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**Access to tuberculosis care in  
rural China  
– comparing the impact of  
alternative control projects**

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## ABSTRACT

**Background** China has the second highest burden of tuberculosis (TB) worldwide. The modern TB control strategies Directly Observed Treatment, Short Course (DOTS) has, since 1992, been adopted by the National TB Control Programme (NTP) with subsidized or free TB care to smear-positive TB patients. After one decade of implementation, the NTP-DOTS project now covers more than 90% of Chinese population, however, the case detection rate of smear-positive TB in China was only 33% based on the 4<sup>th</sup> national TB survey, far below the WHO target of 70%. Prompt and adequate access to and utilization of TB care are critical to TB case detection and effective anti-TB control.

**Objective:** To gain in-depth understanding of the perceptions and experiences of access to TB care among TB patients, health-care providers and TB management staff, to describe and compare health-seeking behaviours, diagnostic delays and patients' expenditures for TB care in new TB patients and patients with longer than two weeks cough; further, to study the equity in access to and utilization of TB care with respect to age, gender, medical insurance, income, education, occupation, disease profiles and the availability of NTP-DOTS project in rural China.

**Methods:** The study was set in two counties in Jiangsu Province, one NTP-DOTS project covered county - Jianhu where subsidized TB care was available in the county TB dispensary, and a non-DOTS county - Funing, where TB care was available both in general hospitals and the TB dispensary financed with out-of-pocket payment. Four sub-studies were implemented (Papers I-IV). Focus group discussion was organized with patients and health-care providers to gain an in-depth understanding of the perceptions and experiences related to access to TB care (Paper I); two cohort studies with 493 new TB patients (paper II and III) and one cross-sectional study with 1204 cough patients (paper IV) were carried out to study the access to and utilization of TB care measured by diagnostic delay, expenditures for TB care and health seeking experiences of patients.

**Main findings:** Participants of the focus group discussion reported that patients who were poor, female, and/or elderly were more reluctant to seek health care and/or tended to seek care at village health stations for cough because of financial difficulties. The mean of diagnostic delay for TB patients was 58 days in Jianhu County and 40 days in Funing County ( $p < 0.01$ ), which was due mainly to the longer provider's (47 vs. 32 days) or doctor's delay in Jianhu (31 vs. 10 days). In Funing, patients at the lowest income quartile had 63% probability of a shorter patient's delay compared to those at highest income group, and poor farmer patients had both longer patient's and doctor's delays in Funing. Less educated patients had a longer patient's delay, and uninsured patients experienced a longer doctor's delay in Jianhu. No significant differences in patient's delay were found in cough patients between the two counties (35 vs. 29 days,  $p > 0.05$ ). Forty percent cough patients in Jianhu and 78 % in Funing chose non-hospitals for their first care seeking. Poor patients and patients with lower education had higher probability to visit a non-hospital first. Less than 2% of TB patients directly visited the county TB dispensary. The economic burden of TB care was heavy in both counties.

Patients' expenditure for TB care before getting a TB diagnosis was 715CNY (Chinese Yuan) in Jianhu, much higher than the 256CNY in Funing ( $p<0.0001$ ), while it was significantly lower in Jianhu than in Funing after TB diagnosis (157 vs. 835CNY,  $p<0.0001$ ).

**Conclusion:** Poor socio-economic status is still the main barrier in access to and utilisation of TB care. The poor TB patients are benefited by the pro-poor NTP-DOTS project after they get the TB diagnosis under the project, but they suffer a heavy economic burden before they enter the NTP-DOTS project. The total patients' expenditure was not reduced substantially in the project county, but shifted from after diagnosis to before diagnosis, which implies delays in diagnosis and treatment. Findings from this study indicate that the pro-poor effects of a vertical TB control project will be reduced when a project is embedded in a market-oriented health system based on fee-for-service revenue, where provider incentives work contrary to patients' interests.

**Key words:** Tuberculosis; DOTS; socio-economic status; diagnostic delay; expenditure; health care seeking; rural; China

## LIST OF PUBLICATIONS

- I. Xu B, Fochsen G, Xiu Y, Thorson A, Kemp JR, Jiang QW. Perceptions and Experiences of Health Care Seeking and Access to TB Health Care – A Qualitative Study in Rural Jiangsu Province, China. *Health Policy* 2004, 69(2):139-149
- II. Xu B, Jiang QW, Xiu Y, Diwan VK. Diagnostic delays in access to tuberculosis care in counties with or without the National Tuberculosis Control Programme in rural China. *Int J Tuberc Lung Dis* 2005; 9(7):784–790
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- IV. Xu B, Diwan VK, Bogg L. Access to Tuberculosis care -- What did the chronic cough patients experience on the way of health care seeking?. (Submitted)

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## LIST OF ABBREVIATIONS

BCG	Bacille Calmette Guerin
CIDA	Canadian International Development Agency
CMS	Co-operative Medical System
CTD	County TB Dispensary
CXR	Chest X-ray
DALY	Disability-adjusted life years
DOTS	Directly observed treatment, short course
FGD	Focus group discussion
GDEP	The Global DOTS Expansion Plan
IEDC	Infectious and Endemic Disease Control
IUATLD	International Union Against Tuberculosis and Lung Disease
MDR-TB	Multi-drug resistant tuberculosis
MOH	Ministry of Health
NTP	National TB control programme
OR	Odds Ratio
PPD	Tuberculin Purified Protein Derivative
RR	Relative risk
SD	Standard deviation
TB	Tuberculosis
VHW	Village health worker
WHO	World Health Organization
WPRO	West Pacific Region Organization

# 1 INTRODUCTION

A woman was crying outside the cash counter of a township hospital in Funing County, China, one of the study sites. She looked thin, weak, and desperate. It was about lunchtime. The cash counter was closed. No other patients passed by. Only the lonely woman was crying helplessly. My student and I were organizing the focus group discussion in this township hospital. We accidentally saw the crying woman when we walked out for a break.

“What has happened”? “May I help you”? “Why are you crying here”? I kept asking her with deep concern in a very soft tone.

“The doctor said I got Tuberculosis”, the woman answered.

“But you can be treated effectively”.

“No, I don’t have money”.

The story seems simple. The woman’s husband was diagnosed as having tuberculosis one month ago, was under treatment and had to pay the cost of treatment out-of-pocket. Because she had also been coughing for several weeks, her husband asked her to see the doctor. “If you have tuberculosis too, I don’t have money for your treatment. You have to go back to your parents, and be treated there”; the husband told his wife. The wife was from a mountainous village of another province, where the man married her after a ‘finding a bride’ trip several years ago. They had two children since then. They were farmers with annual income of less than 2000CNY, which was barely enough to feed them.

“Do your parents have money for your treatment”? I asked.

“No, they are poorer than us. But my husband said I should go back. They can take care of me. I should not come back here unless I’m cured”.

“If you cannot be cured, what will happen”?

“I don’t know. I have no money to come back. I may not see my children again forever”.

“Do you know that there is free treatment for tuberculosis in your hometown”?

“No, I don’t know”.

The director of the hospital and the anti-TB physician found us when we were searching our pockets to find as much cash as possible to help the woman, and declined our help. They confirmed that the woman was an infectious tuberculosis case, and promised that they would try to seek exemption of treatment charges for her.

I was asking myself: Are there really many tuberculosis patients in rural China? Do the farmers really have no money for TB treatment? Why does a woman marry a man she does not know before? How can the man just abandon his wife if she cannot be cured? What kind of tuberculosis care is available in this county and how much does it cost? Why does this woman not know that a free TB care programme has been available in her hometown for at least five years? ..... Further, what are the barriers to TB care for the poor rural Chinese patients?



## 2 BACKGROUND

### 2.1 Tuberculosis

Tuberculosis (TB), an infectious disease with the etiological agent of mycobacterium tuberculosis, has probably killed 100 million people over the past 100 years,<sup>1</sup> although a cure based on chemotherapy was available for the second half of the 20<sup>th</sup> century. In 2002, TB was the world's eighth leading cause of death, and the tenth leading cause of burden of disease and injury, and was responsible for 2.8% of the world's deaths and 2.4 of disability-adjusted life years (DALY).<sup>2</sup>

#### 2.1.1 Global TB epidemiology

There were 8.8 million new cases of TB in 2002, of which 3.9 million were smear-positive. The global incidence rate of TB was growing at approximately 1.1% per year, and the number of cases at 2.4% per year.<sup>3</sup>

Most cases of TB (5-6 million) are people aged 15-49 years. The male to female ratio of reported cases in majority of countries is about 2:1. Twenty-two low or middle-income countries have been recognized as high-burden countries of TB that account for 79% of all TB cases worldwide.<sup>4</sup>

The epidemics of TB vary geographically. Sub-Saharan Africa has the highest incidence rate (290 per 10<sup>5</sup>), but the most populous countries of Asia have the largest numbers of cases; India, China, Indonesia, Bangladesh and Pakistan together account for more than half the global burden. Approximately 80% of new cases occur in 22 high-burden countries.<sup>5</sup>

Longitudinally, TB has decreased steadily in western and central Europe, North and South America and the Middle East.<sup>6</sup> By contrast, there have been striking increases in countries of the former Soviet Union and in Sub-Saharan Africa. Case number increased at 6.0% in the former Soviet Union and 6.4% in Sub-Saharan Africa in 1997-2000, much more quickly than the global average of 1.8~2.4%.<sup>7</sup>

TB thrives in conditions of poverty. Studies in USA, European countries, as well as middle and low-income countries reported that the prevalence of TB was higher among poor populations, and the outcomes of the disease were worse due to lack of TB medical care.<sup>8 9 10 11</sup> Even within the low-income countries, the TB prevalence was unevenly distributed between the rich and poor areas.<sup>12</sup> The vicious cycle of TB and poverty traps the poor countries to a high TB burden. TB is curable and can be controllable with sufficient resources and available TB care. National pro-poor activities against TB are required in the high-burden countries with the global assistances with finances and capacity building.

The general welfare of the society has brought about the decline of TB epidemic in industrialised countries before the widespread use of chemotherapy. With the improved housing, hygiene and nutrition, as well as the improved access to health service, TB, like many other traditional infectious diseases, is no longer a major public health

problem in high and most middle-income countries.<sup>13</sup> From the historical trend of TB in Sweden, a country with well-functioning surveillance system, the TB mortality rate decreased from higher than 200/10<sup>5</sup> in 1910s, to lower than 25/10<sup>5</sup> in 1950s, and the TB registration rate also decreased sharply (Figure 1).<sup>14</sup>

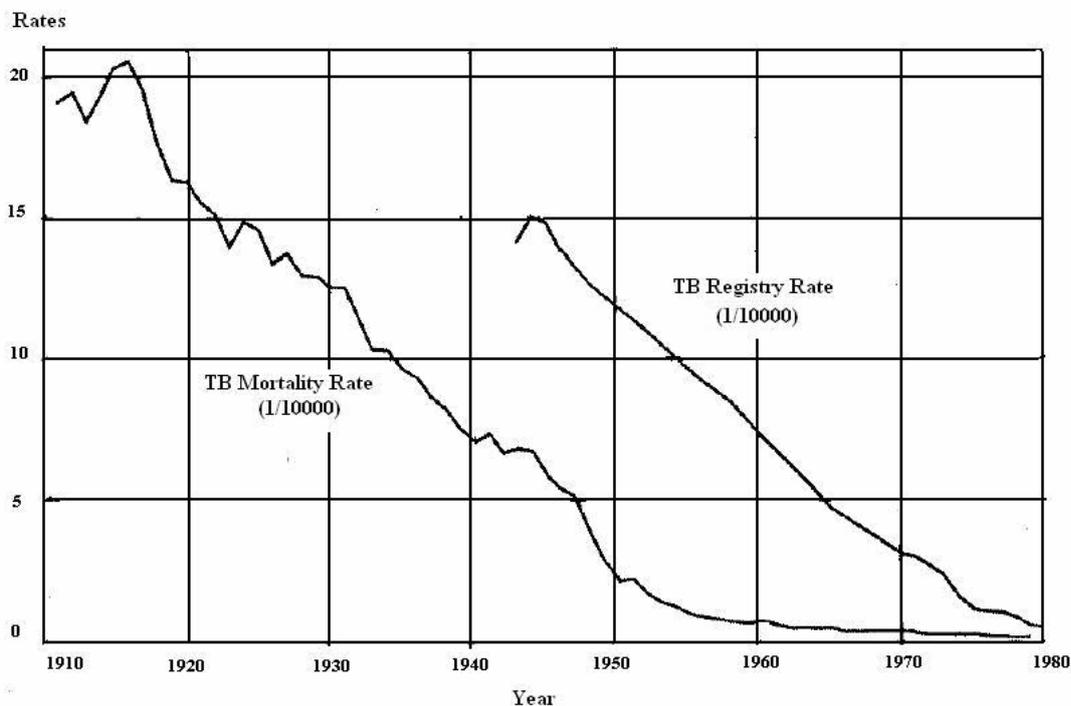


Figure 1 Tuberculosis in Sweden

(Extracted from Puranen BI. Tuberkulos, PhD thesis, Umea University, 1987)

A similar time-series distribution of TB can be found in other industrialized countries. Currently, the annual notification rates of TB in western European countries are lower than 13/10<sup>5</sup>.<sup>15</sup> The high-risk population of TB in these countries is more constrained to homeless, foreign-born immigrants and minority ethnicities.<sup>16 17</sup>

The declining trends of TB are also to be recognized in the relatively wealthy cities of the low-income countries. For example, although TB is epidemic in many of the poor rural areas of China, the TB notification rate in Shanghai, a major business centre of China with a population about 17.4 million in 2004, shows a similar declining trend as the Western countries, which could be attributed to economic growth and improving access to general and TB-specialized health services for Shanghai residents (Figure 2). Currently, TB is a public health problem mainly for the rural immigrants who are informally employed and/or unemployed in Shanghai (Figure 3).

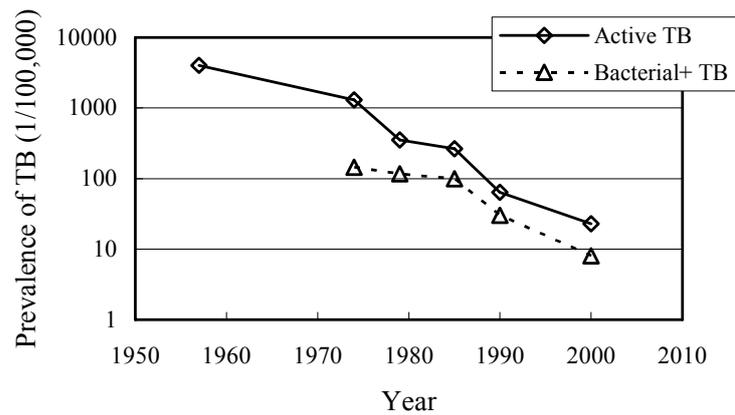


Figure 2 Prevalence of Tuberculosis among the resident population in Shanghai, China

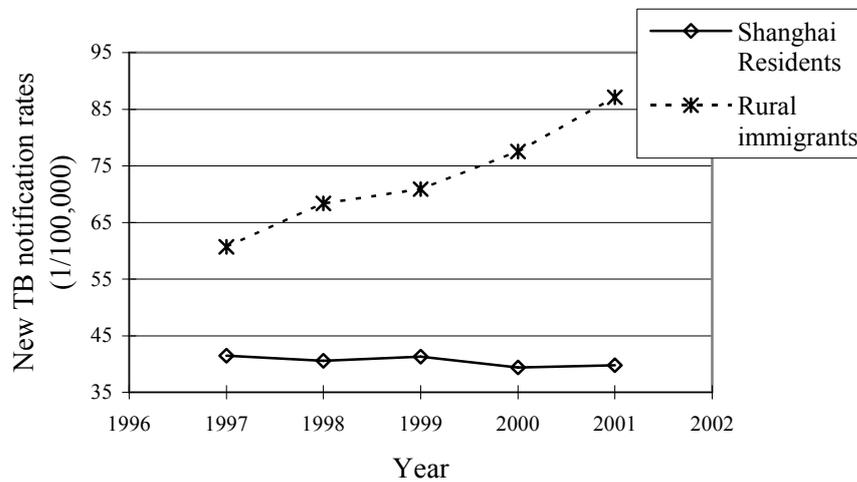


Figure 3 Notification rate of TB among residents and rural immigrants in Shanghai  
(Data source: Shanghai Centre for Disease Prevention and Control)

HIV infection accounts for much of the recent increase in the global TB burden. The high TB notification was most frequently reported in the HIV-epidemic countries. Worldwide, an estimated 11% of new adult TB cases in 2000 were TB-HIV co-infected, and it was 38% in sub-Saharan Africa.<sup>7</sup>

The TB epidemics in the former Soviet Union were deteriorating rapidly mostly due to the socio-economic crisis that followed the collapse of the Soviet Union.<sup>4</sup>

The global increasing threat of drug resistance and multi-drug resistant TB (MDR-TB) is another important reason for the TB epidemic. Drug resistance was observed more frequently in Sub-Saharan countries where TB-HIV co-infecting was dominant, in former Soviet Union countries, and in Asia. The “hot spots” of high-burden MDR-TB are Estonia, Latvia, parts of Russia and China, Iran and Dominican Republic.<sup>18 19</sup> The

non-standardised and interrupted chemotherapy treatment of TB is the main risk factor of MDR-TB.<sup>20</sup>

### **2.1.2 Global TB control**

Since the establishment of the TB sector in the 1<sup>st</sup> Expert Committee of the World Health Organization (WHO) in 1947, case management has persisted as the central technical strategy for tuberculosis control worldwide. The introduction of isoniazid in the early 1950s, and later discovery of pyrazinamide, rifampicin, and other anti-TB medicines, contributes to the major improvement of case management strategy.<sup>21</sup> The anti-TB chemotherapy has been developed from long course of mono- or combined regimes, to short treatment course, to the directly observed standardized short-course chemotherapy at present, accompanied by the managerial policy development under different TB programmes.

During 1948-63, a vertical TB control system was built with a direct line of command from a central tuberculosis division or unit down to the specialised hospitals, clinics, X-ray mobile units, and tuberculin test and BCG teams, together with the vertical training and management. This system was successfully backed by socio-economic development in industrialised countries. Active mass case finding based on chest X-ray (CXR) was effective. The decline in the annual risk of infection was accelerated from 5% in 1910-39 to 13% in 1940s-1970 after the introduction of chemotherapy in the industrialised countries.<sup>22</sup> The same approach was proposed to low-income countries, with the satellite TB clinics responsible for case finding through mass radiography and bacteriological diagnosis, and tuberculosis hospitals for segregation of patients during chemotherapy. Unlike in industrialised countries, there was no decline in TB in most low-income countries due to unsuccessful adoption of mass case finding and specialized case management, lack of recourses to cover the cost, and limited service coverage of the vertical specialized structure.<sup>23</sup>

The integration of general medical delivery to tuberculosis care was adopted after the findings on the efficacy of home treatment and the intermittent regimens with isoniazid and streptomycin. During 1964-76, the delivery of case management activities through the general health infrastructure became a national policy for TB control in most low-income countries. The concept of a national programme is countrywide, and based on simplified technology delivered through the general health services. The TB treatment had been simplified and standardized. The directly observed therapy (DOT) emerged.<sup>24</sup> However, a specialized approach was kept for the managerial functions and support to the health facilities.<sup>23</sup> The success of TB control in this period depended on increased resources, but in most situations, these resources were not allocated to the general health care services. No significant decline of TB was achieved in most of the poor countries during this period.

From 1977 to 1988, with a primary health-care promotion, TB control experienced the integration of managerial functions aiming to reach all members of the communities, and this integration was accelerated by the health sector reform in the late 1980s. At the same time, many countries suffered economic crises. The public health infrastructure was weakened, which resulted in a deterioration of quality of TB case finding and

treatment. The integration policies have brought about a loss of visibility of TB control and a loss of expertise in case management.<sup>23</sup>

The HIV/AIDS pandemic in 1980s caused a sharp increase in TB morbidity,<sup>25</sup> and the dissolution of the former USSR resulted in a significant increase in the TB incidence. The interruption of the secular decline in TB incidence rates occurred in the industrialized countries including US and several European countries such as the Netherlands, Switzerland, Sweden, Norway and Denmark.<sup>26</sup> In 1993, TB was declared a global emergency by the WHO.<sup>27</sup> A new strategic approach to TB control was established, emphasising specialized managerial functions at central, regional and district levels and, therefore, making a clear retreat from the managerial integration. The new strategy, directly observed treatment, short course (DOTS) provided a framework for effective TB control. The five elements of DOTS are: government commitment, infectious case detection using smear microscopy, directly observed standardized short-course chemotherapy, uninterrupted supply of TB drugs and an effective monitoring system. National TB control programmes in many low and middle-income countries have adopted DOTS with a special focus on the poor. With the efforts of WHO, the International Union Against Tuberculosis and Lung Disease (IUATLD), and international societies, the international financing invested in DOTS increased substantially in 1990s. In 2003, DOTS had been successfully implemented in 182 countries. The population coverage was reported to be more than 70% in all regions except in Europe.<sup>28</sup>

As the increasing recognition of the TB-HIV co-epidemic and the spread of MDR-TB, the integrated approach focused on the integration of TB and HIV/AIDS prevention and control has been emphasized since 1999.<sup>29</sup> The Global DOTS Expansion Plan (GDEP) was launched in 2001 by WHO and Stop-TB partnership. The GDEP aims to promote national coalitions between programmes and partners, to create long-term DOTS expansion plans, to address the needs of all countries, and to fill the financial gaps.

### **2.1.3 Case detection of TB**

WHO set the target of detecting 70% of all new sputum smear-positive TB cases, and successfully treating 85% of these cases by 2000 in World Health assembly, 1991, and reaffirm its commitment to reach the target by 2005 in the Stop TB Partners' Forum in Washington. At 70% case detection, 85% cure, and in the absence of HIV infection, the TB prevalence is expected to decrease substantially,<sup>30</sup> and incidence rate should decrease at about 5% to 10% per year.<sup>31</sup>

Case detection rate is the proportion of new smear-positive TB cases notified accounting for all the new smear-positive TB cases in the given population in a given year.<sup>32</sup> Most countries have neither a complete coverage of health service with accurate diagnosis, nor a sufficient recording and reporting system. Thus in practice, the case detection rate is the number of sputum smear-positive cases notified in a given year divided by the estimated number of new smear-positive cases arising in that year.<sup>33</sup>

It should be pointed out that the number of TB cases is under-reported to WHO, and so is the burden of TB in many high-burden and low-income countries because of low case detection rate and weak surveillance system. It was estimated that the overall case detection rate in the 22 high-burden countries were lower than 40%, and over two million smear-positive TB cases were not detected, three quarters (76%) of them in India (33%), China (18%), Indonesia (10%), Nigeria (6%), Bangladesh (5%) and Pakistan (5%).<sup>32</sup>

It is suggested by WHO that TB case-detection should be based on passive case finding because active case finding is not cost-effective.<sup>34</sup> Patients with TB-related symptoms, such as long-term cough should go to health-care facilities for a further examination. Mass-active case finding is not routinely adopted as the cost is far beyond the resources of the poor high-burden countries. Thus, TB case detection is influenced by whether TB patients seek health care, where and when they seek health care, and how accessible TB care is.

It was speculated that as DOTS reaches a nominal 100% coverage in the 22 high-burden countries, the case detection rate under DOTS would saturate at 40-50%, a level much lower than the 70% target.<sup>32</sup> Where are those undetected TB patients? An onion model developed by Dye provides an illustration (unpublished, based on Dye C, et al. 2003).<sup>32</sup> Among all the TB cases, those not presented to any health facility, public or private, are missing in the first layer. The cases that are not presented to the public health system and are not reported by private sectors are missing in the second layer. In the second layer, many patients are never seen by the public health systems that report to WHO; they may be treated, with unknown drug regimens producing unknown outcomes, but are never recorded. Symptomatic cases presented to public health systems, including DOTS programmes, but wrongly diagnosed, are missing in the third layer. Cases presented to public health systems, but not to specialised TB clinics and/or DOTS programmes, are missing in the fourth or fifth layer (the fourth and fifth layers might be combined in some countries). Finally, only those who are presented to health facilities, and are diagnosed as TB under DOTS or diagnosed in general health-care facilities and reported to the TB surveillance system are detected as TB cases (Figure 4).<sup>32</sup>

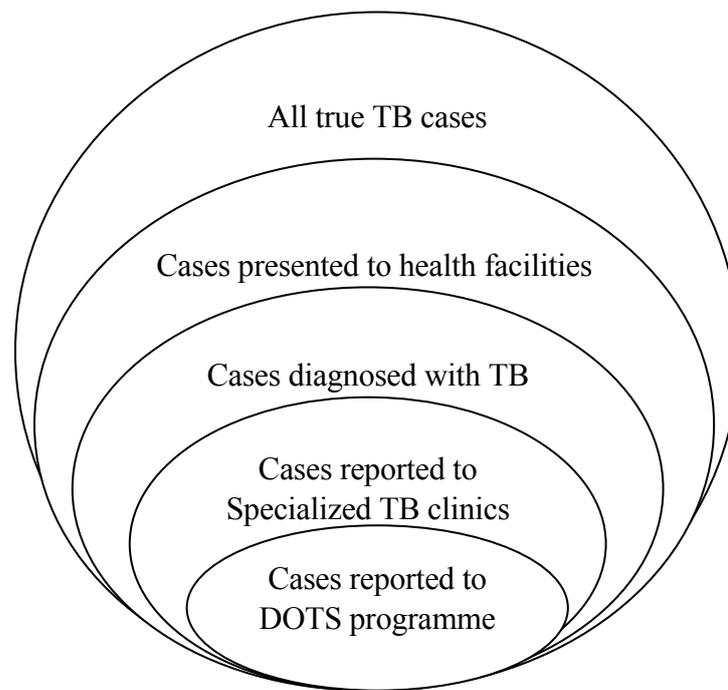


Figure 4 Why are TB cases undetected

(Dye C, unpublished, based on Dye C, et al. What is the limit to case detection under the DOTS strategy for tuberculosis control? *Tuberculosis* 2003; 83, 35–43)

#### 2.1.4 Access to TB care

Barriers to access to TB care could be identified from each step taken by people from the onset of symptoms to diagnosis, treatment and cure in the low-income countries. The barriers could be economic, geographical, socio-cultural and health system related.

##### *Economic barriers*

TB is more common in poor people as described above. During the health care seeking pathway, a proportion of patients, particularly from the poor and vulnerable groups, may drop out completely at any of the stages. Studies of access to TB care in Viet Nam, Malawi and other low-income countries have reported that charges for consultation, diagnosis tests and treatment medicines are not affordable in many cases.<sup>35 36 37</sup> Even under the free DOTS programme, the expenditures on transport, accommodation and subsistence become an economic burden for patients.<sup>38 39</sup> The ill patients will suffer the loss of income, productivity and time, which makes their economic status worse.<sup>40</sup> The economic issue incubates the barriers from socio-economic disparity and gender inequity in access to health care. Women, elderly people, illiterate people, immigrants from poor areas, and minorities are vulnerable in access to TB care due to their low socio-economic status in many countries.<sup>41 42 43</sup>

##### *Geographical barriers*

Health care providing TB diagnosis is often at central levels of health services, rather than integrated into primary-level services. The long distance to the TB care facility and the transport burden can hamper patients' access to TB diagnosis and treatment.<sup>44</sup>

39

### *Social and cultural barriers*

Stigma attached to TB leads to fear of loss of employment, marriage, and fear of social exclusion, which blocks the timely health-care seeking for TB, and causes delays to TB diagnosis and treatment in some areas.<sup>45</sup> Where female education and literacy are low, the consequences of stigma may be particularly marked for the delays in seeking TB care in women. Lack of knowledge and recognition of TB control may result in lack of attention to the disease, and lack of awareness of the importance of early detection and treatment of TB.<sup>46 47</sup> The first contact for TB help at a traditional healer could influence patient's access to TB diagnosis due to the healer's limited knowledge on TB in some Africa countries.<sup>41</sup>

### *Health system barriers*

Patients' care seeking behaviour and access to TB care may also be affected by the motivation, quality and capacity of TB care services. A study from India showed that poor people were often excluded from the TB control programme because of problems in cases administration and treatment compliance.<sup>48</sup> TB diagnosis could also be missed due to the unqualified care staff;<sup>49</sup> the rigid implementation of DOTS and the poor attitudes of health-care providers tend to alienate patients.<sup>50</sup> It should be emphasized that in countries where TB care system is embedded in the general health system, lack of responsiveness and right financing on providing a TB care in the general health system, and lack of proper integration between general and specialized systems can prevent patients from access to TB care.

In studies of access to TB care, determinants from socio-economic, demographic, geographic and health systems should not be considered separately. These determinants are interacted and have different impacts in different study settings at different care stages. The interaction among gender, economic status and stigma to access to TB care was found in Vietnam. The main reasons for delay in health care seeking in women were fear of social isolation, poor attitudes of health providers, while it was fear of individual costs for TB treatment and neglect of symptoms in men. Women with prolonged cough tend to spend less money on health care compared to men.<sup>51</sup> Among them, poverty is undoubtedly a key determinant. Yip's study on determinants of patient choice of medical provider reported that poverty might be the most important factor that causes health-care seeking delay and poor access to TB care.<sup>52</sup>

## **2.1.5 TB in China**

### *2.1.5.1 Epidemiology of TB in China*

China has the second highest burden of TB worldwide, with approximately 1.4 million new TB cases yearly, of which 650 000 are smear positive.<sup>12 53</sup>

Tuberculosis has a long history in China. The well-preserved female corpse unearthed from the Mawangdui tomb of the West-Han Dynasty (206 BC – 25 AD) in 1973 presented the evidence that the ancient lady named XIN Zhui, wife of a royal member, suffered from TB. In the twelfth century in China, TB has been considered as a communicable disease caused by a parasite. In 1930s, among the 450 million Chinese people, 27 million had TB; and the prevalence of TB was approximately 6000/10<sup>5</sup>.<sup>54</sup> When the People's Republic of China was founded in 1949, the prevalence of TB was

approximately 3500/10<sup>5</sup> in urban, and 1500/10<sup>5</sup> in rural areas respectively. The mortality of TB was 200/10<sup>5</sup>. TB (in Chinese: Lao Bing) was notorious for its high fatality, and was the leading cause of death at that time. Whenever people heard of TB, they were frightened by its high fatality. To general people, TB was perceived as having a nine of ten death toll.<sup>55</sup>

During 1950s-1960s, before the “Cultural Revolution”, with the free immunization programme of BCG, and the effective chemotherapy, the prevalence and mortality of TB dropped remarkably to 2000/10<sup>5</sup> and 40/10<sup>5</sup> respectively, a decrease of 43% in prevalence and 80% in mortality.<sup>56</sup> Post-Cultural Revolution, from 1979 to 2000, four national surveys of TB were conducted in 1979, 1984/85, 1990 and 2000 (Table 1).<sup>54,12</sup> There was a decreasing trend in TB epidemic. Compared to 1979, the annual reduction rate was 4.5% in the prevalence of TB, 3.8% in the prevalence of smear-positive TB, and 8.1% (compared to 1984/85) in the TB mortality.

Table 1 Prevalence of TB in China during 1979-2000

Year	Estimated case number. (×10000)	Estimated case of smear+ (×10000)	Prevalence (1/10 <sup>5</sup> )	Prevalence of smear+ (1/10 <sup>5</sup> )	Mortality (1/10 <sup>5</sup> )
1979	690	180	717	187	--
1984/85	570	162	550	165	35.0
1990	593	152	523	134	20.4
2000	450	150	367	122	9.8

(Extracted from the report of MOH for the four national surveys of Tuberculosis in China).

A higher prevalence of TB was reported in the rural areas of China. In 2000, the TB prevalence in poor rural areas was twice as high as in economically developed urban areas (rural 397/10<sup>5</sup> to urban 198/10<sup>5</sup>) and the mortality of TB nearly three times as high. The prevalence of TB rose rapidly after the age of 45 in males, and the increase was relatively slow in females. Males in general have a higher prevalence of TB than females at the age of above 15 years old.<sup>12</sup>

China is facing the threat of MDR-TB, and has been recognized as one of the hot spots of MDR-TB.<sup>57</sup> In the 4<sup>th</sup> National TB survey, drug susceptibility tests were carried out to 466 colonies of *mycobacterium Tuberculosis* isolated from 256 investigation points in 30 municipalities, provinces and autonomous regions. Based on the report of the survey, the initial and acquired drug resistance rates were 18.6% and 46.5% respectively; and the initial and acquired resistance rates of MDR-TB were 7.6% and 17.1% respectively.<sup>12</sup>

Currently, TB is no longer one of the first ten leading causes of death in China although it is still ranked as the second cause of death under the infectious disease category.<sup>58</sup>

### *2.1.5.2 Development of TB control in China*

TB control in China could be traced to 1930s, when the China Anti-Tuberculosis Association was founded. The key strategy of TB control at that period was propaganda on TB knowledge and outpatient care. There were in total about ten clinical TB specialists in China. In 1935, the first “Outpatient Department of Tuberculosis” was established in Beijing headed by the Chinese anti-TB pioneers Dr. He Le and Dr. Qiu Zhu Yuan with the modern medicine model on health education to the outpatients, neighbourhood management and household visits to TB cases, and active case finding with CXR. In 1937, BCG vaccines were produced in Shanghai; about 10,000 children had been vaccinated till 1948.<sup>59</sup>

After the establishment of the PR China, the TB medical care system developed step-by-step, and corresponding to the evolution of global TB managerial system. During the previous leader Mao Zedong’s period, the Chinese health system was prevention orientated, and aimed at equity in health and eradication of major infectious diseases. The coverage of TB care was expanded from organized groups in factories, mining areas, and schools to individual inhabitants, as well as from urban cities to rural counties. The vertical TB system was formed in 1950-60s, with different levels of TB control units: the specialised TB centre/dispensary in national, municipal/provincial, prefectural to county/district levels. The integration of the TB system into the general health care has been encouraged and practiced more or less since 1970s. TB care is available in general hospitals also. There are corresponding levels of hospitals and clinics that are responsible for notification, diagnosis and treatment of TB cases. The anti-TB health providers in township and community hospitals, and the village health workers are considered as the far-ends of TB care in some places of China, particularly in the DOTS-covered areas. The county and district TB centres are the basic units for case detection, case management and treatment, as well as administration of related areas of TB control. In 1995, the number of specialized TB dispensaries and TB care staff nationally were 2,603 and 27,000, respectively.<sup>56</sup>

The main approach of TB case finding has been developed since 1950s. Mass-active case finding was employed during 1950s-1970s with Chest X-Ray, fluoroscopy, and sputum smear tests, which achieved a great success in early case detection. But with a decreasing prevalence, the cost of active case finding increased. Since 1980s, the active case finding approach was hardly used except in high-epidemic areas. Screening in high-risk population was adopted afterward. Children with PPD high-plus positivity, old people, contacts of TB cases and employees in the service enterprises were considered as high-risk populations and were eligible for periodical CXR and/or sputum smear tests. In late 1970s, passive case finding was introduced. Meanwhile, the general hospitals and other non-TB special health facilities were suggested to strengthen their capacity on TB diagnosis, and to refer TB cases to TB-special facilities for treatment if they were unable to cure the patients. Chemotherapy was the main treatment to TB in China including the long-course treatment in the middle of 1950s, the standardized treatment short-course and the DOTS at present.<sup>60</sup> The DOTS-Plus aiming to the surveillance and treatment of drug-resistant TB patients is in the operational research stages.

### *2.1.5.3 The National TB Control Programme*

In 1991, the National TB Control Programme (NTP) developed a 10-year programme with the aim to halve the TB prevalence by 2000 through improving access to TB care for poor rural population. Two projects, the Infectious and Endemic Disease Control (IEDC) Project supported by a World Bank loan and the Ministry of Health supported TB Control Project, were initiated in 1992 and 1993, respectively. These initiatives introduced the WHO-recommended, five-point DOTS strategy. The IEDC project covered some 573 million people in 1,208 rural counties, and provided smear-positive TB patients with free treatment when they sought care in the TB dispensaries across the project counties. The MOH project covered around 136 million people in 356 counties and provided financially subsidised treatment to those smear-positive TB patients identified in the project counties.<sup>61 62</sup> There are some other international granted TB control projects under the NTP including projects in poor areas of China supported by Japanese Government and managed by Japan International Cooperation Agency, and a project in Tibet, Inner Mongolia and Qinghai Province supported by Damien Foundation Belgium.

Remaining are 1042 counties outside the NTP-DOTS project at the end of 2001.<sup>63</sup>

In response to the WHO and Stop-TB partnership's TB control forum in Washington, the NTP-DOTS programme has been expanded with more national and international financial and technological inputs since 2001. Apart from the increased national funding, the World Bank/DFID loan-supported NTP-DOTS was implemented in 16 poor provinces. In 2002, Canadian International Development Agency (CIDA) started co-funding the NTP-DOTS project with free TB care for smear-positive TB cases in Jiangsu, Zejiang and Shangdong Provinces.

In the NTP-DOTS-covered counties, a standardized diagnostic evaluation should be provided to patients presenting to the county or district TB dispensary. Patients with symptoms such as chronic cough, expectoration over 2-3 weeks or haemoptysis are examined by chest fluoroscopy; those with suspicious fluoroscopy findings submit three sputum (night sputum, morning sputum and on-spot sputum) samples for smear microscopy, and chest X-ray examination is performed if indicated. Patients with smear-positive pulmonary TB receive standardized intermittent treatment using streptomycin, isoniazid, pyrazinamide, and rifampin; for retreatment cases, ethambutol is added. Sputum specimens are collected at standardized intervals to document sputum conversion and cure. All TB dispensaries should provide free or subsidized diagnosis and anti-TB therapy for smear-positive TB patients.<sup>61</sup>

The major financing channels for NTP in China were the WB loan and the MOH budget for disease control, and the counterpart fund provided by financial department in province, prefectural and county for this project. The category of expenditure was mainly on goods (including drugs and equipments, etc.). Based on the requirement of the project, each project province should provide on the ratio of 1:1 counterpart fund according to the amount of loan. The counterpart fund was mainly used for patient management and project management, including free diagnosis for suspects, payment of case reporting fee and case management fee.

WHO has called the NTP-DOTS in China ‘one of the most successful DOTS-programmes in the world’.<sup>64</sup> By 2000, 1.8 million TB cases were diagnosed, free treatment was provided to 1.3 million smear-positive cases, and more than 90% were cured.<sup>65</sup> Between 1990 and 2000, the prevalence of pulmonary TB, smear-positive TB, and culture-positive TB had all fallen, respectively, by 32% (95% CI 5-68%), 37% (95% CI 7-66%), and 32% (95% CI 9-51%) more in areas in which the NTP-DOTS was implemented than in non-DOTS areas. For culture-positive disease, a 30% (95% CI 9-48%) reduction in prevalence was directly attributable to the project.<sup>66</sup> However, the achievements are questioned because of a low case detection rate of TB in China, and an overestimation and over attribution were suspected.<sup>67</sup>

#### *2.1.5.4 The convergence management system of TB under NTP*

The China NTP-DOTS not only includes the DOTS treatment strategy, but also partial system reform. The key obstacles to a successful implementation of the NTP-DOTS were identified, e.g. financial barriers to diagnosis and treatment for the patients and regressive provider incentives reducing the motivation for appropriate referrals.<sup>68</sup> The 4<sup>th</sup> national TB survey organized by MOH, WHO and World Bank investigated 365,097 subjects nationally (not including Hong Kong, Macau and Taiwan) with a random cluster-sampling design. It was found that among the 1,340 pulmonary TB patients identified in the survey, 37% reported that financial problems were the most important cause for delays in clinical consultation. More than 67% of the TB patients went to the three-tier health-care sectors, 22% to the private clinics for their first clinical consultation.<sup>12</sup>

Under the NTP, a vertical management system called the Convergence Management System of TB has been built.<sup>69</sup> Patients with TB symptoms may visit any health facilities from pharmacies to village health stations to all levels of general hospitals by their own willingness. But only TB dispensaries, mainly the county TB dispensaries (CTD), are authorized to provide TB diagnosis, treatment and case management. Patients are either self-referred or referred by village health workers or clinicians in township and county general hospitals to CTD to get chest fluoroscopy and smear microscopy for further TB diagnosis. Sputum smear tests are generally not available in township hospitals. The diagnosis of TB follows the NTP criteria, based on the recommendations of WHO and IUATLD.<sup>69 70</sup> The NTP-DOTS project provides free or subsidized TB care to infectious TB patients who are diagnosed and treated in a CTD. To encourage the referral, there are some incentives and subsidy for health workers who report or refer TB suspects who are later confirmed with smear-positive TB at CTD, for example 20 CNY per case under the World Bank loan funded NTP-DOTS project.<sup>61</sup> After getting a smear-positive TB diagnosis, patients enter the free or subsidized treatment process. The staffs in CTD together with the village health workers are responsible for the directly observed supervision chemotherapy (figure 5).

In the non-DOTS counties, no centralized and subsidized TB diagnosis and treatment were available. Patients could get TB diagnosis and treatment in township, county general hospitals as well as in CTDs. TB diagnosis in general hospitals could be confirmed in the CTD periodically based on patients’ smear slides, CXR films, medical

charts, etc. However, the confirmation of TB diagnosis follows the same NTP criteria. The confirmed TB cases were registered and reported to the TB management system.

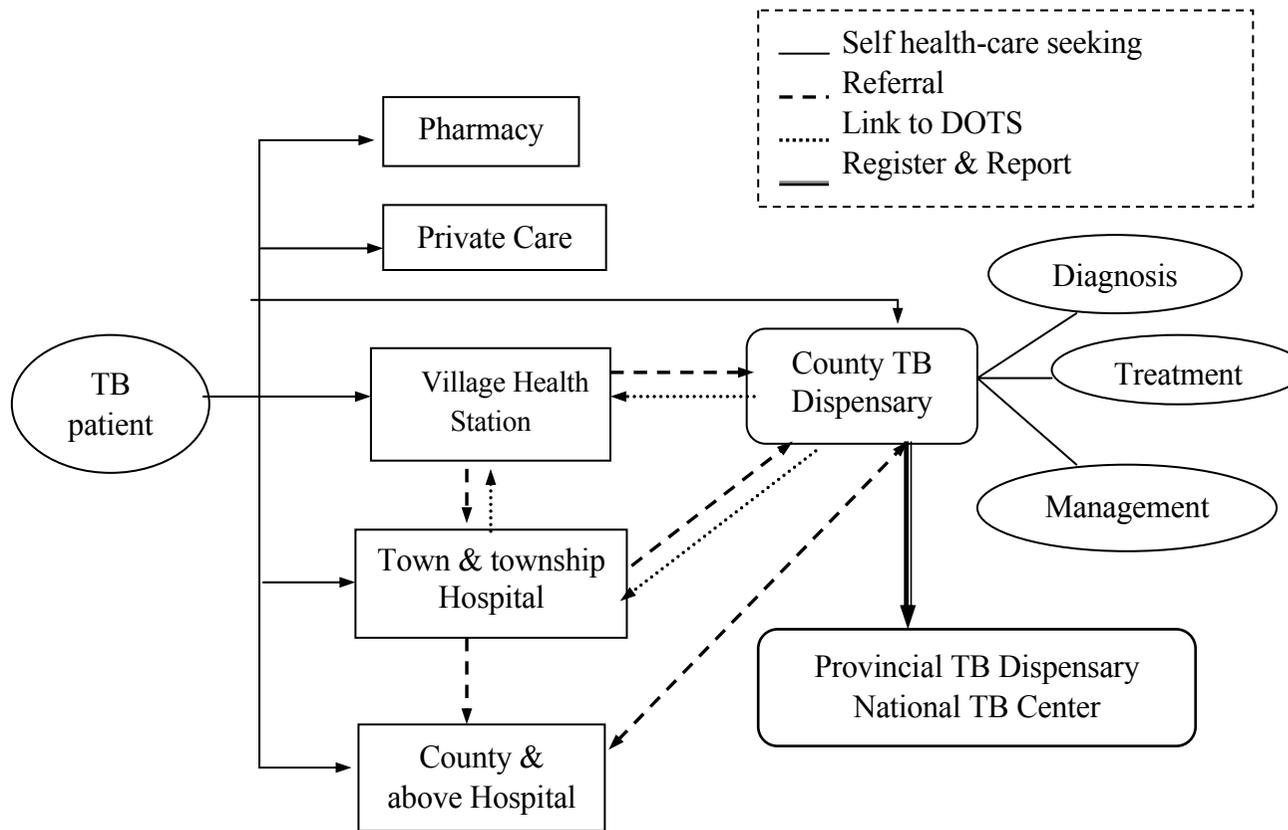


Figure 5 Convergence Management System of TB care under NTP-DOTS in rural China<sup>1</sup>

<sup>1</sup> Extracted based on the National workbook on TB control. Beijing, MOH, China <sup>69</sup>

#### *2.1.5.5 Problems on TB case detection in China*

After one decade of implementation of the DOTS strategy in more than 60% of Chinese population, and the treatment of millions TB patients, the prevalence of TB has decreased slightly, especially in the NTP-DOTS-covered areas. However, with the growth of the Chinese population, the number of smear-positive patients has not decreased substantially between 1990 and 2000. Among the 1,340 TB patients identified in 4<sup>th</sup> national survey, 378 were diagnosed in hospitals or TB dispensaries before the survey; and only 93 were registered in a TB dispensary and under DOTS. The registration rate and detection rate were 7% and 28%, respectively.<sup>12</sup> Till the end of 2003, the case detection rate of smear-positive TB in China was 43% in the NTP-DOTS area and 45% for the whole country,<sup>28</sup> which is far below the WHO target of 70%.

## **2.2 Health reform and its impact on TB care**

### **2.2.1 Health system**

The TB care system, as a part of the health-care system, modifies in parallel with the development and reform of the whole health system.

Health system is the combination of resources, organization, financing and management that culminates in the delivery of health services to the population.<sup>71</sup> Health system is composed of health authority, general and specialized health-care facility, and health related training/research institutions from national level to local level. A health system includes both public and private sectors.<sup>72</sup>

WHO defined health system as all actions in a society that are primarily intended to improve health.<sup>73</sup> The core aims of health system are improving health status; reducing health inequalities; enhancing responsiveness to legitimate expectations; increasing efficiency; protecting individuals, families and communities from financial loss and enhancing fairness in the financing and delivery of health care.<sup>74</sup> In China, three priorities for the Chinese health sector and the health of the Chinese people are: to emphasize the importance of prevention, equity, and to intensify the efforts to control and eradicate major diseases.<sup>75</sup>

### **2.2.2 Health sector reform and DOTS implementation**

To reach its goals, the health system in China has experienced reforms during the last two decades. As described above, the TB care system is embedded in the health system, which is affected by the general health system reform during its evolution, and specifically to each country's own path towards reform, with regard to its own political dynamics, institutional configuration, population characteristics, disease patterns, resources, aspirations, and specifically, the TB epidemics.

The health sector reforms have been launched in both high and low-income countries since 1980s. In the high-income countries, the motives are to increase efficiency, improve systems for cost-containment, secure equity, reduce waiting lists and increase choice of provider.<sup>76</sup> While in the low-income countries, publicly-funded health

systems have been criticized for not achieving adequate improvements in health outcomes, especially for the poor due to lack of prioritisation of cost-effective measures, poor access to quality services resulting in low utilization, non-sustainable financing and poor cost-control.<sup>77</sup> Market-orientated approaches, as a perceived strategy for improving efficiency, have been introduced and reinforced in the health sector reform. Some of the key components of health sector reform are: privatisation, decentralization, management autonomy and professionalisation, separation of purchaser-provider roles, contracting of services, evidence-based care, quality assurance, strengthened patient roles, rational priority setting and reforms of financial flows such as application of user fees in public facilities.<sup>78</sup>

Actual changes and trends from the health sector reform can be influenced by country-specific situations. However, in some countries, total costs for health care have increased faster than economic growth in general. Inequities in financing and access to health-care services have widened and the gains in terms of efficiency have been very limited.<sup>77</sup> The decreased utilization of health service has been found in the poorest and most vulnerable after the implementation of user fees and private insurance schemes.<sup>79</sup><sup>80</sup> Paradoxically, the single insurance schemes and tax financing that were installed in most countries prior to reforms have been found to be both equitable and efficient.<sup>81</sup>

From the equity point of view, health system reform should be seeking to focus public resources on public health threats and those that differentially affect the poor.<sup>82</sup> TB control meets these criteria as a disease prevalent in poor and vulnerable subgroups in low-income countries. The introduction and expansion of DOTS strategy to high-burden countries aims to improve efficiency, equity and quality for effective TB control. DOTS comprises technical strategies for TB control that have been documented as cost-effective, and replaces antiquated costly and sometimes dangerous practices. The free TB care to infectious TB cases increases the service access and utilization by the poor. However, some reported information shows adverse effects of some components of the health sector reform to TB control.<sup>83</sup> One of the most debating issues is that user fees can reduce the access to TB care for the poor through health providers' incentive to charge patients and less motivation to serve TB patients, although there is free TB care for infectious TB cases. Maintaining free care in a fee for service environment is a substantial challenge to the health-care system. Privatisation can be associated with the insufficient incentives to collaborate in TB control and insufficient capability of providing TB care.<sup>84</sup>

### **2.2.3 Health system in China**

After the establishment of the PR China in 1949, China achieved enviable improvement in the health status within 30 years; life expectancy increased from 35 to 68 years; infant mortality rates decreased from 250 to 40 deaths per 1000 live births; and a remarkable decrease in major infectious diseases, such as malaria, tuberculosis, sexually transmitted infection and vaccine preventable infectious diseases. These achievements had been resulted, in part, from the health policies of "prevention first", the emphasis on the needs of the rural population, and intensified efforts to control and eradicate major infectious diseases in the period of Mao Zedong, the first chairman of PR China.<sup>85</sup>

In late 1950s, the network of three-tier curative and preventive services was introduced. The curative service is structured as village doctors and clinics, township health centres (hospitals) and county general hospitals in rural areas; and community health centres (hospitals), district hospitals and tertiary hospitals in urban areas. The preventive service includes anti-epidemic stations (at present, Centres for Disease Prevention and Control), Maternal and Child Health hospitals, family planning centres, etc. There are also specialized hospitals and care centres from county and district levels to a national level for TB, Leprosy, STD, local endemic diseases, dental and ophthalmic care. In terms of TB care, it is available both in specialised TB hospitals and dispensaries, as well as general hospitals.

In Chairman Mao's period, the health-care expenditures in urban and rural sectors of China were financed very differently. In urban, most people were employed, and covered by government and labour insurances. While in rural, basic health care and prevention was financed by the collective economy through the Co-operative Medical System, (CMS), which at its peak, covered 90% of the Chinese rural population.<sup>86</sup>

#### **2.2.4 Health reform in China and its impacts on TB control**

Deng Xiaoping initiated China's economic reform in 1980s, characterized by a remarkable economic growth. During Deng's period, health reform was also launched in China. There are three major policy changes. First, limit the public funds available for health care. As a result, rural health services are now largely provided by fee-for-service practitioners, and patients' ability-to-pay determines supply and demand. Second, the financial independence has been given to the hospitals with the decentralization and market orientation. Hospitals now obtain the revenues from user fees. Bonus systems have been built and there are incentives for hospital management staff and doctors. Consequently, more drugs and high-technology equipments are used in hospitals for maximizing profits.<sup>87</sup> Finally, health insurance systems are subject to a reform. While the social insurance system is being adjusted and re-constructed in the urban areas, the rural CMS collapsed. In 2003, 79% of the rural population and 45% of the urban population was not covered by any type of health insurance.<sup>88</sup>

As the market-oriented economic reform successfully sustained an average growth rate of 8.3% in GDP between 1980 and 2000,<sup>89</sup> monthly disposable income of urban and rural residents increased from 478 and 191 CNY in 1980 to 1,049 and 337CNY in 2002.<sup>90</sup> But the gap between the poor and the rich has been increasing with an increasing Gini coefficient of income of 0.22, 0.29, 0.33, 0.38 and 0.41 in 1980, 1985, 1990, 1995 and 2000 respectively.<sup>91</sup> Poverty related diseases such as TB are more prevalent in the poor compared to the rich.

As a result, the inequity in access to health care has increased, especially in poor rural areas,<sup>92</sup> which affects the health of population, distorts the relationship between medical professionals and patients, and is one of the potential threats to the stability of the society.

Like in the other high-burden countries, the implementation of NTP-DOTS against TB has its pro-poor significance in China with the fee-exemption characteristic. But an effective delivery of the NTP-DOTS depends on how accessible the NTP-DOTS is to the patients, and whether TB control has become a priority of local health authorities, and how the TB control system itself is financed. A study in Shangdong province has reported recently that although smear-positive patients were supposed to obtain free TB care, in some CTD, patients were still charged for unnecessary diagnostic tests and medications, because this was the only way for the CTD to recover the cost of the clinic operations.<sup>93</sup>

## **2.3 Equity in health care utilization**

### **2.3.1 Concepts and measurements**

The health system is not only aiming to achieve the best possible level of health, but also to achieve the most fairness between individuals and groups regarding attained health through its different levels of health services and equity-orientated health financing.<sup>94</sup>

According to the Oxford dictionary, equity is defined as “fairness”, “right judgement”, “principles of justice outside common law or statute law, used to correct laws when these would apply unfairly”.

Barnum and Kutzin defined equity as “involving interaction of the risks of illness across different social groups, the availability and use of services for the illnesses and the ability of different groups to pay”.<sup>95</sup>

Health care utilization is commonly used as a proxy indicator for assessing equity in access to health care. Andersen’s model suggested that people’s use of health services is a function of their predisposition to use services, factors that enable or impede use, and their need for care.<sup>96</sup>

- Need, which refers to health status, perceived by the individual or evaluated by a health provider. Perceived need is largely a social phenomenon, which depends on how people view their own general health, as well as how they experience symptoms of illness, pain and worries about their health and how they judge the importance and magnitude of their problems to seek a professional help. Evaluated need represents professional judgment about people’s health status and their need for medical care, which relies on both biological sciences and social component including the proficiency and incentives of health-care providers.
- Enabling resources, which provide the patient with the means to make use of services, as well as to know where to get health service. The enabling resources are from both supply and demand sides, e.g. income, health insurance, travel distance, health personnel and facilities, etc.
- Predisposing characteristics, which are factors that exist prior to the onset of the ill health and need for care e.g. age, sex, genetic factors, ethnicity, education, occupation, psychological characteristics, and health beliefs related to attitudes, values and knowledge about health and health services.

From the supply side, the priorities of the national health policy, availability of specialized health intervention programmes, financing of the health-care services and orientation of the health sector reform, can also affect people's access to and utilisation of health care. In some cases, due to the mechanism of fee-for-service and bonus related payment, a supplier-induced demand makes patients being prescribed more and more expensive procedures or drugs,<sup>87</sup> which do not merely increase patients' burden, but also increase the risk of interruption of health care utilisation by the poor patients.

There are two main theories for equity in health care utilisation: egalitarian and libertarian. The egalitarian theory points toward that a state sector should be predominant, with health care being distributed according to "need" and financed according to "ability to pay"; while the libertarian theory points toward a mainly private health-care sector with health care being rationed primarily according to willingness and ability to pay. State involvement should be minimal and limited to providing minimum standard of care for the poor.<sup>97</sup>

In Europe, health policy is much more inclined towards the egalitarian viewpoint, payments toward health care should be related to ability to pay rather than to use of medical facilities, and all citizens should have access to health care. Whereas the Americans may, in principle be concerned about ability to pay in access to medical care. In practice the American health care system aims at bringing the medical care received by the poor up to a minimum standard rather than promoting equality of access.<sup>97</sup>

Studies on equity in health care utilization often use the self-rated health or self reported ill health or disease-specific ill health as the needs. The outcome measures can be number of visits for outpatient services, number of bed days for hospital service, number of days to get diagnosis and treatment, payment for the diagnosis and treatment, or more informatively, the consumption of medical resources (in other words: the cost of services). When using the expenditure as an indicator, an equitable expenditure should be progressive or at least proportional in relation to household income.<sup>98</sup> To judge whether the utilisation is equitably distributed, most of the empirical studies have examined the utilization of aggregated health services in relation to income categories. Gender, age, occupation together with education and medical insurance coverage are also recognized as important determinants. Confounding and interactions among these determinants have also been considered.

Van Doorslaer et al compared the equity in health care utilization in 10 European countries and the US. It was found that the distribution of General Practitioner care across income groups was close to what is expected, but in most of the countries studied, pro-rich inequity existed for physician contacts because the rich have a higher than expected rate of use of specialist services compared to their health needs.<sup>99</sup> Khe's study in Vietnam reported that 20% in the lowest income quintile were deterred from seeking health care in public health services due to financial difficulties, compared to 8.2 % in the highest income quintile.<sup>99</sup>

### 2.3.2 Equity in utilisation of health service in China

There is an increasing concern on equity in health and health care utilisation under the health sector reform in China. Bogg's study on maternal health care in China reported that the ratio of negative pregnancy outcomes increased by 170% from 1985-89 to 1990-95, while utilization of hospital delivery and qualified delivery supervision decreased.<sup>78</sup> An analysis on the equity in access to health services in urban China based on the national household health surveys in 1993 and 1998 found that among those in the lowest income group who reported illness but did not obtain treatment of any kind, nearly 70% (as compared with 38% in 1993) claimed financial difficulty as a major reason in 1998. The use of inpatient services dropped significantly from 4.5% in 1993 to 3.0% in 1998, which was more serious in the low-income groups.<sup>93</sup> Another study reported that there were gaps in income and economic burden of health care utilisation between rural and urban, and between the quintiles of income groups (Table 2).<sup>100</sup>

Table 2 Income and insurance coverage and payment for health care as a proportion of income in rural and urban China in 1998

Income quintile	Income per capita (CNY)		Insurance (%)		Payment in % of income per capita			
	Urban	Rural	Urban	Rural	Outpatient/visit		Inpatient/admission	
					Urban	Rural	Urban	Rural
First	1540	649	25.5	4.7	5.5	5.7	176.0	179.3
Second	2663	1118	44.6	5.9	3.9	3.3	126.8	121.5
Third	3692	1539	56.5	7.3	4.0	2.7	104.6	81.8
Forth	5229	2149	67.7	9.6	2.9	2.3	97.0	67.1
Fifth	9773	4253	74.1	17.1	2.0	1.5	68.6	49.9

(Extracted from Gao, et al., 2002).

In July 1, 2005, in his report on China's health sector reform, Gao Qiang, the Minister of Health, pointed out: "with the improvement of health status of the general population, China's health system is facing some major challenges. One of the challenges is that the system can not meet the health care needs of the population, characterized by its low accessibility and high costs." Based on the 3<sup>rd</sup> national health services survey, 48.9% of those who should seek health care due to illness didn't seek health care, and 29.6% of those who should be hospitalised did not seek hospitalisation. The main reasons of the low utilisation are a shortage of health resources; an unreasonable allocation of medical and health resources in rural versus urban areas, primary versus tertiary health care, incomprehension of medical insurance system especially in the poor rural areas (in some rural areas, two third of the poor were due to vicious cycle of poverty and illness); market orientation of public health-care sectors with fee-for-service mechanism, and the chaos in the drug and medical equipment and material market, etc.<sup>101</sup>

Although, there are very few studies addressing the equity in utilisation of TB care in China, as a poverty-related disease, it's reasonable to think that equity in utilisation of TB care will be associated with the accessibility of TB health care to the poor patients, and the function of the specific pro-poor TB control programme.

## 2.4 Conceptual framework for analysis in this thesis

Prompt health care seeking of TB patients, swift and correct TB diagnosis are the critical points to TB case detection, which is also the basis for effective anti-TB treatment. TB case detection is a reflection of whether people who need TB care, i.e. the TB patients and the potential TB patients with TB related symptoms can equitably access to TB care, and utilize TB health services.

The access and utilization of TB care could be influenced by many factors from society, health system, TB services and individual characteristics in rural China (Figure 6).

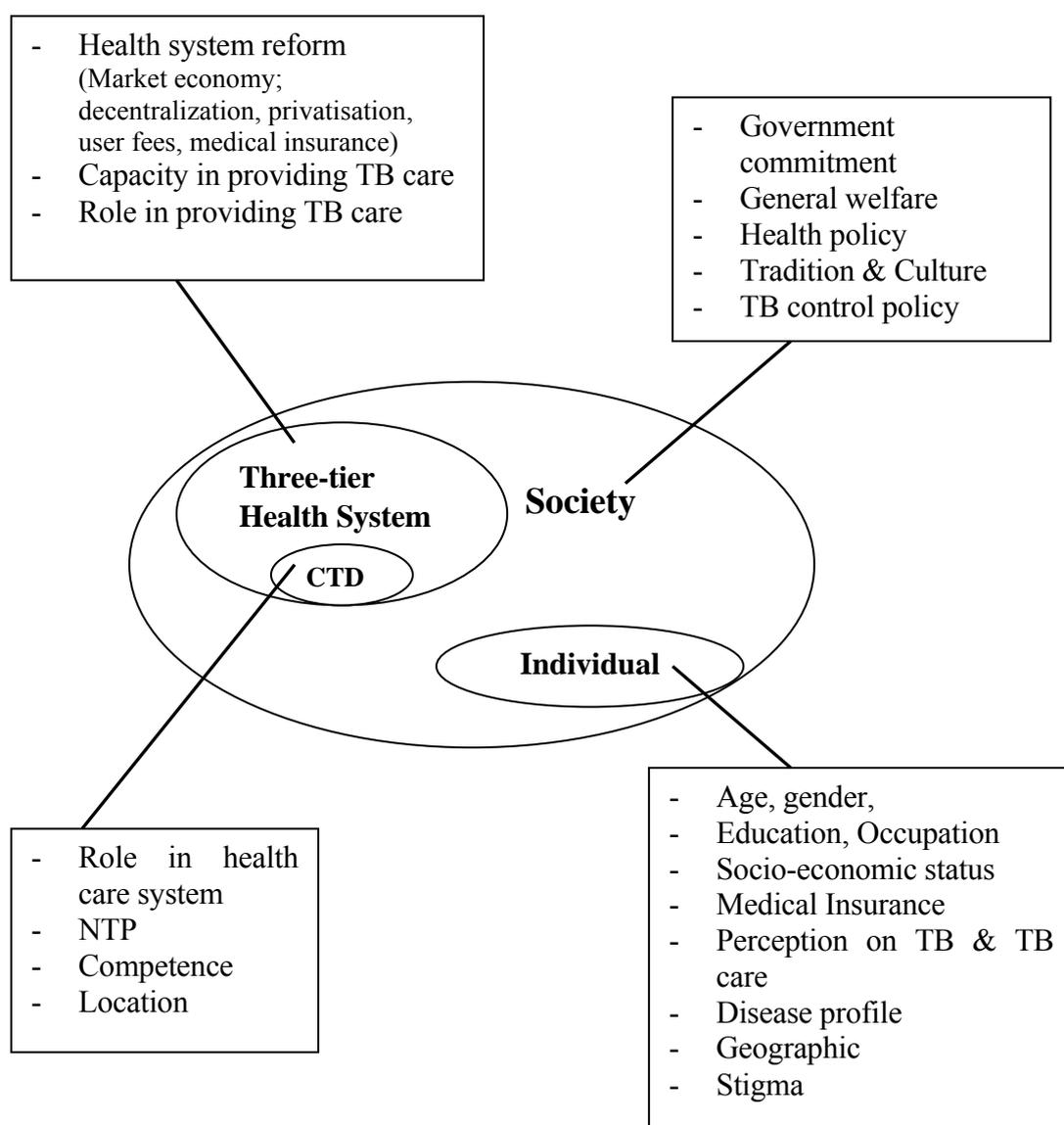


Figure 6 Factors influencing equity in access to TB care in China

The hypothesis of the studies in this thesis is that the NTP-DOTS project covered areas and the non-DOTS areas yield differences in access to and utilisation of TB care. Further the hypothesis is that socio-economic and demographic factors such as income

levels, types of medical insurance, occupation, education, age and gender will influence the access to and utilisation of TB care.

The thesis builds on a conceptual framework, modified from Long,<sup>102</sup> Whitehead<sup>103</sup> and Bogg,<sup>78</sup> which illustrates the circular relationship between TB patients, general as well as TB-specialized health care utilization and socio-economic factors (Figure 7).

1. Apart from the genetic and biologic factors, socio-economic factors influence TB infection.
2. Apart from the genetic and biologic factors, socio-economic factors influence TB development.
3. Different social-economic groups may perceive illness (the symptoms of TB) differently in terms of need for care.
4. Need is not only about people's perceptions of a need for care, but whether health care interventions, with regard to TB, the national TB control programme and the general TB care, can do anything useful towards satisfying that perceived need.
5. How a need translates into a demand is influenced by alternative sources of care, but also by the health care system itself (supply-induced demand).
6. People may have different knowledge and expectations of TB care, culturally related preferences, and therefore differential demand.
7. The actual translation of a demand into care is dependent upon supplies, as well as different factors influencing access to TB care, for example economic, geographic, cultural, organizational factors and the availability of the special TB control programme.
8. The actual pattern of utilization of TB care will depend on health care structure, patients' perception on treatment compliance, and internal organisation. Completing the loop, utilization influences morbidity. The low utilization will jeopardise the interruption of the TB infection transmission if the targeted TB case detection rate of 70% and cure rate of 85% cannot be met. The meaning of "need" is related to this fact.
9. The financial impact (9 & 10, Figure 7) will differ for different socio-economic groups. Completing the second loop the socio-economic impact will influence TB infection, and TB morbidity in ways that may reinforce or counteract the effects of care utilization.

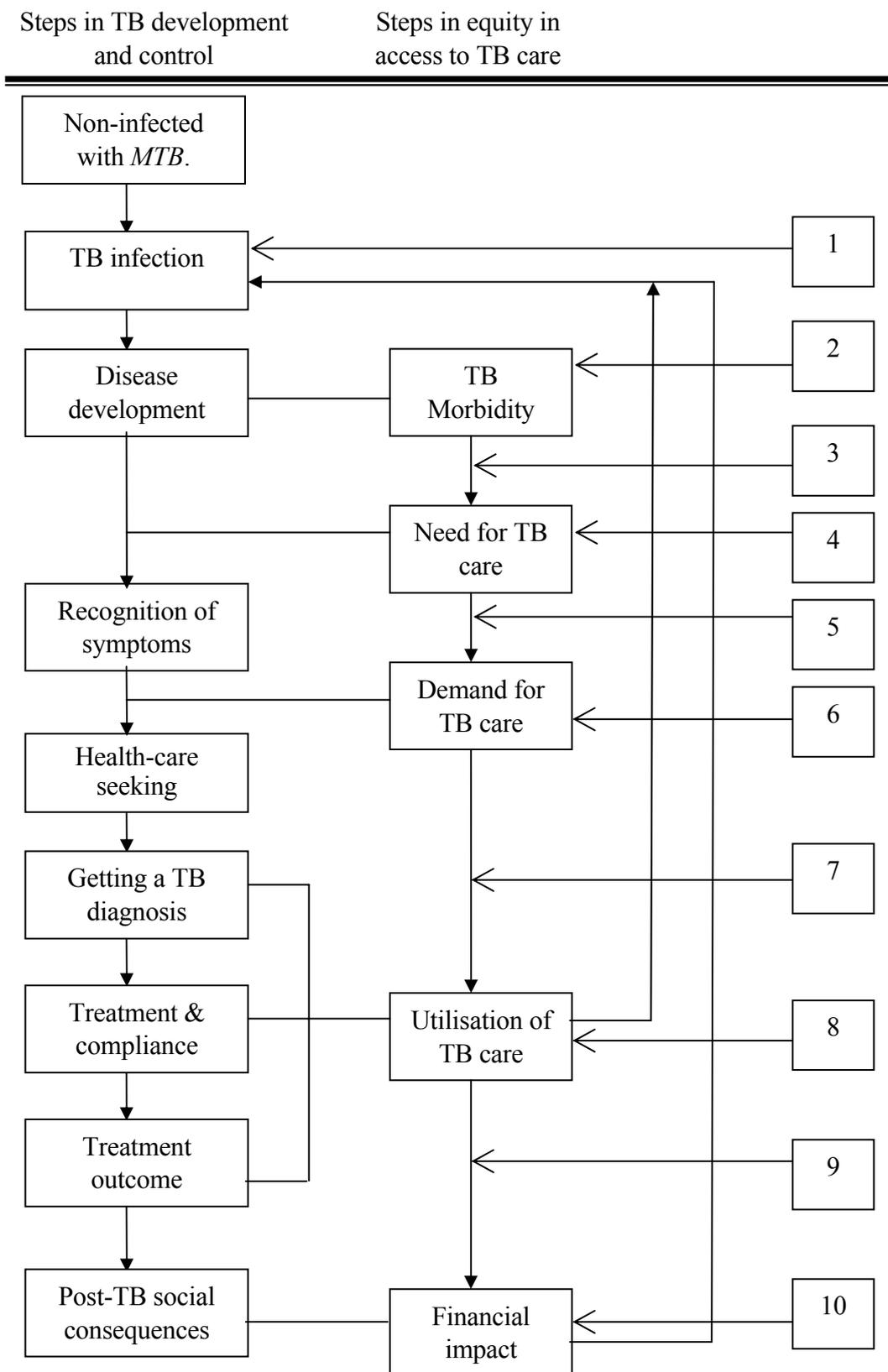


Figure 7 Conceptual framework for analysis of equity in access to TB care  
(Modified from Long NH 2000, Whitehead M 1997 and Bogg L 2002)

## **3 OBJECTIVE**

### **3.1 General objective**

The general objective is to study access to and utilization of TB care for potential TB patients (persons with prolonged cough) and new TB patients in two counties of rural China, and how access and utilisation are affected by the NTP-DOTS projects.

### **3.2 Specific objective**

The specific objectives of this study are to analyse the NTP projects in two counties with reference to the following:

- Describe and compare the TB control strategies in the two counties with respect to diagnosis, treatment and management (integrated into Papers I-IV);
- Gain in-depth understanding of the perceptions and experiences of access to TB care among patients, health-care providers and TB management staff (Paper I);
- Describe and compare health-seeking behaviours of newly diagnosed TB patients and patients' expenditures for TB care, to analyse the equity in utilization of care with respect to age, gender, medical insurance, income, education, occupation, disease profiles and the availability of NTP-DOTS project (Papers II & III);
- Describe and compare potential TB patients' health-seeking behaviour for longer than two-week's cough and analyse the equity in utilization of care with respect to age, gender, medical insurance, income, education, occupation, and the availability of NTP-DOTS project (Paper IV).

## 4 METHOD

### 4.1 Study setting

#### 4.1.1 General description

Jiangsu Province is located in east China (Figure 8-1). Two neighbouring counties in north Jiangsu Province were selected as the study sites: they were Jianhu County (JH) and Funing County (FN) (Figure 8-2). JH County has been covered by NTP-DOTS project since 1996, while FN County has not implemented any specific TB control project till the time of inclusion in this study. Both of the counties were willing to participate in the studies. The study sites were decided based on following considerations: availability of NTP-DOTS project, comparability of demographic, socio-economic and cultural characteristics between counties, willingness to participate in the study by the local health authority, local capacity for implementing the study, and the travelling distance between the study fields and the university where the researchers were located.



Figure 8-1 Map of China

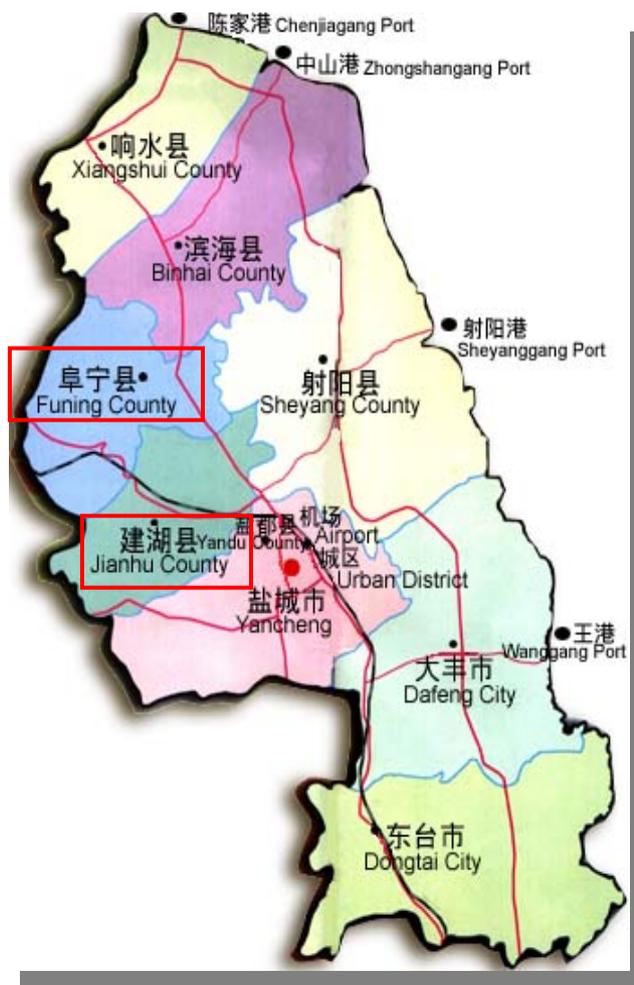


Figure 8-2 Map of North Jiangsu Province

JH and FN are neighbouring counties with similar demographic, socio-economic and cultural characteristics and have an average annual income/agriculture per capita<sup>2</sup> at around 3,500CNY in 2000. The income was above the national average of 2,366CNY<sup>104</sup>, but at the average level for the province (3,595CNY in 2001).<sup>105</sup> FN County had a slightly higher proportion of agriculture population. There are 16 and 24 townships in JH and FN respectively. The three-tier health system is similar and comprehensive in both counties, including village health stations, township hospitals and county hospitals. A village with a population of 4000~5000 usually has a village health station, or 2-3 small villages share a village health station. Each township has a township hospital that provides general medical care. Each county has a county general hospital, and a Chinese-medicine hospital. Both counties have their own county maternal & child health sector, Centre for Disease Control and Prevention (CDC) and a TB dispensary under the CDC. The indicators of health and health service were slightly better in JH (Table 3).

<sup>2</sup> In China, the annual incomes of city/town residents and rural agriculture residents are estimated separately.

Table 3 General information of JH and FN County in 2001

Items	JH County	FN County
Population (10,000 person)	79.7	106.03
Pop. Density (person/KM <sup>2</sup> )	690	732
Agricultural population (%)	70	73
AAI* (CNY / per agricultural capita)	3618	3411
Mortality (per thousands)	5.84	6.22
No. of doctors (per thousands)	3.36	1.8
No. of hospital beds (per thousands)	1.82	1.13

\*AAI: annual average income per capita.

(Extracted based on the annual statistics of Jianhu County and Funing County in 2001).

#### 4.1.2 TB care system and TB control in JH and FN before the study

In both counties, the County TB Dispensary (CTD) is responsible for TB care and case management.

In JH County, National TB control programme with DOTS strategy (NTP-DOTS) has been implemented since 1996. The first NTP-DOTS project in JH was implemented during 1996-1999, which was funded by WHO/West Pacific Region Organization (WPRO). This project provided free TB diagnosis and treatment to newly detected smear-positive TB patients, together with bonus to health providers for case finding. Passive case-finding principle was followed, and TB patients were diagnosed through smear microscopy. Standardised six-month's treatment course was adopted. From 1999 to September 2002, the NTP-DOTS project in JH was financially supported by MOH, China for the first three years, and co-funded by Jiangsu Province in the last year. The strategies of case finding, diagnosis and treatment in the MOH NTP-DOTS project are the same as the WHO/WPRO project, but in the MOH funded DOTS project, smear-positive TB patients should pay 140CNY to the CTD for the six-month's TB treatment course, which covered both the anti-TB drugs and 2-3 times smear microscopy tests and a chest X-ray examination (CXR) at the end of the treatment. No bonus was paid to health providers.

During the period of NTP-DOTS implementation, TB care in JH was centralized with the Convergence Management System. All TB diagnoses in JH are made in the CTD, where patients either self-refer or are referred by physicians in township or county hospitals. The diagnosis of TB follows the criteria of NTP, based upon the guideline recommended by WHO/IUATLD.<sup>69 70</sup> Three sputum samples (overnight and/or, morning and on-spot sputum, advised by MOH, China) were required for smear microscopy. Smear microscopy was not available in township hospitals and the outpatient department of the county hospital. Patients who obtained the smear-positive TB diagnosis received a six-month treatment under the direct observation by the village health workers. All the diagnosed TB patients, including both smear-positive and smear-negative TB patients, should be registered in the CTD, and be reported to the provincial, national TB control programme, and provincial and national infectious disease surveillance. JH County has been identified as a model TB-control county nationally by the MOH since 1997 due to its excellent performance of implementing the NTP-DOTS.

In FN County, NTP-DOTS had not been implemented before this study, and no subsidized TB care was available there. TB medical care was non-centralised; patients could get TB diagnosis and treatment at township hospitals, county hospitals, as well as the CTD. But only those TB patients whose TB diagnoses were confirmed by the CTD would be registered as TB cases, and be reported to the provincial, national TB control programme and the provincial, national infectious disease surveillance. Confirmation of TB diagnosis by the same criteria as NTP was done every three months in the CTD by the specialists in CTD together with the physicians from hospitals. Physicians of the township and county hospitals brought the medical charts, CXR films, and smear slides of patients who obtained the TB diagnosis in township or county hospitals to CTD for diagnosis confirmation. Because the diagnosis confirmation was done every three months, patients in FN usually started TB treatment in township and county hospitals before their TB diagnosis was confirmed in CTD. Only those cases with relatively strong evidence of TB including the smear results, typical TB images from CXR, and severe symptoms were submitted for diagnosis confirmation. The rest of the patients would be treated as TB patients without a registration. Subjects recruited in this study were registered new TB patients only (i.e. those with confirmed diagnosis by CTD).

#### **4.1.3 Implementation of a CIDA co-funded NTP-DOTS project in JH and FN**

From September 18, 2002, both JH and FN were assigned by the Chinese Government to implement a Canadian International Development Agency (CIDA) co-funded NTP-DOTS project built on the five key components of DOTS same as the MOH project. The CIDA project provides free diagnosis and anti-TB treatment to infectious TB cases (i.e. the smear-positive TB cases), in contrast with the subsidized TB treatment in the MOH NTP-DOTS (patient fee of 140CNY). The CIDA funded NTP-DOTS project was adopted in JH without major system changes due to the ongoing MOH project. But in FN, the referral system had to be introduced; capacity building in TB diagnosis, treatment and case management were required, and provision of free TB diagnosis and care to infectious TB cases was introduced. Although information on the CIDA project was disseminated to the hospitals and village health stations through meetings organized by the local health authorities, it was not possible to have the NTP-DOTS fully functional within the remaining study period, with the exception of the provision of free anti-TB drugs to the patients who obtained a smear-positive TB diagnosis in the CTD of FN County. However, neither the MOH nor the CIDA project provided financial subsidies for symptomatic patients before they obtained a smear-positive TB diagnosis.

The introduction of the CIDA project in FN during the study period was not anticipated. Although the recruitments of the study subjects were mainly in 2002, the comparison between the project and non-project counties in this study was, to some extent, complicated by the initiation of the CIDA NTP-DOTS project in FN in the late stage of the study. The effects of the CIDA project would, to some extent, reduce potential differences between the two counties. However, the implementation of CIDA NTP-

DOTS project offered a dual design of cross-sectional and longitudinal comparison in this study, which allowed the researchers to make a comparison of the access to TB care between counties with and without NTP-DOTS project and within counties before and after the implementation of the DOTS project.

#### 4.1.4 Distribution of TB

Before implementing the sub-studies, secondary data analysis on TB epidemics was done in both counties. Information about TB registration, documents and conference materials of TB management was reviewed. Apart from the difference in TB management, the crude reported rates of all pulmonary TB including both smear positive and negative TB were higher in FN, whereas the crude reported rates of smear-positive TB were higher in JH (figure 9). This distribution can be interpreted by the difference in the proportions of smear-positive patients accounting for all the pulmonary TB patients between the counties. In JH County, smear-positive TB patients accounted for two thirds of all pulmonary TB cases, while in FN County, the ratio was one-third in the period of 1997 to 2001 (Table 4). About two thirds of reported TB cases in these two counties were male, which is consistent with the sex-specific TB distribution in the non-HIV epidemic countries.

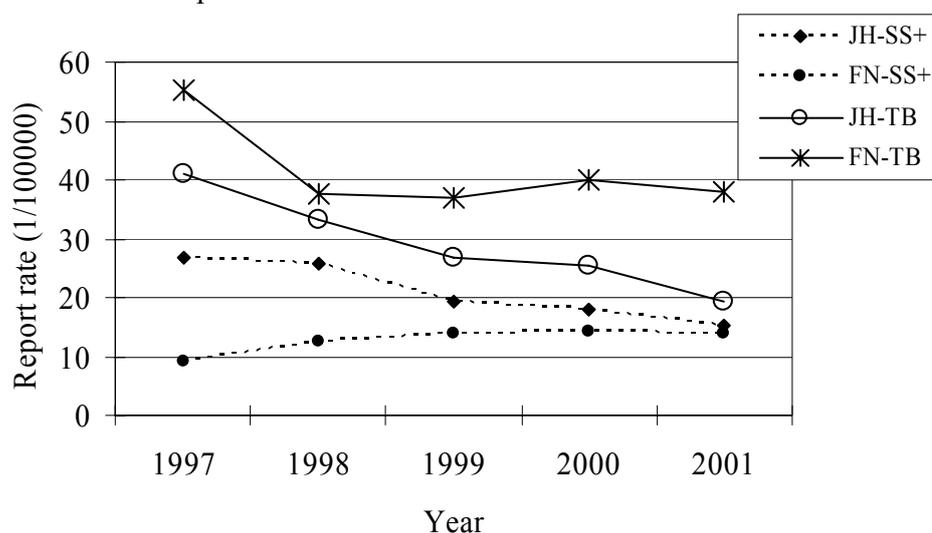


Figure 9 Notification of pulmonary TB and smear-positive TB in JH and FN

Table 4 Proportion of sputum smear positive TB patients diagnosed in JH and FN

Year	JH County				FN County			
	No. of PTB			SS <sup>†</sup> + (%)	No. of PTB			SS + (%)
	SS+	SS-	Total		SS+	SS-	Total	
1997	213	114	327	65%	99	504	603	16%
1998	204	60	264	77%	136	271	407	50%
1999	155	60	215	72%	148	245	393	38%
2000	142	61	203	70%	147	270	417	35%
2001	121	32	153	79%	142	242	384	37%

† SS: sputum smear test.

## **4.2 Study designs and data collection**

### **4.2.1 Focus group discussion (Paper I)**

Focus group discussion (FGD) is a useful method for exploring people's experiences, opinions, wishes and concerns. The method enables researchers to examine people's different perspectives as they operate within a social network. It is particularly suited to the study of attitudes and experiences around specific topics.<sup>106</sup>

In order to obtain an in-depth understanding of the factors that influence TB patients' health care-seeking behaviour and access to TB care, and to know the perception on poverty by local people in the study setting, a qualitative study through FGD was conducted among pulmonary TB patients and health providers from village health stations, township hospitals and county TB dispensaries in JH and FN during late 2001 to early 2002 (Sub-study 1, Paper I).

Participants were recruited using purposive sampling technique to cover health providers from different levels of health facility and TB patients in different stages of treatment. A total of 16 FGDs (8 in each county) were organized, consisting of 5 groups of TB patients, 5 groups of village health workers (VHWs), 6 groups of health providers with 5 groups from township hospitals, and 1 group from a county TB dispensary.

The five patient groups comprised of 9 women and 21 men in different treatment stages. The participants' ages varied from 25 to 78 years old, with a mean of 45 years. Over 85% of the participants were farmers. The average number of participants was 6 in each group.

Twenty-eight VHWs attended the five FGDs. Since most VHWs working with disease prevention in the selected counties are men, the groups included only 3 women. The participants were between 35 and 50 years old. The average number of participants was 6 in each group.

Fifteen female and 15 male health providers from township hospitals and the TB dispensary were recruited for the 6 groups of hospital providers, in average, 5 participants in each group.

The research team consisted of one Chinese epidemiologist, one doctoral student and three master students. Each group had 5 to 6 participants and the discussion lasted for approximately 1.5 hours. FGDs were conducted in a private and comfortable space.

A thematic guide, covering general as well as specific themes and questions, was utilized in the session. The questions focused on perceptions and experiences of TB care-seeking and access to TB care, such as knowledge and stigma of TB, perceived difficulties in care-seeking, and experiences on obtaining and providing TB care. (See appendix 1)

#### **4.2.2 Cohort study on new TB patients (Paper II & Paper III)**

A retrospective cohort study (Sub-study 2, Paper II,) and a retro- and prospective cohort study (Sub-study 3, Paper III) among newly diagnosed and reported TB patients were implemented with the following objectives: to describe and compare the access to TB diagnosis among TB patients as measured in elapsed time from onset of symptoms to TB diagnosis (diagnostic delay), to study the impact of selected socio-economic, demographic, health-care seeking behaviours and disease presentation variables on the diagnostic delay; further, to compare TB patients' actual expenditure for diagnosis and treatment, transport and accommodation in counties with and without NTP-DOTS project, and to assess to what extent the NTP-DOTS subsidies are contributing towards removing financial barriers to TB care. (The sub-study 2 and sub-study 3 could be considered as one cohort study with both retro- and prospective design). The information on TB care seeking experiences and expenditures of the recruited TB patients were collected both retrospectively and prospectively for a period of six months during the treatment courses. The follow-up was completed in the end of June 2003.

Subjects: All registered new TB patients diagnosed during 01/01/2002 to 12/31/2002 were the study subjects.

Data collection:

In Paper II, all the subjects were interviewed at the time of TB diagnosis at the CTD in JH or in the department of internal medicine of township/county hospitals and the CTD in FN by physicians who had received a two-day's training course for implementing the study and interview using questionnaires. A series of semi-structured questionnaires was developed for data collection. The questionnaires covered information on demographic and socio-economic factors, disease profiles and health-care seeking experiences of the subjects and patients' expenditures for TB diagnosis including expenditures on transportation, accommodation, medical care, nutrition, and other expenses (See questionnaire in the Appendix 2).

In Paper III, patients' expenditures, health-care seeking experiences before getting TB diagnosis and their general characteristics were collected in the interview at the time of TB diagnosis. Three follow-up interviews were given to the subjects at the end of 1<sup>st</sup>, 2<sup>nd</sup> and 6<sup>th</sup> month of their treatment courses. Patients' treatment experience, disease progression and expenditures after being diagnosed as TB were collected. (Paper III).

#### **4.2.3 Cross-sectional study among potential TB patients with cough (Paper IV)**

A cross-sectional study among potential TB patients with longer than two weeks cough was done in JH and FN counties (Sub-study 4, Paper IV). Information on the recruited cough patients' health-care seeking experiences from the onset of the current episode of cough to the interview was retrospectively collected. The objective of this study is to compare the health-care seeking experiences of potential TB patients with more than two weeks of cough, with regard to their health-care seeking pathway and delay and expenditures for cough-related medical care in counties with and without NTP-DOTS

project; further, to explore the barriers to potential TB patients' access to TB care in rural China.

**Study setting and study subjects:** One third of the township hospitals (six in JH and eight in FN) were purposively selected, stratified by socio-economic status (low, middle, high) of the townships based on the local statistical report in 2000. The county general hospital in each county was also included in the study. All patients with more than two weeks of cough, who visited the outpatient department of the sampled township hospitals from 1 January 2002 to 31 December 2002, and who visited the outpatient department of internal medicine in the two county general hospitals on 2 April to 23 April 2003 were recruited as the study subjects. There was only one outpatient consulting room of internal medicine in each township hospital. The expected number of patients in the selected township hospitals was 2-3 subjects per day, so data collection in township hospitals lasted for the whole year of 2002. Each county hospital had more than six outpatient consulting rooms of internal medicine, and had hundreds of patient visits every day. The expected recruitments were 5-7 subjects per day. Considering the feasibility of data collection, and not disturbing the hospitals too much, study subjects in county hospitals were recruited for a period of three weeks.

**Data collection:** The subjects recruited in the township hospitals were interviewed using semi-structured questionnaire by the physicians, who had received a two-day training course prior to the interview. The subjects recruited in the county hospitals were interviewed by the researchers and postgraduate students from the School of Public Health, Fudan University. The questionnaire included general demographic and socio-economic information of the subjects and their health-care seeking experiences from the onset of the current episode of cough to the interview (the time and place of their health-care seeking, and the expenditure they had encountered for each care episode) (See appendix 3).

#### **4.2.4 Summary of the study design**

Table 5 summarizes the study design of the four sub-studies

Table 7 Summary of study design of sub-study 1-4

Study	Sub-study 1	Sub-study 2	Sub-study 3	Sub-study 4
Papers	I	II	III	IV
Perspective	Qualitative	Quantitative	Quantitative	Quantitative
Type of Study	Focus Group Discussion	Retrospective cohort study	Retrospective and prospective cohort study	Cross-sectional study
Subjects	TB patients, village health workers, physicians, administrators	Registered new TB patients	Registered new TB patients	Potential TB patients with longer than two weeks' cough
Sampling design	Purposive selection of counties (2), purposive selection of 3 townships of each county (3+3).	Purposive selection of counties (2). All registered patients within one year (2002).	Subjects recruited in sub-study 2 were retrospectively interviewed, and followed up for 6 months during treatment till June of 2003.	Purposive selection of counties (2), purposive selection of 1/3 townships of each county (6+8). Patients who visited sampled township hospitals within one year (2002), and visited the county hospitals within three weeks in Mar-April of 2003.
Data collection	Focus Group Discussion with thematic guide	Semi-structured questionnaire, face-to-face interview.	Semi-structured questionnaire, face-to-face interview.	Semi-structured questionnaire, face-to-face interview.
Information obtained	1. Perceptions and experiences on access to TB care with regard to age, gender, poverty, education, occupation; program availability, TB care service, capacity in case detection, TB treatment and case management. 2. Perceptions on poverty.	1. Diagnostic delay & health facility utilisation for 1 <sup>st</sup> health care 2. Demographic and socio-economic variables. 3. Data on disease and care seeking experiences.	1. Demographic and socio-economic variables 2. Patient's expenditure on medical care, transportation and accommodation before and after TB diagnosis. 3. Data on care seeking experiences and expenditures;	1. Diagnostic delay & health facility utilisation for 1 <sup>st</sup> health care 2. Demographic and socio-economic variable. . 3. Patient's medical expenditure for cough related care 4. Data on care seeking experiences and expenditures;

### 4.3 Main variables & definitions

#### 4.3.1 Poverty and socio-economic status

In this thesis, poverty was defined as income poverty. Self-reported household income and household-based average income were used and grouped into quartile or decile from low to high with ascending income. The group one was considered as the poorest.

It's difficult to choose an indicator to accurately measure socio-economic status of subjects. The findings from FGD gave the research team basic knowledge about what poverty was perceived in these two counties, i.e. lack of cash income, and/or having an annual household income of 2000 CNY or less. Self-reported household and individual income, together with information on family size, housing details such as house structure, size, expenses on building, floor and wall materials and inside decoration, valuables (assets) of the family including TV set, washing machine, refrigerator, telephone and motorcycle, other products (e.g. chickens, ducks and fish) of the family, sizes of lands, etc were collected. Other socio-economic related factors such as education, occupation, holding of medical insurance were also used to reflect the influence from socio-economic status on access to and utilization of TB care.

#### 4.3.2 Diagnostic delay

Diagnostic delay is used to describe the access to TB care for different groups of patients. Figure 4 illustrates the delays defined by Long<sup>102</sup> on “Gender Specific Epidemiology of Tuberculosis in Vietnam” and modified for this study taking in the context of health care system in China.

“Total delay” refers to the duration from first symptoms to TB diagnosis. “Delay to 1<sup>st</sup> health care provider” refers to the duration from the onset of symptoms to first visit to any health care provider. “Provider’s delay” refers to the duration from first visit to any health care provider to TB diagnosis. “Patient’s delay” refers to the duration from the onset of symptoms to the first visit to a township or county and higher level of hospital; “Doctor’s delay” refers to the duration from first hospital visit to TB diagnosis (Figure 10).

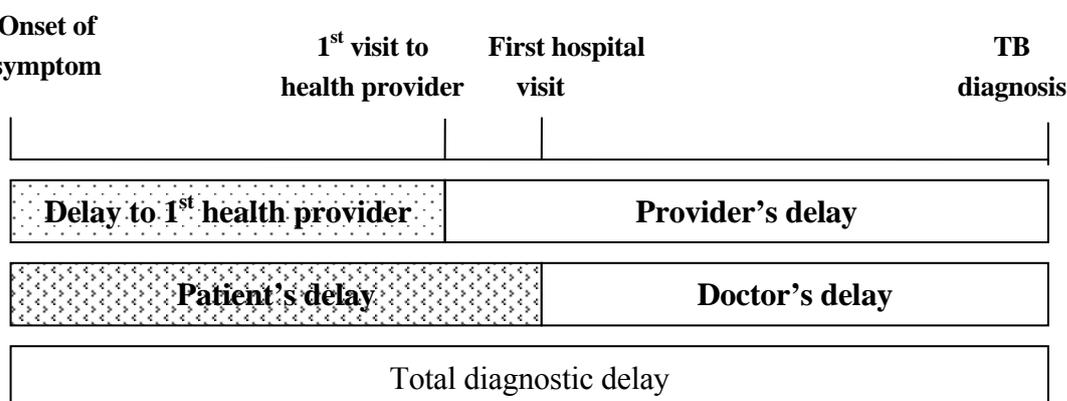


Figure 10 Definitions of diagnostic delays

### **4.3.3 Health-care providers**

In this study, health-care providers (or health providers) include private practitioners, pharmacists (in reality, assistants in the pharmacy), village health workers, and physicians in general hospitals and TB dispensaries. In China, only health-care providers in general and special hospitals/clinics or registered private clinics are defined as certified health care providers. In the village health station, village health workers (VHWs) provide primary health care services; most of them have less than 2 years of medical training. VHWs are available to rural population, especially in the geographically remote areas of China. In the village health station, patients can get care for common illnesses e.g. fever, pain, but also can receive antibiotics for infections. No registration fee is required. The price for the services is usually cheaper than the hospitals, and the payment for the services could be made later if the patients do not have money at the time of illness.

### **4.3.4 TB patients**

This study covered the pulmonary TB patients only.

New TB patient: a patient of pulmonary TB who has never received treatment for TB or has taken anti-tuberculosis drugs for less than one month.<sup>28</sup>

Smear-positive TB patient: based on WHO guideline, a patient has at least two initial sputum smear examinations (direct smear microscopy) positive for Acid Fast Bacilli (AFB); or one sputum examination positive for AFB plus radiographic abnormalities consistent with active pulmonary TB as determined by a treating medical officer; or one sputum examination positive for AFB plus sputum culture positive for *Mycobacterium Tuberculosis*.<sup>70</sup>

Smear-negative TB patients: pulmonary tuberculosis not meeting the above criteria for smear-positive disease. Diagnostic criteria should include: at least 3 sputum smear examinations negative for AFB; and radiographic abnormalities consistent with active pulmonary TB; and no response to a course of broad-spectrum antibiotics; and decision by a clinician to treat the patient with a full course of anti-tuberculosis therapy; or positive culture but negative AFB sputum examinations.<sup>28</sup>

Potential TB patient: in this study, it is an individual aged 15 and above who suffers from a cough for at least two weeks.

### **4.3.5 Patients' expenditure for TB care**

Patients' TB expenditure includes the expenditure for diagnosis and treatment at different levels of health facilities, for accommodation and transportation to and from health facilities before and after obtaining the TB diagnosis. Expenditure for other items, extra nutrition and payments or gifts for doctors were also collected. Considering that patients may not consistently volunteered such information, it was not included into analysis .

#### 4.4 Data analysis

Content analysis with an inductive approach was used for the data from focus group discussions.<sup>107</sup> When implementing the FGDs, the preliminary analysis was performed at the same day of the FGD to adjust the focus of the next FGD. The transcribed materials were coded line-by-line or paragraph-by-paragraph manually. The codes were clustered together, and similar codes were grouped to create tentative categories and sub-categories, and the main themes emerged based on the patterns and relationship between the categories.

Mean, median, quartile and proportion were utilized in descriptive analysis of the quantitative studies with Student's *t*-test, ANOVA, Mann-Whitney test, and  $\chi^2$  test. Considering the skewed distribution of the days of delay and the expenditures, and considering the sample size would be reduced after stratification in the analysis on TB patients, logarithm transformation ( $\log(x+1)$ ) and/or Mann-Whitney test were applied. In the univariate comparison of the difference in delay days within a county, due to small sample size after stratification, Mann-Whitney test was used.

To study the influences to the delay days, and adjust for the potential confounding from age, gender, occupation, education, income, medical insurance, smear result, and haemoptysis, Cox proportional hazard model (Cox regression) was applied. To analyse the influence from demographic, socio-economic factors and disease presentations to patients' selection of visiting a hospital or a non-hospital for their first health care seeking, non-conditional logistic regression was applied. To adjust for the potential confounding from demographic, socio-economic factors and disease presentations to patients' expenditure, general linear model were applied to the difference of patients' expenditure for TB care.

Definitions of independent variable are shown in Table 6. All the dichotomous variables were coded and analysed as 1 to 0. All category variables with more than two categories were coded into dummy variables, which were compared with the highest group.

Table 6 Variable definition in multivariate analysis

Variables	Value label
County	1: JH or with NTP-DOTS; 0: FN or without DOTS
Age	1: <20; 2: 20-39; 3: 40-59; 4: >=60 (Paper II) 1: 15-19; 2: 20-39; 3: 40-59; 4: >=60 (Paper IV)
Gender	0:male; 1:female
Education	0:<=6 yr (primary school); 1: >6 yr
Occupation <sup>†</sup>	1: farmer; 2: work away; 3: non-farmer
Medical insurance	0: uninsured; 1: insured
Income	Quartile from low (group1) to high (group 4)
Smear microscopy result	0: Negative; 1: Positive
Haemoptysis as presenting symptom	0: No; 1: Yes
Cavity in lung	0: No, 1: Yes
1 <sup>st</sup> health facility visit	0: Non-hospital; 1: hospital

†: Occupation was grouped as farmers: farming work on land only, work away: both farming work on land and physical work away from hometown, and non-farmers: no farming work on land.

For comparing patient's expenditures for TB care among different socio-economic groups, and for illustrating the equity in access to TB care, the proportions of patient's expenditure of the total household income were calculated.

#### 4.5 Quality control

For the data from FGD, local language and the translation from Chinese to English were the challenges to the researchers. Each FGD had a moderator and a note-taker who understood the local language. The FGDs were also tape-recorded. The tapes and notes of the FGDs were transcribed into mandarin Chinese, and then translated into English by the research team members including the author of this thesis, one doctoral candidate, and one master student from Department of Epidemiology, Fudan University. Later, the transcribed materials were re-checked by postgraduate students in the same department who originated from north Jiangsu Province and familiar with the local language by comparing the recorded tapes to the transcriptions. And the English translation was compared with the Chinese transcription again by the author of the thesis. Re-translation from English to Chinese was not done. The coding and categorising was carried out in groups by the research team.

Questionnaires: (See appendix). The questionnaires were composed of three parts: the general demographic and socio-economic information, the health care seeking behaviour (reported) and information on disease. The general information parts were designed based on the validated questionnaires used in the three national surveys for rural health service in China. The items for disease (TB) information were extracted from the medical charts. The information on health-care seeking behaviour was designed based on the information from our qualitative study and the discussions with

local TB care managers and staff. A pilot study was done in the CTD in JH before the initiation of the quantitative study.

A two-day's training course was given to the data collectors and the local project administrators in each county. On the training course, the objectives, methods, importance of the study and contents of the questionnaires, skill of interviewing were explained, taught, practiced and discussed.

The research team stayed in the counties during the first month of the quantitative study, checked the completed questionnaires everyday, and answered the questions from the interviewers. They revisited the study fields for an average of three days per month during the whole study period.

Five percent of subjects were re-interviewed for quality control in the end of 2002 in both JH and FN among recruited TB patients. The sampled subjects were interviewed again by the research team from Fudan University and the technical advisor of this study: Dr. Dong Henjing from Heidelberg University. Twenty-three of the twenty-five re-visited subjects (92%) in the quality control provided similar information as the previous interview.

#### **4.6 ETHICAL CONSIDERATIONS**

Ethical clearance of the research protocol for all the studies was granted by the Research Ethical Committee of Karolinska Institutet in December 2002 (Ethical Clearance No. 02-566, 02-567, 02-568, 02-569). In China, the research protocol was accepted by the Institutional Review Board, School of Public Health, Fudan University (IRB#02-07-0003), and the Ethic Committee, Medical Centre of Fudan University.

The studies were neither experiments, nor clinical trials. Informed consent was obtained from all the subjects. Participation was voluntary. The data were processed without names or other identifiable information.

## 5 MAIN FINDINGS

### 5.1 Perceptions and experiences on TB care (Paper I)

#### 5.1.1 Factors influencing patients' health-care seeking behaviours

In both counties, patients' health-care seeking actions were influenced by the financial difficulties. The local annual average income was thought only about 1000-2000CNY, which was perceived as poor. People who did farming only or doing both farming and heavy physical work in and out of the town, people who were old, unable to earn their own daily life, and having a chronic disease were perceived as poor due to lack of cash income. The poor would not seek health care for cough, unless they had cash in hand. Village health stations were the facility visited most often by the poor patients mainly because the service was relatively inexpensive. People, who had better education, stable job, and/or some kind of medical insurance, were more likely to visit hospitals.

Women were found to be hesitating to seek health care for cough, or more likely to seek care in village health stations not only for their poor economic status, but also for their role in family. All the participants agreed that men were primarily responsible for supporting the family, and hence greater importance was attached to their health.

*Since the man is the key person in the family, if he gets sick he has to be treated urgently. But if the woman gets TB, since it's not fatal, she'll probably not see a doctor. (Physician)*

Women's work at home was less valued and their contributions to the family were thought not the same as those of men, which made women to care for their own health less than the health of their husbands and children. But for any serious disease, a common view was that both men and women would go to see a doctor.

Elderly people were also perceived to seek health care much later than young people, and they would normally opt for the village health station for treatment. The reasons for delay were mainly related to poverty and lack of cash income. The elderly people in these two counties were usually living relying on their children.

The respondents said that the very poor (men or women, young or old), would not seek health care for cough, unless they had cash in hand. There were also reported interactions between income and gender, age, and education. Elderly people, women, and people from poor families have the least education. With the lower level of education, most women were unable to get a stable employment or income. The respondents also said that most poor people do not have medical insurance, and have to pay out of pocket for their health care.

Knowledge and perceptions on TB also influenced patients' health-care seeking behaviours. In both counties, the demands (action) for medical care when the symptoms not being perceived as TB-related were not presented as strong as when the symptoms being perceived as TB-related in the FGD. Many patient participants in FGD reported that had they known they had TB, they would have sought medical care much

earlier. Patients had very limited knowledge of TB symptoms although almost all of them knew the historically notorious TB (Lao Bing) and its fatal outcome. Cough was considered as minor ailment. Only when the cough lasted for weeks or months or the haemoptysis occurred, patients perceived their illness being serious, and took action for seeking medical care. Patients did mention that there were some TV programmes or posters on cough-TB relationship, but they only recognized this kind of things after they were diagnosed as TB. For the TB knowledge on newspaper, there were no newspapers in daily life of the agricultural family. Patient participants asked: who would pay attention to this when he or she didn't have TB?

### **5.1.2 Factors influencing patients' access to TB care**

Subsidized TB care was considered to be an important factor in improving access to TB care by all the participants.

After getting a TB diagnosis, patients from JH eulogised the NTP very much. They acknowledged the government caring for them and knowing their difficulty in payment for TB care. Although some of them still felt difficult to pay the 140CNY for the six-month's treatment and had to borrow money, they knew it cost hundreds to thousands to treat TB in the neighbour counties. Patients, especially the old patients, expressed a deep gratitude to the TB doctors in the CTD, and the village health workers who did direct observation of the treatment. Almost no one defaulted the treatment courses. They wished they had known the subsidized NTP-DOTS project before they were referred to the CTD.

Patients in FN complained of the high economic burden of TB medical care. Most of them paid more than 700CNY. The poor patients tended to quit their treatment after first two months of treatment because they felt better at that stage, and because they didn't have enough money to continue their treatment.

*I have been treated for 3 months . . . I have no money. I don't want to continue . . . Farming the land, feeding some pigs, I make about (RMB) 1000 Yuan a year. For this TB, I have spent around three hundred. I have chronic stomach disease. I'm old, so old, I'm not afraid of death. Just die!*  
(Patient)

Both patients and provider participants mentioned that access to TB care might be influenced by poor quality of TB diagnosis. They exemplified that this might be due to the failure of doctors to recognize TB symptoms, that no smear tests were conducted or that the quality of smear tests was poor.

Most of the health providers in township hospitals and village health stations didn't perceive the cough patients' needs for TB care. Many thought TB should have a symptom of haemoptysis. The most often used examination for chronic cough is fluoroscopy and CXR. In JH, unless a 'typical' TB image was recognized through CXR, physicians in general hospitals would not refer patients to the CTD for a smear microscopy. In FN, smear microscopy examinations were available both in hospitals and CTD, but were usually not provided to chronic cough patients.

With regard to TB diagnosis, in JH, staffs in CTD are well trained by the DOTS project and their lab is equipped with all the necessary equipment. But in FN, in the township hospitals, both the attitude of lab technicians and equipment in the lab were poor.

*Our lab is very poor. The ultra-violet lamp was borrowed from another hospital. The reagents for tests were given by another hospital. And the patients used some antibiotics before coming to our hospital. So the sputum smear-positive rate is very low. . . The self-protection funding is “Zero”. No ventilation tunnel, poor equipment. I’m afraid of being infected. So I do it as quickly as possible. Of course, many mistakes are made. (Provider from FN)*

“Fee-for-service” payment mechanism was another factor influencing patients’ access to and utilisation of TB care, which was recognized by both health providers and patients in the FGDs.

The whole period for getting a TB diagnosis could take several weeks to several months accompanied by repeated visits to different levels of health facilities. The focus group discussion participants informed that after coming to a health facility, most of the patients received for one or more week antibiotics through intravenous route both at the village health station or a hospital. Both patients and health providers informed that it was necessary to treat cough with antibiotics, especially cough with fever. Patients usually felt better after the antibiotic treatment, and they would not seek further health care until the next episode of cough came. Some physicians in hospitals criticised the VHWs’ intention to keep patients for better income, the VHWs criticised the high charge of health services in the hospitals. Some patients, most of them from FN County, reported being suspicious of the quality and price of drugs, and the doctor’s motivation. For the “fee-for-service” incentive, patient participants from FN County made a conclusion about all the health providers:

*The doctor is a “business” doctor. If patients are cured, doctors will lose the source of their income. (Patient)*

## **5.2 Diagnostic delay in access to TB care (Paper II, Paper IV)**

### **5.2.1 New TB patients (Paper II)**

*General characteristics and TB diagnosis of subjects:*

During Jan 1<sup>st</sup>, to Dec. 31<sup>st</sup>, 2002, totally 493 subjects were enrolled, 187 in JH County and 306 in FN County. Eighty-six percent (168/187) of new TB cases from JH and 38% (166/306) from FN were smear-positive ( $p<0.01$ ). The background characteristics of subjects between the two counties were comparable except for a higher proportion of farmer patients in JH (Table 7). Ninety-two percent of subjects had an annual average income lower than the local level.

Table 7 General characteristics of new TB patients in JH and FN County

Characteristics		JH County		FN County		<i>p</i> -value <sup>†</sup>
		No.	%	No.	%	
Age (years)	0-19	10	5.4	20	6.5	0.128
	20-39	61	32.6	86	28.5	
	40-59	60	32.1	128	41.5	
	≥60	56	29.9	72	23.5	
Gender	Male	140	74.9	216	70.6	0.314
	Female	47	25.1	90	29.4	
Education <sup>‡</sup>	≤6 years	104	55.6	167	54.6	0.877
	>6 years	83	44.4	138	45.4	
Occupation <sup>§</sup>	Non-farmer	30	16.0	92	30.1	0.002**
	Farmer	138	73.8	188	61.4	
	Work away	19	10.2	26	8.5	
Medical <sup>‡</sup>	Insured	9	4.8	18	5.9	0.612
	Uninsured	178	95.2	287	94.1	
Income compared to local average	<60%	155	82.9	253	83.0	0.999
	60-99%	18	9.6	29	9.5	
	≥100%	14	7.5	23	7.5	
Family income <sup>‡</sup> (CNY, mean)		5258		5658		0.349
Individual income (CNY, mean)		1417		1447		0.793

<sup>†</sup>: *p*-value from  $\chi^2$  test or student's *t*-test. \*\*: *p*<0.01.

<sup>‡</sup>: One missing value

<sup>§</sup>: Occupation was grouped as farmers (farming work on land only), work away (both farming work on land and informally employed for physical work away from hometown), and non-farmers (no farming work on land).

Among the 161 smear-positive patients in JH, smear positive with one, two and three plus (ascending amount of bacteria) were evenly distributed as 37%, 33% and 30%, while only 14 (12%) and 1 of the 115 smear-positive patients in FN had two or three plus results respectively.

#### Diagnostic delay

The mean of total diagnostic delay was 58 days in JH (25~75% in 12-68 days), longer than the 40 days in FN (25~75% in 11-35 days) (*p*<0.01). Provider's delay and doctor's delay were longer, while patient's delay was shorter in JH than in FN (*p*<0.01) (Table 8).

Table 8 Duration of diagnostic delays in TB patients JH and FN County (days)

Delays	Mean $\pm$ SD	Median (Quartile)	<i>P</i> -values <sup>†</sup>
<b>Delay to 1<sup>st</sup> health care provider<sup>‡</sup></b>			0.453
JH County	11.4 $\pm$ 24.1	3(1-13)	
FN County	7.9 $\pm$ 16.1	3(1-5)	
<b>Patient's delay<sup>‡</sup></b>			0.001**
JH County	26.9 $\pm$ 42.7	10(2-34)	
FN County	29.9 $\pm$ 62.7	15(7-32)	
<b>Provider's delay<sup>‡</sup></b>			0.006**
JH County	46.6 $\pm$ 81.8	18(5-49)	
FN County	31.6 $\pm$ 93.8	14(7-31)	
<b>Doctor's delay<sup>‡</sup></b>			<0.000**
JH County	31.1 $\pm$ 77.7	6(2-18)	
FN County	9.6 $\pm$ 73.2	0(0-5)	
<b>Total diagnostic delay<sup>‡</sup></b>			0.001**
JH County	58.0 $\pm$ 82.3	31(12-68)	
FN County	39.5 $\pm$ 95.6	19(11-35)	

<sup>†</sup>: *p*-value from student's *t*-test with the logarithm transformed days of delay. \*\*: *p*<0.01.

<sup>‡</sup>: One missing value in each county.

There were no statistical significant differences in delays between smear positive and negative TB patients, and between before and after the implementation of CIDA funded NTP-DOTS project in each county (*p*>0.05).

Patients who initiated health care seeking in non-hospitals arrived in the hospital later than those who directly went to hospitals in both counties (*p*<0.01) (Table 9).

Table 9 Patient's delay with regard to first health care facility visited (days)

County	First care seeking in	No. of Patients <sup>‡</sup>	Patient's delay Mean $\pm$ SD	<i>P</i> -values <sup>†</sup>
JH	Non-hospitals	76	44.4 $\pm$ 51.8	<0.0001**
	Hospitals	110	14.3 $\pm$ 29.4	
FN	Non-hospitals	240	33.5 $\pm$ 68.7	<0.0001**
	Hospitals	65	16.1 $\pm$ 28.8	

<sup>†</sup>: *p* value from student's *t*-test with the logarithm transformed days of delay. \*\*: *p*<0.01.

<sup>‡</sup>: One missing value in each county.

#### *Influence of socio-economic and non-socioeconomic factors on diagnostic delay*

Considering patients could only obtained TB diagnosis and treatment after they arrived in hospitals, influences of socio-economic and non-socioeconomic factors on patient's delay (the duration from the occurrence of symptoms to first hospital visit) and doctor's delay (the duration from first hospital visit to a TB diagnosis) were further analysed by using univariate comparison and Cox regression analysis. The risk ratio (RR, or named Hazard ratio: HR) generated from the Cox regression was used as an indicator of the probability of having a shorter delay: RR>1 indicates a greater probability, while RR<1 indicates a lower probability.

Age and sex: Patients under 19 years of age were found having a shorter patient's delay in JH (5 vs. 30, 24, and 30 days (mean) for the other age groups in ascending order), and shorter doctor's delay in FN (2 vs. 19, 6, and 7 days (mean)). But in the multivariate analysis, no statistically significant differences were found in patient's and doctor's delay among age groups and between men and women.

Occupation, education and medical insurance: Among the 493 recruited patients, more than 70% were farmers or farmers working away from hometown. Up to 94~95% had no medical insurance. About 55% had less than 6 years' education. It was found in the univariate analysis that in FN, farming patients and patients working away from home had a longer doctor's delay compared to the non-farmers (12 vs. 4 days (mean)). Insured patients in both counties had a shorter doctor's delay (3 vs. 32 days in JH, 7 vs. 10 days in FN (mean)). Patient's delay was longer among lower educated patients in JH (34 vs. 18 days (mean)). After controlling for demographic, socio-economic and symptom variables through Cox regression, in JH, patients with longer education (in years) had an increased probability of having a shorter patient's delay (RR=2.01, 95% CI:1.35-3.01,  $p<0.01$ ); patients who worked outside their hometown had a greater probability for a shorter patient's delay than non-farmers (RR=2:12, 95% CI: 1.12-4.02,  $p<0.05$ ) concerning that they should keep as healthy as possible for the heavy physical work; and insured patients were likely to have a shorter doctor's delay than the uninsured (RR=2.58, 95% CI: 1.20-5.56,  $p<0.05$ ). In FN, farmer patients were 64% less likely to have a shorter patient's delay (RR=0.64, 95% CI: 0.49-0.84,  $p<0.01$ ), and 60% less likely to have a shorter doctor's delay than non-farmer (RR=0.60, 95% CI: 0.39-0.93,  $p<0.05$ ). For farmers working away from hometown in FN, they were 32% less likely to have a shorter doctor's delay compared to non-farmer patients (RR=0.32, 95% CI: 0.13-0.83,  $p<0.05$ ).

Income: The household-based average annual income of patients was 1,417CNY and 1,448CNY respectively in JH and FN. The quartile-grouped income didn't show affect on patient's and doctor's delay in JH. However, in FN, from low to high income quartile (group 1 to group 3), the probability of a shorter patient's delay were, respectively 63% (RR=0.63, 95% CI: 0.45-0.89,  $p<0.01$ ), 72% (RR=0.72, 95% CI: 0.51-1.00,  $p<0.05$ ) and 87% (RR=0.87, 95% CI: 0.63-1.22,  $p>0.05$ ) of that of the highest income quartile (group 4). The lower the income was, the longer the patient's delay would be.

Symptoms: Patients with severe symptom of haemoptysis had an increased probability of a shorter patient's delay in both counties (RR=3.27, 95% CI: 1.77-6.06,  $p<0.01$  in JH, and RR=25.29, 95% CI: 3.31-192.52,  $p<0.01$  in FN). Patients with haemoptysis in FN were found having a lowered probability of a shorter doctor's delay in FN (RR=0.09, 95% CI: 0.01-0.72,  $p<0.05$ ).

## 5.2.2 In potential TB patients with chronic cough (paper IV)

### *General characteristics of subjects:*

Totally 1204 chronic cough patients, 550 in JH and 654 in FN, were recruited; 262 from county hospitals, 942 from township hospitals. Patients from FN had a higher proportion of farmer occupation, a lower coverage of medical insurance, and a lower mean of family or individual income than patients from JH ( $p<0.0001$ ) (Table 10). The average income of patients was 2,701CNY in JH, higher than the 1,766CNY in FN ( $p<0.01$ ). The mean durations of the current cough episode from the occurrence of cough to the interview were 35days in JH and 48days in FN ( $p<0.01$ ). Among these 1204 subjects, 316 in JH and 583 in FN had sought health care at least once before the interview.

Table 10 Background characteristics of chronic cough patients in JH and FN County

Characteristics		JH County		FN County		$p$ -value <sup>†</sup>
		No.	%	No.	%	
Age, years	15-19	35	6.4	44	6.7	0.064
	20-39	152	27.6	185	28.3	
	40-59	181	32.9	253	38.7	
	>=60	182	33.1	172	26.3	
Gender <sup>‡</sup>	Male	327	59.8	409	63.6	0.206
	Female	220	40.2	239	36.4	
Education	<= 6 years	270	49.1	335	51.2	0.429
	>6 years	280	50.9	319	48.8	
Occupation <sup>‡§</sup>	Farmer	311	56.8	452	69.3	<0.0001**
	Work away	21	3.8	33	5.1	
	Non-farmer	216	39.4	167	25.6	
Medical Insurance	Non-insured	434	80.5	605	92.5	<0.0001**
	Insured	107	19.5	49	7.5	
Household income <sup>‡</sup> (mean)		9088		6614		<0.0001**
Individual income (mean)		2701		1766		<0.0001**
Hospitals of interviewing	Township	439	79.8	503	76.9	0.223
	County	111	20.2	151	23.1	

†:  $p$ -value from  $\chi^2$  test or Student's  $t$ -test. \*\*:  $p<0.01$ .

‡: Missing value for gender, occupation, medical insurance, family income and individual income were 9, 4, 9, 18 and 19 respectively.

§: Occupation was grouped as farmers (farming work on land only), work away (both farming work on land and informally employed for physical work away from hometown), and non-farmers (no farming work on land).

### *Health care seeking delays*

The mean delay to 1<sup>st</sup> health care provider was longer in JH than in FN (25 vs. 13 days,  $p<0.01$ ), whereas patient's delay in these two counties had no statistically significant difference (34 vs. 29 days,  $p>0.05$ ). The difference in delays between counties kept the same trends with regard to the implementation of the CIDA NTP-DOTS, but the delay to 1<sup>st</sup> health provider after the implementation of CIDA NTP-DOTS was not significant (24 vs. 17 days,  $p>0.05$ ) between JH and FN (Table 11).

Comparing the delay to 1<sup>st</sup> health care provider and patients delay between the new TB patients (Paper II) and the potential TB patients with longer than two weeks cough (Paper IV), it was found that in both counties, the TB patients had sought health care earlier than the cough patients, the delay to 1<sup>st</sup> health care providers was significantly shorter among the TB patients than the cough patients (11 vs. 25days in JH, 8 vs. 13days in FN,  $p<0.01$ ), but there was no significant difference in the time of reaching hospitals between the TB patients and the cough patients (27 vs. 35days in JH, 30 vs. 29days in FN,  $p>0.05$ ).

Table 11 Delay in health care seeking for chronic cough patients in JH and FN (Days)

County	Mean	Median (25%, 75%)	Mean in CIDA NTP-DOTS		$p$ -value‡
			Before	After	
<b>Delay to 1<sup>st</sup> health care provider</b>					
JH	25.23	15 (5-23)	25.76	23.89	0.769
FN	13.29	5 (3-12)	11.99	16.64	0.139
$p$ -value†	<0.0001		<0.0001	0.111	
<b>Patient's delay</b>					
JH	34.49	20 (15-31)	35.31	32.43	0.655
FN	28.52	21 (15-31)	26.64	33.34	0.067
$p$ -value	0.070		0.058	0.852	

†:  $p$ -value in difference between counties from Student's  $t$ -test. \*\*:  $p<0.01$ .

‡:  $p$ -value in difference between before and after implementation of CIDA NTP-DOTS from Student's  $t$ -test.

### *Influence of economic and non-economic factors on diagnostic delay*

Influence of the availability of NTP-DOTS, economic and non-economic factors on patient's delay in potential TB patients was further analysed through Cox regression, considering that patients could get diagnostic examinations for TB such as CXR and smear microscopy only after they arrived in the hospital. It was found that potential TB patients in JH had a lower probability to have a shorter patient's delay although the difference between the counties was not significantly different (RR=0.884, 95%CI: 0.78-1.00,  $p=0.053$ ). The insured patients visited the hospitals earlier than the uninsured with a RR of 1.36 (95%CI: 1.10-1.68,  $p<0.01$ ).

### **5.3 Health facility selection in access to TB care (Papers II and IV)**

Among all 493 TB patients interviewed (Paper II), only 2% in JH and 1% in FN visited the CTD directly; 41% in JH and 79% in FN choose the non-hospitals for their first health care seeking (Figure 12). Before receiving TB diagnosis, 178 (95%) patients in JH, 147 (48%) patients in FN had at least one hospital/CTD visit, among them, 60 (32%) in JH, 18 (6%) in FN had twice or more hospital/CTD visits.

Similar distribution was found in the 1204 patients with longer than two weeks cough (Paper IV). In JH, 40% patients (222 of 550) visited the village health station and other non-hospitals first, whereas in FN, it was 77.7% (508 of 654). There were only two patients (0.4%) in JH and four (0.6%) in FN who had opted to go directly to the CTD for the first care seeking action (Figure 11).

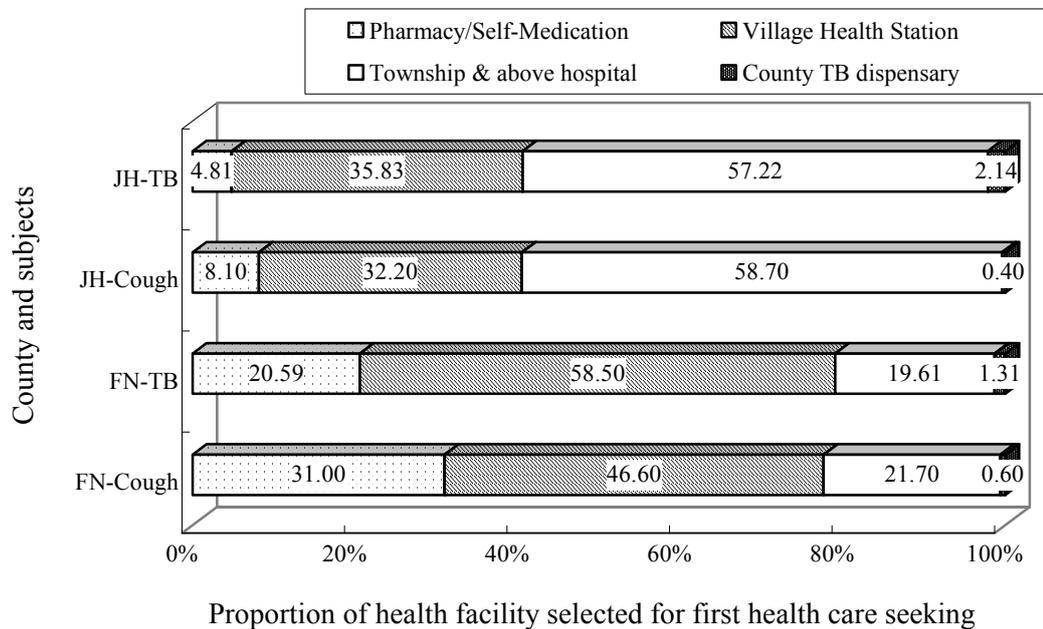


Figure 11 Health facility selection for first health-care seeking action in JH and FN

There were 46 potential TB patients in JH and 68 in FN who had had a hospital visit for longer than two-weeks' cough before the interview, that means they had met the requirements for microscopy tests. Among these patients, 10.9% in JH and 25.0% in FN were examined by smear microscopy ( $\chi^2 = 3.518, p = 0.061$ ).

The impact of economic and non-economic factors on the first health care seeking action in a non-hospital or hospital was analysed through logistic regression.

TB patients in JH were more likely to visit hospital first compared to patients in FN (OR=6.02, 95%CI: 3.91-9.24,  $p < 0.01$ ). Education, insurance and income quartile rank, together with the age and gender, did not show statistically significant effect on the hospital or non-hospital selection ( $p > 0.05$ ) (Table 12) (Paper II).

For potential TB patients with cough of longer than two weeks (Paper IV), patients in JH were more likely to choose hospitals for their first care seeking. Patients who were under 40 years of age were less likely to initiate care seeking in a hospital. Patients with better education had a higher probability to visit a hospital first. Compared to the quartile of patients with highest income, patients' quartiles with descending lower income had decreasing probability to initiate their health care seeking in hospitals (Table 12).

Table 12 Impacts of economic and non-economic factors on hospital visiting for first health care seeking in TB and chronic cough patients in JH and FN County.

Item	TB patients		Cough patients	
	OR (95% CI)	<i>p</i>	OR (95% CI)	<i>p</i>
County: JH/FN	6.02 (3.91,9.24)	<0.0001**	4.47 (3.41,5.86)	<0.0001**
Gender: Male/Female	0.86 (0.53,1.40)	0.55	0.92 (0.69,1.22)	0.557
Age, years				
<20/>=60	1.84 (0.68,4.98)	0.228	0.52 (0.27,0.99)	0.045*
20-39/>=60	1.00 (0.51,1.98)	0.999	0.47 (0.30,0.73)	0.001**
40-59/>=60	1.05 (0.60,1.84)	0.866	0.88 (0.62,1.25)	0.466
Education: >=6y/ <6y	1.66 (0.99,2.78)	0.052	1.82 (1.28,2.60)	0.001**
Occupation				
Farmer/ Non-farmer	1.28 (0.61,2.68)	0.514	0.72 (0.49,1.05)	0.091
Away/Non-farmer	1.89 (0.84,4.27)	0.125	1.83 (0.95,3.54)	0.073
Insurance: With/Without	0.75 (0.29,1.90)	0.541	1.38 (0.88,2.15)	0.156
Income quartile				
Group 1/ Group 4	1.12 (0.61,2.07)	0.720	0.44 (0.29,0.66)	<0.0001**
Group 2 / Group 4	1.07 (0.59,1.92)	0.828	0.46 (0.32,0.68)	<0.0001**
Group 3 / Group 4	0.78 (0.43,1.40)	0.425	0.82 (0.50,1.34)	0.427
Constant	0.168	0.001**	0.62	0.068

## 5.4 Economic burden on patients in access to TB care (Papers III and IV)

### 5.4.1 Patients' expenditure

Among all 493 new TB patients, 465 (94%) subjects returned for treatment, and were followed-up, 98% (183/187) in JH and 92% (282/306) in FN (Paper III). The completion of the six-month's treatment course among the followed-up patients was 95% (173/183) in JH and 91% (258/282) in FN ( $\chi^2=1.520$ ,  $p=0.518$ ). Given those who do not return for treatment were not treated properly, the completion of treatment in all the subjects was significantly higher in JH than in FN (93% vs. 84%,  $p=0.007$ ).

Patients' expenditure for TB diagnosis, treatment, accommodation and transportation to and from the health facilities for TB care before and after TB diagnosis were collected, and compared between counties, and within county between smear positive and negative patients, before and after the implementation of CIDA-DOTS project.

Compared to after diagnosis, before diagnosis expenditure including medical care and transportation/accommodation was higher in JH (715 vs. 157CNY,  $p<0.0001$ ). In FN County, it was significantly higher after TB diagnosis compared to before diagnosis (835 vs. 256CNY,  $p<0.0001$ ). The total patients' expenditure was 872CNY and 1,091CNY respectively in JH and FN ( $p<0.0001$ ). After adjustment for age, gender, occupation, education, medical insurance, household income, haemoptysis and sputum smear results using the General Linear Model, the mean patient's expenditure was 357CNY higher ( $p=0.001$ ) in JH than in FN before TB diagnosis, and 727CNY less in JH ( $p<0.0001$ ) after TB diagnosis. The total mean patient's expenditure was 371CNY less in JH ( $p=0.006$ ). With regard to smear status, no statistically significant differences in items of expenditure between smear-positive and smear-negative patients were found in JH and FN County (Table 13).

Table 13 Patient expenditure for care before and after TB diagnosis (CNY)

County	Mean	Median	Min-Max	<i>p</i> -value <sup>†</sup>
	Total (SS+, SS-) <sup>‡</sup>	Total (SS+, SS-)		
<b>Before obtaining TB diagnosis</b>				
Medical				<0.0001**
JH	686.00 (611.03, 1212.68) <sup>NS</sup>	270 (283,199)	0~12000	
FN	245.38 (358.12, 167.74) <sup>NS</sup>	135 (150, 130)	0~6030	
T & A <sup>§</sup>				<0.049*
JH	29.08 (28.79, 31.27) <sup>NS</sup>	4 (4, 2)	0~1500	
FN	10.90 (14.92, 8.13) <sup>NS</sup>	0 (0, 0)	0~380	
Total				<0.0001**
JH	715.08 (642.82,1243.95) <sup>NS</sup>	280 (285, 206)	0~12000	
FN	256.28 (373.04, 175.87) <sup>NS</sup>	144 (160, 140)	0~6330	
<b>After obtaining TB diagnosis</b>				
Medical				<0.0001**
JH	90.21 (86.61, 116.59) <sup>NS</sup>	146 (146, 146)	0~646	
FN	704.02 (748.01, 673.71) <sup>NS</sup>	567 (560, 570)	0~8756	
T & A <sup>§</sup>				<0.0001**
JH	66.38 (66.99, 61.91) <sup>NS</sup>	55 (55, 56)	0~1202	
FN	130.56 (152.66, 115.35) <sup>NS</sup>	99 (106, 90)	0~1850	
Total				<0.0001**
JH	156.59 (153.60, 178.50) <sup>NS</sup>	171(162, 197)	0~1202	
FN	834.58 (900.67, 789.06) <sup>NS</sup>	690 (660, 690)	10~10606	

†: *p* value from Student's *t*-test in difference between counties. \*: *p*<0.05; \*\*: *p*<0.01.

‡: †: *p* value from student-*t* test with the logarithm transformed expenditures between smear positive and negative (SS+, SS-) patients in each county. NS: *p*>0.05, non-significant.

§: Transportation and accommodation.

Sixty percent (110/183) of patients in JH and 83% (253/282) in FN were recruited before the implementation of the CIDA-DOTS project. At the stage of before TB diagnosis, without the implementation of the CIDA-DOTS project, patients' expenditure was significantly higher in JH than in FN; with the implementation of CIDA-DOTS project, the differences between counties were no longer significant, with a significant increase of patients' expenditure on medical care and the total expenditure in FN (*p*=0.026). At the stage of after TB diagnosis, the patients' expenditure on medical care significantly decreased from 148CNY to 4CNY (*p*<0.0001) in JH, whereas still cost about 508CNY in FN although a decrease was found in FN either with the implementation of CIDA-DOTS project (*p*=0.023). Both medical expenditure and transportation were significantly lower in JH than in FN after TB diagnosis regardless of the implementation of the CIDA-DOTS project (Table 14).

Table 14 Patient's mean expenditure before and after TB diagnosis with and without CIDA-NTP (CNY)

Expenditure	County	Before CIDA-NTP		After CIDA-NTP		<i>p</i> -value <sup>‡</sup>
		<i>m</i> ± <i>s</i>	<i>p</i> -value <sup>†</sup>	<i>m</i> ± <i>s</i>	<i>p</i> -value <sup>†</sup>	
<b><i>Before obtaining TB diagnosis</i></b>						
Medical	JH	672 ± 1500	0.010**	708 ± 1232	0.671	0.082
	FN	204 ± 282		451 ± 994		0.026*
T & A <sup>§</sup>	JH	34 ± 153	<0.0001**	21 ± 37	0.333	0.285
	FN	9 ± 31		20 ± 53		0.096
Total	JH	706 ± 1570	0.006**	729 ± 1248	0.573	0.770
	FN	213 ± 294		471 ± 1037		0.026*
<b><i>After TB diagnosis</i></b>						
Medical	JH	148 ± 64	<0.0001**	4 ± 20	<0.0001**	<0.0001**
	FN	743 ± 882		508 ± 309		0.023*
T & A <sup>§</sup>	JH	65 ± 42	0.019*	69 ± 141	<0.0001**	0.692
	FN	126 ± 173		155 ± 105		0.156
Total	JH	213 ± 74	<0.0001**	73 ± 145	<0.0001**	<0.0001**
	FN	869 ± 998		663 ± 320		0.145

†: *p* value from Student's *t*-test with logarithm transformed expenditures on difference between counties. \*: *p*<0.05, \*\*: *p*<0.01

‡: *p* value from Student-*t* test with logarithm transformed expenditures on difference before and after the implementation of CIDA-NTP in each county. \*: *p*<0.05, \*\*: *p*<0.01

§: Transportation and accommodation

The mean patient's expenditure before diagnosis varied at different levels of health facility. The highest payment was found at county level (tertiary) health facility, 821CNY in JH and 655CNY in FN with approximately 50CNY for transportation and accommodation in both counties. The expenditure at township hospitals and village health stations was considerably less, 310CNY and 268CNY respectively in JH, 211CNY and 134CNY respectively in FN. Expenditure at village health station and other non-hospitals was higher in JH than in FN County (Table 14).

For cough related medical care, the potential TB patients' expenditure (Paper IV) on average was 346CNY in JH and 256CNY in FN, with a similar distribution to the TB patients in different levels of health facilities (Table 15). Expenditures in non-hospitals in JH were higher than in FN (222 vs. 133CNY, *p*=0.016). This could be a reason why more patients directly visited hospitals instead of the village health stations in JH. The better health service indicators with regards to number of doctors in JH (3.36 vs. 1.8 doctors per thousand people) could also be one of the reasons.

Table 15 Patient's expenditure on medical care for TB and cough at different levels of health facilities (CNY)

Health facility	JH County			FN County			$p^\dagger$
	No.	Mean	Median	No.	Mean	Median	
<b><i>TB patients before diagnosis</i></b>							
VHS and similar <sup>‡</sup>	79	268	200	213	134	103	0.027*
Township hospitals	124	310	100	95	211	130	0.142
County hospitals	85	821	296	31	655	210	0.615
<b><i>Cough patients before the interview</i></b>							
VHS and similar <sup>‡</sup>	235	222	100	514	133	110	0.016*
Township hospitals	67	249	127	67	200	121	0.759
County hospitals	63	641	306	116	580	415	0.800

†: student-*t* test with logarithm transformed expenditures. \*:  $p < 0.05$

‡: Village health station and other non-hospital facilities.

#### 5.4.2 Economic burden on the household due to expenditure on TB care

Patients' expenditure on TB medical care and transportation during the whole period accounted for 21.8% (Range: 2-244%) of the annual household income in JH and 34.4% (Range: 2-744%) in FN County. The mean patient expenditure for TB medical care as a proportion of the household income decreased as the income increased in both JH and FN, both before and after TB diagnosis (figure 13). The poorest group on average spent 96% of the household income on TB medical care *before* TB diagnosis in JH and 98% of the household income *after* TB diagnosis in FN (Paper III).

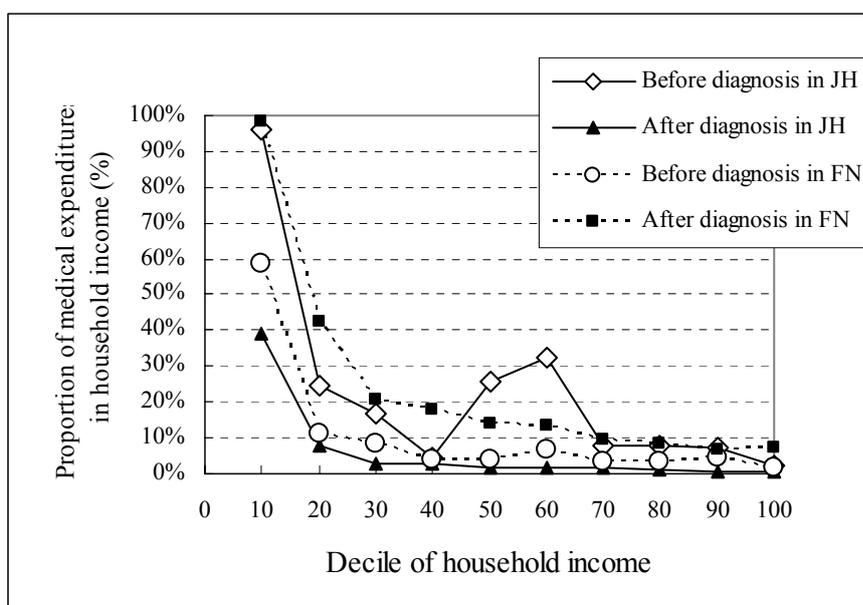


Figure 13 Patients' expenditure on TB medical care before and after diagnosis as a proportion of the household income for income deciles in JH and FN

For the potential TB patients, the proportion of the patient's expenditure for cough-related care accounting for the average income decreased as the income quartile increased, a negative correlation was found in both counties ( $p < 0.01$ ). The poorest quartile spent 50% of their average income for cough care, whereas it was less than 10% for the richest quartile (Paper IV).

## **6 DISCUSSION**

### **6.1 Methodological considerations**

#### **6.1.1 FGD in Chinese context**

Focus group discussions are ideal for exploring people's experiences, opinions, wishes and concerns.<sup>107</sup> Literature on the use of FGD in the Chinese population is scarce, quantitative studies dominate the health care research, although there is an increasing trend of using qualitative research methods in China. Recently, a study of 12 FGDs on health-care providers was reported as a complement to a questionnaire survey on measuring the doctors' satisfaction to their position in an evolving health-care market. The FGDs enabled a deep exploration of the underlying reasons and gave doctors an opportunity to voice their concerns.<sup>108</sup> In the FGDs reported in this thesis, the explorative nature generated data on patients and health-care providers' perceptions and experiences, and the data were useful for further quantitative studies including design of questionnaire and variable definition. This method is extremely meaningful in the context, because very little in-depth research on the perceptions and attitudes of TB patients and providers in China has been reported from a qualitative perspective.

The findings from FGDs are assessed according to the criteria of trustworthiness. The trustworthiness of the findings can be achieved by gathering data from participants with various experiences to shed light on the research question from a variety of aspects.<sup>109</sup> It is important to include the diversity and to make particular efforts to consider the voices that might be excluded. In this study, male and female patient participants with different occupations and socio-economic status were included. Patients were in different TB care stages (treatment completed, treatment ongoing, and treatment interrupted) with their own specific experiences and perceptions of access to TB care. Health provider participants represented different levels of health facilities, including village health workers, physicians, nurses and TB programme staff.

With regard to the gender homogeneity of the participants in each FGD, one problem identified in this study was that there were more male health-care providers than female providers included in the FGD, and no gender specific FGDs (separate for male and female) were organized. The reason is that most health-care providers in the TB control area - especially physicians and programme managers - are male, and about 90% village health workers are male. Women work mainly in nursing, laboratories and data management. The composition of FGDs reflected to a large extent the dominance of male health-care providers in the Chinese health system in rural areas. However, from our observations, both male and female provider participants were active in the discussion to provide own experiences or to general perceptions on TB and TB care. In the FGDs with patients there was no obvious hierarchical pattern in the discussion among the participants. All participants seemed to feel at ease and discussed lively the topics that were introduced by a moderator. Based on the information on tapes and notes from FGDs with TB patient participants, more than fifty percent of the contributions were made by female patient participants.

Due to the obvious considerations to speak correctly, the health providers seemed anxious to answer in a 'correct' way backed up by the government policies and the TB control workbook, especially in the group composed of staff from the county TB dispensary. By organizing more FGDs in township hospitals rather than the county TB dispensary, and by adding more specific issues about social roles and their own experiences of providing health services, providers revealed beliefs and experiences.

### **6.1.2 Precision of quantitative studies**

Precision, or reliability, is to minimize random errors. Precision can be improved in two ways: increase the size of the study, and modify the design of the study to increase the efficiency with which information is obtained from a given number of study subjects.<sup>110</sup>

For any epidemiological study, the sampling process incurs random errors. The purpose of sampling is to measure the effects under study more accurately at a given cost, i.e. to reach a higher degree of precision for the least amount of resources. In general larger sample sizes will incur lower random error. Also the sampling strategy can improve the precision.

Multistage sampling was used in this study, beginning with purposive selection of the study counties. In Paper II on TB patients, all new TB patients during one year were included in the study. In Paper IV on cough patients, one-third of the township hospitals were sampled stratified by the income level of townships, and all eligible cough patients during one year (2002) were included. From the county hospital, all eligible cough patients during a three-week period in the year 2003 were recruited.

The reasons for the sampling strategy were to ensure willingness to participate, to recruit sufficient numbers of subjects, to consider the feasibility in different health facilities (for example, in Paper IV, in the 14 township hospitals and 2 CTDs, usually there were less than 10 patient visits per day, so the daily recruitment was feasible. While in the two county hospitals, there were hundreds of patient visits per day, so three weeks recruitment was acceptable for the hospital involvement, the recruitment amount and the cost). An assumption of the sampling was that patients came to the hospital randomly at the given recruiting period. It should be mentioned that a multistage sampling has its weakness on the precision due to the increasing random error.

Study power was considered before sampling. In Paper IV, using the proportion of chronic cough patients who have been referred to CTD before the interview as an indicator, if 20% of the cough patients in the NTP-DOTS county have visited the CTD, while it is 10% in the non-DOTS county, to reach a study power of 90% at  $\alpha=0.05$  level, a sample size of 286 cases in each county is required. Adding 10% for random errors from multistage sampling, the expected sample size of chronic cough patients is about 320 in each county. In Paper II, using the proportion of TB patients with a longer than two weeks patient's delay as the indicator, if the proportion is 20% in the NTP-DOTS county, while it is 40% in the non-DOTS county, to reach a study power of 90% at  $\alpha=0.05$  level, the expected sample size should be more than 118 new TB patients in each county.

The post study power was examined with the results of Papers II and IV. In Paper II, when comparing patient's delay and doctor's delay between counties with a sample size of 187 new TB patients in JH and 306 in FN, the study power could reach 92%. In

Paper IV, when comparing the delay to 1<sup>st</sup> health care providers in chronic cough patients between counties, the study power could reach 96%. However, for comparing patient's delay among the cough patients between counties, the study power is only 45% at current sample size. In both papers, when comparing the delays between groups with different demographic and socio-economic variables, with the reduced sample size, the study power might also be reduced. The same situation would happen when the subjects were stratified by the un-anticipated implementation of the CIDA NTP-DOTS project although it allows the researchers to compare the delays and expenditure both between counties with and without NTP-DOTS project and within counties before and after the implementation of NTP-DOTS. Longer observation periods will be required to assess the issues in this study with regard to the implementation of the CIDA NTP-DOTS.

Another way of reaching a good precision is to improve the statistical efficiency by altering the methods for subject selection and effect estimation. Multivariate analysis including logistic regression, Cox proportional hazard model, and general linear regression were used in this study for the use of more efficient statistical methods in effect estimation.

### **6.1.3 Internal validity**

Internal validity means minimising systematic error. Internal validity implies validity of inference for the source population of study subjects.<sup>110</sup> Three main types of biases can distort the estimation of an epidemiological measure, i.e., selection bias, information bias and confounding.

In this study, a high validity is anticipated through the design of cohort study, which is considered as less liable to the selection bias than e.g. case control study and cross-sectional design. The recruitment of all new TB patients registered during one year (Papers II & III) made the effect estimation more representative to the new TB patients in population. By diversifying the source of subjects, the recruitment of cough patients on different levels of health facility also reduced the probability of selection bias (Paper IV). But these studies are hospital-based studies. We should always keep in mind that the estimation of effects in terms of delay, expenditure, etc. may not be valid for those cough patients who have not sought care in a hospital, or TB patients who have not been reported to the TB control system.

One of the information biases in this study is the recall bias. In a retrospective cohort study or a cross-sectional study design, the identification of the subjects, their exposure, and their outcome must be based on existing records or memories. Patients' health seeking experiences in terms of date and the amount of expenditures were retrospectively collected (Papers II, III & IV). For those with a long duration, the accuracy of recall might be questioned. To minimize the recall bias, different strategies had been taken including training the investigators, reading previous medical records of the patients (the TB patients usually brought their previous medical records when they sought TB care), using the Chinese lunar terms to help recalling, etc. Due to low income, each payment became considerable to the TB patients, so patients usually remembered how much they had paid for their previous health care seeking although they could not always distinguish the expenditures on diagnosis or on treatment. Indeed,

the 5% re-visits has showed that recalling on care seeking experiences and expenditures was reliable. The possible recall bias could result in misclassification in days of delay and amount of patients' expenditures. With the trained interviewers and the systematic data collection procedures for all study subjects and both counties, the potential misclassifications could mainly be non-differential.

There is a possibility of underreporting the income. In general Chinese people traditionally do not want others to know that they are rich, but they also do not like to be thought of as poor. It's reasonable to consider that the high income group might not have reported their income accurately if it was far above the local perceptions, such as more than 100,000CNY, but there is no reason to believe that they would reduce the self-reported income by several thousands. In our study, the income has been grouped into quartiles; the highest quartile was defined as a household income higher than 7,000CNY in JH or 7,900CNY in FN.

Diagnosis of TB in FN County is subject to an increased possibility of misclassification. The lower proportion of smear-positive TB diagnosis in FN, and the poor capability of diagnosis in township hospitals may suggest incorrectness in TB diagnosis. For example patients with no doctor's delay in FN County, it could be suspected that some patients did not provide all three sputum specimens for sputum smear examination for AFB. However, information about how many patients who were diagnosed with TB based on one sputum specimen and smear examination could not be obtained. It is important to remember that the quarterly confirmation process of TB diagnosis in FN is important and meaningful. In this process, the specialists in the CTD together with the physicians from the township hospitals read the smear slides, CXR films and medical charts to confirm TB diagnosis. The misclassification could also result from the different quality of smear tests and sputum samples between counties. In JH County, the lab was equipped by the NTP. There were specific rooms for smear tests. The technician had obtained training for smear microscopy in the provincial TB dispensary, and the smear slides were monitored by specialists from provincial TB dispensary. The income of the technician was secured by the NTP, and his daily work focused on smear microscopy. Patients were well informed by the referring doctors that they should bring overnight, morning sputum samples when they went to the CTD, and they also obtained clean containers for collecting sputum. But in FN, the labs in township hospitals were used both for TB and other diseases. No specific equipment was provided for smear microscopy. Most of the technicians hadn't been trained on TB diagnosis as in the NTP. Patients were not well informed on how to provide night sputum, morning sputum with good quality. As mentioned in the findings of the qualitative study, the technicians' attitude to smear microscopy was rather negative. The quality of smear tests in FN might cause false diagnosis. Moreover, the sensitivity of smear microscopy recommend by NTP-DOTS is low.<sup>111</sup> It should be mentioned that the subjects in Papers II and III were the whole year's registered TB patients in JH and FN. These sub-studies aimed to reflect the registered TB patients' health seeking experiences, expenditures and diagnostic delays.

The low proportion of smear-positive TB in FN might not only cause the misclassification on patients' disease presentation and their health care seeking experiences, but also cause selection bias. Because physicians in hospitals usually

submitted the most typical TB cases' materials to the CTD for diagnosis confirmation in FN County, missed diagnosis might happen; hence, some TB patients might not be included into the sub-studies on new TB patients (Papers II & III). The effect estimations on delays, expenditures and health care seeking behaviours might be distorted.

#### **6.1.4 Generalizability**

Generalizability is the validity of the inferences as they pertain to people outside the source population. The essence of scientific generalization is the formulation of abstract concepts relating to the study factors.<sup>110</sup>

Can findings from our study be formulated into abstract concepts which could be valid in the whole population of Jiangsu Province, the Chinese rural population? This study is based on observations from only two of China's more than 2,000 counties and the results apply to the population in these two counties. However, given the context of the economic transition, the health care and TB care systems and the strategy of NTP-DOTS projects, these findings are important for other similar populations in rural China. The similarities in findings between this study and the studies from some other high TB burden countries, and also the 4<sup>th</sup> national TB survey in China may assist in generalisation of the results. However, any generalisation should be done with caution.

## **6.2 Diagnostic delay and its impact on TB control**

In passive case-finding approach, early TB case detection is mainly determined by patients' recognition of TB suggestive symptoms, adequate health-care seeking and appropriate diagnostic performance of the health-care providers.<sup>102</sup> In this study, a duration of diagnostic delay in terms of delay to 1<sup>st</sup> health care provider and patient's delay (Papers II and IV), provider's delay and doctor's delay (Paper II) were measured, and the influences of patients' demographic characteristics, socio-economic status and disease presentations on diagnostic delays were analysed to explore the barriers to patients' access to TB care under NTP-DOTS project and non-DOTS. Paper I used the qualitative description to address this issue. The term "delay" is used mainly for indicating who should take action rather than for reflecting who is responsible for the delay.

It was surprising to find that the mean of total diagnostic delay was 58days (median: 31days) in JH, the NTP-DOTS project county, significantly longer than the 40days (median: 19 days) in FN, the non-DOTS county.

### *Delay to 1<sup>st</sup> health care provider and patient's delay – promptness of care seeking*

Although delay to 1<sup>st</sup> health provider was similar in these two counties, the duration to seek care in hospitals, i.e. the patient's delay was significantly shorter in JH than in FN (27 vs. 30days in mean, 10 vs. 15 days in median,  $p<0.05$ ) in TB patients (paper II). The shorter patient's delay of TB patients in JH might be attributed to the implementation of the NTP-DOTS project, which had been implemented in JH for 7 years. Information on the free and/or subsidized NTP-DOTS project has been disseminated through broadcasts, posters and by training health-care providers, and

reinforced year by year. Patients with early TB symptoms could have a shorter patient's delay due to their awareness about TB and availability of treatment (DOTS). However, from the findings in the FGDs, most patients reported that they did not know about TB and the project until they were referred to the CTD. Indeed, only 2% of TB patients in JH and 1% in FN visited the CTD directly. The similarity in patient's delay between TB patients and cough patients in both counties suggests that TB patients may not have recognized the need for TB care but for general health care. It is more likely that a shorter patient's delay existed due to the fact that more patients initiated their first health-care seeking in the hospitals in JH than in FN (59 vs. 21%) and it is because of similar expenditures between the village health stations and the hospitals there, rather than the effects of the implementation of NTP-DOTS project.

Various duration of patient's delay have been reported in Asian countries. In Vietnam, a patient's delay of 7.9 weeks for women and 7.6 weeks for men was reported;<sup>42</sup> in Thailand, the median of patient's delay was 15 days for HIV negative TB patients,<sup>44</sup> in South India, it was 20 days in median;<sup>84</sup> whereas in Taiwan, it was 7 days in median.<sup>112</sup> Patient's delay was related to gender, poverty, distance to health facilities, and lack of knowledge on TB. In our study, one-fourth of the TB patients had a patient's delay longer than one month (Paper II). It was found that poor socio-economic status such as low income, living (income) on farming only and low education was associated with a longer patient's delay. Among the newly diagnosed TB patients, 95% did not have any kind of medical insurance and 92% had an annual average income lower than the local average. In paper I, both the provider and the patient participants of FGDs reported that poor people were reluctant to initiate their health-care seeking, and more frequently visited village health stations rather than hospitals due to lack of money. In paper II, in TB patients of FN, from low to high income quartile, the probability of a shorter patient's delay were significantly increased. Farmers were less likely to have a shorter patient's delay than non-farmers. In JH, less educated patients and patients, who first self-medicated, and then visited the village health station or a pharmacy rather than a hospital, had a longer patient's delay. In rural China, well-educated people usually have a formal-sector employment, which entails not only a better income, but also a medical insurance coverage. Poor patients were more likely to visit a village health station for its lower-fee services, even though the village health workers have only limited medical training. Thus, patients with poorer socio-economic status had a higher risk of a delayed health care seeking in hospitals.

No statistically significant association was found with age and gender in terms of patient's delay, but in the qualitative study, elderly patients and female patients were perceived more reluctant to seek health care (Paper I). The participants in the FGD had pointed out that the key reasons for delay in health-care seeking by elderly and female patients was poverty. (Paper I). Nevertheless, while discussing influence of gender and age on patient's delay, women and the old people's role in the house and family (e.g. income generation), and their education and employment status should also be considered. In the family, men are the main source of cash income. Women's lower education also constrains their access to health education on TB. After leaving primary schools, they work on land and at home, they almost never have a chance to access books and newspapers. For the aged people, their dependence on their children for living and health care, the loss of productivity and the poor education status minimize

their health-care seeking. However, in the multivariate analysis, age and gender were not identified as significant factors to patient's delay (paper II, IV).

*Provider's delay and doctor's delay – promptness of TB diagnosis*

A longer provider's delay (47 vs. 32 days in mean) and longer doctor's delay (31 vs. 10 days in mean) in JH than in FN were reported (paper II). As described above, under the Convergence Management System, the duration from the patient's first health-care seeking to the TB diagnosis depends on when a patient is referred to the CTD and obtains a smear-positive diagnosis. The obvious advantage of this vertical management system in case finding is the accuracy of diagnosis: a much higher smear positive proportion and an evenly distributed smear positive plus were obtained in JH County. As discussed above, findings from the qualitative study (paper I) showed that the equipment in the laboratory in the non-DOTS county for microscopy smear tests was not adequate or in poor. No protection was provided against the risk of infection, and continuing education and training was not provided in lower level hospitals.

The longer provider's and doctor's delays in JH suggest that there are some disadvantages of the Convergence Management System. The TB diagnosis can be delayed due to referral procedures. TB diagnosis and treatment are only available in the CTD, but patients start their health-care seeking from the general health system. Having experienced the market-oriented health reforms in China, the majority of health facilities including those in JH and FN are left to finance their activities through fee-for-service revenue. Health-care providers' income is directly linked to the number of patients treated, and the number of examinations / investigations provided, and the amount and cost of drugs prescribed. This incentive provides a background against which the observed problems with delays in care seeking can be understood. Moreover, a visit to the CTD is not an easy trip for the poor potential TB patients, considering transportation expenditures, time and expenses for accompanying persons. Furthermore, more than one trip is required for patients with a smear-negative result to have repeated smear tests. A study in Vietnam suggests that the TB control programme may cause delayed TB diagnoses due to the use of rigid procedure.<sup>39</sup> A disadvantage of the longer provider's and doctor's delays is the increasing probability of TB transmission to others. One untreated smear-positive TB case can infect 10 to 14 persons over a 12-month period.<sup>113</sup> One-fourth of our subjects in JH had a provider's or doctor's delay up to 3 to 8 weeks. This is one of threats to the primary objective of the NTP-DOTS, to reduce TB prevalence.

Apart from the TB control system, patients' socio-economic status was, an important factor influencing promptness of TB diagnosis. In JH, insured patients were likely to have a shorter doctor's delay than the uninsured. In FN, although income did not have an effect on patient's delay, occupation as farmers or farmers working away from hometown (doing heavy physical work such as in the constructive fields) had longer delay to TB diagnosis (Paper II).

Delays in obtaining TB diagnosis have been reported in several studies in different countries. Long et al. reported an unacceptable significantly longer doctor's delay among women than men (5.4 to 3.8wk), which could be related to knowledge on TB, health-care seeking behavior and the TB care system itself.<sup>102</sup> In South India, a 23 days

health system delay was reported with the increased risk of delay from first consultation with a private provider (AOR=4.0,  $p<0.001$ ).<sup>44</sup> Among the TB patients identified in the 4<sup>th</sup> national TB survey, 37% ascribed their delays in clinical consultation to financial problems.<sup>12</sup> In our study, results from the quantitative sub-studies (Papers II & IV) concentrated more on the income and income-related occupation, education, medical insurance and the system itself. TB patients with lower socio-economic status had higher probability of longer diagnostic delays. Gender effects on provider's or doctor's delays had not been found (Paper II, IV).

The studies on diagnostic delay were institution-based, following the passive case finding strategy implemented in China. Among the TB patients who had obtained a TB diagnosis, their total diagnostic delay could be averagely up to 58 and 40 days in JH and FN respectively. These studies were not population-based and they do not provide information on patients who do not seek care for their illness or seek care only at the village health stations or pharmacies, and may not have received a TB diagnosis. The 4<sup>th</sup> National TB survey reported that 43% of the detected TB cases had never visited health facilities for clinical consultation.<sup>12</sup>

### **6.3 Patients' expenditure and its impact on TB control.**

Results from chronic cough patients showed that the patients' expenditure for cough was substantial, even for the care at village health stations and similar non-hospital facilities. The average expenditure was more than 130CNY (Paper IV). A main aim of the revised NTP-DOTS project was to remove / reduce poor people's financial burden for accessing TB care. If potential TB patients could seek care directly under DOTS project, they should be benefited from the subsidised and/or free TB care. However, findings from our study on TB patients presented a high patients' expenditure both in the NTP-DOTS project county and the non-DOTS county: 872CNY in JH and 1,091CNY in FN (Paper III). Patients' expenditure in total was only 371CNY lower in JH than in FN. It is obvious that TB patients in JH still suffer a heavy economic burden from TB care and interestingly a shift of economic cost to patients from after diagnosis to before diagnosis. The introduction of the CIDA project into the non-DOTS FN County was accompanied by a similar pattern where the cost shifted from after diagnosis to before diagnosis and the total expenditure for the patients remain same as prior to the implementation of subsidised TB control programme.

With the vertical Convergence Management System under DOTS, no smear microscopy services are available in township or county hospitals. Patients should be self-referred or referred by the physicians in hospitals to the CTD for diagnosis and treatment. The physicians will not refer the patients to the CTD unless they see suspect TB based on CXR or fluoroscopy. As discussed earlier, most of the patients will not seek care at the CTD directly. This is because they may be unaware of the DOTS project or lack knowledge about TB-related symptoms. Further, the general three-tier health-care system has been in existence for a long time and has been source of health care for all illnesses including TB. Thus, in the given health-care system diagnosis of TB largely depends on the referral from physicians to CTD.

There are some studies on the impact of the partially reformed health system to the burden of health care in China, although few have examined the patients' actual economic burden for TB care.<sup>36 39</sup> User fees and revenue-related bonus systems have been well-established in China's health system including our study sites during the health sector reform. Based on the report of MOH, in 1980, the proportion of government subsidies, user fees and drug sales in the financing of public hospitals were 21%, 20% and 38% respectively, while they were 9%, 40% and 47% respectively in 2000. The share of health budget in total government expenditure decreased from 4.2% in 1980 to 3.9% in 2002. Consequently, hospitals use more drugs and high technology diagnostics in order to maximize their profits.<sup>87</sup> This change has been accompanied by the increased medical service charges to patients and the supplied-induced demands.<sup>86</sup> Meanwhile, there were still 32 million rural people living in poverty in 2000;<sup>114</sup> and more than 90% of the rural population pay out-of-pocket for their medical care.<sup>115</sup>

In JH and FN, according to the information from local health authorities, all the hospitals are financed mainly through user fees. Bonus-related revenue based on generation of income to the institution has a large influence on the health providers' medical practice. The delays in TB diagnosis and the high patients' expenditures could be a symptom of "moral hazard" due to perverse incentive system. For a disease such as TB, this has an impact on public health by increased probability of transmission due to longer delay in diagnosis and start of treatment for TB. The patient participants in our FGDs perceived that doctors were doing business and doctors would lose their job if they could not earn enough money from the patients (Paper I). In JH and FN, we have met many patients who were given intravenous antibiotics in the village health stations and township hospitals. Most of our patients reported that they had received treatment with antibiotics (Paper I). In the village health stations, daily intravenous antibiotic treatment costs 50-200CNY as presented on the price list board, and it is even more expensive in hospitals. Cough patients with fever usually obtain 3-6 days intravenous treatment based on their ability to pay. This is a large economic burden for a poor farmer prior to getting TB diagnosis (Paper I). During their health seeking in general health system the poorest patients spent 96% of their household income before reaching to the NTP-DOTS project i.e. CTD (Paper III). Whereas in FN, because TB diagnosis and treatment could be done in township and county hospitals, the economic burden of TB care mainly occurred in the treatment stage, which accounted for 98% of the poorest patients' household income (Paper III). Any failure of payment may result in an interruption of TB care seeking both in JH and FN. The increasing expenditure before diagnosis in FN after the implementation of CIDA NTP-DOTS project strengthens the finding of burden shift from after diagnosis to before diagnosis under the vertical TB care system.

Thus, the NTP-DOTS in China is facing the challenges on improving the accessibility of the NTP-DOTS for rural population in the context of a well established general health system, addressing the incentives for referral suspected TB patients, and assuring the quality of TB diagnosis in general health-care facilities. Findings from this study suggest that smear microscopy for suspected TB cases should be set in peripheral hospitals including county hospitals and some township hospitals with big served population. Physicians, technicians and staff in hospitals should get training on TB

knowledge, TB diagnosis and treatment under the NTP-DOTS. Incentives for referring patients and reimbursement for providing smear microscopy should be regulated.

This study suggests that even having an NTP-DOTS project, the poor people's access to TB care has been severely constrained, and must be worse in the poorer areas of China under the similar vertical system without a good integration with the general health system. The 4<sup>th</sup> TB survey reported that the average income of TB patients was as low as 941CNY, and the expenditures for TB medical service was 1,165CNY with 98% of patients paying out of pocket. The MOH's final evaluation report on World Bank loaned TB control project in China described that the referral rate of TB patients from general hospitals was as low as 13%.<sup>61 12</sup> Although, in the NTP-DOTS covered counties, 10-20CNY bonus was provided to each referral for a smear-positive patient, it is obvious that the RMB 20 incentive payment is inadequate to compensate for the revenue loss for referring doctors, let alone, in some of the DOTS covered counties, even the 10-20CNY are not always given to the referring doctors.<sup>61</sup>

Recently, a study in Shandong Province, China reported that in four NTP-DOTS covered counties, TB patients spent 78-3,359CNY in CTD for TB diagnosis, and 68-1,595CNY for drugs, although free TB diagnosis and treatment are available there.<sup>93</sup> This could have the following explanations: 1) in addition to the free drugs from the World Bank TB project, extra drugs are prescribed; 2) patients are required to pay for drugs that should have been provided for free; and 3) unnecessary procedures are ordered (e.g. investigation) in TB dispensaries. In our study, the NTP-DOTS covered county - JH County, is a model county of implementing NTP-DOTS project. Patients' expenditure after they were diagnosed as TB in the CTD was regulated with 140CNY. The county health authority budgets the counterpart funding to the CTD in time, which guarantees the TB staff's income and bonus, and prevents the supply-induced demands.

#### **6.4 Policy impacts of studies on access to TB care in China**

Epidemiology is an important approach in public health practice and plays major roles in the development and evaluation of public health policy as well as in the social and legal arenas.<sup>116</sup> Since the new launch of the second round of NTP-DOTS project in China in 2002, 16 provinces, mostly located in the relatively poor areas, have implemented the NTP-DOTS using a World Bank/ Department for International Development (DFID), UK loan; the remaining provinces and metropolitan cities also implement NTP-DOTS financed by local and/or other international funds. Till June 2005, NTP-DOTS has been expanded to cover 100% of the counties in China. In the circumstance of fast expansion of NTP-DOTS coverage, interventions, policy and strategy adjustments based on the identified barriers in studies on access to TB care will certainly be of great importance in improving TB case detection rate.

Findings from this study, as well as similar preliminary findings from several other studies carried out by researchers from different institutions during 2002-2005 in China, have been disseminated through reports to Chinese government and WHO, through international and national publications and direct communications between the researchers and policy makers. Some of the findings have been acknowledged by the

policy makers of TB control in China. On his report of progress of TB control in China in the 36<sup>th</sup> IUATLD Conference, vice Minister of Health, Wang Longde said that in 2001-2010's National TB Control Programme, TB control will be mainly financed by the government, together with other resources; a collaborative mechanism between the disease control system and medical care system is being implemented, and case report and referral will be strengthened to improve TB case detection.<sup>117</sup> For finding more cases, TB staff will trace suspected TB cases who have obtained referrals, but have not contacted a TB dispensaries; for improving the accessibility of TB diagnosis, smear microscopy will be set in township hospitals with a big serving population and area; and for encouraging referral, subsidies will be provided to health providers in village and township for case reporting.

## 7 CONCLUSIONS AND RECOMMENDATIONS

There was a time when I was sure that the pro-poor TB control programme with DOTS strategy would undoubtedly benefit the poor people; there was a time when I was sure that the professional proficiency and professional moral principles of health-care providers should be the only determinants in medical practice; I cannot say that I think the same now. The recent four years' research experiences on access to TB care have presented me both the positive and negative effects of the NTP-DOTS project in rural China, informed about the barriers to access to and utilisation of TB care both from demand side and supply side, and disclosed the importance of integrating the vertical project into the general health system in the context of the economic status, health status, health policies and social prerequisites (e.g. laws, systems and infrastructures) in a given society.

In conclusion, results from this study indicate that:

1. Most TB patients in rural China live in poor income status. Out-of-pocket payment for health care contributes to the vicious cycle of TB and poverty, and results in the inequity in access and utilisation of TB care. The poor patients are vulnerable in access to and utilisation of TB care, which is reflected by delayed health care seeking, delayed TB diagnosis and high proportion of non-hospital visits among patients with different income, education level, occupation and having a medical insurance. A 5CNY smear microscopy cost can weigh a lot on the poor patients. The payment for TB care can cost the poor family's whole year income. Without the subsidised TB control programme, the payment for TB diagnosis and treatment is large compared to income. From this point of view, the pro-poor NTP-DOTS project is strongly needed, and is helpful in removing patients' economic burden if patients can directly seek TB care in the specialised TB dispensary and obtain a smear-positive TB diagnosis.
2. The DOTS strategy secures the accuracy of diagnosis and completion of standardised TB treatment. But most of TB patients initiate their health-care seeking in the general health system, and their access to TB care rely on the referral by health-care providers in hospitals and village health stations. Even when patients can promptly reach the specialised TB dispensary, the payments and time cost for transportation to and from the TB dispensary can still result in the interruption of care seeking. Thus it is imperative to make smear microscopy available in more peripheral hospitals.
3. The longer provider's and doctor's delay and higher patients' expenditure before TB diagnosis under the NTP-DOTS project and the low smear test rate in chronic cough patients suggests a conflict between the general health system and the vertical convergence TB management system. The total patient expenditure was not reduced substantially, but shifted from after diagnosis to before diagnosis. The shift could imply delays in diagnosis and treatment with an increased risk of infection transmission. Findings from our study indicate that the market incentive structures in the reformed health system appear to have a stronger regressive effect and may result in prolonged delays before effective treatment can be given. Doctors have adapted to new incentive structures with bonus income being linked to the hospitals' fee-for-service revenue and found new ways of keeping revenue at the

old levels, which is reducing or eliminating the effect of the subsidies of the pro-poor NTP-DOTS.

4. The smear-negative TB patients' treatment should also be taken into consideration because without financial support from the project, TB care is unaffordable to the poor. And also the sensitivity of the sputum smear microscopy, the recommended method of TB diagnosis in NTP – DOTS, is low. These patients can become infectious smear-positive TB cases during their disease progression, and they also face a high risk of acquiring drug resistance.

China's NTP-DOTS project has cured over a million poor TB patients since 1990s. To make the project sustainable, to successfully implement an integrated TB control programme organized by the specialised TB control system, cooperated by general health system, and supported by local health authority, and to improve the access and utilisation of TB care, the main challenges are:

1. The resource of implementing a pro-poor NTP-DOTS project should be sustainable. More budgets are required to expand the project to the primary health-care facilities, and to cover both smear positive and negative TB patients.
2. To make the targeted population perceive their needs for TB care, and seek TB care promptly and properly in the specialized TB dispensary, the health education on TB and the dissemination of the DOTS project should have simple, straightforward, easily understood, and eyeball attracting approaches.
3. To set smear microscopy in peripheral hospitals, to encourage referring TB suspects to NTP-DOTS, capacity building should be strengthened including training health-care providers at different levels and installing standardised diagnosis procedures. The inherent conflict between the publicly funded NTP-DOTS and the privately financed health facilities need to be solved with an acceptable incentive structure to address the health-care providers' loss of revenue due to referral or provision of free TB care.
4. Hospitals that are able to make TB diagnosis and treatment, such as county hospitals, should be allowed to provide TB care. The report and management of TB cases can be regulated.

TB is a poverty related disease. While eradication of poverty is still a long-term goal in rural China, a specific pro-poor TB control programme is of great importance. Meanwhile, to implement the NTP-DOTS well, an adjustment of the health sector reform is inevitable. With the improvement of general welfare and an increase of public budget funding of primary health care, with the reconstruction of the rural Co-operative Medical System, and with better access to NTP-DOTS for the rural Chinese population, there is a bright prospect in reducing the disease burden of tuberculosis in rural China.

Recommendation for future researches:

1. Community-based studies on barriers to access to TB care in rural China. Findings from the current study are from patients who have reached hospitals. It is reasonable to assume more serious problems related to access to health care exist among those poor patients who are reluctant to seek healthcare or only visit the village health stations.

2. Hospital-based studies on the referral rates in suspected TB cases, completion rates of the referrals and the barriers to referral from both demand and supply sides. Studies are needed to address realistic incentives for providers and feasible incentives for referrals.
3. Qualitative studies on health-care providers to gain in-depth understanding of their perceptions, attitudes, and expectations on provision of TB care.
4. Intervention study on health education approaches in rural population.
5. Intervention study on involving general hospitals in the TB control programme.
6. Intervention study on active case finding in high risk populations based on the identified barriers from the studies on access to TB care.

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