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, beneficence, nonmaleficence and justice still dominate
- For resource allocation in research funding and the risk assessment of emerging medical technologies, proportionality may be a useful guiding principle
- Invasive neurotechnologies may help severely 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: Fundamental rights, rules and principles as principles. Challenges prima facie concepts of legal positivism and the relation between the law and morality. Proportionality as weighing and balancing principles.

- Modern moral philosophy
  Alan Gewirth (1912-2004)
  Open question: Is the purpose of the Principle of Proportionality to avoid disproportionality or to ensure optimization?

- Biomedical ethics
  - “Big four” principles – autonomy, beneficence, nonmaleficence and justice – are the dominant conceptual framework
  - Not well equipped for macro-level politico-economic decision-making and governance
  - Proportionality is mentioned on only two occasions in Principles of Biomedical Ethics (3): in the context of utility 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

- Exoskeletons under neural control
  Using extracranial or intracranial EEG to operate robotic limbs or full-body exoskeletons.
  Target groups: medical (tetraplegia, neurorehabilitation), military

- Risks of invasive neurotechnologies
  - Neurological: Damage to neural tissue, seizures, neuroinfection, induced maladaptive plasticity, oncogenesis
  - Psychological/psychiatric: Maladjustment, 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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