Sociodemographic factors, health indicators and lifestyle factors among participants in BreastScreen Norway 2006-2016 – a cohort profile

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ABSTRACT

Purpose: To collect information on sociodemographic factors, health indicators, and lifestyle factors in women who attended the nationwide breast cancer-screening program, BreastScreen Norway, with the aim of investigating how these factors influence the risk of breast cancer, other cancer types, and cancer-related outcomes.

Participants: The cohort data includes self-reported responses to questionnaires from 554,149 women aged 50-69 years, who attended BreastScreen Norway during the data collection period, 2006-2016.

Findings to date: Information about sociodemographic factors, health indicators, and lifestyle factors was collected for the current time and retrospectively back to birth. For the cohort, we have complete mammographic screening data, including information about 24,000 breast cancer cases and other cancer types from the Cancer Registry of Norway. These outcomes are aggregating continuously. Data from the cohort have been utilized in studies related to breast cancer and menopausal status.

Future projects: Data will be utilized in studies related to tumour growth and risk of breast cancer as well as other cancer types, in addition to overall and cancer-specific death.

Registration: The cohort profile is not registered in Clinical Trials.

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INTRODUCTION

Breast cancer is the most common cancer in women, worldwide (1) and in Norway (2), and the third most common cause of cancer death worldwide (1). Although the etiology of breast cancer is partly unknown, several risk factors are well established epidemiologically, some of them modifiable (3). Organized screening with mammography is considered secondary prevention and regarded an effective tool for detecting the disease at an early stage, facilitating early and successful therapy, and thereby reducing breast cancer mortality (4,5). An organized screening program for breast cancer (BreastScreen Norway) started in four counties in Norway, in 1996. The program had a staggered implementation and became nation-wide in 2005. BreastScreen Norway is administered by the Cancer Registry of Norway and offers about 620,000 women aged 50-69 a two-view mammographic screening biannually (6). Screening takes place at 30 screening units, while screen reading and further assessment take place at 17 centralized breast centres, mainly located at university hospitals.

To increase knowledge about women’s health indicators, mammographic screening and of breast cancer etiology, epidemiological data and health metrics related to breast cancer have been collected from the women participating in the program since the start. Through 2005, all women invited to screening were asked to complete a one-page questionnaire and hand it in when they showed up for screening (6). For the period 2006-2016, the questionnaire was replaced by two questionnaire forms to systematically collect data about sociodemographic factors, health indicators and lifestyle factors potentially related to breast cancer (7). The questionnaires covered the women’s lives from their current situation back to birth. The data collected provide basis for genuine population-based research, allowing prospective life-course follow-up of women for breast cancer and other cancer diagnoses. The Cancer Registry Regulations have given approval with waiver of informed consent to perform surveillance, quality assurance, and studies based on data collected as a part of participation in BreastScreen Norway (8). Because of transition to a digital invitation system and lack of resources to adapt the questionnaire digitally, the survey ended by January 2016.

PATIENT AND PUBLIC INVOLVEMENT

The questionnaires implemented in 2006 were developed from the questionnaire used 1996-2005, still with the aim of increasing the knowledge about mammographic screening, breast cancer development and etiology, and to improve the screening program. A working group including epidemiologists, radiologists, and women in the target group of the program drafted the questionnaires, which were tested in a pilot before
implementation. All women invited to BreastScreen Norway received the questionnaires as a part of the invitation to the program.

**COHORT DESCRIPTION**

Women in the target population of BreastScreen Norway are offered screening by a personal letter with stated time and place for the examination (6). The invitation includes information about the screening examination and about benefits and harms of mammographic screening to enable the women to make an informed choice about participation. Women who do not attend their given appointment are sent a reminder, and they may reschedule the appointment on their own initiative. We excluded women who requested their data not to be used in research and quality assurance (6). By December 31, 2016, 15,385 women had made such a request, representing 1.6% of all invited women and 1.9% of the participants up to this date (6). About 4% of the women in the target population had opted out of the program, whereof the majority were treated for breast cancer and thus had individual follow-up outside the program.

During the data collection period, from August 1, 2006, to December 31, 2015, all women invited to BreastScreen Norway (N = 759,294) received two paper-based questionnaires together with their invitation to attend the screening program (Figure 1). All invitations were sent by post. Form A, given to all women at first invitation within this 10-year period, collected information on sociodemographic factors, health indicators and lifestyle factors from birth to age 50. If no response was registered, the women received a new form A with their next invitation letter. Form B collected information about lifestyle factors at current time (last two years) and was given at each screening invitation during the 10-year period. Women were asked to bring completed, paper-based questionnaires to the screening unit when they came for examination. Of the 630,201 women who attended the program at least once during the data collection period (83% of all invited), 554,149 (87.9% of all who attended) returned at least one form and thus entered the cohort.

The attendance in the screening program during the data collection period determined the number of potential forms completed. Best-case scenario was entry or having a screening examination in 2006 and regular attendance until 2016, which normally gives five screening rounds, but with the possibility of six, i.e., one A and six B forms completed (Figure 1). The minimum data set would correspond to one screening examination, with one form completed only. Of the 554,149 women who returned at least one form, 7370 (1.3%) returned only form A, 152,610 (27.5%) returned only form B, and 394,169 women (71.1%) returned both forms. Table 1 presents the number of women invited and screened during the data collection period, completion of form A and B, area of residence at invitation to
Table 1. Number (n) of women invited and screened (n and percentage (% of the invited) during the data collection period, completion of questionnaires form A and B (n and % of the invited), by area of residence at invitation to BreastScreen Norway, screening history (first and later) and age at completing the first form.

| Area of residence | Women invited (n = 759,294) | Women screened ever (n = 630,201) | Form A + B (n = 394,169) | Only form A (n = 7,370) | Only form B (n = 152,610) |
|-------------------|-------------------------------|-----------------------------------|-------------------------|------------------------|--------------------------|
|                   | n                             | %                                | n                       | %                      | n                        |
| Rogaland          | 62,047                        | 53,939                            | 33,286                  | 53.6                   | 577                      | 9.0                      | 13,387                  | 21.6                      |
| Hordaland         | 69,250                        | 59,698                            | 33,513                  | 48.4                   | 763                      | 1.1                      | 15,981                  | 23.1                      |
| Oslo              | 77,161                        | 56,217                            | 34,266                  | 44.4                   | 745                      | 1.0                      | 14,811                  | 19.2                      |
| Telemark          | 29,108                        | 24,138                            | 14,615                  | 50.2                   | 231                      | 0.8                      | 6,164                   | 21.2                      |
| Aker              | 43,476                        | 37,168                            | 22,659                  | 52.1                   | 367                      | 0.8                      | 8,991                   | 20.7                      |
| Troms og Finnmark | 37,542                        | 32,293                            | 20,265                  | 54.0                   | 379                      | 1.0                      | 7,970                   | 21.2                      |
| Østfold           | 45,765                        | 37,231                            | 21,753                  | 47.5                   | 439                      | 1.0                      | 8,652                   | 18.9                      |
| Nordland          | 38,396                        | 33,962                            | 21,648                  | 64.6                   | 339                      | 0.9                      | 7,736                   | 20.1                      |
| Trøndelag         | 66,749                        | 57,099                            | 37,732                  | 65.6                   | 640                      | 1.0                      | 13,001                  | 19.5                      |
| Oppland           | 31,986                        | 26,193                            | 17,514                  | 54.8                   | 300                      | 0.9                      | 5,942                   | 18.6                      |
| Møre og Romsdal   | 38,853                        | 30,864                            | 20,492                  | 62.7                   | 359                      | 0.9                      | 6,457                   | 16.6                      |
| Sogn og Fjordane  | 16,930                        | 14,995                            | 11,009                  | 65.0                   | 188                      | 1.1                      | 2,812                   | 16.6                      |
| Vestfold          | 38,538                        | 31,699                            | 20,874                  | 64.2                   | 498                      | 1.3                      | 7,102                   | 18.4                      |
| Hedmark           | 33,638                        | 27,434                            | 17,922                  | 63.3                   | 318                      | 0.9                      | 6,586                   | 19.6                      |
| Akershus Øst      | 63,263                        | 52,307                            | 31,099                  | 49.2                   | 713                      | 1.1                      | 12,431                  | 19.6                      |
| Vestre Viken      | 66,592                        | 54,964                            | 35,522                  | 53.3                   | 514                      | 0.8                      | 14,587                  | 21.9                      |
| All areas         | 759,294                       | 630,201                            | 394,169                 | 51.9                   | 7,370                    | 1.0                      | 152,610                 | 20.1                      |

Screening history

|                  | First screening               | Later screening                 |
|------------------|-------------------------------|---------------------------------|
|                   | n                             | %                               | n                             | %                               |
| Women invited     | 147,358                       | 37.4                            | 3,141                         | 42.6                            | 55,971                      | 36.7                      |
| Women screened    | 246,811                       | 62.6                            | 4,229                         | 57.4                            | 96,639                      | 63.3                      |

Age groups

| Age, years | Mean (SD) | Median (IQR range) |
|------------|-----------|--------------------|
| ≤55 years  | 56.7 (5.9) | 55 (10)            |
| 55-59 years| 59.5 (7.6) | 59 (16)            |
| ≥60 years  | 57.2 (6.0) | 56 (10)            |

BreastScreen Norway, screening history, after first and later screening, and age at completion of the first form.

Both questionnaires collected information about body weight and height (open question, continuous value), smoking habits, alcohol consumption, and physical activity (fixed alternatives). Figure 2 shows completeness for selected variables in form A. Information about birth weight was given for 45% of the women and information about body weight and height at age 7 and 15 years was given for about 75% of the cohort. For all other variables, the completeness was ≥85%. For variables in form B, the completeness was close to, or higher than 90% (Figure 3). The questionnaires are described, and available at BreastScreen Norway’s website (7).

Using the unique person identification number assigned to all Norwegian citizens alive or born after 1960, we can link the cohort to the Cancer Registry of Norway for complete data on breast cancer and other cancer types sharing the same risk factors, such as ovary and colorectal cancer. Table 2 shows numbers and age-specific incidence rates for the six most common cancers in Norwegian women, by age groups (50-74 years and ≥75 years), for the period 2006-2018. The Cancer Registry of Norway regularly collects information from the National Population Register about vital status and dates of migration and death if relevant. Linkage to the Cause of Death Registry may provide information on cause of death. Together, these data sources give possibilities to perform population-based analyses, allowing individual follow-up on malignant diagnoses as well as deaths from 2006 until today.

**FINDINGS TO DATE**

So far, data from this cohort have been utilized in analyses pertaining to quality assurance and improvements of the program. A study evaluating the validity and reliability of selected questions, both in form A and B, showed reasonable results regarding breast cancer and screening history. Based on repeated reporting, body weight and height were found to vary within one kg/cm only (9).

Ursin’s research group have used lifestyle variables from the questionnaires to investigate associations with
breast cancer risk (10-13). A study including more than 4000 women found that daily smoking (20+ cigarettes) was associated with a 41% increase in overall breast cancer risk, and there were significant smoking-related trends for luminal A-like and luminal B-like HER2-negative cancer (10). Current alcohol consumption of six glasses a week versus no consumption was associated with 26% increased risk of Luminal A-like breast cancer. A 15% decreased risk for the same subtype of breast cancer was seen in women who reported current physical activity of ≥4+ hours/week, versus none (11). For other subtypes, the association was inconclusive. Using the same study population and questionnaire data, breast cancer risk has been estimated by lifestyle factors known to increase risk. Compared to women having no increased risk from lifestyle factors, women with five risky lifestyle factors had a two-fold risk, although limited to Luminal A-like breast cancer (12).
The risky lifestyle factors of significance were body mass index (BMI, weight/height$^2$), alcohol, smoking, physical activity and use of menopausal hormone therapy. Using data from 46,428 women screened between 2007 and 2014, the associations between mammographic density, using volumetric breast density as measurement, and breast cancer risk factors from the questionnaires was examined (13). Modest associations were found, although highly significant for BMI, while age at diagnosis appeared modified by menopausal status and other breast cancer risk factors.

Hofvind’s research group used information on BMI from the questionnaires in several studies where different aspects of mammographic density were explored as these two factors are closely related (14). In 28% (n=87,021) of the screening examinations (n=307,015), the breasts were classified as dense. Moreover, questionnaire data have been used in adjusted analyses of breast compression parameters (15-17), and attendance patterns in the program (18,19).

Eskild’s research group used the data to study reproductive factors in Norwegian women (20-23). Based on data from 336,788 women screened between 2006 and 2014, they found age at menopause to be 51 years independent of age at menarche, indicating the reproductive period to increase with decreasing age at menarche (20). Furthermore, among 312,656 women screened between 2006 and 2014, they found a slight decrease in mean age at menarche: 13.4 years among the oldest birth cohorts (1926-1939) and 13.2 years among the youngest (1961-1964) (21). They also found an increase in mean age at natural menopause: 50.3 and 52.7 years, respectively. Their findings indicated an increase in the reproductive period for the youngest birth cohorts. Based on data from 164,608 women with information on their birthweight, the authors found an association between birthweight and age at menopause (22). Furthermore, based on 483,241 women in the cohort, screened between 2006 and 2013, an increased risk of breast cancer was identified for users of hormone therapy, with a substantially higher risk for those who either remained at normal weight or gained weight in adulthood, compared to women who were overweight at a young age.

### Strengths and Limitations

The major strength of this cohort is the individual information about sociodemographic factors, health indicators and lifestyle factors for a high proportion (73%) of the female population aged 50-69 years from a whole nation (Figure 1), covering the women’s lives back to their childhood. Further, multiple data collections have been conducted by repeated screening rounds every two years, which facilitate studies, using trajectory analyses and estimation of effects of changes over time, related to cancer in women. A detailed procedure for management of the questionnaires, collecting, sending, receiving, scanning and pathological verification of cancer diagnoses at the Cancer Registry of Norway, ensures high quality of the cohort data. A unique personal identification number is assigned to all Norwegian inhabitants, facilitating a secure linkage to other data sources, such as other health related registries (e.g., the Cause of Death Registry, Norwegian Patient Registry, Norwegian Prescription Database), biobanks (e.g., Janus Serum Bank) and other data sources that may have information of interest. As far as we are aware, there are limited national or international cohorts of women with similar size, width, or demographics (24,25). Self-reported data, however, has limitations, such as misclassification and recall bias. In addition, women who did not complete the questionnaire(s) might differ from those who did. We have limited knowledge about sociodemographic characteristics of women who did not attend the screening program during 2006-2016 and among those who attended but did not fill any questionnaire. The attendance rate in the program was higher for the oldest age groups, and a recent study showed higher attendance rates by increasing education level and income (26). Married and economically active women attended more frequently than non-married and unemployed. We have also shown that immigrant women attend BreastScreen Norway less frequently than non-immigrant women, while increasing years since immigration increased the attendance rate (27). Compared to non-immigrants, immigrants are shown to have a lower risk of breast cancer.

### Table 2. Number (n) of cases and age-specific incidence rate (number per 100 000 women-years) for the six most common cancer sites in Norwegian women 50-74 and ≥75 years of age, in the period 2006-2018.

| Cancer site (ICD-10) | Age groups | Cancer cases (n) | Age-specific incidence rates per 100 000 women-years |
|----------------------|------------|-----------------|------------------------------------------------------|
| Colon (C18)          | 50–74      | 8,135           | 93.3                                                 |
|                      | 75+        | 9,449           | 334.5                                                |
| Breast (C50)         | 50–74      | 24,091          | 276.3                                                |
|                      | 75+        | 7,966           | 282.0                                                |
| Corpus uteri (C54)   | 50–74      | 6,100           | 70.0                                                 |
|                      | 75+        | 2,722           | 96.4                                                 |
| Ovary etc. (C56, C57.0–4, C48.2) | 50–74 | 3,962 | 45.4                                                 |
|                      | 75+        | 1,774           | 62.8                                                 |

1 International Classification of Diseases, 10$^{th}$ revision
cancer, but the cancer is more often diagnosed in an advanced stage (28). We know that women in Oslo (the capital) attend BreastScreen Norway less frequently compared to women residing in other regions (26), and we also know that Oslo has the highest percentage of immigrant women in the target group for the screening program. Also, use of private clinics in large cities might be a reason for not attending BreastScreen Norway (29). However, the number of private clinics was reduced during the last decade. A compliance rate of 84% indicate a high trust in the governmental program. Some women did not respond to the questionnaire at each screening examination. However, several variables collected in Form B might not change substantially between two or more screening rounds, and the values in the first or the last form might be a representative proxy for the ten-year period (9).

**COLLABORATION**

The questionnaire data were collected as a part of the BreastScreen Norway and are stored at the Cancer Registry of Norway. Regulations on population-based health surveys provide a legal basis for continued use of data from the survey (https://lovdata.no/dokument/SF/forskrift/2018-04-27-645).

All research using these data is subject to approval by the Regional Committees for Medical and Health Research Ethics in Norway. Data sharing outside Norway requires a data transfer agreement, governed by Norwegian law, and must be in accordance with the General Data Protection Regulation (GDPR) that applies in the EU. Researchers interested in these data are advised to identify a collaborator at the Cancer Registry of Norway, with in-depth knowledge of the data and BreastScreen Norway. Further information about ongoing and scheduled studies on these data is available at https://www.kreftregisteret.no/en/screening/breastscreen-norway/ and further procedures for data requests are available at https://www.kreftregisteret.no/en/The-Registries/data-delivery-unit/.

**Data sharing statement**

Research data used in the presented analyses will be available on request, given legal basis according to the GDPR, Article 6 and 9.

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