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FORTE: Forskningsrådet för hälsa, arbetsliv och välfärd

Vetenskapsrådet

SHOULD DRUG RESISTANCE INTERVENTIONS BE EXPEDITED?

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The idea of expediting innovation

- **Providing a privileged pathway** from research to actual product
  - New drugs that escape resistance (for a while)
  - New technical methods of other kinds: diagnostics, surveilance, transmission, etc.
- **”Cutting red tape”**: Relax requirements and/or bypass procedure
  - Patenting
  - Proof of effect
  - Risk assessment
  - Ethical review
  - Licensing process
  - Place in line for any of the above (”fast track”)
- **Point**: get important innovations into use more quickly
- **Reason for expediting programs** stronger in the face of greater needs

The (ethical) case for expediting DR interventions

- **Legal pragmatics**: ”Red tape” is there for a reason that does not apply to Drug Resistance
  - A threat to public health that ”normal innovation pathways” assume as a bottom line
  - May undermine the basis for any future healthcare intervention to be to the benefit of patients
  - Time and tempo is a factor in the DR threat
- **Public health ethics**: balancing individual and population health in the long run
- **Sustainability**: maintaining effectiveness of healthcare and food infrastructure
- **Precaution**: drastic threats and high stakes justify that we accept more uncertainty regarding effectiveness of interventions

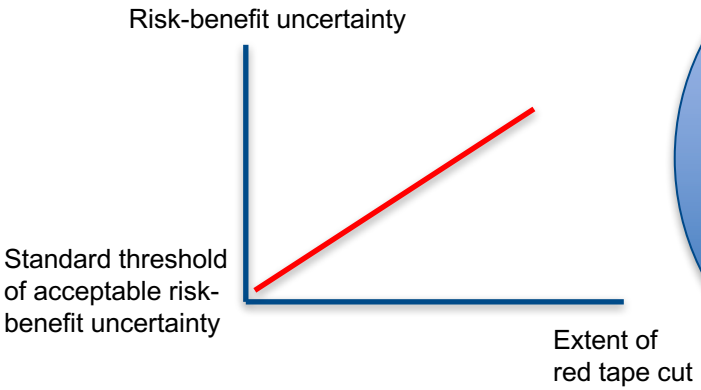
But *how* and *how much*?

- No one claims: no red tape needed at all
- No argument supports a *laissez faire* system
- Whatever we win in speed and tempo, we may lose in effect
- Worse: increased risk of worsening the problem may result

Challenge no. 1: Balancing individual risk and public benefit

- Less red tape ➔ more *uncertainty* of patient benefit

- Less red tape ➔ higher risk of *unforeseen* patient harm



Blunt problem formulation

How much of harmed/killed patients is it worth to slow down DR development to degree X?

WHY?

- Present and future *life* trade-off
- **Present and future *generation* trade-off**

- Principle of responding to need of healthcare
- **Principle of preventing need of health care**

Challenge no. 2: Conflict with professional medical ethics (?)

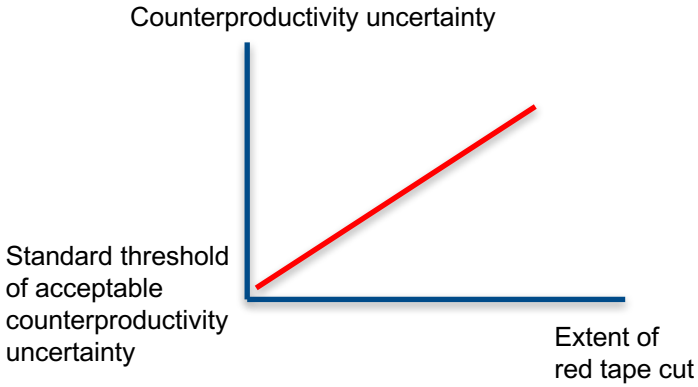
- Responding to actual need of health care trumps avoiding possible future need of health care
- Allocating health care resources according to medical need
- Individual health concerns trump public health and institutional sustainability considerations

Need to reform professional medical ethics?

Do we want doctors and nurses to care less about meeting the needs of their patients?

Provided it would help managing the DR threat, maybe we really do!

Challenge no. 3: Risk of interventions *worsening* the DR problem or other central public health challenges



- Ineffecient interventions provide false sense of security while DR problem grows
- Effectiveness in one dimension undermines prevention of DR in another dimension. Eg. screening programs deter people from seeking health care.
- Prescription regimes and new formulas in farming lead to elevated food prices
- Effected risk-benefit-uncertainty levels unacceptable to the general public

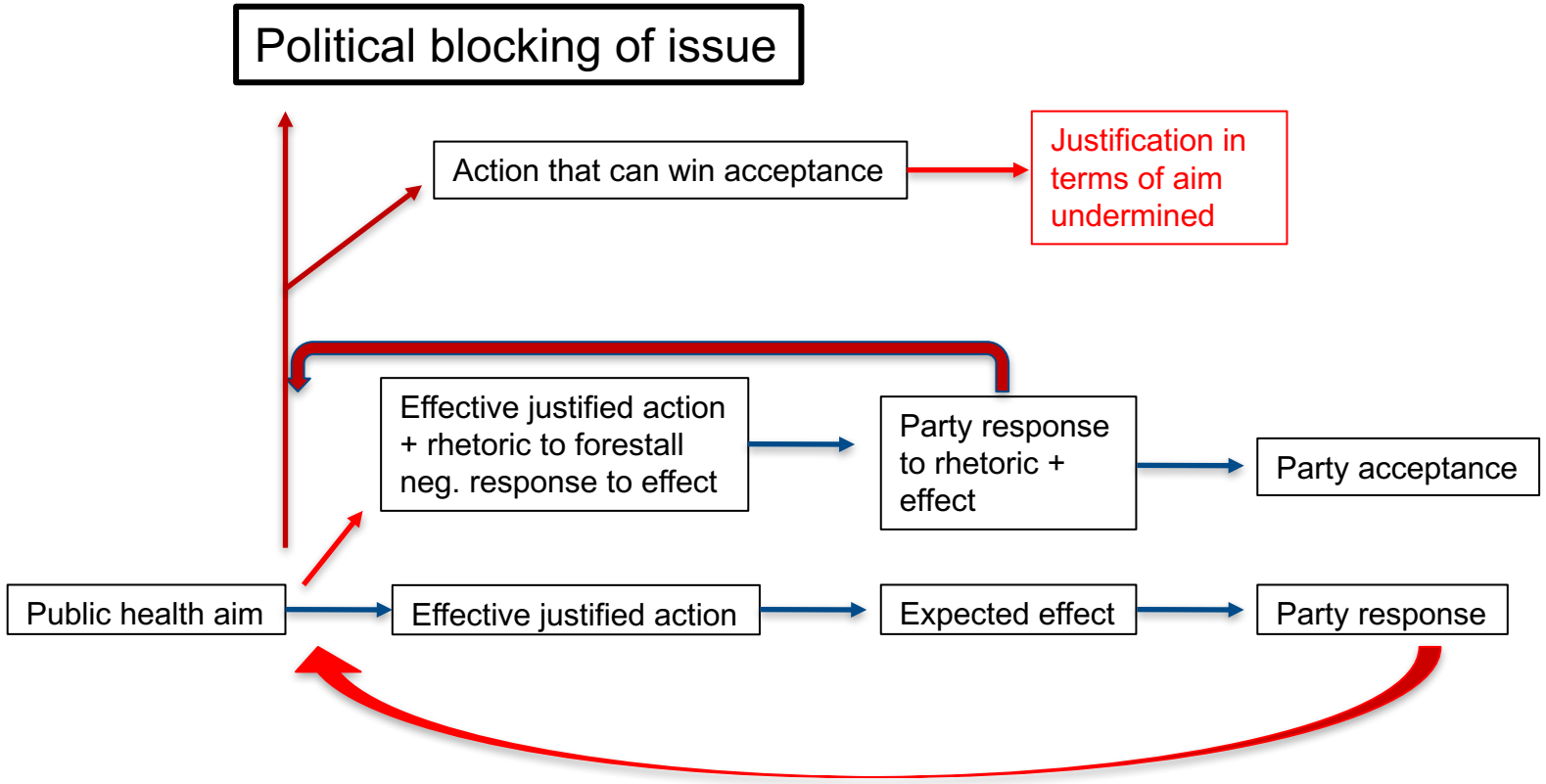
Challenge no. 4: Pragmatic risks due to dynamic responses to expediting program design and effects

- Producers redesigning production and business models in ways that undermine public health or sustainability of health systems
  - Example: Orphan drug expediting pathways ➔ More and more drugs redesigned to become ”like” orphan drugs (”precision medicine”) ➔ Increased overall cost for less certified risk-benefit balance

- Public, professionals, a.o. resist increased uncertainty levels, so that also more measured expediting programs become politically blocked ➔ Imagine a politician answering the blunt problem formulation …

- **If health care becomes less effective and safe, the public and health professionals will have less reason to care about saving it from the DR threat**.
- **Ditto food delivery systems**

The general pragmatic risk challenge for social interventions in the DR area



Provisional conclusions

- Reasons for expediting programs for DR interventions are less strong than they appear at first glance.
- Maintaining the trust of the public and the alliance with health professions introduces major risk factors for such programs.
- Avoiding pragmatic risks of expediting programs may very well undermine their justification in terms of public health.