

Assessing the Quality of Reporting to China's National TB Surveillance Systems

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Abstract

Background: The reliability of disease surveillance may be restricted by sensitivity or the ability of the system to capture all disease. Our objective was to quantify under-reporting and concordance of recording persons with tuberculosis (TB) in the national TB surveillance systems: Infectious Disease Reporting System (IDRS) and TB Information Management System (TBIMS).

Methods: This retrospective review includes patients identified in 2016 from six counties in Guangdong, Jiangsu, Henan, Heilongjiang, Sichuan, and Yunnan provinces. County staff linked TB patients identified from facility-specific health and laboratory information systems with TB patients recorded in IDRS and TBIMS. Under-reporting was calculated as the percentage of TB patients not recorded in IDRS or TBIMS. Timeliness, patients recorded within 24 hours after diagnosis, and concordance, accuracy and completeness of key variables when compared to medical records, were analyzed through comparing sampled patient-records with corresponding patient-records in health facilities. Multivariable logistic regression was used to examine factors associated with under-reporting.

Results: We found 505 (10.7%) patients diagnosed with TB were missing within IDRS and 1451 (30.9%) patients were missing within TBIMS. Of 171 patient-records reviewed in IDRS and 170 patient-records in TBIMS, 12.3% and 6.5% were found to be untimely, 10.7% and 7.1% were found having inconsistent home address. The risk of under-reporting to both IDRS and TBIMS was greatest in TB diagnosis at a tertiary health facilities and non-residents; the risk of under-reporting to TBIMS was greatest with patients aged 65 or older and extrapulmonary TB (EPTB).

Conclusions: We found that more than one in four TB patients were not recorded in TBIMS. It is important to improve the reporting and recording of TB patients. Local TB programs that focus on training, and mentoring high-burden hospitals, facilities that cater to EPTB, and migrant patients may improve reporting and recording. Additional human resources for data collection and management, and monitoring and evaluation systems are needed to improve national surveillance systems and TB prevention, diagnosis and treatment services.

Background

Disease surveillance data is a vital source of information for national and international policymakers, and can be used to evaluate burden and time trends of diseases [1]. However, the reliability of disease surveillance may be limited by sensitivity, or the ability of the system to capture all persons with disease. Many national disease surveillance systems may provide an incomplete picture due to under-reporting diseases of public health importance [2–6].

Tuberculosis (TB) is a disease that has existed for millennia in the world [7]. TB is the leading cause of death from a single infectious disease [8]. The World Health Organization (WHO) indicated that 7 million persons with TB were reported globally in 2018, representing 70% of the estimated 10 million new persons with TB [8]. Thus, 30% of new persons with TB were unknown to national authorities [8]. The gap

is mainly due to a combination of under-diagnosis (persons with TB are not diagnosed with TB) and under-reporting (persons with TB are diagnosed with TB, but not reported in the surveillance system). Under-diagnosis can result in anti-TB treatment initiation delay, which can lead to increased morbidity and mortality and increased duration of TB transmission [9]. Under-reporting can lead to a misinterpretation of TB disease burden. Consequently, resources may not be allocated appropriately.

Although the number of new persons with TB significantly decreased since 2009 [10], China still suffers a high TB burden. In 2018, WHO estimated 866,000 people developed TB disease in China, representing 9% of all new persons with TB worldwide and placing China as second in absolute number of persons with TB in the world [8]. In China, pulmonary tuberculosis (PTB) patients (both clinically-diagnosed and laboratory-confirmed) should be reported to the web-based Infectious Disease Reporting System (IDRS) and recorded in Tuberculosis Information Management System (TBIMS). Extrapulmonary TB patients can also be reported, but unlike PTB, extrapulmonary TB is not mandatory to report. If a patient has both PTB and extrapulmonary TB, the patient is usually reported as PTB, since PTB reporting is mandatory. There may be double entry of this patient, if the patient is reported as both PTB and extrapulmonary TB. IDRS, managed by Chinese Center for Disease Control and Prevention (CDC), contains patient information of 39 infectious diseases including PTB and monitors the epidemic conditions of these infectious diseases. In a report published in 2015, IDRS covered all provincial, prefectural, and county CDCs, 98% of medical institutions at or above the county administrative level, and 94% of community medical institutions [11]. TBIMS is the surveillance system for the national TB program (NTP) and is used for managing the full course of treatment of PTB patients, and does not capture information on TB presumptive patients [12]. TBIMS is accessible by all government-appointed TB-designated facilities, which could be local CDCs, TB dispensaries or TB-designated hospitals [12]. These two systems are independent, but there is a function within the systems to link information about patients diagnosed with TB. In 2018, WHO estimated 71000 (8.2%) TB patients in China were unknown to the NTP [8].

Multiple countries, including Kenya, Spain, Korea, Cape Verde and Egypt, have conducted inventory studies to assess TB under-reporting [13–17]. In 2015, China implemented a study in nine counties to identify TB under-reporting to TBIMS [12]. However, the results of the 2015 study were not representative of TB surveillance system quality in other areas of China. We developed this study to quantify under-reporting to both IDRS and TBIMS in six other counties and to investigate the factors associated with under-reporting patients diagnosed TB to the two surveillance systems. Additionally, we assessed concordance and timeliness of reported patients diagnosed with TB to the two systems. This study may complement our previous study [12] and help us improve our national surveillance strategies and, furthermore, to improve TB prevention, diagnosis and treatment services [18].

Methods

Study setting

China has the largest population of any one country with 1.39 billion people. It is divided into 34 provinces (including 3 special administrative regions) which are further divided into 334 prefectures and almost 3000 counties [12, 19]. We assigned provinces into three regions: eastern region, central region, and western region. Generally, regions decrease in socioeconomic status and increase in TB notification rate as you go from east to west [20].

In China, health facilities are divided into three levels according to their workload, diagnosis and treatment capacity, and responsibilities. Primary health facilities are community hospitals that provide prevention, medical treatment, healthcare, and rehabilitation services directly to single community. Secondary health facilities are regional hospitals that provide comprehensive medical and health services to multiple communities and provide local professional medical education and engage in scientific research. Tertiary health facilities are hospitals that provide highly specialized medical and health services and provide regional professional medical education and engage in scientific research. A reporting card is used by the treating physician to collect patient information; the reporting card may be checked by health workers in the same facility, then this information is entered by either the physician or health worker into IDRS or TBIMS ideally within 24 hours.

Study design

We conducted a retrospective inventory study to quantify under-reporting and identify the socio-demographic factors and other characteristics associated with under-reporting. We matched patient records diagnosed with TB from health facilities in 2016 with TB patient-records within IDRS and TBIMS. We also assessed concordance, data accuracy and completeness of key variables with patient medical records, and timeliness, defined as recording within 24 hours after diagnosis, of matched patients.

Sampling method

We adopted stratified purposive sampling to select six provinces –Guangdong and Jiangsu from eastern China, Heilongjiang and Henan from central China, and Yunnan and Sichuan from western China. In each of the provinces, we selected one county with a high TB burden (more than 200 notified patients in 2016) and capacity (at least 2 local staffs in charge of NTP work) to implement the study. The six counties are Nanshan from Shenzhen, Xingyang from Jiangsu, Yilan from Heilongjiang, Liyang from Henan, Simao from Yunnan, and Lu from Sichuan. Within each county, three facilities participated: the county-level TB designated hospital, the general hospital with the greatest patient load, and one township hospital with chest x-ray capability. All patients diagnosed with TB were included to quantify under-reporting of IDRS and TBIMS.

To assess concordance and timeliness of reporting diagnosed TB patients to IDRS and TBIMS, we included the county-level designated TB hospital. If fewer than 30 TB patients were diagnosed at the designated TB hospital, the largest county-level general hospital was included. If more than 30 TB patients were diagnosed in the sampled health facilities during the project period, we employed simple random sampling method to select 30 TB patients diagnosed in the sampled health facilities from IDRS and TBIMS respectively. If not, we included all TB patients.

Eligibility criteria

We included patients diagnosed with PTB, TB pleurisy, and other extra-pulmonary TB (EPTB) according to national TB diagnosis guidelines [21, 22] from 1 January 2016 and 31 December 2016. Briefly, TB is categorized into the following categories: 1) primary PTB; 2) hematogenous disseminated PTB; 3) secondary PTB; 4) tuberculosis pleuritis; and 5) extrapulmonary TB. PTB patients are classified as (a) lab-confirmed via sputum culture, sputum smear, or pathological examination of lung lesions; (b) clinically diagnosed, patients that do not meet confirmed definition in that they have at least three negative sputum smear results, but may have a combination of chest radiograph suggestive of PTB, signs and symptoms of TB, immunologic reaction to tuberculin, and lesions of TB confirmed by histopathological examination of extra-pulmonary tissues; or (c) presumptive, meets one of the following: children < 5 years who have signs/symptoms and either close contact with smear positive PTB patients or strongly positive PPD reaction, or a patient with only chest imaging showing lesions of active PTB. All presumptive TB patients were excluded.

Data collection

We collected TB patient medical records in health facilities, TB surveillance records in IDRS, and TB patient treatment register records in TBIMS.

From IDRS, we exported name, age, gender, national ID number, report number and date of diagnosis, and other relevant patient characteristics for all TB patients reported in 2016 into an CSV file. From TBIMS, we also exported the same variables for all reported patients in 2016 into a CSV file, along with additional register number and sputum status.

We collected medical records of diagnosed TB patients in selected health facilities. If the health facility had an electronic hospital information system or laboratory information system, we exported records with a TB diagnosis to a CSV file. If electronic data were not available, we reviewed paper medical records from outpatient departments, inpatient wards, and laboratory reports for a TB diagnosis and added these records meeting the eligibility criteria to an MS Excel® (Microsoft Corporation, Redmond, WA, USA) spreadsheet. The Excel spreadsheet included the following information: name, age, gender, national ID number, home address, date of diagnosis, health facility, department of diagnosis, data source (outpatient/inpatient/laboratory), initial diagnosis, type of TB (PTB-clinically diagnosed/PTB-laboratory confirmed/pleurisy or other EPTB) and result of TB laboratory examination. We also investigated whether TB patients reviewed were residents, which was defined as someone recorded in the county or had lived in the county for more than six months, which is usually indicated via self-report in medical records and confirmed based on the type of medical insurance, since non-residents have different insurance categories.

Data deduplication

A duplicate record was defined as a record with the same national ID number, name (a different character was permitted), gender and age (+/- 2 years was allowed) as another record. Name was use as key index

to compare and other variables were used as supplemental value. Final deduplicated database was determined by local study implementers.

Record linkage

We linked the medical records dataset (from general hospitals) and health facilities dataset (from dispensaries, clinics, and examination centers) based on the name of the health facilities, and renamed the new dataset, DX-DATASET. This was done in order to capture data on patients treated at both general hospitals and health facilities. We used a proprietary software to match deduplicated DX-DATASET and IDRS datasets by national ID number, name, age, gender and home address. The software provides a score demonstrating the probability of a match and a health worker reviews results for a final determination of a match. A match was defined as records from the facility dataset and IDRS with the same national ID number and at least one of the same of name, age, and gender. If the national ID number of a record was missing from either the DX DATASET or IDRS dataset, we defined a match as records with the same name, age (+/-2 years), gender, and home address. If a record from DX DATASET did not matched with a record in IDRS, the patient was defined as under-reported in IDRS. We used the same variables and applied the same definitions to match records from TBIMS with DX DATASET. If a record in the DX DATASET was not matched to a record in TBIMS, the record was defined as under-reported in TBIMS.

Data analysis

We used descriptive statistics to describe the characteristics of patients diagnosed with TB at participating health facilities and determined the number of TB patients identified in IDRS and TBIMS. We calculated under-reporting as the number of patients diagnosed with TB, but not reported to IDRS or TBIMS after diagnosis. Percent under-reporting was calculated as the number under-reported TB patients divided by the total number of TB patients diagnosed in the health facility. We described the number and percentage of TB patients by characteristics such as age group, gender, and type of TB. We conducted chi-square tests to assess the association of patient and health facility characteristics with under-reporting. Associations with a p-value < 0.2 were included in the multivariable logistic regression model. Age group and level of institution variables were expressed with dummy variables, while other variables were analyzed as categorical variables. Crude and adjusted odds ratios (OR) were calculated to assess odds of under-reporting; 95% confidence intervals of crude OR and adjusted OR, and p-value in multivariable logistic regression model were used to evaluate statistical significance of examined characteristics. As EPTB was not mandatorily required to be reported in IDRS, the preliminary results showed oversized OR value because of “complete separation error” influenced by variable “Type of TB”. We decided to remove it from IDRS model after confirming of unchanged directions of other variables.

To analyze timeliness and concordance of reporting, we compared the records sampled with corresponding records in health facilities. We defined delayed reporting and recording as the number and percentage of patients diagnosed with TB at the facility but not reported or recorded to IDRS or TBIMS within a day after diagnosis. All analyses were performed in SAS (SAS Institute Inc., Cary, NC, USA).

Results

In our study, we identified a total of 4698 TB patients (702 from primary health facilities, 1479 from secondary health facilities, and 2517 from tertiary health facilities), of which were 4327 PTB patients (3028 patients diagnosed clinically and 1299 patients confirmed in laboratory) and 371 pleurisy or other EPTB patients. Two thirds (n = 3179) of the patients had national ID recorded. The number of TB patients per county ranged from 320 to 1807. Of all the TB patients, 3658 (77.9%) patients were 15 to 64 years of age, 1000 (21.3%) patients were 65 years or older, and only 40 (0.9%) patients were under 15 years old (Table 1). There were 3127 (66.6%) males and 4117 (87.6%) residents. Most TB patients were selected from the outpatient clinic records (3419; 72.8%), 919 (19.6%) were identified from the in-patient records, and 360 (7.7%) were identified from the laboratory records.

Table 1
 Characteristics of diagnosed TB patients in six
 counties in 2016

	Diagnosed	
	patients	%
Total	4698	100
Age		
<=15	40	0.9
15-64	3658	77.9
>=65	1000	21.3
Sex		
Male	3127	66.6
Female	1571	33.4
Type of TB		
PTB-clinically diagnosed	3028	64.5
PTB-laboratory confirmed	1299	27.7
Pleurisy or other EPTP	371	7.9
Patient type		
Outpatient	3419	72.8
Inpatient	919	19.6
Lab	360	7.7
Level of health facility	702	14.9
<=1	1479	31.5
2	2517	53.6
3		
Residence		
Resident	4117	87.6
Non-resident	581	12.4
County		
Nanshan	819	17.4

	Diagnosed	
	patients	%
Liyang	379	8.1
Xingyang	441	9.4
Yilan	320	6.8
Lu	932	19.8
Simao	1807	38.5

After data matching, we found 505 (10.8%) patients diagnosed with TB were missing from IDRS and 1451 (30.9%) patients were missing from TBIMS (Table 2, Fig. 1). Compared with the other five counties, Simao county had the largest under-reporting to IDRS and TBIMS (n = 360, 19.9%; n = 919, 50.9%, respectively).

Table 2
The number and percentage of diagnosed TB patients missing from IDRS and TBIMS in six counties in 2016

County	Total	IDRS		TBIMS	
		Missing patients	Proportion (%)	Missing patients	Proportion (%)
Nanshan	819	50	6.1	283	34.6
Liyang	379	52	13.7	112	29.6
Xingyang	441	33	7.5	43	9.8
Yilan	320	6	1.9	7	2.2
Lu	932	4	0.4	87	9.3
Simao	1807	360	19.9	919	50.9
Total	4698	505	10.8	1451	30.9

The data source, health facility level, residence, and county were statistically significant factors associated with under-reporting to IDRS in the multivariable analysis (Table 3). The odds of under-reporting to IDRS for a non-resident is 2 times that of a resident. The odds of under-reporting to IDRS for outpatient data source is about 3 times that of the laboratory data source. The odds of under-reporting to IDRS for tertiary health facilities is about 13 times that of primary health facilities. The risk of under-reporting to IDRS to IDRS was greatest in Simao, Liyang, and Xingyang counties.

Table 3

Factors associated with under-reporting to IDRS among diagnosed TB patients in six counties in 2016

Variables	Total	Under-reporting		Pearson's chi-square p-value	Crude OR (95%CI)	Adjusted OR (95%CI)	P value
		N	%				
Total	4698	505	10.7				
Age in years							
< 15	40	9	22.5	0.04	2.5 (1.2–5.3)	1.5 (0.6–3.7)	0.4
15–64	3658	383	10.5		ref	ref	
>=65	1000	113	11.3		1.1 (0.9–1.4)	1.3 (1.0–1.6)	0.09
Sex							
Male	3127	301	9.6	0.0005	ref	ref	
Female	1571	204	13.0		1.4 (1.2–1.7)	1.1 (0.9–1.4)	0.4
Data source							
Outpatient	3419	359	10.5	0.06	1.3 (0.9–1.9)	2.7 (1.8–4.1)	< 0.001
Inpatient	919	116	12.6		1.6 (1.0–2.4)	0.7 (0.4–1.1)	0.08
Lab	360	30	8.3		ref	ref	
Level of health facility							
<=1	702	14	2.0	< .0001	ref		
2	1479	110	7.4		4.0 (2.3–6.9)	1.7 (0.8–3.6)	0.1
3	2517	381	15.1		8.8 (5.1–15.1)	12.9 (6.4–25.8)	< .0001
Residence							
Resident	4117	465	11.3	0.0013	ref	ref	
Non-resident	581	40	6.9		0.6 (0.4–0.8)	2.2 (1.2–4.0)	0.009
County							

Variables	Total	Under-reporting		Pearson's chi-square p-value	Crude OR (95%CI)	Adjusted OR (95%CI)	P value
		N	%				
Nanshan	819	50	6.1	< .0001	ref	ref	
Liyang	379	52	13.7		2.5 (1.6–3.7)	5.7 (2.8–11.6)	< .0001
Xingyang	441	33	7.5		1.2 (0.8–2.0)	4.5 (2.1–9.8)	0.0002
Yilan	320	6	1.9		0.3 (0.1–0.7)	1.3 (0.4–3.8)	0.6
Lu	932	4	0.4		0.1 (0.0–0.2)	0.0 (0.0–0.1)	< .0001
Simao	1807	360	19.9		3.8 (2.8–5.2)	4.1 (2.2–7.6)	< .0001

All variables except gender were statistically significant factors associated with under-reporting to TBIMS in the multivariable logistic regression (Table 4). The odds of under-reporting to TBIMS for patients over 65 years of age is almost 2 times that of patients aged 15–64. The odds of under-reporting to TBIMS for clinically diagnosed PTB was about 3 times that of laboratory confirmed PTB, while the odds of under-reporting for TB pleurisy or other EPTB is 9 times that of laboratory confirmed PTB. The odds of under-reporting to TBIMS for diagnosis in tertiary health facilities is 10 times that of diagnosis in primary health facilities. The odds of under-reporting to TBIMS for non-residents is 19 times that of residents. The risk of under-reporting to TBIMS is highest in Simao, Nanshan, and Liyang counties. The risk of under-reporting to TBIMS was lower with factors such as outpatients, inpatients and diagnosis in Xingyang, Yilan, or Lu counties.

Table 4

Factors associated with under-reporting to TBIMS among diagnosed TB patients in six counties in 2016

Variables	Total	Under-reporting		Pearson's chi-square p-value	Crude OR (95%CI)	Adjusted OR (95%CI)	P value
		N	%				
Total	4698	1451	30.9				
Age in years							
< 15	40	16	40.0	0.0005	1.6 (0.8-3.0)	1.0 (0.5-2.0)	0.9
15-64	3658	1079	29.5		ref	ref	
>=65	1000	356	35.6		1.3 (1.1-1.5)	1.7 (1.4-2.0)	< .0001
Sex							
Male	3127	909	29.07	0.0001	ref	ref	
Female	1571	542	34.50		1.29 (1.13-1.46)	1.04 (0.89-1.21)	0.6
Data source							
Outpatient	3419	807	23.60	< .0001	0.54 (0.43-0.68)	0.30 (0.21-0.43)	< .0001
Inpatient	919	513	55.82		2.21 (1.72-2.84)	0.54 (0.37-0.79)	0.002
Lab	360	131	36.39		ref	ref	
Type of TB							
PTB-clinically diagnosed	3028	984	32.50	< .0001	1.98 (1.69-2.32)	2.54 (1.94-3.32)	< .0001
PTB-laboratory confirmed	1299	254	19.55		ref	ref	
Pleurisy or other EPTP	371	213	57.41		5.55 (4.33-7.10)	9.27 (6.50-13.23)	< .0001
Level of medical institution							
<=1	702	14	1.99	< .0001	ref	ref	

Variables	Total	Under-reporting		Pearson's chi-square p-value	Crude OR (95%CI)	Adjusted OR (95%CI)	P value
		N	%				
2	1479	110	7.44		3.95 (2.25–6.94)	1.77 (0.86–3.65)	0.1
3	2517	381	15.14		8.77 (5.11–15.05)	10.01 (4.99–20.11)	< .0001
Residence							
Local	4117	1147	27.86	< .0001	ref	ref	
Non-resident	581	304	52.32		2.84 (2.38–3.39)	18.80 (13.77–25.67)	< .0001
County							
Nanshan	819	283	34.55	< .0001	ref	ref	
Liyang	379	112	29.55		0.79 (0.61–1.03)	1.56 (1.10–2.20)	0.01
Xingyang	441	43	9.75		0.20 (0.14–0.29)	0.47 (0.31–0.70)	0.0003
Yilan	320	7	2.19		0.04 (0.02–0.09)	0.31 (0.14–0.69)	0.004
Lu	932	87	9.33		0.20 (0.15–0.25)	0.11 (0.08–0.16)	< .0001
Simao	1807	919	50.86		1.96 (1.65–2.33)	5.00 (3.80–6.57)	< .0001

In our assessment of concordance and timeliness of reporting to IDRS and TBIMS, 171 records in IDRS and 170 records in TBIMS were included. In IDRS, 18 (10.6%) records of home address and 14 (8.2%) records of diagnosis date were discordant with those in medical records (Table 5). In TBIMS, among demographic variables, the discordant entry of home address was the lowest (12, 7.1%); of all clinical variables, variables about date, including diagnosis date (5, 2.9%), date of follow-up examination at the end 2nd months (6, 3.9%) and date of end course examination (22, 14.0%) were the most discordant with medical records. A total of 21 patients (12.3%) were not reported to IDRS and 11 patients (6.5%) were not reported to TBIMS within a day after reporting TB diagnosis.

Table 5
Concordance of key variables for diagnosed TB patients between facility records and TB surveillance systems (by counties)

Key Variables	Medical records and IDRS		Medical records and TBIMS	
	Patients reviewed in IDRS	Inconsistent with medical records	Patients reviewed in TBIMS	Inconsistent with medical records
Total records				
National ID number	161	3 (1.9%)	148	3 (2.0%)
Patient name	171	1 (0.6%)	170	0 (0%)
Address	169	18 (10.7%)	170	12 (7.1%)
Smear status	-	-	170	4 (2.4%)
DST status	-	-	17	0 (0%)
Diagnosis	-	-	170	1 (0.6%)
Treatment outcome	-	-	168	1 (0.6%)
Diagnosis date	171	14 (8.2%)	170	5 (2.9%)
Registration	-	-	170	1 (0.6%)
Date of Follow-up examination at the end 2nd month	-	-	152	6 (3.9%)
Date of End course examination	-	-	157	22 (14.0%)

Discussion

Our results show that 10.7% and 30.9% of TB patients in the six participating counties were under-reported to IDRS and not recorded for treatment in TBIMS, respectively. The discrepancy in the under-reporting rate between the two systems is mainly because the systems play different roles in the field of public health. Patients diagnosed with PTB in all health facilities should be reported to IDRS, while only patients referred and verified in TB designated health facilities are recorded in TBIMS. There is value in both vertical (TBIMS) and integrated (IDSR) surveillance systems for capturing data, however there are potential implications for double reporting or discordance of variables when both surveillance systems are utilized to capture information for the same disease. For example, patients who were misdiagnosed in non-designated health facilities and those who were not traced by TB designated health facilities could be reported to IDRS, but not recorded in TBIMS. This could account for the difference of the under-reporting rate between the two surveillance systems. The under-reporting rate in both IDRS and TBIMS suggests China's TB surveillance systems may still miss some TB patients. More than one fourth of

under-reporting rate to TBIMS reminds that there may exist greater risks of under-reporting in certain settings than WHO estimated national level (13%) [23]. The under-reported patients, who may not have received proper treatment and support by NTP management, may continue to contribute to TB transmission within their communities.

Our findings are similar to some studies conducted in other countries in which the under-reporting rate of TB ranged from 6–68% [14, 16, 17, 24–30]. Fatima *et al.* estimated that almost 68% of persons with TB were not notified to the NTP in Pakistan, many because a large private sector did not report to the NTP [28]. A study conducted in the Republic of Korea estimated 6% of persons with TB were not reported to the national surveillance system [29]. Our current study shows that the under-reporting rate in TBIMS of the six counties is 30.9%, while a previous study conducted in other areas in China reported the under-reporting rate was 19.3%. The difference between the results of the two studies was mainly because the previous study did not include EPTB except TB pleurisy [12].

Though type of TB was removed from IDRS model, type of TB was found to be significant for under-reporting to TBIMS. Compared with patients with laboratory-confirmed and clinically-diagnosed PTB, patients with TB pleurisy or other EPTB were significantly more likely to be underreported. This under-reporting associated with type of TB was also described in other studies [8, 12, 14, 31, 32]. Additionally, the reporting requirements of TB pleurisy and other EPTB vary by province. In most provinces, medical institutions are not required to report patients with TB pleurisy. Mandatory reporting of other EPTBs is also not required in every province. This is a major challenge and issue; non-standard definitions and reporting requirements severely limits the ability to make comparisons and follow trends.

It is notable from our analysis that the odds of under-reporting are significantly higher in tertiary health facilities compared to primary health facilities. In China, tertiary health facilities are all general hospitals with high medical level, have more than 501 beds, and large numbers of patients being referred to or seeking diagnosis and treatment in these hospitals. Consequently, physicians who are responsible for reporting PTB patients to surveillance systems in tertiary health facilities may spend more time seeing patients than reporting to surveillance systems. Our finding is supported by a study conducted in Kenya, where larger facilities and heavy workload were associated with under-reporting [13]. However, other studies indicated that diagnosis in general hospitals contributes to the notification of TB patients [29, 33]. Our findings emphasize the importance of increasing human resource capacity for data collection, management and reporting of TB patients or shifting these tasks to nurses or non-clinical staff in tertiary health facilities.

Our study revealed substantial under-reporting both to IDRS and TBIMS among non-residents, while the proportion underreported to TBIMS is much higher. This may be due to economic factors. Most non-resident TB patients are more likely to have low income and lack medical insurance [34]. Non-residents with medical insurance generally received less proportion of reimbursement outside of the location to which they are a resident, which may result in refusal of anti-TB treatment. In addition, many non-resident TB patients do not have regular work and a permanent place of residence, which may lead to difficulty in

linking the patient to TB services. To strengthen the surveillance of non-resident TB patients, it is necessary to focus on reporting of non-residents and ensure funding devoted to supporting and following-up of low income and non-resident patients. Though information on which facilities had paper records was not collected, facilities that are smaller and located in lower income areas are more likely (anecdotally) to be paper based, which could potentially contribute to decreased data quality and reporting.

In our study, under-reporting to TBIMS was also associated with old age. Patients over 65 years old were more likely to be under-reported compared to 15–64 years old. This may be related to a higher rate of comorbidity in patients aged 65 or older, which could necessitate treatment in non-TB-designated health facilities. This is consistent with the bivariate analysis in a study conducted in Spain [14]. We also found that the risk of under-diagnosis was high among patients under 15, which is corroborated by various studies indicated younger age as a risk factor of under-reporting [8, 12, 33]. However, Kang et al. found that age did not significantly affect TB reporting [29]. The number of TB patients under 15 years old influences study results. In 2016, WHO estimated about 11% of TB patients in China were under 15 years old [23]. However, in our study, only 0.9% of TB patients identified were under 15 years old. This may be related to the difference in where children seek healthcare services and the facilities sampled in this study. Most pediatric TB patients are treated in children's hospitals and therefore reported by regional or national referral hospitals located in big cities. However, none of the hospitals in our selected six counties included this type of hospital. Further studies including children's hospitals are needed to understand the association between young age and under-reporting of TB patients.

Concordance between systems and reporting of TB patients has been researched in other studies [30, 33, 35–37]. Salyer et al. reported inconsistent smear status of TB patients between records in health facilities and national surveillance database [30]. Podewils et al. reported the poor agreement of HIV status among TB patients [35]. In our study, address and dates in IDRS and TBIMS were the variables most discordant with medical records. Podewils et al. showed similar findings in their study [35]. This may be due to multiple reasons. Physicians may not have time for adequate epidemiological investigation due to high workload burden in both general hospitals and designated facilities. And patients may also have stigma pressure to not give their private information [38]. Address is important for tracing patients and facilitating full course follow-up, thus important to include in reporting and recording as an essential variable. Timeliness of reporting was evaluated in multiple studies by different variables, making comparisons difficult. Some studies reported the proportion of patients with delayed reporting (> 7 days) varied from 18.2–25.7% [29, 33]. Johnson et al. reported 11% of TB patients were not reported to electronic communicable disease surveillance system in one business day [39]. Some studies reported average duration of delay in reporting TB patients (ranged from 4 days to 3 months) [40–42]. There was greater under-reporting to TBIMS compared to IDRS. However, when patients were reported, there was greater delay to reporting in IDRS compared to TBIMS (12.3% vs. 6.5%).

Our study has several limitations. First, we used purposive sampling to select six counties, for ease of introducing and implementing matching software, however this made our findings not representative of

other areas in China. Second, in our study, we focused on healthcare facilities that had capacity to perform chest x-rays (CXR) and had diagnosed at least one TB patient during the project period, which means patients seeking healthcare in the facilities not meeting the criteria were excluded, thus limiting the inclusion of EPTB. It is crucial to ensure that these patients were diagnosed and treated properly. Therefore, under-reporting of under-diagnosed patients deserves further study. Third, children's hospitals were not included in our study, which could bias our results of under-reporting among children.

Conclusions

TB patients were under-reported to both China's national infectious reporting system, IDRS, and TB specific management system, TBIMS. It is important to improve the reporting and recording of TB patients. Local TB programs may focus on reporting and improvement activities in order to support high-patient load hospitals, non-resident patients, and patients with TB pleurisy or EPTB. Human resource capacity for data collection and management could be enhanced and accuracy of data entry could be reinforced to improve national surveillance systems and TB prevention, diagnosis and treatment services.

Abbreviations

TB

Tuberculosis; WHO–World Health Organization; PTB–pulmonary TB; IDRS–Infectious Disease Reporting System; TBIMS–TB information management system; CDC–Center for Disease Control and Prevention; NTP–national TB program; CXR–chest x-rays; EPTB–extra-pulmonary TB; OR–odds ratios

Declarations

Ethics approval and consent to participate: Permission for the study was sought from the National Center for Tuberculosis Control and Prevention, China Center for Diseases Control and Prevention. As this study involved analysis of collected secondary data, waiver of informed consent was sought and approved. This project was also reviewed in accordance with the US Centers for Disease Control and Prevention human research protection procedures and was determined to be nonresearch, program evaluation.

Consent for publication: Not applicable.

Availability of data and materials: All data analyzed during this study may be made available upon request.

Competing interests: The authors declare that they have no competing interests.

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Authors' contributions: LI Tao, YANG Lijia and Sarah E. SMITH were involved in conception and study design. All authors performed in material preparation, data collection and analysis. The first draft of the manuscript was written by LI Tao and YANG Lijia and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript. LI Tao and YANG Lijia contributed equally as first authors, DU Xin and ZHANG Hui contributed equally as corresponding authors.

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Figures

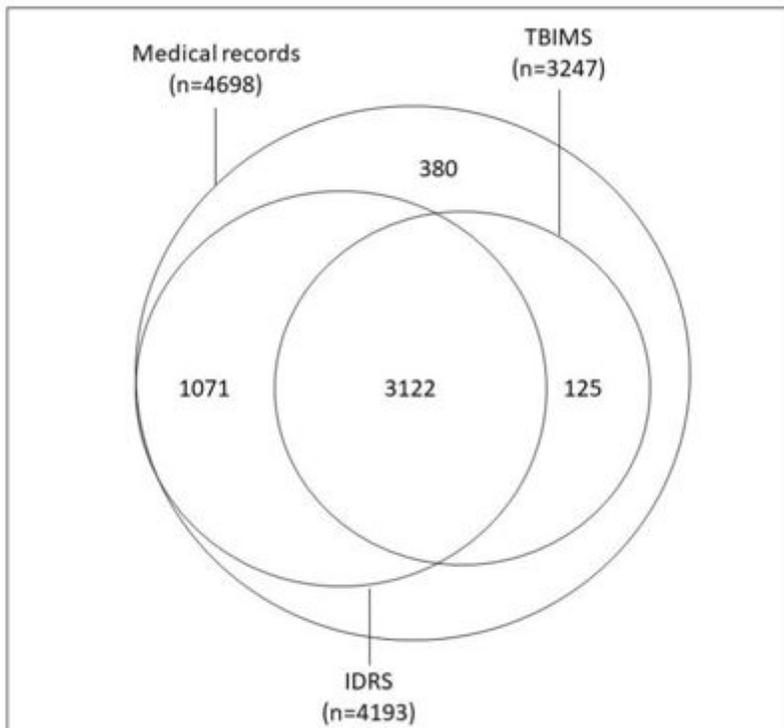


Figure 1

The distribution of TB patients from medical records, IDRS and TBIMS in the six counties in 2016