Integrated Health Tool for planning and costing (IHT)

Tuberculosis module

Target population estimation:

resistance profiles, drug Susceptibility testing and TB prevention

Department for HIV, Tuberculosis, Hepatitis and Sexually Transmitted Infections

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World Health Organization

Integrated Health Tool for planning and costing

END TB

Outline

This presentation provides an overview of the user interface for:

1. Resistance profiles, drug susceptibility testing (DST) and treatment
2. TB prevention and vaccination

1. Resistance profiles, DST and treatment

Resistance profiles, DST and treatment

- A resistance profile (proportion of patients in different resistance categories) is used to represent the estimated need of different types of treatment, based on WHO's treatment guidelines and to ensure provision of appropriate treatment/regimens, following appropriate DST.
- After a patient is diagnosed (as either true or false positive) they all enter allocation to regimens according to a resistance profile and DST to determine appropriate allocation within the profile.
- Children and adults have distinct regimens.
- No further distinction is made in terms of population group or whether a patient is diagnosed in a patient- or provider-initiated programme: all patients are allocated a treatment regime according to a DST-confirmed resistance profile.

Treatment for active TB: resistance profiles (1/2)

- The following treatment profile is used to represent WHO treatment guidelines and to ensure provision of appropriate treatment, following provision of the relevant DST:
  - Rifampicin sensitive
    - with Isoniazid sensitive and resistant subsets
  - Rifampicin resistant (RR)
    - with Fluoroquinolone (FQ) sensitive and resistant (Pre-XDR), with an XDR subset for the latter.
- Assignment of regimens to each branch requires the relevant DST to be conducted. Patients who do not receive a test for RR will receive first line treatment. Likewise, RR patients not receiving a test for FQ resistance will receive inappropriate second-line treatment.
- RR estimates come from the WHO RR burden base. Assumptions, which the user can edit, are made regarding populations with Isoniazid resistance and Fluoroquinolone resistance.

Treatment for active TB: resistance profiles (2/2)

- RR estimates come from the WHO RR burden base. Assumptions, which the user can edit, are made regarding populations with Isoniazid resistance and Fluoroquinolone resistance.
  - Rifampicine resistance is based on fields from the WHO RR burden database
  - The proportion of Fluoroquinolone resistance is stated simple as 20% for the moment. There is an estimate in the RR surveillance database, but it is generally regarded as an underestimate of FQ resistance, especially in countries where FQs are widely prescribed, and we use 20% from a meta-analysis for FQ proportions instead.
  - Different for new and retreatment cases (higher in retreatment cases)
- The proportion of cases with XDR, defined as Pre-XDR and resistant to at least one of Bedaquiline, Linezolid, Levofloacin, Moxifloxacin, is a user input
- There are several other proportions needed among adults and children needed for treatment related costing. These include the proportion of adults and children without severe disease or with TB meningitis. These data are not available from the WHO database and must be estimated in country. Defaults will improve as we gain a better understanding of the data.
- We use the same default values for adults and children, but the user can change this if they have country-specific information.

Additional notes on resistance profiles and DST

- No default data on the coverage of different forms of resistance testing.
- However, the model requires these coverage elements to calculate eligibility for different regimens: in the model, eligibility is conditional on appropriate DST, otherwise first line treatment applies.
- With these coverage levels in place, calculation of DST volumes and treatment eligibility volumes follow.
- The TB Global Plan 2023-2030 calls for universal upfront DST which together with increased TB detection is the fastest way of reducing RR/DR burden.

Drug-sensitivity testing: coverage

- Resistance testing coverage are determined for
  - Rifampicin resistance
  - Isoniazid resistance, among Rifampicin resistant cases
  - Fluoroquinolone resistance, among Rifampicin resistant cases
  - resistance to Bedaquiline, Linezolid, Levofloxacin, Moxifloxacin

- Resistance related number of tests/patient volumes are calculated following the application of resistance profile for each of the categories above

Drug-sensitivity testing: number of confirmations

Number of confirmations are determined for:

- Number presumed Rifampicin and Isoniazid sensitive
- Number confirmed Rifampicin sensitive and Isoniazid resistant
- Number presumed Rifampicin resistant and Fluoroquinolone sensitive
- Number confirmed Rifampicin resistant and Fluoroquinolone resistant, pre-XDR
- Number resistant to at least one of Bedaquiline, Linezolid, Levofloxacin, Moxifloxacin, XDR

Treatment of drug-sensitive TB: non-severe TB

- **Treatment of drug-susceptible TB, Rifampicine and Isoniazid sensitive, adults**
  - Pulmonary and extra-pulmonary TB, adults, aged 15+ without severe TB
    - 6-month 2HRZE/4HR regimen (isoniazid, rifampicin, ethambutol and pyrazinamide, daily)
    - 4-month 2HPMZ/2HPM regimen, for + 12 years (or less than 40 kgs) excluding severe EPTB and pregnant women

- **Treatment of drug-susceptible TB, Rifampicine and Isoniazid sensitive, children**
  - Pulmonary and extra-pulmonary TB, children without severe TB
    - 6-month 2HRZE/4HR regimen (isoniazid, rifampicin, ethambutol and pyrazinamide, daily)
    - 4-month 2HRZ(E)/2HR regimen for children and adolescents

Treatment of drug-sensitive TB: severe TB

- **Treatment of TB meningitis & pericarditis, bones, joint TB , adults**
  - Number drug-susceptible TB with meningitis and pericarditis
    - Initial adjuvant corticosteroid therapy with dexamethasone or prednisolone tapered over 6-8 weeks for TB meningitis and pericarditis only
    - 12-month 2 (HRZE) /10 (HR) regimen for with TB meningitis & pericarditis, bones, joint TB
- **Treatment of TB meningitis and pericarditis, children, aged 0-14**
  - Number drug-susceptible TB with meningitis and pericarditis
    - Initial adjuvant corticosteroid therapy with dexamethasone or prednisolone tapered over 6-8 weeks for TB meningitis and pericarditis only
    - 6-month 6HRZEto for TB meningitis (only)
    - 12-month 2 (HRZE) /10 (HR) for TB meningitis and osteoarticular TB

Treatment of drug-resistant TB, Rifampicine sensitive

- **Treatment of drug-resistant TB, Rifampicine sensitive regimen in Isoniazid resistant, adults, aged 15+**
  - Number confirmed Rifampicine sensitive and Isoniazid resistant
    - Hr-TB regimen: 6(H)REZ-Lfx [6HREZ-Lfx OR 6REZ-Lfx]

- **Treatment of drug-resistant TB, Rifampicine sensitive regimen in Isoniazid resistant, children, aged 0-14**
  - Number confirmed Rifampicine sensitive and Isoniazid resistant
    - Hr-TB regimen: 6(H)REZ-Lfx (pediatric)

Treatment of drug-resistant TB, Rifampicine resistant

- **Treatment of drug-resistant TB in Rifampicine resistant and FQ sensitive, adults, aged 15+**
  - Number confirmed Rifampicine resistant and Fluoroquinolone sensitive
    - 6-month all oral BPaL regimen [bedaquiline, pretomanid, linezolid and Moxifloxacin (BPaLM) regimen] for MDR/RR-TB
    - 9-month, all oral bedaquiline containing regimen for MDR/RR-TB [4-6 Bdq[6]-Lfx[Mfx]-Lzd[2]-E-Z-Hh-Cfz / 5 Lfx[Mfx]-Cfz-Z-E]
    - 9-month all oral bedaquiline containing regimen: 4-6 Bdq[6]-Lfx[Mfx]-Eto-E-Z-Hh-Cfz / 5 Lfx[Mfx]-Cfz-Z-E
- **Treatment of drug-resistant TB in Rifampicine resistant and Fluoroquinolone sensitive, children, aged 0-14**
  - Number confirmed Rifampicine resistant and Fluoroquinolone sensitive
    - 9-month, all oral bedaquiline containing regimen for MDR/RR-TB [4-6 Bdq[6]-Lfx[Mfx]-Lzd[2]-E-Z-Hh-Cfz / 5 Lfx[Mfx]-Cfz-Z-E]
    - 9-month all oral bedaquiline containing regimen: 4-6 Bdq[6]-Lfx[Mfx]-Eto-E-Z-Hh-Cfz / 5 Lfx[Mfx]-Cfz-Z-E

Treatment of drug-resistant TB, pre-XDR

- **Treatment for drug-resistant TB treatment, adults, aged 15+**
  - Number confirmed Rifampicine resistant and Fluoroquinolone resistant, pre-XDR
    - 6-9-months BPaL regimen [bedaquiline, pretomanid and linezolid (BPaL) regimen] for multidrug-resistant tuberculosis with additional fluoroquinolone resistance
    - Longer regimen for DR-TB (18-20 months), contains delamanid (group c), adult and children
    - 18-20 months longer regimen: 2 group B + 2 group B, adult and children

- **Treatment for drug-resistant TB treatment, children, aged 0-14 years**
  - Number confirmed Rifampicine resistant and Fluoroquinolone resistant, pre-XDR
    - Longer regimen for DR-TB (18-20 months), contains delamanid (group c), adult and children
    - 18-20 months longer regimen: 2 group B + 2 group B, adult and children

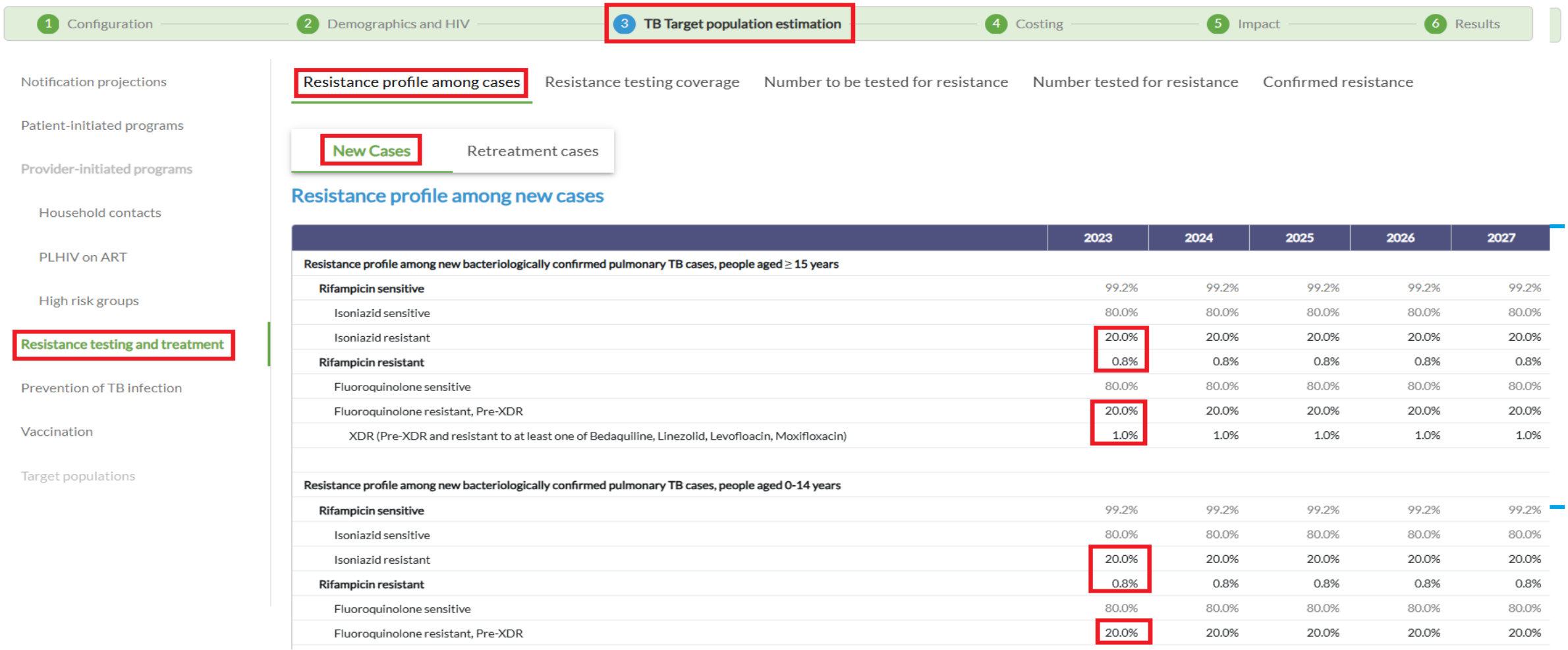
Treatment of drug-resistant TB, XDR

- Treatment of extensively drug-resistant TB (XDR), adult
  - Number Pre-XDR and resistant to at least one of Bedaquiline, Linezolid, Levofloxacin, Moxifloxacin
    - 18-20 months longer regimen for MDR/RR-TB: group A agents + group B agent + group C (total number of drugs to be at least 4), adult
- Treatment of extensively drug-resistant TB (XDR), children
  - Number Pre-XDR and resistant to at least one of Bedaquiline, Linezolid, Levofloxacin, Moxifloxacin
    - 18-20 months longer regimen for MDR/RR-TB: group A agents + group B agent + group C (total number of drugs to be at least 4), child

Treatment of drug-resistant TB, XDR

- Treatment of extensively drug-resistant TB (XDR), adult
  - Number Pre-XDR and resistant to at least one of Bedaquiline, Linezolid, Levofloxacin, Moxifloxacin
    - 18-20 months longer regimen for MDR/RR-TB: group A agents + group B agent + group C (total number of drugs to be at least 4), adult
- Treatment of extensively drug-resistant TB (XDR), children
  - Number Pre-XDR and resistant to at least one of Bedaquiline, Linezolid, Levofloxacin, Moxifloxacin
    - 18-20 months longer regimen for MDR/RR-TB: group A agents + group B agent + group C (total number of drugs to be at least 4), child

Exploring the resistance profile editor



	2023	2024	2025	2026	2027
Resistance profile among new bacteriologically confirmed pulmonary TB cases, people aged ≥ 15 years					
Rifampicin sensitive	99.2%	99.2%	99.2%	99.2%	99.2%
Isoniazid sensitive	80.0%	80.0%	80.0%	80.0%	80.0%
Isoniazid resistant	20.0%	20.0%	20.0%	20.0%	20.0%
Rifampicin resistant	0.8%	0.8%	0.8%	0.8%	0.8%
Fluoroquinolone sensitive	80.0%	80.0%	80.0%	80.0%	80.0%
Fluoroquinolone resistant, Pre-XDR	20.0%	20.0%	20.0%	20.0%	20.0%
XDR (Pre-XDR and resistant to at least one of Bedaquiline, Linezolid, Levofloacin, Moxifloxacin)	1.0%	1.0%	1.0%	1.0%	1.0%
Resistance profile among new bacteriologically confirmed pulmonary TB cases, people aged 0-14 years					
Rifampicin sensitive	99.2%	99.2%	99.2%	99.2%	99.2%
Isoniazid sensitive	80.0%	80.0%	80.0%	80.0%	80.0%
Isoniazid resistant	20.0%	20.0%	20.0%	20.0%	20.0%
Rifampicin resistant	0.8%	0.8%	0.8%	0.8%	0.8%
Fluoroquinolone sensitive	80.0%	80.0%	80.0%	80.0%	80.0%
Fluoroquinolone resistant, Pre-XDR	20.0%	20.0%	20.0%	20.0%	20.0%

6: Additional information: allocation of regimen and treatment options

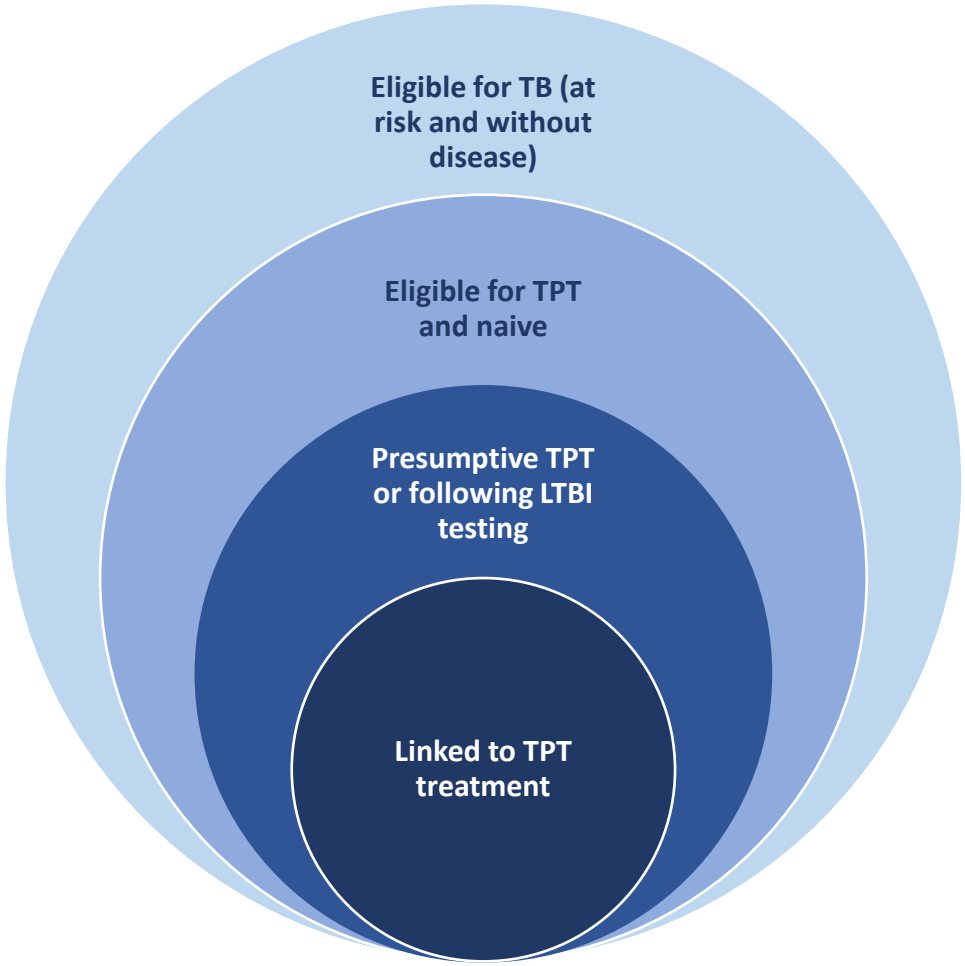
Proportion with non-severe TB (inclusion criterion for short-course regimen)					
People aged ≥ 15 years	95.0%	95.0%	95.0%	95.0%	95.0%
People aged 0-14 years	95.0%	95.0%	95.0%	95.0%	95.0%
Proportion of patients with drug-susceptible TB meningitis and pericarditis (inclusion criterion for longer-course regimen)					
People aged ≥ 15 years	5.0%	5.0%	5.0%	5.0%	5.0%
People aged 0-14 years	5.0%	5.0%	5.0%	5.0%	5.0%
Proportion MDR/XDR-TB patients requiring lung resection surgery					
People aged ≥ 15 years	5.0%	5.0%	5.0%	5.0%	5.0%
People aged 0-14 years	5.0%	5.0%	5.0%	5.0%	5.0%
Patients whose curative treatment options have been completely exhausted					
People aged ≥ 15 years	5.0%	5.0%	5.0%	5.0%	5.0%
People aged 0-14 years	5.0%	5.0%	5.0%	5.0%	5.0%

2. TB Prevention

TB prevention

- The total number of at-risk patients to initiate TPT is collected from the TPT section of each population in the provider-initiated programmes. These are each based on:
  - TPT eligibility (not having active TB and being TPT naïve).
  - Evaluation (or TPT evaluation coverage)
  - TPT initiated presumptively or following LTBI testing, which differs by population according to their estimated risk
  - Linkage to care and TPT initiation
- Patients exposed to drug-sensitive TB and drug-resistant TB receive appropriate regiments.
  - The split between DS and DR exposure is based on the overall split from the resistance profile editor. It is averaged over new and re-treatment status of TB patients. This default value can be edited by the user should she/he have data to suggest a split that differs from the DS-DR split for TB patients treated for active TB.
  - The model does establish an explicit link between DS/DR status and LTBI testing for those TPT patients who receive TPT following an LTBI test.
- The number of adults and children receiving TPT is calculated separately to allow their respective regimens to be costed.
- Note that the input for being TPT naïve is used for costing (only naïve patients are costed). Previously prevention treatment contributes to estimate impact

Cascade of TB prevention



- The total number of people at risk to initiate TPT is collected from the TPT section of each population in the provider-initiated programmes. These are each based on TPT eligibility (not having active TB and being TPT naïve). TPT is initiates presumptively or following LTBI testing
- Patients exposed to drug-sensitive TB and drug-resistant TB receive appropriate regiments.
    - The split between DS and DR exposure is based on the overall split from the resistance profile editor. It is averaged over new and re-treatment status of TB patients. This default value can be edited by the user should she/he have data to suggest a split that differs from the DS-DR split for TB patients treated for active TB.
    - The model does establish and explicit link between DS/DR status and LTBI testing for those TPT patients who receive TPT following an LTBI test.
- The number of adults and children receiving TPT is calculated separately to allow their respective regimens to be costed.

Vaccination

- The model captures the number of infants and neonates (0-11 months and obtained from Demographical component) who receive BCG Immunization.
- This number is used for costing only and its impact is not modeled. (This impact is very small over the short time periods of a typical strategic plans)

Note for exercise material section 3.4

- Follow the demonstration of configuring the resistance profiles for adults and children, new and retreatment patients, in terms of the resistance profile of each.
- Follow the demonstration of reviewing and updating where possible additional information used for treatment option and regimen allocation:
  - Proportion with non-severe TB (inclusion criterion for short-course regimen)
  - Proportion of patients with drug-susceptible TB meningitis and pericarditis (inclusion criterion for longer-course regimen)
  - Proportion MDR/XDR-TB patients requiring lung resection surgery
  - Patients whose curative treatment options have been completely exhausted
- Take note of the data needed to complete the DST and regimen allocation framework
- Note the consequences of not having full DST coverage .
  - Inappropriate regimens will be allocated with suboptimal outcomes, based on assumed resistance characteristics