Using clinical cancer registry data for estimation of quality indicators: Results from the Norwegian breast cancer registry

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ABSTRACT

Introduction: Increased focus on quality indicators and the use of clinical registries for breast cancer for real world studies have shown higher compliance to recommended therapy and better survival. In 2010, the European Society of Breast Cancer Specialist (EUSOMA) proposed quality indicators (QI) covering diagnosis, treatment and follow-up. To become a EUSOMA certified Breast Cancer Unit, 14 specified quality indicators, in addition to other requirements, need to be met. To evaluate the compliance and results of recommended treatment in breast cancer care in Norway and to improve the quality of epidemiological data, the Cancer Registry of Norway (CRN) in cooperation with the Norwegian Breast Cancer Group (NBCG) developed the Norwegian Breast Cancer Registry (NBCR).

The objective of this study is to assess the feasibility of using the NBCR for estimating the EUSOMA QI individually for all hospitals diagnosing and treating breast cancer in Norway.

Methods: To provide researchers with high quality cancer data as well as for the purpose of national cancer statistics, the CRN employs a cancer registry system to 1) longitudinal capture data from all patients from all medical entities that diagnose and/or treat cancer patients (e.g., pathology, radiology and clinical departments) in Norway; 2) curate data, i.e. validate the correctness of collected data, and assemble the validated cancer data as cancer cases; 3) provide data for analytics and presentation. Estimates for 10 EUSOMA QI were calculated at national and hospital level. To compare hospitals, a summary score of QIs was defined for each hospital.

Results: All hospitals currently treating breast cancer patients have the technical ability to submit data to the NBCR for estimation of QIs defined by EUSOMA. Data from pathology and surgery are of high quality. However, data from oncological and radiological departments are incomplete, but improving. This currently hinders three QIs from being calculated. QI on benign to malign diagnosis needs to be calculated at the individual Breast Centre. Over time the adherence to guidelines have improved and the hospital variation for the respective QI have decreased. Two hospitals met all minimum standard on ten QIs in year 2016 and one hospital did not meet one minimum standard, but met all other targets.

Conclusion: The NBCR has since 2012 published annual reports on breast cancer care and for the year 2016 measured 10 of 14 QI defined by EUSOMA. Increased compliance of recommended treatment in Norway has been observed during the years the registry has been active.

1. Introduction

The complexity of breast cancer care involves several specialities where every field within diagnostic, treatment and follow-up has to adhere to the latest guidelines, and measuring the quality of care is therefore a challenging issue. Increased focus on quality indicators (QI) and clinical registries within breast cancer care shows higher compliance to recommended therapy and increased survival [1–5]. Regular audit of quality indicators for the treatment of patients with operable breast cancer proved to be important tools to improve the quality of care, patient satisfaction and outcome [5].

A clinical cancer registry offers an ideal infrastructure for estimating
QIs on a regular basis, and comparison of IQs between hospitals which may facilitate changes in guidelines [6]. For example, several recent published register studies have shown better survival for women undergoing breast conserving therapy compared to mastectomy [7-11]. This new knowledge emphasizes the importance and use of clinical cancer registries.

In 2010, the European Society of Breast Cancer Specialist (EUSOMA) published a position paper with 33 QIs covering diagnosis, surgery, loco-regional treatment, systemic treatment, staging, counseling, follow-up and rehabilitation [12]. To become a EUSOMA certified specialist Breast Centre in 2016, 14 QI were mandatory [13] in addition to other requirements [14].

In Norway, breast cancer is the most common cancer in women [15]. To evaluate the compliance and results of recommended diagnostics and treatment of this disease and to improve the quality of the clinical cancer data, The Cancer Registry of Norway (CRN) in cooperation with the Norwegian Breast Cancer Group (NBCG) developed the Norwegian Breast Cancer Registry (NBCR) run by the Cancer Registry of Norway.

1.1. Aim

The objective of this study is to assess the feasibility of using the NBCR for estimating QI individually for all hospitals diagnosing and treating breast cancer in Norway.

2. Material and methods

The Cancer Registry of Norway (CRN) is a population-based cancer research institute [16]. It is responsible for receiving data from institutions diagnosing or treating cancer patients. The reporting of these data is mandatory by law for all health personnel.

To provide researchers with high quality cancer data as well as for the purpose of national cancer statistics, the CRN employs a cancer registry system divided into three separate entities; 1) Data capture, 2) Data curation, and 3) Data analytics and statistics [17].

2.1. Description of data

The NBCR has designed and implemented the following nine electronic clinical reporting forms: diagnostics; radiotherapy; non-endocrine oncolgy treatment, endocrine treatment, lipofilling, follow-up, surgery, no treatment, completed trastuzumab treatment and completed endocrine treatment. Each of these forms contains only variables relevant to the reported event. These forms are used in the setting of primary breast cancer, recurrent breast cancer and metastatic breast cancer [18]. Data on pathology are submitted directly from the pathology laboratories and are (electronic) copies of the pathology report sent to the physician. 17 electronic pathology reports are implemented, include the following: mastectomy; breast conserving therapy; core biopsy of primary tumour; cytology of primary tumour; axillary clearance; sentinel node; preoperative examination of axillary lymph nodes; histology from surgery on locally relapse, core biopsy from locally relapse; cytology from locally relapse; histology on metastases from surgery; core biopsy from metastases; cytology from metastases, autopsy; hormone receptor analysis; secondary surgery with resection of primary tumour and benign breast pathology. All these forms are saved as an eXtensible Markup Language (XML) file [19].

A reference committee of specialists diagnosing and treating breast cancer from radiology, surgery and oncology originally defined the key variables. The committee regularly updates, removes and adds new variables. Fig. 1 shows that the reference committee is influenced by national guidelines and EUSOMA. Furthermore, how the committee has a two-way communication with the cancer registry. Demo versions of the forms are available at the CRN webpages [20].

2.2. Description of data capturing

The Norwegian Cancer Registry’s Electronic Reporting Service (KREM) is established to facilitate electronic reporting thru the Norwegian Health Network [21]. There are two main options for submitting the forms. They can be submitted by a portal displaying the report forms as web-pages, or thru messaging, if the forms are implemented in the hospitals electronic health records. The message transfer uses electronic Business XML (ebXML) which ensures a secure and reliable exchange of messages between two parties within the Norwegian Health Network [22].

Reports shall be sent at time of primary diagnosis; each surgical event; primary adjuvant treatment; hormone therapy start and end of hormone therapy. Breast cancer patients are followed for 10 years after surgery. In connection with the annual follow-up, a follow-up report is sent regarding relapse status. If a recurrence is observed, a report shall be sent to specify the relapse or metastasis. Reports on pathology are sent to the CRN independently of clinical reports.

The reports from the portal are stored as an XML-file, and passed on to the data curation step, as are the XML-files received through the messages system. The data curation steps are thus independent of the data capture method.

The Norwegian Quality Registry for Breast Cancer were stepwise implemented in all hospitals in Norway. The first registration was done on local registries at Ulleval University hospital in 2008, and the first electronic clinical form was submitted from Østfold hospital to the CRN in 2011.

2.3. Description of data curation

The data curation at the CRN consists of three steps needed to ensure the necessary level of data quality, and converts multiple, independent cancer messages to a cancer case. The cancer cases are the bases for analytics and statistics [17]. The three steps are: a) Cancer message validation that checks the internal validity and correctness of the cancer messages. b) Cancer case calculation generates a cancer case, and calculates the set of variables for the cancer case, based on all cancer messages related to the cancer case. c) Cancer case validation checks the variables for the internal validity and correctness of the cancer case (Fig. 2). This process will also identify missing cancer messages, which will be requested from the hospital which failed to report the data.

Pathology forms are reported as a mixture of structure (code data) and textual descriptions of macroscopic, microscopic and final diagnosis, which need coding. This is presently done manually by medical coders prior to the “cancer message validation” step.

2.4. Data analytics and statistics

Several reports regarding cancer are published from the CRN yearly. The main aim of the annually “Cancer in Norway” is to provide detailed cancer statistics [15]. The registration has from 1953 been considered to be close to complete, 98,8% for the registration period 2001-05 [23]. The annual “Cancer in Norway” calculates incidence, prevalence, age and relative survival among several other calculations within all cancer types. In addition to “Cancer in Norway” all eight National Quality Registers publishes annually reports (breast cancer, colorectal cancer, prostate cancer, lung cancer, hereditary cancer, paediatric solid tumours, gynaecological cancer and malignant melanoma).

Upon application, data may be disclosed for research purposes from the data delivery unit at the CRN [24]. The minimum recommendation from EUSOMA is that hospitals treating breast cancer patients should have at least 150 patients diagnosed per year. For the national results we include all hospitals, while presentations on individual hospitals with less than 150 patients diagnosed per year are not shown.
For each QI, there are a minimum standard (labelled yellow in the figures), and target result (labelled green in the figures).

For testing of changes over time in QIs or differences between hospitals, binominal exact test was used, and p-value less or equal to 0.05 were considered significant. The cancer case coverage for the period 2012–2016 was estimated by the capture-recapture method using clinical forms, pathology forms, and death certificates [25]. To compare survival between counties relative survival was estimated using the Ederer2-method [26]. Analyses were performed using Stata v15 (StataCorp, Texas, USA).

2.5. Summary score of QIs on hospital level

For the comparison between hospitals for all QI, a score of 1 was given for reaching the target result QI, a score of 0.5 for minimum target, and 0 below minimum target. The composite score was then calculated by adding the individual scores, giving a possible range for the score of 0-10. In addition, the hospitals evaluated for all non-zero score for any of the ten QI, thus meeting at least minimum standard for all QI.

3. Quality indicators and former breast cancer reports

EUSOMA have specified 14 mandatory QIs to become a EUSOMA
certified specialist Breast Centre [27]. In this study, the numbering of EUSOMA criteria following the numbering from the year 2016 if not otherwise specified.

The first annual breast cancer report was published in October 2014 presenting data for 2013, and there reports have thereafter been published yearly [28]. The main parameters in the first report were: proportion of breast-conserving treatment, proportion of screening detected breast cancers, histologic type and grading. After this, the breast cancer reports have been published with increasing numbers of indicators. In this study we have presented ten QI defined by EUSOMA from NBCR year 2016, based on the 2010 EUSOMA definition of QIs (ten of 14). Missing data on oncology treatment prevents three QI to be reported, while the fourth and last QI, “The ratio of benign to malign diagnoses”, cannot be calculated using the NBCR as the CRN do not have the legal permission to collect information on benign tumours.

EUSOMA increased the number of mandatory QI for Breast Centre Certification from 14 to 17 in 2018, two have been removed and five added. One of the new QIs has already been presented in the NBCR annual report, i.e. the proportion of patients receiving immediate re-construction [28]. Two of the new QIs can be calculated based on existing data (QI no. 11 and 14, year 2018). The QI “ratio of benign to malign diagnoses” cannot be estimated (see above). The last three new QIs needs information on oncological treatment, which today is inadequate (QI no. 8, 9 and 15, year 2018). From 2018, 13 of 17 QIs can presently be reported from the NBCR.

4. Results

In 2016, the number of breast cancer cases diagnosed in Norway was 3513. The number of hospitals which treated more than 150 patients was 12, while an additional 8 had fewer than 150, but more than 10 patients. The number of patients diagnosed with breast cancer per hospital ranged from 13 to 442 in 2016. The completeness of pathology reports was estimated to be 99%, while clinical reports covering diagnostic work-up was 90% and primary surgery 89%. Reporting of adjuvant treatment was inadequate. For instance, the number of reports on primary adjuvant chemotherapy was 709 and reports regarding start of primary hormone therapy were 529 in 2016.

4.1. National results

The result of the 12 QIs included in the annual breast cancer report for 2016 are presented in Fig. 3, including 10 of the 14 mandatory QIs for EUSOMA certification in 2016. Eleven of the NBCR indicators met the target, while another three met the minimum target, and one did not meet the minimum target. For the EUSOMA QIs, eight indicators met the target, one met the minimum target, and one did not meet the minimum target.

For the EUSOMA criteria # 1, “The proportion of patients receiving a pre-operative diagnosis” in 2016 was 94% (95% CI 93.1%–94.8%), significantly better than both the minimum recommendation of 85 and the target of 90% (Fig. 3). For the EUSOMA criteria # 4, 77% of the axillary dissections resulted in removal of ≥ 10 lymph nodes, below the minimum target of 85% (Fig. 3).

For the EUSOMA criteria # 6, 81% of patients with invasive breast cancer ≤ 3 cm underwent BCT (breast conserving therapy) as primary treatment (Fig. 3).

For the EUSOMA criteria # 11, the proportion of women who underwent surgery once varied between hospitals from 86% to 100% in 2016 (results not shown in figure). For the EUSOMA criteria # 11, the proportion of women who underwent surgery once varied between hospitals from 86% to 100% in 2016 (results not shown in figure), with no hospitals below minimum target, and three hospitals below the target of 90%.

4.2. Comparison of EUSOMA QIs between hospitals

The 5-year survival is stratified in counties, while all other QIs in Fig. 3 can be stratified on hospital level. We chose to use the EUSOMA QI # 6, BCT for tumours ≤ 3 cm, excluding multifocal cases and those treated neoadjuvant, for exploration of differences between the hospitals during the year 2014 to 2016. In 2016, the frequency of breast conserving surgery varied from 72% to 92% between hospitals with more than 150 patients treated (Fig. 4). No hospital was below the minimum target in 2016, and the results have improved from 2014 to 2016.

For the EUSOMA QI # 1, the proportion of patients receiving a pre-operative diagnosis varied from 54% to 100% in 2016, with two hospitals below the minimum recommendation from EUSOMA of 85%, and another two below the target of 90% (results not shown in figure).

For the EUSOMA criteria # 11, the proportion of women who underwent surgery once varied between hospitals from 86% to 100% in 2016, with no hospitals below minimum target, and ten hospitals did not meet the target of 95%, while seven hospitals were above target.

4.3. Non-EUSOMA QIs from the NBCR

Several QIs in the annual breast cancer report are Non-EUSOMA QIs. These QIs are defined by the reference committee. The following are some examples.

A marked reduction in the proportion of women undergoing axillary clearance was observed over time, as there were 786 women in Norway who underwent this surgical procedure in 2014, 535 in 2015 and 365 in 2016 (not shown in the figure). In addition, there was a considerable variation in the proportion of women undergoing axillary clearance at the various hospitals (6–20% in 2016).

Concerning histological grade, tumours classified as grade 3 varied from 12 to 42% (mean 28%). The reported expression of the proliferation marker Ki67 also varied across the laboratories (tumours with less than 15% Ki67 positive cells ranged from 7 to 48%).

Five-year relative survival rate was 90% in 2016 for the entire group. This ranged from 86% to 94% between the hospitals.

4.4. New EUSOMA QI

The new mandatory EUSOMA QI from 2018, “The proportion of women who underwent primary reconstruction after mastectomy” varied markedly between hospitals (4–48%) in 2016. The average for the country was 25%. Minimum standard recommended by EUSOMA is 40%.

4.5. Summary score of EUSOMA QIs on hospital level

In Fig. 5 the summary score for all the 10 EUSOMA QIs are shown. No hospitals had a perfect score of ten, but three hospitals had a score of nine. Two hospitals met all 10 minimum targets, “Sykehuset i Vestfold – Tønsberg”, and “Vestre Viken – Drammen”. “Stavanger Universitetssykehus” did not meet one minimum requirement, but met all other targets, giving a score of nine.

5. Discussion

5.1. Data structure and capture

The diagnostic and therapeutic data reporting structure of NBCR is complicated with several different forms. However, this also provides...
several benefits and opportunities for high quality data. Each form contains few variables and can therefore be completed and submitted online within a few minutes as each form is tailored to the specific medical task. If a patient is treated in different hospitals, which is not uncommon, the data are reported by the hospital performing the procedure/treatment. Missing forms are easily identified, and can be requested by the national quality registry. Statistical methods are available to estimate the completeness/coverage by several independent reporting sources (i.e. capture-recapture methods) [23]. This reporting structure is adaptable and can easily be extended to

Fig. 3. The NBCR Quality Indicators for 2016.

Fig. 4. BCT for tumours ≤ 3 cm, excluding multifocal cases and those treated neoadjuvant.
incorporate new diagnostic methods and treatments, e.g. genomics, by introducing new forms. Similarly, patient reported outcomes (PROMS) can easily be incorporated as a new form [29].

The coverage of breast cancer patients in the registry was 99.9% in 2016, due to the automatic submission of pathology reports from all laboratories in Norway. There has been a gradual increase of clinical information. In 2016, all of the 19 surgical departments treating breast cancer in Norway reported to KREMT. In 2016, the coverage was 90% in diagnostics and 89% in surgical procedures [28]. However, the compliance from oncology and radiology departments is still unsatisfactory. Before KREMT was established, only one clinical report per breast cancer case was sent to the CRN by the surgical department. Today the oncology department also has to report and several initiatives have now been taken to improve reporting, including coding courses, and visits to the hospitals by the CRN coding staff.

The KREMT system will evolve, and future improvements are expected. But in the future the reporting of clinical data using the portal part of KREMT should be replaced by gathering data directly from the hospitals Electronic Health Record (EHR). This requires a structured EHR, currently not in use in Norway. However, several initiatives are ongoing introducing e.g. open EHR systems and a national initiative on archetype [30,31]. The parameters included in NBCR should be used when designing a structured EHR system for breast diseases. One hospital in Norway used a structured EHR from 1988 to 1995, but had to end the use due to quality problems [32].

5.2. Data curation

The main product of the cancer registry is data on cancer cases. However, as all information submitted to the cancer registry is on a cancer message level, these messages needs to be validated and a cancer case with the appropriate variables needs to be created and calculated. Thus, a cancer case is an aggregate of several cancer messages related to the same cancer case for one patient. For instance, a simplified example of a cancer calculation rule would be that the date of diagnosis for a cancer case should be set as the earliest date of a diagnostic procedure (event date), from the cancer messages that are associated with the cancer case.

The medical experts at the CRN have since 1953 defined more than 1000 cancer coding rules, which can be classified into three types (i.e., Cancer Message Validation Rules, Cancer Message Aggregation Rules and Cancer Case Validation Rules) that are employed for each task, respectively. Traditionally, all these cancer coding rules have been specified by chief medical officers at the CRN, implemented into the cancer registry system by medical programmers and applied for validation and aggregation by medical coders [17]. This management of the rules are prone to errors, especially over time as medical knowledge and thus diagnostics and treatment improves. The CRN is therefore implementing all cancer coding rules in the object constraint language (OCL), and the rules are applied in the data curation stage via a rule engine to ensure even better data quality [33].

Pathology reports are reported as a mixture of structured (coded) data and textual macro and micro descriptions and diagnosis, all which need coding. This is presently done manually by medical coders. However, a study conducted at the CRN show promising results using Natural Language Processing (NLP) to automatically extract information from pathology reports. The system also identifies reports that contain ambiguity or other content that should be reviewed by an expert. The system shows potential to encode the reports considerably faster, with less resources, and similar high quality to the manual encoding [34]. Other studies also show good results using NLP on pathology reports [35].

5.3. Definition of QIs

The definition of some QI is not completely the same in NBCR and EUSOMA. For instance, the EUSOMA QI “Proportion of patients (BRCA1 and BRCA2 patients excluded) with invasive breast cancer not greater than 3 cm (total size, including DCIS component) who underwent BCT as primary treatment” differ from the NBCR “BCT for tumours ≤ 3 cm, excluding multifocal cases and those treated neoadjuvant”. NBCR do not have information on hereditary breast cancer and

Fig. 5. Summary score of EUSOMA QIs in 2016.
can therefore not exclude these in the analysis. However, based on the Norwegian guidelines, these patients are recommended mastectomy. Furthermore, primary treatment is comparable with not treated neoadjuvant.

Regarding multifocality, these are excluded in the calculation of the QI in NBCR but not in QI defined by EUSOMA. This might have an influence when comparing the Norwegian and EUSOMA defined QI.

5.4. Comparability between hospitals

The 20 hospitals in Norway treating breast cancers surgically vary both in the number of patients treated and other parameters. One could therefore argue that the results in this study should be adjusted for case-mix (differences in the patient population) to make the comparisons valid. However, the EUSOMA criteria are precise in their specifications/data selection for the quality indicators' minimum target, and target. These targets should be met regardless of differences between hospitals. We therefore argue that one should not do a case-mix correction, as this study’s focus is whether or not the EUSOMA criteria is met, not if they would be meet given another set of patients.

When comparing hospitals, the results have to be interpreted with care since the register is in its beginning. Some differences between the hospitals are larger than anticipated, for example, the indicator showing proportion of women who underwent primary reconstruction after mastectomy in 2016 varied from 4% to 48%. Due to this variation, The Norwegian Breast Cancer Group has appointed a working group to address this rather unexpected variation.

5.5. Some examples of the value of a breast cancer quality registers

Register studies indicate a survival benefit for patients undergoing breast conserving therapy compared to those undergoing mastectomy [7,8,11,36–38]. This seems not to be due to a more advanced disease among patients treated with mastectomy, although randomized controlled trial data to support this statement is lacking. As a consequence, the proportion of women treated with breast conserving surgery has increased in Norway. Focus on oncoplastic procedures has also encouraged the reduction of mastectomies.

The observed variations in grading and Ki67 expression between the hospitals point to the importance of understanding the cause of these differences and may help to decrease the undesirable differences. In clinical practise, both grading and Ki67 provide information of importance for decision on chemotherapy use, and a precise classification may hinder both under- and overtreatment.

In 2015, new guidelines opened for reduced use of axillary clearance based on results following the Z0011 study [39]. Therefore, one would expect less women would undergo axillary clearance. This was reflected in the NBCR, as there were 786 women in Norway who underwent axillary clearance in 2014, and 535 and 365 in 2015 and 2016 respectively.

In addition to publish quality indicators on a yearly basis, the data in the cancer registries are being used in a multitude of medical studies. This includes both pure registry studies, clinical trials and basal molecular studies.

A population-based study on breast cancer patients from Belgium showed that higher-volume hospitals had higher rates of multi-disciplinary team meeting, diagnosis before surgery, neoadjuvant chemotherapy, BCT rate, adjuvant radiotherapy after BCT and follow up mammography [40]. Higher volume was associated with improved survival.

The clinical database of the Danish Breast Cancer Cooperative Group (DBCG) has resulted in a large number of epidemiological research papers. In addition to this, 25% of the cases enrolled in the DBCG have frozen tissue, providing ideal conditions for translational research. DBCG perform large ongoing studies with aim to tailor the therapeutic intervention [41].

A large number of studies have been published based on data from the Swedish National Quality Registry for Breast Cancer (19 from publications year 2017) [42].

In the Netherlands a national breast cancer organization was established in 2011 [43]. They have found that a continuous loop of registration and feedback by clinical auditing provides a powerful tool for quality monitoring and improvement [44]. Within three years’ time they found several guidelines improvements and narrowing of the hospital variation for the respective QI.

The clinical cancer registries mentioned above are good models for our future work with NBCR and by comparing results with our neighbouring countries, the treatment of breast cancer patients will hopefully be further improved.

6. Conclusion

For 2016, 10 of the 14 QIs recommended from EUSOMA can be calculated on a national basis using NBCR. Missing data on oncology treatment prevents three QIs to be reported, while the fourth and last IQ, the ratio of benign to malign diagnoses, cannot be calculated as the CRN do not have the legal permission to have information on benign tumours. The summary score of EUSOMA QIs makes it easy to compare hospitals on a national level.

The registration of treatment administered at all hospitals makes it possible to compare hospitals and follow changes after implementation of new guidelines. Publishing annual reports encourages hospitals with unsatisfactory results to improve their practice. Over time, this understanding will reduce the inequalities between hospitals, improve tailored treatment and increase compliance to national guidelines.

Authors’ contributions

OJHJ and JFN conceived the original idea. OJHJ and JFN wrote the manuscript with critical feedback from RK, ES and BN. All authors contributed to the final version of the manuscript.

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Conflict of interest statement

The authors have no conflict of interests to declare.

Summary table

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<td>• Registry with clinical focus offers an ideal infrastructure for enrolling and following patients in clinical trials.</td>
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<td>• 17 quality indicators defined by European Society of Breast Cancer Specialist (EUSOMA) are mandatory to become a EUSOMA certified Breast Centre.</td>
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<th>What this study has added to the body of knowledge</th>
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<td>• Describes the development and use of the Norwegian Quality Registry for breast cancer.</td>
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<td>• Annual breast cancer reports increases compliance to recommended treatment.</td>
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• Simplify the approval of EUSOMA defined Quality Indicators for a breast cancer unit on a national level.
• Calculating a summary score of EUSOMA Quality Indicators makes it easy to compare hospitals.

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