Comparative Post-Marketing Safety Study of Nirsevimab and Palivizumab : A Pharmacovigilance Analysis Using FAERS and WHO VigiAccess

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BACKGROUND

Respiratory syncytial virus (RSV) remains a primary cause of pediatric respiratory infections, leading to 58,000–80,000 annual hospitalizations in the US for children under five.[1] Until 2023, palivizumab was the only available option for RSV prophylaxis in USA. The recent introduction of the long-acting monoclonal antibody nirsevimab has expanded preventive strategies.

Despite widespread use, real-world comparative safety data for nirsevimab and palivizumab remain limited. Pharmacovigilance databases, including Food and Drug Administration Adverse Event Reporting System (FAERS) and WHO VigiAccess, capture rare and serious adverse events; but differences in reporting patterns, patient characteristics, and safety profiles are not well described.

OBJECTIVE

This study aims to characterize and compare the safety profiles, patient characteristics, and reporting patterns of nirsevimab and palivizumab using data from the FAERS and the WHO VigiAccess database.

METHODS

- **Data Sources:** Adverse event reports were extracted from FAERS and WHO VigiAccess (2023–2025).
- **Study Population:** Deduplicated reports where the study drugs were the Primary Suspect (PS) (FAERS: nirsevimab: 1,023; palivizumab: 2,541. WHO VigiAccess accessed on January 2, 2026: nirsevimab: 1,279; palivizumab: 22,290).
- **Descriptive Analysis:** Frequencies and percentages were calculated at the System Organ Class (SOC) and Preferred Term (PT) levels following MedDRA hierarchy.[2]
- **Signal Detection:** Four disproportionality algorithms were applied: Reporting Odds Ratio (ROR), Proportional Reporting Ratio (PRR), Bayesian Confidence Propagation Neural Network (BCPNN), and Empirical Bayesian Geometric Mean (EBGM).[3]
- **Software:** Analyses were conducted using RStudio (Version 2025.05.1+513; Posit Software, PBC).

RESULTS

WHO VigiAccess Demographic Information

- **Age Distribution**
  - ✓Majority of reports involved infants for both drugs (0–23 months)
    - ✓Nirsevimab: 78.0% , Palivizumab: 62.1%
  - ✓Higher proportion of older/other age groups in palivizumab
- **Gender Distribution**
  - ✓Higher proportion of male reports in palivizumab (52.9%)
- **Geographic Distribution**
  - ✓Nirsevimab reports mainly from Europe (56.8%)
  - ✓Palivizumab reports mainly from Americas (66.8%)
  - ✓Minimal reporting from Asia and Africa

RESULTS

Fig 1. FAERS Demographic profiles for Nirsevimab & Palivizumab

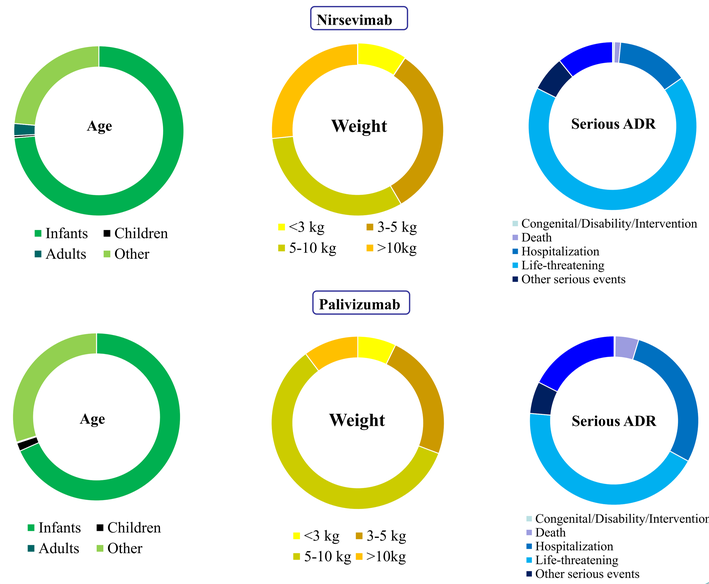


Fig 2. Signal Detection at SOC level from FAERS

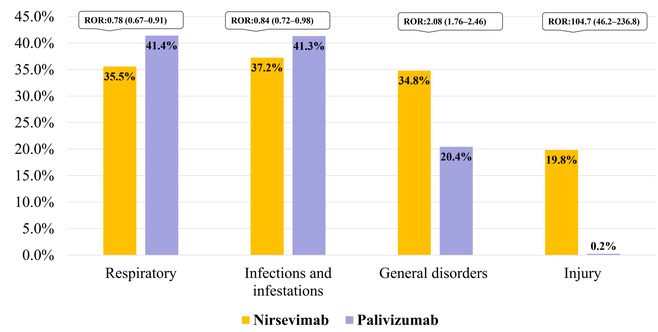


Table 1. Top 3 PTs for Nirsevimab from FAERS

Rank	Preferred Term (PT)	Frequency	%
1	Pyrexia	69	6.7%
2	Apnea	24	2.3%
3	Respiratory distress	20	1.9%

Table 2. Top 3 PTs for Palivizumab from FAERS

Rank	Preferred Term (PT)	Frequency	%
1	Pyrexia	313	12.3%
2	Seizure	54	2.1%
3	Irritability	40	1.5%

RESULTS

Fig 3. Signal Detection at SOC level from WHO VigiAccess

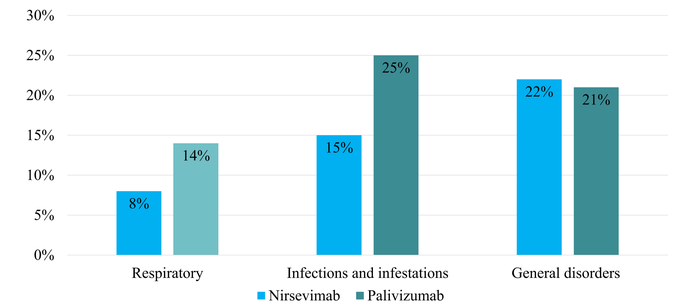
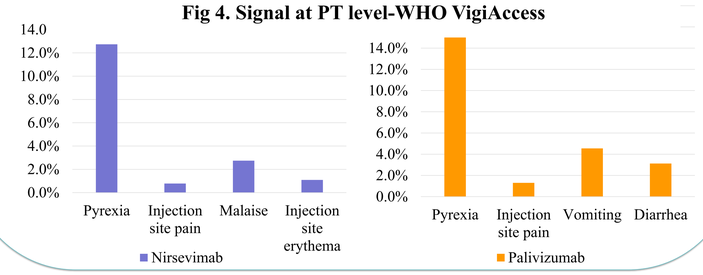


Fig 4. Signal at PT level-WHO VigiAccess



CONCLUSION

- Overall, FAERS and WHO VigiAccess demonstrated broadly consistent safety patterns, with similar SOCs and commonly reported PTs, although minor differences in ranking were observed.
- While most reported events align with known clinical patterns, only a limited number correspond to FDA-approved labeling.
- The elevated ROR for Injury, poisoning and procedural complications with nirsevimab may reflect increased reporting of medication administration and procedural issues rather than direct pharmacologic toxicity.
- These findings highlight the importance of continued pharmacovigilance to monitor emerging safety patterns and support evidence-based clinical and regulatory decision-making.

REFERENCES

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