

Ethics In Health Technology Assessment – A Case Study Of Prosthetic Care And Proposal For An Empirical Approach

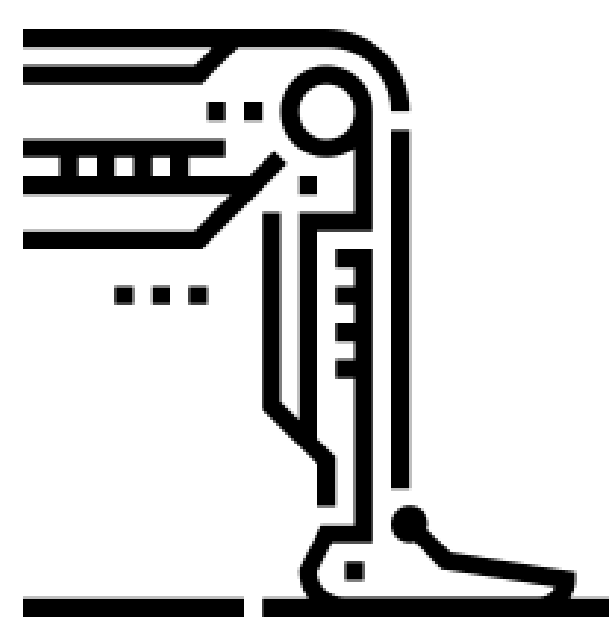
Martina Baumann,

Institute for Technology Assessment and Systems Analysis (ITAS), Karlsruhe, <https://orcid.org/0000-0003-0487-9975>

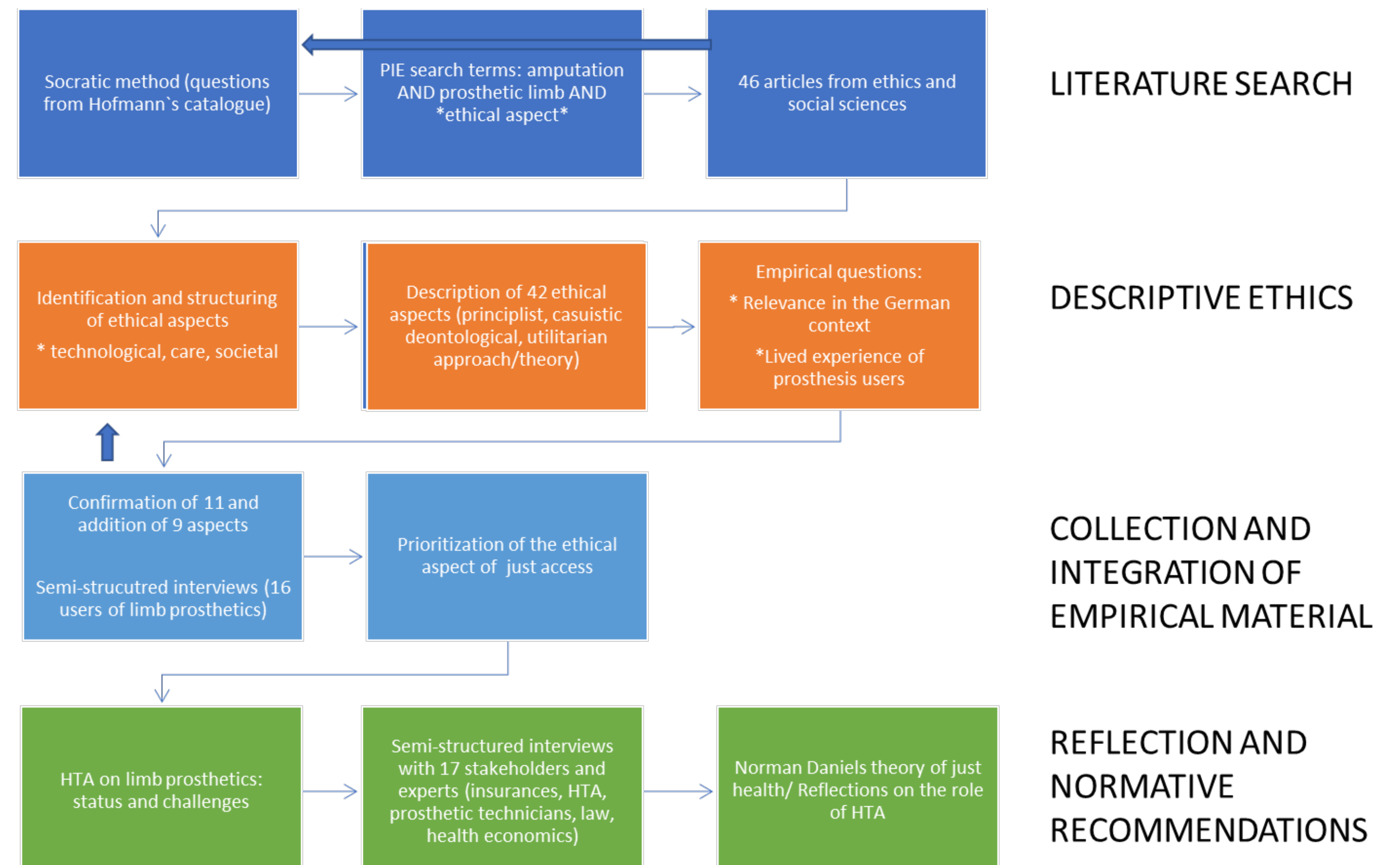
1. Introduction

Medical technologies for smaller groups of patients and with incremental innovation potential, such as limb prosthetics, pose particular methodological challenges for HTA [1,2]. At the same time, HTA of medical technologies is increasingly important to spend scarce resources efficiently in times of multiple crises, aging populations and progressing technological development.

This poster discusses HTA of prosthetic limbs from an ethical, in particular justice perspective. It points out how access to limb prosthetics may be restricted currently, how it could be improved, and which role HTA would have to play here. It is also a case study of ethics in HTA, an assessment domain still often not implemented in HTA reports, contributing to the methodological discussion.



2. Method overview



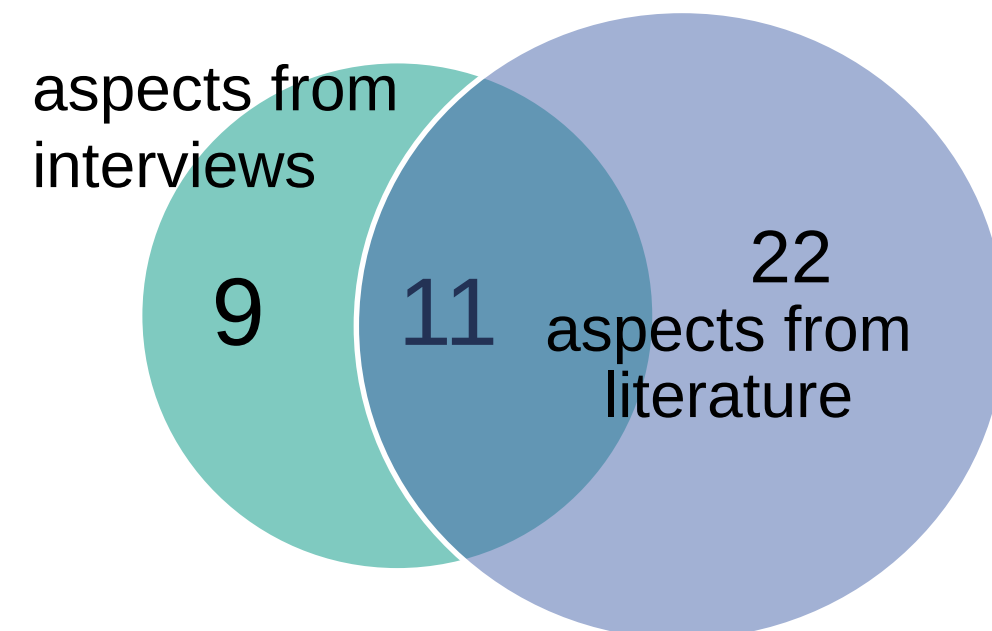
3. Ethical aspects of prosthetic care

46 articles, 16 interviews, 42 ethical aspects

Societal: Sports, self-perception and concept of disability, normality and identity, enhancement, expectation generation by the media

Technological: Privacy and data security, safety, embodiment, responsibility and autonomy

Health care: Informed and user-centred choice, user-centred development



4. Interviews with prosthetic users and health care stakeholders and experts in Germany on reimbursement



Evidence/HTA

- Concept HTA not well-known/used in practice

Communication

- Between stakeholders often lacking

Regulation/law

- Social code book [3] has high relevance for reimbursement; efficiency and usability criteria ill-defined

Reimbursement

- Negative experiences: lack of understanding of insurances, need has to be „proved“ by amputees; fear of the future; law suits to get access

Information

- About prosthetic care options not easily accessible

5. HTA of limb prosthetics

Existing reports

- 8 reports worldwide (none in Germany)
- often restricted recommendations due to low quality of studies (real-life situations, diversity of participants, long-term and societal perspectives)
- low variety of compared technologies

Challenges → solutions

- Practical: Recruitment of participants and expertise → use of evidence from practice
- Regulatory: no relevance of HTA for reimbursement and approval
- Methodological: complexity and incremental innovation → evidence-based practice [4], research registries [5] and outcome research [6]

Potential benefits

- For health care systems/society: limiting prices/costs
- For developers/producers: competitive advantage
- Users/patients: improve access, enhance „real-world“-benefit

Ethical questions

- Not reported/discussed in existing HTAs
- Identified based on Hofmann's catalogue [7]
- System level: distribution of budgets
- Group level: representation in studies
- Individual level: user preferences mirrored in outcomes

6. Discussion and outlook: Reimbursement of limb prosthetics and just health care

- High costs for prosthetics
- Organisational/communication challenges
- Unclearities in reimbursement regulation → high relevance of social courts instead of ethical discussion
- Lack of knowledge about and practical implementation of HTA
- Lack of information for patients

ethical
issues

Just access endangered; discrimination based on age and socio-economic status likely

Criteria for procedural justice [8] and accountability for reasonableness [9] not fulfilled

Incomplete fulfillment of rights of persons with disabilities (UNCOD)

7. Discussion and outlook: Role and method of HTA

The example of prosthetic care shows the need for collaboration between HTA, other disciplines (TA, public health, health service research), patients and policy makers in order to address ethical issues. The most pressing issue identified for prosthetic care in Germany is access to suitable limb prosthetics. HTA may contribute to informing patients and professionals about prosthetic technology from different producers, foster a public debate on rationing in health care, and controlling costs/prices for prosthetic technology. To this end, methodological innovations, infrastructure and training for registries and evidence based practice, as well as raising awareness for the benefits of HTA may be needed.

This case study also showed that a mixed method combining literature and interview studies is suitable to identify and describe a wider range of ethical aspects than a question and literature based (Socratic) approach alone. Overall, the message of this work is that qualitative empirical methods in HTA could help to improve impact of HTA through an investigation of structural, legal, practical, ethical and methodological challenges for a realization of its potential benefits in different technological fields and health system environments.

References

- General: Martina Baumann (2024). HEALTH TECHNOLOGY ASSESSMENT UND ETHISCHE ASPEKTE DER PROTHESENVERSORGUNG. Dissertation. Repository KITopen.
- 1) Tarricone R, Torbica A, Drummond M. Challenges in the Assessment of Medical Devices: The MedtechHTA Project. Health economics. 2017;26 Suppl 1:5-12. doi:10.1002/hec.3469
 - 2) Cutti AG, Lettieri E, Verni G. Health Technology Assessment as Theoretical Framework to Assess Lower-Limb Prosthetics-Issues and Opportunities from an International Perspective. JPO Journal of Prosthetics and Orthotics. 2019;31:P55-P73. doi:10.1097/JPO.0000000000000235
 - 3) Sozialgesetzbuch (SGB) Fünftes Buch (V), §33. Available online: https://www.gesetze-im-internet.de/sob_5/SGB_5.pdf
 - 4) Andrysek J, Christensen J, Dupuis A. Factors influencing evidence-based practice in prosthetics and orthotics. Prosthet Orthot Int. 2011;35(1):30-38. doi:10.1177/0309364610389353
 - 5) ÄrzteZeitung. Beinprothesen-Register in Heidelberg soll Versorgungsqualität erheben. <https://www.aerztezeitung.de/Neuigkeiten/Beinprothesen-Register-in-Heidelberg-soll-Versorgungsqualitaet-erheben-429058.html>
 - 6) Baun K, Conyers D, Miguelez JM. Innovative Outcome Measurement in Upper Limb Prosthetic Rehabilitation. Myoelectric Controls Symposium; July 2020.
 - 7) Hofmann B. Toward a procedure for integrating moral issues in health technology assessment. J of Inter Tech of Health Care. 2005;21(03):312-318. doi:10.1017/S0266462305050415
 - 8) Marckmann G, Schmidt H, Sofaer N, Strech D. Putting public health ethics into practice: a systematic framework. Front Public Health. 2015;3:23. doi:10.3389/fpubh.2015.00023
 - 9) Daniels N. Gerechtigkeit, Gesundheit und Gesundheitsversorgung. In: Biller-Andorno N, Monteverde S, Krones T, Eichinger T, eds. Medizinethik. Springer Fachmedien Wiesbaden; 2021.

Funding This work was partly funded by the German Federal Ministry of Education and Research (Bundesministerium für Bildung und Forschung, BMBF) (16SV7658).