

## Bacillus Calmett-Guerin (BCG) Vaccination “An Overview from Saudi Arabia”

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### Opinion

Since the discovery of the Tubercle bacillus” by Robert Koch on 24<sup>th</sup> March 1882 [1-3], the Mycobacterium tuberculosis infection is still an important and a serious health problem in many developing countries [4-7]. Nearly 8.7 million persons in the world contract the disease annually and about 1.4 million of them die [8]. It is probably one of biggest cause of death by a single pathogen which can be avoided in more than one-quarter of the deaths.

Despite the great progress in tuberculosis (TB) control and treatment the incidence and prevalence of TB are still high in many developing countries. Kingdom Saudi Arabia was classified to be among the middle prevalence countries [9-11]. The incidence rate of TB estimated by tuberculin testing in the developing countries even in the absence of reliable data, ranged between 2-3% which is about 20-50 times greater than that in the developed countries [12]. The incidence of TB in KSA as reported by the World Health Organization was 18/100,000 in 2012 [9].

TB infection is expected to increase more in the developing countries because of high prevalence of Human Immunodeficiency Virus Infection<sup>5</sup> and presence of drug resistant Mycobacteria [13]. Other reasons include difficulties in developing effective health services and the considerable population growth that does not match the growth in social and health services [14].

Bacillus Calmett-Guerin (BCG) vaccine is an attenuated strain of the bovine bacillus; developed by Calmette and Guerin in 1908 [15-17] and the first human being inoculated with BCG was in 1921 [16-19].

Currently, there are three vaccination policies in the world [20]. The first of these is to give BCG vaccination immediately after birth without future booster (which is adopted in KSA) or with one or two revaccinations during the childhood. The second policy is to offer a single dose of BCG vaccination through a campaign to all eligible individuals in that country. The last one is to administer BCG at birth followed by continuous and sustained revaccination of tuberculin negative children until adulthood.

The choice between these policies depends on the prevalence of tuberculosis and Mycobacteria other than Mycobacterium tuberculosis, the economic status of that county, the incidence of BCG complication (such as Lymphadenitis & osteomyelitis), and the malpractice error which may give rise to medical and social problems [20]. An example of such errors was the disaster of Lubeck in Germany in 1929-1930 were 72 out of 250 vaccinated children died because of BCG was contaminated with the virulent kiel strain by professional malpractice [20,21].

In 1976 in the Kingdom of Saudi Arabia (KSA) only 4.0% of the immunized individuals had BCG vaccination [22]. The BCG coverage for the one year aged Saudi children was 49% in 1981, [23] 66% in

1986 [24] and increased to 99% in 1986 [24]. Moreover, in the age group 1-2 years it was reported to be 88% in 1985 [25] and increased to 99% in 1991 [26]. This increase in the rate of immunization can be ascribed primarily to the April 1979, Royal Decree [25,27]. The decree states that birth certificate should not be released by the authorities until the completion of the prescribed immunizations against tuberculosis, diphtheria, tetanus and poliomyelitis.

In KSA, BCG vaccination was included in the expanded programme on Immunization since April, 1979 and is offered soon after birth and up to four weeks of age [25,27]. The dose of BCG is 0.05ml for infants and 0.1mg for children [7]. But the policy in the KSA is to give 0.05ml from birth up to four (4) weeks of age and 0.1ml for those above four (4) weeks [27].

The reduction of BCG vaccination dose in infant in order to avoid high incidence of post BCG vaccine complication (such as lymphadenitis) may result in a decrease of the immunological response in this age group [28]. This makes it necessary to revaccinate at school age.

The epidemiological studies conducted in KSA recommended BCG vaccination at birth and revaccination at school leaving age [29-33]. The different authors in these studies used different does of tuberculin test and therefore their results cannot be compared with one another. All these studies had a cross-sectional epidemiologic design for evaluating the prevalence of positive of Mantoux reactions. The use of a prospective or case control approach might be more desirable [34] and can give more sensitive results and conclusion. However, these recommendations were not implemented until dated.

According to a number of prospective and case-control studies from both the developed and developing countries and indeed since 1930 the effectiveness of BCG vaccination was reported to range from 0-80% [21,35,36]. John et al. [37] reviewed eight major controlled trials of BCG vaccination against tuberculosis, namely the North American, Indians, Chicago, Georgia, Puerto Rico, Georgia-Alabama, England, Madanapalla, and Chingleput trials. The results suggested that some of these trials (North American, Indians, Chicago, and England) had a good methodological quality and a precise statistical analysis. BCG vaccination was reported in these studies to confer a high degree of protection against tuberculosis.

BCG vaccination effectiveness as 80% was reported by the British Medical Research Council after conducting one of the most carefully designed trials in England [21]. The controlled trial carried in Madras, South India, showed that BCG vaccination has no efficacy in protection against tuberculosis [35-36]. But the South India study was found not to be well designed and the accuracy of its results was accordingly doubted [38].

The reasons for the variation in the effectiveness of BCG vaccination against tuberculosis could be due to one or a combination of the following; the use of different BCG strains, the infection with Mycobacteria other than Mycobacterium tuberculosis, differences in the susceptibility, and the nutritional status of the examined populations [5].

In order to ensure a high rate of effectiveness of the current TB control in the KSA the continuation of the current policy of BCG Vaccination given at birth at the KSA is still recommended with more efforts to increase the awareness for the community and the Health Care personnel towards the importance of TB prevention; National Standardization of TB management guidelines for early case detection, prevention, curative, and rehabilitation; as well as unification of electronic reporting system is highly required [39].

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