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How does information on the harms and benefits of cervical cancer screening alter the intention to be screened? A randomized survey of Norwegian women

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Abstract

Objectives—Cervical cancer is the 13th most frequent cancer among women in Norway, but the third most common among women aged 25–49 years. The national screening program sends information letters to encourage screening participation. We aimed to evaluate how women's stated intention to participate in screening and pursue treatment changed with the provision of additional information on harms associated with screening, and to assess women's preferences regarding the timing and source of such information.

Methods—We administered a web-based questionnaire to a panel of Norwegian women aged 25–69 years, and randomized into 3 groups based on when in the screening process additional information was introduced: 1) invited for routine screening, 2) recommended an additional test following detection of cellular abnormalities, and 3) recommended precancer treatment. A fourth (control) group did not receive any additional information.

Results—Among 1,060 respondents, additional information did not significantly alter women's stated intentions to screen. However, it created decision uncertainty when treatment was recommended (8.76–9.09 versus 9.40; 10-point Likert scale; $p=0.004$). Over 80% of women favored getting information on harms and 59% preferred that information come from a qualified public health authority. Nearly 90% of women in all groups overestimated women's lifetime risk of cervical cancer.

Conclusion—Additional information on harms did not alter Norwegian women's stated intention to screen for cervical cancer; yet, it resulted in greater decision uncertainty to undergo

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precancer treatment. Incorporating information on harms in invitation letters is warranted, as it would increase women's ability to make informed choices.

Keywords

Screening; cervical cancer; overdiagnosis; overtreatment; harms; shared decision making; patient involvement

Introduction

Population-based screening has reduced the incidence and mortality of invasive cervical cancer (CC) in Norway (Lönnberg et al., 2015; Nygård et al., 2002) and in other developed countries (Peirson et al., 2013; WHO, 2007). Today, CC ranks globally as the fourth most common cancer among women (Ginsburg et al., 2017) and is the third most frequently diagnosed cancer among women during their productive life years in Norway (25–49 years), but ranks number 13 across all age groups (Cancer Registry of Norway, 2015a). Consequently, CC remains an important target for prevention in Norway, but given that its overall impact across the entire lifespan is lower relative to other cancers, the harms and benefits related to its prevention must be carefully weighed.

Health systems in many countries use reminder letters to promote cancer screening. The Norwegian Cervical Cancer Screening Programme (NCCSP) uses such letters for its targeted screening program of women aged 25–69 years. Women who are not recorded as having taken a Pap test within 3 years receive a letter encouraging them to contact their physician to arrange for a gynecological exam. They receive subsequent reminders if a test result is not registered within 12 months. If the screening test detects cellular irregularities, they receive a letter recommending they contact a physician to undergo further testing. While approximately 70% have been screened within the last 3.5 years, compliance with follow-up testing drops to 63% (Cancer Registry of Norway, 2015b) and less than 50% are consistently screened every 3 years (Pedersen et al., 2017).

The NCCSP has reduced the burden of CC, however the harms and benefits of the program for individuals is less clear. It is also challenging to estimate CC screening population benefits, but two model-based studies estimated that screening prevents between 30–70% of Norwegian CCs (Vaccarella et al., 2014; Burger et al., 2012) and a recent study using registry data estimated that two-thirds of CC cases may have been prevented by screening in Norway (Lönnberg et al., 2015). While this means that ~500 CC may be prevented yearly, over 400,000 women get screened and over 3000 undergo treatment every year in Norway (Cancer Registry of Norway, 2015b). Consequently, most screening and treatment procedures are performed on women who would never have developed invasive CC (McCredie et al., 2008; Östör, 1993), resulting in overdiagnosis and overtreatment. Previous studies have shown that women can experience anxiety linked to test results and discomfort related to the screening process (Gray et al., 2006; Cullen et al., 2004). Furthermore, the harms of conization to treat precancer include increased risk of preterm delivery and other adverse pregnancy outcomes (Jin et al., 2014).

Patient involvement in decision-making, especially decisions involving trade-offs between future benefits and procedure-related risks, is increasingly important and has been identified as a key health policy objective (Norwegian Ministry of Health and Care Services, 2015; Research Council of Norway, 2014). For the NCCSP, invitation letters may be an effective way of increasing participation (Camilloni et al., 2013; Everett et al., 2011), but must provide a balance between encouraging screening and ensuring that women make informed choices based on unbiased information about harms and benefits (Irwig et al., 2006). A study has found that invitation letters in 10 developed countries were biased in favor of participation by omitting important information on harms, for instance overdiagnosis and overtreatment (Kolthoff et al., 2016). Failing to provide such information reduces women's ability to make an informed choice (Kolthoff et al., 2016; Hersch et al., 2015).

In many contexts, intention to perform a given action is predictive of actual performance (Ajzen, 1991). Prior studies demonstrate that providing more complete information about harms and benefits associated with screening can influence women's intention to participate (Hestbech et al., 2016; Perneger et al., 2011; Adab et al., 2003) but that, in Norway, general information about the causes of CC neither alters screening-related anxiety or attendance (Burger et al., 2014). However, no studies have examined the effect of more explicit harm-benefit information on intentions to undergo CC screening in Norway. Accordingly, we aimed to evaluate how providing additional information about potential harms of CC screening and treatment impacts women's stated intention to screen, return for additional testing and pursue recommended treatment, and to assess women's preferences regarding the timing and source of the information.

Methods

Study Design

We conducted a randomized, web-based survey in June 2013 utilizing TNS Gallup's active internet panel of more than 50,000 Norwegians. We targeted a representative sample of Norwegian women aged 25–69 years. We elicited baseline understanding of and anxiety about CC, including perceived health state, personal experiences with screening, knowledge about the causes of CC, and knowledge about CC incidence in Norway.

The survey involved a simplified 3-step CC screening process with each stage represented by a letter. Letter 1A was an initial invitation to routine screening and recommendation to have a Pap test, Letter 2A was a reminder and recommendation to have an additional Pap test done if detected with cellular irregularities and Letter 3A was a recommendation to pursue surgical treatment if discovered with precancer. HPV co-testing and follow-up with colposcopy/biopsy that usually precedes treatment were excluded to limit the burden on participants (see Appendix 1). Letters 1A and 2A were based on the actual text of the NCCSP 2012 letter, albeit simplified when appropriate due to the constraints of the survey format. Since recommendations for treatment are generally sent by healthcare providers and not by the NCCSP, we created letter 3A based on the wording used by the NCCSP in other letters (Appendix 2). To assess the impact of additional information about screening-related harms on stated intentions to participate in initial screening, additional testing and treatment, we created expanded versions of each letter (denoted Letters 1B, 2B, and 3B). The expanded

letters included information on the following harms: the possibility to experience anxiety, the potential need for additional tests, the likelihood of recovery with no treatment and the potential link between conization and adverse pregnancy outcomes.

Women were randomized to one of four groups defined in terms of when and how frequently (1, 2 or 3 times) in the process they were informed of the harms of screening and treatment (see Figure 1). After each stage, women were asked to assess their intention to follow the letter's recommendation (Yes/ No/ Don't know) as well as their decision certainty and level of concern over the results (on Likert scales ranging from 1–10). Women's intention to undergo initial screening, additional testing and treatment were measured regardless of what they had answered at previous stages of the process.

After completing questions assessing intentions, all participants indicated whether they felt that additional pieces of information on screening-related harms should be provided to women. Those who answered affirmatively indicated at which stage of the screening process they preferred getting this information and which source they would prefer receiving it from. A final optional question measured survey fatigue, asking women to evaluate the extent to which they agreed or disagreed with the statement that CC screening prevents cancer.

The primary endpoints of this study were the stated intentions to follow the recommendations at each stage of the screening process. In a previous, related study, 92% of respondents answered "yes" to a participation question when no additional information about HPV-infections was provided and the mean response on a 10-point Likert scale (1="I will absolutely not participate", 10="I will absolutely participate") was 8.31 with a standard deviation of 2.23 (Burger et al., 2014). We hypothesized that the mean score would go down by 0.5 when information on screening-related harms is given. In order to detect such a difference with 80% power and a significance level of 5% we needed 175 respondents in each group. We received funding for approximately 1,060 interviews in total, and increased the survey sample accordingly.

Informed consent was obtained from all participants. All data were de-identified before analysis and the study materials and design was approved by the Regional Committee for Medical and Health Research Ethics, South East, Norway.

Participants

The survey along with a short description of the study's objective was sent to 2,626 women between 25 to 69 years of age. In total, 1,275 (48%) opened the survey invitation. Recruitment ceased by deactivating the website when 1,060 participants had responded, which represents 83% of those who had acknowledged the invitation. Sixty-seven women (6.3%) reported having had a hysterectomy which aligns with the prevalence recorded in Norway (Backe and Lilleeng, 1993). While hysterectomy was not an exclusion criterion, having had one rendered specific questions linked to the screening walkthrough irrelevant and hence, these women were excluded from their analysis.

Proportions were calculated for categorical endpoints with Fisher's exact test used to assess the difference between proportions. Non-parametric analysis of variance (Kruskal-Wallis)

tests were used for continuous variables. All data was analyzed using SPSS version 20 and STATA release 12.

Results

Study participants were generally representative of Norwegian women in terms of geographic location, civil status, and education and women were evenly distributed among the four groups, indicating that randomization achieved reasonable balance (Table 1). Respondents aged between 40 and 60 years were somewhat overrepresented in the sample. Likewise, respondents were slightly wealthier and more likely to be born in Norway.

Of those surveyed, 89% listed CC as one of the three most common cancers among Norwegian women and 42% of the respondents correctly indicated a virus as the cause of CC, while the remaining either did not know (20%) or believed CC was linked to other factors (Table 2). Ninety-seven percent reported that Pap testing plays an important or very important role in CC prevention. While women largely reported (96%) having a Pap test done previously, only 24% declared having had abnormalities discovered. Only a minority (11%) claimed being somewhat or extremely concerned about developing CC.

Providing additional information about harms of CC screening did not significantly alter women's intention to participate in initial screening or follow-up testing (Table 3). Regardless of the additional information, 86.9%–88.1% of women stated that they intended to return for the next screening round and 96.5%–97.5% stated that they would return to their GP to follow-up an abnormal result regardless of their intention to screen or not at the previous stage.

Providing additional information reduced women's intention to seek treatment, but did not decrease their intention to avoid treatment. Rather, such information made women significantly more likely to state that they did not know whether to seek treatment or not (13.1%–14.2% versus 7.1% without information; $p=0.011$) and to be significantly less sure of their decision (8.76–9.09 versus 9.40 on the 10-point Likert scale; $p=0.004$) (Table 3).

Most surveyed women favored providing harm-benefit information (Table 4). Regardless of whether they had been presented with the information in the study, 85.0%–87.9% favored informing women that an additional Pap test could be required; 92.3%–94.9% favored informing women of surgery-related risks; 81.2%–86.0% favored informing women that a complete recovery is possible with no treatment.

Women preferred information about screening-related harms earlier on in the overall process and treatment-related risks later, although there was heterogeneity in the responses (Table 4). Additional information provided to some women during the survey significantly altered their preferences about when to receive information regarding the potential for overtreatment; the tendency was to favor informing at the same stage the subject had actually received the information in the survey.

Finally, women across all ages and socioeconomic strata strongly preferred to receive screening-related information from qualified public health and medical sources such as the

Cancer Registry of Norway (59.0%), GPs (22.1%) or a gynecologist or other specialist (13.4%).

Discussion

The results of our study indicate that expanding the harm-benefit information provided in the invitation letters does not reduce women's stated intention to attend CC screening and follow-up on abnormal results. However, the provision of additional information moderately increased decision uncertainty at the point of considering precancer treatment. Even so, women overwhelmingly endorse the provision of expanded information and prefer to receive it from qualified public health and medical sources.

We hypothesized that women who received additional information on some harms of screening would be less likely to follow recommendations than those who received limited information; however, this was not the case. Most women (89%) indicated CC as one of the three most common cancers among Norwegian women, whereas in reality it ranks thirteenth. However, ~60% of respondents belonged to the higher risk age group (25–49), which can explain why they overestimate the overall risk and why, regardless of the additional information, women continued to state that they would screen. On the other hand, a majority of respondents did not report feeling worried about developing CC, nor did they consider themselves at a high risk for the disease. Optimism bias, *i.e.*, the belief that one is less likely to experience a negative event than others, could account for some of this disparity and has been discussed previously in the screening context (Weinstein, 1980; Ackerson and Preston, 2009). Yet, the majority of women reported that they intended to screen, suggesting that optimism bias was not a major driver of their intentions.

The context in which we tested the effects of harm-benefit information on screening behavior may also explain our results. Most Norwegians support the role of the Cancer Registry in running the screening program and indicated preferring to receive information from the registry rather than from a GP or a specialist. Previous studies on screening programs in Norway have highlighted that Norwegians largely view the welfare state, and a paternalistic approach to screening, in a favorable light (Østerlie et al., 2008). The relatively high coverage of CC in the Norwegian media compared to other cancers (Cancer Registry of Norway, 2017) and trust in the NCCSP could explain why women overestimate the risk of CC and their high intentions to follow recommendations in the letters.

Ensuring informed choice continues to be a challenge for patients, physicians, and public health authorities. Health numeracy poses an issue, with many individuals lacking the skills needed to interpret the health information available (Reyna et al., 2009). Likewise, the information physicians provide regarding overdiagnosis and overtreatment when discussing cancer screening in general may not necessarily meet the needs of individual patients (Wegwarth and Gigerenzer, 2013). The NCCSP has since this survey was undertaken, expanded the information available online to include a more explicit breakdown of the harms and benefits of CC screening. The invitation letter was also re-designed to mention that women might feel anxiety and turmoil awaiting test results. Since 2017, letters explicitly recommend that women speak with their doctor about the pros and cons of CC screening.

Limitations

As our study examined stated intentions to perform an action and not the action itself, it is subject to hypothetical bias. The high intentions to participate at each stage do not reflect the participation rates recorded by the NCCSP, especially for additional testing after abnormal or uncertain cytology results, where loss to follow-up is a documented issue (Cancer Registry of Norway, 2013). However, 95% of our sample reported having had a Pap test previously. A recent study showed that 8% of Norwegian women have never attended screening before (Pedersen et al., 2017), suggesting that our sample may have slightly overrepresented women who adhere to screening guidelines. Though web-based questionnaires offer a unique opportunity to recruit a representative sample within a relatively short period, this sample may underrepresent women that are young, or poor, or from immigrant or underserved backgrounds. These characteristics were all linked to non-participation in Norway (Leinonen et al., 2017) and other nationalized health care settings (Azerkan et al., 2012; Khadilkar and Chen, 2013). Selection bias may also have occurred, as the survey topic was disclosed to women before they chose to participate. As such, a prudent next step would include a prospective study of how rolling-out extended harm-benefit information influences actual screening participation, especially in groups likely to be underrepresented in our sample.

Our survey presented 2,500 out of 3,000 conizations performed annually as “unnecessary”. The results of a recent study indicate a much lower rate of overtreatment, but the study was subject to uncertainty due to identification problem of age-time-period-designs (Vaccarella et al., 2014). However, with intentions to follow recommendations so high and relatively small to no impact of providing additional information, it does not appear that the magnitude of these estimates affected our results.

Finally, women in groups 3 and 4 received additional harm information more than once, potentially leading them to place an increased value on this information. However, we found no evidence that these women were less likely to indicate that they intended to follow recommendations than those in other groups. In addition, in the interest of avoiding survey fatigue linked to excessive information, we did not provide material to help women interpret the information provided, nor did we attempt to ascertain the degree to which the women correctly interpreted the information they received. It is essential that expanded harm-benefit information be presented in a way that will facilitate understanding among the target audience.

Policy implications

With an increasing focus on patient involvement in decision-making, clinicians and other healthcare providers should offer patients balanced information on the harms and benefits of screening to support informed decisions. As women highly favored receiving expanded information and the source to be a qualified public health authority, invitation letters sent by the NCCSP could serve that purpose. A previous study found that Norwegian invitation letters included none of suggested information items on harms and benefits of CC screening and CC-related risks (Kolthoff et al., 2016). Our findings suggest that the provision of

additional information on harms is unlikely to result in substantial reductions in screening participation and supports the proposition to expand the letters.

Conclusions

The results of our study indicate that providing expanded harm-benefit information about screening does not reduce women's intention to participate in CC screening. Since provision of additional information on harms may increase decision uncertainty, it is important to provide this information in an understandable manner to avoid confusion and minimize decision uncertainty.

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Appendix 1

The Cancer Registry of Norway is responsible for managing The Norwegian Cervical Cancer Screening Program. according to the following national guidelines (Cancer Registry of Norway, 2014):

If cytology results are normal, women are recommended to take a new test in three years

If the cytology results are abnormal and show atypical squamous cells of undetermined significance (ASC-US) or low-grade squamous intraepithelial lesions (LSIL), women are triaged with an HPV-test. If HPV-negative, women are recommended to take a new cytology test in 3 years. If HPV-positive, women are recommended to take a new cytology and HPV test in 6-12 months. If the results of this second HPV-test is negative and cytology results are normal or show ASC-US, women are recommended to come back in three years as usual. If the results of the second HPV-test is positive, or negative and combined with cytology results showing LSIL or worse, women are referred to a specialist for a diagnostic colposcopy/biopsy which will be followed by treatment recommendations.

If the cytology results of the first test are abnormal and show atypical glandular cells of undetermined significance (AGUS), high-grade squamous intraepithelial lesions (HSIL), atypical squamous cells- cannot exclude HSIL (ASC-H), adenocarcinoma in situ (ACIS) or other cancerous cells, women are immediately referred to a specialist for a diagnostic colposcopy/biopsy which will be followed by treatment recommendations.

It is important to note that the guidelines were slightly different at the time this study was designed. Previously, women with ASC-US and LSIL were simply recommended to take a new cytology and HPV test in 6-12 months, whereas today, they are triaged first with a reflex HPV-test as described above.

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Appendix 2: The letters

The following 6 information letters were used in the study and have been translated from Norwegian.

Letter 1, version A

Recommendation to have a PAP test taken once every three years

A Pap test can save your life—Norwegian health authorities recommend women between 25 and 69 years of age to have a Pap test taken once every three years. The Pap test can detect abnormal cells that may progress to cervical cancer. Effective treatment for severe cell changes is available. The Cancer Registry sends letters to women between 25 and 69 years of age with no Pap tests taken in the past three years and also to women without recommended follow-up of cell changes discovered by screening. More than half of cervical cancers are diagnosed among the minority of women who have not had their Pap test taken. The Cancer Registry registers all Pap test results from the cervix under the provisions of the Cancer

Registry Regulations.

According to our registry, it is more than three years since you last had a Pap test.

We recommend you to make an appointment with your general physician and have a Pap test taken.

Letter 1, version B

Recommendation to have a PAP test taken once every three years

A Pap test can save your life—Norwegian health authorities recommend women between 25 and 69 years of age to have a Pap test taken once every three years. The Pap test can detect abnormal cells that may progress to cervical cancer. Effective treatment for severe cell changes is available. The Cancer Registry sends letters to women between 25 and 69 years of age with no Pap tests taken in the past three years and also to women without recommended follow-up of cell changes discovered by screening. More than half of cervical cancers are diagnosed among the minority of women who have not had their Pap test taken. The Cancer Registry registers all Pap test results from the cervix under the provisions of the Cancer

Registry Regulations.

According to our registry, it is more than three years since you last had a Pap test.

We recommend you to make an appointment with your general physician and have a Pap test taken.

Benefits and disadvantages to participating in the cervical cancer screening: Why is it important for me to have a Pap test? Most cell changes in the cervix are caused by Human

Papillomaviruses (HPV). HPV infection is very common. HPV occurs both in men and women, and is spread through sexual contact. Most of the HPV infections are harmless and disappear by themselves, but sometimes the infection persists and leads to serious cell changes that can develop into cervical cancer. Treatment is available that effectively reduces the risk of developing cervical cancer. Regular Pap testing (screening) can thereby prevent a large proportion of cancers.

What are the disadvantages of having a Pap test? To participate in a screening program can cause excitement and anxiety until the result of the test is ready. Ask your physician about the advantages and disadvantages of screening or see the web site of The Cancer Registry.

Side effects: Every year, serious cell-changes are detected in 3000 Norwegian women. 2500 of these will make a full recovery without treatment, but we do not know which ones. If the cell-changes are not treated, they can develop into cervical cancer. 1 out of 12 women who have a pap smear taken, has to take one or more control samples due to abnormal cells being found. The cell-changes can be removed with a minor surgical procedure, but this treatment may increase the risk for late-term miscarriage and premature birth in future pregnancies. The surgery is usually recommended to women with two or more abnormal samples.

Letter 2, version A

Letter with recommendation for control of cervical pap-smear

- you should take a new pap-smear—A cervical pap-smear was taken *approximately 6 months ago*. The result of this pap-smear was sent to your doctor along with a recommendation to take a control pap-smear.

We are contacting you now because we have not registered that a control cervical pap-smear has been taken.

A control pap-smear is recommended when the first test showed abnormal cells, or an infection of human papilloma virus (HPV) in the cervix. Such cell-changes usually recede on their own, and most HPV-infections disappear within 6-12 months. We still recommend that you contact your GP to take a control pap-smear.

If you have already taken a control pap-smear, please disregard this letter.

Further information about the Cervical Cancer Screening Programme, including frequently asked questions, can be found at www.kreftregisteret.no/livmorhals

Letter 2, version B

Letter with recommendation for control of cervical pap-smear

- you should take a new pap-smear—A cervical pap-smear was taken *approximately 6 months ago*. The result of this pap-smear was sent to your doctor along with a recommendation to take a control pap-smear.

We are contacting you now because we have not registered that a control cervical pap-smear has been taken.

A control pap-smear is recommended when the first test showed abnormal cells, or an infection of human papilloma virus (HPV) in the cervix. Such cell-changes usually recede on their own, and most HPV-infections disappear within 6-12 months. We still recommend that you contact your GP to take a control pap-smear.

If you have already taken a control pap-smear, please disregard this letter.

Benefits and disadvantages to participating in the cervical cancer screening: Why is it important for me to have a Pap test? Most cell changes in the cervix are caused by Human Papillomaviruses (HPV). HPV infection is very common. HPV occurs both in men and women, and is spread through sexual contact. Most of the HPV infections are harmless and disappear by themselves, but sometimes the infection persists and leads to serious cell changes that can develop into cervical cancer. Treatment is available that effectively reduces the risk of developing cervical cancer. Regular Pap testing (screening) can thereby prevent a large proportion of cancers.

What are the disadvantages of having a Pap test? To participate in a screening program can cause excitement and anxiety until the result of the test is ready. Ask your physician about the advantages and disadvantages of screening or see the web site of The Cancer Registry.

Side effects: Every year, serious cell-changes are detected in 3000 Norwegian women. 2500 of these will make a full recovery without treatment, but we do not know which ones. If the cell-changes are not treated, they can develop into cervical cancer. 1 out of 12 women who have a pap smear taken, has to take one or more control samples due to abnormal cells being found. The cell-changes can be removed with a minor surgical procedure, but this treatment may increase the risk for late-term miscarriage and premature birth in future pregnancies. The surgery is usually recommended to women with two or more abnormal samples.

Further information about the Cervical Cancer Screening Programme, including frequently asked questions, can be found at www.kreftregisteret.no/livmorhals

Letter 3 version A

Letter with recommendation to pursue treatment

Now imagine that you have received the following letter in the mail from your doctor after having taken the control sample:

Information concerning discovered cell-changes in the cervix—We have now gotten the results from the control samples we took, and these confirm the irregular cells. Such cell-changes can develop into cervical cancer if they are not removed. Therefore we recommend performing a surgical procedure to remove these irregular cells, before they can develop into cervical cancer. Further information, including frequently asked questions, can be found at www.kreftregisteret.no/livmorhals

Letter 3 version B

Letter with recommendation to pursue treatment

Now imagine that you have received the following letter in the mail from your doctor after having taken the control sample:

Information concerning discovered cell-changes in the cervix—We have now gotten the results from the control samples we took, and these confirm the irregular cells. Such cell-changes can develop into cervical cancer if they are not removed. Therefore we recommend performing a surgical procedure to remove these irregular cells, before they can develop into cervical cancer.

Benefits and disadvantages to participating in the cervical cancer screening: Why is it important for me to have a Pap test? Most cell changes in the cervix are caused by Human Papillomaviruses (HPV). HPV infection is very common. HPV occurs both in men and women, and is spread through sexual contact. Most of the HPV infections are harmless and disappear by themselves, but sometimes the infection persists and leads to serious cell changes that can develop into cervical cancer. Treatment is available that effectively reduces the risk of developing cervical cancer. Regular Pap testing (screening) can thereby prevent a large proportion of cancers.

What are the disadvantages of having a Pap test? To participate in a screening program can cause excitement and anxiety until the result of the test is ready. Ask your physician about the advantages and disadvantages of screening or see the web site of The Cancer Registry.

Side effects: Every year, serious cell-changes are detected in 3000 Norwegian women. 2500 of these will make a full recovery without treatment, but we do not know which ones. If the cell-changes are not treated, they can develop into cervical cancer. 1 out of 12 women who have a pap smear taken, has to take one or more control samples due to abnormal cells being found. The cell-changes can be removed with a minor surgical procedure, but this treatment may increase the risk for late-term miscarriage and premature birth in future pregnancies. The surgery is usually recommended to women with two or more abnormal samples.

Appendix Table 1

Primary results of intentions to screen, undergo additional Pap testing following the detection of irregular cells, and pursue surgical treatment by exposure to additional risk information.

Survey Randomization				
Variables	No Additional Harm Info	Additional Harm Info	Total	P value
Participate in the next screening round? (stage 1) (N=993)	N=725	N=268	N=993	
Yes	641 (88.4%)	235 (87.7%)	876 (88.2%)	0.374

Survey Randomization				
Variables	No Additional Harm Info	Additional Harm Info	Total	P value
No	26 (3.6%)	6 (2.2%)	32 (3.2%)	
Don't Know	58 (8.0%)	27 (10.1%)	85 (8.6%)	
How uncertain or certain (1–10) are you regarding your decision? (N=981)	8.90	8.63	8.83	0.144
How little or how much would you be concerned over whether the sample is abnormal?	N=725	N=268	N=993	0.032
Not at all/a little	257(35.4%)	116(43.2%)	373 (37.5%)	
Neither very little or very much	288(39.7%)	96(35.8%)	384 (38.7%)	
Somewhat/to a great extent	171(23.6%)	49(18.2%)	220 (22.1%)	
Don't Know	9(1.2%)	7(2.6%)	16 (1.6%)	
Return to your GP to have the recommended test done? (N=991)	N=496	N=495	N=991	
Yes	482(97.2%)	478(96.6%)	960 (96.9%)	
No	0(0.0%)	4(0.8%)	32 (3.2%)	0.192
Don't Know	14(2.8%)	13(2.6%)	27 (2.7%)	
How uncertain or certain (1–10) are you regarding your decision? (N=980)	9.55	9.47	9.51	0.181
How little or how much would you be concerned over whether the sample is abnormal?	N=498	N=495	N=993	0.034
Not at all/a little	38(7.6%)	57(11.5%)	95 (9.6%)	
Neither very little or very much	85(17.1%)	102(20.6%)	187 (18.8%)	
Somewhat/to a great extent	364(73.1%)	321(64.8%)	685 (69.0%)	
Don't Know	11(2.2%)	15(3.0%)	26 (2.6%)	
Return to pursue surgical treatment? (N=993)	N=248	N=708	N=956	
Yes	235(92.9%)	633(85.5%)	868 (87.4%)	
No	0(0.0%)	7(0.9%)	7 (0.7%)	0.005
Don't Know	18(7.1%)	100(13.5%)	118 (11.9%)	
How uncertain or certain (1–10) are you regarding your decision? (N=9.82)	9.40	8.94	9.06	0.0001
How little or how much would you be concerned over whether the sample is abnormal?	N=253	N=740	N=993	0.475
Not at all/a little	10(4.0%)	38(5.2%)	48 (4.8%)	
Neither very little or very much	24(9.5%)	80(10.8%)	104 (10.5%)	
Somewhat/to a great extent	216(85.4)	603(81.5)	819 (82.5%)	
Don't Know	3(1.2%)	19(2.6%)	22 (2.2%)	

Stage 1 = Initial invitation to participate in CC screening; Stage 2 = Request to have an additional Pap test done following the detection of cellular abnormalities; Stage 3 = Recommendation to pursue surgical treatment. The No Harm Info group consists of all individuals who have only seen the standard version of each letter at each stage (i.e. Groups 1, 2, & 3 at Stage 1, Groups 1 & 2 at Stage 2, and Group 1 at Stage 3). The Additional Harm Info group includes all individuals who have seen the expanded information at each stage (i.e. Group 4 at Stage 1, Groups 3 & 4 at Stage 2, and Groups 2, 3, & 4 at Stage 3).

Appendix Table 2

Summary of information needs by exposure to harm information

Survey Randomization				
Variables	No Additional Harm Info (N=276)	Additional Harm Info (N=784)	Total (N=1060)	P value
In connection with CC screening, should women be informed				
...about the potential for additional Pap testing?				
Yes	236(85.5%)	684(87.2%)	920(86.8%)	0.741
- When they are first invited to screen for CC	138(58.5%)	381(55.7%)	519(56.4%)	0.544
- When they are asked to repeat a Pap test	80(33.9%)	260(38.0%)	340(37.0%)	
- When surgical intervention is required	15(6.4%)	32(4.7%)	47(5.1%)	
- Don't know	3(1.3%)	11(1.6%)	14(1.5%)	
No	15(5.4%)	37(4.7%)	52(4.9%)	
Don't Know	25(9.1%)	63(8.0%)	88(8.3%)	
...about the potential side effects of the surgical procedure used to treat serious cellular changes?				
Yes	262(94.9%)	731(93.2%)	993(93.7%)	0.702
- When they are first invited to screen for CC	94(36.0%)	246(33.7%)	340(34.3%)	0.400
- When they are asked to repeat a Pap test	41(15.7%)	137(18.7%)	178(17.9%)	
- When surgical intervention is required	122(46.7%)	343(46.9%)	465(46.9%)	
- Don't know	4(1.5%)	5(0.7%)	9(0.9%)	
No	7(2.5%)	26(3.3%)	33(3.1%)	
Don't Know	7(2.5%)	27(3.4%)	34(3.2%)	
...that many women who have the surgical procedure recommended when abnormal cellular changes are detected would have made a full recovery without treatment?				
Yes	224(81.2%)	667(85.1%)	891(84.1%)	0.277
- When they are first invited to screen for CC	89(39.7%)	307(46.1%)	396(44.5%)	0.024
- When they are asked to repeat a Pap test	51(22.8%)	169(25.4%)	220(24.7%)	
- When surgical intervention is required	76(33.9%)	182(27.3%)	258(29.0%)	
- Don't know	8(3.6%)	8(1.2%)	16(1.8%)	
No	17(6.2%)	36(4.6%)	53(5.0%)	
Don't Know	35(12.7%)	81(10.3%)	116(10.9%)	

Survey Randomization				
Variables	No Additional Harm Info (N=276)	Additional Harm Info (N=784)	Total (N=1060)	P value
Who would you prefer to receive information about cervical cancer screening from?				
	N=274	N=784	N=1058	
The Cancer Registry/other national health authority	161(58.8%)	463(59.1%)	624(59.0%)	
GP	60(21.9%)	174(22.2%)	234(22.1%)	
Gynecologist/other specialist	37(13.5%)	105(13.4%)	142(13.4%)	
I prefer to find information on my own	1(0.4%)	0(0.0%)	1(0.1%)	0.867
Not interested in information	0(0.0%)	5(0.6%)	5(0.5%)	
Other	1(0.4%)	5(0.6%)	6(0.6%)	
Don't know	14(5.1%)	32(4.1%)	46(4.3%)	

Stage 1= Initial invitation to participate in CC screening; Stage 2= Request to have an additional Pap test done following the detection of cellular abnormalities; Stage 3= Recommendation to pursue surgical treatment.

The No Additional Harm Info group consists of all individuals who have only seen the standard version of each letter at each stage (i.e. Groups 1, 2, & 3 at stage 1, Groups 1 & 2 at Stage 2, and Group 1 at stage 3). The Additional Harm Info group includes all individuals who have seen the expanded information at each stage (i.e. Group 4 at stage 1, Groups 3 & 4 at Stage 2, and Groups 2, 3, & 4) at Stage 3.

Figure 1. Flow diagram of recruitment and randomization

Overview of the randomization process. Following the first part of the survey, all participants proceeded through a walkthrough of the CC screening process. A denotes the standard version of each invitation letter, whereas B denotes the expanded version of each letter, which introduced information about harms at different stages in the screening process. Stage 1=Initial invitation to participate in CC screening; Stage 2=Request to have an additional Pap test done following the detection of cellular abnormalities; Stage 3=Recommendation to pursue surgical treatment. Black denotes the use of standard text, whereas gray indicates letters with the expanded text. Participants were randomized before

beginning the questionnaire. Following the screening walkthrough, all participants were asked to indicate their preferences regarding the timing of each additional piece of information, as well as indicate their preferred source of such information.

Table 1

Characteristics of the randomization groups and of the Norwegian population

Variables	Survey Randomization					Norwegian Population *
	Group 1 Control – No Additional Harm Info (N=276)	Group 2 Additional Harm Info at Treatment (N=258)	Group 3 Additional Harm Info at Abnormal Results (N=240)	Group 4 Additional Harm Info at Initial Invitation (N=286)	Total (N=1,060)	
Age (years), mean (SD)	45.79 (10.723)	46.82 (11.072)	46.36 (10.718)	45.38 (10.994)	46.06 (10.880)	
Age (years)						
<30	11 (4.0%)	13 (5.0%)	12 (5.0%)	19 (6.6%)	55 (5.2%)	11.1%
30–39	73 (26.4%)	61 (23.6%)	56 (23.3%)	79 (27.6%)	269 (25.4%)	23.7%
40–49	87 (31.5%)	73 (28.3%)	75 (31.2%)	73 (25.5%)	308 (29.1%)	24.8%
50–59	81 (29.3%)	75 (29.1%)	70 (29.2%)	95 (33.2%)	321 (30.3%)	21.8%
60–69	24 (8.7%)	36 (14.0%)	27 (11.2%)	20 (7.0%)	107 (10.1%)	18.6%
Personal annual income (NOK)	N=230	N=236	N=213	N=240	N=919	
<200,000	20 (8.7%)	24 (10.2%)	18 (8.5%)	17 (7.1%)	79 (8.6%)	22.5%
200,000–399,999	109 (47.4%)	104 (44.1%)	104 (48.4%)	108 (45.0%)	425 (46.2%)	48.0%
400,000–599,999	81 (35.2%)	91 (38.6%)	72 (33.8%)	101 (42.1%)	345 (37.5%)	20.8%
600,000–799,999	18 (7.8%)	12 (5.1%)	15 (7.0%)	13 (5.4%)	58 (6.3%)	6.2%
>800,000	2 (0.9%)	5 (2.1%)	4 (1.9%)	1 (0.4%)	12 (1.3%)	2.5%
Geographic location						
Oslo	64 (23.2%)	56 (21.7%)	64 (26.7%)	76 (26.6%)	260 (24.5%)	27.8%
Southeastern Norway (excluding Oslo)	84 (30.4%)	67 (26.0%)	67 (27.9%)	71 (24.8%)	289 (27.3%)	25.1%
South West	77 (27.9%)	90 (34.9%)	62 (25.8%)	82 (28.7%)	311 (29.3%)	30.9%
North	51 (18.5%)	45 (17.4%)	47 (19.6%)	57 (19.9%)	200 (18.9%)	16.2%
Marital status	N=276	N=258	N=239	N=286	N=1059	
Single	77 (27.9%)	85 (32.9%)	87 (36.4%)	85 (29.7%)	334 (31.5%)	28.7%
Married/cohabitating	199 (72.1%)	173 (67.1%)	152 (63.6%)	201 (70.3%)	725 (68.5%)	71.3%
Education						

Survey Randomization					
Variables	Group 1 Control – No Additional Harm Info (N=276)	Group 2 Additional Harm Info at Treatment (N=258)	Group 3 Additional Harm Info at Abnormal Results (N=240)	Group 4 Additional Harm Info at Initial Invitation (N=286)	Norwegian Population* Total (N=1,060)
High school or vocational training	176 (63.8%)	159 (61.6%)	151 (62.9%)	188 (35.7%)	674 (63.2%)
One year of university	100 (36.2%)	99 (38.4%)	89 (37.1%)	98 (34.3%)	386 (36.8%)
Born in Norway	N=276	N=258	N=239	N=286	N=1,059
Yes	251 (90.9%)	246 (95.3%)	228 (95.4%)	274 (95.8%)	999 (94.3%)
					89.0%

Group 1: No additional harm information (control), Group 2: Additional harm information first provided at Stage 1, Stage 1=Initial invitation to participate in CC screening; Stage 2=Request to have an additional Pap test done following the detection of cellular abnormalities; Stage 3=Recommendation to pursue surgical treatment.

USD1.00 = NOK 5.8772 in 2014

* Statistics Norway, www.ssb.no/english

Table 2

Responses to questions eliciting baseline knowledge about CC, the screening program, and anxiety linked to cancer screening, overall and by group

Survey Sample	
Variables	Total (N=1060)
Perceived Health	
Good/Very good	814 (77.1%)
Neither good nor bad	198 (18.8%)
bad/very bad	43 (4.1%)
Most common cancers among Norwegian women	
Cervical cancer	945 (89.2%)
Approximately how many cases of CC are diagnosed each year in Norway?	
75 or less	71 (6.7%)
300 (correct number)	302 (28.6%)
1000 or more	422 (40.0%)
Don't know	260 (24.6%)
Main reason some women develop CC?	
Genetics/Family history	232 (21.9%)
A virus	447 (42.2%)
Hormones	135 (12.8%)
Smoking	5 (0.5%)
Other	22 (2.1%)
Don't know	217 (20.5%)
Have you had a Pap test done?	
Yes	1010 (96.0%)
Cellular abnormalities detected via previous Pap test?	
Yes	247 (23.4%)
Friends/Family who have developed CC?	
Yes	171 (16.2%)
Pap testing's role in preventing CC?	
Very little/not at all	13 (1.2%)
Neither unimportant nor important	12 (1.1%)
Quite/Very Important	1021 (96.8%)
Perceived Risk of cervical cancer, compared to other women of the same age	
Neither lower or higher	720 (68.1%)
Higher/much higher	109 (10.3%)
How concerned are you about developing CC?	

Survey Sample	
Variables	Total (N=1060)
Very little/not at all	499 (47.1%)
Not very little nor very much	434 (41.0%)
Somewhat/very concerned	121 (11.4%)
Had a hysterectomy?	
Yes	67 (6.3%)
Plans for future pregnancy?	
Yes	127 (12.0%)

The maximum number of missing responses to any given question was 10.

Table 3

Primary results of intentions to screen, undergo additional Pap testing following the detection of irregular cells, and pursue surgical treatment by randomization group.

Survey Randomization					
Variables	Group 1 Control – No Additional Harm Info	Group 2 Additional Harm Info at Treatment	Group 3 Additional Harm Info at Abnormal Results	Group 4 Additional Harm Info at Initial Invitation	Total N=993 P value
Participate in the next screening round? (N=993)					
Yes	N=253 220 (86.9%)	N=245 221 (90.2%)	N=227 200 (88.1%)	N=268 235 (87.7%)	876 (88.2%) 0.351
No	8 (3.2%)	6 (2.4%)	12 (5.3%)	6 (2.2%)	32 (3.2%)
Don't Know	25 (9.9%)	18 (7.3%)	15 (6.6%)	27 (10.1%)	85 (8.6%)
How uncertain or certain (very uncertain=1, very certain=10) are you regarding your decision? (N=981)					
How little or how much would you be concerned over whether the sample is abnormal?					
Not at all/a little	88 (35.3%)	90 (37.3%)	79 (35.0%)	116 (44.4%)	373 (38.2%) 0.309
Neither very little or very much	102 (41.0%)	93 (38.6%)	93 (41.2%)	96 (36.8%)	384 (39.3%)
Somewhat/to a great extent	59 (23.7%)	58 (24.1%)	54 (23.9%)	49 (18.8%)	220 (22.5%)
Don't Know	4 (1.6%)	4 (1.6%)	1 (0.4%)	7 (2.6%)	16 (1.6%)
Return to your GP to have the recommended test done? (N=991)					
Yes	N=252 244 (96.8%)	N=244 238 (97.5%)	N=227 219 (96.5%)	N=268 259 (96.6%)	960 (96.9%) 0.724
No	0 (0.0%)	0 (0.0%)	2 (0.9%)	2 (0.75)	4 (0.4%)
Don't Know	8 (3.2%)	6 (2.5%)	6 (2.6%)	7 (0.6%)	27 (2.7%)
How uncertain or certain (1–10) are you regarding your decision? (N=980)					
How little or how much would you be concerned over whether the sample is abnormal?					
Not at all/a little	22 (8.9%)	16 (6.7%)	23 (10.4%)	34 (13.2%)	95 (9.8%) 0.154
Neither very little or very much	45 (18.2%)	40 (16.7%)	43 (19.4%)	59 (22.9%)	187 (19.3%)
Somewhat/to a great extent	180 (72.9%)	184 (76.7%)	156 (70.3%)	165 (64.0%)	685 (70.8%)
Don't Know	6 (2.4%)	5 (2.0%)	5 (2.2%)	10 (3.7%)	26 (2.6%)

Survey Randomization					
Variables	Group 1 Control – No Additional Harm Info	Group 2 Additional Harm Info at Treatment	Group 3 Additional Harm Info at Abnormal Results	Group 4 Additional Harm Info at Initial Invitation	Total N=993
Return to pursue surgical treatment? N=993					
Yes	N=253 235 (92.9%)	N=245 208 (84.9%)	N=227 196 (86.3%)	N=268 229 (85.4%)	N=993 868 (87.4%)
No	0 (0.0%)	5 (2%)	1 (0.4%)	1 (0.4%)	7 (0.7%)
Don't Know	18 (7.1%)	32 (13.1%)	30 (13.2%)	38 (14.2%)	118 (11.9%)
How uncertain or certain (1–10) are you regarding your decision? (N=982)					
How little or how much would you be concerned over whether the sample is abnormal?					
Not at all/a little	10 (4.0%)	16 (6.5%)	12 (5.3%)	10 (3.7%)	48 (4.8%)
Neither very little or very much	24 (9.5%)	18 (7.3%)	22 (9.7%)	40 (14.9%)	104 (10.5%)
Somewhat/to a great extent	219 (86.6%)	211 (86.1%)	193 (85.0%)	218 (81.3%)	841 (84.7%)
Don't Know	3 (1.2%)	4 (1.6%)	7 (3.1%)	8 (3.0%)	22 (2.2%)

Group 1: No additional harm information (control), Group 2: Additional harm information first provided at Stage 3, Group 3: Additional harm information first provided at Stage 2, Group 4: Additional harm information first provided at Stage 1. Stage 1=Initial invitation to participate in CC screening; Stage 2=Request to have an additional Pap test done following the detection of cellular abnormalities; Stage 3= Recommendation to pursue surgical treatment. Direct comparisons between all individuals receiving additional information at each time point, regardless of original group assignment (*i.e.* comparing all individuals who had seen the additional harm information to those who had not at each stage, regardless of when the information was first introduced) did not alter these findings (see Appendix Table 1).

Table 4

Summary of information needs by randomization group

Survey Randomization					
Variables	Group 1 Control -- No Additional Harm Info (N=276)	Group 2 Additional Harm Info at Treatment (N=258)	Group 3 Additional Harm Info at Abnormal Results (N=240)	Group 4 Additional Harm Info at Initial Invitation (N=286)	Total (N=1060) P value
In connection with CC screening, should women be informed					
...about the potential for additional Pap testing?					
Yes	256(85.0%)	223(86.4%)	211(87.9%)	250(87.4%)	920(86.8%) 0.980
- When first invited to screen for CC	138(58.5%)	127(57.0%)	112(53.1%)	142(56.8%)	519(56.4%)
- When asked to repeat a Pap test	80(33.9%)	81(36.3%)	86(40.8%)	93(37.2%)	340(37.0%)
- When treatment is required	15(6.4%)	13(5.8%)	8(3.8%)	11(4.4%)	47(5.1%)
- Don't know	3(1.3%)	2(0.9%)	5(2.4%)	4(1.6%)	14(1.5%)
No	15(5.4%)	12(4.7%)	12(5.0%)	13(4.5%)	52(4.9%)
Don't Know	25(9.1%)	23(8.9%)	17(7.1%)	23(8.0%)	88(8.3%)
...about the potential side effects of the surgical procedure used to treat serious cellular changes?					
Yes	262(94.9%)	243(94.2%)	224(93.3%)	264(92.3%)	993(93.7%) 0.242
- When first invited to screen for CC	94(36.0%)	74(30.5%)	65(29.0%)	107(40.5%)	340(34.3%)
- When asked to repeat a Pap test	41(15.7%)	43(17.7%)	52(23.2%)	42(15.9%)	178(17.9%)
- When treatment is required	122(46.7%)	124(51.0%)	105(46.9%)	114(43.2%)	465(46.9%)
- Don't know	4(1.5%)	2(0.8%)	2(0.9%)	1(0.4%)	9(0.9%)
No	7(2.5%)	11(4.3%)	8(3.3%)	7(2.4%)	33(3.1%)
Don't Know	7(2.5%)	4(1.6%)	8(3.3%)	15(5.2%)	34(3.2%)
...that many women who have the surgical procedure recommended when abnormal cellular changes are detected would have made a full recovery without treatment?					
Yes	224(81.2%)	222(86.0%)	203(84.6%)	242(84.6%)	891(84.1%) 0.399

Survey Randomization					
Variables	Group 1 Control — No Additional Harm Info (N=276)	Group 2 Additional Harm Info at Treatment (N=258)	Group 3 Additional Harm Info at Abnormal Results (N=240)	Group 4 Additional Harm Info at Initial Invitation (N=286)	Total (N=1060) P value
- When first invited to screen for CC	89(39.7%)	88(39.6%)	91(45.0%)	128(52.9%)	396(44.4%) 0.013
- When asked to repeat a Pap test	51(22.8%)	67(30.2%)	56(27.7%)	46(19.0%)	220(24.7%)
- When treatment is required	76(33.9%)	64(28.8%)	51(25.2%)	67(27.7%)	258(29.0%)
- Don't know	8(3.6%)	3(1.4%)	4(2.0%)	1(0.4%)	16(1.8%)
No	17(6.2%)	13(5.0%)	14(5.8%)	9(3.1%)	53(5.0%)
Don't Know	35(12.7%)	23(8.9%)	23(9.6%)	35(12.2%)	116(10.9%)
Who would you prefer to receive information about cervical cancer screening from?					
	N=274	N=258	N=240	N=286	N=1058
The Cancer Registry/ other national health authority	161(58.8%)	156(60.5%)	133(55.4%)	174(60.8%)	624(59.0%)
GP	60(21.9%)	55(21.3%)	61(25.4%)	58(20.3%)	234(22.1%)
Gynecologist/other specialist	37(13.5%)	34(13.2%)	33(13.8%)	38(13.3%)	142(13.4%)
I prefer to find information on my own	1(0.4%)	0(0.0%)	0(0.0%)	0(0.0%)	1(0.1%)
Not interested in information	0(0.0%)	1(0.4%)	2(0.8%)	2(0.7%)	5(0.5%)
Other	1(0.4%)	1(0.4%)	3(1.3%)	1(0.3%)	6(0.6%)
Don't know	14(5.1%)	11(4.3%)	8(3.3%)	13(4.5%)	46(4.3%)

Direct comparisons between all individuals receiving additional information at each time point, regardless of original group assignment (*i.e.* comparing all individuals who had seen the additional harm information to those who had not at each stage, regardless of when the information was first introduced) yielded generally similar findings though women who received harm information earlier preferred providing information about the possibility that even without treatment, a complete recovery is possible (see Appendix Table 2).