acute care, chronic disease, rehabilitation, prevention, social and end of life situations in older patients.
- This group of patients are considered to have a high degree of frailty and active multiple pathology, requiring a holistic approach. Diseases may present differently in old age, are often very difficult to diagnose, the response to treatment is often delayed and there is frequently a need for social support.
- Geriatric Medicine therefore exceeds organ orientated medicine offering additional therapy in a multidisciplinary team setting, the main aim of which is to optimise the functional status of the older person and improve the quality of life and autonomy.
- Geriatric Medicine is not specifically age defined but will deal with the typical morbidity found in older patients. Most patients will be over 65 years of age but the problems best dealt with by the speciality of Geriatric Medicine become much more common in the 80+ age group.

It is recognised that for historic and structural reasons the organisation of geriatric medicine may vary between European Member Countries.

THE GERIATRIC PATIENT

1. HIGHER AGE GROUP
2. POLYPATHOLGY
3. POOR HOMEOSTASIS
4. TENDENCY TO INACTIVITY and TO BE BEDRIDDEN
5. PSYCHOSOCIAL PROBLEMS

“Ageing…”

- a burden....? / a goldmine...?

- a cost...? / a benefit...?

What is the cost of "ageing"

1. Pension schemes?
2. Health care?

Public expenses for health and welfare

	multiplying factor for 65+	85+
All cost together 10,08	3,78	
Hospital costs	3,63	5,65
Other medical costs	2,29	2,93
Medication	1,00	0,84
CHRONIC CARE 57,78	**7,86**	
Home care	6,46	15,24

Suppressing the “cost” of ageing?

- BY AVOIDING DISABILITY AND DEPENDANCE!

AHAIP

Active and Healthy Ageing Innovation Partnership

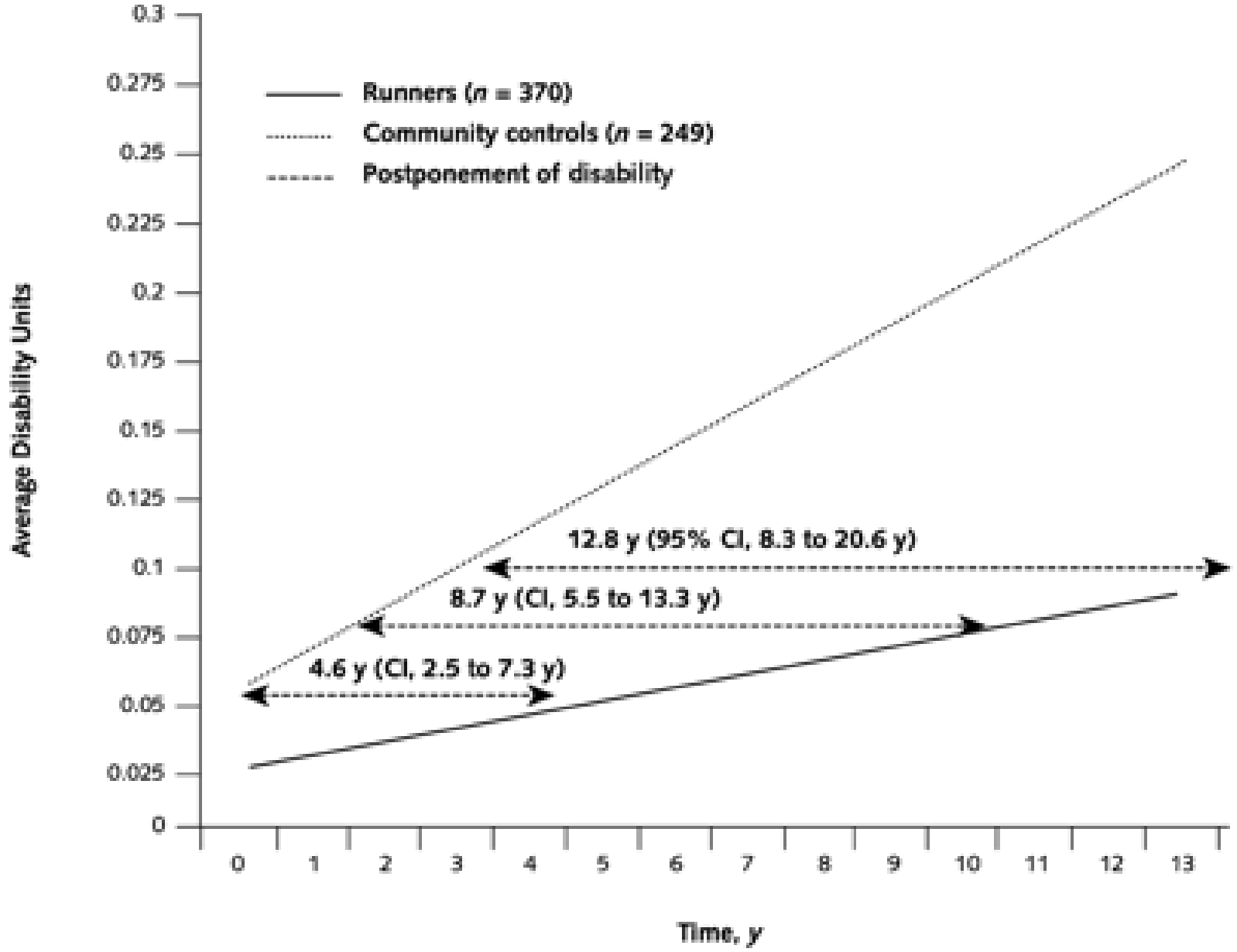
The correct answer - Just on time!

1. Increasing the quality of life of older persons.
2. Diminishing the pressure on health care resources.
3. Stimulating innovation and increasing employment.

AHAIP

Active and Healthy Ageing Innovation Partnership

Concrete: AHAIP aims to increase the **average healthy lifespan** in the EU by two years by 2020.


Runners (n = 370)
Community controls (n = 249)
Postponement of disability
12.8 y (95% CI, 8.3 to 20.6 y)
8.7 y (CI, 5.5 to 13.3 y)
4.6 y (CI, 2.5 to 7.3 y)
Average Disability Units
0.3
0.275
0.25
0.225
0.2
0.175
0.15
0.125
0.1
0.075
0.05
0.025
0
0 1 2 3 4 5 6 7 8 9 10 11 12 13
Time, y

Non-smoking: prolonging life in better condition

	Life expect. on 20 year	In good health
MAN		
• Non smoker	56,7	48,7
• Smoker	49,5	36,5
FEMALE		
• Non smoker	60,9	46,4
• Smoker	53,8	33,8

Bronnum et al, Copenhagen, Tob Control 2001:10;273-8

Practical examples

- Physical exercise
- Stop smoking
- Obesity/undernutrition
- Vit D
- Geriatric approach by the GP and in the General Hospitals
- Adapted geriatric medicines...

We are living in a period of contradictions!

- The trials of new medicines are demonstrating a high efficacy (50-70% positive results)
- In the clinic we see many times only positive results in 20-25%.....

- Why??

We are living in a period of contradictions!

- Studies designed for approval new medicines exclude usually older patients, multi-morbid patients, pregnant woman and children.
- Mean age Colorectal cancer (De): 69yr (M) 75yr (F).

  → only 18% patients > 70yrs in trials.
- In cardiovascular pathology: underrepresentation of women

Thürmann PA Z Evid Fortbild Qual Gesundhwes 2009:103(6):367-70

Upper age limits in studies submitted to a research ethics committee

Time period	% protocols with age limit (65-70-75 or 80)
1994-1999-2004	36-40%
2007	19%

Cruz-Jentoft et al Aging Clin Exp Res 2010: 22(2):175-8

Participation of elderly patients in registration trials for oncology drug applications in Japan.

	Cancer patients	Trials in Japan	Trials overseas
Mean age	70y	59y	55y
% patients older than 65 yrs	66%	35%	28%

Yonemori K et al. 2010:21(10):2112-2118

CLINICAL TRIALS

- Older patients are systematically excluded:
  - By exclusion criteria (co-morbidities, age, etc.)
  - By “paternalistic” ethic committees and families

→This results in mortality and morbidity!

Need for inclusion Frail patients

- With exclusion of frail older persons: failure to evaluate the interventions in the most clinically relevant group in which such intervention is needed.
- We have to design studies that allow participation of persons with physical frailty, while implementing strategies to enhance participation and avoid excessive risk.

Problems with goals of “classical” medical trials

- 5-year survival is not longer a good parameter
- Diminishing the mortality is not longer the prime goal
- We need other trial designs for evaluation of success of therapy, such as:
  - Quality of life
  - Restoring the autonomy
  - Preventing developing the frailty
  - Improving the compliance

CLINICAL TRIALS in older age…

- **Older persons >80: reduced mortality with target SBP of 150mmHg.**
  (Beckett NS et al, NEJM 2008; 358; 1887-98)

- **Randomized Aldactone Evaluation Study (RALES): improved outcomes in severe heart failure.**

  BUT: hyperkalemia-associated morbidity and mortality!!

  (Juurlink DN et al, NEJM 2004; 351; 543-551)

Nothing new ...

- P.Turner ,
- Clinical Pharmacology St.Bartholomew's Hospital London
- Postgraduate Medical Journal 1989: 65: 218-220
- "CLINICAL TRIAL IN ELDERLY SUBJECTS".

Eur J Clin Pharmacol. 2008 Feb;64(2):201-5. Epub 2007 Oct 31.

Paediatric clinical pharmacology: at the beginning of a new era.

Hoppu K.

Abstract

The lack of availability of medicines for children is a large problem. This problem is global. It concerns all children of the world, those in the developing world but also those in the developed world, even in the richest countries. Many generations of paediatricians and other physicians have learned to live with the situation, where **more than half of the children are prescribed off-label or unlicensed medicines**. However, there is no doubt that medicinal products used to treat the paediatric population should be subjected to ethical research of high quality and be appropriately authorised for use in the paediatric population. Within the last 10 years, the pioneering paediatric initiative in the United States and recent encouraging developments in Europe and at the WHO indicate that change may finally be possible. The **developments of the last 2 years have been particularly intensive**. It seems that a new era is beginning which will provide unprecedented opportunities but also great challenges for paediatric clinical pharmacologists and other stakeholders working to **provide children with the medicines they need.**

STOPP and START PROTOCOL

D. Mahoney et al, Cork

- The “Beers’ list” .
- **The STOPP/START Protocol:**
  - List of medicines that are generally contra-indicated in Older persons
  - List of medicines that are frequently not given to ,older persons (or in a too low dosage).

Take home messages

- EUGMS will continue to act at the EMA, the European Parliament and the European Commission to obtain a "**Geriatric Medicines Committee**".
- In every member state the Geriatricians will contact the National Agencies to convince them of the necessity to do something for the problem of the Medicines in older age: This can easily start with an implementation nationwide of the **STOPP/START protocol**.
- The older patients needs now **adapted trials**.