

Increasing transparency in partnerships for health – introducing the Green Light Committee

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Summary

Public–private partnerships have become central to efforts to combat infectious diseases. The characteristics of specific partnerships, their governance structures, and their ability to effectively address the issues for which they are developed are being clarified as experience is gained. In an attempt to promote access to and rational use of second-line anti-tuberculosis (TB) drugs for the treatment of multidrug-resistant TB, a unique partnership known as the Green Light Committee (GLC) was established by the World Health Organization. This partnership relies on five categories of actors to achieve its goal: academic institutions, civil society organizations, bilateral donors, governments of resource-limited countries, and a specialized United Nations agency. While the for-profit private sector is involved in terms of supplying concessionally priced drugs it is excluded from decision-making. The effectiveness of the partnership emerges from its review process, flexibility to modify its *modus operandi* to overcome obstacles, independence from the commercial sector, and its ability to link access, rational use, technical assistance, and policy development. The GLC mechanism may be useful in the development of other partnerships needed in the rational allocation of resources and tools for combating additional infectious diseases.

keywords MDR-TB, partnerships, access to drugs, tuberculosis

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Introduction

Recently, much attention has been devoted to the concept of using public–private partnerships (PPPs) or other novel arrangements between diverse institutions to address health inequities (Birmingham 2000; Smith 2000). The World Health Organization (WHO) has highlighted the importance of building new partnerships with civil society organizations and the for-profit private sector as the ‘future of global health’ (Brundtland 2001a,b). However, several concerns arise over the concept and utility of PPPs, including the appropriate role of PPPs, the transparency of how PPPs function in their operations, and potential conflicts of interests (Buse & Walt 2000a; Reich 2000; Society for International Development 2001; Heaton &

Keith 2002). Although some information exists, details of how and why specific health-based partnerships are formed, governance structures, decision-making processes, accountability, and, ultimately, effectiveness, are rare in the public health literature.

The World Health Organization and its partners have attempted to increase access to second-line anti-tuberculosis (TB) drugs needed to treat multidrug-resistant (MDR) TB in a rational way via a multi-institutional health-based partnership known as the ‘Green Light Committee’ (GLC). WHO’s role in controlling access to second-line drugs, potential conflicts of interests within the partnership, and lack of transparency in its operations and mandate have become the subject of debate (Cullinan 2001; WHO 2001a). In this article, we attempt to clearly outline the

R. Gupta *et al.* **Introducing the Green Light Committee**

governance issues surrounding the GLC and how the structure, *modus operandi*, accountability, and financing of the GLC relate to its overall effectiveness. In addition, the experiences of the GLC may serve as a useful model to promote access to and rational use of resources and tools needed for other infectious disease control efforts.

Defining MDR-TB

Multidrug-resistant-TB, defined as resistance to at least isoniazid and rifampicin (the two most powerful first-line anti-TB drugs), results primarily from human interventions such as improper prescribing practices, lack of patient adherence to treatment, irregular supply of drugs, and low quality drugs (i.e. poor TB control programmes) (Lambregts-van Weezenbeek & Veen 1995; WHO/International Union Against Tuberculosis and Lung Disease (IUATLD) 1997). Treatment of this form of disease involves the use of less effective second-line drugs costing up to US\$ 19 000 for a full treatment regimen (Gupta *et al.* 2001). Currently, programmatic strategies to manage MDR-TB are being developed under the rubric 'DOTS-Plus' to indicate that DOTS, the internationally recommended standard for TB control, is a pre-requisite for implementing DOTS-Plus. DOTS-Plus is more complex than DOTS as: (i) second-line drugs more often cause toxic side-effects, (ii) a more expensive and sophisticated diagnostic methods and strong health infrastructure are required, (iii) second-line drugs must be administered under strict direct observation for up

to 2 years and (iv) monitoring of outcomes and performance of the programme is more complex and costly (WHO 2000; Lambregts-van Weezenbeek & Reichman 2001).

Governance of the GLC**Development of the Working Group on DOTS-Plus for MDR-TB**

In 1999, the WHO established the Working Group on DOTS-Plus for MDR-TB (Working Group) to address the various issues related to the programmatic management of MDR-TB. The Working Group is an open group of over 50 institutions including academic institutions, civil society organizations, donor agencies, bilateral donors, the for-profit private sector (with observer status), governments of resource-limited countries, and United Nations (UN) agencies. It is convened by WHO which also serves as Secretariat for the Working Group. The Working Group aims to advise WHO in developing policy for the management of MDR-TB in resource-limited settings. Structured under this Working Group are four subgroups: a Scientific Panel to develop programmatic guidelines for implementing DOTS-Plus, the Subgroup on Laboratory Issues, the Subgroup on Drug Procurement Issues, and the GLC (Figure 1).

In 1999, the Subgroup on Drug Procurement Issues highlighted the high cost of second-line drugs as one of the major impediments to implementing DOTS-Plus pilot

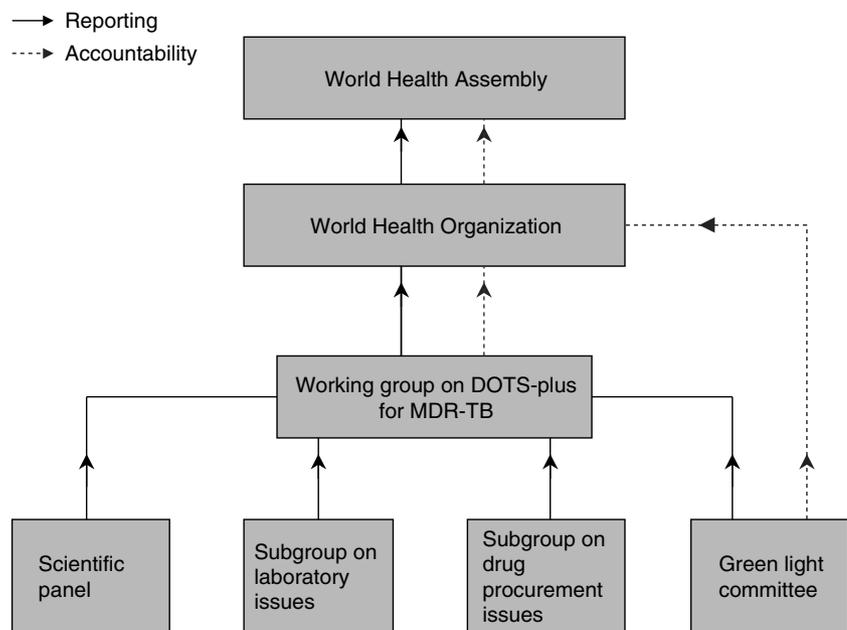


Figure 1 Structure of the working group on DOTS-plus for MDR-TB.

R. Gupta *et al.* Introducing the Green Light Committee

projects (WHO 1999). Ultimately, a mechanism had to be established to increase access to these drugs, but under tightly supervised conditions to promote their rational use and minimize the emergence of resistance to this last line of defence against TB. To promote access to and rational use of the concessionally priced drugs, WHO formed (in 2000) the GLC as a subgroup of the Working Group. Through a strategy described elsewhere (Gupta *et al.* 2001), costs of second-line drugs have fallen by up to 99%. The for-profit private sector (i.e. the pharmaceutical industry) is involved only in the supply of drugs at concessional prices, is not involved in the GLC, and only holds observer status in the Working Group and its subgroups. Thus, a broad global PPP is not reflected in this process (although private, civil society organizations, such as Médecins Sans Frontières and Royal Netherlands Tuberculosis Association, are involved). Accordingly, we use the term 'health-based partnership' to describe the GLC as opposed to the traditional term of 'global PPP', because the latter assumes involvement of a 'corporation (and/or industry association)' as an actor to achieve the goal (Buse & Walt 2000a). Because the GLC does not include the for-profit private sector in its decision-making process (unlike the Global Alliance for Vaccines and Immunizations and the Medicines for Malaria Venture), the concerns raised over traditional PPPs may not be applicable to this model.

Role of the GLC

The primary roles of the GLC are to: (i) review applications for projects wishing to benefit from the concessionally priced second-line drugs, (ii) evaluate the projects to determine whether they adhere to international guidelines for establishing DOTS-Plus pilot projects (WHO 2000) and (iii) inform WHO of its findings, deliberations and recommendations. Technical assistance is promoted (via WHO, which uses Working Group members) to projects deemed adherent to the guidelines and to projects in the application process. Once projects are approved, the GLC also has the task of monitoring these projects to assess their progress and continued adherence to the principles in the guidelines. The final role of the GLC is to exchange experiences and information from various projects to make recommendations to WHO on the development of global policy regarding the management of MDR-TB. Thus, the GLC integrates increasing access to drugs, promoting rational use of drugs, fostering technical assistance, and generating a strong evidence-base for policy development.

The role of the WHO-based Secretariat is to coordinate the activities of the GLC (including meetings, monitoring visits, and facilitating technical assistance when needed),

ensure that applicants meet deadlines and submit complete applications, serve as the focal point for communication with projects, and participate in technical discussions of the GLC on a limited basis. The chair of the GLC presides over the meetings of the GLC, liaises with the chair of the Working Group, and represents the GLC to applicants and other agencies when needed.

Selection of members of the GLC

World Health Organization selects the members of the GLC from the list of members of the Working Group, and WHO ensures that the membership is comprised of: (i) organizations possessing relevant technical capabilities and (ii) at least one representative from the following categories of organization interested in MDR-TB control: academic institutions (Harvard Medical School), civil society organizations (IUATLD and Royal Netherlands Tuberculosis Association), bilateral donors (Centers for Disease Control and Prevention), and governments of resource-limited countries (National TB Programme of Estonia). WHO remains as a permanent member (as the UN agency responsible for the management of tuberculosis), and also serves as the permanent Secretariat. Membership is for at least one 2-year term. The chair (currently Royal Netherlands Tuberculosis Association) is selected by the GLC members (via consensus decision) from its membership for a minimum of a 2-year term. At the end of this term, up to three institutions are requested to step down from the GLC. This maintains continuity while allowing other technical experts of the Working Group to participate in this initiative. Critical to this process has been clearly defining WHO's role as a member of the GLC and its role as Secretariat. To prevent conflict of interest the for-profit private sector was excluded from membership.

Financing

As with the members of the Working Group, members of the GLC are responsible for the costs incurred with activities of the GLC. Whenever possible and primarily for members of resource-limited countries, WHO covers the operational costs of the GLC including costs of meetings, travel costs, and costs of assessment/monitoring visits. Projects are not charged for review of applications, thereby minimizing transaction costs for applicants. However, those projects with extensive financing from donor agencies are requested to cover the costs associated with assessment/monitoring visits. Salaries are not provided to any GLC member or its consultants. Member's sources of finances for participating in the GLC are disclosed within

Table 1 Advantages and limitations of the GLC

Advantages for projects
Access to quality-assured drugs
Access to low-cost drugs
Access to a continuous drug supply
Access to technical assistance
Access to an external monitoring mechanism
Advantages for policy makers
Increased rational use of drugs
Creation of wide evidence base for policy development
Limitations/constraints
Lengthy review time for projects
Significant time commitment for GLC members for adequate review and assessment of projects
Potential weakening of process as price advantage diminishes
Shortage of technically qualified consultants with flexible time schedules

the GLC to protect against conflict of interests. Overall, the operating budget of the GLC for 2001 was US\$ 300 000.

Modus operandi

Conflict of interest among GLC members is assessed for each application and all members sign and are required to adhere to a standard declaration of conflict of interest developed by the WHO Legal Counsel. All recommendations are made by consensus. Each organization is granted two representatives (a primary member and an alternate), but only one vote. In principle, the GLC makes recommendations to WHO. In practice, WHO is an equal member (i.e. is granted one vote) and is part of the consensus recommendation process. However, WHO reserves the right to accept or reject the recommendations of the GLC as, ultimately, WHO is the legally accountable organization. To date, WHO has respected all recommendations of the GLC. Although the GLC responds directly to WHO, it also reports its activities to the Working Group during its annual meeting (Figure 1).

Projects conducted in resource-limited areas which request review and possible support by the GLC must submit an application according to specific instructions (WHO 2001b). A project can be of any scale and led by any organization, but must have government support and commitment for sustainability. The dates of the review cycles, deadlines for receiving applications, the relative concessional prices of second-line drugs, and other information related to the GLC process are made public through WHO publications (WHO 2001a,b), the WHO website (www.who.int) and peer-reviewed journals (Gupta *et al.* 2001; GLC 2002). In its first year, new applications were received and reviewed in four cycles (i.e. once every 3 months), and all GLC-related administrative issues were

discussed during these meetings. In the second year of operation, applications were received and reviewed during six cycles (i.e. once every alternate month). In addition, the GLC is meeting up to six more times during the intervening months to discuss operational issues and to review approved projects. When possible, discussions and decisions are also made during the interim period via e-mail and video/teleconference. Communication of the GLC's comments, questions, and recommendations are made by an assigned focal team (a GLC member or the chair, along with the Secretariat) directly to the project director 4 weeks after the review cycle begins. Site visits (performed by GLC members or selected consultants) are conducted during the review process (assessment) or after the project is approved (monitoring). Data are collected and reviewed on a periodic basis as part of the monitoring process as well. Thus, projects involved in this process benefit from access to quality assured drugs at low cost, technical support, and an independent monitoring mechanism (Table 1).

Preliminary results

From its first meeting in June 2000 to September 2002, the GLC has held 14 meetings. Nineteen projects applied to the GLC and for eight projects, at least one GLC member expressed a conflict of interest and was excluded from the decision-making process accordingly. Ten projects were approved and seven are still under review. The 10 projects approved are conducted in seven countries: Estonia (country-wide), Latvia (country-wide), Malawi¹ (country-wide), Mexico¹ (state-wide), Peru (district-wide), Philippines (district-wide), and the Russian Federation

¹Conditionally approved.

R. Gupta *et al.* **Introducing the Green Light Committee**

(oblast-wide and prison-only) and cover nearly 4000 patients, approximately 2% of the 273 000 new MDR-TB cases (Dye *et al.* 2001). Projects are conducted by national governments, bilateral donors, non-profit private sectors, and/or academic institutions, although all projects require political commitment from the government. Five of these 10 projects have undergone monitoring visits (five were recently approved and/or have just started treatment of patients). The average time for the entire review process is 3.5 months (range is 3–8 months). Review times were lengthy because of: delays in projects responding to the GLC requests for additional information or clarification, submission of incomplete applications, and GLC members being volunteers with full-time commitments to their other professional activities and unable to devote 100% of their time to GLC activities. However, the revised review process should significantly reduce review times. Drug delivery times should be minimized as well (currently the average time from approval to delivery is 3 months), as procurement agents now have experience dealing with the complex market issues facing second-line drugs. It should be noted that no applications have been refused, and the GLC philosophy is, as much as possible, not to reject applications. Instead, the GLC strives to offer advice and technical assistance until the proposed project meets the criteria outlined in international guidelines. However, applicants that do not respond to the GLC within a reasonable period or require extensive technical support and modifications to their project are asked to submit new applications when they are prepared to do so.

Technical assistance

Four applicants have been provided technical assistance in the form of training sessions in the clinical management of patients (Table 2). Members of the Working Group have also assisted in this process by making pre-application visits to four countries (Mexico, Costa Rica, South Africa and Kazakhstan) following invitations from governments of these countries to identify major problems in advance

that may require extensive technical assistance. A training session for applying to the GLC is provided at every meeting of the Working Group. Projects have been strengthened in terms of management of not only MDR-TB patients, but also drug-susceptible patients. Thus, TB control programmes as a whole have benefited from this process.

Contrary to what has been implied (Cullinan 2001; WHO 2001c), the GLC does not control the global use of second-line drugs. Projects not wishing to benefit from the concessional prices have the ability to purchase second-line drugs at market prices just as they did prior to the establishment of the GLC as second-line drugs have been purchased and utilized by countries for many years (Gupta *et al.* 2001). Access to second-line drugs is not restricted or controlled by any institution(s), but access to quality-assured, concessionally priced drugs is promoted only to projects that can demonstrate their ability to manage them properly.

Flexibility in approach is the key factor to the current progress. The GLC has continuously evaluated and modified its *modus operandi* in order to reduce response times to projects. The review process itself has been revised numerous times to counteract unexpected obstacles (such as single-patient requests and emergency requests). Outside consultants with recognized experience often conduct site visits at each stage of the process, and a greater number of experienced consultants will be needed as the number of applications increase. As more and more applications are submitted, a more decentralized process may need to be incorporated whereby 'regional GLCs' are established and work closely with a 'centralized GLC.' While the current members are committed to sustain the GLC, the (expected) increase in applications and subsequent workload may require full-time staff and an external funding source to remain efficient. It also remains to be seen how effective this mechanism will be as more pharmaceutical companies enter the market and choose to sell second-line drugs at GLC-competitive prices. Modifications to the process, such as offering second-line drugs free of charge to approved

Number of meetings	14
Number of applicants	19
Number of projects deemed compliant with guidelines	10
Number of projects under review	7
Number of projects not approved	2
Average time for review process (in months)	3.5 (range: 3–8)
Average time from approval to drug delivery (in months)	3 (range: 1–7)
Number of monitoring missions	9
Number of applicants requesting and given technical assistance	4

Table 2 Summary of GLC activities: June 2000 to September 2002

R. Gupta *et al.* **Introducing the Green Light Committee**

projects, may be needed. Finally, in order to expand access to this initiative, more support is needed for the expansion of DOTS programmes. Current coverage of the 8.7 million new TB cases by DOTS is only 23% (WHO 2002). If DOTS-Plus should only be established in the settings where DOTS is established and effective, then a strong limitation to accessing the GLC mechanism will be the lack of access to basic TB services (i.e. DOTS).

A mechanism for other infectious diseases?

Some have commented about the use of a similar committee for increasing rapid access to and rational use of antiretroviral drugs for the treatment of HIV/AIDS, and for rationally disbursing financial resources to address infectious diseases (Donnelly 2001a,b; Farmer *et al.* 2001). Before this mechanism is considered amongst the other potential approaches, other issues faced by the GLC need to be examined. First, the GLC does not address any issues related to providing funding to projects as ensuring funding is the responsibility of the implementing institution. Secondly, the GLC specifically addresses MDR-TB, which does not affect as many people as HIV/AIDS, malaria, or TB. Thirdly, MDR-TB does not require an emergency response, such as cholera, meningitis, or Ebola, to prevent an epidemic. Fourthly, the GLC itself may need to be modified to provide timely responses, in-depth reviews, continuous monitoring of approved projects, and, ultimately, ensuring its own sustainability, especially as more projects submit applications. Thus, the current state of the GLC is specific to the situation of MDR-TB and would have to be modified substantially in order to be applicable for other infectious disease control efforts.

Conclusions

Increasing access to health commodities while ensuring rational use of the same commodities have often remained as two separate issues for health policy makers. While the integration of these two components remains identifiable in only a few examples, such as the International Coordinating Group for meningitis and the Pan American Health Organization's Revolving Fund (Freeman 1999; WHO 2001d), partnerships in health may serve to be the foundation for future integrative processes. However, partnerships to combat health problems (including PPPs) have come under increasing scrutiny, especially as more initiatives emerge to combat infectious diseases. Issues related to composition, competence, accountability, and, ultimately, legitimacy have all been raised with minimal response to such criticisms (Buse & Walt 2000b; Brugha & Walt 2001; Heaton & Keith 2002). Structural outlines for

governance and parameters for assessment have been proposed (Brugha *et al.* 2002; Buse & Waxman 2001) as has the notion that partnerships are not appropriate in all areas relating to disease control (Widdus 2001). If partnerships are developed and used in the future to bridge equity gaps in health, the GLC experience leads to the conclusion that they will need to be adapted to the epidemiology of the disease they are addressing, incorporate country-level participation as early as possible, work transparently, be publicly accountable, but operate under a fair degree of flexibility to adapt to evolving circumstances, overcome obstacles and improve in efficiency.

Acknowledgements

The authors thank Roy Widdus (Initiative on Public–Private Partnerships for Health), Kent Buse (Yale University) and Ernesto Jaramillo (WHO) for their helpful comments on this paper.

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R. Gupta *et al.* **Introducing the Green Light Committee**

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