



Use of the Recent Infection Testing Algorithm to Estimate Background HIV Incidence in Micro-Epidemic Areas Within Uganda

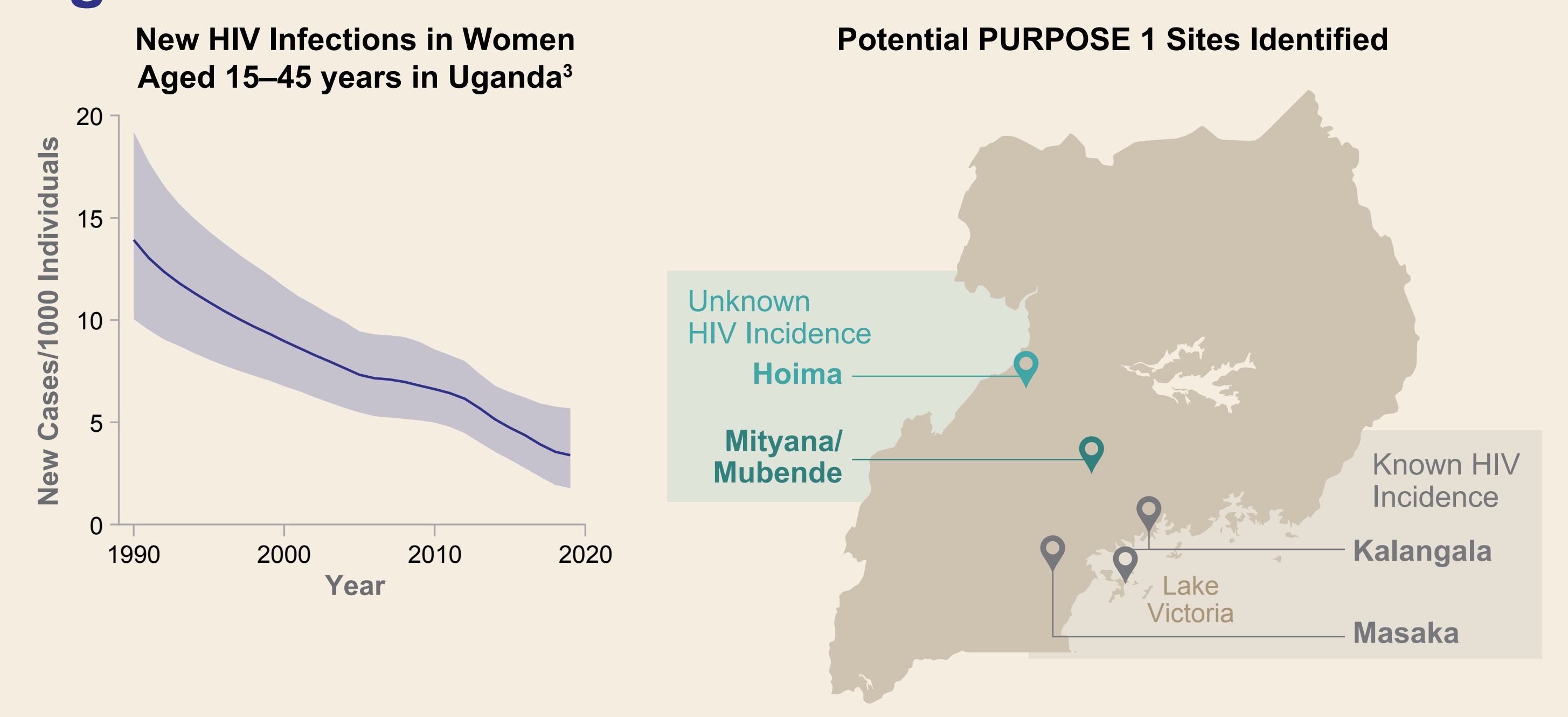
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Introduction

- Accurate estimates of HIV incidence are critical to site selection for pre-exposure prophylaxis (PrEP) clinical trials
- The PURPOSE 1 trial (ClinicalTrials.gov NCT04994509) is using the novel counterfactual background HIV incidence (bHIV) design
 - This trial is evaluating the efficacy and safety of lenacapavir and emtricitabine/tenofovir alafenamide for PrEP in adolescent girls and young women in South Africa and Uganda
 - The primary endpoint will compare HIV incidence in 2 study arms to bHIV of the study population
- A high bHIV (>3.5/100 person-years [PY]) is required for a feasible sample size
- PURPOSE 1 site selection in South Africa was determined by HIV incidence data showing the epidemic remains generalized^{1,2}

HIV Incidence and Potential PURPOSE 1 Sites in Uganda



- In Uganda where HIV incidence has decreased at the national level, 4 potential sites were identified, including 2 (Mityana/Mubende and Hoima regions) that have sociobehavioral characteristics suggesting increasing HIV incidence, but no recent data on bHIV

Objective

- To characterize HIV incidence in 2 regions of Uganda to aid in selection of sites for the PURPOSE 1 study

Methods

- Eligibility criteria: female sex, age 16–25 years, unknown HIV status, and no HIV testing in past 3 months
- A cross-section of adolescent girls and young women were recruited from HIV testing sites and known areas of commercial sex activity, such as bars, nightclubs, lodges, gold mines, factories, farmlands, islands, and landing sites
- HIV diagnosis and confirmation via Alere Determine™ HIV-1/2 (Abbott, Abbott Park, Illinois, USA) and OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test (OraSure Technologies, Bethlehem, Pennsylvania, USA)
- Positive cases were further assessed with Sedia® HIV-1 Limiting Antigen Avidity EIA (Sedia Biosciences Corporation, Beaverton, Oregon, USA) and the following recent infection testing algorithm (RITA) parameters⁴:
 - Cutoff time: 1 year
 - Viral load >75 copies/mL
 - Normalized optical density cutoff ≤1.5
 - Mean duration of recent infection: 166.8 days
 - False recency rate: 6.47%
- Participants diagnosed with HIV were referred to appropriate sites for treatment

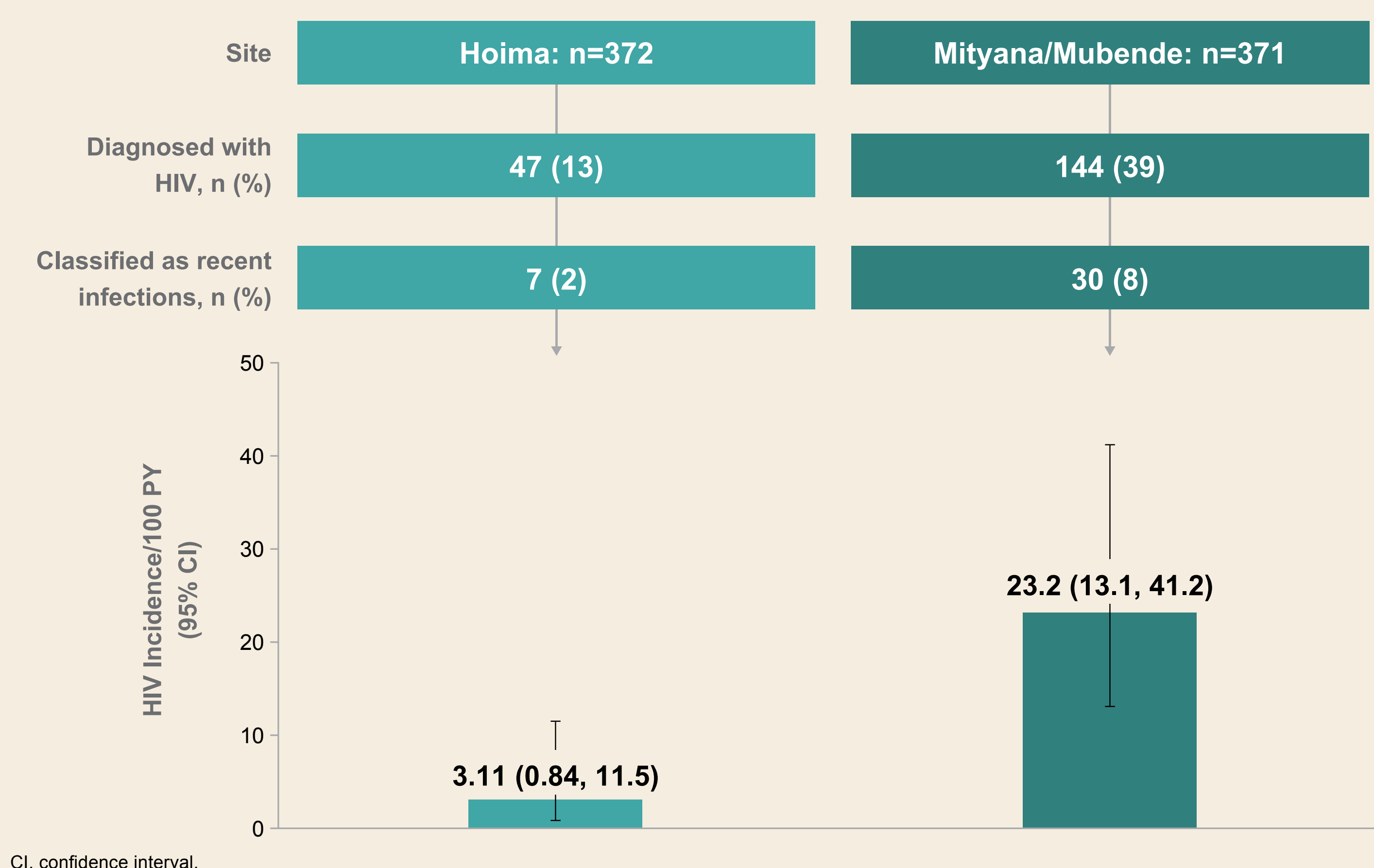
Results

Participant Characteristics

	Hoima n=371	Mityana/Mubende n=371	Total n=742
Median age, years (range)	21 (16–26)	21 (16–25)	21 (16–26)
Secondary education or higher, n (%)	184 (50)	175 (47)	359 (48)
Living with partner/cohabiting, n (%)	40 (11)	69 (19)	109 (15)
Median time living in community, years (Q1, Q3)	1.3 (0.5, 3.3)	1.1 (0.5, 11.5)	1.2 (0.5, 5.5)
Median age at first sex encounter, years (Q1, Q3)	16 (14, 17)	16 (14, 17)	16 (14, 17)
Median months since last HIV test (Q1, Q3)	9 (6, 17)	6 (4, 13)	8 (5, 15)
Sex partners in past 3 months, n (%) [*]			
0	0	0	0
1	53 (14)	20 (6)	73 (10)
≥2	318 (86)	312 (84)	630 (90)
Median number of vaginal sex encounters in past 3 months (Q1, Q3)	100 (25, 100)	100 (24, 100)	100 (24, 100)
Condom use in past 3 months, n (%)			
Never	133 (36)	108 (29)	241 (32)
Rarely	107 (29)	143 (39)	250 (34)
Sometimes	80 (22)	115 (31)	195 (26)
Often	42 (11)	5 (1)	47 (6)
New sex partner in past 3 months, n (%)	214 (58)	304 (82)	518 (70)
Concerned about having HIV, n (%)			
Somehow worried	191 (67)	130 (45)	321 (56)
Very worried	70 (25)	152 (52)	222 (39)
Partner provided financial/material support, n (%) [†]	240 (90)	233 (93)	473 (91)
Primary occupation, n %			
Commercial sex worker, bar/lodge/hotel attendant	239 (64)	240 (65)	479 (65)
Other	132 (36)	131 (35)	263 (35)

^{*}39 participants in Mityana/Mubende group reported no. of sex partners not known; Mityana/Mubende percentages calculated from n=332; total percentages calculated from n=703; [†]105 participants in Hoima and 120 in Mityana/Mubende groups reported not applicable or missing data; Hoima percentages calculated from n=266; Mityana/Mubende percentages calculated from n=251; total percentages calculated from n=517. Q, quartile.

RITA Results



- There were no associations between individual-level characteristics and recent HIV infection
- Mityana/Mubende confirmed as a PURPOSE 1 site due to a bHIV >3.5/100 PY

Conclusions

- Recent infection testing can be used to identify high HIV incidence areas in micro-epidemic settings
- The higher bHIV among adolescent girls and young women in Mityana/Mubende indicates this population is appropriate for HIV prevention studies
- The lack of an association of individual-level characteristics with recent HIV infection is consistent with our understanding of the importance of regional sociostructural factors in HIV acquisition in Uganda

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