Ethical approaches to Innovation in Global Health

World Health Summit Satellite Event
“Innovation in Health: The contribution of biologic medicines to public health“

Berlin, October 10, 2016
Demographic change: aging societies

More chronic degenerative diseases & cancer

Increasing demand for medical & nursing care (with increasing costs!)

Limited financial resources in public health care systems

Limited supply of medical & nursing care

Increasing scarcity of health care resources

Elimination of waste ⇒ increase efficiency

Explicit priority setting ⇒ wise usage of limited resources
Explicit priority setting – Definition

• Explicit, evidence based determination what is more or less important in health care based on clearly defined ethical criteria

⇒ Direct limited health care resources to those areas where they are needed most!

Current situation in most health care systems

• No explicit priority setting

⇒ But: implicit priorities “implemented” in the system by financing infrastructure, reimbursement of services, regulation of providers, market expectations, etc.

⇒ Often does not match primary health needs of the population!

⇒ Today: What role shall biologics play in the hc system?
### Priority setting – distributive justice: 3 levels

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Level 1: Allocation of resources into biologics (vs. other alternatives)

- Central issue: high investment in biologics ⇒ right priorities?
  - Directed towards priority health needs of the population?
  - Higher health gain if resources are invested in other approaches (including prevention)?
  - Are existing inequalities in health status taken into account?

Policy options:

1. Explicit priority setting in public funding for research
   - Health care needs in an ageing society (chronic diseases, multi-morbidity)
   - Priority for disadvantaged (sub-)populations
   - Potential for improving health status in population
   - Priority for common diseases?
   - Cost-effectiveness (efficiency) – anticipative assessment possible?

2. Incentives for pharmaceutical companies to invest in areas with high priority
Level 2: Resource allocation within biologics

- Investment in profitable areas \(\Rightarrow\) populations with rare (genetic) profile are neglected \(\Rightarrow\) „orphan populations“
- Neglect of vulnerable, already disadvantaged subpopulations
- Research with patient subgroups beyond biologics neglected \(\Rightarrow\) higher risks through insufficiently tested interventions

Policy options

- Incentives for investments by pharmaceutical industry in „orphan populations“ (cf. current orphan drug regulation)
- More public research funding in (genetically) rare patient populations
- Challenge: increasing number of „orphan drugs“ \(\Rightarrow\) increasing public spending necessary \(\Rightarrow\) limits? priorities?
Priority setting – distributive justice: 3 levels

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Challenge: many innovative biologicals are expensive

⇒ Affordability: Do public hc systems have to set limits? E.g. based on cost-effectiveness assessment (cf. the NHS)?

At the time of licensing of the drug: effectiveness/benefit under routine conditions difficult to assess

• Studies for licensing: usually assess efficacy under ideal conditions

• Selected, not representative samples

• Surrogate endpoints instead of patient relevant endpoints (⇒ overall survival, quality of life)

• No head-to-head comparison with standard treatment

• Incomplete data transparency (reporting & publication bias)

⇒ Requirements for a needs oriented and fair allocation & distribution are often not met!
Policy options

(1) First: Improve effectiveness/benefit assessment
   - Independent, publicly financed clinical studies after licensing of the drug (patient relevant outcomes)
   - (Initially) coverage only in clinical studies („coverage with evidence development“)
   - (Germany: benefit assessment according to AMNOG too early!)

(2) Improve decision making on the micro level
   - Patients should be fully informed about benefits & risks of new treatments and alternatives (e.g. palliative care in advanced oncological disease)
   - Shared decisions making ⇔ respect patient preferences

(3) Cost-effectiveness assessment (CEA/CUA)
   - Price negotiations with pharmaceutical industry
   - Consider limited coverage of interventions with bad incremental C/E-ratio
   - Goal: unlimited access to real innovations for all patients, exclusion of „pseudo innovations“
Thank you very much for your attention!

Slides: www.dermedizinethiker.de

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<td>Medical need</td>
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<tr>
<td>Justification</td>
<td>• severity of disease</td>
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<td>Evidence-based</td>
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<td>Manage conflict of interest</td>
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<td>Revision &amp; appeal</td>
<td>Meta criterion:</td>
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