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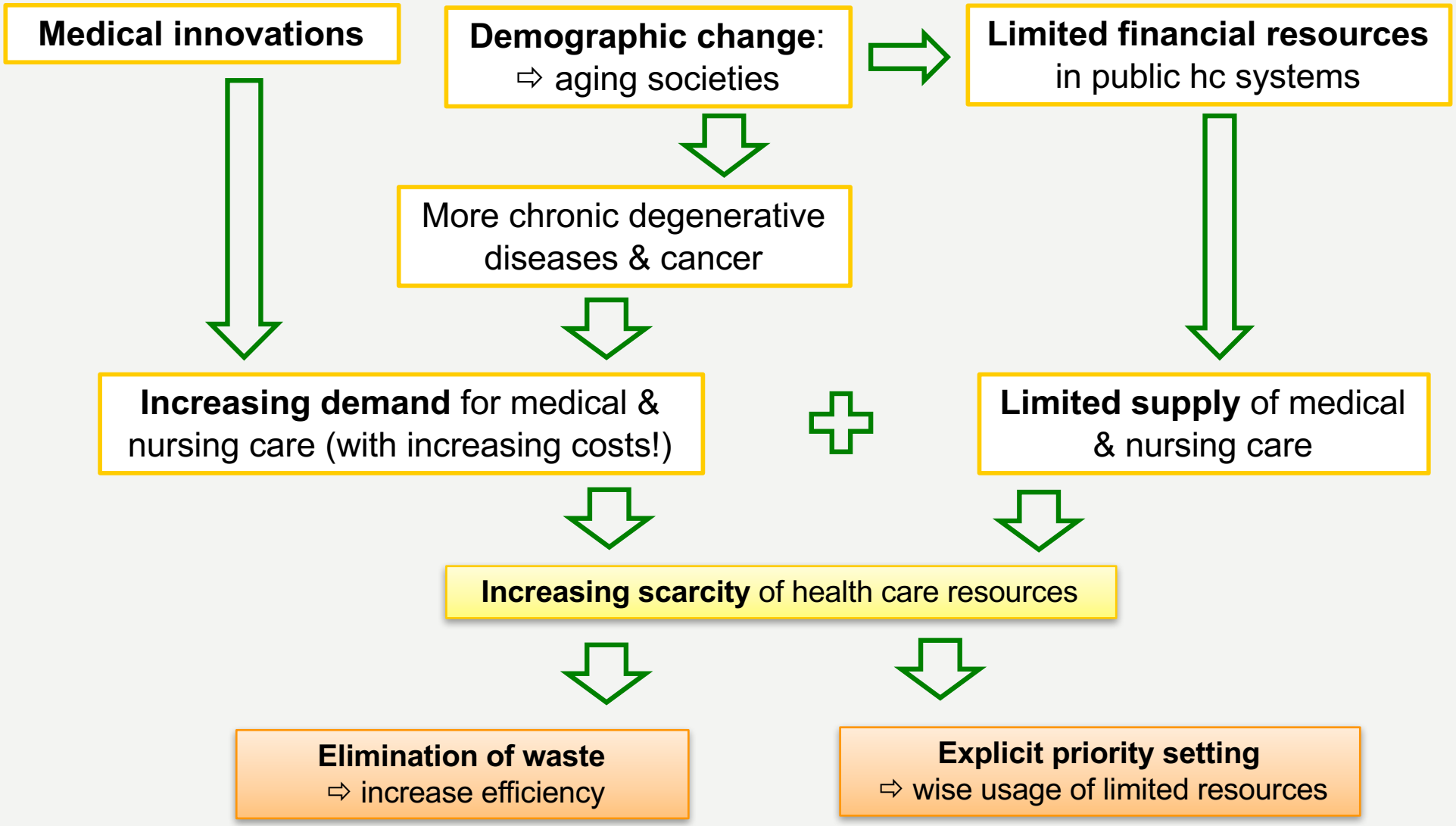
Ethical approaches to Innovation in Global Health

World Health Summit Satellite Event

"Innovation in Health: The contribution of biologic medicines to public health"

Berlin, October 10, 2016

Background


Medical innovations
Demographic change:
⇨ aging societies
Limited financial resources
in public hc systems
More chronic degenerative diseases & cancer
Increasing demand for medical & nursing care (with increasing costs!)
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

Priority setting

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?*

Biologics and priority setting: overview

Priority setting – distributive justice: 3 levels

Level	Area	Explanation
1	**Allocation** of research resources	Allocation of resources *into* biologics (vs. alternative ways to promote health, prevent and treat diseases)
2		Allocation of resources *within* the field of biologics
3	**Distribution** of biologics	Distribution of / access to biologics

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Allocation of research resources (1)

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

Allocation of research resources (2)

Level 2: Resource allocation *within* biologics

- Investment in profitable areas ⇨ populations with rare (genetic) profile are neglected ⇨ „orphan populations“
- Neglect of vulnerable, already disadvantaged subpopulations
- Research with patient subgroups beyond biologics neglected ⇨ 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“ ⇨ increasing public spending necessary ⇨ limits? priorities?

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Distribution of biologicals (1)

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!

Distribution of biologics (2)

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“

Finally…

Thank you very much for your attention!

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Criteria for priority setting

Procedural criteria	Substantive criteria
Transparency	**Medical need**
Justification	• severity of disease
Evidence-based	• urgency of treatment
Consistency	**Expected individual benefit**
Legitimacy	**Cost-benefit ratio**
Manage conflict of interest	
Revision & appeal	Meta criterion:
Regulation	• quality of evidence