#58 Proportionality as a Guiding Principle for Regulating Invasive Neurotechnological Medical Devices

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Main points

- The **principle of proportionality** (**PP**) has a rich conceptual history in legal, political and moral philosophy
- In biomedical ethics the **"big four"** principles – autonomy, beneficience, nonmaleficience and justice still dominate
- For **ressource allocation** in research funding and the **risk assessment** of emerging medical technologies, proportionality may be a useful guiding principle
- **Invasive neurotechnologies** may help severly ill neurological patients but carry substantial risks and pose ethical challenges for society (**cf. poster #57**)
- The **regulatory response** to these newly emerging neurotechnologies should thus proportionally consider issues like the target population, the potential risks for patients and the potential benefit for society from these technologies

The principle of proportionality

Precursors in antiquity

Codex Hammurapi (~1750 B.C.)

"If a man destroys the eye of another man, they shall destroy his eye. If one breaks a man's bone, they shall break his bone"
-> Principle of retaliation (*Lex talionis*)

Aristotle (384-322 B.C.)

Distributive justice as **geometric proportionality**
"For it is reciprocal action governed by proportion that keeps the city together"
(*Nicomachean Ethics*, Book V)

Modern legal and political philosophy

Ronald Dworkin (1931-2013)

Principle Theory [1]: Fundamental rights (e.g. freedom of speech) as prinicples. Challenges *prima facie* concepts of legal positivism and the relation between the law and morality. Proportionality as weighing and balancing principles.

Robert Alexy (1945-)

Principles as arguments [2]: Argumentation is the balancing of principles. Distinction between *rules* and *principles*: *Rules* are all-or-nothing, *principles* are gradual. Collision of principles leads to moral conflicts. Proportionality as a paradigmatic example of the optimization requirement.

Open question: **Is the purpose of the Principle of Proportionality to avoid disproportionality or to ensure optimization?**

Modern moral philosophy

Alan Gewirth (1912-2004)

"When some quality **Q** justifies having certain rights **R**, and the possession of **Q** varies in degree in the respect that is relevant to **Q**'s justifying the having of **R**, the degree to which **R** is had is proportional to or varies with the degree to which **Q** is had." [3]

e.g.: If having decision-making capacity (**Q**) justifies the right to become president (**R**), an unreliable decision-making capacity (**Q**) may impinge on and thus diminish your right to become president (**R**) to the degree to which decision-making capacity wavers.

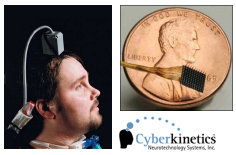
Biomedical ethics

- **"Big four"** principles - autonomy, beneficience, nonmaleficience and justice – are the dominant conceptual framework
- Not well equipped for macro-level politico-economic decision-making and governance [4]
- **Proportionality** is mentioned on only two occasions in *Principles of Biomedical Ethics* [5]: in the context of utitlity and for the "rule of double effect".

Emerging invasive neurotechnological devices

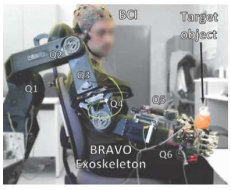
Brain implants

Microelectrode grid for epi- or subdural neural recording and stimulation and wireless information transfer (CorTec GmbH, Freiburg, Germany)
Applications: Brain-computer interfacing, deep brain stimulation



BrainGate™
"Turning Thoughts into Action".
Based on needle electrode array ("Utah array") for intracortical neural recording
Applications: Brain-computer interfacing

Exoskeletons under neural control



Using extracranial or intracranial EEG to operate robotic limbs or full-body exoskeletons.
Target groups: medical (tetraplegia, neurorehabilitation), military [7]

[6]

Risks of invasive neurotechnologies

- Neurological: Damage to neural tissue, seizures, neuroinfection, induced maladaptive plasticity, oncogenesis
- Psychological/psychiatric: Maladjustement, behavioral problems, alienation,"burden of normality", depression
- Societal: impact on disability concepts ("invisible pressure"), safety and privacy of neural data, mechanization of care

Using the principle of proportionality for guidance in research funding and regulation

Proportionality in research funding

- Should the distribution of federal budgets for clinical research (e.g. clinical neuroengineering) be proportionate to the potential number of patients benefitting?
- In terms of optimization: different funding bodies have different primary target groups (e.g. DARPA, soldiers vs. NIH, civilian patients). Should proportionality apply here?

Proportionality in regulating medical devices

- The degree of regulatory scrutiny and oversight should be proportional to the inherent risks to the individual and society
- Guidance and legislation should develop quick response mechanisms to keep up with the current speed of research

References
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