NAoPri
National Audit of
Primary Breast Cancer

NATCAN
National Cancer Audit
Collaborating Centre

National Audit of Primary Breast Cancer

Quality Improvement Plan – September 2024

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The National Cancer Audit Collaborating Centre (NATCAN**)** is commissioned by the Healthcare Quality Improvement Partnership (HQIP) as part of the National Clinical Audit and Patient Outcomes Programme (NCAPOP). NATCAN delivers national cancer audits in non-Hodgkin lymphoma, bowel, breast (primary and metastatic), oesophago-gastric, ovarian, kidney, lung, pancreatic and prostate cancers. HQIP is led by a consortium of the Academy of Medical Royal Colleges and the Royal College of Nursing. Its aim is to promote quality improvement in patient outcomes, and in particular, to increase the impact that clinical audit, outcome review programmes and registries have on healthcare quality in England and Wales. HQIP holds the contract to commission, manage and develop the National Clinical Audit and Patient Outcomes Programme (NCAPOP), comprising around 40 projects covering care provided to people with a wide range of medical, surgical, and mental health conditions. The programme is funded by NHS England, the Welsh Government and, with some individual projects, other devolved administrations and crown dependencies. https://www.hqip.org.uk/national-programmes

The Association of Breast Surgery is a registered charity dedicated to advancing the practice of breast surgery and the management of breast conditions for the benefit of the public. It is a multi-professional membership association, which promotes training, education, clinical trials and guideline composition and adoption. For further information, please refer to the website www.associationofbreastsurgery.org.uk. Registered charity no: 1135699

The UK Breast Cancer Group (UKBCG) is a forum for Clinical and Medical Oncologists. The UKBCG acts as a stakeholder to NICE, NHS England and other organisations; and undertakes key pieces of work, at times in collaboration with other bodies, with the overriding endpoint of improving patient care.
The Group's objectives include advancing the education of clinical and medical oncologists in the subject of breast cancer, concerning its identification, diagnosis and treatment; promoting research for the public benefit in all aspects of breast cancer and publishing the results; and assisting in the treatment and care of persons suffering from breast cancer, or in need of rehabilitation, by the provision of education for healthcare professionals.
Further information on the work of the UKBCG is communicated via this website on a regular basis https://ukbcg.org/. Registered charity no: 1177296

This work uses data that have been provided by patients and collected by the NHS as part of their care and support. For patients diagnosed in England, the data are collated, maintained and quality assured by the National Disease Registration Service (NDRS), which is part of NHS Digital.

NHS Wales is implementing a new cancer informatics system. As a result, the quality and completeness of data from Wales is likely to have been impacted due to implementation of this new system across multiple NHS organisations (Health Boards), which has resulted in data being supplied by both old and new systems. Additionally, and reflecting the uncertainty of data quality, the data submitted to the audit may not have undergone routine clinical validation prior to submission to the Wales Cancer Network (WCN), Public Health Wales.

Contents

Executive Summary

The National Audit of Primary Breast Cancer (NAoPri) has been commissioned to evaluate primary breast cancer care delivered in NHS hospitals across England and Wales. It aims to help NHS organisations to benchmark their primary breast cancer care against measurable standards, to identify unwarranted variation in care, and to provide tools to help services improve quality of care for people with primary breast cancer. The NAoPri will build on the work of the National Audit of Breast Cancer in Older Patients (NABCOP)[1].

The NAoPri Quality Improvement Plan sets out the scope, care pathway, five improvement goals and ten performance indicators for the NAoPri. The plan expands on the 2023 Scoping Report, which described: (i) a review of pertinent guidelines and the wider relevant literature (including external quality standards), (ii) a scoping survey to collect the views of key stakeholders on the delivery of breast cancer care in the NHS, and (iii) priorities identified for improving primary breast cancer care. Further engagement with stakeholders occurred through the presence of the NAoPri at key conferences and via meetings of the NAoPri Audit Advisory Committee (AAC).

The NAoPri will include all people (women and men), aged 18 or over, who are diagnosed in an NHS hospital in England or Wales with breast cancer (ICD-10 diagnosis code: C50; D05) that is not metastatic at presentation (Stage 0 to Stage 3C). The audit will cover the care pathway from first diagnosis of primary breast cancer to the end of the subsequent sequence of planned primary treatments received by these patients. Primary treatment will therefore include all non-metastatic treatments. Treatments may be multimodal and include any of the following: surgery, systemic anti-cancer therapy (SACT), radiotherapy, endocrine therapy, bisphosphonates, palliative and supportive care aimed at relief of symptoms. Short- and long-term outcomes following these treatments will be evaluated.

The following quality improvement goals have been identified for the NAoPri:

1. Improve the movement of patients through the care pathway.
2. Reduce unwarranted variation for patients undergoing surgery.
3. Reduce unwarranted variation for patients having non-surgical oncological treatments.
4. Improve access to breast reconstruction after mastectomy.
5. Improve and reduce unwarranted variation in primary breast cancer outcomes.

The NAoPri has identified ten indicators to monitor progress against these five improvement goals and how they map to clinical guidelines and standards. A range of improvement methods and improvement activities to help deliver the Quality Improvement Plan are also described.

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[1] *National Audit of Breast Cancer in Older Patients.*; Available from: https://www.nabcop.org.uk/.

1. Introduction

1.1 Aim and objectives of the Quality Improvement Plan

The Quality Improvement Plan for the National Audit of Primary Breast Cancer (NAoPri) builds on the previous Scoping Report which sets out the scope of the NAoPri and identified key areas for improvement in the care pathway. The Quality Improvement Plan defines ten key performance indicators, and how they map to the five NAoPri quality improvement goals, national guidelines, and standards. These key performance indicators will be used by the NAoPri to monitor progress towards its quality improvement goals and to stimulate improvements in primary breast cancer care in England and Wales.

The Quality Improvement Plan describes the approach taken to develop the NAoPri's quality improvement goals and performance indicators. In addition, it sets out the range of potential improvement methods and activities that will support implementation of the plan, including strategies for reporting and disseminating audit results.

The Quality Improvement Plan for the NAoPri was developed in consultation with key stakeholders, including people with lived experience of primary breast cancer, and will be reviewed on an annual basis.

1.2 The National Cancer Audit Collaborating Centre

The NAoPri is part of the National Cancer Audit Collaborating Centre (NATCAN) a new national centre of excellence to strengthen NHS cancer services by looking at treatments and patient outcomes across the country. It was set up on 1 October 2022 to deliver six new national cancer audits, including ovarian, pancreatic, kidney, non-Hodgkin Lymphoma, primary breast cancer and metastatic breast cancer. Existing audits in prostate, lung, bowel, and oesophago-gastric cancers moved into NATCAN in 2023. The centre is commissioned by the Healthcare Quality Improvement Partnership (HQIP) on behalf of NHS England and the Welsh Government.

The aim of the ten NATCAN audits is to:

1. Provide regular and timely evidence to cancer services of where patterns of care in England and Wales may vary.
2. Support NHS services to increase the consistency of access to treatments and help guide quality improvement initiatives.
3. Stimulate improvements in cancer detection, treatment, and outcomes for patients, including survival rates.

Further information about NATCAN and key features of its approach to audit can be found in Appendix 1.

2. Background on Primary Breast Cancer

Globally, more than 2 million people are diagnosed each year with invasive breast cancer[2]. Breast cancer is the most common cancer diagnosed within the United Kingdom (UK), and the second most common cause of cancer death in women[3].

Primary breast cancer describes breast cancer which, at diagnosis, has been found only in the breast or nearby lymph nodes; it has not spread to other parts of the body. The extent of a cancer is categorised using the Union for International Cancer Control (UICC) TNM system (8th Edition) (Appendix 2). Broadly, primary invasive breast cancer is classified as either early invasive (Stage 1A to 3A) or locally advanced (Stage 3B and 3C). There is also a form of breast cancer which is non-invasive (Stage 0), termed ductal carcinoma in-situ (DCIS).

At diagnosis, most people are found to have primary breast cancer with 'de novo' metastatic breast cancer accounting for approximately 5% of new invasive breast cancer cases diagnosed each year[4]. Within England, 5-year overall survival for women diagnosed with breast cancer between 2016 and 2020 was almost 100% for Stage 1, 90% for Stage 2, and 70% for Stage 3 disease[5].

2.1 Main issues in primary breast cancer care

The management of breast cancer is increasingly complex and involves a variable sequence of treatments which need to be individualised to each patient (Figure 1). Treatments can include one or more of the following: surgery, radiotherapy, systemic anti-cancer therapy (including chemotherapy and biological therapy), endocrine therapy, bisphosphonates, palliative and supportive care aimed at relief of symptoms (e.g. those with locally advanced disease or those who are not fit for curative treatments).

There are ongoing developments within each of the different treatment modalities. For example, the range of available systemic anti-cancer therapies is expanding, with new treatments being developed for individualised genetic and molecular tumour profiles. Other changes include an increasing use of neo-adjuvant (pre-operative) SACT, and a move towards de-escalating certain treatments to avoid over-treatment and the possible associated morbidity. For example, fewer patients now receive an axillary node clearance than in previous years.

A key component of the scoping work was to build on the areas within primary breast cancer care which were highlighted by the NABCOP for attention (see Section 2.3 for more details). These include:

- Data completeness for key data items, including recurrence.
- Route to diagnosis.
- Triple diagnostic assessment in a single visit.
- Involvement of a Clinical Nurse Specialist (CNS) or key worker.
- Breast surgery for DCIS and early invasive breast cancer.
- Radiotherapy for DCIS and early invasive breast cancer.
- Chemotherapy for early invasive breast cancer.
- Re-operation rates following breast-conserving surgery.
- Short-term morbidity & mortality following adjuvant chemotherapy.
- Use of endocrine and bisphosphonate therapy.
- Relative survival for women receiving surgery for early invasive breast cancer.

Many other performance indicators for breast cancer services can be found in the wider literature. A recent systematic review identified 89 quality indicators from 22 selected documents covering Europe and North America (up to 2021). This review included 34 indicators identified by the European Society of Breast Cancer Specialists (EUSOMA), as well as indicators from the NICE guidelines[6-7].

There was significant heterogeneity across the documents included in the review in the selected performance indicators. The vast majority (75.3%) related to evaluating processes of care rather than structure (12.4%) or outcomes (12.4%), and most (48.3%) related to treatments. Around a quarter of the quality indicators reviewed did not report a minimum standard of care and, where a standard of care was defined, this often varied between different guidelines[7].

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[2] Taylor, C., et al., Breast cancer mortality in 500 000 women with early invasive breast cancer diagnosed in England, 1993-2015: population based observational cohort study. BMJ, 2023. 381: p. e074684.

[3] Cancer Research UK. Breast Cancer Statistics. Breast Cancer Mortality.; Available from: https://www.cancerresearchuk.org/health-professional/cancer-statistics/statistics-by-cancer-type/breast-cancer#heading-Two.

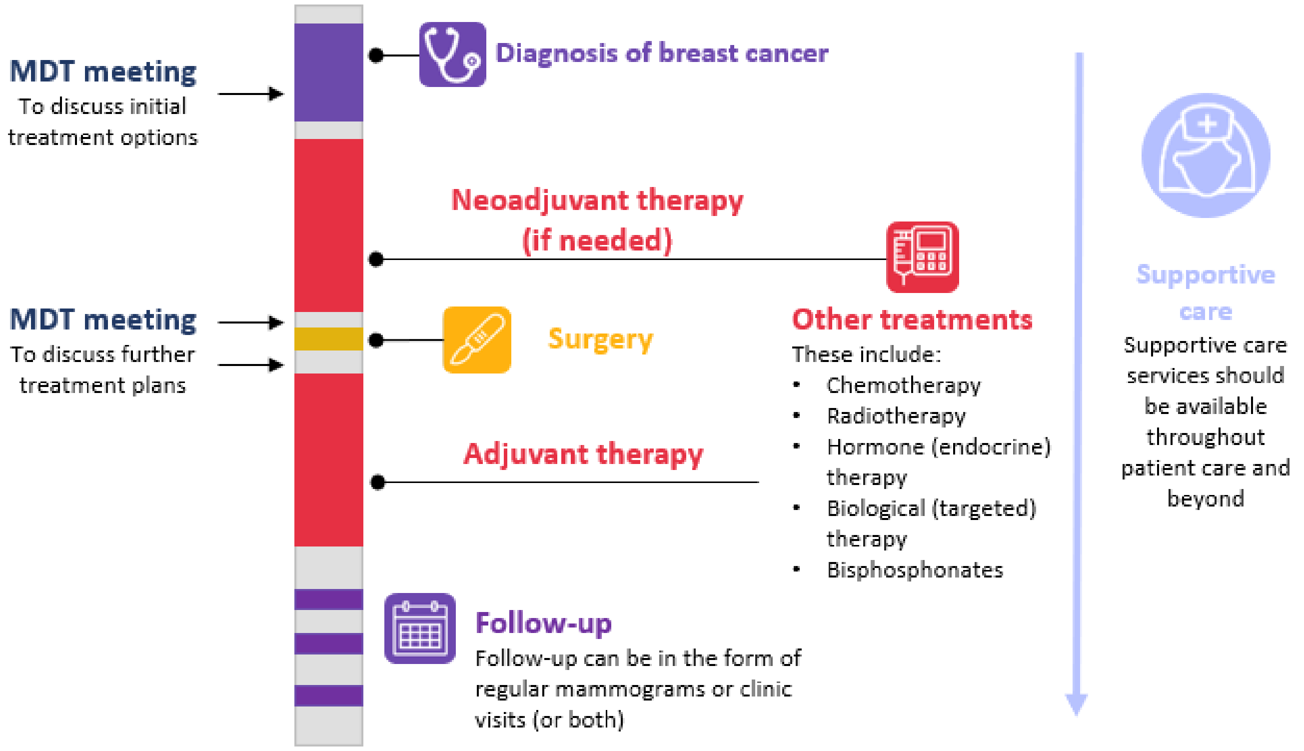
[4] Gong, Y., et al., Incidence proportions and prognosis of breast cancer patients with bone metastases at initial diagnosis. Cancer Med, 2018. 7(8): p. 4156-4169.

[5] NHS England. Cancer Survival in England, cancers diagnosed 2016 to 2020, followed up to 2021.; Available from: https://digital.nhs.uk/data-and-information/publications/statistical/cancer-survival-in-england/cancers-diagnosed-2016-to-2020-followed-up-to-2021.

[6] Biganzoli, L., et al., Quality indicators in breast cancer care: An update from the EUSOMA working group. Eur J Cancer, 2017. 86: p. 59-81.

[7] Maes-Carballo, M., et al., Quality indicators for breast cancer care: A systematic review. Breast, 2021. 59: p. 221-231.

Figure 1. Sequence of steps in a typical primary breast cancer pathway, from diagnosis to treatment, in English and Welsh NHS organisations.



2.2 Management of primary breast cancer

Numerous guidelines on the management of primary breast cancer have been published by national organisations and international groups (Appendix 3). This rich source of information regarding the recommended management of patients with primary breast cancer provides the evidence base for the NAoPri.

Most people with primary breast cancer will receive surgery as their first treatment. However, individuals might receive other treatments before and/or after surgery based on their tumour characteristics, such as the size of the tumour and whether there is evidence of spread to the lymph nodes. Treatment options are also influenced by tumour molecular marker expression, particularly whether the breast cancer is hormone receptor positive or negative, and whether the HER2 status is positive or negative. Together, these give three distinct tumour sub-groups (Table 1).

Table 1. Breast cancer tumour sub-groups

Tumour sub-group	Implication
HER2-ve, HR+ve	The most common tumour sub-group, equating to approximately 65% of all patients with breast cancer. Endocrine therapy is an option.
HER2+ve, (HR+ve or HR-ve)	Treatment strategies are driven by the positive HER2 status, and HER2-targeting therapies are a dominant option. Patients with tumours which are HER2+ve account for around 15-20% of all breast cancer. Endocrine therapy is an option where the tumour is also HR+ve.
HER2-ve, HR-ve	Also known as triple negative breast cancer (TNBC). Accounts for approximately 10-20% of all breast cancer.
Key: HR = hormone receptor	

2.3 Variation in care and outcomes highlighted by NABCOP

The NABCOP highlighted various areas in which patterns of care differed between NHS breast cancer units across England and Wales[8].

At the beginning of the breast cancer care pathway, variation was shown in the proportion of women who received triple diagnostic assessment in a single visit. Although there was no difference in the use of triple diagnostic assessment according to age, there was marked variation identified across different NHS organisations.

For women diagnosed with DCIS, variation was identified in the use of surgery, particularly in those aged 70 years and above. In addition, there was significant variation in the proportion of women with DCIS who received radiotherapy. For example, 60% of those aged 50 to 69 years received adjuvant radiotherapy compared to 27% aged 80 years and above. There was considerable variation in radiotherapy use across NHS organisations, regardless of age.

For women with early invasive breast cancer, variation was identified across several treatment modalities including surgery, radiotherapy, and chemotherapy. There was considerable variation in the use of post-mastectomy radiotherapy across different NHS organisations, regardless of age. Similarly, there was considerable variation in the use of adjuvant chemotherapy and trastuzumab for women with HER2-positive disease. Another example of this were the large differences across organisations in the proportion of older women who received surgery for hormone-sensitive breast cancer compared to women diagnosed with hormone-negative breast cancer, regardless of patient fitness. Breast cancer guidelines recommend treatment options should be determined by “biological age” and not chronological age[9].

The NABCOP also highlighted variation in outcomes. For example, re-operation rates were higher in younger patients and those women with DCIS. In relation to the choice of re-operation procedure, older women had higher rates of mastectomy rather than having further breast-conserving surgery, compared to younger patients. Geographical variation in re-operation rates was seen.

For patients who received adjuvant chemotherapy for early invasive breast cancer, 28% were found to have had at least one treatment-related overnight hospital admission within 30 days of a chemotherapy cycle. Geographical variation in short-term morbidity following adjuvant chemotherapy was also demonstrated across different NHS organisations.

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[8] National Audit of Breast Cancer in Older Patients.; Available from: https://www.nabcop.org.uk/.

[9] National Institute for Health and Care Excellence. Early and locally advanced breast cancer: diagnosis and management. NICE guideline [NG101]. Available from: https://www.nice.org.uk/guidance/ng101.

3. Approach to developing the Quality Improvement Plan

This NAoPri Quality Improvement Plan builds on the Scoping Report which set out the patient inclusion criteria, care pathway and priorities for quality improvement (Section 4). The Quality Improvement Plan describes five quality improvement goals and outlines ten performance indicators that have been mapped to these goals and relevant clinical guidelines (Section 5).

In Section 6 and Section 7, improvement methods and improvement activities are outlined. Finally, Section 8 sets out the approaches to evaluation of the Quality Improvement Plan. Given that this is the first national audit of primary breast cancer in England and Wales, the Quality Improvement Plan is expected to evolve over subsequent years.

3.1 Approach to developing the audit scope

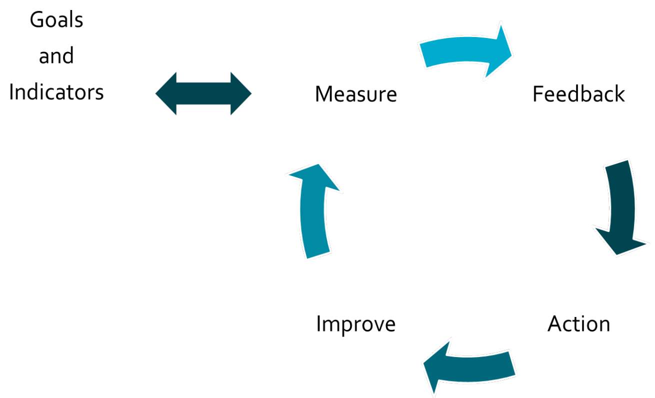
To inform the quality improvement goals and priorities of the NAoPri, the audit team conducted a review of pertinent guidelines and relevant wider literature (including external quality standards) as well as a consultation with key stakeholders. The consultation process included feedback from patient and professional representatives on the AAC and Patient and Public Involvement (PPI) Forum, along with over 250 responses from patients to the scoping survey.

The NAoPri will build on the methodological and clinical work of the NABCOP which finished in September 2022. While the NABCOP included only women aged 50 years and above, the NAoPri will evaluate the care received by ***all*** people diagnosed with primary breast cancer, regardless of age or gender, in NHS hospitals within England and Wales.

3.2 Approach to developing the quality improvement goals and indicators

Clinical Performance Feedback Intervention Theory (CP-FIT)[10] states that developing improvement goals and performance indicators are the first steps in the audit and feedback cycle (Figure 2).

Figure 2: The audit and feedback cycle



Using the priorities for improvement outlined in its Scoping Document, the NAoPri developed a list of 24 candidate performance indicators that mapped to five quality improvement goals. The selection of ten indicators from this list of candidates was informed by the following set of key principles.

- Measurable so that they can be the basis of credible feedback about performance. This property means that the indicators can be defined with available data in a valid, reliable, and fair manner that allows performance to be attributed to a specific unit[11].
- Actionable so that feedback translates into action to improve care. Indicators should therefore be important and address a specific pathway of care that is clear to all stakeholders. Stakeholders should understand the drivers of variation in performance within this pathway and control the levers for change. These changes should be evidence-based and address policy priorities.
- Improvable so that actions have the desired effect on patient care. There should therefore be clear scope for improvement (low baseline levels or large unwarranted variation) and a receptive context, with no unintended consequences. Some interventions may have demonstrated improvements to certain indicators in existing literature.

Some of these properties are difficult to know before evaluating a performance indicator (such as existing levels of performance, the drivers of low performance, or interventions that can improve care). In addition, clinical practice may change over time so that properties of indicators also change (for instance whether they relate to a policy priority). Therefore, we expect to modify the NAoPri's improvement

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[10] Brown B, Gude WT, Blakeman T, van der Veer SN, Ivers N, Francis JJ, et al. Clinical Performance Feedback Intervention Theory (CP-FIT): a new theory for designing, implementing, and evaluating feedback in health care based on a systematic review and meta-synthesis of qualitative research. Implement Sci 2019;14:40.

[11] Geary, R., et al., A step-wise approach to developing indicators to compare the performance of maternity units using hospital administrative data. BJOG: An International Journal of Obstetrics & Gynaecology, 2018. 125(7): p. 857-865.

goals and performance indicators over the duration of the audit. Recommendations will also evolve and become more focused as the NAoPri learns through the audit and feedback cycle.

3.3 Data provision

The NAoPri will use information from routinely collected national healthcare datasets. These capture details on the diagnosis, management, and treatment of every person with a new diagnosis of primary breast cancer in England and Wales. Further details on data provision and acquisition can be found in Appendix 4 and Appendix 5.

3.4 Data limitations

For accurate and timely benchmarking, it is essential that datasets used by the NAoPri:

1. Include all the data items required to measure and risk-adjust performance indicators.
2. Are timely.
3. Have a high-level of case-ascertainment.
4. Have high levels of data completeness.
5. Are accurate.

For patients treated in England, Rapid Cancer Registration Data (RCRD) linked to other national healthcare datasets, will be used for quarterly reporting. For patients treated in Wales, no equivalent of RCRD is currently available and therefore quarterly reporting is not possible for Wales at this time.

The RCRD is compiled from Cancer Outcomes and Services Dataset (COSD) records and other sources and is made available more quickly than the gold standard National Cancer Registration Data (NCRD). The speed of production means that case ascertainment and data completeness are lower, and the range of data items in the RCRD is limited.

For example, the RCRD incorporates a small subset of COSD data items with no information on molecular markers such as endocrine receptor status or HER2 status. It includes information on diagnostic staging, but levels of completeness are lower than in the gold standard Cancer Registration records. This may prevent indicators being defined for specific patient groups and restrict the extent to which potential confounders can be included in a risk-adjustment model. This may prevent indicators being defined for specific patient groups and restrict the extent to which potential confounders can be included in a risk adjustment model. As such, the indicators used for quarterly reporting will require careful consideration and testing.

Currently, there is a lack of information regarding recurrence (both local and distant) within routinely collected national cancer data. From work done by the NABCOP evaluating the recording of recurrence information within the COSD, only 4% of patients had a record of recurrence reported with poor recording across all geographical regions. Rates of recurrence would be an important outcome for the NAoPri to publish and it will be particularly important to improve data quality and completeness of recurrence in the coming years.

Highlighting issues with data quality and completeness has been a common theme for all national cancer audits. It will be important for the audit team to assess this for the whole of the NAoPri cohort and focus efforts on improving data where required.

3.5 Stakeholder involvement

During the set-up phase of the audit, the NAoPri team engaged with various stakeholders including patients, clinicians, representatives of medical associations, and patient charities. This helped inform the design of a scoping survey. The findings of this survey were discussed at the first NAoPri AAC meeting in April 2023 and are described in the Scoping Report.

In May 2023, the NAoPri team attended the Association of Breast Surgery (ABS) annual conference. The ABS conference attracts surgeons, nurse specialists, and wider members of the breast care team, as well as patient representatives. The NAoPri team gave a presentation about the audit and had a conference stand with information for delegates about the new breast cancer audits. The audit team were able to explain the aims of the NAoPri, how it will use national data sources, and how people can get involved. It also provided the opportunity to encourage engagement with the audit processes.

4. Audit scope

4.1. Patient inclusion criteria

The eligibility criteria for the NAoPri are defined as all people (women and men):

- Diagnosed in the audit period with breast cancer (ICD-10 diagnosis code: C50; D05) that is proven only in the breast, with or without spread to local lymph nodes (Stages 0 to IIIC) (see Appendix 2 for stage definitions).
- Aged ≥18 years at diagnosis.
- Diagnosed in an NHS hospital within England and Wales.

The basis for diagnosis may be histological, clinical, or cytological. The NAoPri will exclude individuals identified only from death certificates.

4.2. Care pathway

The audit will cover the pathway from first diagnosis of primary breast cancer to the end of the subsequent sequence of primary treatments received by these patients.

We define primary treatment as any non-metastatic treatments. Treatments may be multimodal and include any of the following: surgery, SACT, radiotherapy, endocrine therapy, bisphosphonates, palliative and supportive care aimed at relief of symptoms.

Short- and long-term outcomes following these different treatments will be evaluated.

5. Quality Improvement Goals & Performance indicators

Details of the five NAoPri quality improvement goals and the associated ten performance indicators mapped to the improvement goals and guidelines are outlined in Table 2 below.

Further information on how the data for these performance indicators will be reported is detailed in the NAoPri metrics table (available to view on the NATCAN website).

Where appropriate, the performance indicators will be presented for specific patient groups as well as for the whole patient population. Consultation with stakeholders highlighted the value of providing information for the following patient subgroups:

- Older (≥70 years) and frail patients,
- Young people with breast cancer (<40 years),
- Men with breast cancer,
- People with triple negative breast cancer.

To illustrate how quality improvement activities can be stimulated by these goals and performance indicators, we have provided an example driver diagram for one of the NAoPri's quality improvement goals (Figure 3). A driver diagram is a type of structured chart which connects a goal with activities that can help organisations achieve it. It can be a useful tool for organisations who want to improve their performance by providing a way to organise, prioritise and plan the activities they will undertake to achieve the desired improvement.

Table 2. NAoPri quality improvement goals and performance indicators

Quality improvement goal	Performance indicator/s*	National Guidance/standards[12, 13, 14,15]
Goal #1 – Improve the movement of patients through the care pathway	Percentage of patients who underwent triple diagnostic assessment (TDA) in a single hospital visit.	*NICE Quality Standard 12 - Quality Statement 1:* Timely diagnosis. People with suspected breast cancer referred to specialist services are offered the triple diagnostic assessment in a single hospital visit.
	Percentage of patients who had contact with a Clinical Nurse Specialist (CNS) recorded after diagnosis.	*NICE NG101 recommendation 1.2 Providing information and psychological support.* All patients with breast cancer should have a named Clinical Nurse Specialist to support them through diagnosis, treatment, and follow-up.
Goal #2 – Reduce unwarranted variation for patients undergoing surgery.	Percentage of patients who had i) breast-conserving surgery or ii) mastectomy within 12 months of diagnosis.	*NICE NG101, ESMO and SIOG guidelines.* Surgery is the choice of primary treatment for non-invasive and early invasive breast cancer in most patients.
Goal #3 – Reduce unwarranted variation for patients having non-surgical oncological treatments.	Percentage of patients who received neo-adjuvant chemotherapy.	*NICE NG101 recommendation 1.11 Primary systemic therapy.* This guidance suggests offering neo-adjuvant chemotherapy to patients with ER-negative, ER positive and HER2-positive breast cancer as an option to reduce tumour size if it is otherwise indicated.
	Percentage of patients who received adjuvant radiotherapy following i) breast-conserving surgery and ii) mastectomy (stratified by recurrence risk).	*NICE NG101 recommendation 1.10 Radiotherapy after breast-conserving surgery* - All women with invasive breast cancer treated with breast-conserving surgery should be offered adjuvant radiotherapy unless they have a very low risk of recurrence. Consider adjuvant radiotherapy for women with non-invasive breast cancer treated with breast-conserving surgery. *NICE NG101 recommendation 1.10 Radiotherapy after mastectomy* – Patients with high-risk of recurrence should be offered adjuvant radiotherapy, but not those with low-risk of recurrence.
	Percentage of patients who received adjuvant chemotherapy.	*NICE NG101 recommendations 1.6 Adjuvant therapy planning and 1.8 Adjuvant chemotherapy for invasive breast cancer* - Adjuvant chemotherapy should be considered based on assessment of predictive and prognostic factors, and possible risks and benefits of the treatment.
Goal #4 – Improve access to breast reconstruction after mastectomy.	Percentage of patients recorded as having had an immediate reconstruction following a mastectomy.	*NICE NG101 recommendation 1.5 Breast Reconstruction* - All patients undergoing mastectomy for breast cancer should be offered breast reconstruction.
Goal #5 – Improve and reduce unwarranted variation in primary breast cancer outcomes.	Percentage of patients who had a re-excision surgery within 12 months of their initial surgical procedure.	*NICE NG101 recommendation 1.3 Surgery to the breast* - Further surgery should be considered if margins are not clear (<1mm).
	Percentage of patients who had an overnight hospital admission for treatment-related toxicity within 30 days of a systemic anti-cancer therapy (SACT) cycle.	National Confidential Enquiry into Patient and Outcome Death (NCEPOD) and National Patient Safety Agency reports have highlighted the need for improvements in the quality and safety of systemic anti-cancer therapy.
	Percentage of patients who survived at least 1, 3 or 5 years from the date of breast cancer diagnosis.	Survival is a key primary outcome in breast cancer research and can be used as an overall marker for treatment success.

* The NAoPri will publish the performance indicators (these may be fewer than ten) in the first State of the Nation Report published in September 2024. Additional indicators (up to a maximum of ten) will be reported in quarterly reports and future State of the Nation reports. The NAoPri will provide further analysis of data quality and contextual indicators (Appendix 6). The publication of indicators is aligned with data availability and completion of robust, methodological development work including appropriate risk-adjustment models.

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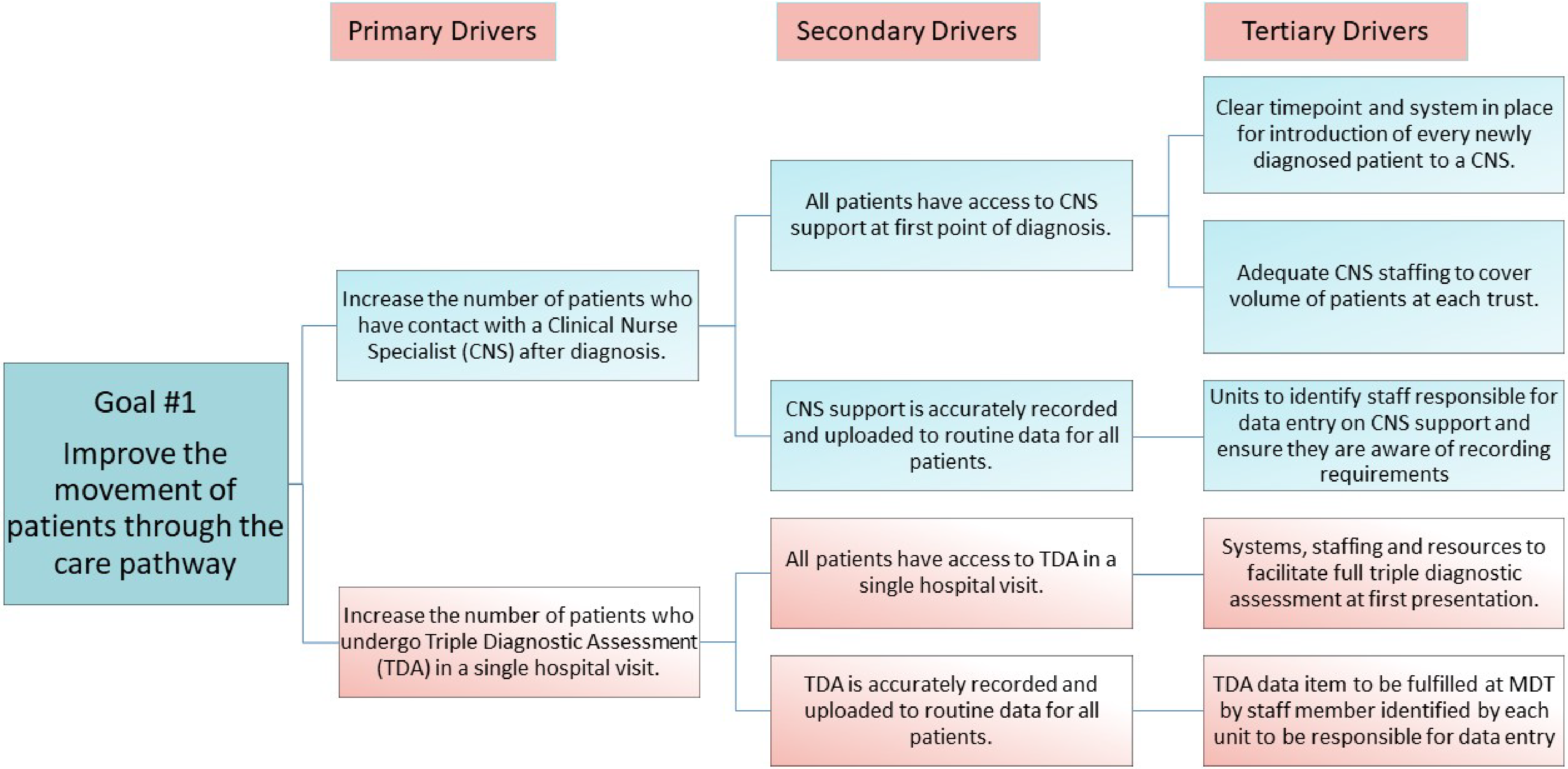
[12] *National Institute for Health and Care Excellence. Breast Cancer. Quality standard [QS12].* Available from: https://www.nice.org.uk/guidance/qs12.

[13] *National Institute for Health and Care Excellence. Early and locally advanced breast cancer: diagnosis and management. NICE guideline [NG101].* Available from: https://www.nice.org.uk/guidance/ng101.

[14] Cardoso, F., et al., *Early breast cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up†.* Ann Oncol, 2019. **30**(8): p. 1194-1220.

[15] Biganzoli, L., et al., *Updated recommendations regarding the management of older patients with breast cancer: a joint paper from the European Society of Breast Cancer Specialists (EUSOMA) and the International Society of Geriatric Oncology (SIOG).* Lancet Oncol, 2021. **22**(7): p. e327-e340.

Figure 3. Example driver diagram: Goal #1 – Improving the movement of patients through the care pathway



Primary Drivers

Secondary Drivers

Tertiary Drivers

Goal #1

Improve the movement of patients through the care pathway

Increase the number of patients who have contact with a Clinical Nurse Specialist (CNS) after diagnosis.

- All patients have access to CNS support at first point of diagnosis.
  - Clear timepoint and system in place for introduction of every newly diagnosed patient to a CNS.
  - Adequate CNS staffing to cover volume of patients at each trust.
- CNS support is accurately recorded and uploaded to routine data for all patients.
  - Units to identify staff responsible for data entry on CNS support and ensure they are aware of recording requirements

Increase the number of patients who undergo Triple Diagnostic Assessment (TDA) in a single hospital visit.

- All patients have access to TDA in a single hospital visit.
  - Systems, staffing and resources to facilitate full triple diagnostic assessment at first presentation.
- TDA is accurately recorded and uploaded to routine data for all patients.
  - TDA data item to be fulfilled at MDT by staff member identified by each unit to be responsible for data entry

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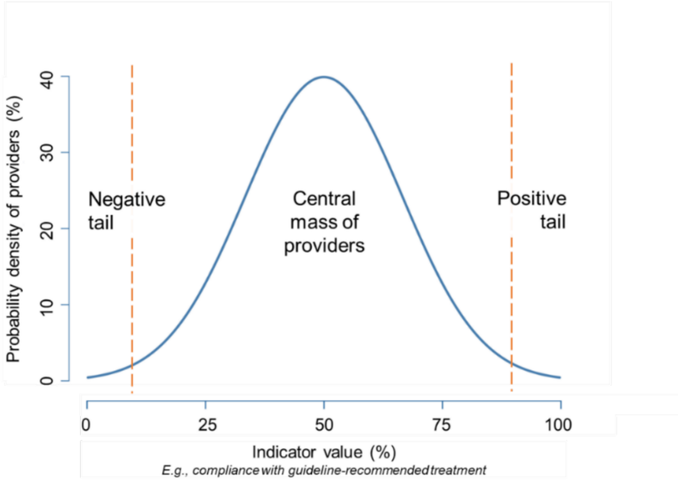
6. Quality Improvement Framework

Figure 4 below shows a hypothetical example of how the values of a performance indicator may be distributed across NHS providers nationally at a single time point. On this indicator, a lower value indicates worse performance. The distribution can be separated into three domains: the negative tail (suggestive of worse performance), the central mass (located around the national average), and the positive tail (suggestive of better performance).

Figure 4. Hypothetical distribution of organisational values on a performance indicator



Each domain is associated with a different set of methods for improving healthcare:

Negative tail

Example methods: Regulation and public reporting of outliers with worse than expected performance

- National clinical audit has traditionally focused on the negative tail to improve healthcare. This approach implies that some NHS providers are doing something systematically worse than their peers that can be resolved through direct intervention. Such intervention may be necessary to assure minimum standards of care and to reduce the distance between the best and worst performing NHS providers. Cancer audits that pre-date NATCAN have formally reported negative outliers.

Central mass

Example methods: Statistical process control and iterative testing of interventions

- Most providers have indicator values that lie in the central mass of the distribution. Efforts focussed here may present the greatest scope for improving overall levels of care nationally. Methods in this domain suggest that all providers can improve their performance, regardless of their current levels. Local audits and evaluations can inform the iterative deployment of interventions which incrementally raise standards of care. Longitudinal monitoring by national clinical audits provides feedback about whether improvements occur or not.

Positive tail

Example methods: Positive deviance

- Some NHS providers perform exceptionally well despite similar constraints experienced by other providers, which presents opportunities to learn and share how this is achieved. 'Positive deviance' approaches assert that generalisable solutions to better performance already exist within the system. Such solutions are likely to be acceptable and transferable within existing resources. These approaches aim to identify local innovations and spread them to other settings.

The NAoPri will select which methods to implement to improve primary breast cancer care after investigating the distributions of its performance indicators (Section 5). This includes the distribution of performance indicator values between providers at a given time point and the values for a provider over time.

To support targeting of improvement interventions and recommendations, the audit will analyse particular patient, hospital and regional factors associated with variation in processes and outcomes of care. For example, for the utilisation of a particular evidence-based treatment, factors associated with utilisation may include advanced age, social deprivation and frailty, clinician preferences, and regional policies. Findings may be reported at an aggregated national or regional (Cancer Alliance) level and can support NHS Trusts to target interventions or evaluation at particular patient populations.

7. Improvement activities

Improvement activities and outputs of the NAoPri will be aligned to the HCIP. The NAoPri will: (1) engage in key collaborations, (2) align with other initiatives in primary breast cancer care, and (3) provide outputs to support quality improvement at the national, regional and local level.

The two principal strategies for reporting the NAoPri results will be producing:

- A short ‘State of the Nation’ (SotN) report for NHS Trusts in England and Health Boards within Wales. This annual report will publish five key recommendations and will highlight where services should focus quality improvement activities. These recommendations will be at the National and Cancer Alliance (regional) level where applicable and reflect the input of the audit teams, AAC and major national stakeholders.
- For England, a quarterly dashboard will facilitate benchmarking and the monitoring of performance at regular intervals so improvements can be tracked over time.

7.1 National and Regional

The NAoPri undertakes various activities that directly support national stakeholders and regional NHS organisations to tackle system-wide aspects related to the delivery of high-quality primary breast cancer services. Table 3 below details possible improvement activities by stakeholder groups.

Table 3. Potential improvement activities to be conducted by stakeholder groups

Stakeholder	**NAoPri activity**
NATIONAL	
NHS England and Wales	Identify issues and make recommendations on the organisation and delivery of primary breast cancer services which might involve national leadership. Recommendations published in audit’s State of the Nation reports.
National incentives	Provide the Care Quality Commission (CQC), Care Inspectorate Wales, and Getting It Right First Time (GIRFT) with information (from audit outputs) to support local visits to NHS organisations and options for aligning recommendations with specific incentives e.g. the Commissioning for Quality and Innovation (CQUIN) framework.
Professional organisations	Identify issues and make recommendations regarding the delivery of primary breast cancer care that fall within the remit of the professional organisations.
REGIONAL	
Cancer Networks / Alliances / Vanguards	Support the monitoring role of Welsh Cancer Networks and the English Cancer Alliances / Integrated Care Boards by publishing results for their region/area.

At a national level, the NAoPri team will also provide the National Cancer Registration and Analysis Service (NCRAS) Data Improvement Leads (in England), and the Wales Cancer Network with information to help them support their NHS organisations to improve the quality of their routine data submissions.

7.2 Local

Table 4 below details ways that the NAoPri supports local NHS cancer services in their care of primary breast cancer patients and possible associated improvement activities.

Table 4. Descriptions of potential improvement activities

NAoPri feedback activity	**Description**
Annual "State of the Nation" Reports	State of the Nation reports that allow NHS organisations in England and Wales to benchmark themselves against clinical guideline recommendations and the performance of their peers.
Web-based dashboard	Results presented for individual NHS organisations that allow the user to compare the results of a selected provider against a peer organisation.
Local Action Plan template	Allows NHS organisations to document how they will respond to the State of the Nation Report recommendations.
Outlier reporting	In the future, the NAoPri will report NHS provider values that are more than three standard deviations from the expected level of performance (i.e. deemed a potential outlier). NAoPri will support potential negative outliers to identify areas for improvement.
Data case studies	Examples of different approaches used by NHS trusts in England to ensure their COSD submissions to NCRAS are as complete and accurate as possible.
Improvement Case Studies	Examples of different approaches used by NHS trusts to improve care quality or recommendations identified from review of processes within positive or negative outlying providers, with a specific focus on the pathway of care.
Interventions	This will include possible interventions that have been identified in the literature linked to the performance indicators assessed by the audit or include interventions developed by Trusts/Alliances in the NHS.
Targets	Recommendations may include targets or thresholds for performance indicators e.g. XX % expected to receive treatment.
Materials supplementary to the State of the Nation Report	Including tools for improving data completeness.

7.3 Improvement tools

The NATCAN website includes a Quality Improvement Resources page with links to the Royal College of Surgeons of England (RCSEng) website and other web-based materials that direct healthcare providers to various quality improvement tools including:

- How to' guides including quality improvement methodology.
- Links to existing resources.
- Links to training courses for quality improvement.
- Good practice repository with available contact information.

7.4 Improvement workshops

The NAoPri will support a range of improvement activities that are aligned to national meetings and quality improvement initiatives of relevant professional bodies. For example, members of the audit team presented at the 2023 Royal College of Radiologists Clinical Oncology Quality Improvement Audit Forum.

As the audit matures the NAoPri will explore how workshops could be utilised to aid the implementation of quality improvement strategies. The NAoPri project team will consult with the AAC regarding workshop content and target audience.

7.5 Designing a National Quality Improvement Initiative

Using the RCRD, the NAoPri will design a National Quality Improvement Initiative aiming "to close the audit cycle" following an approach commonly referred to as the "plan-do-study-act" method .

The design and methodology underpinning this Quality Improvement initiative will be available in the next iteration of the HCIP further to consultation with NAoPri stakeholders.

7.6 Patient and Public Involvement

The NAoPri will strive to involve people with lived experience of primary breast cancer in improvement plans. This includes establishing a standalone NAoPri PPI Forum, a key advisory stakeholder group developed in consultation with patient charities including Breast Cancer Now, Independent Cancer Patients' Voice (ICPV), Força – strength against cancer, Macmillan Cancer Support, use MY data, and Maggie's.

Members of the NAoPri PPI Forum will be regularly consulted on the design of the audit and the communication of its results including:

1. The development and review of patient information materials and summaries of the State of the nation reports.
2. Co-development and/or co-authorship of scientific papers that explore NAoPri results.
3. Developing the design and function of the website to ensure that patients and the public can easily find relevant results together with appropriate explanatory information.
4. Shaping the development of the NAoPri's quality improvement goals, activities and outputs by ensuring this work is relevant from a patient perspective.

7.7 Communication & dissemination activities

The NAoPri will communicate regularly with stakeholders, including patients and the public in the following ways:

- Newsletters – The NAoPri Newsletter is distributed to key stakeholders on a quarterly basis, highlighting quality improvement methods and tools (where appropriate). These are also all published on the NAoPri website.

- Website and Social Media – The NAoPri website will be kept up to date. The @NAoPri_news X account (previously Twitter) will post weekly (and re-post) about key resources, publications or topics of interest to our stakeholders, including tools to aid quality improvement.

- Conferences and Peer Reviewed Papers – The NAoPri will present audit progress at national conferences including at the UK Breast Cancer Group and Association of Breast Surgeons annual meetings. Following the example of the NABCOP, the NAoPri will publish articles in peer reviewed journals such as British Journal of Surgery, British Journal of Cancer, BMJ Oncology, Clinical Oncology and Cancer Epidemiology.

8. Evaluation

The NAoPri will report year-on-year progress against improvement goals to the AAC and in the SotN reports on an annual basis. This will focus on describing how values of performance indicators have changed over time at a national level.

To evaluate the impact of specific NAoPri or other national interventions on the performance of NHS providers, quasi-experimental methods (when allocation of providers to certain groups cannot be controlled) or trial-based methods (when group allocation can be controlled) will be used.

The NAoPri will examine the opportunities for, and strengths and limitations of quasi-experimental and trial-based evaluation methods once it is more fully established.

Appendices

Appendix 1. National Cancer Audit Collaborating Centre (NATCAN)

The National Audit of Primary Breast Cancer (NAoPri) is part of the National Cancer Audit Collaborating Centre (NATCAN), a national centre of excellence launched on 1st October 2022 to strengthen NHS cancer services by looking at treatments and patient outcomes in multiple cancer types. The centre was commissioned by the Quality Improvement Partnership (HQIP) on behalf of NHS England and the Welsh Government with funding in place for an initial period of three years.

NATCAN is based within the Clinical Effectiveness Unit (CEU), the academic partnership between the Royal College of Surgeons of England (RCS Eng) and the London School of Hygiene & Tropical Medicine. The CEU is recognised as a national centre of expertise in analytic methodology and the development of administrative and logistic infrastructure for collating and handling large-scale data for assessment of health-care performance.

NATCAN was set up on 1 October 2022 to deliver six new national cancer audits, including ovarian, pancreatic, breast (two separate audits in primary and metastatic disease) and non-Hodgkin Lymphoma. Existing audits in prostate, lung, bowel, and oesophago-gastric cancers moved into NATCAN in 2023. This critical mass of knowledge and expertise enable it to respond to the requirements of the funders and stakeholders.

The aim of the ten NATCAN audits is to:

1. Provide regular and timely evidence to cancer services with a focus on where patterns of care in England and Wales vary.
2. Support NHS services to increase the consistency of access to treatments and help guide quality improvement initiatives.
3. Stimulate improvements in cancer detection, treatment, and outcomes for patients, including survival rates.

Key features of NATCAN's audit approach

The design and delivery of the audits in NATCAN has been informed by the CEU's experience delivering national audits, built up since its inception in 1998. Key features of all audit projects within the CEU include:

- Close clinical-methodological collaboration
- Use of national existing linked datasets as much as possible
- Close collaboration with data providers in England (National Disease Registration Service [NDRS, NHSE] and Wales (Wales Cancer Network [WCN], Public Health Wales [PHW])
- A clinical epidemiological approach, informing quality improvement activities.
- "Audit" informed by "research".

All these features will support NATCAN's focus on the three "Rs", ensuring that all its activities are clinically relevant, methodologically robust, and technically rigorous.

Organisational structure of NATCAN

Centre Board

NATCAN has a multi-layered organisational structure. NATCAN's Board provides top-level governance and oversees all aspects of the delivery of the contract, ensuring that all audit deliverables are produced on time and within budget and meet the required quality criteria. The Board also provides the escalation route for key risks and issues. It will also consider NATCAN's strategic direction. The Board will meet at 6-monthly intervals and will receive regular strategic updates, programme plans, and progress reports for sign-off. Risks and issues will be reported to the NATCAN Board for discussion and advice.

Executive Team

NATCAN's Executive Team is chaired by the Director of Operations (Dr Julie Nossiter) and includes the Clinical Director (Prof Ajay Aggarwal), the Director of the CEU (Prof David Cromwell), the Senior Statistician (Prof Kate Walker), and the Senior Clinical Epidemiologist (Prof Jan van der Meulen) with support provided by NATCAN's project manager (Ms Verity Walker). This Executive Team is responsible for developing and implementing NATCAN's strategic direction, overseeing its day-to-day running, and coordinating all activities within each of cancer audits. This group meets monthly. The Executive Team will provide 6-monthly updates to NATCAN's Board.

Advisory groups

The Executive Team will be supported by two external groups. First, the Technical Advisory Group including external senior data scientists, statisticians, and epidemiologists as well as representatives of the data providers (NDRS, NHSD and WCN, PHW), co-chaired by NATCAN's Senior Statistician and Senior Epidemiologist, will advise on national cancer data collection, statistical methodology, development of relevant and robust performance indicators to stimulate QI, and communication to practitioners and lay audiences.

Second, the Quality Improvement Team includes national and international experts who have extensive experience in QI and implementation research. This team will provide guidance on the optimal approaches to change professional and organisational behaviour. It will be chaired by NATCAN's Clinical Director and managed by the Director of Operations.

This set up will provide a transparent and responsive management structure allowing each audit to cater for the individual attributes of the different cancer types, while also providing an integrated and consistent approach across the NATCAN audits. The integrated approach will result in efficient production of results through sharing of skills and methods, a common "family" feel for users of audit outputs, and a shared framework for policy decisions and, project management.

Audit Project Teams

Audit development and delivery is the responsibility of each Project Team. The Project Team works in partnership to deliver the objectives of the audit and is responsible for the day-to-day running of the audit and producing the deliverables. It will lead on the audit design, data collection, data quality monitoring, data analysis and reporting.

Each cancer audit Project Team is jointly led by two Clinical Leads representing the most relevant professional organisations, and senior academics with a track record in health services research, statistics, data science and clinical epidemiology, affiliated to the London School of Hygiene and Tropical Medicine. In addition, each audit will have a clinical fellow, who contributes to all aspects of the audits, reinforcing the audits' clinical orientation and contributing to capacity building.

The delivery of the audit is coordinated by an audit manager who is supported by NATCAN's wider infrastructure. Data scientists with experience in data management and statistics and methodologists with experience in performance assessment and QI work across audits.

Audit Advisory Committee / Clinical Reference Groups

Each audit has an Audit Advisory Committee / Clinical Reference Group (https://www.natcan.org.uk/resources/naopri-aac/) representing a wide range of stakeholders. This group will act as a consultative group to the Project Team on clinical issues related to setting audit priorities, study methodology, interpretation of audit results, reporting, QI, and implementation of recommendations.

Effective collaboration within the centre and across audits facilitates the sharing of expertise and skills in all aspects of the delivery process, notably: designing the audits, meeting information governance requirements, managing and analysing complex national cancer data to produce web-based performance indicator dashboards / state of the nation reports, and supporting quality improvement.

This organisation creates "critical mass" and audit capacity that is able to respond to the requirements of the funders (NHS England and Welsh Government) and the wider stakeholder "family".

Audit PPI Forums

Patients and patient charities are involved in all aspects of the delivery of the cancer audits. Each audit has a standalone Patient and Public Involvement (PPI) Forum to provide insight from a patient perspective on strategic aims and specific audit priorities. This will include shaping the development of each audit's quality improvement initiatives by ensuring this work is relevant from a patient perspective. A key activity of the PPI Forums will be to actively participate in the production of patient-focussed audit outputs (including patient and public information, patient summaries of reports, infographics and design and function of the NATCAN website), guiding on how to make this information accessible.

Appendix 2. Breast cancer staging

Stage grouping	T stage	N stage	M stage
0	Tis	N0	M0
Early breast cancer			
IA	T1	N0	M0
IB	T0 / T1	N1(mi)	M0
IIA	T0 / T1 T2	N1 N0	M0
T2	T2 T3	N1 N0	M0
N0	T0, T1, T2 T3	N2 N1, N2	M0
Locally advanced disease			
IIIB	T4	N0, N1, N2	M0
IIIC	Any T	N3	M0
Metastatic disease			
IV	Any T	Any N	M1

Key

T stage (tumour size)

Tis = ductal carcinoma in-situ (DCIS)
T1 = 1mm-20mm
T2 = 21mm-50mm
T3 = 51mm or more
T4 = tumour spread to skin or chest wall

N stage (nodal status)

N0 = no cancer cells in lymph nodes
N1-3 = increasing spread of cancer within lymphatic system
mi = micrometastases

M stage (metastatic status)

M0 = no distant metastases
M1 = distant metastases

Appendix 3. Primary breast cancer care guidelines from UK and international organisations

UK organisations			
Association	**Guideline**	**Author**	**Year**
National Institute for Health and Care Excellence (NICE)	Early and locally advanced breast cancer: diagnosis and management. NICE guideline [NG101].[16]	NICE	2018, updated 2023
NICE	Breast cancer. Quality standard [QS12].[17]	NICE	2011, updated 2016
Association of Breast Surgery (ABS)	Oncoplastic breast surgery: A guide to good practice. [18]	Gilmour et al.	2021
ABS	Axillary surgery following neo-adjuvant chemotherapy – multidisciplinary guidance from the Association of Breast Surgery, Faculty of Clinical Oncology of the Royal College of Radiologists, UK Breast Cancer Group, National Coordinating Committee for Breast Pathology and British Society of Breast Radiology.[19]	Gandhi et al.	2019
ABS	Neo-adjuvant chemotherapy: multidisciplinary guidance.[20]	Doughty et al.	2023
International organisations			
American Society of Clinical Oncology (ASCO)	Use of immune checkpoint inhibitor pembrolizumab in the treatment of high-risk, early-stage triple-negative breast cancer: ASCO guideline rapid recommendation update.[21]	Korde at al.	2022
ASCO	Management of the axilla in early-stage breast cancer: Ontario Health (Cancer Care Ontario) and ASCO guideline.[22]	Brackstone et al.	2021
ASCO	Role of patient and disease factors in adjuvant systemic therapy decision making for early-stage, operable breast cancer: Update of the ASCO endorsement of the Cancer Care Ontario guideline.[23]	Henry et al.	2019
ASCO	Selection of optimal adjuvant chemotherapy and targeted therapy for early breast cancer: ASCO guideline update.[24]	Denduluri et al.	2020
National Comprehensive Cancer Network (NCCN)	NCCN Practical Guidelines in Oncology. Breast Cancer, Version 3.[25]	Gradishar et al.	2022

List of guidelines continues on next page

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[16] *National Institute for Health and Care Excellence. Early and locally advanced breast cancer: diagnosis and management. NICE guideline [NG101]*. Available from: https://www.nice.org.uk/guidance/ng101.

[17] *National Institute for Health and Care Excellence. Breast Cancer. Quality standard [QS12]*. Available from: https://www.nice.org.uk/guidance/qs12.

[18] Gilmour, A., et al., *Oncoplastic breast surgery: A guide to good practice.* Eur J Surg Oncol, 2021. **47**(9): p. 2272-2285.

[19] Gandhi, A., et al., *Axillary Surgery Following Neoadjuvant Chemotherapy - Multidisciplinary Guidance From the Association of Breast Surgery, Faculty of Clinical Oncology of the Royal College of Radiologists, UK Breast Cancer Group, National Coordinating Committee for Breast Pathology and British Society of Breast Radiology.* Clin Oncol (R Coll Radiol), 2019. **31**(9): p. 664-668.

[20] *Association of Breast Surgery. Neo-adjuvant chemotherapy: Multidisciplinary Guidance.* . Available from: https://associationofbreastsurgery.org.uk/media/515633/neaoadjuvant-chemotherapy-manual-v1.pdf.

[21] Korde, L.A., M.R. Somerfield, and D.L. Hershman, *Use of Immune Checkpoint Inhibitor Pembrolizumab in the Treatment of High-Risk, Early-Stage Triple-Negative Breast Cancer: ASCO Guideline Rapid Recommendation Update.* J Clin Oncol, 2022. **40**(15): p. 1696-1698.

[22] Brackstone, M., et al., *Management of the Axilla in Early-Stage Breast Cancer: Ontario Health (Cancer Care Ontario) and ASCO Guideline.* J Clin Oncol, 2021. **39**(27): p. 3056-3082.

[23] Henry, N.L., et al., *Role of Patient and Disease Factors in Adjuvant Systemic Therapy Decision Making for Early-Stage, Operable Breast Cancer: Update of the ASCO Endorsement of the Cancer Care Ontario Guideline.* J Clin Oncol, 2019. **37**(22): p. 1965-1977.

[24] Denduluri, N., et al., *Selection of Optimal Adjuvant Chemotherapy and Targeted Therapy for Early Breast Cancer: ASCO Guideline Update.* J Clin Oncol, 2021. **39**(6): p. 685-693.

[25] Gradishar, W.J., et al., *Breast Cancer, Version 3.2022, NCCN Clinical Practice Guidelines in Oncology.* J Natl Compr Canc Netw, 2022. **20**(6): p. 691-722.

List of guidelines continued from previous page

Association	Guideline	Author	Year
European Society for Medical Oncology (ESMO)	Early breast cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up.[26]	Cardoso et al.	2019
European Society of Breast Cancer Specialists (EUSOMA) International Society of Geriatric Oncology (SIOG)	Updated recommendations from regarding the management of older patients with breast cancer: a joint paper from the European Society of Breast Cancer Specialists (EUSOMA) and the International Society of Geriatric Oncology (SIOG).[27]	Biganzoli et al.	2021
SIOG	HER2-targeted treatment for older patients with breast cancer: An expert position paper from the International Society of Geriatric Oncology.28	Brain et al.	2019
ESMO	ESO-ESMO fifth international consensus guidelines for breast cancer in young women (BCY5).29	Paluch-Shimon et al.	2022
The St. Gallen International Breast Cancer Conference	Customizing local and systemic therapies for women with early invasive breast cancer: the St Gallen International Consensus Guidelines for treatment of early breast cancer.30	Burstein et al.	2021

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[26] Cardoso, F., et al., *Early breast cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up†.* Ann Oncol, 2019. **30**(8): p. 1194-1220.

[27] Biganzoli, L., et al., *Updated recommendations regarding the management of older patients with breast cancer: a joint paper from the European Society of Breast Cancer Specialists (EUSOMA) and the International Society of Geriatric Oncology (SIOG).* Lancet Oncol, 2021. **22**(7): p. e327-e340.

[28] Brain, E., et al., *HER2-targeted treatment for older patients with breast cancer: An expert position paper from the International Society of Geriatric Oncology.* J Geriatr Oncol, 2019. **10**(6): p. 1003-1013.

[29] Paluch-Shimon, S., et al., *ESO-ESMO fifth international consensus guidelines for breast cancer in young women (BCY5).* Ann Oncol, 2022. **33**(11): p. 1097-1118.

[30] Burstein, H.J., et al., *Customizing local and systemic therapies for women with early breast cancer: the St. Gallen International Consensus Guidelines for treatment of early breast cancer 2021.* Ann Oncol, 2021. **32**(10): p. 1216-1235.

Appendix 4. Data provision

The NATCAN Executive Team has worked closely with data providers in England (NDRS, NHSE) and in Wales (WCN, PHW) to establish efficient "common data channels" for timely and frequent access to datasets, combining data needs across all cancer types into a single request in each Nation and only using routinely collected data, thereby minimising the burden of data collection on provider teams.

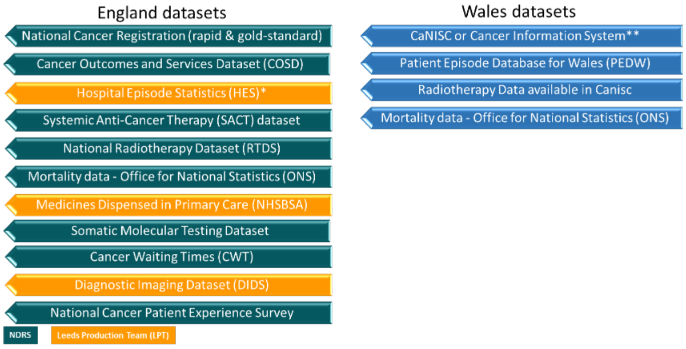
Annual and quarterly data

NATCAN will utilise two types of routinely collected data in England. First, an annual "gold-standard" cancer registration dataset, released on an annual basis with a considerable delay between the last recorded episode and the data being available for analysis, and second, a "rapid" cancer registration dataset (RCRD), released at least quarterly with much shorter delays (3 months following diagnosis). The CEU's recent experience with English rapid cancer registration data, in response to the COVID pandemic has demonstrated the latter's huge potential, despite a lower case ascertainment and less complete staging information[31].

NATCAN will utilise these data across all cancers linked to administrative hospital data (Hospital Episode Statistics/Systemic Anti-Cancer Therapy/Radiotherapy Data Set/Office for National Statistics among other routinely collected datasets, see Figure 5) for describing diagnostic pathway patterns, treatments received and clinical outcomes.

An equivalent data request will be made to the Wales Cancer Network (WCN)/Public Health Wales (PHW).

Figure 5. National datasets available to NATCAN



* Includes inpatient and outpatient data and Emergency care Dataset (ECDS).

** NHS Wales will use Welsh registry information for the initial years data for the audit. From 2022 data submissions will be from either CaNISC or the new cancer dataset forms.

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[31] Nossiter, J., et al., Impact of the COVID-19 pandemic on the diagnosis and treatment of men with prostate cancer. BJU Int, 2022. 130(2): p. 262-270.

Appendix 5: Data acquisition

Patient-level data on many aspects of breast cancer care are routinely collected in hospitals and mandatorily submitted to national organisations (Appendix 4). These existing electronic data flows will be used by the NAoPri to reduce the burden of data collection on staff and patients. This patient data, collected by the National Disease Registration Service (NDRS) for England and the Wales Cancer Network (WCN) for Wales, will be used to report on breast cancer care for the NAoPri. Over time, these national cancer datasets have improved in their completeness, quality, and the richness of information on tumour characteristics, and consequently their ability to be used to describe patterns of care.

The NATCAN's data partners are the National Disease Registration Service (NDRS) and the Wales Cancer Network (WCN). The NDRS will provide data on patients with a registered diagnosis of breast cancer in England NHS trusts whilst the WCN will provide data on patients with a registered diagnosis of breast cancer in Welsh local health boards.

For England, data on patients with primary breast cancer will be provided by the NDRS on a quarterly cycle (based on data from the Rapid Cancer Registration Dataset; RCRD) and on an annual cycle (based on standard Cancer Registration). All data will be provided linked at patient/tumour-level to other national datasets including the COSD, Hospital Episode Statistics (HES) data, the National Radiotherapy Dataset (RTDS), Systemic Anti-Cancer Therapy (SACT) data, Cancer Waiting Times (CWT) data, the Primary Care Prescription Database (PCPD), the Diagnostic Imaging Dataset (DIDS), Somatic Molecular Testing data, and Civil Registration (death) records.

Data from the WCN will be provided on an annual cycle in the first instance. Wales has a different data collection process to England. Data will be provided linked to Patient Episode Data Wales (PEDW) data, Lower Layer Super Output Area (LSOA) data, and Office for National Statistics (ONS) death records.

For accurate and timely benchmarking, it is essential that the data available to the audit include all information required to measure and risk-adjust performance indicators. In addition, data must be readily available, accurate, and with high levels of data completeness, to allow timely reporting.

The NDRS will provide data on patients with a registered diagnosis of breast cancer in English NHS trusts whilst the WCN will provide data on patients with a registered diagnosis of breast cancer in Welsh local health boards.

Registrations of a new breast cancer in England and Wales require information on tumour stage. This will allow the identification of patients with non-invasive or ductal carcinoma in-situ (Stage 0) and those with early invasive or locally advanced breast cancer (Stages I-IIIA) (Appendix 2) for reporting by the NAoPri. Patients with metastatic disease at initial diagnosis will be reported on by the NAoMe.

Appendix 6: Data Quality and Contextual Indicators for the NAoPri

QI Goal	Data quality Indicator	Contextual Indicator
General - improve data quality and completeness.	Percentage of patients with pre-treatment staging and pathological staging assessed.	None
	Percentage of patients with tumour molecular status (ER/PR/HER2) recorded.	
	Percentage of patients with performance status recorded.	
	Percentage of patients with Fitness Assessment Form information recorded.	
Goal #1 – improve the movement of patients through the care pathway.	Percentage of patients with information recorded on Clinical Nurse Specialist contact.	Median time from referral for suspected cancer to first treatment (or percentage of patients who wait longer than 62 days).
	Percentage of patients with information recorded on Triple Diagnostic Assessment.	
Goal #2 – reduce unwarranted variation for patients undergoing surgery.	None	Percentage of patients who had sentinel lymph node biopsy.
Goal #3 – reduce unwarranted variation for patients having non-surgical oncological treatments.	None	Percentage of patients with ER positive tumours who received adjuvant endocrine therapy.
Goal #4 – improve access to breast reconstruction after mastectomy	None	Percentage of patients having immediate breast reconstruction who had autologous reconstruction (compared with implant-based).
		Percentage of patients having immediate breast reconstruction who required further surgery (for implant removal, flap-failure).
Goal #5 – improve and reduce unwarranted variation in primary breast cancer outcomes.	Percentage of patients with information recorded on recurrence.	Percentage of patients who had recurrent disease within 3 years of diagnosis (subject to data quality being sufficient).