



RESEARCH ARTICLE

Tuberculosis Diagnosis in Private Independent Laboratories in Kampala- Uganda Implications for TB Control in the City

D Lukoye^{1*}, D Okello², S Namatovu³, A SSebagereka³, K Mutesasira¹, Mabumba Eldad⁴, M Nandala⁵ and P Suarez⁶

¹TRACK TB Project, Management Sciences for Health, Uganda

²Kampala Capital City Authority, Uganda

³Makerere University School of Public Health, Uganda

⁴National TB/Leprosy Program, Uganda

⁵Management Sciences for Health, Arlington, USA

⁶Central Public Health Laboratories, Ministry of Health Kampala, Uganda



*Corresponding author: Deus Lukoye, TRACK TB Project, Management Sciences for Health, Plot 15 Princess Anne Drive Bugolobi, P.O Box 71419 Kampala, Uganda, Tel: +256752882339, E-mail: deuslukoye@gmail.com

Abstract

Tuberculosis remains the greatest killer globally. Uganda, one of the highest TB burden countries has a rapidly growing private medical sector. Although a large proportion of patients first seek care from the private sector, there is very little if any literature about participation of private independent laboratories in diagnosis of TB. We aimed at assessing this and the extent to which diagnosed TB patients are linked to care.

Methods: We conveniently sampled and reviewed records for seven independent private laboratories registered with the ministry of health covering January-June 2015 period. Data was collected on patient demographics, number of sputum samples analyzed in each and those testing positive for TB. We also collected data on where the diagnosed patients were registered for treatment.

Results: A total of 33,071 samples were analyzed of which 562 were for sputum. Of these, 271 (48%) were for males, 227 (40%) females and 64 (12%) records missed sex classification. The ≤ 14-year-old contributed only 8 (1.4%) and 301 (54%) of the samples did not have age registered. Four hundred and thirty-six (78%) samples were from private for-profit health units and others were self-referrals. Thirty-four (6%) samples analyzed tested positive of which 21 were not traceable in the unit TB registers. About half of the laboratories were enrolled on the national EQA scheme and about half processed two pre-treatment smears required by the NTLTP.

Conclusion: Independent private laboratories in Kampala participate in sputum-smear microscopy for TB diagnosis but majority do not follow national guidelines. Majority of the diagnosed patients are not traceable in the known TB care centers.

Introduction and Background

Tuberculosis is the second greatest killer globally and 95% of the TB deaths do occur in low- and middle-income countries [1]. Uganda, like other developing countries has a large and growing private medical sector. Literature has shown that a large proportion of tuberculosis patients in many high TB- burden countries seek care from private health care providers first [2-4]. Kampala city with the highest incidence of TB in Uganda (450-550 TB cases/100,000 population) has reported slow increase in annual TB case notification over the past six years. TB in this city is mainly diagnosed in public and NGO health facilities. It has been observed that private health facilities also participate in TB diagnosis and treatment in this setting, but there is no published data/evidence on participation of independent private laboratories in TB diagnosis. It was assumed that a big number of TB patients are diagnosed in these laboratories and not linked to health facilities that report to

Kampala Capital City Authority (KCCA) which could lead to the observed slow increase in case notification. We therefore set out to establish this.

Methods

From July 15th-31st 2015, we conveniently sampled and assessed seven *high volume* private independent laboratories registered with the *Allied Medical Practitioners Council* in the five municipalities of Kampala and reviewed their records. Our aim was to establish the number of TB patients diagnosed in these laboratories and the proportion of these linked to care from January to June 2015. Included in this assessment were JICA, Mendata Africare, MBN, NAMELA, Lancet, Ebenezer and LMK laboratories. We collected data about location/division of the laboratory, number of sputum samples analyzed and those testing positive for TB, health units where diagnosed patients were referred for treatment and data on social demographic characteristics of the patients who provided the samples. Our definition of private independent laboratory was one that operates independently of any treatment unit and free to receive samples from all sources, health facilities, community or otherwise. We obtained permission to carry out this assessment from the Directorate of Public Health and Environment of KCCA and laboratory managers provided verbal consent to participate in this exercise.

Results

Laboratory participation in TB diagnosis

Of the seven laboratories assessed, three in the central business division, two in Kawempe, one in Nakawa and one in Makindye, each had analyzed at least one sputum sample during the review period with the exception of Mendata Africare lab (Table 1). Among the remaining six laboratories, Lancet contributed the highest proportion 366 (67%) of the samples. Four of the seven laboratories had only one pre-treatment smear performed per presumptive TB patient as opposed to the two samples which are recommended by the NTL [5]. Four labs reported to carry out tests on both early morning and spot on samples while one lab carried out both tests only on request by the physician. The rest did carry out sputum microscopy on only one sample. Four laboratories did participate in External Quality Assessment (EQA) for sputum smear microscopy. During the review period, all laboratories used only the ZN method to analyze all the sputum samples.

During the review period, a total of 33,071 tests of all types were analyzed in the participating laboratories of which 562 (1.6%) were for sputum. Of the 562 patients whose samples were analyzed 271 (48%) were males, 227 (40%) were females and sex classification were missing on 64 (12%) records. The ≤ 14 -year-old (children) contributed only 8 (1.4%) of the samples analyzed. Two hundred and fifty-three (45%) samples were

for patients > 14 years while 301 (54%) samples did not have their respective age registered. Four hundred and thirty-six (78%) of the samples were from Private For Profit (PFP) health units while 126 (22%) were self-referrals (see Table 1). Thirty-four (6%) of the total number of samples analyzed in the laboratories tested positive for TB.

Linkage of diagnosed TB patients to care

Of the 34 sputum samples that tested positive, 11 (32%) patients could be traced in the NTL unit register at the referral facility. Of the remaining 23 patients testing positive, two were traced in a register at a facility different from that which referred them to the private laboratory. The remaining (21, 61.7%) of the patients could not be traced. Of the 21 patients whose whereabouts were not known after a positive test, 12 (57%) were self-referrals. Records showed that all the samples that were sent to the six laboratories were tested and results received by the patient with exception of three (0.5%) patients who did not pick their results because of incomplete payment. However, none of these had tested positive for TB.

Discussion

In this assessment of independent private laboratories for diagnosis of TB in Kampala city, where we analyze data for six months in seven laboratories, we demonstrate participation of these facilities in TB diagnosis to a tune of a minimum of five TB cases per month in this set up, but almost 60% of them are not linked to care. To the best of our knowledge, this is the first assessment of the kind that explores the potential of these facilities to improve TB case notification in an urban DOTS program.

Our study showed that only one sputum sample is examined pre-treatment for almost half of the laboratories assessed and, for most of the samples it was not clear if this was an early morning or spot sample. This is contrary to the NTL guidelines that requires examination of two samples if microscopy is used (early morning and on-spot) as a diagnostic method before TB is ruled out in any presumptive TB patient [5]. During the assessment, we found out that about half of these laboratories were enrolled on the national EQA scheme for sputum smear microscopy, a gap that could have potentially contributed to this practice. It is therefore possible that some patients might have been missed or diagnosis delayed leading prolonged patient morbidity and disease transmission in the community. However, the cost of processing the samples might also be a deterrent as supported by the failure for some patients to pick their results for the only sample analyzed as a result of incomplete payment of the fees charged. The scope of this study fell short of this analysis, limited to assessing laboratories, not patient interviews to provide some details about affordability of the costs involved.

Table 1: Table showing performance of each laboratory in TB diagnosis by sputum microscopy (Jan-June 2015).

	Total No. sputum samples	Where sample was referred from	No. examined at the laboratory	No. testing positive for TB	No. of diagnosed patients traced in unit registers
NAMELA	1	SR			
MENDATA	0	NA	1	0	0
LMK	35	Norvik	N/A	N/A	0
		UHI	1	0	N/A
		St Louis	2	0	N/A
		Family Medical Centre	2	0	N/A
		Precious clinic	1	0	N/A
		Quality CC	1	0	N/A
		Friend's M.C	1	0	N/A
		Unity Slam Clinic	1	0	N/A
		Mengo Hill	1	0	N/A
		SR	2	0	N/A
		JICA	13	SR	23
LANCET IHK	366	IHK	13	1	0
		Touch Namuwongo	45	1	0
MBN	10	Doctor's House Clinic	321	12	11
		Worker's Treatment Centre	1	0	N/A
		BOU Clinic	1	0	N/A
		Kampala Hospital Kololo	1	0	N/A
		MBN Arua	2	1	0
		Panaroma Centre	2	0	N/A
		SR	1	0	N/A
EBENEZER	137	Kikamulo Health centre	2	0	N/A
		AAR	14	12	N/A
		SR	89	1	N/A
		SAS	1	1	N/A
		Ritah Health Care	1		N/A
		Andrew Medical Clinic	2	0	N/A
		URO Care	1	0	N/A
		Muyenga Dispensary	1	0	N/A
		St Francis Capital clinic	1	0	N/A
		Mengo Hospital	3	0	N/A
		Andrew Clinic	1	0	N/A
		St. Matayo	1	0	N/A
		Entebbe Hospital	2	0	N/A
		Mulago Hospital	1	0	N/A
		Adventist medical C	1	0	N/A
		Nsambya Hospital	2	0	N/A
		Children's Clinic	1	0	N/A
		All saints medical Centre	1	0	N/A
		The surgery	2	0	N/A
		GSKK	1	0	N/A
		Life mate medical	1	0	N/A
		Doctor's hospital	1	0	N/A
		Keethen General clinic	1	0	N/A
		Good lord	1	0	N/A
		Pam Health Clinic	2	0	N/A
		Doctor's hospital	14	1	0
		Keethen General clinic	89	12	0
		Good lord	1	1	0
		Pam Health Clinic	1	1	0

Legend: SR- Self Referral; N/A: Not Applicable.

During the assessment, we noted that almost 80% of the samples/patients were referred from Private For Profit (PFP) health facilities while others presented themselves to these laboratories without referral forms. For purposes of this study we called these self-referrals. This finding demonstrates a strong linkage between PFP

health facilities and the independent private laboratories for TB diagnosis. We could not tell the origin of the self-referrals through our assessment, but we strongly believed that some came from government health units although this cannot be confirmed in this report. We observed that a significant number of records lacked data

on age and sex, the very basic patient demographics, showing a gap in data management at these laboratories. This could result from the gaps in filling request/referral forms but might also have resulted from the gaps in filling laboratory request forms at the private laboratories. None of the laboratories reported having processed follow up sputum samples, most likely because they are not treatment facilities, but this is also the observed during routine surveillance (data not shown) in facilities that provide TB treatment where monitoring of treatment response by microscopy is still a challenge.

Our findings showed that for patients whose age was recorded, only 1.4% of the samples belonged to children ≤ 14 years. This might be a proxy for the low index of TB suspicion among the pediatric age group in private health facilities that majorly refer patients to these facilities. It might also reflect challenges associated with collection of sputum among the suspected TB patients in this age group, as is the case in other diagnostic health facilities. We may conclude that involvement of these facilities plays a minor role with regard to TB case notification among children, one of the major challenges of TB control in Kampala city at the time of this study.

Overall six percent of the samples tested positive for TB on microscopy lower than the WHO estimate of about 10% of bacteriologically confirmed cases among those who get a laboratory test [6]. The laboratories we assessed had a projected annual TB case detection of about 70 cases every year contributing 1.5% to the total notification of pulmonary bacteriologically confirmed TB patients [7]. We think this should have been higher if standards for sputum microscopy were followed which we did not find. However, our major concern was that majority (61%) of these confirmed TB patients could not be traced in any of the facilities that treat and notify TB patients to KCCA. It can be deduced from this study that private independent laboratories take minimal if any extra effort to establish what happens to these patients beyond diagnosis despite the fact that TB remains a notifiable disease. There isn't a tracking mechanism to ensure that such patients are timely linked to care for treatment initiation and follow up. We can also speculate that such patients initiated and continued treatment in the private for-profit health facilities where they were referred from before diagnosis, accessing TB medicines at a cost. It is also possible that some remained in the community using common antibiotics (a very common practice in this city) subjecting close contacts at a prolonged risk of TB transmission. The worst-case scenario could be that some died before they were registered for TB treatment, but this was beyond the scope of our study.

Limitations

The study included laboratory records for only the first six months of the year which might affect representativeness of our results in case there are seasonal

changes with regard to patterns of sputum sample analysis in the private independent laboratories. Secondly, we only included seven of the nine laboratories of the kind. Our data may therefore not be fully representative in case the laboratories that were not covered also do participate in sputum analysis for diagnosis of TB. Records in some facilities were incomplete in terms of the timing of sputum collection (early morning or spot), and patient demographics which were key variables in our analysis. Literature on this subject was scanty to enable us to make important comparisons with what has been established elsewhere in the world.

Conclusion

Independent private laboratories in Kampala participate in sputum-smear microscopy for TB diagnosis but so far contribute minimally to the total TB case notification. A big proportion of patients diagnosed through these laboratories is not linked to care hence not registered in facilities that provide TB treatment or notify TB cases to KCCA. This could lead to prolonged TB transmission (by the affected patients) due to delayed/none initiation of treatment [3] or exacerbation of the current MDR-TB burden if diagnosed patients are initiated on treatment in facilities that are not supported/supervised by KCAA.

Recommendations

Private independent laboratory staff should be oriented/trained in sputum-smear microscopy as one of the ways of addressing the observed gaps. They should all be enrolled on the national EQA scheme to ensure quality sputum-smear microscopy that meets NTLF requirements. Further, the KCCA supervision team should include them on the list of facilities that are monthly supervised by laboratory focal persons and supported with IEC materials as a way of enhancing their capacity to undertake these tasks. A clear referral system with tools including standard operating procedures, referral forms and means of communication should be instituted to ensure that diagnosed TB patients are linked to the known TB treatment facilities in Kampala that notify TB cases to KCCA and the NTLF. The above might improve TB case notification in KCCA but most importantly help timely management of TB patients in health facilities where quality of service delivery is monitored. These could be achieved through clear guidance from KCCA with support from TB implementing partners like the National TB Reference Laboratory, Central Public Health Laboratories, The UNION, TRACK TB project, The Infectious Disease Institute, The Uganda Private Health Support Project, and FHI 360/Communication for Health Communities (CHC) among others.

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Author Contributions

DL, PS, and KM conceived the idea and wrote the report, AS and AN, collected data and reviewed the draft report, DO, authorized the study and reviewed the report EM, participated in the study, MN provided baseline information of private independent laboratories in Kampala.

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