

Unitaid Strategy Review 2017-2021

Final Report Volume 2: Annexes

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Submitted by Itad



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List of Acronyms

ACT-A	Access to COVID-19 Tools Accelerator
Afi	Area for Intervention
AI	Active Ingredient
AIDS	Acquired Immunodeficiency Syndrome
AIRE	Improving the Identification of Respiratory Distress in Children
ALIMA	Alliance for International Medical Action
AMR	Antimicrobial Resistance
ANC	Antenatal Care Clinic
API	Active Pharmaceutical Ingredient
ARR	Automated Respiratory Rate
ASCENT	Adherence Support Coalition to End TB
ATLAS	AutoTest Libre d'Accéder à la connaissance de son Statut VIH
BMGF	Bill & Melinda Gates Foundation
CDC	Centers for Disease Control and Prevention
CEA	Cost-Effectiveness Analysis
CHAI	Clinton Health Access Initiative
CHW	Community Health Worker
CIFF	Children Investment Fund Foundation
COP	Country Operational Plan
CS	Civil Society
CSO	Civil Society Organisation
DALY	Disability-Adjusted Life Year
DFID	Department for International Development
DNDi	Drugs for Neglected Diseases Initiative
DP	Development Partner
DRC	Democratic Republic of the Congo
EJAF	Elton John AIDS Foundation
EME	Evidence, Measurement and Evaluation
EPI	Expanded Program on Immunizations
FDC	Fixed Dose Combination
FGD	Focus Group Discussion
GAD	Grant Agreement Development

GDF	Global Drug Facility
GF	Global Fund to Fight AIDS, Tuberculosis and Malaria
GFF	Global Financing Facility
GH	Global Health
HCD	Human-Centred Design
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
HIVST	HIV Self-Testing
HSBT	Health Systems Benchmarking Tool
HSFP	Health Systems Funding Platform
IAG	International Advisory Group
ICAI	Independent Commission for Aid Impact
IG2	Interceptor® G2
IMCI	Integrated Management of Childhood Illness
INGO	International Non-Governmental Organisation
INSERM	Institut National de la Santé et de la Recherche Médicale
IPTi	Intermittent Preventive Treatment in Infants
IPTp	Intermittent Preventive Treatment in Pregnancy
IRS	Indoor Residual Spraying
ITN	Insecticide-Treated Net
ITPC	International Treatment Preparedness Coalition
IVCC	Innovative Vector Control Consortium
KI	Key Informant
KII	Key Informant Interview
KPI	Key Performance Indicator
LIC	Low-Income Country
LLIN	Long-Lasting Insecticide Net
LMIC	Low- and Middle-Income Country
LSHTM	London School of Hygiene & Tropical Medicine
LSTM	Liverpool School of Tropical Medicine
M&E	Monitoring and Evaluation
MCH	Maternal and Child Health
MDG	Millennium Development Goal
MDR TB	Multidrug-Resistant Tuberculosis

MIC	Middle-Income Country
MNCH	Maternal, Newborn and Child Health
MOH	Ministry of Health
MPP	Medicines Patent Pool
MSF	Médecins Sans Frontières
NgenIRS	Next Generation Indoor Residual Spraying
NGO	Non-Governmental Organisation
NIH	National Institute for Allergies and Infectious Diseases
NNP	New Nets Project
OKPI	Operational Key Performance Indicator
PAHO	Pan American Health Organization
PAPWG	Paediatric ARV Procurement Working Group
PATH	Program for Appropriate Technology in Health
PDP	Product Development Partnership
PEPFAR	President’s Emergency Plan For AIDS Relief
PHC	Primary Healthcare
PLWHA	People Living with HIV/AIDS
PMI	President’s Malaria Initiative
PO	Pulse Oximeter
PRC	Proposal Review Committee
PSI	Population Services International
R&D	Research and Development
R4D	Research For Development
RCT	Randomised Control Trial
RDT	Rapid Diagnostic Test
RfP	Request for Proposals
RG	Royal Guard®
RM	Resource Mobilisation
RMNCH	Reproductive, Maternal, Newborn and Child Health
RQ	Review Question
SDG	Sustainable Development Goal
SFH	Society for Family Health
SMC	Seasonal Malaria Chemoprevention
SP	Sulfadoxine and Pyrimethamine

SSA	Sub-Saharan Africa
ST	Self-Test
STAR	Self-Testing Africa
Swiss TPH	Swiss Tropical and Public Health Institute
TAG	Treatment Action Group
TB	Tuberculosis
TIMCI	Tools for Integrated Management of Childhood Illness
ToR	Terms of Reference
TPH	Tropical and Public Health
TWN	Third World Network
UK	United Kingdom
UNAIDS	The Joint United Nations Programme on HIV and AIDS
UNICEF	United Nations Children’s Fund
USAID	United States Agency for International Development
USG	US Government
VCAG	Vector Control Advisory Group
VfM	Value for Money
WHO	World Health Organization

1 Strategy Review ToRs



TERMS OF REFERENCE Unitaid 2017-2021 Strategy Review

PURPOSE OF THESE TERMS OF REFERENCE

These Terms of Reference (TOR) serve as an overall framework for the services to be provided under this engagement.

DESIRED TIMEFRAME

Requested start date: 25 March 2021

Expected completion date: 31 August 2021

TERMS OF REFERENCE

1. Background

In 2006, the governments of Brazil, Chile, France, Norway and the United Kingdom took the initiative to create Unitaid, an international drug purchase facility, which aimed to scale up access to drugs and diagnostics to fight HIV, tuberculosis and malaria for people who need them most in resource-limited settings.

Today, Unitaid remains an international organization that invests in innovations to prevent, diagnose and treat HIV, tuberculosis and malaria more quickly, affordably and effectively. It also works to improve access to diagnostics and treatment for HIV co-infections such as hepatitis C and human papillomavirus (HPV), and has joined the ACT-A partnership in 2020 in response to COVID-19. Unitaid is a hosted partnership of the World Health Organization (WHO). As of 2020, Unitaid manages a portfolio of over 45 grants worth around US \$1.3 billion.

Unitaid's 2017-21 strategy¹ was developed at a key moment in the transition from the Millennium Development Goals (MDGs) to the Sustainable Development Goals (SDGs). The SDGs, in particular SDG3 (Ensure healthy lives and promote wellbeing for all at all ages), set a holistic and transformational agenda for health and called for novel approaches. It is with this framework in mind that Unitaid developed its 2017-2021 strategy, which crystallized Unitaid's unique mission to maximize the effectiveness of the global health response by catalyzing equitable access to better health products. This strategy places innovation at its core, as a key driver of impact in the global health response and adopts an integrated approach to health to create synergies and efficiencies for health systems and patients in low- and lower-middle income countries (LMICs). Half-way through its implementation in 2019, Unitaid undertook a review. This Midterm Review² assessed how Unitaid is delivering on its Strategy and how Unitaid's impact can be amplified in the future.

With the current strategy period coming to an end, Unitaid is in the process of identifying opportunities and priorities for the next strategic period and defining its strategy for 2022-26, drawing on lessons learned from implementation of the current strategy, the Midterm Review and the organization's

¹ https://unitaid.org/assets/Unitaid-strategy-2017-2021_Dec-2017.pdf

² The Midterm Review report will be made available to the selected bidder.

contribution to the COVID-19 response. The Unitaid Strategy for 2022-26 will be developed during 2021 and the first half of 2022, and presented to the Unitaid Executive Board by June 2022.

The Executive Board mandated an external review of Unitaid’s current strategy to provide key inputs for the ongoing development of the organization’s next strategy. The Board formally requested that the Unitaid Secretariat commission an external review to be conducted by consultants and overseen by the Board leadership, acting as a Steering Committee. The external review is expected to focus on specific aspects of Unitaid’s model and strategy that are particularly relevant to consider for the next strategy. It is expected to develop recommendations to address potential areas for improvements over the next strategy cycle and will complement analyses being conducted by the Unitaid Secretariat.

2. Objectives and scope of the review

Under these Terms of Reference (ToR), the Reviewers will provide Unitaid with an assessment of the relevance, coherence, efficiency and effectiveness of Unitaid’s 2017-2021 Strategy and operating model, with a focus on the key questions and analyses listed below and in Figure 1.

1. **Relevance:** Are Unitaid’s interventions focusing on the right topics?
2. **Coherence:** How well do Unitaid interventions fit in the Global Health space?
3. **Efficiency:** How well are resources being used?
4. **Effectiveness:** Is Unitaid achieving the right objectives?

Figure 1. Key Questions and Scope for Strategy Review

Evaluation Criteria ³	Key Questions	Analyses in Scope ⁴
RELEVANCE	<ul style="list-style-type: none"> + To what extent has Unitaid responded to the needs of targeted beneficiaries / addressed global goals? To what extent has Unitaid selected the right priorities? Were any topical areas or potential innovations missed? + To what extent is the process underpinning the development of disease narratives and areas for intervention (Afi) well-suited for prioritizing focus areas? To what extent have priorities been adapted/course-corrected to respond to significant changes, where these have occurred? + To what extent are or could the outputs of the process be useful to inform other organizations’ priority setting and investments? 	<ul style="list-style-type: none"> + Analysis of investment priorities selected over the strategic period, with focus on: <ul style="list-style-type: none"> • Appropriateness of process and criteria to select areas of focus • Effectiveness of approaches used to identify AfIs (e.g., documents used/consulted, stakeholders engaged) • Extent to which identified cross-cutting priorities (such as antimicrobial resistance, integration) informed the selection of investments • Extent to which outputs of the process (e.g., disease narratives, technology landscapes, etc.) are or could be relevant/useful to other organizations, and opportunities to enhance their utility • Extent to which areas for investment funded by Unitaid are considered responsive to global health priorities and the ‘right’ ones to deliver maximum impact against its mandate
COHERENCE	<ul style="list-style-type: none"> + To what extent does Unitaid’s work complement that of other actors? + To what extent has Unitaid consistently focused on areas for intervention aligned with its strategy, mandate and operating model and where it is well-positioned to deliver results? To what extent do the projects in Unitaid’s portfolio add up to a coherent whole with the potential to drive transformative change? + To what extent are Unitaid’s positioning, work and achievements recognized relative to those of other relevant actors? + To what extent is Unitaid recognized as a key player and as bringing value to its investment areas? 	<ul style="list-style-type: none"> + Analysis of Unitaid’s complementarity, comparative advantage, visibility and value-add: <ul style="list-style-type: none"> • Mapping of Unitaid investments and those of other actors for a selection of key areas, including COVID-19 • Stakeholder perspectives (in particular those of global partners, donors and countries) on Unitaid’s role and contributions, overall and in specific investment areas and its comparative advantage • Stakeholder perspectives on positioning and recognition of Unitaid in relevant global health initiatives, overall and in specific investment areas

³ Based on OECD’s Development Assistance Committee (DAC) evaluation criteria. Assessments along the remaining dimensions (Impact and Sustainability), as well as additional analyses along the dimensions included here, will be conducted through an internal Unitaid review.

Evaluation Criteria ³	Key Questions	Analyses in Scope ⁴
EFFICIENCY	<ul style="list-style-type: none"> + To what extent is Unitaid’s model⁵ fit-for-purpose, fast and agile enough to seize key opportunities and deliver in a timely manner? + To what extent are the trade-offs between rigor and assurance vs. speed and agility appropriate given Unitaid’s mandate, priorities and risk appetite? + To what extent does the grant management model make efficient use of resources (both at Unitaid and implementing organizations)? What opportunities are there to enhance the model to enable the optimal balance between empowering implementers with the flexibility they need to innovate in delivery and ensuring accountability for delivery? 	<ul style="list-style-type: none"> + Analysis of ability to make new investments in response to changing needs (e.g., Advanced HIV Disease, COVID-19) + Analysis of grant management approach focusing on: <ul style="list-style-type: none"> • Mapping of key process steps and deliverables (high level only – it is not expected that the review would conduct a detailed process analysis) • Implementer perspectives and key learning to make the relationship with Unitaid more efficient and effective, including: <ul style="list-style-type: none"> • Unitaid’s expertise • Level of support and flexibility provided to grantees • Efficiency of Unitaid’s grant management approach (with focus on key areas, such as grant development, reporting, disbursement) • Best practices from other organizations in key areas of grant management (e.g., grant development, reporting, disbursement), and potential approaches to tier the portfolio (e.g. by level of investment, by implementer capacity, etc) to enable nimbler processes in certain areas while ensuring fit-for-purpose risk management
EFFECTIVENESS	<ul style="list-style-type: none"> + To what extent is Unitaid’s portfolio delivering against its objectives and providing value for money? Are the results consistent across areas? To what extent are the objectives and associated targets sufficient to drive expected transformations at the grant and portfolio level (e.g. are price reductions sufficient to drive substantive or only incremental change?) + To what extent can objectives and targets be well defined upfront at grant level? At Afi level? 	<ul style="list-style-type: none"> + Meta-analysis of grant/Afi results, assessing degree of achievement and consistency of stated objectives, appropriateness of targets, robustness of the theory of change - including how Unitaid’s approach in these areas has evolved over time - as well as lessons learnt + Analysis of Unitaid’s approach for objective/target setting, and opportunities / trade-offs for alternative approaches at: i) Afi level, ii) grant level (this analysis may involve case studies of a selection of Afis and grants, as well as best practices from other relevant organizations) + Overall analysis of value for money, examining results achieved for a given portfolio against level of investment

3. Review methodology, place of work, and management

Methods: The review will rely on a mixed-methods approach to potentially include but not be limited to: document review, key informant interviews, focus group discussions/workshops, surveys of relevant stakeholders, case studies, best practice analyses, etc. Suggested methods for each set of questions are included in Figure 2. Reviewers are expected to develop and apply rubrics to assess strength of evidence, strength of effect, and level of contribution to inform analysis and reporting of findings.

Figure 2. Suggested methods for analyses

Evaluation Criteria	Key Questions	Suggested Methods (non exhaustive)
RELEVANCE	<ul style="list-style-type: none"> + To what extent has Unitaid responded to the needs of targeted beneficiaries / addressed global goals? To what extent has Unitaid selected the right priorities? Were any topical areas or potential innovations missed? + To what extent is the process underpinning the development of disease narratives and areas for intervention (Afi) well-suited for prioritizing focus areas? To what extent have priorities been adapted/course-corrected to respond to significant changes, where these have occurred? + To what extent are or could the outputs of the process be useful to inform other organizations’ priority setting and investments? 	<ul style="list-style-type: none"> • Stakeholder engagement / interviews to capture their perspectives on whether Unitaid has invested in the right areas given its mandate • Case studies of selection of disease narratives and Afis to assess complementarity of selected grants / potential missed areas / integration of cross-cutting priorities (e.g., antimicrobial resistance) • Best practices of "opportunity identification" based on examples from other organizations

COHERENCE	<ul style="list-style-type: none"> + To what extent does Unitaid’s work complement that of other actors? + To what extent has Unitaid consistently focused on areas for intervention aligned with its strategy, mandate and operating model and where it is well-positioned to deliver results? + To what extent do the projects in Unitaid’s portfolio add up to a coherent whole with the potential to drive transformative change? + To what extent are Unitaid’s positioning, work and achievements recognized relative to those of other relevant actors? + To what extent is Unitaid recognized as a key player and as bringing value to its investment areas? 	<ul style="list-style-type: none"> • Mapping of Unitaid investments and those of other actors for a selection of key areas • Survey of external stakeholders • Stakeholder engagement / interviews to complement/deepen initial survey findings
EFFICIENCY	<ul style="list-style-type: none"> + To what extent is Unitaid’s model fit-for-purpose, fast and agile enough to seize key opportunities and deliver in a timely manner? 	<ul style="list-style-type: none"> • Best practices from other relevant organizations on grant management practices (incl. grant development processes, decision-making approaches, reporting requirements,
Evaluation Criteria	Key Questions	Suggested Methods (non exhaustive)
<ul style="list-style-type: none"> + To what extent are the trade-offs between rigor and assurance vs. speed and agility appropriate given Unitaid’s mandate, priorities and risk appetite? + To what extent does the grant management model make efficient use of resources (both at Unitaid and implementing organizations)? What opportunities are there to enhance the model to enable the optimal balance between empowering implementers with the flexibility they need to innovate in delivery and ensuring accountability for delivery? 	<ul style="list-style-type: none"> disbursement flexibility thresholds) and risk-flexibility profiles • Unitaid implementer survey / in-depth interviews 	
EFFECTIVENESS	<ul style="list-style-type: none"> + To what extent is Unitaid’s portfolio delivering against its objectives and providing value for money? Are the results consistent across areas? To what extent are the objectives and associated targets sufficient to drive expected transformations at the grant and portfolio level (e.g. are price reductions sufficient to drive substantive or only incremental change?) + To what extent can objectives be well defined upfront at grant level? At Afl level? 	<ul style="list-style-type: none"> • Meta-analysis of existing results reports and external evaluations at grant/Afl level • Case studies of selected Afls exploring the extent to which objectives have been articulated upfront (or could have been), appropriateness of targets relative to what is needed to drive meaningful change, and identifying potential areas for strengthening • Analysis of cost versus impact across Unitaid’s portfolio of investments • Stakeholder engagement / interviews • Best practices from other relevant organizations on target setting / impact measurement; particularly those operating early in the value chain and/or focused on innovation

Place of work: It is expected that work under this review will take place entirely remotely. If the Covid-19 context permits that some consultations take place in person, then that can be considered.

Management and communication: The external review will be overseen by the Executive Board Steering Committee, with the direct management and support by the Unitaid Secretariat. The breakdown of roles and responsibilities is detailed in Figure 3.

The Reviewers will be expected to:

1. Organize and deliver a virtual inception/kick-off meeting with the Steering Committee;
2. Coordinate monthly Steering Committee calls to review progress and present interim findings;
3. Present interim findings to other Unitaid governance bodies as needed (such as the Policy and Strategy Committee);
4. Deliver a virtual presentation of the final findings and recommendations to the Unitaid Executive Board.

Figure 3. Unitaid Roles and Responsibilities in this External Review

Role of...	Contracting	Review	Final Report
 Secretariat	<ul style="list-style-type: none"> • Write Terms of Reference (ToR) • Undertake selection process to identify of external reviewer(s) • Complete contracting of reviewer(s) 	<ul style="list-style-type: none"> • Provide input to review activities • Facilitate access to relevant data and stakeholders • Review and provide feedback on interim findings • Organize and participate in Steering Committee calls 	<ul style="list-style-type: none"> • Review final report for factual errors/omissions • Provide response to findings by reviewer(s)
 Board Steering Committee	<ul style="list-style-type: none"> • Define scope of work along with the Secretariat and approve ToR • Validate Secretariat selection of reviewer(s) 	<ul style="list-style-type: none"> • Lead monthly Steering Committee calls with Secretariat and reviewer(s) • Review and provide feedback on interim findings • Provide guidance on next steps 	<ul style="list-style-type: none"> • Review final report before Board approval

4. Stakeholder Consultation

The External Review will feature targeted consultation with a broad range of internal and external stakeholders, including technical experts, civil society, government partners, Board, PRC, Unitaid implementers, Unitaid staff, etc. (Refer to the table below for an illustrative list). The Reviewers are expected to focus consultations with each group on where they are best placed to contribute as per the key questions and areas for analysis.

Stakeholder group	Description
Unitaid Executive Board	Unitaid executive board members and their supporting staff
Unitaid Proposal Review Committee (PRC)	Chair of the PRC and other members as appropriate
Unitaid Secretariat	Senior management and representatives from various teams (e.g. results, strategy, program division, communications, etc)
Unitaid implementers	Executives and project directors from a representative mix of Unitaid implementing partners (in terms of grant size, number of grants, years of experience engaging with Unitaid, and disease area)
Civil society/ Communities	Representatives at global, regional and national levels from civil society organizations and community groups that reflect Unitaid’s investments with regard to disease area and type of investment
Country governments	Key decision makers within Ministry of Health and other relevant ministries; countries selection should consider the extent of Unitaid’s portfolio, disease area, and region (Africa, Asia, Latin America), among others. Countries where Unitaid has an extensive portfolio and/or a formal agreement should be prioritized (<i>e.g. South Africa, India, Brazil, Cameroon, Kenya, Uganda, Mozambique, Rwanda</i>)
Funding partners	Global Fund, President’s Emergency Plan for AIDS Relief (PEPFAR OGAC, CDC, USAID), President’s Malaria Initiative, WHO Foundation

Stakeholder group	Description
UN agencies	WHO, UNICEF, UNDP, UNAIDS, and other relevant agencies
Technical experts	Global, regional, and country-based technical experts including from WHO, UNICEF, technical working groups relevant to Unitaids's core areas of work (HIV, Tuberculosis, Malaria, Co-infections)
Private Sector	Representatives of the private sector, including diagnostic and treatment manufacturers that Unitaids funds directly or indirectly
Other	Academic institutions, innovation partnerships, among others

The Reviewers are requested to dedicate a larger proportion of consultations to external stakeholders and partners and to use focus group discussions where relevant. Further, the proposal should demonstrate a meaningful plan for engagement with civil society and community groups.

5. Timeline and Deliverables

The review will run over the span of ~4-5 months with deliverables to be submitted within the following indicative timeline (see table). It is anticipated that the review will launch in the second half of March 2021 and that the core phase of data collection and analysis will occur between April and May 2021. The aim is to present near final findings and recommendations to the Executive Board at a meeting scheduled in mid-June 2021.

Deliverable	Timeframe
1. Inception report outlining the process for the strategic review including methodology, draft interview guides, a work plan and timeline and a list of interviewees	Early April 2021
2. Interim report on initial findings and recommendations for feedback from the Steering Committee	May 2021
3. Presentation to the Executive Board addressing the key findings related to the implementation of the 2017-2021 Strategy and presents recommendations for the upcoming strategy	June 16-17th 2021
4. Final Report – final report that addresses feedback from the Board and Secretariat	July 2021

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3. Presentation to the Executive Board addressing the key findings related to the implementation of the 2017-2021 Strategy and presents recommendations for the upcoming strategy	June 16-17th 2021
4. Final Report – final report that addresses feedback from the Board and Secretariat	July 2021

8. Payment schedule

SN.	Deliverable	Due Date	%
1	Inception report outlining the process for the strategic review including methodology, draft interview guides, a work plan and timeline and a list of interviewees.	April 2021	24%
2	Interim report on initial findings and recommendations for feedback from the Steering Committee.	May/June 2021	56%
3	Presentation to the Executive Board addressing the key findings related to the implementation of the 2017-2021 Strategy and presents recommendations for the upcoming strategy.	July 2021	15%
4	Final Report – final report that addresses feedback from the Board and Secretariat.	July/August 2021	6%

A fixed payment of USD 474,220 will be made following satisfactory completion of deliverables and submission of corresponding detailed invoices, along with a Financial Statement (using the template to be provided by Unitaïd in due course) detailing the actual level of effort incurred and other costs incurred.

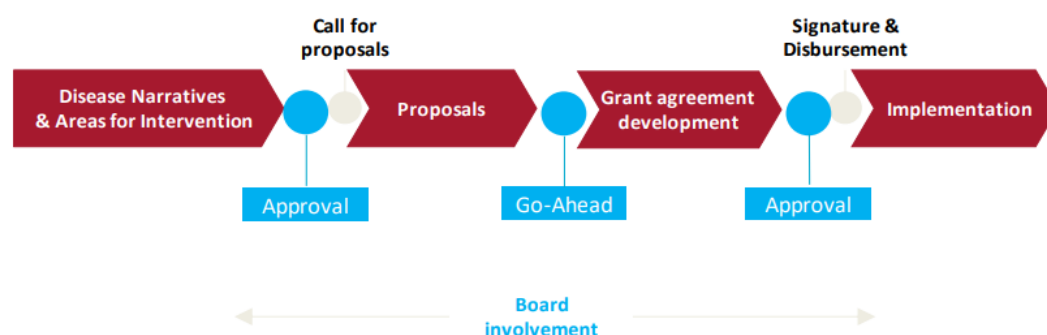
Annex 1. Overview of existing data sources by evaluation criteria

Evaluation Criteria	Data Sources
RELEVANCE	<ul style="list-style-type: none"> + Mid-term review 2019 (incl. interviews with WHO Departments) + Implementer surveys (2018-2020⁶) + External evaluations under new strategy (relevance component)* + Unitaid disease narratives, AfIs, landscape reports + Global disease strategies and partner strategies + Global Fund Strategic Review Report (2020)
COHERENCE	<ul style="list-style-type: none"> + Implementer surveys (2018-2020) + External evaluations under new strategy (for Afi, grant level) + Annual grant portfolio reports (2017-2020)
EFFICIENCY	<ul style="list-style-type: none"> + Mid-term review 2019 (operating model) + Operational KPIs reporting (2017-2020) + Implementer surveys (2018-2020) + Unitaid staff survey (2017, 2019, 2020) and pulse surveys (ad hoc)
EFFECTIVENESS	<ul style="list-style-type: none"> + Annual grant portfolio reports (2017-2020) + Strategic KPI reporting (2017-2020) + External evaluations under new strategy (for Afi, grant level) + Mid-term review 2019 (strategic objectives, investment principles)

*12 external evaluations of Unitaid grants have been completed since the start of the new strategy in 2017 (3 mid-term and 9 end-of-grant). In addition, two evaluations at the Afi/portfolio level are underway and preliminary results will be available in March 2020.

Annex 2. Mapping of Unitaid’s Operating Model

1. **Core Approach**



2 Strategic Review Framework

WS	Modules and overarching questions	Review questions	Indicative criteria for judging performance	Data collection approaches	Data analysis approaches
WS 1 Right Topics	<p>Module 1 Relevance</p> <p>Have Unitaid’s interventions been focusing on the right topics/issues – particularly in a dynamic context?</p>	<p>RQ1 Relevance of AfIs</p> <p>To what extent has Unitaid responded to the needs of targeted beneficiaries/addressed global goals? To what extent has Unitaid selected the right priorities? Were any topical areas or potential innovations missed?</p>	<ul style="list-style-type: none"> ▪ Extent to which investments respond to the needs of targeted beneficiaries ▪ Extent to which identified cross-country priorities (such as AMR, integration) and Unitaid commitments (equity, health systems strengthening, partnerships and VfM) informed the selection of investments. ▪ Extent to which AfIs funded by Unitaid are considered responsive to global health priorities (e.g. Leave no one behind as part of the 2030 Agenda) and the ‘right’ ones to deliver maximum impact against its mandate 	<ul style="list-style-type: none"> ▪ Key informant interviews ▪ Structured document review 	<ul style="list-style-type: none"> ▪ Thematic case studies ▪ VfM analysis (equity, effectiveness)
		<p>RQ2 Prioritisation process</p> <p>To what extent is the process underpinning the development of disease narratives and Afl well suited for prioritising focus areas? To what extent have</p>	<p>Alignment or divergence with best practices (from comparator organisations) in key areas of:</p> <ul style="list-style-type: none"> ▪ Appropriateness of process and criteria to select areas of focus ▪ Appropriateness of process and criteria to targeting interventions based on equity 	<ul style="list-style-type: none"> ▪ Key informant interviews ▪ Structured document review 	<ul style="list-style-type: none"> ▪ Thematic case studies ▪ Comparator study ▪ VfM analysis (equity, effectiveness)

WS	Modules and overarching questions	Review questions	Indicative criteria for judging performance	Data collection approaches	Data analysis approaches
		priorities been adapted/course-corrected to respond to significant changes, where these have occurred?	<ul style="list-style-type: none"> Effectiveness of approaches used to identify AfIs (e.g. documents used/ stakeholders engaged) 		
		<p>RQ3 Transferability</p> <p>To what extent are or could the outputs of the process be useful to inform other organisations’ priority setting and investments?</p>	Extent to which outputs of the process (e.g. disease narratives, technology landscape, etc.) are or could be relevant/useful to other organisations, and opportunities to enhance their utility	<ul style="list-style-type: none"> Key informant interviews Structured document review 	<ul style="list-style-type: none"> Thematic case studies Comparator study
WS 2 Right Ways	<p>Module 2 Coherence</p> <p>What is Unitaids’ Unique Selling Proposition in the Global Health space?</p>	<p>RQ4 Complementarity</p> <p>To what extent does Unitaids’ work complement that of other actors?</p>	<ul style="list-style-type: none"> Evidence of complementarity/duplication of Unitaids’ role at: <ul style="list-style-type: none"> the global level the disease level the level of specific investment areas and in specific geographies 	<ul style="list-style-type: none"> Key informant interviews Structured document review Online survey 	<ul style="list-style-type: none"> Thematic case studies Comparator study Mapping of investments and landscape analysis

WS	Modules and overarching questions	Review questions	Indicative criteria for judging performance	Data collection approaches	Data analysis approaches
		<p>RQ5 Comparative advantage</p> <p>To what extent has Unitaid consistently focused on Afls aligned with its strategy, mandate, and operating model and where it is well positioned to deliver results?</p>	<ul style="list-style-type: none"> ▪ Evidence of comparative advantage of Unitaid’s role at <ul style="list-style-type: none"> ○ the global level ○ the disease level ○ the level of specific investment areas and ○ in specific geographies 	<ul style="list-style-type: none"> ▪ Key informant interviews ▪ Structured document review ▪ Online survey 	<ul style="list-style-type: none"> ▪ Thematic case studies ▪ Comparator study ▪ Mapping of investments and landscape analysis
		<p>RQ6 Internal coherence</p> <p>To what extent do the projects in Unitaid’s portfolio add up to a coherent whole with the potential to drive transformative change?</p>	<ul style="list-style-type: none"> ▪ Evidence of projects in Unitaid’s portfolio add up to a coherent whole (in line with the organisational Theory of Change) ▪ Alignment or divergence with approach to ensuring internal coherence of comparator organisations 	<ul style="list-style-type: none"> ▪ Key informant interviews ▪ Structured document review ▪ Online survey 	<ul style="list-style-type: none"> ▪ Thematic case studies ▪ Comparator study
		<p>RQ7 Visibility and recognition</p> <p>To what extent are Unitaid’s positioning, work and achievements recognised</p>	<ul style="list-style-type: none"> ▪ Evidence of visibility of Unitaid’s role at <ul style="list-style-type: none"> ○ the global level ○ the disease level ○ the level of specific investment areas and ○ in specific geographies 	<ul style="list-style-type: none"> ▪ Key informant interviews ▪ Structured document review 	<ul style="list-style-type: none"> ▪ Thematic case studies ▪ Comparator study ▪ Mapping of investments and

WS	Modules and overarching questions	Review questions	Indicative criteria for judging performance	Data collection approaches	Data analysis approaches
		relative to those of other relevant actors? To what extent is Unitaid recognised as a key player and as bringing value to its investment areas?	<ul style="list-style-type: none"> Alignment or divergence with approach to visibility of comparator organisations 	<ul style="list-style-type: none"> Online survey 	<ul style="list-style-type: none"> landscape analysis
	Module 3 Efficiency How well are Unitaid resources being used?	RQ8 Operating model To what extent is Unitaid’s model fit-for-purpose, fast and agile enough to seize key opportunities and deliver in a timely manner?	<ul style="list-style-type: none"> Ability to make new investments in response to changing needs and priorities (e.g. COVID-19, Advance HIV Disease) Output targets are met in line with allocated budget and the ratio between programme expenditure and outputs achieved increases over time 	<ul style="list-style-type: none"> Key informant interviews Structured document review 	<ul style="list-style-type: none"> Thematic case studies Comparator study Analysis of Unitaid’s grant-making and management approach vis-à-vis VfM best practice VfM analysis (efficiency, equity)
		RQ9 Risk management To what extent are the trade-offs between rigour and	<ul style="list-style-type: none"> Degree of achievement and consistency of stated objectives, appropriateness of targets, robustness of the ToC 	<ul style="list-style-type: none"> Key informant interviews 	<ul style="list-style-type: none"> Thematic case studies Analysis of Unitaid’s grant-

WS	Modules and overarching questions	Review questions	Indicative criteria for judging performance	Data collection approaches	Data analysis approaches
		assurance vs. speed and agility appropriate given Unitaids mandate, priorities, and risk appetite?	<ul style="list-style-type: none"> ▪ Appropriateness of Unitaids approach to objective target setting ▪ Outcome targets are met/exceeded, the ratio between outputs and outcomes achieved for a given portfolio increases over time ▪ Qualitative assessment that the interventions have made a meaningful contribution to outcomes achieved ▪ Evidence that the benefits of programme activities are equitably distributed among those in need ▪ Use of information flows to identify and address risks 	<ul style="list-style-type: none"> ▪ Structured document review 	<ul style="list-style-type: none"> ▪ making and management approach vis-à-vis VfM best practice ▪ VfM analysis (effectiveness, equity)
		<p>RQ10 Grant management model</p> <p>To what extent does the grant management model make efficient use of resources (both at Unitaids and implementing organisations)? What</p>	<ul style="list-style-type: none"> ▪ Alignment or divergence with best practices in ensuring VfM in grant-making and management (as per our literature review) ▪ Potential approaches to improve the model 	<ul style="list-style-type: none"> ▪ Key informant interviews ▪ Structured document review 	<ul style="list-style-type: none"> ▪ Thematic case studies ▪ Comparator study ▪ Analysis of Unitaids grant-making and management

WS	Modules and overarching questions	Review questions	Indicative criteria for judging performance	Data collection approaches	Data analysis approaches
		<p>opportunities are there to enhance the model to enable the optimal balance between empowering implementers with the flexibility they need to innovate in delivery and ensuring accountability for delivery?</p>			<p>approach vis-à-vis VfM best practice</p>
<p>WS 3 Right Results</p>	<p>Module 4 Effectiveness</p>	<p>RQ11 Value for Money</p> <p>To what extent is Unitaid’s organisation and portfolio delivering against its objectives and providing VfM? Are the results consistent across areas? To what extent are the objectives and associated targets sufficient to drive expected transformations at the grant and portfolio level (e.g. are price reduction sufficient to drive substantive or only incremental change?)</p>	<p>Evidence that the portfolio is delivering economy, efficiency, effectiveness, equity</p> <ul style="list-style-type: none"> ▪ Input analysis ▪ Allocation of inputs to activities, as far as is possible ▪ Review of Unitaid KPIs and outcomes measurement 	<ul style="list-style-type: none"> ▪ Key informant interviews ▪ Structured document review 	<p>VfM analysis (economy, efficiency, effectiveness, equity)</p>

WS	Modules and overarching questions	Review questions	Indicative criteria for judging performance	Data collection approaches	Data analysis approaches
		<p>RQ12 Target setting</p> <p>To what extent are objectives and targets well defined up-front and subsequently at grant level? At Afl level? At organisation level?</p>	<p>Evidence that objectives and targets can be well defined up-front at grant/Afl/organisation level.</p>	<ul style="list-style-type: none"> ▪ Key informant interviews ▪ Structured document review 	<ul style="list-style-type: none"> ▪ Thematic case studies

3 List of People Interviewed

3.1 List of Global KIs

Name and surname	Job title	Organisation
Abdallah Makhlof	Director, Supply Division	UNICEF
Ander Ruiz de Gopegui	Spain representative	Unitaid Executive Board
Andrew Lofts Gray	PRC Member	Unitaid
Anneke Hesseling	Professor and Director of the Paediatric TB Research Programm	Desmond Tutu TB Centre at Stellenbosch University
Bernard Fourie	PRC Member	Unitaid
Bernard Pécoul	Director	Drugs for Neglected Diseases Initiative (DNDi)
Bruce Aylward	Senior Advisor to the Director-General and lead for ACT-A	WHO
Cary James	Chief Executive Officer	World Hepatitis Alliance
Chee Yoke Ling	Director of Programmes	Third World Network (TWN)
Cheri Grace	PRC Member	Unitaid
David Curry	Director of Finance and Administration	Unitaid Secretariat
David Ripin	Executive Vice President, Infectious Diseases; Chief Science Officer	Clinton Health Access Initiative (CHAI)
Edward Wangenya	CEO	NGO Delegation (NGO Alliance against Malaria)
Ellen 't Hoen	Medicines Law & Policy	Director
Eric Fleutelot	Technical Director of Major Pandemics Unit	Expertise France
Fifa Rahman	Former NGO Delegate	Health Poverty Action
Gary Johnson	Vice President of Research and Development, Rapid Diagnostics	Abbott
Greg Widmyer	Foundations representative	Unitaid Executive Board
Haitham El-Noush	Norway representative	Unitaid Executive Board
Helen McDowell	Head of Government Affairs	ViiV
James Droop	United Kingdom representative	Executive Board
Janet Ginnard	Director, Strategy	Unitaid Secretariat
Jerome Oberreit	Head of Executive Office and Senior Advisor to the Executive Director	GARDP
Jessica Jones	Program Officer, Market Dynamics for RMNCH and Health Systems Innovation	Bill and Melinda Gates Foundation

Judith Ann Polsky	Senior Manager, Resource Mobilisation	Unitaid Secretariat
Julie Wallace	US Global Malaria Coordinator; Malaria Division Chief	PMI
Katy Godfrey	Technical Advisor, HIV	USA CDC
Keiichi Hara	Japan representative	Unitaid Executive Board
Kenly Sikwese	Communities living with the diseases representative	Unitaid Executive Board
Madame Safiatou Simporé Diaz & Madame Asmaa El-kamchi	African countries representative	Unitaid Executive Board
Maria Luisa Escorel de Moraes	Brazil/Vice-Chair	Unitaid Executive Board
Marisol Touraine	Chair	Unitaid Executive Board
Minghui Ren	Executive Board	WHO
Monique Van Vilet	Financial Controller	Unitaid Secretariat
Ms Dasom Shin	Executive Board	Republic of Korea
Nikki Tyler	Senior Market Access Advisor	USAID Centre for Innovation and Impact
Othoman Mellouk	Access to Diagnostics and Medicines Lead	International Treatment Preparedness Coalition (ITPC)
Philippe Duneton	Executive Director	Unitaid Secretariat
Philip Waweru Mbugua	Executive Director	NGO Delegation (National Organization of Peer Educators)
Pradeep Kakkattil	Director, Office of Innovation and Partnership	UNAIDS
Robert Matiru	Director, Programme Management	Unitaid Secretariat
Rohit Malpani	Executive Board	NGOs
Salome Meyer	Independent Consultant	NGO Delegation (Cancer Prevention and Control)
Stephanie Seydoux	French Ambassador for Global Health	Executive Board
Taryn Barker	Director, Commercial Solutions	Children Investment Fund Foundation (CIFF)
Thibaud Lefort	Head of Global Health Business	Sanofi
Vincent Bretin	Director, Results	Unitaid Secretariat
Yogan Pillay	Country Director - Kenya, South Africa, Nigeria, India; Senior Director, Viral Hepatitis	CHAI

3.2 List of Case Study KIs

3.2.1 TB Prevention Case Study KIs

Name and surname	Job title	Organisation
Brenda Waning	Chief	Global Drug Facility (GDF), Stop TB Partnership
Charles Sandy	Deputy Director for the AIDS and TB Unit	Zimbabwe MOH
David Ripin	Executive Vice President of Access Programs and Chief Science Officer	CHAI
Eluid Wandwalo	Senior Disease Coordinator TB	Global Fund
Gavin Churchyard & Karin Turner	CEO & Director, Global Health Programmes	Aurum Institute
Grania Bridgen	Director	International Union Against Tuberculosis and Lung Disease (The Union)
Hema Srinivasan	Chief Access Officer	MedAccess
Mike Frick	TB Project Co-Director	Treatment Action Group (TAG)
Musoke J Sempala	Fund Portfolio Manager	Global Fund
Sevim S. Ahmedov & Dr Ya Diul Mukadi	Senior TB Technical Advisor & Senior TB Media Advisor	USAID
Tereza Kasaeva	Director, WHO Global Tuberculosis Programme	WHO
Waqo Ejersa	National TB Program	Kenya MOH

3.2.2 Malaria Chemoprevention Case Study KIs

Name and surname	Job title	Organisation
Elaine Roman	TIPTOP Director	Jhpiego
James Tibenderana	Global Technical Director	Malaria Consortium
Joshua Levens	Manager, Advocacy and Resource Mobilisation Partner Committee	RBM
Julie Wallace	US Global Malaria Coordinator; Malaria Division Chief	PMI
Melanie Renshaw	Chief Executive Officer	ALMA
Nnenna Ogbulafor	Director	Nigeria National Malaria Program
Oji Onyemaechi	Nigeria CSO Representative	National Identity Management Commission
Pedro Alonso	Director, Global Malaria Program	WHO
Pierre Hugo	Senior Director Access and Product Management	MMV

Scott Filler	Malaria Unit Director	Global Fund
Susan Youlle	Malaria in Pregnancy Lead	PMI
Tarryn Haslam	Malaria Director	Population Services International (PSI)

3.2.3 HIV Self-test Case Study KIs

Name and surname	Job title	Organisation
Anne Aslett	Global CEO	Elton John AIDS Foundation (EJAF)
Clemence Doumenc-Aidara & Anthony Vautier	Project Director & Technical Director	Solthis
Hans Croukamp & Jared Dobbs	COO & National Sales Manager	Biolytical
Karin Hatzold	Director of STAR	PSI
Liz Corbett	Clinical Epidemiologist	LSHTM
Mariângela Batista Galvão Simão	Assistant Director-General for Drug Access, Vaccines and Pharmaceuticals	WHO
Obinna Onyekwena	Disease Advisor, HIV	Global Fund
Rachel Baggaley	HIV Prevention Team	WHO
Sara Pilot	Managing Director	MTV SAF
Taryn Barker	Director, Adolescence (Commercial Solutions)	CIFF
Thato Chidarikire	Director of HIV Prevention Programmes in the National Department of Health	MoH, South Africa

3.2.4 Fever Management Case Study KIs

Name and surname	Job title	Organisation
Amos Mugisha	Country Director, Tanzania	PATH
Anne Detjen	Health Specialist, Integrated Service Delivery	UNICEF
John Ochero	Fund Portfolio Manager, Kenya	Global Fund
Marine Vignon	Project Director, AIRE project	ALIMA
Mike Ruffo	Project Director, TIMCI project	PATH
Sarah Asimwe	Health Specialist, Tanzania	Global Fund
Smita Kumar	Senior Newborn Advisor	USAID
Yasir Bin Nisar	Medical Officer	WHO

3.2.5 Comparative Landscape Analysis KIs

Name and surname	Job title	Organisation
Adrien de Chaisemartin	Director, Strategy and Performance	Gavi
Cammie Lee	Senior Program Director, Market Shaping	Results for Development (R4D)
David Ripin	Executive Vice President of Infectious Diseases and Chief Science Officer	CHAI
Kerry Pelzman	Assistant Administrator, Bureau of Global Health	USAID
Peter Hansen	Head of Results	Global Financing Facility (GFF)
Roger Li	Head of Strategic Sourcing	Global Fund
Subhanu Saxena	Director, Innovation Introduction	Gates Foundation

4 List of Documents Reviewed

4.1 General Background Documents

- 2017, Executive Board Meeting – Methodology for Developing Strategic Narratives
- 2017, UK Annual Review Unitaid – Summary Sheet
- 2018, Unitaid 2017-2021 Midterm Strategy Review/TERMS OF REFERENCE
- 2019, Strategic Framework for Collaboration
- 2020, Unitaid 2018-2020 FCDO Review
- 2021, PSC Workshop Strategy 2022-2026
- 2021, Unitaid Strategy Development: Interview Guide Extended Management Team
- 2021, Unitaid Strategy Workshop/ PSC Workshop Pre-read document – Appendix
- CEPA, 2020, NgenIRS End-of-Project Evaluation Report
- Dalberg, 2017, Unitaid project evaluation: Achieving Catalytic Expansion of Seasonal Malaria Chemoprevention in the Sahel (ACCESS–SMC)
- FCDO, 2020, FCDO Annual Review of Unitaid
- Global Fund ,2020, Strategic Review 2020, Vol. 2 – Annexes
- Global Fund, 2016, Global Fund Strategy
- Policy and Strategy Committee, 15th Session/Agenda Item 4, 2016, Value for Money Framework
- Policy and Strategy Committee/ 20th Session/Agenda Item 4, 2018, Midterm review of the implementation of Unitaid’s strategy
- Policy and Strategy Committee/ 24th meeting/Agenda Item 5, 2020, Update on the agility mechanism pilot: Unitaid Explore
- Policy and Strategy Committee/21st Session/ Agenda Items 5, 2019, Annex to the Interim Report of the Midterm Strategy Review: Investment Commitments
- Policy and Strategy Committee/21st Session/Agenda Item 5, 2019, Annex to the Interim Report of the Midterm Strategy Review: Investment Commitments
- Policy and Strategy Committee/21st Session/Agenda Item 5, 2019, Annex to the Interim Report of the Midterm Strategy Review: Portfolio
- Policy and Strategy Committee/21st Session/Agenda Item 6, 2019, Annex to the Interim Report of the Midterm Strategy Review: Operating Model Performance
- Policy and Strategy Committee/21st Session/Agenda Item 7, 2019, Lessons learned from implementation: The example of Molecular Diagnostics
- Policy and Strategy Committee/21st Session/Agenda Items 3-9, 2019, Annex to the Interim Report of the Midterm Strategy Review: ToR and Data sources
- Policy and Strategy Committee/Strategy Workshop, 2021, Strategy Development Phase A–Input gathering and analyses/ Unitaid Strategy Workshop
- RBM Partnership to End Malaria, UNOPS, 2020, RBM Partnership to End Malaria Strategy 2021-2025
- Stop TB Partnership, 2019, Global Plan to End TB: 2018-2022: The Paradigm Shift 1

- Stop TB Partnership, UNOPS, 2015, Global Plan to end TB - The Paradigm Shift
- UK, 2018, UK Annual Review Unitaid
- UK, 2019, UK Annual Review Unitaid
- UK, 2020, UK Annual Review Unitaid
- Unitaid Executive Board Meeting 33rd Session/Agenda item 4, 2019, Key Performance Indicators – review Proposed revisions
- Unitaid Executive Board Meeting 33rd Session/Agenda Item 6, 2019, Framework to pilot an agility mechanism
- Unitaid Executive Board Meeting, 2015, Areas for Intervention
- Unitaid Executive Board Meeting, 2015, Strategic Narrative for Malaria and Areas of Intervention
- Unitaid Executive Board Meeting, 2016, UNITAID’s approach to intellectual property
- Unitaid Executive Board Meeting, 2016, Update on intellectual property approach and potential opportunities
- Unitaid Executive Board Meeting/24th Special Session, 2016, Disease Narrative for Tuberculosis and Areas for Intervention
- Unitaid Executive Board Meeting/27th Session,2017, Area for Intervention: Optimizing management of coinfections and comorbidities in people living with HIV
- Unitaid Executive Board Meeting/27th Session/Agenda Item 4, 2017, Grant Portfolio Update
- Unitaid Executive Board Meeting/28th Session,2017, Update to the Executive Board on the Area for Intervention ‘Better tools for integrated management of childhood fever: diagnostics’
- Unitaid Executive Board Meeting/29th Session/ Agenda Item 9, 2018, Key Performance Indicators - 2017
- Unitaid Executive Board Meeting/29th Session/Agenda Item 7-8 , 2018, Grant Portfolio Update
- Unitaid Executive Board Meeting/30th Session, 2018, Area for intervention: Accelerating impact of long-acting technologies in low- and middle-income countries
- Unitaid Executive Board Meeting/30th Session/Agenda item 12, 2018, Lessons learnt from Project Implementation -Example of Seasonal Malaria Chemoprevention
- Unitaid Executive Board Meeting/30th Session/Agenda Item 14, 2019, Area for Intervention: Better tools for the diagnosis and treatment of Plasmodium vivax malaria
- Unitaid Executive Board Meeting/32nd Session, 2019, Annex 2 – Key performance indicators2018
- Unitaid Executive Board Meeting/32nd Session/Agenda Item 10, 2019, Portfolio Performance
- Unitaid Executive Board Meeting/32nd Session/Agenda Item 8, 2019, Report of the Midterm Strategy Review
- Unitaid Executive Board Meeting/33rd Session/Agenda Item 11, 2018, Area for Intervention: Better tools for the diagnosis and treatment of Plasmodium vivax malaria

- Unitaid Executive Board Meeting/34th Special Session/Agenda Item 2, 2020, Reproductive, Maternal, Newborn and Child Health New tools for reducing maternal mortality
- Unitaid Executive Board Meeting/35th Session/ Agenda Item 9, 2020, Annex 1 – One-page Performance Assessment
- Unitaid Executive Board Meeting/35th Session/Agenda Item 10, 2020, Operational Key Performance Indicators 2019
- Unitaid Executive Board Meeting/35th Session/Agenda Item 6, 2020, Reproductive, Maternal, Newborn and Child Health New tools for reducing maternal mortality
- Unitaid Executive Board Meeting/35th Session/Agenda Item 9, 2020, Portfolio Performance
- Unitaid Executive Board Meeting/35th Session/Agenda Item 9, 2020, ANNEX2- StrategicKey Performance Indicators 2019
- Unitaid Executive Board Meeting/37th Session/Agenda Item 15, 2020, Area for Intervention: Better tools for the diagnosis and treatment of Plasmodium vivax malaria
- Unitaid Executive Board Meeting/37th Session/Agenda Item 16, 2020, Reproductive, Maternal, Newborn and Child Health New tools for reducing maternal mortality
- Unitaid Joint session of the FAC and PSC/Agenda Item 3, 2019, Investment Plan 2020-2022
- Unitaid Joint session of the FAC and PSC/Agenda Item 3, 2020, Investment Plan 2019-2022
- Unitaid Joint session of the FAC and PSC/Agenda Item 3, 2020, Investment Plan and Funding Forecast
- Unitaid, 2021, Results Framework 2021
- Unitaid, 2017, MARKET AND TECHNOLOGY LANDSCAPE-HIV RAPID DIAGNOSTIC TESTS FOR SELF-TESTING
- Unitaid, 2017, Technology and Market Landscape - Hepatitis C Medicines
- Unitaid, 2017, TUBERCULOSIS Diagnostics Technology Landscape
- Unitaid, 2017, UNITAID 2016 Grantee Survey
- Unitaid, 2018, AUDITED FINANCIAL STATEMENTS FOR THE YEAR ENDED 31 DECEMBER 2018
- Unitaid, 2018, Grant Management Guidelines
- Unitaid, 2018, Multi-disease Diagnostic Landscape for Integrated Management of HIV, HCV, TB & other coinfections
- Unitaid, 2018, Technology Landscape - Fever Diagnostic Technologic Landscape- First Edition
- Unitaid, 2019, AUDITED FINANCIAL STATEMENTS FOR THE YEAR ENDED 31DECEMBER 2019
- Unitaid, 2019, Cervical Cancer -Screening and treatment of pre-cancerous lesions for secondary prevention of cervical cancer Technology landscape
- Unitaid, 2019, Disease Narrative for HIV

- Unitaid, 2019, Disease Narrative for Malaria
- Unitaid, 2019, Disease Narrative for Tuberculosis
- Unitaid, 2019, Financial Guidelines for Unitaid Grantees
- Unitaid, 2019, Gates Foundation – Year 1 Reporting
- Unitaid, 2019, Grantee Survey
- Unitaid, 2019, Grantee Survey/Agenda Item 4
- Unitaid, 2019, Hepatitis -C Diagnostics Technology Landscape
- Unitaid, 2019, Interim Report of the Midterm Strategy Review
- Unitaid, 2020, Audited Financial Statements
- Unitaid, 2020, Disease Narrative for Hepatitis C
- Unitaid, 2020, Gates Foundation- Year 2 Reporting
- Unitaid, 2020, Grant Implementers Survey Portfolio Performance Annex IV
- Unitaid, 2020, Innovative Delivery Systems for Technology Landscape
- Unitaid, 2020, Minutes of meeting on Wed 19 Sept 2018, general Unitaid + BMGF touch base
- Unitaid, 2020, Minutes of meeting on Wed 22 January 2020: Annual Unitaid + BMGF touch base
- Unitaid, 2020, Point-of-Care Molecular Diagnostics for HIV Joint End-of-Grant Evaluation
- Unitaid, 2020, TERMS OF REFERENCE Hepatitis C Joint Portfolio Level Evaluation and End of Grant Evaluation
- Unitaid, 2020, TERMS OF REFERENCE Unitaid/PSI STAR (Self-Testing Africa) Initiative–phase 2 End of project evaluation
- Unitaid, 2020, Unitaid Evaluation Framework: Guidance
- Unitaid, 2021, End-of-Grant Evaluation -Medicines Patent Pool (MPP II): Expanding Access to Quality, Appropriate, Affordable, Safe and Efficacious Medicines and Technologies in Low and Middle-Income Countries
- Unitaid, 2021, Evaluation of Unitaid’s portfolio of COVID-19 investments
- Unitaid, 2021, Gates Foundation – Year 3 Reporting
- Unitaid, 2021, Minutes of meeting on Monday 8 March 2021: Annual Unitaid + BMGF touch base
- Unitaid, 2021, Reproductive, Maternal, Newborn and Child Health - Thematic Narrative
- Unitaid, 2021, TERMS OF REFERENCE For the end of project evaluation on Unitaid/CHAI Community access to rectal artesunate for malaria (CARAMAL) and Unitaid/MMV Supply Side Grant (for Output 3 only)
- Unitaid, 2021, Unitaid’s Scalability Framework – Guidance for Applicants and Grant Implementers
- WHO, 2014, ‘END TB Strategy - Global strategy and targets for tuberculosis prevention, care and control after 2015’
- WHO, 2015, Global Technical Strategy for Malaria 2016–2030

- WHO, 2016, GLOBAL HEALTH SECTOR STRATEGY ON HIV 2016–2021 TOWARDS ENDING AIDS
- WHO, 2016, GLOBAL HEALTH SECTOR STRATEGY ON VIRAL HEPATITIS 2016–2021 TOWARDS ENDING VIRAL HEPATITIS
- WHO, 2018, 'Review of hosted partnerships Review of Unitaids Report by the Director-General'
- WHO, 2020, Global strategy to accelerate the elimination of cervical cancer as a public health problem

4.2 Case Study Documents

4.2.1 TB Prevention

- Aurum IMPAACT4TB Project Plan, 2017 and 2018 Amendment
- Civil Society Engagement Report 2019
- Concept Note, Nitrosamine Impurities in TB Medicines Initiative
- IMPAACT4TB Appendix 1 Narrative Progress Report Phase 2 Final February 2019
- IMPAACT4TB-2020 Annual Narrative Report Revised 15 April 2021
- IMPAACT4TB Unitaids Annual Narrative Report 2019 Final
- Stop TB Partnership, 2016, Global Plan to End TB
- Unitaids Decisions on Phase 1-2 and Phase 2-3 go ahead, 2018 and 2019
- Unitaids March 2016 TB Disease narrative and AFIs
- Unitaids, 2012, Tuberculosis medicines technology landscape
- Unitaids, 2013, Tuberculosis medicines technology and market landscape – 1st edition
- Unitaids, 2014, Tuberculosis medicines technology and market landscape – 2nd edition
- Unitaids, 2016, Faster cheaper better ways to end tuberculosis
- Unitaids, 2019, Disease Narrative for TB
- Unitaids, December 2018 AFI Long Acting Technologies
- Unitaids, Grant Risk Assessments 2018-2021
- Unitaids, IMPAACT4TB Cost Extension March 2021
- Unitaids, Operational Reviews of IMPAACT 4TB 2018, 2019, 2020
- WHO, 2015, End TB Strategy

4.2.2 Malaria Chemoprevention

- 2018, Revised Gantt Chart for Supply Grant Submitted
- 2018, Revised MMV Supply Grant Budget Submitted

- ACCESS-SMC Logframe Indicators
 - Dalberg, 2017, Unitaid project evaluation: Achieving Catalytic Expansion of Seasonal Malaria Chemoprevention in the Sahel (ACCESS–SMC)
 - ISGlobal & Jhpiego, 2018, 04a TIPTOP Unitaid Annual Report
 - ISGlobal & Jhpiego, 2018, 04b TIPTOP Unitaid Annual/Semi-annual Report
 - ISGlobal & Jhpiego, 2018, 04c TIPTOP Unitaid Annual Report
 - ISGlobal & Jhpiego, 2019, 04d TIPTOP Unitaid Annual/Semi-annual Report
 - ISGlobal & Jhpiego, 2019, 04e TIPTOP Unitaid Annual Report
 - ISGlobal & Jhpiego, 2020, 04f TIPTOP Unitaid Semi-Annual Report
 - ISGlobal & Jhpiego, 2020, 04g TIPTOP Unitaid Annual Report
 - Jhpiego, TIPTOP Project Plan
 - Malaria Consortium & LSHTM, 2017, ACCESS-SMC Cost Extension Executive Summary – Report for Unitaid’s Executive Board
 - MMV, 2018, MMV Supply Grant Logframe Indicators with Updated Targets Submitted to Unitaid
 - MMV, 2018, MMV Supply Grant Reprogramming Request
 - Unitaid & Malaria Consortium, 2016, ACCESS-SMC Project Plan Addendum
 - Unitaid, 2016/2017, Grant Agreement Executive Summary - Report for UNITAID’s Executive Board
 - Unitaid, 2017, ACCESS-SMC Board Resolution
 - Unitaid, 2017, MMV Budget Overview Document
 - Unitaid, 2017, MMV Logframe Indicators Annex 3
 - Unitaid, 2017, MMV Supply Grant Annex 1 Project Plan
 - Unitaid, 2017, MMV Supply Grant Budget Submitted Annex 2
 - Unitaid, 2018, Lessons learned from project implementation: the example of Seasonal Malaria Chemoprevention
 - Unitaid, 2018, MMV Supply Grant Logframe Indicators with Updated Targets
 - Unitaid, 2020, TIPTOP Logframe Revised
 - Unitaid, ACCESS-SMC Extension Budget Overview
 - Unitaid, TIPTOP Budget
 - Unitaid, TITOP Logframe Indicators
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- PEPFAR COP, 2021, Unitaid HIV Investment Summary
 - Unitaid, 2018, Grant Portfolio Update

- Unitaid, 2019, HIV Disease Narrative
- Unitaid, 2019, Portfolio Performance
- Unitaid, 2019, Report of the Midterm Strategy Review
- Unitaid, 2020, April Joint FACPSC Update on 20-22 Investment Plan
- Unitaid, 2020, Portfolio Performance Report
- Unitaid, 2020, Strategic and Operational KPIs
- Unitaid, 2020, TOR_STAR Appendix-1
- Unitaid, 2021, Portfolio Performance Report
- Unitaid, 2021, Strategic and Operational KPIs Annex

4.2.4 Fever Management

- 2020, Fourth disbursement recommendation for the AIRE project, implemented by ALIMA
- 2020, Performance and Disbursement Memo - Expedited Disbursement for COVID-19 Response
- 2020, Second disbursement recommendation for the AIRE project, implemented by ALIMA
- ALIMA Logframe Indicators
- ALIMA, INSERM, SOLTHIS & TERRE DES HOMMES, 2019, ALIMA Project Plan
- Budget Overview Tables
- PATH & Swiss TPH, 2019, PATH Project Plan Annex 1
- PATH Budget
- PATH Logframe Indicators
- PATH Modified Logframe Indicators
- Programmatic Performance Table: Logframe indicators
- Unitaid, 2019, ALIMA- Disbursement Memorandum
- Unitaid, 2019, PATH – Disbursement Memorandum
- Unitaid, 2019, Revised Budget
- Unitaid, 2020, ALIMA -Grant Agreement Amendment
- Unitaid, 2020, TIMCI – Disbursement 2, Performance and Disbursement Memo
- Unitaid, 2020, TIMCI – Disbursement 4, Performance and Disbursement Memo
- Unitaid, 2020, TIMCI-PATH COVID Performance and Disbursement Memo, Expedited Disbursement for COVID-19 Response

- Unitaid, Annex B_ PATH TIMCI 2020 AR programmatic annex
- Unitaid, TIMCI- Annex 1a Grant Agreement Amendment
- Unitaid, TIMCI- Annex 1b Grant Agreement Amendment

5 TB Prevention Case Study

5.1 Introduction

The review team, together with the Secretariat, selected TB prevention for this case study to ensure representation of TB as one of Unitaid’s three priority areas, and the team regarded prevention as a new and potentially challenging area within the TB portfolio. The objective of this case study was to answer questions across the three areas of analysis for this review: Right Topics, Right Ways and Right Results. To accomplish this, the Itad team reviewed documents shared by Unitaid and identified by the team, conducted 12 KIIs, and held one group discussion with the Unitaid Secretariat TB team, between 12 May and 15 June 2021. Interviewees represented development partners, CSOs/NGOs, country governments, development agencies and private sector partners. As with the global KIIs, we asked questions about Relevance, Coherence, Efficiency and Effectiveness.

5.2 Background

Although approximately 23% of the world’s population is infected with TB, until recently treatment focused almost entirely on people with active TB. An estimated 5–10% people infected are likely to progress to active TB, primarily people living with HIV, children under five, and household contacts of a person living with TB. It is treatment of these infected but not active cases that is the focus of Unitaid’s TB prevention work. In 2015 WHO launched the End TB Strategy, which recognised preventive therapy of latent TB infection as an important tool to ensure the elimination of TB.¹

As of 2019, Unitaid had invested approximately \$250m in TB, of which TB prevention – the focus of this case study – represents approximately 23% (\$58.9 million).² Several documents guided and influenced these investments. Unitaid produced a TB medicines technology landscape in 2012, which was updated in 2013 and 2014 and then published as a disease narrative in 2015 and updated in 2019. WHO released guidelines in 2015 that included the 3HP regimen, although the regimen was unaffordable and untested in People Living With with HIV/AIDS (PLWHA). Critically, in 2015 WHO published ‘The End TB Strategy’³ and the Stop TB Partnership released its ‘Global Plan to End TB’,⁴ both of which prioritised prevention, marking a significant change to efforts to control and, in time, end TB.

Unitaid’s Board selected TB prevention as an area for intervention in March 2016, and Unitaid called for proposals for ‘Enabling preventative TB treatment in high-risk groups’ in 2016.⁵ The Unitaid Board accepted the leading proposal in December 2016⁶

¹ Unitaid TB Disease Narrative 2019.

² 2020 Portfolio Performance Report – FINAL.

³ <https://www.who.int/publications/i/item/WHO-HTM-TB-2015.19>.

⁴ http://www.stoptb.org/assets/documents/global/plan/GlobalPlanToEndTB_TheParadigmShift_2016-2020_StopTBPartnership.pdf – which was later updated: http://www.stoptb.org/assets/documents/global/plan/GPR_2018-2022_Digital.pdf

⁵ Board recommendation report: Report on Area for Intervention ‘Enabling preventive TB treatment in high-risk groups’ December 2016.

⁶ Resolution No 18-2016 e. Go-ahead for the ‘IMPAACT4TB’ Proposal.

and the project, managed by the Aurum Institute in South Africa, to start in September 2017 with a four-year grant period,⁷ now being considered for extensions and increase. The consortium included CHAI, KNCV⁸, TAG and GDF. The project aimed to demonstrate that the prevention regimen 3HP is safe when co-administered with dolutegravir in patients living with HIV and to scale up its use among PLWHA and children under five with reductions in price through manufacturer negotiation and reductions in pill burden with the development of a fixed dose combination.

A 2018 UN High-Level Meeting on TB set global targets to reach 30 million people with preventive treatment by 2022 (6 million PLHIV, 4 million children under five, and 20 million household contacts). Pre-COVID projections were that the TB community was on track to reach the PLHIV goals but that household contacts, including children under five, would not be reached.

Several of Unitaid’s grants complement this work, including 1) the WHO Enabler grant of USD \$11.6 million to support the Global TB Programme (2017–21); 2) research grants CaP-TB9 and TB CHAMP;¹⁰ 3) innovation grants to Imperial College to develop a long-acting formulation of rifapentine-isoniazid, the Adherence Support Coalition to End TB (ASCENT) project for digital adherence technologies and TB diagnostics grants (existing and now being called for); and 4) cross-cutting grants to the Medicines Patent Pool (MPP) for use of TRIPS mechanisms and the GDF for quality assurance. PEPFAR and USAID/TB,¹¹ as well as the Global Fund,¹² are also supporting the scale-up of shortened preventive treatment.

5.3 Findings

5.3.1 Relevance

1. Unitaid’s investment in TB prevention was timely, groundbreaking, and highly responsive to push forward the prevention commitments of the End TB Strategy. (*Strength of evidence: High*)

Interviewees widely acknowledged that Unitaid’s commitment was important and helped countries prioritise TB prevention. Although national and global plans included prevention, the limited envelope of resources historically available for TB meant that prevention was largely under-resourced. Unitaid’s commitment raised the level of attention and made funds available, particularly for pre-market research and lowering the cost of the drugs. Several respondents highlighted the unique capability of Unitaid to engage in these types of go-to-launch studies where other TB research funders such as the National Institute for Allergies and Infectious Diseases (NIH) are less likely to engage. Within the TB community, Unitaid is seen as one of the most important donors in research (including paediatric TB) and market shaping for TB and for prevention specifically.

⁷ Resolution No. 14-2017-e. IMPACT4TB-Increasing Market and Public health outcomes through scaling up Affordable Access models of short Course preventive therapy for TB.

⁸ KNCV is a Dutch Tuberculosis foundation <https://www.kncvtbc.org/en/aboutkncv/>

⁹ Studying 3RH (rifampicin/isoniazid) for children.

¹⁰ Studying levofloxacin in prevention of MDR-TB in children.

¹¹ <https://www.usaid.gov/global-health/health-areas/tuberculosis/resources/news-and-updates/global-accelerator-end-tb>

¹² <https://www.theglobalfund.org/en/tuberculosis/>

2. Unitaid’s prioritisation of research within its TB prevention project enabled WHO to rapidly update guidelines for TB prevention, and this in turn helped donors and national governments provide support to prevention. (Strength of evidence: Medium)

Nearly all respondents highlighted that the IMPAACT4TB project demonstrated the safety of using rifapentine with dolutegravir and, importantly, that these data were used by WHO to revise the TB prevention guidelines to support the use of short course 3HP among PLWHA. Unitaid’s support of prevention was very well aligned with WHO’s utilisation of the prevention data. WHO was well positioned to incorporate the project data into the guidelines, and some attributed the speed of the review of the data and adoption of the guidelines to their Unitaid enabler grant. Although USAID/PEPFAR were already engaged in funding prevention prior to the IMPAACT4TB project, the guideline change enabled them to transition their work to the short course therapy. This triangulation of engagement by WHO, Unitaid and Aurum helped to encourage the uptake of short course TB therapy beyond the project’s intervention areas.

5.3.2 Coherence

3. Unitaid’s capacity for investment in innovative financing and rewards for manufacturers is a distinct comparative advantage in the TB field. (Strength of evidence: Medium)

Aside from the Gates Foundation, no other significant donors to TB have the flexibility to invest in private sector partners. For this project, several interviewees highlighted that Unitaid had used its position well to convene likely procurers (e.g. GDF, Pan American Health Organization (PAHO), USAID/PEPFAR, Global Fund and Unitaid) to come to agreement on the volume projections. The resulting volume projections were critical for the price reductions made initially by Sanofi for rifapentine and subsequently by at least one generic manufacturer for a Fixed Dose Combination (FDC). Many acknowledged that the Unitaid grant had made the price of rifapentine affordable for TB prevention, though the long-term impact on the FDC’s price and supply remains to be seen.

4. Unitaid’s work to engage other partners in TB, and specifically TB prevention, is well recognised among the TB community; Unitaid could do more to fully engage with partners to expand impact and ensure complementarity. (Strength of evidence: High)

Unitaid was noted for being very open to working with partners to address gaps in TB control. USAID and Global Fund’s investments in TB prevention are, for the most part, seen as complementary, with Unitaid taking the lead on safety studies and negotiations over supply and price. Although the Unitaid and US government projects were considered for the most part complementary as designed, a few stakeholders noted some overlap in a few implementation countries. WHO’s role as advisor on global TB needs to Unitaid and as provider of normative guidance complements Unitaid’s role as contributor on research and innovation. Aurum’s ongoing collaboration with PEPFAR is, for the most part, understood to be complementary given high TB–HIV coinfection, though one development partner thought this had resulted in the IMPAACT4TB project being more focused on the HIV community and lacking visibility among the TB community. The project’s intentional design to focus on the HIV community could therefore be strengthened by further engagement of the TB community.

As noted in Section 8, the project carefully structured GDF's role around transactional procurement rather than deal negotiation with the manufacturers to avoid duplication and misunderstandings in the roles and responsibilities of the project partners. Some country governments highlighted that they did not have a direct relationship with Unitaid but worked through CHAI. However, donor engagement could be more consistent. Unitaid engaged multiple donors in planning at the early Afl stage but could share more project experience; one stakeholder noted they had not yet heard results to inform strategies at country level. This may be attributable to the fact that implementation research results are delayed due to Covid-19 and supply delays. However, the clinical data are available, project progress highlights are on the project website, and WHO holds an annual symposium at the TB Union where the project presents and discusses progress to all key stakeholders in the TB community.

Unitaid engages with many stakeholders to advance the TB prevention project and its TB portfolio as the opportunities and needs arise, but absence of a regular structured check-in with the Global Fund, the Gates Foundation, Stop TB, or USAID TB teams is a missed opportunity to increase Unitaid's visibility and ensure complementarity. Although time-consuming, several partners expressed an interest in engaging in a more regular, structured way with Unitaid. Likewise, Unitaid is recognised as a convener and could further capitalise on its power as a convener to engage donors in TB. However, respondents also noted that the TB team at the Secretariat 'is really small to be able to engage with other partners meaningfully. They have the expertise but lack time.'

5.3.3 Efficiency

5. IMPAACT4TB is a model for engagement of civil society for Unitaid grants, and more measurement of its impact would help to ensure that Equity is being advanced. (Strength of evidence: High)

Many projects struggle to find a workable mechanism to engage civil society, particularly when the grants are large and the reporting considerable. For the IMPAACT4TB project, engaging the Treatment Action Group to give very small grants (~ USD \$500–1000) to in-country civil society organisations has enabled civil society to obtain sufficient resources to be strong advocates for TB prevention, both with governments at PEPFAR Country Operational Plan (COP) meetings and with people infected with TB. This approach has empowered civil society to do the demand creation for preventing TB. Through this mechanism, civil society is seen to have had real impact, such as expanding the focus on the project from just children under five and PLWHA to include other household members.

While this engagement of civil society probably contributes to Equity, few structures are in place to track and measure the impact of the extensive civil society engagement at project level. By design, the project is achieving Unitaid's two Equity measures of reaching low-income countries (LICs) and benefiting the underserved with its focus on children and PLWHA (and, soon, pregnant women as well). How far the project has advanced Equity could also be considered through measurement of the impact of multiple activities on these vulnerable populations, including the lower cost of products and the reduction in treatment duration. While the project reduced Sanofi's price of rifapentine, some in the TB community believed that Sanofi's lower price offer should have been extended to more countries though the Unitaid Secretariat reported that this was corrected in the subsequent price agreement with the FDC manufacturer. At household level, the design of the project (at the time based on the available evidence) and the timing of the research studies has meant that every member of the household receives a different treatment to prevent TB. While this is undoubtedly confusing, a few stakeholders consider it

inequitable, as some individuals will have more tablets and some treatments will be of longer duration until evidence is available for all to have short course prevention. Also noted was the fact that the project has contributed more to TB prevention among PLWHA, but less to children under five and household contacts; national governments target setting, delays of the 3HP data for children and supply constraints all contributed to these differences. As one partner noted, more broadly achieving Equity in TB may be further challenged by the overall lack of flexibility due to lack of sufficient funding in TB; Unitaid's grant not only provided that critical funding but also has potential to tell a larger story about Equity.

6. Two products were brought to market despite considerable shifting of roles and responsibilities for the manufacturer engagement components of this project. (Strength of evidence: Medium)

The Unitaid-supported agreements resulted in introduction of two important products (a lower-priced rifapentine and groundbreaking FDC). However, several course corrections were needed over the life of the project, and responsibility for engagement with Sanofi and the generic manufacturers shifted on several occasions, resulting in partner confusion and delay. The Aurum team by design was meant to have full oversight on all negotiations and market interventions within the project. However, in response to some gaps identified with the negotiations with Sanofi, Unitaid assumed management; this shift of Unitaid's role and the confusion about multiple partner roles – especially for the FDC manufacturer discussions with GDF, CHAI, MedAccess, Aurum and Unitaid – was perceived as overly time-consuming, which overlapped with periods of delays with the development, dossier review and commercialization of the FDC. Some partners thought Unitaid could have initially taken a more structured approach with fewer back-channel conversations, more clarity on roles, and clearer direction to grantees. Some expressed a concern that this process took a long time and that building trust among so many players can be challenging. Several noted impressive individual Secretariat staff capabilities and highlighted that Unitaid was actively engaged on the risk discussions. There was a perception that Unitaid has complex inner workings, and that 'more planets need to align internally' before deals can be signed with manufacturers. Clarifying team roles and partner expectations and limiting the number of partners and individuals engaged from the start could help to enhance efficiencies in negotiations with manufacturers.

5.3.4 Effectiveness

7. Direct investment in an institution of the global South has benefited Unitaid's in-country presence and transformed a South African organisation into a global player. (Strength of evidence: Medium/High)

Prior to this project, Aurum had considerable experience with management of PEPFAR funds, but had not worked extensively outside South Africa. This positioned Aurum well to receive Unitaid's first large-scale grant to an organisation of the global South. The selection of Aurum to lead this project was recognised as an opportunity for Unitaid to consider de-risking mechanisms to enable a grant to a partner new to Unitaid; these mechanisms included the phased approach for release of funds and including CHAI, an experienced Unitaid partner. From a programmatic standpoint, this phased approach slowed progress, according to some, as work could only proceed with scale-up once the clinical study was complete. However, without the study, PEPFAR would not have signalled support for 3HP which enabled negotiations of the lower price. For its part, Aurum enhanced Unitaid's awareness of the TB landscape, and advised on evidence gaps and

country needs. In the process, Aurum reports that the grant has contributed in both small and large ways to Aurum’s capabilities and growth. For instance, Aurum is now using Unitaid’s Theory of Change model to deliver results to Board, and Aurum is now viewed as a more global player.

8. The long-term impact of Unitaid’s engagement with manufacturers is unclear, and the time has come for Unitaid to examine which investments have had a positive and lasting impact in the market. (*Strength of evidence: Medium*)

Given Unitaid’s ongoing targeted use of financial and volume incentives to manufacturers, understanding the impact of these mechanisms is critical to ensure Unitaid’s value-add. Unitaid is recognised by some as highly capable of being able to look at an area with a barrier to access, diagnose what support is needed and select from a variety of commercialisation incentives and catalytic procurement mechanisms. Others perceived Unitaid may have applied its incentives too universally; an incentive for a small market such as paediatric or Multidrug-Resistant TB (MDR TB) manufacturing may have impact but may not be necessary for a large market like TB prevention, and in practice may dissuade some manufacturers who might have come in without an incentive from entering the market, fearing they would not be able to compete. Others pointed out that GDF usually plays a role in negotiating long-term TB supply contracts but in this case the line of sight on HIV markets were critical for this project. Hence, as mentioned in Section 4 above, GDF was given only a transactional procurement role from the outset. A few respondents noted that the coordination of the supplier relationships was further complicated on the IMPAACT4TB project by the targeted approaches to manufacturer incentives (both financial and nonfinancial), and – despite the consortium and Unitaid agreeing on the role of GDF from the start – this has led to considerable friction, especially between GDF and Unitaid. The Unitaid secretariat clarified that not all the negotiations facilitated by Unitaid on the IMPAACT4TB project required financial incentives; such risk of perceptions is one that Unitaid needs to mitigate with a better communication and stakeholder engagement approach. At least one interviewee suggested that Unitaid should evaluate supplier incentives, potentially across the disease areas over many years, to understand what really does and does not incentivise manufacturers to come into and stay in lower income markets with lower-priced products.

5.4 Conclusions

Unitaid’s work in TB prevention is well positioned for expansion in the next phase of the Strategy. Critical to its success would be to 1) assess the long-term impact of different manufacturer incentives, 2) create a more structured engagement process with key partners such as the US government, Global Fund and the Bill and Melinda Gates Foundation, and 3) use the disease narrative and opportunity cost assessment to lay out Unitaid’s broader TB strategy for the next 5–10-year period. To further the impact of the IMPAACT4TB project, the proposed project extension could be structured to enable further work in demonstrating scalability and to adapt to emerging prevention products. Looking ahead, a cross-cutting project incorporating a range of treatments for prevention along with diagnostics could be designed for transformative impact on TB.

6 Malaria Chemoprevention Case Study

6.1 Introduction

Malaria remains one of Unitaid’s core investment disease areas. This case study set out to evaluate the Relevance, Coherence, Efficiency and Effectiveness of the malaria chemoprevention area for intervention (Afl), with the aims of generating specific data on how Unitaid performed against its 2017–21 Strategy and collecting lessons learned, to inform how Unitaid can optimise its contributions towards malaria chemoprevention in future.

This portfolio was selected as a case study, in partnership with the Unitaid Secretariat, for the following reasons:

- It was believed to represent an example of Unitaid’s flexibility and adaptability alongside changing global goals and priorities;
- Significant supply, demand, and adoption barriers remain in this market;
- Significant Unitaid funds had been committed to this portfolio; and
- The rapid scale-up of SMC across all of West Africa was well known as a huge success, highlighted as an example of Unitaid ‘working at its best’, and considered an area where further learning would be valuable.

The data collection process involved 15 KIIs, including national Ministry of Health (MOH) representatives from Nigeria and Senegal, civil society organisations from the Democratic Republic of the Congo (DRC), senior leadership of all major malaria donors (e.g., the President’s Malaria Initiative (PMI) & The Global Fund), past, current and potential grantees, research and thought leaders, and the World Health Organization (WHO). Interviews were conducted by the Strategic Review team’s malaria technical expert (Mel Miles) between May and June 2021, with all requested interviewees agreeing to participate. A total of 28 associated documents, including grant documents, the Malaria Chemoprevention Afl and malaria chemoprevention update (IPTi focus) Afl, plus excerpts from the global-level document review, were reviewed and included in the final analysis. Data was analysed and rated for quality using the reviews standardised strength of evidence rating scale, with only high- and medium-quality results with strong agreement being included in the final analysis.

6.2 Background

The malaria chemoprevention portfolio has evolved significantly over the course of Unitaid’s 2017–19 Strategy. In October 2019 the Executive Board approved a new Afl that expanded Unitaid’s investments in malaria chemoprevention to include Intermittent Preventive Treatment in Infants (IPTi). Infants represent a high-risk population for malaria, and there is strong evidence that IPTi is both safe and cost-effective as a drug-based prevention tool. Based on robust trials, WHO recommended IPTi in 2010, but as of 2019 only one country, Sierra Leone, had adopted the recommendation and scaled it up nationally. Challenges to scale included both supply,

dosing, and packaging of sulfadoxine and pyrimethamine (SP) as well as demand challenges of adding routine IPTi administration to existing child health programmes.

With the addition of IPTi, Unitaids’ malaria chemoprevention portfolio over the Strategy period included three interventions:

- **Seasonal malaria chemoprevention (SMC):** the monthly administration of SP plus amodiaquine to children under five years of age during malaria season (approximately four months per year) in areas of the Sahel sub-region in Africa where *P. falciparum* is sensitive to both antimalarials.
- **Intermittent preventive treatment in pregnancy (IPTp):** the provision of at least three SP doses, starting in the second trimester of pregnancy, to prevent malaria transmission in pregnant women.
- **Intermittent Preventive Treatment in Infants (IPTi):** SP delivered to infants at a point of care at around 10 weeks, 14 weeks, and nine months of age.

These three interventions reflect work completed and scaled under the Strategy period (SMC), work funded and near completion (IPTp), and an entirely new area of work (IPTi); all of which were included in the case study. However, since a call for IPTi proposals only underwent solicitation in 2020, IPTi was only included in so far as key informants proactively mentioned experiences or engagements with the Secretariate related to the new Afl. As such, the final list of investments included in the case study was as follows:

- **ACCESS-SMC:** Achieving Catalytic Expansion of Seasonal Malaria Chemoprevention (SMC) in the Sahel (USD \$67 million, 2014–18)
- **TIPTOP:** Transforming IPT for Optimal Pregnancy; (USD \$50 million, 2017–22)
- **MMV Supply Side:** Expanding access to preventive chemotherapy in pregnant women (USD \$3.4 million, 2017–20; plus costed grant extension to 2022)

***Population Services International ITPi grant (2021–25)** was in-process and deemed confidential during the course of this review. It was only approved by the board and shared with the review team after case study data collection was completed. As such, the review presents very preliminary, high-level data from KIIs related to execution of the IPTi Afl. However, the full grant documents and plans were not included in this analysis.

6.3 Findings

6.3.1 Relevance

1. **Unitaid’s work in SMC was highly relevant to the global malaria community, filling pressing gaps to solve supply bottlenecks, generate demand, and catalyse unprecedented and rapid national scale-up.** (*Strength of evidence: High*)

There was strong consensus across all stakeholder groups that Unitaids’ supply and demand-side contributions to SMC demonstrated ‘getting out ahead of the curve’ and filling a void in both the necessary systems and national capacity to execute large-scale

SMC campaigns, which many considered ‘high-risk’ prior to Unitaid’s investment. Specifically, the Secretariat’s early and ongoing partnership with The Global Fund and PMI were reported as key factors to its success, with informants consistently mentioning the importance of ‘scale-up coordination’ across these three organisations to ensure projects are highly relevant and strategically well positioned within donor funding strategies to receive follow-on funding. In addition, Unitaid’s contribution to solving the supply side bottlenecks was essential to the subsequent scale-up, and filled a unique gap no other donor had taken on.

That said, both development partners and Low- and Middle-Income Country (LMIC) stakeholders emphasised that SMC implementation via a parallel malaria-specific delivery system made it easy for malaria-specific donors to rapidly fund post-grant completion. The pathway to scale for SMC may be more challenging to apply to other parts of the malaria chemoprevention portfolio which rely on more cross-cutting health system delivery platforms such as Community Health Workers (CHWs), Antenatal Care Clinics (ANCs) and the Expanded Program on Immunizations (EPI).

2. There are differing opinions across stakeholders on prioritising IPTi within Unitaid’s malaria portfolio. Scalability concerns raised, particularly among donors who have to make trade-offs between intervention packages, will need to be closely and strategically managed by the Secretariat to ensure success of this demand-side work. (Strength of evidence: Medium)

The Secretariat conducted a comprehensive consultation process to develop the IPTi-focused Afl in 2019/20, including engagement of all donors and alignment of the Afl with findings from the *WHO Technical Consultation to Review the Role of Drugs in Malaria Prevention for People Living in Endemic Settings*. The final document provides an example of an Afl with a strong rationale and higher risk appetite for the prioritisation of IPTi within the broader portfolio of chemoprevention opportunities. At the time of this case study, the Secretariat was actively using the Afl to evaluate grant proposals.

However, some stakeholders perceived IPTi as a shift away from ‘Unitaid’s sweet spot’ of market shaping for new products, and voiced concern about their ability to successfully achieve results in such a demand-generating, platform-strengthening project requiring intensive engagement in country-level health systems to deliver through non-malaria and, primarily, MOH-funded channels. These informants noted the growing package of effective malaria prevention interventions to choose from, and felt they did not have full visibility into how Unitaid arrived at prioritising IPTi within this context (i.e. prioritisation *within chemoprevention tools and between malaria chemoprevention and other malaria possible malaria areas*). Other stakeholders, including multiple LMICs, CSOs and NGOs, commended Unitaid for engaging with a clear market failure that is in urgent need of funding. In conclusion, further clarification is needed of Unitaid’s catalytic role in this space, as well as a more formalised and ongoing engagement strategy with donors who will be critical to long-term scale-up and sustainability – including the Maternal and Child Health (MCH) community and other donors funding CHWs.

3. Sole focus on public sector delivery channels poses a potential threat to Unitaid’s relevance, as the private sector remains a rapidly growing point of care. (Strength of evidence: Low/medium)

The document review and multiple development partners pointed to the stark absence of any private sector work under Unitaid’s malaria chemoprevention and malaria portfolio at large. Given that chemoprevention relies heavily on health system delivery, and in many countries a high proportion of individuals seeks care in the private sector, there are missed opportunities to leverage the private sector to generate demand for new tools/interventions. Enhanced consideration of the private sector could both increase the relevance and increase the likelihood of success of Unitaid’s demand-side work in the future.

6.3.2 Coherence

4. Internal coherence of the malaria chemoprevention portfolio could benefit from a portfolio management approach that accounts for intervention combinations and prioritisation across the full package of interventions in Unitaid’s malaria portfolio. (Strength of evidence: Medium)

In the context of constrained resources, the malaria community is increasingly adopting an approach based on geographically tailored intervention combinations. As such, stakeholders commented that Unitaid’s ‘one intervention at a time’ approach to grant-making makes it challenging to a) generate evidence of impact across packages of intervention, and b) support decision making on allocation of resources across a growing number of effective prevention interventions. Further, stakeholders reported that internal fragmentation across various Secretariat teams sometimes makes it difficult to understand how malaria investments add up to a coherent whole. Internal prioritisation of interventions in both chemoprevention and the malaria portfolio at large, and a more streamlined plan for donor outreach (including more communication on how Unitaid prioritises interventions internally), would help reduce stakeholder transaction and align Secretariat advocacy efforts with the highest priorities.

5. The malaria chemoprevention portfolio is well aligned with Unitaid’s comparative advantage to address clear market failures; however, there is opportunity for increased coordination, visibility, and recognition of the chemoprevention work. (Strength of evidence: Medium)

Unitaid was described as a ‘considerate and intentional donor who thoughtfully maps investments to the WHO Global Technical Strategy for Malaria’ and spends ‘significant time up-front in consultations’ with a broad group of stakeholders. In addition, Unitaid’s current work in IPTp and IPTi both fill a timely and urgent gap in the malaria chemoprevention space and complement smaller product development and research efforts that had already been conducted in this space. However, given the breadth of the malaria portfolio and the new addition of IPTi as an Afl, there was a sense that, after the initial consultations, the chemoprevention work receives less visibility, both within the Secretariat and externally. Increased visibility with external stakeholders, particularly as part of coordination discussions with donors, will help ensure more broad-scale support for and championing of this work.

6. National governments have suboptimal awareness of Unitaid’s model and market shaping objectives, posing a risk to sustainability and partnership. (Strength of evidence: Medium)

Country-level informants from Senegal, DRC and Nigeria all perceived Unitaid grantees as primarily implementers. There was limited understanding of the time-limited or

catalytic role of Unitaid funding, including the need to transition to other funding sources at the end of the grant. Increased communications and public relations with country stakeholders to communicate the short-term role of Unitaid and ‘prime’ countries to make follow-on funding requests could enhance Unitaid’s Effectiveness. NGO, LMIC and development partners all mentioned that additional country visits and efforts to understand country context by the Secretariate would be highly valued.

6.3.3 Efficiency

7. **Unitaid’s grant management within this portfolio is perceived as highly onerous and thus limits flexibility, particularly for demand-focused country-level work. (Strength of evidence: High)**
8. Nearly all stakeholder groups acknowledged the rigid and highly time-intensive efforts required to win and manage a Unitaid award. Stakeholders expressed sentiments such as ‘lots of micromanagement of grantees’ and ‘they spend too much human and financial capital on process steps.’ They also mentioned that the intensive financial management requirements pose a barrier to selection of grantees from endemic countries. Further, grantees are sometimes disincentivised and/or required to take on significant risk internally when working in the most challenging/poorest health systems where system weakness are a key determinant to scalability. Finally, a few stakeholders mentioned that while human-centred design (HCD) approaches are encouraged by Unitaid, the grant-making and financial management processes do not always accommodate such an iterative design model, and grantees are required to make decisions before the full HCD work is completed. Increased flexibility, with more nimble processes and timelines for reprogramming, could particularly benefit demand-side-focused projects. **While the choice to engage in malaria chemoprevention was a calculated and right-sized risk, the lower risk appetite within grant activities at times limits Unitaid’s ability to address broader delivery system bottlenecks essential to success. (Strength of evidence: Medium)**

Development partners, LMICs and NGO stakeholders all mentioned that within the funded grants themselves there is less flexibility to address broader systems issues necessary to the delivery IPTp and IPTi. While grantees have found small ways to strengthen the underlying delivery systems IPTp/IPTi rely on, the inherent system risks within these interventions remain an urgent (albeit high-risk) gap that will need to be addressed (either by Unitaid or others) to achieve high-quality universal scale post Unitaid investment.

6.3.4 Effectiveness

9. **Unitaid’s work in SMC was highly impactful, resulting in national scale-up across West Africa years after the grant ended and fundamentally changing the malaria chemoprevention landscape. (Strength of evidence: High)**
10. Stakeholders unanimously agreed that the Unitaid SMC investment served as the catalyst to drive national demand and universal scale-up of SMC across the Sahel. Unitaid’s investments solved both upstream product challenges and, most notably, unlocked demand among ministries of health, demonstrating the

impact of the Unitaid model to bring a product to scale. As one donor commented, ‘SMC is in [a] good position now ... and it could never have gotten there if not for Unitaid’s ACCESS SMC project.’ This work was consistently cited as an example of Unitaid’s added value and niche within the donor landscape. **Unitaid’s work in community IPTp and IPTi poses a ‘failure to scale’ risk without additional efforts to strengthen the delivery platforms they rely upon.** *(Strength of evidence: High).*

Community IPTp and IPTi rely on CHW platforms. In many countries these platforms are fragile, not fully institutionalised, and at least partially funded through non-malaria donors. Stakeholders from almost every group expressed either moderate or high concern over a ‘funding cliff’ for community IPTp as the grant comes to an end. Sustainability will require further strengthening of the CHW delivery platform; however, development partners expressed concern that this was outside Unitaid’s area of expertise and core disease partnerships.

Increased coordination with the MCH community, as well as the broader set of funders supporting CHWs, will be essential in order to ensure programme scale past the end of the project. Informants shared those future demand-focused investments relying on health system delivery platforms could consider: a) slightly longer grant timeframes, to account for the increased complexity during the translation and scale period; b) more intensive engagement and coordination from the Secretariat, including Unitaid’s voice and political capital at more frequent milestones along the way, to support scale; and c) expansion of targeted donors beyond malaria donors, e.g. engaging with the World Bank, GFF, and other cross-cutting funders.

11. There was strong consensus that Unitaid’s work in malaria chemoprevention, which targets at-risk women, infants and children, is highly equitable and good value for money. However, there is more work to be done engaging endemic country partners in Unitaid’s efforts to increase demand for IPTp and IPTi. *(Strength of evidence: High)*

Malaria is a disease of the poor and vulnerable. Unitaid’s work in reducing prices and improving access to malaria products such as SP was recognised nearly unanimously as one of the best investments they can make towards Equity. That said, development partners, LMIC, civil society and NGO stakeholders also consistently mentioned that there is an opportunity for Unitaid to do a better job of engaging and funding endemic country partners in their intervention-focused work (as compared to their tool-focused work, which may require less intensive engagement). This could also help ‘grease the wheels’ by bringing country stakeholders from both malaria and other MOH departments along in the process well before scale-up discussions.

6.4 Conclusions

In conclusion:

- The ACCESS-SMC investment is recognised globally as highly relevant and an example of the Unitaid model working at its best.
- There is concern that the same model used for SMC will have less success for other chemoprevention interventions that rely on non-malaria-specific health system delivery platforms.

- There is an opportunity to enhance the Effectiveness and impact of Unitaid’s IPTp and IPTi investments by more directly engaging core donors in co-creating a pathway to scale for both interventions.
- Developing a clear and intentional strategy for the Secretariat’s role in scale-up planning discussions will help ensure that Unitaid’s individual investments add up to a coherent whole. It will also ensure Unitaid is present at the necessary moments with donor- and country-level stakeholders to drive transformational change.
- Increasing the nimbleness of the operating model so that both financial and programmatic workplans can be responsive to HCD findings and changing country contexts (with less churn and approvals) was mentioned by nearly all stakeholders.
- Additional consideration could be valuable for how Unitaid engages in health system strengthening and interventions heavily reliant on national delivery systems to scale. The majority of Unitaid’s malaria portfolio to date (e.g., SMC, ITNs, Indoor Residual Spraying (IRS)) have relied on parallel malaria-specific delivery systems and malaria-specific funding to sustain post-grant. But stakeholders perceived success of the chemoprevention portfolio as reliant on cross-cutting national platforms that are currently not Unitaid’s strength.

7 HIV Self-test Case Study

7.1 Introduction

The objective of this case study was to answer questions across the three areas of analysis for the Strategy review: Right Topics, Right Ways and Right Results. To accomplish this, the Itad team reviewed documents shared by Unitaid and identified by the team, conducted 11 KIIs, and held one group discussion with the Unitaid Secretariat HIV Self-Testing (HIVST) team, between 17 May and 15 June 2021. Interviewees represented development partners, CSOs/NGOs, country governments, global technical experts, development agencies and private sector partners. As with the global KIIs, we asked questions about Relevance, Coherence, Efficiency and Effectiveness.

7.2 Background

The international community has ambitious goals as regards HIV/AIDS, including the 2016 United Nations General Assembly (UNGA) Political Declaration on HIV, which set the goal to eliminate AIDS by 2030.¹³ In response to global goals and agendas, Unitaid adopted an integrated approach to HIV/AIDS with four priority areas, identified through a landscape analysis. These areas are Test; Prevent; Treat, monitor, and support adherence; Co-infections and co-morbidities. Unitaid's HIV and co-infections & co-morbidities portfolio is thus responsive to the key challenge areas in achieving the 95-95-95 target: testing, prevention, treatment, monitoring for adherence, and addressing COIMs. In 2018 Unitaid's HIV and COIMs portfolio comprised 22 grants addressing innovations across these areas, totalling a USD \$496 million investment.¹⁴

HIV self-testing provides a way to overcome challenges in achieving the 95-95-95 target, by testing populations that are currently underserved. HIV self-testing falls in the 'Test' goal to expand testing tools and reaching the estimated 21%, or 8 million people living with HIV (PLHIV) who are yet to be diagnosed.¹⁵ Unitaid has played a role in HIVST since 2015 when it funded the HIV Self-Testing Africa (STAR) initiative. The Afl of HIV self-testing was endorsed by Unitaid in December 2016, and since then Unitaid has invested USD \$100 million in HIVST.¹⁶

Through this investment, Unitaid aims to catalyse the market for HIV self-testing and provide a platform to test populations that have been difficult to reach with conventional testing.¹⁷ Target populations for Unitaid's HIVST approach are those unreached with current testing, including men, partners of people with HIV, and adolescents.¹⁸

Grants include:

¹³ UNITAID 2020 April Joint FACPSC Update on 20-22 Investment Plan, p. 5.

¹⁴ 2019_UNITAID_EB32_2019_12_Unitaid Portfolio Performance.

¹⁵ UNITAID 2020 April Joint FACPSC Update on 20-22 Investment Plan, p. 8.

¹⁶ UNITAID 2020 April Joint FACPSC Update on 20-22 Investment Plan p. 8; UNITAID 2020 April Joint FACPSC Update on 20-22 Investment Plan, p. 25.

¹⁷ KPIs 2020 Annex - UNITAID_EB38_2021_7 Strategic and Operational, p. 3.

¹⁸ UNITAID 2020 April Joint FACPSC Update on 20-22 Investment Plan, p. 8.

- STAR: USD \$68.8 million (PSI USD \$49.7 million and Society for Family Health (SFH) USD \$19.2 million), 2017–21.¹⁹ The Goal of the STAR initiative is to contribute to the reduction of new HIV infections and avert deaths due to HIV infection by increasing demand for and access to HIVST, and, more generally, closing the HIV testing gap.²⁰ STAR's first phase in 2015–17 was implemented by PSI. It helped to generate evidence, informing the WHO's 'Testing and Partner Notification guidelines' which were changed in 2016, followed by the WHO Enabler grant which was amended in 2017 to include HIVST.
- STAR is now in its third phase, approved by the Unitaid Board in 2019 and included in Unitaid's 2020 investment plan, which endorsed the extension of USD \$15 million to expand STAR into six further countries in partnership with PEPFAR, the Global Fund and ClIFF.²¹
- Solthis ATLAS (AutoTest Libre d'Accéder à la connaissance de son Statut VIH) project: USD \$15.7 million budget, 2018–22.²² ATLAS plans to distribute approximately 500,000 test kits to stimulate more investment in West Africa and avert an estimated 6,000 deaths and save over USD \$10 million between 2018 and 2026.²³
- MTV Shuga/Accelerating demand for HIV self-testing among young people (MTV Staying Alive Foundation (MTV SAF)): USD \$10.1 million, 2018–22.²⁴ This project nests storylines on HIV innovation, including HIVST, within the drama series *MTV Shuga*.²⁵ The aim is to reach viewers in order to demystify HIV and provide information on how to access HIV services and generate demand for self-testing. Impact estimates assume that among those watching the show there will be a 10% increase in uptake of HIVST.²⁶
- Challenge Fund (EJAF): USD \$1.5 million, January 2019. This is an HCD challenge fund and campaign undertaken with EJAF and ClIFF to emphasise the importance of HIVST in Kenya.²⁷

¹⁹ KPIs 2020 Annex - UNITAID_EB38_2021_7 Strategic and Operational, p. 9.

²⁰ 2020.13 - Appendix 1 - TOR_STAR 2, p. 2.

²¹ ²¹ UNITAID 2020 April Joint FACPSC Update on 20-22 Investment Plan, p. 30.

²² Portfolio Performance Report 2020 1-pagers - UNITAID_EB38_2021, p.6.

²³ Portfolio Performance Report 2020 1-pagers - UNITAID_EB38_2021, p.6.

²⁴ Portfolio Performance Report 2020 1-pagers - UNITAID_EB38_2021, p.14.

²⁵ HIV-Disease-narrative, pp. 12-13.

²⁶ Portfolio Performance Report 2020 1-pagers - UNITAID_EB38_2021, p.14.

²⁷ HIV-Disease-narrative, p. 13.

7.3 Findings

7.3.1 Relevance

- 1. The investment in HIVST is in line with Unitaids ambition to increase access to most appropriate, innovative, quality-assured, and affordable products, and address global HIV goals. (Strength of evidence: High)**

HIVST has been hailed by interviewed global experts as one of the key innovations that can increase early diagnosis of HIV. It can also increase prevention, due to increased awareness and preventive behaviour that self-testing promotes among currently underserved communities. By expanding access to underserved populations, HIVST can result in PLHIV being aware of their status earlier, increasing preventive behaviour, and demanding treatment.

Unitaid is recognised across informant categories as the key organisation accelerating approval, distribution and affordability of HIVST kits. The investment is in line with Unitaids HIV strategy, falling in the 'Test' category to expand testing tools and reaching the estimated 21%, or 8 million PLHIV, who are yet to be diagnosed.²⁸ This focus is widely seen as drawing on Unitaids mandate and expertise.

- 2. Unitaid has drawn appropriately on its core expertise in bridging the 'upstream' and 'downstream' of innovation to deploy a range of pioneering interventions in HIVST. (Strength of evidence: High)**

Unitaid has played a pivotal role in pushing HIVST as a tool for prevention and access to treatment through a variety of interventions. It has done this by providing the initial evidence of how the self-testing tools could be used in 2014, followed by a second phase after 2016 which funded interventions to support demand and acceleration of uptake of these tools. For instance, in 2017 alone STAR distributed nearly 400,000 HIVST kits, representing 90% of the current HIVST kits in the market at the time.²⁹

- 3. Unitaids investment has effectively encouraged other donors to enter the HIVST space, thanks to its role in generating evidence. (Strength of evidence: High)**

Unitaid investments in HIVST have produced a global public good: specifically, Unitaid has generated much-needed evidence that demonstrated the Effectiveness of HIVST. This evidence has, in turn, galvanised investment in HIVST by other key global health partners. In particular, through STAR, Unitaid generated significant interest in HIVST among countries and scale-up partners, including PEPFAR. Having helped inform the WHO's 'Testing and Partner Notification Guidelines', issued in December 2016, in 2017 the STAR project assisted countries in integrating HIVST into national guidelines and moving forward with distribution.³⁰

²⁸ UNITAID 2020 April Joint FACPSC Update on 20-22 Investment Plan, p. 8.

²⁹ 2018_UNITAID_EB29_2018_6_Grant Portfolio Update.

³⁰ 2018_UNITAID_EB29_2018_6_Grant Portfolio Update.

7.3.2 Coherence

4. Investments in HIVST are internally coherent with other Unitaid HIV investments, and leverage Unitaid’s core comparative advantage in terms of disease focus and market shaping expertise. (Strength of evidence: High)

HIV is widely seen across informants as one of the areas where Unitaid has key expertise, and where its investments provide good complementarity and add up to more than the sum of their parts. The investment in HIVST contributes to Unitaid’s broader objectives – outlined in its HIV disease narrative – in combating HIV, and in particular fills a gap in other investments by targeting populations that are unreached through other types of testing.³¹

A key risk factor that could stop self-testing’s mainstreaming as a global tool in prevention and diagnosis is price. Unitaid has been driving self-testing kit prices down and is well positioned to keep doing so, given its understanding of market dynamics and the steps required for developing and commercialising health products. Unitaid’s role in driving down self-testing kit prices to under USD \$2 each is widely recognised as central across informants, and particularly important for scaling up this technology.

‘This is part of a self-care approach, it promotes empowerment amongst people, it stops wasting staff time and you get a knowledgeable *client as they’ve taken responsibility for that step and link up to treatment or prevention. It was a really smart move of Unitaid to stick their neck out and now all the big donors are now involved which is great as they’ll take on the funding and the private sector. It really is one of the poster children for the Unitaid approach.*’ (Global Health Partner)

5. Investment in HIVST has resulted in more visibility and recognition than is the norm for Unitaid. (Strength of evidence: Medium)

This has been one of the AfIs for which Unitaid has gained greatest visibility, and where the evidence it has produced is widely seen as a reference point. Unitaid is known as a key stakeholder in this field, with a good knowledge of all the technical issues and the key stakeholders regarding HIVST.

While the reasons for increased visibility vis-à-vis other Unitaid investments would deserve more in-depth exploration beyond what was discernible from this study, informants from the Unitaid Secretariat and global health partners felt this was attributable to the innovativeness of the product, the clear pioneering role of Unitaid, and the impact of the intervention.

6. The work on HIVST is a good example of how Unitaid complements the work of other funders, and of how different grants complement each other. (Strength of evidence: High)

The investment in HIVST has brought the evidence on the Effectiveness of self-test kits needed for other funders to invest in the scale-up of this health product.

‘Unitaid is very critical to our work, Unitaid really informs innovation and brings the evidence that is required for countries to make rational decisions on funding. HIV self-testing is one of them where we’ve seen Unitaid’s work really build evidence for HIV self-testing, like the STAR project. It has improved uptake of HIV self-testing and that

³¹ KPIs 2020 Annex - UNITAID_EB38_2021_7 Strategic and Operational, p. 3.

linkage to care from regular testing and that's the core evidence under pinning HIV self-testing scale-up.' (Global Health Partner)

Grantees also report that this investment provides good complementarity across different grants and implementers. For example, in Ivory coast grantees from ATLAS, STAR and MTV held a common launch of ATLAS and MTV Shuga. Grantees are enthusiastic about having a relationship with other grantees and collaborating on international publications to increase the body of knowledge and evidence around HIVST.

7.3.3 Efficiency

7. Through its investment in HIVST, Unitaid demonstrated good levels of risk appetite in order to catalyse innovation and scale-up of a high-potential product. (Strength of evidence: High)

The original investment in HIVST was, at its inception, innovative and risky. There were no products which were market-ready or close to WHO pre-qualification, with the exception of one that had FDA approval. There was also no evidence to inform policy, given that the product had not been widely used among target populations. This Afl was thought to have big potential in terms of improving access, but also presented a lot of uncertainties. Indeed, as evidenced under the 'Effectiveness' section, the risks have paid off and delivered transformative impact.

Despite this, while the initial investment was ambitious and risky, Unitaid's approach to grant management is perceived by grantees as being moderately risk-averse. In particular, grantees reported that they struggle to obtain 'the right to fail', facing strong pressure to deliver on targets. This may limit grantees' capacity to adopt more risky but potentially transformative ways of working. For example, according to a grantee this makes working with local partners in countries with weak health systems challenging. The review team understands there is a balance to be struck between ensuring results and being innovative and risky, but this finding points to a possible explanation as to why Unitaid has struggled to increase delivery of work through national partners.

Two informants proposed that Unitaid could work with innovations that are not pre-qualified by WHO but by other bodies such as the FDA, to try to push new technology and specific innovation more rapidly, given that the WHO process can be challenging and expensive. One informant reported that HIVST suppliers have found these processes to be a barrier and argued that to support innovation you need to be riskier and try to work with other suppliers and partners than those already pre-qualified by WHO.

8. Stakeholders strongly appreciate Unitaid's collaborative approach to grant management, although this does mean that working with Unitaid can be more laborious and time-consuming compared to working with other global health funders. (Strength of evidence: High)

With regards to grant management, all interviewed grantees emphasised the dedication of Secretariat staff and their positive working relationship. One of the strengths of the Secretariat is that they are funders who also understand the technical aspects of implementation. In particular, grantees appreciate the time that Unitaid invests to work collaboratively.

‘They are focused, and they really get what you want to do, GF is such a bit machine it’s harder to get things done. With Gates you are just one of many, I feel the relationship is much better with Unitaid. Once they invest in you, they are really interested in what you do. They try to connect us all with other funders as well.’ (Grantee)

At the same time, grantees reported that the process for accessing funding from Unitaid can be quite laborious compared to other organisations they work with, taking up to a year to get funding. The process does not facilitate speed or flexibility, which can be a problem, particularly when there are any innovations that should be implemented and scaled up quickly. The operational issues related to Unitaid investments were also described as very lengthy and bureaucratic, although they have been shortened over time. Overall, informants felt that the balance between rigour and speed was often weighted too far at the expense of speed. These findings were echoed in the grantee surveys and across the overarching Efficiency analysis of the review.

‘We have a follow-up every two weeks and you know at the beginning its great and you’re implementing the project for three years and you have a touch point every two weeks it can be bureaucratic. It’s the first donor I’ve worked with those wants to meet every two weeks. This can be heavy to have this pressure.’ (Grantee)

9. One area where Unitaid has demonstrated improvement, but still has some way to go, is in promoting implementation through national partners. This is key to improve sustainability and Equity in interventions. (Strength of evidence: High)

Informants reported initial difficulty in resourcing additional time to build capacity with local partners. For instance, one grantee that aimed at working extensively with NGOs and civil society organisations felt that they needed more time to build a partnership with these organisations than Unitaid initially thought was appropriate.

Nevertheless, Unitaid has shown increasing receptiveness to grantees’ proposals for using local partners. In ATLAS, the innovative aspect of the programme was arguably not the product or the way in which it was used (which had already been pioneered by the STAR project), but to work particularly closely with local CSOs and NGOs to ensure the programme was sustainable even in the context of low baseline capacity. Although grantees encountered initial difficulties, they report a change in how Unitaid has been willing to be flexible and foster CSO and NGO engagement.

‘We needed time because the relationship with CSOs was fundamental, and we found at the time Unitaid was really looking at milestones. I think they eventually trusted us, and it’s not about failure because they have been able to adapt the objectives in terms of outputs (not outcomes), they began to understand we could be a bit late and not achieve all milestones.’ (Grantee)

Informants also argued that during COVID-19 Unitaid has been becoming increasingly flexible and supportive. This is echoed in the grantee survey findings. Some reported that Unitaid has increased its acceptance of failure and of learning from it. On the other hand, other informants thought the process for calls for proposal, applying and receiving feedback was not well managed, could be more transparent and more helpful, and could do with more guidance. This finding is also echoed in the grantee

survey results. The approval process for changing course could also be faster: one informant said that, especially when compared to other funders, it is more difficult to deviate from logframe when lessons are learned, and implementation modalities should change.

7.3.4 Effectiveness

10. There was unanimous consensus among informants and literature that this Afi has been very successful in expanding access to testing among underserved populations. (Strength of evidence: High)

Evidence shows that HIV self-testing doubles the overall HIV testing uptake compared to standard testing, and HIVST also seems to be more feasible and acceptable to target populations.³² The investment is widely attributed to have catalysed innovation of HIVST kits, provided affordable kits, produced evidence of Effectiveness of HIVST that has justified further investments, and ultimately delivered millions of test kits to underserved populations.

By December 2019 nearly 4.5 million self-test kits had been distributed as a result of Unitaid's investments.³³ 88 countries have an HIVST policy and another 38 have policies under development.³⁴ 44 countries are already implementing these policies.³⁵

'They are unusually demanding because they want to meet their deliverables and their goals [...] The whole market shaping bit which Unitaid, and PSI did together was exceptionally good [...] and was really focused on meeting WHO requirements to get a product through the pre-qualification process.' (Global Health Partner)

11. The investment is Equity-driven and has improved access to testing to some of the most underserved populations. (Strength of evidence: High)

'We need to help men in HIV, and this will ultimately reduce the risk for women.' (HIVST Global Expert)

This is a technology that can readily be taken to scale in resource-limited settings, given that it is designed to function without needed formal health system infrastructure – although one informant thought that their potential for use in hard-to-reach areas may not yet have been exploited as much as it could be. The test kits can also be used with the help of health care workers, who can help the patient take the test appropriately but allow them to view results in privacy.

Nevertheless, there are concerns as to how Equity is measured at an aggregate level. After funding the products, Unitaid are not going back 5–10 years later to look at how access has changed. Unitaid informants admit having been struggling with the question of following up on access for a while. Opportunities to demonstrate and generate lessons on how HIVST is increasing Equity may be being missed – opportunities which might ultimately prove how this investment is providing transformational rather than incremental change.

³² Johnson et al, JLAS, 2017.

³³ 2020 Portfolio Performance Report – FINAL, p. 11.

³⁴ PEPFAR COP 2021_Unitaid HIV Investment Summary_Jan 2021, p. 8.

³⁵ KPIs 2020 - UNITAID_EB38_2021_7_Strategic and Operational, p. 5.

12. Unitaid’s success in influencing the price of test kits is critical for the sustainability and scale-up of HIVST. (*Strength of evidence: High*)

Unitaid has supported improving the affordability of HIVST kits, which are now available for less than USD \$2 in over 135 countries.³⁶ From a sustainability and scale-up standpoint, as well as an Equity standpoint, Unitaid’s success in driving the price of test kits to under USD \$2 is recognised as particularly important by informants. The increase in affordability of the product is expected to drive sustained procurement of HIVST kits in LMICs. Given Unitaid’s expertise in market shaping, its choice to intervene in this area is appropriate and aligned with global objectives to fight HIV.

The investment has promoted scalability: since initial Unitaid investments in HIVST, there has been a rapid increase in the number of countries now implementing HIV self-testing programmes.³⁷ As evidenced in the relevance section, Unitaid’s role in promoting evidence and regulatory approval has been central to this uptake. One bottleneck identified in interviews is on getting HIVST further mainstreamed within health programmes, in particular beyond countries of investment.

‘The development sector jumps on the next big thing and that either becomes common practice or tends to be deprioritised [...] In order for it to *become bigger*, if it could cross the boundaries as pregnancy self-testing does where it is understood well by the customer. There needs to be some thought around distribution, otherwise self-testing stays as one of the things in the arsenal.’ (Investment partner)

7.4 Conclusions

HIVST is highly innovative and formed a key part of Unitaid’s 2017–21 Strategy. The HIVST portfolio is an example of Unitaid’s unique role at bridging the ‘upstream’ and ‘downstream’ of innovation. Investments in HIVST also leverage Unitaid’s core comparative advantage in terms of disease focus and market shaping expertise.

The work on HIVST is a good example of how Unitaid complements the work of other funders. Through this investment, Unitaid created the conditions for scalability of this product. It did so by generating the evidence needed to encourage other donors to enter the HIVST space and informing the WHO ‘Testing and Partner Notification guidelines’ and shaping the market pricing so that kits can be procured for under USD \$2 each.

Unitaid demonstrated good levels of risk appetite to catalyse innovation and scale-up of a high-potential product which has been able to reach some of the most underserved populations. In doing so, it has upheld its mandate to increase equitable access to health products, as well as contribute towards its overarching HIV strategy.

The main potential area for improvement observed through this case study is in the relative lack of involvement of LMIC partners in delivering grants. As confirmed by informants from the Secretariat and by grantees, Unitaid is increasingly intent on involving local partners. However, grantees report that Unitaid is not always appreciative of the additional time needed to build capacity and implement through local partners. Implementing through less well-known local organisation may, at times, be riskier but is key to improve sustainability and Equity in Unitaid’s interventions. This

³⁶ KPIs 2020 - UNITAID_EB38_2021_7_Strategic and Operational, p. 5.

³⁷ UNITAID_EB32_2019_10_Report of the Midterm Strategy Review.

finding, which echoes others across the Strategy review, raises questions around whether Unitaid is excessively risk-averse in its implementation approach, in stark contrast to the choice of intervention, which (as previously discussed) was risky and innovative.

8 Fever Management Case Study

8.1 Introduction

Fever management is a new investment area for Unitaid, incorporated under the malaria investment portfolio. This case study set out to evaluate the Relevance, Coherence, Efficiency and Effectiveness of this Afl, with the aim of generating specific data on how Unitaid performed against its 2017–21 Strategy and to collect lessons learned, in order to inform how Unitaid can optimise its contributions towards fever management in future. This case study was selected as it represents a new investment area and has not yet been subject to evaluation, as well as to enable an overall technical breadth to be included in the overall review.

The data collection process involved seven KIIs and two focus group discussions (FGDs), including grantee representatives both in-country and at global level, other key/potential donors in this space (Global Fund, USAID), WHO and members of the Unitaid Secretariat. Interviews were conducted by a member of the Strategic Review team (Clare Strachan) during May and June 2021, with all requested interviewees agreeing to participate. A total of 35 documents was reviewed, including disbursement memos and original and up-to-date grant documents provided by Unitaid, as well as relevant excerpts from the overall coded documentation effort for the Strategic Review and other, broader reading from online sources. Data was analysed and rated for quality using the review’s standardised strength of evidence rating scale, with only high- and medium-quality results with strong agreement being included in the final analysis.

8.2 Background

The Afl’s ‘Better tools for integrated management of childhood fever’ was endorsed by the Unitaid Executive Board in June 2017,³⁸ confirming interest in exploring opportunities related to the integrated management of childhood fever in low-resource settings. The Executive Board requested that the Secretariat continue to refine work in this area by i) narrowing the scope of the Afl through greater prioritisation of opportunities, potentially through a step-wise approach focused initially on diagnostics; and ii) further exploring the opportunities and risks related to sustainability and scale-up. The updated Afl was endorsed by the Board in December 2017.³⁹

The approval of the Afl was based on the strong rationale which exists to address the common causes of childhood fever, including malaria, through integrated approaches. Specifically:

- integrated approaches can improve malaria case management;
- many children with malaria are co-infected with other conditions;
- appropriate treatment of non-malarial fevers is needed to improve rational drug use and mitigate resistance against both antimalarials and antibiotics; and

³⁸ Unitaid Executive Board Meeting, 27th Session (EB27), the Unitaid Executive Board endorsed Resolution EB27/R01.

³⁹ Unitaid Executive Board Meeting, 28th Session (EB28), the Unitaid Executive Board endorsed Resolution EB28/2017/7.

- many of the signs and symptoms of severe disease are common across diseases (including malaria), and are often overlooked, leading to high mortality.⁴⁰

A call for proposal was issued in April 2018, focused on improving fever diagnosis in children, and in July 2019 two projects were initiated to enable the pilot introduction of pulse oximeters and the generation of important data on feasibility and cost-effectiveness, with the aim of encouraging effective adoption by countries and funding partners. Key project details are included in Table 1.

Table 1: Unitaïd projects under the fever management Afl

Project name	Improving the Identification of Respiratory Distress in Children (AIRE)	Tools for Integrated Management of Childhood Illness (TIMCI)
Partners	Alliance for International Medical Action (ALIMA) (lead) and Institut National de la Santé et de la Recherche Médicale (INSERM), Solthis and Terre des Hommes	PATH (lead) and Swiss Tropical and Public Health Institute (Swiss TPH)
Timeframe	July 2019–December 2022 (with a possibility of extension)	July 2019–December 2023 (with a possibility of extension)
Grant size	USD \$14.9 million	USD \$28.4 million
Implementation countries	Burkina Faso, Guinea, Mali and Niger ⁴¹	India, Kenya, Myanmar, Senegal and Tanzania ⁴²

In 2019 the International Advisory Group (IAG) for Unitaïd’s fever management grants, which includes representatives from WHO, UNICEF, NGOs, countries, academia and civil society, was established, and it met for the first time in October 2019.⁴³ In April 2020 additional investment though the grant was approved for COVID-19 response, focused on reinforcement of national capacities to mitigate the impact of COVID-19 in selected primary health facilities and hospitals by providing supportive tools to protect health workers and patients and enhancing systems for infection detection and management.⁴⁴

8.3 Findings

8.3.1 Relevance

⁴⁰ Afl, Dec 2017.

⁴¹ ALIMA project plan, 2019.

⁴² TIMCI project plan, 2019.

⁴³ Unitaïd Portfolio Performance Report 2020.

⁴⁴ Unitaïd Portfolio Performance Report 2020.

1. There is broad consensus that the focus of the fever management investment is very relevant in terms of filling a key ‘gap’ based on a well-researched and clearly identified need, and there are few other key funders who may be willing to invest in evidence generation in this space. (Strength of evidence: High)

A strong rationale was put forward for the fever management Afl based on a need to boost integration of case management among children under five at primary healthcare (PHC) level, to further enable differential diagnosis of common causes of childhood fever, and to ensure that the positive benefits of diagnosing and treating malaria are not offset by the inappropriate management of other infections, including potential overuse of antibiotics.^{45, 46} The Secretariat completed a thorough landscape assessment of fever diagnostic tools for use in PHC and explored in depth several specific opportunities for investment before landing on implementation research⁴⁷ surrounding the introduction of pulse oximetry.^{48, 49} The decision was based on a detailed review of what others were doing/not doing, potential impact on the market (i.e. influence on commodity prices), feasibility of assessment and direct linkage to potential guidelines development, overall opportunity for scale-up, and linkage to ongoing malaria investment. There was broad consensus across stakeholder groups⁵⁰ that, as a first phase investment in fever management, the appropriate prioritisation was made.

Pulse oximeters (POs) are a simple, low-cost, reproducible, and non-invasive devices that measure heart rate and oxygen saturation in the blood. They have been proven to effectively diagnose and monitor children with hypoxemia, and are included in WHO Integrated Management of Childhood Illness (IMCI) guidance for use in PHC settings where available and in WHO Guidance on Oxygen Therapy for Children.^{51, 52} POs that are better adapted for primary care use in children in LMICs have recently entered the market, and pilot implementation of these devices is now needed in early-adopter countries in order to lay the foundation for their use in PHC as a standard of practice, as well as to improve Efficiency of referral.^{53, 54, 55}

There was a sense across many informants that ‘the project came along at the right time’ (grantee) and that the ‘entry point’ through malaria was ‘appropriate’ (global

⁴⁵ Update to the Executive Board on the Area for Intervention ‘Better tools for integrated management of childhood fever: diagnostics’, 2017.

⁴⁶ A multi-country review with >1 million patients tested with RDTs. Hopkins H, Bruxvoort K J, Cairns M E, Chandler C I R, Leurent B, Ansah E K *et al.* Impact of introduction of rapid diagnostic tests for malaria on antibiotic prescribing: analysis of observational and randomised studies in public and private healthcare settings. *BMJ* 2017; 356.

⁴⁷ Implementation research (also known as intervention science or operational research) evaluates how various interventions or approaches are adopted and applied in ‘real world’ settings in order to establish an understanding of their effectiveness in different contexts, useful for informing further practice as well as policy.

⁴⁸ Update to the Executive Board on the Area for Intervention ‘Better tools for integrated management of childhood fever: diagnostics’, 2017.

⁴⁹ The other investment options considered were: targeted interventions to ensure a sufficient supply of quality-assured malaria RDTs; approaches to accelerate demand and adoption for fever case management; late-stage product development in multiplex diagnostics for multiple causes of fever; and market introduction for automated respiratory rate counters.

⁵⁰ Global health partners/donors, Secretariat, grantees.

⁵¹ WHO, IMCI Chart Booklet, March 2014.

⁵² WHO, Oxygen Therapy for Children, 2016.

⁵³ Unitaid, Technology Landscape: Fever Diagnostic Technology Landscape, 1st Edition, February 2018.

⁵⁴ ALIMA project plan, 2019.

⁵⁵ TIMCI project plan, 2019.

health partner/ donor) and it presented a good ‘opportunity to boost an integrative approach and go further into RMNCH’ (global health partner/donor).

That there is a specific outcome goal linked closely to sustainability and scalability was also praised across stakeholder groups. The direct goal for both the AIRE and TIMCI projects is to incorporate PO introduction into national fever management/IMCI guidelines, related to a broader effort to revise the global IMCI guidelines based on new emerging evidence.⁵⁶ There is opportunity through this effort for high impact: recent research has shown that hypoxia and malnutrition are strong predictors of mortality in children hospitalised for pneumonia, and pulse oximetry can significantly increase the incidence of correctly treated severe cases as well as reduce the incidence of incorrect treatment with antibiotics. One recent study also found that the combination of pulse oximetry with integrated management of childhood illness is highly cost-effective.⁵⁷

The landscape review also explored funding opportunities for scale-up, identifying, for example, a renewed global health focus in the West Africa region since the Ebola epidemics 2013–16, the emergence of the Sahel Alliance, interest among various multilateral and bilateral donors, and the growth in fund recipient countries in West Africa by the GFF.⁵⁸

2. While the focus is considered largely ‘good for now’, there are calls for clarity on the overall strategic direction of the fever management investment, including on the linkage with the three diseases or as related to an overall MNCH approach. (Strength of evidence: High)

While the fever management investment is currently thought of as a well-considered one, there are calls among global health partners and grantees for implementation research relating to PO introduction to go further to inform the update of guidelines. For example, two global health partners suggested a broader focus in terms of impact, i.e. to also explore the effect of PO introduction on the sensitivity and specificity of the diagnostic algorithm itself, the overall adherence of the protocol and on relevant provider behaviours. At the same time, there is recognition⁵⁹ that the scope needs to be in line with partner capacity and feasibility within relatively tight time frames.

Opportunities clearly exist to catalyse the market introduction of POs if research suggests feasibility and effectiveness in their introduction, and there were calls for clarity across all stakeholder groups outside the Secretariat on the overall strategic direction of the fever management investment, which could inform further projects in this space. It is broadly recognised that there are many opportunities that could benefit from Unitaid support, some of which are already being explored and monitored by Unitaid. For example, Unitaid is encouraging PATH to consider the entire landscape of multimodal devices and to not limit the scope of work to PO+ automated respiratory rate counting, especially in the context of the COVID-19 pandemic. Unitaid is also actively monitoring the biomarker pipeline, including host response biomarkers

⁵⁶ WHO is in the process of revising the IMCI guidelines, with the estimated timeline for publication being 2021/2022, with early operational findings from the project potentially able to inform WHO discussions.

⁵⁷ Evaluating the impact of pulse oximetry on childhood pneumonia mortality in resource-poor settings. Floyd J. et al. Nature. Dec 2015.

⁵⁸ Update to the Executive Board on the Area for Intervention ‘Better tools for integrated management of childhood fever: diagnostics’, 2017.

⁵⁹ Secretariat, global health partners/donors.

for diagnostics that can detect severe disease, as well as diagnostics to distinguish between bacterial and non-bacterial infections.⁶⁰

However, landscape analyses revealed that the pipeline for devices targeted at LMICs is currently limited, and relatively few tests are likely to include malaria. The optimal set of pathogens to be detected by these tests has not yet been identified, owing to poor data on the causes of fever in most settings, and indications are that the unit costs for these various devices could be prohibitive. Notwithstanding, clarification is needed as to whether Unitaid will continue to prioritise downstream over more upstream investments in this space, as well as the extent to which integration with malaria will continue to guide decision making and whether investments could be more aligned with broader MNCH or child health technical agenda.

‘If there is this opening, then there is [a] need to think about what in child health could be relevant to be taken up by Unitaid. There is a lot of work currently around maternal health products, and things are being broadened. There is [a] need to approach the MNCH space not through the big three diseases.’ (Global health partner/donor)

‘The focus on just pulse oximetry is a bit narrow when under the umbrella of fever management. What is the next step for Unitaid’s next strategy? To expand the portfolio on the paediatric side for when say, they go to a child clinic with a cough and fever, not to an HIV, TB or malaria clinic?’ (Global health partner/donor)

3. There were mixed views on the extent to which the implementation research should be adapted to country settings, and the extent to which the intervention should be led by the ‘implementation’ or the ‘research’. (Strength of evidence: Medium)

In general (with some exceptions), global-level stakeholders⁶¹ seemed to be more focused on the macro-level research agenda and the need to aggregate findings across projects and country contexts, whereas stakeholders closer to the implementation tended to be more focused on adaptability of the delivery of the intervention in line with the local context.

As explained by one informant, ‘gathering the information from country level to be fed back into the global level – a bottom-up approach rather than top-down – is the key for this grant.’ (Global health partner/donor). Another informant emphasised the need for flexibility in the delivery, engagement and transition planning based on the specific country implementation context: *‘Myanmar is the least engaged, India sees it much more as a pilot and as such won’t consider major changes until after the results, and Senegal has taken it the most seriously in terms of adapting policy.’* (Grantee)

A number of stakeholders across groups⁶² raised the point that, while Unitaid have a wide knowledge of what is happening globally, they have less insight into the country end and field-level realities, which may reduce their focus on the need for context-specific implementation adjustments.

4. COVID-19 additional response work has, overall, served to boost the relevance of planned fever management activities and helped lay the foundation for effective

⁶⁰ Unitaid and FIND. Biomarkers for acute febrile illness at the point-of-care in low resource settings: Meeting report. December 2020.

⁶¹ Secretariat, global health partners/donors.

⁶² Global health partners/donors, grantees.

local engagement, though some reorientation of project focus under AIRE and TIMCI will be needed. (Strength of evidence: Medium)

The pandemic impacted the implementation of both the AIRE and TIMCI projects (see Section 8.3.4: Effectiveness, below) owing to movement restrictions and shifting priorities in project countries, and additional response funds for COVID-19 were channelled through both projects. It is clear that the entry point for Unitaid's COVID-19 related work here was MNCH and the two projects rather than broader COVID-19 support per se. For example, Unitaid has continued to support the scale-up of pulse oximetry at primary healthcare for children. Key too has been the provision of technical support to ministries of health (MOHs) to execute COVID-19 response plans which included supporting repairs of oxygen equipment in disrepair (via TIMCI project), considered one of the quickest, most cost-effective way to scale access to medical oxygen in the context of COVID-19.⁶³ Unitaid also advocated for essential services to remain fully operational during the pandemic, and investments were made with an emphasis on long-term, resilient oxygen systems. These efforts also served to boost relevance of the projects through awareness raising of the essential role of POs in detecting respiratory distress and delivering oxygen safely. Training modules on the use of POs and quantification efforts are also likely to be useful in paving the way for project-specific capacity building efforts.^{64, 65} The results of the supply and demand analyses and referral facility assessments will also be used to determine a recommended mix of products to meet the immediate respiratory care needs at national, subnational and facility levels. Political sensitivities have also made several countries reluctant to engage with partners in their pandemic response efforts, whereas the projects have reportedly engaged well with MOH and other national stakeholders involved in the pandemic response, which will probably strengthen a trusting foundation for ongoing project work.

However, as indicated by a range of stakeholders⁶⁶ and documentation, in the medium/long term the projects will need to reorientate themselves around the level of PHC and delivery of services to children, rather than being an adult-focused service at tertiary level.⁶⁷

'The current entry point is COVID rather than MNCH sphere.' (Donor/Global health partner)

'COVID-19 changed the focus on how to integrate POs into health facilities.' (Donor/Global health partner)

8.3.2 Coherence

5. There is broad consensus that there is relatively good internal coherence and complementarity across fever management grants, though this could be boosted by more coordinated planning efforts. (Strength of evidence: High)

⁶³ TIMCI Output 6 COVID-19 amendment.

⁶⁴ ALIMA grant amendment, 2020.

⁶⁵ TIMCI Performance and Disbursement Memo, November 2020.

⁶⁶ Secretariat, global health partners/donors, grantees.

⁶⁷ TIMCI Grant Agreement Amendment, 2020.

Secretariat staff described the fever management Afl as *‘unique as they have these two very close projects, with the goal to add up to a coherent whole’*. Various stakeholders also discussed complementarity between partners relating to a similar overall scope of intervention, while focused in different locations and bringing slightly different strengths. Secretariat staff discussed how complementarity has been boosted over time following some amendments to the individual projects: *‘Reprogramming made them more complementary, as opposed to potentially duplicating some efforts. They [will now be] leveraging the results of each other’s projects more.’* Secretariat staff and grantees also agreed that, given the overall similarity in targets, there was scope to develop a common Theory of Change, with joint assessments and common scalability frameworks to be applied across the two projects.

6. Internal coherence and coordination could also have been improved through consideration of the malaria portfolio as a whole during planning and design phases, which may have further clarified the overall strategic direction of fever management investment. (Strength of evidence: Medium)

Fever management as an Afl appears to be seen as a sub-investment area of malaria, rather than as part of the ‘core portfolio’ of Unitaid, as indicated by not being included in the Strategic Review of the core portfolio (2020),⁶⁸ 69 as well as some interviews.⁷⁰ For example: *‘It was an uphill battle to get [fever management] approved by the Board, but really around the question of scale-up. Also always trying to link it back to malaria. Wanted a very specific scope of work that was not going to detract from other work in the big three.’* (Secretariat)

Close linkage to malaria is understandable and logical given the entry point of fever management (and an approach to addressing childhood mortality which aims to ensure that every child who presents with a fever is managed holistically rather than through vertically focused programmes is strategic),⁷¹ but – as also discussed under Relevance above – clarity on the overall vision and direction of the fever management investment may be useful to guide planning and engagement with partners in this space. It was also suggested⁷² that coherence and coordination across projects would be boosted through the development of Theories of Change at portfolio level and that fever management could feature in the malaria-specific version but potentially also others, i.e. relating to MNCH.

7. There is good collaboration across grantees, though this is generally informal and grantee- rather than Unitaid-led and could be more formally strengthened and guided to benefit from cross-learning opportunities more fully. (Strength of evidence: High)

Coherence across both grants is clearly boosted through coordination between both projects, focused largely at the project direct exchange level, and through the IAG. PATH and ALIMA are quite different NGOs (the key discernible differences being that ALIMA is more emergency and fragile setting-oriented, whereas PATH is more focused on stable settings and has extensive experience in the oxygen space and a strong

⁶⁸ Unitaid EB note 37. Strategic assessment of the core portfolio, 2020.

⁶⁹ Unitaid 2020 Joint Investment Plan 2020-2022.

⁷⁰ Secretariat.

⁷¹ Unitaid Strategy 2017 – 2021.

⁷² Secretariat.

presence in global networks)⁷³ and this paves the way for complementarity and cross-learning. In their project plans, both partners outlined key areas of intended coordination and there are various examples where this has played out, for example in the selection of specific POs, aligning of research design components as feasible, in the planning and delivering of COVID-19 response work, and the development of the IAG ToRs and membership.^{74, 75, 76} A joint observer country strategy also exists between PATH and ALIMA which charts their collaboration towards leveraging strengths across the partnership and overall lessons learned for scale-up beyond project countries.⁷⁷ Collaboration is also now under way focusing specifically on transition planning. Grantees both discuss an open and collaborative relationship which is of mutual benefit to both projects, though this is not based on *‘any specific requirement from Unitaid for formalised collaboration’* (grantee). As conveyed by one grantee, *‘we work together to try to get a common point to communicate together and we put strategies together – because both projects are stronger together.’* Two IAG members also reflected on the need for more formalised coordination between the grantees to optimise opportunities for cross-learning and cohesive planning, particularly as a new investment area.

8. Visibility of Unitaid in the fever management space at global level is growing, though remains low at country level, with projects being associated largely with the grantees. (Strength of evidence: Medium)

Despite linkage to the malaria portfolio internally, Unitaid has extended its engagement with a range of fever management/child health actors through its fever management investment, in particular through the planning stages to develop the Afl. For example, the project was presented in the World Forum on Childhood Pneumonia in January 2020 in Barcelona, which was an opportunity to engage with the main stakeholders involved in child health, pneumonia, POs and oxygen.⁷⁸ There are, however, calls to take this further: for example, *‘for people in the know, around oxygen, etc., we know about Unitaid. But a lot of people don’t. It would be wonderful if Unitaid could engage more with the child health task force global group and the various working groups there.’* (Global health partner/donor)

At county level it is reported that visibility of Unitaid tends to be low, with projects largely being associated with the grantees, though it is expected that Unitaid’s profile may grow through their engagement around transition planning in the later stages of the project. Engagement with in-country decision makers and key partners has generally taken place through the IMCI technical working groups.

‘People in the field don’t generally know Unitaid. People discovered it with this project. The Ministry of Health know us and that we are financed in part by Unitaid but for the project, they think of us.’ (Grantee)

⁷³ Unitaid Portfolio Performance Report, 2020.

⁷⁴ ALIMA project plan.

⁷⁵ PATH project plan.

⁷⁶ PATH grant agreement amendment, 2020.

⁷⁷ PATH and ALIMA observer country strategy, 2020.

⁷⁸ Performance and Disbursement Memo for ALIMA for the AIRE project, December 2020.

8.3.3 Efficiency

9. The choice of fever management partners has led to calls for more flexibility within the operating model to enable adaptation to more varied operational contexts and a wider range of partner capacities. (Strength of evidence: Medium)

The project countries for both grants were selected based on feasibility of operations from a health systems, political and security perspective and where there is an existing strong partner presence which would also offer value for money.^{79, 80} The decision to fund ALIMA is well supported, considering specifically its focus on fragile countries and hard-to-reach areas, and hence alignment with overarching Equity goals. There have been calls for more flexibility within the operating model to enable adaptation to more varied operational contexts and a wider range of partner capacities, though the additional workload required at the Secretariat for organisations that have weaker capacity than others is well noted. As conveyed by a Secretariat staff member, *‘a challenge for Unitaid is to figure out how to manage two very different organisations. There is a need to adapt expectations as well. One thing that doesn’t get taken into consideration is the extra resources and strain on Secretariat staff time. We have spent so much more time, around double, with ALIMA, as opposed to other grantees. This was not factored in.’*

10. The evolving operational context has heightened implementation risks, which has contributed to feedback from grantees that requirements for reporting and engagement are demanding, which can also divert attention from local implementation efforts. (Strength of evidence: Medium)

Risk assessments for both projects have been complicated by COVID-19, the evolving emergency response activities initiated through the projects and uncertainty as to when and how the original planned project activities could effectively resume and be impactful within a short timeframe (including within the adjusted post COVID context). Coupled with both grantees being new to working with Unitaid (and some identified capacity issues with ALIMA), this has led to intensive engagement between both grantees and Unitaid, adjustments to plans and budgets, updates to scalability frameworks, as well as various other management responses on the part of Unitaid.⁸¹ ⁸²In response, grantees discussed the *‘fine line which exists between micro-management and partnership’* and the intensity of the project planning, engagement and reporting requirements. For example: *‘If we want to change something, then we think about it ten times before we ask Unitaid. There is some much close follow up, budget updates, justifications etc and it can distract us from engaging locally and getting on with the project.’* (Grantee)

There is broad consensus among stakeholders involved in various ways in Unitaid’s fever management investment⁸³ that it is the evolving context and scale-up

⁷⁹ ALIMA project plan, 2019.

⁸⁰ PATH project plan, 2019.

⁸¹ Performance and Disbursement Memo for ALIMA for the AIRE project, December 2020.

⁸² TIMCI Performance and Disbursement memo, November 2020.

⁸³ Global health partners/donors, Secretariat, grantees.

considerations that could introduce risk under these projects, given the uncertainty they both bring.

8.3.4 Effectiveness

- 11. There is limited demonstration of value for money so far, given the short implementation period and diversion of attention due to COVID-19, though a simplified version of the original operational research plan is now under way and there appears to be general confidence in ability to deliver. (Strength of evidence: Medium)**

Given the clear gap and importance of agreed project activities and the existing infrastructure through which they will be delivered, the general consensus across stakeholders was that the fever management investments will likely offer good value for money, despite the setbacks from COVID-19. Some project preparation activities, linked to the COVID-19 response work, were able to be initiated during the first year, and operational research work has recently started across all countries (early/mid-2021).⁸⁴ Reportedly there were, however, delays in finalising the research protocol, owing largely to differing views in its scope and key aims (predominantly between Unitaid and ALIMA). These have now been resolved through an agreed simplification of the study, focused on process evaluation of PO implementation (acceptability, implementation fidelity, challenges and factors influencing project implementation and realistic evaluation), while dropping elements of the cost-effectiveness and impact assessment components (this adaptation applies to the AIRE protocol only).⁸⁵ While targets have been complicated because of COVID-19, there is broad agreement across grantees and Unitaid that they are considered realistic, though timelines may be ambitious, particularly as relating to the scalability component.

- 12. There is a clear pathway to scalability, though there have been shifts in the landscape due to COVID-19 and timelines are tight for effectively preparing for transition. (Strength of evidence: Medium)**

The Afl comprehensively explored the funding landscape for the scale-up of POs, though there have been some shifts owing to COVID-19. The projects are closely monitoring the effects of the pandemic on the global conditions for POs and other screening tools, including multimodal devices. A range of stakeholders noted that global awareness of POs has increased significantly due to COVID-19, as has demand for the devices, and to better understand these effects the project is monitoring what procurement has taken place in LMICs and where devices are being deployed, as well as if and how policies and normative guidance are being updated or adapted. There may be several funding opportunities for COVID-19-related supplies and equipment available as a result of the pandemic. To support scalability planning, efforts will be needed to continue to create awareness about the project both globally and in the project countries – this was emphasised across stakeholder groups. PATH and ALIMA are working on a joint transition plan on developing civil society engagement plans to sensitise in-country around the need for this research, findings and policy implications,

⁸⁴ Owing to the current circumstances in Myanmar, TIMCI is unable to conduct research there and will be exiting from the country.

⁸⁵ Performance and Disbursement Memo for ALIMA for the AIRE project, December 2020.

and to encourage community support for transition and scale-up of the project interventions. Key, as all stakeholders are aware, is incorporation of POs into national IMCI guidelines, as *political support will come if they see feasibility and demand are strong. Governments will then likely find some money for POs – and then donors can perhaps top that up.*' (Grantee, country)

However, there remains some concern around scalability potential and the responsibility of this being placed on the grantees, as well as the diversity of in-country scale-up environments that need to be effectively considered.

'A lot of this translates into WHO guidelines, but a lot also needs to happen at country level to make sure it is included in policies, strategies, budgets, which often happens after Unitaid investments stop – but you need someone at the table making sure it gets put in proposals, etc. Transition to scale up should be thought about a little bit more. They do not scale up, but scalability is key to their work.' (Global health partner)

13. Efforts have been made to address Equity in the design of the fever management Afl, though there is scope to go further. (Strength of evidence: Medium)

There is broad consensus that, from the perspective of Equity, ALIMA was a good choice of grantee, given its focus on hard-to-reach areas and, in general, on countries with some of the highest under-5 mortality rates in the region (and from those, the countries with the high numbers of under-5 deaths linked to pneumonia).⁸⁶ As mentioned above, Unitaid's experience in engaging with ALIMA has, however, highlighted the need for more flexibility within the operating model to enable adaptation to more varied operational contexts and a wider range of partner capacities. There were also various suggestions among both grantees and global health partners of the need to boost Equity as a core principle in shaping Unitaid's investment decisions in this space. For example:

'Another area is having local partners involved and having smaller grants with capacity development, to get more local academic universities and NGOs involved to have them do some of this work.' (Global health partner/donor)

'Equity – as part of their projects, are their project designs looking at rural or urban/remote areas enough within countries?' (Global health partner/donor)

'If [we] want a more equitable reach, Unitaid needs to understand better different contexts.' (Grantee)

8.4 Conclusions

This case study concludes with the following key points:

- There is broad consensus that the focus of the fever management investment is very relevant in terms of filling a key 'gap' based on a well-researched and clearly identified need. However, there are calls for clarity on the overall strategic direction of the fever management investment, including on the linkage with the three diseases or as related to an overall MNCH approach.

⁸⁶ ALIMA project plan.

- There is broad consensus that there is relatively good coherence and complementarity across both fever management grants, though more linkage with the overall malaria portfolio in terms of planning and evaluation may be useful and help clarify the strategic direction of this investment area. There is good collaboration across grantees though this is generally informal and grantee- rather than Unitaid-led.
- The choice of fever management partners has led to calls for more flexibility within the operating model to enable adaptation to more varied operational contexts and a wider range of partner capacities.
- There is limited demonstration of value for money so far given the short implementation period and dominance of COVID-19, though there appears to be confidence in ability to deliver based on a simplified research scope. There is a clear pathway to scalability, though there have been shifts in the landscape due to COVID-19, and timelines are tight for effectively preparing for transition.

9 Analysis of Unitaid’s Grant-making and Management against VfM Good Practice

This benchmarking exercise is based on VfM good practice as identified by a literature review on VfM good practice in grant-making and management, carried out by Itad in the context of the Fleming Fund evaluation. The literature review that was carried out focused on the following grant-making and management organisations: Bill and Melinda Gates Foundation, USAID, The Global Fund, DFID, UK Aid Direct, UNICEF, Action Aid, Christian Aid, ICAI, BOND⁸⁷ (survey of PWC, KPMG, Triple Line Consulting, Coffey International) and Her Majesty’s Treasury and Cabinet Office.

Elements of good practice are categorised under four main stages of grant-making and management:

- Pre-award
- Award
- Post-award
- Close-out.

Each stage and sub-stage has been rated using the key below, and a summary of strengths and gaps/concerns has been provided in the Table that follows.

Key

Green – in line with good practice
Amber – room for improvement
Red – some concerns

The Table also refers the readers to specific RQ findings (presented in Vol. 1) for further information.

Table 2: Analysis of Unitaid’s grant-making and management against VfM good practice

Grant stage	Elements of best practice	Unitaid approach	Gaps/concerns
Pre-award	Identification of strategic priorities	The selection process is thorough, and ensures alignment between disease narratives, AfIs and awarded grants (see RQ2).	<ul style="list-style-type: none"> • The process is time-intensive (e.g. time between notification of proposal selection and Board approval of grant was rated ‘long’ or ‘very long’ by a majority of the grantees). A question mark was also raised by a number of key informants around the opportunity cost of having the Board reviewing and voting all proposals. • Evidence from multiple sources indicates that beneficiaries (countries and patients/users) could be more involved at all levels, starting in the design phase (see RQ11, Equity). • Alignment between interventions and Unitaid’s strategic priorities could probably be greater if targets were set at AfI/disease level in line with strategic priorities (see RQ2, RQ12).
	Clear Terms of Reference	The information provided with the call (including the TORs) and through Unitaid’s website,	

⁸⁷ BOND is the UK international development network – <https://www.bond.org.uk/>

		webinars and responses to Frequently Asked Questions is found to be helpful by 86% of the grantees surveyed.	
	Cost-effectiveness analysis/assessment of intervention		Our VfM analysis has found that use of cost-effective analysis from the point of view of the purchaser (including use of scenarios) could be used at pre-award stage to enhance VfM (see RQ11).
Award	Agreed results and budget	Results and budget are agreed in advance and the Secretariat checks that good assumptions have been used in costing the activities.	
	Assessment of grantee capability	Capacity of grantees is assessed as part of the grant-making process (see RQ10).	Some concerns have been raised around lack of implementers from LMIC countries linked to lower capacity (see Equity, RQ11).
	Technical and multi-level review of application	The technical review process is thorough and includes an external review panel (see RQ2, RQ10).	Tools and templates provided for use during GAD could be more user-friendly (19% of grantees disagree or strongly disagree that these are friendly, while 44% think they are neither user-friendly nor unfriendly).
Post-award	Dialogue, lessons learned and adaptation	50% of grantees surveyed agree or strongly agree that Unitaid's grant management improved in recent years. A vast majority (94%) also find communication with Unitaid good.	
	Grantees have transparent and accountable procurement systems	Unitaid checks that grantees use transparent and accountable procurements systems.	
	Grantees provided with support with monitoring finances and results	The guidance provided by Unitaid at the beginning of the GAD process, such as leading up to and during the external kick-off meeting, is found useful by a majority of grantees surveyed (75%). 87% of respondents to the survey feel Unitaid's project team is responsive in supporting projects.	The Secretariat is very involved in grant implementation, which is sometimes perceived as counterproductive/time-consuming and sometimes verging on micromanagement (see RQ8, RQ10).
	Evidence of economy (savings)	The organisation is seen as delivering VfM through its market shaping work (as it drives costs of products down) (see RQ11). However, Unitaid's VfM approach does not seem to focus on economy per se, which is not necessarily a bad thing as it allows them to potentially better balance all aspects of VfM, including equity. Their VfM approach is seen as less 'reductionist' than that of other actors in this field (that push more for savings) (see RQ 11, Equity).	
	Risk identification and management	Unitaid has developed a robust risk management framework	Unitaid's risk appetite is potentially too low for an organisation focusing on innovation (RQ9). A

		that represents close to, or actual, best practice for grant-making organisations (see RQ9). 52% of respondents think Unitaid’s risk management approach helps to identify and manage risks in their projects.	number of stakeholders voiced concerns regarding Unitaid privileging low -risk investments as opposed to ‘big bets’.
	Regular expenditure monitoring/low variances	‘Changes made by Unitaid to its tools, process and guidance in 2019–20 have to some extent streamlined grantees’ work and/or increased flexibility to implement my project(s)’ (42% of survey respondents agree or strongly agree). Around 70% of respondents state that Unitaid’s guidance and support is helping them in fulfilling reporting requirements.	42%/65% feel that Unitaid’s programmatic/financial reporting requirements are more complex/challenging compared to those of other major donors. There are some reports of Unitaid’s processes slowing down procurement and other activities.
	Participation of beneficiaries	According to 55% of the grantees surveyed, national community, including beneficiaries, and civil society organisations are engaged in grant project design and implementation to a ‘large’ or ‘very large’ extent.	However, several key informants voiced a concern that not enough organisations from LMICs & MICs are implementing grants (RQ11, Equity). Direct engagement of governments and civil society in LMICs (which is linked by many to chances of sustainability) also appears to be very limited (see RQ11, Equity).
Close-out	Effective evaluation to appraise progress against stated goals and cost-effectiveness and inform future programmes	M&E system includes a results framework, strategic operational KPIs and grant-level Theories of Change and indicators, with 81% of grantees surveyed believing that the results framework helps them articulate potential results/impact. 30% of surveyed grantees thought Unitaid project evaluation provided useful feedback on the performance of our grant and allowed for course correction, while for 58% this was ‘not applicable’.	Evidence from KIIs, however, shows that: <ul style="list-style-type: none"> reporting and synthesis across/access to data from grant reporting is currently not suited to estimate and report results at country level (see RQ11). there are currently no <i>ex post</i> impact evaluations, e.g. more than 12 months after end of grant (see RQ11). not enough evaluations are commissioned at an aggregated level (AfI/country) (see RQ11). Unitaid does not have an impact model, with specific targets per disease/cross-cutting theme (see RQ12).

10 Resource Mobilisation

Resource mobilisation is the lifeblood of any organisation, without which it cannot thrive. At Unitaid, contributions flowed in quickly in the earlier years, with France being by far the lead contributor, followed by the UK. The ingress created a problem for several years of approximately USD \$800 million of funds sitting in account uncommitted to grants.⁸⁸ Reportedly the situation was responsible for the UK switching its contributions from cash to the form of promissory notes, activated when needed.

During the current Strategy period, contribution levels have been uneven over accounting periods, although to an extent this reflects the UK's Promissory Note approach, which only makes funds available when a need is demonstrated, and the unusual events of 2020. Most recently they declined from USD \$249 million (core and non-core) in 2019 to USD \$172 million in 2020, but the latter was supplemented by an unexpected USD \$53 million via the ACT-A initiative to counter the COVID-19 pandemic (see Table 3 below).

Table 3: Voluntary contributions to Unitaid (USD \$)

	2020	2019	2018	2017	2016	2006–15
Core commitments						
BMGF	10,000	10,000	10,000	10,000	10,000	90,000
Brazil	2,031	4,013	7,602	22,107	10,188	80,133
Chile	-	-	1,500	1,500	1,500	32,043
France	93,509	94,550	105,477	95,333	100,616	1,504,798
Japan	1,000	1,000	0	0	0	0
Norway	2,942	2,315	2,342	4,860	5,841	177,168
Rep. of Korea	5,000	5,000	4,000	4,000	4,000	47,000
Spain	1,792	-	0	597	0	81,603
UK	14,687	56,200	53,655	57,217	58,047	499,621
Non-core						
GF	11,851	18,723	2,426	0	0	0
UNOSCC	-	-5	100	0	0	0
Total from core/non-core	142,812	191,796	187,102	195,614	190,192	2,512,366
Contributions from ACT-A						
France	11,948	-				
Norway	39,906					
Rep Korea	1,000					
Total ACT-A	52,854					
Grand total	225,038					

Note:

The 2016 figure differs from the OKPI B 2016 baseline amount of USD \$187 million due to the difference between cash receipts (the financial statement) and the resource mobilisation figures related to the UK contribution, which operates differently from other contributions as it is a promissory note that is drawn down based on certain conditions but is averaged at £44 million per year. The UK's 20-year arrangement with Unitaid features consecutive three-year funding agreements.

⁸⁸ Secretariat – Finance – Curry; Van Vliet.

Unitaid’s Board and Secretariat recognise that resource mobilisation is an area of significant challenge.^{89, 90, 91, 92} The organisation’s risk management system identifies this as the most serious problem that it currently faces (in the ‘red’ area for both ‘severe impact’ and ‘highly likely’).⁹³

One of Unitaid’s operational KPIs – OKPI B (see RQ12) – sets resource mobilisation targets for the current Strategy period. This states a) that there will be two new core donors, which is feasible given the entry of Japan in 2019, and b) that the total annual contribution from donors in 2021 must be USD \$100 million higher than the figure for 2016⁹⁴ (which was USD \$187 million on an adjusted basis), which looks challenging.

There have been some successes over the current Strategy period. In 2019 this resulted in renewed multi-year agreements with France and the Republic of Korea and a first financial contribution from Japan as a new donor. The multi-year agreement with the Republic of Korea includes a 20% increase in annual funding. Most contributions are covered by multi-year agreements. However, UK contributions are likely to decline by an amount in the order of several tens of millions of pounds for 2021 and onwards; France looks to be reducing its contribution from USD \$95 million to USD \$85 million; and there is an uncertain future for the ACT-A work. This is a difficult context, as each current or potential donor also wishes to see other donors making commitments. The reduction in annual contributions was driven by a reduction in contributions by four donors, as well as the Global Fund and Gavi replenishments in 2019. In response to these challenges, Unitaid presented a revised Resource Mobilisation approach to the Board and ramped up outreach, which was cut short by the COVID-19 pandemic. Unitaid developed a USD \$265 million investment case for work under the ACT-A but has faced challenges in mobilising the required level of resources. There are major funding gaps for the overall ACT-A process and Unitaid is working with ACT-A partners to address this problem.

There are dedicated resource mobilisation staff, including those with communications skills, working to an Resource Mobilisation strategy developed in 2018. But a key item they will need in order to elicit significant contributions will be a new Strategy that provides reassurance on the potential for measurable results. ACT-A has, at least, raised Unitaid’s profile and allowed the organisation to demonstrate flexibility.

Within any future Theory of Change, resource mobilisation could arguably be viewed as an organisational output, in that persuading donors to allocate funding to Unitaid is one of the organisation’s key activities, without which no others can take place.

⁸⁹ Unitaid Midterm Review (2019), p. 31.

⁹⁰ Secretariat – Resource mobilisation – Polsky.

⁹¹ Secretariat – Finance – Curry; Van Vliet.

⁹² Board – James Droop.

⁹³ Organisational Risks – Complete Heatmap Q3 2020.

⁹⁴ Note that this is in fact only one part of the target; another states that two new core donors will be found.

11 Organisational Profiles

11.1 Gavi

11.1.1 Overview

Gavi's mission is to protect people's health and save children's lives by increasing equitable use of vaccines in lower-income countries. Gavi aims to pool demand, guaranteeing large vaccine orders to manufacturers ensuring lower risk, and subsequently increasing competition and facilitating a reduction in price. Gavi has extended into markets for other vaccine-related products, applying a similar model to cold-chain equipment. Gavi is not present on the ground but works through partnerships with other organisations such as UNICEF's supply division and the World Bank. Gavi delivers vaccines rather than grants, and does this through support such as routine immunisation, catch-up campaigns, stockpile, or mass campaigns.

11.1.2 Comparative advantage

Gavi's comparative advantage is in the vaccine market and children, tackling vaccine market challenges and having the potential to catalyse additional investment in vaccines.⁹⁵

11.1.3 Scope of investment areas

The Vaccine investment strategy ('VIS 2018') was the process by which the 2021–25 investment strategy was refined from a broad range of disease areas. The shortlisted vaccines were:

Endemic disease prevention

- Diphtheria, pertussis & tetanus-containing (D, T&P containing) boosters.
- Hepatitis B birth dose; A, C, W-containing multivalent meningococcal conjugate vaccines.
- Oral cholera vaccine (OCV).
- Rabies post-exposure prophylaxis (PEP).
- Respiratory syncytial virus (RSV) immunisation products.

The strategy also separately includes inactivated polio vaccine (IPV) and pandemic influenza.

11.1.4 COVID-19

Gavi has moved into the COVID-19 vaccine space by co-leading COVAX, the vaccines mechanism of the Access to COVID-19 Tools (ACT) Accelerator. This mechanism is like GAVI's original activities i.e. it pools risk and aims for equitable distribution of vaccines.

11.1.5 Market Shaping Areas

⁹⁵https://www.who.int/immunization/research/meetings_workshops/10_Mathewson_GaviPDVAC_2019.pdf?ua=1

Gavi was created to address market failure in LICs, such as uncertainties in funding and demand causing manufacturers not to have incentive to invest in new products at affordable prices for LICs. Gavi was created to address the lag time between when a product became available in rich countries and when it was introduced in developing countries.⁹⁶

Market shaping goal (2016–20 strategy) – the healthy markets objective has specific targets such as:

- a) Supply objective – ensuring adequate and secure supply.
- b) Cost – reduce prices to appropriate and sustainable level.
- c) Innovation – incentivise development of suitable and quality products.⁹⁷

11.1.6 Average/approximate size and length of grants:

Gavi's two funding streams, direct contributions and innovative finance, account for 77% and 23% respectively of the Vaccine Alliance's overall funding portfolio. Gavi runs in five-year funding cycles, which enables it to negotiate long-term deals with manufacturers, secure in the knowledge that funding will be available.⁹⁸

11.1.7 Typology of funding recipients and target beneficiaries

Gavi largely funds LMICs directly. Direct beneficiaries are population groups targeted by the vaccines, principally children under five as well as other age groups, depending on the vaccine. Other vaccines are targeted at specific high-risk groups, as the need arises, e.g. Ebola vaccine. Indirectly, Gavi also intends to benefit the overall population owing to widespread disease protection as well as through various linked health systems strengthening initiatives.

11.1.8 Geographic focus

- Core focus is on LMICs, traditionally low-income but increasingly adjusting its model to incorporate specific contexts of middle-income countries.
- Supported 73 countries in 2018, 51% of those in Africa.
- Other countries supported range across Central and South America (e.g., Honduras, Bolivia), Eastern Mediterranean (e.g. Pakistan, Somalia), Europe (e.g. Armenia, Ukraine), South-East Asia (e.g. Bangladesh, Nepal) and Western Pacific (e.g. Cambodia, Papua New Guinea).
- 2016–20 strategy included intensified efforts in 20 priority countries including Afghanistan and Chad. It then added an additional 10 countries, including Central African Republic and Haiti.

11.1.9 Grantees as a group over time (how the size/shape of it, org type, spread, etc.)

⁹⁶ <https://www.gavi.org/our-alliance/market-shaping>

⁹⁷ <https://www.gavi.org/our-alliance/strategy/phase-4-2016-2020/market-shaping-goal>

⁹⁸ <https://en.wikipedia.org/wiki/GAVI>

Grantees are principally countries directly, though CSOs can access Gavi funding to strengthen the role and representation of civil society in country-level coordination— for accountability and for direct involvement in implementation of the country’s health system strengthening proposal or comprehensive multi-year plan for immunisation.

11.1.10 Engagement with civil society

- CSOs have one seat on the Gavi Board and participate in Board committees and task teams.
- Gavi’s governance – CSOs provide input to ensure that its programmes and policies are robust, and maintains a high level of transparency, accountability, and responsiveness.
- CSO support is through the Health Systems Funding Platform (HSFP) – supports countries to advance national health strategies.
- The Gavi CSO Constituency leads the implementation of the Gavi Business Plan activity that aims to increase civil society participation in HSFP processes and development of immunisation policies at country level.
- Itad evaluation of Gavi’s support to CSOs in 2018 found that ‘Gavi has not articulated a clear vision of how CSO support can support Gavi’s wider Strategic Goals’, the structure of CSO model is complex and governance/decision making has not been made in an effective manner.⁹⁹

11.1.11 Approach to measuring impact

- List of indicators used to measure performance categorised according to the strategic period 2016–20 includes six broad categories: mission; disease dashboard; vaccine goal; health systems goal; sustainability goal; and marking shaping goal.¹⁰⁰

11.1.12 Approach to equity and measurement of equity

- Equity is the focus of three vaccine goal indicators – geographic distribution, wealth distribution and maternal education – and implied in others, including breadth of protection.
- Increasing Equity in immunisation delivery is a priority of Gavi’s Health System Strengthening (HSS) support in the 2021–25 strategic period.¹⁰¹

11.1.13 Board composition

- 18 representative seats, 9 seats for unaffiliated individuals and one seat for Gavi’s CEO.¹⁰²

⁹⁹ <https://www.gavi.org/our-impact/evaluation-studies/evaluation-gavi-support-cso-2018>; <https://www.itad.com/wp-content/uploads/2020/03/evaluation-of-gavi-support-to-cso-2018-itad-final-reportpdf.pdf>

¹⁰⁰ <https://www.gavi.org/programmes-impact/our-impact/measuring-our-performance/2016-2020-indicators>

¹⁰¹ <https://www.gavi.org/our-alliance/strategy/phase-5-2021-2025/equity-goal>

¹⁰² <https://www.gavi.org/governance/gavi-board/composition>

11.1.14 Future investment/strategic plans

A new five-year strategy (Phase 5, 2021–25) was approved in June 2019. GAVI’s Phase 5 strategy (2021–25) includes four goals: Vaccines; Equity; Sustainability; and Healthy Markets.

- Vaccine Goal
 - Strengthen countries’ prioritisation of vaccines based on context
 - Support countries to introduce and scale up coverage of vaccines for prevention of endemic and epidemic diseases
 - Enhance outbreak response through availability and strategic allocation of vaccine stockpiles
- Equity Goal
 - Help countries extend immunisation services to regularly reach under-immunised and zero-dose children to build a stronger primary health care platform
 - Support countries to ensure immunisation services are well managed, sustainable, harness innovation and meet the needs of caregivers
 - Work with countries and communities to build resilient demand, and to identify and address gender-related barriers to immunisation
- Sustainability Goal
 - Strengthen national and subnational political and social commitment to immunisation
 - Promote domestic public resources for immunisation and primary health care to improve allocative efficiency
 - Prepare and engage self-financing countries to maintain or increase performance
- Healthy Markets Goal
 - Ensure sustainable, healthy market dynamics for vaccines and immunisation-related products at affordable prices. Focus on a reliable, consistent, and affordable supply
 - Incentivise innovation for the development of suitable vaccines
 - Scale up innovative immunisation-related products through value-added enhancements. Purposeful approach to transformative innovations across immunisation products, services, and practices to deliver on equity commitments

11.1.15 Other aspects on their role/penetration of the overall market shaping landscape

Comparative advantage is in vaccine market challenges, especially relating to children. Gavi is core to this section of the market and works in partnership with other organisations who deliver in other areas.

11.2 The Global Fund

11.2.1 Brief overview

The Global Fund was founded in 2002 as a partnership organisation between governments, CSOs, the private sector and those affected by HIV, TB and malaria. The Global Fund's aim is to accelerate the end of the three diseases, end epidemics and to scale up treatments and tools fighting against them.¹⁰³ It is a financing mechanism rather than a programme implementer, functioning through a grants model to in-country partners, though it does directly fund a range of supportive implementation efforts and contributes a key technical advisory role in many countries that it works in.

The 2017–22 strategy aims to:

- Maximise impact against HIV, TB and malaria
- Promote and protect human rights and gender equality
- Mobilise increased resources
- Build resilient and sustainable systems for health

11.2.2 Comparative Advantage

The Global Fund is working in the same three disease areas as Unitaïd but is a finance mechanism rather than a programme executor. Unitaïd may provide proof of concept, and the Global Fund may be able to provide longevity by taking up Unitaïd's work after grants end. They are therefore key to Unitaïd's scale-up plans.

11.2.3 Scope of investment areas¹⁰⁴

Investments are made in the three diseases HIV, TB and malaria, aiming for priority areas with the greatest burden of disease. The scope of investment is purposefully wide, to increase potential impact. This can be a shortfall in market shaping, something which the Global Fund acknowledges and actively attempts to combat. The Global Fund acknowledge that 'compared to other financing institutions that can engage in market shaping, there is a broad scope'.¹⁰⁵ They see it as critical that the Global Fund takes a nuanced approach to market shaping, tailoring the interventions to each product or country.¹⁰⁶ This also includes close collaboration with partners such as Unitaïd in market shaping.

11.2.4 COVID-19 response

The Global Fund has responded to the COVID-19 pandemic by becoming involved in numerous mitigation methods to reduce the impact that COVID-19 is having both on recipient countries and on progress in HIV, TB and malaria.

These are:

- COVID-19 Tools Accelerator (ACT-A) – accelerating equitable access to COVID-19 tools in diagnostics, health systems and therapeutics.

¹⁰³ <https://www.devex.com/organizations/the-global-fund-to-fight-aids-tuberculosis-and-malaria-gfatm-30677>

¹⁰⁴ <https://www.theglobalfund.org/en/strategy/>

¹⁰⁵ 16 GF/FOPC15/07: 'Market Shaping Strategy Development Update.' July 2015.

¹⁰⁶ https://www.theglobalfund.org/media/4200/bm34_17-annex1marketshapingstrategy_paper_en.pdf

- Response Mechanism (C19RM) – supports countries to mitigate the impact of the pandemic on the three disease areas.
- Situation Reports – bringing together news about the COVID-19 response from across the Global Fund partnership.
- Health Product Supply – providing recommendations on sourcing quality health products for Global Fund grants.
- #UniteToFight – rallying the world into collective action against COVID-19 and the three diseases, to raise the estimated USD \$5 billion the Global Fund has estimated necessary to support the pandemic response.¹⁰⁷

As of January 2021, additional funding to LMICs for the Global Fund’s COVID-19 response totalled USD \$980 million.¹⁰⁸

11.2.5 Geographic focus¹⁰⁹

The Global Fund’s 2021 eligibility list defines the countries eligible, based on the World Bank’s classifications of country income level and disease burden as identified by WHO.¹¹⁰ The investment spread as of June 2019 was:

- a) Sub-Saharan Africa (74%)
- b) Asia and the Pacific (16%)
- c) North Africa and Middle East (4%)
- d) Eastern Europe and Central Asia (3%)
- e) Latin America and Caribbean (2%)

11.2.6 Funding cycle and grants

- The Global Fund funding cycle runs in three-year periods that correspond with donor Replenishment periods. The current funding period is 2020–22, which has a total of USD \$12.71 billion to disperse.¹¹¹
- The model is an allocation-based funding model, depending on the disease burden and income level of the recipient country.¹¹²
- Grant sizes appear to range between around USD \$250 000 and around USD \$400 million.¹¹³ Smaller grants include TB in Sri Lanka,¹¹⁴ and larger committed grants include malaria in the Democratic Republic of the Congo.¹¹⁵

11.2.7 Funding recipients and target beneficiaries

¹⁰⁷ <https://www.theglobalfund.org/en/our-COVID-19-response/>

¹⁰⁸ <https://www.theglobalfund.org/en/news/2021-01-12-global-fund-signs-a-record-breaking-usd8-54-billion-in-grants-to-fight-hiv-tb-and-malaria/>

¹⁰⁹ https://www.theglobalfund.org/media/8752/corporate_2019resultsreport_report_en.pdf

¹¹⁰ https://www.theglobalfund.org/media/10660/core_eligiblecountries2021_list_en.pdf

¹¹¹ <https://www.theglobalfund.org/en/funding-model/>

¹¹² https://www.theglobalfund.org/media/3261/core_budgetingglobalfundgrants_guideline_en.pdf

¹¹³ <https://www.theglobalfund.org/en/funding-decisions/>

¹¹⁴ <https://data.theglobalfund.org/investments/grant/SRL-102-G04-T-00/1>

¹¹⁵ <https://data.theglobalfund.org/investments/grant/COD-M-SANRU/4>

- Targeting high-risk and vulnerable populations who are often marginalised and have decreased access to quality services.
- Key populations for HIV include gay, bisexual, and other men who have sex with men, people who inject drugs, sex workers, and transgender people, and people in prison.¹¹⁶
- Key populations for TB include prisoners, people living with TB/HIV coinfection, migrants, refugees, and indigenous populations.¹¹⁷
- Key populations for malaria are not as well defined as the other two, but include refugees, migrants, internally displaced people, and indigenous populations in malaria-endemic areas.¹¹⁸

11.2.8 Engagement with civil society¹¹⁹

- International level – 3 out of 20 voting seats on the Board are held by community and civil society representatives.
- Country level – Community and civil society participate through the Country Coordinating Mechanism to create requests for funding and overseeing implementation, advocating for increased government health spending and resource mobilisation. The Global Fund creates ways for CSOs to better understand current state and trends of domestic financing for health.
- Local level – Community-based and civil society organisations are implementers of Global Fund grants on a local level.
- Advocacy – On the political level, community, and civil society organisations play an important role in advocating and raising awareness on behalf of the Global Fund.

11.2.9 Approach to measuring impact

- The Global Fund takes a partnership approach to results reporting, reporting against specific KPIs through a strategic performance framework.
- They use specific data points for each disease area, including indicators such as ‘number of people on antiretroviral therapy for HIV’ and ‘number of people with TB treated’.¹²⁰ Programmatic results and impact are then calculated using the data for HIV, TB and malaria in countries where the Global Fund invest each year, producing full national results for the countries where they invest.¹²¹
- There is also a macro ‘lives saved’ figure in the Global Fund’s results which is calculated in conjunction with technical partners using modelling methods

¹¹⁶ <https://www.theglobalfund.org/en/hiv/aids/>

¹¹⁷ <https://www.theglobalfund.org/en/key-populations/>

¹¹⁸ <https://www.theglobalfund.org/en/key-populations/>

¹¹⁹ <https://www.theglobalfund.org/en/civil-society/>

¹²⁰ <https://data.theglobalfund.org/results/all>

¹²¹ <https://www.theglobalfund.org/en/methodology/>

which yield sophisticated estimates, not scientifically exact figures. As of December 2020, this figure stood at 38 million lives saved since 2002.¹²²

11.2.10 Approach to equity and measurement of equity

- VfM framework measures in a similar way to FCDO's 4 Es. The Global Fund measures Economy, Effectiveness, Efficiency, with Equity and Sustainability as cross-cutting themes.¹²³
- Equity through the lens of reaching vulnerable populations, the failure to reach these populations considered as poor VfM.¹²⁴
- Gender equity technical brief in October 2019 advocated for strengthening in-country gender equity approaches.¹²⁵

11.2.11 Board composition¹²⁶

- 20 voting members of the board with equal representation of implementers and donors
- Includes: Non-governmental organisations; communities affected by HIV, TB and malaria; the private sector; and private foundations represented
- 8 non-voting members
- Includes: Board Chair and Vice-Chair; representatives of partner organisations including the World Health Organization and World Bank, as well as the Additional Public Donors constituency

11.2.12 Future investment/strategic plans

The 2017–22 strategy is currently being implemented, and the Global Fund is now developing the new strategy which will begin in 2023. They are crafting this strategy using partnership forums and open consultation.

11.2.13 Market shaping approach

In 2007, the Board approved the Global Fund's first market shaping strategy, calling for the Global Fund to play 'a deliberate and strategic role in improving the impact of grants by influencing market dynamics'.¹²⁷ There are still barriers to access, which the Global Fund define as 'including limited market information, small size, low growth or returns in each market, high barriers to entry or high transaction costs. Without intervention, the Global Fund claims these could lead to lack of availability of products, supply disruptions, unaffordable prices, slow introduction, and adoption of new products in some markets, and a lack of products designed to meet the needs of low- and middle-income countries.'¹²⁸

¹²²<https://www.theglobalfund.org/en/impact/#:~:text=The%20Global%20Fund%20partnership%20has,6%20million%20in%202019%20alone>

¹²³ https://www.theglobalfund.org/media/8596/core_valueformoney_technicalbrief_en.pdf

¹²⁴ https://www.theglobalfund.org/media/8596/core_valueformoney_technicalbrief_en.pdf p.4.

¹²⁵ https://www.theglobalfund.org/media/5728/core_gender_infonote_en.pdf

¹²⁶ <https://www.theglobalfund.org/en/board/>

¹²⁷ https://www.theglobalfund.org/media/4200/bm34_17-annex1marketshapingstrategy_paper_en.pdf p.7.

¹²⁸ https://www.theglobalfund.org/media/4200/bm34_17-annex1marketshapingstrategy_paper_en.pdf

The Global Fund’s market shaping strategy states that the Global Fund will work closely with technical and development partners that focus ‘upstream’ such as Unitaid. The Global Fund positions itself downstream as a financial institution and prides itself on its capabilities in sourcing, gathering market information and informing product selection.¹²⁹ To Global Fund, ‘Unitaid provides expertise on new product introduction, demand generation and intellectual property’.¹³⁰ In practice, Unitaid might provide a grant to generate proof of concept for an innovation, e.g. a new drug, and then the Global Fund may take over the financing of this drug once Unitaid’s grant support ends. This relationship is key to scale-up and requires close coordination between Unitaid and the Global Fund, and they now use the same framework to come to common definitions to enable action in the space, rather than working in siloes.¹³¹

The Global Fund states in its market shaping strategy that Unitaid produce landscape reports which ‘provide a comprehensive overview of current market shortcomings across preventive, diagnostic and treatment products’.¹³² Global Fund also conduct their own analysis to inform procurement strategies. Market shaping interventions by Global Fund and Unitaid in partnership with others include the Paediatric ARV procurement working group (PAPWG) to consolidate procurements and reduce lead times for products.¹³³

Traditionally the Global Fund have viewed their role in market shaping as oriented around procurement, but there are hopes internally that it can start to approach market shaping more strategically and from a centralised point within the Secretariat. They are increasingly focused on building procurement and supply chain capacity within countries.

11.3 USAID

11.3.1 Organisational mission/strategic aims/goals/objectives

The US Agency for International Development (USAID) is an independent federal government agency that received overall foreign policy guidance from the US Secretary of State and has been active for over 50 years.¹³⁴ Its mission is to ‘promote and demonstrate democratic values abroad, and advance a free, peaceful, and prosperous world’.¹³⁵ They aim to support partners towards reducing the reach of conflict, preventing the spread of pandemic disease, and counteracting the drivers of violence, instability, transnational crime, and other security threats.¹³⁶ Promoting Global Health is a key component of USAID’s approach.¹³⁷ US engagement in Global Health includes in policy and programmes, including but not confined to funding and implementing programmes, diplomacy, technical assistance and research and development (R&D).

¹²⁹ https://www.theglobalfund.org/media/4200/bm34_17-annex1marketshapingstrategy_paper_en.pdf p.11.

¹³⁰ <http://unitaid.org/assets/Unitaids-approach-to-intellectual-property.pdf>

¹³¹ https://www.theglobalfund.org/media/4200/bm34_p.13

¹³² https://www.theglobalfund.org/media/4200/bm34_17-annex1marketshapingstrategy_paper_en.pdf

¹³³ https://www.theglobalfund.org/media/4200/bm34_17-annex1marketshapingstrategy_paper_en.pdf p.7.

¹³⁴ https://reliefweb.int/sites/reliefweb.int/files/resources/Full_Report_3837.pdf

¹³⁵ <https://www.usaid.gov/who-we-are/mission-vision-values>

¹³⁶ <https://www.usaid.gov/who-we-are/mission-vision-values>

¹³⁷ <https://www.usaid.gov/sites/default/files/documents/1869/Message-Manual-0305-2019.pdf>

11.3.2 Comparative advantage

USAID's comparative advantage in the global health space is in policy and programmes; funding and implementing programmes, diplomacy, technical assistance and R&D, working through their broad geographic presence and global networks.¹³⁸

11.3.3 Scope of investment areas (diseases and other market shaping influencing areas)

Broad scope of investment areas, not just in health. In health, the scope is:

- Maternal and child health, including family planning, malaria, and nutrition.
- HIV/AIDS, where USAID works with the President's Emergency Plan for AIDS Relief (PEPFAR).
- Infectious diseases including malaria, HIV/AIDS, TB, neglected tropical diseases, pandemic influenza, and global health security.
- Health Systems.
- Innovation and Impact.

11.3.4 Average/approximate size and length of grants

- Seven step processes for grants awarded through a competitive process.
- Size/length unknown varies considerably – range not explicitly stated in aggregate.

11.3.5 Typology of funding recipients and target beneficiaries

- Often implemented grants via civil society, academic, consultancy firms or the private sector. USAID tends not to channel funds directly to countries.
- Targeted mostly at the world's poor and vulnerable, targeting in health those affected by the diseases outlined above.¹³⁹
- Focus on maternal health aimed at mothers and children who are poor, underserved, and vulnerable.¹⁴⁰

11.3.6 Geographic focus (explicitly defined or apparent through investment scope)

Worldwide in over 100 countries in Africa, Asia, Europe and Eurasia, Latin America and the Caribbean and the Middle East.¹⁴¹

11.3.7 Grantees as a group over time (how the size/shape of it, org type, spread, etc.)

Grown in spread over time, increase in number of countries.

11.3.8 Engagement with civil society

¹³⁸ https://www.usaid.gov/sites/default/files/documents/1864/USAIDGlobalHealthRDStrategy_2017-2022.pdf

¹³⁹ https://www.usaid.gov/sites/default/files/documents/1864/gh_framework2012.pdf

¹⁴⁰ https://www.usaid.gov/sites/default/files/documents/1864/gh_framework2012.pdf

¹⁴¹ <https://www.usaid.gov/who-we-are>

USAID provides technical leadership and assistance with civil society. They aim to strengthen citizens' ability to organise and communicate, strengthen a democratic political culture and mobilise constituencies for reform.¹⁴²

11.3.9 Approach to measuring impact

Standard indicators developed with the department of state, and custom indicators selected at the mission level.¹⁴³ Health Systems Benchmarking Tool (HSBT) includes indicators on the ending preventable child and maternal deaths, achieving an AIDS-free generation, and protecting communities from infectious disease.¹⁴⁴

11.3.10 Approach to equity and measurement of equity

USAID accept the need for equity not just to be considered in the planning stage, but actively and carefully monitored over time.¹⁴⁵ USAID gives considerable focus to categorising beneficiaries with the aim of monitoring the specific number of beneficiaries reached through its investments – this is usually activity and estimation based rather than specific modelling efforts per se.

11.3.11 Board composition

No board? Board for food and agricultural development, but not clear whether there is a board for USAID, or for the health focus within USAID.

11.3.12 Future investment/strategic plans as relevant

In a broad sense, due to its intricate link to the US government, the future of USAID depends on the president. Joe Biden has added the USAID administrator to the White House national security team, 'suggesting that the perspective of global development will be represented at the table when key US foreign policy decisions are made'.¹⁴⁶

11.3.13 Other aspects on their role/penetration of the overall market shaping landscape

USAID has been supporting health system strengthening for over two decades, acknowledging global health is linked to marketplace health.¹⁴⁷ Three levers:

- a) Reduce transaction costs – Lowering structural hurdles to market interactions, such as by simplifying, smoothing, or rationalising orders without money necessarily changing hands.
- b) Increase market information – Generating new data, aligning existing analyses, or improving the visibility of existing data to reduce asymmetries of information.

¹⁴² <https://www.usaid.gov/democracy/supporting-vibrant-civil-society-independent-media>

¹⁴³ <https://www.usaid.gov/project-starter/program-cycle/cdcs/performance-monitoring-indicators>

¹⁴⁴ <https://www.hfgproject.org/usaid-health-systems-benchmarking-tool/>

¹⁴⁵ <https://www.usaid.gov/global-health/global-health-newsletter/equity-in-health>

¹⁴⁶ <https://www.undispatch.com/whats-next-for-usaid/>

¹⁴⁷ https://www.usaid.gov/sites/default/files/documents/1864/healthymarkets_primer_updated_2019.pdf

- c) Balance supplier and buyer risks – Transferring financial risks to donors/purchasers to encourage existing and new suppliers to operate more actively in the market.¹⁴⁸

Outputs in market shaping:

USAID’s Healthy Markets for Global Health: A Market Shaping Primer provides an outline to market shaping and toolkit.

Scale Up: USAID have an ‘Introduction and Scale Guide’ and ‘Pathways to Scale guide’ which provide models for scaling up and toolkits to do so.

11.4 Foreign, Commonwealth and Development Office (FCDO)

11.4.1 Organisational mission/strategic aims/goals/objectives

Foreign, Commonwealth and Development Office (FCDO) is a UK ministerial department, created in September 2020 when the Department for International Development (DFID) and the Foreign and Commonwealth Office (FCO) were merged. FCDO now combines UK Aid and Diplomacy in one department, aiming to ‘promote the interests of British citizens, safeguard the UK’s security, defend our values, reduce poverty and tackle global challenges with our international partners’.¹⁴⁹

11.4.2 Comparative Advantage (in Global Health)

- Strategic input into development of WHO policies.
- Technical expertise and assistance.¹⁵⁰
- Source of funding for activities.
- Link to/networks with governments and MoHs in developing countries.

11.4.3 Areas of Comparative Advantage

- Number of non-health areas. In health: women and girls; gender inequality including sexual and reproductive health and rights.¹⁵¹
- Aims to have a ‘development’ thinking and approaches incorporated into technical areas.

11.4.4 Scope of investment areas

The investment scope of FCDO includes development, including governance, economic infrastructure and services and health. Health accounted for 13.9% of UK bilateral overseas development assistance in 2019 (1.43 billion).¹⁵² The scope of FCDO includes health and the three diseases HIV/TB/malaria and includes a wide range of other interventions, including climate investments in adaptation and resilience, and gender-

¹⁴⁸ https://www.usaid.gov/sites/default/files/documents/1864/healthymarkets_primer_updated_2019.pdf

¹⁴⁹ <https://www.gov.uk/government/organisations/foreign-commonwealth-development-office#:~:text=We%20promote%20the%20interests%20of,12%20agencies%20and%20public%20bodies.>

¹⁵⁰ https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/67870/ev651.pdf

¹⁵¹ <https://publications.parliament.uk/pa/cm201617/cmselect/cmintdev/103/10308.htm#footnote-048-backlink>

¹⁵² https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/927135/Statistics_on_International_Development_Final_UK_Aid_Spend_2019.pdf p. 5.

based interventions. FCDO also invests in other multilaterals, including Unitaid, Gavi and the Global Fund, delivering health outcomes through this funding.

11.4.5 Average/approximate size and length of grants

The size of grants ranges from small side-interventions of around £1000+ such as admin costs of Prosperity Fund Low Carbon Energy Programme in Southeast Asia (MREL)¹⁵³ to larger-scale long-term investments reaching to around £4 billion, such as the European Development Fund.¹⁵⁴ Some grants last two years, others – such as the European Development Fund – have already been running over a decade and are projected to run years in the future, too.

11.4.6 Typology of funding recipients and target beneficiaries

There are many different recipient types. Countries, programmes and multilaterals are all funded. FCDO invest in at-risk or fragile countries, seen in its top three funded countries in 2019 including Pakistan and Afghanistan.

- Target beneficiaries – the most vulnerable and marginalised populations, in particular girls and women.¹⁵⁵

11.4.7 Geographic focus

- In 2019, Africa received the most bilateral overseas development assistance from the UK, at £2.99 billion. This was closely followed by Asia at £2.47 billion, and the Americas, Europe and the Pacific received significantly less at £0.24, £0.19 and £0.02 billion respectively.
- The top countries were Pakistan (£305 million), Ethiopia (£300 million) and Afghanistan (£292 million).

11.4.8 Engagement with civil society

- ICAI 2019 review rated DFID’s engagement with CSO’s as Amber/Red, with the headline that DFID values CSOs ‘but its funding and partnership practices do not fully support the long-term health of the civil society sector’, citing weak management practices and insufficient attention to sustainability of results.¹⁵⁶ DFID accepted the recommendations in 2019.¹⁵⁷

11.4.9 Approach to measuring impact

Business cases, logframes and annual reports all measure programmes’ impact and intended impact. Indicators are unique to projects, the FCDO/Unitaid indicators include:

Impact and outcome	Indicators
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¹⁵³ <https://devtracker.fcdo.gov.uk/projects/GB-GOV-3-PF-SEN-913002>

¹⁵⁴ <https://devtracker.fcdo.gov.uk/projects/GB-1-200236>

¹⁵⁵ https://www.ukaidirect.org/wp-content/uploads/2016/10/Value-for-money-guidance_UK-Aid-Direct_August-2019-1.pdf p.7.

¹⁵⁶ <https://icai.independent.gov.uk/html-version/csos/>

¹⁵⁷ https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/804821/civil-society-review.pdf

<p>Impact:</p> <p>Reduced transmission and mortality from HIV, tuberculosis, and malaria by a more effective global health response</p>	<p>Additional number of lives saved (cumulative); Financial savings and health system efficiencies (cumulative); Average rate of return of Unitaid investments</p>
<p>Outcome:</p> <p>Increased equitable access to better health products to prevent, treat and diagnose HIV, tuberculosis, and malaria</p>	<p>Percentage of Unitaid-supported products with complete product development activities; Percentage of critical access barriers overcome; Proportion of project countries with scale-up funding secured at grant closure; Additional number of people who benefit from a Unitaid-supported product (cumulative)</p>

11.4.10 Approach to equity and measurement of equity

- Equity is often talked about in terms of Value for Money, which is extremely important to FCDO, being UK taxpayer money under a high level of scrutiny.
- Equity added as a measure of VfM in 2018; one of the ‘4 Es’ (Economy, Efficiency, Effectiveness, Equity). Renewed focus on the target beneficiaries of vulnerable and marginalised populations, including women and girls. Also focus on demonstrating a disability inclusive approach.¹⁵⁸

11.4.11 Board composition

FCDO Management Board oversees performance and manages risk. It is made up of 19 members including communications, finance and strategy representatives. It also includes representatives for:

- MENA, Afghanistan and Pakistan
- Africa
- Americas
- Indo-Pacific
- ‘Overseas Network Representative’ (UK Ambassador to Zimbabwe)

11.4.12 Future investment/strategic plans as relevant

- The UK Aid budget was cut from 0.7% of national income to 0.5% in November 2020. Investments are now constrained by a significantly smaller budget, which has already had impacts in the health sector, with an 83% cut to UNAIDS funding from £15 million to £2.5 million.¹⁵⁹
- Future investments will be reduced by the cuts to the aid budget, and potentially other contextual factors, e.g. Brexit.

11.4.13 Other aspects on their role/penetration of the overall market shaping landscape

¹⁵⁸ https://www.ukaidirect.org/wp-content/uploads/2016/10/Value-for-money-guidance_UK-Aid-Direct_August-2019-1.pdf

¹⁵⁹ <https://www.devex.com/news/uk-cuts-funding-for-unaid-by-83-99797>

- FCDO are keen to invest in market shaping through funding organisations such as Unitaid. The Unitaid budget currently stands around £800 million over a 19-year commitment period (2007–26), with over £500 million already disbursed.¹⁶⁰
- FCDO aim to mobilise investment into developing countries through catalytic investments with demonstration effects, so Unitaid fits within their mandate. FCDO also hope to mobilise the private sector.¹⁶¹

11.5 Bill & Melinda Gates Foundation

11.5.1 Organisational mission/strategic aims/goals/objectives

- To catalyse innovation for the discovery and translation of transformative solutions to global health and development inequity.¹⁶²
- Mission is to create a world where every person can live a healthy, productive life.¹⁶³
- A non-profit organisation fighting poverty, disease and inequity around the world.
- Focused on using grant-making and advocacy to help solve complex, entrenched problems that affect billions of people, including the AIDS and malaria epidemics, extreme poverty, and the poor state of American high schools.¹⁶⁴
- Philanthropy bridging the gap between public and private sector.¹⁶⁵

11.5.2 Comparative advantage

Discovery & Translational Sciences – the ability to invest in high-risk initiatives with potential for truly disruptive change.¹⁶⁶

11.5.3 Scope of investment areas (diseases and other market shaping influencing areas)¹⁶⁷

Malaria (16%)

HIV (13%)

Maternal, Newborn and Child Health Discovery and Tools (10%)

TB and vaccine development (9%)

Neglected tropical diseases, Pneumonia, Discovery and Translational Sciences (7%)

Enteric and Diarrhoeal diseases, Innovative Technology Solutions (6%)

Special Initiatives (5%)

Integrated Development (4%)

Life Sciences Partnership (1%)

¹⁶⁰ <https://devtracker.fcdo.gov.uk/projects/GB-1-111074>

¹⁶¹ <https://www.gov.uk/government/news/fcdo-competition-launched-to-mobile-investment-in-emerging-and-developing-countries>

¹⁶² <https://www.gatesfoundation.org/our-work/programs/global-health/discovery-and-translational-sciences>

¹⁶³ <https://www.gatesfoundation.org/about>

¹⁶⁴ <https://www.gatesfoundation.org/about/financials/investment-policy>

¹⁶⁵ <https://www.gatesfoundation.org/about/our-role>

¹⁶⁶ <https://www.gatesfoundation.org/our-work/programs/global-health/discovery-and-translational-sciences>

¹⁶⁷ <https://www.gatesfoundation.org/about/financials/annual-reports/annual-report-2019>

11.5.4 Average/approximate size and length of grants

As of 19 December 2020:¹⁶⁸

Global health as a funding area – USD \$1,475,000¹⁶⁹

Number of grants – 1869

Direct grantee support amount – USD \$5.1 billion

Number of grantees – 1190

Length of grants – Approximately two years

Size of grants – USD \$11,50,000 (average)

11.5.5 Geographic focus (explicitly defined or apparent through investment scope)¹⁷⁰

- Africa – improves health and nutrition; gender equality; disease prevention, treatment, and research; water, sanitation, and hygiene; agriculture; and financial services for the poor. Burkina Faso, Nigeria, Ethiopia, Kenya, South Africa.¹⁷¹
- China – addresses domestic health challenges, adaptation of Chinese expertise and technologies in the areas of agricultural development and infectious disease control in low-income countries.¹⁷²
- India – works in collaboration with the government, from health care and sanitation to gender equality, agricultural development, and financial empowerment of the most vulnerable populations.¹⁷³
- Japan – solutions to health and development challenges (vaccine delivery, infectious disease containment and response, water and sanitation, and nutrition).¹⁷⁴
- Middle East – increases access to vaccines, boost agricultural production, improve sanitation, and respond to emergency situations.¹⁷⁵
- North America (USA, Canada) – research, innovation, policy advocacy, and programme investment in education, economic mobility, global health, and development.¹⁷⁶
- Europe – sustaining European donor support, building relationship with programme partners.¹⁷⁷

¹⁶⁸ <https://www.gatesfoundation.org/>

¹⁶⁹ <https://www.gatesfoundation.org/about/financials/annual-reports/annual-report-2019>

¹⁷⁰ <https://www.gatesfoundation.org/our-work#jump-nav-anchor0>

¹⁷¹ <https://www.gatesfoundation.org/our-work/places/africa>

¹⁷² <https://www.gatesfoundation.org/our-work/places/china>

<https://www.gatesfoundation.org/our-work/places/india>

¹⁷⁴ (<https://www.gatesfoundation.org/our-work/places/japan>

¹⁷⁵ <https://www.gatesfoundation.org/our-work/places/middle-east>

¹⁷⁶ <https://www.gatesfoundation.org/our-work/places/north-america>

¹⁷⁷ <https://www.gatesfoundation.org/our-work/places/europe>

11.5.6 Approach to measuring impact

Measures the most critical metrics of progress that support continued learning, adjustment and alignment. Nature and frequency of measurement depends on the type of work. For example, scientific research projects may be measured differently than efforts to expand vaccine coverage.

11.5.7 Approach to equity and measurement of equity

Equity as one of their main targets: ‘We are a non-profit organization fighting poverty, disease, and inequity around the world’.

Gender equality toolbox.¹⁷⁸

11.5.8 Board composition

BMGF controlled by three trustees (Bill Gates, Melinda Gates, Warren Buffett).¹⁷⁹

Executive leadership team:¹⁸⁰

- 16 people
- 2 co-chairs
- 3 trustees

Presidents of the different strands (Global Development, Global Policy & Advocacy, US Program, Global Health, Global Growth & Opportunity, Gender Equality, Vaccine Development and Surveillance, EDD).

Chief Officers (Communications, HR, Operating, Strategy, Financial, Executive).

11.6 Children’s Investment Fund Foundation

11.6.1 Organisational mission/strategic aims/goals/objectives

- Seeks urgent and lasting change for children
- Self-reportedly the world’s largest philanthropy that focuses specifically on improving children’s lives.¹⁸¹
- Returns on smart investments in areas such as children’s early development and adolescent girls are especially high, aim to play a catalytic role as a funder and influencer to deliver urgent and lasting change at scale.
- Original mission in setting up CIFF was to improve the lives of children in developing countries who live in poverty.

11.6.2 Comparative advantage

Focus on children’s health (also their key marketing/positioning effort).

11.6.3 Scope of investment areas (diseases and other market shaping influencing areas)

¹⁷⁸ <https://www.gatesgenderequalitytoolbox.org/>

¹⁷⁹ Though Buffett announced his resignation in June 2021.

¹⁸⁰ <https://www.gatesfoundation.org/about/leadership?division=Executive%20Leadership>

¹⁸¹ <https://ciff.org/about-us/who-we-are/>

Areas of work include maternal and child health, adolescent sexual health.

Within Child health and development, CIFF is active in paediatric and perinatal health, specifically:

NEST – newborn technologies – To make available low-cost technologies to save newborn lives, dramatically reducing preventable deaths among premature and sick newborns in sub-Saharan Africa.¹⁸²

Scaling of Safe Childbirth Checklist – To support two states (Rajasthan and Andhra Pradesh) to strengthen quality improvement of facilities through the Safe Childbirth Checklist.¹⁸³

The Digital Dividend: A Smart Contract for Equitable Healthcare Outcomes – To develop and demonstrate the effectiveness and reliability of a mobile health product, designed to improve services for pregnant women at private and public health facilities in Tanzania and Kenya.¹⁸⁴

India Safe care saving lives – To improve the quality of care in health facilities in India, and save maternal and neonatal lives by working through the government-sponsored health insurance in Andhra Pradesh and Telangana states.¹⁸⁵

Final mile to elimination of mother to child transmission of HIV¹⁸⁶ – in Zimbabwe.

11.6.4 Average/approximate size and length of grants

- 2019 report – total charitable grant payment in maternal and child health and adolescent health – USD \$61 million.¹⁸⁷
- Average size of grants – USD \$80,00,000.
- Average length of grants – 3 to 5 years.
- Overview of grant portfolio.¹⁸⁸

11.6.5 Typology of funding recipients and target beneficiaries

- International NGOs
- Local NGOs

11.6.6 Geographic focus (explicitly defined or apparent through investment scope)

Main geographic areas of focus:

- India – Child Health and Development, Girl Capital, Child Protection, Climate.
- Africa – 29 African countries, with our largest investments in Kenya, Ethiopia, Tanzania, Nigeria, Malawi, Zimbabwe, Ghana, Uganda, South

¹⁸² <https://ciff.org/grant-portfolio/nest-newborn-technologies/>

¹⁸³ <https://ciff.org/grant-portfolio/the-scaling-of-the-safe-childbirth-checklist/>

¹⁸⁴ <https://ciff.org/grant-portfolio/the-digital-dividend-a-smart-contract-for-equitable-healthcare-outcomes/>

¹⁸⁵ <https://ciff.org/grant-portfolio/india-safe-care-saving-lives/>

¹⁸⁶ <https://ciff.org/grant-portfolio/final-mile-to-emtct/>

¹⁸⁷ <http://ciff.org/wp-content/uploads/2020/07/Annual-Report-2019-CIFF.pdf>

¹⁸⁸ <https://ciff.org/grant-portfolio/>

Africa, Sierra Leone, Burkina Faso and Mozambique. Resilient Communities (Child Health and Development, NTDs, WASH), Girl Capital.¹⁸⁹

- China – Support an accelerated transition towards sustainable development and a low-carbon economy.
- Europe – Climate.

Other geographic focus: Southeast Asia, esp. Vietnam, Indonesia, Philippines – Climate & energy decarbonisation, Mexico – Climate, Brazil – protection of the Amazon Rainforest.

11.6.7 Approach to measuring impact

Using a rating system.¹⁹⁰

We have a team of dedicated Evidence, Measurement and Evaluation (EME) specialists who provide internal expertise and oversee a portfolio of third party evaluations to:¹⁹¹

- Assess evidence to inform decision making and generate fresh credible evidence where needed.
- Ensure robust monitoring systems to support programme investments and generate data that can be used for decision making, including course correction with partners where necessary.
- Evaluate impact of our investments, both for learning and accountability purposes.
- Improve and disseminate knowledge to support greater impact.
- Evidence-based approach and ‘Cascade to Impact’ tool.¹⁹²

11.6.8 Board composition

Five trustees, including two founding members.

11.6.9 Future investment/strategic plans as relevant

Africa Strategy for 2020–25: It will focus on harnessing African expertise and growth while ensuring advancements can be organically sustained across three primary countries – Ethiopia, Kenya, and Nigeria.¹⁹³

11.6.10 Summary of (internally identified?) strengths, opportunities, gaps, challenges, threats

Mentioned on website about what did not work – a project in Bihar on preventing and treating diarrhoea in infants in Bihar, India. Project did not consider the system changes that would be required for procurement and was thus unsuccessful.¹⁹⁴

¹⁸⁹ <https://ciff.org/regions/africa/>

¹⁹⁰ <https://ciff.org/impact/zimbabwe-growing-without-hiv/>

¹⁹¹ <https://ciff.org/about-us/data-and-evidence/>

¹⁹² <https://ciff.org/about-us/data-and-evidence/>

¹⁹³ <https://ciff.org/regions/africa/>

¹⁹⁴ <https://ciff.org/impact/what-went-wrong/>

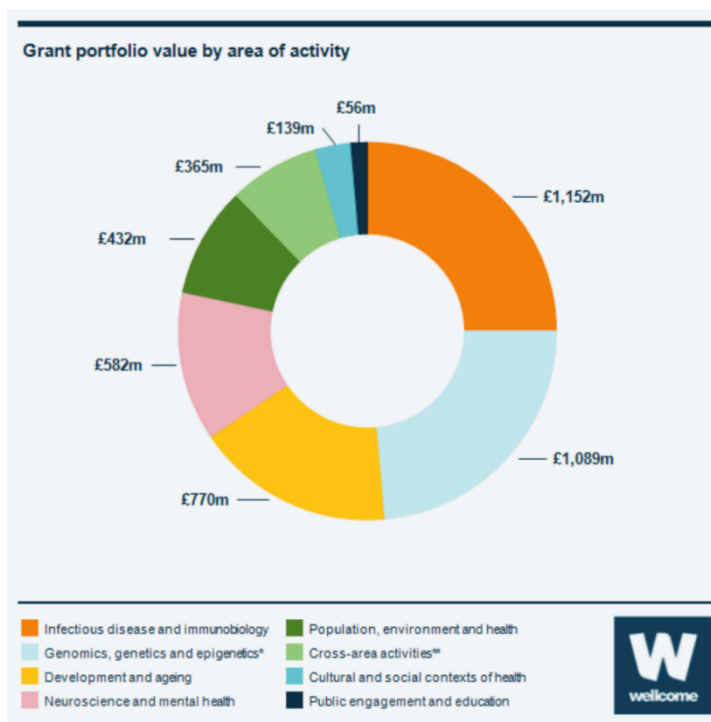
11.7 Wellcome Trust

11.7.1 Organisational mission/strategic aims/goals/objectives

- Support to discovery research into life, health and well-being, and taking on three worldwide health challenges: mental health, infectious disease and climate and health.¹⁹⁵
- Improvement in health for everyone by funding research, leading policy, and advocacy campaigns, and building global partnerships.
- Supports science to solve the urgent health challenges facing everyone.¹⁹⁶

11.7.2 Scope of investment areas (diseases and other market shaping influencing areas)

- Mental health: Working with people who have lived experience of mental health issues to improve research, understanding and treatment of mental health.
- Infectious disease: Working with communities affected by escalating infectious diseases to bring those diseases under control and stop epidemics.
- Including a strong focus on AMR.¹⁹⁷
- Climate and health: Working with the communities most affected by climate change to explore the harmful effects of global heating on health, and to use research to develop ways of protecting people’s health.



¹⁹⁵ <https://wellcome.org/>

¹⁹⁶ <https://wellcome.org/who-we-are/strategy>

¹⁹⁷ <https://wellcome.org/what-we-do/our-work/drug-resistant-infections>

704 grants worth a total of £1,015 million were awarded in 2019/20. 369 of these grants, totalling £306 million, were awarded on our standard response-mode schemes.

11.7.4 Typology of funding recipients and target beneficiaries

- 488 Organisations funded in 91 countries, including 242 UK organisations (76 of which are higher education institutions).¹⁹⁸
- Our funding is concentrated within a few organisations. 75% of our grant portfolio is held by 20 organisations, and 38% is held by the University of Oxford, the Sanger Institute, the University of Cambridge and University College London.¹⁹⁹

Success rates over the past four years are similar by gender (13% for men, 12.7% for women) but differ by ethnicity (8% for UK-based Black, Asian and Minority Ethnic applicants, 14% for UK-based White applicants).

11.7.5 Geographic focus (explicitly defined or apparent through investment scope)

- LMICs
- Africa (including but not limited to Kenya, West Africa, South Africa)
- Asia (including but not limited to Thailand, Laos, Vietnam, India, Malawi, India)

11.7.6 Engagement with civil society

The public engagement we support:²⁰⁰

- Empowers people – helping them access, use, respond to, and create health research and innovation.
- Creates people-centred health research – improving our understanding of people’s experiences and how we use that knowledge to improve Wellcome’s work.
- Helps society value our work – bridging the gaps between Wellcome and society so that research and innovation are trustworthy and valued by people, whether we work with them.

Bringing science and health research closer to the society in which it operates:²⁰¹

- Develops partnerships that support a wide range of people to explore, create and debate science and health research.
- Develops the evidence base for public engagement, and support networks and organisations to measure outcomes and share expertise.
- Develop leaders in public engagement, from a wide range of perspectives and backgrounds.

¹⁹⁸ https://cms.wellcome.org/sites/default/files/2021-03/Report_Wellcome_Grant_Funding_data_2019-20.pdf

¹⁹⁹ <https://wellcome.org/reports/grant-funding-data-2019-2020>

²⁰⁰ <https://wellcome.org/what-we-do/our-work/public-engagement>

²⁰¹ <https://wellcome.org/what-we-do/our-work/public-engagement>

- Encourage a diverse range of organisations to integrate science and research in their work.
- Community Consultation emphasised prioritisation to be given to research involving people in LMICs.²⁰²

11.7.7 Approach to measuring impact

- Belief that in order to achieve greater impact on human health, there is a need to focus on a smaller number of activities – something that we refer to as Flagships. Do not expect to have more than 20 Flagships over the next five years (2017–22).²⁰³
- Reportedly care about impact in the immediate term and expect that by 2022 will have supported interventions that improve the lives of at least 1 million people per annum. In addition, will develop a portfolio of activities that deliver impact in five years – but with the potential to deliver longer and even greater impact on science and in health over the following 10–20+ years.

11.7.8 Approach to equity and measurement of equity

- In the past, Wellcome has played an unintended part in sustaining barriers to inclusive research. Now reportedly using our influence to remove those barriers.²⁰⁴
- Wellcome cannot achieve its vision to support science to solve urgent health challenges facing everyone unless structural inequalities are corrected.
- Diversity, equity and inclusion strategy.²⁰⁵
- Over the next 10 years, our goals are to: become an inclusive employer (Wellcome staff will be representative of the places we work, able to be themselves, and supported to be their best); and become an inclusive funder (the hope is that people funded by Wellcome will be more representative of the global population, able to be themselves, and supported to be their best).
- By 2023: other aims:
 - To have enabled the collection of data on key diversity characteristics of the people we fund through our online grants system.²⁰⁶
 - To have supported the chairs of funding committees to address diversity, equity, and inclusion challenges in their meetings, by providing training in inclusive decision making and bias.
- Piloted new and creative approaches to address differential grant-funding rates for under-represented groups (racially minoritised people, disabled people, women).

²⁰² <https://wellcome.org/grant-funding/guidance/research-involving-people-low-and-middle-income-countries>

²⁰³ <https://wellcome.org/sites/default/files/innovation-for-impact.pdf>

²⁰⁴ <https://wellcome.org/what-we-do/our-work/diversity-and-inclusion>

²⁰⁵ <https://wellcome.org/what-we-do/our-work/diversity-and-inclusion/strategy>

²⁰⁶ <https://wellcome.org/what-we-do/our-work/diversity-and-inclusion/strategy>

- Developed equitable pre-application advice and support for funding applicants and grantholders.
- Embedded inclusive research culture principles into Wellcome's funding decision framework.
- Support equal health outcomes: all Wellcome-funded research will be inclusive in both design and practice, to help drive better science and more equitable health solutions.

11.7.9 Board composition

Board of Governors: 11 board members, including the Chair.²⁰⁷

11.7.10 Future investment/strategic plans as relevant

- See the 7.10 equity approach over the next 10 years
- Diversity, equity and inclusion strategy²⁰⁸
- Over the next 10 years, our goals are to:
 - become an inclusive employer: Wellcome staff will be representative of the places we work, able to be themselves, and supported to be their best
 - become an inclusive funder: people funded by Wellcome will be more representative of the global population, able to be themselves, and supported to be their best
 - support equal health outcomes: all Wellcome-funded research will be inclusive in both design and practice, to help drive better science and more equitable health solutions.

Infectious disease aims for the next 30 years²⁰⁹ – To determine how best to bring diseases under control and stop epidemics, to support research tackling infectious diseases that are already on the rise and those with the potential to become future epidemics or evade current therapies. To focus on the most affected communities, recognising that the overall burden of infectious diseases does not pose an equal threat to everyone's health.

Mental Health aim for the next 30 years²¹⁰ – Over time, we will expand focus beyond interventions for youth anxiety and depression, while continuing to:

- create a more diverse and inclusive mental health science community, underpinned by common metrics and a shared focus on finding new solutions.
- harness the power of population data in a way that balances the needs for privacy of those sharing their data with the needs of open science.
- help form new narratives and dedicate new funding to support the development of more personalised and effective interventions.

²⁰⁷ <https://wellcome.org/who-we-are/governance/board-governors>

²⁰⁸ <https://wellcome.org/what-we-do/our-work/diversity-and-inclusion/strategy>

²⁰⁹ <https://wellcome.org/what-we-do/infectious-disease>

²¹⁰ <https://wellcome.org/news/mental-health-wellcome-looking-forward>

11.7.11 Other aspects on their role/penetration of the overall market shaping landscape

Involved in the Alliance for Accelerating Excellence in Science in Africa with BMGF, DFID, NEPAD and AAS, to support African-led initiatives in key areas of science, particularly health research relevant to Africa.²¹¹

11.8 Global Financing Facility

11.8.1 Organisational mission/strategic aims/goals/objectives

The Global Financing Facility for Women, Children and Adolescents (GFF) is a country-led global partnership committed to ensuring all women, children and adolescents can survive and thrive.

- The GFF's goal is to end preventable maternal, newborn, child, and adolescent deaths and to improve the health and quality of life of women, children, and adolescents. The GFF is a new model for development financing for the SDGs era that helps governments to prioritise critical health and nutrition areas and brings together multiple financing sources in a synergistic, country-led way to close the funding gap for RMNCAH-N by 2030. Currently 67 high-burden, low- and lower-middle-income countries are eligible for GFF support.
- Launched in July 2015, the GFF supports 36 low and lower-middle-income countries with catalytic financing and technical assistance to develop and implement prioritised national health plans to scale up access to affordable, quality care for women, children and adolescents. The GFF also works with countries to maximise the use of domestic financing and external support for better, more sustainable health results. The GFF is squarely focused on prioritising and scaling up evidence-driven investments to improve reproductive, maternal, newborn, child and adolescent health and nutrition through targeted strengthening of primary health care systems – to save lives and as a critical first step toward accelerating progress on universal health coverage (UHC) and the Sustainable Development Goals (SDGs).²¹²
- The GFF has pioneered a shift from traditional development approaches to a more sustainable way forward where governments lead and bring global partners together to support a prioritised, costed national plan.
- Prioritisation through 'investment cases'²¹³
 - The investment case defines a prioritised set of high-impact interventions required to achieve results for women, children, and adolescent health and nutrition and describes the changes that a country wants regarding reproductive, maternal, newborn, child, and adolescent health and nutrition. The investment case is an evidence-based tool tailored to address what is most important to achieve results for women, children, and adolescent in each national context.

²¹¹ <https://wellcome.org/what-we-do/our-work/programmes-and-initiatives-africa-and-asia>

²¹² <https://www.globalfinancingfacility.org/introduction>

²¹³

<https://www.globalfinancingfacility.org/faq#:~:text=The%20GFF%20is%20housed%20at,Foundation%20and%20MSD%20for%20M others>

- It focuses on ‘best-buys’: the evidence-based, high-impact interventions required to reduce morbidity and mortality in an equitable manner while progressively realising the rights and entitlements of women, children, and adolescents. Investment cases identify not only priority interventions to achieve agreed results, but also the main bottlenecks that need to be addressed to deliver these interventions.
- The objective of the investment case process is to shape how resources are directed: to ensure that available financing is targeted at a set of priority investments that will benefit the women, children, and adolescents most in need and to accelerate progress toward universal health coverage.

11.8.2 Scope of investment areas (diseases and other market shaping influencing areas)

- The GFF is squarely focused on prioritising and scaling up evidence-driven investments to improve reproductive, maternal, newborn, child and adolescent health and nutrition through targeted strengthening of primary health care systems.²¹⁴
- COVID 19.

11.8.3 Typology of funding recipients and target beneficiaries

- Country-level partnership: Supporting governments to bring partners in a country-led investment case.
- The GFF partnership is a country-led partnership that brings together an array of stakeholders, including civil society organisations, the private sector, multilateral institutions, and foundations.
- The GFF Trust Fund is not intended to fill the financing gap on its own but to help the government to crowd in additional resources for the investment case from the broader set of partners that are part of the facility and to ensure that the resources available are aligned and work together.²¹⁵

11.8.4 Geographic focus (explicitly defined or apparent through investment scope)

The GFF currently supports 36 LMICs in Africa, Asia, and Latin America with the highest maternal, newborn and child mortality burdens and large gaps in financing to address these challenges.²¹⁶

A total of 67 countries are currently eligible to receive GFF support.

Current partner countries:

- Africa: Afghanistan, Burkina Faso, Cameroon, Central African Republic, Chad, Côte d’Ivoire, Democratic Republic of Congo, Ethiopia, Ghana, Guatemala, Guinea, Kenya, Liberia, Madagascar, Malawi, Mali, Mauritania, Mozambique, Niger, Nigeria, Rwanda

²¹⁴ <https://www.globalfinancingfacility.org/introduction>

²¹⁵

<https://www.globalfinancingfacility.org/faq#:~:text=The%20GFF%20is%20housed%20at,Foundation%20and%20MSD%20for%20M others>

²¹⁶ <https://www.globalfinancingfacility.org/where-we-work>

- Asia: Bangladesh, Cambodia, Indonesia, Myanmar, Pakistan
- Caribbean: Haiti

11.8.5 Engagement with civil society

- Increasingly, more GFF partner countries are including social accountability and advocacy activities in their investment case, with CSOs leading implementation. CSOs have also been instrumental in delivering last-mile services and supporting community-based primary health care.²¹⁷
- The GFF’s governing body, the Investors Group, also includes CSO representation through two principal and two alternate members, along with a newly designated youth representative seat and an alternate.
- CSOs have successfully engaged in the GFF process and contributed to results:
 - In Cote d’Ivoire, the health CSO coalition FENOSCI supported dialogue on health financing reforms and contributed to the development of the investment case by leading capacity building activities and coordinating community feedback to develop a unified campaign for increased resources for health. This advocacy has contributed to a 16% increase in the country’s 2020 health budget.
 - In Kenya, the CSO coalition has developed a scorecard for assessing investment case design and implementation. In addition, the coalition has supported a campaign that helped establish a functional multi-stakeholder country platform.
 - In Nigeria, CSOs in Bauchi State now participate in the pre-qualification and assessment of health facilities and are collaborating with partners to shape the development of a basic minimum package of health services.
 - In Senegal, the local CSO coalition supports the Ministry of Health in monitoring investment case implementation in selected priority regions. CSO advocacy to increase domestic resources for health has led to local mayors committing more budget resources toward family planning, and to religious leaders calling for a percentage of mosque revenues to fund health programmes for women and children.

11.8.6 Approach to measuring impact

- Strong focus on results monitoring
- GFF core impact indicators²¹⁸
- Maternal mortality ratio
- GFF approach to country-focused process monitoring²¹⁹
- How well developed, prioritised and funded the investment case is, how strong the results framework is, whether a multisectoral country platform has been established that focuses on continuous monitoring of implementation, how

²¹⁷ <https://www.globalfinancingfacility.org/our-partnership/civil-society>

²¹⁸ <https://www.globalfinancingfacility.org/results-monitoring>

²¹⁹ <https://www.globalfinancingfacility.org/results-monitoring>

strong is the leadership of the country-led process and how inclusive, with representation from civil society, the private sector, and other stakeholders.

- Process monitoring also includes tracking the health financing (domestic resource budgets and expenditures), IDA and IBRD approvals and disbursements, (virtual)-pooled funding with development partners, and private sector investment.
- The GFF focuses data on the following areas:
 - Guiding the planning, coordination, and implementation of the RMNCAH-N response (IC).
 - Improve the financial sustainability of the investments (specifically DRM) and progress towards UHC.
 - Assessing the effectiveness of RMNCAH-N programme and identifying areas for improvement during implementation.
 - Real time course correction
 - Link to implementation research
 - Ensuring accountability to those affected by RMNCAH-N outcomes as well as to those providing resources (governments at all levels, CSO, donors, other stakeholders).²²⁰

11.8.7 Approach to equity and measurement of equity

- The GFF process addresses equity in several ways. Investment cases are built on rigorous analyses of data, typically including disaggregation by factors such as place of residence, socio-economic status, race/ethnicity, gender/sex, and age.²²¹
- In countries such as Cameroon, the Democratic Republic of Congo, Kenya, Liberia, and Mozambique, this focus on equity led to the prioritisation of the regions or populations that have the worst health and nutrition indicators.
- Another important element of the GFF approach to equity is improving financial risk protection. The approach depends on the specific country contexts and includes mobilising additional domestic government resources for health, so that financial barriers (such as user fees) can be reduced, and developing insurance schemes that cover the costs of key services (or at least significantly reduce the payment for them from users). The GFF uses equitable impact-sensitive tools such as EQUIST for this purpose.
- Another dimension of the approach to equity is the GFF's work on strengthening information systems, such as civil registration and vital statistics systems. These systems are critical for producing disaggregated data; for tracking progress; and for ensuring that all women, children, and adolescents are counted, including by ensuring that all births are registered (which in turn may unlock a host of benefits that are tied to a birth certificate).

²²⁰ https://www.globalfinancingfacility.org/sites/gff_new/files/documents/GFF-Results-Monitoring-Framework.pdf

²²¹ <https://www.globalfinancingfacility.org/how-does-gff-process-promote-equity>

11.8.8 Board composition

- Trust Fund Committee: Chair, and representation from all Donors through direct representation or constituency representation. Donors with no representation are from the for-profit private sector.²²²
- Investors Group Members: Chair, Country Representatives and alternates (Ethiopia, Kenya, Liberia, Senegal), Financiers and alternates (Canada, Japan, Norway, UK, USA), International Organisations and alternates (Gavi, Global Fund), Private sector and alternates (Merck for Mothers, Grand Challenges Canada, Philips), Private Foundations (BMGF), Civil Society (African Health Budget Network, Plan International, Jhpiego, Population Council), Multilateral Organisations and alternates (Office of the UN Secretary General, PMNCH, UNICEF, UNFPA, World Bank, WHO).²²³

11.8.9 Other aspects on their role/penetration of the overall market shaping landscape

The GFF Investors Group — including governments, CSOs, the private sector, UN agencies, Gavi, and the Global Fund — comes together biannually at the global level to discuss progress in financing and implementation at country level and to strengthen collaboration across the partnership. At country level the GFF multi-stakeholder partnership is led by the government.

²²² https://www.globalfinancingfacility.org/sites/gff_new/files/documents/GFF-Trust-Fund-Governance-Document-adopted-sept19.pdf

²²³ <https://www.globalfinancingfacility.org/governance>

12 Evidence Table

The following table summarises the breadth and strength of evidence that supports each of the findings from the review. In addition to those sources listed, the team has used drawn on its extensive experience to complement the analysis.

Finding	KIs	Documents	Grantee survey	Case studies	Comparative analysis	Conclusion
RQ1 – Relevance of Afls						
1.1: The continued commitment to HIV, TB and malaria and a limited expansion to other disease areas is considered appropriate, though could be more clearly defined.	Development Partner, NGO/CSO, Grantee, Private sector, Secretariat	Also see data from RQ12, UNITAID_PSC_2021_Strategy Workshop_Strategy development Phase A, 2018_Dec_Afl P. vivax	Q4	HIV, TB, Malaria, Fever	N/A	HIGH
1.2: Unitaid is recognised by the international community as being responsive to the needs of the targeted beneficiaries, but more can be done to consult directly with LMIC governments, civil society and affected communities to ensure alignment and eventual demand.	NGO/CSOs, Development Partners, Natl Government	Unitaid grants	NA	TB, Malaria	N/A	HIGH
1.3. There is recognition that Unitaid is taking a less disease-specific/product-focused (or 'vertical') approach than in the past, while some KIs think that Unitaid has not gone far enough in terms of pursuing more integrated/platform (or 'horizontal') innovations.	Grantees, PRC, NGO/CSO	MTR, UK annual review Unitaid - Nov 2019, 210217_EMT interview_Ali, UNITAID 2020 April Joint FACPSC Update on 20-22 Investment Plan; UNITAID_2019 October_Joint FACPSC_2_Investment plan 2019-2021; 2017_UNITAID_EB27_4_Grant portfolio update; UNITAID_PSC_2021_Strategy Workshop_Strategy development Phase A	NA	TB, Malaria, Fever	N/A	HIGH
1.4: Intellectual property, medicines and diagnostics were widely considered relevant and important tools, but some respondents perceived an inherent tension between the strategy's pillars of innovation and access.	NGOs/CSOs, Development Partners, Private Sector, Secretariat, Grantees	UNITAID_EB32_2019_10_Report of the Midterm Strategy Review, 2016_Dec_Update on IP approach and potential opportunities and 2021.02 - Appendix 1 - Terms of Reference (ToR)	Q4	TB, Fever	N/A	MEDIUM (HIGH for IP, medicines and diagnostics; low for innovation/access tension)

Finding	KIIs	Documents	Grantee survey	Case studies	Comparative analysis	Conclusion
1.5: With the benefit of hindsight, Unitaid missed some opportunities to 1) build technology and disease area platforms, 2) support cross-cutting tools and systems and 3) challenge IP. But without a clear process to systematically weigh one opportunity against another, it remains unclear whether these missed opportunities might have been better investments; this is covered in RQ2.	Grantees, Development Partners, NGOs/CSOs	HIV Disease Narrative, TB Disease Narrative, Malaria Disease Narrative; UNITAID_2019 October_Joint FACPSC_2_Investment plan 2019-2021; 2020 Portfolio Performance Report – FINAL; 2015_Nov_Strategic narrative for Malaria and Areas for Intervention	NA	HIV, TB, Malaria	N/A	MEDIUM
1.6: Unitaid took steps to examine the strategic rationale behind the selection of AfIs, although this is not consistently documented.	Secretariat, Development Partners	Grant Management Guidelines_final 17Oct2018	NA	Malaria, Fever	N/A	LOW
RQ2 – Prioritisation Process						
2.1: Absence of an approach to consider the inherent values and risks of a given intervention or portfolio makes it difficult to evaluate whether the interventions are the right ones.		2018_Dec_Afl P. vivax, Disease area narratives, Unitaid agreement BMGF Milestone Table - January 2019 – FINAL and 2021, UNITAID 2020 April Joint FACPSC Update on 20-22 Investment Plan Evans et al., Portfolio analysis and R&D decision making. Nature Reviews Drug Discovery (2009). Volume 8, 189–190. https://www.nice.org.uk/	NA	HIV, TB, Malaria, Fever	N/A	HIGH
2.2: Despite Unitaid’s considerable efforts to consult with a wide range of stakeholders, the development of AfIs is still perceived to be heavily reliant on key relationships among the Secretariat, the Board and key global partners.	Grantee, Secretariat, Country Government, Private Sector, Development Partner	UNITAID_PSC21_2019_3_Annex 4_Operating Model Performance; 2018_Dec_Afl Long-acting technologies; UNITAID 2020 April Joint FACPSC Update on 20-22 Investment Plan, UNITAID_EB32_2019_10_Report of the Midterm Strategy Review, TB Disease Narrative; methodology-for-developing-strategic-narratives	NA	Malaria, Fever	N/A	LOW (the perception among KIIs is high but the evidence is low)
2.3: Unitaid has demonstrated flexibility and an ability to course-correct, including shifting resources in and out of disease areas.	NGO/CSO, Secretariat, Development Partner, Grantee	https://unitaid.org/assets/Ensuring-access-to-the-Hepatitis-C-HCV-treatment-revolution-for-HCV-HIV-co-infected-patients-in-LMICs.pdf and https://unitaid.org/assets/Impact-story-paving-the-way-to-hepatitis-c-elimination.pdf ;	Q13, Q35	TB, Fever	N/A	MEDIUM

Finding	KIIs	Documents	Grantee survey	Case studies	Comparative analysis	Conclusion
RQ3 – Global Public Goods						
3.1: Unitaid has generated influential evidence for policy and practice.	CSO/NGO, Development Partners, Secretariat	https://path.azureedge.net/media/documents/NNPproject_brief_final.pdf and mentioned in UK annual review Unitaid - Nov 2017 19976237, Disease Narrative for Hepatitis C, 2017_UNITAID_EB27_4_Grant portfolio update	N/A	HIV, TB, Malaria	N/A	HIGH
3.2: Unitaid’s landscape/horizon-scanning work is considered useful and high-quality, but efforts to translate and disseminate them together with results from projects could be more deliberate.	Development Partner, NGO/CSO, Grantee, private sector, Secretariat	Grant Management Guidelines_final 17Oct2018; TB Disease Narrative; Malaria Disease Narrative	N/A	Malaria	N/A	MEDIUM
RQ4 – Complementarity						
4.1: Unitaid proactively collaborates within the Global Health space, though the lack of formal partnership engagement strategy or specific criteria or macro-level targets to guide strategic decision making on priority foci above the disease level may inhibit opportunity to explore more comprehensive complementarity with other actors in this space.	Development partners; donors; Board members; Secretariat	Unitaid Strategy; various global health partner strategies; Civil Society Engagement Plan (2016); Global Fund’s Framework on Private Sector Engagement; disease narratives; DFID review of Unitaid (2020); Minutes of Unitaid-BMGF meeting on milestones (2019); Grantee survey findings (2021)	Q9	HIV, TB, Malaria, Fever	Yes	HIGH
4.2: Ongoing collaboration across partnership groups still relies to some extent on personal networks rather than more formalised engagement processes and there are opportunities for deeper and broader collaborations across groups.	Development partners; donors; Board members; Secretariat; Civil society; private sector; grantees	Unitaid Strategy; Operating model review (2017); Report of the Midterm Strategy Review (2019); DFID review of Unitaid (2020); Unitaid WHO Enablers Review (2020)	N/A	HIV, TB, Malaria	Yes	HIGH
4.3: The scalability framework is a useful starting point, but more could be done in terms of collaborating with others to enable complementarity when setting the stage for scale-up. There also appears to a lack of clarity	Development partners; donors; Secretariat; Civil	Unitaid Strategy; Civil Society Engagement Plan (2016); Report of the Midterm Strategy Review (2019); Unitaid Scalability Framework: Guidance for Applicants and Grant Implementers (2021)	N/A	Malaria	No – but I think this comes into Effectiveness	HIGH

Finding	KIIs	Documents	Grantee survey	Case studies	Comparative analysis	Conclusion
both internally and externally over what is meant and required for ‘scalability’.	society; grantees					
RQ5 – Comparative Advantage						
5.1: There is broad consensus across stakeholders of Unitaid’s core comparative advantages, variously described as the ‘missing middle’, between research and development and delivery at scale.	Development partners; donors; Board members; Secretariat; Civil society; private sector; grantees	Unitaid Strategy; Grantee survey findings (2021)	Q49, Q50	HIV, Malaria	No	HIGH (owing largely to broad consensus across many KIIs)
5.2: Finding # 2: At the same time, Unitaid’s focus has become more blurred over time with some possible loss of identity.	Development partners; donors; Board members; Secretariat; Grantees	Unitaid Strategy; Unitaid Organigramme revised, March 2021	N/A	Not specifically	No	MEDIUM
RQ6 – Internal Coherence						
6.1: The portfolio as a whole is broad and deliberately spread across the elements of the market shaping value chain, though arguably focused on ‘good gap-filling’ rather than a strategically coherent investment at a macro level.	Development partners; donors; Board members	No	N/A	Fever	No	MEDIUM
6.2: There is relatively good coherence within AfIs/disease areas, with some variability, though there are calls for coherence to be boosted by more joined-up planning, implementation and evaluative efforts across projects and AfIs, as well as more effective cross-grantee working.	Development partners; donors; Board members	AfIs	N/A	HIV, TB, Malaria, Fever	Yes	MEDIUM
RQ7 – Visibility & Recognition						
7.1: There have been notable efforts to raise Unitaid’s profile in recent years, with the primary aim of expanding resource mobilisation opportunities.	Development partners; donors; Board	AfIs; Minutes on BMGF-Unitaid meeting on milestones (2019); Grantee survey findings (2021); DFID review of Unitaid, (2020)	Q51, Q53	No	No	MEDIUM

Finding	KIIs	Documents	Grantee survey	Case studies	Comparative analysis	Conclusion
	members; Grantees					
7.2: However, visibility and recognition continue to vary by disease area, and Unitaids 'added value' can also be hard to distil. The extent to which governments and affected communities in LMICs are aware of Unitaids is also unclear.	Development partners; donors; Board members; Secretariat; Civil society; grantees; LMIC	No	N/A	HIV , Malaria, Fever	No	MEDIUM
RQ8 – Operating Model						
8.1: The model has evolved to become more complex, and now has some inbuilt inefficiencies. While these appear to have improved over time, there remain concerns about the agility of the model – in particular in terms of the time it takes to get grants up and running. At the same time there are divergent views on whether it is important to speed up decision making in order to increase agility, with the risk that this comes at a cost of less consultation, inclusion and rigour.	Unitaid, Grantees DPs NGOs Private sector	MTR, portfolio reviews, review of operating model, FCDO annual review for Unitaids, MOPAN, Fleming Fund UK annual review	Q16, Q17	Fever		HIGH
8.2: The response to COVID-19 helped demonstrate that Unitaids can be more agile, through existing grant infrastructure, and the limited scope for agility within the existing model was further addressed through Unitaids Explore.	Grantees, DPs, Unitaid, NGOs	UNITAID/PSC24/2020/6 UNITAID/EB33/2019/4	Q39	Fever		HIGH/MEDIUM
8.3. Limited agility appears to be linked to governance structures, but there are divergent views about if and how these should be reformed.	DPs NGOs, grantees PS Unitaid	Unitaid/EB33/2019/8 UNITAID/PSC17/2017/3 UK AR 2017 Introduction to Unitaids' briefing from the Secretariat	N/A	Not specifically	Y	HIGH/MEDIUM
RQ9 – Risk						

Finding	KIIs	Documents	Grantee survey	Case studies	Comparative analysis	Conclusion
9.1: Unitaid has developed and is implementing a robust risk management framework that represents close to or actual best practice for grant-making organisations.	Unitaid	UNITAID/PSC17/2017/3 FCDO annual review 2019, 2020 Briefing by Unitaid MOPAN framework (indicator 5.4) UNITAID/EB38/2021/7	Q32	Not specifically		HIGH
9.2: However, Unitaid’s risk appetite is considered to be too low by most stakeholders, given its focus on innovation, with potential implications for returns on investments and equitable impact.	NGOs Unitaid DPs Grantees	UNITAID/PSC17/2017/3 MTR CCSE briefing to the review team (April 2021)	Q7	Malaria	Y	MEDIUM/HIGH
9.3: There is some evidence of flexibility, but this tends to be during finalisation of design – in the window between grant approval and implementation – outside of which flexibility is limited.	Unitaid DPs Grantees NGOs	UNITAID/PSC17/2017/3 MTR FCDO annual reviews	Q26	Fever		HIGH
RQ10 – Grant Management						
10.1: The Secretariat has become more involved with the implementation of grants over time, and it can take a long time for Unitaid and grantees to reach ‘alignment’ in terms of vision and approach.	DPs Grantees NGOs PS Unitaid	Unitaid Strategy 2017-21	Q31, Q36	Malaria, Fever		HIGH
10.2: There is demand and scope for Unitaid to partner with a wider range of grantees and Unitaid has ongoing plans to strengthen in this regard.	DPs Govt grantees NGOs Unitaid	MTR UNITAID/PSC17/2017/3 Grantee network analysis CCSE briefing to review team (April 2021)	N/A	HIV, TB, Malaria, Fever	Y	HIGH
10.3 Pressure has increasingly been placed on the Secretariat staff as a result of the operating model requirements, the growth in both portfolio scope and number of grantees, and the surge capacity needed for Unitaid’s COVID-19 response.	Grantees PS Unitaid	UNITAID/EB33/2019/4 Grantee network analysis	Q29	HIV		HIGH
10.4 Output and results data across grants cannot easily be aggregated or compared and	Grantees	Results framework overview 2021 Scalability framework guidance 2021	Q37	Not specifically		MEDIUM

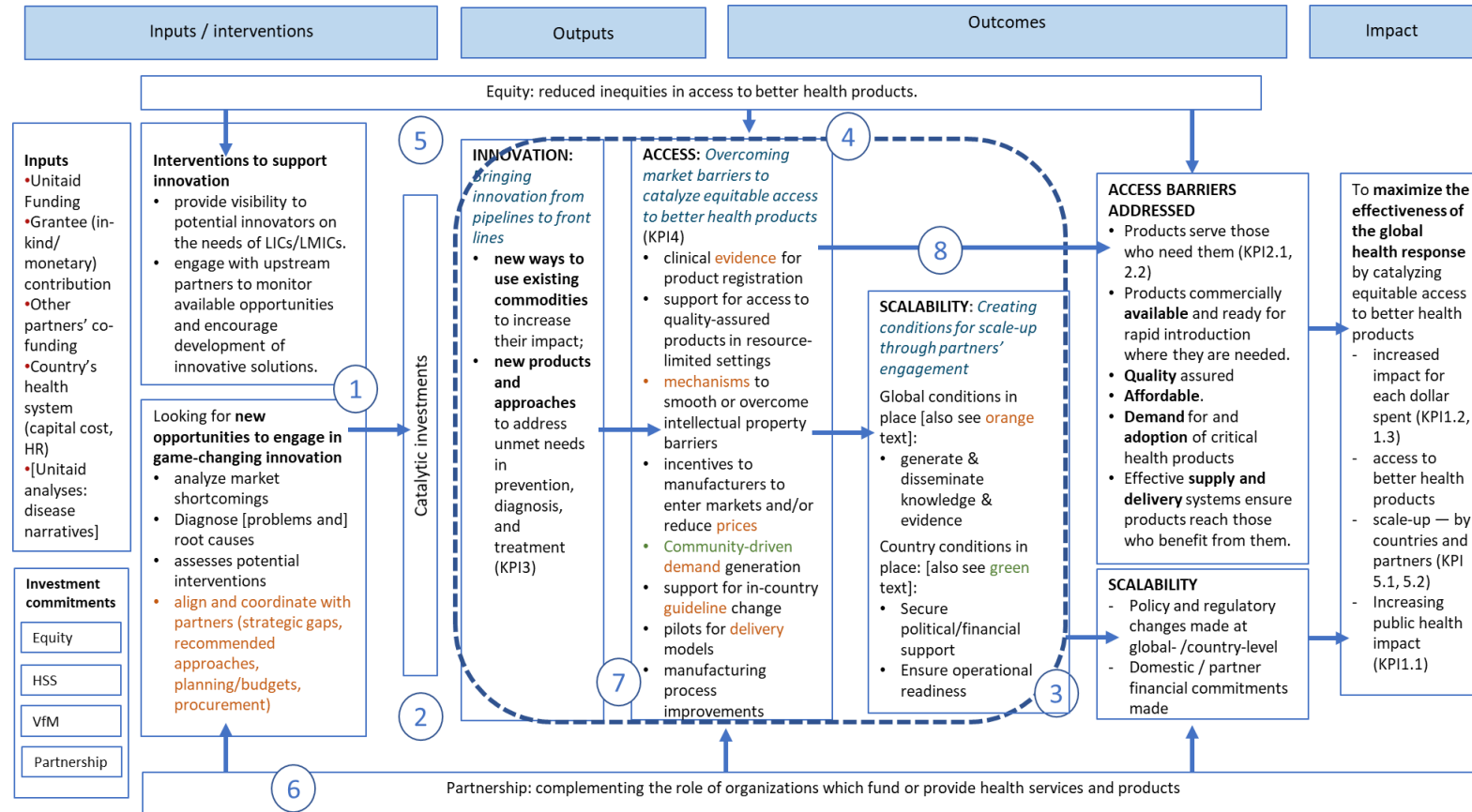
Finding	KIIs	Documents	Grantee survey	Case studies	Comparative analysis	Conclusion
there is a bias to quantitative data, at the expense of qualitative data which may contribute nuanced insight.						
10.5: While critical to the success of grants, scalability and sustainability may be under-considered in project planning and implementation, potentially limiting the Effectiveness of the groundwork required for both and hampering the opportunity for lessons to be learned.	Grantees DPs Unitaid Govts	MTR Scalability framework guidance 2021 UNITAID/PSC17/2017/3	N/A	Malaria		MEDIUM/HIGH
RQ11 – Value for Money						
11.1 Unitaid’s VfM framework compares well to those of many GH organisations and has significantly improved over the Strategy period.	PRC; Sec; dev ptnr; Board; grantee	VfM framework; financial stmts; additional on SOs/OKPIs	Q23, Q31, Q40–41	Malaria	Y	Strong
11.2 Operational KPIs (OKPIs) generally drive Efficiency within the organisation.	Sec	UK annual review; financial stmts; OKPIs internal guidelines	Q16	TB	N/A	HIGH
11.3 Economy and Efficiency are both significantly influenced by WHO hosting, a key foundational element of Unitaid, in both positive and negative ways.	Sec; dev ptnr; Board; grantee	Financial stmts	N/A	Not specifically	N/A	MEDIUM (minimal discussion with WHO)
11.4 The current framework monitors grant Efficiency and Effectiveness during and at the closure of each project. Results vary over this time period but have remained largely positive (in 2019, over a third of projects fully met or exceeded expectations).	Board; dev ptnr; grantee	Project Portfolios; project one-pagers	N/A	HIV, TB, Malaria, Fever	N/A	HIGH
11.5 Effectiveness insufficiently demonstrated to some donors/funding partners/countries.	Board; Sec; dev ptnr; priv sec	Financial stmts; midterm review	N/A	Not specifically	N/A	MEDIUM / HIGH (consistent, tho discussion with additional donors/countr

Finding	KIIs	Documents	Grantee survey	Case studies	Comparative analysis	Conclusion
						ies would help further)
RQ12 – Target Setting						
12.1 Target setting is extensive at Unitaid. It is used as a successful incentivising technique for grantees with their logframes, and with the organisation as a whole, via the framework of SKPIs and OKPIs.	PRC; grantee; Sec; Board	Project one-pagers; NgenIRS Evaluation	N/A	HIV, TB, Fever	N/A	HIGH
12.2 The SKPI for Equity does not focus on the populations who actually benefit from Unitaid grants. The targets used for the organisational KPIs relating to Secretariat expenditure and for resource mobilisation are also problematic.	PRC; grantee; Sec; NGO; Board; priv sec	VfM framework; SKPIs guidelines; midterm review; FCDO prog indo	Q6	HIV, Malaria, Fever	Organisational profiles	HIGH
12.3 OKPIs influence Unitaid organisationally through another set of targets.	Sec; dev ptrn; grantee	Midterm review; UK annual review; financial stmts; GF market shaping strategy midterm review; OKPIs guidelines	Q16, Q13/28–30/54 – HR, Q36/39/43 – risk mgt	TB, Malaria	N/A	HIGH
12.4 Post facto grant targets are a significant absence.	Sec; grantee; Board; dev ptrn	NgenIRS Evaluation model; ICAI report on DFID VfM	Q7	HIV, Malaria, Fever	N/A	HIGH
12.5 Targets are also missing and needed with disease narratives/AfIs/in the Strategy.	Board; NGO; Sec; dev ptrn	SDG 2020 report; DFID results framework; G7 2021 report; midterm review	N/A	HIV	N/A	MEDIUM / HIGH (consistent, though discussion with additional donors/countries would help further)
Equity (cross-cutting)						
E1. Equity is a key declared component of the Unitaid 2017–21 Strategy and its interventions target vulnerable people by design.	Unitaid, Grantees DPs, MOH, Private sector	2017-2021 Strategy, MTR, Disease Narratives, review of operating model, additional doc excerpts	Yes	HIV, Malaria		HIGH

Finding	KIIs	Documents	Grantee survey	Case studies	Comparative analysis	Conclusion
E2. Unitaid’s focus on access barriers filters down to the award selection criteria.	Grantees, DPs, Unitaid, NGOs	2017-2021 Strategy, MTR, UK annual review Unitaid - Nov 2019, Disease Narratives, UNITAID_PSC21_2019_3_Annex 3_Investment Commitments, Grantee Proposal Template, additional doc excerpts	Yes	HIV, TB, Malaria, Fever		HIGH
E3. By addressing access barriers, Unitaid investments tackle inequities.	Unitaid, Grantees DPs, MOH, Private sector	2017-2021 Strategy, MTR, Disease Narratives, review of operating model, additional doc excerpts	Yes	HIV, TB, Malaria, Fever		HIGH
E4. While the 2017–21 Strategy manifests commitment to addressing inequities, the lack of meaningful Equity-related KPIs as well as <i>ex post</i> evaluations makes it difficult to assess whether Unitaid as a whole has delivered one of its core commitments.	Unitaid, grantees, Global Health partners	Analysis of Unitaid M&E reporting, Analysis of KPIs, Unitaid Strategy 2017-2021, Analysis of grant reporting, analysis of KPIs and annual reporting, additional doc excerpts		HIV, TB, Malaria, Fever		MEDIUM
E5. While there is recognition of Unitaid’s increased intention to work through local partners, engagement with them, particularly in LMICs, could be stronger.	CS, Unitaid, grantees	Grant analysis, additional doc excerpts		HIV, TB, Malaria, Fever		MEDIUM
E6. The presence on the Board of community and NGO representation is recognised as an important driver of Equity in the process of defining AfIs. However, this representation could be strengthened in order to enhance Equity in decision making processes.	CS, Grantees, Unitaid	Analysis of grants, Disease Narratives, review of operating model, additional doc excerpts		HIV		MEDIUM

13 Draft Portfolio-Level Theory of Change

While Unitaid uses ToC as a tool in its grant management approach, a portfolio-level ToC has not been articulated. Itad facilitated a preliminary discussion with the Unitaid Secretariat on 23 April to postulate a draft ToC (below). For a variety of reasons, including the compressed timeline of this review and the challenge of simply communicating the complex interventions that Unitaid undertakes, it was not possible to complete planned work on the ToC within available time and resources. We are happy to finalise this work in the final round of comments if the Secretariat can send their feedback on the version we shared. Numbers in the Figure below refer to underpinning assumptions, which are presented on the following page.



Drawing on Unitaid’s analysis of ‘top risks at the end of 2020 (41/47 grants)’²²⁴ and the intervention logic set out in the draft portfolio-level ToC above, we have identified a number of underpinning assumptions. Once agreed these can be monitored and reviewed in the context of the ToC, to guide and strengthen implementation.

Assumption
1 Market shaping/access conditions* are conducive to Unitaid intervention
2. Project pre-conditions** are conducive to Unitaid intervention
3. Project activities ensure effective transition
4. In-country situations are conducive to Unitaid intervention
5. Timelines are realistic (e.g. for intervention design/protocol dev, approvals and regulations
6. Coordination/engagement with key partners is effective
7. Innovations identified that add value
8. Interventions are appropriate to tackle access barriers ***

* Often related to product availability and/or pricing risks.

** In-country risks associated with COVID disruption often classified here.

*** added by Itad review team

²²⁴ Unitaid briefing on Risk, April 2021

14 Cross-Case Analysis Table

Corresponding finding in the report	Malaria chemoprevention	Fever Management	TB prevention	HIVST	Cross-case summary
RELEVANCE					
<p>Alignment with strategic objectives, global commitments and beneficiary needs</p> <p>Finding # 1.1 & 1.2 Finding # 2.2 Finding # 6.1</p>	<p>Unitaid’s work in Seasonal malaria chemoprevention (SMC) was highly relevant to the global malaria community, filling pressing gaps to solve supply bottlenecks, generate demand, and catalyse unprecedented and rapid national scale-up. <i>(Strength of evidence: High)</i></p>	<p>There is broad consensus that the focus of the fever management investment is very relevant in terms of filling a key ‘gap’ based on a well-researched and clearly identified need, and there are few other key funders who may be willing to invest in evidence generation in this space. <i>(Strength of evidence: High)</i></p>	<p>Unitaid’s investment in TB prevention was timely, groundbreaking, and highly responsive to push forward the prevention commitments of the End TB Strategy. <i>(Strength of evidence: High)</i></p>	<p>The investment in HIVST is in line with Unitaid’s ambition to increase access to most appropriate, innovative, quality-assured, and affordable products, and address global HIV goals. <i>(Strength of evidence: High)</i></p>	<p>Unitaid investments appear to be in line with evidence-based gaps and responsive to global priorities.</p>

<p>What's missing?/ Future outlook</p>	<p>Sole focus on public sector delivery channels poses a potential threat to Unitaid's relevance, as the private sector remains a rapidly growing point of care. <i>(Strength of evidence: Low/medium)</i></p>	<p>While the focus is considered largely 'good for now', there are calls for clarity on the overall strategic direction of the fever management investment, including on the linkage with the three diseases or as related to an overall MNCH approach. <i>(Strength of evidence: High)</i></p>			<p><i>Not enough evidence across cases to compare</i></p>
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<p>Global Public Goods/ evidence generation role</p> <p>Finding # 3.1</p>			<p>Unitaid’s prioritisation of research within its TB prevention project enabled WHO to rapidly update guidelines for TB prevention, and this in turn helped donors and national governments provide support to prevention. <i>(Strength of evidence: Medium)</i></p>	<p>Unitaid’s investment has effectively encouraged other donors to enter the HIVST space, thanks to its role in generating evidence. <i>(Strength of evidence: High)</i></p>	<p>Unitaid plays an important evidence generation role that has the potential to shape the actions of other GH players</p>
<p>COHERENCE</p>					

<p>Collaboration/ complementarity</p> <p>Finding # 4.1</p>	<p>There is opportunity for increased coordination, of the chemoprevention work <i>(Strength of evidence: Medium)</i></p>	<p>There is good collaboration across grantees, though this is generally informal and grantee- rather than Unitaid-led and could be more formally strengthened and guided to benefit from cross-learning opportunities more fully. <i>(Strength of evidence: High)</i></p>	<p>Unitaid’s work to engage other partners in TB, and specifically TB prevention, is well recognised among the TB community; Unitaid could do more to fully engage with partners to expand impact and ensure complementarity. Donor engagement could be more consistent. <i>(Strength of evidence: High)</i></p>	<p>The work on HIVST is a good example of how Unitaid complements the work of other funders, and of how different grants complement each other. <i>(Strength of evidence: High)</i></p>	<p>Collaboration and complementarity with partners are usually good but could be more systematic / stronger</p>
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<p>Alignment/ comparative advantage</p> <p>Finding # 1.1 & 1.2 Finding # 5.1</p>	<p>The malaria chemoprevention portfolio is well aligned with Unitaid’s comparative advantage to address clear market failures <i>(Strength of evidence: Medium)</i></p> <p>There are strong and differing opinions across stakeholders on prioritising IPTi within Unitaid’s malaria portfolio. Some stakeholders perceived IPTi as a shift away from ‘Unitaid’s sweet spot’ of market shaping for new products and voiced concern about their ability to successfully achieve results in a space requiring such intensive engagement in country-level health systems <i>(Strength of evidence: Medium)</i></p>		<p>Unitaid’s capacity for investment in innovative financing and rewards for manufacturers is a distinct comparative advantage in the TB field. <i>(Strength of evidence: Medium)</i></p>	<p>Investments in HIVST ... leverage Unitaid’s core comparative advantage in terms of disease focus and market shaping expertise. <i>(Strength of evidence: High)</i></p> <p>Unitaid has drawn appropriately on its core expertise in bridging the ‘upstream’ and ‘downstream’ of innovation to deploy a range of pioneering interventions in HIVST. <i>(Strength of evidence: High)</i></p>	<p>Unitaid investments are generally aligned with its areas of comparative advantage (to address market failures, fill the missing middle and vis-à-vis the three main diseases)</p>
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<p>Internal coherence</p> <p>Finding # 6.2</p>	<p>Internal coherence of the malaria chemoprevention portfolio could benefit from a portfolio management approach that accounts for intervention combinations and prioritisation across the full package of interventions in Unitaids malaria portfolio. <i>(Strength of evidence: Medium)</i></p>	<p>There is broad consensus that there is relatively good internal coherence and complementarity across fever management grants, though this could be boosted by more coordinated planning efforts. <i>(Strength of evidence: High)</i></p> <p>Internal coherence and coordination could also have been improved through consideration of the malaria portfolio as a whole during planning and design phases, which may have further clarified the overall strategic direction of fever management investment. <i>(Strength of evidence: Medium)</i></p>		<p>Investments in HIVST are internally coherent with other Unitaids HIV investments...<i>(Strength of evidence: High)</i></p>	<p>Internal coherence within AfIs is relatively good but could be boosted by a portfolio management approach</p>
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<p>Visibility/recognition</p> <p>Finding # 7.2</p>	<p>there is opportunity for increased visibility, and recognition of the chemoprevention work <i>(Strength of evidence: Medium)</i></p> <p>National governments have suboptimal awareness of Unitaid’s model and market shaping objectives, posing a risk to sustainability and partnership. There was limited understanding of the time-limited or catalytic role of Unitaid funding, including the need to transition to other funding sources at the end of the grant. <i>(Strength of evidence: Medium)</i></p>	<p>COVID-19 additional response work has, overall, served to boost the relevance of planned fever management activities and helped lay the foundation for effective local engagement, though some reorientation of project focus under AIRE and TIMCI will be needed. <i>(Strength of evidence: Medium)</i></p> <p>Visibility of Unitaid in the fever management space at global level is growing, though remains low at country level, with projects being associated largely with the grantees. <i>(Strength of evidence: Medium)</i></p>		<p>Investment in HIVST has resulted in more visibility and recognition than is the norm for Unitaid. <i>(Strength of evidence: Medium)</i></p>	<p>HIVST and COVID-19 have somewhat increased Unitaid’s visibility.</p> <p>Visibility at country level could be strengthened as projects are still largely associated with grantees.</p>
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EFFICIENCY					
Grant-making & management Finding # 8.1	Unitaid’s grant management within this portfolio is perceived as highly onerous and thus inherently limits flexibility . <i>(Strength of evidence: High)</i>	Feedback from grantees that requirements for reporting and engagement are demanding, which can also divert attention from local implementation efforts. <i>(Strength of evidence: Medium)</i>		Stakeholders strongly appreciate Unitaid’s collaborative approach to grant management, although this does mean that working with Unitaid can be more laborious and time-consuming compared to working with other global health funders. <i>(Strength of evidence: High)</i>	Grantees appreciate the collaborative approach but as a result some find grant management more onerous than it would otherwise (a the expensed of implementation)

<p>Risk management/ appetite</p> <p>Finding # 9.2</p>	<p>While the choice to engage in malaria chemoprevention was a calculated and right-sized risk, the lower risk appetite within grant activities at times limits Unitaids ability to address broader delivery system bottlenecks essential to success. <i>(Strength of evidence: Medium)</i></p>	<p>The evolving operational context has heightened implementation risks <i>(Strength of evidence: Medium)</i></p>		<p>Through its investment in HIVST, Unitaids demonstrated good levels of risk appetite in order to catalyse innovation and scale-up of a high-potential product. <i>(Strength of evidence: High)</i></p>	<p>There are mixed views about Unitaids risk appetite. A too low risk appetite however would mean that Unitaids misses opportunities to achieve transformational change.</p>
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EFFECTIVENESS					
Impact/VfM/ performance Finding # 11.5	Unitaid’s work in SMC was highly impactful, resulting in national scale-up across West Africa years after the grant ended and fundamentally changing the malaria chemoprevention landscape. <i>(Strength of evidence: High)</i>	There is limited demonstration of value for money so far, given the short implementation period and diversion of attention due to COVID-19, though a simplified version of the original operational research plan is now under way and there appears to be general confidence in ability to deliver. <i>(Strength of evidence: Medium)</i>	The long-term impact of Unitaid’s engagement with manufacturers is unclear, and the time has come for Unitaid to examine which investments have had a positive and lasting impact in the market. <i>(Strength of evidence: Medium)</i>	There was unanimous consensus among informants and literature that this Afl has been very successful in expanding access to testing among underserved populations. <i>(Strength of evidence: High)</i>	There are some notable reported successes. In many cases, however, long-term results are unknown due to lack of <i>ex post</i> evaluations

<p>Sustainability/ scalability/link with HSS</p> <p>Finding # 11.4</p>	<p>Unitaid’s work in community IPTp and IPTi poses a ‘failure to scale’ risk without additional efforts to strengthen the CHW delivery platforms they rely upon. <i>(Strength of evidence: High)</i></p>	<p>There is a clear pathway to scalability, though there have been shifts in the landscape due to COVID-19 and timelines are tight for effectively preparing for transition. <i>(Strength of evidence: Medium)</i></p>	<p>Greater focus on scale-up, including adaptation to products coming through the pipeline, and inclusion of companion diagnostics might have broadened the potential to drive transformational change in TB prevention. <i>(Strength of evidence: Medium)</i></p>	<p>Unitaid’s success in influencing the price of test kits is critical for the sustainability and scale-up of HIVST. <i>(Strength of evidence: High)</i></p>	<p>Chances of successful scale-up are mixed and could be strengthened by a stronger focus on systems and longer timelines.</p>
<p>EQUITY</p>					
<p>Equitable outcomes</p> <p>Finding # E3 Finding # E4</p>	<p>There was strong consensus that Unitaid’s work in malaria chemoprevention, which targets at-risk women, infants and children, is highly equitable and good value for money. <i>(Strength of evidence: High)</i></p>		<p>but more tracking and measurement is needed to ensure that Equity is being addressed. <i>(Strength of evidence: High)</i></p>	<p>The investment is Equity-driven and has improved access to testing to some of the most underserved populations. <i>(Strength of evidence: High)</i></p>	<p>By targeting at-risk/vulnerable populations and aiming for equitable access Unitaid contributes to equitable outcomes. Although more M&E data would be needed to express a definite judgement</p>

<p>Equity/link with capacity and CSO/LMIC implementers</p> <p>Finding # 10.2 Finding # E5</p>	<p>There is more work to be done engaging endemic country partners in Unitaids efforts to increase demand for IPTp and IPTi <i>(Strength of evidence: High)</i></p>	<p>The choice of fewer management partners has led to calls for more flexibility within the operating model to enable adaptation to more varied operational contexts and a wider range of partner capacities. <i>(Strength of evidence: Medium)</i></p>	<p>IMPAACT4TB is a model for engagement of civil society for Unitaids grants. For the IMPAACT4TB project, engaging the Treatment Action Group to give very small grants (~ USD \$500–1000) to in-country civil society organisations has enabled civil society to obtain sufficient resources to be strong advocates for TB prevention, both with governments and with people infected with TB. <i>(Strength of evidence: High)</i></p>	<p>One area where Unitaids has demonstrated improvement, but still has some way to go, is in promoting implementation through national partners. This is key to improve sustainability and Equity in interventions. <i>(Strength of evidence: High)</i></p>	<p>With a few notable exceptions, such as the IMPAACT4TB grant, there appears to be a need for Unitaids to be more flexible about its grant-making and management requirements in order to be more inclusive and allow stronger participation from LMICs / civil society / communities at all stages.</p>
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15 Unitaid GF Market Shaping Successes

	Global Fund market shaping successes	Unitaid investments				Principal access barriers	Unitaid contribution by principal access barrier	Notes
		Grant short name	Lead implem enter	Grant budget	Grant time frame			
1	EID	EGPAF POC	EGPAF	\$63 million	Aug 2015– Jul 2019	1) Availability 2) Demand & Adoption 3) Affordability 4) Supply & Delivery	1) <u>Availability</u> : * The UCPOC and EGPAF grants have facilitated suppliers to make their product available in the market for POC EID and VL. By the end of the grants, all nine EGPAF countries had POC EID available, and 11 UCPOC countries have POC EID available and nine have POC VL testing available. With these achievements, the portfolio of grants has kick-started/initiated the POC EID and VL diagnostics market in countries. The grants also helped	Note how data generated from projects influenced PEPFAR's

		UCPOC Ph2b	CHAI & UNICEF	\$74.3 million	Oct 2016– Sep 2021	<p>facilitate the availability of products in countries through supporting the registration of products and creating clearer and faster processes for product registration.</p> <p>2) <u>Demand & adoption:</u> * Both grants catalysed the introduction and adoption of POC EID, and to a lesser extent POC VL (noting the different contexts for each type of testing), through procurement of commodities and introduction of testing services. POC EID was non-existent or extremely limited before the grants, but successful procurement of devices/cartridges and incorporation of POC EID into infant testing programmes through the grants have resulted in durable commitments to substantial POC EID testing in many countries. POC VL use has increased in some countries, especially for specific populations, but this was not achieved in all countries, and in many countries scale-up has been limited and long-term commitments remain uncertain.</p> <p>3) <u>Affordability:</u> * Some test price reductions achieved, including through more inclusive pricing, for m-PIMA and GeneXpert – e.g. for GeneXpert, reduction from US\$17.95 to US\$14.90 all-inclusive, and a 33% decrease to US\$12.00 for the cartridge price alone, attributed to Unitaid, the grantees and other partners. Looking at affordability more widely for molecular diagnostics, there have been improvements in manufacturer agreements, especially in terms of the all-inclusive agreement with Hologic. Evidence relating to the cost-effectiveness of POC testing and cost-per-test result returned was developed by EGPAF and CHAI, which some stakeholders considered to be a significant achievement. The WHO guidelines now state that EID testing is cost-effective.</p> <p>4) <u>Supply & Delivery:</u> * Health systems: The projects effectively facilitated the introduction of POC technologies within country health systems, including with regard to</p>	Country Operational Plan (COP) guidance.
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						<p>supply chain and procurement processes, training, data systems and waste management – all with important strides through the project work, although some gaps remain, particularly with regard to robust data systems that align with existing national systems and developing waste management systems.</p> <p>* Delivery models: EGPAF demonstrated the hub and spoke model for POC testing, which has been a key contribution. In relation to sample transport, the EGPAF grant focused on transport between hub and spoke sites and the UCPOC grant focused on sample referrals via integrated referral systems and expansion of dried blood spot. Although the models used were largely successful, concerns remain about sustainability after grant closure, given implementation challenges and the need for continued funding.</p> <p>* Network optimisation: The grants incorporated a more holistic view of diagnostics networks and development of network optimisation plans. The shift in approach to diagnostics network optimisation through the UCPOC grant was appropriate and useful, albeit belated, although countries need to conduct further planning and implementation to reach this goal.</p>	
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2	ped ARV	DNDi peds	DNDi	\$17.3 million	May 2013–Dec 2018	<p>1) Innovation & availability</p> <p>2) Affordability</p> <p>3) Demand & adoption</p> <p>4) Supply & delivery</p> <p>5) Quality</p>	<p>1) <u>Innovation & Availability:</u> * Approval of generic 4-in-1 (abacavir, lamivudine, lopinavir, and ritonavir) paediatric treatment (produced by Cipla with support from DNDi) pending with USFDA. * First generic ped DTG formulations made available, with support from Unitaid-funded incentive program to two generic manufacturers – Viatris (Mylan) and Macleods – via CHAI Optimal grant.</p> <p>2) <u>Affordability:</u> * Price agreement with Viatris and Macleods will lower annual cost of ped DTG by 75%. The agreement makes ped DTG available at EXW US\$ 4.50/90 pack for all public procurers for use in the 121 countries covered in ViiV’s licence for pDTG with the MPP.</p> <p>3) <u>Demand & Adoption:</u> *The new ped DTG formulation of 10mg dispersible, strawberry-flavoured and scored tablets will significantly reduce pill burden and simplify dosing in children. It will also contribute to treatment adherence (previous bitter-tasting syrups were frequently rejected by children and caregivers). * From DNDi project (focused on 4-in-1 ped tx):</p> <p>i) In-country capacity was built in the organisations undertaking the LIVING studies, and in the individuals concerned, many of whom had not been involved in clinical studies previously.</p> <p>ii) The LIVING studies conducted at 12 sites across Kenya, Uganda and Tanzania worked well, and enabled generalised conclusions to be reached. Study results from all three countries confirmed that an ABC/3TC and LPV/r 40/10MG pellets regimen produced improved viral suppression in patients regardless of prior treatment exposure and age at initiation. The principal investigators and their staff found the experience of the study to be rewarding, and it built in-country capacity. All sites visited or interviewed by the evaluators reported that DNDi’s management of the</p>
		Optimal	CHAI	\$70.8 million	Sep 2016–Dec 2022		
		SPAAN	EGPAF	\$3.2 million	Aug 2019–Jul 2020		

							<p>studies, their monitoring, mentoring and support were very well received.</p> <p>iii) To confirm the prima facie acceptability of the pellets to caregivers and CLHIV, DNDi commissioned a further qualitative study, known as the RELIVING study. The study conducted a series of in-depth interviews with groups of caregivers, including mothers, in three sites in Kenya. The RELIVING study reinforced the impressions gained by clinical staff at the study sites that the pellet form of LPV/r was acceptable to the caregivers and the patients, and a significant improvement on the syrup option.</p> <p>4) <u>Supply & Delivery</u>: * Brought first generic suppliers of ped DTG to the market.</p> <p>5) <u>Quality</u>: * Fastest ever regulatory approval of a generic ped ARV formulation (2 years vs 10 years).</p>	
3	tenofovir /lamivudine/dolutegravir (TLD)	Optimal	CHAI	\$70.8 million	Sep 2016–Dec 2022	1) Innovation & Availability 2) Affordability 3) Demand & Adoption	<p>1) <u>Innovation & Availability</u>: * Evidence on efficacy and safety of DTG-based regimens (including in pregnant women, West African populations (HIV-2 genotype), and TB co-infected individuals) from Unitaid-funded clinical trials in LMICs provided to WHO HIV treatment guidelines committee to inform guideline revision.</p> <p>2) <u>Affordability</u>: * In 2017, a landmark pricing agreement made TLD available at an average price of US \$75 per person per year (pppy) in 90+ countries. The agreement was the result of CHAI’s joint collaborations with numerous stakeholders, including the governments of South Africa and Kenya, BMGF, PEPFAR, USAID, Global Fund, UNAIDS, WHO, DFID, Mylan and Aurobindo. The agreement was made possible by the foundation laid through Unitaid’s Optimal grant work in-country and the catalytic procurement. * The cost of TLD fixed dose combination, the WHO preferred first-line adult treatment regimen, has decreased further since 2017 and is currently</p>	
		ADVANCE	Ezitsha Wits RHI	\$19.8 million	Oct 2016–Aug 2022			
		NAMSA L	Institut Bouisson Bertrand	\$3.1 million	Jun 2016–Dec 2021			

		DolPHIN-2	Univ of Liverpool	\$10.8 million	Nov 2016–Jul 2022		<p>available at an average price of US\$ 65 pppy.</p> <p>3) <u>Demand & Adoption:</u></p> <p>* WHO guidelines updated in 2019 to recommend DTG-based regimens as the preferred first-line HIV treatment regimen, based on evidence stemming from Unitaid-funded clinical trials (ADVANCE, NAMSAL, DolPHIN-2) among others.</p> <p>* Immediately following the first generic approval of DTG, in 2017 CHAI and Unitaid engaged with MOHs in Kenya, Uganda and Nigeria to develop and implement a DTG catalytic procurement initiative. The initiative's strategy and plans were aligned with global donors (GF, PEPFAR) to ensure rapid transition to and scale-up of TLD. The catalytic procurement, in combination with early-adopter research in Uganda and Nigeria, was critical because it: (i) gathered key learnings from healthcare worker and patient experience; (ii) generated evidence in real-world settings; (iii) built a market in anticipation of TLD's launch.</p> <p>* The majority of LMICs have adopted or have plans to adopt TLD as the preferred first-line regimen, with inclusion or planned inclusion in over 120 national guidelines (Source: CHAI 2020 HIV market report and WHO 2020 update on HIV policies uptake).</p>	
4	Flucytosine (5FC) for AHD	Optimal	CHAI	\$70.8 million	Sep 2016–Dec 2022	<p>1) Affordability</p> <p>2) Demand & Adoption</p> <p>3) Supply & Delivery</p>	<p>1) <u>Affordability:</u></p> <p>* Secured \$75/pack price for 5FC (compared to \$110 baseline) through volume commitment negotiated jointly with Global Fund, CHAI and USAID GHSC. (Unitaid contribution also referenced in Global Fund Strategic Review Annex, p. 69)</p> <p>2) <u>Demand & Adoption:</u> <i>In progress.</i></p> <p>3) <u>Supply & Delivery:</u></p> <p>* Through the Unitaid-CHAI AHD Initiative's partnership with the Global Fund, PEPFAR, and FHI 360, Viartis and Strides' 5FC products were officially</p>	

							reviewed and qualified by FHI 360 in the first half of 2020. Strides’ 5FC 250mg and 500mg capsules also received approval from the US FDA in March 2020, and Viatris’ 500mg product is currently under review by the WHO PQ programme. These efforts have introduced additional suppliers into LMIC markets at a more affordable price.	
5	SMC	ACCESS-SMC	Malaria Consortium	\$67.4 million	Sep 2014–Feb 2018	1) Demand & Adoption 2) Supply & Delivery	<p>1) <u>Demand & Adoption:</u></p> <ul style="list-style-type: none"> * The project proved that large-scale administration of seasonal malaria chemoprevention is feasible, safe and cost-effective, with a strong public health impact. * Operational guidelines for SMC implementation were developed and widely shared at country level. * Today 13 countries implement SMC at scale, with the number of children accessing at least one dose of SMC reaching 21.5 million in 2019. * By 2022, it is estimated that 26 million children (75% of all eligible children) will be reached with SMC – a 26-fold increase in access since the start of the ACCESS-SMC project. <p>2) <u>Supply & Delivery:</u></p> <ul style="list-style-type: none"> * Demand generation activities expedited the expansion in global production and production capacity of quality-assured SP+AQ. * The project improved the level of SMC supply from two manufacturers – Guilin Pharmaceutical (initial supplier of SMC market) and eventually S. Kant, which received WHO PQ in April, 2021. **With funding from Unitaid, MMV worked with S Kant, an Indian-based pharmaceutical company, to develop a child-friendly, palatable and affordable formulation which has received WHO pre-qualification, resulting in increased supply and greater security of supply for this important protective medicine through two manufacturers. <p>3) <u>Affordability:</u></p>	

							* The cost of delivering the treatment per child fell more than 20% over the life of the project, and today stands at US\$ 3.40 on average.	
6	HIV Self-testing	STAR	PSI	\$68.8 million	Aug 2017– Aug 2021	1) Demand & Adoption 2) Supply & Delivery 3) Affordability	<p>Mainly inputs from STAR evaluation:</p> <p>1) <u>Demand & Adoption</u>: *Unitaid’s funding has significantly contributed to the research evidence based on the cost-effectiveness of the different delivery models. *Through evidence generation Unitaid’s funding in the STAR project supported the first WHO global guidelines on HIVST in 2016. HIVST was recommended to be offered as an additional approach to HIV testing services. *Today 88 countries have policies allowing for HIVST. The demand for HIVST is expected to grow to 29 million kits by 2025.</p> <p>2) <u>Supply & Delivery</u>: * Unitaid’s investment in HIVST demonstrated delivery models with greater ability to reach previously under-served people with limited access to SoC HIV testing and low rates of testing uptake: this includes young people, men and key populations, including female sex workers and</p>	
		ATLAS	Solthis	\$15.7 million	Jun 2018– Nov 2021			
		MTV SAF Shuga	MTV Staying Alive Foundation	\$10 million	Apr 2018– Jun 2021			

		Challenge Fund	EJAF	\$1.5 million	Jan 2019–Dec 2021	<p>men who have sex with men. The STAR project implemented 13 HIVST distribution models (9 community-based and 4 facility-based).</p> <p>* During the implementation of the STAR project, 4 new HIVST products became available with WHO pre-qualification (one during STAR Phase 1 and three during Phase 2).</p> <p>* the number of suppliers of HIVST products has increased from 1 (Orasure) to 5 manufacturers now.</p> <p>3) <u>Affordability</u>:</p> <p>* Cost-effectiveness and affordability of HIVST has dramatically improved as a result of STAR interventions. Self-tests can now be procured for as little as US \$1.50 per kit across 135 LIC, LMIC, and UMIC (compared to approximately US\$40 in the United States and up to US\$15 in South Africa, in the private sector in 2015). This price reduction was achieved thanks to a combination of efforts by multiple partners, including an agreement for one oral self-testing product secured by the Bill & Melinda Gates Foundation. Unitaid and other partners have also secured lower prices using volume pricing and forecasting and by bringing together manufacturers to support an increase in the number of products to improve competition in the marketplace.</p>	
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7	PBO nets	New Nets Project	IVCC	\$66 million	Aug 2018– Dec 2022	<ol style="list-style-type: none"> 1) Innovation & Availability 2) Demand & Adoption 3) Affordability 	<p>Unitaid is a co-funder of the New Nets Project (NNP), along with Global Fund (each organisation contributing \$33 million of funding). The New Nets project aims to generate epidemiological data on the efficacy of dual active ingredient (dual AI) nets (the newest generation of long-lasting insecticide nets), as well as cost-effectiveness and feasibility evidence, to inform a WHO policy recommendation and national implementation guidelines. The project is also undertaking market intervention activities to establish affordability of dual AI nets. Achievements under NNP to date include:</p> <ol style="list-style-type: none"> 1) <u>Innovation & Availability</u>: <i>In progress</i>. The grant is generating evidence on the efficacy of (dual AI) nets for review by VCAG to inform a WHO policy recommendation. 2) <u>Demand & Adoption</u>: <i>In progress</i>. The grant is generating evidence on cost-effectiveness and operational feasibility of dual AI nets to inform country implementation guidelines. 3) <u>Affordability</u>: * End-of-project targeted price for dual AI nets was achieved two years ahead of schedule. The price for the Interceptor G2 (IG2) product was brought down from US \$4.88 in 2018 to US \$2.75 in 2020. 	
8	RTSS	MVIP / RTS,s	WHO	\$9.6 million	Jul 2017– Dec 2020	1) Supply & Delivery	Unitaid is a co-funder of the malaria vaccine work, along with Global Fund and Gavi. Outcomes are <i>in progress</i> .	
Areas warranting additional GF work								

9	TPT	IMPAAC T4TB	Aurum Institute	\$58.9 million	Sep 2017– Dec 2023	1) Innovation & Availability 2) Demand & Adoption 3) Affordability	<p>1) <u>Innovation & Availability:</u> * As of 31 March 2021, more than 20,000 patients, including in nine I4TB project countries, now have access to 3HP. These countries include five I4TB countries (Ethiopia, Cambodia, Malawi and Zimbabwe), as well as Vietnam and Pakistan, which received their first orders of 3HP in 2020. During the first half of 2021, Mozambique, Indonesia and Ghana (from I4TB), as well as Bangladesh, Venezuela, Costa Rica, and Cuba, received deliveries of 3HP and most have started administering it to patients. We expect seven more countries to receive 3HP in the second half of 2021, with additional ones accessing 3HP next year. * The project supported the development and filing of 3HP with a global-level SRA and country NDRA by generic manufacturers through an incentive grant (Macleods being the first one).</p> <p>2) <u>Demand & Adoption:</u> * Inclusion of evidence (from project) on use of 3HP in PLHIV and child contacts in WHO guidelines, paving the way for broader country adoption. * 10 project countries (out of a targeted eight countries) have adopted 3HP in their national guidelines. The project also continues to train civil society groups to advocate for adoption of 3HP for PLHIV and child contacts (18 out of 20 targeted groups were trained in 2020 despite COVID-19).</p> <p>3) <u>Affordability:</u> * Negotiated access price agreement with Sanofi for rifapentine (3HP), bringing the price down from US \$45 to US \$15 and driving demand for 3HP from PEPFAR and Global Fund and accelerating uptake of 3HP in countries. * Established US \$15 per patient ceiling price for Macleods’ generic 3HP product.</p>	
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10	IPTp	TIPTOP	Jhpiego	\$49.7 million	May 2017–Apr 2022	1) Demand & Adoption 2) Supply & Delivery 3) Quality	<p>1) <u>Demand & Adoption</u>: *Evidence generated through Unitaids’ investment has supported inclusion of IPTp in the National Strategic Malaria plans of the project countries. Formal WHO policy recommendation is expected in Q4 2022. *Six additional countries included C-IPTp roll-out in their recent Global Fund proposal for 2021–23 funding (Benin, Burkina Faso, Cameroon, Central African Republic, Congo Brazzaville and Senegal).</p> <p>2) <u>Supply & Delivery</u>: *All TIPTOP districts have improved on the percentage of pregnant women receiving a third dose of intermittent preventive treatment of malaria in pregnancy (IPTp3), exceeding annual targets and the life-of-project targets in three countries. This has been achieved without negatively impacting rates of four antenatal care (ANC4) visits. *Notably, all district ANC4 rates are higher now than in the first month of community-based IPTp (C-IPTp) distribution. Overall, early antenatal care (ANC) is increasing across all countries.</p> <p>3) <u>Quality</u>: * MMV entered into an agreement with a Kenyan manufacturer, Universal Corporation Ltd, in January 2019, and another with SWIPHA, Nigeria, in 2020, to produce WHO-prequalified SP for IPTp. In addition to providing a quality-assured product, these manufacturers will ensure that the packaging and labels carry clear instructions to use SP only for IPTp or intermittent preventive treatment in infants (IPTi). Low-quality versions of SP often lack this important information, which can lead to misuse of the product.</p>
		MMV Supply Side	MMV	\$3.4 million	Sep 2017–Dec 2020		

16 Two Grants as Case Studies for Unitaid's Relationship with the Global Fund

16.1 Introduction

The relationship between Unitaid and the Global Fund is key to the success of scaling up innovative products to help end the three diseases. The interviews for this Report found some variation in KII views on how well the two organisations interact. While time and resources did not allow a full deep dive on this issue, a focus on two sample grants was carried out to test the extent to which the relationship was indeed working.

The grants – New Nets in malaria and Self-testing in HIV (the latter in fact a suite of linked grants) – were from the list of eight grants which Unitaid saw as most successful, rather than from the two where Unitaid saw that 'more work was warranted from the GF' (see EQ 11 in Volume 1 of this Report). Note that the focus studies in this Annex had different objectives from the standard case studies agreed in the Inception Report and presented in Annexes 5, 6 and 8, although one (HIV self-test, Annex 7) features in both, in order to make efficient use of the KIIs and other analysis of this grant already conducted.

16.2 Overall Assessment

The two grants do indeed show strong evidence of a good relationship between the two organisations.

In both cases the grants were developed and implemented by Unitaid in close collaboration with GF throughout. In both instances, the two operated easily as equal partners, not always easy in the global health space. In one of the grants, the New Nets Project (NNP), the reassurance provided by Unitaid's processes and experience in grant management was vital in the GF agreeing to provide half of the funds (\$33 million). However, the WHO proved a less amenable partner, slowing scale-up and demonstrating that current institutional arrangements will sometimes require an effective three-way rather than simply two-way partnership for optimal results.

In both cases, longstanding close professional relationships between key GF and Unitaid staff were vital. The HIVST grant demonstrated how the risks that such dependence creates might be mitigated through establishment of donor groups, with carefully chosen focal points from a range of institutions, but certainly always including Unitaid, GF and WHO as central members.

The approach to demand forecasting across all malaria commodities that was relevant for NNP also suggests useful evidence for how Unitaid might approach disease-wide (rather than just single product-based) AfIs and strategy, if it chooses to develop these.

16.3 New Nets Project Grant

16.3.1 Background

Pyrethroid long-lasting insecticide nets (LLINs) have delivered great progress against malaria vectors. They are safe and cost-effective, acting to reduce transmission both

through immediate protection of those underneath the nets and protection of other humans through the nets' insecticidal bait trap action. However, in the face of growing mosquito resistance to pyrethroid, including even to enhanced piperonyl butoxide (PBO) nets, LLINs require a new range of active ingredients (AIs), which could be added to pyrethroid.

A number of promising potential new AIs exist to add to pyrethroid in nets. But in order to obtain the WHO recommendation which countries and development partners (DPs) tend to require before scaling up, a significant evidence base must be built up in relation to efficacy and safety, including field trial data. NNP is intended to generate that data, together with cost-effectiveness information not required by the WHO but which is also necessary for rational programme decisions. While such trials and their digestion by the WHO usually produce a delay of several years before scaling up can begin, based on encouraging initial data the NNP also intended to begin ordering new AI nets at scale in advance of the WHO decision – an unusual development. As a means to achieve this, Unitaids' NNP was designed in conjunction with a Global Fund initiative, PRO Nets.

While there are manufacturers able to produce the new AI nets, their uncertainty about volumes can lead to unwillingness and relatively high prices, which acts as a brake on access.

16.3.2 Grant agreement

The grant totals USD \$66.0 million, with half of this provided by Unitaids and half from the GF PRO Nets initiative. Its expected duration is August 2018 to December 2022.

Grantees

The grantee selected to lead the NNP's implementation partnership is the Innovative Vector Control Consortium (IVCC), a grantee with a good track record through the previous and positively evaluated Next Generation Indoor Residual Spraying (NgenIRS) grant.²²⁵ IVCC's consortium for this grant consists of: the Alliance for Malaria Prevention; London School of Hygiene and Tropical Medicine; PATH; and Population Services International. IVCC was a natural (perhaps the only) choice, as the only product development partnership in vector control. Although not listed as grantee members in Unitaids' Progress Update summary, important additional work was provided by Imperial College, Tulane University, BMGF²²⁶ and PMI. The nets were manufactured by BASF and Disease Control Technologies.

Key activities

A central objective was to promote affordability of dual AI nets. BMGF undertook to address this, via negotiating volume agreements, in collaboration with Med Access.

²²⁵ In 2020, Unitaids provided 43% of its income through NNP and NGenIRS. Source: IVCC Annual Report 2020.

²²⁶ According to interviewees, BMGF had offered an additional USD \$7 million, but this was refused as BMGF would have wished to be an equal partner in the grant, in joint control of spending decisions (as was GF).

NNP involves two dual AI nets: Interceptor® G2 (IG2, made by BASF) and Royal Guard® (RG, made by DCT). The dual AI nets were trialled in the field in various ways, gathering data on epidemiological data on their efficacy and for cost-effectiveness and feasibility evidence. The locations were moderate to high transmission areas in 14 African countries: Benin; Burkina Faso; Burundi; Cameroon; Côte d'Ivoire; DRC; Ghana; Liberia; Malawi; Mali; Mozambique; Niger; Nigeria; and Rwanda.

NNP seeks to establish the evidence needed to support a WHO policy recommendation.

16.3.3 Implementation

Three of four implementation milestones had been met by December 2020. All six effectiveness pilot studies had been started; all of the lowest-level LLIN storage facilities received the correct nets; and 29,625,599 nets were distributed, almost double the target of 15,045,395.²²⁷

Randomised control trials (RCTs)

Following inception in 2018, IVCC established partnerships with the net manufacturers (BASF and DCT) and with 10 national malaria programmes to conduct RCTs. These comprised evidence pilots to measure both epidemiological and entomological impacts and operational pilots to develop best practice guidelines for the introduction of multi-product campaigns including dual AI nets.

Cross-sectional surveys will be conducted in Burkina, Mozambique, Nigeria and Rwanda. An 18-month cross-sectional survey is under way in Benin, while a six-month cross-sectional survey has already been completed. The Liverpool School of Tropical Medicine (LSTM) and the London School of Hygiene & Tropical Medicine (LSHTM) are involved with these two field trials.

The operational pilots assess total cost of ownership, rather than just conventional cost of goods analysis. This means that all the internal costs of development, manufacturing, marketing and administration of the product as well as company overheads are included, as well as covering the whole life cycle of the product rather than just initial procurement. The analysis benefited from a policy of data transparency by all partners.

Five countries conducting evaluation pilots completed their net distribution campaigns by 2020. Burkina Faso was the first country to receive IG2 nets in October 2019. Due to COVID-19-related lockdowns and travel restrictions, there were some delays in net distribution and data collection in early 2020. However, once restrictions were lifted, Rwanda and Mali were able to complete successful IG2 distribution, as well as collection of epidemiological, entomological, and anthropological data, by shifting from community to door-to-door net distribution, adopting social distancing, and using personal protective equipment.

By the end of 2020, net campaigns will also occur in Nigeria and Mozambique, contributing to a total of over 15 million IG2 and one million RG ordered since the start

²²⁷ This represented approximately 15% of the 188 million LLINs distributed by the GF in 2020.

of NNP. Côte d'Ivoire, Liberia, Ghana, and Malawi will pilot dual AI nets in 2021, and by the end of NNP over 35 million nets will have been distributed in sub-Saharan Africa.²²⁸

Volume guarantee

BMGF, in collaboration with MedAccess, made a volume guarantee agreement with BASF and DCT to offer reduced IG2 and RG pricing. This drew on the cost-effectiveness analysis, which demonstrated that short-term cost challenges could be outweighed by longer-term considerations of benefit and costs over the full life of the nets.

The volume guarantees, combined with a co-payment from NNP, enable countries to procure IG2 for pilot deployments within their current malaria net budgets. The volume guarantee is likely to be ended soon, so as to leave the market open to increased competition.

Co-payment

Additional AIs mean that the cost per unit will inevitably be above that of pyrethroid-only nets. Prior to demonstration of efficacy and ramping up to substantial volumes and levels of competition (which would act to reduce cost, even if it is always likely to exceed that of pyrethroid-only nets), this price premium could discourage programme adoption. The solution was for NNP to offer to pay a co-payment on every net so that purchasers could be guaranteed a reduced price which would not exceed that of pyrethroid-only LLINs. This strategy was also used successfully with the NgenIRS grant. While there was a danger in principle that demand would exceed the fixed co-payment budget, in practice manufacturing capacity was limited, so this problem was not realised.

COVID and other challenges

The COVID-19 pandemic created significant headwinds for NNP in 2020. Net production was suspended in China and Thailand in March, as was all fieldwork and data collection (March until June). IVCC apparently responded well to the situation, protecting health workers and beneficiaries once work recommenced, through transition from community to door-to-door net distribution, personal protective equipment deployment and adoption of social distancing.

Partly as a result of this, the NNP budget has been underspent – only USD \$18.9 million of a planned USD \$29.0 million in 2020, leading to USD \$32.1 million of an expected USD \$42.3 million cumulative up until that date.

16.3.4 Results to date

Unitaid gave this 2018–22 grant its highest rating (A of A–D) in June 2021,¹⁷⁸ offering strong evidence in the grant having met or surpassed all three of its scalability targets – one relating to market share and two relating to price – in spite of COVID-related delays. The scalability risk was assessed as 'Medium Low', given the GF's USD

²²⁸ <https://www.ivcc.com/wp-content/uploads/2020/12/IVCCOV96-Annual-Report-2020-v8.pdf>

\$50 million Net Transition Initiative as a source of future co-payments to facilitate purchases at the current reduced price.

Several KIs saw NNP as effectively addressing the two key barriers – lack of evidence for the prospective WHO approval and high unit cost. Running the trials prior to any distribution (i.e. sequentially rather than consecutively) might have added an estimated 5–8 years to the process. GF forecasts 13 million dual AI nets will have been distributed in 2021, almost seven times 2018’s total volume.

Innovation and availability

In progress. The grant is generating evidence on the efficacy of dual AI nets for review by the WHO’s Vector Control Advisory Group (VCAG) to inform a WHO policy recommendation. The fact that new AIs are being added to continued use of pyrethroid suggests it is highly likely that the new LLINs will be at least as effective as pyrethroid-only ones.

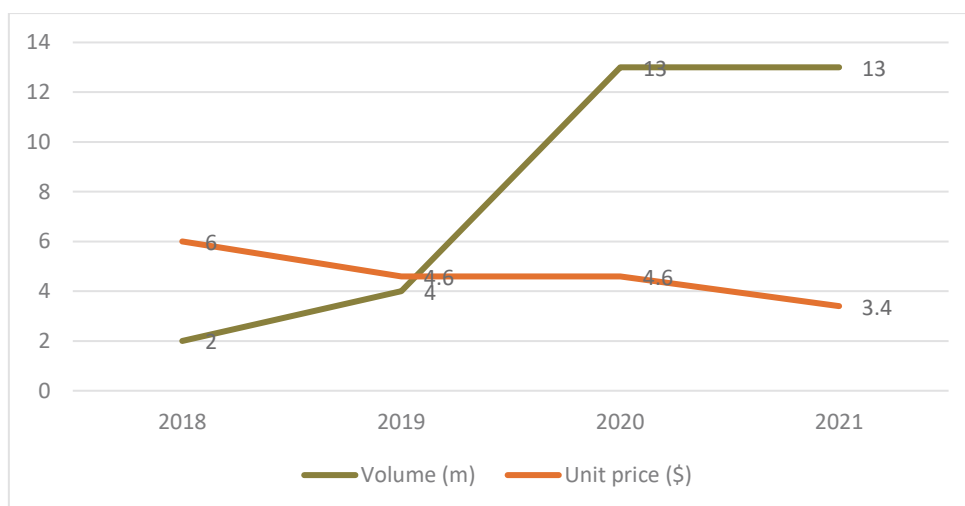
Demand and adoption

This remains in progress, given that a WHO recommendation has not yet been achieved, limiting the scope for uptake. But the grant is generating evidence on cost-effectiveness and operational feasibility of dual AI nets to inform both the WHO decision and country implementation guidelines. Ten countries have so far procured dual AI nets. NNP’s target was that 5% of total LLIN market should be dual AI. This has been surpassed, in that 10% was achieved by December 2020. Unitaid estimates 35 million dual AI nets to have been supplied by mid-2021.

Affordability

The end-of-project targeted price for dual AI nets was achieved two years ahead of schedule. The price for the IG2 net was brought down from USD \$4.88 in 2018 to USD \$2.75 in 2020, against a target of USD \$3.40. The RG price was USD \$2.96 in 2020, exactly as targeted.

Figure 1: IG2 unit price and volumes under NNP



Source: GF Market Shaping workshop

Beyond the purchase price, the operational pilots showed that the new nets exhibited significant cost advantages once full lifetime product operation was considered.

Future

WHO argued against NNP, including within the Unitaid Board – DPs starting distribution on their own evidence and then looking for retrospective WHO approval is a difficult precedent for WHO to accept. But WHO now seems likely to approve IG2 and RG relatively soon, likely in 2022. Scalability looks good for the NNP. GF has committed USD \$50 million, through its Net Transition Initiative, due to run for the three years 2021–23.

The London Malaria Summit’s 2018 ‘Zero by 40’ Declaration aims for malaria eradication by 2040, a feasible goal which is not yet in sight for TB or HIV. Eradication would deliver a very substantial health and economic benefit, as well as likely stimulation for further global health endeavours.

16.3.5 GF relationship throughout the process

The NNP grant was developed through all stages in collaboration with the GF, including: its Afl; an MoU and co-financing agreement; grant proposals/ToR negotiations (following Unitaid preparation of RfPs) and implementation oversight. The provision of substantial GF finance (USD \$33 million) in advance of WHO approval and the fact that the funds were going to be used for grants for which the GF would be directly responsible (rather than countries and Principal Recipients carrying responsibility) were both significant challenges that had to be overcome within the GF.

This required significant reassurance within GF regarding risk mitigation, which was largely met with reference to Unitaid’s stringent grant oversight procedures and experience – both were judged stronger than those of GF.

The smooth running of the process benefited significantly from longstanding good professional relationships between key individuals in relation to malaria at Unitaid and GF as well as to the close physical proximity of the organisations in Geneva. The fact that service delivery results could be included in GF’s annual reported results (infections averted, lives saved) may also have been helpful.

Working closely with GF is especially important with LLINs because GF and its coordinating partners (PMI and UNICEF) so clearly dominate the global LLIN market.

Table 4: 2020 LLIN procurement

Purchaser	Million nets	%
Global Fund	103	41%
PMI	50	20%
UNICEF	50	20%
Others	47	19%
Total	250	100%

Sources: GF: volume actuals, pooled procurement only; PMI: volume actuals from 2020 Annual Report; UNICEF: LLINs market and supply update – UNICEF 2020; Total: 2019 volume in 2020 WHO World Malaria Report, LLINs market and supply update – UNICEF 2020, LLIN Volumes Supplier OTIF Savings-2021 LLIN Allocation Memo – IDA, 2021.

GF's half of the NNP funding was spend first, so it remains open what will happen to any unspent Unitaid grant funds if these remain at the end of the grant period.

For the future, the GF is developing its own grant oversight capability (Strategic Initiatives Project Management Office), learning from projects such as NNP.

16.3.6 Assessment

NNP's results have been independently evaluated and are impressive, especially in the light of a cumulative underspend of 24% at December 2020. The grant was clearly catalytic of GF's USD \$50 million Net Transition Initiative. Further catalytic results are likely to follow a WHO decision on recommendation.

NNP was developed and implemented in close collaboration with GF throughout. This relationship worked well, according to those most closely involved on both sides. When the GF was seeking internal authorisation for this unusual, parallel evidence-gathering and significant product distribution, Unitaid's stringent grant management processes (not always popular with grantees) were an asset in offering reassurance that risks would be managed. The GF has traditionally lacked this grant management capability. WHO was a less amenable partner with NNP, and it should be noted that, as GF technical partner and Unitaid host, WHO is an inherent 'third party' to all GF–Unitaid interactions. WHO recalcitrance has been the main impediment to NNP not having achieved greater scale to date. It is not clear if GF or Unitaid could have managed the relationship with WHO any better than they did.

The NNP grant's concentration on sub-Saharan Africa and on malaria-susceptible populations implies that its results will be strong on Equity grounds, though this is not yet measured in aggregate by GF or Unitaid.

Much of the successful collaboration with the GF seemed to depend on longstanding, good personal relationships, e.g. with the GF's head of malaria, who has been in post since 2011. There is less evidence of strong institutional links which could facilitate a similar success if different people were in position.

An additional noteworthy aspect of the NNP grant was the way in which the forecasting of demand, which was vital for building the volume agreement and investment case, recognised interconnectedness across all malaria control commodities, including treatments and diagnostics.²²⁹ IVCC's work (in collaboration with CHAI and BMGF) to develop integrated malaria commodity forecasts could serve as a useful input for Unitaid if it begins to develop AfIs and strategies that are at disease, rather than only product, level.

16.4 HIV Self-Test Grant

16.4.1 Background

Testing is one of the four priority areas identified in order to address the ambitious goal of eliminating AIDS by 2030, acting as a foundation for both prevention of

²²⁹ The imminent arrival of the RTSS malaria vaccine will also have a large and as yet unclear impact as countries turn some of their funding to malaria immunisation.

transmission and treatment, given HIV’s asymptomatic phase. Large sectors of populations are underserved by current HIV testing, including an estimated 8 million who already have the disease. An easy, affordable self-test (ST) would represent an excellent way to make inroads into these populations, who have been hard to reach and for whom facility-based testing is not working well. This includes men generally, partners of people living with HIV, and adolescents.²³⁰

An oral fluid candidate ST emerged, achieving US FDA approval in 2012, which meant WHO adoption was not a barrier. But initial uptake was disappointing, with suggestions that price and lack of demand within populations were both factors. Three blood-based STs also became available, though also facing limited market uptake.

16.4.2 Grant agreements

Unitaid has played a role in promoting HIV self-testing (HIVST) since 2015 with the first phase of the HIV Self-Testing Africa (STAR) grant launched then. An Afl for HIVST was approved at the end of 2016, calling for a rapid scale-up. The roster of HIVST grants has grown so that at the time of writing it amounts to USD \$96.0 million in total across four grants (with STAR having been extended into three phases).

Grantees

Table 5: Unitaid HIVST grants

Grant	Lead grantee	Amount (USD \$ million)	Duration
STAR (Phases 1–3)	PSI	68.8	Aug 2017–Aug 2021
ATLAS	Solthis	15.7	Jun 2018–Nov 2021
Shuga	MTV Staying Alive Foundation	10	Apr 2018–Jun 2021
Challenge Fund	EJAF	1.5	Jan 2019–Dec 2021

STAR was awarded to Population Services International (PSI, USD \$49.7 million) and the Society for Family Health (SFH, USD \$19.2 million). It is now in its third phase (USD \$15 million), involving partnership with PEPFAR, the GF and CIFF. ATLAS (AutoTest Libre d’Accéder à la connaissance de son Statut VIH) was awarded to French NGO Solthis. Shuga (also known as Accelerating demand for HIV self-testing among young people) is being carried out by MTV’s Staying Alive Foundation. The Challenge Fund was awarded to the EJAF. ATLAS and Shuga have been extended into 2022.

Key activities

STAR aims to increase demand for and access to HIVST, including addressing stigma, discrimination and access barriers. Phase 1 in 2015–17 generated useful evidence,

²³⁰ Unitaid 2020 April Joint FACPSC Update on 2020–22 Investment Plan, p. 8.

while Phase 2 focused on distribution models and scaling challenges, as well as generating further evidence including national-level benefits and cost-effectiveness (see Results below). The initial phases were in Malawi, South Africa, Zambia, Zimbabwe, Lesotho and eSwatini. STAR is now in its third phase, with expansion into six further countries. ATLAS plans to distribute approximately 500,000 test kits to stimulate more investment in West Africa and avert an estimated 6,000 deaths and save over USD \$10 million between 2018 and 2026.²³¹

The Shuga project nests storylines on HIV innovation, including HIVST, within the MTV drama series distributed in various African markets, *Shuga*.²³² The aim is to reach viewers in order to demystify HIV and provide information on how to access HIV services and generate demand for self-testing. Impact estimates assume that among those watching the show there will be a 10% increase in uptake of HIVST.²³³ The Challenge Fund and campaign is undertaken with EJAF and CIFF, aimed at emphasising the importance of HIVST in Kenya.²³⁴

16.4.3 Implementation

STAR Phases 1 and 2 have transitioned to GF funding, while Phase 3 is in the process of this happening. As part of STAR, BMGF negotiated a price reduction of the saliva-based HIVST to USD \$2. The STAR project implemented 13 HIVST distribution models (nine community-based and four facility-based), generating a substantial comparative evidence base.

ATLAS, which started in late 2018, has been significantly delayed by the COVID pandemic. It has produced initial publications and is in the process of transitioning to GF funding in three countries.

MTV Shuga has no transition plan per se, but has made its broadcast and guidance materials available free and clear as may be required by other programmes in future. LSHTM carried out an evaluation of Shuga's effect in South Africa and is now doing the same in Côte d'Ivoire.

COVID and other challenges

The pandemic hit the HIVST grants hard, especially since all involved interactions with populations, which became difficult due to restrictions on movement and contact. Unitaid assessed the level of COVID-related disruption in 2020 to STAR as moderate (20%–40%), ATLAS at a similar level and MTV Shuga as minor (<20%).

16.4.4 Results to date

A UNAIDS study found that self-testing played an important role in contributing to the proportion of people with HIV estimated to be unaware of their condition declining

²³¹ Portfolio Performance Report 2020 1-pagers – UNITAID_EB38_2021, p. 6.

²³² HIV-Disease-narrative, pp. 12–13.

²³³ Portfolio Performance Report 2020 1-pagers - UNITAID_EB38_2021, p. 14.

²³⁴ HIV-Disease-narrative, p. 13.

from 30% in 2015 to 19% in 2019.²³⁵ While attribution analysis is not practicable, Unitaid’s HIVST grants must certainly have played a role within this positive development.

Unitaid’s internal grant performance system²³⁶ awarded ATLAS an overall B rating (of A–D) for 2020, due to delays in roll-out. MTV Shuga also received a B for 2020, with only 45% of the expected number of TV broadcasters and 66% of radio broadcasters using the material, plus a lack of project-generated conferences, journal articles. STAR, too, received a B, given slower than expected progress with Phase 3 (Phases 1 and 2 met all targets). In all cases, COVID-related problems may well have been an important part of the explanation for these shortfalls relative to plans.

Independently evaluated HIVST grant results to date come mainly from the first two phases of STAR, which were jointly evaluated in early 2021.²³⁷ This study found STAR to be ‘overall a highly successful’ project in its catalysis of the HIVST market. STAR ‘generated evidence to attract other scale-up partners, resulting in the total demand for HIVST in LMICs [now being] projected to reach 29 million tests by 2025’.²³⁸ Given modelled assumptions,²³⁹ the STAR grants were forecast to deliver 4.6 million tests directly, and 10.1 million tests additionally procured by funding partners, during the life of the grant. Furthermore, it was forecast that 27 million tests would additionally be procured by funding partners during 2021–25. Based on this and assumptions on health effects,²⁴⁰ the Evaluation suggests an estimated 15,551 lives would be saved, 97,762 HIV infections averted, and 46,500 disability-adjusted life years (DALYs) averted.²⁴¹ However, it is notable that HIVST uptake has not yet matched the speed that was called for in Unitaid’s initial HIVST Afl. Separate modelling also estimated a substantial positive economic impact.²⁴²

But the initial evidence shows significant progress in three dimensions, each representing linked market barriers to be overcome: demand/adoption; supply/delivery; and affordability.

Demand/adoption

²³⁵ UNAIDS. (2020). Global AIDS Update 2020: Seizing the Moment.

https://www.unaids.org/sites/default/files/media_asset/2020_global-aids-report_en.pdf

²³⁶ Portfolio Performance Report 2020 1-pagers - UNITAID_EB38_2021.

²³⁷ APMG Health ‘Unitaid STAR (Self-Testing Africa Initiative): Phase 2 End of Project Evaluation’, May 2021; Washington, DC.

²³⁸ Reference to this figure coming from a source, which was presumably: Unitaid & World Health Organization. (December 2020). Market and Technology Landscape: HIV Rapid Diagnostic Tests for Self-Testing. [PowerPoint Presentation], quoted in APMG Evaluation (2021).

²³⁹ The modelling approach looked at the added health benefit of the tests forecast to be procured by STARS (Phases 1 and 2) and compared this to the number of tests forecast to be procured in the absence of the grant through alternatively procured self-tests and community-based tests. Modelling data from STARS (Phases 1 and 2) Evaluation Report, Annex 6 ‘Modelling Analysis Report’. Note that while much of the modelling seems reasonable, it is surprising that the counterfactual was set to zero HIVSTs being procured in the absence of the grant.

²⁴⁰ These health impacts are based on those of a published study of HIVSTs in Zimbabwe - Cambiano, V., et al. (2015). Assessment of the potential impact and cost-effectiveness of self-testing for HIV in low-income countries. *J Infect Dis*, 212, 570–7. But as a result of testing optimisation, the modelling assumes that yields in South Africa would be 20% higher than this.

²⁴¹ Note: for some reason these totals are greater than those reported in the modelling annex of the same report, which are: 8,520 deaths averted, 53,560 HIV infections averted and 25,476 DALYs averted (p. 69).

²⁴² This estimated that the grants could save USD \$73 million through scale-up, testing optimisation and price reductions, and USD \$156 million further benefits during 2021–25.

Unitaid’s grants have significantly contributed to the research evidence on the efficacy and cost-effectiveness of the different delivery models. This has clearly been the case with STAR, which explicitly aims to increase demand for and access to HIVST. Beyond generation, STAR’s evidence has also been well disseminated to key donors through the HIVST donor group (see below).

STAR evidence from its first phase (2015–17) also supported the first WHO global ‘Testing and Partner Notification Guidelines’ on HIVST in 2016, with HIVST recommended as an additional approach to existing HIV testing services. This was followed by the WHO Enabler grant, which was amended in 2017 to include HIVST. From WHO, HIVST acceptance has rippled out swiftly to national authorities. At the time of writing, 88 countries have policies allowing for HIVST.²⁴³

Supply/delivery

STAR has demonstrated delivery models with improved ability to reach under-served populations.

HIV testing and low rates of testing uptake: this includes young people, men and key populations, including female sex workers and men who have sex with men.

During STAR’s implementation, four new HIVST products became available with WHO pre-qualification (one during STAR Phase 1 and three during Phase 2). At the same time, the suppliers of HIVST products have increased from one (Orasure) to five manufacturers at the time of writing.

Affordability

The affordability, and hence cost-effectiveness, of HIVST has dramatically improved through the STAR programme’s interventions. Self-tests can now be procured for USD \$1.50–\$2 per kit across 135 LICs, LMICs and UMICs (compared to approximately USD \$40 in the United States and up to USD \$15 in the South African private sector in 2015). BMGF achieved a negotiated price reduction to USD \$2 for a limited time and range of countries, but the market developed such that this price continued beyond the expiration of the agreement and spread to other countries – suggesting a clear market shaping success. Unitaid and other partners have also secured lower prices across the range of HIVSTs, using volume pricing and forecasting and bringing together manufacturers to support an increase in the number of products and increased marketplace competition.

Expected further results

Further final grant evaluations are expected in 2022. However, some other evidence, such as LSHTM’s assessment of the effects of MTV Shuga, may emerge before then.

16.4.5 GF relationship throughout the process

Close interaction with GF has been a key feature of much of Unitaid’s HIVST work. While the Afl was produced by Unitaid alone, an experienced ex-GF staffer was

²⁴³ Figure quoted in Unitaid Excel ‘Unitaid-GF market shaping successes’, provided by Unitaid 24 July 2021.

recruited by Unitaid to manage the HIVST (and other related) grants. Unitaid also helped establish a donor group for HIVST in 2017, which included GF, as well as BMGF, PEPFAR, CDC, WHO and others. Focal points were carefully selected and this continues to function well as a coordinating body, especially as regards market shaping, pricing and the generation of data to facilitate subsequent scale-up funding decisions, e.g. at GF and PEPFAR.

GF was closely involved with grant agreements, for example in relation to STAR's Phase 2 extension, although it was less involved with the decisions to embark on ATLAS, MTV Shuga and the Challenge Fund. One aspect which aided GF involvement with implementation and future transition was a requirement that existing GF implementers be used in-country, for example by ATLAS. At present there look to be good prospects for continued close collaboration with GF in STAR Phase 3 and perhaps further HIVST initiatives.

16.4.6 Assessment

Only STAR Phases 1 and 2 have so far been evaluated, but with positive results, even if the HIVST Afl has proven overoptimistic. Forecasts are for a significant catalytic effect, with 4.6 million self-tests procured as part of the grants, leading to a total of 37 million additional tests procured by Unitaid's funding partners during the grant and in the years to 2025.²⁴⁴

It is an open question whether launching STAR Phase 3 earlier, as opposed to ATLAS, Shuga and the Challenge Fund, might not have produced a more rapid transition to scale. This is difficult to assess since, while those three grants did not focus on the rapid scaling that the Afl had called for, they did produce evidence and demand generation which helped establish the foundations for STAR's third phase. Once STAR Phase 3 and the other grants have been evaluated, the overall results will be clearer, even if effects beyond 12 months after grant closure will only be forecasts.

But perhaps most important is that the partnership between Unitaid and GF was a successful one in relation to these grants. It ran throughout the grant cycle. It involved interaction with many elements of GF, from disease specialists to country teams. It was also inclusive, with the two organisations also helping to bring together other important global stakeholders via the donor group.

The grants' concentration on sub-Saharan Africa and on currently underserved HIV-susceptible populations implies that their results will be strong on Equity grounds, though this is not yet measured in aggregate by GF or Unitaid.

Some key lessons from Unitaid's HIVST suite of grants, involving the GF relationship and other aspects, are:

- There was excellent collaboration at country level. This involved implementers, national health authorities, evaluators (e.g. LSHTM) and also, to an extent, both GF and Unitaid country staff. Given that country-level interactions are

²⁴⁴ Note that there was no opportunity to review the evaluation modelling, and the independent evaluators did comment that it lacked any unified model reporting document and that 'several decisions or steps [...] are opaque' (STARS evaluation, pp. 72–3).

sometimes seen as a weakness in the Unitaid model, this is a particularly important success, with good potential for future scale-up.

- The end of grant independent evaluation of STAR Phases 1 and 2 was generally positive and underlined the usefulness of such evaluations. However, it did suggest that greater transparency would be advisable in relation to the modelling of forecasted results. This would have the effect of strengthening credibility regarding grant Effectiveness.
- The donor group mirrored country-level activity with effective coordination at global level. Creating such an institutional link mitigates the risk that good collaborations (e.g. between Unitaid and GF) depend excessively on personal relationships which might not last beyond those individuals' combined time in post. However, it should be noted that it is not sufficient to invite all of the relevant organisations. Care must also be taken in prior identification of who would be the best focal points within each organisation. As the HIVST case proves, this is very much a possibility.
- The Unitaid grant staff had the relevant skill and experience sets, minimising necessary learning. These grants have related strongly to service delivery and that was a good fit to the team (if the grants had been research-related this team might well have not worked so well). Key individuals in the team also knew well both the GF and how the several USG agencies worked, including PEPFAR and CDC. Not all global health staff will navigate well across the multiple USG agencies that participate in global health, each with separate agendas and ways of working.



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