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## Acceptability, feasibility, and effectiveness of caregiver-assisted HIV self-testing among children using an oral mucosal test in Uganda and Zambia: a prospective interventional study

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JG contributed to the study design, scientific administration, and data analysis and interpretation, and drafted the manuscript. NMT contributed to investigation processes, including data collection. NMT, AM, CB, and JK contributed to project administration, data curation, investigation, and formal analysis. SM contributed to data validation, analysis, review, and editing. NM contributed to data collection supervision, project administration, data validation and analysis, review, and editing. TC contributed to data management and analysis. JM contributed to data acquisition, management, and analysis. OC contributed to data acquisition, analysis, manuscript review, and editing. PN contributed to project administration and data validation. KP and DW contributed to scientific administration and data acquisition. BL contributed to data cleaning, management, and analysis. SP contributed to the study design and data analysis. EN, ACA, MI, and AMB contributed to study design and project management. ER contributed to the study design and monitoring. NMT, OC, JM, TC, BL, JG, and DM directly accessed and verified the underlying data reported in the manuscript. RAF contributed to the study design and DM contributed to the data analysis. ER, DM, and RAF reviewed manuscript revisions. GT, ENM, GM, and MM contributed to study design and data acquisition. CS, DO, FO, and ZZ contributed to the study design, data acquisition, and project administration. All authors had full access to all the data and critically reviewed and approved the manuscript with agreed shared accountability for all aspects of the work and had final responsibility for the decision to submit for publication.

Declaration of interests

JG has Abbott stock. All other authors declare no competing interests.

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## Summary

**Background:** During the COVID-19 pandemic, the US President's Emergency Plan for AIDS Relief supported oral caregiver-assisted HIV self-testing (CG-HIVST) to address the gap in HIV diagnosis of children. We aimed to investigate caregiver uptake, results return, acceptability, and potential social harms of CG-HIVST.

**Methods:** This prospective, interventional, study was done at 32 health facilities in Uganda and 15 health facilities in Zambia. Caregivers aged 18 years and older (plus emancipated minors aged 15–17 years in Uganda) living with HIV who were currently accessing HIV care and considered index cases, with no positive responses to an intimate partner violence screen, and with one or more children aged 18 months to 14 years with unknown HIV status were eligible to participate. Eligible caregivers were offered oral HIVST kits to screen their children and primary outcomes were described by caregiver and child characteristics. Following HIVST kit

administration, caregivers were surveyed using a standardised questionnaire to document their perceptions, adverse events, and social harm. Primary outcomes were the uptake of HIVST and the number and proportion of returned screening test results, reactive results, reactive screens with confirmatory HIV testing, confirmatory testing with a positive result, and children who were confirmed HIV-positive who were linked to treatment. This study was registered with [ClinicalTrials.gov](https://clinicaltrials.gov), [NCT04774666](https://clinicaltrials.gov/ct2/show/study/NCT04774666) and [NCT04754386](https://clinicaltrials.gov/ct2/show/study/NCT04754386), and is completed.

**Findings:** From Feb 1 to Oct 31, 2021, 12 998 interested caregivers were screened for eligibility, 4023 of whom were eligible. 3903 (97·0%) accepted HIVST kits to screen their child for HIV (1609 [41·2%] in Zambia and 2294 [58·8%] in Uganda). Among caregivers, 3094 (79·3%) of 3903 were female, and 809 (20·7%) were male. 7601 children were enrolled (3779 [49·7%] were female and 3822 [50·3%] were male). 4766 (97·9%) of 4866 test results were returned in Uganda and 2647 (96·8%) of 2735 in Zambia. 119 (1·6%) of 7413 children had reactive HIVST results, requiring confirmatory testing. Of 116 children with confirmatory testing, 43 were confirmed HIV-positive (HIV prevalence 0·7% [n=32] in Uganda and 0·4% [n=11] in Zambia) and 100% were linked to antiretroviral therapy. Adverse events were rare (11 [0·4%] of 2720) and minor, and there were no reports of social harm or violence. Caregivers surveyed reported the HIVST kit was easy to use (2637 [97·0%] of 2718), they would use it again (2650 [99·1%] of 2674), and they would recommend it to other parents (2615 [97·8%] of 2674).

**Interpretation:** Our findings suggest that oral CG-HIVST is acceptable, feasible, and safe, with no reports of social harm, and has the potential to expand access to HIV testing for children while reducing the service delivery burden on health facilities.

**Funding:** US President's Emergency Plan for AIDS Relief and Wellcome Trust.

## Introduction

Globally, an estimated 1·4 million children (younger than 15 years) were living with HIV in 2023, with only 58% receiving treatment.<sup>1</sup> Progress towards reaching the UNAIDS 95–95–95 targets for children living with HIV continues to lag behind that for adults.<sup>2</sup> Population HIV impact assessments (2015–17) across seven sub-Saharan African countries found that only 61% of children living with HIV were diagnosed.<sup>3</sup> In 2023, diagnosis among children living with HIV was at 66% compared with 86% among adults.<sup>1</sup> There were an estimated 72 000 children living with HIV in Uganda and 58 000 in Zambia, with 23% in Uganda and 29% in Zambia not yet on treatment.<sup>1</sup>

Children are affected by household and health systems factors that make it challenging to receive HIV testing.<sup>4</sup> These factors include underestimation of HIV risk by parents and health-care workers, undiagnosed parents living with HIV, asymptomatic infection, dependence on caregivers to access health care, unstable guardianship, transport costs, and risk of parental HIV status disclosure.<sup>4–8</sup> At the facility level, barriers include the workload of health-care workers, restrictive age of consent regulations, distance to health facilities, overlapping school and clinic hours, and lack of training for health-care workers to discuss HIV testing with parents and children.<sup>4,6,9,10</sup>

Starting in 2017, index testing services, which identify and test biological children of people living with HIV, expanded rapidly, identifying a large number of children living with HIV.<sup>11</sup>

Despite declines in paediatric HIV testing during the COVID-19 pandemic, index testing remained an effective case identification strategy.<sup>12</sup> Typically, people living with HIV have their children tested at a health facility or through a home visit by a health-care worker. Studies from 2018 to 2019 in Zimbabwe and Kenya showed promise for a third option, caregiver-assisted HIV self-testing (CG-HIVST), whereby the caregiver screens the child for HIV using an oral HIVST kit.<sup>13,14</sup> During the COVID-19 pandemic, the US President's Emergency Plan for AIDS Relief collaborated with ministries of health to support the use of oral HIVST kits for children, given the restricted access to health services.<sup>15</sup>

Initial studies from Kenya and Zimbabwe of CG-HIVST in children explored caregivers' perceptions and results interpretation, oral HIVST kit validation, and uptake among people living with HIV.<sup>13,14,16,17</sup> Few caregivers had heard of oral HIVST, yet perceived potential benefits to include convenience, privacy, reduced travel costs, administration ease, and child comfort.<sup>14</sup> A validation study of oral HIVST in children compared HIVST results read by health-care workers (100·0% sensitivity and 99·9% specificity) with blood-based diagnostic tests.<sup>16</sup> Another study showed low uptake (5·6%) of CG-HIVST.<sup>13</sup> Although initial studies showed caregivers can correctly interpret screening results ( $\geq 97\%$ ) with or without a demonstration,<sup>17</sup> questions remained regarding feasibility and acceptability<sup>14</sup> and whether unintended social harms might result. We aimed to estimate the acceptability, feasibility, effectiveness, and potential risk of social harm of oral CG-HIVST for children offered as an index-linked testing approach to people living with HIV in Uganda and Zambia.

## Methods

### Study design

This prospective, interventional, multicentre study was done at 47 health facilities (32 in Uganda and 15 in Zambia), including rural and urban health centres and district hospitals.

In Uganda, we selected regions with the highest estimated number of undiagnosed children living with HIV, including Central 1, Central 2, east Central, mid-Western, mid-Northern, and south Western. We selected facilities within those regions with a high volume of index testing. Within facilities, we recruited the number of caregivers proportional to the facility's contribution to the total eligible population across facilities (proportional allocation). We estimated the sample size at the district level and assigned proportionally to each facility, resulting in a total sample size of 4737. In Zambia, we randomly selected facilities from Lusaka and Southern Province using probability proportional to size sampling. We recruited adult caregivers of approximately 200 children per facility, totalling 3000.

Caregivers provided written informed consent with a waiver of assent or consent for eligible children, according to 45 Code of Federal Regulations 46.116(f)(3). Research assistants instructed caregivers to screen children aged 8 years and older only if they agreed to testing. Children who did not agree could be brought to the facility for routine HIV counselling and testing services. The Excellence Research Ethics and Science Converge Institutional Review Board in Zambia, the Uganda Virus Research Institute's Research Ethics Committee, the Uganda National Council for Science and Technology, and the US Centers for Disease

Control and Prevention Institutional Review Board approved study protocols. This study is registered with [ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT04754386), [NCT04754386](https://clinicaltrials.gov/ct2/show/study/NCT04754386) and [NCT04774666](https://clinicaltrials.gov/ct2/show/study/NCT04774666).

## Participants

We recruited caregivers living with HIV (index cases) from multiple health facility entry points and offered oral HIVST kits (OraQuick; OraSure Technologies, Bethlehem, PA, USA) to screen their children of unknown HIV status at home. Caregivers aged 18 years or older (plus emancipated minors aged 15–17 years in Uganda) accessing HIV care with eligible children were eligible. Biological children (Uganda and Zambia) or non-biological children living in the household of eligible caregivers (Uganda only) were eligible if they were aged 18 months to 14 years and had unknown HIV status. Children with a documented HIV-negative status were eligible if the previous test was completed less than 3 months after breastfeeding cessation or if a new exposure was reported. Breastfeeding children or those weaned less than 3 months before enrolment were excluded. All caregivers responded to a four-item intimate partner violence screen; caregivers with one or more positive responses were excluded and referred for standard-of-care HIV testing and social services. Data on caregiver and child sex were collected during enrolment.

## Procedures

Investigators trained research assistants on all procedures before study implementation. After enrolment, research assistants taught caregivers how to use the oral HIVST kit, including reading results 20–40 min after specimen collection; caregivers then demonstrated its use back to confirm understanding. Research assistants instructed caregivers to give age-appropriate explanations to their children about the reason for testing and advised caregivers to return to the facility for confirmatory testing if the child had a reactive or invalid HIVST result. Research assistants provided caregivers with one test kit for each child that needed testing and a telephone number for counselling support before and after testing. 3 days after test kit distribution, if a caregiver had not reported the results, research assistants telephoned to confirm test administration and document the result. Research assistants conducted a home visit (among those who consented) after three unsuccessful attempts to reach a caregiver. Caregivers reporting a reactive HIV self-test were referred to facilities for confirmatory blood-based rapid diagnostic testing according to the national algorithm. Following the observation of a high proportion of false-positive HIVST results in Uganda, refresher trainings for research staff were conducted at week 3 and week 8 of enrolment.

Once a caregiver reported the HIVST result, research assistants asked caregivers to participate in a post-use survey up to either 1 month (for Uganda) or 4 months (for Zambia) after HIVST administration to understand their perceptions of acceptability and feasibility and to document any adverse events or social harm. In Uganda, all enrolled caregivers were surveyed. In Zambia, a representative sample of caregivers were surveyed: each facility recruited up to 30–45 caregivers of children with a reactive screening result and 30 caregivers of children with a non-reactive result. Research assistants administered the surveys by telephone.

After reporting HIVST results, research assistants notified caregivers with a reactive result of a transportation reimbursement to bring the child or children to the facility for confirmatory testing. Caregivers received 5000 Ugandan Shillings (UGX; approximately US\$1.50), or 70 Zambian Kwacha (ZMW; approximately US\$5.00), per child. The study also provided reimbursements to caregivers who completed the post-use survey—UGX15 000 (approximately US\$4.00) or ZMW40 (approximately US\$3.00)—to defray all costs associated with survey participation.

## Outcomes

We evaluated acceptability using caregiver kit acceptance and willingness to use HIVST again or recommend to other parents. We evaluated feasibility using proportion of returned results and caregiver perception of ease of kit use (eg, understanding instructions and need for assistance), and recommendations for programme improvement. We evaluated effectiveness using coverage of confirmatory testing among children with a reactive HIV self-test and linkage of children who were newly identified as being HIV-positive to antiretroviral therapy (ART). Primary outcomes included the uptake of HIVST and the number and proportion of returned screening test results, reactive results, reactive screens with confirmatory HIV testing, confirmatory testing with a positive result, and children who were confirmed HIV-positive who were linked to treatment. We analysed these outcomes by caregiver and child characteristics and reported by country.

## Statistical analysis

We used frequencies to describe categorical participant characteristics. We estimated the primary outcomes unweighted and weighted to account for study design and 95% CIs, accounting for within-health-facility correlation. Weights for Uganda were the inverse of the target enrolment number at each site divided by the actual enrolment number. We calculated the target enrolment number for each site as the proportional contribution for the site to the overall unmet ART need for the selected districts. This proportion was then applied to the computed study sample size to determine the target enrolment number for the site. Weights for Zambia were the inverse of the actual enrolment number per site divided by the 200 participants expected at each site to yield the same probability of selection for each eligible participant given the probability proportional to size design. Neither sample was nationally representative. In Uganda, the sample was only representative of the included facilities. In Zambia, the sample was representative of facilities in Lusaka and Southern Province. We accounted for correlation within facilities through the use of PROC SURVEYFREQ in SAS using Taylor series variance estimation.

For each country, we calculated the positive predictive value of CG-HIVST. In Uganda, we calculated the number and proportion of false positives among all HIVST results by study week. We tested whether the proportion of false positives was different before and after the second refresher training using logistic regression, accounting for facility-level clustering.

We estimated the history of violence in the home by calculating the proportion of caregivers reporting “yes” to one or more of four prescreening questions on intimate partner violence.

We measured social harm and adverse events by the proportion of caregivers reporting an adverse event or social harm following CG-HIVST at home.

We collected data on electronic tablets using CommCare software.<sup>18</sup> We conducted analyses using Stata version 17 software and SAS version 9.4.

### Role of the funding source

The funders of the study led the study design, data analysis, data interpretation, and writing of the report in collaboration with Catholic Relief Services and subawardees, including Makerere University School of Public Health and Macha Research Trust, who conducted the data collection.

## Results

From Feb 1 to Oct 31, 2021, 12 998 caregivers were screened in Uganda and Zambia (7504 [57·7%] in Zambia and 5494 [42·3%] in Uganda). After applying the exclusion and inclusion criteria before screening for intimate partner violence, 4268 caregivers were eligible for further evaluation (figure 1). Of these 4268 caregivers, 4045 (94·8%) were eligible after screening for intimate partner violence. 65 (3·8%) of 1721 caregivers in Zambia and 158 (6·2%) of 2547 caregivers in Uganda had a history of violence in the home and were referred to standard-of-care HIV testing and social services. Of the 4023 eligible caregivers after final age verification, 3903 (97·0%; 1609 [41·2%] in Zambia and 2294 [58·8%] in Uganda) consented to accept HIVST kits to screen their child for HIV and were enrolled in the study with their 7601 children, with a mean of 1·94 children per caregiver (range one to eight children per caregiver).

Among caregivers, median age was 36 years (range 18–76), 3094 (79·3%) of 3903 were female, and 809 (20·7%) were male (table 1). Most caregivers presented to ART clinics. Among the children, median age was 7 years (range 1–14 years), 3779 (49·7%) of 7601 were female and 3822 (50·3%) were male. In Uganda, 1386 (28·5%) children were non-biological children of caregivers. 1779 (23·4%) children had male caregivers (table 2).

Of the 7601 children who enrolled and received CG-HIVST, nearly all results were returned (4766 [97·9%] of 4866 in Uganda and 2647 [96·8%] of 2735 in Zambia). Across all demographic characteristics, result return was 95% or more in Uganda and 94% or more in Zambia. Of the 4766 HIVST results returned in Uganda, 3932 (82·5%) were returned within 3 days, 4489 (94·2%) within 1 week, and 4721 (99·1%) within 1 month. Of the 2647 HIVST results returned in Zambia, 2643 (99·8%) were returned within 3 days, 2645 (99·9%) within 1 week, and 2647 (100%) within 1 month. Overall, 119 (1·6%) of 7413 children had a reactive HIVST result and required facility-based confirmatory HIV testing. A higher proportion of reactive HIVST results was observed in Uganda (98 [2·1%]) than in Zambia (21 [0·8%]). 116 children with reactive HIV self-tests received confirmatory testing (three were lost to follow-up in Zambia).

Among the 116 children with confirmatory testing, 43 were confirmed HIV-positive, giving an HIV prevalence of 0·7% (32/4766) in Uganda and 0·4% (11/2647) in Zambia. All

children with confirmed HIV-positive results were linked to HIV treatment, with 42 (97.7%) initiating same-day ART. HIV prevalence was similar among biological and non-biological children in Uganda (table 3). The 43 newly diagnosed children living with HIV shared similar demographics to the general population (table 2).

The positive predictive value of HIV self-tests was different in Uganda and Zambia (table 3). In Uganda, the proportion of total HIVST results determined to be false positive decreased from 3.3% (45/1373) in study weeks 1–8 to 0.6% (21/3393) in study weeks 9–26. Among reactive HIVST results in Uganda, the odds of a false-positive result was significantly lower after the second refresher training (odds ratio 0.36 [95% CI 0.15–0.86];  $p=0.021$ ; figure 2). The positive predictive value was 23.7% before and 46.2% after the second refresher training; HIV positivity was 1.0% (95% CI 0.6–1.7) before and 0.5% (0.3–0.8) after the second refresher training.

The caregiver survey was administered to 2251 (98.1%) of 2294 caregivers in Uganda and 469 (29.1%) of 1609 caregivers in Zambia, of whom 86 caregivers in Uganda and 14 in Zambia had a child with reactive or invalid HIV self-tests (appendix p 1). There were no reports of social harm to children screened using HIVST in Zambia or Uganda, and no reports of social harm to caregivers in Uganda. In Uganda, seven (0.3%) of 2251 caregivers reported the following types of issues: the child was initially scared but then relaxed and agreed to testing, other children or the partner were not interested in testing and then either agreed or the caregiver tested when the partner was away, or the child discarded the liquid from the test tube. 12 minor adverse events were reported in 11 (0.4%) of 2720 children, including gum pain (six cases), bleeding (five cases), and itching (one case; appendix p 1).

Among caregivers surveyed, 2650 (99.1%) of 2674 reported they would use an HIV self-test again to test a child. When asked if they would recommend HIVST to other parents, 2185 (99.1%) of 2205 caregivers in Uganda and 430 (91.7%) of 469 in Zambia, reported that they would recommend this testing approach to others. In Uganda, 2201 (97.9%) of 2249 caregivers reported their experience testing their child with an oral HIV self-test was easy or very easy, compared with 436 (93.0%) of 469 in Zambia, and 433 (92.3%) of 469 caregivers in Zambia reported HIVST kit instructions were easy or very easy to understand. In Zambia, 443 (94.5%) caregivers did not need assistance administering the HIV self-test to their child (not measured in Uganda).

To improve CG-HIVST, 1450 (53.6%) of 2704 respondents wanted more information, including community education and mobilisation to increase awareness of this testing option; 1082 (40.0%) respondents wanted increased access, including better access to HIVST for caregivers. Some caregivers recommended improved counselling (110 [4.9%] of 2238 in Uganda and 46 [9.9%] of 466 in Zambia) and improved HIVST kit instructions (80 [3.6%] in Uganda and 48 [10.3%] in Zambia). In the absence of CG-HIVST, caregivers would have chosen the following testing options: home-based testing by a health-care worker (390 [17.5%] of 2226 in Uganda and 126 [28.1%] of 448 in Zambia) or facility-based testing (1782 [79.2%] of 2251 in Uganda and 313 [66.7%] of 469 in Zambia), and 2.4% were uncertain how they would test their child.

## Discussion

The findings of this study suggest a high acceptability and feasibility of CG-HIVST among interested caregivers, as nearly all accepted home-based, CG-HIVST to screen their children using an oral kit and returned their results. This novel testing option was highly effective in linking children with reactive HIVST results to confirmatory testing and all newly diagnosed children living with HIV to treatment. Numerous studies have shown that HIV-related stigma and discrimination deter clients from seeking facility-based testing services,<sup>19</sup> including concerns regarding client confidentiality with an HIV-positive diagnosis.<sup>8,20</sup> CG-HIVST addresses these barriers, affording parents greater autonomy, privacy, and convenience to screen their children at home. This study's findings support previous studies of parents who reported acceptability of home-based oral HIVST among caregivers, with convenience and privacy as potential benefits.<sup>14,21</sup>

A key concern when implementing any screening test is its performance and usability, which depend on its inherent accuracy and the ability of individuals to perform the test. Previous studies have shown the oral HIV self-test is highly sensitive in children compared with blood-based rapid tests performed in a clinical setting by providers.<sup>16</sup> Although health-care workers and programmes have expressed concerns about the ability of caregivers to correctly administer oral HIV self-tests to children,<sup>14</sup> one study conducted in Zimbabwe showed 96% or more of caregivers performed HIVST accurately after receiving a demonstration, including collecting the oral fluid, inserting the flat pad into the buffer solution, using a timer, and interpreting the result.<sup>17</sup> In this study, most caregivers reported the HIVST kit was easy to use, with only 5.5% of caregivers in Zambia requesting administration assistance. Digital results reporting (ie, telephone photograph) could help to ensure result authenticity and credibility, where feasible.

CG-HIVST in children was highly feasible. Nearly all caregivers returned their child's screening result irrespective of country, rural or urban setting, or facility type and nearly all within 3–7 days. Several studies have shown that the distribution of HIVST kits has increased the uptake of HIV testing.<sup>22,23</sup> Because children have a higher risk of AIDS-related morbidity and mortality than adults,<sup>24</sup> failure to follow up or report results could have more devastating consequences for children. In this CG-HIVST study, the proportion of results reported among children (97.5%) was higher than in other HIVST studies among men (83%)<sup>25</sup> or adolescents and youth (59%).<sup>26</sup> Establishing expectations for returning results at the time of test distribution (eg, within 3 days) and expected follow-up procedures (eg, three telephone calls followed by a home visit) might have influenced the high proportion of HIVST results returned, irrespective of demographic characteristics or geographical setting, which is encouraging for programmatic use.

According to the OraQuick instructions for use, the expected positive predictive value among a population with 0.4–0.7% HIV prevalence ranges from 29.2% to 42.0%.<sup>27</sup> The HIVST positive predictive value in this study was 32.7% in Uganda and 61.1% in Zambia, which is expected in this paediatric population with a low HIV prevalence. This finding underscores the importance of blood-based confirmatory testing for every child with a reactive HIV self-test in accordance with national guidelines.<sup>28</sup> Additionally, caregiver

counselling is essential to ensure that caregivers understand that HIVST is a screening test. Thus, a reactive result does not necessarily mean their child is HIV-positive; it indicates the child needs confirmatory testing to establish their HIV status. Although this study provided remote counselling and support, additional qualitative research might provide insights into the experiences of parents whose children have a reactive or false-positive HIVST result to enhance counselling messages. Although health-care workers have expressed concerns regarding loss to follow-up for children requiring confirmation testing,<sup>14</sup> nearly all children with a reactive HIV self-test reported for confirmatory testing with a transport reimbursement. Because children are a population with a low HIV prevalence, this approach could potentially reduce the volume of testing by health-care workers needed to identify one new child living with HIV, while giving autonomy and privacy to caregivers.

However, it is crucial to train health-care workers on the procedures for home-based CG-HIVST. Programmes could consider developing an operational manual to better equip health-care workers to train caregivers on appropriate HIVST kit usage. As programmes consider operational guidance, training of health-care workers to create buy-in for this novel testing approach will be essential. Training could focus on the benefits of home administration by caregivers, the importance of test kit demonstration to improve caregiver competence and confidence with HIV self-test use and result interpretation, establishing timebound expectations (eg, 3 days) for results return with a call back line, and noting the decreased workload at the facility level.

The proportion of false-positive tests returned by caregivers in Uganda decreased after research assistant refresher trainings. Although this might be due to the research team being better equipped to advise caregivers on how to use the test, given the decrease in confirmatory positivity from 1.0% to 0.5% after the second refresher training, training for health-care workers should emphasise that both a strong and faint second line is considered a positive, or reactive, HIVST result. Another study noted that 33% of reactive HIV self-tests were weakly positive.<sup>16</sup> Programmes could consider showing video-based instructions on CG-HIVST administration in waiting areas, as one study in Kenya found this led to higher caregiver understanding than health-care worker counselling.<sup>29</sup>

Nearly all children newly diagnosed with HIV in this study initiated same-day treatment. Non-biological children living in the same household of people living with HIV in Uganda had the same HIV positivity (0.7%) as biological children, which might suggest household clustering of HIV risk. Similarly, an index testing study among paediatric contacts in Zimbabwe found 43.6% of newly diagnosed children were single or double orphans.<sup>13</sup> Index testing programmes could offer testing to all children (ie, biologically and non-biologically related to their caregivers) with an undocumented HIV status living in the same household as people living with HIV, because non-biological children in these households might be affected by other social determinants of health, such as orphanhood, which increase their risk of HIV. Men accounted for nearly 20% of enrolled index caregivers and 12% of newly diagnosed children, highlighting the importance of engaging male caregivers living with HIV. Because 88% of newly diagnosed children were contacts of female caregivers, it could be useful to offer index testing services to the male caregivers of newly diagnosed children to increase HIV testing and case identification among men.<sup>30</sup>

Minor adverse events were reported but uncommon. Reported adverse events included gum pain, bleeding, and itching, which might be due to common administration mistakes, such as scrubbing the gums, observed in another study.<sup>17</sup> However, similar to a study in Zimbabwe,<sup>17</sup> there were no reports of major social harms, such as violence, which might be due to the intimate partner violence assessment carried out before HIV testing was offered and, therefore, those who were recruited might have had a lower risk of violence. Programmes could consider this operational approach to decrease any risk of social harm, as this study screened out 3·8–6·2% of caregivers with a history of violence in the home and referred them to standard-of-care testing and social services. Caregiver counselling remains important, and programmes can include talking points for caregivers to discuss HIVST with their partners and children to facilitate age-appropriate conversations and allay fears.

Study strengths included a large sample and a study population drawn from a wide range of public sector facility types in two different countries. We acknowledge a number of limitations. The study design limited our ability to measure effectiveness, and future research using a control group is recommended to evaluate CG-HIVST compared with the standard of care. This study recruited people living with HIV who were receiving services; however, research is needed on reaching more vulnerable children, whose parents might not present for care or might be deceased. The study did not document the uptake of alternative testing approaches (eg, facility-based testing or home testing by a health-care worker) and, therefore, did not capture the testing preferences of all adult index clients. The study had dedicated research staff, active staff follow-up, and reimbursements, all of which might have contributed to the high proportion of participants returning test results and receiving confirmatory testing. Further evaluation is needed to understand the sustainability and trade-offs in costs to the health system by decreasing facility workload, while supporting transport for confirmatory testing, which was necessary for 1·6% of children. We did not perform parallel blood-based HIV testing for children with non-reactive oral test results because a previous study on the accuracy of CG-HIVST result interpretation documented a negative predictive value of 100·0%<sup>17</sup> and, therefore, we cannot ascertain whether there were any false-negative HIV self-tests. Because the caregiver survey was administered 1–4 months after HIVST and by a research assistant over the telephone, the results are subject to both recall and social desirability bias. Finally, we cannot exclude potential under-reporting of social harms.

Our findings suggest that CG-HIVST in children is acceptable, feasible, effective, and safe, with no reports of social harm. WHO recommends an optimal mix of HIV testing approaches. Incorporating CG-HIVST in national guidelines could expand equitable access to HIV testing for children, while reducing the burden on health facilities and expanding family-centred testing options.

## Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

## Acknowledgments

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## Data sharing

Study protocols for Uganda and Zambia were published on [ClinicalTrials.gov](https://clinicaltrials.gov). Individual level de-identified study datasets and a data dictionary were published on the Harvard Dataverse. Catholic Relief Services processes all data requests, sharing them with the Uganda and Zambia ministries of health, who own the data, which can be accessed through a signed data sharing agreement.

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## Research in context

### Evidence before this study

More than 20 years into the global HIV response, only 66% of the estimated 1·4 million children living with HIV are diagnosed, compared with 86% of adults. To identify the estimated 590 000 children living with HIV who are not on treatment, family-centred testing options are needed to address persistent barriers to HIV testing access for children. A type of HIV screening, known as HIV self-testing (HIVST), has expanded access to HIV testing for other populations. On Jan 17, 2024, we searched MEDLINE (Ovid), Embase (Ovid), CINAHL (EBSCO), and Scopus using the following terms: “HIV”, “self-testing”, “caregiver”, “assisted”, “child”, “pediatric”, and “index” without restrictions on study type, location, or date. Of the 12 publications identified, ten were from either the B-GAP study in Zimbabwe or STEP-UP study in Kenya. Studies on the use of oral assisted HIVST in children suggest that caregivers perceive this approach to address transport costs and time constraints, while increasing convenience, privacy, and child comfort. However, one study showed low uptake among caregivers. A study in Zimbabwe, evaluating feasibility and accuracy, reported that more than 96·0% of caregivers correctly collected oral mucosal samples, used a timer, and interpreted results (sensitivity 100·0%; positive predictive value 33·3%). A validation study of oral HIV self-tests used in children in Kenya and Zimbabwe also had a high sensitivity (100·0%).

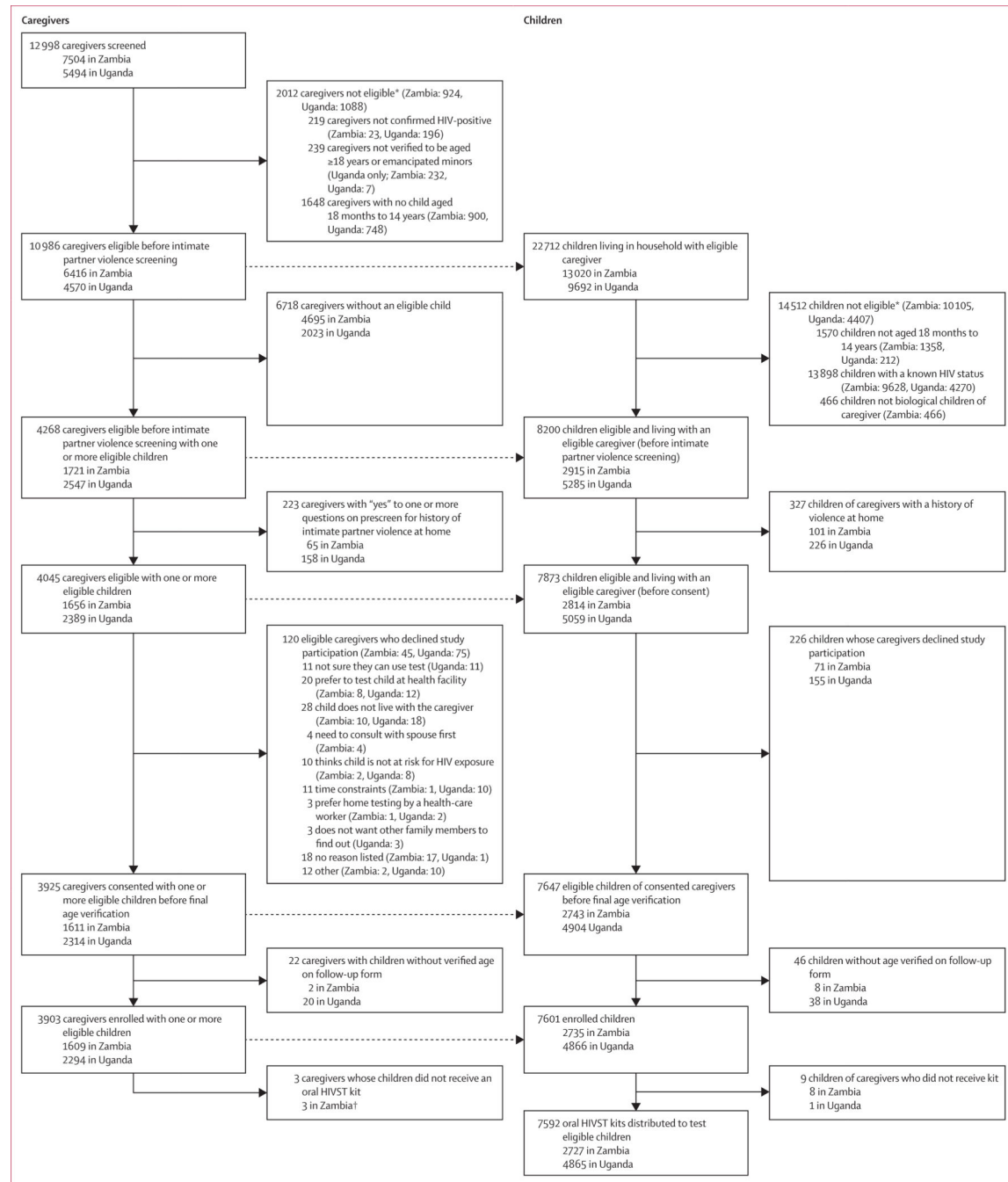
### Added value of this study

To our knowledge, this is the first multicentre study to evaluate the acceptability, feasibility, and effectiveness of home-based caregiver-assisted HIVST (CG-HIVST) with an oral kit at programmatic scale, including assessment for any social harms or adverse events associated with this novel approach, as a part of adult index-linked HIV testing services. Acceptability was evaluated based on caregiver willingness to use oral HIVST kits to screen their children with an unknown HIV status and recommend it to other parents. Feasibility was assessed as a proportion of returned results and perception of ease of kit use. Effectiveness was measured by the proportion of newly identified children who were HIV-positive who were linked to antiretroviral therapy. This study showed high uptake among interested caregivers, with more than 90·0% reporting the HIVST kit was easy to use and they would recommend it to other parents. Nearly all HIVST results were returned and children requiring confirmatory testing received it, with all children who were confirmed HIV-positive being linked to treatment. The positive predictive value varied from 32·7% in Uganda to 61·1% in Zambia. There were no reports of social harm and few reported minor adverse events. The findings of this study show an increased demand for CG-HIVST and the feasibility of safe and effective programmatic implementation.

### Implications of all the available evidence

Globally, more than a third of children living with HIV remain undiagnosed with existing facility and community HIV testing services. CG-HIVST offers another safe and effective option that could address well documented barriers to HIV testing among children. Studies confirm the ability of caregivers to administer HIV self-tests to their children,

show uptake of this approach among interested caregivers, and show effective linkage to confirmatory testing and treatment, when indicated. Additional studies are needed to assess interest in CG-HIVST among people living with HIV with children, replicate these findings, explore the use of this approach in other settings (eg, children of key populations, orphans and vulnerable children programmes, and retail pharmacies), and compare them to non-intervention populations to inform global policy guidance and expand paediatric HIV testing options and access.

**Figure 1: Trial profile**

HIVST=HIV self-testing. \*Categories are not mutually exclusive. †One caregiver in Uganda had another child who received a kit.

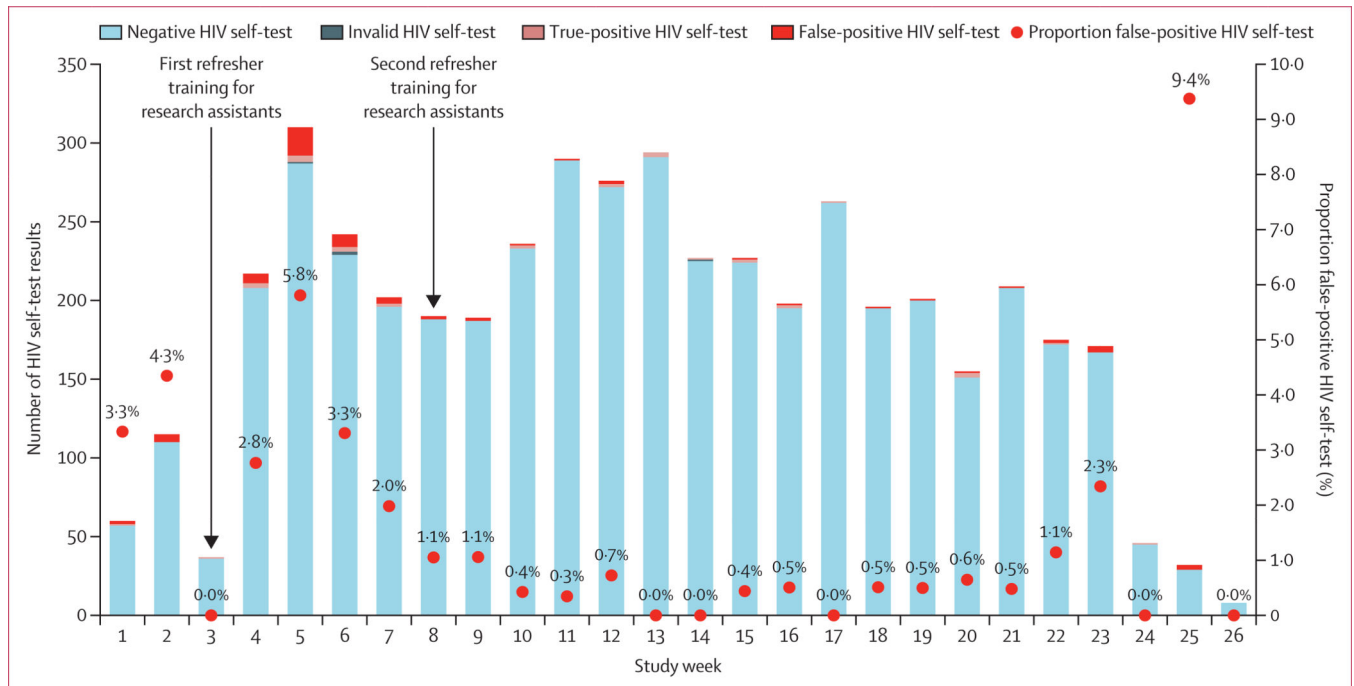


**Figure 2: Number of caregiver-assisted paediatric HIV self-tests returned by result and proportion of false positives by study week, Uganda**

**Table 1:**  
Demographic characteristics of caregivers

|                                                                | Zambia (n=1609) | Uganda (n=2294)   | Total (n=3903)    |
|----------------------------------------------------------------|-----------------|-------------------|-------------------|
| <b>Age, years</b>                                              |                 |                   |                   |
| 18–29                                                          | 455 (28·3%)     | 473 (20·6%)       | 928 (23·8%)       |
| 30–39                                                          | 714 (44·4%)     | 860 (37·5%)       | 1574 (40·3%)      |
| ≥40                                                            | 440 (27·3%)     | 961 (41·9%)       | 1401 (35·9%)      |
| <b>Sex</b>                                                     |                 |                   |                   |
| Male                                                           | 195 (12·1%)     | 614 (26·8%)       | 809 (20·7%)       |
| Female                                                         | 1414 (87·9%)    | 1680 (73·2%)      | 3094 (79·3%)      |
| <b>Marital status *</b>                                        |                 |                   |                   |
| Married or cohabiting                                          | 355/469 (75·7%) | 1440/2235 (64·4%) | 1795/2704 (66·4%) |
| Single or never married                                        | 57/469 (12·2%)  | 117/2235 (5·2%)   | 174/2704 (6·4%)   |
| Widowed                                                        | 19/469 (4·1%)   | 247/2235 (11·1%)  | 266/2704 (9·8%)   |
| Divorced or separated                                          | 38/469 (8·1%)   | 431/2235 (19·3%)  | 469/2704 (17·3%)  |
| <b>Education *</b>                                             |                 |                   |                   |
| None                                                           | 13/467 (2·8%)   | 232/2245 (10·3%)  | 245/2712 (9·0%)   |
| Primary                                                        | 232/467 (49·7%) | 1438/2245 (64·1%) | 1670/2712 (61·6%) |
| Secondary                                                      | 186/467 (39·8%) | 507/2245 (22·6%)  | 693/2712 (25·6%)  |
| Tertiary                                                       | 36/467 (7·7%)   | 68/2245 (3·0%)    | 104/2712 (3·8%)   |
| <b>Region</b>                                                  |                 |                   |                   |
| Lusaka                                                         | 1148 (71·3%)    | NA                | 1148 (29·4%)      |
| Southern                                                       | 461 (28·7%)     | NA                | 461 (11·8%)       |
| Central                                                        | NA              | 1370 (59·7%)      | 1370 (35·1%)      |
| East Central                                                   | NA              | 72 (3·1%)         | 72 (1·8%)         |
| Mid-Northern                                                   | NA              | 89 (3·9%)         | 89 (2·3%)         |
| Mid-Western                                                    | NA              | 99 (4·3%)         | 99 (2·5%)         |
| South Western                                                  | NA              | 664 (28·9%)       | 664 (17·0%)       |
| <b>Residence</b>                                               |                 |                   |                   |
| Rural                                                          | 606 (37·7%)     | 784 (34·2%)       | 1390 (35·6%)      |
| Urban                                                          | 1003 (62·3%)    | 1510 (65·8%)      | 2513 (64·4%)      |
| <b>Facility type</b>                                           |                 |                   |                   |
| Level II health centre, Uganda                                 | NA              | 47 (2·0%)         | 47 (1·2%)         |
| Health centre, Zambia; level III health centre, Uganda         | 616 (38·3%)     | 875 (38·1%)       | 1491 (38·2%)      |
| Referral health centre, Zambia; level IV health centre, Uganda | 721 (44·8%)     | 1023 (44·6%)      | 1744 (44·7%)      |
| Level 1 hospital, Zambia; district hospital, Uganda            | 272 (16·9%)     | 349 (15·2%)       | 621 (15·9%)       |
| <b>Study entry point</b>                                       |                 |                   |                   |
| Antiretroviral therapy clinic                                  | 846 (52·6%)     | 2084 (90·8%)      | 2930 (75·1%)      |
| Inpatient or paediatric ward                                   | 3 (0·2%)        | 1 (<0·1%)         | 4 (0·1%)          |
| Labour ward or postnatal care                                  | 13 (0·8%)       | 9 (0·4%)          | 22 (0·6%)         |
| Maternal child health                                          | 564 (35·1%)     | 110 (4·8%)        | 674 (17·3%)       |
| Outpatient                                                     | 91 (5·7%)       | 0                 | 91 (2·3%)         |

|                                            | <b>Zambia (n=1609)</b> | <b>Uganda (n=2294)</b> | <b>Total (n=3903)</b> |
|--------------------------------------------|------------------------|------------------------|-----------------------|
| Community                                  | 29 (1·8%)              | 70 (3·1%)              | 99 (2·5%)             |
| Counselling and testing                    | 30 (1·9%)              | 9 (0·4%)               | 39 (1·0%)             |
| Malnutrition                               | 0                      | 11 (0·5%)              | 11 (0·3%)             |
| Other                                      | 33 (2·1%)              | 0                      | 33 (0·8%)             |
| <b>Caregiver on antiretroviral therapy</b> |                        |                        |                       |
| Yes                                        | NA                     | 2294 (100%)            | NA                    |
| No                                         | NA                     | 0                      | NA                    |

Data are n (%) or n/N (%). NA=not applicable.

\* Data on caregiver marital status and education were only available for the subset of the study sample who took the caregiver survey.

Table 2:

Demographic characteristics of children

|                                                                | Zambia (n=2735) | Uganda (n=4866) | Total (n=7601) | New diagnosis: confirmed HIV-positive (n=43) |
|----------------------------------------------------------------|-----------------|-----------------|----------------|----------------------------------------------|
| <b>Age, years</b>                                              |                 |                 |                |                                              |
| 1–4                                                            | 761 (27.8%)     | 1251 (25.7%)    | 2012 (26.5%)   | 9 (20.9%)                                    |
| 5–9                                                            | 1087 (39.7%)    | 1982 (40.7%)    | 3069 (40.4%)   | 25 (58.1%)                                   |
| 10–14                                                          | 887 (32.4%)     | 1633 (33.6%)    | 2520 (33.2%)   | 9 (20.9%)                                    |
| <b>Sex</b>                                                     |                 |                 |                |                                              |
| Male                                                           | 1396 (51.0%)    | 2442 (49.8%)    | 3822 (50.3%)   | 19 (44.2%)                                   |
| Female                                                         | 1339 (49.0%)    | 2462 (50.2%)    | 3779 (49.7%)   | 24 (55.8%)                                   |
| <b>Relationship to caregiver</b>                               |                 |                 |                |                                              |
| Biological                                                     | 2735 (100%)     | 3480 (71.5%)    | 6215 (81.8%)   | 34 (79.1%)                                   |
| Non-biological                                                 | NA              | 1386 (28.5%)    | 1386 (18.2%)   | 9 (20.9%)                                    |
| <b>Region</b>                                                  |                 |                 |                |                                              |
| Lusaka                                                         | 1899 (69.4%)    | NA              | 1899 (25.0%)   | 9 (20.9%)                                    |
| Southern                                                       | 836 (30.6%)     | NA              | 836 (11.0%)    | 2 (4.7%)                                     |
| Central                                                        | NA              | 3000 (61.6%)    | 3000 (39.5%)   | 19 (44.1%)                                   |
| East Central                                                   | NA              | 126 (2.6%)      | 126 (1.7%)     | 2 (4.7%)                                     |
| Mid-Northern                                                   | NA              | 151 (3.1%)      | 151 (2.0%)     | 0                                            |
| Mid-Western                                                    | NA              | 219 (4.5%)      | 219 (2.9%)     | 2 (4.7%)                                     |
| South Western                                                  | NA              | 1370 (28.2%)    | 1370 (18.0%)   | 9 (20.9%)                                    |
| <b>Residence</b>                                               |                 |                 |                |                                              |
| Rural                                                          | 1104 (40.4%)    | 1713 (35.2%)    | 2817 (37.1%)   | 20 (46.5%)                                   |
| Urban                                                          | 1631 (59.6%)    | 3153 (64.8%)    | 4784 (62.9%)   | 23 (53.5%)                                   |
| <b>Facility type</b>                                           |                 |                 |                |                                              |
| Level II health centre, Uganda                                 | NA              | 101 (2.1%)      | 101 (1.3%)     | 1 (2.3%)                                     |
| Health centre, Zambia; level III health centre, Uganda         | 1061 (38.8%)    | 1927 (39.6%)    | 2988 (39.3%)   | 13 (30.2%)                                   |
| Referral health centre, Zambia; level IV health centre, Uganda | 1257 (46.0%)    | 2133 (43.8%)    | 3390 (44.6%)   | 23 (53.5%)                                   |
| Level I hospital, Zambia; district hospital, Uganda            | 417 (15.2%)     | 705 (14.5%)     | 1122 (14.8%)   | 6 (14.0%)                                    |
| <b>Caregiver sex</b>                                           |                 |                 |                |                                              |
| Male                                                           | 373 (13.6%)     | 1406 (28.9%)    | 1779 (23.4%)   | 5 (11.6%)                                    |
| Female                                                         | 2362 (86.4%)    | 3460 (71.1%)    | 5822 (76.6%)   | 38 (88.4%)                                   |

|                                   | Zambia (n=2735) | Uganda (n=4866)   | Total (n=7601)    | New diagnosis: confirmed HIV-positive (n=43) |
|-----------------------------------|-----------------|-------------------|-------------------|----------------------------------------------|
| <b>Caregiver age, years</b>       |                 |                   |                   |                                              |
| 18–29                             | 662 (24.2%)     | 875 (18.0%)       | 1537 (20.2%)      | 11 (25.6%)                                   |
| 30–39                             | 1310 (47.9%)    | 1860 (38.2%)      | 3170 (41.7%)      | 20 (46.5%)                                   |
| ≥40                               | 763 (27.9%)     | 2131 (43.8%)      | 2894 (38.1%)      | 12 (27.9%)                                   |
| <b>Caregiver marital status *</b> |                 |                   |                   |                                              |
| Married or cohabiting             | 653/832 (78.5%) | 3043/4741 (64.2%) | 3696/5573 (66.3%) | 26/40 (65.0%)                                |
| Single or never married           | 85/832 (10.2%)  | 240/4741 (5.1%)   | 325/5573 (5.8%)   | 2/40 (5.0%)                                  |
| Widowed                           | 34/832 (4.1%)   | 564/4741 (11.9%)  | 598/5573 (10.7%)  | 4/40 (10.0%)                                 |
| Divorced or separated             | 60/832 (7.2%)   | 894/4741 (18.9%)  | 954/5573 (17.1%)  | 8/40 (20.0%)                                 |
| <b>Caregiver education *</b>      |                 |                   |                   |                                              |
| None                              | 16/828 (1.9%)   | 484/4760 (10.2%)  | 500/5588 (9.0%)   | 2/41 (4.9%)                                  |
| Primary                           | 429/828 (51.8%) | 3087/4760 (64.9%) | 3516/5588 (62.9%) | 30/41 (73.2%)                                |
| Secondary                         | 320/828 (38.6%) | 1059/4760 (22.2%) | 1379/5588 (24.7%) | 6/41 (14.6%)                                 |
| Tertiary                          | 63/828 (7.6%)   | 130/4760 (2.7%)   | 193/5588 (3.5%)   | 3/41 (7.3%)                                  |
| <b>Country</b>                    |                 |                   |                   |                                              |
| Zambia                            | ..              | ..                | ..                | 11 (25.6%)                                   |
| Uganda                            | ..              | ..                | ..                | 32 (74.4%)                                   |

Data are n (%) or n/N (%). NA=not applicable.

\* Data on caregiver marital status and education were only available for the subset of the study sample who took the caregiver survey.

**Table 3:**

Number of paediatric HIV self-tests offered, accepted, returned, and reactive with confirmatory HIV testing and confirmed HIV-positive results among enrolled children

|                           | Uganda                           |                          |                         |                        |                                   |                                                                   | Zambia                           |                         |                         |                        |                                   |                                                                   |  |
|---------------------------|----------------------------------|--------------------------|-------------------------|------------------------|-----------------------------------|-------------------------------------------------------------------|----------------------------------|-------------------------|-------------------------|------------------------|-----------------------------------|-------------------------------------------------------------------|--|
|                           | Eligible children offered HIVST* | Accepted HIVST           | Returned HIVST results  | Reactive HIVST results | Received confirmatory HIV testing | Positive HIV confirmatory test results, positive predictive value | Eligible children offered HIVST* | Accepted HIVST          | Returned HIVST results  | Reactive HIVST results | Received confirmatory HIV testing | Positive HIV confirmatory test results, positive predictive value |  |
| Total                     |                                  |                          |                         |                        |                                   |                                                                   |                                  |                         |                         |                        |                                   |                                                                   |  |
| Unweighted (%)            | 5021                             | 4866 (96.9%; 93.5–100.0) | 4766 (98.0%; 97.0–98.9) | 98 (2.1%; 1.5–2.7)     | 98 (100%)                         | 32 (32.7%)                                                        | 2806                             | 2735 (97.5%; 96.0–98.9) | 2647 (96.8%; 95.5–98.1) | 21 (0.8%; 0.4–1.2)     | 18 (85.7%)                        | 11 (50.0%)                                                        |  |
| Weighted (%)              | NA                               | 96.9% (93.8–100.0)       | 98.2% (97.3–99.0)       | 2.0% (1.4–2.6)         | NA                                | NA                                                                | NA                               | 97.7% (96.4–98.9)       | 97.0% (95.9–98.1)       | 0.7% (0.4–1.1)         | NA                                | NA                                                                |  |
| Age, years                |                                  |                          |                         |                        |                                   |                                                                   |                                  |                         |                         |                        |                                   |                                                                   |  |
| 1–4                       | NA                               | 1251                     | 1227 (98.1%)            | 23 (1.9%)              | 23 (100%)                         | 6 (26.1%)                                                         | NA                               | 761                     | 736 (96.7%)             | 6 (0.8%)               | 5 (83.3%)                         | 3 (60.0%)                                                         |  |
| 5–9                       | NA                               | 1982                     | 1942 (98.0%)            | 48 (2.5%)              | 48 (100%)                         | 21 (43.8%)                                                        | NA                               | 1087                    | 1060 (97.5%)            | 7 (0.7%)               | 6 (85.7%)                         | 4 (66.7%)                                                         |  |
| 10–14                     | NA                               | 1633                     | 1597 (97.8%)            | 27 (1.7%)              | 27 (100%)                         | 5 (18.5%)                                                         | NA                               | 887                     | 851 (95.9%)             | 8 (0.9%)               | 7 (87.5%)                         | 4 (57.1%)                                                         |  |
| Child sex                 |                                  |                          |                         |                        |                                   |                                                                   |                                  |                         |                         |                        |                                   |                                                                   |  |
| Male                      | 2314                             | 2426                     | 2374 (97.9%)            | 43 (1.8%)              | 43 (100%)                         | 18 (32.7%)                                                        | 1424                             | 1396                    | 1352 (96.8%)            | 12 (0.9%)              | 10 (83.3%)                        | 5 (50.0%)                                                         |  |
| Female                    | 2524                             | 2440                     | 2392 (98.0%)            | 55 (2.3%)              | 55 (100%)                         | 14 (32.6%)                                                        | 1382                             | 1339                    | 1295 (96.7%)            | 9 (0.7%)               | 8 (88.9%)                         | 6 (66.7%)                                                         |  |
| Biological child          |                                  |                          |                         |                        |                                   |                                                                   |                                  |                         |                         |                        |                                   |                                                                   |  |
| Yes                       | 3583                             | 3480 (97.1%)             | 3401 (97.7%)            | 77 (2.3%)              | 77 (100%)                         | 23 (29.9%)                                                        | 2806                             | 2735 (97.5%)            | 2647 (96.8%)            | 21 (0.8%)              | 18 (85.7%)                        | 11 (61.1%)                                                        |  |
| No                        | 1438                             | 1386 (96.4%)             | 1365 (98.5%)            | 21 (1.5%)              | 21 (100%)                         | 9 (42.9%)                                                         | NA                               | NA                      | NA                      | NA                     | NA                                | NA                                                                |  |
| Caregiver age, years      |                                  |                          |                         |                        |                                   |                                                                   |                                  |                         |                         |                        |                                   |                                                                   |  |
| 18–29                     | NA                               | 875                      | 857 (97.9%)             | 17 (2.0%)              | 17 (100%)                         | 7 (41.2%)                                                         | NA                               | 662                     | 647 (97.7%)             | 8 (1.2%)               | 6 (74.0%)                         | 4 (66.7%)                                                         |  |
| 30–39                     | NA                               | 1860                     | 1816 (97.6%)            | 49 (2.7%)              | 49 (100%)                         | 16 (32.7%)                                                        | NA                               | 1310                    | 1274 (97.3%)            | 8 (0.6%)               | 8 (100%)                          | 4 (50.0%)                                                         |  |
| ≥40                       | NA                               | 2131                     | 2093 (98.2%)            | 32 (1.5%)              | 32 (100%)                         | 9 (28.1%)                                                         | NA                               | 763                     | 726 (95.2%)             | 5 (0.7%)               | 4 (80.0%)                         | 3 (75.0%)                                                         |  |
| Caregiver sex             |                                  |                          |                         |                        |                                   |                                                                   |                                  |                         |                         |                        |                                   |                                                                   |  |
| Male                      | 1471                             | 1406 (95.6%)             | 1370 (97.4%)            | 20 (1.5%)              | 20 (100%)                         | 3 (15.0%)                                                         | 395                              | 373 (94.4%)             | 350 (93.8%)             | 4 (1.1%)               | 3 (75.0%)                         | 2 (66.7%)                                                         |  |
| Female                    | 3550                             | 3460 (97.5%)             | 3396 (98.2%)            | 78 (2.3%)              | 78 (100%)                         | 29 (37.2%)                                                        | 2411                             | 2362 (98.0%)            | 2297 (97.2%)            | 17 (0.7%)              | 15 (88.2%)                        | 9 (60.0%)                                                         |  |
| Caregiver marital status* |                                  |                          |                         |                        |                                   |                                                                   |                                  |                         |                         |                        |                                   |                                                                   |  |

|                              | Uganda                           |                |                        |                        |                                   |                                                                   | Zambia                           |                |                        |                        |                                   |                                                                   |
|------------------------------|----------------------------------|----------------|------------------------|------------------------|-----------------------------------|-------------------------------------------------------------------|----------------------------------|----------------|------------------------|------------------------|-----------------------------------|-------------------------------------------------------------------|
|                              | Eligible children offered HIVST* | Accepted HIVST | Returned HIVST results | Reactive HIVST results | Received confirmatory HIV testing | Positive HIV confirmatory test results, positive predictive value | Eligible children offered HIVST* | Accepted HIVST | Returned HIVST results | Reactive HIVST results | Received confirmatory HIV testing | Positive HIV confirmatory test results, positive predictive value |
| Married or cohabiting        | NA                               | 3043           | 3034 (99.7%)           | 56 (1.9%)              | 56 (100%)                         | 18 (32.1%)                                                        | NA                               | 653            | 651 (99.7%)            | 11 (1.7%)              | 11 (100.0%)                       | 8 (72.7%)                                                         |
| Single or never married      | NA                               | 240            | 240 (100%)             | 4 (1.7%)               | 4 (100%)                          | 2 (50.0%)                                                         | NA                               | 85             | 85 (100.0%)            | 1 (1.2%)               | 1 (100.0%)                        | 0 (0.0%)                                                          |
| Widowed                      | NA                               | 564            | 562 (99.6%)            | 12 (2.1%)              | 12 (100%)                         | 3 (25.0%)                                                         | NA                               | 34             | 34 (100.0%)            | 1 (2.9%)               | 1 (100.0%)                        | 1 (100.0%)                                                        |
| Divorced or separated        | NA                               | 894            | 888 (99.3%)            | 22 (2.5%)              | 22 (100%)                         | 8 (36.4%)                                                         | NA                               | 60             | 60 (100.0%)            | 0                      | NA                                | NA                                                                |
| <b>Caregiver education*</b>  |                                  |                |                        |                        |                                   |                                                                   |                                  |                |                        |                        |                                   |                                                                   |
| None                         | NA                               | 484            | 482 (99.6%)            | 8 (1.7%)               | 8 (100%)                          | 2 (20.5%)                                                         | NA                               | 16             | 16 (100%)              | 0                      | NA                                | NA                                                                |
| Primary                      | NA                               | 3087           | 3074 (99.6%)           | 69 (2.2%)              | 69 (100%)                         | 24 (34.8%)                                                        | NA                               | 429            | 427 (99.5%)            | 8 (1.9%)               | 8 (100%)                          | 6 (75.0%)                                                         |
| Secondary                    | NA                               | 1059           | 1057 (99.8%)           | 16 (1.5%)              | 16 (100%)                         | 4 (25.0%)                                                         | NA                               | 320            | 320 (100%)             | 4 (1.3%)               | 4 (100%)                          | 2 (50.0%)                                                         |
| Tertiary                     | NA                               | 130            | 130 (100%)             | 3 (2.3%)               | 3 (100%)                          | 2 (66.7%)                                                         | NA                               | 63             | 63 (100%)              | 1 (1.6%)               | 1 (100%)                          | 1 (100%)                                                          |
| <b>Residence</b>             |                                  |                |                        |                        |                                   |                                                                   |                                  |                |                        |                        |                                   |                                                                   |
| Rural                        | 1754                             | 1713 (97.7%)   | 1697 (99.1%)           | 46 (2.7%)              | 46 (100%)                         | 16 (34.8%)                                                        | 1123                             | 1104 (98.3%)   | 1086 (98.4%)           | 6 (0.6%)               | 6 (100%)                          | 4 (66.7%)                                                         |
| Urban                        | 3267                             | 3153 (96.5%)   | 3069 (97.3%)           | 52 (1.7%)              | 52 (100%)                         | 16 (30.8%)                                                        | 1683                             | 1631 (96.9%)   | 1561 (95.7%)           | 15 (1.0%)              | 12 (80.0%)                        | 7 (53.8%)                                                         |
| <b>Facility type</b>         |                                  |                |                        |                        |                                   |                                                                   |                                  |                |                        |                        |                                   |                                                                   |
| Health centre II             | 102                              | 101 (99.0%)    | 97 (96.0%)             | 2 (2.1%)               | 2 (100%)                          | 1 (50.0%)                                                         | NA                               | NA             | NA                     | NA                     | NA                                | NA                                                                |
| Health centre III            | 2043                             | 1927 (94.3%)   | 1896 (98.4%)           | 34 (1.8%)              | 34 (100%)                         | 10 (29.4%)                                                        | 1090                             | 1061 (97.3%)   | 1040 (98.0%)           | 6 (0.6%)               | 5 (83.3%)                         | 3 (50.0%)                                                         |
| Health centre IV or referral | 2167                             | 2133 (98.4%)   | 2097 (98.3%)           | 44 (2.1%)              | 44 (100%)                         | 16 (36.4%)                                                        | 1272                             | 1257 (98.8%)   | 1213 (96.5%)           | 10 (0.8%)              | 10 (100%)                         | 7 (70.0%)                                                         |
| District or level 1 hospital | 709                              | 705 (99.4%)    | 676 (95.9%)            | 18 (2.7%)              | 18 (100%)                         | 5 (27.8%)                                                         | 444                              | 417 (93.9%)    | 394 (94.5%)            | 5 (1.3%)               | 3 (60.0%)                         | 1 (33.3%)                                                         |

Data are n, n (%; 95% CI), % (95% CI), or n (%). HIVST=HIV self-testing.

\* Information on exact age for children and caregivers was collected after enrolment. Data on caregiver marital status and education were only available for the subset of the study sample who took the caregiver survey.