

Status Quo of Claims Data Analyses in the German AMNOG HTA Process – Did Quality Improve?

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BACKGROUND

- In 2011, the Act on the Reform of the Market for Medicinal Products (AMNOG) introduced a new Health Technology Assessment (HTA) standard in Germany.¹
- Core of this process is the submission of an AMNOG dossier (AD) to the Federal Joint Committee (G-BA) at market launch to prove an added benefit of the respective pharmaceutical product.
- As part of Module 3 of the AD, current epidemiological data for the underlying diseases and relevant target populations are a mandatory component.
- A common option to generate these data is the analysis of German Statutory Health Insurance (SHI) claims data.
- The submitted information is evaluated by the Institute for Quality and Efficiency in Healthcare (IQWiG) focusing on applied methodology and transparency.

OBJECTIVES

- Aim of this study was to investigate criticism and potential improvements discussed over time in the assessments from IQWiG on epidemiological data derived from SHI claims data analyses (CDA).

METHODS

- All published AMNOG benefit assessments and the respective IQWiG evaluations published in the timeframe from 01 January 2011 until 31 December 2018 were included in this study and downloaded from the G-BA's homepage.
- In a first step, all Modules 3 of each AD were screened by two independent reviewers regarding the inclusion of studies using SHI claims data for the derivation of epidemiological data for the underlying diseases and relevant target populations.
- For each Module 3 including studies relying on claims data, indication areas as well as the number of used CDAs were examined.
- In a second step, respective IQWiG evaluations were analyzed regarding criticism of methodology, scope, and transparency of the performed CDAs as well as missing critical discussion and further points of criticism that go beyond the data sources used.

RESULTS

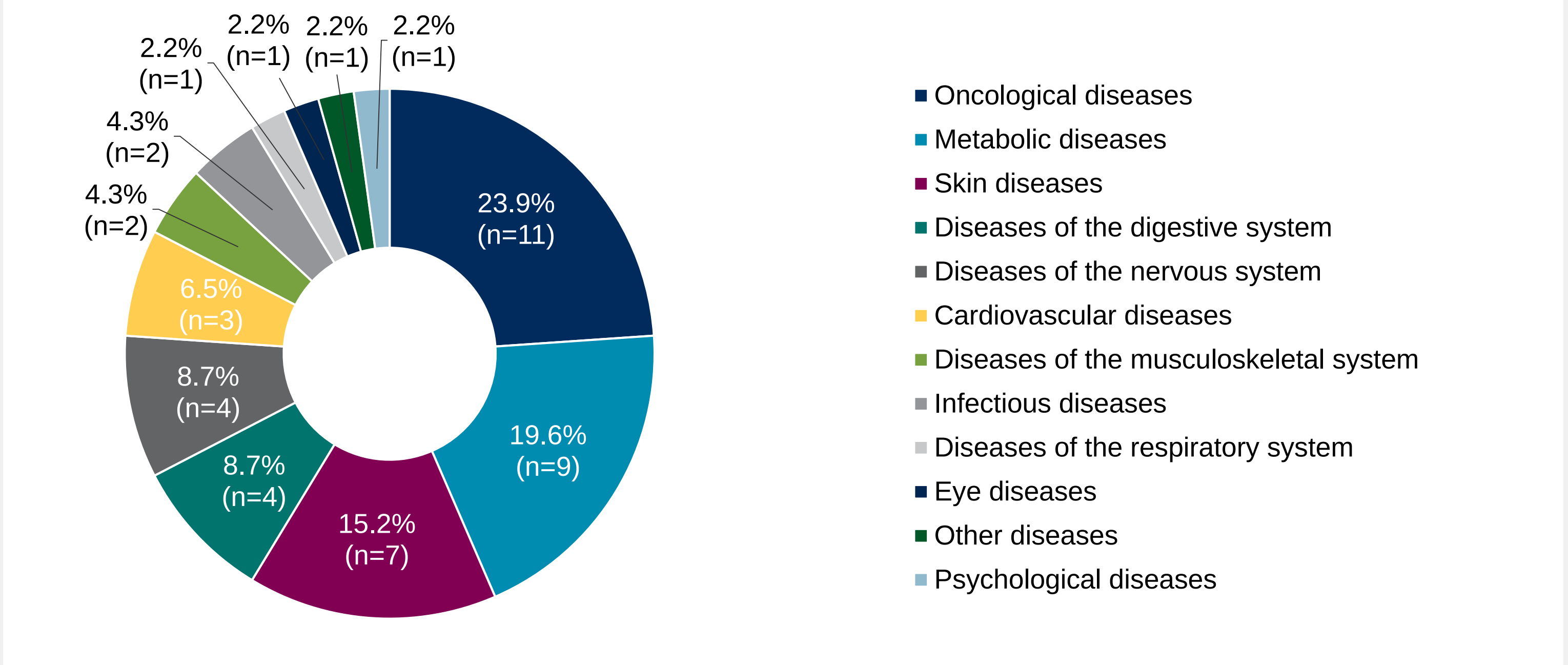
Full Text Analysis

- Until 31 December 2018, N=43 ADs using SHI CDAs for the determination of epidemiological data for the underlying diseases and relevant target populations were identified.
- This corresponds to N=46 CDAs out of N=61 Modules 3 representing N=61 different patient populations (some ADs contained more than one analyses and/or target population).

Indication Areas

- Most commonly, CDAs were performed in oncological diseases (23.9%), followed by metabolic diseases (19.6%), skin diseases (15.2%) as well as diseases of the digestive system (8.7%) (see **Figure 1**).

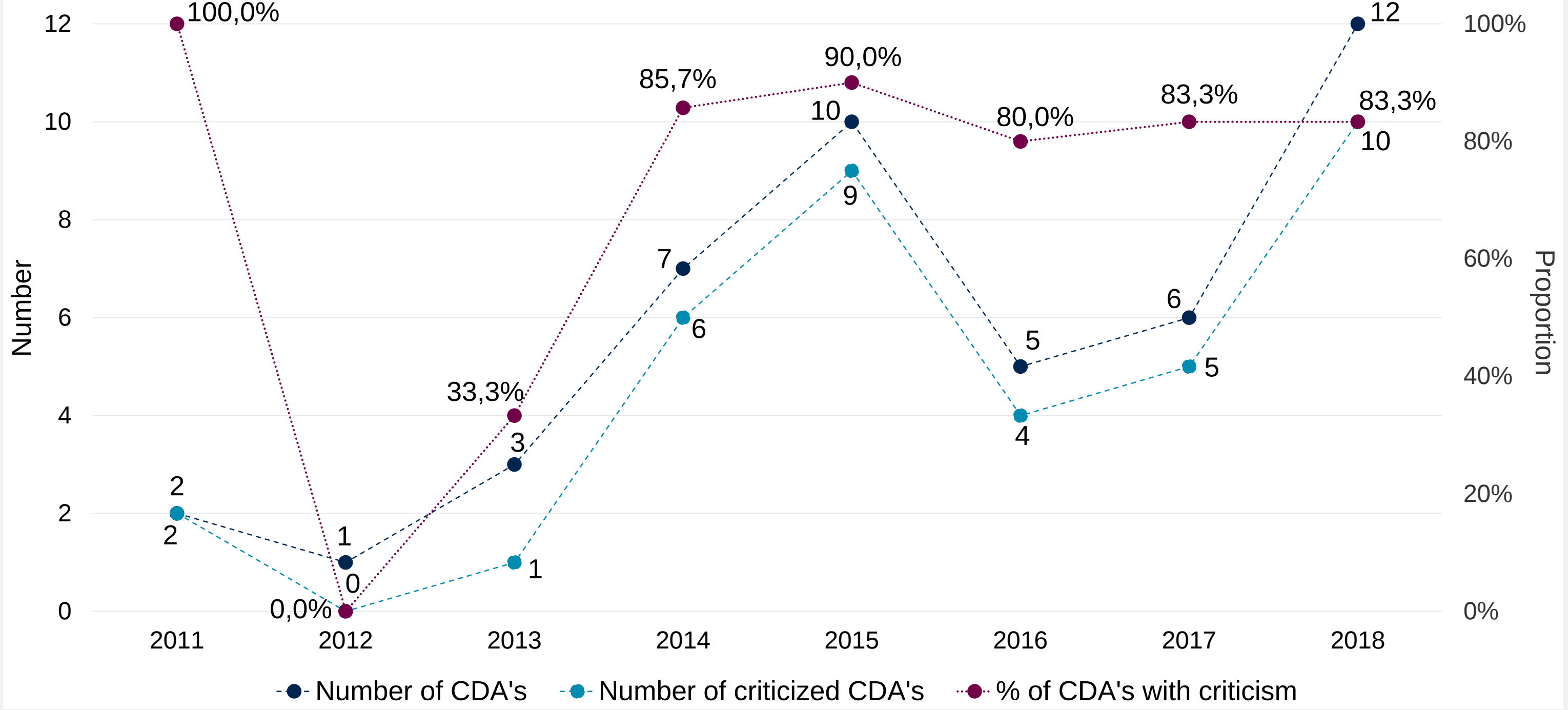
Figure 1. Indication Areas Among the Identified CDAs (N=46)



Criticized Claims Data Analyses

- The number of CDAs used in ADs for the derivation of epidemiology showed an increasing trend from two analyses in 2011 to ten analyses in 2015. In 2016 and 2017, this number decreased briefly to five and six analyses before reaching a maximum of 12 different CDAs conducted in the context of ADs in 2018.
- In the first year of AMNOG 2011, both performed CDAs were criticized while IQWiG had nothing to complain about the analysis employed in 2012. Besides, two out of three CDAs were without complaints in 2013. Since 2014, the proportion of criticized CDAs increased up to 90.0% in 2015. Until 2018, the proportion of CDAs, where the IQWiG raised at least some concerns about the analysis, remained stable around 80.0% to 83.3% (see **Figure 2**).

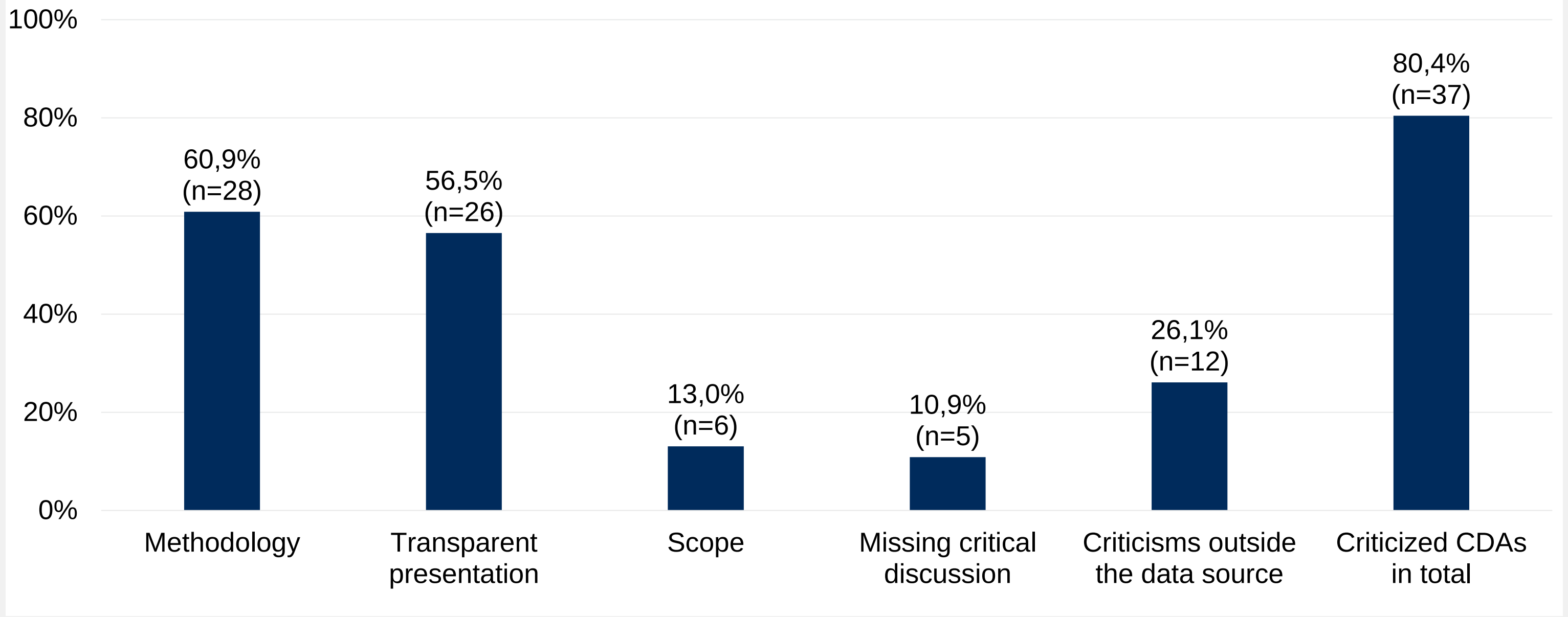
Figure 2. Criticized CDAs in the Context of ADs Over Time



Points of Criticism From the IQWiG

- Over the entire study period, IQWiG raised at least some concerns about the employed data in n=37 CDAs (80.4%).
- The most frequent point of IQWiG's criticism related to the applied methodology (n=28; 60.9%) for the determination of epidemiological data. This included, for example, criticisms concerning an incomplete description of the study approach, the derivation of the target population's definition from the Summary of Product Characteristics as well as uncertainties regarding the selected eligibility criteria.
- According to the IQWiG, a lack of transparency was present in the description of the CDA used in n=26 CDAs (56.5%). Points of criticism were that, for example, detailed information on the specific calculations was missing or the demographic structure and representativeness of the underlying data set regarding the German population were not displayed.
- Less frequently, the IQWiG criticized the scope of the analysis (n=6; 13.0%), like missing plausibility checks for the target population's derivation from publicly available literature or the non-application of the "M2Q" criterion (to ensure the presence of a disease: validation of outpatient diagnoses by two quarters with a verified diagnosis per year).
- A lack of critical discussion regarding potential over- or underestimation of the derived epidemiological data was present in n=5 CDAs (10.9%).
- However, the IQWiG remarked further points of criticism concerning aspects outside the used data source in about one fourth (n=12; 26.1%) of all conducted CDAs. This concerned the representativeness of the morbidity profile of the used database for the SHI population as well as uncertainties due to incorrect or incomplete diagnosis coding in the German healthcare setting (see **Figure 3**).

Figure 3. IQWiG's Points of Criticism Regarding CDAs Used in the Context of ADs (N=46)



Trend of IQWiG's Points of Criticism

- The development of the IQWiG's criticisms over time showed an increasing importance of the CDA's methodology as well as the transparent presentation of the derivation of epidemiological evidence since 2014/2015. While only half of all criticized CDAs in 2015 (n=5; 55.6%) had a lack of methodology and/or transparency, this was the case in 90.0% (n=9) and/or 80.0% (n=8) of all criticized analyses in 2018, respectively.
- IQWiG criticized the scope of an analysis for the first time in 2015 (n=1; 11.1%). This point of criticism gained importance until 2018, when the IQWiG rated the scope as insufficient in half of the criticized CDAs (n=5; 50.0%). In contrast, the importance of a missing critical discussion has decreased from 2013 onwards.
- Besides, the IQWiG identified further points of criticism outside the used database in 50.0% of criticized analyses in 2014 (n=3) and 2016 (n=2). However, the IQWiG criticized those aspects going beyond the used data source only in 20.0% (n=1) and 30.0% (n=2) of the criticized CDAs in 2017 and 2018 (see **Table 1**).

Table 1. Trend of IQWiG's Criticisms Regarding CDAs Used in the Context of ADs Over Time

Year	Methodology		Transparent Presentation		Scope		Missing Critical Discussion		Criticisms Outside The Data Source		Total
	n	%	n	%	n	%	n	%	n	%	
2011	2	100.0	2	100.0	0	0.0	0	0.0	0	0.0	2
2012*											0
2013	0	0.0	1	100.0	0	0.0	1	100.0	0	0.0	1
2014	5	83.3	3	50.0	0	0.0	1	16.7	3	50.0	6
2015	5	55.6	5	55.6	1	11.1	2	22.2	3	33.3	9
2016	3	75.0	3	75.0	0	0.0	0	0.0	2	50.0	4
2017	4	80.0	4	80.0	0	0.0	0	0.0	1	20.0	5
2018	9	90.0	8	80.0	5	50.0	1	10.0	3	30.0	10

* Note: In 2012, no CDA was criticized by IQWiG.

CONCLUSIONS

- Claims data are a well-established source for the determination of epidemiological evidence in the German AMNOG HTA process.
- Especially, in the indication areas of oncology diseases, metabolic diseases, and skin disorders, CDAs were a popular tool for the assessment of epidemiological data.
- However, for acceptance, IQWiG's quality requirements regarding methodology and transparency need to be considered in particular because these were mainly criticized during the last years.
- To ensure adequate reporting quality, new regulations will be in place as of 2020 demanding standardized reporting according to the Reporting Standard for Secondary Data Analyses (STROSA: STandardisierte BerichtsROutine für Sekundärdaten Analysen),² the Recommendations for Securing Good Epidemiological Practice (GEP: Gute Epidemiologische Praxis),³ and the Guideline for Good Practice in Secondary Data Analysis (GPS: Gute Praxis Sekundärdatenanalyse).⁴

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