

E: BCG VACCINE TRIAL

187 GVI Baily: THE EFFICACY OF BCG VACCINATION - A BRIEF REPORT OF THE CHINGLEPUT BCG TRIAL
NTI Newsletter 1980, 17, 108-18.

Even though BCG has been in use for last 60 years, it has always been the subject of controversy, as several scientific studies done all over the world showed the **protective value of BCG** varying from **0 percent to 80**. Because of the controversy over its protective effect and its extensive use in India it was felt necessary to undertake further field trials, wherein all shortcomings of previous trials could be eliminated. The Government of India took the decision to undertake a BCG trial in India. In 1968, the study was carried out in Chingleput district in Tamil Nadu, where **no BCG vaccination** was previously offered. The objective of the study were to obtain i) precise estimate of **the protective effect of BCG** vaccination against tuberculosis in the non infected, ii) effect of BCG vaccination in persons already infected and iii) protective effect of different strains of BCG and iv) epidemiological data on tuberculosis in the community. The entire population of **3,60,000 persons** were registered during a period of two and a half years of intake. All the persons aged one month and above were randomly divided into three main groups.

One group vaccinated with the **Madras vaccine**, the second with **Paris vaccine** and the third with **Placebo**. At the same time all persons were tested with tuberculin, those above 10 years and above were X-rayed and those having X-ray shadows were examined by direct smear and culture. The study population was systematically and intensively followed up by X-ray and sputum examinations to diagnose all the new cases occurring in the community. The protective effect of BCG vaccination is defined as the proportionate reduction in the occurrence of new cases among the vaccinated, initially tuberculin negatives as compared to a similar but unvaccinated group. The protective effect was studied among individuals who were not previously infected, who had no tuberculosis at the time of vaccination and who were either vaccinated or left unvaccinated. The results of **7½ years of follow up** showed that the number of new cases that occurred among the group vaccinated by either of the vaccines or from the unvaccinated group were similar. This showed that **BCG vaccination did not offer any protection against tuberculosis of the lung**. The epidemiological characteristics of the population were high prevalence and incidence of tuberculosis infection and disease and high prevalence of non specific sensitivity. The risk of manifest disease for this recently infected was relatively small, as most of the new cases occurred among those who were tuberculin positive at the time of intake and not from those who were not infected then. **Implications:** Several expert committees appointed both by the authorities in India and by the WHO have examined all the procedures followed up in the study and came to the conclusion

that the study had been meticulously carried out and vaccine used in the trial were the best available ones. The implications of this study was 'should BCG vaccination be given up in India?' Yet another committee appointed jointly by ICMR and the WHO went into the epidemiological aspects of the causation of tuberculosis under Indian conditions and concluded that BCG may not protect against tuberculosis of lung which occurs mostly in adults; it **could provide substantial protection against childhood form of tuberculosis** such as tubercular meningitis, tuberculosis of bones & joints etc. The protective effect of BCG against these forms of tuberculosis was not studied in Chingleput Trial. In India BCG vaccination is recommended to be given at an early age preferably before the end of the first year after birth.

KEY WORDS: EFFICACY, BCG VACCINE, MADRAS VACCINE, FRENCH VACCINE, CHINGLEPUT BCG TRIAL.