Childhood Tuberculosis: Program monitoring and evaluation

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Every breath counts

ROADMAP FOR CHILDHOOD TUBERCULOSIS

TOWARDS ZERO DEATHS

Include the needs of children and adolescents in research, policy development and clinical practices

Collect and report better data, including data on prevention

Develop training and reference materials for health care workers

Foster local expertise and leadership

Do not miss critical opportunities for intervention

Engage key stakeholders

Develop integrated family-centred and community-centred strategies

Address research gaps

Meet funding needs for childhood TB

Form coalitions and partnerships to improve tools for diagnosis and treatment

Collect and report better data, including data on prevention

Overview

- The basics: Tuberculosis recording & reporting
- Monitoring & Evaluation of childhood TB within National TB programs
- Key challenges and needs for Monitoring and Evaluation of Childhood (DR-) TB
- Conclusions

Importance of monitoring & evaluation

Assessing progress

Reliable disease estimates

Program performance / Quality of services

Accountability / Transparency

Changing burden of disease

Control Program

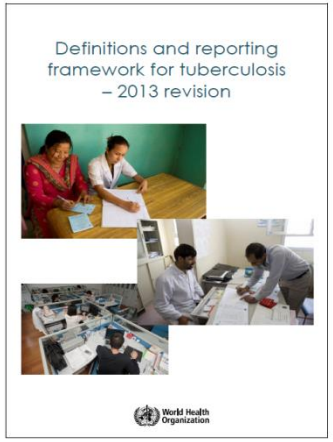
Planning / rational use of resources (drugs, hospital beds, staff, …)

Identifying and targeting vulnerable groups

New emerging challenges

Advocacy / Policy development

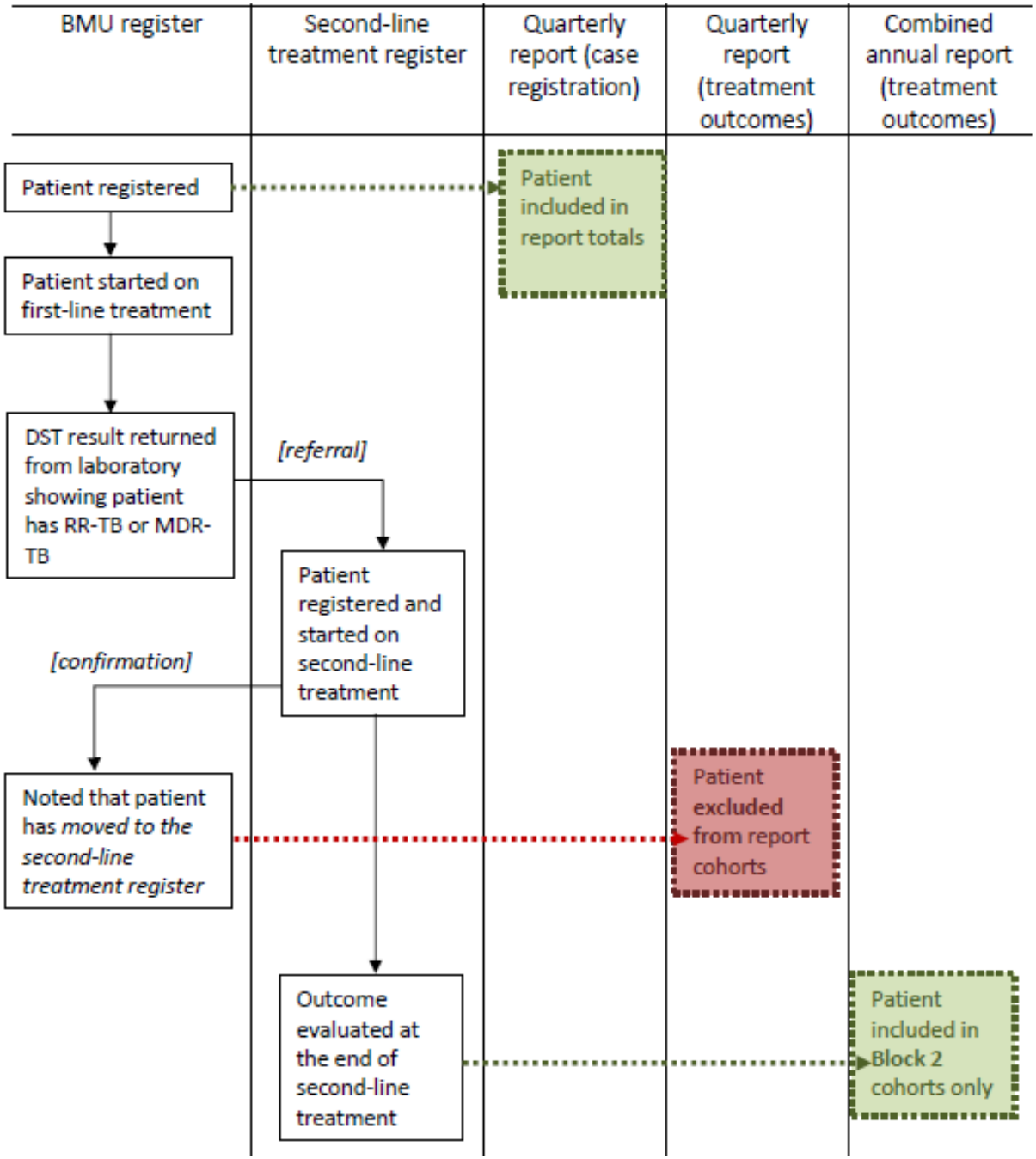
Revised WHO definitions and reporting framework for tuberculosis (2013)



- Recording and reporting of WHO-approved rapid diagnostics such as Xpert MTB/RIF globally
- less judgemental language: terms “defaulter” and “TB suspect” replaced by “lost to follow-up” and “presumptive TB
- treatment outcome definitions of “cured” and “treatment failed” in MDR-TB simplified

WHO 2013: Revised forms, registers and reports

Form name	Form no. in 2006 guide[a]	Form no. in 2008 guide[b]
Request for examination of biological specimen for TB	Form 1	Form 03
Basic management unit TB register	Form 5	Not in guide
Second-line TB treatment register	Not in guide	Form 02
Laboratory register for smear microscopy and Xpert MTB/RIF	Form 2	Form 04
Laboratory register for culture, Xpert MTB/RIF and drug susceptibility testing (DST)	Form 2	Form 04
Quarterly report on TB case registration in the basic management unit	Form 6	Not in guide
Quarterly report on TB treatment outcomes in the basic management unit	Form 7	Not in guide
Combined annual outcomes report for basic TB and for RR-/MDR-TB	Not in guide	Form 07



Patients with DR-TB detected after initiation of 1st line Tx

The Tuberculosis register

Basic management unit TB register (page 1 of 3)

Date of registration	BMU TB no.	Name	Sex (M/ F)	Age	Address	Health facility where treatment card is kept[a]	Date treatment started

Basic management unit TB register (page 2 of 3)

History of previous treatment (*choose one option only*)[b]						Transfer in[d]	Site		Treatment category (*choose one option only*)[c]			TB/HIV activities	
New	Previously treated patients				Previous treatment history unknown		Pulmonary	Extra-pulmonary	Initial regimen with first-line drugs	Retreatment regimen with first-line drugs	Second-line treatment regimen	ART (Y/N)	CPT (Y/N)
	Relapse	Treatment after failure	Treatment after loss to follow-up	Others previously treated									

Basic management unit TB register (page 3 of 3)

Smear (S), culture (C) or Xpert MTB/RIF (X) results and other examinations[e]											Treatment outcome and date outcome determined[f]							Remarks
At the time of TB diagnosis					Month 2 or 3[g]		Month 5		End of treatment		Outcome						Moved to second-line treatment register[i]	
HIV infection (Y/ N/ unknown)[h]	Drug resistance (RR/MDR/ None/ unknown)[i]	S	C	X	S	C	S	C	S	C	Cured	Treatment completed	Treatment failure	Died	Lost to follow-up	Not evaluated		
		Date			Date		Date		Date									

Second-line TB treatment register

Second-line TB treatment register (page 1 of 4)

Unique second-line TB treatment register no.	Date entered in second-line TB treatment register	Name	Sex (M/F)	Age	Address	BMU TB register number / Date entered in BMU TB register	Site of disease (P/EP)	Registration group[a]	Second-line drugs received previously (Y/N/Unk)	Date sample taken for DST	Result of drug susceptibility testing[b]										
											H	R	E	S	Amk / Km	Cm	FQ ___	Other ___	Other ___	Other ___	Other ___

Second-line TB treatment register (page 2 of 4)

Reasons for entering in second-line TB treatment register		Regimen (in drug initials)	Smear (S), culture (C) or Xpert MTB/RIF (X) results[c]												Smear (S) and culture (C) results during treatment[d] (*continued*)											
RR-TB / MDR-TB confirmed	Presumptive RR-TB/ MDR-TB[4]		Start of treatment Month 0			Month 1		Month 2		Month 3		Month 4		Month 5		Month 6		Month 7		Month 8		Month 9		Month 10		Month 11		Month 12	
			S	C	X	S	C	S	C	S	C	S	C	S	C	S	C	S	C	S	C	S	C	S	C	S	C	S	C
		Start date	Date			Date		Date		Date		Date		Date		Date		Date		Date		Date		Date		Date	

Quarterly report on TB case registration in the BMU

Name of BMU: _____ Facility:_____	Patients registered during[a] _____ quarter of year_____
Name of TB Coordinator:_____ Signature: _____	Date of completion of this form: _____

Block 1: All TB cases registered during the quarter[b]

	New	Relapse	Previously treated (excluding relapse)	Previous treatment history unknown	Total
Pulmonary, bacteriologically confirmed					
Pulmonary, clinically diagnosed					
Extrapulmonary, bacteriologically confirmed or clinically diagnosed					

Block 2. All new and relapse cases (bacteriologically confirmed or clinically diagnosed) registered during the quarter by age group and sex

	0–4	5–14	15–24	25–34	35–44	45–54	55–64	>65	Total
Male									
Female									

Block 3: Laboratory diagnostic activity[c]

Patients with presumptive TB undergoing bacteriological examination	Patients with presumptive TB with positive bacteriological examination result

Block 4: TB/HIV activities (all TB cases registered during the quarter)

Patients tested for HIV at the time of TB diagnosis or with known HIV status[d] at the time of TB diagnosis	HIV-positive TB patients	HIV-positive TB patients on ART	HIV-positive TB patients on CPT

Combined annual treatment outcomes report for basic TB and for RR-TB/MDR-TB

Name of BMU: _____ Facility:_____ Date of completion of this form: _____

Block 1. All TB cases (except for TB cases moved to the second-line treatment register) registered in calendar year:[a] _____

TB patient type	No. of cases registered	Treatment outcomes					
		Cured	Treatment completed	Treatment failed	Died	Lost to follow-up	Not evaluated
Bacteriologically confirmed, new and relapse							
Clinically diagnosed, new and relapse							
Retreatment (excluding relapse)							
HIV-positive, all types							

Block 2. TB cases started on a second-line TB drug regimen in calendar year:[b] _____

TB patient type	No. of cases started on second-line TB treatment	Treatment outcomes					
		Cured	Treatment completed	Treatment failed	Died	Lost to follow-up	Not evaluated
All confirmed RR-TB/MDR-TB cases							
HIV-positive RR-TB/MDR-TB cases[c]							
All confirmed XDR-TB cases[c]							

TB Monitoring & Evaluation

Evaluating Childhood Tuberculosis in National Tuberculosis Programs

Example:

Kazakhstan TB Program review 2012 (E. Kurbatova)

Check list: Childhood TB Region/facility where assessment done _____

Policy

What is the definition of childhood/pediatric TB case in your country? ☐0-14 years ☐other (specify)_____

Do guidelines on childhood TB exist? ☐yes, as a separate document (describe) _____

☐yes, sections on children included in other guidelines (which guidelines) _____

☐ children not mentioned in any TB guidelines

Epidemiology, recording & reporting

Total population in region _____ Total number of children living at the region_____ for ___(report. year)

Total number of children living at the region: aged 0-4 y.o___ 5-14 y.o____

Total number of all TB cases registered in the region (including adults and children) _____

Total number of registered pediatric TB cases _____

Which age groups reported for children by the national surveillance: 0-…. , …-… , …-… years

Are children registered in: ☐the same register as all TB cases or ☐a separate register for children with TB

Please fill in below table on registered pediatric TB cases as complete as possible (please use "Other" lines only if 0-4 and 5-14 y.o. groups are not used):

Age groups (as in routine TB R&R system), years	New			Previously treated	TOTAL All cases
	Pulmonary, ss+	Pulmonary, ss-/not done	Extrapulmonary		
0-4 y.o.					
5-14 y.o.					
TOTAL 0-14 y.o.					
Other 0-…. y.o.					
Other …-… y.o.					
Other …-… y.o.					
Other TOTAL 0 -…. y.o.					

Number of children with TB in ____(reporting year) with:

TB meningitis (age 0-4) _____ miliary TB (age 0-4) _____

TB meningitis (age 5-14) _____ miliary TB (age 5-14) _____

Please fill in below table on treatment outcomes in children as complete as possible for ____(cohort year):

Treatment outcome	New			Previously treated			TOTAL All cases		
	0-4 y.o.	5-14 y.o.	All	0-4 y.o.	5-14 y.o.	All	0-4 y.o.	5-14 y.o.	All
Cure/completed									
Death									
Default									
Failure									
Transfer out									
Unknown									

Prevention

Is BCG vaccination used in the country? ☐yes ☐no ☐not assessed/data not available (n/a)

If yes, at which age(s)? 1st vaccination ____ 2nd vaccination ____ 3rd vaccination ____ 4th vaccination ____

What is the BCG coverage? 1st vaccination ____ % 2nd vaccination ____ %

Are routine TST screenings of children used? ☐yes ☐no ☐n/a

If yes, from which age?____ years Type of technique and tuberculin used?_____ How often?_____

Is screening of children who are household contacts of TB cases done? ☐yes ☐no ☐n/a

Is preventive therapy with Isoniazid being used for children? ☐yes ☐no ☐n/a

If yes, what are indications for preventive therapy?

Doses and length of preventive therapy? _____

Are other drugs/regimens used for preventive therapy? ☐yes ☐no ☐n/a If yes, describe _____

Diagnosis

Which approaches are used for diagnosis of tuberculosis in children:

TST: ☐yes ☐no ☐n/a X-ray: ☐yes ☐no ☐n/a Fine needle aspirates: ☐yes ☐no ☐n/a

Smear: ☐yes ☐no ☐n/a Culture: ☐yes ☐no ☐n/a DST: ☐yes ☐no ☐n/a

Molecular methods (e.g. Xpert MTB/RIF, LPA): ☐yes ☐no ☐n/a if yes, list which _____

Other methods (list) _____

Which methods are used in children for obtaining clinical specimens?

Gastric aspiration: ☐yes ☐no ☐n/a Expectoration: ☐yes ☐no ☐n/a

Sputum induction: ☐yes ☐no ☐n/a Other _____

Are children with TB routinely tested for HIV? ☐yes ☐no ☐n/a

If yes, what number (proportion) of children with TB has HIV test result? _____ (____%)

If yes, what number (proportion) of tested children with TB is HIV-positive? (%)

Treatment and care

What are the dosages used for treatment of childhood TB?

	WHO 2006 (mg/kg)	WHO 2010 (mg/kg)	Other (specify)	Maximum (mg)
INH	☐5 (4-6)	☐10 (10-15)		
RIF	☐10 (8-12)	☐15 (10-20)		
PZA	☐25 (20-30)	☐35 (30-40)		
EMB	☐20 (15-25)	☐20 (15-25)		

Is Streptomycin used in first-line treatment regimens? ☐yes ☐no ☐n/a

Length of treatment regimens (months): Pulmonary TB_____ TB lymphadenitis _____

TB meningitis _____ Osteoarticular TB _____

Is second-line drug treatment available for children with drug-resistant TB? ☐yes ☐no ☐n/a

If yes, what are regimens used _____

Is DOT used for children? ☐yes, intensive and continuation phase ☐yes, only intensive phase ☐no ☐n/a

If yes, who provides DOT? ☐healthcare workers ☐parents ☐other_____ ☐n/a

Are children hospitalized for treatment? ☐yes ☐no ☐n/a

What are criteria for hospitalization? _____

Are children in the hospital separated by: sputum status ☐yes ☐no ☐n/a

drug resistance profile ☐yes ☐no ☐n/a

Drugs management

Are pediatric anti-TB drugs formulations available? ☐yes ☐no ☐n/a

If yes, are pediatric anti-TB drugs come from quality assured suppliers? ☐yes, all drugs ☐yes, some drugs ☐no ☐n/a

Do drugs come through GDF? ☐yes ☐no ☐n/a Other sources _____

Which proportion of drugs comes from quality assured suppliers? _____

Which formulations of drugs are available: FDC ☐yes ☐no ☐n/a Loose formulations ☐yes ☐no ☐n/a

What % of each? FDC ____ % loose formulations ____ %

List which drugs are available as loose formulations: ☐INH ☐RIF ☐EMB ☐PZA ☐Other_____

Human resources and HSS

Which level of providers makes the diagnosis of TB in children? _____

Are children with TB treated by TB pediatricians/pulmonologists? ☐yes ☐no ☐n/a

If yes, how many TB pediatricians work in region? _____

If no TB pediatricians available, who treats TB in children (e.g. TB physicians, general pediatricians, family medicine physicians)? _____

Is private sector participates in childhood TB diagnosis and management? ☐yes ☐no ☐n/a

Which factors act as barriers to access care for children? (describe) _____

Key challenges for Monitoring and Evaluation of Childhood (DR-) TB

- Childhood TB underdiagnosed and under-reported
- Currently no consistent methods for estimating the burden of childhood TB
- Case definitions are inconsistently used
- Lack of program indicators for childhood TB management
- Poor monitoring and evaluation of infection control / preventive therapy

Completeness and accuracy of electronic recording of paediatric drug-resistant tuberculosis in Cape Town, South Africa

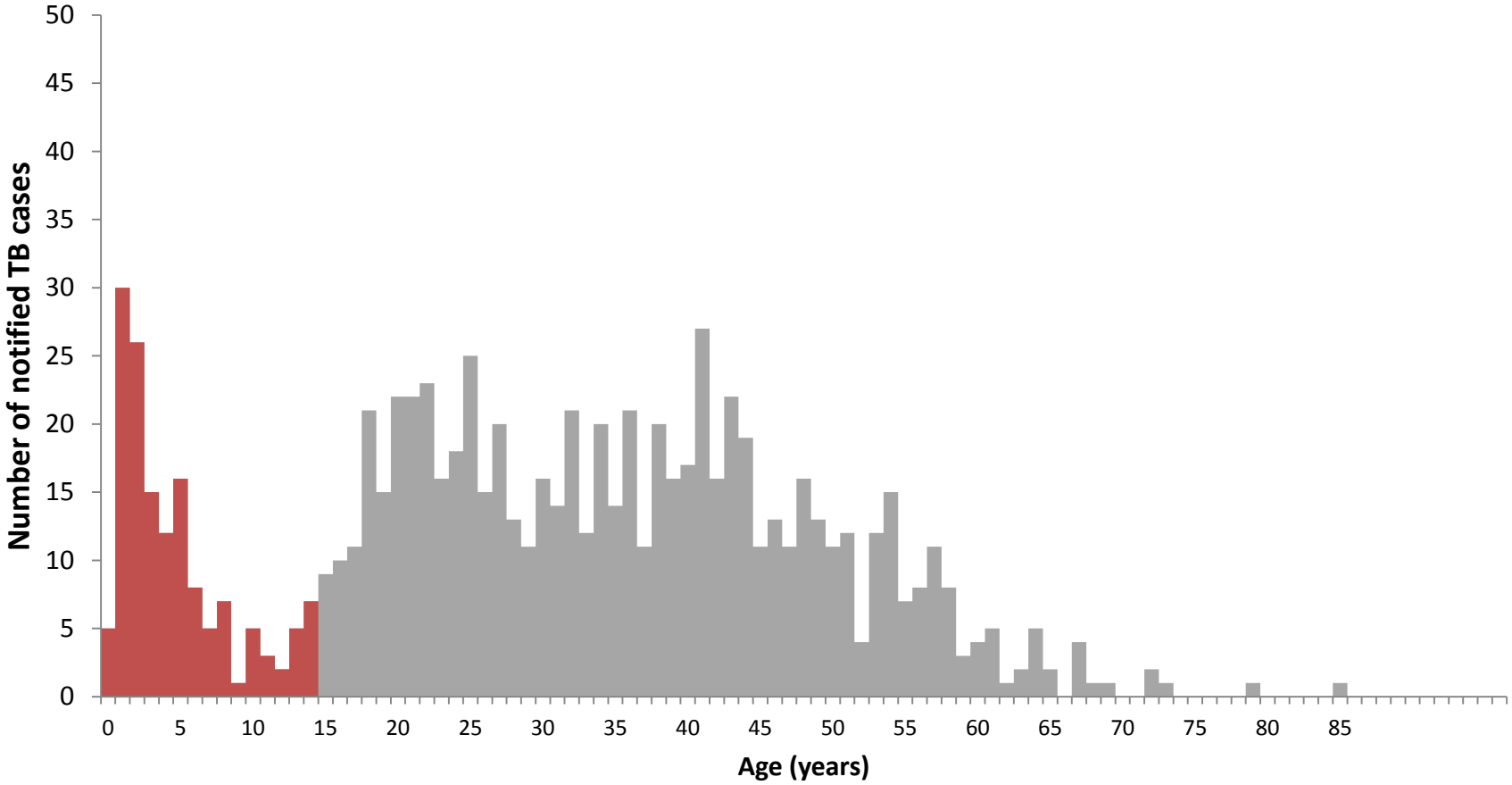
P. C. Rose,[1] H. S. Schaaf,[1,2] K. du Preez,[1] J. A. Seddon,[1,3] A. J. Garcia-Prats,[1] K. Zimri,[1] R. Dunbar,[1] A. C. Hesseling[1]

- **Objective:** To assess the completeness and accuracy of electronic recording of drug-resistant tuberculosis (DRTB) in children in Cape Town.
- **Methods:** Retrospective cohort study on all children aged <15 years treated for DR-TB during 2012. Matching was performed between clinical data and an extracted data set from an electronic register for DR-TB.
- **Results:** 77 children were identified clinically, of whom only 49 (64%) were found. Only 4.4% of all entries were children.
- **Conclusion:** Only two thirds of children clinically treated for DR-TB were recorded in the electronic register, suggesting under-reporting. The prevalence of DR-TB in children was lower than expected, probably suggesting both, under-diagnosis and under-recording of DR-TB in children.

Public Health Action, 2013

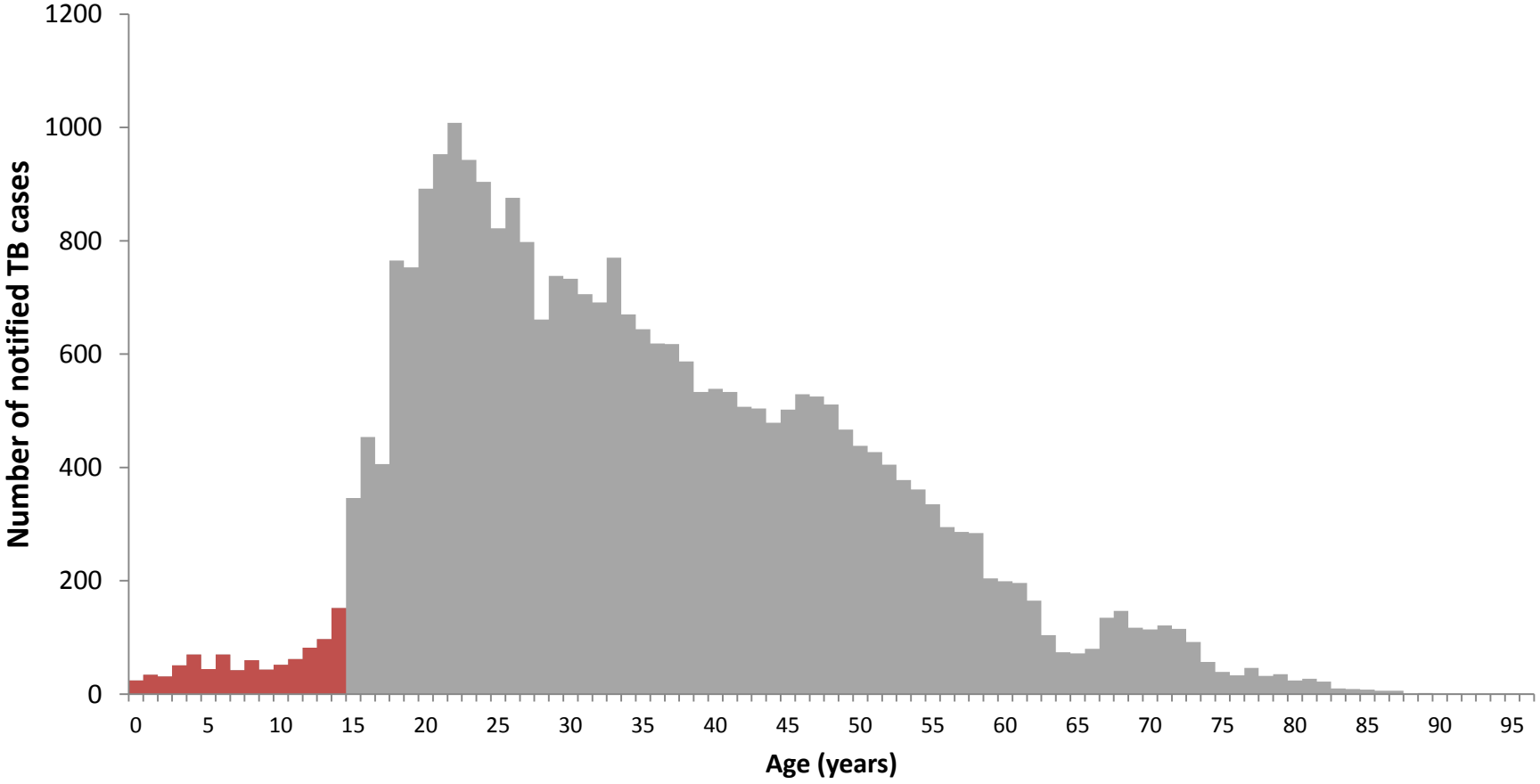
Notification data disaggregated by age

(Data from a suburban setting in Cape Town, 2007 - 2009)

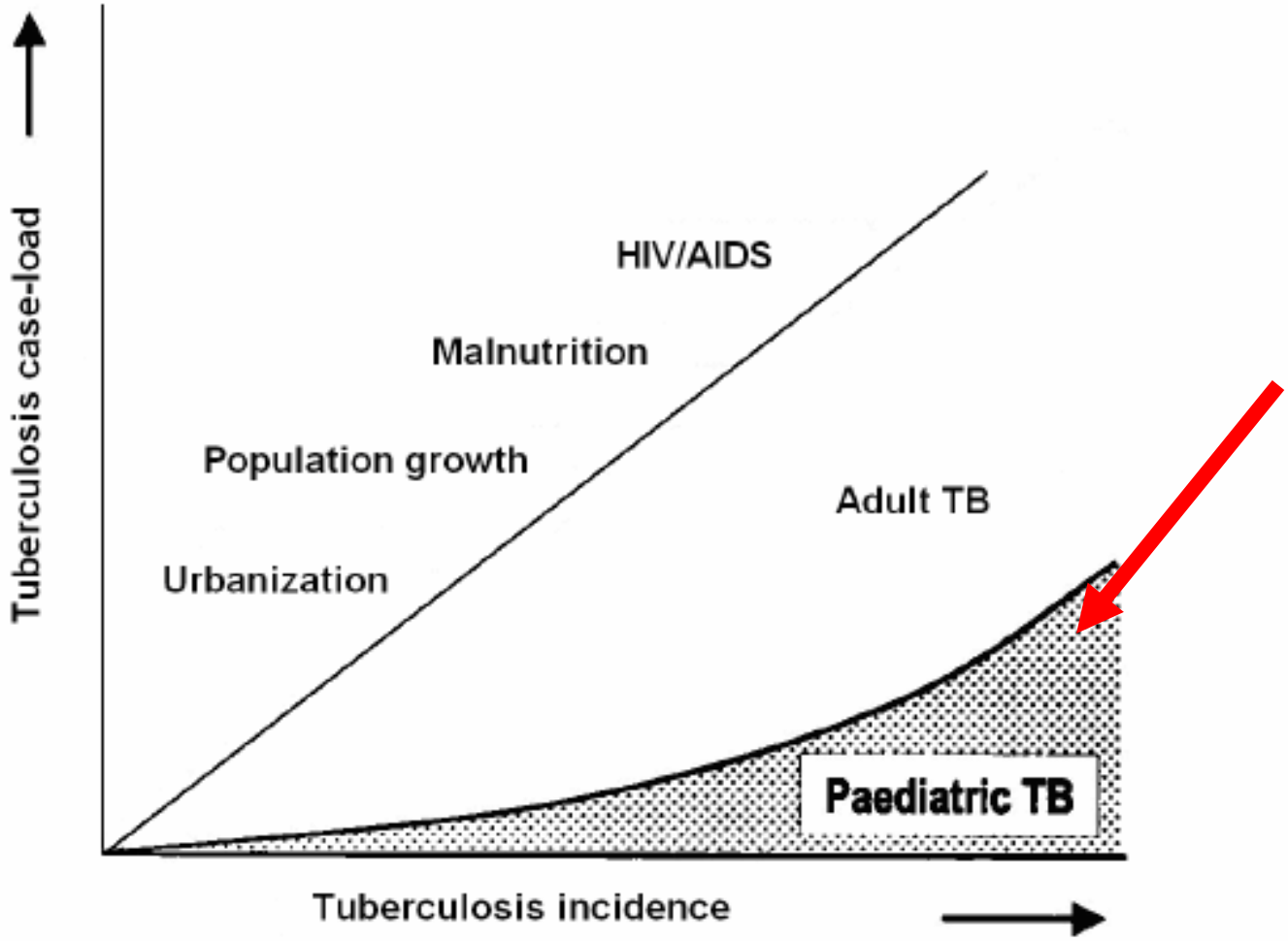


Notification data disaggregated by age (2)

(Data from a country in Central Asia, 2009)

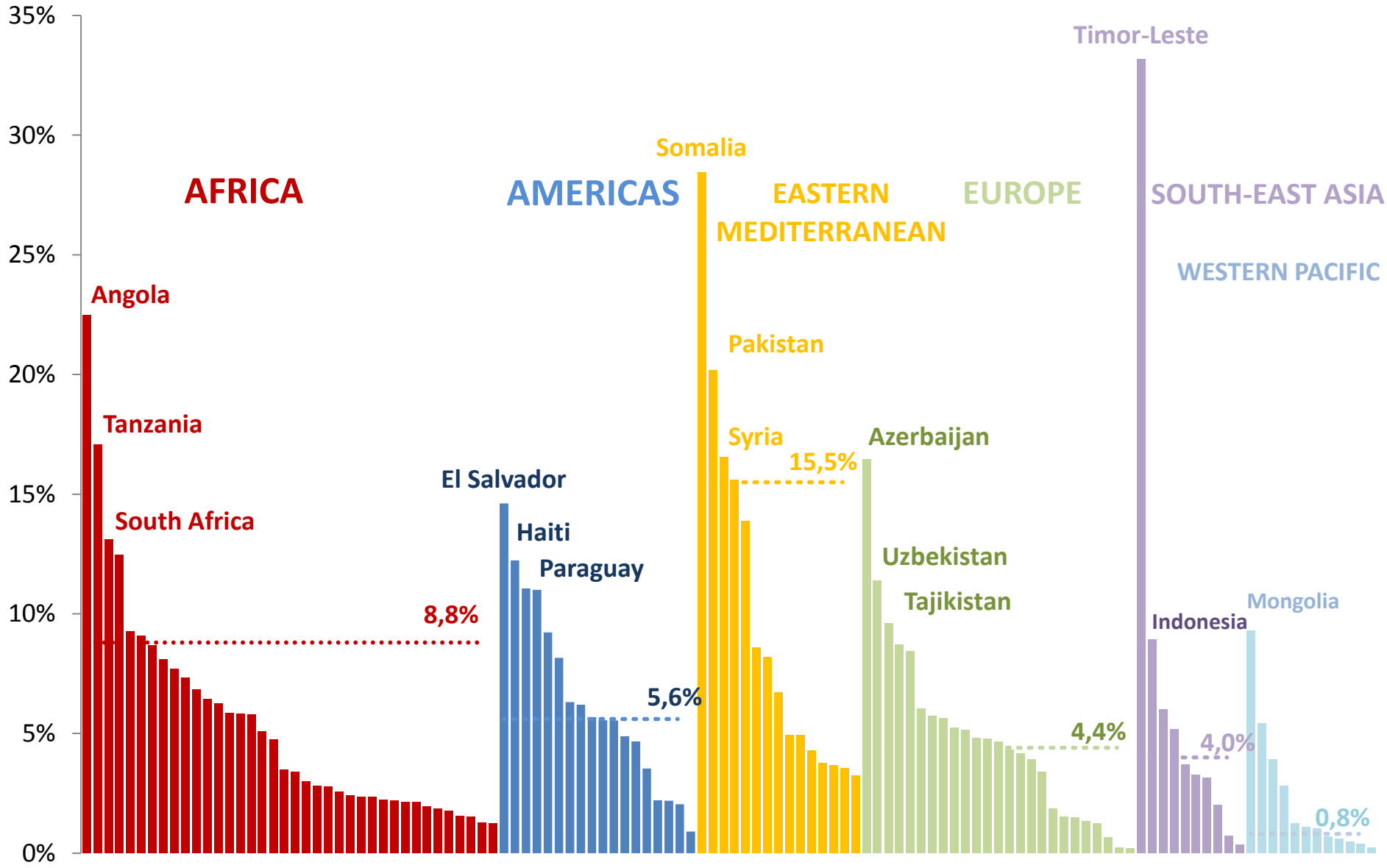


What is the true burden of pediatric tuberculosis?

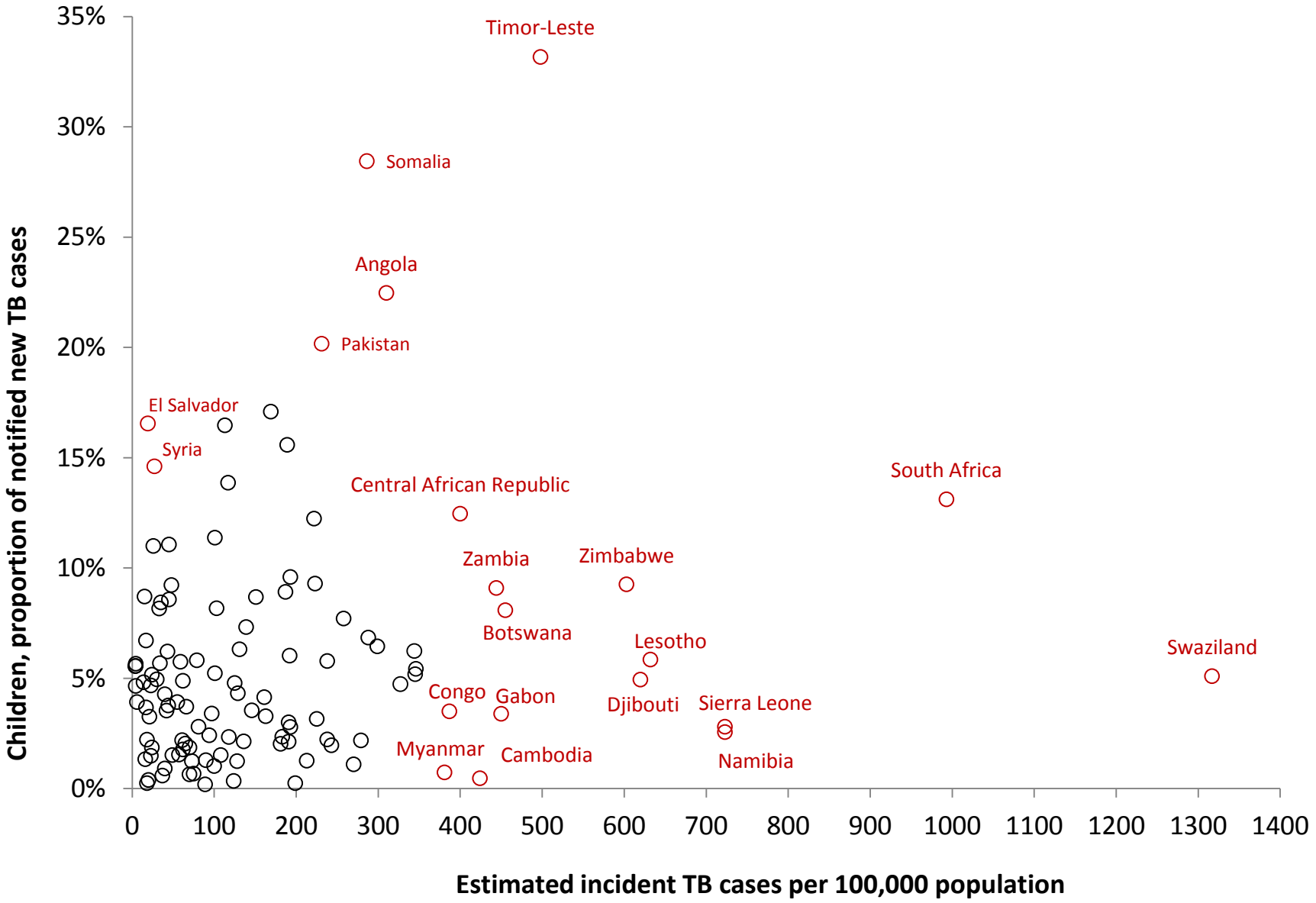


Source: WHO

Proportion of children among notified new tuberculosis cases (all forms), 2011



Proportion of childhood TB vs. estimated TB incidence



Perspectives for preventing under-reporting / Improving childhood TB burden estimates

- Case-based electronic R&R / analysis of age disaggregated data
- More contact-tracing / integration of TB activities in maternal, new-born and child health services
- Use of child contact registers for confirmed adult TB cases??
- Use of severe forms of tuberculosis in childhood (e.g. TBM) as indicator diseases?? (Peter Donald)
- Inclusion of children in TB prevalence surveys

Case definitions for childhood TB

- Programmatic vs. clinical vs. research?
- Inconsistencies (Example: intra-thoracic lymph node disease)
- Confirmation of /certainty about latent infection or disease? Available diagnostic tools?
- Site and severity of disease
- Standardization needed

Original Article

Consensus Statement on Research Definitions for Drug-Resistant Tuberculosis in Children

James A. Seddon,[1,2] Carlos M. Perez-Velez,[3] H. Simon Schaaf,[1,4] Jennifer J. Furin,[5] Ben J. Marais,[6,7] Marc Tebruegge,[8,9,10] Anne Detjen,[11] Anneke C. Hesseling,[1] Sarita Shah,[12] Lisa V. Adams,[13] Jeffrey R. Starke,[14] Soumya Swaminathan,[15] and Mercedes C. Becerra;[16,17]on Behalf of the Sentinel Project on Pediatric Drug-Resistant Tuberculosis

- Consistent terminology for exposure, drug-resistance testing, re-treatment categories, certainty of diagnosis, site and severity of disease, treatment outcomes, etc.

There are currently no tools to implement and effectively monitor infection control and preventive therapy in children exposed to tuberculosis.

Operational challenges in managing Isoniazid Preventive Therapy in child contacts: A high-burden setting perspective

Susan S van Wyk[1*], Anthony J Reid[3], Anna M Mandalakas[1,2], Donald A Enarson[4], Nulda Beyers[1], Julie Morrison[1] and Anneke C Hesseling[1]

(BMC Public Health. 2011)

- Review of routinely collected data in Cape Town 20: a total of 1094 adult TB case folders were reviewed. From all identified contacts, 149 children should have received IPT based on local guidelines; in only 2/149 IPT was initiated.

Adherence to isoniazid preventive chemotherapy: a prospective community based study

B J Marais, Susan van Zyl, H S Schaaf, M van Aardt, R P Gie, N Beyers

Arch Dis Child 2006;91:762–765. doi: 10.1136/adc.2006.097220

- Of 180 children who received preventive chemotherapy in a suburban setting in Cape Town, 36/180 (20%) completed at least 5 months of unsupervised INH mono-therapy.

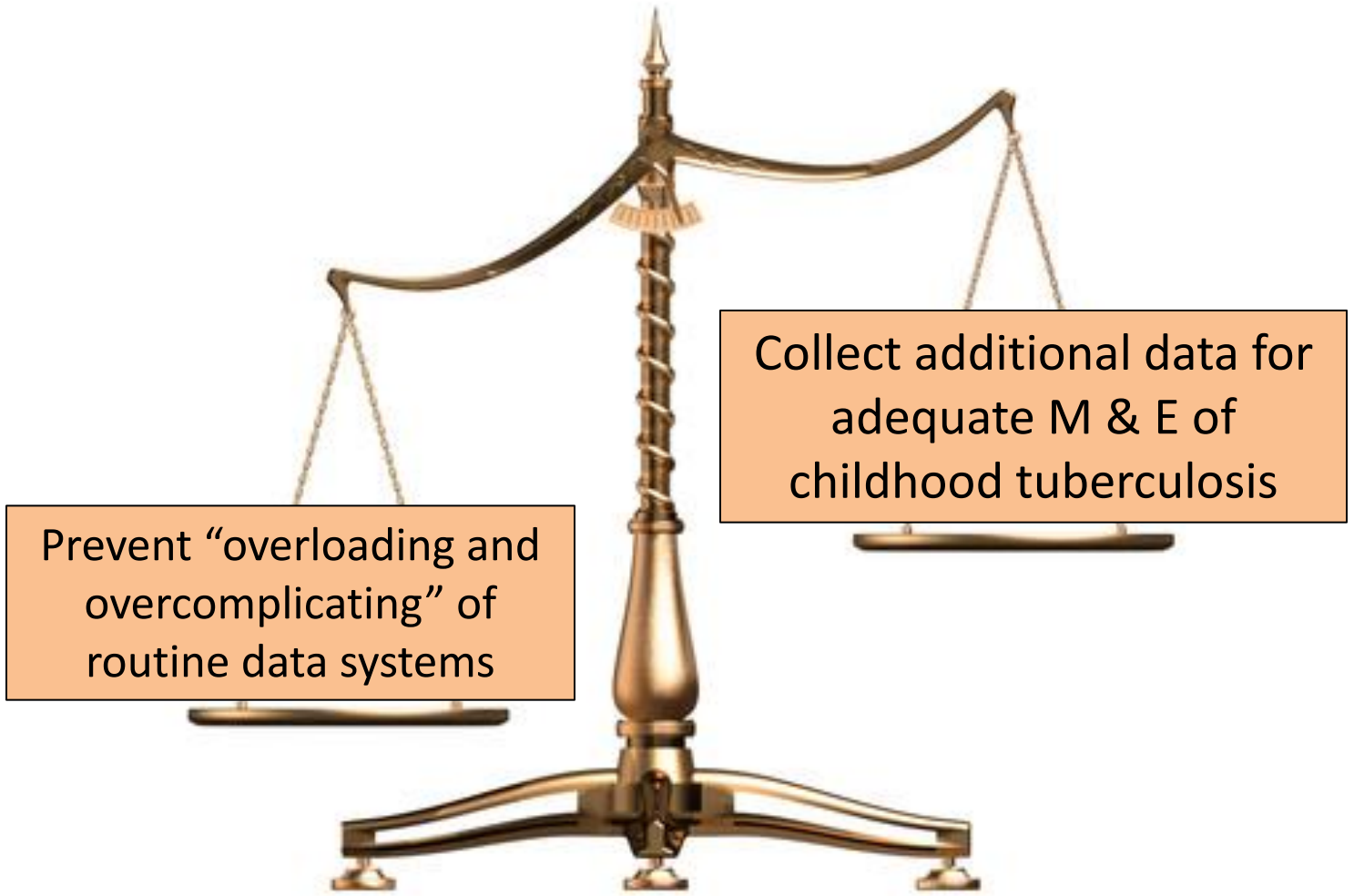
Need for simple program indicators for childhood TB

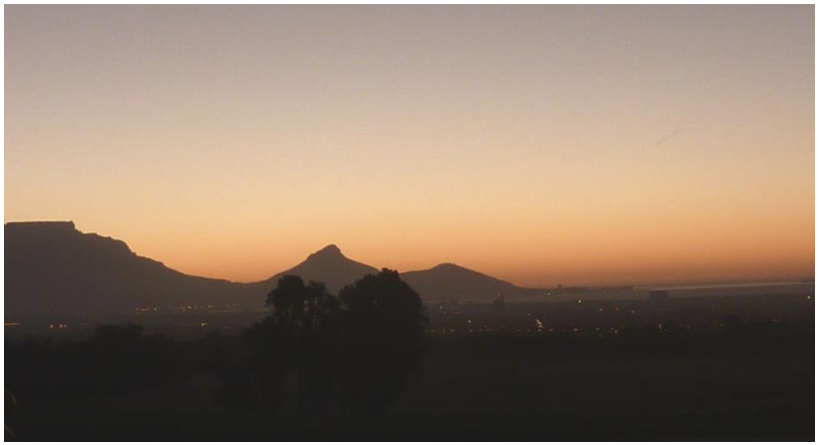
- Number of TB patients diagnosed (with or without DR-TB) with household contacts <5yrs
- Number of contacts screened/provided with preventive therapy?
- Preventive therapy treatment completion rates
- Number of children diagnosed with (DR-) TB
- Spectrum of disease as opposed to pulmonary / extrapulmonary?

Conclusions

- Monitoring & evaluation forms a cornerstone of effective TB control
- Need for increased efforts to assess the burden of tuberculosis in children
- Monitoring of TB exposure and provision of preventive therapy is a key priority
- Need for simple program indicators and measures for childhood TB

Keep the balance!





Thanks!

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