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Full Length Article

The early market access vehicle – An innovative demand-driven model to catalyse introduction of new optimal health products in low- and middle-income countries

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ABSTRACT

Low-and middle-income countries (LMICs) account for a significant proportion of the burden of disease for communicable illnesses globally; with malaria, tuberculosis (TB), and HIV/AIDS being the leading causes of death. Despite this disparity, LMICs often have limited or delayed access to newer optimal health products compared to high-income countries (HICs). This limitation in access, driven by a myriad of barriers, undermines the potential health benefits that could be gained in LMICs through the introduction of better health products. To improve this inequity, governments in HICs, non-governmental organizations, and pharmaceutical companies, often resort to establishing donation programs for LMICs, to circumvent some of the access barriers. While well-implemented donation programs have the potential to improve access to new products, poorly executed donation programmes are common. These often have negative effects such as: overreliance on donations by recipient countries, *dumping* of short-dated or unwanted products, costs of waste disposal where unsuitable or excess products are received, and a lack of focus on access sustainability planning. Unitaid's early market access vehicle (EMAV) is an innovative demand-driven access model for introducing new optimal health commodities in LMICs. An EMAV entails a conditional purchase commitment to the manufacturer for a defined quantity of selected products in exchange for a set of access commitments, required to facilitate equitable access in the target markets. EMAVs are designed to link catalytic donations to pathways for sustainable access. Unitaid, in collaboration with its partners, has leveraged the EMAV to introduce two innovative health products in a number of LMICs. This article discusses the EMAV model and builds the case on why stakeholders working on new product access should consider this approach as an alternative to traditional donation programmes.

1. Background

Low-and middle-income countries (LMICs) account for a significant proportion of the burden of disease for communicable illnesses globally; with malaria, tuberculosis (TB), and HIV/AIDS being the leading causes of death [1,2]. Despite this disparity, LMICs often have limited or delayed access to newer optimal health products compared to high-income countries (HICs) [3]. These access limitations, driven by a myriad of issues, undermine the potential benefits that could be gained in LMICs from the introduction of better health products. Examples of these barriers include: the cost of the new health product could be higher compared to the existing standard of care; stakeholders in the country of use may have concerns driven by lack of experience with the product and consequently low or uncertain demand; or that the process for transition or introduction of the new product is perceived to be laborious and costly [4,5]. To circumvent some of these access barriers,

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governments in HICs, non-governmental organizations, and pharmaceutical companies, often resort to establishing donation programs for LMICs to foster equity in access [6].

While well-implemented health donation programs have the potential to improve access to new products, a significant number of donation programs have been fraught with several challenges [7,8]. These include poor forecasting, inappropriate product type, misaligned timing of donation with required changes in policy to support the new product, gaps in resourcing national programmes for implementation, fragmented and uncoordinated donor efforts, etc [8–10]. The result in many cases is a slow uptake of donated products, and poor outcomes in terms of expected impact. Poorly executed donation programs may also create an enabling environment for practices such as *dumping* of products which may be short-dated in addition [11]. *Dumping* – donating unneeded (or more than needed) – products has resulted in the reluctance of many governments in LMICs to accept donations, deepening the access challenge [8]. Governments have cited the reputational risk of huge expiries, disposal fees accrued from the expiry of short-dated or excessive volumes, and a lack of focus on sustainability planning when the donation programme ends as some of the reasons for such reluctance [8]. Although the World Health Organization (WHO) has established guidelines to help address these challenges with medical donations, a review conducted in 2018 showed that most donation programmes still did not comply with the WHO guidelines [7]. Unitaid, in line with its mandate of accelerating access to innovative health products, identifies the importance of catalytic product introductions with clear sustainability pathways as vital, and hence designed an innovative approach that seeks to address some of the aforementioned challenges.

Unitaid's early market access vehicle (EMAV), implemented through Unitaid's grant implementers, is an innovative demand-driven access model for introducing new optimal health commodities in LMICs. The model is designed to link catalytic donations to pathways for more sustainable access, including support for integrated programmatic use in LMICs. This paper presents the EMAV, discusses its wider impact on accelerating adoption, uptake, and market maturation for public health products, and why stakeholders working on new product access should consider this approach as an alternative to traditional donation programmes.

2. The early market access vehicle

The EMAV is designed as a market intervention mechanism to support the introduction of new innovative public health commodities in LMICs. An EMAV entails a conditional purchase commitment to the manufacturer for a defined quantity of products in exchange for a set of access commitments (affordable pricing, quality assurance, country registration, production volumes etc.) required to facilitate equitable access in the target LMIC markets. In contrast to regular donation programs, an EMAV is catalytic, secures access commitments, and employs a demand-driven approach for the target product. EMAVs also differ from conventional volume guarantees since the target commodity is provided at no product cost to participating governments from the outset. This improves the potential for buy-in and adoption, and possible transition to sustainable procurement by countries. Furthermore, the manufacturer supplies only quantities governments and partners from target countries demonstrate commitment to absorb and sustain.

An EMAV is usually part of a larger programmatic grant initiative aimed at improving access to health products across a selection of LMICs. The funding partner for the EMAV secures the desired access terms in exchange for a commitment to fund up to an agreed volume of commodity procurement from the manufacturer within a defined timeframe. Eligible countries are then invited to apply to the EMAV for the target product, following a call for expressions of interest. Countries are expected to cover shipping and other costs required to deliver and utilize the product in their local settings. Exceptions may be made for the funding partner to cover shipping costs, but to encourage shared ownership, country implementation costs are usually not supported through an EMAV. EMAVs allow participating countries to rapidly gain programmatic experience on the innovative product, on the condition that an informed decision will be taken on adoption and subsequent use. This is achieved through the facilitation of user experience with healthcare workers (HCWs), generation of local evidence where necessary to inform scale-up, and ultimately, establishing the use case for introducing and scaling the product. The ideal target product for an EMAV will be an innovation with significant benefits over the current standard of care, is recommended by the WHO but not widely used in LMICs due to certain access barriers such as cost, feasibility, and questions on use. Country-led programmatic support is also vital for the success of an EMAV. The Unitaid grant implementer sets up and manages the EMAV. The process of operationalizing an EMAV usually entails the following steps:

2.1. Global access agreement

Manufacturers are engaged through an open competitive process for a partnership with Unitaid and the grant implementer. This applies where there is more than one manufacturer for an innovative product, however direct engagement is employed where there is only one manufacturer for the innovation. A global access agreement (addressing relevant access barriers) is negotiated with a willing manufacturer, and a contract is signed with Unitaid, or the grant implementer as deemed appropriate. The terms of the agreement would cover elements such as quality assurance, country registration requirements, price, and volume expectations as relevant for the specific use case or target markets for the product. The obligations of Unitaid and the grant implementer are also defined in the agreement.

2.2. Expressions of interest (EOI) and selection

The call for EOI from eligible countries covers the terms and conditions of the EMAV; indicative global procurement quantity, duration, selection criteria, reporting requirements, application process, frequently asked questions, etc. Eligible countries are expected to express interest indicating the quantity, assumptions and intended coverage. A critical selection criterion is a commitment from the receiving government to scale up the new product, through sustainable financing of subsequent orders should it prove to be suitable for the local setting. It should be noted that this is a commitment to an informed decision, and not a compulsion of the government to adopt and scale up the product if found unsuitable.

2.3. Managing the EMAV

The designated partner managing the EMAV supports and coordinates the logistics required for the operation of the EMAV. These will include ensuring products are available from the manufacturer and meet government guidelines for receiving donated commodities (e.g., remaining shelf life), facilitating purchase orders, review of progress reports and ensuring plans for a sustainable transition of product procurement are on course. Fig. 1 presents a simple.

3. Case studies: Unitaid-funded EMAVs for novel health products

As of April 2023, Unitaid through its partners had utilized the EMAV model to successfully introduce two innovative health products in LMICs:

1. *EMAV for the* VISITECT® CD4 Advanced Disease test*:* Developed by Omega Diagnostics, and now owned by AccuBio, VISITECT® is the world's first true point of care lateral flow assay test that does not require an electronic device to produce a CD4 count result. A CD4

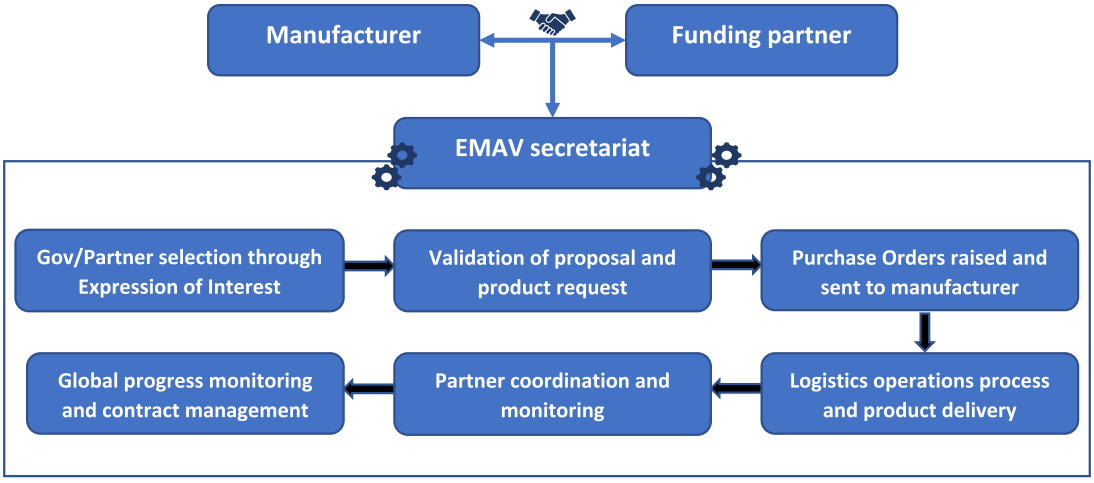

Fig. 1. Summary of the EMAV.

test is recommended by the WHO for all people living with HIV (PLHIV) initiating or re-initiating antiretroviral therapy or failing treatment, to identify persons with advanced disease who have a heightened mortality risk and require further interventions dependent on the CD4 count result [12]. To accelerate introduction in LMICs, Unitaid and the Clinton Health Access Initiative (CHAI) launched the flagship EMAV for the VISITECT test. Unitaid, CHAI, and Omega Diagnostics established an innovative access agreement in 2020 that enabled governments and partners in 138 countries to access VISITECT® at $3·98 Ex Works (EXW) per test [13]. This access price, inclusive of a 34 % reduction on the standard cost, stood as the lowest cost for a CD4 test anywhere in the world [13,14]. The agreement also included volume availability and quality assurance targets for the manufacturer. Unitaid committed to procure up to 500,000 tests through the access agreement, enabling successful EMAV applicants to receive the test at no product cost [15]. Highlight of the terms and conditions for the VISITECT® EMAV is shown in Fig. 2 [15]. An EOI was published in April 2020 with the following key selection criteria: prior experience in AHD screening and treatment, evidence of a gap in the applicant country's CD4 network that could be filled by VISITECT®, availability of other elements of the package of care for AHD, and a plan for transition to sustainable procurement of VISITECT® should the ministry of health find the product a good fit for the country program [15]. The VISITECT®

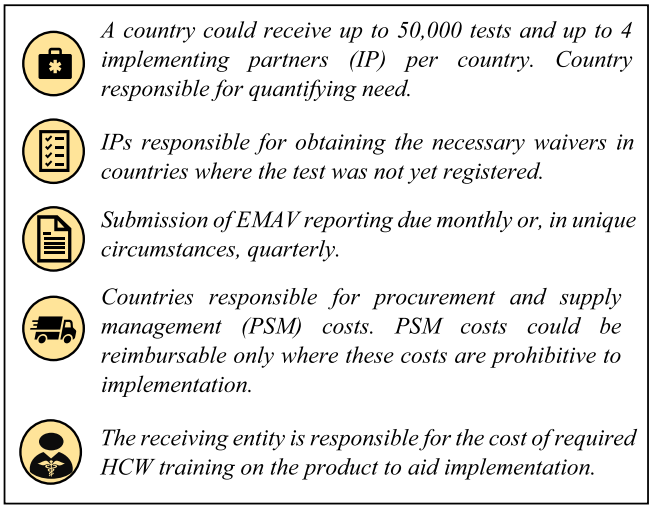

Fig. 2. Highlights of terms and conditions of the VISITECT EMAV.

EMAV was active from April 2020 through December 2021 for applications, while the delivery of tests continued through December 2022.

2. *EMAV for blood-based HIV self-tests (HIVST):* Self-testing has shifted the paradigm for HIV testing [16]. Apart from offering an alternative personal option for PLHIV to find out their status and access antiretroviral treatment services, self-testing offers an important entry point to HIV prevention services for those testing negative [17]. As a result, Unitaid and Population Services International (PSI) in 2020, launched an EMAV for HIVSTs to drive equitable access to these diagnostics [18]. After a request for proposals process, two HIVST products from Viatris (manufactured by Atomo Diagnostics Limited), and Abbott were selected for the access expansion program, with Unitaid committing resources to procure up to 1 million tests across high-priority LMIC markets to stimulate in-country demand [18]. The pricing agreement between Unitaid, PSI, and Viatris was launched first, and secured a reduction in the EXW unit price from $3·40 to $1·99 per test in 135 LMICs [18]. In 2022, rising gas prices, inflation, and other geopolitical factors had a significant impact on supply chain costs, and as a continuation of the work under the EMAV initiative, a pricing agreement was established with Abbott to offer their SRA-approved HIVST for a fixed landing cost, under the Carriage and Insurance Paid To (CIP) incoterm [19]. The EMAV for HIVST pricing agreement is valid through December 2026 and is accessible to country governments, UN organizations, not-for-profit organizations, public health financing mechanisms, and procurement agents in line with the cap listed earlier.

4. Impact and key takeaways

At the close of the VISITECT® EMAV, over 210,000 tests had been ordered across 12 LMICs with direct participation in the initiative (Programmatic data, Clinton Health Access Initiative, Boston, MA, USA 2023). Following the EMAV, at least five of these countries have initiated the implementation of VISITECT at scale, with the procurement transitioned to sustainable funding. We expect this number to grow, as countries finalize national CD4 strategy and procurement planning. As at October 2022, 44 countries had introduced the product and order volumes (via the EMAV and its accompanying negotiated access price) stood at 480,000 tests [20]. By December 2022, AccuBio stated that, EMAV volumes, combined with procurement following the EMAV, had reached 736,650 VISITECT® tests ordered and distributed (Bannister J. 2023. Email to James Conroy, 7 June). In further demonstration of wider access, the two largest procurers of HIV commodities globally; The US President's Emergency Plan for AIDS Relief (PEPFAR), and the Global

Fund, have both listed VISITECT® as a focal product, and procure the test in several countries [21,22].

While the EMAV approach cannot be said to be entirely responsible for these gains, it made major contributions. This experience has shown that the model has the potential to catalyse access over a relatively short duration, and where properly executed, aid transitioning to sustainable procurement by recipient countries. An EMAV is also cost saving, since a 34 % price reduction was secured and carried through for all tests procured from the manufacturer, including the 526,650 tests not paid for by Unitaid. In addition, following the close of the EMAV, in December 2022, the cost of VISITECT® has remained at $3·98 per test with no further intervention [23]. This is evidence of the fact that an EMAV can contribute significantly to affordability, price stability and market maturation of a new health product.

Similarly, pricing agreements in the HIVST EMAV have resulted in cost savings for public sector procurements in eligible LMICs and instigated some competition among the quality-assured products to reduce pricing [18,24]. Before the HIVST EMAV in 2020, the average unit cost for a quality assured HIVST was $3, however, following the intervention, the average unit cost was reduced to $2 per test [24]. Fig. 3 shows the unit cost of HIVSTs before and after the EMAV agreement in 2020, demonstrating the wider impact on the market (Population Services International, Cape Town, South Africa 2023).

Furthermore, following the HIVST EMAV initiative, three out of the six quality-assured manufacturers in 2022 agreed to extend the public sector pricing to willing public–private sector platforms such as community pharmacies in Nigeria, Uganda, and South Africa [24]. This price extension for public health impact is expected to make products more affordable in the targeted private sector platforms, and significantly increase HIVST uptake. This is also evidence of the wide-reaching potential of the EMAV model for improving product access in LMICs [24].

Another benefit of the EMAV strategy is its demand-driven design. With countries or recipients being responsible for the request and quantification for the new commodity, EMAVs reduce the risk of experiencing donation of unwanted or excessive product volumes; a common challenge with standard donation programs [7,8]. While EMAVs may face the risk of overestimated requests, an attempt at mitigating this risk is made through the validation process that occurs during the review of applications. The requirement for applicants to bear PSM costs (which increases with product volume), also helps to mitigate this risk. The risk of dumping short-dated products; another drawback of donation programs,7,8 is also reduced, since EMAVs by design, align with country guidelines for receiving health commodities including thresholds for remaining shelf life set by countries.

Finally, following the successes above and consultations with Unitaid, the Children's Investment Fund Foundation and The Global Fund have launched an EMAV to facilitate the introduction of a new HIV prevention product. The authors consider this a further testament to the potential of this new product introduction model [25,26].

5. Limitations

While the EMAV is an innovative evolving model for improving access to new commodities in LMICs, it is not without its perceived limitations. An EMAV may not be suitable for engaging all LMICs, as some countries may not be able to afford the PSM and other programmatic costs required to roll out a new commodity. Further, EMAVs may not be suitable for special use case products without the substantial demand needed to support the desired access conditions through a market intervention.

6. Conclusion

The authors believe that the EMAV model holds significant promise for improving sustainable and equitable access to innovative public health products in LMICs. The EMAV has catalysed access to two innovative health products in a short space of time, achieved significant cost-savings, and aided the sustainability and maturation of the market for the two commodities targeted. In our experience, this approach helped address multiple access barriers such as affordability, poor buy-in and slow adoption of new optimal health products in LMICs. Funding partners working in product access are encouraged to explore the EMAV model, where fitting, as an alternative strategy to traditional donation programs.

7. Disclaimer

The views expressed in this article are those of the authors and do not necessarily represent the views of their affiliated organizations.

8. Contributions

Ademola O., Ikechukwu A., Aayush S., James C., and Kehinde O., conceptualised the article. Alya O. and Aayush S. acquired and verified data. Ikechukwu A. conducted the initial literature search and developed the initial draft of the manuscript with Ademola O, and Aayush S. Ademola O., Alya O., and Aayush S. developed the figures. Kehinde O., Carolyn A., Karin H., Robert M., and Janet G. edited and provided critical reviews of the manuscript. All authors conducted subsequent reviews, agreed, and approved the final version for publication.

CRediT authorship contribution statement

Ademola Osigbesan: . **Ikechukwu Amamilo:** Writing – review & editing, Writing – original draft, Validation, Project administration, Methodology, Data curation. **Aayush Solanki:** Writing – review & editing, Visualization, Project administration, Methodology, Formal analysis, Data curation. **Robert Matiru:** Writing – review & editing, Supervision. **James Conroy:** Writing – review & editing, Project

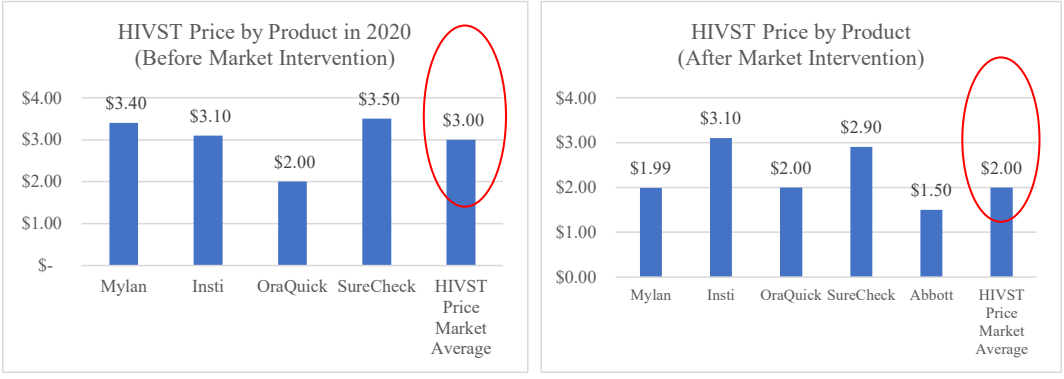

Fig. 3. Average unit cost of HIVST before and post EMAV.

administration, Methodology, Formal analysis. **Alya Omar:** Writing – review & editing, Formal analysis, Data curation. **Karin Hatzold:** Writing – review & editing, Supervision, Project administration. **Carolyn Amole:** Writing – review & editing, Supervision, Project administration. **Kehinde Onasanya:** Writing – review & editing, Validation. **Janet Ginnard:** Writing – review & editing, Validation, Supervision.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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References

[1] Jamison D, Mosley W. Disease control priorities in developing countries: health policy responses to epidemiological change. Am J Public Health 1991;81(1):15–22.
[2] Who. The top 10 causes of death [Accessed 5 February 2023] Fact sheets 2020. https://www.who.int/news-room/fact-sheets/detail/the-top-10-causes-of-death.
[3] Chattu VK, Singh B, Pattanshetty S, Reddy S. Access to medicines through global health diplomacy. Health Promot Perspect 2023 Apr 30;13(1):40–6. https://doi.org/10.34172/hpp.2023.05. PMID: 37309432; PMCID: PMC10257564.
[4] Baker DE. High Drug Prices: So Who Is to Blame? Hosp Pharm 2017;52(1):5–6.
[5] Godman B, Bucsics A, Vella Bonanno P, et al. Barriers for Access to New Medicines: Searching for the Balance Between Rising Costs and Limited Budgets. Front Public Health 2018;6:328.
[6] Khare AK. Drug donations to developing countries. Afr Health 1998 Nov;21(1):8–9.
[7] McDonald S, Fabbri A, Parker L, et al. Medical donations are not always free: an assessment of compliance of medicine and medical device donations with World Health Organization guidelines (2009–2017). Int Health 2019;11(5):379–402.
[8] Bero L, Carson B, Moller H, et al. To give is better than to receive: compliance with WHO guidelines for drug donations during 2000–2008. Bull World Health Organ 2010;88(12):922–9.
[9] Trouiller P, Olliaro P, Torreele E, et al. Drug development for neglected diseases: a deficient market and a public-health policy failure. Lancet 2002;359(9324):2188–94.
[10] WHO Health Product Policy and Standards. Guidelines for Medicine Donations Revised 2010. Geneva: WHO; 2011. https://iris.who.int/bitstream/handle/10665/44647/9789241501989_eng.pdf?sequence=1 [Accessed 5 February 2023].
[11] Kamba P, Ireeta M, Balikuna S, et al. Threats posed by stockpiles of expired pharmaceuticals in low- and middle-income countries: a Ugandan perspective. Bull World Health Organ 2017;95(8):594–8.
[12] WHO. Guidelines for managing advanced HIV disease and rapid initiation of antiretroviral therapy July 2017. Geneva: World Health Organization; 2017. https://iris.who.int/bitstream/handle/10665/255884/9789241550062-eng.pdf?sequence=1 [Accessed 5 February 2023].
[13] Clinton Health Access Initiative. Early Market Access Vehicle for VISITECT® CD4 Advanced Disease Test [online]. CHAI: Boston; 2020. https://www.clintonhealthaccess.org/rfp/early-market-access-vehicle-for-visitect-cd4-advanced-disease-test/ [Accessed 3 March 2023].
[14] Unitaid. New rapid CD4 test could be game-changer for people with advanced HIV disease [online]. Unitaid: Geneva; 2020. https://unitaid.org/assets/New-rapid-CD4-test-could-be-game-changer-for-people-with-advanced-HIV-disease.pdf [Accessed 20 November 2024].
[15] Clinton Health Access Initiative. Call for Expression of Interest: Early Market Access Vehicle for VISITECT® CD4 Advanced Disease [Online]. 2020 Apr 28. https://www.clintonhealthaccess.org/wp-content/uploads/2020/04/VISITECT-Advanced-HIV-Disease-EOI-28-Apr-2020.pdf [Accessed 20 November 2024].
[16] Laxmeshwar C, Hegde A, Dange A, et al. Acceptability, usability, and willingness to pay for HIV self-test kits distributed through community-based, PLHIV network-led and private practitioners models in India: Results from the STAR III Initiative. J Int AIDS Soc 2024;27(1):e26348.
[17] Zhang Y, Johnson C, Nguyen V, et al. Role of HIV self-testing in strengthening HIV prevention services. The Lancet HIV. 2024; **11**(11) Pages e774-e782.
[18] Unitaid. Access to HIV self-tests significantly expanded and costs halved thanks to Unitaid agreement [Online]. 2021. https://unitaid.org/news-blog/access-to-hiv-self-tests-significantly-expanded-and-costs-halved-thanks-to-unitaid-agreement/#en [Accessed 20 November 2024].
[19] Population Services International. Abbott partners with Population Services International and Unitaid to make HIV self-test kits affordable in low- and middle-income countries globally [Online]. 2023. https://www.psi.org/news/abbott-partners-with-population-services-international-and-unitaid-to-make-hiv-self-test-kits-affordable-in-low-and-middle-income-countries-globally/ [Accessed 20 November 2024].
[20] Clinton Health Access Initiative. 2022 HIV Market Report: The state of HIV treatment, testing, and prevention in low- and middle-income countries [Online]. 2022. https://www.clintonhealthaccess.org/wp-content/uploads/2022/12/2022-CHAI-HIV-Market-Report-12.8.22.pdf [Accessed 19 November 2024].
[21] U.S. Department of State. FY 2024 PEPFAR Technical Considerations [Online]. 2023 https://www.state.gov/wp-content/uploads/2023/07/FY-2024-PEPFAR-Technical-Considerations.pdf [Accessed 19 November 2024].
[22] The Global Fund. HIV Information Note: Allocation Period 2023-2025 [Online]. 2022 https://www.theglobalfund.org/media/4765/core_hiv_infonote_en.pdf [Accessed 19 November 2024].
[23] The Global Fund. Pooled Procurement Mechanism Reference Pricing: RDTs version: Q4 2023 [Online]. 2023. https://www.theglobalfund.org/media/7564/psm_hivrdtreferencepricing_table_en.pdf [Accessed 27 November 2024].
[24] CEPA. Unitaid HIV Self Testing (HIVST) area for intervention– Joint end of project Evaluation: Final Report [Online]. 2020. https://unitaid.org/assets/CEPA-evaluation-UNITAID-HIVST_Final-Report.pdf [Accessed 27 November 2024].
[25] AVAC. Launch of CIFF/Global Fund Initiative for the PrEP Ring [Online]. 2024. https://avac.org/event/launch-of-ciff-global-fund-initiative-for-the-prep-ring/ [Accessed 19 November 2024].
[26] The Global Fund. CIFF to propel PrEP revolution with up to US$2 million for immediate access to PrEP rings [Online]. 2024. https://www.theglobalfund.org/en/news/2024/2024-07-21-ciff-propel-prep-revolution-usd2-million-immediate-access-prep-rings/ [Accessed 19 November 2024].