NAoPri

National Audit of Primary Breast Cancer

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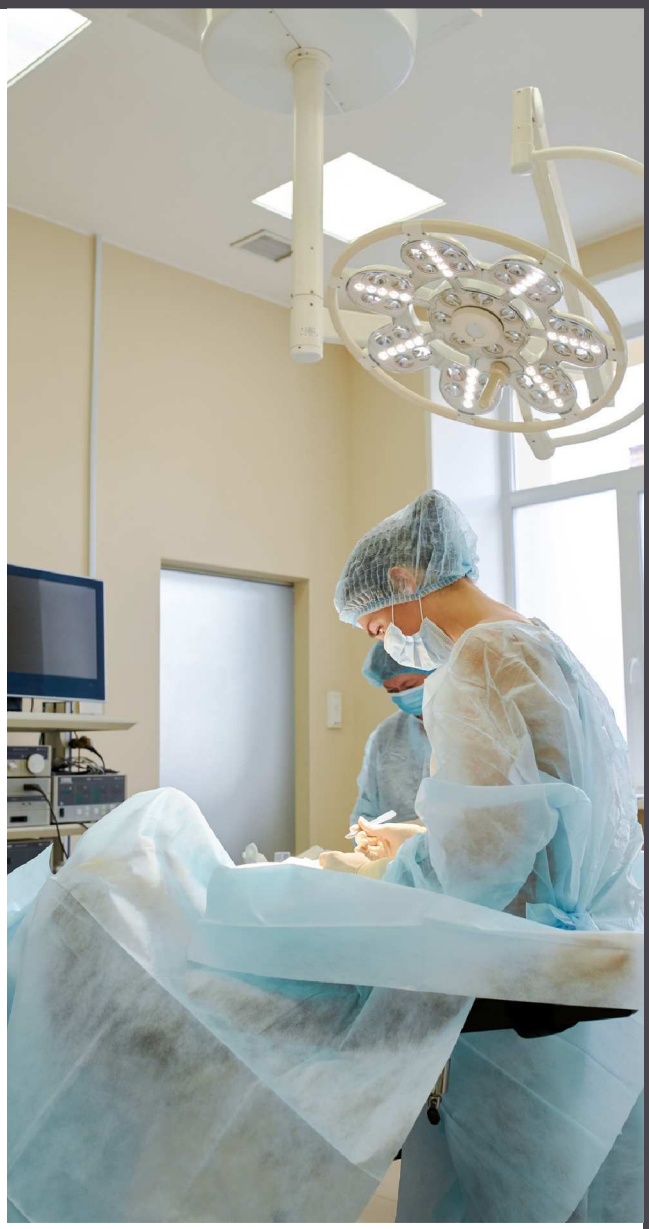
Scoping Document

November 2023



NATCAN

National Cancer Audit Collaborating Centre

Royal College of Surgeons of England

ADVANCING SURGICAL CARE

LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE

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HQIP

Healthcare Quality Improvement Partnership

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NATIONAL DISEASE REGISTRATION SERVICE

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NAoPri

National Audit of Primary Breast Cancer

Citation for this document:
National Audit of Primary Breast Cancer (NAoPri)
Scoping Document 2023
London: Royal College of Surgeons of England, 2023.

This document was prepared by members of the NAoPri project team

Kieran Horgan – Clinical Lead (Surgery)
David Dodwell – Clinical Lead (Clinical Oncology)
Mark Verrill – Clinical Lead (Medical Oncology)
David Cromwell – Senior Methodologist
Melissa Gannon – Methodologist
Jemma Boyle – Clinical Fellow
Jibby Medina – Programme Manager

Royal College of Surgeons of England

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Healthcare Quality Improvement Partnership

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, the Royal College of Nursing, and National Voices. 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

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1. Introduction

This document outlines the structure of the National Audit of Primary Breast Cancer (NAoPri) and describes the activities undertaken to develop the scope of the audit.

The NAoPri is one of six new national cancer audits that will be delivered by the National Cancer Audit Collaborating Centre (NATCAN), which was established to strengthen National Health Service (NHS) cancer services across England and Wales. Information on the NATCAN can be found in **Appendix 1**. The NAoPri will work closely with the other breast cancer audit, the new National Audit of Metastatic Breast Cancer (NAoMe).

The NAoPri will support NHS organisations to benchmark their practice against measurable standards, identify unwarranted variation in practice, and provide tools to help NHS breast cancer services to improve the quality of care received by patients.

To inform the quality improvement (QI) goals and priorities of the NAoPri, the Project Team (**Appendix 2**) has carried out a review of pertinent guidelines and relevant literature, as well as consulting with key stakeholders.

The NAoPri will build on the work of the National Audit of Breast Cancer in Older Patients (NABCOP) which finished in September 2022.[1] While the NABCOP included only women aged 50 years and above, the NAoPri will evaluate the care received by ***all*** patients diagnosed with primary breast cancer in NHS hospitals within England and Wales.

The NAoPri will publish annual State of the Nation reports, which present an overall picture of care and outcomes as measured by audit performance indicators. In addition, to support ongoing local QI, the audit will publish quarterly online dashboards presenting the audit performance indicator findings for all NHS organisations in England and Wales who provide breast cancer services.

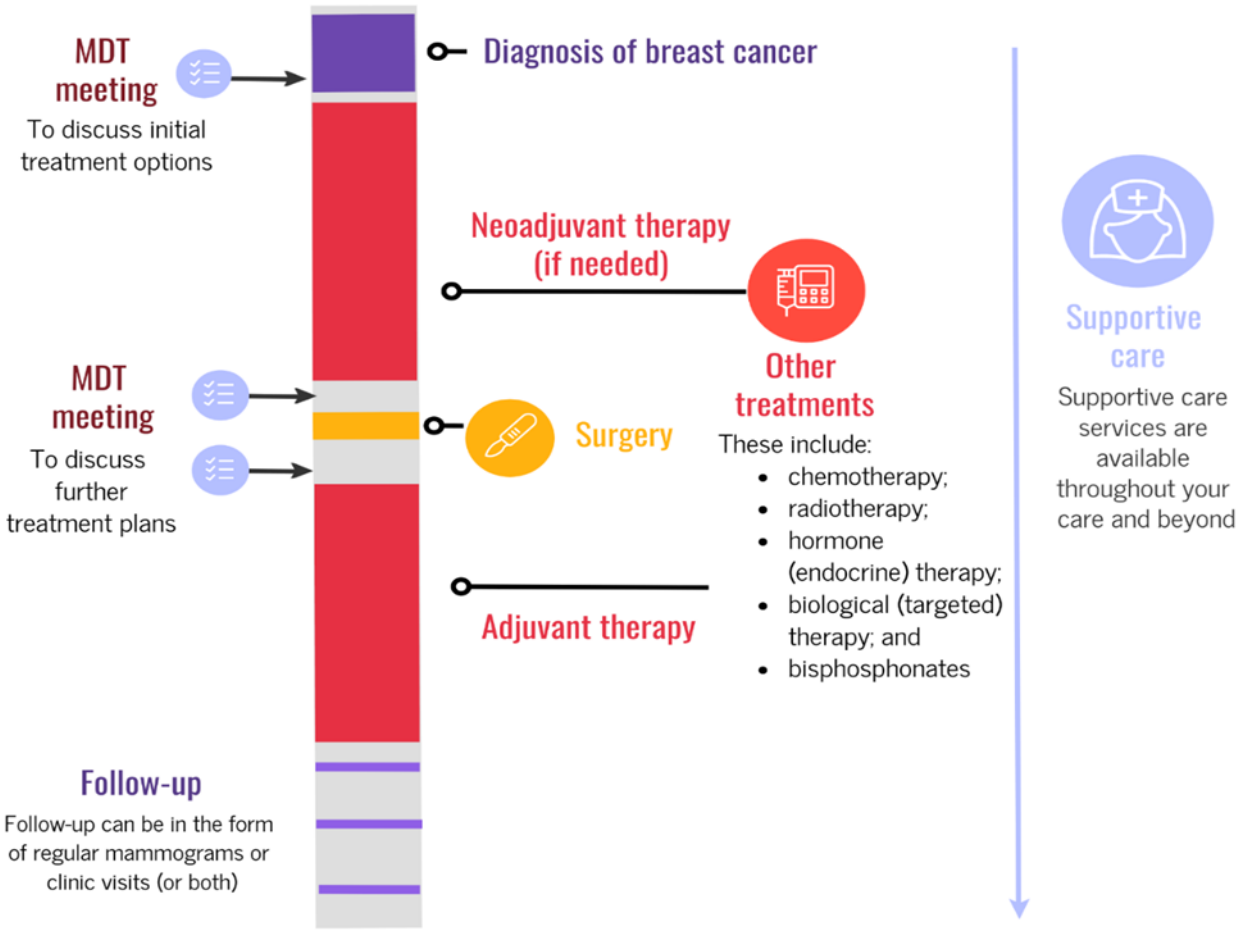
2. Overview of primary breast cancer

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 females.[3]

Primary breast cancer includes breast cancer which, at diagnosis, has not demonstrated spread beyond the breast or nearby lymph nodes to other parts of the body. The extent of a cancer is described using the American Joint Committee on Cancer TNM system (8th Edition) (**Appendix 3**). Broadly, primary invasive breast cancer is classified as either early invasive (stages IA to IIIA) or locally advanced (stages IIIB and IIIC). There is also a form of breast cancer which is non-invasive (stage 0) where the cancer cells are restricted to the walls of the milk ducts (called in-situ).

Most patients are diagnosed with primary breast cancer. Metastatic breast cancer accounts for just 5% of new invasive breast cancer cases diagnosed each year. Within England, 5-year net survival for women diagnosed with breast cancer between 2016 and 2020 was almost 100% for stage I, 90% for stage II, and 70% for stage III.[4]

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



The management of breast cancer is increasingly complex and involves a variable sequence of treatments which are individualised to each patient (Figure 1). Most patients with primary breast cancer will receive surgery as their first treatment. However, patients might receive 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 subgroup	Implication
HER2-ve, HR+ve	The most common tumour subgroup, 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

2.1 Guidelines on the management of primary breast cancer

Numerous guidelines on the management of primary breast cancer have been published by national organisations (Table 2) and international groups (**Appendix 4**). This rich source of information regarding the recommended management of patients with breast cancer will provide the evidence base for the NAoPri and is referred to throughout this document.

Clinical guidelines have been regularly updated to reflect the evolution of breast cancer care, which commonly now involves a combination of modalities: surgery, systemic anti-cancer therapy, radiotherapy, endocrine therapy, and bisphosphonate treatment.

There are ongoing developments within each of the different modalities. For example, the range of available systemic anti-cancer therapies is expanding rapidly, with new treatments being developed for individualised genetic and molecular tumour profiles. Other changes include an increasing use of neo-adjuvant (pre-operative) systemic anti-cancer therapy, 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.

Table 2: *UK clinical guidelines on the management of primary breast cancer.*

Association	Guideline	Author	Year
National Institute for Health and Care Excellence (NICE)	Early and locally advanced breast cancer: diagnosis and management. NICE guideline [NG101].[5]	NICE	2018, updated 2023
NICE	Breast cancer. Quality standard [QS12].[6]	NICE	2011, updated 2016
Association of Breast Surgery (ABS)	Oncoplastic breast surgery: A guide to good practice.[7]	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.[8]	Gandhi et al.	2019
ABS	Neo-adjuvant chemotherapy: multidisciplinary guidance.[9]	Doughty et al.	2023

2.2 Evidence of variation in the care of primary breast cancer within England and Wales

The NABCOP highlighted various areas in which patterns of care differed between NHS breast cancer units across England and Wales.[1]

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 ductal carcinoma in-situ (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 was 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.[5]

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.

3. Stakeholder engagement

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 (Section 3.1). The findings of this survey were discussed at the first NAoPri Audit Advisory Committee (AAC) meeting in April 2023.

In May 2023, the NAoPri team gave a presentation about the audit at 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 had a conference stand with information about both new breast cancer audits and were able to explain the data sources that the audits will use, how people can get involved, as well as encouraging engagement with the audit processes.

3.1 Scoping survey

The scoping survey was undertaken to collect the views of key stakeholders on the delivery of breast cancer care in the NHS and identify priorities for primary and metastatic breast cancer. The survey used open questions to avoid restricting respondents to pre-defined answers, and asked:

1. What aspect of care which affects many patients with primary breast cancer is most in need of improvement?
2. What aspect of care which affects a sub-group of patients with primary breast cancer is most in need of improvement?

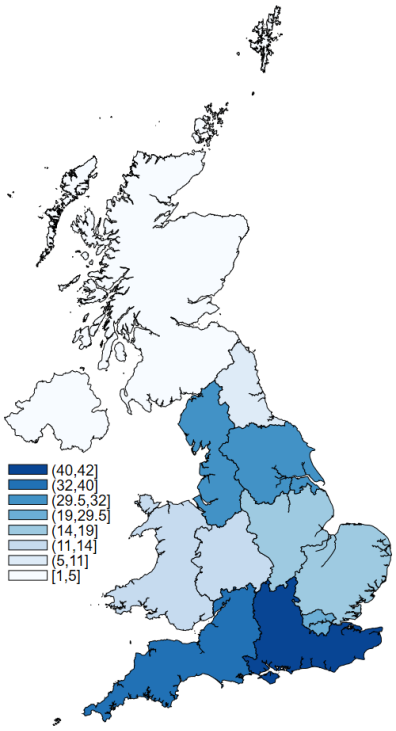
The survey was conducted online during February 2023 and was distributed to a range of stakeholders that included patients, healthcare professionals, relevant professional bodies, and patient charities including individuals from: Breast Cancer Now, Força - strength against cancer, Independent Cancer Patients' Voice (ICPV), Macmillan, Maggie's, Use MY Data, Association of Breast Surgery, UK Breast Cancer Group, British Oncology Pharmacy Association (BOPA), British Society of Breast Radiology, and the Association of Palliative Medicine.

3.2 Survey results

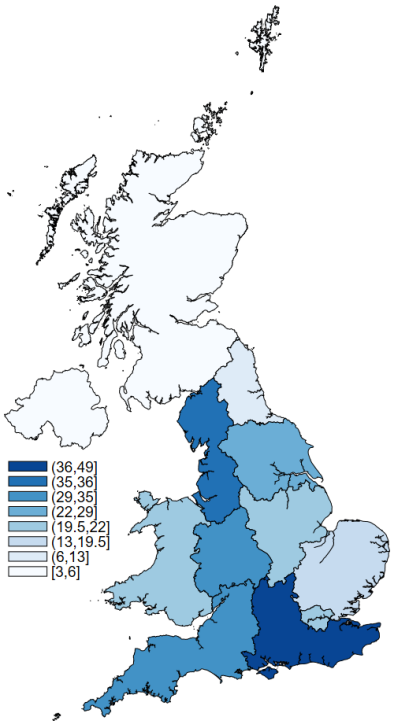
Survey responses were received from 649 participants, of which 613 answered at least one of the questions on the care of patients with primary breast cancer. The respondents included 83 surgeons, 77 oncologists, 70 nurses, and 288 patients or patient advocates. Respondents were from across England and Wales, with additional input from some stakeholders within Northern Ireland and Scotland (Figure 2). Figure 2 shows the regional distribution of individuals responding to the scoping survey, with increasing colour intensity indicating an increasing number of respondents in a region.

Figure 2: *Distribution of respondents to the scoping survey.*

Clinical Respondents (n=256)



Patient/Patient Advocate Respondents (n=285)



Note: The maps include 541 out of the total 613 respondents. 72 respondents were excluded. 8 respondents did not provide their region, 2 respondents did not provide their role, and 62 respondents provided neither their region nor their role.

A large percentage of responses raised concerns related to the organisation of breast cancer services, including:

- availability of staff (nursing and oncology) and the capacity of the cancer workforce,
- patients access to information and patient-centred communication,
- support provided for patients - including information on financial support,
- access to clinical trials, and
- continuity of care between different teams within hospitals or across different hospitals.

Subsequent discussions with stakeholders reinforced the importance of organisational elements of breast cancer services, notably, the number of Clinical Nurse Specialists (CNS) in a breast unit.

The evaluation of these structural dimensions of quality of care is evidently important but will not be auditable within the currently available cancer datasets. One option could have been an organisational audit but this was not included in the service specification of the NATCAN cancer audits. How these topics can be examined needs careful consideration when the service specification of NATCAN is reviewed.

We anticipated that capturing usable information on the quality of symptomatic, supportive, and psychosocial care would be difficult, although we continue to explore this. For some aspects of care relating to the experience of patients, the utility of data collected within the national Cancer Patient Experience Survey (CPES) could be explored.

What areas of primary breast cancer care should the audit focus on in each part of the care pathway?

Table 3 presents the areas of care specified by respondents for each part of the care pathway. While the different elements of the care pathway were identified by a broad range of stakeholders, there was some

clustering of answers within the sub-groups. A common priority highlighted by patients and nurses was support for patients. An area often highlighted by oncologists was access to treatment. Surgeons often highlighted elements related to diagnosis and treatment.

Table 3: *Areas of care highlighted by respondents for each part of the care pathway.*

Care pathway point	Aspect for audit
Diagnosis & staging	Timely referral and diagnosis Timely access to genetic, molecular, and immune-specific testing Timely access to diagnostic investigations (e.g., additional imaging such as CT/MRI scans) Availability of imaging and pathology results to guide treatment decisions within the MDT (e.g., HER2 status)
Supportive care	Improved access to Breast Care Clinical Nurse Specialists Psychosocial support Management of fertility among young women Short and long-term treatment side effects (particularly from endocrine therapy)
Treatment	Timely access to treatments (particularly for neo-adjuvant chemotherapy) Geographical variation in access to treatments (e.g., reconstructive surgery) Patterns of surgery (e.g., re-excision rates and axillary surgery) Use of new systemic anti-cancer drugs and immunotherapy Use of endocrine therapy (e.g., compliance and side effects)

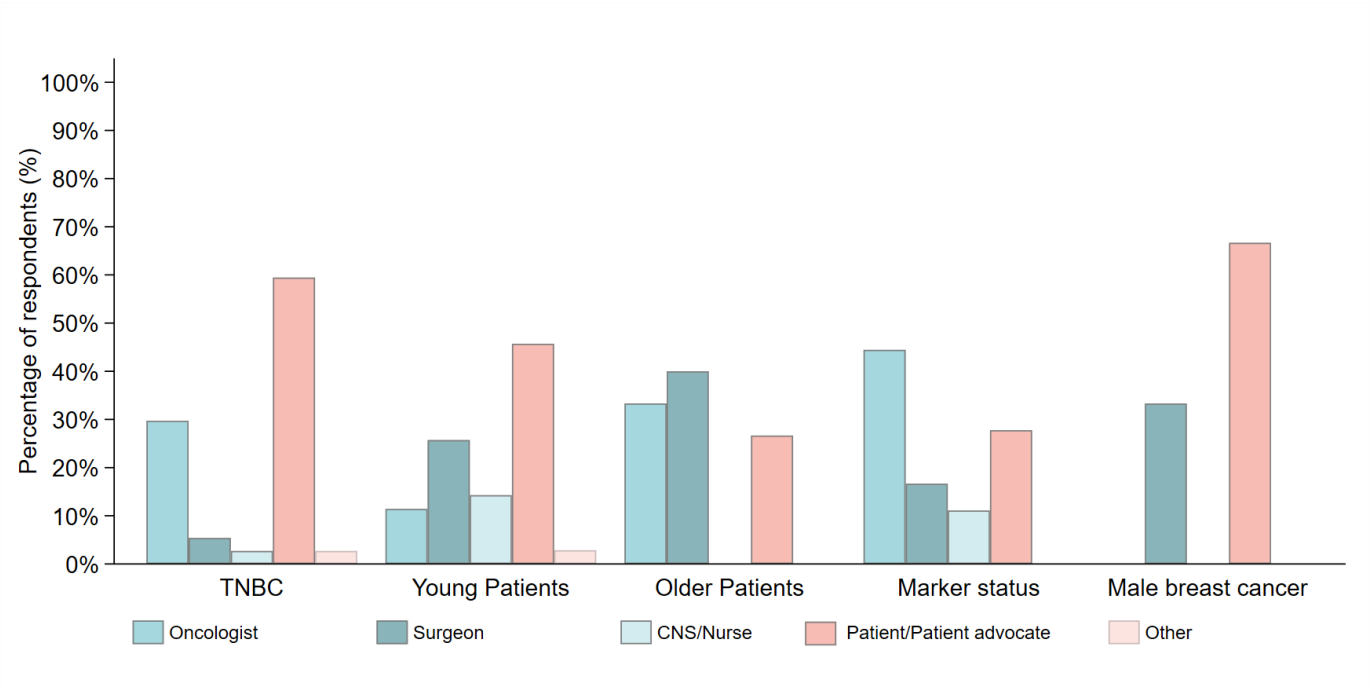
Which patient sub-groups should the audit address?

For patients with primary breast cancer, the following sub-groups (ordered from most frequent to least frequent) were identified as those for whom care was most in need of improvement:

1. Triple negative breast cancer
2. Young patients
3. Old patients
4. Sub-groups defined by biological markers (ER/HER2 status)
5. Male patients

The frequency with which the sub-groups were identified varied across the different types of respondents. Male breast cancer, triple negative breast cancer and young patients were identified most often by patient representatives (Figure 3). Older patients were identified most frequently by surgeons, while patient sub-groups defined by biomarkers were highlighted most frequently by oncologists.

Figure 3: *Patient sub-groups identified as important, stratified by respondents' role.*



4. Proposed scope of the NAoPri

The scope of the NAoPri has been developed following the processes outlined in Section 2. These build on methodological and clinical work done by the NABCOP, as well as involving a review of the wider literature (including external quality standards), and consultation with key stakeholders on priorities for the NAoPri.

Consultation included feedback from patient and professional representatives on the AAC, along with over 250 responses from patients to the scoping survey. Involvement of the members of the standalone NAoPri's AAC patient sub-group (which will be established) will be central to ensuring the experiences and views of patient and patient advocates feeds into the ongoing QI focus of the audit.

4.1 Audit inclusion/exclusion criteria

The eligibility criteria for including patients in the NAoPri is defined as follows:

- All patients (men and women) diagnosed in the audit period with breast cancer (ICD-10 diagnosis code: C50; DO5) that is proven only in the breast, with or without spread to local lymph nodes (stages 0 to IIIC) (**Appendix 3**).
- Patients aged ≥18 years at diagnosis.
- Patients 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 from death certificates only.

4.2 Coverage of care pathway

The audit will cover the pathway from first diagnosis of primary breast cancer. It will evaluate the primary treatments received by these patients.

Primary treatment will include planned treatments with and without curative intent. Treatments may be multimodal and include any of surgery, systemic anti-cancer therapy (SACT), radiotherapy (RT), or interventions aimed at relief of symptoms.

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

4.3 Priorities for quality improvement

The audit's scoping exercise identified priority areas for quality improvement along the care pathway and the NAoPri Healthcare Improvement goals will centre on these.

Priority issues in breast cancer care are:

1. Identifying, and subsequently reducing, variation in care for patients with primary breast cancer undergoing surgery, as well as identifying and improving care that differs from guidance within this area.

This might include but is not limited to: use of breast-conserving surgery versus mastectomy, surgical management of the axilla, and breast reconstruction.

2. Identifying, and subsequently reducing, variation in care for patients with primary breast cancer who receive oncological treatments, as well as identifying and improving care that differs from guidance within this area.

This might include but is not limited to: adjuvant radiotherapy use following breast-conserving surgery for both invasive and non-invasive disease[10], adjuvant radiotherapy use following mastectomy stratified by recurrence risk[11], ultra-hypofractionated radiotherapy (HFRT) use[12], neo-adjuvant and adjuvant systemic anti-cancer therapy use, and endocrine therapy use.

3. Identifying, and subsequently reducing, variation in short-, medium-, and long-term outcomes for patients with primary breast cancer, as well as identifying and improving care that differs from guidance within this area.

This might include but is not limited to: morbidity after surgical procedures (e.g., re-operation rates following breast-conserving surgery) and oncological treatments (e.g., unplanned overnight chemotherapy-related hospital admissions), short- and long-term survival.

4. Improving the movement of patients with primary breast cancer through the care pathway, including a more detailed focus on patient sub-groups.

This might include waiting times (e.g., time to diagnosis, time from diagnosis to treatment).

5. Increasing the percentage of patients with primary breast cancer who have key data items accurately recorded in national cancer datasets.

This might include but is not limited to: improvements in data completeness and quality for diagnostic variables (e.g., triple diagnostic assessment, and Clinical Nurse Specialist (CNS) contact), pathological variables (e.g., tumour size, ER and HER2 status, and TNM staging), patient fitness (e.g., WHO performance status, and NABCOP frailty assessment), treatments (e.g., endocrine therapy, and bisphosphonate use) and outcomes (e.g., cancer recurrence).

Information on the above issues will not be limited to summary statistics on the whole patient population. Where appropriate, we envisage options to explore the above information for specific patient groups (**Appendix 5**), such as:

- Older and frail patients,
- Young patients with breast cancer (e.g., below 40 years),
- Male breast cancer patients, and
- Patients with TNBC.

The NAoPri builds on the work of the NABCOP and will continue the focus on identifying and reporting on variation in care and outcomes. Within the above outlined priorities, associated indicators will be used to highlight where health inequalities exist, complemented by work to understand determinants in care and subsequent outcomes. This will guide the audit's QI initiatives, with the ultimate objective that appropriate processes of care and treatment decisions are available for an individual patient. This encompasses both the best treatment options and access to the most appropriate support. Personalised care is at the core of this, ensuring that pathways of care consider all personal and tumour factors so that patients receive evidence-based management according to current guidelines. The involvement of a clinical nurse specialist is important to ensure individual patient support and that care can be tailored to an individual patient's circumstances and needs and is included as a priority area.

4.4 Potential indicators for the audit of primary breast cancer

Appendix 6 provides examples of some of the potential indicators that could be reported for NAoPri. These are provided to illustrate how the NAoPri can address the priority areas identified within this scope across the care pathway.

A key component of the scoping work was to build on the areas within primary breast cancer care which were reported for older patients and presented by the NABCOP. These include:

- Data completeness for key data items, including recurrence.
- Route to diagnosis.
- Triple diagnostic assessment in a single visit.
- Involvement of a breast Clinical Nurse Specialist (CNS) or key worker.
- 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 for early invasive breast cancer.
- 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.[13,14]

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.[14]

4.5 Methodological considerations

This section considers the construction of the audit cohort and development of indicators linked to the improvement goals, from a methodological perspective and the routine data available.

4.5.1 Routine data sources

Patient-level data on many aspects of breast cancer care are routinely collected in hospitals and mandatorily submitted to national organisations (**Appendix 7**). 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 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 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 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.

4.5.2 Identifying patients with primary breast cancer

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 breast cancer (Stages I-IIIA) (**Appendix 3**) for reporting by the NAoPri. Patients with metastatic disease at initial diagnosis will be reported on by the NAoMe.

4.5.3 Identifying and understanding patient care pathways

Substantial methodological work was carried out as part of the NABCOP to continuously improve and support the robust capture and reporting of data for breast cancer patients. The methodology for the NAoPri will incorporate and build upon that which has been used previously for the NABCOP.[15]

For example, work was undertaken to understand the completeness and consistency of endocrine therapy recording within secondary care data and the Primary Care Prescription Database (PCPD).[16] It highlighted deficiencies in the capture of endocrine therapy from secondary care data and the importance of PCPD for examining patterns of care in this area. Such work will be continued in the NAoPri.

In 2018, a multidisciplinary sub-group of the NABCOP Clinical Steering Group developed a fitness assessment form in order to provide an objective and standardised approach to evaluating overall health and fitness among older patients.[17] The items on the NABCOP fitness assessment form have been incorporated into the updated Cancer Outcomes and Services Dataset (COSD) and these data items will be available for patients captured within the NAoPri. It is hoped that these data items will also be incorporated into the new cancer informatics system for patients diagnosed in Wales in the future.

In addition to its series of Annual State of the Nation Reports, NAoPri will produce peer-reviewed publications to showcase and disseminate its work evaluating changes in clinical practice. This will build on the pattern established by NABCOP. For example, NABCOP evaluated the use of five-fraction ultra-

hypofractionated radiotherapy (HFRT) rather than standard moderate-HFRT following a rapid dissemination of trial-based evidence during the COVID-19 pandemic. This work showed that there had been a rapid shift in clinical practice across England and Wales from less than 1% use of ultra-HFRT in February 2020, to 70% use of ultra-HFRT in April 2020.[12] Learning from such peer-reviewed publications will be incorporated and built upon within the NAoPri.

4.5.4 Issues with routine data for primary breast cancer

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 improvements where required.

For England, the RCRD is a small subset of COSD data items with no pathology information currently available. It includes information on diagnostic staging, but unlike the Cancer Registration records has lower completeness (as it precedes the input from registration staff to improve the completeness of key data items such as stage in Cancer Registration records). As such, the feasibility of quarterly reporting for audit indicators will require testing.

Currently, there is a lack of information regarding recurrence (both local and distant) within national routinely collected data. From work done by the NABCOP evaluating the recording of recurrence information within the COSD, only 4% of patients (n=224,049) had a record of recurrence reported with poor recording across all geographical regions. It will be particularly important to improve data quality and completeness on recurrence information which will be an important outcome for the NAoPri population to enable benchmarking of outcomes and assist efforts in improving patient care.

4.5.5 Strategy for defining organisational-level indicators

Based on the review of external sources, engagement with stakeholders, and synthesis of responses to the scoping survey, a set of indicators will be formulated for the audit and used to engage stakeholders with local activities relating to the audit improvement goals.

Additionally, a key function of the audit will be to ensure the defined indicators are accurate and reliable when produced at an organisational level. In order to achieve this, an indicator will need to meet these conditions:

1. The data required for the indicator are available within the routine data collected in England and Wales.

2. The volume of patients is sufficient to produce indicator values at an organisational level that are not unduly influenced by random variation.

Allocation of patients to NHS organisations

The method of allocation of patients to separate NHS organisations is important as it ensures organisation-level findings are clear, appropriately directed, and can be used to facilitate local QI.

Where indicators relate to diagnosis and staging, an option is to allocate patients to the NHS organisation where the patient is diagnosed. This has the benefit of having a clear link between the diagnosis and staging details and the NHS organisation responsible for ensuring they are available for treatment decisions and completed within the routine data.

An alternative would be to allocate the patient to the NHS organisation where the MDT discussion which uses this information is conducted. For data completeness, this might be appropriate as it would go some way to ensuring the information is recorded. However, any audit recommendations and QI activities around diagnosis and staging would need to engage all organisations involved in these parts of the care pathway, and this alternative approach would require the MDT organisation to communicate clearly with the hospitals referring patients, where these differ.

For indicators related to treatment (such as chemotherapy), reporting options could be by NHS organisation of diagnosis or by NHS organisation of treatment. Which option is used will be determined by the aspect of treatment audited, for example, outcomes following treatment (such as complications) may be best reported by NHS organisation of treatment as this should be where QI activities related to these indicators would be undertaken.

Patient volumes and indicator reliability

For indicators whose values are a percentage or rate, the precision of the organisational-level indicator value is determined by (1) the number of patients on which it is derived, and (2) the overall indicator value for the cohort. If the overall indicator value is small (because there may be few events), the number of patients required to detect a difference between organisations will increase.

The volume of cases for organisational-level indicators will vary across different points along the care pathway, with the largest numbers available for indicators related to diagnosis, staging, and MDT discussions, as this will typically include all patients with primary breast cancer. Conversely, indicators based on receipt of a specific treatment or patient sub-group will have smaller denominators, as they are based on a sub-set of the patient cohort.

For example, when considering the patient sub-groups outlined in Section 3 of this document, the numbers of male breast cancer patients are small. If male breast cancer patients are grouped together with female breast cancer patients, their care may not be apparent. This would need consideration if quarterly dashboards were going to report on sub-groups, as the numbers at organisational level will be small. An alternative approach would be to describe the care of these patients as a separate larger group at a higher level within the “State of the Nation” report.

The NAoPri team will assess how indicators can be defined to ensure they have sufficient statistical power to differentiate between good and poor performance and can confidently describe meaningful variation. One option to improve statistical power is to increase the time period over which data are analysed (i.e., to include patients diagnosed/treated over a period of several years) and use longitudinal rather than cross-sectional charts to ensure organisations are given performance information on their most recent activity. More information about the issues concerning indicator definitions and statistical power is referenced.[18,19]

5. Next steps

5.1 Development of Healthcare Improvement Strategy

Building on the QI priorities identified in the scoping exercise, the audit will develop its Healthcare Improvement Strategy. As part of this process, the audit will undertake several activities, in consultation with key stakeholders through its AAC and Patient and Public Involvement (PPI) forum, including:

- Development of five improvement goals for the audit over the next audit cycle.
- Analysis of national cancer data to identify key performance indicators for annual and quarterly reporting, and mapping of these to the improvement goals.
- Development of improvement methods and activities to support local quality improvement and implementation of audit recommendations.
- Plans for monitoring and evaluation of the audit's impact.

The AAC and PPI forum will provide advice to the audit team on various elements of the audit including the audit improvement goals and associated indicators, the design and content of the State of the Nation report and quarterly dashboards, and opportunities to disseminate audit findings and recommendations.

The PPI forum will be drawn from patient and carer groups and set up in partnership with patient charities. Representation on the PPI forum will aim to be broad and cover a spectrum of patient characteristics including age, deprivation, and stage.

5.2 Communication and dissemination activities

Key activities relating to communication and dissemination include:

- Newsletters - distributed to NHS organisations and key stakeholders (including oncologists, surgeons, nurses, data managers, clinical audit and effectiveness personnel, patient charities and representatives) on a quarterly basis and published on the NATCAN website.
- Website – development, regular review and update of website content and design.
- Social media - regular posts on X (formerly Twitter) about the audit's activities, outputs and plans, and reposting of content of relevance to followers.

Further details about these activities will be set out in the NAoPri's Communications Strategy.

The NAoPri is engaged with social media channels, where it publishes weekly updates. Additionally the audit publishes quarterly newsletters; these are hosted on the NATCAN website and emailed to the audit contacts list which includes oncologists, surgeons, nurses, data managers, clinical audit and effectiveness personnel, patient charities and representatives.

6. Appendices

Appendix 1 – The National Cancer Audit Collaborating Centre (NATCAN)

Note: This content of this Appendix is common to all audits delivered by the NATCAN and does not reflect audit-specific refinements. For example, this Appendix makes reference to Clinical Reference Groups – while the NAoPri has an Audit Advisory Committee (AAC), which performs the same consultative group function. Audit-specific refinements are documented within the body of this report.

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 across the country. The centre was commissioned by the Healthcare 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.

Prior to the launch of NATCAN, the CEU was already the sole provider of national cancer audits in the NHS in England and Wales, incorporating audits in prostate, lung, bowel, and oesophago-gastric cancers, and recently completed an audit of breast cancer in older patients. These audits have helped provide a wider understanding of cancer treatments across England and Wales and have improved services and infrastructure leading to improved outcomes for patients. By consistently placing quality improvement (QI) at the centre of all audits, initiatives which promote QI within NHS cancer services have been developed and areas of best practice identified.

Alongside the NAoPri, NATCAN delivers five other audits in ovarian, pancreatic, metastatic breast cancer, kidney and non-Hodgkin Lymphoma. The aim of these 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.

The audits which the CEU already provided have joined NATCAN (bowel, oesophago-gastric, lung and prostate), bringing the number of NATCAN audits to ten. This critical mass of knowledge and expertise enable it to respond to the requirements of the funders and stakeholders.

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 (Dr Ajay Aggarwal), the Director of the CEU (Prof David Cromwell), the Senior Statistician (Dr 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 activities across the cancer audits. This group meets weekly. The Executive Team 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 or three 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 Clinical Reference Groups

Each audit has a Clinical Reference Group 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 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 will also have 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.

Data acquisition

The NATCAN Executive Team is working 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 for all cancers 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,[20] despite a slightly lower case ascertainment and less complete staging information.

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) 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).

See **Appendix 5** which provides more data on the datasets requested for the NAoPri.

Information governance

NATCAN will comply with legislation and good practice principles to ensure data security and patient confidentiality. The patient-level information received and managed by NATCAN is treated as confidential. When analysing data to produce information on patient care and outcomes, NATCAN audit teams use de-identified data and so individual patients are not identifiable.

HQIP and NHSE are joint data controller for the linked de-identified dataset that is supplied to NATCAN for analysis.

Reporting

Individual cancer audits will produce:

- Annual '*State of the Nation'* reports for NHS Trusts/Health Boards within England and Wales. These reports will highlight where local services should focus quality improvement activities.
- NHS organisational-level results (as well as national and regional results) as a dashboard on the NATCAN website. These dashboard results will be refreshed on a quarterly and annual basis, and the website will include the facility to download activity summaries and outcomes as short PDF documents and presentations.

These outputs will be supported by a range of tools that will support their use by local services and other stakeholders, including slide sets and QI resources. Additional outputs include peer-reviewed publications and presentations at national and international meetings. Newsletters will be disseminated to announce the publication of new results to clinical teams and audit stakeholders.

Summaries of the '*State of the Nation'* reports from each cancer audit will be prepared for patients and the general public and available on the NATCAN website, in addition to information for patients. Patient representatives in the PPI Forums and Clinical Reference/Advisory Groups of each cancer audit will provide input into the development of the audit outputs.

Publication of comparative local outcomes, along with the associated commentary, allow patients to understand the quality of care being offered and enable them to ask Trusts/Health Boards and clinical teams how they plan to put right any deficiencies identified via the audits.

Healthcare improvement

A priority for each audit in NATCAN is the development of a healthcare improvement plan that includes explicit QI goals aiming to improve cancer outcomes as well as the patient experience. These plans will be built around clinically relevant and methodologically robust performance indicators that each audit will develop and disseminate.[19]

The healthcare improvement plan will also set out the key drivers for each QI goal, alongside national and local improvement tools.[21] NATCAN will ensure that its healthcare improvement programme will be closely aligned with related activities implemented by other relevant organisations (e.g., CQC and Getting it Right First Time in England, and NHS Quality Improvement and Patient Safety in Wales).

Each audit within NATCAN will complete at least one national QI initiative using the RCRD, aiming "to close the audit cycle" following an approach commonly referred to as the "plan-do-study-act" method.[22] This will be a first at national level and we envisage that it will become a core element of involvement for the NATCAN QI Team.

Again, NATCAN will build on the CEU's longstanding experience in targeting and designing QI implementation approaches, ensuring that the audit feedback information and recommendations truly reach the clinicians who can act on it, also incorporating specific action plans.

Appendix 2 – The NAoPri project team

The audit will be provided through a partnership that combines clinical leadership, methodological expertise, and project management. Clinical leadership of the NAoPri is provided by:

- Professor Kieran Horgan, Clinical Lead (Surgery)
- Professor David Dodwell, Clinical Lead (Clinical Oncology)
- Dr Mark Verrill, Clinical Lead (Medical Oncology)

The other members of the audit team provide methodological, statistical, and project management expertise and are: Jibby Medina (Programme Manager), David Cromwell (Health Services Research), Melissa Gannon (Statistician), and Jemma Boyle (Clinical Research Fellow). Additional staff will shortly join the project team.

The audit will receive guidance from the Audit Advisory Committee (AAC), which includes representation from patient organisations and healthcare professional groups. These include Breast Cancer Now, Independent Cancer Patients' Voice (ICPV), the Association of Breast Surgery (ABS), the UK Breast Cancer Group (UKBCG), Getting it Right First Time (GIRFT), the Royal College of Radiologists (RCR), and the Royal College of Surgeons of England (RCS Eng). The AAC will usually convene twice a year to advise on the direction of the audit and feedback on interpretation of audit findings. The AAC will also help in the dissemination of audit findings.

The audit will also have a Patient and Public Involvement (PPI) forum whose members represent patient organisations.

Appendix 3 – Breast cancer staging

Stage grouping	T stage	N stage	M stage
DCIS / 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
IIB	T2 T3	N1 N0	M0
IIIA	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)
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

M stage (metastatic status)
M0 = no distant metastases
M1 = distant metastases

mi = micrometastases

Appendix 4 – Primary breast cancer care guidelines from international organisations

Association	Guideline	Author	Year
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.	Korde at al.[23]	2022
ASCO	Management of the axilla in early-stage breast cancer: Ontario Health (Cancer Care Ontario) and ASCO guideline.	Brackstone et al.[24]	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.	Henry et al.[25]	2019
ASCO	Selection of optimal adjuvant chemotherapy and targeted therapy for early breast cancer: ASCO guideline update.	Denduluri et al.[26]	2020
National Comprehensive Cancer Network (NCCN)	NCCN Practical Guidelines in Oncology. Breast Cancer, Version 3.	Gradishar et al.[27]	2022
European Society for Medical Oncology (ESMO)	Early breast cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up.	Cardoso et al.[28]	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).	Biganzoli et al.[29]	2021
SIOG	HER2-targeted treatment for older patients with breast cancer: An expert position paper from the International Society of Geriatric Oncology.	Brain et al.[30]	2019
ESMO	ESO-ESMO fifth international consensus guidelines for breast cancer in young women (BCY5).	Paluch-Shimon et al.[31]	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.	Burstein et al.[32]	2021

Appendix 5 - Overview of patient sub-groups within primary breast cancer

Male patients with breast cancer

To our knowledge, there are no recent observational studies conducted within the UK evaluating male breast cancer care.

Male breast cancer is rare. In the United Kingdom, male breast cancer accounts for less than 1% of all breast cancer cases. The lifetime risk of male breast cancer is approximately 1:1000 compared to 1:8 for women.[33] Due to the low incidence of male breast cancer, observational studies have generally been small and retrospective. Although the NAoPri will provide national data, there will be methodological challenges in reporting information for male patients at provider-level due to small numbers.

Historically, male breast cancer patients were not included in clinical trials. As a result, there is limited evidence regarding their optimal management. Instead, evidence statements have largely been extrapolated from breast cancer trials for female patients. In addition, national and international guidelines specifically for male breast cancer are lacking and limited to a few recommendations incorporated into existing documents.[5,28] This means that ascertaining recommended standards of care for benchmarking within this sub-group of patients will be more difficult.

There are important differences in patient and tumour characteristics between men and women with breast cancer. For example, men tend to have higher proportions of invasive ductal cancers, and smaller proportions of other histological sub-types found in females such as lobular cancer (1% in men versus 12% in women).[34] The vast majority of male breast cancers are hormone-sensitive (average 84.1%) with a lower proportion having HER-2 positivity (average 12.4%).[33] It will be informative to describe patient and tumour characteristics within this sub-group for the first time at a national level.

The literature to date highlights potential areas of interest to examine in breast cancer care for men. For example, there are considerably higher rates of mastectomy in male breast cancer patients. Studies report low rates of breast-conservation surgery (3% to 12%). This is in spite of evidence suggesting that breast-conservation surgery may be a safe alternative in select male breast cancer patients.[35] Similarly, huge variation in the use of adjuvant radiotherapy for male breast cancer patients has been demonstrated, although there is evidence it can improve local control and overall survival, particularly in those with nodal involvement.[36] It will be important to describe care pathways for male breast cancer patients across England and Wales to identify patterns and variation in practice.

A recent international publication using expert consensus, suggested that there were areas of breast cancer care for men which should replicate breast cancer care for women, including primary surgery and adjuvant radiotherapy.[37] Other areas, such as endocrine therapy and genetic testing, were highlighted as contentious and thought to differ the most from the management of female breast cancer. For example, although the vast majority of male breast cancers are hormone-sensitive, variation in the use of adjuvant endocrine therapy has been demonstrated with one systematic review reporting that on average only 58.1% of male breast cancer patients received it.[33] It will be important to differentiate between aspects of the care pathway which are shared or not between men and women.

Most importantly, previous studies have consistently shown that male breast cancer patients have a worse prognosis than female patients. A possible explanation for this is that men present with larger tumours, more advanced disease with nodal involvement, and higher rates of lymphovascular invasion, due to reduced awareness of male breast cancer and the lack of a national screening programme.[34] This might be explored further within the NAoPri work.

Young patients with breast cancer

The definition of young patients with breast cancer includes those below the age of 40 years.[31] Although uncommon, it is the most frequent cancer diagnosed in women in this age-group. A recent study from the US has also suggested that the incidence of breast cancer is increasing in young patients.[38] To our knowledge, the largest study to date in England for young patients with breast cancer is the POSH study which included just under 3,000 patients aged 18-40 years treated between 2000 and 2008.[39] This is therefore an important sub-group for the NAoPri to explore using contemporary data for England and Wales.

Similar to men with breast cancer, young patients are under-represented in clinical trial settings. This includes trials for evaluating treatments, but also for those informing risk-stratification and prognosis, with much of the knowledge extrapolated from older women. There have been several iterations of international consensus guidelines for young patients with breast cancer.[31] As with male patients, due to the lack of evidence and guidance it may be more difficult to recommend standards of care within this sub-group.

The literature also highlights issues within this sub-group of patients. Potential differences in the management of young patients have been described. For example, one area of concern within the surgical management of these patients is the choice of procedure for early invasive breast cancer. High rates of bilateral mastectomies have been described despite a lack of evidence to suggest that this has any survival advantage.[40,41] It will be important to describe care pathways within young patients to identify variation in practice.

Most importantly, studies have demonstrated that younger women have poorer outcomes (recurrence and survival) compared to their older counterparts.[42,43] This is thought to be due to differences in tumour characteristics including a higher proportion of oestrogen-receptor negative, HER2 positive, and grade 3 tumours, and an increased proportion of tumours with vascular or lymphatic invasion. Young women have also been shown to have more advanced disease at presentation. It will be important within NAoPri to describe tumour characteristics within this sub-group and explore any variation in survival and potential reasons for this.

Finally, there are several issues that are unique to this patient sub-group including treatment-related fertility problems and breast cancer during pregnancy. Young women have also been shown to have increased psychosocial issues with subsequently reduced quality of life compared to older women. These areas are more difficult to cover in the scope of NAoPri and will require further consideration.

Triple negative breast cancer

TNBC includes tumours which do not express oestrogen or progesterone receptors and have a negative HER-2 status. They form around 15-20% of breast cancers. They are more common in young patients, ethnic minority groups, and those with BRCA1/2 mutations.[44] Patients with TNBC are described as more likely to have tumours which are larger and have a higher grade.[45] To our knowledge, there are limited studies conducted within the UK on patients with TNBC.[46,47] Previous work conducted by the NABCOP group in women aged 50 years and above demonstrated significant geographical variation in the use of neo-adjuvant and adjuvant systemic anti-cancer therapy.[48] It will be important to explore patient, tumour, and treatment patterns in the whole population of TNBC patients.

There are specific international guidelines available for the treatment of TNBC.[23,49] TNBC is also covered within other broader guidelines.[28] Within UK guidelines, recommendations regarding TNBC cover genetic

testing and neo-adjuvant systemic therapy.[5] There is some variation between guidelines with North America advising neo-adjuvant systemic therapy for tumours greater than 1cm, and European guidelines advocating this for tumours greater than 2cm. It will be essential to describe how well these recommendations are being followed, as well as trying to understand any variation in how patients with TNBC are being treated within England and Wales as part of the NAoPri scope.

Historically, the treatment of TNBC has involved systemic anti-cancer therapy in the form of cytotoxic chemotherapy. However, there has been a lot of progress in the understanding of the biology of these tumours, and a shift towards looking at more detailed tumour biomarkers in order to personalise systemic anti-cancer therapies. This includes the use of immunotherapy agents, for example, pembrolizumab.[50] As a result of these advancements in systemic anti-cancer therapies and associated improvement in pathologic complete response rates, de-escalation of surgical treatments may become possible. In addition, better understanding of the biology of these tumours has facilitated improved prognostication and should allow improved decision-making regarding the requirement for further adjuvant systemic therapy in select patients with residual disease.[44] The NAoPri will maintain an ongoing awareness on these matters.

The most important issue with this subtype of breast cancer is that, compared to the other subtypes (Table 1), it is the most aggressive with an increased risk of earlier recurrence and death, and the least favourable survival.[51] It has been estimated that up to 40% of women with operable TNBC will recur within 5 years, and this is even higher for those who do not have a pathologic complete response following neo-adjuvant systemic therapy.[52] This makes it another important sub-group to explore within the NAoPri scope.

Appendix 6 – Examples of potential performance indicators for the NAoPri

Aspect of Care Pathway	Guideline/Standard/Recommendation	Guideline/Standard description	Potential areas of focus / indicators	Additional evidence from literature
Diagnosis	NICE QS1, 2011 updated 2016 EUSOMA, 2017	People with suspected breast cancer referred to specialist services are offered the triple diagnostic assessment (TDA) in a single hospital visit.	TDA in a single visit *Process measure*	For women aged 50 and over, with early invasive breast cancer not detected at screening, 69% received TDA in a single visit. There was variation according to NHS organisation with 37% of breast units having less than 70% of patients having TDA in a single visit.[1]
Diagnosis	NICE QS4, 2011 updated 2016 NICE NG101, 2018 updated 2023 EUSOMA, 2017	People with newly diagnosed invasive breast cancer and those with recurrent breast cancer (if clinically appropriate) have the ER and HER2 status of the tumour assessed. Ensure that the ER, PR and HER2 statuses are available and recorded at the pre-operative and post-operative multidisciplinary team meetings when systemic treatment is discussed.	Recorded hormone status a) ER status b) HER2 status *Data quality measure*	ER status was missing in approximately 10% of patients with early invasive disease. HER2 status was missing in approximately 17% of patients with early invasive disease.[1]
Surgery: Breast-conserving surgery (BCS)	NICE QS 2011 EUSOMA, 2017	People with early breast cancer undergoing BCS, which may include the use of oncoplastic techniques, have an operation that both minimises local recurrence and achieves a good aesthetic outcome. Proportion of patients (BRCA1 and BRCA2 patients excluded) with invasive breast cancer not greater than 3 cm (total size, including DCIS component) who underwent BCS as primary treatment. Proportion of patients with non-invasive breast cancer not greater than 2 cm who underwent BCS.	BCS for: a) DCIS b) Early-stage invasive *Process measure*	For women aged 50 and over, as age at diagnosis increased, those with ER negative early invasive breast cancer were more likely to receive surgery compared to those with ER positive breast cancer, regardless of fitness.[1]
Surgery: BCS	NICE NG101, 2018 updated 2023 EUSOMA, 2017	Offer further surgery (re-excision or mastectomy, as appropriate) after BCS where invasive cancer or DCIS is present at the radial margins ('tumour on ink'; 0 mm). For women who have had BCS where invasive cancer or DCIS is present within 2 mm of, but not at, the radial margins (greater than 0 mm and less than 2 mm): (1) discuss the benefits and risks of further surgery (re-excision or mastectomy) to minimise the risk of local recurrence, (2) take into account the woman's preferences, comorbidities, tumour characteristics and the potential use of radiotherapy. All breast units should audit their recurrence rates after treatment.	Re-operation rate for: a) DCIS b) Early-stage invasive *Outcome measure*	Variation in re-operation rates following BCS across NHS organisations.[53] Re-operation rates have been shown to be higher for women with DCIS compared to early invasive disease.[1]

Aspect of Care Pathway	Guideline/Standard/Recommendation	Guideline/Standard description	Potential areas of focus / indicators	Additional evidence from literature
		Proportion of patients (invasive cancer only) who received a single (breast) operation for the primary tumour (excluding reconstruction). Proportion of patients (DCIS only) who received just one operation (excluding reconstruction).		
Surgery; Reconstruction	NICE QS 2011 NICE NG101, 2018 updated 2023 EUSOMA, 2017	People with early breast cancer who are to undergo mastectomy have the options of immediate and planned delayed breast reconstruction discussed with them. Offer immediate breast reconstruction to women who have been advised to have a mastectomy, including those who may need radiotherapy, unless they have comorbidities that rule out reconstructive surgery.	Immediate reconstruction rate following mastectomy for: a) DCIS b) Grade 1, node negative disease *Process measure*	Variation in use of immediate reconstruction in older patients.[1]
Oncology; Radiotherapy	NICE NG101, 2018 updated 2023 EUSOMA, 2017	Offer whole-breast radiotherapy to women with invasive breast cancer who have had breast-conserving surgery with clear margins. Consider adjuvant radiotherapy for women with DCIS following breast-conserving surgery with clear margins. Offer adjuvant post-mastectomy radiotherapy to people with node-positive (macrometastases) invasive breast cancer or involved resection margins. Consider adjuvant post-mastectomy radiotherapy for people with node-negative T3 or T4 invasive breast cancer.	Adjuvant radiotherapy for: a) DCIS b) Early-stage invasive *Process measure*	Considerable variation in the use of adjuvant radiotherapy for both DCIS and early-stage invasive disease across NHS organisations.[1]
Oncology; Chemotherapy	NICE NG101, 2018 updated 2023 EUSOMA, 2017	Offer neo-adjuvant chemotherapy to people with ER-negative invasive breast cancer as an option to reduce tumour size. Offer neo-adjuvant chemotherapy to people with HER2-positive invasive breast cancer. Consider neo-adjuvant chemotherapy for people with ER-positive invasive breast cancer as an option to reduce tumour size if chemotherapy is indicated.	Neo-adjuvant systemic anti-cancer therapy for early-stage: a) HER2 positive b) TNBC *Process measure*	Considerable geographical variation in the use of neo-adjuvant chemotherapy in patients aged 50 and over.[48]
Support	NICE NG101, 2018 updated 2023 EUSOMA, 2017	Ensure all people with breast cancer have a named clinical nurse specialist (CNS), or other specialist key worker with equivalent skills, to support them throughout diagnosis, treatment and follow-up.	Seen by a breast CNS/specialist key worker. *Data quality & process measure*	76% of patients included in the NABCOP 2022 Annual Report had completion of this data item. For women aged 50 and over, where data was available, there was variation according to NHS organisation, with some having as low as 50% of patients that had seen a breast CNS.[1]

Appendix 7 – Data sources to be used by the NAoPri

Country	Data source	Content
England	Cancer registry	Data on all aspects of the cancer registration including information from hospital pathology systems and from the Civil Registration (death) records.
England	COSD	Cancer Outcomes and Services Dataset (COSD) data items, are submitted routinely by service providers via multidisciplinary team (MDT) electronic data collection systems to the National Cancer Data Repository (NCDR) on a monthly basis.
England	SMT	Somatic Molecular Testing (SMT) data is data directly from molecular diagnostics laboratories in England and covers tests for genetic mutations occurring only in the tumour.
England	SACT	Systemic Anti-Cancer Therapy (SACT) data contains information on systemic oncological treatment including dates, regime(s) and dose.
England	RTDS	Radiotherapy dataset (RTDS) contains information on radiotherapy treatment including dates, prescription region and dose.
England	PCPD	The Primary Care Prescription Database (PCPD) contains information on prescriptions dispensed within community pharmacies.
England	HES	Hospital Episode Statistics (HES) is the administrative database of all NHS hospital care in England.
England	CWT	Cancer Waiting Times (CWT) data includes information on the first definitive treatment for new, progressive or recurrent cancer.
England	DIDS	The Diagnostic Imaging DataSet (DIDS) includes data on all imaging investigations for a patient.
England	CPES	The National Cancer Patient Experience Survey (CPES) collects data on the experience of patients diagnosed with cancer each year and is a survey sent directly to patients between April and June. Full details can be found at: https://www.ncpes.co.uk/
Wales	Canisc	Cancer Network Information System Cymru (Canisc) contains data on all aspects of the cancer diagnosis, including investigations, care plan and treatment.
Wales	PEDW	Patient Episode Database for Wales (PEDW) is the administrative database of all NHS hospital care in Wales.
Wales	RTH	National Radiotherapy (RTH) data contains information on radiotherapy treatment including dates, prescription region and dose.
Wales	ONS	Office for National Statistics (ONS) death data including date of death and cause of death.

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