Public Engagement and the Ethical, Legal and Social Issues

FROM SYSTEMS MEDICINE TO PERSONALIZED HEALTH, BERN 31.03.2014

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Focus on policy-making …

1. What evidence for informed policy-making?

2. What policy agenda for Europe?

3. What research policy agenda for Europe?

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1. What evidence for informed policy-making?

… from

single and linear systems

to

non-linear networks in systems biology and systems medicine …

….. translating into personalized health and care

(1) highly (in space & time) dynamic personal (health) information

(2) from statistical risks within groups to "individualized evidence"

(3) "virtual individual models" (simulations)

"ICT for health & health for ICT": a radically new vision for healthcare systems!

2. What policy agenda for Europe?

… four European health policy areas …

1. decision-supporting tools

2. “big data”

3. ownership

4. health systems

1. decision-supporting tools

- HTA 3.0 including assumption non-linearity and "individualized evidence"
- translational and transdisciplinary research from first idea to implementation into healthcare systems: systematic early dialogue/PPP (e.g. LAL model)
- "just in time" interventions (JIT)
- orphan drug model & pilots (e.g. Germany: "Heilversuch" with N=25)
- drug/theranostics/CDx/ versus Medical Device/IVD … (use of) health information (HI)
- "virtual twin": in silico "try and error" (simulations, artificial learning)

2. “big data”

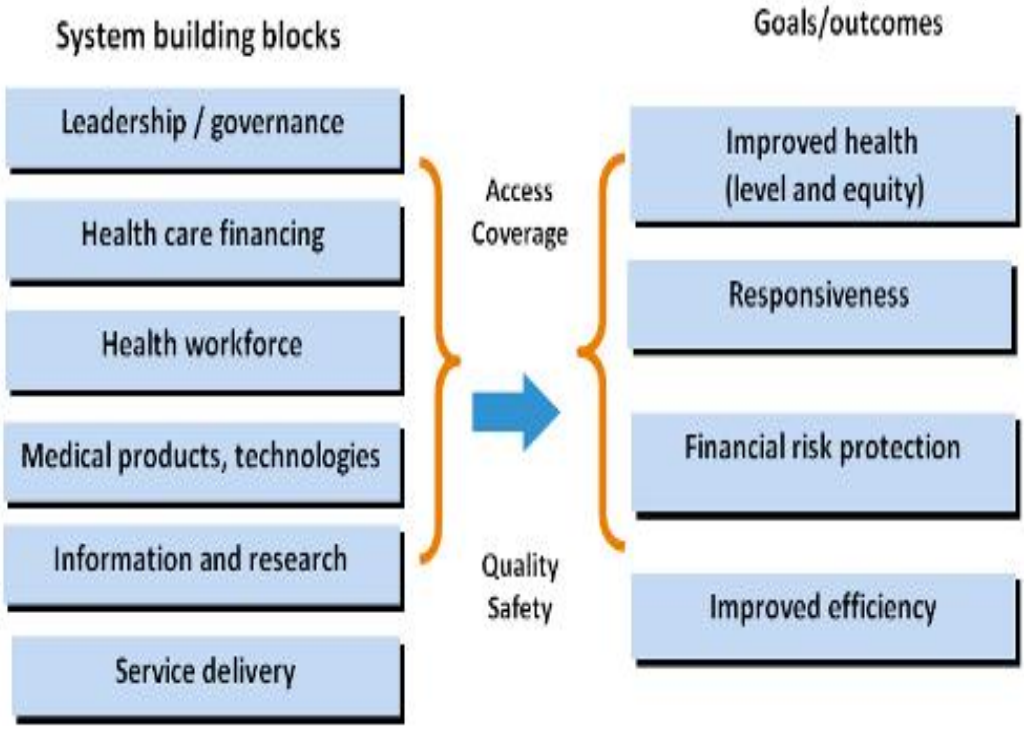
- N=1 trials (monitoring & surveillance): “I am my own reference point”
- N=all trials: mission impossible (information/”big data” will always be incomplete)
- structured and unstructured data for unknown future purposes (more than just data linkage or open access)
- validation, standardization of findings: mission impossible (always a “momentum”)
- “incidental findings”: all findings are important, we just cannot interpret them (yet): “junk versus garbage”
- health information will always be “messy”/chaotic: what (not why) is good enough in most cases!
- “big data” meet governance of information via algorithm providers (QM): rules of impartiality, confidentiality, competence (interpretation of data) and professionalism

3. ownership

- personal files (personal monitoring & surveillance): "I am my own reference point"
- personal ownership/"I am the owner of my data" (property based, excluding right, paternalistic) vs. citizen ownership/control (broader, social right, shared right, democratic)
- the citizen is a unique part of the technology itself ("prosumer", tools: social media, mhealth etc.)
- from individual (blanket or broad) consent & privacy issues to data-users accountability: "trust & trusts"! (… to guarantee data security is dishonest!)
- Health Data Cooperatives (balance between public good – personal benefit, no monetary incentives for individuals!)

4. health systems

- "good governance" – "good" implementation of "good" health policies (e.g. in Europe cross-border directive)
- WHO-EU Regional office (Tallinn, 2008) : six system building blocks



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3. What research policy agenda for Europe?

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Project full title: Personalized Medicine 2020 and Beyond – Preparing Europe for Leading the Global Way

Proposal acronym: PerMed

Type of funding scheme: Coordination and Support Action (Supporting Action)

Work programme topics addressed: HEALTH.2013.4.1-4: Preparing the Future for Health Research and Innovation. FP7-HEALTH-2013-INNOVATION-1. 4.1 COORDINATION and SUPPORT ACTIONS ACROSS THE THEME

Coordinator: BMBF/dlr Germany

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PerMed

- Consortium: Research and Health Ministries (funding bodies)
- Connected to other key European initiatives in Personalized Medicine (e.g. ESF, EuroBioForum, EHFG, EAPM, EPEMED, HOPE, PHGEN, CASyM, 3GBTest)
- Aim: strategic research and innovation agenda (SRIA) for Europe
- 1st Workshop of stakeholders March 27/28th 2014 in Berlin
- Parallel Forum at the European Health Forum Gastein (EHFG), October 1-3, 2014
- Webpage: http://www.permed2020.eu

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Workshop Session: „Regulation, Reimbursement, Market access“

What is different? Regulatory gaps & needs?

... regulatory need: in case of safety and risk!

CSA PerMed Workshop 1, Berlin 27./28.03.2014

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„Regulation, Reimbursement, Market access“ (1/3)

1. Systematic early dialogue for informed policy-making

- Decision Maker (DSM) – HTA
- Manufacturer – HTA
- Manufacturer – HTA – DSM
- Manufacturer - Manufacturer

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„Regulation, Reimbursement, Market access“ (2/3)

2. Data („big data“)

- ownership (citizen owned and controlled), handling, access, open source field, silos
- different purposes/users (beyond health), HiAP
- algorithm user‘s responsibility (validation of processes, regulation, different policies)
- „bottom-up“ policy-making

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„Regulation, Reimbursement, Market access“ (3/3)

3. Assumption of non-linearity, dynamics of information, complexity

i.e. „momentum“: no prediction of risk/phenotype possible, no indication, no validation possible – regulatory need??

4. product/diagnostics (medical device) versus process/tool – no regulatory need ...

5. Outcome data: feedback from market back to DSM (conditional approvals, adaptive (social) licensing and conditional reimbursement)

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... Complementarity??

from ELSI 1.0
to variation of ELSI 1.0 and ELSI 3.0 ...

Variation of ELSI 1.0: Ethical, Literacy, Social implications

ELSI 3.0: Economic, Legal, Systems implications


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