

The Real-World Effectiveness of Palivizumab Programs for High-Risk Infants: A Population-Based Study in Ontario, Canada, 1993-2017

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BACKGROUND

- Respiratory syncytial virus (RSV) is a leading cause of pediatric hospitalizations.
- Currently, no RSV vaccines are licensed; however, prophylaxis (palivizumab) is available to infants at increased risk of RSV-related illness to reduce illness severity.
- In Ontario (Canada), palivizumab has been publicly funded for high-risk infants since 2002 and through a national special access program since 1998.
- National guidelines define high-risk infants as those who <6mo during RSV season and born very preterm or <2yo with chronic lung disease or hemodynamically significant congenital heart disease.
- Objective:** to investigate temporal trends in pediatric admissions and deaths due to RSV, pre vs post introduction of these two palivizumab programs. We further investigated potential differences by socio-economic status (SES).

METHODS

- All births in Ontario during 1993-2015, inclusive, were followed using administrative health data until the earliest of child's 2nd birthday, death or moving out of province.
 - An interrupted time series approach was used. We modeled annual rates of our composite outcome (left) with two interruption points: introduction of the national special access program (SRP) in 1998 and provincial high-risk program (HRP) in 2002.
 - We created a 3-level indicator term for palivizumab (PvB) eligibility. Clearly PvB eligible children met criteria used across all study years; additional details (not available) were required to determine the eligibility of possibly eligible infants (e.g., daycare attendance).
 - PvB ineligible infants did not meet any PvB eligibility criteria and were a reference group.
 - Analyses were stratified by age (<6, 6-12, 12-24 mos) and performed using SAS v9.4 (SAS Institute Inc.; Cary, NC).

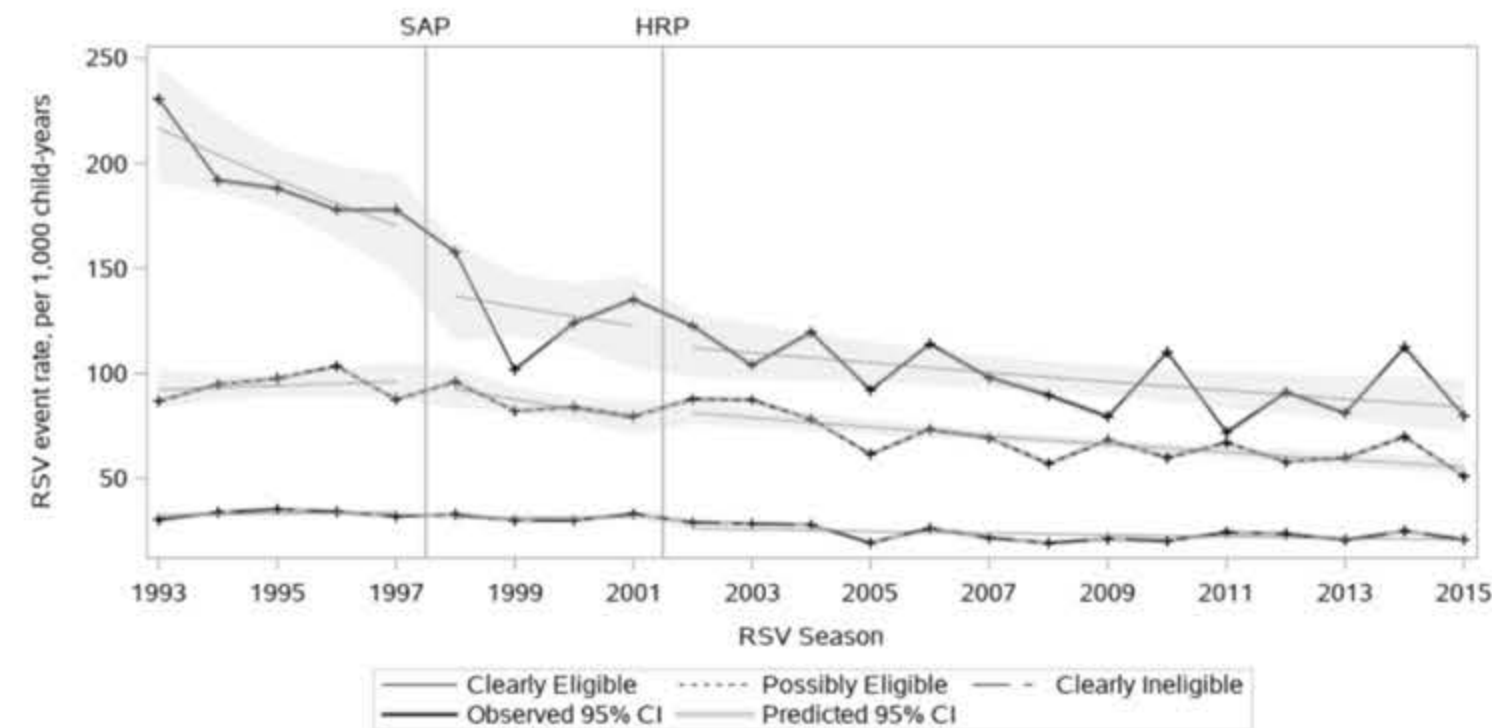
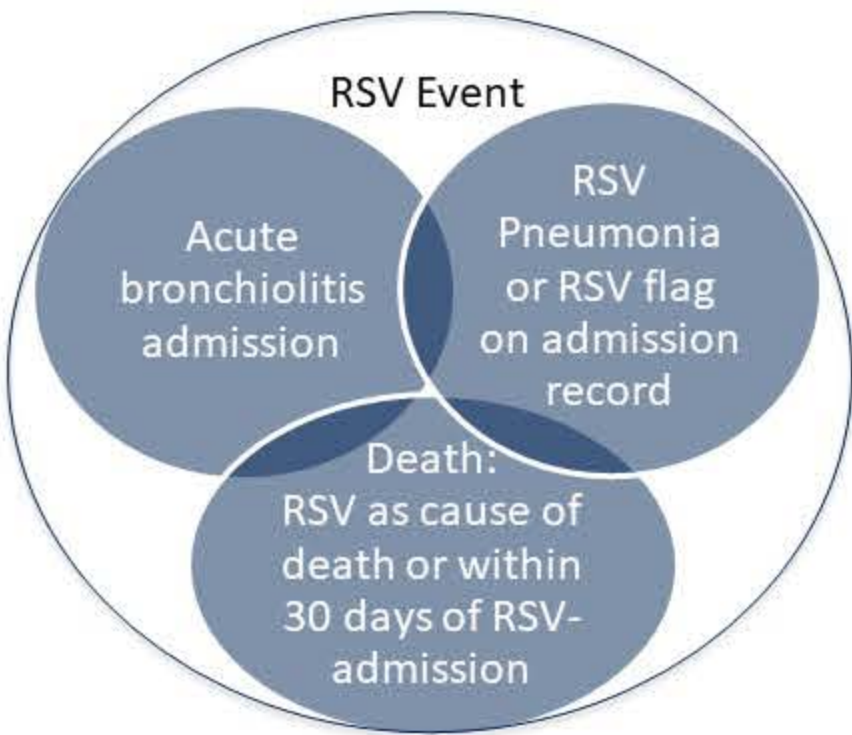


FIGURE 1. RSV event rates among infants <6 mos, according to PvB eligibility
SAP: Special access program, HRP: High Risk Program

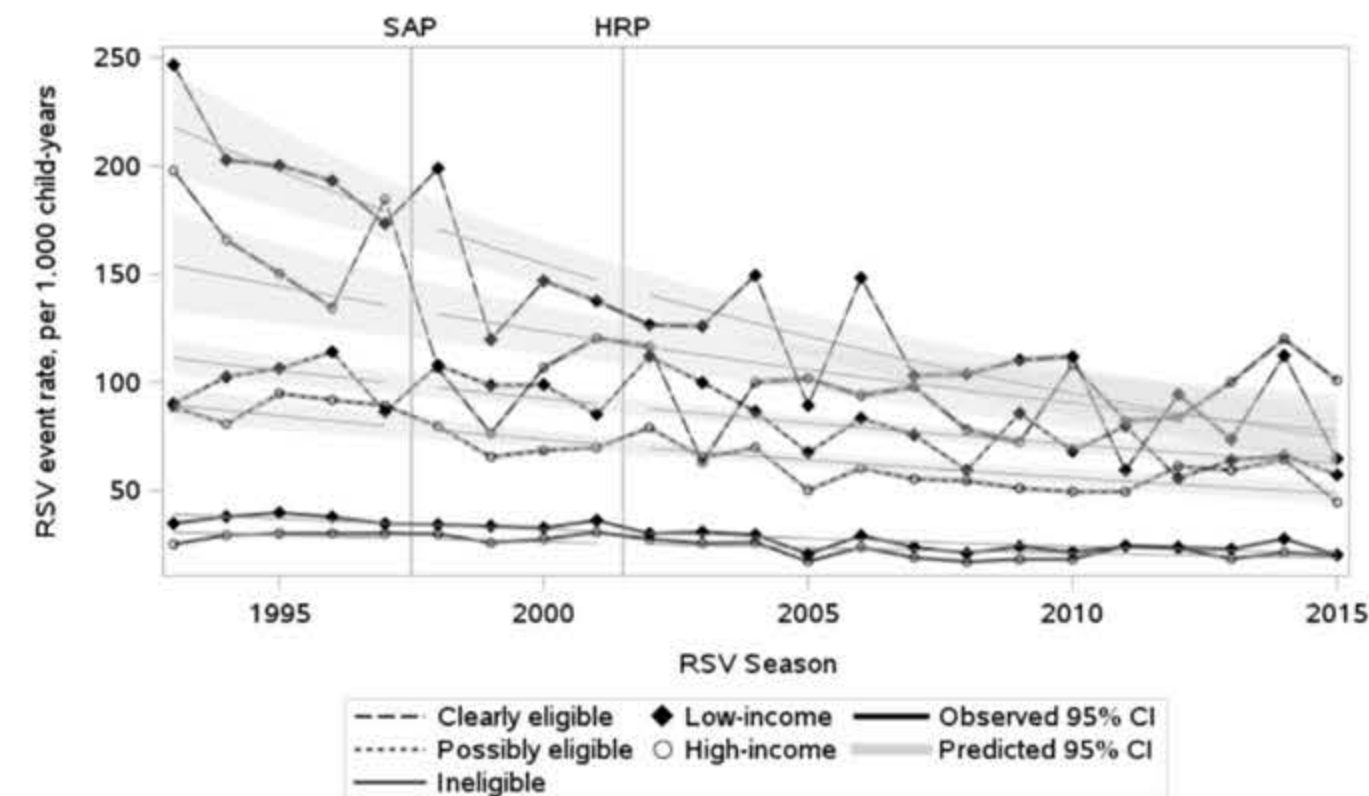


FIGURE 2. Income inequities in RSV rates narrows over time among both infants <6 mos, according to PvB eligibility

RESULTS

- 3M children and nearly 87,000 RSV events were included in this 24-yr study (Table 1).
- Rates were greatest among <6mos (6-11 months and 12-23 months not shown).
- Significant declines were seen following both programs, but particularly among infants <6mos.
- Rates notably declined among PvB eligible infants (65%, from 203.6 to 79.9 per 1000 child-years over the study period) but this was not statistically significant when compared to ineligible infants (Fig 1); 10.4% (95% CI -18.6% to 39.4%)
- RSV rates were higher among low-income infants; this gap narrowed over time for all infants but particularly (and statistically significant) for PvB eligible infants (Fig 2).
- We lacked data on PvB receipt, which would inform the degree to which eligible infants received a full PvB series.

CONCLUSIONS

Using a large, population-based study spanning over two decades, we observed significant declines in RSV-related admissions and deaths among infants following both publicly funded RSV PvB programs, along with evidence to suggest narrowing social inequities. While we cannot firmly attribute causality, the magnitude and timing of these changes, along with diminished social inequities, among PvB-eligible infants are noteworthy. These results also suggest PvB effectiveness is much lower than its clinical efficacy but may be improved, e.g., through enhanced promotion and uptake of available programs.

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