NAoMe

National Audit of Metastatic Breast Cancer

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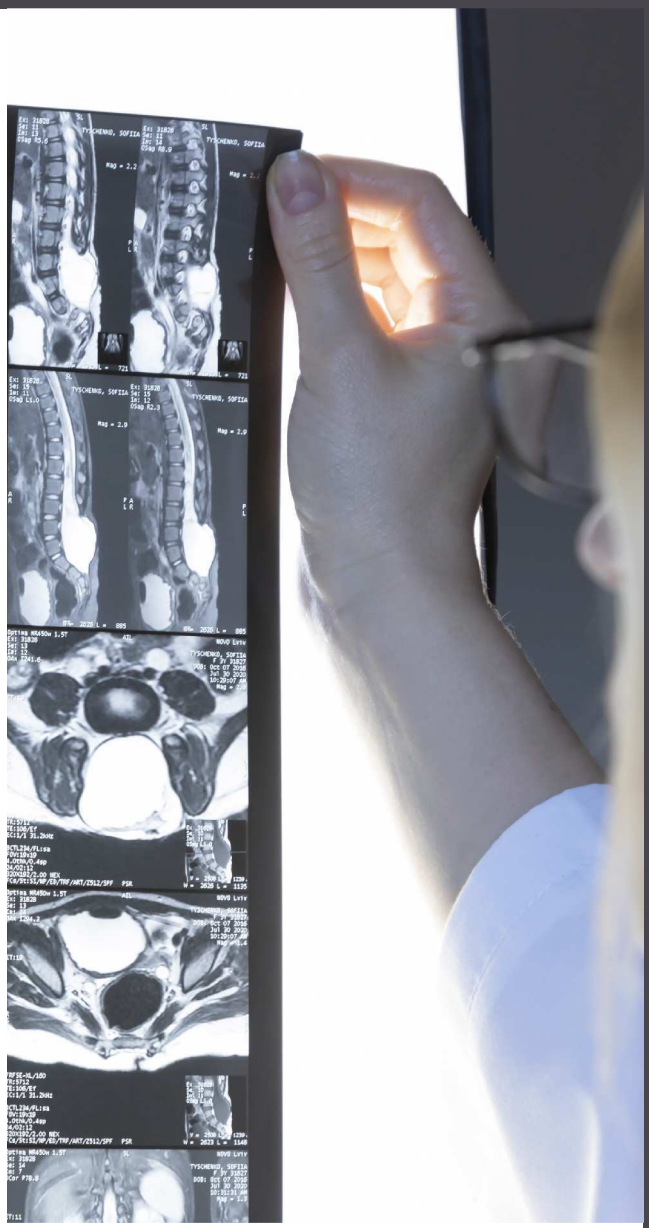
Scoping Document

November 2023



NATCAN

National Cancer Audit Collaborating Centre

Royal College of Surgeons of England

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NAoMe

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HQIP
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

Contents

1. Introduction

This document outlines the structure of the National Audit of Metastatic Breast Cancer (NAoMe) and details the activities undertaken to understand, and subsequently define, the scope of the audit.

The NAoMe is one of six new national cancer audits to 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 NAoMe will work closely with the other breast cancer audit, the National Audit of Primary Breast Cancer (NAoPri).

The NAoMe 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 for the NAoMe, the Project Team (**Appendix 2**) has carried out a review of pertinent guidelines and literature, as well as consulting with key stakeholders. The audit will build on the work of the National Audit of Breast Cancer in Older Patients (NABCOP) which ended in September 2022.[1] While the NABCOP included only women aged 50 years and above, the NAoMe will evaluate the care received by ***all*** patients diagnosed with metastatic breast cancer in NHS hospitals within England and Wales.

When considering metastatic (breast) cancer there are two distinct groups of patients, defined in Table 1 below. The NAoMe will evaluate care for both groups.

Table 1*: Metastatic breast cancer groups*

Group	Defined as
'De novo' metastatic breast cancer	Those diagnosed with metastases at initial presentation - this "de novo" metastatic breast cancer group corresponds to around 5% of all individuals newly diagnosed with invasive breast cancer each year. In England and Wales, this approximately equates to 2500 of the 50000 new diagnoses per year.
'Recurrent' metastatic breast cancer	Those diagnosed with metastatic disease, detected sometime after an initial non-metastatic breast cancer diagnosis.

The NAoMe will publish annual State of the Nation reports, presenting findings from the evaluation of audit performance indicators. In addition to this, 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 metastatic breast cancer

Breast cancer is the most common cancer diagnosed within the United Kingdom (UK), and the second most common cause of cancer death in females.[2] Metastatic breast cancer represents the presence of breast cancer in distant organs commonly bone, lungs, liver and brain, and diagnosed due to symptoms and/or abnormalities presenting on imaging or other investigations. Metastatic breast cancer may occur as a 'de novo' diagnosis, where metastatic spread is present at the time of the initial breast cancer diagnosis, but most commonly occurs some point after the diagnosis and treatment for primary breast cancer, often after a prolonged period of time. Whilst patients with 'de novo' metastatic breast cancer make up 5% of all patients with newly diagnosed invasive breast cancer diagnosed each year, the incidence and prevalence of metastatic breast cancer following an initial primary breast cancer is unknown and estimates vary considerably, reflecting the lack of recording in mandatory national data capture for this group of patients. A recent study using HES data alone suggested that the prevalence in England is around 57,000.[3]

Subgroups

Although breast cancer is molecularly diverse, there are three key tumour subgroups, defined by the molecular characteristics of the cancer, which are important for the audit as they impact patterns of care and subsequent outcomes. The groups and implications are outlined in Table 2. The molecular characteristics determine treatment options and are associated with different survival outcomes.

Table 2*: Breast cancer tumour subgroups and implications for metastatic breast cancer*

Tumour subgroup	Implication
HER2-ve, HR+ve	The most common tumour subgroup, equating to approximately 65% of all patients with metastatic 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 20% of all those with metastatic 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 15% of all patients with metastatic breast cancer.

Key: HR = hormone receptor

Oligometastatic breast cancer (termed OMBC) describes a subset of patients with metastatic breast cancer with limited volume of disease, often defined as ≤5 deposits. Although the incidence of OMBC is not well characterised, there are some data to suggest a significant proportion of patients with new metastatic breast cancer present with oligometastatic disease. The precise definition, staging approach and management of oligometastatic disease are under review currently.

Treatment options

Metastatic breast cancer cannot be cured but can be managed, often for long periods of time, and there is a large range of treatment options designed to control the disease. Such options include endocrine therapy (for HR-positive disease), chemotherapy, HER2-targeting drugs (for HER2-positive disease) and other inhibitors of molecular pathways within breast cancer cells including immune checkpoint inhibitors in some patients with triple negative cancer. The oncological management of metastatic breast cancer has become substantially more complex over the last 10-15 years and there is an increasing number of evolving treatment options.

Various factors will inform treatment options. Determinants of treatment are tumour biology, disease distribution and burden, organ function, performance status and menopausal status, previous treatment and patient choice. Although patient age at the time of diagnosis was found to be a strong determinant of treatment received, patterns of care should be determined by "biological age" and guidelines emphasise that chronological age alone should not determine treatments. Measures of patient fitness/frailty will be important to consider when evaluating indicators and presenting audit results.

Supportive interventions are also available including palliative radiotherapy and anti-resorptive therapies such as denosumab or bisphosphonates. Attention to symptom support, often in conjunction with community or hospital/hospice based palliative care teams, is an important part of management.

Outcomes following a diagnosis of metastatic breast cancer

The point at which metastatic breast cancer is diagnosed (at initial presentation compared with progression/recurrence) will impact the treatment options available along with subsequent outcomes. The timing of distant recurrence is variable and largely dependent on characteristics of the primary tumour, including the molecular sub type and stage. Triple negative breast cancer has a marked peak in recurrence and mortality risk at 2-4 years after primary diagnosis, whilst the corresponding pattern for ER-positive breast cancer tends to be slower and more steady but persistent.[4] Overall survival is, on average, longer for patients with de novo disease. Treatment options for distant recurrent disease are determined by which therapies were previously used and their effectiveness along with a patient's tolerance to them.

2.1 Guidelines on the management of metastatic breast cancer

There are both national and international guidelines covering the management of advanced (metastatic) breast cancer (**Appendix 3**). These sources of information on the recommended management of patients with advanced breast cancer will provide key reference for future NAoMe work and have been referred to throughout this document where relevant. There are similarities in the standards identified by the three sources, including: the value of multidisciplinary teams; access to a clinical nurse specialist (CNS); assessment of estrogen receptor (ER) and human epidermal growth factor receptor 2 (HER2) status for treatment planning; and receipt of prompt, tolerated treatment.

The treatment options available for patients with metastatic breast cancer within national guidelines have changed over time, with increasing numbers of new therapies available within the NHS over the last decade. Recommended treatments within national clinical guidelines commonly include combinations of chemotherapy and targeted agents, endocrine therapy and bisphosphonate treatment. It is important to be aware of these changes, and to capture patient data which include tumour biology and systemic treatments, to ensure that the NAoMe work remains clinically relevant.

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

Despite clear national and international guidelines on the care of patients with metastatic breast cancer, the NABCOP Annual Reports previously highlighted variation in the patterns of chemotherapy treatment and outcomes, among women with de novo metastatic breast cancer aged 50+ years.[5,6]

Other studies have also reported variation in the patterns of care and treatment provided to patients with metastatic breast cancer across England and Wales.[7,8]

3. Stakeholder engagement

The NAoMe project team has engaged with various stakeholders during the audit set-up phase in order to inform the scope of the audit. Details of these engagements are provided below.

- In November 2022 the PT met with Breast Cancer Now to discuss priorities for the audit and they shared early thoughts on potential indicators.
- From February to April 2023 the audit conducted a Scoping Survey activity (described within Section 3.1).
- In April 2023 the audit had the first AAC meeting where initial scoping survey findings were discussed and stakeholders had further opportunity to provide feedback on which areas of care the audit should focus on.
- In May 2023 the NAoMe team gave a presentation about the audit at the Association of Breast Surgery (ABS) annual conference. The ABS conference attracts surgeons, oncologists, nurse specialists, and wider members of the breast care team, as well as patient representatives. The NAoMe had a dedicated audit stand with information about both new breast cancer audits and we were able to explain the data sources that the audits will use, how people can get involved, and encourage engagement with the audit processes. They had contact with around 200 delegates.
- In June 2023 the launch of the NAoMe was presented at the Royal College of Radiologists and at the UK Oncology Forum annual conference.

3.1 Scoping Survey

A scoping survey was developed 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 metastatic breast cancer is most in need of improvement?
2. What aspect of care which affects a subgroup of patients with metastatic breast cancer is most in need of improvement?

The survey was conducted online using Survey Monkey. Initial piloting of the survey, with members of the AAC, took place from 24th January 2023 to 6th February 2023.

Following this, on 23rd February 2023 a link to the online survey was sent to all stakeholders identified through the audit's contact list which included: healthcare professionals involved in the care of patients with breast cancer and in clinical audit, relevant professional bodies and charities, and patient representatives including individuals from: all NHS organisations across England and Wales, 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. The survey was open until 13th March 2023, with several email prompts to encourage engagement and cascading of the survey link via twitter, professional groups, and patient charities.

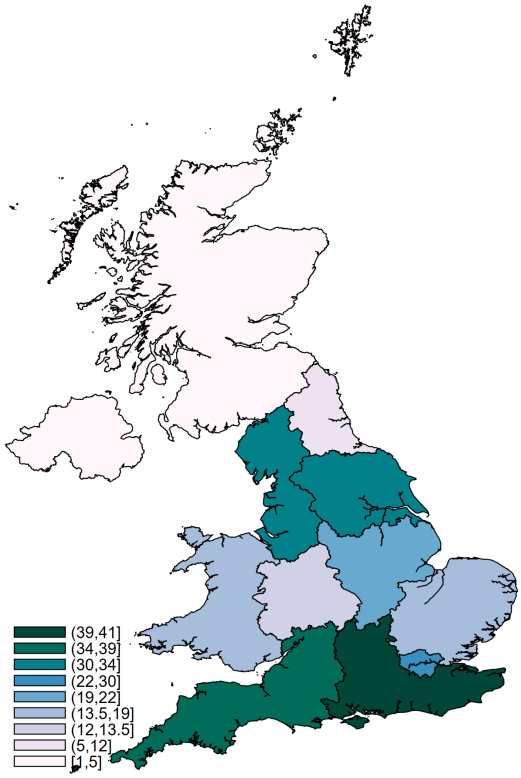
A second wave of the online survey was circulated to healthcare professionals with a particular focus on garnering more oncological responses. This wave was open from 16th March 2023 to 28th April 2023.

3.2 Survey results

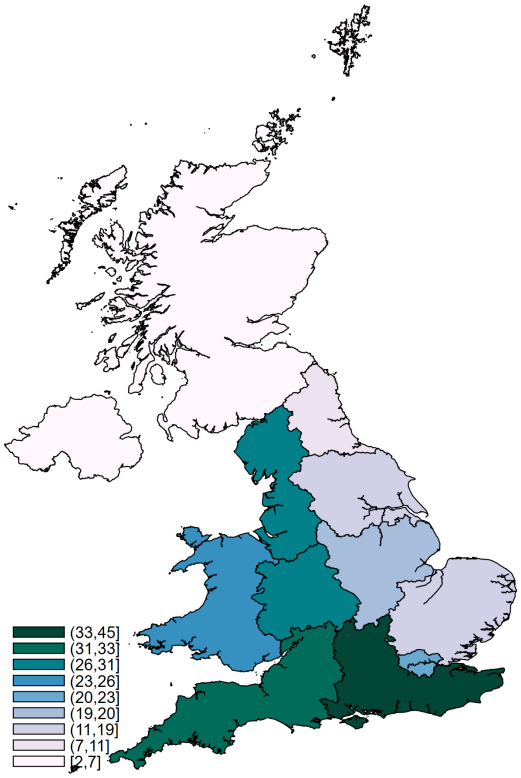
Survey responses were received from 649 stakeholders of which 539 answered at least one of the questions around the care of patients with metastatic breast cancer. The respondents included 77 surgeons, 79 oncologists, 77 nurses, and 265 patients or patient advocates. Respondents were from across England and Wales, with additional input from some stakeholders within Northern Ireland and Scotland. Figure 1 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 1: *Distribution of respondents to the scoping survey*

Clinical Respondents (N=260)



Patient/Patient Advocate Respondents (N=263)



Note: The maps include 523 out of the total 539 respondents. 16 respondents were excluded – 6 did not provide their region, 2 did not disclose their role, and 8 provided neither their region nor their role.

A large percentage of responses related to the organisation of breast 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 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 services, notably, the availability of a Clinical Nurse Specialist (CNS) dedicated to the care of patients with metastatic disease in a breast unit.

The evaluation of these structural dimensions of quality of care is evidently important but they will not be auditable within the routine data that the audit will have available. One option could have been an organisational audit, but this was not included in the service specification of the NATCAN cancer audits, and so this option is not covered here. How these topics can be examined will not be overlooked and we

recommend consideration be given to including them when the service specification of the 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 metastatic breast cancer care should the audit focus on in each part of the care pathway?

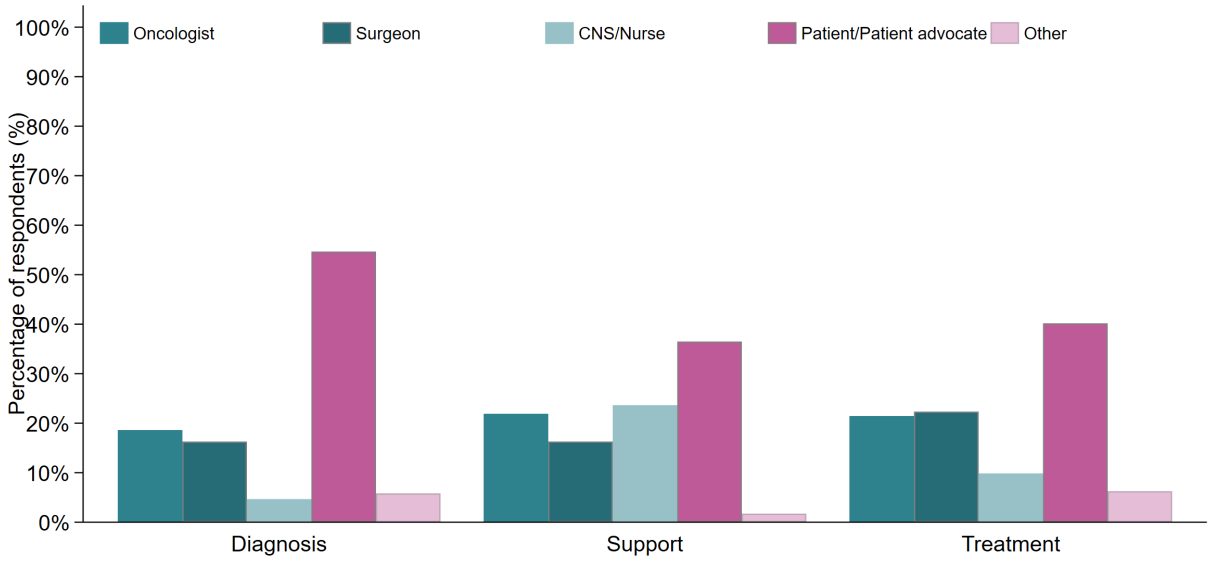
Table 3 presents the areas of care mentioned by respondents for each part of the care pathway. While the different elements of the care pathway were identified by a broad range of stakeholders, there was some clustering of answers within the respondent subgroups defined based on role (Figure 2).

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/diagnosis Timely access to appropriate imaging and results Timeliness of investigations & availability of pathology and scan results for treatment decisions Use of genetics/molecular/immune-specific testing and re-biopsy to guide treatment decisions
Supportive care	Access to a dedicated clinical nurse specialist / psychological support
Treatment	Use of new drugs/ immunotherapy / palliative treatment Timely access to treatment Geographical variation in treatment Use of surgery

Where 'diagnosis' was the aspect of the care pathway identified, patients accounted for the largest group of respondents. Where 'support' was highlighted CNS/nurses and oncologists accounted for the largest clinical group, whilst where 'treatment' was highlighted both oncologists and surgeons were similarly represented within the responders.

Figure 2: *Parts of the care pathway identified as most in need of improvement, stratified by respondents' role*



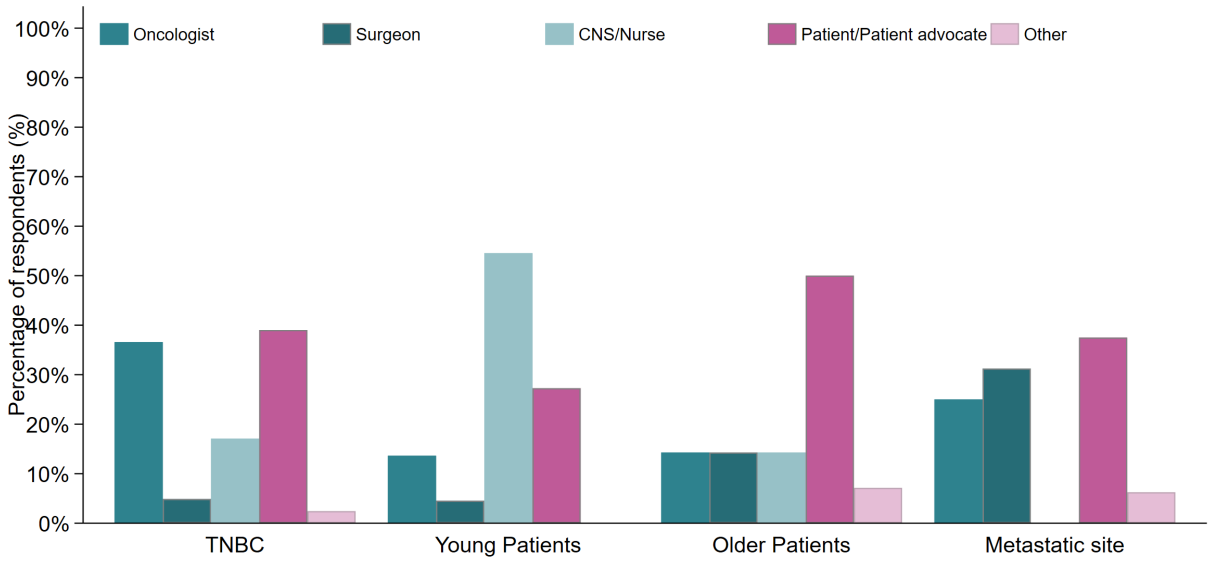
Which patient subgroups should the audit address?

For patients with metastatic breast cancer, several subgroups were identified as being those for whom care was most in need of improvement. These are presented in Table 4 below.

Table 4: *Patient subgroups highlighted by respondents*

Patient subgroup	Associated scoping survey finding
Triple negative breast cancer (TNBC)	Patients with TNBC (ER/PR and HER2 negative) were most frequently identified as the patient group for whom care was most in need of improvement.
Young patients	Young patients were identified as a patient group of importance for the audit to look at most frequently by CNS/nurses (Figure 3). Aspects of care relating to patients with children and fertility support were reported.
Older patients	Older patients were highlighted most frequently by patients who responded.
Site of metastases	Site of metastases was most frequently highlighted by surgeons. Where respondents highlighted important patient groups based on the site of metastases, the most frequently reported were brain, bone metastases and oligometastatic disease.

Figure 3: *Patient subgroups identified as important, stratified by respondents' role.*



4. Proposed scope of the NAoMe

The NAoMe scope has been developed based on the findings from the activities outlined in the previous chapters. These build on work done by the NABCOP, as well as involving a review of the wider literature (including external quality standards), and consultation with stakeholders on priorities for the NAoMe and areas of breast cancer care most in need of improvement.

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 NAoMe AAC patient subgroup (which we will establish) will be crucial for having the experiences and views of patients and patient advocates feed into the ongoing QI focus of the audit.

4.1 Audit inclusion/exclusion criteria

Eligibility for inclusion in the NAoMe is defined based on the following criteria:

- All patients (male and female) with a recorded diagnosis of invasive breast cancer (ICD-10 C50) with evidence of metastatic spread in the audit period
- Age at diagnosis ≥18 years
- Diagnosed in an NHS hospital within England and Wales

Individuals identified from death certificates only will not be included.

4.2 Priorities for quality improvement

The audit's scoping activities identified various priority areas for quality improvement along the care pathway. We envisage the NAoMe's Healthcare Improvement Goals will centre on these.

Priorities in the care of patients with metastatic breast cancer are:

1. Increasing the percentage of patients with metastatic progression/recurrence who have the date and type of progression/recurrence recorded in national cancer datasets.
    (1) Previous NABCOP work has highlighted poor recording of these data.
    (2) This would also act as a measure of patients discussed at an MDT to have their care and treatment managed (NICE QS 12 – statement 5; WHO Global BC IIF 1).
2. Increasing the percentage of patients with metastatic progression/recurrence who have staging and tumour pathology details recorded in national cancer datasets (NICE QS 12 – statement 4; WHO Global BC IIF 2).
3. Reducing variation in the timeliness and receipt of systemic anti-cancer treatment for de novo or progressive/recurrent metastatic breast cancer (NICE QS 12 – statement 4; WHO Global BC IIF 4; BC Now The Unsurvivors 3).
4. Increasing the percentage of patients with de novo or progressive/recurrent metastatic breast cancer who are supported by a breast clinical nurse specialist (NICE QS 12 – statement 6; WHO Global BC IIF 3; BC Now The Unsurvivors 4).
5. Improving outcomes following a diagnosis of de novo or progressive/recurrent metastatic breast cancer.

These priorities highlight two key aspects of work for the audit. The first is the need to establish the baselines from which change in practice and outcomes can be measured. A second is defining the range of outcomes that are important for patients and which are feasible for the audit to measure.

The NAoMe 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.

4.3 Potential indicators for the audit of metastatic breast cancer

A key component of the scoping work was to review the areas of metastatic breast cancer care which were reported by the NABCOP. That audit presented on the following aspects for patients presenting with (de novo) metastatic breast cancer:

- The percentage of patients with metastatic disease at initial presentation
- Route to diagnosis, patient and tumour characteristics, by age at diagnosis
- Use of chemotherapy – the percentage of patients receiving chemotherapy
- Short-term mortality – the percentage of patients who died within 30 days of their last reported cycle of chemotherapy
- Relative survival among women receiving chemotherapy

In addition, the completeness of recurrence information in national cancer datasets in England and Wales for all patients (aged 50+ years) with breast cancer was reported by the NABCOP.

A rapid review of publications on the delivery of services for metastatic breast cancer found there to be few instances of Quality Improvement (QI) performance indicators specifically for patients with metastatic breast cancer. We also did not identify another national clinical audit on this topic in other Organisation for Economic Co-operation and Development (OECD) member countries from whose experience lessons could be learnt.

Examples of potential audit indicators based on reviewed quality standards / areas of care for monitoring, identified from national/global sources, are provided in **Appendix 4**, along with initial comments on their feasibility for audit using the routine data available.

4.4 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 availability of information within the routine data to be used by the audit.

4.4.1 Routine data sources

Patient-level data on many aspects of breast cancer care are routinely collected in hospitals and mandatorily submitted to national organisations. These existing national cancer datasets linked to other relevant health care datasets will be used by NAoMe to reduce the burden of data collection on staff and patients, whilst the audit will strongly encourage greater completeness of the relevant items' returns. Over time these national cancer datasets have improved in their quality and richness of information on tumour characteristics, as well as 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 metastatic 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). Data from the WCN on patients with a diagnosis of metastatic breast cancer will be provided on an annual cycle in the first instance. Wales has a different data collection process to England.

All data will be provided linked at patient/tumour-level to other national datasets; details of these can be found in **Appendix 5**.

For accurate and timely benchmarking it is essential that the data available to the audit:

- include all information required to measure and risk-adjust audit performance indicators
- allow for timely reporting
- have high levels of data completeness
- are accurate

For England, the RCRD is based on a small subset of COSD data items with no breast cancer specific information (e.g. ER status). It includes information on diagnostic staging, but unlike the Cancer Registration records has lower completeness (due to the input from registration staff to improve the completeness of key data items such as stage in standard Cancer Registration records). As such, the dashboard to report indicators on a quarterly basis will require careful development and testing.

A key requirement for the NAoMe will be having data items that allow the characteristics of a patient's metastatic breast cancer to be described sufficiently accurately at the point of diagnosis to apply the desired inclusion criteria and define important patient subgroups. The information available for describing metastatic breast cancer tumours in the national cancer datasets differs according to whether it is de novo or progressive/recurrent MBC. This is described further in the following sections.

4.4.2 Identifying patients with metastatic breast cancer

At initial diagnosis

National cancer datasets in England and Wales collect data on diagnosis of patients with new breast cancer. They require information to be provided on tumour stage and the results from assessing the presence/absence of metastatic spread. This information will be used to identify patients with de novo metastatic breast cancer. We will define patients as having metastatic breast cancer at initial diagnosis where either stage 4 disease is recorded or metastatic status is recorded as M1.

For some patients no diagnosis stage or metastatic status information is provided within the routine cancer data. Metastatic spread can be discovered following initial treatments, meaning in essence the known cancer stage will change over time. This will be important to be aware of and accounted for when defining the cohort, for example where pre-treatment and post-surgical stage differ with more accurate staging following surgery.

At progression/recurrence

National cancer datasets in England and Wales collect data on date and type of cancer progression/recurrence following an initial cancer diagnosis. Within the cancer data collected for patients in England this is referred to as the non-primary cancer pathway and allows for data capture on disease progression or recurrence.

These data will be used to identify patients with metastatic breast cancer at progression/recurrence, with patients defined as having progressive/recurrent metastatic breast cancer where distant (rather than local or regional) progression/recurrence is recorded.

4.4.3 Issues with routine data for metastatic 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 NAoMe cohort and focus efforts on improvements where required.

Currently, there is a lack of information regarding recurrence (both local and distant) within national routinely collected data. Work done by NABCOP suggests only 4% of patients (n=224,049) had a record of recurrence reported with poor recording across all geographical regions. Of note only 20% of patients with a recorded breast cancer death had a recording of recurrence.[6] As such, these data are insufficient by themselves for identifying the cohort of patients with metastatic breast cancer at progression/recurrence. It will be important for the data quality and completeness on recurrence information to improve in order to accurately define the NAoMe cohort.

With known data completeness/quality issues around the recording of progression/recurrence and a percentage of patients with no stage information at initial diagnosis it is necessary to consider other ways to ensure the audit cohort includes as many patients with metastatic breast cancer known to NHS organisations, whilst retaining transparency on who is included to ensure audit findings are interpretable and able to prompt local QI. The audit will do this by extracting data recorded in other linked data sources that indicate the likely presence of metastatic disease. This will be used to identify eligible patients and will be based on searching within the (linked) routine health care datasets for “markers” associated with metastases at initial diagnosis or at recurrence or progression. Timings and knowledge of any previous breast cancer diagnosis will be used to determine whether metastatic spread was present at the initial diagnosis or developed over time either as disease progression or recurrence.

We propose using the following “markers” for metastatic breast cancer in the routine datasets to define the cohort:

1. Recording of an ICD-10 code for metastatic cancer along with an ICD-10 code for invasive breast cancer (C50) within the diagnosis fields of the HES-APC/PEDW datasets (i.e. the records of patients being admitted to hospital either with an overnight stay or as a day case).
    a. The use of codes commencing C77 (except C77.3 for axillary and upper limb lymph nodes), C78, C79
    b. These codes can identify the site of metastases (lung, liver, brain, bone, etc.).
    c. The marker used does not require a period of remission to be defined and applies equally well to identifying distant metastases due to progression as well as recurrence.
    d. Where more than one admission contains these ICD-10 codes the date of recurrence / progression could be defined as the earliest admission date.

2. Receipt of a therapy specifically only given for metastatic breast cancer. This might be: chemotherapy or targeted therapy for metastatic breast cancer, radiotherapy to metastases, surgery for liver/lung/brain metastases, hormone/endocrine therapy. Some therapies will only act as a marker for distant metastases after a person has had a period of "remission". For example, finding a patient had received endocrine therapy in the Primary Care Prescription Dataset (PCPD) is much more likely to be associated with metastatic breast cancer if it occurred at least five years after the initial diagnosis with a previous period of no endocrine therapy recorded. For therapies that are only associated with the treatment of distant metastases (e.g. radiotherapy for bone metastases), a period of remission is not required. Such therapies can indicate disease progression as well as recurrence. As above, the date of recurrence / progression could be defined as the earliest date of the given treatment.
3. Record of treatment for progression or recurrence in Cancer Waiting Times data.
4. The receipt of a pattern of diagnostic investigations associated with metastatic breast cancer. This might be: a CT scan, PET-CT, or MRI. The utility of this type of marker on its own is unclear as the result of the scan will not be available. Consequently, this option will be ignored in this discussion. However, it might provide a way to provide a more accurate date for the date of recurrence / progression if combined with information on the receipt of treatment after a period of remission.

Based on an associated date, where this is beyond the initial breast cancer diagnosis and not within a pre-defined time frame, we envisage using the above "markers" to define a date of recurrence / progression. As this will be based on having a hospital admission with metastatic cancer diagnosis codes recorded or starting treatment for metastatic breast cancer, this date may be later than the clinically identified date of metastatic recurrence / progression recorded in a patient's medical record, particularly where there is a delay between diagnosis of metastases and subsequent activity. The degree to which this inaccuracy matters will depend upon the type of indicator.

The audit team will evaluate construction of the audit cohort based on the data available in one of two approaches.

(1) Using all available sources of information to define a patient as having metastatic breast cancer at progression/recurrence. Where multiple "markers" are flagged the earliest associated date will be used to determine "diagnosis" of metastatic breast cancer.
(2) Limiting to "markers" that correspond most closely to the required data items; that is, the ICD-10 codes highlighting the presence of metastatic cancer and describe the type of metastases.

In considering these two approaches, the fundamental issue will be how to balance including as many eligible patients as possible while not including "falsely" labelled patients, ensuring the sample is representative and the method is sufficiently transparent to enable local QI based on the audit findings. Whilst using multiples sources would increase the number of patients identified it also has the potential to distort the cohort. Approach (2) offers the simplest approach, and reduces the number of sources of potential error although we anticipate it will limit the cohort size. It is worth noting that if the hospital admissions data sources are comprehensive the benefit of using other routine data sources is likely to be more limited.

The audit will examine the performance of using each approach for identifying patients with metastatic breast cancer. Many of the previous published studies that have developed algorithms to identify patients with recurrent cancer were able to evaluate the performance by comparing the patients identified via the algorithm with the patients with recurrent cancer recorded in a reference dataset (created from medical record review) or by comparison with datasets derived from clinical trials. This enabled the studies to

calculate the sensitivity / specificity of their algorithms; some studies reported the details for different algorithm designs and distinguished between algorithms having a high sensitivity / moderate specificity and a moderate sensitivity / high specificity. The audit will not have such reference data to perform an equivalent evaluation. It is possible that the audit will be able to identify a few NHS trusts that submit the required recurrence / progression data for a very high percentage of their patients and these NHS trusts might have cared for sufficient patients for an assessment of sensitivity / specificity in a sample of patients.

4.4.4 Strategy for defining organisational-level indicators

Based on the review of external documents on the care of metastatic breast cancer, our engagement with stakeholders and synthesis of responses to the scoping survey we will put together a set of indicators for the audit which will be used to support stakeholders with local activities relating to the audit improvement goals.

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

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

An important consideration for the audit to ensure organisation-level findings are clear and enable local QI is how to allocate patients to NHS organisations.

Where indicators relate to diagnosis and staging, one option is to allocate patients to the NHS organisation in which the patient is diagnosed. This would have 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 with MBC for review, 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 is used will be determined by the aspect of treatment being 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 largest numbers available for indicators related to diagnosis, staging and MDT discussions as this will typically include all patients with MBC. Conversely indicators focusing on a subgroup of patients will have smaller denominators. Indicators may also be defined among patients starting treatment for metastatic breast cancer, for example when looking at aspects of care around treatment including outcomes following treatment, and so will be based on a subset of the patient cohort.

Depending on the type of indicator the denominator will need to be carefully determined to ensure the indicator clearly reflects the care provided to patients and accounting for the two distinct groups eligible for inclusion within the whole cohort of patients:

I. Patients diagnosed with metastatic/stage 4 disease at initial presentation (de novo metastatic breast cancer).
II. Patients who have metastatic disease following an initial diagnosis of non-metastatic breast cancer.

Indicators will be split into two measures defined in relation to patient group, as described above, where the care is expected to differ based on this timing of metastatic diagnosis, for example in the case where treatment options and outcomes for recurrent/previously treated metastatic breast cancer compared with de novo metastatic breast cancer. Additionally there may be the need to use this approach because of initial difficulties in identifying metastatic breast cancer diagnosed following an initial diagnosis of non-metastatic breast cancer.

The NAoMe team will assess how indicators can be defined to ensure they have sufficient statistical power to differentiate between good and poor performance. One option to improve statistical power will be 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 can be found in the referenced articles.[9,10]

5. Next steps

5.1 Development of the Healthcare Improvement Strategy

Building on the QI priorities identified in the scoping activities, the NAoMe team will develop its Healthcare Improvement Strategy. As part of this process, the audit will undertake several activities, in consultation with key stakeholders via its Audit Advisory Committee 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 / 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 forum will aim to be broad and cover a spectrum of patient characteristics including age and deprivation.

5.2 Communication and dissemination activities

Key activities relating to communication and dissemination include:

- Newsletters: distributed to NHS organisations and key stakeholders on a quarterly basis, and published on the audit website
- Website: development and regular review/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 detail about these activities will be set out in NAoMe's Communications Strategy

The NAoMe 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 NAoMe 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 Metastatic Breast Cancer (NAoMe) 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 NAoMe, NATCAN delivers five other audits in ovarian, pancreatic, primary breast, 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 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 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,[11] 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 detail on the datasets requested for the NAoMe.

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.[10]

The healthcare improvement plan will also set out the key drivers for each QI goal, alongside national and local improvement tools.[12] 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.[13] 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 NAoMe Project Team

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

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

The other members of the audit project team provide methodological, statistical and project management expertise and are: Jibby Medina (Programme Manager), David Cromwell (Health Services Research), Melissa Gannon (Statistician). An additional Data Scientist and a Clinical Research Fellow 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), METUPUK, Association of Breast Surgery (ABS), UK Breast Cancer Group (UKBCG), Getting it Right First Time (GIRFT), Royal College of Radiologists (RCR), Royal College of Surgeons of England (RCS Eng). The AAC will convene twice a year to advise on the direction of the audit and feedback on interpretation of audit findings. The AAC will help in the dissemination of audit findings.

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

Appendix 3 – Relevant international and national guidelines

Reviewed external standards which include reference to metastatic breast cancer.

NICE Quality Standard 12 (2011; updated 2016)[14]

Statement 4 - People with newly diagnosed invasive breast cancer and those with recurrent breast cancer (if clinically appropriate) have the oestrogen receptor (ER) and human epidermal growth factor receptor 2 (HER2) status of the tumour assessed.

Statement 5 - People with breast cancer who develop metastatic disease have their treatment and care managed by a multidisciplinary team.

Statement 6 - People with locally advanced, metastatic or distant recurrent breast cancer are assigned a key worker.

WHO Global Breast Cancer Initiative Implementation Framework, 2023[15]

- It is crucial that patients with metastatic breast cancer are discussed by a multidisciplinary tumour board and that a common strategy is defined.
- No treatment should be initiated without the histological confirmation of malignant disease. For de novo metastatic breast cancer, a biopsy of the primary tumour is needed; for recurrent metastatic breast cancer, a biopsy of one of the metastatic lesions is recommended.
- Starting as early as possible, supportive oncology (including palliative care) and psychological support are also fundamental.
- A fundamental indicator for tracking the timeliness of access to cancer treatments is the interval between metastatic breast cancer diagnosis and start of treatment.
- It is important to monitor the proportion of patients still on treatment 12 months after its start to track treatment abandonment. Since metastatic breast cancer is an incurable disease, some form of treatment is almost always necessary.

Breast Cancer Now. The Unsurvivors. 2019[16]

- We believe a crucial element of follow-up support is that information on the signs and symptoms of secondary breast cancer must be given to all patients treated for primary breast cancer, at a time and in a manner that suits them.
- It is crucial that people with secondary breast cancer are diagnosed promptly so they can begin treatment and access supportive care as quickly as possible.
- Timely access to treatment and care can relieve symptoms and have a dramatic impact on quality of life.
- Access to a CNS is particularly important for people with secondary breast cancer who will be on lifelong treatment and often have very complex emotional and supportive care needs.

EUSOMA/ABC quality indicators for metastatic breast cancer care. 2023[17]

- Ensure patients with MBC have appropriate and equitable access to multidisciplinary opinions and care teams, to select optimal treatment based on guidelines, to appropriately select patients for nonstandard management on a case-by-case basis and disease characteristics, and to select patients for clinical trials.
- Appropriate pathological characterisation of disease.
- Appropriate treatment (endocrine therapy; chemotherapy, targeted therapy; immunotherapy)
- Bone modifying agents.
- Brain radiotherapy.
- Appropriate use of tumour markers.

NICE. Advanced breast cancer: diagnosis and treatment (CG81). Key priorities. 2009 updated 2017[18]

- Assess oestrogen receptor (ER) and human epidermal growth factor receptor 2 (HER2) status at the time of disease recurrence if receptor status was not assessed at the time of initial diagnosis. In the absence of any tumour tissue from the primary tumour, and if feasible, obtain a biopsy of a metastasis to assess ER and HER2 status.
- Offer endocrine therapy as first-line treatment for the majority of patients with ER-positive advanced breast cancer.
- Healthcare professionals involved in the care of patients with advanced breast cancer should ensure that the organisation and provision of supportive care services comply with the recommendations made in 'Improving outcomes in breast cancer: manual update' (NICE cancer service guidance [2002]) and 'Improving supportive and palliative care for adults with cancer' (NICE cancer service guidance [2004]), in particular the following two recommendations:
    - 'Assessment and discussion of patients' needs for physical, psychological, social, spiritual and financial support should be undertaken at key points (such as diagnosis at commencement, during, and at the end of treatment; at relapse; and when death is approaching).'
    - 'Mechanisms should be developed to promote continuity of care, which might include the nomination of a person to take on the role of "key worker" for individual patients.'
- A breast cancer multidisciplinary team should assess all patients presenting with uncontrolled local disease and discuss the therapeutic options for controlling the disease and relieving symptoms.
- Consider offering bisphosphonates to patients newly diagnosed with bone metastases to prevent skeletal-related events and reduce pain.
- Use external beam radiotherapy in a single fraction of 8Gy to treat patients with bone metastases and pain.

Appendix 4 – Examples of potential performance indicators for the NAoMe

Aspect of Care Pathway	Potential areas of focus/indicators	Guideline/Standard/ Recommendation	Patient subgroup?	'De novo' metastatic breast cancer	'Recurrent' metastatic breast cancer	Interpretation	Target	Comments on feasibility given the routine data available to the audit
Diagnosis & Staging	Breast centres can demonstrate they have a clear pathway in place to provide documentation and discussion of goals of care with patients and their families for patients with MBC.	EUSOMA/ABC	-	X	X	Yes /No		Information not part of routine data collection.
Diagnosis & Staging	BRCA testing	EUSOMA/ABC; ESMO[19]	Patients with triple negative breast cancer.	X	X	Yes /No		Germline testing information collected in COSD (CR6170).
Diagnosis & Staging	Percentage discussed at MDT at least once / care managed by MDT	EUSOMA/ABC; NICE CG81; NICE QS12; WHO	-	X	X	Higher is better	99%	MDT discussion collected in COSD (CR8110).
Diagnosis & Staging	Percentage of patients with de novo MBC for whom ER and HER2 status have been determined through a biopsy.	EUSOMA/ABC; NICE CG81; NICE QS12; WHO; ESMO	-	X		Higher is better	98%	Established as feasible within the routine data collected.
Diagnosis & Staging	Percentage of patients with recurrent MBC, submitted to a biopsy of a metastatic lesion for biomarker re-assessment	EUSOMA/ABC; NICE CG81; NICE QS12; WHO; ESMO	-		X	Higher is better	65%	Unclear if information collected is on the submission of the biopsy or also on the results of the re-assessment.
Diagnosis & Staging	Improvements in cancer registry data collection: stage at diagnosis including de novo metastatic disease and breast cancer relapse data	-	-	X	X			-
Support	Seen by a breast CNS/named key worker	EUSOMA/ABC; NICE CG81; NICE QS12; WHO; BC Now	-	X	X			Unclear if information is available on CNS contact following a diagnosis of recurrent breast cancer.

Aspect of Care Pathway	Potential areas of focus/indicators	Guideline/Standard/ Recommendation	Patient subgroup?	'De novo' metastatic breast cancer	'Recurrent' metastatic breast cancer	Interpretation	Target	Comments on feasibility given the routine data available to the audit
Treatment	Percentage of patients who received endocrine-based therapy as first-line treatment ("endocrine-based therapy" may denote endocrine therapy alone, or endocrine therapy in combination with a targeted agent)	EUSOMA/ABC; NICE CG81; ESMO	Patients with ER-positive, HER2-negative cancer.	X	X	Higher is better	80%	For recurrent MBC treatment likely to depend on that options are received for initial BC.
Treatment	Percentage of patients treated with first or second-line chemotherapy, who also thereafter received endocrine-based therapy (ie maintenance therapy).For the purpose of this definition, ovarian function suppression or ablation alone is also considered to be endocrine-based therapy.	EUSOMA/ABC	Patients with ER-positive, HER2-negative cancer.	X	X	Higher is better	75%	For recurrent MBC treatment options are likely to depend on that received for initial BC.
Treatment	Percentage of patients who received cytotoxic monotherapy	EUSOMA/ABC	All patients who received chemotherapy in the first and second lines of therapy.	X	X	Higher is better	80%	For recurrent MBC treatment likely to depend on that received for initial BC.
Treatment	Percentage of patients who received pertuzumab & trastuzumab based therapy in the first line of therapy.	EUSOMA/ABC; ESMO	Patients with HER2-positive cancer.	X	X	Higher is better	80%	For recurrent MBC treatment likely to depend on that received for initial BC.
Treatment	Percentage of patients who received anti-HER2 therapy in the second line of therapy.	EUSOMA/ABC; ESMO	Patients with HER2-positive cancer.	X	X	Higher is better	95%	For recurrent MBC treatment likely to depend on that received for initial BC.
Treatment	Percentage of patients who received a bisphosphonate or denosumab (first and second line)	EUSOMA/ABC; NICE CG81	Patients with bone metastases.	X	X	Higher is better	90%	For recurrent MBC treatment likely to depend on that received for initial BC.

Aspect of Care Pathway	Potential areas of focus/indicators	Guideline/Standard/ Recommendation	Patient subgroup?	'De novo' metastatic breast cancer	'Recurrent' metastatic breast cancer	Interpretation	Target	Comments on feasibility given the routine data available to the audit
Treatment	Percentage of patients who received brain radiotherapy. (Note: In the context of this definition, "brain radiotherapy" includes radio-surgery and/or whole-brain radiotherapy, with or without surgery.)	EUSOMA/ABC	Patients with brain metastases (at initial diagnosis of metastases, 1st or 2nd progression).	X	X	Higher is better	95%	Brain as RT site is not recorded in RTDS.
Treatment	Percentage of patients whose treatment strategy was changed based on the results of tumour markers alone (not recommended but sometimes unavoidable)	EUSOMA/ABC	-	X	X	Lower is better	5%	Not part of routine data collection.

Appendix 5 – Data sources to be used by the NAoMe

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. It forms three datasets, of admitted patient care (HES-APC), outpatients (HES-OP) and accident & emergency (HES-AE).
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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