

# Market assessment of tuberculosis diagnostics in China in 2012

TB Diagnostics Market Analysis Consortium\*

## SUMMARY

**OBJECTIVE:** To assess the 2012 served available market for tuberculosis (TB) diagnostics in China in the sector served by the China Centre for Disease Control and Prevention (CDC) and the hospital sector in China, including both designated TB hospitals and general hospitals.

**DESIGN:** Test volumes and unit costs were assessed for tuberculin skin tests, interferon-gamma release assays (IGRAs), smear microscopy, serology, cultures, speciation tests, nucleic-acid amplification tests (NAATs), drug susceptibility tests and adenosine-deaminase tests (ADA). Data were obtained from electronic databases (CDC sector) and through surveys (hospital sector), and were estimated for the two sectors and for the country as

a whole. Test costs were estimated by staff at China CDC, and using published literature.

**RESULTS:** In 2012, the China CDC and hospital sectors performed a total of 44 million TB diagnostic tests at an overall value of US\$294 million. Tests used by the CDC sector were smear microscopy, solid and liquid culture and DST, while the hospital sector also used IGRAs, NAATs, ADA and serology. The hospital sector accounted for 76% of the overall test volume and 94% of the market value.

**CONCLUSION:** China has a very large TB diagnostic market that encompasses a wide range of diagnostic tests, with the majority being performed in Chinese hospitals.

**KEY WORDS:** tests; costs; volumes; diagnosis

TUBERCULOSIS (TB) remains a major global public health problem, with 9 million incident cases and 1.5 million deaths in 2013.<sup>1</sup> One of the main barriers to effective TB control is timely and accurate diagnosis. Almost 3 million TB cases and three quarters of multidrug-resistant TB (MDR-TB) cases were estimated to have remained undiagnosed in 2013.<sup>1</sup> Despite progress in the development of new technologies, many countries still rely on poorly sensitive smear microscopy for TB detection.<sup>2</sup> There remains an urgent need for more sensitive, affordable and rapid diagnostic tests for TB.<sup>3</sup>

To encourage TB diagnostics research and development, the Foundation for Innovative New Diagnostics (FIND) and The Special Programme for Research and Training in Tropical Diseases published a global market assessment for TB diagnostics in 2006.<sup>4</sup> This report showed that globally over one billion US dollars (USD) was spent annually on TB diagnostics. Almost a decade later, much has changed in the diagnostics world, with many World Health Organization (WHO) approved new technologies

entering the market.<sup>3,5</sup> There is a need to capture the current market for TB diagnostics, especially with a focus on the emerging markets such as the BRICS (Brazil, Russia, India, China, South Africa) countries, which account for 46% of the estimated global TB burden. Updated market analyses for Brazil and South Africa have recently been completed by our Consortium.<sup>6,7</sup>

China, the world's most populous country with the second largest economy in the world, provides promising potential for the development and use of new TB diagnostics. China has the second largest number of TB cases worldwide after India, and has reported high rates of drug-resistant TB.<sup>8</sup> In 2012, there were a total of 900 678 notified TB cases in China, which accounted for 15% of global notified cases for that year. Furthermore, it was estimated that there were 60 000 cases of MDR-TB, accounting for 13.3% of the global burden.<sup>1</sup>

In recent years, China has made great strides in TB control by attaining the 2005 global targets for TB control, a 70% detection rate and an 85% cure rate. A high level of political commitment and leadership has been demonstrated by major increases in the

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central government budget for TB control,<sup>9,10</sup> peaking at US\$367 million in 2012. Since 2005, the DOTS strategy has been provided for all TB patients.<sup>11</sup> Furthermore, the launch of The China Information System for Disease Control and Prevention (CISDCP) in 2004 facilitated real-time surveillance of 39 infectious diseases, including TB.<sup>12</sup> Subsequently, in 2005, an Electronic Tuberculosis Information Management System (TBIMS) was phased in for the collection of more detailed data on individual patients pertaining to diagnosis, treatment and case management.<sup>13</sup>

Under the leadership of the China Center for Disease Control and Prevention (China CDC), a network of TB control institutions was created, providing TB diagnosis, treatment and case management.<sup>14</sup> China's public health system has undergone extensive reform and includes a dynamic TB control programme, as described in the National TB Control Guide (2011–2015).<sup>14</sup>

In this article, we describe the served available market (SAM) for TB diagnostics in China in 2012. In addition to the nationwide market, we also show the market segmentation of the CDC and hospital sectors.

## METHODS

### Setting

TB control institutions in China include TB dispensaries, and hospitals designated by local health authorities to provide TB care (designated hospitals). First, there are TB dispensaries, which are responsible for case detection and treatment. The National TB Control and Prevention Guide (2011–2015)<sup>14</sup> mandates the TB dispensaries to carry out case management and follow-up as well as TB-related education. There are approximately 3490 dispensaries established at four vertical levels: national, provincial, prefectural and county.<sup>15</sup> Second, designated hospitals provide testing and treatment services. These include TB hospitals, chest/pulmonary hospitals, infectious disease hospitals, and general hospitals with a TB clinic.<sup>16</sup> Non-designated general hospitals (referred to here as general hospitals) are the first point of health care entry for most patients. A TB diagnosis cannot be confirmed, nor can presumptive TB patients be treated at a general hospital, which requires referral to TB control institutions and reporting of all presumed cases through the CISDCP.<sup>13,14</sup> The 2010 National Tuberculosis Prevalence Survey found that general hospitals were the most common point of health care entry, where 56.2% of TB patients first reported for care.<sup>11</sup>

The recommended diagnostic algorithm for pulmonary TB (PTB) in adults in China is shown in

Appendix Figure A.\*<sup>17</sup> Briefly, patients with suspected PTB undergo a chest X-ray and provide three sputum smears. Where laboratory capabilities exist, culture is performed on at least two specimens. Interferon-gamma release assays (IGRAs) are used as ancillary tests in China for the diagnosis of active PTB as well as for the detection of latent tuberculous infection (LTBI).<sup>14</sup> For the detection of drug-resistant TB, drug susceptibility testing (DST) is recommended for re-treatment sputum smear-positive TB patients, chronic TB patients, patients with treatment failure, and new patients who are still sputum smear-positive after 3 months of treatment.<sup>17</sup> TB diagnosis, including chest X-ray examination and smear microscopy at the first visit, as well as anti-tuberculosis drugs for up to 8 months, are provided free of charge by TB control institutes.<sup>17,18</sup>

### Tests included in this market assessment

Data on the volume of tests performed and the cost per test for the year 2012 were collected for the China CDC and hospital sectors for all diagnostics used for the detection of LTBI, for the initial diagnosis of active TB and for follow-up testing, and for DST. These included tuberculin skin tests (TSTs), IGRAs, serology (over 20 commercial antibody-based rapid and enzyme-linked immunosorbent assays are available on the Chinese market<sup>19</sup>), sputum smear microscopy (SSM), solid and liquid culture, and nucleic-acid amplification tests (NAATs) such as polymerase chain reaction (PCR) and line-probe assays (LPAs), *Mycobacterium tuberculosis* speciation tests, phenotypic DST and the adenosine deaminase test (ADA). Although the Xpert<sup>®</sup> MTB/RIF assay (Cepheid Inc, Sunnyvale, CA, USA) is currently used in China, it had not yet been approved for routine use in 2012 and was therefore not included in this analysis.

### Methods used for calculation of test volumes

As described in detail in our previous analyses for Brazil<sup>7</sup> and South Africa,<sup>6</sup> three methods were used to estimate test volumes. A bottom-up method was used for volumes of tests used in the CDC sector for which data were retrieved from the database of the National Tuberculosis Reference Laboratory of China. This represented the test volumes for all TB dispensaries.

Test volumes in both the designated and general hospitals were estimated using a middle-out approach, in which survey results from a representative sample of hospitals were extrapolated to estimate the total volume for this sector. This approach was used in designated hospitals and general hospitals for test volumes and prices charged. Structured question-

\* The appendix is available in the online version of this article, at <http://www.ingentaconnect.com/content/ijatld/ijatld/2016/00000020/00000003/art00006>

naires were sent out to 18 designated hospitals at provincial ( $n=6$ ), prefectural ( $n=6$ ) and county ( $n=6$ ) levels. Two sample sites from East, Central and West China were chosen at each level. As no data were available on the number of hospitals designated for TB, we conservatively estimated that there was only one designated hospital per city (whereas there might in fact have been more than one for some cities), at the provincial and prefectural levels (34 province-level cities, 345 prefecture-level cities<sup>20</sup>), and roughly one designated hospital in 25% of all county-level cities (CDC internal data). According to the National TB Control and Prevention Guide (2011–2015), China is in the process of transferring all TB care and services to designated TB hospitals.<sup>14</sup> To estimate the overall test volumes for all designated hospitals, survey results were extrapolated by multiplying the average numbers of tests performed in each region and respective administrative level by the corresponding number of estimated designated hospitals at each of these levels and regions.

To estimate the test volumes in general hospitals, the same survey was conducted in 60 general (i.e., non-designated) hospitals, where hospitals were again stratified by their level as classified by the National Health and Family Planning Commission (NHFPC),<sup>21</sup> and their geographic locations. The national test volumes for general hospitals were estimated by multiplying the average numbers of tests from the surveyed hospitals by the estimated number of general hospitals at different geographic regions and levels, respectively.<sup>15</sup> Level 1 hospitals were excluded due to their limited laboratory capacity.<sup>21</sup>

A top-down approach was used when database or survey data were not available, in which case test volume information was acquired from manufacturers. This method was used for the volume of IGRAs and the number of pyrazinamide (PZA) DST tests used in the hospital sector.

As data collection was based on aggregated programme data in which individual persons were not identifiable, no ethics approval was sought.

#### *Methods used for the calculation of test costs in China*

All costs (from a health system perspective) and prices are presented in 2012 USD. Costs and prices were collected in Chinese renminbi (RMB) and converted into USD using the World Bank official exchange rate for 2012 (6.31:1).<sup>22</sup>

Most TB tests provided by the China CDC sector are free of charge for TB patients. To have a realistic estimate of the actual costs for TB tests performed in the CDC sector, the unit costs were determined by a components approach, using the average costs for reagents and consumables, labour, equipment amortization and laboratory overheads, including water, electricity, security and building costs. These test costs were calculated by CDC staff using procurement cost

data for reagents, consumables and equipment and interviews with laboratory staff to obtain information on the hands-on time per test. Per expert consensus, a standard overhead cost of 20% was applied.

As it was not possible to assess the highly variable costs of tests in the hospital sectors, the price charged per test was used for this sector. Due to government-imposed pricing controls for health services and diagnostics in Chinese hospitals, the prices charged by hospitals for TB tests were in a designated range across the country.<sup>23</sup> We assessed the range of prices charged per test from the hospital surveys and from four provincial price bureaux,<sup>24–27</sup> and used the mean of the range per test as the test prices for the hospital sector. These estimated prices were corroborated by in-country experts.

To estimate the national overall market value for TB diagnostics, including the CDC and hospital sectors, the CDC cost per test was used when the same test was performed in both sectors. For tests that were performed in hospitals only, unit costs were estimated by the CDC staff who perform the tests, except for the LPA, where cost was taken from a recent publication and adjusted for 2012.<sup>28</sup> When using the published test cost, data for the same components as described above were used, with adjustments made for the 2012 exchange rate and a 3% inflation rate per year. For serology and PCR, the hospital price charged per test was used in the calculation of the overall market value, as no reagent costs were available.

The SAM, defined as the total volume and value of TB diagnostics in China, was calculated for the country as a whole, and for the CDC and hospital sectors separately. Three different market values were calculated. First, the value of the CDC sector market was calculated by multiplying the volume of each test in the CDC sector by the CDC-estimated test costs. Second, the value of the hospital-sector market was calculated by multiplying the test volumes of the hospital sector (both designated hospitals and general hospitals) by the average hospital-sector price charged. Finally, the value of the overall TB diagnostic market was calculated by multiplying the total volume of each test performed in both sectors by the CDC sector cost or the unit cost estimated by CDC for tests performed solely in the hospital sector. All unit costs are presented in Table 1.

#### *Sensitivity analysis*

A sensitivity analysis was performed to reflect variations in labour and overhead costs in different parts of the country and at different service levels. A sensitivity analysis was only performed for those diagnostic tests for which the breakdown of cost components was available. We calculated the variation in the hourly labour cost based on the maximum and minimum annual salaries across the country in

**Table 1** Unit cost per diagnostic test for the CDC sector and prices charged by hospitals (USD) in China

Diagnostic test	Cost/test in CDC sector USD	Price charged/test in hospital sector USD	Cost/test used to calculate overall market value USD	Sensitivity analysis: range in unit cost/test used to calculate overall market value
TST	—	2.77	1.77	1.69–1.85
IGRA*	—	66.36–94.70	73.90	70.77–77.07
Serology†	—	3.17	3.17	Average of prices charged was used
Smear (ZN+fluorescence microscopy)	1.30	2.77	1.30	1.22–1.42‡
Culture (liquid)	19.01	15.85	19.01	18.12–19.99
Culture (solid)	10.18	4.75	10.18	9.65–10.83
Speciation test	— <sup>§</sup>	4.75	5.10	4.86–5.38
PCR†	—	15.85	15.85	Average of prices charged was used
ADA	—	1.58	0.88	0.84–0.93
LPA + micro-array	—	87.16	28.36	32.92–36.89
Solid DST (SIRE)	33.90	12.68	33.90	32.09–36.13
Solid DST (SIREOA)	41.70	19.02	41.70	39.51–44.36
Solid DST (SIRE+5 drugs)	—	85.58	53.88	51.19–57.05
Liquid DST (SIRE)	—	38.03	92.30	88.39–96.28
Liquid DST (SIREP)	—	53.20	122.27	117.11–127.50
Liquid DST (SIREOA)	—	57.05	129.36	123.91–134.89

\* The average prices of imported and various Chinese IGRA tests. The average price of IGRA in general hospitals (US\$66.36, Appendix Table A.4) is lower than that in the designated hospital (US\$94.70, Appendix Table A.3) as there were higher volumes of Chinese IGRA used in general hospitals than in designated hospitals.

† The costs were estimated by China CDC except for serology and PCR.

‡ The cost of smears is the average cost of ZN and fluorescence smears combined.

§ PNB and TCH were used for speciation tests in the CDC sector and were included in the cost of culture.

CDC = China Centre for Disease Control and Prevention; USD = United States Dollars; TST = tuberculin skin test; IGRA = interferon-gamma release assay; ZN = Ziehl-Neelsen; PCR = polymerase chain reaction; ADA = adenosine deaminase; LPA = line-probe assay; DST = drug susceptibility test; S = streptomycin; I = isoniazid, R = rifampicin; E = ethambutol; O = ofloxacin; A = amikacin; P = pyrazinamide; PNB = para-nitrobenzoic acid; TCH = thiophene-2-carboxylic acid hydrazide.

2013. According to National Bureau of Statistic of People's Republic of China,<sup>29</sup> the maximum and minimum of hourly wages (converted from annual salaries data) were 22.2% above and 10.8% below the average hourly wage, 22 RMB/h (US\$3.44/h). We also searched the literature for costing studies in China to find a range for laboratory overhead costs. Previous studies reported overhead costs ranging from 15% to 25%,<sup>28,30–33</sup> which were used as our range of variation.

## RESULTS

### *TB diagnostic test volumes and costs in the CDC sector*

The volume of TB tests performed in the CDC sector in 2012 was 10.6 million tests at a value of US\$18.1 million (Appendix Table A.2, Figures 1 and 2). SSM represented a volume of 10.3 million tests (97%), at a cost of US\$13.4 million or 74% of the CDC sector market value. For culture, both solid and liquid media were used, for a total volume of 0.29 million tests and a value of US\$3.3 million. DST (solid or liquid medium) contributed <1% of testing in the CDC sector in 2012, and accounted for 8% of the market value in this sector. TST was not performed in the CDC sector in 2012 due to a reagent problem, and IGRAs were not used in this sector. CDC sector tests were used entirely for the diagnosis and follow-up of active TB.

### *TB diagnostic test volumes and market value at designated hospitals*

A total of 12 million tests were performed in 2012 in designated hospitals. When using the price charged per test the total value amounted to US\$89 million

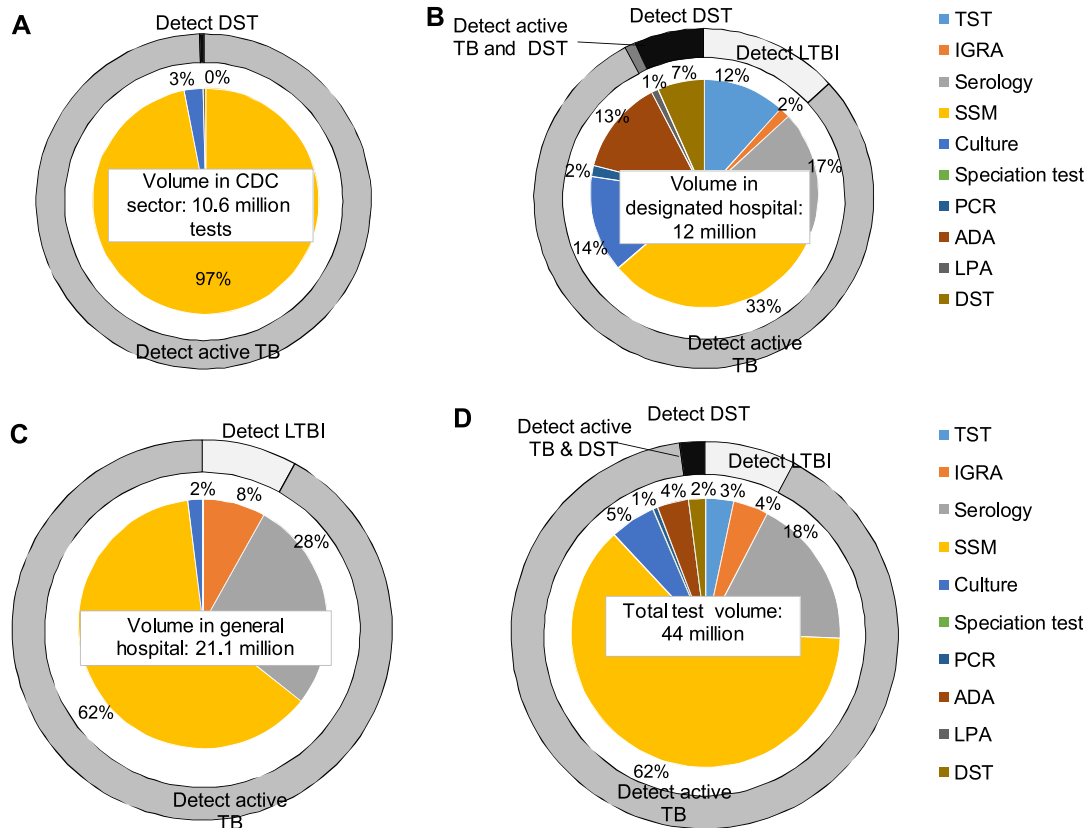
(Appendix Table A.3, Figures 1 and 2). The highest volumes of tests performed were SSM and serology, with 4.1 and 2.2 million tests performed, at a value of respectively 11.4 million and US\$6.9 million. First- and second-line DST accounted for 7% of the total test volume (0.8 million) and 23% of the total market value in designated hospitals (US\$20 million). Culture, using solid and liquid media, represented a volume of 1.7 million tests at a value of US\$12 million. A limited number of NAATs (LPA, micro-array, PCRs) were performed in designated hospitals: 0.3 million tests at a value of US\$14 million, 16% of the market value. For TST, 1.5 million tests were performed at a value of US\$4 million.

### *TB diagnostic test volumes and market value in the general hospitals*

A total of 21 million tests were performed in general hospitals, amounting to an estimated value of US\$170.5 million (Appendix Table A.4, Figures 1 and 2). The highest volume of tests was SSM, with approximately 13 million tests (US\$36.3 million). Approximately 0.4 million solid cultures were performed, amounting to a value of US\$1.9 million. IGRA tests, which were used as an ancillary test for the diagnosis of PTB and/or as a test for LTBI, had the largest market share (66% of the total) in general hospitals, with a dollar value of US\$112.4 million for 1.7 million tests.

### *Served available overall market (both sectors) in China in 2012*

Overall, an estimated total of 44 million tests were performed nationwide in the combined health sec-



**Figure 1** TB diagnostic test volumes performed by **A)** the CDC, **B)** designated hospitals, **C)** general hospitals, and **D)** overall test volumes by test and their diagnostic purpose, China, 2012. Inner circles show the test volume breakdown by diagnostic purpose in each market segment. Outer circles show the test volumes broken down by diagnostic purpose. Tests for the diagnosis of LTBI include TST and IGRA. IGRAs were also used as part of the diagnostic panel in some cases. Tests for active TB include serology, SSM, culture, speciation tests, PCR and ADA. Tests for active TB and DST refer to LPA (LPA and micro-array). Tests for DST include first- and second-line conventional DST. DST = drug susceptibility testing; CDC = China Centers for Disease Control and Prevention; TB = tuberculosis; LTBI = latent tuberculous infection; TST = tuberculin skin test; IGRA = interferon gamma release assay; SSM = sputum smear microscopy; PCR = polymerase chain reaction; ADA = adenosine deaminase; LPA = line-probe assay. This image can be viewed online in colour at <http://www.ingentaconnect.com/content/ijatld/ijtd/2016/00000020/00000003/art00006>

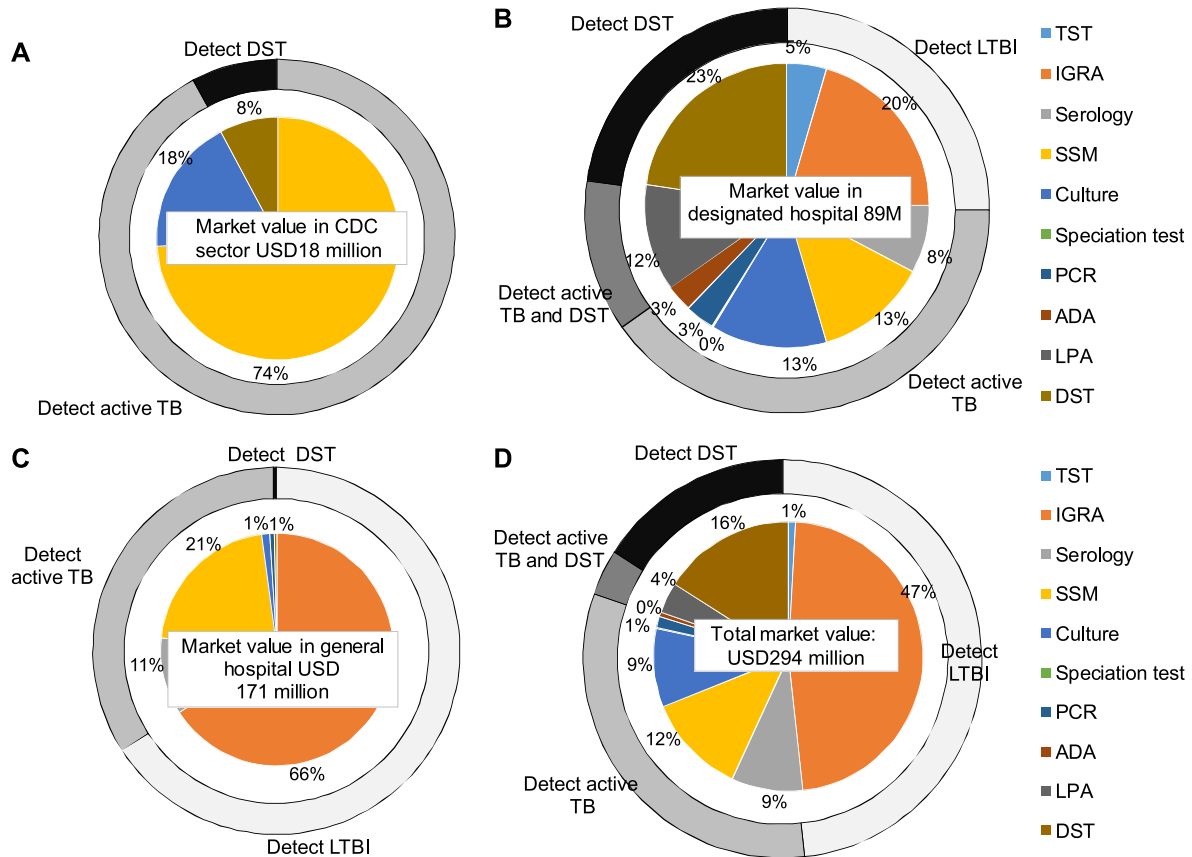
tors, at a value of US\$294 million (Table 2). The cost spent on TB diagnostics per notified TB case in China in 2012 was US\$327. The largest overall volume per type of test was SSM: 27.4 million tests (62% of the overall test volumes), at a value of US\$35.7 million (12% of the overall market value). The largest contributor to the market value was IGRAs, at a value of US\$139 million (47%), for 1.9 million tests (4%). Tests for LTBI (TST and IGRA combined) were only performed in the hospital sector in 2012, accounting for 3.3 million tests, at a value of US\$141.9 million, i.e., 48% of the total market. The main reason for their large contribution to the market value was the high unit cost for IGRA tests, estimated at US\$73.9 per test in China. Culture (solid and liquid) amounted to a total of 2.4 million tests (5%), at a value of US\$27.8 million (9%). Phenotypic DST was performed using solid media in the CDC sector, and both solid and liquid media by the hospitals. A total of 0.9 million DSTs were performed at a value of US\$47.1 million (16%).

The hospital sector contributed 76% (33.6 million)

of all tests performed, corresponding to 94% (US\$276.5 million) of the total market value. In the hospital sector, 63% of the tests were performed in general hospitals, which accounted for 66% of the market value in hospital sector. The main contributor to the high market share in the general hospitals was the use of IGRA, which was almost nine times that in designated hospitals.

## DISCUSSION

Our findings demonstrate a sizeable market for TB diagnostics in China in 2012 and high spending on diagnosis per TB case notified. The average amount spent on TB diagnostics per notified case was US\$327 in China as compared to US\$208 per case notified in Brazil and US\$280 in South Africa in 2012.<sup>7</sup> In comparison to the 2006 global market report, the testing volume in China had increased substantially by 2012.<sup>4</sup> A total of 9.4 million SSM and 0.65 million cultures were performed in 2003–2004 (M Perkins, FIND, personal communication), compared to 27.5



**Figure 2** Market value of TB diagnostics in **A)** the CDC sector, **B)** designated hospitals, **C)** general hospitals and **D)** overall market value by test and their diagnostic purpose, China, 2012. Inner circles show the test volume breakdown of each TB diagnostic in each market segment. Outer circles show the test volumes broken down by their diagnostic purpose. Tests for the diagnosis of LTBI included serology, TST and IGRA. IGRAs were also used as part of the diagnostic panel in some cases. Tests for active TB included SSM, culture, speciation tests, PCR and ADA. Tests for active TB and DST refer to LPA (LPA and micro-array). Tests for DST include first- and second-line conventional DST. DST = drug susceptibility testing; CDC = China Centers for Disease Control and Prevention; USD = US dollar; TB = tuberculosis; LTBI = latent tuberculous infection; TST = tuberculin skin test; IGRA = interferon gamma release assay; SSM = sputum smear microscopy; PCR = polymerase chain reaction; ADA = adenosine deaminase; LPA = line-probe assay. This image can be viewed online in colour at <http://www.ingentaconnect.com/content/ijutld/2016/00000020/00000003/art00006>

million and 2.4 million, respectively, in 2012. Due to the growth of the Chinese economy and resulting improved household incomes, Chinese patients may now be more likely to seek medical care at the early stages of the disease. Furthermore, due to increased funding and strengthened laboratory capacity,<sup>9</sup> more diagnostic tests were performed in 2012 than in 2003–2004. Despite the decreasing incidence of TB in China, the market outlook for TB diagnostics in China therefore suggests strong growth. Note that the overall market value of US\$294 million is a reflection of the expenditures on TB diagnostics, and is not equivalent to the sales potential for manufacturers, which have been addressed by members of our team in a different publication.<sup>34</sup>

The majority of TB diagnostic tests were performed in the hospital sector, and the market was more diverse in the designated hospitals than in the China CDC and the general hospitals. Designated and general hospitals together contributed 76% to the overall test volumes and 94% to the overall market

value. The large market in the general hospitals was likely due to the large numbers of hospitals, and the fact that they are the most common first point of medical contact for notified TB patients.<sup>11</sup> The tests used in general hospitals were therefore predominantly SSM, and there was a lack of more complex tests, such as those used to detect drug resistance. Designated hospitals played an increasingly important role in TB diagnosis, as mandated by the 2011–2015 National TB policy.<sup>14</sup> Various TB tests were used in the designated hospitals, including DST and several of the latest WHO-endorsed tests to detect active TB as well as drug resistance. The fact that many of these tests were not included in the national diagnostic algorithm (Appendix Figure A) may encourage Chinese policy makers to revise the algorithm to create a standardised diagnostic process for TB in the designated hospitals.

Overall, TB diagnostic testing in China in 2012 still relied on a few conventional TB tests, predominantly SSM, which contributed more than half (62%) of the

**Table 2** Total overall TB diagnostic market value (in USD) for the CDC and hospital sectors, using estimated costs in China, 2012

Diagnostic test	CDC sector n (%)	Hospital sector* n (%)	Total tests done n (%)	Unit cost USD	Overall market value, USD <sup>†</sup> (% of total value)	Range of market value based on sensitivity analysis USD <sup>‡</sup>
TST	—	1 459 537 (100)	1 459 537 (3)	1.77	2 580 766 (1)	2 464 128–2 707 015
IGRA	—	1 885 250 (100)	1 885 250 (4)	73.90	139 312 590 (47)	133 418 512–145 301 021
Serology	—	7 942 101 (100)	7 942 101 (18)	3.17	25 173 061 (9)	25 173 061
Smear (ZN+fluorescence microscopy)	10 278 562 (37)	17 210 208 (63)	27 488 770 (62)	1.30	35 669 287 (12)	33 469 538–39 124 260
Culture (solid)	240 888 (12)	1 813 485 (88)	2 054 373 (5)	10.18	20 914 261 (7)	19 818 544–22 246 729
Culture (liquid)	44 924 (12)	315 921 (88)	360 845 (1)	19.01	6 858 154 (2)	6 538 630–7 213 323
Speciation	—	27 200 (100)	27 200 (<1)	5.10	138 746 (<1)	132 116–146 271
PCR	—	261 052 (100)	261 052 (1)	15.85	4 137 117 (1)	4 137 117
ADA	—	1 669 525 (100)	1 669 525 (4)	0.88	1 475 571 (1)	1 406 845–1 551 944
LPA + micro-array	—	123 917 (100)	123 917 (<1)	28.36	10 801 006 (4)	4 079 966–45 712 215
Solid DST (SIRE)	25 035 (7)	358 812 (93)	383 848 (1)	33.90	13 013 563 (4)	12 319 028–13 868 862
Solid DST (SIREOA)	13 481 (4)	305 673 (96)	319 153 (1)	41.70	13 307 604 (5)	12 609 762–14 156 769
Solid DST (SIRE+5 drugs) <sup>§</sup>	—	22 480 (100)	22 480 (<1)	53.88	1 211 307 (<1)	1 150 738–1 282 535
Liquid DST (SIRE)	—	106 336 (100)	106 336 (<1)	92.30	9 814 602 (3)	9 398 814–10 237 616
Liquid DST (SIREP)	—	6 000 (100)	6 000 (<1)	122.27	733 617 (<1)	702 663–764 978
Liquid DST (SIREOA)	—	69 485 (100)	69 485 (<1)	129.36	8 988 744 (3)	8 609 740–9 372 471
Total	10 632 761 (24)	33 576 982 (76)	44 179 872 (100)		294 129 998 (100)	275 429 203–301 855 188

\* Includes general and designated hospitals.

† Calculated based on the unit test costs estimated by China CDC.

‡ The sensitivity analysis was performed based on the range in unit test costs listed in Table 1.

§ DST for nine second-line drugs was used in 11 provincial designated hospitals per expert consensus.

TB = tuberculosis; USD = United States Dollars; CDC = China Centre for Disease Control and Prevention; TST = tuberculin skin test; IGRA = interferon-gamma release assay; ZN = Ziehl-Neelsen; PCR = polymerase chain reaction; ADA = adenosine deaminase; LPA = line-probe assay; DST = drug susceptibility test; S = streptomycin; I = isoniazid; R = rifampicin; E = ethambutol; O = ofloxacin; A = amikacin; P = pyrazinamide; PNB = para-nitrobenzoic acid; TCH = thiophene-2-carboxylic acid hydrazide.

overall test volumes. The second most commonly used TB test was serology, although the WHO has issued a policy against the use of serology for active TB.<sup>35</sup> The availability of a large number of commercial serological tests made in China<sup>19</sup> provides additional evidence of their popularity in China.

In terms of market value or expenditure, IGRAs accounted for 47% of the total market value, all of this outside the China CDC sector. While the WHO and the International Standards for TB Care have discouraged the use of IGRAs for active TB,<sup>36</sup> these tests are commonly used, and probably for active TB rather than LTBI screening. Again, the availability of domestic IGRAs by Chinese companies is a reflection of their growing popularity.

Several more sophisticated tests such as NAAT, culture and DST contributed little to the overall test volumes, at 1%, 5% and 2%, respectively. However, this will likely change as the next 5-year National Plan for TB has been set to expand culture to more than 80% of county TB laboratories and to provide DST and rapid speciation tests in all prefectural and provincial TB laboratories.<sup>14</sup> It is therefore expected that the market share for culture, DST and molecular tests will grow in the coming years.

A limitation of this study was the exclusion of chest X-rays (multipurpose use), blood culture and histopathology. It is also possible that the actual number of general hospitals was lower than our estimate, as accurate data on the number of general hospitals with TB clinics were not available. However, this overestimating effect was to a certain extent offset by the exclusion of Level 1 general hospitals. The number of designated hospitals may have exceeded our conservative estimate, as there may have been more than one designated hospital in some of the more affluent eastern provinces. Finally, the unit test costs may be different from our estimation in different regions across the country, similar to the variation in prices charged by different hospitals.

This analysis of the served available market for TB diagnostics in China in 2012 describes the volumes and costs of the various tests that were in use for the diagnosis of LTBI and active TB, DST and treatment follow-up, as well as their market division in the CDC and hospital sectors. This report will help test developers understand the current and potential market for new replacement or add-on TB diagnostic technologies in China.

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article are his own. MDP, CCB and currently, also CMD are employed by FIND, a non-profit organisation that collaborates with industry partners, including Cepheid and Hain diagnostics among others, for the development, evaluation and demonstration of new diagnostic tests for poverty-related diseases. All other authors have no financial or industry conflicts.

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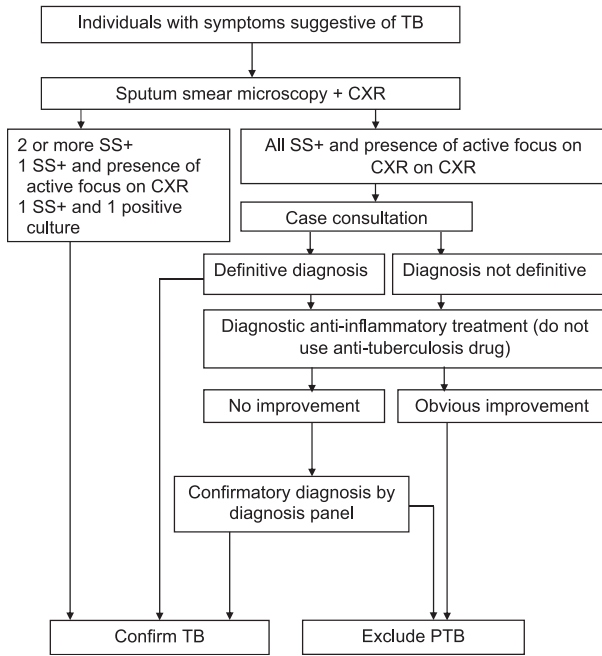
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APPENDIX



**Figure A** Recommended diagnostic algorithm for individuals aged >15 years with symptoms presumptive of PTB in China. TB = tuberculosis; CXR = chest X-ray; SS+ = sputum smear-positive; PTB = pulmonary tuberculosis.

**Table A.1** Estimated unit costs (in USD) according to cost estimations done by the China CDC for TB diagnostic tests with breakdown by components, 2012

	TST*	IGRA	ZN	Fluorescence microscopy	Solid culture	Liquid culture	Speciation*	LPA*†	ADA*	Solid DST (SIRE)	Solid DST (SIRE+5 drugs)	Liquid DST (SIRE)*	Liquid DST (SIRE-OA)*
Reagents and consumables	1.42	61.14	0.71	0.71	7.35	13.06	3.96	25.12	0.70	24.44	40.61	98.94	104.85
Labour	0.06	0.44	0.30	0.24	1.01	0.87	0.29	3.24	0.04	3.67	4.16	0.60	0.60
Equipment	NA	0.00	0.07	0.19	0.12	1.91	0.00	0.57	0.00	0.13	0.13	2.36	2.36
Overheads (20%)	0.29	12.32	0.22	0.23	1.70	3.17	0.85	5.79	0.15	5.65	8.98	20.38	21.56
Total	1.77	73.90	1.29	1.37	10.18	19.01	5.10	28.36	0.88	33.90	53.88	122.27	129.36

\* Costs for speciation, liquid DST, LPA, ADA, speciation and TST were estimated by the CDC, although these tests were not routinely performed in CDC laboratories.

† The cost of LPA was retrieved from a previous publication<sup>12</sup> and adjusted for inflation and 20% overhead.

USD = United States Dollars; CDC = China Centre for Disease Control and Prevention; TB = tuberculosis; TST = tuberculin skin test; IGRA = interferon-gamma release assay; ZN = Ziehl-Neelsen; LPA = line-probe assay; ADA = adenosine deaminase; DST = drug susceptibility test; I = isoniazid; R = rifampicin; E = ethambutol; O = ofloxacin; A = amikacin; P = pyrazinamide; NA = not available.

**Table A.2** Volume and estimated total costs (in USD) of TB diagnostic tests in China CDC sector, 2012

Diagnostic test	Estimated unit costs/test USD	Tests done in CDC sector <i>n</i>	Total costs in CDC sector USD	Market segmentation in the CDC sector %
TST	Not done			
IGRA	Not done			
Serology	Not done			
Smear (ZN+fluorescence microscopy)	1.30	10 278 562	13 385 250	74
Culture (liquid)	19.01	44 924	853 817	5
Culture (solid)	10.18	240 888	2 452 327	13
Speciation test	Not done			
PCR	Not done			
ADA	Not done			
LPA	Not done			
Solid DST (SIRE)	33.90	25 035	848 773	5
Solid DST (SIREOA)	41.70	13 481	562 095	
Solid DST (SIRE+5 drugs)	Not done			
Liquid DST (SIRE)	Not done			
Liquid DST (SIREZ)	Not done			
Liquid DST (SIREOA)	Not done			
Total		10 602 890	18 102 263	100

USD = United States Dollars; TB = tuberculosis; CDC = China Centre for Disease Control and Prevention; TST = tuberculin skin test; IGRA = interferon-gamma release assay; ZN = Ziehl-Neelsen; PCR = polymerase chain reaction; ADA = adenosine deaminase; LPA = line-probe assay; DST = drug susceptibility test; S = streptomycin; I = isoniazid, R = rifampicin; E = ethambutol; O = ofloxacin; A = amikacin; Z = pyrazinamide.

**Table A.3** Volume and market value (in USD) of TB diagnostic tests in designated hospitals, China, 2012

Diagnostic test	Price charged for test USD	Tests done in designated hospitals <i>n</i>	Market value in designated hospitals USD	Market segmentation in designated hospitals %*
TST	2.77	1 453 450	4 030 962	5
IGRA	94.70 <sup>†</sup>	191 446	18 130 164	20
Serology	3.17	2 167 843	6 871 135	8
Smear (ZN+fluorescence microscopy)	2.77	4 127 360	11 446 720	13
Culture (liquid)	15.85	315 921	5 006 674	6
Culture (solid)	4.75	1 404 749	6 678 680	8
Speciation test	4.75	27 200	129 319	<1
PCR	15.85	189 345	3 000 713	3
ADA	1.58	1 669 525	2 645 840	3
LPA	87.16	123 917	10 801 006	10
Solid DST (SIRE)	12.68	319 049	4 044 992	4
Solid DST (SIREOA)	19.02	305 673	5 813 107	5
Solid DST (SIRE+5 drugs) <sup>‡</sup>	85.58	22 480	1 923 832	2
Liquid DST (SIRE)	38.03	106 336	4 044 475	4
Liquid DST (SIREZ)	53.20	6 000	319 200	<1
Liquid DST (SIREOA)	57.05	69 485	3 964 260	4
Total		12 499 778	88 851 079	100

\* The market in the hospital sector was calculated based on the prices charged to patients per test.

<sup>†</sup> The average price of imported IGRAs and various Chinese IGRA tests. The average price of IGRA in general hospitals (\$66.36, Appendix Table A.4) is lower than that in the designated hospital (\$94.70, Appendix Table A.3), as there were higher volumes of Chinese IGRA used in general hospitals than in designated hospitals.

<sup>‡</sup> At 11 provincial designated hospitals DST was performed against 9 second-line drugs according to expert consensus.

USD = United States Dollars; TB = tuberculosis; TST = tuberculin skin test; IGRA = interferon-gamma release assay; ZN = Ziehl-Neelsen; PCR = polymerase chain reaction; ADA = adenosine deaminase; LPA = line-probe assay; DST = drug susceptibility test; S = streptomycin; I = isoniazid, R = rifampicin; E = ethambutol; O = ofloxacin; A = amikacin; Z = pyrazinamide.

**Table A.4** Volume and market value (in USD) of TB diagnostics tests in general hospitals, China, 2012

Diagnostic test	Price charged for test USD	Tests done in general hospitals n	Market value in general hospitals USD	Market segmentation in general hospitals %*
TST	2.77	6 087	16 882	<1
IGRA <sup>†</sup>	66.36	1 693 805	112 407 088	66
Serology	3.17	5 774 258	18 301 926	11
Smear (ZN+fluorescence microscopy)	2.77	13 082 847	36 283 650	21
Culture (liquid)	Not done			
Culture (solid)	4.75	408 736	1 943 279	1
Speciation test	Not done			
PCR	15.85	71 707	1 136 404	1
ADA	Not done			
LPA	Not done			
Solid DST (SIRE)	12.68	39 764	504 135	<1
Solid DST (SIREOA)	Not done			
Solid DST (SIRE+5 drugs)	Not done			
Liquid DST (SIRE)	Not done			
Liquid DST (SIREZ)	Not done			
Liquid DST (SIREOA)	Not done			
Total		21 077 204	170 593 364	100

\* The market in the hospital sector was calculated based on the prices charged to patients per test.

<sup>†</sup> The average price of imported IGRAs and various Chinese IGRA tests. The average price of IGRA in general hospitals (\$66.36, Appendix Table A.4) is lower than that in the designated hospital (\$94.70, Appendix Table A.3), as there were higher volumes of Chinese IGRA used in general hospitals than in designated hospitals. USD = United States Dollars; TB = tuberculosis; TST = tuberculin skin test; IGRA = interferon-gamma release assay; ZN = Ziehl-Neelsen; PCR = polymerase chain reaction; ADA = adenosine deaminase; LPA = line-probe assay; DST = drug susceptibility test; S = streptomycin; I = isoniazid, R = rifampicin; E = ethambutol; O = ofloxacin; A = amikacin; Z = pyrazinamide.

**Table A.5** Breakdown of volume and market value (in USD) of TB diagnostic tests in designated and general hospitals, China, 2012

Diagnostic test	Tests done in designated hospitals n	Market value in designated hospitals* USD	Tests done in general hospitals n	Market value in general hospitals* USD
TST	1 453 450	4 030 962	6 087	16 882
IGRA	191 446	18 130 164	1 693 805	112 407 088
Serology	2 167 843	6 871 135	5 774 258	18 301 926
Smear (ZN+fluorescence microscopy)	4 127 360	11 446 720	13 082 847	36 283 650
Culture (liquid)	315 921	5 006 674	Not done	
Culture (solid)	1 404 749	6 678 680	408 736	1 943 279
Speciation test	27 200	129 319	Not done	
PCR	189 345	3 000 713	Not done	
ADA	1 669 525	2 645 840	71 707	1 136 404
LPA	123 917	10 801 006		
Solid DST (SIRE)	319 049	4 044 992	39 764	504 135
Solid DST (SIREOA)	305 673	5 813 107	Not done	
Solid DST (SIRE+5 drugs)*	22 480	1 923 832	Not done	
Liquid DST (SIRE)	106 336	4 044 475	Not done	
Liquid DST (SIREZ)	6 000	319 200	Not done	
Liquid DST (SIREOA)	69 485	3 964 260	Not done	
Total	12 499 778	88 851 079	21 077 204	170 593 364
Breakdown in the hospital sector, %	37	34	63	66
Proportion of the overall market, %	28	30	48	58

\* The market in the hospital sector was calculated based on the prices charged to patients per test.

USD = United States Dollars; TB = tuberculosis; TST = tuberculin skin test; IGRA = interferon-gamma release assay; ZN = Ziehl-Neelsen; PCR = polymerase chain reaction; ADA = adenosine deaminase; LPA = line-probe assay; DST = drug susceptibility test; S = streptomycin; I = isoniazid, R = rifampicin; E = ethambutol; O = ofloxacin; A = amikacin; Z = pyrazinamide.

**RESUME**

**OBJECTIF :** Evaluer le marché des outils de diagnostic de la tuberculose (TB) en Chine en 2012, dans le secteur servi par le Centers for Disease Control and Prevention (CDC) de Chine et le secteur hospitalier (incluant à la fois les hôpitaux destinés à la TB et les hôpitaux généraux).

**SCHEMA :** Les volumes de tests et leur coût unitaire ont été évalués pour le test cutané à la tuberculine, le test de libération de l'interféron-gamma (IGRA), la microscopie de frottis, la sérologie, la culture, les tests de spéciation, les tests d'amplification de l'acide nucléique (NAAT), les tests de pharmacosensibilité (DST) et les tests d'adénosine désaminase (ADA). Les données ont été obtenues à partir de bases de données électroniques (secteur du CDC) et à travers des enquêtes (secteur hospitalier), et ont été estimées pour les deux secteurs et

pour le pays entier. Le coût des tests a été estimé par le personnel du CDC en Chine et grâce à la littérature publiée.

**RÉSULTATS :** En 2012, les secteurs du CDC et des hôpitaux ont réalisé un total de 44 millions de tests de diagnostic de la TB pour un coût d'ensemble de US\$294 millions. Les tests utilisés par le secteur du CDC ont été la microscopie de frottis, la culture en milieu solide et liquide et le DST, tandis que le secteur hospitalier a également utilisé les IGRA, les NAAT, les ADA et la sérologie. Le secteur hospitalier représentait 76% du volume total et 94% de la valeur marchande.

**CONCLUSION :** La Chine a un immense marché de diagnostic de la TB qui comprend une large gamme de tests de diagnostic, la majorité étant réalisée dans des hôpitaux chinois.

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**RESUMEN**

**OBJETIVO:** Describir el mercado disponible atendido de los medios diagnósticos en el 2012 en la China, en el sector de cobertura de los Centros para el Control y la Prevención de las Enfermedades (CDC) del país y el sector hospitalario (incluidos los hospitales designados de atención de la tuberculosis [TB] y los hospitales generales).

**MÉTODOS:** Se evaluaron los volúmenes y los costos unitarios de la prueba cutánea de la tuberculina, las pruebas de liberación de interferón gama (IGRA), la baciloscopia, las pruebas serológicas, los cultivos, las pruebas de identificación de especie, las pruebas de amplificación de ácidos nucleicos (NAAT), las pruebas fenotípicas de sensibilidad a los medicamentos (DST) y las pruebas de determinación de la desaminasa de adenosina (ADA). Los datos se obtuvieron a partir de bases de datos electrónicas (en el sector de los CDC) y mediante encuestas (en el sector hospitalario) y se

calcularon las cifras en ambos sectores y a escala nacional. La estimación de los costos de las pruebas se logró con la colaboración del personal de los CDC y los datos comunicados en las publicaciones científicas.

**RESULTADOS:** En el 2012, se practicaron en ambos sectores 44 millones de pruebas diagnósticas de la TB por un valor total de US\$294. Las pruebas utilizadas en el sector de los CDC fueron la baciloscopia, los cultivos en medio sólido y medio líquido y las DST; en el sector hospitalario se practicaron además las IGRA, NAAT, ADA y las pruebas serológicas. El sector hospitalario representó el 76% del volumen total de las pruebas y el 94% del valor comercial.

**CONCLUSIÓN:** La China cuenta con un vasto mercado para los medios diagnósticos de la TB, que comporta una amplia gama de pruebas diagnósticas, las cuales se practican en su mayor parte en los hospitales del país.

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