INTERIM REPORT

CONFIDENTIAL

Evaluation of the Global Drug Facility (GDF) --Appendix

Stop TB Partnership Coordinating Board

Presentation of Interim Report to the Coordinating Board

Brasilia, April 4, 2003

APPENDIX CONTENTS

THE GDF WAS CREATED TO DIRECTLY ADDRESS A KEY SHORTCOMING IN DOTS IMPLEMENTATION AND TO INDIRECTLY FACILITATE DOTS EXPANSION

Expected impact of GDF

- Direct
- Indirect

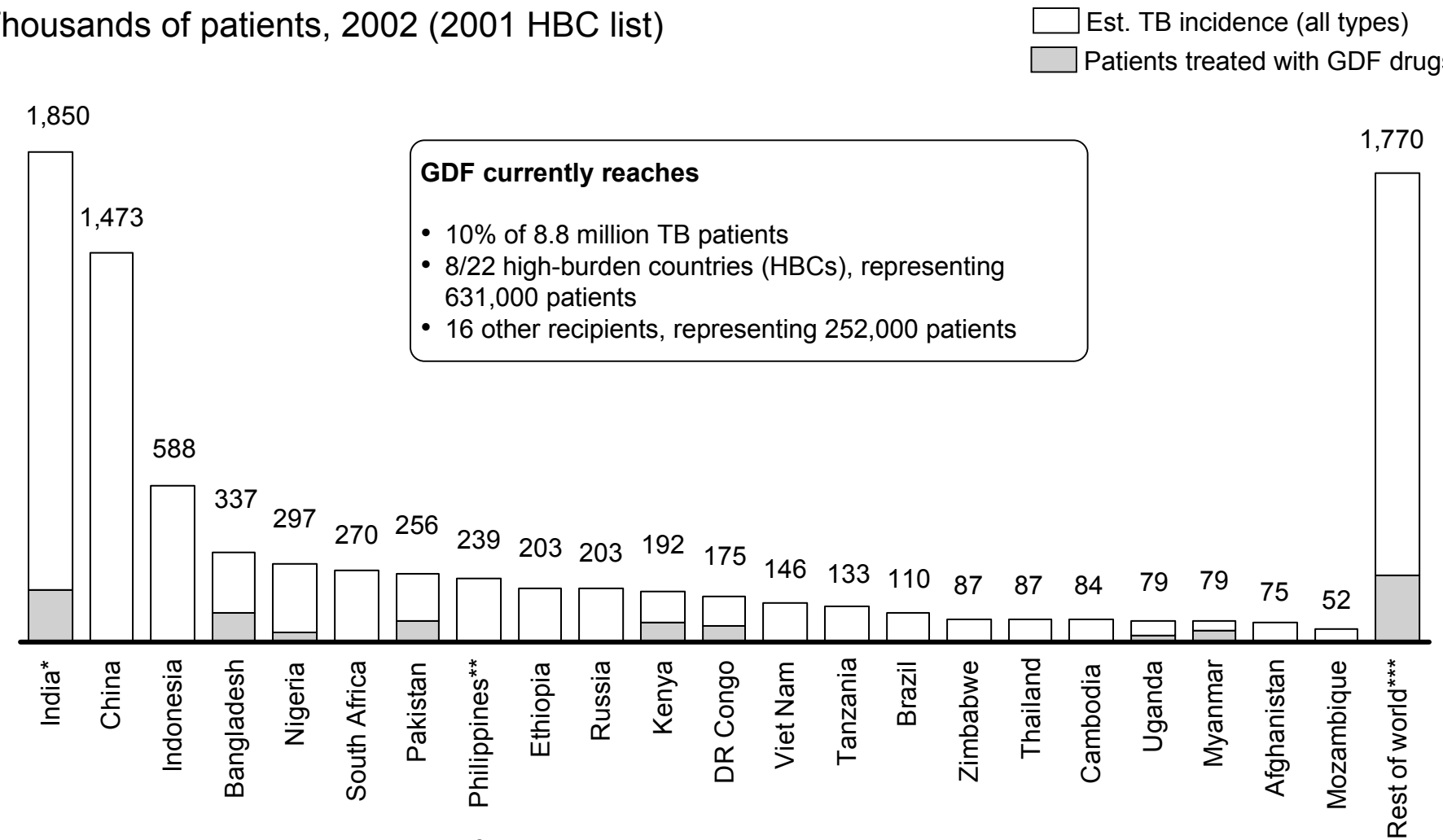
DOTS success factors	Description / examples
Drug supply	• A regular, uninterrupted supply of all essential anti-TB drugs
Government commitment	• Government commitment to TB control through DOTS, as evidenced by level of priority given to TB control, establishment of dedicated TB budget, appointment of senior staff, etc.
Infrastructure	• E.g. well-functioning in-country drug distribution, warehouses, clinics, lab equipment
Funding	• Funding for ongoing TB control operations (e.g. salaries, supplies) and for expansion (e.g. training)
Technical assistance	• Building medical / nursing / management capacity

"The Global Drug Facility (GDF) will expand access to, and availability of, high quality TB drugs and will thereby facilitate DOTS expansion"

Source: GDF Prospectus, team analysis

GDF HAS DEVELOPED BROAD REACH IN LESS THAN TWO YEARS OF OPERATION

Thousands of patients, 2002 (2001 HBC list)



* India received a grant to buy drug from local suppliers

** Direct procurement

*** 16 recipients: Djibouti, DPR Korea, Liberia, Moldova, Somalia, Sudan, Tajikistan, Togo, Armenia, Central African Republic, Congo, Gambia, Mauritania, Uzbekistan, Zambia, Orissa State (India)

Source: WHO, GDF, team analysis

GDF HAS HAD SIGNIFICANT POSITIVE EFFECT IN MANY COUNTRIES…

	Description	Country examples
High effect: transforming DOTS expansion	• GDF intervention has catalyzed significant expansion of country plans for DOTS treatment and mobilized major resource contribution and political commitment by other partners to accelerate implementation of country DOTS plan	• Moldova, Myanmar, Nigeria
Medium effect: facilitating DOTS expansion	• GDF intervention has addressed major drug needs and stimulated the marshalling of further resources against major (e.g. regional) gaps in DOTS treatment	• Kenya, Uganda, Philippines
Low effect: supporting DOTS expansion	• GDF intervention has addressed some of country drug needs and had limited influence on other aspects of DOTS expansion	• Somalia, India

Source: country visits, team analysis

… AT BOTH DIRECT AND INDIRECT GOALS

	Nigeria	Myanmar	Moldova	Uganda	Kenya	Philippines	India	Somalia
Direct goal: Expanding access to high quality TB drugs								
Alleviating drug shortage due to lack of funds	✓	✓	✓	✓	✓	✓	✓	✓
Alleviating drug shortage due to poor procurement practices				✓		✓	✓	
Indirect goal: Facilitating DOTS expansion								
Improving drug management through standardization and innovations*	✓	✓		✓	✓	✓		
Releasing resources for other aspects of TB management		✓		✓				✓
Mobilizing political and partner commitment	✓	✓	✓		✓	✓		

* (e.g. patient boxes, 4FDC)

Source:Interviews, country visits, monitoring reports, team analysis

CASE EXAMPLE: HIGH GDF EFFECT ON MOLDOVA

Background

- Medium burden country, annual TB incidence 2,400 cases per year
- Key drug access issues
  - Funding gap
- GDF interaction
  - Applied Feb 01
  - Order placed Jul 01
  - Drugs received Oct 01

GDF impact on TB control

- DOTS coverage
  - 0% (2000) -> 70% (2002) -> 100% (2003 expected)
- Case detection
  - 31% (2002)
- Patients treated ('03)
  - 1,950

GDF impact against…

Direct goals

- Granted drugs for 1,950 patients per year, making an early commitment to the country's nascent DOTS program

Indirect goals

- Key driver for rapidly expanding DOTS in the country
  - Solidified government commitment to adopt and implement DOTS strategy as policy
  - Ensured government budget was allocated for TB
  - Ensured acceleration of DOTS plan from 5 years to 1
- Attracted additional funds for DOTS expansion
  - GDF reports and presentation at IUATLD conference provided relevant information/transparency and increased Moldova's visibility in donor community
  - After successful GDF application, other donors stepped in (e.g. Global Fund, USAID)

Source: country visits, interviews

CASE EXAMPLE: HIGH GDF EFFECT ON MYANMAR

Background

- HBC, annual TB incidence 79,000 cases per year
- Key drug access issues
  - Funding gap
- GDF interaction
  - Applied Feb 01, Sep 02
  - Order placed Aug 01
  - Drugs received Mar 02

GDF impact on TB control

- DOTS coverage
  - 85% (2000) -> 100% 2003 (expected)
- Case detection
  - 56% (2001) -> 70% by 2003 (expected)
- Patients treated ('03)
  - 43,750

GDF impact against…

Direct goals

- GDF alleviated drug shortage due to lack of funds, and supplies drugs for 44,000 patients today
- *"…GDF has provided Myanmar a sense of security on drugs, given the TB program more stability and a push for DOTS expansion…"*

Indirect goals

- GDF presence catalyzed additional funding for TB:
  - GOM has increased TB drug budget 4-fold
  - WHO, has both increased its budget and is ploughing back ~$100,000 p.a. from drugs to other areas of TB
- Social mobilization programs have begun
  - *"Before securing drugs, we would not dare touch social mobilization…"*
  - *"GDF is like a bullet…no point firing the gun without it";*
- NGOs are expanding activities in Myanmar as drug shortage is not an issue any more

Source: country visits, interviews

CASE EXAMPLE: HIGH GDF EFFECT ON NIGERIA

Background

- HBC, annual TB incidence 297,000 cases per year
- Key drug access issues
  - Funding gap
- GDF interaction
  - Applied May 01
  - Order placed Dec 01
  - Drugs received Oct 02

GDF impact on TB control

- DOTS coverage
  - 47% (2000) -> TBD
- Case detection
  - 12% (2000) -> TBD
- Patients treated (’03)
  - 37,100

GDF impact against…

Direct goals

- GDF grant covered drug supply for 16 states that did not have access to drugs, allowing DOTS coverage to expand to the entire country

Indirect goals

- In-country partners who procure drugs (from different sources) for their ‘sectors’ planning to standardize and coordinate procurement through GDF
- GDF involvement increased government commitment at both levels:
  - Federal government committed further 9M
  - State governments, e.g. Kano, funding upgrade of treatment facilities and equipment
- New CIDA grant will fund training and further infrastructure development
- *“Global Fund grant will cover the infrastructure that will be required to expedite DOTS expansion using GDF drugs”*

Source: country visits, interviews

CASE EXAMPLE: MEDIUM GDF EFFECT ON PHILIPPINES

Background

- HBC, annual TB incidence 279,000 cases per year
- Key drug access issues
  - Poor procurement
- GDF interaction
  - Applied July 02
  - Order placed Jan 03
  - Drugs not yet received

GDF impact on TB control

- DOTS coverage
  - 100%, no change
- Case detection
  - 53% -> 70% expected within one year, reaching Stop TB goal by 2004
- Patients treated ('03)
  - 170,000 (DP)
  - 16,000 (grant to PPM)

GDF impact against…

Direct goals

- Alleviated drug shortage caused by poor procurement, reducing lead times (from >1 year to ~3 months) and prices vis-à-vis local suppliers (from ~$19 to $10 per Rx)
- *"Drug shortage is one of the weakest links in the NTP, not because of shortage of funds, but lengthy process…"*
- *"With GDF drugs, we can treat all TB cases now…"*

Indirect goals

- High quality GDF drugs one of the cornerstones to PPM experiment, helping private practitioners *"…overcome suspicion of quality that private sector has for public sector drugs…"*
- GDF application increased partner communication and alignment *"…GDF was the first really big event that forced us all to sit down and think about what to do…"*

Source: country visits, interviews

CASE EXAMPLE: MEDIUM GDF EFFECT ON UGANDA

Background

- HBC, annual TB incidence 79,000 cases per year
- Key drug access issues
  - Lack of funds
- GDF interaction
  - Applied May 01
  - Order placed Nov 01
  - Drugs received Dec 02

GDF impact on TB control

- DOTS coverage
  - 100% (2000)
- Case detection
  - 50% (2000)
- Patients treated ('03)
  - 23,250

GDF impact against…

Direct goals

- Alleviated drug shortage caused by lack of funds (grant)
  - *"…GDF's coming is a blessing… there was no money for drugs…"*
  - *"…it will be easier to expand DOTS and scale up rapidly because the drugs are there…"*
- Reduced drug prices (direct procurement: $10 per treatment vs. previous procurements at $30 per treatment)

Indirect goals

- GLRA redirecting funds formerly used for drug procurement ($500,000 covering 14,000 patients) to expand support to 3 additional districts

Source: country visits, interviews

CASE EXAMPLE: MEDIUM GDF EFFECT ON KENYA

Background

- HBC, annual TB incidence 192,000 cases per year
- Key drug access issues
  - Lack of funds
- GDF interaction
  - Applied Feb 01
  - Order placed Aug 01
  - Drugs received Feb 02

GDF impact on TB control

- DOTS coverage
  - 100%
- Case detection
  - 47%
- Patients treated ('03)
  - 75,000 patients

GDF impact against…

Direct goals

- Timely GDF intervention as Kenya faced a funding gap after KNCV pulled out of TB program in 2001
- GDF prices 30-80% lower than previous government procurements

Indirect goals

- GDF grant increased visibility of NLTP in the MoH, increasing MoH commitment to TB
  - *"…having the GDF is great for the NTP manager to get the government to do what it would not do otherwise…"*
- GDF drug packaging has improved drug management
  - *"…previous order from IDA came in "buckets" of thousands of pills, which we had to re-package by ourselves…"*

Source: country visits, interviews

CASE EXAMPLE: LOW GDF EFFECT ON INDIA

Background

- HBC, annual TB incidence 1.9 million cases per year
- Key drug access issues
  - Funding gap
- GDF interaction
  - Applied Jul 01
  - Order placed Oct 02
  - Drugs not yet received

GDF impact on TB control

- DOTS coverage
  - 40% (2001) -> 100% (2005 expected)
- Case detection
  - 57% (2002)
- Patients treated ('03)
  - 200,000 (expected)

GDF impact against…

Direct goals

- Alleviated drug shortage caused by lack of funds, covering estimated 200,000 TB patients
- Potentially a source to meet emergency supply needs of RNTCP

Indirect goals

- No significant change in political / partner commitment
- However, funds like GDF and GF have encouraged more dialogue and joint planning between in-country donors compared to earlier

Source: country visits, interviews

CASE EXAMPLE: LOW GDF IMPACT ON SOMALIA

Background

- HBC, annual TB incidence 34,600 cases per year
- Key drug access issues
  - Lack of funds
  - Lack of central government
- GDF interaction
  - Applied Feb 01
  - Order placed Aug 01
  - Drugs received Jun 02

GDF impact on TB control

- DOTS coverage
  - 80-90%
- Case detection
  - TBD
- Patients treated ('03)
  - 2,700

GDF impact against…

Direct goals

- Alleviated drug shortage caused by lack of funds, covering 2,700 TB patients
- However, system capacity constrained and facing security issues
  - *"…If GDF helped eliminate all the drug shortfall, that would not have much impact as the other infrastructure is working at the limit of its capacity…"*

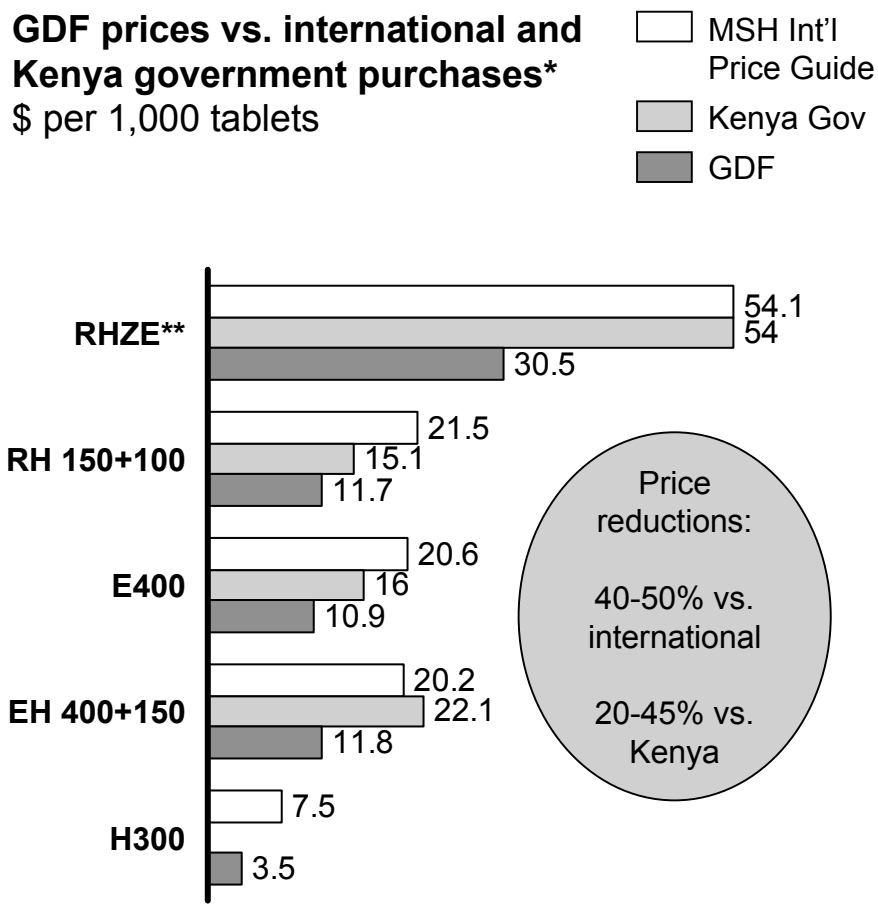
Indirect goals

- No significant change in political / partner commitment, partly because of low awareness of GDF
  - *"…we heard about the GDF for the first time when McKinsey called for the interview…"*

Source: country visits, interviews

AT THE SYSTEM LEVEL, GDF HAS ALSO IMPROVED THE PRICE AND QUALITY OF TB DRUGS, BENEFITING ALL PURCHASERS

GDF prices vs. international and Kenya government purchases*
$ per 1,000 tablets



GDF impact on treatment standards

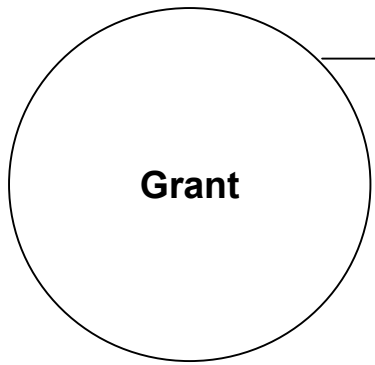
- Promoted the use of logistically superior, patient-friendly treatment regimens: 4FDC, blister packs, and patient packs
- Used its relationship with the WHO to promote the development of a 'white list' of pre-approved TB drug suppliers, which can now be used by all buyers
- Raised awareness of shortcomings of local manufacturers:

"…*after GDF brought up price and quality issues of TB drugs, the government of Indonesia is now asking local manufacturers for bio-availability data and justification of ~$30 per patient treatment price…*"

* Gov. of Kenya procurement before GDF
** RHZE 150+75+400+275

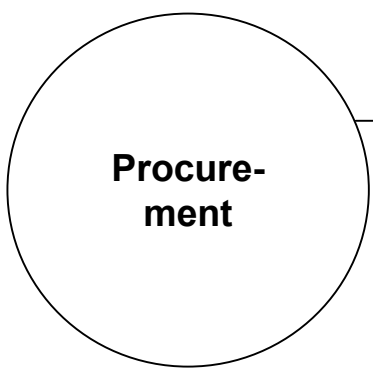
Source: GDF, MSH 2002 International Price Indicator Guide, Kenya NTP, team analysis

GDF's UNIQUE VALUE PROPOSITION HAS BEEN KEY TO MEETING ITS GOALS: WHILE ALL THREE ELEMENTS HAVE THEIR OWN BENEFITS…



- **Grants increased leverage** of GDF and Stop TB network to mobilize government and partner commitment
  - E.g. Gov. of Kenya delivered on commitment to buy TB drugs after receiving 'orange light' on M&E mission
- **Grants free up resources** for other aspects fo the TB program

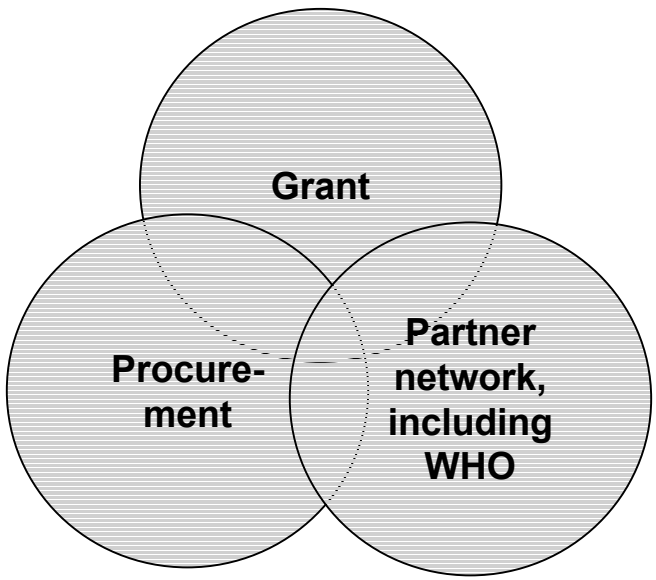
- **WHO** performed **normative role** of setting treatment standards, e.g. 4FDC and **certification of manufacturers** via EDL white list
- **Partners** performed **in-country technical assistance**



- **Procurement capability** allowed GDF to have **impact in countries with funds but poor procurement**, e.g. Philippines

Source: team analysis

… IT IS THEIR BUNDLING IN THIS VALUE PROPOSITION THAT GIVES THE GDF GREATER IMPACT



- **Grants-in-kind** of **GDF procured drugs** is more powerful for **mobilizing partners** than grants alone
  - Country examples: Moldova, Myanmar, Nigeria
  - *"…why would anyone build capacity for diagnosis and treatment when there are no drugs to give people at the end of the process?…"*
  - Precedent in leprosy: *"…In leprosy, we changed the world when we were able to give free drugs in '95, everything else happened around that…"*
- **Grants and the partner network** allowed GDF partners to provide relevant TA to support the drug grant
- **Grants and the WHO link** allowed GDF to **guarantee sufficient demand** to encourage manufacturers to produce the drugs and formulations recommended by WHO, and to reduce prices
- **Grants-in-kind linked to procurement** reach countries faster than through separate granting and procurement processes, and with fewer 'leakages'
  - *"…even if GDF had given them money, it would have been a headache and impact would not have happened so fast. Drugs in kind is great"*

- This bundle does not necessarily need to reside in a legal entity: shared decision-making and operations between two or three entities that collectively cover all three elements would also be effective

Source: team analysis

RE-EVALUATION OF GDF'S VALUE PROPOSITION

	Questions to address
'Client' base	• Which countries benefit most from GDF's value proposition?
Value proposition	• How does GDF's value proposition fit with needs of different client segments?
Resources required	• What resources (e.g. funds, partner access, etc.) does GDF need to deliver on its value proposition? • How might access to resources change over the next few years, and what are the implications for GDF?

Source: team analysis

THREE BENEFICIARY SEGMENTS CAN BE IDENTIFIED FOR GDF

Three key dimensions…

- Availability of affordable, high-quality drugs
- Willingness and ability of government to take concerted action to address TB burden
- Presence of GDF partners in country

…define three beneficiary segments*

- "Natural beneficiaries"
  - No reliable supply of affordable, high-quality drugs, due to limitations of funding or procurement
  - Government willing and able to take action on TB
  - GDF partners present in country
- "Challenging beneficiaries"
  - No reliable supply of affordable, high-quality drugs, due to limitations of funding or procurement
  - No willing or able government *or*
  - Few or no GDF partners in country
- "Opportunistic beneficiaries"
  - Countries which usually have funds and ability to procure own drugs, but may benefit from GDF support (e.g. on a periodic or regional basis)

* Countries with emergency drug needs could fall into either of the first two segments

Source: country visits, interviews, team analysis

GDF SHOULD TAKE DIFFERENT APPROACHES TO DIFFERENT BENEFICIARY SEGMENTS

Segment	Example countries	GDF approach
• "Natural beneficiaries"	• Most countries, e.g. Moldova, Nigeria	• Approach proactively
• "Challenging beneficiaries"	• Somalia, Myanmar	• Recognize that impact will be harder to achieve • Expend more efforts on identifying in-country coordinating mechanisms and in-country technical partners
• "Opportunistic beneficiaries"	• India, South Africa	• Unlikely to be able to serve with classic approach • Maintain dialogue, e.g. through Stop TB partnership, to identify emerging opportunities to serve these countries. E.g. the institution of a drug pricing commission in South Africa, where drug prices are 3-4 times higher than GDF prices, may increase sensitivity to GDF's value proposition

Source: team analysis

ALL OF GDF's POTENTIAL BENEFICIARIES FACE A RANGE OF CHALLENGES FOR EXPANDING DOTS

Most important constraints in HBCs

Key barriers to DOTS expansion, 2003

	Financing	Infrastructure	DOTS access	Laboratories	Human Resources	HIV/AIDS	Community Awareness	Private sector	Drugs	Political Commitment	Monitoring	Decentral-ization
Nigeria	x	x	x		x							x
Bangladesh					x			x			x	x
Ethiopia		x			x					x		x
Philippines							x	x			x	
Pakistan					x			x				
Russia	x		x						x			
DR Congo	x	x							x	x		
Kenya					x	x	x	x				
Vietnam			x		x			x	x			
Tanzania		x			x			x				

Source: WHO, team analysis

GDF HAS BEEN ABLE TO MEET MANY OF THESE NEEDS BY MOBILIZING ITS PARTNER NETWORK OR THE GOVERNMENT

Most important constraints in HBCs

Constraint	Example from country visits
Human resources	• CIDA funded TB personnel training in Nigeria after GDF grant
Decentralization	• NGO's procuring drugs in Nigeria decided to all procure through GDF
Private sector	• Philippines public-private partnership applying DOTS principles
Infrastructure	• Nigerian government (fed and state) committing to infrastructure upgrades
Political commitment	• Moldovan government committing to DOTS expansion plan
Access to DOTS	• DOTS expansion to 16 regions in Nigeria once GDF drugs arrive there
Financing	• Other donors stepping in to Moldova after GDF grant
Community awareness	• Myanmar MOH beginning social mobilization plans
Monitoring	• --
Drugs	• --
Laboratories	• --
HIV/AIDS	• --

Source: WHO Report 2003: Global TB Control, country visits, team analysis

GDF DOES NOT NEED TO ALTER/EXPAND ITS PROPOSITION, BUT CAN MEET DRUG-RELATED GAPS THROUGH BETTER PARTNER MOBILIZATION

Issue: Does GDF need to hire its own team/fund activities to plug drug-related gaps, e.g., drug management, lab training, consumables?

From GDF's operational perspective…,

- Few barriers common across countries: any one new activity would help only a subset of countries
- GDF has been able to influence most barriers by mobilizing its partner network. Better execution on this dimension will further improve GDF's impact

From a customer need perspective…

- Any new service line would require GDF to obtain significant funding, expertise, or both, e.g.
  - Changing the Ugandan procurement system from 'push' to 'pull' required DELIVER to "…*get DANIDA funding and do one year of consulting work… and that was in a favorable environment where the government wanted change and DANIDA was pushing for it…"*
- Such new areas would likely overlap with activities of STB technical partners, leading to duplication
- New activities, especially those not directly related to drug supply, could detract focus from GDF's core operations

Recommendations

- GDF should not directly provide such assistance to countries
- However, GDF should:
  - Explicitly assess these barriers during application and M&E
  - Mobilize partners to provide assistance where needed
  - Where no partners available, develop one-off solutions
- At a systemic level, GDF should continue to facilitate low-investment, high-impact actions, e.g. the Washington conference on FDC, sharing best practices like transition to FDC, use of drug grant in PPM

GDF'S REVISED (2003) DRUG PROCUREMENT APPROACH IS APPROPRIATE TO ITS GOALS

	GDF approach	Other possible approaches	Rationale for GDF approach
Supplier Tender	• LICB with pre-qualification	• ICB • Direct procurement	• Drug quality is critical, and most efficiently ensured with LICB with pre-qualification, where pre-qualification is open to all suppliers
Contract	• Flexible volume with assurance of minimum demand • Time-limited • 2+ suppliers per drug	• Fixed volume • Long duration • Unique supplier	• In-country demand forecasting not yet at a level to accurately calculate total demand • Ongoing commitments do permit calculation of minimum expected demand • Multiple suppliers with time-limited contracts encourage continuous supplier improvement and new supplier entry
Stock of goods	• None	• Stockpile	• Countries are served with one year buffer which serves as 'local' stockpile • Drugs are delivered to countries with 80% shelf life remaining, so stockpiles on TB drugs (shelf lives 24-36 months) would be small, with rapid turnover, so expensive and likely to go to waste
Other	• QA agent: direct contract • Transport and insurance: direct contract or sub-contract via procurement agent	• Direct contract or sub-contract for any / all of QA / transport / insurance	• QA is key concern and QA agent incentives need to be closely aligned with GDF's, which is more easily achieved with direct contract than via a sub-contract through a procurement agent

Source: interviews, team analysis

POSSIBLE NEGATIVE EFFECTS OF GDF

- We reviewed the possible negative effects of GDF:
  - On local suppliers
  - On local / regional procurement capacity
  - Becoming a monopsony
  - Risk of over-standardization

Work in progress

GDF PROCUREMENT ACTIVITY HAS LOW POTENTIAL FOR NEGATIVE IMPACT ON LOCAL PROCUREMENT ABILITY, BUT GDF SHOULD INCREASE EMPHASIS ON PHASE-OUT

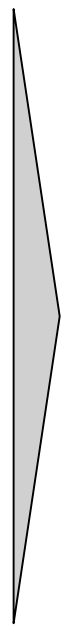
Skills required in procurement	Potential GDF impact		Recommendations
• Demand forecasting	Positive	• Application supports forecasting • GDF can mobilize partners to help with demand forecasting	• Continue to mobilize partners to help if this is a bottleneck
• Budget allocation	Positive	• Application encourages TB drug budget line	• Continue to encourage / enforce
• Procurement agent selection, e.g. own procurement dept. vs agency selected via ICB • Supplier evaluation / selection • Price negotiation	Neutral to potentially negative	• In countries with poor overall procurement, reliance on GDF procurement for TB drugs could inhibit development of in-country procurement ability, making the counry dependent on GDF or international aid agencies • GDF does not aim to grant 100% of country needs	• Develop three-step phase-out – Phase out grant – Help build procurement ability – Monitoring / oversight x 2 years • Help domestic suppliers quality for 'white-list' status – Mobilize technical assistance – Offer flexibility on pricing during bidding process*
• Quality assessment • Drug registration and clearance	Neutral to positive	• GDF asks for efficient application of in-country QA, registration, and clearance rules, not waiver	• --
• In-country drug distribution	Positive	• Application helps identify distribution bottlenecks • GDF can mobilize partners to help with in-country drug distribution	• Continue to mobilize partners to help if this is a bottleneck

* E.g. 'emerging' suppliers could be allowed to win tender even if bidding x% higher than established suppliers

Source: interviews, country visits, team analysis

GDF's EFFECT TO DATE ON LOCAL SUPPLIERS HAS BEEN NEUTRAL TO POSITIVE

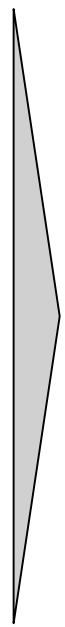
- Countries with own TB drug supply have chosen not to use GDF, even if GDF procurement was cheaper, e.g. South Africa, where local prices are three times GDF prices, and Romania. GDF impact on these countries' suppliers is therefore nil
- Many countries served by GDF do not have local TB suppliers, and before GDF's arrival, procured internationally. E.g. in Nigeria, TB drugs are purchased by technical partners from a number of suppliers, e.g. from India. GDF impact on local suppliers in these countries is therefore nil
- GDF has stimulated the development of a WHO 'white list' of high-quality suppliers of TB drugs. Local suppliers who qualify can therefore more easily have access to international markets. GDF impact in this case is positive
- GDF has stimulated governments of some countries that have local manufacturers to evaluate more closely drug quality and price, e.g. in Indonesia and Romania. GDF impact in this case is positive
- Some countries, e.g. Philippines and Romania, have asked about how to encourage their local producers to qualify for the WHO white list



- Information from countries suggests that GDF's impact to date on local TB drug suppliers has been neutral to positive
- With the expansion of the WHO white list, GDF will likely be able to be more flexible in meeting country requests for supply of quality drugs from local sources

GDF's IMPACT ON REGIONAL PROCUREMENT EFFORTS HAS BEEN NEUTRAL AND SHOULD CONTINUE TO BE SO

- Current information from countries served is that no major regional procurement efforts were underway at the time of GDF's establishment, and that no such efforts have been shelved or undermined
- GDF's direct procurement service line does not compete directly with any potential regional procurement effort. Countries will continue to have the option to choose either / both
- GDF's mission does not call for it to become a TB drug monopsony. GDF does not aim to grant more than 30% the of world market–indeed there are a number of HBCs that it will likely not serve at all. GDF's control of the supplier base will therefore not be enough to inhibit the development of regional procurement networks, if others are willing to develop them
- GDF's value proposition depends on offering grants-in-kind to countries. Centralized procurement is currently the most efficient way to do this



- To date, GDF has had no observable impact on the development of any potential regional procurement networks
- GDF's mission is compatible with the existence of regional procurement networks
- GDF's business model is best served by a central procurement model. GDF itself should not switch to regional procurement

Work in progress

GDF SHOULD ALSO IMPROVE KEY OPERATIONAL AREAS

	Issue	Recommendations
Advocacy / awareness building	• Low awareness of GDF's broader mandate limits GDF's ability to coordinate efforts for DOTS expansion • *"The first time we heard of GDF was when you called…"* • *"What the countries see is drugs coming from WHO…"*	• Engage in significant brand-building both with beneficiaries and within the WHO, e.g. – Creating a budget for advocacy and brand building – Articulating messages strongly linking DOTS and GDF – Increasing contacts between high-level GDF / Stop TB officials and government officials – Proactively approaching NGOs and technical advisors relevant to each country – "*GDF could do more to make itself better known throughout WHO and influence organizational learning*"
Partner mobilization	• Variable involvement of in-country WHO officers • Insufficient focus on mobilizing partners to tackle key in-country bottlenecks • Low engagement with technical partners outside of core group	• Fully leverage WHO partner across all countries for advocacy / government communications / partner relationships / facilitation of drug entry to port • More proactively involve partners in application process – Strengthen applications with partner input – Assign 'ownership' of country bottlenecks identified – Map list of in-country stakeholders during application process and engage with non-core partners – Make M&E visits involve all relevant in-country partners
Procurement	• Initial procurement approach not in line with donor expectations • Direct procurement service line currently similar in structure and requirements to grant-kind-service line	• Redesign tender process to be via international open tender, with multiple suppliers for each product* • Publicize new process to undo negative perception • Review appropriateness of application review and monitoring requirements for direct procurement • Review cost / revenue proposition of direct procurement

* currently being implemented

Source: country visits, interviews, team analysis

IMPROVING THE BUSINESS EFFECTIVENESS OF GDF

● Strong
◑ Medium
○ Weak

Assessment

Fund raising and grant making

• Fundraising	◔	• Four major donors with sustained commitment for years 1 and 2 • Commitment shortfall for 2003, and no commitments yet for 2004+ • Many donors and Coordinating Board members expect a better breakdown of financials, at least a separate P&L: *"the materials shown at the Cape Town conference were really not helpful"* • Few systematic efforts to proactively work with large donors like GF and WB and align process. Miscommunication at the country level about the GDF (e.g. in India –WB not updated on GDF's new procurement approach)
• Grant-making	●	• Disbursed over 80% of funds received

Source: team analysis

IMPROVING THE BUSINESS EFFECTIVENESS OF GDF

Recommendations

Fund raising and grant making

- **Fundraising**
  - Explore different donor segments for their potential to fund GDF activities –see chart 28
  - Systematic brand building and advocacy with donors, with a compelling story
  - Develop transparent statement of sources and uses of funds, identifying spend on drug procurement, activities related to grant-making (e.g. M&E), personnel salaries, and WHO overhead
  - Assign clear responsibility in CB for fundraising, as well as a function in the management team

Source: Team analysis

IMPROVING THE BUSINESS EFFECTIVENESS OF GDF

● Strong
◑ Medium
○ Weak

Application review

	Assessment	
• Advocacy and awareness building at system and country level	◑	• Largely restricted to emails during application time, communicated through WHO office or STB partners and some interaction during country visits; limited advocacy budget • Country stakeholders often not aware of the GDF – *"First time we heard of the GDF was when you set up this interview"*– or unclear about GDF, GF, GAVI: "*all are called Global Something"*
• Technical Review Committee	●	• Well-functioning team highly regarded for its experience and technical expertise, independent and not influenced by WHO. Some concerns voiced about the sustainability of TRC members devoting 10+ days / year
• Team capacity for application review and M&E	○	• Team is working overtime today, with two secondments, unlikely to manage increased applications and more volume
• Review lead times	◑	• Time between submission and TRC review (48 days) and between STB WC decision and order placement (87 days) are much longer than targeted

Source: Team analysis

IMPROVING THE BUSINESS EFFECTIVENESS OF GDF

Application review

Recommendations

- Advocacy and awareness building at system and country level
  - Based on the criteria to identify countries that GDF can have most impact in, pro-actively reach out with partner support to help prepare applications
    - Concerted awareness building campaigns with active communication to all relevant parties
      - Independently pursue advocacy opportunities e.g. Visits to potential recipient countries even before application
      - Communicate to National TB Program, Ministry of Health budget arm, Ministry of Finance, National Drug Authority in charge of drug registration
    - Higher profile visits of GDF leadership i.e. JW Lee and Ernst Loevinsohn's visit to Nigeria
    - Branding of GDF drugs
  - Consider extra support for non-traditional / NGO applicants with a major role in TB control
- Team capacity for app. review and M&E
  - Secure funding for more GDF staff capacity for application review and M&E

Source: Team analysis

IMPROVING THE BUSINESS EFFECTIVENESS OF GDF

Recommendations (continued)

Application review

- Technical Review Committee
  - Increase direct interaction between the TRC and the STB CB/WC by:
    - Instituting a system of direct communication between the two bodies, e.g., TRC submits a summary of deliberations and policy issues for discussion in the Board meeting; a Board member can occasionally attend and observe TRC meetings
    - Potentially encouraging some joint membership between the two bodies
  - Allow for more "virtual" TRC meetings and increase frequency, to ensure a more sustainable time commitment from members and reduce review-approval process times
  - Identify and eliminate any potential gaps in expertise which are critical to GDF's future proposition and business model, e.g., in-country drug management
  - Frame key technical guidelines of the GDF and ensure partner alignment on core technical principles of the GDF (e.g., treatment standardization around 4FDC, importance and approach of in-country drug management)
  - Develop mechanisms for knowledge management to capture the institutional memory of the TRC and ensure consistency in decision-making despite rotation of TRC members

Source: Team analysis

IMPROVING THE BUSINESS EFFECTIVENESS OF GDF

Procurement

	Assessment	
• Procurement agent / supplier selection	◑	• First approach to selecting procurement agents and suppliers was designed for rapid launch, and was not in line with international procurement norms expected by many partners and donors
• Procurement lead time	◑	• MEG lead times were longer than expected for blister packs, leading to delayed shipment to a number of countries, esp. Liberia, Nigeria, and Togo
• Quality assurance	◑	• OK, with one exception of 6/90 batches failing tests. However, there is much concern about the quality standards of the current supplier
• Price negotiations	●	• Achieved prices significantly below international norms
• Product range	◑	• No children's products
• Product packaging / info	◑	• Missing user-friendly information, disease information

Source: Team analysis

IMPROVING THE BUSINESS EFFECTIVENESS OF GDF

Procurement

	Recommendations
• Procurement agent / supplier selection	• Use multiple suppliers
• Procurement lead time	• Re-evaluate timing of in-country visits pre-order placement, which are currently initiated after positive WC decision and have several weeks lead and lag time
• Quality assurance	• Evaluate supplier capabilities in line with international standards
• Product range	• Consider expanding to children's formulations
• Product packaging / information	• Consider including relevant and country-specific information, as well as information publicizing benefits of GDF drugs (e.g. FDC, quality control)

Source: Team analysis

IMPROVING THE BUSINESS EFFECTIVENESS OF GDF

Coordination of Stop TB partners

Assessment

• Partner presence in target countries	◕	• Key international TB technical partners present in most countries. However, In countries where they are not present, e.g. Somalia, GDF has not proactively established partnerships with leading partners, NGOs
• Role of partners in application process	◑	• Positive and helpful in cases where applications come from NTPs, where partners help with application preparation. Poor in cases where applications come from NGOs and / or where partners are not present
• GDF-related TA	◯	• Very limited evidence of technical assistance provided beyond what partners would otherwise have provided

Source: Team analysis

IMPROVING THE BUSINESS EFFECTIVENESS OF GDF

Coordination of Stop TB partners

	Recommendations
• Partner presence in target countries	• Identify TB program gaps during application and mobilize partner support to get beyond what partners were already doing
• Role of partners in application process	• Identify TB program gaps during application and mobilize partner support to get beyond what partners were already doing
• GDF-related TA	• Align partner's technical advice and standards, e.g. on 4FDC

Source: Team analysis

APPENDIX CONTENTS

GDF'S FULL VALUE PROPOSITION DEPENDS ON PROVIDING GRANTS

GDF can help de-bottleneck drug shortages via direct procurement alone…

…but having an impact at non-drug bottlenecks is dependent on the 'carrot' of providing grants and the 'stick' of post-grant M&E

GDF intervention	Potential bottlenecks in DOTS expansion
Direct procurement • Allows countries to buy quality drugs more cheaply through GDF, and thereby reduce problems in drug supply for DOTS	**Drug supply**
Grants • Encourage governments to develop strong DOTS plans to win grant and attract other donors • With associated M&E, encourage governments to honor commitments to be eligible for more aid	**Political commitment and planning**
• Allow funds to be reallocated to meet resource gaps in non-drug areas • Allow funds to be used to buy more technical assistance • Allow GDF to mobilize and coordinate actions of partners	**Other bottlenecks, e.g.** • Human resources • Infrastructure • Laboratories

Source: Interviews, team analysis

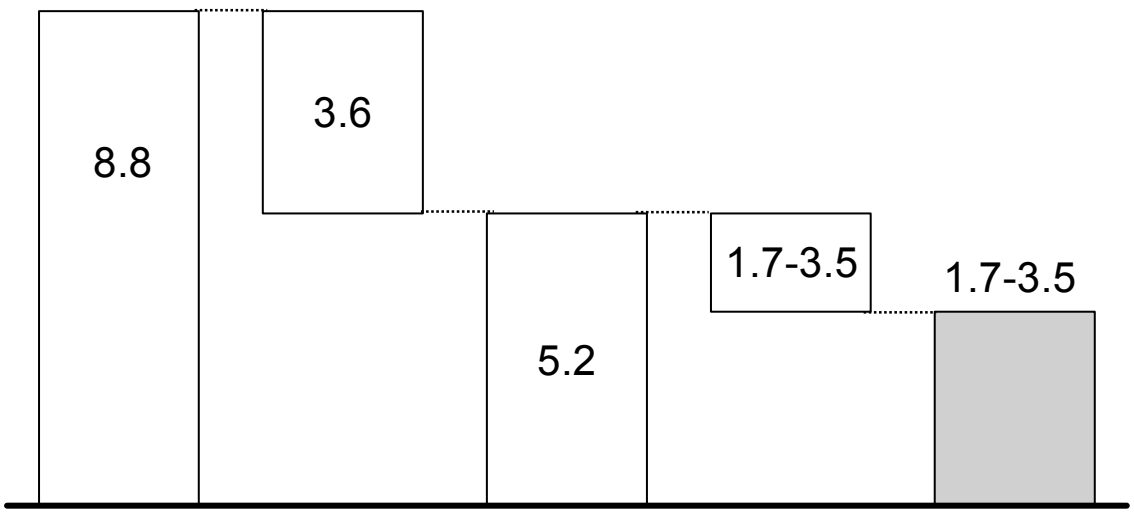
WITHOUT GRANTS, GDF's IMPACT BECOMES DIMINISHED ACROSS ALL POSSIBLE SCENARIOS

Scenario	Description	Implications for GDF
Direct procurement agent	• Donor gives grant to country, and maintains M&E function • Country has choice of procurement agent, including GDF	• GDF would lose – Financial leverage (both carrot and stick) to encourage DOTS expansion – Ability to promote standardization of TB treatments – Access to a range of countries with non-level playing fields
Recommended procurement agent	• Donor gives grant to country and maintains M&E function • Donor recommends GDF as procurement agent	• GDF would lose financial leverage to encourage DOTS expansion
Mandated procurement agent	• Donor gives grant to country and mandates GDF as procurement agent • Donors delegates M&E function to GDF	• No diminished impact for the GDF, but only if donor agrees to GDF-driven application, review and M&E process and decision-making, so that GDF retains the carrot and the stick • Would any donor give up this degree of control over M&E?

GDF's DIRECT GRANT-MAKING ROLE CAN BE SUSTAINED WITH FUNDING LEVELS OF ~$20-40 MILLION PER YEAR

TOP-DOWN ESTIMATE

Million cases p.a., 2002



Estimated TB incidence

Less: Cases in "opportu-nistic" beneficiaries

Cases in "natural" and "challenging" beneficiaries

Less: 1/3-2/3 demand that GDF will not meet

1/3-2/3 demand that GDF will meet through grants

- It is neither necessary nor desirable for GDF to grant 100% of a country's needs
  - Discourages countries' from having budget lines
  - Makes exit harder
  - Reduces competition and local procurement capacity
- At $10-12 per treatment course, GDF will require ~$20-40M per year for drug grants

GDF will prioritize grant recipients based on ability to have impact on their DOTS program, in addition to drug need. Hence, focus on "natural" and "challenging" beneficiaries

Grants of 1/3-2/3rd of country needs is adequate for GDF to catalyze DOTS expansion
- 30% budget gap in HBCs
- Meaningful level for leverage
- Countries can use direct procurement for the rest

DIFFERENT DONOR SEGMENTS CAN BE EXPLORED FOR THEIR POTENTIAL TO FUND GDF ACTIVITIES

	Description	Issues to explore
Current GDF donors	• CIDA, Netherlands government, (« founding » donors) • USAID, World Bank	• Views on GDF impact and continuing alignment of GDF operations with donor objectives • Position vis-à-vis Global Fund • "What GDF would have to look like" to continue being funded by current donors
Other TB donors	• DFID, JAICA, other governments	• Awareness of GDF • Views on GDF and alignment of GDF operations with donor objectives • "What GDF would have to look like" to be funded by other TB donors
Other donors	• Funders of leprosy programs, e.g. Nippon Fnd to WHO, Novartis Fnd	• Consideration of diverting leprosy funds to other needs • Current level of involvement in TB
	• Other institutional donors interested in public health	• Willingness to fund TB projects • Awareness of GDF
	• Pharma companies	• Willingness to manufacture 4FDC as grants-in-kind
	• In-country corporate donors (e.g. Shell in Nigeria)	• Willingness to 'adopt-a-country' • WHO mechanisms for receiving corporate donations
	• Individual donors	• Willingness to 'adopt-a-country' • WHO mechanisms for receiving individual donations

Source: team analysis

AFTER TWO YEARS OF OPERATION, GDF HAS A COMPELLING MESSAGE TO COMMUNICATE WITH DONORS

	Key message
Magnitude of impact	• GDF has a proven track record of impact with a unique value proposition :1.8 million cumulative patients have been treated with GDF drugs, across 24 countries
Speed of impact	• Combination of grant and procurement leveraging WHO channels delivers needed drug to countries very quickly • GDF value proposition stimulates and catalyzes DOTS expansion even before arrival of drugs
Cost-effectiveness of impact	• Incremental cost per patient treated ~$12 • Added benefit of catalyzing other needed initiatives

Source: team analysis

GDF HAS TWO MAIN OPTIONS FOR WORKING WITH THE GLOBAL FUND

Work in progress

GDF FINANCIALS SUMMARY

USD

Lower end scenario

	2001-2002	% Rev	% COGS		2003	% Rev	% COGS	2004	% Rev	% COGS
Inflows (donations, grants-in-kind)	**23,167,485**				**15,248,611**			**24,236,343**		
Inflows excluding carry over	**20,969,249**									
Cost of goods sold (procurement costs)	**17,383,381**	82.9%			**12,498,010**	82.0%		**19,949,458**	82.3%	
Drug cost, procurement service fee, freight, insura	17,383,381				12,498,010			19,949,458		
Selling, general, and administrative expenses	**3,585,868**	17.1%	20.6%		**2,750,601**	18.0%		**4,286,884**	17.7%	
Advocacy and communications	127,126	0.6%	0.7%		187,470	1.2%	1.5%	299,242	1.2%	1.5%
Technical assistance and monitoring	511,806	2.4%	2.9%		367,970	2.4%	2.9%	587,357	2.4%	2.9%
Quality assurance	508,066	2.4%	2.9%		365,281	2.4%	2.9%	583,065	2.4%	2.9%
General and administrative	**1,086,788**	5.2%	6.3%		**1,080,000**	7.1%	8.6%	**1,720,000**	7.1%	8.6%
GDF fixed term	217,533	1.0%		Senior P staff	480,000	3.1%		640,000	2.6%	
GDF short term	471,056	2.2%		Junior P staff	360,000	2.4%		720,000	3.0%	
STB Secretariat*	240,000	1.1%		G staff	240,000	1.6%		360,000	1.5%	
Seconded staff**	158,200	0.8%								
Indirect cost to WHO	1,352,082	6.4%	7.8%		749,881	4.9%	6.0%	1,097,220	4.5%	5.5%
Operating carry over	2,198,236	10.5%								

Higher end scenario

	2001-2002	% rev	% COGS		2003	% rev	% COGS	2004	% rev	% COGS
Inflows (donations, grants-in-kind)	**23,167,485**				**18,540,626**			**29,590,840**		
Inflows excluding carry over	**20,969,249**									
Cost of goods sold (procurement costs)	**17,383,381**	82.9%			**14,997,612**	80.9%		**23,939,350**	80.9%	
Drug cost, procurement service fee, freight, insura	17,383,381				14,997,612			23,939,350		
Selling, general, and administrative expenses	**3,585,868**	17.1%	20.6%		**3,543,014**	19.1%		**5,651,490**	19.1%	
Advocacy and communications	127,126	0.6%	0.7%		224,964	1.2%	1.5%	359,090	1.2%	1.5%
Technical assistance and monitoring	511,806	2.4%	2.9%		749,881	4.0%	5.0%	1,196,968	4.0%	5.0%
Quality assurance	508,066	2.4%	2.9%		438,337	2.4%	2.9%	699,678	2.4%	2.9%
General and administrative	**1,086,788**	5.2%	6.3%		**1,080,000**	5.8%	7.2%	**1,720,000**	5.8%	7.2%
GDF fixed term	217,533	1.0%		Senior P staff	480,000	2.6%		640,000	2.2%	
GDF short term	471,056	2.2%		Junior P staff	360,000	1.9%		720,000	2.4%	
STB Secretariat*	240,000	1.1%		G staff	240,000	1.3%		360,000	1.2%	
Seconded staff**	158,200	0.8%								
Indirect cost to WHO	1,352,082	6.4%	7.8%		1,049,833	5.7%	7%	1,675,755	5.7%	7%
Operating carry over	2,198,236	10.5%								

Source: STB Secretariat; GDF; team analysis

ASSUMPTIONS FOR FINANCIAL PROJECTION

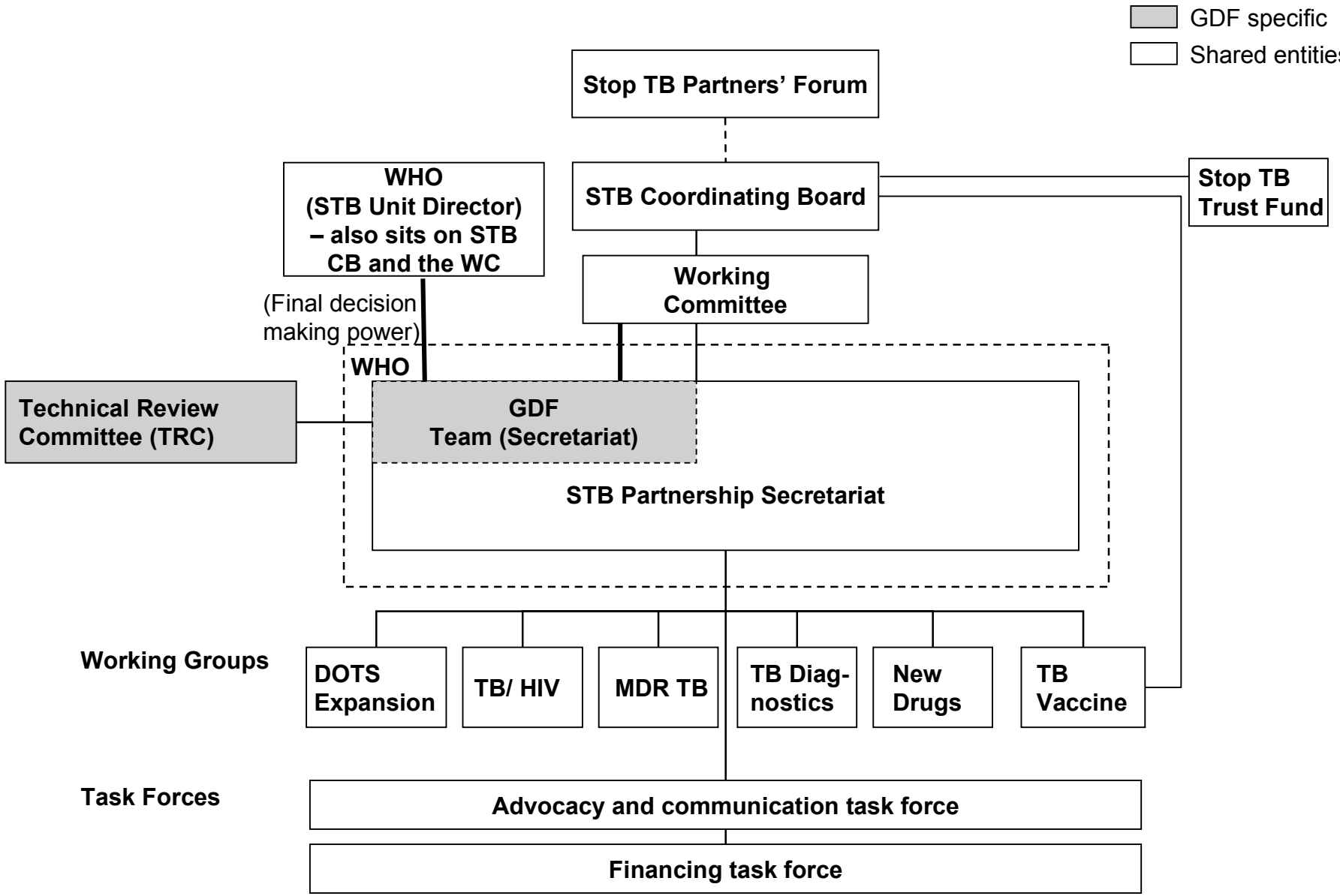
	Common assumptions	Lower end scenario assumptions	Higher end scenario assumptions
Drug cost	• Continue current commitments • Continue to serve DOTS expansion plan of current countries – Average 40% DOTS expansion • Commitment to new countries are 1.1M each TRC round – Average of most recent TRC rounds (TRC 5 being 0.7M, TRC 6 being 1.6M)		• High end reflects 20% drug price appreciation
Operating cost	• HR increases to 4 senior staff; 8 junior staff; 6 general support staff – 160,000 USD per senior staff, 120,000 USD per junior staff, 60,000 USD per general staff – 4 senior staff is CEO, COO/CFO, Procurement and M&E manager – 8 junior staff will cover 80+ countries	• Technical assistance proportion of drug grant is maintained • WHO indirect costs gradually decreases to 5% of drug costs from current 7.8% reflecting lower costs from the WB trust fund	• Technical assistance proportion of drug grant increases from 2% of drug costs to 4% • WHO indirect costs stabilizes at 7%

Source: STB Secretariat; Team analysis

APPENDIX CONTENTS

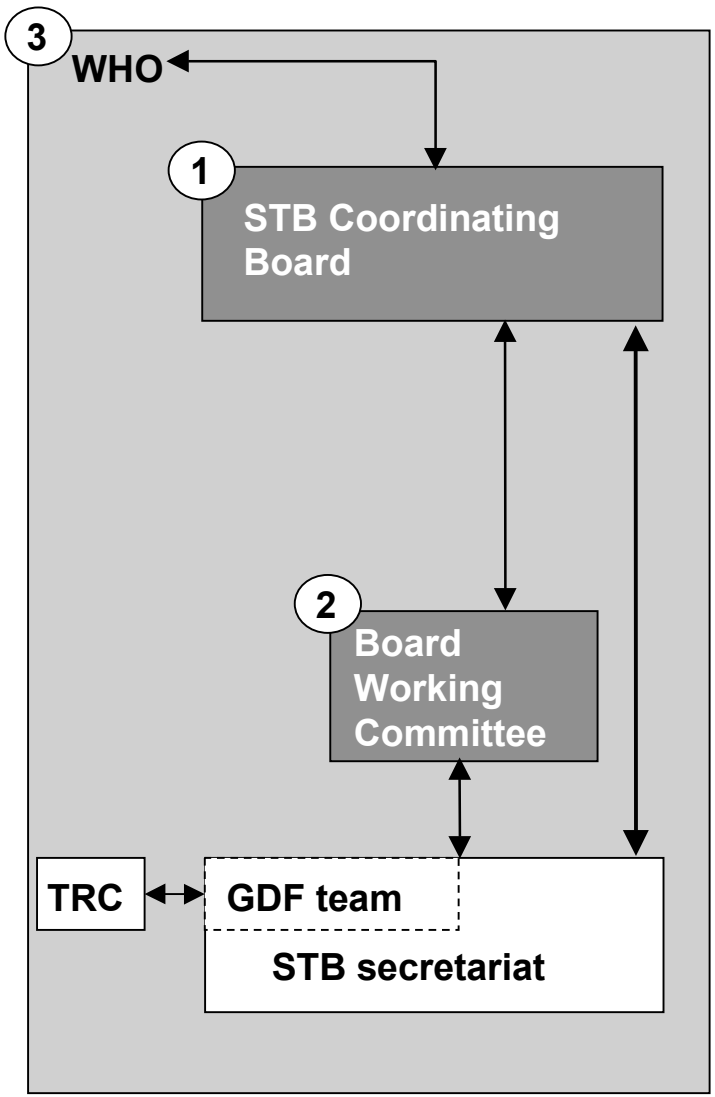
- **Should the STB Partnership continue to support GDF? If so, what changes are needed to its role, proposition, business model?**
- **What resources must the STB Partnership commit to GDF over the next 3 years? How should GDF work with the GF?**
- **Should the GDF continue its current governance/ administrative model with WHO? What changes are required, if any?**
- **Should the GDF expand scope?**
- **Country-specific feedback from country visits**

TODAY, GDF SITS IN WHO WITH FINAL ACCOUNTABILITY TO WHO, BUT ADVISORY INPUTS FROM THE STB CB AND WC



Source: STB framework, MoU, GDF prospectus

THERE ARE THREE ENTITIES INVOLVED IN GOVERNANCE OF THE GDF



1 Stop TB Coordinating Board (STBCB)

- Advisory role, focused on coordinating the actions of autonomous partners
- Aims at representation of all key stakeholders
- Decisions are reached by consensus, are non-binding on partners and can be overruled by WHO
- Covers all activity areas of Stop TB Partnership; no GDF specific ToR (except WHO MOU)
- Meets twice per year, plus phone conferences where needed

2 Board Working Committee (WC)

- 6 member subcommittee of the STB CB representing stakeholder groupings, selected by consensus
- Collaborates with the GDF Secretariat activities on a regular basis (assists in preparing work plans, reports for Board meeting and related background papers, liaises with board members on any follow up, does not make decisions); no GDF-specific detailed ToR

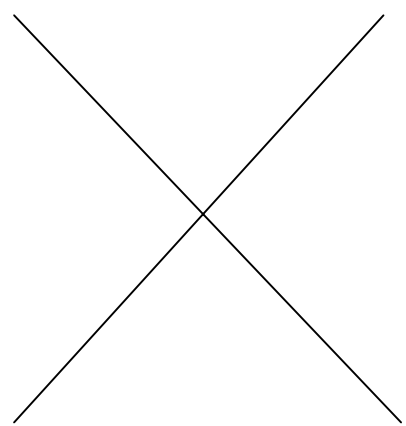
3 WHO

- Provides jurisdictional personality for STB Partnership and GDF, including capacity to contract, acquire property and institute legal proceedings
- Has final decision power on all recommendations of the Board

Source: Basic Framework for the Global Partnership to Stop TB; STB Coordinating Board: Operational issues to the Stop TB Framework

MANY ORGANIZATIONAL OPTIONS WERE CONSIDERED FOR GDF IN 2000–2001

EXAMPLES-NOT EXHAUSTIVE

Legal status	Housed by Inter-governmental Organization	Housed by NGO	Standalone
Independent legal identity	**Global Fund for Aids, TB and Malaria** (WHO, start up phase) • **Council of International Organizations of Medical Services** (at WHO)	**Medicines for Malaria Venture** (at Global Forum for Health)	• **IAVI** • **Global Alliance for TB Drug Development** • **Global Fund for Children's Vaccines**
"Borrowed" legal identity	**GAVI** (in UNICEF) **Roll Back Malaria** (in WHO) • **Stop TB** (in WHO) • **Polio Eradication Initiative** (at WHO) • **Global Alliance for the Elimination of Leprosy** (in WHO) • **Special Programmes: TDR, HRP** (in WHO)	• **Mectizan Expert Committee** (at Task Force for Child Survival) • **Gates Children's Vaccine Program** (at PATH) • **Malaria Vaccine Initiative** (at Path) • **International Commission on Harmonization** (at IFPMA)	

Physical housing

Source: Institutional arrangements for Governance and Management of the Global TB Drug Facility: A Discussion Paper; McKinsey analysis

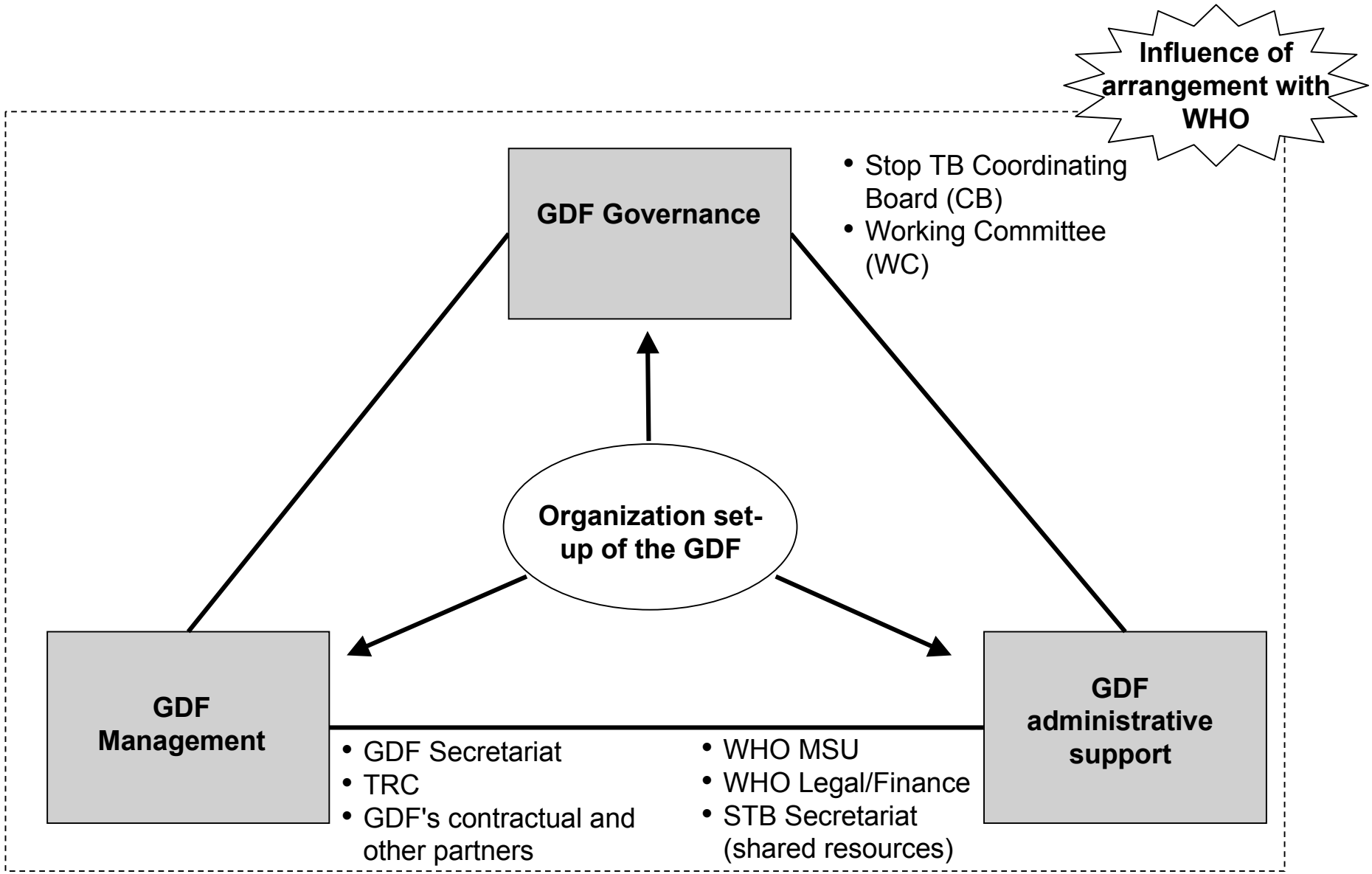
THE STB CB DECIDED TO LAUNCH GDF AS A BORROWED LEGAL ENTITY HOUSED IN WHO FOR A TRIAL PERIOD OF TWO YEARS

Selected option

Options considered	Expected benefits	Drawbacks/ risks
1. Independent entity housed within WHO	• Access to WHO to regional/local infrastructure • Credibility through WHO brand name • Co-use of STB Secretariat for advocacy, administrative and resource mobilization functions • Access to STB partners and WHO technical departments	• Constraints through existing WHO operating procedures • Time required to create independent legal entity and potential challenges for WHO to relate to such an entity
2. Borrowed legal identity housed in WHO	• **As in option 1** • **Shorter set up time** • **Coordination of GDF and STB partnership efforts through joint policy setting in CB**	• **Constraints through existing WHO operating procedures** • **Board only advisory - dependent on WHO not unduly influencing decision making**
3. Independent GDF housed by another STB Partner (KNCV, IUATLD)	• Same mission synergies as with STB • Working relationships with some national TB programs, STB partners and some bilateral donors • Experience in procurement/supply management	• IUATLD and KNCV would have to scale up, particularly in regards to communication/ financial agreements with recipient countries • Own comparative advantage in procurement functions would be decreased as would not be able to serve as GDF procurement agent
4. Independent standalone entity	• No baggage from existing set-up, ability to tailor administrative, managerial, and governance systems/structures to needs of GDF	• Higher start-up costs and time • Potentially lost synergies/coordination with STB • Lack of bilateral commitment • UN concerns about establishment of yet another entity to serve public health needs

Source: Global TB Drug Facility: Options for governance (Core Technical Group); Institutional arrangements for Governance and Management of the Global TB Drug Facility: A Discussion Paper; McKinsey analysis

WE REVIEWED THREE AREAS TO ASSESS GDF's ORGANIZATIONAL SET-UP, WHICH ARE ALL IMPACTED BY THE ARRANGEMENT WITH WHO



THE CURRENT ORGANIZATIONAL MODEL HAS MET THE NEEDS OF THE GDF TO A LARGE EXTENT

● Fully met
◑ Somewhat met
○ Did not meet

Areas reviewed	Needs of the GDF at start-up	Assessment of whether these needs were met
Governance	• Well-functioning board with clear roles and representation from key TB stakeholders • Alignment with STB goals • Short set-up time • Quick and efficient decision making and robust oversight	◑ • Agreement at the highest level on need for and value add of GDF in STB CB, WC and WHO • Committed and stable funding in first 2 years • Relatively well-functioning STB CB with balanced representation, collaborative working style and focus on getting things done • Delegation of grant review and oversight of work planning/ budgeting to WC to enable fast decision-making. • However, limited engagement, oversight and sense of responsibility among CB/WC w.r.t. GDF (discussed later)
Management	• Lean and innovative management team • Credibility with and access to countries • Strong and independent technical expertise • Smooth coordination with other TB efforts and key partners	● • Strong core team – Visionary and technical competent leadership – Highly committed, hard-working, innovative staff with “can-do” attitude – Secondments to increase technical expertise – Strong use of outsourcing to keep staff lean • Strong TRC with high credibility, committed group and independent functioning • Access to expertise knowledge, in country infrastructure and credibility through WHO affiliation and brand name • Ready access to partners within Stop TB partnership rather than having to build from scratch • However, given lean team and reliance on a few core people can be problematic (as it currently is)
Administration	• Quick set-up with low costs, given scale of operations • Adequate flexibility to allow GDF to respond quickly and innovatively to countries' needs	◑ • Rapid start up through use of WHO’s administrative services and physical infrastructure • GDF MSU perceived to be relatively flexible and service-oriented • However, much time and energy spent in negotiating with WHO’s Legal Department for contracts (discussed later)

Source: Interviews; team analysis

GDF'S GOVERNANCE HAS MET EXPECTATIONS ONLY PARTLY, TO DATE

● Needs fully met
◑ Somewhat met
○ Not met

Needs in startup phase	Assessment	Supporting examples/quotes
Representation from key stake holders	◑	• *"From my perspective, the STB board includes all the important constituencies for the GDF, creating a separate board would have meant duplication"* • *"If the GDF had been independent of WHO it would have been difficult to attract such high caliber people, to the board and the TRC"* • *"If this had been a GDF board, it would have looked different more procurement and management expertise in addition to technical knowledge"* • *"GDF could have engaged a broader range of stakeholders from other donors, industry, bilateral partners etc., which if could not do because of its governance arrangement"*
Clear roles and responsibilities	◔	• No GDF-specific TOR in STB basic framework outlining roles and responsibilities of the STB CB and the WC. MOU includes basic outline, but is not known to many board members • Many gaps in oversight of GDF and lack of clarity on who is responsible, e.g., strategic oversight, audit, financial controls, fund raising • *"The role of the working committee regarding GDF, I really don't know?"*
Alignment with STB goals	●	• Common boards for STB and the GDF has helped in alignment of goals
Short set-up time	●	• "A real benefit of integrating GDF into STB was that we did not need to create a separate board. Everything was in place and ready to go"
Quick and efficient decision making and robust oversight	◑	• TRC-WC approval process works smoothly and without major delays. GDF is agenda item in 95% of STB CB and WC meetings. However, overall time spend on GDF is low and flow of information, while adequate, is often not clear and suitable for decision making (e..g, P&Ls) • Given STB CB and WC's role is advisory and WHO may not want to demonstrate undue influence, key strategic decisions, risk management and preemptive solutions to issues (e.g., succession planning) do not happen • *"We (the STB) get presentations a couple of time a year – it's a dog and pony show and that's the end of that"*

Source: Interviews, team analysis

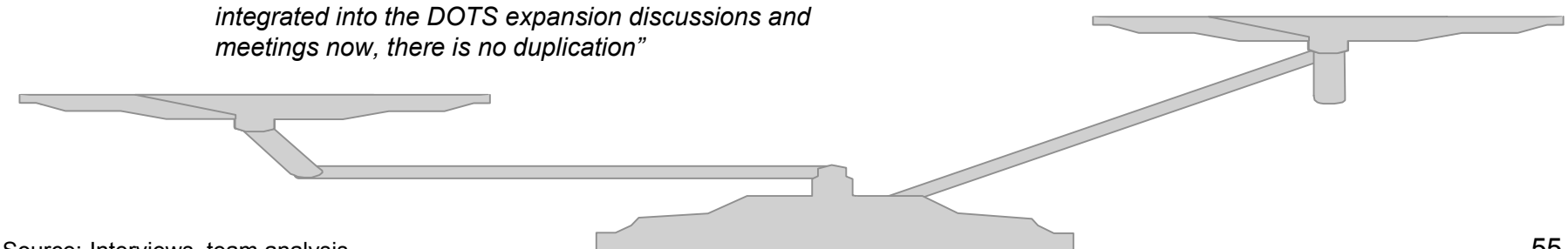
THE ARRANGEMENT WITH WHO HAS ALSO LARGELY HELPED THE GDF DELIVER ON ITS CORE FUNCTIONS

Expected benefits have materialized, especially at country level…

Credibility	• Benefited from WHO "brand name" to rapidly build confidence in quality of drugs and services provided by GDF and waive in-country taxes and registration process – *"The drugs are coming from WHO, they must be of good quality" – NTP manager*
Infrastructure	• Established communication with countries through WHO country/region office, with links to MoH/NTP and STB technical partners
Access to knowledge/ expertise	• Accessed relevant expertise in WHO technical departments (e.g. developed white list of suppliers with EDM, TB Monitoring and Evaluation) • Recruited high quality TRC members due to WHO association • Benefited from physical closeness to relevant knowledge – *"A lot can get done in a corridor conversation or by walking up one floor"*
Rapid start up/ cost effectiveness	• Benefited from quick and easy start up and scale economies using STB Secretariat and WHO MSU • Did not need to recruit separate board, leveraged STB CB
Coordination	• Ensured daily coordination for joint goals for DOTS expansion and joint policy setting in STB CB through integration of GDF into STB Secretariat – *" GDF is fully integrated into the DOTS expansion discussions and meetings now, there is no duplication"*

… And attempts have been made to mitigate risks at a system/administrative level

Interference	• MOU defined roles of key entities (WHO, Secretariat, CB, WC) to ensure no undue influence of WHO on GDF decisions/ operations
Administrative delays	• Management team used methods like short-term contracts to overcome delays in response time caused by inflexible systems
Constraints on innovation	• Special regulations in GDF MOU with WHO to ensure no stifling of entrepreneurial spirit (e.g., procurement process)



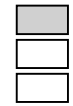
Source: Interviews, team analysis

WHO IS NOT SEEN TO HAVE UNDUE INFLUENCE ON GDF'S GOVERNANCE

	Current situation	Assessment and implications
Direct influence	• MOU with WHO ensures that WHO has the final decision-making power in all areas, while the Stop TB Coordinating Board has advisory powers • GDF team is WHO staff (except secondments) • GDF Manager reports to WHO Director of STB	• WHO is not seen as using its legal power to undo the Board's recommendations or exert undue pressure • Further, partners do not feel that GDF is more accountable to WHO than the partnership (e.g., India's application to the TRC; early GDF procurement processes; institution of Trust Fund in the World Bank to receive GDF's funding) • However, the system seems to work more due to the buffering role played by current leadership and management from WHO. Hence, concerns have been raised about sustainability and the need for stronger institutional mechanisms to limit WHO's potential influence
Indirect influence	• 10 of 26 board members are either WHO staff or selected/recommended by WHO • All decision-making by consensus, no voting • Low level of board engagement and direct knowledge of GDF operations - with all information being provided and shaped by the GDF Secretariat • No direct channels of communication between the TRC and Stop TB Board, GDF team is always the intermediary	• Some concern about indirect "board capture" – Through strong representation of WHO staff on board, (even though not as representatives of the organization) – Through GDF Secretariat, staffed by WHO employees – By WHO culture - *"If one operates in an environment where certain things do not fly, you will not even try".* • STB CB and WC have little visibility into the TRC's functioning and vice-versa. TRC decisions often include some policy-making, which the Board is ignorant of

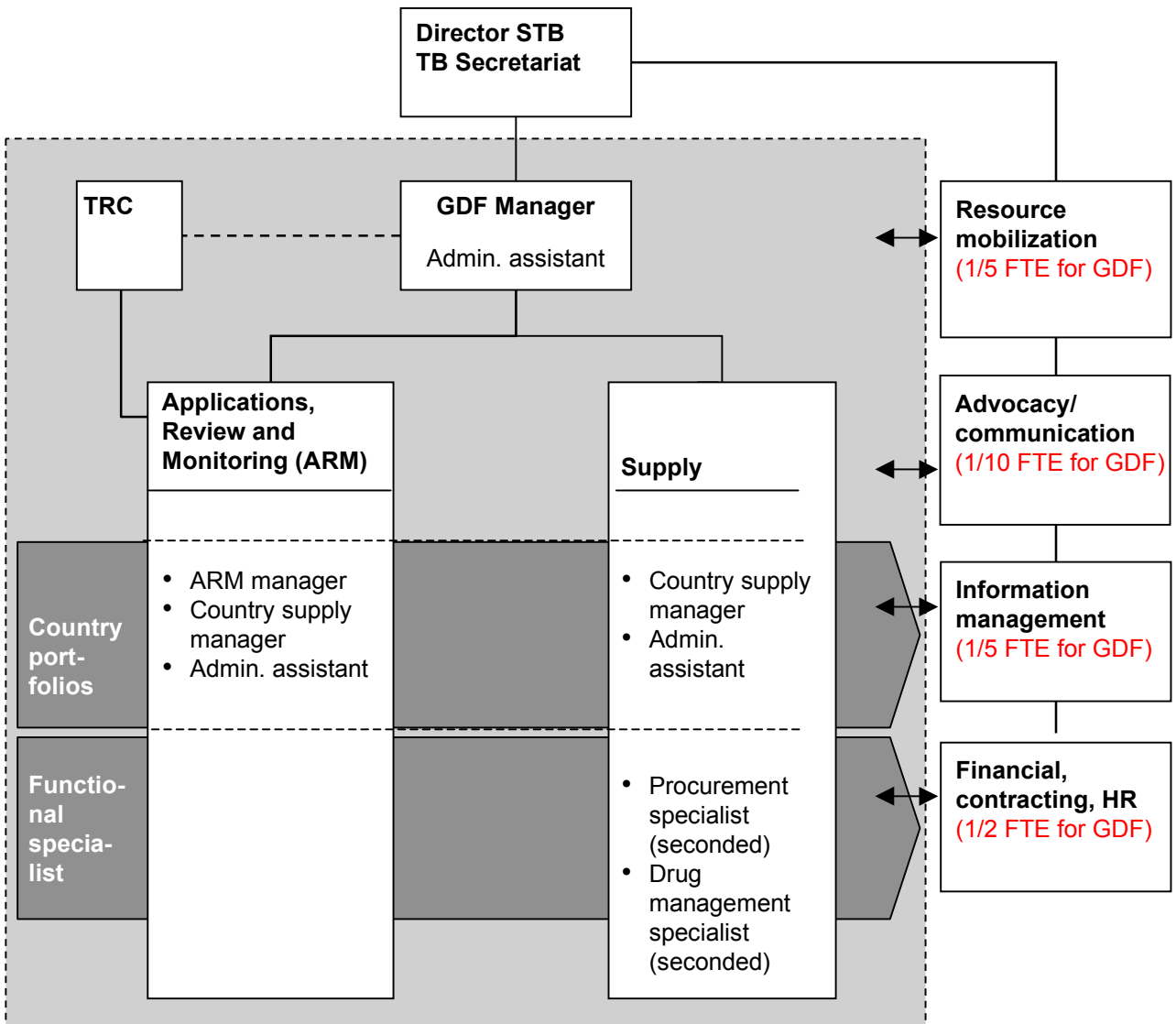
Source: Interviews and team analysis

GOING FORWARD, THE CURRENT GOVERNANCE MODEL IS UNLIKELY TO FULLY MEET GDF'S NEEDS



Challenges	Examples/quotes
Diverging opinions about future direction	• *"GDF should expand scope if countries need it and if the Global Fund will use this service"* • *"GDF should not over-step its boundaries should not expand into TB microscopes, 2nd line drugs, ARV and bednets… We need to question whether this is really a 'grow or die' business?"*
Concerns about accountability and decision making	• *"As a TRC member I am at a loss to understand the decision making process in the CB. Neither part has visibility to each other's roles, functioning and decisions"*
Gaps in execution of key board role, compounded by limited time/attention devoted to the GDF	• *"As the GDF gets bigger and more complicated and represents a larger spend of the partnership, it deserves more than to be item 8 or 9 on the agenda"* • *"The GDF is an enterprise in its own right. It can be run under the same umbrella as the STB partnership, but must be run in a more business-like manner"* • *"We need some sort of audit committee of the board or even an external auditor to review the GDF processes, financials, operations on a regular basis. The CB is too large and clumsy to do this well"* • *"There is no clear role delineation between fund raising/fiduciary oversight, technical oversight, strategic oversight, etc. with respect to the GDF"*
Inadequate briefing materials from GDF to the STB CB	• *"We need to get materials to the board earlier and synthesize better so that you do not have so much paper that you can choke a horse. Issues need to be flagged more clearly to avoid confusion"* • *"The more I think about this, the more I feel that the board does not know enough about the GDF. There is not enough flow of information from the WC and the GDF, especially as the GDF constitutes the bulk of funds. As a Board member, I feel disconnected"*

GDF'S MANAGEMENT TEAM HAS STAYED LEAN WITH A FLUID STRUCTURE AND ROLES SUITED TO THE NEEDS OF A 'START-UP'



- **Lean GDF core team**
  - Total of 9 FTEs (6 professionals, 3 support staffs)
  - 3 seconded
  - Receives part time support from STB secretariat (total of 1FTE)
- **Emerging structure:**
  - Primary cut is by functions (demand, supply), secondary cut by countries (i.e., countries have separate contact for ARM and supply
  - Supply side has functional specialists in procurement and drug management (not country specific), ARM does not have any functional expertise (e.g., in M&E)
  - No separate resources or responsibilities for GDF's resource mobilization, marketing operations

GDF'S MANAGEMENT HAS MET EXPECTATIONS WELL, TO DATE

● Needs fully met
◑ Somewhat met
○ Not met

Needs in startup phase	Assessment	Quotes/examples
Lean and innovative management team	●	• Made significant progress in making GDF operational in a short time with a very lean staff • Leveraged secondments and WHO departments to increase technical expertise (e.g. procurement and drug management) • Demonstrated high level of commitment, "can do attitude" and willingness to experiment, which cited be partners and countries as very impressive • Team members have demonstrated ability to grow into stretch role and if coached, have potential to develop further • *"Highest marks for hard work, conscientious, enthusiasm, responsive - absolutely no complaints on that"; "Jacob and Ian are very good to deal with; prompt in responding, very cooperative and constructive – it is a pleasure to work with them"*
Strong leadership	●	• To many partners, Ian Smith represents the GDF – *"Ian has demonstrated excellent management and leadership skills. He is a innovative thinker with a fresh perspective. He has found a way to apply private sector approaches in a public sector setting despite huge opposition"*
Credibility and access to countries	◑	• Has accessed countries through WHO and partner links in countries. WHO linkage has provided credibility to solicit applications
Access to technical expertise	●	• The TRC is highly regarded as a technically competent, independent and well-balanced team with depth of functional and regional expertise – "*One of the most impressive and capable group of people –they take their job seriously"* • TRC processes work smoothly; GDF Secretariat is seen to *"be doing a very good work in preparing for meetings";*
Smooth coordination with other TB efforts and partners	◑	• *"Along with J.W. Lee, Jacob Kumaresan and Ian has ensured that the GDF is accountable and leverages all partners"; Do not sense any real strong paranoia among partners that the GDF Secretariat is not accountable to them. GDF actively follows up on the CB's suggestions"* • After initial issues in working with WHO departments, GDF and WHO have learned to actively cooperate, e.g. with the DOTS expansion Working Group and EDM – *" There was need for fine-tuning earlier, now there is no duplication… our efforts are fully integrated"*

Source: Interviews; team analysis

HOWEVER, THERE ARE SIGNIFICANT ISSUES FOR GDF'S MANAGEMENT GOING FORWARD

Key challenges	Issues
Leadership transition	• While there is good regard for the GDF team, partners are not convinced that anyone else is ready to be his successor and will have the experience and maturity to manage WHO/other partners and internal politics. • Finding the right balance of managerial, technical and political savvy could be an issue - *"The Board should be deeply worried about the management transition"* • *"With Jacob and Ian leaving, people with the technical credibility are leaving. This will be a significant challenge for the GDF"; "I was not so concerned about the role of WHO in the GDF or the perception that WHO had too much influence so long as Ian was there because although he is WHO staff, he (with Jacob's support) did a good job of trying to keep the GDF out of WHO politics. I am not so sure now…"*
Staff shortage and gaps; **Few robust professional systems and functional expertise**	• Staff is perceived to be high on enthusiasm but low on experience – " *They are all young outsiders, very young and inexperienced …'cowboy mentality'"; " could have recruited some experienced WHO or UNICEF people as consultants to provide counsel and mitigate perception of inexperience"* • Significant staff and expertise shortage results in important functions not receiving sufficient attention, particularly advocacy/brand building; internal/external M&E; financial and strategic planning; and knowledge management/ documentation; This is exacerbated by short term contracts (8 of 12 months/year one staff member is on leave) • Some people have also suggested that the GDF should tap a broader range of expertise through secondments or consulting contracts, beyond WHO - *"Do not make these things work well by working in a vacuum in a little teacup of your own"* • Finally, as the team expands and leadership changes, it will be critical to institutionalize values and ensure next GDF leader embraces them; another concern is that coaching culture may be lost with change in GDF leadership • *"GDF is a very small and efficient team, where the void of one person has a big effect on the others and the functioning of the team itself"* • *"People we have now know where certain information can be found, however new people joining the team will have difficulty"* • *"Current knowledge management tools were basically developed by Ian, therefore as Ian leaves it is unclear who has the skills and the responsibility to continue on this front"*
Evolving organizational structure	• GDF's reporting structure works on two dimensions - country servicing and functional expertise, both of which are expanding in parallel. Developing an appropriate matrix reporting structure to deliver against this would be critical • Emerging matrix structure matches current functions, but important issues need to be addressed: – Shared responsibility for country between supply and demand side requires close coordination between ARM country officer and supply country officer, which can be cumbersome and cause delays as the team expands – It is not entirely clear where direct procurement function fits into the organizational structure; will require marketing and branding efforts that are currently not accounted for (and thus get neglected) – No clear ownership in current structure for GDF financial and business planning, operations and management systems (spread across GDF and STB Secretariats)

Source: Interviews; team analysis

AN ANALYSIS OF CRITICAL ROLES VS. CURRENT SKILLS REVEALS FOUR GAPS

Role-Skill Grid

Level of expertise

H = High (relevant degree or equivalent for task required,4+ yrs of experience, level of competence ideal fit with task)

M = Medium (some relevant training for task required, 1-3 years of experience, competence level ok fit with task)

L = Low (little formal training and experience, competence level currently below task)

	Leadership/Partner relations		Financial Planning/Mgt		Strategic planning		Knowledge/ Data mgt		Documentation/ Secretarial		Resource Mob/ Communications		Marketing/Surveying		Country management		Monitoring/ Perf Mgt		TB tech. assistance/expertise		Pharmacological knowl		Procurement expertise		Drug/ Distribution mgt	
	Resp	Exp.	Resp	Exp.	Resp	Exp.	Resp	Exp.	Resp	Exp.	Resp	Exp.	Resp	Exp.	Resp	Exp.	Resp	Exp.	Resp	Exp.	Resp	Exp.	Resp	Exp.	Resp	Exp.
Core GDF Team																										
Ian Smith	X	H	X	H	X	H	X	H			X	H	X	M	X	M	X	M	X	H						
Virginia Arnold			X	M	X	M	X	M			X	M			X	M	X	M								
Robert Matiru							X	M							X	M							X	M		
Lucy							X	M	X	H					X	M										
Sarah Jane									X	M																
Vitalis Adu									X	M																
Secondments																										
Hugo Vrakking															X	H			X	H	X	M	X	H	X	M
Tom Moore													X	L							X	H	X	M	X	H
Anna																	X	M								
STB Secretariat																										
Jacob Kumaresan	X	H									X	H			X	H	X	H	X	H						
Lina Abrahams			X	M																						
Mary Meehan									X	M																

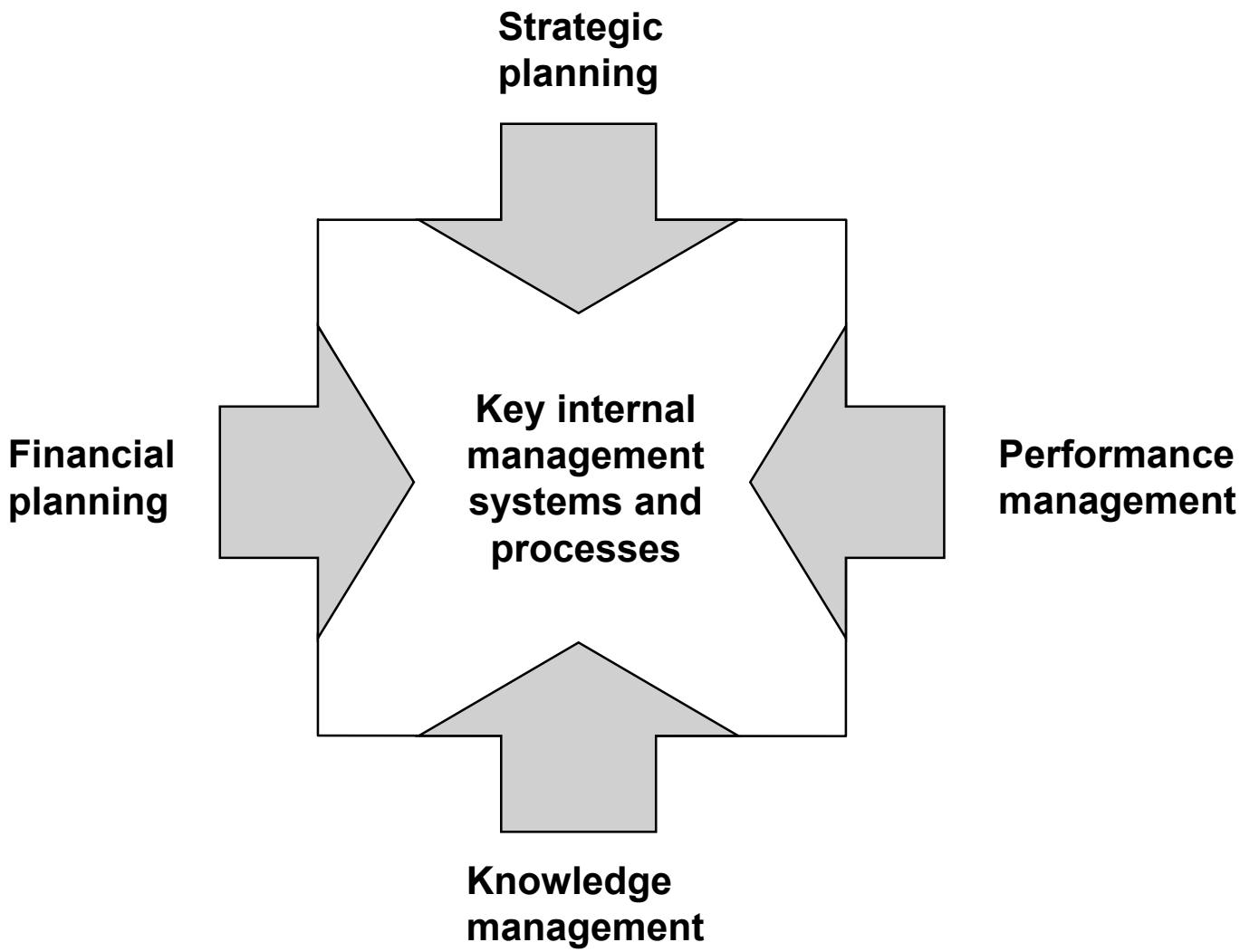
Gap in strategic and financial planning

Gap in marketing and fund raising

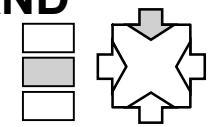
Gap in M&E

Potential gap in procurement/ drug mgt once secondments end

GDF'S INTERNAL MANAGEMENT SYSTEMS AND PROCESSES HAS 4 KEY AREAS



GDF HAS BEGUN MORE SYSTEMATIC PLANNING THROUGH "WORK PLANS" AT AN EXECUTION LEVEL; HOWEVER, STRATEGIC, OPERATIONAL AND FINANCIAL PLANNING REMAINS A GAP



Description of current system

- Strategy planning instruments are the biannual work planning, weekly team meetings and ad hoc retreats
- **Work planning** is driven by activities that need to take place
- Recently team decided to split **weekly team meetings** into two meetings (country meeting - operations, staff meeting - strategy) due to increasing number of countries and need of focus on strategy
  - Agenda for planning meetings are decided through informal discussions and e-mail among key people
- **Retreats** not only cover strategic discussion topics but also personal work and development planning

Strengths/ weaknesses

Strengths

- Good balance between formal and informal planning processes
- Weekly staff meetings which is a topic and event driven approach is being balanced with country meetings focused on operations
- Good effort to move away from tactical operation tracking meetings for increase in strategic idea generation

Weaknesses

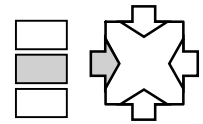
- High level strategic planning is dependent on STB Coordinating Board, however accountability is unclear

Recommendations

- Continue efforts to increase innovative strategic planning. However, need to institute more disciplined and coordinated process for strategic, financial and operational planning as GDF size and complexity increases, beyond the work plan
- Make efforts to create links of planning to not only target setting but also other processes such as performance management, people and budget
- Assign clear accountability for the review of high level strategic issues to the STB CB or WC

Source: Interviews; team analysis

AS GDF MOVES FORWARD, DEDICATED PROFESSIONAL FINANCIAL PLANNING WILL BE REQUIRED



Description of current system

- Financial planning is driven by the work plan developed annually
  - Cost requirement is measured against the previous year's spending
- Every year planning is lead by Ian Smith with communication with the STB secretariat and the GDF staff with discussions based on the 5 year strategy plan
- Once the financial plan is developed, it is presented to the board for approval

Strengths/ weaknesses

Strengths

- Financial planning has been flexible and was responsive to the needs of the countries

Weaknesses

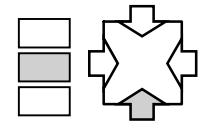
- Resource mobilization has been weak
  - Reliance on donors is high, where donors do not always meet expectations
- Planning and reporting formats inadequate to support oversight and decision-making

Recommendations

- Have own accounting set-up as GDF grows operations
  - Work amount is increasing and current 1/3 FTE will not be enough
- Revise reporting formats for more transparency and to improve donor confidence. GDF also needs expertise in financial planning and controls

Source: Interviews; team analysis

KNOWLEDGE MANAGEMENT NEEDS TO BE PLANNED OUT AND SYSTEMIZED



Description of current system

- Knowledge assets have been developed on an ad hoc basis
- Knowledge is often in tacit form with a few people
- Some knowledge assets have been formalized on an as-needed basis, e.g.,
  - Monitoring spreadsheet covering the basic indicators of the recipient countries
  - Country spreadsheet tracking various tasks to take place for time process management
  - Template of letters which is linked with the country spreadsheet
  - Expert database has been recently developed containing information such as contact details and language capability
  - Files of e-mail correspondence with countries
  - Shared drive

Strengths/ weaknesses

Strengths

- Knowledge assets developed used effectively, as a tool to increase efficiency for every day work
- Clarity on "who is in charge of what", therefore information is easily accessible
- Assigned responsibility for documentation and update of existing knowledge assets, therefore information is updated appropriately

Weaknesses

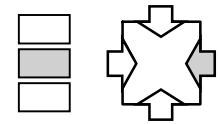
- Current model relies much on one person (Ian) taking initiative in developing knowledge assets, however will need to formalize process for planned development
- Difficult to navigate information without prior knowledge as information is fragmented
- Information is not accessible to the partners

Recommendations

- Set clear role and accountability for identifying gaps to fill and developing the tools to fill the gap
- GDF's plans to move towards an integrated information system and to provide online resources for partners are desirable moves towards the right direction

Source: Interviews; team analysis

AS GDF MOVES FORWARD, COACHING AND LEARNING CULTURE SHOULD BE INSTITUTED



Description of current system

- Bi-annual reviews based on WHO's PMDS (Personal Management and Development System)
  - Individuals are required to define their objectives and outputs for yearly and midterm reviews
  - Evaluation is based on self review and the supervisor review
- There are bi-annual feedback sessions with less discussion on performance but more discussion on future plans
- Personal development opportunities through training courses are available, however link with performance is unclear

Strengths/ weaknesses

Strengths

- GDF has been able to create a culture of informal coaching and learning
- Expectations of individual is clear through the objectives agreed through the PMDS

Weaknesses

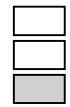
- Review is based entirely on the work plan which does not capture all aspects of work that is done by an individual
- Review results need to be used, moreover both negative and positive feedback are necessary for the development of the individual
- There are other aspects of work other than the work plan, i.e. leadership, communication etc. that should be reviewed

Recommendations

- Institute the current coaching and learning culture in order to continue within the organization
- Devise methods of recognizing performance even within the structure of PMDS
- Review other important aspects of work other than the work plan, e.g., leadership, communication, that should be reviewed
- Coaching and 2-way feedback mechanism for development of both individual and supervisor
- Incorporate training in business/ management skills to complement technical skills

Source: Interviews; team analysis

WHO HAS PROVIDED ADMINISTRATIVE SERVICES TO GDF WITHIN ITS EXISTING STRUCTURE



	Description
Recruitment	• Regular WHO recruitment process with one GDF representative on selection board
Services for personnel, payroll	• GDF employees have the same status as WHO employees with health insurance, pension management
Treasury, accounting, finance	• WHO provides for basic treasury, accounting and finance functions – Reconciliation – Allotment of funding – Payment of expenditures
Legal and contract	• Contracts are made according to WHO standards – Donor contracts (CIDA, WB) – Procurement contracts (IAPSO) – Sub-contractor contracts
Others	• Visa and travel, translation services • Conference facilities • IT services • Office space • Security • Utility costs • Etc.

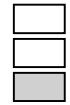
Source: Interview

WHO'S ADMINISTRATIVE SUPPORT WAS EFFECTIVE IN THE START-UP PHASE

Needs during start-up	Assessment	Quotes/examples
Access to the right people with the right skills	◕	• GDF was able to recruit talent with WHO's reputation • Provides attractive salary that is exempted from tax duties • However, WHO's hiring norms make it difficult to execute long-term contracts efficiently, thereby increasing reliance on short-term contracts with limitations (e.g., 8/9 of GDF staff is on short-term contracts, with 1 month breaks p.a.)
Quick set-up with low costs	●	• *"GDF has been able to set up its activities quickly by taking advantage of the existing functions of WHO"* • *"Launching a new organization requires large set up costs, and being housed in WHO and leveraging their services has minimized their set up costs"*
Adequate service level with no major gaps	◕	• GDF has had a good relationship with the MSU and is not aware of any major glitches • WHO travel system is seen as very helpful (fixed per diems, visa office for consultants, UN passports for staff members)
Flexibility and fast response time	◑	• WHO has been flexible in allocating resources for the GDF, which has been increasing lately • *"Having to follow the rules of WHO has been difficult and queries have delayed procedures"* • *"Initial procurement contract took a long time to set up, moreover the prolongation of the contract also took 3 months which should have taken much less than that"*

Source: Interview

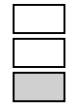
HOWEVER, GOING FORWARD GDF WILL REQUIRE MORE FLEXIBLE AND TIME/COST-EFFICIENT ADMINISTRATIVE SUPPORT



Issues raised	Quotes/examples
Hiring constraints due to WHO administrative rules and processes	• Difficulty to hire long term staff due to WHO personnel regulations/quotas currently circumvented by hiring junior staff through short term contracts and secondments of more senior staff by partners • Questionable whether sustainable model in the future especially if GDF wants to expand scope, and wants to attract and retain high caliber talent • Mandatory one month breaks and prolongation restriction of key team members beyond 4 yrs. limit continuity
Cost of WHO support	• Due to high charges on donations by WHO, donors (i.e. CIDA) initiated a trust fund with the World Bank for lower charges • Similar organizations that are housed within UN agencies have a lower cost for admin – GAVI has been able to receive administrative support from UNICEF, its host organization resulting in a ~0% admin cost over budget – Global Fund takes advantage of a 4% admin cost over budget (vs. GDF has ~6% admin cost over budget)
Constraints from legal and financial services	• *"Current WHO policies do not foster for partnerships but focus on the benefits of WHO" (e.g. the contract delay with IAPSO)* • *"Going forward as complexity increases, GDF will require a dedicated financial support function"* • WHO accounting system does not meet GDF requirements, i.e. no tracking of country allocation of donor money

Source: Interview

A RANGE OF ADMINISTRATIVE SERVICE OPTIONS ARE AVAILABLE, HOWEVER EACH OPTION SHOULD BE WEIGHED OUT



	Description	Pros	Cons
Full service contract (e.g. GDF)	• Fixed percentage charge on incoming donations/ funds • Covers all administrative services and infrastructure • All fiscal and diplomatic privileges of host organization is provided	• Administrative work is minimized for determining cost • High flexibility I.e. regarding changes in office space	• Lack of transparency with low correlation between services used and costs paid
Itemized service contract (e.g. GF)	• Each service is priced • Covers administrative services for which price has been negotiated • Fiscal and diplomatic privileges can be negotiated with government/ bi-lateral support	• Increased transparency where costs are directly related to services	• All services and prices need to be negotiated, which can limit actual range of services provided • Quality of services are not ensured
In-house functions with outsourced services (e.g. MMV)	• In-house functions are supplemented with outsourced services • Services are outsourced to external commercial providers specializing in specific services	• Flexibility in procuring services through minimized investments • Increased quality and range of services • Greater timeliness	• Increased operational risks • Accessibility of quality services need to be ensured
Hybrid model (e.g. TDR)	• A hybrid of dedicated services, itemized contracts and outsourced services	• Dedicated services will ensure timeliness • Separate payment of itemized and outsourced services will provide opportunity for cost effectiveness	• Prices have to be negotiated
Shared services	• Bring together functions that are frequently duplicated across organizations requiring similar services and offer these services, through a shared services center that operates as a freestanding business	• Bundling of the service requirement and attractiveness as a business will reduce costs	• Set up process will need extensive coordination and agreement among the different parties

Source: Team analysis

GOING FORWARD, GDF FACES SIGNIFICANT ISSUES, WHICH WILL REQUIRE A STRONG ORGANIZATIONAL SET-UP

GDF needs to make key decisions, going forward

Setting strategic direction, e.g.,

- What should GDF's future value proposition, business model and targets/milestones be to meet the STB Partnership's goals?
- How will GDF secure funding of ~$25 million p.a. for the next few years?
- How should GDF redefine its relationships with STB partners going forward?

Managing transition from launch to consolidation, e.g.,

- Who will provide the right leadership to the GDF, given recent departures from the team?
- What is the right management structure, systems, skills to serve 3.4 million patients by 2004 vs. ~900,000 in 2002 today to launch a new service line (direct procurement) and initiate rigorous M&E?
- How to build the "GDF brand" among donors, countries and partners?

Improving business and administrative efficiency, e.g.,

- Does the current MoU with WHO allow GDF to access critical services at cost and service levels competitive with world-class procurement agents?
- How can GDF hire the best-in-class talent to meet its needs, working within or outside of WHO norms?

Hence, requirements from organization set-up

Governance

- Clear decision making mandate and accountability
- Active engagement of board in strategic dialogue
- Strong oversight/audit of financial, operational/technical, performance monitoring and succession planning
- Active role in fund raising

Management

- Strong leadership with credibility in dealing with WHO/other STB partners
- Broader and deeper management and technical expertise
- Sufficient staff to handle higher workload
- Formal internal processes for strategic, financial and operational planning, performance monitoring, talent and knowledge management

Administration

- Efficient, fast and flexible administrative support
- Swift legal, contracting and audit processes, especially tuned into the needs of a broader partnership versus WHO alone

THE CURRENT ORGANIZATIONAL SET UP IS UNLIKELY TO MEET THESE REQUIREMENTS (1/2)

	Issues raised in interviews/ review	Implications
Governance	• Widely diverging opinions on CB regarding GDF's role going forward, but limited strategic dialogue – *"We should definitely expand into ARV's"; "ARV's? No way"* • Limited clarity among board members regarding accountability,decision-making and targets/performance measures for the GDF – *"Who is the GDF accountable to in meeting its performance targets? In fact, what are the GDF's targets?" ; "I hope you will analyze and interpret the financials..do not understand it"* • Concern about gaps in execution of key responsibilities and (e.g.financial oversight, risk management, succession planning, fundraising) regarding the GDF – *"This a fragile system if there are any conflicts. It has worked so far but as we expand we need more engagement and oversight"; " GDF doest not need 27 technically-minded nice people trying to reach a consensus, it needs 3-4 tough decision makers"*	• Unclear how consensus on major strategic decisions will be reached, who will make decision, by what process and who will be accountable – STB CB/WC does not have and will not take the responsibility and WHO, which is finally accountable may not want to use undue influence • Weak risk management • Instability due to apparent difficulty to foresee or plan for problems before they arise (e.g., leadership changes, funding gap)
Management	• Challenge to replace a strong leader while maintaining momentum. Need to decide on right profile given future direction and critical tasks at hand (e.g. organization builder, procurement expert or a fundraiser?) – *"Finding someone who can step into Ian's shoes will be tough. I can not readily think of anyone in the TB world"* • Targeted tripling customer base to 2.4 in 2003 cannot be achieved at current staff levels (3 professionals, 2 admin)	• Further GDF expansion in the short term may be limited by internal changes and capacity

Source: Interviews; McKinsey analysis

THE CURRENT ORGANIZATIONAL SET UP IS UNLIKELY TO MEET THESE REQUIREMENTS (2/2)

	Issues raised in interviews/ review	Implications
Management (ctd)	• Skill/coverage gaps in functional areas – *Systems* (e.g. financial - currently handled by part time accountant in STB Secretariat; nascent financial management and controls; similar issues for knowledge management and strategic planning) – *Marketing/fundraising*:(1/5 FTE for fundraising/ communications is insufficient for fundraising, market research and GDF brand building) – *M&E:* (nascent, handled part time, with insufficient expertise on team given critical importance for GDF's value proposition) • Current organization structure and roles fluid and somewhat intransparent to outsiders	• Increased risk due to inadequate financial systems • Inability to deliver on value proposition • Reduced credibility with key stakeholders
Administration	• Cumbersome and lengthy WHO hiring rules for long term contract (up to one yr; 8/9 staff are on short term contracts) – *"It would have taken us forever to get our staff in place. That is why we resorted to short term contracts"* • Forced 1 month contract breaks and maximum length of 4 year employment in same department for short term staff • Little clarity on payments- *"Who pays what to whom for which services??".* E.g., Payments to WHO for admin support do not include STB Secretariat staff working for GDF. Further, costs are seen as being on the high side for small organization ($1.3 M over first 2 years) • Delays caused by lengthy legal processes (e.g., procurement) – *"WHO legal does not see itself as a service provider, interested in a high quality swift review, more as a watchdog of WHO"*	• Difficulties to attract high caliber talent • Gaps in staff coverage (8 out of 12 months/yr one staff member on break) and loss of institutional memory • Reduced competitiveness compared to best in class procurement agencies

Source: Interviews; McKinsey analysis

STB SHOULD RETAIN GDF WITHIN WHO AS AN EMBEDDED LEGAL ENTITY, BUT WHO MUST DELEGATE A CLEAR GOVERNANCE ROLE TO THE WC

Key priorities	Recommendations
Vest a body with clear accountability for the GDF and transparent decision making responsibility and processes	• The WC should be entrusted with this role, even as GDF continues to be a embedded legal entity within WHO. It would require WHO's agreement and defining clear bylaws with clear roles and responsibilities and decision making protocols for each entity to ensure accountability • Precedents exist for such an arrangement
Ensure improved financial/ operational oversight for the GDF	• Strengthen/refocus WC on its core task to "guide and evaluate the operations of the GDF Secretariat" with four focus areas and decision making powers on behalf of the board: – Provide strategic direction; help prepare recommendations to the board in collaboration with the Secretariat – Monitor financial/operational performance against targets – Develop fundraising strategy in collaboration with GDF staff – Provide operational oversight in key areas, e.g. review TRC recommendations, procurement tendering process • Composition: Representative group, 4-6 involved CB members
Improve reporting and communication processes	• Formalize pre-syndication process, lead time, and formats for GDF presentations (especially financial reporting) to the board/WC to provide adequate preparation time and information for deliberations • WC should co-opt non-voting member of the TRC to ensure direct communication flow and expertise

AS GDF MOVES FROM START-UP TO CONSOLIDATION, MANAGEMENT MUST BE STRENGTHENED ON ALL DIMENSIONS

Key priorities	Recommendations
Hire GDF senior manager to provide credibility to GDF team	• Interim STB Director to make search key priority, leveraging support of WC • Consider re-negotiating MoU for a director level post (i.e., same level as director of STB Secretariat) to reflect importance of position and to attract high caliber person • In candidate selection, ensure deep managerial expertise in addition to technical skills, fit with culture and ability/credibility to manage multiple partners including WHO
Close coverage/skill gaps in functions critical to GDF's business model • Professionalize financial monitoring/planning and knowledge management • Strengthen GDF marketing/ resource mobilization • Set up and maintain high quality M&E mechanisms	• Hire professionals for three positions and invest in related systems: – COO/CFO: Responsible for financial/operational planning processes, expanding current knowledge management systems, internal performance management, and interfacing with WHO administrative/legal services – Marketing/Fundraising Manager: Responsible for developing GDF-specific fundraising and communications strategy, as well as marketing plan for direct procurement – M&E Specialist: Responsible for developing robust M&E mechanisms to track GDF impact in countries and ensure mobilization of partners for execution
Increase clarity of organizational structure and delineation of responsibilities	• Clarify, adapt and formalize current tacit matrix structure ensuring clear single-point responsibilities for countries and functions

HR AND LEGAL ASPECTS OF ADMINISTRATION COULD BE MODIFIED TO ALLOW MORE FLEXIBILITY WITHIN WHO PROCEDURES

Key priorities	Recommendations
Reduce total administrative costs and increase transparency of services received. Alternatively, increase efficiency with growing scale of operations	• While administrative costs will be reduced with the introduction of the Trust Fund, they are still higher than benchmarks compared on a per staff basis • With growth in GDF's activities, GDF must negotiate with WHO for a cap on payments to WHO (in absolute terms, not as % of budget), to benefit from growing scale of operations
Increase flexibility in WHO hiring procedures/rules for GDF to • Ensure continuity of staff on short term contracts and reduce time spent on contract breaks • Ensure ability to swiftly hire for at least a few long term positions and thus increase attractiveness to senior candidates	• Negotiate with WHO for the following (illustrative): – Exception to rule that short term staff needs to change department after 4 yrs (or alternatively, ensure these contracts can be transformed into long term contracts) – Reduce contract breaks to 2 weeks maximum – Secure 2 long term positions (e.g., CFO/COO) with exceptions to usual WHO quotas
Increase speed of response from WHO departments to GDF's needs (e.g., Legal and contract, treasury/accounting/ finance)	• Negotiate with WHO to have a GDF-dedicated person for these functions in the respective WHO departments • Further, these personnel should be directed to serve GDF from a partnership, not WHO perspective • Precedents exist for such an arrangement

APPENDIX CONTENTS

KEY MESSAGES

- **Evaluation of concept of "expansion" of the GDF**
  The Global TB Drug Facility has been successful in large part because of the STB Partnership's commitment, funding and technical support. Similarly, the success of a GDF for any disease requires a well-functioning disease partnership. Hence provision of a GDF-type model for malaria or HIV must be driven by the respective partnerships for those diseases. The initial lead in catalyzing these discussions and coordinating activities can come from a body like the WHO with the mandate across these diseases and relationships with the partnerships

- **Disease-specific fit**
  A robust case can be made for a GDF-like model for specific drugs/diagnostics in MDR-TB, malaria and HIV/AIDS to expand access to quality, cheap products and facilitate rational use. The "TB one-stop shop" concept (diagnostics/consumables), while important, does not fully lend itself to such a model. There are clear system and country level benefits from leveraging the GDF brand, systems and learnings/best practices across these disease areas

- **Recommendations**
  From an external perspective, "GDF"s for malaria and HIV and a GLC-GDF convergence are desirable and feasible. Given that these disease areas are outside the STB Partnership's scope, this should happen via specific partnership-driven implementation, resourcing and funding and a WHO umbrella over disease-specific GDFs. The implications for the STB Partnership are overall positive, i.e. a) reputation benefit (impact beyond TB, advisory role to 'new' GDFs, more visibility for funding); b) no loss of focus or need to go outside of area of technical expertise; and c) no need to supply funding/resources. This would call for a loose-tight organization structure (franchising or "business" units), that leverages synergies but allows disease coalitions to maintain control on key technical aspects. The new "overall GDF", while maintaining its unique model and independence, should continue to be housed in WHO with a borrowed legal identity

THE SUCCESS OF A GDF FOR ANY DISEASE REQUIRES A WELL-FUNCTIONING DISEASE PARTNERSHIP

A supportive ("willing") and well-functioning ("able") partnership critical to GDF's success…

- **Full alignment:** Demand for the model must come primarily from the disease partnership – need agreement on importance of drug access issues, relevance of GDF model and commitment to using the GDF
- **Technical support:** Partners must be *willing* and *able* to define technical guidelines and protocols, support GDF for technical review/M&E visits and provide technical assistance to countries
- **Funding support:** Donors in each partnership will need to contribute to a core fund to support GDF's direct grant-making role and/or work closely with other key donors and align systems

…As seen in the case of the TB GDF and the STB Partnership's role

- Normative role: GDF works with WHO units like DOTS Expansion and EDM (FDC, white list)
- Fund raising: Donors on STB CB committed to STB goals finance the GDF's activities
- In-country technical assistance: GDF relies on partners like MSH and IUATLD to provide services

"GDF has worked well largely due to a reasonably well-functioning partnership and support for setting up such a facility. In the absence of a similar situation in HIV/AIDS and malaria, the facility will not succeed"

- **Provision for a GDF-type model for malaria or HIV/AIDS must be driven by the respective disease partnership, which should demand, resource and house such an effort**
- **The STB Partnership neither can nor needs to provide the resources (people/money) for such an effort**

EACH OF MDR-TB, MALARIA AND HIV/AIDS HAVE UNIQUE ACCESS ISSUES WHICH DIFFER FROM ISSUES IN TB CONTROL

MDR-TB (GLC process)

- **Requires more rigorous application, review and M&E**
  - Rational use more critical, given no further treatments available and alternative uses of MDR-TB drugs
  - Limited reliable data on drug resistance patterns
- **Relatively higher funding requirements**:
  - Lowest GLC-negotiated price = $500/patient
  - No grant-making role in current GLC model, but mandated agent relationship with GF
- **Emphasis on awareness-building and working through specialized centers:** Few countries have identified and prioritized MDR-TB issues
- **Modified negotiation approach with suppliers**
  - Products either patented or restricted supplier base
  - Hence, price negotiation done by GLC/MSF vs. proc. agent

Malaria

- **Pre-work on technical guidelines at system and country level**
  - No comprehensive data on drug resistance patterns; few revised drug policies
  - Standardized treatment guidelines possible only at a regional level
  - Pre-qualification of suppliers
- **Ability to work with non-traditional partners (private sector, NGOs)**
  - Treatment at community level
- **Modified negotiation approach with suppliers**
  - Products either patented or restricted supplier base
  - Supply issues different from pure generics, e.g., patent-holders have stake in preventing resistance (e.g. Novartis and Coartem)

HIV/AIDS

- **Pre-work on standardization at system and country level**
  - Need consensus and WHO-mandated treatment regimens
- **More sophisticated negotiation approach and political savvy**
  - Highly visible political and contentious issues
  - Debate around patent rights, TRIPS, regional and local procurement/supply, etc.
- Similar issues to MDR-TB
  - **More rigorous application, review and M&E**
  - **Emphasis on awareness-building and working through specialized centers**
  - **Modified negotiation approach with suppliers**
  - **Significantly higher funding requirements**

Source: Interviews; Team analysis

FURTHER, THE PARTNERSHIPS FOR MDR-TB, MALARIA AND HIV/AIDS ARE AT DIFFERENT STAGES OF READINESS FOR SUCH A MODEL

MDR-TB: Good support	Malaria: Willing but needs to build capability	HIV/AIDS: Lack of clarity on basic partnership itself
• GLC is a well-regarded body with strong technical review, credibility with external donors like GF and support from STB Partnership • The Stop TB CB and DOTS Plus Working Group have already initiated discussions for the potential convergence of GDF and GLC	• RBM is interested in using the GDF for advanced anti-malarials • However, much skepticism on capability of the current RBM Partnership - *"The malaria program is in shambles today"; "RBM needs to be a well-functioning partnership, which can support the GDF. That is not the case now, might be in 6 months"*	• Unclear on which group is the decision maker; heavy politicization of issues - *"ARVs are politically very contentious. No justification to enter this area today till this is resolved"* • Perceived historical enmity between TB and HIV groups - *"GDF for HIV/AIDS is a non-starter due to the political enmity between the TB and HIV communities. The chasm has not healed"*

Source: Evaluation of the RBM Partnership; expert interviews; team analysis

PARTNERSHIPS WILL ALSO NEED TO FUND THE GRANT-MAKING ROLE OF THE GDF OR ENSURE A MANDATED AGENT RELATIONSHIP WITH GF

ROUGH ESTIMATES

GDF needs direct funding to maintain its grant-making role

Assumptions*:
- GDF will serve ~ 25% of world demand, as in TB
- Price reductions in line with experience in TB and other areas (e.g., GLC, MSF)

	GDF funding required USD million p.a.
MDR-TB	• 75
Malaria	• 30
HIV/AIDS	• >1,000

Two options to meet these funding needs

Direct funding from donors in the disease partnership to the GDF

- More relevant for **malaria** (situation similar to 1st line TB drugs). Hence, RBM donors would need to mobilize funds

And/or

Mandated procurement agent relationship with GF/direct-to-country donors

- Could work for **MDR-TB** and **HIV/AIDS**, provided:
  - GDF and GF are fully aligned on goals
  - GDF retains control on application review, approval and M&E
  - Country and partners recognize that GDF has the "carrot" and "stick"

* Workings are provided in the following section

Source: Literature review; expert interviews; team analysis

HENCE, EACH DISEASE PARTNERSHIP MUST SATISFY A CHECKLIST BEFORE IT ADOPTS A GDF MODEL

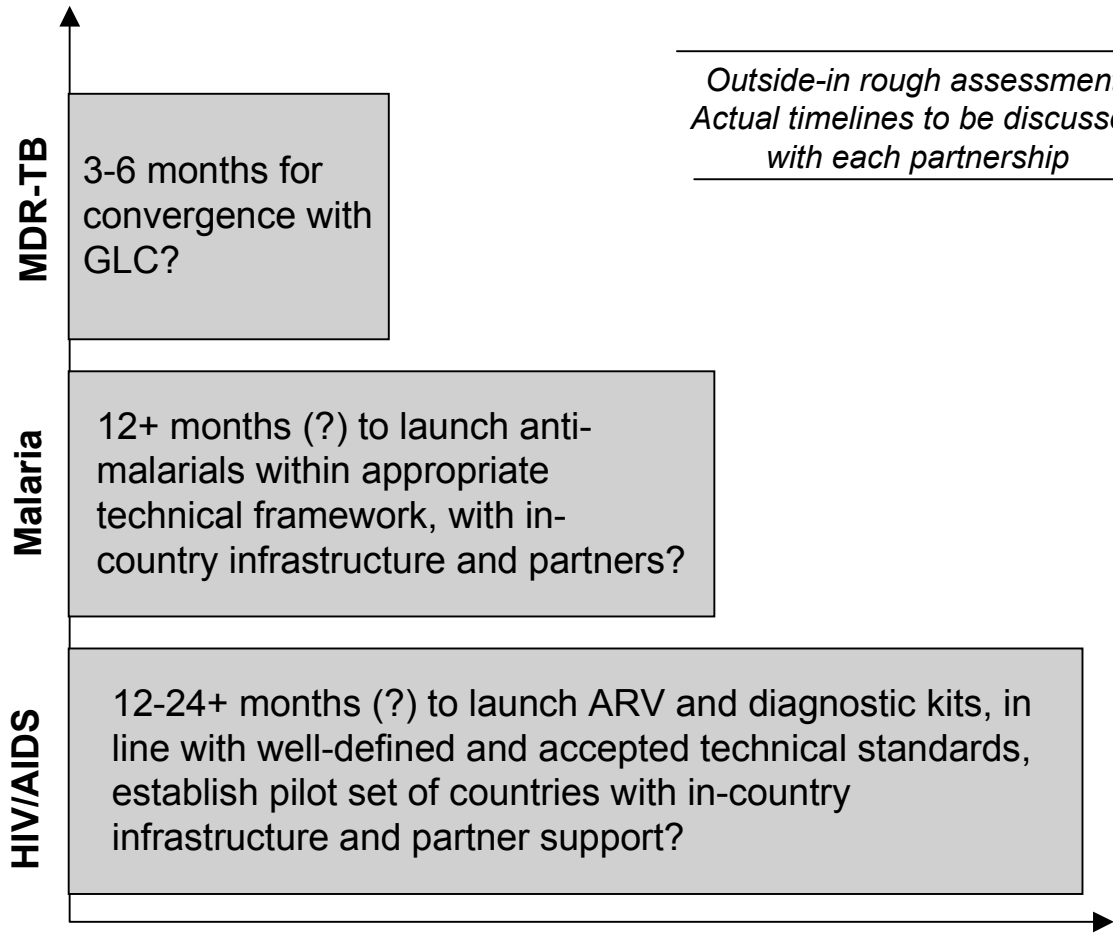
MDR-TB	Malaria	HIV/AIDS
✓Strong TRC, with rigorous application process, approval guidelines and M&E mechanism ✓Robust negotiation process for continuous reduction in drug prices ✓Annual funding of ~$75M from STB donors to the GDF *or* mandated procurement agent status with key donors like the GF	✓Standardization of treatment regimens and protocols, at system, regional or country level ✓Well-functioning RBM Secretariat and Partnership (e.g., clearly defined goals, global malaria strategy, partner roles) ✓Robust negotiation process for continuous reduction in prices ✓Pre-qualification of suppliers ✓Annual funding of ~$30M from RBM donors to the GDF	✓Well-defined partnership forum with clear mandate to decide on access issues, overcoming political barriers ✓Standardization of treatment regimens and protocols at system and country level ✓Robust negotiation process for continuous reduction in prices ✓Annual funding of >$1B from key donors to the GDF *or* mandated procurement agent status with key donors like the GF

Source: Expert interviews; document review; team analysis

THIS PROCESS WILL HAVE DIFFERENT LEAD TIMES FOR EACH DISEASE, BUT PRE-WORK CAN BE INITIATED FOR ALL IN PARALLEL

- Each disease will have different lead times, given differences in
  - Priorities and preparedness of countries
  - Technical readiness of partnerships
  - Time required for standardization of treatment regimens
- However, (WHO) could initiate pre-work on all 3 disease areas in parallel
  - Strong technical and economic case for each of the three diseases
  - Strong demand from key stakeholders for such a model

Outside-in rough assessment; Actual timelines to be discussed with each partnership



Time required for pre-work to set up GDF model for other areas

Caveat: Each of the disease teams should be resourced adequately and separately, else there is a risk of loss of focus and some areas being compromised

Source: Team analysis

THE DISEASE-SPECIFIC GDF CAN OFFER MANY BENEFITS TO THE RELEVANT DISEASE PARTNERSHIP

Disease GDF's functions

- Advocacy and awareness building at system and country level
- Managing application and communication with countries; coordinating TRC meetings
- Legal and registration issues
- Branding; social marketing, packaging
- Management of donors and setting up mechanisms to interface with GF, WB
- Disseminating best practices across countries and disease areas

+ coordinating role in

- Price negotiations
- Organization of procurement: selection of procurement agent / supplier selection /reducing lead time
- Quality assurance of drugs

Partnership's functions

- Standardization of treatment protocols and defining product list
- Harmonizing treatment protocols with countries
- Set criteria for rational use, prerequisites for countries/projects to meet
- Fundraising/grant making
- Technical review of application and approval
- Monitoring and evaluation
- Mobilize in-country partners
- Joint advocacy and awareness building

Source: Interviews; team analysis

KEY MESSAGES

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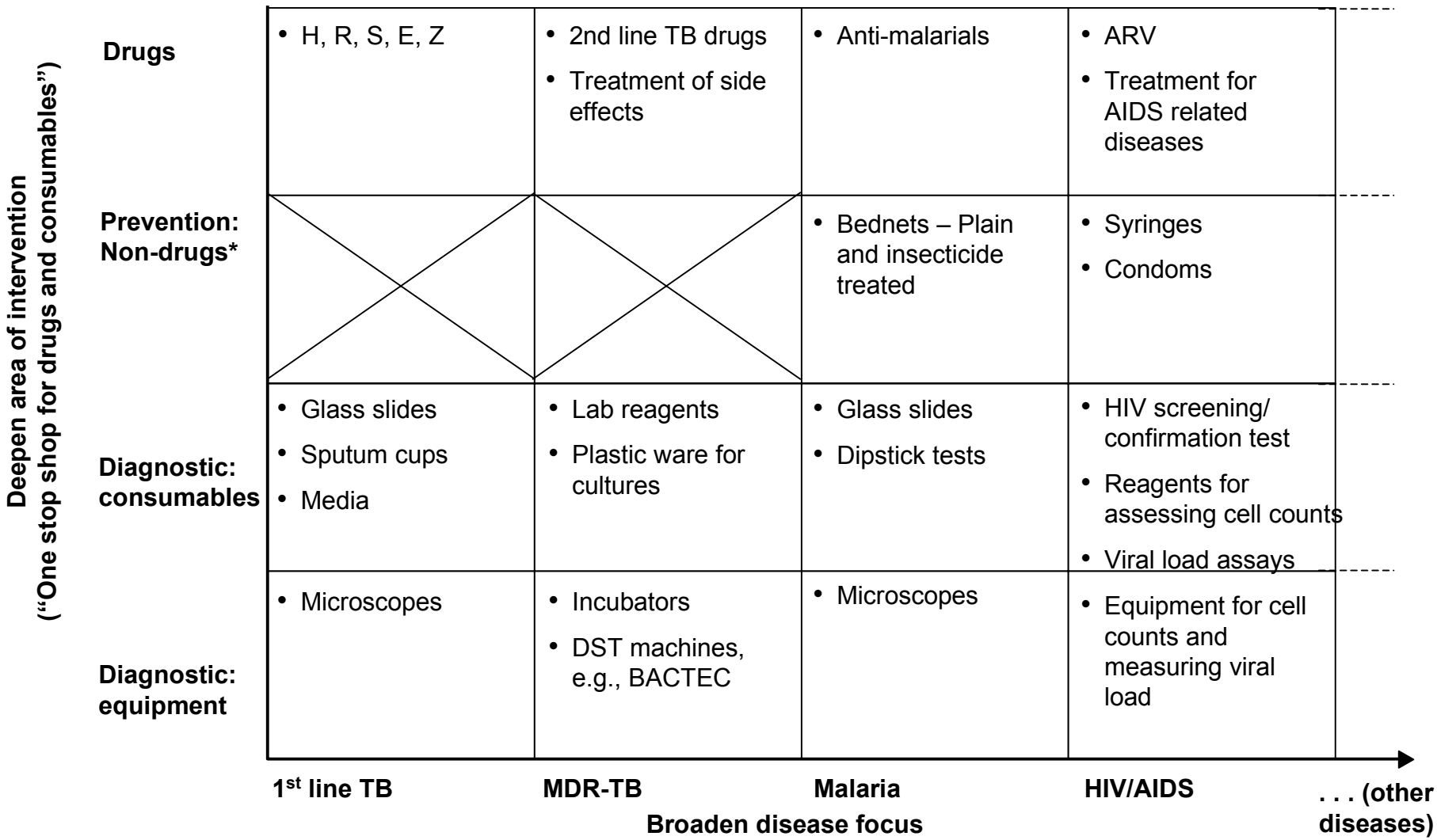
DISEASES/PRODUCTS BEYOND 1st LINE TB DRUGS HAVE BEEN ASSESSED FOR A FIT WITH A GDF-LIKE MODEL

FRAMEWORK – NOT EXHAUSTIVE



* Vaccine have been excluded from this analysis

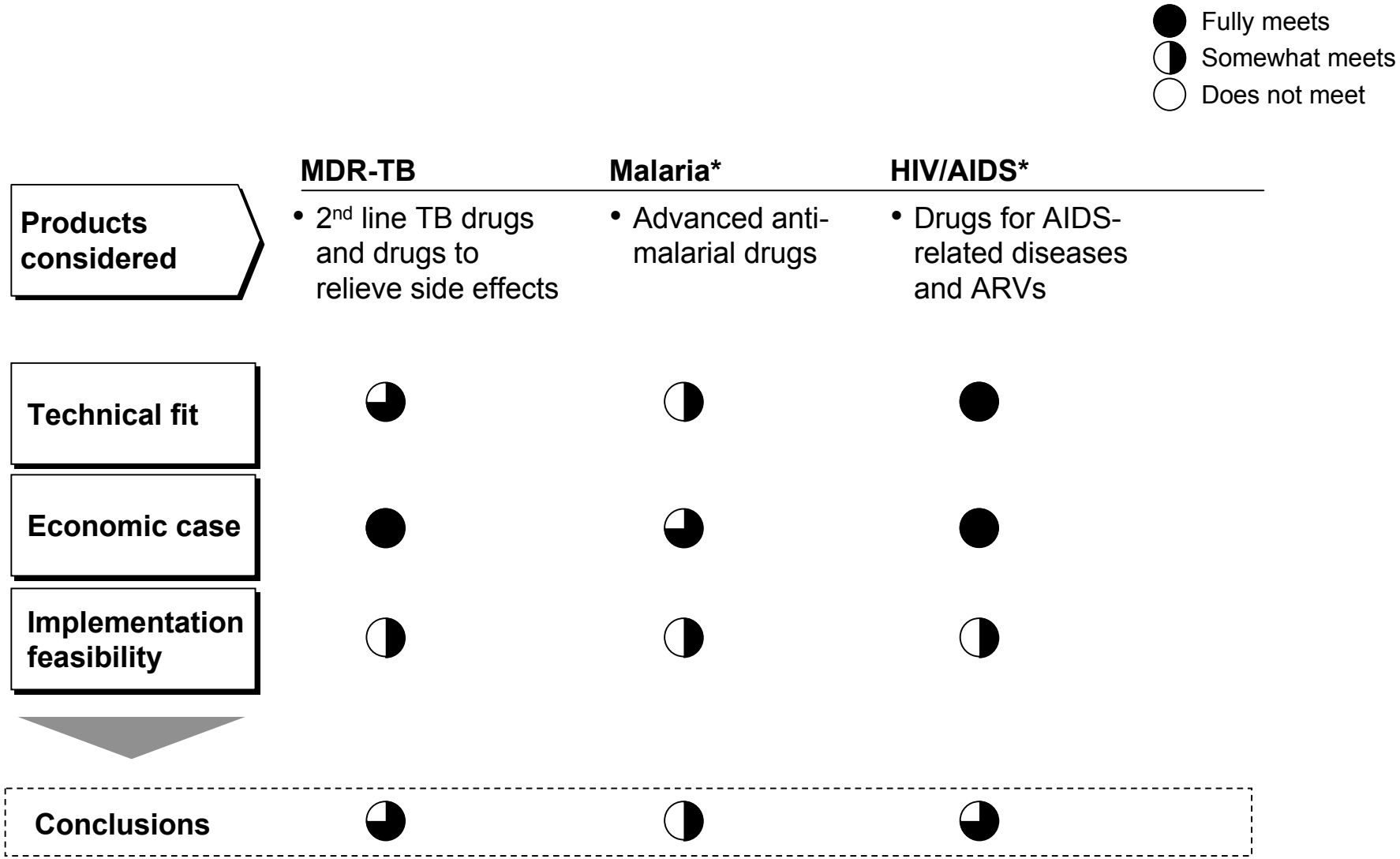
Source: Team analysis

DISEASES/PRODUCTS MUST FULFILL THREE CRITERIA TO JUSTIFY A GDF-LIKE MODEL

Criteria	Key elements	Description
Technical fit	• Rational drug use critical	• Technical review and M&E needed to enforce right treatment protocols to minimize risk of creating resistance and transmission
	• Standardization/innovation possible and necessary	• Treatment standardization and innovations in drug delivery (e.g. packaging) important for compliance, treatment success and drug management
Economic case	• Global pooled procurement superior to regional/local mechanisms	• Buying power leverage to significantly reduce prices, ensure quality, influence product norms and stabilize demand forecasts
	• Unmet treatment demand due to drug shortages	• Drug shortage - due to resource gaps and/or procurement problems - a key issue in disease control
Implementation feasibility	• Availability of partnership support in-country	• Current/potential support assured for technical assistance from in-country partners
	• Government commitment	• Willingness to launch a national disease control program with adequate funding/ people support and infrastructure

Source: Team analysis

DRUGS: MDR-TB, MALARIA AND HIV/AIDS LARGELY MEET THESE CRITERIA



* Commodities like bednets, condoms have not been included here

Source: Team analysis

MDR-TB: GLC SHOWS MANY SYNERGIES WITH A GDF-TYPE MODEL

● Fully meets
◐ Somewhat meets
○ Does not meet

Products

- 2nd line TB drugs
- Side effect mitigators

Market situation

Current market size	• ~300,000 incidence p.a. (~4% of new TB cases) • ~750 patients treated through GLC process
Potential market size	• 300 million USD*
Suppliers	• Several suppliers exists such as Macleods, Microlabs, Rotex, Gland Pharma, CJ Corp.
Procurement	• IDA, MSF

Assessment- Summary

			Comments
Technical fit	• Rational drug use critical	●	• Drugs have alternative uses. Resistance will induce incurable disease, increase transmission of MDR-TB and affect other areas
	• Standardization / innovation possible and necessary	◐	• GLC has established standardized treatment regimens
Economic case	• Global pooled procurement superior	◐	• High prices ($500-4000/treatment), despite >95% reduction. • Small patient base/country, hence no leverage in negotiations at a country level
	• Unmet treatment demand	●	• <1% of patients benefit from the GLC concessional prices
Imp. feasibility	• Availability of partnership support	◐	• Many of DOTS-Plus projects are currently run by NGOs
	• Government commitment		• Varies. Relatively low priority for countries where DOTS not fully functional and resource-constrained

* Assuming $1,600/treatment and price reduction potential of 40%
Source: interviews; GLC; WHO; Dye et al., JID, 2002; team analysis

MDR-TB DISEASE OVERVIEW

Incidence

- ~300,000 new cases occur p.a.

Distribution

By region or country

- Highest rates of MDR-TB (as percent of TB cases) in Estonia (14%), Henan Province, China (11%), Latvia (9%), Ivanovo (9%), Tomsk oblast, Russia (7%)
- Highest numbers of MDR-TB cases are in China 68,400, India 63,100, Pakistan 26,200, Philippines 7,600, Russian Federation 5,900

By socio-economic status

- Middle and low income countries carry 95% of TB burden

Key partners/ donors

Country partners

- International organizations i.e. WHO
- NGOs i.e. MSF, Partners in Health etc.

Donors

- Bill and Melinda Gates Foundation, Eli Lily, Inc, etc.

* 273,000 new cases in 2000

Source: WHO

MDR-TB: ASSESSMENT OF FIT WITH GDF MODEL

● Fully meets
◑ Somewhat meets
○ Does not meet

Technical fit

Criteria		Comments
• Rational drug use critical	●	• Resistance will induce incurable disease, increase transmission of MDR-TB • The regimens frequently induce side effects • Drugs have alternative uses e.g. respiratory infections, genito urinary infections, etc. – Drug resistance will create problems beyond drug resistance to MDR-TB
• Standardization / innovation possible and necessary	◕	• GLC has established standardized treatment procedures (DOTS+) – Most patients are being treated on individualized treatment regimens (ITR) however with a limited set of drugs – Standardized treatment regimens (STR) exist for several cohorts based on results of drug resistance surveys

Source: WHO; Medical Access; team analysis

MDR-TB: ASSESSMENT OF FIT WITH GDF MODEL

● Fully meets
◑ Somewhat meets
○ Does not meet

Economic case

Criteria		Comments
• Global pooled procurement superior	◑	• However, prices are still high ($500-4000/treatment), despite >95% reduction – *"With the increase of number of patients to be treated, we will be able to bring the prices down even further"* • Small patient base/country, hence no leverage in negotiations at a country level – *"Bolivia is procuring drugs for 10 patients"*
• Unmet treatment demand	●	• <1% of patients benefit from the GLC concessionary prices – 1,500 patients have been treated through GLC provided drugs over the past 2 years – Not many countries have benefited from GLC's low prices • 10 projects in 7 countries* are leveraging GLC's low prices • Others have to find means to fulfill prerequisites and allocate resources to treat more patients

* As of November 2002
Source: WHO; Medical Access; team analysis

MDR-TB: ASSESSMENT OF FIT WITH GDF MODEL

● Fully meets
◑ Somewhat meets
○ Does not meet

Implementation feasibility

Criteria		Comments
• Availability of partnership support	◕	• Many of DOTS-Plus projects currently run by NGOs – 5 out of 10 projects are run by NGOs • e.g. Harvard Medical School/Partners in Health in 3 districts of LIMA, Peru – Some projects originally applied to treat a larger patient cohort but limited patient number due to financial constraints
• Government commitment	○ - ◑	• Varies. Relatively low priority for countries where DOTS not fully functional and resource-constrained – Moldova will only consider MDR-TB treatment in 2004 with Global Fund grant, once DOTS is stabilized

Source: WHO; GLC; country visits; team analysis

MALARIA: GOOD CASE FOR A GDF-LIKE MODEL, IF IMPLEMENTATION CAN BE ASSURED

● Fully meets
◑ Somewhat meets
○ Does not meet

Products

- ACT(Artemisinin-derivative Combination Therapies) i.e. Coartem, AS+AP, AS+AQ
- Effective anti-malarials i.e. Mefloquine, Amodiaquine, Primaquine, Quinine

Market situation

Incidence
- 300 M acute cases p.a.
- 2.4B people exposed to risk

Potential market size
- ~120M USD*

Suppliers
- Large local generic supplier base for basic drugs
- Few suppliers producing combinations (FDCs and blisters), Amodiaquine
- 80% Quinine's raw material from one producer

Procurement
- Local and international agents depending on product

Assessment - Summary

		Comments
Technical fit	◑	• High risk of morbidity, mortality and resistance due to inappropriate treatment. However, treatment is relatively short, so compliance more likely
• Rational drug use critical • Standardization / innovation possible and necessary	◕	• Requires rational combination treatment schemes based on resistance surveys and pharmacokinetics considerations • Packaging innovations will help increase compliance
Economic case	◕	• Several suppliers for the modern drugs and diagnostics, in some cases • Wide price ranges for some drugs e.g. Artemisin (1.5-3.0 USD/treatment)
• Global pooled procurement superior • Unmet treatment demand	◕	• Restricted raw material production for Quinine and Artemisin derivatives • Some countries restrict use of effective drugs due to high prices
Imp. feasibility	◑	• Potentially available, but activities need to be catalyzed/coordinated
• Partnership support • Government commitment	◑	• Country program infrastructure and people resources need to be strengthened, though malaria is top health priority

* Assuming 1$ per Tx + 1$ per diagnostic kit; 50% of patients requiring such drugs; ~ 60% price reduction

Source: Interviews; RBM; WHO; MSF; team analysis

MALARIA DISEASE OVERVIEW

Incidence

- 300-500 million cases occur p.a.
- 1-2 million deaths p.a.
- 2.4 billion people, more than 40% of the people in the world are at risk

Distribution

By region or country

- 90% of burden is in sub-Saharan Africa

By socio-economic status

- Burden of disease falls mainly on 2 groups: young children and pregnant women; I.e. more than 90% of deaths attributed to malaria each year occur in African children

Key partners/ donors

Country partners

- International organizations i.e. RBM, WHO, International Federation of the Red Cross
- NGOs i.e. MSF, Merlin, Children Fund, etc.

Donors

- CIDA, DANIDA, DFID, USAID, SIDA, etc.

Source: WHO; RBM Infosheet March 2002;Drug resistance in malaria, Bloland, WHO

MALARIA: ASSESSMENT OF FIT WITH GDF MODEL

● Fully meets
◑ Somewhat meets
○ Does not meet

Technical fit

Criteria		Comments
• Rational drug use critical	◑	• High risk of morbidity, mortality and resistance due to inappropriate diagnosis and treatment. However treatment is relatively short, so compliance more likely, i.e. treatment is as short as 3 days – Currently 50-75% of patients treated for malaria on presumptive diagnosis do not have malaria • Requires rational combination treatment schemes based on resistance surveys and pharmacokinetics considerations – Risk of inadequate dosage/ duration of treatment and mismatching pharmacokinetics of compounds in FDCs – Compliance can be further reduced by single application treatments
• Standardization / innovation possible and necessary	◕	• There is clear need for standardizing treatment with affordable high quality drugs – Current situation is that new drug policies are largely dependent on cost and other operational factors rather than effectiveness of the treatment – Prequalification has been done for artemisin-derived products • Packaging innovations will help increase compliance – RBM negotiated with Novartis for Coartem® packages with images on the package that assist patients/ health workers

Source: WHO; RBM; team analysis

MALARIA: ASSESSMENT OF FIT WITH GDF MODEL

Fully meets
Somewhat meets
Does not meet

Economic case

Criteria		Comments
• Global pooled procurement superior	◕	• Several suppliers for the modern drugs and diagnostics, in some cases, e.g. Mefloquine • Wide price ranges for some drugs e.g. Artemisin (1.5-3.0 USD/treatment) • Restricted raw material production for Quinine and Artemisin derivatives – Ensured supply will encourage production of raw material
• Unmet treatment demand	◕	• Effective drugs are in need – Increasing cases of resistance over generic anti-malarials – Ineffective and low-quality drugs are prevalent in the market e.g. counterfeit drugs and drugs produced with large intra- and inter-batch variability • Some countries restrict use of effective drugs due to high prices, e.g. in Kenya, cost was one of the contributing factors that hindered the revision of the anti-malarial drug policy between acknowledgment of resistance in 1989 and change of policy in 1998

Source: Interviews; RBM; WHO; Shretta et al., Trop Med Int Health 2000; team analysis

MALARIA: ASSESSMENT OF FIT WITH GDF MODEL

● Fully meets
◑ Somewhat meets
○ Does not meet

Implementation feasibility

Criteria		Comments
• Partnership support	◑	• Potentially available, but activities need to be catalyzed/ coordinated
• Government commitment	◑	• Country program infrastructure and people resources need to be strengthened, though malaria is top health priority – Most countries identify Malaria as a priority public health disease e.g. Nigeria – However, some countries have weak national programs, leading to treatment mainly through the private sector e.g. Uganda – Some countries deploy drugs that are no longer effective due to expensive price of modern combination drugs

Source: Interviews; RBM; WHO; team analysis

HIV/AIDS: STRONG FIT WITH GDF-LIKE MODEL; HOWEVER, VERY LARGE, COMPLEX AND POLITICAL MARKET

● Fully meets
◑ Somewhat meets
○ Does not meet

Products

- ARV
- AIDS related disease treatment

Market situation

Current market size	• Estimated people living with HIV/AIDS = 40M, of which 5-6M people need ART initially; cumulative increase in patient load p.a.
Potential market size	• At least $7.2B initially (rough estimates)
Suppliers	• R&D companies; generic manufacturers
Procurement	• WHO, UNICEF, local procurement

Assessment - Summary

			Comments
Technical fit	• Rational drug use critical	●	• Risk of creating drug resistance and mother-to-child transmission
	• Standardization / innovation possible and necessary	◕	• WHO driving standardization; Some countries have tried it, e.g. Brazil, South Africa • Need innovative packaging due to complex treatment regimens in 2nd line treatment
Economic case	• Global pooled procurement superior	◕	• High prices with wide price ranges, e.g. a 1-year treatment course with nelfinavir can cost from 2,336USD (Brazil) to 8,300USD (Guatemala)
	• Unmet treatment demand	●	• Worldwide only 5% people in need of treatment are receiving it
Imp. feasibility	• Partnership support	◕	• Many NGO's active in the countries
	• Government commitment	○ - ◑	• Varies by country

* Under the assumption of ARV 2400$ per Tx and price reduction projections of 40%

Source: interviews; Commitment to action for expanded access to HIV/AIDS treatment, WHO; MSF; team analysis

HIV/AIDS DISEASE OVERVIEW

Incidence

- 5 million new cases occur p.a.
- 3 million deaths p.a.
- 42 million people living with HIV/AIDS

Distribution

By region or country

- Approximately 70 percent of patients (29.4 million) live in Sub-Saharan Africa, and another 17 percent (7.2 million) live in Asia

By socio-economic status

- 38.6 million adults and 3.2 million children younger than 15 years are living with HIV/AIDS

Key partners/ donors

Country partners

- International organizations i.e. WHO, UNAIDS, UNICEF
- NGOs e.g. MSF

Donors

- Bill and Melinda Gates Foundation, DANIDA, HIVOS, JIDA, NORAD, DFID, USAID, etc.

Source: UNAIDS AIDS Epidemic update 2002; WHO

HIV/AIDS: ASSESSMENT OF FIT WITH GDF MODEL

● Fully meets
◑ Somewhat meets
○ Does not meet

Technical fit

Criteria		Comments
• Rational drug use critical	●	• Availability of treatment is critical – In situation of lack of treatment, low willingness to do voluntary testing increases risk • Higher incidence of horizontal transmission due to risk behavior – Risk of vertical transmission due to lack of prophylaxis – Higher risk of transmission with higher viral load – Higher incidence and severity of AIDS-related diseases • Inadequate adherence to ART(antiretroviral treatment) may lead to sub-optimal exposure of drugs, increasing the risk of treatment failure and viral resistance – ART + prophylaxis of AIDS-related diseases is complex with the necessity to follow structured administration schemes – Treatment has to continue life-long
• Standardization / innovation possible and necessary	◕	• WHO is driving standardization; Some countries have standardized, e.g. Brazil – There exists challenges to standardization efforts • *"New drugs (for HIV/AIDS) are appearing almost daily making it difficult to converge drug use"* • Need innovative packaging, i.e. pill boxes used in Khayelitsha, South Africa to support adherence

Source: Interviews; WHO; team analysis

HIV/AIDS: ASSESSMENT OF FIT WITH GDF MODEL

● Fully meets
◑ Somewhat meets
○ Does not meet

Economic case

Criteria		Comments
• Global pooled procurement superior	◑	• High prices with wide price ranges – 1-year treatment course with Nelfinavir can cost from 2,336USD (Brazil) to 8,300USD (Guatemala) – Prices have come down by up to 88% for 3TC, ddC, ddI and AZT between 1996-2000 – Honduras and Panama have struck favorable deals • Many of the drugs are under patent, so deals with the R&D companies have to be negotiated
• Unmet treatment demand	●	• Worldwide only 5% people in need of treatment are receiving it • Moreover availability of treatment will create further demand for voluntary testing and subsequently treatment – Demand for HIV testing increased after implementation of DOT-HAART in Haiti

Source: Interviews; RBM; WHO; team analysis

HIV/AIDS: ASSESSMENT OF FIT WITH GDF MODEL

● Fully meets
◑ Somewhat meets
○ Does not meet

Implementation feasibility

Criteria		Comments
• Partnership support	◕	• Many NGO's active in the countries – *"There are more than 3800 NGOs involved with fighting AIDS in Uganda"*
• Government commitment	○ - ◑	• Varies by country – Lingering denial among both social and political leaders in some countries provides the epidemic with an ideal environment for continued spread. E.g., In Myanmar HIV testing is authorized only in government institutions

Source: Interviews; RBM; WHO; MSF; team analysis

THE "ONE STOP TB SHOP" CONCEPT SHOWS LIMITED FIT WITH THESE CRITERIA AND SHOULD NOT BE A HIGH PRIORITY FOR GDF AT THIS POINT

	Diagnostics/ preventives	Comments	Recommendation
One-stop TB shop	• Sputum cups • Glass slides	**Technical fit** • Standardization is not important and quality is not an issue **Economic case** • Basic consumables – commodity pricing • Cheap local production often available, hence government commitment for global sourcing unlikely	**No** • Mobilize partners if identified as shortcoming
	• Microscopes • Reagents	**Technical fit** • Technical assistance is needed however could be provided through partners, i.e. training, maintenance • Standardization would be helpful, i.e. if staff is transferred to a different health center, however could be coordinated through NTP **Economic case** • Contribution to the TB budget is small compared to drugs • Procurement for microscopes and reagents is an issues in few countries (4/22 HBC – WHO 2003 report)	**Conditional yes** • Check quality and recommend coordination for standardization of equipment and reagents in application and M&E process • Mobilize partners if identified as shortcoming • Expand only if – Partner support is unavailable – Critical mass of countries find shortages a key barrier to DOTS implementation

Source: Interviews; team analysis

ASSESSMENT ON DIAGNOSTICS AND NON-DRUG PREVENTIVES

	Diagnostics/ preventives	Comments	Recommendation
MDR-TB	• Lab reagents for drug susceptibility tests (DST) • Incubators • DST machine	**Technical fit** • Proper drug susceptibility testing is crucial for the treatment of MDR-TB • Technical staff has to be trained thoroughly **Economic case** • There is room for negotiation in the prices for expensive technical lab equipment • Demand is small because only few laboratories needed to perform DST in a given country	**Conditional yes** • Check quality of diagnosis in application and M&E process (Is already embedded into Green Light Committee requirements) • Mobilize partners if identified as shortcoming • Expand only if – Partner support is unavailable – Critical mass of countries find shortages a key barrier to DOTS+ implementation

Source: Interviews; team analysis; Guidelines for establishing DOTS+ projects

ASSESSMENT ON DIAGNOSTICS AND NON-DRUG PREVENTIVES

	Diagnostics/ preventives	Comments	Recommendation
Malaria	• Dipstick diagnostic tests	**Technical fit** • Quality is an issue – Needs to last humidity and temperature – Needs to ensure appropriate level of sensitivity/specificity • Diagnostics should take place for rational treatment **Economic case** • There is room for price reduction	**Yes** • Diagnostics is a key barrier to rational treatment – Current situation is that 50% of patients treated with anti-malarials are not malaria patients
	• Permanets (permanently impregnated bednets)	**Technical fit** • Quality is an issue – Impregnation must last for 20 washings • Prevention is an integral part of rational drug use • Standardization is possible where prequalification has been done (WHO pesticide evaluation system; WHOPES) **Economic case** • Global pooled procurement can increase negotiation power with the two suppliers, Sumitomo and Vestergaard	**Yes**

Source: Interviews; team analysis; Specifications for netting materials, WHO; Guerin et al. Lancet 2002; Steketee et al., Am J Trop Med Hyg 2001; Hastings et al. Parasitol Today 2000

ASSESSMENT ON DIAGNOSTICS AND NON-DRUG PREVENTIVES

HIV/AIDS

Diagnostics/ preventives	Comments	Recommendation
• Diagnostic kits	**Technical** • Diagnostics should take place for rational treatment • Quality needs to be ensured • There is need for standardization – Currently +20 different diagnostic kits are available **Economics** • Diagnostic tests are a major cost contributing factor in many HIV/AIDS projects, i.e. contributes 30-50% in Botswana	**Yes**
• Viral load assays • Cell counts	**Technical fit** • Use is not crucial for rational treatment **Economic case** • Pooled procurement will ensure lower prices	**No**
• Condoms, syringes	**Technical fit** • Rational use should be enforced • Prevention is an integral part of rational use of drugs **Economic case** • Pooled procurement will ensure lower prices and availability	**No** • Prevention efforts should be a prerequisite for ARV application approval • Check for prevention measures in application and M&E process

Source: Interviews; Sources and prices of selected drugs and diagnostics for people living with HIV/AIDS, WHO; team analysis

OTHER DISEASES COULD ALSO POTENTIALLY BENEFIT FROM A GDF-TYPE MODEL

ROUGH OUTSIDE-IN ASSESSMENT

○ Not available
◑ Available, not cost effective
● Available, cost effective

Two screens to identify diseases:

- 1st screen for prioritization
  - **Materiality** – L of mortality/mo
  - **Inequity –** Hig burden on developing cou
  - **Treat-ability** – Availability of diagnostics, treatments or
- 2nd screen to eva fit with GDF-type model
  - Technical fit
  - Economic case
  - Implementation feasibility

Work-in-progress

Disease area	Death per year (millions, 2001)	DALY (million, 2001)	Ratio of DALY from developing countries* (Inequity)	Availability of -Vaccine -Treatment -Cure
				●
				◑ **
				◔
				◑
				◔
				◔
				◕
				◑ ***
				◕
Chagas disease	0.02	0.7	17	◔ ***
Dengue	<0.01	0.4	8,075	◔
Leprosy	<0.01	0.1	40	◕
Cholera				
Ebola				

* DALYs per capita in developing vs. high-income countries
** Vaccines/cures available for some ARI, enteric, and meningitis pathogens and strains
*** Effective cure only when given early in disease progression

Source: WHO:2001 World Health Report; McKinsey analysis

KEY MESSAGES

- **Evaluation of concept of "expansion" of the GDF**
  The Global TB Drug Facility has been successful in large part because of the STB Partnership's commitment, funding and technical support. Similarly, the success of a GDF for any disease requires a well-functioning disease partnership. Hence provision of a GDF-type model for malaria or HIV must be driven by the respective partnerships for those diseases. The initial lead in catalyzing these discussions and coordinating activities can come from a body like the WHO with the mandate across these diseases and relationships with the partnerships

- **Disease-specific fit**
  A robust case can be made for a GDF-like model for specific drugs/diagnostics in MDR-TB, malaria and HIV/AIDS to expand access to quality, cheap products and facilitate rational use. The "TB one-stop shop" concept (diagnostics/consumables), while important, does not fully lend itself to such a model. There are clear system and country level benefits from leveraging the GDF brand, systems and learnings/best practices across these disease areas

- **Recommendations**
  From an external perspective, "GDF"s for malaria and HIV and a GLC-GDF convergence are desirable and feasible. Given that these disease areas are outside the STB Partnership's scope, this should happen via specific partnership-driven implementation, resourcing and funding and a WHO umbrella over disease-specific GDFs. The implications for the STB Partnership are overall positive, i.e. a) reputation benefit (impact beyond TB, advisory role to 'new' GDFs, more visibility for funding); b) no loss of focus or need to go outside of area of technical expertise; and c) no need to supply funding/resources. This would call for a loose-tight organization structure (franchising or "business" units), that leverages synergies but allows disease coalitions to maintain control on key technical aspects. The new "overall GDF", while maintaining its unique model and independence, should continue to be housed in WHO with a borrowed legal identity

FROM AN EXTERNAL PERSPECTIVE, "GDF"S FOR MALARIA AND HIV ARE DESIRABLE AND FEASIBLE

Interviews with:

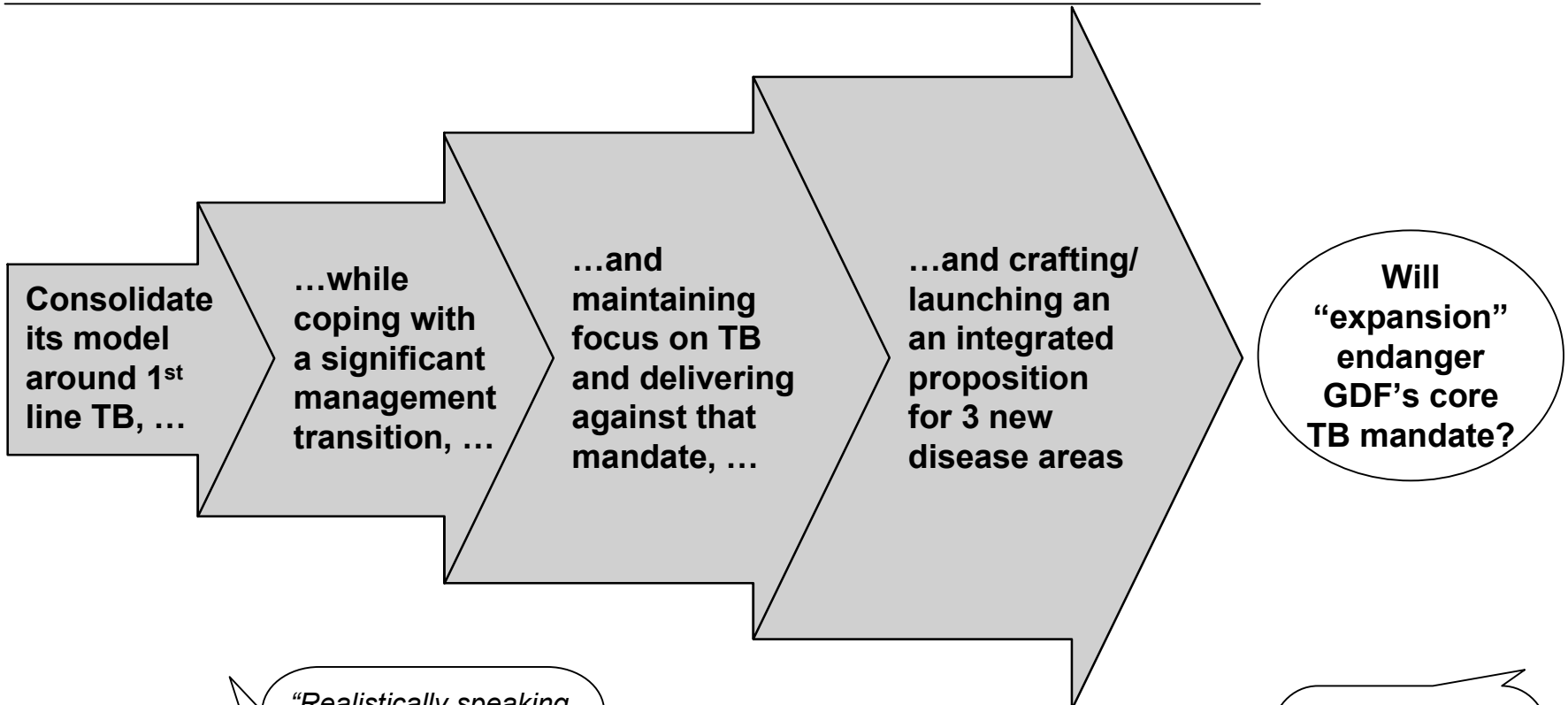
- **Stop TB key stakeholders**
- **Other disease partnerships**
- **Potential recipient countries**

Why GDF	Explanation
Better to build on a tried-and-tested model	• Demonstrated proof of concept in limited time -"*GDF has actually delivered drugs in under 1 year – would rather use something that is already up and running"* • Is up the learning curve on procurement by building on best practices –"*On balance, of all the procurement models that exist, GDF is the best and opportunity for expanded scope should be explored"* • Model is flexible enough to be expanded to other areas; *"GDF is effective for patented and commodity products - the approaches are not that different. Even for bed-nets and diagnostics, we are looking at relatively few suppliers – similar situation to patented drugs"; " GDF experience would be invaluable in ARVs"*
Synergies at a system and country level	• Countries cite synergies in: – Some country-level networks and application processes – *"Would rather deal with one agency than three"* – Common drug management infrastructure and issues • System level synergies include common awareness-building, application procedures, procurement and sharing of best practices

Source: Expert and country interviews; team analysis

HOWEVER, THERE HAVE BEEN CONCERNS THAT THE CURRENT GDF WILL LOSE FOCUS ON TB IF GDF "EXPANDS" AND HAS TO SUPPORT OTHER DISEASES WITH PEOPLE/FUNDS

Some stakeholders question whether GDF can successfully …



"We need to question - is GDF really a "grow or die" business?"

"Realistically speaking, will take at least 1-2 years for GDF to improve its business model, strengthen organization.. prove itself before expanding"

"Innovation and drug management in a limited disease arena – is the main value of GDF"

"Hard to picture GDF developing the same "soup-to-nuts" competency for everything else, that it can claim for 1st line TB drugs"

"Keep overall goal of GDF in mind – Drive DOTS expansion with GDF as the hook. Do not lose sight of that goal, till Stop TB goals achieved"

Source: Interviews; team analysis

THESE FEARS ARE MISPLACED. THE CURRENT GDF IS NOT "EXPANDING" AND IN FACT, THE STOP TB PARTNERSHIP COULD ENJOY SOME BENEFITS

Fears on loss of focus are unlikely to materialize, if various disease partnerships take ownership of their respective GDF

- No risk of loss of focus on TB as the current GDF team will continue to serve the STB mandate and consolidate/grow current operations
- The STB Partnership does not need to invest its own resources for "expansion". Seed funding to explore feasibility and initiate discussions can come from WHO or the respective disease partnerships

Further, the Stop TB Partnership might actually enjoy some benefits if the GDF model moves beyond TB

- Positive reputation for STB as a innovative and impactful initiative, e.g., the Partnership could
  - Release a white paper on the GDF model and learnings for other diseases to catalyze demand from other areas
  - Host conference on access issues
- Increased visibility for STB could encourage new partners and donors to sign on
- Potentially improved cost-effectiveness through shared infrastructure for brand building, procurement and administration
- Potentially improved leverage for GDF brand in countries with combined scope

THE BODY TAKING THE LEAD IN CATALYZING DISCUSSIONS WITH OTHER PARTNERSHIPS MUST MEET THREE REQUIREMENTS

What is needed	Rationale	Implications for coordinating body
Increased visibility at a system and country level	• GDF remains relatively "below the radar" at a system level (even within WHO and STB partners) and in countries. This diminishes its ability to attract partners, donors and encourage more countries to apply	• Must have technical credibility, with strong linkages to countries and partners/donors
Improved access to funding and talent resources	• GDF's success for both - 1st line TB and an expanded scope - depends on a critical infusion of funds to support its grant-making role, talented leadership/ senior management and increased staff capacity	• Must be able to mobilize increased funding and attract talent to the GDF
Better leverage in discussions with disease partnerships	• GDF will need to facilitate discussions on contentious issues with key disease partnerships/stakeholders, who have varying interests and political agendas	• Must be a political "heavyweight" to lend support to the GDF in these discussions

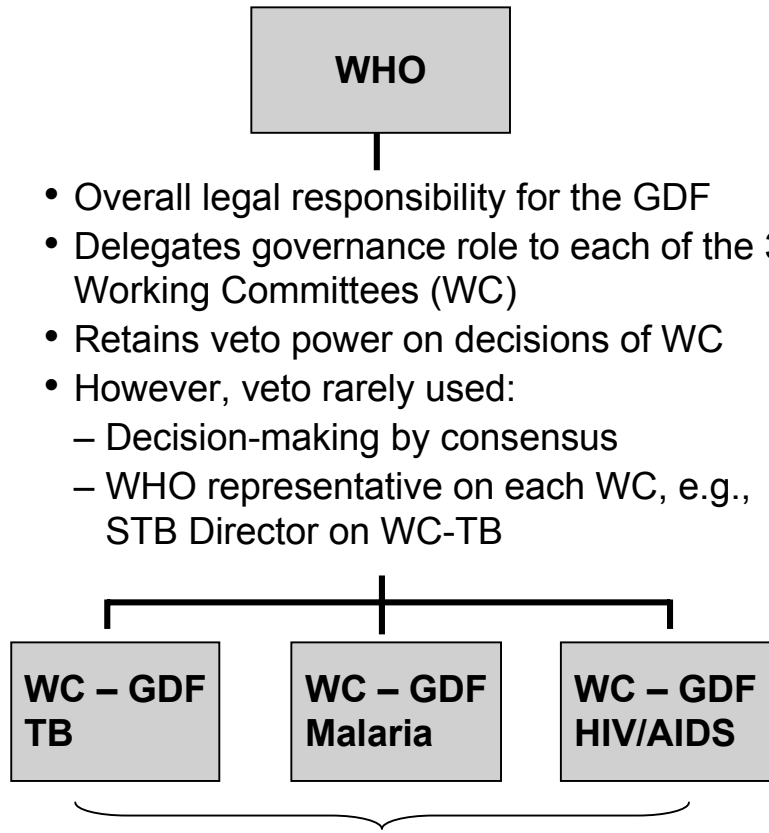
Source: Team analysis

THE WHO IS IN THE BEST POSITION TO MEET THIS NEED

Key recommendations

- **An expanded GDF should have a legal identity within an established multilateral organization**
  - Better addresses needs of increased visibility, access to funding/talent and leverage
  - Few significant other benefits with an independent identity, e.g., improved operational efficiency, political independence
  - Disillusionment with creating new stand-alone public health bodies
- **WHO is in the best position to provide this legal identity for GDF**
  - Clear technical mandate across disease areas
  - Provided good governance for GDF to date with a hands-off role at the center, working harmoniously with the STB Partnership
  - Critical to GDF's success in countries. This linkage will be stronger if GDF is housed within WHO than otherwise
  - No strong case made yet to move GDF out of WHO to other institutions/private sector

Potential outline



Source: Expert interviews; team analysis

WHILE THERE ARE SYNERGIES ACROSS DISEASES, ECONOMIES OF SCOPE ARE TOO MODEST (AND IN NON-CORE AREAS) TO JUSTIFY ONE SINGLE GDF

Critical component of business model

High
Medium
None

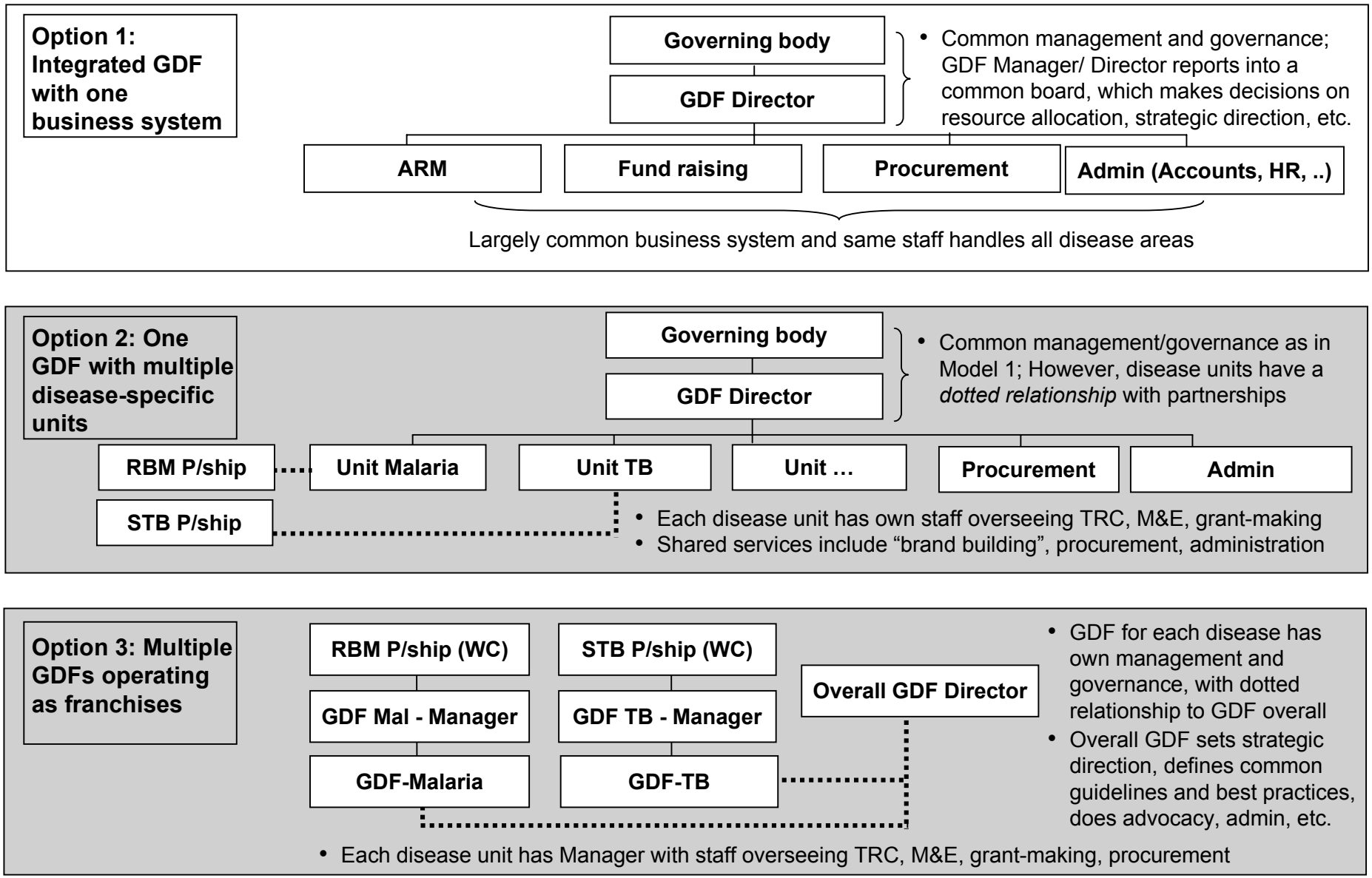
Elements of GDF business model	Key components	Economies of scope between 3 diseases	Rationale
Application, review and approval	• Advocacy/awareness • Application process • TRC review • Country visit	◕ ◕ ◔ ◔	• Common awareness-building at a system/ country level and application generation • However, independent TRC and country visit teams as technical experts/partners, issues and country networks differ across diseases; though visits can be coordinated
Grant making	• Fund raising • Donor management	◑ ? ◑ ?	• Donors potentially differ across STB, RBM and HIV/AIDS partnerships • Further, GDF would need to keep funding streams independent across 3 diseases to minimize conflict in grant-making
Procurement and supply	• Agent/supplier selection • Price/quality negotiations • Order generation and fulfillment	◕ ◔ ◕	• Procurement process elements can be executed together • However, price/volume negotiations with suppliers (especially patented products) would be largely specific to a disease/product area
Partner mobilization for M&E, technical assistance	• Developing/nurturing partner network to ensure related technical assistance • Regular M&E visits	◔ ◔	• Different technical partners for each disease

Best practices can be shared across areas, e.g., donor management, application, M&E, negotiation approach

Source: Interviews; Team analysis

A LOOSE-TIGHT ORGANIZATION STRUCTURE WOULD BE OPTIMAL TO SUPPORT GDFS IN MULTIPLE DISEASE AREAS

Likely and preferred approaches



Source: Team analysis

A LOOSE-TIGHT STRUCTURE, I.E. DISEASE SPECIFIC UNITS OR FRANCHISE MODEL BEST MEETS THE NEEDS OF DIFFERENT DISEASES

Preferred option

What organization structure must deliver to support expansion	Evaluation of options		
	1: Integrated GDF with one business system	2: One GDF with multiple disease-specific units	3: Multiple GDFs operating as franchises
• **Encourage ownership** within disease partnerships	✗	✓	✓✓
• **Tailor approach** to disease-specific needs and **ensure focus** on each disease	✗	✓	✓✓
• **Build on success, leverage synergies and stay lean** vs. building yet another new mechanism	✓	✓✓	✓
• **Allow for clear decision-making and accountability**	✗	✓ ✓?	✓ ✓?

Way forward

- Preferred options: Option 2 or 3
- Going forward, WHO must first discuss/evaluate these options with each of the disease partnerships before finalizing the structure

Source: Team analysis

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APPENDIX CONTENTS

- **Should the STB Partnership continue to support GDF? If so, what changes are needed to its role, proposition, business model?**
- **What resources must the STB Partnership commit to GDF over the next 3 years? How should GDF work with the GF?**
- **Should the GDF continue its current governance/ administrative model with WHO? What changes are required, if any?**
- **Should the GDF expand scope?**
- **Country-specific feedback from country visits**

WORK-IN-PROGRESS

CONTENTS

CONTEXT AND DESCRIPTION OF VISIT TO UGANDA

Context of country visit

- **Highlights of the country's TB situation**
  - High burden country
- **Relationship of the country to the GDF**
  - Applied and approved for drugs in 2001, scheduled to be delivered in 2002
  - Drugs have arrived, however are still in clearance
  - To receive drugs till 2004
- **In-going rationale for selecting country for country visit**
  - High burden country

Interviews and visits conducted

- **Pre-visit interviews**
  - Robert Matiru (WHO)
- **Country visit interviews**
  - Dr. Oladaop Walker, WHO Representative
  - Dr. Joseph Serutoke, WHO Drug Procurement
  - Dr. Francis Adatu-Engwau, NTLP Manager, MOH
  - Dr. Joseph …., NTLP Secretary, MOH
  - Francis Otim, National Drug Authority (NDA)
  - Peter Wilbur, JSI, DELIVER project manager
  - Dr. Kawuma, GLRA
  - Dr. Peter Okwero, World Bank Health Specialist (TB, malaria, HIV)
- **Follow on interviews**
  - Dr. Guiliano Gargioni

SUMMARY OF FINDINGS FOR UGANDA – GDF IMPACT

PRELIMINARY DRAFT

Success

- Meeting Uganda's TB drug needs via both grant and direct procurement
- Drugs at ~$10 per treatment compared to previous purchases of ~$30 per treatment
- Innovative blister packs and 4FDCs are welcomed and seen as a competitive advantage of GDF, improving ease the administration and reducing risk of drugs being stolen for sales outside TB programs
- GLRA is expanding its support to 3 more districts from its former 25, as they were able to redirect funds that were formerly used for procuring drugs
- GDF has recognized the importance of working well with the National Drug Authority (NDA) for drug registration

Concerns

- Drugs still not released from clearance facility
  - Drugs has not been registered with NDA, at time of arrival in port
  - Concern that GDF was not being proactive enough in solving the problem of $36,000 storage and clearance charges
    - "GDF asked for policy requirements after the order was put in"
    - "GDF is requesting the government to first pay for the additional clearance fee incurred so that the drugs could be released, and then sort out responsibility"

ASSESSMENT OF GDF'S IMPACT ON THE COUNTRY'S TB CONTROL PROGRAM TO DATE - SUCCESSES

PRELIMINARY DRAFT

On DOTS expansion and TB control/ treatment

- Drug shortage will be met with GDF drugs
  - *"GDF's coming is a blessing… there was no money for drugs…"*
  - *"It will be easier for us to expand DOTS and scale up more rapidly because the drugs are there…"*

On political and partner commitment and alignment

- TB is high priority for the government along with AIDS

GDF's impact to date

On TB drug management

- GLRA has been able to expand TB management support into 3 more regions as funds for drugs have been freed up by GDF
  - GLRA was buying $500,000 worth of drugs covering 14,000 patients ($35 / patient) up until this year
  - Since GDF is supplying drugs, GLRA has taken this money and used it to expand activities to three new regions and to purchase vehicles and other supplies for MOH
  - Overall GLRA spending has remained same

On related TB capacity building

- Not yet observed

ASSESSMENT OF GDF'S IMPACT ON THE COUNTRY'S TB CONTROL PROGRAM TO DATE – DRAWBACKS/ IMPROVEMENT AREAS

PRELIMINARY DRAFT

On DOTS expansion and TB control/ treatment

- GDF could initiate dialogue with MOH earlier to ensure alignment with overall TB strategy and influence on key issues as needed

On political and partner commitment and alignment

- Not observed

GDF's improvement area

On TB procurement and drug management

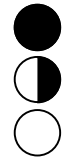
- Drugs have not been released from clearance
  - Drugs were not registered by the time of arrival
  - Concern was raised of GDF's proactiveness in resolving the clearance issue
- *"GDF should help with drug* supply*, not just the drug…"*
- GDF should contact NDA with new list of suppliers as soon as tender results are available

On related TB capacity building

- *"…not really having a catalyst function"*

UGANDA'S EXPERIENCE IN INTERACTING WITH THE GDF

BACK UP



High / Exceeds expectations
Average / Meets expectations
Low / Below expectations

	Dimension	Assessment	Comments
Fund raising /grant making	• Grant making process	●	
Application review	• Advocacy and awareness building	◕	• Satisfied with the ease and clarity of the application • The realistic implementation of the country plan and GDF requirements will be difficult due to lack of human resources and lack of drugs
	• Application, review and approval	◕	
	• Feedback from TRC	◕	
	• Approval process	◕	
Procurement	• Drug selection	◑	• Communication of rationale for the selection of drugs provided need to be more active • Needs to improve on speed and communication of the web tracking system
	• Drug order/delivery	◕	
	• Procurement	◑	
Coordination of Stop TB partners	• M&E	○	• M&E and capacity building has not been observed yet • GDF was able to free funds of the GLRA to redirect funds to operational activities, expanding TB control support to 3 more regions
	• Political commitment and coordination between stakeholders	◕	

OBSERVATIONS FROM UGANDA TB PROGRAM – IMPLICATIONS TO GDF GOING FORWARD

What GDF needs to do to get direct procurement orders	• WB direct procurement through GDF "*by default", "…based on emergency need"* • *"It's acceptable for the government to go through a single reputable WHO-related source, if $ are coming from the WB"*
GDF's value proposition and future	• "*At the beginning, saw GDF as 'more than procurement', but since then, changed my mind…"* • "*Current value proposition is getting drugs, period. This is not sustainable if they don't have funds. Others could do this too, except if the GDF has more volume and can get better prices"* • *"Has a future for three reasons: it has the dollars, it is decreasing prices, and it can standardize treatment across regions"* • Donors should give money to GDF because…"clear focus and mandate, good prices, and less risk of corruption, and StopTB / WHO links" • *"..should consider offering training on drugs as well"* • *"GDF needs to either fund TA or do it to have broader impact"*
What it takes to get the system to change	• DELIVER worked with the MOH to change the procurement system from push to pull, and this will start Jan 2003. It took *"… one year of consulting, DANIDA funded studies, government recognition of need for change, and DANIDA threat: 'we've been funding for ten years, we expect to see some change'"*
How to have influence with MOH	• "*You don't need to have huge market share to influence the government. The other way to do it is to have something that the MOH needs. JSI DELIVER doesn't do any procurement, but it has procurement experts who go and help the MOH procurement people, and can influence things that way…"*

OBSERVATIONS FROM UGANDA TB PROGRAM – IMPLICATIONS TO GDF GOING FORWARD

Expanded Scope

- *TB*
  - *"Get this right first…"*
  - *Should expand to TB diagnostics, and also fund / give TA support for drug distribution"*
  - *"If you can provide a good package including diagnostics, that will solve a lot of problems"*
- HIV
  - *"GDF will have all the guns pointing at it"*
  - *"could get HIV test kits, but even these are not standardized yet, and GDF cannot do that"*

OBSERVATIONS FROM UGANDA TB PROGRAM – GDF'S PERFORMANCE COMPARED TO OTHERS

Government and other procurement

- …GOU did an ICB using a WB loan, at around $30 per treatment course
- Also uses own procurement, NMS, Joint Medical Stores (private), and IDA. IDA has registered over 100 drugs in Uganda, is very strict with suppliers, does its own inspection. "a *well respected…"*
- "GDF is better than WB… they are a mess, 15 months later and still no drug. They got a company based on price only, and it wasn't registered with the NDA. Paperwork supplied was pathetic, and the E looked exactly like the R. NDA complained, and the WB withdrew…"
- DFID used a procurement agent to get malaria drugs…"*got rejected by the NDA*"
- GLRA purchased drugs from Wolff, procured centrally by GLRA

Role of Global Fund is unclear going forward

- *"Nobody knows what they are. Just some big monster. They don't know what to do with the money"*
- Coordination that is required is easier said than done
  – E.g. more than 3800 NGOs are involved with fighting AIDS in Uganda
- Governance structure of the CCM is not resolved, therefore it is unclear who has the decision making authority
- 3 year proposal will be funded. Expected that they would be able to use GDF because "cheap and good", so GDF direct procurement might become reality
- *"GF is in for a big shock… like all the 'funding' agencies, it doesn't appreciate the scale or complexity of what it is taking on, and the need to work with the MOH and partners. GAVI is realizing that. If Uganda goes with GAVI's pentavalent vaccine, the price will go from $3 to $20… GAVI is just beginning to understand the implications of that at the country level…".*

OTHER LEARNINGS FROM UGANDA TB PROGRAM

Central commodity database

- For the coordination of partners, a common commodity drug database is in the process of being developed
  - Keeps track of all MOH and donor inputs for essential health commodity supplies
  - Alerts impending stock outs or shortages in various product categories

Preprinted order form

- Attempts to switch to pull order from push order for essential drugs and supplies including TB drugs
  - Current system determines the drug need based on drugs available, and allocates the drugs down the health system
  - However with the new preprinted order form, each facility will determine current stock, quantity needs and total costs
  - Formerly costs were unknown at the lower levels of the health system, however in the new form, unit costs are given reinforcing responsible distribution of drugs and supplies

CONTENTS

CONTEXT AND DESCRIPTION OF VISIT TO NIGERIA

Context of country visit

- **Highlights of the country's TB situation**
  - 4th high burden country
  - NGOs such as NLR, DFB, GLRA are supporting 21 states out of 37 states
  - States that are not covered through the NGOs, are not covered through DOTS and do not have quality TB drugs with issues of fake drugs
- **Relationship of the country to the GDF**
  - Applied and approved for drugs in 2001
  - Received drugs October 2002 covering ~30% of TB drugs in country
  - To receive drugs till 2004
- **In-going rationale for selecting country for country visit**
  - High burden country

Interviews and visits conducted

- **Pre-visit interviews**
  - Dr. Kibuga (WHO AFRO)
- **Country visit interviews**
  - Dr. Sofola, NTBLCP Manager, MOH
  - Dr. Awe, WHO NPO TB
  - Dr. Samson, ex-NLR, Regional NPO
  - Dr. Osubor, CIDA
  - Gwarzo Sani, Nat'l AIDS/HIV/STD Program Coordinator
  - Mustafa Muhammed, MOH Procurement Officer
  - Dr Eggers, NLR
- **Follow on interviews**
  - Dr. Osho, DFB
  - Dr. Taylor, WHO Essential Drug Advisor

SUMMARY OF FINDINGS FOR NIGERIA – GDF IMPACT

PRELIMINARY DRAFT

Success

- Expansion of DOTS program to the entire country would not have happened if not for GDF
  - NTP has tried to get state governments on board for DOTS treatment, however the commitment required for TB drugs was too much of a burden
  - GDF supplied drug to 16 states that did not have DOTS, allowing DOTS programs to begin in those states
- GDF has been able to increase government commitment
  - Government has committed · 9M to TB upon the arrival of the GDF drugs (would not have happened otherwise)
  - Got government to invest more in infrastructure (e.g. Kano state)
- GDF has been able to contribute to donor coordination
  - Uncoordinated drug procurement by partners transitioning to coordinated procurement through GDF, which will result in uniform drugs across country
  - Allowed NLA to remain operative by providing TB drugs that required allowed them to justify utilizing the existing leprosy infrastructure
  - CIDA grant of xxx USD will facilitate the GDF drug management by funding training and infrastructure

Concerns

- Lagos state has attempted to procure 100,000 USD of drugs from GDF through WHO, however due to the extensive requirements will withdraw to other source

ASSESSMENT OF GDF'S IMPACT ON THE COUNTRY'S TB CONTROL PROGRAM TO DATE - SUCCESSES

BACK UP

GDF's impact to date

On DOTS expansion and TB control/ treatment

- GDF drugs additive to existing supply and now covers +100% buffer for 16 states that did not have drugs
- CIDA funding supporting infrastructure, diagnostics, and training for DOTS expansion in six states
- Global Fund will expedite DOTS expansion using GDF drugs

On political and partner commitment and alignment

- Government interest has increased in TB
  - *"Along with TB, GDF has become widely known to the government with the NTP and WHO talking about GDF all the time"*
- ·9M "counterpart" government funding after GDF grant
- Not only has federal government increased its funds, but also states and LGAs are increasing investments beyond salaries in refurbishment of labs/ infra-structure

On TB drug supply/management

- Drug procurement changing from partners procuring different drugs at different times to all planning to use GDF direct procurement
  - Uniformity
  - Minimization of importation problems
- GDF introduced 4FDC to Nigeria
- Web tracking system is very useful in tracking where the drugs are on delivery
- Expecting fake drugs to disappear as free high-quality drugs distributed across country

On related TB capacity building

- NTP training healthcare workers using CIDA funds
- State funds (e.g. Kano state) being released for refurbishing TB clinics

ASSESSMENT OF GDF'S IMPACT ON THE COUNTRY'S TB CONTROL PROGRAM TO DATE – DRAWBACKS/ IMPROVEMENT AREAS

BACK UP

On DOTS expansion and TB control/ treatment

- Eventually would like to see GDF offer support and transfer of technology to build local production capacity bringing it to international standards
  - "Would like to see in the future Nigeria manufacture drugs creating jobs in the country"
  - Local capacity will simplify issues rising fro importation

On political and partner commitment and alignment

- GDF could generate more political commitment by having 'high-level' meetings with MOH and government

GDF's improvement area

On TB procurement and drug management

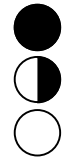
- GDF's drugs arrived 6 months later than expected due to the request for blister packaging
- 2nd batch of drugs were missing several documents, which delayed the process increasing clearance costs to be covered by the NTP

On related TB capacity building

- N/A

NIGERIA'S EXPERIENCE IN INTERACTING WITH THE GDF

BACK UP



High / Exceeds expectations
Average / Meets expectations
Low / Below expectations

	Dimension	Assessment	Comments
Fund raising /grant making	• Grant making process	●	
Application review	• Advocacy and awareness building	◑	• Country found out about the GDF, only at the 2nd round, otherwise would have applied during the 1st round • In-country partnership had already developed the plan doing most of the work
	• Application, review and approval	◕	
	• Feedback from TRC	◕	
	• Approval process	◕	
Procurement	• Drug selection	◑	• Country is on its own to develop transition plan to 4FDCs • Drugs have arrived late due to the request for blister packages • Satisfied tracking system offered
	• Drug order/delivery	◑	
	• Procurement	◕	
Coordination of Stop TB partners	• M&E		• Not applicable as country has just received the drugs
	• DOTS expansion	●	• GDF drugs have successfully initiated the government's support in investment into the TB program • GDF drugs have enabled the deployment of CIDA funds in capacity building efforts
	• Political commitment	●	
	• Health infrastructure (physical and personnel)	◕	

OBSERVATIONS FROM NIGERIA TB PROGRAM

Implications to GDF going forward

GDF's value proposition and future

- GDF drugs have diplomatic status b/c of WHO link which makes importation process easier
- NTP and partners discussing switching all procurement to GDF, with positive response
- GDF procurement of diagnostic supplies would be welcome. *"we get stuff that has been bought in drums and repackaged"*
- 'Cascaded' training of NTP managers will be welcome *"you don't need to train the whole country"*

How to have influence with MOH

- "*Step through the protocol and diplomacy, by having high level GDF related personnel to visit recipient country. A signed letter is not enough to have the government feel obligations toward commitment"*

GDF's performance compared to others

Government and other procurement

- *"In the past, IDA went for the cheapest, therefore packaging of the drugs were awful"*
- *"IDA sent us drugs in 10,000 pill bottles –we would have had to re-package everything, so we re-exported them instead"*

Role of Global Fund

- *"Global Fund grant will cover the infrastructure that will be required to expedite DOTS expansion with the GDF drugs"*
- Global Fund grant is an additive to the GDF, moreover as NTP prefers procurement through GDF, going forward Global Fund grant will improve drug management of the GDF drugs

OTHER LEARNINGS FROM NIGERA TB PROGRAM

Weight bands for patient packages

- GLRA is currently undergoing a pilot in one of the states, offering patient packages that differ by weight band, which will simplify monitoring and administration of drugs by the health care worker

CONTENTS

CONTEXT AND DESCRIPTION OF VISIT TO THE PHILIPPINES

Context of country visit

- **Highlights of the country's TB situation**
  - HBC, 7th worldwide, 2nd in WPRO
  - TB is GOP's #1 health priority
  - Strong performance on DOTS coverage (close to 100%) and treatment success (>80%), but moderate case detection (~53%)
  - Drug shortages due to procurement problems one of the main challenges for the NTP
- **Relationship of the country to the GDF**
  - Applied and approved for emergency grant, regular grant (for public-private mix- PPM) in 2002 and direct procurement using WB loan in Feb 2003
  - Drugs will arrive only in May 2003 – delayed shipment at DoH's request
- **In-going rationale for selecting country for visit**
  - HBC
  - Drug grant and direct procurement
  - PPM experiment

Interviews and visits conducted

- **Pre-visit interviews**
  - Tom Moore (GDF)
- **Country visit interviews**
  - Dr. Charles Yu (PHILCAT)
  - Dr. Rod Romulo (PHILCAT, Philippine TIPS)
  - Dr. Melvin Q. Magno (World Vision/CIDA)
  - Dr. Jaime Lagahid (NTP)
  - MoH officials from Bids & Awards Committee; Bureau of Health Facilities; Bureau for Food & Drugs; Procurement and Logistics Service; Bureau of International Health Operations
  - Dr. Dongil Ahn and Dr. Takeshi Kasai, WHO
  - Dr. Seiya Kato, Chief Advisor, JICA
  - Dr. Jayshree Balachander, WB
- **Courtesy meetings**
  - Attended the 1st Philippines TB Summit, convened by DoH and PHILCAT
  - Dr. Jean-Marc Olive (WHO WR)
  - Dr. Myrna Cabotaje (NTP Director)
  - Dr. Manuel Dayritt (Secretary, Ministry of Health)
  - Dr. Antonio Lopez (Under Secretary, Ministry of Health)

SUMMARY OF FINDINGS FOR PHILIPPINES – GDF IMPACT

Success

- GDF could **alleviate drug shortage caused primarily by procurement-related issues**, i.e. "free" drugs was not the prime motivator of the DoH's application. As a result, GDF could potentially have the following benefits:
  - Significantly **reduce lead times** in procurement vis-à-vis ICB (>1 year to ~ 3 months) and **prices** vis-à-vis local suppliers (~$19 to $10/treatment)
  - NTP expects to **increase case detection** from 53% to 70% within a year with GDF alleviating drug shortage problems and will meet Stop TB's goals by 2004
- **FDC seen as welcome move to ease drug management**, prevent mono-therapy and reduce incidence of drug resistance
- Free and quality drugs from GDF **one of the cornerstones to PPM experiment** with private practitioners – *"overcame suspicion of quality that private sector has for public sector drugs"; "set optimistic mood that TB was getting international attention"*
- **High awareness of the GDF in all interactions** with most stakeholders, with good understanding of GDF's benefits on price, quality, lead times and FDC
- **NTP coordinated application to GF with GDF grant**, to demonstrate additionality and GDF experiment of joint application (DoH/NTP, WHO and PhilCAT) has helped in writing the GF application as well

Concerns

- Based on observations in meetings, GDF needs to more **clearly explain the procedures for direct procurement** to countries and standardize that process
- Overall, no real concerns, though actual impact of the GDF can be seen only after the drugs have been received by the Philippines in May 2003

Too early to comment accurately on successes and concerns as drugs will arrive only in May 2003 (Delay at request of NTP)

CONTEXT OF THE PHILIPPINES' APPLICATION TO THE GDF

Source of information on the GDF

- NTP received information on the GDF from 3 sources in early 2002
  - WHO WPRO, which encouraged the NTP to put in an application in 2002, given procurement-related problems
  - STB members - Dr. Dayritt (sits on STB CB) and PHILCAT (STB partner; on TRC)
  - Conferences, e.g., 2002 Washington Drug Management Conference, IUATLD Conference and World Bank recommendation in context of WB loan
- Application to GDF was jointly developed by NTP, WHO and PHILCAT

Drug situation and rationale for application

- The NTP has no major problem with funding for TB drugs (fixed budget, WB loan)
- However, in 2002, it faced significant procurement problems
  - Despite a WB loan for TB drugs, it was unable to get the ICB mechanism functioning smoothly due to NTP and WB procedural issues. Hence, the initial procurement took over 1 year → delays and drug shortages
  - Local suppliers were significantly more expensive (~ 1000 peso/treatment = ~$19); On the other hand, international suppliers sometimes failed quality checks, could not ramp up capacity to meet order or could not deliver reliably on time
- Further, the NTP was planning an experiment to bring private practitioners under DOTS and free drugs from a credible source like GDF could help catalyze this
- The NTP/MoH has since placed orders with the GDF under all 3 service lines (100% of Philippines TB drugs will be from GDF from 2003):
  - Emergency grant to cover 69,000 patients in 2003 (including buffer stock)
  - Regular grant to cover 5,000, 16,000 and 50,000 patients in 2003, 2004, 2005, respectively under the public-private mix (PPM) experiment
  - Direct procurement of $4M for 2 years (2003 and 04) using WB loan

ASSESSMENT OF GDF'S IMPACT ON PHILIPPINES' TB CONTROL PROGRAM TO DATE - SUCCESSES

TOO EARLY TO SAY – DRUGS NOT ARRIVED YET

GDF's impact to date

On DOTS expansion and TB control/ treatment

- Expected to overcome drug shortage and help drive case detection from 53% to 70% by 2003-4
  - *"Drug shortage is one of the weakest links in the NTP, not because of shortage of funds, but lengthy process"*
- GDF direct procurement to cover 170,000 patients and grant 16,000 patients under PPM in 2003, vs. 110,000 treated in 2001
  - *" Government priority today is SS+ cases. With GDF drugs, can treat all TB cases"*
- Significant catalyst for PPM experiment – provision of "free" drug, quality perception given WHO (vs. DoH image) and FDC to standardize regimens

On political/partner commitment and alignment

- No significant change in commitment, given already high involvement and TB is #1 national health priority. No shortage of budget for TB drug purchases from MoH
- However, helped set positive experience of joint applications between partners
  - *" GDF was the first really big event that forced us all to sit down and think about what to do. We had bits and pieces earlier in our heads, no one wrote it down and put it on paper"*

On TB drug management

- NTP expects easier drug management, fewer non-standard regimens, less mono-therapy due to FDC and 100% drug sourcing from GDF
- Lower prices ($10) versus local sourcing ($17-19)
- Reduced lead times versus ICB using WB funds, though prices are the same from both sources
- Similar quality, but higher perceived quality of GDF drugs (*"From WHO/GDF"*) – helpful for PPM experiment

On related TB capacity building

- No support from GDF and none expected - *"We see GDF as part of the jigsaw. Happy to get drugs from it, but do not need its help in other areas, where we have already coordinated partners' roles"*

ASSESSMENT OF GDF'S IMPACT ON PHILIPPINES' TB CONTROL PROGRAM TO DATE – DRAWBACKS/ IMPROVEMENT AREAS

TOO EARLY TO SAY – DRUGS NOT ARRIVED YET

On DOTS expansion and TB control/ treatment

- GDF should have a clear plan on sustainability of its grant to a country. If it cannot guarantee a long term commitment, countries would find it difficult to shift to GF. N/a of direct procurement

On political and partner commitment/alignment

- GDF should actively identify, test and build on existing partner mechanisms in a country versus creating alternative channels. E.g., use PACT's M&E system vs. new M&E visits
- Where GDF's grants are made directly to NGOs or states, it should work through the central program t ensure coordination, else the NTP loses its "negotiating leverage" to have parties accept conditions

GDF's improvement area

On TB procurement and drug management

- Would like to see local suppliers qualify under the WHO's white list. Local suppliers expected to a) be largely on par with GDF prices on full-cost basis; b) help DoH in in-country distribution (infrastructure/ TA); and c) support social mobilization campaign
- Would prefer "GDF not to have a hands-off policy w.r.t. in-country drug management" – at least make it a specific prerequisite during application
- Need clearer processes and requirements for direct procurement – some confusion today among various parties on how direct procurement will work
- Emergency grant should have a shorter lead time than 3 months, else not meeting urgent need

On related TB capacity building

- None mentioned. However, if possible, would like funds provided to support transition to 4FDC, e.g. for orientation of NTP officials
- GDF having other service lines, like drug management, is not critical to its proposition to countries like the Philippines (given active participation of partners like JSI, AIM). However, in specific situations, this could be another value-added service if needed

PHILIPPINES'S EXPERIENCE IN INTERACTING WITH THE GDF

● High / Exceeds expectations
◑ Average / Meets expectations
○ Low / Below expectations

	Dimension	Assessment	Comments
Fund raising /grant making	• Grant making process	○	• No specific feedback.
Application review	• Advocacy and awareness building • Application, review and approv • Feedb • Appro	○ ○ ○	• Satisfied with the ease and clarity of the application and information – *"We just followed the guidelines and matrix… User friendly website"; " Has one of the best application forms, asks for little but critical information and builds on what countries need to TB control"* pful – *"Tom Moore's visit really helped clarify et with several key stakeholders"* ust – *" They ask the right questions and have the obe where needed"*
Procurement	• Drug s • Drug order/delivery • Procurement	○ ○	back, as drugs have not been received yet Would like to reduce lead time on emergency supplies to ~ 1 month • Some confusion on guidelines and requirements on direct procurement – need better communication from GDF
Coordination of Stop TB partners	• M&E • Political commitment and coordination between stakeholders	○ ○	• No specific feedback. Would like to see GDF build on existing country mechanisms versus creating parallel TA and M&E systems

TO BE COMPLETED - WIP

OBSERVATIONS FROM PHILIPPINES TB PROGRAM – IMPLICATIONS TO GDF GOING FORWARD (1/2)

What GDF needs to do to get direct procurement orders

- Active advocacy and awareness building with all key stakeholders, e.g., all groups take credit for bringing GDF to the DoH's notice
  - *"They were running around in circles on ICB, we recommended GDF";"They did not realize they qualified for GDF, we looked up the website and showed them"*
- Enlightened and pragmatic MoH – technically strong ministry, bureaucrats and MoH officials, close involvement with STB (Dr. Dayritt on CB)
  - *"We source over 100 items, should hand as many to those who do a better job"*
  - *"Secretary signed the GDF application. They strongly support direct procurement"*
  - *"Even if ICB and GDF give us the same prices, we would prfer GDF for FDC vs. loose drugs and quicker lead times"*
- Quickly refine its direct procurement model, streamline and communicate processes, costs, and establish some track record so that more countries could use it - *" looks like early stage of development of this service line…need proof of concept first"*

GDF impact if grant making role is dropped

- GDF can have impact even when NTP has sufficient funds, if there are other procurement-related problems causing drug shortage (GoP has fixed budget line for TB)
  - *"Countries will use GDF sans grant if they have local quality problems. In the P, we have higher local prices, quality issues and delays if we went with local suppliers + anyway, needed to invest in training with GDF grant, so decided to go for 100% of our need"*

GDF can build a case around how it helps avoid MDR

- 80-90% of MDR cases originate in the private sector, mainly due to drug misuse and non-standardized regimens (one study indicated over 210 regimens among 200 private doctors studied); Philippines has unconfirmed estimates of 4-6% MDR incidence
- GDF, through FDC and provision of free "quality" (because of WHO association) drugs, is a catalyst to the PPM experiment. Doctors are more willing to sign up for DOTS, use WHO quality-assured drugs and FDC prevents misuse
- Philippines also has a GLC-approved pilot project for MDR-TB treatment

OBSERVATIONS FROM PHILIPPINES TB PROGRAM – IMPLICATIONS TO GDF GOING FORWARD (2/2)

Feedback on expanded scope for the Philippines

- "One stop shop" – TB consumables
  - Limited value in "one stop shop for TB" - these consumables are low-tech items, which local suppliers already source from China at very competitive rates
  - Microscopes are provided by partners like JICA, WHO
  - *"Could be a good idea for GDF if it has the capacity, but this is not as critical a role as what GDF plays in drugs"*
- Some level of interest to expand scope to **malaria** (No major HIV/AIDS challenge)
  - Revised malaria drug policy in favour of combination therapies in 2002, given wide resistance to 1st line drugs (>25%)
  - However, 3 issues: a) similar procurement issues and delays as in TB drugs; b) funds shortage given lower priority than TB/budget reduction and increased cost of drugs now (though GF grant now approved); c) Local implementation issues given poor drug compliances (self-medication, wrong doses), hence, would like patient-wise blister packs

Role for GDF in WPRO HBCs

- 7 HBCs in WPRO, including China, Philippines, Vietnam, Cambodia, Indonesia
- However, potentially little need for GDF in many of these countries
  - **Grant making:** Funds shortage is not a major issue – funding gap for TB reduced from 40% to 10% of need since 1999, post WB, JICA and GF grants/loans. Further, these funding sources are often medium-long term commitments versus yearly grants from GDF
  - **Procurement:** Most countries either have a reasonably well-functioning procurement mechanism or rely on support from JICA. In fact, in China, JICA along with WHO has a GDF-type model of drug grants
  - **Technical support**: DoH, WHO and other technical partners active in the region; strong relationship between WHO and NTPs in WPRO
- *"If GDF had existed 5 years ago, it would definitely have been a critical element of the TB control program in the region. Since the map of partners was developed in1999, no strong need for GDF other than in specific cases like the Philippines"*

OBSERVATIONS FROM PHILIPPINES TB PROGRAM – GDF'S PERFORMANCE COMPARED TO OTHERS

Government and other procurement

- **ICB process using WB funds – prices similar to GDF but took over a year**
  - ICB needs GoP drug registration and supplier certification requirements to be dropped in initial bidding to allow participation of international suppliers.
  - However, the winner not able to meet these requirements post-bid in required timeframe
  - Hence, awarded to 2nd lowest cost bidder and process restarted
  - In-between delays with communication to and fro from WHO
  - However, good competitive price of ~ $11/treatment (Indian company)

- **Local suppliers - higher prices and supply delays → risk to NTP's credibility**
  - Selected through sealed bids with procurement conducted by GoP
  - However, chronic drug shortage as suppliers could not meet deadlines, shipping delays
  - Quality also suffered sometimes, and some did not pass bio-availability testing, creating artificial shortage and "emergency situation"
  - Prices much higher than ICB = ~$19/treatment

- WorldVision/CIDA, a NGO, does own procurement using sealed bids involving local suppliers. No quality or delay issues. Would be open to sourcing from the GDF if it continues its program in the Philippines

OTHER LEARNINGS FROM THE PHILIPPINES TB PROGRAM (1/2)

Public-private mix (PPM) experiment

- Significant percent of TB patients treated by private general practitioners (GPs), using non-standardized regimens ("210 regimens among 200 GPs surveyed) with poor quality, expensive drugs from the private market
- Objective and structure of PPM pilot:
  - Goal: Encourage GPs to accept DOTS, report cases to NTP, increase success rate
  - GPs offered "free" quality FDC drugs sourced from GDF with training, in return for acceptance of DOTS treatment and increased case notification
- Joint program management by
  - PHILCAT (national coalition of NGOs) with local PHILCAT chapters taking up program supervision and M&E. PHILCAT will also undertake "train the trainer" programs and certify doctors under the PPM program (TIPS program)
  - PHILHealth – National Insurance system – will help set up patient information systems, patient-unique ID, reimburse cost of treatment, program audits
  - NTP infrastructure at provisional and local level and WHO oversight
- Program will be supported by 1-year media campaign for de-stigmatization
- Prerequisites to initiate a PPM pilot in other countries: a) Existence of large private sector TB treatment; b) private sector enjoys a relatively more positive image/TB stigma; c) coordinated NGO activity across the country upto the local level; d) enlightened program leadership and cooperation in the NTP and private sector

Efforts to increase case detection from 53% today to 70% by 2003-4

- Involving other government departments, e.g. Defence (army), Prisons, Agriculture, Indigenous people (all present at 1st Philippines TB Summit and co-signed declaration against TB)
- Asked for Global Fund grant primarily to increase community involvement, PPM and awareness building for de-stigmatization
- Building buffer stocks with GDF grant to meet needs of estimated 170,000 patients to ensure no drug shortage – *"Presence of at least a 1 year buffer stock will automatically help increase case detection"*

OTHER LEARNINGS FROM THE PHILIPPINES TB PROGRAM (2/2)

Handling of transition to 4FDC

- Using pilot approach vs. large scale change: Piloting in 1 province only in each of 16 regions from 2004 with GDF drugs
- Has timetable for transition
  - Already prepared training materials and FDC treatment guidelines
  - Will conduct orientation in April for key people, health workers
  - Plans publicity around launch – launch FDC in July to coincide with "Lung Month"
  - Will use 2nd half of 2003 to recall loose drugs from provinces
- Aims to get all stakeholders on board
  - Training and guidelines prepared with WHO support
  - In March quarterly PACT (inter-agency partner coordination body) meeting, plan to discuss transition, get partner support and funding

Process learning for GDF: Benefits of good advocacy

- Good advocacy and awareness building creates strong goodwill with all key stakeholders and more support for actions like direct procurement
- Most stakeholders had used STB/GDF website, heard GDF presentation at the Washington Drug Management Conference and IUATLD conference and Tom Moore's visit in 2002 and presentations to key people/forums provided very useful publicity for the GDF

PACT - partner mobilization/ coordination

- WHO has helped coordinate partners' programs on the ground in WPRO countries along with the NTP
  - Developed map of TB program with NTP and identified gaps. Most WPRO countries have strong DoH/NTP
  - WHO played a brokering role to rope in partners to fill gaps
  - Hence, does not need the GDF to take on additional roles
- In the Philippines, for example, PACT meets every 2 months to discuss progress, update each other and agree on future actions, coordinated by NTP and WHO

CONTENTS

CONTEXT AND DESCRIPTION OF VISIT TO MYANMAR

Context of country visit

- **Highlights of the country's TB situation**
  - HBC, Xth worldwide, 2nd in SEARO
  - TB is GOM's #2 health priority
  - Drug shortages due to funding gap – significant resource crunch on all dimensions in Myanmar as the country does not receive assistance from traditional donors or technical partners due to the political situations
- **Relationship of the country to the GDF**
  - Applied and approved for GDF grant in June 2001 in Round I; has received drugs in 2 tranches in Dec'01andMar'02 and has completed one M&E visit
  - In the process of applying for 2nd year grant, and transitioning to 4FDC
- **In-going rationale for selecting country for visit**
  - HBC
  - Long track record with GDF grant
  - Low involvement of traditional STB/GDF partners, significant funding gap

Interviews and visits conducted

- **Pre-visit interviews**
  - Holger Sawert (WHO); Ginni Arnold (WHO)
  - Katherin Watt (?)
- **Country visit interviews**
  - Dr. Antonio Borra and Dr. Myo Paing (WHO)
  - Dr. Aye Htun (NTP Deputy Director, MoH), Dr. Kyin and Dr. Noe (NTP)
  - Dr. Ti Ti (NTP, Laboratory Facilities, Microbiologist)
  - Dr. PeThet Htoon (Director, International Health Div, MoH)
  - Dr. Myo Myint (Myanmar Medical Association)
  - Dr. Myint Thoung, Dr. Aye (Central Medical Stores Depot)
  - Dr. Soe Myat Tun (Director, Food & Drug Administration)
  - President, Myanmar Maternal & Child Welfare Association (MMCWA)
  - Dr. Tin Nyunt (Director, National Health Laboratories)
  - Dr. Myint San (District TB team leader, Thanlyin)
  - Dr. Win Maung (Zonal TB Officer, Yangon)
  - Dr. Michael Pastoors (Malteser, Myanmar representative)
  - Guy Stallworthy, Natasha Howard (PSI, Myanmar)
  - Dr. Frank Smithuis (Director, MSF Myanmar)
- **Field visits**
  - Zone 1 TB Centre and NTP Store for Lower Myanmar
  - Mayangone and Thanlyin TB Health Centers

SUMMARY OF FINDINGS FOR MYANMAR – GDF IMPACT

Success

- The GDF drug grant significantly **alleviated drug shortage due to lack of resources.** It supplies drugs for 80% of all TB patients in Myanmar today. – *"GDF has provided Myanmar a sense of security on drugs, given the TB program more stability and a push for DOTS expansion"- Director, International Health, MoH*. As a result of the grant:
  - DOTS expansion will increase from 85% in 2000 to 100% by end 2003; Case detection is also expected to improve from 56% in 2003 to ~70% in 2003
  - Social mobilization campaigns have been launched as the NTP now has adequate drugs to treat new cases
- GDF presence has **catalyzed additional funding for TB**. The GOM has increased TB drug budgets 4-fold and WHO, which earlier used 80% of its budget for TB drugs, has both increased its budget and is ploughing back ~$100,000 p.a. from drugs to other aspects like training, technical assistance, transition to FDC
- GDF's "free of charge" drugs is **helping the public-private program** by encouraging more patients to enroll into public healthcare system or private doctors to treat patients under DOTS
- **NGOs are expanding activities in Myanmar** as drug shortage is not an issue any more
- Work on the GDF application **helped in the pre-work for Myanmar's application to the GF**, although success in obtaining the GF grant was not related to the GDF grant

Concerns

- Serious concerns voiced about the **sustainability of the NTP if GDF withdraws support** – *"GDF must ensure sustainability, else the credibility of the entire TB program will be at stake. NTP is putting in a lot of resources in social mobilization and publicizing drugs as 'free of charge'. Would be difficult to suddenly change policy if GDF withdraws in 2 years"*
- Substantial **confusion on transition to 4FDC** and little planning on how to strengthen the health infrastructure with increased workload
- **GDF does not seem to be adequately reaching out to NGOs** working in the TB area in Myanmar, which could be a missed opportunity

CONTEXT OF MYANMAR'S APPLICATION TO THE GDF

Source of information on the GDF

- NTP Director heard about GDF in 2001 at the Kathmandu Conference of the WHO (SEARO) region on TB
- Applied and approved in June 2001 (1st round)

Drug situation and rationale for application

- NTP launched DOTS in 1997 but could not make much progress on expansion and case detection given serious resource gaps resulting in drug shortages
- As a result, only Category I and II patients were treated (priority for infectious case) and only 10% of Category III patients were treated
- Source of drugs: 10% purchased by MoH and rest through donations from WHO, UNDP-HDI, some NGOs like Sasakawa Foundation, MSF
- Given continued resource gap and shortage of drugs to expand DOTS and case detection, NTP applied to GDF in 2001

ASSESSMENT OF GDF'S IMPACT ON MYANMAR'S TB CONTROL PROGRAM TO DATE - SUCCESSES

On DOTS expansion and TB control/ treatment

- Begun large-scale social mobilization (mass media, World TB Day, poster campaigns on "free drugs"), working with agencies like PSI and GF funds. *"Before securing drugs, we would not dare touch social mobilization"; "GDF is like a bullet. Earlier, there was no point firing the gun without it"; "free drugs have facilitated drug access for the poor"*
- Free drugs from GDF is helping the PPM program – NTP gives free drugs and training to GPs in return for treatment under DOTS and case notification. Also helps prevent MDR-TB due to standardized treatment and quality drugs vs. private market fakes. Treatment in the private sector currently costs ~$100 for drugs + $100 for consulting
- Improved case detection from 56% in 2001 to 70%(projected) in 2003.

On political/partner commitment and alignment

- GOM has increased budget for TB drugs 4X in last 2 years (though partly due to steep depreciation in the kyat)
- WHO has also increased TB budget from $300K in 2000-02 to $400K in 2002-04. Also, earlier 80% of budget was used for drugs vs. only 20% now with the GDF grant, thus releasing ~$100,000 for training, lab facilities, etc.
- Some NGOs are expanding activities as drug shortage is not an issue now (see explanation under learnings from Myanmar)

GDF's impact to date

On TB drug management

- Significantly lower prices – *"GDF drugs that cost $.25M would have cost $.50M had WHO sourced them"*

Per treatment price (in $)	WHO	GDF	MOH (local)
Cat I	13	5.09	
Cat II	31	11.9	
Cat III	11	4.17	

- No major change in quality; comparable with WHO
- GDF grant has also convinced the MoH to move from intermittent loose drug regimen to daily FDC in the 2nd year application

On related TB capacity building

- MoH/NTP compulsorily undertook a review of the national distribution system for the GDF grant, conducted with WHO, GDF and technical partners. Detailed feedback and explanation of concepts (e.g., FIFO), was provided. However, few recommendations implemented due to funds shortage

ASSESSMENT OF GDF'S IMPACT ON MYANMAR'S TB CONTROL PROGRAM TO DATE – DRAWBACKS/ IMPROVEMENT AREAS

On DOTS expansion and TB control/ treatment

- Given GDF funds 80% of TB drugs, there are serious concerns within NTP, the MoH and WHO on the future and credibility of the program post-GDF. NTP and GDF have also not had any discussions on this. Hence, should help NTP plan for financial sustainability

On political and partner commitment and alignment

- While GDF has a good relationship with the NTP and WHO, it has not reached out to NGOs involved in TB in Myanmar – *"We thought drugs came from GTZ, not GDF!! We have not met with any GDF delegates so far"; "We did not know NTP was thinking of moving to daily FDC".* This could be a lost opportunity in streamlining drug procurement across agencies

GDF's improvement area

On TB procurement and drug management

- Much confusion on transition to 4DC. Would need more support from GDF in planning transition from loose drugs to 4FDC, including training and logistics management support
- Little thought has been given to how to strengthen the health infrastructure with increased workload (moving from intermittent to daily regimen, with doubling of case load = 400% increase in workload of health-workers)

On related TB capacity building

OBSERVATIONS FROM MYANMAR TB PROGRAM – IMPLICATIONS TO GDF GOING FORWARD (1/3)

Expanded scope – HIV/AIDS, malaria and MDR-TB

- **Malaria:** Keen to use GDF due to expectation of free drugs (critical given overall resource gaps). However, even if funds received from GF, will use GDF because of:
  - Lower prices with bulk procurement
  - Assured quality
  - Single supply source, hence easier to manage vs. 3-4 different sources and releases manpower/system costs
- **MDR-TB:** Not keen to source drugs yet
  - 1-2% annual incidence (500-1000 cases). Hence, not high priority given other areas
  - Risk of drug misuse, as only 2 centers available for testing for MDR today and DOTS Plus is not used. Would defer treatment till proper controls are established
  - Also testing some traditional Burmese medicines in this area
- **HIV/AIDS:** Negligible ARV in country. Would be interested, but after some pre-work:
  - Negligible infrastructure for diagnosis/treatment – only 2 institutions that can do CD4/8 counts + do not have healthcare infrastructure to provide lifelong treatment
  - Still pushing NAP to develop treatment guidelines and M&E mechanism
  - Might want to pilot in some areas with more basic drugs (vs. advanced ARV with many side-effects) first
- **Example: Feedback from NGO on procurement of anti-malarials**
  - Sources combination anti-malarials for its program in Myanmar today. Trying to introduce pre-packaging in 4 different blister pack sizes for different weights, with user-friendly instructions/leaflets.
  - Unable to do so given its volumes are sub-scale, quality issues with local suppliers and high costs with imported packs
  - Hence, would *"benefit enormously from global bulk procurement that does such sourcing and innovation"; "GDF's role in lateral thinking and facilitating social marketing would be great"*

OBSERVATIONS FROM MYANMAR TB PROGRAM – IMPLICATIONS TO GDF GOING FORWARD (2/3)

Feedback on GDF as "one stop shop for TB"

- *"One-stop shop for TB would be an excellent idea"* – Rationale:
  - Quality assurance and standardization. E.g., currently, each NGO operating in Myanmar must source its own microscopes. As a result, there are many makes in the system, requiring different parts, different training, which makes transfer of lab technicians difficult and increases need for retraining
  - Releases manpower and funds
  - Sputum cups are currently procured through WHO, but orders are placed only once a year. Shortages often occur during the year

Financial sustainability of Myanmar's NTP

- GDF is apparently one of the most important supporters for the NTP in recent years and hence, *"the GDF grant was a huge development"*
- Given the current political situation and the fund-starved situation, there is a much concern that an exit by GDF in 2-3 years could significantly disrupt the NTP and undermine its credibility. More so, if the NTP and partners have invested resources in social mobilization and improved case detection/# patients
- GDF must therefore undertake discussions with the NTP on financial sustainability and help plan for continuation/phase-off

Role of WHO at country level

- WHO is an important partner for Myanmar's NTP, at a country level
  - Provides $150-200,000/year, initially for purchase of drugs, now training, lab facilities and other technical assistance
  - Important partner in helping NTP develop applications for grants like GDF, GF
  - Key technical partner on the ground, e.g. gaining agreement on moving from loose drugs to FDC and supporting transition process through guidelines, training, etc.

OBSERVATIONS FROM MYANMAR TB PROGRAM – IMPLICATIONS TO GDF GOING FORWARD (3/3)

Advantages of grant-in-kind

- A cash grant may not have had the same impact as a drug grant, given delays in the grant moving through the system and drugs being procured for NTP – *"Even if GDF had given them money, it would have been a headache and impact would not have happened so fast. Drugs in kind is great"*
- Further, WHO would also consider using its drug budget for Myanmar to procure via the GDF given significantly lower (50%) prices.

GDF support ("value added services") beyond drug supply

- **Transition to 4FDC:** The evaluation team noted quite a bit of confusion on how to move from current treatment regimens to FDC along with intermittent to daily; what is sequence, training needed, where/how to pilot and roll out, how to phase out old drug stocks, etc. As a result, NTP has also delayed its 2nd year application to GDF. Hence, NTP would like support in helping Myanmar transition to 4FDC *("GDF should be more hands on on this")*. E.g.,
  - Training on logistics supply management to key people to plan for transition
  - Help NTP in formulating guidelines
  - Training on lab processes to test the drugs to providing equipment for the National Reference Laboratory. (on this aspect, was unclear exactly what role GDF could play in this and what is the value of the GDF beyond the funding role)
  - Sharing of best practices by other countries moving from loose drugs to FDC
- **In-country drug management:** Need logistics management training for moving drugs to local level, issues being poor understanding of ordering processes, logistics planning, M&E, etc. Support would be in areas like managing drug stocks with patient flow, calculating orders, record keeping, etc.

MYANMAR'S EXPERIENCE IN INTERACTING WITH THE GDF – FEEBACK ON PROCESS

Feedback on process

Fund raising /grant making

- Level of grant was adequate, covering 80% of Mynamar's needs
- Only concern on future sustainability

Application/ review

- Satisfied with the ease and clarity of the application (*"Pleasant surprise on how convenient the process was!")*
- However, lead time of 2 weeks found too short to prepare and send the application was very tight and required intense discussions and clearances within the MoH

Procurement

- Quality found comparable to drugs from WHO. Drug registration procedures have also been waived
- No major concerns on procurement, However, 2 minor issues:
  - Central Stores has some coordination issues with GDF. Both consignments were shipped prior to sending documentation to Myanmar for import clearances. As a result, unnecessary problems and drugs lie uncleared in port for some days
  - Documents with the 1st consignment were incomplete w.r.t. country of origin, value, quantity, etc. resulting in delay in customs clearance. 2nd consignment had fewer gaps
- Some delays in receipt of drugs. Consignment expected in Sept'01 and Feb'02 were received in Dec'01 and Mar/Apr'02 respectively

Coordination of Stop TB partners

- M&E and capacity building has not been observed yet
- GDF was able to free funds of the GLRA to redirect funds to operational activities, expanding TB control support to 3 more regions

OTHER LEARNINGS FROM MYANMAR'S TB PROGRAM (1/2)

Involvement of NGOs – Myanmar Maternal & Child Welfare Association (MMCWA)

- Started in 1991, MMCWA is a nationwide volunteer-based organization with 2.5 million volunteers, who work at the grassroots level to complement the government's health-worker infrastructure
- MMCWA volunteers work in multiple areas, including TB, leprosy, malaria, nutrition, birth spacing, HIV/AIDS, adolescent health, care of elderly and maternal/child care
- Volunteers are largely women, 18 years+ recruited through personal networks, paying a small 200 kyat ($0.25) membership fee for life. All wear a identifiable yellow uniform (hence called a "Yellow Brigade") and offer their services on a pro bono basis
- MMCWA workers closely administer the DOTS program at the local level by visiting patients, observing them taking drugs, reporting back to the clinics, following up/counseling in case of drop-outs, etc.
- The system seems to work due to strong pride of association with a national institution ("Yellow Brigade", strong positive press) and community encouragement and pressure to join/stay
- Funding for MMCWA comes from national and international donors (e.g., JOICEF, UNICEF, UNDP)

OTHER LEARNINGS FROM MYANMAR'S TB PROGRAM (2/2)

NTP leveraging GDF grant to encourage entry of new NGOs

- **Example 1: New NGO covering a district in Myanmar**
  - Earlier MoH policy for NGOs wanting to "adopt a district" – need to bring in entire package of drugs, technical assistance, training, lab supplies etc. With GDF grant now, does not need drugs as part of the package
  - NGO's budget was ~ $70,000 p.a., which could have been significantly higher if drugs had to be sourced. Further, it could not have convinced donors to finance TB drugs. *"If we had to spend $300K vs. $75K, we would have to find another donor, which would have been very difficult "*
  - Would also not like to invest time in drug procurement – *"Do not believe a technical NGO's time should be spent replicating existing infrastructure"*

- **Example 2: NGO taking up social marketing campaign with MoH/NTP**
  - NGO working with NTP to "brand" DOTS and FDC and increase social awareness + de-stigmatization
  - Campaign possible largely because of GDF drug grant – *"To start such a program, we can now assume 2 things - no drug shortage and something like DOTS or 4FDC that you can build a brand around"*

CONTENTS

Work – in - progress

CONTEXT AND DESCRIPTION OF VISIT TO INDIA

Context of country visit

- **Highlights of the country's TB situation**
  - HBC, 1st worldwide; TB is key GOI health priority
  - Strong TB Control program (RNTCP), expanding rapidly to cover 100% of population by 2004
  - High treatment success (>80%), but moderate case detection (~57%)
  - Strong domestic pharmaceutical base with low cost and quality suppliers
  - Presence of several donors, including $142 million loan from WB from 1997-2004

- **Relationship of the country to the GDF**
  - Made 3(?) applications to GDF, before being approved in 2002; several issues during the negotiation process
  - Drugs yet to arrive in country, expected in April 2002

- **In-going rationale for selecting country for visit**
  - HBC with unique grant conditions
  - Importance case to understand GDF proposition to countries with strong NTP, domestic supplier base, drug procurement system and donor presence

Interviews and visits conducted

- **Pre-visit interviews**
  - Ian Smith (GDF)

- **Country visit interviews**
  - Dr. V. Salhotra (RNTCP)
  - Dr. Jai Narain (WHO SEARO, HIV/TB)
  - Dr. Reuben Granich, Dr. Fraser Wares (WHO SEARO, STB)
  - Dr. Ying-Ru Lo (WHO SEARO, MO - HIV/AIDS)
  - Dr. M. K. Banerjee (WHO SEARO, Malaria Program)
  - Dr. K. Ravi Kumar (WHO, National Professional Officer, Malaria) and Dr. Rajpal S. Yadav (WHO-Malaria; Malaria Research Center)
  - Mr. Dinesh Nair (DFID)
  - Mr. Tulsi Kanti-Ray (DANIDA)
  - Dr. Peter Heywood, Dr, Sunita Singh (World Bank)
  - Ms. Ritu Khushu (Strategic Alliances, RNTCP Partner for in-country drug management)
  - Dr. Rajiv Chauhan (WHO TB Consultant, Maharashtra State)
  - Dr. Ambe (TB Control Society)

SUMMARY OF FINDINGS FOR INDIA – GDF IMPACT

Success

- GDF's grant facilitated more rapid DOTS expansion than planned. It **addressed funds shortage** to cover drugs for an 200 million additional population (estimated 200,000 TB patients), who were not covered by WB, NTP or other donor funding
- "Once the GDF system is up and running", NTP also expects to use the GDF facility for **emergency grants** to meet temporary shortages if India's procurement system has any problems
- GDF is also potentially *"**encouraging dialogue between in-country partners** and is being used as an 'advocacy statement' to rope in new donors"*

Concerns

- **Going forward, GDF value proposition in India is not clear**
  - Renegotiation of WB loan and other funding sources expected to more than meet India's TB funding needs. GDF not seen to have the funding strength to meet India's needs *("GDF needs $10-12 million to make a meaningful impact in India, else only plugging a small gap")*
  - Meeting primarily emergency needs may not have significant impact on the NTP
  - No perceived impact by GDF on any other dimension, e.g., prices, quality, drug management system, innovation/standardization
- **Inadequate and inexperienced HR/capacity** in GDF strains communication with and increases burden on in-country partners
- GDF must **learn to be more flexible** in meeting the needs of countries with very varied needs, while trying to ensure standardization
- Some start-up issues for the GDF which caused confusion in countries [specific example of transition from loose drugs to FDC for DPR Korea (SEARO country)]

RATIONALE OF INDIA'S APPLICATION TO THE GDF

TB and drug situation

- Rapid DOTS expansion since 2001 under the RNTCP
- Strong program management today, with strong drug management set-up, low prices (~ $7-8/treatment), good quality
- Committed WB loan of $142M covering ~700M population, grants from DFID and DANIDA to cover an additional 100M, leaving a gap of 200M to be covered
- Procedural issues in ICB (using WB loan), which resulted in delays (>9 months) causing drug stock-outs 2-3 times. WB disbursement was also suspended once as a result. Partners provided emergency supplies on these occasions to bail out the RNTCP

Rationale for application and experience

- India applied to GDF in the 1st round in 2001; put "under consideration" as application was primarily for buffer stock, which GDF was not geared to provide (not seen as meeting the "additionality" principle)
- India's 2nd application was also not immediately approved because:
  - Drug issues: Indian program does not use FDC, has different dosages from WHO EDL and needs packaging in individual patient boxes, which GDF was not geared to do
  - GDF's supplier, MEG/Swizera was not allowed to supply for India under Indian regulations
- Issues subsequently resolved in 2002. GDF will supply India with drugs as per RNTCP specifications using their Indian supplier. However, procedural issues still exist and drugs are yet to arrive in India (expected in April 2003)

ASSESSMENT OF GDF'S IMPACT ON INDIA'S TB CONTROL PROGRAM TO DATE - SUCCESSES

TOO EARLY TO SAY – DRUGS NOT ARRIVED YET

On DOTS expansion and TB control/ treatment

- GDF grant will serve 200,000 more patients not covered under grants from other donors, and accelerate DOTS expansion. India will meet 100% coverage by 2003-4 versus later

On political/partner commitment and alignment

- No significant change in commitment
- However, funds like GDF and GFATM have encouraged more dialogue and joint planning between on-country donors versus earlier

GDF's impact to date

On TB drug management

- Could help reduce lead times versus ICB using WB funds, once system is set up, though this has not been demonstrated to date. GDF could therefore help meet emergency supplies
- No significant impact on drug prices (GOI prices may be lower than GDF), quality, standardization and innovations (which were already ahead of GDF practices at that time)

On related TB capacity building

- No support from GDF and none expected. No change in partner support in any TA areas either

ASSESSMENT OF GDF'S IMPACT ON INDIA'S TB CONTROL PROGRAM TO DATE – DRAWBACKS/ IMPROVEMENT AREAS

On DOTS expansion and TB control/ treatment

- XX

On political and partner commitment and alignment

- XX

GDF's improve-ment area

On TB procurement and drug management

- Suggestions for GDF:
  - GDF must learn to be more flexible in dealing with countries like India- *"Cannot use the one size fits all approach"*
  - More proactively seek to learn and disseminate best practices, e.g., patient boxes
  - Encourage local suppliers in each country to undergo pre-qualification under GMP to help strengthen the local supplier base, where relevant

On related TB capacity building

- Besides drug procurement, GDF could:
  - Provide support in transition planning from loose drugs to FDC, e.g., share best practices, rope in partners to revise guidelines, train staff, etc. (see DPR Korea example)
  - Develop training package on logistics management

INDIA'S EXPERIENCE IN INTERACTING WITH THE GDF

BACK UP

● High / Exceeds expectations
◑ Average / Meets expectations
○ Low / Below expectations

	Dimension	Assessment	Comments
Fund raising /grant making	• Grant making process	●	
Application review			clarity of
			of the
			rements
			human
Procurement			for the
			need to
	• Procurement	◑	Needs to improve on speed and communication of the web tracking system
Coordination of Stop TB partners	• M&E	○	• M&E and capacity building has not been observed yet
	• Political commitment and coordination between stakeholders	◕	• GDF was able to free funds of the GLRA to redirect funds to operational activities, expanding TB control support to 3 more regions

Work-in-progress

OBSERVATIONS FROM INDIA'S TB PROGRAM – IMPLICATIONS TO GDF GOING FORWARD

Need to strengthen GDF HR capacity to serve countries

- India (NTP and partners) have experienced many communication issues with GDF primarily due to a short-staffed situation, e.g., long delays in responding to queries, no single interface point, partners not clear on expected role
- *"The GDF team is very competent and works very hard. However, they are spread very thin and not able to focus adequately on the country and procurement process.*

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mandated to support the GDF. Further, communication between GDF and WHO is not clear on wh

Work-in-progress

RELEVANT LEARNINGS FROM INDIA'S TB PROGRAM (1/2)

Designing/executing a successful NTP (including transition from regimens)

- tbd

Work-in-progress

RELEVANT LEARNINGS FROM INDIA'S TB PROGRAM (2/2)

Drug procurement and management system

- tbd

Work-in-progress

CONTENTS

CONTEXT AND DESCRIPTION OF VISIT TO MOLDOVA

Context of country visit

- **Highlights of the country's TB situation**
  - A medium high burden country
    - Population of only 4 million
    - With TB incidence at 63/100,000
  - DOTS coverage rate is ~70% with plans for 100% by 2005
  - Has been approved for Global Fund grant for TB and HIV

- **Relationship of the country to the GDF**
  - 1st round recipient (2001) of grant
  - Monitoring visit took place in August 2002
  - To receive drugs till 2004

- **In-going rationale for selecting country for country visit**
  - One of the first countries to receive GDF drugs
  - Known as a success case for GDF being developed into a movie

Interviews and visits conducted

- **Pre-visit interviews**
  - Eva Nathanson (WHO/EURO)
  - Andrey Zagorskiy (MSH)

- **Country visit interviews**
  - Dr. G. Timbalari, NTP Director
  - Dr. V. Burinschi, Manager NTP
  - Dr. P. Ursu, WHO LO
  - Prof. B. Parii, Director National Institute of Pharmacy (Dr. Safta and 2 other)
  - Ms. L. Buracovschi, MOH Chief of Pharmaceutical Department
  - Dr. V. Soltan, Coordinator of Health Public Program of Soros Foundation
  - Dr. D. Laticevschi, "Caritas Luxembourg", TB project in prisons
  - Mr. V. Filatov, USAID Coordinator of programs

- **In-country local visits conducted**
  - Chisinau city TB Hospital (DOTS area)
  - Lapusna judet facilities (DOTS area)
  - Chisinau municipal TB Hospital (DOTS area)
  - "Basa-Farm" pharm office and warehouse

SUMMARY OF FINDINGS FOR MOLDOVA – GDF IMPACT

Key areas of success

- Key driver for rapidly expanding DOTS in the country
  - Catalyzed government commitment to adopt and implement DOTS strategy as policy
  - Subsequently ensured acceleration of plan from 5 years to 1 year, by limiting use of GDF drugs to DOTS areas
  - Ensured government budget was allocated for TB
  - Provided drugs without which DOTS could not have been implemented
- Catalyst for attracting additional funds for DOTS expansion
  - GDF led the way with willingness to take risk through early commitment
  - Once successful, other donors stepped in (e.g. Global Fund, USAID)
  - GDF reports and presentation at IUATLD conference provided relevant information/transparency and increased Moldova's visibility
- GDF has built excellent relationship with NTP program and government
  - Seen as real partner, with willingness to adapt to needs and a high level of professionalism (following through on commitments made)

Key areas of concern

- GDF "brand name" is limited to providing grants in form of high quality drugs ("the Santa Claus of drugs")
  - Nobody interviewed associates GDF with monitoring and capacity building, not even when explicitly probed
- Direct procurement function of GDF not widely known
  - MoH has heard of it, but did not seem very knowledgeable on specifics
  - MSH does not seem to promote GDF procurement in drug management/procurement courses
  - MoE procures drugs, not sure whether they have been approached at all
- GDF not linked well to other organizations working on TB in Moldova
  - No representation at CCM other than WHO
  - 2 major donors did not know much at all about GDF, MSH is much better known, but not seen as linked to GDF

SUMMARY OF FINDINGS FOR MOLDOVA – COUNTRY EXPERIENCE

Fund raising /grant making

- GDF's approval and subsequent reports on Moldova seen as a critical catalyst for other donors to step in
  - Other donors came in after only after country adopted DOTS (with GDF being key driver) (e.g. GFATM, SIDA, USAID etc.)
  - GDF report on Moldova at IUALTD conference, Moldova film, country reports raised visibility

Application review

- Initial GDF awareness building with NTP manager was done through WHO country liaison officer, WHO regional office reached out to MoH (no internet at NTB Institute at the time)
- In-country and donor advocacy for GDF largely reliant on the NTP manager. However, GDF/MSH Moldova reports and film seen as very helpful tools
- GDF has ensured measures for government support; e.g. May 2001 joint meeting of GDF with Ministry of Finance to ensure continued government commitment to TB financing
- GDF's standard form experienced as user-friendly, except detailed budget estimate
- Team was very flexible in extending deadline, and WHO extremely helpful in preparing and translating the proposal

Procurement

- Government feels comfortable with quality of GDF drugs established through quality control tests, GMP documents and registration of drugs in 40 countries
- Direct procurement would require formal registration of drugs in order to participate in tender. Would also require additional funding (GFATM did not finance first line drugs)
- Long time to get the drugs into the country (5 months)

Coordination of Stop TB partners

- Monitoring currently executed through units within National TB institute supervised by NTP manager
- MSH has offered training and technical support in drug management, but not seen as a partner of GDF
- GDF not seen as having any significant role in monitoring and evaluation. Monitoring mission perceived as being a one-time, purely GDF related event, with little feedback to NTP manager
- GDF is not viewed as a catalyst for capacity development

ASSESSMENT OF GDF'S IMPACT ON THE COUNTRY'S TB CONTROL PROGRAM TO DATE - SUCCESSES

BACK UP

On DOTS expansion and TB control/ treatment

- GDF drugs have been critical incentive for accelerating DOTS expansion in Moldova
  - GDF drugs only allowed to be used in judets using DOTS
  - As a result, country's DOTS expansion to all judets will be achieved in 2 instead of 5 years
- MDR-TB is increasingly a problem, and NTP manager hopes GDF can work with GLC to procure MDR-TB drugs

On political and partner commitment and alignment

- GDF has been key catalyst for implementation DOTS strategy and building sustained government commitment
  - TB budget item in MOH (rising ever since GDF came in) for funding of training, salaries and drugs required in addition to GDF grant
- "MoH today has two priorities, TB and HIV/AIDS" (NTP manager)
  - MoH about to hire Aids/TB manager

GDF's impace to date

On TB drug supply/management

- Goal of access to high quality of the drugs achieved - clinics and GPs now have required TB drugs in stock
- Delivery time faster and more dependable than local benchmark.
  - Local procurement can take 6+ months, due to delays in payment by government and currency issues, GDF took about 5 months
- FDCs are welcome due to ease of administering

On related TB capacity building

- GDF has been a catalyst in getting other donors and organizations to focus on the aspects of TB that it doesn't cover, e.g. MSH on drug management and USAID launching a major effort in surveillance, lab upgrade and management training

ASSESSMENT OF GDF'S IMPACT ON THE COUNTRY'S TB CONTROL PROGRAM TO DATE – DRAWBACKS/ IMPROVEMENT AREAS

BACK UP

On DOTS expansion and TB control/ treatment

- Currently, STB still relies strongly on WHO liaison office for DOTS expansion and liaising with local authorities. But for WHO office, TB is just one priority among many, understaffed to really focus
- Influencing DOTS expansion beyond drug supply will require more active networking with other players on the ground through STB partnership (e.g. USAID, will give a $ 4 Million grant for lab/monitoring, but not familiar with GDF)

On political and partner commitment and alignment

- GDF not directly involved with new CCM, which is expected to play the strategy setting role for TB (only through WHO). Needs to find a way to build presence through its partners (WHO, USAID, World Bank)

GDF's improvement area

On TB procurement and drug management

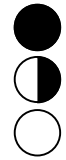
- Govt and other TB related players (e.g. USAID, Caritas) are not sufficiently infored about GDF direct procurement opportunities. GDF should leverage WHO, MSH and NTP manager more actively in spreading the word and should create collateral
- Initial delivery of drugs took 5 months, should aim to shorten time
- MSH provides drug management training, however, nobody associates MSH with GDF – need to work on better integration/ joint message

On related TB capacity building

- GDF not seen as an entity involved in either monitoring or capacity building, and it is not associated with its partners who perform these functions. GDF's brand name is limited to providing cheap drugs ("Santa Claus of drugs")

MOLDOVA'S EXPERIENCE IN INTERACTING WITH THE GDF

BACK UP



High / Exceeds expectations
Average / Meets expectations
Low / Below expectations

	Dimension	Assessment	Comments
Fund raising /grant making	• Grant making process	●	
Application review	• Advocacy and awareness building	◕	• Accessibility is high and easy to understandable/clear materials • Need someone on the ground in order to give effective feedback
	• Application, review and approval	◕	
	• Feedback from TRC	◑	
	• Approval process	◕	
Procurement	• Drug selection	◕	• Communication of rationale for the selection of drugs provided need to be more active • Needs to improve on speed and communication of the web tracking system
	• Drug order/delivery	◑	
	• Procurement	◕	
Coordination of Stop TB partners	• M&E indicators	◑	
	• M&E visit	◕	
	• M&E feedback	◕	
	• DOTS expansion	●	• GDF has successfully brought the government's attention to expanding DOTS
	• Political commitment	◕	
	• Health infrastructure (physical and personnel)	◔	• GDF is not viewed as a capacity builder

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CONTEXT AND DESCRIPTION OF VISIT TO KENYA

Context of country visit

- **Highlights of the country's TB situation**
  - # 11 on high burden country list
  - DOTS population coverage: 100%
  - Estimated case detection: 47%
  - Treatment success rate: 80%
  - Estimated adult TB cases HIV+: 49%
  - Approved for GF grant for TB program
- **Relationship of the country to the GDF**
  - Recipient of GDF drugs; first shipment in Feb 2002, with monitoring visit in September 2002
  - Approved for the second year, with a "orange light" indicating TRC's concerns on government commitment
- **In-going rationale for selecting Kenya for country visit**
  - Recipient of GDF drugs (2nd year); hence, long track record with GDF
  - High TB burden country, with high HIV/AIDS co-infection
  - Test willingness to use GDF for direct procurement using grants from the GF/other donors

Interviews and visits conducted

- **Pre-visit interviews**
  - Robert Matiru, GDF
  - Renee Herminez, KNCV
- **Country visit interviews**
  - Dr. Amos Kutwa, NLTP Manager
  - Dr. John Mansoer, Technical Advisor, TB/Leprosy, CDC
  - Dr. Kanangi, NLTP program
  - Dr. Eriki, WHO Kenya Representative
  - Dr. Richard Muga, Director of Medical Services
  - Prof. Julius Meme, Permanent Secretary, MoH
  - Dr. Bibiana Njue, National Drug Regulatory Authority, MoH
  - Dr. Kosgei, Chief Pharmacist/Registrar, MoH
  - Steve Kinsett, Catherine Lwenya, Jane, JSI-Deliver
  - Dr. Bedan Gachanga, USAID
  - Dr. Chebet, National AIDS Program
  - Dr. Ochola, Head, Division of Malaria Control
  - Dr. Njiru, Chief Finance Officer, MoH
  - Mr. Kiriki, Mr. Keneke and Mr. Buchi, KEMSA
- **In-country local visits conducted**
  - Voluntary Counseling & Testing Center, Madari Slum, Nairobi
  - KEMSA Central Stores, Nairobi

SUMMARY OF FINDINGS FOR KENYA – GDF IMPACT

Assessment of GDF's impact on the Kenya's NLTP to date

- **What has worked - positive impact of GDF drug grant**
  - GDF grant is very well-regarded as timely and critical, given Kenya faced a serious funding gap when KNCV pulled out of the TB program in 2001
  - GDF prices are significantly lower than prices obtained through local and international procurement agents and the grant has helped treat additional patients
  - Further, the GDF grant has helped increase the visibility of the NLTP in the MoH and ensure that the MoH demonstrate political commitment to the TB program and meet GDF conditions
- **What has not worked**
  - There has been little impact on other elements of the DOTS program (e.g., case detection, drug management, infrastructure), on mobilization of partners and donors in TB
  - Further, general awareness of the GDF, its benefits and services is low. It is also unclear whether Kenya would use the GDF for direct procurement using its own funds/other grants
- **Expanded scope:** MoH would like GDF to extend grant of free drugs for other TB products, MDR-TB, HIV/AIDS and malaria as well, primarily due to resource gaps in these areas and not due to perception of synergies. However, given common infrastructure for drug management and VCT clinics to treat TB-HIV patients, there are potential synergies in jointly approaching TB and HIV/AIDS

Key learning from Kenya

- GDF's "orange light" system of conditional grants does work to enforce governments to adhere to their commitments, primarily due to a fear that the grant would otherwise be withdrawn

SUMMARY OF FINDINGS FOR KENYA – COUNTRY EXPERIENCE

	What has worked	What has not	Implications/Kenya feedback to GDF
Application, review and approval	• Easy application process. • No issues on speed, communication, etc.	• Little awareness of GDF model, prices, benefits, partners, direct procurement model, etc. in the NLTP, MoH • Some confusion on names of GF, GDF, GAVI; *"global used too often"*	• GDF must more strongly/proactively advocate its model and benefits to the MoH and other decision-makers in the country, more so if it wants to move to direct procurement business
Fund raising and grant making	• Grant timely given withdrawal of other donor support	• MoH does not fully agree with principle of additionality restricted to TB program given shared healthcare infrastructure across diseases and huge resource gaps on all fronts	• Should GDF revisit how it defines additionality?
Procurement services	• No issues with delivery times, communication, waiver of taxes, expedited drug registration, etc. • Satisfied with quality, especially since drugs are seen to be coming from WHO	• No awareness of GDF prices and potential savings versus other agents (Crowne, GTZ) • Not positioned to exploit direct procurement business, i.e., cannot tender, MoH not keen on single source unless donor-mandated (e.g., 100% of vaccines sourced from UNICEF)	• Need to increase visibility with key decision makers on GDF benefits • GDF should work with donors on direct procurement, versus countries pulling it in - *"Feacham has to advocate and mandate the GDF"*
Monitoring & evaluation	• TRC concerns reflected in "orange light" in round II forced government to meet promises	• Feedback to NLTP and other partners not clear/adequate • Worried about sustainability at end of 3 year GDF grant	• GDF must help countries plan for phase out of the drug grant by helping identify mechanisms to access funding
Capacity development/ technical assistance	• No impact of GDF	• Feel lack of training to transition from current regimens to 4FDC • Overall system is capacity constrained (e.g. labs, healthcare workers), hence, drug supply alone has not improved case detection and DOTS expansion	• GDF must explicitly budget/plan for training to facilitate transition to 4FDC and TB awareness building. Materials could also be included with the drug shipment • GDF needs different business model if its mandate is to impact DOTS and TB control; free drugs alone is inadequate

ASSESSMENT OF GDF'S IMPACT ON KENYA'S TB CONTROL PROGRAM TO DATE - SUCCESSES

BACK UP

On DOTS expansion and TB control/ treatment

- No explicit impact of the GDF on areas like improved case detection, treatment success or investment in TB healthcare infrastructure

On political and partner commitment and alignment

- Improved leverage with governments due to "orange light" post M&E visit for 2nd year grant
  - TB drug line item introduced in budget
  - Government delivered on its commitment to buy more drugs
  - Increased visibility of NLTP with the MoH – *"Having the GDF is great for the NTP manager to get the government to do what it would not do otherwise"*
- Increases communication between and coordination between NGOs/partners (e.g., when GDF missions visit; at time of writing proposal)

GDF's impact to date

On TB drug management

- Free drugs, which covered gap, when KNCV exited the TB program in 2001
- Lower prices – 30-80% lower than prices from local procurement agents and __% lower than IDA prices
- Positive impact on local suppliers – Aventis prices have fallen from $1000to $50 for a treatment; local supplier moving from loose tablets to registering for 3/4FDC with MoH
- Better inventory planning as GDF supply more reliable, keep them informed (as against two-year waiting time to get drugs with a World Bank grant received in 2001)

On related TB capacity building

- Attended the Drug Management Workshop in Washington – found it helpful to exchange experiences with other countries, plan for drug management programs and follow-up reports to MSH (Tom Moore)

ASSESSMENT OF GDF'S IMPACT ON THE KENYA'S TB CONTROL PROGRAM TO DATE – DRAWBACKS/ RECOMMENDATIONS FROM KENYA

BACK UP

On DOTS expansion and TB control/ treatment

- Add advocacy materials to drug shipment – will help awareness building
- Kenya would like scope of additionality to be extended beyond TB drugs or the TB control program to other horizontal aspects of the healthcare system – *"NTP is not operating in a isolated manner – a lot of healthcare infrastructure is shared"*
- Expand GDF's scope to the entire TB package (e.g., lab supplied, M&E systems, vehicles, logistics support, etc.)

On political and partner commitment/ alignment

- GDF needs to more proactive aligning political and partner commitment

GDF's improvement area

On TB drug management

- NLTP manager would like to source 100% of drugs from GDF using a combination of grant and direct procurement – *"As a NLTP manager and not policy-maker, I would like to source 100% from GDF –talk with 1 person, 1 cheque, 1 set of standards, etc. – makes my life easier and I can focus on other area and work with other partners"*
- Standardize packaging: Currently, packaging is not differentiated across drugs. Further, uneven sized boxes makes logistics planning difficult
- Delivery time too long for Round 1 – 7-9 months

On related TB capacity building

- GDF could be more proactive in ensuring deliverables on in-country drug management (e.g. # trucks, training)
- Transition to new treatment standards:
  - Help country to move from current to new standard w.r.t. training, etc.
  - Work with WHO to influence normative, standard setting role (4FDC) and get other donors to be aligned on support to countries
- GDF could help the country plan for the post-GDF phase to continue sustaining the TB program

KENYA'S EXPERIENCE IN INTERACTING WITH THE GDF

BACK UP

High / Exceeds expectations

Average / Meets expectations

Low / Below expectations

	Dimension	Assessment	Comments
Fund raising /grant making	• Grant making process		• The outstanding drug requirement has not been fulfilled
Application review	• Advocacy and awareness building		• Satisfied with the level explanation provided with the pilot and coaching
	• Application, review and approval		• Feasibility of implementation in light of time, human resources and money has not been adequately reflected in the approval
	• Feedback from TRC		
	• Approval process		
Procurement	• Drug selection		
	• Drug order/delivery		
	• Procurement		
Coordination of Stop TB partners	• M&E indicators		
	• M&E visit		
	• M&E feedback		
	• DOTS expansion		• GDF has successfully brought the government's attention to expanding DOTS
	• Political commitment		
	• Health infrastructure (physical and personnel)		• GDF is not viewed as a capacity builder

OTHER OBSERVATIONS FROM KENYA VISIT

BACK UP

GDF does not have brand recognition / identity today

- Some confusion in countries about different agencies and GDF's name/role
- *"Global Fund, Global Drug Facility, Global Alliance…Global word used quite loosely" – MoH official*
- *" I did not know GDF was a WHO agency" – MoH official*

What GDF needs to do to get direct procurement orders

- To gain access to direct procurement business, GDF needs to
  - Proactively approach MoH as early as possible in the country's budgeting cycle
  - Explicitly highlight benefits of procuring through the GDF (e.g., prices, quality) in a *"very transparent manner".* Very little awareness of GDF benefits currently – *"We only know GDF is a good partner, do not know about its prices or other benefits" – MoH official*
  - Get donors like the WB and GF on board to waive international competitive bidding requirement; *" Feacham has to advocate and mandate the GDF, else country will not use the GDF"*
  - Control overheads to norms established by other players (GTZ 2.4%, UNICEF and WHO 5-6%)
- GDF will probably get the same treatment for drug grant and direct procurement, since registration is the same, and all boxes marked "WHO" will have the same treatment at the port

Potential synergies and issues between HIV and TB at country level

- Potential synergies
  - Benefits to patient - can integrate TB and HIV through Voluntary Counseling and Testing Centers (VCT), given high rate of TB and HIV co-infection (50%)
  - Can conduct common technical assistance (e.g., CDC) and training for lab technicians and health workers
- Potential issues
  - *"TB is a service-oriented program with clear measurable outcomes while HIV/AIDS is an advocacy-oriented program with soft targets. Has not started any care or drugs or training yet. Combining the two programs will reduce quality of care and adherence to targets in TB"*
  - Politics of combining HIV and TB even at a country level are potentially not smooth. The two groups have not demonstrated the willingness to work together yet despite multiple attempts at coordinating efforts. Further, fear of being dwarfed by HIV/AIDS – *" If you throw TB into AIDS, you will be enveloped by an enormous amorphous program"*

Planning for phase-out of GDF support

- Kenya would like the GDF to actively help the country to sustain TB drug supply/program after the grant ends, else there remains tension from year to year

CONTENTS

CONTEXT AND DESCRIPTION OF VISIT TO SOMALIA

Context of country visit

- **Highlights of the Somalia's TB situation**
  - One of the highest TB prevalence due to the war and continued sporadic fighting limits access
  - Absence of government role in TB program is supplemented by the WHO with coordination of NGOs
  - Success rate is 88%, largely due to the NGO involvement in the field
  - DOTS coverage is about 80-90%
- **Relationship of the country to the GDF**
  - Received GDF grant since 2001;
- **In-going rationale for selecting country for country visit**
  - Has received GDF grant and drugs; currently applying for year 2
  - Unique situation of TB program running in a government-less environment, through WHO and various NGOs coordinated by SACB

Interviews and visits conducted

- **Pre-visit interviews**
  - Robert Matiru, GDF
  - Emanuele Capobianco, WHO Representative
- **Country visit interviews**
  - Dr. Yakoub, WHO Somalia Consultant for Essential Drugs
  - Mr. Mohammedi, WHO Somalia Head of Logistics
  - Dr. Bashir, WHO Somalia Acting TB Medical Officer
  - Ms. Lubna Alaman, WFP Somalia
  - Dr. Iamanol, SACB Coordinator (Somalia Aid Coordination Body)
  - Dr. Mario Maritano, EU Health Coordinator (donor)
  - Dr.Mutisya, INTERSOS (NGO)
  - Dr. Rusagara, NPA (NGO)
  - Mr. Luc Van Dooren, ECULINE
- **In-country local visits conducted**
  - ECULINE warehouse

SUMMARY OF FINDINGS FOR SOMALIA

Assessment of GDF's impact on the country's TB control program to date

- No perceived impact on TB program in Somalia pot GDF grant: Grant of drugs has not resulted in additionality w.r.t. number of patients treated, though the WHO budget has been reallocated for other technical/normative assistance. This could be due to:
  - Drug supply is not the main bottleneck, system is capacity constrained with security issues - *"If GDF helped eliminate all drug shortfall, this would not have much impact as the other infrastructure is working at the limit of its capacity"*
  - GDF has not been able to mobilize stakeholders working in Somalia – there is no awareness (outside of WHO) of the GDF. This is primarily due to the complete absence of a central government authority in Somalia and potentially GDF's inability to develop relationships with non-government bodies
  - Further, GDF has not been able to mobilize its traditional Stop TB partners to act in Somalia

Country's experience in interacting with the GDF

- No awareness of the GDF among any of the stakeholders – donors, NGOs, SACB, etc. Common comment was *"Heard about the GDF the first time when McKinsey asked for the interview"*
- No specific feedback otherwise

Learning from Somalia

- *Learning for GDF:* GDF must develop a way to more effectively identify key stakeholders in a country outside of MoH/NTP and WHO and build awareness/work with them, e.g., NGOs. Else, impact will be limited/negligible as in the case of Somalia
- *Learning for other countries:* Somalia's system of DOTS implementation through "manyattas" for nomadic populations has been quite successful and can be replicated

ASSESSMENT OF GDF'S IMPACT ON THE SOMALIA'S TB CONTROL PROGRAM TO DATE - SUCCESSES

BACK UP

On DOTS expansion and TB control/treatment

- No feedback

On political and partner commitment and alignment

- No role played by GDF

GDF's impact to date

On TB drug management

- No change in drug management situation. Did not have stock-outs pre- or post-GDF grant; similarly, no change in lead times or quality of the drugs received from WHO or Norway grant to date

On related TB capacity building

- No feedback

ASSESSMENT OF GDF'S IMPACT ON THE COUNTRY'S TB CONTROL PROGRAM TO DATE – DRAWBACKS/ IMPROVEMENT AREAS

BACK UP

On DOTS expansion and TB control/ treatment

- Would like GDF to cover 100% of Somalia's drug needs through a grant, so that the WHO budget can be allocated to other normative/ technical elements of the TB program
- Low case detection due to capacity bottlenecks (# NGOs, # TB clinics) and security situation, not drug shortfall. Hence, GDF grant can have limited impact, unless system capacity is increases

On political and partner commitment/alignment

- No change in number or extent of involvement of other NGOs in Somalia post GDF. In fact, GDF's usual technical partners (IUATLD, KNCV, MSH) are all absent in Somalia
- GF grant for TB was not approved – no feedback from GF on reasons for the same to date

On TB drug management

- Much confusion in the field between different protocols across WHO, Norway and GDF drugs. 100% sourcing from GDF would also help Somalia simplify in-country drug management (e.g., dosage, tablet form/color) - *"When I review the Ethambutol requirements, I get so confused. The nurse on the periphery would be lost" – WHO official";*
- Would like GDF to standardize FDC and drug form/packaging/ color to prevent leakage of drugs into the private sector

On related TB capacity building

- Would like GDF to provide more training support (technical knowledge, materials/manuals) for transition to 4FDC and encourage standardization, given none of the NGOs have this ability

SOMALIA'S EXPERIENCE IN INTERACTING WITH THE GDF

BACK UP

Key areas of concern

Application review

- Even WHO officials had no knowledge of GDF product lines, website, etc., given transition in team. Was completely surprised that GDF had direct procurement, drug prices, etc. Other partners were completely unaware of the GDF- *" Did not know about GDF, thought it was the same as the GF"*
- Recommendation: GDF must improve advocacy, awareness building and brand building among all key stakeholders

Procurement

- Have heard of IAPSO's web-tracking system, but do not use it as it is very frustrating to use the Internet in such countries

Coordination of Stop TB partners

- Only WHO official knew of and interacted with the GDF. With his transfer, there is no contact with GDF
- GDF has not met with any of the other key stakeholders in Somalia or encouraged its partners to invest in Somalia
- Suggestions from country meetings are:
  - GDF must learn to work with SACB and coordinate actions
  - GDF must help stimulate other aspects of the TB program (e.g., lab supplied, capacity in clinics). GDF grants can help release $ for other parts of the TB program
  - GDF can also help enforce tough conditionalities since these would be tied to grant money/drugs

SOMALIA'S EXPERIENCE IN INTERACTING WITH THE GDF

BACK UP

● High / Exceeds expectations
◑ Average / Meets expectations
○ Low / Below expectations

Dimension	Assessment	Comments
Fund raising /grant making		
Application review		
Procurement		
Coordination of Stop TB partners		

WAITING FOR INPUT – WORK IN PROGRESS

OTHER LEARNING/OBSERVATIONS FROM SOMALIA

Treatment of nomadic tribes through "manyattas"

- Guarantor ("damein") signed up for each TB patient. This is usually a close relative of the patient who is a permanent resident in the town
- The guarantor agrees to provide food/shelter for the patient in the town and trace the patient if he defaults. In some cases, the guarantor can be taken to court and pay a fine if the patient defaults
- Since the guarantor is a respected citizen, there is social pressure from the entire community on the patient to complete the treatment and ensure no "loss of honor" for the guarantor
- Outcomes:
  - 90%+ patients in Somalia are covered under this system
  - Very low drop-out rates of <3% since the program was begun

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CONTEXT AND DESCRIPTION OF VISIT TO ROMANIA

Context of country visit

- **Highlights of the country's TB situation**
  - 34% DOTS expansion in 24 pilots with 100% DOTS expansion plan by 2005
  - HIV and MDR-TB are stabilized
  - Approved for GF grant in TB program
- **Relationship of the country to the GDF**
  - No prior relationship
- **In-going rationale for selecting country for country visit**
  - High burden within the Euro region with no relationship with GDF

Interviews and visits conducted

- **Pre-visit interviews**
  - Dr Lucica Ditiu, TB Regional Adviser for Balkans
  - Malgosia Grzimska, WHO Euro focal point
- **Country visit interviews**
  - Dr. Rafila, Managing Director of Ministry of Health and Family
  - Dr. Stoicescu, Manager of National Program for Tuberculosis Control
  - Dr. Husar, NTP Supervisor
  - Dana Condrea, Relief Fund for Romania
  - Dr Angheluta, World Bank Project Director in MOH
  - Dr Predoiu, A&A Director
  - Dr Ursoiu, A&A Pharma Manager
  - Dr Victor Olsavszky, WHO Liaison Officer
- **In-country local visits conducted**
  - Institute of Pneumology "Marius Nasta"
  - A&A Warehouse

The week we arrived, MOH Secretary of State for Clinical, MOH Secretary of State for Public Health, the National Insurance House Director have been changed, therefore did not wish to meet with us for meetings

SITUATION ASSESSMENT OF ROMANIA

Situation
Key reason for Romania not applying to GDF is due to sufficient local supply

Issues discussed	Romania's response
Discussion 1: What is the rationale for selecting local production?	• Government's criteria for selection of drugs was more weighted towards price rather than quality with priority given towards local production, moreover the **local production was the cheapest among the registered drugs** • Moreover, registration of drugs will become more flexible as **Romania will enter the EU community** and eventually market will become truly competitive
Discussion 2: How is the quality of the drugs?	• Local production do not have GMP, however the drugs produced have **achieved ~80% cure rate** in the past • Moreover, concerning the sustainability of the quality, **government regulations requiring GMP** will be in effect starting from January 2004 – 20% of companies will drop out, however these companies represent only 2-3% market share
Discussion 3: How reliable is the drug procurement process?	• 2002 August was the **first attempt** for centralized procurement and an **ISO9001 certified procurement agent, A&A**, had been approved for most of the TB drug procurement • NTP along with other technical partners such as MSH are **working to have the right criteria in place** for the tendering process for procurement agents

- Although there are concerns regarding procurement selection criteria and the country's receptiveness to opening the market up, those issues are slowly being addressed through the government commitment and market environment change
- GDF has no clear role to play in Romania's TB control

OTHER LEARNING/OBSERVATIONS FROM ROMANIA

Drug management

- Double monitoring mechanism for TB situation by the Insititute of Pneumology and the National Insurance House with real time communication between the two organizations
  - If any organization were to find abnomalies in the reports they receive from the district level, they would consult each other immediately

Insurance based funding

- Funds for TB control is more easily mobilized, as government is able to generate a stable source of fund from national insurance fee on payroll
- More responsible spending, as there is an extra party, the National Insurance House, who oversees the national insurance funds, becomes accountable for the use of funds as well as the NTP/MoH

Procurement

- Procurement agent A&A has subsidiaries in each of the regions which increases accessibility for the hospitals and clinics in each of the regions where company provides for A/S at incremental costs
  - A&A has established a hotline with the district hospitals to provide services such as lab equipment repair, etc.

Source: Interviews