

# Do invitations for cervical screening provide sufficient information to enable informed choice? A cross-sectional study of invitations for publicly funded cervical screening

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## Summary

**Objective:** To investigate whether invitations for publicly funded cervical screening provide sufficient information to enable an informed choice about participation.

**Design:** Cross-sectional study using a checklist of 23 information items on benefits and harms from cervical screening and the risks related to cervical cancer.

**Material:** Invitations to publicly funded cervical screening in 10 Scandinavian and English-speaking countries.

**Setting:** Ten Scandinavian and English speaking countries.

**Participants:** Sixteen screening units representing 10 Scandinavian and English speaking countries.

**Main outcome measures:** Number of information items presented in invitations for cervical screening.

**Results:** We contacted 21 coordinating units from 11 countries and 20 (95%) responded. Of these, four units did not issue invitations, but the remaining 16 coordinating units in 10 different countries supplied a sample. The invitations for cervical screening were generally information poor and contained a median of only four out of 23 information items possible (17%), ranging from 0 to 12 (0–52%). The most important harms of cancer screening, overdiagnosis and overtreatment, were typically downplayed or unmentioned. The same applied to other important harms, such as false-positive results and the psychological consequences from an abnormal test result. The majority of invitations took a paternalistic approach. While only two invitations (17%) included a pre-assigned appointment date, eight (70%) of the invitations contained strong appeals for participation.

**Conclusions:** Invitations to cervical cancer screening were information poor and biased in favour of participation. This means that informed choice is not possible, which is in conflict with modern requirements for personal involvement in medical decisions.

## Keywords

public health, communication, ethics

## Introduction

It is generally agreed that the offer of screening in publicly funded programmes must include the

possibility of participants making an informed choice. This requirement is based on the principle of autonomy – a fundamental concept in today's medical ethics.<sup>1</sup> The General Medical Council states that a person needs balanced, unbiased information of high quality on the benefits, harms and uncertainties related to an intervention to make an informed choice.<sup>2</sup> Arguably, more detailed and comprehensive information should be provided when healthy people are offered preventive interventions such as cancer screening, compared to patients who are actively seeking treatment for a condition. At least four arguments support this: first, screening is an intervention initiated by the healthcare system, and not by a patient trying to solve a health problem. Second, interventions with modest or uncertain benefits merit a detailed consideration of harms, the risk of which is certain with any medical intervention. Third, a benefit for some will come at the expense of harm for others.<sup>3</sup> Fourth, a healthy individual is likely to be in a better position to balance benefits against harms than someone who is already sick and perhaps emotionally vulnerable. Finally, when healthy people experience unanticipated harms or complications, it may undermine trust in the healthcare system.

Many cancer screening programmes have policies that specify their responsibility to ensure informed choice. Since a written invitation is the only source of information distributed to all potential participants, it seems obvious to use that invitation to provide the required information. However, those responsible for the invitations are, in most cases, also responsible for the screening programme. Herein lies a conflict of interest since high participation rates are pivotal to the justification for and efficiency of any screening programme, but information about harms may discourage participation.<sup>4</sup> A study of women's willingness to participate in cervical screening has shown that providing evidence-based

information on the benefits, harms and uncertainties of screening is likely to make some decline the offer, but not differentially those at higher risk.<sup>5</sup> Furthermore, evidence suggests that informed choice is associated with greater satisfaction with the process of care and, crucially, improved adherence to the intervention.<sup>6</sup> Therefore, a high participation rate should not be prioritised at the expense of an informed choice or respect for individual autonomy.

A study of invitations for publicly funded screening mammography in Scandinavian and English-speaking countries showed that they were information poor and biased in favour of participation.<sup>7</sup> Since the independent review of screening mammography in the UK,<sup>8</sup> the information material has been revised, reflecting a greater recognition of the importance of harms.

In the present study, we examined invitations to publicly funded cervical screening to assess whether they provided information that enables an informed choice.

## Materials and methods

We collected invitations to cervical screening from the following Scandinavian and English speaking countries: Australia, Canada, Denmark, England, Finland, Ireland, New Zealand, Northern Ireland, Norway, Scotland and Sweden. All have publicly funded cervical screening programmes that are nationally or regionally coordinated.

We used the search engine Google to identify coordinating units. We contacted them by email or telephone and requested invitations (letters and any enclosed leaflets or brochures) sent to women inviting them to their first cervical screen, regardless of screening modality. Two authors (SKK and MSH) evaluated all information material independently, and any disparities about what information to include in our analysis were settled by discussion. We used a checklist containing 23 information items on the benefits and harms of cervical screening and the risks related to cervical cancer (Table 1), most of which have been used in previous studies, for example in a study of the content of invitations for publicly funded screening mammography.<sup>7</sup> We modified the checklist to better capture items specific to cervical screening. Additionally, we recorded whether the invitations contained an appeal for participation and/or a pre-assigned appointment. Contrary to previous studies of invitations to screening using the checklist, we excluded information about sensitivity and specificity, as we deemed these more relevant for researchers and clinicians than for lay people. Due to the lack of randomised controlled trials (RCTs) on

cervical screening, the quantification of benefits and harms is based on population-based observational studies and the evidence is heterogenous and inconclusive. For this reason, we have not assessed whether the information provided was evidence-based.

Our analysis consisted of a descriptive assessment of the invitation material. We counted the total number of information items present in the invitations, as well as the number of information items provided in each individual invitation, and calculated percentages and the median number of information items.

## Results

We identified 21 coordinating units and 20 (95%) responded. Australia and three units in Canada (British Columbia, Nova Scotia and New Brunswick) could not supply a sample as they do not issue invitations but use public advertisements. Thus, we obtained samples from 16 units, including ten different countries (See Appendix 1 online). All five regions of Denmark issue the same information leaflet and the invitation letters differ only slightly, so Denmark was treated as one unit, reducing the total number of coordinating units to 12.

For Sweden, we evaluated a national sample invitation letter that is used by a wide range of regions. The sample invitation letter may be modified locally but the accompanying leaflet, which contains the bulk of the information, cannot be modified. For New Zealand, we evaluated a national information brochure that is used nationwide and a sample invitation letter that may vary as each general practice team has their own system for inviting women.

## Information items

The invitations included a median of four of the possible 23 information items (17%), ranging from zero in Norway and the Canadian province of Saskatchewan to 12 (52%) in Denmark. Our two independent assessments of the invitations identified a total of 32 (12%) and 42 (15%) information items out of a possible 276 in 16 samples. After discussion we agreed on 51 items (18%; Appendix 2). The discrepancies were mainly caused by oversight but were also due in part to dissimilarities in what could be accepted as a description of overdiagnosis and false-positive results. These discrepancies were resolved after discussion among all four authors. The information items were mainly presented in the information leaflets, whereas the invitation letters generally addressed practical issues. We found that graphics were sparingly used. The majority of leaflets included

Table 1. Information items about cervical screening in invitation letters and leaflets.

Information items	Norway	Saskatchewan, CA	Ontario, CA	Ireland	Finland	Manitoba, CA	Scotland	Northern Ireland	England	New Zealand	Sweden	Denmark	No. (%) of invitations (n = 12)
Lifetime risk of developing cervical cancer	—	—	—	—	—	—	—	—	—	1	—	—	1 (8)
Lifetime risk of dying from cervical cancer	—	—	—	—	—	—	—	—	—	1	—	—	1 (8)
Survival from cervical cancer	—	—	—	—	—	—	—	—	—	—	—	—	0
Relative risk reduction of death from cervical cancer	—	—	—	—	—	—	—	—	—	—	—	—	0
Absolute risk reduction of death from cervical cancer	—	—	—	—	—	—	—	—	—	1	—	—	1 (8)
Relative risk reduction of total mortality	—	—	—	—	—	—	—	—	—	—	—	—	0
Absolute risk reduction of total mortality	—	—	—	—	—	—	—	—	—	—	—	—	0
Relative risk reduction of developing cervical cancer	—	—	—	—	1	1	1	1	1	—	1	—	6 (50)
Absolute risk reduction of developing cervical cancer	—	—	—	—	—	—	—	—	—	1	—	—	1 (8)
Number needed to screen to avoid one death from cervical cancer	—	—	—	—	—	—	—	—	—	—	—	—	0
Proportion of screened women who would be recalled as a result of an inadequate result	—	—	—	—	—	—	—	1	1	—	—	1	3 (25)
Proportion of screened women who would be recalled as a result of an abnormal result	—	—	—	—	—	1	1	1	—	—	1	—	4 (33)

(continued)

Table 1. Continued.

Information items	Norway	Saskatchewan, CA	Ontario, CA	Ireland	Finland	Manitoba, CA	Scotland	Northern Ireland	England	New Zealand	Sweden	Denmark	No. (%) of invitations (n = 12)
Proportion of women with a positive test result who would have early stages of cervical cancer (CIN2+/CIN3+) (positive predictive value)	—	—	—	—	—	—	—	—	—	—	—	1	1 (8)
Overdiagnosis and overtreatment	—	—	—	—	1	1	1	—	1	—	1	1	6 (50)
Quantification of overdiagnosis and overtreatment	—	—	—	—	—	—	—	—	—	—	—	1	1 (8)
Risks related to conisation	—	—	—	—	—	—	—	—	—	—	1	1	2 (17)
Quantification of risks related to conisation	—	—	—	—	—	—	—	—	—	—	—	1	1 (8)
Psychological distress related to false positive results	—	—	—	—	—	—	—	—	1	—	1	1	3 (25)
Pain/discomfort related to the cytology test	—	—	—	1	1	—	1	1	1	1	1	1	8 (67)
False positive results	—	—	—	1	—	—	—	1	—	1	—	1	4 (33)
Quantification of false positive results	—	—	—	—	—	—	—	—	—	—	—	1	1 (8)
False negative results	—	—	1	1	—	—	1	1	1	—	—	1	6 (50)
Quantification of false negative results	—	—	—	—	—	—	—	—	—	—	—	1	1 (8)
Total	—	—	1	3	3	3	5	6	6	6	6	12	
Pre-assigned date	—	—	—	—	1	—	—	—	—	—	1	—	2 (17)
Appeals for participation	1	1	1	—	1	1	1	1	—	—	1	—	8 (67)

illustrations of the female sex organs as well as photographs of smiling women of different ages, but apart from those, the invitations did not contain any images or graphics.

### *Risks of cervical cancer*

Only one out of 12 invitations (8%) provided information about the lifetime risk of developing cervical cancer and the lifetime risk of dying from cervical cancer in absolute numbers, and none provided information about survival rates (Table 1).

### *Benefits from cervical screening*

All invitations mentioned that the main benefit of screening was to reduce the risk of developing cervical cancer. However, only seven out of 12 invitations (58%) indicated the size of the benefit, and six of those seven described it as a relative risk reduction rather than an absolute risk reduction or the number needed to screen. This makes the relative risk reduction of developing cervical cancer the information item most often provided to communicate the benefits, with estimates ranging from a 75% to 90% reduction. An absolute risk reduction of 0.9% was not provided but could be derived from the following statement: 'With regular 3-yearly screening one out of 570 women will develop cervical cancer. Without screening one out of 90 women will develop cervical cancer' (New Zealand).

No invitation expressed the benefit as the number needed to screen to avoid one case of cervical cancer. Only one invitation (8%) mentioned the reduction in risk of death from cervical cancer, and the effect of screening on total mortality was not mentioned in any invitation (Table 1).

### *Harms from cervical screening*

Despite being the most important harms of screening, overdiagnosis and overtreatment were only mentioned in six invitations (50%). Only one information leaflet (8%) gave detailed information, but framed it positively, saying that 'between 25 and 50% of the most severe cell changes will progress into cancer if not treated' (Denmark), as opposed to saying that between 50% and 75% of the most severe cell changes will never progress to cancer.

Pain and discomfort related to the cytology test were mentioned in eight (67%) of the 12 invitations, making this the most commonly mentioned harm, as well as the most common information item (Table 1).

Two out of 12 invitations (17%) mentioned the risks related to conisation, but only one (8%) quantified the risk (Table 1). The risks mentioned were preterm delivery, severe bleeding and constriction of the cervix after conisation.

False-positive results were mentioned in four out of 12 invitations (33%) and false-negative results were mentioned in 6 (50%). The following sentences exemplify how the concepts were framed: 'It [cervical screening] may not always detect early cell changes' (England) or, 'It [cervical screening] may miss some changes' (Scotland). Only one invitation (8%) gave an estimate, saying that '50 out of 100 women', and '5 out of 100 women' will receive a false-positive or false-negative result, respectively (Denmark). The importance of false-negative tests was downplayed; 'any cell changes will usually be picked up in a future smear test' (Ireland, Denmark), and false-positive tests were dismissed saying that 'The test is safe and reliable' (Finland).

The psychological harm from receiving an abnormal test result<sup>9-11</sup> was mentioned in three out of 12 invitations (25%) and described as anxiety or worry.

The proportion of screened women recalled as a result of an inadequate test was mentioned in three out of 12 invitations (25%), while the proportion of screened women recalled as a result of an abnormal result was mentioned in 4 (33%). Only one invitation (8%) mentioned both (Table 1). The proportion of women with a positive test result and precursors of cervical cancer (CIN2+/CIN3+) was mentioned in one invitation (8%) (Table 1).

### *Appeals for participation*

Only two out of 12 invitations (17%) gave a pre-assigned date for a screening appointment (Finland and Sweden). However, a direct appeal for participation, for example 'Cervical screening: it's best to take the test' (Northern Ireland) and 'The cervical screening test – put it on your list!' (Scotland), appeared in eight invitations (67%) (Table 1).

## **Discussion**

### *Summary of main results*

We found that the invitations for cervical screening were information poor and biased in favour of participation. The benefits from screening were mentioned and quantified more often than the harms. The most important harms, overdiagnosis and overtreatment, were generally downplayed or left unmentioned. We found the same for other important harms, such as false-positive results and the

psychological consequences of having an abnormal test result. The number of included information items varied widely, from 0 to 12 of 23 possible. This may reflect public debate and awareness of the importance of informed choice in individual countries and regions.

Seventy percent of the invitations used a paternalistic framing by directly encouraging participation. Only two invitations gave a pre-assigned appointment, which is much less than, for example, in mammography screening.<sup>7</sup>

### *Problems with current practice*

Overdiagnosis has many serious consequences. It turns healthy people into patients who will need consultations, treatment for harmless lesions and follow-up examinations, with associated anxiety and reduced quality of life. We find it striking that most invitations omit information about the magnitude of overtreatment and its related harms, especially for women aged less than 25 years, who are the target for a first invitation to screening. Women in this age group are less likely to benefit from screening and more likely to experience overtreatment due to their low incidence of cervical cancer, their higher prevalence of transient HPV infection and their greater likelihood of future pregnancy.<sup>12,13</sup> Providing information on overdiagnosis in decision aids increases the number of women making an informed choice,<sup>4</sup> but the lack of information on harms may lead to disappointment, anger, reduced trust in healthcare in general, and potentially to litigation.<sup>14</sup> Providing detailed information about the low risk that identified cell changes would progress into cancer, regardless of treatment, would likely also reduce the psychological harms of being recalled and treated.

Most invitations emphasised the benefits in a way that would be expected to increase uptake. For instance, the annual absolute number of diagnoses and deaths from cervical cancer was frequently mentioned, followed by the annual absolute number of lives saved. This might frighten some women into participation as the absolute numbers were presented out of context with population size. In contrast, no invitations mentioned that women have 59–69%<sup>15</sup> chance of surviving cervical cancer once it is diagnosed, which could be a relatively reassuring message.

The invitations rarely quantified benefits, and those that did used relative risk reductions rather than absolute risk reductions or the number needed to screen. Studies about evidence-based risk communication have found that relative risk reductions are harder to understand and generate more unrealistic

expectations compared to the same information presented as absolute risk reductions.<sup>16,17</sup> If the aim of communication is to assist women to understand the likelihood of a benefit, relative risks should be avoided in favour of absolute risks, and the harms should be presented in the same way using the same denominator, so that the chances of experiencing benefits and harms are directly comparable.<sup>16</sup>

Women were often directly encouraged to attend, but were not given specific estimates of the benefit. For example one invitation letter says, ‘The purpose is to reduce the number of cases and mortality from cervical cancer’ (Norway), and an information leaflet says, ‘Early detection and treatment of changes in the cells of the cervix can prevent cervical cancer’ (Ireland). Neither an estimate of the case-specific mortality reduction nor the reduction in the risk of developing cervical cancer was given in either case.

A pre-assigned appointment is a method to nudge women to undergo cervical screening.<sup>18</sup> It is difficult to opt out when society and experts who presumably know more about the issue than the invitee has decided to extend a free offer. It is also well-known that an opt-in offer reduces participation compared to an opt-out offer.<sup>19</sup> This approach is problematic as it bypasses informed choice in the same way as direct encouragement to participate. Invitations should convey the message that a decision not to attend screening can be based on sound reasoning and is not irresponsible or unwelcome.<sup>7</sup>

### *Strengths and limitations of the study*

We included a large number of countries in this study and achieved a very high response rate. However, only Scandinavian and English-speaking countries are included as we were restricted by language.

Two independent authors read all information material and we used an information checklist adopted from previous studies. In this way, we believe we have captured the key information items.

### *Strengths and limitations in relation to other studies*

Several studies have evaluated information material for screening mammography. Screening invitations,<sup>7</sup> information pamphlets<sup>20,21</sup> as well as website presentations of information<sup>22</sup> have been under close scrutiny. The same is not the case for cervical screening and our study is, to our knowledge, the first to systematically evaluate invitations to this screening programme. Contrary to previous studies, we have not assessed whether the information was evidence-based as there is a lack of RCTs on the effect of cervical

screening. To our knowledge, only one cluster randomised trial of moderate quality has addressed the question of cervical screening effectiveness and its setting in rural India, which has a particularly high prevalence of cervical cancer, limits its external validity for Scandinavian and English-speaking countries.<sup>23,24</sup>

From an ethical perspective, balanced comprehensive information is important; however, studies suggest that this might not have a substantial effect on the ability of women to make truly informed choices.<sup>25</sup> One study has suggested that emotional factors are likely to have a greater effect than information in decision aids,<sup>26</sup> and balanced information in invitations to screening may therefore only be a small step towards true informed choices. To ensure informed choice in the best way possible revised invitations should be tested in lay people and preferably developed using a citizen's jury.

## Conclusion

Invitations for cervical screening are information poor and biased in favour of participation. This means that an informed choice is not enabled, which is in conflict with modern requirements for personal involvement in medical decisions. Our findings underline the need for a revision of invitations to cervical screening programmes.

## Implications

When revising the UK invitation to breast screening, it was specifically recognised that the information should be unbiased and balanced and that it should not contain encouragement of participation. This is a new development that should be extended to other types of screening, including cervical screening.<sup>8</sup>

Invitations to cervical screening should provide more information on the benefits, harms and uncertainties of screening presented in an understandable way that allow benefits and harms to be directly compared, that is by presenting absolute numbers with a common denominator. Additionally, there should be links to more detailed information online for those who wish it. Information should be balanced and should reflect the best available evidence. Suggestive headlines and direct appeals to attend screening, as well as pre-assigned appointments, should be abandoned and it should be made clear that non-participation might be a rational choice.

## Declarations

**Competing Interests:** None declared.

**Funding:** None declared.

**Ethical approval:** Not required because our study did not involve human subjects.

**Guarantor:** SKK is the lead author and guarantor. The guarantor accepts full responsibility for the work and/or the conduct of the study, had access to the data, and controlled the decision to publish. The guarantor affirms that the manuscript is an honest, accurate and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if registered) have been explained.

**Contributorship:** JB conceived the idea for the project. SKK drafted the protocol in co-operation with MSH, JB and KJJ. SKK and MH extracted data and analysed data independently. All authors contributed to revisions with important intellectual content. All authors had full access to all data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

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