



Volume XXVI, Number 3 IMMUNIZE AND PROTECT YOUR CHILDREN

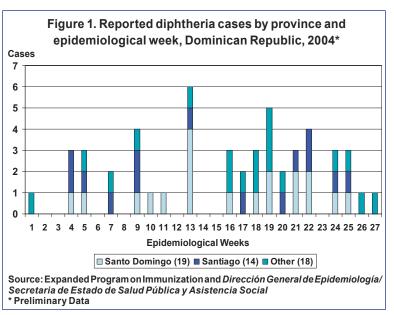
June 2004

Diphtheria Outbreak in the Dominican Republic

Diphtheria is an endemic disease in the Dominican Republic. In the last five years, between 35 and 50 cases have been reported. Until epidemiological week 27 of 2004, the Dominican Republic reported 51 cases of diphtheria, all of them in children between 1 and 14 years of age. The *Corine*- The national authorities have initiated outbreak control measures. Actions implemented to guarantee adequate case management include use of diphtheria antitoxin, antibiotics, and support measures. Prophylactic antibiotics and vaccination appropriate for the age and immunization status have been

bacterium diphteriae has been isolated in 12 (24%) of the 51 reported cases and toxigenicity test results are pending.

Preliminary analysis of the available data indicates that the most affected age group this year is that of children aged 1-4 years (67% of the cases), which represents an annual cumulative incidence of 3.8 cases per 100,000 children in this age group. The cases occurred mainly in Santo Domingo -National District and Province of Santo Domingo- (19 cases) and



advocated for the management of the contacts. For areas at risk, intensification of diphtheria vaccination activities is being done. Further actions in order to guarantee that the newborn cohorts receive adequate diphtheria protection with 3 primary doses of diphtheria vaccine and boosters in accordance with their age are being planned.

The fact that diphtheria is endemic in the Dominican Republic and the majority of cases have occurred in the 1-4 year old age group strongly suggests that one of the main

the Province of Santiago (14 cases), where approximately 42% of the population live. The other 18 cases occurred in 15 of the remaining 29 provinces of the country (Figure 1). The majority of the cases present with unknown or incomplete vaccination history and come from areas of extreme poverty and overcrowding. The case-fatality rate in the different health facilities was 43% in the children referral hospital of Santo Domingo and 8% in the referral hospital of Santiago. No deaths have been reported in the other health care facilities.

causes of disease endemicity and the current outbreak is low vaccination coverage. The presence of pockets of susceptibles in areas of poverty and/or with limited access to routine vaccination services is a call for action to improve coverage in all communities.

Editorial: This note is to alert the countries of the Region and encourage them to strengthen their routine vaccination services, evaluate their risk areas, take preemptive measures, and strengthen the epidemiological surveillance of vaccinepreventable diseases.

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Influenza Vaccination among Risk Groups in Costa Rica: An Evidence-based Decision

Influenza is a highly infectious viral disease characterized by seasonal outbreaks. Attack rates are usually high, resulting in an increase in doctor visits and hospitalizations that can be quite concerning in view of the threat of a pandemic. Influenza mortality refers not only to the disease caused by the virus, but also to the complications it can cause among people suffering from chronic diseases and among demographic groups at risk¹.

Following an analysis of the epidemiology of influenza and its complications, the health authorities of Costa Rica officially introduced a plan of action aimed at strengthening surveillance for influenza virus through the development of a network of sentinel sites in Costa Rica. The three components of the plan of action were²:

- 1. Strengthening surveillance for influenza and other respiratory viruses;
- 2. Vaccinating high-risk groups against influenza; and
- 3. Standardizing protocols for clinical management of respiratory infections.

The implementation of this plan has helped define more accurately the burden of influenza in the country, allowed for the identification of seasonal trends, and supported international virus surveillance for development of an effective influenza vaccine. In addition, the treatment protocols for respiratory infections have been updated, and influenza vaccination of high-risk groups has been added to Costa Rica's official immunization schedule.

Surveillance of respiratory infections

Respiratory tract infections are the most frequently reported illnesses in the country. During the period from 1995 to 2002, the incidence rate of respiratory infections in Costa Rica ranged from 127 cases per 1,000 population during years of endemic disease to 247 cases per 1,000 population during epidemic years.

Surveillance for acute respiratory infections has demonstrated the seasonal nature of these illnesses. This is particularly relevant for Costa Rica since the country is located in an intertropical convergence area. In addition to the country's climatic conditions, the high influx of international visitors to and from North America, Central America, and Europe during influenza epidemic seasons most likely influences the influenza epidemiology in Costa Rica.

The analysis of the seasonal patterns on the basis of hospital discharges for influenza (1990-2002), and the use of three-

month running averages to smooth the curve, show two annual peaks of infection of different magnitude. A major peak occurs during the months of May through July, and a second peak occurs during September to November (Figure 1).

Strengthening of laboratory surveillance

From 1998, the National Hospital of Children (HNN - *Hospital Nacional de Niños*) started diagnosing respiratory viral infections and collecting samples from hospitalized children. The HNN clinical samples with positive results were sent to the virology laboratory of the School of Microbiology of the University of Costa Rica (UCR), where, in collaboration with the Centers for Disease Control and Prevention (CDC) in Atlanta, viral isolation, molecular typing, and study of the influenza virus were performed. Results showed that the A/Sydney/05/97(H3N2) influenza strain circulated from 1998 through 2000, the A/NewCaledonia/20/99(H1N1) strain circulated in September 2000, and the A/Panama/2007/99(H3N2) strain circulated in July 2001. In 1999 and 2001, several influenza B

Figure 1. Discharges and three month running averages of discharges from influenza, Costa Rica, 1990 to 2002 Number of discharges 30 25 20 15 Jan-96 Jul-96 Jan-98 Jul-94 Jan-95 Jul-95 Jan-97 Jan-99 Jul-97 Jan-00 Jan-93 Jul-93 Jul-98 Jul-99 Discharges ---- 3-month running average of discharges Source: Database of hospital discharges, Caja Costarricense de Seguro Social (1990-2002)

strains were also isolated.

In 2002, the sentinel surveillance network for influenza and other respiratory viruses was implemented (Figure 2). Protocols were established for the proper management and study of samples from two sentinel sites: the HNN and the National Hospital of Geriatrics. These centers systematically send to the National Reference Laboratory (INCIENSA) viral samples from suspected influenza cases reported by inpatient and outpatient services, including emergency rooms. Results are published weekly for users of the network and positive isolates are

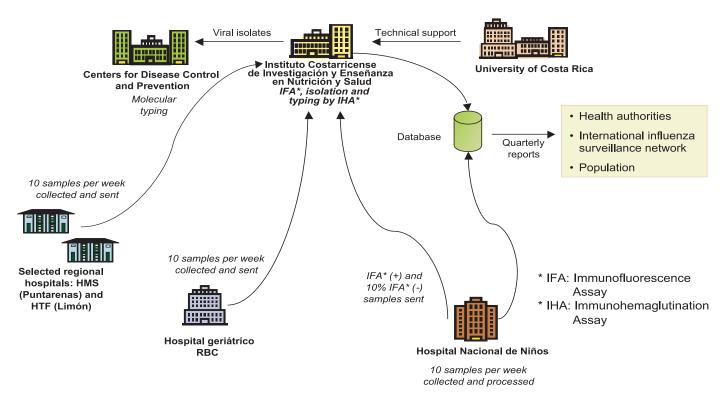
shipped to the CDC for molecular characterization.

The surveillance network has also allowed the study of respiratory infection outbreaks in communities of the country where the differential diagnosis of febrile diseases in endemic areas of dengue has been difficult. In 2004, the laboratory surveillance network will be expanded to include two more sentinel sites located in regional hospitals of the coastal zones.

Hospitalization and outpatient visits

During 2002, groups at opposite ends of the age spectrum were at greatest risk for hospitalization (12.0 times more in children aged <5 years and 14.2 times more in adults aged \geq 65 years) and death (4.9 times more in children aged <5 years and 61.7 times more in adults aged \geq 65 years) in comparison to the 5-64 year age group (Figures 3 and 4). In that same year, discharges from influenza and pneumonia represented 2.2%

Figure 2. Influenza sentinel surveillance network



of total hospital discharges; however, the proportion was 7.6% among children aged <5 years and 4.9% among adults aged \geq 65 years. The average hospital stay was 5.7 days among children aged <5 years and 14 days among adults aged \geq 65 years.

In 2001, influenza was the cause of 5% of total consultations in emergency rooms and 9% of outpatient consultations. Furthermore, it was the main cause of disability among the population in general, with an average of 3.3 days of disability per episode.

Vaccination of groups at risk

The savings in costs and services that the Costa Rican Social Security Fund (CCSS - *Caja Costarricense de Seguro Social*) would accrue as a result of a reduced number of consultations and hospitalizations following vaccination against influenza among at-risk populations were estimated according to vaccination among children aged <5 years and adults aged \geq 65 year using a 70% vaccine effectiveness, and a 75% coverage rate among the target population.

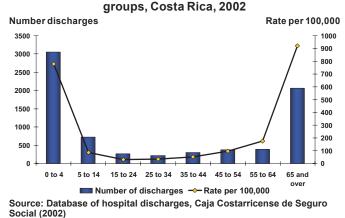
Since Costa Rica does not have an influenza registry measuring incidence to help determine target groups for influenza vaccination, estimates were calculated using data from the National Institute of Statistics and Census (INEC – *Instituto Nacional de Estadísticas y Censos*). The age groups of <5 years and \geq 65 years with associated illnesses were identified as populations at risk, representing respectively 12.5% (n=52,016) and 25% (n=54,061) of the total population. In order to identify the expected benefit range, two scenarios were calculated: disease incidence under endemic conditions (attack rate of 15% in <5 years and 20% in \geq 65 years) and disease incidence under epidemic conditions (attack rate of 25% in both <5 years and \geq 65 years). The scenarios were based on an outpatient visit frequency of 80% in both age groups and a hospitalization frequency of 15% and 20%, respectively. Vaccination costs included vaccine purchase, staff salary and training, and management of waste generated by the activity (US \$401,014). Costs avoided through outpatient visits and hospitalizations were assessed on the basis of the consultation and hospitalization estimates, and the average stay due to influenza specific to each age group, under an endemic scenario (US \$4,034,366), and also under an epidemic scenario (US \$5,362,918).

From the health services perspective, it was determined that during endemic periods 7,818 consultations and 1,750 hospitalizations due to influenza and its complications would be avoided. During epidemic periods, 42.4% and 39.6% additional consultations and hospitalizations, respectively, would be avoided. Cost reductions that the services could potentially achieve as a result of this vaccination strategy were estimated to vary between US \$3,633,352 and US \$4,961,904, according to the endemic and the epidemic scenarios, respectively. Potential net savings per vaccinated individual would amount to US \$46.0 and US \$62.0 according to those scenarios.*

As a result of this study, Costa Rica has been administering influenza vaccine since 5 January 2004 to children aged 6 months to 4 years and adults over 65 years with associated illnesses (chronic respiratory disease, diabetes, heart disease, chronic kidney disease, weakened immune systems, liver disease, moderate to serious malnutrition). The composition of the vaccine used is the one recommended for the Northern Hemisphere for the 2003-2004 influenza season (A/New Caledonia/20/99/H1N1, A/Moscow/10/99(H3N2), and AB/ Hong Kong/330/2001).

^{*} Preliminary estimates.

Figure 3. Number of hospital discharges and rates (per 100,000 population) from influenza and pneumonia by age

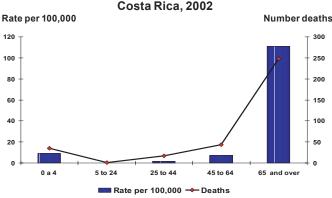


Conclusions

The implementation of the influenza control plan in Costa Rica has resulted in the following:

- The development of the diagnostic capability for identification and characterization of the influenza virus epidemiology, ultimately allowing for the cost-benefit evaluation of vaccination among groups at risk. This is essential in the decision taken by Costa Rica to include influenza vaccination in the immunization schedule in 2004.
- The comprehensive plan of action for influenza prevention and control was implemented. It is primarily aimed at improving the quality of life and health care services of groups who are highly vulnerable to influenza illness and death, particularly young children and older adults suffering from chronic ailments.
- The plan will also promote the strengthening of influenza surveillance and will help with measuring the impact of prevention and control interventions implemented by Costa Rica.
- The availability of an effective influenza vaccine, especially among high-risk groups³, is a cost-beneficial intervention

Figure 4. Deaths and mortality rates (per 100,000 population) from influenza and pneumonia by age groups,



Source: Death registry, Instituto Nacional de Estadísticas y Censos (2002)

for immunization and public health programs. Countries should strive to prevent these infections and their complications through cost-beneficial vaccination strategies, based on the analysis of their epidemiological situation, and the identification of interventions that optimize both impact and equity in the assignment of health resources.

Source: Hugo Arguedas (Ministry of Health, Costa Rica), Vicenta Machado (Costa Rican Social Security Fund, CCSS), Ana Morice (Costa Rican Institute of Research and Education in Nutrition and Health, INCIENSA).

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Current Recommendations for the Use of BCG to Prevent Severe Tuberculosis: Use of a Single BCG Vaccination as Early as Possible in Life

The World Health Organization (WHO) estimates that tuberculosis caused 1.8 million deaths and 8.3 million new cases in the year 2000. Tuberculosis is a mycobacterial disease that affects a variety of organs with pulmonary tuberculosis being the most common form of disease. Initial infection with *Mycobacterium tuberculosis* results in both immune and non-immune inflammatory responses including circulating antibodies, delayed hypersensitivity, increased macrophage activity, and granulomatous inflammation. Granulomatous reactions limit the dissemination of the organism in the body, thus preventing more wide-spread and severe disease. The majority of initial infections heal without disease manifestation; the infection enters a latent phase with a life-time risk of reactivation of 10 to 20 per cent which can lead to severe disease.¹ In approximately 5% of persons, the initial infection can progress to pulmonary or disseminated tuberculosis affecting other organs by lymphohematogenous spread, e.g., tuberculous meningitis. While more common in adults, the disease may be more serious in infants and children.

Control of tuberculosis includes the use of Bacillus Calmette-Guérin (BCG) vaccine, as well as identifying and treating TB cases. The original BCG vaccine strain became available in 1921 and was recommended for widespread use in the early 1950s by the WHO.² Studies show that BCG vaccination reduces the "hematogenous spread of the TB bacilli from the site of primary infection".³ BCG does not prevent initial infection (nor pulmonary disease) but exerts a protective effect against forms of tuberculosis that require lymphohematog-

enous spread of the bacilli after initial infection, e.g., massive dissemination (i.e., miliary TB) and tuberculous meningitis. As summarized by, WHO³, this reduction in hematogenous dissemination of the bacilli reduces the risk of immediate disease and the risk of reactivation but not the risk of infection. BCG vaccination's greatest impact is the reduction in the risk of miliary tuberculosis, tuberculous meningitis, and death from these forms.

For example, a child previously vaccinated with BCG that stimulated immunity, who subsequently becomes infected with the tubercle bacilli will have a reduced risk of dissemination of the bacilli, resulting in a reduced risk of severe disease such as tuberculous meningitis. However, the child's initial infection could still result in pulmonary tuberculosis.

To be most effective, BCG must be administered prior

revealed poor protection. Finally, of 7 clinical trials with a wide age range of study participants (most were older than infants), only 2 showed a protective effect (around 80%) while the others showed little or no protection. The review concluded that the evidence supports vaccination in the first year of life.

Some countries elect to revaccinate those who, although previously vaccinated with BCG, failed to produce a scar or who are skin test negative. The assumption being that if the first dose failed to produce a scar, or did not result in a positive skin test, there is poor protection. However, there is poor correlation between skin-test conversion or size of induration or scaring (although there is less data for scaring) with protective immunity. In addition, some European countries vaccinate tuberculin skin-test negative adolescents.

BCG Use in the

As the WHO Regional

Office for the Americas,

the Pan American Health

Organization supports

the recommendation of a

single dose of BCG given

within the first year of life

and preferably at birth.

BCG vaccine is currently

used in most countries in

the American Region,

with the exception of the

USA and Canada, which

never used BCG routine-

ly. With the exception of a

few other countries in the

Region, mostly in the Ca-

ribbean, the majority of

newborns are vaccinated

at birth with BCG. Five

countries recommend a

Americas

to a primary infection. In the developing world, the age of greatest risk for the most severe forms of tuberculosis subsequent to infection is within the first 5 years of life. Epidemiologically, the age group of 5-15 years has low rates of disease and low rates of severe disease. Thus, BCG has traditionally been given at birth, i.e., prior to those primary infections resulting in relatively more frequently in severe disease.

WHO currently recommends that a single dose of BCG be given as early as possible after birth in all populations at high risk and in the neoAn anteroposterior X-ray of a patient diagnosed with advanced bilateral pulmonary tuberculosis



Source: Centers for Disease Control and Prevention, Public Health Image Library.

natal period "to protect against severe forms of the disease (miliary spread and meningitis)". WHO discourages repeated vaccination with booster doses of BCG.⁴ This is based on the observation that there is no definitive evidence that repeated BCG vaccination confers additional protection against tuberculosis although it may be protective against leprosy. In addition, available data indicate that BCG given after the first year of life may be less effective.

The International Union Against Tuberculosis and Lung Disease (UNION) conducted a literature review to evaluate the impact of the age of receipt of BCG on the effectiveness of BCG in preventing severe TB disease. Protection was found to be greatest when BCG was given before 1 year of age.⁵ Six studies evaluated children over 1 year of age. Three prospective studies showed protection of <30% while 3 retrospective studies demonstrated an effectiveness of 16% to 74%. The UNION publication concluded that "vaccination of older children does not offer protection against TB that is as reliable as vaccination at an earlier age." Further review by the UNION of the vaccination of adolescents and adults

booster dose or revaccination after 5-6 years of age.

Editorial Comment

Considering both WHO's and the UNION's recommendations, and the absence of data to support revaccination, each country in the Americas that uses a 2-dose BCG schedule should justify why they pursue a schedule that does not follow current international recommendations and for which there are little or no data to support its use.

In reality, there have been few well conducted studies on the subject. Several studies have been conducted on booster doses but only indirectly.^{2,5,6} These include studies in Hungary and Poland which unfortunately did not address the issue of effectiveness or efficacy. A study from Chile showed that revaccination did not provide additional protection. A study in Malawi, one of the few formal evaluations of repeated BCG vaccination, showed no protection against pulmonary tuberculosis from a second dose (it did provide an additional 50% protection against leprosy).6

TechNet21 2004 Consultation in Antalya, Turkey



TechNet, or technical network for strengthening immunization services, is a loosely established group of experts and organizations such as WHO (World Health Organization), PAHO (Pan American Health Organization), UNICEF¹, GAVI², SING³, BASIC II⁴, PATH⁵ and other partner organizations, collaborating to

support the management and operational logistics of national immunization programs.

The TechNet21 meeting was organized by WHO and the Department of Public Health of Akdeniz University. It took place from 22-25 March in Antalya, Turkey, with participation from 116 members. It featured excellent presentations on the introduction of new vaccines; methods to improve immunization coverage, cold chain, injection safety, logistics; and experiences in training methodology. The main issues discussed during TechNet21 are presented in the following table.

Topics	Conclusions and recommendations
PQS (Performance Quality Safety)	 The PQS (Performance, Quality, Safety) is replacing the PIS (Product Information Sheets), which has served as reference for cold chain equipment requirements since 1979. The PQS will cover all needs related to purchases or enquiries regarding specifications of equipment and other supplies required by the Expanded Program on Immunization (EPI). The information contained in the PQS will follow WHO and UNICEF verification standards. The PQS will make up for current shortcomings by focusing on the following three factors: Performance: all selected products will have proper standard specifications. Quality and reliability: equipment will follow specifications appropriate with field conditions. Safety: product specifications will ensure that neither user, patient, nor environment are hurt during the product's life cycle. Major benefits of the PQS are that: It will be revised annually allowing for norms and standards to be continuously updated. Protocols will be developed and verified. The use of products will be monitored to verify their performance under different conditions or in the field. The PQS will be published in English, French, and Spanish and a Web page will be available for questions. The first issue is expected for 2005.
Accidental freezing of vaccines and the case of hepatitis B vaccine	 While it is important to prevent vaccines from exposure to heat, which can weaken vaccine potency and cause cumulative and irreversible damage, accidental freezing is an equally worrisome problem and is probably responsible for more damage than heat. One of the most cold-sensitive (or freeze-sensitive) vaccines is the hepatitis B vaccine. Obtaining the vaccine's thermostability would greatly help with disease elimination since it would facilitate the early administration of the first dose for newborns, especially in remote or tropical areas where no health centers are available. A study conducted in Hanoi, Vietnam, has produced encouraging preliminary results. It suggests that seroconversion of the third dose of hepatitis B vaccine incurs an insignificant loss of protection (1%) when the vaccine has been exposed to temperatures over 27°C.
R12-CFC refrigerant	 R12-CFC refrigerant will no longer be in use after 2005. An inventory of R12-CFC equipment is needed to program an adequate replacement schedule.
New vaccines	• Countries are increasingly using single-dose vaccine presentations and introducing new vaccines. As a consequence, they need to increase their storage capacity.
Vaccine safety	 A review of the next steps regarding final disposal of syringes and needles was conducted. Pros and cons of some options were studied to find the solutions that would be most appropriate for implementation in developing countries, such as the use of safety boxes, incinerators, sterilizer drums, and needle destroyers.

More information and all the presentations made during the meeting can be found on the internet site: www.technet21.org.

¹ United Nations Children's Fund.

² Global Alliance for Vaccines and Immunization.

³ Safe Injections Global Network.

⁴ Basic Support for Institutionalizing Child Survival (1999-2004)

⁵ Programme for Appropriate Technology in Health.

Measles Surveillance in the Americas: Final Data, 2003

Country						
	Total augmented			Confirmed Cases		Total confirmed Cases 2002
	Total suspected Cases notified	Discarded	Clinical	Laboratory and EPI Link	Total	
Anguilla	0	0	0	0	0	0
Antigua & Barbuda	1	1	0	0	0	0
Argentina	579	578	0	0	0	0
Bahamas	4	4	0	0	0	0
Barbados	4	4	0	0	0	0
Belize	43	43	0	0	0	0
Bermuda	0	0	0	0	0	
Bolivia	574	574	0	0	0	0
Brazil	18838	18729	0	2	2*	1*
British Virgin Islands	1	1	0	0	0	0
Canada	15	0	0	15	15*	6*
Cayman Islands	0	0	0	0	0	0
Chile	244	243	0	1	1*	0
Colombia	2107	2107	0	0	0	139**
Costa Rica	24	23	0	1	1*	0
Cuba	1093	1055	0	0	0	0
Dominica	0	0	0	0	0	0
Dominican Republic	604	604	0	0	0	0
Ecuador	462	462	0	0	0	0
El Salvador	251	251	0	0	0	0
French Guiana	18	18	0	0	0	
Grenada	2	2	0	0	0	0
Guadeloupe				-		-
Guatemala	603	603	0	0	0	0
Guyana	43	43	0	0	0	0
Haiti	22	22	0	0	0	0
Honduras	332	332	0	0	0	0
Jamaica	195	195	0	0	0	0
						-
Martinique		4156	0	44	 44*	0
Mexico Montserrat	4200	4156	0	0	0	0
Netherlands Antilles	0	0	0	0	0	
	354	354	0	0	0	0
Nicaragua				-	-	-
Panama	237	237	0	0	0	0
Paraguay	423	423	0	0	0	0
Peru	1580	1580	0	0	0	0
Puerto Rico	0	0	0	0	0	0
St. Kitts & Nevis	0	0	0	0	0	0
St. Lucia	3	3	0	0	0	0
St. Vincent & Grenadines	2	2	0	0	0	0
Suriname	21	21	0	0	0	0
Trinidad & Tobago	25	25	0	0	0	0
Turks & Caicos	2	2	0	0	0	0
U.S. Virgin Islands	0	0	0	0	0	
United States	49	7	0	42	42†	41§
Uruguay	2	2	0	0	0	0
Venezuela	1809	1809	0	0	0	2392
TOTAL	34766	34514	0	105	105	2579

... No information provided

† Of which 11 cases are imported

* Due to importation

** Of which 53 cases are imported

§ Of which 17 cases are imported

Updated: 13 July 2004

Source: MESS-FCH/IM except for Brazil, Canada, Costa Rica, Cuba, and USA

(continued from page 5)

The UNION supports WHO's recommendation and agrees that no data exist to justify additional doses of BCG to control severe tuberculosis (as stated previously, it may be effective for leprosy). The UNION position is that "There is no evidence that this increases protection against tuberculosis.... Re-vaccination schemes often fall into the lowest tuberculosis risk period in life (age 5-14 years) and target a population where protection from BCG vaccination is dubious or variable at best."

This is an important programmatic point. As pointed out by the UNION the absence of data on booster doses of BCG does not imply a true lack of effectiveness or efficacy. But regardless, even if a study showed efficacy, it would not be effective since so few of infected children who subsequently developed severe disease get their initial infection during the period from 5-15 years of age. Most children who get severe tuberculosis that EPI programs hope to prevent with BCG vaccination become infected in the first years of life. Vaccination (primary or secondary) at later ages may not be effective programmatically. Or, as the UNION states "Re-vaccination at school entry is likely to be inefficient (even if it were efficacious) because it falls into the period of life when the risk of TB is lowest".

The use of alternative schedules by some countries in the Americas (and in other Regions) may be related to changes in WHO recommendations as more information was collected and added to the body of the scientific literature over the years. For example, a 1964 WHO recommendation states that "the second vaccination coverage should take place before the school-leaving age (12-15 years)." The 1974 WHO recommendation also alluded to revaccination of school children and those who did not respond to the first dose. In 1980, when most countries had already initiated national EPI programs. a WHO Study Group recommended that in countries with high prevalence, BCG should be administered "as early in life as possible." However, they also recommended that the target age group for BCG vaccination should be determined by the epidemiologic situation in the country. WHO's 1995 recommendation against revaccination was reiterated by

WHO in 2001.⁷ Furthermore, some countries may opt to use a 2-dose BCG schedule to impact on the epidemiology of leprosy. PAHO recommends that all countries examine their BCG schedules to ensure that they follow recommended guidelines.

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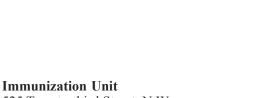
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