Background: The phenomenon of condom migration remains a major concern whenever new HIV prevention approaches are being considered to strengthen the existing preventive arsenal.

In the context of a demonstration project on the implementation of a pregnancy test for recently acquired HIV infection (TasP) and exposure prophylaxis (PrEP) among female sex workers (FSWs) in Cotonou, Benin, we are using a combination of biomarkers for sexual exposure to assess condom migration and the trends in condom use over time.

Objective: Preliminary assessment of the validity of recent self-reported unprotected sex, compared to a gold standard comprising several biomarkers, based on recruitment visits carried out between October 2014 and June 2015 in a TasP/PrEP demonstration project among FSWs in Cotonou, Benin.

Methods: Details on the overall study are provided in another poster presented at this conference.

At their recruitment visit in the study, two weeks following their screening visit where HIV was tested, the confidentiality criteria are assessed, a questionnaire on socio-demographic characteristics and sexual behaviour is administered to the participants. They also undergo a physical examination, where blood and genital samples are collected.

Recent unprotected sex, based on questionnaire data, is defined as not having used a condom for at least one sexual intercourse or having had at least one episode of condom breakage or slippage in the last 2 days. To build this variable, we used questions that were specific to clients, regular partners and other non-paying partners.

The biomarkers used included:

- Prostate-specific antigens (PSA) on vaginal samples
- Y chromosome DNA (YcDNA) on vaginal samples
- Assessema gonorrhoeae (NG) and Chlamydia trachomatis (CT) on cervical samples
- Human chorionic Gonadotropin (hCG) on urine samples
- Papanicolaou (p30) was detected using the commercially available Abvacard p30 PSA assay (Abacus Diagnostics, West Hills, CA, USA).
- YcDNA was detected using an in-house PCR assay using the primer set CTT CCG CAT CCA CTT CCG CAT (5’-ATT CTT CCG CAT CCG CAT-3’), specific for a 229-bp region in the sex-determining region, a gene located on the short arm of chromosome Y.

NG and CT were detected using the NG/CT ProbeType® assay from Becton Dickinson (Cockeysville, MD, USA).

PSA was detected using the commercially available Abvacard p30 PSA assay (Abacus Diagnostics, West Hills, CA, USA).

The pregnancy tests used a simple urine assay from Intec Laboratories (Xiamen, China).

Recent unprotected sex based on biomarkers was defined as the presence of at least one positive test among the biomarkers tested for. This was considered as gold standard for recent sexual exposure.

We assessed the sensitivity (Se), specificity (Sp), positive and negative predictive values (PPV and NPV) of self-reported recent unprotected sex in comparison to the gold standard.

The difference in frequency of unprotected sex between self-report and gold standard was assessed using the McNemar chi-square test.

Written informed consent was obtained from all participants. This study and all its procedures were approved by the ethics committee of the CHU de Québec, Québec, Canada, and by the National Ethics Committee for Health Research in Benin.

Results: 198 FSWs (55 for TasP and 143 for PrEP) were recruited in the study during October 2014 and June 30, 2015.

Median age of all participants was 32.5 years and 44% of them were from Benin, whereas the others were from surrounding countries.

During the last 2 days, 159 (80.3%), 36 (19.2%) and 0 participants had had sex with their clients, regular partners and other non-paying partners, respectively. Corresponding figures were 188 (94.9%), 80 (40.4%) and 4 (2.0%) in the last 14 days.

Consistent condom use (CCU) in the last 2 (14) days was reported at 98.3% (93.0%) with clients and 13.3% (8.8%) with regular partners. CCU was 75% with other non-paying partners in the last 14 days.

10.5% of FSWs had reported at least one episode of condom breakage or slippage when having sex with clients in the last 2 days (20.3% in the last 14 days). No such episode occurred with other partners.

Results for combined biomarkers were available for 190 subjects.

Table 1 shows recent self-reported unprotected intercourse (UI) with any type of partner (including condom breakage or slippage), PSA and YcDNA results for PrEP and TasP subjects separately. There was no difference in the prevalence of self-reported recent unprotected UI except for HIV-infected women where self-reported UI was less frequent than positive PSA and YcDNA PCR.

Results (continued):

- Table 2 shows NG and CT prevalence among FSWs recruited in a TasP/PrEP demonstration study in Cotonou, Benin.
- Table 3 shows a comparison between recent self-reported UI and the PSA results. Although the proportion of self-reported UI is significantly lower than that of positive PSA results, the difference is not statistically significant.
- As the PSA PCR can remain positive for up to 14 days following UI, table 4 shows a comparison between self-reported UI over the last 14 days and the PSA results. Surprisingly, the proportion of self-reported UI over the last 14 days is significantly higher than the proportion of positive PSA-PCR results.
- Table 5 shows a comparison between recent self-reported UI and the PSA results. Concordance between the results is 83.6%. The kappa coefficient is 0.60.
- 13 out of the 25 FSWs (52%) with infection by either NG or CT were positive for PSA or Yc-PCR vs. 58/165 (35.2%) of the uninfected control group. The difference in frequency of unprotected sex between self-report and gold standard was assessed using the McNemar chi-square test.

Discussion: Despite very high levels of self-reported condom use with clients, the proportion of FSWs admitting unprotected sex in the last 2 days is ~20% and ~50% in the last 14 days, largely because of very low CCU with regular partners and relatively high rates of condom breakage or slippage.

When using PSA only as a measure of recent UI leading to semen exposure, we did not find much difference with self-reported UI in the last 2 days. This could be partly due to the fact that 2 days is the upper limit of time for a positive PSA following semen exposure. Indeed, there is indication that the majority of women with a positive PSA report no reported unprotected sex only, but also that the majority of women reporting UI in the last 2 days had a negative PSA.

Recent self-reported UI in the last 14 days was significantly lower according to self-report (23.7%) than according to biomarkers (43.7%).

No 58 87 145 (76.3) 190
Total (%) 83 (43.7) 107 (56.3) 190

For the comparison between self-report and biomarkers: Se: 30.1%; Sp: 81.3%; PPV: 55.5%; NPV: 60.0%

Table 6 shows a comparison between recent self-reported unprotected sex and recent unprotected sex based on a combination of biomarkers among FSWs recruited in a TasP/PrEP demonstration study in Cotonou, Benin.

Table 2. NG and CT prevalence among FSWs recruited in a TasP/PrEP demonstration study in Cotonou, Benin.

Table 3. Comparison between recent self-reported unprotected sex and PSA results among FSWs recruited in a TasP/PrEP demonstration study in Cotonou, Benin.

Table 4. Comparison between recent self-reported unprotected sex in the last 14 days and PSA results among FSWs recruited in a TasP/PrEP demonstration study in Cotonou, Benin.

Table 5. Comparison between PSA and Yc-PCR DNA results among FSWs recruited in a TasP/PrEP demonstration study in Cotonou, Benin.