TB surveillance guidance: core indicators

Dr Giorgi Kuchukhidze
Epidemiologist
Division of Country Health Programmes
WHO Regional Office for Europe

Regional TB Action Plan (M&E framework).

World Health Organization

European Region

Reporting frequency

Rapid (weekly or monthly): detect and act on sudden changes in number diagnosed with a new TB episode

Regular (quarterly): monitor provisional core indicators for epidemiological trends and programmatic responses

Consolidated (annually): monitor a final larger set of indicators for epidemiological trends and programmatic responses

"Core" indicators for all countries

No changes:

- People diagnosed with TB disease
- Testing coverage and results for drug resistance among people with bacteriologically confirmed pulmonary TB

Updates:

- People requiring treatment for TB disease

World Health Organization

European Region

Notifications vs enrolment on treatment

All people diagnosed with TB should be **notified**

Regardless of whether or not they started treatment for TB

Track reasons for any gaps

"Core" indicators for all countries

People diagnosed with TB disease:

- Number of people diagnosed with a new episode of TB

Treatment initiation:

- % of people diagnosed with TB in each of the following categories:
  - started on TB treatment
  - died before starting treatment
  - lost to follow-up before starting treatment

World Health Organization

European Region

Reference: Table 4.6 at https://iris.who.int/handle/10665/376612

Treatment outcomes vs case outcomes

Treatment outcomes restricted to those who **started** treatment (assesses treatment performance)

Case outcomes are for all people **diagnosed** with TB (notified cases), including those who did not start treatment (assesses programmatic performance)

World Health Organization
European Region

Example: lost to follow-up

Treatment outcome:

- % of TB patients out of those **who started TB treatment** who were lost to follow-up

Case outcome:

- % of the total number of **people diagnosed with TB** and registered as a TB case who were lost to follow-up

World Health Organization
European Region

Questions?

"Core" data items to be recorded for every person with TB disease

These are needed so that the "core" indicators can be calculated

World Health Organization

European Region

"Core" data items to be recorded for every person with TB disease

Notification:

- Age and sex
- Registration date
- History of previous TB treatment
- Anatomical site
- Method of diagnosis
- Drug susceptibility test dates and results
- HIV status
- Date started on antiretroviral therapy

Reference: Table 5.1 at https://iris.who.int/handle/10665/376612

World Health Organization

European Region

"Core" data items to be recorded for every person with TB disease

TB treatment:

- Treatment regimen type eligibility
- Was treatment started?
- Reason if treatment was not started
- Date treatment started
- Treatment duration

World Health Organization
European Region

Reference: Table 5.1 at https://iris.who.int/handle/10665/376612

"Core" data items to be recorded for every person with TB disease

Result of TB treatment:

- Treatment outcome
- Date outcome assigned

World Health Organization

European Region

Calculation of totals for reporting template

(Shaded areas are for annual reporting only)

World Health
Organization

European Region

Block 1: Notifications

	New episodes			Re-registered cases
	New cases	Recurrent cases	Unknown previous treatment history	
Pulmonary, bacteriologically confirmed	*REG.1*	*REG.2*	*REG.3*	*REG.8*
Pulmonary, clinically diagnosed	*REG.4*	*REG.5*	*REG.6*	*REG.9*
Extrapulmonary, bacteriologically confirmed or clinically diagnosed	*REG.7*			*REG.10*
Total new episodes	*REG.11 = REG.1+REG.2+REG.3+REG.4+REG.5+REG.6+REG.7*			
Total notified	*REG.12 = REG.1+REG.2+REG.3+REG.4+REG.5+REG.6+REG.7+REG.8+REG.9+REG.10*			

Block 1: Notifications

	New episodes				Re-registered cases
	New cases	Recurrent cases	Unknown previous treatment history		Re-registered cases
Pulmonary, bacteriologically confirmed	REG.1	REG.2	REG.3		REG.8
Pulmonary, clinically diagnosed	REG.4	REG.5	REG.6		REG.9
Extrapulmonary, bacteriologically confirmed or clinically diagnosed	REG.7				REG.10
Total new episodes	REG.11 = REG.1+REG.2+REG.3+REG.4+REG.5+REG.6+REG.7				
Total notified	REG.12 = REG.1+REG.2+REG.3+REG.4+REG.5+REG.6+REG.7+REG.8+REG.9+REG.10				

Block 1: Notifications

	New cases
Pulmonary, bacteriologically confirmed	*REG.1*

Formula:

registered_date in the reporting period *and*
denotifed != Y *and*
tx_history = N *and*
disease_site = P *and*
diagnosis_method = B *and*
transfer_in != Y

Calculation of indicators from reported totals

Block 1: Notifications

	New episodes			Re-registered cases
	New cases	Recurrent cases	Unknown previous treatment history	
Pulmonary, bacteriologically confirmed	*REG.1*	*REG.2*	*REG.3*	*REG.8*
Pulmonary, clinically diagnosed	*REG.4*	*REG.5*	*REG.6*	*REG.9*
Extrapulmonary, bacteriologically confirmed or clinically diagnosed	*REG.7*			*REG.10*
Total new episodes	*REG.11 = REG.1+REG.2+REG.3+REG.4+REG.5+REG.6+REG.7*			
Total notified	*REG.12 = REG.1+REG.2+REG.3+REG.4+REG.5+REG.6+REG.7+REG.8+REG.9+REG.10*			

Block 1: Notifications

	New episodes		
	New cases	Recurrent cases	Unknown previous treatment history
Pulmonary, bacteriologically confirmed	*REG.1*	*REG.2*	*REG.3*
Pulmonary, clinically diagnosed	*REG.4*	*REG.5*	*REG.6*

% of people diagnosed with a new episode of pulmonary TB whose disease was bacteriologically confirmed:

(REG.1. + REG.2. + REG.3.) × 100 /

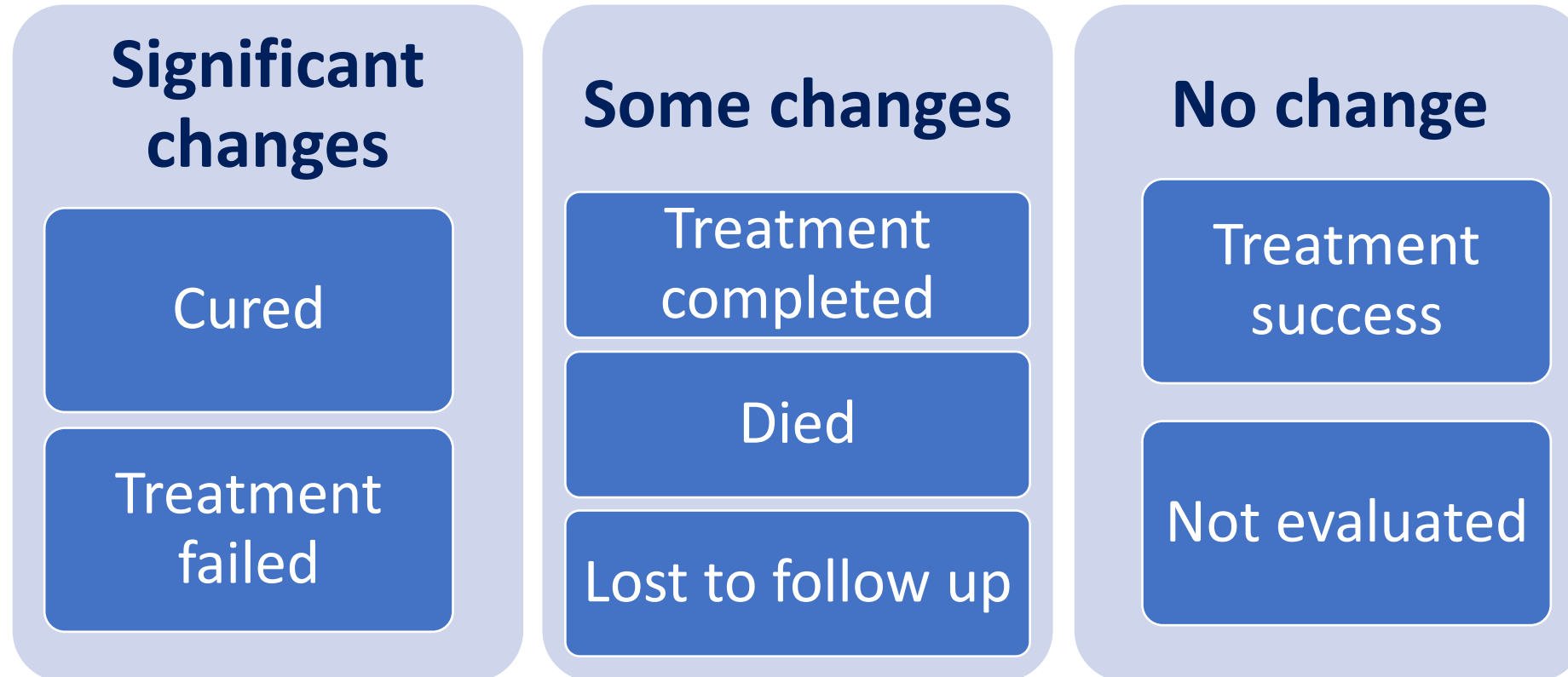(REG.1. + REG.2. + REG.3. + REG.4 + REG.5 + REG.6.)

Questions?

New methodologies

Treatment outcomes

Definitions revised by a WHO expert consultation in November 2020

They are now applicable to **all treatment regimens**, irrespective of drug resistance, drug type, or treatment duration

World Health Organization

European Region

Revised treatment outcomes

Significant changes

Cured

Treatment failed

Some changes

Treatment completed

Died

Lost to follow up

No change

Treatment success

Not evaluated

World Health Organization
European Region

Updated treatment outcome definitions: Cured

A pulmonary TB patient with bacteriologically confirmed TB at the beginning of treatment who completed treatment as recommended by the national policy with evidence of bacteriological response and no evidence of failure

Bacteriological response = conversion with no reversion

- Conversion = 2 consecutive cultures (or 2 consecutive smears if DS-TB) at least 7 days apart are **negative**

- Reversion = 2 consecutive cultures (or two consecutive smears if DS-TB) at least 7 days apart are **positive,** either after conversion or if patient was not bacteriologically confirmed

World Health Organization

European Region

Updated treatment outcome definitions: Treatment failed

A patient whose treatment regimen needed to be terminated or permanently changed to a new regimen or treatment strategy

Reasons for the change include:

- no clinical response and/or no bacteriological response

- adverse drug reactions

- evidence of additional drug resistance to medicines in the regimen

Change of treatment regimen

Record outcomes of current treatment as **failure**

Create a new treatment record for the person, now as **re-registered case**

Record the new treatment regiment and new date of initation

World Health Organization
European Region

Disaggregation by regimen type

Enrolment and treatment outcome indicators now disaggregated by regimen type and not by treatment history or drug resistance status

World Health Organization

European Region

Block 8: Enrolment on treatment among all people diagnosed with a new episode of TB

Regimen type appropriate for the person	Started on treatment in this facility
Regimens designed to treat rifampicin-susceptible TB (irrespective of HIV status)	*ENR.5*
Regimens designed to treat rifampicin-susceptible TB (people living with HIV)	*ENR.5.H*
Short (≤12 months) regimens designed to treat rifampicin-resistant TB (RR-TB/MDR-TB/pre-XDR-TB/XDR-TB)	*ENR.6*
Long (>12 months and ≤24 months) regimens designed to treat rifampicin-resistant TB (RR-TB/MDR-TB/pre-XDR-TB/XDR-TB)	*ENR.7*

Block 9: Treatment outcomes: short (≤ 12 months) treatment regimen

Regimen type appropriate for the person	Cohort size after accounting for transfers
Regimens designed to treat rifampicin-susceptible TB (irrespective of HIV status)	*OUT.1*
Regimens designed to treat rifampicin-susceptible TB (people living with HIV)	*OUT.1.H*
Short (≤12 months) regimens designed to treat rifampicin-resistant TB (RR-TB/MDR-TB/pre-XDR-TB/XDR-TB)	*OUT.8*

Block 10: Treatment outcomes: longer (> 12 and ≤ 24 months) treatment regimen

Regimen type appropriate for the person	Cohort size after accounting for transfers
Long (>12 months and ≤24 months) regimens designed to treat rifampicin-resistant TB (RR-TB/MDR-TB/pre-XDR-TB/XDR-TB)[c]	*OUT.15*

Transfers of patients between facilities

Old:

Treatment outcomes are recorded and reported by the facility where the patient <u>started</u> treatment

New:

Treatment outcomes are recorded and reported by the facility where the patient <u>completed</u> treatment

Block 8: Enrolment on treatment among all people diagnosed with a new episode of TB

Optional for calculating, not necessarily to be included in the reporting

Registered in this facility	Transferred **in** to start treatment after registration in another facility	Transferred **out** after registration to start treatment in another facility	Net registered in this facility after accounting for transfers	Died before treatment started	Lost to follow-up before treatment started	Started on treatment in this facility
ENR.1a	ENR.1b	ENR.1c	ENR.1 = (ENR.1a + ENR.1b − ENR.1c)	ENR.2	ENR.3	ENR.4 = (ENR.1 − ENR.2 − ENR.3)

Block 9: Treatment outcomes: short (≤ 12 months) treatment regimen

Optional for calculating, not necessarily to be included in the reporting

Started treatment in this facility	Transferred **in** to continue treatment after starting treatment at another facility	Transferred **out** to continue treatment in another facility after starting treatment in this facility	Cohort size after accounting for transfers
OUT.1a	OUT.1b	OUT.1c	OUT.1 = (OUT.1a+OUT.1b-OUT.1c)

Questions?

Additional "core" indicators

(for countries with case-based digital surveillance systems)

People with presumptive TB:

- Number of diagnostic tests performed for TB using WHO-recommended rapid diagnostic tests (WRDs)

- % of tests for TB that were positive using WRDs

People diagnosed with TB disease:

- % of people diagnosed with a new episode of TB who were initially tested with a WRD

World Health Organization

European Region

Additional "core" indicators

(for countries with case-based digital surveillance systems)

Contacts of people diagnosed with bacteriologically confirmed pulmonary TB disease:

- % of household contacts who were evaluated for TB (disease or infection)

- % of household contacts who were started on TB preventive treatment, out of those eligible

World Health Organization

European Region

Optional indicators and disaggregations

Many more indicators and disaggregations are listed

These are optional and are for countries with case-based digital surveillance systems and can be considered according to country priorities

World Health Organization

European Region

Thank you

For more information, please contact:

eurotb@who.int

World Health Organization

European Region