Prevalence and Incidence Estimations in German AMNOG Applications: The Role of Real-world Evidence (RWE)

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BACKGROUND

- 90% of the German population is insured in the Statutory Health Insurance (SHI), which covers nearly all healthcare services with only little co-payments for patients.
- German health insurance claims data therefore constitute an important basis for RWE on morbidity and healthcare costs.
- In 2011, the Act on the Reform of the Market for Medicinal Products (AMNOG) was enacted in Germany to counter rising healthcare costs.
- The AMNOG obliges pharmaceutical companies to submit a benefit dossier to the Federal Joint Committee (FJC) at market launch, estimating prevalence, incidence, and annual therapy costs and providing granular data on medical benefits in terms of morbidity, mortality, and health-related quality of life. All information must be up-to-date with current, high-quality evidence.
- Pharmaceutical companies are entitled to negotiate a national reimbursement price only if the FJC declares an additional benefit over the selected comparator therapy.
- Until now, the role of RWE in German AMNOG applications in terms of utilization, quality, and impact on benefit ratings and price discounts is unclear.

OBJECTIVE

- The aim of this study was to investigate the extent to which RWE was used for estimation of prevalence and incidence in German AMNOG assessments and also its impact on benefit ratings and price discounts.

RESULTS

Types of RWE data

- In total, 167 AMNOG assessments were included in the analyses.
- RWE was incorporated in 49% (n=81) of these dossiers to assess prevalence and incidence, and the size of target populations. German health insurance claims data were employed in 22 dossiers (27%); registry data in 10 dossiers (12%); and other data sources like IMS, Delphi panels, Kantar Health data, INSIGHT Health data, and Megapharm data in 55 dossiers (68%). IMS data were included in 44 of these assessments. Multiple data sources were used in 6 dossiers.

Table 1. SHI Target Population: Estimates Stated in the Dossiers Compared to Estimates Stated by the FJC

<table>
<thead>
<tr>
<th>N=167</th>
<th>Underrated</th>
<th>Accepted as given*</th>
<th>Overrated</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>RWE</td>
<td>Y</td>
<td>25</td>
<td>31%</td>
<td>36</td>
</tr>
<tr>
<td>Other data</td>
<td>Y</td>
<td>23</td>
<td>27%</td>
<td>53</td>
</tr>
<tr>
<td>German health insurance claims data</td>
<td>Y</td>
<td>8</td>
<td>39%</td>
<td>14</td>
</tr>
<tr>
<td>Registry data</td>
<td>Y</td>
<td>40</td>
<td>20%</td>
<td>75</td>
</tr>
<tr>
<td>Other data</td>
<td>Y</td>
<td>4</td>
<td>40%</td>
<td>5</td>
</tr>
<tr>
<td>Y</td>
<td>17</td>
<td>31%</td>
<td>19</td>
<td>35%</td>
</tr>
</tbody>
</table>

A margin of +10% was assumed.

* Y = RWE: Y - real-world evidence; N = RWE: N - real-world evidence

Benefit rating and price discount

- Of all AMNOG assessments using RWE, 40% were declared to prove an additional benefit of the new pharmaceutical over the selected comparator.
- However, a causal relationship between the use of RWE and the benefit rating is equivocal, as the benefit rating mostly depends on clinical evidence. Rather, RWE on incidence and prevalence, as well as size of target populations, is more important for the subsequent price negotiations, as it has influence on the budget impact.
- Price negotiations were completed for 99 AMNOG assessments.
- A t-test evaluating the association between the use of RWE and negotiated price discounts revealed no statistically significant difference between assessments that did incorporate RWE data and assessments that did not (P>0.18).
- The t-tests remained inconclusive after stratification by data source (claims data, registry data, and other data).

Conclusions

- German health insurance claims data comprise comprehensive information such as demographics, outpatient care, prescriptions, devices and aids, incapacity to work, and sick leave payments.
- German claims data are particularly useful for prevalence and incidence analyses, since diagnoses, procedures, and prescriptions are documented routinely and patient histories can be evaluated over longer time periods.
- This is of special value regarding the target population and cost estimations, which are of paramount importance in price negotiations following the AMNOG assessment.
- German claims data constitute a reliable and valid data source for assessing epidemiologic evidence in German AMNOG assessments. Indication-specific claims data analyses are a meaningful complement to literature research.
- Additional benefit ratings are most likely driven by clinical evidence, whereas price negotiations depend heavily on estimations of target populations, which should be backed up by robust real-world evidence.

Figure 1. Data Sources of RWE in AMNOG Assessments

Figure 2. Disease Areas for RWE in AMNOG Assessments

CONCLUSIONS

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Figure 3. Use of RWE Stratified by Type of Assessment