EPH70

Claims data analysis of health care resource use and costs of respiratory syncytial virus prevention in infants in Germany

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BACKGROUND

- Respiratory syncytial virus (RSV) infections are a leading cause of hospitalization with severe acute respiratory infections, particularly in the first year of life.
- Until 2023, the monoclonal antibody palivizumab, which needs to be administered monthly during the RSV season, was the only available intervention to prevent RSV disease in at-risk infants.
- In the European Union, palivizumab is authorized "for the prevention of serious lower respiratory tract disease requiring hospitalization caused by respiratory syncytial virus (RSV) in children at high risk for RSV disease" [1].
- The population of "high risk" is comprised of infants born at 35 weeks of gestational age (wGA) or less facing their first RSV season, and children less than 2 years of age with bronchopulmonary dysplasia (BPD) or hemodynamically significant congenital heart disease (CHD) [2].
- In Germany, due to the high costs associated with palivizumab-use, reimbursement of its use in pre-term infants is further restricted to infants born at 29 wGA or less, who are entering their first RSV season.
- Epidemiological studies on the size of the at-risk population for RSV and knowledge about palivizumab immunization patterns are limited.

OBJECTIVE

- The overall aim of the study is to generate epidemiological data for infants that have an increased risk of severe RSV disease and are eligible for treatment with palivizumab.
- The objectives of this study are:
  - To determine the size of the at-risk population for RSV in the German statutory health insurance (SHI).
  - To analyze palivizumab immunization patterns in the German SHI population, stratified by year and risk profile, and to determine the palivizumab immunization patterns (mean number of administrations and related costs) in these groups.

METHODS

Data source

- Study data were obtained from the WIG2 Database containing anonymized healthcare claims data of approximately 4 million insurants in Germany.
- SHI population data were received from the Federal Office for Social Security (BAS, RSA-SA statistics) [3].

Study design and population

- We retrospectively analyzed SHI claims data of infants born from 2015 to 2019 in Germany.
- The infant population eligible for palivizumab immunization, consisting of preterm infants born at 29 wGA or less, or with CHD or BPD was identified in the data using ICD-10 codes.
- We defined 2 at-risk groups: Risk group 1 (BPD/CHD/<29wGA); Risk group 2: (risk group 1 + otherwise healthy pre-term at 29-35 wGA). Infants not in risk group 2 were considered as healthy.
- Resource use and costs related to palivizumab immunizations during the first year of life were determined in the data using hospital remuneration numbers and operation and procedure codes for inpatient administrations, and ATC code J06BB16 for outpatient administrations.

Model calculation

- The extrapolated number of at-risk infants within Germany resp. the SHI population is thereby determined by:

$$n_{GG}^{SHI} = \frac{n_{GG}^{DB}}{N_{GG}^{DB}} \times N_{GG}^{SHI} \quad \text{and} \quad n^{SHI} = \sum_{GG} n_{GG}^{SHI}$$

(with SHI = SHI population; DB = database; GG = gender group)

RESULTS

Risk groups

- The total population contains 144,543 newborns with an observable follow-up period of 1 year (see Table 1).
- 5,024 (3.5%) of all newborns belong to risk group 1; 14,747 (10.2%) of all newborns belong to risk group 2.
- Extrapolating risk group 1 to all infants born between 2015 and 2019 and insured within any SHI resulted in a number of 120,603 (95%-CI: 117,928-124,515) infants corresponding to 24,121 per year.
- The extrapolated risk group 2 consists of 354,034 (95%-CI: 350,380-361,264) newborn children.

Table 1: At-risk infants (<1 year) identified in the database by risk group and projection, birth cohorts 2015-2019

Birth year/ cohort	Database: Newborn infants (up to 1 year follow up), N	Database: Risk group 1 n (%)	Database: Risk group 2 n (%)	Database: Healthy (%)	Projection SHI: Risk group 1 n	Projection SHI: Risk group 2 n
2015	32,723	1,173 (3.6%)	3,391 (10.4%)	96.4% / 89.6%	23,758	68,720
2016	31,959	1,193 (3.7%)	3,549 (11.1%)	96.3% / 88.9%	26,057	77,545
2017	28,858	949 (3.3%)	2,903 (10.1%)	96.7% / 89.9%	23,388	71,546
2018	26,478	896 (3.4%)	2,477 (9.4%)	96.6% / 90.6%	24,049	66,497
2019	24,525	813 (3.3%)	2,427 (9.9%)	96.7% / 90.1%	23,351	69,726
Total	**144,543**	**5,024 (3.5%)**	**14,747 (10.2%)**	**96.5% / 89.8%**	**120,603**	**354,034**

Immunization patterns

- During the study period, 1.3% of all infants received at least one dose of palivizumab, ranging between 1.2% and 1.5% across birth cohorts (Table 2).
- 25.3% of the children belonging to risk group 1 received palivizumab, respective 12.9% belonging to risk group 2.
- The mean number of doses for all children who received palivizumab was 4.6 and slightly higher within risk group 1 with 16.2% of doses administered in inpatient setting and 83.8% administered in the outpatient setting.

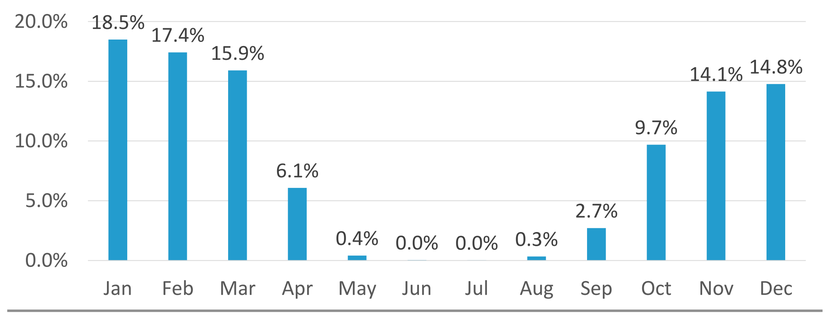
Table 2: Proportion of children receiving immunization with palivizumab and number of administrations, by risk group, birth cohorts 2015-2019

Palivizumab administrations	Risk group 1	Risk group 2	Total population
N	5,024	14,747	144,543
n (infants who received palivizumab)	1,272 (25.3%)	1,906 (12.9%)	1,947 (1.3%)
No. of administrations per infant - Mean (SD)	4.8 (2.0)	4.6 (2.0)	4.6 (2.0)
No. of administrations per infant - Median	5	5	5
No. of infants with 1 administration	83 (6.5%)	144 (7.6%)	153 (7.9%)
No. of infants with 2 administrations	116 (9.1%)	191 (10.0%)	193 (9.9%)
No. of infants with 3 administrations	154 (12.1%)	228 (12.0%)	239 (12.3%)
No. of infants with 4 administrations	185 (14.4%)	304 (15.9%)	306 (15.7%)
No. of infants with 5 administrations	249 (19.6%)	343 (18.0%)	350 (18.0%)
No. of infants with 6 administrations	224 (17.6%)	330 (17.3%)	335 (17.2%)
No. of infants with 7 administrations	159 (12.5%)	241 (12.6%)	244 (12.5%)
No. of infants with 8 administrations	79 (6.2%)	95 (5.0%)	97 (5.0%)
No. of infants with >8 administrations	23 (1.8%)	30 (1.6%)	30 (1.5%)

Seasonality of administration

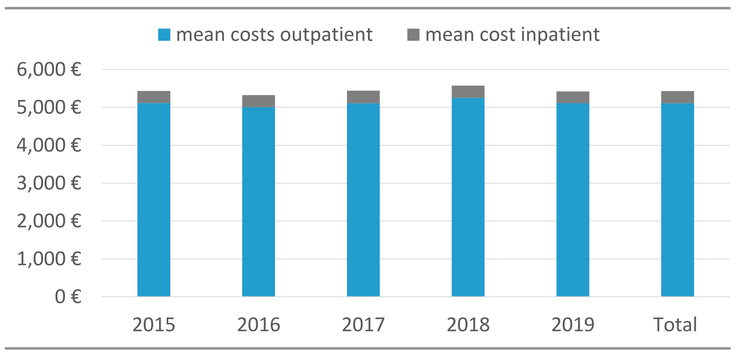
- Most doses dispensed in January and decrease afterwards.
- While (nearly) no immunization occurs from May to August, the increase starts from September.

Figure 1: Monthly proportion of palivizumab doses administered in the outpatient setting, birth cohorts 2015-2019



Costs

Figure 2: Mean costs per infant receiving palivizumab by setting of administration, birth cohorts 2015-2019



- Per immunized infant average costs of €5,428 (SD = €3,269) incurred.
- The biggest share (94.1%, resp. €5,108) was attributable to outpatient administration of palivizumab.
- Mean costs did not differ between risk groups.
- For the SHI population total costs per year of 50.6 million Euro (95%-CI: €49.2M-€51.9M) can be estimated.

CONCLUSION

- This study was the first to estimate RSV immunization rates and associated resource use and costs in Germany.
- Despite the high risk of severe RSV disease, the overall share of infants who benefit from existing prophylaxis with palivizumab is low.
- New interventions (such as long-acting monoclonal antibodies) may have the potential to prevent lower respiratory tract disease associated with RSV in a broader infant population.

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M. Wick, A. Poshtiban, R. Kramer, M. Bangert and O. Damm are employees of Sanofi and may hold shares and/or stock options in the company.

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