PLANNING ADAPTIVE RISK REGULATION

International Conference, 7 – 8 January 2016, London, UK

www.irgc.org/event/planning-adaptive-risk-regulation

STEPP UCL

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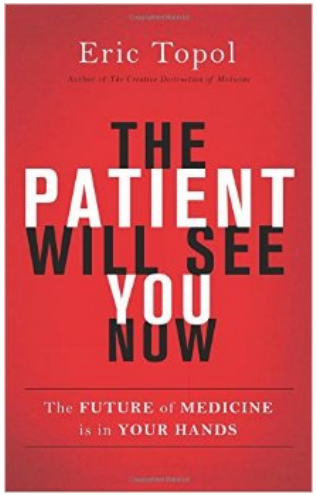
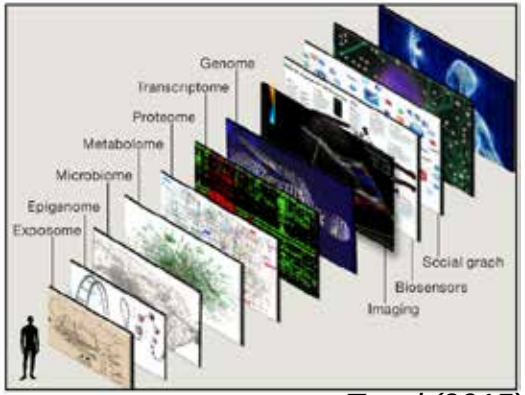
The Revolution of Personalized Medicine

Gérard Escher (EPFL, IRGC)



Personalized medicine : the “-omics and data revolution”



Topol (2015)

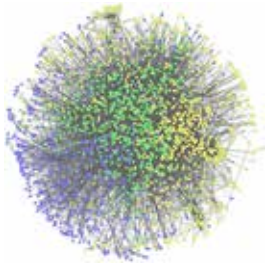
The **Digital YOU** : the sum of your genomic, proteomic, microbiomic, metabolomics data, *combined with* a digital record of your vital signs over time ...

This data will be informative – to say the least – particularly when you compare your digital self with the digital versions of others in your situation.

Peter Cullis, The Personalized Medicine Revolution

Science megatrend

Convergence of computer science, nanotechnology, biotechnology and cognitive science (« info-nano-bio-cogno » convergence),



-> leading to a deluge of data (big data)

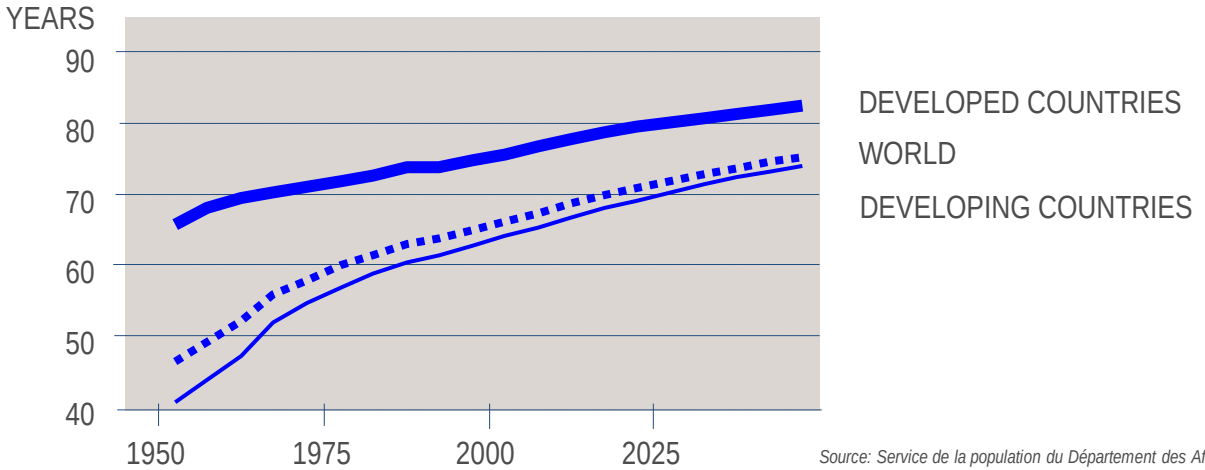
+

-> the capacity to **extract meaning** (smart data)

The aging challenge

Increase of life expectancy

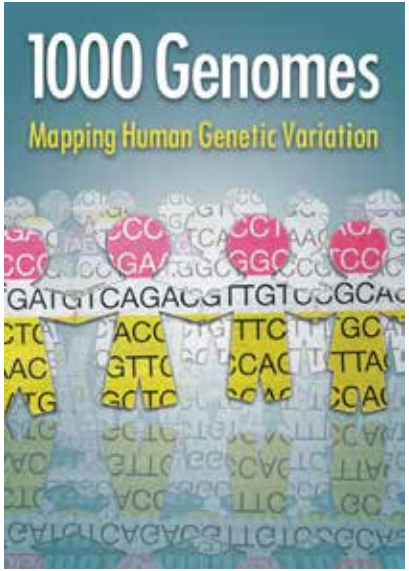
The proportion of older persons (over sixty) will more than double over the next fifty years. 2 billion human beings will be > 60 years in 2050 (20% of the world population)



Source: Service de la population du Département des Affaires Sociales et Economiques du Secrétariat des Nations Unies

Consequences on personalized medicine

- Sequencing of individual genomes will be a commodity. Making sense of the genomes will require huge cohorts.
- Personalized medicine will become a major industry of the future, particularly as the health-maintenance industry increasingly engages in an anti-aging agenda.
- Identification (and soon correction ?) of predisposing genes and risk factors
- Tailored prevention program (life style, nutrition, drugs) with continuous recording of many bio-parameters by integrated biosensors (watches, glasses, contact lenses, clothes…):



Challenges in personalized medicine

Data
- Quality of data collected
- Making sense of data : to understand complex traits massive cohorts are required.
- Danger of «spurious correlations» in data analysis;
- Data privacy and security concerns

Doctors
- Genetic and «probalistic» counselling is difficult and unfamiliar to many doctors.
- Medical curriculum today lacks crucial parts to understand and practise genomic medicine (math, bio-informatics …)

Technology
- Driver of personalized medicine. Expect more «game changers» (like crispr/cas9 -)

Dangers for precision medicine

1. Underestimating the precision medicine revolution
    - Generalized use of non-health data for health purposes with privacy and security concerns
    - Incidence on clinical trials and health insurance

2. Not benefitting from precision medicine
    - «data silos» due to privacy or national regulations or commercial interests
    - Right balance between individual rights and public health concerns, between protection and innovation

3. Bypassing the health system
    - Probable rise of DTC and *gene-hype*
    - The «data cowboys» might bypass and neutralize the health system

Bejing IRGC expert workshop (Aug 2015):

Strong Baseline Protections While Promoting Data Access and Sharing

- Personal medicine is a **global** phenomenon
- **Quality of data** as first ethical imperative, implying certification of providers, controlled and tiered access etc
- **Informed consent** seen as dynamic, adaptive, and the patient as an **active user**
- Use-based view of **privacy** : focus on what is used not what is collected
- **Accountable** systems : data cannot be used against the individual (+incidental findings)

Workshop report available at irgc.org

International (adaptive) regulation …

- «Framework for responsible sharing of genomic and health-related data by the «Global Alliance For Genomic And Health»
- Universal Declaration of Human Genome and Human Rights (UNESCO 1998)
- Need for a «Nagoya protocol» for human genetic data and resources ?

JOIN the two major codes of the 20th century : Genetic Code and the Universal Declaration of Human Rights.