Evaluation of China's Health Information System from the Perspective of TB Underreporting

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Thesis submitted in partial fulfillment of
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ABSTRACT

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Abstract

Background: As the country with the third largest TB epidemic, China has a major responsibility to control the prevalence of TB. A standardized health information system is required to monitor the TB epidemic and the performance of the national TB control program. However, the capacity of the health information systems to detect infectious diseases in China need further enhancement. It is widely perceived that the problems of underreporting exist in China's infectious diseases reporting systems, but little is known about the extent of underreporting as no rigorous empirical research has been conducted. Therefore, the aim of this study is to empirically analyze the issues of TB underreporting, identify weaknesses in the health information systems, and make suggestions for improvement.

Methods: This study utilized a mixed method approach to evaluate China's health information system by identifying the problems of TB underreporting in Zhenjiang, China. Using the data of 2,136 TB cases from the hospital information and TB information management systems, we analyzed the extent to which TB cases are underreported through chi-square test and multivariable logit regression. We subsequently conducted policy document review and evaluated the transcripts from 19 interviews to investigate the key factors causing TB underreporting.

Results: Our study indicates that approximately 29.3% of TB cases in Zhenjiang city are unreported. The unreported rates of outpatients are higher than the unreported rates of inpatients except the cases in Jurong Hospital. Generally, inpatients who did not reside in their jurisdiction had higher unreported rates than those inpatients living in their jurisdiction for a long period. Moreover, patients without a personal ID card had

higher unreported rates than those with ID cards. Additionally, underreporting among inpatient was significantly higher than non-in-hospital referrals.

Through in-depth interviews, we discovered the potential factors causing TB underreporting are poor system design and some human resource related issues. More specifically, for the former one, hospitals use different electronic systems to record patient information, which often causes confusion when TB reporters search the records for a TB diagnosis. The lack of a self-check function reduces the accuracy of data reported. Moreover, the health information systems lack interoperability among different health facilities, which slows the transfer of information and creates room for mistakes. For the latter one, clinicians and hospital statisticians reflected that the heavy workload and low financial incentives made them reluctant to report TB cases timely and accurately. What's more, the absence of specific and unified standards for health workers from different cities, counties, and facilities with which to comply is also evident. The limited requirements of government intensified the chaos generated during the establishment of information systems at the local level. The political context of inadequate incentive policies and low degree of supervision aggravated the quality of implementation.

Conclusion: We found that the lack of self-check function, lack of data standardization, lack of system interoperability and accessibility, heavy workload for healthcare workers, lack of awareness of reporting, lack of financial incentives, absence of surveillance, and lack of guidance and role clarity are associated with TB underreporting. Our study reveals the important role of system design, government leadership, and qualified, dedicated, and well- paid health personnel play in ensuring the accuracy of data.

Contents

List of Tables

List of Figures

1. Introduction

According to a World Health Organization (WHO) report, tuberculosis (TB) is one of the top 10 causes of death worldwide, and it is responsible for more deaths than HIV and malaria. In 2016, 10.4 million people were victims of TB, and approximately 480,000 of them developed multidrug-resistant TB (MDR-TB) [1]. To end the global TB epidemic, WHO put forth the "End TB Strategy." As a significant part of the sustainable development goals, the "End TB Strategy" set a target of 80% reduction in the TB incidence rate and a 90% decrease in the number of TB deaths until 2030 compared to 2015 [2]. Government stewardship and accountability with monitoring and evaluation are required to achieve these goals.

As the country with the third largest TB epidemic, China has a major responsibility to control the prevalence of TB. After the nationwide scale-up of the WHO-recommended DOTS (directly observed treatment, short-course) strategy, China has made an impressive improvement in reducing smear-positive TB cases [3]. At the beginning, the CDC was the leading institution for preventing and treating TB [4,5,6]. General hospitals adopted a passive role, and they were usually not required to treat TB patients, except MDR-TB cases. In other words, CDC was responsible for all the services relating to TB, including treatment, management, and public healthcare [5,6]. However, to strengthen the DOTS-based TB treatment network, solve the MDR-TB problems caused by inappropriate treatment, and reduce the missing cases that occurred during the referral process, China had created a new model called the "TB-designated hospital model." All the services relating to TB diagnosis and treatment were shifted from CDC to designated hospitals in some eastern and western provinces [5]. The local

TB dispensaries and CDC are merely in charge of TB public health, including health education, training, and supervision. Tuberculosis patients are now required to be registered and referred to the TB-designated hospitals for free essential TB care (covering X-ray, smear test, and first-line anti-TB medicine), and the public health staff in TB-designated hospitals are responsible for promptly reporting the case to CDC [5,6]. During this process, a standardized health information system is required for monitoring the TB epidemic and the performance of the national TB control program.

The lack of effective health information systems hampers the accuracy of estimating the actual TB incidence rate, which represents a public health concern [7]. As a result, the reinforcement of data reporting systems to improve the measurement of the actual disease burden and the effect of interventions has gained global attention [8]. For example, India, which has the highest number of TB cases, conducted a pilot study to determine the effectiveness of the mobile interface in TB notification voice-based system for the private health institutes' reporting of TB cases [9]. Indonesia, which has the second largest TB epidemic, considering its vast territory, prioritized the strategy of creating a seamless care network to find missing cases [10]. Furthermore, WHO is currently providing support for countries to strengthen routine reporting systems, increase data accuracy, and help to undertake rigorous surveys to monitor the progress of TB control [11]. However, whether the efforts to improve health information systems can address the problems of data underreporting and increase data accuracy is doubtful [9-11].

China has drastically improved its TB estimates since implementing a nation-scale web-based system of mandatory TB reporting in 2005 [12]. Its more accurate estimates of the TB burden are helpful not only in guiding national policy-making but

also understanding the global trends of TB incidence. China's experience can function as a valuable reference for worldwide surveillance and response to threats from TB. Therefore, this thesis assesses the extent of the underreporting of TB cases in China, and factors associated with the underreporting, thereby improving the quality of TB case reporting and surveillance.

1.1 Background

In 1991, China introduced the National TB Control Program and adopted the WHO-recommended TB control strategy, DOTS [13]. The national program gained substantial success in detecting and controlling TB. The cure rate of TB increased to 95% for new cases within two years of adopting DOTS [14]. With the expansion of the DOTS strategy, China tentatively established vertical monitoring and reporting systems with provincial and township supervision [15]. Despite these achievements, the detection rate for new smear-positive cases was only 54% in 1998, which might be due to the inadequate referral of TB suspects and confirmed cases from the hospital system to the TB dispensary (CDC) system [15]. Therefore, a new model called the "designated-hospital model" has been implemented in the eastern part of China since 2003 [16]. Tuberculosis treatment services have transformed from TB dispensaries or CDC to designated hospitals. These selected general hospitals established TB clinics to provide standard TB care services and performed patient management [17-19]. In this case, the responsibility of TB prevention and control has been divided. The designated hospitals are responsible for TB diagnosis, treatment, and reporting TB cases to the local CDC, whereas the local CDC is mainly in charge of TB public healthcare, including health education, training, supervision, and reporting the TB epidemic to upper-level CDC [20]. Other non-designated hospitals have no authorization to

diagnose and treat TB patients, and they must refer suspects to the designated hospitals [20]. Empirical research indicated that this designated-hospital model is the better policy option for TB prevention and control in China [17].

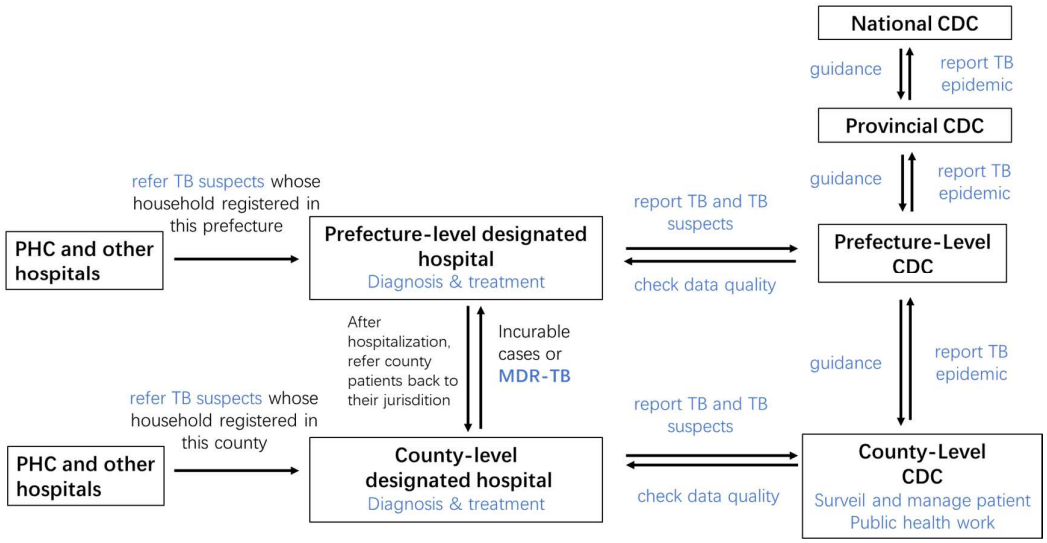

Figure 1: Designated-hospital Model

The Ministry of Health of China (now called National Health Commission) has issued standard specifications of TB diagnosis, treatment, and reporting. The suspected TB patient is required to undergo 3 times' acid-fast bacilli test of sputum smear, Mycobacterium test of sputum smear, and Chest X-ray. When two pieces of acid-fast bacilli in sputum sample or one acid-fast bacilli in sputum plus one Mycobacterium sputum sample show a positive result, the patient is confirmed to have TB, and this case should be promptly reported to CDC [15]. After the confirmation of TB, new patients are started on a course of directly observed treatment and instructed to take sputum tests at the end of the second, fifth, and sixth months [15]. Moreover, CDC personnel or local TB dispensary staff surveil patients at a regular frequency depending on the drug regimen. All the therapeutic outcomes and test results need to be regularly uploaded to

CDC until the treatments are completed [15].

During the entire diagnosis and treatment process, the surveillance and management of TB in China primarily relies on three health information systems: hospital information system (HIS), infectious disease reporting information management system (IDRIMS), and TB information management system (TBIMS). Hospital clinicians record patients' information into HIS. If a patient is identified as a TB suspect, he/she should be referred to designated hospital and his/her information is required to be correctly reported to IDRIMS within 24 hours. Once the patient is confirmed to have TB, the designated hospital should update his/her detailed information to TBIMS within 48 hours, including basic personal information, diagnostic results, treatment regimen, and referral [21]. The data uploaded to IDRIMS and TBIMS allow the CDC personnel to supervise and manage TB patients.

1.2 Overview of China's TB-related Health Information System

Infectious Disease Reporting Information Management System

The Chinese Government established a routine reporting system for selected infectious diseases in the 1950s [22]. However, the outbreak of SARS in 2003 made the Chinese government realize the problems in the old disease surveillance system, which could not obtain timely and accurate information in terms of the extent and distribution of the epidemic [22]. In the past, local hospitals and clinics mainly used paper-form reporting sheets to report cases to local CDCs, and local CDCs periodically submitted report summaries to the upper-level CDCs, usually once a month [22]. Such delayed and incomplete reports from hospitals to the public health system exacerbated the difficulty of controlling the infectious disease epidemic [23]. To solve the problems

in the disease surveillance system, the Chinese government established a web-based real-time reporting system called "infectious disease reporting information management system" (IDRIMS).

The infectious disease reporting information management system provides a common platform that enabled all the healthcare institutes across the country, including general hospitals, specialized hospitals, and township and village clinics and private clinics, to report real-time case information of 37 types of notifiable infectious diseases via the Internet within 24 hours after the confirmation of the patients' diagnosis [22, 24]. Nearly all the health institutes can access IDRIMS and directly upload patients or suspects' information; thus, CDCs at all levels are able to identify the characteristics (e.g., location, age, and gender) of the disease outbreak and appropriately and immediately respond to the disease epidemic, which has largely improved the efficiency and effectiveness of controlling infectious diseases in China over the past decades.

TB Information Management System

In 2005, encouraged by the success of IDRIMS, the Chinese government developed a new web-based system called the "TB information management system" (TBIMS) as an additional part of IDRIMS to collect more detailed real-time TB data [19]. The TBIMS data are based on the IDRIMS data. Once a patient is verified to have TB, his/her presumptive TB information in the IDRIMS dataset can be transferred to the TBIMS dataset as a confirmed case. Authorized public health staff can subsequently use the data reported to TBIMS for tracing and managing TB patients.

The TBIMS covers multidrug-resistant TB (MDR-TB) and HIV-associated TB

[25]. It also includes more details than IDRIMS, such as treatment regimen, testing results, and some tracing records [21]. As the TB patients usually need long-term treatment, clinicians and public health staff have previously used paper sheets to document the patients' condition and treatment records every month. By contrast, public health staff nowadays can access TBIMS to trace information in a timely manner [21,25]. Research revealed that in contrast to paper recording, TBIMS usage has significantly reduced reporting errors [25,26].

Hospital Information System

The hospital information system (HIS) in China has progressed in these decades. In 2007, 80% of prefecture and above-level hospitals have constructed HIS [27]. This system electronically stores patients' general information, including personal ID, demographic information, diagnosis results, and treatment regimen and expenditure, which can largely improve the efficiency and quality of healthcare work [28].

However, the development of HIS in China is unbalanced and lacking in standardization [29]. Hospital information systems vary among hospitals, and they are usually neither integrated nor interoperable [30]. Even within one hospital, the hospital may have other information systems developed by different IT firms, causing difficulty in data sharing [30] and thus limiting the hospitals' patient administration capability.

Nearly all the healthcare institutes are equipped with IDRIMS; hence, a health institute simultaneously has at least two different information systems: one is HIS for patient administration and the other is IDRMIS for reporting infectious diseases. Unfortunately, these two systems do not automatically share information. Health

personnel have to manually record patients' information twice—once into HIS and another time into IDRMIS, which largely increases the workload and unnecessarily burdens the staff responsible for health information management. From 2011, to remind clinicians or other health staff to promptly report infectious diseases to IDRMIS, a module called "infectious disease report card" was added to HIS. Clinicians who forget to fill in the infectious disease report card cannot consequently make the next-step prescription [25].

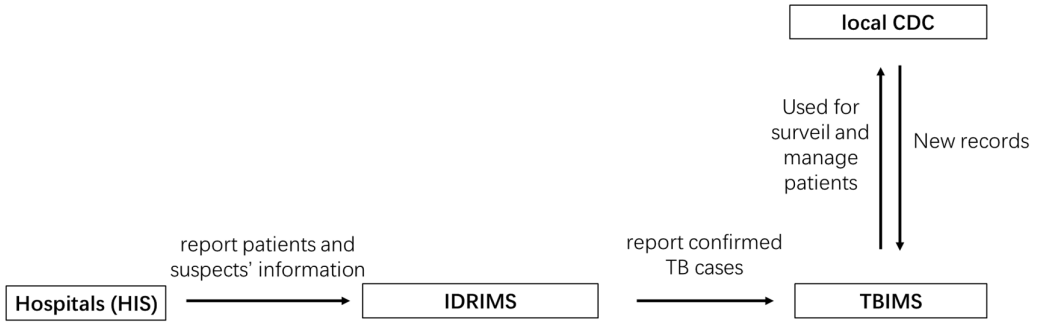

Figure 2: Relationship between HIS, IDRIMS, and TBIMS

1.3 Problems Relating to Reporting Infectious Diseases

The underreporting rate of infectious diseases is supposed to be chiefly reduced with the development of health information technology. However, the underreporting of infectious diseases is still a common problem worldwide.

Wubuli et al. noted that in Xinjiang Province, TB cases might be missed by routine notification systems because private providers who lacked authorization to diagnose TB still performed diagnoses, and they usually did not report TB cases to the local CDC [31]. Chen et al. indicated that the underreporting of brucellosis in Shanxi Province of China was serious because it was influenced by the key steps in surveillance, including reporting methods and the underreporting, completeness, and

accuracy of data over the years [32]. Hanqing He et al. discussed the potential underreporting problems of HBV in Zhejiang Province. They mentioned that only 17.85% of HBV cases in IDRIMS registered with personal ID numbers, which increased the possibility of underreporting. Moreover, as the Chinese name is easily confusable and the lunar birthday is commonly used, ensuring the quality of data by checking names and birthdays became difficult for health personnel [33]. Guo et al. stated that the reporting rate of infectious diseases in China, estimated by the national CDC, was 91.87% in 2013, but this figure was over-estimated [34]. Peng also mentioned the absence of evidence to prove that the underreporting rate was significantly lower than the rate before the extensive use of health information systems [35]. Although the Chinese government has issued documents to strictly investigate the underreporting problems, no scientific studies have specifically identified the reasons causing data underreporting.

Other developing countries have encountered similar problems. Cowling et al. described the TB data in India as unreliable because India neither maintained a vital monitoring system nor conducted a national TB prevalence survey [9]. Only 45% of the new smear-positive TB cases were reported by private providers due to poor regulation [9]. In Indonesia, although a case-based electronic data capture system reached full coverage in 2015, merely 28% of all the estimated TB cases were notified by the public sectors [10]. Furthermore, as the electronic reporting system was primarily used by the public sector, the TB reporting rate was 65% lower than the actual number of TB patients in the private sector [10].

Many developed countries are also incapable of avoiding the problem of underreporting infectious diseases. Melosini et al. revealed that the rate of TB

underreporting in Italy was up to 27% in patients with a confirmed TB diagnosis, which was primarily affected by the absence of revision of reported TB cases [36]. Mellou et al. estimated that the underreporting rates of salmonellosis and shigellosis cases in Greece were 47.7% and 52.0%, respectively, which was unacceptably high. They also concluded that the lack of personnel and technical support, the long or complicated reporting forms, and the inadequacy of electronic reporting systems contributed to the high underreporting rate [37-39].

The purpose of health surveillance systems is to provide timely, accurate, and complete evidence for health policy-makers and managers to respond to and address public health concerns. Ensuring the completeness and accuracy of reporting infectious diseases is an essential element of achieving the goal [40,41]. Although WHO and each country increased the investment in strengthening the disease reporting system, the problem of underreporting and the related limitation in health information systems hindered the stakeholders around the world from appropriately performing an epidemiological estimation.

1.4 Rationale and Study Aim

Indeed, China's health information systems can easily miss reporting cases in areas that lack adequately trained health workers, effective communication and information sharing between hospitals and CDC, and tangible benefits for health personnel [21,22]. The problems of underreporting are believed to exist in China's infectious diseases reporting systems, but little is known about the extent of underreporting due to the lack of rigorous empirical research [44,45]. Therefore, the aim of this thesis is to empirically analyze the issues of TB underreporting, explore the

reliability of health information systems that are established to track TB in China, identify weaknesses in the system, and propose suggestions for improvement.

The specific objective of this study is to identify the issues of TB underreporting and comprehensively explore the factors causing these issues. Thereafter, we can determine the seriousness of data underreporting and consequently suggest some pertinent measures to the government to solve the problem. Given the lack of research that rigorously reveals these problems in China, this study seeks to fill the evidence gap to enhance the government's awareness of the seriousness of TB underreporting and underscore the necessity of improving the health information system.

Objective 1: Examine the extent to which the TB cases are underreported

Objective 2: Investigate the key factors causing TB underreporting

Objective 3: Develop policy recommendations to improve China's health information systems

2. Methods

2.1 Study Design

This study used a mixed methods approach to identify the problems of TB underreporting and investigate the potential factors causing these problems. A sequential explanatory design was applied to explain and interpret the quantitative results by policy document review and in-depth interview.

Through the quantitative phase, we examined the data underreporting problems and calculated the TB underreporting rate by linking the data records, such as the patients' ID number and characteristic variables from the HIS and TBIMS databases.

Then a policy document review was conducted to clarify the existing standards and the detailed procedure for TB reporting. The last phase consisted of in-depth interviews with health managers and workers related to TB treatment and management from the study hospitals and CDC to further explore the factors associated with data underreporting and the challenges in data management.

2.2 Setting

Zhenjiang, a prefectural city consisting of several county-level cities, was selected as the study site. Located in the eastern area, Zhenjiang represents the developed region in China, where the coverage rate of TB DOTS strategy has reached 100% in 2005 [40]. Moreover, as one of the pilot cities of the Gates Foundation TB Project in China–Phase II, Zhenjiang has comprehensively established the designated-hospital model and built relatively integrated health information systems, including HIS, IDRIMS, and TBIMS [40]. These well-functioning systems could support our research in terms of basic data collection and analysis. Therefore, we selected three county-level cities in Zhejiang, namely Yangzhong (YZ), Danyang (DY), and Jurong (JR), with retrogressive GDP per capita of US$23,000, US$18,700, and US$12,300, respectively.

In each county, we visited a designated hospital and a local CDC. Table 1 outlines the healthcare institutions studied in this project.

Table 1: Healthcare institutions studied in this project

	Location	**Hospital**	**CDC**
County-level	Yangzhong (YZ)	Yangzhong People's Hospital	Yangzhong CDC

County-level	Danyang (DY)	Danyang People's Hospital	Danyang CDC
County-level	Jurong (JR)	Jurong People's Hospital	Jurong CDC
Prefecture-level	Zhenjiang		Zhenjiang CDC

2.3 Data Collection

2.3.1 Quantitative data

We planned to gather the information of TB patients diagnosed in January 2015–December 2017 from two systems: HIS and TBIMS. The targeted population comprised the confirmed TB patients who were diagnosed and treated in YZ, DY, and JR during the same period. However, due to some practical problems, we only collected the outpatient and inpatient information from DY People's Hospital, the inpatient information from YZ People's Hospital, and the inpatient information from JR People's Hospital. Data were gathered from two systems, namely the HIS and TBIMS databases. Table 2 summarizes the sources of data.

Table 2: Data sources

System	Data
HIS in DY People's Hospital	Outpatient and inpatient TB records
HIS in YZ People's Hospital	Inpatient TB records
HIS in JR People's	Inpatient TB records

Hospital	
TBIMS	Reported TB records

2.3.1.1 Inclusion criteria

HIS:

From January 1, 2015 to December 31, 2017, the patients' diagnosis result includes the term "tuberculosis," or the sputum smear and sputum culture result was "positive," were included. The excluded cases were suspected TB; extra-pulmonary TB; old TB; the diagnosis results marked with "?", "to be checked," or "to be excluded"; and duplicate records.

TBIMS:

From TBIMS, all the TB patients' information reported by DY, YZ, and JR People's Hospital from September 1, 2014 to February 1, 2018 were extracted.

2.3.1.2 Variables

From the Outpatient service records:

We gathered the following information from the Outpatient service records: name, gender, date of birth, age, ID card number, registered permanent residence, current address, diagnosis time, and diagnosis result.

From the Inpatient records:

We collected the following information from the inpatient records: name, gender, date of birth, age, ID card number, registered permanent residence, current

address, admission time, discharge time, admission department, discharge department, and diagnosis result.

2.3.2 Qualitative data

2.3.2.1 Policy document review

We gathered policy documents related to infectious disease reporting from government ministries and departments in China. The documents include:

- Law of the People's Republic of China on the Prevention and Treatment of Infectious Diseases. (Ministry of Health of the People's Republic of China)
- Standards and Procedure for Reporting TB (The Chinese Center for Disease Control and Prevention)
- Operation Manual of Tuberculosis information management system (The Chinese Center for Disease Control and Prevention)

2.3.2.2 In-depth Interview

Key informant interviews with 19 research participants were conducted. The key informants directly associated with the process of TB reporting and TB treatment were selected through referral with assistance from local collaborators. The local collaborators helped to identify the potential key informants with sufficient working experiences and knowledge in TB treatment and reporting. The participants consisted of the leaders who were responsible for TB prevention in hospital, the clinicians who directly treated TB patients, TB statisticians in hospital, leaders in local CDC, and TB statisticians in the local CDC. Table 3 provides the details of the research participants.

Table 3: Research participants

Site	Institute	Participants	Number
Danyang	Hospital	leader	1
		clinician	2
		statistician	2
	CDC	leader	1
		statistician	1
Yangzhong	Hospital	leader	1
		clinician	2
		statistician	1
	CDC	leader	1
		statistician	1
Jurong	Hospital	leader	0
		clinician	1
		statistician	1
	CDC	leader	1
		statistician	1
Zhenjiang	CDC	leader	1
		statistician	1
Total			19

For each individual interview, the local collaborator explained the aim of this research to the respondents prior to their participation in the study. After obtaining the

participants' informed consent, Danju Zhou started and audio recorded the interviews with the permission of each participant. All the interviews were conducted in the private meeting room at interviewee's work place anonymously, and the interview place was kept isolated from irrelevant people. The interviews were conducted in Chinese, and they lasted for 30 minutes. Danju Zhou was responsible for taping, transcribing, and translating all the qualitative interviews from Chinese to English.

The initial goal of these in-depth, open-ended interviews was to gain a complementary understanding of the cause of TB underreporting and to obtain an evaluation of health information systems from the relevant health workers. The interview topics included the following:

1. Detailed procedure of reporting TB
2. Participants' responsibility and working condition
3. Relevant policies and their implementation
4. Challenges and expectations of the participants for the health information systems within their particular working context

The specific in-depth interview questions are listed in Appendix A.

2.4 Data analysis

2.4.1 Quantitative data

The first step involved record linkage between the HIS and TBIMS databases. We subsequently compared all the confirmed TB cases in the HIS of each hospital in 2015–2017 and the cases in TBIMS. The confirmed TB cases that appeared in HIS but remained unreported in TBIMS were considered as underreported cases. We calculated

the rate of underreport as follows

$$\frac{The confirmed TB cases that are not in TBIMS}{All the confirmed TB cases in the designated hospital} \times 100\%.$$

According to the Law of the People's Republic of China on Prevention and Treatment of Infectious Diseases, designated hospitals must report to TBIMS within 24 hours all cases of active pulmonary tuberculosis (initial treatment, re-treatment, and smear positive) and patients who failed in the initial treatment. As the patient information obtained from each designated hospital is in accordance with the reporting standard, we define the denominator "All the confirmed TB cases in the designated hospital" in this paper as the number of TB cases we found in HIS after being filtered by our data inclusion criteria described in chapter 2.3.1.1.

Cross linkage was consequently performed by Excel, and a "Find duplicates" query on multiple tables was created, selecting the fields "name," "personal ID," "gender," and "date of birth" either alone or in combination. According to the diagnosis time, we searched the TBIMS of the same year for the patient information recorded in a designated hospital. The record time in TBIMS shall not be earlier than the patient's diagnosis time. For those without any record of that patient in the TBIMS of the same year, we searched previous records to check whether the patient was retreated. The result sets were then double checked manually to ensure accuracy.

Since Jurong Hospital was not able to provide patient's name and their personal ID number, we manually compare all the information, such as "gender", "date of birth", "address", "date of hospital admission", and "date of reporting" to clarify whether the patients' information in HIS can match their information in TBIMS, which might overestimate the underreporting rate.

After identifying the underreported cases, we conducted a bivariable analysis to compare the quantitative variables for unpaired data. For the categorical indicators such as age group, address, and discharge department, we performed a chi-square test to evaluate the TB patients' specific characteristics that differed between the reported and unreported cases. We also identified the possible confounders through multivariable logistic regression and direct acyclic diagram. A p-value of less than 0.05 was considered statistically significant. We analyzed the data using STATA 14.

2.4.2 Qualitative data

2.4.2.1 Policy document review

After full-text review of policy documents, the eligible data was extracted and filled into the pre-designed flow chart. Then, the flow chart of the procedure for TB reporting was drawn to show the detailed standards for TB reporting.

Consistency was accessed by comparing policy documents and in-depth interview. Discrepancies in policies were verified using data from key informants.

2.4.2.2 In-depth interview

We reviewed the transcripts of interviews by applying a thematic analysis [47]. NVivo 11 was used for initial coding and pattern exploration. At the beginning, we developed the draft coding nodes based on the interview guidelines. The transcripts were subsequently coded to refine the nodes. We did not generate new codes unless new themes emerged. After coding, we summarized each node to present the pertinent issues. The quotations were also cited as the interpretation of potential factors related to TB underreporting. The process of data analysis was iterative, inductive, comparative and interactive with data collection simultaneously until generalizations being

elaborated to construct conclusion.

3. Results

3.1 The extent to which TB cases were unreported

3.1.1. Characteristics of TB cases

We collected 2,136 confirmed TB cases from the HIS databases of the three hospitals. The medical records included demographic characteristics such as age, gender, address, and occupation (Table 4).

The average age of the 2,136 TB patients was 55.9 years; meanwhile, the average ages of patients in Yangzhong People's Hospital, Jurong People's Hospital, and Danyang People's Hospital were 66.4, 62.3, and 53.5 years, respectively. The number of male patients was 2–3 times higher than the number of female patients in the three hospitals. The number of inpatients was relatively evenly distributed each year; however, the number of outpatients in Danyang People's Hospital drastically decreased from 2015 to 2017. Patients who selected outpatient treatment were more likely to lose their ID information (19.1%) in HIS than inpatients (< 9%), and the outpatients consisted of more people from other cities (outpatients, 5.8%; inpatients, 3.4%).

In Jurong People's Hospital, more than 34% inpatients received their initial diagnosis in other departments in hospital; by contrast, the rates in Danyang and Yangzhong were merely 8.6% and 18.4%, respectively. Most inpatients were farmers whose average health expenditure was approximately RMB7,000 (US$1,014). Table 4

presents a summary of the socio-demographic characteristics of TB cases.

Table 4: Socio-demographic characteristics of TB cases

Variable	DY Hospital, Outpatient (n = 1034), Average, or No.	DY Hospital, Inpatient (n = 639), Average, or No.	YZ Hospital, Inpatient (n = 234), Average, or No.	JR Hospital, Inpatient (n = 229), Average, or No.
Age	51.2	57.3	66.4	62.3
<= 35	281	124	14	21
>35 <= 65	471	256	77	99
>65	282	259	143	109
Sex				
Male	731	465	179	179
Female	303	174	55	50
Personal Identity card				
Have	837	630	213	N/A
Not have	197	9	21	N/A
Admission Year				
2015	660	229	87	77
2016	269	204	70	69
2017	105	206	77	78
Current Address				
Under jurisdiction	974	617	229	221
Not under jurisdiction	60	22	5	8
In-hospital Referral				

Yes		55	43	79
No		584	191	150
Job				
Farmer			209	185
Non-Farmer			25	44
Fee (Yuan)			6939.5	7202.0
Total	1034	639	234	229

3.1.2. Association between patients' characteristics and TB underreporting

Among the 2,136 confirmed TB cases in HIS that should have been reported to TBIMS, we identified 626 cases that were missing in the TBIMS database, indicating an alarming rate of unreported cases of up to 29.3%. The rate of unreported cases in inpatient records for Danyang People's Hospital (13.3%) was slightly lower than the inpatient records for Yangzhong People's Hospital (17.5%). However, the rate of unreported cases in Jurong People's Hospital abnormally reached 54.1%. The high rate of unreported cases was also found in the Outpatient records in Danyang People's Hospital (36.4%). Table 5 provides a summary of the overall unreported TB cases.

Table 5: Overall unreported TB cases

Confirmed TB cases which should be reported. (N)	Confirmed TB cases which were actually reported. (N)	Unreported cases (N)	Rate of unreported cases

DY Hospital (Outpatient)	1034	658	376	36.4%
DY Hospital (Inpatient)	639	554	85	13.3%
YZ Hospital (Inpatient)	234	193	41	17.5%
JR Hospital (Inpatient)	229	105	124	54.1%
In total	2136	1510	626	29.3%

Table 6: Socio-demographic characteristics of tuberculosis cases by reported status (via bivariable analysis)

	TB Cases Unreported / Confirmed Outpatient Cases	TB Cases Unreported / Confirmed Inpatient Cases		
	Danyang people's hospital (n = 1034),	Danyang people's hospital (n = 639),	Yangzhong People's hospital (n = 234),	Jurong People's hospital (n = 229),
Variable	Average, or No. (%)	Average, or No. (%)	Average, or No. (%)	Average, or No. (%)
Age	47.4 / 51.2 ***	58.7 / 57.3	68.1 / 66.4	62.7 / 62.3
<= 35	131 / 281 (46.6) ***	16 /124 (12.9)	1 / 14 (7.1)	8 / 21 (38.1)
>35 <= 65	165 / 471 (35.0)	30 / 256 (11.7)	16 / 77 (20.8)	54 / 99 (54.5)
>65	80 / 282 (28.4) ***	39 / 259 (15.1)	24 / 143 (16.8)	62 / 109 (55.9)
Sex				
Male	258 / 731 (35.3)	66 / 465 (14.2)	34 / 179 (19.0)	100 / 179 (55.8)
Female	118 / 303 (38.9)	19 / 174 (10.9)	7 / 55 (12.7)	24 / 50 (48.0)
Personal Identity card				

Have	229 / 837 (27.4) ***	82 / 630 (13.0)	36 / 213 (16.9)	N/A
Not have	147 / 197 (74.6) ***	3 / 9 (33.3)	5 / 21 (23.8)	N/A
Admission Year				
2015	305 / 660 (46.2) ***	39 / 229 (17.0)	22 / 87 (25.3) *	66 / 77 (85.7) ***
2016	48 / 269 (17.8) ***	27 / 204 (13.2)	6 / 70 (8.6) *	31 / 69 (44.9)
2017	23 / 105 (21.9) ***	19 / 206 (9.2)	13 / 77 (16.9)	22 / 78 (28.2) ***
Current Address				
Under jurisdiction	354 / 974 (36.7)	78 / 617 (12.6) ***	40 / 229 (17.5)	117 / 221 (52.9)
Not under jurisdiction	22 / 60 (36.7)	7 / 22 (31.8) ***	1 / 5 (20.0)	7 / 8 (87.5)
In-hospital Referral				
Yes		20 / 55 (36.4) ***	10 / 43 (23.3)	52 / 79 (65.8) *
No		65 / 584 (11.1) ***	31 / 191 (16.2)	72 / 150 (48.0) *
Job				
Farmer			35 / 209 (16.7)	99 / 185 (53.5)
Others			6 / 25 (24.0)	25 / 44 (56.8)
Fee			7384.5 / 6939.5	7468.4 / 7202.0
Total	376 / 1034 (36.4)	85 / 639 (13.3)	41 / 234 (17.5)	124 / 229 (54.1)

*Note: *P < .05; **P < .01; ***P < .001.*

Table 7: Association between unreported TB cases and patients' socio-demographic characteristics (via multivariable analysis)

Odds Ratio (95% Confidence Interval)

	Danyang people's hospital (Outpatient)	Danyang people's hospital (Inpatient)	Yangzhong People's hospital (Inpatient)	Jurong People's hospital (Inpatient)
Age				
<= 35	1.0	1.0	1.0	1.0
>35 <= 65	0.81 (0.57, 1.16)	0.86 (0.44, 1.69)	5.43 (0.55, 53.94)	4.34 (0.92, 20.39)
>65	0.74 (0.49, 1.11)	1.17 (0.60, 2.26)	3.62 (0.38, 34.63)	3.13 (0.68, 14.46)
Sex				
Male	1.07 (0.78, 1.45)	1.34 (0.76, 2.36)	1.50 (0.60, 3.76)	1.44 (0.51, 4.09)
Female	1.0	1.0	1.0	1.0
Personal Identity card				
Have	1.0	1.0	1.0	N/A
Not have	7.26 (4.94, 10.69) ***	2.61 (0.58, 11.65)	1.72 (0.56, 5.27)	N/A
Admission Year				
2015	1.0	1.0	1.0	1.0
2016	0.24 (0.16, 0.35) ***	0.75 (0.43, 1.30)	0.28 (0.10, 0.76) *	0.02 (0.01, 0.08) ***
2017	0.33 (0.19, 0.57) ***	0.46 (0.25, 0.85) *	0.68 (0.31, 1.52)	0.03 (0.01, 0.10) ***
Current Address				
Under jurisdiction	1.0	1.0	1.0	1.0
Not under jurisdiction	1.69 (0.92, 3.11)	3.75 (1.43, 9.85) **	0.84 (0.08, 8.55)	14.57 (0.72, 294.52)
In-hospital Referral				
Yes		4.99 (2.67, 9.34) ***	1.35 (0.57. 3.21)	1.48 (0.53, 4.11)

No	1.0	1.0	1.0
Job			
Farmer		1.0	1.0
Non-Farmer		1.81 (0.58, 5.66)	0.99 (0.60, 1.66)

Tables 6 and 7 summarize the results of the bivariable and multivariable analyses and outline the socio-demographic characteristics of TB cases by reported status. In the bivariable analysis, we found that both age and address were the demographics with any significance. Age was significant for the outpatient cases for Danyang People's Hospital where the average age of patients not reported was 47.4 years, whereas the average age of all the confirmed TB cases was 51.2 years. Non-reporting was significantly higher among the younger outpatient group than the older outpatient group (Age<=35: 46.6%; Age>65: 28.4%) in Danyang People's Hospital. Address of registration was also a significant factor for the inpatient cases for Danyang People's Hospital. Patients residing in the jurisdiction of the hospital were less likely to not be reported than patients who did not reside in the jurisdiction (12.6% and 31.8%, respectively). The other characteristics that proved significant were possession of a personal identify card, year of hospital admission, and presence or absence of an in-hospital referral. With regard to the outpatient cases for Danyang People's Hospital, patients without a personal ID were much more likely to not be reported than those patients with an ID card (76% and 27%, respectively). However, for all the inpatient cases, the possession or non-possession of a personal ID card was not associated with

TB underreporting. The admission year was likewise a factor in reporting. All the cases demonstrated that the highest unreported rate occurred in 2015 compared to the other years. Finally, inpatients in Danyang People's Hospital and Jurong People's Hospital who had received in-hospital referrals were more likely to not be reported than inpatients who did not have in-hospital referrals (Danyang: 36.4% and 11.1%, respectively; Jurong: 65.8% and 48%, respectively).

The results of the multivariable analysis slightly differed from the bivariate analysis results. In the multivariable analysis, age was not significant, but location, possession of a personal identify card, year of admission, and in-hospital referral still played an important role in reporting, as previously indicated. However, in contrast to the bivariable analysis results, inpatients in Jurong People's Hospital who had received in-hospital referrals did not prove to be significantly associated with TB underreporting (OR = 1.48, 95%, CI = 0.53–4.11).

3.2 Factors associated with TB underreporting

Before we investigate the potential factors associated with TB underreporting, we should initially examine the entire procedure for reporting TB and clarify the roles of different information systems.

Figure 3 illustrates the multiple steps in the reporting process. It describes the procedure of TB records' transfer from HIS to IDRIMS and TBIMS. We have developed this figure illustrating information flow for reporting TB through policy documents review and in-depth interviews.

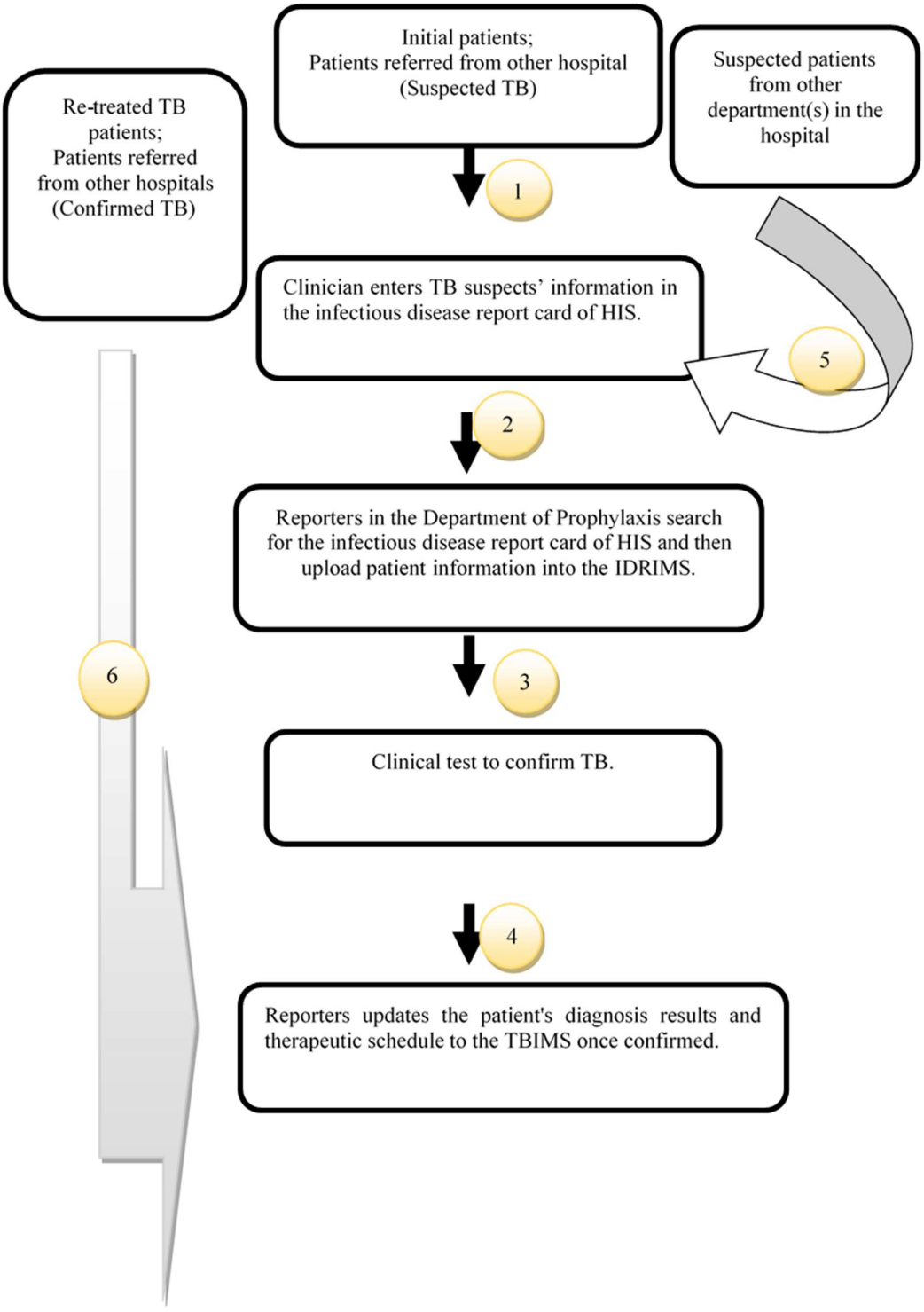

Figure 3: Procedure for reporting TB

Process 1 & 5: A TB suspect could be referred to designated hospitals from other departments in the designated hospital, other hospitals or primary health care (PHC) facilities. In principle, the first clinician in the hospital or PHC facility (some PHC facilities are able to perform X-ray tests) who judge the patients as TB suspects after chest X-ray test is responsible for filling in the infectious disease report card in HIS.

TB clinicians in the designated hospitals are not granted permission to check if the patient's card was created in the IDRIMS by other hospitals. Therefore, when patients are referred from other medical facilities they are required to bring a referral sheet, which indicates if they have been confirmed with TB or not. If not, the TB clinician needs to fill in the infectious disease report card in HIS.

Process 2: The infectious disease report card completed by TB clinician in the designated hospital is stored in the HIS system on the hospital intranet. Then the reporters in the Department of Prophylaxis search for the infectious disease report card on the HIS daily and manually upload the suspected TB patient information into the IDRIMS on the national external internet.

Process 3: Sputum smear test, sputum culture test and X-ray tests are usually conducted in designated hospitals to confirm TB. The clinical test results are sent to the TB clinic on paper and stored electronically in the hospital laboratory information system (LIS).

Process 4: Reporters will update the patient's information of diagnostic tests in the IDRIMS after manually retrieving test results through the hospital internal network. Next, they need to click on a confirmation button, the patient information will be automatically transferred from the IDRIMS to the TBIMS system. Patients' therapeutic schedule and tracking records are subsequently updated in the TBIMS by CDC personnel. If the infectious disease report cards are created by other hospitals, the reporters will manually enter the information in the TBIMS.

Process 6: For the re-treated TB patients and the confirmed TB patients referred from other hospitals, clinicians are not required to complete the infectious disease card and medical staff can skip steps 1,2,3 and 4. But reporters need to update their information in the TBIMS.

As the preceding steps imply, the usage of web-based systems largely reduces the workload of clinicians and statisticians compared with paper-form recording; however, reporting TB remains a complicated process. In the next chapters, we identify the problems of TB underreporting based on the quantitative and qualitative analyses.

Through in-depth interviews with 19 stakeholders related to TB treatment and management, we identified several areas that might cause TB underreporting, such as health information system and human resource-related issues.

3.2.1 Factor 1: Health Information System

System Software Design

Hospitals use different electronic systems to record patient information, which often causes confusion when TB statisticians search the records for a TB diagnosis. For example, the HIS of Danyang People's Hospital allows for the completion of diagnosis results in narrative form. However, depending on the complexity of the narrative, the information could be difficult for a TB statistician to understand, and the information might be incorrectly entered into IDRIMS and TBIMS. By contrast, the HIS of Yangzhong People's Hospital neither allows for the completion of diagnosis results in narrative form nor includes an option to enter "suspected tuberculosis." Consequently, clinicians might not enter information on suspected cases and then fail to update the system if the case is confirmed, resulting in an unreported TB case.

"Some clinicians like to use their own marks to write the diagnosis results. For example, they record the retreated TB patients as 'fz' (FuZhen, the abbreviation of the Chinese term for 'retreated'), and they usually record the suspected TB patients as 'TB-' or 'TB?'. Consequently, we experience extreme difficulty in identifying the patients in the hospital intranet through our searching engine. Sometimes it is confusing for us to determine if the TB patients should be reported or not." (Statistician 1, DY People's Hospital)

"I hope our HIS can include the option of 'suspected tuberculosis,' or at least

add a remark blank to remind me that this person still needs further smear examination. The clinician occasionally phones me not to report the patient to TBIMS because the patient hasn't received yet all the three-times smear tests. But sometimes I am busy…… so after the patient was confirmed as TB, you know…." (Statistician 3, YZ People's Hospital)

"I will only report the information that I find within our hospital intranet. If I am confused about something, I can contact the clinician through WeChat." (Statistician 1, DY People's Hospital)

Furthermore, the lack of a self-check function reduces the accuracy of data reported. Patients require a valid ID to be entered into TBIMS. However, neither HIS nor IDRIMS can automatically identify the validity of a patient's ID number without which the information cannot be transferred to TBIMS. Therefore, in some cases, although the patient information was entered in IDRIMS, it could not be transferred to TBIMS without a valid ID number.

"Patients can get treatment only if they bring their ID card or health insurance card; even if they forget to bring the card, we still have to treat them. Infectious disease is very dangerous, and we cannot simply send home [patients with this disease]. Thus, usually when we don't know their ID number, we would type something like '000000000000000000' into HIS and ask for their ID number through a phone call several days later. However, patients sometimes don't answer the phone." (Clinician 5, JR People's Hospital)

Moreover, HIS, IDRIMS, and TBIMS lack an automatic function of identifying duplications; instead they rely on the statisticians' manual identification and deletion, and this step constitutes an additional burden for statisticians. The statisticians reveal that if they believe that they recognize a patient's name, they presume it is a duplication and eventually decide to not enter it to avoid its manual removal in the future. However, if statisticians are mistaken and the patient is in fact a new one, an unreported case ensues.

"There is no function to automatically identify the duplication of patients' records. Therefore, I have to sort the patients' names, check their names one by one, and then delete any duplication." (Statistician 1, DY People's Hospital)

(When the interviewer mentioned one TB patient's name that the statistician did not report to TBIMS): "XXX (the patient's name)? I remember him. He is a retreated patient. He has come to our hospital several times." (After checking the report history): "It's impossible. I definitely remember that I have reported this person." (Statistician 3, YZ People's Hospital)

Another problem is language barrier. As one statistician in JR People's Hospital acknowledged, *"it is difficult for me, an old woman, to understand the English appearing in the screen. After every system update, I feel that I need a longer time to adapt to the new modules."*

Data Linkage

Another weak spot in the system is the lack of connection between the hospital intranet (HIS) and extranet systems (IDRIMS, TBIMS). For instance, in process 2 (Figure 3), HIS automatically reminds the clinician to fill in an infectious disease report

card. However, this information does not automatically transmit to the external network (IDRIMS, TBIMS) but instead relies on TB statisticians to manually perform the step. The software used for the national systems is often different from the software for hospital systems, and staff reported struggling with the use of software with which they are unfamiliar.

"If you ask me whether the current software is convenient, I would sometimes say no. Nonetheless, I have already adapted to it. I just hope that the government does not change the software too frequently. I am already 60. I don't like computers." (Statistician 2, DY People's Hospital)

"In our hospital, HIS and the laboratory information system are built by different companies. These systems don't share information, which causes inconvenience in searching for the detailed records from the two systems. I hope we can have an integral information system built by only one company." (Statistician 1, DY People's Hospital)

Second, the health information systems lack interoperability among different health facilities. Tuberculosis statisticians can merely access the systems in their own hospitals; thus, if a patient is transferred from another hospital, the statistician has to contact the referring hospital to obtain patient information. This form of communication slows the transfer of information and creates room for mistakes. For instance, the first medical institution (non-designated hospital) to diagnose a patient with suspected TB is responsible for reporting the suspected case to IDRIMS. However, whether a patient's information has been reported to IDRIMS is impossible for statisticians in the designated hospital to ascertain. Duplication or a case of missing records arises if that patient's card either has been created or has not been created as a TB suspect in IDRIMS

by other hospitals.

"I only have the authority to check the patients' information reported from our hospital." (Statistician 1, Statistician 2, DY People's Hospital; Statistician 3, YZ People's Hospital; Statistician 4, JR People's Hospital)

"The patients referred from other hospitals would bring a referring sheet, which indicates whether or not they have been reported to TBIMS. If they are confirmed TB patients, we usually believe that they have been reported by their previous hospitals. Nonetheless, we have no authority to check if they indeed had been reported to TBIMS." (Statistician 3, YZ People's Hospital)

"We don't contact the referring hospital. How dare that hospital not report! (laughing). The CDC checks underreporting very frequently." (Statistician 4, JR People's Hospital)

"Consider migrant workers—those individuals who are usually from very poor, remote rural areas. They work for projects from one city to another city. Such types of patients are the most difficult to trace. They seldom pick up our phone call. Some of them don't even have health insurance cards, and they would use their friends' ID cards to visit doctors. How, then, am I supposed to deal with them? I have my own work to do." (Clinician 2, DY People's Hospital)

The problem of information systems lacking interoperability and connection also occurs among different departments in hospital. In process 5 (Figure 3), if the patient information filed by the first doctor in other departments was inaccurate, the doctor in TB clinic would not check the patient's information, and the statisticians of the Department of Prophylaxis would rarely contact the clinical doctor for double-

checking purposes, thereafter increasing the risk of underreporting.

Moreover, HIS is incapable of automatically connecting with TBIMS, thus requiring statisticians to manually transfer this information and keep up with any updated information. This lack of automatic connection is further complicated during process 4. Once the lab results confirm a TB positive diagnosis, statisticians do not have any communication with clinical doctors before uploading this information to TBIMS, which could cause misinterpretation and trigger mistakes in the reporting.

"I will only report the information that I find within our hospital intranet. If I am confused about something, I can contact the clinician through WeChat." (Statistician 1, DY People's Hospital)

"With regard to TB reporting, no one has contacted me before. My duty is simply to fill in the infectious disease card, that's all. Reporting is the responsibility of others, but I don't know what happens in other departments." (Clinician 1, DY People's Hospital)

3.2.2 Factor 2: Health Resource-related Issues

a) Human Workforce

Workload

Clinicians and nurses responsible for TB care in these hospitals already have a heavy workload, and they are reluctant to add the reporting of TB cases to their workload by undertaking the additional procedures of TB reporting. Although the infectious disease report card functions as a mandatory notification for clinicians to enter patients' information into HIS before making drug prescription, lack of time caused further issues as clinicians reported being excessively busy to fill in the

infectious disease report cards. Some clinicians disclosed that they enter new TB cases as re-treated cases to avoid the need to complete all the steps in the system (occurring in processes 2 and 6).

"Yes, [this aspect is] definitely a loophole. If the clinician clicks the button of 're-treated patient' to skip the process of filling in the infectious disease card, no one in the hospital can find out if the patient is reported to TBIMS, unless the CDC personnel come to check our underreporting rate. If you ask me whether I have done the same thing before, my answer is 'no.' However, I believe that others may have done so." (Clinician 2, DY People's Hospital)

"Aside from reporting TB cases, my daily work includes many other activities such as reporting all cases of infectious diseases, vaccination, and giving primary care. Sometimes I have much free time; at other times I feel I am too busy to die—[my perspective] depends on how many patients come here today. Nonetheless, it's impossible to hire another statistician to help me, as I do not always find myself in busy situations." (Statistician 3, YZ People's Hospital)

As previously mentioned, HIS is incapable of automatically connecting with TBIMS, thus requiring statisticians to manually transfer this information and keep up with any updated information. This step increases the burden on the TB statisticians and reduces the time and resources to focus on accurate reporting procedures. This lack of automatic connection is further complicated during process 4. Once the lab results confirm a TB positive diagnosis, statisticians do not have any communication with clinical doctors before uploading this information to TBIMS, which could cause misinterpretation and trigger mistakes in the reporting.

Additionally, some adverse reactions and other complications of the patient cannot be fed back. Records in TBIMS about whether the patient chooses outpatient treatment or hospitalization are nonexistent, and the CDC can only check this information through phone calls. This approach is a massive waste of manpower and material resources in patient management, resulting in the lack of sufficient manpower and funding for the CDC personnel to focus on TB underreporting. For example, only one person is responsible for reporting TB cases, supervision, and all other work in the CDC of Jurong, thus causing difficulty in guaranteeing work quality.

"My work includes reporting and checking the TB patients' information, writing a monthly review of TB epidemiology, tracing patients, visiting each patient's home, and reminding patients to take their medicines. I am the only TB personnel here. It's absolutely impossible for me to spend too much time in dealing with patients who are difficult to trace." (Statistician 6, JR CDC)

b) Institution Related to Human Resource

Incentive Policy

Lack of financial incentives adds to the problems of health personnel. Tuberculosis does not receive the earmarked funds in institutional budgets and therefore does not always obtain the necessary funding. Government funds for TB tend to go to the entire pool of the total funds, which are uniformly allocated by institution and are not necessarily spent on TB prevention and treatment. In addition, the standard of subsidy for the TB specialist is unclear; TB specialists are inadequately compensated for their work, which engenders a lack of enthusiasm and attention to detail.

"I really dislike filling in the infectious disease report cards. It's so time-

consuming, but I do not receive extra money." (Clinician 1, DY People's Hospital)

"I should receive RMB50 (roughly US$7.30) per patient as a bonus for managing and tracing TB patients, but I never see it. Perhaps the amount is already included in my salary, but my salary is so low. I think it's unfair that my heavy work is only worth RMB50." (Statistician 5, JR CDC)

"Government-specific funds for TB tend to go into the entire pool of the total funds of the local CDC. Tuberculosis prevention is important, but the prevention of HIV and hepatitis BC is also important. As the standard of subsidy for the TB specialist is unclear, we tend to allocate some TB funding to other projects of infectious disease prevention." (Leader 1, ZJ CDC)

Supervision and Accountability

An important factor influencing all the preceding issues is the lack of leadership or guidance in TB prevention and treatment. Chinese health facilities have a fair amount of autonomy [25] and lack of strict accountability to comply with TB reporting procedures. The absence of specific and unified standards for health workers from different cities, counties, and facilities with which to comply is also evident. Specifically, this aspect concerns the particular reporting requirements to fulfill, the types of information systems to be designed, and the extent of achieving the goal of TB prevention and treatment. The limited requirements of government intensified the chaos generated during the establishment of information systems at the local level. The political context of inadequate incentive policies and low degree of supervision aggravated the quality of implementation.

Municipal-level CDCs should perform data checks; however, provincial CDCs

are reluctant to supervise these municipal-level CDCs unless the central government initiates an investigation on underreporting. Additionally, even some hospitals stipulate that a missing case will result in a decrease in the bonus for related personnel due to the difficulty of tracing responsibility to an individual; nonetheless, this regulation has never been implemented.

"There are no detailed standards and indicators for us to do work. The upper-level CDC only requires us to decrease the TB epidemiology to reduce the TB underreporting rate. However, they didn't tell us how to reach the goals and the extent to which we should we achieve these goals. We are really confused about this situation. The same confusion also happens to the provincial CDC, as they don't know how to surveil and guide us as well. Thus, in practice, unless the central government clearly tells us that they would come to investigate our work quality and check certain statistical rates, we are in a situation in which 'we do work and we surveil ourselves.'" (Leader 1, ZJ CDC)

Moreover, the low financial incentives, low quality of supervision and the chaos in role clarity made most clinicians and staff not aware of the importance of timely TB reporting. They regard diagnosis and treatment as their only responsibility, and hospitals lack the personnel responsible for TB reporting as well as other public health-related work. Misunderstanding the need for accurate TB reporting was shared among the statisticians and CDC personnel interviewed for this study. For example, one staff member at Jurong People's Hospital only reported patients with positive sputum smear, resulting in underreporting. Furthermore, when the CDC personnel arrived to check underreporting, they usually decided to skip the untraceable patients with incorrect information. They sometimes also missed the re-treated patients who had already left

records in the TBIMS dataset.

"Recently our hospital leader has taken the issue of underreporting very seriously. He often holds conferences to emphasize the importance of the timely reporting of infectious diseases." (Clinician 3, Clinician 4, YZ People's Hospital)

"I need to diagnose and treat TB patients every day; I am truly busy. You cannot expect me to check the accuracy of the reported information, which is not my duty. The statistician is responsible for that task." (Clinician 1, DY People's Hospital)

"The CDC personnel do come to check the quality of the reported information. I believe that I have done a very good job thus far because no one has asked me if I have missed one case." (Statistician 5, JR People's Hospital)

"I am the only TB personnel here. It's absolutely impossible for me to spend too much time in dealing with the patients who are difficult to trace and check the quality of the statisticians' work." (Statistician 6, JR CDC)

4. Discussion

4.1. The extent to which TB cases were unreported

Our study examined TB reporting records and medical records from three hospitals. Our results reveal that approximately 30% of TB cases in Zhenjiang city are unreported. These findings support the results of previous studies that have uncovered problems with underreporting TB cases within the Chinese surveillance system, causing an underestimation of the actual TB incidence rate.

As our results indicate, the TB unreported rates of outpatients are higher than the TB unreported rates of inpatients, except for the cases in Jurong People's Hospital

(this hospital is discussed in chapter 4.4). This finding may be due to the checking and update of inpatient records on a regular basis. Hospitalization also provides an easier approach for health staff to contact patients, offering more time for the correct completion of information.

In Danyang People's Hospital, inpatients who did not reside in Danyang had higher unreported rates than those inpatients living in Danyang for a long period. This finding is not surprising, as the hospital might have less information on record for patients beyond their jurisdiction. However, living outside Danyang lacked a significant effect on reporting rates for outpatients in the same hospital. We speculated that this result might be due to the relatively clear division of work for the outpatient clinicians but unclear division of work for the in-hospital health staff. Patients living in hospital receive longer term treatments than outpatients, which requires several in-hospital health staff members to work together; thus, each health staff member might think that the others would complete the report work, causing TB underreporting. However, this interpretation cannot explain the cases in Yangzhong and Jurong People's Hospital, which needs further investigation.

The fact that outpatients in Danyang People's Hospital without a personal ID card had higher unreported rates than those outpatients with ID cards underscores the importance of patient information in accurate reporting. Additionally, underreporting among inpatient referrals in Danyang People's Hospital was significantly higher than non-in-hospital referrals. Through in-depth interviews, we discovered a flaw in the manner by which information is transferred within the hospital, suggesting an urgency to strengthen the communication and data linkage of health information systems.

The rest of this section discusses the manner by which key factors have affected

the study hospitals' underreporting of TB cases from two perspectives, namely health information system and human resource-related issues (health workforce and institutional development). It also analyzes the policy implications of these results.

4.2. Factors associated with TB underreporting

In this section, we evaluate China's health information system from two standpoints: system design and human resource-related issues.

System Design

The main problems regarding health information systems can be summarized into two parts: lack of data standardization and self-checking function, and lack of data linkage function.

As indicated in chapter 3.2.1, the failure of information systems in validating patients' ID and identifying duplicated cases exacerbates the health staff's workload and hampers the accuracy of data. The lack of data standardization often causes confusion when TB statisticians search the records for a TB diagnosis. The English user interface avoids the ease of use.

More importantly, health information systems lack interoperability and accessibility within a hospital, between a hospital intranet and a national external net, and among different health facilities. As hospitals in China have a considerable degree of autonomy, they design or select HIS software by themselves to simply meet their specific needs, thus considerably limiting the possibility for sharing information with other providers or public health agencies [21]. This limitation increases not only the workload for health staff but also the probability of losing data quality. Furthermore, the fact that only higher-level CDC can access the data of its lower jurisdiction level

determines the hierarchical nature of the information systems. However, given the increasing number of internal migrant workers and the long period of TB treatment schedule, such hierarchical information systems can hardly trace the patients moving from one place to another, adding difficulty in the timely surveillance of TB [21, 25].

The technical problems confronting China's information systems are likewise perplexing for other low and middle-income countries (LMICs) [50-63]. For example, a World Bank report recognized Indonesia as one of the countries with minimal use of data and information systems for both monitoring and evaluation [51], and this depiction may be due to poor data integrity and lack of open access to raw data [52]. In Indonesia, the reporting forms in each health center are different, which results in missing data and hampers the data standardization process [53]. Nurses and other healthcare workers are also confused about the precise material to document and the proper means of documentation [54]. Even data are correctly reported from the front line; in most cases, access to these data is prohibited [55].

India, Namibia, and Thailand encounter the same problems of data standardization and accessibility. Incompleteness and poor quality of records, irregularities in the generation of reports, and data duplication and inconsistencies are commonly observed in healthcare institutions at all levels [56-63]. In India, health institutions generate fragmented health data that are often duplicated and inconsistent, and a comprehensive HIS is unavailable to provide government and researchers with essential information for analyzing and surveilling data quality [57]. In Namibia, the process of building information systems is supported by many different donors, which causes poor coordination and duplication and unmatching of software functions [58]. In Thailand, the data collected by community health nurses are mainly recorded on

paper and stored in cabinets. Some information may enter the government database, but nurses and other healthcare workers cannot access it [59].

Human Resource-related Issues

As previously mentioned, the flaws in system design increase the workload of TB specialists. The shortage of health workers and the lack of awareness of the importance of the prompt reporting of cases are two major barriers that likely exist in China's health system, which are probably driven by inadequate financial incentives, low supervision, and lack of a clear guidance. The phenomenon identified was common across all the study sites, as discussed in Chapter 3.2 before.

In the 1990s, China and many other developing countries underwent a period of health sector reform, which resulted in the decentralization of governance and financing [49]. Although China aimed to build an integral health information system for infectious disease control, its goal was harmed by the insufficient financing, diminished capacity of the health workforce, and low planning capability caused by decentralization [50].

In other developing countries, the shortage of health workers and their lack of motivation are main factors hampering the development of health information systems as well. In Namibia, a large number of systems, databases, and processes are fully manual and paper-based, which significantly increase the work burden of health workers [58]. In India, private hospitals record data based on their own unique needs, which indicates that private hospitals usually lack the motivation to follow the national reporting standard without a mandatory legislation. Moreover, health workers lack financial incentives to record and keep data [60]. Workforce shortages similarly occur

in Bangladesh in the aspects of data entry and system engineering [61].

In terms of disease surveillance, developing countries also encounter the same problems as China does. For instance, in India, no independent authority is in charge of checking data quality. However, the Statistics Division is responsible for compiling data and simultaneously monitoring the performance of data reporting, which triggers conflict of interest and fails to ensure the transparency and effectiveness of health information systems [57]. In Bangladesh, neither a data quality assurance system is enforced in the routine HIS nor a data quality assessment plan is implemented to systematically monitor the quality of routine data [61].

Overall, the reporting system relies on system design, health personnel responsible for entering and checking the information, and relevant policies to support implementation. All of these factors leave room for errors, which help to explain the unreported cases found in the quantitative data.

4.3 Implications for Policy and Practice

Many countries have implemented effective TB surveillance on a national basis, but the number of reported cases is still considerably less than the actual incidence. Our study reveals that even in a developed city of China with an established TB reporting system, the rate of TB underreporting remains high, suggesting the presence of additional problems with reporting in less developed regions with fewer resources and a lower level of expertise. According to the latest report from WHO, a national survey on the TB underreporting problems in Indonesia revealed that the rate of unreported cases was 40% in 2017 [50]. All the studies indicate that the actual burden of TB and the precise number of patients who can receive standard treatment are uncertain,

rendering the goal of WHO's "End TB Strategy" more difficult to fulfill.

To solve these problems, governments of some LMICs have devised several plans to strengthen their health information systems. The experiences and government stewardship of these LMICs can function as valuable references for our future work. For example, in 2017, Indonesia created and made publicly available a step-by-step manual for clarifying roles and a set of working guidelines to reduce variations and errors during the data preparation process and agency coordination [55]. A fully functional frontline digital health information system and integrated health cohort data, which enables the real-time use of routine data and open access for frontline workers, is planned in the future health strategy of the Ministry of Health by 2019 [51]. In Bangladesh, to respond to the global need for reporting health data, the central government has emphasized the reinforcement of health information systems as a key goal of the next health sector program (2017–2021), based on the work done for the current program (2011–2016) [62-65]. The Bangladesh Ministry of Health has also approved a Monitoring and Evaluation Strategy and Action Plan for the health sector, with a focus on strengthening the routine HIS and integration of different data sources [66].

Overall, based on our findings, the WHO report, and the accounts of other countries' experiences, the following methods can be applied to strengthen the TB surveillance systems and reduce the rate of reporting TB underreporting:

1. Simplify the national electronic reporting system to enhance its user friendliness, modify the logic modules for self-checking, and open the authorization of reviewing data for more TB health facilities.

2. Establish integrated information systems, especially in hospitals, or at least stipulate universal and standard indicators for system design to connect different information systems and automatically transfer data.

3. Set up mandatory notification. In Brazil and China, for instance, the method of linking the supply of drugs to the notification of cases has generated benefits [50]. However, the finding mentioned in chapter 3.2.1 suggests that we still need to focus on the potential loopholes in mandatory notification.

4. Emphasize the importance of reporting all the TB cases to healthcare providers.

5. Increase health workforce capacity and funding for data collection and management. In areas faced with serious shortage and uneven distribution of hospital health workers, the deployment of community health workers and approaches with a public–private mix for TB control and care is proved to be practical in Ethiopia and Pakistan [67-69].

6. Provide clear guidance for TB treatment, surveillance, and management. Clarify the division of work for both the outpatient clinicians and in-hospital health staff.

7. Establish strong regulatory frameworks with effective implementation to ensure collaboration between hospitals and local CDC. Local CDC is responsible for supervising the quality of work of general hospitals, yet the regulations is hard to be rigorously implemented due to the parallel political position between the CDC and hospitals. Therefore, effective inter-organizational collaboration may require powerful regulatory frameworks

for local CDC to play a positive role in supervising the work of hospitals based on the TB program guidelines.

8. Besides the collaboration between the local CDC and hospitals, CDC should also actively collaborate with health administrative departments. Researchers indicated that the proportions of feedback from health administrative departments to CDCs were lower than 30% at all levels. In China, the health administrative departments have significant influence on the activities of CDCs. The performance and the quality of infectious disease surveillance of CDCs might be compromised by the lack of clear and incentive feedback from the health administrative departments [70].

9. As the local capacity to use and benefit from routine data systems remains weak, investment in national prevalence surveys and technical support is necessary for improving the measurement of the disease burden and the effects of interventions. In this regard, WHO has published a detailed checklist and an inventory study to assess TB underreporting [71].

4.4 Limitations of the Study

Due to some practicality of the study hospitals, the variables collected from each one are different, thus increasing our difficulty in performing a multivariable analysis and determining whether some invisible characteristics of the hospital would affect the results.

Among the inpatients in Jurong People's Hospital, 74 (32.3%) were born on January 1. As the patient ID and name were not provided by this hospital, we speculated that the patient ID information that had been inputted in its HIS was wrong. We could

merely use all the other variables, including age, gender, date of diagnosis, and address for record linkage, which might overestimate the underreporting rate.

Additionally, the inclusion criteria for selecting confirmed TB cases were excessively stringent. Diagnosis records with any uncertain mark or vocabulary were excluded, which might undervalue the actual rate of underreporting.

5. Conclusion

Our study indicates that approximately 30% of TB cases in Zhenjiang city are unreported. The potential factors causing TB underreporting are poor system design, lack of data standardization, lack of system interoperability and accessibility, heavy workload for healthcare workers, lack of awareness of reporting, lack of financial incentives, absence of surveillance, and lack of guidance and role clarity.

Furthermore, our study reveals the important role of system design, government leadership, and qualified, dedicated, and well-paid health personnel in ensuring the accuracy of data. The thesis also stressed that policy makers should focus on the personnel and institutional context with which information systems are functioning, as on the system design. The underreporting of TB hinders the capacity to accurately evaluate the course of the disease, representing a public health problem which may lead to an increase in the risk of disease transmission and drug resistance development. The lack of this epidemiological data causes extreme difficulty in control and prevention, also impacts on the cost of TB management. Therefore, a reliable TB surveillance and reporting system is essential for accurately grasping the disease and developing appropriate strategies through which to end this pandemic.

Appendix:

Interview Outline for Information System

One: Centers for Disease Control

1. The Head of Zhenjiang Center for Disease Prevention and Control

Purpose

1) To know about the use of TBIMS and the supporting measures in Zhenjiang CDC.

2) To know the opinion of the head of Zhenjiang CDC on the use of TBIMS

3) To know problems on management of TB patients in TBIMS and his suggestions.

Interview Outline

1) Introduce the use of TBIMS in the CDC.

A. Report: what is the reporting standard and reporting process of designated hospitals and non-designated hospitals? How does the CDC handle the reported data?

B. Analysis and its implication: will the data be analyzed? Which index are generally required? What is the implication of the analysis? Is the reporting unit aware of the analysis implication?

C. Quality check: Does anybody assess the quality of the collected data?? If so, who? How to assess? How to check it?

D. Information exchange: Do you have any information feedback?

Yes:

1. Which institutions and what mechanisms?

No:

1. Does anybody contact the hospital for further verification if something is wrong about the data?

2. Do you think is it necessary to provide feedback? What are the reasons or obstacles of failing to provide feedback?

2) How many people are responsible for the management of TBIMS in CDC? What are the responsibilities? Is there any special training? Do you have any regular performance appraisal and quality assessment?

3) How much fund do you have for TB related management? Where do you mainly spend that fund? Is the fund sufficient?

4) What policies on management of TB patients do you have in CDC?(How to manage the patients from different districts, how to manage the floating patients?) What is the status quo of implementation

5) How municipal CDC cooperate with the designated hospitals, county and district CDC, grass-roots health institutions under the TBIMS and the IDRIMS?

6) Please provide a comprehensive evaluation of TBIMS.

A. Does the data processing, collection and analysis meet the management requirements of TB patients? Is it convenient for epidemic surveillance and patient tracking (especially for immigrants and referral patients)?

B. What is the satisfaction rate of the TBIMS? (system operation, data analysis, patient management, communication with institutions, etc.)

C. Is there any missing report or data mismatch in the system? How often? What is the

most possible reason according to your knowledge?

D. What challenges do you still face?

7) What are your opinions and suggestions on the information system to meet the needs of reporting and managing patients of infectious diseases?

2. Zhenjiang CDC TBIMS Special Statistician

Purpose

1) To know the quality of collected data in the TBIMS and the challenges of daily use.

2) To know the opinions and evaluations of the Special Statistician in Zhenjiang CDC on the TBIMS.

3) To know the Special Statistician's suggestions on th' improvement of the TBIMS.

Interview Outline

1) Briefly introduce your responsibility in TB data management.

a. How long have you been in this job? How long is your pre-job training? Will the CDC assess the quality regularly?

B. How to deal with data of TB patients uploaded from hospitals or grass-root health institutions?

C. How much time has been spent on the TBIMS? What is the workload?

D. How do you deal with non-local TB patients in general? Do you contact CDC in

their location?

E. Are you satisfied with the current job? (Workload, compensation, etc.)

2) Do you assess the quality of the collected data? If so, who? How to assess? How to check it?

A. Is there any information feedback?

Yes:

1. Which institutions and what mechanisms?

No:

2. Does anybody contact the hospital for further verification if something is wrong about the data?

3. Do you think is it necessary to provide feedback? What are the reasons or obstacles of failing to provide feedback?

B. How CDC reacts if something is wrong about the data? Does anybody take the responsibility?

3) Please provide a comprehensive evaluation on the TBIMS.

a. Is the interface user-friendly and easy to understand? Is the system fully functional logically?

B. Does the data processing, collection and analysis meet the management requirements of TB patients? Is it convenient for epidemic surveillance and patient tracking (especially for immigrants and referral patients)?

C. What is your satisfaction rate of the TBIMS? (system operation, data analysis,

patient management, communication with agencies, etc.)

D. Is there any missing report or data mismatch in the system? How often? What is the most possible reason according to your knowledge?

E. What are your difficulties in daily operation? How to solve it?

4) What are your opinions and suggestions on the information system to meet the needs of reporting and managing patients of infectious diseases?

Two: Designated Hospitals

1. Leaders who are responsible for infectious diseases in designated hospitals

Purpose

1) To know the status and policies of TB management in designated hospitals

2) To know his opinions, evaluation and suggestions on HIS and TBIMS

Interview Outline

1) Please give a brief introduction on the status quo of TB patients reporting in hospital.

A. Who is the currently responsible for registering TB patient data and upload it to TBIMS? Is this person full-time? How long is the training? Who is the trainer?

B. How do you refer patients inside the hospital if you find TB patients in different departments of the hospital? Is the referral rate high currently? Does the hospital have any special policies for referral of TB patients in non-infectious departments?Are clinicians in non-infectious departments trained in reporting infectious diseases?

C. How to manage and report non-local patients, duplicate smear-negative TB patients,

recurrent patients, outpatient patients and in-hospital referral patients? (Go down the details here)

D. What is the investment in TB control in the hospital? Is there any support for special statistician? Is there any person responsible for information system construction and maintenance? (How important is this in the hospital?)

2) Please introduce the usage of hospital information system.

A. System docking: Is the HIS docked with other system like TBIMS, IDRIMS?

If it is not docked:

1. Do you want it to have such feature? What improvements will it bring to your work after docking? What are the possible difficulties?

B. Information exchange: Is there any information feedback?

Yes:

1. Which institutions and what mechanisms? (It is required to mention the non designated hospitals which refer the patients)

No:

2. Do you contact that institution for further verification if something is wrong with data?

3. Do you think is it necessary to provide feedback? What are the reasons or obstacles of failing to provide feedback?

3) Please introduce the treatment management and expenses of TB patients.

A. Do the health administration departments or medical insurance policy have limits on

hospitalized days, total expenses and self owned expenses for TB patients?

B. Do you have any special payment methods for TB patients? (prepaid in lump sum? Pay by project?)

C. Is there any other health departments or health insurance policy that may affect information management of TB patients?

4) Please provide a comprehensive evaluation of the information system in hospital.

A. Does the data processing, collection and analysis meet the management requirements of TB patients, especially for migrants and referrals?

B. Does the information system meet the requirements of the Infectious Diseases Prevention Law?

C. What is your satisfaction rate of the information system in hospital? (System operation, data input, analysis, reporting, patient management, communication with other departments, communication with other institutions, etc.)

D. Is there any missing report or data mismatch in the system? How often? What is the most possible reason according to your knowledge?

E. What challenges do you still face?

5) How to cooperate with CDC and grass-root health institutions under the information system?

6) What are your opinions and suggestions on the information system to meet the needs of reporting and managing patients of infectious diseases?

2. Record Clerk (TBIMS Special Statistician) in Disease Control Department of Designated Hospital

Purpose

1) To know the status quo of the operation of the information system and the standards and procedures for uploading data in designated hospital.

2) To know the quality of reporting data and the possible reason of missing reports in designated hospitals.

3) To know the opinions, evaluation and suggestions of designated hospitals on HIS and TBIMS

Interview Outline

1) Please briefly introduce your work.

A. How do you deal with reported data of TB patients from various departments?

B. How long have you been in this job and how long is your pre-job training? Will the hospital conduct performance appraisal regularly?

C. How frequent is the transfer of staff in disease control department? Is it frequent? (If it is frequent, how can you guarantee the quality?)

D. How do you think of your workload ?

E. Are you satisfied with the current job? (Workload, compensation, etc.)

2) What are the standards and procedures for uploading information of TB patients and their medical records in designated hospitals under the information system?

A. What is the standard of reporting patients? (suspected cases, floating population, outpatient patients, referral patients in hospital, duplication smear negative patients, TB pleurisy patients, etc.)

B. What is the procedure of reporting patients? ↑

C. Is the HIS docked with other information systems (such as TBIMS and IDRIMS)?

Yes:

1. Do the records upload to the disease control department automatically? Or Does the disease control department automatically grab the records of TB patients in HIS and report?

No:

1. Do you want it to have the feature of automatic uploading in the future? What improvements will it bring to your work? What are the possible difficulties?

D. Does the HIS push notification to you?

E. Does the staff in disease control department have access to the information of the entire hospital ? (if the other party is confused, explain the purpose of the question to him, such as unable to check the data if something is wrong in the data, etc.)

3) Do you access the quality of the collected data? If so, who? How to assess? If so, how to check it? (Will you check the data quality for TBIMS? Will check it by comparison with HIS?)

A. Is there any information feedback?

Yes:

1. Which institutions and what mechanisms? (It is required to mention the non designated hospitals which refer the patients)

2. Is there any channel to provide the feedback to various departments? Will you contact the doctor when there is logical mistake?

No:

1. Do you contact that institution for further verification if something is wrong with data?

2. Do you think is it necessary to provide feedback? What are the reasons or obstacles of failing to provide feedback?

B. How to deal with errors and missing in data (such as missing ID)? （Is there any possibility to delete the error record manually?）

C. Is there any mechanism to avoid quality problems such as missing, duplicate report in the information system? Is there an automatic logic check?

D. Who shall be accountable for the quality problem in data? Are there any rewards and punishments for reporting TB information?

4) Please provide a comprehensive evaluation of reporting system in the hospital.

A. Is the interface user-friendly and easy to understand? Is the system fully functional logically? Do you have any difficulties in daily operation, such as confused functions of the system, operation failures, etc.? How to solve it?

B. Is it easy to meet the format requirement when uploading data? What is the amount of narrative answers, does it increase the workload?

C. Does the data processing, collection and analysis meet the management requirements of TB patients, especially for migrants and referrals from other hospital and inside the hospital?

D. What is your satisfaction rate of the TBIMS? (System operation, data input, analysis, reporting, patient management, communication with other departments, communication with other institutions, etc.)

E. Is there any missing report or data mismatch in the system? How often? What is the most possible reason according to your knowledge?

F. What are your difficulties in daily operation? How to solve it?

5) What are your opinions and suggestions on the information system to meet the needs of reporting and managing patients of infectious diseases?

3. TB clinicians in designated hospitals

Interview Outline

1) How to contact the head of TBIMS special statistician after receiving TB patients?

A. Please indicate the differences among the outpatients, inpatients, non-local patients and referred patients? What is the specific process? What information should you provide to him?

B. Are you willing to see that the HIS is docked with TBIMS in the hospital? What improvements will it bring to your work? What are the possible difficulties?

2) Does the special statistician contact clinicians regularly to check the data quality of TB patients in HIS? If so, how to check it?

A. Is there any channels to provide feedback among various departments? How to cooperate with different departments? Will you actively remind and communicate about TB patients?

B. Will you contact the non designated hospitals in which the referred patient was to confirm the information?

C. Who shall be accountable for the quality problem in data? Are there any rewards and punishments for reporting TB information?

D. Is there an infection surveillance team in the hospital to supervise the quality? How about the quality assessment about monthly missing report and infection control in hospital?

E. What do you think is the most possible reason for data mismatch?

3) What else do you want to say about the reporting process of TB patients?

4) What are your opinions and suggestions on the information system to meet the needs of reporting and managing patients of infectious diseases?

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