



Maastricht University *Leading in Learning!*

PHGEN II – Key Issues

Leuven, 22./23.09.2011

Public Health Genomics
European Network

"European Best Practice Guidelines for Quality Assurance, Provision and Use of Genome-based Information and Technologies"

DG SANCO [Contract No. 2008302, July 2009 – June 2012]

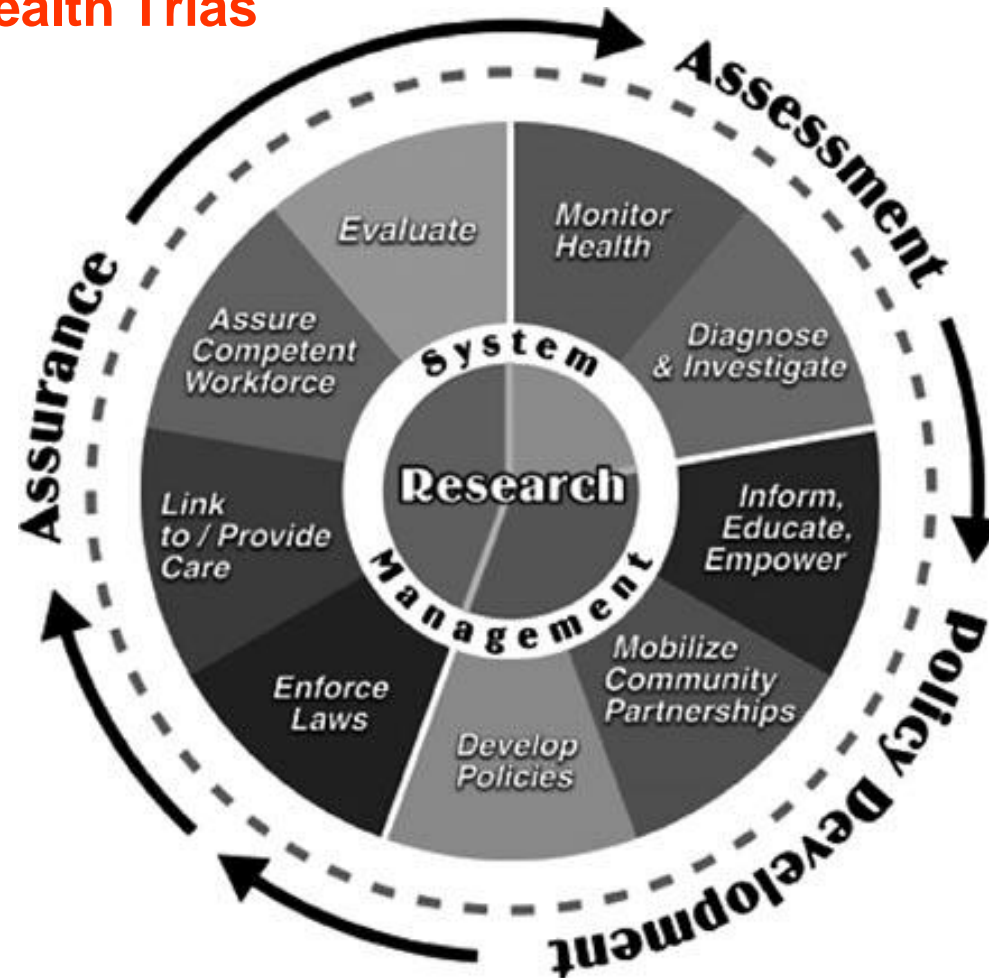
www.phgen.eu

Public Health

versus

Population Health

Public Health Trias



[IOM, 1988]

e.g. Cancer?



[IOM, 1988]

„ ... doing the right (1) things right (2)“

(1) = PHGEN II (BP Guidelines)

(2) = PHGEN III (Implementation of PHGEN II)

2011 - Paradigm shift in Public Health / Healthcare due to genomics & related technologies

... genomics is a „moving target“ ...

... from the

Human Genome Project

to the

Personal Genome Project ...

... from

single systems

to

non-linear networks in systems biology and systems medicine

...

NIH Vision

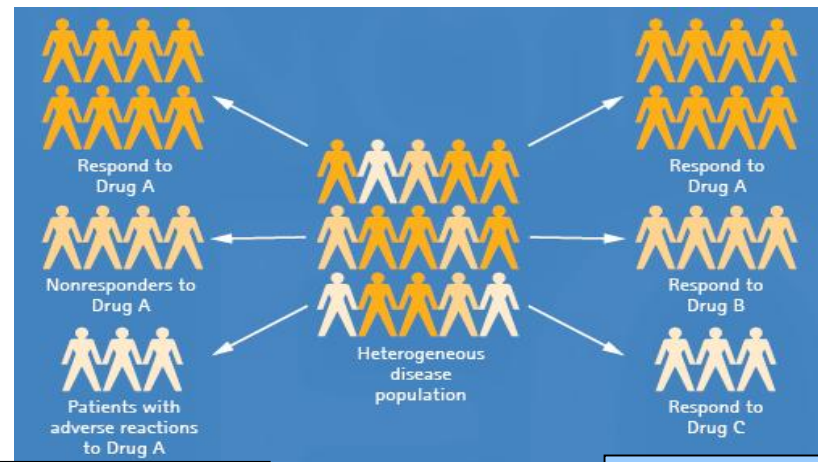


Paradigm shift in Public Health due to genomics - beyond the 4 P's

1. from common complex diseases to “multiple rare diseases”
2. from diseases to “diseasomes”
3. from risk factor to “risk pattern”
4. from clinical utility to “personal utility”

Pharmacogenomics [Ilhan Celik, EHFG, 2010]

Stratified Medicine is about adapting the treatment (molecule, dose, schedule,...) according to the patient's characteristics for better efficacy and less adverse events.



Stratified Medicine

- Patient sub-population
e.g. molecular testing for tumor mutation

versus

Personalized Medicine

- Individual patients
e.g. cancer vaccine made from the patient's tumor

Challenges

- Common complex diseases = a sum of “rare health problems”
- EbM: N =1 trials (“personal utility”) instead of RCTs (“clinical utility”) – HTA of the future?
- Individual risk patterns (RR, AR: population vs. individual level)
- Reimbursement of “rare health problems”
- Market authorization of personalized drugs for various indications (“disease-specific” (“drugome”) /”drug cocktails”/ Medical Devices)
- Personal regulations/laws
- Cross-border Patient Directive (“data follow the person”) & HiAP
- Incentives for PPP?
- Personal data interoperability
- Ownership/Access of/to data
- “Prosumer” (health literacy)
-

PHGEN II

**We have to define today
what kind of (policy) „guidelines“ we need for tomorrow!**

... taking into account e.g.

- dynamics of the field: genomics is a „moving target“ (from HG to PG)
- genome-environment interactions changing permanently over time and space (incl. epigenomics: „from cell to society to cell“)
 - health information instead of biomarkers
- systems network thinking of biomedicine and environment (incl. social environment): e.g. „diseasomes“ and „social networks“
 - P4 medicine (predictive, preemptive, personalised, participatory): „a change of view that changes everything“
 - the changing roles of patients and doctors



IT Future of Medicine

www.itfom.eu



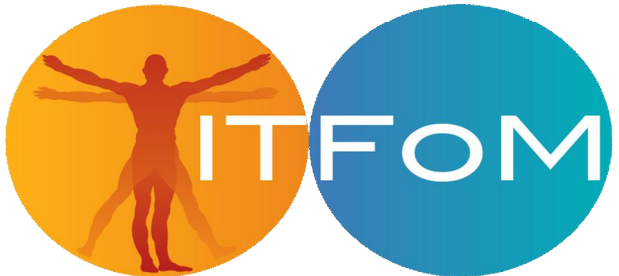
Rationale – „the virtual human“

Data-rich, individualised medicine poses unprecedented challenges for ICT, in hardware, software solutions.

We propose a data-driven, individualised medicine of the future, based on molecular/physiological/anatomical/environmental data from individual patients.

We make general models of human pathways, tissues, diseases and ultimately of the human as a whole.

Individualised versions of the models, produced for each patient, will then be used to identify personalised prevention/therapy schedules and side effects of drugs.



FUTURE OF MEDICINE

ICT



- (1) the tool (integrating in a holistic and comprehensive way all kinds of data now and in the future)
- (2) the solution (precision medicine)

What is (a) the right information and (b) right intervention (prevention, therapy) for the person at that moment?

>> holistic & comprehensive,
market driven & customer centric approach!



PHG in National Institutes of Public Health

Finnland
Belgium
Poland
The Netherlands
Germany
Croatia
Italy ...

- platform for the development of national strategies
- vehicle for the promotion of sustainability

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