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# Is Health Diplomacy Keeping Pace with Global Health Developments? Implications for Access to Medicines Strategies in the Post-2015 MDG Framework

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## Abstract

As the 2015 deadline to achieve the Millennium Development Goals (MDGs) draws near, efforts to ensure access to essential medicines face new challenges in light of new resource constraints. To help assess those challenges, a summary analysis of published data was undertaken to examine the increasing discontinuity between the geographic focus of donor-country programs on low-income countries (LICs) and the geographic location of the increasing majority of the poor and the global burden of preventable disease within middle-income countries (MICs). This disconnect has put new pressure on both donor and government resources for essential medicines, prompting greater consideration of strategies through which global health investments can leverage market resources to achieve global health goals and benefit the poor in both LICs and MICs.

To help assess the policy environment for strategy change, country-level health workers from low and middle-income countries with high burdens of disease who participated in the International AIDS Conference (AIDS 2012) in Washington, DC, were surveyed to examine their views of the respective responsibilities of various institutions to finance access to essential medicines in their countries. While the 102 respondents rated the future financing responsibility of their governments higher than any other entity (4.8 versus 3.6-4.0,  $p < 0.0001$ ), most did not distinguish responsibility levels among a range of international organizations. Nor did the respondents anticipate any decrease in the future financing responsibilities of those entities, with seven of nine rated significantly higher in the future than in the past. The limited understanding of the roles and reach of different global health institutions is highlighted as an impediment to improving access-to-medicines strategies because it likely constrains the ability of country level stakeholders to engage in the global health strategy dialogue.

Sitting at the intersection of the trade and health agendas, the access-to-essential-medicines field is built on the uneasy links between global public health programming and private sector drug research, development and marketing agendas. The two analyses combine to highlight major health diplomacy challenges inherent in reconciling the broad range of state and non-state actor perspectives within the post-2015 development agenda.

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## Introduction

The United Nations (UN) Millennium Declaration encouraged the pharmaceutical industry “to make essential drugs more widely available and affordable by all who need them in developing countries” (United Nations, 2000), and various UN bodies have often emphasized the importance of developing strong partnerships with the private sector and with civil society organizations to pursue development and poverty eradication goals (Panel of Eminent Persons on United Nations-Civil Society Relations, 2004; Ki-moon, 2009). As the 2015 deadline to achieve the Millennium Development Goals (MDGs) draws near, one in three people worldwide and one in two in Africa lack access to essential medicines (World Health Organization [WHO], 2004). We suggest it is timely to consider what role “health diplomacy” should play in this arena.

Well-funded global partnerships have led to the roll-out of new rotavirus, pneumococcal and/or pentavalent vaccines in 37 low and middle-income countries (LMICs) in 2011,<sup>1</sup> and have supported the 18 percent increase in antiretroviral therapy (ART) coverage from 2009 to 2010 (United Nations, 2012). In addition, mechanisms for improving medicine access in LMICs have been tried and tested over the last decade. Pooled procurement schemes, voluntary licensing agreements, tiered pricing and product development partnerships for neglected diseases have all contributed with differing degrees of success in helping improve access in LMICs (Chaudury et al., 2005; Waning et al., 2009; Mahoney, 2011; Moon et al., 2011; Huff-Rousselle, 2012).

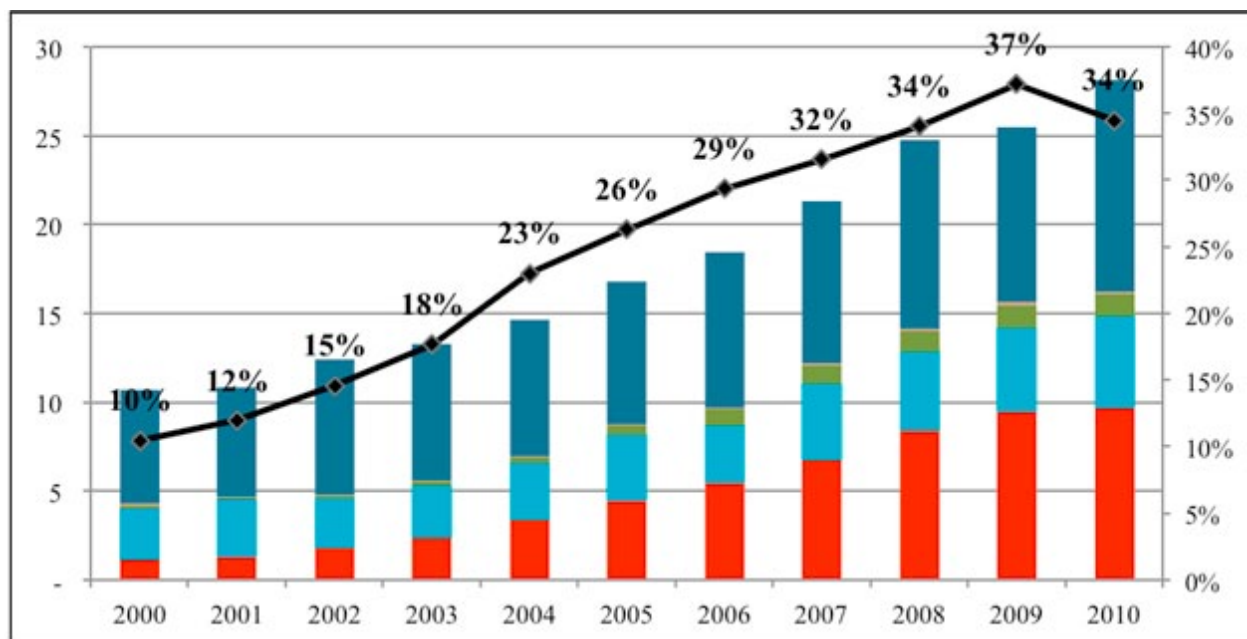
Despite progress and the widespread acknowledgment of the importance of essential medicines<sup>2</sup> to improving global health, access remains a major challenge. According to the MDG Gap Task Force Report, from 2007 to 2011 selected essential medicines were only available in 50 percent and 67 percent of public and private facilities, respectively (United Nations, 2012). Patients in LMICs continue to pay more for their medicines, in spite of lower ability to pay and higher out-of-pocket healthcare costs (United Nations, 2012). Further, reliance on direct out-of-pocket financing for chronic disorders constitutes a real economic threat to many individuals and represents an obstacle to increasing access to medicines for poor populations (Hogerzeil et al., 2013).

## New Resource Constraints

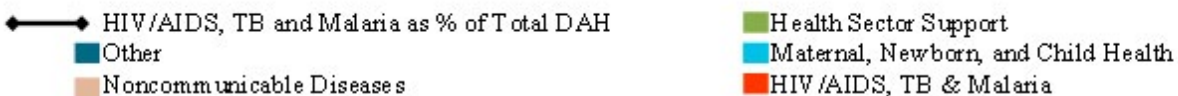
As illustrated in Figure 1, donor health financing in LMICs increased by some 164 percent between 2000 and 2010, reaching a peak of \$28.2 billion before stalling in 2011 and 2012 (Institute for Health Metrics and Evaluation [IHME], 2012). The increase in development assistance for health (DAH) over this period was largely focused on HIV, tuberculosis (TB) and malaria, which received an increasing share of DAH each year from 2000 until 2009, totaling some 34 percent of DAH by 2010. The leveling off of DAH in the wake of the 2008 financial crisis has put new pressure on both donor and LMIC governments and non-governmental organizations (NGOs) supporting access-to-medicines efforts. One response to those pressures has been to focus more effort on low-income countries (LICs) and less on middle-income countries (MICs). Other responses have been to look beyond traditional DAH program approaches to those which can influence global rather than country-level health product markets, recognizing that the DAH total represents a small fraction of the overall \$7 trillion global health economy (measured in total health expenditure, international dollars, 2010), some \$1.8 trillion of which is based in LMIC (World Bank, 2012).

<sup>1</sup> Funded by the GAVI Alliance (United Nations, 2012)

<sup>2</sup> The WHO defines essential medicines as “those that satisfy the priority health care needs of the population” (WHO, 2013). The WHO further stipulates that the identification of essential medicines should be accomplished with “due regard to disease prevalence, evidence on efficacy and safety, and comparative cost-effectiveness” (WHO, 2013).



**Figure 1.** DAH by health area (bars, in billions USD) and HIV/AIDS, TB and malaria as a share of total DAH (line), 2000-2010, based on IHME data (2012).



The comparison of the \$28 billion in donor spending in LMICs with the \$1.8 trillion LMIC health market prompts consideration of strategies through which global health investments can potentially leverage a greater portion of market resources to achieve global health priorities. Though not entirely unique in doing so, the access-to-medicines agenda provides particularly rich experience and current challenge in the greater utilization of trade and other international negotiations as vehicles for public health. Sitting at the intersection of the trade and health agendas, the field is built on the uneasy links between global public health programming and private sector drug research, development and marketing agendas. Its issues are intrinsically complex and sometimes confrontational, reflecting the broad range of state and non-state actor perspectives, with often competing national and international interests spanning the health and trade sectors.

### New Demands on Global Health Diplomacy

In recent years, interest in the field of health diplomacy has expanded in concert with the growth of global health resources, attention, and actors, with several scholars noting the multi-stakeholder, multi-sector nature of global health diplomacy in the 21st century (Cooper & Hocking, 2000; Walt, 2000; Kickbusch, Silberschmidt & Buss, 2007; Adams, Novotny & Leslie, 2008; Fidler, 2009). While governments continue to dominate international health negotiations in formal bodies, the lead actors in crafting the consensus declarations of major global health conferences are often government representatives who are not a part of the formal diplomatic corps, together with representatives from in-

ternational organizations, NGOs, civil society and the private sector. The shift of venue beyond state-dominated platforms has further enhanced the role of non-state actors in the global health strategy process, with the associated dialogue increasingly carried out in multi-stakeholder arenas such as international conferences, the governing boards of global health initiatives and partnerships, and the country-level committees in LMICs which coordinate funding proposals, influencing activities and roles of various implementers and donors.

This paper aims to explore the complexity of health diplomacy in the access-to-medicines arena through two complementary data analyses.<sup>3</sup> First, we present a short analysis of the potential influence of shifting disease burden and DAH across country income levels that is currently influencing access to medicines for AIDS, TB and malaria. Second, we present the results of a survey of country-level workers from LMICs that examines their understanding of the global health architecture when it comes to financing access to those same medicines. We do so recognizing the rising influence of international conferences on the deliberations within the governing boards of global health institutions such as the WHO, the GAVI Alliance and UNAIDS; and the increasing standing of their country-level attendees as stakeholders in the global health strategy dialogue at the nexus of the overlapping fields of “health diplomacy” and “public diplomacy” (Drager & Fidler, 2007).<sup>4</sup> In our discussion of the findings, we identify several major factors which influence the environment in which access-to-medicines strategies are being considered, before concluding with recommendations to address these factors and strengthen health diplomacy efforts in the post-2015 development framework.

## Methods

**A. Analysis of disease burden and DAH by income level.** Several descriptive analyses were conducted of publicly available secondary data to demonstrate the distribution of burden of disease, lack of access to ART, DAH, per capita health expenditure, and out-of-pocket health expenditure across country income levels. Country income level was based on World Bank classifications for the year in question using the Bank’s GNI per capita measure calculated via the Atlas method (World Bank, 2013). Databases used include: World Development Indicators (total health expenditure, out-of-pocket health expenditure) (World Bank, 2012); AIDSinfo (2011 HIV prevalence and lack of access to ART) (UNAIDS, 2012a); WHO data files (estimated TB and malaria cases for 2011 and 2010 respectively) (WHO, 2012a; WHO, 2012b); World Population Prospects (2010 and 2011 total population) (United Nations, 2011); and the Institute for Health Metrics and Evaluation’s (IHME) Development Assistance for Health Database (2000-2012 DAH) (IHME, 2012). The data year analyzed is the most recent year for which data are available in each case. This analysis builds on work by Sumner (2012) and Glassman, Duran and Sumner (2011).

**B. Health worker survey.** A survey of country-level health workers was conducted in August and September 2012 in person at the International AIDS Conference (AIDS 2012) in Washington, DC, and online to follow up or complete initial interviews. The AIDS 2012 venue was chosen as a platform for interviewing health workers for both convenience purposes and to target for inclusion those workers who were more likely connected and aware of the landscape of global actors affecting the response to HIV, TB and malaria.

<sup>3</sup> For the purposes of this paper the authors use Fidler’s definition of health diplomacy as “policy-shaping processes through which state, non-state and other institutional actors negotiate responses to health challenges, or utilize health concepts or mechanisms in policy-shaping and negotiation strategies, to achieve political, economic, or social objectives.” (2009).

<sup>4</sup> Public diplomacy is generally defined as “government’s process of communicating directly with foreign publics in an effort to bring about understanding for...current policies and national goals...ideas and ideals, as well as for...institutions and culture” (Tuch, 2009, p. 2).

Trained survey enumerators identified a convenience sample targeting country-level health workers from 15 countries pre-selected for their high burden of HIV, TB and malaria who were attending AIDS 2012.<sup>5</sup> The target country selection was based on countries' contributions to the global burden of the three diseases and on the severity of their national epidemics.<sup>6</sup> Forty-two high-burden countries were identified and divided into three ability-to-pay categories (low, medium, and high) based on HIV-prevalence adjusted GNI per capita.<sup>7</sup> Five countries were selected from each of the three ability-to-pay categories for inclusion in the survey based on the size of the countries' populations affected by the three diseases. The selected countries, shown in Appendix A with disease burden indicators, together accounted for 71 percent of the global burden of HIV, 58 percent of the global burden of TB, and 43 percent of the global burden of malaria.

Using a five-point Likert scale, respondents were asked to rate the roles of various global health institutions in scaling up access to medical technologies (drugs and diagnostics) for HIV/AIDS, TB and malaria in their countries in two different time periods: over the past five years and over the next five years. Survey questions asked respondents to rate entity roles in four different areas: access to second-line ART, access to pediatric ART formulations, advocating for access, and financing access. "Don't Know" was a response option for each question.

Given our focus on respondents' understanding of the access-to-medicines architecture, this paper reports on the frequency of "Don't Know" responses and on respondents' ratings of the role of entities in past and future financing.<sup>8</sup> Nine entities rated by respondents were included in the analysis: respondents' own national governments, the Bill & Melinda Gates Foundation (BMGF), the Global Fund to Fight AIDS, TB and Malaria (Global Fund), UNAIDS, UNICEF, UNITAID, the United States' Agency for International Development and President's Emergency Plan for AIDS Relief (USAID/PEPFAR), the World Bank, and the WHO. Mean responses were analyzed overall and across ability-to-pay categories and health worker type categories. The latter was based on respondents' self-classification of their organization into one of three types: (1) government, (2) an NGO whose primary role is service provision and/or program implementation, or (3) an NGO whose primary role is civil society mobilization and advocacy. One sample t-tests were conducted to compare scores between entities and to compare the past and future ratings of entity roles. The Kruskal Wallis test of analysis of variance in non-parametric data was used to assess differences in entity ratings by ability-to-pay and health worker type categories.

## **Results**

The summary analysis of published data for country burden of disease and economic status illustrates the framing for decision making influencing the current and anticipated flow of DAH resources for access to medicines for AIDS, TB and malaria. It also provides context to assess the results of the survey of country-level health workers and their views on the roles and responsibilities of various international entities in financing access-to-medicine efforts. The rationale for reporting the results of these two analyses together is the opportunity to consider health diplomacy challenges from two essential perspectives: that of donor organizations as reflected by the direction of their resource flows;

<sup>5</sup> The sample included 102 respondents from 15 countries. In total, AIDS 2012 attendees included 17,066 delegates, 11,725 participants from outside the United States, with representation from 183 countries (International AIDS Society, 2012).

<sup>6</sup> Countries were considered to be high-burden countries if they contributed to 84 percent of the global burden of HIV/AIDS, or had a national HIV prevalence of at least three percent, or contributed to 80 percent of the global burden of malaria or tuberculosis. Based on these criteria 42 countries were considered for inclusion.

<sup>7</sup> Countries whose HIV-prevalence-adjusted GNI per capita was between 0-15,000 made up the low-ability-to-pay category (LAP); those between 15,001 and 100,000 made up the medium-ability-to-pay category (MAP); and those between 100,001 and 9,000,000 made up the high-ability-to-pay category (HAP). The categories included 13, 13 and 16 countries, respectively.

<sup>8</sup> Other elements of the survey are to be submitted for publication separately.

and that of cooperating LMIC countries as reflected by the views of their country-level health workers. Together, these analyses allow for consideration of both LMIC and donor diplomacy realities and how they may influence each other.

**A. Analysis of disease and DAH by income level.** Based on the indicators analyzed, the greatest burden of disease exists in countries now classified as MICs. Figure 2 compares the burden of disease and burden of lack of access to essential medicines across low, medium and high-income countries for HIV, reporting both the number of people living with HIV and the number eligible for but not receiving ART. In 2011, one and a half times as many people in MICs (3.5 million) were without access to antiretroviral treatment than in LICs (2.2 million) in 2011. In 2011 there were nearly twice as many (20.5 million) people living with HIV in MICs than in LICs (11.3 million).

Figure 3 presents the malaria and TB burdens across income levels using the estimated number of new cases of each in 2010 and 2011 respectively. In 2011, 6.4 million new TB cases occurred in MICs versus 2.1 million in LICs; and in 2010 there were an estimated 131.7 million new malaria cases in MICs compared to 87.5 million in LICs. MICs rather than LICs host a greater share of the burden of HIV/AIDS, TB and malaria.

Figure 4 compares IHME estimates of official DAH for LMICs from bilateral and multilateral donors and US-registered NGOs in 2000 and 2010. While LICs received a greater share of more limited resources in 2000, by 2010, MICs received a greater share of a much bigger aid allocation (\$7.5 billion versus \$6.3 billion for LICs). LIC's accounted for 46 percent of the 2010 total and 56 percent of the 2000 total.<sup>9</sup>

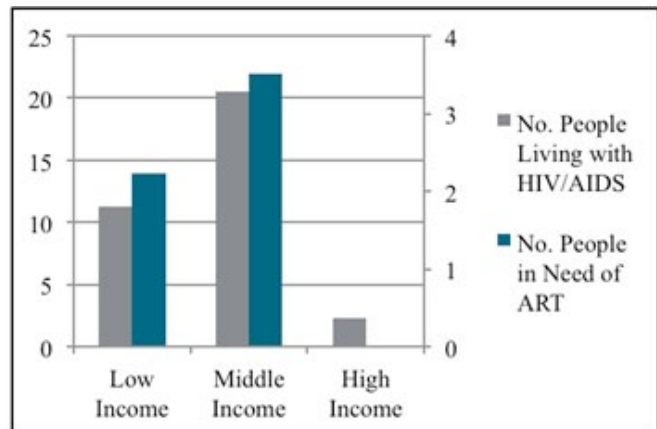


Figure 2. Distribution of HIV prevalence (2011) and lack of access to ART (2011) by World Bank income level.

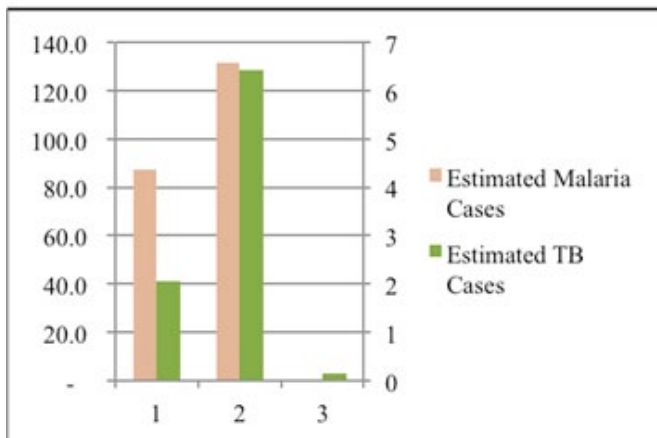


Figure 3. Distribution of new malaria (2010) and TB (2011) cases by World Bank income level.

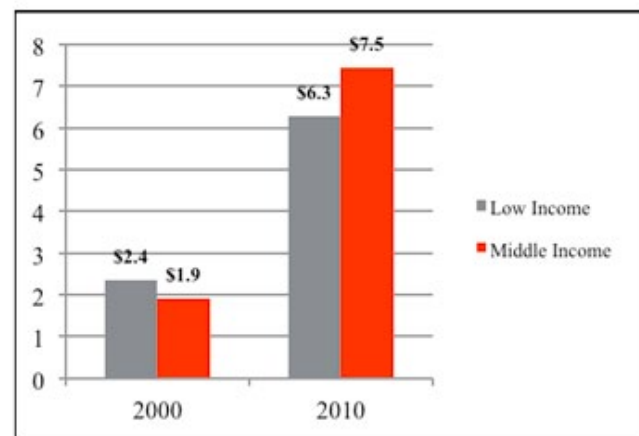


Figure 4. DAH (in billions, 2010 USD), 2000 & 2010 by World Bank income level (n=152)

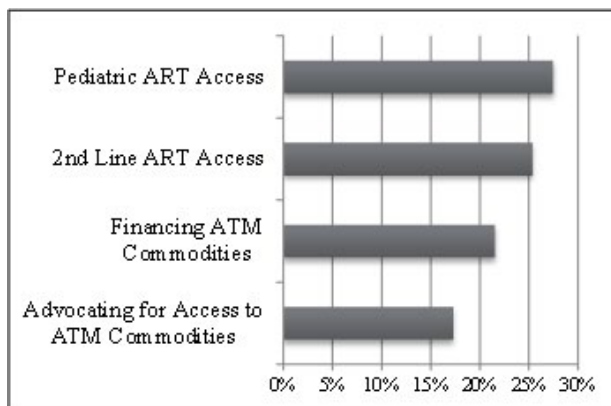
<sup>9</sup> Note: Figure 7 includes only the portion of DAH allocable to specific countries, which totaled 40 percent of measured DAH in 2000 and just under 50 percent of all DAH in 2010.



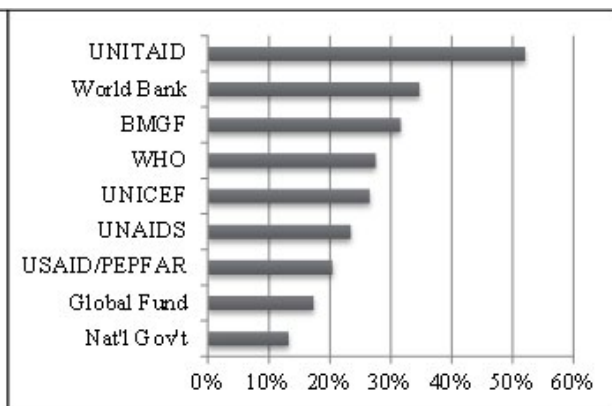
**B. Health worker survey.** A total of 102 respondents were surveyed with reasonably even representation across both ability-to-pay categories and health worker types, as shown in Table 1. By ability-to-pay category, 30 percent, 25 percent and 45 percent were drawn from low, medium and high ability-to-pay countries, while 35 percent, 34 percent and 24 percent represented government health workers, NGO program implementers, and civil society advocates, respectively. Some seven percent of the respondents represented “other” health organizations, primarily research institutions. Respondents reported an average of 8.5 years of experience in their area of work (n=100). Government respondents reported working at all levels of the health system, including the national (65 percent), regional (21 percent), district (9 percent) and community (6 percent) levels (n=34). Approximately one-third (36 percent) reported provision of clinical services as part of their job (n=35). Respondents reported working in a variety of areas, including supply chain management, provision of clinical services, advocacy, policy, disease epidemiology, general treatment and prevention programs, and programs targeting vulnerable populations.

Table 1. Respondents	
102 total respondents	
By Country Ability-to-Pay Category	
Low	30%
Medium	25%
High	45%
By Health Worker Type	
GOV - Government	35%
NGO - Health Service/ Program Implementation	34%
CSA - Civil Society/Advocacy	24%
Other	7%

**“Don’t Know” responses.** An average of one-fifth to one-quarter of respondents selected “Don’t Know” rather than rating entity roles in each of the four access areas (Figure 5). The average numbers of respondents selecting “Don’t Know” across the four access areas by entity are displayed in Figure 6. Respondents indicated a relative familiarity with the access-to-medicines roles of actors like the national government, the Global Fund, and USAID/PEPFAR, but less familiarity with other entities—with 23-52 percent of respondents insufficiently familiar with the other entities’ roles to be able to rate them.

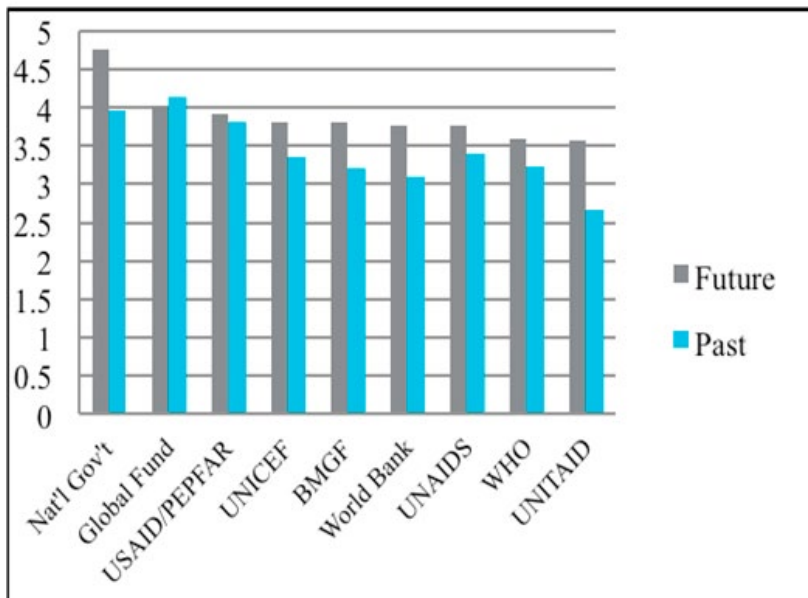


**Figure 5.** Average number of “Don’t Know” responses regarding the role of entities to date in four access-to-commodities areas



**Figure 6.** Average number of “Don’t Know” responses regarding the entity roles in four access-to-commodities areas

**Financing responsibility scores.** Of those who considered themselves familiar enough to rate the entities, average ratings of entity financing responsibilities are shown in Figure 7, with the “past” ratings representing the importance of the entity’s role in financing access to essential commodities over the last five years, and the “future” ratings representing the financing responsibility of entities moving forward. Overall, respondents assigned the greatest future financing responsibility to their national governments, which received a mean score nearly one full point higher than any other multilateral, bilateral or foundation entity. The mean difference between national government scores and each of the other entities ranged from 0.74 to 1.65, with difference in means significant at the 99.99 percent confidence level based on one-sample t-tests. The “ability-to-pay” category was a significant predictor of differences in entity scores of the future financing responsibility for national governments ( $H=13.80$ ,  $df=2$ ,  $p<0.01$ ), UNITAID ( $H=8.78$ ,  $df=2$ ,  $p<0.01$ ), and USAID/PEPFAR ( $H=10.28$ ,  $df=2$ ,  $p<0.01$ ). Respondents from high-ability-to-pay countries ranked the future financing responsibility of their national governments higher than did respondents from other countries, and ranked the responsibility of UNITAID and USAID/PEPFAR to be lower than did respondents from other countries. Variance in entity scores by healthworker type was not statistically significant for any entity.



**Figure 7.** Mean ratings of future responsibility of entities and past role of entities in financing access to commodities for HIV/AIDS, tuberculosis and malaria, by entity

The mean differences between ratings of all other entities’ future responsibility (other than the national government) were smaller and, other than a few exceptions, were not significant at the 95 percent confidence level (see full results in Appendix B). Across all entities except the Global Fund and PEPFAR, respondents rated the future responsibility significantly higher than they rated the entities’ roles to date. The significant differences in past and future ratings for each entity ranged from 0.24 to 0.81, with the difference in means significant at the 95 percent level based on one-sample t-tests (see Appendix C).

Respondents indicate through these ratings that they think most entities should do more in the way of financing going forward than they have in the recent past. Other than assigning greater future responsibility to their national governments, respondents did not distinguish different levels of financing responsibility among the entities. Entities for which financing is a core responsibility (e.g., Global Fund, PEPFAR, World Bank, UNITAID) were not assigned any more responsibility than entities which have an important role in access-to-medicines efforts but for which financing is not a core responsibility (e.g., UNICEF, UNAIDS, WHO). This last trend, together with the high proportions of “Don’t Know” responses, suggests a poor understanding of the core functions of the various actors in the global health architecture among respondents.

## Discussion

From the analyses of the distribution of DAH and burden-of-disease data, the survey of country-level health workers, and from review of the cited literature, key points emerge. First, amidst constrained resources, donors are increasing their focus on LICs while the burden of poverty and disease is steadily shifting to MICs. This finding alone suggests that the access-to-medicines agenda should include greater emphasis on strategies and governance vehicles that leverage small increments of DAH into more efficient and equitable outcomes in global health markets which benefit the poor in both MICs and LICs. Second, many if not most of the country-level health workers participating in an influential international conference on AIDS have a limited understanding of the different roles and strategies of a range of global-level institutions influencing access to medicines in their countries through the provision of financing, technical and operational assistance, and multilevel advocacy.

**1. Shift in the geographic classification of poverty, disease and donor health resources.** Today, around 72 percent of the world's population lives in MICs. This shift in population distribution occurred with the transition of several large population countries to middle-income status, such as China in 1999 and India in 2007. This shift has been accompanied by a decrease in the percentage of the population in LICs living below \$1.25 per day.<sup>10</sup> In 1990 nearly all of the world's poor lived in LICs; by 2007, that figure dropped to just 29 percent (Sumner, 2012).<sup>11</sup>

With their new status, MICs have become home to an increasing percentage of the global burden of disease, including child mortality. Nearly twice as many children under five die of all causes in MICs (4.4 million) than in LICs (2.4 million) (World Bank, 2013). Using 2004 global burden-of-disease data, Glassman, Duran and Sumner (2011) demonstrated that, when looking at all-cause global disability-adjusted life years (DALYs), DALYs associated with HIV/AIDS and DALYs associated with tuberculosis, the majority of each occurred in MICs. Development and humanitarian assistance programs targeting health now face a more difficult task when it comes to apportioning technical and financial resources and articulating to what extent they are focused on poor people and poor countries.

The majority of people unable to access certain essential health medicines and medical products live in MICs. The number of children not vaccinated against diphtheria (DPT-3) was more than three times greater in MICs than in LICs between 2005 and 2010 (Glassman, Duran & Sumner, 2011). While LICs are substantially worse off than MICs with respect to population-adjusted health outcomes (under-five mortality, prevalence of HIV, TB and malaria cases, access to antiretroviral treatment), the greater absolute numbers found in MICs have important financial and strategic implications in terms of achieving global health goals.

Given their greater public and private resources, MICs are expected to finance a progressively greater share of their health systems and disease responses.<sup>12</sup> The MIC governments' growing share of health financing is already evident, and the survey results above indicate support among country-level health workers for greater financing responsibility on the part of their respective governments.

<sup>10</sup> For example, the percent of the population living below \$1.25 per day (PPP) decreased in China from 60.2 percent in 1990 to 13.1 percent in 2008 and in India from 53.6 percent in 1988 to 32.7 percent in 2010 (World Bank, 2012).

<sup>11</sup> Chandy and Gertz (2011) similarly estimate about 66.6 percent of the world's poor lived in MICs in 2009.

<sup>12</sup> This is illustrated by recent decisions of the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund) and the United Kingdom's Department for International Development (DFID). The Global Fund has deemed G20 upper-middle-income countries (e.g., Brazil, China, Mexico, and Russia) ineligible for phase 2 grant renewals (Global Fund, 2011). The Fund's new funding model, to be implemented in 2013, explicitly indicates a focus on countries with "the highest disease burden and the least ability to pay" (p. 1), and eligibility criteria will require lower-middle and upper-middle-income country proposals to demonstrate a focus of 50 percent and 100 percent (respectively) of budget resources on "underserved and most-at-risk populations and/or highest impact interventions" (p. 8) and to achieve counterpart financing of 20-60 percent (Global Fund, 2013). DFID will reduce the number of countries to which it delivers bilateral aid from 87 in 2008/2009 to 27 by 2016 (DFID, 2011). DFID reports this decision was not solely due to resource constraints, but based on a review taking into account country need, other donor investments, and the potential of DFID bilateral investments to make an impact. Of the 16 countries to be graduated from United Kingdom aid between 2011 and 2016, the majority (12/16) are MICs. Of the 27 countries to continue to receive aid, the majority (18/27) are LICs.

Total LMIC financing of domestic AIDS responses, led by MIC governments, reached its highest level in 2011, when domestic government contributions (\$8.6 billion) exceeded international assistance (\$8.2 billion) (UNAIDS, 2012b). Today, 56 of 99 MICs are now funding more than half of their own national AIDS responses. Among the BRIC countries (Brazil, Russia, India and China), Brazil and Russia each pay for nearly all of their epidemic responses, China finances about 80 percent of its national response, and South Africa, with \$2 billion invested in HIV in 2011, leads among MICs in terms of its share of financing. Among non-BRIC countries, Mexico and Botswana (both MICs) finance nearly all of their AIDS responses (UNAIDS, 2012b).

Though above the WHO minimum threshold of \$35-50 per capita to provide basic lifesaving services, per capita health expenditure in MICs, at \$369 (international dollars) in 2010, remains quite low relative to the \$4,660 (international dollars) per capita health expenditure in high-income countries. A high proportion of MIC health expenditures is borne by households, with out-of-pocket spending in MICs accounting for over one-third of total health spending (Figure 8). Those households have little voice or choice in their care. Institutional capacities required to support greater civil society engagement and private sector partnering in health service strengthening strategies for the poor are generally weak in MICs and are limited or entirely absent in international assistance programming.<sup>13</sup>

**2. Limited understanding of global health landscape.** Results from the survey illustrate a limited understanding on the part of country-level health workers participating in the 2012 International AIDS Conference on the different roles and strategies of a range of global level institutions influencing access to medicines in their countries. While health workers appear to value the concept of increasing country ownership through their responses, they do not distinguish the roles of financing and non-financing entities. Nor did they anticipate any decrease in the future responsibilities of those international entities to finance access to medicines in their countries. This suggests that both state and non-state actors in the global health system should do more to ensure their roles are clear and understood among the various constituencies.

Over the last decade, there has been considerable growth in the number and diversity of institutional actors making up the global health landscape generally, and in the access-to-medicines space in particular.<sup>14</sup> The complexity of the landscape of actors involved in achieving access-to-medicines goals, including MDG Target 8E, is likely to further increase. The debate around access to essential medicines has been fundamentally influenced by the roles taken by traditional and new global health governance actors in this opaque environment. Government representatives of emerging economic powers like Brazil, India and South Africa have become more engaged in international policy-making debates involving access to medicines. Despite actual or potentially negative impacts on their international trade relationships, some LMIC governments have approved compulsory licences for production of generic versions of patented drugs so as to respond effectively to domestic health concerns (Beall & Kuhn, 2012). Domestic-level entities in LMICs are increasingly involved in production and procurement of essential drugs (Waning, Diedrichsen & Moon, 2010; UNAIDS, 2012c).

<sup>13</sup> For example, the consultations held as a part of the Bellagio Initiative on The Future of Philanthropy and Development in the Pursuit of Human Wellbeing (which was led by the Institute of Development Studies, the Resource Alliance, and the Rockefeller Foundation) found that though MICs are observing such trends as growing local resource mobilization and growing citizen participation, they also face barriers to philanthropic growth including a lack of credibility of the sector and lack of appropriate tax incentives (Bellagio Initiative, 2011). Regulatory systems, a part of the WHO's building blocks of health systems, need strengthening in LMICs. Though a priority in particular for HICs importing products from LMICs, regulatory systems strengthening is not addressed in most global health initiatives (Preston, Valdez & Bond, 2012).

<sup>14</sup> Numerous institutions have become involved in the access to medicines landscape in just the last 15 years. These include major global health partnerships (e.g., StopTB in 2001 and the Global Fund in 2002); important US presidential initiatives (e.g., PEPFAR in 2003 and the President's Malaria Initiative in 2005); private foundations (e.g., expansion of Gates Foundation global health activities beginning with a \$750 million contribution to the now GAVI Alliance in 2001 and the Clinton Health Access Initiative in 2002); a United Nations drug-purchasing facility (UNITAID in 2006); disease-specific drug-purchasing facilities for tuberculosis (Global Drug Facility in 2001) and malaria (Affordable Medicines Facility - malaria in 2008). There were also product development partnerships (e.g., FIND and DNDi in 2003, the CD4 Initiative in 2005, Malaria Medicines Venture in 1999, TB Alliance in 2000); and other initiatives (e.g., Malaria No More in 2006, Medicines Patent Pool in 2010).

NGOs and civil society groups have also increased their voice and weight in the dialogue with this sector of non-state actors increasingly recognized as a critical force in global health governance (Gostin, 2007; Fidler, 2007; Lee, 2001). With this emergence, international conferences have become an important space for informing and influencing national and international-level health policy development. Of particular note is how the 1996, 1998 and 2000 International AIDS Conferences in Vancouver, Geneva and Durban helped to hasten and shape the historic 2001 United Nations General Assembly Special Session (UNGASS) on HIV/AIDS, specifically with respect to access to treatment. Through the well-placed 15,000-plus delegates from around the world, the Vancouver conference catapulted limited examples of ART treatment success to international headlines. Two years later, the Geneva conference highlighted disparities in treatment access with its “Bridging the Gap” theme, and two years hence the Durban conference inspired wide support for scaling up access to treatment in LMICs, bringing home to delegates from around the world the particular urgency of the epidemic in sub-Saharan Africa (Wainberg, 2005; De Cock, 2012). The momentum carried over into the governing bodies of intergovernmental organizations in 2001, helping to mobilize a World Health Assembly (WHA) resolution (WHA 54.10) on scaling up the response to HIV/AIDS and a broad set of regional declarations by heads of state in early 2001 which helped to form the political foundation for the UNGASS Declaration in which they were prominently referenced (United Nations, article 6, 2001). Further evidence of the influence of the biennial AIDS Conference extended to the 2002 gathering in Barcelona where Bill Clinton and Nelson Mandela led a group of nine current and former presidents and prime ministers, committing their personal efforts to build greater support for expanded treatment, prevention and education efforts.

The influence of international conferences is just one example of the benefits of the evolution of the global health landscape to “open source anarchy,” with institutional pluralism opening spaces for more frequent, diverse and inclusive dialogues more likely to contribute to innovation and collaborative solutions (Fidler, 2007). Notwithstanding those benefits, there are widespread calls for greater clarity, if not wholesale restructuring, to achieve a more effective platform for international prioritization, health norm setting, and equitable financing (Gostin et al., 2011; Dybul, Piot & Frenk, 2012; Frenk & Moon, 2013). Whatever the path forward, a limited understanding of the roles of global health institutions is likely to be an impediment to evolving improved global health governance in this complex space. This contributes to what some scholars have observed as the “chaos in global health,” with widespread competition among actors and priorities, a lack of structure, and a lack of delineation between the roles of different actors (Ng & Ruger, 2011).

With the increasing democratization of the global health strategy dialogue, a significant lack of understanding among local stakeholders of the different roles and strategies of the global level institutions influencing access to medicines in their country should be cause for concern. It is likely to constrain their ability to engage in the global health strategy dialogue, to bring essential perspective and prioritization to access-to-medicines negotiations, or to bring political pressure to bear for needed institutional reform.

**3. Health diplomacy challenge to leverage global health markets.** In 2010 the global health economy was valued at \$7 trillion (international dollars, PPP adjusted), or roughly 10 percent of the world economy (World Bank, 2012). The global pharmaceutical market is growing and projected to reach \$1.1 trillion by 2015 (International Federation of Pharmaceutical Manufacturers & Associations [IF-

PMA], 2011). By comparison, the \$28 billion of DAH in 2010 made up less than one-half of one percent of the global health economy. In crude comparative terms, a one percent growth in the overall global health economy focused efficiently and equitably on the poor in LMICs is the rough equivalent of doubling official DAH.

In stark contrast to grim forecasts on the availability of additional DAH in the coming decade, LMIC demand for medicines is expected to grow with the increasing purchasing power of the middle class. Home to 26 percent of the world's middle-class people in 1990, LMICs accounted for 58 percent of the middle class in 2010 and are projected to account for 80 percent by 2030 (United Nations Development Programme, 2013). Emerging-economy countries are projected to account for 28 percent of pharmaceutical sales by 2015, a 150 percent increase over 2005. By 2015, LMIC markets are expected to account for 70 percent of the \$400-430 billion in revenues from generic medicines (IFPMA, 2011).

MDG 8 and MDG Target 8E efforts have been somewhat unique in that the strategies adopted to achieve them can operate outside of what has been the mainstay of bilateral and multilateral development efforts, the "country-program." Despite their many advantages in increasing demand for and access to life-saving products and technologies, country-program-modeled efforts are largely constrained to generate value within the context of national boundaries. In contrast, trade and other international agreements are instruments that can influence the access-to-medicines agenda—positively or negatively—at a policy and partnership level well beyond national borders.

The tension between trade and health is a key feature of today's global health system and its governance that reflects a built-in competition between market-driven and social justice principles (Blouin et al., 2007). Though not unique to the access-to-medicines field, the diversity and number of stakeholders involved puts a high premium on approaches that bring together diverse groups and interests to develop shared strategies. These stakeholders include health ministries, industry and trade, public, multilateral, private non-profit, private for-profit and academic actors. Not surprisingly, there is an inherent tension within the agendas of stakeholders from the health and trade sectors that come together to negotiate the access-to-medicines agendas (Beauchamp, 2003). Within this community, civil society actors advance social justice approaches to health and make the majority of innovative proposals to address major global health issues at their source. In contrast, pharmaceutical companies and many states are driven by what can be termed a "market justice" approach to health, guided by financial imperatives and a belief in the ability of the market to bring equity. In practice, this often stands at odds with social concerns.

Within the access-to-medicines realm, broad concerns about participation, transparency and accountability in global health governance are sharpened and heightened. NGOs and civil society groups are increasingly concerned by the UN's engagement of the private sector and trade associations (Conflict of Interest Coalition, 2011). Meanwhile, private sector groups express concerns of exclusion. Civil society actors have also criticized the presence of the pharmaceutical industry on consultation panels during the civil society forums on non-communicable diseases (NCDs), suggesting conflicts of interest would compromise the development of health policy that would put the interests of NCD patients first (Cox, 2011; Conflict of Interest Coalition, 2011; Lincoln et al., 2011). Conversely, civil society advocates have also expressed concern over the lack of civil society inclusion in Trans-Pacific Partnership (TPP) negotiations (MSF Action Campaign, 2013; Public Citizen, 2013), where leaked documents suggested a

US position in favour of stronger intellectual property protections. Acceptance of stronger protections would undermine the advances made in access to medicines via flexibilities built into the Agreement on Trade-Related Aspects of International Property Rights (TRIPS) (Gleeson & Friel, 2013).

The pressing health diplomacy challenge—and opportunity—in the access-to-medicines arena is to build understanding and clarity of the roles and responsibilities of the various stakeholders in order to effectively address these concerns. Given the political and financial context for the near-term, at least, there appear to be limited alternatives. In particular, with anticipated financial constraints, new efforts will require approaches that are not premised on major increases in DAH or on major changes in existing DAH spending patterns. Consequently, the global access-to-medicines agenda is more likely to expand through strategies and governance vehicles that leverage small increments of DAH into more efficient and equitable outcomes in global health markets.

### **Conclusions: Strengthening Health Diplomacy for Access to Medicines Post-2015**

The dialogue on what should come after the MDGs has garnered significant engagement across the global health and diplomatic communities, among them: a UN High-Level Panel of Eminent Persons on the Post-2015 Development Agenda tasked to prepare its recommendations for the UN Secretary-General; the UN Development Group's organization of eleven global thematic consultations, as well as national consultations in more than 60 countries; and several civil society efforts to coordinate input.<sup>15</sup> Numerous entities have offered detailed proposals and recommendations for the next development framework, while others have spoken in favour of the simplicity of the original goals, cautioning against undue expansions and complexity.<sup>16</sup>

In the post-2015 development agenda, stronger and more focused health diplomacy efforts will be required to address issues around access to medicines. From our review we conclude that:

- recent trends of shifting disease, poverty and DAH dynamics have resulted in an increasing disconnect between the geographic focus of donor-country programs on LICs and the geographic location of the increasing majority of the poor and the global burden of preventable disease within MICs;
- in an environment of stagnating levels of development resources and intensifying competition, strategies that leverage broader global health markets for essential medicines may have greater impact on the poor in both LICs and MICs than those conceptualized and confined within the narrower DAH space; and
- the emerging influence of greater stakeholder engagement in global health policy development may be compromised by a general lack of distinction made with respect to the different roles, reach and leverage of—and points of governance engagement with—the various organizational entities within the global health landscape influencing access to essential medicines.

We have demonstrated how the shifting global economic and epidemiological landscape is paralleled by a shifting governance landscape. To more effectively address access to essential medicines, the post-2015 agenda will need to address the challenges raised by the interlinking of trade and health dialogues, im-

<sup>15</sup> These include the UN and Global Call to Action against Poverty's World We Want 2015 campaign and My World platform, the Overseas Development Institute's Post-2015 platform (a clearinghouse on research and reporting relevant to the post-2015 development agenda), and the Brussels-based Beyond 2015 coalition (an alliance of more than 500 organizations).

<sup>16</sup> See, for example, the ONE Campaign's report, *Open for Development: Achieving Greater Post-2015 Results through an Open Design Process, Monitoring System and Data Portals* (ONE, 2013); Results for Development Institute's *Post-2015 Education MDGs* (Schweitzer et al., 2012); *Save the Children's vision for a post-2015 framework* (2012); the Centre for International Governance Innovation and Korea Development Institute's *Post-2015 Development Agenda* (Bates-Earner et al., 2012); the Oxfam International position on the post-2015 development goals (2013); in addition to hundreds of papers submitted through the consultation processes.

prove the understanding of the respective roles and leverage of the existing international organizations by those most active within the system, and facilitate connections between trading nations more broadly so as to enable a shift from narrower donor-recipient relationships to broader nation-to-nation development cooperation for health. Furthermore, the system will need to embrace the essential elements of good process—equitable participation, transparency and accountability—while acknowledging and addressing the existing tensions head on. Recognizing the shifting landscape and working collaboratively to address the challenges they bring will be a critical element of global health diplomacy post-2015.

**Disclaimer of Interest**

The authors declare they have no conflict of interests.



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**Appendix A: Selected Countries with Disease Burden Indicators**

Country	Contribution to Global HIV Burden (2009)	National HIV Prevalence (%) (2009)	Contribution to Global TB Burden (2010)	National TB Incidence (new cases/100,000) (2010)	Contribution to Global Malaria Burden (2010)	National Malaria Incidence (new cases/1000) (2010)
Low Ability to Pay						
Kenya	4.5%	6.3%	1.4%	298	4.9%	113.2
Tanzania	4.2%	5.6%	0.9%	177	9.3%	194.2
Uganda	3.6%	6.5%	0.8%	209	11.8%	331.6
Zimbabwe	3.6%	14.3%	0.9%	633	0.7%	51.6
Mozambique	4.2%	11.5%	1.5%	544	1.6%	65.1
<b>Total</b>	<b>20.1%</b>		<b>5.5%</b>		<b>28.3%</b>	
Medium Ability to Pay						
South Africa	16.8%	17.8%	5.6%	981	0.0%	0.2
Nigeria	9.9%	3.6%	2.4%	133	4.1%	24.5
Cote d'Ivoire	1.4%	3.4%	0.3%	139	1.8%	87.2
Ethiopia	5.4%	2.1%	2.5%	261	4.3%	49.1
Cameroon	1.8%	5.3%	0.4%	177	2.0%	94.2
<b>Total</b>	<b>35.3%</b>		<b>11.2%</b>		<b>12.2%</b>	
High Ability to Pay						
China	2.2%	0.1%	11.4%	78	0.0%	0
Brazil	1.9%	0.5%	1.0%	43	0.4%	1.7
Russia	2.9%	1.0%	1.7%	106	0.0%	0
India	7.2%	0.3%	26.1%	185	1.7%	1.3
Thailand	1.6%	1.3%	1.1%	137	0.0%	0.5
<b>Total</b>	<b>15.9%</b>		<b>41.3%</b>		<b>2.1%</b>	

HIV/AIDS data from UNAIDS Report on the Global AIDS Epidemic 2010; TB indicators from WHO Global Tuberculosis Control 2011; malaria data from WHO World Malaria Report 2011

**Appendix B: Differences between Entity Ratings of Responsibility for Financing Essential Commodities for HIV/AIDS, TB and Malaria - Mean differences\* between entity scores (row entity minus column entity), with one-sample t-test results**

	Nat'l Gov't	Global Fund	PEPFAR	UNICEF	BMGF	World Bank	UNAIDS	WHO	UNITAID
Nat'l Gov't									
Global Fund	<b>0.74</b> t=19.5 p<0.0001 (n=93)								
PEPFAR	<b>0.86</b> t=14.3 p<0.0001 (n=88)	0.10 t=0.77 p>0.05 (n=88)							
UNICEF	<b>1.01</b> t=16.15 p<0.0001 (n=84)	0.24 t=1.54 p>0.05 (n=84)	0.12 t=0.69 p>0.05 (n=81)						
BMGF	<b>1.43</b> t=16.15 p<0.0001 (n=86)	0.19 t=1.54 p>0.05 (n=86)	0.07 t=0.69 p>0.05 (n=83)	-0.05 t=-0.02 p>0.05 (n=80)					
World Bank	<b>1.06</b> t=16.65 p<0.0001 (n=86)	0.28 t=1.74 p>0.05 (n=86)	0.19 t=0.88 p>0.05 (n=83)	0.04 t=0.18 p>0.05 (n=82)	0.11 t=0.22 p>0.05 (n=82)				
UNAIDS	<b>1.60</b> t=16.81 p<0.0001 (n=87)	0.31 t=1.81 p>0.05 (n=87)	0.19 t=0.94 p>0.05 (n=83)	0.09 t=0.25 p>0.05 (n=82)	0.15 t=0.29 p>0.05 (n=82)	0.04 t=0.05 p>0.05 (n=83)			
WHO	<b>1.65</b> t=19.48 p<0.0001 (n=86)	<b>0.43</b> t=2.92 p<0.05 (n=86)	0.30 t=1.95 p>0.05 (n=83)	0.16 t=1.31 p>0.05 (n=82)	0.23 t=1.37 p>0.05 (n=81)	0.14 t=1.06 p>0.05 (n=83)	0.11 t=1.03 p>0.05 (n=84)		
UNITAID	<b>1.57</b> t=19.81 p<0.0001 (n=67)	<b>0.42</b> t=3.06 p<0.05 (n=67)	<b>0.22</b> t=2.07 p<0.05 (n=64)	0.31 t=1.44 p>0.05 (n=62)	0.71 t=1.5 p>0.05 (n=65)	0.14 t=1.19 p>0.05 (n=63)	0.13 t=1.16 p>0.05 (n=63)	0.06 t=0.15 p>0.05 (n=62)	

\*Mean differences that were significant at the 95% level are in bold

**Appendix C: Differences between Past and Future Entity Ratings of Responsibility for Financing Essential Commodities for HIV/AIDS, TB and Malaria**

	Mean Past Rating (Std Dev)	Mean Future Rating (Std Dev)	Mean Difference*	One-sample T-test
Nat'l Gov't	3.96 (1.22)	4.77 (0.59)	<b>0.81</b> (n=95)	t=13.49 p<0.0001
Global Fund	4.14 (1.11)	4.02 (1.39)	-0.12 (n=92)	t=-0.82 p>0.05
PEPFAR	3.8 (1.33)	3.91 (1.49)	0.09 (n=78)	t=0.69 p>0.05
UNICEF	3.36 (1.26)	3.8 (1.39)	<b>0.28</b> (n=68)	t=2.89 p<0.05
BMGF	3.21 (1.27)	3.8 (1.37)	<b>0.52</b> (n=65)	t=4.01 p<0.05
World Bank	3.09 (1.32)	3.77 (1.46)	<b>0.45</b> (n=66)	t=4.3 p<0.05
UNAIDS	3.4 (1.35)	3.76 (1.44)	<b>0.24</b> (n=80)	t=2.32 p<0.05
WHO	3.23 (1.41)	3.6 (1.48)	<b>0.31</b> (n=72)	t=2.35 p<0.05
UNITAID	2.66 (1.35)	3.58 (1.47)	<b>0.82</b> (n=38)	t=5.14 p<0.05
<i>*Mean differences that were significant at the 95% level are in bold</i>				