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Women's acceptability of and experience with primary human papillomavirus testing for cervix screening: HPV FOCAL trial cross-sectional online survey results

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3 1 Women's acceptability of and experience with primary human papillomavirus testing for cervix
4 2 screening: HPV FOCAL trial cross-sectional online survey results
5 3
6 4

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4 53 **ABSTRACT:** (word count 257)
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8 55 **Objective:** To study participant's acceptability of and attitudes towards human papillomavirus
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10 56 (HPV) testing compared to cytology for cervical cancer screening, and what impact having an
11
12 57 HPV positive result may have in future acceptability of screening.
13

14
15 58 **Design:** Cross-sectional online survey of clinical trial participants.
16

17 59 **Setting:** Primary care, population-based Cervix Screening Program, British Columbia, Canada.
18

19 60 **Participants:** A total of 5,532 participants from the HPV FOCAL Trial, in which women received
20
21 61 HPV and cytology testing at study exit were included in the analysis. Median age was 54 years.
22
23 62 The median time of survey completion was 3 years after trial exit.
24

25 63 **Outcome measures:** Acceptability of HPV testing for primary cervical cancer screening
26
27 64 (primary); attitudes and patient perceptions towards HPV testing and receipt of HPV positive
28
29 65 screen results (secondary).
30

31 66 **Results:** Most respondents (63%) were accepting of HPV testing, with the majority (69%)
32
33 67 accepting screening to begin at age 30 with HPV testing. Only half of participants (54%) were
34
35 68 accepting of an extended screening interval of 4 to 5 years. In multivariable regression, women
36
37 69 who reported HPV testing as acceptable were more likely to have received an HPV positive
38
39 70 screen test result during the trial (OR=1.41 95%CI: 1.11,1.80), and were older (OR= 1.01,
40
41 71 95%CI:1.00,1.02).
42
43

44 72 **Conclusions:** In this evaluation of acceptability and attitudes regarding HPV testing for cervix
45
46 73 screening, most are accepting of HPV testing for screening; however, findings indicate
47
48 74 heterogeneity in concerns and experiences surrounding HPV testing and receipt of HPV positive
49
50 75 results. These findings provide insights for the development of education, information, and
51
52 76 communication strategies during implementation of HPV-based cervical cancer screening.
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3 78 **Trial Registration:** ISRCTN79347302 and ClinicalTrials.gov Identifier: NCT00461760
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7 80 **ARTICLE SUMMARY**
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11 82 **'Strengths and limitation of this Study'**
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13

- 14 83
15
16 84 • Measures of acceptability and patient perceptions of HPV testing within a primary cervix
17 screening program.
18 85
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20 86
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22 87 • Reports on acceptability of increased screening interval and delayed onset of screening
23 initiation, and impact of a positive HPV test result.
24 88
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26 89
27
28 90 • Recommendations for key health promotion messaging to address potential barriers to
29 HPV testing for primary cervical screening.
30 91
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32 92
33
34 93 • Limitations include that participants were recruited from a large clinical trial on HPV
35 testing for cervical cancer screening and may not be representative of the general
36 screening population.
37 94
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45 98 **Funding:** This work was supported by the Canadian Institutes of Health Research (CIHR) MCT-
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101 INTRODUCTION

102

103 It is well established that persistent infection with an oncogenic strain of the human
104 papillomavirus (HPV), the most common sexually transmitted infection around the world, is the
105 causative agent for most cervical cancers [1,2]. There is a robust body of evidence regarding
106 the superior performance of HPV vs. cytology screening in detection of cervical intraepithelial
107 neoplasia (CIN) grade 2 or worse (CIN2+) and greater protection against cervical cancer [3–5].
108 As such, several countries around the world have implemented primary HPV testing for cervical
109 cancer screening, including Australia, the Netherlands, and the UK, with many other
110 jurisdictions in various planning stages for HPV-based screening implementation. A shift to an
111 HPV-based screening approach results in different program guidelines and, thus, a different
112 experience for the person undergoing screening. The very high negative predictive value of
113 HPV testing permits the interval between screens to be extended to 5 or more years compared
114 to cytology testing, recommended every 2 to 3 years in most jurisdictions [5–7]. Due to high
115 prevalence and regression rates of HPV infection in younger women, HPV-based screening
116 may not be recommended until 25 to 30 years of age [5,6]. In addition, being screened for
117 cervical cancer with a test for a sexually transmitted infection can result in anxiety and concern
118 for those undergoing screening [8,9].

119

120 With such a transformative change in what is arguably a well-established screening paradigm, it
121 is crucial to examine women's readiness or acceptance of HPV testing compared to cytology
122 testing for screening, to ensure engagement in screening is not hampered by a change in
123 technology or guidelines. This unintended consequence was illustrated in Australia, prior to the
124 change in the national program from cytology to HPV screening, when a 2017 petition opposing
125 the changes garnered 70,000 signatures [10]. Respondents to the Australian survey indicated
126 concerns about such things as the extended interval and missing cancer cases in younger

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3 127 women as a result of the program change [10]. Despite enhancements to screening efficacy and
4
5 128 safety, a successful change in technology requires acceptance by those who undergo
6
7 129 screening. Anticipating women's questions and concerns prior to implementation of program
8
9 130 changes can mitigate resistance to change and assist in the design of targeted education
10
11 131 strategies.
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16 133 This analysis is of the 48-month exit survey for the Human Papillomavirus For Cervical Cancer
17
18 134 Screening Trial (HPV FOCAL). HPV FOCAL is currently the only North American trial comparing
19
20 135 primary HPV testing to cytology (liquid-based) for screening within an organized program, which
21
22 136 also provides us with the unique opportunity to assess women's experiences with HPV testing in
23
24 137 a population-based program setting. The primary objective of this analysis was to explore
25
26 138 participant's acceptability of and attitudes towards HPV testing compared to cytology for cervical
27
28 139 cancer screening, and what impact having an HPV positive result may play in future
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30 140 acceptability of screening.
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143 **METHODS**

144 **Participants**

145 Survey participants were recruited through the HPV FOCAL trial, a publicly funded randomized
146 control trial comparing primary HPV testing every four years (HPV arm) to liquid-based cytology
147 testing (cytology arm) every two years for cervical cancer screening (ISRCTN79347302). HPV
148 FOCAL recruited women, 25-65 years of age, from two largely metro areas in British Columbia
149 who were due for cervical cancer screening from 2008 through to 2012. Trial design and
150 primary outcome results have been previously described in detail [3,11–14]. Participants were
151 provided with information on HPV, HPV testing and cervical cancer upon enrollment and
152 throughout the trial follow-up period. A total of 9552 women were randomized to the HPV arm
153 and 9457 women to the cytology arm. Women from both the HPV and cytology arms completed
154 trial exit screening between 2012 and 2016, where they received HPV and cytology co-testing at
155 the exit screen. Results were provided to their primary care provider, who then conveyed them
156 to the participants. From August 2017-February 2018 women from both arms who had attended
157 the 48-month exit screen were invited to complete the online exit survey (FIGURE 1).

158

159 **HPV FOCAL exit survey**

160 The survey included 26 items that asked participants about HPV knowledge and information
161 seeking before and during the study, acceptability of HPV testing, willingness to increase the
162 screening interval, commencement screening age for HPV testing, attitudes and concerns about
163 test positive results and communication needs around screening results, in addition to
164 demographic details (SUPPLEMENTARY FILE). Responses included 7- and 5-point Likert
165 scales, and survey responses were linked to HPV FOCAL trial screen test results. Survey items
166 were based upon previous HPV FOCAL surveys assessing HPV testing acceptance [15] The
167 survey was distributed and managed using the web-based platform of Fluidsurveys

1
2
3 168 (www.fluidsurveys.com). The survey was pilot tested and revised for face and content validity
4
5 169 with approximately 20 women, aged 30 and above prior to distribution to FOCAL participants.
6

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9 171 **Patient and public involvement**

11 172 Patient concerns and questions identified the need for the study. Patients were involved in pilot
12
13 173 testing and revision of the survey.
14

15 174

18 175 **Response rate and inclusion criteria**

19
20 176 Participants from the HPV FOCAL trial from both the HPV and cytology arms who had
21
22 177 completed their study 48 month exit screen, had indicated consent to be contacted for future
23
24 178 research, and for whom email addresses were available were eligible for survey invitation. The
25
26 179 invite to complete the survey was sent via email, with one reminder sent a month later for those
27
28 180 who had not initiated or completed the survey. Participants were provided with a unique study
29
30 181 identifier to access the survey and no personal identifiers were captured during survey
31
32 182 completion. Participants were informed they had the option to complete none, some, or all of the
33
34 183 survey with completion of survey questions as indication of consent.
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39 185 Survey completeness was reviewed, and duplicate surveys, where the same woman completed
40
41 186 all or some of the survey more than once, were identified. For those with a duplicate entry, the
42
43 187 first complete survey was used in the analysis with all other survey attempts discarded.

44
45 188 Response rate (%) was the sum of completed surveys plus partial surveys, divided by the
46
47 189 number of invitations sent to eligible valid email addresses, as per the American Association for
48
49 190 Public Opinion Research guidelines[16]. Non-response included: refusals (clicked the survey
50
51 191 link, but did not complete consent or any items), and those assumed eligible with no response
52
53 192 received. Email addresses that were undeliverable were considered invalid and not included in
54
55 193 the analysis.
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194 **Statistical analysis**

195 Survey respondents were compared to HPV FOCAL trial participants on age, study arm, and
196 location of trial recruitment to explore if survey sample was representative of FOCAL trial
197 population.

198
199 Our main outcome of HPV testing acceptability was assessed by response to the question
200 “having an HPV test instead of a Pap to screen for cervical cancer is acceptable to me”, which
201 was dichotomized from a 5-point Likert scale, with those reporting strongly agree or agree,
202 categorized as ‘accepting’, and those reporting neutral, don’t know, disagree and strongly
203 disagree as ‘not accepting’ of HPV testing. This categorization was chosen to capture those
204 who were truly accepting and biased towards the null. Only complete surveys were included,
205 with those who were missing or preferred not to answer excluded. Participants were classified
206 as being HPV positive, if they received an HPV positive screening result at any point during their
207 participation in the HPV FOCAL trial, otherwise a participant was classified as HPV negative.

208
209 Bivariable analysis explored differences in acceptability of HPV testing based on demographics,
210 HPV screening test result, and length of time since study exit. Factors associated with
211 acceptability, such as HPV screening starting at 30 years of age and increased screening
212 interval, were also examined.

213
214 Socio-demographics and attitudes towards HPV testing were explored descriptively with Chi-
215 square and Fisher’s exact tests (where applicable) for categorical variables and median score
216 test for continuous variables.

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3 218 Multivariate logistic regression was used to explore the association of the acceptability of HPV
4
5 219 testing with *a priori* identified confounding variables that reached $p < 0.2$ in bivariable analysis.
6
7 220 Level of significance was 0.05. All statistical analyses were performed in SAS 9.4 and R4.02.
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10 221

11 222 **Ethics Approval**

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13 223 Ethics approvals for survey was received by the University of British Columbia Research Ethics
14
15 224 Board (H06-04032). In addition, a privacy review was undertaken to ensure the survey complied
16
17 225 with provincial privacy legislation.
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21 227 **RESULTS**

22
23 228 Survey invites were administered from August 2017 through to February 2018. A total of 14,535
24
25 229 participants from both the HPV and cytology arms in HPV FOCAL trial were identified as eligible
26
27 230 to receive 48-months exit online survey, of which 13,176 were delivered to a valid email address
28
29 231 (FIGURE 1). There were 5,532 surveys completed, of which 4,938 were fully and 594 partially
30
31 232 completed.
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34 233

35 234 **Characteristics of respondents**

36
37 235 The median age of participants completing the survey was 54 years (IQR: 46,62) (Table 1). The
38
39 236 median time of survey completion was 3 years after study exit. The majority of respondents
40
41 237 (67%) had completed college or higher education and 77% reported living with a partner.
42
43 238 Survey respondents were comparable to HPV FOCAL trial participants based on study arm, age
44
45 239 at HPV FOCAL trial enrollment, and geographical location. Survey respondents and non-
46
47 240 respondents were comparable by study arm and marital status, but those who responded to the
48
49 241 survey were slightly older than non-responders, although this was not a meaningful difference.
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244 **Acceptability of HPV testing for Screening**

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246 Overall, 63% of survey respondents agreed or strongly agreed that HPV testing for cervical
247 cancer screening was acceptable, with 37% not agreeing (11% disagree, 16% neutral, 10%
248 don't know) (Table 1). There were no significant associations between acceptability of HPV
249 testing and marital partnership status, time since study exit, education or income. Women who
250 received an HPV positive result at any point during HPV FOCAL trial and who were older were
251 more accepting of HPV testing compared to those who remained HPV negative during trial
252 participation.

253
254 In multivariate analysis, women who reported HPV testing as acceptable were more likely to
255 have received an HPV positive screen test result at some point during the trial (OR 1.41 95%CI
256 1.11,1.80, p=0.005), and were older (OR 1.01, 95%CI 1.00,1.02, p=0.01) (Table 2).

257
258 Over half of respondents (54%) agreed with the statement "I would be willing to have an HPV
259 test every 4-5 years instead of a Pap every 3 years". There was a significant difference in
260 acceptability of an extended screening interval between those who reported being accepting of
261 HPV testing compared to those who were not accepting. Overall, 69% responded that HPV
262 testing starting at age 30 was acceptable, with over 80% of those who were accepting of HPV
263 testing reporting agreement with a higher screening age (30 years or over) compared to Pap
264 testing (Table 1).

265
266 In addition, 66% of respondents reported that an extended screening would not result in less
267 visits to their healthcare provider for other medical reasons, indicating that despite the extended
268 interval recommended with HPV-based screening, women would continue to see their providers
269 for medical reasons as needed.

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3 **270 Attitudes towards an HPV Positive Test Result:**
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7 272 Survey respondents were asked to rate their level of agreement with a variety of statements
8
9 273 regarding attitudes surrounding receipt of HPV positive results (Table 3). Women were asked if
10
11 274 they would be more concerned about receiving a positive HPV test or an abnormal Pap result,
12
13 275 for which most respondents (73%) reported that both screening outcomes would concern them
14
15 276 equally. However, those that reported HPV testing to be acceptable, reported that an HPV
16
17 277 positive result would concern them more (14%) than an abnormal Pap. This was statistically
18
19 278 different compared to those who were not accepting of HPV testing, who responded that
20
21 279 abnormal Pap test results would concern them more. The difference in distribution between
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23 280 these responses was statistically significant.
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28 282 Most respondents who were not accepting of HPV testing indicated that having a sexually
29
30 283 acquired infection would concern them differently than having abnormal Pap results. The
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32 284 relationship between level of agreement with HPV testing acceptability and ones' level of
33
34 285 concern about having a sexually acquired infection was significant. Regardless of a
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36 286 respondent's reported HPV testing acceptability, most respondents felt it important to them to
37
38 287 know who gave them HPV and when they acquired HPV (72% and 78% respectively). Most
39
40 288 respondents indicated they disagreed or were neutral regarding feeling judged for having HPV,
41
42 289 and there was no significant relationship between feeling judged and level of agreement with
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44 290 HPV testing. More respondents who were accepting of HPV testing indicated they would feel
45
46 291 comfortable telling their partner if they had HPV, which was in contrast to those who were not
47
48 292 accepting of HPV testing; these differences indicated a significant relationship between HPV
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50 293 testing acceptance and comfort disclosing HPV status to a partner. Regardless of level of
51
52 294 agreement with HPV testing, most respondents (79%) indicated they would feel concerned
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54 295 about transmitting HPV to their partner(s). More respondents who were accepting of HPV
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3 296 testing would feel confident in the recommendations from their provider for the management of
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5 297 their HPV positive results. There was a significant association between level of agreement with
6
7 298 HPV testing and degree of confidence with provider recommendations.
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11 300 **Sources of information for HPV testing and screening:**

13 301 Overall, the most reported important sources of information were health care providers and BC
14
15 302 Cancer, the agency that is responsible for the cervix screening program in British Columbia
16
17 303 (Table 4). In addition, those that are accepting of HPV testing were more likely to look to their
18
19 304 health care providers and BC Cancer as important sources of information. Regardless of one's
20
21 305 level of agreement with HPV testing for screening, friends and family or social media were not
22
23 306 as important as health care providers and BC Cancer for sources of information.
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26 307

28 308 **DISCUSSION**

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32 310 Acceptability of, and attitudes, towards primary HPV testing were analysed from 5,532 women
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34 311 who completed HPV testing as part of the HPV FOCAL trial, which was embedded within an
35
36 312 organized population-based cervical cancer screening program. Most respondents (63%) were
37
38 313 accepting of HPV testing for cervix screening and for screening with HPV testing to begin at age
39
40 314 30 (69%). Just over half were accepting of HPV testing with the extended screen interval of 4 to
41
42 315 5 years (54%). Although most women were accepting, the proportion of respondents indicating
43
44 316 they disagreed with or were neutral in their acceptance of HPV testing and of extended intervals
45
46 317 was higher than we expected considering this was a group of people who were provided with
47
48 318 education and information about HPV, HPV testing, and cervical cancer. These findings are
49
50 319 similar to other studies that indicate women have concerns about the extended interval
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52 320 recommended with HPV testing [10,17–19], stemming from a belief that a cancer diagnosis may
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54 321 be missed through extension of the interval. Considering study participants received information
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3 322 regarding HPV, the natural history of HPV and cervical cancer, and the rationale for HPV testing
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5 323 compared to the Pap test, these findings indicate that additional research and patient
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7 324 engagement is needed to gain insights and identify and develop resources or procedures to
8
9 325 address barriers to HPV testing and an extended screening interval.
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14 327 This multivariate analysis found that those who received positive HPV test results at some point
15
16 328 during the trial were more likely to be accepting of HPV testing for cervix screening than those
17
18 329 who never received an HPV positive result. Those who tested HPV positive would have
19
20 330 received additional information and counseling from their healthcare provider and or a Study
21
22 331 nurse, which would have included information that would not necessarily have been provided to
23
24 332 those who tested HPV negative. This additional reinforcement of education, and an opportunity
25
26 333 for dialogue when receiving the positive result, may have facilitated improvement in knowledge
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28 334 and subsequently, enhanced acceptance of HPV testing. Other findings have indicated that
29
30 335 increased HPV and HPV screening knowledge can be a facilitator of HPV screening
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32 336 acceptance[20].
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37 338 One of the concerns with an extended screening interval is if women would be less likely to
38
39 339 consult with the health care provider for other medical reasons. When we asked participants if
40
41 340 they would be less willing to see a healthcare provider for other medical reasons if the interval
42
43 341 for cervix screening were increased, most respondents said they would not be less willing,
44
45 342 indicating that the extended interval for cervix screening would not prevent them from seeking
46
47 343 care as needed. This finding can provide reassurance to healthcare professionals who have
48
49 344 concerns that the extended screening interval recommended with HPV-based screening would
50
51 345 lead to fewer visits to a clinician, given that the cervical screen visit is often an opportunity for
52
53 346 the clinician to assess other preventive care or medical issues [21].
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3 348 Respondents' concerns regarding receipt of HPV positive results were varied. Nearly 93% of the
4
5 349 respondents never received an HPV positive result during the HPV FOCAL trial. As a result, the
6
7 350 majority of responses evaluate attitudes and experiences for those who did not actually receive
8
9 351 HPV positive results, and therefore, reflect how the respondents would hypothetically feel if they
10
11 352 were to receive HPV positive results. Of the respondents, 7.5% had received an HPV positive
12
13 353 result at some point during their trial participation.
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17
18 355 Most participants indicated that having HPV would cause them concern about having cervical
19
20 356 cancer. The majority of participants reported that having either an abnormal Pap or a positive
21
22 357 HPV test would concern them; however, for those that had tested positive for HPV, they
23
24 358 reported that an HPV test would concern them more compared to an abnormal Pap. Overall,
25
26 359 participants' perceptions about HPV positive results and cervical cancer indicate that increased
27
28 360 knowledge regarding the specificity of HPV testing for cervical cancer screening is needed.
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361

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32
33 362 Receipt of positive HPV results has been associated with higher anxiety and distress compared
34
35 363 to receipt of abnormal Pap results[22–24], which may be due to the fact that HPV is a sexually
36
37 364 transmitted infection and has been associated with levels of shame and stigma [25,26]. Most
38
39 365 respondents in our survey indicated that receiving results for a sexually acquired HPV infection
40
41 366 would concern them differently than having an abnormal Pap test result; however, this belief
42
43 367 varied depending on a participant's acceptability of HPV testing. Women who were not
44
45 368 accepting of HPV testing indicated that a HPV positive result would concern them differently
46
47 369 than abnormal Pap results, compared to those who were accepting of HPV testing [22–
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49 370 24][25,26]. Most respondents, whether they accepted HPV testing or not, felt it important for
50
51 371 them to know who gave them HPV and when they got it (71% and 78% respectively). These
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53 372 findings together are reflective of other research findings[9,27,28] and indicate that when
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55 373 developing education and communication strategies, emphasis should be placed on the high
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3 374 prevalence of HPV in the population, the transient nature of most HPV infections, bringing
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5 375 awareness to the fact an infection may have been acquired several years prior to a positive test
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7 376 result. Differentiating HPV from other STIs may minimize anxiety and facilitate normalization
8
9 377 and acceptance[25,29].
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13 379 Almost 75% of the respondents indicated they felt an HPV positive result would affect their
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15 380 relationship with their partner, or they weren't sure, and almost 80% would be concerned about
16
17 381 transmitting HPV to their partners, with many feeling they would be judged for being HPV
18
19 382 positive. The stigma associated with HPV, concerns about infidelity and potential partner
20
21 383 reactions to the HPV result may underlie these concerns. Previous research has indicated some
22
23 384 women question whether partner notification with HPV is necessary [29,30]. Unlike other STIs
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25 385 such as chlamydia or gonorrhoea where partner notification is recommended for testing and
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27 386 treatment purposes, there is usually no medical reason to notify the partner of a woman who
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29 387 tested positive for HPV.
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34 389 Healthcare providers, as trusted and valued sources of information, can influence patients'
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36 390 decision-making patterns regarding health care decisions [17,31] Reflecting other findings, the
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38 391 respondents in this survey indicated that the most important sources of information for them
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40 392 were their healthcare providers and the provincial screening program [17,31]. As a result,
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42 393 program planning for HPV-based screening should ensure health care providers are provided
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44 394 with education and training surrounding HPV prior to program changes, to ensure they are
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46 395 prepared to address women's questions and concerns regarding the paradigm shift from
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48 396 cytology to HPV-based screening.
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53 398 This study is not without limitations. Survey participants were part of a large clinical trial and
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55 399 were given information about HPV, HPV testing and cervical cancer upon enrollment and,
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3 400 therefore, may not be representative of the general screening population of British Columbia.
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5 401 The response rate may be considered low at 41%; however, those who have stronger opinions
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7 402 about their screening choices may have been more likely to respond to the survey than those
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9 403 who are more trusting of the health care system and accepting of any future policy changes. In
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11 404 addition, survey respondents were representative of overall participants in the HPV FOCAL trial.
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13 405 The majority of respondents completed the survey approximately 3 years after trial completion
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15 406 and it is possible there was loss of recall of HPV related information provided to them when they
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17 407 consented to participate in the trial, which for many was up to 7 years prior to survey
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19 408 completion. The potential lag time between trial entry and survey completion may impact
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21 409 women's attitudes and beliefs surrounding HPV testing. In addition, most of the participants in
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23 410 this trial were over the age of 50, highly educated and primarily from two urban geographic
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25 411 regions and may not be representative of all screen eligible people in various regions of British
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27 412 Columbia.
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32 414 **CONCLUSIONS**

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37 416 In this study, within an organized screening setting, evaluating acceptability and attitudes
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39 417 around HPV testing from women undergoing HPV-based screening, most are accepting of HPV
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41 418 testing for screening; however, further research is needed to understand factors that can
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43 419 increase acceptability. These findings contribute to the growing body of evidence demonstrating
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45 420 that concerns and experiences surrounding HPV testing and receipt of HPV positive results are
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47 421 complex and varied. As many cervix screening programs begin HPV-based screening and are
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49 422 planning implementation strategies, attention to patient engagement to address potential
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51 423 barriers will be important. As HPV-based screening becomes standard of care, it is plausible
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53 424 that concerns with this paradigm shift will eventually be alleviated with increasing knowledge
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3 425 and familiarity. These findings provide insight into areas of importance that should be
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5 426 considered for development of education, information, and communication strategies.
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17 **Figure 1:** Study flowchart and participant disposition
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464 **Table 1:** Demographic characteristics of respondents and bivariable analysis of acceptability of
 465 HPV testing
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		Having an HPV test instead of a Pap smear to screen for cervical cancer is acceptable to me			
		Total (N)	Not acceptable (Disagree/Neutral/Don't know)	Acceptable (Agree)	p-value
Total (N)		5336	1993 (37.4%)	3343 (62.6%)	
Age	median [IQR]	5336	53.35 [45.35, 61.19]	54.23 [45.64, 61.72]	0.051
Marital Status^a					
	Living with a partner	3806	1438 (78.7)	2368 (76.6)	0.095
	Living without a partner	1115	390 (21.3)	725 (23.4)	
Education^a					
	Complete College or higher	3317	1250 (68.5)	2067 (66.7)	0.221
	Incomplete post-secondary or less	1607	576 (31.5)	1031 (33.3)	
Income^a					
	Less than \$75000	1501	529 (32.0)	972 (34.0)	0.175
	\$75,000 or more	3014	1126 (68.0)	1888 (66.0)	
HPV Testing Status during FOCAL trial					
	Never tested HPV positive	4937	1867 (93.7) 37.8%	3070 (91.8) 62.2%	0.015*
	At least one HPV positive result	399	126 (6.3) 31.6%	273 (8.2) 68.4%	
Time since exit from FOCAL trial, Years					
	median [IQR]	5336	3.09 [2.26, 3.91]	3.04 [2.23, 3.93]	0.616
I would be willing to have an HPV test every 4-5 years instead of a Pap every 3 years^a					
	Agree	2858	386 (19.5)	2472 (74.2)	<0.001*
	Disagree	1096	744 (37.6)	352 (10.6)	
	Neutral	1353	847 (42.8)	506 (15.2)	
Receiving HPV testing starting at age 30 is acceptable to me^a					
	Agree	3635	944 (47.8)	2691 (81.0)	<0.001*
	Disagree	682	423 (21.4)	259 (7.8)	
	Neutral	981	608 (30.8)	373 (11.2)	
If cervical cancer screening was to occur every 4 or 5 years, instead of every 3 years, I would be less likely to visit my health care provider for other health reasons. ^a					
	Agree	1062	405 (20.4)	657 (19.7)	0.814
	Disagree	3517	1303 (65.7)	2214 (66.4)	
	Neutral	735	274 (13.8)	461 (13.8)	

Table Notes: ^a Missing values up to 5,336 = not reported or prefer not to answer, * significant to p<0.05

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479 **Table 2:** Multivariate analysis of predictors for participants who are accepting of HPV testing
480 instead of Pap testing for cervical cancer screening.
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Variable	OR (95% CI)	P-value
Age at survey completion (years)	1.01 (1.00,1.02)	0.01
Received HPV positive results during study (Yes vs No)	1.41 (1.11,1.80)	0.005
Education (Incomplete post-secondary or less vs Complete College or higher)	1.06 (0.93,1.21)	0.41
Marital status (Living without a partner vs Living with a partner)	1.04 (0.88,1.22)	0.67
Income (\$75000 or more vs. less than \$75000)	0.97 (0.84,1.12)	0.68

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487 **Table 3:** Experiences receiving HPV positive results

	HPV testing instead of Pap testing for cervical cancer:			p-value
	Total (N)	Not acceptable	Acceptable	
	5336	1993 (36.0%)	3343 (60.4%)	
What would concern you most: Being told you had abnormal Pap results, or being told you had HPV?^a				
Being told I have abnormal Pap test results	668	274 (14.0)	394 (11.9)	<0.001*
Being told I have HPV	683	197 (10.0)	486 (14.7)	
Both would concern me equally	3855	1464 (74.7)	2391 (72.2)	
Neither would concern me	67	26 (1.3)	41 (1.2)	
Having an infection that is sexually acquired (HPV) doesn't concern me any differently than abnormal Pap results would^a				
Agree	1412	442 (24.8)	970 (31.5)	<0.001*
Disagree	2465	974 (54.6)	1491 (48.4)	
Neutral	987	369 (20.7)	618 (20.1)	
It would be important for me to know who gave me HPV^a				
Agree	3468	1251 (70.3)	2217 (71.7)	0.094
Disagree	545	188 (10.6)	357 (11.5)	
Neutral	859	340 (19.1)	519 (16.8)	
It would be important for me to know when I got HPV^a				
Agree	3795	1372 (76.9)	2423 (78.3)	0.131
Disagree	432	151 (8.5)	281 (9.1)	
Neutral	650	260 (14.6)	390 (12.6)	
I think people would judge me for having HPV^a				
Agree	1775	663 (37.4)	1112 (36.0)	0.307
Disagree	1419	495 (27.9)	924 (30.0)	
Neutral	1666	617 (34.8)	1049 (34.0)	
I would feel comfortable telling my partner if I had HPV^a				
Agree	3391	1198 (67.4)	2193 (71.3)	0.016*
Disagree	709	284 (16.0)	425 (13.8)	
Neutral	755	296 (16.6)	459 (14.9)	
I would not be concerned about transmitting HPV to my partner^a				
Agree	515	174 (9.8)	341 (11.1)	0.095
Disagree	3825	1400 (78.7)	2425 (79.0)	
Neutral	509	205 (11.5)	304 (9.9)	
Being HPV positive would not affect my relationship with my partner^a				
Agree	1249	445 (25.1)	804 (26.3)	0.035*
Disagree	2003	708 (39.9)	1295 (42.3)	
Neutral	1584	622 (35.0)	962 (31.4)	
Having HPV would not cause me any concern about cervical cancer^a				
Agree	181	52 (2.9)	129 (4.2)	0.012*
Disagree	4112	1499 (84.1)	2613 (84.8)	
Neutral	569	231 (13.0)	338 (11.0)	
I would feel confident in the recommendations from my healthcare provider for follow-up of my HPV positive result^a				
Agree	3876	1323 (74.0)	2553 (82.5)	<0.001*
Disagree	226	97 (5.4)	129 (4.2)	

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Neutral	780	369 (20.6)	411 (13.3)
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Table Notes : ^a Missing values up to 5,336 = not reported or prefer not to answer,, * significant to p<0.05

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490 **Table 4:** Important sources of HPV information

			Having an HPV test instead of a Pap smear to screen for cervical cancer is acceptable to me		
		Total (N)	Not acceptable	Acceptable	p-value
		5336	1993 (36.0%)	3343 (60.4%)	
Health Care Provider^a					
	Important	3405	1128 (59.3)	2277 (70.1)	<0.001*
	Neutral	1256	560 (29.5)	696 (21.4)	
	Not Important	487	213 (11.2)	274 (8.4)	
BC Cancer (organizes screening in BC)^a					
	Important	2713	907 (48.7)	1806 (56.9)	<0.001*
	Neutral	1649	673 (36.1)	976 (30.8)	
	Not Important	673	283 (15.2)	390 (12.3)	
Govt Websites (ex: Canadian Cancer Society/Public Health Agency Canada)^a					
	Important	2111	734 (39.9)	1377 (44.2)	0.011*
	Neutral	1914	748 (40.6)	1166 (37.5)	
	Not Important	928	359 (19.5)	569 (18.3)	
Other websites (WebMd, blogs)^a					
	Important	1597	567 (31.3)	1030 (33.7)	0.112
	Neutral	1997	776 (42.8)	1221 (40.0)	
	Not Important	1273	469 (25.9)	804 (26.3)	
Friends/family^a					
	Important	1336	453 (25.0)	883 (28.9)	0.012*
	Neutral	1865	725 (40.0)	1140 (37.3)	
	Not Important	1670	634 (35.0)	1036 (33.9)	
Social media^a					
	Important	580	197 (10.9)	383 (12.6)	0.004*
	Neutral	1562	633 (35.1)	929 (30.7)	
	Not Important	2693	975 (54.0)	1718 (56.7)	

Table Notes : ^a Missing values up to 5,336 = not reported or prefer not to answer,, * significant to p<0.05

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4 504 **Acknowledgements:** We thank the thousands of women of BC who participated in the HPV
5 505 FOCAL Trial and completed this survey, and the hundreds of BC collaborating clinicians. We
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7 507 Colposcopy Program; the BC Centre for Disease Control Public Health Laboratory; the
8 508 University of British Columbia; BC Cancer Surveillance and Outcomes Unit; Women's Health
9 509 Research Institute; and the Canadian Institutes of Health Research.
10 510

11 511 **Contributors:** LWS involved in conception, design and implementation of the research
12 512 presented here, drafting and review of manuscript; CSR conducted statistical analysis and
13 513 contributed to drafting and review of manuscript; LG conducted statistical analysis; MK, ML,
14 514 REM, GS, SP ELF and DV are co-investigators on the HPV FOCAL Study and were involved in
15 515 FOCAL trial design and trial management; AJC and GO are co-principal investigators of the
16 516 FOCAL Study and oversaw conduct of the trial; all authors take responsibility for the credibility
17 517 of the data and analysis and critically reviewed the paper and approved the final version.
18 518

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21 521

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23 523 investigators on industry funded (Hologic Inc, and Roche) investigator-led adjunct studies to the
24 524 HPV FOCAL Trial, designed to compare the performance of different HPV testing assays. No
25 525 investigators personally benefitted financially. Funding for these adjunct studies was not applied
26 526 to the operation of the HPV FOCAL results presented in this paper. ELF served as an
27 527 occasional advisor for companies involved with HPV vaccines (Merck, GSK) and HPV
28 528 diagnostics (Roche). He also holds a patent "DNA methylation markers for early
29 529 detection of cervical cancer," registered at the Office of Innovation and Partnerships,
30 530 McGill University, Montreal, Quebec, Canada.
31 531

32 532 **Patient consent for publication:** Not required
33 533

34 534 **Ethics approval:** Ethics approvals for survey was received by the University of British Columbia
35 535 Research Ethics Board (H06-04032).
36 536

37 537 **Provenance and Peer review:** Not commissioned; externally peer reviewed.
38 538

39 539 **Data availability Statement:** Deidentified participant data is available upon consideration and
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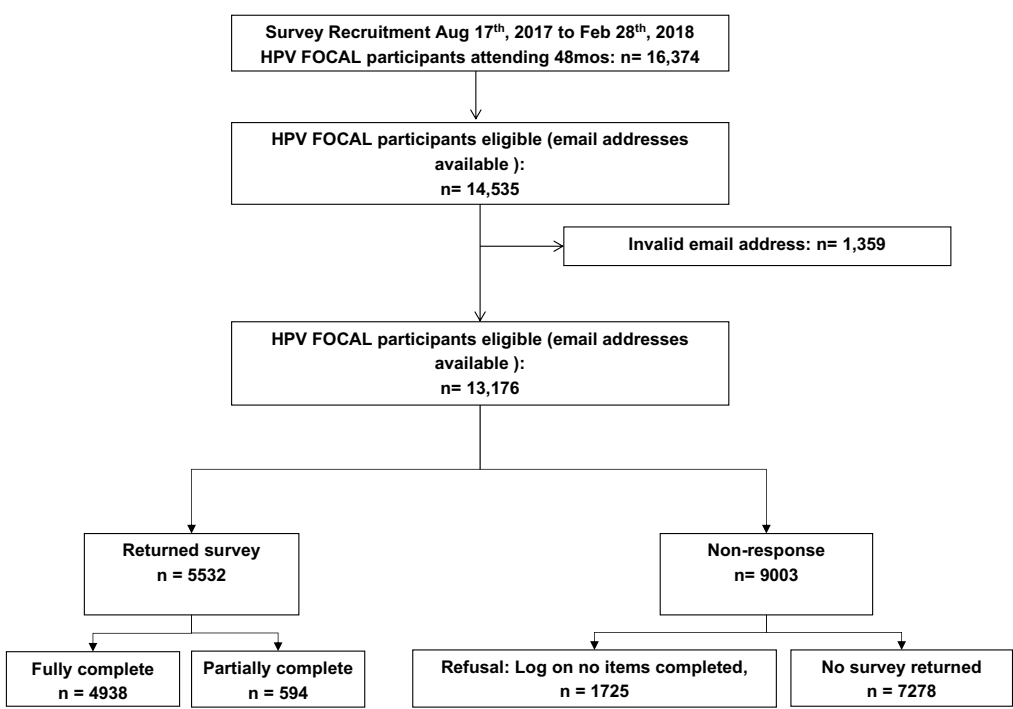
REFERENCES

- 1 Walboomers JMM, Jacobs M v., Manos MM, *et al.* Human papillomavirus is a necessary
2 cause of invasive cervical cancer worldwide. *Journal of Pathology* 1999;**189**:12–9.
3 doi:10.1002/(SICI)1096-9896(199909)189:1<12::AID-PATH431>3.0.CO;2-F
- 4 Castellsagué X. Natural history and epidemiology of HPV infection and cervical cancer.
5 *Gynecologic Oncology* 2008;**110**. doi:10.1016/j.ygyno.2008.07.045
- 6 Ogilvie GS, van Niekerk D, Krajden M, *et al.* Effect of screening with primary cervical HPV
7 testing vs cytology testing on high-grade cervical intraepithelial neoplasia at 48 months:
8 The HPV FOCAL randomized clinical trial. *JAMA - Journal of the American Medical*
9 *Association* 2018;**320**:43–52. doi:10.1001/jama.2018.7464
- 10 Melnikow J, Henderson JT, Burda BU, *et al.* Screening for cervical cancer with high-risk
11 human papillomavirus testing updated evidence report and systematic review for the us
12 preventive services task force. *JAMA - Journal of the American Medical Association*
13 *2018*;320:687–705. doi:10.1001/jama.2018.10400
- 14 Ronco G, Dillner J, Elfström KM, *et al.* Efficacy of HPV-based screening for prevention of
15 invasive cervical cancer: Follow-up of four European randomised controlled trials. *The*
16 *Lancet* 2014;**383**:524–32. doi:10.1016/S0140-6736(13)62218-7
- 17 Arbyn M, Ronco G, Anttila A, *et al.* Evidence regarding human papillomavirus testing in
18 secondary prevention of cervical cancer. *Vaccine*. 2012;**30**.
19 doi:10.1016/j.vaccine.2012.06.095
- 20 Dijkstra MG, van Zummeren M, Rozendaal L, *et al.* Safety of extending screening
21 intervals beyond five years in cervical screening programmes with testing for high risk
22 human papillomavirus: 14 year follow-up of population based randomised cohort in the
23 Netherlands. *BMJ (Clinical research ed)* 2016;**355**:i4924. doi:10.1136/bmj.i4924
- 24 McBride E, Marlow LAV, Forster AS, *et al.* Anxiety and distress following receipt of results
25 from routine HPV primary testing in cervical screening: The psychological impact of
26 primary screening (PIPS) study. *International Journal of Cancer* 2020;**146**:2113–21.
27 doi:10.1002/ijc.32540
- 28 Bennett KF, Waller J, Ryan M, *et al.* The psychosexual impact of testing positive for high-
29 risk cervical human papillomavirus (HPV): A systematic review. *Psycho-Oncology*.
30 *2019*;28:1959–70. doi:10.1002/pon.5198
- 31 Obermair HM, Dodd RH, Bonner C, *et al.* It has saved thousands of lives, so why change
32 it?' Content analysis of objections to cervical screening programme changes in Australia.
33 *BMJ Open* 2018;**8**. doi:10.1136/bmjopen-2017-019171
- 34 Ogilvie GS, van Niekerk DJ, Krajden M, *et al.* A randomized controlled trial of Human
35 Papillomavirus (HPV) testing for cervical cancer screening: Trial design and preliminary
36 results (HPV FOCAL Trial). *BMC Cancer* 2010;**10**. doi:10.1186/1471-2407-10-111
- 37 Ogilvie GS, Krajden M, van Niekerk DJ, *et al.* Primary cervical cancer screening with HPV
38 testing compared with liquid-based cytology: results of round 1 of a randomised
39 controlled trial -- the HPV FOCAL Study. *British journal of cancer* 2012;**107**:1917–24.
40 doi:10.1038/bjc.2012.489

- 1
2
3 594 13 Coldman AJ, Gondara L, Smith LW, *et al.* Disease detection and resource use in the
4 595 safety and control arms of the HPV FOCAL cervical cancer screening trial. *British journal*
5 596 *of cancer* 2016;**115**:1487–94. doi:10.1038/bjc.2016.368
6
7 597 14 Ogilvie GS, Kraiden M, van Niekerk D, *et al.* HPV for cervical cancer screening (HPV
8 598 FOCAL): Complete Round 1 results of a randomized trial comparing HPV-based primary
9 599 screening to liquid-based cytology for cervical cancer. *International journal of cancer*
10 600 2017;**140**:440–8. doi:10.1002/ijc.30454
11
12 601 15 Ogilvie GS, Smith LW, van Niekerk DJ, *et al.* Women’s intentions to receive cervical
13 602 cancer screening with primary human papillomavirus testing. *International Journal of*
14 603 *Cancer* 2013;**133**:2934–43. doi:10.1002/ijc.28324
15
16 604 16 The American Association for Public Opinion Research. Standard Definitions: Final
17 605 dispositions of case codes and outcome rates for surveys. 9th Edition. 2016.
18 606 17 Dodd RH, Mac OA, McCaffery KJ. Women’s experiences of the renewed National
19 607 Cervical Screening Program in Australia 12 months following implementation: a
20 608 qualitative study. *BMJ open* 2020;**10**:e039041. doi:10.1136/bmjopen-2020-039041
21 609 18 Silver MI, Rositch AF, Burke AE, *et al.* Patient concerns about human papillomavirus
22 610 testing and 5-year intervals in routine cervical cancer screening. *Obstetrics and*
23 611 *Gynecology* 2015;**125**:317–29. doi:10.1097/AOG.0000000000000638
24
25 612 19 Gerend MA, Shepherd MA, Kaltz EA, *et al.* Understanding women’s hesitancy to
26 613 undergo less frequent cervical cancer screening. *Preventive Medicine* 2017;**95**:96–102.
27 614 doi:10.1016/j.ypmed.2016.11.028
28
29 615 20 Tatar O, Thompson E, Naz A, *et al.* Factors associated with human papillomavirus (HPV)
30 616 test acceptability in primary screening for cervical cancer: A mixed methods research
31 617 synthesis. *Preventive Medicine*. 2018;**116**:40–50. doi:10.1016/j.ypmed.2018.08.034
32 618 21 Saraiya M, Berkowitz Z, Yabroff KR, *et al.* Cervical cancer screening with both human
33 619 papillomavirus and papanicolaou testing vs papanicolaou testing alone: What screening
34 620 intervals are physicians recommending? *Archives of Internal Medicine* 2010;**170**:977–86.
35 621 doi:10.1001/archinternmed.2010.134
36
37 622 22 McBride E, Tatar O, Rosberger Z, *et al.* Emotional response to testing positive for human
38 623 papillomavirus at cervical cancer screening: a mixed method systematic review with
39 624 meta-analysis. *Health Psychology Review* 2020;:1–35.
40 625 doi:10.1080/17437199.2020.1762106
41
42 626 23 Dodd RH, Mac O, Brotherton JML, *et al.* Levels of anxiety and distress following receipt
43 627 of positive screening tests in Australia’s HPV-based cervical screening programme: A
44 628 cross-sectional survey. *Sexually Transmitted Infections*. 2020;**96**:166–72.
45 629 doi:10.1136/sextrans-2019-054290
46
47 630 24 McCaffery K, Waller J, Forrest S, *et al.* Testing positive for human papillomavirus in
48 631 routine cervical screening: Examination of psychosocial impact. *BJOG: An International*
49 632 *Journal of Obstetrics and Gynaecology*. 2004;**111**:1437–43. doi:10.1111/j.1471-
50 633 0528.2004.00279.x
51
52 634 25 Waller J, v Marlow LA, Wardle J, *et al.* The association between knowledge of HPV and
53 635 feelings of stigma, shame and anxiety. *Sex Transm Infect* 2007;**83**:155–9.
54 636 doi:10.1136/sti.2006.023333
55
56
57
58
59
60

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2
3 637 26 Shepherd MA, Gerend MA. The blame game: Cervical cancer, knowledge of its link to
4 638 human papillomavirus and stigma. *Psychology and Health* 2014;**29**:94–109.
5 639 doi:10.1080/08870446.2013.834057
6
7 640 27 Kosenko KA, Hurley RJ, Harvey JA. Sources of the uncertainty experienced by women
8 641 with HPV. *Qualitative Health Research* 2012;**22**:534–45. doi:10.1177/1049732311424404
9 642 28 Patel H, Moss EL, Sherman SM. HPV primary cervical screening in England: Women’s
10 643 awareness and attitudes. *Psycho-Oncology* 2018;**27**:1559–64. doi:10.1002/pon.4694
11 644 29 Smith L, van Niekerk D, Coldman A, *et al.* Recommendations for Implementing Human
12 645 Papillomavirus-Based Cervical Cancer Screening: Lessons Learned from the HPV FOCAL
13 646 Trial. *Journal of obstetrics and gynaecology Canada : JOGC = Journal d’obstetrique et*
14 647 *gynecologie du Canada : JOGC* 2016;**38**:723–6. doi:10.1016/j.jogc.2016.04.009
15
16 648 30 Bennett KF, Waller J, Ryan M, *et al.* Concerns about disclosing a high-risk cervical human
17 649 papillomavirus (HPV) infection to a sexual partner: A systematic review and thematic
18 650 synthesis. *BMJ Sexual and Reproductive Health*. 2019. doi:10.1136/bmjsex-2019-200503
19 651 31 Rahman M, Laz TH, McGrath CJ, *et al.* Provider recommendation mediates the
20 652 relationship between parental human papillomavirus (HPV) vaccine awareness and HPV
21 653 vaccine initiation and completion among 13- to 17-year-old US adolescent children.
22 654 *Clinical Pediatrics* 2015;**54**:371–5. doi:10.1177/0009922814551135
23
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Figure 1: Study Flowchart and participant disposition



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2 **Thank you for contributing to the HPV FOCAL Study! As you know the purpose of the study was to**
3 **evaluate HPV testing for cervical cancer screening in BC. The results of the FOCAL study will be very**
4 **important as Canadian programs consider adopting HPV testing to screen for changes that may lead to**
5 **cervical cancer. We are interested to learn about your experience and understanding of HPV testing**
6 **for cervical cancer screening. ***As a reminder, ALL women who completed a 4 year exit screen**
7 **received both a Pap smear and an HPV test*****
8
9

10 **Your input is important to us and can help plan for the future of cervical cancer screening in BC. Please**
11 **take a few moments of your time to complete the attached survey. You do not have to answer any**
12 **questions you do not feel comfortable answering.**
13
14

15 First we would like to ask about your HPV knowledge before and during the study.

16
17
18 **1) Please rate the following question according to how much you agree or disagree with the statement:**
19 **I know more about HPV and cervical cancer now than I did before I participated in the study:**

- 20
21
22 Strongly Disagree
23 Disagree
24 Neutral
25 Agree
26 Strongly agree
27 Not Sure

28
29
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31
32 **2) I was aware of my cervical screen (Pap and HPV test) results at completion of the study:**

- 33
34 No
35 Yes
36 Not sure

37
38
39
40 **3) Please rate the following question according to how much you agree or disagree with the statement:**
41 **I had enough time to ask my health care provider questions about HPV testing and/or my results.**

- 42
43
44 Strongly Disagree
45 Disagree
46 Neutral
47 Agree
48 Strongly agree
49 Don't know
50 Not applicable

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56 CTRL IA Exit Survey 12June2017

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- 4) Please rate the following question according to how much you agree or disagree with the statement:
I feel my health care provider was able to answer my questions about HPV:

- Strongly Disagree
 Disagree
 Neutral
 Agree
 Strongly agree
 Don't know
 Not applicable

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- 5) Please rate the following statements regarding HPV testing:

Having my health care provider collect a sample for HPV testing for cervical cancer screening would be:

	<---	<--	<-	Neutral	->	-->	--->	
Accurate	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Inaccurate
Safe	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Unsafe
Protect my health	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Harm my health
Acceptable	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Unacceptable

6) Which of the following have been important sources of information for you about HPV/HPV testing?

	Not at all important	Not that important	Neutral	Somewhat important	Very important
My health care provider	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BC Cancer Agency (including the BC Cancer Agency website)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Government websites (ie: Canadian Cancer Society, Health Canada, Public Health Agency of Canada, BC Ministry of Health)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other websites (ie: WebMD, blogs, etc)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Friends/family	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Social Media (ie: facebook, twitter, etc)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Other comments:.....

1
2 Next we would like to ask how you feel about HPV testing to screen for cervical cancer.
3

4 *As a reminder, there are over 100 types of the human papillomavirus (HPV), of which about 40 affect the*
5 *genital region. HPV is very common and most sexually active people will have an infection at some point*
6 *in their lives, however it usually disappears without a person experiencing any symptoms. Only in cases*
7 *where a cancer causing HPV type persists for many years, is there a risk that it may lead to cervical*
8 *cancer.*
9
10

11 **7) Please rate the following question according to how much you agree or disagree with the statement:**
12 **Having an HPV test to screen for cervical cancer instead of a Pap smear is acceptable to me:**
13

- 14
15 Strongly Disagree
16 Disagree
17 Neutral
18 Agree
19 Strongly agree
20 Don't know
21
22
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24

25 Comments:.....
26

27
28 **8) I would be willing to have an HPV test every 4 or 5 years instead of a Pap test every 3 years:**
29

- 30 Strongly Disagree
31 Disagree
32 Neutral
33 Agree
34 Strongly agree
35 Don't know
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40 Comments:
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Evidence suggests that HPV testing is ideally started no earlier than 30 years of age. Should HPV testing be adopted in the province, it would be available for women starting at age 30 or 35. However, cervical cancer screening could still start at age 25 using the Pap smear as currently recommended in BC.

9) Receiving HPV testing for cervical cancer screening, starting at age 30 is acceptable to me.

- Strongly Disagree
- Disagree
- Neutral
- Agree
- Strongly agree
- Don't know

10) If cervical cancer screening was to occur every 4 or 5 years, instead of every 3 years, I would be less likely to visit my health care provider for other health reasons.

- Strongly Disagree
- Disagree
- Neutral
- Agree
- Strongly agree
- Don't know

Next we would like to understand some of your thoughts about HPV testing compared to the Pap test.

11) What would concern you most: 1) being told you had "abnormal Pap test results" or 2) being told you were "positive for HPV"? (Check ONE only)

- Neither would concern me
- Being told I have abnormal Pap test results
- Being told I have HPV
- Both would concern me equally

Please explain:

.....

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Next, we would like to learn about your experience of receiving HPV results.

12) If you tested HPV positive during the HPV FOCAL trial, or if you were to test positive for HPV, please rate your level of agreement with the following statements:

	Strongly disagree	Disagree	Neutral/uncertain	Agree	Strongly Agree
Although HPV is sexually acquired, having an infection that is sexually acquired does not concern me any differently than abnormal Pap results would.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
It would be important for me to know who gave me HPV.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
It would be important to me to determine when I got HPV.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I think people might judge me for having HPV.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I would feel comfortable telling my partner about my HPV positive result.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I would not be concerned about transmitting HPV to a sexual partner.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Receiving a positive HPV result would not affect my relationship with my sexual partner.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Having HPV would not cause me any concern about developing cervical cancer.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I would feel confident in the follow up and/or treatment my provider would recommend for my positive HPV result.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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Other comments:.....

**13) Please rate the following statements according to how much you agree or disagree:
 If I tested positive for HPV I felt/would feel:**

	Strongly disagree	Disagree	Neutral/uncertain	Agree	Strongly agree
Reassured	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Relieved	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Guilty	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Worried	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Upset	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Surprised	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Other comments:

14) If you were aware of your results at the end of the trial and they were negative/normal, how confident were you with the safety of these results?

- Very unconfident
- Somewhat unconfident
- Neutral
- Somewhat confident
- Very confident
- Didn't know my results
- Not applicable/results were positive

Next we would like to ask about your thoughts about the possibility of women collecting their own sample for HPV testing for cervical cancer screening by inserting a soft Q-tip or brush into the vagina that can then be returned to the laboratory and tested for the presence of HPV. With self-collection, a woman would not need to see a health care provider for pelvic exam for sample collection. Self-collected specimens tested for HPV have been shown to be equivalent to HPV samples taken by a health care provider for detecting abnormalities of the cervix.

15) Please rate the following statements regarding self-collected samples:

Collecting my own sample for cervical cancer screening would be:

	<---	<--	<-	Neutral	->	-->	--->	
Accurate	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Inaccurate
Safe	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Unsafe
Protect my health	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Harm my health
Acceptable	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Unacceptable

16) I would be willing to collect my own sample/specimen for cervical cancer screening:

- Strongly Disagree
- Disagree
- Neutral
- Agree
- Strongly agree
- Don't know

Comments:

.....

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2
3 Finally we'd like to ask some questions that may help us better understand associations between HPV
4 and various other factors.
5
6

7 **17) What is the highest level of education you have achieved?**
8

- 9
10 No formal education
11 Some elementary school
12 Completed elementary school
13 Some high school
14 Completed high school
15 Some post-secondary training (Trades, college, university)
16 Completed trade/vocational/apprenticeship program
17 Completed college
18 Completed university (bachelor degree)
19 Completed university (master degree or higher)
20
21
22
23
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26

27 **18) Please indicate your current marital status:**
28

- 29 Single (living WITHOUT a partner)
30
31 Single (living WITH a partner)
32
33 Married or common law
34
35 Divorced
36
37 Separated (but still legally married)
38
39 Widowed
40
41
42

43 **19) Not including new partners you have had since you completed the HPV FOCAL study, please**
44 **indicate to the best of your recollection, how many male partners you have had vaginal**
45 **intercourse with:**
46

- 47 0
48 1-10
49 11-49
50 50+
51
52
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20) Please enter the total years you have used the following hormonal birth control methods. If never used, please enter "0". **(survey build, enter in months)**

Method	Total years used	Please place a checkmark in this column if you used this method while participating in the HPV FOCAL study
Oral contraceptive pill	--	<input type="checkbox"/>
Contraceptive patch	--	<input type="checkbox"/>
Contraceptive vaginal ring	--	<input type="checkbox"/>
Hormonal IUD	--	<input type="checkbox"/>
Injection (ie: Depo-provera)	--	<input type="checkbox"/>
Morning after pill or emergency contraceptive pill	--	<input type="checkbox"/>
Implant	--	<input type="checkbox"/>

We are trying to better understand how use of specific substances (ie: alcohol, tobacco and marijuana) impacts a woman's potential to develop a long term HPV infection. These following questions help us determine if there is an association between HPV infection and different substances.

21) Have you ever smoked cigarettes?

- Yes (daily). For approximately how many years: __
- Yes (less than daily)
- Not at all

22) Were you a regular cigarette smoker during your participation in the HPV FOCAL Study?

- Every day....Approximately how many cigarettes did you smoke per day? __
- Some days...Approximately how many days did you smoke each week? __
- Not at all

(Survey build). Only link to Q22 if answered "every day" or "some days" to Q21

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7 **23) During your participation in the HPV FOCAL Study, how often did you use marijuana:**

- 8
9 Never
10 Less than once a month
11 1-3 times a month
12 Once a week
13 More than once a week
14 Every day

15
16
17
18
19 **Survey build: skip Q24 if answered "never" to Q23**

20 **24) Please indicate the ways you used marijuana during the HPV FOCAL study:**

- 21
22
23 Smoking
24 Vaporizing
25 Edible (ie: cakes, cookies, candy, drinks, etc)
26 Pill/capsule
27 Other

28
29
30
31 **25) During your participation in the HPV FOCAL Study, how often did you drink alcoholic beverages?**

- 32
33
34 Never
35 Once a month or less
36 2-3 times a month
37 Once a week
38 2-3 times a week
39 4-6 times a week
40 Every day

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56 CTRL IA Exit Survey 12June2017

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2 **26) Please estimate your total household income (everyone in your household, excluding**
3 **roommates):**
4

- 5 Less than \$10,000
- 6 \$10,001-25,000
- 7 \$25,001-50,000
- 8 \$50,001-75,000
- 9 \$75,001-100,000
- 10 More than \$100,000
- 11
- 12
- 13
- 14
- 15

16 Thank you for completing this survey! Your responses are highly valued and impact guidelines and
17 recommendations as the province of British Columbia considers changes to cervical cancer screening
18 practices. If you have any questions or comments please feel free to contact the HPV FOCAL study at
19 hpvfocal@bccancer.bc.ca
20

21
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25
26 **SURVEY BUILD: Link to a separate section where respondents can enter their name and contact info to**
27 **be entered into a draw. We will offer an incentive for survey completion.**
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STROBE Statement—Checklist of items that should be included in reports of *cross-sectional studies*

	Item No	Recommendation	Page No
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	1
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4
Objectives	3	State specific objectives, including any prespecified hypotheses	4
Methods			
Study design	4	Present key elements of study design early in the paper	6
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	6
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants	6
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	NA
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	6,7
Bias	9	Describe any efforts to address potential sources of bias	6-8
Study size	10	Explain how the study size was arrived at	7-8
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	6-8
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	8
		(b) Describe any methods used to examine subgroups and interactions	8
		(c) Explain how missing data were addressed	8
		(d) If applicable, describe analytical methods taking account of sampling strategy	8
		(e) Describe any sensitivity analyses	8
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	9
		(b) Give reasons for non-participation at each stage	9
		(c) Consider use of a flow diagram	17
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	9
		(b) Indicate number of participants with missing data for each variable of interest	9, 18
Outcome data	15*	Report numbers of outcome events or summary measures	18
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	18

		(b) Report category boundaries when continuous variables were categorized	n/A
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	n/a
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	9-11
Discussion			
Key results	18	Summarise key results with reference to study objectives	12-15
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	15-16
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	16
Generalisability	21	Discuss the generalisability (external validity) of the study results	16
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	24

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.

BMJ Open

Women's acceptability of and experience with primary human papillomavirus testing for cervix screening: HPV FOCAL trial cross-sectional online survey results

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Manuscripts

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3 1 Women's acceptability of and experience with primary human papillomavirus testing for cervix
4 2 screening: HPV FOCAL trial cross-sectional online survey results
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6 4

7 5 Laurie W Smith^{1,2}, C. Sarai Racey^{2,3}, Lovedeep Gondara⁴, Mel Krajden^{3,5}, Murette Lee^{3,6}, Ruth
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32 29

33 30 Word Count: (currently:3977)
34 31

35 32 Key Words: human papillomavirus; HPV; HPV testing for cervix screening; attitudes and
36 33 acceptance HPV testing.
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4 53 **ABSTRACT:** (word count 257)
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8 55 **Objective:** To study participant's acceptability of and attitudes towards human papillomavirus
9
10 56 (HPV) testing compared to cytology for cervical cancer screening, and what impact having an
11
12 57 HPV positive result may have in future acceptability of screening.
13

14
15 58 **Design:** Cross-sectional online survey of clinical trial participants.
16

17 59 **Setting:** Primary care, population-based Cervix Screening Program, British Columbia, Canada.
18

19 60 **Participants:** A total of 5,532 participants from the HPV FOCAL Trial, in which women received
20
21 61 HPV and cytology testing at study exit were included in the analysis. Median age was 54 years.
22
23 62 The median time of survey completion was 3 years after trial exit.
24

25 63 **Outcome measures:** Acceptability of HPV testing for primary cervical cancer screening
26
27 64 (primary); attitudes and patient perceptions towards HPV testing and receipt of HPV positive
28
29 65 screen results (secondary).
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31 66 **Results:** Most respondents (63%) were accepting of HPV testing, with the majority (69%)
32
33 67 accepting screening to begin at age 30 with HPV testing. Only half of participants (54%) were
34
35 68 accepting of an extended screening interval of 4 to 5 years. In multivariable logistic regression,
36
37 69 women who received an HPV positive screen test result during the trial (OR=1.41 95%CI:
38
39 70 1.11,1.80), or were older (OR= 1.01, 95%CI:1.00,1.02) were more likely to report HPV testing
40
41 71 as acceptable.
42
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44 72 **Conclusions:** In this evaluation of acceptability and attitudes regarding HPV testing for cervix
45
46 73 screening, most are accepting of HPV testing for screening; however, findings indicate
47
48 74 heterogeneity in concerns and experiences surrounding HPV testing and receipt of HPV positive
49
50 75 results. These findings provide insights for the development of education, information, and
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52 76 communication strategies during implementation of HPV-based cervical cancer screening.
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3 78 **Trial Registration:** ISRCTN79347302 and ClinicalTrials.gov Identifier: NCT00461760
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7 80 **ARTICLE SUMMARY**
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10 81
11 82 **'Strengths and limitation of this Study'**
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14 83

- 15
16 84 • Measures of acceptability and patient perceptions of HPV testing within a primary cervix
17 screening program.
18 85
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22 87 • Reports on acceptability of increased screening interval and delayed onset of screening
23 initiation, and impact of a positive HPV test result.
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28 90 • Recommendations for key health promotion messaging to address potential barriers to
29 HPV testing for primary cervical screening.
30 91
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34 93 • Limitations include that participants were recruited from a large clinical trial on HPV
35 testing for cervical cancer screening and may not be representative of the general
36 screening population.
37 94
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101 INTRODUCTION

102
103 It is well established that persistent infection with an oncogenic strain of the human
104 papillomavirus (HPV), the most common sexually transmitted infection around the world, is the
105 causative agent for most cervical cancers [1,2]. There is a robust body of evidence regarding
106 the superior performance of HPV vs. cytology screening in detection of cervical intraepithelial
107 neoplasia (CIN) grade 2 or worse (CIN2+) and greater protection against cervical cancer [3–5].
108 As such, several countries around the world have implemented primary HPV testing for cervical
109 cancer screening, including Australia, the Netherlands, and the UK, with many other
110 jurisdictions in various planning stages for HPV-based screening implementation. A shift to an
111 HPV-based screening approach results in different program guidelines and, thus, a different
112 experience for the person undergoing screening. The very high negative predictive value of
113 HPV testing permits the interval between screens to be extended to 5 or more years compared
114 to cytology testing, recommended every 2 to 3 years in most jurisdictions [5–7]. Due to high
115 prevalence and regression rates of HPV infection in younger women, HPV-based screening
116 may not be recommended until 25 to 30 years of age [5,6]. In addition, being screened for
117 cervical cancer with a test for a sexually transmitted infection can result in anxiety and concern
118 for those undergoing screening [8,9].

119
120 With such a transformative change in what is arguably a well-established screening paradigm, it
121 is crucial to examine women's readiness or acceptance of HPV testing compared to cytology
122 testing for screening, to ensure engagement in screening is not hampered by a change in
123 technology or guidelines. This unintended consequence was illustrated in Australia, prior to the
124 change in the national program from cytology to HPV screening, when a 2017 petition opposing
125 the changes garnered 70,000 signatures[10]. Respondents to the Australian survey indicated
126 concerns about such things as the extended interval and missing cancer cases in younger

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3 127 women as a result of the program change [10]. Despite enhancements to screening efficacy and
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5 128 safety, a successful change in technology requires acceptance by those who undergo
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7 129 screening. Anticipating women's questions and concerns prior to implementation of program
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9 130 changes can mitigate resistance to change and assist in the design of targeted education
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11 131 strategies.
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16 133 This analysis is of the 48-month exit survey for the Human Papillomavirus For Cervical Cancer
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18 134 Screening Trial (HPV FOCAL). HPV FOCAL is currently the only North American trial comparing
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20 135 primary HPV testing to cytology (liquid-based) for screening within an organized program, which
21
22 136 also provides us with the unique opportunity to assess women's experiences with HPV testing in
23
24 137 a population-based program setting. The primary objective of this analysis was to explore
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26 138 participant's acceptability of and attitudes towards HPV testing compared to cytology for cervical
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28 139 cancer screening, and what impact having an HPV positive result may play in future
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30 140 acceptability of screening.
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142 **METHODS**

143 **Participants**

144 Survey participants were recruited through the HPV FOCAL trial, a publicly funded randomized
145 control trial comparing primary HPV testing every four years (HPV arm) to liquid-based cytology
146 testing (cytology arm) every two years for cervical cancer screening (ISRCTN79347302). HPV
147 FOCAL recruited women, 25-65 years of age, from two largely metro areas in British Columbia
148 who were due for cervical cancer screening from 2008 through to 2012. Participants of the HPV
149 FOCAL Trial were engaged in cervical cancer screening through a large population-based
150 screening program, and representative of women at average risk of cervical cancer in North
151 America [11] Trial design and primary outcome results have been previously described in detail
152 [3,11–14]. Participants were provided with information on HPV, HPV testing (including
153 differences between Pap and HPV testing, and the reasons behind an extended interval
154 between negative HPV screens) and cervical cancer upon enrollment and throughout the trial
155 follow-up period. A total of 9552 women were randomized to the HPV arm and 9457 women to
156 the cytology arm. Women from both the HPV and cytology arms completed trial exit screening
157 between 2012 and 2016, where they received HPV and cytology co-testing at the exit screen.
158 Results were provided to their primary care provider, who then conveyed them to the
159 participants. From August 2017-February 2018 women from both arms who had attended the
160 48-month exit screen were invited to complete the online exit survey (FIGURE 1).

161

162 **HPV FOCAL exit survey**

163 The survey included 26 items that asked participants about HPV knowledge and information
164 seeking before and during the study, acceptability of HPV testing, willingness to increase the
165 screening interval, commencement screening age for HPV testing, attitudes and concerns about
166 test positive results and communication needs around screening results, in addition to
167 demographic details (SUPPLEMENTARY FILE). Responses included 7- and 5-point Likert

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3 168 scales, and survey responses were linked to HPV FOCAL trial screen test results. Survey items
4
5 169 were based upon previous HPV FOCAL surveys assessing HPV testing acceptance [15] The
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7 170 survey was distributed and managed using the web-based platform of Fluidsurveys
8
9 171 (www.fluidsurveys.com). The survey was pilot tested and revised for face and content validity
10
11 172 with approximately 20 women, aged 30 and above prior to distribution to FOCAL participants.
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15 174 **Patient and public involvement**

16 175 Patient concerns and questions raised during the trial period identified the need for the study,
17
18 176 but patients were not involved in the construction of the survey[16]. However, a sample of
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20 177 women who undergo cervical cancer screening in BC were involved in pilot testing of the survey
21
22 178 for the purposes of face validity and survey flow and logistics. Based on this feedback, revisions
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24 179 were made to the survey to clarify wording of questions and format of layout.
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30 181 **Response rate and inclusion criteria**

31 182 Participants from the HPV FOCAL trial from both the HPV and cytology arms who had
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33 183 completed their study 48 month exit screen, had indicated consent to be contacted for future
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35 184 research, and for whom email addresses were available were eligible for survey invitation. The
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37 185 invite to complete the survey was sent via email, with one reminder sent a month later for those
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39 186 who had not initiated or completed the survey. Participants were provided with a unique study
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41 187 identifier to access the survey and no personal identifiers were captured during survey
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43 188 completion. Participants were informed they had the option to complete none, some, or all of the
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45 189 survey with completion of survey questions as indication of consent.
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52 191 Survey completeness was reviewed, and duplicate surveys, where the same woman completed
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54 192 all or some of the survey more than once, were identified. For those with a duplicate entry, the
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3 193 first complete survey was used in the analysis with all other survey attempts discarded.
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5 194 Response rate (%) was the sum of completed surveys plus partial surveys, divided by the
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7 195 number of invitations sent to eligible valid email addresses, as per the American Association for
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9 196 Public Opinion Research guidelines[17]. Non-response included: refusals (clicked the survey
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11 197 link, but did not complete consent or any items), and those assumed eligible with no response
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13 198 received. Email addresses that were undeliverable were considered invalid and not included in
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15 199 the analysis.
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17 200 **Statistical analysis**

18 201 Survey respondents were compared to HPV FOCAL trial participants on age, study arm, and
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20 202 location of trial recruitment to explore if survey sample was representative of FOCAL trial
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22 203 population.
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26 205 Our main outcome of HPV testing acceptability was assessed by response to the question
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28 206 “having an HPV test instead of a Pap to screen for cervical cancer is acceptable to me”, which
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30 207 was dichotomized from a 5-point Likert scale, with those reporting strongly agree or agree,
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32 208 categorized as ‘accepting’, and those reporting neutral, don’t know, disagree and strongly
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34 209 disagree as ‘not accepting’ of HPV testing. This categorization was chosen to capture those
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36 210 who were truly accepting and biased towards the null. Only complete surveys were included,
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38 211 with those who were missing or preferred not to answer excluded. Participants were classified
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40 212 as being HPV positive, if they received an HPV positive screening result at any point during their
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42 213 participation in the HPV FOCAL trial, otherwise a participant was classified as HPV negative.
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46 215 Bivariable analysis explored differences in acceptability of HPV testing based on demographic
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48 216 factors such as age, income, and education, in addition to HPV screening test result, and
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50 217 length of time since study exit. Factors shown to be potentially associated with acceptability,
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3 218 such as HPV screening starting at 30 years of age and increased screening interval, were also
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5 219 examined[16,18,19].
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9 221 Socio-demographics and attitudes towards HPV testing were explored descriptively with Chi-
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11 222 square for categorical variables and median score test for continuous variables.
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15 224 Multivariate logistic regression was used to explore the association of the acceptability of HPV
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17 225 testing with *a priori* identified confounding variables that reached $p \leq 0.2$ in bivariable analysis.
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19 226 Level of significance was 0.05. All statistical analyses were performed in SAS 9.4 and R4.02.
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24 228 **Ethics Approval**

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26 229 Ethics approvals for survey was received by the University of British Columbia Research Ethics
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28 230 Board (H06-04032). In addition, a privacy review was undertaken to ensure the survey complied
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30 231 with provincial privacy legislation.
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34 233 **RESULTS**

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36 234 Survey invites were administered from August 2017 through to February 2018. A total of 14,535
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38 235 participants from both the HPV and cytology arms in HPV FOCAL trial were identified as eligible
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40 236 to receive 48-months exit online survey, of which 13,176 were delivered to a valid email address
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42 237 (FIGURE 1). There were 5,532 surveys completed, of which 4,938 were fully and 594 partially
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44 238 completed.
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244 **Characteristics of respondents**

245 The median age of participants completing the survey was 54 years (IQR: 46,62) (Table 1). The
246 median time of survey completion was 3 years after study exit. The majority of respondents
247 (67%) had completed college or higher education and 77% reported living with a partner.
248 Survey respondents were comparable to HPV FOCAL trial participants based on study arm, age
249 at HPV FOCAL trial enrollment, and geographical location. Survey respondents and non-
250 respondents were comparable by study arm and marital status, but those who responded to the
251 survey were slightly older than non-responders (median of 51 years vs. 49 years), although the
252 difference was not clinically significant.

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255 **Acceptability of HPV testing for Screening**

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257 Overall, 63% of survey respondents agreed or strongly agreed that HPV testing for cervical
258 cancer screening was acceptable, with 37% not agreeing (11% disagree, 16% neutral, 10%
259 don't know) (Table 1). There were no significant associations between acceptability of HPV
260 testing and marital partnership status, time since study exit, education or income. Women who
261 received an HPV positive result at any point during HPV FOCAL trial and who were older were
262 more accepting of HPV testing compared to those who remained HPV negative during trial
263 participation.

264

265 In multivariate analysis, women who reported HPV testing as acceptable were more likely to
266 have received an HPV positive screen test result at some point during the trial (OR 1.41 95%CI
267 1.11,1.80, p=0.005), and were older (OR 1.01, 95%CI 1.00,1.02, p=0.01) (Table 2).

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3 269 Over half of respondents (54%) agreed with the statement “I would be willing to have an HPV
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5 270 test every 4-5 years instead of a Pap every 3 years”. There was a significant difference in
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7 271 acceptability of an extended screening interval between those who reported being accepting of
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9 272 HPV testing compared to those who were not accepting. Overall, 69% responded that HPV
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11 273 testing starting at age 30 was acceptable, with over 80% of those who were accepting of HPV
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13 274 testing reporting agreement with a higher screening age (30 years or over) compared to Pap
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15 275 testing (Table 1).
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20 277 In addition, 66% of respondents reported that an extended screening would not result in less
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22 278 visits to their healthcare provider for other medical reasons, indicating that despite the extended
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24 279 interval recommended with HPV-based screening, women would continue to see their providers
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26 280 for medical reasons as needed.
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30 282 **Attitudes towards an HPV Positive Test Result:**

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34 284 Survey respondents were asked to rate their level of agreement with a variety of statements
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36 285 regarding attitudes surrounding receipt of HPV positive results (Table 3). Women were asked if
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38 286 they would be more concerned about receiving a positive HPV test or an abnormal Pap result,
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40 287 for which most respondents (73%) reported that both screening outcomes would concern them
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42 288 equally. However, those that reported HPV testing to be acceptable, reported that an HPV
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44 289 positive result would concern them more (14%) than an abnormal Pap. This was statistically
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46 290 different compared to those who were not accepting of HPV testing, who responded that
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48 291 abnormal Pap test results would concern them more. The difference in distribution between
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50 292 these responses was statistically significant.
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3 294 Most respondents who were not accepting of HPV testing indicated that having a sexually
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5 295 acquired infection would concern them differently than having abnormal Pap results. The
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7 296 relationship between level of agreement with HPV testing acceptability and ones' level of
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9 297 concern about having a sexually acquired infection was significant. Regardless of a
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11 298 respondent's reported HPV testing acceptability, most respondents felt it important to them to
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13 299 know who gave them HPV and when they acquired HPV (72% and 78% respectively). Most
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15 300 respondents indicated they disagreed or were neutral regarding feeling judged for having HPV,
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17 301 and there was no significant relationship between feeling judged and level of agreement with
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19 302 HPV testing. More respondents who were accepting of HPV testing indicated they would feel
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21 303 comfortable telling their partner if they had HPV, which was in contrast to those who were not
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23 304 accepting of HPV testing; these differences indicated a significant relationship between HPV
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25 305 testing acceptance and comfort disclosing HPV status to a partner. Regardless of level of
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27 306 agreement with HPV testing, most respondents (79%) indicated they would feel concerned
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29 307 about transmitting HPV to their partner(s). More respondents who were accepting of HPV
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31 308 testing would feel confident in the recommendations from their provider for the management of
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33 309 their HPV positive results. There was a significant association between level of agreement with
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35 310 HPV testing and degree of confidence with provider recommendations.
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41 311 **Sources of information for HPV testing and screening:**

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43 313 Overall, the most reported important sources of information were health care providers and BC
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45 314 Cancer, the agency that is responsible for the cervix screening program in British Columbia
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47 315 (Table 4). In addition, those that are accepting of HPV testing were more likely to look to their
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49 316 health care providers and BC Cancer as important sources of information. Regardless of one's
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51 317 level of agreement with HPV testing for screening, friends and family or social media were not
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53 318 as important as health care providers and BC Cancer for sources of information.
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DISCUSSION

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322 Acceptability of, and attitudes, towards primary HPV testing were analysed from 5,532 women

323 who completed HPV testing as part of the HPV FOCAL trial, which was embedded within an

324 organized population-based cervical cancer screening program. Most respondents (63%) were

325 accepting of HPV testing for cervix screening and for screening with HPV testing to begin at age

326 30 (69%). Just over half were accepting of HPV testing with the extended screen interval of 4 to

327 5 years (54%). Although most women were accepting, the proportion of respondents indicating

328 they disagreed with or were neutral in their acceptance of HPV testing and of extended intervals

329 was higher than we expected considering this was a group of people who were provided with

330 education and information about HPV, HPV testing, and cervical cancer. These findings are

331 similar to other studies that indicate women have concerns about the extended interval

332 recommended with HPV testing [10,20–22], stemming from a belief that a cancer diagnosis may

333 be missed through extension of the interval. Considering study participants received information

334 regarding HPV, the natural history of HPV and cervical cancer, and the rationale for HPV testing

335 compared to the Pap test, these findings indicate that additional research and patient

336 engagement is needed to gain insights and identify and develop resources or procedures to

337 address barriers to HPV testing and an extended screening interval.

338

339 This multivariate analysis found that those who received positive HPV test results at some point

340 during the trial were more likely to be accepting of HPV testing for cervix screening than those

341 who never received an HPV positive result. Those who tested HPV positive would have

342 received additional information and counseling from their healthcare provider and or a Study

343 nurse, which would not necessarily have been provided to those who tested HPV negative. This

344 additional information would have reinforced the education participants were provided at trial

345 baseline, including the prevalence of HPV in the population, the transient nature of HPV and the

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3 346 long natural history between HPV infection and cervical dysplasia development. In addition,
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5 347 those with HPV positive results would have received additional follow-up and management by
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7 348 the time the survey was administered. The reinforcement of education, an opportunity for
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9 349 dialogue when receiving the positive result, and the fact that those with a positive HPV result
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11 350 would have received treatment for detected dysplasia, may have facilitated improvement in
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13 351 knowledge and subsequently, enhanced acceptance of HPV testing. Other findings have
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15 352 indicated that increased HPV and HPV screening knowledge can be a facilitator of HPV
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17 353 screening acceptance[18].
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22 355 One of the concerns with an extended screening interval is if women would be less likely to
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24 356 consult with the health care provider for other medical reasons[16]. When we asked participants
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26 357 if they would be less willing to see a healthcare provider for other medical reasons if the interval
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28 358 for cervix screening were increased, most respondents said they would not be less willing,
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30 359 indicating that the extended interval for cervix screening would not prevent them from seeking
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32 360 care as needed. This finding can provide reassurance to healthcare professionals who have
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34 361 concerns that the extended screening interval recommended with HPV-based screening would
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36 362 lead to fewer visits to a clinician, given that the cervical screen visit is often an opportunity for
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38 363 the clinician to assess other preventive care or medical issues [23].
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43 365 Respondents' concerns regarding receipt of HPV positive results were varied. Nearly 93% of the
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45 366 respondents never received an HPV positive result during the HPV FOCAL trial. As a result, the
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47 367 majority of responses evaluate attitudes and experiences for those who did not actually receive
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49 368 HPV positive results, and therefore, reflect how the respondents would hypothetically feel if they
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51 369 were to receive HPV positive results. Of the respondents, 7.5% had received an HPV positive
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53 370 result at some point during their trial participation.
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3 372 Most participants indicated that having HPV would cause them concern about having cervical
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5 373 cancer. The majority of participants reported that having either an abnormal Pap or a positive
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7 374 HPV test would concern them; however, for those that had tested positive for HPV, they
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9 375 reported that an HPV test would concern them more compared to an abnormal Pap. Overall,
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11 376 participants' perceptions about HPV positive results and cervical cancer indicate that increased
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13 377 knowledge regarding the specificity of HPV testing for cervical cancer screening is needed.
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18 379 Receipt of positive HPV results has been associated with higher anxiety and distress compared
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20 380 to receipt of abnormal Pap results[24–26], which may be due to the fact that HPV is a sexually
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22 381 transmitted infection and has been associated with levels of shame and stigma[27,28]. Most
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24 382 respondents in our survey indicated that receiving results for a sexually acquired HPV infection
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26 383 would concern them differently than having an abnormal Pap test result; however, this belief
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28 384 varied depending on a participant's acceptability of HPV testing. Women who were not
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30 385 accepting of HPV testing indicated that a HPV positive result would concern them differently
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32 386 than abnormal Pap results, compared to those who were accepting of HPV testing. Most
33
34 387 respondents, whether they accepted HPV testing or not, felt it important for them to know who
35
36 388 gave them HPV and when they got it (71% and 78% respectively). These findings together are
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38 389 reflective of other research findings[9,29,30] and indicate that when developing education and
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40 390 communication strategies, emphasis should be placed on the high prevalence of HPV in the
41
42 391 population, the transient nature of most HPV infections, bringing awareness to the fact an
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44 392 infection may have been acquired several years prior to a positive test result. Differentiating
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46 393 HPV from other STIs may minimize anxiety and facilitate normalization and acceptance[16,27].
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51 395 Almost 75% of the respondents indicated they felt an HPV positive result would affect their
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53 396 relationship with their partner, or they weren't sure, and almost 80% would be concerned about
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55 397 transmitting HPV to their partners, with many feeling they would be judged for being HPV
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3 398 positive. The stigma associated with HPV, concerns about infidelity and potential partner
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5 399 reactions to the HPV result may underlie these concerns. Previous research has indicated some
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7 400 women question whether partner notification with HPV is necessary[16,31]. Unlike other STIs
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9 401 such as chlamydia or gonorrhoea where partner notification is recommended for testing and
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11 402 treatment purposes, there is usually no medical reason to notify the partner of a woman who
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13 403 tested positive for HPV.

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16 405 Healthcare providers, as trusted and valued sources of information, can influence patients'
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18 406 decision-making patterns regarding health care decisions[20,32] Reflecting other findings, the
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20 407 respondents in this survey indicated that the most important sources of information for them,
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22 408 were their healthcare providers and the provincial screening program [[20,32]]. In this cohort,
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24 409 the least important sources of information were social media and friends and family, providing
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26 410 reassurance that women in this cohort seek information from reputable sources such as health
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28 411 care providers and the screening program compared to the internet, or friends and family.
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30 412 These findings demonstrate that program planning for HPV-based screening should prepare
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32 413 health care providers with adequate education and training surrounding HPV prior to program
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34 414 changes, to ensure they are equipped to address women's questions and concerns regarding
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36 415 the paradigm shift from cytology to HPV-based screening.

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39 417 This study is not without limitations. Survey participants were part of a large clinical trial and
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41 418 were given information about HPV, HPV testing and cervical cancer upon enrollment and,
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43 419 therefore, may not be representative of all people eligible for cervix screening in British
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45 420 Columbia. However, participants of this study are reflective of the current population engaged in
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47 421 the screening program, who receive cytology testing with the Pap smear, and not HPV testing
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49 422 as standard of care. As a result, their concerns and feedback are informative for programs
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51 423 planning for a shift from cytology to HPV-based screening. The response rate may be
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3 424 considered low at 41%; however, those who have stronger opinions about their screening
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5 425 choices may have been more likely to respond to the survey than those who are more trusting
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7 426 of the health care system and accepting of any future policy changes. In addition, survey
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9 427 respondents were representative of overall participants in the HPV FOCAL trial. The majority of
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11 428 respondents completed the survey approximately 3 years after trial completion and it is possible
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13 429 there was loss of recall of HPV related information provided to them when they consented to
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15 430 participate in the trial, which for many was up to 7 years prior to survey completion. The
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17 431 potential lag time between trial entry and survey completion may have introduced recall bias
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19 432 and impacted women's attitudes and beliefs surrounding HPV testing; however, the impact of
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21 433 this potential bias would be small as we found no significant difference between acceptability
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23 434 and time between trial entry and survey completion. In addition, most of the participants in this
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25 435 trial were over the age of 50, highly educated and primarily from two urban geographic regions
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27 436 and may not be representative of all screen eligible people in various regions of British
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34 439 **CONCLUSIONS**

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39 441 In this study, within an organized screening setting, evaluating acceptability and attitudes
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41 442 around HPV testing from women undergoing HPV-based screening, most are accepting of HPV
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43 443 testing for screening; however, further research is needed to understand factors that can
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45 444 increase acceptability. These findings contribute to the growing body of evidence demonstrating
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47 445 that concerns and experiences surrounding HPV testing and receipt of HPV positive results are
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49 446 complex and varied. As many cervix screening programs begin HPV-based screening and are
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51 447 planning implementation strategies, attention to patient engagement to address potential
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53 448 barriers will be important. As HPV-based screening becomes standard of care, it is plausible
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55 449 that concerns with this paradigm shift will eventually be alleviated with increasing knowledge

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3 450 and familiarity. These findings provide insight into areas of importance that should be
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5 451 considered for development of education, information, and communication strategies.
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Figure 1: Study flowchart and participant disposition

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489 **Table 1: Demographic characteristics of respondents and bivariable analysis of acceptability of**
 490 **HPV testing**
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		Having an HPV test instead of a Pap smear to screen for cervical cancer is acceptable to me			
		Total (N)	Not acceptable (Disagree/Neutral/Don't know)	Acceptable (Agree)	p-value
Total (N)		5336	1993 (37.4%)	3343 (62.6%)	
Age	median [IQR]	5336	53.35 [45.35, 61.19]	54.23 [45.64, 61.72]	0.051
Marital Status^a					
	Living with a partner	3806	1438 (78.7)	2368 (76.6)	0.095
	Living without a partner	1115	390 (21.3)	725 (23.4)	
Education^a					
	Complete College or higher	3317	1250 (68.5)	2067 (66.7)	0.221
	Incomplete post-secondary or less	1607	576 (31.5)	1031 (33.3)	
Income^a					
	Less than \$75000	1501	529 (32.0)	972 (34.0)	0.175
	\$75,000 or more	3014	1126 (68.0)	1888 (66.0)	
HPV Testing Status during FOCAL trial					
	Never tested HPV positive	4937	1867 (93.7)	3070 (91.8)	0.015*
	At least one HPV positive result	399	126 (6.3)	273 (8.2)	
Time since exit from FOCAL trial, Years					
	median [IQR]	5336	3.09 [2.26, 3.91]	3.04 [2.23, 3.93]	0.616
I would be willing to have an HPV test every 4-5 years instead of a Pap every 3 years^a					
	Agree	2858	386 (19.5)	2472 (74.2)	<0.001*
	Disagree	1096	744 (37.6)	352 (10.6)	
	Neutral	1353	847 (42.8)	506 (15.2)	
Receiving HPV testing starting at age 30 is acceptable to me^a					
	Agree	3635	944 (47.8)	2691 (81.0)	<0.001*
	Disagree	682	423 (21.4)	259 (7.8)	
	Neutral	981	608 (30.8)	373 (11.2)	
If cervical cancer screening was to occur every 4 or 5 years, instead of every 3 years, I would be less likely to visit my health care provider for other health reasons. ^a					
	Agree	1062	405 (20.4)	657 (19.7)	0.814
	Disagree	3517	1303 (65.7)	2214 (66.4)	
	Neutral	735	274 (13.8)	461 (13.8)	

Table Notes: ^a Missing values up to 5,336 = not reported or prefer not to answer, * significant to p<0.05

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504 **Table 2:** Multivariate analysis of predictors for participants who are accepting of HPV testing
 505 instead of Pap testing for cervical cancer screening.
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Variable	OR (95% CI)	P-value
Age at survey completion (years)	1.01 (1.00,1.02)	0.01
Received HPV positive results during study (Yes vs No)	1.41 (1.11,1.80)	0.005
Education (Incomplete post-secondary or less vs Complete College or higher)	1.06 (0.93,1.21)	0.41
Marital status (Living without a partner vs Living with a partner)	1.04 (0.88,1.22)	0.67
Income (\$75000 or more vs. less than \$75000)	0.97 (0.84,1.12)	0.68

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512 **Table 3:** Experiences receiving HPV positive results

	HPV testing instead of Pap testing for cervical cancer:			p-value
	Total (N)	Not acceptable	Acceptable	
	5336	1993 (36.0%)	3343 (60.4%)	
What would concern you most: Being told you had abnormal Pap results, or being told you had HPV?^a				
Being told I have abnormal Pap test results	668	274 (14.0)	394 (11.9)	<0.001*
Being told I have HPV	683	197 (10.0)	486 (14.7)	
Both would concern me equally	3855	1464 (74.7)	2391 (72.2)	
Neither would concern me	67	26 (1.3)	41 (1.2)	
Having an infection that is sexually acquired (HPV) doesn't concern me any differently than abnormal Pap results would^a				
Agree	1412	442 (24.8)	970 (31.5)	<0.001*
Disagree	2465	974 (54.6)	1491 (48.4)	
Neutral	987	369 (20.7)	618 (20.1)	
It would be important for me to know who gave me HPV^a				
Agree	3468	1251 (70.3)	2217 (71.7)	0.094
Disagree	545	188 (10.6)	357 (11.5)	
Neutral	859	340 (19.1)	519 (16.8)	
It would be important for me to know when I got HPV^a				
Agree	3795	1372 (76.9)	2423 (78.3)	0.131
Disagree	432	151 (8.5)	281 (9.1)	
Neutral	650	260 (14.6)	390 (12.6)	
I think people would judge me for having HPV^a				
Agree	1775	663 (37.4)	1112 (36.0)	0.307
Disagree	1419	495 (27.9)	924 (30.0)	
Neutral	1666	617 (34.8)	1049 (34.0)	
I would feel comfortable telling my partner if I had HPV^a				
Agree	3391	1198 (67.4)	2193 (71.3)	0.016*
Disagree	709	284 (16.0)	425 (13.8)	
Neutral	755	296 (16.6)	459 (14.9)	
I would not be concerned about transmitting HPV to my partner^a				
Agree	515	174 (9.8)	341 (11.1)	0.095
Disagree	3825	1400 (78.7)	2425 (79.0)	
Neutral	509	205 (11.5)	304 (9.9)	
Being HPV positive would not affect my relationship with my partner^a				
Agree	1249	445 (25.1)	804 (26.3)	0.035*
Disagree	2003	708 (39.9)	1295 (42.3)	
Neutral	1584	622 (35.0)	962 (31.4)	
Having HPV would not cause me any concern about cervical cancer^a				
Agree	181	52 (2.9)	129 (4.2)	0.012*
Disagree	4112	1499 (84.1)	2613 (84.8)	
Neutral	569	231 (13.0)	338 (11.0)	
I would feel confident in the recommendations from my healthcare provider for follow-up of my HPV positive result^a				
Agree	3876	1323 (74.0)	2553 (82.5)	<0.001*
Disagree	226	97 (5.4)	129 (4.2)	

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Neutral	780	369 (20.6)	411 (13.3)
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Table Notes: : ^a Missing values up to 5,336 = not reported or prefer not to answer,, * significant to p<0.05

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515 **Table 4: Important sources of HPV information**

			Having an HPV test instead of a Pap smear to screen for cervical cancer is acceptable to me		
		Total (N)	Not acceptable	Acceptable	p-value
		5336	1993 (36.0%)	3343 (60.4%)	
Health Care Provider^a					
	Important	3405	1128 (59.3)	2277 (70.1)	<0.001*
	Neutral	1256	560 (29.5)	696 (21.4)	
	Not Important	487	213 (11.2)	274 (8.4)	
BC Cancer (organizes screening in BC)^a					
	Important	2713	907 (48.7)	1806 (56.9)	<0.001*
	Neutral	1649	673 (36.1)	976 (30.8)	
	Not Important	673	283 (15.2)	390 (12.3)	
Govt Websites (ex: Canadian Cancer Society/Public Health Agency Canada)^a					
	Important	2111	734 (39.9)	1377 (44.2)	0.011*
	Neutral	1914	748 (40.6)	1166 (37.5)	
	Not Important	928	359 (19.5)	569 (18.3)	
Other websites (WebMd, blogs)^a					
	Important	1597	567 (31.3)	1030 (33.7)	0.112
	Neutral	1997	776 (42.8)	1221 (40.0)	
	Not Important	1273	469 (25.9)	804 (26.3)	
Friends/family^a					
	Important	1336	453 (25.0)	883 (28.9)	0.012*
	Neutral	1865	725 (40.0)	1140 (37.3)	
	Not Important	1670	634 (35.0)	1036 (33.9)	
Social media^a					
	Important	580	197 (10.9)	383 (12.6)	0.004*
	Neutral	1562	633 (35.1)	929 (30.7)	
	Not Important	2693	975 (54.0)	1718 (56.7)	

Table Notes : ^a Missing values up to 5,336 = not reported or prefer not to answer,, * significant to p<0.05

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5 530 FOCAL Trial and completed this survey, and the hundreds of BC collaborating clinicians. We
6 531 also extend gratitude to many partners including: The BC Cancer Cervix Screening and
7 532 Colposcopy Program; the BC Centre for Disease Control Public Health Laboratory; the
8 533 University of British Columbia; BC Cancer Surveillance and Outcomes Unit; Women's Health
9 534 Research Institute; and the Canadian Institutes of Health Research.

10 535

11 536 **Contributors:** LWS involved in conception, design and implementation of the research
12 537 presented here, drafting and review of manuscript; CSR conducted statistical analysis and
13 538 contributed to drafting and review of manuscript; LG conducted statistical analysis; MK, ML,
14 539 REM, GS, SP ELF and DV are co-investigators on the HPV FOCAL Study and were involved in
15 540 FOCAL trial design and trial management; AJC and GO are co-principal investigators of the
16 541 FOCAL Study and oversaw conduct of the trial; all authors take responsibility for the credibility
17 542 of the data and analysis and critically reviewed the paper and approved the final version.

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21 546

22 547 **Competing interests:** MK and AC were principal investigators, and GO, DV and EF were co-
23 548 investigators on industry funded (Hologic Inc, and Roche) investigator-led adjunct studies to the
24 549 HPV FOCAL Trial, designed to compare the performance of different HPV testing assays. No
25 550 investigators personally benefitted financially. Funding for these adjunct studies was not applied
26 551 to the operation of the HPV FOCAL results presented in this paper. ELF served as an
27 552 occasional advisor for companies involved with HPV vaccines (Merck, GSK) and HPV
28 553 diagnostics (Roche). He also holds a patent "DNA methylation markers for early
29 554 detection of cervical cancer," registered at the Office of Innovation and Partnerships,
30 555 McGill University, Montreal, Quebec, Canada.

31 556

32 557 **Patient consent for publication:** Not required

33 558

34 559 **Ethics approval:** Ethics approvals for survey was received by the University of British Columbia
35 560 Research Ethics Board (H06-04032).

36 561

37 562 **Provenance and Peer review:** Not commissioned; externally peer reviewed.

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39 564 **Data availability Statement:** Deidentified participant data is available upon consideration and
40 565 reasonable request.

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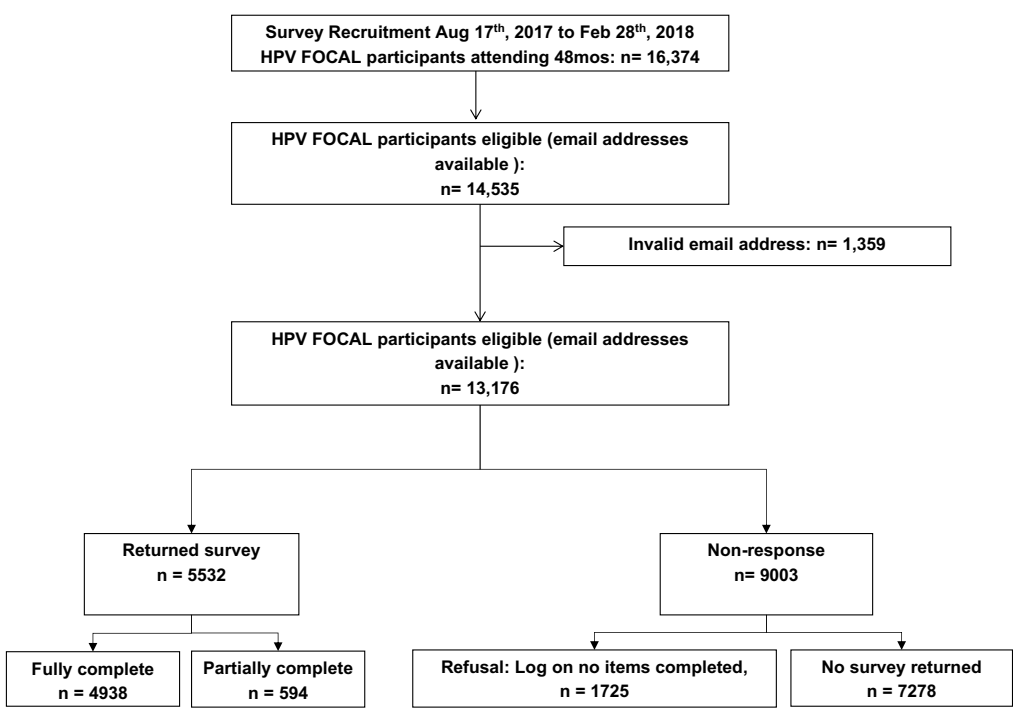
REFERENCES

- 1
2
3 577
4 578
5 579 1 Walboomers JMM, Jacobs M v., Manos MM, *et al.* Human papillomavirus is a necessary
6 580 cause of invasive cervical cancer worldwide. *Journal of Pathology* 1999;**189**:12–9.
7 581 doi:10.1002/(SICI)1096-9896(199909)189:1<12::AID-PATH431>3.0.CO;2-F
8 582 2 Castellsagué X. Natural history and epidemiology of HPV infection and cervical cancer.
9 583 *Gynecologic Oncology* 2008;**110**. doi:10.1016/j.ygyno.2008.07.045
10 584 3 Ogilvie GS, van Niekerk D, Krajden M, *et al.* Effect of screening with primary cervical HPV
11 585 testing vs cytology testing on high-grade cervical intraepithelial neoplasia at 48 months:
12 586 The HPV FOCAL randomized clinical trial. *JAMA - Journal of the American Medical*
13 587 *Association* 2018;**320**:43–52. doi:10.1001/jama.2018.7464
14 588 4 Melnikow J, Henderson JT, Burda BU, *et al.* Screening for cervical cancer with high-risk
15 589 human papillomavirus testing updated evidence report and systematic review for the us
16 590 preventive services task force. *JAMA - Journal of the American Medical Association*
17 591 2018;**320**:687–705. doi:10.1001/jama.2018.10400
18 592 5 Ronco G, Dillner J, Elfström KM, *et al.* Efficacy of HPV-based screening for prevention of
19 593 invasive cervical cancer: Follow-up of four European randomised controlled trials. *The*
20 594 *Lancet* 2014;**383**:524–32. doi:10.1016/S0140-6736(13)62218-7
21 595 6 Arbyn M, Ronco G, Anttila A, *et al.* Evidence regarding human papillomavirus testing in
22 596 secondary prevention of cervical cancer. *Vaccine*. 2012;**30**.
23 597 doi:10.1016/j.vaccine.2012.06.095
24 598 7 Dijkstra MG, van Zummeren M, Rozendaal L, *et al.* Safety of extending screening intervals
25 599 beyond five years in cervical screening programmes with testing for high risk human
30 600 papillomavirus: 14 year follow-up of population based randomised cohort in the
31 601 Netherlands. *BMJ (Clinical research ed)* 2016;**355**:i4924. doi:10.1136/bmj.i4924
32 602 8 McBride E, Marlow LAV, Forster AS, *et al.* Anxiety and distress following receipt of results
33 603 from routine HPV primary testing in cervical screening: The psychological impact of
34 604 primary screening (PIPS) study. *International Journal of Cancer* 2020;**146**:2113–21.
35 605 doi:10.1002/ijc.32540
36 606 9 Bennett KF, Waller J, Ryan M, *et al.* The psychosexual impact of testing positive for high-
37 607 risk cervical human papillomavirus (HPV): A systematic review. *Psycho-Oncology*.
38 608 2019;**28**:1959–70. doi:10.1002/pon.5198
39 609 10 Obermair HM, Dodd RH, Bonner C, *et al.* It has saved thousands of lives, so why change
40 610 it?' Content analysis of objections to cervical screening programme changes in Australia.
41 611 *BMJ Open* 2018;**8**. doi:10.1136/bmjopen-2017-019171
42 612 11 Ogilvie GS, van Niekerk DJ, Krajden M, *et al.* A randomized controlled trial of Human
43 613 Papillomavirus (HPV) testing for cervical cancer screening: Trial design and preliminary
44 614 results (HPV FOCAL Trial). *BMC Cancer* 2010;**10**. doi:10.1186/1471-2407-10-111
45 615 12 Ogilvie GS, Krajden M, van Niekerk DJ, *et al.* Primary cervical cancer screening with HPV
46 616 testing compared with liquid-based cytology: results of round 1 of a randomised
47 617 controlled trial -- the HPV FOCAL Study. *British journal of cancer* 2012;**107**:1917–24.
48 618 doi:10.1038/bjc.2012.489
49
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3 619 13 Coldman AJ, Gondara L, Smith LW, *et al.* Disease detection and resource use in the safety
4 620 and control arms of the HPV FOCAL cervical cancer screening trial. *British journal of*
5 621 *cancer* 2016;**115**:1487–94. doi:10.1038/bjc.2016.368
6
7 622 14 Ogilvie GS, Krajden M, van Niekerk D, *et al.* HPV for cervical cancer screening (HPV
8 623 FOCAL): Complete Round 1 results of a randomized trial comparing HPV-based primary
9 624 screening to liquid-based cytology for cervical cancer. *International journal of cancer*
10 625 2017;**140**:440–8. doi:10.1002/ijc.30454
11
12 626 15 Ogilvie GS, Smith LW, van Niekerk DJ, *et al.* Women’s intentions to receive cervical
13 627 cancer screening with primary human papillomavirus testing. *International Journal of*
14 628 *Cancer* 2013;**133**:2934–43. doi:10.1002/ijc.28324
15
16 629 16 Smith L, van Niekerk D, Coldman A, *et al.* Recommendations for Implementing Human
17 630 Papillomavirus-Based Cervical Cancer Screening: Lessons Learned from the HPV FOCAL
18 631 Trial. *Journal of obstetrics and gynaecology Canada : JOGC = Journal d’obstetrique et*
19 632 *gynecologie du Canada : JOGC* 2016;**38**:723–6. doi:10.1016/j.jogc.2016.04.009
20
21 633 17 The American Association for Public Opinion Research. Standard Definitions: Final
22 634 dispositions of case codes and outcome rates for surveys. 9th Edition. 2016.
23 635 18 Tatar O, Thompson E, Naz A, *et al.* Factors associated with human papillomavirus (HPV)
24 636 test acceptability in primary screening for cervical cancer: A mixed methods research
25 637 synthesis. *Preventive Medicine*. 2018;**116**:40–50. doi:10.1016/j.ypmed.2018.08.034
26
27 638 19 Ogilvie GS, Smith LW, van Niekerk D, *et al.* Correlates of women’s intentions to be
28 639 screened for human papillomavirus for cervical cancer screening with an extended
29 640 interval. *BMC Public Health* 2016;**16**. doi:10.1186/s12889-016-2865-8
30
31 641 20 Dodd RH, Mac OA, McCaffery KJ. Women’s experiences of the renewed National Cervical
32 642 Screening Program in Australia 12 months following implementation: a qualitative study.
33 643 *BMJ open* 2020;**10**:e039041. doi:10.1136/bmjopen-2020-039041
34
35 644 21 Silver MI, Rositch AF, Burke AE, *et al.* Patient concerns about human papillomavirus
36 645 testing and 5-year intervals in routine cervical cancer screening. *Obstetrics and*
37 646 *Gynecology* 2015;**125**:317–29. doi:10.1097/AOG.0000000000000638
38
39 647 22 Gerend MA, Shepherd MA, Kaltz EA, *et al.* Understanding women’s hesitancy to undergo
40 648 less frequent cervical cancer screening. *Preventive Medicine* 2017;**95**:96–102.
41 649 doi:10.1016/j.ypmed.2016.11.028
42
43 650 23 Saraiya M, Berkowitz Z, Yabroff KR, *et al.* Cervical cancer screening with both human
44 651 papillomavirus and papanicolaou testing vs papanicolaou testing alone: What screening
45 652 intervals are physicians recommending? *Archives of Internal Medicine* 2010;**170**:977–86.
46 653 doi:10.1001/archinternmed.2010.134
47
48 654 24 McBride E, Tatar O, Rosberger Z, *et al.* Emotional response to testing positive for human
49 655 papillomavirus at cervical cancer screening: a mixed method systematic review with
50 656 meta-analysis. *Health Psychology Review* 2020;:1–35.
51 657 doi:10.1080/17437199.2020.1762106
52
53 658 25 Dodd RH, Mac O, Brotherton JML, *et al.* Levels of anxiety and distress following receipt of
54 659 positive screening tests in Australia’s HPV-based cervical screening programme: A cross-
55 660 sectional survey. *Sexually Transmitted Infections*. 2020;**96**:166–72. doi:10.1136/sextrans-
56 661 2019-054290
57
58
59
60

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2
3 662 26 McCaffery K, Waller J, Forrest S, *et al*. Testing positive for human papillomavirus in
4 663 routine cervical screening: Examination of psychosocial impact. *BJOG: An International*
5 664 *Journal of Obstetrics and Gynaecology*. 2004;**111**:1437–43. doi:10.1111/j.1471-
6 665 0528.2004.00279.x
7
8 666 27 Waller J, v Marlow LA, Wardle J, *et al*. The association between knowledge of HPV and
9 667 feelings of stigma, shame and anxiety. *Sex Transm Infect* 2007;**83**:155–9.
10 668 doi:10.1136/sti.2006.023333
11
12 669 28 Shepherd MA, Gerend MA. The blame game: Cervical cancer, knowledge of its link to
13 670 human papillomavirus and stigma. *Psychology and Health* 2014;**29**:94–109.
14 671 doi:10.1080/08870446.2013.834057
15
16 672 29 Kosenko KA, Hurley RJ, Harvey JA. Sources of the uncertainty experienced by women
17 673 with HPV. *Qualitative Health Research* 2012;**22**:534–45. doi:10.1177/1049732311424404
18 674 30 Patel H, Moss EL, Sherman SM. HPV primary cervical screening in England: Women’s
19 675 awareness and attitudes. *Psycho-Oncology* 2018;**27**:1559–64. doi:10.1002/pon.4694
20 676 31 Bennett KF, Waller J, Ryan M, *et al*. Concerns about disclosing a high-risk cervical human
21 677 papillomavirus (HPV) infection to a sexual partner: A systematic review and thematic
22 678 synthesis. *BMJ Sexual and Reproductive Health*. 2019. doi:10.1136/bmjsex-2019-200503
23
24 679 32 Rahman M, Laz TH, McGrath CJ, *et al*. Provider recommendation mediates the
25 680 relationship between parental human papillomavirus (HPV) vaccine awareness and HPV
26 681 vaccine initiation and completion among 13- to 17-year-old US adolescent children.
27 682 *Clinical Pediatrics* 2015;**54**:371–5. doi:10.1177/0009922814551135
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Figure 1: Study Flowchart and participant disposition



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2 Thank you for contributing to the HPV FOCAL Study! As you know the purpose of the study was to
3 evaluate HPV testing for cervical cancer screening in BC. The results of the FOCAL study will be very
4 important as Canadian programs consider adopting HPV testing to screen for changes that may lead to
5 cervical cancer. We are interested to learn about your experience and understanding of HPV testing
6 for cervical cancer screening. ***As a reminder, ALL women who completed a 4 year exit screen
7 received both a Pap smear and an HPV test***
8
9

10 Your input is important to us and can help plan for the future of cervical cancer screening in BC. Please
11 take a few moments of your time to complete the attached survey. You do not have to answer any
12 questions you do not feel comfortable answering.
13
14

15 First we would like to ask about your HPV knowledge before and during the study.

16
17
18 **1) Please rate the following question according to how much you agree or disagree with the statement:**
19 **I know more about HPV and cervical cancer now than I did before I participated in the study:**

- 20
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22 Strongly Disagree
23 Disagree
24 Neutral
25 Agree
26 Strongly agree
27 Not Sure

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32 **2) I was aware of my cervical screen (Pap and HPV test) results at completion of the study:**

- 33
34 No
35 Yes
36 Not sure

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40 **3) Please rate the following question according to how much you agree or disagree with the statement:**
41 **I had enough time to ask my health care provider questions about HPV testing and/or my results.**

- 42
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44 Strongly Disagree
45 Disagree
46 Neutral
47 Agree
48 Strongly agree
49 Don't know
50 Not applicable

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- 4) Please rate the following question according to how much you agree or disagree with the statement:
I feel my health care provider was able to answer my questions about HPV:

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- Strongly Disagree
 Disagree
 Neutral
 Agree
 Strongly agree
 Don't know
 Not applicable

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- 5) Please rate the following statements regarding HPV testing:

Having my health care provider collect a sample for HPV testing for cervical cancer screening would be:

	<---	<--	<-	Neutral	->	-->	--->	
Accurate	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Inaccurate
Safe	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Unsafe
Protect my health	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Harm my health
Acceptable	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Unacceptable

6) Which of the following have been important sources of information for you about HPV/HPV testing?

	Not at all important	Not that important	Neutral	Somewhat important	Very important
My health care provider	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BC Cancer Agency (including the BC Cancer Agency website)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Government websites (ie: Canadian Cancer Society, Health Canada, Public Health Agency of Canada, BC Ministry of Health)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other websites (ie: WebMD, blogs, etc)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Friends/family	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Social Media (ie: facebook, twitter, etc)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Other comments:.....

Next we would like to ask how you feel about HPV testing to screen for cervical cancer.

As a reminder, there are over 100 types of the human papillomavirus (HPV), of which about 40 affect the genital region. HPV is very common and most sexually active people will have an infection at some point in their lives, however it usually disappears without a person experiencing any symptoms. Only in cases where a cancer causing HPV type persists for many years, is there a risk that it may lead to cervical cancer.

**7) Please rate the following question according to how much you agree or disagree with the statement:
Having an HPV test to screen for cervical cancer instead of a Pap smear is acceptable to me:**

- Strongly Disagree
- Disagree
- Neutral
- Agree
- Strongly agree
- Don't know

Comments:.....

8) I would be willing to have an HPV test every 4 or 5 years instead of a Pap test every 3 years:

- Strongly Disagree
- Disagree
- Neutral
- Agree
- Strongly agree
- Don't know

Comments:

Evidence suggests that HPV testing is ideally started no earlier than 30 years of age. Should HPV testing be adopted in the province, it would be available for women starting at age 30 or 35. However, cervical cancer screening could still start at age 25 using the Pap smear as currently recommended in BC.

9) Receiving HPV testing for cervical cancer screening, starting at age 30 is acceptable to me.

- Strongly Disagree
- Disagree
- Neutral
- Agree
- Strongly agree
- Don't know

10) If cervical cancer screening was to occur every 4 or 5 years, instead of every 3 years, I would be less likely to visit my health care provider for other health reasons.

- Strongly Disagree
- Disagree
- Neutral
- Agree
- Strongly agree
- Don't know

Next we would like to understand some of your thoughts about HPV testing compared to the Pap test.

11) What would concern you most: 1) being told you had "abnormal Pap test results" or 2) being told you were "positive for HPV"? (Check ONE only)

- Neither would concern me
- Being told I have abnormal Pap test results
- Being told I have HPV
- Both would concern me equally

Please explain:

.....

CTRL IA Exit Survey 12June2017

Next, we would like to learn about your experience of receiving HPV results.

12) If you tested HPV positive during the HPV FOCAL trial, or if you were to test positive for HPV, please rate your level of agreement with the following statements:

	Strongly disagree	Disagree	Neutral/uncertain	Agree	Strongly Agree
Although HPV is sexually acquired, having an infection that is sexually acquired does not concern me any differently than abnormal Pap results would.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
It would be important for me to know who gave me HPV.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
It would be important to me to determine when I got HPV.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I think people might judge me for having HPV.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I would feel comfortable telling my partner about my HPV positive result.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I would not be concerned about transmitting HPV to a sexual partner.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Receiving a positive HPV result would not affect my relationship with my sexual partner.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Having HPV would not cause me any concern about developing cervical cancer.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I would feel confident in the follow up and/or treatment my provider would recommend for my positive HPV result.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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Other comments:.....

13) Please rate the following statements according to how much you agree or disagree:

If I tested positive for HPV I felt/would feel:

	Strongly disagree	Disagree	Neutral/uncertain	Agree	Strongly agree
Reassured	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Relieved	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Guilty	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Worried	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Upset	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Surprised	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Other comments:

14) If you were aware of your results at the end of the trial and they were negative/normal, how confident were you with the safety of these results?

- Very unconfident
- Somewhat unconfident
- Neutral
- Somewhat confident
- Very confident
- Didn't know my results
- Not applicable/results were positive

Next we would like to ask about your thoughts about the possibility of women collecting their own sample for HPV testing for cervical cancer screening by inserting a soft Q-tip or brush into the vagina that can then be returned to the laboratory and tested for the presence of HPV. With self-collection, a woman would not need to see a health care provider for pelvic exam for sample collection. Self-collected specimens tested for HPV have been shown to be equivalent to HPV samples taken by a health care provider for detecting abnormalities of the cervix.

15) Please rate the following statements regarding self-collected samples:

Collecting my own sample for cervical cancer screening would be:

	<---	<--	<-	Neutral	->	-->	--->	
Accurate	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Inaccurate
Safe	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Unsafe
Protect my health	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Harm my health
Acceptable	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Unacceptable

16) I would be willing to collect my own sample/specimen for cervical cancer screening:

- Strongly Disagree
- Disagree
- Neutral
- Agree
- Strongly agree
- Don't know

Comments:

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3 Finally we'd like to ask some questions that may help us better understand associations between HPV
4 and various other factors.
5
6

7 **17) What is the highest level of education you have achieved?**
8

- 9
10 No formal education
11 Some elementary school
12 Completed elementary school
13 Some high school
14 Completed high school
15 Some post-secondary training (Trades, college, university)
16 Completed trade/vocational/apprenticeship program
17 Completed college
18 Completed university (bachelor degree)
19 Completed university (master degree or higher)
20
21
22
23
24
25

26
27 **18) Please indicate your current marital status:**
28

- 29 Single (living WITHOUT a partner)
30
31 Single (living WITH a partner)
32
33 Married or common law
34
35 Divorced
36
37 Separated (but still legally married)
38
39 Widowed
40
41

42
43 **19) Not including new partners you have had since you completed the HPV FOCAL study, please**
44 **indicate to the best of your recollection, how many male partners you have had vaginal**
45 **intercourse with:**
46

- 47 0
48 1-10
49 11-49
50 50+
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20) Please enter the total years you have used the following hormonal birth control methods. If never used, please enter "0".

Method	Total years used	Please place a checkmark in this column if you used this method while participating in the HPV FOCAL study
Oral contraceptive pill	--	<input type="checkbox"/>
Contraceptive patch	--	<input type="checkbox"/>
Contraceptive vaginal ring	--	<input type="checkbox"/>
Hormonal IUD	--	<input type="checkbox"/>
Injection (ie: Depo-provera)	--	<input type="checkbox"/>
Morning after pill or emergency contraceptive pill	--	<input type="checkbox"/>
Implant	--	<input type="checkbox"/>

We are trying to better understand how use of specific substances (ie: alcohol, tobacco and marijuana) impacts a woman's potential to develop a long term HPV infection. These following questions help us determine if there is an association between HPV infection and different substances.

21) Have you ever smoked cigarettes?

- Yes (daily). For approximately how many years: __
- Yes (less than daily)
- Not at all

22) Were you a regular cigarette smoker during your participation in the HPV FOCAL Study?

- Every day.....Approximately how many cigarettes did you smoke per day? __
- Some days...Approximately how many days did you smoke each week? __
- Not at all

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4 **23) During your participation in the HPV FOCAL Study, how often did you use marijuana:**
5

- 6
7 Never
8 Less than once a month
9 1-3 times a month
10 Once a week
11 More than once a week
12 Every day
13
14
15
16

17 **24) Please indicate the ways you used marijuana during the HPV FOCAL study:**
18

- 19 Smoking
20 Vaporizing
21 Edible (ie: cakes, cookies, candy, drinks, etc)
22 Pill/capsule
23 Other
24
25
26
27

28 **25) During your participation in the HPV FOCAL Study, how often did you drink alcoholic beverages?**
29

- 30
31 Never
32 Once a month or less
33 2-3 times a month
34 Once a week
35 2-3 times a week
36 4-6 times a week
37 Every day
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2 **26) Please estimate your total household income (everyone in your household, excluding**
3 **roommates):**
4

- 5 Less than \$10,000
6
7 \$10,001-25,000
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9 \$25,001-50,000
10
11 \$50,001-75,000
12
13 \$75,001-100,000
14
15 More than \$100,000

16 Thank you for completing this survey! Your responses are highly valued and impact guidelines and
17 recommendations as the province of British Columbia considers changes to cervical cancer screening
18 practices.
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STROBE Statement—Checklist of items that should be included in reports of *cross-sectional studies*

	Item No	Recommendation	Page No
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	1
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4
Objectives	3	State specific objectives, including any prespecified hypotheses	4
Methods			
Study design	4	Present key elements of study design early in the paper	6
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	6
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants	6
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	NA
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	6,7
Bias	9	Describe any efforts to address potential sources of bias	6-8
Study size	10	Explain how the study size was arrived at	7-8
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	6-8
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	8
		(b) Describe any methods used to examine subgroups and interactions	8
		(c) Explain how missing data were addressed	8
		(d) If applicable, describe analytical methods taking account of sampling strategy	8
		(e) Describe any sensitivity analyses	8
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	9
		(b) Give reasons for non-participation at each stage	9
		(c) Consider use of a flow diagram	17
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	9
		(b) Indicate number of participants with missing data for each variable of interest	9, 18
Outcome data	15*	Report numbers of outcome events or summary measures	18
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	18

		(b) Report category boundaries when continuous variables were categorized	n/A
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	n/a
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	9-11
Discussion			
Key results	18	Summarise key results with reference to study objectives	12-15
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	15-16
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	16
Generalisability	21	Discuss the generalisability (external validity) of the study results	16
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	24

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.