Thirty-Third Board Meeting

Global Fund support for co-infections and co-morbidities

GF/B33/11
Board Decision
Geneva, Switzerland

Purpose of the paper: To present the Strategy, Investment and Impact Committee's recommendation (GF/SIIC14/DP02) to the Board, regarding the Global Fund's role in financing the co-infections and co-morbidities of HIV/AIDS, Tuberculosis and Malaria.

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The Global Fund

I. Decision Point

1. Based on the recommendation of the Strategy, Investment and Impact Committee (SIIC), the following decision point is recommended to the Board:

Decision Point: GF/B33/DPXX: Policy on Co-Infections and Co-Morbidities

1. ***The Board acknowledges its approval of an interim measure for the financing of Hepatitis C virus treatment until the approval of a broader policy on co-infections and co-morbidities of HIV/AIDS, tuberculosis and malaria (GF/B32/DP07).***

2. ***Based on the recommendations of the Strategy, Investment and Impact Committee, the Board approves the framework for financing co-infections and co-morbidities of HIV/AIDS, tuberculosis and malaria, as set forth in GF/B33/11.***

3. ***Accordingly, the Board notes this decision point supersedes GF/B32/DP07.***

II. Relevant Past Decisions

2. Pursuant to the Governance Plan for Impact as approved at the Thirty-Second Board Meeting,[1] the following summary of relevant past decision points is submitted to contextualize the decision point proposed in Section I above, and is required in documents presenting decisions only.

Relevant past Decision Point	Summary and Impact
GF/B32/DP07: Global Fund Financing of Hepatitis C Treatment[2]	The Board approved an interim measure for continued funding of Hepatitis C virus treatment until there is an outcome to broader discussions on the role of the Global fund with respect to funding treatment of co-infections and co-morbidities of HIV/AIDS, tuberculosis and malaria. The decision point proposed in this paper would establish a broader policy on such co-infections and co-morbidities, and therefore supersede the interim measure adopted by the Board under GF/B32/DP07.

[1] GF/B32/DP05: Approval of the Governance Plan for Impact as set forth in document GF/B32/08 Revision 2.
[2] http://www.theglobalfund.org/Knowledge/Decisions/GF/B32/DP07/

III. Action Required

3. This paper presents the Board with the SIIC's recommendation on the Global Fund's role in financing co-infections and co-morbidities of HIV/AIDS, tuberculosis and malaria (COIM). The recommendation requests the Board to adopt a framework that provides criteria and guidance for when such financing may be appropriate, as outlined below.

IV. Executive Summary

4. At the Thirty-Second Board Meeting in November 2014, the Board adopted an interim measure with respect to the continued financing of Hepatitis C virus treatment. In taking this decision, the Board acknowledged the SIIC's plan to engage in a broader discussion on the Global Fund's role in financing COIM.

5. At its 14th Meeting in February 2015, the SIIC discussed the options for financing COIM presented by the Secretariat. Based on the analysis presented by the Secretariat, and the discussion among SIIC members, the committee agreed to recommend a framework on financing COIM to the Board for approval.

6. The framework on financing COIM that is proposed in this paper aims to establish criteria for when COIM interventions could be financed by the Global Fund in accordance with its mission and objectives. The purpose of the framework is to

a. Provide guidelines to countries, where appropriate, on developing an investment case for COIM funding within their relevant country allocations; and

b. Provide guidance to the Technical Review Panel (TRP) on assessing COIM funding requests.

7. If approved, the Secretariat and TRP would review and potentially recommend funding requests that contain COIM interventions to the Board in accordance with the proposed framework and standard access-to-funding processes. Furthermore, the previously approved interim measure for Hepatitis C virus treatment would be superseded by this decision.

V. Global Fund support for Co-Infections and Co-Morbidities (COIM)

01 Background.

8. The issues raised by the question of financing for COIMs are broad, and relate to the Global Fund's financing of new technologies and its support for country ownership. As new health technologies are introduced and countries consider broad health needs, the Global Fund expects to see an increase in the number of country requests for financing new health interventions that address the burden of HIV, tuberculosis (TB), malaria, and their co-infections and co-morbidities (COIMs). How the Global Fund decides to support COIMs and new technologies has the potential to impact the lives of people living with the three diseases, the scale up of new and existing health interventions, and the Global Fund's model of partnership and country-ownership.

9. This paper presents a discussion of the framework for COIM financing that the SIIC recommends to the Board for approval. The framework proposed moves beyond existing processes into developing and providing guidance on financing COIMs to ensure impact and increase accountability, while maintaining the overarching principles of country ownership and a flexible approach to countries.

02 The landscape of COIMs.

10. A co-infection is the occurrence of two or more infections - either concurrently or sequentially - and includes both acute and chronic infections. HIV, a chronic infection, suppresses the immune system and thus increases the risk of secondary infections. Opportunistic infections (OIs) is the term given to infections which arise either as new infections or reactivations when the immune system is weakened. Before the widespread availability of antiretroviral therapy, OIs such as *Pneumocystis jiroveci* pneumonia (formerly PCP), cryptococcal meningitis, and non-tuberculous mycobacteria (NTM) were common causes of death in persons living with HIV. It is also noted that both Malaria and Tuberculosis are important co-infections of HIV.

11. A co-morbidity occurs when two or more acute or chronic conditions exist, either concurrently or sequentially. The term is reserved for situations in which at least one of the conditions is a non-communicable disease (NCD).[i] People living with chronic, non-communicable diseases, such as diabetes or alcohol use disorders, have a higher risk of developing communicable diseases, such as TB, due to their immunosuppression. As treatment for HIV has become more widely available, non-communicable diseases now account for a greater proportion of morbidity and mortality in HIV infected populations.

12. The universe of COIMs associated with HIV/AIDS, TB, and malaria is wide, containing both opportunistic and non-opportunistic infections, non-communicable diseases such as cancer and heart disease, and other conditions, such as malnutrition. As HIV is a lifelong infection, many co-infections and illnesses will occur throughout. This paper seeks to focus on those which are the most important to the morbidity and mortality of those infected with the three diseases and/or have an impact on prevention.

13. Within this universe, some COIMs interact exclusively with HIV, TB, or malaria, while others are shared by two or all three of the diseases. An illustrative matrix (see Figure 1) details many of the co-infections and co-morbidities of the three diseases. This paper focuses on several important COIMs to illustrate the implications for the Global Fund. Of note, this paper does not discuss directly the important interaction between TB and HIV, as both diseases form part of the core mandate of the Global Fund.

Figure 1. Matrix of HIV, TB, and malaria co-infections and co-morbidities

<table>
<tr><th rowspan="2">Global Fund Area</th><th colspan="4">Universe of co-infections and co-morbidities</th></tr>
<tr><th colspan="2">Co-infections</th><th colspan="2">Co-morbidities</th></tr>
<tr><td rowspan="3">HIV</td><td rowspan="2">Opportunistic infections[ii]</td><td rowspan="2">Invasive candidiasis
Isosporiasis
Non-tuberculous mycobacteria
Coccidioidomycosis
Pneumocytis jiroveci pneumonia (PCP)
Cryptococcocal disease
Tuberculosis

Crytosporidiosis
Cytomegalovirus
Toxoplasmosis
Herpes simplex
Histoplasmosis</td><td>AIDs-defining cancers[iii]</td><td>Kaposi sarcoma
Non-Hodgkin lymphoma
Cervical cancer</td></tr>
<tr><td>Non-AIDS defining cancers[iv]</td><td>Hodgkin lymphoma
Anal
Liver
Colorectal
Prostate
Breast
Lung</td></tr>
<tr><td>Non-opportunistic infections[v,vi]</td><td>Hepatitis B
Hepatitis C
Human papillomavirus
Sexually transmitted infections
Pneumonia and bacterial infections</td><td>Chronic diseases[vii,viii]</td><td>Cardiovascular
Liver
Opiate addiction</td></tr>
<tr><td>TB</td><td colspan="2">Pneumonia[ix] and bacterial infections[x]</td><td colspan="2">Autoimmune disease
Diabetes
Silicosis
Tobacco use
liver disease</td></tr>
<tr><td>HIV and TB</td><td colspan="2">Hepatitis
Sexually transmitted infections[xi,xii,xiii]</td><td colspan="2">Diabetes[xiv]
Lung disease
Lung cancer</td></tr>
<tr><td>HIV, TB, and Malaria</td><td colspan="2">Helminths[xv]
Leishmaniasis[xvi,xvii]
Neglected tropical diseases[xviii]</td><td colspan="2">Malnutrition[xix,xxxxi]</td></tr>
</table>

03 Historical Global Fund support of COIM.

14. As a country-driven global health financing partnership, the Global Fund has historically relied on countries and the Technical Review Panel (TRP) to prioritize WHO-recommended interventions and ensure Global Fund financing for the three diseases is targeted for public health impact across diverse country contexts. For HIV, the tacit criteria used has been that funding is available to support those interventions that directly have an effect on the prevention and morbidity/mortality related to HIV. Thus the Global Fund routinely supports interventions that screen for and treat opportunistic infections of HIV, such as cryptococcal meningitis, that are in line with normative guidance related to HIV care. Activities related to HIV care (as defined by normative guidance) have always been part of Global Fund-supported activities, and this is not expected to change under the proposed framework.

15. The Global Fund has not generally provided support for COIMs which indirectly affect morbidity, such as NCDs like heart disease, diabetes, and certain cancers that are co-morbidities with HIV and TB. There is greater variation in Global Fund support for non-opportunistic infections. The Global Fund

supports funding requests for STIs diagnosis and treatment, does not support HPV vaccination, cervical cancer screening, or efforts to prevent, screen and treat silicosis, and intermittently supports country-driven requests for prevention and treatment of hepatitis B and C.[3]

04 Burden of disease and costs of specific COIM's.

a. Hepatitis C

16. More than 185 million people have been infected with the hepatitis C virus (HCV), of which 130-150 million (70-80%) have chronic infection and will harbor a chronic HCV infection for the rest of their lives if not treated. In the absence of treatment, chronic HCV infection can cause liver cirrhosis, liver failure, and hepatocellular carcinoma.

17. The most recent (and unpublished) estimates from WHO (2015) suggest that approximately 2.8 million persons with HIV have also been infected with Hepatitis C. Of those, approximately 2-2.2 million have chronic HCV infection. This is significantly lower than prior estimates (2013), which placed the number of HIV/HCV co-infected people at 4-5 million people.[xxii] Injection drug use is a key risk factor for co-infection of HIV and HCV. Among those who have HIV, the prevalence of co-infection with HCV in people who inject drugs (PWID) is highest in East Asia, South East Asia, and North America, at 96%, 90%, and 84%, respectively.

18. Recently, a number of direct acting antivirals (DAAs) have shown success with cure rates, assessed through sustained virological response, above 90% in Phase II and III trials. Several are already marketed, and can cost from $900 in many low and lower middle income countries, up to $40,000 thousand dollars for a 12-week treatment program in wealthier countries.[xxiii] Recent cost analyses show that if the same strategic market dynamics that drove down the cost of HIV antiretroviral treatment in the 1990s are used for new HCV treatments, drug regimen prices could be as low as $100-250 per 12 week treatment course.[xxiv] Indeed, the price of Sofosbuvir has already been negotiated down as low as $900 per 12 week course in some countries, and a voluntary licensing agreement has already been reached that will enable generic manufacturers to sell the drug in 91 countries that have a per capita income of less than $1,900.[xxv]In addition to drug costs, hepatitis C co-infection programs would also have costs associated with diagnosis, labs and clinic visits.

b. Human papillomavirus (HPV) and Cervical Cancer

19. HPV is easily transmitted through sexual contact and can result in cervical cancer. Cervical cancer is one of the three AIDS-defining cancers and is the second most common cancer in women worldwide, with 528,000 new cases and 266,000 deaths occurring each year.[xxvi] More than 85% of these deaths occur in low- and middle-income countries.[xxvii] There is some evidence that the presence of HPV infection may increase the risk of HIV transmission.[xxviii] HIV increases the risk and persistence of HPV,[xxix] and increases the risk of its progression to squamous intraepithelial lesions, precancerous lesions, and cervical cancer.[xxx] Women with HIV are five times more likely than women without to develop cervical cancer.[xxxi] In the opposite direction, risk estimates range from a 2- to 4-fold increase of HIV infection following HPV infection.[xxxii]

[3] Prior to the Board's November 2014 adoption of interim measures for Hepatitis C treatment financing (GF/B32/DP07), applications for funding of Hepatitis C treatment would be recommended by the TRP after close scrutiny of the country context, including well-documented evidence that Hepatitis C treatment and funding is available to the general population and that funding from the Global Fund is to fill-in the gap for HIV infected individuals, as outlined in the 20110 TRP Report for Round 10 Proposal (GF/B22/13).

20. Interventions include vaccination to prevent infection with HPV and screening and treatment of cervical cancer and precancerous lesions. Two HPV vaccines are licensed for use in many countries and supported by GAVI. Screening is recommended for every woman 30-49 years of age and is central to reducing female cancer mortality.[xxxiii] Women who are under 30 and HIV-infected or living in a high HIV prevalence area should undergo screening. In high HIV prevalence countries, WHO recommends that women who screen positive for cervical cancer be offered HIV testing and counseling. For low- and middle-income settings, the recommended screening technologies are VIA or HPV nucleic acid testing. VIA screening can cost under $5.[xli] Recommended treatment for precancerous lesions is cryotherapy, with LEEP used when the clinical presentation is too severe to perform cryotherapy.[xxxiv] Cryotherapy costs varied in a study in Ghana from $47 to $84.[xli]

c. Silicosis

21. Silicosis is a lung disease that is associated with working in silica-exposed occupations, such as mining, well drilling, sandblasting, ceramic and glass production, and iron smelting. Patients with silicosis have 2.8 to 39 times the risk of developing pulmonary tuberculosis, and 3.7 times the risk of developing extra-pulmonary tuberculosis compared to healthy controls.[xxxv] The intensity of silica exposure and the severity of the silicosis is directly proportional to the risk of developing tuberculosis, and the risk is lifelong even if exposure ceases.[xxxvi,xxxvii] A key issue in mining communities in southern Africa is not only the high prevalence of TB, but also of silicosis and HIV, which act as risk factors for TB. The risks of silicosis and HIV infection combine multiplicatively. TB is as much a silica-related occupational disease in miners with HIV as in miners without, and South African miners with both HIV and silicosis have considerably higher pulmonary TB incidence rates than those reported from other Africans with HIV.[xxxviii]

22. The primary intervention to prevent silicosis is to maintain a level of dust control at which the disease will not occur ($106-109 saved/DALY).[xxxix] Silicosis is incurable. Disease management should include early detection of silicosis and TB cases through monitoring of current and former workers in workplaces with known silica-exposure; establishment of surveillance programs; prevention of disease progression and development of TB; and disability reduction.[xl]

d. Diabetes mellitus

23. Diabetes mellitus (DM) is a non-communicable co-morbidity of TB with a large and rapidly growing burden throughout the world. The relationship between DM and HIV is mainly due to the effects of medication and the fact that as people living with HIV (PLHIV) live longer, some of these will develop DM.

24. Currently, 5-30% of tuberculosis patients around the world also have diabetes. DM is associated with a three-fold increase in risk of developing active TB, which can be even higher in persons with poor glucose control.[xli] The growing burden of diabetes contributes to high levels of TB in the community, and the proportion of TB cases attributable to diabetes globally is likely to increase over time.[xlii] It is estimated that in 2030, 12.6% of TB will be attributable to DM, and the top three countries for TB prevalence – India, China, and Indonesia – will experience some of the largest effects on rising prevalence rates for DM.[xliii]

25. Among those with active TB, diabetes may negatively affect TB treatment outcomes. A systematic review in 2011 found that co-morbid TB and diabetes patients undergoing TB treatment had a 1.69-fold increased risk in failure or death (combined), 1.89-fold increased risk in death, and a 3.89-fold increased risk in relapse.[xliv] There is also evidence that TB can trigger the onset of diabetes, or worsen glycemic control in people with diabetes. Interfering drug-drug interactions may also occur between the medications for TB and diabetes.[xlv]

26. Limited systematic evidence on the feasibility and effectiveness of interventions for co-morbid TB and diabetes patients exists. There are currently no international guidelines for the prevention, diagnosis, or treatment of a co-morbidity of HIV and diabetes.

e. Nutritional Supplementation

27. Many countries have used nutritional supplements and food packages, not only to serve the goal of improving the biological response to HIV and TB treatments, but also to improve the treatment adherence behavior of patients. Malnutrition is a cross-cutting co-morbidity across HIV, TB, and malaria.

28. HIV and TB infections cause an increase in metabolic rate and thus, the energy needs for the body. Under-nutrition also increases the risk of developing active TB and worsens treatment outcomes, especially for multi-drug resistant TB.[xlvi] Under-nutrition increases the severity of TB, and the risk of poor treatment outcomes and relapse.[xlvii] Similarly, poor diet increases the risk of HIV disease progression.[xlviii]

29. A key principle in WHO recommendations for nutrition and tuberculosis is the inclusion of nutrition screening, assessment, and management within TB treatment and care programs. Although effectiveness evidence is limited, nutritional support could improve access and adherence to TB treatment and act as an income replacement in order to help alleviate the catastrophic economic and social costs of TB. Where access and adherence are suboptimal, a package of enablers and social benefits, which may include food assistance, may be appropriate.[xlix]

Table 3. Burden of Specific Co-Infections and Co-Morbidities (COIM)

COIM	Primary disease area	Total global burden of disease (BoD)	BoD within primary disease population	Acute country/ regional challenge	Costs of COIM	Other donors	Funding level *(estimates)*
Hepatitis C	HIV	185 M infected with HCV[1]	2.8 M cases[li]	Eastern Europe/Central Asia, Southeast Asia	$440M-$790M[4]	UNITAID, MSF	$20M for 3 years by UNITAID and MSF and Coalition

[4] To calculate a budget impact of HCV, estimated cases in all of Europe and North America, 80% of Latin America, and 50% of Western Pacific were excluded, assuming that these populations are not Global Fund-eligible. Further, it was assumed that only 50% of co-infected patients would be in HIV care and treatment programs, and would therefore have the possibility of receiving HCV diagnosis and treatment. The price of HCV treatment was varied between $300-$1000 per 12 weeks. For genotypes requiring 24 weeks, or 12 weeks with the addition of pegylated interferon, it was assumed the treatment cost was double the cost of the 12-week sofosbuvir and ribavirin regimen. The total cost of HCV diagnosis and treatment among PLHIV in GF-eligible countries would be between $440 million and $790 million.

							Internationale Sida[lii]
Human papillomavirus and cervical cancer	HIV	528,000 new cervical cancer cases and 266,000 deaths annually[liii]	HPV prevalence in HIV+ women 56.6% in Africa, 31.1% in Asia, and 57.3% in South/Central America[liv]	Sub-Saharan Africa, Latin America, Eastern Europe[lv]	$106M-$190M per year[5]	Pink Ribbon Red Ribbon (PRRR), GAVI	PRRR: $15M per year for 5 years (Zambia)
Silicosis	TB	18-51% prevalence among silica-exposed workers	2.8 to 39 times the risk of developing pulmonary tuberculosis[lvi]	India, China, Brazil, South Africa[lvii]	Approx. $4.6M per year[6] for screening in 4 Southern African countries; estimated cost to test for and treat TB in the same population is $33M [lviii]	Mining companies, WB, Global Fund, International Organization for Migration, UNAIDs, DFID	Focus has been on TB broadly: Global Fund (2013): $102M in SADC countries; DFID (2013): $220,000 matching private sector pledges from SADC countries; International Organization for Migration: $6.5M in Southern African mining sector
Diabetes mellitus	TB	285 M people[lix]	TB patients have 5-30% prevalence of DM[lx]	India, China, and Indonesia[lxi]	$376BN in 2010, $490BN in 2030 for ALL diabetes	e.g. World Diabetes Foundation (WDF)	WDF current project portfolio for ALL diabetes: $324.9M;[lxii] largely domestically funded
Malnutrition	TB and HIV	805 M people without	Under-weight people 12.4 times more	Afghanistan, Bangladesh	$10BN to achieve	ODA, EC, World	$940M ODA in basic nutrition in 2013[lxvii];

[5] The potential budget impact of cervical cancer prevention programs in low- and middle-income countries depend on the screening technologies employed. Rough modeling made the following assumptions: 50% of female PLHIV are in HIV care and would receive the cervical cancer screening program. The program would screen women every 3 years, unless women screen positive, in which case they would subsequently be screened annually. To approximate this, on average, it was assumed that women were screened every 2 years. It was assumed that 25% of the screening tests would yield positive results necessitating follow-up confirmation and precancerous lesion treatment. It was assumed 15% of lesion treatments would require the more expensive LEEP technology, but the rest would be treatable with cryotherapy. The cost of treatment or palliative care in those who had progressed to cancer was not include. Screening for other HPV-caused cancers, such as anal cancer, was not considered. When a VIA-based strategy is employed, the total annual cost for 100 low- and middle income countries is $106 million per year. A PAP-based strategy would cost $191 million per year. Almost three-quarters of the cost is associated with follow-up in the fraction of women with positive screening test results. This portion of the cost may decline over time, since the prevalence of lesions will be lower over time in a population that is repeatedly screened and treated.

[6] Based on data from March 2014 that estimates 500,000 mineworkers in South Africa, Lesotho, Mozambique, and Swaziland. There is little data on the prevention and treatment costs of silicosis. This calculation uses a $9.27 screening cost from Kenya (chest X-Ray) only.

		enough food[lxiii]	likely to develop TB than healthy people (U.S. study)[lxiv]	, Brazil, Cambodia, China[7,lxv]	WHO 2020 targets	Bank, UNICEF, WFP, Gates[lxvi]	$500M LMIC spending on direct interventions [lxviii]

05 Discussion

30. Countries and the Global Fund may decide to pursue a range of beneficial objectives when considering the financing of COIMs. An objective may be to increase impact on HIV, TB or malaria, such as through the funding of STI interventions; or to save the lives of people living with one of the three diseases, such as through funding of curative HCV therapy in PLHIV. Countries may also seek to support comprehensive service packages which include COIM interventions, such as HCV support within harm reduction packages or nutritional support within TB care packages.

31. Countries and the Global Fund may seek to shape markets for critical health products by providing financing and scale-up of health products, or may seek to support integration of service delivery platforms for greater impact and cost-effectiveness. For example, the Global Fund currently partners with UNICEF and others to support the financing of the entire Integrated Community Case Management (iCCM) approach which improves results against malaria and other causes of febrile illness. Often, entire packages are synergistic and it makes sense to coordinate funding of the whole package. To date, the Global Fund has sought to support country-led prioritization of investments within national plans to fight the three diseases. These positive objectives should be considered alongside the potential risks of expanding financing for COIMs that could displace financing for or slow scale-up of critical interventions against the three diseases.

32. The SIIC considered three options for financing COIMs. First, the SIIC considered the Global Fund maintaining current processes for financing COIMs, which favors country-led process and flexibility. Under this approach, the Global Fund would not introduce specific guidance on funding COIMs or the introduction of new health technologies. Countries, the TRP and the Global Fund would continue to prioritize funding of COIMs with country allocations in the absence of additional guidance. This approach would prioritize country-level decision-making and allow for case by case decisions between countries, the TRP and the Global Fund Secretariat.

33. However, the SIIC recognized that this option does not provide additional clarity on where the Global Fund should or should not seek to support COIM investments. This option may fail to prioritize Global Fund financing for COIMs where impact or integration of programs may have substantive benefits. It was discussed how under this approach, financing of COIMs could potentially reduce country-level impact, slow scale-up of other critical interventions, or create perverse incentives within countries if investments are not carefully considered.

34. Second, the SIIC considered the option that certain COIMs should be beyond the mandate of the Global Fund in all cases and should therefore be excluded for financing. Under this approach, the Global Fund would narrowly finance only the key interventions directly aimed at the prevention and treatment of HIV, TB, malaria, and COIMs uniquely associated with AIDS or which increase HIV transmission.

[7] Top 5 countries with highest number of tuberculosis cases.

Funding for other COIMs, such as HCV treatment and HPV screening and treatment for example, would never be considered for Global Fund financing.

35. However, the SIIC found significant disadvantages to this approach, noting that it would radically change the Global Fund's model of partnership, strongly decrease Global Fund's support for country-ownership, and would limit Global Fund support for people living with the three diseases and a COIM. Furthermore, it is not aligned with the current strategy of maximizing the health impact of investments in the three diseases for women and children's health or health systems strengthening, and would make it difficult to undertake a more differentiated, flexible and tailored approach to meet the diverse health needs of countries. Finally, this approach may result in poorer alignment with national health strategies, create contrived boundaries to service delivery that are troubling at the patient level and which may hinder effective delivery of health services, and would forgo significant opportunities to save the lives of people living with the three diseases and a COIM.

36. Finally, the SIIC discussed and endorsed an approach where the Global Fund would provide enhanced guidance through a framework on financing for COIMs. This framework, detailed below, would prioritize the scale-up of existing, core interventions, for the three diseases but would provide flexibility and accountability for where a strong investment case is made by country partners for financing COIMs.

37. As countries' indicative allocations can be distributed across the disease areas in ways that provide the most impact, an investment case for COIM interventions would need to demonstrate impact and value for money. In settings where the key interventions are not scaled-up, it is unlikely that investment cases for COIM interventions would be proposed by countries or accepted by the TRP and the Secretariat.

38. The advantages of this option were discussed by the SIIC and included that adopting such a framework would allow continued country prioritization of interventions, including COIM interventions under circumstances consistent with the principle of country ownership, while ensuring that Global Fund financing remains closely linked to and targeted at the three diseases. This option would also provide greater impact and accountability around COIM investments than currently existing processes, while avoiding the problems inherent in the other approaches. If approved, the Secretariat will continue to monitor the impact of financing of COIMs under this framework.

VI. Recommendation

39. Based on the discussion outlined in this paper, the SIIC recommends that the Board approve the framework for financing COIM set forth below:

Framework for Financing Co-infections and Co-Morbidities of HIV/AIDS, Tuberculosis and Malaria (COIM).

1. The framework aims to define the criteria for when COIM interventions could be financed by the Global Fund. The purpose of this framework is to:

    a. Provide countries clearer guidelines, where appropriate, on developing a strong investment case for COIM funding within their country allocations;

    b. Provide the TRP stronger guidance on assessing requests for COIM funding from countries in country concept notes.

2. This approach supports country ownership and impact, while ensuring that Global Fund financing remains closely linked to and targeted at the three diseases.

3. This decision and framework is subject to the existing global disease split, and allocation methodology, and will not prejudge future allocations.

4. The Global Fund will consider financing a COIM intervention when there is sufficient evidence the intervention:

    a. Is based on a strong investment case considering impact and cost within the context of existing programs within that country; and

    b. Extends the life expectancy, prevents and/or reduces mortality and morbidity, of people living with HIV, TB and malaria by acting directly on HIV, TB or malaria; or

    c. Is an effective health intervention that prevents or treats a COIM that has a disproportionate impact on people living with HIV, TB or malaria;

    And where:

    d. Financing would not detract from or displace financing for cost-effective HIV, TB or malaria interventions; and

    e. Global Fund financing would not displace resources from other funding sources; and

    f. There is alignment with national policy guidelines; and

    g. Interventions are synergistic and can be integrated with other HIV, TB or malaria delivery platforms.

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