

HEALTH-RELATED QUALITY OF LIFE IN THE GERMAN EARLY BENEFIT ASSESSMENT

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BACKGROUND

Health-related quality of life (HRQoL) is generally defined as the personal well-being in important areas of life including physical, mental, social, family-, and work-related factors. HRQoL is measured as patient-reported outcome (PRO) via questionnaires or surveys.

The inclusion of HRQoL data is regularly requested and a deciding factor in the German early benefit assessment ("AMNOG procedure"), especially if the essential efficacy criterion of a therapy is not curation of a disease or prolongation of survival. A prolonged survival of only a few weeks or months is not considered sufficient for overall benefit if it is as the expense of HRQoL.

Both the Institute for Quality and Efficiency in Healthcare (IQWiG) and the Joint Federal Committee (G-BA) place high methodical demands on HRQoL data so that HRQoL data are only considered in a fraction of benefit assessments.

OBJECTIVE

We analysed all benefit assessments to determine how often HRQoL data were considered in the benefit assessment (G-BA resolution) and whether consideration of HRQoL had an impact on the awarded additional benefit.

METHODS

Using the AMNOG database from Pharm-Analytics, all terminated early benefit assessments until 01/01/2022 were analysed. G-BA resolutions were assessed for consideration of HRQoL data. Assessments with evaluated additional benefit between 01/01/2017 and 01/01/2022 were further analysed with regard to:

- + disease area
- + extent of additional benefit

RESULTS III

Consideration of HRQoL data by the G-BA across disease areas

Regarding the disease areas as per definition of the G-BA, HRQoL data were considered most often in oncology in absolute numbers (n = 113), but proportionally most often in diseases of the musculoskeletal system (69%). Of note, in the therapeutic indication psychiatric diseases no HRQoL data have been considered by the G-BA so far (Figure 3).

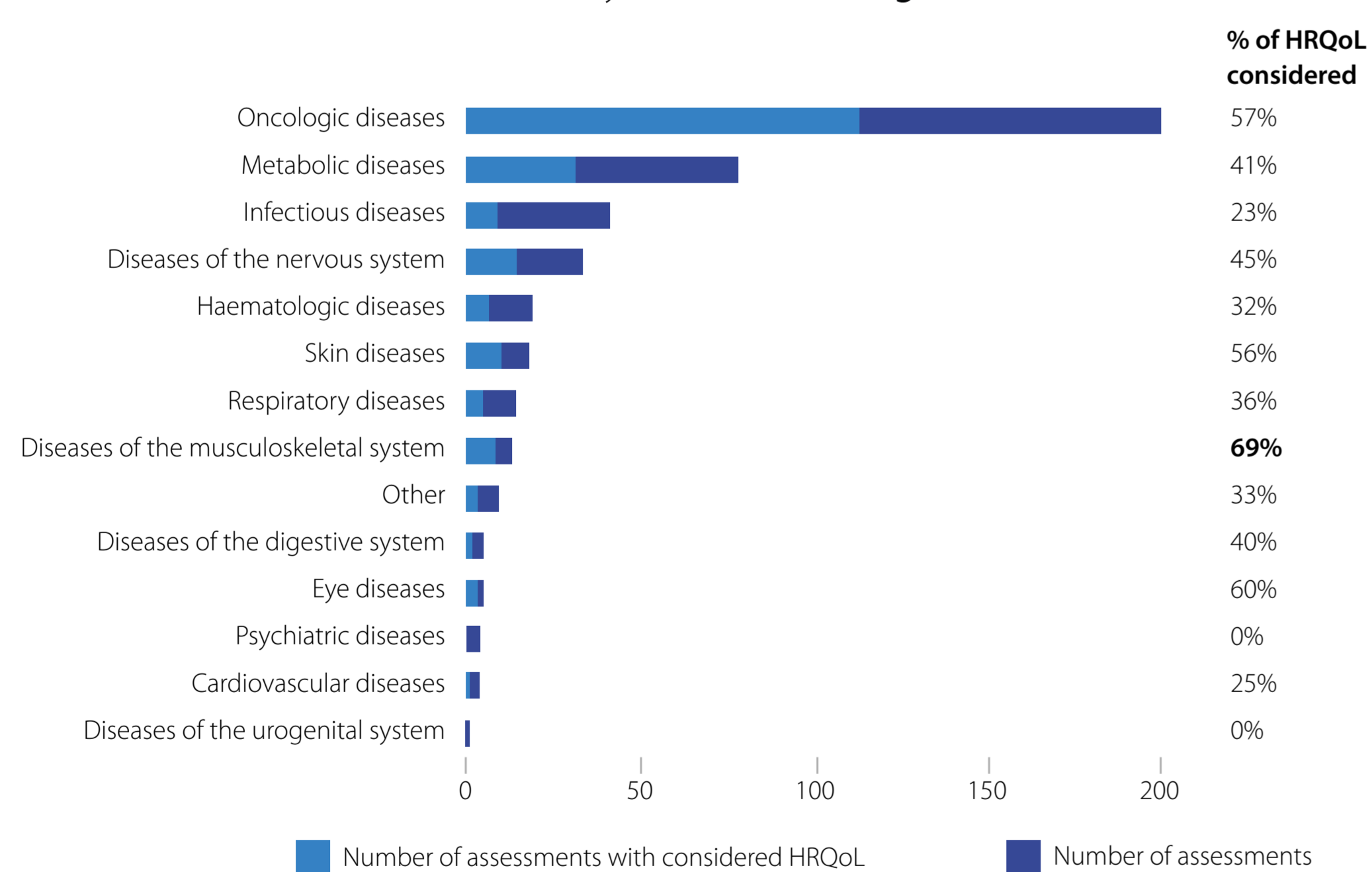
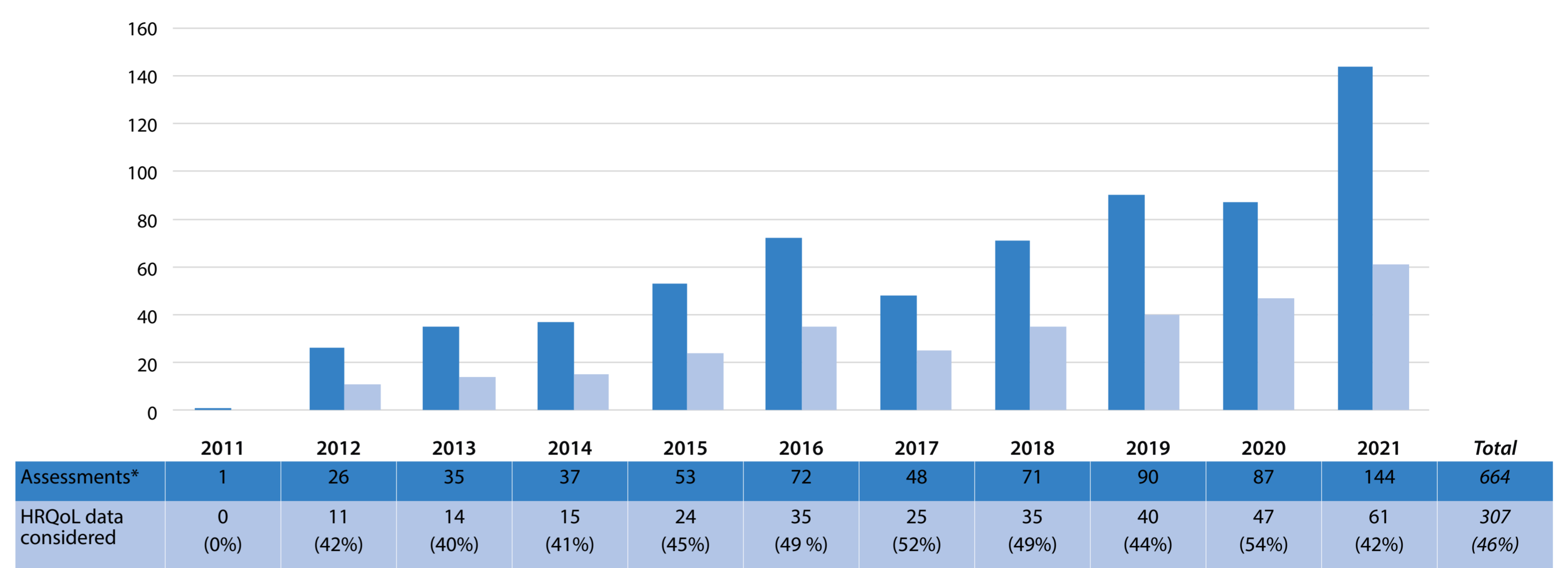


Figure 3: Number and percentage of assessments with considered HRQoL data among number of assessments per disease area (2017–2021)

RESULTS I

Consideration of HRQoL data by the G-BA since the beginning of AMNOG

Since the start of the AMNOG (early benefit assessment for new drugs in Germany, since 2011) HRQoL data have been considered by the G-BA. Until the end of 2021, a total of 664 procedures were completed by the G-BA (all procedures with resolution by 01/01/2022). Among these, data on HRQoL were considered by the G-BA in 307 benefit assessments (46%). With the growing number of assessments, the number of procedures with considered HRQoL data grew steadily over the years. However, the percentage of assessment with considered HRQoL data among all assessments remained nearly constant (Figure 1).



* Assessments with evaluated additional benefit, not considered: assessments with direct allocation to a reference price group, suspended assessments, discontinued assessments and exemptions
Figure 1: Proportion of benefit assessments with considered health-related quality of life (HRQoL) data among all assessments (2011–2021)

RESULTS II

Impact of considered HRQoL data on the extent of additional benefit

Between 2017 and 2021 HRQoL data were considered by the G-BA in 208 of 442 terminated benefit assessments (47%). 54 of these 208 assessments (26%) showed a positive effect in HRQoL (Table 1).

Table 1: Highest awarded benefit per assessment (all benefit assessments with evaluated additional benefit from 2017 until 2021)

Extent of additional benefit	All assessments (N = 442)	HRQoL data not considered (n = 234)	HRQoL data considered (n = 208)	Advantage HRQoL (n = 54)
Major	7 (1.6%)	1 (0.4%)	6 (2.9%)	4 (7.4%)
Considerable	74 (16.7%)	18 (7.7%)	56 (26.9%)	29 (53.7%)
Minor	68 (15.4%)	23 (9.8%)	45 (21.6%)	9 (16.7%)
Non-quantifiable	99 (22.4%)	50 (21.4%)	49 (23.6%)	10 (18.5%)
Not proven	193 (43.7%)	142 (60.7%)	51 (24.5%)	2 (3.7%)
Less benefit	1 (0.2%)	0 (0.0%)	1 (0.5%)	0 (0.0%)

Assessments in which the G-BA considered HRQoL data have more often been granted a higher additional benefit. In particular, HRQoL data were considered in 6 out of 7 assessments (86%) with the highest possible additional benefit (major additional benefit) but only in 26% of assessments (51/193) without additional benefit (Table 1).

This can also be seen in the distribution of awarded benefits between assessments with and without considered HRQoL data. The majority of G-BA assessments in which HRQoL data were not taken into account show no additional benefit (142/234, 61%). Conversely, assessments in which HRQoL data were considered display a nearly equal distribution among the awarded benefit categories (Figure 2).

Extent of additional benefit (Highest benefit)

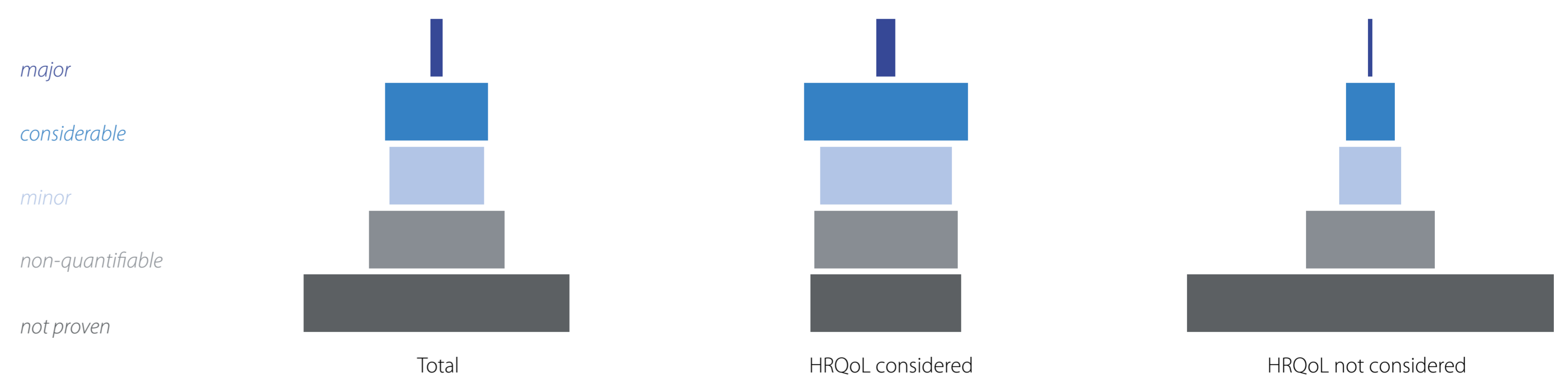


Figure 2: Distribution of awarded benefits among all assessments, assessments with considered (HRQoL) and assessments without considered HRQoL 2017–2021 (percentage)

CONCLUSIONS

- + The additional benefit tends to be higher in benefit assessments in which HRQoL data are considered. Thus, submission of HRQoL data can be beneficial in the early benefit assessment.
- + Consideration of HRQoL data by the G-BA varies between indications.
- + HRQoL data do not automatically lead to an additional benefit as the high methodical requirements posed by the G-BA need to be met.
- + In general, consideration of HRQoL data is a potential indicator of a high-quality study.