

HTA152 - Practical Challenges of Implementing a New Patient-Reported Outcome (PRO) in Oncology Under the German Pharmaceutical Market Restructuring Act (AMNOG)

Results From a Qualitative Focus Group Study

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BACKGROUND

- Cancer as a chronic disease with lifelong individual consequences requires PROs to capture potential side effects beyond clinical endpoints, but PROs are still not exhaustively considered in health technology assessment (HTA)
- Cancer diagnosis and therapy can lead to financial distress that affects patients’ quality of life [1] and mortality [2-4]
- PROs to comprehensively measure financial effects of cancer are currently under development [5, 6]

STUDY AIM

To analyze the conditions, needs and challenges for the implementation of a new oncological PRO under the German AMNOG from a regulatory perspective

METHODS

- Semi-structured focus group with n=6 representatives from four German HTA and payer authorities
- Qualitative content analysis of transcript to identify key themes and topics relevant for the development of a new PRO within the categories of 1) status quo, 2) conditions and 3) challenges
- Part of the Financial Effects of a Tumor Disease (FIAT) study, that aims to develop and validate a PRO measuring financial effects of a tumor disease in Germany

RESULTS

STATUS QUO

- PROs play a role almost exclusively in the measurement of health-related quality of life (HRQoL) under AMNOG in line with the German law (SGB V)
- HRQoL data is less often considered to determine an additional benefit in oncology due to data availability or minor quality

CHALLENGES

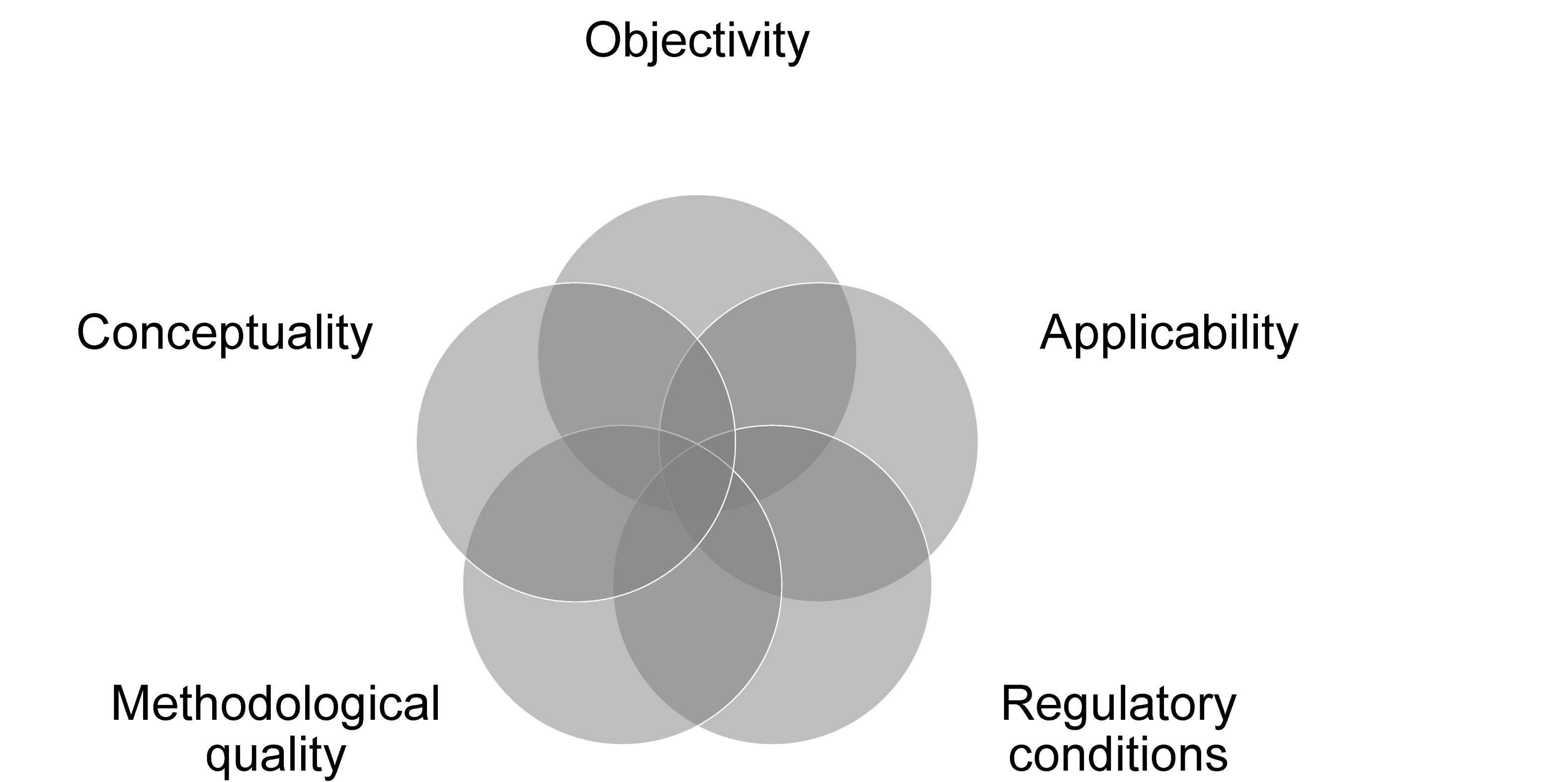
- 1) Generic PROs hampered by the chronic nature of cancer with different stages and severity of illness
- 2) Time horizon
- 3) Degree of specialization of the instrument
- 4) To objectify of a subjectively perceived phenomena
- 5) PROs to be subsumed under HRQoL as a patient-relevant outcome
- 6) Further application in economic evaluations, which might get a practical impact in the AMNOG in the future.

CONCLUSION

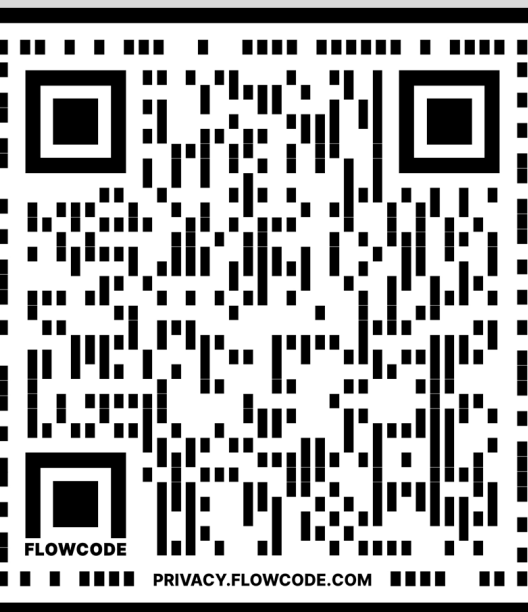
- The integration of new PROs under AMNOG is currently limited by legal regulations
- Profound evidence about the construct of financial effects of a tumor disease needs to be gathered beforehand using validated instruments to emphasize the importance for patients
- Further integration of a PRO measuring financial effects of a tumor disease under AMNOG beyond HRQoL should be discussed, e.g. by considering productivity losses in economic evaluations

CONDITIONS

Based on the analysis, five categories should be considered in the development of a PRO that intends to be implemented within the German AMNOG process



RELATED PROJECT INFORMATION



RESEARCH TEAM



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