

Boosting Knowledge Toward Action on Adult Pertussis Vaccination

Technical Report
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Background

Vaccination is one of the most effective public health interventions of our time. Yet poor awareness and lack of knowledge of the life altering consequences of vaccine-preventable diseases (VPDs) such as pertussis have impacted the livelihood of individuals considered at-risk and placed greater pressure on already constrained social and health care services.

2030 marks the end of the United Nations (UN) Decade of Healthy Ageing (2021–2030). By 2030, it is predicted the number of people aged 60 years and older will be 34% higher than today, reaching 1.4 billion. (1) By 2050, this population is expected to have more than doubled to 2.1 billion and will outnumber adolescents and young people aged 15–24 years. (1)

Parallel to the process of population ageing is the increasing prevalence of people living with noncommunicable diseases (NCDs), such as diabetes, heart, and lung conditions as well as disorders that compromise the immune system. NCDs kill 41 million people each year, which is equivalent to 71% of all deaths globally. (2) In Europe, diabetes, cardiovascular diseases, cancer, chronic respiratory diseases, and mental disorders together represent ~86% per cent of total deaths and 77% of the disease burden. (3) In developed nations, about one in four adults have at least two chronic conditions, and more than half of all older adults have three or more chronic conditions.(3)

The rapid ageing of the population and the vulnerabilities that may prevail, together with the rise in chronic co-morbid conditions requiring complex health management, are driving an unprecedented demand for health and social care. Globally, lower respiratory infections resulted in more than 1.5 million deaths in adults 50 years or older in 2017 and accounted for 23 million years of life lost due to premature mortality. (4) Infectious diseases (such as influenza, pneumonia, shingles, pertussis, diphtheria, tetanus, and hepatitis) increase the risk of hospitalization, disability, and death among older people and are associated with a loss of functional ability and autonomy.(5)

Maintaining and improving the health of ageing populations is essential to prevent further burden on acute and long-term care systems due to the rise in NCD prevalence. The societal opportunities that arise from increased longevity largely depend upon maintaining and improving functional ability in older age. Additional years dominated by poor health, social isolation, and dependency on care have negative implications for older people and the entire society.

Vaccination is a frontline public health action and one of the most successful health measures of modern times, preventing up to six million deaths worldwide every year. (6) The World Health Organization (WHO) has rated vaccination as one of the most effective public health interventions of our time, second only to clean water. The societal value of immunization is well known during childhood years. Unfortunately, and despite clear evidence in support of adult vaccination, uptake rates remain suboptimal among the adult population.

A respiratory disease which has seen a serious upward trend in older adult populations is pertussis or more informally known as whooping cough. A significant percentage of older people infected with the bacterium *Bordetella pertussis* experience considerable morbidity and even mortality. Pertussis vaccination is not routinely recommended in adults, except for new parents, adults working with children, or health care workers. However, it has long been suggested that adult pertussis vaccination be a funded recommendation to control the repeated outbreaks and reduced the associated disease burden. (8)

Knowledge, risk perception, public funding, and physician recommendations are important factors that help adults make informed decisions about vaccinated against pertussis. Disease under-recognition and under-notification is a major hindrance to the awareness of this infectious disease and an improvement in uptake rates of pertussis vaccination. Greater awareness of the benefit of vaccinations through targeted public health messages is needed among older people and health care professionals.

The Emerging Threat of Pertussis

Pertussis is endemic in all countries. It is a highly infectious human respiratory disease transmitted through airborne droplets with a particularly high reproduction number (R_0). A single primary case may give rise to 12–17 new cases over the course of the infectious period in immune-naïve populations. Its level of contagiousness is comparable to that of measles, and higher than influenza, mumps, rubella, polio, or smallpox. (9,10)

Globally, estimates suggest there were 24.1 million pertussis cases and 160,700 deaths from pertussis in children less than 5 years of age in 2014. (11) The incidence of adult pertussis is estimated to be 200 to 500 per 100,000 persons, however as pertussis is underdiagnosed and underreported, the actual burden of disease in adults aged 65 years and older is unknown and therefore underestimated. (12)

The WHO reported 166,592 and 129,265 pertussis cases worldwide in 2009 and 2010, respectively, with cases in older age groups steadily rising. (13) In Australia, in 2008, 60% of pertussis notifications were reported in adults 20 years and over with a total of 14,435 cases, the highest on record. (13) Pertussis-related hospitalizations of adults show longer periods of acute care in older individuals, with average length of stays of 6.3 and 8.7 days for those 10–50 years of age and 50 years of age, respectively. (14)

Outbreaks periodically occur every two to five years, with evidence of an increasing shift of disease burden in adults. (11) High rates of pertussis infection are observed among adults in the community and even in highly immunized populations. Added to this it has been suggested that pertussis outbreaks are significantly under-recognized in aged care facilities and thought to reflect waning of the immunity from childhood vaccination. (15)

The increasing incidence of pertussis among adults, especially those who are aged 65 years and over or with NCDs such as chronic obstructive pulmonary disease (COPD) is of particular concern. In contrast to children, pertussis in adults presents in an atypical manner without classical symptoms. The presentation of pertussis in older adults can make diagnosis challenging as the source of infection may be young children. The morbidity in healthy adults is mainly associated with prolonged cough, with the average duration being 44 days. (16) Increasingly there are reports of complications increasing with age that include hemoptysis, otitis media, pneumonia, urinary incontinence, rib fractures, pneumothorax, cough syncope, seizures, and loss of consciousness triggered by coughing episodes. (16)

Recent evidence shows that pertussis-associated deaths occur in older populations as well as the very young. (16) In fact, the highest mortality is usually noted among adults over 74 years of age. (17, 18) Furthermore, emerging data shows that individuals with COPD are at high risk of contracting pertussis. Worldwide, it is estimated that 3.17 million deaths were caused by COPD in 2015 (i.e., 5% of all deaths globally in that year). (20) COPD prevalence is also likely to increase in coming years due to higher smoking rates and ageing populations in many countries.

Studies have linked the risk for pertussis to the prevalence of COPD in Italy which is approximately 15% with an age-dependent increase in proportion of COPD cases. (19) Those who develop pertussis can also experience exacerbation of pre-existing COPD symptoms and are more susceptible to other infections. These trends should be a trigger for serious concerns when viewed in the context of the WHO Global Burden of Disease Study that reports a prevalence of 251 million cases of COPD globally in 2016.(20)

Gaps in Adult Pertussis Vaccination

Many countries do not include adult pertussis vaccines in the national immunization plans despite evidence of immunogenicity of pertussis vaccines in people above the age of 55 years. (21) For those countries where it is available and fully funded vaccine uptake and successes seem largely related to pediatric programs.

Since the introduction of effective pertussis vaccines in the 1940s, the incidence of pertussis has decreased by over 80%. (22) Despite successful infant vaccination programs, pertussis remains widespread in many low- and middle-income countries resulting in a global resurgence in all populations. Several factors contribute to this observed resurgence, including a failure of both natural immunity to previous infection and vaccination to provide life-long protection; low vaccine coverage combined with absent or inconsistent recommendations for booster vaccination; and the cyclical nature and genetic variance of the disease. (26)

While pertussis is vaccine-preventable, neither natural nor vaccine-induced protection is life-long. Therefore, older adults may be potentially at risk of more severe outcomes of pertussis infection or of an increase in severity of pre-existing conditions due to this infection regardless of health status.

Infant and childhood pertussis vaccination programmes are often prioritized over older adult pertussis programs, yet older adults are at higher risk for adverse health outcomes and becoming a source of transmission upon infection.

The European Union (EU) has led the way to a certain extent in terms of recommendations and policy direction appreciating that the lack of vaccination programmes for the older population may contribute to substantial morbidity and mortality in late adulthood.(23) Routine immunization for older adults is now recommended against pertussis every 10 years.(24) The European Union Geriatric Medicine Society (EUGMS) and the International Association of Gerontology and Geriatrics-European Region (IAGG-ER) have also recommended a revised vaccine schedule directed to adults over 60 years of age.(25)

This emphasis is not reflected in other regions and countries which are at increasing risk of outbreaks due to a lack of attention to immunizing older adults and / or lack of booster programs.

Policy Implications

The resurgence of pertussis observed in recent years seems to be a complex but real phenomenon especially for older adults. (26) There are many countries in which adult pertussis vaccination is not recommended in the national immunization plan, and no reliable data are currently available to estimate the extent of pertussis by existing surveillance systems.

It is also well recognized that the immunity elicited by vaccines can wane over time, and that this effect is much more pronounced with vaccines against diseases caused by pathogens that have complex life cycles or antigenic variation (e.g. influenza, pertussis). (27) This decrease in immunity years after a childhood vaccine is likely to result in outbreaks or epidemics adding further stress to an over-burdened health care system.

Infected older individuals may also transmit pertussis to unprotected infants. Pertussis control measures have even failed in some countries with high pertussis vaccination coverage rates, leading to increased incidence rates. In 2014, this scenario caused the WHO to declare pertussis as resurgent in some countries which led to recommendations regarding pertussis surveillance and national immunization programs. (27)

Recommendations and funding for pertussis vaccination for adults varies greatly between individual countries and as previously mentioned the scarcity of coverage data is a barrier. Given the estimates of a much larger incidence of the disease and resulting loss of function and autonomy with poor health outcomes, the social and economic burden of pertussis in adults is substantial, and therefore, adult pertussis vaccination and broader use of the booster vaccination would be justified within national plans.

Today, the views of influential professional, patient, and ageing organizations representing millions of older people are largely absent from the policy dialogue. The following facts call for urgent action to help influence adult vaccination pertussis vaccination:

- The incidence of pertussis among adults is increasing globally, especially older adults and those with NCDs such as COPD
- Pertussis has serious life-altering consequences and sometimes death for at-risk populations including older people and those with compromised immune systems
- Neither natural nor vaccine-induced protection is life-long against pertussis hence the need for booster vaccines
- A serious lack of public awareness exists among consumers, families and patients, professional, and advocacy groups in relation to the value of pertussis vaccination
- Pertussis is an important vaccine within every adult immunization schedule

IFA and its networks are uniquely positioned to bring various perspectives to the forefront and provide a platform for knowledge exchange and education so that pertussis is on the agenda for patient, ageing and professional organizations to promote and help to influence policy.

Boosting Knowledge Toward Action on Adult Pertussis Vaccination aims to gather new evidence to raise awareness and educate patient, ageing and professional organizations to promote and help to influence policy.

National Adult Pertussis Vaccine Policies

Vital to strategic vaccination planning, a gap analysis methodology was used to gather data and intelligence on the status of adult pertussis vaccine programs, (National Immunization Advisory Group) NITAG recommendations and funded programs, and pathways to vaccination in Brazil, India, Spain, Vietnam, and Mexico. In addition, regulatory processes and pathways for vaccine recommendations and funding of an adult pertussis vaccine are described in this report.

To supplement the gap analysis in-depth interviews were conducted with six key influencers to supplement the desk research with the intention of calling for greater attention on the need for adult pertussis vaccines in national immunization plans.

The semi-structured interviews included open-ended questions on the status of adult pertussis vaccination in the country of interest, barriers to introducing vaccines, and recommendations for informing future policy. With permission, the interviews were recorded and transcribed, and analyzed thematically.

Brazil

Brazil, in 2020, had an estimated population of 212.6 million with 26% of the population being under the age of 15 years and 9.6% aged 65 years and over. As the global population continues to rise, the number of older people in Brazil is expected to dramatically increase. It is predicted that by the year 2050 the population of older adults in Brazil will triple to approximately 65 million compared with 20 million in 2010. (28)

An ageing population is associated with an increased prevalence and burden of NCDs. In 2019, 74.7% of all deaths in Brazil were due to NCDs including cardiovascular disease responsible for 28%, and respiratory diseases and diabetes collectively contributing to 11%. (30)

Vaccine Regulatory Process

Established in 1991, the Technical Advisory Committee on Immunizations (CTAI) advises the Ministry of Health (MoH) on immunizations. During the COVID-19 pandemic the ministry of health created a specific expert advisory group solely. Some states in Brazil may create state-level immunization advisory groups to address location specific concerns.

The process to develop and grade evidence-based recommendations includes: (32-34)

- The MoH chooses the vaccines to be evaluated using a Health Economic Evaluation (HEE). This evaluation is funded by the MoH, and typically cost-effectiveness analysis or cost-utility analysis are used during the HEE.
- The HEE is a tool to evaluate the costs and health effects to estimate the relative value of different health intervention strategies, contributing to a potentially more efficient allocation of resources.
- The CTAI discusses and evaluates the inclusion and / or withdrawal of vaccines from the basic calendar of the MoH based on disease burden, vaccine characteristics, and other factors such as: programmatic capacity, sustainability, affordability, and budgetary impact.
- The Comissão Nacional de Incorporação de Tecnologias no Sistema Único de Saúde (CONITEC) then analyzes the demand for incorporation and must meet the conditions for the incorporation of new medicines, medical products, and procedures into the Sistema Único de Saúde (SUS), which is the Brazilian public health system.
- CONITEC then makes recommendations on the incorporation of the vaccine being considered and evaluated into the SUS in a report indicating the efficacy, accuracy, effectiveness, and safety of the technology.
- The process is forwarded by the CONITEC Executive Secretariat to the MoH and specifically to the Secretary of Science, Technology and Strategic Inputs.
- The Secretary of Science, Technology and Strategic Inputs makes the final decision on incorporation of the vaccine to be added to the SUS.
- The Secretary of Science, Technology and Strategic Inputs of the MoH may request a public hearing before its decision, according to the relevance of the matter. The final decision is published in the Federal Official Gazette.

Pertussis Vaccine Recommendations

Brazil does not focus on adult pertussis vaccination and only includes policies for vaccinations in pregnant women and healthcare workers, and special at-risk groups who are immunocompromised. Unfortunately, pertussis has been overshadowed in public health conversation by other pressing infectious such as the COVID-19 pandemic, influenza, and even polio.

While a wider range of vaccines can be accessed in private clinics, much of the population is immunized through the public SUS. These vaccines (including pertussis) are typically provided through the Family Health Strategy in clinics called vaccine rooms, which are the responsibility of local municipal governments. (32-34)

Infants and children

The pertussis vaccine was introduced to the basic routine calendar in Brazil in September 2012, following WHO recommendations to increase vaccine coverage. The vaccine is available at the age of 2, 4, and 6 months of age, with a booster at 15 months and 4 years. (31)

Adults

Currently, Brazil only funds a pertussis vaccination for pregnant women and health care workers who work with infants. The vaccine available for pregnant women is recommended at 20 weeks gestation. The funded adult dTap vaccine is available from the 27th week of pregnancy and can be administered up to 20 days before the anticipated date of delivery. (34)

Despite population ageing and increasing prevalence of NCDs in Brazil, there is a lack of awareness and policy dialogue around the need for adult pertussis vaccination.

Spain

In 2020 the population of Spain was approximately 46.8 million with 20% of the population aged 65 years and older. Like many countries around the world, the demographic landscape in Spain shows a growing ageing population. Since 1971, the population aged 65 years and older has grown at an annual rate of 1.47%, from 9.8% to 20% of the population in the year 2020. (37, 38)

The burden of NCDs is expected to rise alongside rapid population ageing. As of 2019, 90.8 % of deaths in Spain were due to NCDs with most caused from cardiovascular diseases (28%) and cancers (26%). Spain, a country that already faces a high burden of disease from NCDs must ready itself for the advanced ageing population and the impact of NCDs as they can greatly increase complications faced by pertussis and other VPDs. (38)

Vaccine Regulatory Process

Established in 1991, the Committee for Immunization Programs and Registry (“the Committee”) supports the Public Health Commission, which is a part of the International Council of the National Health System (CISNS), by surveilling VPDs and evaluating immunization programs through careful consideration of epidemiological data and scientific evidence. (39)

The Committee assesses modifications to national vaccine programs such as the addition of a new vaccine after it has been approved for market authorization by the European Medicines Agency (EMA), which authorizes all new vaccines for countries in the EU. (39)

To add vaccines to immunization programs, first the Public Health Commission requests the Committee to prepare a proposal. This proposal is then passed onto the CISNS for their decision on the recommendations. The Committee generates recommendations based on 5 criteria (39):

1. Burden of disease
2. Vaccine effectiveness and safety
3. Repercussions of the proposed modifications to the vaccine program
4. Ethical aspects of the modification
5. Cost-effectiveness analysis

The Committee determines vaccine recommendations after careful evaluation of scientific data, ethical implications, and financial analysis. Although the CISNS approves recommendations for the national vaccination schedule, the 19 official autonomous communities of Spain determine their individual vaccination programs based on these recommendations. While the official immunization schedules are similar, some regions have introduced certain vaccines not in the national recommendations such as those for chickenpox or pneumococcus. (40)

Pertussis Vaccine Recommendations

The national vaccine schedule outlined by the CISNS recommends vaccinations against pertussis for all children, pregnant women, and health care workers in obstetrics or pediatrics. (42-45) Tdap is a funded vaccine recommended to healthcare workers in obstetrics or pediatrics who may be in close contact with risk groups such as pregnant women and infants who may not have been vaccinated against pertussis.

Vaccinations in Spain are funded through the national healthcare system and can be obtained from health care providers such as nurses and practitioners through primary health centers. (40)

Infants and children

The CISNS recommends and funds a combined vaccine which protects children against six diseases – diphtheria, tetanus, pertussis, polio, haemophilus influenzae type b, and hepatitis B. There are currently two recommended schedules outlined (41,42):

2 + 1 schedule:

- The hexavalent vaccine is administered at 2 and 4 months with a booster at 11 months.
- A combined dose of DTaP, the vaccine for infants and young children, and polio vaccine (IPV) is given at 6 years.

3+ 1 schedule:

- The hexavalent vaccine is administered at 2, 4, and 6 months with a booster at 18 months.
- A DTaP dose is administered at 6 years.

Adults

Funding for adult pertussis vaccinations is for pregnant women and healthcare workers in the obstetric and pediatric fields (43, 44):

- Tdap is the vaccine for older children and adults (diphtheria, tetanus, and acellular pertussis vaccine) is recommended for pregnant women starting at 27 weeks gestation, but preferably week 27 or 28.
- Tdap is recommended for healthcare personal if they have not been previously vaccinated against pertussis.

A major factor contributing to the lack of adult pertussis vaccination in Spain is the lack of awareness of the true prevalence of pertussis among adults. Pertussis can be difficult to diagnose in adults as it does not present with typical symptoms and this in effect means that epidemiological data in Spain may inaccurately report case levels. Coupled with more common respiratory diseases that are robustly surveilled and monitored, physicians are likely to misdiagnose pertussis in adults for other respiratory diseases. This in turn leads to a lack of standard of care when it comes to the diagnosis of adult pertussis infections.

Health care professionals need to be made aware of the true case of pertussis so that they can begin to see the value in adult pertussis vaccination. To increase awareness, better epidemiological studies need to be conducted to highlight the true impacts of pertussis vaccination. This data can be used not only to educate health care professionals, but to present as strong evidence for the funding of adult pertussis vaccination through national immunization plans.

Mexico

The population of Mexico in 2020 was approximately 128.9 million with 26.61% of the population aged less than 15 years and 7.26% aged 65 years and older. Despite representing a relatively small percentage of the total population, the number of adults 65 years of age and older is projected to more than triple by the year 2050 to about 28 million people. (46, 47)

NCDs account for 80% of all deaths in Mexico including cardiovascular diseases, respiratory diseases, and diabetes (24%, 6%, and 15% respectively).(46, 47) With an increasing older population, a life-course approach to health is critical to prevent the burden of NCDs and their associated risk of greater morbidity and mortality from VPDs.

Vaccine Regulatory Process

The New Molecule Committee (NMC), established in 2008 by The Federal Commission for the Protection Against Sanitary Risks (COFEPRIS), is responsible for drug approvals, including vaccines. For a vaccine to be approved for market authorization, the following steps occur (48-50):

1. Consultation meeting with the NMC.
2. A Good Manufacturing Practice (GMP) inspection from COFEPRIS.
3. Submission of a registration dossier to third party or directly to COFEPRIS for approval.

Once a vaccine is approved, the National Immunization Task Advisory Group (NITAG) known as the National Vaccination Council (CONOVA), makes recommendations regarding vaccination policy. CONOVA coordinates the introduction of vaccines, national immunization schedules, and subsequently the target populations.

The following are key steps for vaccine recommendations and distribution (48-50):

1. CONOVA assesses the vaccine by viewing epidemiology data and cost-effectiveness analysis.
2. CONOVA makes vaccine recommendations to the National Center for Infant and Adolescent Health (CeNSIA).
3. Once CeNSIA approves the vaccine, the Coordinating Commission for Negotiating the Price of Medicines and Other Health Inputs (CCNPNM) negotiates vaccine pricing with manufacturers.
4. Finally, the Ministry of Finance approves the budget for purchasing and distribution of the vaccines.

CONOVA recommends vaccine policy based on epidemiological and cost-effectiveness analyses. However, a lack of existing epidemiological data on some VPDs can make it difficult to build the health and business case for the Ministry of Finance to allocate resources for scaling up national vaccination programs. Due to difficult process in adding new vaccines to the national immunization plan, an immunization law allows for state governments and Social Security Institutions (SSIs) to purchase vaccines directly from manufacturers based on demand and risk profiles of diseases in the different regions. (55-57)

Mexico's immunization program is offered through local health units for those with a National Health Card, this includes vaccinations against pertussis. Vaccinations can also be obtained through private clinics. (48, 55)

Pertussis Vaccine Recommendations

In Mexico recommendations for adult pertussis vaccination have been outlined for the past several years to include:

- Universal vaccine for adults aged 19–64 years with an initial dose of Tdap followed by td boosters every 10 years
- 65 years of age and older additional Tdap dose followed by booster every 10 years

The funding for the above recommendations can be difficult to predict as pricing needs to be negotiated with congress every year. However, a key component to successful funding in the past has been the inclusion of experts in ageing and vaccination in key government roles such as a vaccinologist as Minister of Health, who understands the long-term benefits of vaccinating older adults against VPDs including pertussis.

Infants and children

A combined vaccine that protects children against five diseases – diphtheria, tetanus, and acellular pertussis vaccine (DTap), polio (IPV) is recommended and funded through the National Immunisation Plan of Mexico. (51, 52, 56)

- The vaccine is administered at 2, 4, and 6 months, followed by a booster at 18 months.
- Tdap vaccines is not funded for adults and older adults.

Adults

- Tdap (combined tetanus, diphtheria, and acellular pertussis vaccines) is funded for pregnant women from 20 weeks to 32 weeks gestation.
- Tdap vaccines is not recommended or funded for adults and older adults.

Even with successful funding, there are barriers for older adults to be vaccinated against pertussis, one of which is the awareness of the general population as to the availability of vaccines. Mexico has been very successful in children vaccination as there are national weeks every year dedicated to vaccines, however the attention for adult vaccination is not approached with the same stamina.

Furthermore, older adults living in rural and remote areas find it harder to gain access to health-care providers to get the appropriate vaccines. There have been some efforts to reach people in isolated areas, but due to the COVID-19 pandemic, these interventions have been stalled.

To ensure future funding for adult pertussis vaccination and to address the barriers, continued public health efforts are critical to bringing awareness to communities on the importance of adult pertussis vaccination and prioritizing the need to invest in strategies that will target isolated populations.

India

In 2020, of a population of 1.4 billion, 27.34% of the population was under the age of 15 years, and 6.24% aged 65 years and over. This demographic situation is going to change drastically in the coming decades, as the percentage of older persons is expected to rise to about 20% by 2050. (57, 58)

Currently, 63% of all deaths in India result from NCDs and in 2020, it was estimated that two in every three people aged 60 years and above suffered from a chronic condition with 23% having multiple comorbidities. (58)

Vaccine Regulatory Process

India's National Technical Advisory Group on Immunization (NTAGI) was established in 2001 by the Department of Family Welfare (DFW). The NTAGI provides recommendations regarding vaccination policy to the Ministry of Health and Family Welfare (MoHFW) based on epidemiology, burden of disease, cost-effectiveness, and the priority of vaccine policy in comparison to alternative public health interventions. (59, 60) In case of insufficient data, the NTAGI consults with experts and draws conclusions based on collective member agreement.(59-61).

The NTAGI includes a Standing Technical Sub-Committee (STSC) responsible for conducting ongoing surveillance on VPDs. The STSC branches into ad-hoc groups to address new evidence, such as the introduction of a new vaccine to the Universal Immunization Program (UIP).

The following outlines the pathway for vaccine recommendations (59-61):

1. MoHFW and the STSC defines the research question, and an ad-hoc group is created to address the issue.
2. The ad-hoc group gathers scientific evidence, consults with experts, and synthesizes findings.
3. The STSC reviews the evidence and presents recommendations to the NTAGI.
4. The NTAGI sends final recommendations to the MoHFW.

Pertussis Vaccine Recommendations

There are currently no funded programs for adult pertussis vaccination in India. Although globally cases of pertussis have increased significantly, a lack of surveillance and evidence on the burden of pertussis in India causes policymakers to dismiss the concern expressed by advocacy organizations and refrain from adding the adult pertussis vaccination to the national immunization plan. As pertussis may present with common symptoms and have a similar course of treatment as other respiratory conditions misdiagnosis may have contributed to the low incidence of pertussis observed in India. For example, in a 2011 study, the incidence of pertussis in adults was negligible but results found more than 50% of older adults lacked any remaining pertussis antibodies from childhood vaccination.(74)

Currently, the government has prioritized vaccinating children against pertussis due to observing a high incidence in children below the age of 6 years. Vaccination within the Universal Immunization Program in India is administered at various sites including community health centers, sub-district hospitals, district hospitals, and outreach sites in rural areas. Vaccinations can also be obtained through private clinics.(62-65)

Various health organizations have made recommendations for adult pertussis vaccinations but there is no systematic plan by the government to examine the necessary data to drive policies forward. Recommendations from professional associations include (62):

1. Association of Physicians of India (API): Tdap dose, followed by a booster every 10 years; Tdap for pregnant women.
2. Indian Medical Association (IMA): Tdap dose for those 10 to 18 years, followed by a booster every 10 years; Tdap for pregnant women in the third trimester.
3. Federation of Obstetric and Gynecological Societies of India (FOGSI): Tdap for pregnant women; Tdap for those 65 years and older, if unvaccinated as a child, or adults in close contact with infants.

Infants and children

The UIP recommends and funds a combined vaccine which protects children against five diseases – diphtheria, tetanus, and acellular pertussis vaccine (DTap), polio (IPV). (63-65)

- The vaccine is administered at 6, 10, and 14 months.
- A DTP booster is administered at 16 to 24 months, followed by a second booster at 5 to 6 years.

Adults

- Tdap (combined tetanus, diphtheria, and acellular pertussis vaccines) is not funded, however the combined tetanus and diphtheria (Td) vaccine is funded for pregnant women although this does not protect against pertussis.(65)

Studies have reported concerns over rising incidence rates of adult pertussis, however highlight that underdiagnosis and underreporting are significant barriers to assessing the true burden of the disease.(74) Particularly in light of waning or absent immunity to pertussis of older adults in India, there is a critical need for robust data collection to ascertain the current levels of pertussis among adults so as to model expected burden of disease as population ageing and NCD prevalence converge.

Vietnam

In 2020, the population of Vietnam was estimated to be 97.3 million with 23.5% less than 15 years of age and 7.9% aged 65 years and older.(75) The population of Vietnam aged 65 years and older has grown at an annual rate of 0.80% from 5.3% in 1971 to 7.9% in 2020. By the year 2050, it is estimated that 20.4% of the total population of Vietnam will be aged 65 years and older.(66)

Currently, 77% of all deaths in Vietnam are caused by NCDs with cardiovascular diseases accounting for 31%, respiratory diseases for 6%, and diabetes for 4%. The risk of mortality and morbidity of VPDs including pertussis increases for older persons who experience NCDs and thus presents a risk for the nation's ageing population. (66, 67)

Vaccine Regulatory Process

The Committee on the Use of Vaccine and Biological Products established in 1997 is tasked to improve evidence-based decision-making and provide recommendations for vaccines to the MoH. (68, 69) Historically, the NITAG has been supported financially by donor organizations such as the Gates Foundation from 2012 to 2015, and starting in 2016, the WHO Regional Office for the Western Pacific (WPRO).

To introduce new vaccines, the NITAG has relied on guidelines presented from national and international institutions with greater emphasis on recommendations from the WHO. The NITAG is working towards utilizing a health technology assessment (HTA) to support new vaccine recommendations. (68-70)

Pertussis Vaccine Recommendations

Currently Vietnam has observed a low incidence rate of adult pertussis cases, therefore many policymakers and physicians fail to see pertussis as an issue for older adults and the need for adult pertussis vaccination on the national immunization program.

As with the other countries studied, health system funding is limited and therefore the national immunization plan tends to focus on where data identified a pertussis epidemic has occurred. Data currently show a high level of pertussis cases in children who have not yet reached the age of pertussis vaccination or have not entirely been immunized. Therefore, Vietnam is in the process of adding pregnant women to the recommended vaccination groups within the national immunization program as part of an early pertussis vaccination program.

The current budget for the national immunization program is limited to vaccines that policy-makers deem as having a high return on investment, and that are likely to have high uptake among targeted populations. However vaccine uptake rates are typically suboptimal as many negative perceptions against vaccination currently exist in Vietnam. Some HCPs believe the COVID-19 pandemic and the role of vaccination as a public health prevention tool may help to improve public perceptions to vaccination and thereby coverage rates.

The NITAG is in the process of developing new guidelines on creating vaccine recommendations using cost-effectiveness analysis and evaluating scientific data. Currently, it only recommends the pertussis vaccine for children.(69-71)

While there are no recommendations for adult pertussis vaccinations, there is a reference by the MoH to strengthen the Expanded Program on Immunizations (EPI) (71-73):

1. Advocate and mobilize investment from central and local governments to continue EPI activities.
2. Create policies for sustainable investment towards the EPI.
3. Focus public health messaging to address anti-vaccine movements.
4. Prioritize and support isolated regions to increase their access to vaccines.
5. Improve evidence-based research and economic evaluations to introduce new vaccines to the EPI.

Vaccines under the EPI are administered at community health centers during immunization days which occur for 2 to 3 days every month. To reach isolated regions, mobile vaccination units are dispatched every 2 to 3 months to these areas to administer the vaccine. Vaccines can also be acquired through private health centers.(73, 74)

Infants and children

The EPI currently funds a pentavalent vaccine which protects children against diphtheria, tetanus, pertussis, polio.

- The vaccine is administered at 2, 3, and 4 months.
- A DTP booster is administered at 18 months.

Adults

- Tdap (combined tetanus, diphtheria, and acellular pertussis vaccine) is not funded for adults.

The lack of adult pertussis vaccination in Vietnam, including for health care workers and pregnant women, indicates a critical need to collect and examine evidence-based data on the incidence of pertussis in the country.

Summary

Immunization programmes across and within countries vary greatly depending upon demographic trends, epidemiology, health system funding, and priorities set out by NITAGs and other regulatory bodies. In Brazil and Spain, pertussis vaccination is recommended and funded for adults, namely pregnant women and health care workers in contact with infants. In Mexico, the immunization program covers pregnant women but not health care workers. In India and Vietnam, pertussis vaccination is not available for either pregnant women or health care workers. Notably and unfortunately, the interactions of older adults as caregivers of young children are not factored into criteria for evaluating the risk of transmission of pertussis between these two vulnerable at-risk groups.

The evidence of increasing pertussis rates in older adults globally, as well as the increase in population ageing and rising prevalence of NCDs which are associated with greater mortality and morbidity of pertussis, are all causes of great concern when setting national funding and health system priorities. Recommendations for older adults have only been provided by advocacy organizations and researchers but have not yet influenced any policy change.

While each country studied faces unique challenges, there are overarching similarities that can be used to inform adult pertussis vaccination policies. Despite there being robust regulatory processes and pathways within each country for the development of vaccine recommendations and funding, the critical driving force is epidemiological data. Studies have shown a generalized underreporting of pertussis prevalence among adults, leading to the undervaluation of the potential benefits of expanding vaccination programs beyond infants and children.

The findings herein indicate the importance of creating a roadmap on which to build multi-stakeholder engagement to influence and shape policy toward improving adult pertussis vaccination programs.

Actions for Adult Pertussis Vaccination

The growing burden of pertussis has serious consequences for not only older adults and their communities but on nations and the globe, as with all VPDs in the context of demographic changes like population ageing and migration on the global scale. To comprehensively evaluate and respond to the emerging threat of pertussis, several actions must be taken which involve multisectoral collaboration.

1. Data Collection:

Incomplete reporting and lack of attention towards pertussis cases among older adults contributes to the lack of awareness of the true burden and severity of pertussis in adults.

Data collection is a critical element to help generate concern for older adult pertussis cases, guide policy dialogue, and present as a strong argument for funding and therefore equitable access to pertussis vaccination.

2. Informing Policy:

Patient organizations, academia, health care professionals, and governments all have a vested interest in building awareness around diagnosis and impact of pertussis among at-risk groups including older adults and those living with NCDs.

Intersectoral collaboration will ensure that evidence is shared across networks through various knowledge translation means such as webinars, reports, and meetings, to generate public and policy dialogue surrounding adult pertussis vaccination.

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International Federation on Ageing

1 Bridgepoint Drive, Suite G.238
Toronto, ON, M4M 2B5, Canada

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