TESTING INTERVENTIONS FOR DRASTIC PUBLIC HEALTH THREATS

"SOCIAL VALUE", PRAGMATIC RISKS AND THE CHALLENGE OF "HEALTH-RELATED RESEARCH" ETHICS

THE CASE OF DRUG RESISTANCE

CHRISTIAN MUNTHE[1], NIELS NIJSINGH[1], KARL PERSSON DE FINE LICHT[2]

1. Dept. of Philosophy, Linguistics & Theory of science, and the Centre for Antibiotic Resistance Reserach, CARe, University of Gothenburgh
2. RISE: Research Institutes of Sweden; Dept. Of Philosophy, Linguistics & Theory of science, and the Centre for Antibiotic Resistance Reserach, CARe, University of Gothenburgh

Important news in the new CIOMS guidelines

1. SCOPE

- Biomedical research ➔ **Health-related** research

2. VALUE BASE

- Knowledge & health ➔ knowledge & **Social value**

Meaning? Signal?

- Public health on equal footing with (individual) health in portal statutes. Apparently large difference to Helsinki Decl.

- Inclusion of research that targets social institutions and practices, rather than somatic and natural causal webs ➔ evidence based health policy

- Broader set of value considerations that determine and might balance individual risks and benefits: public goods, institutional qualities, popularly/culturally embraced concerns

- Standard consent regimes often not viable/feasible (more later!). Beyond H.D. standard assumption

- **Focus on the pragmatics of (public) health interventions:** having them actually deliver what may ideally justify them. **Increasing apparent conflict w. H.D.**

Framework for assessing testing interventions for drastic public health threats

- Challenging disease outbreaks: ebola, zika …
- Climate change and mass migration ...
- **Drug resistance**

- Underlying mechanisms (at least) as much social as biomedical/natural. Impact requires complex **packages of biomedical measures *and* interventions for social change**
- Complicated task to show actual effect
- **New panorama of research ethically relevant risks**: harm or counterproductivity on massive scales due to social and institutional factors
- **Good case for testing, but also for ethical assessment of such research**: Chapter by us in forthcoming book on drug resistance ethics, ed. by Michael Selgelid & Zeb Jamrozi (Springer).

Focus here:

- **Important and peculiar risk factor**: institutional and social responses to intervention packages that would be justified in ideal circumstances may create grave suboptimality, outright counterproductivity and irreversible harm ➔ **pragmatics, something very different from ”side-effect” risks**

Drug resistance: three types of interventions

1. **Innovation stimulation**: Interventions to incentivise and speed up the development of new drugs (antibiotics, antivirals, etc.)
   - ”Expedited programs”: fast track, priority review, etc.
   - Financial incentive schemes: subsidies, modified patent-constructions, etc.

   PRAGMATIC RISK: Producers and innovators incentiviced to overly focus on that for which there is a specific reward, undermining important and effective drug development in other areas, while research is bent to focus on mostly unrealistic targets.

2. **Stewardship stimulation**: Interventions to optimise the use of (new) drugs in light of resistance development.
   - Prescription guidelines/regulations
   - Changing general institutional and regulatory frameworks

   PRAGMATIC RISK: Policy changes fail to attract the public support needed for them to be politically feasible/institutionally effective

3. **Environmental health action**: Internalising external environmental cost of production practices driving drug resistance.
   - Taxing regimes, eg. for food that depends on the use of resistance driving drugs
   - Penalising (criminally or financially) drug producers allowing resistance driving emissions

   PRAGMATIC RISK: See 2 + producers are incentivised to move production to unregulated territory

Implication for research ethical review

- Very good reason for having responses to drastic public health threats tried out as health interventions in a scientific manner
- Likewise good reason for such trials to be subjected to ethical review that includes the social and institutional aspects of the ”social value” of such research
- **Assessing the potential for benefit** that may justify such trials needs to include the pragmatic risks of counterproductivity
- **Trial designs** should include controlling for the pragmatics (in contrast to standard assessment of biomedical research trials, where loss of effect due to pragmatic imperfection is typically ignored).
- Important for review to **identify drastic pragmatic risks** that threaten to block effective health policies for long times, and demand **stopping criteria** to curb these.

Playback towards the new CIOMS guidelines

- Are the guidelines trying to swallow too much? ➔ pushing research ethical review into an evidence based policy-making pipe dreams?

Not necessarily, but it is a challenge

- Are the institutions of reseach ethical review (boards, etc.) prepared to rise to the task?

No, neither resources or routines suffice

- Is the (apparent) conflict with H.D. a problem?

Yes

UNIVERSITY OF GOTHENBURG

PHILOSOPHY, LINGUISTICS & THEORY OF SCIENCE
FLOV.GU.SE

CENTRE FOR ETHICS, LAW AND MENTAL HEALTH
CELAM.GU.SE

CENTRE FOR ANTIBIOTIC RESISTANCE RESEARCH
CARE.GU.SE

GOTHENBURG RESPONSIBILITY PROJECT
GRP.GU.SE

FORTE: Forskningsrådet för hälsa, arbetsliv och välfärd

Vetenskapsrådet

Thank You!

Free of charge symposium:

Ethics and Value Challenges in Antibiotic Resistance Management, Policy & Research

15-16 November, 2017

Main Auditorium, University of Gothenburg

More info & registration: http://care.gu.se/conference-in-ethics--nov-2017