Equity in healthcare service use and financing in China

Studies on general healthcare and tuberculosis

Jiang, W.

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Equity in healthcare service use and financing

in China

studies on general healthcare and tuberculosis

Weixi Jiang

Equity in healthcare service use and financing in China: studies on general healthcare and tuberculosis

ACADEMISCH PROEFSCHRIFT

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aan de Universiteit van Amsterdam
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ten overstaan van een door het College voor Promoties ingestelde commissie,
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door Weixi Jiang
geboren te Sichuan

To Zhihong and Wen, for dedicating their life and love to raise me

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Chapter 1

Introduction

1.1 General background and the research projects

1.1.1 A brief introduction of the research background

Health is a basic human right, and achieving higher degree of equity in healthcare has been a challenge for countries all over the world. The issue of equity in healthcare has rich connotations, and has been studied from multiple angles. While equity in the healthcare outcomes is the ultimate goal, improving the equity in healthcare service use and financing will pave the way to achieving this goal. The equity status in healthcare service use and in financing are inter-related, and are often connected with a broader economic, political and social context. Since the 1980s the international community has been calling for efforts to achieve universal health coverage and better equity in healthcare, and progress has been made in many countries, which, however, is far from satisfaction especially in many low-and-middle-income countries (LMICs). Now constant efforts are still needed to improve equity in healthcare service and financing. In addition, the outbreak of Covid-19 which has disproportionately affected the socially vulnerable groups -- for example, the elderly dwelling in long-term care homes, migrants gathering in collective dormitories and impoverished people living in slums -- has shown that improving the accessibility of healthcare for these left-behind populations is an urgent mission that calls for systematic global efforts(1).

The healthcare system in China has also been undergoing constant reforms along with economic reforms. Numerous studies have been conducted to investigate the impacts of policy changes on equity in the healthcare system, and have revealed challenges in accessing and affording quality healthcare, especially for socially vulnerable groups. Tuberculosis (TB) is an infectious disease of poverty and the poorer are more likely to be infected and often have financial difficulties to complete treatment(2,3). Therefore, to study healthcare service delivery and financing specifically for the disadvantaged patient group this thesis focuses on TB patients. Currently, there is a lack of overall assessment on the equity status throughout the healthcare seeking process, and the effectiveness of multiple policy interventions to improve the healthcare for vulnerable groups such as TB patients remain unclear. The key research questions this thesis hopes to address are how different demographic and socio-economic factors would impact the whole healthcare seeking procedure, and what effective interventions are to improve healthcare service delivery and affordability for certain groups of patients of poor socio-economic status under the current health system in China.

1.1.2 A brief introduction to the research projects

This thesis reports on a series of studies on equity in general healthcare service use and financing in China, as well as on a socially vulnerable group: tuberculosis (TB) patients. The thesis is composed of three research projects as follows：

The first project was a survey on the healthcare needs, healthcare service utilization and expenditure among residents in Jiangsu province, China. This study investigated the demographic and socio-economic factors associated with health care seeking processes, and explored the equity implications of these associations. Specifically, one baseline survey on basic demographic features, health and economic status, and 10 follow-up surveys on perceived health care needs, health service use (self-treatment, outpatient, and inpatient) and medical expenditure were conducted in 400 households, 200 in one rural and 200 in one urban county.

The second project focused on TB patients to explore the effects of financing and payment policy interventions on the healthcare service use and financial burden of TB patients, and is based on the China National Health Commission (NHC)-Gates TB Project Phase II. This project piloted a comprehensive TB prevention and control model in three prefectures in eastern, central and western China, respectively. This model involved financing and payment policy interventions including improving the reimbursement rate of public health insurance for TB patients, cash transfer and reforming the payment approach from fee-for-service to case-based payment to control the treatment cost. A mixed-method approach combining both quantitative and qualitative methods was used to evaluate the effectiveness of the interventions. There are two complementary studies under the project: one on the patterns of health service use, and the other on the financial burden for TB patients in China before and after the project implementation. Data collected included structured patient surveys, key-informant interviews with policy makers, and focus group discussions (FGD) with caregivers and patients.

The third project focused on drug-resistant TB (DRTB) patients, a subgroup that are more vulnerable compared to drug-susceptible TB patients. It investigated how policy changes have influenced case finding and treatment of DRTB patients of different demographic and socio-economic status. It was based on the China NHC-Gates TB project Phase III, during which a comprehensive TB

control model was implemented in three provinces. At the time of the project many policies were issued and implemented aiming at improving DRTB case detection treatment and management. This study conducted a survey on DRTB related policies and used the registry data of presumptive and diagnosed DRTB patients from Zhejiang, to examine changes in the programmatic performance with regard to case detection, treatment and management of DRTB patients from 2015 to 2018.

1.1.3 Conceptual framework and working definitions of equity in healthcare service use and financing.

The works of A. Wagstaff, E. van Doorslaer and A. J. Culyer established the theoretical basis of equity analysis in healthcare most used in modern literature. They firstly identified defects in each existing definition of equity in healthcare, for example, the notion of achieving equality in healthcare expenditure fails to consider the role of "needs", while the definition "distribution according to need" was also vague as the interpretations of "need" were often in conflict with each other. Another popular definition stated "equality of the access" to healthcare without a clear explanation of the meaning of "access". To resolve the confusions in these definitions, they proposed a principle that equity in healthcare requires "the distribution of care which directs to equal distribution of health" (4).

Based on this principle, Van Doorslaer and Wagstaff decomposed healthcare equity into two dimensions: healthcare delivery and financing, and developed their working definitions. Equity in health care delivery was defined as "persons in equal need of healthcare should be treated the same", which reflects the concept of horizontal equity. In practice, the "vertical equity of healthcare" notion that people with greater needs of healthcare should use more health services is also used to develop analysis metrics. Equity in healthcare financing is defined as "the financing of healthcare according to the ability to pay", which also reflects the concept of vertical equity that people with higher ability to pay should pay more for healthcare.

With these working definitions the degree of equity in these two dimensions of healthcare become measurable in empirical research. Though healthcare needs cannot be directly measured, people of the same health status should have the same health care "needs", and health status can be evaluated with multiple variables and metrics. As for the working definition of equity in healthcare financing, income or other measurement of wealth could be a good indicator of

ability to pay. Contribution with reference to income or wealth level is widely accepted in measuring the level of equity in healthcare financing of different modes at the country level. Most empirical research assessed the equity in healthcare financing through examining the progressivity of healthcare financing(4,5). Here healthcare financing concerns the overall health budget including both the direct payments of the user as well as indirect contributions of health insurances and government taxes. The notion "progressivity" in finance is originally used to describe the design of tax systems that "tax rate increases as the taxable amount increases"(6). In healthcare financing, progressivity refers to the pattern of the distribution of contribution to healthcare expenditure that the wealthier pay more with regard to their wealth proportion in the society. The concentration index (CI) and Kakwani index (KI) are most commonly used tools to measure the equity in health care delivery and financing in correspondence with the above working definitions.

The CI is derived from the concentration curve which plots the cumulative distribution of a healthcare-related variable (y axis), like the quantity of healthcare service used, against percentiles of the other variable of interest following certain ranks (x axis). If the healthcare-related variable is binary such as the use/non-use of certain services, then cumulative prevalence along the rank is used (7). The other variable of interest should enable ranking among the individuals/groups, such as income or wealth. The CI is conceptually defined as "twice the signed area between the concentration curve and the line of equality (the 45-degree line)", which measures how "distant" the actual distribution is from the perfect equity. Mathematically, it could also be calculated as "the covariance between the healthcare variable and the fractional rank of the socio-economic variable"(8).

The working definition of equity in healthcare service delivery implies a decomposition of what may affect service use into "need" and "non-need" factors. Under perfect equality only those "need" factors indicating health status should be correlated with healthcare use, while socio-economic variables such as income are considered irrelevant. Therefore, the concentration index which assesses the correlation between socio-economic factors and healthcare, can be standardized after adjusted for need-factors through ordinary least squares (OLS) estimation(9). The horizontal inequity index (HI), which captures the difference between the predicted demand after controlling for non-need variables and the actual demand, has also been widely used. Alternatively, equity in health service

use can be assessed through analyzing the patterns of healthcare utilization with regard to the non-need factors. Despite some controversies, the CI and HI still serve as important indicators of the degree of equity that enable comparisons across countries and time periods(10).

The KI is often used to evaluate the equity in health care financing. It compares the distribution of contribution to healthcare expenditure with the distribution of wealth. This index is calculated as twice the (signed) area between the concentration curve of healthcare financing and the Lorenz curve, where the Lorenz curve plots the cumulative income or wealth (y axis) against percentiles of the population following income or wealth ranks (x axis)(8). Unlike the case of CI where there is a "line of equality", the Lorenz curve does not imply "perfect equality" for healthcare financing. If the healthcare financing is more progressive than the income distribution, which means that the rich contribute a higher proportion to healthcare expenditure with regard to the proportion of their wealth, it will be more socially desirable than just equaling the income distribution. However, progressivity does not necessarily imply a desirable status of equity in health care financing, as the poor could pay much less simply because of limited access to care(11). Therefore, equity in healthcare utilization and financing need to be combined to give a comprehensive view on the healthcare system.

1.2 Contexts of the economic and health system reforms and disease control programs in China

1.2.1 A brief introduction to the economic development in China

The economic development of China accelerated along with the Reform and Opening beginning in the late 1970s. Though China has become the second largest economy globally and its achievements in economic development have been widely acknowledged, the geographic inequity in economic development has become a critical challenge, and also the root for many social problems. The eastern coastal areas first enjoyed the reform and opening policies, and GDP per capita for provinces in this area is equivalent to that in developed countries, whereas some inland and western provinces have lagged behind. For example, in 2019 GDP per capita in Jiangsu, an eastern coastal province and the site for the first study, reached over 18,000 USD, almost 4 times that of Gansu, a western province(12). Within a province the level of economic development could also be imbalanced, for example, the GDP per capita in the richest prefecture in Jiangsu is nearly two times higher than that in the poorest prefecture (13).

The imbalance in economic development has led to considerable disparities in the capacity to invest in infrastructure and social welfare across the country, despite the fiscal transfer payment from the central government to provincial and prefectural/municipal level governments in less developed regions. As a result, the healthcare resources mostly centre in developed regions, and the benefit packages of the public health insurances and the financial support for patients are also more generous in these areas (14). In recent years, with the significant progress of infrastructure development and poverty alleviation programs, the less developed regions have largely improved their capacity in healthcare service delivery and financial support for patients. Nevertheless, challenges in accessing and affording quality healthcare still exist for vulnerable groups.

Moreover, the system of registered residence (Hukou) in China is another barrier for accessing quality healthcare. As the eastern developed regions have more job opportunities and higher salary levels, huge populations have migrated to these regions for work. However, social welfare provisions in many places are still limited to people with local Hukou, which is difficult for the migrants of low socio-economic status to obtain (15).

1.2.2 Healthcare system in China

The reforms of the healthcare system in China have been progressing alongside changes in economic structure and the level of economic development. The old cooperative medical scheme collapsed after the beginning of the economic reform in the mid-1980s. In 2009, a new round of healthcare system reform was initiated, aiming at ensuring accessibility and affordability of healthcare for all Chinese people, which paralleled the United Nations (UN) Sustainable Development Goal of achieving universal health coverage (UHC)(16).

Currently, the healthcare system in China is financed through three channels: government input, social security funds and out-of-pocket (OOP) payment from citizens. According to the analysis of National Health Accounts in China in 2018, the government expenditure accounted for 27.7% of the total health expenditure (THE), almost the same as in 2012, while the absolute amount almost doubled. Meanwhile, the proportion of social funds increased from 35.7% to 43.7%, and for OOP payment the proportion decreased from 34.3% to 28.6%. Nevertheless, the decrease in the OOP payment slowed down in recent years (17).

The public health insurance system has been established in China to pool funds from government subsidy, social contribution and individual premiums to co-

finance the clinical healthcare services together with individual OOP payment. After the collapse of the old cooperative medical scheme, the insurance coverage dropped to less than 30% in the early 1990s, and most of the rural population were left uncovered(18). Faced with unmet healthcare needs, the government established three public health insurance schemes to provide financial protection for patients: the urban employee's basic health insurance (UEBMI, compulsory for urban employees), the urban resident's basic health insurance (URBMI) and the new cooperative medical scheme for rural residents (NRCMS) (19). In recent years, the URBMI has been integrated with the NRCMS to be the urban-rural resident's basic health insurance (URRBMI), which enrols people without a formal employer in both rural and urban areas(20). Currently the public health insurance covers 95% of the national population(21). As for the proportion of financing from each channel, UEBMI is co-financed by the employer (usually 6-8% of the total base) and the individual employee (2% of the individual base salary)(22), while for URRBMI the government subsidy amounts to about twice the individual premium(23).

Under the current healthcare system in China, clinical healthcare services are mostly delivered in public hospitals, and a three-grade public hospital system has been established. The Grade 3 hospital is usually a general hospital at the prefecture level or above, sometimes a rich county also has Grade-3 hospitals. The Grade 2 hospital is typically a general hospital in a less developed county, or community hospital in developed regions. The Grade 1 hospitals are mostly primary health care centres in the urban and rural community offering basic clinical (including basic inpatient) healthcare services as well as public health services. Along with the introduction of a market-oriented economy, the government lessened the control on health care providers and increased their autonomy just like the decentralization process in other sectors(24). Meanwhile, the government reduced financial support for public hospitals and now public hospitals mainly rely on revenue from medical services for operation and expansion. Therefore, public hospitals have incentives to provide expensive, or unnecessary services to gain more revenues, and supplier-induced demand is widely identified as a cause of surging medical cost(25).

The public health insurance schemes in China also have several problems that have led to undesirable outcomes regarding equity in healthcare service use and financing. First of all, disparities across health insurance schemes are significant, as the benefit packages for URBMI and NRCMS (or URRBMI) are less generous

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than UEBMI. For example, the reimbursement rate is rather low for outpatient services under URBMI and NRCMS(26). However, people enrolled in URBMI/NRCMS/URRBMI are usually those without formal jobs and often have lower socio-economic status (SES), who often prefer outpatient services which are less costly in terms of time and money and who have to pay mostly out-of-pocket. Besides, for those who get enrolled in URBMI or NRCMS in a county, the reimbursement rate is only around 55% for inpatient healthcare services in prefecture-level Grade 3 hospitals outside that county when patients are referred from lower-level hospitals, while this rate is over 80% in county-level hospitals (without formal referral from county-level hospital the reimbursement rate is even lower)(27). Although these differential reimbursement rates have been designed to avoid irrational use of the scarce healthcare resources aimed for serious illnesses, the financial burden is very heavy for those rural patients who have serious illnesses and need comprehensive healthcare in higher-level hospitals, despite the additional reimbursement provided by critical illnesses insurance that was introduced in 2012(28).

Besides, there are also disparities in benefit packages across geographic areas for the same type of health insurance due to the imbalanced economic development. The more developed areas have higher salary levels, and thus higher payment base for UEBMI, and also more fiscal revenues to subsidize the URBMI and NRCMS. With sufficient funding, the public insurance schemes could provide more generous benefit packages covering more types of medicines or more types of diseases for stronger financial protection. The medical assistance system, which provides additional reimbursement in addition to the public health insurance, also suffers from the same problem of inequity across regions.

1.2.3 TB prevention and control system in China

TB is an infectious disease of poverty. Many risk factors of TB infection, such as malnutrition, overcrowding and homelessness, are directly related to low socio-economic status (2,29). Globally, the disease burden of TB falls mostly on low-and-middle income countries (LMICs). India, Indonesia and China are the top 3 countries with high TB burden ranked by caseload, and the countries with low TB incidence are mostly in the American and European regions (30). Target 3.3 of the Goal 3 (good health and well-being) of the Sustainable Development Goals (SDG) requires the end of the global TB epidemic in 2030, which is interpreted in the End TB strategy of WHO as reducing TB incidence and death

rates by 80% and 90% respectively in 15 years(16). Besides, the SDGs listed poverty elimination as Goal 1, and Target 3.8 of Goal 3 also highlighted achieving universal health coverage and ensuring access to quality health care for all(31). Considering the close correlation between TB and poverty, establishing a TB control system that can ensure access to quality TB healthcare services for poor patients is crucial for both ending TB and eliminating poverty. China accounted for 8.4% of the global new TB cases in 2019(30). The TB prevention and control system in China has been transformed from the original Center for Disease Control and Prevention (CDC)-led model to the integrated model in most provinces. Under the CDC-led model, CDC, or the TB dispensaries which were often affiliated with CDC, provided TB public health services such as disease monitoring, patient registration for treatment and follow-up visits, as well as clinical medical services such as diagnostic tests and treatment. Nevertheless, the clinical capacity of CDC/TB dispensaries was very limited, and the clinical services were often restricted to basic tests and dispensing drugs free-of-charge. Patients still had to go to hospitals if they had serious illnesses or comorbidities. To address the challenges in the quality of clinical services, the new integrated model uses TB designated hospitals, usually general or infectious disease hospitals, to provide clinical service. The CDC remains responsible for health monitoring, supervision, and working with primary health workers in patient management such as regular follow-up visits. First-line drugs and sputum smear microscopy are still free of charge for patients in designated hospitals. However, more complex tests, auxiliary drugs and other clinical services that are not covered or only partially covered by the public health insurances have caused considerable financial burden for TB patients(32,33).

China also has a high burden of drug-resistant TB (DRTB), and it took up 14% of the global rifampin-resistant TB (RRTB, rifampin is the most critical first-line anti-TB drug) /multidrug resistant TB (MDRTB) cases in 2019(30). It is estimated that 7.1% of new TB patients and 21% of previously treated patients have RR/MDRTB in China, higher than the global average of 3.4% and 18% respectively(30). The treatment of RR/MDRTB usually requires second-line drugs that are more toxic and expensive, and often less effective(34). Under the current TB prevention and control system in China, the diagnosis and treatment of DRTB can only be conducted in TB designated hospitals at prefecture level or above, which are usually Grade-3 hospitals located in cities. The diagnosis of

DRTB takes 1-3 months with traditional test technologies, and the standard second-line treatment takes 18 months including both inpatient and outpatient treatment. However, the reimbursement rate in prefecture-level hospitals under public health insurances is much lower than in primary or county-level hospitals. The direct medical costs plus indirect medical costs such as transportation and accommodation have caused a huge financial burden for patients, especially for those from rural areas, in spite of the assistance policies gradually introduced in many regions(35–37). The gaps between the estimated number of patients and those enrolled in treatment, as well as the low treatment success rate (54% in 2017) for RR/MDR-TB patients on second-line treatment as reported by WHO strongly indicate an urgent need for policy interventions toward quality healthcare for DRTB patients (30).

1.3 Literature review

1.3.1 Studies on the equity in healthcare service use and financing internationally
Equity in healthcare service use and financing has been a hot research topic internationally. Most empirical studies on this topic followed the framework and measurement tools proposed by Adam Wagstaff et al. as introduced. These studies either examined equity in healthcare service use and financing separately, or explored both dimensions in a single comprehensive study.

As for equity in healthcare service use, a large amount of studies described its utilization patterns with regard to SES factors, or evaluated the degree of equity in healthcare service use for a certain country as a whole or for certain groups of population using established indexes such as CI or HI. In high-income countries, public healthcare service delivery showed relatively good performance in equity, as observed in studies in 2000s and 2010s. In Quebec, Canada, higher SES was only associated with greater likelihood of registration with a family doctor and likelihood of visiting primary healthcare centres (PHC), while the use of emergency rooms and the frequent use of PHC services seemed pro-poor (the probability of using these services decreased as SES status increased after adjustment for health status)(38). For UK and Spain, studies showed that the distribution of healthcare services provided in the public sector was either pro-poor or without significant socio-economic inequalities (39–41). In Italy people of lower SES were more likely to use primary care, and the inpatient service use showed good equity in terms of the distribution across different SES groups(42). Nevertheless, the use of certain types of services such as outpatient specialist

care in Italy, and child vaccination in Ireland, were relatively more common in high-income households(42,43). In developing countries where huge gaps exist across geographic areas and social classes, the equity situation observed was often worse in poor regions with limited government investment. One study in India found that both outpatient and inpatient care were pro-rich, and a higher level of horizontal inequity was observed in the rural population compared to the urban(44). One study in Brazil revealed that inequity in healthcare use could also be attributed to insurance coverage and urban location in addition to income level(45). Another study in urban Vietnam found that the utilization of non-communicable disease (NCD) public healthcare services showed more inequity in slum areas compared with non-slum areas(46).

Besides SES factors, health service utilization was widely examined across demographic factors such as gender and ethnicity. For many types of healthcare services such as NCD care, the inequities in healthcare service use regarding gender and ethnicity may reflect certain intrinsic inequity rooted in the society. Several studies in both developed and developing countries found that women, compared with men of similar health status or with the same type of diseases, used more services of low costs such as preventive care, but fewer services of high cost such as specialist care and inpatient care, indicating that women were socially and economically disadvantaged in mobilizing resources to access healthcare (47–51). With regard to ethnicity in the USA, disparities in healthcare use were identified across ethnic groups(52), and the Affordable Care Act was shown to benefit the non-Hispanic white the most and the black the least in terms improvement in the access to healthcare(53). In Denmark where public healthcare services (except dental care) were provided without co-payment, no disparities in utilization across ethnic groups (indigenous Danish versus immigrants and their descendants) were observed(54). In general, higher government investment in public healthcare services to reduce OOP payment is crucial to mitigate the disparities in healthcare service utilization due to differential ability to pay, either because of lower income or because of incapacity to determine the use of economic resources.

Another group of studies examined a comprehensive range of determinants of healthcare service use. In many studies healthcare service use is divided into a two-part decision-making process: decision on whether or not to use and decision on the frequency of using healthcare services, and the two-part model (TPM) could capture factors associated with the decision at each stage(55,56).

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Regression results of the TPM can also be used to calculate the HI index. This approach found that in Chile the healthcare service use was generally pro-rich, in South Korea almost equitable, while in Belgium lower-income patient groups used more hospital services and services from general practitioners with respect to their predicted need(57–59). Partha Deb *et al* further used Bayesian estimation on the extended TPM to solve the endogeneity problem of health insurance in the TPM that the selection of health insurance plans is correlated with patients' health status and thus the healthcare needs, which would undermine the validity of TPM. The application of this model to USA survey data showed that SES factors had a stronger impact on ambulatory care than on inpatient care(60). Huber argued that a dichotomous decomposition of differences in healthcare use into those attributed to need- and non-need factors fails to consider the heterogeneity in preferences that also leads to variations in healthcare service use. He proposed a micro-simulation approach to TPM and further decomposed the HI into individual and behaviour-related contributions(61). This approach identified a considerable contribution of heterogeneity in the healthcare seeking behaviours to the overall inequality in healthcare service utilization in Palestine (62). In general, results from these methodological innovations are mostly consistent with previous studies regarding the basic socio-economic patterns of healthcare service use, while the influence of the SES factors may differ.

There is also rich literature focusing on the equity in healthcare financing[1]. Four major sources of health care financing are often examined in empirical studies: tax, social/public insurance, private insurance and OOP direct payment. Studies have shown that a tax-financed system is the most progressive approach, while private insurance and OOP are typically very regressive, and social insurance could be either progressive or regressive but still more equitable compared to OOP direct payment (5,63–65). Nevertheless, the progressivity of the overall financing scheme, or even for a particular financing approach like OOP, largely depends on the overall economic development level, on the health service delivery system as well as on the structure of healthcare financing (the proportional contribution of each financing source). One recent study in the USA

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[1] These studies focused on the equity in healthcare financing from domestic sources. In many LMICs development assistance for health (DAH) accounted for a large proportion of the national healthcare budget, as reported by Nirmala Ravishankar et al. in the paper Financing of Global Health: Tracking Development Assistance for Health from 1990 to 2007, *Lancet* 2009; 373: 2113–24

showed that the expansion of Medicaid and the implementation of the Affordable Care Act, both financed through federal tax, resulted in a more equitable financing scheme (66). In countries where the burden of OOP direct payment is considerable but poorer patients still seek care, OOP would be regressive, and the overall healthcare financing could be regressive or progressive depending on the proportion of OOP(11,67–70). However, in underdeveloped countries where direct payments have largely discouraged poor patients from seeking care, the KI of OOP could be positive (meaning that the rich could pay even more with respect to their wealth proportion), simply because the poor have no access to care(11). Besides, the progressivity of a certain financing approach could be different across income groups. One study on the governmental health insurance (GHI) in Palestine found that for the richer half of the population, the richer contributed more and the GHI equalized the income distribution after payment. But this effect was not significant for the poorest group(71).

Given that healthcare financing structure influences equity in healthcare service use, and that the pattern of healthcare financing is also a result of service use, many studies used an integrative approach to analyse both issues. Benefit incidence analysis (BIA), which evaluates the public subsidies received across income groups through using healthcare services, is often conducted in addition to the progressivity calculation of payment contribution (also called finance incidence analysis, FIA). Intuitively, in a country where direct co-payment for healthcare is prevailing and occupies a considerable share of total health expenditure (THE), the health insurance scheme will benefit the richer more, who would not be deterred from seeking care due to OOP payment and use more of the subsidized services compared with the poorer. Most studies in LMICs also found that the distribution of the service benefits from health insurance was generally pro-rich, and such a pro-rich pattern was more significant for the healthcare services of high cost such as inpatient care(72,73). One study in Spain using the insurance value approach, which added the monetized benefits of healthcare services to income, found that the benefit distribution was progressive after adjustment for needs(74). Redistributional effects of healthcare financing could also be observed through tracing the flow of funds in the system, although this could be rather complicated considering the public-private mix nature of the system(75). Another holistic framework is the Affordability Ladder Program (ALP) approach which investigates the whole healthcare seeking process through step-by-step analysis, taking into account the perceived healthcare needs,

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informal care, formal care and payment for healthcare. Several studies have used this framework to explore factors associated with each step of healthcare, with a focus on the differential impacts of non-need factors for different steps(76–79). In sum, the correlation between the equity in healthcare service use and financing does not have a general pattern and is context-specific. Nevertheless, subsidized high-cost services with co-payment tends to favour the rich.

As expanding health insurance coverage is deemed a crucial strategy to achieve universal health coverage and provide financial protection, many studies examined the impacts of health insurance on healthcare service use and financial burden. Studies generally confirmed the positive association between health insurance coverage and improved health service use for patients of lower SES, which was observed for a variety of insurance types (government-run public health insurance, social health insurance or community-based insurance) but differed across countries with respect to different care types such as preventive care, maternal care, specialist care or inpatient care(80–90). Nevertheless, gaps in service use still exist for the previously insured and uninsured(91), and supply-side interventions such as strengthening the service delivery system may be combined with expanding insurance coverage to achieve major improvements in equity in healthcare service use, as evidenced in Turkey(92). As for the impact of health insurance coverage on reducing the financial burden and catastrophic health expenditure (CHE), results are rather mixed, especially for LMICs where health insurance with co-payment increased healthcare service use, thereby increasing OOP payment at the same time(80,86,89,93). In general, the effects of health insurance coverage on the equity in healthcare service use and financing tend to differ across different contexts, and largely depend on the specific benefit packages provided.

1.3.2 Studies on the equity in healthcare service use and financing in China

Previous studies in China have continuously examined the equity issue in healthcare service use and financing along with the healthcare system reform. Studies using data from the 1980s and 1990s found a worsening state of equity in healthcare, which coincided with the increasing imbalances in economic development and the collapse of the old cooperative medical schemes for the rural population(18,94–96). Since the beginning of healthcare reform in 1990s following the establishment of the three public insurance schemes, UEBMI, URBMI and NRCMS, many studies found that the expansion of coverage for all

three insurance schemes improved the equity of healthcare for the targeted enrolees in terms of increasing healthcare service use by the poor and reducing the percentage of OOP payment(97–102). Studies also observed the narrowing-down of the urban-rural gap in utilization of general healthcare services, and also for certain types of healthcare such as maternal care(103–105). Nevertheless, challenges widely exist in further improving the equity in healthcare service use and financing.

Numerous studies have found that disparities in the benefit packages across health insurance schemes and geographic areas resulted in inequity in healthcare service use and financial burden, and ultimately, in health outcomes. Enrolment in UEBMI or living in a developed region was associated with more use of healthcare service (e.g. tertiary hospital inpatient care), a higher actual reimbursement rate and better financial protection(106–112). Nevertheless, the overall financial protection provided by the public schemes has been insufficient, as evidenced by a high percentage of OOP payment and a considerable probability of incurring CHE (around 13% according to the National Health Service Survey in 2000s and 2010s)(113–115). One recent study on data from 2010-2016 revealed an increasing trend in equity in terms of decreasing likelihood of CHE and higher level of financial protection(116). For NRCMS specifically, while the effective reimbursement rate was improved and co-payment reduced alongside coverage expansion, the financial burden for rural patients was still high, especially for the residents of lowest income level due to the escalating total medical cost(117–119).

The high OOP payment ratio of the healthcare financing system may carry a risk of distorting the healthcare service use and the insurance subsidy towards pro-rich inequity(120,121). One study using data from the 2000s in an underdeveloped province showed the OOP could be progressive due to the fact that poor people still did not seek care with insurance(122). Another study in a developed region found that high-cost care like hospitalization was pro-rich, while outpatient care also favoured those enrolled in UEBMI which provided considerable coverage for outpatient services(123). The effect of NRCMS was found to be limited in improving healthcare utilization(124,125)

As the fragmentation of health insurance schemes has been identified as a barrier for equity in healthcare(126), many recent studies have focused on the equity implications of the integration of URBMI and NRCMS, which share similar financing structures. Researchers found that the integrated insurance scheme,

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URRBMI, increased the benefit for enrolees, and decreased the inequity with respect to the benefit distribution across income groups(127,128). However, results regarding the effects of such integration on reducing catastrophic expenditure for the overall population, and specifically for the poor, were mixed(129,130), and a higher degree of pro-rich inequity in healthcare service use was observed under URRBMI compared with NRCMS(26). The scale of financing for URRBMI, indicated by the percentage of income, also seemed not enough to meet the rising demand for healthcare services, which may hinder the further improvement in benefit packages and financial protection(20). For UEBMI, there is also a call for the integration of the personal medical savings account (MSA) and a social-risk pooling account (SPA) to increase the level of risk pooling and alter the pro-rich nature of MSA(131).

Besides demand-side reform on health insurance schemes, researchers also investigated the supply side reform, especially regarding strengthening the primary healthcare system to improve the accessibility and quality of care for the poor population. Studies have found that government investment in primary healthcare institutions significantly increased, and consequently the total primary healthcare resources largely increased(132–134). Studies in different provinces found increased use of PHC in counties under URRBMI, however, a shrinking trend in the proportion of PHC health resources in the health system after 2009 was also observed(127,135). Besides, inequity in primary healthcare resource allocation still exists geographically, which is mostly centred in Eastern China(132). Strengthening the PHC system and optimizing the use of PHC services have been challenging for the ongoing healthcare reform.

In addition to exploring the general equity of the ongoing healthcare reform, a large volume of literature specifically focused on three major types of disparity in healthcare rooted in Chinese society: gender, rural-urban, and migrant vs. local. China has a long history of gender inequity in social power; the rural-urban dual structure in China has led to disparities in resource allocation(136); and the imbalances in economic development has resulted in large numbers of internal migrant workers. For rural-urban disparities, while studies have found narrowed gaps in access to healthcare, gaps in expenditure increased, and inequity in service use still existed as urban patients were more likely to use high-quality services, e.g. grade-3 hospitals(137–141). Regarding gender disparity, studies found that younger girls and older women (> 65) were more disadvantaged in healthcare seeking, and men expended more on healthcare after adjustment for

other factors(142–144). As for migrant status, studies reported inequitable healthcare use for rural-to-urban migrants compared to local residents after adjustment for needs(145). While enrolment in public health insurances was associated with higher probability of care seeking and increased level of financial protection, SES still played a strong role in determining the quantity and quality of healthcare service accessed by the migrants(145–149). It was also revealed that improvements in the access to healthcare unequally benefited the sons compared with the daughters in migrant families(150). These disparities suggest a need for developing policies aimed at these socially vulnerable groups in addition to general reforms of the healthcare system.

In general, existing literature has analysed a wide range of aspects of inequity in healthcare in China. Nevertheless there is a lack of full-spectrum investigation on the impacts of demographic and SES factors throughout the whole healthcare seeking process, starting from healthcare needs, to healthcare service use and payment for healthcare. Besides, these factors may also have potentially differential effects for the rural and urban population due to the fact that the observed rural-urban difference in healthcare entails multiple disparities in economic development, social protection and healthcare resource allocation. Such research could also shed light on how to further improve the healthcare coverage and financial protection for the most disadvantaged rural poor.

1.3.3 Studies on the financing and healthcare service use for TB/DRTB patients in LMICs and China

Treatment of TB requires a robust delivery system as the treatment of drug-susceptible TB takes 6-8 months. It is critical to guarantee the accessibility and affordability of standard TB care as sub-standard treatment or treatment interruption will increase the risk of relapse and developing drug resistance(151). Globally, the disease burden of TB falls mostly in LMICs, and international funding for TB has increased largely since 2000s. It was estimated that in 2019, international funding accounted for 44% of total TB funds in the 21 high burden countries except Brazil, Russia, India, China and South Africa (Brics)(30). These international TB funds, channelled through international organization like Global Fund, have been used mainly to strengthen the local TB programs in terms of staff recruitment and training, drug and equipment procurement and implementing the directly observed therapy-short course (DOTS) management strategy (152,153). Nevertheless, TB patients in LMICs may still face a high

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financial burden of treatment due to direct and non-direct medical costs and income loss(3), and financial difficulties have been widely identified as a barrier to treatment adherence and completion.

TB patients in China face the unique difficulties brought up by the TB control system in accessing affordable healthcare services in addition to the common problems in the general healthcare system. Studies before the transition of the TB control model in China revealed heavy financial burden of TB treatment and a considerable proportion of patients receiving sub-standard TB clinical services outside TB dispensaries(154–157). Studies during and after the transition of the TB control model generally showed shortened treatment delays and improved clinical quality under the integrated model. However, overuse of healthcare services and higher treatment cost were also observed due to the profit-driven motivation of the hospitals(32,158–161). Such profit-driven behaviours as unnecessary hospitalization and irrational use of second-line anti-TB drugs were especially serious in TB specialist hospitals(159,160).

Besides, the financial protection provided by the health insurance schemes, especially the NRCMS which covered most of the rural poor, is very limited, and poor patients are much more likely to incur CHE(162,163). Many healthcare services such as rapid tests, chest X-rays and auxiliary drugs prescribed at outpatient visits are not covered by the health insurance schemes, and patients need to pay for them out-of-pocket(32,164). Studies also reported the high financial burden as a major reason for delays in seeking care and treatment default for TB patients, most of whom are of low SES (33,165). In sum, the distorted incentives for healthcare workers to prescribe unnecessary treatment, and the insufficient financial protection provided by public insurance schemes are the two key factors contributing to the high financial burden of TB, which need to be addressed to achieve the SDG target of ending TB in 2030.

Regarding the problem of insufficient financial protection, many studies have examined the impacts of interventions that provided material incentives for TB patients, mainly in the form of cash transfer, non-cash incentives such as food vouchers, or microfinance interventions. These interventions, implemented alone or together with other interventions such as psychological support, were found to have positive effects in improving treatment adherence and reducing risk factors of TB(166–170). However, most of these interventions were conducted in underdeveloped countries with weak public health insurance systems, and very few interventions used insurance-based approaches such as

increasing the reimbursement rate for TB. As for the cost control challenge, the diagnosis-related group (DRG) payment approach (for TB specifically, a case-based payment which sets a fixed payment rate per TB case prospectively) could alter the provider incentive and potentially solve the cost problem(171).

Studies in China have found mostly positive results regarding the impact of case-based payments on regulating healthcare service use and medical cost reduction(172–175). However, the positive impacts may be compromised by problems arising in implementation, for example excluding patients whose treatment cost is higher than the predetermined case limit, or cost transfer to patients without local health insurance(171,174,176). For TB specifically, only one study suggested that a case-based payment approach with no co-payment for patients may be feasible and beneficial under the NRCMS(177). In general, there is a lack of evidence as to the effects of adopting a model combining increased reimbursement rates and case-based payment on the treatment adherence and financial burden of TB patients. In particular, it remains unknown whether this approach could protect the most economically vulnerable groups from financial difficulty.

Diagnosis and treatment of DRTB are more challenging under the current health system in China, as the same type of problems encountered in TB are even graver for DRTB due to the much longer treatment period needed. DRTB patients tend to have lower SES than ordinary TB patients, enjoy lower reimbursement rates in higher-level hospitals outside their county/prefecture of insurance enrolment, and need more healthcare services and medicines of high cost that are not covered by the public health insurances (especially some types of extremely expensive second-line drugs). However, the current financial protection in the form of health insurance reimbursement and subsidized treatment is far from sufficient(36,37,178–180). Studies have also revealed long treatment delays and high rates of treatment interruption or default among DRTB patients in China, even in the most developed areas like Shanghai and Zhejiang. And financial difficulty was identified as a major barrier to accessing care(35,181,182). The treatment success rate of MDRTB in China was less than 50% according to a study in 2018(183).

Studies on interventions to improve DRTB care performance involved both supply-side investments to upgrade clinical capacity and demand-side policies to improve patients' access and adherence to treatment. Previous studies have found that the use of rapid drug susceptibility testing (DST) technologies such

as Genechip and GeneXpert in the screening for DRTB, that produce test outcomes in 1-2 days, effectively shortened treatment delays and reduced the likelihood of pre-diagnosis attrition(184–188). As for treatment adherence, review studies showed that directly observed therapy (DOT), comprehensive psychosocial support or other psychosocial support could improve adherence to DRTB to some extent, while the reported default rates were still high(189,190). Another study found that patient counseling as a single intervention or counseling combined with financial support can increase the cure rates among MDRTB patients who are facing social stigma and economic hardship(191). One comprehensive program in China which provided universal health coverage for MDRTB patients with a capped treatment package was shown to effectively decrease the diagnostic delay, increase the initiation and completion rates of standard treatment and reduce patients' financial burden, although 15% of the diagnosed patients still did not initiate or complete treatment(192).

Many provinces in China have implemented multiple policies and strategies to improve DRTB control following pilot projects supported by international funders. These strategies include supply-side governmental fiscal support to procure DST equipment and reagents for designated hospitals, as well as demand-side policies of improving the reimbursement rate of DRTB and cash transfer to patients(180,193). However, there has been no overall assessment on the impacts of these strategies on the diagnosis and treatment of DRTB. Moreover, some beneficial policies can only be enjoyed by patients with local Hukou or residence permit, or those who enrolled in health insurance in the places where they seek care. Therefore, the equity implications of these policies are also worth exploring. These equity implications are closely related to the inequity challenges for the overall healthcare system in China. A comprehensive assessment of the impacts of these policies on the socially vulnerable DRTB patients would shed light on how to further improve the accessibility and affordability of healthcare services for population groups that have been left behind during the healthcare reform.

1.4 Objectives of this thesis

This thesis aimed to examine the equity in healthcare service use and financing in China through exploring the impact of non-need factors on the healthcare service use and payment for the Chinese population, and identify effective interventions to improve accessibility and affordability of the healthcare services

for a socially vulnerable group, TB/MDRTB patients in China. The specific objectives were:

1) To examine the association between demographic and socio-economic factors and patients' perceived healthcare needs, healthcare service use and expenditures for both rural and urban population in Jiangsu Province, China.

2) To investigate changes in the healthcare service use, out-of-pocket (OOP) health expenditure and financial burden of TB patients before and after the implementation of a new financing and payment model for TB treatment.

3) To investigate how DRTB-related policy changes impacted on the programmatic performance with regard to screening, diagnosis, treatment and management of DRTB patients, and explore whether these policy changes have equally influenced patients of different demographic and socio-economic characteristics.

Each of the three specific objectives corresponds to one research project, which will be presented in chapter 2, chapter 3 and chapter 4, and chapter 5. A general discussion and conclusion on the research findings will be presented in chapter 6.

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Chapter 2

General situation of the equity in health service use and health care financing in China

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Weixi Jiang, Xiaolin Xu, Shenglan Tang, Ling Xu, Yaoguang Zhang, Chris Elbers , Frank Cobelens, Lijing Yan**.** Inequity in healthcare needs, health service use and financial burden of medical expenditures in China: results from a consecutive household monitoring study in Jiangsu Province. *BMC Health Serv Res* 2019;19:9

Abstract

Background: Although public medical insurance covers over 95% of the population in China, disparities in health service use and out-of-pocket (OOP) health expenditure across income groups are still widely observed. This study aims to investigate the socio-economic disparities in perceived healthcare needs, informal care, formal care and payment for healthcare and explore their equity implication.

Methods: We assessed healthcare needs, service use and payment in 400 households in rural and urban areas in Jiangsu, China, and included only the adult sample (N=925). One baseline survey and 10 follow-up surveys were conducted during the 7-month monitoring period, and the Affordability Ladder Program (ALP) framework was adopted for data analysis. Negative binomial/zero-inflated negative binomial and logit regression models were used to explore factors associated with perceived needs of care and with the use of self-treatment, outpatient and inpatient care respectively. Two-part model and logit regression modeling were conducted to explore factors associated with OOP health expenditure and with the likelihood of incurring catastrophic health expenditure (CHE).

Results: After adjusting for covariates, rural residence was significantly associated with more perceived healthcare needs, more self-treatment, higher probability of using outpatient and inpatient service, more OOP health expenditure and higher likelihood of incurring catastrophic expenditure ($P<0.05$). Compared to the Urban Employee Basic Medical Insurance (UEBMI), enrollment in the New Rural Cooperative Medical Scheme (NRCMS) or in the Urban Resident Basic Medical Insurance (URBMI) was correlated with lower probability of ever using outpatient services, but with more outpatient visits when people were at risk of using outpatient service ($P<0.05$). NRCMS/URBMI enrollment was also associated with higher likelihood of incurring CHE compared to UEBMI enrollment (OR=2.02, $P<0.05$); in stratified analysis of the rural and urban sample this effect was only significant for the rural population.

Conclusions: The rural population in Jiangsu perceived more healthcare needs, had a higher probability of using both informal and formal healthcare services,

and had more OOP health expenditure and a higher likelihood of incurring CHE. The inequity mainly exists in health care financing, and may be partially addressed through improving the benefit packages of NRCMS/URBMI.

Background

The Chinese health care system has experienced rapid changes along with socio-economic reform. On the supply side, the government has in recent years been investing in health care infrastructure, especially in primary health care institutions (1). On the demand side, three public health insurance schemes, the Urban Employee Basic Medical Insurance (UEBMI), the Urban Resident Basic Medical Insurance (URBMI) and the New Rural Cooperative Medical Scheme (NRCMS), were gradually established since late 1990s. Currently over 95% of the Chinese population are covered by these three public insurance schemes, leaving less than 5% not covered by any insurance scheme, and medical services are mostly financed through the co-payment mechanism of the insurance schemes(2). Inpatient medical services are covered with reimbursement rates ranging from 50% to 90% for different schemes at different levels of hospitals, but the reimbursement rates for outpatient services are still rather low for URBMI and NRCMS(3,4).

Many studies have assessed equity in health care utilization and financing in terms of insurance types and income. Recent studies on the three public insurance schemes generally show that they improved people's access to formal care, including both outpatient and inpatient services, and narrowed the gaps in service use across income groups with the expansion of insurance coverage(3,5–8). Nevertheless, one report from the World Bank showed that the separation in the management of the financing and benefit packages of health insurance schemes across insurance types and regions weakened the risk-pooling effect, and caused inequity problems(9). The high proportion of out-of-pocket (OOP) health expenditure also indicated obstacles to accessing health care and high financial burden of health care (10–12). For each type of insurance specifically, research on URBMI and UEBMI reveals that these schemes benefited patients from higher income groups more, as poorer patients were less likely to use expensive care, thus receiving less reimbursement than the well-off, and the urban insurance systems failed to reduce the OOP health expenditure for the disadvantaged group(6,13,14). For NRCMS studies show that the expansion of NRCMS narrowed the gaps in inpatient service use and encouraged poorer patients to seek informal and preventive care. However they also showed that the care utilization pattern under NRCMS was still pro-rich and that NRCMS did not lower health expenditure nor provide sufficient protection for the

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poor(7,8,15).

A rich literature also explored inequity in health care regarding a series of demographic and socio-economic factors. Several recent studies revealed that with the expansion of insurance coverage, the rural-urban disparities in health service utilization and reimbursement rate substantially narrowed in recent years, but still exist (16–18). Rural patients enjoyed lower reimbursements and bore a high burden of medical expenditure with reference to their income level(17,19). Studies also showed how ethnic minority, income, education and insurance coverage may have a differential impact on the service use pattern of rural and urban populations(20,21). Nevertheless, there is a lack of systematic analysis on how demographic and socio-economic factors would impact on the whole health seeking process under the current health care system, starting from health care needs to payment for services for both rural and urban population.

In this study we referred to the Affordability Ladder Program (ALP) which provides a holistic approach to examining equity in the health care system from the demand-side perspective through step-by-step analysis, taking into account the perceived health care needs, informal care, formal care and payment for health care (22). Several studies have used this framework to explore access to and payment for healthcare services in other countries(22–25). This framework also allowed the exploration of the potential differential or synergistic impact of a certain factor on health equity in each step of the entire health care seeking path, which was not possible in most previous studies and were the main original contribution of our research. This study was located in Jiangsu, a relatively well-developed province in eastern China with a per capita GDP of $14,000 in 2015, where over 95% of the population were covered by one of the three public health insurance schemes(26). We focused on the equity implication of non-need factors for health care such as residence, income and insurance coverage(27), and explored how these factors may influence each ladder step of health care for the rural and urban population, respectively.

Methods
Sampling Design
One urban district (Gusu) and one rural county (Jinhu) in Jiangsu were selected as study sites. Gusu and Jinhu are located in southern and northern Jiangsu

respectively, and the GDP per capita (RMB 136,556) in Gusu is twice as in Jinhu (RMB 65,535). Disproportionate stratified sampling was applied with a sample size of 200 households in each site. A list of households with non-communicable disease (NCD) patients was obtained from the local health bureau, and 100 households were randomly selected from the list in each site. The other 100 sample households were randomly selected from the rest of the households in the study sites. As the sample size is relatively small, the households with NCD patients were over-sampled in order to increase the total events of service use. The project also aims to look at NCD management for which the results are yet to be published.

Data Collection
This study consisted of a baseline survey and 10 follow-up surveys over 7 consecutive months during 2015-2016, with the first 6 surveys conducted bi-weekly and the last 4-monthly (the first 6 surveys were in phase 1, the remaining 4 were in phase 2 when survey frequency was reduced with regard to respondents' feedback that the surveys in phase 1 were too frequent). One knowledgeable person from each household, usually the household head, signed informed consent before the interview, and answered on behalf of all members in the household. The baseline survey gathered participants' basic demographic, socio-economic and health information, as well as inpatient service use and expenditure in the past year. Each follow-up survey contained 6 questionnaires concerning chronic disease management for different NCDs, emergent illness (including emergent conditions of NCDs), patients' utilization of self-treatment, outpatient and inpatient services as well as medical costs and out-of-pocket payments.

The baseline survey and the last follow-up survey of phase 1 (6th) and phase 2 (10th) were conducted through face-to-face interviews by trained interviewers in the participants' homes. For other follow-up surveys participants were asked to choose between: 1) filling survey questionnaires themselves; 2) call interviewers when disease/health service use occurred; 3) face-to-face interview at home; or 4) telephone interview for the follow-up survey. More than 90% of households chose face-to-face interview, a few opted for telephone interview and almost no households filled the survey questionnaires themselves or called interviewers.

All questionnaires were checked by supervisors of the interviewers before transferring to the investigators. For quality assurance, a 5% sample of the questionnaires were randomly selected and double-checked by investigators through telephone re-interview; the rate of concordance exceeded 95%. Data was double entered, and inconsistencies, outliers and missing values were also double-checked in order to ensure data quality. Datasets were encrypted in storage and de-identified during data analysis to protect participants' confidentiality.

Data analysis

We included only the adult population in the analysis as children usually do not make care seeking decisions themselves(28). Descriptive analyses were conducted to examine the demographic and socio-economic characteristics of the overall sample as well as of the urban and rural sample separately. The chi-squared test and t-test were applied to test for significance of differences between the rural and the urban sample. Based on the ALP framework(22) we identified 6 key outcome variables of interests throughout the care-seeking path as shown in Table 1. The total of reporting emergent illness episodes, conducting self-treatment, outpatient service use, inpatient service use, and the total amount of OOP health expenditure were aggregated over the 7-month survey period. Catastrophic health expenditure was defined as total OOP health expenditure exceeding 10% of household income(29). The data were analyzed using STATA 13.1(StataCorp, Texas, USA).

Table 1: Key outcome variables identified based on the ALP framework

Healthcare seeking path	Outcome variables
Perceived health care needs	1) number of self-reported emergent illness episodes
Health service use	
Informal care	2) self-treatment
Formal care	3) outpatient service use
	4) inpatient service use
Payment for health care	5) total OOP health expenditure
Financial burden of health care	6) catastrophic health expenditure (CHE) during the survey period

Multivariate regression models were used to explore factors associated with each

of these outcome variables of interests. As preliminary analyses showed that there were many "zeros" in the data (no emergent illness, no service use and no health expenditure), we considered standard Poisson/negative binomial (NB) models versus zero-inflated Poisson (ZIP) /negative binomial (ZINB) models for the first three outcomes which were count variables, and a generalized linear model (GLM) versus a two part model combining logit regression and GLM for the OOP health expenditure(30). The zero-inflated models have two processes that separately model the likelihood of not being at risk of having the event (process 1, note that a positive coefficient or relative risk >1 implies a lower probability of being at risk) and the total number of events given that one is at risk (process 2). The two-part model estimates the likelihood of incurring any OOP medical expenditure and the amount of expenditure if incurred in two steps(30). As for model selection, we considered the Akaike Information Criterion (AIC) and the Bayesian Information Criterion (BIC) of each model first, and Vuong's closeness test for ZINB *vs.* the standard negative binomial model if AIC and BIC preferred different models(31). Based on these criteria we selected the ZINB model for the total episodes of self-reported emergent illness, the NB model for self-treatment, the ZINB model for outpatient service use and two-part models combining logit regression and GLM for OOP health expenditure (see supplemental materials for details). As only 9 patients in our sample were admitted more than once, we coded inpatient service use as a binary variable of use/non-use. Logit regression was conducted to analyze factors associated with the likelihood of ever using inpatient services and incurring CHE.

As for the independent variables, we focused on the effects of factors reflecting socio-economic status (SES), including rural/urban residence, education level, income, employment and the status of health insurance, and adjusted for factors that may affect both these SES factors and the outcomes, including age, gender, marital status and presence of NCDs. Age, income and education level were treated as categorical variables in the regression models. As for insurance, we grouped people with the new cooperative medical scheme (NRCMS) together with those enrolled in urban resident basic medical insurance (URBMI), as they provided similar benefit packages and only 6% of the sample were enrolled in URBMI. The average income per capita was divided into 3 groups: the richest 33.3%, middle 33.3% and poorest 33.3% for the whole sample. Standard errors were adjusted for household clustering considering the intra-household

correlation.

Results

Sample Characteristics

Four-hundred households participated and completed the surveys, totaling 1057 people. We included the 925 adult participants in the analyses. Table 1 shows the demographic, socio-economic, health status and the descriptive analysis of the six outcome variables for the overall sample as well as the samples Gusu (urban) and Jinhu (rural) separately. The sample included 463 adult participants in the urban area and 462 in the rural area. The gender distribution was almost balanced, and 44.1% were over 60 years old. Participants in the urban area had higher socio-economic status in terms of education, employment and income. In the rural sample 27.9% of participants had never completed primary school education, while this was only 2.6% in the urban sample. The average income per capita of the households in the urban sample was almost twice that in the rural sample. Over 95% of the sample were covered by public health insurance, therefore we could not explore the effects of having no public health insurance on health care utilization. Over 70% of urban sample were covered by UEBMI while in the rural sample 87.5% were enrolled in the NRCMS. As for NCD status, 45.7% of the sampled population had at least one type of NCD, and this rate was slightly higher in the rural area. Descriptive analysis on the six outcome variables showed that the rural sample had more self-reported emergent illness episodes, used both more informal and formal health care services, had higher OOP health expenditure and higher likelihood of incurring CHE .

Table 2: Basic characteristics of study participants (%)

	Total sample	Gusu (urban)	Jinhu (rural)
	n=925	n=463	n=462
Gender			
male	51.2	47.08	49.6
Age			
average (sd)	54.5 (17.0)	53.5(18.8)	55.5(15.0)
18-29	10.7	12.3	9.1
30-59	45.2	41.3	49.1

>=60	44.1	46.4	41.8
Marriage			
married	85.4	85.3	85.5
Education			
Below primary	15.2	2.6	27.9
primary and junior high	48.7	41	56.3
senior high school and above	36.1	56.4	15.8
Employment			
employed	55.0	37.8	72.3
retired	27.1	50.8	3.3
unemployed	21.4	17	26.2
Health insurance			
UEBMI	40.5	73.4	7.6
URBMI	6.2	7.6	4.8
NRCMS	49	10.6	87.5
other and no insurance	4.3	8.4	0.2
Mean household income per capita (RMB)			
average (sd)	2135(1395)	2807(1462)	1462(920)
With NCD			
yes	45.7	43.8	47.6
Self-reported emergent illness episodes			
mean (sd)	0.98(1.66)	0.40(1.12)	1.56(1.90)
Total times of self-treatment			
mean (sd)	0.39(0.94)	0.06(0.37)	0.71(1.19)
Total times of outpatient service			
mean (sd)	0.66(1.34)	0.35(0.96)	0.97(1.57)
% inpatient service use	6.0	3.9	8.0
Total OOP health expenditure			
mean (sd)	594(4266)	201(1940)	991(5697)
% CHE	16.8	6.5	27.1

Factors associated with health care needs

Table 3 shows the association between perceived health care needs and a

series of demographic, health status and socio-economic factors, using the ZINB model. Process 1 of the model showed that, after adjusting for other covariates, people with rural residence were much more likely to be at risk of reporting emergent illness as compared to their urban counterparts (OR=0.02, 95% CI: 0.00, 0.26). Having any NCD also increased the probability of such risk (OR=0.33, 95% CI: 0.11, 0.91). Process 2 of the model shows that, after adjusting for other factors, having a NCD was in addition associated with reporting more emergent illness episodes (IRR=1.39, 95%CI: 1.02, 1.89). People enrolled in NRCMS/URBMI also tended to report more emergent illness episodes compared to those enrolled in UEBM, (IRR=1.67, 95% CI: 1.03, 2.71). Education level seemed negatively associated with the number of self-reported emergent illness episodes, and the association was almost significant for those with highest education level (senior high school and above).

Table 3: Regression analysis of factors associated with self-reported emergent illness episodes using ZINB model

	Process 1		Process 2	
	OR	95% CI	IRR	95% CI
Age				
<30	ref.		ref.	
30-59	0.24	0.03, 1.81	0.76	0.30, 1.88
>=60	0.41	0.05, 2.84	0.73	0.30, 1.78
Male	0.88	0.31, 2.50	0.91	0.68, 1.24
Rural residence	0.02	0.00, 0.26	0.73	0.41, 1.29
Married	0.76	0.28, 2.02	0.93	0.65, 1.32
Education Level				
no education	ref.		ref.	
primary and junior high	1.36	0.18, 9.78	0.86	0.64, 1.16
senior high school and above	0.76	0.07, 7.22	0.6	0.36, 1.01
Employed	1.17	0.36, 3.77	1.07	0.79, 1.43
Insurance				
UEBMI	ref.		ref.	
NRCMS/URBMI	1.75	0.66, 4.65	1.67	1.03, 2.71
Income level				

poorest 33.3%	ref.		ref.	
middle 33.3%	0.92	0.19, 4.29	0.94	0.67, 1.32
richest 33.3%	0.75	0.19, 2.86	0.85	0.58, 1.23
With NCD	0.33	0.11, 0.91	1.39	1.02, 1.89

(OR: odds ratio. IRR: incident rate ratio. Process 1 modeled the likelihood of not being at risk of reporting self-reported illness, process 2 modeled the total number of self-reported emergent illness episodes given that one is at risk. The sample size is the same as described in table 2. All estimates were adjusted.)

Factors associated with use of self-treatment, outpatient and inpatient service
Table 4 shows the analyses of the numbers of self-treatments, outpatient service use and inpatient service use for a series of demographic, health status and socio-economic factors, using different regression models. Multivariable NB regression of self-treatment on these factors showed that older age, rural residence and having NCD were significantly associated with increased use of self-treatment, and the effect was particularly strong for rural residence (IRR=6.07, 95% CI: 2.86, 12.88). As for outpatient service use, multivariable regression analysis using the ZINB model showed that rural residence was associated with much higher probability of being at risk of using outpatient services (i.e. using any of these services) compared to urban residence (OR=0.02, 95%CI: 0.00, 0.10).Conversely, after adjusting for other covariates , enrollment in NRCMS/RBMI significantly decreased the probability of using any outpatient service compared to UEBMI (OR=13.29, 95% CI: 1.34, 132.24), which means NRCMS/RBMI may discourage outpatient service use. Nevertheless, for those who were at risk of using outpatient service, NRCMS/RBMI was significantly associated with more use (IRR=2.75, 95% CI: 1.13, 6.72). Multivariable logit regression of inpatient service use showed that rural residence and having NCD were associated with higher probability of using inpatient service (P<0.05), while men were less likely to use inpatient service than female (P<0.05)

Table 4: Regression analysis of factors associated with self-treatment, outpatient service and inpatient service use

	Self-treatment		Outpatient service use				Inpatient service use	
	NB		ZINB-proc1		ZINB-proc2		logit	
	IRR	95% CI	OR	95% CI	IRR	95% CI	OR	95% CI
Age								
<30	ref.		ref.				ref.	
30-59	2.41	1.24, 4.69	0.64	0.13, 3.07	0.75	0.32, 1.75	0.34	0.10, 1.15
>=60	2.27	1.10, 4.68	0.76	0.10, 5.93	0.59	0.25, 1.40	1.11	0.31, 3.97
Male	0.94	0.67, 1.30	1.66	0.48, 5.76	0.98	0.71, 1.37	0.37	0.18, 0.77
Rural residence	6.07	2.86, 12.88	0.02	0.00, 0.10	0.56	0.17, 1.85	3.56	1.60, 7.93
Married	0.87	0.57, 1.31	0.59	0.08, 4.13	0.86	0.55, 1.35	1.85	0.75, 4.52
Education Level								
no education	ref.		ref.				ref.	
primary and junior high school	1.09	0.77, 1.53	0.5	0.05, 4.97	0.71	0.47, 1.08	1.27	0.54, 2.99
senior high school above	0.87	0.49, 1.54	1.3	0.04, 39.13	0.71	0.33, 1.52	1.7	0.53, 5.57
Employed	0.91	0.62, 1.33	1.45	0.28, 7.57	1.07	0.72, 1.58	0.61	0.28, 1.30
Insurance								
UEBMI	ref.		ref.				ref.	
NRCMS/URBMI	1.48	0.75, 2.91	13.29	1.34, 132.24	2.75	1.13, 6.72	1.1	0.46, 2.62
Income level								
poorest 33.3%	ref.		ref.				ref.	
middle 33.3%	0.89	0.61, 1.30	0.26	0.02, 2.86	0.79	0.56, 1.12	1.52	0.69, 3.33
richest 33.3%	0.61	0.34, 1.09	0.21	0.00, 13.65	0.71	0.42, 1.20	1.07	0.46, 2.50
With NCD	1.49	1.12, 1.99	0.06	0.00, 4.97	1.21	0.80, 1.85	2.65	1.41, 4.95

(OR: odds ratio. IRR: incident rate ratio. Proc: Process. Process 1 of ZINB modeled the likelihood of not being at the risk of using outpatient service, and process 2 modeled the total times of outpatient service use given that one is at that risk. The sample size is the same as described in table 2. All estimates were adju

Out-of-pocket (OOP) payment and financial burden across income groups

Table 5 shows the results of regression analyses of factors associated with OOP health expenditure using a two-part model combining logit regression and GLM, as well as factors associated with CHE using a logit model. Similar to the results of the analysis on inpatient service use, NCD and rural residence were significantly associated with higher probability of incurring medical expenditure and CHE (P<0.001) after adjusting for other covariates. For those who had out-of-pocket health expenditure, men tended to spend less than women, and men were also less likely to incur catastrophic expenditure (P<0.05). People in NRCMS/RBMI were also twice likely to incur CHE as those enrolled in UEBMI (OR=2.02, 95% CI: 1.10, 3.73), after adjusting for other variables.

Table 5: regression analysis of factors associated out-of-pocket health expenditure and CHE

| | OOP health expenditure | | | | Catastrophic health expenditure logit | |
| | part1-logit | | part2-GLM | | | |
	OR	95% CI	Coef.	95% CI	OR.	95% CI
Age						
<30	ref.				ref.	
30-59	1.46	0.73, 2.92	57.7	-1810.2, 1925.7	1.01	0.40, 2.59
>=60	1.07	0.51, 2.21	1898.1	-722.9, 4519.0	1.13	0.44, 2.94
Male	0.8	0.58, 1.11	-2207.4	-4337.5, -77.3	0.58	0.38, 0.89
Rural residence	6.6	3.95, 11.03	1094.2	-802.5, 2991.0	2.92	1.61, 5.30
Married	1.16	0.72, 1.86	595	-620.0, 1810.0	0.94	0.53, 1.67
Education Level						
no education	ref.				ref.	
primary and junior high	0.68	0.42, 1.11	1788.4	-634.9, 4211.7	0.97	0.57, 1.64
senior high school and above	0.62	0.32, 1.18	2199.7	-761.7, 5161.1	0.73	0.34, 1.54
Employed	0.9	0.58, 1.39	712.9	-1453.9, 2879.8	0.61	0.37, 1.02
Insurance						
UEBMI	ref.				ref.	
NRCMS/URBMI	1.33	0.8, 2.19	238.5	-640.6, 1117.7	2.02	1.10, 3.73
Income level						
poorest 33.3%	ref.				ref.	
middle 33.3%	1.06	0.69, 1.61	-237.4	-1661.7, 1186.8	0.72	0.43, 1.20
richest 33.3%	1.09	0.69, 1.74	877.2	-2167.2, 3921.6	0.57	0.31, 1.05
With NCD	1.99	1.42, 2.78	212.8	-1245.0, 1670.6	2.97	1.93, 4.58

(Part 1 of the two-part model used logit regression to estimate the likelihood of incurring OOP health expenditure, and part 2 used GLM to model the amount of OOP health expenditure if occurred. All estimates were adjusted.)

Stratified analysis on the rural and urban sample
We further explored the effects of demographic and SES factors on these outcomes of interests for urban and rural population separately. Gender played a role in the rural but not in the urban area. Compared to women, men in the rural area tended to report fewer emergent illnesses, use less inpatient and outpatient services, and thus less often incurred catastrophic expenditure. It is also noticeable that for the rural sample, people enrolled in NRCMS/URBMI were more likely to incur CHE compared to those enrolled in UEBMI, and being in the richest tertile also decreased the likelihood of incurring CHE. Nevertheless, insurance category and income were not significantly associated with the possibility of incurring CHE in the urban sample, and only NCD status seemed to have an effect on CHE ($P<0.05$) (see supplemental material for all result tables).

Discussion
Findings from this study revealed a clear rural-urban distinction: the rural population tended to have more perceived health care needs, had a higher probability of using both informal (self-treatment) and formal (outpatient and inpatient) healthcare services, and had more OOP health expenditure and a higher likelihood of incurring catastrophic expenditure after controlling for other factors. The rural-urban difference in perceived health care needs may be due to unobserved disparities in health status, for example, healthier people are more likely to move to urban areas to seek job opportunities. In our study situated in a developed region, the rural population have access to care upon need, non-need factors such as income seemed to have no effect on health care utilization, and insurance type only had an impact on outpatient service use. Nevertheless, while the expansion of insurance coverage, mainly NRCMS/URBMI, and the investment in health care infrastructure have been narrowing the gaps in service use, people in rural areas are still facing a higher financial burden of treatment.

Besides the rural-urban difference, people enrolled in UEBMI were less likely to incur catastrophic expenditures, and our separate analysis of the rural and urban

sample showed that this protective effect is significant for the rural population, but no for the urban population. While previous studies have revealed that current benefit packages of NRCMS are not sufficient to protect people from catastrophic spending(4,32), our study also suggests that we may need to improve the coverage range and reimbursement rate of NRCMS/URBMI to reduce the possibility of catastrophic expenditure, which is particularly urgent when more poor people start to seek care. We also noticed that while enrollment in NRCMS/RBMI indicates lower probability of using any outpatient care, it was associated with increased numbers of visits for those who were at risk of using outpatient service. This finding suggests that as NRCMS/URBMI provides little coverage for outpatient services, people may delay care seeking until the disease is serious, which may in turn lead to higher expenditure for treatment.

As the health care reform in China continues, NRCMS is being, or has been, integrated with URBMI in many regions. Several studies on this integration show that it narrowed the rural-urban gaps in inpatient benefit, improved the quality of health care and reduced the health care expenditure of the rural population(33,34). The integration of all the three public insurances has just started to be piloted in some cities(35). Although some studies have revealed that such integration would encounter administrative and technical challenges(36,37), it is still regarded by many researchers as a critical way of reducing inequity across insurance schemes and regions(9,37,38). In our study we emphasize that there is a need to reduce the gaps in benefit packages for UEBMI and NRCMS/URBMI, in view of the increasing health care demands from the rural population.

In this study we investigated and identified the inequity in health care needs, service use and financing between rural and urban population, as well as across different types of public insurance. Nevertheless, this study also has several limitations. As mentioned above, it was conducted in the most developed eastern area of China where in 2017 less than 0.8% of the rural population still lived in absolute poverty(39). Findings from this study may underestimate the level of inequity in health care with regards to the overall situation in China, as poorer people in this area were still able to access inpatient care despite of the high OOP medical expenditure. External validation of the results was also not possible as we only have data in Jiangsu. The short monitoring period and changes in the

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frequency of follow-up surveys also restricted us in observing seasonal changes in health care needs or service use. Besides, CHE is a household-level variable and we realize that when we use individual regressors as proxy for their household-level equivalents, we introduced measurement error 'on the right-hand side', leading to attenuation bias. On the other hand, the fact that we included all adults from a household in our ample tends to neutralize this bias. In light of these findings and limitations, future research may increase the number of study sites and extend the length of monitoring to get a more complete understanding of the equity issues in health care across regions in China at different developmental stages. Besides, the reason why men in rural area made less use of inpatient services remains unclear, and deserves further investigation.

Conclusion

The rural population in Jiangsu perceived more health care needs and had a higher probability of using both informal and formal health care services than the urban population. Rural population also had higher OOP health expenditure, and NRCMS /URBMI provided less sufficient protection from catastrophic expenditure as compared to UEBMI. While the expansion of the coverage in NRCMS/URBMI has narrowed the gaps in health care utilization, the inequities in health care financing may be further addressed through improving the benefit packages of NRCMS/URBMI.

List of abbreviations
OOP: out-of-pocket
ALP: Affordability Ladder Program
CHE: Catastrophic Health Expenditure
UEBMI: Urban Employee Basic Medical Insurance
NRCMS: New Rural Cooperative Medical Scheme
URBMI: Urban Resident Basic Medical Insurance
NCD: Non-communicable disease
NB: Negative Binomial
ZIP: Zero-inflated Poisson
ZINB: Zero-inflated Negative Binomial
GLM: Generalized Linear Model
CI: Confidence Interval
AIC: Akaike Information Criterion

BIC: Bayesian Information Criterion
SES: Socio-economic Status

Declarations

Ethics approval and consent to participate

Consent for publication

Anonymized information was used in this manuscript to ensure confidentiality

Availability of data and materials

The datasets generated and/or analyzed during the current study are not publicly available due to the fact that the data are owned by the National Health Commission China. The data could be available after obtaining consent from the National Health Commission China.

Competing interests

Funding

Authors' contributions

The study was designed by Weixi Jiang under the guidance of FC, organized and coordinated the data collection process, and WJ participated in the data collection. XX and WJ cleared the dataset. WJ conducted literature search and wrote the manuscript as the first author. ST, FC, CE and LY provided suggestions on data analysis framework and data interpretation, and helped revise the draft. All authors reviewed the draft manuscript and provided comments on the finalization of the manuscript. All authors have read and approved the

manuscript in its current state.

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Supplemental Materials

Table 1: The AIC, BIC and results of Vuong test of different regression models for each outcome variable

Outcome variable: number of self-reported emergent illness episodes		
	AIC	BIC
Poisson	2596.1	2663.7
Negative binomial	2336.5	2408.9
Zero-inflated poisson	2379.9	2515.1
Zero-inflated negative binomial	2301.9	2441.9
Vuong test of ZINB vs. standard negative binomial: z = 3.70 Pr>z = 0.0001		
Outcome variable: total times of self-treatment		
	AIC	BIC
Poisson	1375.6	1451.0
Negative binomial	1292.6	1365.0
Zero-inflated poisson	1303.2	1438.4
Zero-inflated negative binomial	not concave	
Outcome variable: total times of outpatient visits		
	AIC	BIC
Poisson	2200.8	2268.4
Negative binomial	1917.8	1990.3
Zero-inflated poisson	1972.3	2107.5
Zero-inflated negative binomial	1900.7	2040.8
Vuong test of ZINB vs. standard negative binomial: z = 3.43 Pr>z = 0.0003		
Outcome variable: total OOP health expenditure		
	AIC	BIC
Glm	17743.2	17810.5
Two-part model: logit+glm	7978.6	8108.5

Table 2: Regression analysis of factors associated with self-reported emergent illness using NB model: rural vs urban

	Rural sample		Urban sample	
	IRR	P>z	IRR	P>z
Age				
<30	ref.		ref.	

30-59	1.12	0.727	1.05	0.931
>=60	1.04	0.902	0.77	0.680
Male	0.80	0.038	1.25	0.304
Married	1.03	0.886	0.80	0.540
Education Level				
no education	ref.			
primary and junior high	0.94	0.627	ref.	
senior high school and above	0.61	0.030	1.17	0.583
Employed	0.96	0.772	0.90	0.719
Insurance				
UEBMI	ref.		ref.	
RBMI	1.95	0.011	0.77	0.459
Income level				
poorest 33.3%	ref.		ref.	
middle 33.3%	1.03	0.820	0.74	0.525
richest 33.3%	0.89	0.454	0.92	0.856
With NCD	1.54	0.000	2.40	0.006

Table 3: Regression analysis of factors associated with the total times of conducting self-treatment using NB model: rural vs urban

	Rural sample		Urban sample	
	IRR	P>z	IRR	P>z
Age				
<30	ref.			
30-59	1.92	0.086	5.39	0.025
>=60	1.81	0.148	5.13	0.064
Male	0.89	0.463	1.25	0.614
Married	0.94	0.793	1.10	0.849
Education Level				
no education	ref.			
primary and junior high	1.06	0.768	ref.	
senior high school and above	0.68	0.203	3.31	0.009
Employed	0.91	0.660	0.24	0.121
Insurance				
UEBMI	ref.		ref.	
RBMI	1.55	0.248	1.02	0.968

Income level				
poorest 33.3%	ref.			
middle 33.3%	0.96	0.832	0.30	0.050
richest 33.3%	0.96	0.871	0.04	0.000
With NCD	1.56	0.005	1.25	0.676

Table 4: Regression analysis of factors associated with outpatient service use using NB model: urban vs. rural

	Rural sample		Urban sample	
	IRR	P>z	IRR	P>z
Age				
<30	ref.			
30-59	-0.151	0.689	0.035	0.950
>=60	-0.370	0.362	-0.249	0.699
Male	-0.391	0.007	0.190	0.403
Married	-0.011	0.961	-0.227	0.544
Education Level				
no education	ref.		ref.	
primary and junior high	-0.019	0.919		
senior high school and above	-0.551	0.087	-0.012	0.966
Employed	-0.106	0.600	0.045	0.884
Insurance				
UEBMI	ref.		ref.	
RBMI	1.005	0.017	-0.203	0.590
Income level				
poorest 33.3%	ref.		ref.	
middle 33.3%	0.072	0.694	0.200	0.670
richest 33.3%	-0.358	0.086	0.559	0.233
With NCD	0.535	0.000	0.911	0.006

Table 5: Regression analysis of factors associated with inpatient service use using logit model: urban vs. rural

	Rural sample		Urban sample	
	Coef.	P>z	Coef.	P>z
Age				
<30	ref.		ref.	
30-59	0.86	0.689	1.04	0.950
>=60	0.69	0.362	0.78	0.699

Male	0.68	0.007	1.21	0.403
Married	0.99	0.961	0.80	0.544
Education Level				
no education	ref.		ref.	
primary and junior high	0.98	0.919		
senior high school and above	0.58	0.087	0.99	0.966
Employed	0.90	0.600	1.05	0.884
Insurance				
UEBMI	ref.		ref.	
RBMI	2.73	0.017	0.82	0.590
Income level				
poorest 33.3%	ref.		ref.	
middle 33.3%	1.07	0.694	1.22	0.670
richest 33.3%	0.70	0.086	1.75	0.233
With NCD	1.71	0.000	2.49	0.006

Table 6: Regression analysis of factors associated with OOP health expenditure using a two-part model combining logit regression and GLM: urban vs. rural

	Rural sample				Urban sample			
	Logit		GLM		Logit		GLM	
	OR	P>z	Coef.	P>z	OR	P>z	Coef.	P>z
Age								
<30	ref.				ref.			
30-59	1.32	0.558	-614.0	0.549	0.96	0.946	-1174.6	0.055
>=60	1.00	0.997	1202.6	0.367	0.62	0.446	639.0	0.654
Male	0.74	0.167	-2258.3	0.086	0.94	0.812	-1905.9	0.269
Married	1.09	0.784	647.4	0.344	1.37	0.454	288.8	0.787
Education Level								
no education	ref.							
primary and junior high	0.76	0.331	1891.9	0.184	ref.			
senior high school	0.45	0.047	1113.7	0.452	1.36	0.346	2456.0	0.184

and above								
Employed	0.89	0.673	779.8	0.550	0.74	0.456	-1047.5	0.303
Insurance								
UEBMI	ref.				ref.			
RBMI	1.94	0.087	43.3	0.944	0.85	0.676	-15.7	0.983
Income level								
poorest 33.3%	ref.				ref.			
middle 33.3%	1.15	0.561	-228.3	0.790	0.76	0.605	-1248.3	0.334
richest 33.3%	1.19	0.522	947.4	0.650	0.70	0.512	-530.9	0.579
With NCD	1.85	0.003	174.6	0.832	2.52	0.010	-7.9	0.992

Table 7: Logit regression analysis of factors associated with the likelihood of incurring CHE: urban vs. rural

	Rural sample		Urban sample	
	OR	P>z	OR	P>z
Age				
<30	ref.		ref.	
30-59	0.38	0.118	2.29	0.526
>=60	0.47	0.230	1.48	0.755
Male	0.45	0.003	1.02	0.967
Married	1.14	0.696	0.53	0.197
Education Level				
no education	ref.		ref.	
primary and junior high	1.23	0.471		
senior high school and above	0.21	0.006	1.62	0.340
Employed	0.67	0.180	0.49	0.368
Insurance				
UEBMI	ref.		ref.	
RBMI	7.30	0.033	1.89	0.359
Income level				
poorest 33.3%	ref.		ref.	
middle 33.3%	0.78	0.379	0.74	0.758

richest 33.3%	0.27	0.010	0.89	0.908
With NCD	2.53	0.000	7.06	0.002

Chapter 3

Impact of an innovative financing and payment model on tuberculosis patients' health service use in China

Abstract

Background: Tuberculosis (TB) prevalence is closely associated with poverty in China, and poor patients face more barriers to treatment. Using an insurance-based approach, the China-Gates TB program Phase II was implemented between 2012 and 2014 in three cities in China to improve access to TB care and reduce the financial burden on patients, particularly among the poor. This study aims to assess the program effects on service use, and its equity impact across different income groups.

Methods: Data from 788 and 775 patients at baseline and final evaluation were available for analysis respectively. Inpatient and outpatient service utilization, treatment adherence, and patient satisfaction were assessed before and after the program, across different income groups (extreme poverty, moderate poverty and non-poverty), and in various program cities, using descriptive statistics and multi-variate regression models. Key stakeholder interviews were conducted to qualitatively evaluate program implementation and impacts.

Results: After program implementation, the hospital admission rate increased more for the extreme poverty group (48.5% to 70.7%) and moderate poverty group (45.0% to 68.1%), compared to the non-poverty group (52.9% to 64.3%). The largest increase in the number of outpatient visits was also for the extreme poverty group (4.6 to 5.7). The proportion of patients with good medication adherence increased by 15 percentage points in the extreme poverty group and by ten percentage points in the other groups. Satisfaction rates were high in all groups. Qualitative feedback from stakeholders also suggested that increased reimbursement rates, easier reimbursement procedures, and allowance improved patients' service utilization. Implementation of case-based payment made service provision more compliant to clinical pathways.

Conclusion: Patients in extreme or moderate poverty benefited more from the program compared to a non-poverty group, indicating improved equity in TB service access. The pro-poor design of the program provides important lessons to other TB programs in China and other countries to better address TB care for the poor.

Background

Tuberculosis (TB) prevalence is closely associated with poverty in China. The 2010 National Tuberculosis Prevalence Survey shows that TB prevalence is much higher in rural areas than urban areas (163 vs 73 per 100 000), and higher in the less developed western region than the developed eastern region (212 vs 66 per 100 000) (1). Some 83% of TB patients live in households with incomes below the regional median, and the average per capita household income of rural TB patients is 50% less than the local regional median (2).

Low-income TB patients in China face greater financial barriers to quality treatment and have lower treatment adherence (3, 4). Currently, TB treatment guidelines by the World Health Organization (WHO) and China Center for Disease Control and Prevention (CDC) recommend that rifampicin-sensitive newly diagnosed TB patients should receive 6 months of outpatient treatment and relapse TB patients eight months (5-7). A national survey in 2010 indicated that 10% of TB patients had intermittent treatment, and another 22% terminated before completing treatment. 15% of patients who terminated treatment reported that financial difficulties were the cause for their poor adherence (1). TB patients with lower household incomes and education levels were more likely to report non-compliance (3). Since 1990s, first-line anti-TB drugs and basic diagnostic tests during the standard treatment course are provided free of charge (8). However, the overall cost of TB treatment is substantial, and poor TB patients are more likely to have catastrophic health expenditure. A study in three cities in China found that over 94% of households in the poorest quintile, compared to 43 % in the richest quintile, had catastrophic expenditure due to TB treatment (4).

Several factors add to the financial barriers for poor patients to access TB treatment. First, many poor patients are covered by the New Rural Cooperative Medical Scheme (NCMS) or Urban Resident Basic Medical Insurance (URBMI), which have less comprehensive coverage and lower reimbursement rates for TB services compared to the Urban Employee Basic Medical Insurance (UEBMI) (9). Second, low-income rural TB patients more often go to smaller regional hospitals that have a lower capacity to diagnose and treat complex cases. This may lead to over-provision of unnecessary and often expensive services not covered by the government free treatment policy or health insurance, such as computed tomography (CT) scans, branded second-line anti-TB drugs, liver protection and other ancillary drugs, the cost of which may further deter poor

patients from completing treatment (10). In addition, many poor patients live in rural and remote areas. Seeking treatment may therefore require travelling a considerable distance, incurring substantial transportation and accommodation costs (10) and possible loss of income.

To improve access to TB care and reduce the financial burden, particularly in rural areas, the China-Gates TB program Phase II was implemented between 2012 and 2014 in three prefectures from eastern (Zhenjiang), central (Yichang) and western (Hanzhong) China. The program context and intervention details have been documented elsewhere (8). Briefly, the new TB financing and payment model includes: 1) increasing health insurance reimburse rates for hospitalization and outpatient TB services to 70%; 2) changing the provider payment method to case-based payment from the current fee-for-service, to incentivize cost containment by TB-designated hospitals. For practical reasons, the case-based payment design included distinct payment packages for inpatient and outpatient services; 3) providing transportation and subsistence allowances to TB patients who adhered to treatment (including those without health insurance). Equity assessment at study baseline revealed that rural residents in project counties had less service utilization, but more out-of-pocket payment per hospital admission compared to urban employees and urban residents (11). Analysis of the rural TB patients enrolled in the NCMS also revealed low reimbursement rate and high financial risk (12). Service access and financial risk protection for TB patients with lower socioeconomic status were identified as major gaps in TB care (8).

There is rich international literature suggesting that public subsidies for health programs frequently benefit richer more than poorer people (13, 14). Whether a health insurance-based approach can effectively target the poor and improve equity is therefore of great concern. This study aims to address this issue by considering the impact of the China-Gates TB program (Phase II) on service utilization, treatment adherence and patient satisfaction across three income groups identified as consisting of those living in: extreme poverty, moderate poverty and non-poverty.

Methods

Study setting

Quantitative data were obtained from cross-sectional surveys with TB patients at the baseline of the program in 2012 and final evaluation in 2014. Three

counties (one low-income, one middle-income and one high-income) were selected in each of the three project prefectures (Zhenjiang, Yichang and Hanzhong). In each of the above 9 counties, TB patients who had been diagnosed for more than six months (eight months for relapse patients) were identified from the China Center for Disease Control and Prevention's (CDC) TB information management system (TBIMS), which is a national registry for the compulsory reporting and management of confirmed TB cases. Ninety TB patients were randomly sampled from each of the nine counties' TBIMS. When less than 90 patients were present in a county, all patients were sampled. One of the county was excluded from analysis due to an unexpected restructuring of regional TB management system, leading to incomparable data at baseline and final evaluation. Face-to-face interviews were conducted using a structured questionnaire, which included information on patient socio-economic background, treatment history, and satisfaction. A total of 788 patient questionnaires were analysed from the baseline survey and 775 from the final evaluation survey.

Income grouping and poverty status

The self-reported per capita annual income of a patient's household was used for income grouping. Following the World Bank's definition of extreme poverty globally and the poverty line for upper-middle income countries, those with incomes less than USD 1.9 a day (RMB 4369 per annum) were classified as being in extreme poverty, those with incomes between USD 1.9 to 5.5 a day (RMB 12 647 per annual) were classified as being in moderate poverty, and the rest were classified as non-poverty households (15). This classification was validated to be relevant to local poverty standards in Zhenjiang, Yichang and Hanzhong. The local living assistance standards for urban residents announced by the Department of Civil Affairs all three cities in 2014 were similar to or higher than the World Bank standard of extreme poverty.

Measuring service utilization, adherence, and patient's satisfaction

Inpatient and outpatient service utilization indicators were analysed, including the hospital admission rate, average number of hospital admissions per patient, rate of hospital re-admission within three days of discharge, average length of stay for the first admission, and average number of outpatient visits during a treatment course (six months for new patients, and eight months for relapse patients). Medication adherence was characterized using the following indicators:

proportion of patients refusing treatment, taking medications as prescribed, and terminating treatment. Patient satisfaction was measured relating to: treatment outcome, reimbursement rate, reimbursement procedures, attitudes of doctors and nurses.

Statistical analysis

Utilization of inpatient and outpatient services, patient adherence and satisfaction were examined for each poverty status at baseline and at final evaluation using descriptive statistics.

The effect of the program on the rate of hospital admission, rate of re-admission within three days after discharge, and proportion of patients with good medication adherence were analysed using multivariate logistic regression model. Number of outpatient visits over the whole treatment course were analysed using Poisson regression. All regression models included the following explanatory variables: period (baseline, final evaluation), poverty status and the interaction term between poverty status and period as explanatory variables. All models were controlled for county fixed effects and cluster-robust standard errors were used for statistical testing. A set of control variables were included in all regression models, including gender, age, marital status, TB type (new, relapse), education level, employment status and health insurance type. The models estimated were thus of the form:

Outcome= f (poverty status, period, poverty status*period, control variables, county fixed effect)

All analyses were performed using Stata 14 (Version 14, StataCorp, College Station, TX. Statistical significance was assessed at P=0.05.

Qualitative interviews and analyses

Qualitative data were obtained during the final evaluation period of the program in 2014. Semi-structured in-depth interviews were conducted with city- and county-level health administrators (n = 12), health insurance managers (n = 20) and hospital managers (n = 12) to understand their perceptions of the program impacts on poor TB patients' service utilization and equity. Two focus group discussions (FGDs) were held with healthcare providers in TB designated hospital and primary care doctors in each study county to explore their views of the program impacts on service provision and patient adherence. Each group consisted of 5−6 physicians and nurses who provided outpatient and/or inpatient

TB care and were responsible for TB patient management. In addition, two FGDs with TB patients were organized in each study county to gain understandings of patients' care seeking and treatment experiences and level of satisfaction. TB patients were quota sampled based on their gender, household income and type of health insurance coverage. Each group consisted of six TB patients and was held in a private room in the hospital. All interviews were conducted by experienced evaluation team members and recorded after obtaining the permission of participants.

The Framework approach (16) was used to analyse the qualitative data. A framework constructed using the topic guide, field notes and categories emerging from the transcripts, was applied to the data to identify themes. Data from different stakeholders and other sources were triangulated. The key findings were also validated by external consultation.

Results

A total of 788 patient questionnaires were analysed from the baseline survey and 775 from the final evaluation survey. The socio-economic characteristics of patients were similar in both samples, except for their health insurance coverage (Table 1). At baseline, 34% of patients were classified as in extreme poverty and 42% in moderate poverty compared to 36% and 40% at final evaluation.

Table 1. Characteristics of TB patients at baseline and final evaluation

Sample Characteristics	Baseline (n = 788)	Final evaluation (n = 775)	P value
Gender (%)			
Male	74.8	70.7	0.07
Age (%)			
< 30	6.2	7.4	
30−59	46.7	41.0	0.07
≥ 60	47.1	51.6	
Marriage (%)			
Married	80.3	78.2	0.29
Residence (%)			
Rural	92.5	90.0	0.083
Patient category (%)			
New patient	81.4	82.2	0.67

Education level (%)			
None	20.2	25.0	
Primary	32.9	33.6	
Secondary	34.0	28.7	0.052
High school and above	12.9	12.8	
Insurance type (%)			
UEBMI	6.4	9.3	
URBMI	2.8	3.2	
NCMS	87.8	82.2	
URRBMI	0.0	2.5	0.000
Private insurance	1.8	0.4	
other insurance	0.3	0.3	
no insurance	1.0	2.2	
Employment (%)			
Currently working (including farming)	53.3	49.0	0.092
Income level (%)			
Extreme poverty	34.0	36.1	
Moderate poverty	42.0	40.0	0.642
Non-poverty	24.0	23.9	

UEBMI: Urban employee basic medical insurance, URBMI: Urban resident basic medical insurance, NCMS: New corporative medical scheme, URRBMI: Urban rural resident basic medical insurance.

After program implementation, utilization of inpatient and outpatient services increased, but to different extents in different poverty groups. The hospital admission rate increased from 48.1% to 68.1% among all patients, and the increase was greater for the extreme poverty and moderate poverty groups (Table 2). The average number of hospital admissions decreased from 1.4 to 1.2, and the rate of re-admissions decreased from 23.0% to 15.5%. The length of stay for the first hospital admission increased in the extreme and moderate poverty groups, but decreased in the non-poverty group. The number of outpatient visits increased from 4.8 to 5.7 among all patients, and the increase was highest in the extreme poverty group.

Table 2. Inpatient and outpatient service utilization at baseline and final evaluation (by income group)

Indicator	Period	Extreme poverty	Moderate poverty	Non-poverty	Total
Hospital admission rate (%)	Baseline	48.5	45.0	52.9	48.1
	Final evaluation	70.7	68.1	64.3	68.1
Average number of hospital admissions	Baseline	1.5	1.3	1.3	1.4
	Final evaluation	1.3	1.2	1.2	1.2
Average rate of hospital re-admissions (%)	Baseline	29.2	17.5	23.0	23.0
	Final evaluation	21.2	11.9	12.6	15.5
Average length of stay of the first admission (days)	Baseline	21.1	22.6	26.1	23.0
	Final evaluation	24.0	24.7	25.6	24.7
Average number of outpatient visits during treatment course*	Baseline	4.6	5.0	4.8	4.8
	Final evaluation	5.7	5.7	5.8	5.7

*Only patients who had been diagnosed as TB for more than 6/8 months at the time of survey were included for analysis of outpatient visits.

After program implementation, medication adherence improved the most in the extreme poverty group (Table 3). The proportion of patients refusing treatment decreased in the extreme poverty and non-poverty groups, but not in the moderate poverty group. The proportion of patients taking medication on schedule as prescribed increased by 15 percentage points in the extreme poverty group, and 10 percentage points in the other two groups. The proportion terminating treatment also decreased the most in the extreme poverty group, followed by the moderate poverty group.

Table 3. Program effect on patients' treatment adherence and satisfaction

Indicator	Period	Extreme poverty	Moderate poverty	Non-poverty	Total
Proportion of patients who refused treatment (%)	Baseline	4.9	2.4	2.7	3.3
	Final evaluation	2.9	2.9	1.6	2.6
	Baseline	75.4	81.6	81.0	79.3

Proportion of patients taking medications as prescribed (%)	Final evaluation	90.5	93.1	92.3	92.0
Proportion of patients terminating treatment (%)	Baseline	19.0	13.0	15.9	15.7
	Final evaluation	5.9	4.9	6.0	5.5
Proportion of patients who satisfy with the treatment outcome (%)	Baseline	94.7	92.1	93.1	93.2
	Final evaluation	96.8	96.1	98.4	96.9
Proportion of patients who satisfy with the reimbursement rate (%)	Baseline	86.2	86.9	88.3	87.0
	Final evaluation	90.9	89.5	89.0	89.9
Proportion of patients who satisfy with the reimbursement process (%)	Baseline	93.1	90.5	92.3	91.8
	Final evaluation	93.3	90.6	93.3	92.3
Proportion of patients who satisfy with doctor's attitude (%)	Baseline	96.1	96.6	99.0	97.1
	Final evaluation	99.1	98.2	99.2	98.8
Proportion of patients who satisfy with nurse's attitude (%)	Baseline	96.9	97.3	99.0	97.6
	Final evaluation	99.1	97.8	98.4	98.4

Over 90% of patients reported satisfaction with treatment outcome, procedure, and the attitudes of doctors and nurses in both baseline and final evaluation surveys, and the proportion satisfied were slightly higher at final evaluation compared to baseline (Table 3). Reimbursement rates were satisfactory to the smallest proportion of patients but were still seen as acceptable to around 87% before and 90% after program implementation. The satisfaction did not seem to vary by poverty group.

The multivariate regression results are shown in Table 5. As expected, the overall hospitalization rate was substantially higher for members of the non-poverty group ($OR = 1.44$, $P = 0.05$). However, while program implementation appears to have considerably increased the hospitalization rate for all income groups ($OR = 2.83$, $P = 0.01$), the increase was much lower for the non-poverty group ($OR = 0.56$, $P = 0.04$), indicating increased equity of access. The re-admission rate did not seem to change after the program and there were no significant variations across poverty groups. The number of outpatient visits increased for all groups,

and intra-group differences were not significant. The proportion of patients with good medication adherence improved significantly ($OR = 2.88$, $P = 0.01$), and there were again no significant differences across poverty groups. Patient satisfaction with treatment outcomes improved after the program but satisfaction with the reimbursement rate did not change.

Table 4 Program effect for different income groups

	Hospital admission		Rate of re-admission		Average number of outpatient visits		Good medication adherence		Satisfaction with treatment outcomes	
	Odds ratio	P value	Odds ratio	P value	Coefficient	P value	Odds ratio	P value	Odds ratio	P value
Poverty status (Moderate poverty as reference group)										
Extreme poverty	1.1	0.7	2.2	0.06	-0.1	0.21	0.7	0.23	1.5	0.07
Non-poverty	1.4	0.05	1.5	0.08	-0.1	0.27	0.9	0.55	1.3	0.48
Period (baseline as reference group)										
Final evaluation	2.8	0.01	0.6	0.11	0.1	0.01	2.9	0.01	2.0	0.04
Income level* Period										
Extreme poverty *Final evaluation	1.0	0.98	1.1	0.9	0.1	0.16	1.1	0.88	0.7	0.44
Non-poverty *Final evaluation	0.6	0.01	0.8	0.46	0.1	0.16	0.9	0.72	2.6	0.16
Gender (male as reference group)										
Female	0.7	0.01	1.2	0.46	0.0	0.28	1.1	0.62	1.5	0.16
Age group (<30 as reference group)										
30–59	0.9	0.82	2.7	0.01	0.0	0.46	0.9	0.68	0.8	0.58
60+	1.2	0.08	1.0	0.83	0.0	0.89	1.0	0.83	1.9	0.08
Type of TB (newly diagnosed as reference group)										
Relapse	1.0	0.76	1.2	0.49	-0.1	0.14	0.6	0.01	0.5	0
Marital status (single as reference group)										
Married	1.0	0.89	1.2	0.52	0.1	0.23	1.1	0.56	0.8	0.57
Education (no formal education as reference group)										
Primary	1.0	0.68	0.9	0.68	0.0	0.30	1.0	0.97	1.0	0.95
Secondary	1.1	0.67	1.2	0.46	0.1	0.21	1.2	0.52	1.1	0.87
≥ High school	1.0	0.84	1.2	0.64	0.1	0.16	2.1	0.01	0.5	0.04
Insurance type										
UEBMI	0.4	0.04	1.0	0.96	0.0	0.86	1.6	0.17	0.5	0.35
NCMS	0.4	0.01	1.3	0.46	0.0	0.64	1.4	0.38	0.8	0.82
URRBMI	0.3	0	1.4	0.65	0.1	0.06	1.9	0.59		

Private	1.1	0.91		0.07		0.0	0.84	0.7	0.52	0.8	0.85
No insurance	0.4	0.06	0.3			-0.1	0.70	1.3	0.46	0.8	
Other insurance	0.9	0.96	1.8	0.69		0.4	0.01	0.6	0.59		
Working status (currently no working as reference group)											
Currently working	0.6	0	0.9	0.57		0.0	0.95	0.8	0.33	1.3	0.38

UEBMI: Urban employee basic medical insurance, URBMI: Urban resident basic medical insurance, NCMS: New corporative medical scheme, URRBMI: Urban rural resident basic medical insurance.

The qualitative results support the quantitative findings on increased outpatient and inpatient TB service use, and allow identification of some of the underlying reasons. First, most health administrators, health insurance managers, hospital managers and TB care providers thought that the increased health insurance reimbursement rate for TB care and the simplified reimbursement procedure for patients had a positive impact on service use, particularly among poor TB patients. Several TB care providers explained that the reimbursement rate for TB outpatient care was low before the introduction of the program, for example, only 20% of eligible expenditure would be reimbursed by NCMS, as compared to 80% after program implementation. Most TB patients also expressed their satisfaction with the increased reimbursement rate. Second, hospital managers mentioned that an upgraded IT system for case-based payment allowed patients to receive insurance reimbursement at the time of bill payment. Previously, paying a substantial deposit at admission or paying out-of-pocket while receiving treatment placed a major burden on poor patients. Some terminated treatment due to an inability to afford such payments even though a large proportion was expected to be reimbursed subsequently by insurance. Third, patients found transport and subsistence allowances provided effective motivation to undertake follow-up visits, especially for poor patients living in remote rural or mountainous areas. Travelling to a hospital could take many hours and entail significant costs, sometimes requiring an over-night stay. The allowances partially offset such costs, and disbursement of a lump sum payment upon completion incentivized treatment adherence.

The current direct exemption of reimbursable expenses (at time of bill payment upon discharge) is good for poor patient, and rich patients may not care. (TB hospital manager)

I received RMB 180 for transportation and nutrition allowance. It helps me. Maybe you (policy maker) can consider giving more for those who live far away. (TB patient, FGD)

Some hospital managers and providers considered the design of the health insurance reimbursement package to be in line with the standard TB clinical treatment pathway, which to some extent improved quality of TB care and case management. Several providers said that after program implementation, they prescribed TB treatment-related tests according to the clinical guideline and strengthened coordination with primary healthcare providers to follow up TB patients and encourage them to attend scheduled hospital visits. In FGDs with

TB patients, many patients said they had frequent contacts with healthcare providers.

Before the program, we only did some of the tests (like liver function test, blood test, kidney function) occasionally. After patients are discharged, we didn't follow them anymore. Now, there is emphasis on standard treatment and quality, so we have improved on tests. Those necessary tests are done every month. If patients have adverse reactions, they can receive timely treatment. (TB doctor, FGD)

"Now after a patient leave the hospital, we inform the village doctor to supervise the patient, and call the patient every month to remind him/her of the follow-up visit. (TB doctor, FGD)

Discussion

Overall, the China-Gates TB program Phase II has improved inpatient and outpatient TB care access, reduced re-admissions, enhanced medication adherence, and improved patient's satisfaction with treatment outcomes. It was also found to be pro-poor and to have improved equity in inpatient TB care access across different poverty groups: the program effects on hospital admissions were greater for the extreme poverty and moderate poverty groups, compared to the non-poor group. Program effects on outpatient service utilization were similar across different groups, and number of outpatient visit did not correlate with poverty status.

One commonly suggested potential adverse consequence of case-based payment is that facilities may under-provide necessary services to control costs (17-19). On the contrary, the increased number of outpatient visits observed in this study and qualitative findings from the study suggest that patients were in fact better managed, i.e. more in line with established clinical guidelines. This was probably mainly because the payment standard for the outpatient package was generous in terms of covering the full cost of services and drugs recommended by the clinical treatment guideline.

While the reduced gap in terms of inpatient service use between poor and non-poor TB patients indicates improved equity, it remains difficult to assess with existing data if the high levels of hospitalization following the intervention implementation represent an improvement in service provision, as a majority of TB patients may only require outpatient treatment according to global and national treatment guidelines. The original case-based payment design was a

standard payment rate for inpatient and outpatient TB services combined, aiming to promote substitution of hospitalization by outpatient treatments and to avoid unnecessary hospitalization. However, during the program implementation, significant challenges were encountered from hospitals and health insurance agencies in program regions due to expected reduction in revenue, and difficulty in management. As a result, two payment packages were implemented for inpatient and outpatient services separately, the design of which was unable to reduce hospitalization. The detailed implementation challenges and consequences were discussed in detail in another paper by the same study team. Nevertheless, the decreasing gap in inpatient service utilization between the extreme-poverty group and non-poverty group could have positive effects, as qualitative interviews revealed that many extreme-poverty patients were elderly patients and had several co-morbidities (such as diabetes, hypertension, and kidney diseases) or side effects from TB treatment. Better access to inpatient services may improve the management of complex TB cases with co-morbidities. Future studies are needed to access the health service quality and appropriateness, and treatment outcomes.

The pro-poor effects can be explained by several features. First, the program required reimbursement rates for all insurance schemes to be no less than 70% for covered inpatient and outpatient services. Before the program, there was wide variation in reimbursement rates by the three major health insurance schemes. NCMS and URBMI reimbursed 60−75% of inpatient expenses, whereas UEBMI reimbursed 85−95% (11). NCMS and URBMI had no or low reimbursement rates for outpatient expenses (11). Poor TB patients usually enrol in NCMS and URBMI schemes which have lower reimbursement rates. The program reduced the disparity in reimbursement rates, thereby favouring the poor. Second, an upgraded IT system that allowed immediate insurance reimbursement was most beneficial for poorer patients, as they were not required to pay a large amount of cash at the point of service use, and then got a reimbursement later. Third, transport and subsistence allowances provided strong incentives to poor patients, many of whom live in remote rural areas and had higher transportation costs, to seek care. Fourth, medical financial assistance was provided by the Department of Civil Affairs for a relatively small number of eligible low-income households, further reducing their financial burden. Fifth, from the supply side, the implementation of case-based payment, clinical pathways, and case management

probably improved the treatment and management quality more in under-developed areas, where many poor patients resided.

Despite great improvements in TB management, poor TB patients still face a number of barriers and challenges in accessing health care and completing treatment. Some TB services and drugs were excluded from insurance program reimbursement. For example, in many counties, CT scans, branded liver-protection drugs and ancillary drugs were not covered by insurance, nor restricted by the cost limit of case-based payment (6). Though case-based payment was designed to restrict the provision of unnecessary tests and drugs, their actual use was not uncommon. For instance, a significant proportion of patients reported having adverse reactions to free anti-TB drugs, and were therefore given more expensive second line drugs and in some cases were encouraged to take liver-protection drugs, or be admitted for inpatient care. In order to further reduce the financial barriers to care for poor TB patients, the types of services covered by insurance should be expanded, with appropriate safeguards to control unnecessary use of more expensive treatments.

The study was not without limitations. There was very limited quantitative information on patient case-mix and service details (such as prescriptions and procedures). Therefore, appropriateness and quality of services cannot be assessed objectively. Service quality can only be inferred from reported patient satisfaction and qualitative feedback from patients, doctors and administrators. Besides, the program consists of multiple concurrent interventions that may be synergistic or antagonistic, and thus the effects of each individual intervention cannot be evaluated separately.

Conclusions

The China-Gates TB program Phase II effectively improved TB patients' access to inpatient and outpatient services and improved medication adherence across all income groups. Patients in households classified as in extreme or moderate poverty benefited more from the inpatient service coverage of the program compared to a non-poverty group, indicating improved equity in inpatient TB service access. The pro-poor design of the program provides important lessons to other TB programs in China and other countries to better address TB care for the poor. The study also identified other difficulties poor TB patients face that need to be further addressed.

List of abbreviations
CDC: Center for Disease Control and Prevention
CT: computed tomography
FGD: Focus-group discussion
NCMS: New cooperative medical schemes
TB: Tuberculosis
TBIMS: Tuberculosis information management system
UEBMI: Urban employee basic medical insurance
URBMI: Urban resident basic medical insurance
WHO: World Health Organization

Ethics approval and consent to participate
Ethical approval of the study was issued by the Institutional Review Board of Chinese Center for Disease Control and Prevention. Consent form was obtained before individual data collection and could be provided upon request.

Consent for publication
Consent form was obtained before individual data collection and could be provided upon request.

Availability of data and materials
The datasets generated and analysed during the current study are not publicly available due to the regulations of China CDC. Readers of the article need to discuss with China CDC and obtain their permission before the release of the dataset.

Competing interests
All authors declare no competing interests.

Author Contributions
Di Dong conducted literature search. Sheng-Lan Tang, Di Dong, Wei-Xi Jiang, Jia-Ying Chen, Li Xiang, Qiang Li, Fei Huang and Hui Zhang designed the study,

collected the data and interpreted the data, Di Dong, Qian Long, and Wei-Xi Jiang conducted data analysis. Di Dong prepared the manuscript; Qian Long, Henry Lucas, Sheng-Lan Tang, and Wei-Xi Jiang revised the manuscript and provided valuable suggestions to improve the manuscript.

Acknowledgements

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Chapter 4

Impact of an innovative financing and payment model on the equity in tuberculosis patients' healthcare financing in China

Abstract

Background: In response to the high financial burden of health services facing tuberculosis (TB) patients in China, the China-Gates TB project, Phase II, has implemented a new financing and payment model as an important component of the overall project in three cities in eastern, central and western China. The model focuses on increasing the reimbursement rate for TB patients and reforming provider payment methods by replacing fee-for-service with a case-based payment approach. This study investigated changes in out-of-pocket (OOP) health expenditure and the financial burden on TB patients before and after the interventions, with a focus on potential differential impacts on patients from different income groups.

Methods: Three sample counties in each of the three prefectures: Zhenjiang, Yichang and Hanzhong were chosen as study sites. TB patients who started and completed treatment before, and during the intervention period, were randomly sampled and surveyed at the baseline in 2013 and final evaluation in 2015 respectively. OOP health expenditure and percentage of patients incurring catastrophic health expenditure (CHE) were calculated for different income groups. OLS regression and logit regression were conducted to explore the intervention's impacts on patient OOP health expenditure and financial burden after adjusting for other covariates. Key-informant interviews and focus group discussions were conducted to understand the reasons for any observed changes.

Results: Data from 738 (baseline) and 735 (evaluation) patients were available for analysis. Patient mean OOP health expenditure increased from RMB 3,576 to RMB 5,791, and the percentage of patients incurring CHE also increased after intervention. The percentage increase in OOP health expenditure and the likelihood of incurring CHE were significantly lower for patients from the highest income group as compared to the lowest. Qualitative findings indicated that increased use of health services not covered by the standard package of the model was likely to have caused the increase in financial burden.

Conclusions: The implementation of the new financing and payment model did not protect patients, especially those from the lowest income group, from financial difficulty, due partly to their increased use of health service. More financial resources should be mobilized to increase financial protection,

particularly for poor patients, while cost containment strategies need to be developed and effectively implemented to improve the effective coverage of essential healthcare in China.

Background

China is among the countries with the highest burden of tuberculosis (TB). According to the WHO Global Tuberculosis Report 2017, China ranked 3rd in terms of incident TB cases and 2nd on multi-drug resistant TB (MDR-TB) [1]. In order to achieve the relevant Sustainable Development Goal (SDG) proposed by the United Nations and end the TB epidemic by 2030, standard medical treatment needs to be made accessible and affordable for all TB patients [2].

Currently the TB service delivery system in China has been undergoing a transformation whereby responsibility for provision of clinical services is being gradually shifted from TB dispensaries to designated hospitals, typically general hospitals or infectious disease hospitals, in most of the provinces [3]. This transformation has had considerable cost implications, as studies have shown that, while quality of care has often been improved, income-pursuing behaviors, such as over-prescription and unnecessary hospitalization have driven up the treatment cost of TB [4-7]. Previous studies also show that although over 95% of the Chinese population is covered by the three public health insurance systems – Urban Employee Basic Medical Insurance (UEBMI), Urban Resident Basic Medical Insurance (URBMI) and New Cooperative Medical Schemes (NCMS) [8] – TB patients bear a high economic burden for medical treatment, especially low-income and rural patients [6,9-12]. Financial factors are also frequently mentioned as a major reason for non-adherence to treatment, suspended treatment and eventual non-cure [13-17]. As a majority of TB patients live in poor households [18, 19], it seems likely that the financial protection provided by the current health insurance schemes is far from sufficient.

In response to the financial difficulties faced by patients, the China-Gates TB project, Phase II has implemented a new financing and payment model as one component of a set of interventions that aims at improving TB control in China. Before project implementation, studies from the baseline survey have found that the medical cost was relatively high in the project area [4]. The effect of NCMS on reducing catastrophic health expenditure (CHE) for TB patients was very limited [9], and the percentage of poor patients who incurred CHE was much higher than the rich [20]. The new model focuses on improving the reimbursement rate for TB patients and introducing hospital payment reforms, moving from a fee-for-service to a case-based payment approach. A treatment guideline was also launched with a standard service package, the cost of this being covered under the new model. Transportation and subsistence allowances are also provided to patients who adhere to treatment. The other components

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such as establishing a comprehensive TB control model, are documented elsewhere [12].

While increasing the reimbursement rate appears to have obvious potential benefits for patients, the implications of the case-based payment approach are not clear. By setting a fixed payment rate for each case, case-based payment aims to reduce non-necessary medical services by altering provider incentives. Diagnostic-related group (DRG) case-based payment mechanisms have been implemented in numerous developed and developing countries, and in some cases have demonstrated effectiveness in cost containment [21-23]. Previous studies in China have found mixed results regarding the impact of case-based payments in terms of reducing medical costs for different types of disease, but little evidence of reduced overall inpatient expenditure [25-29]. In addition, it has been found that the impact may be compromised by problems that have arisen in project implementation, for example with hospitals excluding patients whose treatment cost is higher than the payment limit [25, 29]. For TB specifically, at least one study suggests that a case-based payment approach with no co-payment for patients may be feasible and beneficial under the NCMS [30]. However, there is a lack of evidence as to the effects in terms of cost control and patient financial burden of adopting a model combining increased reimbursement rates and case-based payment. In particular, it remains unknown whether this approach could protect the most economically vulnerable groups from financial difficulty.

At the end of the second phase of the China-Gates TB project, a team led by Duke Global Health Institute carried out an evaluation of the effects of the interventions on equity in access to/use of TB services, and on changes in financial protection for TB patients. This article aims to investigate changes in the out-of-pocket (OOP) health expenditure and financial burden of TB patients before and after the implementation of the new model，while a companion paper by Dong et al. which is published in the same issue considers changes in service utilization. It also examines the equity implications of the new model for patients from different socio-economic groups, especially those living in poverty.

Methods

The study was conducted in Zhenjiang, Yichang and Hanzhong, three prefectures located in eastern, central and western China respectively. In each prefecture, three sample counties at different levels of economic development were selected, one economically disadvantaged and located in a remote area to ensure that we

included a substantial number of patients living in poverty. A mixed-method approach, including a patient questionnaire survey and qualitative interviews, was used to investigate patients' financial burden due to TB treatment.
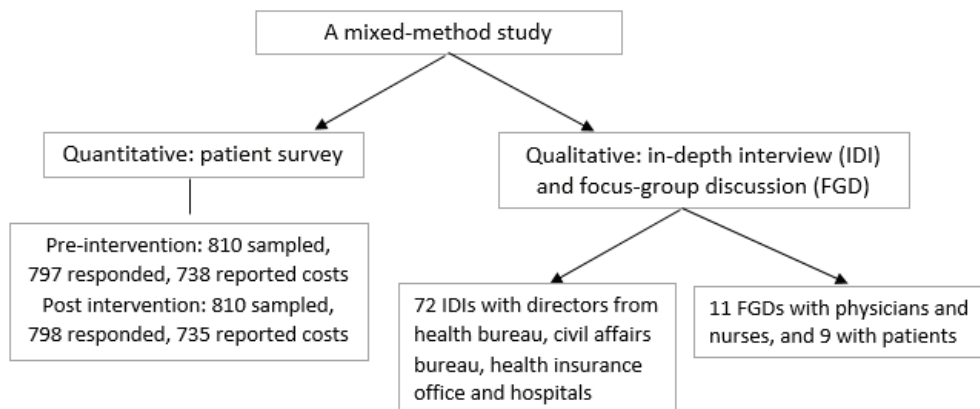

Figure 1: Flow chart of the study design

Data collection
Patient survey
The intervention period was from April 2014 to March 2015. The baseline survey was conducted in 2013 and the final evaluation late in 2015, with 90 patients randomly sampled from the list of registered TB patients in each county for both surveys. The inclusion criterion for the baseline required that patients had completed treatment before the survey, and for the final evaluation that patients started and completed treatment during the intervention period. Face-to-face interviews were conducted by trained investigators using a structured survey questionnaire which collected basic demographic information and data on socio-economic status, treatment procedures and expenditures. All questionnaires were checked on site for completeness and internal logic, and they were captured for analysis using a double-entry procedure in EpiData (http://www.epidata.dk/).
Qualitative interviews
Qualitative data were gathered during the evaluation of the project and used to gain an understanding of stakeholders' perceptions of the effects of the new payment model on financial protection for TB patients. Semi-structured, in-depth interviews were conducted with participants responsible for the development and implementation of local policies, including officers of the local health bureau

and civil affair bureau, health insurance managers and hospital managers at city-level and county-level，a total of 72 interviews across all study sites. Focus group discussions (FGD) were also conducted among care-givers (physicians and nurses, $n = 11$ in total) and TB patients who completed the 6-month first-line treatment during the intervention period ($n = 9$ in total), with each group consisting of 5–6 participants. Gender, household income, type of health insurance coverage and distance from downtown were considered to ensure diversity of participants in the patient FGDs. The topic guides were developed and piloted before formal interview. All qualitative interviews were conducted by scholars with qualitative study experience. All interviews were conducted in a private room, and were recorded after obtaining the oral consent from the interviewees.

Data analysis

Quantitative

Out-of-pocket (OOP) health expenditure, calculated by adding up direct health expenditures for all outpatient and inpatient services, and the percentage of patients incurring CHE, defined as OOP health expenditure over 10% of annual family income or 40% of annual non-food expenditure [20], were used to evaluate patients' treatment expenses and financial burden before and after the intervention. Chi-square tests were conducted to examine if there were significant differences between the baseline and final patient samples in terms of demographic and socio-economic characteristics including age, gender, insurance cover and family income.

In order to explore the new model's potential differential impact on patients from different income groups, especially the effect on the poorest patients that are most susceptible to financial difficulty, patients were categorized, based on the per capita income of their household, as extremely poor (below the 1.9 USD per capita per day defined by the World Bank, which equated to 4,369 RMB per capita per year), moderately poor (1.9-5.5 USD per capita per day or 4,369-12,647 RMB per capita per year, defined by the World Bank as the poverty line for middle and high income countries) and non-poor ($\geqslant$ 5.5 USD per capita per day or 12 647 RMB per capita per year) [31]. *T*-tests were used to determine if there were significant differences in OOP health expenditure before and after the intervention for all patients and for selected subgroups. Linear regression was used to model the effect of the intervention on the natural logarithm of OOP, and logistic regression to estimate the effect on the percentage of patients incurring CHE. The regression models were estimated both for all patients and for patients

from different income groups, in both cases using other demographic and socio-economic factors as explanatory variables and controlling for county fixed effects. Crude and standardized (adjusting for age, gender and patient category) concentration indices for OOP health expenditure, were calculated to assess the degree of equity across income groups in the financing of TB treatment before and after the intervention [32]. The quantitative data were analyzed using STATA 13.1(StataCorp, Texas, USA).

Qualitative

The qualitative data were analyzed using the thematic analysis approach [33]. The analysis framework was developed based on a topic guide and emerging themes from the transcripts, and was refined during the coding process. All qualitative data were coded, sorted and classified according to the framework, and discussed across the research team till reaching consensus. The trustworthiness of data was enhanced by triangulating findings from different respondents and methods. We used the original Chinese texts for analysis, and translated the quotations into English. The analysis was conducted using NVIVO 9.0 (QSR International, Melbourne, Australia).

Results

Characteristics of the patients surveyed

A total of 797 and 798 patients agreed to participate in the baseline and evaluation surveys respectively, and 738 (baseline) and 735 (evaluation) reported their out-of-pocket health expenditure and were included in the analysis. Table 1 indicates that there were no significant differences between the baseline and final samples with respect to gender, age, employment, education and household income. Most were male and new patients. Around 50% were aged over 60, and 85% had never completed high school. Half were not employed at the time of the survey. Some 1/3 lived in households below the poverty line and 24% were above the non-poor threshold. Over 80% were covered by the NCMS, as most lived in rural area. Overall, most are likely to come from the low socio-economic group, as reflected by their education and income status.

Table 1: Characteristics of patient samples before and after intervention (%)

	Before intervention (n = 738)	After intervention (n =735)	P-value[1]
Gender			
Male	555 (75.2%)	532 (72.4%)	0.218

Age			
< 30	45 (6.1%)	58 (7.9%)	
30–59	352 (47.7%)	309 (42.0%)	0.065
≥ 60	341 (46.2%)	468 (50.1%)	
Marital status			
Married	595 (80.6%)	575 (78.3%)	0.278
Patient category1			
new patient	594 (81.4%)	602 (81.9%)	0.791
Education level			
None	140 (19.0%)	166 (22.7%)	
Primary school	242 (32.8%)	247 (33.7%)	
Secondary school	262 (33.5%)	221 (31.1%)	0.119
≥ high school	94 (12.7%)	99 (12.5%)	
Insurance type			
UEBMI	45 (6.1%)	69 (9.4%)	
resident insurance	21 (2.8%)	45 (5.9%)	
NCMS	648 (87.8%)	598 (81.6%)	0.000
other insurance	16 (2.2%)	5 (0.7%)	
no insurance	8 (1.1%)	18 (2.5%)	
Employment			
Employed	403 (54.6%)	369 (50.2%)	0.091[2]
Unemployed	40 (5.4%)	55 (7.5%)	
Retired	252 (34.2%)	86 (11.7%)	
lost ability	35 (4.7%)	91 (12.4%)	
other	8 (1.1%)	134 (18.2%)	
Income group[3]			
< 1.9 USD	243 (33.2%)	240 (33.5%)	
1.9–5.5 USD	314 (42.9%)	303 (42.3%)	0.970
≥ 5.5 USD	175 (23.9%)	174 (23.2%)	

1. P-value for chi-square test. 2. P value for comparison employed vs unemployed
3. The numbers in the three categories do not add up to total due to missing data
UEBMI, Urban Employee Basic Medical Insurance; NCMS: New Cooperative Medical Schemes.

Out-of-pocket health expenditure

The mean OOP health expenditure was RMB 3576 (median 1752) before and
RMB 5791 (median 2700) after the implementation of the new financing model
(Table 2). The most significant increase ($P < 0.001$) was for the poorest, whose
mean OOP expenditure more than doubled, while the moderately poor

experienced an increase of almost 70%. Only for patients in the highest income group was the percentage increase relatively limited and not statistically significant.

Table 2: Out-of-pocket health expenditure before and after intervention by income group (RMB)

Income group	Before intervention		After intervention		% change		P-value
	Mean	Median	Mean	Median	Mean	Median	(Means)
< 1.9 USD	2876	1428	5961	2700	107.3	89.1	< 0.001
1.9–5.5 USD	3656	1752	6169	2780	68.7	58.7	0.002
⩾ 5.5 USD	4409	2400	4972	2570	12.8	7.1	0.4
overall	3576	1752	5791	2700	61.9	54.1	< 0.001

The overall degree of inequality in OOP payments also increased, as is reflected by the positive value of the concentration index before and negative value after implementing the new model (Table 3). This result remains unchanged after adjusting for age, gender and patient category. The concentration curves are depicted in Figure 2, which clearly shows that the accumulated share of total OOP health expenditure paid by poor people was higher after the intervention, as the curve for the intervention period always lies above the baseline.

Table 3: Concentration Index of OOP health expenditure before and after intervention

Period	Crude	Standardized
Before intervention	0.0918	0.0878
After intervention	-0.0262	-0.0049
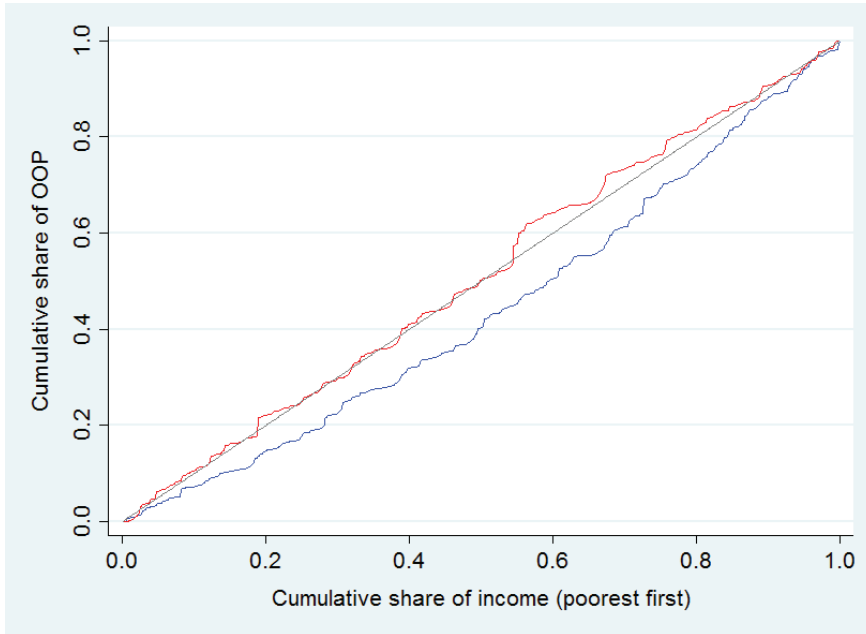
Figure 2: Concentration curve of out-of-pocket health expenditure before and after intervention

Financial burden

For the overall sample, the percentage of patients that incurred CHE increased from 47.8% to 56.3% using the 10% of household income threshold (CHE_10), and from 32.4% to 36.5% using the 40% non-food expenditure threshold (CHE_40) after implementation of the new model, and the increase was statistically significant for the former. The financial burden of TB treatment increased for both lower income groups ($P < 0.05$ for CHE_10). Only patients who were relatively well-off experienced no significant change in either CHE index. It is notable that the financial burden was extremely high for the poorest patients, with over 82.5% of those who lived below the poverty line spending more than 10% of their household income, and a majority spending 40% of their non-food expenditure, on medical services after the intervention.

Table 4: Percent of households incurring CHE before and after intervention by income group

Income group	CHE_10/%			CHE_40/%		
	Before intervention	After intervention	*P*-value	Before intervention	After intervention	*P*-value
< 1.9 USD	72.8	82.3	0.016	43.0	52.0	0.055
1.9–5.5 USD	41.6	52.2	0.009	27.3	32.5	0.163
⩾ 5.5 USD	25.1	31.0	0.221	27.5	22.8	0.316
Overall	47.8	56.3	0.001	32.4	36.5	0.113

CHE_10: 10% of household income threshold; CHE_40: 40% non-food expenditure threshold.

Factors associated with the financial burden of TB care

Table 5 shows the results of an OLS regression of the logarithm of direct OOP health expenditure (model 1) and logit regressions of CHE (model 2 and 3) on project intervention, after adjusting for the covariates gender, age, education, employment status, insurance cover and controlling for county fixed effects. Results from the OLS regression again clearly show that implementation of the new model was associated with a significant increase in OOP health expenditure. Results from the logit regressions also reveal a significant increase in the percentage of patients incurring CHE after project implementation for both the 10% of family income and 40% of non-food expenditure thresholds.

Differential influences of the model on the OOP health expenditure and financial burden of patients from different income groups are also observed, as is reflected by the statistically significant coefficients for the interaction term of the intervention period and the highest income group for both models 1 and 3. The OOP health expenditure of this group did not increase as much as that for the poorest, and their financial burden remain relatively unchanged. It is also notable that being covered by UEBMI and NCMS is associated with lower OOP health expenditure and reduced likelihood of incurring CHE.

Table 5: Regression of the logarithm of out-of-pocket and logit regressions of catastrophic health expenditure on an intervention dummy variable and other cofactors

	Model 1: log	Model 2: CHE_10%	Model3: CHE_40%

	OOP					
	Coef.	P>|t|	Odds ratio	P>|t|	Odds ratio	P>|t|
Intervention period						
After intervention	0.572	0.013	1.86	0.033	1.50	0.021
Income group						
< 1.9 USD	ref.		ref.		ref.	
1.9–5.5 USD	0.217	0.063	0.29	<0.001	0.59	0.001
⩾ 5.5 USD	0.436	0.025	0.14	<0.001	0.72	0.275
Period*income group						
< 1.9 USD	ref.		ref.		ref.	
1.9–5.5 USD	-0.144	0.280	0.81	0.451	0.87	0.286
⩾ 5.5 USD	-0.426	0.046	0.71	0.168	0.52	0.001
Gender						
male	0.03	0.743	1.12	0.424	1.13	0.382
Age						
age 30–59	-0.047	0.868	1.13	0.702	1.47	0.374
Age ⩾ 60	0.188	0.454	1.61	0.121	2.90	0.022
Patient category						
relapse	-0.011	0.911	0.97	0.873	0.87	0.275
Marriage						
married	0.176	0.004	0.94	0.629	1.01	0.928
Education						
no education	ref.		ref.		ref.	
primary	0.08	0.410	1.13	0.506	1.42	0.087
secondary	0.256	0.006	1.26	0.141	1.05	0.800
⩾ high school	0.312	0.130	1.32	0.287	1.46	0.014
Insurance type						
other	ref.		ref.		ref.	
UEMBI	-0.492	0.009	0.41	<0.001	0.42	0.004
NCMS	-0.441	0.005	0.64	0.016	1.06	0.824
Employment						
Working	-0.246	0.022	0.71	0.002	0.70	<0.001

CHE_10: 10% of household income threshold; CHE_40: 40% non-food expenditure threshold.
UEBMI, Urban Employee Basic Medical Insurance; NCMS: New Cooperative Medical Schemes.
Coef.: Coefficient
OOP: Out-of-pocket

The qualitative data revealed a variety of stakeholder opinions as to the impact of the model, and provided insights into factors contributing to the high OOP health expenditure and financial burden following the intervention. Policy makers (directors of local health and family planning bureau and health insurance office) in the three study sites generally thought that the new financing and payment model would be beneficial for TB patients and could effectively reduce their financial burden. On the other hand, some directors of the insurance office admitted that patients with serious comorbidities had been excluded from the intervention and thus their costs were not subject to the cost limit set by the case-based payment policy.

"The policies are good…the reimbursement increased to 70% and patients financial burden are relieved……" (Director of Health and family planning bureau, prefecture level)

"Many patients have comorbidities. Originally it was stipulated that the hospitals bear the cost exceeding the fixed rate. However, if the patients have serious comorbidities, like chronic obstructive pulmonary disease and hemoptysis, their treatment costs were really high and sometimes they even need to be transferred to Intensive Care Unit..We could not apply case-based payment for these patients." (Director of health insurance office, prefecture level)

Focus group discussions with TB patients reinforced the finding that patients still bear a considerable financial burden for treatment, especially those with comorbidities. Many patients said they took liver-protection and other auxiliary drugs in addition to TB medication, even though these drugs were not included in the standardized TB treatment package. These patients could therefore not enjoy the higher reimbursement rates and nor were the costs of the drugs restricted by the case-based payment limit. In addition, the costs for patients who were transferred to higher level hospitals due to their severe condition were also not covered by the new model. In focus groups discussions with physicians it was argued that the standard treatment package was very limited, which meant that a number of the medical services commonly used by the patients were not included, especially for those with comorbidities. Some physicians also conceded that their income levels were correlated with the net revenue of the department, mainly generated from service provision and drug sales.

"You have to take these liver-protection drugs, and they cannot be reimbursed for us young people (without special insurance)." (TB patient, FGD)

"I had hemoptysis and I was transferred to xxx Hospital (prefecture-level TB

designated hospital) from the xx hospital (county-level hospital)……I was hospitalized for over a month. Then one month after the discharging from the hospital my conditions relapsed, and the doctors in xxx Hospital asked me to go for more checks in xxxx Hospital (prefecture-level general hospital) where I spent over 20 000 RMB……" (TB patient, FGD)

"The treatment of comorbidities are not included in the new reimbursement policy…Patients' complications typically happened when they were readmitted into the hospital, and in this situation they could not enjoy the new policy either." (TB physician, county-level, FGD)

(Our income) is correlated with the net income of the department. He (the hospital manager) set a line….For example, you treat 100 patients and bring in such an income, and how much you can take from the income… (TB physician, prefecture-level, FGD)

Discussion

This study shows that the average OOP health expenditure and financial burden on the patients increased after implementing the new financing and payment mode. National statistics show that the average outpatient cost per visit increased 13.3% and average inpatient cost per admission increased 11.1% over the intervention period. Clearly, the percentage increase following the intervention was much higher and cannot be fully explained by the general rising trend in healthcare costs [34]. As evidenced in the companion paper by Dong et al., the new model contributed to a substantially increased use of outpatient and inpatient services, especially for the lowest income group. Their hospitalization rate increased from 48.5% to 70.7%, and the number of outpatient visits from 4.6 to 5.7. From an equity perspective, the reduced differences in service use across different income groups can be seen as a positive outcome of the intervention. No one would wish to see poorer patients avoiding CHE by choosing not to access the services they need. Nevertheless, the intervention also resulted in an increased inequality in OOP payments for TB care. Clearly the model did not provide sufficient financial protection to offset the substantially increased costs resulting partly from the increase access promoted by the intervention, and both the project designers and implementers at the national and local levels may not have fully anticipated this situation.

Qualitative results from the study offer several possible reasons why poorer patients paid more out-of-pocket during the intervention period. While the new model encouraged poor patients to start and adhere to regular treatment, many

of the medical services they received were not included in the standard treatment package, and were thus not reimbursed at a higher rate. The costs of these medical services were also not restricted by the case-based payment limit as defined by the project policies. Studies have shown that patients in lower socio-economic status tend to delay treatment [35], and thus they are more likely to result in more treatments for complications or comorbidities eventually, thus increasing out-of-pocket payments for services not covered by the model. Moreover, if their condition was severe, they risked being excluded from the project because physicians in these designated hospitals were concerned that their department/unit would have to incur a deficit if the treatments they provide to the patients with serious co-morbidities are paid for using the case-based payment. Alternatively, they might be transferred to higher level hospitals where they would not enjoy the benefits of the new policies. From the physician side, as their incomes are closely related to the net income of the department, they had an incentive to exclude patients with severe comorbidities from the program, or prescribe medical services outside the treatment package to increase revenue.

In light of the financial difficulty faced by the poor patients, future policies concerning the financing of TB treatment might need to consider a strategy that is more supportive. A systematic review on interventions to reduce illness and injury related financial burden shows that eliminating or largely reducing copayments in current insurance schemes is effective in reducing OOP medical payments [36]. Evidence from cash transfer programs to support TB households in low and middle income countries also shows that this strategy could increase the TB cure rate [37], and one study in Peru also finds a reduction in CHE [38]. Based on this international experience and findings from our study, improving the reimbursement rate for all TB related medical services is necessary to reduce poor TB patients' financial burden. However, it is also critical to ensure that the costs of all these medical services are restricted by the case-based payment; otherwise there remains an incentive for physicians to pursue income by prescribing unnecessary drugs and treatments. In addition, more financial resources, for example earmarked funds from government, should be mobilized to subsidize poor patients, especially those with complications and comorbidities.

This study has several limitations. One major limitation is that we did not have a formal list of patients who were included in the program throughout their treatment and those who were excluded. Nevertheless, as the new model was required by the government to be implemented in all designated hospitals, it would seem likely that the vast majority of patients were included. It can also be

argued that assessment of the model under the current health system implies that its effectiveness may have been influenced by implementation barriers known to be imbedded in that system, for example the tendency for hospitals to avoid innovations that they perceive as potential threats to income generation. We did not ask about complications and comorbidities in the survey, and we cannot exclude the possibility that the patients enrolled in treatment during the project had more severe conditions and incurred higher costs for this reason. In addition, recall bias is likely as we asked patients about the whole treatment period since the onset of symptoms.

Conclusions

The mean out-of-pocket health expenditure and financial burden of TB patients increased after the implementation of the new model and we would argue that the limitations mentioned above did not substantially influence this conclusion, given the degree of the observed increase. Apparently, the new financing and payment model was not successful in protecting poor patients from financial difficulty during their treatment. Future research may be required to look into strategies to provide more financial protection for poorer patients and impose effective cost control.

List of abbreviations

CHE: catastrophic health expenditure
DRG: diagnostic-related group
FGD: focus-group discussion
NCMS: new cooperative medical schemes
OOP: out-of-pocket
TB: tuberculosis
UEBMI: urban employee basic medical insurance
URBMI: urban resident basic medical insurance

Ethics approval and consent to participate

Ethical approval of the study was issued by the Institutional Review Board of Chinese Center for Disease Control and Prevention. Consent form was obtained before individual data collection and could be provided upon request.

Consent for publication

Consent form was obtained before individual data collection and could be

provided upon request.

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Chapter 5

The equity in the screening, diagnosis and treatment of DRTB patients in China: results from a study of the DRTB registration database in Zhejiang

Published as
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Abstract

Objectives To examine changes in the screening, diagnosis, treatment and management of drug-resistant tuberculosis (DRTB) patients, and investigate the impacts of DRTB related policies on patients of different demographic and socio-economic characteristics.

Design A retrospective cohort study using registry data, plus a survey on DRTB-related policies.

Setting All prefecture-level Centers for Disease Control in Zhejiang Province, China

Main outcome measures Alongside the care cascade we examined: 1) reported number of presumptive DRTB patients; 2) percentage of presumptive patients with drug susceptibility testing (DST) records; 3) percentage of DRTB/rifampicin-resistant (RRTB) patients registered; 4) percentage of RR/MDRTB patients that received anti-DRTB treatment; 5) percentage of RR/MDRTB patients cured/completed treatment among those treated. Multivariate logistic regressions were conducted to explore the impacts of DRTB policies after adjusting for other factors.

Results The number of reported presumptive DRTB patients and the percentage with DST records largely increased during 2015-2018, and the percentage of registered patients who received anti-DRTB treatment also increased from 59.0% to 86.5%. Patients under the policies of equipping GeneXpert plus expanded criteria for DST had a higher likelihood of being registered compared with no GeneXpert (adjusted odds ratio, aOR=2.57, 95% CI: 1.20, 5.51), while for treatment initiation the association was only when further expanding the registration criteria (aOR=2.38, 95% CI: 1.19, 4.79). Patients with registered residence inside Zhejiang were more likely to be registered (aOR=1.96, 95% CI 1.52, 2.52), treated (aOR=3.83, 95% CI 2.78, 5.28) and complete treatment (aOR=1.92, 95% CI 1.03, 3.59) compared with those outside.

Conclusion The policy changes on DST and registration have effectively improved DRTB case finding and care. Nevertheless, challenges remain in

servicing vulnerable groups such as migrants and improving equity in the access to TB care. Future policies should provide comprehensive support for migrants to complete treatment at their current place of residence.

Introduction

Drug-resistant tuberculosis (DRTB) has become a global concern in recent years. It is estimated that globally in 2018, 3.4% of new TB patients and 18% of previously treated patients developed rifampicin-resistant forms of disease (RRTB) including multi-drug resistant TB (MDR-TB), in which there is additional resistance to isoniazid, and 7.1% and 21% respectively in China.[1] Currently China accounts for 14% of the RR/MDR-TB disease burden, and one recent projection suggested the incidence of RR/MDR-TB would triple without interventions to change current conditions.[2] The RR/MDR-TB epidemic has posed a great challenge to achieve the SDG target of ending TB in 2030 in China.[3]

The diagnosis and treatment of DRTB can be very costly in terms of both time and money,[4] and barriers to accessing DRTB diagnosis and care exist worldwide.[5] The diagnosis of DRTB takes 1-3 months using traditional technology, and the treatment of RR/MDR-TB lasts for up to two years. DRTB patients generally have lower socio-economic status, and the cost of treatment is so high that the current financing policies in the form of health insurance reimbursement and subsidized treatment are far from sufficient.[6-8] For China specifically, the public health insurance programs provide very limited coverage for outpatient services that are required for around 20 months for RR/MDR-TB patients. In addition, some second-line anti-TB drugs and auxiliary drugs are often not covered.[9-11] Previous studies in several countries including China have also revealed long treatment delay, high pre-diagnosis and pre-treatment attrition as and high loss-to-follow-up during the treatment course.[12-17] Moreover, the MDR-TB treatment success rate in China was less than 50%.[18] These formidable barriers for DRTB patients to accessing and adhering to standard treatment call for strong supporting policies for patients to receive and complete treatment.[19] Previous studies have validated the utility of rapid drug susceptibility testing (DST) technologies such as Genechip and GeneXpert in the screening for DRTB, and shown that these technologies could improve DRTB case finding, shorten treatment delays and decrease pre-diagnosis attrition.[13, 20–24] As for treatment adherence, one comprehensive program in China that provided universal health coverage to MDR-TB patients was shown to improve access to and affordability of diagnosis and quality treatment of MDRTB.[5] Studies on other intervention strategies showed that directly observed therapy (DOT) or other reminding approaches through digital technologies could

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improve the treatment adherence and outcomes of TB/MDRTB.[25, 26] Patient counseling alone or combined with financial support can also increase the cure rates among MDRTB patients.[27]

In China some provinces, along with or after the roll-out of international donor-funded projects, have implemented policies to improve DRTB control, including allocating special funds to equip DRTB-designated hospitals with DST facilities and reagents, improving health insurance benefit packages and providing subsidies to patients.[11,28] However, there is limited evidence on the impact of implementing these policies on DRTB case finding and care thereafter. The equity issues underlying the case finding and care procedures for DRTB patients are also understudied, especially considering that the eligibility for policies issued in a certain region is often linked with patients' registered residence, work and health insurance status.

This study aims to examine changes in the programmatic performance with regard to screening, diagnosis, treatment and management of DRTB patients in Zhejiang from 2015 to 2018 through a cascade analysis approach.[29] In addition, as the policies and guidelines on this whole procedure of DRTB care changed during this period, this study systematically summarizes these changes and investigates how these policy changes have influenced case finding and treatment of DRTB patients. We also explore whether these policy changes have equally influenced patients of different demographic and socio-economic characteristics.

Methods
Study settings

Zhejiang is a province located in the eastern area with its GDP ranking 4th in China,[30] and has a growing migrant population in recent years. Under the current TB control model in Zhejiang, the prefecture-level designated hospital, usually one in each prefecture, is responsible for the diagnosis and treatment of DRTB patients, while the Center for Disease Control (CDC) and primary health care facilities conduct patient management. Patients who are clinically suspected to have DRTB are to be referred for DST and should be reported in the Tuberculosis Information Management System (TBIMS) as presumptive DRTB patients. Their sputum samples are to be sent to the prefecture-level designated hospital for DST. If diagnosed with DRTB, these patients should be registered in the TBIMS database for diagnosed patients as such. The criteria regarding what types of DRTB should be registered have being changing over time.

Study Design

This study included a questionnaire survey on the DRTB policies/programs among the 11 prefecture-level CDCs and a quantitative analysis of the TBIMS records of presumptive and diagnosed DRTB patients.

Questionnaire survey on DRTB policies/programs

A questionnaire on the DRTB related policies was distributed to the CDC of all prefectures in Zhejiang in collaboration with Zhejiang provincial CDC. After preliminary consultation with the provincial CDC, the questionnaire was designed to include policies in four areas: 1) eligibility of presumptive DRTB patients for DST; 2) eligibility for registering DRTB patients based on the type of drug-resistance (including rifampin mono-resistance (RMR), multi-drug resistance(MDR), extensive drug-resistance (XDR) and mono-resistance to other types of drugs); 3) DST technology and payment for DST and 4) financing policies, including both health insurance benefit packages and government subsidies for supporting the DRTB treatment. Detailed questions on the eligibility for financial support regarding the types of DRTB, the registered permanent residence and the region of health insurance enrollment were also included in the questionnaire (see supplementary materials). If the policies had changed at any time after 2015, we collected information on the policy details before and after the change as well as the year of change.

TBIMS records

De-identified TBIMS records of presumptive and diagnosed DRTB patients from 2015-2018 in Zhejiang were retrieved from the TB Prevention and Control Center of China CDC. The dataset of presumptive DRTB patients included demographic information (prefecture of registration, age, sex, ethnicity, occupation and registered residence), drug-resistance test profile (the date of sending the sample, conducting the test and reporting the result, the type of test and the test result), as well as a unique registration number if registered as a DRTB patient in the diagnosed patient dataset. Only those DRTB patients recorded in the diagnosed patient dataset have a traceable treatment history and are managed under a specialized guideline for DRTB patients. The dataset of diagnosed DRTB patients contained the same demographic information and diagnostic data as the dataset of presumptive patients, plus the treatment information including the starting date of anti-DRTB treatment including both second-line (RR/MDR-TB) and adapted first-line (mono-resistance to isoniazid)

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treatment, TB treatment history, current state of treatment (under treatment or ended), and the ending date of treatment as well as the reason of ending the treatment (cured/treatment completed/death/lost-to-follow-up/others) if ended. In TBIMS the treatment status referred to whether the patient received treatment in Zhejiang. If patients were registered but returned to their hometown for treatment, it could be shown as "treatment refused".

Patient and Public Involvement Statement
Patients or the public were not involved in the design, or conduct, or reporting, or dissemination plans of our research.

Data analysis
Using datasets of the presumptive and registered diagnosed patients, a seven-step cascade of diagnosis and care was constructed for each year from 2015 to 2018 : 1) reported presumptive DRTB patients; 2) presumptive patients who had DST; 3) diagnosed DRTB, and RR/MDRTB (including RMR, MDR and XDR) patients; 4) registered RR/MDRTB patients; 5) RR/MDRTB patients that ever received anti-DRTB treatment; 6) RR/MDRTB patients that were under treatment 6 months after treatment initiated; 7) RR/MDRTB patients that had been cured or completed treatment, as shown in Figure 1. Diagnosed DRTB patients were defined as patients with a DST result showing resistance to at least one type of first-line anti-TB drug. As in all but one prefectures only RR/MDRTB patients were required to be registered and thus had available data on treatment history before 2019, we only analyzed RR/MDRTB patients for step 4-7. Descriptive analyses were conducted to explore the reasons for attrition at each step based on the relevant records in the datasets. Patients' ethnicity was categorized as Han and other minority groups. Frequencies of patient characteristics were also calculated across patient groups at each step of the cascade to examine potential factors associated with the attrition. For step 3-5 the frequencies of some patient characteristics of interests, including age, sex, drug-resistant type, occupation and registered residence were calculated separately for each year to examine the trends from 2015 to 2018.
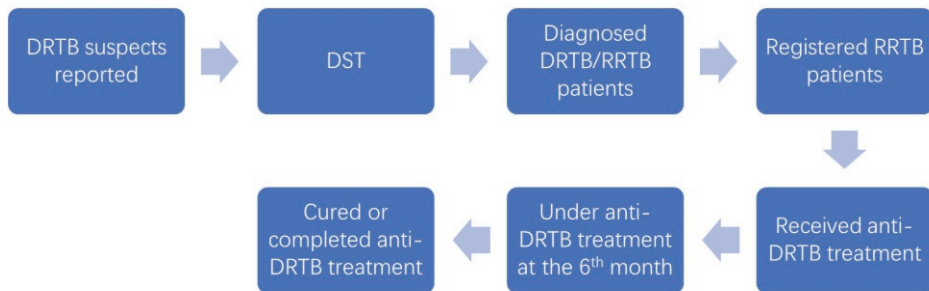
Figure 1: Seven steps of the DRTB diagnosis and care cascade

Mixed-effect two-level logistic regressions, with fixed slope and random intercept specification were conducted to explore factors associated with the likelihood of being registered for RRTB patients, the likelihood of receiving anti-DRTB treatment if registered, and the likelihood of getting cured or completing treatment (the latter only for those who initiated treatment before 2017 because of the 2-year treatment duration). This model showed better fit to the data than the fixed-effect model based on the likelihood-ratio test. The DRTB related policies were summarized along the four areas in the questionnaires. Besides patient-level variables, the policies implemented in each prefecture and each year, categorized according to the different combinations of policies in the four areas, were included in the model. Per-capita GDP of the prefecture was divided into three groups, as the numbers assembled in three intervals: RMB 55,000-70,000, 80,000-100,000, and above 120,000, and also included in the model as a categorical variable. Standard errors were estimated accounting for clustering, considering the intra-prefecture correlations.

Results
DRTB policy change from 2015-2018 in Zhejiang
Results from the questionnaire survey on DRTB policies showed that the major change in the eligibility of patients for DST was the expansion from high-risk patients (including smear positive relapse, treatment failure, positive sputum bacteriology after two months' treatment), to all bacteriologically positive TB patients. As for the testing technology, the major change was the introduction of the rapid DST assay GeneXpert MTB/RIF that combines testing for

Mycobacterium tuberculosis with screening for rifampicin-resistance with a same-day result, while the costs for the test were all covered, or mostly covered by the government. The criteria for DRTB patient registration (implying eligibility for specialized DRTB patient management) also expanded from MDR/XDR-TB to RR-TB, and one prefecture even expanded to any DRTB before 2018. In most prefectures these changes in DST eligibility and equipment as well as the registration criteria happened in 2017, while almost all others had adopted the new polices and introduced GeneXpert earlier (supplemental table 1).

The financing policies to support DRTB treatment in Zhejiang consisted of both health insurance and medical assistance policies, and in most prefectures these policies had been implemented in 2015. These financing policies aimed to improve the benefit package for DRTB patients through a three-layer coverage system: 1) increasing the reimbursement rate of outpatient treatment to 70%-90%, the same level as for inpatient treatment; 2) the out-of-pocket (OOP) expenditure exceeding a certain amount, typically RMB 20,000-30,000, could be further reimbursed at a rate of 55%-85% through a supplemental health insurance program for critical illnesses; 3) the OOP expenditure after health insurance reimbursement could be covered by the medical assistance, with a payment limit varying from 11,000 RMB to over 60,000 RMB across prefectures. As for the eligibility for the insurance policies, those with public health insurance enrolled outside Zhejiang, usually migrants without formal jobs, were excluded. In 5 out of the 11 prefectures RMR patients were still not eligible for the expanded public health insurance benefit package up to 2019. For the medical assistance, in 6 out of the 11 prefectures only patients with registered residence ("Hukou") in Zhejiang were eligible, and for the other 4 prefectures with assistance policies the eligibility had been expanded to all residents in this prefecture. Up to 2018, RMR patients in 5 prefectures were still excluded from the medical assistance (supplemental table 2).

Cascade analysis of DRTB care from 2015-2018
Table 1 shows the screening and diagnosis of DRTB patients from 2015-2018. In general, the results suggested increased capacity to find DRTB patients. The number of reported presumptive DRTB patients increased from 9285 to 23916, with the largest increase from 2016 to 2017 coinciding with the change in screening policy in most prefectures. The percentage of patients with test results also increased from 69.3% to 78.1%. Along with the increase in the volume of

DST there was an increase in the number of diagnosed DRTB patients except for 2018, and a decrease in the percentage of patients diagnosed among those tested. RR/MDR-TB patients accounted for around 40%-50% of the total DRTB patients.

Further analysis on the types of diagnostic tests patients received revealed an increasing trend in the percentage of patients taking rapid DST as well as the percentage of patients tested with both conventional culture-based and rapid DST. The percentage of presumptive patients without DST profile for unknown reasons as recorded in the TBIMS dataset, which indicates pre-diagnosis attrition, dropped dramatically from 17.3% to 2.7% (supplemental table 3).

Table 1: Diagnostic cascade starting from presumptive DRTB patients

Year	No. of presumptive DRTB patients	Patients with test records		Diagnosed DRTB patients		Diagnosed RR/MDR-TB patients	
		No.	%	No.	%	No.	%
2015	9285	6434	69.3	1031	16.0	503	48.8
2016	10997	8438	76.7	1258	14.9	529	42.1
2017	21768	14764	67.8	1729	11.7	716	41.4
2018	23916	18670	78.1	1580	8.5	663	42.0

Table 2 shows the registration and treatment for diagnosed RRTB patients from 2015-2018. While the actual number of registered RRTB patients increased, the percentage of registered RRTB patients dropped in 2017, and this percentage increased again to 84.6%. The percentage of registered patients that received anti-DRTB treatment increased from 59.0% to 86.5%, and the percentage of those treated who received at least 6 month's treatment remained above 90%. Around 70% of patients diagnosed in 2015 and 2016 completed treatment. Duration of treatment could be longer than 2 years, as 38 out of the 283 patients starting treatment in 2016 were still shown as under treatment at the time we retrieved the data (see supplemental table 4).

Table 2: Registration and treatment cascade for diagnosed RRTB patients.

Year	Diagnosed RR/MDR-TB patients	Registered		Received anti-DRTB treatment		Under treatment 6 months after treatment initiated		Cured or completed treatment	
		No.	%	No.	%	No.	%	No.	%
2015	503	383	76.1	226	59.0	215	95.1	158	73.5

2016	529		410	77.5	283	69.0	263	92.9	182	69.2
2017	716		502	70.1	360	71.7	334	92.8	/	/
2018	663		561	84.6	485	86.5	462	95.3	/	/

Factors associated with the registration and treatment of DRTB patients

Table 3 shows the characteristics of patients across each step of the care cascade. Around 70% of the presumptive and diagnosed patients were male, and around 98% of them were Han People. Only around 40% of the patients had formal jobs other than farming or unemployment. While under the assumption of perfect equity we would expect that the percentage of patients with different characteristics remained the same from the diagnosed to the treated group, it decreased from 30.3% to 27.0% for older patients, 28.1% to 22.5% for RMR patients, and from 24.4 to 17.0% for patients with registered residence outside Zhejiang, i.e., migrants. An increase was observed regarding the percentage of patients ever taking rapid DST.

Table 3: Patient characteristics across each step of the care cascade

	Presumptive DRTB patients	Diagnosed DRTB patients	Diagnosed RR/MDR-TB patients	Registered RR/MDR-TB patients	RR/MDR-TB patients recevied treatment
N	65966	5598	2411	1859	1357
Age (%)					
>=60	41.3	35.9	30.3	29.8	27.0
Gender (%)					
Male	70.6	73.6	72.5	72.7	72.7
Ethnicity					
Han (%)	97.7	98.0	97.9	98.0	98.8
Patient type (%)					
new patient	70.2	65.2	51.8	51.4	48.8
Drug-resistanct type (%)					
RMR	/	12.1	28.1	20.8	22.5
MDR	/	30.4	70.6	78.0	76.1
XDR	/	0.5	1.2	1.2	1.4
Non-rifampicin resistant	/	56.9	/	/	/
Registered residence (%)					
outside Zhejiang	23.4	25.2	24.4	22.3	17.0

Job category (%)					
farmers	49.0	48.0	43.8	45.0	45.5
unemployed	12.4	13.0	14.1	14.2	14.0
other	38.6	39.0	42.1	40.8	40.5
Test type (%)					
fast test	/	38.6	46.5	46.1	49.2

Figure 2 shows the changes in the characteristics of diagnosed, registered and treated RR/MDR-TB patients from 2015-2018. The percentage of diagnosed RMR patients that received adequate treatment was low in 2015 and 2016, but increased dramatically from 2017, coinciding with the policy change. The gaps between the proportion of older patients in the diagnosed and the treated group also narrowed. Nevertheless, over the four years there remained a 7-10 percentage decrease in the proportion of patients with registered residence outside Zhejiang from the diagnosed to the treated patient group, indicating that migrants were still more likely to drop out after diagnosis compared with the local residents. Gender and job category were not obviously associated with the pre-treatment attrition in this univariate analysis.
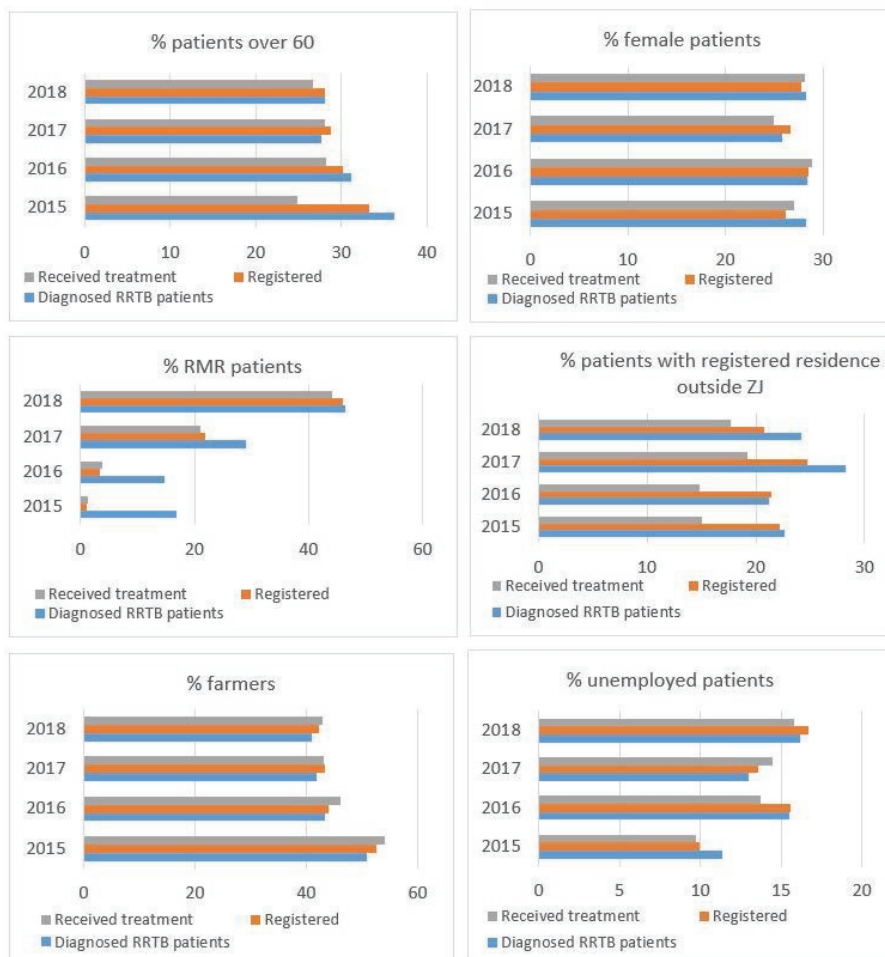
Figure 2: Characteristics of diagnosed, registered and treated RR/MDR-TB patients, 2015-2018

To systematically investigate the impact of policies on DRTB case finding and care, we divided the combination of policies in different areas of DRTB implemented in each prefecture for each year during 2015-2018 into four categories, considering both policy implications and the number of cases in each category. As shown in Figure 3, since 2017 all prefectures had equipped GeneXpert and expanded the eligibility criteria for DST as well as registration, except for two prefectures which still did not register RMR patients.
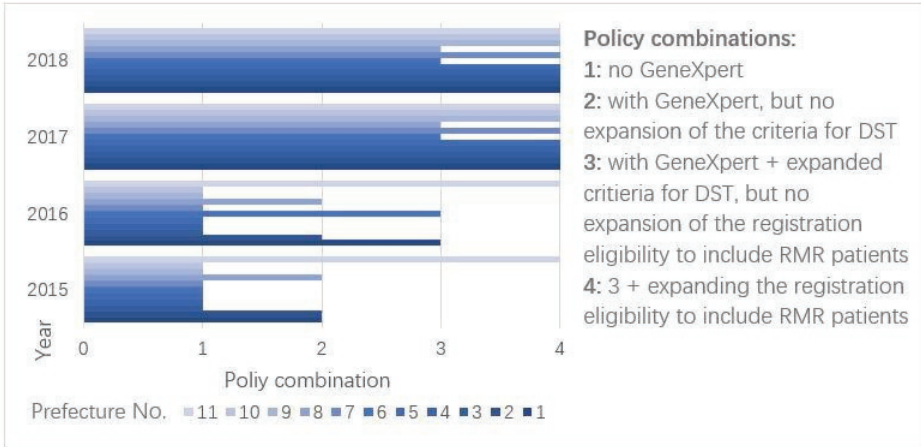
Figure 3: Combination of DRTB policies implemented in each prefecture from 2015-2018

Table 4 shows the results of mixed-effect two-level logistic regression of the factors associated with registration among diagnosed RRTB patients, as well as with receiving anti-DRTB treatment among those registered. After adjusting for other factors, patients under the policy of providing GeneXpert together with expanding eligibility for DST (category 3, adjusted odds ratio (aOR) =2.57, 95% CI: 1.20, 5.51) had a significantly higher likelihood of being registered compared to patients not provided with GeneXpert, while this association was not significant for providing GeneXpert testing without expanding eligibility (category 2). A positive association with receiving anti-DRTB treatment was significant only for the policy combination of providing GeneXpert and expanding eligibility for both DST and registration (category 4, aOR=2.38, 95%CI: 1.19, 4.79). Not surprisingly, MDR/XDR-TB patients were much more likely to be registered compared with RMR patients due to the registration policy in earlier time periods. In addition, patients with registered residence inside Zhejiang were more likely to be registered (aOR=1.96, 95% CI 1.52, 2.52) or treated (aOR=3.83, 95% CI 2.78, 5.28). Older age was associated with lower likelihood both of being registered (aOR=0.69,95% CI 0.53, 0.90) and of receiving anti-DRTB treatment (aOR=0.40, 95% CI 0.30, 0.52).

Tables 4: Factors associated with registration for diagnosed RRTB patients, and with receiving anti-DRTB treatment for registered RRTB patients.

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	Registration (n=2367)				Receiving treatment (n=1824)			
	OR	P>z	95% CI		OR	P>z	95%CI	
Age								
>=60	0.69	0.006	0.53	0.90	0.40	0.000	0.30	0.52
Gender								
male	1.08	0.554	0.85	1.37	0.87	0.425	0.62	1.22
DR type								
MDR/XDR-TB	5.93	0.000	3.10	11.36	0.91	0.789	0.45	1.84
Patient type								
new patient	1.22	0.146	0.93	1.59	0.52	0.000	0.37	0.72
Treatment history	NA							
no treatment					ref.			
1st-line drug only					0.58	0.044	0.34	0.99
2nd-line drug used					1.11	0.748	0.58	2.12
Policy category								
1	ref.				ref.			
2	1.18	0.626	0.61	2.29	0.87	0.776	0.34	2.25
3	2.57	0.015	1.20	5.51	1.44	0.257	0.77	2.68
4	2.08	0.054	0.99	4.37	2.38	0.015	1.19	4.79
Registered residence								
in Zhejiang	1.96	0.000	1.52	2.52	3.83	0.000	2.78	5.28
Job category								
farmers	ref.				ref.			
unemployed	1.21	0.017	1.04	1.42	0.90	0.651	0.58	1.40
other jobs	0.92	0.281	0.80	1.07	0.94	0.784	0.60	1.47
Per capita GDP								
highest group	ref.				ref.			
middle group	1.72	0.122	0.87	3.42	2.20	0.025	1.10	4.38
lowest group	1.70	0.099	0.90	3.20	1.15	0.643	0.63	2.12
_cons	0.32	0.002	0.16	0.66	1.85	0.207	0.71	4.78
prefecture var(_cons)	0.18		0.09	0.39	0.18		0.03	0.92

Tables 5 shows the results of the mixed-effect two-level logistic regression analysis of factors associated with the likelihood of completing treatment for patients who initiated treatment before 2017. All prefectures had some kind of financing policies in 2015 and 2016, and most prefectures had not yet expanded the eligibility of patients for DST or registration. We therefore used the individual level data on utilization of rapid DST to assess the impact of rapid

testing on treatment completion. After adjusting for other factors, older patients were less likely to complete treatment (aOR=0.24, P<0.001), while registered residence inside Zhejiang was associated with higher probability of completing treatment (aOR=1.92, P=0.04). These two factors had significant impacts of the same direction on the registration, treatment initiation and treatment completion of RR/MDRTB patients. Utilization of rapid DST was not associated with treatment completion in this study.

Table 5: Factors associated with the likelihood of completing treatment for patients that initiated treatment before 2017

	OR	P-value	95% Conf.	Interval
Age				
>=60	0.24	<0.001	0.14	0.42
Gender				
male	0.79	0.442	0.44	1.44
Drug-resistance type				
MDR/XDR-TB	0.50	0.086	0.23	1.10
Patient type				
new patient	1.06	0.820	0.64	1.77
TB treatment history				
no treatment history	ref.			
first-line drug only	0.74	0.355	0.39	1.40
second-line drug used	1.07	0.847	0.56	2.02
Test type				
fast test	0.70	0.096	0.46	1.06
Registered residence				
in Zhejiang	1.92	0.040	1.03	3.59
Job category				
farmers	ref.			
unemployed	0.84	0.635	0.42	1.71
other jobs	1.44	0.278	0.74	2.79
Per capita GDP				
highest group	ref.			
middle group	0.94	0.939	0.20	4.39
lowest group	1.07	0.921	0.30	3.74
Year of sending sample				
2015	ref.			
2016	1.23	0.164	0.92	1.64

_cons	5.58	0.001	2.01	15.50
prefecture var(_cons)	0.21		0.04	1.10

Discussion

Results from this study clearly revealed the positive impacts of the combined policy changes regarding DST of presumptive DRTB patients and registration for proper management of diagnosed patients. However, inequity challenges remain in terms of servicing vulnerable groups, e.g. migrant workers and the older population, in the registration, treatment and management of DRTB.

Effectiveness and challenges of the policy interventions

The expansion of the eligibility criteria of presumptive DRTB patients referred for DST, together with the increased funding support to equip the facilities and guarantee the supply of reagents for rapid DST like GeneXpert, have greatly improved the capacity for DRTB case finding. The significant effects of the combined policies compared to providing GeneXpert alone indicates that in order to effectively improve case finding we need to not just introduce new technologies, but also support and expand their use. The inclusion of RMR in the registration and management of DRTB patients closed the management gap between RMR and MDR/XDR-TB patients, and also improved the treatment rate for RR/MDR-TB.

It is obvious that these reforms in the DRTB policies and regulations have effectively changed the practices in DRTB control. Nevertheless, no policies aiming at migrants were issued between 2015 and 2018, and during these four years the degree of inequity between local and migrant patients did not seem to be mitigated either. The improved insurance benefit package was only available for those with public health insurance enrollment in Zhejiang, and in many prefectures receiving medical assistance still required local registered residence during 2015-2018. In addition, older people were less likely to be registered or receive treatment. This may be because they were more likely to give up treatment due to the high cost and long course of the standard treatment, and health workers may not register them once they refused to provide information necessary for registration. All these findings were consistent with previous studies that age and migration for work, as well as health system factors such as lack of clear eligibility criteria for DST and limited capacity to provide DST were associated with attrition at different stages of the cascade.[14, 16, 31–33] Nevertheless, no impacts were observed of other factors, such as association between treatment experience and treatment outcome, and data on other socio-

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economic factors such as financial difficulties were not available in this study.

Equity challenges regarding migrant populations

The growing number of migrants in China and other parts of the world are posing a challenge to TB control.[31, 34–36] Although one systematic review found no significant differences in treatment adherence between migrant and long-term resident MDRTB patients,[37] several studies identified barriers for migrants to accessing TB diagnosis and care mainly in terms of knowledge gaps and financial difficulty,[38, 39] and these barriers would likely to be more substantial for migrant MDRTB patients. In our study, only around 40% of the DRTB patients had a formal job other than farmers or self-employment. In China people with a formal job will be compulsively enrolled in the urban employee basic medical insurance at the place of work as required by law. However, migrants without a formal job often choose to participate in the health insurance for residents in their hometown which requires lower premium compared to the more developed region they migrated to, and thus cannot benefit from the reimbursement policy in their working place. Besides, they often have to pay the full cost of treatment first before they get reimbursed when they return home. Therefore, it is expected that many of these DRTB patients would choose to go back to their hometown for treatment, or even refuse treatment. The need for migrant DRTB patients to travel long-distances and the substandard or even absent treatment received would increase the risk of disease transmission and treatment failure. A study in Shanghai, a well-developed city in eastern China, showed that financial incentives were effective for migrant TB patients to complete treatment.[40] In terms of these findings, policies aimed at encouraging migrant DRTB patients to be treated and managed at their current place of residence need to be developed, and this is particularly urgent for regions with a large migrant population.

Limitations

One major limitation of our study is that almost all prefectures had some form of financing policy since 2015 and there were no individual-level data on whether the patient benefited from these financing policies. Therefore, in this study the impacts of these financing policies could not be explored. Furthermore, other potentially important socio-economic factors like education and income were not available in our dataset, limiting the scope of the equity analysis.

Nevertheless, these limitations would not influence our conclusions that changes in the screening and registration policies of DRTB patients have largely increased the case finding and management capacity of DRTB patients, while during the period 2015-2018 differences between the local and migrant patients in the registration, treatment initiation and treatment outcome remained. We did not consider population changes either as the resident population only increased 5% from 2015 to 2018 in Zhejiang. [41] Future research should collect more individual-level data on the implementation of the health insurance and medical assistance policies to investigate the impacts of these demand-side policies on DRTB treatment more directly, and explore what kind of financing policies provided for migrants could increase their likelihood of initiating and completing anti-DRTB treatment.

Declarations

Ethical approval

Competing interests

Funding

Contributorship statement

All authors have read and approved the manuscript in its current state.

Data sharing statement

Data may be obtained from a third party and are not publicly available. The data from the TBIMS used in this study are owned by China CDC. The data could only be accessed after obtaining permission from China CDC.

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Supplemental Materials

1. Policy survey questionnaire

Drug-resistant tuberculosis related policy survey in Zhejiang

Prefecture: _____
Institute: _____
Date: _____(YY/MM/DD)

1. Eligibility criteria for drug-resistant tuberculosis (DRTB) patient screening
    1) The current eligibility criteria of patients referred for screening are: _____
       ___
    2) Are there any changes in the eligibility criteria after 2014: _____yes/no
       If yes: year of change_____, and the eligibility criteria for patients referred for screening before policy change_____

 (If the eligibility criterion is the "high-risk" TB patients, please specify the definition of high-risk TB patients in your prefecture, for example, smear positive after two months' treatment or others).
2. Test tools for drug susceptibility testing (DST)
    1) Has GeneXpert been equipped in the prefecture-level designated hospital? If yes, it was equipped in the year _____
    2) Under what conditions would patients be referred for traditional DRTB tests after screening? _____
    3) Please list other types of DST conducted in the prefecture, including both molecular and traditional_____.
    4) Does the government provide funds to secure the supply of the reagents for rapid DST now? _____(Yes/no). If yes, at which year did the government begin to provide such funds? ____.
3. Financing of DST
    1) Does the patient need to pay out-of-pocket for the DRTB rapid screening test now? _____ (yes/no). If yes, how much does the patient need to pay? RMB_____, accounting for _____% of the total cost
    2) Does the government pay for the DRTB rapid screening test now? (yes/no). If yes, how much does the government pay for each test? RMB_____, accounting for _____% of the total cost
    3) Does the health insurance pay for the DRTB rapid screening test now? _____ (yes/no). If yes, _____% of the cost would be reimbursed by the health insurance.
    4) Does the health insurance pay for the DRTB rapid screening test now?

(yes/no) . If yes, _____% of the cost would be reimbursed by the health insurance.

5) Have the polices on the financing of DST ever been changed after 2014? If yes, the year of change is _____. Before the policy change, the patient paid for RMB____ for the screening test, accounting for _____% of the total cost;

The government paid for _____% of the total cost;

the health insurance schemes reimbursed _____% of the total cost;

other funding resources paid for _____% of the total cost

4. DRTB patient registration

1) Currently what types of DRTB patients would be registered and managed in the TB information management system (TBIMS)? (Please check all that apply)

a. XDR and MDRTB b. rifampin mono-resistant (RMR) patients c. Mono-resistant to other type of first-line drug

2) Has this policy been changed after 2014? _____(yes/no). If yes, please specify the types of DRTB patients that were registered and under management before policy change. (please check all that apply)

a. XDR and MDRTB b. rifampin mono-resistant (RMR) patients c. Mono-resistant to other type of first-line drugs

5. DRTB treatment

1) The standard anti-DRTB treatment regimen includes _____ months' hospitalization, and the total treatment length is _____months

2) Health insurance policies:

a) Has the specialized outpatient reimbursement program for DRTB treatment been implemented in your prefecture now? _____(yes/no) If so, this policy began in the year_____. The reimbursement rate for outpatient service is _____%, and the annual limit line for compensation is RMB_____.

b) The reimbursement rate for DRTB inpatient service is _____%, the deductible is RMB_____, and the annual limit line for compensation is RMB_____.

c) Has DRTB treatment been included in the serious disease reimbursement program of the health insurance? _____(yes/no). If yes, this program started in the year_____, for the out-of-pocket payment over RMB_____, the reimbursement rate is _____%, and the annual limit line is RMB_____.

d) Could RMR patients enjoy the health insurance policies for anti-DRTB treatment now? _____(yes/no). If yes, at which year could the RMR patients start to enjoy such policies? _____.

e) Are these health insurance policies only eligible for those who enrolled in the local health insurance schemes? _____(yes/no). If no, at which year could patients with health insurance outside your prefecture/Zhejiang province start to enjoy such policies? _____.

f) Could the health insurance policies be enjoyed if patients do not

get cured after the standard treatment length? _____(yes/no). If yes, how long could patients enjoy these policies? _____.

3) Other government financial assistance policies for DRTB patients
   a) Are there any other financial assistance policies for DRTB patients in your prefecture? _____(yes/no). If yes, at which year were they launched? Please briefly describe the policy? （How much money given to DRTB patients, how to deliver such assistance, etc.）_____
   b) Could RMR patients enjoy the financial assistance policies for now? _____(yes/no). If yes, at which year could the RMR patients start to enjoy such policies? _____.
   c) Could patients without local registered residence (Hukou) enjoy the policy now? _____(yes/no). If yes, at which year could the RMR patients without local Hukou enjoy such policies? _____.
   d) How long could the patients enjoy these policies after diagnosis? _____

6. Any other DRTB related policies, please describe here_____

2. Supplementary result tables

Table 1: Year of policy change regarding the screening test and registration in the 11 prefectures

Prefecture No.	Year of policy change		
	screening range	test technology	registration policy
1	2016	2015	2017
2	2017	2014	2014
3	2017	2017	2017
4	2017	2017	2017
5	2017	2017	2017
6	2009	2016	2019
7	2017	2017	2017
8	2017	2015	2019
9	2017	2017	2017
10	2017	2017	2015
11	2000	2012	2012

Table 2: Starting time and eligibility for health insurance and medical assistance policy coverage, 2015-2018

Prefecture No.	Health insurance policy			Medical assistance		
	starting time	insurance outside ZJ	RMR	starting time	registered residence	RMR

					outside ZJ
1	2018	N	Y	2013	N	N
2	2013	N	Y	2013	Y	Y since 2015
3	2016	N	N	2014	Y	N
4	2017	N	Y	2015	Y	N
5	2016	N	N	2015	N	N
6	2019	N	N	2012	N	Y
7	2014	N	N	2014	Y	N
8	2013	N	N	2015	N	Y
9	2014	N	Y since 2017	No policy		
10	2013	N	Y	2015	N	Y
11	2011	N	Y	2015	Y	Y

Table 3: The diagnostic test for presumptive DRTB patients from 2015-2018

Year	No. of presumptive patients reported	% took fast DST	% took traditional DST	% took both tests	Patients with no DST records (%)		
					total	not TB	unknown reason
2015	9285	18.2	51.3	0.2	30.7	13.4	17.3
2016	10997	30.4	46.9	0.5	23.3	11.6	11.7
2017	21768	30.9	42.8	5.8	32.2	25.6	6.6
2018	23916	64.4	33.8	20.1	21.9	19.3	2.7

Table 4: Reasons for not completing anti-DRTB treatment according to the registration records

Year	Total	Under treatment		Dead		lost-to-follow-up		Other reasons	
		No.	%	No.	%	No.	%	No.	%
2015	68	11	16.2	17	25.0	13	19.1	27	39.7
2016	101	38	37.6	15	14.9	15	14.9	33	32.7

Chapter 6

General discussion and conclusion

6.1 Factors that contribute to the inequity in the healthcare system in China

6.1.1 Financial protection provided by the public health insurance

Results from our studies are consistent with extensive existing literature suggesting that the healthcare services covered by the public health insurance schemes in China, especially the URBMI and NRCMS, have been very limited. In chapter 2 we found that NRCMS/URBMI failed to provide sufficient financial protection against CHE for the rural population, even in the relatively developed part of China, with regard to their increased healthcare service use. In chapters 3 and 4 we revealed that the new financing policies, which improved the reimbursement rate, still did not reduce the overall likelihood of incurring CHE, as many healthcare services used by patients were not covered by the health insurance and needed to be paid out-of-pocket. Patients enrolled in NRCMS were more likely to incur CHE compared to those enrolled in UEBMI and URBMI during the implementation of the new financing policies. In general, the public health insurance system, which achieved a coverage of over 95% in China, did improve the equity in healthcare utilization, as the rural poor started to seek healthcare services under insurance coverage. However, with the increase in healthcare service use among the rural poor, the insufficient financial protection provided by NRCMS/URRBMI may deteriorate the equity in healthcare financing, as the rural poor incurred higher OOP health expenditure.

To address equity in healthcare service use and financing, previous studies called for integration of healthcare insurance schemes. But the key issue is whether the integration could improve benefit packages for enrollees. The differential financing structure and remarkable gaps in the benefit packages make the integration of UEBMI with NRCMS and URBMI very challenging(1). Before 2015 neither NRCMS nor URBMI offered reimbursement for outpatient services, whereas UEBMI covered outpatient services with a personal medical savings account co-funded by individual and corporate contributions. In recent years, the benefit packages within each insurance scheme have been steadily improved, especially regarding the coverage of outpatient services in response to the rising burden of NCDs that require long-term outpatient treatment. Starting around 2015, the NRCMS and URBMI, or the new URRBMI, began to reimburse outpatient services in designated hospitals, be it at low levels (payment limit RMB 200-400 per year across provinces). Besides, all three public insurance schemes have implemented special programs for specific types of chronic diseases that need regular outpatient treatment, including diabetes, cancer and

uremia, the list expanding to more diseases year by year. But as the health insurance funds are managed at the prefectural level, geographic disparity maintains. And inequity could be "created" between patients with covered diseases and those with uncovered diseases. Moreover, there is still a lack of research on whether these special programs can reduce the OOP expenditure for patients that are covered.

Other supplementary programs to the basic health insurance have also been developed and implemented in recent years. The critical illness insurance program (CII), which typically offers additional reimbursement for OOP expenditure over RMB 20000, has been found potentially effective in reducing OOP expenditure and incidence of CHE(2–4). However, one study found the CII did not decrease the OOP for rural inpatients, and the long-term effects of the CII are not clear(3,5). An additional problem exists in the current reimbursement procedure of the CII in many places, which requires that people pay first with OOP, and then get reimbursed with proof of receipts. This could prohibit poor patients who are short of OOP money from receiving the benefit. Another program, medical financial assistance (MFA), was found to be ineffective in providing financial protection due to its low coverage and limited funding(6,7). Moreover, healthcare services that were not reimbursable under the basic public insurance schemes were still not covered by these supplementary programs. The result is the financial burden could still be high after multiple reimbursement, as evidenced by a study on MDRTB patients who enjoyed financial assistance policies (8).

In sum, the high proportion of OOP payment in the financing for healthcare services in China has dual equity implications that are unfavorable for the poor. As revealed in many empirical studies, the high OOP will distort healthcare service use patterns towards pro-rich, especially for those "expensive" services. Meanwhile, under the health insurance schemes, the rich who use more of the expensive but subsidized healthcare services than the poor will enjoy a bigger share of insurance subsidy. Therefore, the key issue to be addressed to enhance the equity of healthcare in China is how to further improve the level of financial protection provided by the public health insurances to guarantee accessible healthcare services for the poor.

6.1.2 Profit-driven incentive of healthcare providers

The profit-driven incentive of the healthcare providers has become an underlying factor that impacts on the effects of pro-equity health system reforms in China.

Such incentive is related to the general context that public hospitals in China are largely autonomous and rely on medical revenues for their sustainability, thus deviating from their social responsibility to provide commonly affordable healthcare(9,10). Previous studies have identified a correlation between provider motivation and prescription behavior, and ultimately healthcare cost(11–13). The direct effect of the distorted motivation is physicians' preference for drugs that could generate more income instead of drugs that are most appropriate for patients, thus more expensive drugs are prescribed leading to high financial burden for patients. Moreover, given the limited budget of the health insurance funds, the escalating healthcare costs could deter the health insurance agency from expanding the benefit packages or from implementing more generous reimbursement policies. Effective cost control is therefore crucial for sustainable improvement in the level of financial protection provided to patients by public health insurance schemes.

To control healthcare cost, the global budget payment system (GBPS), which sets a prospective payment limit for medical institutions, and the diagnosis-related group (DRG) payment under GBPS, have been widely implemented by health insurance agencies in China, replacing fee-for-service payment. While studies found that GBPS and DRG were effective in curtailing insurance payment and medical costs, most of these studies were for a specific disease type, or conducted in a single hospital/county; more evidence is needed regarding the effects of GBPS on overall health expenditure(14–17). One study even found risen OOP as doctors used coping strategies such as decomposed hospitalization to evade cost control under these payment approaches (18).

While GBPS and DRG may help control insurance expenditure through rigid payment limits, they do not necessarily reduce patients' OOP payment and financial burden, as healthcare providers may be inclined to use multiple "strategies" to avoid deficits as long as their salaries depend on revenue from medical services. These "strategies", such as transferring outpatients with serious conditions to other hospitals or prescribing un-reimbursable drugs/medical services that are not necessary, would increase the financial burden and curtail the quality of clinical service. The challenges in the implementation of case-based payment in the Gates TB project, as discussed in chapter 4, revealed how such incentives to increase revenue and avoid deficit resulted in increased OOP expenditure for patients. In sum, the profit-driven motivation of healthcare providers tends to increase OOP expenditure and the financial burden of patients.

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Altering such motivation to control the irrational escalation of healthcare cost is very challenging under the current financing schemes of public hospitals in China.

6.1.3 Disadvantaged and left-behind populations under the healthcare system reform: TB and migrant TB patients

As revealed in chapters 3-5 and other studies, TB patients, especially migrant TB patients, encountered more difficulties in accessing healthcare services and were easily susceptible to financial predicament. The reason for the rise in their difficulties is that TB treatment is centralized in designated hospitals at county-level and above (DRTB in prefecture-level hospital and above), mostly Grade 3 hospitals. As a result, the hierarchical reimbursement rate design, which aims to encourage patients to seek healthcare for non-serious conditions in primary care facilities, would inevitably lead to low reimbursement rates for TB patients. In addition, patients living in remote areas may incur travel cost because of the centralized treatment. In chapter 4 we found that it is very difficult for the health insurance system to increase the reimbursement rate for a single disease. To offer additional reimbursement for patients after they have paid OOP, most of the study sites appropriated specialized funds to the CDC that is responsible for patient management. As mentioned in chapter 1.3.3, the social vulnerability of TB patients and the significance of controlling TB infection strongly suggest that TB patients should be guaranteed affordable care throughout their treatment period. Therefore, the discordance in treatment and reimbursement policies that contribute to financial predicament for TB patients needs to be resolved.

As for migrant TB/DRTB patients, their migrant status often prohibited them from receiving benefits that are delivered according to the registered residence (Hukou). Besides, as we discovered in chapter 5, migrant DRTB patients are likely to work in the informal sector, thus are not enrolled in local health insurance nor eligible for additional reimbursement in their place or of work. Although one systematic review found no significant difference in treatment adherence between migrant and long-term resident MDRTB patients(19), several studies identified barriers for migrants to accessing TB diagnostic and care services, which include knowledge gaps, lack of health insurance coverage and financial difficulties(20–22). These barriers would be more substantial for migrant MDRTB patients. One systematic review of health insurance coverage found that employers tended to cut social welfare including UEBMI for rural-to-urban migrant workers, and the NRCMS those migrants enrolled in at their

hometown had very limited coverage for healthcare services used at their place of work. The divisive nature of different public insurance schemes regarding the funding sources and benefit packages also hindered transferring health insurance enrollment across insurance types or geographic regions (21). Currently the National Health Security Admission in China is pushing forward the instant settlement of reimbursement for healthcare expenditure outside the province of insurance enrollment, along with the development of information systems (23). Nevertheless, the effects of such policy changes on healthcare seeking and the financial burden for migrant TB/DRTB patients remain to be evaluated.

6.2 Policy implications and recommendations for China and other LMICs

6.2.1 Reform of health insurance structures and payment approach to improve the affordability of healthcare

As discussed in the previous section, improving the coverage and reimbursement of public health insurance, as well as controlling the healthcare cost, are two indispensable approaches to improve the affordability of healthcare. Considering the complexity of the problems revealed in the current literature and our studies, we hereby propose policy recommendations on the reform of health insurance structures and the payment approach in the short term and long term.

First of all, managerial improvements regarding the procedure of reimbursement can be pushed forward with the development of information technology. The inter-provincial instant settlement of health insurance reimbursement should be accelerated to cover all types of healthcare services so that migrant patients do not need to pay full cost before returning home for reimbursement. Moreover, the reimbursement provided by different insurance or assistance programs should be further integrated to provide cost reduction at the time of paying for healthcare services. These strategies will largely lower the threshold of care-seeking, especially for those disadvantaged groups such as migrants or the poor. Cost-control strategies should be implemented at the same time to reduce the OOP payment for patients. While GBPS and DRG payment have been widely implemented as cost control strategies, it is critical to avoid loopholes such as decomposed hospitalization. Besides, the costs of all medical services, whether covered by public insurance or not, should be restricted by the cost limit of case-based payment. For example, in order to receive full payment from the health insurance office, the average percentage of medical services not covered by health insurance should not exceed a certain limit. The development of hospital

information systems may be able to solve some technical problems regarding the supervision of provider behaviors. In addition to payment reform, centralized purchasing of drugs and supplies by the public health insurance has the potential to significantly lower the price of many drugs and medical supplies, thus enabling the expansion of the range of healthcare services under coverage.

In the long-term, policy reforms should be considered that bridge the gaps across insurance schemes and regions, and further improve the benefit packages and reimbursement rate, especially for NRCMS and URBMI/URRBMI. The implementation of these policies definitely needs more financing support from the government. The integration of the three health insurance schemes and the provision of equal benefit packages may be an ultimate equity goal that needs a long way to achieve. Nevertheless, as far as the author can perceive, abolishing the personal medical savings account of UEBMI can improve the equity level among UEBMI enrollees as well as facilitate the future integration of all insurance schemes through eliminating the major structural differences between UEBMI and other insurance schemes. These expansions in the benefits provided to patients will also be more realistic and feasible along with an effective control of healthcare costs. As discussed above, the key issue lies in altering the profit-driven motivation of healthcare providers. A theoretically thorough solution is to cut the correlation between physicians' income and medical revenue while strengthening the supervision on the quality of clinical services. In the USA the Affordable Care Act of 2010 developed comprehensive performance-based payments approaches which linked the quality and efficiency of healthcare services to payment(24). The design of these incentive mechanisms definitely needs the contribution from clinical experts, and future research future policy research may consider pilots of such interventions.

6.2.2 Policy implications on improving equity in healthcare financing and service use for TB/DRTB

While the reforms on the general healthcare system outlined above will also benefit TB/DRTB patients, these reforms take time, and the socially vulnerable TB/DRTB patients do need urgent supporting policies to complete treatment. China and other LMICs usually have specialized funding or programs, financed by both domestic and international sources, to support TB patients through delivering free anti-TB drugs and tests and providing subsidies during treatment. In light of the difficulties in changing the health insurance policy for a single disease and the effectiveness of cash transfer interventions, increasing the multi-

source financing for such TB programs to provide stronger financial support to patients is therefore suggested, in addition to those reforms on the general healthcare systems(22). Specialized funding can be set up, co-financed by the government budget and charity funds from both domestic and international donors, to provide financial assistance to patients based on their actual health expenditure and indirect medical costs. This is particularly important for TB patients with comorbidities as the treatment for such comorbidities is often not covered by existing TB programs. The delivery approach of subsidies can also be designed as an incentive to encourage patients to complete TB treatment. In chapter 3 we have found that the transportation and nutrition allowance distributed upon visiting the TB clinic did encourage patients to adhere to treatment.

As for migrant TB/DRTB patients, considering the additional risk of transmission or loss-to-follow-up during treatment, these patients should be supported by policies to be treated and managed at their current place of residence, especially for the richer regions with large number of migrant workers. In additional to pushing forward the inter-provincial instant settlement of health insurance reimbursement, the financial subsidies available for local patients should also be provided to migrant patients. The successful experience of providing financial incentives to encourage TB patients to complete treatment indicates the potential for the roll-out of such policies in developed regions(25). Improving the health education for migrant TB patients who are mostly of low education level is also necessary for them to complete treatment(26).

The situation of migrant of DRTB patients is more challenging as they often lose their jobs after diagnosis and may still prefer to return home despite supporting policies considering the high living cost in major cities. Under such circumstances, the CDC in their hometown should be informed beforehand to ensure that the migrant DRTB patients have access to standard care and are continued under management once they return home. Duplicate examinations could also be avoided through improved cross-region collaboration to reduce patients' financial burden. Considering that the migrant workers contribute their workforce to the developed regions as well as the tight government budget in the less developed regions, the more developed regions may continue providing financial support for these migrant DRTB patients even if they choose to return home for treatment. Such policies could both improve the equity of the healthcare system through guaranteeing access to healthcare for migrant DRTB

patients who are mostly of low SES and who have been left behind in the general healthcare reform, and benefit the whole society in terms of controlling, and ultimately eliminating TB.

6.3 Research limitations and implications for further studies

6.3.1 Research limitations

As discussed in the limitation section of each chapter, there are two major limitations of this thesis. First is the generalizability of the research. For chapter 2 and chapter 5, the studies were conducted in Jiangsu and Zhejiang, both economically developed eastern provinces in China where very few people still live in absolute poverty. People in these regions will seek care despite the low reimbursement rate provided by the health insurances and are able to afford expensive healthcare services. Therefore, the level of equity in healthcare service use may be higher compared to other provinces, and the impact of SES factors on care seeking may also be different in the less developed regions. For chapter 5, while the authors think that the combination of introducing new technologies with supporting policies to guarantee reagents for testing may have similar positive effects on case detection and treatment initiation in less developed regions, the degree of these effects may differ as poorer DRTB patients may need more support to start standard treatment.

The second limitation lies in the incompleteness of data. For chapters 3-5 we did not have individual-level data on whether patients benefited from a certain policy. Our studies are also more of an evaluation of policy implementation in the real world than of the policy itself, and we were also not able to explore the effects of policies in areas where there was no policy change, as was the case for the financing policies for DRTB patients in Zhejiang (chapter 5). Besides, some information that may affect the outcomes was not available in our studies, such as patients' comorbidities for the analysis on changes in patients' service use and financial burden (chapters 3 and 4), and income and other SES factors for the analysis of changes in patients' treatment initiation and completion (chapter 5). Nevertheless, the associations between policy interventions/changes and the outcome indicators we found in these studies were strong, and the conclusions on the direction of policy impacts should be robust.

6.3.2 Implications for future studies

Research on the equity in healthcare service use and financing in China, in the context of ongoing healthcare and broader social reform, should continue to

provide evidence on the impact of reform policies, identify challenges and gaps in realizing the goal of improving the access to and financial protection of healthcare, and propose potential strategies to address these challenges. Research on the impacts of demographic and SES factors on the whole process of healthcare, as well as the social patterns of service use and financing burden of healthcare, can be conducted continuously to monitor the impacts of healthcare reforms on the equity of the healthcare system. The geographic diversity of study sites and the length of monitoring can be increased to get a more comprehensive understanding of the equity issues in healthcare across regions at different developmental stages. Such monitoring studies are especially meaningful alongside the implementation of new policies. Besides, qualitative studies can also be conducted to explore how and why patients adjust their behaviors after policy change, which could provide additional information on the interpretation of policy effects.

As for research on healthcare for socially vulnerable groups, like TB/DRTB patients, especially migrant TB/DRTB patients, future studies may look at strategies to impose effective cost control and provide more financial protection for poorer patients. Considering the long treatment duration and infectious nature of TB/DRTB, the key issue is to encourage patients to adhere to treatment through removing financial barriers to care, especially for the rural poor living in remote areas and rural-to-urban migrants. For migrant DRTB patients especially, the high treatment cost may discourage them from even initiating standard treatment. In terms of the complexity of these challenges, more comprehensive policies, such as case-based payment covering all healthcare services for the whole treatment period, plus additional health insurance reimbursement and cash transfer, deserve to be piloted and evaluated in future research, especially for the most disadvantaged patient groups like rural-to-urban migrants. Besides, along with the development of the TB information surveillance system, the treatment history across medical institutions may become available under a personal profile(27). These more complete individual-level data could be utilized to better explore the impacts of policies on the healthcare seeking for TB/DRTB patients.

6.4 Conclusions

This thesis mainly contributed to the real-world evidence regarding equity in healthcare service use and financing in China in the context of the ongoing

healthcare system reform with a focus on disadvantaged patient groups such as TB/DRTB patients, and evaluated the impacts of several policy interventions on the healthcare service use and financial burden of these patients. The pattern of general healthcare service use has achieved a good level of equity in some areas in China, and can be greatly improved through policy interventions such as improving the reimbursement rate for the socially vulnerable group like TB patients. However, equity in the financing of healthcare in China remained at a relatively low level despite of the policy interventions, as indicated by the high OOP health expenditure and high likelihood of incurring CHE for socially vulnerable patients. Besides, some disadvantaged groups have not equally enjoyed the improved benefits from healthcare policy reforms, like internal migrant patients, or have encountered more financial difficulties due the discordance in the treatment and reimbursement policies, like TB patients. The high financial burden of healthcare is mainly attributed to the insufficient financial protection provided by the public health insurance system, especially for the URBMI and NRCMS, as well as to the profit-seeking motivation of healthcare providers which leads to high medical costs. Future research may continue monitoring the equity status in healthcare service use and financing alongside the ongoing healthcare system reform with special focus on socially vulnerable patient groups, and pilot more comprehensive policy combinations to support the healthcare seeking of disadvantaged patients.

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Summary

Health is a basic human right, and achieving higher degree of equity in healthcare has been a challenge for countries all over the world. Improving the equity in healthcare service use and financing are important pathways to elevate the health status of the overall population, especially for socially vulnerable groups.

Chapter 1 introduces the topic of the thesis and its objectives. The equity status in healthcare service use and financing are inter-related, and are often connected to a more general economic, political and social context. China has made substantial achievements while facing critical geographical disparities in economic development along with the opening-up reform. The healthcare system in China has also been undergoing constant reforms along with the economic and social transformations. In 2000s the three public health insurance schemes, the urban employee's basic health insurance (UEBMI), the urban resident's basic health insurance (URBMI) and the new cooperative medical scheme for rural residents (NRCMS) were established to provide financial protection for patients. This thesis aims to contribute to the real-world evidence regarding the equity in healthcare service use and financing in China in the context of the ongoing healthcare system reform, with a focus on the disadvantaged patient groups such as tuberculosis/drug-resistant tuberculosis patients. It also aims to evaluate the impacts of several policy interventions on the healthcare service use and financial burden of these patients. The complex equity impacts of changes in the healthcare system in China can provide rich evidence and experiences relevant for other countries which are also undergoing economic, social and health system reforms.

In **chapter 2,** our study on the equity status of healthcare service use and financing for the general population in Jiangsu province shows that the rural population in Jiangsu perceived more health care needs and had a higher probability of using both informal and formal health care services than the urban population. The rural population also had higher out-of-pocket health expenditure, and enrolling in NRCMS/URBMI was associated with higher likelihood of incurring catastrophic health expenditure compared to UEBMI after adjusting for other factors. These results clearly show that NRCMS/URBMI provided a lower level of financial protection compared to UEBMI. While the expansion of population enrollment in NRCMS/URBMI has narrowed the gaps

in health care utilization, the inequities in health care financing may be further addressed through improving the benefit packages of NRCMS/URBMI.

As for the socially vulnerable group of tuberculosis patients, **chapter 3 and 4** evaluated the impacts of a new financing and payment model on their healthcare service use and financial burden. This model was comprised of a set of interventions including improving the reimbursement rate of public health insurance for tuberculosis, cash transfer and reforming the payment approach from fee-for-service to case-based payment to control the treatment cost. Results showed that these interventions effectively improved tuberculosis patients' access to inpatient and outpatient services and improved medication adherence across all income groups. Patients in households classified as in extreme or moderate poverty benefited more from the inpatient service coverage of the program compared to the non-poverty group, indicating improved equity in inpatient service access. However, the mean out-of-pocket health expenditure and financial burden of tuberculosis patients increased. Apparently, the new financing and payment model was not successful in protecting poor tuberculosis patients from financial difficulty during treatment. We also found that the case-based payment was not strictly implemented, largely due to the profit-driven incentive of healthcare providers, i.e. their income was related to the department revenues from medical services. Under such an incentive many medical services received by patients were not included in the pre-determined standard treatment package, and thus not reimbursable under the project, which contributed to the increased financial burden of patients.

In **chapter 5** we evaluated the impacts of policy changes on the case finding and treatment of drug-resistant tuberculosis patients of different demographic and socio-economic status in Zhejiang, where policy interventions in multiple areas related to the prevention and control of drug-resistant tuberculosis were implemented during 2015-2018. Results showed that introducing rapid drug-sensitivity testing technologies like GeneXpert, combined with supporting policies of expanding the eligibility criteria of presumptive patients referred for such test as well as the criteria of patients registered for management, have greatly improved the detection and treatment of drug-resistant tuberculosis patients. Corresponding financing and administrative policies which guaranteed the optimal use of these new technologies were crucial to ensure that all patients

in need have access to them. However, we observed that even when these policies were in place, challenges remained with regard to providing appropriate services to vulnerable groups such as internal migrants, as eligibility for additional reimbursement or subsidies was often limited to local residents.

Chapter 6 provides a discussion of the thesis' findings and their implications for policy and future research. In sum, the healthcare service use among the general population has achieved a good level of equity across income groups in some areas. For some disadvantaged groups like tuberculosis patients, equity in healthcare service use can also be greatly improved through policy interventions such as improving the reimbursement rate and cash transfer. However, the level of equity in financing of healthcare remained relatively low despite the policy interventions, as indicated by the high out-of-pocket health expenditure and high likelihood of incurring catastrophic health expenditure for socially vulnerable patients. Besides, some disadvantaged groups such as internal migrants have not equally enjoyed the improved benefits from healthcare policy reforms. Based on these findings, policy recommendations are proposed that the health insurance structures and payment approach should be reformed to mitigate the benefit gaps across insurance types and improve the affordability of healthcare. In addition to policy reforms for the healthcare system overall, specialized policies should be developed that include improvement of reimbursement and cash transfer to provide additional support for tuberculosis/drug-resistant tuberculosis patients, especially for those who are internal migrants. For both China and other countries undergoing health system reforms, special attention should also be paid to the synchronization of policies when developing and implementing pro-equity interventions in real-world settings, for example, constraining or removing the profit-driven incentive of healthcare providers in reforming healthcare financing and payment policies, and adopting supporting policies to guarantee the optimal usage of a new technology.

The major limitation of the work in this thesis that both the study on general healthcare service use and financing and the DRTB study were conducted in eastern provinces, the most developed regions in China. This limits its generalizability to less affluent regions of the country. Besides, for each study the individual-level data lacked some information such as comorbidities (chapter 3-4) or socio-economic factors like income (chapter 5), which can be potential confounders, or limited the scope of our equity analysis. In light of these findings and limitations, future studies may consider monitoring the impacts of

demographic and socio-economic factors on healthcare seeking pathways throughout the healthcare reform in more study sites of different levels of economic development. As for research on the healthcare for socially vulnerable groups such as tuberculosis patients and migrants, more comprehensive policies that include both multi-source financing, cash transfer and payment reform deserve to be piloted. These pilot interventions should also be evaluated mainly in terms of their effectiveness in mitigating disparities in healthcare service use and reducing the financial burden of the disadvantaged patients.

Samenvatting

Gezondheid is een mensenrecht, en hoe tot een meer billijke verdeling ('*equity*') in gezondheidszorg te komen is een uitdaging voor landen wereldwijd. Verbetering van de *equity* in het gebruik van gezondheidszorg en de financiering daarvan zijn belangrijke stappen op weg naar een betere gezondheid voor de bevolking in zijn algemeenheid, en voor kwetsbare bevolkingsgroepen in het bijzonder.

Hoofdstuk 1 geeft een inleiding op het onderwerp van dit proefschrift en op de doelstellingen. *Equity* in het gebruik van gezondheidszorg en *equity* in de financiering daarvan hangen onderling samen, en zijn vaak verbonden met een meer algemene economische, politieke en maatschappelijke context. China heeft aanzienlijke prestaties geleverd ten overstaan van cruciale geografische ongelijkheid in economische ontwikkeling die ontstond met de hervormingen waarbij land en economie werden opengesteld. Met die economische en maatschappelijke veranderingen is ook het gezondheidssysteem in China voortdurend aan hervormingen onderhevig geweest. In het eerste decennium van de huidige eeuw werden drie publieke verzekeringen in het leven geroepen om patiënten financiële bescherming te bieden: de basisverzekering voor werknemers in stedelijke gebieden (UEBMI), de basisverzekering voor stedelijke inwoners (URBMI) en het nieuwe coöperatieve medische stelsel voor rurale inwoners (NRCMS). Dit proefschrift beoogt praktisch bewijs aan te dragen over de mate van *equity* in het gebruik van gezondheidszorg en in de financiering daarvan in China in de context van de voortgaande hervormingen van het gezondheidssysteem, met speciale aandacht voor achtergestelde groepen zoals patiënten met tuberculose of geneesmiddelen-resistente tuberculose. Ook beoogt dit proefschrift het effect te evalueren van verscheidene beleidsinterventies op het gebruik van gezondheidszorg door, en de financiële lasten daarvan voor, deze groepen patiënten. De complexe *equity*-effecten van de veranderingen in het Chinese gezondheidssysteem bieden een rijk palet aan bewijsmateriaal en ervaringen die mogelijk relevant zijn voor andere landen die in het proces zijn van economische, sociale en gezondheidszorg-hervormingen.

In **hoofdstuk 2** laat ons onderzoek naar *equity* in het gebruik van gezondheidszorg en de financiering daarvan onder de algehele bevolking van de provincie Jiangsu zien dat rurale inwoners een grotere gezondheidszorgbehoefte hadden en vaker van formele en informele

gezondheidszorgvoorzieningen gebruik maakten dan stedelijke inwoners. De rurale bevolking had ook hogere 'out-of-pocket' gezondheidszorguitgaven, en na correctie voor andere factoren was deelname in NRCMS/URBMI geassocieerd met een grotere kans om catastrofale gezondheidsuitgaven te moeten doen in vergelijking tot deelname in UEBMI. Deze resultaten geven duidelijk aan dat NRCMS/URBMI een geringere mate van financiële bescherming bood dan UEBMI. Hoewel de uitbreiding van deelname in NRCMS/URBMI de kloof in gebruik van gezondheidszorg heeft gedicht, zou de financiële ongelijkheid verder moeten worden aangepakt door het pakket dat door NRCMS/URBMI wordt gedekt uit te breiden.

Ten aanzien van de maatschappelijk kwetsbare groep van de tuberculosepatiënten evalueerden **hoofdstukken 3 en 4** de effecten van een nieuw model voor financiering en betaling op hun gebruik van gezondheidsvoorzieningen en de financiële last als gevolg daarvan. Dit model omvatte een aantal interventies, waaronder een verbetering van de vergoeding voor gezondheidskosten door de publieke verzekering, rechtstreekse betaling (*'cash transfer'*) en een hervorming van de betalingswijze van betaling per verrichting (*'fee-for-service'*) naar betaling per ziektegeval (*'case-based payment'*), dit teneinde de behandelkosten onder controle te krijgen. De resultaten lieten zien dat deze interventies tot effectieve verbetering leidden van de toegang van tuberculosepatiënten tot intra- en extramurale zorg, evenals van hun therapietrouw, ongeacht inkomensniveau. De dekking voor ziekenhuisopname kwam meer ten goede aan patiënten uit huishoudens die waren geclassificeerd als extreem of matig arm dan aan patiënten uit niet-arme huishoudens, wat wijst op verbeterde *equity* in de toegang tot intramurale zorg. Desondanks stegen voor tuberculosepatiënten de gemiddelde *out-of-pocket* gezondheidszorguitgaven en de financiële lasten. Klaarblijkelijk was het nieuwe financierings- en betalingsmodel niet succesvol in het beschermen van arme tuberculosepatiënten tegen negatieve financiële gevolgen van hun behandeling. Wij vonden ook dat van *case-based* betaling strikt genomen geen sprake was, vooral als gevolg van winstoogmerk van gezondheidswerkers doordat hun inkomen afhankelijk was van de revenuen van hun ziekenhuisafdeling. Door deze financiële prikkels werden allerlei medische diensten aan patiënten verleend die niet waren opgenomen in het tevoren vastgestelde standaard behandelpakket, en daarmee niet door het project werden vergoed, leidend tot toegenomen financiële lasten voor

patiënten.

In **hoofdstuk 5** onderzochten wij het effect van beleidsaanpassingen op de detectie en behandeling van patiënten met geneesmiddelen-resistente tuberculose met verschillende demografische en economische status in Zhejiang. Hier waren over de periode 2015-2018 diverse beleidswijzigingen doorgevoerd met betrekking tot preventie en bestrijding van resistente tuberculose. Wij vonden dat de introductie van snelle resistentietesten zoals GeneXpert, in combinatie met ondersteunend beleid waarin de zowel criteria om voor zulke testen in aanmerking te komen als de criteria om voor behandeling in aanmerking te komen werden verruimd, de detectie en behandeling van patiënten met resistente tuberculose aanzienlijk hadden verbeterd. Corresponderende financiële en administratieve beleidsaanpassingen die optimaal gebruik van deze nieuwe technologieën garandeerden bleken cruciaal om alle patiënten die dat nodig hadden toegang tot deze interventies te geven. Evenwel zagen wij dat, zelfs wanneer deze aanpassingen waren doorgevoerd, er lacunes bleven bestaan in de verlening van de juiste zorg aan kwetsbare groepen zoals interne migranten, dit omdat vaak uitsluitend de als plaatselijk inwoners geregistreerde patiënten voor additionele vergoedingen of subsidies in aanmerking kwamen.

Hoofdstuk 6 bespreekt de bevindingen uit dit proefschrift en geeft de implicaties daarvan aan voor beleid en verder wetenschappelijk onderzoek. Al met al is in China op het niveau van de algehele bevolking een goede mate van *equity* tussen verschillende inkomensgroepen bereikt met betrekking tot gebruik van gezondheidszorg, althans in sommige gebieden. Voor sommige achtergestelde groepen, zoals tuberculosepatiënten, kan de *equity* in gebruik van gezondheidszorg ook aanzienlijk worden verbeterd door aanpassing van het verzekeringsbeleid zoals verhoging van het vergoedingspercentage en *cash transfer*. De mate van *equity* in de financiering van gezondheidszorg bleef ondanks deze aanpassingen echter relatief laag, zoals te zien aan de hoge *out-of-pocket* gezondheidszorguitgaven en de grote kans op catastrofale uitgaven onder maatschappelijk kwetsbare patiëntgroepen. Bovendien hebben bepaalde achtergestelde groepen zoals interne migranten niet gelijkelijk van deze beleidsaanpassingen geprofiteerd. Beleidsaanbevelingen op basis van deze bevindingen omvatten hervorming van de verzekeringsstructuren en de betalingswijze, gericht op het dichten van de kloof in vergoeding tussen de verschillende verzekeringen en verbetering van de betaalbaarheid van gezondheidszorg. Naast

beleidshervormingen voor het algehele gezondheidszorgsysteem zouden ook specifieke beleidsaanpassingen moeten worden ontwikkeld, waaronder verbetering van het vergoedingspercentage en *cash transfer*, als aanvullende ondersteuning voor patiënten met tuberculose en resistente tuberculose, met name de interne migranten onder hen. Voor China, evenals voor andere landen die hervormingen van hun gezondheidszorg doormaken, dient ook bijzondere aandacht te worden besteed aan de synchronisatie van beleidswijzigingen bij de ontwikkeling en implementatie van *pro-equity* interventies in dagelijkse praktijk. Voorbeelden hiervan zijn het inperken of wegnemen van winstprikkels voor gezondheidswerkers bij de hervorming van gezondheidszorgfinanciering en aanpassing van de betalingswijze, en de invoering van ondersteunend beleid om optimaal gebruik van nieuwe technologieën te garanderen.

De voornaamste beperking van het wetenschappelijk werk in dit proefschrift is dat zowel het onderzoek naar algemeen gebruik en financiering van gezondheidszorg als het onderzoek onder resistente tuberculosepatiënten werd uitgevoerd in oostelijke provincies, het meest ontwikkelde deel van China. Dit beperkt de generaliseerbaarheid naar de minder welvarende delen van het land. Daarnaast ontbrak in elk onderzoek bepaalde informatie op individueel patiëntniveau, zoals co-morbiditeit (hoofdstukken 3 en 4) en socio-economische variabelen waaronder inkomen (hoofdstuk 5). Dit kan de mogelijkheid om voor *confounders* te corrigeren en de reikwijdte van de *equity* analyse hebben beperkt. In het licht van de bevindingen en genoemde beperkingen, zouden toekomstige onderzoeken zich kunnen richten op het monitoren van de effecten van demografische en socio-economische factoren op de routes die patiënten bewandelen om de juiste zorg te verkrijgen, gedurende het hele proces van gezondheidszorghervorming en in meer gebieden en populaties met uiteenlopende niveaus van economische ontwikkeling. Met betrekking tot maatschappelijk kwetsbare groepen als tuberculosepatiënten en migranten, zouden pilots kunnen worden gedaan van brede combinatie-interventies samengesteld uit financiering uit meerdere bronnen, *cash transfer* en veranderde betalingswijze. Deze pilots zouden vooral moeten worden geëvalueerd in termen van effectiviteit in het terugbrengen van ongelijkheid in het gebruik van gezondheidszorg en vermindering van financiële lasten voor achtergestelde patiëntgroepen.

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Health is a basic human right. Improving the equity in healthcare service use and financing are important pathways to elevate the health status of the overall population, especially for socially vulnerable groups.

This thesis evaluates the impacts of several policy interventions on the healthcare service use and financial burden of Chinese patients, with a focus on the disadvantaged patient groups such as tuberculosis/drug-resistant tuberculosis patients.