Resource Toolkit

on GFATM 2023-2025 Funding Opportunities for Hepatitis

Version: December 2022[1]

[1] This Toolkit is considered a 'living' document and will be updated as needed

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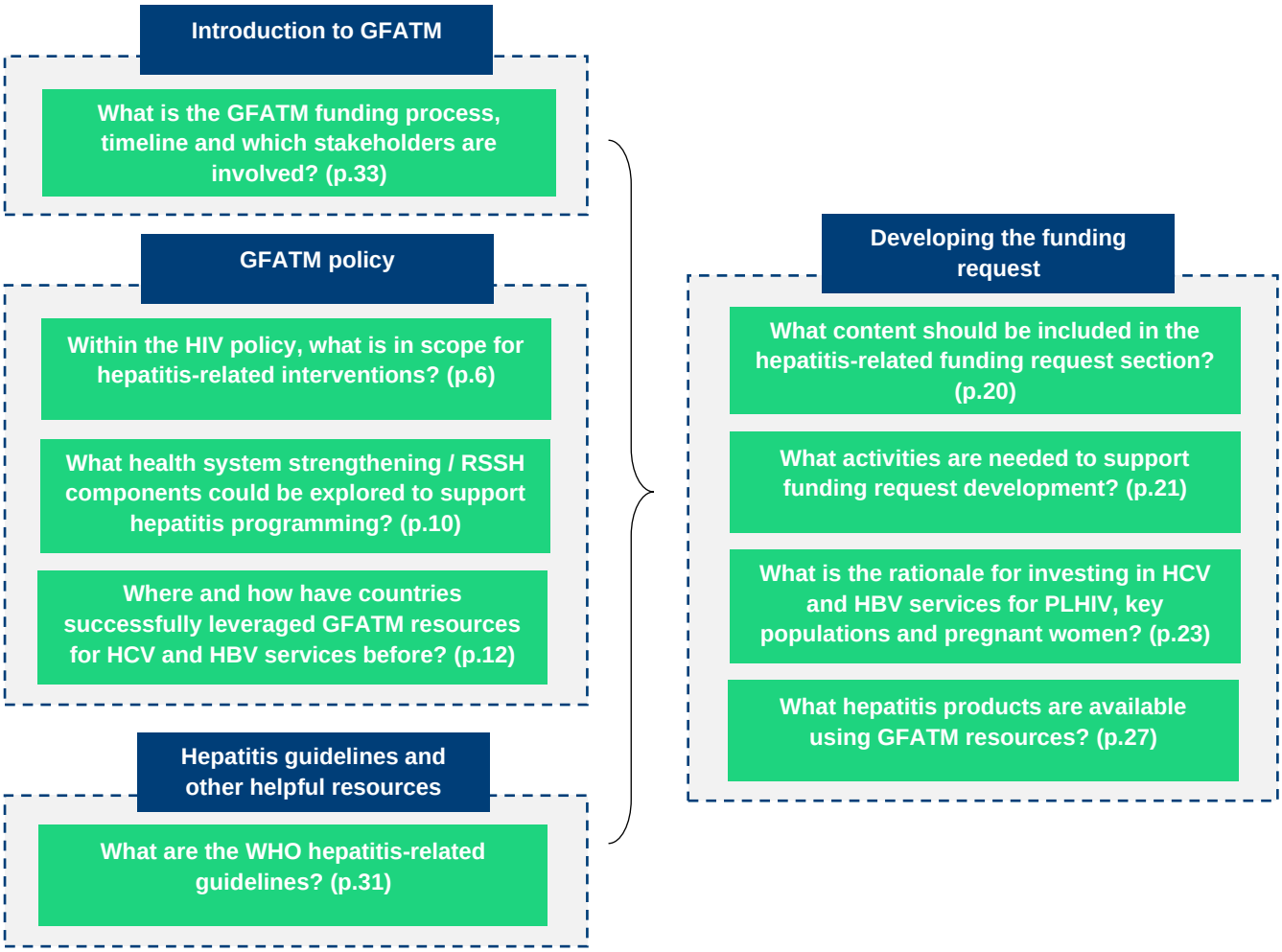
How to Use Toolkit

- This Toolkit is a comprehensive resource intended to be used by a wide set of stakeholders interested in exploring and including funding requests for GFATM resources to support hepatitis-related interventions in the 2023-2025 application (including but not limited to Ministry of Health, partners, civil society, and others).
- As not every section will be relevant to each user, the below navigation chart may help direct readers to the sections needed.



Glossary

ANC	Antenatal Care
ART	Antiretroviral therapy
CCM	Country Coordinating Mechanism
CE	Conformitè Europëenne
CHAI	Clinton Health Access Initiative
CHW	Community health worker
DAA	Direct-acting antiviral
EIA	Enzyme Immunoassays
ERP	Expert Review Panel
EXW	Ex-Works
FDC	Fixed Dose Combination
FOB	Freight on Board
FPM	Fund Portfolio Manager
FR	Funding Request
GAC	Grant Approval Committee
GFATM	The Global Fund to Fight AIDS, Tuberculosis and Malaria
HBeAg	Hepatitis B e-Antigen
HBsAg	Hepatitis B s-Antigen
HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
HCVST	Hepatitis C Virus Self-Test
HepB BD	Hepatitis B Birth Dose Vaccine
HIV	Human Immunodeficiency Virus
HRI	Harm Reduction International
INPUD	International Network of People Who Use Drugs
LFA	Local Fund Agent
LMIC	Low- and Middle- Income Countries
M&E	Monitoring & Evaluation
MOH	Ministry of Health
MMT	Methadone Maintenance Therapy
MTCT	Mother to Child Transmission
NFM4	New Funding Model 4
NGO	Non-governmental Organization
NSP	National Strategic Plan
OST	Opioid Substitution Therapy
PAAR	Prioritized Above Allocation Request
PLHIV	People Living with HIV
PMTCT	Prevention of Mother to Child Transmission
PPM	Pooled Procurement Mechanism
PQ'd	Pre-qualified
PR	Principal Recipient
PrEP	Pre-exposure Prophylaxis
PWID	People Who Inject Drugs
RDT	Rapid Diagnostic Test
RSSH	Resilient and Sustainable Systems for Health
SR	Sub-Recipient
SRH	Sexual and Reproductive Health
STI	Sexually Transmitted Infection
TB	Tuberculosis
TDF	Tenofovir Disoproxil Fumarate
TRP	Technical Review Panel
UNAIDs	United Nations Programme on HIV/AIDS
UNICEF	United Nations Children's Fund
UNODC	
US FDA	U.S. Food and Drug Administration
UQD	Unfunded Quality Demand
VL	Viral Load
WHO	World Health Organization

Introduction

Established in 2002, the Global Fund to fight AIDS, TB, and Malaria (GFATM) raises and invests funding to support efforts to end HIV, TB, and malaria as public health threats in countries worldwide. Since inception, GFATM has contributed to lifesaving programs across more than 100 low- and middle-income countries (LMIC). To inform the scope of these investments, GFATM typically facilitates strategy consultations to review and evolve funding policies every five years – with the latest strategy being for 2023-2028 period. In recent years, this has led to evidence-based expansions of policy to include interventions that address key co-infections and co-morbidities within the selected populations that GFATM supports.

Focusing on viral hepatitis, in 2015, GFATM published its first policy on HIV co-infection and co-morbidity commodity procurement, allowing for countries to request resources for the procurement of hepatitis C (HCV) drug and diagnostic commodities for people living with HIV (PLHIV) co-infected with HCV. Since then, GFATM policies have further evolved to support countries to integrate viral hepatitis prevention, diagnosis, and treatment into multiple service settings, including those that serve PLHIV, key populations and pregnant women. This approach is supported by a clear clinical rationale and delivering these services within existing HIV platforms has been demonstrated as feasible in many settings.

To date, these GFATM investments have proven to be catalytic for hepatitis programming in several countries. Rwanda, for example, began utilizing GFATM resources (through HIV grant underspend) in 2017 to support efforts to screen, diagnose HCV in all PLHIV on anti-retroviral therapy (ART) and initiate all co-infected persons on treatment. The integration of Rwanda's viral hepatitis program within its robust HIV program, supported by GFATM, and the adoption of a simplified public health approach to HCV testing and treatment, facilitated the decentralization and task-sharing of HCV services. The catalytic impact of GFATM investments contributed to Rwanda's success in micro-eliminating HCV among PLHIV in 2019. To date, all PLHIV have benefited and continue to benefit from continuous screening of hepatitis B virus (HBV) and HCV. The program continues to leverage GFATM support to procure diagnostic and treatment commodities which have contributed to over six million Rwandans screened and over 60,000 HCV treated patients.

Today, countries requesting GFATM HIV funding support for 2023-2025 are eligible for resources to address viral hepatitis needs among people living with HIV (PLHIV), key populations, and pregnant women. There is also scope to strengthen these services with programmatic investments under GFATM Resilient and Sustainable Systems for Health (RSSH) policy. Considering limited financial resources for hepatitis programs, this next funding round will be a critical opportunity for introducing and/or strengthening hepatitis programs within the population scope while using existing service delivery platforms, including HIV, harm reduction, antenatal, and primary care.

This toolkit aims to equip stakeholders interested in exploring this funding opportunity. Stakeholders interested in leveraging GFATM funding for hepatitis programming, must evaluate and define a strong, well-informed funding ask appropriate for the country context. Requesting resources for all populations in the GFATM funding scope will not make sense for every country context.

This toolkit provides a summary of policy scope for which populations can be supported with viral hepatitis services and potential activities to support viral hepatitis-related programming (i.e., health systems strengthening investments) it also includes country case studies of where GFATM resources have previously been leveraged for hepatitis programming, sections on the rationale for hepatitis-related investments, available products, global guidelines/resources, and outlines how to approach defining and advocating for funding ask.

Note: The next GFATM investment opportunity that countries can access is called "New Funding Model 4" and commonly referred to "NFM4" or "grant cycle 7". Windows for proposal submissions start in March 2023 and funding is available for the period of 2023-2025. Throughout the document the terminology used to describe the funding 'application' is used interchangeably with 'ask', 'submission', 'concept note', 'request' and 'proposal'.

GFATM Hepatitis-related Policies

GFATM policies have evolved to increasingly present a major opportunity for countries to request resources for viral hepatitis, harm reduction, and triple elimination. These policies can be found in GFATM HIV-related policy and guidance documents. Countries eligible for HIV funding allocation can explore these hepatitis-related funding opportunities for their context. Programmatic investments could also be made to support hepatitis service delivery through RSSH funding asks. Below summarizes this policy evolution and latest scope.

See **Country Case Studies** for examples of where GFATM support has been successfully applied for and utilized for hepatitis programming in Cambodia, Myanmar, Rwanda, Uganda, and Vietnam

2015

Policy on co-infections and co-morbidities

In 2015, GFATM published its policy on co-infections and co-morbidities ('COIM' policy), allowing for countries to request resources for the procurement of HCV drug and diagnostic commodities for PLHIV co-infected with HCV. This was a conditional policy and would only be considered if the investment aligned with country priorities and didn't displace financing for HIV. Since this policy was established, countries are increasingly including HCV rapid diagnostic tests (RDTs), viral load (VL) kits, and direct acting antivirals (DAAs) in their concept note submissions and allocating grant underspend to HCV commodities as well.

2020

Technical brief on harm reduction for people who use drugs

In 2020, GFATM published a technical brief[2] on Harm Reduction for People Who Use Drugs outlining "how interventions for people who use drugs are to be incorporated into funding requests to the Global Fund" and "strongly recommend that all countries with evidence of HIV transmission among people who use drugs include in their proposals harm reduction programs for people who use drugs". As the primary funder of harm reduction activities in LMICs, GFATM's brief clarifies that requests for harm reduction support can include HCV RDTs, viral load kits, and DAAs for people who inject drugs (PWID), whether they are PLHIV co-infected with HCV or people at risk for HIV infection that are mono-infected with HCV. The brief states that "Global Fund policy allows for the full harm reduction package to be included in funding requests, including HCV testing and treatment" – this includes all WHO-recommended disease-specific interventions, alongside sterile needles and syringes, naloxone, and opioid substitution therapies (OST).

[2] Note: active link to this brief is no longer available. Instead, stakeholders can refer to the latest Global Fund (November 2022): Technical Brief on Harm Reduction for people who use drugs

2021

GFATM 2023-2028 Strategy

The GFATM 2023-2028 strategy articulates support of widened scope for hepatitis programming – encouraging countries to integrate viral hepatitis prevention, diagnosis, and treatment into multiple service settings, including ART clinics, HIV prevention services, antenatal (ANC), sexual and reproductive health (SRH) and harm reduction settings – reaching PLHIV, key populations, and pregnant women. The term 'key populations' is used within HIV programs to encapsulate five vulnerable populations: men who have sex with men, sex workers, people in prisons and other closed settings, people who inject drugs, and trans and gender diverse people. For harm reduction, the strategy sets out the importance to close gaps in HIV prevention coverage including comprehensive harm reduction.

2022

Prioritization frameworks and technical briefs

In advance of the 2023-2025 application process, GFATM is publishing documents to guide Country Coordinating Mechanisms (CCMs) to understand the funding scope available. These policy documents articulate the scope of hepatitis-related interventions – this includes the following:

- Among PLHIV and key populations, access to prevention, screening, diagnosis and treatment for HBV and HCV, and vaccination for HBV can be provided regardless of HIV status. These services can be integrated into a number of different settings such as ART clinics, HIV prevention services, SRH settings, and harm reduction sites. There is an emphasized focus on including these interventions within harm reduction services for PWID and people in prisons/closed settings.
- Harm reduction is now a HIV "program essential" for applicants, meaning all applicants must describe status of harm reduction progress in the funding request; core and high impact countries must articulate a full plan harm reduction implementation in their applications. Top priority harm reduction interventions are needle and syringe programming (NSP), OST, and naloxone for overdose.
- Triple elimination of vertical transmission of HIV, syphilis, and HBV is a new focus supported by GFATM for pregnant and breast-feeding women: "Applicants are encouraged to prioritize integrated approaches to eliminate mother-to-child transmission of HIV, syphilis, and hepatitis B (triple elimination). This includes screening for HIV, syphilis, and HBV at ANC and linkage to tenofovir prophylaxis for pregnant and breastfeeding women with HBV who meet WHO eligibility criteria. As part of triple elimination efforts, the Global Fund can support integrated service delivery investments necessary for countries to move to hepatitis B vaccine birth dosing (excluding the vaccine costs)".

See **Annex 2** for more on GFATM Harm Reduction Resources and Policy Highlights

GFATM HEPATITIS-RELATED SCOPE SUMMARY

Within proposals with a HIV allocation, countries can request resources for the following interventions:

See **RSSH** for potential hepatitis-related programmatic investments that could be considered within the proposal

For PLHIV and all key populations regardless of HIV status[3]:

- ✓ Screening, testing + treatment for hepatitis B and hepatitis C, vaccination for hepatitis B within HIV prevention and treatment services, SRH services and harm reduction services
- ✓ For PWID and people in prisons and closed settings, HBV and HCV services to be delivered as part of harm reduction services and regardless of HIV status

See **Hepatitis Products Available to GFATM-supported Programs** for more information including pricing

For pregnant and breast-feeding women:

- ✓ HIV, syphilis, and hepatitis B testing during ANC visit + confirmatory testing and prophylaxis treatment
  - Note: Hepatitis B birth-dose vaccine for newborns is not covered by GFATM, but a case for resources to support programmatic delivery can be made. Other funding sources for Hepatitis B birth-dose (HepB BD) vaccine will need to be identified. Note, the vaccine cost is estimated to be US$0.24 per dose
  - Countries with established programming prioritization in prevention of vertical transmission of HIV and/or syphilis could be well placed to integrate HBV components

For harm reduction services:

- ✓ Provision of harm reduction interventions to be comprehensive and include OST, sterile needles and syringes, overdose prevention (naloxone) and other elements of the WHO recommended package of harm reduction interventions for people who inject drugs. Includes HBV vaccination, HBV and HCV screening, diagnosis, and treatment.
- ✓ Delivery within harm reduction settings including within prison/closed settings
- ✓ GFATM harm reduction policies, especially now as a 'program essential', enable countries to review these services and secure funding to improve coverage. (Only 1% of PWID living in countries with sufficient coverage of harm reduction interventions).[4]

[3] 'Key populations' include those defined by WHO as men who have sex with men, sex workers, people in prisons and other closed settings, people who inject drugs, and trans and gender diverse people. GFATM also includes sexual partners of key population groups within their policy. GFATM also include 'Prevention Package for Adolescent Girls and Young Women (AGYW) and Male Sexual Partners in High HIV Incidence Settings' and 'Prevention Package for Other Vulnerable Populations (OVP)' = defined as 'those who experience an increased vulnerability to HIV compared to the general population. Depending on the country context, this may include children and young people (aged 10-24 years), adolescent girls and young women (including those who are pregnant), orphans, people with disabilities, people living in extreme poverty, the homeless, mobile workers, displaced populations, and other migrants.'

[4] UNAIDs: Annotated outline of the global AIDS Strategy 2021–2026 (2020); Larney, S et al: Global, regional, and country-level coverage of interventions to prevent and manage HIV and hepatitis C among people who inject drugs: a systematic review (2017)

GFATM HEPATITIS-RELATED SCOPE SUMMARY

2023-2025 application process – GFATM documents that articulate scope of hepatitis-related investments:

See **Annex 3** for a summary of hepatitis-related activities from the Modular Framework Handbook

- Global Fund (July 2022): HIV Information Note
- Global Fund (July 2022) Modular Framework Handbook
- Global Fund (November 2022): Technical Brief on Harm Reduction for people who use drugs
- Global Fund (November 2022): Technical Brief on Prisons and Other Closed Settings

Documents to be published that may help further clarify scope:

- Guidance Note on Supporting Health and Longevity among People with HIV – to be published in December 2022

Opportunity Analysis:

- Considering limited funding for hepatitis programs, this next funding round will be a critical opportunity for countries to request GFATM funding to introduce and/or strengthen hepatitis programs, utilizing existing service delivery platforms (HIV, harm reduction, ANC, and primary care).
- Although GFATM scope cannot be used to fund comprehensive national hepatitis programs, funding can be mobilized to deliver hepatitis services among the specified target populations and to leverage HIV, ANC and harm reduction platforms and human resources to strengthen hepatitis programming. For some countries this could present an opportunity to complement existing hepatitis services; for other contexts, these policies could enable the introduction of hepatitis services for the first time.
- Requesting resources for all populations in the GFATM funding scope may not make sense for every country context. Stakeholders interested in leveraging GFATM funding for hepatitis programming, must evaluate and define a funding ask appropriate for the country context. Understanding the context of the HIV program performance and priorities, can help stakeholders identify opportunities to integrate hepatitis services.
- To access GFATM financing for hepatitis services for these target populations, countries will need to formulate a strong investment case informed by epidemiology, programmatic needs, and priorities (informed by relevant national strategic plans (NSPs) that speak to HIV, hepatitis, maternal and child health, harm reduction), potential impact/rationale including targets/cost at national and subnational levels, and how these investments can help improve outcomes for PLHIV, articulate program readiness, and plan for integration and implementation.
- Intentional stakeholder coordination and targeted country support will be needed to 1) ensure key stakeholders, including MOH, community advocates and partners, are aware of the widened policy, 2) The right stakeholders in-country carefully evaluate what hepatitis-related GFATM funding requests to prioritize based on country context (i.e., define the ask) and initiate advocacy and engagement with relevant stakeholders involved in prioritization for GFATM and concept note development to ensure hepatitis priorities are included in country proposal.

See **Tools: Funding Ask, Activities Checklist** for resources focused on what to include in funding ask and activities that may need to be undertaken

See **GFATM Application Process Overview** for more details on stakeholders involved in proposal development (including CCM)

Resilient and Sustainable Systems for Health (RSSH) allocation – through a 'Hepatitis Lens'

GFATM encourages countries to evaluate the role of RSSH-related investments beyond the stated investment scope for vertical programming of HBV and HCV within HIV-specific allocations for PLHIV, key populations, and pregnant women.

Countries should think about programmatic/systems strengthening investments (see below) within RSSH modules rather than solely within HIV allocation modules. Thus, there is scope for such programmatic investments to 1) directly support delivery of GFATM-supported integrated hepatitis services for the specified scope of populations and settings, and 2) potential to strengthen health programs overall, which could benefit populations beyond GFATM specified scope.

RSSH Interventions Related to Hepatitis Eligible for GFATM Support (not exhaustive):

- As outlined in the RSSH Information Note, RSSH activities have been framed by GFATM to support countries' efforts towards universal healthcare (UHC) by strengthening health systems and breaking down disease-specific silos.
- Within the Modular Framework Handbook, GFATM outlines pre-defined potential modules, interventions, and activities countries can explore for cross-cutting and health system strengthening; this includes 10 RSSH modules, broken down into over 50 interventions and over 400 activities.
- During country dialogue, applicants are encouraged to assess which activities are highly relevant to their context and consider their inclusion within the proposal.
- There are many potential areas where hepatitis could be considered within RSSH-activities – see examples below. These are starting point ideas. It is recommended to view this table (and Annex 4) as non-exhaustive and to review the contents alongside the Modular Framework Handbook and RSSH Information Note.

See **Annex 4** for longer summary of potential RSSH/hepatitis-related activities

Note: the table contents is summarized from the Modular Framework Handbook which contains pre-defined modules, interventions and activities. Activities listed have been framed to give an idea of how these programmatic investments could support hepatitis service delivery.

Table 1: Potential RSSH investments to support hepatitis programming

Module	Intervention	Example activities to support delivery of hepatitis services as part of strengthening of health systems (non-exhaustive)
Human Resources for Health and Quality of Care	Education and production of new health workers (excluding community health workers (CHWs))	• Training of health care workers and other staff to support roll-out of hepatitis services integrated within HIV, SRH, harm reduction, and ANC service settings • Implementation of supportive supervision for healthcare workers involved in delivery of integrated services that include hepatitis • Training and mentorship approaches to support community health workers that are involved in the delivery and/or referral to integrated services that include hepatitis • Development and roll-out of multi-disease training tools including digital solutions
	In-service training (excluding CHWs)	
	Integrated supportive supervision for health	

	workers (excluding CHWs)	
	CHWs: selection, pre-service training and certification; In-service training, Integrated supportive supervision	
Laboratory Systems (including national and peripheral)	National laboratory governance and management structures	Laboratory systems strengthening activities which could benefit multiple diseases, including hepatitis testing - e.g., • Optimizing existing equipment/platforms capacity which support testing for HIV, TB or other disease programs to also support disease testing for HCV and/or HBV • Multi-disease specimen transport and diagnostic network optimization exercises and implementation • Bring together multiple disease quantification efforts to determine laboratory consumables and diagnostics needs • For health facilities delivering integrated diagnostic services including hepatitis testing (e.g., antenatal care setting, harm reduction sites), efforts to assess and strengthen access to integrated diagnostics and referral/patient linkages could be carried out (e.g., assessment of availability of needed diagnostics, assessment of speed and quality of specimen referral networks for priority diseases and establishment of integrated referral networks) • Ensuring laboratory information systems are well integrated between facilities and diseases to capture/management of patient data and pathway • Interventions to improve the laboratory supply chain for the benefit of GFATM-supported disease testing and beyond • Establish and implement all-inclusive pricing modalities for laboratory reagents that include service, maintenance, and training for equipment • Maximize lab systems and monitoring and evaluation (M&E), training opportunities through a multi-disease approaches
	Laboratory Information Systems	
	Network optimization and geospatial analysis	
	Laboratory supply chain systems	
	Specimen referral and transport system	
Monitoring and Evaluation Systems	Routine reporting	M&E activities including multiple diseases like hepatitis - e.g., • Developing and implementing national M&E framework, indicators, reporting tools/forms • Efforts to implement interoperable and integrated M&E systems across diseases systems • Adoption of M&E systems • Improving M&E data quality e.g., disease-specific and/or cross-cutting data quality assurance activities such as disease specific data quality audits • Digital and health information management improvements e.g., innovative digital health tools such as utilizing SMS (short message service) to improve patient engagement and follow up, using mobile apps to upgrade electronic health records, logistics and patient management information systems
	Data quality	
	Analyses, evaluations, reviews, and data use	

Country Case Studies

This section includes examples from countries where GFATM resources have been requested and leveraged to support hepatitis-related interventions. Where possible, information on country context, support requested (with excerpts from the application), what was approved, and impact has been included.

Note: GFATM Data Explorer website provides a public resource of prior country funding application request documents

Cambodia

Addressing HCV coinfection among PLHIV

Addressing HBV MTCT among pregnant women

- In Cambodia, HCV prevalence in the general population is estimated at 1.6%.
- From 2017 to 2019, underspend in the GFATM HIV portfolio was reprogrammed to screen, diagnose, and treat 68% of the national adult cohort on ART for HCV.
- Results from the HIV/HCV co-infection program have informed the development of a national strategic plan (NSP) and clinical guidelines towards the goal of Cambodia reaching 2030 HCV elimination targets.[5]
- For the latest grant period (2020 - 2022), Cambodia secured continuation of HCV screening and treatment of the unscreened HIV ART cohort (approximately 20,000 PLHIV) under the HIV Prioritized Allocation funding:
    - "Intervention: Prevention and management of co-infections and co-morbidities. Key activities: HCV care and treatment: screening of all unscreened currently registered PLHIV and newly registered PLHIV, provision of HCV treatment for co-infected PLHIV."[6]
- During implementation, ministry stakeholders aligned to expand access to partners of PLHIV and those on pre-exposure prophylaxis (PrEP).

- In Cambodia, HBV prevalence (HBsAg) among mothers is estimated to be 4%
- Through a collaborative partnership between the relevant Ministry-led programs, the first prevention of mother to child transmission (PMTCT)[7] Strategy (2007 – 2015) focused solely on HIV and achieved a reduction of HIV MTCT HIV from 37%in 2007 to 14% in 2018. Cambodia's second PMTCT Strategy (2016 – 2020) expanded this effort to include syphilis and HBV.
- For three successive GFATM cycles, Cambodia has leveraged RSSH portions of GFATM funding to support elements of integrated ANC services.
- For the current grant period (2020 - 2022) RSSH allocation, GFATM supports triple elimination efforts in Cambodia, by including HBV screening within the ANC setting:
    - Intervention: "Introduce Triple Elimination through antenatal screening/treatment for HBV in Phnom Penh area health centers, referral hospitals and National Hospitals (total of 100,000 ANC clients a year, >25% national total). Phnom Penh has been selected for initial introduction because capacity to treat HBV in pregnancy is already in place in the National Hospitals, which is not yet the case in most rural provinces. Additionally, its proximity will facilitate close monitoring and problem-solving during the introduction".[8]

[5] BMJ Global Health (Dec 2020), Initial success from a public health approach to hepatitis C testing, treatment and cure in seven countries: the road to elimination

[6] Cambodia GFATM HIV Funding Application 2020 – 2022

[7] Also known as vertical transmission

[8] Cambodia GFATM RSSH Funding Application 2020 – 2022

Myanmar

Addressing HCV coinfection among PLHIV

Addressing HCV infection among key populations (people who inject drugs, sex workers and men who have sex with men)

- Myanmar's HCV prevalence is 2.65% among general population. There are an estimated 93,000 PWID, with HCV prevalence among this group estimated at 56%.
- HIV NSP (2021-2025) aimed to micro-eliminate HCV within PWIDs, and planned to treat ~50,000 of HCV within the NSP coverage period.
- Within the 2020-2022 funding request, within the main allocation for HIV, Myanmar requested funding support for HCV care among PLHIV and comprehensive services for PWID and persons in prisons:
    - "The comprehensive harm reduction package, or HIV prevention package for PWID, includes the provision of sterile needle and syringe, expanded access to psychological counselling/ psychoeducation (new), condom access, testing and treatment of Sexually transmitted infections (STIs), community-based HIV screening and referral for HIV testing, referral to and follow-up of ART treatment, overdose management, Hepatitis C (HCV) testing and treatment, and access or referral to OST, drug treatment and other social welfare services. Community-based overdose management will be initiated with Naloxone (new). The National AIDS Program (NAP), the National Hepatitis Program (NHP) and the Drug Dependency and Treatment Research Unit (DDTRU) of the Ministry of Health and Sports will collaborate on the provision of HCV treatment services for 10,000 PWID for those co-infected with HIV/Hepatitis C (new)."[9]

See **Annex 5** for example application language from Myanmar 2020-2022 Application

- Myanmar received approval to procure sufficient commodities (VL and DAAs) to find and treat 10,000 HIV/HCV co-infected patients in key populations such as PLHIV on ART, PWIDs, female sex workers and men who have sex with men from 2021-2023
    - Due to instability within the country, implementation was disrupted though expected to resume in 2023.

[9] Myanmar HIV, TB [including hepatitis C] and building resilient and sustainable systems for health GFATM Funding Application 2020 – 2022

Rwanda

Addressing HCV coinfection among PLHIV

- Before the launch of Rwanda's HCV elimination program in 2018, the HCV antibody prevalence was estimated at 4%.
- Rwanda's HCV program was initiated in 2014 prioritizing high-risk populations for HCV infection – beginning with the PLHIV ART cohort, which was supported through reprogramming of unspent GFATM resources.[10] Rwanda began utilizing GFATM underspend in 2017[11], which enabled the integration of Rwanda's viral hepatitis program within its robust HIV program and utilization of trained health providers from within the HIV program. Similarly, the viral hepatitis program used the HIV diagnostics infrastructure for sample transportation and laboratory functions. This momentum led to a political commitment by Rwanda in 2018 to eliminate HCV within five years. This commitment combined with the already-established integration of the program within HIV, enabled the government to negotiate the lowest-ever price for World Health Organization (WHO) Pre-Qualified (PQ'd) Direct Acting Antivirals (DAAs) at US$60 per person per course. In addition, through pooling of volumes, Rwanda secured a 60% reduction in the price of viral load cartridges for both HIV and HCV viral load tests. These catalytic investments contributed to Rwanda's success in micro-eliminating HCV among PLHIV in 2019 and helped advance towards the political commitment of Rwanda in 2018 to eliminate HCV within five years.
- In 2021, Rwanda continues to leverage GFATM resources to scale-up its HCV program in an integrated manner with the HIV program and services. To date, the HCV program has screened over 6 million people and initiated over 60,000 people on treatment. For the current grant period (2020 – 2022), Rwanda included specific language for HCV resourcing for HIV/HCV co-infection and has secured US$3 million for HCV commodities under the HIV Prioritized Allocation Funding Request:
    - "Viral load suppression data from the RPHIA (Rwanda Population-based HIV Impact Assessment (national survey)) shows that 90.1%of PLHIV on treatment are virally suppressed. There is need to prevent and treat opportunistic infections that can arise in about 10%of PLHIV on ART who are not virally suppressed. Moreover, as the program has been performing well and reducing HIV-related deaths, HIV has become a chronic condition. Therefore, there is an age shift whereby a higher proportion of PLHIV are above 55 years old and are more likely to develop NCDs. Hence, focus on comorbidities is paramount. Main activities: Hep B and C RDTs and treatment drugs OI medicines."[12]

[10] BMJ Global Health (Dec 2020), Initial success from a public health approach to hepatitis C testing, treatment and cure in seven countries: the road to elimination

[11] Bulletin WHO – Policy & Practice (2018), Controlling hepatitis C in Rwanda: a framework for a national response

[12] Rwanda GFATM HIV Funding Application 2020 – 2022

Uganda

Addressing HBV MTCT among pregnant women as part of a Triple Elimination Approach

- Chronic HBV prevalence in the general population is 4.1 percent in Uganda.
- Within the 2020-2022 Joint TB-HIV funding request, Uganda articulated gaps in syphilis and hepatitis B diagnosis and management within HIV PMTCT services and requested resources to address these gaps under the 'Prevention of mother-to-child HIV transmission (dual elimination of MTCT of HIV and syphilis)' module:
    - Interventions to include: "HIV/syphilis/hepatitis B services that include identification, treatment and care of infected HIV pregnant and breastfeeding women and their exposed infants; strengthening the human resource and infrastructure capacity; improvement in logistics and supplies; promotion of advocacy and community mobilization; enhancing referral links with other programmes and services; and strengthening monitoring, quality assurance and evaluation. The overall goal is to achieve and sustain elimination of MTCT of HIV, syphilis and hepatitis B through reducing transmissions by 95%"[13]
- During implementation, GFATM resources were used to test over 30% of the pregnant women population for HBV. This funding contributed to the procurement of HBV VL kits, shared sample transport logistics and laboratory platform, procurement and monitoring & evaluation leading to significant system strengthening (RSSH).
- These investments have been catalytic in strengthening the overall ANC platform including the commencement of HBV screening as part of routine ANC testing (2022) in selected sites.

[13] Uganda GFATM Joint TB-HIV Funding Application 2020 – 2022

Vietnam

Addressing HCV coinfection among PLHIV

Addressing HCV infection among people accessing methadone services and people in prisons

- Vietnam's HCV prevalence is between 1%1% and 3.3%%. Among PLHIV, HCV prevalence is estimated at 34.4%.
- HCV commodities (RDTs, VL, and DAA) have been included in the national social health insurance scheme as of late 2018, with DAA reimbursable at 50%of cost at public facilities, with the rest co-paid by patients. With overall high prices of DAA in Vietnam, access is limited for most of the population who are unable to afford the co-payment required. This is particularly so for vulnerable groups such as PLHIV, PWID and prisoners.
- Under the 2018 – 2020 GFATM HIV grant, Vietnam requested a budget of US$1.2 million for 16,000 DAA treatment courses for PLHIV co-infected with HCV as part of the Prioritized Above Allocation Request. In 2020, Vietnam secured this allocation through underspend during the grant cycle. The following language was used to advocate for HCV funding back in 2018:
    - "HIV epidemic in Vietnam is driven by people who inject drugs (PWID). Since sharing injecting equipment is a major transmission route for Hepatitis C, prevalence among PWID is very high ranging from 31% to 98% as reported in previous study (Sereno L et all, 2012). Among HIV patients, data from Integrated Biological and Behavioural Surveillance (IBBS) show prevalence of HCV coinfection at 27% (Nadol P et al 2015). There is remarkable development of direct-acting agents (DAAs) as "break-through" medicines for hepatitis C treatment in recent years. Up to 95% of people with hepatitis C infection can be cured in 3 to 6 months. These new medicines are more efficacious, having less adverse effects and convenient for patients, compared to older medicines, e.g., interferon or pegylated interferon with ribavirin. Hepatitis C is major cause of cirrhosis, liver cancer in Vietnam. Without treatment, HIV/HCV co-infected patients could die because of advanced hepatitis such as decompensated cirrhosis and liver cancer. However, as new medicines, DAA has not [yet] been included for reimbursement by health insurance, thus access to the lifesaving treatment of HCV is not yet available for HIV/HCV co-infected patients. VAAC proposes to provide treatment for 1,000 HIV/HCV co-infected patients with SOF/LDV for 3 months. Estimated at least 900 patients will be cured from hepatitis C. Providing hepatitis C treatment service will be capacitated for 40 doctors and nurses at 10 selected OPCs in 2 provinces."[14]
- Subsequently, in reaction to challenges faced by patients to progress through the cascade of care, the co-infection program requested an additional US$500,000 from the GFATM to provide approximately 11,500 VL tests free of charge for patients unable to access VL via health insurance, as well as cover co-payment for patients unable to afford the same.
- With GFATM funding, from May 2021 to June 2022, Vietnam successfully reached its goal of initiating 16,000 patients with HCV on treatment.
- Some of the factors contributing to the success of the program implementation included:
    - Commitment and support from MOH leaders in the form of the issuance and dissemination of legal documents to provinces to provide implementation guidance and reinforce program goals.

[14] Vietnam GFATM HIV Funding Application 2020 – 2022

- The coinfection program technical working group advocated to the national HIV program and GFATM to expand reach from the initial target population of only PLHIV coinfected with HCV to address HCV mono-infection among Methadone Maintenance Treatment (MMT) clients and people in prisons. This enabled the program to utilize all treatment courses within the planned implementation period and broadened access to HCV care among those who face increased risk of HIV and HCV infection.
- The use of GFATM resources to cover some portion of HCV VL, enabled access by patients previously unable to access or co-pay for VL.
- Adoption of a diversified service delivery model to include mobile clinics and blood sample referral for VL rather than patient referrals in peripheral areas.
- Increased patient awareness through distribution of IEC materials including pamphlets.
- Standardized training curriculum for healthcare workers and checklists for supervisory and mentorship site visits.
- Coverage of RDTs and other blood tests by the national health insurance for eligible patients.
- Leveraging the program's success, Vietnam intends to request for additional funding from the GFATM to diagnose and treat another 13,000 patients in the next few years. Thus far, the country has secured approval from the GFATM to procure commodities for another 5,000 treatment courses along with some VL to arrive in early 2023.

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Lessons Learned from Case Studies

Stakeholders to develop the funding ask:

- Evaluating how and where GFATM resources could be leveraged to support hepatitis-related services requires engaging multiple stakeholders to build a strong understanding of the landscape and consensus on what the funding ask could be.
- Engagement could include those involved in supporting HIV, viral hepatitis, harm reduction and/or maternal child health services across national program staff, community members, technical working groups, technical assistance, and technical partners.
- When aligning on proposed interventions consider using a patient-centered approach to outline the individual groups' progress through the cascade of care, identify challenges, and then outline solutions.
- Depending on the proposed intervention, explore engagement with the programs and implementers delivering care for PLHIV and/or key populations and/or pregnant women.
- Pre-developed relevant NSPs that speak to HIV, hepatitis, maternal and child health and/or harm reduction can help to inform and justify the requested resources. If a national program for hepatitis has been established, they may be best placed to develop program targets and costing.
- Engagement with those involved in HIV grant implementation can also help shape the hepatitis-related funding ask.

Advocacy approach:

- Not all those involved in proposal development will be aware of GFATM latest policies, therefore it is important to increase awareness of hepatitis-related policies.
- Take a multi-pronged engagement approach to garner buy-in across stakeholders/representatives.
- Process can take many months and requires lots of partner coordination; it is important to be proactive.
- Identify who is the best stakeholder to advocate for the funding ask within respective settings
- If possible, leverage existing or establish relationships with stakeholders directly involved in the CCM and/or CCM Oversight Committee to understand the proposal development process and gauge funding priorities being discussed.
- When you identify that CCM members and others who can influence the development of the proposal are not aware of the hepatitis need/interventions, active outreach and awareness-building will be important and can even lead to the creation of 'hepatitis champions' within the CCM. It might be helpful to identify potential influencers around these individuals, and start from there
- Approach stakeholders with an ask that:
    - Has solid clinical rationale supported by data
    - Clear implementation plan built with MOH alignment
    - Good M&E plan for measuring progress
    - Is well aligned with GFATM priorities
    - Articulates non-GFATM commitments that will support intervention
- Even if funding is not secured during the targeted cycle, efforts to bring partners together, and advocate around a defined need can lay a solid foundation for engaging on future funding opportunities/cycles.

See **Tools: Funding Ask, Activities Checklist** for resources focused on what to include in funding ask and activities that may need to be undertaken

Community role:

- Community voices are critical. They are important representatives and champions of the funding ask – in many contexts, the voices of those representing people living with viral hepatitis and other community members were highly effective advocates for inclusion of hepatitis elements in funding applications.
- When stakeholders are discussing and aligning on funding gaps and priorities, coordination, and inclusion of all relevant community members, representing people living with hepatitis, HIV, TB and malaria and people from key populations, can ensure all voices are heard and advocates have a shared alignment and messaging to those involved in proposal development decisions.

- Can be difficult to garner support for interventions for people who inject drugs without representation of these community members within the CCM/proposal development.
- For NFM4, maximize the opportunity to capture community priorities within a new community-focused annex of the proposal submission.

See **GFATM Application Process Overview** for more details on stakeholders involved in proposal development

Tools

Funding Request – Content Required

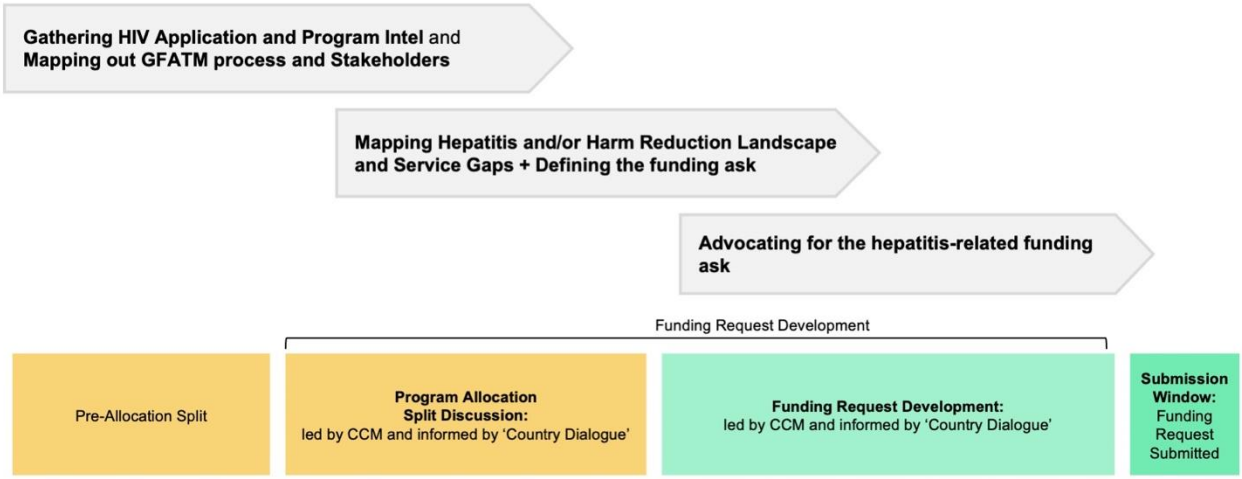
To access GFATM financing for hepatitis services for target populations, requires a strong investment case that is context-relevant and aligned with in-country priorities from community, ministry, and technical stakeholders. For the proposed intervention, the funding ask should articulate:

- Epidemiology
  - Disease burden of HCV and/or HBV
  - Population size
- Programmatic needs and priorities
  - How the proposed intervention aligns with National Strategic Plans (NSPs), elimination goals, community needs and GFATM priorities
  - Current service coverage and gaps
- Potential impact/rationale including targets/cost at national and subnational levels
  - Population targets and timelines, supported by estimated budget
  - What proportion/number of target population will be reached
  - Clinical benefits of the intervention e.g., improved HIV outcomes, reduced risk of HIV and HCV transmission
  - If relevant, articulate what these investments could lead to e.g., introduction/demonstration of services will enable development of a service delivery model that can be further scaled in future with additional funding
- Articulate program readiness and absorption capacity
  - Contexts that are well-positioned to absorb additional resources and implement have improved chances of securing the resources
  - Articulate who will implement and why they will do a good job
  - Articulate how progress against plan will be measured e.g., M&E
- Articulate non-GFATM financial commitments / co-financing e.g., domestic resources and/or other donors, that will support proposed intervention
- Articulate the plan for integration and implementation including what programmatic investments are needed to support successful implementation e.g., training, diagnostic infrastructure, digital tracking

See **Annex 5** for example application language from Myanmar 2020-2022 Application

Activities Checklist

Figure 1: Illustrative sequencing of funding request development



Objectives of this process could include:

- Inclusion of defined hepatitis-related ask within the Prioritised Allocation and/or PAAR
- Inclusion of hepatitis-related priorities within Communities & Civil Societies Funding Priorities Annex

Table 2: Example activities to support hepatitis-related funding request advocacy and development

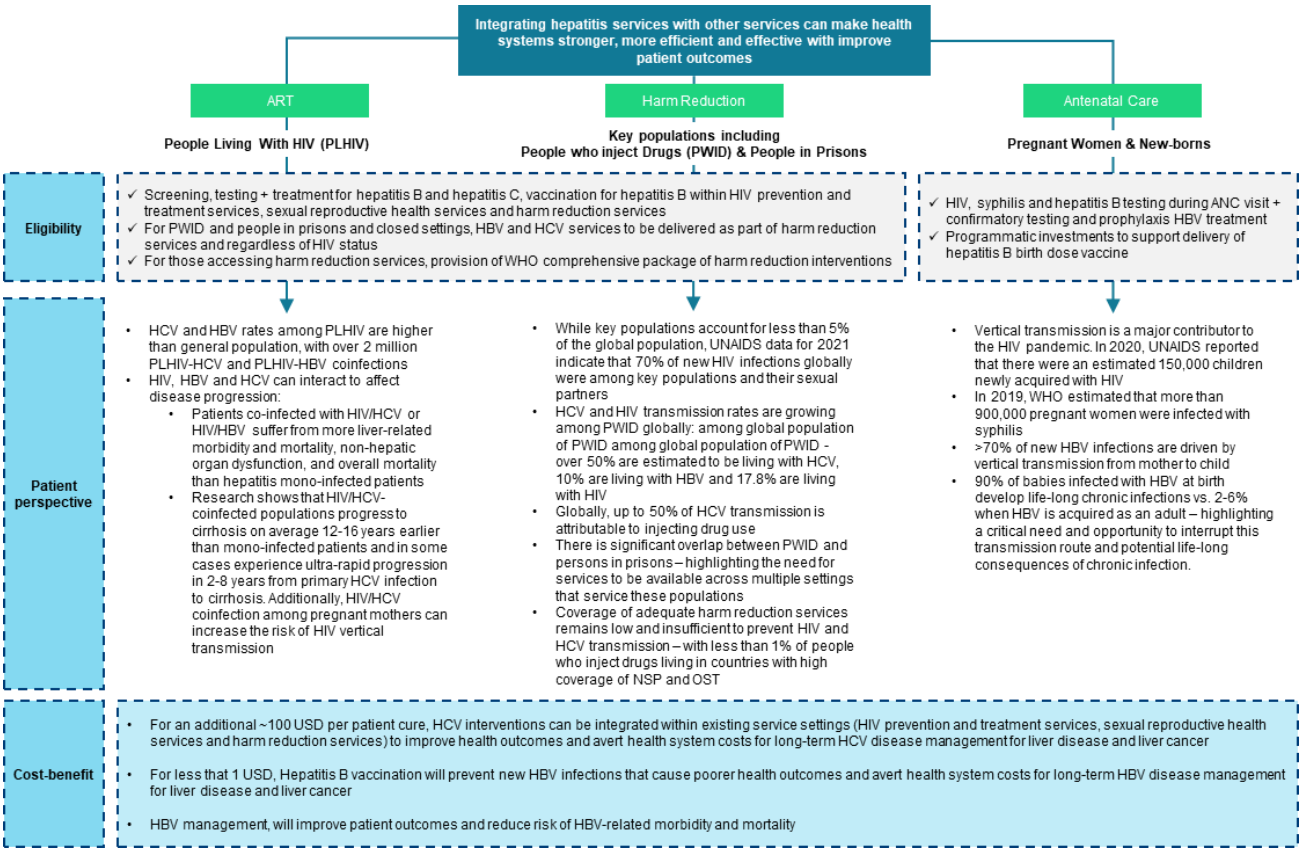
Gathering HIV Application and Program Intel ** Note: this intel can help identify opportunities for synergies and where hepatitis programming can optimize HIV prevention and treatment outcomes*	Determine: ☐ Is the country eligible for HIV funding in 2023-2025 allocation? ☐ Which application window will the country submit into? ☐ What type of proposal is the country submitting? See **GFATM Application Process Overview** for more details Engage with stakeholders and review the prior HIV funding request and HIV landscape, to understand*: ☐ The status of HIV epidemic and program ☐ How is the GFATM-supported HIV program performing? ☐ Are there some gaps the program is struggling with? ☐ What are the priority HIV areas – i.e., vertical transmission, key populations, harm reduction, advanced HIV disease? ☐ How does the HIV allocation amount compare to previous cycle? ☐ For this cycle, how much has the CCM indicated will be allocated to RSSH? ☐ What are the priorities within the relevant NSPs that speak to HIV, hepatitis, maternal and child health, harm reduction?
Mapping out GFATM process and stakeholders	Map out: ☐ How will the concept note development for HIV occur? ☐ Who is involved in developing the concept? i.e., CCM stakeholders ☐ Who is involved in writing the proposal? ☐ What is the process for input, review, and approval? ☐ What is the overall timeline and key decision-making dates?

	▯ When are there forums for civil society and community members to discuss funding priorities? And who will participate in this? Are there opportunities for hepatitis advocates to engage in this process? ▯ When mapping stakeholders, identify where there are existing relationships and interest in hepatitis-related programming versus where new relationships and awareness-raising will be required ▯ Identify if there are CCM and/or community stakeholders who could represent a hepatitis-related funding ask in the proposal development process
Mapping Hepatitis and/or Harm Reduction Landscape and Service Gaps **+** **Defining the funding ask**	▯ Identify stakeholders to engage and to understand the hepatitis-related landscape and needs e.g., Ministry of Health, local non-governmental organizations (NGOs) focused on services for PLHIV / key populations / pregnant women, community members, technical partners ▯ Determine which stakeholders should be engaged to provide input on prioritizing and defining the funding ask Landscape intel to understand: ▯ Review relevant NSPs that speak to HIV, hepatitis, maternal and child health, harm reduction to inform the defining of funding priorities and identify content that could be used/adapted to define targets and investment case for funding ask ▯ Summarize the hepatitis burden and gaps in existing programming across PLHIV, key populations, and pregnant women ▯ Formulate initial evaluation on where GFATM funding policies could be leveraged to address program gaps Using consultative stakeholder engagements through workshops and meetings to build consensus on: ▯ Understanding the GFATM hepatitis-related policies and hepatitis-related landscape/context ▯ Determine hepatitis-related gaps and priorities in services for target populations and how the GFATM policies could be used to mobilize resources to address gaps ▯ For the proposed GFATM-supported intervention, evaluate: o Epidemiology and need o Propose targets and costing o Program – who and where could this work be done o Program infrastructure readiness to integrate/expand proposed hepatitis-related services o Where GFATM versus non-GFATM resources will be used to support proposed program
Advocating for the hepatitis-related funding ask *Note: during advocacy, the funding ask may need to be adjusted/iterated on*	▯ Determine critical stakeholders and when to engage them ▯ Review who has existing relationships they can leverage for these engagements ▯ Using stakeholder and timeline mapping, build an advocacy work plan. Include hepatitis community members/ civil society groups. Across advocacy effort, ensure clear roles and responsibilities and track progress using the work plan ▯ Develop materials to support advocacy efforts e.g., articulating the widened GFATM policy and proposed funding ask ▯ Coordinate and facilitate advocacy engagements

Rationale for Making Hepatitis-related Investments Among Populations in Scope

For applicants interested in articulating rationale for investments during the funding advocacy process and/or within the funding request submission, the figure and text below can be used as a starting point.

Figure 2: Summary of rationale for making hepatitis-related investments among PLHIV, people who inject drugs and people within closed/prison settings, and pregnant women and new-borns



In 2019, there were an estimated 1.5 million new HIV, HBV, and HCV infections respectively. While decades of investments have resulted in strong progress in HIV diagnosis and treatment, HBV, and HCV lag with around 10% and 26% of those with chronic HBV and chronic HCV diagnosed and even fewer treated.[15] A lack of progress in viral hepatitis means poorer outcomes for people living with HIV (PLHIV), key populations, and pregnant women and their newborns. An estimated one in ten people with HIV are thought to be co-infected with viral hepatitis.[16,17] Most new HBV infections are driven by vertical transmission[18] which can be effectively prevented through screening and treatment prophylaxis in pregnant women, and timely HepB BD vaccination among newborns.

[15] WHO: Global progress report on HIV, viral hepatitis and sexually transmitted infections (2021)
[16] Platt, L et al: Prevalence and burden of HCV co-infection in people living with HIV: a global systematic review and meta-analysis (2016)
[17] Platt, L et al: Prevalence and burden of HBV co-infection among people living with HIV: A global systematic review and meta-analysis (2019)
[18] Also referred to as mother-to-child transmission (MTCT)

ART and Harm Reduction

HCV and HBV rates among PLHIV are higher than in the general population, with over 2 million PLHIV-HCV and PLHIV-HBV coinfections. When left untreated, HBV or HCV can cause liver damage, hepato-cellular carcinoma (liver cancer) and mortality. HBV and HCV are a leading cause of mortality among PLHIV[19].

HIV, HBV, and HCV can interact to affect disease progression:

- Patients co-infected with HIV/HCV or HIV/HBV suffer from more liver-related morbidity and mortality, non-hepatic organ dysfunction, and overall mortality than hepatitis mono-infected patients.[20]
- Research shows that HIV/HCV-coinfected populations progress to cirrhosis on average 12-16 years earlier than mono-infected patients and in some cases experience ultra-rapid progression in 2-8 years from primary HCV infection to cirrhosis.[21]
- Additionally, HIV/HCV coinfection among pregnant mothers can increase the risk of HIV vertical transmission.[22]

Effective ART and harm reduction programs can prevent cirrhosis, liver cancer, and death by integrating HCV and HBV screening, diagnosis, and care among PLHIV, people who use drugs (PWUD), and prisoners – for HCV curative treatment with DAAs will help progress towards eliminating the disease within these populations. For PLHIV, viral hepatitis diagnosis and care will optimize their HIV and overall health outcomes. For HIV-negative PWUD and prisoners, viral hepatitis services in screening, diagnosis and treatment provide a novel opportunity to strengthen HIV prevention services and outcomes.

While key populations account for less than 5 percent of the global population, UNAIDS data for 2021 indicate that 70 percent of new HIV infections globally were among key populations and their sexual partners.[23] Furthermore, key populations face alarmingly high rates of co-infections and co-morbidities, such as viral hepatitis, STIs, mental health, and substance use issues. Among prisoners, for example, UNODC estimates that up to 50% use or inject drugs[24], with unsafe injecting practices - a major risk factor for the transmission of HIV and HCV. HCV and HIV transmission rates are growing among PWIDs globally: among global population of PWID - over 50% are estimated to be living with HCV, 10% are living with HBV and 17.8% are living with HIV[25]. Coverage of adequate harm reduction services remains low and insufficient to prevent HIV and HCV transmission – with less than 1% of people who inject drugs living in countries with high coverage of NSP and OST.[26]

Key populations often overlap. For example, a transgender woman may also be a sex worker and a person who inject drugs. She may have periods of incarceration, often as a result of her gender identity, substance use or means of generating income. Key populations, in addition to having inadequate access to health services, frequently experience stigma, discrimination, violence and criminalization, hampering efforts to provide access to health services needed.

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[19] Sherman KE, Rockstroh J, Thomas D. Human immunodeficiency virus and liver disease: An update. Hepatology. 2015; van der Helm J, Geskus R, Sabin C, et al. Effect of HCV infection on cause-specific mortality after HIV seroconversion, before and after 1997. Gastroenterology. 2013; Hernando V, Perez-Cachafeiro S, Lewden C, et al. All-cause and liver-related mortality in HIV positive subjects compared to the general population: differences by HCV co-infection. J Hepatol. 2012; Rockstroh JK, Mocroft A, Soriano V, et al. Influence of hepatitis C virus infection on HIV-1 disease progression and response to highly active antiretroviral therapy. J Infect Dis. 2005; Weber R, Sabin CA, Friis-Møller N, et al. Liver-related deaths in persons infected with the human immunodeficiency virus: the D:A:D study. Arch Intern Med. 2006

[20] Konopnicki, D et al: Hepatitis B and HIV: prevalence, AIDS progression, response to highly active antiretroviral therapy and increased mortality in the EuroSIDA cohort (2005); Maria D Hernandez, Kenneth E Shermany: HIV/hepatitis C coinfection natural history and disease progression (2011); Pineda, JA, et al. HIV coinfection shortens the survival of patients with hepatitis C virus-related decompensated cirrhosis (2005)

[21] Pineda JA, Romero-Gómez M, Díaz-García F, et al. HIV coinfection shortens the survival of patients with hepatitis C virus-related decompensated cirrhosis. Hepatology. 2005; Ragni MV, Eghtesad B, Schlesinger KW, Dvorchik I, Fung JJ. Pretransplant survival is shorter in HIV-positive than HIV-negative subjects with end-stage liver disease. Liver Transpl. 2005; de Lédinghen V, Barreiro P, Foucher J, et al. Liver fibrosis on account of chronic hepatitis C is more severe in HIV-positive than HIV-negative patients despite antiretroviral therapy. J Viral Hepat. 2008

[22] Polis, C et al: Impact of Maternal HIV Coinfection on the Vertical Transmission of Hepatitis C Virus: A Meta-analysis (2007)

[23] UNAIDS: Global Update (2022)

[24] https://www.unodc.org/unodc/en/hiv-aids/people-who-inject-drugs-in-prison.html

[25] Degenhardt, L et al: Global prevalence of injecting drug use and sociodemographic characteristics and prevalence of HIV, HBV, and HCV in people who inject drugs: a multistage systematic review (2017)

[26] Larney, S et al: Global, regional, and country-level coverage of interventions to prevent and manage HIV and hepatitis C among people who inject drugs: a systematic review (2017)

Antenatal Care

While most pregnant women are screened and treated for HIV during antenatal care (ANC) to prevent transmission to their babies, coverage of interventions to prevent vertical transmission of HBV has lagged. [27] Investments in HIV ANC platform can be further leveraged to maximize touch points for women and children and ensure the provision of comprehensive care for HIV and other diseases such as HBV and syphilis; this is key for a triple elimination approach, preventing vertical transmission and ensuring optimal mother and child health and survival.

Vertical transmission is a major contributor to the HIV pandemic. In 2020, UNAIDS reported an estimated 150,000 children newly acquired HIV and 1.8 million children were living with HIV. Without interventions, HIV can be transmitted from women living with HIV to their babies during pregnancy, labor, delivery, and after delivery through breastfeeding. Infants and young children infected with HIV can result in early mortality, higher risk of morbidity, shorter life expectancy, and significant lifelong socioeconomic costs. [28]

Syphilis can be transmitted through sexual exposure or from mother to child during pregnancy. If left untreated, more than half of the pregnancies among women with active syphilis can result in adverse birth outcomes including stillbirth, early neonatal death, low-birthweight, or serious neonatal infections. In 2019, WHO estimated that more than 900,000 pregnant women were infected with syphilis.[29] The total number of congenital syphilis was estimated at 661,000 which included 355,000 adverse birth outcomes. 57% of these occurred in pregnant women who had attended ANC but were not screened for syphilis.[30]

It is estimated that viral hepatitis is responsible for 1.1 million deaths from acute infection and hepatitis-related liver cancer. In 2019, WHO estimated 820,000 deaths annually are attributed to HBV infection. The primary routes of transmission are vertical and early childhood transmission. Notably, 90% of babies infected at birth develop life-long chronic infections versus a much smaller percentage of 2-6% when HBV is acquired as an adult[31], highlighting a critical need and opportunity to interrupt this transmission route and potential life-long consequences of chronic infection.

Several countries have adopted policies on the use of the dual HIV/syphilis RDT within ANC settings. Among these, countries have demonstrated growing momentum towards the triple elimination agenda with active and growing HBV programs. These countries have showcased political will, financing mechanisms and models of implementation and integration, often building off the foundation of the dual HIV/syphilis ANC services. Despite momentum, gaps throughout the continuum of care do persist, with HBV testing rates still well below those for other disease areas.

Opportunity for Integrated Service Delivery for Pregnant Women

WHO recommends that all pregnant women should be tested for HIV, syphilis, and HBsAg at least once and as early as possible in pregnancy.

Despite overlapping synergies within reproductive, maternal, newborn, and child health (RMNCH) platforms, the planning, implementation, and reporting of these three disease interventions often does not occur in coordination, resulting in gaps that make services less accessible to women and their families.

Routine multi-disease testing at the first ANC visit is one of many integration opportunities throughout the cascade of care to accelerate elimination of MTCT. Multiplex testing allows providers to test for different diseases at once and provides a more comprehensive clinical diagnosis.

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[27] World Health Organization. Global progress report on HIV, viral hepatitis and sexually transmitted infections, 2021
[28] World Health Organization. Global Guidance on Criteria and Processes for Validation: EMTCT of HIV, syphilis, and HBV (2021)
[29] World Health Organization. Global Guidance on Criteria and Processes for Validation: EMTCT of HIV, syphilis, and HBV (2021)
[30] Korenromp EL, Rowley J, Alonso M, Mello MB, Wijesooriya NS, Mahiané SG et al. Global burden of maternal and congenital syphilis and associated adverse birth outcomes— Estimates for 2016 and progress since 2012. PLOS ONE. 2019;14:e0211720. doi: 10.1371/journal.pone.0211720.
[31] US Centers for Disease Control and Prevention (CDC) Hepatitis Statistics

Globally, studies have shown the feasibility of integrating HBV screening into existing PMTCT programs and highlight integration as a more cost-effective approach.

1. A feasible and acceptable approach for simultaneous triple point-of-care screening in rural India
    i. Simultaneous triple point-of-care screening strategy for syphilis, HBV, and HIV was offered to ~1,000 pregnant women during ANC visits. Early simultaneous screening enabled timely initiation of prophylaxis/treatment (within 3 days). The approach was preferred by 99.3%of participants[32]
2. In Democratic Republic of Congo and Mozambique, studies demonstrated the feasibility to integrate HBV testing and treatment of pregnant women into existing HIV and syphilis PMTCT programs[33,34]
3. Integrated approach for triple elimination was found to be highly cost-effective in Cambodia
    ii. Integrating prevention across diseases into existing ANC framework found potential to reduce the total time required to provide care for HCWs and significantly reduce rates of MTCT across all three disease areas[35]

[32] Pai NP, Kurji J, Singam A, Barick R, Jafari Y, Klein MB, Chhabra S, Shivkumar P. Simultaneous triple point-of-care testing for HIV, syphilis and hepatitis B virus to prevent mother-to-child transmission in India. Int J STD AIDS. 2012 May;23(5):319-24. doi: 10.1258/ijsa.2011.011139. PMID: 22648884.

[33] Thompson P, Morgan CE, Ngimbi P, Mwandagalirwa K, Ravelomanana NLR, Tabala M, Fathy M, Kawende B, Muwonga J, Misingi P, Mbendi C, Luhata C, Jhaveri R, Cloherty G, Kaba D, Yotebieng M, Parr JB. Arresting vertical transmission of hepatitis B virus (AVERT-HBV) in pregnant women and their neonates in the Democratic Republic of the Congo: a feasibility study. Lancet Glob Health. 2021 Nov;9(11):e1600-e1609. doi: 10.1016/S2214-109X(21)00304-1. Epub 2021 Aug 17. Erratum in: Lancet Glob Health. 2021 Nov;9(11):e1507. PMID: 34416175; PMCID: PMC8607275.

[34] Loarec A, Nguyen A, Molfino L, Chissano M, Madeira N, Rusch B, Staderini N, Couto A, Ciglenecki I, Antabak NT. Prevention of mother-to-child transmission of hepatitis B virus in antenatal care and maternity services, Mozambique. Bull World Health Organ. 2022 Jan 1;100(1):60-69. doi: 10.2471/BLT.20.281311. Epub 2021 Dec 2. PMID: 35017758; PMCID: PMC8722623.

[35] Lei Zhang, Yusha Tao, Joseph Woodring, Kim Rattana, Samreth Sovannarith, Tung Rathavy, Kannitha Cheang, Shafiqul Hossain, Laurent Ferradini, Serongkea Deng, Chay Sokun, Chham Samnang, Mari Nagai, Ying-Ru Lo, Naoko Ishikawa, Integrated approach for triple elimination of mother-to-child transmission of HIV, hepatitis B and syphilis is highly effective and cost-effective: an economic evaluation, *International Journal of Epidemiology*, Volume 48, Issue 4, August 2019, Pages 1327–1339.

Hepatitis Products Available to GFATM-supported Programs

GFATM has implemented the Pooled Procurement Mechanism (PPM) to consolidate recipient demand for health products and negotiate procurement terms on behalf of recipients. The negotiated prices and terms are published on reference price lists by GFATM and are periodically negotiated and updated (link). HBV and HCV treatment commodities are included in the list of medicines eligible for procurement under the pooled procurement mechanism of GFATM.

To streamline the procurement process of health commodities through their PPM, GFATM have deployed an online platform, wambo.org. Wambo.org allows buyers to search for, compare quality and prices, and purchase quality-assured products. Originally wambo.org only allowed the purchase of HIV, tuberculosis (TB), and malaria-related commodities with GFATM grants. Then from November 2019, the GFATM Board allowed countries to use domestic resources to purchase commodities on wambo.org in what is commonly referred to as the wambo.org pilot. Countries are eligible to purchase HBV and HCV commodities using domestic funds through wambo.org.

CHAI market reports and memo may be useful additional resources to review products, procurement considerations, and commodity costs by country:

- HBV market report (2022) – link
- HCV market memo (2022) – link
- HCV market report (2021) – link

HBV vaccine

There are no HBV vaccines listed on GFATM PPM reference pricing. Countries could explore securing HBV vaccines through UNICEF platform – where pricing extracted in November 2022 outlined HepB BD vaccine could be procured for a cost as low as US$0.24 per dose and HBV adult vaccine cost US$0.30 per dose.

Diagnostics

Based on GFATM's Quality Assurance Policy, grant funds can be used to procure diagnostic products that meet base global quality standards. The criteria include products that have been 1) WHO Pre-Qualified (WHO PQ'd (2) authorized by regulatory authorities of the founding members of the Global Harmonization Task Force (i.e., CE-mark, US FDA, etc.) or (3) determined acceptable for procurement by GFATM based on advice of the WHO Expert Review Panel (ERP).

The following are HBV/HCV diagnostic products published on GFATM's list of HIV Diagnostic test kits and equipments classified according to the Global Fund Quality Assurance Policy:

Table 3: HBV tests published on GFATM's list of HIV Diagnostic test kits and equipments classified according to the Global Fund Quality Assurance Policy

HEPATITIS B		
Product	**Manufacturer**	**Approval**
Rapid Diagnostic Tests (RDTs)		
First Response HBsAg Card Test	Premier Medical Corporation	CE-mark
STANDARD Q HBsAg Test	SD Biosensor	ERPD
Determine HBsAg 2	Abbott Diagnostics	WHO PQ
Bioline HBsAg WB	Abbott Diagnostics	WHO PQ
Enzyme Immunoassays (EIAs)		

DS-EIA-HBsAg-0,01	RPC Diagnostic Systems	WHO PQ
Murex HBsAg Version 3	DiaSorin	WHO PQ
Murex HBsAg Confirmatory Version 3	DiaSorin	CE-mark, TGA
Elecsys Anti-HBc IgM	Roche	CE-mark
Elecsys Anti-HBc II	Roche	CE-mark
Elecsys HBeAg	Roche	CE-mark
Elecsys Anti-HBs II	Roche	CE-mark
Elecsys HBsAg II	Roche	CE-mark
Viral Load (VL)		
Alinity m HBV	Abbott Diagnostics	CE-mark
RealTi*m*e HBV Viral Load Assay	Abbott Diagnostics	CE-mark
artus HBV RG RT-PCR Kit / artus HBV QS-RGQ Kit	Qiagen	CE-mark
cobas HBV Test	Roche	CE-mark
AccuPower HBV Quantitative PCR Kit	Bioneer	CE-mark
Xpert HBV Viral Load	Cepheid	CE-mark

Table 4: HCV tests published on GFATM's list of HIV Diagnostic test kits and equipments classified according to the Global Fund Quality Assurance Policy

HEPATITIS C		
Product	**Manufacturer**	**Approval**
Rapid Diagnostic Tests (RDTs)		
Bioline HCV	Abbott Diagnostics	WHO PQ
INSTI HCV Antibody Test	bioLytical Laboratories Inc	CE-mark
Rapid Ant-HCV Test	InTec Products	WHO PQ
OraQuick HCV Rapid Antibody Test Kit	OraSure Technologies	CE-mark
First Response HCV Card Test	Premier Medical Corporation	CE-mark
STANDARD Q HCV Ab Test	SD Biosensor	WHO PQ
Enzyme Immunoassays (EIAs)		
ARCHITECT HCV Ag assay	Abbott Diagnostics	WHO PQ
Monolisa HCV Ag-Ab ULTRA V2 assay	Bio-Rad Laboratories	WHO PQ
Murex anti-HCV Version 4	DiaSorin	WHO PQ
INNOTEST HCV Ab IV	Fujirebio Europe NV	WHO PQ
INNO-LIA HCV Score	Fujirebio Europe NV	WHO PQ
Elecsys® Anti-HCV II	Roche	CE-mark
Viral Load (VL)		
Abbott Realtime HCV	Abbott Diagnostics	WHO PQ
Alinity m HCV	Abbott Diagnostics	WHO PQ
artus HCV RG RT-PCR Kit / artus HCV QS-RGQ Kit	Qiagen	CE-mark
Cobas HCV Test	Roche	WHO PQ
AccuPower HCV Quantitative RT-PCR Kit	Bioneer	CE-mark
Xpert HCV Viral Load	Cepheid	WHO PQ

HBV Screening

Screening for hepatitis B is done with HBsAg, and RDTs for this are included in the Global Fund Pooled Procurement Reference Price list at US$0.65 – 0.95 EXW. These prices align with previous years; on average, the cost of HBsAg in public programs was US$0.77 in 2021 and US$0.67 in 2022.

Countries that are implementing dual testing of HIV/syphilis in the ANC setting may be using either single tests for the respective diseases or the dual test kit – and can now opt to bring in the HBV single test to take a triple elimination approach. More recently, building off the foundation of HIV/syphilis dual testing and the value of an integrated product, several manufacturers offer products which test for HIV, syphilis, and HBV while other manufacturers have combination test products that are in development. More are needed with regulatory approvals. Additional data on the feasibility and acceptability of using combination tests and its impact on screening uptake and cost efficiencies would support further use.

HCV Screening

Currently HCV antibody tests used for screening can be procured under GFATM PPM, with pricing for RDTs ranging between US$0.80 and US$1.10 Ex Works (EXW). This aligns with trends over the years where prices have remained at or near the US$1 price point. The cost of RDTs in public programs across a sample of high-burden countries in 2020 was on average US$1.09. Similarly, in the following years, the cost of RDTs in public programs across a sample of high-burden countries was on average US$0.90 (2021) and US$1.09(2022)[36].

Although no HCV self-test (HCVST) is approved by WHO, GFATM has indicated that procurement of HCVST could be supported by GFATM resources if a product comes to market and meets quality criteria.

Viral Load (HBV and HCV)

The multi-disease diagnostics platforms used for HIV viral load also have HBV and HCV viral load tests, most with CE-mark or WHO PQ. A PQ process does not yet exist for HBV VL, however, presently there are four HCV VL assays which have WHO PQ status. The commodity procurement could be discussed in negotiation with HIV viral load to potentially pool volumes and access more affordable pricing. Implementation could also leverage HIV pathways through integrating sample transport, result return, and other operational systems.

Based on updated 2020 WHO guidance, Hepatitis B e-antigen (HBeAg) test, can also be considered as an alternative to HBV viral load for pregnant women. At present, there is no WHO PQ process for HBeAg. Multiple products are in the market with options of RDT and laboratory-based immunoassays, which hold stringent regulatory authority (SRA) approvals. Although recommendations exist for the use of HBeAg as a viable alternative to HBV VL for pregnant women, test performance has varied across settings. HBeAg RDT products may be more affordable with fewer implementation requirements compared to HBV VL, however, studies have demonstrated varied performance in terms of sensitivity and specificity for both HBeAg RDTs and laboratory-based immunoassays, highlighting the need to validate HBeAg testing.

Countries may reference other molecular pricing agreements like the ASLM Diagnostic Pricing Database and discuss procurement directly with suppliers and may include viral hepatitis testing into existing HIV viral load and early infant diagnostic procurement.

Treatments

Medicines procured under GFATM PPM are either WHO-PQ'd or ERP reviewed. Countries can use these reference pricing to estimate commodities budget in their proposal. These prices are EXW or Freight on Board (FOB) prices, and countries would incur additional cost of PSA service fees, freight cost, insurance cost, etc.

[36] CHAI Hepatitis Market Reports

While procurement service agents service fees are capped by GFATM and is typically around 1.5% for anti-retrovirals and DAAs, freight costs are on actuals.

HCV treatment: Current 12 weeks course of SOF/DCV fixed dose combination (FDC) under PPM is US$74.45, which aligns with significant reduction in DAA prices over the last six years. The US$74.45 (FOB) is one of the lowest prices for WHO-PQ'd SOF/DCV FDC across LMICs. Currently, only Rwanda is accessing WHO-PQ'd SOF/DCV at a lower price of US$60 (in-country cost).

HBV treatment: Since tenofovir disoproxil fumarate (TDF) is the mainstay of both HIV and HBV treatment and has similar recommended dosing, HBV programs benefit from market shaping work leading to reduction in TDF price for HIV. TDF is currently listed at US$2.4 per bottle reference price under GF PPM and is the benchmark price for WHO-PQ'd TDF. This can be accessed for HIV or HBV treatment by programs.

Table 5: GFATM-supported HBV and HCV products summary

Product Area	Product	Price (ex-works USD)	Unit	Source
Hepatitis B	Rapid Diagnostic Test	0.65-0.90	per test	Pooled Procurement Mechanism Reference Pricing: RDTs (Sept 2022)
	Viral Load	No PPM pricing shared. Estimated*: 8.90 – 16.00	per test	* CHAI HBV Market Report
	Tenofovir 300mg	2.40	30 tablets	Pooled Procurement Mechanism Reference Pricing: HIV (Oct 2022)
	Entecavir 0.5mg	8.50	30 tablets	
	Entecavir 1mg	15.00	30 tablets	
	Entecavir 0.5mg	22.50	90 tablets	
	Entecavir 1mg	38.00	90 tablets	
Hepatitis C	Rapid Diagnostic Test	0.8-1.10	per test	Pooled Procurement Mechanism Reference Pricing: RDTs (Sept 2022)
	Viral Load	No PPM pricing shared. Estimated*: 8.90 – 17.05	per test	* CHAI HCV Market Report
	Daclatasvir 30mg	9.00	28 tablets	Pooled Procurement Mechanism Reference Pricing: HIV (Oct 2022)
	Daclatasvir 60mg	12.00	28 tablets	
	Sofosbuvir 400mg	16.50	28 tablets	
	Sofosbuvir/Daclatasvir 400/60mg	24.00	28 tablets	
	Sofosbuvir/Ledipasvir 400/90mg	26.25	28 tablets	
	Sofosbuvir/Velpatasvir 400/100mg	58.00	28 tablets	

Note: no GFATM PPM pricing information for HBV vaccines, viral load, OST, naloxone, or needles/syringes is available.

Please refer to **WHO Guidelines for viral hepatitis** testing and treatment for guidance on how to use hepatitis products

Relevant Global Resources

Guidelines and Policy/Information Briefs

- WHO: Guidelines for the prevention, care, and treatment of persons with chronic hepatitis B infection (2015) - link. Note: WHO are currently reviewing these guidelines with updated guidelines expected in 2023 (these will hopefully include recommendations that reflect a simplified treatment pathway in LMIC)
- WHO: Guidelines for the care and treatment of persons diagnosed with chronic hepatitis C virus infection (2018) - link
- WHO: Considerations for adoption and use of multi-disease testing devices in integrated laboratory networks: information note (2017) - link
- WHO: Prevention of mother-to-child transmission of hepatitis B virus: Guidelines on antiviral prophylaxis in pregnancy (2020) - link
- WHO: Updated recommendations on simplified service delivery and diagnostics for hepatitis C infection (2022) - link
- WHO: Consolidated Guidelines on HIV, viral hepatitis and STI prevention, diagnosis, treatment and care for key populations (2022) - link

Progress

- WHO: Global progress report on HIV, viral hepatitis, and sexually transmitted infections (2021) - link
- Harm Reduction International (HRI): Global State of Harm Reduction (2022) - link

Additional Resources

- UNODC, INPUD, et al (2017): Implementing comprehensive HIV and HCV programmes with people who inject drugs, offering practical guidance and case studies on creating and delivery programs with and for people who use drugs - link
- HRI: Making the investment case for harm reduction (2020) - link
- CHAI market reports and memo may be useful resources to review products, procurement considerations, and commodity costs by country:
    - HBV market report (2022) – link
    - HCV market memo (2022) – link
    - HCV market report (2021) – link
- Unitaid: Landscape of Innovative Tools and Delivery Strategies for eliminating vertical transmission of HIV, syphilis, hepatitis B, and chagas in endemic areas (2022) - link
- WHA: White Paper on preventing vertical transmission of HBV (2022) - link

Acknowledgments

This publication was developed by Clinton Health Access Initiative (CHAI). We would like to thank our partners for being part of a consultative process and providing reviews and input on this Toolkit, including:

Elizabeth Fraser Pediatric AIDS Foundation

Harm Reduction International

International Network of People Who Use Drugs

Médecins Sans Frontières

PATH

The Hepatitis Fund

World Hepatitis Alliance

World Health Organization

We are grateful to all our partners for helping in the dissemination of this Toolkit.

We are also grateful to the GFATM for inviting CHAI to be part of the consultation process on the new HIV guidance documents for the next funding round.

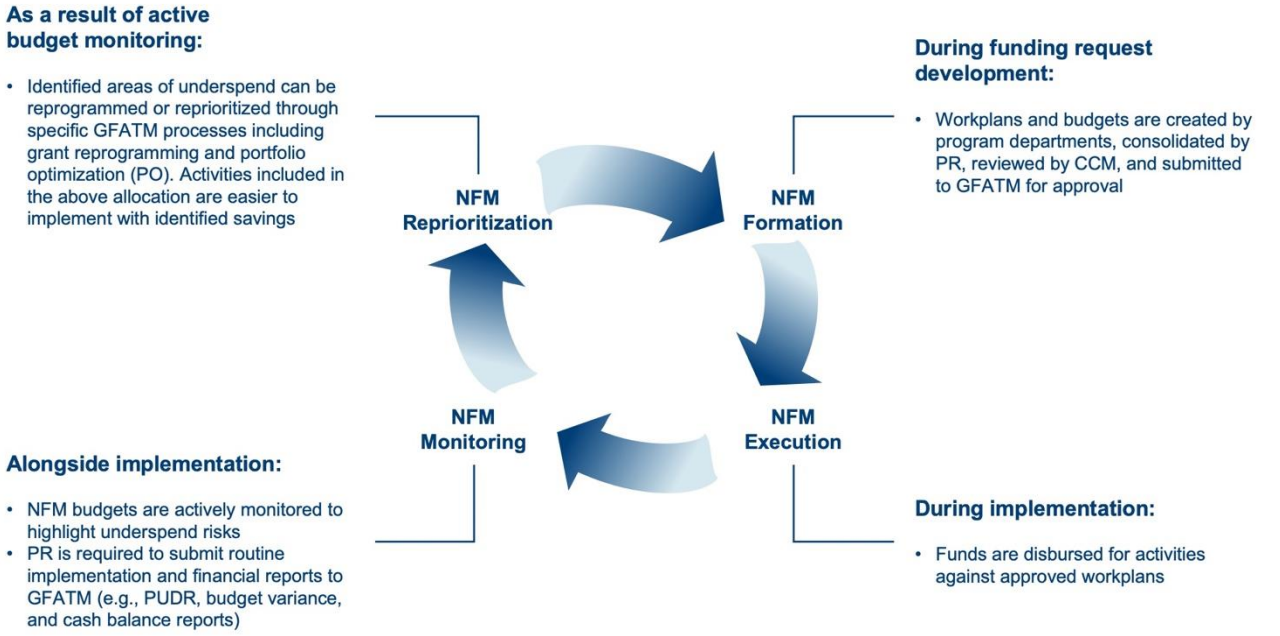
Finally, we would like to acknowledge the generous support provided by the UK's Foreign, Commonwealth and Development Office (FCDO) in making this report possible.

Annex

Annex 1: New Funding Model 4 Application Process

Country GFATM grants are typically awarded every three years and are managed by several stakeholders both within the country and in Geneva to provide either implementation or grant oversight support. GFATM country grants follow the **Figure 1** cycle from formation to reprioritization over the period of implementation.

Figure 3: Adapted from Putting Funds for UHC to Better Use: Alignment between Public Financial Management and Health Financing to Move Toward Fiscally Sustainable UHC (2016), Results for Development, Washington, D.C



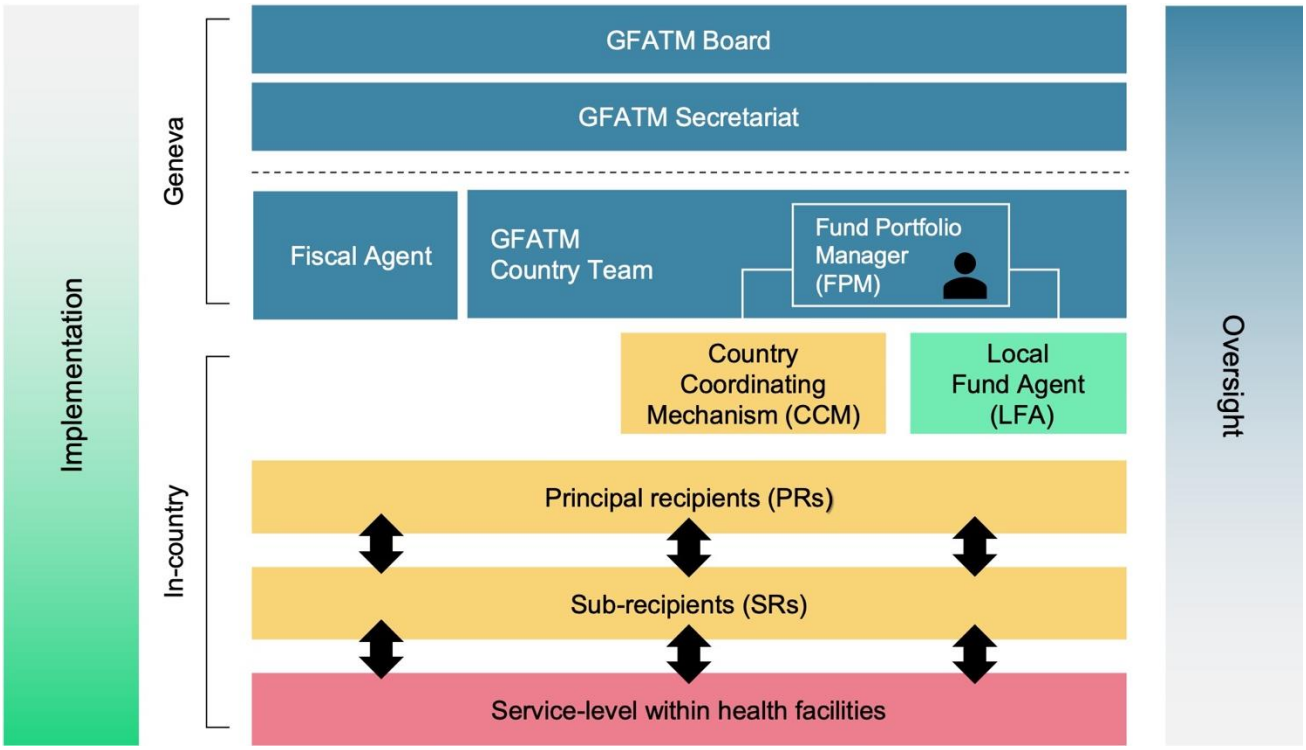
The next GFATM investment opportunity that countries can access is called “New Funding Model 4” and commonly referred to “NFM4” or “grant cycle 7”, with proposal submissions starting in 2023 and funding available for the period of 2023-2025. The sections below will provide details on the stakeholders, timeline and NFM4 application process.

Note: Throughout the document the terminology used to describe the funding ‘application’ is used interchangeably with ‘ask’, ‘submission’, ‘concept note’, ‘request’ and ‘proposal’.

Stakeholders

From developing a funding request, to grant reviews/finalization to implementation and oversight of the program – there are many stakeholders involved. GFATM funding application process sets out to be multi-stakeholder, inclusive and very much country-owned and driven under the leadership of the Country Coordinating Mechanism (CCM).

Figure 4: Overview of stakeholders (non-exhaustive)



GFATM Board (Geneva)

- Formal governance structure that includes representatives of donor and recipient governments, non-governmental organizations, private sector, and affected communities
- Approves or rejects funding applications based on Technical Review Panel and Secretariat review

GFATM Secretariat (Geneva)

- Responsible for the GFATM operations, including raising funds for investments (replenishment rounds), managing grant applications, monitoring grant performance and reporting information to the GFATM Board and wider public, coordinating investment strategy consultations, development of technical briefs and other application information for countries
- Negotiates grant agreement with, and disburses funds to, the Principal Recipient
- Contracts with Local Fund Agents to routinely check on the progress of programs

Technical Review Panel (TRP) Not shown in diagram above

- Independent international panel of technical experts in health and development
- Provide an independent review of country proposals to assess the technical components and provide feedback on make recommendations to the Board on what should be funded

Fiscal Agent

- External agent intended to provide financial management support to GFATM and assess potential financial risks

GFATM Country Team

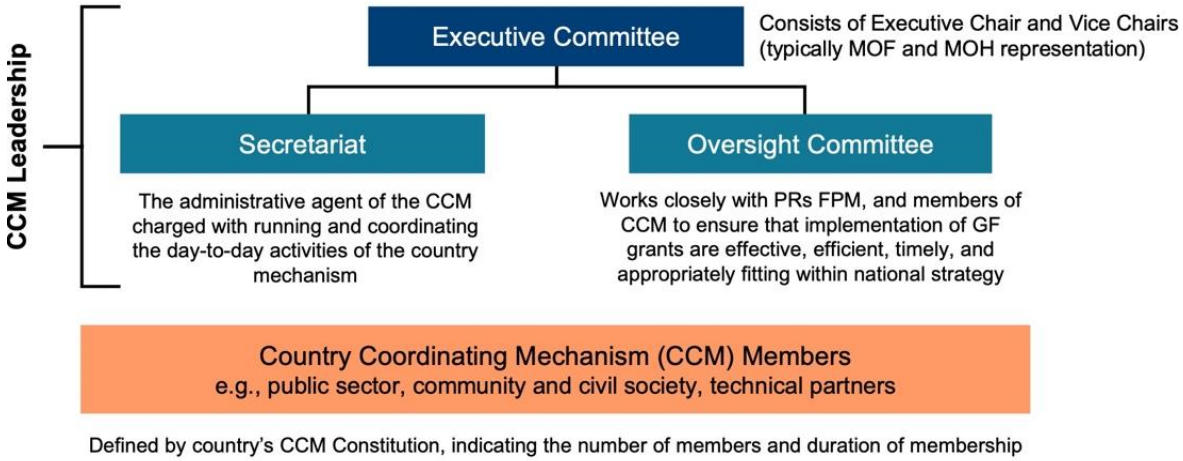
- Country-focused teams to support grant making coordination for a specific country

Fund Portfolio Manager (FPM)

- The FPM role is embedded within the Country Team and contributes directly to the delivery of GFATM investments by leading and managing the grant negotiation on behalf of the assigned country and the GFATM Secretariat. The FPM's capacity is also used to manage the local fund agent (LFA), to provide both implementation and financial oversight and to be a liaison between the Global Fund investment strategy and national planning in country
- During the development of the funding request, the FPM regularly engages with the CCM and the consultants to advise on investments and can be a resource to help determine whether interventions are eligible for funding under NFM4, if not clearly outlined in Global Fund policies. The FPM should be consulted for any major decisions during the funding request development, including changes to the allocation split.

Country Coordinating Mechanism (CCM)

Figure 5: CCM leadership structure



- The CCM is typically a collective of multiple stakeholders that are responsible for aligning on programmatic gaps and prioritization for funding request, coordinating, and populating the funding application request forms
- Once the grant is approved, the CCM is involved in overseeing grant implementation
- Multiple stakeholders (typically 15-30 people) can participate in the CCM with representation across different sectors e.g., affected communities, relevant ministries (health or finance), technical partners, donor organizations, civil society, youth organizations, academia, private sector, media, trade unions
- The Secretariat strongly encourages that the CCM includes people who are affected by the disease focus i.e., community members with HIV, TB and/or malaria
- The CCM will work together to develop and submit a proposal that reflects the epidemics, national priorities, and plans of their country context. Depending on the structure of the CCM in countries, they may be more involved in the development of the funding request or may serve more as a forum for final review and approval to be consulted at a high-level throughout the process by the consultants hired to develop technical materials
- The CCM is encouraged to think through implementation support and can include any technical assistance needs/budget within the country's proposal
- The CCM structure is typically supported by a leadership structure that includes an Executive Committee, Secretariat and Oversight Committee (illustrated above). This structure can vary from country to country.
- CCM will review grant performance (via reports from PR and visiting implementation sites), if there are challenges in implementation the CCM should work to support and help address challenges

- Within the CCM, an appointed secretariat will support administrative tasks such as scheduling meetings, work planning, dissemination of documents, etc.
- Contact info for country CCMs can be accessed on the GFATM website here

Local Fund Agent (LFA)

- An entity contracted by GFATM Secretariat to provide an independent review of how funds are being utilized in country and will verify the reports from PRs on grant performance
- The LFA provides perspectives on risks to grant implementation and will make recommendations to GFATM based on grant performance

Principal Recipient (PR)

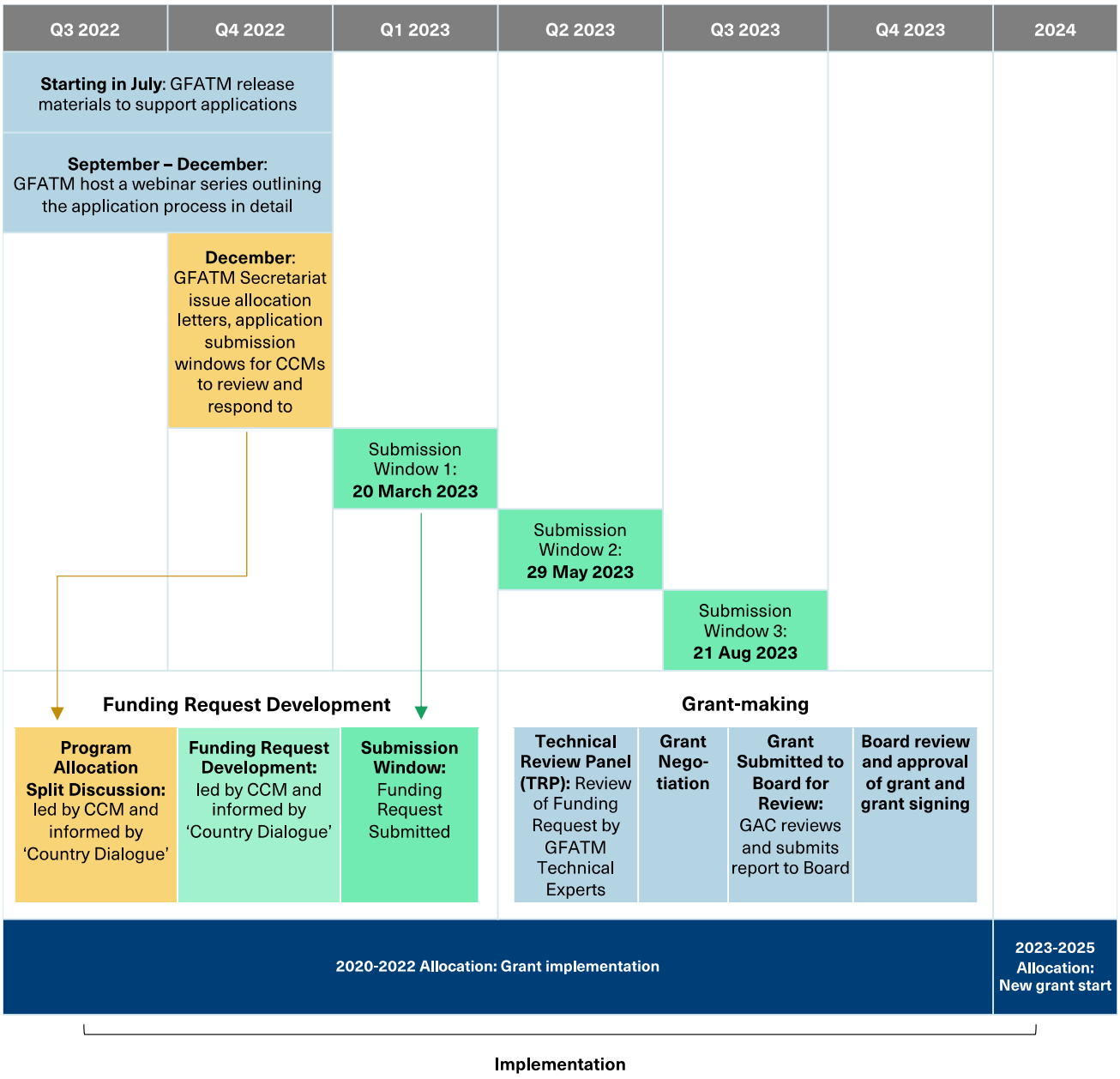
- Nominated by the CCM to be the primary receiver and manager of grant funds and to be responsible for program implementation
- The PR can be any type of organization including governmental and non-governmental
- A PR can contract with and funnel any funding to sub-recipients to implement different parts of the program
- PR will submit reports to CCM for review and monitoring of grant implementation and progress
- There can be more than one PR in each country per grant, depending on the implementation arrangement
- PR selection process can be lengthy, so most often countries will maintain the same PR for multiple funding cycles
- In NFM4 application process, the PRs must be determined by the CCM at the point of the allocation split decision made by the CCM

Sub-Recipient (SR)

- Selected by Principal Recipients to deliver activities related to the grant – SRs report to PRs when it comes to the monitoring and evaluation of the grant implementation
- Sub-recipients may further select sub-SRs to support with implementation if approved by the PR and found necessary for efficient and effective intervention delivery
- SRs are determined by the PRs and submitted at the point of NFM4 application submission. SR appointments can be further revised during grant making as needed.
- If Sub-SRs are necessary, they can be determined by SRs during grant implementation

Funding Timeline for 2023-2025 Investments

Figure 6: NFM4 funding timeline outline



GFATM grants run on three-year cycles, with the next funding allocation period set for 2023-2025. Across 2023, there are three application submission windows staggered across the year for countries to submit applications: March 20, May 29, and August 21, 2023. Note, during country application development for the next allocation period, grant implementation for the 2020-2022 allocation period is expected to be ongoing – this is to limit gaps in funding between different grant cycles.

Building off the latest GFATM strategy for 2023-2028 period, materials to support the application process were released on GFATM website during Q3 and Q4 2022 (link). This includes (non-exhaustive):

Application information

- Application Instructions for NFM4
- Applicant Handbook
- Funding Request Forms and Materials

Allocation-specific information Notes

Includes the policy scope for these investment areas:

- HIV Information Note
- Tuberculosis Information Note
- Malaria Information Note
- Resilient and Sustainable Systems for Health (RSSH) Information Note

Note: hepatitis-related investment scope identified through review of the HIV and RSSH Information Notes is summarized in the respective **policy** sections

Modular Framework Handbook (Link)

- A guidance document aims to support applicants with standard application modules for HIV, TB, Malaria and RSSH and includes illustrative 'menus' of activities and interventions under each module.
- The modular arrangement across key pillars and interventions reflects the GFATM investment strategy for 2023-2028
- Applicants are recommended to use this document in conjunction with GFATM Information Notes, GFATM Technical Briefs, available technical partner guidance and the Country Dialogue process to identify strategic investment areas relevant for their context

See **Annex 3** for a summary of hepatitis-related activities from the Modular Framework Handbook

Technical Briefs and Guidance notes on specific GFATM funding policy areas (Link)

- To complement these materials, GFATM also launched a recorded webinar series for stakeholders to learn more about applying for funding in 2023-2025 allocation period – this information is targeted at CCMs, technical assistance providers and partners (link).

Funding Process for 2023-2025 Investments

Allocation Letter

In December 2022, the GFATM Secretariat will publish an application submission window tracker – with proposed submission dates for each country eligible for funding allocation. Although the Secretariat will propose a submission window, country stakeholders can decide which window they submit in to – in some instances, countries may choose an earlier window. Submission window selection should consider the country's current grant (NFM3) implementation period end date and desired NFM4 implementation start. Countries with grants ending at the end of 2023 must submit in the March window to complete the grant-making process in time for the January 2024 start date, otherwise risk an interruption in the funding. Countries whose current grants end in mid-2024 are encouraged to apply by the March or May windows. Before end of 2022, the Secretariat will issue direct allocation letters to countries eligible to apply for funding support within the 2023-2025 allocation period. These letters will include:

- The total eligible allocation
- The proposed split of the allocation across eligible disease funding HIV, TB, and/or Malaria
- The recommended application approach the country is expected to undertake
- A recommendation for countries to indicate Resilient and Sustainable Systems for Health (RSSH) investments

- Opportunities for matching funds[37]

Depending on country eligibility, GFATM may invite a country to apply for HIV and/or TB and/or Malaria. If a country is eligible for multiple diseases, GFATM Secretariat will include recommendations of disease program allocation split within the letter. Country stakeholders and CCM members must review this allocation split and either confirm or propose changes.

Opportunity for hepatitis-related funding falls within HIV and RSSH allocation scopes – see **policy** sections, including ideas on RSSH-related funding asks to support hepatitis services

While responding to the allocation letter, countries are encouraged to include an indication of how much funding will be allocated to RSSH investments – all countries eligible for funding are eligible to request RSSH investments. RSSH investments are targeted at strengthening health systems to support implementation of disease-specific programming. Rather than GFATM Secretariat proposing an allocation to these types of investments, country stakeholders are required to determine the RSSH investment need for their country context.

The RSSH Information Note (link) reminds:

"The Global Fund's new Strategy 2023 – 2028 calls for action to rise above disease-specific silos toward building resilient and sustainable systems for health (RSSH) in a way that places people and communities, not diseases, at the centre of the health system to achieve universal health coverage (UHC)"

"A single integrated funding request across HIV, TB, malaria and RSSH is encouraged for those applicants requesting funding for the three diseases. If an applicant decides to submit separate funding requests, careful consideration should be given to RSSH. Applicants can present their RSSH funding requests within a disease-specific request or as a standalone RSSH request"

Country Dialogue and CCM Program Allocation Split Discussion

Prior to the selected submission window, the CCM must coordinate to engage stakeholders in a country dialogue to determine program gaps and funding prioritization to be articulated in the application. The country dialogue kick-off meetings can happen as early as the CCM deems necessary but often happens within one to two months prior to the delivery of the allocation letter. During these meetings, all GFATM stakeholders represented within the CCM, PRs, and SRs are invited to articulate national priorities that fall within GFATM's strategic investment areas. The **figure 4** provides an overview of the country dialogue.

Meetings will continue beyond the kick-off to detail programmatic priorities, available funding from either domestic resources or other donors, and ultimately the funding gap where GFATM investment may be most salient. Prioritization of key investment areas should be guided by national needs, review of National Strategic Plans (NSPs)/Health Systems Strengthening Plans (HSSPs), and lessons learned from prior grant

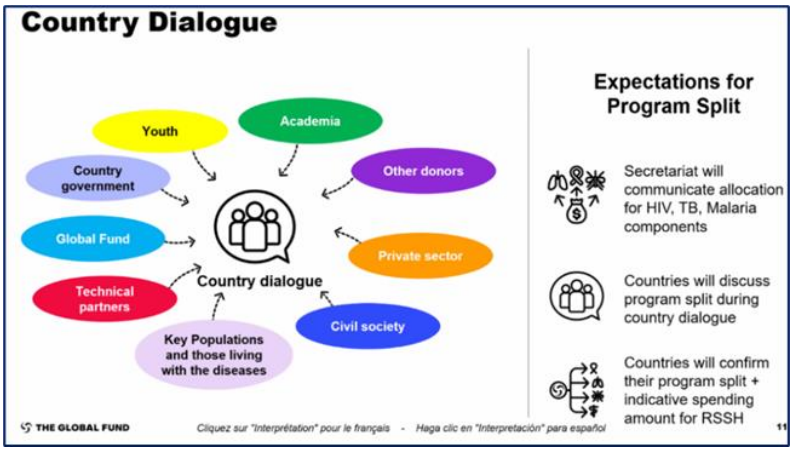
[37] Matching funds from GFATM are designed to inspire innovation and ambitious, evidence-based programming approaches to increase impact in identified priority areas. While GFATM cannot be prescriptive in how countries should spend their allocations, matching funds provide an opportunity for specific GFATM priorities to be considered. Allocation letters will indicate select priorities based on GFATM-identified country need. Matching funds may be by GFATM awarded to countries for the following areas:

- HIV: Prevention for key populations, adolescent girls and young women, and their sexual partners.
- TB: Find and successfully treat the missing people with drug-susceptible and drug-resistant tuberculosis (TB).
- TB: Scale up TB prevention.
- TB: Country readiness for innovation and quality TB programming.
- Malaria: Malaria elimination in Southern Africa.
- RSSH: Scaling-up programs that remove human rights and gender-related barriers.
- RSSH: Incentivizing RSSH quality and scale.
- RSSH: Effective community systems and responses that contribute to improved health outcomes, and equitable access to integrated people-centred quality services.
- RSSH: Equitable access to quality health products through innovation, partnership, and promoting sustainable sourcing and supply chains at global, national, and community levels (NextGen Market Shaping).

Available matching funds will be dependent on resource availability following GFATM funding replenishment effort

implementation and TRP reviews. These discussions and consensus building among GFATM stakeholders serve as guidance for the allocation split decisions to be made following delivery of the allocation letters. Ideally, allocation splits should be decided by the CCM, submitted to the GFATM Secretariat, and confirmed by the FPM prior to the development of the detailed NFM4 application, which can be referred to as Funding Request (FR) Development. For NFM4, CCMs are required to include the amount of funding to be allocated from each eligible disease allocation towards RSSH at the time of the allocation split decision. Note: this step is an update from previous cycles that requires the decision on RSSH at an earlier stage of the application process. At the time of this split decision, identification and communication with PRs should also occur.

Figure 7: Country Dialogue Overview. Source: GFATM Webinar Series 2022



Funding Request Development

Completion of all application materials can take anywhere from three to six months depending on the availability of updated NSPs, resource mapping information, and coordination among the multiple stakeholders that are engaged in the process. The bullets in the **Figure 5** provide some of the best practices to consider during FR development.

Figure 8: Best Practices during FR Development. Source: GFATM NFM4 Webinar Series 2022

Best Practices during FR Development

- CCM to develop and share an **engagement roadmap** for the country dialogue
- Use **data & evidence** as basis for discussions on prioritization
- Consider how areas highlighted in **Global Fund strategy** can drive bigger impact towards national and global goals.
- **Mobilize in-country partners**, including for RSSH, to strengthen quality of country dialogue
- Actively **seek input from Community and Civil Society groups**: e.g., by using the new priorities annex when discussing Funding Request prioritization
- Ensure **writing teams are representative** of all CCM constituencies, including communities, and also include relevant expertise (for example for RSSH). Best practice: relevant RSSH stakeholders in the disease-specific FR writing teams (and vice versa)
- Give CCM members enough **time to meaningfully review** FR drafts for informed endorsement

See **Country Case Studies: Lessons Learned** for how stakeholders may participate

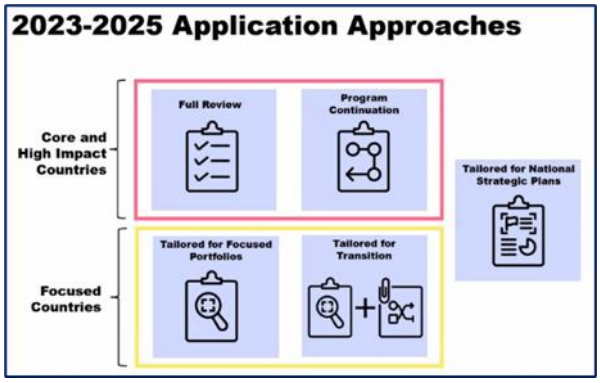
See **Activities Checklist** for what stakeholders may participate

Application Submission Approach

GFATM have developed several different application approaches. Within the allocation letters sent to countries, the Secretariat will propose which application process a country should undertake (application form templates link). These include:

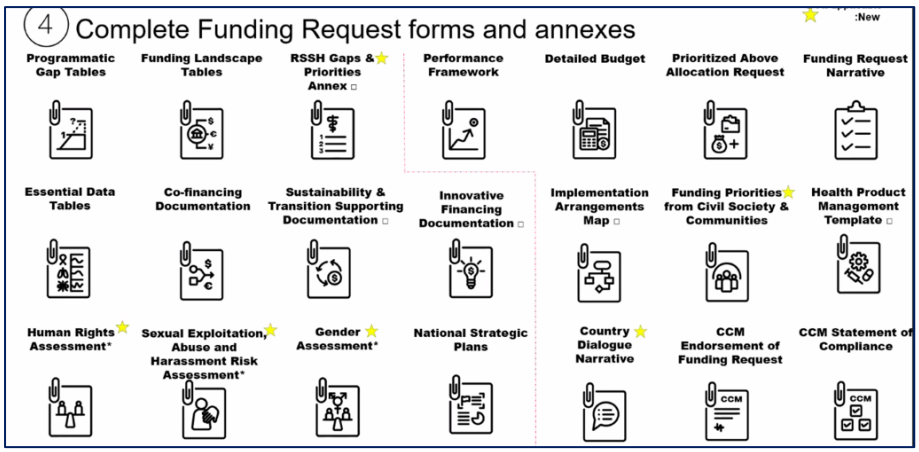
- **Full Review:** comprehensive review and articulation of country priorities
- **Program Continuation**: by invitation only, typically for a high-performing country where there are minimal changes to the program approach
- Tailored Applications

Figure 9: Application Approaches. Source: GFATM NFM4 Webinar Series 2022



- **For National Strategic Plans (NSP):** application can include references to existing NSPs and costing to reduce repetition of existing information
- **For Focused Portfolios:** typically for countries with lower disease burden and a smaller funding allocation targeted at specific focus areas
- **For Transition:** for countries that are projected to transition for GFATM funding

Figure 10: NFM4 application forms. Source: GFATM NFM4 Webinar Series 2022



The application package requires applicants to populate many submission documents as seen. Details on each can be found on the GFATM website here. Note: GFATM Data Explorer website provides a public resource of prior country funding application documents.

New Annexes Alert!

Funding Priorities from Civil Society & Communities:

- GFATM 2023-2028 Strategy includes focus on being person-centred and maximizing community engagement
- To support this, GFATM have introduced new mandatory 'Funding Priorities from Civil Society & Communities' annex to be include with proposals
- This annex intends to formally capture funding priorities (e.g., the top ~20 asks) articulated by communities and civil society during the Country Dialogue. It presents an opportunity for civil society and communities to ensure other/alternative funding priorities like hepatitis services are captured (ideally both within the main proposal and the annex)
- During proposal review, this annex will be reviewed to ensure the funding priorities listed are reflected in the main proposal/funding requests

RSSH Gaps & Priorities:

- Mandatory annex for Core and High burden countries only if they include RSSH allocations in their application

Prioritized Allocation and Prioritized Above Allocation Requests (PAAR)

In the funding application, activities can be submitted under the Prioritized Allocation ('main') request and under Prioritized Above Allocation Requests (PAAR). The PAAR should include the further investments that the CCM has identified that would be good to make if additional funding becomes available during grant implementation. The PAAR submission contains activities that total at a minimum of 30% of the total prioritized allocation. Over the course of the three-year grant implementation, it is likely that efficiencies will be realized through NFM monitoring – enabling these PAAR activities to be supported. During the process of grant reprogramming, stakeholders will be able to readily advocate for specific PAAR activities to implement. At a later stage, grants can undergo a process referred to as Portfolio Optimization (PO), where anticipated underspends are reprioritized across country grants and again guided by activities within the PAAR.

All funding activities within the prioritized allocation and PAAR requests should be built to be context specific and build applications directly informed by country NSPs as the foundation.

The full application detailing activities within the prioritized allocation and PAAR are submitted by the CCM Secretariat by the selected Submission Window deadline.

TRP review, grant-making, GAC, and Board Approval

Following submission, the proposal is reviewed by the TRP to assess the technical strengths of the application and make recommendations. The TRP typically have up to ten days to review all application documents ahead of the TRP meeting to debate whether to recommend an application for grant-making. Applications should be strategically focused and technically sound and presented in a clear, succinct structure with sound rationale for the proposed investments. At this negotiation stage, the TRP may recommend countries to re-prioritize interventions and/or, if there are certain funding requests that a country has included in their PAAR that the TRP determines to be strong but can't be funded at grant start due to limited resources, the TRP may recommend these components to be listed as Unfunded Quality Demand (UQD).[38]

Once ready, the TRP responds to the CCM with a decision to have the country either significantly review the submission or to have the country proceed to grant making where minor content revisions may be requested along with a second detailed budget review. For example, the TRP may identify efficiencies within the prioritized allocation budget and suggest some PAAR activities can shifted to be funded from grant start. Once the country completes the grant-making stage, the submission is finalized and shared with the Grant Approval Committee (GAC) for review, ahead of sharing the application with the Board. Once Board has reviewed and approved, an agreement is developed and signed between the Secretariat and PR, enabling the new grant to start.

See **Tools: Funding Ask, Activities Checklist** for resources focused on what to include in funding ask and activities that may need to be undertaken

[38] Unfunded Quality Demand (UQD):

- These components have been reviewed by TRP and found to be strategically focused and technically sound and therefore if resources become available during grant-making e.g., through savings/efficiencies that generate underspend and/or donor interest, this funding can be allocated to UQD
- GFATM produces a living list of country-specific UQD and funding description/amount is on the GFATM website (link) - this is a way that GFATM shares the funding opportunities that they would invest in if the resources become available during grant-making and/or is a list that other donors can review and invest in
- Within the list accessed in September 2022, several countries had hepatitis-related and harm reduction UQD requests listed

Annex 2: GFATM Harm Reduction Resources and Policy Highlights

In November 2022, GFATM published the Technical Brief on Harm Reduction for People Who Use Drugs – Priorities for Investment and Increase Impact in HIV Programming (Allocation Period: 2023-2025). The brief is meant to help applicants to the GFATM plan for and scale up effective HIV and hepatitis C programming for people who use drugs, particularly those who inject.

There are several GFATM documents that contain content relevant to harm reduction. Beyond the technical brief, relevant resources applicants may wish to refer to:

- HIV Information Note
- Modular Framework Handbook
- Technical Brief on Prisons and Other Closed Settings – Priorities for Investment and Increase Impact in HIV Programming (Allocation Period: 2023-2025)
- Technical Brief on Removing Human Rights-related Barriers to HIV-related Services (Allocation Period: 2023-2025)

Below includes a summary of a few headlines that are positive for harm reduction funding in NFM4:

- Harm reduction is now a HIV "program essential" – This means all countries must describe status of their harm reduction programs in their funding requests and those countries classified as 'high impact' country must describe their plan for implementation. Top priority harm reduction interventions are needle and syringe programming (NSP), opioid substitution therapy (OST) and naloxone for overdose.
- Programming for people who use drugs - Funding requests can include programs for people who use/inject drugs and their sexual partners, rather than only people who inject drugs. This allows increased scope for stimulant harm reduction.
- Human rights "program essentials" – The following components must be included in funding requests: integrating human rights protections into HIV and TB services; removing stigma in health care and other settings; access to justice/legal support; and advocacy, including community led advocacy, on decriminalisation and other policy change.
- Emphasis on community-led monitoring – The technical brief on harm reduction highlights the key role for people who inject drugs in planning, delivery and evaluation of services and policy change.
- Clarity on hepatitis B and C – For NFM4, the Global Fund will fund hepatitis B and C treatment for people who inject drugs regardless of HIV status if strong epidemiological case is provided and proposed plan is part of comprehensive HIV programming.

Annex 3: Summary of Hepatitis-related Activities from the Modular Framework Handbook. (Note: Hepatitis-related components in BOLD)

Module	Intervention	Scope and Description of Intervention Package -Illustrative activities
Source: HIV section of Modular Framework Handbook		
Treatment, Care and Support	Integrated management of common co-infections and co-morbidities (adults and children)	Activities related to strengthening prevention and management of common co-infections and co-morbidities among people living with HIV (PLHIV). It includes hepatitis, STI, cervical cancer, mental health, and noncommunicable diseases (NCDs). For example: • **Diagnosis, and treatment for hepatitis B and C, vaccination for hepatitis B with a focus on people who use drugs and pregnant and breastfeeding women, including support for birth dose of hepatitis B vaccination.** • Diagnosis and treatment of STIs, including syphilis with a focus on KPs, AGYW, pregnant and breastfeeding women. • Linkage of people living with HIV, women, and adolescents to HPV vaccine services, and screening, triage, and secondary preventive treatment of HPV and cervical cancer; with a focus on AGYW. • Routine screening and management of mental health, including sexual identity development, depression, anxiety, and trauma. • Evidence-based interventions to address harmful alcohol or drug use. • Screening and management of hypertension, diabetes, and obesity in PLHIV of 40 years and older → Activities related to management of TB/HIV co-infection should be included under the module “TB/HIV” → **Activities related to strengthening the broader health system for the management of co-infections and co-morbidities should be included under the respective RSSH modules**
Prevention Package among Priority and key populations: - Men Who Have Sex with Men (MSM) and their Sexual Partners - Sex Workers, their Clients and Other Sexual Partners - Transgender People and their Sexual Partners	Sexual and reproductive health services, including STIs, hepatitis, post-violence care	Activities related to sexual health service provision. For example: • Screening, testing and treatment of asymptomatic STIs, including periodic serological testing for asymptomatic syphilis infection, asymptomatic urethral gonorrhea, rectal gonorrhea, chlamydia trachomatis. • **Prevention, screening, testing and treatment for hepatitis B and hepatitis C, vaccination for hepatitis B** • Routine STI check-ups. • Contraception/family planning information and services

<table>
<tr>
<td>- People in Prisons and Other Closed Settings
- People Who Use Drugs (PUD) (injecting and noninjecting) and their Sexual Partners
- Other Vulnerable Populations (OVP) [1]
- Adolescent Girls and Young Women (AGYW) and Male Sexual Partners in High HIV Incidence Settings

1: Vulnerable populations are those who experience an increased vulnerability to HIV compared to the general population. Depending on the country context, this may include children and young people (aged 10-24 years), adolescent girls and young women (including those who are pregnant), orphans, people with disabilities, people living in extreme poverty, the homeless, mobile workers, displaced populations, and other migrants.</td>
<td></td>
<td>• Screening for cervical cancer and HPV.
• Pregnancy testing
• Syndromic and clinical case management for patients with STI symptoms.
• Delivery of anal health care, including anal cancer screening and linkages.
• Integration of HIV prevention into sexual and reproductive health services, drop-in centers, shelters, community centers, including youth-friendly services.
• Post-violence counseling, referral and linkages to post exposure prophylaxis (PEP), clinical investigations, medical management, clinical care, forensics management and medical-legal linkages, psychosocial support, including mental health services and counselling.
• Training of health personnel
• Transgender People and Partners specific: Gender affirming care; Integration of and referrals to hormone therapy as part of HIV service package</td>
</tr>
<tr>
<td></td>
<td>Pre-exposure prophylaxis (PrEP) programing</td>
<td><u>Activities related to Pre-Exposure Prophylaxis (PrEP) for those at substantial risk of HIV infection. For example:</u>

• Design and delivery PrEP program, including planning, determining eligibility, and service delivery requirements.
• Adherence support, including peer-led adherence support.
• PrEP information and demand creation, including peer-based approaches
• Referrals/Linkages to HIV/STI prevention, testing, treatment, care and clinical monitoring, hepatitis B vaccination, other primary health care (PHC) services

→ Procurement of PrEP commodities including different formulations such as oral, vaginal ring, longacting, daily, should be included here.</td>
</tr>
<tr>
<td></td>
<td>Needle and Syringe programs for PWID</td>
<td>Activities related to needle and syringe programs, including virtual interventions, for people who inject drugs (PWID). For example:

• Procurement and distribution of needles and syringes through direct and secondary distribution, mobile clinics, peer-driven interventions, safe collection and disposal of used needles and syringes.
• Procurement of needles and syringes, including low dead space syringes and other safe injecting commodities.
• Provision of basic healthcare and injecting-related first aid, including wound care and treatment of skin infections.
• Referral and link to behavioral interventions, HIV testing, care and treatment and primary health care (PHC) services.</td>
</tr>
</table>

		• **Prevention, screening, testing and treatment for hepatitis B and hepatitis C, vaccination for hepatitis B.**
	Opioid Substitution Therapy and other medically assisted drug dependence treatment for PWID	Activities related to opioid substitution therapy (OST) programs including virtual interventions, for people who inject drugs. For example • **Procurement and distribution of OST, including provision of take-home doses** • Development of OST protocols and policies that address the needs of pregnant clients and drug interactions for those on OST and ART/TB medications. • Training of service providers. • Referral and link to behavioral interventions, HIV testing and counseling, care and treatment. • **Prevention, screening, testing and treatment for hepatitis B and hepatitis C, vaccination for hepatitis B**
	Overdose prevention and management for PWID	Activities related to preventing overdose and management for people who inject drugs. For example: • Information and education about preventing overdose and strategies for minimizing overdose risk. • **Procurement of naloxone and support for distribution and administration by first responders, for example peers, partners, family, NGOs/CBOs.**
	Harm reduction interventions for drug use for prisoners	Activities related to harm reduction for prisoners. For example: • Needle and syringe programs. • Opioid substitution therapy. • Distribution of naloxone. • Distribution of condoms. • Prevention, screening, testing and treatment for hepatitis B and hepatitis C, vaccination for hepatitis B. • Wound care and treatment of skin infections. • TB screening and treatment.
Elimination of Vertical Transmission of HIV, Syphilis and Hepatitis B	Integrated testing of pregnant women for HIV, syphilis and hepatitis B	Activities related to integrated testing for HIV, syphilis and hepatitis B among pregnant women and linkages to treatment. For example: • Tools and job aids to provide integrated HIV testing services. • Training, combined with supportive supervision or group problem solving. • **Linkage to rapid initiation of HIV, syphilis, and hepatitis B treatments.** • Activities related to quality improvement, mentoring, combined with in-service training where appropriate.

		• Virtual interventions, educational programs and campaigns, peer mentorship and navigation, community mobilization and empowerment, incentives for antenatal care (ANC) attendance. • **Commodities for testing services, including dual HIV/syphilis test kits and Hepatitis B testing for pregnant women.** **→ Treatment costs for HIV, syphilis and hepatitis should be included under the module "Treatment, Care and Support".** **→ Activities related to strengthening the broader health system to support quality ANC and postnatal care should be included under respective RSSH modules.** **→ Opportunities for integration between HIV and reproductive, maternal, newborn, child and adolescent health (RMNCAH) platforms should be prioritized, where feasible. Integrated training costs should be budgeted under the relevant interventions in the module "RSSH/PP: Human Resources for Health (HRH) and Quality of Care".**
	Post-natal infant prophylaxis	<u>Activities related to postnatal prophylaxis and prophylaxis for high-risk infants. For example:</u> • Tools and job aids for routine and enhanced prophylaxis for high-risk HIV-exposed infants. • Antiretrovirals (ARVs) for infant prophylaxis. • **Linkages to hepatitis B vaccination.** **→ Activities related to strengthening the broader health system to support quality postnatal care should be included under respective RSSH modules.** **→ Opportunities for integration between HIV and reproductive, maternal, newborn, child and adolescent health (RMNCAH) platforms should be prioritized, where feasible. Integrated training costs should be budgeted under the relevant interventions in the module on "RSSH/PP: Human Resources for Health (HRH) and Quality of Care".**

Annex 4: Potential Areas where Hepatitis could be Considered Within RSSH-Activities

It is recommended to view this table as non-exhaustive and to review its contents alongside the Modular Framework Handbook and RSSH Information Note

Note: the table contents has been summarized from the Modular Framework Handbook which contains pre-defined modules, interventions and activities. Activities listed have been framed to give an idea of how these programmatic investments could support hepatitis service delivery.

Table: Potential RSSH investments to support hepatitis programming

Module	Intervention	Example activities to support delivery of hepatitis services as part of strengthening of health systems (non-exhaustive)
Health Sector Planning and Governance for Integrated People-centered Services	Health sector planning and governance for integrated people-centered services	• Assessments and development of national legislation, strategies, policies, regulations, protocols and guidelines, including for hepatitis • Development / revision of disease-specific plans and budgets that include hepatitis, aligning these with the national health sector strategy and relevant sub-system strategies e.g., national laboratory, Health Management Information Systems (HMIS), Human Resources for Health (HRH), community health and supply chain strategic plan • Development of models and plans for service delivery integration where hepatitis is integrated with other disease platforms (e.g., within ART clinics, harm reduction settings, Antenatal care setting), including development and implementation of referral pathways for facility-facility care and community-facility service integration • Coordinated planning, programming, and implementation, for example by conducting cross-programmatic efficiency analyses, including hepatitis
	Integration/coordination across disease programs and at the service delivery level	
Community Systems Strengthening	Community-led monitoring	Community groups and services can play an important role in improving access and/or engagement with services targeted at key populations - activities that could be considered: • Mapping of community-led and community-based organizations and networks and their service packages • Advocacy to sustain/scale-up access to services among key and vulnerable populations • Creation and/or strengthening of platforms that improve coordination, joint planning and effective linkages between communities and formal health systems (e.g., peer educators or counsellors), other health actors and broader movements such as human rights and women's movement • Capacity building and mentorship of community organization (e.g., counselling, data entry and reporting for program monitoring and evaluation, etc.)
	Community-led research and advocacy	
	Community engagement, linkages and coordination	
	Capacity building and leadership development	
Health Financing Systems	Health financing strategies and planning	• Domestic resource mobilisation efforts towards UHC to include hepatitis within UHC scope
	Community-led advocacy and monitoring of domestic resource mobilization	• Capacity building to develop and implement advocacy campaigns for domestic resource mobilization for hepatitis and UHC

	Health financing data and analytics	• Costing of hepatitis-related health sector plans, national strategic plans, investment cases and health economic analyses, operational plans and program implementation, specific health intervention(s) to inform strategic planning and the design of payment for results modalities • Use of tailored cost-effectiveness and budget impact analyses to inform the adoption or prioritization of (new) technologies, interventions/intervention mixes across populations and geographies and service delivery modalities.
	Policy, strategy, governance	Inclusion of hepatitis among: • National health products management, procurement and supply chain management (PSM) coordination, supportive supervision and monitoring mechanisms including integration of disease specific products in the national system • Development or update of the essential medicines lists, essential diagnostics lists, national drug formularies and standard treatment guidelines (STGs) and consolidated testing guidelines. • Development or update of a national strategy for procurement and supply chain management (PSCM) and logistics master plan/implementation plan
Health Products Management Systems	Storage and distribution capacity, design & operations	• Assessment of supply chain landscape, analysis and redesign of processes for optimal product flow • Development of SOPs and best practices, trainings and relevant tool development
	Planning and procurement capacity	• Development of quantification and forecasting tools for various tiers of governance and health system, capacity building in the design and use of these tools • Development of SOPs, guidelines, best practices for quantification and forecasting, capacity building of those involved • Assessment of procurement channels, collection and sharing of market intel, price negotiations, product flows in-country • Including hepatitis in integration and streamlining processes if any
	Supply chain information systems	• Capacity building in the design and deployment of dashboards • Development of stock monitoring reports and dissemination and reporting for evidence-based decision-making including performance monitoring mechanisms and indicators) • Including hepatitis in integration and streamlining processes if any
Human Resources for Health (HRH) and Quality of Care	Education and production of new health workers (excluding CHWs)	• Training of health care workers and other staff to support roll-out of hepatitis services integrated within HIV, SRH, harm reduction, and ANC service settings • Implementation of supportive supervision for healthcare workers involved in delivery of integrated services that include hepatitis • Training and mentorship approaches to support community health workers that are involved in the delivery and/or referral to integrated services that include hepatitis • Development and roll-out of multi-disease training tools including digital solutions
	In-service training (excluding CHWs)	
	Integrated supportive supervision for health workers (excluding CHWs)	
	CHWs: selection, pre-service training and	

	certification; In-service training, Integrated supportive supervision	
Laboratory Systems (including national and peripheral)	National laboratory governance and management structures Laboratory Information Systems Network optimization and geospatial analysis Laboratory supply chain systems Specimen referral and transport system	Laboratory systems strengthening activities which could benefit multiple diseases, including hepatitis testing - e.g., • Optimizing existing equipment/platforms capacity which support testing for HIV, TB or other disease programs to also support disease testing for HCV and/or HBV • Multi-disease specimen transport and diagnostic network optimization exercises and implementation • Bring together multiple disease quantification efforts to determine laboratory consumables and diagnostics needs • For health facilities delivering integrated diagnostic services including hepatitis testing (e.g., antenatal care setting, harm reduction sites), efforts to assess and strengthen access to integrated diagnostics and referral/patient linkages could be carried out (e.g., assessment of availability of needed diagnostics, assessment of speed and quality of specimen referral networks for priority diseases and establishment of integrated referral networks) • Ensuring laboratory information systems are well integrated between facilities and diseases to capture/management of patient data and pathway • Interventions to improve the laboratory supply chain for the benefit of GFATM-supported disease testing and beyond • Establish and implement all-inclusive pricing modalities for laboratory reagents that include service, maintenance, and training for equipment • Maximize lab systems and monitoring and evaluation (M&E), training opportunities through a multi-disease approaches
Monitoring and Evaluation Systems	Routine reporting Data quality Analyses, evaluations, reviews, and data use	M&E activities including multiple diseases like hepatitis - e.g., • Developing and implementing national M&E framework, indicators, reporting tools/forms • Efforts to implement interoperable and integrated M&E systems across diseases systems • Adoption of M&E systems • Improving M&E data quality e.g., disease-specific and/or cross-cutting data quality assurance activities such as disease specific data quality audits • Digital and health information management improvements e.g., innovative digital health tools such as utilizing SMS (short message service) to improve patient engagement and follow up, using mobile apps to upgrade electronic health records, logistics and patient management information systems
Program Management	Coordination and management of national disease control programs	• Establish and maintain hepatitis strategy and technical advisory groups for strong coordination across departments within the MOH and non-governmental stakeholders from relevant sectors • Develop, update and disseminate policy documents and clinical guidelines • Conduct regular program reviews and evidence-based decision-making at various levels of health system and various operational aspects (supply chain, service delivery, etc.) • Evaluate gaps and resources required to deliver RSSH and HIV investments, including those investments for delivery of hepatitis-

		related services, e.g., in human resources for health, supply chain, M&E, etc. • Provide updates including successes and challenges to senior leadership of MOH and other governmental departments and advocate for resources as required

Annex 5: Example Excerpts of Application Language from Myanmar 2020-2022 'HIV, TB [including hepatitis C] and building resilient and sustainable systems for health' Application (Tailored for NSP Application) – published on GFATM Data Explorer

1.2 Contextual Information not Included in NSPs

Hepatitis C

Epidemiology: A 2015 national survey among the general population in Myanmar found that the prevalence of hepatitis B was 6.5%and hepatitis C was 2.7%%. Hepatitis C prevalence among people who inject drugs (PWID) from a 2017-2018 Integrated Biological and Behavioural Surveillance (IBBS) survey was particularly high – with an estimated 56%prevalence overall and a range from 27%in Myitkyina to 85%in Waimaw [Note: Both townships are in Kachin State]. Co-infection of HIV and hepatitis C among PWID ranged from 4%4% in Mandalay to 55%in Bamaw [Note: The latter township is also in Kachin State]. However, prevalence decreased across all sites from 2014 to 2018 except in Mandalay, Bamaw and Waimaw -- the latter two with a significant increase in co-infection. Hepatitis B prevalence was reportedly lower than hepatitis C among PWID at 7.7%as was HIV/hepatitis B co-infection. Across the country, about 3.3 million people live with viral hepatitis B and close to 1.3 million live with viral hepatitis C, some of whom go on to develop the disease.

Among PWID in general who develop TB, at least one in three also have HIV and two out of three have hepatitis C antibodies. Most of the disease burden associated with hepatitis C infection results in the development of chronic liver disease and standardized mortality ratios for liver-related deaths that are 16 to 46-fold higher in infected individuals than in the general population. Amongst those who are HIV-infected, hepatitis B co-infection, hepatitis C co-infection and dual co-infection rates were estimated to be 2.2%%, 20.1%%, and 20.7%%, respectively. Although there is no screening for viral hepatitis for regular TB patients, pre-treatment screening of MDR-TB patients includes hepatitis C antibodies and hepatitis B antigen. Though the official report has not been published for Myanmar, generally, the prevalence of viral hepatitis among MDR-TB patients is about 5%5% and 3%3% for hepatitis B and hepatitis C, respectively.

Opportunities, gaps and challenges: Nationwide delivery of integrated and basic HIV, hepatitis C and TB services are included in the MOHS' basic 'Essential Package of Health Services' (EPHS) which will be implemented nationwide in 2020. From the perspective of MOHS – as stated in the NSP IV on HIV and AIDS – the NAP will take the lead in collaborating with the National Hepatitis Control Program in managing the response to co-infection with HIV and hepatitis C, with priority attention given to people with HIV/hepatitis C co-infection. People with hepatitis C will be prioritized for TB screening and testing.

Development partners and implementing organizations currently supporting hepatitis C treatment include a comprehensive one-stop-shop model providing harm reduction, HIV, hepatitis C and TB services, that is supported under the Global Fund, Access to Health Fund, MSF and PEPFAR/USAID (Annex 1 and 2: National Hepatitis Control Program and Partner Support and Myanmar National Strategic Plan on Viral Hepatitis, 2016-2020).

Limited facilities with inadequate service provision, low HIV and health literacy, and traditional taboos and perceptions, combined with fear of revealing drug use practice and general high stigma for all key populations, particularly among men who have sex with men (MSM), means that most individuals who present for treatment for hepatitis C and HIV are already in later stages of illness. More recent data suggests that high sustained virologic response (SVR) rates can still be achieved in these harder to treat groups (cirrhotic, treatment-experienced, with baseline resistance-associated substitutions) without the addition of ribavirin. Delivery of hepatitis C therapy requires a simplified approach which provides low cost laboratory testing and effective drugs and requires minimal infrastructure. Increased screening and

access to treatment for hepatitis C provides an opportunity for integrated screening, linkage and follow up of HIV/hepatitis C co-infected individuals and management of both HIV and hepatitis C infections.

Rationale for Hepatitis C treatment for people co-infected with HIV and/or TB: Efforts in prevention and treatment of hepatitis C are limited and need to be expanded among key populations in Myanmar. The prevalence of hepatitis C antibody positivity among PWID is estimated to be high with treatment access being very limited. As a result of limited access and barriers, PWID who are co-infected with hepatitis and HIV could die due to liver complication while on ARV with a good CD4 count and undetectable viral load. It is critical to take initiative to improve access to hepatitis C treatment in order to improve the overall quality of life of people who are co-infected. There is a robust body of evidence demonstrating the value from achieving SVR in all stages of liver disease and shows a significant mortality benefit of achieving SVR in patients at all stages of fibrosis.

Opportunities for integration:

Health Management Information Systems: DHIS2 has become the common health information platform and modules for HIV, TB and viral hepatitis have been rolled out in all 330 townships. During the next funding cycle, malaria data will be merged into DHIS2. Both HIV and TB use OpenMRS to assist in the care of patients.

Integrated Service Delivery: Decentralization of basic TB service to integrated primary care level facilities including Station Hospitals, intends not only to improve the access to TB services and reduce catastrophic health expenditures, but also empower the basic health system and strengthen patient-centered care. As an example, digital X-ray will be scaled-up at lower levels as an essential multipurpose medical tool. Hepatitis C diagnosis and treatment will be decentralized to ART centers. Comprehensive Standard Operating Procedures for heath in prisons and closed settings (including TB, HIV, STIs, Hepatitis) was developed and launched in 2018.

The HIV, TB, Malaria and Hepatitis Programs recognize that significant efficiency gains can be made through further integration of services such as: i) cross-cutting training programs for health and community workers, ii) joint planning, supervision and reviews, iii) harmonization of incentive schemes for health care workers and volunteers, iv) multipurpose use of laboratory equipment and diagnostic tools, and v) streamlining use of IT equipment. Moving forward, the programs will establish cross-cutting areas of common interest and explore cost sharing mechanisms. The results of this exercise will benefit the upcoming grant making process for all four diseases.

Annex 6: Summary of Countries that Requested Resources for HCV and/or HBV Services in 2020-2022 Applications

The table has been built by reviewing the country applications submissions published on GFATM Data Explorer website (*Vietnam – based on country intel) and instead illustrates that many countries are thinking about hepatitis-related priorities within PLHIV and key populations and pregnant women.

The table only captures what was submitted as requests to GFATM, not what was approved and allocated resources. Note, this list is not exhaustive. The review focused on applications with HIV modules. Over a hundred countries are eligible for HIV funding from GFATM – the review focused more on those countries in the regions of Africa and Asia.

HCV treatment for PLHIV coinfected with HCV	HCV screening and treatment as part of harm reduction services for people who inject drugs	HBV screening and/or prophylaxis as part of services for pregnant women
• Burkina Faso • Burundi • Cambodia • Cameroon • Central African Republic • Côte d'Ivoire • Ethiopia • India	• Bangladesh • India • Kenya • Mozambique • Myanmar • Nepal • Nigeria • Senegal	• Benin • Burkina Faso • Burundi • Cambodia • Central African Republic • Djibouti • Eritrea • Malawi

• Guinea-Bissau • Kenya • Laos • Mauritius • Mongolia • Myanmar • Rwanda • Sudan • Vietnam*	• South Africa • Tanzania	• Mozambique • Niger • Papua New Guinea • Timor-Leste

For further country case studies on harm reduction and hepatitis services, please refer to Harm Reduction International: Global State of Harm Reduction (2022) - link