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Tdap vaccine and pregnancy. Why is it important? Safety and efficacy of the vaccine

Vacuna Tdap y embarazo. ¿Porque es importante su administración? Seguridad y eficacia de la vacuna

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ABSTRACT

Pertussis (Bordetella pertussis) is a highly contagious respiratory disease that poses a significant threat to infants under six months of age, in whom clinical manifestations may be atypical and complications severe or fatal, including apnea, pneumonia, encephalopathy, and death. Despite the availability of effective vaccines for decades, pertussis continues to be a public health problem, with recurring epidemic cycles. Since the childhood vaccination schedule is not completed until six months of age, newborns and infants remain vulnerable. Tdap vaccination during pregnancy has been shown to be an effective and safe strategy for preventing the disease at this stage. Administering the vaccine between 20 and 36 weeks of gestation—preferably at least two weeks before delivery—ensures adequate transplacental transfer of antibodies, conferring passive protection to the newborn. Numerous observational studies and meta-analyses have shown significant reductions in hospitalizations, severe illness, and mortality in infants born to vaccinated mothers. Likewise, no significant maternal, obstetric, or neonatal risks have been observed. Nor has maternal vaccination been shown to clinically interfere with the infant's immune response after receiving their own vaccination schedule. Vaccination coverage among pregnant women in Peru is still suboptimal, highlighting the need for health personnel to commit to recommending and implementing this intervention in every pregnancy as an integral part of prenatal care.

Keywords: Whooping cough; Pertussis; Bordetella pertussis; Tdap vaccine; Maternal vaccination.

La tos ferina (Bordetella pertussis) es una enfermedad respiratoria altamente contagiosa que representa una amenaza significativa para los lactantes menores de seis meses, en quienes las manifestaciones clínicas pueden ser atípicas y las complicaciones graves o letales, incluyendo apnea, neumonía, encefalopatía y muerte. A pesar de la disponibilidad de vacunas eficaces desde hace décadas, la tos ferina continúa siendo un problema de salud pública, con ciclos epidémicos recurrentes. Dado que el esquema de vacunación infantil no se completa sino hasta los seis meses, los recién nacidos y lactantes permanecen vulnerables. La vacunación con Tdap durante el embarazo ha demostrado ser una estrategia eficaz y segura para prevenir la enfermedad en esta etapa. Al administrar la vacuna entre las semanas 20 y 36 de gestación —preferentemente al menos dos semanas antes del parto se logra una adecuada transferencia transplacentaria de anticuerpos, confiriendo protección pasiva al neonato. Numerosos estudios observacionales y metaanálisis han evidenciado reducciones significativas en hospitalizaciones, enfermedad grave y mortalidad en lactantes nacidos de madres vacunadas. Asimismo, no se han observado riesgos significativos maternos, obstétricos ni neonatales relevantes. Tampoco se ha demostrado que la vacunación materna interfiera clínicamente con la respuesta inmunitaria del lactante tras recibir su propio esquema de vacunación. La cobertura vacunal en gestantes en el Perú aún es subóptima, lo que resalta la necesidad del compromiso del personal de salud para recomendar e implementar esta intervención en cada embarazo, como parte integral del cuidado prenatal. Palabras clave: Tos ferina; Bordetella pertussis; Vacuna Tdap; Vacunación en el embarazo.

INTRODUCTION

Pertussis, also known as whooping cough, coqueluche, or pertussis, is a highly contagious acute respiratory infection caused by the bacterium Bordetella pertussis. This disease poses a particularly serious threat to infants under six months of age, in whom it can be potentially fatal, and represents a significant disease burden for health systems. Accord-



ing to the World Health Organization (WHO), 170,000 cases of whooping cough were reported annually between 2010 and 2019⁽¹⁾.

Despite the availability of safe and effective vaccines for more than five decades, pertussis continues to be a global public health problem. In Peru, it is considered an endemic disease with a cyclical epidemic pattern every 3 to 5 years.

The current childhood immunization schedule for pertussis begins at 2 months of age and is completed at 6 months, with two subsequent boosters⁽²⁾. This leaves younger infants—who experience the most severe and lethal forms of the disease—unprotected. Various strategies have been evaluated to reduce this risk, such as vaccinating the newborn's immediate environment (the "nest" or "cocooning" strategy); however, these have not proven sufficiently effective.

Currently, maternal immunization has been established as the most effective and safest intervention to protect newborns and infants against pertussis in their first six months of life⁽³⁾. This strategy has been incorporated for several years into immunization programs in many countries, both in our region and globally. Nevertheless, as in other countries, maternal Tdap vaccination coverage in Peru is still below optimal levels, limiting the impact of this intervention in preventing severe cases of pertussis in newborns and infants.

This scenario highlights the urgent need to understand this matter and to strengthen knowledge about this strategy among healthcare personnel, who play a key role in promoting and administering the vaccine opportunely during prenatal care. Promoting greater acceptance of and access to maternal vaccination is essential to reducing neonatal morbidity and mortality associated with this vaccine-preventable disease.

DESCRIPTION OF THE DISEASE

Pertussis is a highly contagious acute respiratory disease caused by Bordetella pertussis, clinically characterized by episodes of paroxysmal coughing followed by a prolonged, strident inhalation. Although it usually occurs in childhood, the most severe forms occur more frequently in infants, especially those under six months of age. In this population, clinical presentation is often atypi-

cal, with episodes of apnea predominating over the classic paroxysmal cough. The infection can be potentially fatal and associated with serious complications, such as pulmonary hypertension, heart failure, pneumonia, seizures, encephalopathy, and even death, particularly during the first months of life, before the infant has been able to complete their primary vaccination schedule⁽⁴⁾.

The disease is transmitted from person to person, with young people and healthy adults being the most common reservoirs. Pertussis is a vaccine-preventable disease, and the implementation of immunization programs has contributed significantly to the reduction of pertussis cases and deaths among children since the World Health Organization's (WHO) Expanded Program on Immunization (EPI) was launched in 1974.

The management of pertussis faces multiple challenges. The introduction of the acellular vaccine against Bordetella pertussis, which replaced the whole-cell vaccine, has reduced adverse events associated with these vaccines, but studies have shown a higher incidence of disease over time, because this acellular formulation protects against disease but not against infection, allowing transmission by asymptomatic carriers or those with mild symptoms⁽³⁾. On the other hand, since the first report of erythromycin resistance in Bordetella pertussis in 1994 in the United States, resistant strains have been identified in other countries, including Peru, which is a growing concern, given that macrolides are the basis of antibiotic treatment for this disease(5, 6).

CURRENT SITUATION IN PERU

Peru is currently experiencing an pertussis outbreak; as of epidemiological week 28 (July 11, 2025), 1,475 cases have been reported, compared to 32 cases in 2024 for the same week, with the department of Loreto having the highest number of cases⁽⁷⁾ (Fig. 1). As usual, the highest incidence of cases is observed in children under 4 years of age, especially those under 6 months (Fig. 2). In terms of mortality, 18 deaths have been reported to date, 10 of them in children under 6 months, with a case fatality rate of 8.47% in children under 2 months⁽⁸⁾ (Fig. 3).

This increase in cases is part of a global resurgence of pertussis, with significant increases in several countries in the Region of the Americas.

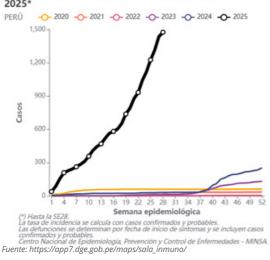


As a result, the Pan American Health Organization/World Health Organization (PAHO/WHO) has urged Member States to strengthen their epidemiological surveillance systems and maintain continuous, detailed, and disaggregated monitoring of coverage⁽¹⁾.

PERTUSSIS VACCINATION DURING PREGNANCY

The recommended vaccine during pregnancy is

1. GRÁFICA DE TENDENCIA ACUMULADA DE TOS FERINA 2020-2025. Tendencia acumulada de casos de Tos Ferina, 2020 -



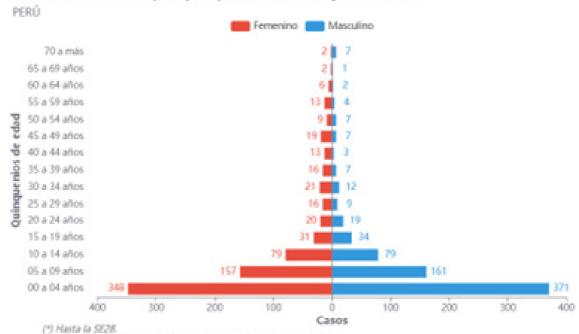
Tdap, which contains a standard dose of tetanus toxin and reduced concentrations of diphtheria toxin and the acellular pertussis fraction. It is recommended for people over 7 years of age, pregnant women, and as a booster every 10 years in adults. In Peru, a single dose is indicated from 20 weeks of pregnancy until week 36, and it should be repeated in each pregnancy. It is important not to confuse it with the pediatric DTP or DTaP vaccines, used in children under 7 years of age, which have a higher concentration of their components and a different immunization schedule⁽²⁾.

The Tdap vaccine administered from 20 weeks of gestation protects both the mother and the newborn against whooping cough, tetanus, and diphtheria. Administration of the Tdap vaccine allows maternal antibodies to be transferred through the placenta, conferring passive immunity that protects the newborn and infant, especially during the period of maximum vulnerability. Not only does it prevent infection, but it also reduces the rate of hospitalization and the risk of mortality in infants under 3 months of age⁽⁹⁾.

It has been shown that antibody levels against Bordetella pertussis, both those acquired through natural infection and those induced by

2. DISTRIBUCIÓN DE CASOS DE TOS FERINA POR QUINQUENIOS DE EDAD.

Casos de Tos Ferina por quinquenios de edad y sexo, 2025*



La tasa de incidencia se calcula con casos confirmados y probables. Las defunciones se determinan por fecha de inicio de sintomas y se incluyen casos confirmados y probables. Centro Nacional de Epidemiología, Prevención y Control de Enfermedades - MINSA,

Fuente: https://app7.dge.gob.pe/maps/sala_inmuno/

3. Tabla de defunciones por Tos Ferina, Semana Epidemiológica 27, Perú 2025.

Defunciones y letalidad por curso de vida. Perú, 2024-2025*



Grupos de edad	2024		2025	
	Defunciones	Letalidad %	Defunciones	Letalidad %
< 2 meses			5	8.47
2 a 6 meses	1	20	5	4.10
7 a 11 meses			1	1.49
1 a 4 años	1	10.0	6	1.51
5 a 11 años			1	0.31
12 a 17 años				
18 a 29 años				
30 a 59 años				
60 años a más				
TOTAL	2	0.80	18	1.39

Fuente: Sistema de Información Not

Elaborado por: Centro Nacional de Epidemiologia, Prevención y Control de Enfermedades-MINSA.

Elaborado por Centro Nacional de Epidemiología, Prevención y Control de Enfermedades del Ministerio de Salud del Per

vaccination, decrease progressively over time. For this reason, the administration of the Tdap vaccine is recommended during each pregnancy, regardless of previous vaccination history⁽¹⁰⁾.

Maternal Tdap vaccination has proven to be a cost-effective strategy, and its introduction into Peru's National Immunization Program in 2019 is supported by a local cost-effectiveness study⁽¹¹⁾.

According to official reports, national coverage of the Tdap vaccine during pregnancy reached 93% in 2024. However, it is important to note that planning is not based on the updated nominal register and only 35% of the target population is scheduled. So far in 2025, through the end of June, the recorded coverage of Tdap in pregnant women in Peru stands at 39%⁽¹²⁾.

EFFICACY AND EFFECTIVENESS OF THE TDAP VAC-CINE DURING PREGNANCY

Most studies on the efficacy and effectiveness of the Tdap vaccination during pregnancy have been observational in nature due to ethical considerations. Currently, there is solid evidence supporting that the implementation of this strategy significantly reduces morbidity and mortality from pertussis in newborns and infants under 6 months of age.

Costa Rica, recognized for having one of the most robust national immunization programs in the region, was one of the first countries in

the world to adopt this strategy in 2011. In 2022, the country published a historical review of the impact of pertussis vaccines and showed a significant decrease in hospitalizations and deaths from pertussis in children under 1 year of age, especially those under 6 months, following the introduction of the Tdap vaccine in pregnant women⁽¹³⁾.

In England, an observational study involving 26,684 pregnant women reported a 91% reduction in mortality and a 68% reduction in hospitalizations for severe cases in children under 3 months of age⁽¹⁴⁾.

In the United States, a cohort study involving 675,167 mother-child pairs found that children of vaccinated mothers had a 43% lower risk of pertussis infection and a 68% lower risk of hospitalization for this disease, compared to children of unvaccinated mothers⁽¹⁵⁾.

Another cohort of 74,791 pregnant women in California, United States, showed that the effectiveness of the Tdap vaccine in preventing pertussis-related hospitalizations was 85% in infants younger than 2 months and 72% in infants younger than 3 months, when the vaccine was administered between 27 and 36 weeks of gestation. It has been determined that at least two weeks after administration of the vaccine are required to allow passive transfer of maternal antibodies⁽¹⁶⁾.



In Brazil, a time series analysis demonstrated a protective effect of maternal vaccination in children under 1 year of age, with the greatest impact in the first 2 months of life (HR 0.90; 95% CI: 0.82–0.98)⁽¹⁷⁾. Similarly, a case-control study conducted in the same country found that Tdap vaccination during pregnancy reduced the risk of pertussis in infants younger than 8 weeks by 82.6%(18).

In addition, a meta-analysis that included 22 studies with a total of 1.4 million pregnant women and 855,546 mother-child pairs in the United States, the United Kingdom, Canada, Belgium, Vietnam, and New Zealand reported that the effectiveness of maternal Tdap vaccination ranged from 69% to 91% in preventing infection, 91–94% in preventing hospitalizations, and up to 95% in reducing neonatal mortality due to pertussis⁽¹⁹⁾.

Nguyen et al. conducted a systematic review and meta-analysis of 29 studies, which found a 78% reduction in the incidence of Bordetella pertussis infection in infants younger than 3 months (OR: 0.22; 95% CI: 0.14-0.33)(20).

TDAP VACCINE SAFETY DURING PREGNANCY

The safety of the Tdap vaccine during pregnancy has been extensively evaluated, and the available evidence consistently shows that it is not associated with significant adverse events for either the mother or the fetus.

The most common adverse effects in pregnant women are usually mild and transient. These include local reactions at the injection site in 2.6% of cases, fever in less than 3%, and, less frequently, systemic symptoms such as headache, malaise, and myalgia^(21,22).

Regarding possible obstetric complications, some studies have reported an increase in the incidence of chorioamnionitis and hypertensive disorders of pregnancy. However, reviews of observational studies have identified a slight albeit statistically significant—increase in cases of chorioamnionitis, without observing any relevant clinical impact, such as preterm births or the need for admission to a neonatal ICU^(19,21).

In Australia, a cohort study of more than 1,000 pregnant women showed that there was no association between Tdap vaccination and the occurrence of chorioamnionitis or other adverse perinatal outcomes such as preterm delivery, preeclampsia, intrauterine growth restriction, low Apgar scores, admission to the neonatal ICU, or the need for mechanical ventilation(23).

Similarly, in the United States, a retrospective cohort study involving more than 16,000 vaccinated pregnant women found no association between Tdap administration during pregnancy and the risk of preterm birth, low birth weight, birth defects, fetal or neonatal death, or neonatal intensive care unit admission^(21,24).

Likewise, other studies have not demonstrated an association between Tdap vaccination and the development of hypertensive disorders of pregnancy^(20,22). Nor has any association been found between maternal Tdap vaccination and the development of autism spectrum disorder in exposed infants⁽²⁵⁾.

IMMUNE INTERFERENCE

One concern associated with administering the Tdap vaccination during pregnancy is the potential immune interference—known as blunting between maternal antibodies transferred to the newborn and a possible reduction in the immunogenicity of the infant diphtheria, tetanus, and pertussis (DTP) vaccination series⁽²⁶⁾.

In Brazil, a cohort study was conducted with 318 pregnant women, in which the levels of different IgG antibodies associated with protection against Bordetella pertussis (PT, PRN, and FHA) were evaluated in their children after completing the whole-cell DTP childhood vaccination schedule, similar to that used in Peru. It was observed that, at birth and at one month of age, infants born to vaccinated mothers had significantly higher antibody levels. However, at 7 months of ageafter receiving the third dose of DTP—IgG levels against pertussis toxin (PT) were lower compared to infants whose mothers had not been vaccinated during pregnancy, while PRN and FHA levels remained without significant differences. The authors note that the clinical relevance of this blunting phenomenon is still uncertain and that, to date, no association with an increased risk of disease has been demonstrated(27).

On the other hand, a more recent observational cohort study conducted in Canada evaluated the immune response in infants born to



mothers who received the Tdap vaccine during pregnancy. It was observed that, when using the DTaP 3+1 childhood vaccination schedule—similar in number of doses to the schedule used in Peru—no statistically significant differences were found in the antibody levels generated by infants, compared to children of unvaccinated mothers. It should be noted that, unlike Canada, Peru uses the whole-cell DTP vaccine, which has been shown to induce a more robust immune response⁽²⁸⁾.

RECOMMENDED SCHEDULES

Since 2015, the World Health Organization has recommended administering the Tdap vaccine during each pregnancy, ideally during the second or third trimester, and preferably at least 15 days before delivery⁽²⁹⁾. In the United States, both the CDC's Advisory Committee on Immunization Practices (ACIP) and the American College of Obstetricians and Gynecologists (ACOG) recommend its administration between 27 and 36 weeks of gestation, although they emphasize that it can be safely administered outside this interval if necessary⁽³⁰⁾.

In Canada, the recommendation is to vaccinate between weeks 27 and 32, although it is considered safe from week 13 of pregnancy⁽³¹⁾. For its part, the United Kingdom has progressively modified its schedule since 2012, when Tdap for pregnant women was incorporated into the national immunization program. Currently, its administration is indicated between weeks 20 and 32 of pregnancy⁽³²⁾.

Similar schedules are recommended in other countries such as Australia, Spain, Costa Rica, Chile, Argentina, and various nations in the region.

CONCLUSION

Pertussis remains a public health problem, with a particular impact on infants under six months of age, who are at greater risk of serious complications and death. In the face of this threat, maternal vaccination with Tdap has proven to be a highly effective and safe strategy for protecting newborns in their first months of life, when they have not yet started or completed their immunization schedule.

Scientific evidence supports the need to administer the Tdap vaccine during each pregnancy, regardless of previous vaccination history, ideally between 20 and 36 weeks, and at least two weeks before delivery, to ensure adequate transplacental antibody transfer.

Furthermore, available studies have shown that vaccination during pregnancy does not significantly affect the infant's immune response to their regular vaccination schedule.

The active commitment of health personnel, particularly the team providing prenatal care, is essential to promote systematic vaccination in all pregnant women. Only in this way will it be possible to reduce neonatal morbidity and mortality from this vaccine-preventable disease be reduced and effectively protect the most vulnerable population.

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