**Tuberculosis patient expenditure on drugs and tests in subsidised, public services in China: a descriptive study**

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**Abstract**

*Objective*: To measure patient expenditure on additional drugs and tests in public services where TB drugs are supplied for free.

*Methods*: Questionnaire survey of patients currently on treatment in eight TB dispensaries in two provinces; in depth interviews with providers at the facilities.

*Results*: Eighty six percent of patients were prescribed liver protection drugs (141/163), 93% had one or more tests in the last month (n=151), and almost a quarter (23%, n=38) were on treatment past the World Health Organization recommended treatment duration. All but 2 patients were charged for something in cash at each visit: on average 287 Chinese Yuan (40 US dollars) in the previous month. For patients below the poverty line, drug and test expenditure was 1.85 times their average household monthly income. Average charges varied little between income categories. In terms of actual anti-tuberculosis drugs prescribed, 17.8% (29/163) of regimens were inadequate by international standards. Providers reported they prescribe liver protection drugs to avoid medical negligence, and they believed they were effective; and the government subsidy for providing TB treatment was simply not enough.

*Conclusions*: Despite an ostensibly fully subsidised TB programme in China, our results show that, according to our sample, patients are charged substantive amounts irrespective of income. Research is needed to confirm these practices are widespread but this needs to be coupled with financing strategies to tackle it.

**Key words**: tuberculosis, costs, treatment, liver protection drugs, China

**Introduction**

The government in China has been tackling tuberculosis (TB) for over 50 years [1]. Since 2000, renewed government commitment has been matched with additional financial support from the Global Fund, World Bank and bilateral aid donors. The national TB control guidelines include free anti-TB drugs for six months to new TB patients, and for eight months to re-treatment patients. Tests include one free X-ray test for a TB suspect at first visit, one free sputum smear test for suspects whose X-ray tests are abnormal, and one free sputum smear test for patients under free anti-TB treatment, and providers are given a subsidy to provide the drugs.

However, there is evidence that patients still pay (table 1) [2,3,4,5]. Even in provinces where TB drugs are free, patients are still charged for drugs [7] . One study has stratified by the income level of the patient (if costs vary with income, then the burden is spread; but if fixed then lower income groups are particularly disadvantaged). They estimated that the expenditure was 35% of monthly household income in lower income groups [7] compared to 17% in the higher income group, but the denominator and cut offs were not given in the paper.

There has been little research on what the charges are made up of. Xu and colleagues found that health facilities in the study areas charge TB patients to increase their income through excessive tests [6]. In earlier work, we discovered that [8] many patients are prescribed “liver protection” drugs, for which there is no research or rationale for use[13].

This is currently policy relevant. Pilot programmes to reduce these additional charges are being considered, with patients being reimbursed through the New Medical Insurance System for liver protection drugs; and the World Bank and donor supported programmes supplying free anti-tuberculosis drugs are being reviewed. Our study aimed to examine how much patients were paying for drugs and tests, and relate this to their income.

Table 1. A summary of research measuring TB expenditure/household income for TB treatment

|  |  |  |  |
| --- | --- | --- | --- |
|  | Meng et al 2004[2] | Xu et al 2006[6] | Liu et al 2007[7] |
| TB care expenditure as % of annual household income | 4 counties:  27% to 119% | 2 counties:  22% to 34% | 4 provinces:  13% to 40% |
| Expenditure/household income stratified by income group? | No | No | 1 province only:  Poor: 35% HH income Rich: 17% HH income |

**Methods**

The patient survey was conducted in Chongqing and Sichuan provinces in southwest China, with a population of over 30 million and 87 million respectively. According to a nationwide TB epidemiological survey in 2000[9], the prevalence of active TB in Chongqing and Sichuan provinces was 549/100,000 and 544/100,000 respectively, which is higher than the national average of 367/100,000, and also higher than the rate in the mid-west region of China ( 451/100,000). We selected four counties from each province as examples of the entire provinces, in terms of socio-economic development, geographic and transportation conditions (Table 2). We firstly classified all the counties and districts in the two provinces into eight levels in terms of per capita GDP, then considering the balance of terrain (urban or rural, hilly or plain, Chongqing or Sichuan), we finally selected one county/district from each economic level. Each county has a TB dispensary and we collected data in these eight selected TB dispensaries. This resulted in us selecting, in the category up to 15,000 Yuan GDP, 4 out of the 42 counties; and for the category 15,000 Yuan GDP, 4 out of the 22 counties. Thus if anything slightly richer counties were over-represented in the sample.

Table2. Characteristics of study counties

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Province | County | Population  (10 000 persons) | GDP per capita  (1,000 Yuana) | Terrain | Sputum-positive TB patients registered in 2007\* |
| Chongqing | YZ | 60.1 | 34.7 | Urban, hilly | 237 |
|  | SPB | 74.6 | 22.2 | Urban, hilly | 251 |
|  | RC | 82.2 | 9.9 | Rural, hilly | 373 |
|  | YY | 130.6 | 4.6 | Remote, mountainous | 749 |
| Sichuan | CD | 301.8 | 29.9 | Urban, plain | 734 |
|  | DJY | 61.0 | 15.2 | Rural, plain | 34 |
|  | NJSZ | 53.8 | 11.5 | Urban, plain | 41 |
|  | NJLC | 76.6 | 7.5 | Rural, plain | 75 |

\*Data source: routine statistics from each TB dispensary (2008). Data for Sichuan was limited to the 4th quarter of 2007 due to political sensitivity.

a In 2008, 1000 Yuan is equal to 139.4 US dollars.

**Patient survey**

All pulmonary tuberculosis patients currently on treatment were enrolled in the study as they attended health facilities for treatment. This included new (defined as patients who had not been previously treated for TB) and re-treatment patients (defined as those who were previously treated for TB whose treatment failed, who defaulted, or who relapsed). The initial intention was simply to estimate across all patients the percentage of costs on TB drugs in relation to monthly family income. Sample size calculations were based an overall estimate the total cost of treatment across all income categories. Using health staff for surveys in China is common but introduces substantive interviewer and respondent bias. We therefore carefully trained and supervised four postgraduate students to interview patients, who collected data over one month. We intercepted the patients under anti-TB treatment as they finished their consultation and left the TB dispensary, and continued to recruit on a daily basis until the required number of patients was interviewed. We asked patients about drugs and tests prescribed in the last month and the cost of these, as well as basic data on income, age and sex. Research supervisors checked the questionnaires as soon as they were completed, and interviewed the interviewers to make sure all the items in the questionnaire were correctly understood and filled in. The data were double entered by two research supervisors.

We categorized various drugs and tests reported by the participants and presented this data by new and re-treated patients and against standard regimens. We categorized anti-TB drugs according to WHO guidelines and definitions of first and second line drugs [10, 11]. We categorized liver protection drugs using a modified version of WHO standard definitions[12] to be used in the evaluation and research of herbal medicines, which we also used in a systematic review of liver protection drugs [13]. Ancillary drugs were categorized according to their functions, including a) anti-inflammatory drugs, b) drugs for symptomatic treatment (to relieve cough, asthma or hemoptysis), and c) drugs to reinforce patients’ immunity.

We classed regimens as “adequate” if they met WHO criteria for first or second line treatment. We classed regimens as “inadequate” if they did not meet internationally accepted criteria. This included prescribing single-drug therapy; double therapy in intensive phase; second line anti-TB drugs for non drug-resistant patients; Chinese medicines only; and different combinations of WHO-recommended drugs, second line drugs, unclassified anti-TB drugs and Chinese medicines.

**Data analysis**

Using the reported income data, we categorised each patient into three levels of monthly family income: below the poverty line, below national average but above the poverty line, and above national average. Income levels for the general population are available from national economic and social development survey conducted by the National Bureau of Statistics of China; we used the most recent data from “Statistical Communiqué of the People’s Republic of China on the 2007 National Economic and Social Development” [14]. Based on the Statistical Communiqué, poverty line and national average income were 1067 Yuan and 8963 Yuan per capita per year respectively. We divided these by 12 months to obtain income per capita per month, and then calculated the poverty line and average income per family per month by multiplying by 3.48, the mean family size in our sample. The levels for poverty line and national average of monthly family income were estimated to be 310 Yuan and 2600 Yuan respectively. We tabulated income category against costs.

**Identifying provider views**

We interviewed eleven TB medical practitioners from all eight TB dispensaries in two provinces. After providing verbal informed consent, semi-structured interviews lasting 20 to 40 minutes were conducted in Mandarin by the principal investigator, an assistant took notes, and the sessions were recorded. Standard topic guides were used to ensure relevant areas were covered during interviews. We used the Framework approach [15] to analyze the qualitative data and identify themes, and managed the data in MAXqda software using Chinese characters; we have described these methods elsewhere [16].

Ethical approval for the study was provided by Chongqing Medical University.

**Results**

**Patient survey**

We enrolled 180 patients, of which 17 declined to participate: the 163 patients seen were new (137) and re-treatment patients (26). Patients were mostly men (68%), average age 42 years; 81% (134) had a family income below the national average. Overall, the mean monthly family income of the study population was 1612 Yuan (standard deviation (STD) 244.8, n=165). Health insurance coverage was relatively low, with 61% covered (Table A1).

Doctors were extending treatment beyond the standard six months for patients in 23% (32/137) of new patients at the time of interview; and beyond the standard of 8 months for 23% (6/26) of patients being retreated (Table A2). Drugs prescribed during these extensions were charged for.

*Types of tuberculosis drugs*

For new patients, two thirds were prescribed the standard TB drug regimen (provided to practitioners for free), 17.5% were given other standard regimens, and 15.3% were prescribed drugs or regimens that were inadequate (Table A3). For retreatment patients, non-standard regimens and inadequate prescribing was higher (34.6% and 30.6% respectively). Across all patients, 17.8% of treatments were inadequate, as defined in our methods.

*Liver protection drugs, ancillary drugs and tests*

Liver protection drugs were prescribed to 86% of patients, mostly manufactured herbal products (Table 3); in all there were 25 types of liver protection drugs identified which we categorized into four categories. In our study, none of the TB patients showed abnormal liver function. Liver protection drugs are prescribed to prevent possible liver damage induced by anti-TB drugs. Because no obvious difference between new and retreatment patients was evident, the data are presented combined.

Ancillary drugs were prescribed to 35% of all patients, including anti-inflammatory drugs, drugs for symptomatic treatment (to relieve cough, asthma or haemoptysis) and drugs to reinforce patients’ immunity; a total of 30 different types of ancillary drugs were identified.

Two thirds of all patients had two or more additional tests (tests carried out in addition to those provided for free) in the previous month; additional X-rays had been carried out on 68% of patients in the previous month. Less than 10% of patients had no test in the previous month.

Table 3 Additional drugs and tests in the last month (new and retreatment patients combined, N=163)

|  |  |  |
| --- | --- | --- |
|  | n | (%) |
| **ADDITIONAL DRUGS** |  |  |
| **Liver protection drugs1** | **141** | **86.5** |
| Manufactured herbal products | 83 | 50.9 |
| Vitamin + other non-herbal substances | 28 | 17.2 |
| Pharmaceutical preparations | 13 | 8.0 |
| Combinations of above | 12 | 7.4 |
| **Ancillary drugs2** | **57** | **35.0** |
| Anti-inflammatory | 6 | 3.7 |
| Drugs for symptomatic treatment\* | 30 | 18.4 |
| Immune stimulants | 13 | 8.0 |
| Combinations of above drugs | 6 | 3.7 |
| **ADDITIONAL TESTS** |  |  |
| Sputum smear test | 75 | 46.0 |
| X-ray | 112 | 68.7 |
| Blood testa | 119 | 73.0 |
| Other testsb | 15 | 9.2 |
| **Number of tests** |  |  |
| 0 | 12 | 7.4 |
| 1 | 43 | 26.4 |
| 2+ | 108 | 66.2 |

1Missing data for type n=5; 2 Missing data for type n=2

\*Drugs for symptomatic treatment include drugs to relieve cough, asthma or hemoptysis.

a Blood test includes liver function test, renal function test and blood routine test.

b Other tests include urine test, biopsy, B ultrasound, sputum culture and computerized tomography (CT).

*Test and drug costs*

Out of the 163 patients, only two were not charged any money. Patients were charged for liver protection drugs (86%, n=141), ancillary drugs (35%, n=57) tests (92%, n=151), and TB drugs (36%, n=59). This includes patients on extended anti-TB treatment who had to pay for the anti-TB drugs in the extended period.

The mean cost to patients of various drugs and tests prescribed during the previous month was 286.9 Yuan; spending on liver protection drugs represented over 43% of this cost. Total average expenditure on drugs and tests was relatively consistent between the three income groups (Table 4).

For patients below the poverty line, drug and test expenditure alone represented 1.85 times their average household income.

Table 4 Patient expenditure on drugs and tests in the previous month by income category

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Average income and expenditure | Average expenditure in the last month in Yuan  (% MMI) by income group | | | Mean cost |
| Income below poverty line (<310 Yuan) | Income below average (310 to 2600 Yuan) | Income above average  (>2600 Yuan) | Mean cost in Yuan (% ) |
| Patients | 24 | 110 | 29 |  |
| **Average income (Yuan)** | 142.5 | 1257 | 4121 |  |
| **Expenditure (Yuan)** |  |  |  |  |
| 1. Anti-tuberculous drugs | 28.5 | 34.5 | 21.4 | 31.3(11) |
| 2. Liver protection drugs | 101.9 | 115.0 | 165.3 | 122.0(43) |
| 3. Ancillary drugs | 44.9 | 51.2 | 81.9 | 55.7(19) |
| 4. Tests | 88.8 | 79.5 | 62.9 | 77.9(27) |
| **Total (Yuan)** | **264.1** | **280.1** | **331.5** | **286.9** |
| **Expenditure (% household income)** | 185% | 22% | 8% |  |

**Semi-structured interviews**

We identified four themes from the analysis of interviews conducted with TB medical practitioners.

*1) Medical practitioners acknowledge charges:* Most practitioners acknowledged they charged patients, and that the financial burden of TB treatment is marked (Annex, box 1). However, they reported that they prescribed liver protection drugs and tests according to a patient’s financial status; they avoid prescribing liver protection drugs, or prescribe cheaper drugs, to patients who cannot afford them. A few thought expensive liver drugs were more effective.

*2) Medical negligence a perceived threat:* Most practitioners reported that they prescribe liver protection drugs to ‘safeguard’ themselves from medical disputes. They described often that the relationship between them and their patients was “tense”; of particular concern was fear of being blamed by patients who experience complications of treatment or liver damage. To ensure they are not held responsible for liver damage when a patient refuses liver protection drugs, several doctors told us they ask patients to sign their medical records to state they have refused the drugs (Annex, box 2).

*3) Practitioners believe in liver protection drugs:* Most practitioners said that they had not studied the effects of liver protection drugs, but believed they worked, some saying that the Chinese population needed them to help tolerate Western drugs (Annex, box 3), and because anti-TB drugs cause liver damage and incidence of liver damage is high. Other additional drugs they believe increase patients’ immune system or treat patients’ complications and symptoms can make patients feel better more quickly.

One practitioner thought liver protection drugs were a psychotherapeutic placebo for patients but still thought it best to prescribe it. A few acknowledged the side effects of liver protection drugs.

*4) Government subsidies for managing TB patients are too low:* Practitioners stated that subsidies for managing TB patients are too low compared to workload. A few said they received subsidies for transfer, tracking and managing TB patients, but mostly these were village and township practitioners: many practitioners in TB dispensaries said they received no subsidies for managing TB patients, and they did the TB work mainly depending on their conscience. Some said that other incentives are often earned based on performance (Annex, box 4).

**Discussion**

In China surveys are often done by health staff but this introduces substantive interviewer and respondent bias. We wanted accurate data on financial burden against TB treatment costs which providers would probably hide. For this reason, data collection was done by carefully supervised students rather than government staff. This limited the number of participants, counties and study sites.

This study is facility-based and only county TB dispensaries were studied, but they are the main facility for patients with uncomplicated TB being treated as outpatients, so these patients probably did not have complicated disease, and there is no reason to believe they belong to a particularly poor group. As the performance at TB dispensaries in these provinces tends to be rather similar, we selected eight TB dispensaries as representative and illustrative of the situation across the provinces.

We collected data from virtually all patients attending and the findings were dramatic in relation to excessive prescribing. Blood and X-ray examination recommended almost monthly for over 70% of patients, and the majority of patients prescribed liver protection drugs, for which there is no rationale in Western medical terms [13]. This results in high charges to people below the poverty line. Overall the charges do not seem to vary much with the income status of the patient.

Previous studies in other provinces and counties of China have already shown the burden to many TB patients caused by charging [2,3,6,7]. However, none of these studies examined charging against income level, or disaggregated the various components of additional charging. Importantly, this study shows that the various costs are fairly consistent across income groups, and the burden is very high for low income groups in these two provinces.

Why are they being prescribed? Income generation is probably the main factor, yet there remains this enduring reported belief that liver protection drugs prevent adverse effects, indeed, many practitioners they perceived they would be regarded as negligent if they did not prescribe these drugs. Currently the doctor-patient relationship is a somewhat uneasy relationship in China [17,18]. The practitioners claim they prescribe to avoid accusations of negligence: what is unclear is whether they truly believe this, or whether it is just a convenient tradition that earns income. What is critical to the argument is that the prescribers were clearly dissatisfied with government subsidies for providing TB care [6, 8].

Potentially charging could contribute to low completion for TB treatment in this region found in other studies in Chongqing [8]. So charging, with probable effects on adherence, coupled with the finding that one fifth of patients in this study had regimens that were inadequate or irrational, including single drug therapy, will increase the chance of MDR TB developing and spreading.

Despite the small sample size, sometimes data like this can be of value. In health services in China practices are widespread yet often not acknowledged or discussed. This can be true for differences between actual adherence rates and government statistics, and issues around charging in the government sector. In this policy environment, sometimes quite small research studies that demonstrate, for example, high charges, then require policy makers and others to acknowledge this and open a discussion. Policy makers then need to evaluate the phenomenon more widely, or do something about it. Since the economic reform, health service providers in China have increasingly relied on user fees resulting in over-prescriptions of drugs and tests. This is at odds with the global TB programme, WB/DFID funded project, and donor pro-poor policies that try to ensure TB treatment is free. Further work to confirm these findings can be generalised across the country needs to be linked with financial strategies to mitigate them.

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