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Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2020-044630
Article Type:	Original research
Date Submitted by the Author:	10-Sep-2020
Complete List of Authors:	Marlow, Laura; King's College London, Cancer Prevention Group, School of Cancer and Pharmaceutical Sciences; University College London, Research Department of Behavioural Science and Health Forster, Alice; UCL, Research Department of Behavioural Science and Health McBride, Emily; University College London, Health Behaviour Research Centre Rockliffe, Lauren; The University of Manchester, School of Health Sciences, Faculty of Biology, Medicine and Health Kitchener, Henry; University of Manchester Waller, Jo; King's College London, Cancer Prevention Group, School of Cancer and Pharmaceutical Sciences; UCL, Research Department of Behavioural Science and Health
Keywords:	Public health < INFECTIOUS DISEASES, PREVENTIVE MEDICINE, PRIMARY CARE, QUALITATIVE RESEARCH

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Information needs among women taking part in primary HPV screening in England: A content Analysis

Running title: HPV information needs

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Funding

Our study was funded by Public Health England (PHE, no grant number was given). PHE funded Emily McBride from 03/01/2016 until 30/09/2017. EM was funded by the National Institute for Health Research (NIHR) from 01/10/2017 [grant number DRF-2017-10-105]; the views expressed in this article are not necessarily those of the NHS, the NIHR or the Department of Health and Social Care. JW, LM and AF are funded by Cancer Research UK (grant numbers C7492/A17219 and C49896/A17429).

Competing interests

The authors declare no conflict of interest.

Abstract

Objectives: Introducing primary HPV testing to cervical screening programmes means changes to the results women receive. We explored additional information needs among women undergoing HPV primary screening.

Design: Women were sent a postal questionnaire shortly after receiving their results and 6 and 12 months later. Each questionnaire asked if women had any unanswered questions about cervical screening or HPV testing. Free-text responses constituted the data. Themes were identified using Content Analysis.

Setting: NHS Cervical Screening Programme, England

Participants: 381 women who recorded one or more free-text responses.

Results: The most common theme represented women's emotional responses and attempts to understand their results. This theme was raised by 45% of women overall, but was as high as 59% in the HPV cleared group. General questions about the cause and epidemiology of HPV were raised by 38% of women and were more common among those testing HPV Positive with normal cytology (52%). Questions about the purpose and procedure for HPV testing were most common among HPV-negative women (40%, compared to 16%-25% of the other results groups). Questions about future implications of test results, were raised by 20% of women, and this theme was most common among those with persistent HPV.

Conclusions: Despite provision of information alongside screening invitations, women can still have unanswered questions following receipt of their results. Details about the epidemiology of HPV and why cervical screening procedures are changing should be included with screening invitations. Some results groups may benefit from additional tailored information with their result letter.

Strengths and limitations of this study

- Participants had been tested for HPV as part of routine cervical screening
- Participants represented a range of test results
- Two thirds of women did not leave a free-text response.
- Questionnaires were completed at least two weeks after receiving results.
- Those with less education were less likely to leave a free-text comment.

Keywords

cervical screening, HPV testing, information, informed choice, concerns, misunderstanding

Introduction

Cervical screening programmes have traditionally involved looking for abnormal cytology but HPV primary screening can provide many benefits [1] and has already replaced cytology-based cervical screening in England, Australia, the Netherlands and Wales, and several other countries are expected to follow in the coming years [2,3]. HPV testing looks for presence of the HPV virus. Where HPV is found the sample is looked at for cytology. Women with HPV positive/abnormal cytology results are referred for colposcopy, women with HPV positive/normal cytology are recalled 12 months later. Based on a large pilot study in England, around 13% of women aged 25-64 years will be told they are HPV positive [4,5], compared with ~6% who currently receive an abnormal cytology result (with or without HPV). These figures are expected to decrease dramatically as cohorts offered HPV vaccination move into the programme. Nevertheless, many women will be receiving an HPV positive result, warranting careful consideration of how these results are communicated.

Of particular concern is that some women will be learning about the link between cervical cancer and a sexually transmitted infection (STI) for the first time, which may come as a shock and could raise concerns about sexual relationships [6-8]. In a review of studies exploring understanding of HPV and information needs [9], women found it difficult to incorporate new information about HPV testing into their pre-existing understanding of cervical screening and often sought additional information after being told they were HPV-positive. The review identified uncertainty about HPV transmission, prevention, symptoms, risk factors (for HPV and cervical cancer), whether HPV could cause other cancers, treatment, fertility and the natural history of the virus. However, most of the studies included were small qualitative studies carried out before 2007, half of which used samples of women who had not actually been tested for HPV. More recently, qualitative interviews with women who were told they were HPV positive in an HPV self-sampling trial, identified some key themes: intense affect (feelings and emotions) after receiving positive results, importance of discussing results with a provider, information seeking, confusion about purpose and meaning of HPV versus Pap tests [10].

Establishing women's information needs in the context of primary screening is vital to inform patient education and communication strategies. Clear information provided at the appropriate time-point (e.g. alongside results) may help to minimise the adverse psychological responses to HPV-positive results that have been identified [11]. The aims of this study were to i) identify the information needs of women participating in primary HPV screening and ii) to explore how these might vary according to women's HPV and cytology results. This study is part of a broader psychological evaluation of HPV primary testing in England [12].

Methods

Participants

Participants were women aged 24-65 years who attended for cervical screening in England in one of five sites piloting HPV primary testing (between 2016 and 2017). Recruitment was stratified to ensure data were collected from women receiving different screening results (see Supplementary Figure 1): i) negative for HPV, ii) HPV-positive with normal cytology and iii) HPV-positive with abnormal cytology.

We also recruited two groups of women who had initially tested positive for HPV with normal cytology, and who had re-attended at 12-month follow-up and either iv) had persistent HPV i.e. they were still HPV-positive with normal cytology or v) had cleared the infection i.e. they now tested HPV negative. A group of women undergoing conventional cytology screening were also recruited but we have excluded their data from the present analyses.

Procedure

The data reported here were collected from cross-sectional surveys sent to women at three time points: shortly after receiving their results (baseline), 6-months, and 12-months. The full protocol is available elsewhere [12], but in brief women were contacted by post within two weeks of receiving their screening result letter and invited to complete and return a consent form and questionnaire. Women who returned the questionnaire were also sent questionnaires 6 and 12 months later. The primary outcome measures assessed in the questionnaire were anxiety and general distress [11]. Health Research Authority (HRA) approval was granted on 26/09/2016 (Research Ethics Committee reference: 16/LO/0902 and Confidentiality Advisory Group reference: 16/CAG/0047). We did not use any Patients or public involvement in the design, conduct, or reporting of this study.

Measures

At each of the three time-points, women were asked "Do you have any unanswered questions about cervical screening or HPV testing?" and space for an open response was provided. Free-text responses to this question constituted the primary data for analyses. At the end of the baseline questionnaire there was also a space provided for "any other comments". Free-text responses recorded here were also included where they were relevant to the aims of this analysis (irrelevant comments were excluded, for example comments about practical aspects of the survey study). Socio-demographic information including age, marital status, education and ethnicity were also collected. Information on women's screening results was collected directly from the screening laboratories.

Analysis

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3 Content analysis was used to explore women's free-text responses. Responses from all three time
4 points were analysed together. Content analysis can be defined as "subjective interpretation of the
5 content of text data through the systematic classification process of coding and identifying themes"
6 [13]. Responses were typed into an excel spreadsheet and two authors (LR and EM) immersed
7 themselves in the baseline data. An initial coding frame was developed using an inductive,
8 conventional content analysis approach (i.e. avoiding preconceived categories) [14]. Three senior
9 members of the research team then coded the data for 20% of the baseline participants (n=60),
10 before refining the coding frame. All responses (from each time point) were then independently
11 double coded. Any discrepancies were discussed. Multiple codes were allocated to individual
12 responses when appropriate. We used 2-by-5 chi-square tests to explore differences in the
13 proportion of women citing each major theme by result group. Sub-themes are reported
14 descriptively.

23 Results

24
25 Overall 921 women who had undergone HPV primary screening returned their baseline
26 questionnaire (see Figure 1). A total of 507 free-text responses were recorded (baseline=329/921, 6
27 months=110/762 and 12 months =68/537). Women testing HPV-positive with normal cytology and
28 those with persistent HPV were most likely to leave a free-text response (50%); HPV-negative
29 women were least likely (26%) to do so. Free-text responses were also more common among
30 women in the youngest age group and those with a degree qualification (see Table 1 for sample
31 characteristics). We have described each theme below with the prevalence of themes reported in
32 Table 2 (overall and by results group). Illustrative examples of women's comments are presented in
33 Table 3.

41 *Reaction to and understanding of results*

42
43 Across all results groups (except HPV-negative), the most common theme was 'reaction to and
44 understanding of results'. This theme was most frequently present in comments made by HPV
45 positive women (with normal or abnormal cytology, 51% and 54% respectively) and by women who
46 had cleared HPV at 12-months (59%). Women expressed a wide range of emotional responses to
47 their results including shock, worry and relief. Comments included questions about the exact
48 meaning of their result, including clarification about which HPV type they had. Implications for
49 sexual relationships were raised by a number of women, including requests for clarification of what
50 their result meant for future sexual relationships, concern about re-infection within a relationship
51 and the possible consequences of infection for their partner. A lack of confidence in HPV results and
52 requests for cytology were recorded by 5% of women (12% of women who were HPV negative and
53 21% had cleared HPV). Having previously experienced an abnormal result or approaching the end of
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3 cervical screening eligibility were reasons that women gave for concern about not having a cytology
4 test.
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6 *Questions about HPV and cervical cancer*

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8 Over a third of women who left a comment recorded a question about HPV (38%) and this was more
9 common among women who were HPV-positive with normal cytology (52%) or who had persistent
10 HPV (41%). Women asked about various aspects of HPV epidemiology including questions about the
11 timeline of infection, latency and clearance. Women's questions about HPV also included requests
12 for clarification about the cause of their HPV, frequently including references to their long-term or
13 sexual relationships. The potential for preventing future HPV infections and treating current ones
14 was also raised. Some women expressed a more general lack of understanding about HPV, saying
15 they had never heard of it or did not know what it was.
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18
19 A smaller number of women provided comments about cervical cancer (14% across all results
20 groups). A range of general questions were raised about the risk of developing cervical cancer. Some
21 women also asked about other specific causal risk factors for cervical cancer (e.g. polycystic ovary
22 syndrome, contraceptive implants, previous cancer diagnosis or treatment).
23
24

25 *Purpose and procedure for HPV testing*

26
27 'Purpose and procedure for HPV testing' was the most common theme for HPV-negative women
28 (40%) but was also raised by HPV-positive women (16-24%) and women who had cleared HPV (24%).
29 Questions about the purpose of HPV testing were predominantly to clarify how HPV testing fit with
30 their existing knowledge of cervical screening, but some women mentioned being unaware they had
31 been tested for HPV until they received their results. Some HPV-negative women wanted to clarify
32 whether their sample had been cytology tested or why cytology was not also performed.
33
34

35
36 Women also made comments about the timing of tests, particularly in relation to repeat HPV
37 testing. They wanted to be reassured that the recommended intervals were 'soon enough' or
38 'adequate'. Several women also commented on the delivery of their results, for example saying that
39 the results had not been clear from the letter they received and that further discussion with their GP
40 had been needed.
41
42

43 *Future implications of test results*

44
45 The theme 'Future implications of the results' was identified in 19% of the comments and was most
46 commonly recorded for women with persistent HPV (30%). These comments related specifically to
47 clinical management, with requests for clarification about what would happen next for them.
48 Implications for fertility, for their partners being tested and advice on clearing HPV was mentioned
49 by a few women.
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Information seeking and (di)satisfaction

Some women described their experiences of seeking additional information about HPV. This predominantly included experiences of searching online or contacting their GP surgery to discuss their result further (with a GP or nurse) and was recorded for 22% of those leaving a comment. A number of women indicated satisfaction, or more commonly lack of satisfaction, with the information they had received.

Discussion

This study found women undergoing primary HPV testing for cervical screening can have additional information needs after receiving their results. Requests for more information about the epidemiology and cause of HPV were common across all results groups, so this seems to be important information to communicate to women taking part in screening. Other questions were more common among women receiving particular results; for example women receiving an HPV positive result (with normal cytology) often had questions about the meaning of this result and wanted advice about the implications for sexual relationships. Women with abnormal cytology seemed to have fewer questions about HPV and the meaning of their result, but expressed more worry and concern. This suggests there may be merit in including results-tailored information alongside the delivery of results. However, the wide range of themes identified and the personalised nature of many questions means signposting to additional information will also be important.

Some of our themes relating to women's understanding of HPV and cervical cancer were similar to other studies [8,9], supporting the need to provide women with information about the cause and epidemiology of HPV. Women's desire to develop a coherent model of what HPV is, the timeline of infection and its cause and consequences is supported by theoretical models of illness representation which suggest that these aspects are important for understanding HPV and cervical cancer and consequently for coping with being given an HPV-positive result [15,16].

Previous studies have suggested that women are often shocked to learn about the sexually transmitted nature of HPV [6,7]. Implications for sexual relationships was not the most common theme identified and while this question was raised by some women (particularly those who test HPV-positive with normal cytology), it is reassuring that this was not more widespread in women's responses. Some themes such as the impact of HPV on fertility or questions about the impact for male partners, were raised by very few women suggesting these are unlikely to be major areas of concern.

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3 The main strength of this study is that we included women who had been tested for HPV as part of
4 routine cervical screening, meaning we were able to compare responses across results groups.
5
6 However, there are some limitations. The overall response rate for the questionnaire was low and of
7 those responding, less than half recorded a free-text response. We cannot be sure if women who
8 chose not to leave a free-text response had no information needs or just did not state them. In
9
10 addition, since the questionnaires were completed at least two weeks after receiving results, women
11 may already have sought answers to any questions they initially had. It is therefore likely that our
12 study underestimates the number of questions women have upon receiving their result. Women
13 from lower socio-economic backgrounds were less likely to return the questionnaire [11] and those
14 with less education were less likely to leave a free-text comment. It is therefore possible that the
15 results under-represent the concerns of women from lower socio-economic backgrounds.

16
17 A number of implications arise from this study. Firstly, it is important that women are made aware of
18 HPV before being tested. For some women, including information about HPV in invitation letters will
19 not be sufficient so sample-takers have an important role in ensuring women know they are having
20 an HPV test. In some instances, this may be simply by drawing their attention to the information
21 leaflet that they receive with their screening invitation, but for some women this will lead to
22 additional questions which sample-takers should be prepared to answer.

23
24 Secondly, information provided to women alongside their results should ideally be tailored to the
25 result being communicated. Many of the women who were HPV-positive or had recently cleared
26 HPV had questions about the meaning of their result and some described contacting their GP
27 surgery to discuss this. This is consistent with findings in the US, where women receiving HPV
28 positive results felt a sense of urgency to discuss it with their Health care provider and felt reassured
29 after this had happened [10]. It is important that staff in primary care are well equipped to answer
30 women's questions or to direct them to the best source of information. This may involve answering
31 questions about HPV themselves or directing women to online information materials (e.g. the NHS
32 screening website). In particular, the information needs recorded by women were frequently
33 interlinked with their personal information and medical history, reflecting attempts to make sense of
34 their results. There are likely to be women who want to discuss their specific results and this might
35 also include how their risk relates to their past screening history or other health conditions. For
36 these women, knowing who they can contact (e.g. a specific helpline, a cancer charity helpline, their
37 GP) will be important.

38
39 Finally, for some women there was confusion about why changes were being made to the screening
40 programme and concern about the fact that their sample had not been checked for abnormal cells.
41 It is important to explain why screening is changing and to reassure women that HPV testing is

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3 better than cytology, with the changes being made to improve the screening programme. It might
4 also be useful to clarify specifically that this is safe even for women who are at the end of screening
5 (mentioned by some women in their 60s) or those who have previously had abnormal cytology
6 results. The recent public backlash following changes to the cervical screening programme in
7 Australia has highlighted the importance of explaining the rationale behind and safety of changes
8 being made in public health [17].
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13 Women taking part in HPV-based cervical screening continue to have additional information needs.
14 Information about the epidemiology of HPV, why the cervical screening procedure is changing and
15 the meaning and implications of different results, should be provided in materials accompanying
16 results. Tailored information and signposting to additional materials and resources would also help
17 to ensure women can find the information they need
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24 25 **Author contributions**

26
27 JW, LM, AF and HK conceived the study. JW, LM, EM and AF developed the measures. EM and JW
28 managed the project. All authors contributed to the analyses. LM drafted the paper. All authors
29 contributed to the final version of the manuscript. We would like to thank all the laboratory staff
30 who made recruiting for the psychological evaluation possible, as well as Kirsty Bennett and Fatima
31 Osmani who contributed to recruitment and data entry. We also thank Julieta Patnick for her helpful
32 comments.
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39 **Data sharing statement**

40 Data is available from the corresponding author upon reasonable request.
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45 **Patient and public involvement**

46 No patient involved.
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For peer review only

Table 1: Sample characteristics of women participating in HPV primary testing who did and did not record a free-text response during the course of the study (n=921)

	Free-text response recorded at any time		No free-text response recorded		χ^2 (df), p-value
	N	Row %	n	Row %	
Overall	381	41.4	540	58.6	
Result group					
HPV negative	65	26.2	183	73.8	$\chi^2(4)=38.49, p<.001$
HPV positive, cytology normal	126	50.0	129	50.0	
HPV positive, cytology abnormal	67	39.4	103	60.6	
Persistent HPV	91	50.8	88	49.2	
Cleared HPV	29	43.9	37	56.1	
Age					
24-34	171	46.7	195	53.3	$\chi^2(3)=10.63, p=.014$
35-44	66	32.7	136	67.3	
45-54	80	41.0	115	59.0	
55-65	64	41.0	92	59.0	
Marital status*					
Current partner	281	40.7	410	59.3	$\chi^2(1)=.79, p=.375$
No partner	95	44.4	119	55.6	
Education**					
Degree or higher	189	48.8	198	51.2	$\chi^2(2)=14.62, p=.001$
Qualifications below degree	177	36.0	314	64.0	
No formal qualifications	7	38.9	11	61.1	
Ethnicity					
White (British or other)	356	42.7	527	57.3	$\chi^2(1)=4.77, p=.029$
Other ethnicity***	20	28.6	50	71.4	

*Marital status: current partner (married, civil partnership, living with partner, in a relationship) and no partner (single, divorced, widowed). **No formal qualifications included those with no qualifications and those who were still studying with no previous qualifications. ***Other ethnicity includes: Asian/Asian British, Black/African/Caribbean/Black British, Mixed/Multiple ethnic groups, other ethnic group.

NOTE: Where n does not add up to n=921, this is due to missing data

Table 2: Number of women mentioning each major and sub-theme overall and by test result group

	Overall (n=381)	HPV negative (n=65)	HPV positive, cytology normal (n=129)	HPV positive, cytology abnormal (n=67)	Persistent HPV (n=91)	Cleared HPV (n=29)	χ^2 (df), p-value
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Reaction to and understanding of results	170 (45)	11 (17)	69 (54)	34 (51)	39 (43)	17 (59)	$\chi^2(4)=27.72,$.001
Emotional response	85 (22)	5 (8)	28 (22)	24 (36)	18 (20)	10 (35)	
Meaning of results	72 (19)	1 (2)	35 (27)	11 (16)	21 (23)	4 (14)	
Impact on sexual relationships	41 (11)	0	25 (19)	4 (6)	11 (12)	1 (3)	
Confidence in results	20 (5)	8 (12)	4 (3)	1 (2)	1 (1)	6 (21)	
Questions about HPV	143 (38)	8 (12)	67 (52)	20 (30)	37 (41)	11 (38)	$\chi^2(4)=31.13,$ <.001
General lack of understanding	24 (7)	2 (3)	15 (12)	6 (9)	4 (4)	0	
Epidemiology of HPV	63 (17)	2 (3)	30 (23)	5 (8)	20 (22)	6 (21)	
Cause of HPV	32 (8)	1 (2)	20 (16)	3 (5)	6 (7)	2 (7)	
Prevention/Treatment of HPV	28 (7)	0	11 (9)	7 (10)	9 (10)	1 (3)	
HPV vaccination	39 (10)	3 (5)	20 (16)	2 (3)	11 (12)	3 (10)	
Questions about cervical cancer	52 (14)	5 (8)	24 (19)	7 (10)	14 (15)	2 (7)	$\chi^2(4)=6.58,$.160
Risk of cervical cancer	45 (12)	3 (3)	20 (16)	7 (10)	14 (15)	2 (7)	
Other cervical cancer risk factors	14 (4)	3 (5)	7 (5)	1 (2)	2 (2)	1 (3)	
Purpose and procedure for HPV testing	85 (22)	26 (40)	20 (16)	16 (24)	16 (18)	7 (24)	$\chi^2(4)=16.51,$.002
Purpose	22 (6)	11 (17)	5 (4)	4 (6)	2 (2)	0	
Procedure	18 (5)	10 (15)	3 (2)	1 (2)	0	4 (14)	
Timing	36 (9)	4 (6)	12 (9)	5 (8)	11 (12)	4 (14)	
Delivery of results	15 (4)	4 (6)	1 (1)	7 (10)	3 (3)	0	
Future implications of test results	73 (19)	1 (2)	30 (23)	10 (15)	27 (30)	5 (17)	$\chi^2(4)=21.76,$ <.001
Clinical management	39 (10)	1(2)	14(11)	4 (6)	19 (21)	1 (4)	
Fertility/sexual health	13 (3)	0	5 (4)	1 (3)	3 (3)	3 (10)	
Advice on clearing HPV	18 (5)	0	10 (8)	2 (3)	5 (6)	1 (3)	
Testing for partners	7 (2)	0	4 (3)	2 (3)	1 (1)	0	
Information seeking/(di)satisfaction	85 (22)	8 (12)	37 (29)	14 (21)	22 (24)	4 (14)	$\chi^2(4)=8.25,$.083
Information seeking	30 (8)	3 (5)	15 (12)	7 (10)	5 (6)	0	
(Di)satisfaction	73 (19)	6 (9)	31 (24)	12 (18)	20 (22)	4 (14)	

Table 3: Examples of each quote

Reaction to and understanding of results	
Emotional response	<p><i>"I am very worried in case I end up with cervical cancer"</i> [HPV+, cyto norm; 55-65 years]</p> <p><i>"I feel quite distressed about the results and the letter ... has caused me stress and anxiety"</i> [HPV+, cyto abnorm; 24-34 years]</p> <p><i>"I was advised I do not have HPV, I have had this persistently for years, I am so relieved"</i> [HPV cleared; 24-34 years]</p>
Confidence in results	<p><i>"I have a family history of abnormal cells being found, but I was not tested for anything other than HPV. I would like to have a further test to confirm no abnormal cells"</i> [HPV-; 35-44 years]</p> <p><i>"Because I have previously had abnormal cells... I was not reassured by my HPV-negative result"</i> [HPV-; 45-54 years]</p> <p><i>"I am uneasy about the fact that cells have not been checked for abnormality, especially as no further tests will be offered to me"</i> [HPV -; 55-65 years]</p>
Meaning of results	<p><i>"I was cleared of HPV last year, why has it come back?"</i> [HPV+, cyto norm; 45-54 years]</p> <p><i>"I have had two smears now both HPV-positive. How long can a person be HPV-positive for HPV?"</i> [HPV persistent; 45-54 years]</p> <p><i>"My previous test was positive and this one was negative. Does this mean it is still present but not active?"</i> [HPV cleared; 24-34 years] <i>"I caught genital warts at 23 - is this somehow different?"</i> [HPV+, cyto norm; 24-34 years]</p>
Impact on sexual relationships	<p><i>"Not sure what this means for future sexual relationships"</i> [HPV+, cyto abnorm; 24-34 years]</p> <p><i>"Can it be perpetuated by continuously being passed from one partner to the other?"</i> [HPV+, cyto norm; 55-65 years]</p> <p><i>"Should I tell sexual partners?"</i> [HPV+, cyto norm; 24-34 years]</p> <p><i>"Initially I worried about what my husband would think"</i> [HPV persistent; 55-65 years]</p> <p><i>"I blame my partner for this"</i> [HPV+, cyto norm; 35-44 years]</p>
Questions about HPV	
General lack of understanding	<p><i>"I didn't even know I had been tested for HPV. Have never heard of it before"</i> [HPV+, cyto norm; 35-44 years]</p> <p><i>"I don't really understand what HPV is"</i> [HPV+, cyto norm; 24-34 years]</p>
Epidemiology of HPV	<p><i>"How long does HPV last? What will happen if it doesn't go away?"</i> [HPV+, cyto norm; 24-34 years]</p> <p><i>"Has it gone and come back again or have I had it for 3 years?"</i> [HPV+, cyto norm; 35-44 years]</p> <p><i>"I'm still unclear as to what makes some peoples CIN1 cells disappear while others develop further"</i> [HPV+, cyto abnorm; 35-44 years]</p> <p><i>"Will it ever go away? Or get worse?"</i> [HPV persistent; 55-65 years]</p>
Cause of HPV	<p><i>"I don't understand how I have got HPV"</i> [HPV+, cyto norm; 24-34 years]</p> <p><i>"I have not been sexually active for 6 years and can't understand why I have got it with only having one long-term partner"</i> [HPV+, cyto abnorm; 35-44 years]</p>
Prevention/treatment for HPV	<p><i>"Should I now always use condoms for sex?"</i> [HPV+, cyto norm; 24-34 years]</p> <p><i>"Is there something I can take to get rid of HPV?"</i> [HPV+, cyto norm; 35-44 years]</p> <p><i>"Are there really no ways to treat the HPV virus?"</i> [HPV persistent; 55-65 years]</p>

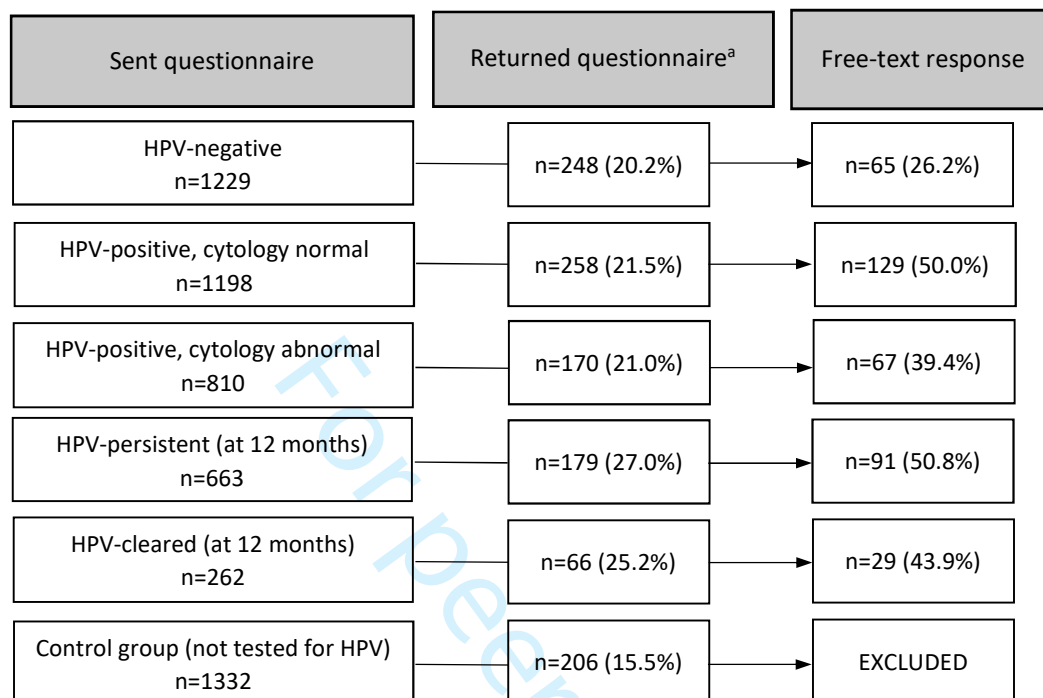
HPV vaccination	<p><i>"I had the HPV vaccine, why didn't it work?"</i> [HPV+, cyto norm; 24-34 years]</p> <p><i>"I'd like to know if I could be offered the vaccine and whether it would work for me"</i> [HPV+, cyto norm; 35-44 years]</p> <p><i>"I have been considering having the vaccine but unsure of benefits at my age"</i> [HPV cleared; 35-44 years]</p>
Questions about cervical cancer	
Risk of cervical cancer	<p><i>"What are the chances of this becoming cancerous?"</i> [HPV+, cyto norm; 55-65 years]</p> <p><i>"What proportion of women who have had 2 smears detecting high risk HPV will go on to develop cervical cancer?"</i> [HPV persistent; 45-54 years]</p>
Other cervical cancer risk factors	<p><i>"There is a vast history of cancer in my family. Am I more likely to get cancer?"</i> [HPV+, cyto norm; 55-65 years]</p> <p><i>"I have a contraception implant - does this affect HPV or my chances of developing cervical cancer"</i> [HPV+, cyto norm; 24-34 years]</p>
Purpose and procedure for HPV testing	
Purpose	<p><i>"I am not sure if HPV test covers more, less or the same as a normal smear test"</i> [HPV-; 45-54 years]</p> <p><i>"I do not know if one is more thorough and effective than the other"</i> [HPV-; 35-44 years]</p> <p><i>"Was given no information that would be a different test other than smear"</i> [HPV+, cyto norm; 45-54 years]</p>
Procedure	<p><i>"Was the HPV an additional test in addition to a normal smear test?"</i> [HPV-; 45-54 years]</p> <p><i>"Why when HPV is not present they don't test the sample"</i> [HPV cleared; 24-34 years]</p>
Timing	<p><i>"Why can't I be re-tested in 6 months instead of waiting another year?"</i> [HPV+, cyto norm; 45-54 years]</p> <p><i>"Is having my next smear in 1 year soon enough? Could my cells change quickly enough to be cancerous before then?"</i> [HPV+, cyto norm; 45-54 years]</p> <p><i>"I would like to be reassured that the intervals between tests are adequate to pick up any changes to my body"</i> [HPV cleared; 35-44 years]</p>
Delivery of results	<p><i>"I haven't received a letter with my results and I don't ever recall receiving results"</i> [HPV-; 35-44 years]</p> <p><i>"I had lots of questions that I could not get answered because results come in letter form"</i> [HPV+, cyto abnorm; 24-34 years]</p>
Future implications of test results	
Clinical management	<p><i>"My test was positive two times and I want to meet a specialist"</i> [HPV+, cyto norm; 45-54 years]</p> <p><i>"I had a second positive HPV and have not been invited for further testing which the nurse said I would be. I am wondering why"</i> [HPV persistent; 55-65 years]</p> <p><i>"Am I now having a colposcopy because I have had HPV for 2 years?"</i> [HPV persistent; 45-54 years]</p>
Fertility/sexual health	<p><i>"I am due a second test in 1 years time, but I am hopefully aiming to be pregnant around then, is this a major problem?"</i> [HPV+, cyto norm; 24-34 years]</p> <p><i>"Will it increase my chances of miscarriage?"</i> [HPV persistent; 24-34 years]</p>
Advice on clearing HPV	<p><i>"What can I do in the next 12 months to help myself?"</i> [HPV+, cyto norm; 24-34 years]</p> <p><i>"Is there anything I can do to stop HPV developing into cancer?"</i> [HPV persistent; 24-34 years]</p>

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Testing for partners	<i>Why men don't get test for it if they can transmit it?</i> [HPV+, cyto abnorm; 24-34 years]
Information seeking and (di)satisfaction	
Information seeking	<i>"I contacted my GP for more information"</i> [HPV+, cyto norm; 24-34 years]
(Di)satisfaction	<i>"It's not explained in a very useful manner"</i> [HPV persistent; 24-34 years]
	<i>"I want to have more information about HPV"</i> [HPV+, cyto norm; 45-54 years]
	<i>"On receiving letter about results I felt I had lots of questions that I could not get answered"</i> [HPV+, cyto abnorm; 24-34 years]

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Supplementary Figure 1: Overall response rate and proportion of women leaving a free-text response during the course of the study



^a Excluding questionnaires that were returned late or where participants were an ineligible age (n=21).

BMJ Open

Information needs among women taking part in primary HPV screening in England: A content analysis

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2020-044630.R1
Article Type:	Original research
Date Submitted by the Author:	09-Nov-2020
Complete List of Authors:	Marlow, Laura; King's College London, Cancer Prevention Group, School of Cancer and Pharmaceutical Sciences; University College London, Research Department of Behavioural Science and Health Forster, Alice; UCL, Research Department of Behavioural Science and Health McBride, Emily; University College London, Health Behaviour Research Centre Rockliffe, Lauren; The University of Manchester, School of Health Sciences, Faculty of Biology, Medicine and Health Kitchener, Henry; University of Manchester Waller, Jo; King's College London, Cancer Prevention Group, School of Cancer and Pharmaceutical Sciences; UCL, Research Department of Behavioural Science and Health
Primary Subject Heading:	Public health
Secondary Subject Heading:	Qualitative research
Keywords:	Public health < INFECTIOUS DISEASES, PREVENTIVE MEDICINE, PRIMARY CARE, QUALITATIVE RESEARCH

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3 **Information needs among women taking part in primary HPV screening in England: A content**
4 **Analysis**
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6 Running title: HPV information needs
7

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Abstract

Objectives: Introducing primary HPV testing to cervical screening programmes means changes to the results women receive. We explored additional information needs among women undergoing HPV primary screening.

Design: Women were sent a postal questionnaire shortly after receiving their results and 6 and 12 months later. Each questionnaire asked if women had any unanswered questions about cervical screening or HPV testing. Free-text responses constituted the data. Themes were identified using Content Analysis.

Setting: NHS Cervical Screening Programme, England

Participants: 381 women who recorded one or more free-text responses.

Results: The most common theme represented women's emotional responses and attempts to understand their results. This theme was raised by 45% of women overall, but was as high as 59% in the HPV cleared group. General questions about the cause and epidemiology of HPV were raised by 38% of women and were more common among those testing HPV Positive with normal cytology (52%). Questions about the purpose and procedure for HPV testing were most common among HPV-negative women (40%, compared to 16%-25% of the other results groups). Questions about future implications of test results, were raised by 20% of women, and this theme was most common among those with persistent HPV.

Conclusions: Despite provision of information alongside screening invitations, women can still have unanswered questions following receipt of their results. Details about the epidemiology of HPV and why cervical screening procedures are changing should be included with screening invitations. Some results groups may benefit from additional tailored information with their result letter.

Strengths and limitations of this study

- The study benefits from the inclusion of participants who had been tested for HPV as part of routine HPV primary cervical screening
- Participants had a range of HPV and cytology screening results which allowed us to compare information needs between results groups,
- Two thirds of women did not leave a free-text response.
- Questionnaires were completed at least two weeks after receiving results so women participants may already have sought additional information.
- Those with less education were less likely to leave a free-text comment.

Keywords

cervical screening, HPV testing, information, informed choice, concerns, misunderstanding

Introduction

Cervical screening programmes have traditionally involved looking for abnormal cytology but HPV primary screening can provide many benefits [1] and has already replaced cytology-based cervical screening in England, Australia, the Netherlands and Wales, and several other countries are expected to follow in the coming years [2,3]. HPV testing looks for presence of the HPV virus. Where HPV is found the sample is looked at for cytology. Women with HPV positive/abnormal cytology results are referred for colposcopy, women with HPV positive/normal cytology are recalled 12 months later. Based on a large pilot study in England, around 13% of women aged 25-64 years will be told they are HPV positive [4,5], compared with ~6% who currently receive an abnormal cytology result (with or without HPV). These figures are expected to decrease somewhat as cohorts offered HPV vaccination move into the programme [6]. Nevertheless, many women will be receiving an HPV positive result, warranting careful consideration of how these results are communicated.

Of particular concern is that some women will be learning about the link between cervical cancer and a sexually transmitted infection (STI) for the first time, which may come as a shock and could raise concerns about sexual relationships [7-9]. In a review of studies exploring understanding of HPV and information needs [10], women found it difficult to incorporate new information about HPV testing into their pre-existing understanding of cervical screening and often sought additional information after being told they were HPV-positive. The review identified uncertainty about HPV transmission, prevention, symptoms, risk factors (for HPV and cervical cancer), whether HPV could cause other cancers, treatment, fertility and the natural history of the virus. However, most of the studies included were small qualitative studies carried out before 2007, half of which used samples of women who had not actually been tested for HPV. More recently, qualitative interviews with women who were told they were HPV positive in an HPV self-sampling trial, identified some key themes: intense affect (feelings and emotions) after receiving positive results, importance of discussing results with a provider, information seeking, confusion about purpose and meaning of HPV versus Pap tests [11].

Establishing women's information needs in the context of primary screening is vital to inform patient education and communication strategies. Clear information provided at the appropriate time-point (e.g. alongside results) may help to minimise the adverse psychological responses to HPV-positive results that have been identified [12]. The aims of this study were to i) identify the information needs of women participating in primary HPV screening and ii) to explore how these might vary

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3 according to women's HPV and cytology results. This study is part of a broader psychological
4 evaluation of HPV primary testing in England [13].
5

6 7 **Methods**

8 9 *Participants*

10 Participants were women aged 24-65 years who attended for cervical screening in England in one of
11 five sites piloting HPV primary testing (between 2016 and 2017). Women testing HPV negative were
12 invited for routine recall, whereas those testing positive had reflexive cytology and were managed
13 accordingly (see Supplementary file 1 for a flow diagram and additional contextual information
14 about cervical screening in England). Recruitment was stratified to ensure data were collected from
15 women receiving different screening results (see Supplementary Figure 2): i) negative for HPV, ii)
16 HPV-positive with normal cytology and iii) HPV-positive with abnormal cytology.
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19 We also recruited two groups of women who had initially tested positive for HPV with normal
20 cytology, and who had re-attended at 12-month follow-up and either iv) had persistent HPV i.e. they
21 were still HPV-positive with normal cytology or v) had cleared the infection i.e. they now tested HPV
22 negative. A group of women undergoing conventional cytology screening were also recruited but we
23 have excluded their data from the present analyses.
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26 27 *Procedure*

28 The data reported here were collected from cross-sectional surveys sent to women at three time
29 points: shortly after receiving their results (baseline), 6-months, and 12-months. The full protocol is
30 available elsewhere [13], but in brief women were contacted by post within two weeks of receiving
31 their screening result letter and invited to complete and return a consent form and questionnaire.
32 Women who returned the questionnaire were also sent questionnaires 6 and 12 months later. The
33 primary outcome measures assessed in the questionnaire were anxiety and general distress [12].
34 Health Research Authority (HRA) approval was granted on 26/09/2016 (Research Ethics Committee
35 reference: 16/LO/0902 and Confidentiality Advisory Group reference: 16/CAG/0047).
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38 39 *Patient and Public Involvement*

40 Neither patients nor the public were involved in the design, conduct, analysis or interpretation of
41 this study.
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44 45 *Measures*

46 At each of the three time-points, women were asked "Do you have any unanswered questions about
47 cervical screening or HPV testing?" and space for an open response was provided. Free-text
48 responses to this question constituted the primary data for analyses. At the end of the baseline
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3 questionnaire there was also a space provided for “any other comments”. Free-text responses
4 recorded here were also included where they were relevant to the aims of this analysis (irrelevant
5 comments were excluded, for example comments about practical aspects of the survey study).
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7 Socio-demographic information including age, marital status, education and ethnicity were also
8 collected. Information on women’s screening results was collected directly from the screening
9 laboratories.
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13 *Analysis*

14 Content analysis was used to explore women’s free-text responses. Responses from all three time
15 points were analysed together. Content analysis can be defined as “subjective interpretation of the
16 content of text data through the systematic classification process of coding and identifying themes”
17 [14]. Responses were typed into an excel spreadsheet and two authors (LR and EM) immersed
18 themselves in the baseline data. An initial coding frame was developed using an inductive,
19 conventional content analysis approach (i.e. avoiding preconceived categories) [15]. Three senior
20 members of the research team then coded the data for 20% of the baseline participants (n=60),
21 before refining the coding frame. All responses (from each time point) were then independently
22 double coded. Any discrepancies were discussed. Multiple codes were allocated to individual
23 responses when appropriate. We used 2-by-5 chi-square tests to explore differences in the
24 proportion of women citing each major theme by result group. Sub-themes are reported
25 descriptively.
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36 **Results**

37 Overall 921 women who had undergone HPV primary screening returned their baseline
38 questionnaire (see Figure 2). A total of 507 free-text responses were recorded (baseline=329/921, 6
39 months=110/762 and 12 months =68/537). Women testing HPV-positive with normal cytology and
40 those with persistent HPV were most likely to leave a free-text response (50%); HPV-negative
41 women were least likely (26%) to do so. Free-text responses were also more common among
42 women in the youngest age group and those with a degree qualification (see Table 1 for sample
43 characteristics). We have described each theme below with the prevalence of themes reported in
44 Table 2 (overall and by results group). Illustrative examples of women’s comments are presented in
45 Table 3.
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54 *Reaction to and understanding of results*

55 Across all results groups (except HPV-negative), the most common theme was ‘reaction to and
56 understanding of results’. This theme was most frequently present in comments made by HPV
57 positive women (with normal or abnormal cytology, 51% and 54% respectively) and by women who
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3 had cleared HPV at 12-months (59%). Women expressed a wide range of emotional responses to
4 their results including shock, worry and relief. Comments included questions about the exact
5 meaning of their result, including clarification about which HPV type they had. Implications for
6 sexual relationships were raised by a number of women, including requests for clarification of what
7 their result meant for future sexual relationships, concern about re-infection within a relationship
8 and the possible consequences of infection for their partner. A lack of confidence in HPV results and
9 requests for cytology were recorded by 5% of women (12% of women who were HPV negative and
10 21% had cleared HPV). Having previously experienced an abnormal result or approaching the end of
11 cervical screening eligibility were reasons that women gave for concern about not having a cytology
12 test.

20 *Questions about HPV and cervical cancer*

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22 Over a third of women who left a comment recorded a question about HPV (38%) and this was more
23 common among women who were HPV-positive with normal cytology (52%) or who had persistent
24 HPV (41%). Women asked about various aspects of HPV epidemiology including questions about the
25 timeline of infection, latency and clearance. Women's questions about HPV also included requests
26 for clarification about the cause of their HPV, frequently including references to their long-term or
27 sexual relationships. The potential for preventing future HPV infections and treating current ones
28 was also raised. Some women expressed a more general lack of understanding about HPV, saying
29 they had never heard of it or did not know what it was.

30
31 A smaller number of women provided comments about cervical cancer (14% across all results
32 groups). A range of general questions were raised about the risk of developing cervical cancer. Some
33 women also asked about other specific causal risk factors for cervical cancer (e.g. polycystic ovary
34 syndrome, contraceptive implants, previous cancer diagnosis or treatment).

43 *Purpose and procedure for HPV testing*

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45 'Purpose and procedure for HPV testing' was the most common theme for HPV-negative women
46 (40%) but was also raised by HPV-positive women (16-24%) and women who had cleared HPV (24%).
47 Questions about the purpose of HPV testing were predominantly to clarify how HPV testing fit with
48 their existing knowledge of cervical screening, but some women mentioned being unaware they had
49 been tested for HPV until they received their results. Some HPV-negative women wanted to clarify
50 whether their sample had been cytology tested or why cytology was not also performed.

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52 Women also made comments about the timing of tests, particularly in relation to repeat HPV
53 testing. They wanted to be reassured that the recommended intervals were 'soon enough' or
54 'adequate'. Several women also commented on the delivery of their results, for example saying that
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3 the results had not been clear from the letter they received and that further discussion with their GP
4 had been needed.
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6 7 *Future implications of test results* 8

9 The theme 'Future implications of the results' was identified in 19% of the comments and was most
10 commonly recorded for women with persistent HPV (30%). These comments related specifically to
11 clinical management, with requests for clarification about what would happen next for them.
12 Implications for fertility, for their partners being tested and advice on clearing HPV was mentioned
13 by a few women.
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20 21 *Information seeking and (di)satisfaction* 22

23 Some women described their experiences of seeking additional information about HPV. This
24 predominantly included experiences of searching online or contacting their GP surgery to discuss
25 their result further (with a GP or nurse) and was recorded for 22% of those leaving a comment. A
26 number of women indicated satisfaction, or more commonly lack of satisfaction, with the
27 information they had received.
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30 31 **Discussion** 32

33 This study found women undergoing primary HPV testing for cervical screening can have additional
34 information needs after receiving their results. Requests for more information about the
35 epidemiology and cause of HPV were common across all results groups, so this seems to be
36 important information to communicate to women taking part in screening. Other questions were
37 more common among women receiving particular results; for example women receiving an HPV
38 positive result (with normal cytology) often had questions about the meaning of this result and
39 wanted advice about the implications for sexual relationships. Women with abnormal cytology
40 seemed to have fewer questions about HPV and the meaning of their result. This may in part be
41 because they had been referred for colposcopy and even if they had not yet attended and had the
42 opportunity to ask questions, they would have received an additional information leaflet with their
43 results letter. They did, however, express more worry and concern. These differences suggest there
44 may be merit in including results-tailored information alongside the delivery of results. However,
45 the wide range of themes identified and the personalised nature of many questions means
46 signposting to additional information will also be important.
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56
57 Some of our themes relating to women's understanding of HPV and cervical cancer were similar to
58 other studies [9,10], supporting the need to provide women with information about the cause and
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3 epidemiology of HPV. Women's desire to develop a coherent model of what HPV is, the timeline of
4 infection and its cause and consequences is supported by theoretical models of illness
5 representation which suggest that these aspects are important for understanding HPV and cervical
6 cancer and consequently for coping with being given an HPV-positive result [16,17].
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10 Previous studies have suggested that women are often shocked to learn about the sexually
11 transmitted nature of HPV [7,8]. Implications for sexual relationships was not the most common
12 theme identified and while this question was raised by some women (particularly those who test
13 HPV-positive with normal cytology), it is reassuring that this was not more widespread in women's
14 responses. Some themes such as the impact of HPV on fertility or questions about the impact for
15 male partners, were raised by very few women suggesting these are unlikely to be major areas of
16 concern. Studies exploring the psychological impact of testing HPV positive in the context of
17 organised screening show no differences in distress across result groups, but anxiety can be slightly
18 higher in HPV positive women, at least in the short term [e.g. 12, 18].
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26 The main strength of this study is that we included women who had been tested for HPV as part of
27 routine cervical screening, meaning we were able to compare responses across results groups.
28 However, there are some limitations. The overall response rate for the questionnaire was low and of
29 those responding, less than half recorded a free-text response. We cannot be sure if women who
30 chose not to leave a free-text response had no information needs or just did not state them. In
31 addition, since the questionnaires were completed at least two weeks after receiving results, women
32 may already have sought answers to any questions they initially had. It is therefore likely that our
33 study underestimates the number of questions women have upon receiving their result. Women
34 from lower socio-economic backgrounds were less likely to return the questionnaire [12] and those
35 with less education were less likely to leave a free-text comment. It is therefore possible that the
36 results under-represent the concerns of women from lower socio-economic backgrounds. Future
37 research on HPV information needs should focus on these harder to reach groups.
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46 A number of implications arise from this study. Firstly, it is important that women are made aware of
47 HPV before being tested. For some women, including information about HPV in invitation letters will
48 not be sufficient so sample-takers have an important role in ensuring women know they are having
49 an HPV test. In some instances, this may be simply by drawing their attention to the information
50 leaflet that they receive with their screening invitation, but for some women this will lead to
51 additional questions which sample-takers should be prepared to answer.
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57 Secondly, information provided to women alongside their results should ideally be tailored to the
58 result being communicated. Many of the women who were HPV-positive or had recently cleared
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3 HPV had questions about the meaning of their result and some described contacting their GP
4 surgery to discuss this. This is consistent with findings in the US, where women receiving HPV
5 positive results felt a sense of urgency to discuss it with their Health care provider and felt reassured
6 after this had happened [11]. It is important that staff in primary care are well equipped to answer
7 women's questions or to direct them to the best source of information. This may involve answering
8 questions about HPV themselves or directing women to online information materials (e.g. the NHS
9 screening website). In particular, the information needs recorded by women were frequently
10 interlinked with their personal information and medical history, reflecting attempts to make sense of
11 their results. There are likely to be women who want to discuss their specific results and this might
12 also include how their risk relates to their past screening history or other health conditions. For
13 these women, knowing who they can contact (e.g. a specific helpline, a cancer charity helpline, their
14 GP) will be important.

15
16 Finally, for some women there was confusion about why changes were being made to the screening
17 programme and concern about the fact that their sample had not been checked for abnormal cells.
18 It is important to explain why screening is changing and to reassure women that HPV testing is
19 better than cytology, with the changes being made to improve the screening programme. It might
20 also be useful to clarify specifically that this is safe even for women who are at the end of screening
21 (mentioned by some women in their 60s) or those who have previously had abnormal cytology
22 results. The recent public backlash following changes to the cervical screening programme in
23 Australia has highlighted the importance of explaining the rationale behind and safety of changes
24 being made in public health [19].

25
26 Women taking part in HPV-based cervical screening continue to have additional information needs.
27 Information about the epidemiology of HPV, why the cervical screening procedure is changing and
28 the meaning and implications of different results, should be provided in materials accompanying
29 results. Tailored information and signposting to additional materials and resources would also help
30 to ensure women can find the information they need

31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 **Contributorship Statement**

52 JW, LM, AF and HK conceived the study. JW, LM, EM and AF developed the measures. EM, JW and LR
53 managed the project. All authors contributed to the analyses. LM drafted the paper. All authors
54 contributed to the final version of the manuscript. We would like to thank all the laboratory staff
55 who made recruiting for the psychological evaluation possible, as well as Kirsty Bennett and Fatima
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3 Osmani who contributed to recruitment and data entry. We also thank Julieta Patnick for her helpful
4 comments.
5

6 7 **Competing interests**

8 The authors declare no conflict of interest.
9

10 11 **Funding**

12 Our study was funded by Public Health England (PHE). No grant number was given. PHE funded Emily
13 McBride from 03/01/2016 until 30/09/2017. EM was funded by the National Institute for Health
14 Research (NIHR) from 01/10/2017 [grant number DRF-2017-10-105]; the views expressed in this
15 article are not necessarily those of the NHS, the NIHR or the Department of Health and Social Care.
16 JW, LM and AF are funded by Cancer Research UK (grant numbers C7492/A17219 and
17 C49896/A17429).
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23 24 **Data sharing statement**

25 Data is available from the corresponding author upon reasonable request.
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Table 1: Sample characteristics of women participating in HPV primary testing who did and did not record a free-text response during the course of the study (n=921)

	Free-text response recorded at any time		No free-text response recorded		χ^2 (df), p-value
	N	Row %	n	Row %	
Overall	381	41.4	540	58.6	
Result group					
HPV negative	65	26.2	183	73.8	$\chi^2(4)=38.49, p<.001$
HPV positive, cytology normal	126	50.0	129	50.0	
HPV positive, cytology abnormal	67	39.4	103	60.6	
Persistent HPV	91	50.8	88	49.2	
Cleared HPV	29	43.9	37	56.1	
Age					
24-34	171	46.7	195	53.3	$\chi^2(3)=10.63, p=.014$
35-44	66	32.7	136	67.3	
45-54	80	41.0	115	59.0	
55-65	64	41.0	92	59.0	
Marital status*					
Current partner	281	40.7	410	59.3	$\chi^2(1)=.79, p=.375$
No partner	95	44.4	119	55.6	
Education**					
Degree or higher	189	48.8	198	51.2	$\chi^2(2)=14.62, p=.001$
Qualifications below degree	177	36.0	314	64.0	
No formal qualifications	7	38.9	11	61.1	
Ethnicity					
White (British or other)	356	42.7	527	57.3	$\chi^2(1)=4.77, p=.029$
Other ethnicity***	20	28.6	50	71.4	

*Marital status: current partner (married, civil partnership, living with partner, in a relationship) and no partner (single, divorced, widowed). **No formal qualifications included those with no qualifications and those who were still studying with no previous qualifications. ***Other ethnicity includes: Asian/Asian British, Black/African/Caribbean/Black British, Mixed/Multiple ethnic groups, other ethnic group.

NOTE: Where n does not add up to n=921, this is due to missing data

Table 2: Number of women mentioning each major and sub-theme overall and by test result group

	Overall (n=381)	HPV negative (n=65)	HPV positive, cytology normal (n=129)	HPV positive, cytology abnormal (n=67)	Persistent HPV (n=91)	Cleared HPV (n=29)	χ^2 (df), p-value
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Reaction to and understanding of results	170 (45)	11 (17)	69 (54)	34 (51)	39 (43)	17 (59)	$\chi^2(4)=27.72,$.001
Emotional response	85 (22)	5 (8)	28 (22)	24 (36)	18 (20)	10 (35)	
Meaning of results	72 (19)	1 (2)	35 (27)	11 (16)	21 (23)	4 (14)	
Impact on sexual relationships	41 (11)	0	25 (19)	4 (6)	11 (12)	1 (3)	
Confidence in results	20 (5)	8 (12)	4 (3)	1 (2)	1 (1)	6 (21)	
Questions about HPV	143 (38)	8 (12)	67 (52)	20 (30)	37 (41)	11 (38)	$\chi^2(4)=31.13,$ <.001
General lack of understanding	24 (7)	2 (3)	15 (12)	6 (9)	4 (4)	0	
Epidemiology of HPV	63 (17)	2 (3)	30 (23)	5 (8)	20 (22)	6 (21)	
Cause of HPV	32 (8)	1 (2)	20 (16)	3 (5)	6 (7)	2 (7)	
Prevention/Treatment of HPV	28 (7)	0	11 (9)	7 (10)	9 (10)	1 (3)	
HPV vaccination	39 (10)	3 (5)	20 (16)	2 (3)	11 (12)	3 (10)	
Questions about cervical cancer	52 (14)	5 (8)	24 (19)	7 (10)	14 (15)	2 (7)	$\chi^2(4)=6.58,$.160
Risk of cervical cancer	45 (12)	3 (3)	20 (16)	7 (10)	14 (15)	2 (7)	
Other cervical cancer risk factors	14 (4)	3 (5)	7 (5)	1 (2)	2 (2)	1 (3)	
Purpose and procedure for HPV testing	85 (22)	26 (40)	20 (16)	16 (24)	16 (18)	7 (24)	$\chi^2(4)=16.51,$.002
Purpose	22 (6)	11 (17)	5 (4)	4 (6)	2 (2)	0	
Procedure	18 (5)	10 (15)	3 (2)	1 (2)	0	4 (14)	
Timing	36 (9)	4 (6)	12 (9)	5 (8)	11 (12)	4 (14)	
Delivery of results	15 (4)	4 (6)	1 (1)	7 (10)	3 (3)	0	
Future implications of test results	73 (19)	1 (2)	30 (23)	10 (15)	27 (30)	5 (17)	$\chi^2(4)=21.76,$ <.001
Clinical management	39 (10)	1(2)	14(11)	4 (6)	19 (21)	1 (4)	
Fertility/sexual health	13 (3)	0	5 (4)	1 (3)	3 (3)	3 (10)	
Advice on clearing HPV	18 (5)	0	10 (8)	2 (3)	5 (6)	1 (3)	
Testing for partners	7 (2)	0	4 (3)	2 (3)	1 (1)	0	
Information seeking/(di)satisfaction	85 (22)	8 (12)	37 (29)	14 (21)	22 (24)	4 (14)	$\chi^2(4)=8.25,$.083
Information seeking	30 (8)	3 (5)	15 (12)	7 (10)	5 (6)	0	
(Di)satisfaction	73 (19)	6 (9)	31 (24)	12 (18)	20 (22)	4 (14)	

Table 3: Examples of each quote

Reaction to and understanding of results	
Emotional response	<p><i>"I am very worried in case I end up with cervical cancer"</i> [HPV+, cyto norm; 55-65 years]</p> <p><i>"I feel quite distressed about the results and the letter ... has caused me stress and anxiety"</i> [HPV+, cyto abnorm; 24-34 years]</p> <p><i>"I was advised I do not have HPV, I have had this persistently for years, I am so relieved"</i> [HPV cleared; 24-34 years]</p>
Confidence in results	<p><i>"I have a family history of abnormal cells being found, but I was not tested for anything other than HPV. I would like to have a further test to confirm no abnormal cells"</i> [HPV-; 35-44 years]</p> <p><i>"Because I have previously had abnormal cells... I was not reassured by my HPV-negative result"</i> [HPV-; 45-54 years]</p> <p><i>"I am uneasy about the fact that cells have not been checked for abnormality, especially as no further tests will be offered to me"</i> [HPV -; 55-65 years]</p>
Meaning of results	<p><i>"I was cleared of HPV last year, why has it come back?"</i> [HPV+, cyto norm; 45-54 years]</p> <p><i>"I have had two smears now both HPV-positive. How long can a person be HPV-positive for HPV?"</i> [HPV persistent; 45-54 years]</p> <p><i>"My previous test was positive and this one was negative. Does this mean it is still present but not active?"</i> [HPV cleared; 24-34 years] <i>"I caught genital warts at 23 - is this somehow different?"</i> [HPV+, cyto norm; 24-34 years]</p>
Impact on sexual relationships	<p><i>"Not sure what this means for future sexual relationships"</i> [HPV+, cyto abnorm; 24-34 years]</p> <p><i>"Can it be perpetuated by continuously being passed from one partner to the other?"</i> [HPV+, cyto norm; 55-65 years]</p> <p><i>"Should I tell sexual partners?"</i> [HPV+, cyto norm; 24-34 years]</p> <p><i>"Initially I worried about what my husband would think"</i> [HPV persistent; 55-65 years]</p> <p><i>"I blame my partner for this"</i> [HPV+, cyto norm; 35-44 years]</p>
Questions about HPV	
General lack of understanding	<p><i>"I didn't even know I had been tested for HPV. Have never heard of it before"</i> [HPV+, cyto norm; 35-44 years]</p> <p><i>"I don't really understand what HPV is"</i> [HPV+, cyto norm; 24-34 years]</p>
Epidemiology of HPV	<p><i>"How long does HPV last? What will happen if it doesn't go away?"</i> [HPV+, cyto norm; 24-34 years]</p> <p><i>"Has it gone and come back again or have I had it for 3 years?"</i> [HPV+, cyto norm; 35-44 years]</p> <p><i>"I'm still unclear as to what makes some peoples CIN1 cells disappear while others develop further"</i> [HPV+, cyto abnorm; 35-44 years]</p> <p><i>"Will it ever go away? Or get worse?"</i> [HPV persistent; 55-65 years]</p>
Cause of HPV	<p><i>"I don't understand how I have got HPV"</i> [HPV+, cyto norm; 24-34 years]</p> <p><i>"I have not been sexually active for 6 years and can't understand why I have got it with only having one long-term partner"</i> [HPV+, cyto abnorm; 35-44 years]</p>
Prevention/treatment for HPV	<p><i>"Should I now always use condoms for sex?"</i> [HPV+, cyto norm; 24-34 years]</p> <p><i>"Is there something I can take to get rid of HPV?"</i> [HPV+, cyto norm; 35-44 years]</p> <p><i>"Are there really no ways to treat the HPV virus?"</i> [HPV persistent; 55-65 years]</p>

HPV vaccination	<p><i>"I had the HPV vaccine, why didn't it work?"</i> [HPV+, cyto norm; 24-34 years]</p> <p><i>"I'd like to know if I could be offered the vaccine and whether it would work for me"</i> [HPV+, cyto norm; 35-44 years]</p> <p><i>"I have been considering having the vaccine but unsure of benefits at my age"</i> [HPV cleared; 35-44 years]</p>
Questions about cervical cancer	
Risk of cervical cancer	<p><i>"What are the chances of this becoming cancerous?"</i> [HPV+, cyto norm; 55-65 years]</p> <p><i>"What proportion of women who have had 2 smears detecting high risk HPV will go on to develop cervical cancer?"</i> [HPV persistent; 45-54 years]</p>
Other cervical cancer risk factors	<p><i>"There is a vast history of cancer in my family. Am I more likely to get cancer?"</i> [HPV+, cyto norm; 55-65 years]</p> <p><i>"I have a contraception implant - does this affect HPV or my chances of developing cervical cancer"</i> [HPV+, cyto norm; 24-34 years]</p>
Purpose and procedure for HPV testing	
Purpose	<p><i>"I am not sure if HPV test covers more, less or the same as a normal smear test"</i> [HPV-; 45-54 years]</p> <p><i>"I do not know if one is more thorough and effective than the other"</i> [HPV-; 35-44 years]</p> <p><i>"Was given no information that would be a different test other than smear"</i> [HPV+, cyto norm; 45-54 years]</p>
Procedure	<p><i>"Was the HPV an additional test in addition to a normal smear test?"</i> [HPV-; 45-54 years]</p> <p><i>"Why when HPV is not present they don't test the sample"</i> [HPV cleared; 24-34 years]</p>
Timing	<p><i>"Why can't I be re-tested in 6 months instead of waiting another year?"</i> [HPV+, cyto norm; 45-54 years]</p> <p><i>"Is having my next smear in 1 year soon enough? Could my cells change quickly enough to be cancerous before then?"</i> [HPV+, cyto norm; 45-54 years]</p> <p><i>"I would like to be reassured that the intervals between tests are adequate to pick up any changes to my body"</i> [HPV cleared; 35-44 years]</p>
Delivery of results	<p><i>"I haven't received a letter with my results and I don't ever recall receiving results"</i> [HPV-; 35-44 years]</p> <p><i>"I had lots of questions that I could not get answered because results come in letter form"</i> [HPV+, cyto abnorm; 24-34 years]</p>
Future implications of test results	
Clinical management	<p><i>"My test was positive two times and I want to meet a specialist"</i> [HPV+, cyto norm; 45-54 years]</p> <p><i>"I had a second positive HPV and have not been invited for further testing which the nurse said I would be. I am wondering why"</i> [HPV persistent; 55-65 years]</p> <p><i>"Am I now having a colposcopy because I have had HPV for 2 years?"</i> [HPV persistent; 45-54 years]</p>
Fertility/sexual health	<p><i>"I am due a second test in 1 years time, but I am hopefully aiming to be pregnant around then, is this a major problem?"</i> [HPV+, cyto norm; 24-34 years]</p> <p><i>"Will it increase my chances of miscarriage?"</i> [HPV persistent; 24-34 years]</p>
Advice on clearing HPV	<p><i>"What can I do in the next 12 months to help myself?"</i> [HPV+, cyto norm; 24-34 years]</p> <p><i>"Is there anything I can do to stop HPV developing into cancer?"</i> [HPV persistent; 24-34 years]</p>

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Testing for partners	<i>Why men don't get test for it if they can transmit it?</i> [HPV+, cyto abnorm; 24-34 years]
Information seeking and (di)satisfaction	
Information seeking	<i>"I contacted my GP for more information"</i> [HPV+, cyto norm; 24-34 years]
(Di)satisfaction	<i>"It's not explained in a very useful manner"</i> [HPV persistent; 24-34 years]
	<i>"I want to have more information about HPV"</i> [HPV+, cyto norm; 45-54 years]
	<i>"On receiving letter about results I felt I had lots of questions that I could not get answered"</i> [HPV+, cyto abnorm; 24-34 years]

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Supplementary File 1 – additional information on HPV primary screening in England

Figure 1 – flow chart of HPV primary screening in the English HPV primary screening pilot sites

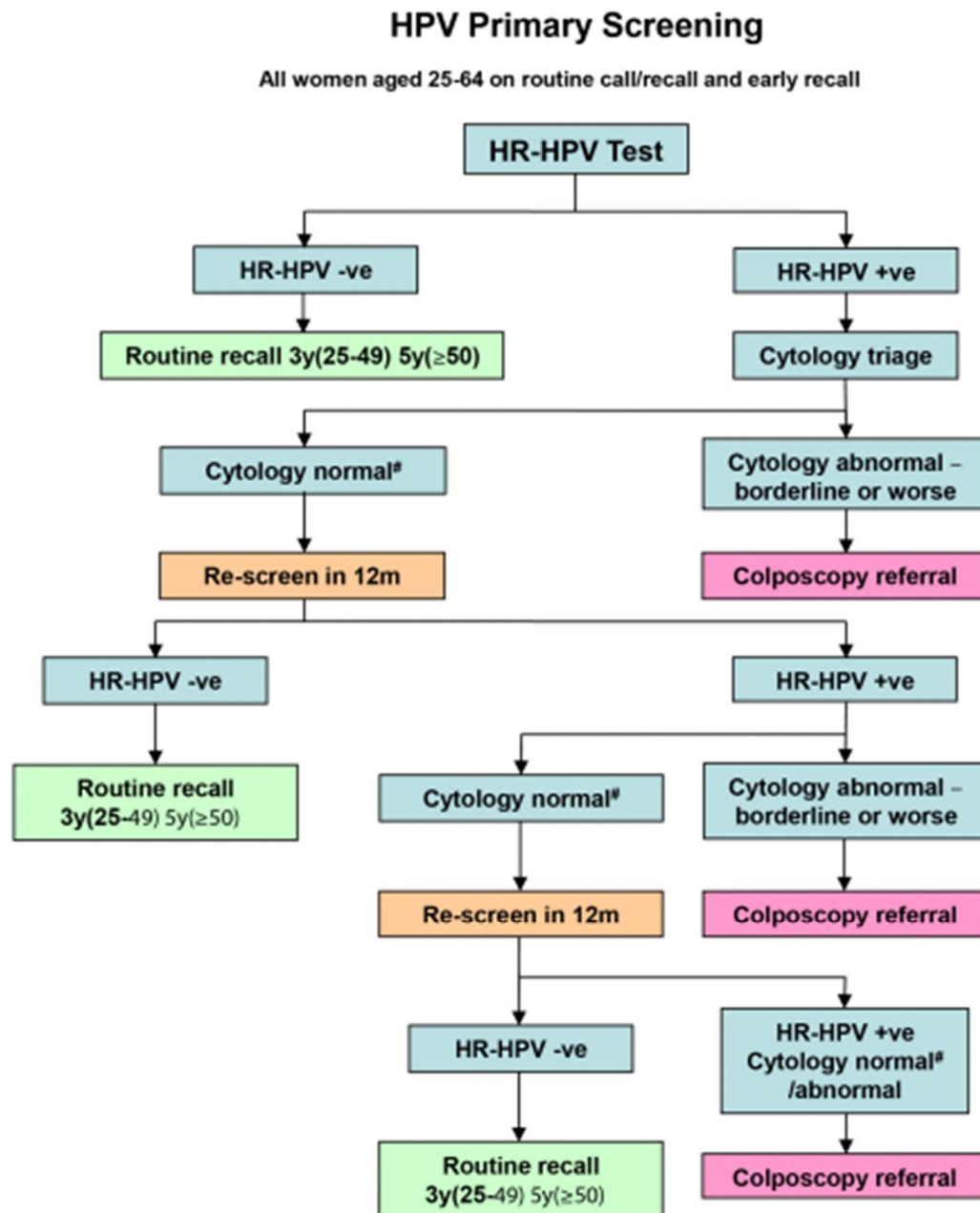


Figure from <https://phscreening.blog.gov.uk/2017/06/14/what-gps-need-to-know-about-the-introduction-of-primary-hpv-testing-in-cervical-screening/>

Additional information

Cervical screening in England is organised as a national call-recall programme and is free at the point of use. From the age of 24.5 years, women are invited for screening by letter every three years until age 49 years and every five years from age 49-64 years. The invitation is sent in the post and includes a leaflet with further information on cervical cancer, HPV and the screening procedure

(https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/871893/Cervical_screening_helping_you_decide.pdf).

Screening is usually carried out by a nurse at a woman's general practice (GP) surgery but may sometimes be delivered at a sexual health or well-woman clinic. Women receive their screening results by post and if they are

referred for colposcopy, they also receive a colposcopy leaflet

(<https://www.gov.uk/government/publications/cervical-screening-colposcopy/cervical-screening-having-a-colposcopy>).

As HPV primary screening was first piloted in certain areas and then rolled out gradually across England over the course of a year, there was no public health campaign to launch HPV primary screening.

The current study took place in the context of the HPV primary screening pilot, where women were sent the following information about HPV testing with their invitation.

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NHS Cervical Screening Programme

HPV primary screening

This leaflet tells you about HPV primary screening. This is a test carried out on the sample of cells we take during cervical screening.

- HPV stands for 'human papillomavirus'.
- Primary screening means that it is the first test carried out on the sample of cells from your cervical screening.

HPV primary screening makes no difference to how your screening sample is taken.

For more information about going for screening, please read our leaflet *NHS cervical screening*.

Why have I been sent this leaflet?

You live in an area where HPV primary screening is being used in the NHS Cervical Screening Programme. This isn't happening everywhere in England yet.

What is HPV?

The human papillomavirus (HPV) is very common. Most women get it at some point in their lives. There are many types of HPV, and most of them clear up by themselves without causing any problems. However, some types can cause cells in the cervix to change and become abnormal. These abnormal changes can, if left untreated, go on to turn into cervical cancer.

HPV is easily passed on during intimate sexual contact between partners; between men and women and between partners of the same sex. The virus has no symptoms. This means that you or a partner may have had HPV for many months or years without knowing it.

What is HPV primary screening?

Once your cervical screening sample is sent to the laboratory, the first test carried out on it will be to look for HPV. If HPV is found, your sample will also be looked at for abnormal cells. Looking for abnormal cells is called 'cytology'. Cytology is still the test used for most cervical screening at the moment. If you don't have HPV, then it is extremely unlikely that you will have any abnormal cervical cells.

HPV primary screening should benefit women because:

- more abnormal cervical cells will be picked up
- women without HPV can be reassured that they are at extremely low risk of developing cervical cancer.

Are all women being offered HPV primary screening?

Not yet. We are starting HPV primary screening in a few areas from 2013. This is to help us plan how this change to the screening programme can be put in place across the whole of England.

In places where HPV primary screening isn't being used yet, women will either

- not have an HPV test or
- have an HPV test only after their sample has been checked for abnormal cells (cytology).

What screening results might I get?

There are three main types of results from HPV primary screening.

No HPV found (HPV negative)

If no HPV is found, then no further tests will be carried out. If you don't have HPV, then it is highly unlikely that you will have any abnormal cervical cells. Even if you did, it would be extremely unlikely that they would cause a problem. You will simply be called back for screening again in three or five years' time (depending on your age).

HPV found (HPV positive) but no abnormal cervical cells found

If HPV is found, the sample will also be tested for abnormal cervical cells. If none are found, your result will say you have HPV, but no abnormal cells. You will be asked to come back for screening again in 12 months' time. This is so we can check that the HPV has been cleared by your immune system. If it hasn't cleared, you may be at greater risk of developing abnormal cervical cells.

HPV found (HPV positive) and abnormal cervical cells found

There are several grades of abnormal cells. Some are more serious than others. You can read about this in our leaflet *What your abnormal result means*. If you have HPV and any grade of abnormal cervical cells, then you will be referred for colposcopy. Colposcopy is a closer examination of the cervix. It is carried out in much the same way as cervical screening. For

more information, you can read our leaflet *The colposcopy examination*.

It is also possible to have an 'inadequate' result. This is when the laboratory cannot get an HPV test result from your sample, or cannot see if abnormal cells are present or not. If you have an inadequate result, you may be asked to have cervical screening again in three months' time. The delay is so that there are enough cells again to get a sample from.

Can I get treatment for HPV?

No, there isn't a treatment to get rid of the virus. For most women, their immune system will get rid of HPV – like getting rid of a common cold. But we can treat abnormal cervical cells, especially if they are found early on. Most types of cervical cancer take a long time to develop. Treating abnormal cells early on means that cervical cancer can be prevented.

Where can I get more information?

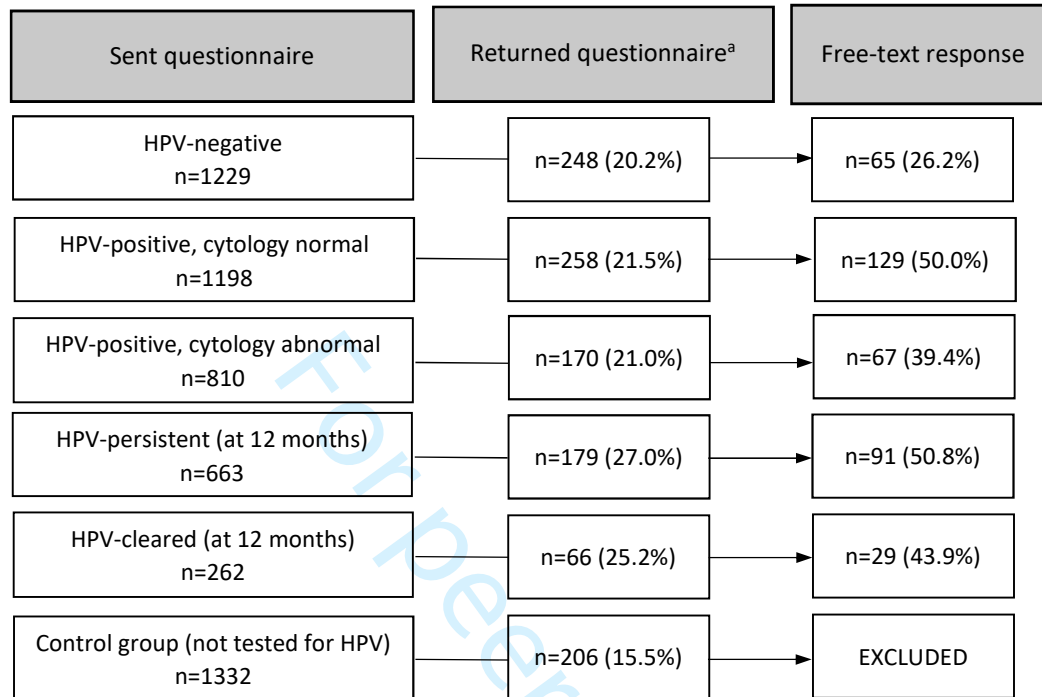
If you would like more information about HPV primary screening, or anything else in this leaflet, you can

- talk to the nurse at your GP practice;
- visit our website at www.cancerscreening.nhs.uk/cervical

Copies of the leaflets mentioned can also be downloaded from our website.

A large print version of this leaflet is available at www.cancerscreening.nhs.uk/cervical

Supplementary Figure 2: Overall response rate and proportion of women leaving a free-text response during the course of the study



^a Excluding questionnaires that were returned late or where participants were an ineligible age (n=21).

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3 **Information needs among women taking part in primary HPV screening in England: A content**
4 **Analysis**
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6 Running title: HPV information needs
7

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Abstract

Objectives: Introducing primary HPV testing to cervical screening programmes means changes to the results women receive. We explored additional information needs among women undergoing HPV primary screening.

Design: Women were sent a postal questionnaire shortly after receiving their results and 6 and 12 months later. Each questionnaire asked if women had any unanswered questions about cervical screening or HPV testing. Free-text responses constituted the data. Themes were identified using Content Analysis.

Setting: NHS Cervical Screening Programme, England

Participants: 381 women who recorded one or more free-text responses.

Results: The most common theme represented women's emotional responses and attempts to understand their results. This theme was raised by 45% of women overall, but was as high as 59% in the HPV cleared group. General questions about the cause and epidemiology of HPV were raised by 38% of women and were more common among those testing HPV Positive with normal cytology (52%). Questions about the purpose and procedure for HPV testing were most common among HPV-negative women (40%, compared to 16%-25% of the other results groups). Questions about future implications of test results, were raised by 20% of women, and this theme was most common among those with persistent HPV.

Conclusions: Despite provision of information alongside screening invitations, women can still have unanswered questions following receipt of their results. Details about the epidemiology of HPV and why cervical screening procedures are changing should be included with screening invitations. Some results groups may benefit from additional tailored information with their result letter.

Strengths and limitations of this study

- The study benefits from the inclusion of participants who had been tested for HPV as part of routine HPV primary cervical screening
- Participants represented had a range of test-HPV and cytology screening results which allowed us to compare information needs between results groups,
- Two thirds of women did not leave a free-text response.
- Questionnaires were completed at least two weeks after receiving results so women participants may already have sought additional information.
- Those with less education were less likely to leave a free-text comment.

Keywords

cervical screening, HPV testing, information, informed choice, concerns, misunderstanding

Introduction

Cervical screening programmes have traditionally involved looking for abnormal cytology but HPV primary screening can provide many benefits [1] and has already replaced cytology-based cervical screening in England, Australia, the Netherlands and Wales, and several other countries are expected to follow in the coming years [2,3]. HPV testing looks for presence of the HPV virus. Where HPV is found the sample is looked at for cytology. Women with HPV positive/abnormal cytology results are referred for colposcopy, women with HPV positive/normal cytology are recalled 12 months later. Based on a large pilot study in England, around 13% of women aged 25-64 years will be told they are HPV positive [4,5], compared with ~6% who currently receive an abnormal cytology result (with or without HPV). These figures are expected to decrease ~~dramatically~~ somewhat as cohorts offered HPV vaccination move into the programme [6]. Nevertheless, many women will be receiving an HPV positive result, warranting careful consideration of how these results are communicated.

Of particular concern is that some women will be learning about the link between cervical cancer and a sexually transmitted infection (STI) for the first time, which may come as a shock and could raise concerns about sexual relationships [76-98]. In a review of studies exploring understanding of HPV and information needs [109], women found it difficult to incorporate new information about HPV testing into their pre-existing understanding of cervical screening and often sought additional information after being told they were HPV-positive. The review identified uncertainty about HPV transmission, prevention, symptoms, risk factors (for HPV and cervical cancer), whether HPV could cause other cancers, treatment, fertility and the natural history of the virus. However, most of the studies included were small qualitative studies carried out before 2007, half of which used samples of women who had not actually been tested for HPV. More recently, qualitative interviews with women who were told they were HPV positive in an HPV self-sampling trial, identified some key themes: intense affect (feelings and emotions) after receiving positive results, importance of discussing results with a provider, information seeking, confusion about purpose and meaning of HPV versus Pap tests [110].

Establishing women's information needs in the context of primary screening is vital to inform patient education and communication strategies. Clear information provided at the appropriate time-point (e.g. alongside results) may help to minimise the adverse psychological responses to HPV-positive results that have been identified [121]. The aims of this study were to i) identify the information

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3 needs of women participating in primary HPV screening and ii) to explore how these might vary
4 according to women's HPV and cytology results. This study is part of a broader psychological
5 evaluation of HPV primary testing in England [132].
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8 **Methods**

9 *Participants*

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11 Participants were women aged 24-65 years who attended for cervical screening in England in one of
12 five sites piloting HPV primary testing (between 2016 and 2017). Women testing HPV negative were
13 invited for routine recall, whereas those testing positive had reflexive cytology and were managed
14 accordingly (see Supplementary file 1 for a flow diagram and additional contextual information
15 about cervical screening in England). Recruitment was stratified to ensure data were collected from
16 women receiving different screening results (see Supplementary Figure 21): i) negative for HPV, ii)
17 HPV-positive with normal cytology and iii) HPV-positive with abnormal cytology.
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21 We also recruited two groups of women who had initially tested positive for HPV with normal
22 cytology, and who had re-attended at 12-month follow-up and either iv) had persistent HPV i.e. they
23 were still HPV-positive with normal cytology or v) had cleared the infection i.e. they now tested HPV
24 negative. A group of women undergoing conventional cytology screening were also recruited but we
25 have excluded their data from the present analyses.
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28 *Procedure*

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30 The data reported here were collected from cross-sectional surveys sent to women at three time
31 points: shortly after receiving their results (baseline), 6-months, and 12-months. The full protocol is
32 available elsewhere [132], but in brief women were contacted by post within two weeks of receiving
33 their screening result letter and invited to complete and return a consent form and questionnaire.
34 Women who returned the questionnaire were also sent questionnaires 6 and 12 months later. The
35 primary outcome measures assessed in the questionnaire were anxiety and general distress [124].
36 Health Research Authority (HRA) approval was granted on 26/09/2016 (Research Ethics Committee
37 reference: 16/LO/0902 and Confidentiality Advisory Group reference: 16/CAG/0047).
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40 *Patient and Public Involvement*

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42 We did not use any PNeither patients or the public involvement were involved in the design,
43 conduct, analysis or reporting interpretation of this study.
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46 *Measures*

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48 At each of the three time-points, women were asked "Do you have any unanswered questions about
49 cervical screening or HPV testing?" and space for an open response was provided. Free-text
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3 responses to this question constituted the primary data for analyses. At the end of the baseline
4 questionnaire there was also a space provided for “any other comments”. Free-text responses
5 recorded here were also included where they were relevant to the aims of this analysis (irrelevant
6 comments were excluded, for example comments about practical aspects of the survey study).
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8 Socio-demographic information including age, marital status, education and ethnicity were also
9 collected. Information on women’s screening results was collected directly from the screening
10 laboratories.
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15 *Analysis*

16 Content analysis was used to explore women’s free-text responses. Responses from all three time
17 points were analysed together. Content analysis can be defined as “subjective interpretation of the
18 content of text data through the systematic classification process of coding and identifying themes”
19 [143]. Responses were typed into an excel spreadsheet and two authors (LR and EM) immersed
20 themselves in the baseline data. An initial coding frame was developed using an inductive,
21 conventional content analysis approach (i.e. avoiding preconceived categories) [154]. Three senior
22 members of the research team then coded the data for 20% of the baseline participants (n=60),
23 before refining the coding frame. All responses (from each time point) were then independently
24 double coded. Any discrepancies were discussed. Multiple codes were allocated to individual
25 responses when appropriate. We used 2-by-5 chi-square tests to explore differences in the
26 proportion of women citing each major theme by result group. Sub-themes are reported
27 descriptively.
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37 **Results**

38 Overall 921 women who had undergone HPV primary screening returned their baseline
39 questionnaire (see Figure 21). A total of 507 free-text responses were recorded (baseline=329/921, 6
40 months=110/762 and 12 months =68/537). Women testing HPV-positive with normal cytology and
41 those with persistent HPV were most likely to leave a free-text response (50%); HPV-negative
42 women were least likely (26%) to do so. Free-text responses were also more common among
43 women in the youngest age group and those with a degree qualification (see Table 1 for sample
44 characteristics). We have described each theme below with the prevalence of themes reported in
45 Table 2 (overall and by results group). Illustrative examples of women’s comments are presented in
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55 *Reaction to and understanding of results*

56 Across all results groups (except HPV-negative), the most common theme was ‘reaction to and
57 understanding of results’. This theme was most frequently present in comments made by HPV
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3 positive women (with normal or abnormal cytology, 51% and 54% respectively) and by women who
4 had cleared HPV at 12-months (59%). Women expressed a wide range of emotional responses to
5 their results including shock, worry and relief. Comments included questions about the exact
6 meaning of their result, including clarification about which HPV type they had. Implications for
7 sexual relationships were raised by a number of women, including requests for clarification of what
8 their result meant for future sexual relationships, concern about re-infection within a relationship
9 and the possible consequences of infection for their partner. A lack of confidence in HPV results and
10 requests for cytology were recorded by 5% of women (12% of women who were HPV negative and
11 21% had cleared HPV). Having previously experienced an abnormal result or approaching the end of
12 cervical screening eligibility were reasons that women gave for concern about not having a cytology
13 test.
14

15 *Questions about HPV and cervical cancer*

16 Over a third of women who left a comment recorded a question about HPV (38%) and this was more
17 common among women who were HPV-positive with normal cytology (52%) or who had persistent
18 HPV (41%). Women asked about various aspects of HPV epidemiology including questions about the
19 timeline of infection, latency and clearance. Women's questions about HPV also included requests
20 for clarification about the cause of their HPV, frequently including references to their long-term or
21 sexual relationships. The potential for preventing future HPV infections and treating current ones
22 was also raised. Some women expressed a more general lack of understanding about HPV, saying
23 they had never heard of it or did not know what it was.
24

25 A smaller number of women provided comments about cervical cancer (14% across all results
26 groups). A range of general questions were raised about the risk of developing cervical cancer. Some
27 women also asked about other specific causal risk factors for cervical cancer (e.g. polycystic ovary
28 syndrome, contraceptive implants, previous cancer diagnosis or treatment).
29

30 *Purpose and procedure for HPV testing*

31 'Purpose and procedure for HPV testing' was the most common theme for HPV-negative women
32 (40%) but was also raised by HPV-positive women (16-24%) and women who had cleared HPV (24%).
33 Questions about the purpose of HPV testing were predominantly to clarify how HPV testing fit with
34 their existing knowledge of cervical screening, but some women mentioned being unaware they had
35 been tested for HPV until they received their results. Some HPV-negative women wanted to clarify
36 whether their sample had been cytology tested or why cytology was not also performed.
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38 Women also made comments about the timing of tests, particularly in relation to repeat HPV
39 testing. They wanted to be reassured that the recommended intervals were 'soon enough' or
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3 'adequate'. Several women also commented on the delivery of their results, for example saying that
4 the results had not been clear from the letter they received and that further discussion with their GP
5 had been needed.
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8 *Future implications of test results*

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10 The theme 'Future implications of the results' was identified in 19% of the comments and was most
11 commonly recorded for women with persistent HPV (30%). These comments related specifically to
12 clinical management, with requests for clarification about what would happen next for them.
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14 Implications for fertility, for their partners being tested and advice on clearing HPV was mentioned
15 by a few women.
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22 *Information seeking and (di)satisfaction*

23 Some women described their experiences of seeking additional information about HPV. This
24 predominantly included experiences of searching online or contacting their GP surgery to discuss
25 their result further (with a GP or nurse) and was recorded for 22% of those leaving a comment. A
26 number of women indicated satisfaction, or more commonly lack of satisfaction, with the
27 information they had received.
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32 **Discussion**

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34 This study found women undergoing primary HPV testing for cervical screening can have additional
35 information needs after receiving their results. Requests for more information about the
36 epidemiology and cause of HPV were common across all results groups, so this seems to be
37 important information to communicate to women taking part in screening. Other questions were
38 more common among women receiving particular results; for example women receiving an HPV
39 positive result (with normal cytology) often had questions about the meaning of this result and
40 wanted advice about the implications for sexual relationships. Women with abnormal cytology
41 seemed to have fewer questions about HPV and the meaning of their result. This may in part be
42 because they had been referred for colposcopy and even if they had not yet attended and had the
43 opportunity to ask questions, they would have received an additional information leaflet with their
44 results letter. ~~but~~ They did, however, expressed more worry and concern. ~~This~~ These differences
45 suggests there may be merit in including results-tailored information alongside the delivery of
46 results. However, the wide range of themes identified and the personalised nature of many
47 questions means signposting to additional information will also be important.
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3 Some of our themes relating to women's understanding of HPV and cervical cancer were similar to
4 other studies [98,109], supporting the need to provide women with information about the cause and
5 epidemiology of HPV. Women's desire to develop a coherent model of what HPV is, the timeline of
6 infection and its cause and consequences is supported by theoretical models of illness
7 representation which suggest that these aspects are important for understanding HPV and cervical
8 cancer and consequently for coping with being given an HPV-positive result [165,176].
9

10
11 Previous studies have suggested that women are often shocked to learn about the sexually
12 transmitted nature of HPV [76,87]. Implications for sexual relationships was not the most common
13 theme identified and while this question was raised by some women (particularly those who test
14 HPV-positive with normal cytology), it is reassuring that this was not more widespread in women's
15 responses. Some themes such as the impact of HPV on fertility or questions about the impact for
16 male partners, were raised by very few women suggesting these are unlikely to be major areas of
17 concern. [Studies exploring the psychological impact of testing HPV positive in the context of
18 organised screening show no differences in distress across result groups, but anxiety can be slightly
19 higher in HPV positive women, at least in the short term \[e.g. 12, 18\].](#)
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23 The main strength of this study is that we included women who had been tested for HPV as part of
24 routine cervical screening, meaning we were able to compare responses across results groups.
25 However, there are some limitations. The overall response rate for the questionnaire was low and of
26 those responding, less than half recorded a free-text response. We cannot be sure if women who
27 chose not to leave a free-text response had no information needs or just did not state them. In
28 addition, since the questionnaires were completed at least two weeks after receiving results, women
29 may already have sought answers to any questions they initially had. It is therefore likely that our
30 study underestimates the number of questions women have upon receiving their result. Women
31 from lower socio-economic backgrounds were less likely to return the questionnaire [121] and those
32 with less education were less likely to leave a free-text comment. It is therefore possible that the
33 results under-represent the concerns of women from lower socio-economic backgrounds. [Future
34 research on HPV information needs should focus on these harder to reach groups.](#)
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38 A number of implications arise from this study. Firstly, it is important that women are made aware of
39 HPV before being tested. For some women, including information about HPV in invitation letters will
40 not be sufficient so sample-takers have an important role in ensuring women know they are having
41 an HPV test. In some instances, this may be simply by drawing their attention to the information
42 leaflet that they receive with their screening invitation, but for some women this will lead to
43 additional questions which sample-takers should be prepared to answer.
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3 Secondly, information provided to women alongside their results should ideally be tailored to the
4 result being communicated. Many of the women who were HPV-positive or had recently cleared
5 HPV had questions about the meaning of their result and some described contacting their GP
6 surgery to discuss this. This is consistent with findings in the US, where women receiving HPV
7 positive results felt a sense of urgency to discuss it with their Health care provider and felt reassured
8 after this had happened [119]. It is important that staff in primary care are well equipped to answer
9 women's questions or to direct them to the best source of information. This may involve answering
10 questions about HPV themselves or directing women to online information materials (e.g. the NHS
11 screening website). In particular, the information needs recorded by women were frequently
12 interlinked with their personal information and medical history, reflecting attempts to make sense of
13 their results. There are likely to be women who want to discuss their specific results and this might
14 also include how their risk relates to their past screening history or other health conditions. For
15 these women, knowing who they can contact (e.g. a specific helpline, a cancer charity helpline, their
16 GP) will be important.

17
18 Finally, for some women there was confusion about why changes were being made to the screening
19 programme and concern about the fact that their sample had not been checked for abnormal cells.
20 It is important to explain why screening is changing and to reassure women that HPV testing is
21 better than cytology, with the changes being made to improve the screening programme. It might
22 also be useful to clarify specifically that this is safe even for women who are at the end of screening
23 (mentioned by some women in their 60s) or those who have previously had abnormal cytology
24 results. The recent public backlash following changes to the cervical screening programme in
25 Australia has highlighted the importance of explaining the rationale behind and safety of changes
26 being made in public health [197].

27
28 Women taking part in HPV-based cervical screening continue to have additional information needs.
29 Information about the epidemiology of HPV, why the cervical screening procedure is changing and
30 the meaning and implications of different results, should be provided in materials accompanying
31 results. Tailored information and signposting to additional materials and resources would also help
32 to ensure women can find the information they need

Contributorship Statement

33
34 JW, LM, AF and HK conceived the study. JW, LM, EM and AF developed the measures. EM, JW and LR
35 managed the project. All authors contributed to the analyses. LM drafted the paper. All authors
36 contributed to the final version of the manuscript. We would like to thank all the laboratory staff
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3 who made recruiting for the psychological evaluation possible, as well as Kirsty Bennett and Fatima
4 Osmani who contributed to recruitment and data entry. We also thank Julieta Patnick for her helpful
5 comments.
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8 **Competing interests**

9
10 The authors declare no conflict of interest.
11

12 **Funding**

13
14 Our study was funded by Public Health England (PHE). No grant number was given. PHE funded Emily
15 McBride from 03/01/2016 until 30/09/2017. EM was funded by the National Institute for Health
16 Research (NIHR) from 01/10/2017 [grant number DRF-2017-10-105]; the views expressed in this
17 article are not necessarily those of the NHS, the NIHR or the Department of Health and Social Care.
18 JW, LM and AF are funded by Cancer Research UK (grant numbers C7492/A17219 and
19 C49896/A17429).
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24 **Data sharing statement**

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26 Data is available from the corresponding author upon reasonable request.
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Table 1: Sample characteristics of women participating in HPV primary testing who did and did not record a free-text response during the course of the study (n=921)

	Free-text response recorded at any time		No free-text response recorded		χ^2 (df), p-value
	N	Row %	n	Row %	
Overall	381	41.4	540	58.6	
Result group					
HPV negative	65	26.2	183	73.8	$\chi^2(4)=38.49, p<.001$
HPV positive, cytology normal	126	50.0	129	50.0	
HPV positive, cytology abnormal	67	39.4	103	60.6	
Persistent HPV	91	50.8	88	49.2	
Cleared HPV	29	43.9	37	56.1	
Age					
24-34	171	46.7	195	53.3	$\chi^2(3)=10.63, p=.014$
35-44	66	32.7	136	67.3	
45-54	80	41.0	115	59.0	
55-65	64	41.0	92	59.0	
Marital status*					
Current partner	281	40.7	410	59.3	$\chi^2(1)=.79, p=.375$
No partner	95	44.4	119	55.6	
Education**					
Degree or higher	189	48.8	198	51.2	$\chi^2(2)=14.62, p=.001$
Qualifications below degree	177	36.0	314	64.0	
No formal qualifications	7	38.9	11	61.1	
Ethnicity					
White (British or other)	356	42.7	527	57.3	$\chi^2(1)=4.77, p=.029$
Other ethnicity***	20	28.6	50	71.4	

*Marital status: current partner (married, civil partnership, living with partner, in a relationship) and no partner (single, divorced, widowed). **No formal qualifications included those with no qualifications and those who were still studying with no previous qualifications. ***Other ethnicity includes: Asian/Asian British, Black/African/Caribbean/Black British, Mixed/Multiple ethnic groups, other ethnic group.

NOTE: Where n does not add up to n=921, this is due to missing data

Table 2: Number of women mentioning each major and sub-theme overall and by test result group

	Overall (n=381)	HPV negative (n=65)	HPV positive, cytology normal (n=129)	HPV positive, cytology abnormal (n=67)	Persistent HPV (n=91)	Cleared HPV (n=29)	χ^2 (df), p-value
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Reaction to and understanding of results	170 (45)	11 (17)	69 (54)	34 (51)	39 (43)	17 (59)	$\chi^2(4)=27.72,$.001
Emotional response	85 (22)	5 (8)	28 (22)	24 (36)	18 (20)	10 (35)	
Meaning of results	72 (19)	1 (2)	35 (27)	11 (16)	21 (23)	4 (14)	
Impact on sexual relationships	41 (11)	0	25 (19)	4 (6)	11 (12)	1 (3)	
Confidence in results	20 (5)	8 (12)	4 (3)	1 (2)	1 (1)	6 (21)	
Questions about HPV	143 (38)	8 (12)	67 (52)	20 (30)	37 (41)	11 (38)	$\chi^2(4)=31.13,$ <.001
General lack of understanding	24 (7)	2 (3)	15 (12)	6 (9)	4 (4)	0	
Epidemiology of HPV	63 (17)	2 (3)	30 (23)	5 (8)	20 (22)	6 (21)	
Cause of HPV	32 (8)	1 (2)	20 (16)	3 (5)	6 (7)	2 (7)	
Prevention/Treatment of HPV	28 (7)	0	11 (9)	7 (10)	9 (10)	1 (3)	
HPV vaccination	39 (10)	3 (5)	20 (16)	2 (3)	11 (12)	3 (10)	
Questions about cervical cancer	52 (14)	5 (8)	24 (19)	7 (10)	14 (15)	2 (7)	$\chi^2(4)=6.58,$.160
Risk of cervical cancer	45 (12)	3 (3)	20 (16)	7 (10)	14 (15)	2 (7)	
Other cervical cancer risk factors	14 (4)	3 (5)	7 (5)	1 (2)	2 (2)	1 (3)	
Purpose and procedure for HPV testing	85 (22)	26 (40)	20 (16)	16 (24)	16 (18)	7 (24)	$\chi^2(4)=16.51,$.002
Purpose	22 (6)	11 (17)	5 (4)	4 (6)	2 (2)	0	
Procedure	18 (5)	10 (15)	3 (2)	1 (2)	0	4 (14)	
Timing	36 (9)	4 (6)	12 (9)	5 (8)	11 (12)	4 (14)	
Delivery of results	15 (4)	4 (6)	1 (1)	7 (10)	3 (3)	0	
Future implications of test results	73 (19)	1 (2)	30 (23)	10 (15)	27 (30)	5 (17)	$\chi^2(4)=21.76,$ <.001
Clinical management	39 (10)	1(2)	14(11)	4 (6)	19 (21)	1 (4)	
Fertility/sexual health	13 (3)	0	5 (4)	1 (3)	3 (3)	3 (10)	
Advice on clearing HPV	18 (5)	0	10 (8)	2 (3)	5 (6)	1 (3)	
Testing for partners	7 (2)	0	4 (3)	2 (3)	1 (1)	0	
Information seeking/(di)satisfaction	85 (22)	8 (12)	37 (29)	14 (21)	22 (24)	4 (14)	$\chi^2(4)=8.25,$.083
Information seeking	30 (8)	3 (5)	15 (12)	7 (10)	5 (6)	0	
(Di)satisfaction	73 (19)	6 (9)	31 (24)	12 (18)	20 (22)	4 (14)	

Table 3: Examples of each quote

Reaction to and understanding of results	
Emotional response	<p><i>"I am very worried in case I end up with cervical cancer"</i> [HPV+, cyto norm; 55-65 years]</p> <p><i>"I feel quite distressed about the results and the letter ... has caused me stress and anxiety"</i> [HPV+, cyto abnorm; 24-34 years]</p> <p><i>"I was advised I do not have HPV, I have had this persistently for years, I am so relieved"</i> [HPV cleared; 24-34 years]</p>
Confidence in results	<p><i>"I have a family history of abnormal cells being found, but I was not tested for anything other than HPV. I would like to have a further test to confirm no abnormal cells"</i> [HPV-; 35-44 years]</p> <p><i>"Because I have previously had abnormal cells... I was not reassured by my HPV-negative result"</i> [HPV-; 45-54 years]</p> <p><i>"I am uneasy about the fact that cells have not been checked for abnormality, especially as no further tests will be offered to me"</i> [HPV -; 55-65 years]</p>
Meaning of results	<p><i>"I was cleared of HPV last year, why has it come back?"</i> [HPV+, cyto norm; 45-54 years]</p> <p><i>"I have had two smears now both HPV-positive. How long can a person be HPV-positive for HPV?"</i> [HPV persistent; 45-54 years]</p> <p><i>"My previous test was positive and this one was negative. Does this mean it is still present but not active?"</i> [HPV cleared; 24-34 years] <i>"I caught genital warts at 23 - is this somehow different?"</i> [HPV+, cyto norm; 24-34 years]</p>
Impact on sexual relationships	<p><i>"Not sure what this means for future sexual relationships"</i> [HPV+, cyto abnorm; 24-34 years]</p> <p><i>"Can it be perpetuated by continuously being passed from one partner to the other?"</i> [HPV+, cyto norm; 55-65 years]</p> <p><i>"Should I tell sexual partners?"</i> [HPV+, cyto norm; 24-34 years]</p> <p><i>"Initially I worried about what my husband would think"</i> [HPV persistent; 55-65 years]</p> <p><i>"I blame my partner for this"</i> [HPV+, cyto norm; 35-44 years]</p>
Questions about HPV	
General lack of understanding	<p><i>"I didn't even know I had been tested for HPV. Have never heard of it before"</i> [HPV+, cyto norm; 35-44 years]</p> <p><i>"I don't really understand what HPV is"</i> [HPV+, cyto norm; 24-34 years]</p>
Epidemiology of HPV	<p><i>"How long does HPV last? What will happen if it doesn't go away?"</i> [HPV+, cyto norm; 24-34 years]</p> <p><i>"Has it gone and come back again or have I had it for 3 years?"</i> [HPV+, cyto norm; 35-44 years]</p> <p><i>"I'm still unclear as to what makes some peoples CIN1 cells disappear while others develop further"</i> [HPV+, cyto abnorm; 35-44 years]</p> <p><i>"Will it ever go away? Or get worse?"</i> [HPV persistent; 55-65 years]</p>
Cause of HPV	<p><i>"I don't understand how I have got HPV"</i> [HPV+, cyto norm; 24-34 years]</p> <p><i>"I have not been sexually active for 6 years and can't understand why I have got it with only having one long-term partner"</i> [HPV+, cyto abnorm; 35-44 years]</p>
Prevention/treatment for HPV	<p><i>"Should I now always use condoms for sex?"</i> [HPV+, cyto norm; 24-34 years]</p> <p><i>"Is there something I can take to get rid of HPV?"</i> [HPV+, cyto norm; 35-44 years]</p> <p><i>"Are there really no ways to treat the HPV virus?"</i> [HPV persistent; 55-65 years]</p>

HPV vaccination	<p><i>"I had the HPV vaccine, why didn't it work?"</i> [HPV+, cyto norm; 24-34 years]</p> <p><i>"I'd like to know if I could be offered the vaccine and whether it would work for me"</i> [HPV+, cyto norm; 35-44 years]</p> <p><i>"I have been considering having the vaccine but unsure of benefits at my age"</i> [HPV cleared; 35-44 years]</p>
Questions about cervical cancer	
Risk of cervical cancer	<p><i>"What are the chances of this becoming cancerous?"</i> [HPV+, cyto norm; 55-65 years]</p> <p><i>"What proportion of women who have had 2 smears detecting high risk HPV will go on to develop cervical cancer?"</i> [HPV persistent; 45-54 years]</p>
Other cervical cancer risk factors	<p><i>"There is a vast history of cancer in my family. Am I more likely to get cancer?"</i> [HPV+, cyto norm; 55-65 years]</p> <p><i>"I have a contraception implant - does this affect HPV or my chances of developing cervical cancer"</i> [HPV+, cyto norm; 24-34 years]</p>
Purpose and procedure for HPV testing	
Purpose	<p><i>"I am not sure if HPV test covers more, less or the same as a normal smear test"</i> [HPV-; 45-54 years]</p> <p><i>"I do not know if one is more thorough and effective than the other"</i> [HPV-; 35-44 years]</p> <p><i>"Was given no information that would be a different test other than smear"</i> [HPV+, cyto norm; 45-54 years]</p>
Procedure	<p><i>"Was the HPV an additional test in addition to a normal smear test?"</i> [HPV-; 45-54 years]</p> <p><i>"Why when HPV is not present they don't test the sample"</i> [HPV cleared; 24-34 years]</p>
Timing	<p><i>"Why can't I be re-tested in 6 months instead of waiting another year?"</i> [HPV+, cyto norm; 45-54 years]</p> <p><i>"Is having my next smear in 1 year soon enough? Could my cells change quickly enough to be cancerous before then?"</i> [HPV+, cyto norm; 45-54 years]</p> <p><i>"I would like to be reassured that the intervals between tests are adequate to pick up any changes to my body"</i> [HPV cleared; 35-44 years]</p>
Delivery of results	<p><i>"I haven't received a letter with my results and I don't ever recall receiving results"</i> [HPV-; 35-44 years]</p> <p><i>"I had lots of questions that I could not get answered because results come in letter form"</i> [HPV+, cyto abnorm; 24-34 years]</p>
Future implications of test results	
Clinical management	<p><i>"My test was positive two times and I want to meet a specialist"</i> [HPV+, cyto norm; 45-54 years]</p> <p><i>"I had a second positive HPV and have not been invited for further testing which the nurse said I would be. I am wondering why"</i> [HPV persistent; 55-65 years]</p> <p><i>"Am I now having a colposcopy because I have had HPV for 2 years?"</i> [HPV persistent; 45-54 years]</p>
Fertility/sexual health	<p><i>"I am due a second test in 1 years time, but I am hopefully aiming to be pregnant around then, is this a major problem?"</i> [HPV+, cyto norm; 24-34 years]</p> <p><i>"Will it increase my chances of miscarriage?"</i> [HPV persistent; 24-34 years]</p>
Advice on clearing HPV	<p><i>"What can I do in the next 12 months to help myself?"</i> [HPV+, cyto norm; 24-34 years]</p> <p><i>"Is there anything I can do to stop HPV developing into cancer?"</i> [HPV persistent; 24-34 years]</p>

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Testing for partners	<i>Why men don't get test for it if they can transmit it?</i> [HPV+, cyto abnorm; 24-34 years]
Information seeking and (di)satisfaction	
Information seeking	<i>"I contacted my GP for more information"</i> [HPV+, cyto norm; 24-34 years]
(Di)satisfaction	<i>"It's not explained in a very useful manner"</i> [HPV persistent; 24-34 years]
	<i>"I want to have more information about HPV"</i> [HPV+, cyto norm; 45-54 years]
	<i>"On receiving letter about results I felt I had lots of questions that I could not get answered"</i> [HPV+, cyto abnorm; 24-34 years]

For peer review only