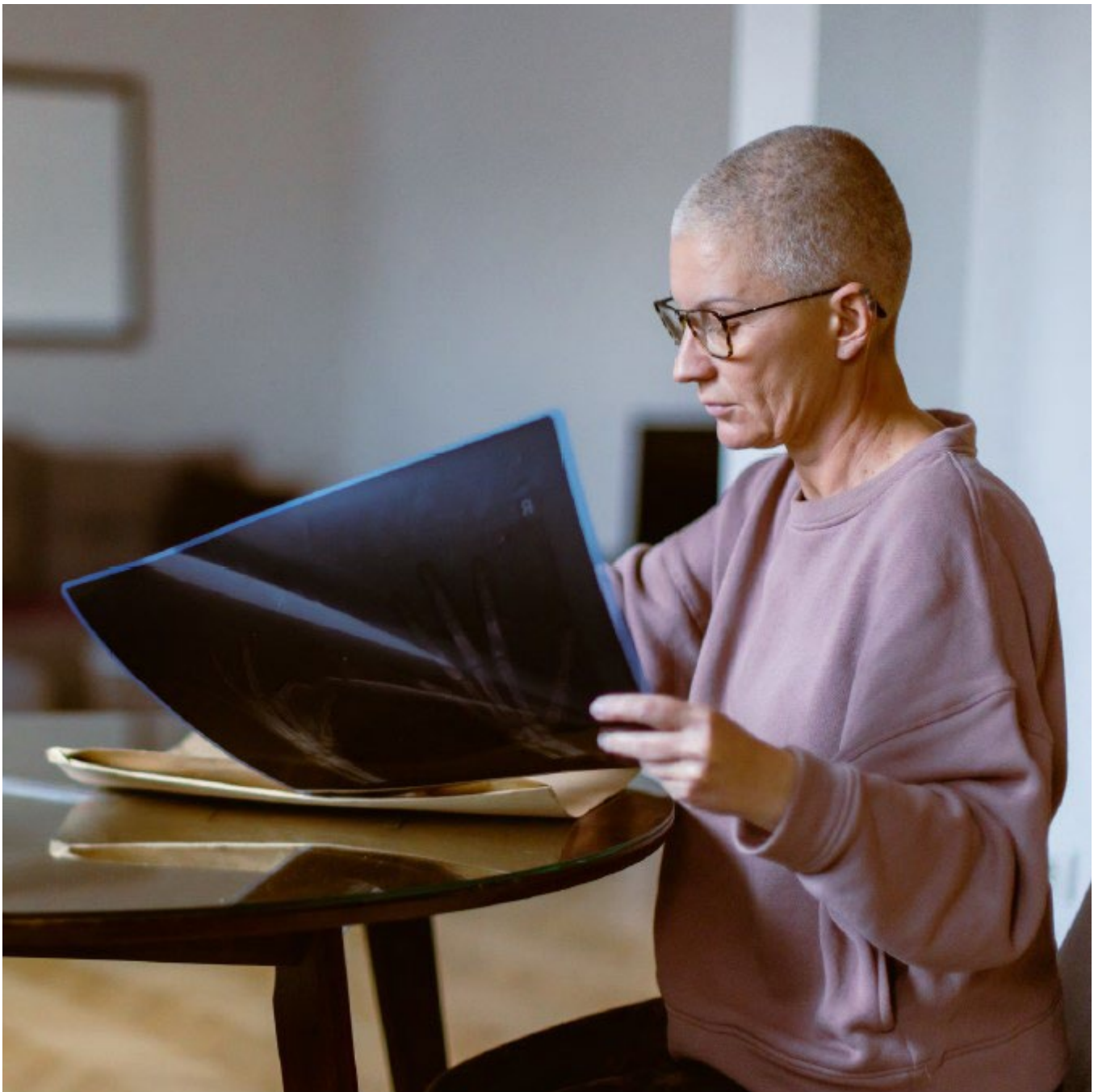


National Audit of Metastatic Breast Cancer

State of the Nation Report 2024

Methodological Supplement



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



ASSOCIATION OF
BREAST SURGERY

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



UKBCG

The UK Breast Cancer Group (UKBCG) is a forum for Clinical and Medical Oncologists. The UKBCG acts as a stakeholder to NICE, NHS England and other organisations; and undertakes key pieces of work, at times in collaboration with other bodies, with the overriding endpoint of improving patient care.

The Group's objectives include advancing the education of clinical and medical oncologists in the subject of breast cancer, concerning its identification, diagnosis and treatment; promoting research for the public benefit in all aspects of breast cancer and publishing the results; and assisting in the treatment and care of persons suffering from breast cancer, or in need of rehabilitation, by the provision of education for healthcare professionals.

Further information on the work of the UKBCG is communicated via this website on a regular basis <https://ukbcg.org/>. Registered charity no: 1177296



NATIONAL DISEASE REGISTRATION SERVICE

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



Rhwydwaith
Cancer Cymru
Wales Cancer
Network

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

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Introduction

This document accompanies the National Audit of Metastatic Breast Cancer (NAoMe) State of the Nation (SotN) Report. The purpose of this document is to provide detail on the data sources and methods used to manage and analyse the data included within the SotN report.

Overview of audit design

Inclusion and exclusion criteria

The NAoMe aims to include all people diagnosed with metastatic breast cancer. The NAoMe defines metastatic breast cancer as breast cancer that has spread beyond the breast and regional lymph nodes. There are two distinct cohorts of people with metastatic breast cancer identified within NAoMe (Table 1):

- 1) “De-novo” metastatic breast cancer – metastatic disease identified at initial diagnosis.
- 2) Recurrent metastatic breast cancer – metastatic disease identified following initial treatments for primary breast cancer.

The approach outlined in Table 1 is required for the identification of the recurrent cohort. This is because information regarding the date and type of recurrent disease is largely missing in both English and Welsh cancer datasets. We acknowledge that this approach will not identify all patients with recurrent breast cancer.

Table 1. Definitions of the de-novo and recurrent cohorts of people with metastatic breast cancer used in the 2024 State of the Nation Report.

<i>De-novo cohort</i>
People who had an initial diagnosis of Stage 4 breast cancer (2019-2021) OR People with an initial diagnosis of Stage 0-3 (or unknown stage) breast cancer between January 2019 and December 2021 and who had an ICD-10 diagnosis code of MBC in HES (England) or PEDW (Wales) data within 12 months of their initial date of diagnosis. The latter group corresponds to the individuals who were only found to have metastatic disease after treatment commenced.
<i>Recurrent cohort</i>
Step 1: We identified people with an initial diagnosis of stage 0-3 (or unknown stage) breast cancer between January 2015 and December 2021 and who had an ICD-10 diagnosis code of MBC in HES (England) or PEDW (Wales) admissions data at least 12 months after their initial date of diagnosis. The 12-month threshold is used by the NAoMe because metastatic disease may be identified after treatment commenced. Step 2: The cohort was limited to those people identified in step 1 whose first admission (day case or overnight) containing an MBC diagnosis was between January 2019 and December 2021.

De-novo cohort

Women and men were included for analysis within the SotN 2024 Report if they met the following criteria:

- Aged 18 years or over at the point of diagnosis (no upper age limit).
- Registered diagnostic ICD-10 code of C50 (invasive breast cancer) or D05.1 (ductal carcinoma in-situ (DCIS)).
- Evidence of metastatic disease (Stage 4) with a valid diagnosis date from 1st January 2019 to 31st December 2021
- Evidence of primary breast cancer (Stage 0 to Stage 3, or unknown) and evidence of metastatic breast cancer within 12 months of the initial date of diagnosis.

Recurrent cohort

- Aged 18 years or over at the point of diagnosis (no upper age limit).
- Initial diagnosis of primary breast cancer (Stage 0 to Stage 3, or unknown) at presentation between 1st January 2015 and 31st December 2021 (England) or 31st December 2022 (Wales).
- Evidence of metastatic disease (Stage 4) in Hospital Episode Statistics (HES) or Patient Episode Database for Wales (PEDW) data at least 12 months after the initial date of diagnosis
- First date of admission containing metastatic disease between 1st January 2019 and 31st December 2021.

Women and men were excluded from both cohorts for analysis if they met the following criteria:

- Breast cancer reported on the death certificate only.
- Date of diagnosis corresponds to date of death.
- Previous diagnosis of breast cancer before 1st January 2015. *This exclusion was not possible for England within this cohort of patients and was applied for Wales only.*
- Bilateral breast cancer. *This exclusion was not possible for England within this cohort of patients (laterality information not provided) and was applied for Wales only.*
- Multiple cancer registrations during the audit period.
- Diagnosed and treated outside of an NHS organisation in England or Wales.
- Place of diagnosis not provided, or the patient is assigned to an NHS organisation with no active breast unit.
- Diagnosed and treated within an NHS organisation with less than 30 allocated registrations of breast cancer per year.

Sources of Data

Patient-level data on many aspects of breast cancer care are routinely collected in hospitals and mandatorily submitted to national organisations. These existing electronic data flows are used by the NAOme to reduce the burden of data collection on staff and patients.

The NAOme uses this patient data, collected by the National Cancer Registration and Analysis Service (NCRAS) in England¹ and the Wales Cancer Network (WCN), to report on breast cancer care for all people aged 18 years and over diagnosed with either de-novo or recurrent metastatic breast cancer. [Appendix 1](#) provides more detail on the data sources listed above and the information they contain.

English datasets

For patients in England, the NCRAS provided data from its Cancer Analysis System (CAS), which collates patient data from a range of national data feeds across all NHS acute hospitals.

These data feeds include:

- National cancer registrations, including information directly from hospital pathology systems.
- Cancer Outcomes and Services Dataset (COSD) data items.
- Systemic Anti-cancer Therapy (SACT) data.
- Radiotherapy dataset (RTDS).
- Hospital Episode Statistics (HES) data, including Admitted Patient Care (APC), Outpatients (OP), and Accident & Emergency (A&E) data.
- Office for National Statistics (ONS), including date and cause of death.
- Primary Care Prescription Database (PCPD), including information on endocrine therapy.

¹ As with cancer registries in other countries, cancer registrations in England can take up to 5 years after the end of a given calendar year to reach 100% completeness and stability. NDRS uses an active system of gathering information on cancer diagnoses from multiple sources across the patient pathway. Completeness varies by tumour type because different patient pathways provide different opportunities for data flows into NDRS. The 'Gold standard' cancer registration dataset that is used in cancer statistics bulletins and available for analysis outside of NDRS contains over 98% of all the people that will eventually be found by the registration process, and the completeness for a calendar year of data increases over time. More information about the cancer registration process can be found [here](#).

Data from the above sources were provided for the cohort of people diagnosed from 1st January 2015 to 31st December 2021². These data were used to describe the care, treatment and outcomes of all people with metastatic breast cancer in England.

Welsh datasets

For patients in Wales, the WCN provided national cancer registrations data using the Cancer Network Information System Cymru (Canisc) electronic patient record system. The cancer record for each patient was linked to the following data:

- Patient Episode Database for Wales (PEDW).
- Office for National Statistics (ONS), including date and cause of death.

Data from the above sources were provided for the cohort of people diagnosed from 1st January 2015 to 31st December 2022. These data were used to describe the care, treatment and outcomes of all people with metastatic breast cancer in Wales.

Data Definitions

Coding of key data items

Diagnosis date

The date of diagnosis³, which is used to define the audit group and subsequently used within relevant analyses, was provided within the Cancer Registration dataset for English patients and within the Canisc dataset for Welsh patients. This is calculated using a methodology in accordance with the European Network of Cancer Registries. NB: The date of metastatic recurrence was not available within the datasets provided and was estimated using the approach described in Table 1.

Death

Record of death for an individual patient was coded where a date of death was provided within the ONS data.

Censoring date for patients alive at the end of the audit period

For those patients with no ONS date of death, a “date last known alive” or censoring date is calculated for use in any survival analyses.

- For English patients provided by the NCRAS, this is taken to be the vital status date provided. If this date is missing, the day after the last reported date of death is used.
- For Welsh patients, the day after the last reported date of death is used.

Treatment allocation

Chemotherapy or targeted therapy

For England, the SACT data item “drug group” was used to identify those who received treatment with chemotherapy or targeted therapy. Records of specific drugs were used to flag chemotherapy or targeted therapy for patients treated in England.

For chemotherapy, this included: cabazitaxel, capecitabine, carboplatin, cisplatin, cyclophosphamide, docetaxel, doxorubicin, epirubicin, eribulin, etoposide, fluorouracil, gemcitabine, methotrexate, mitomycin, mitoxantrone, paclitaxel, vindesine, and vinorelbine. For CDK4/6 inhibitors, this included: abemaciclib, palbociclib and ribociclib. For anti-HER2 treatments, this included: alemtuzumab, gemtuzumab, herceptin, herzuma, lapatinib, neratinib, ontruzant,

² <https://www.natcan.org.uk/resources/timeliness-of-the-national-cancer-registration-dataset-ncrd/>

³ Based on the data available this was the date of biopsy for most cases.

pertuzumab, phesgo, syd985, trastuzumab, trazimera and tucatinib.

For Wales, Canisc data were used to flag use of chemotherapy. Within the Welsh data there was no information on the drug used or cycle dates. This meant that any analysis beyond a “Yes/No” receipt of chemotherapy was not possible. There is also no information on targeted therapies within the Welsh data.

Endocrine therapy

For England, the PCPD data were used to identify those patients who received treatment with endocrine therapy for the purposes of risk-adjustment.

For Wales, Canisc data are used to flag use of endocrine therapy. Again, within the Welsh data, there is no information on the drug used or cycle dates so analysis beyond a “Yes/No” receipt of endocrine therapy is not possible.

Patient characteristics

The NAOme uses data on patient characteristics provided from several data sources. Broadly, information on patient characteristics is captured within the cancer registry datasets (Cancer Registration and Canisc), typically being measured or captured around the time of diagnosis. The NAOme focuses on patient demographics and measures of fitness.

Patient fitness

For most analyses, where patient fitness is accounted for, the NAOme is interested in the fitness of a patient at the point of diagnosis / recurrence, and when treatment decisions are made. This is because the NAOme aims to understand what patient and tumour factors influence the choice of treatment(s) offered to a patient. These factors are considered when the audit produces information by individual NHS organisation so their statistics can be compared even though their patient populations may vary.

World Health Organisation (WHO) performance status (PS)

The World Health Organization (WHO) performance status (PS) classification is a measure of how disease(s) can affect a person’s ability to manage on a daily basis, [Oken *et al* 1982] and ranges from a score of 0 (fully active) to 4 (Completely disabled; cannot carry on any selfcare; totally confined to bed or chair).⁴ The NAOme uses various sources of data on WHO PS to understand treatment decisions for a patient; the table below highlights where the value is recorded in the data the NAOme receives (see [Appendix 2](#) for the definition of each WHO PS value).

Table 2. Sources of WHO Performance Status information.

WHO Performance Status sources		
Country	Source	Associated date
England	COSD	MDT discussion date
England	SACT	Regimen/cycle start date
Wales	Canisc	Investigation date

WHO PS at diagnosis / recurrence is then calculated for a patient based on the following criteria:

- There is a valid recorded value (e.g., between 0 and 4).
- The value provided has an associated date that is prior to the date of treatment starting⁵ and within two months of diagnosis.

Where there are multiple records of a patient’s WHO PS that fulfil the above criteria, the value closest to diagnosis is taken. Where multiple values have the same date the highest value (i.e. worst health) is taken. Historically, this

⁴ Oken MM, Creech RH, Tormey DC, Horton J, Davis TE, McFadden ET, et al. Toxicity and response criteria of the Eastern Cooperative Oncology Group. American Journal of Clinical Oncology. 1982;5(6):649-56

⁵ Based on dates for surgery or anti-cancer treatments.

information is poorly recorded for breast cancer patients within routine data.

Charlson Comorbidity Index (CCI)

The presence of comorbidities is not captured within a single data item by the national registration services. The NAOme team therefore uses the Royal College of Surgeons of England (RCS) modified Charlson Comorbidity Index (CCI) [Armitage *et al* 2010]⁶ to describe these. The CCI is a commonly used scoring system for medical comorbidities, consisting of a grouped score calculated based on the absence (0) and presence (≥ 1) of 14 pre-specified medical conditions ([Appendix 3](#)).

The CCI was calculated using information on secondary diagnoses (ICD-10 codes) recorded in HES APC/PEDW within the 24-month period prior to a patient's diagnosis.

For the purpose of analysis, the CCI is grouped into three categories:

- **0** - none of the 14 pre-specified comorbidities.
- **1** - only 1 of the 14 pre-specified comorbidities.
- **2+** - 2 or more of the 14 pre-specified comorbidities.

Secondary Care Administrative Records Frailty (SCARF) Index

Among older patients, frailty plays an important role in what breast cancer treatments are offered to patients. This is because in those who are frail, the ability to tolerate stressors such as surgery, radiotherapy or chemotherapy may be significantly reduced, which can lead to morbidity and mortality. NHS organisations are recommended to screen for frailty using a formal assessment tool, although assessment is limited by the lack of an agreed instrument and the potential inaccuracies of simple tools.

The Secondary Care Administrative Records Frailty (SCARF) Index⁷ is based on the 'cumulative deficit' model [Clegg *et al* 2016], and describes frailty in relation to 32 different symptoms, signs, diseases and disabilities (referred to as deficits; [Appendix 4](#)). The index translates the 32 deficits into ICD-10 codes and counts the number of deficits in HES APC/PEDW records within the 24-month period prior to a patient's diagnosis. This methodology, described in the publication by Jauhari *et al.*, was internally validated and produces the type of pattern that would be expected from a measure of frailty.

Tumour characteristics

The NAOme uses data on tumour characteristics provided from several data sources. [Appendix 5](#) defines the key tumour characteristics in terms of the data source and what analyses they are used in.

Staging for patients in the de-novo cohort

For people whose overall breast cancer stage is not reported in the primary data sources, overall staging is calculated from the individual T, N, M stage, using the UICC TNM classification system ([Appendix 6](#)).

People are reported as having "unknown" overall stage, if there is lack of full information on all three TNM components, or if the stage recorded in the datasets contradicts the ICD-10 diagnosis (e.g., stage 0 recorded for ICD-10 code of C50, invasive cancer). Where the ICD-10 code D05 (non-invasive) is recorded with no associated stage information, stage is assumed to be "0".

Additionally, ICD-10 diagnosis codes recording secondary cancer within hospital admissions data are used to identify evidence of metastatic disease within HES and PEDW.

⁶ Armitage JN, van der Meulen JH, Royal College of Surgeons Co-morbidity Consensus G. Identifying co-morbidity in surgical patients using administrative data with the Royal College of Surgeons Charlson Score. *Br J Surg*. 2010;97(5):772-81.

⁷ Jauhari Y, Gannon MR, Dodwell D, *et al.* Construction of the secondary care administrative records frailty (SCARF) index and validation on older women with operable invasive breast cancer in England and Wales: a cohort study. *BMJ Open* 2020;10:e035395. doi: 10.1136/bmjopen-2019-035395

Completeness of key data items

Appendix 5 summarises the key data items used in the 2024 SotN report. Various clinical factors will inform treatment options for people with MBC alongside patient preferences. These factors include tumour biology, disease distribution and burden, organ function, physical fitness, menopausal status, and previous treatments. The recording of this clinical information in national cancer datasets is vital to understand patterns of care within the NHS.

Complete information about the date and type of recurrent disease is fundamental for the effective running of the NAOme. In relation to the de-novo cohort, the completeness of clinical factors collected at the time of diagnosis was excellent for age at diagnosis and sex but was lower for other items, particularly performance status (England and Wales) and oestrogen and progesterone receptor (ER / PR) status and human epidermal growth factor receptor 2 (HER2) status. Data completeness for ER status for England is lower than in previous [NABCOP](#) annual reports due to a new method of analysis. The percentage reported here reflects the data quality as received by the NAOme, without augmentation with data for endocrine therapy prescription, to highlight the need for improved data quality.

Indicator definitions

The NAOme uses key indicators to monitor progress against the audit's healthcare improvement goals. These indicators align with national guidelines and standards.

Definitions of how the eight indicators included in the 2024 SotN report were derived from data for England and Wales are described in Table 3. Some indicators are further focused on subgroups of patients as defined by sex and stage of the disease, as these factors are important determinants of whether particular treatments are suitable for patients.

Table 3. Indicator definitions for the 2024 SotN report.

Indicator	Cohort	Numerator	Denominator	Risk-adjustment (see appendix 7)
Percentage of patients with newly diagnosed metastatic breast cancer (MBC) discussed in a multi-disciplinary team (MDT).	De-novo	Number of people who are discussed at an MDT. For England and Wales, there is a dedicated data item for MDT discussion. This was considered to be a “Yes” if there was a record of MDT discussion either 30 days before or after the date of diagnosis.	All people included in the reporting period, with de-novo metastatic breast cancer.	No
Percentage of patients with recurrent MBC who had a metastatic lesion biopsied to inform care.	Recurrent	Number of people who have the metastatic lesion biopsied to reassess for the ER and HER2 status. England - this was reported as “Yes” if there was a record of a biopsy either 30 days before or after a diagnosis of recurrent metastatic breast cancer. Wales - information was not available for Wales.	All people included in the reporting period, with recurrent metastatic breast cancer.	No
Percentage of patients who had reported contact with a Clinical Nurse Specialist (CNS).	De-novo	Number of people who have contact with a CNS. For England and Wales, there is a dedicated data item for CNS contact.	All people included in the reporting period, with de-novo metastatic breast cancer.	No
Percentage of patients with ER positive MBC who received CDK 4/6 inhibitors as first line treatment.	De-novo	Number of people who have treatment with a CDK 4/6 inhibitor initiated. England - reported as “Yes” if there was a record of use of a CDK 4/6 inhibitor within 12 months of the date of diagnosis in the SACT dataset. Wales - information was not available for Wales.	All people included in the reporting period, with de-novo metastatic breast cancer with ER positive and HER2 negative or unknown status. Excludes people who died within 30 days of diagnosis.	Yes
Percentage of patients with HER2 positive MBC who received anti-HER2 therapy as first line treatment.	De-novo	Number of people who have treatment with an anti-HER2 therapy initiated. England - reported as “Yes” if there was a record of use of anti-HER2 therapy within 6 months of the date of diagnosis in the SACT dataset. Wales - information was not available for Wales.	All people included in the reporting period, with de-novo metastatic breast cancer with HER2 positive disease. Excludes people who died within 30 days of diagnosis.	Yes

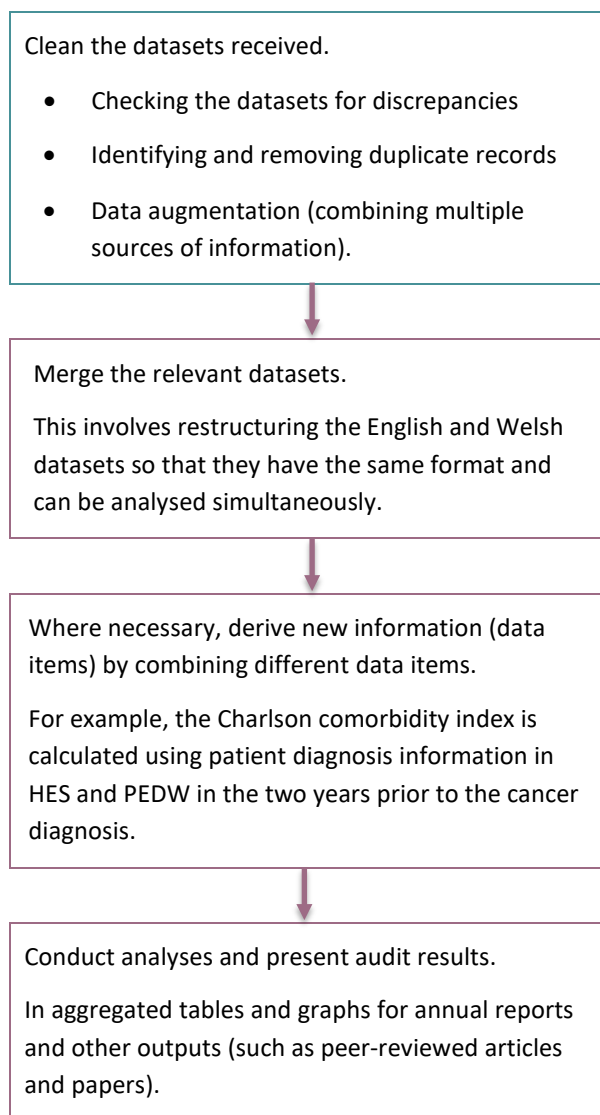
Indicator	Cohort	Numerator	Denominator	Risk-adjustment (see appendix 7)
Percentage of patients who received chemotherapy.	De-novo	Number of people who have treatment with chemotherapy initiated. For England and Wales, this was reported as “Yes” for the de-novo cohort if there was any record of use of chemotherapy.	All people included in the reporting period, with de-novo metastatic breast cancer.	Yes
	Recurrent	Number of people who have treatment with chemotherapy initiated. England - reported as “Yes” if there was a record of use of chemotherapy after the date of recurrence, or within 30 days before the date of recurrence if this was more than 12 months after the initial diagnosis. Wales - information was not available for Wales for the recurrent cohort.	All people included in the reporting period, with recurrent metastatic breast cancer.	Yes
Percentage of patients with death recorded within 30 days of a chemotherapy cycle.	De-novo Recurrent	Number of patients who die within 30 days of a chemotherapy cycle. England - reported as “Yes” if there was a record of death within 30 days of the last cycle of any chemotherapy recorded in the SACT dataset. This was the same for both the de-novo and recurrent cohorts. Wales - information was not available for Wales.	All women included in the reporting period, with de-novo or recurrent metastatic breast cancer. Men were excluded from this analysis due to small numbers.	Yes
Percentage of patients who survived at least 1 or 3 years from the date of breast cancer diagnosis.	De-novo	Number of patients who survive for at least 1 or 3 years from the date of breast cancer diagnosis. For England and Wales, ONS mortality data was used to ascertain date of death.	All people included in the reporting period, with de-novo metastatic breast cancer.	No – presentation of national figures only

Statistical Analysis

Preparation for analysis

The NAOme project team, based at the National Cancer Audit Collaborating Centre (NATCAN)⁸ in the Clinical Effectiveness Unit (CEU)⁹ received the national data from NCRAS and WCN between February and March 2024. A series of steps are performed to prepare these complex and large datasets for analysis.

Specifically, using specialised statistical software¹⁰, the project team:



Analysis

All statistical analyses were conducted using Stata version 17.

Most results in the NAOme 2024 SotN Report are descriptive. The results of categorical data items are reported as percentages (%). Results are typically provided as an overall figure and broken down by diagnosing NHS organisation, by age at diagnosis or by sex. Note that within tables in the SotN Report, the total percentage may not equal 100%, due to rounding

⁸ The NATCAN is the home of the ten national cancer audits in England and Wales.

⁹ The CEU is an academic collaboration between The Royal College of Surgeons of England and the London School of Hygiene and Tropical Medicine, and undertakes national clinical audits and research. Since its inception in 1998, the CEU has become a national centre of expertise in methods, organisation, and logistics of large-scale studies of the quality of surgical care.

¹⁰ Stata® is a statistical package for data analysis, data management, and graphics (<https://www.stata.com/>)

Overall survival

Overall survival was calculated within Stata using Kaplan-Meier survival analysis methods. 1- and 3-year overall survival was calculated from the date of breast cancer diagnosis using ONS mortality data.

For those patients with no ONS date of death, a “date last known alive” or censoring date was calculated for use in survival analyses.

- For English patients provided by the NCRAS, this was taken to be the vital status date provided; where this date was missing, the day after the last reported date of death was used.
- For Welsh patients, the day after the last reported date of death was used.

We follow the Office for National Statistics (ONS) policy on the publication of small numbers to minimise the risk of patient identification from these aggregate results. Within figures showing findings by NHS organisation, percentages are not presented for those NHS organisations with less than 10 patients within the patient group of interest, over the audit period. Where additional data is suppressed to prevent back-calculation of suppressed data, the risk-adjusted percentage is retained (if a risk-adjusted percentage is provided).

NHS organisations

The NAOme presents organisation-level findings by the NHS organisation of diagnosis / metastatic recurrence. This is because this is the organisation where care decisions are likely to be made. Where this information is not provided for a patient or where the organisation assigned does not fulfil the pre-specified inclusion criteria¹¹ for including the patient in the NAOme, the following steps are followed to assign a diagnosing NHS organisation:

1. Use the surgery provider code (as provided within HES/PEDW) which fulfils the NAOme pre-specified inclusion criteria; use the provider code associated with the earliest record of primary surgery (breast conserving surgery or mastectomy).
2. Use the MDT provider code for English patients, which fulfils the NAOme pre-specified inclusion criteria; use the provider associated with the earliest MDT discussion date.

Patients diagnosed and treated across both England and Wales cannot be linked across the two national data sources within the routine datasets used by the audit, as no patient identifiable data are released. Thus, patients provided by the NCRAS can have a Welsh local health board code assigned, with no further record of treatment within an English NHS trust, or vice versa. These patients cannot be included in the NAOme analysis due to the uncertainty around whether the full care pathway for such a patient is captured within the data provided.

Any NHS organisations with the equivalent of fewer than 30 people diagnosed with breast cancer each year are not included in audit reporting. Additionally, there are tertiary centres that mainly provide oncological treatment for people with breast cancer. This includes the Christie NHS Foundation Trust, Clatterbridge Cancer Centre NHS Foundation Trust, and Velindre NHS Trust. These tertiary centres are not included directly within audit outputs where findings are reported by the diagnosing NHS organisation. This is because patients are not diagnosed at these centres.

For each of the scenarios above, where possible, any patients recorded as being diagnosed at one of these centres were reassigned to the NHS organisation where the primary diagnostic multidisciplinary team meeting took place or where surgery was undertaken.

¹¹ A private hospital code provided; the organisations diagnoses less than 30 patients aged 50+ years with breast cancer each year; the organisation is a tertiary centre; the hospital is in a different country to the data provider; the organisation has no active breast unit.

Risk adjustment of indicators

For analyses evaluating receipt of different treatments across NHS organisations, statistical models were fitted to calculate a “risk-adjusted” percentage to account for differences in case-mix, allowing comparison across NHS organisations. Such models included clinically relevant patient and tumour factors likely to contribute to treatment decisions.

The models were then used to estimate the probability of an individual having the treatment; these individual probabilities were summed to calculate an expected number of outcomes. This was combined with the observed outcomes to produce the risk-adjusted indicator value for each NHS organisation (a method known as indirect standardisation). Details of the patient and tumour characteristics adjusted for are provided in the data tables and within [Appendix 7](#).

Handling of missing data

Missing values were imputed to create an estimated value, to ensure all patients contributed to the statistical models used for risk adjustment.

Presentation of results

Cancer system

Results are presented within the 2024 SotN report and accompanying data tables at a national level (England and Wales separately) and organisational level. At organisational level, there are 114 English NHS trusts and 6 Welsh local health boards for which data is provided. In addition, there are 20 English NHS Cancer Alliances which provide regional level information. The NATCAN frequently asked questions (number 17) provides information on the NATCAN outlier policy¹².

¹² <https://www.natcan.org.uk/faqs/faqs-for-professionals/>

Appendix 1: Routine data sources

Overview of the data sources and content provided for the NAOme SotN Report.

Country	Data source	Content
England	Cancer registry	Data on all aspects of the cancer registration including information from hospital pathology systems.
England	COSD	Cancer Outcomes and Services dataset (COSD) 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	SACT	Systemic Anti-Cancer Therapy (SACT) data contains information on chemotherapy dates, regimen(s) and dose(s).
England	RTDS	Radiotherapy dataset (RTDS) contains information on radiotherapy treatment including dates, prescription region and dose.
England	HES	Hospital Episode Statistics (HES) is the administrative database of all NHS hospital admissions in England; records were supplied by NHS Digital to NCRAS.
England	PCPD	Primary Care Prescription Database (PCPD) contains information on the use of endocrine therapy.
Wales	Canisc	Cancer Network Information System Cymru (Canisc) contains data on all aspects of the cancer registration including investigations.
Wales	PEDW	Patient Episode Database for Wales (PEDW) is the administrative database of all NHS hospital admissions in Wales.
Wales	RTH	Radiotherapy data (RTH) contains information on radiotherapy treatment.
England & Wales	ONS	Office for National Statistics (ONS) death data including date of death and cause of death.

Appendix 2: WHO Performance Status

WHO Performance Status values and corresponding definition.

WHO Performance Status	Definition
0	Fully active, able to carry on all pre-disease performance without restriction.
1	Restricted in physically strenuous activity but ambulatory & able to carry out work of a light or sedentary nature.
2	Ambulatory and capable of all self-care but unable to carry out any work activities. Up & about more than 50% of waking hours.
3	Capable of only limited self-care, confined to bed or chair more than 50% of waking hours.
4	Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair.
5	Dead.

Appendix 3: Charlson Comorbidity Index

Pre-specified conditions included in the assignment of Charlson Comorbidity Index.

Conditions			
Myocardial infarction	Dementia	Diabetes mellitus	Metastatic solid tumour
Congestive cardiac failure	Chronic pulmonary disease	Hemiplegia or paraplegia	AIDS/HIV infection
Peripheral vascular disease	Rheumatological disease	Renal disease	
Cerebrovascular disease	Liver disease	Any malignancy	

Appendix 4: Secondary Care Administrative Records Frailty Index

Pre-specified deficits included in the calculation of the Secondary Care Administrative Records Frailty Index.

Deficit			
Activity limitation	Diabetic complications	Hypotension	Requirement for care
Anaemia	Falls	Ischaemic heart disease	Respiratory disease
Arthritis	Foot problems	Incontinence	Skin ulcer
Cardiac arrhythmias	Fragility fracture	Neurodegenerative disorders	Sleep disturbance
Cerebrovascular disease	Hearing impairment	Nutritional Problems	Social vulnerability
Chronic kidney disease	Heart failure	Osteoporosis	Thyroid disease
Cognitive and mental health problems	Heart valve disease	Peptic ulcer	Urinary system disease
Diabetes	Hypertension	Peripheral vascular disease	Visual impairment

Appendix 5: Key Data Items

Details of data items used within the NAOme SotN Report including data source and where they are used.

Item	Where data comes from		Indicator
	England	Wales	
Identification of NAOme de-novo cohort or NAOme recurrent cohort	ICD-10 codes in HES within 12 months of diagnosis	ICD-10 codes in PEDW– within 12 months of diagnosis	Definition of cohort; source of metastases
Non-invasive grade	COSD BR4160	Canisc	Data completeness: risk-adjustment
Invasive grade	COSD BR4170	Canisc	Data completeness; risk-adjustment
ER status	COSD BR4220 COSD BR4230 (ER Score)	Canisc	Recorded molecular marker status; risk-adjustment
HER2 status	COSD BR4280 COSD BR4310 (HER2 ISH)	Canisc	Recorded molecular marker status; risk-adjustment
PR status	COSD BR4290 COSD BR4300 (PR Score)	Canisc	Data completeness
Tumour stage	COSD CR0520 COSD CR0620 COSD CR0910	Canisc	Data completeness; risk-adjustment
Source of metastases	COSD CR6970	Canisc	Identification of NAOme de-novo cohort and stage; risk-adjustment
Nodal stage	COSD CR0540 COSD CR0630 COSD CR0920	Canisc	Data completeness; risk-adjustment
Overall stage	COSD CR0580 COSD CR0610 COSD CR0940	<i>Not available</i>	Data completeness; risk-adjustment
WHO performance status	COSD CR0510 SACT	Canisc	Data completeness
Multidisciplinary team discussion	COSD CR3080 COSD CR0430 COSD CR3190	Canisc	MDT discussion
Biopsy of metastatic lesion	COSD CR1010	<i>Not available</i>	Biopsy of metastatic lesion
Clinical Nurse Specialist indication code	COSD CR2050	Canisc	Contact with a CNS after diagnosis, data completeness

Appendix 6: Breast Cancer TNM stage groupings

Stage grouping	T stage	N stage	M stage	
DCIS / Stage 0	Tis	N0	M0	Key: Tumour size – T1 = 1-20mm; T2 = 21-50mm; T3 = 51+mm; T4 = tumour spread to skin or chest wall. Nodal status – N0 = no cancer cells in lymph nodes; N1-3 = increasing spread of cancer within lymphatic system; mi = micro-metastases.
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	

Appendix 7: Risk-adjusted indicators

Details of the characteristics adjusted for in those figures within the NAOme 2024 SoTN Report Data Tables.

Indicator	Characteristics included in risk-adjusted statistical model
Percentage of people with ER positive MBC who received CDK 4/6 inhibitors as first line treatment	Logistic regression models fitted with age (spline), grade, source of metastases, Charlson comorbidity index, SCARF index, diagnosis year.
Percentage of people with HER2 positive MBC who received anti-HER2 therapy as first line treatment	Logistic regression models fitted with age (spline), grade, source of metastases, ER status, Charlson comorbidity index, SCARF index, diagnosis year.
Percentage of people who received chemotherapy	Logistic regression models fitted with age (spline), grade, source of metastases (de-novo only), Charlson comorbidity index, SCARF index, diagnosis year, ER status, HER2 status, diagnosis year.
Percentage of women with death recorded within 30 days of a chemotherapy cycle	Logistic regression models fitted with age (linear), grade, source of metastases (de-novo only), Charlson comorbidity index (de-novo only), SCARF index, diagnosis year, ER status, HER2 status, diagnosis year.