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Burden of tuberculosis and challenges related to screening and diagnosis in Ethiopia

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ABSTRACT

Introduction: One-third of tuberculosis (TB) cases in Ethiopia are missing from care for reasons that are not well studied. The aim of this study was to assess TB burden and identify challenges related to TB screening and diagnosis in Ethiopia.

Methods: A facility-based cross-sectional study was conducted in seven health facilities selected from two regions and 2 city administrations of Ethiopia using stratified random sampling procedures. The data of 1,059,065 patients were included from outpatient department, HIV clinic, diabetic, and maternal-child health clinics. Data were collected from October to December 2018 using a retrospective review of three years' facility data (2015 to 2017) supplemented by a semi-structured interview with purposively selected health care workers and heads of the health facilities.

Results: A total of 1,059,065 patients visited the health facilities in three years, of these, 978,480 (92.4%) were outpatients. Of the total, 20,284 (2%) were presumptive TB cases (with 14 days or more cough), 12.2% (2483/20,284) of which had TB. For the type of TB, 604 (24.3%) were smear-positive pulmonary TB (PTB), 789 (31.8%) were smear-negative PTB, 719 (29%) were extra-pulmonary TB, and data were missing for the rest. TB screening was integrated into HIV clinic, outpatient department, diabetic clinic but not with the maternal and child clinics. High patient load, weak TB laboratory specimen referral system, and shortage of TB diagnostic tools including Xpert MTB/RIF assay and chest X-ray, were the major challenges in the screening and diagnosis of TB.

Conclusion: The burden of TB was high in the study setting, and frequent interruption of laboratory reagents and supplies hampered TB screening and diagnostic services. Realizing the END-TB strategy in such resource-limited settings requires sustainable TB diagnostic capacity and improved case detection mechanisms, with national TB programs strongly integrated into the general health care system.

1. Introduction

Tuberculosis (TB) is the leading cause of mortality and morbidity among infectious diseases around the globe. According to the 2018 global TB report of the World Health Organization (WHO) [1], 10 million people developed TB and 1.6 million died in 2017, where 300,000 deaths were among HIV-positive patients. There were fewer than 10 new cases per 100,000 populations in most high-income countries [1], which clearly indicate TB as the disease of the poor. For instance, in Africa, where only 13% of the world population are

Abbreviations: AFB, acid fast bacilli; ANC, ant-natal care; ART, anti-retroviral therapy, DOTS, directly observed treatment, short course; eHMIS, electronic Health Management Information System; EPTB, extra pulmonary tuberculosis; FMoH, Federal Ministry of Health; HIV, human immunodeficiency virus; MDR-TB, multi-drug resistant tuberculosis; NGOs, non-governmental organizations; NTB, National TB program; PFSA, Pharmaceutical Fund and Supply Agency; PMTCT, prevention mother to child transmission; PNC, postnatal care; TB, tuberculosis; WHO, World Health Organization

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represented, an estimated 24% of existing TB cases worldwide occur in the region [2], and access to essential TB diagnostics, care and treatment services are very limited [3,4]. Similarly, Ethiopia is among countries highly affected by TB epidemics and one of the least developed in the world. According to the 2018 global TB report, there were 117,705 TB cases reported in the country, 28,600 died (3600 TB/HIV co-infected) and of the annual $93 million needed for TB care and control, the country's domestic contribution was only 11% [1].

Concerted efforts during the past two decades were performed under the directly observed treatment, short course (DOTS) strategy and later the Stop TB strategy have made remarkable progress worldwide in controlling TB and providing better care and treatment. The overall TB control effort requires a rigorous screening, diagnosis, and treatment of patients [5]. However, there were large gaps between the estimated number of new TB cases and the number of TB reported to national TB programs as the 2018 WHO report indicated: of 10 million estimated new cases worldwide, only 6.4 million (64%) cases were reported. Due to a mix up of missed or delayed diagnosis, and problems with access to quality of care, the risk of premature mortality, sufferings, and catastrophic financial consequences are substantial [6].

In Ethiopia, the TB case detection was 68%, which was below the WHO's target [7], and is even lower among women and children. TB case notification was 117,705, despite 172,000 estimated cases. Over two-thirds of TB cases in the country were pulmonary TB (PTB) cases, while the burden of extra pulmonary TB (EPTB) was 31%, twice the global proportion [1].

Even if the national TB program (NTP) guideline identified who should be screened and investigated for TB, practically, fewer patients were screened and scrutinized [7]. Ethiopia has been using the passive case finding, which misses the less advantaged patients in the community [8]. DOTS geographic coverage is 90%, whereas the health facility coverage is 75% [9] and despite the existence of TB guideline, the implementation of screening and diagnosis of TB remains suboptimal [7]. In the country, 89% of public hospitals provide smear microscopy and about 80% of them have provided chest X-ray [10]; however, only 8% of TB patients initiated TB care in those facilities [11]. At the primary care level, lack of adequate TB care services made the TB patient-pathways to care long and complex [12].

There is a growing concern on how to increase TB case detection in Ethiopia [7]. For this reason, the country endorsed the WHO TB control strategy the “End TB Strategy” in 2015, putting systemic screening of contacts and risk groups as critical components [13,14]. We, therefore, described here the TB burden and challenges related to TB screening and diagnosis in Ethiopia.

2. Methods and materials

2.1. Study setting and design

The study was conducted in two of the 9 regional states and 2 city administrations of Ethiopia: Oromia National Regional State, and the Harari National Regional State, Addis Ababa City Administration, and Dire Dawa City Administration. In Addis Ababa City Administration, the capital of Ethiopia, there were 899 public and private health facilities, of which 195 (22%) were providing TB care and treatment services. In Dire Dawa City Administration, there were 71 public and private health facilities, of which 21 (42%) were providing TB care and treatment services, and for Harari National Regional State, there were 44 health facilities and 16 (36.4%) of these had TB care and treatment services. Oromia National Regional State covers one-third of the country's population, where we selected East Hararghe zone, one of the 20 zones of the region, for this study. In the zone, there were 662 public and private health facilities, of which 59 (9%) were providing TB care and treatment services (Table 1). This cross-sectional study was conducted from October to December 2018 using a retrospective review of three years’ facility data (2015 to 2017) supplemented by a semi-structured interview with purposively selected health care workers and heads of the health facilities.

2.2. Sampling procedures

The selection of health facilities followed stratified random sampling. The study included two National Regional States and two City Administrations. Two regions (Oromia and Harari National Regional States) were randomly selected from nine (9) regional states of Ethiopia. East Hararghe zone was selected randomly from Oromia National Regional State. We included two City Administrations (Dire Dawa and Addis Ababa). A total of seven health facilities, 4 urban and 3 rural, were selected. These were: Zewditu Memorial Hospital and Kazanchis Health Center from Addis Ababa; Sabian General Hospital and Melka Jebdu Health Center from Dire Dawa; Haramaya General Hospital and Chelenko Primary Hospital from East Hararghe zone of Oromia National Regional State; and Hiwot Fana Specialized University Hospital from the Harari National Regional State. Fig. 1 summarizes the site selection process.

The study included the data of 1,059,065 patients from outpatient department, HIV clinic, diabetic, and maternal-child health. The study was supplemented by semi-structured interviews. With purposive sampling, facilities’ heads and other health care workers were selected. Based on this, a head of each health facility ($n = 7$), and a focal health care provider at each facility's DOTS clinic, ART clinic, outpatient department or diabetic clinic, and maternal child health ($n = 28$) were included to provide information.

2.3. Data collection and analysis

Data sources were primarily the electronic health management information system (eHMIS): a national facility-based health data aggregation system that enables all health care services organizations and providers to register and capture data according to the national guideline [17]. At all health facilities, data were entered into computers through eHMIS by trained data clerks. We also reviewed TB registers, laboratory registers (primarily acid-fast bacilli and Xpert MTB/RIF assay registration books), outpatient department (OPD) registers, antenatal care register, delivery register, postnatal care register, family planning register, prevention of mothers to child transmission of HIV (PMTCT) register, anti-retroviral therapy register, diabetes mellitus register, and central triage register. Data were abstracted from computer-based and/or paper-based sources or archives using a checklist.

To supplement the secondary data, semi-structured interviews were held, using interviewer-administered open-ended questions, with the selected health facilities’ heads and health care workers at respective units of selected health facilities to assess the challenges related to TB screening and diagnosis. Trained experts conducted the interviews.

Only new visitors of OPDs attendees, for patients with follow up such as diabetes, PMTCT, and ART, a patient counted once. Data were managed through checking the presence of required data, completeness of checklists, and identifying sources to get missed data. Based on this, when data were missed from the electronic records, the data were collected from paper based-records. Trained data collators revisited the health facilities up to three times and contacted different health care workers that have been working at health facilities’ units during the three years. Finally, data were entered and cleaned using Microsoft Excel 2010. Descriptive data analysis was performed by Microsoft Excel 2010. The data collected through semi-structured interviews were analyzed by considering the key-words related to screening and diagnoses of TB and explained narratively. We used the National TB control guidelines of Ethiopia for the screening, diagnosis, and treatment of TB cases, for case definition and treatment outcomes [7].

The semi-structured interviews had questions related to the functionality and use of Xpert MTB/RIF Machine. The questions were designed to understand if the facilities have a functional Xpert MTB/RIF

Table 1
Administrative regions/zone of Ethiopia with the number of resident population and number and type of health facilities that providing TB care and treatment services, Ethiopia, 2019.

Administrative regions/ Zone	Population [16]	The number and types of available health facilities [15]				Health facilities providing TB care and treatment services
		Hospitals	Health center	Non-governmental organization	Clinics including health post	
Addis Ababa City Administration	3.3 million	44	97	8	750	195 (22%)
Dire Dawa City Administration	466,000	6	15	0	50	21 (42%)
Harari National Regional State	226, 000	6	8	0	30	16 (36.4%)
East Hararghe zone	3.2 million	5	116	0	541	59 (8.9%)

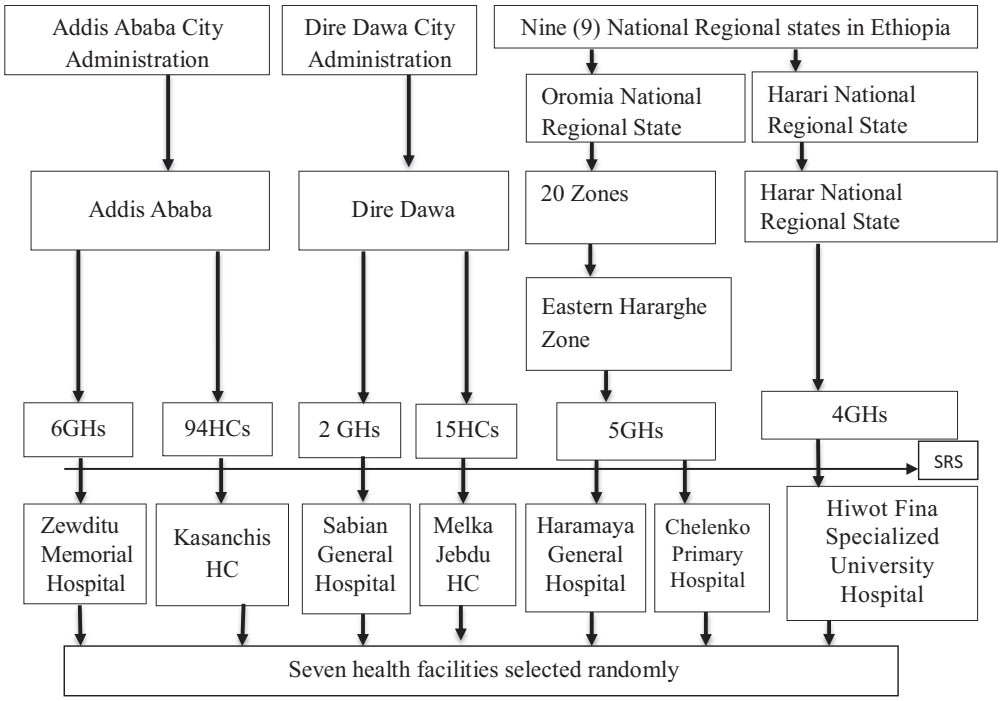


Fig. 1. Diagrammatic presentation of sampling procedure.
GHs = government hospitals, HCs = health centers, SRS = simple random sampling

Machine, how they get preventive and curative maintenance services, from where the facility supplies are coming from, and if there were challenges to the use of Xpert MTB/RIF technology. Similarly, there were questions related to chest X-ray, understanding if the facilities have a functional chest X-ray machine, its type and capacity, and if there were challenges in the management and use of such technologies. The interviews also enabled to capture information on TB patient flow process at OPDs, challenges in the process, and how the facilities handle data.

TB screening and diagnosis related were also included to understand if TB screening and case detection activities are practiced at different departments, including OPD, MCH (ANC, FP, PMTCT, PNC, Labor ward), ART, and diabetic clinics. We also captured detailed information on costs associated with TB patients, from registration to treatment.

2.4. Ethical consideration

The Institutional Review Board (IRB) of the College of Health Sciences, Addis Ababa University approved the study. Letters of permission were obtained from respective health facilities. Informed verbal consent was obtained from each head and health care workers to ensure that they have participated in the study voluntarily.

3. Results

3.1. Health facilities' descriptions

All the seven health facilities had different units/services, including outpatient departments, ante-natal care, delivery services, postnatal care, anti-retroviral therapy, diabetes mellitus, and family planning among others. Four of the facilities were located in urban area. The daily patients flow and the number of health care workers vary based on the type and location of health facilities. All five hospitals had smear microscopy, Xpert MTB/RIF assay, and chest X-ray services. Two health facilities had only smear microscopy (Table 2).

In seven health facilities, there were no special OPDs for patients reporting cough. Like other patients, they follow the standard; they visit central triage first as Ethiopia has implemented a centralized card room. To contact health care workers at OPDs, a patient registered on a piece of follow-up card and medical card. After visiting the center triage room, they passed through a long process within the compound of facilities. Tuberculosis patients' pathways in particular health facilities showed (Fig. 2).

3.2. TB burden and treatment outcomes

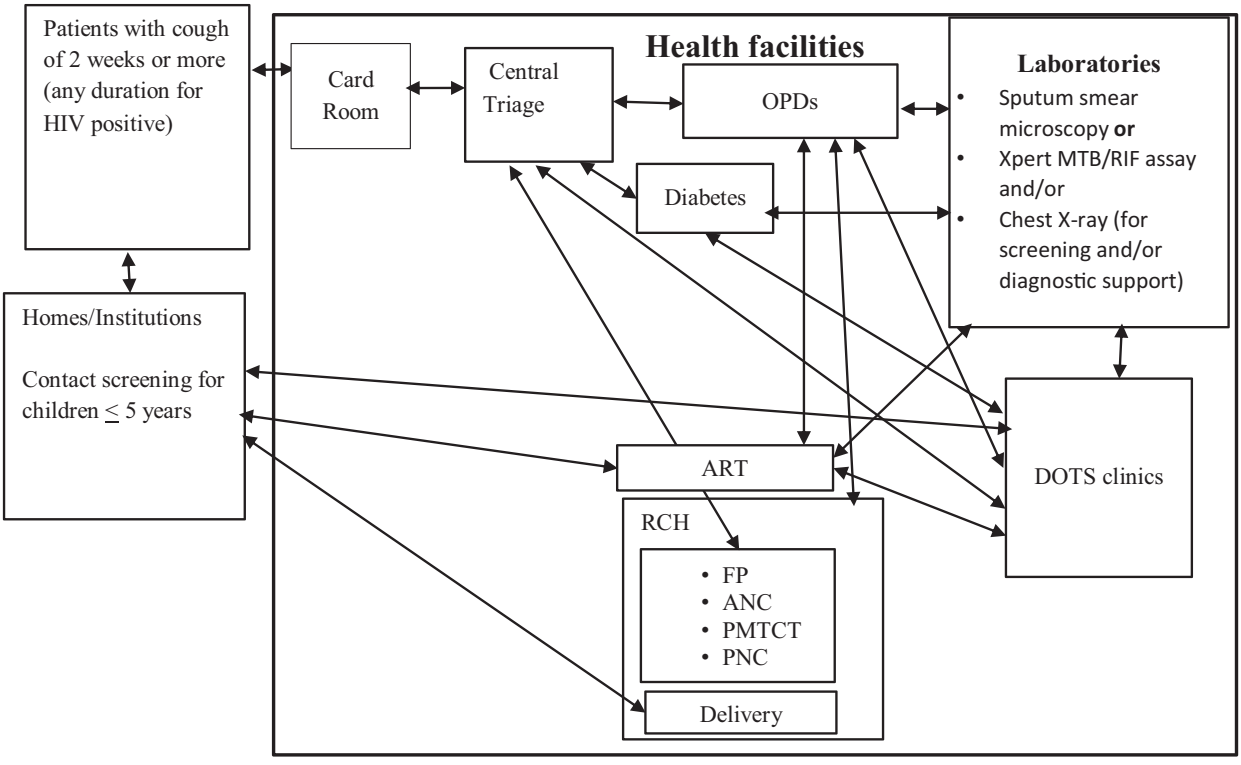
A total of 1059,065 patients visited the health facilities in three

Table 2
Resource and service capacity of study health facilities in Ethiopia, 2019.

Name of health facilities	Available health units/services	laboratory and X-ray capacity for TB	Setting	Catchment population	Patients follow-up / month	No. of Health workers
Sabian General Hospital	Medical, Surgical, Pediatric, Obstetrics wards, DOTS, ART, DM, Immunizations	X-ray Xpert MTB/RIF Smear Microscopy	Urban	70,711	9000	72
Melka Jebdu Health Center	OPDs, ANC, delivery, PNC, DOTS, ART, DM, FP, Immunization	Smear Microscopy	Rural	32,533	2430	38
Hiwot Fina Specialized University Hospital	Medical, Surgical, Pediatric, Obstetrics and Gynecology wards, DOTS, ART, DM, Immunizations	X-ray Xpert MTB/RIFSmear Microscopy	Urban	5.8 million	15,000	378
Haramay General Hospital	Medical, Surgical, Pediatric, Obstetrics wards, DOTS, ART, DM, Immunizations	X-ray Xpert MTB/RIF Microscopy	Rural	1,143,909	10,500	177
Zewditu Memorial Hospital	Medical, Surgical, Paediatric, Obstetrics and Gynecology wards, DOTS, ART, DM, Immunizations	X-ray Xpert MTB/RIF Smear Microscopy	Urban	5 million	32,628	535
Kazanchis Health Center	OPDs, ANC, delivery, PNC, DOTS, ART, DM, FP, Immunization	Smear Microscopy	Urban	74,849	8750	48
Chelenko Primary Hospital	Medical, Surgical, Pediatric, Obstetrics wards, DOTS, ART, DM, Immunizations	X-ray, Xpert MTB/RIFSmear Microscopy	Rural	675,000	14,940	82

OPDs: outpatient departments; ANC: ante-natal care; PNC: postnatal care; DOTS: directly observed treatment, short course; ART: ant-retroviral therapy; DM: diabetes mellitus; FP: family planning.

years. Of these, 978,480 (92.4%) visited the outpatient department, 34,477 (3.3%) visited the anti-retroviral therapy clinic, 27,656 (2.6%) visited the prevention of mother to child transmission of HIV clinic, and 18,452 (1.7%) visited the diabetes clinic (Table 3). Of all patients who had visited health facilities, 20,284 (2%) presumptive TB cases (with 14 days of cough) were identified. Overall, the prevalence of TB cases among presumptive TB cases was 12.2% (2483/20,284). Of 2483 patients enrolled into care, 2314 (93.2%) were screened for HIV; 311 (13.4%) were found HIV seropositive. Of enrolled, bacteriologically confirmed were 604 (24.3%), 789 (31.8%) were clinically diagnosed but were smear-negative TB, and 719 (29%) were diagnosed as extra-pulmonary TB. Overall, the treatment success rate was 1973 (79.4%), in which 455 (18.3%) were cured, and 1518 (61.1%) completed the treatment. Unsuccessful treatment rate was 139 (5.6%), in which 9



OPDs: outpatient departments; ART: anti-retroviral therapy; RCH: reproductive and child health; FP: family planning;
ANC: antenatal care; PNC: postnatal care; PMTCT: prevention of mother to child transmission; DOTS: directly observed treatment, short course.

Fig. 2. Tuberculosis patients' pathways in government health facilities in Ethiopia, 2019.
OPDs: outpatient departments; ART: anti-retroviral therapy; RCH: reproductive and child health; FP: family planning; ANC: ante-natal care; PNC: postnatal care; PMTC: prevention of mother to child transmission; DOTS: directly observed treatment, short course.

Table 3
Patients flow, TB notifications, and treatment outcomes at study health facilities for three years (2015–2017), Ethiopia, 2019.

Patients follow at selected units in last three years					TB notification				HIV			Treatment outcomes				
Years	OPDs	ART	DM	PMTCT	Presumptive TB	Bacteriological confirmed	Clinical diagnosed	EPTB	HIV screened	HIV +	Total enrolled	Cured	Completed	Failed	Died	LTFU
Sabian General Hospital																
2015	58,585	743	194	1110	ND	21	45	47	108	36	113	24	90	1	5	2
2016	55,419	787	794	1528	490	41	66	95	199	47	202	24	115	0	4	9
2017	62,029	854	1531	1779	1116	57	85	85	210	23	210	31	203	1	6	6
Melka Jebdu Health Center																
2015	17,364	88	6	528	ND	4	47	14	65	2	65	5	54	0	4	2
2016	15,056	91	7	800	115	14	45	29	84	2	88	3	61	0	0	9
2017	18,636	95	10	1116	186	30	35	19	84	7	84	10	81	0	1	0
Hiwot Fina Specialized University Hospital																
2015	38,812	1860	196	532	2045	44	63	48	132	8	157	41	115	0	1	0
2016	42,420	2120	205	956	2380	49	42	53	144	16	155	42	113	0	0	0
2017	59,520	2190	445	1124	3064	60	36	44	144	17	146	50	96	0	0	0
Haramaya General Hospital																
2015	36,073	241	523	2742	680	8	37	17	52	8	67	20	32	0	6	4
2016	38,629	258	572	2223	754	59	36	39	132	7	135	21	67	0	8	2
2017	27,933	261	602	2064	1508	39	55	31	123	1	125	26	51	0	4	3
Zewditu Memorial Hospital																
2015	89,540	7011	2994	1464	ND	4	19	39	121	28	62	7	54	2	4	7
2016	115,054	7022	4745	1528	1518	8	10	34	117	25	55	4	49	0	3	6
2017	114,949	7239	3512	1479	2930	11	9	35	110	33	66	6	40	0	2	2
Kazanchis Health center																
2015	53,616	1115	176	867	186	11	19	25	87	21	186	44	90	0	2	3
2016	34,368	1186	280	792	90	4	13	13	92	13	101	22	41	1	6	1
2017	52,752	1247	202	588	90	8	0	6	79	11	115	28	56	1	1	0
Chelenko Primary Hospital																
2015	15,025	22	440	896	1023	68	46	17	71	3	127	6	37	2	1	2
2016	14,436	23	490	1588	1143	30	52	16	93	1	148	28	42	1	2	7
2017	18,264	24	528	1952	966	35	29	13	67	2	76	13	31	0	2	3
Total	978,480	34,477	18,452	27,656	20,284	604	789	719	2314	311	2483	455	1518	9	62	68
Percentage (%)	92.4	3.3	1.7	2.6	2	24.3	31.8	29	93.2	13.4	12.2	18.3	61.1	0.4	2.5	2.7

OPDs: outpatient departments; ART: anti-retroviral therapy; DM: diabetes mellitus; PMTCT: prevention of mother to child transmission; EPTB: extra pulmonary tuberculosis; HIV: human immunodeficiency virus; LTF: lost to follow up; ND: no data.

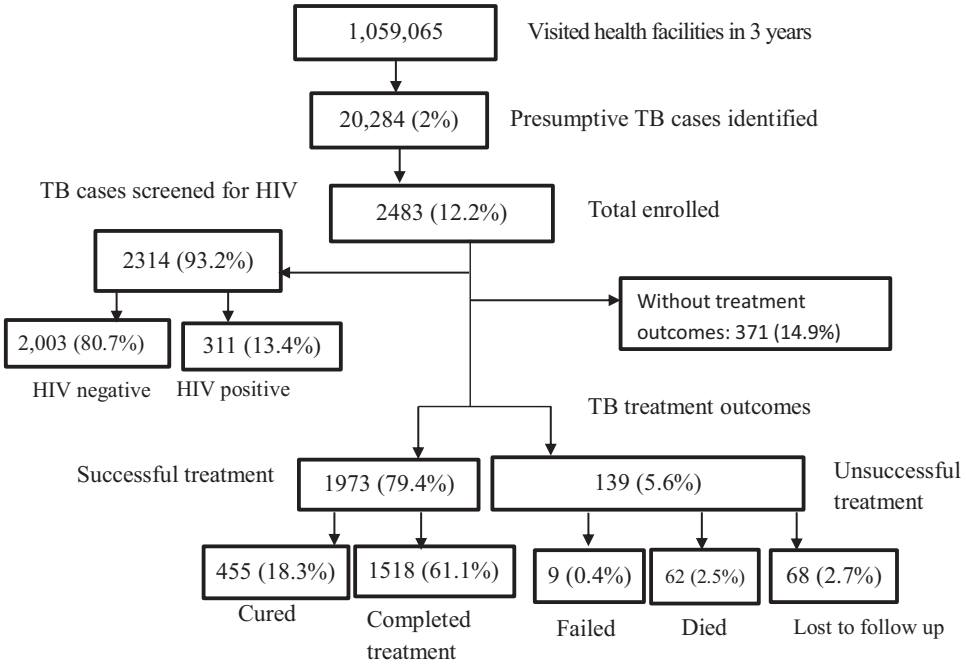


Fig. 3. Hospital attendees and presumptive TB cases screened and diagnosed for TB and HIV and TB treatment outcomes.

(0.3%) treatment failed, 62 (2.5%) died, and 68 (2.7%) were lost to follow up (Fig. 3). TB treatment outcomes of 371 (14.9%) TB cases were not documented. Tuberculosis case detection was not integrated into maternal health in formal ways, such as ante-natal care, delivery and postnatal care.

3.3. Presumptive TB cases and TB diseases

In three years of the study, at study facilities the number of presumptive TB cases were increased from 3934 (19.4%) in 2015, 6490 (32.0%) in 2016 to 9860 (48.6%) in 2017. Similarly, bacteriological confirmed pulmonary TB cases were increased from 121 (20%) in 2015 to 273 (45%) in 2017 (Fig. 4).

3.4. Challenges related to TB screening and diagnosis

3.4.1. Screening of TB

In all hospitals and health centers there were no health services insurance schemes. Patients paid out of their pockets except for the payment services exempted such as anti-TB drugs and supplementary drugs (i.e. vitamin B6). However, if TB patients were admitted as in-patients, they were expected to pay for services like non-TB patients. At hospitals, TB symptoms screenings were conducted at OPDs, diabetes mellitus clinic, ART, and only at PMTCT from the maternal care units. None was done at maternal health care units. The main screening symptom is cough of two weeks or more except for known HIV positive that screened for cough of any duration but the interviewee indicated as the screening of TB was less implemented at the facility when compared with as per the national TB guideline. The TB symptoms screening recording format was found at health facilities units, such as OPDs, DM clinic, ART, and only at PMTCT from maternal care units; however,

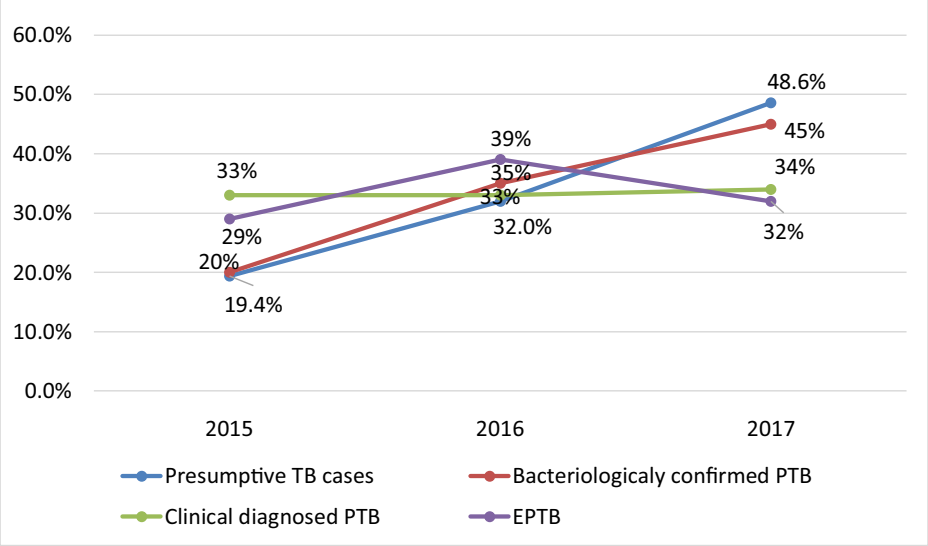


Fig. 4. Presumptive TB cases and TB types by years, 2015–2017.

Table 4
TB screening, mobile communication, and data handling at study health facilities in Ethiopia, 2019.

TB related activities	Health facilities						
	Sabian General Hospital	MelkaJebdu Health Center	HiwotFina Specialized University Hospital	Haramaya General Hospital	Zewditu Memorial Hospital	KazanchisHealth Center	Chelenko Primary Hospital
TB screening /detection							
OPD:	Yes	Yes	Yes	Yes	Yes	Yes	Yes
If patients with cough >2wks (any duration for HIV/AIDS patients)							
Maternal and child health							
Ant-natal care	No	No	No	No	No	No	No
PMTCT	Yes	Yes	Yes	Yes	Yes	Yes	Yes
labor ward	no	no	no	no	no	no	no
postnatal	no	no	no	no	no	no	no
Family Planning	No	No	No	No	No	No	No
ART	Yes	Yes	Yes	Yes	Yes	Yes	Yes
DM service	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Mobile communication							
Network providers							
Ethiopia-telecom							
Proportion of patients 80 70	75	70	100	100	70		
Who owned mobile phone (%)							
Data handling							
Hard copy	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Electronic	Yes	Yes	Yes	Yes	Yes	Yes	Yes

DM: diabetes mellitus.

there were no organized reports for how many patients screened for TB at the OPDs and linked to DOTS clinic for anti-TB treatment. There were no separate diabetes clinics rooms except in two facilities but diabetic patients had been treated and followed their treatment through OPDs.

During interviews, the health facilities heads and other health care workers reported the main challenges faced included: insufficient resources both financial and human resources, interrupted supply of reagents, equipment and supplies at the laboratories. Data were handled in both paper-based and electronically in all health facilities through health management information system (HMIS). The majority of patients had mobile phones. Regarding the cost, like other patients, presumptive TB cases paid for the registration. The payment related to registration depends on a facility whether public or private. At public health facility to find the medical card the payment varies on average from 1–5 birr or 0.04–0.2 $ and at private, 50–100 birr or 1.7–3.3 $. After that, if patients complained (self-present) for cough of 2 weeks or more, health care workers ordered acid-fast bacilli for free and/ or chest X-ray for which patients have to pay (Table 4).

3.4.2. Diagnosis of TB

All selected hospitals had at least one TB diagnostic facilities such as smear microscopy or Xpert MTB/RIF assay and chest X-ray. The Xpert MTB/RIF assay had been maintained and supplied by the government through the Pharmaceutical Fund and Supply Agency (PFSA). A major concern related to Xpert MTB/RIF assay commonly was a shortage of cartridges supply in all hospitals, while shortage of power was reported in one facility. The calibration of Xpert MTB/RIF assay had been performed by a government institution, which is Ethiopian Public Health Institute (EPHI). Xpert MTB/RIF assay was present or installed at central laboratories in some facilities, while in others, it was available at TB laboratory. The patients had paid for chest X-ray which varies among hospitals depending on types of chest X-ray whether regular or digital. In all hospitals, there was no radiologist, and long waiting time to get X-ray examination was also reported. Due to lack of Xpert MTB/RIF assay, health centers had been sending their patients or sample to nearby health hospitals through a specimen referral system, which is already in place but weak (Table 5). During the interviews, study participants indicated that there was delay returning specimens back to the facility.

4. Discussion

In this study, we found that the number of presumptive TB cases were 20,284 and the number of TB cases diagnosed bacteriological or clinical were 2483 in three years (2015–2017). Passive screening for TB cases performed at outpatient departments, antiretroviral therapy clinics, diabetes mellitus clinics, and at prevention of mother to child transmission of HIV units; it did not at maternal health services units (i.e. family planning, ANC, Delivery, and PNC). The acknowledged challenges facing the TB control program performance related to TB screening and diagnosis included insufficient resources both financial and human resources, interrupted supply of reagents, equipment and supplies at the laboratories, and delay of referred samples return back to the facility.

One in ten presumptive TB cases (12.2%) were diagnosed with TB and this is comparable with a study from Addis Ababa (10%) [18]. Presumptive TB cases increased by the years of this study from 19.4% in 2015 to 48.6% in 2017. Bacteriologically-confirmed TB cases also increased by the years of study from 20% in 2015 to 45% in 2017 (Fig. 4). This could be due to Xpert MTB/RIF assay introduced by the NTP. This is corroborated with a study from central Ethiopia that showed that Xpert MTB/RIF assay increased TB detection rate by 47.4% compared with smear microscopy [19].

In Ethiopia, TB case finding follows a passive TB case finding approach as facilities' heads and other health care workers indicated. It has started since DOTS' strategy was endorsed in 1994 as a preferred method with the recommendation of "case detection by sputum smear microscopy among symptomatic patients' self-reporting to health facilities" [9].

The result of this study indicated that the screening of TB was not integrated into maternal health care units, except in the PMTCT. In Ethiopia, screening for TB case finding activities has been done mainly for patients visiting at the OPDs, targeted screening for clinical risk groups namely, HIV or diabetic patients, and increased exposure to TB (e.g. prisons) [7]. TB case finding has been given less emphasis in other departments, such as RCH clinics where the majority of females attend. However, a study in Ethiopia revealed that, from infectious diseases, TB is ranked as the number one killer among females [20]. Another study

Table 5
TB diagnostic service availability and challenges at study sites in Ethiopia, 2019.

TB laboratories	Health facilities						
	Sabian General Hospital	Melka Jebdu Health Center	Hiwot Fina Specialized University Hospital	Haramaya General Hospital	Zewditu Memorial Hospital	Kazanchis Health Center	Chelenko Primary Hospital
1 Microscopy -Present or absent	Present and functional at all health facilities						
2 Chest X-ray							
Have a functional CXR	Yes	No	Yes	Yes	Yes	No	Yes
Types of CXR	Digital X-ray	N/A	Normal X-ray	Normal X-ray	Digital X-ray	N/A	Digital X-ray
Challenges related to CXR	Shortage of radiologists	NA	Shortage of radiologists	Shortage of power supply Shortage of radiologists	Shortage of radiologists	NA	Shortage of radiologists
Health insurance	No	No	No	No	No	No	No
Out of pockets	Yes	Yes	Yes	Yes	Yes	Yes	Yes
How much is the chest X-ray service?	40 Birr (1.4US$)	NA	30 Birr (1US$)	35 Birr (1.2US$)	15 Birr (0.5 US $)	NA	50 Birr (1.5US$)
Has a functional Xpert MTB/RIF assay	Yes	No	Yes	Yes	Yes	No	Yes
Who maintain or services or calibrate?	Government	NA	Government	Government	Government	NA	Government
Xpert MTB/RIF assay linked with the central lab (TB lab)?	TB lab	NA	TB lab	Central lab	TB lab	NA	Central lab
Xpert MTB/RIF assay							
Cartridges supply by whom?	Government	NA	Government	Government	Government	NA	Government
Shortage of cartilage supply	Yes	NA	Yes	Yes	Yes	NA	Government
Shortage of power supply related to Xpert MTB/RIF assay	No	NA	No	Yes	No	NA	No
Shortage of trained personnel	Mentioned at all health facilities						

NA: not applicable for those facilities that had no diagnostic equipment at study time, next question (s) skipped; CXR: chest X-ray.

from Tanzania also showed that the prevalence of smear-positive TB among women with a cough attending RCH was 3.8% [21]. The current practice of TB case finding in Ethiopia not only reduces national TB program (NTP) efforts of putting more infectious TB cases into care but also has a detrimental effect on women's lives and their children [22]. To simplify patient flow and to reduce waiting times, to integrate TB screening and diagnostic into ante-natal care services would influence the TB program to obtain more TB cases [23]. Thus, in Ethiopia, the screening and diagnosis of TB among this group need to get due emphasis.

TB control program activities that related to screening and diagnosis challenged as indicated by the interviewee. For this, the reasons they mentioned were high patient flow when compared with few health care workers working at health facilities particularly for hospitals, which affected screening of target groups. For the diagnosis of TB, many challenges identified: lack of diagnostic materials such as Xpert MTB/RIF assay at some facilities particularly at health centers, and interruption of supply of reagents (e.g. cartridges). The challenges in screening identified in this study are in line with a study done in North Ethiopia [24]. And also the diagnostic challenges indicated in a study from South-West Ethiopia showed that over one-third of TB smear microscopy was not requested; and among patients sent to the laboratory, almost 10% had missed results in laboratory registers [25]. These all might have contributed to less TB detection rate in Ethiopia that calls for innovative case finding approaches [8]. To improve TB screening needs a supply and demand side. To refine the supply side depends on technologies and screening algorithms, while addressing the knowledge gap enhances demand-side among clients as a study from Philippines revealed [26]

Moreover, lack of chest X-ray was a challenge identified by interviewees. For this reason, the facilities enforced to refer their patients to other referral linked government facilities. Subsequently, TB patients were incurred high out of pocket costs (e.g. 200 Birr or 7 US$), if they visited private health institutions. In Ethiopia, patients have to pay for the cost of registration or the issue of medical cards. In diagnosis process, if patients fulfilled the screening criteria (i.e. coughing for 2 or more weeks except for HIV positive with any duration), the patients had not paid for AFB, but paid for chest X-ray given that it was ordered by physician or health care workers. If TB patients are admitted in the inpatient wards, they are expected to pay for the services except for AFB, anti-TB drugs and vitamin B6. Beside, screening and diagnosis of eligible patients have not been performed as per the guideline of NTP as indicated by the interviewees. This is in line with studies done elsewhere in Ethiopia [24,27-28]. Thus, the NTP is expected to monitor and evaluate the policy on the guideline compliance in order to achieve the high caliber End TB goal.

We observed that the patients' pathway to be screened and diagnosed for TB was a long process in any given health facility (Fig. 2); that is why a scholar has argued that quality of health care is beyond the coverage [29]. A similar finding was reported in a study done in five countries (11). The long pathway process leads to substantial total delay and a lack of timely treatment and care of TB patients [30]. Those facilities with no Xpert MTB/RIF assay sent the samples to the facilities that had Xpert MTB/RIF assay by already established referral system according to NTP. In this case, sometimes the samples were delayed as indicated by the participants we interviewed.

Though good progress has been made in documenting the activities either by paper-based or electronically, still many other activities have to be performed. About 14.9% of TB cases treatment outcomes were not recorded. In addition to this, presumptive TB cases were not properly recorded; other options were explored and obtained them from laboratory registries (AFB and/ or Xpert MTB/RIF assay). Therefore, we strongly recommend the registration log book for presumptive TB cases should be prepared and used.

The drivers of strengths in our study, among others, found in that its large sample size for three years, its large area coverage and supplemented key informant interviews that enabled us to identify the burden of TB at study setting and explored the challenges for TB screening and diagnosis in Ethiopia. Despite it having these drivers of strengths, some factors with potential to pose limit our study worth mention. In our study, we observed data incompleteness that is common in retrospective data review [31] and in Ethiopia, on average report completeness in a study of eHMIS was 78.6% [32]. As a result; presumptive TB cases could be underestimated and underreported for the study population.

5. Conclusion

The burden of TB was high in the study setting, and frequent interruption of laboratory reagents and supplies hampered TB screening and diagnostic services. Realizing the END-TB strategy in such resource-limited settings requires sustainable TB diagnostic capacity and improved case detection mechanisms, with TB programs strongly integrated into the general health care system. The national TB program also recommended as prepare and use a separate presumptive TB cases register log at health facilities.

6. Availability of data and materials

Data will be available upon request from the correspondence author

CRediT authorship contribution statement

Hussen Mohammed: Conceptualization, Project administration, Data curation, Formal analysis, Writing - original draft, Writing - review & editing. **Lemessa Oljira:** Supervision, Data curation, Writing - review & editing. **Kedir Teji Roba:** Supervision, Data curation, Writing - review & editing. **Esther Ngadaya:** Supervision, Data curation, Writing - review & editing, Funding acquisition. **Tigest Ajeme:** Data curation, Project administration, Writing - review & editing. **Tewodros Haile:** Data curation, Writing - review & editing. **Achenef Kidane:** Data curation, Writing - review & editing. **Tsegahun Manyazewal:** Supervision, Data curation, Writing - review & editing. **Abebaw Fekadu:** Supervision, Data curation, Writing - review & editing. **Getnet Yimer:** Supervision, Data curation, Writing - review & editing, Funding acquisition, Project administration.

Declaration of Competing Interest

Authors declared that there are no conflicts of interest.

Ethical statement

The Institutional Review Board (IRB) of the College of Health Sciences, Addis Ababa University approved the study. Letters of permission were obtained from respective health facilities. Informed verbal consent was obtained from each head and health care workers to ensure that they have participated in the study voluntarily.

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