



Ministry of Health & Family Welfare
Government of India



Standard Operating Procedures for Adult BCG Vaccination under programmatic implementation study in India





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List of abbreviations

ABDM	Ayushman Bharat Digital Mission
ACSM	Advocacy Communication and Social Mobilization
AD	Auto Disabled
AEFI	Adverse Effect Following Immunization
ANM	Auxiliary Nurse Midwife
API	Application Programming Interface
ART	Antiretroviral Therapy
ASHA	Accredited Social Health Activist
ATT	Anti-Tuberculosis Treatment
AVD	Alternate Vaccine Delivery
AWW	Anganwadi Worker
BCG	Bacillus Calmette–Guerin
BDO	Block Development Officer
BMI	Body Mass Index
BMO	Block Medical Officer
BMW	Bio Medical Waste
CBAC	Community Based Assessment Checklist
CCH	Cold Chain Handler
CCP	Cold Chain Point
CHC	Community Health Centre
CHO	Community Health officer
CPCB	Central Pollution Control Board
CS	Civil Surgeon
CTD	Central TB Division
DCGI	Drug Control General of India
DHO	District Health Officer
DHR	Directorate of Health Research
DIO	District Immunization Officer
DMHO	District Medical Health Officer
DPM	District Program Manager
DPT	Diphtheria Pertussis Tetanus
DRTB	Drug Resistant TB
DSTB	Drug Sensitive TB
DTF	District Task Force
DTFI	District Task Force for Immunization
DTO	District TB Officer
DVS	District Vaccine Store
EPI	Expanded Programme of Immunization
FAQ	Frequently Asked Questions

HCW	Health Care Worker
HHC	Household Contact
HIV	Human Immunodeficiency Virus
HWC	Health and Wellness Centre
IAP	Indian Association of Paediatrics
ICDS	Integrated Child Development Scheme
ICMR	Indian Council of Medical Research
ID	Intra Dermal
IEC	Information Education Communication
IGRA	The Interferon Gamma Release Assay
ILR	Ice Lined Refrigerator
IMI	Intensified Mission Indradhanush
IV	Intra Venous
JSI	John Snow India Pvt Ltd
LHV	Lady Health Visitor
LWE	Left Wing Extremist insurgency
MLA	Member of Legislative Assembly
MLC	Member of Legislative Council
MNREGA	Mahatma Gandhi National Rural Employment Guarantee Scheme
MO	Medical Officer
MOHFW	Ministry of Health and Family Welfare
NCCMIS	National Cold Chain Management Information System
NGO	Non profile Organization
NHM	National Health Mission
NIRT	National Institute for Research in Tuberculosis
NPSN	National Public Health Surveillance Network
NTEP	National Tuberculosis Elimination Programme
OG	Operational Guidelines
OPV	Oral Polio Vaccine
PHC	Primary Health Care
PHI	Public Health Institute
PLHIV	People Living with HIV
PMTBMBA	Pradhan Mantri TB Mukh Bharat Abhiyaan
PPM	Public Private Mix
PRI	Panchayat Raj Institute
PSU	Public Sector Undertaking
RGI	Registrar General of India
RI	Routine Immunization
RNTCP	Revised National Tuberculosis Control Program
SDG	Sustainable Development Goals
SHS	State Health Society
SIO	State Immunization Officer

SOP	Standard Operating Procedure
STDC	State Training and Demonstration Centre
STFI	State Task Force for Immunization
STO	State TB Officer
STS	Senior Treatment Supervisor
TPT	Tuberculosis Preventive Treatment
UIP	Universal Immunization Program
UNDP	United Nations Development Programme
USHA	Urban Social Health Activist
VHND	Village Health and Nutrition Day
WMF	Wastage Multiplication Factor
VVM	Vaccine Vial Monitor
WHO	World Health Organization



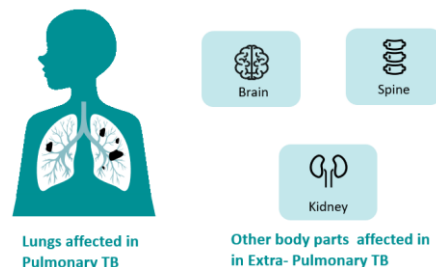
Chapter: 1

Tuberculosis

1.1 Tuberculosis

Tuberculosis (TB) is an infectious disease caused by *Mycobacterium Tuberculosis*. It is mostly transmitted by inhalation of infected droplet nuclei which are discharged in the air when a patient with untreated TB coughs or sneezes.

TB usually affects the lungs i.e., pulmonary TB, but it can also affect other parts of the body (extra-pulmonary TB), such as the brain, the kidneys, the spine, etc.



Although TB is an infectious disease, all forms of TB are not infectious such as extra-pulmonary TB and latent TB. When a microbiologically confirmed pulmonary TB patient coughs or sneezes, TB bacteria spread into the air as droplets. People nearby may inhale these bacteria and get infected. TB does not spread through handshakes, using public toilets, sharing food and utensils, blood transfusion, and casual contact.

Anyone can be affected by TB but there are few conditions that increase the likelihood of developing active TB disease. These include close contact with a person with pulmonary TB, living in an overcrowded environment, smoking, HIV infection, malnutrition, diabetes patients, patients on immunosuppressive drugs (anti-cancer, corticosteroids etc.), people with certain lung diseases like silicosis which causes scarring of the lungs and elderly population aged 60 years and above¹.

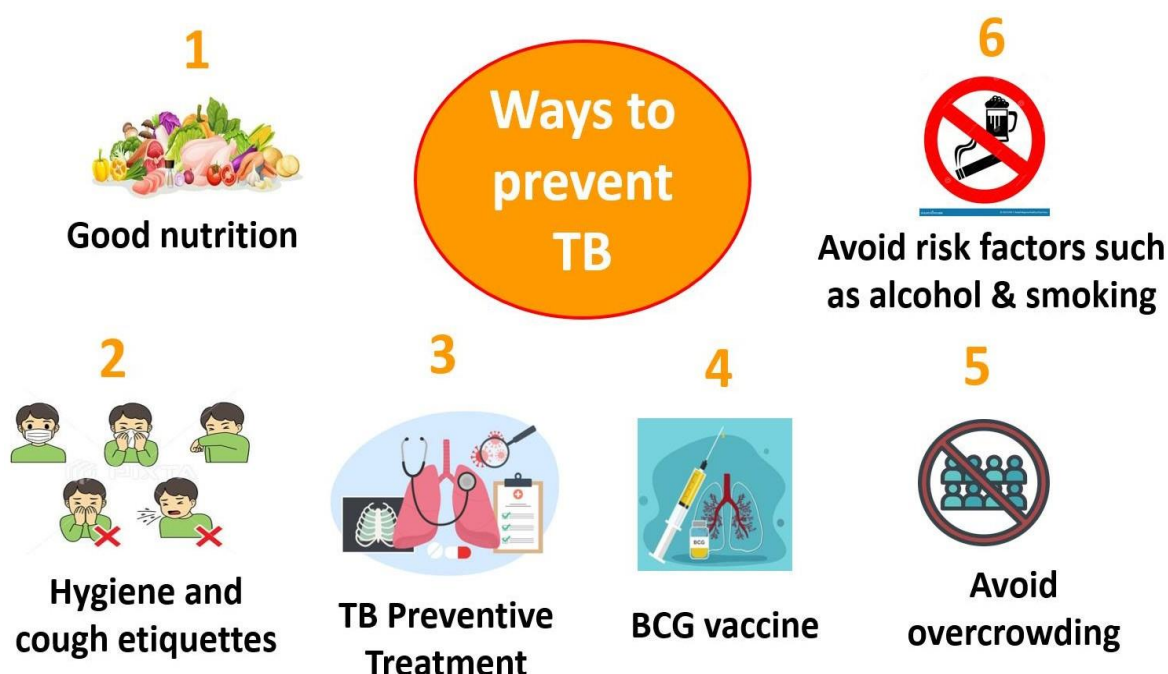
1.2 TB disease burden and financial implications

2022 marks a milestone year for TB surveillance efforts in India, with notification of 24.2 Lakh cases translating to a case notification rate of approximately 172 cases per lakh population. As per India TB report 2022, the estimated point prevalence of microbiologically confirmed pulmonary TB among persons aged more than 15 years was 316 per lakh population at national level².

The disease disproportionately affects the households with low socio-economic status adding to a financial burden on them, thereby resulting in detrimental effects like delayed care seeking, inadequate adherence and poor treatment outcomes.

1.3 TB disease prevention strategies:

- Maintaining good nutrition and hygiene, avoiding overcrowding, covering mouth and nose while coughing, sneezing etc are proven effective measures to reduce spread of TB infection.
- The most promising way to prevent TB is by early detection and treatment of infected TB patients.
- Tuberculosis Preventive Treatment (TPT) is offered in the community to contacts of positive pulmonary TB patients and to select high risk population.
- The pharmacological and immunological effects of TPT and BCG vaccination respectively would complement each other as in developing preventive efforts to accelerate decline in TB cases.
- Patients with sputum positive pulmonary disease should cover their mouth while coughing, sneezing and talking to reduce the transmission of TB bacteria.



1.4 TB treatment

TB is completely curable, if the prescribed drugs are taken regularly for the full duration. TB treatment is available free of cost at all government and identified private and NGO health facilities.

1.5 Helpline and application for information on TB

- TB Aarogya Saathi app (freely downloadable in Play Store) provides basic information on TB and provides references to study materials.
- Additionally, one can reach out on the **Ni-kshay Sampark** toll-free number 1800

11 6666 for further counselling and support.

1.6 NTEP commitments towards TB elimination

The National Tuberculosis Elimination Programme (NTEP), previously known as Revised National Tuberculosis Control Programme (RNTCP), aims to strategically achieve Sustainable Development Goals (SDGs) in India by 2025, five years ahead of the global SDG targets.

	India 2025	SDG 2030
Reduction in TB Incidence Rate against baseline of 2015	80%	80%
Reduction in TB Mortality rate against baseline of 2015	90%	90%

Strategic interventions implemented in the last 5 years by the National TB Elimination Programme (NTEP) are:

- A. Strengthening diagnostics by expansion of Rapid Molecular tests.
- B. Strengthening treatment services by daily drugs for Drug Sensitive TB (DS-TB) management and new all oral regimen with shorter duration of treatment for Drug Resistant TB (DR-TB) to provide injection free treatment regimen, reduce pill burden and facilitate better treatment outcomes.
- C. Strengthening TB Preventive Treatment among house-hold contacts (HHC) and PLHIVs.
- D. Single Window for Delivery of Care for HIV and TB at all ART Centres.
- E. Active Case Finding (ACF) among clinically & socially vulnerable population.
- F. Scaling up of digital technologies for real time data management and surveillance for evidence-based actions.
- G. Multisectoral actions to address the social determinants of TB.
- H. Private Sector Engagement (PSE).
- I. Ni-kshay Poshan Yojana providing financial assistance for nutrition support.
- J. Pradhan Mantri TB Mukht Bharat Abhiyaan (PMTBMBA) leveraging community support to provide TB patients with increased nutritional, diagnostic, and vocational support delivered within the community.
- K. Research and development including TB vaccine.

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Chapter: 2

BCG Vaccination in adults

2.1 Bacillus Calmette-Guérin (BCG) vaccine

Bacillus Calmette–Guérin (BCG) vaccine is one of the oldest vaccines first used in humans in 1921. BCG vaccination became a part of the National Tuberculosis Control Programme (NTP) in 1962. India launched Expanded Programme of Immunization (EPI) in 1978 with BCG, OPV, DPT and typhoid-paratyphoid vaccines.³



BCG vaccine presentation The BCG vaccine is supplied as a lyophilized (freeze-dried) preparation in vacuum-sealed, multi-dose, amber-colored vials. It must be reconstituted with “BCG-only” diluents supplied by the manufacturer as the diluents are specifically designed for the needs of that vaccine, with respect to volume, pH and chemical properties. The reconstituted BCG vaccine must be used within 4 hours of reconstitution. The reconstituted BCG vaccine is highly heat sensitive and must be protected from light and heat.

2.2 Safety of BCG vaccine:

The safety profile of BCG is well established. BCG vaccine has an excellent track record for safety and efficacy, whether used alone or when co-administered with other vaccines in the paediatric population.^{4,5} A systematic review including 22 studies from both high and low-middle income countries conducted in 2021 concluded that BCG revaccination carries minimal risk.⁶ The BCG-REVAC trial of BCG revaccination of over 200,000 school children in two Brazilian cities showed that there were no deaths, permanent injuries or cases of disseminated TB reported.⁷

2.3 Countries with multiple BCG vaccination policy:

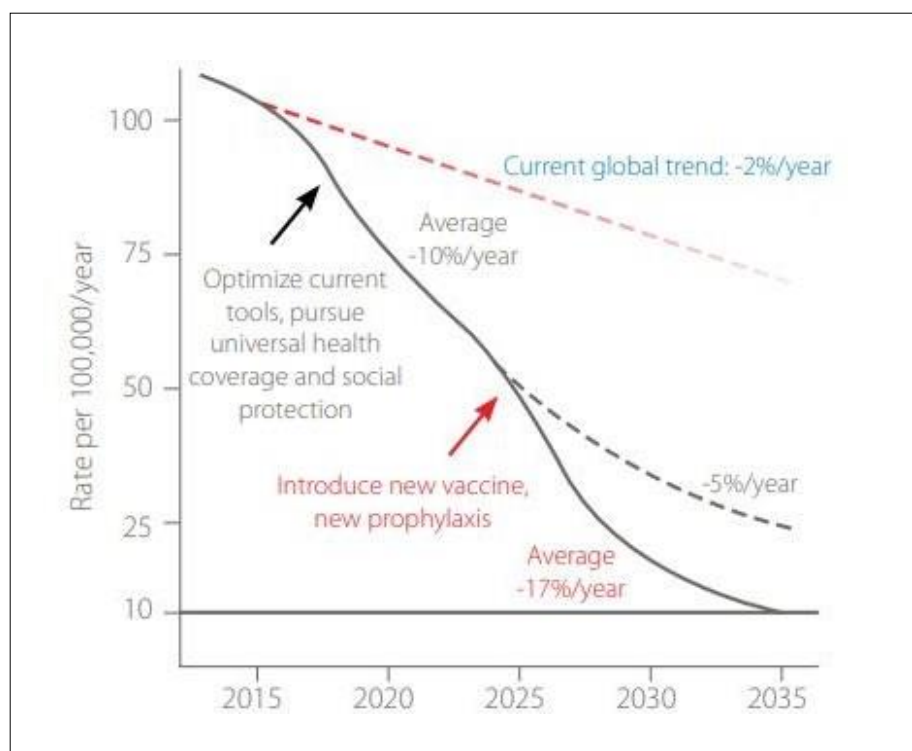
Recent evidences and experience from the countries following a revaccination policy has demonstrated the effectiveness of BCG vaccination for individuals of higher age groups. Sixteen countries recommend multiple BCG vaccinations in elder children and adolescents.⁸

2.4 Rationale for Adult BCG vaccination In India:

Licensed TB Preventive Treatment (TPT) is currently offered to only a select subset of the population. The subset includes: - People living with HIV (+ ART) in adults and children >12 months and Infants <12 months with HIV in contact with active TB, Household contacts below 5 years of pulmonary TB patients, household contacts 5 years and household contacts 5 years and above of pulmonary TB patients, patients on immunosuppressive therapy, having silicosis, on anti-TNF treatment, on dialysis and preparing for organ or hematologic transplantation. Long treatment time and adherence by the patients pose challenges for TPT uptake in the community. All NTEP interventions have cumulatively contributed to an annual rate of decline in TB incidence of around 2% in India.²

These lead to the perceived need for an effective TB vaccine. Attention has returned to BCG with potential benefits of BCG revaccination, or 'boosting' beyond paediatric age group.⁹ Re-analysis of the Chingleput BCG vaccine trial indicated that the BCG vaccination in a community offered modest protection with 36% efficacy against the development of TB disease at the end of 15 years.¹⁰ Another study among adults in India cited BCG revaccination to be immunogenic.¹¹

The current global rate of decline of TB incidence is 1.5% to 2% per year which is not enough to meet End TB targets. One of the modelling studies has shown that besides accelerating current tools and practices, 17% decline per year in TB incidence can be achieved by introducing vaccine and new treatment regimens.¹²



Source:- Bending the curve Ending TB, WHO Annual Report 2017

Recently a modelling analysis was conducted with the objective of determining the potential impact of vaccination on tuberculosis burden in India using data from the national prevalence survey. Findings of the analysis showed that an infection preventing vaccine with 50% efficacy covering 50% of the unvaccinated general population each year with average 10 years of vaccine-induced immunity would avert 12% of cumulative incidence, while a disease preventing vaccine would avert 29% of cumulative incidence. In terms of mortality, an infection-preventing vaccine would avert 8.5% of cumulative TB deaths between now and 2030, while a disease-preventing vaccine would avert 21%.¹³ A systematic review and meta-analysis of 14 case-control studies examined BCG against meningitis and miliary TB. The study revealed that the incidence of TB meningitis was reduced by 73%.¹⁴ To conclude, these studies highlight that BCG vaccination confers a high degree of protection against severe forms of TB.

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Protocol of Adult BCG vaccination study in India

After a careful review of literature and available evidence on safety, efficacy, cost-effectiveness, sustainability and global experience, the Ministry of Health & Family Welfare is planning to conduct a programme implementation research study of BCG vaccination in adults in close collaboration with ICMR/DHR.

A letter and study protocol were issued informing states and UTs to seek their consent for participating in the study. 23 states and UTs have consented to participate in the study. The list of participating states is given in the subsequent section.

Study Title: Effect of BCG vaccination amongst vulnerable adult population on reducing TB disease: a programmatic study.

Study design: Programmatic stratified cluster randomized parallel arm

Study Objectives :-

Objective 1 - Programmatic stratified cluster Randomized parallel arm study

Primary objective: To evaluate the effectiveness of a strategy to vaccinate vulnerable individuals older than 18 years with BCG vaccine under programmatic settings on the occurrence of notified TB cases up to a period of 36 months post-intervention.

Secondary objectives:

- To determine the effectiveness of adult BCG vaccination against active tuberculosis with annual review.
- To determine safety of adult BCG vaccination under programmatic settings in vaccinated individuals with annual review.

Study Outcomes:-

Primary Outcome

Change in notified TB cases from baseline in intervention districts; net adjusted for decline in control districts, as per Ni-kshay portal during 36 months post intervention adjusted for other programmatic interventions (to be measured bi-annually).

Secondary outcome

Vaccine effectiveness will be calculated using the following formula: $VE = (1 - aOR) \times 100\%$ for overall adult BCG vaccination against active TB in the nested case-control test negative design. Adverse events following immunization (AEFI) with BCG will be monitored.

Study settings

A restricted randomization process followed for the study with 50% of the NTEP districts of the consenting State/ UT are allocated to intervention arms and the rest 50% NTEP districts allocated to control arms. 23 States/ UTs have consented to participate in the study as mentioned in the table below:

Andaman & Nicobar Islands	Haryana	Puducherry
Andhra Pradesh	Himachal Pradesh	Punjab
Assam (2 districts)*	Jammu & Kashmir	Rajasthan (4 districts)*
Chhattisgarh	Jharkhand	Tamil Nadu
Dadra & Nagar Haveli & Daman & Diu (1 district)*	Karnataka (6 districts)*	Telangana
Delhi	Madhya Pradesh	Tripura
Goa	Maharashtra	Uttar Pradesh
Gujarat	Odisha	

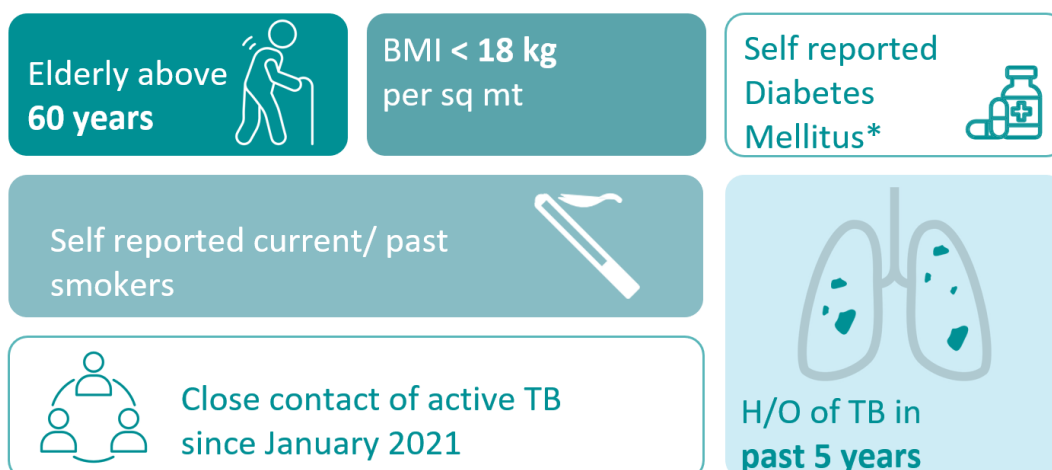
**select number of intervention districts.*

A total of 547 NTEP districts from these 23 States and UTs underwent randomization and 274 districts are allotted in intervention arm whereas 273 districts are allotted in comparator arm.

Inclusion criteria:-

Any 18 years plus individual fitting into any of the following 6 criteria and willing to take vaccine is eligible for Adult BCG vaccination

1. History of TB disease – People who are reported to have at least one episode of TB in past 5 years.
2. Close contacts of TB patients - This will include contacts of current TB patients as well as all those contacts of index TB cases enrolled in Ni-kshay from 1st January 2021
3. Individuals with a Body Mass Index of less than 18 kg per sq.mts
4. Individuals aged 60 years or above
5. Individuals with a history of smoking tobacco (Current user / Past User)- self reported
6. Individuals with history of Diabetes (Self- reported). Wherever feasible, documentary evidences of diagnosis and treatment for diabetes will be obtained.



**Wherever feasible, documentary evidences of diagnosis and treatment for diabetes will be obtained*

Exclusion criteria

1. Individual's age <18 years
2. Those who haven't consented / unable to communicate and give consent to take Adult BCG vaccine
3. Individuals who do not meet any of the above mentioned 6 eligibility criteria
4. Individuals with a known history of immunodeficiency or on immunosuppressive drugs or recipients of any procedure interfering with immune status or transplant or malignancy
5. Individuals with a known history of HIV
6. Individuals with a history leading to high-risk of HIV infection :-
 - Individuals like Female Sex Workers (FSW), Men who have Sex with Men (MSM), Transgender (TG)/Hijras and Injecting Drug Users (IDU) etc. with a history of high-risk behaviour
 - Individuals with a history of blood transfusion in last 3 months (self-reporting)
7. History of known severe reactions with BCG or any other vaccines administered
8. Pregnant or lactating women
9. Currently sick/ seriously ill/ bed-ridden due to any reason.

Special Consideration:



Individuals currently on **ATT (Anti Tuberculosis Treatment)** are **not eligible** for BCG vaccine. One can get adult BCG vaccine **4 weeks after completion of current treatment.**



Sick and hospitalized individuals will be vaccinated **after recovery** and medical advice before taking vaccine.



Individuals on **TB Preventive Treatment (TPT)** would be vaccinated 4 weeks after completion of TPT as per NTEP guidelines.



Individuals who received adult BCG vaccine and eligible for TPT to be provided TPT 4 weeks post vaccination

Randomization, Allocation And Blinding

A restricted randomization process will be followed with an aim to balance the following three co-variables between intervention and control clusters:

1. Adult population size in absolute number: allowing for a two-sided margin of 2 lakh
2. TB case notification rate per 100,000 population for past three years: allowing for a two- sided margin of 20 per 100,000 population
3. Population Proportion of Scheduled caste and Scheduled tribe individuals as a measure of socio-economic scale: allowing for a two-sided margin of 2%

Clusters will be allocated in a 1:1 ratio to intervention and control districts. The study population, NTEP as well as the ICMR investigators and field team will be aware of the group allocation of the districts, however, for data analysis, study statistician will be kept unaware of the groups.

STUDY PROCEDURES

Preparatory activities

- Protocol finalization by ICMR and CTD

- Ethics approval by ICMR- CECHR (Central Ethics Committee on Human Research)
- List randomized districts by ICMR
- Development of operational guidelines for BCG vaccination in adults by CTD and Immunization Division
- Supply of vaccine and logistics by CTD & Immunization Division
- Training of all relevant stakeholders, orientation of staff in intervention districts by CTD & Immunization Division
- Preparation of IEC material by CTD
- Customization of IT platform by CTD & Immunization Division

Intervention districts:

- Bacille Calmette-Guérin vaccine (BCG) in adults - Danish Strain BCG: 0.1ml Intradermal on the right upper arm administered once at study enrolment through the public health system along with current NTEP practices for prevention of TB disease.
- Intervention district will start vaccination only after a district assessment based on a standardized checklist. Programmatic activities needed for adult BCG vaccination programmatic study such as securing vaccine and logistics supplies, training of relevant Human Resources, securing finances, head count survey, micro-planning, social mobilization, and community sensitization will be undertaken prior to the start of vaccination.
- Adverse events following immunization (AEFI) with BCG will be reported and investigated as per AEFI surveillance and response operational guidelines 2015 published by the MoHFW.
- Intervention district will continue routine activities for prevention, diagnosis and treatment of TB along with its notification of TB disease and its notification as per NTEP guidelines

In Control districts:

- No BCG vaccination in adults.
- Routine activities for prevention, diagnosis and treatment of TB along with its notification of TB disease and its notification as per NTEP guidelines.
- Head count survey & follow-up of eligible control population.

Outcome Related Variables

In intervention and control clusters, following data from Ni-kshay portal will be analyzed

1. Number of all notified cases at the district level
2. Age and sex of patient
3. Address of patient
4. Basis of diagnosis: Microbiologically-confirmed TB case / Clinical TB case
5. Patient category: (New, Retreatment etc. as available in Ni-Kshay)
6. Date of diagnosis:
7. Date of BCG Vaccination (in intervention districts)
8. Adverse Events Following Immunization (in intervention districts)
9. Site of disease: Pulmonary / Extra-pulmonary
10. Rifampicin resistance: Resistant / sensitive / not available (& other drug resistance pattern by laboratories)

STUDY MONITORING:

Support from ICMR institutes, WHO-NPSN and State General Health Systems field teams will be sought to constitute monitoring teams in all intervention as well as control districts. Responsibilities will include monitoring of immunization activities, facilitating TB case notification as well as AEFI reporting as per a standardized checklist

SAFETY EVALUATION:

Current AEFI surveillance and response operational guidelines, 2015 published by the MoHFW will be used. Data on AEFIs reported, recorded and investigated will be shared with ICMR team for safety evaluation.

STATISTICAL ANALYSIS PLAN:

Difference in proportion of TB cases per 100,000 population notified through Ni-kshay, between intervention and control districts will be measured. The period of follow-up for each district will be up to 36 months post initiation of adult BCG vaccination study.

Interim analysis will be conducted at 12, 24 and 36 months of follow-up and each interim dataset will be reviewed by a Data Safety and Monitoring Board (DSMB), specially constituted for the study.

The primary outcome will be the difference in population proportion of notified TB cases between the intervention and control groups, adjusting for within-cluster correlation in the outcome. Regarding safety evaluation, the number and proportion of individual and aggregate adverse events that are related to adult BCG vaccination will be calculated.

For secondary objective sub-analysis will be conducted in selected health facilities to measure effectiveness of adult BCG vaccination against active tuberculosis. This analysis will be repeated every year for next five years using Ni-kshay.

STUDY DESIGN:-

B] For Secondary Objective 1: Multi-centric health facility-based, test-negative, case–control study
Study population.

The study will include patients tested for tuberculosis (diagnosed & not diagnosed as active TB) in selected health facilities in India.

- **Cases:** Active tuberculosis case defined as a patient found to be positive on any one or more of the TB diagnosis tests including smear microscopy, CBNAAT, Truenat, solid culture (LJ), liquid culture, Line Probe Assay (LPA) or clinical presentation (signs, symptoms) suggestive of active TB with a decision to treat as TB by the treating physician
- **Controls:** Individuals attending the same health facilities, with sputum or clinical sample found negative for smear microscopy, CBNAAT, Truenat, solid culture (LJ), liquid culture, LPA. Test negative individuals with high clinical/CT/laboratory results suggestive of TB will be excluded as controls.

Primary exposure: BCG vaccination

Exposure referent period: 28 days after administration of BCG

Study period: The study will be done over a 3-month period from study implementation.

Exclusion criteria:

The individual will not be enrolled in the study of this secondary objective, if the individual :-

1. is unwilling to participate
2. is unable to communicate and give consent
3. cannot give sputum sample due to whatever conditions
4. has a fe for the BCG vaccine
5. is pregnant / lactating woman so could not be given BCG vaccine
6. is person living with HIV or immunocompromised for any reason, so could not be given BCG

vaccine

7. is person with active tuberculosis, so could not be given BCG vaccine
8. is person on TB preventive treatment (TPT), so could not be given BCG vaccine

Recruitment strategies

A systematic screening of all patients at selected health facilities will be done for those who seek care from these health facilities. This would be done by sensitization of the hospital staff at the beginning of the study, followed by the site coordinator review. Patients meeting the case definition will be asked (directly or through their physician) and individuals meeting the control definition will be followed up by telephone to provide consent to participate in the study and will be enrolled, if willing. Patients will be interviewed only for confirming the adult BCG vaccination status. Rest all information will be collected from Ni-kshay for cases as well as controls. Adult BCG vaccination status entered in Ni-kshay will be verified during these interviews.

Sample size:

For a case-control design, the formula to calculate the minimum sample size of cases (N_1) is: $N_1 = (z/d)^2 [1/A(1-A) + 1/CP^2(1-P^2)]$

Where C is the control to case ratio; P^2 denotes the prevalence of vaccine exposure in the control group (i.e. vaccine coverage in the population being studied); $A = P^2(1 - VE)/(1 - P^2(VE))$ where VE denotes the anticipated vaccine effectiveness; z denotes the (1- α) percentage point of the standardized normal distribution (normally this is based on an $\alpha = 0.05$ and thus $z = 1.96$); and d is determined by solving the equation where denotes the CI width. The number of controls needed are then calculate as $C \times N_1$.

Assuming 40% controls vaccinated with BCG, 30% vaccine effectiveness, 95% confidence interval, 5% precision, 1:1 case-control ratio, we will need 3662 cases and controls, each (total 7324). Inflating the sample size for adjusted and stratified analysis, 4000 cases and controls each making a total of 8000 will be required.

Equal number of cases and controls will be recruited from selected health facilities. Matching of controls will be done at facility level.

Data collection:

Data will be collected using Ni-kshay (online case-based TB surveillance system) under routine programme conditions. To facilitate identification of cases and control following will be done at the selected health facilities.

All individuals undergoing TB testing will be enrolled in Ni-kshay. All test results will be entered in Ni-kshay for the enrolled individuals. Additional variables will be added in Ni-kshay for all enrolled individuals as below:

- Selected as case under study, for active TB diagnosed during study period... (Yes / No)
- Selected as matched Control under the study, out of those tested negative for TB tests (Yes / No)
- Linking of Cases and their matched control (using select check box)
- Whether Adult BCG vaccine was given (Yes / No)
- If no the reason thereof -
 - ✓ Individuals age <18 yrs
 - ✓ Individuals with a known history of immunodeficiency or on immune suppressive drugs or recipients of any procedure interfering with immune status or transplant or malignancy
 - ✓ History of known severe reaction to BCG or any other vaccines administered
 - ✓ Pregnant or lactating women
 - ✓ Currently sick due to any reason.
- If yes, TBWIN registration number
- If TB-WIN registration number is not available; verification using authentic vaccination card, immunization registry, medical records (Yes / No)

- BCG scar on right upper arm (yes / No)
- Hospitalization in current disease episode or management (Yes / No)

In addition to the complete list of variables from Ni-kshay for the cases and controls, following additional variables will be identified and linked with the records

- ✓ State, city
- ✓ Health Facility (PHI) ID Patient unique ID
- ✓ Age
- ✓ Sex Religion
- ✓ Socioeconomic status
- ✓ Urban/rural residence
- ✓ Occupation
- ✓ Test results
- ✓ Interim status / outcome of Cases

Information from TB-WIN will be fetched regarding the vaccination:-

- ✓ Vaccine administration Date of Adult BCG Vaccination
- ✓ Place of Vaccination (Health Facility ID)
- ✓ Type of eligible category for adult BCG vaccination: -
 - History of TB disease
 - Close contacts of TB patients
 - Individuals with a Body Mass Index of less than 18 kg per sq.mts
 - Individuals aged 60 years or above
 - Individuals with a history of smoking tobacco (Current user / Past User)
 - Individuals with history of Diabetes (Self- reported)
- ✓ Adverse Events Following Immunization (AEFI) details

Data management:

Existing data collection tools i.e. Ni-kshay and TBWIN will be used. All information as mentioned above will be extracted from these two applications. No other paper-based recording or reporting will be used. For testing results, medical records like laboratory register, vaccine registers, treatment cards, notification registers etc will be maintained by the respective health facilities as per routine.

Data entry will be done by respective health facilities using the two applications which have internal validations, cleaning and verification including the matching of controls with cases will be carried out by the central data management unit at Central TB Division.

Data analysis plan:

Descriptive analysis will be carried out to characterize the study participants. Cases and controls will first be described by baseline characteristics followed by cases and controls for background characteristics using chi-square for categorical variables and t-test/median test for continuous variables.

For the primary VE analysis, individuals with adult BCG vaccination will be compared with unvaccinated individuals. Persons with reported prior infection or disease will be included in the primary analysis as vaccination is given regardless of prior infection status. A simple logistic regression will be used to estimate the crude odds ratio with 95% confidence intervals and p- value. Variables with a p-value <0.20 will be selected for multiple logistic regression. After assessing for multi-collinearity, relevant covariates will be identified as confounders by comparing the -2 log likelihood ratio values of the models with and without the potential confounder(s). Effect Measure Modification will be checked by comparing the -2 log likelihood ratio values of the models with and without the interaction terms for effect modifiers. If effect modification exists, VE and CIs will be reported for each subgroup separately. Multiple logistic regression will be used to calculate the adjusted odds ratio (aOR) with 95% CI after

adjusting for relevant known confounders.

Vaccine effectiveness will be calculated using the following formula: $VE = (1 - aOR) \times 100\%$.

Primarily, VE will be calculated for overall adult BCG vaccination against active TB.

Secondary analyses will include vaccine effectiveness in eligible sub-groups of vaccinated individuals. A sensitivity analysis will be done for some key variables to assess the robustness of the VE estimate. This would include: a) documented versus verbal report of adult BCG vaccination to assess how the extremes of exposure misclassification would impact the VE; b) Presence and absence of scar as a result of adult BCG Vaccination

Ethical Consideration:

Safety of BCG is well-established; neonatal BCG vaccination has been successfully administered in the Universal Immunization Program in India as well as many other countries for many years. There is minimal risk of adverse events with BCG vaccination; in case of adverse events, these will be managed at local public health facilities. Acceptance of BCG vaccine will be purely voluntary and the individual may withdraw from the study at any point of time. And will not have any effect on any health services that an individual is supposed to receive.

3 levels of consents/ willingness taken into consideration: -

- The written consent was obtained from States and UTs for their participation in the study.
- The willingness of eligible beneficiaries will be obtained by the surveyor at the time of house-to-house visit. The reasons for non-participation of individuals will be recorded in Headcount Survey format by the surveyor.
- The written consent from eligible beneficiaries at the session site will be obtained and recorded by the vaccinator/ support staff in consent register before administering the vaccine.

Consent register will be kept at each vaccination site with the consent written/pasted in local language on the left page of the register and line list of beneficiaries vaccinated with their signatures/ thumb impressions on the opposite page of the register. The ANMs are to photo document the consent pages with signature of the beneficiaries and submit the digital copies to the concerned Medical Officer – Planning Unit. MO- Planning Unit to preserve the consent register for 3 years post completion of the adult BCG vaccination study.

Consent will also include willingness to participate in the follow-up of the study ie. monthly for initial 3 months and later on quarterly for next 33 months. Beneficiaries would be screened for TB and also asked general questions regarding any side effects post vaccination. Eligible individual's vaccination data will be recorded in TB-WIN and data for follow up will be recorded in Ni-kshay. Consent form enclosed as annexures. No additional data will be collected by ICMR as part of this study. Only anonymized data will be shared with ICMR for data analysis.

Roles of study partners

- The study will be jointly conducted by Central TB Division (CTD) and Indian Council of Medical Research (ICMR).

CTD & Immunization Division; MoHFW	Seeking consent from States/ UTs for participation
	Identification of vulnerable adult individuals
	Provision of BCG vaccine & necessary logistics through immunization Division. Vaccination of eligible vulnerable adults with BCG vaccine as per protocol

(Implementation partner)	Recording, reporting & management of AEFI by Immunization Division
	Screening of presumptive patients and diagnosis of TB
	TB case Notification using Ni-kshay web portal and overall data management
	Adult TB vaccine coverage analysis with help of Immunization Division
ICMR (Research partner)	Randomization of districts into intervention and control group
	Support NTEP in TB case notification and safety monitoring as per requirement
	Data analysis and interpretation



Preparedness for Adult BCG vaccination campaign including microplanning

4.1 State and district campaign preparedness assessment

State and district-level preparedness assessment checklists would assess and identify strengths and weaknesses at state, district and block levels to take corrective actions for effective and successful implementation of Adult BCG vaccination in a campaign mode.

State Immunization Officer (SIO) and State TB Officer (STO) should jointly review and fill in the required details whereas District Immunization Officer (DIO) and District TB Officer (DTO) of intervention districts should jointly review the preparedness and submit the information as per checklist. District checklists will be reviewed at the state and necessary action to be taken, wherever required. Immunization and NTEP partners to support district, State/UT and MoHFW in reviewing the preparedness. All intervention districts are to submit their filled checklists to States/ UTs within **one week of receipt** of district preparedness checklist. All consented states to submit their filled checklist to **Central TB Division and Immunization Division within one week of receipt** of the State assessment checklist. Both the checklists are self-reported.

Once the data is submitted it will be reviewed by the state and national team and monitors would visit selected geographies for validation and necessary corrective actions.

4.2 Micro-planning for adult BCG vaccination campaign

The microplanning for Adult BCG vaccine would be initially top-down i.e. the tentative list of the various cohorts of beneficiaries (past history of TB Patients and close contacts of active TB cases) would be shared from the district level, followed by the bottom-up approach wherein the immunization and NTEP team at the sub-district level would be validating the list shared by the District team/ TU/PHI.

4.2.1 Headcount Survey for adult BCG vaccination

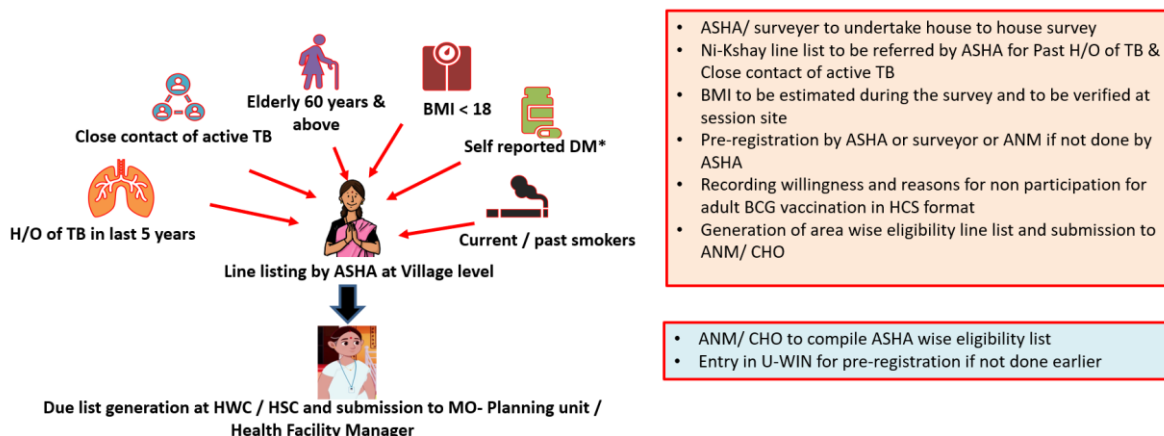
State TB / District TB / PHI to share the available list of eligible beneficiaries such as Community Based Assessment Checklist (CBAC) survey and Ni-kshay line list. Frontline workers validate the list of beneficiaries through headcount survey. All efforts should be made to encourage pre-registration of beneficiaries by surveyors and/ or other support staff to ensure the availability of online records for all eligible beneficiaries. Vaccinators can pre-register the eligible individuals or may consider on-site registration post validation of the eligibility.

The objective of the headcount survey is to cover the entire population and list out all eligible beneficiaries. Health Worker should plan to conduct the surveys only during non-RI and non- IMI days and ensure completion of the activity within 15 days for an area, in such a way that at least 25-30 households are covered every single day.

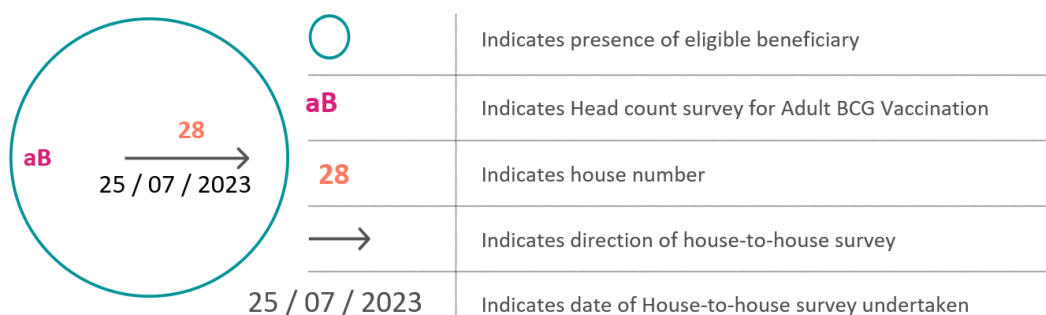
Surveyor must inform the eligible beneficiaries on bringing the photo ID* to be used to register the beneficiary at session site. Health Worker to fill in survey formats (paper based) and will pre-register eligible beneficiaries in TB-WIN portal. All eligible beneficiaries are to

be registered as fresh entries.

(Note:- * Photo IDs such as Aadhaar Card, Driving License, PAN Card, Health Insurance Smart Card issued under the scheme of Ministry of Labour, MNREGA Jo Card, Official identity cards issued to MPs/MLAs/MLCs, Passbook issued by Bank/Post Office, Passport, Pension Document, Service Identity Card issued to employees by Central/State Govt./PSUs/ Public Limited Companies, Smart Card issued by RGI under NPR, Voter ID Card.)



House marking for head-count survey:



The supervision teams should visit and validate areas and households to ensure HCS is done. Repeat survey if :-

1. ≥ 3 consecutive households not visited for survey and/ or
2. ≥ 2 consecutive households have eligible beneficiaries but not enlisted in the survey.

4.2.2 Identification of adult BCG Vaccination session sites:

Adult BCG vaccination session sites should be set up at the same locations as that of routine immunization session site. These sites will be termed as Adult BCG Vaccination Campaign Sites (ABVC sites). Further, additional session sites may be created as per the need of the program. Adult BCG vaccination sessions will be conducted on non-RI days and Non- IMI Days to ensure uninterrupted routine immunization services are provided to children and pregnant women. Every CHO should ensure that opportunity of monthly Ni-kshay Diwas is utilized for:

- A. Adult BCG vaccination awareness generation during the campaign.
- B. Pre-registration of eligible individuals in TB-WIN if found eligible and not registered previously by ASHA.
- C. Vaccination of the eligible beneficiaries following consent.
- D. Follow up post vaccination for AEFI.

The periodicity of follow up is monthly during the first 3 months after vaccination and quarterly post initial 3 months until 36 months from the date of vaccination. Every effort must be taken to ensure that Adult BCG vaccination sessions are ear-marked and not mixed with RI/ IMI session sites. If any fixed session site is conducting routine immunization / IMI session parallelly with a separate vaccinator, then care should be taken to separately mark and conduct adult BCG vaccination sessions.

Each adult BCG vaccination session is to be planned for maximum upto 70 beneficiaries per session. Additional vaccinator can be considered for an injection load maximum upto 150 per session site provided logistics and space is available. **Care must be taken to create separate session sites in TB-WIN for additional vaccinator.**

Mobile teams or additional session site(s) can be planned for hard-to-reach areas, unserved or underserved areas, settlements of migratory populations, international borders or LWE areas (Left Wing Extremist insurgency), for vacant sub-center, workplaces/ residential institutions as per need (e.g., tea garden, mines, old age homes etc. Due care should be undertaken while setting up additional session sites to minimize the vaccine wastage.

Following are the differences between Adult BCG Vaccination Campaign (ABVC) and Universal Immunization Program (UIP)

Particulars	Adult BCG vaccination campaign	Universal Immunization Program
Age of beneficiaries	18 years and above aged individuals belonging to the identified 6 groups.	All pregnant women and children up to 16 years
Headcount survey	Once, before the campaign	Biannually
Record of willingness and non -willingness	Surveyor to record willingness and reasons for non-willingness in HCS format	Not applicable
Session creations in IT Platform	Ear-marked sessions for adult BCG vaccination in TB-WIN	Sessions marked for pregnant women and children in U-WIN
Vaccine and logistics changes in e-VIN	Separate material marking for adult BCG vaccination	Not applicable
Team at session site	Vaccinator + ASHA/link workers/ AWW Presence of TB champions** and PRI to be leveraged.	Vaccinators + ASHA + AWW
IEC	Dedicated IEC material for adult BCG vaccination to be displayed	IEC material for RI / IMI to be displayed
Mobilizers	ASHA/ link workers. TB champions and PRI members to support	ASHA & AWW/ link worker
Vaccine availability at session site	Only BCG vaccine and BCG diluents	All UIP vaccines and diluents
Logistics at session site	Vaccine carrier with conditioned ice packs, 0.1 ml AD syringes, reconstitution syringes, hub cutter, vial opener, cotton swabs, consent registers, materials for bio medical wastemanagement (red/ black bag etc)	As per UIP norms

Anaphylaxis kit/	Separately prepared for each Adult BCG vaccination session sites	One Anaphylaxis kit/session as per UIP guidelines
Privacy	Privacy Screen/Curtain is essential as per gender sensitivity	As per UIP norms
Maximum injection load	Up to 70 injection load	As per UIP norms
Registrations	Pre-registration by ASHA during House-to-house survey or on site by vaccinator	Self-registration or pre-registration as per UIP norms
Consent	Consent before adult BCG vaccination is mandatory for this study. Consent to be documented in a separate register and to be preserved for 3 years post vaccination.	Not applicable
4 key messages	Dedicated Adult BCG vaccine	As per UIP
Follow up	Post vaccination active follow-up to be taken at predefined periodicity. Purpose of follow up is to establish safety and efficacy.	As per UIP
Certificate of vaccination	As per study	As per UIP
AEFI reporting	To MO-Planning unit, DIO, DTO, & Nikshay Sampark	To DIO and MO-Planning unit
Monitoring and supervision	NTEP & UIP Staff	UIP programme supervisor
Incentives	To be booked under NTEP	To be booked under UIP

** A TB Champion is a person who has been affected by TB and successfully completed the treatment. TB Champions, in their capacity as survivors, are role models and can provide valuable support to those with TB and their families.

4 Key messages post adult BCG vaccination

Remind the beneficiary about 4 key messages for adult BCG vaccination

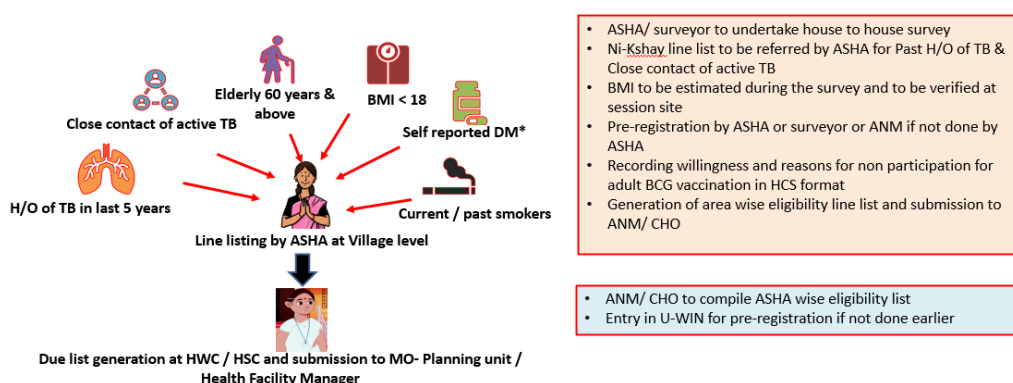


- 1 Which vaccine was given and which disease it can prevent
- 2 How and when wellness follow up will be taken
- 3 What are the minor side effects and how to deal with them
- 4 Where and whom to approach if any serious or severe side effects observed

4.2.3 Human Resource planning

Each adult BCG vaccination session site will have a team consisting of vaccinator (CHO/ ANM), ASHA, AWW, TB Champion/ link workers. Presence of TB champions to be leveraged wherever possible. ASHA/ AWW/TB champions/ volunteers to be used for ID card verification, taking height / weight, data verification, seeking consent and ensuring that beneficiaries are kept under observation for 30 minutes post vaccination. Alternate Vaccine Delivery (AVD) to be used for adult BCG vaccination campaigns. Expenses to be booked in NTEP under budget head of Latent TB Infection.

ABVC Session planning in TB-WIN:



- Health Facility Manager will create the session for "Adult BCG vaccination campaign" in TB-WIN once the eligibility list is generated by the vaccinator and the sessions will be created at least 15 days prior for seamless execution. Once the sessions are created, the vaccinator would be assigned by the Health Facility Manager.
- Adult BCG vaccination sessions to be conducted for maximum 3 months in campaign mode on non-RI/ IMI days. **States and UTs to ensure that eligible population is covered within 1st month of the campaign and next 2 months to be used for mop-ups.** For example, if in a particular state, RI sessions are conducted on every Tuesday and Friday then ANM needs to plan Adult BCG vaccination sessions for remaining 4 days (Monday, Wednesday, Thursday and Saturday) in a week. Sample village session micro-planning is shown as below:

	Avg population	Eligible Beneficiaries (20%)	Sessions required @70 injection load/session	ANM days required
Village A	1000	200	3	3
Urban Ward B	2000	400	6	6

Villages/ wards where the eligible beneficiaries are not covered in the first month, remaining beneficiaries may be vaccinated during the mop-up rounds planned at an interval of 30 days and 60 days from the first session.

4.2.4 Duration of session



Adult BCG Vaccination sessions may be conducted from 9 AM to 2 PM, however timings should be flexible and subject to local requirements. The vaccinator must stay at the session site until session ends. Vaccinator must “close the session” online on TB-WIN platform immediately after completion of the session.



Initial hours of the session can be used for the preparation and registration of beneficiaries on TB-WIN.



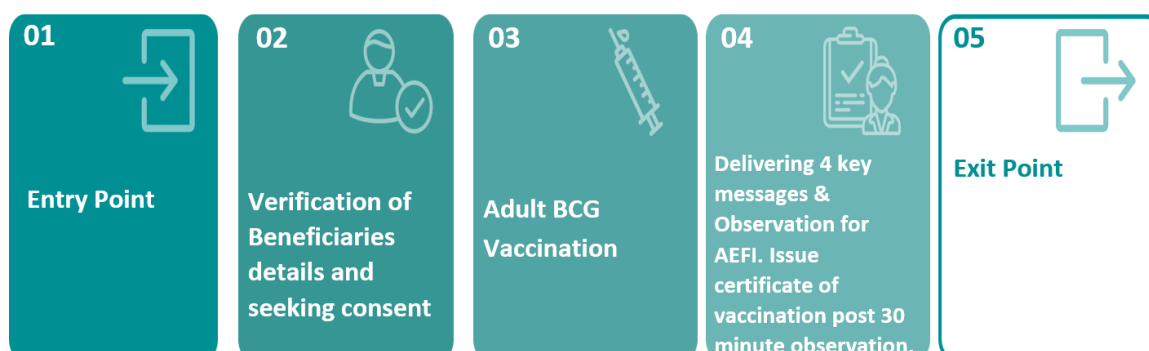
ANM should stay back at the session site for at least an hour after the last beneficiary has been vaccinated to ensure reporting and management of any AEFI, updating the records and other activities.

Health workers should engage with the leaders/ local influencers of the community to identify an appropriate date, venue, and timing of the session (flexible timings), if required, especially in areas where the target population (such as daily wages, factory workers, nomadic population, etc.) may not be available during regular session time. District administration can utilize flexible session timings to reach and maximize vaccination.

4.2.5 Vaccine and logistic planning

It should be ensured that the stocks of BCG vaccine, and diluent, to be used under Adult BCG vaccination and UIP are to be kept separately at all stores and never be mixed. Vaccine and logistics to be calculated in accordance with the number of beneficiaries in TB-WIN and vaccine- logistics transactions to be recorded in e-VIN. One additional vaccine carrier with conditioned ice packs should be provided for immediate replenishment of ice packs as per need. Refer to chapter on cold chain management for further details.

4.2.6 Flow of Beneficiaries at Adult BCG Vaccination session site



At adult BCG vaccination session sites, vaccination and waiting areas should be well designated to ensure that beneficiaries are under observation for 30 minutes post vaccination. If adult BCG vaccination sessions are scheduled at a health facility, then the vaccination area and waiting areas should be separated from curative services (i.e., separate times of the day or separate spaces depending on the facility).

4.2.7 Communication materials at Session Site

Dedicated Adult BCG vaccination IEC material should be displayed at the session site. Please refer on communication for further details.

4.2.8 Community Engagement and Mobilization

Engagement with community leaders / influencers and mobilizers, PRI members, TB champions about BCG vaccination and infection prevention measures must be undertaken in all the phases of vaccination- preparatory phase, implementation phase and post-implementation phase.

4.2.9 Leveraging presence of TB champion

TB champion if eligible then should be motivated to take the Adult BCG vaccine. He / she would act as a role model for community awareness generation and social mobilization. They can support in identifying individuals who had TB in the past 5 years and close contacts of currently active cases. TB champions can support beneficiary ID verifications at adult BCG vaccination session sites. TB Champions can be of help in taking periodic post vaccination follow up.

4.2.10 Immunization Bio Medical Waste Management

Strictly adhere to MoHFW's Immunization Bio Medical Waste Management guidelines 2021. Kindly refer to chapter no 7 for further details.

4.2.11 Adverse Event Following Immunization

Each adult BCG vaccination session site must be equipped with dedicated anaphylaxis kit and each session site should be linked with AEFI management center. ANM should be aware about the mobile no. of MO and location of the center. Each vaccinator and medical officer should be trained in management of AEFI. State TB Officer and District TB Officers must be included in State and District AEFI Committees respectively. Kindly refer to chapter on Safe injection practices and AEFI for further details.

4.2.12 Monitoring & Supervision

Adult BCG vaccination session sites to be supervised to ensure quality of care is being provided with safety and to ensure that no consented eligible beneficiary is left out and no vaccination is given without consent. For three to five session sites a supervisor will be deployed for closed supervision at the session site. Besides national and state supervisors, district and block level supervisors to be included. It should include Senior Treatment Supervisor (STS), TBHV, LHV and PHN and CHOs.

Key points to remember

- Head count survey will be conducted by the Front-line Health Workers to enlist the eligible beneficiaries.
- Pre-registration of beneficiaries in TB-WIN will be done during the head-count survey by ASHA or by vaccinator if not done by ASHA.
- Onsite registration can be done by vaccinator.
- Validation of the beneficiaries will be done by the vaccinator at session site prior to vaccination.
- Dedicated Adult BCG vaccination session would be conducted on non-RI and non- IMI days at the immunization session sites.
- Minimum one dedicated adult BCG vaccination session per month per ASHA should be planned until all eligible beneficiaries are vaccinated during the campaign.
- Adult BCG vaccination sessions will be created in TB-WIN portal at Cold Chain Points (CCPs) by Health Facility Manager. Vaccinators would be assigned by the Health Facility Manager in TB-WIN portal.
- Vaccine and cold chain planning will be on e-VIN with dedicated "Adult BCG vaccination" material marking.
- Coverage of vaccination would be monitored by Immunization and NTEP Division against the eligible beneficiaries.
- All the expenses incurred during the adult BCG vaccination campaign to be booked in the NTEP LTBI budget head under PIP.



Human Resources: Capacity Building

5.1 Training approach for Adult BCG vaccination campaign

Cascade of training i.e. national, state, district and sub district level training on adult BCG vaccination will be conducted well in advance. Each district will prepare a block/ planning unit wise training calendar and share it with the state. SIO & STO will track district-wise progress on trainings. DIO & DTO will ensure quality, participation and timely completion of all training.

5.2. Thematic areas of training:

1. Clinical overview of TB disease, NTEP and UIP
2. Rationale of adult BCG vaccination
3. Adult BCG Vaccination - study protocol
4. Microplanning
5. Vaccine & cold chain management
6. Injection safety & AEFI
7. Social mobilization and communication strategy
8. Recording and reporting
9. Monitoring and supervision
10. Financial norms

5.3 Suggestive training matrix

Level	Topics	Participants	Duration	Training platform and training materials	Timeline
National ToT	Orientation on adult BCG vaccination programme implementation study, protocol and Standard Operating Procedures	State immunization Officers, State TB Officers, State IEC officers, STDC directors, state level master trainers identified by states, national representative from developmental partners	2 days	Physical SOP, FAQ, PPTs, IEC assets etc,	4 to 8 weeks prior implementation
State ToT		District Immunization Officers, District TB Officers, District IEC officers, DPM-NHM, DPC-NTEP, PPM coordinator in charge of ACSM activities, state representatives from developmental partners	2 days	Class-room training SOP, FAQ, PPTs, IEC assets etc,	4 to 8 weeks prior implementation
District level trainings	Orientation on adult BCG vaccination programme implementation study, protocol and Standard Operating Procedures	BMO/ THO, Medical Officers/ CHO, Senior Treatment Supervisors (STS) of NTEP, Public Health Nurse, district cold chain handler, VCCM,	1 day	Classroom training SOP, FAQ, PPTs, IEC assets etc	4 to 6 weeks prior implementation
Sub-district level trainings	Protocol, Procedure of line listing of beneficiaries, social mobilization, reporting mechanism, AEFI management	Health Supervisor, CHO, LHV, ANM, cold chain handler at cold chain points, ASHA Coordinator, ASHAs, TB Champions,	4 hours	Classroom training PPTs, FAQ, IEC assets etc	2 to 4 weeks prior implementation

Detailed training agenda annexed.



Chapter: 6

Vaccine & cold chain management

Effective vaccine and logistics management is essential for the successful implementation of the Adult BCG vaccination programme. The key steps to be taken for efficient supply chain management include:

1. Estimating the requirement of BCG vaccine doses and essential logistics well in advance keeping in mind vaccine wastage rate.
2. Undertaking an assessment of existing cold chain space and dry space availability at each level of the supply chain and develop an augmentation plan if needed, based on the vaccine doses and other logistic requirements.
3. Ensuring that vaccine and diluent supplied to the session sites are from the same manufacturer.
4. Availability of written vaccine and logistic movement plan that includes designated responsible person at each cold chain point; details of vaccine and logistics supplies, alternate vaccine delivery (AVD) plan, and Bio Medical Waste Management (BMW) plan.

6.1 Cold chain for Adult BCG vaccination and assessment of cold chain storage

All Cold Chain Handlers at SVS, RVS, DVS and CCP should ensure that a dedicated ILR (wherever possible) is earmarked for Adult BCG Vaccination. Dedicated racks in WIC are to be identified and labelled for "Adult BCG vaccination campaign". At CCP where dedicated ILR is not available, the vaccine for Adult BCG vaccination and its diluent should be marked and stored in a separate box.

Diluent ampoules can be stored in ambient temperature but must be stored in ILR at least 24 hours before the session starts to match up their temperature with BCG vaccine during reconstitution and avoiding the thermal shocks. Dedicated dry space is to be identified and used for storage of diluents, 0.1 ml AD syringes, reconstitution syringes.

BCG Vaccine storage in ILR



The BCG vaccine should be placed just above measles - rubella vaccine.

6.2 Estimation of the Adult BCG vaccine and diluents

Since, Adult BCG vaccine will be given in campaign mode, strong mobilization efforts should be taken to vaccinate all eligible individuals in stipulated time period with minimal vaccine wastage.

In campaign mode, estimated vaccine wastage would be maximum 10% with Waste Multiplication Factor (WMF) as 1.11.

The requirement of Adult BCG vaccine and diluents would be:

Adult BCG doses (in number) = Target for adult BCG * 1 dose* 1.11 (WMF)

Adult BCG vials (in number) = Adult BCG doses/10 (for a vial containing 10 doses)

Adult BCG diluent ampoules (in number) = Adult BCG vials (in number)

It should be ensured that the stocks of BCG vaccine, diluent, and other logistics to be used under Adult BCG vaccination and UIP are kept separate at all stores and never mixed.

6.3 Estimation of 0.1 ml AD and reconstitution syringes

Total 0.1 ml AD syringes required = Adult BCG doses (in number)

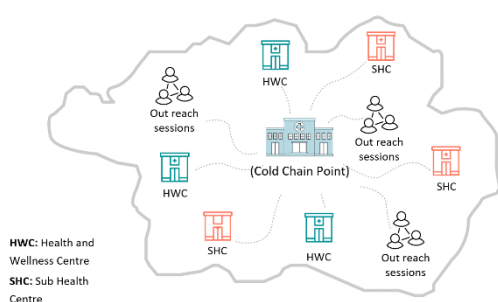
Only one reconstitution syringe is to be used per vial, so ensure supply of the adequate number of reconstitution (diluents) syringe.

Reconstitution syringes requirement can be calculated as below:-

Total disposable reconstitution syringes = Adult BCG vials*1.11 (WMF)

It should be ensured that the stocks of 0.1 ml AD syringes and reconstitution syringes to be used under Adult BCG vaccination project and UIP are kept separate at all stores and never mixed.

6.4 Estimation of cold space



During the adult BCG vaccination activities, a substantially larger dedicated cold chain space is needed. The cold chain space available at the CCP for adult BCG vaccination activities can be calculated by subtracting the estimated volume of space needed for RI services from the total available cold chain space.

Cold chain volume

Each dose of BCG vaccine would occupy 2.66 cm³/ dose in secondary packing. A small ILR of 45 litre is sufficient for storing 17308 (45*1000/2.6) doses of BCG.

Example:

Calculating a cold chain space need of a PHC for Adult BCG vaccination with population of 30000. The target cohort for Adult BCG vaccination would be roughly ~20% of the total population.

Diluent ampoules should be equal to the number of BCG vials needed. Diluents should be checked for expiry date, batch and breakage.

6.5 Requirement of ice packs for Adult BCG vaccination

For adult BCG vaccination activities, ice pack requirements to be calculated based on the number of session planned. Vaccine carriers require 4 ice packs each and 4 extra icepacks as a replacement set during the day. The number of days needed for getting required number. of frozen ice packs can be calculated by dividing 25 or 40 (Freezing capacity of small-DF is 25 and that of Large DF is 40 per day). Ice Pack freezing for Adult BCG vaccination campaign may be done using Deep Freezers. However, it should be ensured that the freezing plan of UIP is not disturbed.

Daily ice pack requirement = No. of daily sessions x 8 ice packs

Example:

A PHC has 6 adult BCG vaccination sessions planned then, the total requirement for 1-day at the PHC is
- 6 sessions x 8 ice packs = 48 ice packs

Additional ice packs for cold boxes for storage and transportation should be considered as per UIP norms

As a backup plan in case of non-availability of sufficient cold chain space for freezing the ice-packs, private firms or hired facility for ice freezing should be explored and expenditure to be booked under NTEP budget head i.e. Others including Operating Costs (OOC) of Latent TB Infection

6.6 Alternate Vaccine Delivery (AVD)

The AVD used under UIP will be used for Adult BCG vaccination campaign however all the payment for AVD used for Adult BCG vaccination campaign is to be borne by NTEP. **UIP funds are not to be used for Adult BCG Vaccination.**

6.7 Transportation

The POL for the transport of vaccines from the higher stores to lower stores and in between stores for Adult BCG vaccination Project is to be borne by NTEP. **UIP funds are not to be used for Adult BCG Vaccination.**

6.8 Vaccine storage during session site







BCG vaccine is most sensitive to light and also heat post reconstitution and must be kept in the hole of the conditioned ice pack once reconstituted at the session site.

Picture 1: Vaccine placement during the session site

6.9 Vaccine Vial Monitor (VVM)

The Vaccine Vial Monitor (VVM) is a label containing heat-sensitive material, which is placed on the vaccine vial/cap to register cumulative heat exposure between the time period of exit from the manufacturing site till the time of use. The combined effects of time and temperature causes the inner square of the VVM to darken gradually and irreversibly.

HOW TO READ A VVM

-  ✓ Vaccine
-  ✓ Vaccine OK use first
-  ✗ Do not use the vaccine
-  ✗ Do not use the vaccine

Picture 2: Vaccine Vial Monitor

*for BCG vaccine, the VVM is placed on the cap of the vial and only indicates the exposure of the dry vaccine; not after reconstitution. The status of the VVM should be checked before opening the vial.

6.10 NO Open Vials Policy



4 hrs.



Open vial policy is **NOT** applicable on BCG vaccine. The vaccinator must use the vial within 4 hours after reconstitution. The date and time of the vial opening must be clearly written on the cap of the vial.

6.11 Reverse cold chain



The partially used BCG vials and empty vials must be returned back to cold chain point and stored in ILR in a separate container (preferably different colour box) or separate vaccine carrier with **"NOT TO BE USED- Opened Adult BCG vials"** label clearly marked.

These vials should be discarded after 48 hours. If required, additional cold boxes for storing the returned vials can be demanded from the Immunization Division. In case of any reported AEFI, they will not be discarded but retained separately for investigation. All efforts should be made towards maximum consumption of the open vials within 4 hours of opening. The vaccine wastage can be prevented if sessions



are planned based on accurate beneficiary load and effective social mobilization.

6.12 Entry of Adult BCG vaccine in eVIN:

1. Separate 'Adult BCG vaccine' material tag is added in eVIN.
2. Adult BCG (Dose) and Adult BCG Diluent (Dose) materials to be added under 'Adult BCG vaccine' category (10 doser vial).
3. The state Immunization officer/State nodal person for Adult BCG Vaccination to instruct the SPO/POIT of state to add the 'Adult BCG vaccine' in the identified districts where the Adult BCG Vaccination will be conducted. (Please note: The 'Adult BCG vaccine' is not to be added and distributed in all the districts/CCPs of the state. Only intervention districts in the state will have these vaccines).
4. The SVSM, RVSM, DVSM will follow the usual process of indent management for the Adult BCG vaccine distribution from the higher stores till the last CCP level. However, consumption of vaccine needs to be monitored to avoid wastage and encourage proper planning
5. The state store user to receive the vaccines from the GMSD or manufacturer through the usual indent/stock -in principles in eVIN.
6. POITs of the state/UT to add the Material tag and materials for specific District domain and in the DVS and all the CCPs of the identified district.
7. The cold chain handler user will issue the vaccines to the designated vaccination centres using "Issue/Net utilization" transaction similar to RI vaccines, Reason code: "Issued for adult BCG vaccination".
8. For physical recording and reporting of Adult BCG vaccination project, separate dedicated pages in the vaccine stock register and vaccine distribution register should be marked and entires also to be done for the Adult BGV vaccine under the eVIN portal. The physical stocks of vaccine doses and syringes to be used for adult BCG vaccination campaign should match with eVIN portal and stock register.
9. Separate dedicated pages are to be marked for Adult BCG vaccination in vaccine stock register, and vaccine distribution register. These pages should be named as:
 - a) BCG Vaccine for Adult BCG vaccination.
 - b) Diluent of BCG vaccine for Adult BCG vaccination.
 - c) 0.1 ml Ad Syringes for Adult BCG vaccination.
 - d) Reconstitution syringes for Adult BCG vaccination.
10. All the discards should be entered in the eVIN portal and in the pages of registers for adult BCG vaccination campaign with proper reason code.
11. States to ensure the orientation of all the concerned users on the SOP for Adult BCG vaccine entry in eVIN.

Points to remember:

- Doses needed for BCG vaccination = target population (~20% of the total population) * 1 dose * 1.11 (wastage multiplication factor during intensified activities)
- Number of diluent needed for BCG vaccination = number of BCG doses needed
- Only use the diluents supplied/packaged by the manufacturer with the vaccine, since the diluents are specifically designed for the needs of that vaccine, with respect to volume, pH level and chemical properties.
- Only 1 reconstitution syringe to be used per vial.
- Only 0.1 ml AD syringe to be used for the BCG vaccination. Open vial policy is NOT applicable on BCG vaccine.
- Dedicated cold chain space to be allotted for Adult BCG vaccination. Registers and e-VIN will have separate "Adult BCG vaccine" sections. Expenses for AVD, freezing plan if any should be booked under NTEP. Don't mix stock for UIP and Adult BCG Vaccination.



Safe Injection practices, Bio Medical Waste Management and Adverse Event Following Immunization in adult BCG vaccination

7.1 Safe Injection Practices

Safe injection practices are defined as those that

- Do not harm the recipient.
- Do not expose the healthcare workers to any avoidable risk.
- Do not result in waste, which is dangerous for the community.

Following are the steps to ensure injection safety during adult BCG vaccination: -

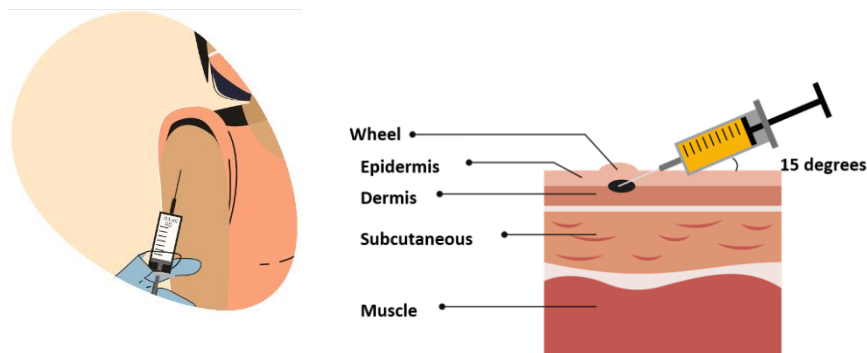
- All vaccinators should use only 0.1 ml AD syringes for Adult BCG vaccination.
- For each beneficiary always use a new sterile packed 0.1 ml AD syringe. Similarly, use a new sterile 2ml or 3 ml disposable reconstitution syringe for each vial of BCG to be reconstituted.
- Do not use AD and reconstitution syringes that have damaged packaging, or have passed the manufacturer expiry date.
- Do not use BCG vaccine and diluent if there is a visible damage, loss or disfigured VVM, disfigured label or has passed the manufacturer expiry date.
- Ensure correct “**Bundling**” i.e. BCG vaccines are to be supplied with BCG-only diluents from same manufacturer. 0.1 ml AD syringes, and reconstitution syringes to be supplied as per need.
- Always write date and time of opening on the cap of each BCG vial.
- Do not use BCG vaccine 4 hours after reconstitution.
- Do not touch the needle at any stage, never pre-fill the syringes and never attempt to recap the syringes.
- Do not touch or contaminate the septum of the vial.



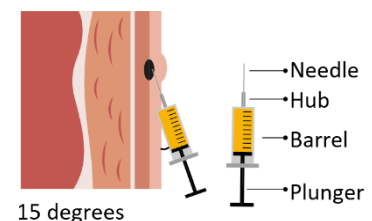
- Do not put the syringes on the table or in a tray after the injection.
- Do not move the plunger until you are ready to fill the syringe with the vaccine and do not inject air into the vial as this will lock the syringe.
- Do not draw air into the syringe. In case air accidentally enters the syringe, remove the needle from the vial. Holding the syringe upright, tap the barrel to bring the bubbles towards the tip of the syringe. Then carefully push the plunger to the dose mark (0.1 ml for Adult BCG) thus expelling the air bubble.
- Wash your hands with soap before and after the vaccination session.
- If the skin at the site of injection is visibly dirty, wash the area with water and dry it completely before vaccinating.
- Cut the hub of the AD syringe immediately after administering the injection using the hub cutter. Cut reconstitution syringe immediately using the hub cutter after reconstitution of the vials.

7.2 Accurate injection technique for Adult BCG Vaccination

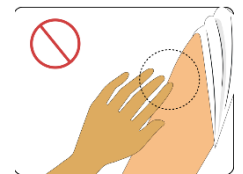
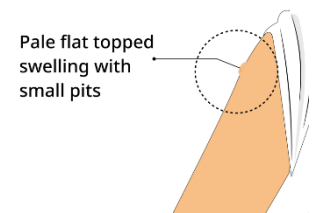
The accurate dose for Adult BCG vaccine is 0.1 ml. to be given intradermally with 0.1ml AD syringe. **Site for adult BCG vaccination is right upper arm-lateral.**



- Gently stretch and support the skin with the thumb and forefinger. Lay the syringe and needle almost flat along the beneficiary's skin.
- Gently insert the needle into the top layer of the skin. Hold the syringe barrel with the bevel (hole) of the needle facing upwards. And place the syringe and needle almost flat (10 to 15 degrees) along the beneficiary's skin.
- Place your other thumb on the lower end of the syringe near the needle to hold the needle in position, but do not touch the needle. Insert the tip of the needle under the surface of the skin just past the bevel.



- Hold the plunger end of the syringe between the index and middle fingers. Press the plunger slowly with the thumb.
- There will be some resistance while the wheel forms.
- A pale flat-topped swelling with small pits like an orange peel should appear on the skin.
- Remove the needle smoothly at the same angle as it went in.
- The beneficiary may gently hold a clean swab over the site if it is bleeding.
- Do not rub or massage the area.



7.3 Safe disposal of Biomedical Waste post immunization

The following steps should be adopted for disposal of biomedical waste generated at session sites/PHCs/CHCs/ district hospitals, etc.

A. At the Session site

Step 1: At the session site, Auxiliary Nursing Midwifery (ANM) cut the hub of the AD syringe immediately after administering the injection using the hub cutter, that cuts the plastic hub of the syringe, which along with the needle, will be collected in the puncture-proof container of the hub cutter. Cut the hub of reconstitution syringe immediately after reconstitution.

Step 2: Segregate and store the plastic portion of the cut syringes in the **red bag** or container. The bags or containers should bear the biohazard symbol.

Step 3: Collect the broken vials/ampoules made of glass in the puncture proof container of hub cutter, used cotton swab in yellow bag.

Step 4: Plastic wrapper of syringe, cap of the needle and empty paper/cardboard boxes should be collected in **black bag** and discarded as dry general waste as per Solid Waste Management Rules, 2016.

Step 5: The opened (used & partially used) vaccines should be returned to the CCP as per existing CBWTF guidelines & MoHFW guidelines for proper disposal.

All the BMW generated at outreach sessions shall be returned to the CCP/PHC and should be discarded as per the guidelines.

B. At Cold Chain Point (CCP) or Health Care Facility (HCF)

Step 6: From an outreach session send all bags and the hub cutter to designated Cold Chain Point (PHC/UPHC/DH/SDH/RH/CHC) or Health Care Facility (HCF) for disinfection and disposal by the designated person at the HCF or CCP. The designated person may pre-treat and dispose the waste or hand-over to Common Biomedical Waste Treatment Facility (CBWTF).

Step 7: Treat the collected material of red & blue bag or container and hub container

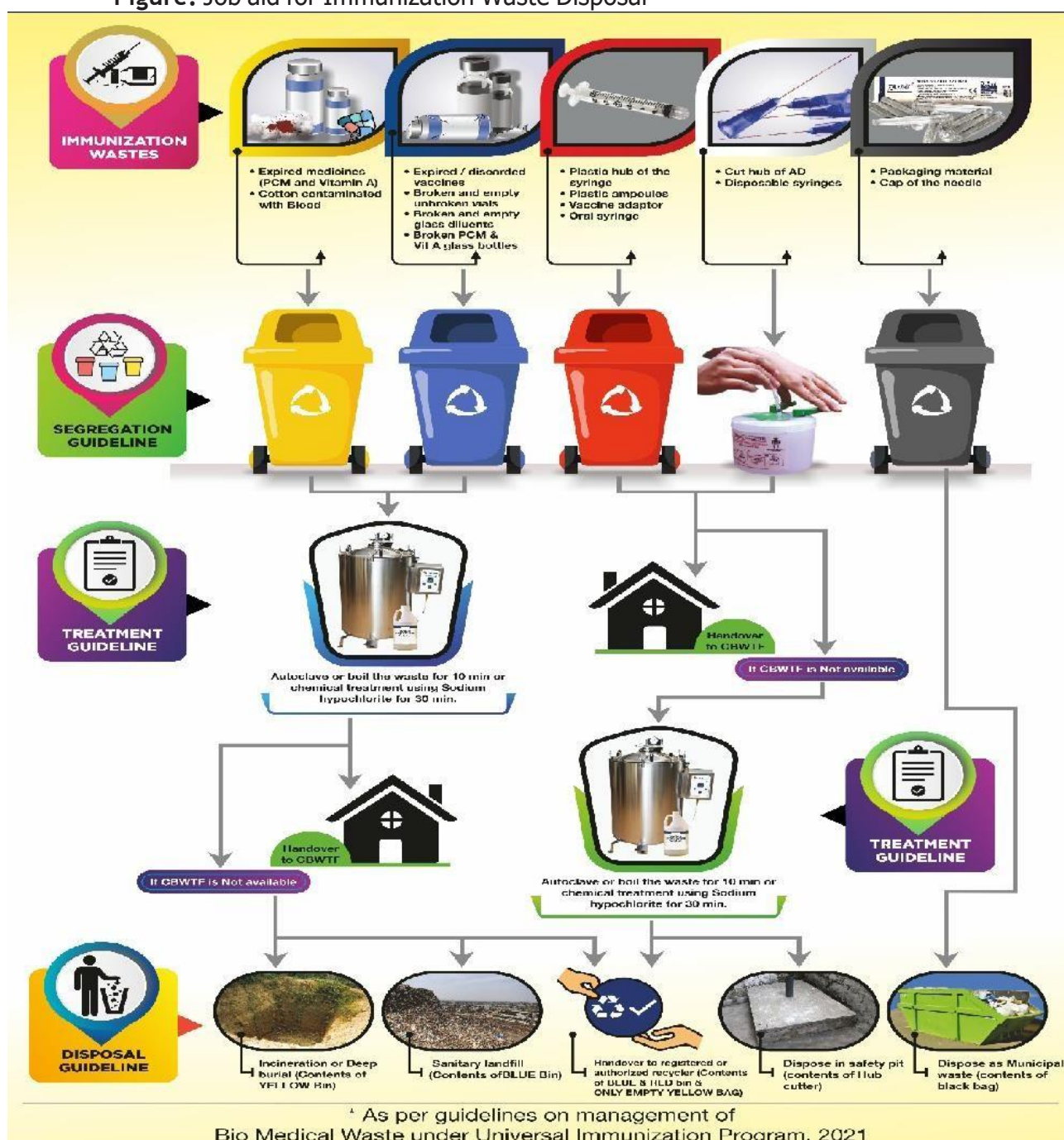
in an autoclave/micro-waving/hydroclaving or provide chemical treatment using 1% sodium hypochlorite solution for 30 minutes to ensure that this results in disinfection. Health facilities and workers (government and private) should follow the national guidelines issued by MoHFW and Central Pollution Control Board (CPCB) 2021 for treatment and disposal of Immunization Waste.

Step 8: The hub cutters should be washed properly with 1% sodium hypochlorite before reuse.

Step 9: Maintain a proper record of generation, treatment and disposal of waste at the district hospital/ CHC/PHC/UPHC in order to assess that waste (needles/syringes/vials) reported back matches with the stock issued to health worker/ vaccinator at the beginning of each session day.

The graphical representation is as follows:

Figure: Job aid for Immunization Waste Disposal



7.4 Adverse Event Following Immunization (AEFI)

The BCG vaccine has been used since many years under the Universal Immunization programme and is a very safe vaccine. An Adverse Event Following Immunization (AEFI) is any untoward medical occurrence which follows immunization but which does not necessarily have a causal relationship with the use of the vaccine. The adverse event may be any unfavorable or unintended sign, abnormal laboratory finding, symptom or disease. The community is to be sensitized over potential minor and rare serious/ severe side effects. ANM should notify AEFI cases in UWIN - SAFE-VAC application or toll-free number of Ni-kshay Sampark - 1800-11-6666.

It is important to remember that the vaccine recipients in the target group are likely to have or have pre-existing co-morbidities. The likelihood of coincidental events occurring following BCG vaccination may be higher in this target population. Therefore, every adverse event following BCG vaccination should be managed and reported as per guidelines. Investigations of AEFIs will also need to be conducted within the stipulated timeline and causality assessments completed within 100 days of notification.

7.4.1 Specific AEFIs reported with BCG vaccination

BCG vaccination causes a specific local reaction that starts as a papule (lump) two or more weeks after immunization, which becomes ulcerated and heals after several months, leaving a scar. This is a normal response to BCG vaccine and not an adverse event. Keloid (thickened scar tissue) from the BCG lesion is more common among Asian and African populations. The most common adverse reactions to BCG vaccination are injection site abscess and regional lymphadenitis. The majority of abscesses heal within a month without medical/surgical intervention. Conservative approach worked best for local site abscess.¹⁵

Bannister *et al* on the safety of BCG revaccination systematically reviewed 24 research articles for AEFI related to BCG revaccination and has concluded that revaccination with BCG vaccine carries minimal risk.⁶ The BCG-REVAC, a cluster-randomised trial of BCG revaccination of over 200,000 school children in two Brazilian cities showed that there were no deaths, permanent injuries or disseminated infections reported.⁷ The lower risk of lymphadenopathy in older participants was related to immunosenescence.

Case definition and treatment for AEFI associated with BCG vaccine (very rare)

Adverse event	Case definition and tentative Timeline	Reaction type and rate	Treatment
Injection site reaction	papule, mild ulceration or scar	Very common	Heals on its own and may not need medical intervention

Disseminated BCG infections	Widespread infections occurring within 1 to 12 months after BCG vaccination and confirmed by isolation of mycobacterium bovis BCG strain. Usually in immunocompromised individuals.	Very rare 1 per 230 000 - 640 000	Should be treated with anti-tuberculous regimens including isoniazid and rifampicin
Lymphadenitis (includes suppurative lymphadenitis)	A least one lymph node enlarged to >1.5 cm in size (one adult finger width), or a draining sinus over lymph node Almost exclusively caused by BCG and occurring within 2 to 6 months after receipt of BCG vaccine, on the same side as inoculation (mostly axillary)	Uncommon to rare 1 per 10 ³ - 10 ⁴	Heals spontaneously (over months) and best not to treat unless lesion is sticking to the skin. If so, or if already draining, surgical drainage and local instillation of anti-tuberculosis drugs. Systemic treatment with anti-tuberculosis drugs is ineffective.
BCG Osteitis / osteo-myelitis	Inflammation of the bone with isolation of mycobacterium bovis BCG strain. It may develop in 1 to 12 months post vaccination.	Uncommon to very rare 1 per 3333 -10 ⁶	Should be treated with anti-tuberculous regimens including isoniazid and rifampicin
Immune re-constitution inflammatory syndrome (IRIS)	Usually seen in association with HIV infection	Very rare 1 per 640 000	

(source: - AEFI surveillance and response guidelines 2015 & WHO Immunization Safety Manual 3rd edition)

Case definition and treatment for other potential AEFI post BCG vaccine

Adverse event	Case definition	Treatment
Anaphylactic reaction (acute hypersensitivity reaction)	Exaggerated acute allergic reaction, occurring within 2 hours after immunization, characterized by one or more the following: <ol style="list-style-type: none"> 1. wheezing and shortness of breath due to bronchospasm 2. one or more skin manifestations, e.g. hives, facial oedema, or generalized oedema. Less severe allergic reactions do not need to be reported 3. laryngospasm, laryngeal oedema 	Self-limiting; anti-histamines maybe helpful
Anaphylaxis	Severe and immediate allergic reaction (within 1 hour) leading to circulatory failure with or without bronchospasm and/or laryngospasm/laryngeal oedema	Adrenaline injection
Local reactions like pain, swelling and redness, fever etc.		Trivial and self-limiting.

7.4.2 Managing AEFIs

Immediate AEFI post BCG vaccination is rare. However, vaccinators and medical officers must be trained in identification and management of AEFIs. Timely attention and management of AEFIs can prevent serious clinical consequences and helps in maintaining confidence of the community. Most common AEFIs could be minor local injection site reactions but vaccine recipients might experience fainting or anaphylaxis which is a very rare but severe and potentially fatal allergic reaction. Health Workers must be trained to distinguish anaphylaxis from fainting (vasovagal syncope), anxiety and breath-holding spells, which are common benign reactions.

AEFIs may occur while vaccination sessions are being held in facilities and in outreach sessions and outside of the sessions. Ensure clinical case management of AEFIs as level appropriate and referral to the next level if required. Ensure availability of emergency drugs and medical equipment to deal with an adverse event. Regularly check the emergency (AEFI/ Anaphylaxis) kits (functional status of equipment and expiry of drugs & syringes). Ensure ANM is familiar with and that the anaphylaxis kit is certified every quarter. Each adult BCG vaccination campaign site must be equipped with Anaphylaxis kit. Expenses for Anaphylaxis kit if dedicatedly required for adult BCG vaccination session site and AEFI kit for AEFI management center to be booked under the NTEP LTBI Budget head.

At the session site:

Health workers and medical officers must be vigilant so that AEFIs can be prevented, detected timely and managed. At the session site, health worker or vaccinator should

follow the guidelines as mentioned below:

- Ensure recipients wait for 30 minutes at session site after vaccination and monitor the health condition of the recipient.
- Advise paracetamol tablets for mild to moderate fever, local pain and swelling at injection site, malaise etc.
- Ask the beneficiary to visit the nearest health facility, if minor adverse events persist beyond 2-3 days.
- In case of adverse events/discomfort/illness, other than minor events, the beneficiary should visit the nearest health facility.
- Anaphylaxis kit with inj. adrenaline within expiry date must be available at outreach session sites.
- Vaccinators should be trained to immediately administer a single dose (0.5 ml – adults) of adrenaline deep intramuscularly into the opposite limb to that in which the vaccine was given to any suspected case of anaphylaxis at the session site. 0.5 ml dose of adrenaline (1:1000) should be given by tuberculin syringe OR 20 units should be given by insulin syringe. Either 24 G or 25 G needle should be used for deep intramuscular injection.

Age group	Volume of adrenaline (mL)	Equivalent volume of adrenaline in units
0-1 years	0.05	2.0
1-6 years	0.1	4.0
6-12 years	0.2	8.0
12-18 years	0.3	12.0
Adults	0.5	20.0

TUBERCULIN SYRINGE – 1.0 mL	INSULIN SYRINGE – 40 UNITS
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- If a medical officer (MO) is available at the session site, then MO to give Inj. Hydrocortisone IM or slow IV(200 mg for > 12 years).
- Arrange for immediate transportation to the identified AEFI management centre or any health facility with a doctor.



arrange for transportation (108/102/PHC ambulance) to to higher centre with appropriate facilities for diagnosis and treatment.

- Inform Medical Officer immediately by telephone about serious/severe AEFIs.
- Emergency numbers (102, 108, etc.) for transporting cases to AEFI management center / Higher health facility with a vaccinator team.

AEFI management centres

Each health facility staffed with a MO in the government as well as the private sector should be identified and designated as an AEFI management centre under Universal Immunization Program. Each PHC, CHC, district hospital, etc should prepare a list of such centres dispersed geographically in their jurisdiction area so that in the event of an AEFI, the beneficiary can be quickly referred and managed. The micro plan of each

session should include the name, address and phone number of the MO of the AEFI management centre. All the MOs of the designated AEFI management centres should be trained in standard AEFI management and reporting procedures. All AEFI management centres should be provided with AEFI treatment kits and standard AEFI reporting forms¹⁶.

Difference between the AEFI and anaphylaxis kit is shown in the table below:-

	Anaphylaxis kit	AEFI kit
Where is it used?	At outreach vaccination session site	1. At fixed vaccination session site, located at health facility with presence of medical officer (PHC/ CHC/Subdistrict/ District hospitals/ private health facility) 2. At AEFI management centres
Who will use?	Trained ANM/ vaccinator	Trained doctor
What are the contents?	Contains :- <ul style="list-style-type: none"> • 1 ml ampoule of adrenaline (1:1000 aqueous solution) - 3 in no • Tuberculin syringes(1ml) or insulin syringes (without fixed needle of 40 units) - 3 in no • 24/25 G one-inch needles - 3 in no • guidelines/ job aid with dose calculation • certification format for expiry date of adrenaline 	In addition to the contents of the Anaphylaxis kit, it has <ul style="list-style-type: none"> • Inj. Hydrocortisone (100mg)- 1 vial • I/V fluids (Ringer lactate/Normal saline) – 1 unit in plastic bottle • I/V fluids (5 % dextrose)- 1 unit in plastic bottle • IV cannula/scalp vein set (2) • IV drip set (1) • Disposable syringe – 5 ml with 24 / 25G IM needle -3 sets • Cotton wool/ Adhesive tape – 1 • AEFI Case reporting format (CRF) • Label showing date of inspection • Expiry date of Inj. Adrenaline and shortest expiry date of any of the components • Drug dosage tables for Inj. Adrenaline and hydrocortisone • Updated contact information of DIO, Medical Officer(s) of PHC/RH, referral center and local ambulance services

Anaphylaxis kit



The contents of the anaphylaxis and AEFI kit must be **verified** on quarterly basis for expiry date

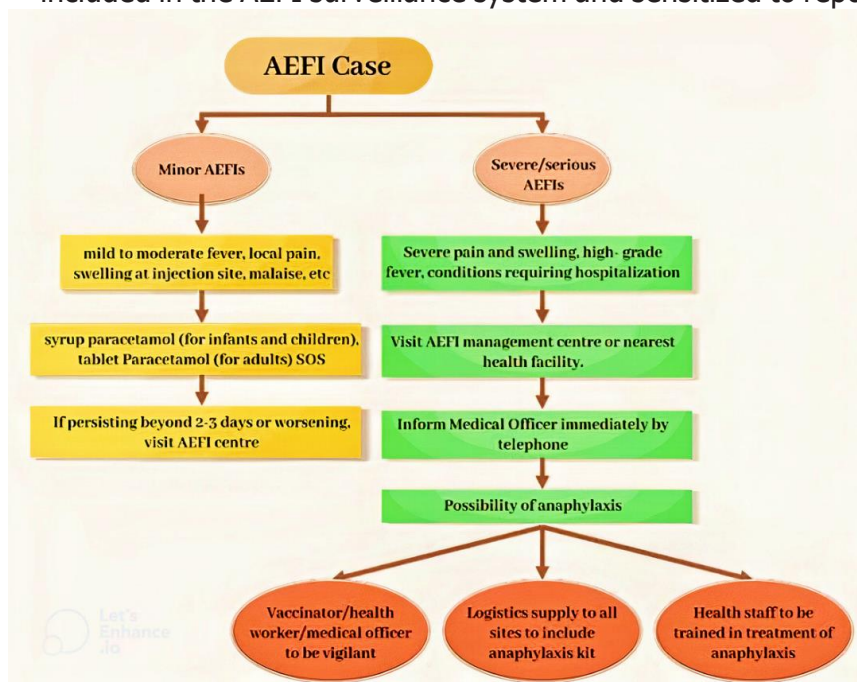
The **expiry date and dose** of the adrenaline should be written on the outside of the emergency kit.

Adrenaline that has a brown tinge must be discarded.

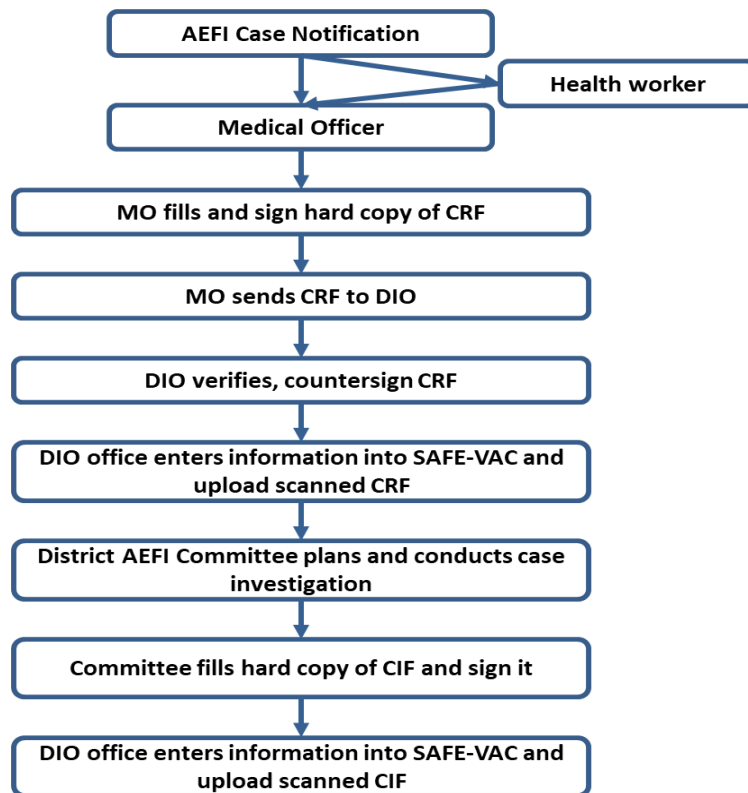
Timeline for reporting AEFIs

For the purpose of reporting, AEFIs can be minor, severe and serious. Most vaccine reactions are minor and settle on their own. Severe and serious reactions are rare. Any adverse event following any vaccination must be reported. Minor AEFIs can be reported by the vaccinator/health staff to the AEFI surveillance system through the UWIN-SAFE-VAC application. Vaccinators/health staff can also report hospitalizations and deaths and cluster cases through the UWIN-SAFE-VAC portal.

Sensitization of doctors to whom the target population is likely to seek treatment to be aware of the revaccination programme and to immediately report any adverse event to the DIO or ask the vaccine recipient to inform the health worker/vaccinator or TB staff. Specialists (internal medicine, chest physicians, surgeons, dermatologists or general practitioners, others) who are likely to see cases of known/expected adverse events related to BCG vaccination (such as BCG lymphadenitis/osteomyelitis/osteitis/disseminated BCG infection/keloids, etc.) should also be sensitized to report such cases to the system. The DIO and district TB officer should seek cooperation from different medical associations in the district (IMA, Association of Physicians, or surgeons, etc.). Medical colleges and large tertiary and secondary care hospitals in public and private sector in the districts should be included in the AEFI surveillance system and sensitized to report such adverse events.



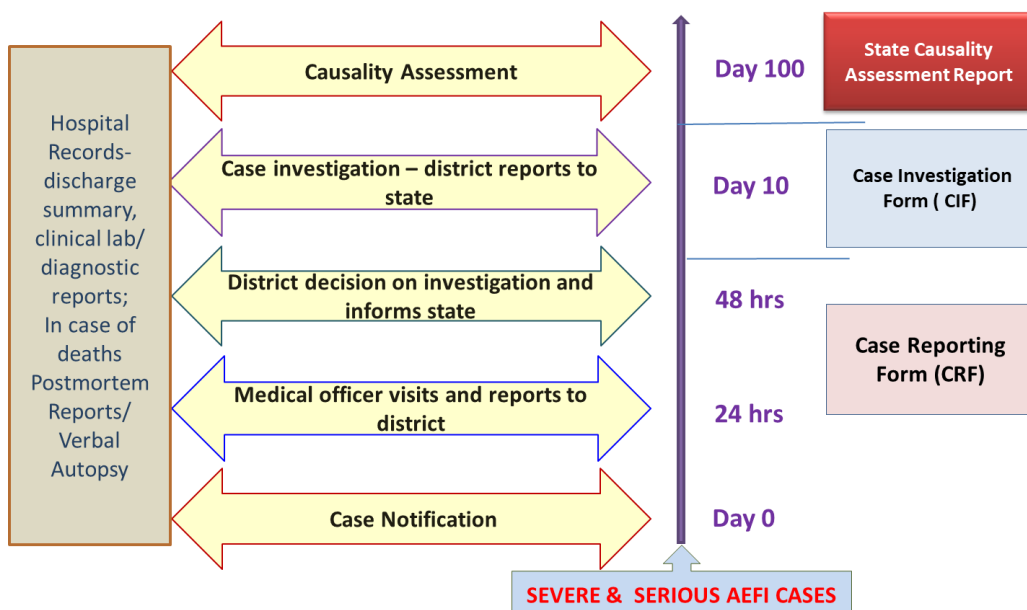
An AEFI can be reported anytime irrespective of time duration between vaccination and adverse event on SAFEVAC or between adverse event and reporting. A serious or severe AEFI case needs to be reported immediately to the concerned Medical Officer or the appropriate health authorities. It is important to note that other than anaphylaxis and hypersensitivity reactions and minor reactions (local and systemic) which occur within the first hours or couple of days of BCG vaccination, all other serious adverse events occur weeks or months following vaccination. It is important to sensitize health workers regarding the delayed onset of such events and to report them for investigations as soon as they suspect them.



7.4.3 Investigations and causality assessments

Once the serious and severe AEFIs get reported, these have to be investigated by the DIO under guidance of the District AEFI Committee within 10 days of notification. The state AEFI committees are then tasked with the responsibility of conducting causality assessments of these reported and investigated cases within 100 days of notification. The timelines in AEFI surveillance are mentioned in the figure given below:

Figure 1:



For more details on AEFI reporting, investigation and causality assessment, please refer to AEFI Operational Guidelines 2015 by MoHFW.

AEFI reporting in TB-WIN

There will be a provision for reporting of AEFIs from TB-WIN and sharing of data and information between TB-WIN and SAFE-VAC.

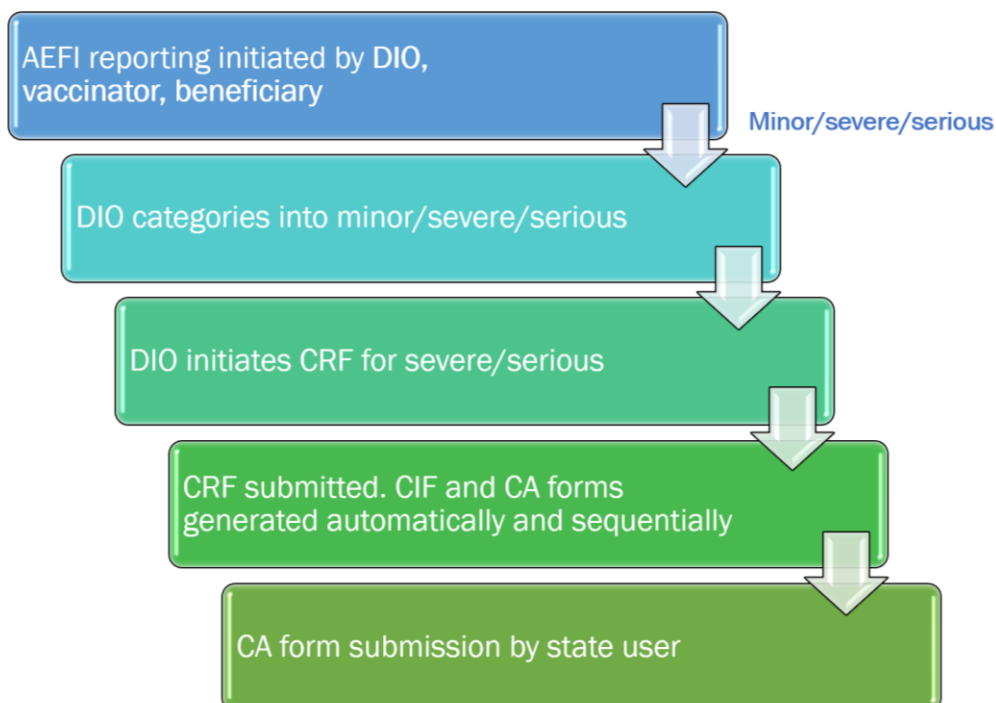
Vaccinators can view the list of beneficiaries in vaccinator module of the TB-WIN. From the list, vaccinator can report AEFI of identified beneficiary through a button "Report AEFI" against each beneficiary. Some of the data points in the AEFI reporting form will be auto-populated by system and others will have to be filled in by the vaccinator.

After completing the form and filling information in all mandatory data field. The vaccinator can click "Submit" button to submit the form. With a "Submit" button, a confirmation message will appear on the screen. After confirmation, the data will be submitted and transported to SAFE-VAC through APIs and an AEFI ID will be reverted to TB-WIN from SAFE-VAC for reference.

There will be a provision to Health Facility Manager (HFM) can view all the beneficiaries in the jurisdiction of health facility and can search for any particular beneficiary. HFM can follow the similar steps to report an AEFI.

Similar provision will be made District immunization Officers (DIO) at the district level.

Reporting AEFI Cases in TB-WIN-SAFEVAC



7.4.4 Follow up post Adult BCG vaccination for safety and recording of AEFI

The periodicity of follow up would be monthly for initial 3 months and on quarterly basis post 3 months until 36 months from the date of vaccination. Beneficiaries would be asked for general questions if they experienced any side effects post vaccination.

7.4.5. AEFI Committees at different level

- **National AEFI Committee** should include representatives from the National TB Elimination Programme for adult BCG vaccination. Experts like pulmonologist, orthopaedics, TB Specialist, HIV specialist etc should be included in National AEFI Committee as per need of the case.
- **State AEFI Committee** should include State TB Officer in causality assessment of AEFI reported post adult BCG vaccination. States may consider including experts like pulmonologist, TB Specialist, orthopaedics, HIV specialist etc should be included in State AEFI Committee as per need of the case.
- **District AEFI Committee** should include District TB Officer for AEFI reported post adult BCG vaccination. District may consider including experts like pulmonologist/ Medical Specialist, TB Specialist, orthopaedics, HIV specialist etc. for AEFI reported post adult BCG vaccination as per need of the case.

For more details on AEFI reporting, investigation and causality assessment, please refer to chapter 9 in AEFI Operational Guidelines 2015 by MoHFW.

Points to remember:

- BCG vaccines have an excellent track record for safety and efficacy, whether alone or when co-administered with other vaccines.
- AEFI post adult BCG vaccination are almost similar to that of reported with BCG administration. Only 0.1 ml AD syringe to be used for the BCG vaccination.
- BCG vaccine should not be given in contraindicated population to avoid
- Each adult BCG vaccination session site must be equipped with dedicated management kit.
- AEFIs must be reported as per Ministry of Health and Family Welfare's
- All health staff and doctors should be sensitized to report adverse events with onset upto a year following BCG vaccination to the AEFI surveillance system.
- Any adverse event occurring beyond a year following vaccination can also be reported to the system. There is no upper limit for reporting of the AEFIs.
- Always follow safe injection practices to avoid harm to vaccinator, community and environment.
- Immunization Bio Medical Waste to be managed as per revised MoHFW's
A copy of AEFI information to be also provided to the District Tuberculosis Officer immediately after reporting.
- AEFI Committees to include pulmonologist, TB Specialist, orthopaedics, HIV etc for AEFI reported post adult BCG vaccination as per need of the case.

References:

- 15 Villanueva P, Wadia U, Crawford N, Messina NL, Kollmann TR, Lucas M, Manning L, Richmond P, Pittet LF, Curtis N. Revaccination with Bacille Calmette-Guérin (BCG) is associated with an increased risk of abscess and lymphadenopathy. *NPJ Vaccines*. 2022 Jan 14;7(1):6
- 16 Ministry of Health and Family Welfare. Government of India. Operational guidelines of initial management of anaphylaxis using injection adrenaline by ANMs 2018. Available from [file:///C:/Users/DELL/Downloads/Adrenaline%20Operational%20Guidelines%20FINAL%20\(1\).pdf](file:///C:/Users/DELL/Downloads/Adrenaline%20Operational%20Guidelines%20FINAL%20(1).pdf). Accessed on 17th August 2023

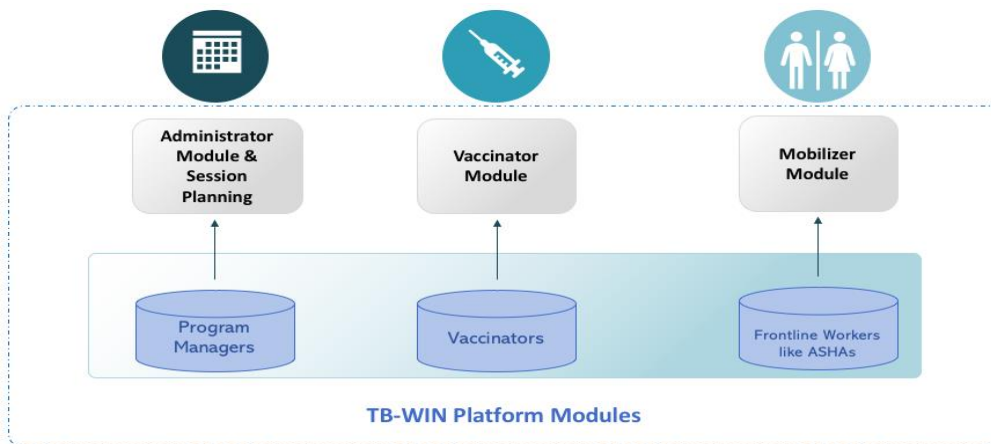
Chapter 8

Recording and Reporting for Adult TB Vaccination

TB-WIN - DIGITAL PLATFORM FOR DATA RECORDING & REPORTING

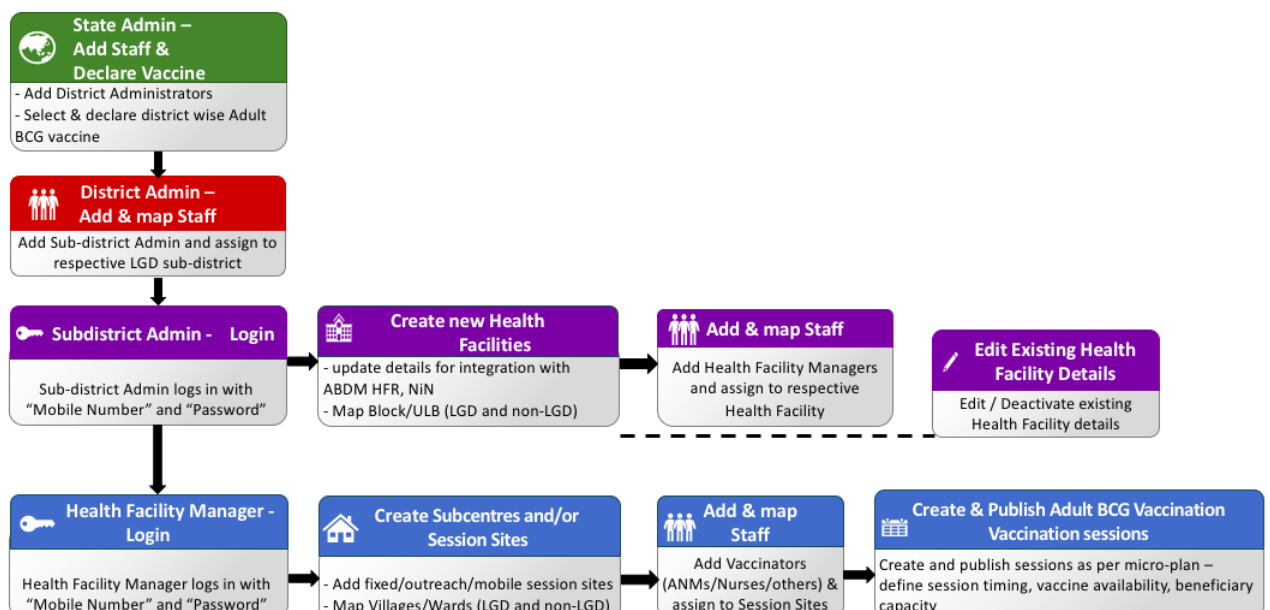
Building on the successful roll-out and implementation of eVIN as a tool for vaccine supply chain strengthening, Co-WIN for beneficiary management & recording and reporting of COVID vaccination and U-WIN for routine immunization & Intensified Mission Indradhanush, MoHFW is now leveraging U-WIN for the Adult BCG Vaccination by development of TB-WIN.

KEY MODULES OF TB-WIN



ADMINISTRATOR MODULE

Workflow



The data of all Service Delivery Points (Health Facilities, Subcentres and Session Sites) and all Users (State administrators, District administrators, Sub-district administrators, Health Facility Managers, Vaccinators, ASHAs) existing in U-WIN will be replicated in TB-WIN till a fixed date. There will be no need to create these Service Delivery Points and Users again in TB-WIN and the users will be able to login to TB-WIN using the existing U-WIN credentials.

Any new Service Delivery Points (Health Facilities, Subcentres and Session Sites) and users (State administrators, District administrators, Sub-district administrators, Health Facility Managers, Vaccinators, ASHAs) after initiation of the campaign will need to be created in TB-WIN directly.

Under TB-WIN - District, Sub-Districts, Villages/Wards will be created as per the LG Directory and LG codes will be referred. Sub-District and Villages/Wards will be auto-created in the system and there will not be any provision to create any block and village.

Health Facility will be created beneath the Sub-Districts. While creation of the Health Facility, there would be an option to tag the Block / Urban Local Body from pre-populated drop down menu options as per the LG Directory.

Further Subcentres will be created within the Health Facilities. Villages/Wards to be mapped under Sub-Centre and list of villages/wards will be as per the LG Directory.

Further Session Sites will be created under Subcentres where they are present. Where there are no Subcentres under the Health Facility, then the Session Sites can be created directly also.

However an additional option for tagging of non-LGD Block/Villages/Urban Local Bodies/Wards to their respective health service delivery structure (Health Block/Health village) will also be available

Table below to be referred for the creation of entities –

Staff Roles and major activities to be undertaken

Entity:	To be created by:
District	Auto Created
Sub-District	Auto Created
Health Facility/ Cold Chain Point	To be created by Subdistrict Administrator
Block - LGD/non-LGD (Health)	To be tagged while Health Facility creation (wherever applicable)
Urban Local Body - LGD/non-LGD	To be tagged while Health Facility creation (wherever applicable)
Subcentre	To be created by Health Facility Manager
Session Site	To be created by Health Facility Manager
Village/Ward - LGD/non-LGD (Health)	Auto Created

Staff roles and major activities to be undertaken

USER	MAJOR ACTIVITIES
State Administrator	Creation of District Administrator
	Vaccine Declaration - add Adult BCG vaccine for intervention districts
District Administrator	Creation of Subdistrict Administrator
Subdistrict Administrator	Creation of Health Facilities
	ABDM and eVIN Integration - Authentication & Tagging
	Creation of Health Facility Manager
Role of Health Facility Manager	Creation of Subcentre
	Creation of Vaccination Session Sites
	Creation of Vaccinator
	Adult BCG Vaccination Session Creation and publishing
	Session Management - Reschedule/Cancel/Edit ongoing session
Role of Vaccinator	Creation of ASHA worker and mapping village/ward
	Pre-registration of Beneficiaries > 18 years based on inclusion criterion
	Conducting Vaccination Sessions - <ul style="list-style-type: none"> • Start Planned Vaccination Session • Beneficiaries - <ul style="list-style-type: none"> a) registered - search & add in ongoing session b) walk-in, not registered - on-site registration • Beneficiary Verification & confirm that physical consent form submitted • Update BCG vaccination history of child & BCG scar presence • Record Adult BCG Vaccine dose given in present visit • Download/share Vaccination e-certificate • End Session
	View the Session site wise and ASHA wise list of Vaccinated beneficiaries and upcoming Due-list
	Report AEFI
Role of Mobilizer	Pre-registration of Beneficiaries > 18 years based on inclusion criterion
	View list of Vaccinated beneficiaries for pre-defined time period and tagged areas
	View Due-list of beneficiaries who have been pre-registered and not vaccinated for pre-defined time period and tagged areas

Session Planning and Management by Health Facility Manager

The Health Facility Manager (HFM) will be responsible for the **Creation and publishing of Adult BCG Vaccination Sessions**.

The **Vaccination Session Sites** tab will be used for creating sessions while the **Session Status** tab will be used for viewing the ongoing, scheduled, cancelled, and completed vaccination sessions.

Session type to be selected as **Adult BCG Vaccination**, select the Dates from the calendar for the planned upcoming sessions - dates can be entered for up to next 3 months. The dates on which session have already been created and published will be highlighted and non-selectable in the calendar menu. Next select the Start time and End time for the session and the Total Beneficiary Capacity for the planned session.

The screenshot shows the 'Create Vaccination Session' form in the m-kahay application. The form is titled 'Create Vaccination Session' and is part of the 'Vaccination Session Sites' tab. It includes the following fields and buttons:

- Session Site Name:** BCG SC test site
- Session Type:** Adult BCG Vaccination
- Date:** 25/9/2023
- Start Time:** 08:00 AM
- End Time:** 03:00 PM
- Total Beneficiary Capacity:** 10
- Buttons:** Save As Draft, Publish

REGISTRATION OF BENEFICIARIES ON TB-WIN

All the beneficiaries > 18 years who are eligible for Adult BCG vaccination based on any of the 6 inclusion criterion captured during the head count survey are to be registered on TB-WIN. The Mobilizer and Vaccinator modules will be used to register surveyed population through:

- **At Home Registration** - based on the information collected by the ASHAs/other mobilizers during the head count survey, there will be provision for ASHAs to pre-register beneficiaries at time of head count survey or the Vaccinators (mainly ANMs) can collect this data from the ASHAs/ other mobilizers in hard copy format and pre-register the beneficiaries in the Vaccinator module.
- **On-Spot Registration at Session Site** - beneficiaries coming to the Adult BCG vaccination session site will be checked for existing record on TB-WIN through their mobile number/reference ID/Photo ID number/ABHA ID. If unregistered, vaccinator would be able to register beneficiaries who report to the session site directly as walk-ins.

MOBILIZER MODULE

The major activities that can be done through the Mobilizer Module by the ASHAs and other mobilizers are -

- Provision for **Pre-Registration** of Beneficiaries > 18 years based on inclusion criterion based on headcount survey & household visits by mobilizers including ASHAs
- option to view and download list of **Pre-registered Beneficiaries** in previous months/ selected intervals
- Getting details of **Sessions Planned** in their tagged areas
- option to view and download list of **Vaccinated Beneficiaries** in previous months/ selected intervals
- option to view and download **Due-list of Beneficiaries** for mobilization

It will help facilitating the activities of mobilizers for routine immunization in their catchment area

Pre-Registration of Eligible Beneficiaries for Adult BCG Vaccination

1. The ASHA must first select the Session site and area (Village/ward) for which she wants to pre-register the beneficiary. After that click on the arrow on the bottom of the screen to see the option to open the Pre-registration form.

The screenshot shows a mobile application interface for pre-registration. At the top, there is a header bar with a menu icon, the text 'MADHYA PRADESH | DEWAS | Kusmantiya PHC', and a user profile icon. Below the header, there are three dropdown menus: 'Session Sites' (showing 'AWC no. 34'), 'LGD Villages' (showing 'Select from the list'), and 'Health Villages' (showing 'Select from the list'). Below these menus, there is a message 'No Sessions Available' and a note 'Note: Published sessions of next 1 week will be visible'. At the bottom of the screen, there is a blue button with a plus icon and the text 'Pre Registration', and a blue circular button with a white 'X' icon.

2. Click on Pre-registration and then enter the **mobile number, year of birth, date of birth**. Then in **the Type of Category field**, select the inclusion criterion based on which the beneficiary is being pre-registered from the 6 inclusion criterion in the drop down menu (multi-select option)

Complete the form by entering the **first name, middle and last name, gender, Photo ID type** and **Photo ID number, address, pincode** for the beneficiary.

Click on Submit button to complete pre-registration

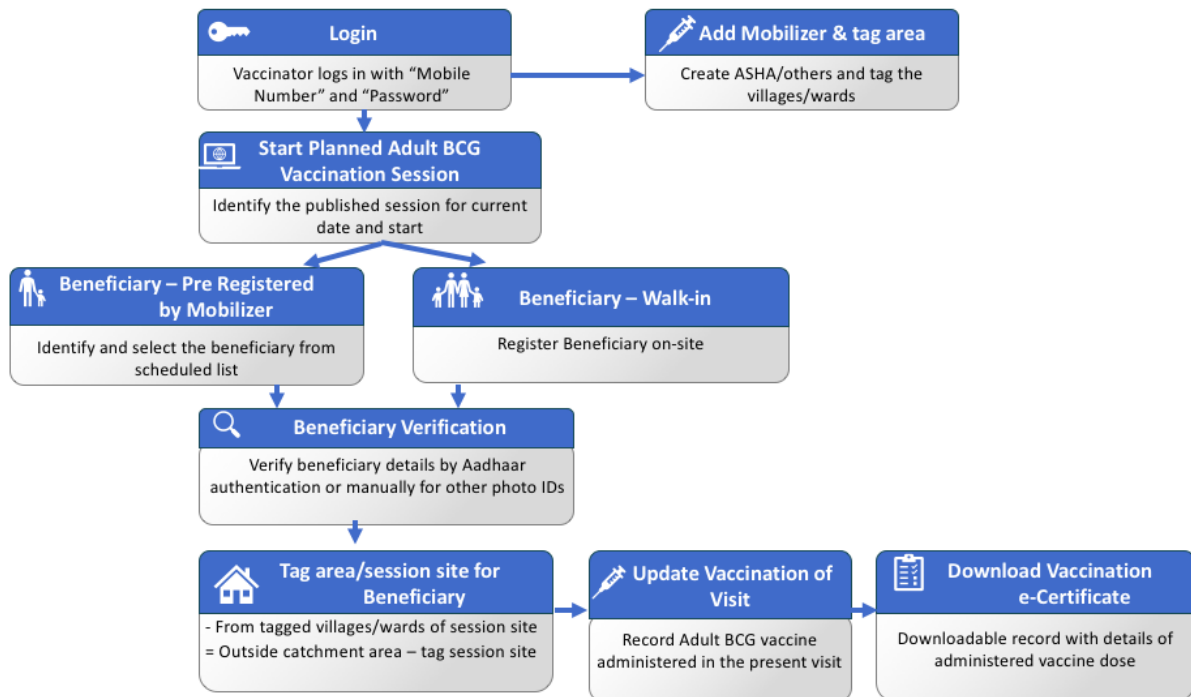
In case the beneficiary is already registered in Ni-kshay, please enter the Ni-kshay ID first while starting to fill the pre-registration form. Click on Verify button to validate the Ni-kshay ID and some of the fields will be auto-filled based on information record of the beneficiary in Ni-kshay. Fill the remaining fields in the form and submit to complete the pre-registration process.

VACCINATOR MODULE

The major activities that can be done through the Vaccinator Module by the ANMs/Staff nurses/others are -

- **ASHA Management** - add ASHA workers or mobilizers and map the villages/wards to them
- **Pre-Registration of Beneficiaries eligible beneficiaries**
- View list of Pre-registered Beneficiaries - session site wise or ASHA wise
- **Conducting Vaccination Sessions**
 - For Walk-in beneficiaries - on-spot registration for new beneficiaries, while for already registered beneficiaries search and add in ongoing session
 - Verification
 - administer and update vaccine dose administered
 - generation of Vaccination e-certificate
- **View list of Vaccinated Beneficiaries** - session site wise or ASHA wise
- **Report AEFI**

Workflow



The homepage will have tabs for **Dashboard** with session details, **ASHA management**, **Vaccinated Beneficiaries**, **Pre-registered Beneficiaries** and **Eligibility List**.

The screenshot shows the BCG SC test site dashboard. The left sidebar contains navigation links: Dashboard, Asha Management, Vaccinated Beneficiaries, Pre-Registered Beneficia..., and Due List. The main content area displays session details for 'Kusmaniya PHC' and 'BCG SC test site'. It shows two sessions: one 'ON GOING' on 21 Sep 2023 with 99 slots left, and another 'YET TO START' today with 100 slots left. A note at the bottom states: 'Note: Published sessions of next 1 week will be visible'.

SESSION NAME	AGE GROUP	DATE	SLOTS LEFT	STATUS
BCG SC test site - Adult BCG Vaccination	18Y-99Y	21 Sep 2023 (8:00 AM-5:00 PM)	99	ON GOING
BCG SC test site - Adult BCG Vaccination	18Y-99Y	Today (8:00 AM-5:00 PM)	100	YET TO START

Note: Published sessions of next 1 week will be visible

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Conducting Adult BCG Vaccination Session

1. Select the **"Dashboard"** tab and then select the Health Facility & Session Site from the drop down menus where the vaccinator intends to conduct the session on present date. Only those Health Facilities and session site will be visible to which he/she has been tagged by the Health Facility Manager or the Sub-district administrator.
2. Under the Session details all the planned vaccination sessions for the vaccinator will be visible for the next 1 week. From this list select the session that is to be conducted today.
3. The page for this particular Adult BCG Vaccination session will open with details of the session timing, slot availability, option to search for walk-in beneficiaries which are already registered on TB-WIN or Pre-register walk-in beneficiaries.
4. Click on the **"Start Session"** button on the top right of the screen. A pop-up that **"Are you sure you want to start the session"** will appear. Proceed by clicking on Yes & the session will start.

BCG SC tes...

< ADULT BCG VACCINATION, 18Y-99Y (Today) (8:00 AM - 5:00 PM) ●

SLOTS AVAILABLE # 100 / 100

On-site Registration

Filter

Search By Search Members Search Cancel

REGISTRATIONS

Scheduled 0 Verified 0 Vaccinated 0 Rejected 0

Name	Mobile	Id Proof	Id Number	Type	Action
No records found					

Items per page: 10 0 of 0

End Session

Session has started. You can start vaccinating the Beneficiaries!

version: 1.0

5. Vaccinator can search the registered beneficiary from **filter>search by** option. There are multiple options to search the beneficiary from TB-WIN like Mobile, Reference ID, Photo ID number which was used for registration.
6. After search, vaccinator can add the identified beneficiary into the session from allocate list by clicking on plus sign.
7. Now beneficiary is allocated to the session and appear in the schedule list

BCG SC tes...

< ADULT BCG VACCINATION, 18Y-99Y (Today) (8:00 AM - 5:00 PM)

SLOTS AVAILABLE # 99 / 100

On-site Registration

Filter

Search By Search Members Search Cancel

REGISTRATIONS

Scheduled 1 Verified 0 Vaccinated 0 Rejected 0

Name	Mobile	Id Proof	Id Number	Type	Action
Lalita Kumari	9857849943	PAN Card	*****484j	Past TB Patient (last 5 years), Age >= 60 Years	

Items per page: 10 1 - 1 of 1

End Session

Beneficiary Allocated To Session

reserved | version: 1.0

8. A pop-up window will open titled **"Member Verification"** at the 2nd step after clicking on the beneficiary

There are two options for this - either Aadhaar e-KYC or Manual Verification through Aadhaar, Driving License, PAN Card, Pension Passbook, NPR Smart Card, Voter ID, Unique disability ID and Ration card with photo.

9. The next step of verification is of "Personal details". The Photo ID number, name, gender will be auto filled. Enter the Year of Birth for verification and select the checkbox for **'vaccinator has taken the consent on the physical copy from beneficiary before administering the vaccination'** then Proceed by clicking on **"Continue"**.

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10. This will bring to the screen with a message **"Member Verified Successfully"** and beneficiary details. Complete verification process by clicking on Continue. Also the beneficiary moves from the Scheduled list to the Verified List.

11. Next step is to undertake and update the vaccines given in this session. The next screen will open titled **"Member Vaccination"**. First select the village or ward to which the beneficiary belongs from the drop down list. All the LGD or Health villages and/or the LGD or Health wards which are tagged to the session site while creation by HFM will be visible in drop downs. This area tagging of beneficiary is to be done based on the current location where he/she is based. If the beneficiary is from outside the catchment area of the session site, then select the **tag to session site** option. This tagging is very important so that the beneficiary appears in the vaccinated list of the ASHAs and/or the Session sites so that they can be effectively tracked by the Healthcare workers.

Then respond for beneficiary whether **BCG vaccination taken at birth/childhood?** and **BCG scar present ?**

Then the dose of Adult Bacillus Calmette Guerin (BCG) vaccine for which this beneficiary is eligible will be visible. Select after administration.

Member Vaccination

Lalita Kumari
Female | 63 yr | 1960

LGD Village
Amoda

Health Village
Select from the list

☐ Tag To Session Site

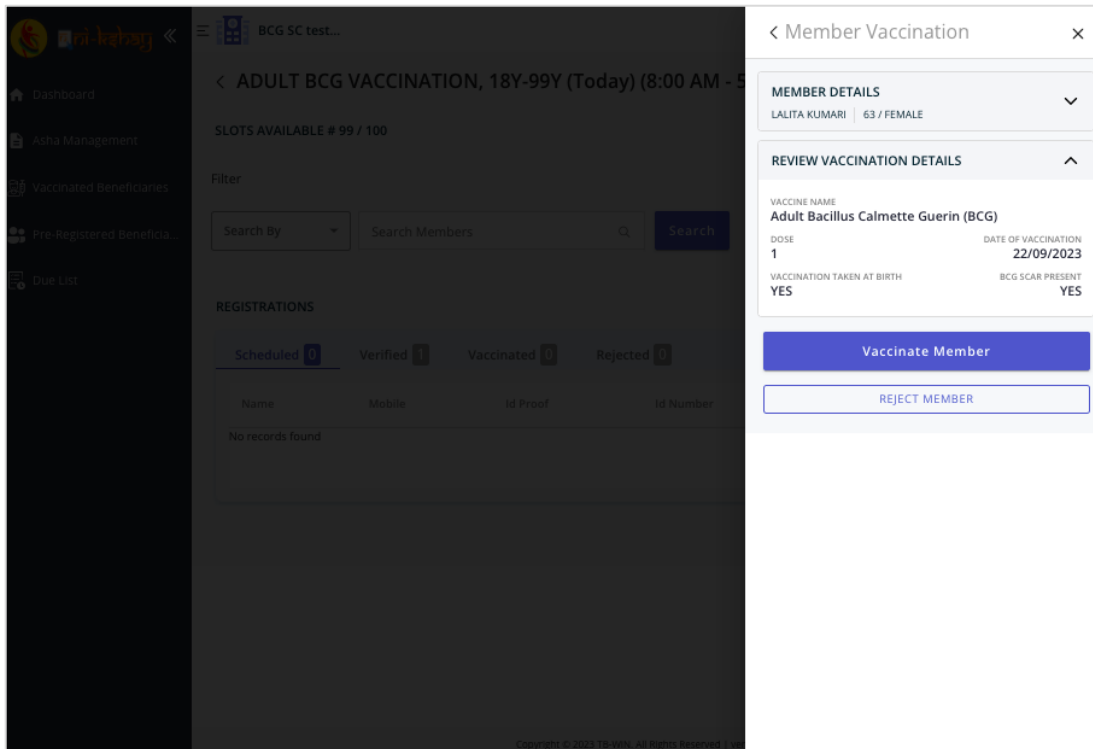
BCG vaccination taken at birth/childhood ?
☒ Yes ☐ No

BCG Scar Present ?
☒ Yes ☐ No

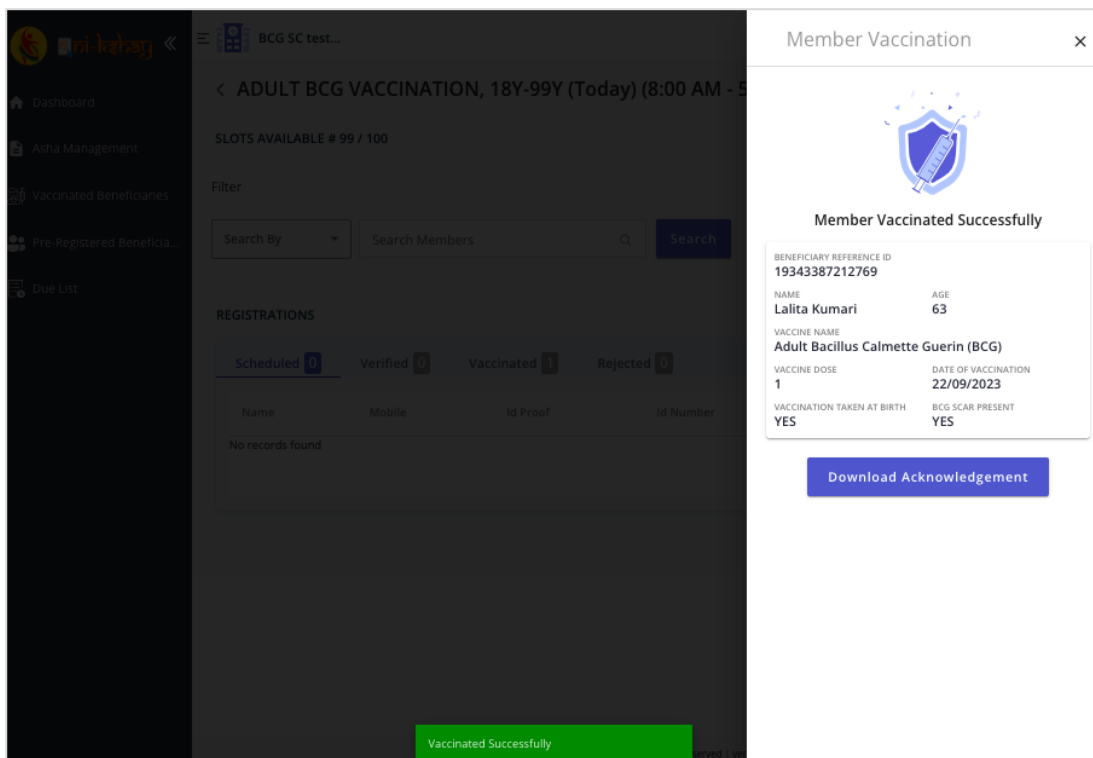
Vaccination

☒ Adult Bacillus Calmette Guerin (BCG)

12. The beneficiary may then be vaccinated by the vaccinator and proceed to update the same online. The screen will have the member details and vaccination details which includes the vaccine name, dose and date of Vaccination.
13. On completion of vaccination, click on the **"Vaccinate Member"** tab. In case for some reason the vaccination could not be done proceed by clicking on "Reject Member" and selecting the reason from drop down menu options that why the vaccination could not be done.



14. So, by clicking on "Vaccinate Member", you will come to the next screen with a message **"Member Vaccinated Successfully"** and vaccination details. There would be a tab to **Download Acknowledgement** of this vaccination. Also the beneficiary moves from the Verified list to the Vaccinated List.




15. This e-Vaccination Certificate will have beneficiary details, the details of the Site of vaccination (Vaccinated At) and name of the vaccinator who administered the vaccine doses (Vaccinated By) will also reflect in the certificate. **Also details of the type of vaccine given, date of vaccination and status will be there.**

There will be information on whom and where to reach out to in case of adverse events or further

queries followed by a declaration by the beneficiary.

The certificate will also have a QR code which can be scanned by any QR code scanner and it will display the key information about the beneficiary, location of vaccination and the vaccine doses received.



सम्यक्सेव जगते
Ministry of Health & Family Welfare
Government of India

ADULT BCG VACCINATION E- CERTIFICATE

Ref ID: 19343387212769
Year of birth: 1960
Vaccinated By: Chameli Chouhan
ABHA Id: N/A

Name: Lalita Kumari
Vaccination Date: 22-09-2023
Vaccinated At: BCG SC test site
ABHA Address: N/A


Type of Vaccine	Date of vaccination	Status
Adult Bacillus Calmette Guérin (BCG)	22-09-2023	Completed

In case of any adverse events, kindly contact the nearest Health Center/ Healthcare Worker/ District Immunization Officer Pharmacovigilance Programme of India Toll Free no 1800-11-1454

For any other queries on TB symptoms and services or counselling please reach out to District TB Officer or reach out on toll free number 1800-11-6666.

Declaration:-
I have been explained the potential benefits and risks of BCG vaccination and I understood the effects of BCG Vaccination. I agree to receive BCG vaccine and for the future follow-ups by health care personnel in this regard. I declare that I myself provided my consent for Adult BCG Vaccination, that my decision was voluntary and has not been influenced by any person.

Lalita Kumari



16.After the entries for all beneficiaries are completed for the session, the vaccinator must complete the session by selecting the End Session button. **As per current functionality the sessions will stay ongoing till vaccinator ends the session or till upper limit of 5 pm of next day after which the session will be auto-ended by the system. All Vaccinators must ensure that the entries are completed within this time frame.**

Vaccinated Beneficiaries

Vaccinator has the option to see the vaccinated beneficiaries list Session -site wise. They can select the session site, time period (filter by pre-set options or date range) to see the list of vaccinated beneficiaries in the selected session site and they can download the complete list in excel format.

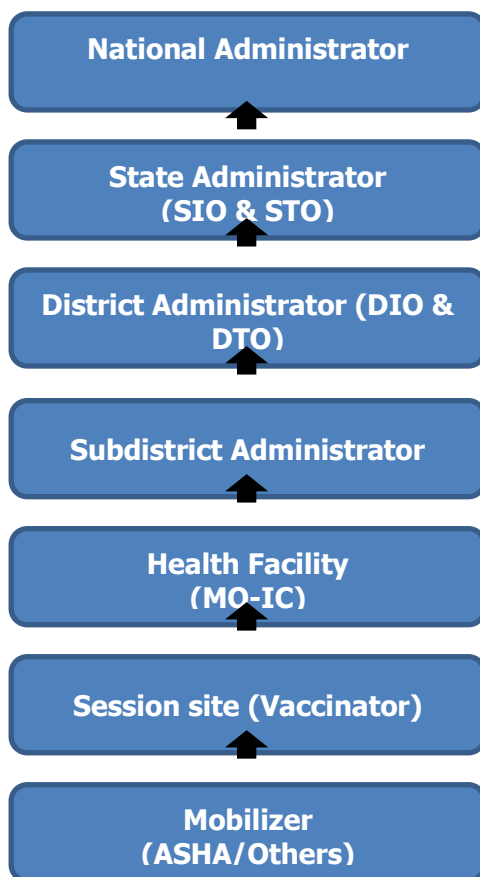
Pre-Registered Beneficiaries

Vaccinator has the option to see the list of pre-registered beneficiaries through this vaccinator

login. They can select the time period (date range) to see the list of pre-registered beneficiaries and they can download the complete list in excel format

REPORTS MODULE

The various levels which have access to TB-WIN are summarized below -



There will be drill down option (National<State<District<Sub-district<Health Facility<Session Site) at each level based on the level of login. These reports can be downloaded in excel format.

There will be an option in the reports to get data of following duration – Today (present date), Cumulative (from initiation to present date), Date Range (max 1 month)

A. Coverage Report

The real-time data entry will be done by Vaccinators at the Adult BCG Vaccination session sites updating vaccine doses administered to all the beneficiaries.

The will get aggregated in the **Coverage report** which can be accessed at all levels from the National Administrator to the Health Facility level. This report will be updated every hourly.

The coverage report will have the following data elements -

1. Sessions Planned and Sessions Held
2. Number of beneficiaries vaccinated
3. Inclusion criterion on which the beneficiary was eligible

B. Registration Report

This report on the Registrations done will be available to program Managers. Has the data of the fresh

registrations done (pre-registration and on-site). This report will be updated every hourly.

C. Adult BCG Vaccination Sessions Status

Session Status - The created Adult BCG Vaccination sessions could be categorized under 3 groups – completed, ongoing, scheduled. This report will have line-list of all published sessions with timing of planned session, actual time when session was started by vaccinator and name of the vaccinator assigned for the session. This report will be updated every hourly.

Upcoming sessions - this report will have details of future, upcoming sessions planned and published by the Health Facility Managers as per the micro-plan.

AEFI REPORTING

There will be a provision for reporting of AEFIs from TB-WIN and sharing of data and information between TB-WIN and SAFE-VAC.

Vaccinators can view the list of beneficiaries in vaccinator module of the TB-WIN. From the list, vaccinator can report AEFI of identified beneficiary through a button “Report AEFI” against each beneficiary. Some of the data points in the AEFI reporting form will be auto-populated by system and others will have to be filled in by the vaccinator.

After completing the form and filling information in all mandatory data field. The vaccinator can click “Submit” button to submit the form. With a “Submit” button, a confirmation message will appear on the screen. After confirmation, the data will be submitted and transported to SAFE-VAC through APIs and an AEFI ID will be reverted to TB-WIN from SAFE-VAC for reference.

There will be a provision to Health Facility Manager (HFM) can view all the beneficiaries in the jurisdiction of health facility and can search for any particular beneficiary. HFM can follow the similar steps to report an AEFI.

Similar provision will be made District immunization Officers (DIO) at the district level.

RECORDING & REPORTING ON NIKSHAY FOR FOLLOW-UP OF BENEFICIARIES

Ni-kshay adult BCG vaccination follow-up module will include the following components:

1. Beneficiary enrollment – Intervention and Control districts
2. Two tasklists made available via the Task List Module
3. Adult BCG vaccination Follow Up Module
4. Report/Registers in the Ni-kshay Reports Portal.

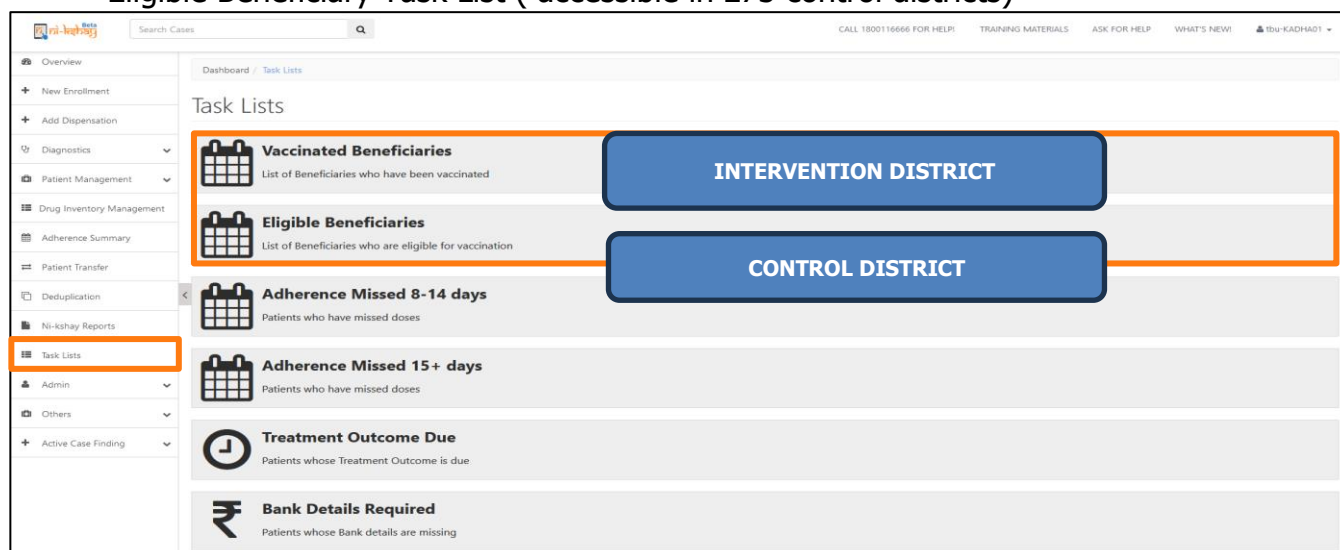
- **In Intervention districts**

All vaccinated beneficiaries would be registered in TB-WIN will be enrolled via backend in Ni-kshay and for existing enrollments, vaccinated beneficiary flag will be updated

- **In Control districts**

All eligible population would be manually enrolled in Ni-kshay by NTEP staff

- Vaccinated Beneficiary Task List (accessible in 274 intervention districts)
- Eligible Beneficiary Task List (accessible in 273 control districts)



- The Follow Up Module (accessible in 274 intervention and 273 control districts) will allow users to record 14 sessions/beneficiary across 3 years including AEFI.


Follow-Up variables:

- Follow Up Done (Y/N)
- Beneficiary Reference ID
- Name
- Age
- Village
- Vaccination Date
- AEFI (Y/N)

If yes, list AEFI due to BCG (drop-down), Others (Specify)

- Outcome of FU – Health, Presumptive TB Infection, Confirmed TB Diagnosis, Probable AEFI, Death, Migrated, Could not be contacted

- Reports and Registers of vaccinated beneficiaries and follow-up sessions will be made available on the Ni-kshay Reports Portal.



TB Notification

Directory

Reports

Patient wise List

Vaccinated Beneficiary Register

Eligible Beneficiary Register

Beneficiary Follow-Up Register

NI-kshay Reports

Vaccinated Beneficiary Register

0 info

State

Goa

District

North goa

TB Unit

Select TB Unit

Select Date

Notification Date

Date From:

20 / 06 / 2023

Date To:

20 / 09 / 2023

View By:

☒ Current Facility
 ☐ Diagnosing Facility

Health Facility Sector Type

All

Age

All

Type of Case

All

Gender

All

Site of Disease

All

Clear Filters

Generate Excel

TB Notification

Directory

Reports

Vaccinated Beneficiary Report

Eligible Beneficiary Report

Beneficiary Follow Up report

Vaccinated Beneficiary Report

0 info

State

Goa

District

North goa

TBUnit

All TBUnit

Frequency

Monthly

Year

2023

Month

August

Date Type

Date of Registrati

Generate Excel



Communication strategy for Adult BCG vaccination

Objective of the communication strategy

To provide timely, simple, and targeted communication to gain commitment from all key stakeholders for successful rollout of adult BCG vaccination. Major thrust of communication lies in addressing **vaccine hesitancy and mitigating unintended crisis i.e., AEFI**

Components of communication Strategy

9.1 Advocacy

Advocacy is the process of building support and gaining consensus by creating a positive environment for fostering a commitment for any new initiative, in this case BCG vaccination for increasing its coverage.

Key stakeholders for advocacy activities

- Elected representatives and parliamentarians (MPs, MLAs, members of legislative councils, PRI representatives)
- a. State level government officials (State TB Officers, Principal Secretary (Health), Mission Director- National Health Mission, Directorate of Health and Family Welfare, State Immunization Officers, medical colleges)
- b. District level government officials (District Magistrates, Cluster Development Officers, BDOs, District TB Officers, District Health Officer, District Immunization Officer, Medical Officers)
- c. Block level government officials, Development partners, Community Based Organizations
- d. Community influencers such as religious leaders, faith leaders, self-help group members and PRI Members.

Plan for advocacy activities

Sl	Target group	Action	Modalities of engagement	Materials needed
1.	Policy makers and program managers (state/district/block)	<ul style="list-style-type: none"> Orientation about BCG vaccination 	<ul style="list-style-type: none"> Meetings Exposure visits 	<ul style="list-style-type: none"> SoP of BCG vaccination
2.	Program managers at State and district levels, private practitioners	<ul style="list-style-type: none"> Orientation about BCG vaccination 		<ul style="list-style-type: none"> PowerPoint slides SoP of BCG vaccination Detailed FAQs
3	Media	<ul style="list-style-type: none"> Awareness about BCG vaccination introduction Reporting of positive stories 	Media briefings/workshop	<ul style="list-style-type: none"> Media kit containing: Press release FAQs
4	Community influencers like religious leaders, self-help groups, PRI members	<ul style="list-style-type: none"> Awareness about BCG vaccination introduction Advocacy with the community about importance of vaccination 	<ul style="list-style-type: none"> Community meetings 	<ul style="list-style-type: none"> FAQs

Key activities at National level

1. Development of Advocacy plan at National level
2. Organizing of briefing with ministers
3. Development and dissemination of advocacy package (FAQs, leaflets, multimedia material, media kits)
4. Organizing of pre-launch sensitization events with journalists and leveraging on existing media agencies for advocacy activities

Key activities at State level

1. Developing and adapting communication packages, plan and materials in local languages
2. Organizing advocacy events with religious leaders and faith-based institutions

Key activities at District level

1. Leveraging on existing advocacy platforms under NTEP such as Ni-kshay Diwas and community meetings with TB Champions
2. Organizing advocacy events with religious leaders, PRI members, TB champions

Capacity building

Objective of capacity building is to empower all key stakeholders with accurate information of vaccination and either impart or refresh interpersonal skills in mobilizing the target population of vaccination, by resolving misconceptions associated with it.

Key stakeholders for capacity building

1. IEC officers at national, state and district level
2. Government officials from NTEP and general health system at National, State and District level (STO, DTO, DIO, DTO, CMHO etc.)
3. Development partners
4. Community health workers of NTEP and general health, PRI members, religious leaders, TB Champions
5. Staff of Ni-kshay Sampark helpline

Key activities at National Level

1. Development of National capacity building plan including plan for cascade trainings at state and district level
2. Development of training modules of ToT and cascade training for IEC officers and government officials
3. Development of training modules for Staff of Ni-kshay Sampark helpline
4. Media briefings for media professionals
5. Training development partners who can further strengthen their network

Key activities at State level

1. Development of state capacity building plan
2. Development of master trainers for conducting state and district level trainings
3. Translation and contextualization of training modules for IEC officers, government officials and staff of Ni-kshay Sampark helpline
4. Training of frontline workers (ANM, ASHA, CHO, STS, PRI members, TB Champions) in social mobilization, Interpersonal skills and AEFI management

Key activities at District level

1. Identifying online and offline training platforms at district level.
2. Organizing trainings of district officials, community health workers, IEC officers and stakeholders from district level.

Media engagement

In order to create and maintain a conducive environment for roll-out of Adult BCG vaccination, involving traditional media as well as new age media in selected geographies is imperative. It will broadly be used for advocacy and awareness generation.

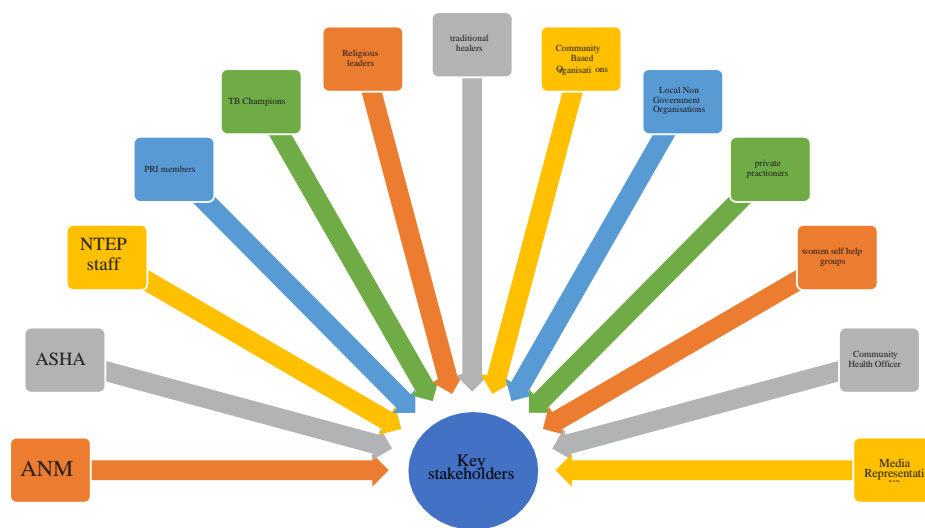
The steps in planning phase wise engagement activities include the following:

1. Mapping of media sources at state, district level and further down in select geographies.
2. Preparation of IEC materials suitable for all communication channels (newspaper, articles, leaflets, posters, miking in state specific languages).
3. Media tool kits containing fact sheets of global and country burden of TB and efficacy of vaccine, importance of BCG vaccination and vaccine roll out strategy and FAQ.
4. Press release.
5. Responses to FAQs for media professionals, community health workers, program managers.
6. Securing Op-eds, opinion pieces from subject experts and policy makers.

Social mobilization and community engagement

Social mobilization and community engagement is a critical step in increasing vaccine coverage especially for facilitating dialogue with the community regarding benefits of vaccine and debunking the myths associated with it. Social mobilization plan will be contextualized to urban, rural, and tribal settings and will mainly focus on increasing uptake of the vaccine among target groups.

Key stakeholders involved in social mobilization are listed below:



Key activities at National level

1. Mapping of key stakeholder at National level including partners for social mobilization.
2. Preparation of social mobilization plan and its dissemination to key stakeholders.
3. Preparation of appropriate IEC materials and key messages and its distribution through all communication channels.
4. Preparation of training material for capacity building and conduct of National ToT.

Key activities at state level

1. Mapping of key stakeholder at state level (IEC officers, State TB Officers, PRI representatives, Partner representatives)
2. Preparation of social mobilization plan at state level and its dissemination to key stakeholders.
3. Translation of IEC materials and key messages and its distribution through relevant communication channels.
4. Monitoring of cascade trainings of key stakeholders.

Key activities at district level

1. Mapping of key stakeholder at district level (NTEP staff at district level, community health workers, community influencers, Community Based Organizations, NGOs, TB Champions, religious leaders, PRI members).
2. Distribution through all communication channels.
3. Monitoring of cascade trainings of key stakeholders.
4. Conducting special mobilisation sessions with groups who are traditionally known to be resistant to vaccines.
5. Leveraging on existing platforms of NTEP such as Ni-kshay Diwas, community meetings with TB Champions.

Crisis communication

Objective of the crisis communication is to prepare the relevant stakeholders in rapid response to any crisis e.g., Adverse Effect Following Immunization (AEFI) that can affect the vaccine uptake adversely.

Key activities at National level

1. Formation of crisis management committee containing key national, state and district officials including representatives of AEFI committee, advocacy groups and media professionals.

2. Formation of crisis management plan at national level in consultation with the committee members.
3. Mapping of media resources (traditional media and digital media) and spokesperson at national level.
4. Preparation of **advocacy material and key messages** (Fact sheets of AEFI and FAQs) regarding crisis management for community health workers, program managers and media professionals.

Key activities at District and block level

1. Conducting cascade trainings district and block level key stakeholders.
2. Sensitisation of community health workers, traditional healers, Community Based Organisations, NTEP staff in debunking the myths around AEFI.
3. Creating positive messages among regional media. Editorials on AEFI management.
4. Periodic media monitoring of both traditional and new age media to ensure sustained dissemination of positive information.



Monitoring and Supervision

Adult BCG vaccination campaign provides an opportunity to strengthen the health system in terms of immunization and TB service delivery.

Monitoring & Supervision would be carried out at all the phases of the campaign i.e.

1. Before the launch- Preparatory phase
2. During the campaign
3. After the campaign is over- Post implementation

A team of national and state observers shall supervise and monitor all activities during the preparatory implementation and post-implementation phases across the country. These teams shall guide and evaluate the progress and share their findings with the state and district task forces, and subsequently at the national level for further action.

10.1 Monitoring and Supervision of implementation

National Level

Review of the state preparedness checklists and assessment of progress achieved in addressing the identified issues at regular intervals will contribute to effective implementation and will also strengthen the TB & Immunization service delivery. Field visits by national observers will provide real- time information. The observers must visit the health facilities at all levels to assess the preparedness of states prior to introduction.

State Level

Review of the preparedness checklists of the districts will be done by the State TB Officers & State Immunization Officer (SIO). It is recommended that a state team be formed to oversee the implementation process. Officers from various departments can also be involved in the state- level training to enable participation in monitoring. Field visits by the STO & SIO must focus on checklist findings and visit the district training sessions. Issues identified must be shared with state and district task forces for corrective actions.

10.1.1 State task force for Adult BCG vaccination campaign (STFI)

STFI should be convened periodically to steer key messages for all activities for the campaign in the state, including commitment and support from various departments and stakeholders. The STFI to include State TB Officer along with other members, partners and stakeholders.

Issues identified in preparedness assessment should be addressed during meetings of the STF, State AEFI committee and the State Health Society (SHS) for ensuring smooth

implementation of the campaign.

Before the launch of the campaign, ensure that AEFI surveillance system is strengthened with reporting of AEFI cases following other vaccines also. The increased AEFI reporting during the campaign may be blamed on the BCG vaccine. This may affect the acceptance and demand for Adult BCG vaccines in other states and districts. However, the medical fraternity across all cadres should be reassured as increased sensitivity in reporting of AEFIs actually is in the interest of the program.

District Level

District-level monitoring provides information on vaccine availability, microplanning, training, vaccine coverage, vaccine stocks, wastage rates, social mobilization and communications. Monitoring of these activities will be done by all immunization partners.

10.2 District Task Force (DTF) for Adult BCG vaccination campaign

DTF should be convened periodically to steer all activities for the campaign in the district, including obtaining commitment and support from various departments and stakeholders. The DTFI to include District TB Officer along with other members, partners and stakeholders. Issues identified in activities essential for smooth implementation of the campaign in the district should be addressed during meetings of DTF, district AEFI committee and District Health Society. Districts should make best use of lessons learnt from the polio program and introduction of other new vaccines to strengthen routine immunization.

The DTF should monitor preparations for reporting and managing AEFIs. It should monitor the status of AEFI trainings, reporting and investigation of serious/severe AEFIs following all vaccines (not just BCG). It should also ensure that the district AEFI committee is active and meets at least once a quarter.

Key routine immunization & TB partners at district level are expected to proactively extend support in providing quality information/monitoring data to DTF for guiding and taking appropriate actions.

10.3 District-Level Monitors' Briefing

To build capacity of district- and block-level officials, government and partners are responsible for monitoring the preparedness and implementation of the campaign in the districts. Monitors are expected to use standardized monitoring formats. These monitors will share monitoring feedback at respective levels as per timelines.

10.4 Monitoring vaccine, logistics and cold chain at PHC

BCG vaccine should be stored between +2°C and +8°C. Available records must be examined for supply, utilization and balance of vaccines with AD syringes. Records should be cross-verified physically to see whether there is a logical association between vaccines and AD syringes supplied and used. eVIN is an important tool to monitor vaccine stock and cold chain status at all levels. Program officers are encouraged to physically validate the data recorded in eVIN and also in the NCCMIS.

Session site monitoring

This captures information on vaccine supply and the availability of logistics, functioning of alternate vaccine delivery (AVD) system, injection practices of ANMs, injection safety and waste disposal, record keeping and inter-personal communication of service providers.

District and block level monitoring

This provides information on coverage, vaccine stocks, wastage rates, etc.

Rapid monitoring RCM Rapid Convenience monitoring

Following the campaign, simultaneous rapid monitoring will also be initiated to assess implementation status of campaign, identify gaps/bottlenecks and provide feedback for immediate corrections. The findings will be very useful in introduction/expansion of Adult BCG vaccination in the country. All immunization & TB partners will assist the MoHFW in undertaking rapid monitoring through standardized rapid monitoring formats along with standard operating procedures. Rapid monitoring will be done at block and session level, for which separate formats will be developed.



Financial Norms for adult BCG vaccination campaign

The expenditure to be booked under NTEP budget head i.e. Others including Operating Costs (OOC) of Latent TB Infection.

Sl	Activities	Norms
1	To develop sub-centre microplans using bottom up planning with participation of ANMs, ASHAs, AWWs level, (for logistics)	@ Rs 100/- per sub health center
2	For consolidation of micro plans at block level / PHC and district level	Rs. 1000 per block/ PHC and Rs.2000 per district
3	Focus on slum & underserved areas in urban areas/ other areas	Hiring of ANM@ Rs 450/session / slum o 10,000 population and Rs 75/session as contingency.
4	Alternative Vaccine Delivery in very hard-to-reach areas for sessions for the adult BCG vaccination campaign	Rs. 450 per Adult BCG vaccination session
5	Alternative Vaccine Delivery in hard-to-reach areas for sessions for the adult BCG vaccination campaign	Rs. 200 per Adult BCG vaccination session
6	Alternative Vaccine Delivery in other areas for sessions for the campaign	Rs. 90 per Adult BCG vaccination session
7	Mobilization of beneficiary through ASHA or other mobilizers for adult BCG beneficiaries	Rs. 150 per adult BCG vaccination session Two mobilizers will be present at each session site (ASHA/AWW/link worker). Each mobilizer may be paid Rs 75 with a maximum limit of Rs 150 per session site.
8	ASHA incentive for house-to-house survey before the campaign	Rs 300 once for the campaign. This amount may be paid to the ASHA. If no ASHA is identified or available, the same may be paid to the link worker/AWW, subject to a total ceiling of Rs 300.*
9	ASHA incentive for eligibility list preparation (For monthly updating of due list of beneficiaries)	Rs 300/month × 3 months (if mop-up is required). This amount may be paid to the ASHA. If no ASHA is identified or available, the same may be paid to the link worker/AWW, subject to a total ceiling of Rs 300.*
10	Honorarium of vaccination team (ANM, ASHA, AWW, TB Champions/ volunteer) (maximum upto 4 members per session)	Unit cost of Rs 100 per team member per session

Sl	Activities	Norms
11	Red/Black/ Yellow plastic bags etc. for adult BCG vaccination sessions required during the campaign and mop-up	Rs. 3/bags/session
12	AEFI & Anaphylaxis Kit:	@ 1 AEFI kit/Cold Chain Point: - @ Rs. 200/- per AEFI kit per CCP 1 Anaphylaxis kit/vaccinator: Rs. 100/- per anaphylaxis kit per ANM/Vaccinator
13	Printing and dissemination of survey formats, tally sheets, monitoring forms, etc. (digital system is encouraged to use)	@ Rs.30/surveyor
14	Cost of transportation (POL) of vaccines from district vaccine store to Cold Chain Point, over and above the approved in PIP:	Rs.16000/district/month*
15	Miscellaneous cost (including Ice pack freezing from hired / private firms if required)	Rs 10000 /district/month for 3 month
16	IEC :- Poster, Banner, Hoarding :- Poster: 2/session, Banner: 1/session Hoarding: 1/CCP, Miking for 2 days (Before & During)/session Additional pool for innovations to create awareness, mobilization, etc	Rs 25000/district/month for 3 month
17	Planning and review meetings to be conducted: <ul style="list-style-type: none"> Planning meeting of 30 persons each per district for arranging training materials, refreshments and other miscellaneous expenses. Weekly Review Meeting up to 3 meetings of 30 persons each per district Weekly Review Meeting up to 3 meetings of 10 persons each per CCP 	Rs 40,000 /per month per district for 3 months
18	Mobility support to vaccinator for conducting sessions outside allocated subcentre or place of posting Mobility support for supervision of these activities Mobility support for mobile teams in far-flung/scarcely populated/scattered areas.	Any additional requirement may be discussed or approved by DTFI. Some areas may require allocation of funds above the budgeted norms based on the geographical access. States to decide the financial norms for budgetary calculation & distribution to districts as per local need. *
19	Mobile Team mobility for hard-to-reach area for 2 day	Unit cost @ Rs. 1500 per vehicle per day per CCP
20	Indelible marker, Pen, Zipper Bag, Chalks, etc	Unit cost @Rs. 50/- per session

*Revised as per letter issued for financial norms for Intensified Mission Indradhanush 5.0 dated 04th July 2023 via letter number T-13020/23/2017-Imm (Pt-2) FTS No.3194232

Financial norms for the Adult BCG vaccination Campaign

Revised training norms under RCH (as per GOI letter D.O.No. A-11033/101/07- Trg, dated 28th Jan 2015)

sl.	Budget Head	Final Proposed Norms
1	DA to Group A equivalent Participants	Rs 700/- per day
2	DA to Group B, C & D or equivalent participants	Rs 400/- per day
3	Honorarium/ per diem to Group A & B equivalent participants	Rs 500/-
4	Honorarium/ per diem to Group C & D or equivalent participants	Rs 300/-
5	TA to Group A, B,C & D or equivalent participants.	TA rules of Central/ State Govt.(whichever applicable)
6	Hiring of Vehicle by Trainer	State norms of hiring of vehicle will apply
7	Honorarium to Guest faculty at District and sub-district, State/Regional/National level (Experts/Specialists of area, faculty of medical college, centre of excellence, program officer dealing with program)	Rs 600 (district) Rs 1000 (State) & 1500 (National Level) per day
8	Honorarium to professional/ Faculty/ Trainers from Medical Colleges^^^ for monitoring of trainings in field as Observer (Checklist/Handholding the training/Action taken decision)	District to Block- Rs 500/-, State to to State/ District/ Block level – District/Block 1000/- and National 1500/- (one training in a day with complete observer report) Report to be copied to respective concern division, State headquarters/ SIHFW and in Ministry (MOHFW)
9	Food to participants (breakfast, working tea & lunch & Dinner for residential trainings)	Rs 250/- participants/day at district level and 350 at State and 400 at National level (subject to actual)
10	Accommodation for Trainers where residential facility is not available	Up to Rs 3000 (district level) Rs 4000 (at state level), & 5000 (National Level) per day (subject to actual). Above are the maximum limits and subject to receipt.
11	Accommodation for participants where hostel facility is not available	Up to Rs 1000 (district level) Rs 2000 (at state level), & 3500 (National Level) per day (subject to actual). Above are the maximum limits and subject to receipt.
12	Incidental expenses (Photocopy, job aids, flip charts etc)	Rs 300/- participants/day (subject to actual)
13	Venue hiring (in absence of training institute)	Rs 5000/- per day at district/block level per dayRs 10,000 per day at State level per day and Rs 20,000 per day at National level per day
14	Institutional overhead for the use of institutional facilities	15% of total training expense^



Role of Stakeholders and Partners

Adult BCG vaccination campaign is a collaborative effort of NTEP along with Immunization division and multiple other partners. However, the whole campaign is to be led by the NTEP at the National, State and District level.

Broad role of stakeholders is enlisted below:

At National Level

SI	Organization/ Stakeholders	Roles and Responsibilities
	Central TB Division, MoHFW	<ol style="list-style-type: none"> 1. Fulcrum for Adult BCG vaccination. 2. The overall planning and execution of adult BCG vaccination in collaboration with Immunization Division 3. Ensuring necessary administrative approvals such as constituting technical committee, study protocol, consent from States/ UTs, financial approval, ethics approvals) 4. Development of Standard Operating Procedure in collaboration with Immunization Division 5. Development of learning resource packages and IEC material 6. Development of preparedness assessment checklist reporting formats and monitoring plan of the supervisors at state/ district and block/ urban planning unit 7. Sensitization and capacity building and of relevant stakeholders 8. Mobilisation of financial resources 9. Procurement of BCG vaccine, syringes and necessary logistics 10. Coverage analysis and follow up 11. Collaboration with immunization partners for making necessary changes in Ni-kshay platform

Immunization Division, MoHFW	<ol style="list-style-type: none"> 1. Assist CTD in overall planning and execution 2. Co-development of SoP 3. Supply chain of vaccine and logistics 4. Cold chain space assessment in the select geographies under consideration 5. Collaboration with CTD for making necessary changes in e-VIN for vaccine logistics and TB-WIN for other operations 6. Support capacity building 7. Monitoring and supervision
Indian Council for Medical Research	<ol style="list-style-type: none"> 1. Development of study protocol and ethics approval 2. Randomization of intervention and control districts 3. Data analysis in the study sites
Technical Expert Committee for Adult BCG Vaccination	<ol style="list-style-type: none"> 1. To guide the Central TB Division in implementation study of TB Vaccination in India 2. To guide in the development of Standard Operating Procedure for Adult BCG Vaccination in India 3. To monitor and review the progress of Adult BCG Vaccination study implementation. 4. To guide in the Communication plan for Advocacy, Awareness generation and Risk Mitigation during Adult BCG Vaccination.
WHO – NTEP & NPSN	<ol style="list-style-type: none"> 1. Technical assistance to CTD and Immunization division for development of SoP 2. Share feedback and recommendations to guide future strategies in Adult BCG vaccination.
Immunization Partner (JSI, UNDP)	<ol style="list-style-type: none"> 1. Technical assistance in capacity building, field implementation and monitoring and supervision 2. Assist in cold chain assessment and IT support by UNDP
UNICEF	<ol style="list-style-type: none"> 1. Cold Chain assessment 2. Pre-campaign assessment and supportive supervision using standardized checklists

At state level

SI	Organization/ Stakeholders	Roles and Responsibilities
	State TB Officer	<ol style="list-style-type: none"> 1. Constitution of State Operations Group (SOG) with representatives such as State Immunization Officer, State Finance Officer (NHM), Focal eVIN-UWIN, NTEP partners, State IEC focal, State Cold Chain Officer. SOG to guide the operationalization of guidance provide by NOG 2. Capacity building of district level and sub district level stakeholders, cover- age analysis and ensuring availability of adequate HR 3. Support Immunization division in field operations 4. Collection of filled preparedness assessment checklist of all districts from State Immunization Officer 5. Follow up on study objectives throughout study duration 6. Maintain finances and ensure proper planning
	State Immunization Officer	<ol style="list-style-type: none"> 1. Ensuring uninterrupted supply of BCG vaccine and necessary logistics for the study 2. Overall microplanning and execution in discussion with STO 3. AEFI monitoring 4. Managing AEFI in field and crisis management if any
	WHO – NTEP & NPSN	<ol style="list-style-type: none"> 1. Capacity building through state and district level ToTs. 2. Conduct rapid monitoring of adult BCG Vaccination prepared-ness and introduction. 3. Assist in the data analysis (Microplanning, feedback sharing for daily activity review) at the state and district level. 4. Monitor implementation at the block/district levels with feedback to DTFI and STFI. 5. Share feedback and recommendations to guide future strategies in Adult BCG vaccination.
	Immunization partner (JSI, UNDP)	<ol style="list-style-type: none"> 1. Technical assistance in capacity building, field implementation and monitoring and supervision
	Field implementation staff – NTEP & Immunization at district level	<ol style="list-style-type: none"> 1. Preparation of list of vaccine beneficiaries, social mobilization 2. vaccinating eligible beneficiaries 3. Safety surveillance 4. Follow up



Annexures

Annexure 1: - Suggestive agenda for Training of Trainers (ToT) and cascade trainings

Suggestive agenda for National and State ToT

Time	Topics
9:30 – 9:45 AM	Welcome and introduction
9:45 – 10:15 AM	Key note address
10:15 – 11:00 AM	Tuberculosis disease, Clinical overview, burden and strategies
11:00 - 11:15 AM	Tea Break
11:15 – 11:45 AM	Introduction to adult BCG Vaccination
11:45 – 12:30 PM	Orientation to protocol
12:30 -1:30 PM	Micro-planning and recording & reporting formats
1:30 - 2:00 PM	Lunch Break
2:00 – 2:30 PM	Injection techniques – video demonstration, Safe injection practices, Bio Medical Waste Management
2:30- 3:30	Session site creation and recording reporting in TB-WIN
3:30 - 3:45	Tea Break
3:45 – 4:45 PM	Group work on microplanning formats
4:45 – 5:30 PM	AEFI on adult BCG vaccination
5:30- 5.45 PM	Recap of the day and vote of thanks
Day 2	
9:30 –9:45 AM	Welcome
9:45 – 10:15 AM	Recap of the previous sessions
10:15 – 11:00 AM	Vaccine & Cold Chain Management
11:00 – 11:15 AM	Tea Break
11:15 – 12:00 PM	Advocacy, communication and social mobilization and media handling
12:00 – 1:00 PM	Frequently Asked Questions (FAQs)
1:00 – 1:45 PM	Lunch Break
1:45 – 2:15	Financial norms
2:15 – 3:00 PM	Job aids for program manager, MO, ANM and vaccinator
3:00 - 4:00 PM	Roll-out Plan (logistics, training and monitoring)
4:00 – 4:30 PM	Open discussion
4:30 – 4:45 PM	Vote of thanks and closing remarks
4.45 -5:00 PM	High tea

Suggestive agenda for district level trainings

Time	Sessions Topic
9:30 – 9:45 AM	Welcome and introduction
9:45 – 10.00 AM	Key address
10.00 – 10.15 AM	Tuberculosis disease, Clinical overview, burden and strategies
10.15 – 10.30 AM	Introduction to Adult BCG Vaccination
10.30 – 11.00 AM	Orientation to protocol
11.00 - 11.10 AM	Tea Break
11.10 -11.45 AM	Micro-planning and formats
11.45 – 12. 00 AM	Vaccine & Cold Chain Management
12.00 – 1.00 PM	TB-WIN, Ni-kshay and recording reporting
1.00 - 1.30	Lunch
1.30– 2.00	Injection techniques & AEFI surveillance and its management
2.00- 2.45 PM	Frequently Asked Questions
2.45- 3.15 PM	Advocacy, communication and social mobilization and media handling
3.15 - 3.30	Tea Break
3.30-4.00 PM	Roll-out Plan (logistics, training and monitoring) & financial forms
4.00 – 4.05 PM	Closing remarks

Suggestive agenda for block/ PHC level training

Time	Sessions Topic
9:45 – 10:00 AM	Welcome and introduction
10.00 – 10.15 AM	Tuberculosis disease, and Clinical overview
10.15 – 10.30 AM	Introduction to Adult BCG Vaccination
10.30 – 11.00 AM	Orientation to House to House survey and beneficiary estimation. Orientation to consent form
11.00 - 11.10 AM	TEA BREAK
11.10 -12.10 AM	Frequently Asked Questions
12.10 – 12.30 AM	Advocacy, communication and social mobilization
12.30 – 1.00 PM	TB-WIN, Ni-kshay and recording reporting
1.00 - 1.30	Injection techniques & AEFI and its management, addressing community concerns
1.30–2.00	Financial forms
2.00- 2.05	Closing remarks

Suggestive training agenda for mobilizers

Time	Sessions Topic
9:45 – 10:00 AM	Welcome and introduction
10.00 – 10.15 AM	Tuberculosis disease, and Clinical overview
10.15 – 10.30 AM	Introduction to Adult BCG Vaccination
10.30 – 11.00 AM	Orientation to House to House survey and beneficiary estimation. Orientation to consent form
11.00 – 11.10 AM	TEA BREAK
11.10 -11.30 AM	Financial norms, communication and social mobilization
11.30 – 12.00 AM	Frequently Asked Questions
12.00 – 12.20 PM	U-Win, Ni-kshay and recording reporting
12.20 – 12.30	Closing remarks

Annexure 2:- Consent for the Adult BCG Vaccination

Title of the study: Effect of BCG vaccination in vulnerable adult population in reducing TB disease: a programmatic study

Conducted by:

Central TB Division, Ministry of Health and Family Welfare, Government of India in collaboration with Indian Council of Medical Research.

(A) Information for the eligible beneficiary

Greetings.

- (1) The Government of India has set a goal of TB elimination by 2025. BCG vaccination of vulnerable group of adults is an important intervention for potential reduction of new TB cases in the community. BCG vaccine has been historically given to newborn babies in India since 1978, and has proven to be a safe and effective vaccine in preventing severe forms of TB disease and related TB mortality in children. Since the immunity against TB reduces over a period of time, in order to boost the immunity and give protection against TB in adults, the Government of India is implementing this study. Under the National TB Elimination Programme, the government provides free diagnosis and treatment to all TB patients and is implementing several strategies for preventing TB disease. In order to achieve the national target of ending TB by 2025, the Ministry of Health & Family Welfare, Govt. of India along with the State Governments / UTs has decided to give adult BCG vaccine to vulnerable individuals for further decreasing the risk of TB disease.
- (2) Under this study, adult BCG vaccination is being offered to all adults over 60 years of age and adults above 18 years of age fulfilling any of these criteria :- (a) history of TB in last 5 years, (b) close contacts of an active TB case, (c) Body Mass Index less than 18 KG/ meter square, (d) self-reported smokers (current/ past), (e) known case of Diabetes Mellitus.
- (3) Under this study, adult BCG vaccination will not be offered to individuals who are (a) pregnant / lactating, (b) currently on TB treatment / TB preventive treatment, (c) have diseases like HIV/ cancer/ on immunosuppressant medications/ are transplant recipient, (d) currently sick/ seriously ill/ bed ridden, (e) have a history of blood transfusion in last 3 months, (f) have a history of known severe reactions to BCG or any other vaccines, (g) with high risk behaviors like injectable drug users, sex workers etc.
- (4) BCG vaccine is overall safe. Following vaccination you will observe formation of papule, mild ulceration or scar formation at the injection site (1 in 10 vaccinated individuals). However, in some individuals with HIV-AIDS/ cancer with compromised immunity status, on immunosuppressant medications/ transplant recipient, seriously ill/ bed ridden, a history of known serious reactions to BCG or any other vaccines may experience side-effects. Some may experience suppurative lymphadenitis (Uncommon to rare ie 1 in 1,000 to 10,000), disseminated BCG disease (very rare ie 1 in ~2.3 lakh to 6.4 lakh), BCG osteitis (uncommon to rare ie 1 per ~3.5 thousand to 10 lakhs vaccinated), immune reconstitution inflammatory syndrome -IRIS (very rare ie 1 per 6.4 lakhs).
- (5) You have been identified as an eligible person for BCG vaccination, since you are above 18 years of age and because of your vulnerability for TB disease as per the above-mentioned criteria. BCG vaccination can potentially benefit you by reducing your risk of getting TB disease in future.
- (6) Post vaccination, you will be followed up every month for first 3 months and thereafter every 3 months till 3 years after the date of vaccination. During the follow up we will ensure your wellness and look for

any side effects of vaccination. You will also be regularly screened for any signs/ symptoms suggestive of TB. If required we will also offer you appropriate diagnosis, treatment and care free of cost.

- (7) There will be **“no compensation”** provided after Adult BCG vaccination to you for your participation or any adverse event. However, if you experience any side effects, we will provide all necessary treatment and care “free of cost” in the nearest and appropriate government health facility.
- (8) All your personal information will be kept confidential and will be shared only with the study team. In the process of this study, your Ayushman Bharat Health Account (ABHA) number can be shared for purposes as may be notified by Ayushman Bharat Digital Mission (ABDM) from time to time including provision of healthcare services.
- (9) In case you do not want to get BCG vaccine, it is fine and you will continue to receive all usual services by the public health system that you are entitled to.
- (10) Your decision to accept or refuse BCG vaccine is **completely voluntary**. You can say **“NO”** to getting the BCG vaccine injection or withdraw from the study without giving any reason. If you agree, you will be given an injection in the right upper arm. You will only feel a slight pinch. You will be able to continue with your routine work after injection. In case you have any discomfort any time after the injection, please contact us or your nearest public health facility.

If you have any questions, please ask and we will try to answer all of them.

(B) Undertaking by the beneficiary

I have been explained the above information including the potential benefits and risks of BCG vaccination as mentioned in A (4) para in a language that I understand. I do not belong to any of the exclusion criteria as mentioned in A (3).

I am aware that my personal identifiable information excluding Aadhaar number / Virtual ID number can be used and shared for purposes as mentioned above. I give my consent to use ABHA Id (if required) for the study purpose and I reserve the right to revoke the given consent at any point of time for vaccination and subsequent follow up as per government guidelines. I agree to receive BCG vaccine and follow up thereafter. I am willing to take vaccine and sign the register too.

Yes ☐

No ☐

Name of the recipient:

Age: Sex:

Date:

Place:

