

Disease Burden of Respiratory Syncytial Virus in the US and Germany: A Comparative Analysis of Real-World Data Availability and Opportunities

Diehl M¹, Somani P¹, Witte J², Kulkarni A¹, Saikumar S¹, Patel N¹, Braegelmann K², Flume M³ ¹Trinity Life Sciences, Waltham, MA, USA, ²Vandage GmbH, Bielefeld, Germany, ³J.L. Glennie Consulting Inc., Aurora, ON, Canada



- Retrospective analyses of medical claims data serve as a cornerstone in HEOR, supporting clinical and economic studies around disease burden
- Respiratory syncytial virus (RSV) is one of the leading respiratory tract infections resulting in hospitalizations amongst pediatric patients under the age of one across jurisdictions. Assessing burden of illness and risk of severe disease progression plays an important role in communicating the need for new avenues of disease prevention and treatment

Objectives

- Compare dataset-specific methodologies in two unique healthcare systems (i.e., USA and Germany) by assessing RSV disease burden in pediatric patients under the age of one in claims data
- Identify gaps driven by the commercial availability of data across geographies and the corresponding impact on the level of visibility on patients' lives for characterization of unmet need
- Discuss implications for life sciences companies interested in leveraging claims analyses in these markets to support strategic decision making

Methods

- This study estimated RSV incidence, patients' risk status, site of care utilization and hospital treatment rates in pediatric patients with RSV using claims data in the United States (Komodo[®] Healthcare Map) and in Germany (DAK-insurance data)
- Komodo Healthcare Map[™] closed, "payer-complete" claims data was selected for its comprehensive representation across all payer types and broad capture of patient lives in the US. **DAK-Gesundheit**, a closed claims data source curated by Germany's third-largest statutory health insurance provider, was selected for its comprehensive capture of pediatric patients across all health settings



- This study **compares how RSV disease** burden amongst infants under the age of one can be quantified using claims data in the USA and Germany, including the differences in each geography's available data and associated benefits and limitations these present to support strategic decision making
- The pediatric population was defined as patients under the age of one during the analysis period, with 1+ diagnosis claims for any ICD-10 codes for RSV, over the 2022-23 RSV season (Jul 2022 – Jun 2023). This diagnosis threshold was selected since RSV is an acute condition and patients may not be coded with RSV multiple times during an episode.
 - RSV infection rates amongst the overall cohort and three risk status groups were assessed (at risk, pre-term/low birth weight, term birth)
 - ✓ Site of care utilization was reported in aggregate for the RSV season, irrespective of the number of RSV infections
- Results from each country were evaluated, and comparisons between each study's methodology was performed including associated benefits and limitations



Discussion

- Incidence rates and methods were comparable for both US and German claims. Both countries use ICD-10 coding, a global, standardized system maintained by the World Health Organization and have capture across both inpatient and outpatient settings. Both datasets also provide insight into their underlying universe of capture allowing researchers to project incidence estimates to national totals and size respective populations in each region; however, they each adjust visibility for date of birth in infants under the age of one, impacting pediatric epidemiology estimates
- Factors related to pediatric risk status, such as pre-term birth rates are not visible in the US, limiting exploration into the "at risk" population. US claims blind infant medical encounter dates and diagnosis claims. As a result, while there is value in establishing the burden of RSV amongst high-risk group infant patients, there is limited scope for organizations to effectively measure this within the US
- RSV-related visit rates in DE were comparable to inpatient and ER rates in the US. ER and inpatient visit rates are not reported separately in Germany, but as an aggregate. A key benefit in US claims data is visibility by all sites of care, helping further delineate RSV episode severity. In Germany, it remains unclear what proportion of patients required more intensive care (e.g., overnight stay)
- Inpatient reporting detail in US claims data is limited due to diagnosis-related group (DRG) bundling of hospital stay claims. Procedure rates can be measured by proxy using ICD-10 procedure codes and CPT codes, as observed with ventilation rates reported amongst hospitalized patients, however, US claims data must be linked with hospital chargemaster data to have capture details around treatments patients received within the inpatient setting

Conclusions

- Both German and US claims datasets can support robust publication-grade HCRU studies, with each region having unique strengths and weaknesses in measuring disease burden based on how patient claims are reported. These must be carefully considered through robust analysis design
- US claims data provides additional clinical specificity by delineating ER and **inpatient visits** and re-hospitalization rates for each. However, it underrepresents inpatient treatment and procedure rates if not linked to hospital chargemaster data
- While Germany offers rich data linked across several settings of care to inform HCRU use cases for more holistic decision-making, there is a lack of differentiation between ER and inpatient utilization, impacting the ability to delineate episode severity. Inconsistent RSV coding and/or limited capture within outpatient settings also affects the ability to accurately assess site of care utilization for the condition

Limitations

- Across both US and Germany, ICD-10 codes may underestimate the true incidence rate of RSV due to inconsistent / imperfect coding practices by healthcare providers. COVID-19 pandemic also affected coding and testing practices, impacting the accuracy of diagnoses of hospitalized RSV patients
- Findings across both regions are specific to the claims datasets and business rules leveraged; results may vary based on alternate methodologies and patient capture across different datasets

Acknowledgments

Connect With Us: (III) TrinityLifeSciences.com (IIII)

Trinity would like to thank Komodo Health for providing US RSV patient claims data for this study, and Grace Jiang for supporting with the US data analysis

linkedin.com/company/trinitylifesciences



ssaikumar@trinitylifesciences.com mdiehl@trinitylifesciences.com



Disease Burden of Respiratory Syncytial Virus in the US and Germany: A Comparative Analysis of Real-World Data Availability and Opportunities

Diehl M¹, Somani P¹, Witte J², Kulkarni A¹, Saikumar S¹, Patel N¹, Braegelmann K², Flume M³ ¹Trinity Life Sciences, Waltham, MA, USA, ²Vandage GmbH, Bielefeld, Germany, ³J.L. Glennie Consulting Inc., Aurora, ON, Canada



- Retrospective analyses of medical claims data serve as a cornerstone in HEOR, supporting clinical and economic studies around disease burden
- Respiratory syncytial virus (RSV) is one of the leading respiratory tract infections resulting in hospitalizations amongst pediatric patients under the age of one across jurisdictions. Assessing burden of illness and risk of severe disease progression plays an important role in communicating the need for new avenues of disease prevention and treatment

Objectives

- Compare dataset-specific methodologies in two unique healthcare systems (i.e., USA and Germany) by assessing RSV disease burden in pediatric patients under the age of one in claims data
- Identify gaps driven by the commercial availability of data across geographies and the corresponding impact on the level of visibility on patients' lives for characterization of unmet need
- Discuss implications for life sciences companies interested in leveraging claims analyses in these markets to support strategic decision making

Methods

- This study estimated RSV incidence, patients' risk status, site of care utilization and hospital treatment rates in pediatric patients with RSV using claims data in the United States (Komodo[®] Healthcare Map) and in Germany (DAK-insurance data)
- Komodo Healthcare Map[™] closed, "payer-complete" claims data was selected for its comprehensive representation across all payer types and broad capture of patient lives in the US. **DAK-Gesundheit**, a closed claims data source curated by Germany's third-largest statutory health insurance provider, was selected for its comprehensive capture of pediatric patients across all health settings



- This study **compares how RSV disease** burden amongst infants under the age of one can be quantified using claims data in the USA and Germany, including the differences in each geography's available data and associated benefits and limitations these present to support strategic decision making
- The pediatric population was defined as patients under the age of one during the analysis period, with 1+ diagnosis claims for any ICD-10 codes for RSV, over the 2022-23 RSV season (Jul 2022 – Jun 2023). This diagnosis threshold was selected since RSV is an acute condition and patients may not be coded with RSV multiple times during an episode.
 - RSV infection rates amongst the overall cohort and three risk status groups were assessed (at risk, pre-term/low birth weight, term birth)
 - ✓ Site of care utilization was reported in aggregate for the RSV season, irrespective of the number of RSV infections
- Results from each country were evaluated, and comparisons between each study's methodology was performed including associated benefits and limitations



Discussion

- Incidence rates and methods were comparable for both US and German claims. Both countries use ICD-10 coding, a global, standardized system maintained by the World Health Organization and have capture across both inpatient and outpatient settings. Both datasets also provide insight into their underlying universe of capture allowing researchers to project incidence estimates to national totals and size respective populations in each region; however, they each adjust visibility for date of birth in infants under the age of one, impacting pediatric epidemiology estimates
- Factors related to pediatric risk status, such as pre-term birth rates are not visible in the US, limiting exploration into the "at risk" population. US claims blind infant medical encounter dates and diagnosis claims. As a result, while there is value in establishing the burden of RSV amongst high-risk group infant patients, there is limited scope for organizations to effectively measure this within the US
- RSV-related visit rates in DE were comparable to inpatient and ER rates in the US. ER and inpatient visit rates are not reported separately in Germany, but as an aggregate. A key benefit in US claims data is visibility by all sites of care, helping further delineate RSV episode severity. In Germany, it remains unclear what proportion of patients required more intensive care (e.g., overnight stay)
- Inpatient reporting detail in US claims data is limited due to diagnosis-related group (DRG) bundling of hospital stay claims. Procedure rates can be measured by proxy using ICD-10 procedure codes and CPT codes, as observed with ventilation rates reported amongst hospitalized patients, however, US claims data must be linked with hospital chargemaster data to have capture details around treatments patients received within the inpatient setting

Conclusions

- Both German and US claims datasets can support robust publication-grade HCRU studies, with each region having unique strengths and weaknesses in measuring disease burden based on how patient claims are reported. These must be carefully considered through robust analysis design
- US claims data provides additional clinical specificity by delineating ER and **inpatient visits** and re-hospitalization rates for each. However, it underrepresents inpatient treatment and procedure rates if not linked to hospital chargemaster data
- While Germany offers rich data linked across several settings of care to inform HCRU use cases for more holistic decision-making, there is a lack of differentiation between ER and inpatient utilization, impacting the ability to delineate episode severity. Inconsistent RSV coding and/or limited capture within outpatient settings also affects the ability to accurately assess site of care utilization for the condition

Limitations

- Across both US and Germany, ICD-10 codes may underestimate the true incidence rate of RSV due to inconsistent / imperfect coding practices by healthcare providers. COVID-19 pandemic also affected coding and testing practices, impacting the accuracy of diagnoses of hospitalized RSV patients
- Findings across both regions are specific to the claims datasets and business rules leveraged; results may vary based on alternate methodologies and patient capture across different datasets

Acknowledgments

Trinity and Vandage would like to thank Komodo Health for providing US RSV patient claims data for this study, and Grace Jiang for supporting with the US data analysis

ssaikumar@trinitylifesciences.com Ask A Question: (\mathbb{X}) mdiehl@trinitylifesciences.com

Connect With Us: (III) TrinityLifeSciences.com (IIII)

linkedin.com/company/trinitylifesciences