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Review

Recommendations to control pertussis prioritized relative to economies: A Global Pertussis Initiative update

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ABSTRACT

Pertussis is a vaccine-preventable disease that causes morbidity and mortality, particularly in infants and children <5 years of age. The Global Pertussis Initiative (GPI) recommendations represent a systematic evaluation and prioritization of strategies to prevent pertussis-related infant and child deaths, reduce global disease burden and prevent resurgence through vaccination strategies and public health policies at national, regional and local levels. The GPI recommendations are based on clinical trials and observational and surveillance data, which are essential in the planning, implementation and evaluation of vaccination practices and best use of available resources. Many low- and middle-income countries (LMIC) continue to use whole-cell pertussis (wP) vaccines for primary vaccination, while most high-income countries have replaced wP with the less-reactogenic acellular pertussis (aP) vaccines. This present manuscript pertains to discussions held during the GPI's meeting on November 11–13, 2016, in Cape Town, Republic of South Africa. The GPI recommends that LMIC aim for high coverage of infant series pertussis vaccines as a priority. In LMIC and countries with constrained vaccine funding, if wP vaccines are currently used, wP should continue to be used. Furthermore, given that protection against disease and death due to pertussis in neonates is a key priority of the GPI, it recommends that ap immunization in pregnancy should be implemented as a priority in all countries if resources allow. Given that surveillance and epidemiology data on which to base vaccine decisions are important, the GPI also suggests that, in areas where wP vaccines are implemented, standardization and calibration of wP vaccines are checked, considering the many different manufacturers and variable standards of production and quality control. In addition, as immunity to pertussis wanes following the primary infant series of vaccination, the GPI further recommends that toddlers, adolescents, healthcare and childcare workers receive booster vaccine doses, where resources allow.

Contents

Abbreviations: AE, adverse event; aP, acellular pertussis; DTaP, diphtheria-tetanus-pertussis; DTP3, third dose of diphtheria-tetanus-pertussis vaccine; DTP4, fourth dose of diphtheria-tetanus-pertussis vaccine; DTP5, fifth dose of diphtheria-tetanus-pertussis vaccine; GPI, Global Pertussis Initiative; HIC, high-income countries; LMIC, low- and middle-income countries; PCR, polymerase chain reaction; Tdap, tetanus-reduced diphtheria toxoid-acellular pertussis; UNICEF, United Nations Children's Fund; WHO, World Health Organization; wP, whole-cell pertussis.

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1. Introduction

Pertussis is a vaccine-preventable disease that causes morbidity and mortality, particularly in infants and children <5 years old [1]. It is estimated that ~53,500 (0.9%) of the 5.941 million deaths in 2015 were due to pertussis in this age group [2]. Data from a modelling study estimated there were even 160,700 deaths from pertussis in children <5 years old in 2014, largely from the African region (58%) [3]. These estimates should be viewed with caution, however, due to the paucity of reliable surveillance data, particularly from low- and middle-income countries (LMIC) [1,3].

The Global Pertussis Initiative (GPI), formed in 2001, aims to increase awareness of pertussis as an important and preventable disease that warrants greater global public health attention, to improve understanding of the increasing incidence of reported pertussis and to develop effective immunization strategies for better control of pertussis. The GPI promotes this through regional- and topic-focused meetings and by publishing consensus recommendations for pertussis prevention and treatment.

In 2007, the GPI recommendations proposed, for high-income countries (HIC) and those with available resources, the use of acellular pertussis (ap) vaccines in adolescents and adults.[4] Considering the challenges in pertussis vaccination in LMIC, the GPI perceived a need to update the above GPI 2007 recommendations [4]. To address this task, the group invited 25 experts in the field of pertussis or related disease areas, comprising academics and physicians from across the world, to discuss the GPI's 2007 recommendations [4] and formulate revisions based on their economies at the GPIs 9th Global Roundtable meeting, 11–13 November 2016 in Cape Town, Republic of South Africa. The current manuscript provides updated GPI recommendations as discussed during this meeting.

2. Methods

Academic and healthcare provider experts from 11 countries were selected based on their therapeutic area expertise, publishing record, data access and knowledge, as well as their ability to contribute effectively in generating evidence-based recommendations, in particular for LMIC. Local advisors also helped to identify the influential vaccine experts. Of 25 invited experts, 17 were able to participate, of whom 14 were from LMIC. Attendees presented the current pertussis situation in their respective countries or regions, followed by open discussion on specific topics. Of note, a workshop on the future solutions for challenges faced during pertussis vaccination in Africa was held where all experts expressed their views and advised on solutions unanimously. Specific revisions on the 2007 recommendations were proposed during the meeting, and all the experts openly discussed the merits and limitations of each of the proposed revisions until consensus or majority consensus was reached. No unresolved issues remained by meeting conclusion.

3. Pertussis

Pertussis is an acute respiratory infection caused by the bacterium *Bordetella pertussis*; it is characterized by a protracted cough that often persists for several weeks, with intense paroxysms [5]. The disease is particularly severe in infants [6], especially those <6 months old, in whom first symptoms are frequently apnoea or respiratory distress without fever. The disease can progress rapidly in infants, often leading to death, despite antibiotic treatment, ventilator support or extracorporeal membrane oxygenation [7]. The WHO estimated that in 2013, pertussis caused around 63,000 deaths in children <5 years of age [1]. Pertussis can be debilitating in adolescents [6]; for them, pertussis-related complications may include broken ribs due to violent coughing and pneumonia [8]. Adults with pertussis complain of cough, disrupted sleep and interference with daily activities and work [9]. Complications in adults (e.g., sinusitis, pneumonia, rib fracture) are more frequent than in adolescents [10].

3.1. Epidemiology of pertussis

World Health Organization (WHO) data indicate that, since 1980, incidence of pertussis has fallen significantly and proportionately by increasing coverage of infants and children with three doses of the diphtheria-tetanus-pertussis (DTP3) vaccine (Fig. 1) [11].

In 2015, more than half of all estimated pertussis-related deaths of children <5 years of age occurred in Africa [12]. In a modelling study based on data from 2014 in children <5 years of age, India and Nigeria were shown to have the highest numbers of pertussis-related deaths (24% and 23% of total, respectively) [3]. Waning immunity may also contribute to the increased incidence of pertussis in adolescents and adults [13–16] who are an important reservoir of circulating *B. pertussis* and have a significant role in transmission of the disease to unvaccinated infants [12,16].

3.2. Pertussis surveillance

Surveillance of pertussis disease incidence and pertussis-related mortality are particularly important in LMIC, as adequate policy can only be established and implemented based on effective surveillance data [17]. Pertussis surveillance data in LMIC is often lacking, such that the trends in disease epidemiology remain mostly unknown [18]. The key factors responsible for poor or no surveillance in LMIC are: absence of confirmatory diagnostic facilities; lack of standardized clinical case definitions; nonstan-

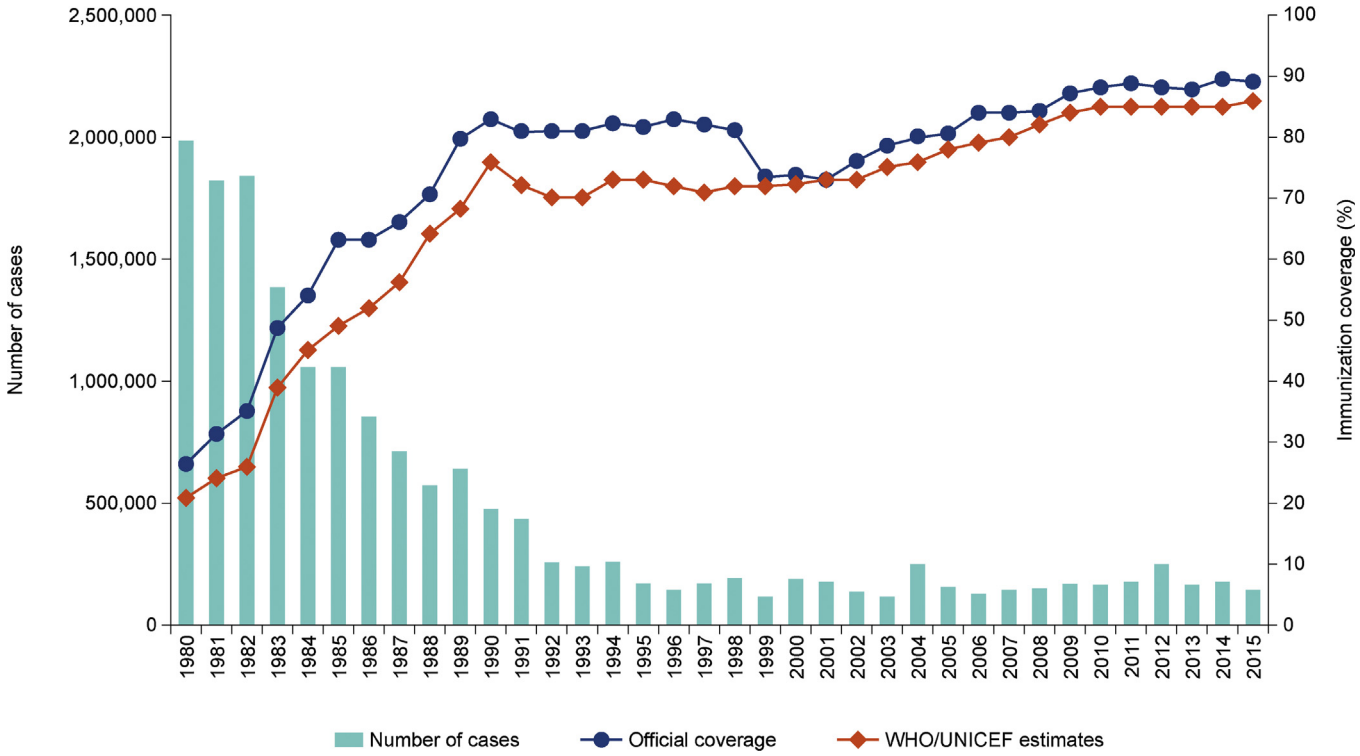

Fig. 1. Pertussis global annual reported cases and DTP3 coverage, 1980–2015 [11]. DTP3, three doses of the diphtheria-tetanus-pertussis vaccine; UNICEF, United Nations Children's Fund; WHO, World Health Organization.

Table 1
Current pertussis surveillance systems.

Pertussis surveillance systems
• Estimated pertussis incidence varies widely from country to country due to different surveillance systems used [46].
• The WHO has recommended the use of standardized clinical case definitions, criteria for laboratory confirmation and case classifications for pertussis [47]. It has also recommended reporting monthly aggregate data stratified by age groups and immunization status when DTP3 coverage is <90% and case-based surveillance (including information on age, immunization status and final outcome) when coverage is ≥90% [47].
• Implementing a global surveillance system for pertussis is challenging since countries employ different vaccination strategies and vaccine coverage targets, and not all countries perform laboratory confirmation of the disease [46,48,49].
• In the Asia-Pacific region, South Korea has had a rigorous national surveillance system in place since 1954; this was updated following WHO-recommended clinical case definitions in 2001, and again in 2010, to collect more complete and detailed information [50].
• Surveillance in LMIC is often scant, and nonavailability of laboratory-confirmed data leads to an underestimation of disease burden, as well as an inability to assess vaccine effectiveness and strategies.

DTP3, diphtheria–tetanus–pertussis vaccine; LMIC, low- and middle-income country; WHO, World Health Organization.

dardized pertussis case reporting systems; and low pertussis awareness among healthcare workers [18,19]. During pertussis outbreaks, identification of cases through active surveillance should begin with systematic specimen collection and fast transport of the specimen to laboratories equipped with adequate infrastructure [19]. Surveillance approaches at a country level should be mindful of the limited duration of immunity of the current pertussis vaccines. An active regional or country surveillance will pick up break-through clinical cases. One hospital-based surveillance study in South Africa, and two population-based community surveillance studies in Pakistan and Zambia, used the US Centers for Disease Control and Prevention case definition to identify and report pertussis in hospitalized infants <12 months old. Overall incidence of laboratory-confirmed (per polymerase chain reaction [PCR]) pertussis was 23 (in the Republic of South Africa), 2.47 (Pakistan) and 5.2 (Zambia) per 1000 infants [20–22]. Inadequate surveillance in LMIC is an important bottleneck in understanding pertussis disease burden and there is a need for a standardized surveillance system (Table 1).

4. Pertussis vaccines

Although whole-cell pertussis (wP) vaccines have been highly effective in reducing notified pertussis cases since their introduction in the 1940s, reports of adverse events (AEs) led to the development of the less reactogenic aP vaccines, containing purified components of *B. pertussis*, that are available as combination vaccines with tetanus and diphtheria toxoid, as well as a number of other antigens [23]. Though relatively simple in production, achieving a consistently high quality wP vaccine is demanding. The wP vaccines produced in different countries, using varied antigenic content and methods of production, evoke different immune responses following vaccination [1]. Both the aP and wP vaccines show high initial efficacy, with waning immunity with both vaccines, as expected [23]. Immunity acquired from the primary series of the aP vaccine may wane faster than that provided by wP vaccines, the latter providing protection against pertussis for 4–8 years after a full three-dose schedule [24,25]. It is estimated that, when wP vaccines are efficacious, a primary DTP3 series followed by one

booster dose provides protection for ≥6 years in individuals from countries using wP vaccines, whereas in countries using aP vaccines, immunity declines within several years after vaccination [1]. Local and systemic AEs in infants, following immunization with aP vaccines, were less frequent than in those immunized with wP vaccines [26]. The superior tolerability of ap vaccines makes them also suitable for use in older children, adolescents and adults [26]. In addition, ap vaccines have good safety and tolerability when administered in pregnancy [1]. However, the higher cost of aP vaccines must be considered within healthcare budgets at individual country level.

5. Vaccination strategies

The WHO has set a goal of ≥90% vaccination coverage with DTP3 of assured quality at national and regional levels for all children, including those infected with human immunodeficiency virus. It recommends that vaccination start at 6 weeks of age, with successive doses 4–8 weeks apart [1]. Depending on the local epidemiology, vaccination schedule and vaccine used, a booster dose (DTP4) is recommended for children 1–6 years of age.

wP vaccines, in combination with diphtheria and tetanus vaccines, are used in most African countries, while aP vaccines in combination with other antigens may be available through the private sectors [17]. Similarly, in India, only wP vaccines are used in national immunization programmes, while aP vaccines are also licensed and available through the private sector but coverage remains minimal [27]. Interestingly, UNICEF has reported that some middle-income countries request for procurement assistance through UNICEF as they encounter difficulties in securing the DTaP vaccine through their regular supply channels [28]. National programmes (mostly in LMIC), using wP vaccines for primary vaccination series, are encouraged to continue with the same schedule [1]. Wherever possible, it should include a fourth dose. Countries seeking to switch from wP to aP vaccines for the primary series must ensure a sustained supply of aP and ap vaccines for additional paediatric booster doses, or for immunization in pregnancy [1].

5.1. Vaccination during pregnancy

There is growing evidence that vaccination of pregnant women who are given ap vaccines during the second or third trimester is highly effective in protecting new-borns from pertussis, and reducing morbidity and mortality in infants too young to be vaccinated [1,29,30]. In vaccinated pregnant women, the fetus is provided with maternal antibodies through the placenta, thus protecting infants who are too young to be vaccinated [31]. Results of a randomized, placebo-controlled, phase 1 study in 48 healthy pregnant women 18–45 years of age, who received either the tetanus-reduced diphtheria toxoid and acellular pertussis (Tdap) vaccine or placebo at 30–32 weeks' gestation, revealed that a Tdap booster dose in pregnancy did not cause serious AEs [32]. Infants whose mothers received Tdap during pregnancy showed high concentrations of anti-pertussis antibodies during their first 2 months of life; there is some evidence of reduced responses to pertussis vaccines given to the infants of vaccinated mothers (immune blunting) available at this early stage, yet no evidence of reduced clinical efficacy has been reported [32–34]. However, a recent study suggests that the blunting issue reported after the primary series may be able to be resolved with a booster aP vaccine dose [35]. Further studies on this matter are awaited. Immunization in pregnancy is currently recommended by several national health organizations, mostly in HIC, including Argentina, Australia [36], Belgium, Israel, New Zealand, Switzerland, United Kingdom and United States [29,37]. An observational cohort study in pregnant women in the United Kingdom found no increased risk of stillbirth or other AEs following Tdap immunization [38], while another study confirmed that vaccine effectiveness was sustained at >90% in the 3 years following the introduction of maternal immunization [39]. Vaccination of pregnant women with Tdap should be prioritized based on its safety and ability to protect infants from severe pertussis and death. For countries already using aP vaccines, ensuring availability and access for pregnant women should be prioritized over ap booster doses for other adults. The successful implementation of immunization during pregnancy in LMIC requires a sustained supply of safe, effective and affordable ap vaccines, as well as an assured delivery system in place [12].

6. Updated GPI recommendations relative to LMIC economies

Where the aP vaccine is already in use, the GPI recommends the use of aP vaccines in all age groups, because of their better tolerability compared with wP vaccines. Countries (especially LMIC) currently using wP vaccines for primary immunization in infants should continue doing so and aim to achieve or maintain DTP3 coverage ≥90%. However, efforts should be made to encourage use of a fourth dose (DTP4) in toddlers (e.g., ∼18 months old) and a fifth (DTP5) at 5–6 years old, preferably with a less reactogenic aP vaccine, to ensure acceptance and prolonged protection until at least adolescence.

In countries where the use of aP vaccines is approved or being considered, but availability and costs limit patient access, the GPI recommends that pregnant women should be prioritized to receive the ap vaccine ahead of all other groups. The GPI strongly recommends the use of ap vaccines in every pregnant woman; it also encourages its use as booster doses in adolescents, where funding and supply make this feasible. Cocooning, the immunization of close contacts of infants too young to be vaccinated themselves, is practiced in some HIC as a means of reducing risk of infection; however, difficulties with implementing this strategy have been documented [1,37,40]. Perceived barriers to cocooning include: insufficient knowledge (46.6%); cost (31.4%); lack of transportation (26.0%); work commitments (13.3%); and fear of needles (13.3%) [41]. This resource-intensive, costly strategy to reduce disease burden in infants is not recommended in LMIC. Immunization of childcare and healthcare workers is a GPI recommendation, but only feasible in countries where aP vaccines are available and funded. The GPI considers the use of ap vaccine in pregnant women to be a higher priority than in childcare and healthcare workers. Key GPI recommendations for LMIC are summarized in Table 2.

Table 2
Key GPI recommendations for LMIC.

- LMIC using wP vaccines are recommended to continue their use for primary vaccination in infants.
- All LMIC should aim for high coverage (≥90%) of infant series with wP vaccines.
- In areas where wP vaccines are implemented, standardization and calibration of the vaccines are necessary.
- ap immunization in pregnancy should be implemented, if resources allow.
- Pertussis surveillance and epidemiology data on which to base policy decisions are important.

aP, acellular pertussis; LMIC, low- and middle-income countries; DTP4, fourth dose of diphtheria tetanus and pertussis vaccine; DTP5, fifth dose of diphtheria tetanus and pertussis vaccine; GPI, Global Pertussis Initiative; wP, whole-cell pertussis.

7. Future direction and next steps

Differences in available resources, vaccination policies and vaccination coverage among countries, along with the absence of detailed disease surveillance in many LMIC, have led the GPI to urge improved surveillance in all countries. The GPI considers that surveillance, supported by access to diagnostic tools such as PCR, provides informative understanding of local pertussis disease trends. Comprehensive surveillance reports that estimate true disease burden can motivate health authorities to develop improved policies. More safety/efficacy data of wP vaccines are needed before policies on its use beyond infancy can be developed. These data should come from vaccines in current use, the reporting of AEs and real-world experience of vaccination in infants and children. An affordable ap vaccine for pregnant women would substantially reduce infant disease burden. Maternal immunization with ap-containing vaccines has been reported to be cost-effective in many studies [42–44] (see Table 3).

8. Summary and conclusions

wP vaccines are effective, despite being more reactogenic than aP vaccines and requiring more quality control. As the cheaper alternative, they are the logical and preferred vaccine option for countries with constrained vaccine resources, especially LMIC. For these countries, the GPI recommends continued use of the wP vaccine to maintain or raise DTP3 coverage to ≥90%. The GPI also suggests that, in areas where wP vaccines are implemented, standardization and calibration of the vaccines are important, given the many different manufacturers and variable standards of production and quality control. It also recommends prioritization of funds for ap vaccination of every pregnant woman before use in other adults. The GPI emphasizes the need for improved pertussis surveillance to assess the true disease burden, and to motivate the development and funding of an effective and affordable ap vaccine (either containing pertussis antigens only or in combination with tetanus and diphtheria toxoids [45] in sufficient quantities to be truly available to all.

Table 3
Pertussis vaccination schedules followed in some selected* LMICs across the world [51].

Country	Vaccines used	Vaccination schedules followed
Argentina	DTaPHibHepBIPV	2, 4, 6 months
Brazil	DTwP	15 months; 4 years
	DTwPHibHepB	2, 4, 6 months
China	DTaP	3, 4, 5 months
Cuba	DTwP	18 months
	DTwPHibHepB	2, 4, 6 months
Gabon	DTwPHibHepB	6, 10, 14 weeks
Ghana	DTwPHibHepB	6, 10, 14 weeks
India	DTwP	16–24 months; 5 years
	DTwPHibHepB	6, 10, 14 weeks
Kenya	DTwPHibHepB	6, 10, 14 weeks
Mexico	DTaPHibIPV	2, 4, 6, 18 months
	DTwP	4 years
Morocco	DTwP	18 months; 5 years
	DTwPHibHepB	2, 3, 4 months
Peru	DTwP	18 months; 4 years
	DTwPHibHepB	2, 4, 6 months
Senegal	DTwPHibHepB	6, 10, 14 weeks
South Africa	DTaPHibHepBIPV	6, 10. 14 weeks; 18 months
	DTaPHibHepIPV	6, 10, 14 weeks; 18 months
Thailand	DTwP	1.5, 4 years
	DTwPHep	2, 4, 6 months
	DTwPHepB	2, 4, 6 months
Turkey	DTaPHibIPV	2, 4, 6, 18 months
Zambia	DTwPHibHepB	6, 10, 14 weeks

aP, acellular pertussis; DTwP, diphtheria and tetanus and whole cell pertussis; HepB, hepatitis B; Hib, haemophilus influenza; IPV, inactivated polio vaccine.
* LMICs selected randomly across the world.

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Conflict of interest

The GPI is funded by an educational grant from Sanofi Pasteur. The authors are Steering Committee members of the GPI, and have received honoraria for their participation from Sanofi Pasteur. The GPI is not influenced in any way by Sanofi Pasteur. GPI members hold the full right to determine meeting agenda items and to lead the discussions and outputs. Sanofi Pasteur representatives might have attended the meetings, but as observers only and they do not influence the findings of the group.

Author contributions

All authors were responsible for idea generation, critical review, and input into the manuscript drafts, as well as approval of the final draft for submission. All authors had full access to the study data and take full ownership for the integrity of the data and accuracy of the data analysis.

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