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Using HIV self-testing to increase the affordability of community-based HIV testing services: A longitudinal analysis in Lesotho

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GMR, FTP provided guidance throughout data collection, cleaning and analysis. MD drafted the paper; all authors revised and approved the final manuscript.

Compliance with Ethical Standards - All procedures performed involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

The research project has been approved by the National Health Research Ethics Committee of Lesotho and the Research Ethics Committee of the London School of Hygiene and Tropical Medicine.

Informed consent was obtained from all individual participants included in the time and motion study.

Keywords: HIV testing services; HIV self-testing; Community-based; Costs and Cost Analysis; Longitudinal Studies; Efficiency, Organizational; Africa, Southern; Lesotho

Abstract

Objectives:

This study estimates the costs of community-based HIV testing services (HTS) in Lesotho and assesses the potential efficiency gains achieved by adding HIV self-testing (HIVST) and then self-testing booths.

Design:

Micro-costing analysis using longitudinal data from a real-world intervention.

Methods:

We collected data prospectively on provider's costs and programmatic outcomes over three time periods of approximately eight months each, between May 2017 and April 2019. The scope of services was extended during each period as follows: 1) HTS only, 2) HTS and HIVST, 3) HTS and HIVST with individual HIVST booths where clients were encouraged to self-test on-site followed by on-site confirmative testing for those with reactive self-test. For each implementation period, we estimated the full financial and economic implementation costs, the incremental costs of adding HIVST onto conventional HTS and the cost per HIV positive case identified.

Results:

Costs per HIV-positive case identified increased between period 1 (US\$956) and period 2 (US\$1,249) then dropped in period 3 (US\$813). Full versus incremental cost analyses resulted in large differences in the magnitude of costs, attributable to methods rather than resource use: e.g. in period 3, the average full and incremental cost estimates for HTS were US\$34.3 and US\$23.5 per person tested, and for HIVST were US\$37.7 and US\$14.0 per kit provided, respectively.

Conclusions:

In Lesotho, adding HIVST to community-based HTS improves its overall affordability regarding HIV-positive case finding. The reporting of both full and incremental cost estimates increase transparency for use in priority setting, budgeting and financial planning for scale-up.

Introduction

Lesotho has the second highest HIV burden in the world at a prevalence of 25.6% (30.4% among women and 20.8% among men) and an annual incidence of 1.1% among adults in 2017 ^[1]. In recent years, the country made considerable progress towards the United Nation's 90-90-90 targets (by 2020, 90% of all people living with HIV will know their HIV status, 90% of all people with diagnosed HIV infection will receive sustained antiretroviral treatment (ART), and 90% of all people receiving ART will have viral suppression) ^[2]. In 2017, among the estimated 306,000 people living with HIV (PLHIV), 81% reporting knowledge of status, 92% of those are on ART, and of those who are on ART, 88% are virally suppressed ^[1].

Nationally, the total number of people tested for HIV increased from 221,616 in 2009 to 1,109,345 in 2017, while the proportion of new HIV-positive diagnosed out of all those tested (HIV yield rate) decreased from 18% to 4% over the same period ^[3]. Population Services International (PSI), a global non-governmental health organisation (NGO), provides most community-based HIV testing services (HTS) in Lesotho ^[4], including door-to-door and mobile outreach services. In 2015, community-based index testing, which is HTS for sexual partners and biological children of people diagnosed with HIV, was added to PSI services under the CID-LINK project, achieving an average HIV yield rate of 4.2% with 79% of linkage to care among those diagnosed between May 2015 and November 2017 ^[5].

Yet, reaching the first 90 target called for innovative methods to reach undertested groups, notably men and young people (aged 15-24) among whom awareness of HIV positive status was only 76.6% and 67.6% respectively ^[1, 3, 6, 7]. Following demonstrated success elsewhere in southern Africa, the Lesotho Ministry of Health (MOH) added HIV self-testing (HIVST)

to the HTS strategy in 2017 with technical support and funding provided by the STAR (HIV Self-Testing Africa) Initiative ^[8-13].

Provision of multiple services delivered jointly alongside conventional HTS has the theoretical potential to achieve economies of scope ^[14, 15], through efficiency gains that reflect sharing of overheads, common fixed costs or through joint learning by staff for services provision or demand creation ^[16, 17]. In particular, HIV self-testing can increase total testing numbers, but may also increase the programme's technical efficiency when provided alongside standard testing services if more people are diagnosed at a given cost ^[18]. However, relatively few data exist on how costs change over time during implementation of national HTS ^[12, 19] or whether new testing modalities have succeeded in increasing a programme's efficiency.

The objective of this study was to estimate the costs of community-based HTS implementation in Lesotho before and after integration of HIVST. We aim to investigate potential efficiency gains from the addition of self-testing and from continuous programme development.

Methods

Setting and intervention

In Lesotho, the community-based HTS programme was expanded in five districts over two years starting in May 2017 ^[4]. The programme was offering community-based HTS. HIVST was added as an alternative option to conventional HTS in December 2017. Finally, from September 2018, individual HIVST booths were introduced at mobile outreach sites and clients were encouraged to self-test on-site (Figure 1). These are defined as period 1, 2 and 3, respectively.

Two community-based HTS interventions were assessed: 1) mobile outreach with tents providing HTS, and 2) index testing where counsellors travel to the index case household and offer testing door-to-door to all those in the area, so avoiding stigmatisation. At the mobile outreach site, the client was offered the option to receive HTS or to self-test on-site at the HTS tent (with or without the HTS provider supervision) with immediate confirmatory testing available, or to take the kit away for use off-site. All HIV-positive clients were offered a home visit by a counsellor for index testing. If the client refused a home visit, HIVST kits were offered to their sexual partner(s). If the client accepted a home visit, the contact details of the sexual partners (index cases) were recorded. The index cases were contacted by the provider by telephone and offered HIV testing either at the nearby health facility, or during a home visit by the providers. During home visits, index cases who refused conventional testing by the providers could opt for HIVST. A more detailed presentation of the community-based HTS is published elsewhere ^[4]. Client flows for the mobile outreach and index testing models are presented in **Appendix Figures S1 & S2**, <http://links.lww.com/QAD/B821>. When individual HIVST booths were introduced, the revised strategy allowed multiple clients to self-test at the same time and encouraged clients with a reactive self-test to get immediate confirmatory testing and referral for linkage to care. Because the same team and resources are used to provide these two HTS interventions (single provider potentially conducting these two activities in the same day), we analyse costs of this intervention as one and use the term “community-based HTS” to cover the two testing approaches.

The analysis is divided in three time periods corresponding to major changes in the HTS strategy presented in **Figure 1**.

Study design and data collection

We conducted a micro-costing study alongside programme implementation over two years (May 2017 – April 2019) from a provider's perspective (PSI). We collected data on costs and programmatic outcomes prospectively following guidelines ^[14, 20, 21].

We conducted two types of cost analysis for HTS and HIVST. A full cost analysis where we estimated the financial and economic (e.g. donated goods and services) costs of all resources used in running the HTS and HIVST programmes independently from each other, including PSI Lesotho headquarter costs ^[14]. Because HIVST is added onto the existing HTS as an alternative option within community-based HTS, we also estimated incremental costs where shared costs (such as operational costs) are fully allocated to the full package of community-based HTS, thus accounting only for the new inputs that were required by the new intervention ^[21]. The composition of cost categories in the full versus incremental cost analysis for each activity is presented in **Appendix Table S1**, <http://links.lww.com/QAD/B821>.

Firstly, we analysed PSI financial reports, referred as top-down costing, collating all financial expenditures from financial reports and categorising each line item by cost category allocating them to distribution model ^[22]. Based on these reports, the average purchasing cost per HIVST kit, including freight costs, was US\$2.71. Costs were allocated to community-based activities following predefined allocation factors. A more detailed description of this costing method is described elsewhere ^[23]. We estimated quarterly cost averages to allow for comparison between periods. Secondly, a time and motion study (TMS) was conducted to observe staff providing both HTS/index testing and HIVST services and allocate personnel costs based on the time spent on each activity ^[24, 25]. The TMS differentiates between supervised and unsupervised (provider is absent at least while the client waits for the self-test

results) HIVST episodes on-site. This study also estimates provider's indirect time which corresponds to the personnel time spent not seeing any clients, travel time and administrative work. In the case of the incremental HIVST costing analysis, providers' indirect time is allocated fully to conventional HTS, while in the full HIVST cost analysis, indirect time is shared between HTS and HIVST, following time allocations from the TMS. Methods and results for the TMS are presented in **Appendix text document S1 and Table S3**, <http://links.lww.com/QAD/B821>. Thirdly, we used a bottom-up costing approach through site observations and interviews with senior staff to include the economic costs not captured in financial reports. All local goods costs were adjusted for inflation over time using the gross domestic product deflators in the local currency, then all costs were converted to 2019 United States dollars (US\$) using the Central Bank of Lesotho exchange rate for each year^[14]. Start-up, training and other capital costs were annualized over the assumed years of useful life of each item using a 3% discount rate, which was varied in sensitivity analysis^[14]. Research costs were excluded. We calculated the average costs per person tested with HTS, per HIVST kit distributed, and per HIV-positive identified as the conventional HTS and HIVST costs respectively, by dividing the relevant total costs by the relevant outcomes for each period. Output data were collected from paper-based monitoring and evaluation (M&E) forms filled by HTS providers, compiled in an excel database, cleaned using consistency checks, and analysed by PSI M&E officers. Confirmed yield rate was defined as the proportion of new HIV-positive cases out of all clients tested with HTS, including confirmatory testing following a reactive self-test.

Sensitivity and scenario analysis

We conducted a series of univariate sensitivity analyses to assess the impact of key cost assumptions on the average incremental costs per HIVST kit distributed and costs per HIV-

positive case identified for the latest costs data (period 3). For the costs per HIVST kit distributed and per HIV-positive case identified, the sensitivity analysis assessed the impact of the discount rate used to annualize capital costs to capture the influence of not discounting or using a higher local central bank discount rate (base: 3%; 0%; 15%), the years of useful life of start-up costs (base: 2 years; 1 year; 3 years). For the costs per HIVST kit distributed only, the durations of sessions for providing HTS and HIVST services estimated from the TMS (+/-20%) – TMS results were not affecting costs per HIV-positive case identified because all personnel members were involved in HIV testing only and the TMS only affects the allocation between the types of testing. For the costs per HIV-positive case only, we also assessed the years of useful life of vehicles (base: 15 years; 10; 20) – absent for the incremental cost per HIVST kit distributed.

We also added a scenario analysis to inform the scale-up of the programme to the other districts. In the scenario analysis, we assessed headquarter and field-based personnel costs (+/-10%) reflecting variation of headquarter costs and the shift of HIVST distribution by lay providers rather than professional counsellors; the volume of HIVST kits distributed (+/-10%) which could vary according to the personnel capacity to provide unsupervised on-site HIVST or to the effect of HIVST stock-outs; the market price of HIVST kits to reflect a hypothetical price approximately equal to the current cost of a rapid kit (US\$1) ^[26]. For HIVST costs only, we also varied the proportion of unsupervised HIVST session on-site, allowing for more clients to self-test with the same number of staff available. For costs per HIV-positive case detected only, we varied the number of HIV-positive test to reflect the variation of yield (+/-10%). Variations in individual parameter values informed our best/worst case scenario in which all the parameters were combined to yield the lowest/ highest average costs.

Ethical approval was obtained from the National Health Research Ethics Committee of Lesotho and the London School of Hygiene and Tropical Medicine Ethics Committee (protocol numbers: ID64-2018 and 14887 respectively).

Results

Outcomes of the community-based HTS and HIVST activities

In period 1, HTS activities are gradually increasing and reach a peak of 11,000 tests conducted monthly (**Figure 2. a.**). In period 2, mainly on-site HIVST is provided by HTS counsellors who, consequently, reduce their HTS activities both at the mobile outreach and index testing. In period 3, we observe an increase of the number of HIVST kits used on-site, and kits provided for off-site use, with the addition of individual booths. The number of HIV-positive case finding is increasing and is driven by index testing activities (**Figure 2.b.**). Yield is constant in periods 1 and 2 (at 3%), until the introduction of HIVST booth in period 3 where it gradually increases to an average of 5%.

Results from the time and motion study and implication for the estimation of full versus incremental HIVST costs

There are two central findings from using the TMS to allocate shared costs (**Appendix Table S3**, <http://links.lww.com/QAD/B821>). First, indirect time accounts for a significant proportion of the daily working hours of a provider. The way this time is allocated in the calculation of personnel costs has a significant impact on total costs in both the full and incremental costs analysis. Second, the difference between average observed time spent on-site by counsellors to provide unsupervised and supervised HIVST services is important (mean (standard deviation): 10.4 (3.2) minutes versus 24.1(5.2) minutes, respectively – $t(53)=-8.6, p<0.01$).

Costs analysis

For both HTS and HIVST, the main drivers of costs are personnel costs at headquarters and in the field, followed by testing supplies and vehicle operation and maintenance (**Figure 3**). The average HTS cost per test conducted is US\$32.2 in period 1. In period 2 and 3, when an incremental costing method is applied to HIVST, HTS average costs are US\$35.0 and US\$34.3, and HIVST average costs are US\$15.4 and US\$14.0. In the case of a full costing approach, where joint costs are shared, HTS average costs are US\$28.5 and US\$23.5, and HIVST average costs are US\$43.3 and US\$37.7, in period 2 and 3, respectively. HIVST incremental financial costs, which includes only directly STAR project financial contributions for HIVST, were US\$6.0 and US\$5.6 in period 2 and 3, respectively. Total costs are increasing over time and are driven by increasing personnel costs (**Figure 3**). Cost per HIV-positive case identified increases between period 1 (US\$956) and period 2 (US\$1,249), in the transition to distributing HIVST, but is the lowest in period 3 (US\$813), when booths allowed onsite self-testing and immediate confirmatory testing, (**Table 1**). Detailed total and average costs for all three periods for the full and incremental costs analysis are presented in **Appendix Tables S4.a, S4.b and S4.c**, <http://links.lww.com/QAD/B821>.

Sensitivity and scenario analysis

Average costs per HIVST kit distributed and per HIV-positive case identified remained robust when key cost parameters were varied (**Figure 4.a.** and **Figure 4.b.**). Start-up and capital costs account for a small proportion of the community-based HTS, therefore, our assumptions on the life years of start-up costs, vehicle life and discount rate applied have only a small impact on our results (ranges from US\$14.0 - US\$14.1 and US\$808.6 - US\$825.6 for cost per kit and cost per HIV-positive respectively). The variation by 20% of

the length of observed testing episodes used for personnel costs allocation has a slightly stronger effect on average cost per kit (range: US\$12.3 - US\$15.7).

For both scenario analyses, we looked at factors potentially reducing average costs. The variation of headquarter-based personnel costs only has a minor effect (ranges from US\$14.0 - US\$14.1 and US\$808.0 - US\$817.0) on cost per kit and cost per HIV-positive respectively. The reduction of the HIVST kit price and increase of distribution volumes reduced average cost per kit distributed (US\$12.3 and US\$12.8 respectively) but only had a minor effect on cost per HIV-positive (US\$796.9 and US\$810.0 respectively). As expected, a reduction of field-based personnel costs impacts on the average costs per HIV-positive (US\$754.7) but the effect is less important on cost per kit (US\$13.0). The yield strongly affects cost per positive (US\$738.6). A 50% reduction of the level of supervision by PSI staff for on-site HIVST can also reduce costs per kit distributed (US\$12.0) but is likely also to have effects on impact. Finally, the best-worst case scenarios show ranges of US\$8.5 - US\$16.9 and US\$668.6 - US\$969.3 for cost per kit and cost per HIV-positive respectively.

Discussion

We found that the addition of HIVST increases the overall programme's affordability for HIV-positive case finding. The increase of HIV-positive case finding, and yield is driven by an increase in index testing activities, thanks to the efficient introduction of self-testing and booths in period 3, allowing more staff to conduct index testing instead of being mobilized at the mobile outreach. TMS data were also used to value potential impact on costs of efficiency gains in services provision, particularly regarding high personnel costs. As suggested by the scenario analysis, an increase of unsupervised on-site HIVST could have a significant impact on HIVST average costs, allowing more staff to focus on index testing or other activities.

Recent best practice guidelines on cost-effectiveness analysis recommend the use of quality-adjusted life years gained (QALYs) and disability-adjusted life year averted (DALYs) for valuing health outcomes ^[27]. Previous work suggests that cost-per-diagnosis is strongly correlated with cost per disability-adjusted life year averted when evaluating HTS and that it can be used as a metric to assess an intervention's cost-effectiveness ^[28]. Our micro-costing study, within its scope and timeframe, does not capture all individual and population-based costs and benefit of the intervention, therefore, these results should not be interpreted for cost-effectiveness analysis.

Our HIVST full economic average costs estimates are higher than recently published estimates by Mangenah et al ^[23]. The authors published a full economic average cost per HIVST kit distributed at US\$8.15, US\$16.42 and US\$13.84 in Malawi, Zambia and Zimbabwe, respectively. The HIVST model was door-to-door only, where community-based agents were offering HIVST kits directly to households without immediate confirmatory testing and the costs reported per HIVST kit distributed. HIVST full costs are higher in Lesotho because HIVST volumes distributed were lower potentially leading to diseconomies of scale, and HIVST kits were distributed in the communities by either professional or lay counsellors resulting in higher field personnel costs. Because the test results were not reported, results from Mangenah et al. are not comparable with average cost per positive case identified. In addition, our costs are higher to those reported in a recent studies on costs of HIV testing in sub-Saharan Africa including Lesotho ^[29-32]. This difference may be explained by several factors. We included above service level costs, and our intervention is managed by an international NGO with high quality of services and M&E reporting relative to public sector. Furthermore, HIV-positive case finding in communities require additional staff time and equipment such as vehicles ^[4]. Finally, the number of positive cases identified was relatively low in a context where 81% of PLHIV already know their status with a yield of 3% ^[1].

The differences in personnel cost allocation between full (personnel costs associated with travel and administrative activities is shared between HTS and HIVST based on the volume of activities^[21]) and incremental (personnel costs of time spent on indirect client activities is allocated to the existing intervention HIVST is being added to) costing approaches have a significant impact on costs. This is particularly relevant for community-based interventions in remote areas where provider's indirect time is significant ^[33, 34]. Budgeting of HIVST using incremental costs risks to underestimate needs if HTS is not running well. Incremental HIVST costing, only considering financial costs, assumes that the existing intervention has the capacity (particularly human resources) to absorb the new intervention. They may be applicable in a case of low HIVST distribution where the staff has the capacity to absorb the added testing modality and the effect on the services it is being added to is minor. This was not the case in Lesotho but is shown to highlight how incremental costs can potentially vary between interventions.

Programme costs and cost per HIV-positive identified tend to increase over time ^[29]. The increase in total costs over time is mainly explained by an increase of the team size in the field. Integration of HIVST improved the HTS efficiency as defined by increased rates of HIV positive case finding which is a great achievement in the current HIV testing landscape, where increasing HIV testing coverage makes it increasing harder to identify new HIV positive cases.

Cost and cost-effectiveness studies for HIVST need to account for capacity to improvement over time in order to avoid over-estimating costs (period 2 to 3). New programmes should encourage implementation research and use early results to inform programme strategy. For instance, we applied this strategy with the ATLAS project on HIV self-testing in West Africa to identify opportunities for task shifting from medical doctors to less scarce health care workers ^[35].

As well as guiding sustainable national scale-up for Lesotho, these data have relevance to other countries considering the addition of self-testing to community-based HTS ^[36]. First, HIVST can be added to improve community-based program efficiency and allow a reallocation of scarce human resources to other key activities in the HIV response. Second, community-based interventions can incur important indirect personnel costs such as travel time to sites, other costing analyses should be transparent and report their inclusion/exclusion. Third, full and incremental costing approaches can provide a range to estimate health system needs for scale-up. The risks of using costs not fit for purpose or setting can lead to under-budgeting and depleting health system through cross-subsidization from core health services, or rejecting potentially cost-effective intervention seen as too expensive.

Our study has limitations. First, because HIVST was introduced in all sites of the intervention at the same time, there were no control sites against which to evaluate the effect of HIVST introduction. Second, only new positive cases detected are reported, the volume of known seropositive clients retesting was not reported and cannot be estimated. Third, stock-outs happened in period 3, limiting the number of kits distributed and potentially impacting on our costs, this might overestimate our average costs per kit distributed and per positive case identified.

To our knowledge, this is the first cost analysis using longitudinal data from a real-world intervention on HTS efficiency gains before and after introduction of HIVST. We showed that adding HIVST to community-based HTS can improve its overall affordability regarding HIV-positive case finding. We also highlighted the importance of transparency in reporting methods for priority setting, budgeting and financial planning.

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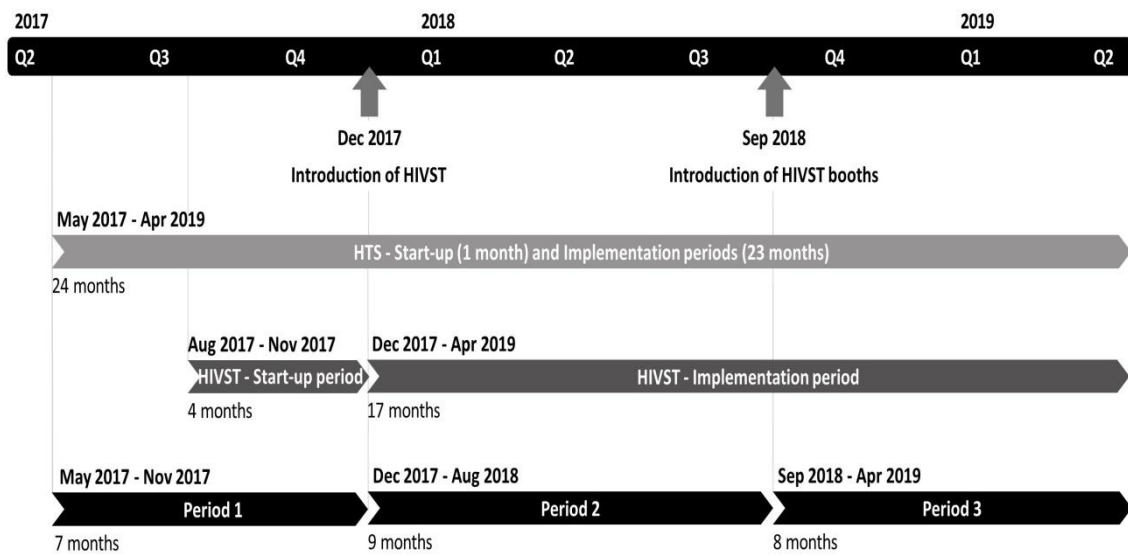
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Figure 1. Timelines of the community-based HIV testing services, major changes in strategy and analysis periods



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Figure 2. Outcomes of the community-based HTS and HIVST provision between May 2017 and April 2019: Volume of HTS and HIVST (2.a.), number of new HIV-positive case identified and yield (2.b.)

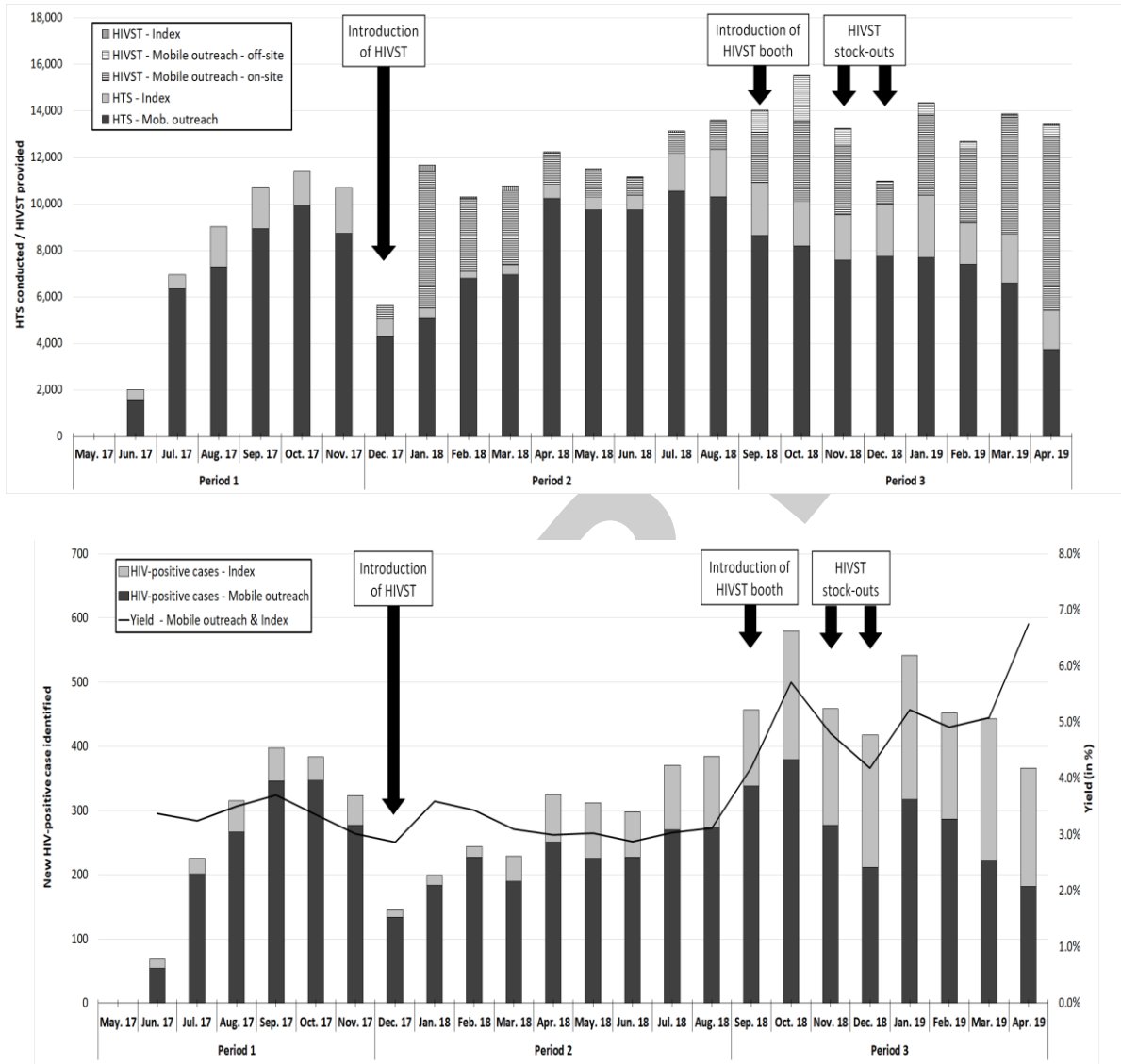
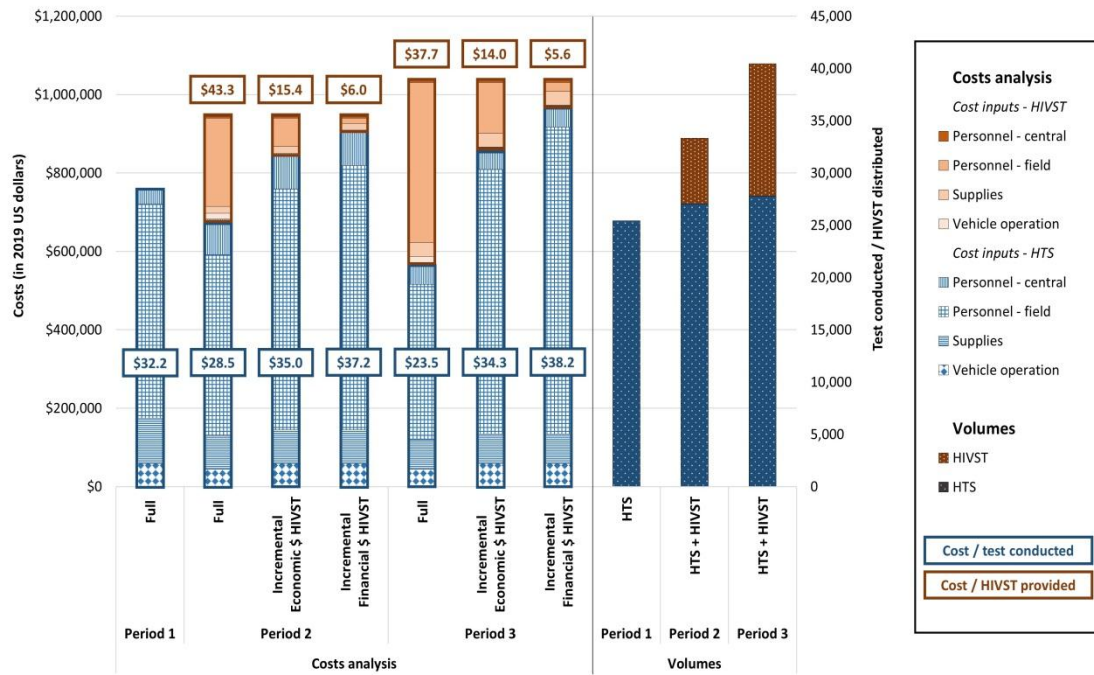


Figure 3. HTS and HIVST costs drivers, average costs and volumes per analysis period (in 2019 US\$)



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Figure 4. Results from the sensitivity and scenario analysis on (4.a.) the costs per HIVST kit distributed in period 3 and (4.b.) on the costs per HIV-positive case identified in period 3 (in 2019 US\$)

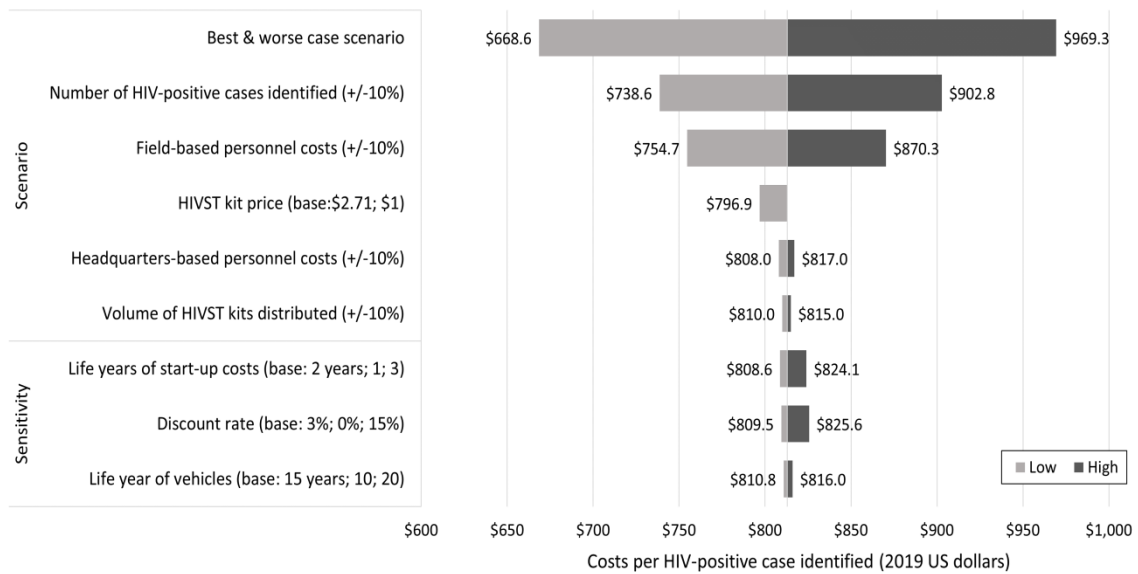
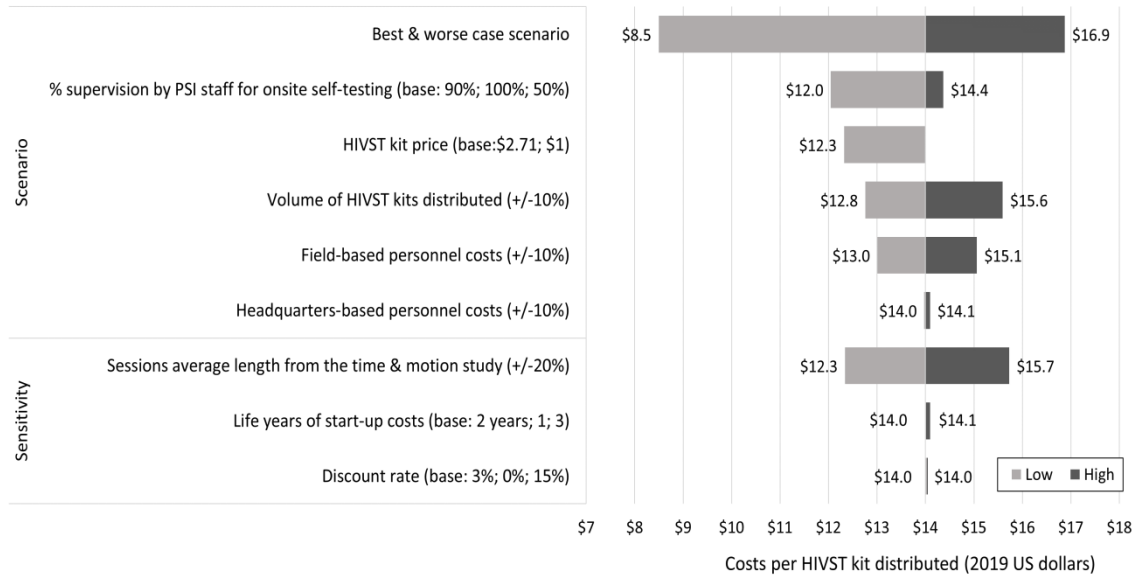


Table 1. Quarterly averages of total and average costs per HIV-positive case identified with community-based HTS during the period May 2017 – April 2019 (in 2019 US\$)

	Period 1	Period 2	Period 3
Total costs (HTS and HIVST services)	819,640	1,043,448	1,131,003
HIV-positive cases identified	858	836	1392
Yield (%)	3.4	3.1	5.0
Cost per HIV-positive case identified	956	1,249	813