Integrated Health Tool for planning and costing (IHT)

Tuberculosis module

Target population estimation: provider-initiated programmes

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World Health Organization

Integrated Health Tool for planning and costing

END TB

Outline

1. Target population estimation:
    a. purpose
    b. design
    c. calculation approach
2. Exploring provider-initiated programmes in the user interface

1.a Purpose of the target population estimation component

Overview

- The purpose and uses of target population estimation (TP) component are to:
  a. estimate target populations needed for costing of a TB strategy/strategic plan
  b. facilitate building and maintaining explicit links between the “TB target population estimation” and “Costing” components so that impact estimates accurately refer to that of a country-specific costed strategy
  c. estimate the impact of a given TB strategy.

- The focus of this presentation is on the target populations needed to cost treatment and care cascades, e.g. the number of people or patients receiving:
  i. clinical evaluation (patient-initiated) and systematic screening (provider-initiated)
  ii. diagnosis and DST (drug susceptibility testing)
  iii. appropriate treatment, first line and second line
  iv. prevention for those eligible, presumptive or following LTBI (Latent Tuberculosis Infection) testing
  v. other population not following the TB care cascade model: HIV-TB collaboration, TB vaccination.

Impact of a given strategy

- Impact is discussed in other sessions, so not going into detail in this presentation.

- Overview:

  - Strategic-level modelling with the statistical modelling tool
    - The impact model can do more comprehensive impact modelling, but that may require technical modelling outside of IHT TB. Within IHT TB, its uses are also limited to ‘strategic level’ impact modelling.

  - A country might ask questions such as what is the projected impact of:
    - Increased systematic screening
    - Increasing prevention in PLHIV on ART
    - Increasing prevention among populations living in high TB prevalence settings.

  - As we go through the section, anticipate how to represent your strategy in the tool.

  - As the impact questions and the package of interventions become more nuanced, more technical inputs and analyses are needed by the user to ultimately provide answers with confidence.

Resource needs based on costed services

- **Resource needs(t) = Target population(t) x Population in need(t) x Coverage(t) x Unit cost(t)**, where:

- **Target population:** Interventions are linked to a population meant to receive the intervention or health service.
  - For example, diagnosis with microscopy is linked to the number of bacteriologically positive notified cases .
- **Population in need (PIN):** Specification for a proportion of the population that is eligible for the intervention.
  - For example, a proportion of all notified cases may need patient support.
- **Coverage:** These are used to configure costing elements and provides and specifies a given strategy
  - For example, the proportion of patients diagnosed with Xpert may increase from 40% in the first year of the plan to 90% by 2030, following WHO guidelines and TB Global Plan strategy
  - Contact tracing in household contacts of index cases could be increased from 40% to 100% by 2030, following WHO guidelines and the TB Global Plan strategy
- **Unit costs:**
  - Units cost are configured in the costing component, and is the subject of other sessions

Role in costed strategies

- The TP component interfaces with the costing component to:
  - provide estimates of TPs/volumes needed for costed services
  - synchronize coverage settings between the TP component and the costing component to ensure that estimated impact refer to that of the strategic plan being costed.
- The TP component represents a TB control strategy in terms of coverage targets in key intervention areas:
  - The model representations strategic coverage targets and a key user task is to represent a strategy in the framework.
  - These inputs rely on default data and expert inputs to reflect country-level specifics.

1.b Design of the target population estimation component

Design of the component: Process

Projection of key TB indicators: Notification, TB Incidence and TB Deaths. Projection is based on conceptually and practically different methods:

- Statistical model - ‘state space methods’ (SSM) – limited user inputs needed
- Dynamical modelling – extensive user inputs needed

Target population projections are built upon defined populations, each with a defined care cascade following steps from screening or clinical evaluation, diagnosis & DST to treatment and prevention

The choice of populations in the model is based on a compromise to best:

- reflect country-level contexts and situations
- structure service provision around WHO guidelines for TB detection, treatment and prevention
- reflect relevant service characteristics linked to distinct populations. For example, population categories are based on age, pulmonary status, HIV status and TB treatment resistance profile. Services can be provided in patient- or provider-initiated settings.

Design of the TP component: Data

- Default data provide the user with a good starting point when costing a strategic plan, which can then be refined. The TP component prepares a comprehensive default database and loads defaults into the user interface.
- This is built mostly on publicly available data:
  - Latest TB programme data reported to WHO (for example notification, drug resistance surveillance and LTBI estimates databases).
  - Burden-related indicators estimated and reported by WHO, including TB incidence and TB mortality. **Note that WHO do not provide projections of these indicators**, and that is why the tool uses appropriate methods (statistical or dynamical models) to project trends for the relevant indicators. The projections are benchmarked against the most recent WHO estimates, where possible.
- TP 'splits', for example, the proportion of pulmonary and extra-pulmonary TB clinically assessed and diagnosed, are based on the latest year of data in WHO databases, and the 'splits' assumed to hold constant going forward.

1.c Calculation approach for the target population estimation component

TP component calculation approach

- Populations reached by provider-initiated programmes provide a simpler starting point than those that define patient-initiated programmes as the target population is more directly based on inputs.
- Calculations are designed to quantify a treatment and care cascade, e.g.,:
  - Screening for TB disease
  - Diagnosis of TB disease
  - DST for those with diagnosed TB disease
  - Treatment for those with diagnosed TB
  - Prevention for those without TB disease but at high risk for active TB and eligible for TPT
- Calculations and process flows for patient-initiated programmes are very similar, with a few additional calculation elements added

Populations for provider-initiated programmes

- **Household contacts (HH contacts)**
  - Ages 0-4, Aged 5-14, Aged 15+
- **PLHIV on ART**
  - Without serious illness and with serious illness (we expect more opportunistic infections among PLHIV with severe disease/compromised immune system)
  - CLHIV, 0 to 9 years HIV-negative, CLHIV, 10 to 14 years, PLHIV, 15+ years
- **High risk groups (HRG)**
  - Prisoners, miners exposed to silica, general population living in high prevalence settings
  - Additional populations at high risk of TB infection can be defined

Population characteristics

Each population must be specified in terms of:

- **Population size**
  - For HH contacts and PLHIV on ART this information is obtained from inputs & calculation and from the IHT HIV component respectively.
  - For HR groups the user must define population sizes, for example the size of the prison population or of a displaced population, to be screened.
- **Prevalence estimates for active (for the treatment branch) and latent TB (for the prevention branch)**
  - For HH contacts and PLHIV on ART default active and latent prevalence estimated are provided.
  - For HR groups the user defines active TB prevalence via a relative risk (RR) variable which expresses TB prevalence in a HR group relative to the general population.

Process flow of TB care cascade

- **Screening** for TB (population appropriate screening algorithm)

  - TP_screen + FP_screen, function of TB prevalence and SE and SP of screening algorithm

- **Diagnosis** of TB (appropriate diagnostic method)

  - TP_diag + FP_diag, function of TB prevalence and SE and SP of diagnostic algorithm/method

- **Drug susceptibility testing** for regimen allocation (appropriate drug sensitivity test or tests)

  - Rifampicin sensitive (and within this group Isoniazed sensitive or resistant) or Rifampicin resistant (and within this group, Fluoroquinolone sensitive or resistant)

- **TB regimen** based on assumed resistance profile or established via DST

Screening for provider-initiated programmes

Each treatment and care cascade requires the specification of:

- **A screening algorithm**
  - WHO recommended algorithms are provided as default options.
  - The user can select and configure a screening algorithm from a list of options and the user can configure the algorithm to have one or two screening steps.
  - Each screening algorithm is associated with an overall (displayed) sensitivity and specificity.
- **A diagnostic algorithm**
  - The user can specify the proportion of cases referred for diagnostic evaluation that are evaluated with different methods, e.g. smear microscopy and Xpert.

Screening calculations

- The cascade starts with the number being screened which is determined by the population size and screening coverage setting:
  - TB and LTBI prevalence estimates are used to **split** the population into **active TB, latent TB and those without active or latent TB.** The algorithms are defined for pulmonary TB and the proportion pulmonary TB among active TB cases must be specified.
- The screening sensitivity (**SE_screen**) determines the number True Positive TB cases (TP) proceeding to diagnostic evaluation:
  - TP_screen = Number screened x Prev TB x **SE_screen**
- The screening specificity (**SP_screen**) determines the number of False Positive TB cases (FP) proceeding to diagnostic evaluation
  - FP_screen = Number screened x (1-Prev TB) x (1-**SP_screen**)
- **Number eligible to be referred for diagnostic evaluation: TP_screen + FP_screen**

Diagnostic evaluation calculations

- The diagnostic step works the same for patients referred for diagnostic evaluation following the screening step.
    - TB prevalence among patients referred for diagnosis from the screening step is given by:
        - TBPrev_diag = TP_screen / [TP_screen + FP_screen]
- The diagnostic sensitivity (**SE_diag**) of the diagnostic steps determines the number True Positive TB cases (TP) proceeding to the treatment cascade:
    - TP = Number to received diagnostic evaluation x Prev TB x **SE_diag**
- The diagnostic specificity (**SP_diag**) determines the number of False Positive (FP) TB cases proceeding to the treatment cascade
    - Number to receive diagnostic evaluation x (1-PrevTB_diag) x (1-**SP_diag**)
- **Number eligible to proceed to DST and appropriate treatment: TP_diag + FP_diag**

TB preventive treatment (TPT)

- After the number of patients with a positive diagnostic evaluation is estimated the remaining population is eligible for TP prevention, either:
    - Presumptively due to being at very high risk, e.g. child contacts or PLHIV with low CD4 count, or
    - Following a test for latent TB infection
        - Tuberculin Skin Test (TST) or TB antigen-based skin tests for the diagnosis of TB infection (TBST) or Interferon-Gamma Release Assay (IGRA)
- Each of these two options, presumptive TPT or TPT following testing, has a coverage specification.
- The model does not currently link TPT to DST for resistant index cases in the process flow. It is however handled as a costing element.

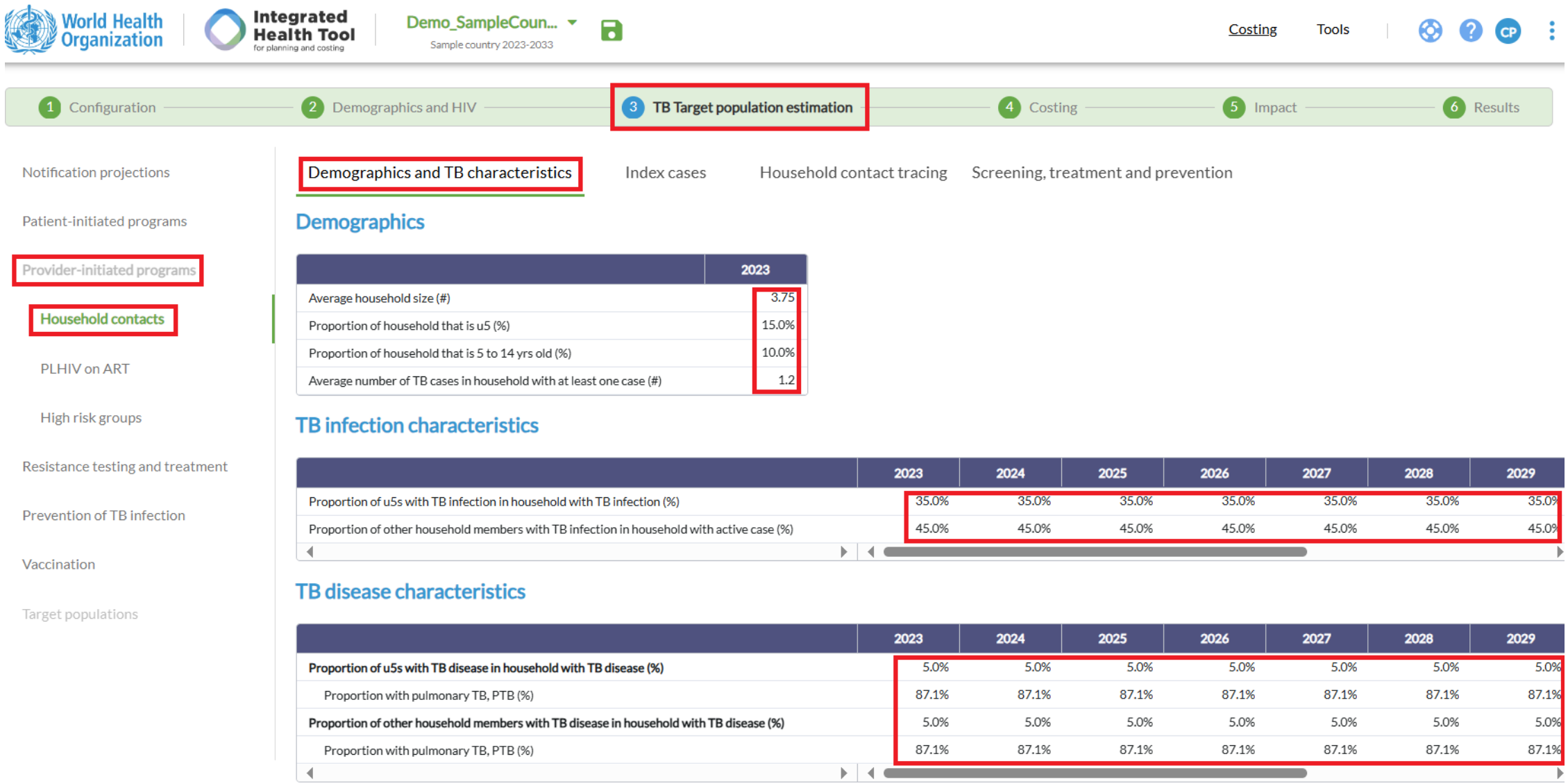
2. Exploring provider-initiated programmes in the user interface

Population groups of provider-initiated programmes

Provider initiated programmes in the target population estimation component in the user-interface:

- HH contacts
- PLHIV on ART
- HR groups
    - High-risk groups in provider-initiated programmes are assumed to be adults (15+). Children (U15) at high risk for TB disease are assumed to detected via HH contact tracing processes

Household contacts



User inputs for household contact tracing programmes

- As with all populations in the TP component, the population size, TB and LTBI prevalence must be defined/specified.
- Demography: HH size, proportion of HH 0-4, proportion of HH 5-14.
- Epidemiology of TB:
  - LTBI prevalence
    - among 0-4 (assuming same value for 5-14)
    - among 15+.
  - Similarly for TB prevalence
- And further specifying the proportion of active TB cases that has pulmonary TB noting that extra-pulmonary TB is handled in patient-initiated programmes only.
- Default LTBI and TB prevalence are obtained from systematic review. Country users can replace these estimates with data from representative in-country studies where available

Additional calculation elements for HH contact tracing

- HH contacts eligible to be screened:
  - Age 0-4: **HH_PropU5 x Adult notifications x HH_Size**
  - Age 5-14: **HH_Prop5to14 x Adult notifications x HH_Size**
  - Age 15+ : **HH_Prop15+ x Adult notifications x (HH_Size-1)**
  - ‘Adult notifications’ are the adult ‘Index Cases'

Screening and diagnostic inputs

- The user specifies a screening coverage
- Currently a recommended screening algorithm specific to the population is provided.

  The user can also configure a custom screening algorithm up to two steps, implemented sequentially or in parallel.
- For example, for contacts 0-4 of age:
  - **CC3-3 - Parallel screening with TB symptoms and CXR is the default,** with SE=97.3% and SP=34.6%
- For diagnostic evaluation, a default assumption is made that Xpert is used. The user can configure which proportion of cases are screened with each diagnostic tool.

Additional screening and diagnostic output elements in the user interface

- These inputs all enable the user to see basic algorithm performance monitoring outputs:
  - **NNTS**: the number of patients screened to refer one true TB case for diagnostic evaluation, the number of true and false positive patients.
  - **NNTT**: the number of patients screened to diagnose one TB case, the number of true and false positive patients.
- Note that generally NNTT is around 10 for patient-initiated programmes.
- In provider-initiate systematic screening programmes, this figure can be significantly higher. For example, NNTT > 40 is not unusual and depends on the prevalence of TB in the screened population and the SE and SP of the screening and diagnostic tools used.
- The TB Global Plan 2023-2030 showed that systematic screening in much wider populations is need to achieve 2030 impact targets. Screening must also be broader in scope, finding TB earlier including finding sub-clinical to shorten disease duration and limit community-level transmission.

Screening outputs to inform screening algorithm

Screening outputs

	2021	20
Number screened	16,828	
Number referred for diagnostic evaluation of TB disease	11,277	
# True positives	819	
# False positives	10,458	
True cases found (%)	7.3%	
TP:FP	0.1	
Number of true positive cases missed	23	
Number screened to refer to one true case of diagnostic evaluation	20.6	

Screening outputs to inform diagnostic algorithm

Diagnosis outputs

	2021	2022	2023
Number received diagnostic evaluation	11,277	11,022	10,
Number diagnosed with TB	1,001	979	
# True positives	688	672	
# False positives	314	307	
True cases found (%)	68.7%	68.7%	68
TP:FP	2.2	2.2	
Number of true positive cases missed	131	128	
Number evaluated to confirm one TB case	16.8	16.8	

Additional notes on other provider-initiated screening programmes

- The process flow for PLHIV on ART and high-risk groups works exactly as for household contacts.
- Except that for PLHIV on ART, patient volumes for different age groups and their proportions with severe and non-severe HIV disease (based on CD4 < 200 cells per mm3 which is associated with higher risk for opportunistic infections) come from the IHT HIV component, instead via calculations based on inputs as is the case for HH contact.
- Patients with severe disease are expected to receive appropriate services for inpatients settings.
- For HR groups the user specifies the population size as a proportion of the 15+ total population. Noting again that children U15 are assumed to by found via HH contact tracing.
- Recommended screening algorithms for both PLHIV on ART and high risk-groups are pre-configured
- Extra-pulmonary TB is found only in patient-initiated programme, as assumption that is aimed at simplifying provider programme configuration.

Note for exercise section 3.1

- Follow the demonstration of configuring a screening and diagnostic programme for child contacts
- Take note of the data needed to define their population sizes and TB characteristics, such as TB prevalence and latent TB prevalence
- In which of the underserved populations do most TB occur?
- Are there key populations in provider-initiated programmes which are not represented in the model?
- Are you able to describe the key elements of the proposed national strategy in terms of populations reached? Are coverage targets clearly stated and is the proposed strategy well represented in the model?
- Take note of the summary outputs for screening and diagnostic algorithms. What are the NNTS and NNTT for each population? How do they respond to TB prevalence inputs?