HPV Self-sampling in the Under-screened Population (Cervical Screening) - Consultation Responses

1-
Name:
Email:
Organisation: Manchester University
Role:
Condition: Cervical screening

This is an extremely good and effective expansion
Well worth the additional expense
It will increase uptake
There may be occasional women that opt for this by not attending smears deliberately but likely will be few

2-
Name:
Email:
Organisation:
Role:
Condition: Cervical screening

As a woman aged 62 who has been unable to have cervical screening for the last 10 years I've been closely following the progress of patient self screening options, & I would have been happy to participate in trialling this option. I have always had cervical screening when offered, but I find the existing option of cervical testing carried out at my Doctors surgery an absolutely horrendous procedure which I've been unable to have since my late 50s for personal psychological reasons. I would happily carry out the self sampling test

myself at home and look forward to being able to do this in the future.

I hope this feedback is useful.

3-

Your name:		Email address:	
Organisation name (if applicable):			
Role/job title (or member of the public):	Sample taker in sexual health setting, colposcopist		
Do you want your name published alongside your response on the UK NSC website?		No	

Document name and section or page number	**Document text or issue your comment relates to**	**Your comment** Please add extra rows as required
Consultation on offering HPV self-sampling to under-screened people in the NHS Cervical Screening Programme	Consultation recommendations	I think self sampling would be a welcome addition to the screening programme but many women would prefer it to the current need to be examined and if they work out that they only need to wait 6 months to get a self-sampling kit the default rate will rise and demand for self sample kits will be much higher than the current defaulter numbers would indicate.

This document doesn't have page numbers which is unhelpful		As self sampling would reduce appointments needed in primary care this would be welcome. The unintended consequence will be further deskilling of the primary care workforce in speculum examination. It will also reduce opportunities for training in speculum examination You may find that hard pressed GP practices encourage self sampling to relieve pressure on themselves- e.g.books in for smear test and is sent to do self sample Another unintended consequence will be the opportunity to discuss contraception and sexual health matters. May miss observation of vulval conditions such as lichen sclerosis These aren't reasons not to offer self sampling but it should be acknowledged that there may be downsides as well
HPV Self-Sampling for Cervical Cancer Screening: A Rapid Review [Draft for comments]	title	The screening is not for cervical cancer, it is looking for precancerous warning signs, and this is an important distinction. Clinicians are constantly trying explain this to women and the title of this document is very unhelpfully reinforces the message that he test looks for cancer. The clinical implications of this are evident e.g. in the anxiety of

		individuals attending for colposcopy who think they have cancer when they only have pre-cancerous changes
HPV Self-Sampling for Cervical Cancer Screening: A Rapid Review [Draft for comments] page 9	Proportion of women with a positive test result who attend clinic for diagnostic investigations and treatment (including cytology followup)	I could not find anything in the document about this Do people who screen positive on a self sample have a higher default rate for colposcopy than people whose sample was taken by a clinician? Will it result in increased colposcopy referrals? Are self samplers more likely to DNA at colposcopy clinics?
Consultation on offering HPV self-sampling to under-screened people in the NHS Cervical Screening Programme This document doesn't have page numbers which is unhelpful	Any proposals to add alternative self-sampling kit delivery strategies to the CSP should be supported by UK research evidence demonstrating their effectiveness (for example improved uptake and/or improved detection and treatment of CIN2+).	I don't think you have presented real life evidence of improved uptake improved detection and treatment of CIN2+.

		What would be the pathway for some who screened HPV+ve as there is no cytology? Do they go straight to colposcopy or do they go for a conventional screening test? I can't find this information

4-

Your name:		Email address:	
Organisation name (if applicable):	The New Hall Lane Practice, Preston		
Role/job title (or member of the public):			
Do you want your name published alongside your response on the UK NSC website?	☐Yes ☐No		

Document name and section or page number	**Document text or issue your comment relates to**	**Your comment** Please add extra rows as required
Adult screening programme, Cervical cancer, UK NSC screening recommendation	Self-sampling for HPV and screening interval from 3-5years	I think self-sampling for HPV will increase the cervical smear screening programme intake. It will make easier for working women to get them self-screened and also help in ethnic minorities. Screening interval in women aged 25-49 can be increased to 5yrs, but it needs robust HPV vaccination programme.

5-
Name:
Email:
Organisation: The New Hall Practice, NHS England
Role:
Condition: Cervical screening

I feel this would be a great pilot for vulnerable groups (sex workers who do not access clinical services) and disability groups where a self taken sample may be easier or the only way they are able to provide a sample)
Thanks

6-

Your name:		Email address:	
Organisation name (if applicable):	The Amwell Group Practice		
Role/job title (or member of the public):			
Do you want your name published alongside your response on the UK NSC website?	☐Yes X☐No		

Document name and section or page number	**Document text or issue your comment relates to**	**Your comment** Please add extra rows as required

HPV Self-sampling UK NSC consultation	Please support women of HPV screening age to participate in this quick, cost-effective procedure. You Screen = Cancer Research UK – Page 2	We were part of a pilot study that supported self-swab – HPV screening in women or were overdue their smears. It was such a simple reliable process. Our cervical smear defaulters are generally women from specific cultural background who find the process uncomfortable, women who have had a traumatic sexual history and women who find it difficult to get an appointment. We have self swab for sexual health screening, it makes sense to do this too. It would free up a considerable amount of time in General Practice.

7-
Name:
Email:
Organisation: Leander Family Practice
Role:
Condition: Cervical screening

The UK NSC is currently consulting on whether to offer an HPV self-sampling option to under-screened people in the cervical screening programme.

Re this consultation (NB: I am unable to edit the consultation form and attach, please accept this as a response):

I strongly believe it will help many women come forward and greatly help our targets and attendance, if patients can self sample and there is initially no speculum examination involved, women who haven't been sexually active, women who are embarrassed or shy, if they can self swab, will almost certainly take part in this type of screening.

I am very much in favour of this recommendation being introduced.

8-

our name:		Email address:	
Organisation name (if applicable):	NHS Ayrshire and Arran		
Role/job title (or member of the public):			
Do you want your name published alongside your response on the UK NSC website? No			

Comments:
HPV Self-Sampling for Cervical Cancer Screening: A Rapid Review p65
"In the opportunistic offering of sampling arm, 65.5% returned self-samples compared with 12.9% in the systematically direct mailout arm."
In my experience of working as a GP and offering bowel screening cards to patients overdue screening, there was better uptake following the in consultation screening discussion when the patient was able to physically take a card from reception, than when they had to telephone a number and request for a card to be sent to their home address in the post. I found this created a barrier and often there was continued non-engagement when I next reviewed. I strongly encourage this proposal to include the option for self-sampling to be available WITHIN the general practice setting as an option. Continuity of care is incredibly powerful for overcoming fear and emotional barriers through a relationship of trust.

YouScreen Cost-Effectiveness Analysis Final Report - Executive Summary 15-08-2024 page7
A GP opportunistic offer was cost effective in all sensitivity analyses and may be a good place to start a roll out for under and unscreened women
I agree that this would be a good place to start.

9-

Your name:		Email address:	
Organisation name (if applicable):	Havens Health surgery		
Role/job title (or member of the public):			
Do you want your name published alongside your response on the UK NSC website?	☐Yes ☒No		

Document name and section or page number	**Document text or issue your comment relates to**	**Your comment** Please add extra rows as required
		I don't have any comments about specific document or page, but want to say that I have shared this with GP partners at my surgery and we are in support of this new way self-screening for HPV.

10-

Your name:	[redacted]	Email address:	[redacted]
Organisation name (if applicable):			
Role/job title (or member of the public):	Member of the public		
Do you want your name published alongside your response on the UK NSC website?	☐~~Yes~~ ☐No		

Document name and section or page number	**Document text or issue your comment relates to**	**Your comment** Please add extra rows as required
HPV Self-Sampling for Cervical Cancer Screening: A Rapid Review [Draft for comments] p. 45	Table 5 Characteristics of Included Studies for Uptake Question	The table says that Brewer 2021 (attached) did not use a reminder. This is incorrect. See Brewer et al 2019 (attached) for full study methods.
HPV Self-Sampling for Cervical Cancer Screening: A Rapid Review [Draft for comments] p. 65	"Our rapid review did not find studies that offered opportunistic self-sampling kit in GP primary care"	Brewer 2021 (attached) offered 2,780 women opportunistic self-sampling in primary care.
		As a person who is eligible for cervical-cancer screening in the UK, I urge you to offer self-sampling as a part of the NHS Cervical Screening

		Programme. I would far prefer to take a self-sample than go through the indignity, embarrassment, discomfort/pain, and inconvenience of a healthcare-professional-taken sample.

11-
Name:
Email:
Organisation: NHS Dumfries and Galloway, NHS Scotland
Role:
Condition: Cervical screening

In response to the above consultation, it has been pointed out by a member of our local cervical screening steering group that a study of defaulters offered self-sampling in Dumfries and Galloway showed a 20% uptake as compared to the YouScreen study which showed around 7% uptake in the mail out group.
An article describing the intervention can be accessed here: https://www.sciencedirect.com/science/article/abs/pii/S1386653224000969.
In short, there is broad support from our local cervical screening steering group for the proposal.

12-

Your name:	Inga Churchman	Email address:	
Organisation name (if applicable):	Wargrave House Surgery and Solutions4Health (Sexual Health Services for Herefordshire)		

Role/job title (or member of the public):	Sexual Health Nurse	
Do you want your name published alongside your response on the UK NSC website?	☐X Yes	☐ No

Document name and section or page number	**Document text or issue your comment relates to**	**Your comment** Please add extra rows as required
HPV Self-Sampling for Cervical Cancer Screening: A Rapid Review [Draft for comments]	P65- Question: • Are HPV self-sampling screening strategies acceptable to those that have not attended the regular cervical screening programme, and does this vary according to patient and test characteristics?	The subsequent discussion doesn't detail variation according to pt and test characteristics- only the % who found it acceptable/ unacceptable and the reasons why. It would be helpful to have a breakdown of age/ ethnicity/ sexual and gender identity of non-attenders. Moving to self-sampling for hrHPV for non-attenders will undoubtedly increase updake, but won't address the issues that prevented them attending to begin with. Will self-sampling hrHPV positive people subsequently attend for cytology? If not, this achieves little towards the goal of reducing the incidence of cervical cancer in the population. Invitation and subsequent non-responder letters that are sent to women by the Screening Programme are 'one size fits all'- perhaps further exploration of targeted information letters would be helpful. I find trans men, lesbian women and those who perceive they have never had (penetrative hetero-normative) sex, do not see themselves at risk. I also

		find a significant number of menopausal/ post-menopausal women, who have previously participated in the programme throughout life, stop attending due to fear of pain and embarrassment. They frequently book appts- with every intention of attending, but then cancel on the day or DNA. Greater emphasis in the non-responder invitation letter offering reluctant attenders an opportunity for 1:1 discussion with the GP Practice Nurse or local provider would be helpful, to enable discussion of options, such as timing/ venue/ lubrication/ vaginal oestrogen/ chaperones etc.

13-

Your name:	Dr Srividya Sundararajan	Email address:	
Organisation name (if applicable):	University of Bristol, University Hospital of Bristol and Weston		
Role/job title:	PhD student, Senior Research Fellow in O&G		
Do you want your name published alongside your response on the UK NSC website?		Yes	
Document name and section or page number	**Document text or issue your comment relates to**	**Your comment** Please add extra rows as required	
		I would like to respond to the consultation as both healthcare professional and as a common public Please find attached my comments as a word document on the rapid review draft. In general, Tesha et al have done an excellent work on the rapid review .	

		Although there are some queries I have raised with the actual draft, the conclusion is very clear, and the self-sampling method seem to be less sensitive for CIN2 and above. Based on the above, self-sampling although might increase uptake , may not improve diagnostic accuracy of screening for hrHPV. I have based my comments on the gov.uk guidance about screening programmes. As a general public, my suggestion might be to roll it out to non-attenders and note the change in diagnosis of CIN 2 or 3 ? Please do not hesitate to contact me for any further feedback.
HPV Self-Sampling for Cervical Cancer Screening: A Rapid Review ,Abstract, Page 2	*Page 2: There is interest within the National Screening Committee to incorporate self-sampling into the cervical screening program in the UK, specifically for non-attenders.(1)*	Non-attenders needs defining in the abstract, assuming this includes individuals who opt-out of the screening programme.
HPV Self-Sampling for Cervical Cancer Screening: A Rapid Review ,Abstract, Page 2	*Page 2: Similarly, there is high concordance between the arms in which the overall agreement was 87.1% and the kappa value of 0.70. The*	Is this overall agreement between screened studies or is this the agreement between the two arms of the studies included that is, self-sampled vs clinician collected?

HPV Self-Sampling for Cervical Cancer Screening: A Rapid Review, Page 6, Introduction	*Page 6: The development of cervical cancer from CIN3 can take over a decade.*	This can be worded differently. This implies that we have a decade to treat CIN3. however, we need to ensure complete excision. The referenced article quotes “he time from HPV infection to cervical cancer will usually take 10–20 years or longer, and leaves great opportunity for screening and early detection
HPV Self-Sampling for Cervical Cancer Screening: A Rapid Review,Page 6, Introduction	*Page 6: Indeed, the reasons for non-participation are multifarious, but may include insufficient time to attend a clinic, lack of awareness, anxiety regarding a gynaecological examination, or physical discomfort during specimen collection. Participation is often reduced in some patient populations, including those in minority ethnic groups, those of low socio-economic status, and transgender and non-binary people with a cervix.*	Although, all points of non participation is accurately recorded in this sentence, this gives the impression that the issue is from the participants only. Unsure if there is any evidence on the service provision constraints like establishment of walk-in clinics ?
HPV Self-Sampling for Cervical Cancer Screening:	*Page 7: What is the accuracy of HPV testing in self-collected*	Individual and patients have been used interchangeably in this page. Assuming they both refer to screened population

A Rapid Review, Page 7 , Aims and objectives	*samples compared with health professional collected samples, and does this vary according to patient and test characteristics? To compare the diagnostic accuracy of HPV-DNA testing on self-collected samples with testing on samples collected by a healthcare professional, in individuals who do not participate in a regular cervical screening programme*	
HPV Self-Sampling for Cervical Cancer Screening: A Rapid Review, Page 7 , Aims and objectives	*Page 7: Aim- In cervical screening non-attenders, what is the level of concordance between HPV-DNA testing in self-collected samples and clinician / health professional collected samples, and does this vary according to patient and test characteristics?*	Does the rapid review look at accuracy in non-attenders and individuals who have opted out of screening (never had a smear test or has not had a smear test since screening changed to HPV?) or does the review include non-attenders as in any individual who has not been consistently having screening test? Suggest perhaps have a definition index at the end of each page or a more consistent use throughout the guidance.

	III. What is the uptake of cervical screening in screening non-attenders offered HPV self-sampling *compared with those offered health professional sampling, and does this vary according to patient and test characteristics?* *Objectives- in individuals who do not participate in a* *regular cervical screening programme*	
HPV Self-Sampling for Cervical Cancer Screening: A Rapid Review, Page 9, Page 10	*Page 9 and 10: Accuracy of HPV testing in self-collected samples compared with health professional collected* *Samples* *The level of concordance between HPV-DNA testing in self-collected samples and health professional collected samples in cervical screening non-attenders*	Regarding describing eligibility criteria for screening studies- Population tab in Objective 1, Page 9- describes individuals eligible for cervical screening Population tab in Objective 2, page 10- describes individuals eligible for cervical screening . But in keeping with the objective question, do you mean individuals eligible for cervical screening but are non - attenders?
HPV Self-Sampling for Cervical Cancer Screening: A Rapid Review, Page 10,	*Page 10: Outcomes - Cohen's Kappa statistic*	I am unclear regarding use of this in the context of concordance for hrHPV. The Cohen's Kappa is used to assess the extent to which multiple authors agree on screening articles to include in systematic

		reviews. Alternatively, this can be used to assess qualitative analysis on agreement between two groups in research. If Kappa co-efficient was used to show consensus between reviewers (although in this case, full article was only reviewed by the lead author), this has to be uniformly reported across the whole document. https://handbook-5-1.cochrane.org/chapter_7/7_2_6_0_introductory_text.htm
HPV Self-Sampling for Cervical Cancer Screening: A Rapid Review, Page 11	*Page 11: Uptake of cervical screening in screening non-attenders offered HPV self-sampling compared with those offered health professional sampling*	Can this sentence be simplified please? Maybe change to Uptake of cervical screening by HPV self-sampling method when compared to health professional sampling method in non-attenders
HPV Self-Sampling for Cervical Cancer Screening: A Rapid Review, Page 11	*Page 11: Individuals eligible for cervical screening who did not participate in the standard cervical screening programme, did not respond to invitations to attend for clinician-based cervical screening, are under-screened*	Can this sentence be simplified please? Maybe change to Individuals who were invited to participate in standard cervical screening programme but did not respond to invitation or did not participate in the screening programme . In general, there needs to be a disclaimer somewhere in the document that when invitation is sent out, we assume that this is adopted to the language that is registered as acceptable to the individual. In cases where this is not applied, the primary care service or the government has a failsafe method to ensure the communication is sent out in languages acceptable to the individuals screened.

HPV Self-Sampling for Cervical Cancer Screening: A Rapid Review, page 11	*Page 11: Uptake of HPV based cervical screening (absolute response rate)* • *Relative response rate* • *Response difference*	Is this Absolute response rate= total responders/ total individuals invited for screening Relative response rate= Responders of that method/ total individuals for that method? Or is the denominator all those invited for both methods? Response difference= Absolute- relative response rate / 100? Might need explaining in the legend or elsewhere in the document please
HPV Self-Sampling for Cervical Cancer Screening: A Rapid Review, page 12	*Page 12: Individuals eligible for cervical screening who do not attend for health professional testing*	Under population description, does this mean individuals who are eligible and have been invited for screening but who do not attend for health professional testing? I think this is an umbrella term and needs defining – i.e., individuals who do not wish to take screening with health professional, individuals who do not attend for health professional testing and individuals who attend but prefer the method of health professional testing
HPV Self-Sampling for Cervical Cancer Screening: A Rapid Review, page 13	*Page 13: PRISMA diagram, Figure 1*	Records, studies and reports used I am assuming all are studies and can this either be changed to studies uniformly or records ? Also, is this PRISMA diagram of screening the whole study (where only NT was involved) Or is this incorporating both reviewers please?
HPV Self-Sampling for Cervical Cancer Screening: A Rapid Review, page 13	*Page 13: PRISMA diagram, figure 1*	There is computational error in the number of studies excluded. In the right hand boxes, the number of records excluded is n=257. But actually adding up your data, this adds upto 255. So the total new

		studies included will be 90 and hence the total number of studies in your rapid review is 195. This could potentially impact the degree of freedom in your statistical analysis. This could also change your heterogeneity calculation and chi squared analysis. Please ensure that these numbers add up
HPV Self-Sampling for Cervical Cancer Screening: A Rapid Review,page 14, Accuracy of HPV testing in self-collected samples compared with health professionalcollected samples	*Page 14: The relative sensitivity/specificity reported in the detection of CIN2+ was reported in 46 studies. The assay used in these studies included PCR (28), HC2 (11) and some studies used more than two assays (11).*	My understanding is the sensitivity calculation for this section only concentrated on hrHPV testing and not CIN. The issue then is are these 46 studies reporting both HPV and CIN sensitivity? Also in general, this paragraph needs rewriting – maybe methods , techniques and instruments used should be described first. Then describe the reported methods? In the next paragraph , the authors have implied that only 13 studies out of 56 were eligible for meta-analysis. Is this from the 194 studies that were included in the PRISMA diagram for rapid review/ systematic review?
HPV Self-Sampling for Cervical Cancer Screening: A Rapid Review, page 15-22	*Page 15-22: TABLE 1 – Description of studies included Characteristics of Studies on Test Accuracy of HPV Testing in Self-selected Samples*	The studies included range from 1999-2024. In a systematic review and also in a rapid review, using evidence that lasts more than a decade can be very challenging. This could potentially impact the results , particularly in the context that we have now moved onto screening hrHPV predominantly.
HPV Self-Sampling for Cervical Cancer Screening: A Rapid Review, page 14-22	*Page 14-22: TABLE 1 and The accuracy question included 56 studies – 32 studies from the referenced reviews and 24 from the*	The table has 57 studies included. This is computational error I think. Also there is type in the year in Table 1 page 15

	top-up search (Table 1).	
HPV Self-Sampling for Cervical Cancer Screening: A Rapid Review, page 23	*Page 23: TABLE 2*	Please include the studies used to calculate pooled sensitivity and specificity as a reference at the end of the table or in the paragraph where table was referenced
HPV Self-Sampling for Cervical Cancer Screening: A Rapid Review, page 24	*Page 24: The self-sampling devices which were used included brush (22), swab (20), lavage (2) and others (5). The self-sampling was reported done mostly in the clinical setting (35), followed by at home (5). The most used assay was PCR (25).*	Are the numbers in the bracket here the number of studies in each category of sampling – eg 22 studies sampled using brush, 20 used swab ets or just the referencing style to indicate the study?
HPV Self-Sampling for Cervical Cancer Screening: A Rapid Review, page 25-33	*Page 25-33: TABLE 3*	The paragraph in page 24 states 50 studies reviewed but the table includes 51 studies Kappa scores don't seem to have been reported in all the studies included in Forest plot/Meta-analysis. They seem to have been derived from the data provided. But this can be misleading. Please can all the studies included be referenced at the end too?
HPV Self-Sampling for Cervical Cancer Screening: A Rapid Review, page 50	*Page 50: TABLE 6*	Please can we describe absolute participation, relative participation and difference in participation in the table legend.
HPV Self-Sampling for Cervical Cancer Screening: A Rapid Review, page 50	*Page 50: Seven studies were not included in the meta-analysis as, fairer comparisons, only those that reported*	In page 39, its been stated that 38 studies were included in this category but if seven were not suitable for meta-analysis, this leaves 31 studies for analysis.

	uptake for both the self-sampling and control arms were included leaving 30 studies	
HPV Self-Sampling for Cervical Cancer Screening: A Rapid Review, page 50	*Page 50: The difference in participation between those who were in the self-sampling arms and those in the control arms is shown in Figure 6.*	This refers to the Forest plot of included study. So will have to describe as " the difference in participation rates of each study included in meta-analysis"
HPV Self-Sampling for Cervical Cancer Screening: A Rapid Review, pages 52-59	*Page 52-59: TABLE 8*	The paragraph in page 52 says 54 studies were included but the table ahs only 53 studies
HPV Self-Sampling for Cervical Cancer Screening: A Rapid Review, pages 62-63	*Page 62-63: Figure 8 ,9 and 10*	There is already marked heterogeneity demonstrated in Figures 6 and 7. Since the studies included have all had different research models, unsure if figures 8 ,9 and 10 add any extra benefit to the rapid review. Can they be omitted? The figures also look slightly out of focus in the lower border
HPV Self-Sampling for Cervical Cancer Screening: A Rapid Review, page 65	*Page 65: The YouScreen Study was a feasibility clinical trial embedded within the English Cervical Screening Programme to estimate the impact of offering self-sampling to non-attenders in practice.*	Maybe change to *The YouScreen Study was a feasibility clinical trial embedded within the Cervical Screening Programme in England Programme to estimate the impact of offering self-sampling to non-attenders in practice.*

14-
Name: [redacted]
Email:
Organisation:
Role:
Condition: Cervical screening

I am writing in response to your request for feedback regarding cervical screening.

As a disabled woman (wheelchair user), and someone with an obstetric injury making passage of a speculum anatomically impossible, I am writing to implore you to make self taken, at home cervical screening available to all, as quickly as possible.

Disabled women in particular are an already marginalised and underserved group within healthcare generally, and face specific barriers to accessing cervical screening in its current form. Travelling to the surgery or clinic can be challenging and expensive, and premises are often unsuitable e.g. no step free access, examination rooms too small to manoeuvre, having to be examined with the door open as the room is too small for the door to close with a wheelchair inside, and no accessible toilets.

The test itself, which currently requires a clinician taken sample from the cervix, is anatomically impossible for the many women for whom speculum passage is either impossible or not tolerated. This includes women like myself with obstetric injuries, those with FGM and survivors of sexual trauma.

There is no justification for either of these groups to be excluded from screening given that a scientifically validated self-taken vaginal swab or urine sample negates the requirement for either a clinic visit or a speculum examination, and continuing to deny us access to this amounts to criminal negligence.

15-

Your name:	Sally Faulkner	Email address:	
Organisation name (if applicable):	Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust		
Role/job title (or member of the public):	Health Improvement Specialist		
Do you want your name published alongside your response on the UK NSC website?	☐ Yes	☐ No	

Document name and section or page number	**Document text or issue your comment relates to**	**Your comment** Please add extra rows as required
	General comment	We fully support the recommendation to offer the option of self-sampling to under-screened individuals in the NHS Cervical Screening Programme (CSP). As a large mental health trust covering parts of the North East and North Cumbria we are aware of the stark health inequalities that our populations of service users experience. Screening uptake is much lower amongst people with severe mental illness (SMI) and cervical screening in particular is one of the programmes that remains a challenge for a number of reasons, including accessibility problems, a history of trauma, lack of familiar healthcare providers. Some service users miss being invited to be

		screened either because they are not registered with a GP, have no fixed abode, or do not have family or carers to pass on invites that have gone to their home address. As a Trust we have made inroads to improving screening uptake over the past few years through the development of inpatient screening pathways. We recognise that inpatients who are in hospital for a prolonged period of time (sometimes many years) may miss screening opportunities as a result of their time spent in hospital and are working through pathways for all national screening programmes. To highlight the urgent need for screening amongst our service users, within our first cohort identified as eligible for cervical screening, less than 30% were up to date with their cervical screening; one individual's last screening was 25 years ago, whilst another was 12 years ago when they were flagged for 12-month recall. Despite us being able to effectively identify service users who are eligible for screening, many of the barriers to screening acceptance still remain. We would like to draw attention to the fact that many people with severe mental illness do not routinely access primary care services, therefore the offer of HPV self-sampling within this setting would again 'miss' many of this under-screened population group. We strongly feel that offering HPV self-sampling via secondary care mental health services (particularly in inpatient settings) would be a very effective means to engage with a population group that are under-screened. HPV self-sampling offers a means to access screening that removes a substantial number of existing barriers including the aforementioned accessibility problems, history of

		trauma, lack of familiar healthcare providers, along with staff capacity to escort/transport service users to appointments, anxiety experienced as a result of having a screening appointment. We would be very interested to be involved in any future piloting of HPV self-sampling in mental health settings.

16-

Your name:	Athena Lamnisos	Email address:	
Organisation name (if applicable):	The Eve Appeal		
Role/job title (or member of the public):	CEO		
Do you want your name published alongside your response on the UK NSC website?		☐XYes	☐No

Document name and section or page number	**Document text or issue your comment relates to**	**Your comment** Please add extra rows as required
HPV Self-Sampling for Cervical Cancer Screening Pg 4	Pg 4: A precursor of cervical cancer which is classified according to the severity of dysplasia as CIN1 (low grade), CIN2 (moderate grade) and CIN3 (high grade).	CIN2 is classed as high grade Note on language – need to test 'self-sampling' in terms of being understandable. Alternatives: 'self-testing' 'home HPV testing' 'self HPV testing'

HPV Self-Sampling for Cervical Cancer Screening Pg 6 - Rationale	Page 6: CIN2 (moderate grade)	CIN2 is classed as high grade
HPV Self-Sampling for Cervical Cancer Screening Pg 5	Page 5: LLETZ	Definition should be Large Loop Excision of the Transformation Zone This needs explanation in any patient facing resources.
HPV Self-Sampling for Cervical Cancer Screening Pg 6 - Rationale	Page 6: Clinical guidelines recommend monitoring CIN1 lesions for progression to more severe dysplasia, whilst CIN2+ lesions should be managed by removing the abnormal cells, most frequently by large loop excision of the cervical transformation zone (LLETZ).	What would help people in any comms is full explanation of these terms, and using one consistently. Even in the document text pulled here you can see they use dysplasia, CIN and abnormal cells- very confusing for people to see several terms for the same thing This is the current guidance for treating CIN 2: 4.7 Conservative management of CIN2 • Individuals can be offered conservative management of CIN2 if: • the colposcopic examination is adequate and has excluded CIN3 and an invasive lesion • a CIN2 lesion occupies no more than 2 quadrants of the cervix • CIN2 has been diagnosed on histology and reviewed at MDT to exclude an undercall or overcall • they agree to regular 6 monthly follow up colposcopic examinations including repeat cervical sampling and repeat biopsy (if indicated by the presence of a more severe lesion (CIN3) on colposcopic examination) • they understand the time period for resolution of CIN2 can be at least 24 months (as described in research published in 1993, 2017 and 2018

		• Treatment must be offered if the CIN2 has not resolved within 24 months. • All cases must be discussed by the MDT to ratify a decision for conservative management. Outcomes should be subject to regular local audit. https://www.gov.uk/government/publications/cervical-screening-programme-and-colposcopy-management/3-colposcopic-diagnosis-treatment-and-follow-up
Consultation on offering HPV self-sampling to under-screened people in the NHS Cervical Screening Programme Pg 1 - Background	Page 1: Barriers such as pain, fear, embarrassment, and inconvenience can stop people going for cervical screening	Could this be expanded upon to include results from Eve's You Gov survey (June 2024) and include specific barriers that we know impact screening uptake but can be addressed. Eg past experience of sexual trauma, lack of hoists, lack of information in accessible formats
Consultation on offering HPV self-sampling to under-screened people in the NHS Cervical Screening Programme - Pg 4 – Consultation recommendation	Page 4: The self-sampling kit delivery strategy should be based on the approach taken in the YouScreen trial – either as an opportunistic offer, direct mail-out	How will direct mail out link with NHS Cervical Screening Administration Service - they are reliant on GP practices updating relevant change of address documentation so up to date addresses are available on national screening systems. Currently, this causes significant issues and may impact on return rates for direct mail out Opportunistic offer in relevant settings so that there is some context / discussion is the strongest offer.

Consultation on offering HPV self-sampling to under-screened people in the NHS Cervical Screening Programme Pg 4 - Consultation recommendations	Page 4: Consultation on offering HPV self-sampling to under-screened people in the NHS Cervical Screening Programme Pg 1 - Background	This needs to include information in different formats and information that informs a person that if they test positive for HPV, they will need to undergo a cervical screening test.
Cost-effectiveness analysis of the YouScreen trial: a modelling study Pg 92-94	Page 92-94: Figures 15-17	Need to ensure these are aligned to up to date guidance: https://www.gov.uk/government/publications/cervical-screening-care-pathway/cervical-screening-care-pathway
Cost-effectiveness analysis of the YouScreen trial: a modelling study Pg 104	Page 104: CIN 2	High grade not moderate
Cost-effectiveness analysis of the YouScreen trial: a modelling study Pg 104	Page 104: Colposcopists	Can be nurses, not usually gynaecologists
Cost-effectiveness analysis of the YouScreen trial: a modelling study Pg 105	Page 105: HPV 16/18	We only test for strains, in the UK, under specific circumstances, it is not routine and needs a special arrangement with the lab. There are an increasing number of privately available self-tests and direct to consumer tests (eg Superdrug). These often test for strains of HPV that are not high grade. Leads to confusion in results. Clear communication about what is being tested for required.

17-

Your name:		Email address:	
Organisation name (if applicable):	LEICESTERSHIRE COUNTY COUNCIL		
Role/job title (or member of the public):			
Do you want your name published alongside your response on the UK NSC website?		☐Yes	xNo

Document name and section or page number	**Document text or issue your comment relates to**	**Your comment** Please add extra rows as required
Cost-effectiveness analysis of the YouScreen Trial: a modelling study An Executive Summary August 2024 (Page 4)	**Page 4: Lifetime cost-effectiveness**: The following scenarios were created for a hypothetical cohort of 10 million unvaccinated women in England who turned 26 in 2021 and thus be eligible for YouScreen offers. Results are presented per 100,000 women. The model assumes women who return a self-sample will continue to receive and return a self-sample to age 64.	With the roll out of the single dose HPV vaccination (September 2023) the expected unvaccinated population will be reduced in many areas of England. Though this is post-modelling it should have been referenced as a planned approach for awareness. Also, the model assumes those returning a self-sample will continue to receive and return a self-sample to age 64. However, this model does not illustrate how the cost and benefit of the model would be communicated to the patient.
Cost-effectiveness analysis of the YouScreen Trial: a modelling study An Executive Summary August 2024 (Page 5)	Page 5: In combination, these probabilities suggest that there is a reasonably high certainty that a strategy involving an opportunistic GP offer would be cost-effective (86% probability at WTP £30,000 per	The acknowledgement of QALY is important to appreciate the 'non-monetary' cost benefit also.

	QALY), but less certainty regarding whether a GP opportunistic offer should be used on its own or in combination with direct mail-out.	
Cost-effectiveness analysis of the YouScreen Trial: a modelling study An Executive Summary August 2024 (Page 7).	Page 7: Conclusions: 1. Offering self-sampling to never screened and under-screened women in England across a range of ages as part of the National Cervical Screening Programme, particularly when offered in a GP setting, is both effective and cost-effective. 2. Additionally, direct mail-out only is cost effect relative to the status quo and could be considered whether opportunistic offering is a GP setting is not possible. ----------	1. In agreement with this statement from the cost-effectiveness study, but if the screening programme progresses this should be revisited. 2. Though a 'direct mail out approach' seems most cost effective, return rates may reduce and sample adequacy rates may increase as expanded out across all non-participants of usual screening pathway. There is also a risk of the sample taking kit being an increased risk for some of the population, who may not be aware of the swabs breaking point (8cm) and how to seek help if this should happen. Self-sampling did lead to some pain discomfort and embarrassment which may increase the risk of not participating in the future. ----------

	4. A GP opportunistic offer was cost effective in all sensitivity analyses and may be a good place to start a roll out for under and unscreened women.	4. In agreement with the proposed pilot/roll out idea, as this is already taking place within local Primary Care Networks. Though from the final study '*Cost-effectiveness analysis of the YouScreen Trial: a modelling study'* the combined opportunistic and mail-out options would return the most beneficial cost benefit.
HPV Self-sampling in under screened population consultation cover note (page 5).	Page 5: Self-sampling for HPV testing can be offered to under-screened people eligible for the Cervical Screening Programme in the 4 UK countries, where service commissioners think self-sampling would be a helpful addition to the programme. If implemented, the option would be provided alongside traditional clinician-collected sampling.	Would the change in service commissioners from NHS England to Integrated Care Board's (planned for April 2026) need to be acknowledged as part of the proposal to ensure consistency and reduced programme disruption ahead of the proposal being agreed?
The Daffodil Centre Cost-effectiveness analysis of the YouScreen Trial: a modelling study Report 15 August 2024	Page 16: Additionally, it is important to note that self-collected HPV tests under the YouScreen screening pathways are not available to women beyond the screen end age of 64 years, while women under clinician-collection pathway are still	Acknowledgment of this inequality should be factored into the YouScreening programme as a potential concern for underserved communities as this further widens a health inequalities gap. Is there any suggestion on programme expansion to support equality?

(Page 16) Part B: exploratory modelling using a single cohort approach considering extension of the trial results to the whole population: lifetime cohort modelling	receiving regular tests when they are aged above 64 (shown in the national screening coverage in National Health Service England 2022). Therefore, it is possible that women in the No YouScreen pathway will receive additional screening tests not offered to YouScreen women.	

18-

Your name:		Email address:	
Organisation name (if applicable):	Royal College of Nursing Women's Health Forum		
Role/job title (or member of the public):			
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Document name and section or page number	**Document text or issue your comment relates to**	**Your comment** Please add extra rows as required
HPV Screening for Cervical Cancer.	Page 2	Term "Non-attenders" should be non-responders

A rapid Review	Abstract: paragraph 2 Findings: Conclusion and Recommendations	Terms PP analysis and ITT analysis needed to be defined Term Compliance should be changed to concordance
	Page 6 Rationale paragraph 2	This paragraph does not reference women who are the vast majority of those who require screening. Suggest language of addition: Women and those with a cervix.
	Page 64	That statistic that HCP's offering self- taken samples opportunistically Results in 5 times higher response than mail-all sampling kits is impressive, and clinically important.
	Page 65 Para 1	The discussion covers concerns of women in taking the sample and acceptability of self-sampling, but it does not include reference to disabled women and autistic women who may not have the physical dexterity or the mental capacity to undertake self-sampling.
Consultation Document	Page 1 Introduction	The introduction needs to state that screening is for women and those with a cervix at the outset, rather than people as men do not need cervical screening. This is a women's health issue, and the use of "people" in the introduction diminishes the importance of women.

	Background	The phrase “rarely or never attend “ should be changed to engage with screening. RCN guidance states that physically disabled women should be offered screening in their own home. Last sentence change nurse or doctor to healthcare professional, this is because screening is also carried out by Nursing associates and midwives. The examples of barriers need to expand to include the experience of physically disabled women and women with autism who experience physical barriers, sensory barriers and negative attitudes as barriers.
	Page 3	Change term non-attenders to non-responders as more accurate and less judgemental

	You screen trial and cost effectiveness	Change GP setting to Primary care as the majority of sampling is carried out by Nurses and Nursing Associates in Primary Care
	Page 4 Consultation recommendation	This is a robust recommendation that is supported by the evidence. The use of validated self-sample kits should be offered to non-responders either opportunistically or vis targeted mail out, to increase coverage of screening. This is to be used along traditional HPV screening and has enormous potential to compliment the screening programme.
Cost Effectiveness of the You Screen Trial	Page 4 Findings	Please change the term GP opportunistic model to Primary care. Very few GP undertake cervical sampling, the vast majority is undertaken by Nurses and Nursing Associates. This term is used throughout the document and undervalues the enormous contribution made by nursing staff.
	Page 5 Findings	Findings clearly illustrate the cost-effectiveness of self-sampling and the potential to prevent an estimated further 4 % of deaths from cervical cancer and should be supported.
YouScreen: Executive Summary	Page 1 Paragraph 1	Please change GP setting to Primary Care to reflect the contribution of Nursing staff who carry out most of the screening.
	Page 7	The summary of this study clearly demonstrates the potential of YouScreen to compliment the current HPV screening programme by offering additional

	Conclusions	choice that is convenient to women both through targeted mail out and opportunistic self, particularly for older women. It has potential to reduce deaths from cervical cancer and we support its implementation.

19-

Your name:		Email address:	
Organisation name (if applicable):	LGBT Foundation		
Role/job title (or member of the public):			
Do you want your name published alongside your response on the UK NSC website?		No	

Document name and section or page number	**Document text or issue your comment relates to**	**Your comment** Please add extra rows as required
Consultation on offering HPV self-sampling to under-screened people in the NHS Cervical Screening Programme	An under-screened person is an individual who is overdue for their routine cervical screening appointment by at least 6 months or has never attended	This definition risks excluding those who are under-screened because they have not been recalled. Trans men, masc and non-binary people with a male gender marker will be missed by call/recall systems, so it may be difficult to identify that they are overdue for screening.

	The self-sampling kit delivery strategy should be based on the approach taken in the YouScreen trial – either as an opportunistic offer, direct mail-out, or both direct mail-out and an opportunistic offer, depending on the feasibility of implementing each strategy. The opportunistic strategy achieved a higher response rate than direct mail-out and is encouraged	As above, direct mail-out kits risk missing those who are underscreened due to issues with NHS call/recall systems. Additionally, opportunistic offers are more likely to be made during contraceptive or gynaecological health visits, of which lesbian and bisexual women, and trans men, masc and non-binary people are less likely to attend. A targeted approach for this cohort would be beneficial.
	Appropriate information should be developed to facilitate personal informed choice to participate in the screening programme.	When surveyed, trans and non-binary people spoke of the need for inclusive general resources, whose language did not exclude the experiences of people who may need screening that are not women. They also requested specific literature aimed at trans and non-binary people, with more details about their care needs (Alison M Berner et al., 'Attitudes of Transgender Men and Non-Binary People to Cervical Screening: A Cross-Sectional Mixed-Methods Study in the UK', British Journal of General Practice 71, no. 709 (August 2021): e614–25, https://doi.org/10.3399/BJGP.2020.0905.)

20-

Your name:	[redacted])	Email address:	[redacted]
Organisation name (if applicable):	NHS Grampian		
Role/job title (or member of the public):	[redacted]		
Do you want your name published alongside your response on the UK NSC website?	☐Yes ☒No		

Document name and section or page number	**Document text or issue your comment relates to**	**Your comment** Please add extra rows as required
Consultation on offering HPV self-sampling to under-screened people in the NHS Cervical Screening Programme: Recommendation	Recommendation to offer HPV self-screening to under-screened people	We are universally supportive of the implementation of HPV self-sampling in some form to the cervical screening programme, and feel that self-sampling could reduce barriers to accessing screening in under-screened individuals. However, we have some concerns that restricting self-sampling to individuals overdue for screening may lead to individuals that would otherwise attend to deliberately become overdue to access self-sampling.
Consultation on offering HPV self-sampling to	Self-sampling kit delivery strategy	We are universally supportive of the implementation of an opportunistic model of kit delivery. While we appreciate the value of an additional

under-screened people in the NHS Cervical Screening Programme: Recommendation		direct mail-out strategy, we have some additional concerns surrounding this. The increased packaging required for a direct mail-out approach likely reduces the environmental sustainability of self-sampling, and - as noted in cost-effectiveness analysis - there is potential for additional direct mail-out to not be cost-effective. Furthermore, in the absence of any clinician interaction, language and literacy may act as barriers to comprehension of instructions and informed consent. However, we feel a solely opportunistic approach would likely miss under-screened individuals with minimal engagement with the health service. Mitigating this potential inequity may outweigh environmental concerns and the possibility of reduced cost-effectiveness – particularly in the context that a direct mail-out approach is currently used in the delivery of QFIT kits in bowel screening.
Consultation on offering HPV self-sampling to under-screened people in the NHS Cervical Screening Programme: HPV tests & link to HPValidate findings	Internal Control – Aptima HPV Assay	Within the consultation document, both discussion of HPV tests and recommendations reference the use of the two tests contained within HPValidate. We have some concerns surrounding the lack of an internal control for cervical sampling adequacy in the Aptima HPV Assay, in contrast to the use of beta-globin as an internal control in the Cobas HPV Test. We feel that a test with an internal control would be preferential for self-sampling in order to exclude samples taken incorrectly.

Consultation on offering HPV self-sampling to under-screened people in the NHS Cervical Screening Programme: 2. YouScreen Trial	Potential for differential uptake between under-screened groups	We have some concerns that the benefit of HPV self-sampling may vary across under-screened groups, and this may further widen health inequalities experienced by under-screened groups that do not derive as much benefit. As noted within YouScreen, response rates to direct mail-out varied significantly between age group and ethnic group. Furthermore, we feel that issues may arise with direct mail-outs sent to households belonging to cultural or religious groups in which HPV infection is stigmatised – particularly in cases when an under-screened individual lives with a partner or wider family. As such, we feel it is important that consideration is given to mitigating any potential issues surrounding this prior to implementation of a self-sampling strategy.

21-

Your name:		Email address:	
Organisation name (if applicable):	Cervical Screening Wales (Public Health Wales)		
Role/job title (or member of the public):			

Do you want your name published alongside your response on the UK NSC website?		☐Yes X No
Document name and section or page number	**Document text or issue your comment relates to**	**Your comment** Please add extra rows as required
	General comments on the proposed recommendation	Cervical Screening Wales welcomes the proposed recommendation in support of the introduction of self-sampling into the cervical screening programme. We note the evidence supporting the use of self-sampling as a viable alternative to clinician-taken samples for the purpose of HPV testing as a primary screening test. We agree with the intent to offer under-screened individuals an alternative to clinician-taken sampling.
	Defining “under-screened individuals” as those who have not taken up the offer of screening within 6 months of their initial invitation.	In Wales, individuals continue to be reminded of the offer of screening for up to 6 months after their initial invitation. At 12 months the GP is sent a final non-responder notification.

		Whilst we recognise the need for some degree of flexibility in determining how programmes may best offer self-sampling, it is important to ensure the population likely to benefit from this is defined clearly. The screening programmes across the UK should strive to have similar approaches so as to avoid a postcode lottery. Consistent application of the definition will help reduce variation in practice and ensure the offer is equitable.
	Waiting times and access for clinician-taken sampling	In Wales, participants are called for screening by Cervical Screening Wales and invited to make an appointment with their GP practice. Most participants are able to access appointments in a timely manner. However, we are concerned that where there are delays in access to appointments, self-sampling may be cited as a preferable offer to waiting for a clinician-taken sample. This would subvert the intent of offering self-sampling only to under-screened individuals.

	Potential for participants to delay screening in order to access self-sampling	With the recommendation to offer self-sampling to those who have not taken up screening within a given period of their initial invitation, there is the potential for individuals to consciously delay taking up their offer so that they can access self-sampling. This could introduce further inequity into the screening programme where individuals with knowledge of the pathways are effectively able to make an active choice.
	Permissive recommendation leading to variation and inequity	Whilst we support the proposal to recommend self-sampling as a permissive modification to the screening pathway for under-screened individuals, we recognise the potential for variation across and within the UK nations that may arise with this approach. For individuals in border regions particularly, this may lead to confusion and undermine confidence in the screening programme. Recommended pathways would be helpful to avoid this concern.

	Communication	We note the importance of communication in ensuring participants understand the offer of self-sampling in full. In particular, that reflex cytology cannot be undertaken on a self-sample therefore further clinician-taken sampling may be indicated. Setting expectations at the outset in order that individuals understand the pathway will be key. It is important that the offer of self-sample is presented in a way that supports (and does not coerce) the individual to make an informed choice whether or not to undertake screening.

22-

Your name:		Email address:	
Organisation name (if applicable):			
Role/job title (or member of the public):	Member of the public		

Do you want your name published alongside your response on the UK NSC website?		☐ Yes X☐No
Document name and section or page number	**Document text or issue your comment relates to**	**Your comment** Please add extra rows as required
		I think HPV self sampling should be made available as the first choice option to everyone in the screening programme. I think the existing invasive test is unacceptable because the harm of the test itself is not proportionate to the risk of the disease, and it's continued use as a first line of testing is an example of medical misogyny and an abuse of women. I have opted out of screening due to poor experiences of the current testing regime and would only ever consider rejoining the programme if self sampling was available as easily and reliably as it is already through private providers. Private providers provide a result for self sampling within 7 days, and break down your result by strains of HPV tested for, whether these are high or lower risk, as well as giving a positive or negative result for each strain. I want this, not a result that just says 'normal' which is uninformative and patronising.

		I left the screening programme because I was given inaccurate information about the delay in results in 2019, during the switchover to primary HPV testing. I was told in my screening appointment that results would take two to three weeks. I found out later, from speaking to the hospital Cytology Department myself, having been given the number by my GP's receptionist to chase my result, that the delay in my area was actually 8-10 weeks at that time. I consider this performing an invasive procedure without informed consent. I was also tested by a bank nurse who triggered a freeze trauma response, requiring trauma counselling that was paid for in part by my GP practice. I requested they pay for the 2 sessions I needed to go back to work, and they paid for 4 sessions from a total of 20, over 18 months. (evidence available on request). I no longer use an NHS GP for any reason as a result of this experience. I delayed my first Covid vaccination and broke the rules on travel in place at the time to avoid going back to the health centre where my GP practice was based and receive treatment at my nearest vaccination centre, due to the distress taking part in screening had caused. I would never have participated in the cervical screening programme at all if I had been given accurate information on the risk of the disease, rather than the bullying and coercive information provided. Participation in this programme has been overwhelmingly more harmful than

		beneficial for me as an individual, although I recognise there is a benefit at population level. I am extremely unlikely to participate in any kind of screening, for any condition, in future because of the impact this programme has had on my trust in healthcare professionals and the accuracy and reliability of information from NHS sources. I think it is wrong to persist with the traditional brush test when a less invasive option is available, and vaccination has now lowered the risk of disease still further. I think the programme should roll out self sampling without any further delay, and improve the information on risk provided to people you want to get tested.

23-

Your name:		Email address:	
Organisation name (if applicable):	NHS Lothian (substantive), University of Edinburgh (hon)		
Role/job title (or member of the public):	Director, Scottish HPV Ref Lab (NHS Lothian) & Lead HPV Research Group (Uni of Ed)		
Do you want your name published alongside your response on the UK NSC website?		X☐Yes	☐No

Document name and section or page number	**Document text or issue your comment relates to**	**Your comment** Please add extra rows as required
General comment	Cost effectiveness of the You Screen trial & Cover note	In the cost effectiveness piece “under-screened” women are (as I understand it) those who are overdue by 12 (or 15?) months with no further distinction. I see that the proposal going forward would be to define an under-screened woman as someone who was 6 months late or who has never attended. At risk of stating the obvious, there is significant difference between the former and the latter in terms of their risk. I see that age will not be considered a factor nor other variables such as deprivation or immunisation status for the offer of self sampling. The burden of disease will reside in vaccine ineligible (outside age range) women from deprived backgrounds who have never been screened. Do the programme think it would be possible to make priority for these most vulnerable groups and tailor messages and strategies to support them. I didn’t see any qualitative information/data in the document pack.
General Comment	Cost effectiveness of the You Screen trial & Cover note	Reading the documents I wasn’t entirely sure how self sampling was going to be offered - apologies if that sounds obstreperous! I think the suggestion is direct mail out will supplement primary care offer – presumably this will be affected by rurality/geography..who is empowered to make that decision – local boards/authorities?

General comment	Cover note and rapid review	I don't think the HPV tests should be confined to those that were evaluated in HPV Validate as this stifles competition and does not allow for the incorporation of new technologies as they evolve – (the pace of development is rapid in this field)
General comment	(there isn't a document that has an algorithm)	We are asked to comment on feasibility but I didn't see an algorithm for the sample and management "pathway" hence this question/comment: Will the HPV result on the self sample be used as the "definitive" screening result **or** will it require confirmation on a clinician taken LBC sample (I understand that confirmation of the HPV result on the LBC sample was required in YouScreen – so assume the cost effectiveness analysis was based on this)? If confirmation is required what will happen to the not inconsiderable number of women who are swab HPV positive and follow up LBC HPV negative.? PPV of an HPV test for CIN2+ on a vaginal swab is ~25 % - this was observed in Sweden in the defaulter population and also a recent research study in Scotland, irrespective of confirmation on an LBC sample. Nationwide registry-based trial of risk-stratified cervical screening - PubMed & High-risk HPV mRNA testing on self-samples offered to those who do not attend for organised cervical screening - real world data from the Dumfries and Galloway region in Scotland - PubMed I understand that logistics/practicalities may be challenging but my recommendation would be to use the result of the swab as the relevant

		screening result; if there are false positives, this is the nature of screening tests and enhanced sensitivity is perhaps particularly relevant for this group who have defaulted. One would also imagine that the communications around an individuals' result would be "cleaner"
Page 6 Rapid review	Page 6 "Persistent genital infection with Human Papillomavirus (HPV), one of the most common sexually transmitted infections, is responsible for an estimated 99.7% cases of cervical cancer"	99.7% is inaccurate; ~8% of cervical cancer have undetectable HPV Deep sequencing detects human papillomavirus (HPV) in cervical cancers negative for HPV by PCR - PubMed and the WHO now formally recognises HPV independent cervical cancer as an entity, albeit a rare one. Expectation management is important with cervical screening messages; HPV testing will detect most but not all cases.
Page 64 Rapid review	Page 64 "The percentage of unsatisfactory samples was very low 0.9 (95%CI; 0.6 to 1.2)"	I would suggest that this is likely driven by under-reporting in the literature (ie authors simply disclose the valid results). HPValidate and other overseas programme data (where self sampling is used routinely) suggest that it may be higher than this and could be device-test specific.

24-

Your name:		Email address:	
Organisation name (if applicable):	Yorkshire Cancer Research		
Role/job title (or member of the public):			

Do you want your name published alongside your response on the UK NSC website?	X☐Yes Please state Yorkshire Cancer Research ☐No

Document name and section or page number	**Document text or issue your comment relates to**	**Your comment** Please add extra rows as required
Consultation on offering HPV self-sampling to under-screened people in the NHS Cervical Screening Programme (Cover note)	Consultation recommendation	Yorkshire Cancer Research funds world-leading cancer research across the prevention, diagnosis and treatment of cancer, with the intention of reducing cancer incidence and years lost to the disease in Yorkshire and beyond. Yorkshire Cancer Research supports the introduction of self-sampling for HPV testing as part of the NHS Cervical Screening Programme (NHSCSP), to improve the uptake of cervical screening among under-screened populations. The HPValidate study showed that a significant majority of women (85%) would prefer the choice between self-sampling and clinician screening, illustrating the potential of greater choice to increase screening rates. For 2023/2024, 71.9% of women who are eligible for cervical screening and registered with their GP in Yorkshire were up to date with their screening. Whilst this is higher than the national average (69.9%), it is below the efficiency standard of 75% and the optimal standard of 80%. The consultation cover note states that the introduction of self-sampling to under-screened population could increase programme participation levels. This is supported by the Rapid Evidence Review, which shows high levels of consistency between self-collected and clinician collected cervical screening samples. Furthermore, the cost-effectiveness analysis of the YouScreen trial shows that self-sampling to never screened and underscreened women is a cost-effective strategy.

		The YouScreen trial estimated that routine roll out of self-sampling both opportunistically in a primary care setting and systematically via direct mailout would increase coverage in the Cervical Screening Programme by 7.4% over a three-year screening round. On this basis, this would increase coverage in Yorkshire to 79.3%, above the efficiency screening standard and close to the optimal standard. Nearly 104,000 additional screens over a three-year period would take place in Yorkshire as a result of the expansion of the introduction of self-sampling, on the basis of the YouScreen methodology.
Consultation on offering HPV self-sampling to under-screened people in the NHS Cervical Screening Programme (Cover note)	3. HPV tests	Yorkshire Cancer Research believes that alternative testing devices such as urine devices should also be validated for use on self-collected samples to maximise access to the NHSCSP. In particular, the Coli-Pee urine testing device should be validated. It is innovative in comparison to other urine collection devices because it is able to collect first void urine (up to the first 20ml of urine) and allows immediate mixing with preservative.1 These are key determinants for maximum efficacy. The cover note for the consultation explains that when the YouScreen Trial was conducted, no HPV tests were validated for use on self-collected samples. To address this, the HPValidate study evaluated the accuracy of self-collected sampling in comparison to clinician collected sampling for HPV testing. This study tested three collection devices and two HPV tests used by laboratories in the UK. The HPValidate study did not validate urine testing devices. However, a growing body of evidence shows that urine self-sampling has a similar accuracy to other self-sampling methods.1-3. Research shows that common barriers to cervical screening include inconvenience and embarrassment.4 The validation of a urine testing device for use with self-collected samples could help to address these barriers. A UK study found that when women were asked their preferred sample, more women preferred a urine sample compared to a vaginal or cervical sample.5

		Research has also shown that urine self-sampling may be more cost effective than other self-sampling methods. A 2023 study used modelling based on the NHSCSP HPV primary screening pathway, which was adapted for self-sampling.6 Costs were calculated for clinician led and self-sampling approaches through sources including published studies, NHS staff costs and manufacturer costs. This showed that the average cost per screen was £40.37 for vaginal self-sampling and £38.57 for urine self-sampling. If uptake in nonattenders increased by 15% and 50% of current screeners converted to self-sampling, the NHSCSP would save £19.2 million for urine self-sampling or £16.5 million for vaginal self-sampling per year. Assumptions of uptake were based on a study which surveyed the screening preferences of 3672 women who were eligible for screening in England.7 The validation of urine testing devices for use on self-collected samples could increase uptake in older age cohorts on the NHS Cervical Screening Programme. The Yorkshire Cancer Research funded Catch-Up Screen trial aims to screen 10,000 women aged between 60-79, who have not attended for primary HPV testing since its roll out by the NHS in 2019. This ongoing study uses the Colli-Pee urine testing device to demonstrate the acceptability of this sampling method and aims to determine whether a catch-up screen is likely to reduce cancer incidence in this cohort. The target population for the Catch-Up Screen overlaps with the upper age of the NHS Cervical Screening Programme. It is possible to measure the response of this population in relation to previous screening history. Typically, coverage decreases for women aged between 60-64 for reasons including previous pain or embarrassment. However, in 60–64-year-olds who did not attend their last invitation to cervical screening, approximately 50% have participated in Catch-Up Screen to date. The study has also reported high levels of acceptance of this testing method among women aged over 60.

HPV Self-Sampling for Cervical Cancer Screening: A Rapid Review	Results	The Rapid Evidence Review is not restricted to reviewing a specific self-sampling method or laboratory HPV assay. However, a significant majority of studies included in the review use swab-based HPV testing devices. Alternative HPV testing devices could be explored in greater detail by the review. The evidence for urine self-sampling has not been systematically included within the Rapid Evidence Review. Other systematic reviews have considered both vaginal and urine sampling methods. For example, a 2024 systematic review included studies regarding the acceptability and accuracy of urine self-sampling devices in comparison to other devices.8 Many of these studies do not feature in the Rapid Evidence Review. Three studies included in the Rapid Evidence Review involve urine testing devices. None of the three studies involving urine testing devices report on whether samples were taken at home or in a healthcare setting. Evidence on the impact of the setting of urine testing should be included in the evidence review, in order to make an effective judgement on the acceptability of this method among under-screened groups.
HPV Self-Sampling for Cervical Cancer Screening: A Rapid Review	Abstract	The abstract of the Rapid Evidence Review highlights that self-sampling caused anxiety in 35% of participants and that 60% of participants reported that self-sampling did not fit with values. However, Table 9 illustrates the imprecision of these estimates, with self-sampling causing anxiety estimated from four studies (95%CI: 3%-91%) and fit with values estimated from just two studies (95%CI: 8%-96%). Quoting these figures without confidence intervals in the abstract could mislead readers as to the level of anxiety and the fit with values which is related to self-sampling. The Rapid Evidence Review should include additional studies regarding these issues, to improve the accuracy of its estimates and provide clarity on the behaviours associated with selfsampling.

		References 1. National Institute for Health and Care Excellence. Colli-Pee for first void urine collection. 2021. Accessed: 12/02/2025. Available from: https://www.nice.org.uk/advice/mib273/resources/collipee-for-first-void-urine-collection-pdf2285965812665797 2. Van Keer S, Peeters E, Vanden Broeck D, De Sutter P, Donders G, Doyen J, et al. Clinical and analytical evaluation of the RealTime High Risk HPV assay in Colli-Pee collected first-void urine using the VALHUDES protocol. Gynecol Oncol. 2021;162(3):575-83. 3. Cadman L, Reuter C, Jitlal M, Kleeman M, Austin J, Hollingworth T, et al. A Randomized Comparison of Different Vaginal Self-sampling Devices and Urine for Human Papillomavirus Testing-Predictors 5.1. Cancer Epidemiol Biomarkers Prev. 2021;30(4):661-8. 4. Bennett KF, Waller J, Chorley AJ, Ferrer RA, Haddrell JB, Marlow LA. Barriers to cervical screening and interest in selfsampling among women who actively decline screening. J Med Screen. 2018;25(4):211-7. 5. Sargent A, Fletcher S, Bray K, Kitchener HC, Crosbie EJ. Cross-sectional study of HPV testing in self-sampled urine and comparison with matched vaginal and cervical samples in women attending colposcopy for the management of abnormal cervical screening. BMJ Open. 2019;9(4):e025388. 6. Huntington S, Puri Sudhir K, Schneider V, Sargent A, Turner K, Crosbie EJ, et al. Two self-sampling strategies for HPV primary cervical cancer screening compared with clinician-collected sampling: an economic evaluation. BMJ Open. 2023;13(6):e068940. 7. Drysdale H, Marlow LA, Lim A, Sasieni P, Waller J. Self-sampling for cervical screening offered at the point of invitation: A cross-sectional study of preferences in England. Journal of Medical Screening. 2022;29(3):194-202. 8. Aimagambetova G, Atageldiyeva K, Marat A, Suleimenova A, Issa T, Raman S, et al. Comparison of diagnostic accuracy and acceptability of self-sampling

		devices for human Papillomavirus detection: A systematic review. Preventive Medicine Reports. 2024;38:102590.

25-
Name: Health Protection Team
Email:
Organisation: Lancashire County Council
Role: Public Health
Condition: Cervical screening

Please see response from the Health Protection Team, Public Health, Lancashire County Council.
The studies report good findings and that participants have reported positive experiences of the self-sampling tests. Almost half of the residents did say they would like a recommendation of whether to use the self-sampling option or clinician screening.
Public health considerations:

- Testing and options should be clearly communicated, with a full range of materials to capture all population groups: language-specific, health literacy (i.e. production of audio formats) and the creation of easy read materials for learning disability populations.
- Appreciate the cost effectiveness elements, but a wider offer to all women would be an excellent and innovative option. From all of the scoping work that has been undertaken previously, we know fear and embarrassment is a key barrier and this option provides a significant opportunity to reduce this.

26-
Name:
Email:
Organisation: Daye
Role:

Condition: Cervical screening

Daye welcomes the opportunity to respond to your consultation on offering HPV self-sampling to under-screened populations. We fully support this initiative as a critical step toward achieving the NHS's 2040 cervical cancer elimination goal.

Our attached response highlights the Daye Diagnostic Tampon (DDT) , a CE-marked, MHRA-registered self-sampling device validated by peer-reviewed studies as a patient-preferred, clinically robust alternative to swabs. Key evidence includes:

- 99.2% valid result rate (vs. 90.8% for clinician swabs), reducing retest burdens
- 30% lower production costs and reduced plastic waste vs. swabs, aligning with NHS Net Zero targets.
- 100% preference rates in low-resource settings (Tanzania trial) and 98% satisfaction among UK users.

We urge the NSC to:

- Adopt device-neutral procurement frameworks to include tampons alongside swabs.
- Integrate sustainability metrics into device selection criteria.

Our ongoing North West London pilot (Spring 2025) and partnerships with ICBs demonstrate readiness to support NHS implementation. We would welcome further dialogue on how the DDT can amplify the success of this initiative.

Thank you for your consideration. Please find our full response attached. (below)

Daye welcomes the UK NSC's consultation on HPV self-sampling for under-screened populations as a pivotal step toward eliminating cervical cancer by 2040. As a leader in innovative cervical screening solutions, we align with the recommendation and advocate for expanding self-sampling options to include the Daye Diagnostic Tampon (DDT). Our CE-marked

MHRA registered DDT offers a clinically validated, sustainable alternative to swabs, with 99.2% valid result rates and no significant accuracy difference from clinician-collected samples (McNemar's p = 0.845). Already deployed to 1500+ UK users with 98% satisfaction, the DDT addresses systemic barriers through: familiarity, cost and sustainability.

We advocate for device choice—including non-insertive options for disabled users—and stand ready to support NHS pilots through our Spring 2025 North West London initiative, currently under ethics review. To address the persistently low cervical screening rates in North West London, we are partnering with GP surgeries to pilot the DDT with NHS patients focused on increased access and patient choice. This evidence-based approach ensures equitable, scalable progress toward the 2040 target. This response outlines evidence supporting the tampon's clinical accuracy, cost-effectiveness, and acceptability, while addressing implementation considerations such as accessibility, sustainability, and equitable choice.

1. Alignment with the Recommendation

Support for self-sampling: Daye strongly endorses offering self-sampling to under-screened groups. Barriers like embarrassment, pain, and inconvenience disproportionately affect marginalised communities, including disabled individuals, ethnic minorities, and LGBTQ+ populations. The DDT addresses these challenges through:

- Familiarity: Tampons are widely used (98.5% of participants in our trials had prior tampon experience), reducing intimidation compared to swabs.
- Comfort: 73–78% of users reported high comfort levels with the DDT.
- Ease of use: Perceived ease increased from 63.5% to 74.5% post-sampling

Call for device choice: While HPValidate focuses on swabs, evidence shows tampons are equally accurate and preferred by users.

Our data from 260 participants demonstrates:

Metric	DDT performance	Clinician swab (CCS)
Sensitivity	82.9%	90.6%

Specificity	91.6%	90.6%
Valid result rate	99.2%	90.8%

Recommendation: The NHS should offer both tampons and swabs to maximise uptake, ensuring equitable access to preferred devices.

2. Evidence Quality and Consistency

Clinical accuracy

The DDT meets NHS standards with:

● 92.5% sensitivity and 96.0% specificity compared to collated reference standards.

● No significant difference in results between DDT and clinician swabs (McNemar's test: p = 0.845).

● The DDT demonstrates superior valid result rates (99.2%) compared to both clinician-collected samples (90.8%) and self-swabs (95.4%).

● These metrics exceed HPValidate's acceptance criteria for self-sampling devices.

● 79.5% sample return rate demonstrates high user compliance.

● Only 1.1% inadequate samples, significantly lower than traditional methods.

Cost-effectiveness

● Tampons cost 30% less to produce than swabs.

● Reduced clinic visits and higher valid rates lower system-wide costs, aligning with YouScreen's cost-effectiveness findings.

Sustainability

● DDT uses biodegradable organic cotton and bio-based applicators, supporting NHS Net Zero targets. A more sustainable approach in comparison to plastic swabs.

Quality assurance

● The Daye Diagnostic Tampon is classified as a Class A in vitro diagnostic device under the In Vitro Diagnostics Regulation (IVDR) (EU) 2017/746. This is an EU regulation that

sets standards for in vitro diagnostic medical devices

● It has a CE certification (this indicates compliance with EU health, safety, and environmental protection standards) and is registered with the MHRA (Medicines and Healthcare products Regulatory Agency). The MHRA is the UK's regulatory body responsible for ensuring the safety and effectiveness of medicines and medical devices. Registration with MHRA is mandatory for placing medical devices on the UK market.

● Daye ensures that its products are manufactured to the highest standards, operating within facilities which are certified with GMP (Good Manufacturing Practice - standards ensuring consistent production and quality control in manufacturing) and ISO13485 (an international standard for quality management systems in medical device manufacturing).

● All test panels associated with the DDT have been validated in accordance with UKAS (United Kingdom Accreditation Service) requirements. Testing is conducted in laboratories that are certified by both CQC (Care Quality Commission) and UKAS in the UK, ensuring compliance with rigorous quality standards.

Feasibility and Implementation

Ongoing pilots

Daye is poised to support rollout through:

● NHS Northwest London pilot: Offering DDT to underserved populations (Spring 2025 launch, currently undergoing ethics)

● Multi-region expansion: Partnerships with ICBs in Birmingham, Liverpool, and Newcastle to replicate NHS pilot (once funding is secured)

Accessibility

For disabled individuals or those unable to insert devices, research has shown that people prefer the use of a tampon over a swab with regards to ease of use. In addition, our research with the Liverpool women's hospital post menopausal women with vaginal atrophy reported less

bleeding when using the tampon in comparison to the swab.
Recommendation: Provide non-insertive alternatives (e.g., urine testing) alongside tampons/swabs.
Training and Education
● Develop multilingual guides and video tutorials tailored to low-literacy populations.
● Partner with community organisations to distribute kits in trusted settings (e.g., pharmacies, faith centers).

4. Global and Equity Considerations
Acceptability in diverse populations
● Our Tanzania trial: 100% of participants preferred tampons over swabs, citing comfort and confidence.
● Our UK STAMP trial focus groups: 90% preferred DDT, with 74% citing ease of use.
Policy integration
● Advocate for DDT inclusion in NHS Cervical Screening Programme guidelines.
● Align with international frameworks (WHO's cervical cancer elimination strategy).
5. Key Questions for UK NSC
1. Device neutrality: Will procurement frameworks allow tampons as an option alongside swabs?
2. Disability inclusion: How will the programme accommodate non-insertive sampling for disabled users?
3. Sustainability criteria: Will carbon reduction metrics influence device selection?

Conclusion
The DDT offers a clinically validated, sustainable, and patient-preferred solution to boost

cervical screening uptake. By embracing device choice and addressing accessibility barriers, the NHS can reduce disparities and accelerate progress toward eliminating cervical cancer.
Page 10 (HPValidate Limitations): "HPValidate focused on swabs/brushes, but our STAMP study demonstrates tampons achieve higher sensitivity (82.9% vs. 57.14% for high-vaginal swabs) and a 99.2% valid result rate – critical for reducing NHS retest burdens. We recommend expanding validated device options to include tampons." ● Page 7 (Cost-Effectiveness): "The YouScreen analysis (Document 3, p. 15) notes cost-effectiveness depends on HPV test costs. Daye's tampon is 30% cheaper to produce than swabs and reduces plastic waste. Including tampons could further optimise cost savings."
Page 8 (GP Opportunistic Strategy): "The GP-based approach aligns with Daye's NW London pilot , which targets under-screened populations via primary care. Our data shows 98% satisfaction with nurse-led aftercare, reducing follow-up costs" ● Page 20 (Mail-Out Limitations): "While mail-out alone is less effective, combining it with GP offers mirrors Daye's hybrid model. Our Tanzania trial achieved 100% preference for tampons in low-literacy settings, suggesting mail-out could succeed with intuitive devices."
Page 64 (Acceptability Gaps): "The review cites 18.5% discomfort with self-sampling. Daye's focus groups show tampons reduce pain (73–78% comfort rates) due to familiarity – critical for populations avoiding speculum exams." ● Page 14 (PCR Superiority): "PCR-based assays (endorsed here) are used in Daye's service. Our STAMP trial confirms PCR on tampons detects 92.5% of CIN2+ cases, outperforming non-PCR methods in HPValidate."

4. Cross-Cutting Recommendations

● Device Neutrality:

"The consultation prioritises swabs/brushes, but Daye's data shows tampons are equally accurate and preferred. We urge explicit inclusion of tampons in procurement frameworks."

● Non-Insertive Options:

"For disabled users, we recommend parallel provision of cervical brushes (validated in HPValidate) alongside tampons and urine testing to ensure inclusivity."

● Sustainability Metrics:

"The NHS Net Zero target isn't addressed in cost analyses . Tampons' biodegradable design aligns with NHS carbon goals and should factor into device selection."

Conclusion

Daye's evidence fills critical gaps in the consultation's clinical, economic, and equity analyses. By emphasising device choice, sustainability, and accessibility, we can strengthen the NSC's final recommendation while positioning the tampon as a frontline solution.

Turner, F., Drury, J., Hapangama, D.K. and Tempest, N. (2023). Menstrual Tampons Are Reliable and Acceptable Tools to Self-Collect Vaginal Microbiome Samples. International Journal of Molecular Sciences, [online] 24(18), p.14121. doi:https://doi.org/10.3390/ijms241814121.

https://www.medrxiv.org/content/10.1101/2024.12.02.24318200v1

Sent an attached paper titled: Diagnostic Accuracy of the Daye Diagnostic Tampon Compared to Clinician-Collected and Self-Collected Vaginal Swabs for Detecting HPV: A Comparative Study

Authors

Valentina Milanova[1], Michelle Gomes[1], Kalina Mihaylova[1], John Luke Twelves[2], Jan Multmeier[3], Hana McMahon[4], Hannah McCulloch[5], Kate Cuschieri[4]

27-
Name:
Email:
Organisation: NHS Ayrshire & Arran
Role:
Condition: Cervical screening

Feedback from NHS Ayrshire & Arran Cervical Screening Steering Group

Firstly , In favour of this but There would have to be big changes to SCCRS to allow it to work in the way the study describes

- The original study was published in the Lancet Opportunistic offering of self-sampling to non-attenders within the English cervical screening programme: a pragmatic, multicentre, implementation feasibility trial with randomly allocated cluster intervention start dates (YouScreen)
- Defaulters were defined as overdue a test by at least 6 months

"The opportunistic approach elicited almost five-fold higher uptake than direct mailout, highlighting the important role and influence of primary care on screening and the efficacy of an in-person offer.
I would also suggest that opportunistic self-sampling should be offered in sexual health clinics and gynaecology outpatients, where people attend but may not be getting a vaginal examination"

- The practices that participated were recruited by advert- more practices applied than were expected , but it could mean that some practices would not join in 'business as usual' giving out kits, reducing effectiveness
- There is no mention of any financial incentive to practices to take part. There is a potential risk, given that practices are very overstretched, that practices stop doing examinations and delay tests by 6 months and give out kits to save on their workload

- I note a comment

"GP practices were closed to recruitment in (approximately) reverse order of opening (September to November 2021), with preference given to those with particularly poor recruitment to conserve kit supplies and avoid kit wastage."

- This suggests some practices did not get good recruitment so generalising the programme in a way that relies on GPs offering opportunistic tests may not get such a good response rate, and while opportunistic postal tests would be an option, this was less cost effective
- The paper states that in England

invitation letters are sent every three years to women aged 25–49 and every five years to women aged 50–64. A single reminder letter is sent approximately three months after invitation.

In Scotland 3 reminders are sent. I am not aware of the response rate after each round of reminders- would this change the effectiveness of this self sampling model, and would self sampling be available after first default etc?

- In the study, when defaulters who had not consulted their GP were identified:

A pre-notification letter was sent to women's homes, followed by a kit about a week later. The 15-month timepoint provided a screening offer that was distinct from both the last reminder and the next routine invitation. Prior consent was not sought as the offer was made as a clinical service. However, a study-specific mechanism enabled women to opt-out of receiving mailed kits and data sharing.

- Would SCCRS be able to be reconfigured to manage this? How much would it cost and who funds it? Does that affect the cost effectiveness of the proposal?
- Presumably the swabs could not be processed in the usual machine , what are the implications for the labs and SCCRS in terms of integrating this in terms of infrastructure/ software? It takes a long time to develop and test software for SCCRS

- Are the programme going to do something specific in their awareness-raising to highlight that practitioner screening is still the gold standard? i.e. better sampling and therefore better detection of HPV, ability to visualise cervix with direct referral to specialist rather than waiting for a HPV result? I worry that with the way self-testing is being sold at present, absolutely no one will think it worthwhile to attend for practitioner screening if you can just default and wait for a self-test.
- Six month defaulting – for young people in particular I'm not sure that six months really counts as a 'proper' default. I don't think a six month defaulter cut-off is going to necessarily target the cohort of women who struggle with intimate examination, and will pick up a lot of women who just have busy lives and would attend for practitioner screening if we offered them better options.

28-

Your name:		Email address:	
Organisation name (if applicable):	Royal National Institute of Blind People (RNIB)		
Role/job title (or member of the public):			
Do you want your name published alongside your response on the UK NSC website?		Yes, use organisation name 'RNIB'	

Document name and section or page number	**Document text or issue your comment relates to**	**Your comment** Please add extra rows as required
		This is an inaccessible form, please see attachment 'RNIB Cervical At Home Screening Consultation Response Feb 2025'

RNIB Cervical at home screening consultation response
25 February 2025

RNIB welcomes the opportunity to respond to this consultation on the potential of introducing HPV self-sampling in the UK. We largely support this idea on the basis that accessibility for blind and partially sighted people is considered throughout both in-person cervical screening and at-home cervical screening processes. We have therefore outlined potential barriers and considerations for both screening services. This is particularly important because any patient who receives a positive test result from an at-home cervical screening test would have to attend an in-person follow-up.

We have outlined barriers and considerations for the entire screening process, from receiving an invitation letter to receiving test results and any potential follow up. This is due to these barriers making completing cervical screening difficult for some, and impossible for others, if not addressed. Therefore, it is crucial that all communications as well as the medical tests are created accessibly which we have detailed below.

RNIB's work on cervical screening across the UK
RNIB is pleased to see that this is a UK wide consultation which we hope will mean that there will be a consistent roll out of at-home cervical screening across the nations if adopted. Otherwise it can be challenging to mitigate various barriers to inclusion imposed for blind and partially sighted people when different medical solutions are used in different countries.

RNIB estimates that there are approximately 215,000 women with sight loss who are eligible for screening in the UK (aged 25 - 64)[1], which means it is imperative that we find an accessible solution to cervical screening that all blind and partially sighted people can benefit from in the same ways as our sighted counterparts.

Right to receive accessible health information and medical tests in the UK

Everyone in the UK has the right to receive information in a format that they can access and understand. The Equality Act 2010 applies if you live in England, Wales and Scotland. This requires service providers, which include health and social care services, to make reasonable adjustments. This includes the provision of information in alternative formats.

In England, NHS and social care providers are also covered by the Accessible Information Standard which requires them to record a person's required format for communications and ensure they get the information in the format they need.

In Wales the "All Wales Standards for Accessible Communication and Information for People with Sensory Loss" were introduced in 2013. The All Wales Standards require all written communication, such as appointment letters, to be provided to people with sensory loss in accessible formats.

The Patient Rights (Scotland) Act 2011 aims to improve patients' experiences of using health services and to support people to become more involved in their health and health care.
The Act includes the statement "Communication about a patient's health and wellbeing is clear accessible and understood."

Everyone in Northern Ireland, has the right to receive information in a person's required format, that they can access and understand. The duty to make reasonable adjustments is contained in the Disability Discrimination Act 1995. In Northern Ireland, Health and Social Care organisations are also bound by the "Quality Standards for Health and Social Care" (Department of Health, Social Services and Public Safety 2006). This requires them to consider the diverse needs of the public, services users, carers and staff alike, in any information and communication.

Additionally, there is a legal requirement under the Human Rights Act 1998; Section 75 of the Northern Ireland Act 1998; Race Relations Order 1997; the Disability Discrimination Order 2006 and the Health and Social Services (Reform) Northern Ireland Act 2009, to ensure that health and social care, make their services, including information, accessible.

A blind or partially sighted person receiving a medical test that they are unable to complete independently could put them at a serious disadvantage which likely contravenes the Equality Act (2010) and the Disability Discrimination Act (1995).

Accessible health information is vital to ensuring that patients with specific communications needs can:

- Access services in a timely manner;
- Maintain their right to privacy in their healthcare concerns;
- Consent to their care; and
- Engage with vital screening services, and therefore obtain early diagnosis and treatment.

RNIB has been working to improve the accessibility of cervical screening in each of the UK countries which we have briefly outlined below.

England

RNIB has heard from many people in England eligible for cervical screening that they do not receive their invitation letters in their required format. We have assisted in a legal case whereby a visually impaired woman was routinely not receiving her first, second (18 weeks later) or third (32 weeks later) invitation letter in her required reading format. We have been told this was due to NHS England cervical screening systems being incompatible with recording or creating alternative formats. Since then, we have been told that their new IT system will become compatible in the coming months. We will continue to campaign to ensure that this happens as not receiving accessible invitation or outcome letters puts blind and partially sighted people eligible for screening at risk of becoming non-responders.

Northern Ireland

Currently, there is no Accessible Health Information (AHI) standard in Northern Ireland. Whilst we are aware that the implementation of the AHI standard in Great Britain has been uneven, the lack of an AHI in Northern Ireland distinctly disadvantages those living with a sensory impairment.

At RNIB, we know that our service users often struggle to attend routine appointments. The reasons for did not attends (DNAs) are complex, but key factors for blind and partially sighted people include inaccessible information relating to their appointment, transportation, and the inability of blind and partially sighted individuals and/or their carers to take time off work for appointments [2]. In Northern Ireland, social deprivation has been suggested as a key driver of DNAs, as lower-income patients and carers cannot afford to take time off work [3]. This is of particular concern for those living with sight loss, as only 27 per cent of blind and working age blind and partially sighted adults in the UK are currently in employment [4], and because carers in Northern Ireland are not protected against indirect discrimination, owing to the inapplicability of the Equality Act (2010).

The UK's exit from the European Union must also be considered when developing a UK-wide self-sampling strategy. Northern Ireland is part of the United Kingdom, but not Great Britain - Northern Ireland is often forgotten when devising UK-wide strategies post-exit. In terms of health, post-exit, Northern Ireland has faced the possibility of drug shortages and increased costs owing to manufacturers' inability to comply with 'UK only' labelling guidelines [5]. In Northern Ireland, key products for blind and partially sighted people (e.g., Braille readers) are currently unable to be sold – despite being able to be sold in other parts of the UK – owing to the UK's exit from the European Union. For this reason, we urge supply chain issues to be considered at every stage of the development, launch and review of any self-sampling cervical screening.

We further recommend that any self-sampling kits should be uniform across the UK. After the temporary loss of cervical screening accreditation in the Belfast Trust, along with a cervical screening recall in Northern Ireland's Southern Trust, many cervical screening samples from Northern Ireland are now being sent to England to address the backlog. As this practice is likely to continue for some time, we would urge uniformity in the development and distribution of self-sampling kits across the UK, as this will allow samples from Northern Ireland to be screened elsewhere when significant backlogs occur.

Scotland

In September 2024 RNIB Scotland carried out interviews to draw out patient experiences. Our response to this consultation draws on interviews about cervical screening with women with sight loss.

Accessible information and inclusive communication are of the utmost importance to screening uptake for blind and partially sighted people.

RNIB Scotland's 2020 report "Communication Failure?" found that "whilst good policies may exist on paper – too often people with sight loss receive information in formats they can't read – even when healthcare providers know they have sight loss."
(See RNIB Scotland, "Communication Failure?" at
Reports and publications from RNIB Scotland | RNIB)

The information needs of blind and partially sighted people cannot continue to be treated as an afterthought, and systems must be in place to make alternative formats readily available on request, whether that's large print, braille, or audio.

As one person explained to us:
"There are major problems with the [screening] letters, they are inaccessible. I have to wait for somebody to visit me to read my letters."

In 2022-23, RNIB Scotland was directly involved in the development of the Equity in Screening Standards (Scottish Equity in Screening Strategy 2023-2026), supporting the call for equity in access for all eligible people, across the full screening pathway. This included the need for accessible screening appointment letters.

We have heard directly from people with sight loss that their experiences of cervical screening have been unpleasant. This is due to the lack of communication before the sample taking, leading to individuals feeling disempowered and vulnerable:

"Tests were done in practice by my GP. These were fine with no issues. Service then moved to the nurse in the practice who was rude and rough. She told me not to be stupid, I was behaving like a child. The nurse did not explain to me what she was doing. It was unpleasant and I didn't return to have another screening."

“I only went once, and it went disastrously wrong. It was very painful. I didn’t know what was going to happen, or when it was going to happen. I have not and will not go back. The nurse took no time to explain what she was going to do. She did not tell me what the procedure entailed. Having to position myself on the table with no sight was incredibly difficult, not knowing what to do caused me difficulties.”

This approach needs drastic change. To prevent blind and partially sighted people from feeling undignified and disrespected, there must be staff awareness and training about the right approach when supporting someone with a visual impairment. This would also ensure that people with sight loss do not avoid future health screening appointments.

Wales (Cymru)

It’s been 14 years since the Equality Act 2010 put a duty on public bodies to proactively ensure that people’s access and communication needs are met.

It has also been a decade since the All Wales Standards for Accessible Communication and Information for People with Sensory Loss (All Wales Standards) were introduced by the Welsh Government. The All Wales Standards set out the level of service delivery that people with sensory loss should expect when they receive healthcare. This includes receiving written information in their preferred accessible format.

However, our research has found that personal and confidential information is consistently provided to blind and partially sighted people in a standardised, written format that they cannot read. Blind and partially sighted people describe how limitations with the Cervical Screening Wales IT systems mean that there’s no possibility of them providing appointment or test result letters in anything other than size 10 printed letters. The only alternative on offer is to receive a phone call with a screening technician to relay your test results. Whilst this may seem like a viable alternative, we have concerns around the capacity of technicians to be able to make calls on top of their day-to-day work and how the technicians would be supported if they have to give results that would worry or distress patients. In addition, the nature of cervical screening is very personal, and not everyone will want to discuss it with a stranger. Everyone

should be able to access their appointment information and test results in their required accessible format. Having accessible formats that blind and partially sighted people can read independently and in private is the only way to establish equity.

The reasons for Did Not Attends (DNAs) are complex, but inaccessible information relating to appointment and results is certainly a factor. In fact, RNIB Cymru research found that one in three (32 per cent) blind and partially sighted people have missed a healthcare appointment or had their healthcare affected because they did not receive information in their required format.[6]

Issues facing blind and partially sighted people when accessing cervical screening

Accessible communication and information

Blind and partially sighted people have a legal right to receive accessible information about their health and care, including alternative formats like large print, email, braille and audio. Accessible health information enables blind and partially sighted people to manage their own health with the same level of independence and privacy as everyone else. They face serious risks to health and wellbeing due to a lack of accessible health and care information. It affects patients' safety, independence, privacy and dignity. Missed medical appointments, delayed test results, misunderstood treatment instructions, unread medication labels and letters from doctors are all consequences of inaccessible health information.

RNIB has heard from many blind and partially sighted people accessing cervical screening that they do not receive their invitation letter, supporting information and/or test results in their required reading format. More often than not they receive this in standard print letters through the post, which they are unable to read. This means that they might be forced to rely on sighted assistance to read their letter. The nature of these letters could be sensitive and the imposed dependency for sighted assistance can put blind and partially sighted people in a humiliating and undignified position and violate their right to privacy. Alternatively the inaccessible invitation letters could go unread meaning that blind and partially sighted people are missing out on their screening without being aware, potentially leading to worse health outcomes and increase the number of under-screened people. Furthermore, receiving inaccessible test results could lead to having to wait for sighted assistance to find out whether you have tested positive or negative. This can be an anxiety inducing and disempowering experience particularly when patients would like to digest their own medical information first, before sharing with others.

Inaccessible transport and environment

A key barrier to in-person cervical screening for blind and partially sighted people is making journeys safely, affordably and confidently, to and from GPs. The majority of people with sight loss are not legally permitted to drive, which denies them the ability to travel directly from home to the GPs, which can be quicker, more reliable, and discrete. Some blind and partially sighted people use taxis to and from GPs, but the cost can be unaffordable. Blind and partially sighted people are more reliant on public transport to attend medical appointments. This can be problematic when the network and frequency of public transport is limited, which is often the case in rural areas. Often individuals need to use a combination of walking and multiple modes of public transport to get to and from the GP which can be tiring cognitively as well as physically, as can the experience itself.

Lack of public transport availability restricts where people with sight loss can travel to, due to a myriad of reasons including inadequate provision, low frequency, high cost, strikes or bad weather. And since all public transport journeys involve an element of walking to and from bus stops or train stations, inaccessible walking routes can also reduce or prevent blind and partially sighted people's ability to use public transport.

Some blind and partially sighted people choose to walk to GPs. This is dependent on the pedestrian routes being familiar to the individual, safe with adequate accessible crossings and free from pavement obstructions.

Often GP surgeries are inaccessible to blind and partially sighted people due to poor signage and wayfinding tools, lack of contrast in fittings and surfaces, inadequate lighting, distracting music and other noise, obstacles in walkways and/or unintuitive layouts. This, combined with other patients, can create a busy, hectic environment that is unhelpful, disorienting and frustrating for blind and partially sighted people attempting to locate seating or treatment rooms. In addition, these inaccessible layouts can cause physical harm with undetectable obstacles putting blind and partially sighted people at risk of collisions.

Staff awareness of sight loss and reasonable adjustments

Some blind and partially sighted patients might choose to ask for staff assistance to navigate the GP environment, which means they need to locate the reception desk to request assistance. Unfortunately, these are not always in easily locatable places. If GP staff had sight loss awareness training, they may proactively identify themselves and offer support so that blind and partially sighted people do not need to find the reception desk. However, this often does not happen.

Blind and partially sighted people can have poor patient experiences, when GP staff lack understanding of how to adequately support them when attending a medical appointment. This could be due to lack of sight loss awareness training. This can limit staff's ability to provide good verbal directions, point out useful landmarks, and provide safe sight guiding. Even when these interactions take place, blind and partially sighted people can feel unsupported and uncomfortable, and may be treated like a burden or a novelty. These interactions can be tiring, frustrating, and disabling, meaning that blind and partially sighted people could decide not to participate in cervical screening, even if this puts their health at risk.

Blind and partially sighted people who have accessed cervical screening have described situations where their sight loss was not taken into account before, during and after the procedure. One example of this is a lack of explanation of what the procedure will entail or what medical devices will be used. This puts blind and partially sighted people at a disadvantage, in a vulnerable position, and could increase feelings of anxiety and fear.

In addition, often health professionals do not identify themselves or who else is in the room with the patient, which can cause anxiety when the patient cannot assess the privacy of the appointment for themselves, especially when they will need to remove some of their clothes.

Accessibility of at-home cervical screening

As outlined above, it is critical to ensure that blind and partially sighted people proactively and consistently receive information and communications regarding their cervical screening in formats they are able to read, understand and refer back to. This also must be the case for at-home cervical screening. Therefore, all invitation to at-home cervical screening, information about the at-home test, instructions to complete the test and return instructions as well as test results and outcome letters need to be made available in

alternative formats. In addition, the patient's communication needs and other reasonable adjustments should be recorded on the various NHS Screening IT systems, to ensure that blind and partially sighted people receive their required formats proactively, routinely and in a reasonable time frame. In England the introduction of the NHSE Reasonable Adjustment Digital Flag Project could be a tool that screening services use to do this. It would also allow them to fulfil their obligations under the Equality Act (2010).

It is also imperative to ensure that the at-home cervical screening test kit is accessible and usable to blind and partially sighted people.

The NHS must ensure that accessibility is an integral element of any new medical test. All medical products, processes and information need to be designed accessibly from inception. These designs need to be created in consultation with blind and partially sighted people, the third sector and accessibility experts. When products, processes and information are not designed accessibly or accessibility is retro fitted this creates barriers to blind and partially sighted people's access to screening and likely contravenes the Equality Act (2010).

The following are a selection of excerpts taken from RNIB guidelines designed to provide a basic guide to assess products for an initial level of accessibility. It does NOT replace an expert assessment and user testing, but following these guidelines does ensure there is at least a minimum level of accessibility, which need to be included in any product design for an at-home cervical screening test. For more comprehensive support or to receive the guidelines in their entirety, please contact: Khadija.raza@rnib.org.uk

1: Instructions

- The user should be able to access the product easily so there needs to be clear instructions.
- The instructions must be available in suitable alternative formats (braille, audio, electronic, large print).
- The information contained in diagrams must be provided to users who cannot see them. This could be achieved by providing a textual description of the diagram, or the diagram could be explained within the text. There is no need to remove diagrams, only ensure that the information is available to everyone.
- Instructions should be clear and easy to understand by someone unfamiliar with the product or type of product.

- Instructions will need to be in a clear sans serif font, a minimum size of equivalent to 14-point Arial and in a good colour contrast with a minimum ratio of 4.5:1.

2: Packaging

- The user should be able to access the product easily and remove it from its packaging.
- A user with limited dexterity can open the packaging without difficulties.
- All on-pack information should be made accessible to the user by ensuring that it is written in a clear sans serif font size 14 or above, on a plain, high contrast, matt background. There should also be an accessible QR code for those who want to access on-pack information digitally using their assistive technology.

3: Handling

- A product must be easy to orientate and use.
- A visually impaired and/or older person can easily locate and identify the front, back, top, and bottom of the product by touch and sight.
- A person with limited dexterity or strength, such as an older person with arthritis, must be able to lift, open, turn, grip or rotate the product effectively in order to use it as intended.
- All functions of the product can be carried out easily without regular reference to instructions. The product is intuitive and/or easy to learn for someone who is not technically confident.
- The controls are simple to understand. When using multi-function/mode buttons it needs to be clear to the user what is happening when. Good feedback is essential as well as the ability to undo something with ease in case of a mistake.

4: Visual information (on product and via electronic displays).

- A person with some useful residual vision will use the visual cues on the product so there are several areas which need to be considered to make the visuals as good as possible for as many people as possible.
- The controls and buttons need to be clearly visible with good colour contrast, so the user knows what button to press and where it is. This applies to both tactile buttons and touch screen.

- The button itself should contrast with the background of the product and the text on the button also needs to contrast with the button background.

5: Tactile information

- Users who do not have useful residual vision will need to be able to differentiate between the buttons on the product.
- Buttons and controls are easy to distinguish by touch
- If the buttons have different shapes and are different types of buttons their identification is easier. Different shape and size buttons can be used to differentiate between key functions.
- Buttons can be grouped according to function to make them easier to learn.
- The size of the buttons needs to be sufficient for people with dexterity problems to be able to push or turn. Consider that some people may have reduced sensitivity in the fingertips (due to diabetes and so on).
- Additionally, any dials must not be too stiff to turn but on the other hand they cannot be too easy so that it is possible to turn the dial by mistake.
- There is tactile feedback that makes it clear when a button has been pressed or when a dial has been turned.

6: Auditory information

- When a product is switched on there should be immediate audio response to indicate it is receiving power.
- If the product is switched off, or to standby, using a button on the product then the user should be informed of this before the unit powers down.
- Audible tones emitted by the product easily distinguishable from each other.
- Audio tones should be intuitive (e.g. don’t use a discordant note to indicate a successful completion of an option).
- The use of more than four or five different audio tones for different functions will make it difficult to remember what each audio tone means.
- If audio tones are used to provide feedback when increasing or decreasing a feature, such as power or time changes, then there could be a definite trend in the pitch of the tones used that makes the direction of the change clear.
- Audio tones should be used to alert the user of a failure or error.

- Any audio implemented needs to be intuitive and it should be immediately obvious that an error has happened or that there is a fault.

Best Practice of Improving Medical Testing Accessibility

RNIB has been working alongside NHS England Bowel Screening to improve the accessibility of the FIT kit. This was due to the frequent complaints we received on the inaccessibility of bowel screening information, test kits and results, leading to many blind and partially sighted people no longer participating in bowel screening. NHSE Bowel Screening created the FIT aid to assist blind and partially sighted people and those with manual dexterity problems to be able to complete the bowel screening FIT tests with more independence and dignity. The FIT aid has recently completed its pilot stage and is now available on request. We will continue to work with NHSE Bowel screening to ensure that blind and partially sighted people are proactively sent the FIT aid and any surrounding information and communications in their required format.

References

[1] Data from RNIB sight loss data tool.

UK sight loss, age band and sex, by severity

	Mild sight loss	Moderate sight loss	Severe sight loss	Total
Women aged 25-64	146,000	52,000	17,000	215,000
Women aged 50-70	178,000	71,000	28,000	277,000
Men and women aged 50-74	450,000	188,000	77,000	715,000

Definitions:

- Severe sight loss is defined as best-corrected visual acuity of worse than 6/60 in the better-seeing eye.
- Moderate sight loss is defined as best-corrected visual acuity of worse than 6/18 but better than or equal to 6/60 in the better-seeing eye.
- Mild sight loss is defined as best-corrected visual acuity of worse than 6/12 but better than or equal to 6/18 in the better-seeing eye.

Note: The World Health Organisation define partial sight as visual acuity of worse than 6/12 - Blindness and vision impairment (who.int). This is also the standard of vision required for driving: "You must also meet the minimum eyesight standard for driving by having a visual acuity of at least decimal 0.5 (6/12) measured on the Snellen scale (with glasses or contact lenses, if necessary) using both eyes together or, if you have sight in one eye only, in that eye." Taken from Driving eyesight rules - GOV.UK (www.gov.uk).

Further Sources:
Prevalence rates from: The economic impact of sight loss and blindness | RNIB | RNIB.

Population estimates from 2018-based population projections: Subnational population projections for England: 2018-based - Office for National Statistics for example, and equivalent publications in the devolved nations statistical agencies.

[2] NHS England (2023), NHS: Reducing did not attends DNAs in outpatient services

[3] BBC NI, 22 November 2024. BBC News: Poorer patients missing surgery as they 'can't afford time off work'

[4] Slade (2019) Labour Force Survey 2018: comparison of people with sight loss to the rest of the population. RNIB.

[5] Campbell, John (2024). BBC NI, 21 October. BBC News: NI could face medicine shortages, warns pharmaceutical body

[6] RNIB Make It Make Sense Report Wales

29-
Name: Rebecca Curtayne
Email:
Organisation: Healthwatch England
Role: External Affairs Manager
Condition: Cervical screening

Please find Healthwatch England's response to the consultation on HPV self-sampling, which closes on 26 February. I have attached it in a separate document but have also pasted below in the body of the email if that is an easier format for you.
I am happy to be named on your website.

I am submitting a response to your consultation on HPV self-screening, on behalf of Healthwatch England, the statutory patient and public voice body for people who use NHS and adult social care services in England. We undertake national research and also collate evidence from the network of 153 local Healthwatch, which are based in every part of England.
We are writing to support your recommendation that HPV self-sampling should be introduced for underserved groups as part of the national programme. However, we are also urging you to make it an option for all women who request one, in the interests of equity and as a way to maximise uptake.
Our stance is driven by a report we produced in 2024, *Cervical screening, my way*. This presents findings of polling we commissioned of 2,400 women, all of whom were hesitant about attending their next cervical screening appointment. We also commissioned local Healthwatch to carry out 30 semi-structured interviews with 30 younger, disabled, or minority ethnic women, to amplify voices that are not always heard and who generally face service barriers.
We shared and discussed our findings with NHS England's national director for vaccinations and screening. His team asked us to present the findings at an NHSE webinar on how to meet NHSE's new 2040 elimination goal. Our chief executive was also interviewed

on Radio 4's Woman's Hour programme, alongside a King's College researcher from the YouScreen trial, about women's views on self-sampling and our report has been referenced in a Royal College of Nursing clinical guideline on cervical screening of physically disabled and autistic women.

About our polling

Given that official statistics already tell us how many women don't attend screening, we commissioned Savanta to run a poll that would capture the views only of women who said they would be unsure or unlikely to take up their next (or first ever) cervical screening invitation.

Savanta reached 2,444 women aged between 24 and 65 living in England between 19th March 2024 - 10th April 2024. Data were weighted by gender, age, region and Social Economic Grade. The poll included a 400 boost for minority ethnic groups to capture a statistically significant sample to compare their experiences with White women.

Key findings from the polling:

- **72% of women we polled said they would use a self-screening kit if it was available for free on the NHS**.
- Women aged 30-39 were likely (76%) to want this option than women in the 60-64 age group (68%).

We asked poll participants whether they agreed with a series of statements about the potential pros and cons of self-sampling.

Benefits of self-sampling, selected by poll respondents:

- Privacy (53%)
- Avoiding discomfort (52%)
- Easier to find time (47%)
- No need to book (43%)
- (Avoiding) Past negative experience of screening (27%).

In our in-depth interviews, women described these benefits:

- Convenience
- Able to do it at home in your own time
- Don't need to book an appointment
- Don't need to get undressed in front of a stranger
- Don't need to travel, which can be difficult for people in chronic pain

Interviewees said being given a choice of screening by a health professional, or self-sampling was important.

"I'd love it! I wouldn't have to go anywhere, I can do in my own time, I don't have anybody looking at my body. Like I'm not the most confident about my body. As long as I had like instructions and firstly the video description of what I have to do an when. I think there should be an option to choose whether you would you prefer to go to your GP or would you prefer to do it at home."

- Young woman interviewed by Healthwatch Blackburn and Darwen

Disadvantages of self-sampling selected by polling respondents:

- Concern about accuracy (41%)
- Cannot ask anyone if you're doing it correctly (31%)
- Concern about follow-up testing if the result was abnormal (17%)
- May not work (10%)

Interviewees with physical and learning disabilities were more likely to say that self-sampling wouldn't be for them because:

- It wouldn't be practical
- It might be painful
- They would need someone else to do it for them
- Or they would prefer a healthcare professional carrying it out.

Other interviewees raised a variety of concerns, including worries they wouldn't do the screening correctly, not wanting to ask a partner for help, lack of privacy or hygiene at home, and having to repeat the process if the results were inconclusive.

Why HPV self-sampling should be an available option to all women

Cervical screening by its nature is a procedure that puts women in a vulnerable position and can cause pain, embarrassment, anxiety for cultural reasons, or at worst, make women relive past sexually, violent or abusive traumatic experiences.

We believe that the NHS national screening programme should respond by empowering all women with a choice of attending screening by a professional or a self-sampling route. Many women will welcome the latter as being less invasive and as a method that literally puts the control over the screening in their own hands.

This option would avoid the risk of women who may become aware of the screening programme's criteria for being selected for self-sampling, delaying responding to screening invitations in the first place because they know they'll eventually be offered a self-screen

option. This could lengthen the recommended durations between screening and risk delays in detecting HPV and further investigations for cervical cancer.

Polling findings on key reasons for screening hesitancy

The top reasons selected by our poll respondents for their hesitancy, were:

- Worries about it causing physical discomfort: 38%
- Embarrassment at having to undress in front of a healthcare professional: 26%
- Not currently sexually active so don't feel the need to go: 21%
- A past traumatic experience unrelated to screening has put them off: 15%.

The percentages were higher for women who'd never attended screening before than those that had (on physical discomfort for example, 50% versus 32%).

Women of Asian heritage were more likely (30%) than White (26%) or Black (20%) women to say one reason for their hesitancy was embarrassment at having to undress in front a healthcare professional.

Difficulties booking appointments at GP surgeries, not enough time, and lack of convenient appointments were also highlighted.

The impact of past trauma

New research we will be publishing in March 2025, shows that 67% of women have experienced trauma in their lives, according to a nationally representative poll of 3,571 women and men.

Nearly half (49%) of these women had avoided health services as a result at some point, and 37% of these women had not disclosed past trauma to a health care professional.

We believe that offering self-sampling as an option to all women, protects women who have experienced past trauma, who may not wish to disclose reasons for not attending speculum-based screening.

Finally, we acknowledge that self-sampling is not the sole solution to improving uptake. Our research found that the most important factor in relation to the current screening programme, was having sensitive healthcare staff who talk through any concerns beforehand and who proactively explain adjustments that can be made during the appointment. Women also wanted same-gender staff, and wider choice of appointment times, to fit around caring responsibilities.

Our submission ends with a story from one of the young women we interviewed. Her involvement in our research prompted her to give screening another go.

‘I delayed booking my appointment by a year’

[redacted], has only recently attended her scheduled cervical screening after delaying it by a year:

“Although I got a reminder letter, I delayed booking my appointment by a year, as I found the last one I went to, around four years ago, really stressful.”

She thinks healthcare professionals who perform the screening need more training to understand women's discomfort and go at their pace during the appointment: "What we need is more awareness and more understanding of women's hesitations and their medical history which can impact how they react to cervical screening.

“I think for some women a self-test kit would be the only way they would consider having their smear test. For myself, I would still choose to go to a health professional who is trained to do this.

"I recently went for my overdue smear and after explaining my vaginismus to the nurse, she was great, really supportive and let me take control of the appointment. Crucially she didn't rush me and wasn't dismissive of my pain.”

Your name:	Dr Matejka Rebolj, Senior Epidemiologist Dr Laura Marlow, Senior Researcher Ms Hannah Drysdale, PhD student Prof Jo Waller, Professor of Cancer Behavioural Science Dr Adam Brentnall, Senior Lecturer in Biostatistics	Email address:	[redacted]
Organisation name (if applicable):	Centre for Cancer Screening, Prevention, and Early Detection Wolfson Institute of Population Health Queen Mary University of London		

Role/job title (or member of the public):	(please see above)	
Do you want your name published alongside your response on the UK NSC website?		Yes

Document name and section or page number	**Document text or issue your comment relates to**	**Your comment** Please add extra rows as required
Cover letter	"Self-sampling for HPV testing can be offered to under-screened people eligible for the Cervical Screening Programme in the 4 UK countries, where service commissioners think self-sampling would be a helpful addition to the programme. If implemented, the option would be provided alongside traditional clinician-collected sampling." "An under-screened person is an individual who is overdue for their routine cervical screening appointment by at least 6 months or has never attended." "The self-sampling kit delivery strategy should be based on the approach taken in the YouScreen trial – either as an opportunistic offer, direct mail-out, or both direct mail-out and an	We welcome a targeted implementation of HPV self-collection for under-screened people to improve their engagement with the NHS cervical screening programme in the four UK countries. Delaying this implementation increases the risk of preventable cervical cancer cases and deaths. The latest data from early adopters of HPV self-collection in routine cervical screening highlight the crucial role of how this is implemented. The operational experience that has accumulated within the NHS from studies such as YouScreen, HPValidate, or PaVDaG, will undoubtedly be helpful in this respect. Nevertheless, translation into improved health outcomes is not straightforward, even when a routine implementation is preceded by strong data from local trials.1 The consultation documentation provides very little further detail on implementational aspects. Improving health outcomes will predominantly depend on these factors: 1. The extent to which HPV self-collection will increase the number of people screened, particularly among those who are most at risk of developing cervical cancer.2,3 To achieve a high uptake, we would like to draw attention to the need to think about communications and other interventions that accompany the offer of HPV self-collection for the under-screened. 4,5

	opportunistic offer, depending on the feasibility of implementing each strategy. The opportunistic strategy achieved a higher response rate than direct mail-out and is encouraged." "Appropriate information should be developed to facilitate personal informed choice to participate in the screening programme."	2. Ensuring the introduction of self-sampling does not widen existing socioeconomic inequalities in cervical screening uptake. Unpublished research from our team (manuscript in preparation) suggests that some marginalised groups (e.g. women with disabilities and physiological issues) may struggle to self-collect. 3. Whether those who are HPV-positive complete the recommended clinical management.6 Without it, efforts to increase uptake will not be followed by a reduced cancer burden. Understanding the communications and other needs of the affected individuals will be pivotal. 4. There is a pressing need to understand the attitudes of health care providers towards self-sampling and their knowledge of the test as women will likely need their support. Evidence from the Australian screening programme suggests that knowledge and preferences for screening tests may vary across health care providers.7 5. The extent to which the availability of HPV self-collection for those who are overdue will affect screening participation among those who would otherwise participate through clinician collection.3,8 Delaying participation among the well-screened to meet the conditions for self-collection may (slightly) increase their risk of cervical cancer; if such a delay is combined with using a less sensitive screening test (which may be the case with self-collection),9,10 then the harm could be more substantive.11 Even though well-screened people are not the primary target of this consultation, these risks need to be appropriately communicated. Furthermore, consideration needs to be given to women who were previously overdue and became regular attenders through self-collection. Will these women be unable to use self-sampling at the next screening interval? If so, they, like regular attenders, could delay participation to become re-eligible.

		6. The combination of the self-collection device, HPV assay, the transport conditions, and the laboratory processing protocols results in an accurate identification of people with high-grade cervical intraepithelial neoplasia (CIN2+, CIN3+). Ideally, the accuracy of HPV testing on self-collected samples would be similar to the accuracy achieved on clinician samples; but as the alternative in those who are overdue screening is no screening at all, less sensitive options could still be useful. Robust accuracy data is lacking,12 but it is likely that the evidence will become more complete over time. Given the current uncertainties, however, it may be worthwhile considering shorter routine recall intervals for those with negative HPV tests on self- as opposed to clinician-collected samples. To demonstrate that HPV self-collection for the under-screened – be it through an opportunistic offer or a direct mailout – will result in saving more lives that the current programme, the routine implementation should be comprehensively monitored with high-quality data. The ability of the (English) cervical screening programme to do so has been successfully demonstrated in the past e.g., with the implementation of HPV testing in triage of cytological abnormalities13- 15 and in primary screening.16-18 Depending on the outcomes, a comprehensive evaluation should guide the fine-tuning of an on-going implementation. Consideration needs to be given to the invitation strategy that is chosen. Unpublished research from our team (manuscripts in preparation) has shown that opportunistic and direct mailout approaches may address different barriers to screening participation (emotional vs practical factors). As a result, the adopted strategy may influence the barriers self-sampling helps women to overcome. Furthermore, we note that the document only recommends that the self-sampling kit delivery strategy should be based on the approach taken in the YouScreen trial – either as an opportunistic offer, direct mail-out, or both direct

		mail-out and an opportunistic offer. It is likely that other methods for kit delivery might be considered in future, such as through the NHS app. We wonder whether UK NSC will offer guidance on whether different approaches from YouScreen may be considered for non-attenders, and under what circumstances. Noting also an even stronger case for prospective evaluation planning and monitoring of novel strategies with high-quality data.
	"We have found that the selfsampling screening has similar accuracy as clinician-collected samples especially when PCRbased assays are used. Similarly, there is high concordance between the arms in which the overall agreement was 87.1% and the kappa value of 0.70." "Mail-to all strategies had more uptake in both intentions-to-treat analysis with a participation difference of 11.3 and per protocol with a participation difference of 7.7 analysis while opt-in had the same uptake with the clinician-collected sample in the PP analysis but with higher uptake in the ITT analysis (participation difference of 6.5)."	In the first part, the rapid review focuses on establishing the relative accuracy of HPV testing on self-collected tests compared with that on clinician-collected tests. The review concludes that the accuracy is "similar". This is not how we interpret the available evidence. We wish to point out the following: 1. One of the primary objectives of this review is stated as: "To compare the diagnostic accuracy of HPV-DNA testing on self-collected samples with testing on samples collected by a healthcare professional, in individuals who do not participate in a regular cervical screening programme". Although this wording could be interpreted in different ways, we understand it as a requirement to evaluate test accuracy for the purpose of primary cervical screening, in well-screened populations, with validated HPV assays. This rapid review: - Includes predominantly studies undertaken in referral populations i.e., in people who were referred because of abnormal cytology. This results in a spectrum effect which is likely associated with an optimistic bias for evaluating the relative test sensitivity.1,12 Spectrum effects are also a reason why referral population studies are not representative for evaluation of test specificity in primary screening. - Misclassifies some referral population studies as primary screening studies. - Includes a large number of true but irrelevant primary screening studies. The majority of the primary screening studies in Table 1 are from populations that had previously not been offered cervical screening, and/or used HPV assays that have not been considered as acceptable within the NHS. 19

		One representative primary screening study, the Scottish PaVDaG, 9,20 was included in Table 1. It is unclear whether this study was included in the calculation of the relative test accuracy in Table 2. - Does not include and discuss the available evidence on test accuracy from real-world implementation of self-collection in primary screening. - Uses self- and clinician-test result concordance to underpin the evidence on the relative test accuracy. In the context of HPV-based screening, where the virus is common but the goal is to detect the much rarer outcome of CIN2+, test concordance is not an informative measure.21 As a result, the conclusions from the rapid review appear much stronger than they should be given the available literature. We have also noticed some errors in the extraction of study data to meta-analyse the effect of self-collection on the increase in the screening uptake. For example, Lam et al. reported data from the Copenhagen pilot in which self-collection was offered to a random sample of all people who were at least one year overdue for screening.22 Although the study had no control arm, Table 5 suggests that it did. It is, therefore, unclear what data from the study by Lam et al. were included in the calculations underpinning Table 6 and Figure 6. We do not recognise the study-specific estimate in Figure 6, and it is likely that error was introduced. Hence, we recommend that the rapid review of the evidence is thoroughly checked for errors, and that consideration of the evidence is focused on informative studies and outcomes.
Rapid review of the evidence	"Self-sampling for HPV testing can be offered to under-screened people eligible for the Cervical Screening Programme in the 4 UK countries, where service commissioners think self-sampling would be a helpful addition to the programme. If	We welcome a targeted implementation of HPV self-collection for under-screened people to improve their engagement with the NHS cervical screening programme in the four UK countries. Delaying this implementation increases the risk of preventable cervical cancer cases and deaths.

	implemented, the option would be provided alongside traditional clinician-collected sampling." "An under-screened person is an individual who is overdue for their routine cervical screening appointment by at least 6 months or has never attended." "The self-sampling kit delivery strategy should be based on the approach taken in the YouScreen trial – either as an opportunistic offer, direct mail-out, or both direct mail-out and an opportunistic offer, depending on the feasibility of implementing each strategy. The opportunistic strategy achieved a higher response rate than direct mail-out and is encouraged." "Appropriate information should be developed to facilitate personal informed choice to participate in the screening programme."	The latest data from early adopters of HPV self-collection in routine cervical screening highlight the crucial role of how this is implemented. The operational experience that has accumulated within the NHS from studies such as YouScreen, HPValidate, or PaVDaG, will undoubtedly be helpful in this respect. Nevertheless, translation into improved health outcomes is not straightforward, even when a routine implementation is preceded by strong data from local trials.1 The consultation documentation provides very little further detail on implementational aspects. Improving health outcomes will predominantly depend on these factors: 1. The extent to which HPV self-collection will increase the number of people screened, particularly among those who are most at risk of developing cervical cancer.2,3 To achieve a high uptake, we would like to draw attention to the need to think about communications and other interventions that accompany the offer of HPV self-collection for the under-screened. 4,5 2. Ensuring the introduction of self-sampling does not widen existing socioeconomic inequalities in cervical screening uptake. Unpublished research from our team (manuscript in preparation) suggests that some marginalised groups (e.g. women with disabilities and physiological issues) may struggle to self-collect. 3. Whether those who are HPV-positive complete the recommended clinical management.6 Without it, efforts to increase uptake will not be followed by a reduced cancer burden. Understanding the communications and other needs of the affected individuals will be pivotal. 4. There is a pressing need to understand the attitudes of health care providers towards self-sampling and their knowledge of the test as women will likely need their support. Evidence from the Australian screening programme

		suggests that knowledge and preferences for screening tests may vary across health care providers.7 5. The extent to which the availability of HPV self-collection for those who are overdue will affect screening participation among those who would otherwise participate through clinician collection.3,8 Delaying participation among the well-screened to meet the conditions for self-collection may (slightly) increase their risk of cervical cancer; if such a delay is combined with using a less sensitive screening test (which may be the case with self-collection),9,10 then the harm could be more substantive.11 Even though well-screened people are not the primary target of this consultation, these risks need to be appropriately communicated. Furthermore, consideration needs to be given to women who were previously overdue and became regular attenders through self-collection. Will these women be unable to use self-sampling at the next screening interval? If so, they, like regular attenders, could delay participation to become re-eligible. 6. The combination of the self-collection device, HPV assay, the transport conditions, and the laboratory processing protocols results in an accurate identification of people with high-grade cervical intraepithelial neoplasia (CIN2+, CIN3+). Ideally, the accuracy of HPV testing on self-collected samples would be similar to the accuracy achieved on clinician samples; but as the alternative in those who are overdue screening is no screening at all, less sensitive options could still be useful. Robust accuracy data is lacking,12 but it is likely that the evidence will become more complete over time. Given the current uncertainties, however, it may be worthwhile considering shorter routine recall intervals for those with negative HPV tests on self- as opposed to clinician-collected samples. To demonstrate that HPV self-collection for the under-screened – be it through an opportunistic offer or a direct mailout – will result in saving more lives that the current programme, the routine implementation should be

		comprehensively monitored with high-quality data. The ability of the (English) cervical screening programme to do so has been successfully demonstrated in the past e.g., with the implementation of HPV testing in triage of cytological abnormalities13- 15 and in primary screening.16-18 Depending on the outcomes, a comprehensive evaluation should guide the fine-tuning of an on-going implementation. Consideration needs to be given to the invitation strategy that is chosen. Unpublished research from our team (manuscripts in preparation) has shown that opportunistic and direct mailout approaches may address different barriers to screening participation (emotional vs practical factors). As a result, the adopted strategy may influence the barriers self-sampling helps women to overcome. Furthermore, we note that the document only recommends that the self-sampling kit delivery strategy should be based on the approach taken in the YouScreen trial – either as an opportunistic offer, direct mail-out, or both direct mail-out and an opportunistic offer. It is likely that other methods for kit delivery might be considered in future, such as through the NHS app. We wonder whether UK NSC will offer guidance on whether different approaches from YouScreen may be considered for non-attenders, and under what circumstances. Noting also an even stronger case for prospective evaluation planning and monitoring of novel strategies with high-quality data. References: Rebolj M, Sargent A, Njor SH, Cuschieri K. Widening the offer of human papillomavirus self-sampling to all women eligible for cervical screening: Make haste slowly. Int J Cancer 2023;153(1):8-19. 2. Burger EA, Sy S, Nygard M, Kim JJ. The Cost-Effectiveness of Cervical Self-Sampling to Improve Routine Cervical Cancer

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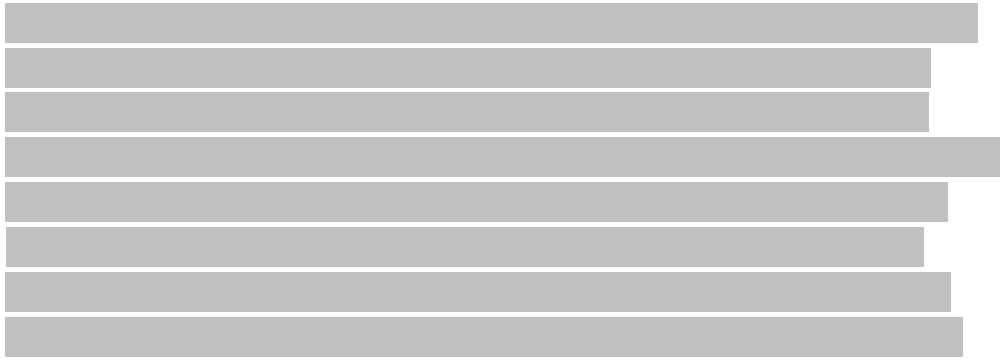
Your name:		Email address:	
Organisation name (if applicable):	Roche Diagnostics Limited		
Role/job title (or member of the public):			
Do you want your name published alongside your response on the UK NSC website?		☐Yes	☑No

Document name and section or page number	**Document text or issue your comment relates to**	**Your comment** Please add extra rows as required
N/A	N/A	We are very grateful for the opportunity to respond to the public consultation and fully support the move towards HPV self-sampling in under-screened people to improve engagement with the National Health Service Cervical Screening Programme (NHSCSP). Rates of HPV positivity, cytological abnormalities and cervical cancer mortality are higher in the under-screened population compared to those attending routine screening.[1-3] Therefore, the offer of HPV self-sampling would support the earlier detection and intervention in this at-risk group, help drive increases in screening rates and provide an important advancement towards the goal of eradicating cervical cancer by 2040.[4]

		The UK is lagging behind many countries, including Australia and the Netherlands, in implementing HPV self-sampling within their national programmes.[5] We urge the National Screening Committee to consider existing and emerging evidence from clinical trials and real-world settings and ensure that further local pilots or evaluative rollouts are non-duplicative, address known gaps, and are undertaken with a view to swift implementation of the most suitable technologies and workflows, nationally. <u>References</u> 1.Musselwhite et al. Racial/Ethnic Disparities in Cervical Cancer Screening and Outcomes. Acta Cytol. 2016;60(6):518-526 2.Lam et al. Prevalence of Human Papillomavirus in Self-Taken Samples from Screening Nonattenders. J Clin Microbiol. 2017 Oct;55(10):2913-2923 3.Lam et al. High-grade cervical intraepithelial neoplasia in human papillomavirus self-sampling of screening non-attenders. Br J Cancer. 2018 Jan;118(1):138-144 4. Mahase E. NHS England says it will eliminate cervical cancer by 2040. BMJ. 2023 Nov 15;383:2693 5.Serrano et al. Worldwide use of HPV self-sampling for cervical cancer screening. Prev Med. 2022 Jan;154:106900. doi: 10.1016/j.ypmed.2021.106900. Epub 2021 Nov 30. PMID: 34861338.
N/A	N/A	The following comment covers the CE-IVD status of the Cobas® HPV assay (Roche Diagnostics) for use with self-collected samples. This is

		being shared for complete transparency. Additional information can be provided upon request. The Cobas® HPV assay for use on the Cobas® 4800/5800/6800/8800 systems (Roche Diagnostics) includes an extended claim for self-collection. This means that, in addition to clinician-collected cervical samples, the assay is CE-IVD approved for healthcare worker–instructed self-collected vaginal specimens, collected using a FLOQSwab® (Copan, US) or Evalyn® brush (Rovers Medical Devices, Netherlands) and resuspended in Roche Cell Collection Medium (Roche Diagnostics) or PreservCyt® Solution (Hologic, UK).[1] With HPV self-collection, individuals can collect their own vaginal samples in private within a healthcare setting, following simple instructions either from the packaging or from trained personnel. Suitable settings include (but are not limited to) mobile clinics, laboratory patient service centres, urgent care clinics, retail care clinics, emergency departments, or GP surgeries. This approach brings testing closer to the patient and makes it more accessible. Once collected, samples are resuspended immediately by trained personnel and sent under controlled conditions to a laboratory for testing. Samples are analysed on the cobas® 4800/5800/6800/8800 systems in the same way as clinician-collected cervical samples. The YouScreen trial has shown that opportunistically offering self-sampling in a healthcare setting is an effective way to reach under-screened populations. [2] This would help deliver much-needed cervical

		screening to those at risk by conveniently integrating self-sampling into visits for other health-related appointments and would be considered 'on-label' if utilising the workflow, assay and collection devices described above. At present, the CE-IVD status of the cobas® HPV assay does not cover the independent collection of self-samples in a home environment.[1]  <u>References</u> 1.Cobas® 4800/5800/6800/8800 HPV Test Method Sheets. Available at https://elabdoc-prod.roche.com/ or by request. 2.Lim et al. YouScreen Joint Steering Group. Opportunistic offering of self-sampling to non-attenders within the English cervical screening programme: a pragmatic, multicentre, implementation feasibility trial with randomly allocated cluster intervention start dates (YouScreen). EClinicalMedicine. 2024 Jul 16;73:102672
Cover note, page 3	Page 3: 'Building on the findings	The findings of the YouScreen study and the cost-effectiveness analysis

	from the trial, the YouScreen team collaborated with the Daffodil Centre at the University of Sydney to conduct modelling that evaluated the cost-effectiveness of the YouScreen approach to offering self-sampling to under-screened people'.	highlight the importance of a rapid roll-out in the NHSCSP to capture as many under-screened people as possible. All three self-sampling models (mail-out, GP opportunistic and combined) for underscreened women were predicted to reduce cancer cases and deaths. Over the lifetime of 100,000 unvaccinated eligible people, and compared to current practice without self-sampling, self-sampling is predicted to reduce cervical cancer cases and deaths by 2.7% and 3.0% for mail-out, 2.9% and 3.4% for GP opportunistic, and 4.5% and 3.4% for the combined model. Moreover, self-sampling approaches were more cost-effective than not offering self-sampling, for a cohort of unvaccinated eligible people. The most cost-effective was GP opportunistic self-sampling (£2,284 per additional QALY). Direct mail-out (£9,392 per QALY) and combined (£8,181 per QALY) were also cost-effective relative to the status quo of screening without self-sampling. GP opportunistic and combined were relatively insensitive to HPV vaccination, however, the cost-effectiveness of direct mail-out was reduced. Two additional publications (references and summaries below) provide further evidence of the cost-effectiveness of self-sampling in UK settings. **Additional UK-based cost-effectiveness publications:**

		Huntington et al (2023)[1] *A cost-consequence analysis was developed to compare the costs and effects of three sampling strategies for HPV primary screening in England, using a cohort of 10,000 women aged 25-65 years eligible for the National Health Service Cervical Screening Programme. The analysis compared clinician-collected cervical samples, self-collected first-void (FV) urine, and self-collected vaginal swabs. The results demonstrated that self-sampling methods were less costly, with an average cost per complete screen of £38.57 for FV urine and £40.37 for vaginal swabs, compared to £56.81 for clinician-collected samples. This shows that self-sampling could provide a less costly alternative while improving access to cervical screening.* *Kitchener et al (2016)*[2] *A cost-effectiveness analysis was conducted as part of a cluster randomised trial in primary care across Greater Manchester and Grampian, Scotland. It found that sending unsolicited vaginal self-sampling kits was likely cost-effective for women who had not attended their first cervical screening invitation within six months, compared to standard practice.* In summary, self-sampling screening strategies, especially those that involve a GP opportunistic offer, are strongly supported by compelling clinical and economic evidence. The extended claim for self-collection on the Cobas® HPV assay (details in previous comment) is ideally suited for an opportunistic offer, and also as a component of a combined

		model, for use in the NHSCSP. This workflow is already being used in other countries, including Peru, India, Singapore, Vietnam and the United States.[3] Another important consideration is that an opportunistic offer, especially in a clinical setting, will create less plastic waste than direct mail out of kits, given the low return rates observed in YouScreen. Utilising an opportunistic offering would help to reduce health inequalities, by targeting the under screened and never screened populations, while also striving to minimize waste and work towards delivering a net zero service, as set out in the NHS Long Term Plan.[4-6] <u>References</u> 1.Huntington et al. Two self-sampling strategies for HPV primary cervical cancer screening compared with clinician-collected sampling: an economic evaluation. BMJ Open. 2023 Jun 6;13(6):e068940 2.Kitchener et al. A cluster randomised trial of strategies to increase cervical screening uptake at first invitation (STRATEGIC). Health Technol Assess. 2016 Sep;20(68):1-138. 3.Garcia et al. Academic accountability to local communities and society through Programme Science: a case study from the HPV self-sampling programme HOPE in Peru. J Int AIDS Soc. 2024 Jul;27 Suppl 2(Suppl 2):e26297. 4.NHS England. Delivering a net zero NHS. Accessed on 25/02/2025:https://www.england.nhs.uk/greenernhs/a-net-zero-nhs/ 5.NHS England. National ambition. Accessed on

		25/02/2025:https://www.england.nhs.uk/greenernhs/national-ambition/ 6.NHS England. NHS clinical waste strategy. Accessed on 25/02/2025:https://www.england.nhs.uk/estates/nhs-clinical-waste-strategy/#:~:text=The%20strategy%2C%20when%20implemented%2C%20aims,treat%20infectious%20waste%20on%2Dsite.
Cover note, Page 4	Page 4: 'Published after the Glasgow University 2024 rapid evidence review, the HPValidate findings provide key UK evidence on self-sample accuracy and acceptability. Its findings complement the 2024 review and the YouScreen study.'	The conclusions drawn in the 2024 Rapid Evidence Review were for PCR-based assays only, specifically target amplification-based DNA assays, which were found to have high accuracy and excellent concordance with clinician-collected samples. The suitability of other assays, including mRNA technologies, was not reviewed in the 2024 Rapid Evidence Review. The HPValidate trial did not provide a robust conclusion on test accuracies nor allow for comparisons between the different workflows due to limitations in the trial design, sample storage conditions and epidemiological characteristics.[1] Therefore, the suitability of other assays, including mRNA technologies, remains uncertain, especially as previous publications have advised against their use for vaginal self-collected samples due to concerns about lower clinical sensitivity compared to cervical clinician-collected samples.[2] There are also concerns over the stability of mRNA given that it is a more labile molecule than DNA and more evidence is needed on the impact of storage conditions on clinical samples.[3]

		To our knowledge, no country has implemented HPV self-sampling with an mRNA-based assay and Australian Guidelines specifically recommend only PCR-based assay technologies for HPV self-sampling.[4] Moreover, the Dutch cervical screening programme uses a PCR-based assay for HPV self-sampling. References 1. Mathews et al. HPValidate: clinical validation of hrHPV test system using self-collected vaginal samples in NHS England commissioned laboratories providing cervical screening services. Accessed 25/02/2025: https://www.qmul.ac.uk/fmd/media/smd/documents/research/hpv-self-collection-test-accuracy-report-hpvalidate-lot1.pdf 2.Arbyn et al. Accuracy and effectiveness of HPV mRNA testing in cervical cancer screening: a systematic review and meta-analysis. Lancet Oncol. 2022 Jul;23(7):950-960. doi: 10.1016/S1470-2045(22)00294-7. Epub 2022 Jun 13. Erratum in: Lancet Oncol. 2022 Aug;23(8):e370 3.Connor et al. Effect of time and temperature on the stability of HPV and cellular nucleic acid using simulated dry self-samples. J Virol Methods. 2025 Apr;333:115101. 4.Requirements for cervical screening (Second edition 2024). Australian Commission on Safety and Quality in Health Cares. Accessed 25/02/2025: https://www.safetyandquality.gov.au/publications-and-resources/resource-library/requirements-cervical-screening-second-

		edition-2024

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Your name:		Email address:	
Organisation name (if applicable):	FTWW: Fair Treatment for the Women of Wales		
Role/job title (or member of the public):			
Do you want your name published alongside your response on the UK NSC website?		☐No – ONLY the organisation's name may be published	

Document name and section or page number	**Document text or issue your comment relates to**	**Your comment** Please add extra rows as required
General		We are concerned at limited references to the needs of disabled and house / bed-bound women and would recommend that additional consideration is given to their specific requirements. We would suggest that engagement with affected individuals and their advocates is prioritised so as not to perpetuate exclusion from any proposals and practice.

		Examples of where additional needs should be considered include: • Information and instructions made available in a range of formats (including easy read, Braille, BSL explainer videos) • Advice and guidance for those who are disabled / bed-bound and cannot either: - Undertake a self-performed screening test - Access GP or other external healthcare provider for a screening test In some instances, those affected might not have healthcare professionals regularly visiting their homes to perform screening tests, so carers may need additional and easily / routinely accessible advice and guidance to help them support or assist the person for whom they're caring.

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Your name:	Professor Susan Sherman (on behalf of NIHR funded research team detailed below)	Email address:	
Organisation name (if applicable):	University of Sheffield		

Role/job title (or member of the public):	Professor of Psychology
Do you want your name published alongside your response on the UK NSC website?	X **Yes** ☐No

Authors: Susan Sherman[1], Emma Kemp[1], Julius Sim[2], Carolyn Chew-Graham[2], Andrew Finney[2], Charlotte Harper[2], Alycia Hirani[3], Laura Marlow[4], Georgina Moore[3], Samantha Renke[5], Katie Wright-Bevans[2]

[1]University of Sheffield, Sheffield, United Kingdom, [2]Keele University, Keele, United Kingdom, [3]Patient and Public Involvement stakeholders, [4]Queen Mary University of London, London, United Kingdom, [5]Samantha Renke Official Ltd, London, United Kingdom

Nature of submission

We are the research team (including PPI [patient and public involvement] co-investigator and PPI stakeholders) for NIHR grant NIHR204322 which is exploring improving uptake of cervical screening for physically Disabled women and people with a cervix. We comment on the consultation documents from this perspective and present some findings from our patient study to inform the consultation process.

Consultation Documents

We welcome the offer of HPV self-sampling to underserved populations. However, when we review the documents through a disability lens, we would make the following points:

1. There are more than 8 million Disabled women in the UK (https://researchbriefings.files.parliament.uk/documents/CBP-9602/CBP-9602.pdf)
2. To our knowledge, none of the research on self-sampling to date has systematically collected data on disability status. This has implications for the consultation documents (see first 2 rows):

Document name and section or page number	**Document text or issue your comment relates to**	**Your comment** Please add extra rows as required
The rapid review (p64)	P64: “The percentage of unsatisfactory samples was very low 0.9 (95%CI; 0.6 to 1.2) [-]. The small percentage of the unsatisfactory sample is an important advocacy tool for women with fear of participating in self-sampling because of doubting its results and self-efficacy in performing it which is the greatest reported barrier to self-sampling (Nelson et al 2014).”	We don’t know what the percentage of unsatisfactory samples would be for Disabled women, since to our knowledge, these data have not been collected. Our data suggest that many Disabled women and people with a cervix would be concerned about whether they had done the test correctly (64.6% in our sample), and the evidence to provide this advocacy is not yet there for this population.
The rapid review (p64)	P64: “…while adherence to follow-up was 80.5 (95%CI 72.2 to 86.7) which encourages the applicability of this method [-]. One of the challenges of self-sampling is loss of follow-up, however, this level of adherence assures the linkage of those with positive results to further	Studies measuring adherence to follow-up have not measured disability status to our knowledge. Given the challenges Disabled people face in accessing cervical screening detailed in our research and elsewhere, while HPV self-sampling will provide many Disabled people with an acceptable alternative to conventional screening, adherence to follow up will only be achieved by making conventional screening more accessible.

Document name and section or page number	Document text or issue your comment relates to	Your comment Please add extra rows as required
	assessment for identification of precancer and cancer".	
Executive summary (p7)	"1. Offering self-sampling to never screened and under-screened women in England across a range of ages as part of the National Cervical Screening Programme, **particularly when offered in a GP setting**, is both effective and cost-effective" *[emphasis added]*	We would especially welcome self-sampling to be offered in a GP setting for physically Disabled women and people with a cervix. We would further welcome the offer of a sample taker offering to assist with the test as needed.

Further evidence informed by NIHR (NIHR204322)

As part of an NIHR funded grant (https://www.dev.fundingawards.nihr.ac.uk/award/NIHR204322) under the Research for Patient Benefit programme looking at improving access to cervical screening for physically Disabled women and people with a cervix, we conducted a patient-facing survey exploring the problems and solutions related to accessing cervical screening for physically Disabled people. As part of this survey, we investigated the acceptability of HPV self-sampling and clinician-assisted sampling as an alternative to speculum-based cervical screening for Disabled people and future screening preferences.

Materials and data will be uploaded to the project Open Science Framework page as they become available: https://osf.io/ufx8r/

Method

We conducted a cross-sectional online survey in July 2024. Participants (N=1000) were aged 25-64 (M=41, SD=10.8), eligible for cervical screening, identified as having a physical disability, condition, impairment or difference and had not had a total hysterectomy. Participants rated statements (developed with our team of PPI stakeholders who all have lived experience of physical disability) about screening preferences including suitability of HPV self-sampling.

Preliminary results

As data collection is ongoing, full statistical analysis of the data has not yet been conducted.

Participants were also asked to share any comments about the survey. Open-ended responses suggest that participants were interested to know more about self-sampling and appeared enthusiastic about self-sampling becoming available in the future. Participants also indicated that self-sampling could help to reduce cervical screening related anxiety for physically Disabled people.

A further round of data collection is underway, final analyses will be completed by April 2025.

Our interim recommendations

1. We would welcome the offer of HPV self-sampling to under-screened and never screened patients.
2. We would welcome HPV self-sampling being offered opportunistically through the GP surgery and would further welcome the offer of a smear taker administering the self-sampling kit for the patient where appropriate.
3. We would recommend that the materials to support self-sampling are designed to be fully inclusive (infographics across the world currently use illustrations depicting apparently able-bodied women, noting of course that some disabilities are less or not visible).
4. We would urge an improvement in access to conventional cervical screening for physically Disabled people to offer genuine patient choice and facilitate adherence to follow-up from self-sampling.
5. We note that only 63.5% of our sample felt they would be able to do self-sampling and 53% would choose self-sampling if offered a choice. It is important that the NSC continues to explore ways to make conventional cervical screening more accessible for Disabled people.
6. We would urge the inclusion of disability measures in future research about self-sampling.

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Your name:	Luke Nottage	Email address:	

Organisation name (if applicable):	Becton Dickinson UK Ltd	
Role/job title (or member of the public):	Medical Affairs Manager	
Do you want your name published alongside your response on the UK NSC website?		Yes

Document name and section or page number	**Document text or issue your comment relates to**	**Your comment** Please add extra rows as required
Cover note	P.4 'Self-sampling for HPV testing can be offered to underscreened people eligible for the Cervical Screening Programme in the 4 UK countries, where service commissioners think self-sampling would be a helpful addition to the programme. If implemented, the option would be provided alongside traditional clinician-collected sampling.'	Becton Dickinson UK Ltd (BD) fully endorses the consultation recommendation. Integrating HPV self-sampling into the NHS Cervical Cancer Screening Programme offers significant advantages for enhancing cervical cancer prevention and addressing current screening challenges. The proposal to include self-sampling assays, where individuals collect their own samples at home and send them to a laboratory for analysis, addresses several key issues and has strong support from recent evidence. A screening paradigm that includes self-sampling as an option has the potential to increase the uptake of cervical screening compared to the current standard-of-care currently seen in the UK. Self-sampling will contribute to both the NHS ambition to eliminate cervical cancer by 2040 and the WHO goal of achieving 70% cervical screening coverage by 2030 whilst improving health outcomes and experience for women and those with a cervix. Given the success of self-sampling in other countries and its positive impact on hard-to-reach populations, it represents a significant opportunity to advance cervical cancer prevention and achieve better health outcomes in the UK. By prioritising high-risk populations, fostering collaboration and optimising communication and operational strategies, the UK can harness the power of self-sampling technologies to expand

		preventative care and move towards equitable cervical cancer elimination.
Cover note	Section 3 – HPV tests. Page 4: ‘The study identified four effective self-collection device and HPV test combinations in an English setting. These can inform kit and platform choices for under-screened people, who face higher risks of HPV and developing cervical cancer and need accessible, innovative screening approaches.’	The HPValidate study only assessed HPV self-collection performance when the sample was collected in a clinical environment (primary care and colposcopy clinics). The HPV assays evaluated in the HPValidate study are not validated by their manufacturers for HPV self-collected samples when collected outside of a clinical environment and therefore have no ‘on-label’ claim within their instructions for use for collection in an at-home setting. This represents a restriction in the wider deployment of self-collection for the screening programme. The HPV assays evaluated in HPValidate have a requirement to immediately resuspend the sample in a liquid medium at the point of collection which may present a risk in an at-home setting. HPV assays that are validated for dry sample swab collection and transport to testing laboratories with suitable sample stability claims would alleviate this risk. One of the HPV assays evaluated lacks an internal cellularity control mechanism to detect whether human cellular material is present in the sample. This presents a risk of false negative results if used in a selfcollection setting, particularly as sample collection is conducted in the absence of healthcare providers. Only HPV assays with internal cellularity control should be considered for HPV self-collected samples. One of the HPV assays evaluated detects HPV mRNA. The World Health Organisation recommends using HPV DNA as the primary screening test. The HPValidate study only evaluated the two incumbent HPV assays that are currently in use in the English Cervical Screening Programme. Currently 8 assays have been evaluated and accepted for use in the cervical screening programme for primary HPV screening and HPV triage of

		borderline and low-grade abnormalities, and as a ‘test of cure’ of treatment. Within this list of UK accepted assays, the BD Onclarity HPV test is the only assay that currently has manufacturer intended use claims for self-collected vaginal specimens either in the clinic or an at-home setting. UK evaluations of HPV self-collection for cervical screening should include previously approved assays for clinician collected samples that have an on-label claim for HPV self-collected vaginal samples in both clinic and at home settings. UK validation for HPV self-collection should not unfairly favour incumbent suppliers in future national procurements.
Cover note	Section 3 – HPV tests. Published after the Glasgow University 2024 rapid evidence review, the HPValidate findings provide key UK evidence on selfsample accuracy and acceptability. Its findings complement the 2024 review and the YouScreen study. See report summarising the results of the HPValidate study.’	BD recommends that the UK National Screening Committee utilise international data from comparable health systems that have already adopted HPV self-collection into their programmes (European examples include the Netherlands and Sweden). Current UK evidence generated by the HPValidate study gives incumbent HPV assays an apparent advantage due to their current usage in the UK screening programme at the time of UK evidence generation.
Cover note	Tests and associated workflows which have been validated in the UK for use in elfsampling should be used. For example, those included in the HPValidate study can	BD recommends a wider UK evaluation of HPV assays and collection kits for self-collected samples outside of the incumbent HPV assay technology currently employed by the screening programme. There is a need to give a fair opportunity for every regulated test and associated workflow to be evaluated prior to procurement processes. As recommended in the HPValidate report further validations should consider the performance of HPV assays when self-collection occurs outside

	inform the choice of selfsampling kits and testing platforms for under-screened people in the CSP.'	of a clinical environment (at-home) to fully inform decisions on a wider roll-out that can maximise the potential for increased uptake of cervical cancer screening.
YouScreen (exec summary)	P2: 2. YouScreen Mail-out only – assumes that self-sampling kits are only offered to non-attenders under the YouScreen trial protocol via the direct mail-out pathway.'	The cost-effectiveness analysis only appears to compare opt-out mailing invitation strategies which have been shown to be both less effective and less cost effective than opt-in strategies. 1. Costa et al., Br J Cancer 2023 Mar;128(5):805-813. doi: 10.1038/s41416-022-02094-w 2. Wong and Wong, BMC Public Health 2024 Sep 10;24(1):2461. doi: 10.1186/s12889-024-19881-0
YouScreen (exec summary)	P2-3: '2. YouScreen Mail-out only – assumes that self-sampling kits are only offered to non-attenders under the YouScreen trial protocol via the direct mail-out pathway. 3. YouScreen Opportunistic only – assumes that self-sampling kits are only offered to nonattenders under the YouScreen trial protocol via the GP opportunistic pathway. 4. YouScreen as it occurred (combined GP opportunistic and direct mail-out) – assumes that self-sampling kits are offered to	By not including an opt-in mailing strategy AND requiring a GP visit for options 3 and 4, this approach misses an opportunity for significant savings in the screening programme by avoiding excess waste due to unused kits not being returned, and the significant cost savings by avoiding a clinic visit for the majority of women and people with a cervix who will test HPV negative. In addition, adding a GP visit requirement will not allow coverage to reach women and people with a cervix who do not attend the clinic (this population will remain underor never-served).
Rapid review	P2: this rapid review is intended to address questions on the	Previous meta-analyses have shown that DNA-based PCR self-collection tests have the best performance and are non-inferior to physician-collected

	accuracy, concordance, uptake and acceptability of selfsampling over clinician-collected samples'	samples. Heterogeneity in the data could have been greatly reduced, if not eliminated, had this criterion been applied to study selection. It is now clear that both the workflow and the HPV assay need to be optimised to ensure acceptable clinical performance, a topic which was largely absent from this review. 1. Connor L, Elasifer H, Sargent A, Bhatia R, Graham C, Cuschieri K. 2023. Influence of resuspension volume on dry sampling devices taken for human papillomavirus testing: implications for self-sampling. BioTechniques 74:77-84 2. Inturrisi F, Aitken CA, Melchers WJG, van den Brule AJC, Molijn A, et al. 2021. Clinical performance of high-risk HPV testing on self-samples versus clinician samples in routine primary HPV screening in the Netherlands: An observational study. Lancet Reg Health Eur 11:100235 3. Vaughan L, Gary D, Shah M, Lewellen L, Galbraith L, Parvu V. 2024. Variables that impact HPV test accuracy during vaginal self collection workflow for cervical cancer screening. Gynecol Oncol Rep 54:101421
Rapid review	Table 9, page 60: - Stated that self-sampling caused anxiety = 35.2% (2.8% to 91.1%) - Stated that self-sampling did not fit with values = 59.9% (8.1% to 96.2%)	Both these statements represent a very small number of studies (2-4, with carve out for separate devices) and are not representative of the majority of studies included here, or in previous meta-analyses. The "does not fit with values" is likely describing lavage which is not a mainstream self-collection technique and considerably more invasive and less user-friendly than using a small swab or brush device. Including them as summary finding (page 2) is misleading at best, especially when one of the quoted studies (lavage) only has 25 participants.

35-

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Email:

Organisation: Manchester Cytology Centre and Virology department, Manchester University NHS Foundation Trust

Role: [redacted]

Condition: Cervical screening

Please find below a collated response from the Leads and Managers at Manchester Cytology Centre and Virology department for the NSC consultation on HPV self-sampling.

We support the implementation of an offer of self-sampling to under-screened individuals eligible for the cervical screening programme, based on the evidence provided in the recent consultation. Due process should be given if this offer is extended to all women who are overdue by at least six months, as this could potentially lead to an increase in self-sampling and a corresponding drop in routine LBC collection if women decide to delay their routine invite.

According to the YouScreen coverage model, a 7.4% increase could result in approximately 650 self-samples being received weekly in the North-West. However, there are several issues that need to be addressed for this initiative to be successful. One significant challenge is the scale of laboratory work required, especially considering that the Evalyn and FLOQSwab methods validated in HPValidate involve manual workstreams. To cope with this, additional resources such as estates, staffing, and equipment like class 2 biosafety cabinets will be necessary for preprocessing samples. It is essential to consider collaboration with manufacturers to automate the pre-processing of self-samples. Customising the current pre-analytics for LBC could also support self-sampling, but without automation, the volume of samples received could lead to backlogs and delays in processing.

HPValidate experienced an increase in invalid test results when samples were delayed in testing. To avoid additional costs generated by repeat testing, strict acceptance criteria is required. Clear communication is needed to ensure that kits are sent back promptly to allow testing within a set timeframe. This is particularly important for validated workstreams that lack an internal control, to prevent reporting potentially false-negative results.
Additionally, clear screening pathways are required to facilitate the reporting and follow-up of women (e.g poor attenders with a negative history, and those with abnormal/complex history). Laboratories must be confident in the management protocols that will be established to avoid mismanagement.

HPValidate and YouScreen revealed discrepancies in results, such as HPV positive on self-sampling and HPV negative on LBC across different workflows. To avoid reputational damage to the programme, clear communication is necessary to maintain women's trust in the current system. For instance, will women who receive a positive self-sampling result be satisfied with returning to a 5-year recall once they receive a negative LBC result?

Lastly, across eight laboratories in England different IT systems are in use, careful consideration and time is required to be able to implement a pilot across cytology, virology, histology, and colposcopy departments to ensure the workflows can be tested and ensure that the percentage of electronic requesting is maintained.

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Role/job title (or member of the public):	Senior Obstetrics and Gynaecology Trainee		
Do you want your name published alongside your response on the UK NSC website?		☒ Yes ☐ No	

Document name and section or page number	**Document text or issue your comment relates to**	**Your comment** Please add extra rows as required
UK National Screening Committee: Consultation on offering HPV self-	Consultation recommendation	Response by:

sampling to under-screened people in the NHS Cervical Screening Programme		**Jennifer Davies-Oliveira – Senior Obstetrics and Gynaecology Trainee** Dr Jen Davies is a Senior Obstetrics and Gynaecology Trainee in the Wales Deanery, UK with interests in screening and early detection of Gynaecological Cancers. Jen has a passion for narrowing cervical screening health inequity gaps, with a particular interest in minority groups, including the LGBTQ+ and ethnically diverse communities. **Emma Crosbie - Professor of Gynaecological Oncology at The University of Manchester** Emma is a Consultant Gynaecological Cancer Surgeon whose research interests include screening, prevention and the early detection of gynaecological cancers, as well as developing new treatments and interventions for women with established disease. **Stephanie Gillibrand – Research Fellow at The University of Manchester** Stephanie Gillibrand is a Research Fellow based in the Centre for Primary Care at The University of Manchester. Stephanie's research

		focuses on health inequalities and experiences of healthcare services for marginalised and under-served groups**.** **Caroline Sanders – Professor of Medical Sociology at The University of Manchester** Caroline is Professor of Medical Sociology within the Division of Population Health, Health Services Research and Primary Care at The University of Manchester. Caroline's research interests focus on patient and carer experiences of healthcare, as well as health and care inequalities. **Consultation response** Based upon research undertaken by The University of Manchester, the authors recommend that HPV self-sampling options be provided to under-screened people in the cervical screening programme. We also want to draw attention to the fact that the **NSC is not considering the use of urine-self sampling**, despite there existing strong evidence to suggest that this method is as accurate to vaginal self-swabbing.

		• While the incidence of cervical cancer has fallen since the 1990s, screening coverage has also declined, in part due to barriers to care faced by some individuals and communities. • Self-sampling methods, including vaginal swabs and urine, were seen by many to be less invasive, less stressful, and offered more control over their own bodies and health. • A national rollout of self-sampling alongside the traditional 'smear test', accompanied by accessible and appropriate information, could help to reduce disparities in access to, and outcomes of, cancer care. Under-served communities, including those from some ethnically diverse communities, older and younger groups, people from more socially deprived areas, those with lower education levels, and those with intellectual disabilities are typically less likely to attend cervical screening. Those who have experienced sexual violence are also less likely to attend regular screening, as are those who have experienced homelessness. Against this background, we set out to explore the barriers to screening uptake and how they may overlap with other barriers to healthcare. We also sought to understand how the introduction of self-sampling methods (including vaginal swabs and urine) may help to overcome these barriers.

		Barriers to screening There are a number of reasons why some people are unable or unwilling to attend screening appointments. On an individual level, these can include a lack of knowledge or awareness, embarrassment, or fear of discomfort or pain associated with the speculum examination. At a systemic level, these barriers can be childcare responsibilities or inflexible working patterns, mirroring other known barriers patients face in accessing primary care. Working with 46 participants from across Greater Manchester, we investigated attitudes to, and experiences of, cervical screening. Many participants described negative past experiences as barriers to attending future screening appointments, with pain and discomfort a common point raised by participants of all backgrounds: "*I'm normally quite good at like gritting my teeth through something, but I was just fully in tears, it was so painful*."

		Other participants, especially those from ethnic minority backgrounds and those with mental health conditions, highlighted a lack of empathy or feeling of being rushed by the healthcare professionals (HCPs) carrying out the screening. This feeling of disempowerment, and a lack of control over their own bodies, reflects wider concerns around women's experiences of health and care services. The speculum itself was a significant element of participants' discomfort and often formed part of their reluctance to attend screening appointments. *"[...]before they even put a speculum anywhere near you, you're tensing your body up. And she's like, what you doing that for, I've not even touched you yet."* Despite these barriers, many participants said they felt screening attendance was compulsory, and a necessity to their health. **Improving access**

		Self-sampling alternatives to cervical screening, such as vaginal self-swabbing or urine sampling, may help to overcome some of the barriers reported by participants, and improve screening coverage. Overall, these approaches were welcomed by all participant groups, being seen as more accessible than the traditional speculum method, as well as less invasive and less stressful. These methods also increased feelings of control and autonomy. Being able to do screening in their own homes was highlighted as a key benefit, with participants generally seeing it as more practical and convenient. However, it is important to note that some participants would prefer to attend a GP practice. The removal of the need for the speculum was particularly welcome among participants, and ultimately, participants felt that self-sampling methods gave patients a choice in which method was most suitable for them. Consequently, there was a sense that self-sampling methods would increase the propensity for screening amongst the groups sampled. There was some confusion and scepticism towards self-sampling methods, as to why they were not already offered, given the relatively

		low invasiveness compared to the speculum test. This was sometimes expressed alongside concerns about the accuracy of self-sampling methods, and participants' confidence in taking the self-sample. *"I'm just a bit, still a bit confused about why, having [...] had a really painful experience, about why that has ever been necessary, if it's possible to just have a wee."* This response from a participant of our study demonstrates the extent to which urine self-sampling can be considered a preferable option to screening. With evidence to suggest the accuracy of urine self-sampling is as precise as vaginal swabbing, the NSC should consider extending self-sampling options to include urinary tests as well. **Recommendations** The findings of this research suggest a national rollout of self-sampling alongside existing 'smear tests' would help to remove some of the barriers to cervical screening. The NSC should also consider extending self-sampling methods to include urinary deposits. This would also support work to narrow inequities in health outcomes, providing more choice to women who would otherwise face challenges in accessing or

		engaging with healthcare services. This should be reflected in an update to the Women's Health Strategy, led by the Department of Health and Social Care. In order for self-sampling to be perceived as a reliable alternative to traditional cervical screening, participants identified the need for accessible and appropriate information on the self-sampling methods, suggesting this should include diagrams and video explainers of how to use the self-sampling methods, highlighting that written information alone would not suffice. Alongside this information, participants noted that the rationale for introducing self-sampling should be clearly communicated to patients. For instance, the accuracy of self-sampling methods and how they work should be clearly explained to inform patients about why these were being offered as an alternative to the healthcare practitioner-taken cervical sample. There is also a role for the Office for Health Improvement and Disparities (OHID) in leading on the creation and dissemination of this guidance, with particular focus on those communities and individuals known to face the strongest barriers to screening.

		Cervical screening is an essential tool in the armoury to eliminate cervical cancer, ensuring the best outcomes for the patients, and lowering the cost to health services. It is therefore vital that screening is made as accessible as possible, to ensure the greatest burden of disease does not fall on individuals and communities who already face additional barriers to accessing healthcare. A national rollout of self-sampling methods would help fulfil the promise of successive governments, and aid in addressing health inequities for under-served groups.

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Do you want your name published alongside your response on the UK NSC website?	X Yes ☐ No

Document name and section or page number	**Document text or issue your comment relates to**	**Your comment** Please add extra rows as required.
Cover note, page 4	Consultation recommendation	Cancer Research UK (CRUK) agree with the overall permissive recommendation to offer self-sampling to under-screened people in the eligible population. We note some remaining evidence gaps and likely implementation barriers but support the overall recommendation and hope that it will be introduced as it will provide an opportunity to a specific cohort who are currently not attending cervical screening to take part in the programme. We would encourage close monitoring and evaluation by UK NSC to ensure that the recommendation is updated based on evidence and feedback during and after rollout. These gaps include: • Cost-effectiveness • Further understanding of inequalities in acceptability as well as confidence carrying out self-sampling, and crucially, how to address barriers and support equal access to cervical screening. • Further validation of the self-sampling device and HPV test combinations identified in HPValidate. • Continued research to understand the effectiveness and feasibility of urine tests as a self-sampling method. Urine testing has been reported as a much-preferred method to vaginal tests, especially among women from an ethnic minority (1). We acknowledge that preferences for at-home testing compared to sampling in a general practice setting are mixed and can vary across different demographic groups (2). However,

		the opportunistic offer of self-sampling in primary care would be the preferred method when rolling out self-sampling, as this led to higher uptake in YouScreen than direct mailout (3). We note that there was variation between practices in terms of self-sampling provision and uptake (3, 4) - we encourage identifying and sharing best practice across participating GPs. Direct mailouts should still be considered if opportunistic sampling is turned down, or if it is most feasible option for implementation. Appropriate support and pathways will be needed to ensure uptake of follow-up tests, such as colposcopy, for those who are under screened but test HPV positive from self-sampling. Of note is the high compliance of follow-up in the YouScreen study, where nearly 90% attended follow-up. Protocols from the study should be utilised to ensure similar uptake. Clear guidance should be given to health professionals on how to have conversations with patients that support informed choice. CRUK have some outstanding questions and suggestions to optimise the recommendation and minimise any unintended consequences – outlined below.
Cover note, page 4	Appropriate information should be developed to facilitate personal informed choice to participate in the screening programmed.	Any harms and benefits of self-sampling over clinician-taken sample should be accurately and accessibly communicated. Materials provided to participants for the YouScreen study could be adapted and updated after user testing (3). For example, some research suggests some women do not trust the accuracy of self-sampling or lack the confidence to complete the test. Accessible information and clear instructions could help to mitigate these barriers (1, 2).

		We would like UK NSC to acknowledge this in any recommendation, and encourage providers to appropriately tailor information, ideally developed by co-design, to be accessible and support informed decision making. Examples suggested by research participants include practice swabs and instructional videos (1).
Cover note, page 4	An under-screened person is an individual who is overdue for their routine cervical screening appointment by at least 6 months or has never attended.	Please provide a rationale for the definition of an under-screened person being at least six months overdue for their routine cervical screening appointment. If this is an evidence gap, future research could consider: 1) When the person was last screened 2) The results of the last screen 3) Extenuating circumstances (such as pregnancy) Although the current suggestion of overdue by 6 months reflects the YouScreen protocol (3), we are not aware of a consensus optimal definition of 'under-screened', which should be clarified. Our understanding is that the suggested definition is 6 months since being overdue for cervical screening, as opposed to 6 months after receiving an invitation – therefore, could delayed invitation effect the eligible cohort? If so, we would suggest scoping of how many people this is predicted to affect to mitigate the possibility of offering self-sampling prematurely ahead of an invite for clinician-collected sampling.
Cover note, page 4	...where service commissioners think self-sampling would be a helpful addition to the programme. If implemented, the option would be	We are concerned about the potential for exacerbating inequalities specifically in relation to geographical variation in access to self-sampling. The local commissioning approach is pragmatic, but the risk of inconsistency in implementation needs to be mitigated. We assume that screening commissioners based in regional teams will lead responsibility for ensuring that this is implemented. However, for example in England, Cancer alliances, ICBs, Local Medical Committees and Local authority public health teams should be engaged at the same time. We urge UK NSC to provide guidance for national screening commissioners to consider

	provided alongside traditional clinician-collected sampling.	setting clear expectations for local commissioners to implement within a nationally mandated timeframe and provide assurance that self-sampling is being implemented in line with the evidence, and that all local stakeholders have been engaged. Local screening commissioners should report to the national team and providing an explanation if they are not implementing in a timely way. A public comms strategy should be prepared that includes FAQs for the public. For example, there may be frustration because of geographical variation in access to self-sampling. Pre-planned, clear, and transparent communication will be crucial. This could be user-tested ahead of any announcement/change in recommendation.
Cover note, page 4	If implemented, the option would be provided alongside traditional clinician-collected sampling.	We strongly agree that self-sampling should be offered as a choice, with clinician-collected sampling being the alternative. Previous research found a majority (85%) of people who currently attend screening would prefer to have a choice, but a large proportion (48%) reported a preference to be given a recommendation (5). Researchers recommend solutions such as incorporating decision-support tools along with invites or using a default test option. While self-sampling evidence still builds, we suggest clinician-collected sampling remains the default option, and self-sampling (at GP or home) is an additional option for those who would prefer that. For example, for the opportunistic method within primary care, people would still be offered a clinician-taken sample and if they decline again, be offered to self-sample. Considering the direct mailout approach, after being 6 months overdue, a person would receive another invite for clinician-collected screening, and within the same invite be offered self-sampling as a second option if preferred. The research also found that those with a lower education were more likely to say they would worry about having a choice or would not want a choice (5), which could lead to inequalities in participation.

		It should be noted that the current evidence relates to screening attendees - there is a gap in understanding choice/guidance preferences in the under-screened cohort.

References

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2. Gillibrand S, Gibson H, Howells K, Urwin S, Davies JC, Crosbie EJ, et al. Exploring the barriers to cervical screening and perspectives on new self-sampling methods amongst under-served groups. BMC Health Services Research. 2025;25(1).
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Document name and section or page number	**Document text or issue your comment relates to**	**Your comment** Please add extra rows as required
--	-- overall statement – recommendation around	Our findings from a local recent qualitative study in Greater Manchester supports the conclusions of the consultation that self-sampling should be introduced.

Document name and section or page number	**Document text or issue your comment relates to**	**Your comment** Please add extra rows as required
	communication of introduction of self-sampling	The conclusions from our study find that self-sampling, if introduced alongside the traditional method, should increase screening amongst under-screened groups. It should be noted that our study looked at two types of self-sampling: urine sampling and self-swabbing, and found both to be equally acceptable, and that the introduction of both of these methods should be considered alongside the traditional method. We especially support the consultation conclusion that self-sampling should be introduced alongside the traditional smear test. Our study found this was important because participants were unfamiliar with the new methods, and therefore the importance of choice between methods was paramount. In particular, the smear test has been 'normalised', and therefore our study found that other, new, self-sampling methods were met with some scepticism and queries around efficacy. Put simply, participants were confused that if self-sampling was effective in detecting HPV and could be a viable alternative, why they weren't already offered it. This caused some suspicion and cause for concern.

Document name and section or page number	Document text or issue your comment relates to	Your comment Please add extra rows as required
		“This could be framed to the public in terms of research breakthrough and progress, recognising the need for more choice over screening methods, and being responsive to patients’ needs and existing barriers.” (Gillibrand et al 2025, p13)
	Addition of existing evidence/literature	Our study: “Exploring the barriers to cervical screening and perspectives on new self-sampling methods amongst under-served groups” was published in January 2025 in BMC Health Services Research (open access, freely available). Due to the time of publishing, it was not picked up in the review. The qualitative study explored the barriers to screening amongst under-screened groups (on the basis of social risk factors associated with lower screening uptake) and their perspectives towards self-sampling (both urine sampling and self-swabbing) as an alternative to the traditional speculum test. Under-screened groups in our study was defined on the basis of groups who are typically less likely to attend screening on the basis of socio-demographic characteristics (i.e. age, ethnicity, socio-economic status),

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		of which these groups we selectively sampled from. We recruited 46 participants from diverse social backgrounds. Overall, 46 % of our sample were considered non-regular attenders, just under one third (n=15) had never attended, had missed at least one, and/or were not planning to attend again. Self-sampling methods including vaginal swab and urine collection were positively received by participants, and may address some existing barriers through the proponents of enhanced choice – between self sampling or traditional methods and location (i.e. doing the sample at home or at the GP practice, which also dovetailed with convenience) leading to greater empowerment. The removal of the speculum and lack of invasive examination by a healthcare professional was also positively received. Participants welcomed the introduction of self-sampling methods, with the majority of participants (across participant groups) describing the benefits of self-sampling methods in comparison to traditional methods, including offering the choice of sampling method and location (i.e. at home or at the GP practice). This, along with the opportunity to self-

Document name and section or page number	Document text or issue your comment relates to	Your comment Please add extra rows as required
		sample was seen to make cervical screening less invasive, in particular, as these sampling methods removed the need for the speculum and examination from healthcare professionals. Participants did not identify a significant preference for either self-sampling device, but welcomed the addition of both alongside the traditional method. The introduction of self-sampling alongside traditional methods may reduce barriers to screening, and may boost screening rates for under-screened but only if they are implemented with appropriate information and sufficient communication. Failure to implement self-sampling without these considerations may threaten to undermine the identified and important benefits of self-sampling methods. Some participants (from Pakistani/Pakistani British, White British backgrounds, Muslim faiths and those with neurodevelopmental disorders) raised concerns about the usability of the self-sampling methods, pertaining to dexterity, ease of use and accuracy. While our findings suggest that both self-sampling methods should be made

Document name and section or page number	Document text or issue your comment relates to	Your comment Please add extra rows as required
		available, we acknowledge that further investigation in this area could enhance the successful implementation of these new interventions.
HPV self-sampling in under screened consultation cover note Dec 2024, Consultation recommendation, bullet 1 (page 4)	bullet 1 (page 4) Classification of 'under-screened' Recommendation (bullet 1): An under-screened person is an individual who is overdue for their routine cervical screening appointment by at least 6 months or has never attended	The committee should consider a wider classification and targeting of 'under-screened', on the basis of social risk factors for disproportionate levels of attending cervical screening (e.g. socio-economic status). It is not clear how any of these risk factors were accounted for in the cost-effectiveness and effectiveness study. Our study sampled participants on the basis of categorical social risk factors as identified in the existing literature on the known characteristics associated with lower screening levels. Findings from our study suggests that urine-collection and swabbing self-sampling alongside traditional smear test may improve uptake amongst under-screened groups.
HPV self-sampling in under screened consultation cover note Dec 2024, Consultation	Consultation recommendation, bullet 2 (page 4)	It is possible that opportunistic mailout did not receive a higher response rate because participants were unfamiliar with the self-sampling approach and hesitant to use it. This likely links to intersecting barriers to engaging in research and engaging with healthcare services, likely

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recommendation, bullet 2 (page 4) Also YouScreen Project Report_FINAL_15-08-2024, Summary, page 6	Also YouScreen Project Report_FINAL_15-08-2024, Summary, page 6 Suggested amendment to the recommendation bullet 2: The self-sampling kit delivery strategy should be based on the approach taken in the YouScreen trial–either as an opportunistic direct mail-out and an opportunistic offer, depending on the feasibility of the strategy. The opportunistic strategy achieved a higher response rate than direct mail-out and is encouraged.	prevalent amongst under-screened groups. This underscores points raised in this submission about the need for sufficient information and communications surrounding self-sampling. It is worth noting that our study found that people would like to have a choice about where to do the self-sampling test – either at a GP or at home. The majority were happy to do the test at home, but some wanted the option to do with a HCP or a nurse. Implications should be considered if those who receive the mail out self-sampling require further assistance or would like to do the self-sampling in a clinical GP setting or with a healthcare practitioner present. Furthermore, a GP based approach offers the opportunity for questions and concerns to be addressed (provided it is handed out by a healthcare practitioner). N.b. It is not clear in the YouScreen report who the self-sampling was handed out by, and this may be an important factors which influences engagement and uptake.

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HPV self-sampling in under screened consultation cover note Dec 2024, Consultation recommendation, bullet 5 (page 4)	Consultation recommendation, bullet 5 (page 4) Information to facilitate personal informed choice around participation – what should be in this information and how it should be delivered.	Findings from our study support this recommendation, however further clarity is needed here: The information should address prominent concerns and questions around efficacy, be free from bias, and provide sufficient information about self-sampling works, to mitigate the effects of the normalised acceptance of traditional methods. The appropriate information provided should be tailored and personalised where appropriate and or feasible. In particular, the information should be provided in different languages (depending on local/individual need), accessible language (i.e. for autistic people and people with learning disabilities) and key questions around efficacy should be addressed in this information. (Gillibrand et al 2025) “Information on self-sampling methods should be targeted appropriately to different under-screened groups, with the most appropriate

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		communication channels and mechanisms utilised (e.g. translated materials and dissemination via the voluntary sector to enhance reach)…. If appropriate information is not provided or delivered effectively, this otherwise risks the legitimacy of self-sampling methods being accepted as a viable alternative to the traditional speculum method, meaning an enhanced choice for women may be not sufficiently realised." (Gillibrand et al 2025, p13)
YouScreen Project Report_FINAL_15-08-2024, Discussion, page 58	YouScreen Project Report_FINAL_15-08-2024, Discussion, page 58 "Notably, all of the self-sampling scenarios were comparatively more cost-effective for cohorts who were older in 2021(aged41or 56)than for the baseline cohort of unvaccinated women turning 26 in 2021,and also cost-saving (while also improving QALYs overall)relative to the status quo without self-sampling for GP opportunistic only and the combined approach "	Our study found no difference by age for preference for self-sampling, and indeed all social groups were supportive of self-sampling. A possible explanation for this is those turning 26 and unvaccinated have other confounding social factors which reduce their likelihood to engage in screening at all (especially as younger age is associated with lower screening uptake). This should be considered in the interpretation of the results.

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	Cost effectiveness of scenarios based on age.	

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Your name:		Email address:	
Organisation name (if applicable):	Great Chapel Street Medical Centre		
Role/job title (or member of the public):			
Do you want your name published alongside your response on the UK NSC website?		☐ **Yes**	☐ No

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Cost effectiveness analysis of the youscreen trail: a modelling study P12-14	P12-14: Modelling based on YouScreen trial data	Mail out response rates may be over estimated compared to specialist homeless practice lists due to the transient nature of patients and post not always being received (so less eligible women are likely to receive the self-sampling tests by mail out). GP opportunistic rates may be under estimated compared to specialist homeless practice lists due to there being targeted resource which could be directed towards offering self-sampling to women overdue for screening. There is the possibility of a greater than predicted uptake of self-sampling with specialist homeless GP practices.
Cost effectiveness analysis of the youscreen trail: a modelling study P20-21, 47	P20-21, 47 Impact of HPV immunisation	Women experiencing homelessness are more likely to have faced multiple disadvantage throughout their lives and may therefore have more risk factors and have been less likely to have been vaccinated against HPV (and constitute the 11% of girls not vaccinated) and therefore more likely to remain at risk of HPV infection and benefit more from self-sampling compared with vaccinated individuals.
Cost effectiveness analysis of the youscreen trail: a modelling study p61	P61Effectiveness and cost effectiveness	Agree that from the analysis already showing the effectiveness and cost effectiveness within the study, fully support the role of out self-sampling in under-screened women through GP opportunistic/targeted approach.

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		In mainstream practice this could be combined with mail out to increase overall uptake.
Rapid Review	Methodology	No evidence that Rapid Review paper specifically reviewed inclusion health / vulnerable populations.
Rapid Review	Results	Would be good to see the outcomes as comparative data due to reason for underscreening. E.g. women who have experienced sexual trauma/assault / homeless women / religious or values based reticence etc as expect this might show even more compelling data for these populations.
Rapid Review	Discussion	Would be good to see future discussions around health equity and vulnerable / inclusion health populations as more flexible screening approaches like this are likely to have a bigger proportional impact on these patient groups. It would be good to see these groups being specifically included in any future screening trials etc. Specifically with regards to homelessness, opportunistic screening / supported screening by community health services are likely to be much

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		more successful than any mail-out initiatives due to lack of address / mobile population and mistrust of health services – plus low levels of literacy and English. Reducing barriers to screening need to take this into account as part of addressing health inequalities.