CONFIDENTIAL

Evaluation of the Global TB Drug Facility

STOP TB PARTNERSHIP

C/O WORLD HEALTH ORGANIZATION

Final Report

April 2003

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List of Abbreviations

CDC: Centers for Disease Control and Prevention
CIDA: Canadian International Development Agency
DOTS: Directly Observed Therapy, Short-course
DEWG: DOTS Expansion Working Group
EDM: Department for Essential Drugs and Medicines, WHO
4FDC: Four Fixed-dose Combination Drug
GDF: Global Drug Facility
GF/GFATM: Global Fund Against AIDS, Tuberculosis and Malaria
GLC: Green Light Committee
GLRA: German Leprosy Relief Association
GNP: Gross National Product
HBC: High burden country
IUATLD: International Union Against Tuberculosis and Lung Disease
KNCV: Royal Netherlands Tuberculosis Association
MDR: Multi-drug resistance
MoU: Memorandum of Understanding
MSH: Management Sciences for Health
NGO: Nongovernmental organization
NTP: National Tuberculosis Program
PHILCAT: Philippines Coalition Against Tuberculosis
STB: Stop TB
STBCB: Stop TB Coordinating Board
TA: Technical assistance
TB: Tuberculosis
TRC: Technical Review Committee
UNDP/IAPSO: United Nations Development Program/Inter-Agency Procurement Services Office
USAID: United States Agency for International Development
WC: Working Committee
WHO: World Health Organization

Background for the evaluation

Globally, tuberculosis (TB) is the leading curable cause of death due to an infectious disease. Although a cure has been available for fifty years and a cost-effective public health strategy to control TB (DOTS) has been promoted for much of the last decade, nearly two million people still die from TB each year. Only 27% of patients currently have access to DOTS worldwide.

Shortages of TB drugs are frequent and serious in many parts of the world, and have hampered the expansion of DOTS. Such drug shortages are a result of insecure financing, poor planning and inadequate procurement mechanisms. While poor drug supply is not unique to TB control, its impact may be especially severe. Drugs are essential to TB prevention and cure. Inadequate and erratic supplies severely undermine the TB control program and are contributing to the emergence of multi-drug resistant TB (MDR-TB).

In March 2000, the Stop TB Initiative convened a Ministerial Conference on "Tuberculosis and Sustainable Development" for representatives from twenty high burden countries (HBCs). These twenty countries comprised 80% of the global TB burden. The resulting "Amsterdam Declaration to Stop TB" called for the establishment of a Global Drug Facility (GDF) for TB to support "new international approaches towards ensuring universal access to, and efficient national systems of, procurement and distribution of tuberculosis drugs."

During the Stop TB DOTS Expansion Working Group meeting held in Cairo in November 2000, a Core Technical Group comprising representatives of the key stakeholders was created to finalize the draft prospectus for GDF. The Stop TB Coordinating Board (STBCB) endorsed this Prospectus in Bellagio in February 2001.

In addition to endorsing the Prospectus, the Board made two specific recommendations at that time. First, it proposed that GDF be managed by the World Health Organization (WHO). Second, the Board asked that GDF's performance and its governance arrangement be evaluated after two years, to review its impact and longer term potential.

This evaluation is an assessment of GDF's performance at the two-year mark. In January 2003, the Board asked McKinsey & Company (McKinsey) to evaluate the performance and organizational effectiveness of GDF as an external independent assessor. Our evaluation addresses four questions:

- What has been the impact of GDF to date, at a country and system level, and should the Stop TB Partnership continue to support it?

- What changes are required to GDF's operations and organization to improve its effectiveness? Hence, what additional funding is required?
- Should GDF continue with its current governance model with WHO? What changes are required, if any?
- Should the Stop TB Partnership consider an expanded scope for GDF, beyond offering first line TB drugs?

It is too early to measure GDF's impact in terms of tangible health outcomes and quantitative indicators. GDF was set up in early 2001; it approved its first grant in April 2001 and made its first drug shipment as recently as October 2001. Only a few countries are in the second year of their grant. Therefore, this evaluation is based on the model and processes employed by GDF, and on preliminary results from countries receiving GDF grants.

The evaluation was conducted by McKinsey during January-April 2003 with the support of a wide range of Stop TB partners and other relevant stakeholders *(Exhibit 1)*. The evaluation team visited 10 countries for in-depth discussions with country stakeholders and select field visits. Eight of the countries visited are current GDF grant recipients, while two have not applied for GDF support. The team received inputs from over one hundred and eighty international, regional and local experts from multilateral and bilateral organizations, technical agencies, nongovernmental organizations (NGOs), academia, foundations and developing countries. It also reviewed a wide range of internal and external documents relevant to this evaluation. The results and recommendations of the evaluation were presented to the STBCB at its meeting in Brasilia on April 4, 2003.

The evaluation team would like to thank everyone who contributed his or her time and expertise to this effort.

The findings from this evaluation are presented in the following report. It is structured in five sections as follows:

Executive Summary

1. GDF's impact to date and future role
2. Strengthening GDF's operations and organization, and funding need
3. Clarifying the governance structure of GDF
4. Stop TB Partnership's posture towards an expanded scope for GDF

Executive summary

GDF is well on its way to meet its objectives as outlined two years ago and the Stop TB Partnership should continue to fully support it. GDF has demonstrated results in improving access to TB drugs in many countries. It has also had success, though to a less extent, in catalyzing DOTS expansion. GDF could improve its effectiveness by strengthening advocacy, mobilization of partners and procurement practices. Furthermore, as GDF evolves from a start-up organization to a larger, more steady state form, key changes must be made to its organization to fill the leadership vacuum and skill gaps, recruit more staff and formalize key management systems.

GDF's unique three-part bundled model comprising grant making, procurement and partner mobilization for technical assistance (TA) is critical to its success. Maintaining GDF's direct grant making role is necessary for continued impact. To do this, the Stop TB Partnership must ensure funding of $20-30 million per annum for each of the next three years. However, GDF faces a serious funding gap, even to meet its 2003 commitments, which must be urgently addressed.

The current governance model, with WHO providing a legal entity and administrative support and the Stop TB Partnership providing an advisory "Board" and funding, has functioned acceptably, though not optimally. Going forward, the model should be maintained, but roles should be clarified.

Finally, a GDF-type model for diseases like HIV/AIDS and malaria is feasible and practical, if certain pre-requisites are in place. However, the respective disease partnerships should drive such an effort, and not the Stop TB Partnership. The Stop TB Partnership can gain some reputation benefits from such a move without risk of loss of focus on TB.

1. GDF's impact to date and future role

GDF was set up in early 2001 with a two-part mission: first, to expand access to high quality TB drugs and second, to indirectly facilitate DOTS expansion. It delivers its mandate through a unique bundled model that includes three elements: providing grants, procuring drugs, and mobilizing partners for TA.

GDF has demonstrated proof of concept as an innovative and high impact model for increasing access to TB drugs:

- *GDF is having a positive effect in countries.*
  It is too early to report the GDF's impact in terms of tangible health

outcomes. However, in its first two years of operations, it has made grants that reach 10% of the estimated 8.8 million TB patients worldwide in 24 countries, including 8 HBCs. In many countries, GDF has been able to achieve a positive effect beyond access to drugs by catalyzing expansion of DOTS plans, and securing additional support from donors and technical partners.

- *GDF offers multiple benefits at a system level.*
  GDF's bulk purchasing has helped achieve significant price reductions in TB drugs. By promoting standardization and innovation in drugs and packaging, GDF is encouraging patient compliance and rational use. It has also facilitated increased access to treatment for underprivileged communities. Finally, GDF is helping increase awareness of price and quality standards by promoting the creation of a white list of suppliers through WHO.

- *GDF's services are being delivered in a resource-effective manner.*
  GDF has set up operations with a lean team, in a short time period, with low overhead costs. Fears of negative effects on regional and local procurement and supply mechanisms remain unfounded.

- *The GDF model is a key driver of its success.*
  GDF's unique three-part "bundled" proposition provides substantially higher impact than would an unbundled model. In addition, GDF's success stems from its focused mandate for TB drugs, support from a well-functioning partnership like Stop TB, and a strong and committed management team with dynamic leadership.

We believe that the Stop TB Partnership should continue to support GDF to fulfill its mandate. Specifically, we recommend that GDF:

- Maintain and strengthen its bundled model. However, innovations and modifications in the delivery of individual elements are possible and desirable.

- Focus on its "core beneficiaries" for its grants, i.e. countries where access to drugs is one of the main barriers to DOTS expansion. These countries would most benefit from GDF's multiple services.

- Remain focused on its core services. GDF does not need to directly offer services beyond drug supply, for example, in-country drug management. Instead, it should proactively review these areas during application/ monitoring and actively mobilize partners to address any gaps.

2. Strengthening GDF's operations and organization, and funding need

GDF has accomplished a great deal in its first two years. It established sources of funding; launched operations in a short time; put in place a dynamic and innovative team that is widely respected; and successfully accessed administrative support through WHO. Going forward, to achieve its full potential, deliver successfully on its direct and indirect goals and increase the confidence of key partners, it must now strengthen all these areas.

However, GDF faces a significant funding shortfall in the coming months to meet even its 2003 commitments. Furthermore, GDF needs $20-30 million per annum over the next three years. The Partnership urgently needs to address the 2003-funding gap; it should also consider pre-funding, or at least pre-committing donations, to enable GDF to actually guarantee grants to countries for the desired period of time. Specific processes for fundraising and oversight should also be developed to avert such a problem again.

We believe that GDF must maintain its direct funding role in the near-term. The ability to directly provide grants is essential to ensuring that countries comply with its conditions. Over time, GDF should explore whether it is possible to establish mutually beneficial relationships with the Global Fund and other key donors, and gradually phase out its funding role.

In addition to securing funding, we recommend that GDF pursue selected operational improvements, build its management team, and develop flexible and responsive administrative support:

- *Operational improvements in advocacy, partner mobilization, and procurement are needed.*
  Generally, systems and processes were set up quickly and efficiently, and are independent and technically credible. However, some processes like procurement have not met expectations. Other areas like building awareness of GDF, and mobilizing partners and M&E are nascent and need to be fully developed. Strengthening execution in these areas is critical to increase GDF's impact, especially to fulfill its broader mandate beyond access to drugs.

- *The management team must be strengthened.*
  Although the current team and leadership is widely respected for its dynamic, innovative, "can do" spirit, this team needs to be strengthened by augmenting staff strength and skill sets; establishing more formal business systems to facilitate planning and execution; and recruiting credible and stable leadership to fill the current vacuum.

- *GDF must ensure more flexible and responsive administrative support.* The administrative arrangement with WHO helped launch GDF quickly, with low overhead. However, an administrative arrangement that offers more flexible staffing and legal support, more cost-effective services, greater transparency in payments and services, and a partnership-oriented attitude is now necessary.

3. Clarifying the governance structure of GDF

GDF was set up in 2001 as an "embedded legal identity housed in WHO". It has a unique governance model that needs to balance the roles of WHO, which provides the legal umbrella for GDF, and the Stop TB Partnership, which provides funding and TA through its partners.

We believe that the current governance model has reasonably met the needs of GDF. Stop TB partners are broadly aligned on its mandate. Furthermore, WHO has had a relatively "hands-off" direct role in governance. This has given the Stop TB Partnership and GDF management team much needed flexibility.

However, the STBCB has provided little strategic direction for GDF. There is significant disagreement on the STBCB on major issues like GDF's scope and potential to expand. Roles of WHO, the STBCB, and the Working Committee (WC) have not been clearly specified and there is lack of clarity on which party is responsible for GDF's successes or its mistakes.

We believe that the current model continues to be appropriate for GDF's governance. However, WHO and the STBCB must clarify their respective roles and establish clear accountability for decision-making, oversight, and legal liability.

4. Stop TB Partnership's posture towards an expanded scope for GDF

A GDF model to address access-related issues for other disease areas is both feasible and desirable. In particular, HIV/AIDS and malaria are disease areas where such an approach makes sense from a technical, business, and implementation perspective, although there are important issues in each area that must be addressed. Of course, not all diseases may need as sophisticated or integrated a model as the GDF's bundled model. Only diseases that demonstrate a technical, economic and implementation fit would most benefit from this model.

However, this is not an expansion of the activities of the current GDF, but of the GDF model to other diseases. Furthermore, demand for such a model for HIV/AIDS or malaria must come from the respective disease partnership. As seen

in the case of TB, partnership support is critical for the success of a GDF model. Hence, the Stop TB Partnership cannot drive expansion of the GDF model for other diseases.

With respect to the convergence of GDF and GLC, such a move is desirable and feasible as it would yield synergies in areas like application, advocacy and procurement operations and some aspects of M&E, both for the respective secretariats and countries that interact with them. However, unique technical and supply related aspects of GLC must be maintained.

We believe that the current GDF faces little risk of losing focus on TB in the event of such expansion of the GDF model; people and funding resources for TB are unlikely to be used in a different disease area. Instead, the Stop TB Partnership and GDF could potentially benefit from an enhanced reputation, from cost savings through shared infrastructure, and from increased leverage with countries.

The Stop TB Partnership does not need to proactively encourage such expansion. However, it could encourage such a move in a limited manner by releasing a white paper or holding a conference to discuss this subject with relevant stakeholders.

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Main report

The following report gives the results of the evaluation of GDF conducted by McKinsey during January-April, 2003. The objective of the evaluation was to provide an independent external assessment of GDF's impact to date; ways to improve its effectiveness and funding required; robustness of its governance model and changes if any; and feasibility of an expanded scope for GDF.

The report references supporting exhibits that are attached. These provide detailed findings and analysis to support the conclusions and recommendations contained in this report.

1. GDF'S IMPACT TO DATE AND FUTURE ROLE

This section reviews GDF's current role, its effectiveness at a country and system level to date, and lays out recommendations for its role going forward. Since it is too early to measure GDF's "impact" in terms of tangible health outcomes, this section focuses on the following dimensions: early feedback from countries, the robustness of GDF's business model, its resource-effectiveness, the strength of its management team and the level of support from relevant partners.

In summary, based on the results in its first two years of operations, GDF has demonstrated proof of concept as an innovative and potentially high impact model. It has shown positive results at a country and system level in addressing drug access issues, and to a less extent, catalyzing DOTS expansion. These benefits have been delivered in a resource-effective manner with few negative effects. GDF's unique three-part "bundled" proposition of grant making, procurement and partner mobilization for TA is key to its impact. Other contributing factors are its focus on TB, the supportive role played by the Stop TB Partnership and GDF's dynamic team and leadership. The Stop TB Partnership should continue to support the GDF in its current role and mandate.

1.1. Introduction to GDF: role, services and structure

Current role of GDF and services provided

GDF was set up in early 2001 with a two-part mission: first, to expand access to high quality TB drugs and second, to indirectly facilitate DOTS expansion *(Exhibit 2)*. GDF fulfills this mission through four distinct functions:

- *Grant making:* GDF offers a grant of first-line TB drugs to countries that qualify for support.
- *Application, review, monitoring and evaluation (M&E):* Each country's application for a grant is scrutinized by a Technical Review Committee (TRC), followed by an ongoing M&E process post-grant, in order to ensure rational use of the drugs within the DOTS system.
- *Procurement:* Drugs are procured through a contractual partner on a centralized pooled basis and shipped to the country's port of entry. Countries are responsible for in-country drug management and delivery.
- *Partner mobilization:* GDF helps mobilize Stop TB partners to provide technical support to the country in several areas, including preparing the application, conducting M&E and setting up in-country drug management.

In addition to drug grants, GDF also offers a direct procurement service. This is a nascent service line for countries that have the ability to fund their drug purchases with own funds, loans or monetary grants from donors. These countries can use GDF's procurement mechanism and benefit from its negotiated prices, quality assurance and lead times.

Structure of GDF

GDF is structured as a lean partnership. It has a small and dedicated Secretariat that provides administrative support and ensures alignment in decision-making and execution across GDF's various roles (i.e. grant making, procurement and partner mobilization for TA). These elements are delivered through GDF's contractual and collaborating partners (*Exhibit 3)*. GDF is legally governed by WHO; it is an "embedded legal entity housed within WHO". In practice, WHO executes its role through its participation in the STBCB, which acts as a "Board" for GDF. The governance and housing arrangement with WHO facilitates access to WHO's country infrastructure, coordinated TA [since WHO also houses the secretariat of the DOTS Expansion Working Group (DEWG)[1] of the Stop TB Partnership] and administrative support. WHO thus plays a "general" contractor role for GDF[2].

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[1] DEWG is one of the six working groups of the Stop TB Partnership, and has the responsibility for mobilizing, supporting and coordinating TA on a global and country basis for the expansion of DOTS

[2] Developing Successful Global Health Alliances. Bill & Melinda Gates Foundation. April 2002. In a "general contractor" model, one partner is the clear leader, decision maker, and controller of funds – and its staff coordinates and steers the alliance. Since the general contractor model places substantial power in the hands of one partner, it

1.2. GDF's impact to date

GDF seems to be well on its way to meeting both its goals of expanding access to drugs and facilitating DOTS expansion. It has developed a broad reach across countries in less than two years of operation *(Exhibit 4*) and has helped drive price reductions, standardization and improved awareness of quality and prices at a system level. Benefits have been delivered in a resource-effective manner with few negative effects.

GDF's benefits at a country level

GDF's drug grants currently reach 10% of the estimated 8.8 million TB patients worldwide. These grants serve 8 of 22 HBCs representing 631,000 patients, as well as another 16 non-HBC countries representing 252,000 patients, with significant growth targeted for 2003.

The evaluation team studied in detail eight countries supported by GDF *(Exhibit 5)*. Based on these countries, GDF seems to have had varying levels of positive impact:

- *High (transformative) effect:* In countries like Moldova and Nigeria, GDF's intervention has catalyzed political commitment within the country, thus encouraging significant expansion of country plans for DOTS treatment. In addition, partners have mobilized financial and non-financial support. In these countries, GDF has demonstrably accelerated and expanded the DOTS programs.

  For example, in Moldova, GDF's grant of drugs ensured the government's commitment to DOTS and helped reduce the time for DOTS rollout from five years to one year. It also helped the government secure funding for other areas of DOTS implementation. In Nigeria, GDF provided drugs for sixteen provinces not covered by DOTS, thus expanding DOTS programs to cover the entire country. The grant also catalyzed funding from donors and the government (federal and state level) for infrastructure improvements. Further, technical agencies that bought drugs from separate sources are now

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can be highly effective in environments requiring speed and risk taking. To function effectively, however, the general contractor must be a leader in the field – that is, an organization that others are willing to subcontract to. The general contractor also must create valuable opportunities for the subcontractors, for instance encouraging them to expand their expertise in desired ways, as well as ensuring that the overall alliance goals are relevant to them and that subcontractors feel ownership of the various initiatives.

coordinating procurement through GDF's direct procurement service. This has helped simplify drug management across Nigeria.

- *Medium (facilitating) effect:* In countries like Kenya, Uganda and the Philippines, GDF's intervention has addressed major drug needs and helped marshal additional resources to close major gaps in DOTS treatment.

  For example, in Uganda, GLRA, a program partner, sourced TB drugs worth $500,000 per annum at $35 per treatment. GDF's grant now ensures that more patients are treated due to lower drug costs, and allows GLRA to re-allocate that funding to expand its activities to three new regions and purchase equipment and vehicles for TB programs. In the Philippines, GDF plays three roles. Its emergency grant has helped meet urgent drug needs. Its regular drug grant is a key element of the public-private partnership developed by PHILCAT, the national association of NGOs addressing TB, and the Ministry of Health. Free GDF drugs will provide an incentive for private practitioners to adhere to DOTS, undergo relevant training and notify cases to the National TB Program (NTP). Finally, the NTP is buying TB drugs through GDF's direct procurement service to overcome various procurement-related issues contributing to delays and quality issues.

- *Low (supporting) effect:* In countries like Somalia and India, GDF's intervention has addressed some of the country's drug needs. However, it has had limited influence on other aspects of DOTS expansion.

  In Somalia, for example, the TB program is hampered by severe infrastructure constraints, which GDF's drug grant alone cannot address. Further, GDF has also not been able to build relationships with non-traditional partners in a government-less environment. In India, although the GDF grant will help treat 200,000 incremental patients annually, its role is primarily to provide funding for these treatments. Since the NTP already has an effective procurement mechanism, suppliers and partners in place, there is limited need for GDF's other services. Consequently, GDF's impact on the overall TB program is relatively low.

GDF's benefits at a system level

At a system level, GDF has begun to have a positive effect in several areas *(Exhibit 6)*:

- *Price of TB drugs:* Since GDF combines centralized pooled procurement with a grant making function, it is able to leverage its bulk purchases and guarantee minimum demand to negotiate prices with drug manufacturers. Even in countries with limited/no GDF grant, it has indirectly helped raise awareness of prices and make shortcomings of local suppliers apparent.

- *Treatment standards:* GDF has helped promote the use of logistically superior and patient-friendly treatment regiments, like fixed dose combination (FDC) drugs, blister packs and patient packs. Further, its insistence on using these drugs only in a DOTS setting with a robust TB control plan encourage rational use in a country.

- *Quality awareness:* GDF has also used its relationship with the WHO to develop a "white list" of pre-approved TB drug suppliers.

- *Access to treatment for underprivileged communities:* Although GDF does not claim a direct link between its drug grant and improved access for the poorer sections of society, it has the potential to have impact in this area. GDF's selection criteria for countries to receive grants focuses on countries with a per capita GNP of less than $3,000, with an emphasis on countries below $1,000. Second, GDF's grants ensure that drugs are provided free of charge to ensure access to poor patients. Finally, since GDF drugs support DOTS expansion and are "additional" in the system, a "trickle-down" effect of these drugs to the poorest sections of society can be expected.

Resource effectiveness to deliver benefits

GDF has delivered these benefits in a resource-effective manner.

- *Lean team:* GDF has a lean partnership model, with a small core staff of nine full-time people and contractual and collaborating partners for most services. This model ensures GDF has access to the best resources (for example, relevant technical partners from the Stop TB Partnership); the flexibility to select the right partners (for example, procurement, quality assurance through limited international competitive bidding); and no duplication of available services (for example, drug management expertise). WHO's role as a "general contractor" has also facilitated fast decision-making, risk taking and the ability to select the right partners based on need.

- *Cost-effective set-up:* GDF's benefits have been delivered in a cost-effective manner *(Exhibit 7)*. It has spent $11.7 per patient treated to date, which is approximately a 17 percent overhead. This overhead

appears reasonable, given TA, M&E and quality assurance are drug-related expenses. If such expenses are excluded from overheads, GDF overheads are 12 percent of total spend. Furthermore, GDF's drug prices are significantly lower compared with other options. Hence, overhead as a percentage of total spend may seem higher. These expenses include secondments from partners and per diem costs for participation in the TRC and country visits. However, other types of partner services such as support to a country in preparing the application or advice on drug management are not included.

- *Basic operations set up in less than one year:* GDF received its first application from Togo in January 2001 and made the first round of TRC decisions in April 2001. Moldova received the first shipment of drugs in October 2001. In less than two years of operations, GDF has received fifty-four grant applications, approved forty and supplied drugs to nineteen applicants. This includes four countries which are now in their second year of grant. However, some parts of the GDF model, including M&E capability, active partner mobilization and advocacy, are not fully in place yet.

Assessment of potential negative effects of GDF

We have evaluated three possible areas where GDF could have negative effects, as described in Exhibits 8-10. Overall, GDF's activities have low potential for negative impact.

- *Effect of global pooled procurement:* Some concerns have been voiced that the GDF could negatively affect regional and local procurement capacity. We believe these concerns are over-stated. GDF is unlikely to negatively impact local procurement ability or any regional procurement efforts.

- *Effect of making grants-in-kind:* There are some concerns that GDF could become a monopsony due to a bundling of its grant and procurement role. However, GDF's effect to date on local suppliers has been neutral to somewhat positive. In fact, it has tried to proactively address such concerns. For example, GDF has facilitated the creation of a "white list" of suppliers to encourage a broad base of quality suppliers across regions.

  Some partners are also concerned that countries could become over-dependent on GDF and sustainability of the TB program in these countries could be affected. For example, a country could discontinue a budget line for TB drugs if it receives a GDF grant. It is not in GDF's interest to build such dependence. In fact, GDF explicitly aims to avoid

dependence by insisting on a separate budget line for TB drugs and monitoring that the grant is truly "additional" in the system. For example, Kenya was shown an "orange light" during it application for a second round of grants as it did not adhere to the grant's conditions. Kenya subsequently met these conditions.

Going forward, GDF could further mitigate potential negative effects by actively engaging NTPs and donors in discussions on the financial sustainability of a country's TB plans and a gradual phase-out of GDF's grant making role.

- *Effect of driving standardization/innovations*: Some partners have argued that GDF should not promote standardized regimens like 4FDC drugs and should simply provide the products demanded by countries. The Stop TB Partnership should resolve such issues in discussions with WHO, as setting normative standards does not fall under GDF's mandate.

1.3. Factors contributing to GDF's impact

GDF's unique three-part bundled proposition

The GDF proposition has three main elements *(Exhibit 11)*:

- *Grant making:* GDF provides drug grants to countries that demonstrate a need and whose applications are approved by the TRC and the STBCB.
- *Procurement*: GDF provides global pooled procurement and delivery to a country's main port of entry through UNDP/IAPSO, GDF's current procurement agent.
- *Partner network, including WHO*: GDF mobilizes Stop TB partners for various services, including advocacy, support to countries to develop applications, M&E and in-country TA related to the drug grant.

In the GDF model, the above three elements have been combined under one operating entity with aligned decision-making. While each of these elements is valuable in its own right, it is the unique bundling under one operational entity that enables its full impact for the following reasons *(Exhibit 12)*:

- Grants-in-kind have proven effective to mobilize both partners and governments.

- Grants and a partner network allow the Stop TB partners to provide TA to support the grant. Such assistance has more impact when drug supply is assured. Similarly, a drug grant with coordinated partner support for drug management, training and other services has a greater likelihood of drugs reaching patients.

- Grants and procurement allows GDF to lower prices by pooling demand, ensure timely procurement and promote standardization/ innovation in treatment.

- Grants-in-kind linked to procurement reach countries faster than through separate granting and procurement processes and with fewer leakages.

An unbundled system, i.e. a separate funding agency that makes grants to countries *and* countries independently procuring drugs from public or private sector agents *and* technical partners independently supporting countries will not have the same impact. Such a set-up cannot encourage standardization/ innovation, drive prices down through bulk procurement, reduce delays and leakages, or align support from partners.

The bundle does not need to necessarily reside in one legal entity. Instead, shared decision-making and operational alignment between two or three bodies that collectively cover these three elements would also be effective.

Other factors contributing to GDF's impact

In addition to GDF's bundled proposition, there are three other factors that have contributed to its good start, namely:

- *Focused mandate:* GDF has been able to demonstrate early benefits because of its complete focus on first line TB drugs, which is a relatively narrowly defined group of products (about 10 products). As a result, GDF has been able to focus on price negotiations; standardization and innovation in first line TB drugs; and develop a targeted set of partners in only one disease area.

- *Support from a well-functioning partnership:* The Stop TB Partnership can be credited with supporting GDF from inception. Partners have been aligned on GDF's goals, proposition to customers and operating model; key Stop TB donors have provided funding support; and Stop TB partners have provided TA. For example, WHO created the white list of suppliers and guidelines for introduction of FDC; MSH has seconded functional experts and facilitated the Washington Drug

Management Conference; IUALTD, KNCV, CDC and others have provided experts for the TRC, country visits and in-country support.

- *Committed management team:* GDF's management team is a fresh, dynamic and innovative group with strong leadership. All stakeholders have commended this team for the quick start up of GDF's operations (discussed in more detail under 2.3).

1.4. GDF's role and proposition going forward – Recommendations

Customers - GDF should focus on its "core" beneficiaries

HBCs and other developing countries with a high TB burden will continue to need GDF in the near-to-medium term. These countries lack the funds and/or procurement capacity to access high quality, cheap TB drugs.

However, GDF is not likely to serve all these countries. Some countries do not need GDF at all; others need it in varying degrees. The level of impact that GDF can have also varies by country. Accordingly, there are three dimensions that define which countries are likely to most benefit from GDF's services:

- *Availability of affordable, high quality drugs:* GDF best serves countries where access to TB drugs, due to a funding gap and/or problem with setting up an efficient procurement system, is one of the main barriers to DOTS expansion. Where there are other major problems with the country's TB program, a GDF drug grant alone will not be adequate. For example, in the case of Somalia, which has severe capacity constraints in physical and human resource infrastructure.

- *Willingness and ability of the government to take concerted action to address the TB burden:* Countries with a committed and strong Ministry of Health and NTP office are more able to leverage GDF well. Such countries are better able to develop a robust TB plan, coordinate with other partners to fill gaps and ensure quality implementation and monitoring of conditions associated with the GDF grant. In the absence of a strong ministry or NTP, GDF's ability to have impact is diminished significantly.

- *Presence of GDF's partners in that country:* The GDF model strongly relies on technical partners to support the country on other aspects of the TB program, for example, drug management expertise and staff training. GDF delivers most of its services through the technical partners in the Stop TB Partnership like WHO, IUALTD, KNCV, MSH and CDC. Hence, countries with a strong presence of these partners are

better able to leverage GDF. In countries where these partners have a smaller/no presence, GDF has been unable to identify and work with new partners, for example, in Myanmar and Somalia.

Based on these three dimensions, GDF's potential beneficiaries can be classified into three groups. Of these, the "natural" and "challenging" beneficiaries should represent GDF's "core" constituents *(Exhibit 13)*:

- *"Natural" beneficiaries:* Countries that meet all the above criteria. These countries can best leverage GDF and therefore, have the highest potential for impact. GDF should approach them proactively.
- *"Challenging" beneficiaries:* Countries that have similar access issues as "natural beneficiaries", but lack a strong ministry of health, NTP or traditional partners. The need for GDF is high in these countries, but it would have a challenging time serving them. GDF needs to expend more effort in these cases.
- *"Opportunistic" beneficiaries:* Countries that have little fit with the GDF proposition. These are often large countries, with a relatively strong domestic supplier base and procurement capacity, ample funding for TB programs and support from many partners. GDF cannot and should not serve these countries with its classic model. It probably still makes sense to maintain a dialogue and tap into opportunities to collaborate on specific issues, for example, emergency drug needs.

Even with its "core" beneficiaries, GDF should proactively emphasize planning for phase-out, although it is too early for such a move in countries where it currently operates. GDF should initiate such discussions with countries and help them develop a timetable to ensure a sustainable TB plan, initially phasing out the grant (in favor of other donors or lenders like the Global Fund and World Bank) and later phasing out procurement support.

Services – Continue current services with improved partner mobilization

GDF primarily addresses drug access constraints for its beneficiaries. Its services begin with reviewing applications for assistance and end with supplying drugs to the country. GDF does not distribute drugs within the country or directly provide TA. Instead, it aims to identify major barriers to DOTS expansion other than drug supply and mobilize partners to address them *(Exhibit 14)*.

Some countries and partners have argued for GDF to expand its model to actively provide and/or fund services related to the drug grant. These might

include in-country drug management support, lab facilities, training and procurement of consumables.

From a country and operational perspective, such an expansion in GDF's services is neither necessary nor practical *(Exhibit 15)*. Instead, GDF should explicitly assess these barriers during application and monitoring; identify gaps; and mobilize partners to address them. However, at a systemic level, it should continue to facilitate high-impact low-investment efforts, which would also help to increase awareness of the GDF brand. These include conferences on related areas like drug management and proactive sharing of best practices across countries and partners in areas like planning for transition to FDC and using a GDF grant for public-private collaboration.

2. STRENGTHENING GDF'S OPERATIONS AND ORGANIZATION, AND FUNDING NEED

GDF is off to a good start and seems to be well positioned to make progress towards its direct and indirect goals. Although its full impact in terms of health outcomes is yet to be seen, GDF's proposition and model are robust. This section reviews GDF's core functions, processes, human resources and administrative set-up to assess their effectiveness to date and for the future; outlines recommendations on necessary improvements; and provides an estimate of the financial resources required to allow GDF to fulfill its mandate.

In summary, GDF has launched operations in a very short time and established core functions and processes quickly. Its management team is dynamic and credited with much of the success to date. However, to achieve its full potential and increase confidence of donors and partners, GDF must improve execution in multiple areas over the next 12 months. This includes raising money for grants; improving operations in advocacy, partner mobilization and procurement; strengthening the management team's leadership, skills and formal systems; and ensuring more flexible administrative support. To do this, the Stop TB Partnership must ensure direct and stable funding of $20-30 million per annum for the next three years to GDF. It is critical that the immediate funding gap in 2003 also be addressed urgently. In addition, GDF should explore a mutually beneficial relationship with the Global Fund (GF) and other key donors/lenders as a recommended agent.

2.1. GDF's grant making function

Rationale for GDF's own grant making role

Effectiveness of GDF's full value proposition depends on it providing grants *(Exhibit 16)*. This gives GDF both the "carrot" (i.e. leverage to ensure that countries accept technical and other requirements) and the "stick" (i.e. M&E to enforce performance) to ensure impact beyond supplying drugs alone. In the absence of grants, GDF's impact diminishes across all possible scenarios *(Exhibit 17)*. As a direct or recommended agent, GDF would lose this "carrot and stick".

While a mandated agent relationship could still work, as in the case of Global Fund's relationship with the Green Light Committee (GLC) for second line drugs for MDR-TB, it is unlikely that a donor would agree to such a relationship for generic, widely manufactured drugs like first line TB drugs. Therefore, GDF needs access to its own funding to maintain its ability to provide grants. GDF should still pursue the direct procurement model for

countries receiving funding from GF or other sources, as this proposition also furthers the aims of GDF. (This is further explained below).

Performance to date on grant making

GDF has received relatively stable funding for grant making in the first two years. Its requirements for 2001 and 2002 were largely met, with a small shortfall in 2002. Core donors like CIDA and the Government of Netherlands have maintained or increased their involvement, and new donors, like USAID and the World Bank, have joined. Over eighty percent of funds received to date have been disbursed.

However, as discussed at the STBCB Meeting in April 2003, GDF faces a significant funding shortfall in 2003. (This is further explained in section 2.5). There are a several possible drivers for the funding shortfall. One driver is clearly the lack of advocacy and brand building on both the international and country levels. Another is inadequate cash flow planning or the flagging of financial issues on a proactive basis. As a result, the Board only recently engaged on major fundraising issues, including the serious financial crunch expected in mid 2003.

Recommendations to strengthen GDF's grant making

GDF's direct grant-making role can be sustained with funding levels of $20-40 million per year, based on top-down estimates *(Exhibit 18)*. We reached this conclusion based on the three assumptions:

- First, GDF should prioritize countries based on both, needs and its ability to have a positive impact. Therefore, "natural" and "challenged" countries are the top priorities. These countries represent roughly 60% of the 8.8 million annual estimated TB cases worldwide, or 5.2 million patients.
- Second, it is neither necessary nor desirable for GDF to grant 100% of these countries' drug needs to catalyze DOTS expansion. Providing 100% of a country's needs could cause a dangerous monopoly situation and make exit harder for GDF.
- We believe that GDF should meet one to two thirds of a country's needs, on a case-by-case basis. At one to two thirds of 5.2 million patients, GDF could realistically support 1.7-3.5 million patients (i.e. 20-40% of estimated TB cases world-wide). At $10-12 per treatment, this represents a funding requirement of $20-40 million for GDF.

Other funding sources – Recommendations

In addition to gaining its own funding, GDF should explore developing relationships with large donors and lenders. These might include GF, the World Bank and other bilateral agencies. In such a relationship, the donor or lender would align its application process with GDF's and relax conditions already addressed in GDF's application process, like the need for M&E.

These agent relationships would be mutually beneficial. GDF would gain an additional source of leverage with countries (although less than if it had its own grant) and also some income through fees on direct procurement deals. For the donor or lender, such a relationship is a quick and reliable way to have impact in a country. Grants-in-kind require less set-up time and have less potential for leakage. Furthermore, GDF is an established, recognized organization in many countries today.

GDF's grant function could coexist with direct support from other donors/ lenders for the next few years. Over the next 3-5 years, on a country-by-country basis, GDF should gradually reduce its grant function. As its bundled proposition ensures robust technical and M&E processes within each country, and as its relationships with donors/lenders are strengthened, GDF should proactively initiate a phased ramp down in discussions with donors/lenders and countries.

2.2. Operational improvements in the business system

The GDF business system comprises four distinct functions – grants (this has been covered in section 2.1), application/review, procurement and coordination of Stop TB partners. These functions were assessed individually and as a business system to evaluate their effectiveness to date and their ability to meet the future needs of GDF.

Assessment of the current system

In summary, GDF's business model has served it well in meeting the needs of an organization in "start-up" mode *(Exhibit 19)*. Countries find its application processes simple and effective and the TRC is widely regarded as a highly competent and independent review body. A cost-effective procurement mechanism was set up in under six months, prices have been negotiated to achieve significant reductions and drug delivery time has been reduced substantially as compared with countries' earlier mechanisms. GDF has also mobilized Stop TB partners in a variety of ways, including secondments for functional expertise, participation in the TRC, country visits and TA.

However, since the GDF model is a relatively new concept and was set up quickly with a lean team, two issues have developed that need to be addressed. First, some procedures like selection of procurement agent and suppliers were set up using unconventional approaches to ensure speed. These procedures were not fully in line with expectations of partners and donors. While they have since been modified, GDF is yet to communicate these changes externally to undo the negative perceptions. Second, some important initiatives have been downgraded in priority potentially due to lack of staff. These initiatives include actively building awareness of GDF among donors, partners and countries, building M&E capacity and tools, and actively identifying new partners in countries where traditional partners have limited presence or gaps.

Key improvements required – Recommendations

GDF should focus on three key areas for operational improvements. These are highlighted below and further discussed in Exhibit 20.

- *Build awareness/advocacy for GDF:* There is relatively low awareness of GDF and its benefits, both within some countries and in relevant multilateral, bilateral and other agencies. This limits GDF's ability to execute its broader mandate of catalyzing DOTS expansion, raising adequate funds and coordinating efforts among donors, Stop TB partners, and in-country agents. Therefore, GDF needs to engage in significant "brand building" at both a system and country level, including systematic communication of its mandate, model, benefits and future requirements to key stakeholders.

- *Mobilize partners:* Mobilizing partners to deliver TA is a key element of the GDF proposition, especially to fulfill GDF's broader mandate of facilitating DOTS expansion. However, GDF is yet to develop a robust process that will identify key stakeholders in each country, mobilize them to address key bottlenecks, and facilitate relationships with non-traditional partners outside its core group. Developing a mechanism to fully leverage in-country WHO officers/infrastructure and partners, set up regular communication with them and ensure closer coordination with the DEWG will be a key requirement for GDF to deliver impact going forward.

- *Strengthen procurement:* Many concerns have been raised about the robustness of GDF's initial procurement approach. Most of these concerns have been addressed in the recently revised tendering approach. However, GDF needs to explicitly communicate these changes to key stakeholders to undo any negative perceptions.

Second, direct procurement is a new service offering that is unlikely to operate with the same procedures and economics as drug grants. Many countries are unaware of GDF's direct procurement services and there is some confusion on how this model would work. Direct procurement may require GDF to more proactively build relationships with the ministry of health and finance in countries and with donors to these countries; modify its application and technical review process; or waive selected grant and M&E requirements that are unrelated to direct procurement. GDF also needs to clearly articulate its role versus that of its procurement agent, and develop an economic model for itself, its agent and countries that meets the needs of all parties. GDF also needs to needs communicate its approach to countries.

In addition to the above three areas, more detailed feedback on specific areas of improvement has been provided to GDF's management team.

2.3. Human resources plan

Assessment of current management and systems

At start-up, GDF's management team was expected to be lean and innovative, and to quickly build credibility and access to countries. Additionally GDF needed to access strong and independent technical expertise to evaluate applications, and to coordinate with other TB efforts with minimal duplication.

GDF's management team has largely met expectations *(Exhibit 21)*. The success of GDF has been widely credited to the team's dynamism, innovation, "can-do" spirit, and strong and technically competent leadership. The TRC is highly credible and has functioned independently; countries have welcomed its feedback. The management team has also accessed country, technical and functional expertise effectively through WHO and other partners; it has leveraged secondments rather than build skills from scratch and duplicate resources.

However, going forward, the team will need to be strengthened to fully meet the needs of a growing GDF *(Exhibit 22)*. GDF plans to significantly expand the number of countries its supports. Many of these countries are in their second year of the grant, and require close monitoring. GDF's current team is significantly understaffed to meet these needs. Furthermore, the team is relatively young and has limited "business" experience. The team also lacks skills in key areas of marketing/brand-building, fundraising and M&E, and developing management systems. The current leadership transition will be a challenging period, as the GDF tries to replace a strong leader while maintaining momentum.

The risks of not addressing these human resource issues are high. They include limiting GDF's growth due to inadequate financial and operating systems, and reducing GDF's credibility with donors and other key stakeholders.

Key improvements required – Recommendations

While these human resource gaps are serious, they are typical for an organization moving from start-up mode to steady-state operations, as it tries to formalize management roles, structure, and systems, and as it builds a "business" mindset for decision-making and operations.

The following recommendations suggest ways to strengthen GDF's management team, skill sets and systems. However, care should be taken not to over-compensate for these formal mechanisms or introduce highly specialized roles. The GDF team culture of innovation, flexibility, speed and focus on "getting the job done" is critical to its future success and should not be compromised.

GDF's human resources plan must address three key areas:

- *Hire a GDF senior manager to provide credibility and stability to the team:* The search should be a key priority. The Stop TB Partnership could consider re-negotiating the MoU for a more senior post, to reflect the importance of the position and to attract high caliber talent. Candidates should fit with GDF's culture and have substantial managerial expertise, technical skills, and credibility with key partners, including WHO, to be able to manage them. Additionally, the candidate must have a strategic mindset and an ability to raise GDF's profile.

- *Close coverage/skill gaps in functions critical to GDF's business model:* GDF needs to professionalize three key areas, namely planning (strategic, financial and operational); monitoring and knowledge management; and marketing/resource mobilization. To do this, GDF needs to hire professionals for three positions and invest in related systems, namely:

  - COO/CFO: to be responsible for financial and operational planning processes, managing internal performance, and interfacing with WHO's administrative/legal units.

  - Marketing/Fundraising Manager: to be responsible for developing GDF-specific fundraising and communications strategy, as well as marketing plan for direct procurement.

  - M&E Manager: to be responsible for developing robust M&E mechanisms to track GDF impact in countries and ensure adherence to grant conditions; mobilizing partners for execution; and expanding the current knowledge management systems.

- *Increase clarity of organizational structure and delineation of responsibilities:* Clarify, adapt and formalize current tacit matrix structure to ensure clear single-point responsibilities for countries and functions.

2.4. Improvements in administrative support

WHO currently provides all administrative support to GDF: legal, accounting, payroll/human resources, physical infrastructure, and travel services. The rationale for this structure was to help GDF set up operations quickly and at low cost, with the flexibility to respond appropriately to countries' needs.

Assessment of the current set-up

On balance, GDF has been able to start operations quickly by using WHO's administrative and travel services, and by capitalizing on WHO's physical infrastructure. The Management Services Unit (MSU) catering to GDF's needs is also perceived to be flexible and service-oriented. However, the GDF team has spent much time with HR negotiating staffing (for example, contract breaks and fixed term staff positions) , and with Legal, Finance and Accounts to finalize contracts and release payments.

GDF needs efficient, cost-effective and flexible administrative support. Hiring people on short-term contracts and overly relying on secondments could be a barrier to hiring high caliber and stable talent. Delays due to discussions on contract terms could also potentially affect GDF's efficiency and its credibility with suppliers and other business partners. Lack of transparency on payments undermines the confidence of key donors. Finally, legal, contracting and audit processes should be aligned with the needs of the broader partnership supporting GDF, and not WHO alone.

Key improvements required – Recommendations

Going forward, GDF could renegotiate its MoU with WHO to allow for more flexibility, better service and cost-effectiveness, specifically for staffing and legal processes. Specific recommendations are discussed in Exhibit 23.

2.5. Total funding requirement and projected gap

Total funding needs

Based on GDF's aspirations and its requirements going forward, the Stop TB Partnership must ensure funding of at least $20-30 million per annum to GDF for each of the next three years *(Exhibit 24)*. Over 80% of this amount represents drug costs. Furthermore, over 80% of this funding is required to meet commitments to current beneficiaries alone, namely current drug grants and projected growth in TB case detection and treatment in these countries. At a minimum, the Partnership must ensure that GDF has sufficient funding to meet its current commitments to countries.

Gap and implications of shortfall

GDF is in a financially precarious position today. Its current funding is likely to run out by July 2003, which represents a shortfall of $7-9 million for 2003 alone. Furthermore, no funds have been committed for 2004 and 2005. As a result, GDF will not be in a position to meet current commitments to countries. It may need to cancel further TRC meetings to approve new beneficiaries.

Such actions could negatively affect GDF's credibility with countries. It would affect the nascent TB program that has been launched or accelerated in many countries with GDF grants. In Myanmar, for example, where GDF meets 80% of drug needs, the NTP is initiating a nationwide social mobilization campaign to de-stigmatize TB and to publicize drugs as "free of charge". While such actions would improve case detection, the ability of the NTP to deliver drugs to meet increased demand will be hampered if GDF support is reduced.

Ways to address the gap – Recommendations

GDF urgently needs to address the funding gap. Avenues for closing the gap range from increasing commitments from current donors to recruiting wealthy donors and companies to "adopt a country" with moderate funding needs, as described in Exhibit 25.

More importantly, the STBCB must make three key decisions:

- Create a small taskforce on the Board and entrust it with raising funds to meet the immediate 2003 requirements of GDF.
- Agree on clear accountability in GDF's management team for financial planning and fund-raising, with oversight from the Board, to ensure cash flow requirements are systematically projected and future grants planned.

- Consider developing a mechanism for pre-funding or at least pre-committing donations, to lend stability to GDF's operations. This could be in the form of a one-time fund to cover GDF's grant responsibilities for the next three years. This fund could be replenished annually based on actual grants made and projections.

By fully funding grants up front, GDF would be able to honor its commitments to a country and prevent a repeat of the current funding crisis.

3. CLARIFYING THE GOVERNANCE STRUCTURE OF GDF

GDF was set up in 2001 as an "embedded legal identity housed in WHO". This model was seen as the best option to the meet the governance needs of GDF *(Exhibit 26)*. At that time, the STBCB agreed to review the governance arrangement and WHO's role, in particular, at the two-year mark. This section lays out the assessment of GDF's governance model, its effectiveness and recommendations to strengthen it.

In summary, GDF needs a governance model that must balance the roles of WHO and the Stop TB Partnership. WHO provides the legal umbrella for GDF and administration, while the Partnership provides a ready "Board" and funding. The current governance model has worked moderately well. GDF's governance was set up in short time; partners are broadly aligned on its mandate; and WHO has played a relatively "hands-off" role. However, the Board has provided little strategic direction for GDF and there is significant disagreement on major issues like GDF's scope and partners' respective roles. Hence, while the current model continues to be appropriate going forward, the Board and WHO need to agree on clear roles for various parties to ensure responsibility for decision-making, oversight and legal liability.

3.1. Assessment of the current governance model

Rationale for the current model

The governance model of GDF can be defined along two dimensions: (a) nature of GDF's legal identity for accountability and oversight and (b) housing or GDF's physical location for administrative support and infrastructure. The latter has already been discussed under Section 2.4. Based on these two dimensions, the STBCB was offered four governance models, finally deciding in favor of an "embedded legal identity housed in WHO".

The chosen governance model for GDF can be described as a "general contractor" model, with WHO as the general contractor[3]. WHO has played an active role in housing GDF, providing a legal umbrella, allowing access to critical technical resources and staffing the GDF team. At the same time, it has had to work closely with the Stop TB Partnership whose support is critical for the success of GDF to align GDF's goals with that of the larger TB community; to provide funding and TA; and to take "ownership" for GDF.

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[3] Developing Successful Alliances, Bill & Melinda Gates Foundation, April 2002. This paper describes five structural models common to global health alliances. See Footnote 1

Such an arrangement was expected to deliver many benefits. GDF could gain credibility through the WHO association and enjoy easier access to WHO's regional/local offices and technical departments. The set-up time would be shorter than setting up a board from scratch. GDF could also better coordinate its activities with those of the Stop TB Partnership through joint policy setting at the Board-level, and share the Stop TB Secretariat for some advocacy, administrative and resource mobilization functions.

At the same time, the Board recognized two potential risks that had to be mitigated. First, the relationship between the Stop TB Partnership and WHO for the governance of GDF was likely to be ambiguous. Second, WHO could enjoy undue influence over GDF's operations as GDF was housed in WHO with a largely WHO management team.

Assessment of the model

The governance model has moderately satisfied the needs of GDF *(Exhibit 27)*. The governance mechanism for GDF was set in place rapidly. This was possible because WHO provided a ready legal identity and the STBCB, as an "advisory" Board, was already in place. This model also ensured alignment of goals of Stop TB and GDF on DOTS expansion, treatment standards and other drug access-related issues.

Despite initial concerns, based on interviews with Stop TB partners and our observations, WHO has maintained a relatively "hands off" role. This has given the Stop TB Partnership and GDF's management team flexibility in decision-making and day-to-day management. Indeed, WHO has played a balanced role on many occasions. For example, it has maintained a neutral role during GDF's discussions for a procurement agent and India's application for a drug grant. On the other hand, WHO has played a constructive "hands-on" role within countries to support GDF. It has made available WHO's local and regional staff and infrastructure and expertise of technical departments like the "TB Strategy and Operations" team of the STB Department and the Department for Essential Drugs and Medicines (EDM). This relatively smooth functioning to date can partly be attributed to the cordial relationships between partners; the temporary governance arrangement that ensured greater cooperation; and the STBCB's more technically oriented role.

The Board also delegated some of its responsibilities to the Working Committee (WC). This Committee comprises 4-6 Board members and provides some oversight for GDF, namely support in preparing annual work plans and reviewing the TRC's recommendations. However, the terms of reference for the WC are too broad for it to play its role effectively.

There are key gaps on governance that if not addressed, could significantly affect GDF's credibility, performance and risk management going forward. Critical strategic, funding, people and other decisions must be taken for GDF in the next few months. For example, how will GDF secure funding of $20-30 million per annum for the next few years? How should it redefine its relationships with Stop TB partners? Who should the new GDF leader be? To make these and other decisions effectively, GDF needs a governing authority with three clear responsibilities:

- Clear mandate to make decisions for GDF and provide strategic direction
- Explicit "audit" role, to ensure no gaps in oversight on major issues like fund-raising and performance management
- Legal liability for GDF's actions

There is much confusion and little consensus today among key stakeholders about the roles of WHO, the STBCB and the WC on all these dimensions.

3.2. Governance model going forward - recommendations

Some level of ambiguity in the governance of the GDF is unavoidable given the balance required in the roles of the Stop TB Partnership and WHO.

- *WHO:* is the only party that can have legal liability for GDF and would therefore like to ensure strong control over it. In fact, WHO's charter would make it impossible for it to relinquish its authority to another body. WHO also plays a critical role in ensuring GDF's impact through its regional and local country resources and central technical units.
- *Stop TB Partnership:* is critical to help GDF deliver its proposition, especially grant making and partner mobilization for TA. Therefore, it would like to have an active role in the governance of GDF. However, in the absence of a legal status for the Partnership, it cannot have legal responsibility for GDF.

Despite this ambiguity, it is both necessary and possible to have some clarity in roles to deliver the above three responsibilities of a governing body. Exhibits 28 and 29 lay out the proposed governance model. It largely reflects the current legal and formal set-up with some changes, and aims to clarify the roles of the various entities.

- *WHO:* remains legally responsible for GDF. It holds the final veto power on all decisions and the STB Director is entrusted with this responsibility. However, rather than have an additional decision-

making loop to clear decisions, WHO would exercise its influence through two channels: a) the STB Director's participation on the STBCB, along with a significant presence of WHO or WHO nominated people on the Board; and b) nominating the STB Director as the Chairman of the WC.

- *STBCB:* is technically an "advisory board" that makes recommendations to WHO as it cannot legally influence decisions. In practice, however, it has a strong influence as donors on the Board control fund inflows to GDF. Hence, it acts as the "Board" for GDF, making key policy recommendations and providing oversight on major areas.

- *WC:* The Board may choose to appoint a Working Committee to "operationalize" its role, as it currently does. The Board is a 27-member heterogeneous group that meets only twice a year on a much broader TB agenda. It would therefore find it cumbersome to provide robust and regular governance for GDF. The WC could operate as a "Board Sub-Committee". It would comprise 4-6 key parties from the Board and meet every quarter or more regularly, as needed. Its role would be to provide closer oversight for GDF, review pre-work for key decisions and flag major concerns or recommend actions to the STBCB *(Exhibit 30)*. The WC will not have decision-making powers. Nominating the STB Director as Chairman of the WC would ensure WHO's influence over it.

Going forward, the Board should validate and clarify the specific terms of reference for each entity under this model.

4. STOP TB PARTNERSHIP'S POSTURE TOWARDS AN EXPANDED SCOPE FOR GDF

Given the early positive effects of the GDF for TB, some other disease partnerships like Roll Back Malaria and a few Stop TB partners have expressed an interest in "expanding" the scope of GDF beyond first line TB drugs. Hence, the Stop TB Partnership requested that this report address the feasibility of expanding the mandate of GDF to other diseases like HIV/AIDS and malaria, and test the feasibility of converging GDF and GLC[4]. This section lays out what "expansion" of GDF should mean, a framework to assess fit of a GDF-type model for other diseases and a suggested posture for the Stop TB Partnership towards "expansion".

In summary, "GDF"s for diseases like malaria and HIV/AIDS are desirable and feasible from a technical, business and implementation rationale, though some issues need to be addressed. However, such an effort can be undertaken only by the respective disease partnerships as a partnership plays a critical role in the success of the GDF model. This is amply demonstrated in the case of TB and the role of the Stop TB Partnership. Hence, the respective disease partnership must demand, promote and resource "GDFs" for HIV/AIDS and malaria. In case of such "expansion" in the GDF model, the current GDF for TB faces little risk of losing focus on TB since people and funding resources for TB are unlikely to be used for a GDF for HIV/AIDS or malaria. On the contrary, the Stop TB Partnership could enjoy some reputation benefits from this move. It could also potentially benefit from some cost savings through shared infrastructure and services and increased leverage for GDF with countries. The Partnership does not need to actively promote expansion of the GDF model, but could encourage such a move in a limited manner by releasing a white paper or holding a conference on the subject with relevant stakeholders. With respect to a convergence of GDF and GLC, such a move would yield operational and administrative synergies at a country and overall level. However, MDR TB has unique technical and other requirements that must be maintained.

4.1. Understanding of "expanded" scope for GDF

[4] WHO and its partners have attempted to increase access to second-line anti-TB drugs needed to treat MDR TB in a rational way via a multi-institutional health-based partnership known as the 'Green Light Committee' (GLC). GLC is a sub-group of the Working Group on Dots-Plus for MDR-TB. The Dots-Plus Working Group is one of the six working groups of the Stop TB Partnership. It is convened by WHO, which also serves as the Secretariat for the Working Group. (Increasing transparency in partnerships for health – introducing the Green Light Committee. Gupta et al. 2002)

Importance of partnership support for success of the GDF model

A supportive (willing) and well-functioning (able) disease partnership is critical to GDF's success *(Exhibit 31)*. A partnership plays three critical roles:

- *Full alignment:* Demand for a GDF-type model must come primarily from the high-burden countries and the disease partnership. Partners, including countries, need to agree on the importance of drug access issues and the relevance of the bundled GDF model to address them.
- *Technical support:* Partners must be willing and able to define technical guidelines/protocols; and support GDF by providing resources for technical review, M&E visits and TA to countries.
- *Funding support:* Donors in the partnership must be willing to contribute to a core fund to support GDF's direct grant-making role. Alternatively, the partnership must work closely with other key donors/lenders and align funding mechanisms.

The importance of a partnership is clearly demonstrated in the case of the current GDF for TB on all these dimensions

Implications for the Stop TB Partnership

The provision of a GDF-type model for malaria or HIV/AIDS must therefore be driven by the respective disease partnership. The partnership must demand, resource and house such an effort to ensure its success. The Stop TB Partnership is not in a position to convince other partnerships to adopt its model, force the pace of such "expansion" unilaterally or provide people and monetary resources to support such a move.

Hence, the question of "expansion" of the current GDF for TB is moot. The relevant issue is one of expansion of the "GDF model". This is a decision for the respective disease partnerships to make and not the Stop TB Partnership. The Stop TB Partnership therefore needs to consider which diseases could potentially adopt a GDF type model, what are the implications for the Partnership and how it should react to such a move.

One possible scenario for how "expansion" could happen

One scenario for "expansion" of the GDF model could therefore be as follows:

- Some disease partnerships initiate the move for a GDF-type model for their respective diseases to address major access issues.

- The Stop TB Partnership does not drive such "expansion". However, it can extract some reputation benefits for having nurtured an innovative mechanism like GDF, by sharing learnings from its experience with other disease areas.

- However, other disease partnerships may not unilaterally move on such an effort. Hence, an established multilateral body could initially catalyze such a move. Such a body would have the increased visibility needed to initiate such an effort; better access to funding and talent to support it; and the necessary leverage in discussions with disease partnerships. The WHO, for example, which has the technical mandate for these disease areas and the experience with the current GDF for TB, could be this body.

However, not all disease partnerships can move at the same pace as they are at different stages of readiness to address access issues and adopt a GDF-type model *(Exhibit 32)*. Hence, every partnership would need to meet a checklist before adopting the GDF model to ensure full impact. Similarly, each disease has unique needs, which calls for modifications in the delivery of individual elements of the current GDF model *(Exhibit 33)*.

At this juncture, it is premature to determine the mechanism by which these disease-specific GDFs would relate to each other. However, if individual disease partnerships would like to retain strong oversight of the respective GDFs (as in the case of TB), one possible scenario is that these could evolve as disease-specific GDF units (like business units in a company) or GDF franchises *(Exhibit 34)*. This is also a likely scenario given that there are a few but limited economies of scope in the business system across diseases, restricted largely to advocacy, application, procurement and administrative support. In either case, these GDFs would share some level of common strategic direction, brand-building/advocacy, administrative support and potentially, application process and procurement through a common central team. Individual partnerships could retain control over coordination of technical review, grant making, specialized supplier negotiations and partner mobilization for M&E and TA. Such a development could impact the Stop TB Partnership, but is outside its immediate sphere of influence.

Convergence of GDF and GLC

Both GDF and GLC are part of the Stop TB Partnership. Convergence of GDF and GLC is desirable and feasible as it would yield synergies in areas like application, advocacy and procurement operations and some aspects of M&E, both for the respective secretariats and countries that interact with them. However, the GLC model has notable differences, which must be maintained

even with convergence. For example, it has negotiated an exclusive 95% discount in prices of patented second line drugs with suppliers. It also enjoys a mandated agent relationship with GF, given the high importance of a mechanism to ensure rational use of second line drugs. Hence, it is unlikely to need its own direct funding for grant making. On the other hand, the need for robust technical review and M&E could be higher.

4.2. Fit of the GDF model with other disease areas

Given the possibility of expansion of the GDF model, there is interest in identifying diseases that would benefit from this model. Specifically, the evaluation team was requested to assess the fit of this model for malaria, HIV/AIDS and a "one-stop shop" for TB consumables and diagnostics. The following section describes a framework to address this issue and lays out recommendations.

Diseases and their relevant products must fulfill three sets of criteria to benefit from a "GDF" model *(Exhibit 35)*:

- *Technical fit:* implies that rational use is critical. Hence, a robust technical review and M&E mechanism is required to ensure that a country is in a position to use drugs in a rational manner. Standardization and innovation are also desired and should be possible in order to encourage patient compliance in user-friendly settings. This justifies a grant-making role (or an equivalent mechanism) that serves as the "carrot and stick" for countries to accept such technical conditions and establish relevant systems.

- *Economic case:* for a "GDF" model implies that global pooled procurement will deliver greater benefits than regional or local mechanisms. There should also be substantial unmet demand for treatment due to drug shortages, caused by gaps in funding and/or procurement capability.

- *Implementation feasibility:* checks for political readiness/commitment to address the issue and availability of technical partners to provide in-country delivery support accompanying the drug grant, if such implementation support is critical.

Diseases that meet all three criteria would most benefit from the GDF's bundled model. Diseases that meet only one or two of these criteria may not need as sophisticated or integrated a model.

Malaria and HIV/AIDS both meet these criteria to varying degrees, but overall, would benefit from a GDF model for specific drugs and diagnostic products, with some disease-specific modifications *(Exhibit 36)*. The concept of a "one-

stop shop" for all TB-related products (i.e. diagnostic equipment, consumables) was also explored. These products show little fit with the above criteria *(Exhibit 37)*. GDF could actively intervene only in rare cases for such products, which can be addressed on a case-by-case basis.

4.3. Recommendations for the Stop TB Partnership to capture benefits from "expansion"

From an external perspective, on balance, "GDFs" for malaria and HIV/AIDS are desirable and feasible and the implications for the Stop TB Partnership are positive *(Exhibit 38)*. These disease areas demonstrate a technical, economic and implementation fit with a GDF model. Such a move would build on a tried-and-tested mechanism that is flexible enough to meet disease-specific needs. It would also leverage synergies at a country and system level.

The Stop TB Partnership and the GDF for TB will benefit from such a move in three ways:

- This move would likely increase the brand awareness of GDF at a system level with reputation benefits for the Stop TB Partnership. This could attract new partners and donors.
- Multiple GDFs could increase leverage with countries, given the critical role these GDFs would play in drug access for these countries.
- The GDF for TB could potentially reduce its cost base by sharing some expenses and infrastructure with the other GDFs. For example, advocacy, brand building and administrative support.

The Partnership's concerns on loss of focus on TB or diverted resources are also unlikely to materialize. Given the different disease GDFs should be resourced separately other than the central shared staff, the staff in the current GDF for TB would not serve other disease partnerships. Further, the Stop TB Partnership is not driving "expansion". Hence, it does not need to fund the activities of the other disease partnerships.

Convergence of GDF and GLC would be beneficial to the Stop TB Partnership, beneficiary countries and the respective secretariats. However, the convergence must retain the unique technical and supply-related aspects of GLC and GDF.

Finally, while the Stop TB Partnership should not proactively drive such "expansion", it can encourage such a move in a limited manner to extract some reputation benefits. Specifically, over the next few months, it could release a

white paper on GDF and learnings from this model for other disease areas; organize a conference along similar lines on innovative models to address drug access issues; and/or be available to share best practices with other disease areas. The Partnership does not need to undertake specific actions beyond these.

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