section was intimated for suitable action.

The budget allotted was also limited and the SRC had to plan team visits frugally. Therefore, Dr Arora had to study all the reports and arrange the teams itinerary so as to visit the ailing DTCs on priority or where the teams' personal guidance would be most useful. Sometimes, he would split the team into two so that more DTCs were covered by personal visits. During the visits, the team worked systematically, and even visited far flung PHIs to get the first hand knowledge of its working and problems. They offered solutions wherever possible and made lists of the unresolved ones. These were presented to the STO at the state headquarters. The teams also took note of a host of new ideas of a minor nature. These were brought to the notice of NTI for further discussions. If valid, these were kept in reserve to be included in the concerned manuals when revision took place. Till he attained superannuation, Dr Arora worked tirelessly. Like majority of the Central Health Services (CHS) MOs in those days,

he too retired without getting a single promotion. Thanks to Tikku Commission; today the MOs have time bound promotions. During his tenure he was in touch with every DTC under his charge either through correspondence or personal visits. He gathered voluminous data continuously some of which were fit for scrutiny and incorporation when the manuals were revised.

## 3.6. Milestones in BCG work

From 1951 onwards, India was covered by the BCG Mass Campaign. Approximately 170 (more than 190 at times) full-fledged teams, toured the country setting up BCG vaccination centres in both rural and urban parts, offering BCG vaccination to all. It was the first organised effort outside Europe and was the biggest campaign undertaken by any country in medical history. Even though jeeps were provided, it was to the credit of the teams that they set up camps in so many inaccessible places. India's vast network of rural areas had no pliable roads. Sometimes, even bigger towns could be reached



Dr. Kul Bhushan BCG Research officer,

with great difficulty. Infrastructure like lodges and hostels was inadequate.

Added to these difficulties was the cumbersome two step procedure of the vaccination itself: every one had to receive a pre-vaccination tuberculin test with 5TU PPD RT22 batch of the tuberculin, come back for tuberculin reaction measurement three to four days later and if her/his reaction was less than 8 mm in size, she/he would become eligible to receive BCG vaccination. The teams tuberculin tested 165 million and vaccinated 65 million<sup>56</sup>. In 1964, as Dr Kul Bhushan recalls in "My experiences of Mass BCG Vaccination ".....Combined efforts of



Dr. Pyarelal, Medical Officer Awarded gold medal for eradication of last case of Smallpox in India

the teams...helped the campaign .... I saw dedicated workers busy for 18 hours a day....I have known one who slept 16 hours a day and divided the remaining eight hours, judiciously into bits of two hours each between dressing, getting ready for the day's work, sipping tea, meeting friends and taking well earned rest and food! I cannot forget the technician whose woolen suits served as a mobile refrigerator for the vaccine.... Those who walked 8-10 miles a day to cover houses in hilly areas testing small two digit figures.... It was a pleasure to see systematic coverage of areas in some states... . In a few others...it was not so... I was disappointed to see teams leaving vast areas uncovered.... I realised how easy it is to convince the public but not administrators"57...



BCG Mass Campaign team at work

Besides conferring the benefits of BCG vaccination, the campaign produced a wealth of data on the tuberculin sensitivity patterns prevalent in the country and indicated the hitherto unsuspected extent of the TB burden. There was an additional benefit as pointed out by Dr Benjamin. Besides making BCG available to anyone residing anywhere in the country either urban or rural, it also served as the biggest ever health education programme undertaken anywhere in the world. The masses of India became aware that the utilities provided by the Department of Health that could be used by them gratis<sup>56</sup>.

However, an assessment of the campaign's methodology had to be made because of three major reasons. First, the teams had no option but to set up vaccination centres in some central place. announcements Despite and propaganda for people to avail of the facility, it was obvious that only action takers came to the centre. That left a large proportion of people uncovered. Second, the screening tuberculin test proved to be a deterrent. Because of fear of two pricks, absenteeism increased. It is not strange for people to question receiving two pricks for the same disease that they are not suffering from. The third was a technical



Mr. Vijay Singh, BCG Team Leader



BCG given by Multi Purpose Workers (MPWs) at Health Centres



A milestone in Campaign's History VI All India BCG Workers Conference at Bangalore on 13-14th Jan 1962 Benjamin addressing the delegates

one. Evidence from the earlier campaigns indicated that a majority of people over 20 years of age were tuberculin positive and therefore, ineligible for vaccination. About 97% of children (0-9 years) were tuberculin negative. The teams, therefore, were burdened with a lot of redundant work. It would be beneficial to restrict BCG to 0-19 years<sup>58</sup>.

The NTI studied these problem areas systematically. The 6th All India BCG Workers' Conference was held on January 13th and 14th, 1962, at the NTI premises. Over 100 delegates from various states attended. Doctors D'Silva (UNICEF) RH Bland (WHO) also and attended and represented their organisations. Dr PV Benjamin presided. Among others, Drs GVJ Baily and Kul Bhushan of NTI presented papers. Based on the NTI studies on door-to-door BCG vaccination, Dr Baily pointed out that the coverage of vaccination improved (up to 8%) by adopting house-to-house vaccination strategy. However, the procedure was slow and the output of work would be low due to time taken up

in registration of every individual of the household. Instead the team visits could be utilised as part of the DTP (such as assisting in diagnosing TB cases)<sup>56</sup>. Presenting his paper on freeze-dried BCG vaccine produced at Guindy Laboratory in Madras, Dr Kul Bhushan stated that though liquid vaccine produced slightly higher allergy than the freeze-dried vaccine, the level achieved by the latter was guite adequate. Further studies would be undertaken to assess the qualities of the Madras vaccine, as it was new<sup>59</sup>.

This led the GOI to create a DTC in each of the 318 districts. Based on the recommendations given by the conference, the GOI suggested integration of the BCG campaign with DTC. The conference was the most significant held so far. Firstly, because of the discussion regarding integration of the campaign with the GHS. Secondly, because of the presence of administrative MOs. Thirdly, because decision was taken to introduce house to house vaccination campaign during the Third Five Year Plan. Ultimately, in 1978 the BCG campaign was

integrated with GHS and became part of Universal Immunization Programme (UIP).

In 1964, Gothi found that BCG vaccination could be given directly without tuberculin test. There were not many large or untoward reactions to BCG<sup>60</sup>. In 1965, Dr Kul Bhushan suggested that direct vaccination in 0-20 year age group could be carried out because it was the most vulnerable<sup>61</sup>. There were added advantages gained over the mass campaign method in terms of systematic coverage and proper record keeping. In accordance with these findings and studies, a manual for BCG workers was prepared and field tested. By 1966, 44 of the 189 BCG teams were integrated with the DTCs and gave satisfactory outputs.

However, another issue arose. Would there be any immunological interferences especially among children below one year, because they would be receiving both BCG and smallpox vaccinations? Dr Kul Bhushan found no evidence of immunological interference between the two vaccines

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even when administered simultaneously. Surprisingly, the acceptability of the simultaneous procedure was higher than when BCG was given alone<sup>61</sup>. By the time this scheme could be fully implemented the smallpox vaccination was discontinued, as it got eradicated in 1975.

In 1973, Baily literally wound up the mass campaign approach by making the PHC personnel like Auxiliary Nurse Midwives (ANMs) and Basic Health Workers (BHWs) responsible. They would give BCG to new borns in their areas by vaccinating them once a month in nearby sub-centres. This had great operational advantages besides reducing vaccine wastage<sup>62</sup>.

Another problem emerged following the introduction of direct BCG vaccination. As the coverage of BCG vaccination increased in the population, tuberculin surveys would be progressively rendered difficult. One may not obtain sufficient number of unvaccinated persons to represent the population to carry out tuberculin surveys for assessing the prevalence of infection. Are there ways in which information of prevalence of infection could be elicited from BCG vaccinated persons? For e.g., could BCG vaccination induration size be used as an indicator of infection with M.tb? In 1974, Gothi and others presented a paper showing that vaccination induration could be used as an indicator of tuberculous infection. Vaccination induration of 14 mm or more on fifth or sixth day appeared to be the best criterion for demarcating the infected from the non-infected. Even though there were other choices, e.g., 12 mm or 14 mm on second day etc., the choice of 14 mm on fifth or sixth day of vaccination satisfactorily demarcated persons infected with *M.tb* from those non-infected<sup>63</sup>.

Under Dr Kul Bhushan, the All India BCG Assessment Team was instituted for assessment work of the mass BCG teams in different parts of the country. The team was small and had to tour extensively in the most adverse conditions. During the days of the steam engine, it would take three days for the team to reach a city or town in Rajasthan from Bangalore. From there, the team had to reach its destination on whatever transport provided by the state government. It had the additional task of retesting groups of population vaccinated with two BCG vaccine strains: the Madras freeze dried vaccine and the Japan freeze dried (glutamate) vaccine. For the BCG vaccine laboratory, Guindy, it had to carry out a comparison of stock solutions of RT22 and 23 batches of tuberculins. It is to the credit of this small team that it conducted the two studies among 5-16 year old school children in West Bengal. The study was inconclusive but indicated that the increase in the storage temperature resulted in the higher loss of potency of the vaccines<sup>59</sup>. In addition, Dr Raj Narain and others had also taken up the task of comparing the allergy producing capacity of the Madras and Danish BCG vaccines. They found that the allergy producing capacity of both the vaccines was not different<sup>64</sup>.

## **3.6.1. Controlled clinical trial** for efficacy of BCG vaccine

NTI was also concerned with the efficacy of the BCG vaccine itself. BCG vaccination was the only available protective measure against TB. Different trials had not revealed credible proofs quantifying its efficacy. Many, including late Sri C Rajagopalachari even thought that its efficacy was not fully proven and strongly advocated against its continued large scale use. It would be in the interest of the country to undertake a well designed trial to seek clear answers to the major issues Therefore, confronting it. as stated earlier in Chapter 2, the NTI had been vigorously planning to conduct a major BCG trial and had even reserved certain areas in the country as vaccination free zones. was in touch with the It international scientific community, various vaccine production centres and experts in the field. In January 1964, it initiated intensive discussions with the WHO experts and representatives from United States Public Health Service (USPHS). It was agreed that any

trial undertaken must not interfere with the progress of NTI and NTP; and because such a trial was expensive and prolonged, it would have to be designed with utmost care and efficiency.

After extensive discussions, the USPHS agreed to give a grant from the PL480 funds in India. WHO agreed to provide the services of Dr J Guld and some funds. The NTI decided to spare the services of Dr Raj Narain as its first Project Director; experienced field supervisors, investigators and provide other key staff requirements; office

accommodation; transport and some equipment so that this important work could begin immediately<sup>65</sup>. Dr Guld began his regular visits to NTI and started several BCG vaccine and tuberculin related studies: effects of diluents, sterilising agents, ampoule to ampoule variations in the potency of tuberculin dilutions; comparative studies of different antigens and BCG vaccine different strains. Besides Dr Guld, Dr G etc. Weijsmuller and others from USPHS visited the NTI and started several feasibility studies.

Ultimately, the project named



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Feasibility Prevention Trial (Chingleput BCG Trial Team) with Drs Raj Narain & Guld taken at NTI, in November 1967

Feasibility Study for ТΒ Prevention Trials became part of the ICMR and moved out of the campus to its own building<sup>65</sup>. In time, its studies showed that the major BCG trial would be best if conducted in Chingleput district of Tamil Nadu than in other areas reserved for the purpose. Field work began and the office was moved to Madras. In spite of shifting of the project camp to Madras, NTI continued to assist the BCG Trial by providing technical guidance and replacement of staff. When Dr Raj Narain retired, Dr Baily joined as the Director of this study and continued to serve till the first report was published<sup>66</sup>.

The BCG trial was completed as scheduled. After a period of twelve and a half years, it brought out a revolutionary report. It showed that BCG vaccination did not offer any protection against TB of the lung. Several expert committees appointed both by the authorities in India and by the WHO 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<sup>66</sup>. The implications of this study was: Should BCG vaccination be given up in India? Another committee appointed jointly by ICMR and the WHO went into the epidemiological aspects of the causation of TB under Indian conditions. It concluded that though BCG may not protect against TB of lung which occurs mostly in adults, it could provide substantial protection against childhood forms of TB such as tubercular meningitis, TB of bones and joints, etc. The protective effect of BCG against these forms of TB was not studied in Chingleput Trial. In India BCG vaccination policy was revised and it was recommended to be given at an early age preferably before the end of the first year after birth by integrating under UIP<sup>67</sup>. BCG vaccination policies in other countries were also revised as a consequence of the Chingleput study findings.

## **3.7. Expanding horizons of research**

A careful review of Annexure II would surprise scholars of any

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