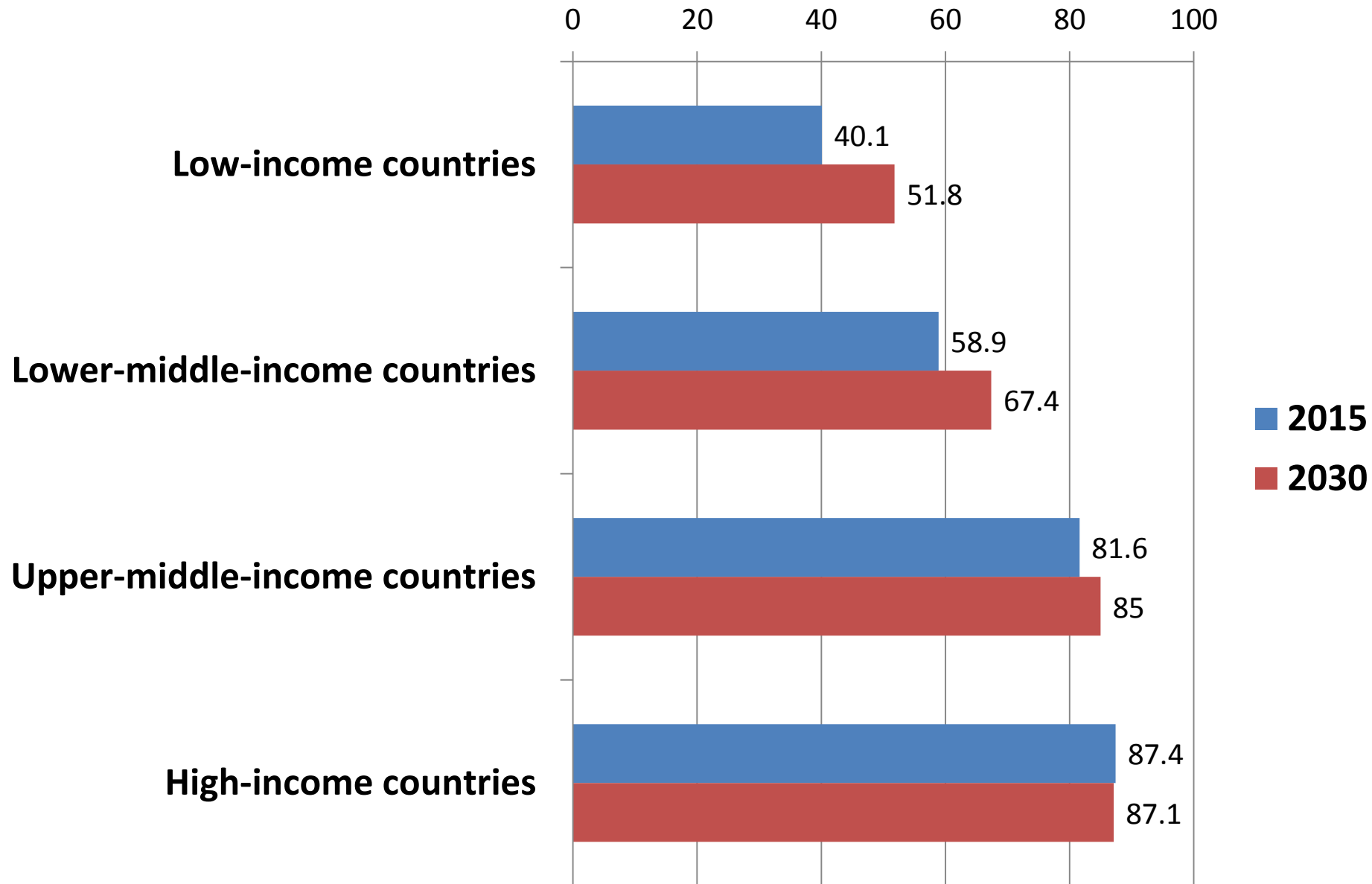




New Policies Needed to Reduce the Global Burden of Ageing Related Pathologies

**Daria Khaltourina,
Hyderabad, India,
2014**

Share of Deaths due to Non-communicable Diseases



Ageing

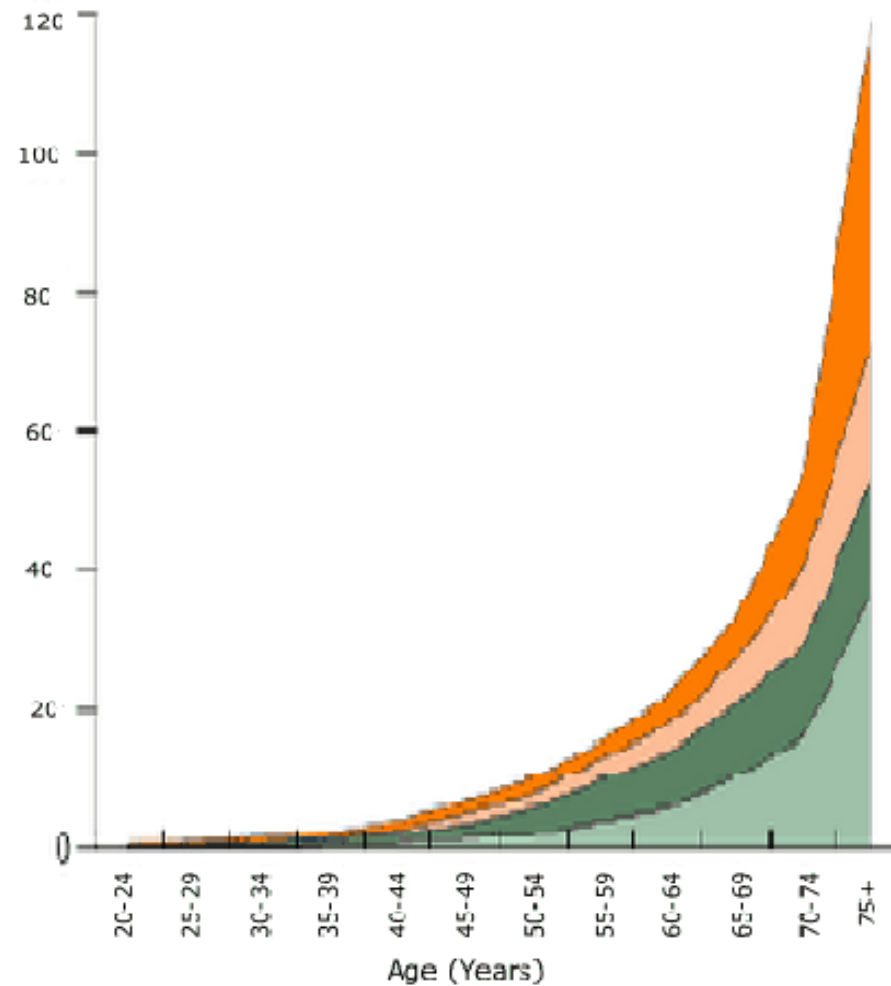
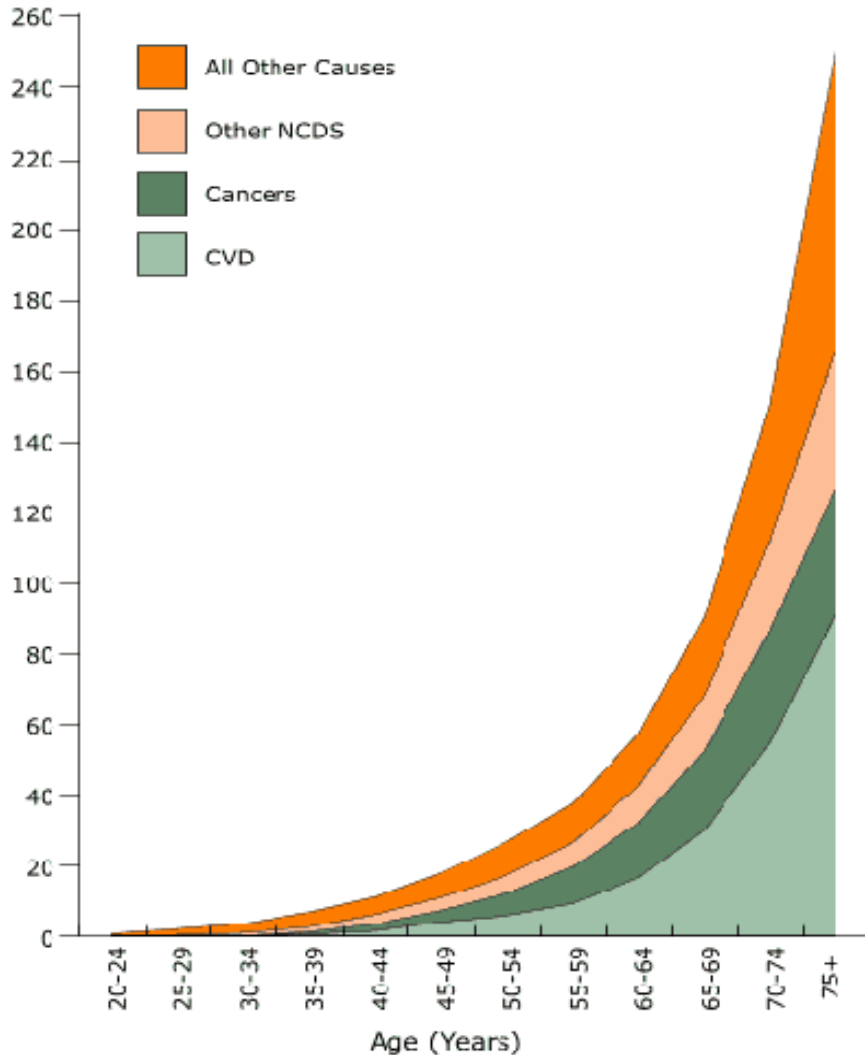
Socially

- Personal growth
- Professional growth
- Accumulation of knowledge
- Greater prestige
- Better social relationship

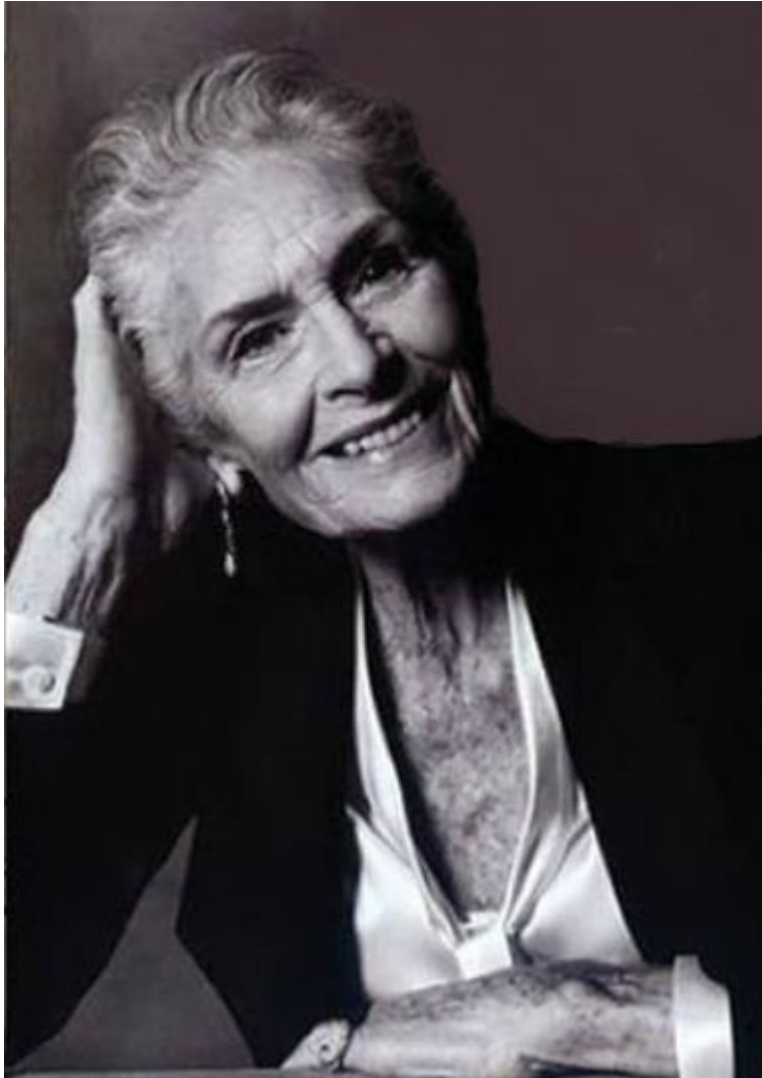
Biologically

- Cognitive decline
- Motor skill function decline
- Vision impairment
- Frailty
- Illness
- Mortality

Cumulative Mortality Rates in Men and Women in the rural Vietman (Minh et al., 2006)



Legal Background



- “The Right to Health” is granted by a number of international treaties, as well as the national constitutions
- By signing this Constitution, the Parties of the WHO acknowledged that "governments have a responsibility for the health of their peoples which can be fulfilled only by the provision of adequate health and social measures".
- Non-Communicable Diseases are one of the top priorities of the World Health Organization and national governments.

Initiatives to Develop Aging Prevention Technologies

- A number of researchers managed to extend lives or control degenerative aging in mammals
- Google opened a new company “Calico” to develop
- A number of biomedical companies claimed that they aim to develop drugs and therapies to control degenerative aging processes (Geron, In Silico, Quantum Pharmaceuticals, AstraZeneca, etc.)

Key Problems

- Low priority of preventing ageing degenerative processes
- Low funding comparing to disease oriented research
- Prohibitively expensive and complex process of new drug approval
- Even more restrictive approaches to the innovative technologies to compensate for ageing-related degeneration
- Lack of established clinical practice methods
- Lack of educational materials in biology of ageing

Policy 1. Naming the problem

- Degenerative ageing processes should be acknowledged as the major threat for public health which needs to be addressed

ageing is a
disease

ageing is a
syndrome

ageing is not a
disease, but it
needs to be
addressed

Opinions in the scientific community

Preventing Degenerative ageing Process Can Be More Effective Than Treating ageing-related NCDs

- Positive example: preventing cardiovascular damage through statins intake
- Pharmacological blood pressure control among elderly people
- Vaccination of the elderly people against pneumonia

Policy 2. Ensure Greater Funding of Research in the Biology of Ageing

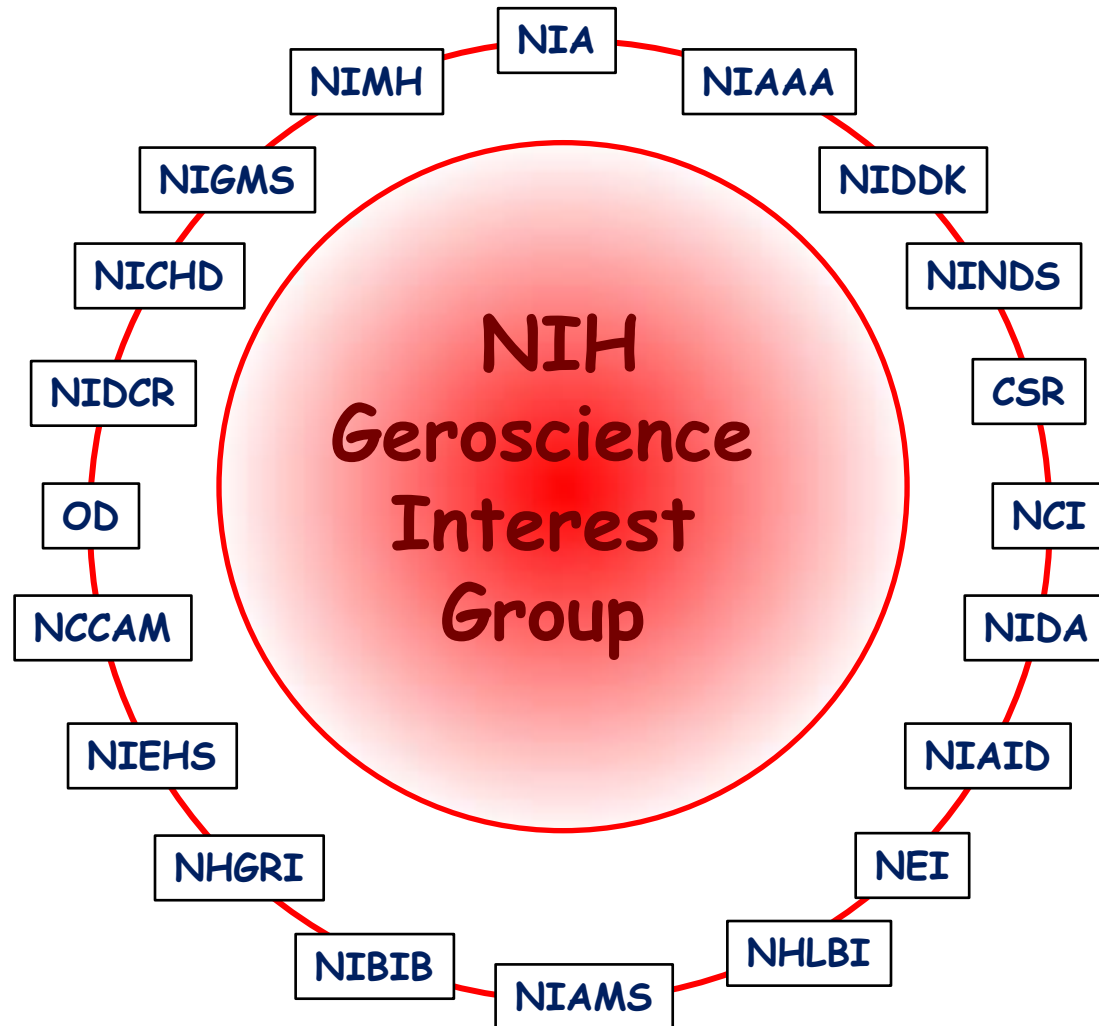
- Right now biomedical science is funded on the principle of “Fight on Disease X”



In an ageing world,
the single disease
model may have
already run its course
- the time has
arrived for a new
model.

Jay Olshansky

Positive Examples from the USA: National Institute of Health and The Geroscience Interest Group



by Felipe Sierra, National Institute of Aging, the USA

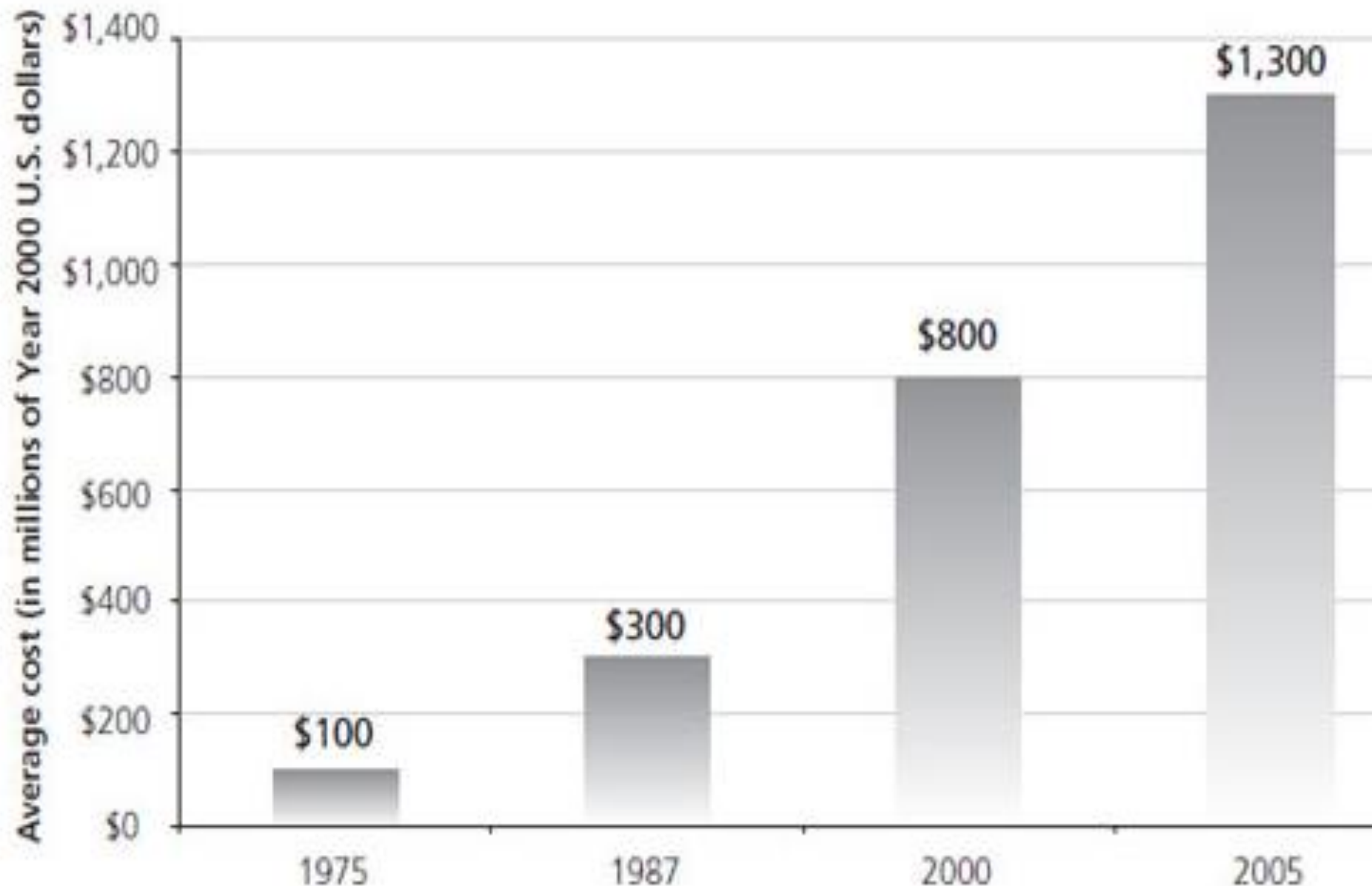
Education in Biology of Ageing

- Some countries have low capacity in biomedical education in general, it is not a priority
- There is only one university course on biology of ageing online
- There are no textbooks on ageing biology
- Governments should promote inclusion of ageing biology courses into the biology programs

Policy 3. Provide Beneficial Regulation for Biomedical Technologies to Prevent Ageing

Promising Interventions	Problems of Translation
Life-style interventions	The cost is not covered by insurance programs for the elderly in most cases
Medicines (substances)	Enormous cost of clinical trials
Food supplements	Supplement effectiveness is often uncertain, as the producers do not invest into clinical trials fearing the regulation
Cell-based medical products	Stem cell treatments are treated by FDA as prohibitively as drugs.
Personalizes medicine, including genetic testing	Genetic testing company is challenged legally in the USA. China introduces some regulation
Innovative methods for drug delivery (nano-delivery)	Every application requires another set of clinical trials
Artificial tissues and organs to replace the ill ones	Some governments bad xenotransplantation

Average Cost to Develop One New Drug



Registering drugs and therapies to prevent and treat ageing is legally impossible in most countries

It is only possible to register drugs and therapies to cure certain diseases (with some exception)

Companies trying to provide ageing control treatments often get challenged legally by the governments

As a result, pharmaceutical industry does not invest into the research in biology of ageing

Low investments results in low governmental funding as well

Problems result in the delay of translational research

Solutions

- Anti-aging treatments should be considered legitimate and desirable pharmacological interventions
- Ageing-related degenerative process should be considered disease or syndromes (like atherosclerosis or metabolic syndrome)
- Develop specific diagnostic criteria (ageing biomarkers) for ageing and ageing related degenerative processes

Stagnation in Preventive Medicines

- It is generally not possible legally to register medicines to prevent a disease in healthy individuals
- Very few exceptions: vaccines, antimalarials
 - Statins and polypil are prescribed for atherosclerosis, which is considered a disease
 - It would be very problematic to register a new medicine to which is proved to prevent ageing
 - This comes from the outdated model of health which ignores the ageing-associated health risks

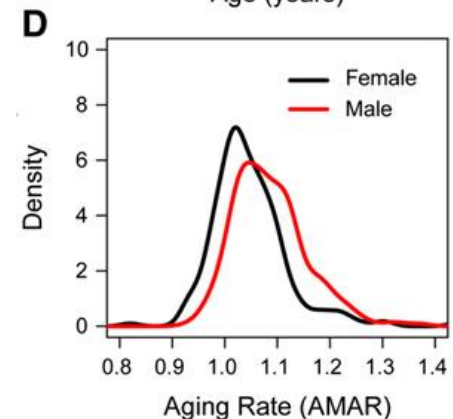
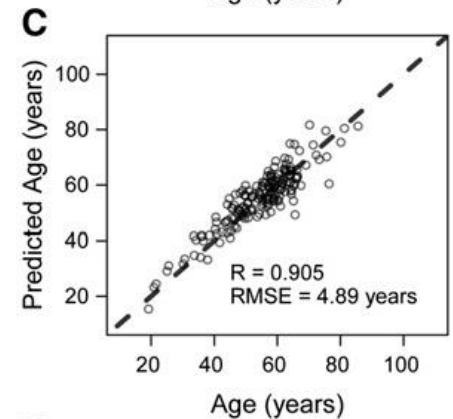
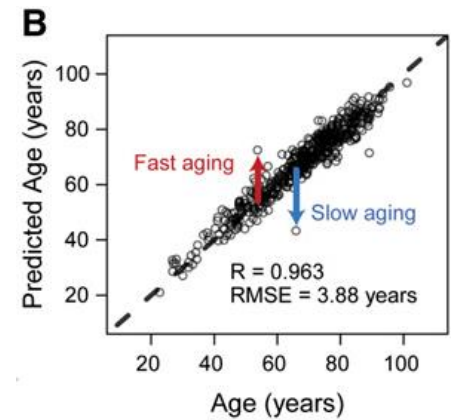
Clinical trial process is extremely expensive, yet necessary

- The US pharmaceutical industry produces 20-40 new registered drugs per year
- The average cost to develop new drugs increased up to 1.3 billion dollar in 2005; phase III takes about 40% of the cost
- Most biomedical companies cannot afford this kind of investment, which affects their financial performance
- Food supplements do not get tested sufficiently for health effects due to prohibitive cost of clinical trials
- Clinical trials of anti-ageing cures can drag on for decades, which is financially unendurable

Solution 1. Development and legal adoption of alternative intervention testing mechanisms

Biomarker systems:

- Morphological
- Pathological
- Metabolic
- Epigenetic
- Cellular level biomarkers
- Cognitive
- *Etc.*



Solution 2: Advocating for expansion of conditional approval practice for gerontoprotective drugs and therapies

- There can be different modes of conditional registration depending upon effectiveness and safety data
- One possible solution is to postpone Phase III clinical trial to post-market stage
- Transparency and informed consent of the patient is necessary

Examples of conditional therapy registration

- Federal Food, Drug, and Cosmetic Act (FD&C Act), Art. 356 offers fast track review of such a drug if it is intended for the treatment of a serious or life-threatening condition (cancer, HIV)
- HPV vaccines prevent pre-cancer conditions but, there is not enough data to claim cancer prevention. At the same time, over 100 million doses have been distributed
- The Japanese Government has stated that conditional approval or commercial use will be adopted for stem cell therapies

Conditional registration initiatives:



The US Senator Kay Hagan sponsored the Transforming the Regulatory Environment to Accelerate Access to Treatment (TREAT) Act in 2012 to accelerate the review and approval process for medicines;

Japanese Government proposed conditional registration of stem cell based therapies