
Genomics, a major component of future health policy

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Definition of the term “personalised medicine”

“ medical model using characterisation of individuals' phenotypes and genotypes (e.g. molecular profiling, medical imaging, lifestyle data) for **tailoring the right therapeutic strategy for the right person at the right time, and/or to determine the predisposition to disease and/or to deliver timely and targeted prevention**. Personalised medicine relates to the broader concept of **patient-centred care**, which takes into account that, in general, healthcare systems need to better respond to patient needs;”
(*EU Council conclusions on personalised medicine for patients, 7 December 2015*)

The Genetic Tsunami.....



- ◆ Identification of new target for drugs
- ◆ Identification of individual characteristics associated to lower response to treatment or adverse reactions to medicinal products
- ◆ Identification of underlying mechanisms for complex diseases (and identification of gene-environment interaction)
- ◆ Impact on screening programs from population stratification according to genetic risk

tailoring the right therapeutic strategy for the right person at the right time

determine the predisposition to disease

to deliver timely and targeted prevention



- ◆ Large amount of information, allowing a more and more precise characterization of patients

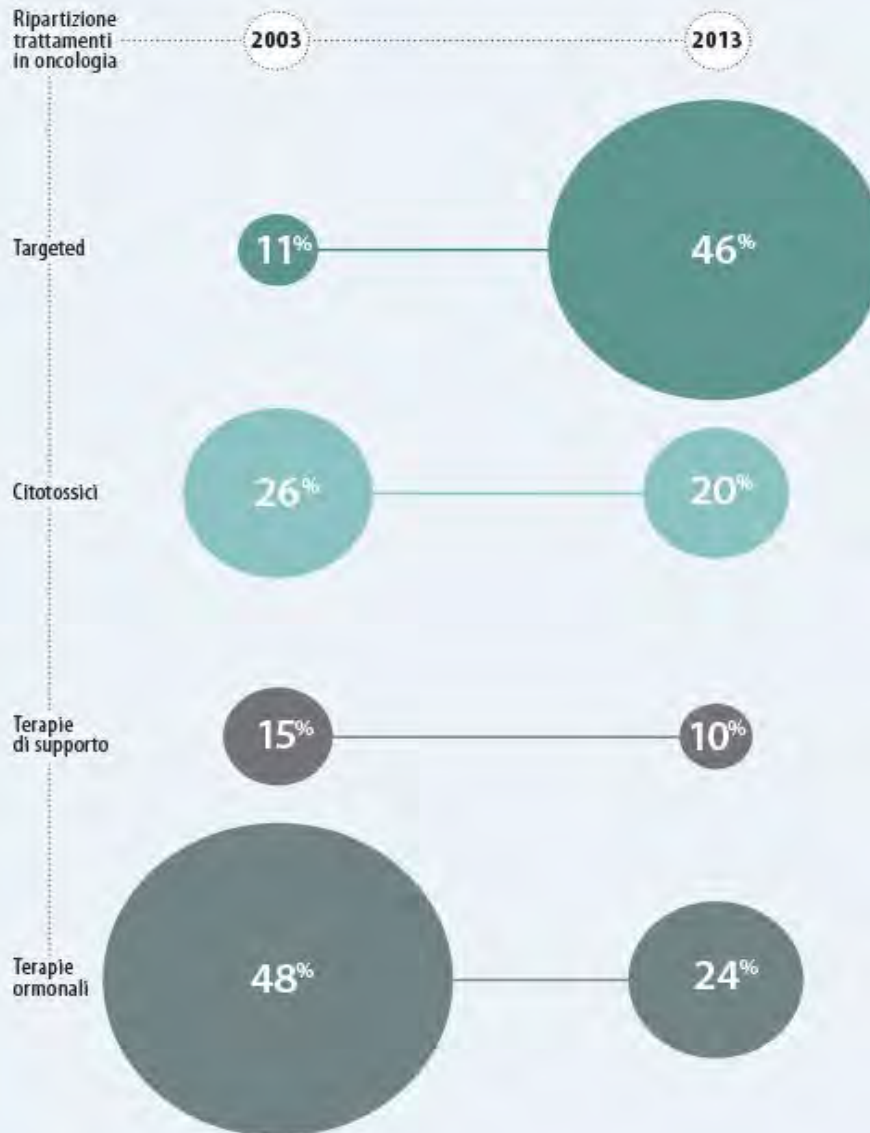
- ◆ A concept of medicine ("precision medicine") **is sewn on individual differences**

- ↳ beyond traditional risk factors measured by public health professionals such as sex, age, socio-economic status, physiological parameters or clinical biomarkers

PREVENTION
Management
genetic **DNA**
engineering

Oncologia: punta più avanzata della medicina di precisione

In dieci anni, i pazienti oncologici hanno visto aumentare di quattro volte le opzioni personalizzate di approccio alla loro malattia.



Initiatives for governance of genomics in health care

Recommendations “Genomics in public health” (State-Regions agreement March 2013)

They recognize 3 strategic elements for policy priorities:

- **Rules and criteria for integrating genomics into healthcare**
- **The crucial role of research**
- **Citizens' awareness of the benefits and limitations**

Beyond genomics in public health

- ◆ Impact on health policies is still limited
- ◆ Need for a joint effort between public health professionals, geneticists and scientists to produce useful knowledge to support decisions on how to incorporate genomic medicine in prevention and treatment (Boccia et al., 2014)
- ◆ Great opportunities for innovation and leverage for system development
- ◆ **“Holistic” vision aimed at harmonizing policies among different sectors**

Initiatives for governance of genomics in health care

- ◆ EU Council conclusions on personalised medicine for patients, 7 December 2015
- ◆ National board (autumn 2015) within Superior Health Council Presidency
→ **Health System innovation Plan based on '-omics' sciences**, now submitted to State-Regions Board

Healthcare innovation Plan based on ‘-omics’ sciences

General Objectives

- 1) Transferring genomic knowledge in healthcare practice, with an approach that focuses on the individual.
- 2) Increase the effectiveness of prevention, diagnosis and treatment of higher-burden diseases, taking into account individual differences in genetic profile, lifestyles and the environment, and providing professionals with the resources needed to tailor interventions.
- 3) Promoting cultural, scientific and technological innovation of the healthcare system.

Healthcare innovation Plan based on '-omics' sciences

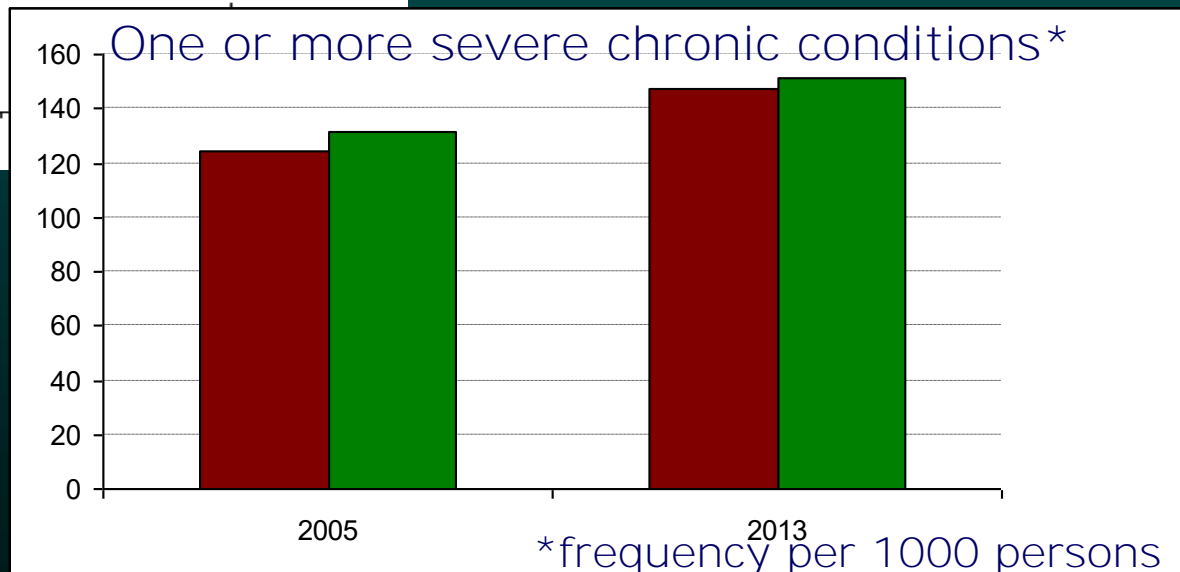
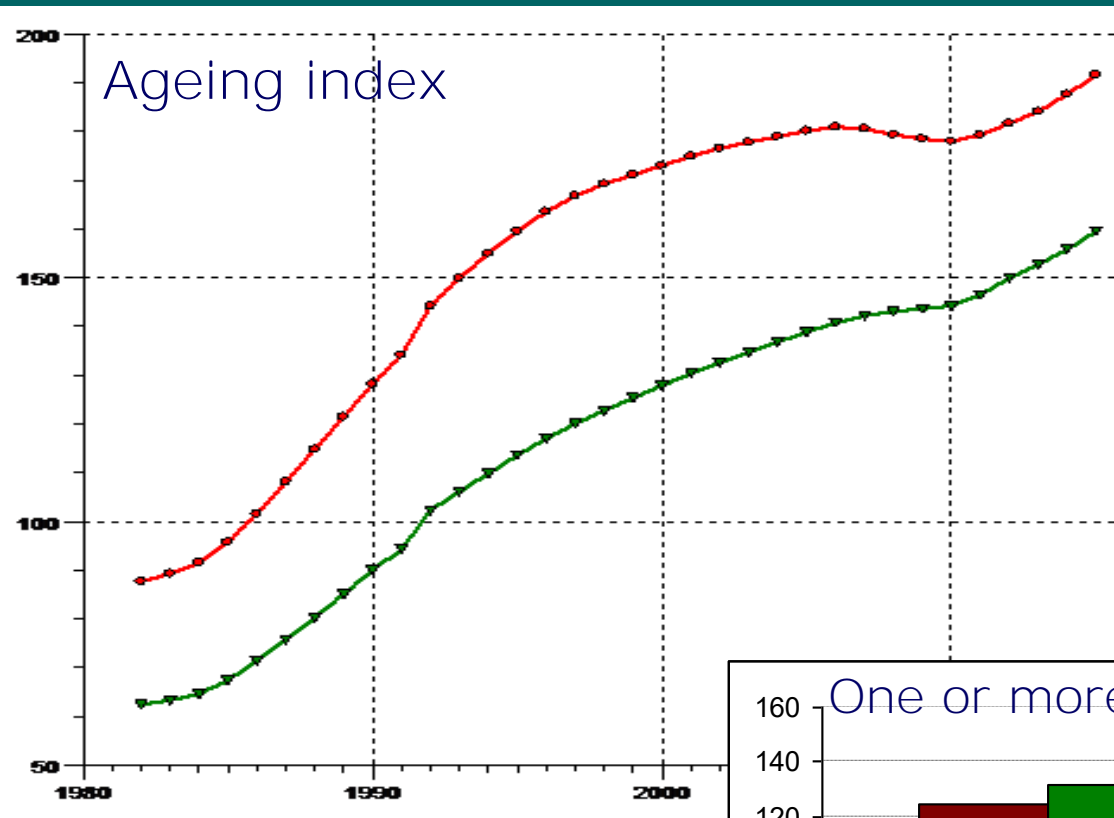
Within National Health Service:

- Aware of the profound innovation of '-omics' sciences: health impact and driver for entire country system development;
- Aiming at expressing a strategy of 'innovation management' of genomics but also to include it in the current planning context;
- Prudently and wisely taking the opportunities currently offered by genomics to achieve the defined health objectives within ongoing challenges

....challenges for the health care system

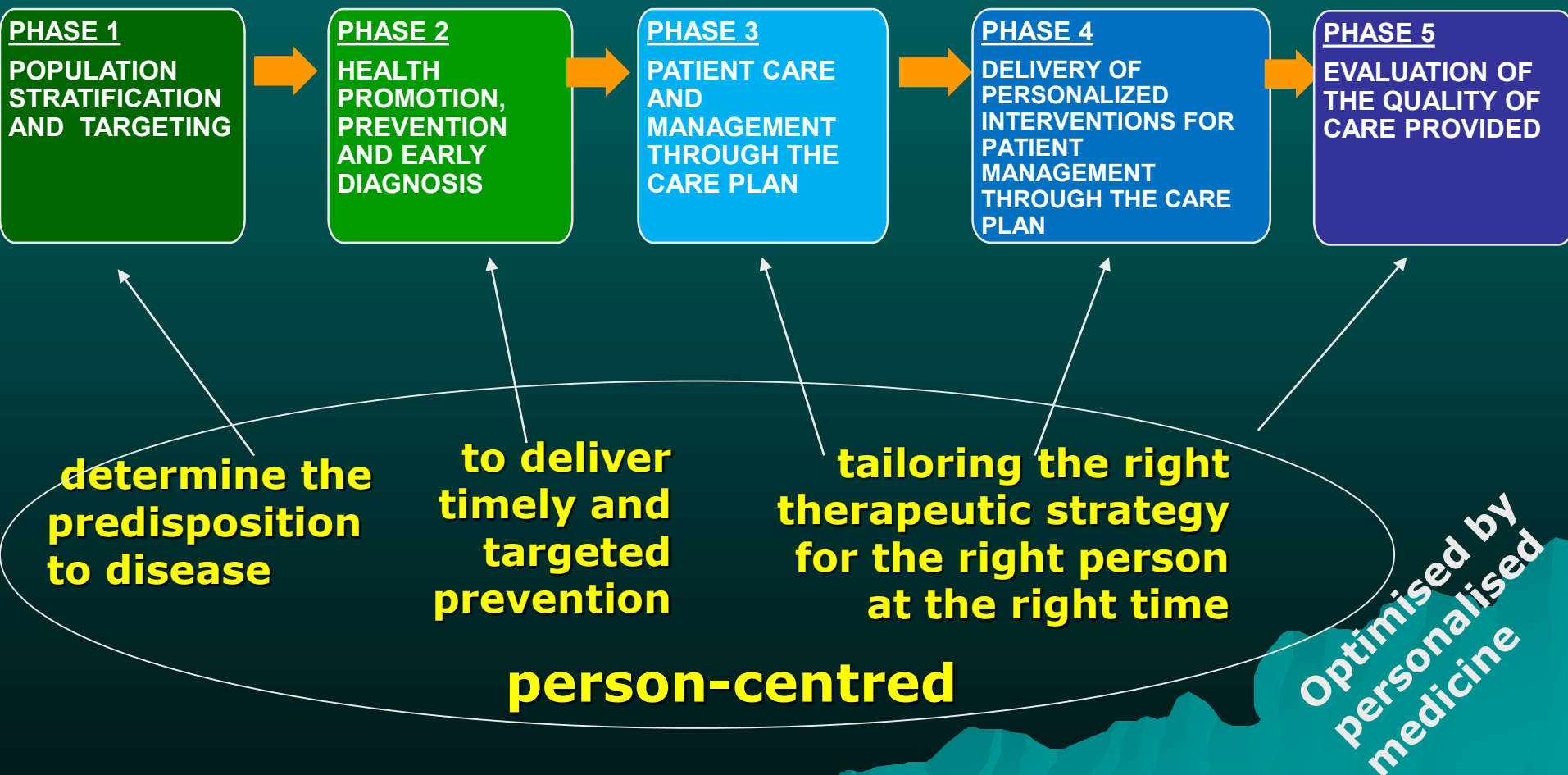
- ◆ Ensuring sustainability
- ◆ Rapidly evolving technologies
- ◆ Assessing risks and benefits of innovations, considering ethical, financial, social and legal implications (prices, rates, data protection)
- ◆ Appropriate integration into practice by guaranteeing the principles of solidarity, universality and equity of access to high quality care

....demographical and epidemiological scenario



...addressing chronic morbidity

Regions currently implementing National Plan for Chronic Morbidity (State-Regions Agreement 2016)



Genomics in National Health Service: recommendations (and challenges) on instruments and rules

- Need to manage the development of research and innovation and the evaluation of applicability in the health care system
- In a context of limited resources, necessary to identify instruments that can strengthen test validity and cost/benefit profiles of treatments
 - ... adaptation of methodologies ... beyond the clinical trial?
 - needs for HTA evaluations not only on tests/treatments but also on organisation models and system rules
 - take into account legal, ethical and social implications associated with an individualized treatment approach
 - inclusion within Essential Levels of Healthcare

Genomics in National Health Service: recommendations (and challenges) on instruments and rules

- Need for tools for the introduction of new knowledge into clinical practice and diagnostic-care pathways
- Need for a system of criteria and quality standards and accreditation of supply
- Investments on information systems (....administrative health information systems still “silos”-based)

Genomics in National Health Service: Training and Information

**Revolution of society as a whole → system-based
and continuous improvement
on literacy/training/empowerment**

- Necessary to strengthen knowledge of health personnel about the application of new techniques for diagnosis and treatment
 - ↪ also reinforcing the role of General Practitioner in management (mechanisms, adverse events, living with the disease, ...) of "new" chronic morbidities
- To disseminate information to citizens on risks and potential of tests and treatments
 - ↪ Ensuring proper access and appropriateness of use

... a renewed attention to the patient

- Physician-patient alliance to ensure transparency, sharing and active participation by both the therapeutic process
- Individuals do not only differ in their biological variability, but to psychological factors, behavioral, social, cultural and economic conditions (in a lifecourse perspective) which influence the manifestation of the disease and its response to treatment
 - ◆ Importance of the interview with the patient
 - ◆ physicians who are prepared on all aspects of patient care
 - ◆ professionals with different skills working together and ensuring an approach from different perspectives



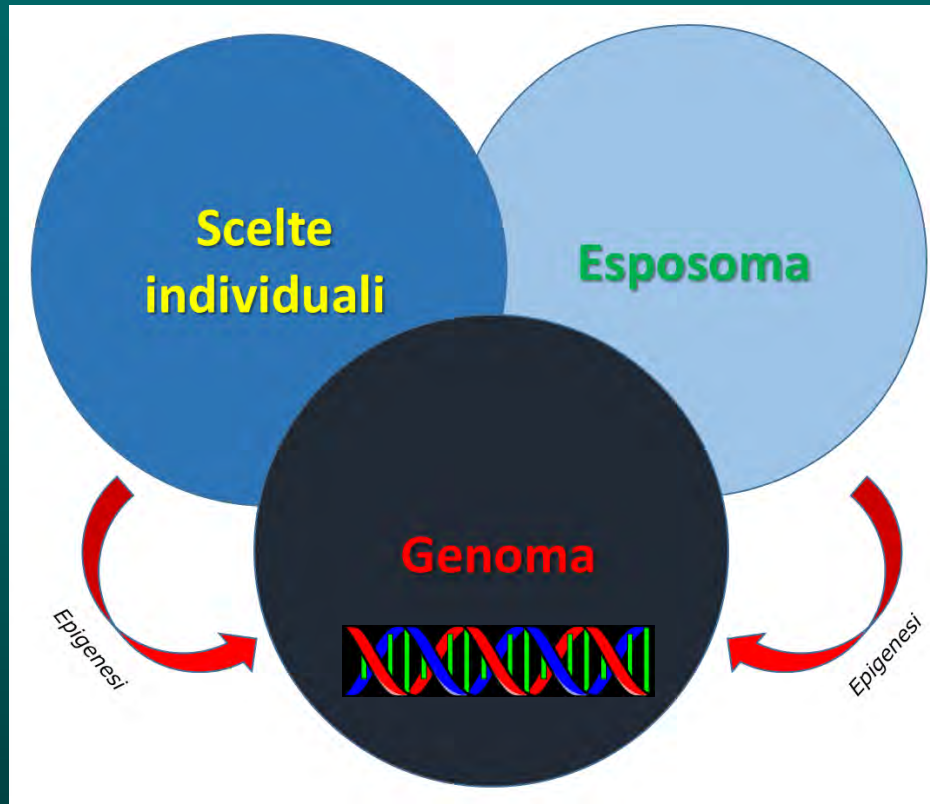
Alimentazione



Attività fisica



Farmaci



Inquinamento ambientale



Microbioma



It is much more important to know what sort of a patient has a disease than what sort of a disease a patient has (Sir William Osler, 1849-1919)

*Grazie per
l'attenzione!!!*

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