

Financial Distress of a Cancer Disease As a Patient-Relevant Outcome Under the German Pharmaceutical Market Restructuring Act (AMNOG)?

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Objectives

We aim to understand the current status of reporting financial distress among cancer patients in clinical trials included in the Federal Joint Committee (G-BA) early benefit assessments (EBA) in Germany.

Background

- Cancer patients in Germany’s solidarity-based healthcare system often face financial distress, impacting health outcomes like health-related quality of life (HRQoL), depression and anxiety [1-4].
- Financial distress is a personal, economic, and societal challenge.
- The current AMNOG legislation for evaluating the clinical benefit of innovative drugs centers on mortality, morbidity, HRQoL and complications as patient-relevant endpoints within the EBA process [5].
- EORTC-QLQ-C30, a cancer HRQoL measure, includes financial distress as one item [6]. The questionnaire is approved by the G-BA and in EBA for innovative drugs [7].

Methods

- Data base: All G-BA EBA oncology drug dossiers using the EORTC-QLQ-C30 questionnaire and their related resolutions and justifications up to January 1, 2024.
- Data extraction: Financial distress reporting in dossiers including presented quantitative data of related clinical trials, endpoint discussion regarding financial distress in resolutions and justifications.
- Evaluation: Qualitative content analysis and descriptive statistics for financial distress reporting status in EBA.

Results

Table 1: Financial Distress in Early Benefit Assessments of oncology drugs in Germany

Analysis	N (%)
Number of EBA Dossiers in oncology	379
EORTC-QLQ-C30 Dossiers	210 (56%)
Dossiers including Financial Distress data	120 (57%)
Number of clinical trials	114
Number of active ingredients	60
Number of analyses	252
Effects on Financial Distress (Intervention vs. Control)*	
Number of analyses with reduced Financial Distress	147 (58%)
Number of analyses with significant reduced Financial Distress**	28 (19%)
Mean number of patients per analysis*	373
Mean response rate per analysis*	29%
As of: January 1, 2024	
* Analyses performed only for available data	
** p < 0,05	

- 90/210 did not report results of the subscale for financial distress despite using the EORTC-QLQ-C30.
- If the missing data was addressed by pharmaceutical companies in the provided dossiers, they mainly argued that financial distress would not be a patient-relevant endpoint in a solidarity-based healthcare system.
- G-BA resolutions rarely addressed missing data of the subscale for financial distress; only 3/90 justifications referred to it.
- Most of the included analyses could not demonstrate a significant difference between intervention and control group regarding reduction of financial distress.

Conclusion and further research

- Rising financial distress from cancer necessitates future action by healthcare systems and their regulatory authorities.
- Financial distress data has already been collected as part of HRQoL in clinical trials but is often missing in dossiers for EBA. G-BA resolutions rarely address missing financial distress data in their resolutions and justifications. However, it should be considered and assessed as part of HRQoL under the current AMNOG legislation due to the relevance of the topic.
- Reporting data of financial distress in EBA dossiers adds valuable, patient-relevant information for decision-making that should be considered by both sides - regulatory authorities and pharmaceutical companies. It could also enhance differentiation for indication with smaller additional benefits and inform later price negotiations.
- Due to missing data of financial distress in the dossiers and the small sample sizes of the analyses, quantification of the degree of effects on financial distress in clinical trials remains limited.
- Future clinical trials should include specific financial distress measures to highlight its role in healthcare decisions.
- Limitations: Different methods of statistical measures were applied in studies which limits comparability of results.
- Further research should pool results of the subscale across clinical trials beyond EBA data to determine the level of financial distress and to identify patterns of it among drug-based therapy trials.

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Poster presented at ISPOR Europe, November 17-20, 2024, Barcelona

This research is not funded. The authors declare that there is no conflict of interest.

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