

"Specimen transport systems in the Central African region: one key to improving access to TB diagnostics and care services?"



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INTRODUCTION

Provision of early tuberculosis diagnosis including universal DST is one pillar of the End TB strategy. In 2015 however, there was a 4.3 million TB case detection gap due to underreporting and underdiagnosis of new TB cases. Globally, only 132 120 cases of MDR/RR-TB (out of an estimated 580 000 incident cases) were detected.

Access to WHO recommended rapid molecular diagnostic tests such as the Xpert MTB/RIF is needed to ensure early detection and prompt treatment of TB and MDR TB. Efficient TB laboratory networks are thus critical for the timely provision of accurate laboratory results and optimal patient management.

Central Africa countries share high TB disease incidence, suboptimal performance with regards to TB indicators. TB laboratory networks extension at all tiers of the health care system in these countries is challenging in view of locally limited human and financial resources.

In such context, efficient and cost effective national and transnational TB specimen transport systems would represent one key factor to improve access to TB and MDR TB diagnostics and care (see figure 1) .

The objective of this study was to assess the implementation status of specimen referral systems in the Central African region and to assess available resources to guide the elaboration of related national strategies and policies .

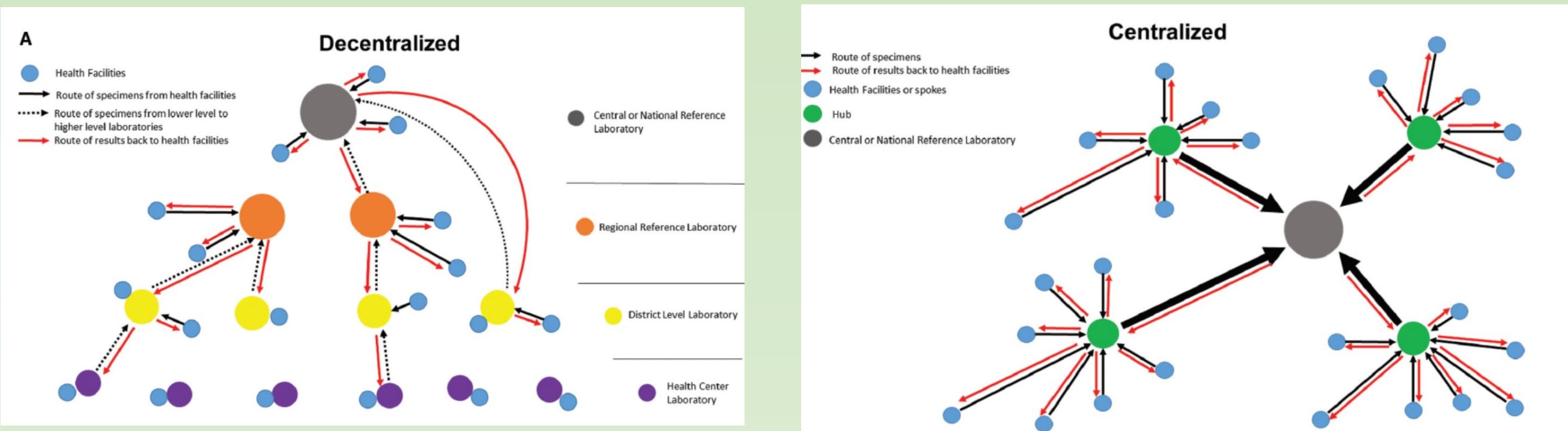


Figure 1: Sample referral models for delivery of healthcare services.

Fonjungo PN et al, CID, 2017;64(6):796–803

METHODS

- TB laboratory capacity within the public healthcare system (microscopy, Xpert MTB RIF, culture and phenotypic DST). was systematically assessed in each of the 10 Central African countries
- Specimen transport systems were evaluated using a uniform questionnaire directed at national TB programs reviewing availability of guidelines, SOP and training modules.
- A review of existing international resources (recommendations, regulations, procedures and training programs) was undertaken to derive specimen transport best practices that could inform national TB programs

RESULTS

Table 1: Burden of TB disease in the Central African Region (WHO Global TB report, 2016)

Country	Population (millions)	TB incidence (per 100 000)	MDR TB Incidence (per 100 000)	DRS
Angola *	25	370	16	no
Burundi	11	122	4.5	no
Cameroon	23	212	8.1	no
Central African Republic *	5	391	4.3	no
Chad*	14	152	6.3	no
Congo Brazzaville *	5	379	15	no
DR Congo *	77	324	13	yes
Gabon	2	456	23	no
Equatorial Guinea	<1	172	7.8	no
Sao Tome	<1	97	19	no

* Listed among the top 30 TB high burden countries

* Listed among the top 30 TB/HIV high burden countries

Table 2: TB laboratory capacity in the Central African Region (2016).

TB Laboratory testing capacity					
Country	1 AFB lab /100K habitants	1 Culture/5M	1st line DST lab/5M	Xpert nb (/100 K habitants)	Xpert MTB/RIF recommended as initial diagnostic test for presumed TB cases
Angola *	No	No	No	3 (0,01)	Yes
Burundi	Yes	No	No	1 (0,01)	
Cameroon	Yes	No	No	3 (0,01)	No
Central African Republic *	Yes	Yes	Yes	1 (0,02)	No
Chad	No	No	No	2 (0,01)	No
Congo Brazzaville *	No	No	No	1 (0,02)	
DR Congo *	Yes	No	No	39 (0,05)	No
Gabon	Yes	Yes	Yes	2 (0,12)	No
Equatorial Guinea	Yes	Yes	No	1 (0,2)	No
Sao Tome	Yes	No	No	0	

Table 3: Diagnostic indicators (new and relapse TB cases) (WHO Global TB report, 2016)

Country	% tested with rapid diagnostics at time of diagnosis	% bacteriologically confirmed among pulmonary
Angola *	/	51
Burundi	8	88
Cameroon	2	74
Central African Republic *	1	61
Chad*	1	54
Congo Brazzaville *	3	51
DR Congo *	10	83
Gabon	/	54
Equatorial Guinea	17	72
Sao Tome	/	38

End TB Strategy recommended target level for tested using a WHO-recommended rapid diagnostic (WRD) at the time of diagnosis (by 2025) :

90 % of new and relapse TB patients

Table 4: Status of national sample referral systems

Components	TOTAL
National policies	1/5
National standards /guidelines	1/5
Internal sample reference system	2/5
External sample reference system (ie. to SNL)	4/5
SOP	2/5
Transport logs	2/5
Trained staff	3/5
Sample type	
Follow up and monitoring	0/5

- 5/10 countries completed a standardized questionnaire assessing components essential to national referral transport system.
- Only one country had national planning elements in place (SOP, guidelines and policies). Others relied on IATA and/or WHO regulations and standards.
- Most were referring samples (sputum) externally for culture and DST testing
- None had indicators in place to enable follow-up and monitoring of specimen referral systems
- Referral systems were often financed externally (Global Fund, partners) raising the issue of sustainability once implemented

Table 4: Overview of available international resources for biological samples transport

Category	Author/ organization	Title	Language	Year	Scope/Target audience
TRANSPORT REGULATIONS					
Recommendation	UNECE	UN Recommendations on the Transport of Dangerous Goods: Model Regulations <ul style="list-style-type: none">• aims at presenting a basic scheme of provisions that will allow uniform development of national and international regulations governing the various modes of transport• basis for international and national regulations addressing transport by air, road, rail, sea http://www.unece.org/trans/danger/publi/unrec/rev19/19files_e.html	F/E/S	2015 (July)	governments and international organizations concerned with the regulation of the transport of dangerous goods
Legal framework (agreement)	UN	European Agreement concerning the International Carriage of Dangerous Goods by Road <ul style="list-style-type: none">• Aims to facilitate and develop international transport while improving safety and environmental impact. http://www.unece.org/fileadmin/DAM/transport/danger/publi/adr/adr2015/ADR2015e_WEB.pdf	E	2014	EU member states
Recommendation	WHO	Guidance on regulations for the Transport of Infectious Substances 2015-2016 <ul style="list-style-type: none">• Aims to assist shippers with classifying, documenting, marking, labelling, and packaging infectious substances• provides practical guidance to facilitate compliance with applicable international regulations for the transport of infectious substances by all modes of transport, both nationally and internationally http://www.who.int/hr/publications/who_hse_jhr_2015_2/en/ http://www.who.int/entity/hr/e-Guide_2015_12_Mar_15.pptx	E/F/S	2015	Shippers of infectious substances
Regulations and standards		IATA dangerous goods regulations <ul style="list-style-type: none">• Rules and guidelines on dangerous goods transportation• Global reference for shipping dangerous goods by air	F/E/S/G/R		shippers, freight forwarders, ground service providers and airlines
BIOSAFETY/INFECTION CONTROL					
Guidance	WHO	Laboratory Biosafety Manual – Third Edition <ul style="list-style-type: none">• Practical guidance on biosafety techniques for use in laboratories at all levels• Regulations for the transport of infectious substances are reflected (part IV.15) http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_CSR_LYO_2004_11/en/	F/E/S/P	2005	Countries aiming to develop national codes of practice for securing microbiological assets
Guidance	WHO	Tuberculosis laboratory biosafety manual: <ul style="list-style-type: none">• Describes the basic requirements for facilities and practices, which can be adapted to follow local or national regulations or as the result of a risk assessment. http://www.who.int/iris/bitstream/10665/93398/1/9789242504637_fre.pdf?ua=1	F/E	2012	TB programmes directors, TB laboratories managers, laboratory technicians, especially in high-burden, low resource settings
LABORATORY GUIDELINES, TRAINING MODULES AND PROCEDURES					
Best practices, standardized procedures	GLI/STOP TB partnership	Mycobacteriology Laboratory Manual, 1st edition http://www.stopthb.org/wp/gli/assets/documents/gli_mycobacteriology_lab_manual_web.pdf	E	2014 (April)	TB laboratories
Guidance and best practices	GLI/STOP TB partnership	GLI Practical Guide to TB Laboratory Strengthening <ul style="list-style-type: none">• Section 2.2: Specimen collection, transport and registration• Includes specimen logs, registers and examination request forms http://www.stopthb.org/wp/gli/assets/documents/gli_practical_guide.pdf	E	2017 (March)	TB laboratory managers and technicians, programme managers, Non officials, partners
Training	WHO	Infectious Substances Shipping Training - a course for shippers classroom <ul style="list-style-type: none">• Modules addressing the classification, documentation, marking, labelling, packaging of infectious substances, and the preparation of shipments requiring the use of dry ice http://www.who.int/iris/bitstream/handle/10665/2504637/1/shipping_training/tr/	E/F/S/	2015	shippers of infectious substances
Training	Stop TB partnership/GLI (FIND, KNCV, US CDC, USAID and WHO)	Training Package on XPERT MTB/RIF Module 3: Collecting and transporting sputum specimens <ul style="list-style-type: none">• Modular Xpert MTB/RIF training package in PowerPoint format for country customization. http://stopthb.org/wp/gli/TrainingPackage_XPERT_MTB_RIF.asp	E/F/P/R	2015	basic users, supervisors, clinicians
Training	GLI	Training Package: Programme Modules for Diagnostic Network Strengthening Module 3: Plan and Establish a Sample Referral Network for TB Diagnosis http://stopthb.org/wp/gli/assets/documents/PW3%20Referral%20Network.zip	E	2017 (June)	TB programme and laboratory managers and their implementation partners
Standard operating procedure	TB CARE I (J)	Standard Operating Procedure (SOP): Sample conditions and transport for culture procedure http://www.tbcare1.org/publications/toolbox/tools/sops/29_Specimen_Condition_Transport.doc	E		TB laboratories
Standard operating procedure	FIND	Specimen Collection Manual_TB 03-03_V1.0.doc https://www.finddx.org/wp-content/uploads/2016/03/Specimen-Collection-Manual_TB-03-03_V1.0.doc	E		TB laboratories

- Numerous international resources exist to guide the elaboration of national planning and training documentation. However, few best practices and training modules were available in languages used in the Central African region (French, Spanish, Portuguese)

RECOMMENDATIONS

- Central Africa countries all share high TB disease burden coupled with suboptimal performance and limited TB lab capacity.
- In this region, national TB program policies and strategies need to more systematically address sample transport systems.
- Locally relevant TB specimen transport guidance and training programs should be elaborated in a language accessible to the end users.
- Clear standards should be provided for sample referral within national laboratory networks and with international partner laboratories to ensure optimal access to tuberculosis diagnosis including universal DST.
- Financial resources should be secured to sustain these transport systems.