Re-Evaluation of Annual Cytology using HPV self-sampling to Upgrade Prevention (REACH UP): a feasibility study in women living with HIV in the UK

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INTRODUCTION

UK guidelines for cervical cancer screening are based on the assumption that most women living with HIV (WLWH) are also high-risk (HR) human papillomavirus (HPV) positive. We aimed to study the prevalence of HR-HPV in WLWH in the UK and to assess feasibility and acceptability of HR-HPV self-sampling in this group.

METHODS

WLWH attending 6 HIV Services in London/South England, with no history of cervical cancer, were enrolled. Participants self-collected a vaginal swab for HR-HPV detection at baseline and after one year (1Y), completed an entry survey about sexual/gynaecological history, attitudes towards annual screening and perception of HR-HPV self-sampling at baseline, and an exit questionnaire on acceptability of self-sampling and study procedures at 1Y. Information on cervical smears was obtained from NHS records (baseline and Y1).

RESULTS

Sixty-seven women (86.5% black ethnicity), median (range) age 47 (24-60) years, median CD4+ 683 (interquartile range [IQR] 527-910) cells/mm3, 95.4% undetectable HIV viral load, were enrolled (Table 1).

Table 1: Demographic characteristics of participants

		n
Number of women		67 (100.0)
Enrolment date		21/10/2019-06/03/2020
Age, years	Median (range)	47 (24,60)
Ethnicity	White	6 (8.9)
	Black	58 (86.6)
	Mixed	3 (4.5)
Years from HIV diagnosis	Median (range)	13 (1,29)
Years of ART*	Median (range)	10 (1,23)
Receipt of concomitant medications		44 (65.6)
Nadir CD4+ T-cell count (cells/mm^3), n=54	Median (IQR)	247 (117, 410)
Current CD4+ T-cell count (cells/mm^3), n=65	Median (IQR)	683 (527, 910)
Current viral load, n=65	Undetectable	58 (89.2)
	Detectable, ≤50 cp/ml	4 (6.2)
	Detectable, > 50 cp/ml	3 (4.6)

* ART: antiretroviral therapy; IQR: interquartile range; cp: copies

All women performed the vaginal swab at baseline (although in 2 cases the sample did not reach the lab). Out if the 22 women with only one swab available, 20 (90%) missed their second time point at year 1, when the COVID-19 pandemic necessitated implementation of remote consultations.

At baseline, nineteen women (28%) had no cervical smear results. Nineteen women did not attend for their cervical smear after one year as well. However, only 4 (0.5%) women had no smear test available during the follow up. Among the 30 women with only one smear sample available, 50% missed the first time point.

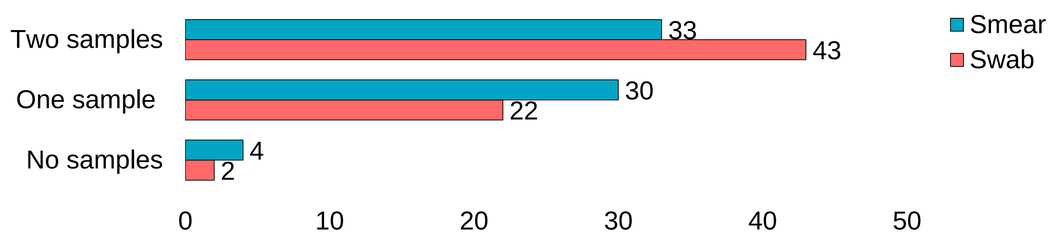

Figure 2: Number of cervical swabs and smear tests performed during the follow-up

85% of the HR-HPV PCR results on vaginal swab were concordant between time points.

HR-HPV ON VAGINAL SWAB	YEAR 1 DETECTED (+)	YEAR 1 NOT DETECTED (-)	YEAR 1 missing/undetermined
Baseline DETECTED (+)	**16**	2	4
Baseline NOT DETECTED (-)	4	**19**	17
Baseline missing/undetermined	-	3	2

Table 2: Results of HR-HPV PCR on self-taken vaginal swab at baseline and at year 1

31/33 (94%) of the HR-HPV PCR results in cervical smear were concordant between time points

HR-HPV ON CERVICAL SAMPLE	YEAR 1 DETECTED (+)	YEAR 1 NOT DETECTED (-)	YEAR 1 missing/undetermined
Baseline DETECTED (+)	**-**	-	-
Baseline NOT DETECTED (-)	2	**31**	15
Baseline missing/undetermined	2	13	4

Table 3: Results of HR-HPV PCR on operator-taken cervical sample at baseline and at year 1

- At baseline, only in 43.3% of the cases there was concordance between the result on cervical and vaginal sample (i.e both resulted negative), while 20.9% of the positive swabs were not confirmed positive by the molecular test done on the smear.
- At year 1, in 55% of the cases there was concordance between the results on the different samples (ie. 22 both negative and 3 both positives.
- 39% of women had a positive HR-HPV result at any time-point on vaginal swab
- HR-HPV was detected in none of the cervical baseline samples and in 4/48 (0.8%) of the Y1 samples. In three of these women, HR-HPV was detected on the vaginal swabs at both time points.
- Cytology performed on the cervical samples where HR-HPV was detected on cervical sample was normal in all 4 cases.

Forty-six (68%) completed the exit survey.

Women were asked if both self-testing and cervical smear were equally good at preventing cervical cancer, which test they would prefer. Thirty (65%) of women reported they preferred the self-testing over smear test.

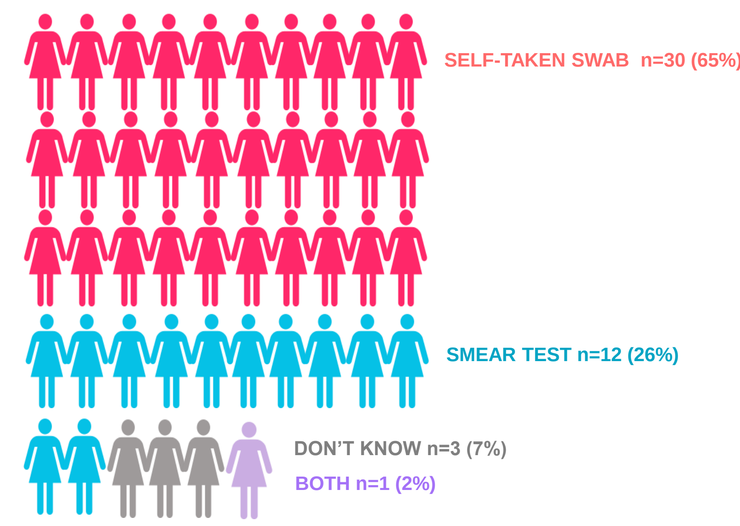

Figure 2: Women's preference for self-testing or cervical smear

On a scale 0-100, how acceptable are self-taken swabs to you?

On a scale 0-100, how easy to perform are self-taken swabs to you?

On a scale 0-100, how likely would you be to perform vaginal swabs out of research trial?

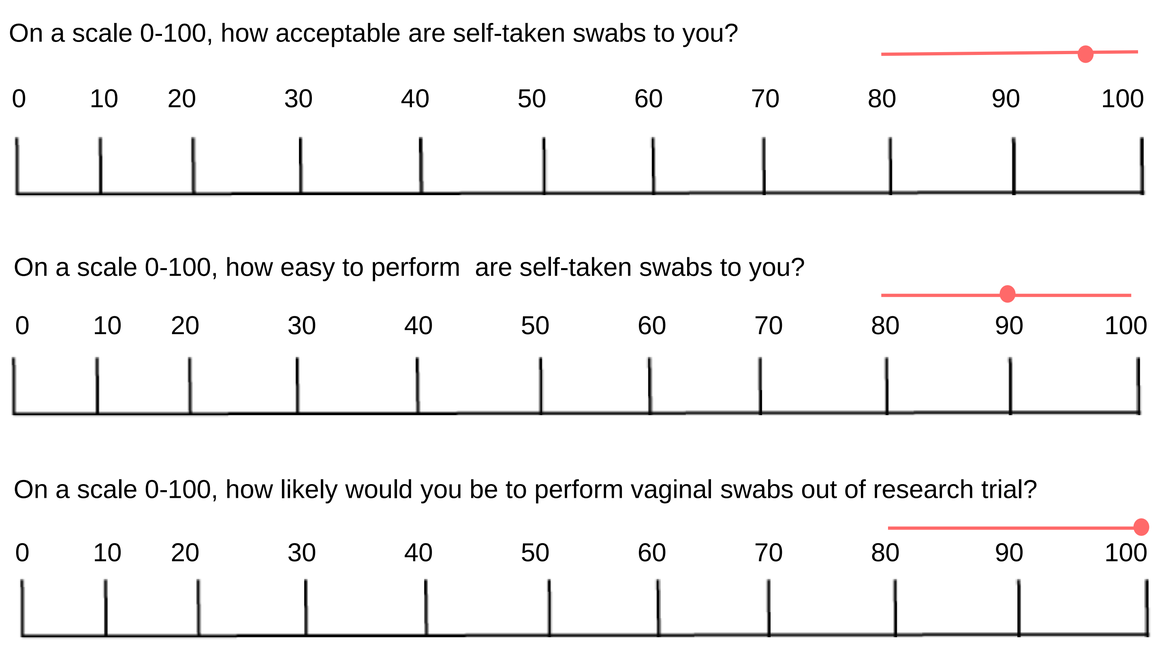

Figure 3: Visual scale 1-100 to assess acceptability, feasibility and acceptance of self-testing. Horizontal lines represent IQR and dots median.

The exit questionnaire had open questions about potential benefits and problems with the two tests. The main concern about self-testing was not being able to perform the test well enough in order to have reliable results.

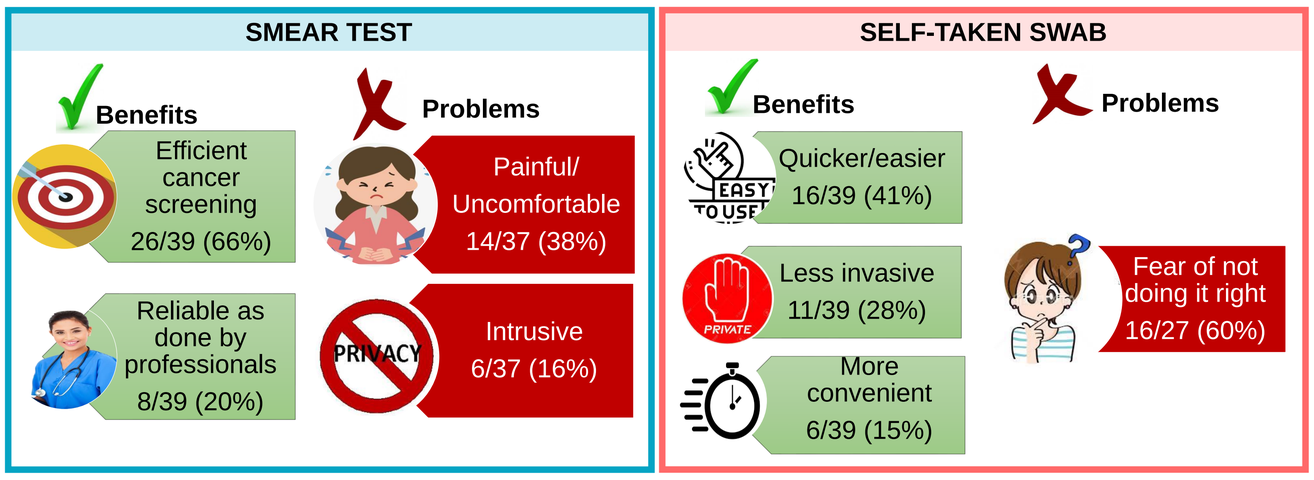

Figure 4: Answers to open questions in the exit survey on benefits and problems of smear test and self-sampling

CONCLUSIONS

- The prevalence of HR-HPV in the UK population of WLWH is relatively low and stable over a short period of time.
- Even if only half of our cohort attended annually for their smear test, most had at least one smear test done over 2 years, even during the Covid-19 pandemic.
- Self-sampling appears to be acceptable even by a population of women aware of the need of repeated smear tests and with low self-reported barrier to cervical cancer screening adherence.
- All women enrolled did at least one self-sampling for the detection of HR-HPV without reporting any side effects. However, many had concerns about the reliability of the results of self-sampling. Confidence in self-sampling can be increased by offering counselling before taking the test and providing educational material with detailed description of the procedure.

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