THE DEFINITION AND ROLE OF QUALITY OF LIFE IN GERMANY’S EARLY ASSESSMENT OF DRUG BENEFIT

David Lohrberg, Matthias Augustin, Christine Blome
Institute for Health Services Research in Dermatology and Healthcare, University Medical Center Hamburg-Eppendorf, Germany. Contact: d.Lohrberg@uke.de

BACKGROUND & OBJECTIVES

EARLY DRUG BENEFIT ASSESSMENT (EBA)
Since January 2011, pharmaceutical manufacturers are obliged to submit dossiers presenting benefits over comparative treatment when launching new products in the German pharmaceutical market. If no additional benefit is demonstrated, the drug’s price may not exceed the costs for comparative treatment. Benefit dossiers are subject to a scientific evaluation usually conducted by the Institute for Quality and Efficiency in Health Care (IQWiG). Following a hearing process in which manufacturers may reply to the dossier evaluation and experts contribute their views, the Federal Joint Committee (G-BA) decides on the drug’s additional benefit. Main criteria for this decision are: mortality, morbidity, quality of life (QoL) and side effects. Our research question was: How is QoL defined in the early drug benefit assessment and what roles does it play?

RESULTS

QoL is not easily defined
• IQWiG: QoL is a complex or multidimensional construct including physical, social and psychological aspects
• G-BA: no explicit definition, but accepts QoL data if effects are statistically significant and clinically relevant. Implicit understanding: QoL is something being measurable with validated QoL instruments
• Manufacturers: wider understandings of QoL also linking compliance, adherence, patient preference, treatment satisfaction, work productivity to the concept of QoL. Further elements: well-being, feeling better, noticeable alleviations or limitations in daily life or work ability, the effect of the disease on daily life, and patient emotional and health status

Role of QoL may be underestimated
• Additional benefit for QoL only granted twice (among 66 EBA’s)
• Qualitative analysis shows: role of QoL is more complex
• IQWiG and G-BA frequently highlight the importance of QoL data, especially in palliative situations
• Due to a lack of statistically significant and clinically relevant QoL data, additional QoL benefit hasn’t been demonstrated in more than 2 cases

DISCUSSION

• IQWiG’s QoL definition is also widely used in the scientific community. Conveying a rather methodological stance on QoL, the institute focuses on the validity of the instruments and the clinical and statistical relevance of the data
• The G-BA chose a cautious stance on QoL. Having to trade legally, the committee did not engage in a theoretical debate, but focused on the respective drug assessments at hand
• Manufacturers applied wider understandings of QoL indicating a certain degree of uncertainty regarding the definition and operationalization of QoL. This may be due to a regulatory gap, as IQWiG and G-BA did not explicitly define QoL prior to the first assessments conducted

CONCLUSIONS

QoL plays an important role in Germany’s new system of drug benefit assessment. QoL data are not only appraised as a relevant endpoint per se, but are also consulted in order to put outcomes regarding mortality, morbidity and side effects into context. Due to a rather fast legislation and implementation of early benefit assessment in Germany and the fact that QoL is not easily or universally defined, key players had difficulty agreeing on shared QoL understandings.

METHODS

QUALITATIVE CONTENT ANALYSIS
To trace the definition and role of QoL in early benefit assessment, all assessments completed by 2013 (n=66) were qualitatively analyzed regarding QoL content. The summaries of the dossiers, dossier evaluations, verbatim protocols of the oral hearings and the G-BA’s decisions were processed. Documents were searched for the term QoL and synonyms. We analyzed passages referring to the definition and role of QoL and reduced the original text sources to key content. Identifying recurring themes of references, a system of codes was created categorizing findings on the definition and role of QoL within early drug benefit assessment. The qualitative content analysis was conducted by two researchers independently reviewing and discussing the results at the different stages indicated below:

- Manufacturer’s dossier
- Hearing process
- Scientific evaluation
- Benefit: yes/no
- Quality of Life

- Key Content
- Text Search & Extraction
- Coding
- Synopsis of typical QoL references

Documents


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