A NEW PERSPECTIVE ON TB DRUG PROCUREMENT.

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CONCEPT PAPER: COORDINATING BOARD MEETING 24-25 APRIL 2006

SUBJECT: TECHNICAL ASSISTANCE SERVICE LINE

1. Executive Summary

In recognition of the importance of effective tuberculosis (TB) drug management (DM) for DOTS expansion, the Global Drug Facility (GDF) provides limited technical assistance (TA) to programmes receiving GDF drugs. This assistance, provided primarily during GDF in-country missions and to a lesser extent via training workshops, is intended to assure effective distribution and use of GDF drugs and safeguard the value of donated drugs.

Over the last year, the GDF has received numerous requests from national tuberculosis programmes, Stop TB Partners, the Technical Review Committee, as well as the Stop TB Coordinating Board, to adopt a more robust approach to facilitating TA. Some stakeholders have indicated that limited financial resources undermine partner ability to respond to GDF requests for pro-bono TA. In addition, a 2004 internal review of DM systems in 14 countries receiving GDF drugs revealed that despite GDF efforts to facilitate TA, DM bottlenecks contributed to a significant number of stock-outs of TB drugs at different levels in several countries.

In April 2005, the GDF commissioned a stakeholder analysis to better understand programme needs for TA. The key conclusions for the survey were as follows:

- High demand (78%) for TA among GDF supported countries.
- 22% of GDF programmes reported lack of access to TA.
- Financial and information constraints are often cited as reasons why GDF-supported programmes have unmet TA needs.
- 62% of respondents felt that the GDF does not play a large enough role in facilitating TA.

In response to these findings and partner recommendations, in late 2005, the GDF began developing a conceptual approach that would serve to strengthen existing GDF TA services.

GDF proposes to adopt a more practical and concrete role by offering TA as one of it core programmatic services. As a standard service, TA would be provided in one of two ways: either directly by GDF staff or brokered by the GDF to technical agencies.

Through existing regionally-based GDF staff, known as Regional Support Officers (RSO), who will possess key technical expertise in drug management and/or procurement, the GDF would include the management of TA as part of their terms of reference. RSOs would be responsible for managing requests for TA from country programmes. When appropriate and feasible, RSOs would provide the TA themselves. In other circumstances, TA would be contracted out by the GDF to appropriate technical agencies.

Brokered TA could be provided to GDF-supported countries in the form of grants, where TA is subsidized in part or in full by donors or the GDF. Additionally, countries who are interested and able to purchase the TA services could do so in the form direct procurement.

The TA required will vary widely according to country and situation, in terms of complexity and the amount of resources (finances and time) required. For this reason TA has preliminarily been conceptualized in 3 categories: short term (1week - 6 months), medium term (6-24 months), and long term (>24 months).

2. Introduction

Proposal: GDF seeks to expand its current technical assistance mechanism into a comprehensive TA service line that would be available to National TB Control Programmes (NTP) in the form of grants or direct procurement.

Problem expanded TA service will address: A TA service would work to address the apparent need for TA, as expressed by the numerous recommendations and requests from NTPs and partners to assist in strengthening a range of anti-TB drug management issues including: quantification, procurement, distribution, reporting and administration among others.

Goal of expanded TA service: The direct goal of an expanded TA service line is to strengthen the DM capacity of NTPs and to ensure uninterrupted access to high quality anti-TB medicines. The indirect goal is to increase in cure rates, prevention of potential cases of MDR-TB, and to a decline in TB incidence.

Anticipated outcomes resulting from this intervention: By providing access to TA services through the GDF, NTPs would not be hindered by lack of resources and/or information when seeking to obtain TA for programme activities. The GDF expects such a service to ultimately increase the efficiency and effectiveness of NTPs managing anti-TB drugs.

Population served*:* NTPs would be the direct beneficiary of these activities, while the populations covered by the NTPs would indirectly benefit from its services through more effective programme implementation.

3. Background

As part of existing TA services, the GDF regularly provides DM consultancy to programmes receiving GDF drugs. This consultancy, which involves identifying DM concerns and issuing recommendations, occurs during monitoring missions that are coordinated by the GDF to assess programme performance and adherence to GDF terms and conditions. The missions are led by partner-recruited or privately contracted consultants. During the missions, consultants conduct a rapid assessment, assist in drug calculations and forecasting, and issue recommendations on DM to NTP managers. Following the missions, the GDF refers all identified concerns to the relevant Ministry of

Health, the NTP and technical partners, who may elect, if they are willing and/or able, to engage in further support.

A 2003 external evaluation concluded that this model adequately met programme needs. The evaluation strongly recommended against further GDF involvement in TA.[1] However, since that time, the GDF has received numerous requests from NTPs, Stop TB Partners, the Technical Review Committee, as well as the Stop TB Coordinating Board, to adopt a more robust approach to facilitating TA. Some of these stakeholders have indicated that limited financial resources undermine partner ability to respond to GDF requests for pro-bono TA.[2] In addition, a 2004 internal review of DM systems in 14 countries receiving GDF drugs revealed that despite GDF efforts to facilitate TA, DM bottlenecks contributed to a significant number of stock-outs of TB drugs at different levels in several countries.[3]

At the 12th meeting of the GDF's Technical Review Committee, the following comment was made regarding GDF's approach to the provision of technical assistance.

The GDF "*should have an expanded mandate and funds available to improve drug management capacity in the regions and countries in the short, medium and long term strategies including: coordination and contracting technical assistance in drug management; identification and development of cluster focal points to coordinate, provide and contract technical assistance (where appropriate); provision of training in DM at regional/ country level including field visits with partnering of experts and fellows from DM training programmes; organization of DM conference (GDF).*"

In response to the aforementioned requests and findings, in early 2005, the GDF began developing a conceptual approach that would serve to significantly strengthen existing GDF TA services.

4. Problem

In April 2005, the GDF commissioned a stakeholder analysis to better understand programme needs for TA in DM. The main objectives of the survey were to 1) approximate the current demand for TA in TB DM; 2) evaluate the GDF's effectiveness in linking this demand and supply; and 3) determine the feasibility and benefit of expanding existing GDF TA services. The GDF received 32 responses from National TB Programme (NTP) managers, as well as responses from two suppliers of TA in TB DM, and two regional World Health Organization (WHO) offices.

The survey findings indicate that approximately 22% of programmes receiving GDF drugs have an unmet need for TA in TB DM. While the vast majority of NTP respondents perceive value in GDF TA services provided during monitoring missions (88%), only 33% of those in need of further support feel that the GDF has played a role in facilitating additional TA. This limited role may be attributed to funding and

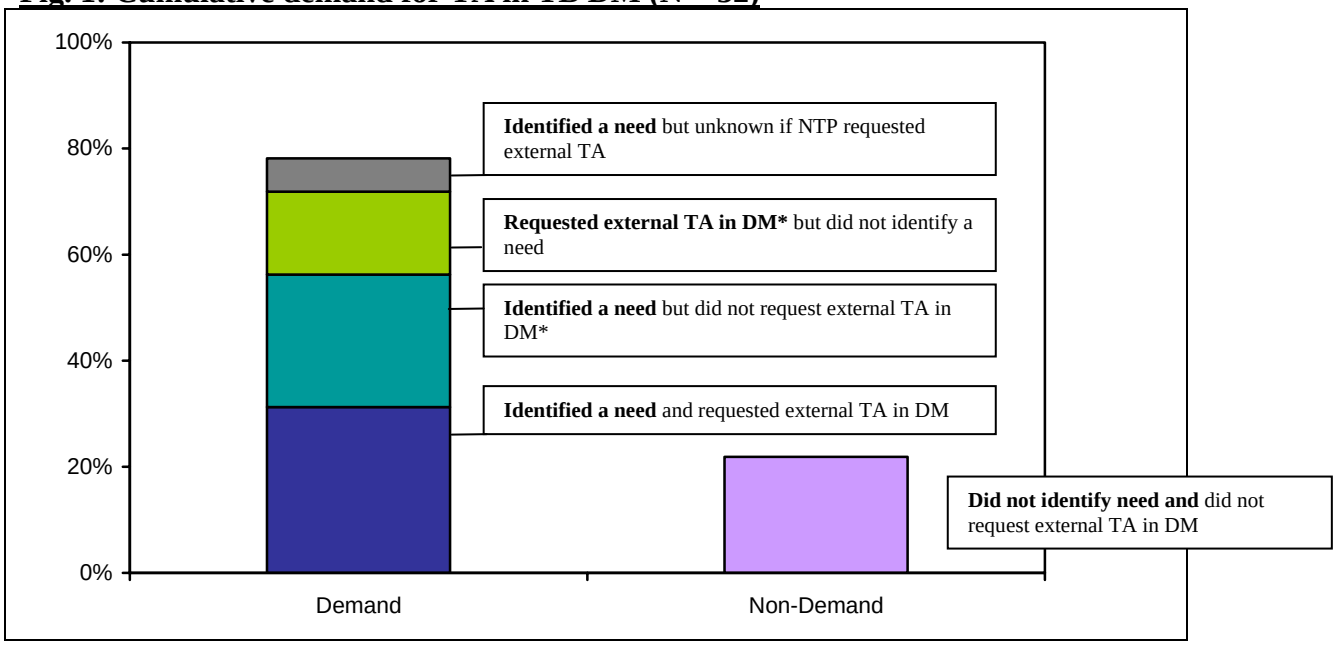
[1] McKinsey Evaluation of the Global TB Drug Facility. Geneva. 2003
[2] Stop TB Coordinating Board 2004; 10th Meeting of the Global Drug Facility Technical Review Committee, 2004; Review of 58 GDF monitoring dossiers showing, on average, 1 request/month in 2004 to provide/facilitate TA.
[3] Internal Review of DM Systems in Countries Approved During 1st Year of GDF Support. Unpublished. Geneva. 2004

information gaps; programmes and partners cited a lack of funds for TA, while some programmes cited difficulty in identifying suppliers. The findings further suggest that these constraints could be addressed if GDF expands its current TA services into a functional mechanism whereby NTPs receive a reliable and effective source of subsidized TA in DM and where by they have access to a reliable database of TA providers.

5. Demand for TA

The survey indicated a high level of demand for TA across regions: 78% of respondents indicated that they had either identified a specific need for TA or had requested external TA in TB DM since beginning a GDF grant (Figure 1).

Fig. 1: Cumulative demand for TA in TB DM (N = 32)



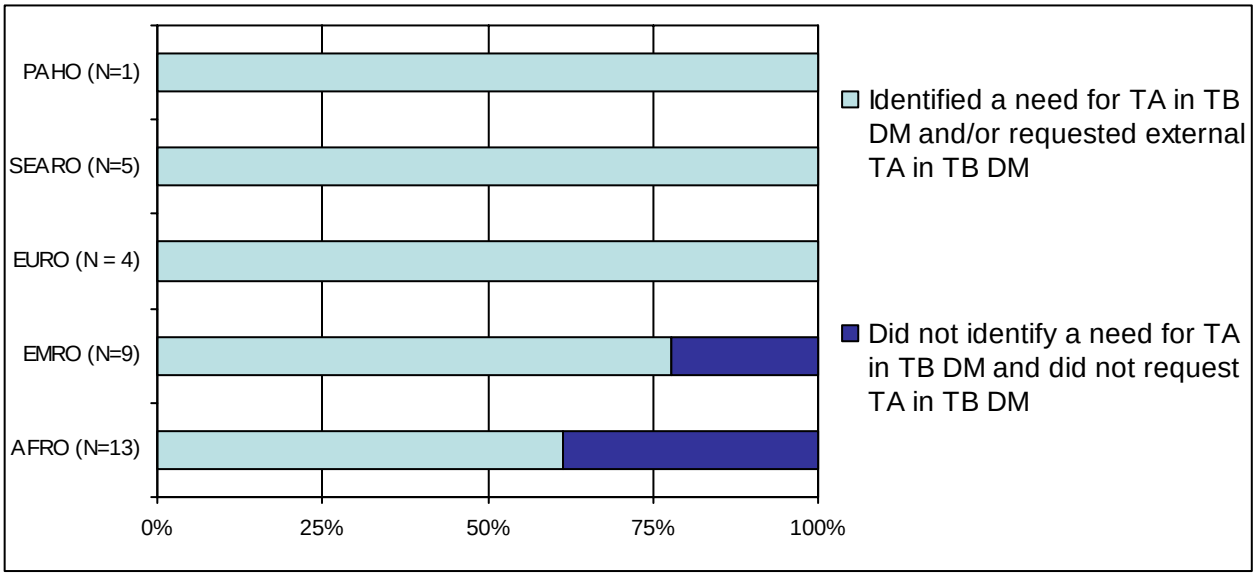
*NOTE: Includes one respondent that regularly receives external TA without issuing requests for the service. *See below for explanations provided by respondents as to why a request for external TA was not made.

Of those respondents that identified a need for external TA (N = 8), a slim majority cited that they were unable to identify a supplier of TA and/or the necessary funds. More specifically, 25% of this population could not identify a supplier of TA, 12.5% could not identify both a supplier and the necessary funds, 25% did not believe the need for TA to be immediate, and 25% found an alternative solution. In one instance, it did not occur to the NTP to request external TA in TB DM.

Of those respondents that requested external TA but did not identify a need (N = 4), it is likely that an agency other than the NTP identified the need that prompted the request or that the respondent interpreted the question differently than the survey intended.

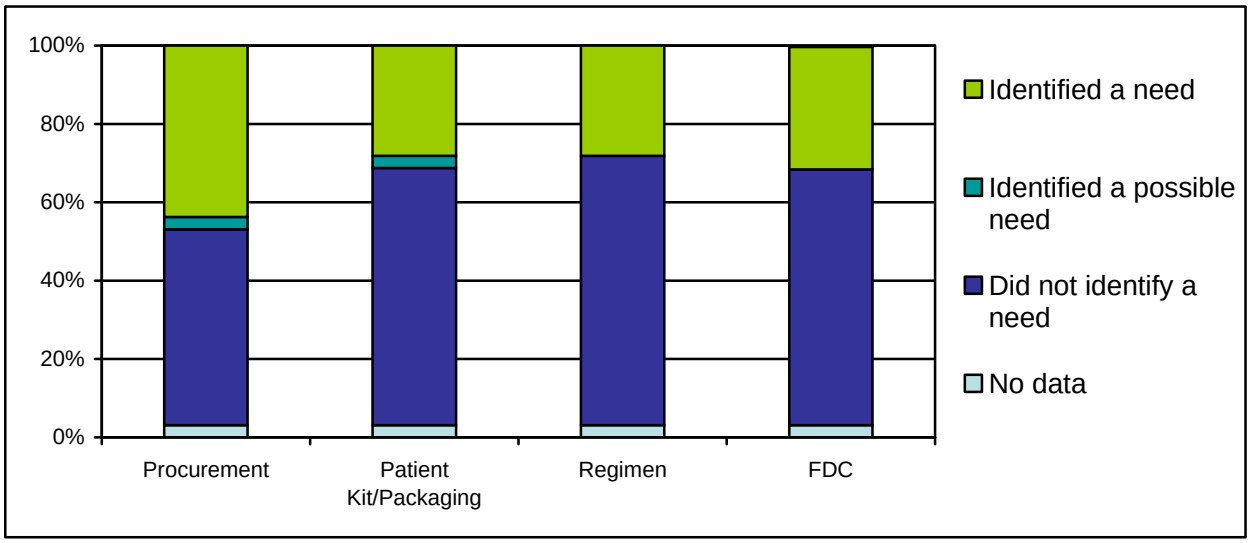
Overall, however, there is a clear trend showing demand for TA in all regions in which the GDF operates (Figure 2).

Fig. 2: Regional demand for TA (N = 32)



Further analysis suggests that the DM areas in need of TA are not uniform across countries; different respondents identified different DM areas to be in need of TA (Figure 3). However, the data suggests that of the four areas of DM with which the GDF is particularly concerned[4] (namely, procurement, transition to 4FDC, regimen change, and packaging including patient kits), procurement is the most common area of concern.

Fig. 3: Demand for TA in specific areas of TB DM (N = 32)



In addition to the findings from the survey, the GDF has received (and indeed continues to receive) many request and recommendations to provide TA to beneficiary countries.

[4] In December 2004 the GDF reached agreement that it had a responsibility to ensure 1) that any GDF recommendation or requirement to change TB regimen, transition to 4FDC and/or adopt new packaging or patient kits, did not cause additional burden to the programme or jeopardize GDF drug and 2) had a GDF grant did not undermine or prevent the development of national procurement capacities.

These recommendations are issued by pre-delivery missions, grant monitoring missions, direct procurement missions, and/or the Technical Review Committee of the GDF. In some circumstances requests are made directly from country programmes or technical partners. Table 1 illustrates some of the TA requests that the GDF has received over the last year. It is by no means an exhaustive list, but provides further insight into the types of requests being directed to the GDF.

Table 1: Recommendations for TA received by the GDF

Recommendation to the GDF for TA	Country	Source
Contribute to the implementation of a reliable system of drug management.	Congo	Monitoring Mission
Support training of NTP central and zonal staff in drug management.	Eritrea	Monitoring Mission
GDF should assist with technical support and regarding drug management through partner in Liberia (i.e. UNDP)	Liberia	Desk Audit
Explore possibilities of provision of technical assistance for improvement of drug management component of NTP through partners, particularly for development of drug management guidelines and training of core NTP staff.	Nepal	Direct Procurement Mission
GDF should Include pharmacists in the training of the supervisors.	Rwanda	Monitoring Mission
Provide technical support for the reactivation and capacity building for the Central Medical Store	Sierra Leone	Monitoring Mission
In collaboration with WHO/SOM, assists with the organization of a workshop on rational use of drugs and stock management for Field store staff.	Somalia	Monitoring Mission
Provide guidance and assistance to NPTCCD for receiving technical assistance on drug management including use of FDC.	Sri Lanka	Pre-Delivery Mission
Coordinate with partners to provide technical support in particular for drug management.	Sudan	Technical Review Committee
In collaboration with WHO arrange for training workshop as soon as possible on Drug & stock management System.	Syrian Arab Republic	Monitoring Mission
The NTP could benefit from exposure to trainings in drug management – particularly stock management.	Turkmenistan	Monitoring Mission
GDF to consider training health staff from each region (especially nurses) and doctors from the Penitentiary System in the use of 4FDC and DOTS regimens to reinforce and augment existing PATH activities.	Ukraine	Pre-Delivery Mission
GDF is also requested to offer materials and possibly TA to realize a smooth role out of 4FDC into the rest of the country.	Zambia	Monitoring Mission
Ensure technical assistance is provided to resolve drug management problems and to support the NTP in the transition to FDC use.	Central African Republic	Monitoring Mission
Assure Technical Assistance should be provided to resolve drug management problems and to support the NTP in the transition to FDCs use	Indonesia	Direct Procurement Mission
"Nous avons encore besoin de l'appui de "GDF" pour améliorer la gestion des médicaments. Disposez vous de logiciel de gestion? Sinon pouvez vous nous conseiller dans le sens de la bonne gestion des médicaments?"	Mali	Direct Communication

6. GDF's Existing TA

Currently, the primary mechanism by which the GDF delivers TA to recipient countries is through in-country missions. During pre-delivery country missions, annual grant monitoring missions and direct procurement missions, two areas of the tuberculosis control efforts are assessed: *general management of the NTP* and *drug management of anti-TB drugs*. Specialists in these fields are recruited by the GDF through partnering organizations or through private contracting to conduct the assessments.

During the missions, the tuberculosis control and drug management experts conduct rapid programme assessments, assist in drug forecasting, and issue recommendations to the NTP. The provision of ad-hoc technical assistance is provided on-the-spot to NTP managers and other appropriate staff. Following these missions, the GDF refers recommendations and identified concerns to relevant technical partners, who may elect, if they are willing and/or able, to engage in further support with the national programme.

7. Proposal to Expand GDF TA Services

GDF proposes a more proactive, comprehensive and robust role in the provision of TA. The expansion of TA into a funded, sustainable core service available to countries would permit the GDF to more effectively respond to the various TA requests it receives. TA would be provided in one of two ways: either directly by regionally-based GDF staff or brokered to appropriate donors and/or technical partners working at the country level.

Regarding direct TA from GDF staff, currently the GDF is in the process of establishing regionally-based staff, known as Regional Support Officers (RSO)[5]. These individuals, who will assist with all the overall GDF activities in the regions, will possess key technical expertise in the area(s) of drug management and/or procurement. Pending the expansion of TA, managing TA requests in their corresponding geographic areas would be incorporated into the RSOs terms of reference. This would include assisting the NTPs directly to address "short-term" TA needs (see explanation on "short-term" assistance below). The direct provision of TA by the RSOs would only be available for countries receiving a GDF grant.

For the latter mechanism, where GDF out-sources TA to external agencies, RSOs will be responsible for managing TA in countries in their region by following-up on requests, liaising with country programmes, and contracting with appropriate technical partners to provide the TA in question.

The GDF will provide TA in the form of grants, as well as, through direct procurement. Due to reasons of feasibility, TA provided directly by RSOs would only be available to grant countries, while contracted TA could be utilized in either grant countries or in countries procuring TA through the GDF depending on the situation.

As a practical illustration, it is envisioned that when a request for TA is submitted the RSO would organize an initial in-country assessment. If the technical assistance issues are a “quick fix” then it may be feasible that the RSO provide the TA themselves, or arrange with an upcoming GDF monitoring mission that these specific issues be addressed. In the case where the TA requirements are more substantial and complex, organizing a full diagnosis of problem would be required to determine the type of consultation needed. Diagnosis refers to defining the precise technical area, duration of intervention, and/or training needs. The RSO would solicit in-country technical programmes and donors to provide the TA.

[5] Further description of the implications on the expansion of GDF staff under section "GDF Technical Assistance Service-Line sub-team"

Depending on the country and on the situation the TA requirements will vary in terms of complexity and the amount of resources (finances and time) necessary. It is proposed that the GDF conceptualize TA in 3 categories:

I. Short term (1 week - 6 months)
II. Medium term (6 - 24 months)
III. Long term (>24 months)

Short-term TA (1 week - 3 months):

Short-term TA refers to those activities that have a limited duration of a few weeks up to 6 months. Such TA does not require prior assessment or data collection and analysis and may be based on a monitoring mission recommendation and/or a request from the NTP. In most circumstances the solution does not require changes in policies or legal regulations.

The main objective of short term TA is to resolve a very specific known drug management issue. It addresses specific aspects within a function of the drug management cycle. Examples of such issues include: drug quantification, introduction of standard operating procedures for reconstitution of Patient Kits, FDCs, storage re-design, streamlining stock management and reporting.

The principal activities that will be untaken during short term TA include targeted training and follow-up, and/or hands-on direct TA where the recipient and providers work together in a practical manner to address the DM issues in question.

The technical resources required in the implementation of short term TA will be drawn from a wide variety of existing tools developed by different Stop TB Partners. Some of these tools may require minor adaptations to according to the local situation. Selection of the appropriate tools and the modifications (if necessary) will be done by the contracted TA provider.

In short term TA the RSO may be capable of providing the necessary assistance. If not, it is the responsibility of the RSO to contract TA locally/regionally; or if possible to utilize an existing donor-funded local source of TA; or request donor country mission support through existing mechanisms

Funding for the activities technical assistance may come from various sources. As a first resort the RSO should work to identify existing TA support mechanisms in country or region that may be in a position to provide their services as part of their mandate of work. Another avenue of funding is the GFATM. If a country is the recipient of a GFATM grant they may be in a position to programme funds for TA. Finally, the GDF should access to some funds to support the TA for a certain number of countries.

Mid-term TA (6-24 months):

Mid-term TA will be necessary in those circumstances where an intervention of 6-24 months in duration is required. An initial targeted assessment of the drug management will be conducted at the request of the NTP and/or monitoring mission recommendations. As with short term TA, it does not require major changes in policies or legal regulations.

Mid-term TA would address broader drug management issues that may impede successful functioning of a TB programme or make the TB programme inefficient. Such issues may include: streamlining distribution from central to peripheral level using existing facilities and resources; establishing a Drug Management Information System (DMIS); or the implementation of existing TB drug management tools (DM guides, assessment and monitoring and evaluation guides and methodologies, inventory management software, tendering procedures, standard contract forms, supplier performance monitoring mechanisms, etc).

Some of the specific activities required could include: a brief survey (indicator based, quantitative, etc.), workshops for stakeholders, focused trainings, hands-on direct TA - e.g. developing documents and SOPs, a follow-up, evaluation of impact.

As with short-term TA, the technical resources required for mid-term TA could include: existing training courses and tools developed by STPs that may require adaptation to local conditions.

The RSO will be the coordinator for ensuring the provision of TA. He/she may contract TA locally/regionally/internationally and will work with donors and donor-funded programmes in the field. Funding for mid-term TA could be funded by donors, with the GDF, when necessary, providing partial financial support. (This will require the RSO to have an extensive knowledge of donors, donor activities and funding cycles).

Long term TA (> 2 years):

Long term technical assistance will be required for countries with critical drug management problem. Countries with failing TB programmes (TB drugs completely misused, threat of drug resistance spread) will need more intensive technical assistance for over 24 months. Determining if such TA is required will be based on strong TRC recommendations, monitoring missions, and/or STP recommendations. A programme with serious programme issues will require a comprehensive pharmaceutical management assessment and often may require changes in national pharmaceutical policies.

The main objective of long term TA is to design and implement a comprehensive drug management system or major elements thereof. It will work to develop local capacity to successfully manage the TB drug supply system (i.e. in circumstances when a TB control programme is being decentralized or centralized).

In order to reach its goals the following activities may be necessary: a comprehensive pharmaceutical assessment; development and approval of implementation plan; work at policy level to ensure legal support for interventions; trainings; hands-on TA; monitoring and evaluation of full country programme.

The technical resources will come from a variety of sources. The TA provider will utilize existing training courses, tools and DM methodologies developed by STPs or other sources. Furthermore, due to the degree and complexity of the DM issues to be addressed in-country, it may require new country/problem-specific tools to be developed. Creation of such tools will be the responsibility of the TA provider.

GDF Technical Assistance Service-Line sub-team:

To accommodate the expansion into TA the GDF will be required to increase its current staff.

A TA Coordinator will be hired to work at the GDF main office at the WHO in Geneva. This individual will be responsible for the overall coordination of TA services including;

- Development of a strategic implementation plan (policy and procedural development, comprehensive costing and concrete timelines).
- Creation of standard operating procedures (eligibility requirements, application and review, operation of technical advisory committee, monitoring and evaluation).
- Liaison/negotiation with Stop TB partners and other donors.
- Management of RSOs.

The TA coordinator should have the following key experience:

- Solid background in drug management (pharmacist or medical officer with specific experience in pharmaceutical management).
- Experience with TB control programmes,
- Experience working with donors and familiarity of funding cycle, existing donor mechanisms for provision of TA including drug management.

In addition to the TA coordinator, Regional Support Officers based in the WHO regional offices will have the following specific skills relevant to their partial responsibilities as regional GDF focal points for TA:

- Solid background in drug management (pharmacists preferred) and/or procurement.
- Knowledge and skills in negotiating/collaborating with donors (identifying funding opportunities, writing proposals, etc).
- Ability to provide specific on-the-spot TA when necessary.
- Familiarity with TB drug management tools available from STP.

Currently, the GDF already one RSO based in Cairo covering the Eastern Mediterranean Region (EMRO). The appointment of a Southeast Asia Region (SEARO) RSO is under way and expected to be in place by 3rd quarter 2006. In addition, a Procurement Officer (PO) is being hired to specifically assist the National TB Programme in India. TA in drug management will be part of the PO India's scope of work. The RSO responsible for the Africa Region (AFRO) is expected in 4th quarter 2006 and in 2007 two to three additional RSOs may be hired for the European Region (EURO), Western Pacific Region (WPRO) and, if feasible, for the Americas Region (AMRO).

8. Collaboration with Partners

An important aspect that will impact the effectiveness of the GDF expanded TA service line will be the degree to which the GDF is able to collaborate with partnering

organizations. As mentioned above the TA Coordinator and the RSO are required to have a well developed knowledge of the existing TA programmes, as well as a detailed database with this information. Many international donor agencies already have developed mechanisms for the provision of TA (USAID, DFID, CIDA, KFW) and there are many agencies or initiatives with technical expertise in drug management working in the same countries as GDF (RPM Plus of MSH, DELIVER of JSI, TASCIII, TBCAP). It will be crucial for the GDF TA coordinator to engage these groups, when appropriate establishing memorandums of understanding, defining specific avenues of collaboration. At the regional level, RSOs must be fully aware of the agencies working in their portfolio of countries and should work with field missions to ensure "buy-in" by these groups.

9. Cost Estimates

The preliminary financial implications for the GDF include the salaries and operating costs for the additional staff. Table 2 provides a summary of the initial costs involved. This is cost estimate for the initial establishment and operation of the TA service line. As the TA programme develops, progressing into the brokerage of TA with external agencies, the funds required is expected to increase. At this stage, it is extremely difficult to provide an accurate estimation on the expected total costs of brokering TA, as fees range from a few thousand dollars to tens of thousands of dollars depending on the consultancy required. Furthermore, it will be the responsibility of the TA Coordinator and the RSO to proactively seek donated TA services as a first resort. During the initial phase of the TA service line within the GDF, the TA coordinator will be responsible for a thorough market analysis which will include a comprehensive financial forecasting, according past TA requests and cost estimates provided by existing technical agencies.

Table 2: Estimated annual costing for implementation of TA staff expansion

Position	**Location**	**Annual Salary[6] (US$)**	**Operating Costs[7] (US$)**
Technical Assistance Coordinator- P4	GDF HQ Geneva	189,558	50,000
Regional Support Officer - WPRO - P3	Regional Office- Western Pacific	158,483	50,000
Regional Support Officer - EURO - P3	Regional Office - Europe	158,483	50,000
Regional Support Officer - AMRO - P3	Regional Office - Americas	158,483	50,000
Sub-total		665,007	200,000
TOTAL		**$ 865,007**	

10. Preliminary Next Steps

Upon the approval for the expansion of the current GDF technical assistance mechanism into a comprehensive service line, the preliminary next steps have been detailed below in order to move forward with the creation of an effective and efficient strategic plan for development and implementation. It is important to once again note that it will be the

[6] Includes salaries and associated costs for the employment (insurance and other allowances)
[7] Includes costs for travel to/within regions and/or funds for initial activities (trainings, short term TA).

responsibility of the TA Coordinator to develop a detailed strategic implementation plan, which would encompass many of the general steps presented below. The "next steps" are the immediate next steps necessary to initiate the process.

Next Steps:

- Hire a TA coordinator GDF in Geneva: 3rd - 4th Quarter 2006.

- Hire Regional Support Officers according to the following timeline:
  - EMRO: A*lready in place* - 2nd Quarter 2005
  - SEARO: 3rd Quarter 2006
  - AFRO: 4th Quarter 2006
  - EURO/WPRO: 2nd-3rd Quarter 2007
  - AMRO: TBD

- Formally establish a technical advisory subgroup from the GDF Technical Review Committee.

- Develop a detailed implementation strategy.

- Creation of the policies and processes including:
  - Eligibility requirements.
  - Application procedures/documents.
  - Application review and approval procedures/documents
  - TA assessment procedures (determining if and what type of TA is required).
  - Monitoring and evaluation mechanism.

- Develop matrix for drug management, including an inventory sources of technical assistance (i.e. skills matrix which includes organizations and individual consultants).

- Identify existing tools vis-à-vis drug management.

- Identify which of the GDF donors' regulations/conditions allow use of funding for activities other than procurement of TB drugs (GDF).

- Develop a proposal to donors, including the GDF strategic plan, expected outcomes, collaboration, and budget.