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## Impact of a maternal immunization program against pertussis in a developing country

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### ABSTRACT

**Background:** Pertussis disease is a growing concern for developing countries. In Argentina, rates of illness and death peaked in 2011. More than 50% of fatalities due to pertussis occurred in infants younger than two months of age, too young for vaccination. In 2012, the government offered immunization with a vaccine containing Tdap to all pregnant women after 20 weeks of gestation with the intent of reducing morbidity and mortality in young infants.

**Methods:** Maternal acellular pertussis vaccine impact on reducing infant disease burden was estimated based on data from the Argentinean Health Surveillance System. We divided Argentinean states in two groups experiencing high (>50) and low (≤50) Tdap vaccine coverage and compared these two groups using a Bayesian structural time-series model. Low coverage regions were used as a control group, and the time series were compared before and after the implementation of the Tdap program.

**Findings:** We observed a relative reduction of 51% (95% CI [−67%, −35%];  $p = 0.001$ ) in pertussis cases in high coverage states in comparison with the low coverage areas. Analysis of infants between two and six months showed a 44% (95% CI [−66%, −24%];  $p = 0.001$ ) reduction in illness. Number of deaths was highest in 2011 with 76 fatalities, for an incidence rate of 2.9 per 100,000. Comparing with 2011, rates decreased by 87% to 10 subjects, or 0.9 per 100,000 in 2013.

**Interpretation:** We show an age-dependent protective effect of maternal Tdap immunization in a developing country for infants younger than six months.

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### 1. Introduction

Pertussis disease is a growing concern for developing countries [1,2]. Despite high rates of childhood immunization, the bacteria continues to be a significant public-health problem with outbreaks occurring in Australia [3], Japan [4], North America [5] and many countries from Europe [6] and Latin America [7–9]. Despite is a cyclic disease peaking every 3–4 years, its incidence increased during the last decade in Argentina, where rates of illness and death peaked in 2011, primarily affecting infants during their first year of life [7]. More than 50% of fatalities due to pertussis occurred in infants younger than two months of age, too young for vaccination.

Pertussis immunization with whole-cell vaccine at 2, 4 and 6 months of age followed by a booster at 15–18 months was introduced in Argentina in 1978. A second whole-cell vaccine booster was added for six year olds in 1985, followed by a third booster with acellular pertussis (Tdap) at age 11 since 2009 [10]. During that same year, the Ministry of Health recommended immunization using Tdap for health-care workers in contact with infants under the age of 12 months. And in 2011, vaccination with Tdap was instituted for household contacts of very low birth weight infants (<1500 g).

In February 2012, in response to increasing death rates due to pertussis in the previous year, Ministry of Health offered immunization with a three or four-component vaccine containing Tdap to all pregnant women after 20 weeks of gestation with the intent of reducing morbidity and mortality in young infants [11]. The recommendation was based on evidence of high levels of transplacental

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tal antibody transfer, and reports of infant protection when born to mothers immunized with acellular vaccine [12–15].

Information about the effectiveness of maternal immunization against pertussis in reducing disease burden in infants is limited. A recent English study reported that maternal immunization between 28 and 38 weeks of gestation with acellular pertussis conferred approximately 90% protection against infant disease [16]. In the UK, infants are immunized with three doses of acellular vaccine at 2, 3 and 4 months of age followed by a preschool booster. However, the consequences of maternal immunization in prevention of infant disease in the developing world, where – in addition to experiencing different environmental and socioeconomic challenges – mothers are primed in infancy with whole cell vaccine (instead of acellular pertussis) and their infants are also immunized with whole cell vaccine, have not been described. In this manuscript, we aimed to address this question by estimating the impact of the maternal pertussis vaccine immunization program in Argentina.

## 2. Methods

### 2.1. Study population

Estimation of maternal acellular pertussis vaccine impact on reducing infant disease burden was based on data from the Argentinean Health Surveillance System (known as SNVS). SNVS records reports of mandatory notifiable diseases (Law 15,465), including pertussis. The SNVS is a network that connects different effectors distributed in 24 jurisdictions (23 provinces and the City of Buenos Aires). The software consists of two modules: clinical (C2) and laboratory (SIVILA). Both collect information from different sources: C2, that from the medical consultation (outpatient or inpatient), and SIVILA, from laboratories analyzing samples. Both modules were used to define cases of pertussis. Information is uploaded online by designated public officials and serves as a real-time monitoring system for disease control. Available information about patients on SNVS includes gender, age, duration of symptoms and laboratory results. Analysis was performed in cases identified between January 2010 and December 2013. Data was extracted in March 2014.

Public health officials reported vaccine coverage and mortality online from the 24 jurisdictions to DiNaCEI every three months. Incidence rates were estimated using data from the population census conducted in 2010 by the National Institute of Statistics and Census.

### 2.2. Pertussis case definitions

The Argentinean Ministry of Health conducts periodic training workshops on pertussis clinical manifestations and diagnosis criteria in all jurisdictions.

Definitions of suspected pertussis, prompting laboratory confirmation, were stratified by age. Suspected pertussis in infants younger than age six months included those with acute respiratory illness (ARI) and at least one of the following signs: apnea, cyanosis, stridor, vomiting after coughing or paroxysmal cough. In patients between 6 months and 11 years, suspected pertussis required persistent cough  $\geq 14$  days accompanied by one or more of the following symptoms: paroxysmal cough, inspiratory whoop, or vomiting after coughing without other apparent cause. Finally, persistent cough for 14 or more days without other accompanying symptoms established a diagnosis of suspected pertussis in patients older than 11 years of age.

A diagnosis of pertussis was confirmed in patients with suspected illness and *B. pertussis* isolation in culture and/or amplifica-

tion of *B. pertussis*-specific DNA by PCR and/or serology by anti-pertussis toxin IgG, or in patients with symptoms and epidemiologically linked to a laboratory-confirmed case.

### 2.3. Statistical analysis

Incidence rates for confirmed pertussis disease were calculated per 100,000 subjects and by age group in the study period spanning January 2010 to December 2013. The incidence of confirmed pertussis was also calculated individually for all 24 jurisdictions.

Maternal immunization with Tdap during pregnancy and infant vaccination with whole-cell pertussis vaccines at six (using DTPw-Hib-HBV) and 15–18 (DTPw-Hib or DTPw-Hib-HBV) months were assessed using reports from number of doses administered by immunization offices from all jurisdictions to DiNaCEI. Vaccine coverage was calculated as the ratio between the number of doses administered and the number of individuals to be vaccinated  $\times 100$ . Case fatality rates (CFR) were calculated as the percentage of subjects with fatal pertussis among those with confirmed illness. Maternal immunization was recommended on February 1st, 2012.

Although we have detailed information on the number of cases of pertussis disease, their geographical and timing of occurrence, we do not have the vaccination status of these cases, because the data source (SNVS) was not designed to collect data for research study and calculate effectiveness of immunopreventable diseases. This is a critical limitation, as we cannot compute direct estimates of vaccine effectiveness. For this reason, we used an indirect method that relied on a time series analysis. For this purpose, we divided Argentinean states in two groups with high and low Tdap vaccine coverage, defining high coverage for states with  $>50\%$  immunization rates (based on acceptable rates for a vaccine recently introduced in the calendar in pregnant women). We then compared these two groups using a Bayesian structural time-series model [17]. Low coverage regions were used as a control group, and the time series were compared before and after the implementation of the Tdap program on February 2012. The model was used to predict how the high Tdap coverage time series would have evolved after implementation of the vaccination program if the Tdap coverage had been low. The difference between the actual observed data and the prediction during the post-intervention period was reported as the estimate of the effect of the vaccination strategy. This is a conservative estimate as the comparison group is low coverage rather than no vaccination.

Chi square test were used for analysis where appropriate. A *p* value of  $<0.05$  was considered significant. Statistical analysis was performed using the Epi Info7 program, and the R statistical package.

## 3. Results

### 3.1. Pertussis immunization

Maternal Tdap immunization was instituted in February 2012 and reached 50.9% coverage in the first year. Tdap administration increased by 16.3% (95% CI, 16.1–16.4%,  $p < 0.001$  for comparison) to 67.2% in 2013. (Fig. 1).

A 4.6% (95%CI, 4.3–4.9%;  $p < 0.001$  for comparison) increment in whole-cell coverage was observed in infants at age six months between 2010 and 2013. The 15–18-month old booster immunization rate was reduced by 7.6% (95%CI, 7.2–7.9%;  $p < 0.001$  for comparison) from 2010 to 2013.

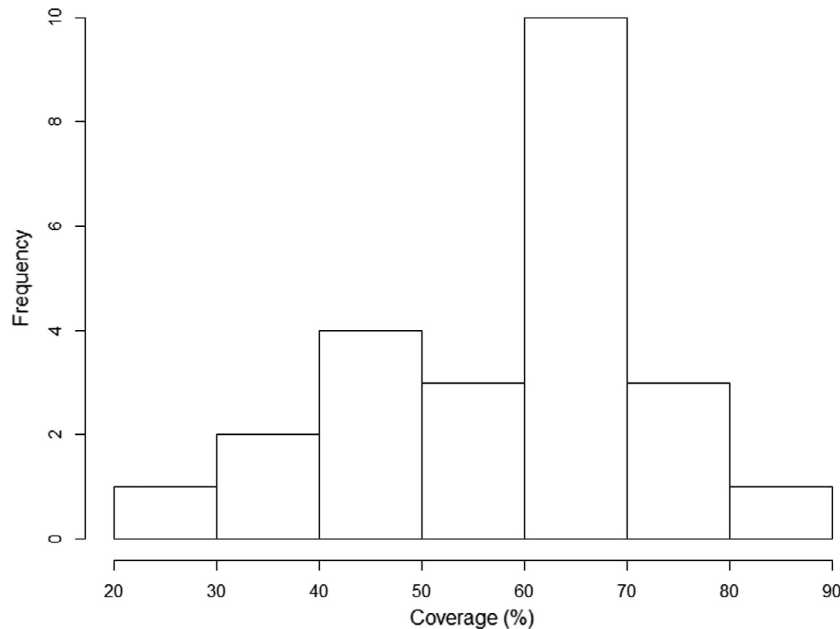


Fig. 1. Maternal Tdap vaccination coverage distribution by jurisdictions across the country.

### 3.2. Pertussis disease burden

Between 2010 and 2013, 6865 inpatient and outpatient cases of pertussis were confirmed in Argentina (Table 1). Pertussis burden was highest in 2011 with 2821 cases, representing 41% of events in the study period for an incidence rate of 7 per 100,000. Rates decreased by 60% (95% CI 57.7%–63.2%;  $p < 0.001$  for 2011 vs. 2013 comparison) in 2013 to 2.8 per 100,000 reflecting 1112 confirmed cases.

The incidence of pertussis in infants younger than twelve months of age was 43-fold higher than in the general population (187 vs. 4.2 per 100,000 subjects). In fact, infants younger than 12 months accounted for 82.4% ( $n = 4760$ ) cases, while infants younger than six months represented 53.4% ( $n = 3672$ ) and those younger than two months 20.7% ( $n = 1426$ ). Notably, 96.4% reported cases were younger than age ten years. The disease affected males and females equally.

### 3.3. Pertussis seasonality

Disease peaked at different times of the year during the study period. An early peak between September 2011 and March 2012 (spring and summer), was followed by a series of lower peaks in disease burden during the post-vaccination period in February 2013 (summer) and between June and July 2013 (winter). All twenty-four jurisdictions reported cases of pertussis between 2010 and 2013 (Fig. 2).

### 3.4. Impact of maternal immunization

To ascertain the impact of maternal immunization, we subsequently divided Argentinean states in two groups with high and low Tdap vaccine coverage (defining high coverage as  $>50\%$  of the target population). Interestingly, low Tdap coverage states exhibited a second disease peak in 2012 that was not observed in high Tdap regions (Fig. 3). This low coverage-specific disease peak was more evident in infants younger than two months of age representing a relative reduction of 51% (95% CI  $[-67\%, -35\%]$ ;  $p = 0.001$ ) in pertussis cases in high coverage states during 2012 in comparison with the low coverage areas. (Fig. 4) Analysis of infants between two and six months showed a 44% (95% CI  $[-66\%, -24\%]$ ;  $p = 0.001$ ) reduction in illness (Figs. 5 and 6). The effect was not significant when examined in children aged 6–48 months (19%; 95% CI  $[-43\%, 3.7\%]$   $p = 0.055$ ).

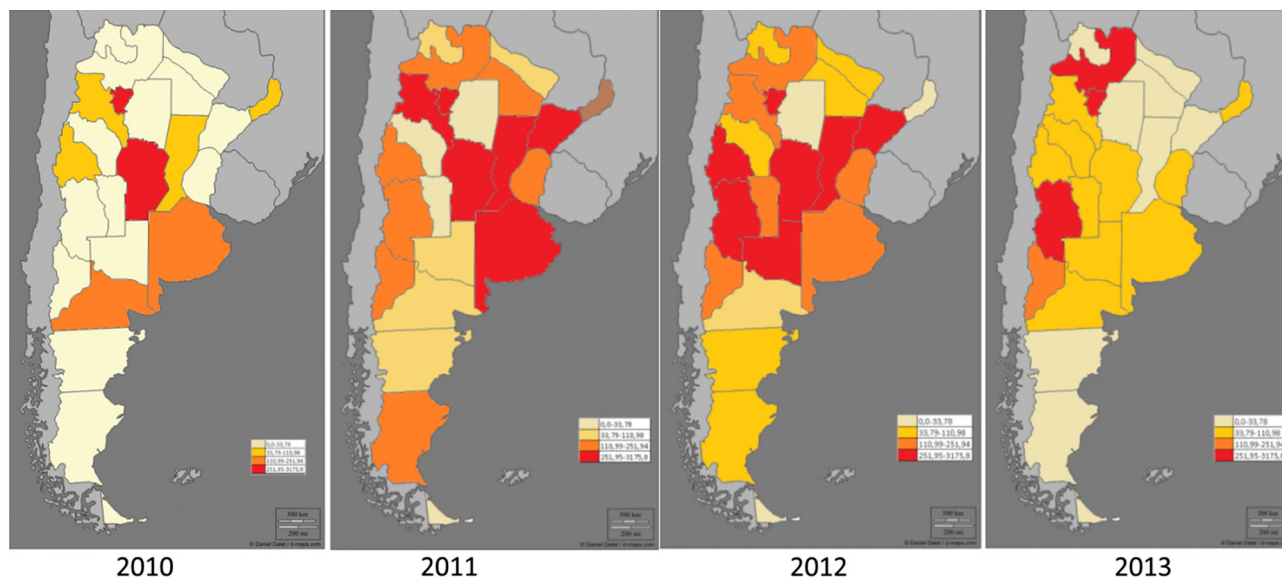
### 3.5. Pertussis deaths

Between 2010 and 2013, 134 patients were reported dead from pertussis in Argentina (CFR = 1.7%). Number of deaths was highest in 2011 with 76 fatalities, representing 56.7% deaths in the study period for an incidence rate of 2.9 per 100,000. Comparing with 2011, rates decreased by 87% to 10 subjects, or 0.9 per 100,000 in 2013.

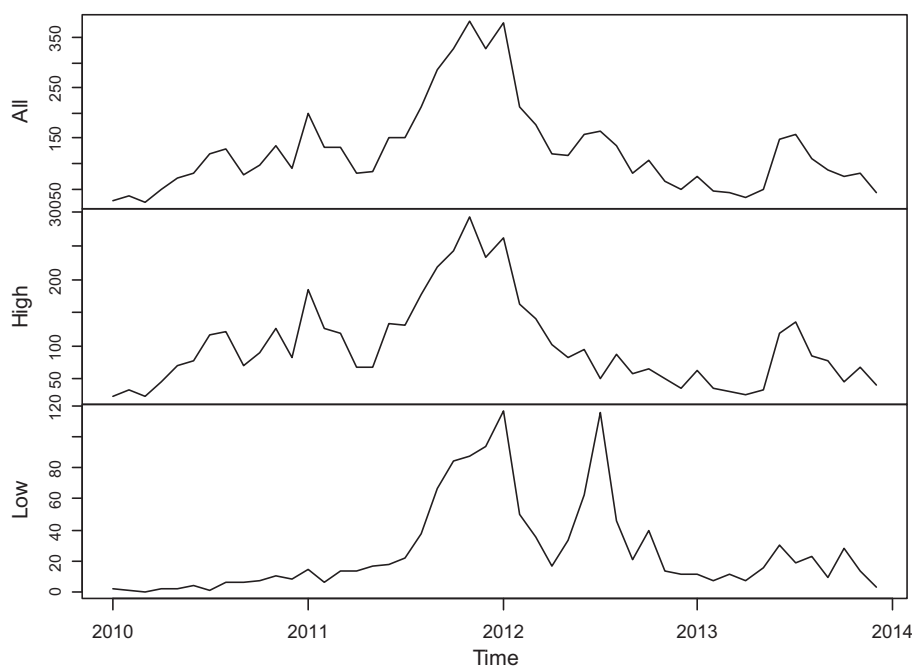
Deaths were more common in infants younger than six months, who experienced 52.5% of fatalities, 89.8% of them in infants

**Table 1**  
Pertussis morbidity and mortality during 2010–2013 in Argentina.

		Years				
		2010	2011	2012	2013	2010–2013
Morbidity	Confirmed cases (n)	1009	2821	1923	1112	6865
	Confirmed cases incidence rate ( $\times 100,000$ )	2.5	7	4.8	2.8	4.2
	Confirmed cases < 12 months (n)	854	2355	1510	895	5657
	Confirmed cases < 12 months incidence rate ( $\times 100,000$ )	112.9	311.4	199.7	118.4	187
Mortality	Pertussis fatal cases (n)	16	76	32	10	134
	Pertussis mortality rate < 12 months ( $\times 100,000$ )	2.1	9.8	3.9	1.3	4.3
	Case fatality rate ( $\times 100$ )	1.4	2.7	1.7	0.9	1.7



**Fig. 2.** Pertussis incidence rate in infants under 1 year of age ( $\times 100,000$ ) by jurisdictions, Argentina. Vaccination program established in February 2012.



**Fig. 3.** Monthly pertussis cases according to Tdap vaccination coverage. Vaccination program established in February 2012.

younger than 2 months. This youngest age group had 59.2% of all deaths in 2011, and 40% in 2012 and 2013.

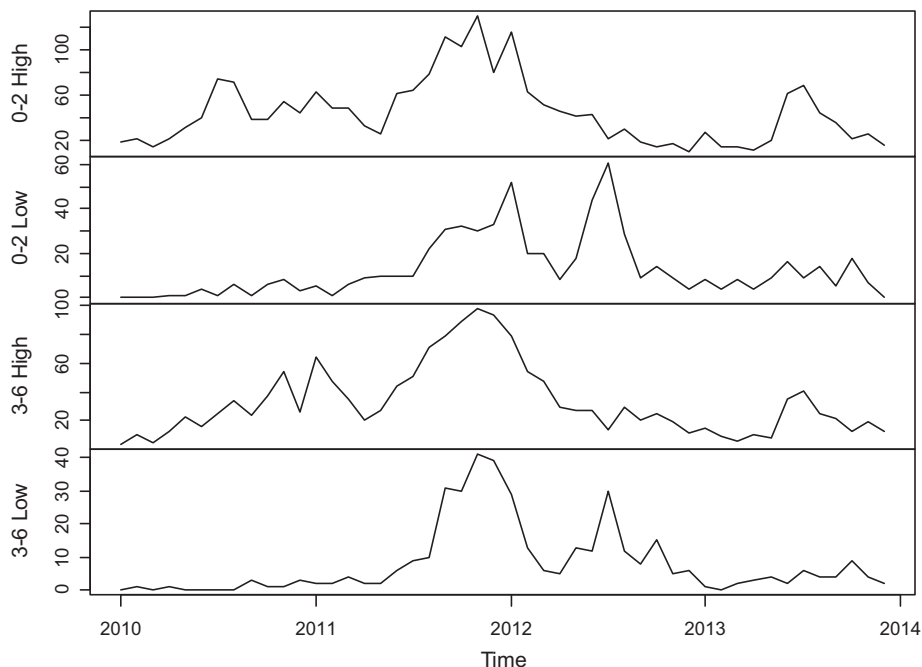
Information about pertussis immunization was available from 102 (76.1%) of 134 infant fatalities. Eighty-four (82.3%) of them had not received whole-cell pertussis vaccine, 11 (10.7%) received a single dose, three (3%) received two doses, and four (4%) three doses. Sixty-three (61.7%) of these 102 subjects were younger than two months, the minimal age for vaccination.

#### 4. Discussion

In this study, we provide evidence for an age-dependent protective effect of maternal Tdap immunization in young infants in a developing country. Tdap in Argentina resulted in a 51% relative

decrease in reported pertussis cases among infants younger than age two months, when comparing states with high and low vaccination coverage. This effect decreased to 44% among 3–6 months old infants and, as expected, was not detected in those older than age six months. This is a conservative estimate of the effect of this immunization strategy, as the comparison group is represented by states with low immunization coverage rather than no vaccination.

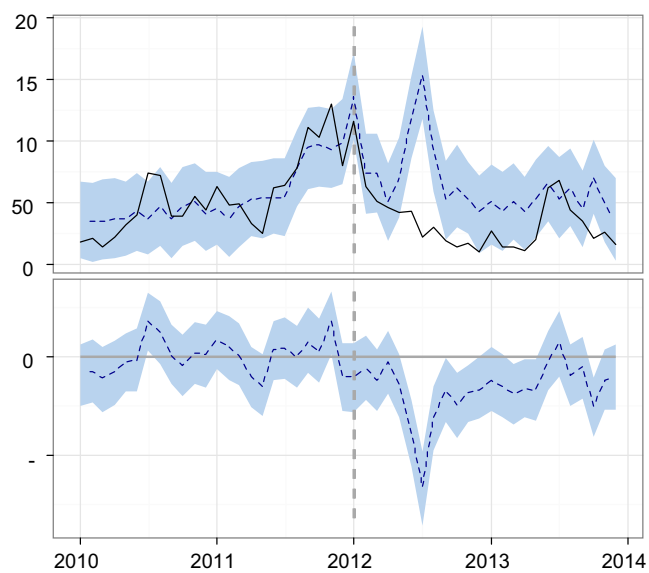
Pertussis re-emergence represents a significant problem worldwide. Several potential explanations have been proposed to explain this situation, including improved public health reporting and disease awareness [5,7,18,19], the use of more sensitive PCR methods [20,21], a possible antigenic drift in circulating pertussis strains due to vaccine pressure [22,23], and a shorter duration of protection conferred by acellular vaccines leading to waning



**Fig. 4.** Monthly pertussis cases according to Tdap vaccination coverage and age group. Vaccination program established in February 2012.



**Fig. 5.** Relative effect reduction in pertussis cases in infants younger than 2 months of age. Pertussis cases in infants 0–2 month of age in high (black line) and low (dashed line) coverage areas (top panel) and incremental impact of the vaccination program as predicted by the time series model (bottom panel). Vaccination program implemented on February 2012.



**Fig. 6.** Relative effect reduction in pertussis cases in infants 3–6 months of age. Pertussis cases in infants 3–6 month of age in high (black line) and low (dashed line) coverage areas (top panel) and incremental impact of the vaccination program as predicted by the time series model (bottom panel). Vaccination program implemented on February 2012.

immunity (a problem not affecting the public sector in Argentina that represents 95%, where infants receive whole cell vaccines) [24,25,19].

In Argentina, activities to strengthen the National Surveillance System and the laboratory diagnosis began in 2008 and intensified in 2011. That year coincided with the higher pertussis peak, following similar patterns in other Latin American countries including Chile and Uruguay [8,9]. To address this pertussis surge, Argentina implemented maternal Tdap immunization in early 2012. Interestingly, immunization rates countrywide ranged between 50% and 68%. These rates were comparable to the 60% achieved in the United Kingdom [16] and significantly higher than

the 16–19% reported in the United States for 2012 [26]. As experienced in the past in other situations with different vaccines, establishing a maternal immunization program led to a reduction in whole cell vaccination rates at 18 months in the community.

Our study design was not powered to show an impact on pertussis deaths when comparing high and low coverage states for Tdap. While the absolute number of fatalities decreased from 76 in 2011 to 10 in 2013 (and a low number of six in 2014 [not shown]), future studies will be necessary to assess the effectiveness of Tdap in reducing mortality from pertussis in Argentina. Differences in the estimated vaccine effect with a recent British report

describing 90% effectiveness against disease may be ascribed to various non-exclusive factors. For instance, in addition to potential environmental and logistical factors influencing outcome, we were unable to estimate efficacy in our evaluation and, hence, methodologies for assessing the impact of Tdap differed between studies.

Unlike in the United States, United Kingdom and Australia, where recent outbreaks exhibited an age shift towards adolescents and adults [27–30], the main affected age group in Argentina was infants younger than one year of age. This difference may be explained in part by disease underreporting at older ages in Argentina, much like in other countries in the region [7–9].

Our study has significant limitations. First, Since individual data on vaccination status was unavailable due to the SNVS design, estimation of vaccine effectiveness was not possible. Therefore, we resorted to a time series analysis to assess the impact of maternal vaccination on pertussis disease in young infants. In this case, lack of information on individual vaccination status for cases led us to select categories based on average immunization rates in different jurisdictions. The cutoff calculation based on averages allowed us to standardize the data for a more accurate analysis. Second, whether the observed reduction have been affected by the cyclic behavior of the disease is unclear. Future studies are needed to address this question. Third, we cannot discard that the results have been influenced by an increasing disease awareness or the improvement in the surveillance system. However, there is no reason to believe that may have been a difference between high and low coverage areas

In summary, this is –to our knowledge– the first study to report the impact of maternal Tdap immunization in reducing pertussis disease in young infants in developing countries. We used national surveillance data to assess the impact of maternal immunization strategy in infant pertussis with state-of-the-art laboratory techniques. Furthermore, in the context of a broader immunization window to enhance opportunities for vaccination, disease burden was reduced by half in our most vulnerable population.

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