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### Case Study of the Access to the Bacillus Calmette-Guérin Vaccine against Tuberculosis in the United States

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#### **ABSTRACT**

Bacillus Calmette-Guérin (BCG) is a vaccine that is used worldwide to prevent tuberculosis. Some developed countries, such as the United States, do not routinely administer this vaccine. This article presents the case study of a family who struggled to obtain the BCG in the months before a planned trip to a country in which tuberculosis is prevalent. The application of the BCG vaccination and its availability in the United States, particularly for children, is discussed.

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#### **CASE REPORT (2008)**

A couple residing in Port Orange, Florida, USA, planned to take their young child to visit Bangladesh, where tuberculosis is prevalent. The parents believed that the Bacillus Calmette-Guérin (BCG) vaccine would be routinely administered to their child because it is commonly provided to all newborns in many parts of the world. At the age of 22 months, she had not received a BCG vaccination, despite the efforts of her parents to try to obtain one for her. Concerned that the child would be exposed to tuberculosis during the family's month-long trip, they asked their family practice physician for a BCG vaccination during well-child visits and at other immunizations. The physician was hesitant, because the BCG vaccine is not generally given to children in the United States, but requested a BCG vaccine from the Centers for Disease Control and Prevention.

The vaccine was obtained after 8 months. The tuberculin syringe specific for BCG vaccination was not available at the well-child clinic, and the child was inoculated by a nurse with no experience in administering the BCG vaccine. The BCG vaccine is typically administered in a highly specific manner, intradermally over the deltoid muscle, by a trained specialist. In this family's case, the vaccine was administered via multiple punctures of the skin on the anterolateral aspect of the left thigh. There was no immediate or delayed skin reaction at the vaccination site. The physician advised that a tuberculin sensitivity test (Mantoux test) be performed on the child after 2 to 3 months to confirm reactivity.

No reaction was observed with the tuberculin sensitivity test. The physician advised a repeat BCG vaccination. The child's parents consulted a pediatrician at a different facility who thought he could more easily obtain the BCG vaccine. However, this was not the case, and the pediatrician advised the parents to get the child inoculated in the country of travel. The initial physician, at the family practice office, also found himself unable to obtain the vaccine; he stated that it would take several months to get additional vaccine. In response to their inability to obtain a second vaccine, the family decided to postpone their trip for 6 months.

## OVERVIEW

Tuberculosis is an infectious disease caused by the bacterium *Mycobacterium tuberculosis*. Infection via contaminated droplets is the typical mode of transmission. It also may be transmitted in unpasteurized milk. Tuberculosis is prevalent in third-world countries, where overcrowding and poor sanitation are common.

Bacillus Calmette-Guérin is a vaccine for preventing tuberculosis. It is provided to newborns in more than 100 countries with a high prevalence of tuberculosis to prevent childhood tuberculosis, tubercular meningitis, and miliary tuberculosis.<sup>1</sup> According to the Center for Disease Control Website, "Bacillus Calmette-Guérin vaccination is not generally administered in the United States because of the low prevalence of tuberculosis, the variable effectiveness of the vaccine against adult pulmonary tuberculosis, and the vaccine's potential interference with the tuberculin sensitivity test. Bacillus Calmette-Guérin vaccination is advised only for specific individuals who meet certain criteria that places them at greater risk for infection, and on the recommendation of a tuberculosis specialist."<sup>2</sup>

## EPIDEMIOLOGY

Infection by the *M. tuberculosis* bacterium is estimated to result in 8.3 million new cases of tuberculosis and approximately 2 million deaths worldwide annually, making it the second leading cause of death from infectious disease in the world.<sup>3</sup> From 1985 to 1994, the number of tuberculosis cases in the United States among children younger than 15 years of age increased 33%, from 1257 to 1675 cases, and the total number of cases increased 18%, from 2.42 to 2.85 per 100,000 in the population.<sup>4</sup> More than 14,000 cases were reported in the United States in 2005. The increasing number of children with tuberculosis in the United States suggests the continuing spread of *M. tuberculosis* within American communities, and indicates a need for assertive monitoring of children in contact with infected adults. The large increase in cases among minorities and foreign-born individuals emphasizes the need to target prevention and control activities to these groups.<sup>5</sup>

The Centers for Disease Control and Prevention recommends that the BCG vaccination should be administered only to children who have a negative tuberculin sensitivity test and are persistently exposed to, and cannot be isolated from, adults who are untreated or unsuccessfully treated for tuberculosis, or who have tuberculosis caused by drug-resistant strains of *M. tuberculosis*.<sup>6</sup>

## DISCUSSION

It is difficult to identify individuals who are untreated or ineffectively treated for tuberculosis, particularly in third-world countries. Many individuals do not know they are infected and may consequently go on to infect others. Many who do know they are infected feel stigmatized and hide the fact that they have the disease. Tuberculosis can be contracted during airplane trips as well as at supermarkets, hotels, and other places where people congregate. A significant number of people infected with TB are identified during chest radiographs, prescribed for reasons unrelated to TB. The current World Health Organization recommendation for treatment of TB is a 6-month regimen of multiple oral medications. However, many infected individuals do not take their medications, in part, perhaps, because it can be prohibitively expensive, yet, many patients are unaware that government subsidies of tuberculosis medications exist.

On average, BCG vaccine decreases the risk of TB by 50%. The vaccine has a higher rate of success in safeguarding against tuberculosis death, meningitis, and disseminated disease than it does for total TB cases.<sup>7</sup> A 60-year follow-up study of continuing efficacy of the BCG vaccine in American Indians and Alaska Natives revealed that the usefulness of BCG vaccine continued for 50 to 60 years.<sup>8</sup> In the United States, BCG is not generally recommended for use because TB is not prevalent in the population, and the possibilities are small that infants and young children will become exposed. Another rationale for the limited availability of the vaccine is that the vaccine causes an individual to develop TB antibodies, thus causing them to have future positive results on tuberculin skin tests. Thus, while the TB skin test is the best existing test for TB infection, extensive use of the BCG vaccine would make the skin test significantly less useful.<sup>9</sup>

The BCG vaccine has been available since the 1950s. Various health care entities have differing strategies with respect to the timing of the BCG vaccination. Some vaccinate babies a few days after birth; others only inoculate high-risk groups, for example, children who live in households in which a member of the family has tuberculosis.

The BCG vaccine is administered as a single intradermal injection over the deltoid muscle. It is administered via a 1.0-mL syringe with a 26-gauge needle with the beveled side facing upwards. The suggested dose is 0.05 mL (0.05 mg) for children younger than 12 months of age. The dose is 0.1 mL (0.1 mg) for individuals older than 12 months of age. Unfortunately, administration in the present case was at a different site, with a different technique, and at an undetermined dose. In some countries (e.g., Peru, Mongolia, Turkey and Persian Gulf States) BCG is given to the same person several times in an effort to

maintain optimum immunity to TB. Reimmunization with BCG is not advised in other countries.<sup>10</sup> There is no evidence that reimmunization provides additional protection; large studies of Japanese school children suggest it provides no safeguard.<sup>11</sup> Because of the lack of evidence for protection, the World Health Organization does not support reimmunization.<sup>12</sup>

## CONCLUSIONS

It is currently difficult to obtain BCG vaccine in the United States. The vaccine has specific administration requirements, and many medical professionals are not familiar with these requirements. The increasing prevalence of tuberculosis in global travel necessitates a better understanding of the BCG vaccine. General practitioners should be able to communicate with their patients the indications, as well as the benefits and risks, of the vaccine.

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