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Trends in compliance with two-dose influenza vaccine recommendations in children aged 6 months through 8 years, 2010–2015

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Abstract

Background—Children aged 6 months through 8 years may require two doses of influenza vaccine for adequate immune response against the disease. However, poor two-dose compliance has been reported in the literature.

Methods—We analyzed data for >2.6 million children from six immunization information system (IIS) sentinel sites, and assessed full vaccination coverage and two-dose compliance in the 2010–2015 influenza vaccination seasons. Full vaccination was defined as having received at least the recommended number of influenza vaccine doses (one or two), based on recommendations from the Advisory Committee on Immunization Practices. Two-dose compliance was defined as the percentage of children during each season who received at least two doses of influenza vaccine among those who required two doses and initiated the series.

Results—Across seasons, ≥1-dose influenza vaccination coverage was mainly unchanged among 6–23 month olds (range: 60.9%–66.6%), 2–4 year olds (range: 44.8%–47.4%), and 5–8 year olds (range: 34.5%–38.9%). However, full vaccination coverage showed increasing trends from 2010–11 season to 2014–15 season (6–23 months: 43.0%–46.5%; 2–4 year olds: 26.3% to 39.7%; 5–8 year olds, 18.5% to 33.9%). Across seasons, two-dose compliance remained modest in children 6–23 months (range: 63.3%–67.6%) and very low in older children (range: 11.6%–18.7% in children 2–4 years and 6.8%–13.3% in children 5–8 years). In the 2014–15 season, among children who required and received 2 doses, only half completed the two-dose series before influenza activity peaked.

Conclusions—Improved messaging of the two-dose influenza vaccine recommendations is needed for providers and parents. Providers are encouraged to determine a child's eligibility for two doses of influenza vaccine using the child's vaccination history, and to vaccinate children early in the season so that two-dose series are completed before influenza peaks.

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Keywords

Influenza vaccine; Two-dose compliance; Full influenza vaccination coverage; Timing of dose administration; Children; Immunization information systems

1. Introduction

Since 2008, the Advisory Committee on Immunization Practices (ACIP) recommends all children aged 6 months to 18 years receive annual influenza vaccination, and children aged 6 months through 8 years receive two doses of influenza vaccine during their first vaccination season to achieve adequate immune response [1]. The antigenic components of the influenza vaccine often change yearly to best predict circulating influenza strains. Children who received influenza vaccines in previous seasons likely do not require two doses in the current season; however, in some circumstances, e.g., when a new strain (such as H1N1) is added to an influenza vaccine, two doses are still necessary. Therefore, ACIP also recommends two doses to some children after their first influenza seasons depending on their vaccination histories [2–6].

Poor compliance with the two-dose influenza recommendations has been reported in the literature [7–10]. In 2013, using data from population-based Immunization Information Systems (IIS) from eight sentinel sites, CDC published trends in compliance with two-dose influenza vaccine recommendations among children aged 6 months through 8 years from the 2007–08 through the 2011–12 influenza vaccination seasons [8]. Using IIS data from six sentinel sites, our objectives were: 1) to update the above-mentioned report to show trends in full influenza vaccination coverage and two-dose compliance from the 2010–11 through the 2014–15 seasons, and 2) to investigate timing of dose administration among these children, stratified by influenza vaccine doses recommended and received.

2. Methods

IIS are confidential, population-based databases of consolidated immunization data from vaccine providers [11]. IIS sentinel sites, which include North Dakota (ND), Michigan (MI), Minnesota (MN), New York City (NYC), Oregon (OR, six counties containing 56% of the state population), and Wisconsin (WI) in the 2013–17 period, are selected state/city-based IIS with high data quality. Among these sites, childhood immunization information could be included in the IIS without any consent and with no right to opt out in OR, ND, and NYC. Childhood immunization information could be included in the IIS with implicit consent, with a right to opt out, in the other sites. Three sites (MI, NYC, and ND) mandated all immunization providers to report childhood immunizations to the IIS, Oregon mandated public immunization providers and pharmacies to do so, and there are no mandates in MN and WI [12]. The enrollment of children under 6 years old was >95% for all sites [13]. The sentinel sites are funded by the Centers for Disease Control and Prevention for vaccination coverage evaluation in their pediatric populations, which are approximately 10% of the United States pediatric population.

We analyzed records for >2.6 million children during each influenza vaccination season (July 1 through June 30) from the 2010–11 season through the 2014–15 season. Children were included in the analysis if they were aged 6–23 months, 2–4 years, or 5–8 years throughout each influenza vaccination season. Children aging into or out of an age group were excluded to ensure all children had the same opportunity for vaccination. Children known to have moved out of the state/city jurisdiction or children known to be deceased were excluded from the analysis.

Regardless of product type (e.g., nasal spray or injectable vaccine), we considered a dose valid if it complied with ACIP's minimum age and interval recommendations for influenza vaccination (i.e., inactivated influenza vaccine given to a child aged ≥ 6 months and the interval to the previous dose in the same influenza season was ≥ 4 weeks, with a grace period of four days allowed for both criteria; live attenuated influenza vaccine given to a child aged ≥ 2 years, administered ≥ 24 days from a previous influenza vaccine dose, and ≥ 28 days from a previous live vaccine). If a child received more than two valid doses in the same season (<0.1% of all children did so in our dataset), the third or later doses were considered extraneous and excluded from analyses. We only counted valid doses for influenza vaccination calculations.

Our primary outcomes were full vaccination coverage and two-dose compliance. Full vaccination coverage was classified as having received at least the recommended number of influenza vaccine doses (one or two), based on ACIP recommendations for that season. Two-dose compliance was defined as the percentage of children during each season who received at least two doses of influenza vaccine among those who required two doses and initiated the series. Our secondary outcomes were partial vaccination coverage, timing of vaccine dose administration in each season, and mean dose intervals between the two doses for each season. Partial vaccination coverage was classified as having received only one influenza vaccine dose when recommended to receive two doses.

For each child in the selected cohorts, we evaluated the child's eligibility for two doses of influenza vaccines according to ACIP's yearly recommendations [2–6] by assessing full vaccination histories in the IIS. The percentage of children requiring two doses was calculated by dividing the total number of children requiring two doses by the total number of children in the IIS, stratified by age and influenza season. To calculate vaccination coverage rate, we divided the total number of children who were fully or partially vaccinated by the latest Census population estimates in the area for the corresponding year, and further stratified by age and influenza season. Full and partial coverage combined constituted ≥1 dose coverage. To assess the timing of vaccine dose administration in each season, we calculated the cumulative percentage of all influenza vaccine doses administered by month throughout each season, stratified by children's status, including children who: (1) required one dose and received ≥1 doses; (2) required two doses and received only one dose; (3) required two doses and received ≥2 doses. For children who required and completed two doses, we also calculated mean intervals between the two doses for each season. We used SAS®, version 9.3 (SAS Institute, Inc.) and Microsoft® Excel® 2010 (Microsoft Corp.) for all analyses.

3. Results

3.1 Population Description and Percentage of Children Requiring 2 Doses

At the six sentinel sites, the number of children aged 6 months through 8 years ranged from 2,633,557 in the 2014–15 season to 2,826,448 in the 2010–11 season. Across sites, the number of children varied from a low of 60,033 in North Dakota (2014–15) to a high of 850,051 in New York City (2010–11). The percentage of children who required two doses was the highest in the 6–23-month age group across all seasons (range: 81.0% to 95.9%), followed by the 5–8-year age group (range: 41.4% to 79.8%) and the 2–4-year age group (range: 38.3% to 75.3%) (Table 1). Within each age group, the percentage of children who required two doses was the highest in the 2010–11 season when the pandemic influenza A (H1N1) virus strain was first included in the seasonal influenza vaccine and the lowest in the 2014–15 season when the influenza strains in the vaccine remained unchanged from the previous season (Table 1).

3.2 Trends in Full and Partial Influenza Vaccination Coverage

Table 2 shows the latest Census population estimates in the sentinel site area for each age group, which were used as denominators in the calculation of vaccination coverage rate. From the 2010–11 through the 2014–15 influenza vaccination seasons, ≥1-dose influenza vaccination coverage was mainly unchanged within each age group, ranging from 60.9%–66.6% in children aged 6–23 months, 44.8%–47.4% in children aged 2–4 years, and 34.5–38.9% in children aged 5–8 years. However, full vaccination coverage increased for all age groups: it increased from 43.0% in the 2010–11 season to 46.5% in the 2014–15 season in children aged 6–23 months; from 26.3% in the 2010–11 season to 39.7% in the 2014–15 season in children aged 2–4 years; from 18.5% in the 2010–11 season to 33.9% in the 2014–15 season in children aged 5–8 years (Fig. 1).

3.3 Trends in Two-dose Compliance

Two-dose compliance in children aged 6–23 months was >60% in all analyzed influenza vaccination seasons; this was higher than in children aged 2–4 and 5–8 years where two-dose compliance was <20% for both groups across all seasons (Fig. 2). It slightly increased for children aged 6–23 months from 63.3% in the 2010–11 season to 67.1% in the 2014–15 season, and most of the increase occurred from the 2010–11 season to the 2011–12 season. For the older groups, two-dose compliance declined after the 2010–11 season (18.7% in the 2010–11 season to 11.6% in the 2011–12 season for the 2–4 year olds; 13.3% in the 2010–11 season to 6.8% in the 2011–12 season for the 5–8 year olds), and then slowly caught up in the following seasons. Nonetheless, it remained lower in the 2014–15 season (15.9% and 9.2% for the 2–4 year olds and 5–8 year olds, respectively) than in the 2010–11 season for both groups.

3.4 Timing of dose administration and Mean Dose Intervals

Fig. 3 shows the timing of influenza vaccine dose administration in children, stratified by children's vaccination status, for the 2014–15 season; the pattern in each of the other seasons was similar (data not shown). There were lags in the timing of dose administration

among children who required two doses and received only one dose, compared with the timing of first dose administration among children who required and received two doses (80% of the children who required and received two doses completed the first dose by late November vs. 80% of the children who required two doses and received only one dose completed the dose by early January). This lag was most pronounced in the youngest group (data not shown). Among children who required two doses and received ≥2 doses, approximately 50% completed both doses by late December, and 80% completed both doses by early February; the median time intervals between the two doses were approximately 7 weeks (range: 42–46 days across all seasons), while the maximum interval in each season was >300 days.

4. Discussion

Our analysis showed increasing trends of full influenza vaccination coverage in children aged 6 months through 8 years from the 2010–11 season to the 2014–15 season, which are consistent with the National Immunization Survey (NIS) data [14]. The overall full influenza vaccination coverage remained low. Compared with NIS data on full influenza vaccination coverage among children aged 6–23 months in the 2011–12 season [14], among the four sites that were comparable geographically, our full coverage rates were within the confidence intervals of NIS estimates for two sites; were very close (0.5% lower) to the lower boundary of the NIS confidence interval for one site; were outside (3.5% lower than the lower boundary) the NIS confidence interval for one site.

Monitoring two-dose compliance can inform vaccine programs of different issues than monitoring vaccination coverage. Non-compliance to two-dose recommendations may indicate vaccine access barriers or unawareness of the recommendations rather than vaccine hesitancy or avoidance because this metric is based on a subset of population that initiated the series. Two-dose compliance increased slightly in children aged 6–23 months from the 2010–11 season to the 2014–15 season but remained largely unchanged in older children. Therefore, the increasing trends of full influenza vaccination coverage in children aged 2–4 years and 5–8 years were likely because fewer children in later seasons were recommended to receive two doses since there was no major change in the influenza vaccine. Of note, the relatively higher two-dose compliance in the 2010–11 season in older groups may be attributed to higher awareness among providers of the new component of pandemic H1N1 strain in the seasonal influenza vaccine, which required more children to receive two doses. This effect was not obvious in children aged 6–23 months because they were less likely to have had the opportunity to receive influenza vaccine in previous seasons and thus required two doses anyway.

There are several possible reasons for low two-dose compliance: (1) the complexity of ACIP’s influenza vaccination recommendation in some years and several changes over the years may make it difficult for providers to realize which children require two doses, especially for older children; (2) providers and/or parents may not know the importance of two dose completion; (3) convenience of access to vaccination may be a barrier to parents with busy schedules, particularly with older children who have fewer wellness visits; (4) providers may not have access to full vaccination history of children to assess eligibility for

two doses; and (5) late availability of influenza vaccine may delay initiating first dose and impact two-dose completion [15]. Therefore, improved messaging of the two-dose influenza vaccine recommendation, and convenient access to vaccination (i.e., complementary vaccination settings such as schools, extended office hours) are needed. One study found that campaigns providing better information regarding the vaccine and the disease, and convenient access to vaccination can facilitate influenza vaccination in children [16]. Providers are encouraged to submit data to IIS to enhance the system, and use consolidated vaccination histories in IIS to assess children's eligibility for two doses, especially for older children, who may be perceived to not need two doses. Clinical decision support functions in IIS and other electronic health systems can also make recommendations to providers on patients' vaccine needs. In addition, patient reminders can also be considered as they are positively associated with in-office influenza vaccination [17]. Lastly, the lags observed in the timing of dose administration among children who required two doses and received only one dose, compared with the timing of first dose administration among children who required and received two doses, might reflect a subset of the population with differing access to vaccination services, knowledge of vaccination recommendations, or motivation to receive influenza vaccination for their children, but the reasons for this delay would require further investigation beyond the scope of this analysis.

Children who require two doses of influenza vaccine are not optimally protected from influenza disease if they only receive one dose. Studies have shown that although children may develop antibodies after one dose, no protection from disease in terms of clinic visits and lab-confirmed influenza cases has been observed when compared with children who did not receive any dose [18–20]. In the United States, influenza activity can peak from October to March, but since 1976, >60% of the seasons' peak months were in February or later [2]. It is encouraging that across all seasons, 80% of children who required two doses and received both doses did so by the end of January. However, when influenza activity peaked in late December during the 2014–15 season, only half of these children had completed both doses (Fig. 3). Moreover, the median intervals between two doses were approximately seven weeks. These results demonstrate the importance of administering two influenza vaccine doses when recommended, and completing the two-dose series early in the season whenever possible. Shortening the interval between administration of the first and second doses, within ACIP recommendations, can increase the proportion of children who are optimally protected against influenza disease early in the season.

There are at least two limitations in this analysis. First, data from the six sentinel sites may not represent the U. S. population. Although previously published IIS sentinel site data were very close to the NIS national data on influenza full vaccination coverage in children 6–23 months [8, 14], the current IIS sentinel sites cover different geographical areas and therefore may have different vaccination coverage and compliance rates. Second, incomplete vaccination histories in IIS data may underestimate vaccination coverage and two-dose compliance, especially in older children who visit their physician's office less frequently but receive influenza vaccination in other places. However, although IIS sentinel sites are only required to have >85% children enrollment, the actual enrollment of children was >95% for each sentinel site [13], which minimizes potential underestimation for influenza vaccination rates.

In summary, two-dose compliance remained low in children aged <9 years, especially in older children (2–8 years) from the 2010–11 through the 2014–15 influenza vaccination season, which impacted full influenza vaccination coverage. In the 2014–15 influenza season, among children who required two doses and received ≥2 doses, only half completed the two-dose series before influenza activity peaked based on data from IIS. Improved messaging of the two-dose influenza vaccine recommendations, convenient access to influenza vaccination, and high levels of reporting of influenza vaccinations to IIS are needed for providers and parents. Providers are encouraged to determine children's eligibility for two doses of influenza vaccine using consolidated vaccination histories in IIS. Moreover, early vaccination and shortened two-dose intervals within ACIP recommendations may facilitate early completion of the two-dose series so that more children are protected before influenza activity peaks.

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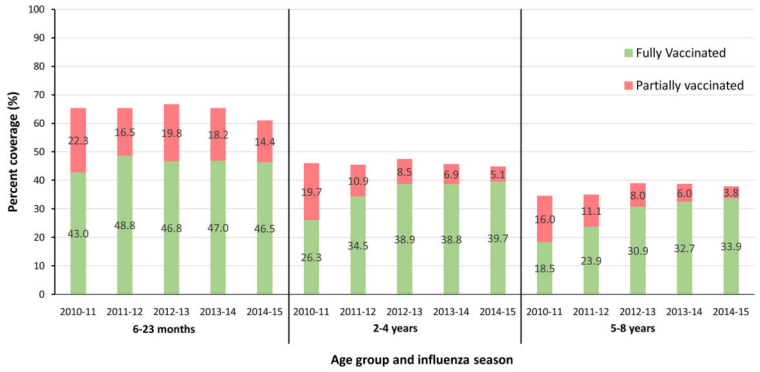

Fig. 1.

Influenza vaccination coverage* among sentinel site children aged 6 months through 8 years by age group and influenza season, 2010–2015

*Census data were used as denominators and Immunization Information Systems data from the six sentinel sites were used as numerators.

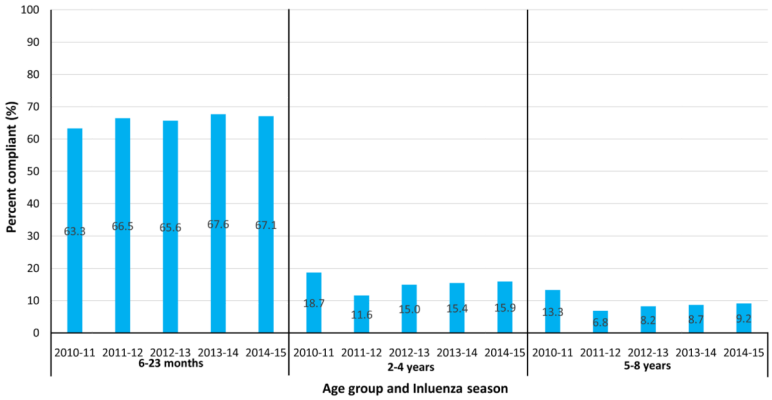

Fig. 2.

Two-dose compliance* with influenza vaccine recommendations among sentinel site children aged 6 months to 8 years by age group and influenza season, 2010–2015

*Two-dose compliance was defined as the percentage of children during each season who received at least two doses of influenza vaccine among those who required two doses and initiated the series.

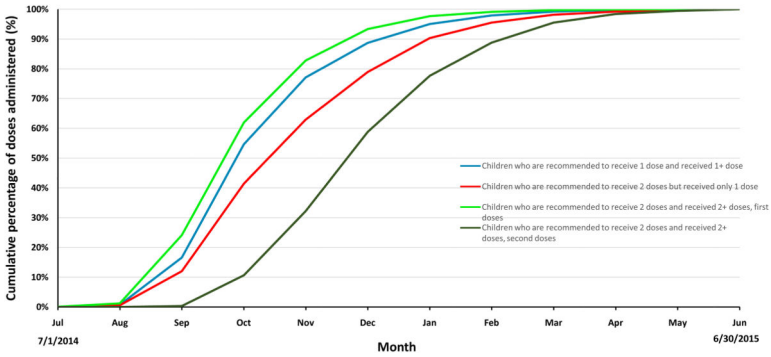

Fig. 3.

Timing of cumulative influenza vaccine dose administration, stratified by total doses recommended and received*, in sentinel site children aged 6 months through 8 years, 2014–2015

*Each line represents 100% of children in the specified category.

Table 1

Influenza Vaccination Recommendations and Percentage of Children who needed 2 doses, 6 sentinel sites, 2010–11 Through 2014–2015 Influenza Seasons

Influenza Season	Recommendations	Children who needed 2 doses, by age group, %		
		6–23 months	2–4 years	5–8 years
2010–11	"All children aged 6 months–8 years who receive a seasonal influenza vaccine for the first time should receive 2 doses. Children who received only 1 dose of a seasonal influenza vaccine in the first influenza season that they received vaccine should receive 2 doses, rather than 1, in the following influenza season. In addition, for the 2010–11 influenza season, children aged 6 months–8 years who did not receive at least 1 dose of an influenza A (H1N1) 2009 monovalent vaccine should receive 2 doses of a 2010–11 seasonal influenza vaccine, regardless of previous influenza vaccination history. Children aged 6 months--8 years for whom the previous 2009–10 seasonal or influenza A (H1N1) 2009 monovalent vaccine history cannot be determined should receive 2 doses of a 2010–11 seasonal influenza vaccine." [2]	95.9	75.3	79.8
2011–12	All children aged 6 months–8 years who receive a seasonal influenza vaccine for the first time should receive 2 doses. "Vaccination providers should note that, in previous seasons, children aged 6 months through 8 years who received only 1 dose of influenza vaccine in their first year of vaccination required 2 doses the following season. However, because the 2011–12 vaccine strains are unchanged from the 2010–11 season, children in this age group who received at least 1 dose of the 2010–11 seasonal vaccine will require only 1 dose of the 2011–12 vaccine. Children in this age group who did not receive at least 1 dose of the 2010–11 seasonal influenza vaccine, or for whom it is not certain whether the 2010–11 seasonal vaccine was received, should receive 2 doses of the 2011–12 seasonal influenza vaccine." [3]	83.4	58.1	71.0
2012–13	All children aged 6 months–8 years who receive a seasonal influenza vaccine for the first time should receive 2 doses. "Children aged 6 months through 8 years need only 1 dose of vaccine in 2012–13 if they received a total of 2 or more doses of seasonal vaccine since July 1, 2010. Children who did not receive a total of 2 or more doses of seasonal vaccine since July 1, 2010, require 2 doses in 2012–13. In settings where adequate vaccination history from before the 2010–11 season is available, children aged 6 months through 8 years need only 1 dose of vaccine in 2012–13 if they have received any of the following: • 2 or more doses of seasonal influenza vaccine since July 1, 2010; or • 2 or more doses of seasonal influenza vaccine before July 1, 2010, and 1 or more doses of monovalent 2009(H1N1) vaccine; or • 1 or more doses of seasonal influenza vaccine before July 1, 2010, and 1 or more doses of seasonal influenza vaccine since July 1, 2010. Children for whom one of these conditions is not met require 2 doses in 2012–13." [4]	91.1	48.7	58.2
2013–14	All children aged 6 months--8 years who receive a seasonal influenza vaccine for the first time should receive 2 doses. "Children aged 6 months through 8 years need only 1 dose of vaccine in the 2013–14 influenza season if they received a total of 2 or more doses of seasonal vaccine since July 1, 2010. Children who did not receive a total of 2 or more doses of seasonal vaccine since July 1, 2010, require 2 doses in the 2013–14 season." In settings where adequate vaccination history from before the 2010–11 season is available, "if a child aged 6 months through 8 years is known to have received at least 2 doses of seasonal influenza vaccine during any prior season, and at least 1 dose of a 2009(H1N1)-containing vaccine (i.e., 2010–11, 2011–12, or 2012–13 seasonal vaccine or the monovalent 2009 [H1N1] vaccine) then the child needs only 1 dose for the 2013–14 season. Using this approach, children aged 6 months through 8 years need only 1 dose of vaccine in the 2013–14 season if they have received any of the following:	91.1	44.2	50.1

Influenza Season	Recommendations	Children who needed 2 doses, by age group, %		
		6–23 months	2–4 years	5–8 years
	• 2 or more doses of seasonal influenza vaccine since July 1, 2010 or; • 2 or more doses of seasonal influenza vaccine before July 1, 2010 and 1 or more doses of monovalent 2009(H1N1) vaccine or; • 1 or more doses of seasonal influenza vaccine before July 1, 2010, and 1 or more doses of seasonal influenza vaccine since July 1, 2010. Children aged 6 months through 8 years for whom one of these conditions is not met require 2 doses in the 2013–14 season." [5]			
2014–15	All children aged 6 months–8 years who receive a seasonal influenza vaccine for the first time should receive 2 doses. Children aged 6 months through 8 years need only 1 dose of vaccine in the 2014–2015 influenza season if they received at least 1 dose of the 2013–14 seasonal influenza vaccine or if they received a total of at least 2 doses of seasonal influenza vaccine since July 1, 2010. All other children require two doses. In settings where vaccination history from before July 1, 2010, is available, "children aged 6 months through 8 years need only 1 dose of vaccine for 2014–15 if they have received any of the following: 1) at least 1 dose of 2013–14 seasonal influenza vaccine; or 2) 2 or more doses of seasonal influenza vaccine since July 1, 2010; or 3) 2 or more doses of seasonal influenza vaccine before July 1, 2010, and 1 or more doses of monovalent 2009(H1N1) vaccine; or 4) 1 or more doses of seasonal influenza vaccine before July 1, 2010, and 1 or more doses of seasonal influenza vaccine since July 1, 2010. Children in this age group for whom one of these conditions is not met require 2 doses for 2014–15." [6]	81.0	38.3	41.4

Table 2

Census Estimates for Children Aged 6 Months Through 8 Years Residing in the Six Sentinel Sites, 2010–11 Through 2014–15 Influenza Seasons

Influenza Season	Census estimates for children, by age group[a]		
	6–23 months	2–4 years	5–8 years
2010–11	201,164	804,657	1,206,316
2011–12	201,426	805,703	1,203,539
2012–13	200,852	803,409	1,208,163
2013–14	200,772	803,088	1,210,130
2014–15	201,531	806,124	1,201,790

[a]Birth cohort selection used in this analysis was the “period of time assessment – not allowing aging in or out” method [21]. Children have to be in the particular age group throughout the entire influenza season (July–June). For example, children aged 6–23 months during the 2010–11 influenza season were born during 7/1/2009 to 1/1/2010.