RESEARCH ARTICLE

RSV Hospitalizations in Comparison With Regional RSV Activity and Inpatient Palivizumab Administration, 2010–2013

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ABSTRACT

OBJECTIVES: To compare pediatric respiratory syncytial virus (RSV) hospitalizations in the United States to regional RSV activity and inpatient palivizumab administration.

METHODS: We characterized inpatients, excluding newborns, with RSV from the Pediatric Health Information System (July 2010–June 2013). RSV regional activity timing was defined by the National Respiratory and Enteric Virus Surveillance System. RSV hospitalization season (defined by at least 3 SDs more than the mean regional baseline number of RSV hospitalizations for 3 consecutive weeks) was compared with RSV regional activity season (2 consecutive weeks with ≥10% RSV-positive testing). Logistic regression was used to determine predictors of hospitalization timing (ie, during or outside of regional activity season). We also assessed the timing of inpatient palivizumab administration.

RESULTS: There were 50 157 RSV hospitalizations. Mean RSV hospitalization season onset (early November) was 3.3 (SD 2.1) weeks before regional activity season onset (early December). Hospitalization season offset (early May) was 4.4 (SD 2.4) weeks after activity season offset (mid-April). RSV hospitalization and activity seasons lasted 18 to 32 and 13 to 23 weeks, respectively. Nearly 10% of hospitalizations occurred outside of regional activity season (regional ranges: 5.6%–22.4%). Children with chronic conditions were more likely to be hospitalized after regional activity season, whereas African American children were more likely to be hospitalized before. Inpatient palivizumab dosing was typically initiated before the start of RSV hospitalizations.

CONCLUSIONS: There is regional variation in RSV hospitalization and activity patterns. Many RSV hospitalizations occur before regional activity season; high-risk infants may require RSV immunoprophylaxis sooner.

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Respiratory syncytial virus (RSV) is the leading cause of lower respiratory infections in infants and children.[1–6] More than 100 000 children are hospitalized for RSV per year, making RSV the most common diagnosis for hospitalized infants.[6–8] RSV infection can be particularly severe in children <1 year of age and infants with congenital heart disease, prematurity, and chronic lung disease.[9,10]

The Centers for Disease Control and Prevention (CDC) defines the start of RSV regional activity season as ≥10% positive RSV testing for 2 consecutive weeks.[11] RSV regional activity season varies each year and between regions[12–15] and is affected by climate, population density, and social and demographic factors.[16–18] Although there is no RSV vaccine, certain children at high risk are given prophylaxis with palivizumab, an RSV monoclonal immunoglobulin, which can reduce RSV hospitalizations.[19,20] The latest policy statement from the American Academy of Pediatrics (AAP) recommends that palivizumab administration for these children at high risk begins at the start of regional activity season.[21] One study found that using RSV regional activity data to determine when to initiate prophylaxis rather than using a set initiation date (November) would increase protection by 15%.[15] To do so, however, it is essential to further characterize the RSV regional activity season.

It is possible that some children may benefit from palivizumab before the start of RSV regional activity season. One study using a national health insurance database noted that 27% of RSV hospitalizations occurred before the first dose of palivizumab was administered at the start of the regional activity season,[20] although this study only assessed privately insured patients who had received at least 1 dose of palivizumab and did not address regional differences in RSV activity and hospitalizations. Light et al[22] found that ∼10% of RSV hospitalizations occurred outside of the regional activity season at the state level in Florida. Few, if any, studies have examined the relationship between the timing of RSV regional activity season and RSV hospitalizations at the national level. A substantial number of RSV hospitalizations before the start of regional activity season could indicate that high-risk infants may benefit from prophylaxis even earlier.

In this study, our primary aim was to characterize the epidemiology of RSV hospitalizations in a nationally representative sample of children's hospitals in comparison with RSV regional activity and determine what factors predict whether hospitalizations will occur during or outside of the regional activity season. Our secondary aim was to characterize the timing of inpatient palivizumab dosing compared with RSV infections and hospitalizations.

METHODS

Study Design and Data Source

This was a retrospective observational study. Patient data were collected using the Pediatric Health Information System (PHIS), an administrative database operated by the Children's Hospital Association. The PHIS database includes patient data; International Classification of Diseases ninth revision (ICD-9) diagnostic and procedure codes; date-stamped billing data for laboratory, imaging, and medications; and other administrative data for 44 free-standing children's hospitals. Data quality and reliability are assured through the Children's Hospital Association and participating hospitals.

Regional RSV activity data were obtained from the National Respiratory and Enteric Virus Surveillance System (NREVSS), which collects weekly RSV antigen testing results from participating laboratories.[11,23,24] Between July 2010 and June 2012, NREVSS included data for laboratories reporting RSV testing results for ≥30 weeks per season and ≥10 RSV tests per week on average; data were taken from 179 and 174 laboratories in the 2010–2011 and 2011–2012 seasons, respectively.[11,23] For the 2012–2013 season, NREVSS included results for 462 laboratories reporting results for ≥1 week and with 1 RSV test per week on average.[11]

Subjects

The subjects for this study were pediatric patients admitted (as inpatients) to 1 of the 44 PHIS hospitals with a discharge date between July 1, 2010 and June 30, 2013. Patients were included if they had a primary ICD-9 code for RSV (466.11: RSV bronchiolitis; 480.1: RSV pneumonia; or 079.6: other RSV) at hospital discharge. All newborns (defined based on newborn billing codes) and patients cared for in the NICU were excluded.

Data Analysis

NREVSS

RSV regional activity season was defined, per the CDC and NREVSS, as the period with ≥2 consecutive weeks of ≥10% RSV-positive testing in a region.[11]

PHIS

Admission dates for patients in PHIS were categorized by week so as to correspond with RSV regional activity data. To have a standardized way of comparing hospitalizations across regions, we defined the beginning and end of an RSV hospitalization season as occurring when the total number of hospitalizations per week within a region was greater than or equal to the interseasonal baseline number of RSV hospitalizations for that region for 3 consecutive weeks. For each region, the interseasonal baseline was calculated by taking the mean number of hospitalizations per week from June to September (the months with the fewest RSV hospitalizations) and adding 3 SDs.[18] We chose 3 SDs because this threshold seemed to best reflect the level above which RSV hospitalizations remained elevated consistently over time. In addition, utilizing a threshold of a specific number of RSV hospitalizations for all regions (as opposed to a region-specific definition of hospitalization season) could lead to a hospitalization season onset that is either too early or too late, depending on the region (Supplemental Fig 3). Sensitivity analyses using 8 possible definitions for RSV hospitalization season were performed. Overall patterns were similar when different definitions for hospitalization season were used. For example, the median number of weeks' difference between the least and most strict definitions for RSV hospitalization season onset was only

1 week. Thus, for simplicity, we will present data for only the 1 definition of hospitalization season described above. Demographic data for study patients, as well as whether they had complex chronic conditions (identified by using ICD-9 diagnoses),[25] were also extracted from PHIS.

Regions

Data were grouped into 1 of the 10 US Department of Health and Human Services (DHHS) regions. See Supplemental Fig 4 for a map of the regions and Table 2 for region names as defined by DHHS.[24] Florida (region 11 in our study) is typically analyzed by NREVSS separately because the RSV season there usually begins earlier and lasts longer compared with other regions.[11,23,24]

Inpatient Palivizumab Administration

As part of a separate secondary analysis, we determined which children received palivizumab while inpatients. Pediatric patients admitted to PHIS hospitals between July 1, 2010 and June 30, 2013, who received palivizumab, identified based on clinical transaction classification code 171607, were included regardless of primary diagnosis; newborn and NICU patients were excluded. The timing of inpatient palivizumab administration was compared with RSV regional activity and hospitalization seasons.

Statistical Analyses

Descriptive statistics were performed, including means and SDs of weeks between RSV regional activity, RSV hospitalization, and inpatient palivizumab administration across 10 regions (not including region 11) and 3 seasons. In addition, multivariable logistic regressions were used to assess predictors (demographics and presence of a complex chronic condition) of the outcome of timing of RSV hospitalization. Two separate regressions were run to assess predictors of hospitalization (1) before (compared with during or after) regional activity season and (2) after (compared with before or during) regional activity season by using Stata SE 12.1 (StataCorp, College Station, TX). The institutional review board at Columbia University reviewed and approved this study.

RESULTS

RSV Regional Activity and Hospitalizations

RSV regional activity season lasted 13 to 23 weeks depending on the region and season between July 1, 2010 and June 30, 2013. Regional activity season typically started between October and January and ended between March and May, aside from in region 11, where the season began as early as July.[11,23,24] Table 1 summarizes RSV regional activity and hospitalization patterns by region. Figure 1 depicts these patterns graphically, with the individual regions grouped geographically (Supplemental Fig 4) and by similar RSV regional activity and hospitalization patterns.

A total of 50 157 patients (between 14 439 and 18 962 per year) with a primary diagnosis of RSV were admitted to PHIS hospitals between July 1, 2010 and June 30, 2013 (Table 2). Mean length of stay was 3.7 (SD 5.4; range 1–234) days. RSV hospitalization season lasted 18 to 32 weeks in regions 1 to 10 (Table 1, Fig 1). Hospitalization season began between September and January and ended between March and June. Most (89.2%) occurred between November and March. Total number of RSV hospitalizations per month was highest in January and lowest in July.

Hospitalization season could not be defined in region 11 because patients were persistently admitted for RSV in this region. There were only 3 weeks with zero RSV admissions in this region during the 3-year study period, compared with a range of 13 to 53 weeks with zero RSV admissions in the other regions.

A total of 9.8% of hospitalizations occurred outside of regional activity season (ranges: 5.6% in region 9 to 22.4% in region 2); hospitalizations occurred outside of regional activity season more than 10% of the time in 5 regions (Table 2). Mean RSV hospitalization season onset was 3.3 (SD 2.1) weeks before regional activity season started. Hospitalization season peak occurred 1.6 (SD 3.6) weeks after regional activity peak. Mean hospitalization season offset was 4.4 (SD 2.4) weeks after regional activity season offset.

In multivariable analyses, hospitalizations before regional activity season were more likely among black versus white patients (adjusted odds ratio [aOR] 2.50, 95% confidence interval [CI] 2.25–2.79) as well as patients with private versus public insurance (aOR 1.16, 95% CI 1.05–1.29).

TABLE 1 Characteristics of Patients Admitted With a Diagnosis of RSV and Receiving Palivizumab, July 2010–June 2013

Characteristic	RSV Admissions % (N = 50, 157)	Inpatient Palivizumab Doses % (N = 8100)
Male sex	55.6 (27 891)	55.6 (4503)
Age, mo		
0–6	61.3 (30 728)	59.9 (4189)
7–12	14.7 (7374)	21.4 (1730)
13–24	13.4 (6743)	15.4 (1248)
>24	10.6 (5312)	3.4 (275)
ICU stay	15.8 (7921)	68.0 (5511)
Mortality	0.1 (53)	3.0 (241)
Insurance		
Government	66.5 (33 339)	63.2 (5115)
Commercial	28.8 (14 456)	32.2 (2604)
Other	4.7 (2362)	4.7 (381)
Race		
White	57.9 (29 049)	56.1 (4546)
Black	17.5 (8751)	16.8 (1358)
Other	24.6 (12 357)	27.1 (2196)
Chronic condition	15.9 (7967)	92.0 (7449)

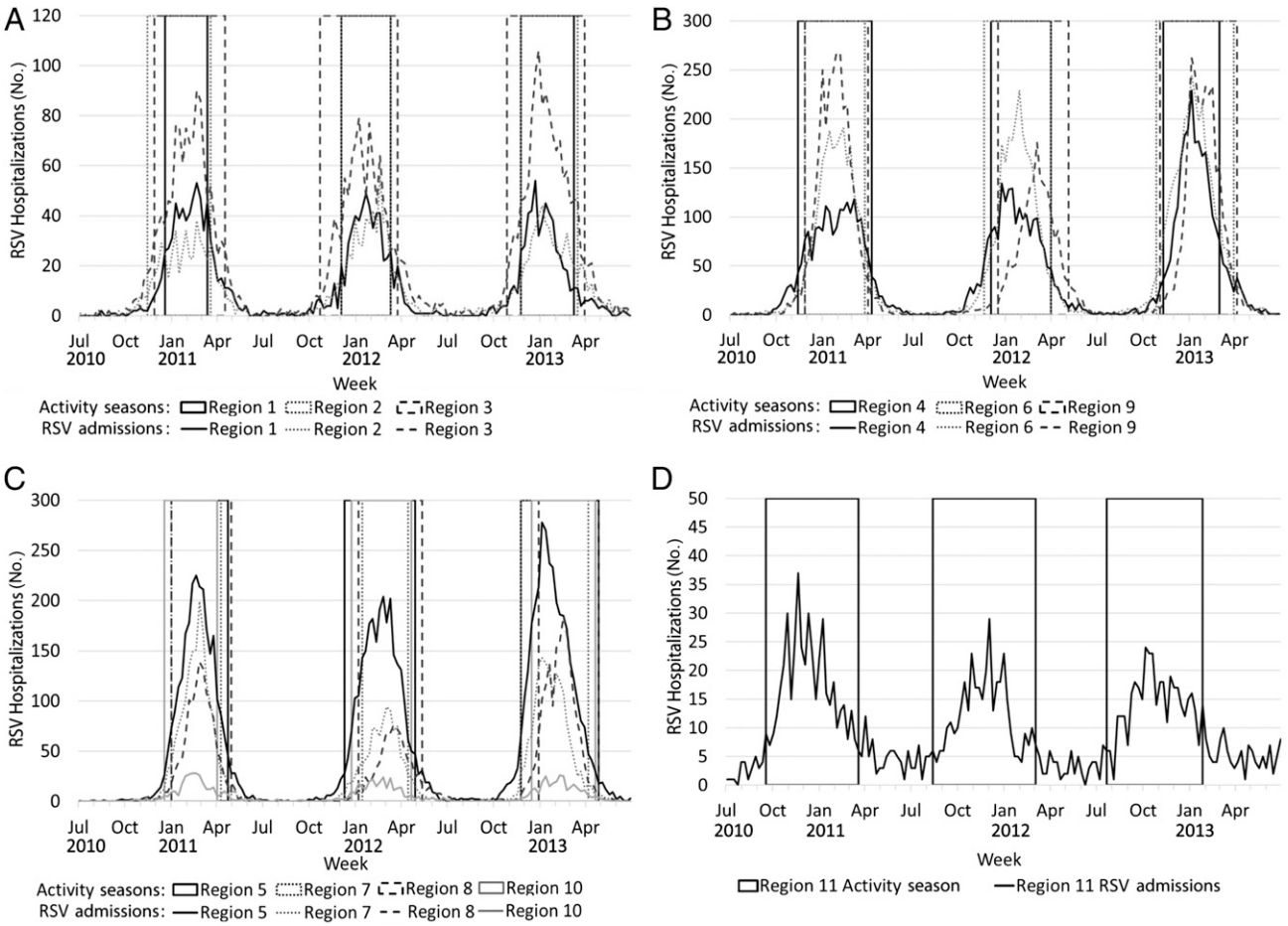

FIGURE 1 Comparison of RSV admissions and regional activity season (July 2010–June 2013) among regions.

Children with a chronic condition were more likely to be hospitalized after regional activity season (aOR 1.52, 95% CI 1.36–1.69). Hospitalization timing also varied by region and patient age (see Table 3).

Inpatient Palivizumab Administration

A total of 8100 inpatient doses of palivizumab were administered at PHIS hospitals between July 1, 2010 and June 30, 2013, to 5743 unique inpatients. The highest number of inpatient palivizumab doses was administered during the final season (July 2012–June 2013). Inpatient palivizumab administration patterns differed depending on the region, with doses being given over a range of 21 to 44 weeks per season in regions 1 to 10 (Table 2); the majority of doses were given between October and April (Fig 2). Palivizumab was given throughout the year in Florida. Characteristics of patients who received palivizumab are listed in Table 1.

Of the 7744 inpatient palivizumab doses given in regions 1 to 10 (RSV hospitalization season could not be calculated in region 11), 392 (5.1%) were given before, 7317 (94.5%) were given during, and 35 (0.5%) were given after RSV hospitalization season (Table 2). Of the 8100 inpatient palivizumab doses given across all 11 regions, 1527 (18.9%) doses were given before, 6291 (77.7%) were given during, and 282 (3.5%) were given after RSV regional activity season. The first inpatient dose of palivizumab in a region was given at a mean of 6.6 (SD 6.3) weeks before RSV hospitalization season onset and 9.9 (SD 6.5) weeks before regional activity season onset. However, in 2 regions (3 and 10), the first palivizumab dose was given at the start of or after hospitalization season onset during at least 1 season. In addition, the first palivizumab dose was given more than 12 weeks before the start of RSV hospitalization season onset in 4 regions (5, 8–10) for at least 1 season. The last inpatient dose of palivizumab in a region was given at a mean of 0.7 (SD 3.6) weeks before RSV hospitalization season offset and 3.7 (SD 3.4) weeks after regional activity offset.

DISCUSSION

This nationally representative study showed that RSV hospitalization and regional activity patterns are seasonal and vary greatly depending on the region, consistent with other studies.[12–15] Hospitalization and regional activity seasons generally began later and were shorter in northern and midwestern regions and began earlier and lasted longer in southern regions, which is also consistent with previous published data.[12–15] Similarly, RSV hospitalizations and regional activity in Florida seemed to have no distinct peak, with cases occurring

TABLE 2 Comparison of RSV Hospitalization and Regional Activity Data Across Regions, July 2010–June 2013

Region Number	Region Name[a]	Total Bed Count per Region[b]	Mean Hospitalization Season Length, wk	Mean Regional Activity Season Length, wk	Mean Duration of Inpatient Palivizumab Dosing, wk	Hospitalizations in Regional Activity Season, %	Palivizumab Doses Given in Regional Activity Season, %	Palivizumab Doses Given in Hospitalization Season, %	Hospitalization Season Onset	Regional Activity Season Onset	Palivizumab Dosing Onset
1	Boston	777	25.7	14.7	30	78.7	69.4	90.7	Oct–Nov	Nov–Dec	Aug–Sep
2	New York	390	26.0	17.0	27.7	77.6	69.1	94.0	Oct–Nov	Nov–Dec	Sep–Oct
3	Philadelphia	1298	28.3	22.3	27	89.6	89.5	99.0	Oct	Oct–Nov	Sep–Oct
4	Atlanta	1502	29.7	19.0	29.3	84.3	70.3	98.5	Oct	Nov–Dec	Sep–Oct
5	Chicago	2865	27.7	21.0	34	94.0	76.1	93.3	Oct–Dec	Nov–Dec	Aug–Sep
6	Dallas	2146	28.0	20.3	30	91.8	82.0	96.5	Sep–Oct	Oct–Nov	Aug–Oct
7	Kansas City	691	25.7	16.3	25.7	90.9	62.5	88.7	Nov–Dec	Nov–Jan.	Sep–Oct
8	Denver	743	21.0	18.3	25.3	92.7	68.5	85.0	Dec–Jan	Dec–Jan	Sep–Nov
9	San Francisco	2198	24.3	21.0	31	94.4	83.8	95.0	Nov–Jan	Nov–Dec	Sep–Oct
10	Seattle	250	13.0	17.7	20.7	86.6	83.2	96.0	Dec–Jan	Dec	Nov–Dec
11	Florida	531	—[c]	28.3	—[c]	80.6	67.1	—[c]	—[c]	July–Sep	—[c]

[a] DHHS region city name for regions 1 to 10; hospitals are not necessarily located in these cities.
[b] 2013 numbers used for simplicity.
[c] Could not be defined given persistent RSV hospitalizations and dosing of palivizumab throughout the year.

year round. Overall, RSV hospitalization and regional activity patterns tend to mirror each other, although ∼10% of hospitalizations occurred outside of regional activity season (higher in some regions). RSV hospitalization season consistently began before and lasted longer than regional RSV activity season. The degree of difference may be a function of the hospitalization season definition, but it is clear that many children are hospitalized for RSV before the start of RSV regional activity season as defined by the CDC. In addition, the initiation of inpatient palivizumab administration typically began before the RSV hospitalization season and well before regional activity season.

Previous studies have confirmed that regional differences exist in RSV seasonality. Previous studies have found distinct RSV activity patterns among the 4 US census regions.[12,13,26] Subdividing the United States into 11 smaller regions, as done here, illustrates additional dissimilarities among regions. RSV activity can differ within regions and from year to year.[1,8,10,27] Furthermore, different areas within the same state can have vastly different patterns of RSV activity; for example, regional RSV activity season can last between 7 and 11 months long, depending on the region, in Florida.[22] Using regional activity data from individual cities instead of set calendar dates can increase the proportion of patients appropriately receiving palivizumab before RSV becoming prevalent in an area.[15] Studying RSV hospitalizations can provide additional data. Light et al[22] demonstrated that ∼10% of hospitalizations for RSV occurred outside of regional activity season in Florida. We also found a large proportion of patients being hospitalized for RSV before the start of regional activity season in some areas. Because RSV hospitalizations may be more indicative of more severe disease than RSV activity thresholds and because children with chronic conditions were more likely to be hospitalized after regional activity season, it may be beneficial to use local RSV hospitalization patterns as a guide for when to administer palivizumab in certain cases.

Our data also demonstrate that inpatient palivizumab dosing began consistently

TABLE 3 Predictors of Hospitalization Before and After Regional Activity Season

Variable	aOR (95% CI)	
	Before Regional Activity Season	After Regional Activity Season
Male sex (reference: female)	0.99 (0.91–1.09)	1.00 (0.92–1.08)
Age group (reference: 0–6 mo)		
7–12 mo	1.32 (1.17–1.48)***	0.93 (0.83–1.05)
13–24 mo	1.32 (1.16–1.49)***	0.74 (0.65–0.84)***
>24 mo	1.28 (1.11–1.48)**	0.68 (0.59–0.79)***
Race (reference: white)		
Black	2.50 (2.25–2.79)***	1.00 (0.90–1.12)
Other	1.34 (1.20–1.49)***	0.89 (0.81–0.98)*
Insurance (reference: public)		
Private	1.16 (1.05–1.29)**	1.11 (1.01–1.22)*
Other	1.00 (0.81–1.23)	1.43 (1.21–1.68)***
Presence of chronic condition	1.01 (0.90–1.14)	1.51 (1.36–1.69)***
Region (reference: northeast, regions 1–3)		
South (regions 4, 6, and 9)	0.83 (0.74–0.93)**	0.50 (0.45–0.55)***
Northwest and Midwest (regions 5, 7, 9, and 10)	0.71 (0.63–0.80)***	0.33 (0.30–0.37)***

* $P < .05$; ** $P < .01$; *** $P < .001$.

before the initiation of RSV hospitalization season. Palivizumab dosing was initiated after the start of hospitalization season in only 2 of the 30 seasons studied. While the AAP recommends utilizing the start of regional activity season to time the first dose of palivizumab to high-risk patients,[21] our study showed that, on average, inpatients received the immunoglobulin over 2 months before the start of regional activity season. It is possible that hospitals may be utilizing RSV hospitalization data to determine when to begin dosing palivizumab to their inpatients. Palivizumab was given to inpatients in 4 regions, however, more than 12 weeks before the start of hospitalization season in at least 1 season, which may not be an effective use of resources. One study conversely found that RSV hospitalizations were more frequent before the initiation of palivizumab dosing (including outpatient dosing) for the season.[20] This may be a product of a difference in inpatient and outpatient patterns of palivizumab initiation or that the population of children's hospitals studied in PHIS may not be representative of the overall population. While we do not know when outpatient palivizumab dosing began in relationship to our study, it is possible that inpatient providers (compared with those in the outpatient setting) are more familiar with RSV hospitalization patterns and use these patterns when dosing palivizumab to inpatients. Our study also demonstrated that 275 patients received palivizumab after 24 months of age, even though palivizumab has not been recommended outside of the first 2 years of life even with earlier AAP guidelines.[28] It is possible that other children who did not

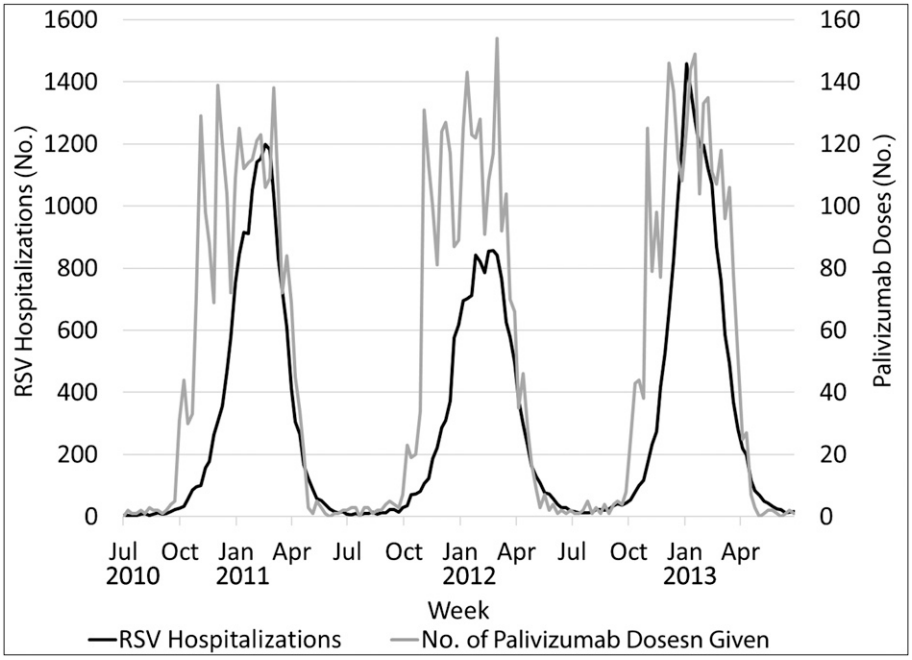

FIGURE 2 Comparison of national RSV admissions and inpatient palivizumab dosing (July 2010–June 2013).

qualify for palivizumab (ie, not of the appropriate gestational age or with congenital heart disease or chronic lung disease) also received the drug, but this study was unable to assess this further with the available data. Given that palivizumab is expensive and that few children qualify,[21] it would be beneficial to optimize when and to whom the immunoglobulin is given.

Our study has limitations. While PHIS represents hospitals across the United States, it does not include any community hospitals or patients from all states, so our findings may not be completely generalizable. The number of hospitals per region also varies. Further research should focus on determining if these findings apply to community hospitals, other states, and at a more local level. In addition, our study specifically included patients with an RSV-specific ICD-9 code but did not examine those with general codes for bronchiolitis or viral pneumonia as some studies have done in the past.[9,29] Not all cases of RSV are confirmed by laboratory testing, so our study may underestimate the number of patients admitted for RSV. In addition, we studied palivizumab administration in the inpatient setting given the availability of data in PHIS, but palivizumab is usually given to outpatients. We cannot be certain if palivizumab dosing in the outpatient and inpatient settings follow the same patterns.

CONCLUSIONS

Hospitalizations for RSV tend to mirror the data for RSV regional activity and differ depending on the region. Thus, using regional activity data to guide palivizumab administration to children at high risk, as recommended by the AAP, is crucial. Many RSV hospitalizations also occurred before the RSV regional activity season, so it may be beneficial to use local RSV hospitalization data in addition to regional activity patterns to guide when to give palivizumab.

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