Principles for Public Health Ethics
– Ethical Foundations for Good Genomic Governance

Peter Schröder
Public Health Genomics European Network (www.phgen.eu)
Good Genomic Governance

Thesis 1:

Public Health Policies and Genomics can best and most comprehensively be discussed under the roof of the (multi-)discipline called “Public Health Genomics”
Good Genomic Governance

Thesis 2:

In this context, good genomic governance is the process whereby public institutions steer and conduct the allocation of research funds and public health by considering basic ethical principles.
Good Genomic Governance

Thesis 3:

What principles are the primary benchmarks for Public Health Genomics?

There would be a shortcoming to use medical ethics or bioethics frameworks for ethical orientation in Public Health Genomics.
“Public health practice in the twenty first century can no longer ignore the knowledge derived from genetic and molecular science. An understanding of the cellular mechanisms of disease will be as important to the public health community as an understanding of the social determinants of health.”

Ron Zimmern / Hilary Burton
Public Health Genomics

“Public Health Genomics (PHG) is the responsible and effective translation of genome-based knowledge and technologies into public policy and health services for the benefit of population health.”

Bellagio Statement 2005
Public Health Genomics

„Are we assuring the right health interventions (Health Needs Assessment, Health Technology Assessment)

in the right way (Quality Management & Policy Impact Assessment)

in the right order and at the right time (Priority Setting & Health Targets)

in the right place?“ (Concept of Integrated Health Care & Health Management)
Chances and Challenges for Public Health Genomics

“… to rethink and systematically evaluate every condition of public health interest…”

Chances and Challenges

• earlier & higher precision of **risk strata** (distinction between and identification of high, moderate and low risk groups)

• **stratified prevention** instead of “one prevention strategy for all” (“prevention paradox”: low genetic penetrance and high frequency of genetic susceptibilities with minor effects as the specific challenge for public health (genomics))

• **minimising “faulty prevention”** (examples of target-orientated vaccination or of sports and sudden death)
Chances and Challenges

• genetic factors as “necessary but not sufficient” determinants in the development of complex diseases and health problems

• shift in the definitions: from “genetic test” to “genetic determinant” to “individual health information”
Public Health Genomics and EC

The call by DG SANCO

The European Commission called for a “networking exercise … to lead to an inventory report on genetic determinants relevant to public health. This network will identify public health issues linked to current national practices in applying genetic testing and on that basis will contribute to developing best practice in applying genetic testing.”

DG SANCO: Community action in the field of public health (2003-2008), Work plan 2005
PHGEN

Public Health Genomics
European Network

January 1st 2006 - December 31st 2008 (36 months)

EU Project: 2005313
Objectives of PHGEN

1. Networking exercise covering all EU Member States, Applicant Countries, and EFTA-EEA

2. Identification and Listing: Key experts relevant to PHG in these countries

3. Inventory of PHG-Issues & Priorities in Europe
Objectives of PHGEN

4. “co-operation and exchange of information in order to enhance coherence and disseminate best practice”.

5. Identify legal diversities and barriers in a cross boarder market.

6. To promote and stimulate the countries’ efforts in this emerging field by developing PHGEN and by supporting effective networking in order to reach sustainability.
„In the long run
PHGEN will serve the European Commission
as an ‘early detection unit’
for horizon scanning, fact finding, and monitoring
of the integration of genome-based knowledge
and technologies into public health.“
WP 6: Policy Development

„Standards and Guidelines which promote the appropriate use of genetic information“

• Analysis of legal diversities (e.g. conflicting laws) and barriers in a cross-border market

• Analysis of EC treaties for PHG

• Analysis of European best practice standards, guidelines & laws

• Analysis of economic implications & PHELSI

• Development of policies on education, information and empowerment
Cross Sectional Working Group on Ethical Benchmarks
(coordinated by Peter Dabrock / Peter Schröder)

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Good Genomics Governance – Legal Aspects

Governance in genomics: a conceptual challenge for public health genomics law
Tobias Schulte in den Bäumen

Public Health Genomics European Network (PHGEN)
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Free download from www.ijph.it
Where do we get ethical guidance from for *Good Genomic Governance (in Public Health)*?
Ethical Guidance from the Hippocratic Oath – Historic Source of Medical Ethics

„I will prescribe regimen for the good of my patients according to my ability and my judgement and never do harm to anyone.“
Hippocratic Oath & Ethical Tradition

„I will prescribe regimen for the good of my patients according to my ability and my judgement and never do harm to anyone.“

Doing Good / Beneficence [ ~ Salus aegroti suprema lex]
Hippocratic Oath & Ethical Tradition

„I will prescribe regimen **for the good of my patients** according to my ability and my judgement and never do harm to anyone.“

Doing Good / Beneficence [ ~ Salus aegroti suprema lex]

Avoiding Harm / Non-Maleficence [ ~ Primum nil nocere]
Hippocratic Oath & Ethical Tradition

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Doing Good / Beneficence [ ~ Salus aegroti suprema lex]

Avoiding Harm / Non-Maleficence [ ~ Primum nil nocere]

→ Paternalistic Attitude
Something’s missing … or even wrong?

• 1972: „Patient’s Bill of Rights“ (AHA)

• Rights-Talk: A Patient does have Autonomy & Rights

• Scarce Medical Resources. „Seattle's God Committee“, “Benefits and Burdens of Research“ → Justice

„The Hippocratic ethic will be relegated to the ash heap of history – a benevolently paternalistic morality that may have worked for a culture in which patients were patient – when they were (as the word *patient* implies) passive, long-suffering, ignorant, and believed to be incapable of making choices.”

Principles of Bioethics

Respecting Persons
Doing Good
Avoiding Harm
Justice
Principles of (Bio-)Medical Ethics

Belmont Report (1978)

„respect for persons“  →  Respecting Persons
„beneficence“      →  Doing Good
„justice“          →  Avoiding Harm
                      Justice
Principles of Bioethics

**Belmont Report (1978)**
- "respect for persons"
- "beneficence"
- "justice"

**Respecting Persons**
**Doing Good**
**Avoiding Harm**

**Beauchamp / Childress (1979)**
- "(respect for) autonomy"
- "beneficence"
- "non-maleficence"
- "justice"
Principles of Bioethics

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- "respect for persons"
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**Respecting Persons**

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**Justice**

**Beauchamp / Childress (1979)**

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- "non-maleficence"
- "justice"

**Individual Ethics**: Guiding principles for intra-personal actions (nurse/physician-patient).

**Social Ethics**: Guiding principles for social, structural and institutional aspects – i.e. for public policy.
## (Bio-)Medical Ethics principles matrix

<table>
<thead>
<tr>
<th>Individual Ethics</th>
<th>Moral Aim: Maximizing good consequences</th>
<th>Moral Aim: Doing the right things / respecting rights</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rubric: Hippocratic Utility</td>
<td>• Beneficence</td>
<td>• Respect for Autonomy</td>
</tr>
<tr>
<td>• Nonmaleficence</td>
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| Social Ethics | - | • Justice |
“Hippocrates had nothing to say about public health.”

There is a „difference between the individualistic orientation of bioethics and the population and societal focus of public health. [...] [It] is a difference between the perspectives of the public health and policy world, on the one hand, and the world of clinical medicine (in which bioethics has principally operated), on the other.

More difficult will be the tension produced by the predominant orientation in favor of civil liberties and individual autonomy that on finds in bioethics, as opposed to the utilitarian, paternalistic, and communitarian orientations that have marked the field of public health throughout ist history.“

Public Health Ethics does not have to be only:
- Communitarian
- Paternalistic
- Utilitarian!

→ Orientation from *Mid-Level Principles*! (Although methodologically related to the bioethics scholarship, yet another normative framework than Bioethics).
Methodology – Where do we get principles for PHE from?

Ethics (Discipline Reflecting Morality)

Morality
(Set of Norms / Values of a person/community)

Applied Ethics Discourse A (e.g. Business Ethics)

Applied Ethics Discourse B (e.g. Bioethics)

Applied Ethics Discourse C (e.g. Public Health Ethics)
Theories – Principles – Rules – Judgements

Theories

\[ \uparrow \quad \downarrow \]

Principles

\[ \uparrow \quad \downarrow \]

Rules (e.g. in Codes)

\[ \uparrow \quad \downarrow \]

(More) Concrete Rules

(e.g. in Guidelines)

\[ \uparrow \quad \downarrow \]

Singular Judgments

(in Particular Situations)
Why focus on Principles for a Framework …

… rather than on virtues / rules / codes / guidelines or other specified norms for primary orientation in applied ethical discourses?

„[R]ules often are inadequate to cover complex situations; at times they come into conflict, and they are frequently difficult to interpret or apply. Broader ethical principles will provide a basis on which specific rules may be formulated, criticized and interpreted.“

Belmont Report
PHE-Principles as Benchmarks (for PHG)

<table>
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<td>Social Ethics</td>
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<td>• Justice</td>
</tr>
<tr>
<td></td>
<td>• Maximizing Health and Well-Being</td>
<td></td>
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<td></td>
<td>• Efficiency</td>
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<td></td>
<td>Proportionality</td>
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A concise set of broad PHE Principles (+ PH relevant Specifications)

• **Maximising Health / Well-Being**
  – Primary orientation on „numbers“ and outcome

• **Respect for Human Dignity**
  – No instrumentalisation, no sacrifice
  – Self-Determination, Self-Responsibility, Informed Contract / Consent
  – Avoiding Force

• **Social Justice**
  – Distribution of benefits and burdens (research, health programmes)
  – No stigmatisation, no discrimination
  – Empowerment of risk groups and individuals
  – Responsiveness to a sufficient level of the diverse dimensions of well-being (health, attachment, education, capabilities)

• **Efficiency**
  – Awareness of Scarcity of Public Money, saved money can be used for other goods

• **Proportionality (cross cutting principle)**
  – In all balancing of goods: Be responsible with finding means to the envisaged aims
Thank you!

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