Value judgments in evidence-based medicine and health technology assessment

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Background: Benefits and harms estimation of medical measures plays a principal role in clinical and ethical controversies. Biased and hence false-leading decision-making information about benefits and harms of medical measures contradicts the ethical commandments of a caring and not harming clinical care. An adequate patient clarification and the informed consent are to be implemented appropriately only if a valid information about benefits and harms is available. And finally, we need a high quality information about benefits, harms and costs of medical measures to allow a fair health care under scarce resources. The goal of evidence-based medicine (EBM) is defined as to improve analyses and evaluation of benefits and harms of medical interventions and to make these accordingly trustworthy (valid) by way of systematic reviews, meta-analyses, health technology assessment (HTA) or so-called S3-guidelines. Thus, there exists a close connection between EBM and ethics. In practice, however, the genesis of evidence-based information is confronted with different problems. Sometimes, the gold standard for a valid clinical trial - the RCT (randomized-controlled trial) - is partially infeasible for methodical or also for ethical reasons. Or even though RCTs are feasible, they are not carried out due to lacking knowledge, external interests or missing financing, or they are performed in a methodically incorrect way. As a consequence, there emerge various problem areas with respect to benefits and harms evaluation in form of reviews, guidelines or HTAs. Such considerations are, for example: „When should studies be excluded from meta-analysis due to methodological shortcomings and when shouldn‘t?“ or ”What endpoints of the study are relevant for patients and what are not?“. Value judgements play a central role in these consideration processes mostly in an implicit, covert way.

Research aims: The phenomenon of value judgments in systematic medical benefits and harms evaluation was critically analysed. In so doing, various types of value judgements could be distinguished. Furthermore, a framework was developed that helps to identify the appropriate value judgement systematically. Further research is needed to further specify relevant value judgments and to apply the framework to enhance transparency when dealing with value judgments in HTA.

Publications
- **Strech D, Soltmann B, Weikert B, Bauer M, Pfennig A** [forthcoming in *Journal of Clinical Psychiatry*]
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- **Strech, D.** (2010) [Value judgements in the analysis of evidence. Largely non-transparent, frequently contentious and never avoidable], in *Zeitschrift für Evidenz, Fortbildung und Qualität im Gesundheitswesen (ZEFQ)*, 104, 168–176 [German language]
- **Strech D** (2010) [The ethics of a restrictive regulation of trial registration], in: *Ethik in der Medizin*, online first [German language]
- **Strech, D.** (2007): Four levels of value judgments in outcome assessment. A systematic approach to the implicit normativity in evidence based medicine. German Journal for Evidence and Quality in Health Care (ZaeFQ), 101(7), 473-80 [German language]
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