The Social Value of Knowledge in Medical Research

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The Social Value of Knowledge in Medical Research

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Aim

- Defense of the social value of knowledge (SVK) in medical research as necessary condition

- Offering a new justification for the Social Value of Knowledge that avoids common critique

The Social Value of Knowledge (SVK)

What Makes Clinical Research Ethical? (Emanuel et al. 2000)

- One of seven principles for clinical research (Emanuel et al. 2000)
- **The principles: social value**, validity, fair subject selection, favorable risk-benefit ratio, independent review, informed consent, respect for subjects
- Research involving human subjects must aim at socially valuable knowledge in order to be ethically justified

SPECIAL COMMUNICATION

What Makes Clinical Research Ethical?

Ezekiel J. Emanuel, MD, PhD
David Wendler, PhD
Christine Grady, PhD

Many believe that informed consent makes clinical research ethical. However, informed consent is neither necessary nor sufficient for ethical clinical research. Drawing on the basic philosophies underlying major codes, declarations, and other documents relevant to research with human subjects, we propose 7 requirements that systematically elucidate a coherent framework for evaluating the ethics of clinical research studies: (1) value—enhancements of health or knowledge must be derived from the research; (2) scientific validity—the research must be methodologically rigorous; (3) fair subject selection—scientific objectives, not vulnerability or privilege, and the potential for and distribution of risks and benefits, should determine communities selected as study sites and the inclusion criteria for individual subjects; (4) favorable risk-benefit ratio—within the context of standard clinical practice and the research protocol, risks must be minimized, potential benefits enhanced, and the potential benefits to individuals and knowledge gained for society must outweigh the risks; (5) independent review—unaffiliated individuals must review the research and approve, amend, or terminate it; (6) informed consent—individuals should be informed about the research and provide their voluntary consent; and (7) respect for enrolled subjects—subjects should have their privacy protected, the opportunity to withdraw, and their well-being monitored. Fulfilling all 7 requirements is necessary and sufficient to make clinical research ethical. These requirements are universal, although they must be adapted to the health, economic, cultural, and technological conditions in which clinical research is conducted.

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WHAT MAKES RESEARCH involving human subjects ethical? Informed consent is the answer most US researchers, bioethicists, and institutional review board (IRB) members would probably offer. This response reflects the preponderance of existing guidance on the ethical conduct of research and the near obsession with autonomy in US bioethics.[1-4] While informed consent is necessary in most but not all cases, in no case is it sufficient for ethical clinical research.[5,6] Indeed, some of the most contentious contemporary ethical controversies in clinical research, such as clinical research in developing countries,[9-13] the use of placebos,[14-16] phase 1 research,[17,18] protection for communities,[20-24] and involvement of children,[25,26] raise questions not of informed consent, but of the ethics of subject selection, appropriate risk-benefit ratios, and the value of research to society. Since obtaining informed consent does not ensure ethical research, it is imperative to have a systematic and coherent framework for evaluating clinical studies that incorporates all relevant ethical considerations.

In this article, we delineate 7 requirements that provide such a framework by synthesizing traditional codes, declarations, and relevant literature on the ethics of research with human subjects. This framework should help guide the ethical development and evaluation of clinical studies by investigators, IRB members, funders, and others.

THE 7 ETHICAL REQUIREMENTS

The overarching objective of clinical research is to develop generalizable knowledge to improve health and/or increase understanding of human biology[30,31]; subjects who participate are the means to securing such knowledge.[32] By placing some people at risk of harm for the good of others, clinical research has the potential for exploitation of human subjects.[33,34] Ethical requirements for clinical research aim to minimize the possibility of exploitation by ensuring that research subjects are not merely used but are treated with respect while they contribute to the social good.[30]

For the past 50 years, the main sources of guidance on the ethical conduct of clinical research have been the Nuremberg Code,[35] Declaration of Helsinki,[36] Belmont Report,[37] International Ethical Guidelines for Biomedical Research Involving Human Subjects,[38] and similar documents (TABLE 1). However, many of these documents were written in response to specific events and to avoid future scandals.[30,31] By focusing on the instigating issues, these guidelines tend to

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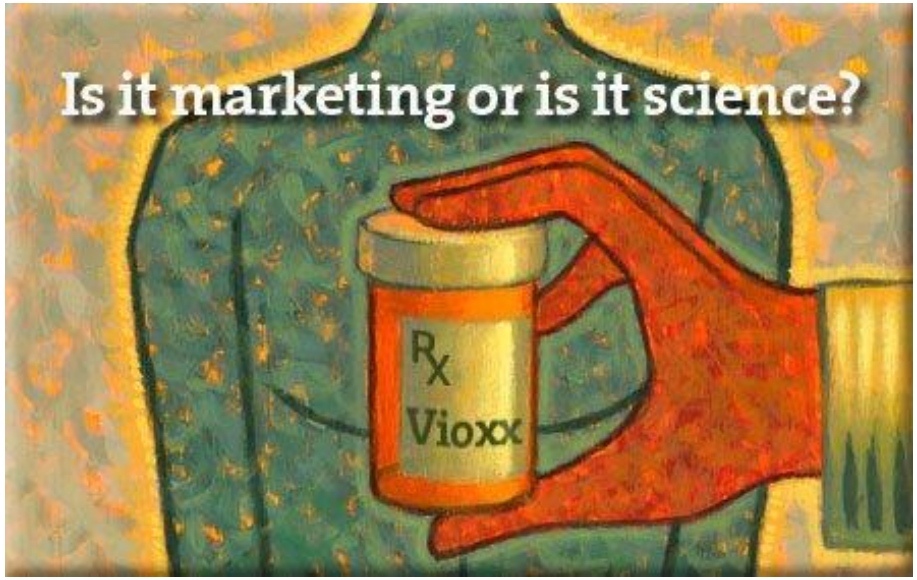
When is research socially valuable? (I)



Seeding Trials

Cancer Research

When is research socially valuable? (II)

- When it results in “useful” knowledge
- When it fosters health and health care of future patients (Wenner 2015)
- When it yields a clinical benefit (Rid and Wendler 2011)
- When it contributes to the welfare of the community in which research is conducted (Wenner 2015)

SVK as a necessary ethical condition

The Social Value of Knowledge is necessary to make research ethical

- It legitimizes the use of scarce resources
  [Allocation argument]

- It avoids exploitation
  [Exploitation argument]
- Justification to expose research subjects to risks and potential harms
- Avoiding that a whole community that provides research participants to the researchers is exploited

SVK in international guidelines (I)

Nuremberg Code (1947: §2)

Declaration of Helsinki (2013: §§16,17)

CIOMS (WHO-UNESCO 2015 Draft: Guideline1)

Nuremberg Code

1. Voluntary human consent is essential
2. Experimental results should results in good for so
3. Anticipated results should justify the experiment
4. Avoid all unnecessary physical and mental sufferi
5. No experiment if there is a chance of death/disabi
6. Minimize risk of subjects
7. Proper preparations and facilities to protect subje
8. Experiments conducted only by qualified persons
9. Subjects can withdraw at anytime
10. Terminate experiment if results are known or with judgement

SVK in international guidelines (II)

The Council for International Organizations of Medical Sciences (WHO-UNESCO 2015 Draft), Guideline 1

"... Clinicians, researchers, policy makers, public health officials, patients, pharmaceutical companies and others rely on the results of research for activities and **decisions that impact individual and public health, welfare, and the use of limited resources**.

Researchers, regulators, research ethics committees, and sponsors must ensure that proposed studies are scientifically sound, build on an adequate prior knowledge ... and are **fair to study participants and the communities in which the research is conducted.**"

Objections to the SVK (I)

[Allocation argument]

- Only constraint: resources must not be used for projects that violate legitimate moral restrictions of a society
- Squander of resources is no natural constraint to research (Wertheimer 2013)
- Private versus publically funded research

Objections to the SVK (II)

[Exploitation argument]

- SVK does not serve as sufficient or necessary preventive measure for exploitation of research subjects (Wertheimer 2015)

- Exposing research subjects to risks is unproblematic as long as the anticipated medical benefits to subjects exceed the risks and burdens

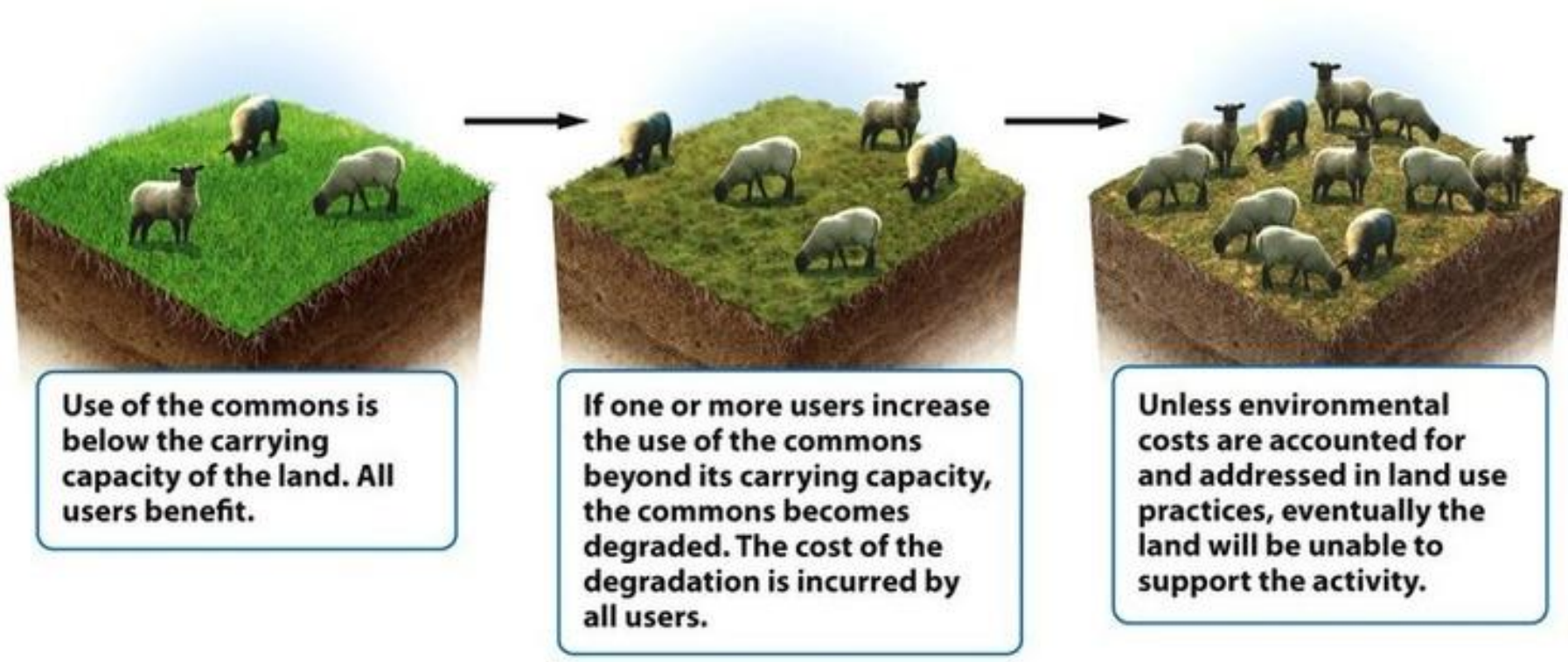
How to defend the SVK

- Despite the critique of the Social Value of Knowledge, is there a valid justification to keep the Social Value of Knowledge as ***necessary*** condition?

- The strategy is to find a justification for the Social Value of Knowledge that makes the critique redundant

- To do this, I will refer to the tragedy of the commons problem

The tragedy of the commons



The common good in medical research

PUBLIC TRUST

- Researchers are tempted to gain a comparative advantage by conducting ethically questionable studies
- Questionable research exhausts public trust and the “fund” of social support
- This leads to a cumulative disadvantage for all researchers

Safeguarding public trust

Researchers are interested in safeguarding

PUBLIC TRUST

Why SVK?

Claim: SVK avoids the depletion of public trust

- Research without social value can be considered as produced knowledge without meaningful contribution
- SVK as “the public confidence in the research endeavor” (see Rid and Wendler 2011).
- Lack of social value leads to lack of social trust when public resources are squandered for the personal goals of researchers

Justification of the SVK (I)

The “old ” (implicit) justification of the Social Value of Knowledge

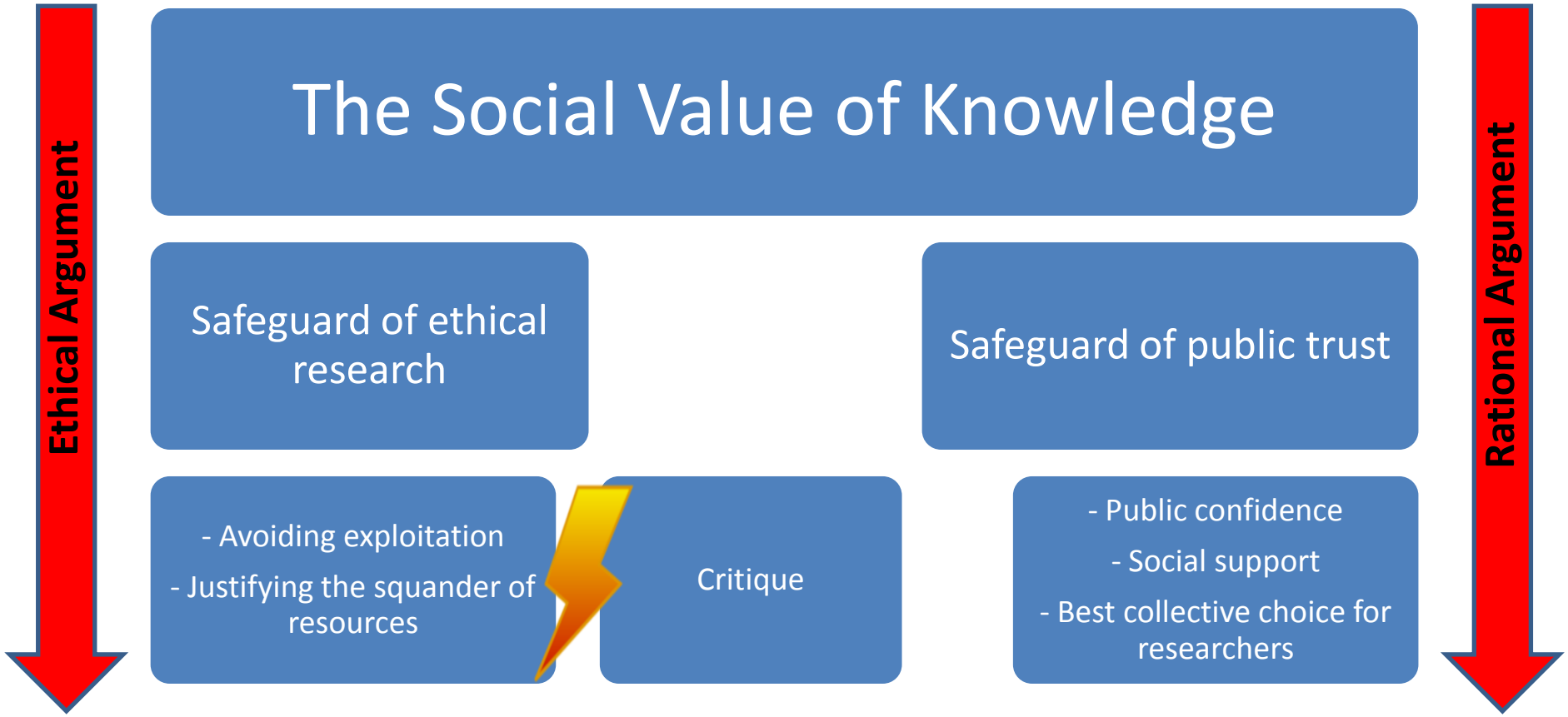
- The Social Value of Knowledge is a safeguard of ethical research
- However, debunkers have criticized the Social Value of Knowledge as a safeguard of ethics

Justification of the SVK (II)

The “new” justification of the Social Value of Knowledge

- The Social Value of Knowledge is a safeguard of public trust
- It is individually and collectively rational for researchers to adhere to the SVK principle
- The former critique does not apply anymore

Justification of the SVK (III)



THANK YOU!

Appendix

Social Value in International Guidelines (II)

The Council for International Organizations of Medical Sciences (WHO-UNESCO 2015 Draft), Guideline 1

"... Clinicians, researchers, policy makers, public health officials, patients, pharmaceutical companies and others rely on the results of research for activities and **decisions that impact individual and public health, welfare, and the use of limited resources**.

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