The Global Drug Facility and its role in the market for tuberculosis drugs

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Universal access to high-quality treatment is central to the Global Plan to Stop TB. The Global Drug Facility (GDF) was launched in 2001 to help to achieve this goal, through services including the supply of affordable, quality-assured drugs to countries in need. We assess the scale of GDF drug supplies worldwide and find that the GDF commands a substantial proportion of the market for drugs for first-line and second-line treatment regimens, having supplied, for example, first-line drugs for roughly 35% of cases reported worldwide in 2011. Significant potential remains for GDF expansion, especially in the provision of second-line drugs, which would be aided by future increases in case detection.

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Introduction

Tuberculosis is a global public health priority. The disease is closely linked to poverty, with 22 low-income and lower-middle-income countries accounting for more than 80% of all new tuberculosis cases worldwide every year.[1] Although in most cases tuberculosis can be cured with cost-effective chemotherapy,[2,3] not all patients have access to high-quality treatment.[4,5] This situation is especially pressing in resource-poor settings with weak tuberculosis management capacity, where challenges include interruptions in drug supplies and substandard or counterfeit drugs.[6] These factors not only reduce the chances of treatment success, but also increase the risk of drug resistance.

The Global Plan to Stop TB, launched in 2001, provides a framework with which to address these and other important issues in tuberculosis control.[7,8] In particular, as a means for widening access to high-quality tuberculosis drugs, the Global Drug Facility (GDF) was launched in the same year.[9,10] Among several functions, the GDF aims to mediate the supply of tuberculosis drugs to countries in need, while simultaneously assisting and strengthening national tuberculosis programmes.

Despite substantial progress in global tuberculosis control in the past few decades, substantial challenges remain (appendix p 4). Moreover, the landscape of funding for global health has changed substantially in recent years,[11] raising important strategic questions for financing mechanisms in general.[12] The GDF is no exception, and faces fundamental questions about its future role in tuberculosis control. To start to answer these questions, one must first understand the role of the GDF in the market for tuberculosis drugs. We characterise the proportion of worldwide drug supplies mediated by the GDF, its development and geographical distribution in the past decade, and potential avenues for its future growth, in accordance with the Global Plan to Stop TB.[13] We first give a brief overview of the function of the GDF, and then present our analysis of the scale of GDF involvement in the worldwide tuberculosis drug market, with respect to both first-line and second-line drugs. Finally, we discuss strategic questions arising from our analysis, for the financing and delivery of tuberculosis drugs.

Overview of GDF operations

GDF-supplied drugs are subject to internationally standardised quality assurance criteria.[14] Supplies of these drugs operate through two channels: grants for countries without financial resources that are selected on the basis of donors' specific criteria, and direct procurement for countries that have sufficient financial resources (either their own or through grants provided by other donors) but do not have the capacity to procure their own quality-assured drugs. For example, in 2011 first-line and second-line treatments ordered through the GDF exceeded US$122 million in value (excluding in-country delivery—ie, ex works—and excluding consumables such as syringes). Such GDF operations are done in partnership with the Global Fund, and on an intermittent basis with the Pan American Health Organization, the United Nations Development Programme, the United Nations Children's Fund, and the World Bank, with grants funded by public donors including the Canadian International Development Agency, the UK Department for International Development, the Kuwait Fund, the United Nations Foundation, UNITAID, and the US Agency for International Development.[15]

For recipient countries, key services provided by the GDF include the provision and timely delivery of affordable quality-assured drugs; technical assistance in drug procurement and management, including that of drug stocks and supply chains; and programme monitoring and evaluation. From a market perspective, the GDF has an intermediary role between national tuberculosis programmes, donors, and drug manufacturers by consolidating demand and public funds from donors, thus aiming to provide a stable, identifiable market for manufacturers, while lowering prices.[9]

In the future, more extensive consolidation by the GDF of public funding for quality-assured tuberculosis drugs, and an accompanying increase in GDF drug supplies, could catalyse new market transformations—eg, by attracting new manufacturers into the market of quality-assured drugs, while reducing treatment prices further and enabling active competition against potentially substandard drugs, including those available on the private market.[16] Similar market-shaping effects have been discussed in the context of malaria and HIV control.[17,18]

See **Online** for appendix

To estimate how much of the tuberculosis drug market the GDF has commanded, we note first that the endpoint of any drug supply programme is the patient with tuberculosis; therefore, in market terms, we use new and retreatment cases as a proxy for the total potential market size (as in the work of Norval and colleagues[19]), and define the GDF market share as:

$$\frac{\text{Treatment available through GDF supply in a given year}}{\text{Number of new and previously treated cases arising in that year}}$$

This value represents a true proportion because the denominator and numerator both have consistent units of numbers per year. The numerator is from GDF procurement data for 120 countries worldwide and the denominator is from publicly available WHO global incidence data (appendix).

As illustrated in the appendix (p 5), the GDF drug supply data show some year-to-year irregularity at the country level, attributable to supply chain management and reporting, rather than the availability of drugs at a particular time. As a simple proxy for the number of drugs available in any given year, we therefore smooth the GDF supply data with a moving average. Further details are provided in the appendix, including an illustration of the effects of smoothing from a national to a global scale.

Figure 1A shows the dynamics of global GDF supply in first-line drugs, including the effect of smoothing. Since operations began in 2001, the number of treatments supplied has increased steadily; since 2005, the overall trend seems to have stabilised at 2·0–2·5 million treatments supplied per year. Appendix p 6 suggests that GDF-supplied treatments have undergone a shift since 2007, from grants to direct procurement—this mainly represents a transition, in several countries, from a GDF grant to Global Fund support.

Figure 1B illustrates the dynamics of two measures for the denominator of the equation for market share: officially reported cases and all estimated cases during the same period, restricting attention here to cases without documented multidrug-resistant tuberculosis. To address uncertainty in estimated cases, we follow annex 1 of WHO's global tuberculosis report[1] in the use of a beta distribution to model the rates of case detection and of drug sensitivity testing. With Monte Carlo simulations, we present the mean for the equation, and the 2·5th and 97·5th percentiles. Figure 1C plots a ratio of the data in figure 1A and 1B, illustrating a decreasing

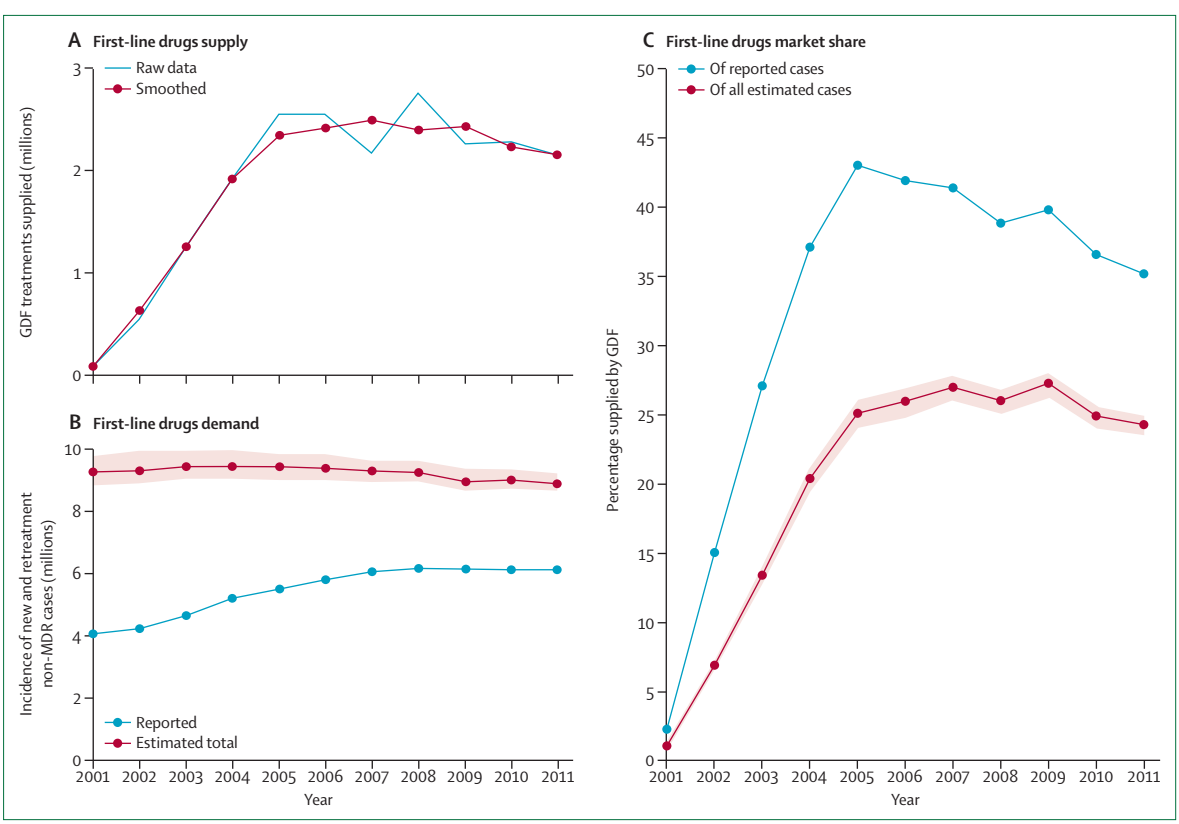

Figure 1: **Global dynamics relevant to first-line drugs**
(A) Dynamics of GDF supply, showing results of a moving average, used to smooth over the GDF grant cycle. (B) Reported and estimated worldwide incidence of tuberculosis cases, taken from WHO data. (C) A ratio of data in (A) and (B), with use of smoothed GDF data; market share is plotted as defined in the main text. In (B) and (C), the shaded area represents the 95% uncertainty interval associated with estimated cases. GDF=Global Drug Facility. MDR=multidrug-resistant.

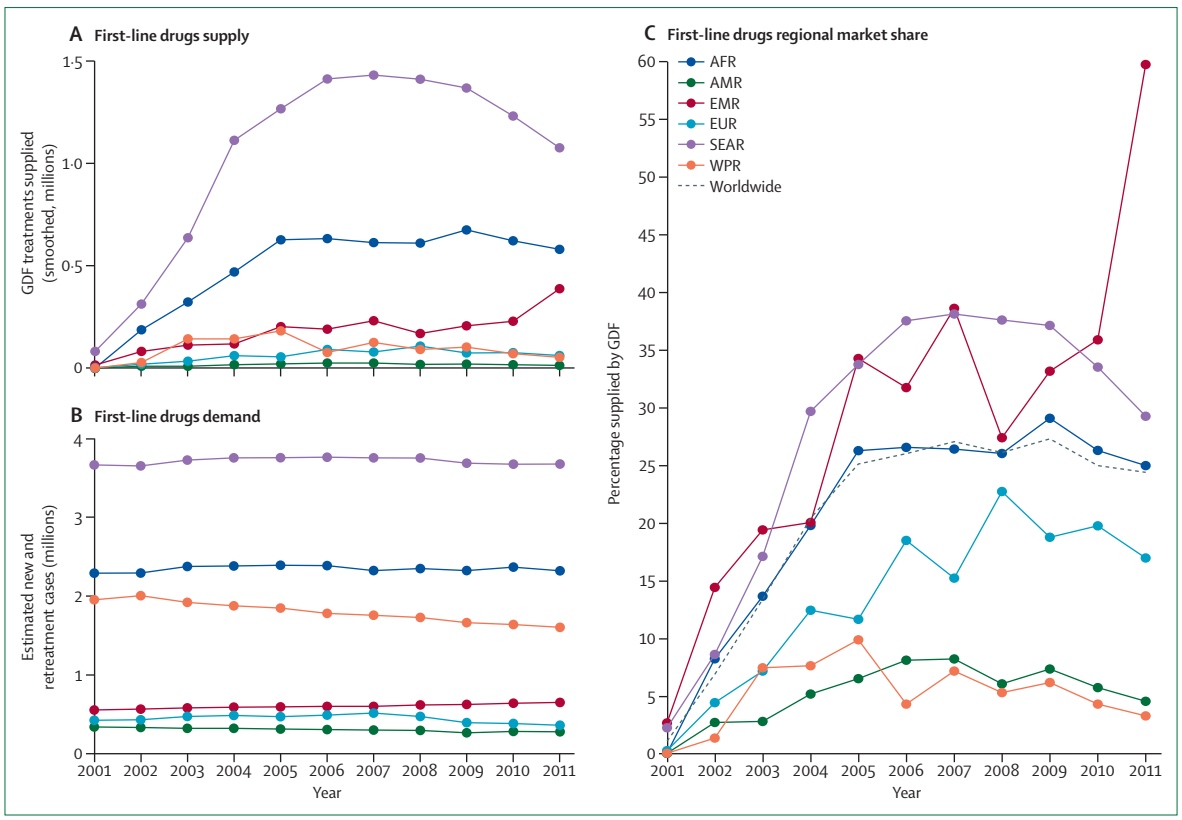

Figure 2: **Regional disaggregation relevant to first-line drugs**
(A) Dynamics of GDF supply. (B) Estimated worldwide incidence of new and previously treated tuberculosis cases: qualitatively similar dynamics apply for reported cases. (C) Plot of the ratios of data in (A) and (B), on a regional basis, with smoothed GDF data. Uncertainty intervals have been omitted for clarity. GDF=Global Drug Facility. AFR=WHO African Region. AMR=WHO Region of the Americas. EMR=WHO Eastern Mediterranean Region. EUR=WHO European Region. SEAR=WHO South-East Asia Region. WPR=WHO Western Pacific Region.

trend in GDF first-line drugs market share with respect to reported cases since 2005. In 2011, total GDF first-line drug supplies accounted for 35·4% of reported cases. However, with respect to all estimated drug-sensitive cases, this market share is 24·4% (95% CI 23·6–25·1).

To explore geographical variations in drug supply and demand, figure 2C disaggregates the time course of GDF participation in the first-line drugs market, by WHO region: it illustrates that the WHO African, eastern Mediterranean, and southeast Asia regions have been best supplied by GDF drugs relative to estimated new and retreatment cases in those areas. Individual countries within these regions make varying contributions; for example, the rapid increase in supplies received by the eastern Mediterranean region in 2011 is largely accounted for by Pakistan. By contrast, the remaining regions, the Americas, European, and western Pacific regions, were under-represented by GDF supplies.

Similarly, for second-line drugs, figure 3A shows that absolute numbers of GDF-supplied, second-line treatments have been increasing steadily. Even as notifications increased over time, the estimated incidence of multidrug-resistant tuberculosis remained roughly stable (figure 3B). In 2011, GDF supplies accounted for 31·7% of notified cases and 4·2% (95% CI 3·8–4·5%) of all estimated cases (figure 3C). Although figure 3A and 3C indicate that GDF supplies of second-line drugs have a lower market share than those of first-line drugs, they also show that GDF supplies of second-line drugs are still in a growth phase. This trend is consistent with recent GDF procurement data indicating that 29 800 second-line patient treatments were supplied by the GDF in 2012—an increase of 52·0% from 2011 (calculations adjusted for changes in recommended treatment duration; see appendix for further information). Overall, in the context of the second-line drugs market, the disparity between reported and estimated multidrug-resistant tuberculosis cases (also shown in appendix p 4) draws attention to rates of drug sensitivity testing as a key determinant of the potential market size.

Figure 4 once again disaggregates these dynamics by region with respect to estimated cases. Of all regions, GDF supply of second-line drugs to the Americas has been strongest; both the peak and the steep decline are attributable to Peru in particular, where the incidence of multidrug-resistant tuberculosis has increased in the past decade.[20] Conversely, recent procurement changes in

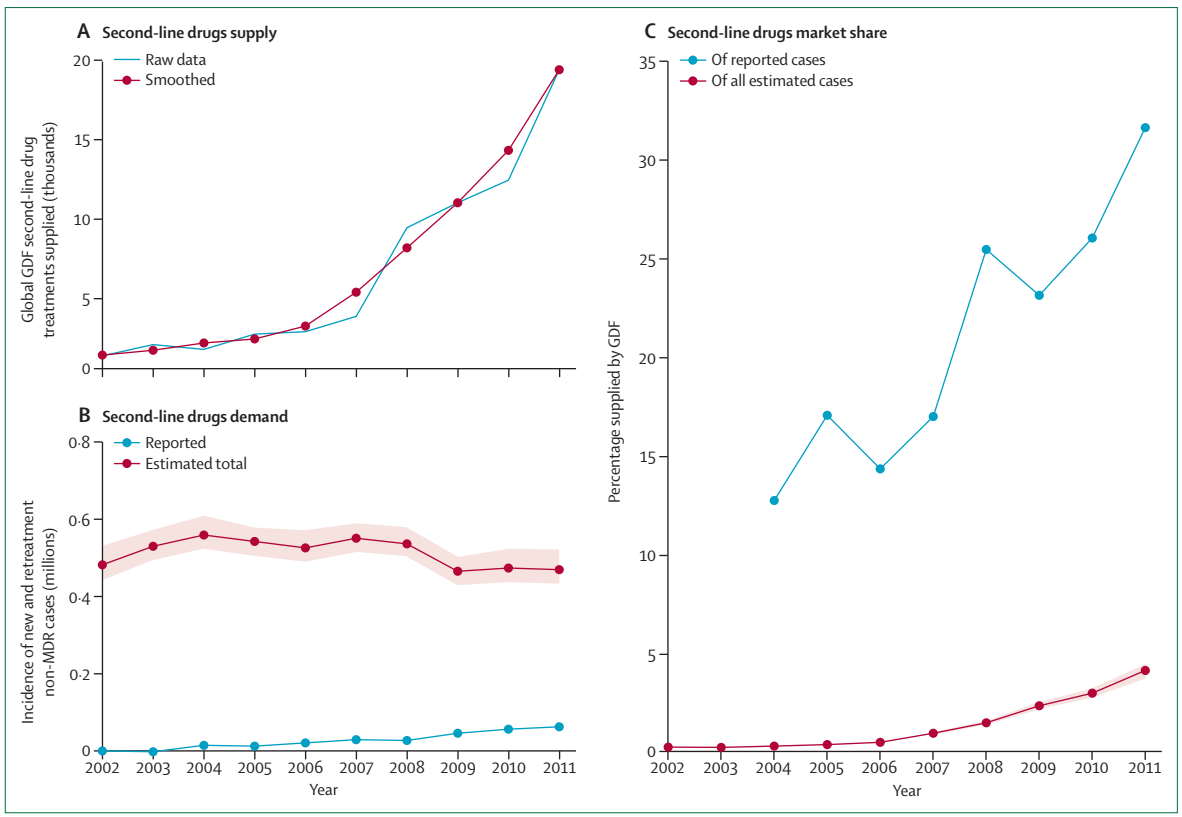

Figure 3: **Global dynamics relevant to second-line drugs**
(A) Dynamics of GDF supply. (B) Reported and estimated worldwide incidence of multidrug-resistant tuberculosis among new and previously treated cases. (C) A ratio of data in (A) and (B). Market share is plotted only from 2004 onwards; before this period, the global data are dominated by individual countries, notably Peru, where sparse multidrug-resistant notifications (B) give unreliable estimates of market share with respect to notified cases. GDF=Global Drug Facility. MDR=multidrug-resistant.

Peru have substantially reduced GDF supplies of second-line drugs there since 2009. Nonetheless, other regions and countries are roughly in accordance with the 3–4% market share (figure 3C).

We now consider the geographical distribution of patients not treated with GDF-supplied drugs. If increased supplies are judged to be necessary to fulfil GDF's central public health objectives (see discussion), this is an initial approach for the identification of the regions that represent the key gaps in GDF coverage. We refer to those cases not treated by GDF-supplied drugs as "unmet demand", which is measured as the difference between numbers of new and retreatment cases, and GDF-supplied treatments. As we discuss later, these patients might in fact receive treatment, but potentially not with standardised treatment or quality-assured drugs. To explore how this unmet demand is distributed worldwide, we take the contribution of a given region as the ratio of regional to total global unmet demand.

We assess this ratio under two scenarios: present notifications, as measured by cases reported in 2011; and a "scale-up" scenario—the reported cases that might instead have occurred with increased rates of case detection and drug sensitivity testing, for example through deployment of diagnostic devices such as GeneXpert MTB/RIF.[21] As a guide for this second scenario, we use projections for 2015 by the Global Plan to Stop TB:[13,22] a case detection rate of 84%, and drug sensitivity testing for 20% and 100% of new and previously treated cases, respectively (see appendix for further details). For comparison, corresponding rates in 2011 were estimated at 66·0%, 3·8%, and 6·0%, respectively.[1]

Figure 5 compares WHO regions in 2011 for both scenarios. For first-line drugs (upper row), on the basis of current reported cases, global unmet demand seems to be concentrated in the WHO southeast Asia and western Pacific regions; in these areas, the dominant contributions come from India and China, respectively. Under a scale-up scenario, the situation is qualitatively similar, with the exception being that the African region (especially South Africa) becomes more prominent.

In the bottom row of figure 5, the contrast between present notifications and a scale-up scenario illustrates the substantial effect that scaled-up drug sensitivity testing could have on the demand for second-line drugs. Nonetheless, in both scenarios, Russia is consistently prominent. However, under a scale-up scenario, the

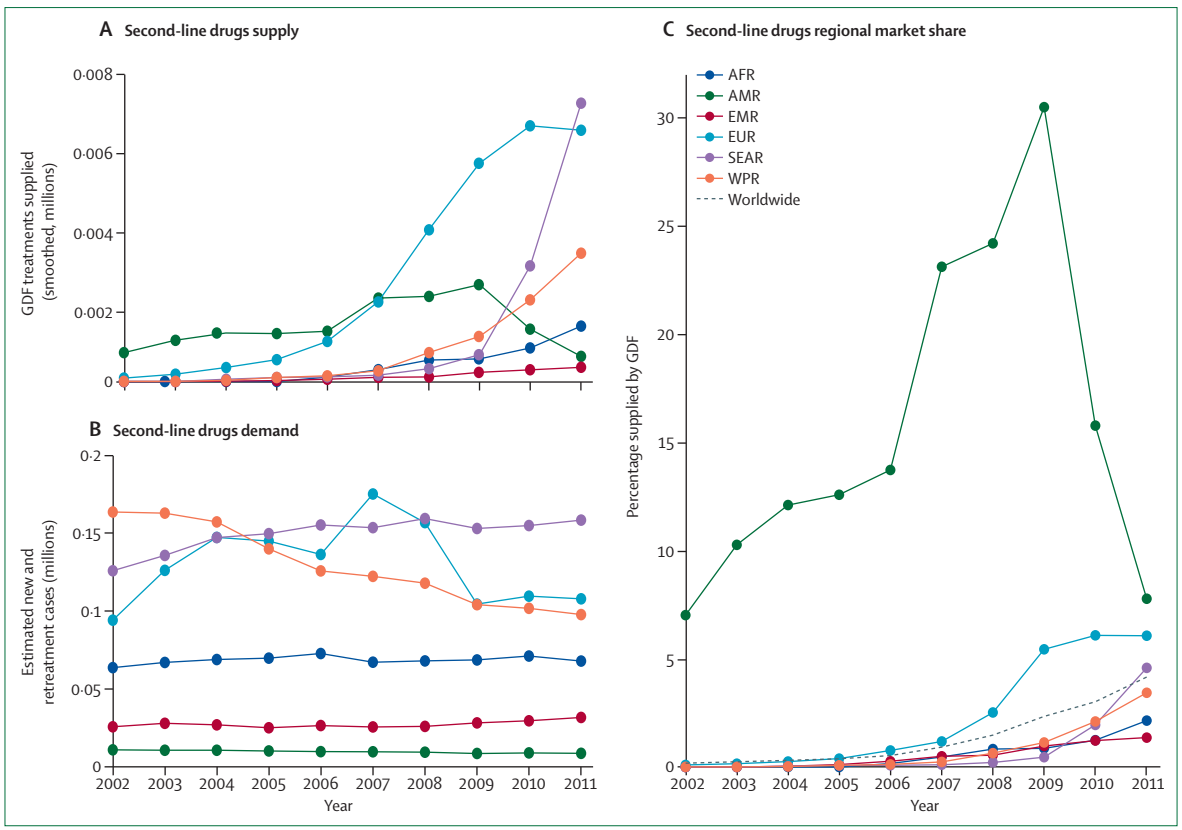

Figure 4: **Regional disaggregation relevant to second-line drugs**
(A) Dynamics of GDF supply, by region. (B) Reported and estimated incidence of tuberculosis cases, by region, among new and previously treated cases. (C) Plot of ratios of data in (A) and (B) on a regional basis, using estimated incidence of multidrug-resistant tuberculosis among new and previously treated cases. Uncertainty intervals are omitted for clarity. GDF=Global Drug Facility. AFR=WHO African Region. AMR=WHO Region of the Americas. EMR=WHO Eastern Mediterranean Region. EUR=WHO European Region. SEAR=WHO South-East Asia Region. WPR=WHO Western Pacific Region.

southeast Asian region (in particular India) would also account for an appreciable proportion of unmet demand worldwide.

Discussion

A noteworthy result from our analysis, relating to fundamental strategic questions for the GDF, is that the market share in first-line drugs has been falling gradually since 2005 (figure 1C). To some extent, this decrease could be accounted for by increasing numbers of untreated patients, which alone would present obvious public health concerns. However, the decrease might also be due to more patients being treated in the public sector with drugs not supplied by the GDF.

With respect to the latter case, the consolidation of public funds—whether by the GDF or not—has a two-fold rationale: it maximises leverage for reduced prices on quality-assured first-line drugs and second-line drugs, thus enabling wider access to these drugs, while also minimising the use of public funds for procurement of drugs of uncertain, potentially substandard, quality.[6,23,24] Thus, if the decline in figure 1C arises partly from an increase in other procurement mechanisms, a need to better standardise and integrate these mechanisms arguably exists, to most effectively widen access to quality-assured drugs, while adhering to procurement standards. This integration could be done, for example, through Voluntary Pooled Procurement, a scheme run by the Global Fund as part of its Procurement Support Service for recipients in need. In this case, a central question for the GDF is what part it should play in such consolidation.

The private healthcare sector represents another important factor behind existing gaps in GDF coverage, since GDF supplies only operate through public national tuberculosis programmes. Indeed, evidence suggests that the private sector has a potentially substantial role in global tuberculosis control;[25] treatment in this sector is often not standardised and inappropriate;[26,27] and evidence suggests the presence of substandard and counterfeit drugs in the private marketplace.[16] All of these factors are of potential concern with respect to treatment success, and the generation of drug-resistant strains. Nonetheless, initiatives including Public–Private Mix[28,29] are examples of broad efforts to engage with the private sector, and

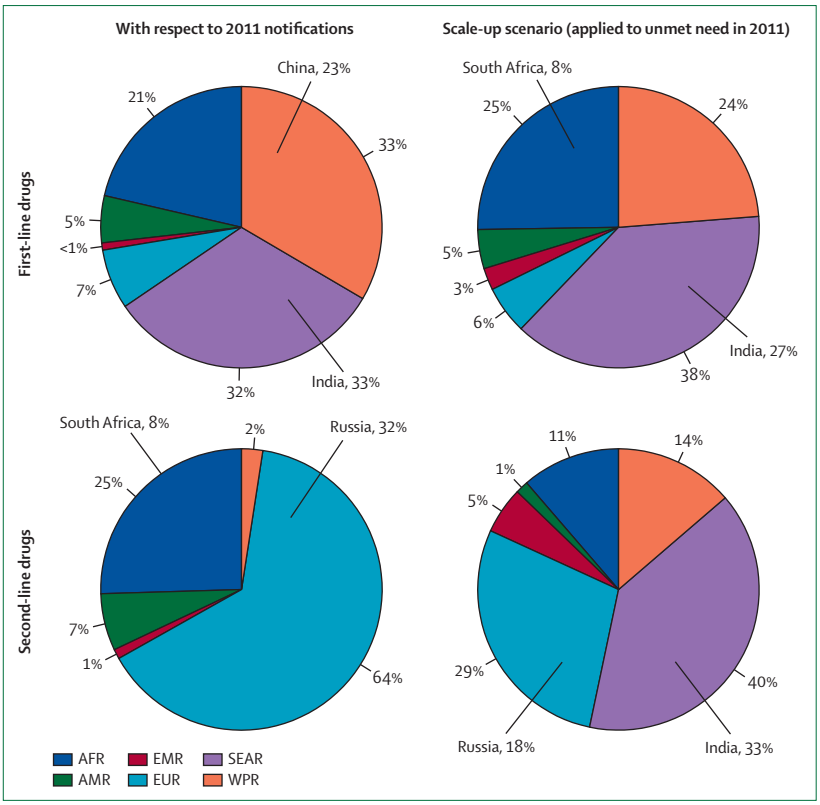

Figure 5: **Geographical distribution of cases not treated by Global Drug Facility-supplied drugs (unmet demand) as of 2011, for both first-line drugs (upper row) and second-line drugs (lower row)**
Data are plotted on the basis of reported cases (left-hand column) and estimated cases (right-hand column) under a scenario derived from the Global Plan to Stop TB, for scale-ups in case detection and drug sensitivity testing (see main text for further information). In some regions, unmet demand is dominated by individual countries; to illustrate this finding, in each chart the two foremost regions are annotated with labels for those countries that make the greatest contribution to unmet demand. AFR=WHO African Region. AMR=WHO Region of the Americas. EMR=WHO Eastern Mediterranean Region. EUR=WHO European Region. SEAR=WHO South-East Asia Region. WPR=WHO Western Pacific Region.

in particular to make standardised, quality-assured treatments available to private practitioners—a potential major channel for the GDF supply of quality-assured drugs.

Overall, the risk of drug resistance, arising from the use of substandard first-line drugs,[23] emphasises the potential public health importance of replacing these drugs with quality-assured drugs at the lowest possible cost. Moreover, and as described previously, sufficient consolidation and expansion in the market for quality-assured drugs could open the way for fundamental, potentially self-sustaining market transformations,[17] such as increased competition among manufacturers, and improved commitment of public funds towards quality-assured drugs. In this case, a key question is what amount of expansion might be needed to catalyse such changes.

Our analysis does have some limitations. Among methodological caveats, although the smoothing process for GDF data offers a straightforward approach for estimation of standing drug availability at any given time, it might also run the risk of overlooking the potential for actual fluctuations (or volatility) in a country's drug availability, arising from the dynamics of national drug supply and consumption. With the exception of global events such as the capreomycin shortage in 2011, this volatility might be more notable at the country level than at the aggregate, regional, or global scale (appendix p 5). Nonetheless, future work might explore this idea through the adoption of a more "bottom-up" approach from the country level, aiming to model and aggregate national stock data from a more dynamic perspective. Such an approach would, for example, incorporate the shelf-life of tuberculosis drugs more systematically than the smoothing approach we have adopted here. Second, with respect to the numerator in the equation for market share, we note that stringent inclusion criteria for counting treatments yield conservative estimates for GDF drug supply data. Future work might seek to compare these against alternative estimates for enumeration of treatments.

Such caveats notwithstanding, our analysis shows that, of the public market now apparent through notified cases, the GDF commands a substantial share of both first-line drugs and second-line drugs. Depending on future GDF strategy, as discussed previously, potential exists for growth in drug supplies through the GDF, including through the private sector; for second-line drugs in particular, such potential would be widened substantially by future increases in case detection and drug sensitivity testing. The next steps include investigation of how GDF's quality-assured drugs and programmatic effects might affect epidemiology, by leading to higher cure rates, lower death rates, and reduced transmission. How GDF involvement affects prices of quality-assured drugs and (more generally) how it could affect the market for drugs not subject to such standards (eg, by incentivising more manufacturers to register as quality-assured providers) should also be assessed. Lastly, for now-costly second-line drugs in particular, investigation is needed into how the implementation of new diagnostic methods (such as Xpert MTB/RIF[21]) might result in the identification of many new cases of multidrug-resistant tuberculosis, thus in the long term leading to lower second-line drug prices, and potentially more effective control of this disease in low-income, high-burden countries.

In conclusion, impressive progress in global tuberculosis control has been made in recent decades. Substantial challenges remain in achievement of universal, equitable, and uninterrupted access to high-quality treatment, and to address these challenges, concerted action is needed to close the present funding gaps. If fragmentation of public funds could challenge existing gains, then halting and reversing of any such trends would be an important example of such concerted action. The GDF, in partnership with the Global Fund, UNITAID, and public donors, could well be important in achievement of this goal.

Contributors
NA designed the study, did the analysis, and wrote the report. TC-L provided data, and contributed to data interpretation and to writing of the report. AV provided data and contributed to study design. CD designed the study, interpreted the data, and contributed to writing of the report.

Conflicts of interest
NA was partly funded for this analysis by the Stop TB Partnership. TC-L is a staff member of the Stop TB Global Drug Facility and WHO. AV has been a member of the Stop TB Partnership. CD is a staff member of WHO. The authors alone are responsible for the views expressed in this publication, which do not necessarily represent the decisions, policy, or views of WHO.

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