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HIV self-testing positivity rate and linkage to confirmatory testing and care: a telephone survey in Côte d'Ivoire, Mali and Senegal

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24 **ABSTRACT**

HIV self-testing (HIVST) empowers individuals by allowing them to decide when and where to
test and with whom to share their results. From 2019 to 2022, the ATLAS program distributed ~
400 000 HIVST kits in Côte d'Ivoire, Mali, and Senegal. It prioritised key populations, including
female sex workers and men who have sex with men, and encouraged secondary distribution
of HIVST to their partners, peers and clients.

To preserve the confidential nature of HIVST, use of kits and HIVST results were not systematically tracked. Therefore, an anonymous phone survey was conducted to estimate HIVST positivity rates and linkage to confirmatory testing and care. This two-step survey involved an initial recruitment phase from March to June 2021 where participants were encouraged via leaflets to call a free phone number and complete a sociobehavioural guestionnaire.

This was followed by a second phase in September and October 2021, where participants who reported a reactive HIVST result were re-contacted to complete a further questionnaire. Of the

2 615 participants recruited during the first phase, 89.7% reported consistent results (2 visible

39 lines and result interpreted as reactive; one line and interpreted as non-reactive; or no/one line

40 and interpreted as invalid). HIVST positivity rates varied between 2.4% to 9.1% based on

41 calculation methods (i.e. self-interpreted result or reported number of lines, inclusion or

42 exclusion of don't knows and refusals).

43 The second phase saw 78 out of 126 eligible participants complete the questionnaire. Of the 27

44 who reported a consistent reactive result in the first phase, 15 (56%, 95%CI: 36 to 74%)

underwent confirmatory HIV testing, with 12 (80%) confirmed as HIV-positive, all of whombegan antiretroviral treatment.

47 The confirmation rate of HIVST results was fast, with 53% doing so within a week and 91%

48 within three months of self-testing. Two-thirds (65%) went to a general public facility, and one-

49 third to a facility dedicated to key populations.

50 The ATLAS HIVST distribution strategy reached people living with HIV in West Africa. Linkage to

51 confirmatory testing remained sub-optimal in these first years of HIVST implementation.

52 However, if confirmed HIV-positive, almost all initiated treatment. HIVST constitutes a relevant

- 53 complementary tool to existing screening services.
- 54

55 *Keywords:* AIDS, HIV self-testing, HIV testing services, diagnosis, knowledge of status, awareness fo 56 status, gay, bisexual, sex work, linkage to confirmatory testing and care, phone-based survey, key 57 populations, West Africa.

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Introduction

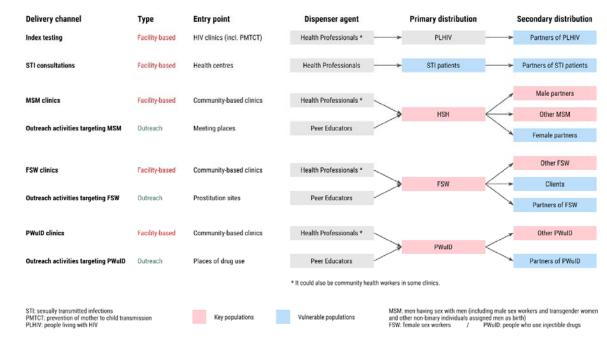
Early testing followed by successful linkage to antiretroviral treatment for those diagnosed with HIV can drastically reduce the risk of onward HIV transmission and mortality [1–6]. In 2021, according to the United Nations Program for HIV/AIDS (UNAIDS), 81% of the adult population living with HIV in West and Central Africa knew their status. Only 77% of them were on antiretroviral treatment [7], below the 95-95-95 UNAIDS targets for 2030 [8].

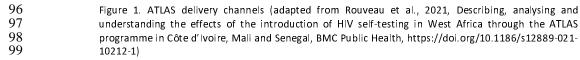
HIV self-testing (HIVST) is the process by which a person who wants to know their HIV status collects their own sample (oral fluid or blood), performs the test, and then interprets the results themself, often in a private setting [9]. It is an innovative tool that empowers individuals and guarantees the confidentiality of the test [10]. Individuals may decide when and where to test and with whom they want to share their result. It has been shown to be effective in screening populations vulnerable to HIV acquisition and transmission that are often hardly reached through conventional approaches [11–13]. Since 2016, the World Health Organization (WHO) has recommended HIVST as a complementary testing approach [14].

Following the experience gained in Eastern and Southern Africa under the STAR project [15–21], the UNAIDS funding agency sought to stimulate HIVST in West Africa. The ATLAS programme (*AutoTest de dépistage du VIH*: *Libre d'Accéder à la connaissance de son Statut*) aimed to promote, implement, and expand HIV self-testing in Côte d'Ivoire, Mali, and Senegal. Country national prevalence was comparatively low in West Africa in 2021: 1.9% (1.7%-2.2%) in Côte d'Ivoire, 0.8% (0.6%-1%) in Mali, and 0.3% (0.3%-0.4%) in Senegal according to Unaids[22].

In the ATLAS project's catchment areas, HIVST was integrated into existing testing policies, programs, and
 activities. A total of 397 367 HIVST kits were distributed free of charge between July 2019 and February 2022
 as part of the national AIDS strategy in these three countries. At the time of ATLAS' implementation, in 2019,
 only small-scale pilot studies on HIVST had previously been conducted in Senegal and Côte d'Ivoire, and none
 existed in Mali.

85 The design of the different delivery channels and the priority populations were developed with country 86 stakeholders: national AIDS programs/councils, international institutions including the WHO, international 87 and national non-governmental organisations involved in local HIV programs, and civil society and 88 community leaders. ATLAS HIVST distribution was organised through eight different operational delivery 89 channels (figure 1): five were facility-based (delivery of HIVST kits through public or community-based health 90 facilities), and three used community-based approaches involving outreach activities engaging female sex 91 workers (FSW), men who have sex with men (MSM), and people who use drugs (PWUD) [23]. Peer educators 92 conducted these outreach activities through group activities (e.g. talks, discussion groups, night visits, social 93 events, or parties) and face-to-face activities (e.g. home visits). Outreach activities represented the majority 94 (~85%) of ATLAS's distribution volume.



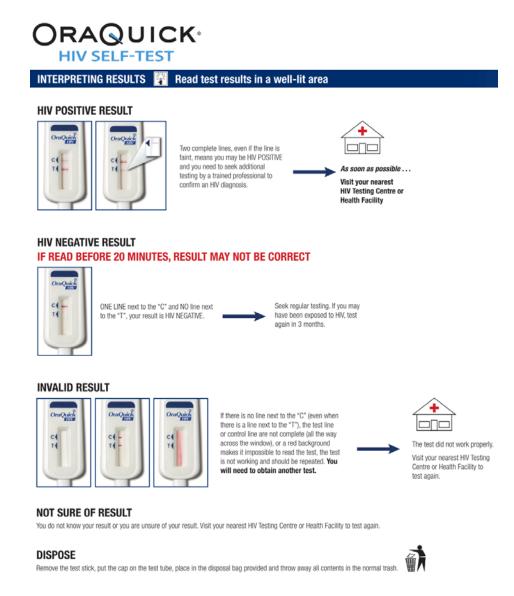


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ATLAS activities relied on both primary and secondary distribution. HIVST kits were distributed by peer educators and healthcare professionals to primary contacts for their personal use (primary distribution). With secondary distribution, primary contacts were provided HIVST kits and invited to redistribute them to their peers, partners, and clients. These secondary contacts were often members of key populations that can be more difficult to engage in HIV prevention, along with other peripheral vulnerable populations. This chainreferral distribution of HIVST implies that end-users were not limited to primary contacts.

106 Only oral self-testing (OraQuick HIV Self-Test®) has been distributed through ATLAS. OraSure 107 Technologies, the manufacturer of the OraQuick test, accompanies each HIVST kit with a user manual for 108 result interpretation. OraQuick HIVST should be interpreted as follow: reactive if two lines (C & T) are visible, 109 even barely; non-reactive if only the C (control) line is visible; invalid if no line is visible or if only the T (test) 110 line is visible.

111 In addition to the manufacturer's instructions (figure 2), locally adapted brochures and explanatory 112 videos in French and local languages have been developed to help users perform the test, interpret the result 113 and know what actions should be taken following a non-reactive, a reactive or indeterminate result. They 114 also encouraged people with a reactive HIVST to seek confirmatory HIV testing and care. Free phone lines 115 have been set up in each country, and operators of these lines were trained about HIVST.



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Figure 2. Guidelines for interpreting HIVST result, extracted from the English version of the manufacturer instructions for use (OraQuick HIV Self-Test®)

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120 To preserve the anonymity and confidentiality of HIVST and not impede their use, ATLAS has decided, in 121 line with WHO recommendations, not to track the use and outcomes of distributed HIVST kits directly. Such 122 tracking can be logistically challenging and costly and could limit the distribution, redistribution and use of 123 HIVST [24]. Without systematic tracking, it was challenging to obtain information on who was using the 124 HIVST, the results of the tests and the linkage to confirmatory testing and treatment. These are crucial 125 indicators to assess program effectiveness and impact. For instance, the positivity rate can be related to the 126 yield of new individuals diagnosed with HIV and would suggest that the testing modality is indeed reaching 127 those in need. Diagnosed individuals must seek confirmatory testing and be linked to care to maximise 128 health benefits and decrease onward transmission.

We conducted an innovative survey by setting up an anonymous and free telephone platform in Côte d'Ivoire, Mali and Senegal while preserving anonymity and encouraging voluntary participation. This survey among ATLAS HIVST users showed that HIVST secondary distribution was feasible and acceptable. Participants reported that they appreciated the ease of use of HIVST, its discretion and the fact that they are autonomous in carrying out the test. Finally, HIVST appeared as a relevant additional approach for those

usually distant from community activities and HIV testing services, and has the potential to reach, beyondkey populations, partners, clients, and other groups vulnerable to HIV [25].

A complementary survey was conducted among those with an HIVST reactive result. Here we report on
 HIVST's positivity rates and linkage to confirmatory testing and care.

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Materials and Methods

140 Sources of data

141 The ATLAS program embedded multiple research activities, from qualitative studies to economic 142 analyses, which have been described in detail elsewhere [26–30].

143 It included a voluntary phone survey. Between mid-March and mid-June 2021, dedicated survey flyers 144 were distributed with the HIVST kits inviting self-test users in each country to call a toll-free number to 145 complete a questionnaire (phase 1). All calls from the three countries were rerouted to a telephone platform 146 located in Abidjan and operated by Ipsos Côte d'Ivoire, which was selected following an international call for 147 tenders. The questionnaire, which lasted 20 to 30 minutes, collected information on sociodemographic 148 characteristics of HIVST users, testing history, sexual and preventive behaviours, HIVST use and difficulties 149 encountered. Participation in the survey was rewarded with 2 000 XOF (\approx 3.40 USD) of phone communication 150 credit. In order to participate in the survey, participants had to be of legal age to use an HIVST on their own 151 without parental permission (16 years in Côte d'Ivoire, 18 years in Mali, and 15 years in Senegal) and had to 152 have used an HIVST provided to them through the ATLAS project.

153 As the survey was anonymous, there was a risk that some HIVST users may participate more than once or 154 that individuals who have never used HIVST tried to participate to receive the financial incentive. To limit 155 these risks, several measures were taken: (i) the leaflet distributed with the HIVST kits had a unique 9-digit 156 number generated by the research team that was requested prior to participation in the survey; (ii) the same 157 unique number could not be used twice; (iii) the financial incentive was only paid out once the questionnaire 158 was fully completed (however individuals could refuse to answer any particular question); (iv) the same 159 telephone number could not be used twice to receive the telephone credit. These unique 9-digit numbers 160 were generated non-sequentially and were grouped by country, delivery channel and implementing partner. 161 Thus, any unique number could indirectly identify the delivery channel where the HIVST kit was initially 162 dispensed.

163 In total, 2 615 participants were recruited for phase 1 [25]. During the interviews, each participant was 164 asked about the number of lines that appeared when reading the HIVST result and their self-interpretation of 165 it (reactive or non-reactive). Those who reported two lines or a reactive result were asked for their consent 166 to be called back a few months later to participate in a complementary survey and, if consented, to provide a 167 phone contact.

168 Between September 27th and October 22th 2021, eligible participants who agreed to be re-contacted 169 were phoned to complete a 5-minute questionnaire (phase 2) on linkage to confirmatory testing and care.

The interviews were conducted in either French, English, Bambara, or Wolof. On-the-fly translation into other local languages was also available. Compensation of XOF 2 000 (≈3.40 USD) in the form of telephone credit was given to participants who completed the phase 2 questionnaire. Unlike in phase 1, it was not a financial incentive: participants were informed about it only at the end of the interview. Interviews were not audio-recorded. Questionnaires' responses were captured on a computer and stored in a database managed by PAC-CI, an Ivorian research institute with expertise in clinical research.

At the end of the survey, collected telephone numbers (for appointments and rewards) were deleted from the database. All procedures have been described in a publicly available data management plan (https://dmp.opidor.fr/plans/3354/export.pdf).

179 Data analysis

Based on phase 1 participants' self-reports, we distinguished those having reported HIVST results consistent with both the reported number of visible lines and the reported self-interpretation (2 visible lines and result interpreted as reactive; one line and interpreted as non-reactive; or no/one line and interpreted as invalid), an inconsistent result, or a partial result (they refused to answer or answered they didn't know to one or both questions).

185 To estimate HIVST positivity rates, we separately considered the self-interpreted results and the reported 186 number of lines on the HIVST. For each source, we made three hypotheses (low, central and high) about 187 "don't know" and refusals (DK-R). Using self-reported results, the low hypothesis considered DK-R as non-188 reactive, and the high hypothesis as reactive, while DK-R were excluded from both the numerator and the 189 denominator in the central hypothesis. Using the reported number of visible lines, the low hypothesis 190 considered DK-R as one line, and the high hypothesis as two lines, while DK-R were excluded from both the 191 numerator and the denominator in the central hypothesis. Positivity rates were stratified by respondents' 192 gender, country, and distribution channel.

We described the selection of eligible participants for phase 2 questionnaires and corresponding participation rates. To assess any participation bias, characteristics of phase 2 participants were compared with individuals eligible for phase 2 but who did not participate and with phase 1 participants not eligible for phase 2.

Among phase 2 eligible participants who completed their questionnaire, linkage to confirmatory testing, the proportion being confirmed HIV positive and treatment initiation were described, stratified by the reported number of lines and self-interpreted HIVST result in phase 1 questionnaire. Confidence intervals (95% confidence interval, 95%CI) were computed using Wilson's method with Yate's continuity correction.

We also explored (i) for those who did not link to confirmatory testing, the main reported reason; and (ii) for those who did link to confirmatory testing, the type of facility was confirmatory testing was performed and the time between HIVST and confirmatory testing.

All analyses have been performed using R version 4.2.2 [31]. A dedicated anonymised dataset and the corresponding R script are available on Zenodo (https://doi.org/ 10.5281/zenodo.7986077) to allow replication of the analysis.

207 . Ethics

ATLAS research protocol (version 3.0, October 8 2020) has been approved by the WHO Ethical Research Committee (January 12, 2021, reference: ERC 0003181), the National Ethics Committee for Life Sciences and Health of Côte d'Ivoire (November 27, 2020, reference: 191-20/MSHP/CNESVS-km, IRB:000111917), the Ethics Committee of the Faculty of Medicine and Pharmacy of the University of Bamako, Mali (November 16, 2020, reference: 2020/254/CE/FMPOS/FAPH), and the National Ethics Committee for Health Research of Senegal (January 26, 2021, protocol SEN19/32, n°8 MSAS/CNERS/Sec).

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Results

216 **HIVST results**

Of the 2 615 participants recruited in phase 1, 2 346 (89.7%) reported a self-interpreted HIVST result consistent with their reported number of visibles lines on the HIVST: 2 292 (88.0%) reported one line and self-interpreted it as non-reactive, 50 (1.9%) two lines and reactive and 4 (0.2%) none or one line selfinterpreted as invalid (table 1). In contrast, 48 (1.8%) reported inconsistent answers: 10 (0.4%) one line and self-interpreted it as reactive, 35 (1.3%) two lines and non-reactive and 3 (0.1%) no line and non-reactive.

Finally, 221 (8.5%) reported a partial result: 147 (5.6%) reported 0, 1 or 2 lines, but did not know how to interpret the result or refused to answer; 46 (1.7%) self-interpreted their result, but did not know or refused to report the number of lines; and 28 (1.1%) did not know or refused to answer to both questions

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Table 1. Self-reported HIV self-test (HIVST) result, reported number of lines on the HIVST, and positivity rates according to different hypotheses among participants of the first phase of the survey in Côte d'Ivoire, Mali, and Senegal (2021).

Phase 1 participants	2615 (100%)
Consistent answer (C)	2346 (89. 7%)
$2 \text{ lines / reactive}^{\dagger} (C_i)$	50 (1.9%)
1 line / non-reactive (C ₂)	2 2 92 (88%)
0-1 line/ invalid (C₃)	4 (0.2%)
Inconsistent answer (I)	48 (1.8%)
$1 \text{ line} / \text{reactive}^{\dagger} (I_1)$	10 (0.4%)
$D line / reactive^{\dagger} (I_2)$	0 (0%)
2 lines/ non-reactive † (I ₃)	35 (1.3%)
Dline / non-reactive (I4)	3 (0. 1%)
2 lines/invalid [†] (I ₅)	0 (0%)
Partial answer (P)	221 (8.5%)
O line / DK-R (P1)	1 (<0.1%)
1 line / DK-R (P ₂)	117 (4.5%)
$2 \operatorname{lines} / \mathrm{DK-R}^{\dagger} (\mathrm{P}_{3})$	29 (1. 1%)
DK-R / reactive [†] (P ₄)	2 (<0.1%)
DK-R / non-reactive (P₅)	44 (1.7%)
DK-R / invalid (P ₆)	0 (0%)
DK-R / DK-R (P7)	28 (1.1%)
Positivity Rate	
Based on self-interpreted test results	
Low hypothesis (DK- R as not reactive) $(C_1 + _1 + _2 + P_4) / n$	62 / 2615 (2.4 %)
Central hypothesis (DK-R excluded) (C ₁ + ₁ + ₂ + P ₄) / (C + + P ₄ + P ₅ + P ₆)	62 / 2440 (2.5 %)
High hypothesis (DK-R as reactive) (C ₁ + ₁ + ₂ + P ₁ +P ₂ +P ₃ +P ₄ +P ₇) / n	237 / 2615 (9.1%)
Based on the reported number of lines	
Low hypothesis (DK-R as 1 line) (C ₁ + I ₃ +I ₅ + P ₃) / n	114 / 2615 (4.4 %)
Central hypothesis mid (DK-R excluded) (C ₁ + I ₃ +I ₅ + P ₃) / (C + I + P ₁ + P ₂ + P ₃)	114 / 2541 (4.5 %)
High hypothesis (DK-R as 2 lines) (C1 + 3 + 5 + P3+ P4 + P5 + P6+ P7) / (C + + P1 + P2 + P3)	188 / 2615 (7.2 %)

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229 HIVST positivity rates

Based on self-interpreted HIVST results, the overall positivity rate was 2.4% when DK-R were considered non-reactive (Table 2, low hypothesis). By excluding DK-R from the numerator and the denominator (central hypothesis), the positivity rate increased to 2.5%. Considering DK-R as reactive (high hypothesis) increased the positivity rate to 9.1%. Estimates based on the reported number of visible lines on the HIVST were 4.4%, 4.5% and 7.2%, respectively, for low, central and high hypotheses. Positivity rates ranged from 1.8% to 9.8% in Côte d'Ivoire, 3.5% to 7.8% in Mali, and 1.2% to 15.0% in Senegal depending on the hypothesis (e.g., low or high; Table 2).

Positivity rates were higher among participants recruited through community-based distribution channels: 4.8% for men and 4.9% for women in the MSM-based channels, and 4.6% for men and 4.2% for women in the FSW-based channels (central hypothesis based on the number of lines). In the other distribution channels (PWUD-based and facility-based), positivity rates were slightly lower: 3.1% for men and 2.9% for women.

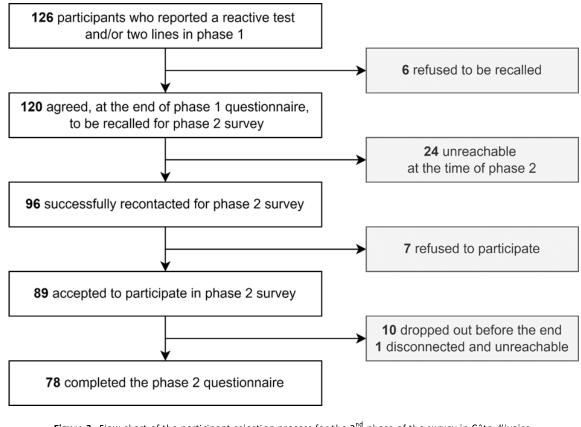
242 Participation in phase 2

During phase 1, 126 individuals reported two lines or self-interpreted their result as reactive, thus were identified as eligible for phase 2 (table 1). Among them, 6 had refused to be re-contacted after phase 1 (figure 3). Among the 120 (95%) who agreed to be re-contacted, 24 (20%) were unreachable at the time of the phase 2 survey, and 96 (80%) were successfully re-contacted. Among the latest, 89 (93%) accepted to participate in the phase 2 survey. Ten dropped out before the end of the interview, and 1 disconnected and was unreachable afterwards. As a result, 78 participants completed phase 2 questionnaire.

The participants who completed the phase 2 questionnaire had similar sociodemographic characteristics (e.g. country, sex, distribution channel, age group, marital status) compared to those eligible for phase 2, but that did not complete it, and to phase 1 participants not eligible for phase 2 (table S1). For most participants (86%), phase 2 questionnaire was completed between 4 and 6 months after phase 1 questionnaire (table S5).

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Figure 3. Flow chart of the participant selection process for the 2nd phase of the survey in Côte d'Ivoire, Mali, and Senegal (2021).

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Table 2. Positivity rates based on self-interpreted HIVST results or the reported number of visible lines, by distribution channel, gender and country, among participants of the first survey phase in Côte d'Ivoire, Mali, and Senegal (2021).

			MSM-ba	sed channels	FSW-ba	se d channels	Others de	elivery channels	Total
			Man	Woman	Man	Woman	Man	Woman	
		Côt e d'Ivoire	2.5% (16/650)	1.4% (1/73)	1.5% (5/339)	1.2% (3/245)	0% (0/60)	0% (0/23)	1.8% (25/1 390)
	1.	Mali	4.6% (14/306)	0% (0/29)	1.9% (5/269)	3.9% (14/360)	9.1% (1/11)	0% (0/9)	3.5% (34/984)
	Low	Senegal	4.9% (2/41)	0% (0/1)	0% (0/12)	0% (0/80)	0% (0/66)	2.4% (1/41)	1.2% (3/241)
		Overall	3.2% (32/997)	1.0% (1/103)	1.6% (10/620)	2.5% (17/685)	0.7% (1/137)	1.4% (1/73)	2.4% (62/2 615)
ositivity rate based		Côt e d'Ivoire	2.7% (16/597)	1.4% (1/71)	1.6% (5/311)	1.4% (3/221)	0% (0/58)	0% (0/21)	2.0% (25/1 279)
n	Combust	Mali	4.7% (14/301)	0% (0/29)	1.9% (5/257)	4.1% (14/345)	9.1% (1/11)	0% (0/9)	3.6% (34/952)
self-reported HIVST	Central	Senegal	6.1% (2/33)	0% (0/1)	0% (0/11)	0% (0/65)	0% (0/61)	2.6% (1/38)	1.4% (3/209)
esults		Overall	3.4% (32/931)	1.0% (1/101)	1.7% (10/579)	2.7% (17/631)	0.8% (1/130)	1.5% (1/68)	2.5% (62/2 440)
	High	Côt e d'Ivoire	10.6% (69/650)	4.1% (3/73)	9.7% (33/339)	11% (27/245)	3.3% (2/60)	8.7% (2/23)	9.8% (136/1 390
		Mali	6.2% (19/306)	0% (0/29)	6.3% (17/269)	8.1% (29/360)	9.1% (1/11)	0% (0/9)	6.7% (66/984)
		Senegal	24.0% (10/41)	0.0% (0/1)	8.3% (1/12)	19.0% (15/80)	7.6% (5/66)	9.8% (4/41)	15.0% (35/241)
		Overall	9.8% (98/997)	2.9% (3/103)	8.2% (51/620)	10.0% (71/685)	5.8% (8/137)	8.2% (6/73)	9.1% (237/2 61
	Low	Côte d'Ivoire	4.2% (27/650)	5.5% (4/73)	4.7% (16/339)	2.0% (5/245)	0% (0/60)	4.3% (1/23)	3.8% (53/1390)
		Mali	4.9% (15/306)	3.4% (1/29)	4.5% (12/269)	5.3% (19/360)	9.1% (1/11)	0% (0/9)	4.9% (48/984)
		Senegal	12.2% (5/41)	0% (0/1)	0% (0/12)	5.0% (4/80)	4.5% (3/66)	2.4% (1/41)	5.4% (13/241)
		Overall	4.7% (47/997)	4.9% (5/103)	4.5% (28/620)	4.1% (28/685)	2.9% (4/137)	2.7% (2/73)	4.4% (114/2 615
ositivity rate based		Côt e d'Ivoire	4.2% (27/641)	5.5% (4/73)	4 8% (16/331)	2.1% (5/241)	0% (0/60)	4.5% (1/22)	3.9% (53/1368)
'n	Combust	Mali	5.0% (15/298)	3.4% (1/29)	4.5% (12/264)	5.5% (19/344)	9.1% (1/11)	0% (0/9)	5.0% (48/955)
ne reported number	Central	Senegal	13.2% (5/38)	0% (0/1)	0% (0/10)	5.3% (4/75)	5.3% (3/57)	2.7% (1/37)	6.0% (13/218)
f visible lines		Overall	4.8% (47/977)	4.9% (5/103)	4.6% (28/605)	4.2% (28/660)	3.1% (4/128)	2.9% (2/68)	4.5% (114/2 54:
		Côte d'Ivoire	5.5% (36/650)	5.5% (4/73)	7 1% (24/339)	3.7% (9/245)	0% (0/60)	8.7% (2/23)	5.4% (75/1 390)
		Mali	7.5% (23/306)	3.4% (1/29)	6.3% (17/269)	9.7% (35/360)	9.1% (1/11)	0% (0/9)	7.8% (77/984)
	High	Senegal	19.5% (8/41)	0% (0/1)	16.7% (2/12)	11.2% (9/80)	18.2% (12/66)	12.2% (5/41)	14.9% (36/241)
		Overall	6.7% (67/997)	4.9% (5/103)	6.9% (43/620)	7.7% (53/685)	9.5% (13/137)	9.6% (7/73)	7.2% (188/2 615

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DK: don't know. R: refusals. FSW: female sex workers, MSM: men having sex with men, PR: positivity rate. Shaded cells indicated cells with less than 50 participants. Low hypothesis: DK-R as non-reactive or 1 line. Central hypothesis: DK-R excluded from the numerator and the denominator. High hypothesis: DK-R as reactive or 2

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lines.

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265 Linkage to confirmatory testing and care

266 Overall, 34 of the 78 participants of phase 2 survey (44%) reported having performed confirmatory 267 testing. Linkage was higher for those who reported 2 lines and correctly self-interpreted their result as 268 reactive: 56% (95%CI: 36-74%), followed by those who reported two lines but did not know or refused to 269 report their test interpretation with a linkage rate of 44% (95%CI: 22-69%). Not surprisingly, linkage to 270 confirmatory testing was lower (36%; 95%CI: 19-57%) among those who reported 2 lines but incorrectly 271 self-interpreted the result as non-reactive (table 3). Finally, among the 8 participants who reported none 272 or one line or did not know how many lines and incorrectly self-interpreted the result as reactive, only 2 273 linked to confirmatory testing.

The main reason given for not linking to confirmatory testing was that "their HIVST was non-reactive" (18/44, 41%, and although 8 of these 18 reported a reactive result in phase 1 questionnaire); followed by "not knowing that a confirmation test was required" (10/44, 23%); and "not having time" (8/44, 18%) (table S2).

When participants were linked to confirmatory testing, it was a short time after performing their HIVST: 53% linked in less than one week and 91% in less than 3 months (table S3).

280 Most participants (65%) performed their confirmatory testing in a general public facility (health 281 centre, hospital, clinic or maternity), and 35% chose a community-based clinic or health centre dedicated 282 to key populations (table S4).

Among the 34 linked to confirmatory testing, 19 (56%, 95%CI: 38-72%) were confirmed HIV-positive, and 18 (95%, 95%CI; 72-100%) initiated antiretroviral treatment. Among the 27 who reported a consistent reactive result in the phase 1 questionnaire, 15 (56%, 95%CI: 36-74%) linked to confirmatory test, 12 (80%) were confirmed HIV-positive and all started treatment (100%).

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Table 3. Linkage to confirmatory testing, proportion being confirmed HIV positive and treatment initiation, by reported number of lines and self-interpreted HIVST
result among eligible participants of the second phase of the survey who completed their questionnaire in Côte d'Ivoire, Mali, and Senegal (2021).

Reported number of lines/	Completed phase 2	Linked to confirm	Linked to confirmatory testing		Confirmed HIV positive		Initiated ART	
self-interpret ed HIVST result	n	n (%)	95%Cl	n (%)	95%Cl	n (%)	95% Cl	
Overall	78	34 (44%)	33% to 55%	19 (56%)	38% to 72%	18 (95%)	72% to 100%	
2 lines / reactive	27	15 (56%)	36% to 74%	12 (80%)	51% to 95%	12 (100%)	70% to 100%	
1 line / reactive	7	1 (14%)	1% to 58%	0 (0%)	0% to 80%			
2 lin es / non-reactive	25	9 (36%)	19% to 57%	3 (33%)	9% to 69%	3 (100%)	31% to 100%	
2 lin es / DK-R	18	8 (44%)	22% to 69%	4 (50%)	22% to 78%	3 (75%)	22% to 99%	
DK-R / reactive	1	1(100%)	5% to 100%	0 (0%)	0% to 95%			

291 DK: don't know. R: refuse to answer. CI: confidence interval.

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Discussion

Our study reveals that the strategy deployed by the ATLAS program, through secondary distribution of HIVST and targeted channels, successfully reached people living with HIV in West Africa. However, linkage to confirmatory HIV testing and access to care remained sub-optimal during these initial years of HIVST implementation. Moreover, among participants who confirmed their reactive self-test result with a traditional facility-based HIV test, a significant proportion quickly proceeded with this confirmation (more than half in less than a week and the vast majority in less than three months). Furthermore, if individuals were confirmed HIV-positive, almost all began antiretroviral treatment.

The implementation of a telephone survey, aimed at gathering information from HIVST users while preserving anonymity and without interfering with secondary distribution, has proven to be very useful to evaluate the ATLAS project. However, its high cost makes it difficult to integrate it into national strategies for assessing the impact of HIVST. Nevertheless, other impact evaluation methods, such as data triangulation[27] and modelling, may prove more suitable for routine monitoring of HIVST's impacts.

306 In our study, most participants (90%) demonstrated a consistent interpretation between the number 307 of lines reported and the declared result of their HIVST. However, 2% of them reported an inconsistent 308 interpretation of the results. Among them, a small number reported the presence of two visible lines, 309 suggesting potential issues in interpreting the number of visible lines on HIVST kits. In the context of the 310 ATLAS program, the distribution strategy combining primary and secondary approaches has led many 311 HIVST users to perform their HIVST without receiving advice from a healthcare professional or a trained 312 peer educator. Although the HIVST is not designed to require supervision, it is essential to have received 313 information on its use before proceeding with the test. However, the lack of supervision is likely 314 insufficient to explain the inconsistencies observed [32]. Some inconsistencies may result from a 315 misunderstanding of the terms "reactive" and "non-reactive", particularly considering that HIVST was a 316 new tool in our context and that traditional terms used to describe conventional HIV testing are 317 "positive" and "negative". This possible misunderstanding of the terms is also highlighted by the fact that 318 8 participants reported a "reactive" result in phase 1 questionnaire and then in phase 2 that their test 319 was "non-reactive" as the main reason for not linking to confirmatory testing. Specific qualitative 320 interviews or focus groups discussion with HIVST users could help better understand how they perceive 321 different terms.

322 According to our estimates, HIVST positivity rates range from 1.8% to 9.8% in Côte d'Ivoire, 3.5% to 323 7.8% in Mali, and 1.2% to 15.0% in Senegal depending on how missing results (e.g., "don't know" and 324 refusals) are classified. It is important to interpret these HIV positivity rates while considering the 325 treatment-adjusted prevalence (i.e., removing those on treatment from the numerator and denominator 326 of HIV prevalence), a more reliable indicator for evaluating the effectiveness of targeted screening 327 programs [33]. In West Africa, the treatment-adjusted prevalence remained relatively low in 2021: 0.6% 328 in Côte d'Ivoire, 0.7% in Mali, and 0.06% in Senegal, according to UNAIDS data 329 (https://aidsinfo.unaids.org/). Our results suggest that the ATLAS HIVST distribution strategy successfully 330 reached people living with HIV. In 2021, the observed HIV positivity rates for conventional HIV testing 331 were 1.4% in Côte d'Ivoire, 2.2% in Mali, and 1.0% in Senegal [34]. These rates were slightly lower to 332 those we identified with HIVST based on our lower (conservative) assumption. Between 2020 and 2021, 333 ATLAS implementing partners collected spontaneous feedback from HIVST users. This unpublished data 334 collection was non-systematic and varied from one partner to another. Among 4 463 documented 335 feedbacks, HIVST was reactive for 188 cases (4.2%), consistent with our estimates based on the reported 336 number of visible lines (4.5%, central hypothesis).

Overall, these results for HIVST positivity are generally higher than the average overall positivity of HIV testing services (excluding HIVST) in West Africa. For instance, in 2020 an estimated 1.9% of all HIV tests performed were found to be positive in the region (95% credible intervals: 1.3 to 2.7%) [34]. Further, among 15-24 and 25-34 years old, which constitute more than 80% of our sample, overall positivity was, respectively, 0.9% (0.7 to 1.3%) and 1.6% (1.2 to 2.2%). Collectively, these results provide evidence that HIVST is a high-yield testing modality that can address the unmet HIV testing needs of key populations and their partners.

344 Our linkage to confirmatory testing estimates were based on small numbers resulting in large 345 confidence intervals. Nevertheless, the overall proportion was clearly sub-optimal (44%, 95% confidence

346 interval from 33% to 55%). However, this estimate includes some individuals who did not adequately self-347 interpreted their HIVST result as reactive. When considering only those who reported two lines and self-348 interpreted their result as reactive, the linkage rate increased to 56% (36% to 74%). This percentage is 349 close to that was observed in a study conducted in Kenya on HIV testing of FSW male partners using 350 HIVST secondary distribution, where 65% of men with a reactive result had a confirmatory test [35]. 351 Linkage to confirmatory testing happened relatively quickly after HIVST use: 53% did it in less than a week 352 and 91% in less than three months. Similar results were observed in a study in the general population in 353 Zambia[36], and a study among MSM in Nigeria [37]. For those who did confirmatory testing and were 354 confirmed HIV positive, initiation of antiretroviral treatment was almost systematic, showing good 355 linkage to care after confirmatory testing, as observed in many HIVST studies in sub-Saharan Africa [38– 356 40].

357 Previous analyses of ATLAS data showed that HIVST could reach people not reached by conventional 358 HIV testing approaches [41], particularly partners and clients of key populations and key population 359 members not self-identifying as such [25]. It is consistent with the finding that two-thirds of participants 360 who did confirmatory testing went to a general health facility rather than a community clinic dedicated to 361 key populations. In a study conducted in 2018 in Côte d'Ivoire among MSM, one-third of the participants 362 preferred community-based testing, one-third expressed no preference, and one-third preferred 363 undifferentiated HIV testing services (general population), mentioning the lack of discretion and 364 anonymity of community-based sites and the desire to avoid the gaze of others [42].

ATLAS' HIVST distribution strategy successfully reached people living with HIV in West Africa, although linkage to confirmatory testing remained sub-optimal in these first years of HIVST implementation. We showed that HIVST has the potential to reach more hidden populations and constitutes a relevant complementary tool to existing screening services. To fully harness the potential of self-tests, messaging around HIVST and its interpretation could be improved.

Appendices

Table S1. Eligibility and participation in phase 2 survey by sociodemographic characteristics, distribution channel, HIV testing history, the reported number of lines and the self-interpreted HIV self-testing (HIVST) result

372 373

	Overall N=2 615	Eligible for phase 2 completed the questionnaire	Eligible for phase 2 but did not complete the questionnaire	Not eligible for Phase 2	p-value
	(phase 1 participants)	N=78	N=42	N = 2495	(Chi² test)
Country					0.9
Côte d'Ivoire	1 3 90 (5 3%)	39 (50%)	20 (48%)	1 331 (53%)	
Mali	984 (38%)	31 (40%)	18 (43%)	935 (37%)	
S en egal	241 (9.2%)	8 (10%)	4 (9.5%)	229 (9.2%)	
Sex and distribution channel					0.3
man MSM-based channels	997 (38%)	35 (45%)	14 (33%)	948 (38%)	
woman MSM-based channels	103 (3.9%)	5 (6.4%)	0 (0%)	98 (3.9%)	
man FSW-based channels	620 (24%)	22 (28%)	10 (24%)	588 (24%)	
woman FSW-based channels	685 (26%)	14 (18%)	15 (36%)	656 (26%)	
man other-based channels	137 (5.2%)	1 (1.3%)	2 (4.8%)	134 (5.4%)	
woman other-based channels	73 (2.8%)	1(1.3%)	1 (2.4%)	71 (2.8%)	
Age group					0.5
24 years or younger	1 164 (45%)	27 (35%)	20 (48%)	1 117 (45%)	
25-34 years	1063 (41%)	38 (49%)	16 (38%)	1 009 (40%)	
35 years or older	388 (15%)	13 (17%)	6 (14%)	369 (15%)	
Aarital status					0.3
single	1761 (67%)	54 (69%)	28 (67%)	1 679 (67%)	
living with partner / married	757 (29%)	18 (23%)	12 (29%)	727 (29%)	
divorced / separated / wido wed	97 (3.7%)	6 (7 7%)	2 (4.8%)	89 (3.6%)	
Educational level					0.057
none / primary	503 (19%)	13 (17%)	10 (24%)	480 (19%)	
secondary	1 4 32 (5 5%)	50 (64%)	28 (67%)	1 354 (54%)	
higher	680 (26%)	15 (19%)	4 (9.5%)	661 (26%)	
First time testers					0.3
yes	1078 (41%)	38 (49%)	20 (48%)	1 020 (4 1%)	
, No	1537 (59%)	40 (51%)	22 (52%)	1 475 (59%)	

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	Overall N= 2 615 _(phase 1 participants)	Eligible for phase 2 completed the questionnaire N=78	Eligible for phase 2 but did not complete the questionnaire N=42	Not eligible for Phase 2 N = 2495	p-value (Chi² test)
esult and number line					<0.001
2 lines / reactive	50 (1.9%)	27 (35%)	20 (48%)	3 (0.1%)	
1 line / not reactive	2 2 92 (88%)	0 (0%)	0 (0%)	2 292 (92%)	
0 line / not reactive	3 (0.1%)	0 (0%)	0 (0%)	3 (0.1%)	
2 lines/ not reactive	35 (1.3%)	25 (32%)	9 (21%)	1 (<0.1%)	
1 line / reactive	10 (0.4%)	7 (9.0%)	3 (7.1%)	0 (0%)	
0-1 line/ invalid	4 (0.2%)	0 (0%)	0 (0%)	4 (0.2%)	
2 lines/ DK-R	29 (1.1%)	18 (23%)	9 (21%)	2 (<0.1%)	
1 line / DK-R	117 (4.5%)	0 (0%)	0 (0%)	117 (4.7%)	
Oline / DK-R	1 (<0.1%)	0 (0%)	0 (0%)	1 (<0.1%)	
DK-R / reactive	2 (<0.1%)	1(1.3%)	1 (2.4%)	0 (0%)	
DK-R / not reactive	44 (1 7%)	0 (0%)	0 (0%)	44 (1.8%)	
DK-R / DK-R	28 (1.1%)	0 (0%)	0 (0%)	28 (1.1%)	

Table S2. Main reason for not linking to confirmatory testing among phase 2 participants who did not link to confirmatory testing, by reported number of lines and self-interpreted HIVST result.

	Overall	2 lines /	1 line /	2 lines /	2 lines /
	overall	reactive	reactive	non-reactive	DK-R
My test was non-reactive	18 (41%)	6 (50%)	2 (33%)	5 (31%)	5 (50%)
l didn't know he should get a confirmatory test	10 (23%)	2 (17%)	2 (33%)	5 (31%)	1 (10%)
l didn't have time	8 (18%)	3 (25%)	0 (0%)	3 (19%)	2 (20%)
l feared that others would know the result	2 (4.5%)	0 (0%)	0 (0%)	1 (6.2%)	1 (10%)
l already knew the result before using HIVST	2 (4.5%)	1 (8.3%)	1 (17%)	0 (0%)	0 (0%)
l had no specific reason	2 (4.5%)	0 (0%)	1(17%)	1 (6.2%)	0 (0%)
l didn't know where to take the test	1 (2.3%)	0 (0%)	0 (0%)	1 (6.2%)	0 (0%)
The testing site was too far away	1 (2.3%)	0 (0%)	0 (0%)	0 (0%)	1 (10%)
Total	44 (100%)	12 (27 3%)	6 (13.6%)	16 (36 4%)	10 (22.7%)

382 Table S3. Time between HIVST and confirmatory testing among phase 2 participants who did link to confirmatory testing, by reported number of lines and self-383 interpreted HIVST result.

	Overall	2 lines /reactive	1 line /reactive	2 lines /non-reactive	2 lines /DK-R	DK-R / reactive
less than a week	18 (53%)	12 (80%)	0 (0%)	0 (0%)	6 (75%)	0 (0%)
between 1 and 2 weeks	4 (12%)	1 (6.7%)	0 (0%)	2 (22%)	1 (12%)	0 (0%)
between 3 and 4 weeks	2 (5.9%)	1 (6.7%)	0 (0%)	0 (0%)	1 (12%)	0 (0%)
between one and two months	7 (21%)	1 (6.7%)	0 (0%)	5 (56%)	0 (0%)	1 (100%)
more than 3 months	3 (8.8%)	0 (0%)	1 (100%)	2 (22%)	0 (0%)	0 (0%)
Total	34 (100%)	15 (44 2%)	1 (2.9%)	9 (26 5%)	8 (23.5%)	1 (2.9%)

384

DK: don't know. R: refuse to answer

385

386

Table S4. Place of confirmatory testing among phase 2 participants who did link to confirmatory testing, by reported number of lines and self-interpreted HIVST result.

	Overall	2 lines /reactive	1 line /reactive	2 lines /non-reactive	2 lines /DK-R	DK-R / reactive
Health Center / Hospital / Clinic / Maternity	12 (35%)	3 (20%)	0 (0%)	6 (67%)	3 (38%)	0 (0%)
Community Clinic / KP-dedicated Health Center	22 (65%)	12 (80%)	1 (100%)	3 (33%)	5 (62%)	1 (100%)
Tot al	34 (100%)	15 (44.2%)	1 (2.9%)	9 (26.5%)	8 (23.5%)	1 (2.9%)
DK: don't know. R: refuse to ar	swer					

388

389 Table S5. Time between phase 1 and phase 2 interviews among phase 2 participants who did link to confirmatory testing, by reported number of lines and self-390 interpreted HIVST result.

	Overall	2 lines /reactive	1 line /reactive	2 lines /non-reactive	2 lines /DK-R	DK-R / reactive
between 4 and 6 months	67 (86%)	24 (89%)	5 (71%)	21 (84%)	17 (94%)	0 (0%)
less than 4 months	8 (10%)	3 (11%)	0 (0%)	4 (16%)	1 (5.6%)	0 (0%)
more than 6 months	3 (3.8%)	0 (0%)	2 (29%)	0 (0%)	0 (0%)	1 (100%)
Total	34 (100%)	15 (44.2%)	1 (2.9%)	9 (26.5%)	8 (23.5%)	1 (2.9%)

391

DK: don't know. R: refuse to answer

392

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398

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Data, scripts, code, and supplementary information availability

- 399 Data, scripts and code are available online on the Zenodo website.
- 400 (https://doi.org/ 10.5281/zenodo.7986077);

401 Conflict of interest disclosure

The authors declare that they comply with the PCI rule of no financial conflicts of interest in relation to the content of the article. They declare no conflict of interest.

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