Introduction

The primary objective of cancer screening and treatment is to reduce the risk of cancer death. Screening may reduce this risk by detecting cancer at an early stage in its development when it is asymptomatic and curable. Treatments generally depend on the stage and other characteristics of the cancer and the patient. Consequently, screening will be most effective if it induces ‘down-staging’, i.e. shifting advanced-stage cancers, for which treatments are less efficient or non-existent, to earlier stages for which effective staging, i.e. shifting advanced-stage cancers, for which treatments are less efficient or non-existent, to earlier stages for which effective therapeutic modalities, the benefit in terms of reduced breast cancer mortality declines while the harms, including overdiagnosis, are unaffected. Future improvements in breast cancer patient management will further deteriorate the benefit-harm ratio of screening.

Methods

The Norwegian mammography screening programme was initially piloted in four counties from 1995 to 1996. The remaining counties were gradually enrolled from 1999 until nationwide coverage was achieved in 2005. Women were invited to mammography screening according to birth cohorts, approximately corresponding to years of birth. Women were invited to mammography screening at age 50–70 years in 1999 and at age 55–70 years subsequently. Women opted out of mammography screening. The programme included prevalent screening for women aged 50–59 years from 2005.

Setting

The Norwegian cancer registry provides reliable registration of cancer incidence and mortality since 1960, well before the results of early randomized trials on screening mammography were published. The Norwegian mammography screening programme was initially piloted in four counties from 1995 to 1996. The remaining counties were gradually enrolled from 1999 until nationwide coverage was achieved in 2005. Women were invited to mammography screening according to birth cohorts, approximately corresponding to years of birth.
to the age range 50–69 years with biennial screening interval.\textsuperscript{17} Around 80% of invited women attend screening mammography.

**Design**

We estimated NNI each year from 1986 to 2016 based on estimated breast cancer mortality rates (MR) in a screened Norwegian population and breast cancer MR in the same population without screening. The numbers of women needed to invite to prevent one breast cancer death within 10 years were computed using three inputs: (i) observed breast cancer mortality among Norwegian women aged 50–75 years from 1996 to 2016; (ii) four scenarios of breast cancer mortality reductions over 10 years after screening introductions (i.e. screening effectiveness); and (iii) proportions of breast cancer deaths associated with breast cancers diagnosed before or after screening introduction in the different Norwegian counties. Then after, we used three scenarios of overdiagnosis to estimate the change over time in the ratio of overdiagnosis to breast cancer deaths prevented. Note that the assumed mortality reduction associated with breast cancer screening allows calculation of the hypothetical mortality among invited women, had they not been invited. Similarly among uninvited women, the hypothetical mortality had they been invited can be calculated, as described below.

**Data sources and study population**

We retrieved individual data on residence at diagnosis, birth year and time and cause of death for all women diagnosed with breast cancer (ICD10: C50) during the period 1953–2016 from the Cancer Registry of Norway. We followed women until death, emigration, or December 2016, whichever came first. We obtained information on the annual size of the source population in each county and each age from Statistics Norway from 1986 to 2016, such that we could calculate annual MR for this period. The influence of screening on the risk of breast cancer death is to be examined among women in screening ages plus a lead time (6 years, say). Hence, only women aged 50–75 at death were included in analyses, totaling 10 520 women who died of breast cancer in Norway from 1986 to 2016.

**Statistical analysis**

For each breast cancer case, we recorded if the date of diagnosis was before the date of screening introduction in the given county to the age range 50–69 years with biennial screening interval.\textsuperscript{17} Around 80% of invited women attend screening mammography.

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Using Poisson regression, we estimated the observed breast cancer MR for each year up to 2016. Restricted cubic splines with five knots were used to flexibly adjust for non-linear effects of year at death and reduce the standard error of the estimated rate. Using MR from the regression model, we defined NNI as the number of women aged 50–75 years of age to be invited to screening within a given year $y$ associated with one less breast cancer death during that year.

$$\text{NNI}_y = \frac{1}{\text{MR without screening}_y} - \text{MR with screening}_y \quad (1)$$

The MR, and thus the NNI, are estimated in 1-year periods based on women aged 50–75. The 1-year periods facilitates comparison with other studies, which may have differing time-perspectives. The NNI expresses the expected effect of introducing screening in a hitherto unscreened population. We estimated observed MR, which after the introduction of screening is a mixture of the MR in a population without screening and the MR in a population with screening:

$$\text{Observed MR}_y = \text{MR without screening}_y \cdot (\text{prop}_m)_y + \text{MR with screening}_y \cdot (1 - (\text{prop}_m)_y)$$

In this equation, prop$_m$ is the proportion of women who died in a given year and was diagnosed before introduction of screening in their county. We considered in a first scenario that breast screening can reduce breast cancer mortality by 20% in a population of women aged 50–75 years of age invited to screening. This 20% reduction corresponds to the reduction reported by the Independent Review in UK.\textsuperscript{2} If we let $c_y$ be the assumed relative effect of screening (a 20% reduction in breast cancer mortality corresponds to $c_y = 0.80$) in year $y$, we have the following relation:

$$\text{MR with screening}_y = \text{MR without screening}_y \cdot c_y \quad (3)$$

Substituting this into the previous formula,\textsuperscript{2} we obtain:

$$\text{MR without screening}_y = -\frac{\text{Observed MR}_y}{(\text{prop}_m)_y - 1} \cdot c_y - (\text{prop}_m)_y \cdot \text{MR with screening}_y \quad (4)$$

Since the effect of the screening programme is not known and may have changed over time, we considered a range of estimates. Three scenarios had constant relative effects of 20% on breast cancer mortality (Scenario I), 8.7% (Scenario II) or 5% (Scenario IV), respectively, and one scenario had a linearly decreasing relative effect from 20% in 1996 to 8.7% in 2016 (Scenario III). Scenario I is based on the findings of the UK Panel,\textsuperscript{2} whereas Scenario II is based on Birnbaum et al.\textsuperscript{17} who estimated that 15% of advanced-stage cancers were moved to early stage (in situ and Stage 1) cancers (see below) by screening. Scenario III is based on assuming a change from the effect observed in randomized trials to a more modern scenario with effect exclusively mediated through a stage shift. Scenario IV is based on a recent study of the Norwegian mammography screening programme.\textsuperscript{16} Although the study could not identify an effect of screening mammography on breast cancer death rates in its main analysis, a quantitative bias analysis suggested that a beneficial effect in the order of a 5% reduction might be compatible with the study’s findings. We consider this a lower bound for any non-negligible effect.

The following formula was used to calculate the effect of screening $c_y$ in Scenario II. $\text{prop}_{eater}$ is the proportion of early-stage cancers, $\text{prop}_{adv}$ is the proportion of advanced-stage cancers, $r_{adv}$ is the 10-year breast cancer-specific MR for patients diagnosed with advanced-stage cancer and $\text{MR}_{adv/cas}$ is the breast-cancer-specific MR ratio comparing patients with advanced-stage cancer to patients with early-stage cancer. We estimated $r_{adv}$ and $\text{MR}_{adv/cas}$ based on the Norwegian data on stage-specific survival from 2000 to 2016.

$$\left( \text{prop}_{adv} \cdot (0.85 \cdot r_{adv} + 0.15 \cdot \frac{\text{MR}_{adv/cas}}{\text{MR}_{in situ}}) + \text{prop}_{eater} \cdot \frac{\text{MR}_{in situ}}{\text{MR}_{adv/cas}} \right) = 1 - c_y$$

The numerator reflects breast cancer-specific mortality when 15% of patients, who would have had a clinical diagnosis with advanced-stage cancer, instead have their cancer detected as early-stage due to screening, whereas the denominator gives the breast cancer-specific mortality without screening, i.e. without a stage-shift. Based on the estimated Norwegian rates and this formula, we estimate a relative effect of screening on breast cancer mortality of 8.7%, i.e. $c_y = 0.923$.

We weighted the MR of each county by the inverse of the square of the SE of the MR of each county. We estimated 95% CI for NNI were estimated via the 95% CI for the denominator of the NNI calculation. The SE for the denominator of the NNI calculation. The SE for the denominator of the NNI calculation.
In this equation, \( N \) is the number of observed deaths.

In addition, we repeated the analysis with DASR to take the change in age distribution into account. The standard population was set to the Norwegian female population in 1996 to show how the effect of mammography screening would have changed had the age distribution been held constant since the first introduction of screening in a Norwegian county. We consider the DASR analysis as our primary analysis, as it facilitates comparisons with other countries. The non-standardized analysis shows the development of the actual population in Norway invited to screening (see Supplementary material S1).

Using the same models as above, but substituting incidence rates for MR (Formulas 1 and 4), we could similarly estimate NNI to overdiagnose one woman to compare the benefits of screening with the harms. Again, the starting point was observed rates coupled with an assumed level of overdiagnosis. The Research Council of Norway has estimated that 17.5% of breast cancers found among women invited to screening would represent overdiagnosis,\(^{19}\) a figure in line with the 20% reported by UK independent Panel for women based on the Malmo and Canadian trials.\(^{2}\) Overdiagnosis is defined as the proportion of excess cancers among cancers diagnosed during screening period in women invited for screening, definition C in the Independent UK Panel.\(^{20}\) We took 20% for overdiagnosis Scenario A. In addition, we considered alternative scenarios with 10% (Scenario B) and 40% overdiagnosis (Scenario C), respectively. As a measure of the benefit–harm ratio, we divided the NNI for overdiagnosis by the corresponding NNI for saving a woman from dying of breast cancer within 10 years.

All analyses were performed using STATA\(^{\text{TM}}\) version 15.1.

IRB approval
The study has used data from the Cancer Registry of Norway.

The interpretation and reporting of these data are the sole responsibility of the authors, and no endorsement by the Cancer Registry of Norway is intended nor should be inferred. No further approval from an ethics committee was needed to conduct the study.

**Results**

From 1980 to 1996, incidence rates of invasive breast cancer in Norway steadily increased in all age groups (figure 1A–C). Following breast screening introduction in 1996, sharp increases in incidence were observed among women aged 50–75 years of age, but not in other age groups. After an increase after 1980, breast cancer mortality stabilized around 1985. In 1995, mortality started to markedly decline in all age groups, and from 1996 to 2016, age-adjusted breast cancer death rates dropped by 44% from 81.2 to 49.0 per 100,000 women aged 50–74 years.\(^{21}\)

During the period 1986–2016, a total of 10,580 breast cancer deaths were identified for women aged 50–75 at death. We excluded 60 deaths because of missing information regarding county. A total of 10,520 deaths were included in the analysis (Supplementary table S1).

The numbers of women who need to be invited to screening associated with one less breast cancer death within 10 years (NNI) in 1996 and 2016 taking a time horizon of 10 years are summarized in table 1 together with ratios of numbers of overdiagnosed breast cancers per breast cancer death prevented thanks to screening.

The observed breast cancer mortality has decreased 46% from 74 per 100,000 in 1986 to 40 per 100,000 in 2016 in women aged 50–75. In Scenario I, screening is assumed to reduce the breast cancer mortality by 20% throughout the observation period. NNI was estimated as 731 (95% CI: 644–830) women in 1996, and 1,364 (95% CI: 1,181–1,577) women in 2016, which corresponds to an increase in NNI by 87%. Scenario II with a constant screening effect of 8.7% estimated the NNI in 1996 as 1,685 (95% CI: 1,474–1,926) women and 3,318 (95% CI: 3,019–4,099) women in 2016 corresponding to a relative increase of NNI by 97%. Scenario III with a linear developing screening effect from 20% in 1996 to 8.7% in 2016 yielded an estimated 354% increase in NNI from 731 (95% CI: 644–830) women in 1996 to 3,318 (95% CI: 3,019–4,099) women in 2016. Scenario IV with a constant screening effect of 5% estimated the NNI in 1996 as 2,934 (95% CI: 2,560–3,362) women and 6,338 (95% CI: 5,423–7,406) women in 2016 corresponding to a relative increase of NNI by 116%. Time changes in NNI are graphically displayed in Supplementary figures S1 and S2.

Because overdiagnosis is related to screening and unrelated to changes in mortality, the number of women with overdiagnosed breast cancer relative to NNI to save one woman from dying of breast cancer nearly doubled from 1996 to 2016 in every scenario with and without age-adjustment (table 2).

The joint effects of screening effectiveness and of overdiagnosis result in increasing ratios of overdiagnosed breast cancers per breast cancer death prevented from before 1990 when efficient therapies were not available to years when patient management was progressively more efficient (table 3). In addition, decreasing screening effectiveness leads to marked increases in ratios of overdiagnosed breast cancers for each breast cancer death prevented.
Discussion

This population-based study found a substantial increase over time in numbers of Norwegian women aged 50–69 who need to be invited to screening mammography in order to prevent one breast cancer death. The increase was a consequence of the substantial decrease in breast cancer mortality among Norwegian women aged 50–75. As overdiagnosis is unaffected by changes in screening effectiveness the ratio of overdiagnosed breast cancers for each breast cancer death increased markedly over time.

Our results follow the logic that if deaths due to a cancer become rarer, the absolute mortality risk reduction due to screening for that cancer will be diminished. Consequently, the number of subjects who need to be invited for preventing one breast cancer death will increase with the availability of increasingly potent therapeutic modalities. In addition, the NNI will be further inflated if the ability of screening to reduce the risk of cancer death proves lower than the 20% reduction suggested by randomized trials. The continued decrease in mortality in Norway after the mid-1990s could only be a screening effect if the relative effect of screening had increased over the period, which seems implausible. The declining mortality, also seen in unscreened age groups, is therefore also an effect of improved patient management.

A major strength of this study is that it is based on the nationwide Norwegian population invited to mammography screening, which virtually eliminates selection bias. The year-by-year estimation of NNI has allowed more accurate estimation of changes in NNI due to factors other than screening effectiveness.

Table 1 Age-standardized NNI to avoid one breast cancer death and the number of women with overdiagnosed breast cancer per BC death prevented

| Scenarios of screening effectiveness* | Year | NNI and 95% CI, 10-year follow-up | Change in NNI (%) | No. women with overdiagnosed BC per BC death prevented |
|-------------------------------------|------|----------------------------------|-------------------|-----------------------------------------------------|
| Scenario I (20%)                   | 1996 | 731 (644–830)                    |                   | 3.2                                                 |
|                                     | 2016 | 1364 (1181–1577)                 | 87                | 5.4                                                 |
| Scenario II (8.7%)                 | 1996 | 1685 (1474–1926)                 |                   | 7.4                                                 |
|                                     | 2016 | 3518 (3019–4099)                 | 109               | 14.0                                                |
| Scenario III (20–8.7%)             | 1996 | 731 (644–830)                    |                   | 3.2                                                 |
|                                     | 2016 | 3518 (3019–4099)                 | 381               | 14.0                                                |
| Scenario IV (5%)                   | 1996 | 2934 (2560–3362)                 |                   | 12.8                                                |
|                                     | 2016 | 6338 (5423–7406)                 | 116               | 25.2                                                |

Notes: Level of overdiagnosis is assumed to be 20% (overdiagnosis Scenario B). The change describes the increase in NNI from 1996 to 2016. a: % reduction in breast cancer mortality associated with screening mammography. See the Methods section.

Table 2 Age-standardized NNI to overdiagnose one woman and the number of women with overdiagnosed breast cancer per breast cancer death prevented

| Scenarios of overdiagnosis* | Year | NNI and 95% CI, 10-year follow-up | Change in NNI (%) | No. women with overdiagnosed BC per BC death prevented |
|-----------------------------|------|----------------------------------|-------------------|-----------------------------------------------------|
| Scenario A (10%)            | 1996 | 439 (406–475)                    |                   | 1.7                                                 |
|                             | 2016 | 462 (435–491)                    | 5                 | 3.0                                                 |
| Scenario B (20%)            | 1996 | 229 (211–248)                    |                   | 3.2                                                 |
|                             | 2016 | 252 (236–269)                    | 10                | 5.4                                                 |
| Scenario C (40%)            | 1996 | 123 (113–135)                    |                   | 5.9                                                 |
|                             | 2016 | 147 (137–158)                    | 20                | 9.3                                                 |

Notes: Level of screening effectiveness is assumed to be 20% (screening effectiveness Scenario I). The change describes the increase in NNI from 1996 to 2016.

Table 3 Ratios of the number of overdiagnosed women per breast cancer death prevented according to scenarios outlined in tables 1 and 2

| Overdiagnosis scenarios | 10% | 20% | 40% |
|-------------------------|-----|-----|-----|
| 20                      | 1.7 | 3.0 | 5.4 |
| 8.7                     | 3.8 | 7.6 | 14.0|
| 20–8.7                  | 1.7 | 7.6 | 14.0|
| 5                       | 6.7 | 13.7| 25.2|

A potential limitation is that some women who died at the earliest ages of the screening age will not have had an effect of screening, since they will have been diagnosed before receiving the invitation to the screening programme. This misclassification is however conservative as it would lead to an underestimation of NNI throughout the period.

Previous studies that estimated NNI for screening mammography obtained highly variable results depending on the absolute reduction in breast cancer MR considered, the age range of screened women, the time horizon, and whether the NNI was estimated for women invited to screening or for women who were actually screened (reviewed in 23). In any event, NNI estimates in previous studies (including those of the UK Panel) are...
not contemporary as they are based on historical data before more widespread use of tamoxifen and do not account for any change in breast cancer mortality reductions due to improved patient management. In principle, improved management may increase the number of women who could benefit from earlier detection through screening, which is a limitation to our results. However, a previous study has found that relative screening benefits would be unaffected by improved management.11

Because of the unknown effect of screening on breast cancer mortality in the Norwegian female population, we had recourse to scenarios based on plausible estimates for screening effectiveness. Moreover, the way we computed NNI allows comparisons between studies. The UK Panel found an NNI of 235 women invited during 20 years based on UK data with a screening effect based on a review of randomized trials from 1963 to 1991 (i.e. 20% reduction in breast cancer mortality and 20% overdiagnosis associated with screening).2

Our analyses found NNI values for 2009 somewhat higher (379 vs. 235; Supplementary table S2), likely due to considering a younger age interval for breast cancer mortality.26 Regardless, the most important result is the 87% NNI increase with age-adjustment from first introduction of mammography screening in 1996 until 2016 (table 1). Similarly, the level of overdiagnosis remains a contentious issue. We therefore included three different scenarios with 10%, 20% and 40% overdiagnosis, which all showed more than a 50% increase in the number of women overdiagnosed per breast cancer death prevented from 1996 to 2016 after age standardization with 20% breast cancer mortality reduction.

Autier et al.24 were the first to investigate the development in NNI as a result of an assumed decrease in breast cancer mortality. They estimated an increase in NNI of 50% from 952 women invited during 10 years in 2001 to 1429 women invited during 10 years in 2015 based on an assumed 50% decrease in breast cancer mortality from 1985 to 2015 unrelated to screening and a screening effect of 20% (Supplementary table S2). If we were to use a similar screening effect, we estimate a 41% increase in NNI over the same period without age-adjustment. However, this study is not based on assumed decreases in breast cancer mortality, but on decreases observed in Norway. Likewise, the Scenario II is based on the method used by Birnbaum et al.,11 but applied to Norwegian data instead of US SEER data. Owing to differences in mortality trends over time and in age-specific MR, the NNI found in Scenario II are comparable to NNI found using US SEER data. More importantly, increases in NNI with decreasing breast cancer mortality were quite similar in our study and in studies of Birnbaum et al.11 and Autier et al.24

The adoption of newer screening modalities such as digital mammography or tomosynthesis may have increased screening sensitivity and thus increase screening benefits. However, the Norwegian breast cancer programme has demonstrated the absence of added value of tomosynthesis.25 Digital mammography is somewhat more sensitive than film-based mammography for very dense breasts but leads to more recalls and more detection of in situ breast cancers, without reducing rates of interval cancers.26 27 So, digital mammography may have increased harms associated with screening without meaningful increase in benefits.

In conclusion, what does not change with declining mortality and increasingly potent therapies are the harms due to screening, mainly the overdiagnosis and associated overtreatment. Hence, the benefit-to-harm balance of screening mammography can be expected to increasingly tilt towards the harms, and we expect this deterioration in benefit-to-harm ratio to continue due to ongoing improvement in therapies. A direct consequence of decreasing effectiveness but constant harm is the deterioration of the cost-effectiveness of screening mammography,28–30 and our study makes further calls for an analysis of the development in the health and economic costs per woman saved from dying of breast cancer.31

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**Supplementary data**

**Supplementary data** are available at EURPUB online.

**Data availability**

The study has used data from the Cancer Registry of Norway. The data included 10 580 women aged 50–69 years diagnosed with breast cancer who died from the disease when aged 50–75 years in 1986–2016 in Norway. Authors are according to Norwegian laws not allowed to share data but refer readers to contact Cancer Registry of Norway to apply for data access.

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**Conflicts of interest:** None declared.

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**Key points**

- Assuming a relative effect of mammography screening at 20% on breast cancer mortality, the number of women who needs to be invited to save one life has increased by 87% from 1996 to 2016.
- The number of women overdiagnosed with breast cancer per woman saved from dying of breast cancer has increased substantially from 1996 to 2016.
- The deterioration in benefit-to-harm ratio of breast screening will continue due to steady improvement in therapies.
- This study supports the need for re-evaluation of national screening programmes in high-income countries.

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