

**Unitaid HIV Self Testing
(HIVST) area for intervention
– Joint end of project
evaluation**

Final Report

Supplementary Appendices



10 June 2022

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Appendix H Summary of Evaluation Findings: STAR 1 and 2

The evaluation conducted a review of the STAR Phase 1 and 2 evaluations across the dimensions of OECD DAC evaluation criteria. This informed lines of enquiry in the key informant interviews and country case studies, and assessment of the extent to which the current portfolio applied the lessons and recommendations from past evaluations.

A summary qualitative rating was developed for each evaluation criteria, with a high level summary of key findings within each criteria.

Table H.1: Summary of STAR Phase 1 and 2 evaluations

'Rating'	OECD Evaluation Criteria	STAR Phase 1	STAR 2
	Relevance	<ul style="list-style-type: none"> ✓ “Bold move” from Unitaid given the early stage of the HIVST market, underscoring Unitaid’s role and comparative advantage in GH architecture. Largest HIVST demonstration project. 	<ul style="list-style-type: none"> ✓ Crucial intervention to decrease the testing gap, particularly in helping to reach those not reachable by conventional testing. ✓ Equity oriented framework and improved access to HIVST for key populations, AGYW and men ✓ Reduced stigma and discrimination ✓ Demonstrated Safety HIVST M Cost-effectiveness and suitability compared to community-based peer testing
	Coherence		<ul style="list-style-type: none"> ✓ High coherence with other HIV testing interventions (ART, ANC, PrEP, VMMC) ❖ PEPFAR yield threshold challenge ✓ CSOs ❖ National AIDS Councils
	Efficiency	<ul style="list-style-type: none"> ✓ Coordination/management by STAR Core team/PSI and results measurement ✓ Risk mitigation, management ✓ 83% HIVST distribution through CBD 	<ul style="list-style-type: none"> ✓ Value for money ✓ Balance between commodities, supply, delivery ❖ Layering grantees in South Africa ❖ Inflexibility in implementation period / Unitaid approval process ✓ Timeliness: pick up quickly on buy-in generated by P1; continuation during Covid ✓ National Authority Collaboration ✓ Models: 9 CBD, 4 facility (8 NEW)

- ✓ Indicates positive leaning finding
- ❖ Indicates an issue/challenge identified
- M Indicates more mixed findings

'Rating'	OECD Evaluation Criteria	STAR Phase 1	STAR 2
●	Effectiveness	<ul style="list-style-type: none"> ✓ Affordability ✓ Demand&Adoption <ul style="list-style-type: none"> ✓ As of Oct 2017: 41 countries had national HIVST policies (23 LMICs). Mostly SSA, with less progress in AP and LAC regions ✓ Awareness and acceptability of HIVST in countries and global (extensive knowledge management/dissemination) ✓ Without the STAR project, the WHO guidelines on HIV self-testing would have been produced a few years later ✓ Supply&Delivery 	<ul style="list-style-type: none"> ✓ Affordability ✓ Demand&Adoption <ul style="list-style-type: none"> ❖ Cost of some CBD models > facility models ❖ Facility models moderate effectiveness ✓ As of July 2020, 88 countries had HIVST policies, 41 countries implementing, 31 had policy in-development. ❖ Facility HIVST: some gains, but did not reach men at scale Results show reaching 1st time testers requires targeting/innovation to find underserved spaces and sub-populations. (cannot 'mass distribute'). Covid brought innovation: pharmacy direct distribution, online, retail ✓ Supply&Delivery <ul style="list-style-type: none"> ✓ 100% national PSM systems procuring WHO-recommended HIVST ❖ Stock outs 2 countries, did not impact outcomes <p>Factors: Implementation-Research Consortium, #dissemination, early GF and PEPFAR engagement, lens on producing data to inform WHO</p>
●	Impact (testing gap)	<p>Public Health impact</p> <p>Linkage to care – current evidence limited on uptake of care and treatment following HIVST Issues with methods to monitor linkage, and service models</p> <p>Linkage to prevention – some evidence. Missed opportunity was integration of HIVST with other interventions</p>	<ul style="list-style-type: none"> ✓ Helped to close the HIV testing gap; however, challenges remain regarding a significant global funding gap for HIVST through 2025. ✓ By 2020: 3 countries met 90- targets, 1 close ✓ Equity - poorest, underserved <p>Main limitation to impact is that ongoing scale-up is unlikely under either MoHs or PEPFAR and will depend on other motivated funders, the private sector and consortium of partners entering the arena. With a strong preference for proven linkage and facility-based distribution by ministries of health and PEPFAR, community distribution is only likely to continue as a relatively small proportion of future HIVST in all countries, despite innovation and reach into remote and under-served populations depending on these modalities.</p>

- ✓ Indicates positive leaning finding
- ❖ Indicates an issue/challenge identified
- M Indicates more mixed findings

'Rating'	OECD Evaluation Criteria	STAR Phase 1	STAR 2
●	Sustainability	<ul style="list-style-type: none"> ✓ Social Impact (convenience, confidentiality, choice) ✓ Health system efficiencies (CB testing reduces load on health service testing) 	<ul style="list-style-type: none"> ✓ Enabling env't: national governments have strongly endorsed HIVST, see its value, and have been able to fast-track it into mainstreamed systems ❖ Concerns on gov't preference for facility models ❖ Transition of demand generation in Lethoso, M&E in many countries ✓ HIVST viewed as critical for 95-95-95 2030 targets ✓ HIVST as a triage tool brings cost reduction/time saving ✓ National Capacity built, regulatory (most countries), supply chain ✓ Securing funding (KPI 3.1) full achieved ❖ Missed Private sector models (S.Africa excellent examples) <p>STAR shifted thinking about HIV testing in general - there was a clear link between HIVST and self-care and the movement towards democratization of health and letting people do things on their own and be more in control of their health.</p> <p>Multiple studies of STAR show high variation in cost by model and country. To SA gov't – justification for funding hinged on reaching high risk groups not accessing conventional testing, thus long-term cost-benefit of finding them.</p> <p>Facility model offers health system efficiencies of 1/8th staff input</p>

- ✓ Indicates positive leaning finding
- ❖ Indicates an issue/challenge identified
- M Indicates more mixed findings

OECD Criteria	Evaluation recommendations (green = STAR 1 evaluation)
Overarching	Advocate for the sustainability of high-impact community-based HIVST models and clearly communicate the equity imperative to scale up to funders and national governments.
Relevance Design	<p>When selecting countries in the future consider both disease burden but also qualities of regional leadership and expertise. Fund a mix of different countries in various regions with diverse needs that could catalyze a new technology.</p> <p>Develop guidance for choosing countries for new funders.</p> <p>Continue to fund operational research but develop agency guidelines and training to minimize perceived conflict of interest.</p> <p>Relevance of community distribution in countries with focused epidemics</p> <p>Expand partnerships with a wide range of potential scale-up partners, including the private sector, to expand reach and sustainability.</p> <p>Continue to partner closely with scale-up partners, in addition to improving partnerships with national governments, local innovation partners, and the private sector to ensure sustainability.</p>
Efficiency	<p>2 yr Unitaid approval process – scope for lighter touch?</p> <p>Streamline funding approval processes and limit layers of approval to improve timely replies to grantees. Ensure grantees have adequate autonomy for adjusting plans with limited bureaucracy in keeping with a catalytic, innovative granting agency.</p> <p>M&E that allow for increased experimentation/risk taking, rather than stifling innovation</p> <p>Develop more transparent quantitative metrics related to supply chain and procurement (e.g., stock-outs, expired products, % of consignments delivered on time in full (OTIF)).</p>
Unitaid portfolio synergies / positive externalities	<p>Leverage equity lessons from STAR and improve agency-wide health equity key performance indicators (KPIs) to better reflect strategic objectives, including clear expectations for grants to report on disaggregated results and differentiation of unique subgroup needs (age, gender, ethnicity, rurality, etc.)</p> <p>Identify and share lessons from HIVST that could be applied to other self-testing technologies for other diseases:</p> <ul style="list-style-type: none"> • digital health tools to support patient testing and navigation; • frameworks for identifying the right mix of self-testing and provider testing; • focus on regulatory barriers and rigorous research with direct links to WHO guideline process and national policy-makers; • Research consortium approach with frequent in-person meetings to build trust among a large network of stakeholders <p>Clearly scope and define Unitaid’s role in the development ecosystem and review best practices and innovations in catalytic funding models.</p>

Appendix I Distribution and procurement of HIVST kits by country

Figure I.1 shows the total number of HIVST kits distributed by STAR 3 and ATLAS as of the end of 2021. Distribution in Côte d'Ivoire and Mali were highest, followed by Uganda and Nigeria. The pilot nature of the HIVST projects reflects these volumes.

Figure I.2 shows the total number of kits distributed nationally (funded by all donors, including Global Fund, PEPFAR, and Unitaid HIVST projects) by country. Uganda significantly outpaces countries in HIVST procurement, followed by other STAR 3 countries. As per stakeholder interviews in Uganda there is strong government leadership in HIVST and multiple funders are supporting HIVST.

Data were obtained from ATLAS and STAR 3 2021 annual reports.

Figure I.1: Cumulative number of kits distributed by STAR 3 and ATLAS, as of 2021 Annual Reports

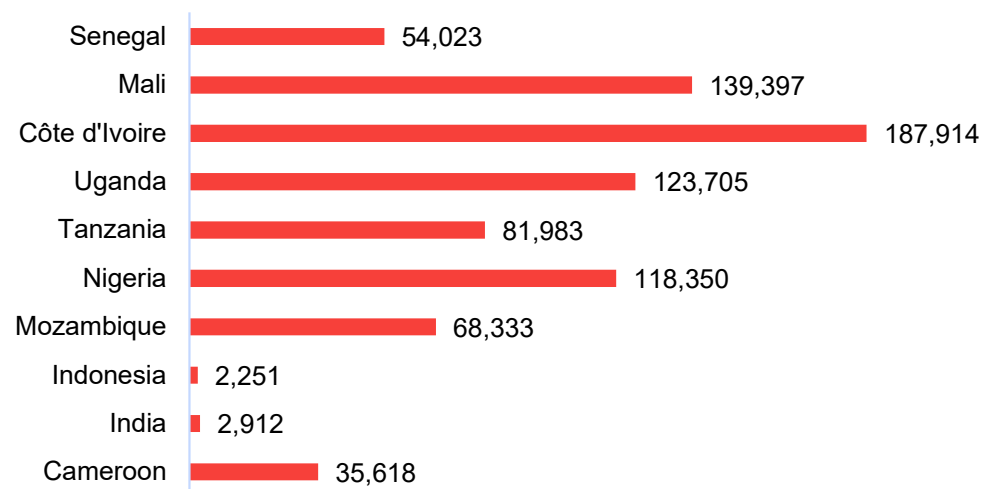
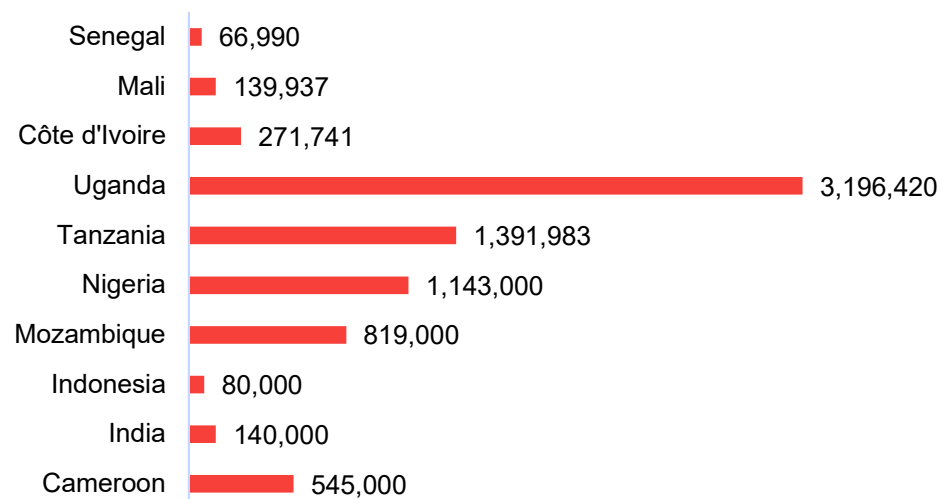


Figure I.2: Cumulative number of kits distributed nationally (funded by all donors), as of 2021 Annual Reports



Appendix J Budget Analysis

All budget analyses display actual project expenditure for the period up until December 2021 (dark purple), and projected 2022 expenditure (light purple), based on 2021 financial reporting and the 2022 disbursement request in the 2021 Annual Report.

ATLAS

The ATLAS budget analysis in Figures J.1-3 use the project 2018 budget of US\$15.7m. Dark blue bars in figures J.2-J.3 represent target budget per output/ expense group (as a % of total budget), and purple data labels show the combined actual and projected expenditure (as a % of total budget).

Annual budget expenditure (Figure J.1): Overall, 93% of the budget was spent by the end of 2021 and is projected to be fully spent by project close in June 2022. The annual consumption rate increased from 6% in 2018 with delays in implementation leading to underspending in the first 2 years of the project. A course-correcting acceleration of activities was achieved, resulting in ‘catch up’ in years 3 and 4.

Expenditure by output (Figure J.2): The expenditure for Output 2 (implementation of service delivery models) was highest with a budget of US\$4.6m and was the most advanced by December 2021. Additional freight costs were cited in ATLAS reporting and variance analysis as leading to slight overspending for Output 2 (which also included procurement and supply chain).

Figure J.1: ATLAS actual and projected annual expenditure as a percentage of total budget (2018-2022)

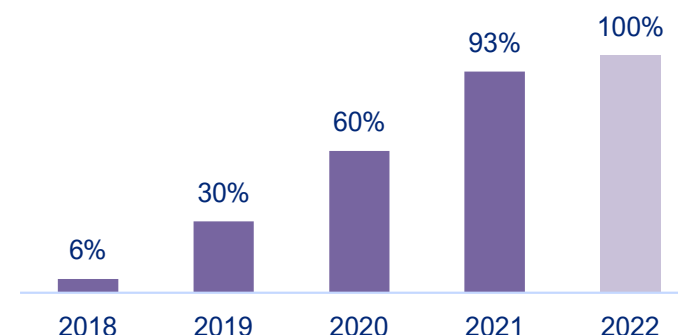
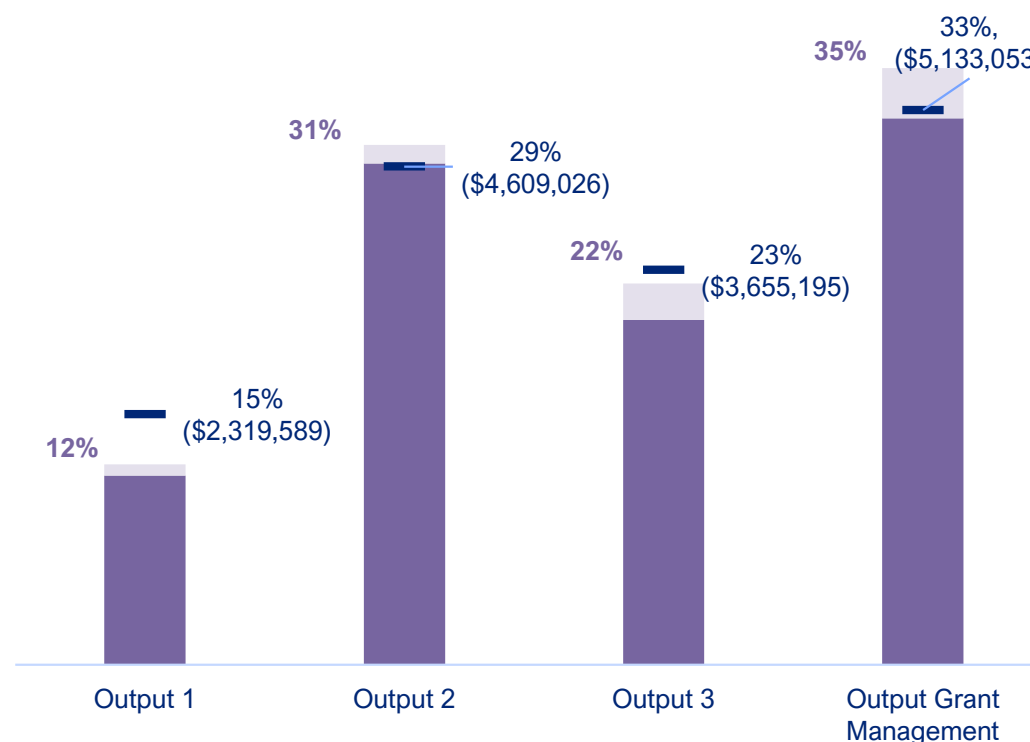
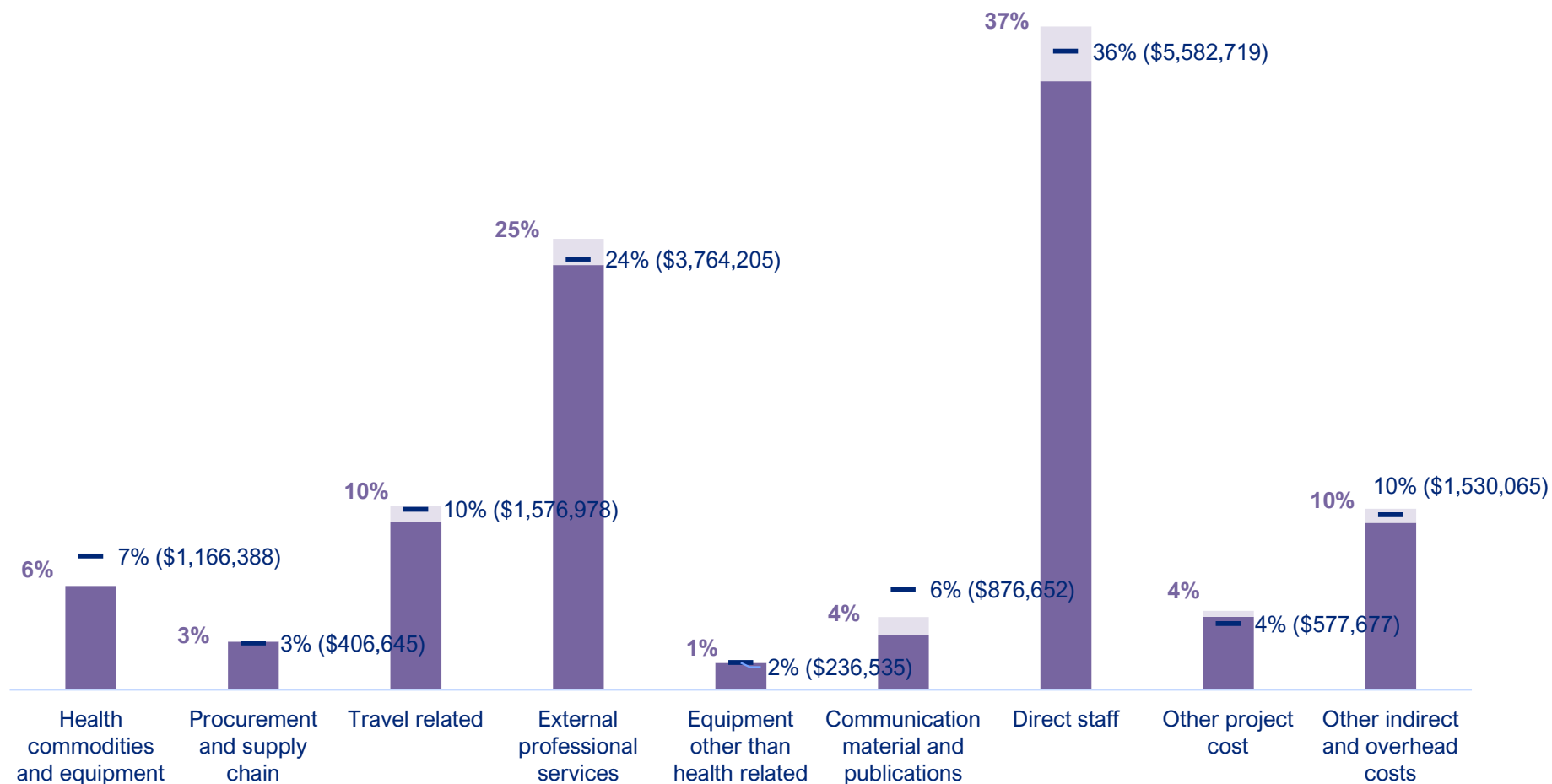


Figure J.2: ATLAS actual and projected expenditure as a percentage of total budget by Output (2018-2022)



Expenditure by expense group (Figure J.3): The expense group 'communication material and publications' was the least advanced, as only a portion of planned activities have occurred so far with delays until 2022. Expenditure on health commodities and equipment is also low compared to the original budget, however in April 2021 procurement targets for HIVST kit distribution were revised downward by 20% to account for delays due to COVID-19.

Figure J.3: ATLAS actual and projected expenditure as a percentage of total budget by Expense Group (2018-2022)



STAR 3

The analysis of STAR 3 expenditure in Figures J.4-6 contains several limitations and caveats: i) 2022 projected expenditures exceed 100% of the HIVST program budget as they reflect inclusion of new outputs (e.g. HepC and COVID-19 activities within STAR 3) which could not be disaggregated owing to limitations in reports of projected expenditure; ii) significant budget reallocations within STAR 3; iii) the addition of the market intervention in 2020 and 3 new outputs in 2021 (excluded from analysis as out of scope for the evaluation: HepC self-testing, COVID-19 self-testing, and private sector initiative); iv) blended financial reporting meant that some STAR 2 data was included in 2020.

The original STAR 3 budget was \$16.9 million which is used in this analysis (Figures J.4). Figures J.5-6 use the original budget plus \$3.5m allocated to the market intervention. Dark blue bars in figures J.5-J.6 represent target budget per output/ expense group (as a % total budget), and purple data labels shows actual and projected expenditure (as a % total budget).

Annual budget expenditure (Figure J.4): Overall, 76% of the total STAR 3 grant had been spent by December 2021, with 134% projected to be spent by December 2022. Spending in excess of the budget is likely due to limitations in the analysis outlined above.

Expenditure by output and expense group (Figures J.5 and J.6): Activities from 2021 were delayed and carried forward to 2022. This includes \$1.8m for procurement of HIVST kits, and costs of distribution, communication materials, staff, finalisation of scale-up and dissemination of findings.

Figure J.4: STAR 3 actual and projected annual expenditure as a percentage of total budget (2020-2022)

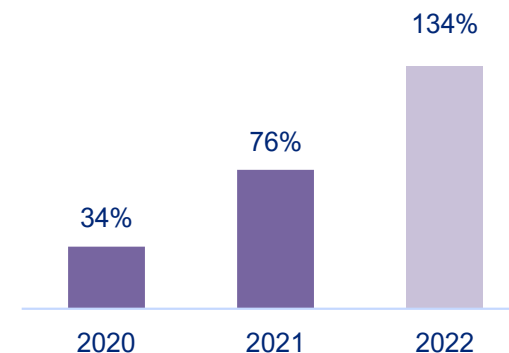


Figure J.5: STAR 3 actual and projected expenditure as a percentage of total budget by Output including Market Intervention (2020-2022)

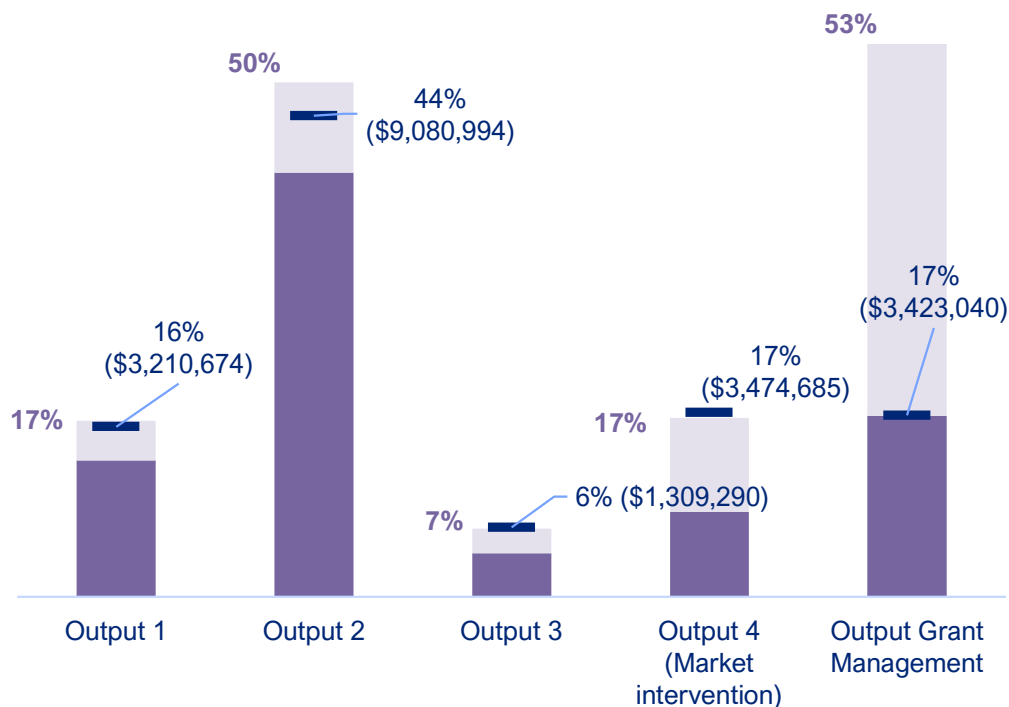
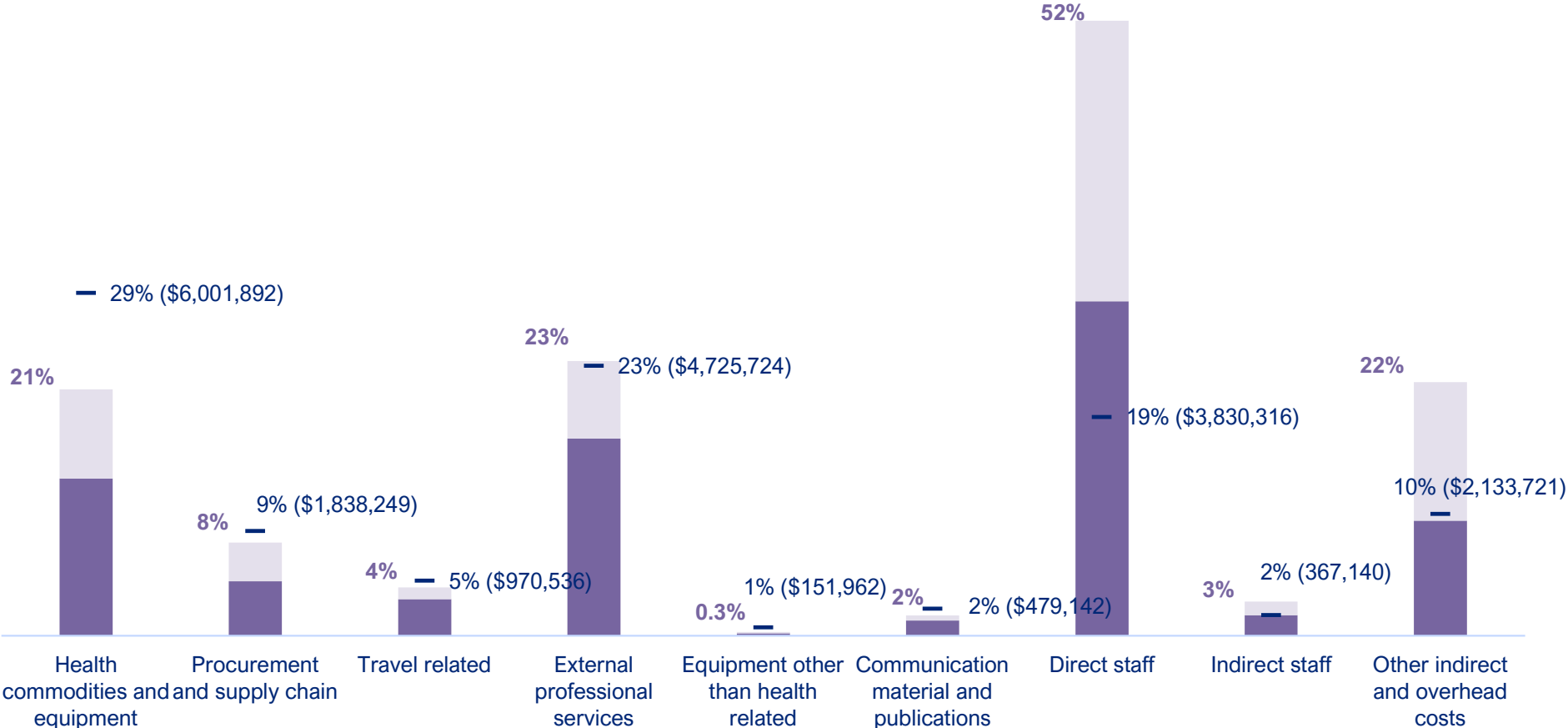


Figure J.6: STAR 3 actual and projected expenditure as a percentage of total budget by Expense Group including Market Intervention (2020-2022)



MTV Shuga

The analysis of MTV Shuga expenditures in Figures J.7-9 was based on the original budget of US\$10.1m (2018). The expenditure analysis in Figures J.7-9 contains the caveat that 2022 projected expenditures exceed 100% of the program budget as they reflect inclusion of new activities (television series in Nigeria and South Africa). Dark blue bars in figures J.8-J.9 represent budget per output/ expense group (as a % of total budget), and purple data labels shows actual and projected expenditure (as a % of total budget).

Annual budget expenditure (Figure J.7): Overall, 87% of the budget had been spent by December 2021, with 114% of the budget expected to be spent by 2022 (a total of \$11.5m, see text on caveats above). Delays in implementation in Côte d'Ivoire led to underspending in the first 2 years of the project. A course-correcting acceleration of activities and budget consumption was achieved in 2020 and 2021.

Expenditure by output (Figure J.8): The expenditure for output 2 (implementation of mass media campaigns) is the highest with projected total expenditure at \$8.6m and was the most advanced by December 2021. Expenditure for output 3 (data demonstrating youth demand) was the least advanced by December 2021. Due to delays in implementing the LSHTM-led evaluation, costs have not been invoiced.

Figure J.7: MTV Shuga actual and projected annual expenditure as a percentage of total budget (2018-2022)

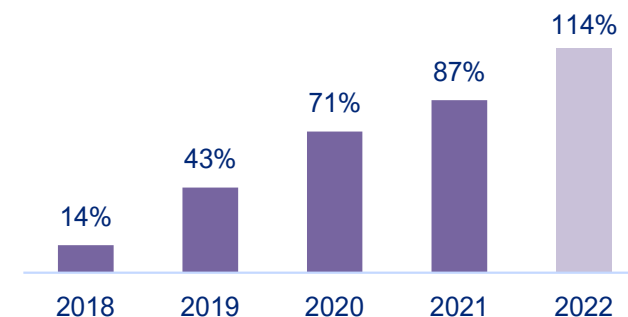
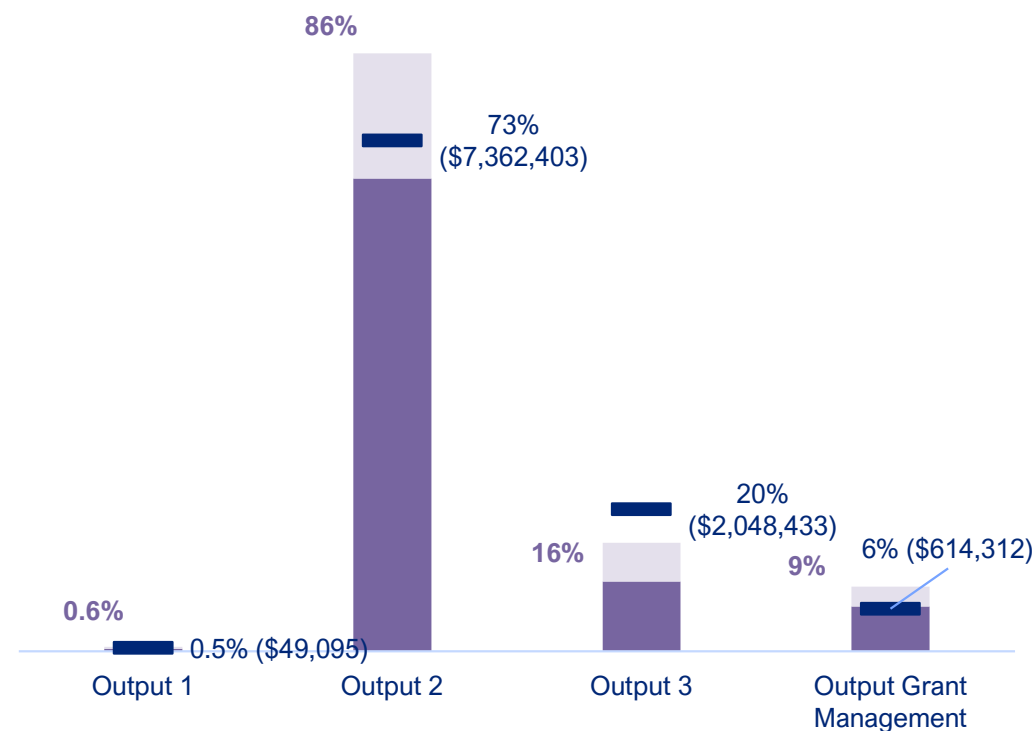
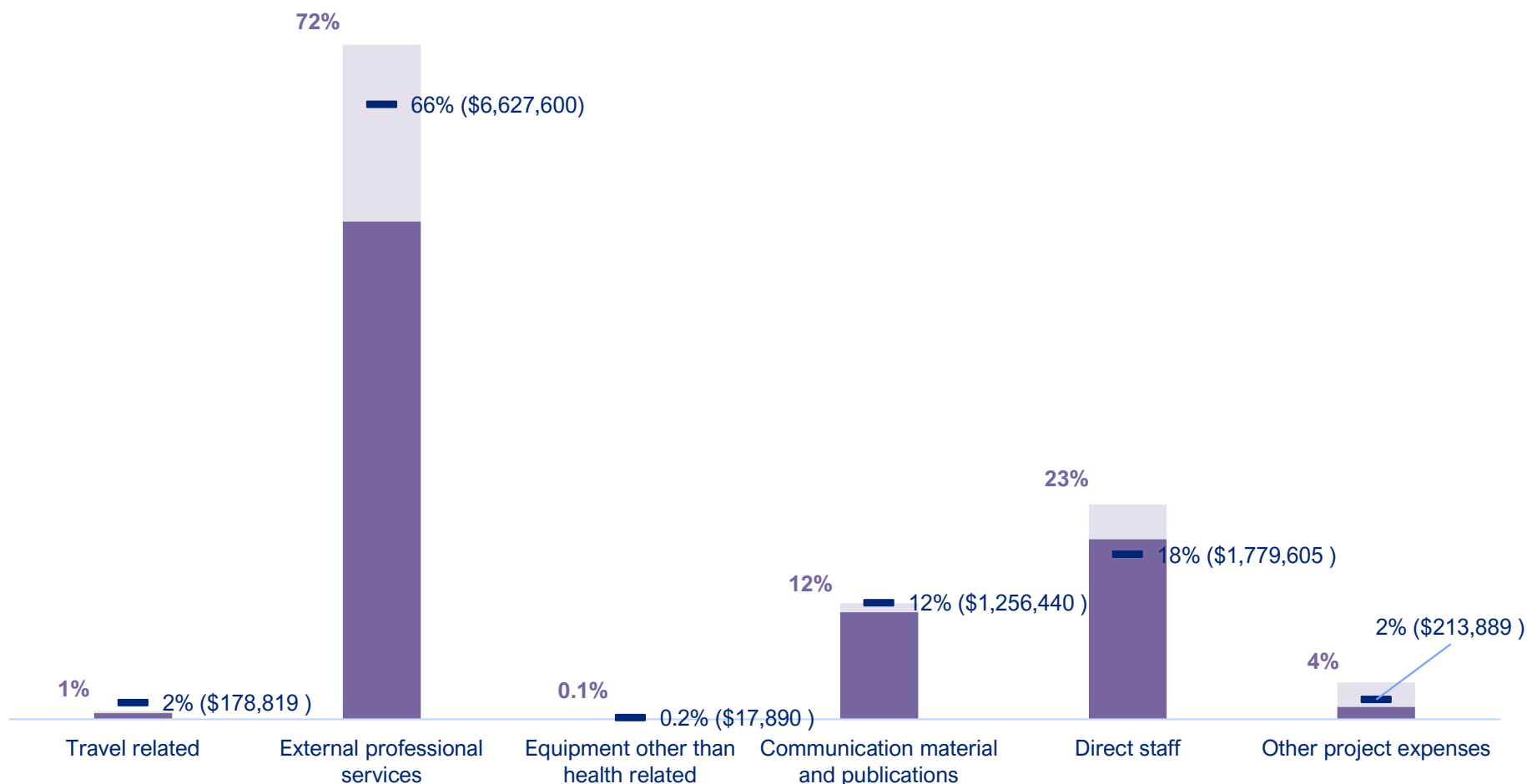


Figure J.8: MTV Shuga actual and projected expenditure as a percentage of total budget by Output (2018-2022)



Expenditure by expense group (Figure J.9): Reported cost savings include lower costs for equipment and activities in Côte d'Ivoire as they were transitioned to an online format and limited travel-related costs overall due to COVID-19. Funds saved were reprogrammed for use in Nigeria. Note the analysis excludes a projected cost of \$9,600 for COVID-19 protective equipment.

Figure J.9: MTV Shuga actual and projected expenditure as a percentage of total budget by Expense Group (2018-2022)



Appendix K Findings by OECD-DAC Criteria (portfolio level)

Table K.1 presents analysis of the HIVST portfolio by OECD-DAC evaluation criteria.



Table K.1: Summary Findings by OECD-DAC Evaluation Criteria of the Unitaid HIVST portfolio

Evaluation dimension	Key Findings	Extent achieved*	Strength of evidence**
Relevance	<ul style="list-style-type: none"> Unitaid's HIVST portfolio was highly relevant and fit-for-purpose to the objectives of bringing HIVST to scale in high burden countries with a large testing gap and creating sustainable market conditions for a new and innovative diagnostic tool. The investments highlight the complexity in moving from evidence to policy, and county readiness, and encouraging donor financing for scale. The phasing of all HIVST grants was appropriate as they leveraged the foundation created by early STAR phases and catalytic impact of the 2019 WHO guidelines on donor readiness. PSI, Solthis and MTV SAF were appropriate partners for the HIVST grants, suitably expanding and partnering with relevant sub-grantees in select countries. HIVST projects were suitably tailored to reach high-risk populations not accessing conventional HIV testing services, including in highly stigmatised contexts. The catalytic EMAV for blood-based tests (BBT) has been highly relevant for expediting access to HIVST by creating conditions for a more diverse range of available products. However earlier intervention to lower the price of BBTs may have mitigated current lower demand for BBT. The HIVST portfolio responded to several STAR 1&2 evaluation recommendations, including a greater focus on demand generation via the MTV Shuga grant. Notably, private sector models were introduced in the final year of STAR 3. 	Fully achieved	
Coherence	<ul style="list-style-type: none"> The HIVST portfolio was highly coherent with global partners in that it intentionally sought to establish alignment with HIV scale-up donors and a multisectoral HIV response via ILO collaboration. At country level, there was strong synergy with existing HIV service provision and partners. Linkage to prevention services was weak in some contexts and also limited by service availability. Unitaid's HIVST investments have been conceptually coherent as a portfolio and are being leveraged for other Unitaid self-testing investments. At an operational level there are some examples of synergies between the HIVST investments but also missed opportunities. Demand creation for PrEP and HIVST through the MTV Shuga platform was a novel channel supporting the goals of Unitaid's Afls and promoting self-care in target populations. 	Largely achieved	



*Not achieved, slightly achieved, moderately achieved, largely achieved, fully achieved

** Poor, limited, moderate, strong

Findings by OECD-DAC Criteria (portfolio level)

Evaluation dimension	Key Findings	Extent achieved*	Strength of evidence**
Efficiency	<ul style="list-style-type: none"> Across the portfolio, grants underestimated the time required for preparatory groundwork prior to HIVST delivery. Notwithstanding these delays, as well as the COVID-19 pandemic, milestones were largely on track at the end of 2021. Risks due to the COVID-19 pandemic were well-managed by implementers and Unitaaid. The COVID-19 pandemic most significantly disrupted the Global Fund/STAR 3 timelines and ATLAS research. Grant expenditure reflect the slower pace of project delivery during year 1, rising in subsequent years. The composition of grant budgets across Unitaaid categories was regarded as appropriate by stakeholders and key to the overall success of grants. Overall, Unitaaid management of the HIVST portfolio was regarded as highly supportive and responsive. Some decision-making processes however were viewed as lengthy, resulting in uncertainty, misalignment and compressed timelines for grantees. Across the portfolio, there were intentional approaches that helped ensure value for money and work towards affordable and sustainable models. STAR 3 and ATLAS are widely regarded as ‘government owned and led’ through intentionally integrating the projects within national HIV programmes. Overall, there was strong engagement of civil society and community-based organisations involved in national HIV responses, reflecting the focus of the HIVST portfolio to reach KP and AGYW communities. 	Largely achieved	
Effectiveness		Largely achieved	
<i>Demand & Adoption</i>	<ul style="list-style-type: none"> The HIVST portfolio of grants has significantly “moved the needle” on the enabling national policy environment for HIVST. Unitaid catalytic funding for HIVST in West Africa has helped “break the barriers” to country demand and adoption, with the ATLAS project demonstrating feasibility of HIVST in a concentrated epidemic and providing engaged TA across multiple countries to facilitate wider regional uptake. STAR 3 programmatic data indicate evidence of good linkage to treatment in many settings, though weak linkage to prevention (VMMC and PrEP). While overall country partners highly regarded HIVST as a valuable addition to HTS, concerns were raised regarding confidentiality and linkage approaches, and messaging within the workplace model. MTV Shuga demand creation model was positively associated with HIVST awareness and use, and with knowledge of PrEP, however in South Africa young people did not have confidence in supply. More upfront work to prime programs for introduction and use of Blood-based tests (BBT) (both at the end-user and programmatic levels) may have paved the way for more rapid demand and uptake of BBTs. 		
<i>Affordability</i>	<ul style="list-style-type: none"> The market intervention was critical in achieving price parity between blood based and oral fluid HIVST (< US\$2), facilitating integration of BBTs into the global HIVST arena and country experience with BBT. This likely would not have been possible without the Unitaaid investment. Work to improve understanding and transparency of HIVST pricing has been beneficial, including with regards to its cost effectiveness, but the more expensive HIVST sticker price remains a concern for some stakeholders. Affordability in the private sector remains a key concern for stakeholders who are highly supportive of expanding HIVST availability in this channel. 		

Findings by OECD-DAC Criteria (portfolio level)

Evaluation dimension	Key Findings	Extent achieved*	Strength of evidence**
<i>Supply & Delivery</i>	<ul style="list-style-type: none"> STAR 3 and ATLAS have demonstrably strengthened national Procurement and Supply Management (PSM) for HIVST. Overall country capacity in procurement and supply chain remains a weaker aspect in the transition to Global Fund grants. 		
Sustainability & Scalability (global and country)	<ul style="list-style-type: none"> Unitaid's HIVST portfolio has significantly accelerated global conditions for scale across dimensions of sustainable access conditions, coordination with donors/partners and evidence dissemination. STAR 3 and ATLAS have significantly contributed to the Unitaid country conditions for scale up. As the projects were sub-national there remains significant work to scale nationally (or in key areas). 	Largely achieved*	
Impact: Equity	<ul style="list-style-type: none"> The HIVST portfolio has contributed to more equitable access to HIV services and information among different populations and regions, and accelerated access to HIV innovations in under-invested regions. 	Fully achieved	
Positive externalities and strategic benefits	<ul style="list-style-type: none"> Unitaid's HIVST portfolio has contributed to opening the gates for self-testing of other diseases, provided a platform for Covid-19 and HCV self-testing introduction and accelerated global guidelines on self-testing. The Covid-19 pandemic has helped to normalize self-testing, and has been an accelerator for self-care, including HIVST. 	n/a	



*Not achieved, slightly achieved, moderately achieved, largely achieved, fully achieved




** Poor, limited, moderate, strong




Appendix L Unitaid KPI Table (portfolio level)

Table L.1 presents the portfolio level assessment of progress against Unitaid KPIs. KPIs 2,3 and 5 were in scope for this evaluation, plus a qualitative assessment of impact (KP4). Quantitative impact estimates were contracted separately by Unitaid will be referenced in the next evaluation report as available and where useful for Unitaid.

Table L.1: KPI Analysis for Unitaid HIVST portfolio

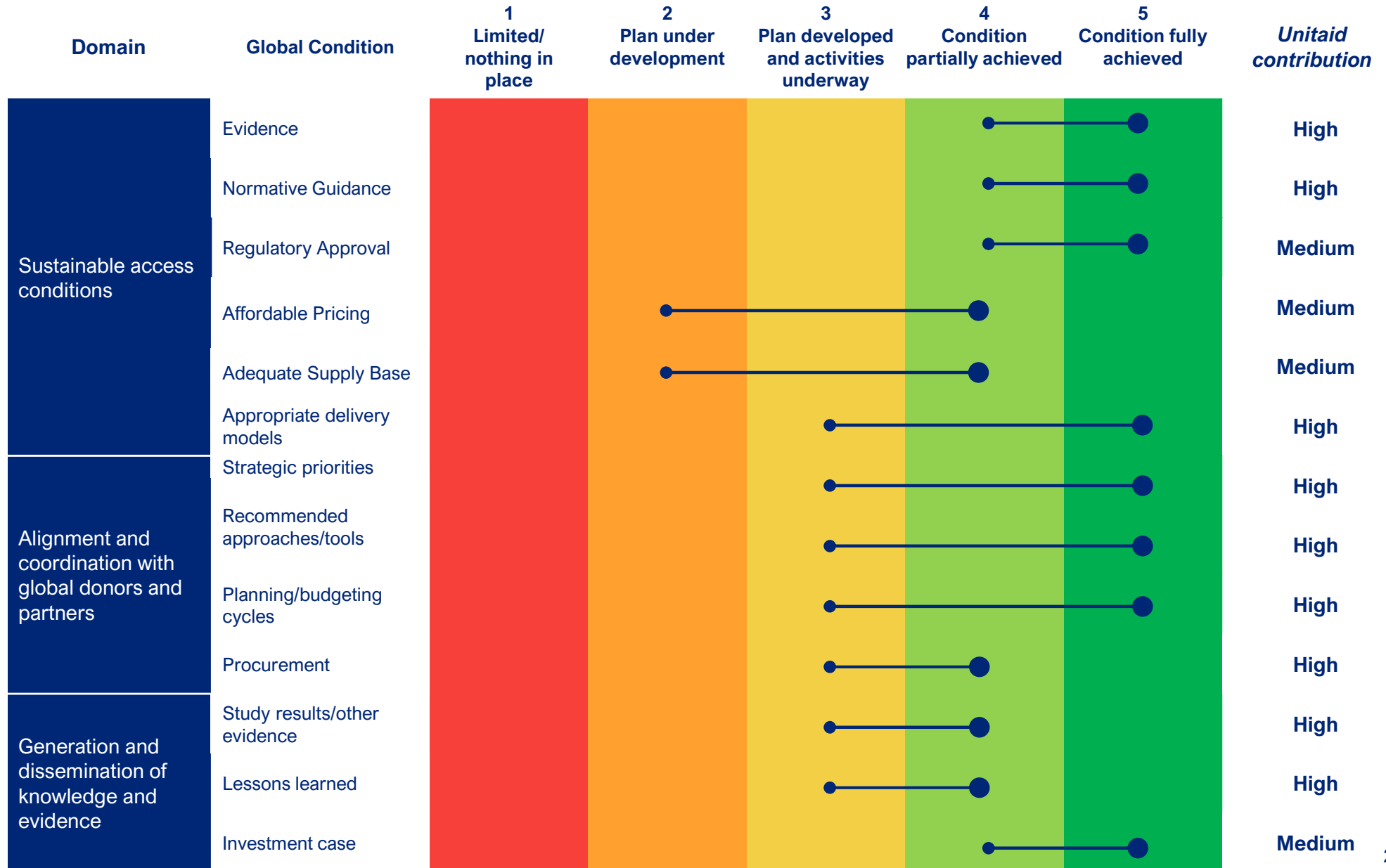
KPI	Evidence of Progress	Level of grant contribution	Strength of evidence ^{***}
KPI 2: Overcoming Access Barriers			
Affordability	<ul style="list-style-type: none"> +The market intervention was critical in achieving price parity between blood based and oral fluid HIVST (< US\$2), facilitating integration of BBTs into the global HIVST arena and LMIC country experience with BBT. This likely would not have been possible without the Unitaid investment. +Work to improve understanding and transparency of HIVST pricing has been beneficial, including with regards to its cost effectiveness. -The more expensive HIVST sticker price remains a concern for some stakeholders. -Affordability in the private sector remains a key concern for stakeholders who are highly supportive of expanding HIVST in this channel. 	Medium	
Demand & Adoption	<ul style="list-style-type: none"> +HIVST portfolio has significantly moved the needle on enabling national policy environment for HIVST: grants supported operational readiness of countries and integration of HIVST in HTS guidelines in all ATLAS and STAR 3 countries (except India). +Unitaid catalytic funding for HIVST in West Africa has helped “break the barriers” to country demand and adoption, with the ATLAS project demonstrating feasibility of HIVST in a concentrated epidemic and providing engaged TA across multiple countries to facilitate wider regional uptake. +STAR programmatic data indicate evidence of good linkage to treatment in many settings. -STAR programmatic data indicate weaker linkage to prevention (VMMC and PrEP). -While overall country partners highly regarded HIVST as a valuable addition to HTS, concerns were raised regarding confidentiality and linkage approaches, and messaging within the workplace model. +MTV Shuga demand creation was positively associated with HIVST awareness and use, and with knowledge of PrEP. -However, in South Africa the LSTHM evaluation reported young people did not have confidence in supply (real or perceived). -More upfront work to prime programs for introduction and use of Blood-based tests (BBT) (both at the end-user and programmatic levels) may have paved the way for more rapid demand and uptake of BBTs. 	High	

KPI	Evidence of Progress	Level of contribution	Strength of evidence
KPI 2: Overcoming Access Barriers			
Supply & Delivery	<p>+STAR 3 and ATLAS have demonstrably strengthened national Procurement and Supply Management (PSM) for HIVST, having achieved a majority of PSM milestones with handover to NFM3 and PEPFAR procurement underway or shortly anticipated.</p> <p>+WHO PQ CRP workshops have been held in Cameroon, Uganda, and Mozambique to accelerate the registration of WHO PQ HIVST kits.</p> <p>-In some countries, procurement and supply chain capacity remains a weak point in the transition to Global Fund and PEPFAR grants and scaling up and need to integrate HIVST within HTS.</p>	High	
KPI 3: Scalability			
KPI 3.1- Securing Funding	<p>+Between NFM2 and NFM3, the Global Fund increased its HIVST investment from US\$ 17m to US\$ 71.8m (the matching CIFF grant comprises US\$ 47.9m of the NFM3 value)</p> <p>+The Global Fund is now preparing the Modular Framework for NFM4 (2024) which will require all country HIV funding requests to include HIVST and to report on HIVST, which is not required in NFM3.</p> <p>+PEPFAR has increased HIVST financing, and procured 4 million HIVST kits in 2021, as well as complementary support for services.</p>	High	
KPI 3.2- Scaling up coverage	<p>+Joint design of STAR 3 with Unitaid, Global Fund, CIFF and WHO, paved a direct path from STAR 3 distribution projects to implementation at a much larger scale under NFM3.</p> <p>+ATLAS has catalysed spillover in the WCA region, with 90% of WCA countries including HIVST in NFM3 proposals.</p> <p>+The approach of working through governments and building on existing HIV services by civil society and CBOs, with significant capacity strengthening, has resulted in strong country leadership to expand coverage underpinned by national policies and tools.</p> <p>+The EMAV to lower the price of the Viatrix/Mylan BBT, together with HIVST volumes financed by NFM3 positively contributed to the HIVST market resilience and consumer choice and has given more confidence to manufacturers of anticipated volume growth (see next).</p> <p>+/-The 2021 WHO HIVST demand forecast projects total LMIC demand to reach 27.7m tests by 2025. This is a slight reduction from the 2020 forecast of 29m tests in 2025 driven by slower growth for early adopter countries and reduced expectations for India, Indonesia and the Democratic Republic of the Congo</p> <p>-As the projects were sub-national there remains significant work to scale nationally (or in key areas), including PSM</p> <p>+ MTV Shuga reached audiences beyond South Africa and Côte d'Ivoire and MTV SAF reports Netflix Africa has picked up both series.</p>	High	

KPI	Evidence of Progress	Level of contribution	Strength of evidence
KPI 4: Impact (qualitative assessment)			
	<p>+the STAR 3 pilots monitoring linkage to treatment and prevention show an overall high linkage to ART, indicating HIVST channels are successfully identifying PLHIV who were unaware of their status and connecting them to services. This contributes to reducing morbidity and mortality from HIV, as well as ongoing transmission and new infections.</p> <p>+STAR 3 countries are amongst those with the largest burden of HIV that were not yet implementing HIVST. Prioritisation of these countries, and expansion of pilots under NFM3 and PEPFAR, and the planned mandate of NFM4 for all HIV grants to include HIVST suggests HIVST will have significant impact at-scale over the next 5 years.</p>	Medium	
KPI 5: Equity			
KPI 5.1- Investing for the poorest	<p>+Free provision of HIVST and information by HIVST and MTV Shuga through multiple channels directly catered to KP, AGYW and other high-risk groups without financial means or social capital to obtain information and HIV services.</p> <p>+The EMAV which reduced the price of the Viatris/Mylan BBT to < US\$2 made it more accessible to LMIC markets, with uniform pricing agreed between public and private sector procurement to facilitate expanding the reach of HIVST.</p> <p>-Price in the private sector in select countries with pilots/nascent advocacy was regarded by stakeholders as too high for most groups.</p>	High	
KPI 5.2 - Investing for the underserved	<p>+ HIVST models were highly regarded by community stakeholders as having democratised access to HIV services among excluded populations.</p> <p>+In South Africa, MTV Shuga’s mass media and demand creation platform reached both young people with key messages on HIV prevention and HIVST and was found to also reach men and women equally, helping connect with young men who are a commonly underserved group.</p> <p>+Unitaid’s investment in WCA has contributed to accelerating access to HIV product and service innovations and capacity strengthening in a region that receives less donor funding.</p> <p>+Platforms established by the HIVST grants are being leveraged for self testing in HCV and COVID-19. The foundational STAR research on HIVST helped to accelerate WHO’s guidelines on HCV self-testing, thereby also supporting services for other under-served populations.</p>	High	

Appendix M Global conditions for scale-up

Global conditions for HIVST scale up were assessed by triangulating the scalability reports from the HIVST grants with stakeholder interviews. This assessment considers the additional contribution of STAR 3, ATLAS and MTV Shuga, in light of the evidence and normative guidance for HIVST established by earlier STAR phases.



Appendix N Country conditions for scale-up

Change in country conditions for HIVST scale up were assessed for the 3 countries covered in the evaluation country case studies: India, Cameroon, Côte d'Ivoire, using Unitaid definitions of country conditions for scale up (Table N.1). The time period under review is from the start of the grant to the end of 2021. The main data sources for this assessment were program scalability reports and government and key partner materials, triangulated with stakeholder interviews.

Table N.1: Change in country conditions for HIVST scale-up in country case study geographies

	Baseline (2018, 2020*)			End of grant evaluation (2021)		
	Political & financial support (4)	Programmatic & operational readiness (5)	Community driven demand (2)	Political & financial support (4)	Programmatic & operational readiness (5)	Community driven demand (2)
India*				●		●●
Cameroon*	●			●●●	●●●●	●●
Côte d'Ivoire	●●	●		●●●	●●●●	●●

Appendix O Interview Guides

Appendices O.1- O.5 present interview guides for grantees, global stakeholders, country stakeholders, manufacturers and the Unitaid Secretariat. These interview guides were further tailored to the individual projects, countries, and stakeholder groups i.e. technical partners, funders, etc.

O.1 Grantee Consultations

1. Please describe the main objectives and areas of work of the project – as per its original design, and any changes over time as the project was implemented (including reasons for these).
2. How did the project design respond to the needs and country circumstances/epidemic typology?
 - i. What key population groups was the project intending to benefit?
 - ii. What consultations did you embark on during the design stage and do you think there was adequate consultation during design (and reprogramming stages) to ensure relevance?
 - iii. On what basis were project countries selected? In your view, were the assumptions made in country selection and country approach validated over the course of the project? Please elaborate.
3. How did the project design and implementation engage with governments? With Civil Society/Community-based organisations?
4. In your view, to what extent did Unitaid and grantees apply lessons learned/recommendations from STAR 1&2 to the design and implementation of this grant?
5. Regarding efficiency in the HIVST projects, please share your views on the following aspects:
 - i. Project timeline and scope – was it ‘right sized’ for grant objectives?
 - ii. Budget allocations (e.g. commodities to other costs)
 - iii. Risks and mitigations
 - iv. Unitaid’s management/responsiveness
6. In your view, what worked well and less well in implementation of the project (e.g. in regard to HIVST delivery models tested, integration HIVST with national systems)
 - i. How well did HIVST grant align to Unitaid’s PrEP Afl? (e.g. Cote d’Ivoire and globally)
 - ii. In your view, was there adequate time for the MTV SAF project to influence behaviour change? What if anything do you think could have been done differently?
7. What evidence is there in relation to the project contributing to Unitaid’s access barriers? Specifically:
 - i. Affordability (e.g. cost-effectiveness of HIVST model, PEPFAR, Global Fund support)
 - ii. Demand and adoption (e.g. drivers of country policy and implementation)
 - iii. Supply and delivery (e.g. changes to supply chains, forecasting)
8. How has the HIVST project contributed to national readiness for scale and catalysed uptake in other countries?
9. In your view, how has the HIVST grant positively influenced the country and global enabling environment for self-testing/self-care for HIV and other diseases?

O.1 Grantee Consultations (cont.)

10. Overall, what has been the key value add of the project to closing the HIV testing gap? What is your view on what the HIVST country / product landscape would have looked like in the absence of the project?
11. Are there any best practice approaches across project countries you would like to highlight? Please elaborate
12. Do you have any recommendations to strengthen Unitaids effectiveness in HIVST ? (e.g. in terms of future HIVST investments, Unitaids approach to project design and working with grantees, the role of HIVST within comprehensive prevention interventions for HIV and linkage to treatment, approaches to ensure sustainability and scalability of HIVST funding)

O.2 Global Level Stakeholders

1. To what extent have Unitaids grants in HIVST (STAR phase 3, ATLAS, MTV SAF, HIVST market intervention) been relevant in relation to the needs of the HIV response, global guidance, HIVST market landscape, and country circumstances?
2. To what extent were Unitaids projects aligned with the efforts of other donors/ partners and governments? Please elaborate.
3. To what extent have Unitaids projects contributed to catalysing the global HIVST market and supply in terms of volume, diversity, and prices?
4. To what extent have the projects contributed to the supply and delivery of HIVST in countries including aspects such as supporting in country product registrations and strengthening supply chain processes (e.g., forecasting, procurement, distribution, M&E, post market surveillance, and QA systems)?
5. To what extent have the grants contributed to country and global enabling environment for HIVST – such as national strategies, integration of HIVST with other HIV/Health services?
6. With regards to sustainability and scale up: what has been the contribution of Unitaids projects to securing funding for HIVST and other conditions for scale?
7. In your view, how have the HIVST grants contributed to increasing equity in access to HIV Testing, treatment and comprehensive prevention services?
8. In your view, what are the positive or negative externalities of the HIVST grants in terms of the country and global enabling environment for self-testing/self-care for HIV and other diseases?
9. Overall, what has been the key value add of the projects to closing the HIV testing gap? What is your view on what the HIVST country / product landscape would have looked like in the absence of the project?
10. Do you have any recommendations for Unitaids investments in HIVST of self-care more broadly going forward?

O.3 Country Level Stakeholders

1. What was the situation regarding HIV testing in general and HIVST in particular at the start of the Unitaid projects?
2. To what extent has the project been relevant in relation to HIV response needs and country circumstances and the work of other partners providing HIV services in the country?
3. To what extent did project implementation collaborate with national authorities and achieve integration in health systems?
4. What were key successes and challenges in terms of implementation of the project – what worked well or less well?
5. What have been the main achievements of Unitaid’s HIV-self testing investments in country? What is the significance of these achievement in terms of:
 - i. making HIVST products available at lower prices that are affordable for governments and other donors?
 - ii. increasing demand in country and uptake for scale-up of cost-effective HIVST products?
 - iii. improving supply and delivery systems to ensure that products reach those in need (including underserved and vulnerable populations) in a reliable and timely way?
 - iv. any other issues?
6. How have the HIVST grants contributed to national readiness for scale and the global enabling environment for scale?
7. In your view, to what extent has the HIVST project contributed to an enabling environment for self-testing/self-care for HIV and other diseases? To what extent was the impact of the projects equitable?
8. Overall, what has been the key value add of the project to closing the HIV testing gap? What is your view on what the HIV testing gap would look like without the project?
9. Are there any best practice approaches across project countries you would like to highlight? Do you have any recommendations for Unitaid how to be more effective in catalysing sustainability and scalability of HIVST (or for other disease areas)?

O.4 Unitaid Secretariat

1. To what extent have the STAR Phase 3, ATLAS and MTV SAF grants been relevant in relation to Unitaid’s strategy and objectives for impacting the HIVST landscape? With the benefit of hindsight, do you think this was the right approach for impact or would alternate approaches have been better?
 - i. What was the strategic rationale for country selection for these grants?
2. What demand and access barriers persisted after STAR Phases 1&2 that Unitaid sought to address through these subsequent/ later grants?
3. In your view, how were Unitaid’s STAR Phase 3 (including market shaping), ATLAS and MTV SAF grants complementary to, and synergistic with other funders and partners? How did this evolve over time?

O.4 Unitaid Secretariat (cont.)

4. Going forward, what are the key lessons learnt from the project design and implementation to inform Unitaid engagement and working with grantees? To what extent were synergies between grants well harnessed and were risks well managed?
5. What do you view as Unitaid's value add role as a funder of HIVST, drawing on the experience of these projects, and what more can it do to enhance its effectiveness?
6. What is Unitaid's view on the significance of the results achieved with regards to the targeted access barriers (affordability, demand and adoption, supply and delivery)? What might have been progress in the absence of the projects (hypothetical) and what are key challenges remaining?
7. What is your view with regards to the progress made on transition at the project level and on global level scale up of HIVST?
8. To what extent did the HIVST investments leverage / build on Unitaid's existing portfolio in diagnostics, preventative therapies, and projects targeting similar access barriers, particularly for marginalised and vulnerable groups? (e.g. HCV)
9. In your view, what are the positive externalities of the HIVST grants in terms of enabling environment for self-testing/self-care for HIV and other diseases (were there any negative externalities)?
10. Overall, what has been the key value add of the projects and what is your view on what the HIVST landscape would have looked like in the absence of the project? What are your early thoughts in terms of key recommendations to guide Unitaid's work in the HIVST area going forward?

O.5 Manufacturers

1. What is your perspective on the current landscape for HIVST? (Please comment on technologies available and manufacturer incentives for innovation, pricing, demand, country level supply and systems issues)
2. How has this evolved (positively or negatively in your view) since your engagement with PSI and Unitaid?
3. What do you view as the contribution of Unitaid and PSI on HIVST as well as the self-testing market more broadly globally and in countries? What is your sense on what might have been the case in the absence of these investments?
4. What are the prospects for scaling-up the market for HIVST further? What are supporting factors and what might be key challenges/ issues?
5. From your perspective to what extent did Unitaid engage well with manufacturers and are there ways in which Unitaid could have engaged differently that may have been better?
6. What are the big gaps/ outstanding issues in this market going forward and what might be a suitable role for Unitaid in this regard?



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