Real-World Study of Breast Cancer Epidemiology and Treatment Patterns: A Pilot Study to Assess Electronic Health Record–Derived Data in the United Kingdom

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Conclusions

- In the first published analysis evaluating outcomes in patients with breast cancer (BC) from the Flatiron Health Research Database-United Kingdom, subtype distributions and outcomes were aligned with national benchmarks from the United Kingdom (UK)[1-3]
- Most patients in this BC cohort were diagnosed with early BC (eBC) compared with those diagnosed with de novo metastatic BC (mBC). The proportion of patients with eBC who later developed mBC was similar to those diagnosed with de novo mBC
- The majority of patients with eBC received adjuvant treatment only; most patients were alive at the end of the study period
- In line with expectations, patients with eBC had longer real-world overall survival (rwOS) than those with mBC; triple-negative breast cancer (TNBC) was associated with shorter rwOS than other subtypes
- As dataset coverage expands across National Health Services (NHS) Trusts, this electronic health record (EHR)-derived data may fill an unmet need for timely, robust evidence to inform breast cancer care and policy in the UK

Plain Language Summary

New cancer treatments are tested in clinical trials. However, it is important to collect information from routine clinical practice ("real-world evidence") once the treatments are approved. The researchers used a new database that included existing hospital data to look at treatment patterns and patient survival for breast cancer in the United Kingdom. They found that most people with breast cancer are diagnosed in early stages, and most of those people receive adjuvant therapy (treatment with drugs after surgery). People with early-stage breast cancer survived much longer than those with metastatic breast cancer (breast cancer that has spread to other parts of the body), and people with the triple-negative breast cancer subtype had shorter survival than other subtypes. This information aligns with similar datasets gathered in the United Kingdom and could be used in the future to provide important information that could inform breast cancer care.

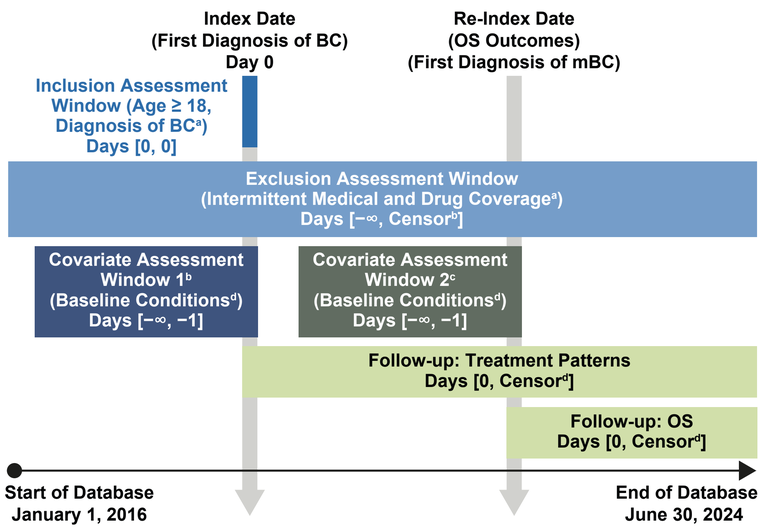
Introduction

- Robust real-world evidence (RWE) is critical for advancing BC care in the UK, yet most data are derived from clinical trials, limiting generalizability
- Existing UK data sources, including national registries, are constrained by limited clinical detail and delayed data availability
- To address these gaps, we utilized the Flatiron Health database of oncology EHR-derived RWE
- The aim of this study was to describe patient demographics, clinical and tumor characteristics, treatment patterns, and clinical outcomes of patients with eBC and mBC

Methods

- This UK-based RWE study used NHS EHR-derived RWE data from 1665 patients in the Leeds Teaching Hospitals NHS Trust (LTHT) network
  - LTHT serves ~5.4 million people, with > 1.5 million patient contacts annually across seven hospitals
  - LTHT provides secondary care (eg, diagnostics, treatments, surgeries) accessed via general practitioner referrals
  - Data were anonymized in Flatiron Health's Trusted Research Environment by removing personal identifiers and included in the Breast Cancer Flatiron Health Research Database[4,5]
- Patients (≥ 18 years) diagnosed with BC and who had at least 2 documented clinical visits recorded in the Flatiron Health database within the study period (January 1, 2016 to June 30, 2024) were included (**Figure 1**)
- BC subtypes were:
  - HR+ (estrogen receptor [ER]/progesterone receptor [PR] ≥ 1% by immunohistochemistry [IHC]) and HER2– (IHC0/1 or 2+ and fluorescence in situ hybridization [FISH] negative) BC
  - HER2+ (IHC 2+ and FISH positive or IHC3+, regardless of HR status) BC
  - TNBC (ER and PR < 1% by IHC and HER2–)
- Patients whose BC subtype changed over time were excluded
- For outcomes analyses, patients were required to have at least 1 year of data; date of diagnosis must be within the outcomes identification period, which ended June 30, 2023

Figure 1. Study Design



[a]At least 2 documented clinical visits recorded in the Flatiron Health database occurring during the study period. [b]Assessment in patients with eBC. [c]Assessment in patients who had de novo mBC and in those who had eBC and later developed mBC. [d]Patients who were still alive at the end of the outcomes identification period or lost to follow-up were censored at their last confirmed activity date.
BC, breast cancer; eBC, early breast cancer; mBC, metastatic BC; OS, overall survival.

- Patient demographics, clinical and tumor characteristics, and treatment patterns were described for patients with eBC and mBC
- Treatment patterns up to third-line (3L) therapy were summarized, including most common systemic regimens and treatment sequences from BC diagnosis to earliest of last activity date, end of data availability, death, or completion of 3L therapy
- rwOS was assessed by the Kaplan-Meier method from date of BC diagnosis (eBC or de novo mBC) to death from any cause. In patients with metastatic disease, rwOS was assessed from mBC diagnosis to death from any cause. Patients still alive at end of follow-up were censored at last activity date
- Real-world invasive disease-free survival (rw-iDFS; time from surgery until first occurrence of invasive breast cancer recurrence, distant recurrence, second primary invasive cancer, or death from any cause) was assessed in patients with eBC using the Kaplan-Meier method

Results

- Of 1665 patients in the dataset, 1451 met the inclusion criteria (**Table 1**)
  - Mean age was 63 years and 99% were female
  - Most patients (92%) had eBC, among whom 89% underwent surgery
  - Subtype distribution was 74% HR+/HER2− BC, 16% HER2+ BC, and 11% TNBC
  - Eastern Cooperative Oncology Group (ECOG) performance status was unknown/not documented in 93% of patients
  - Among patients with mBC, more had recurrent mBC (58%) than de novo mBC (43%)

Results (continued)

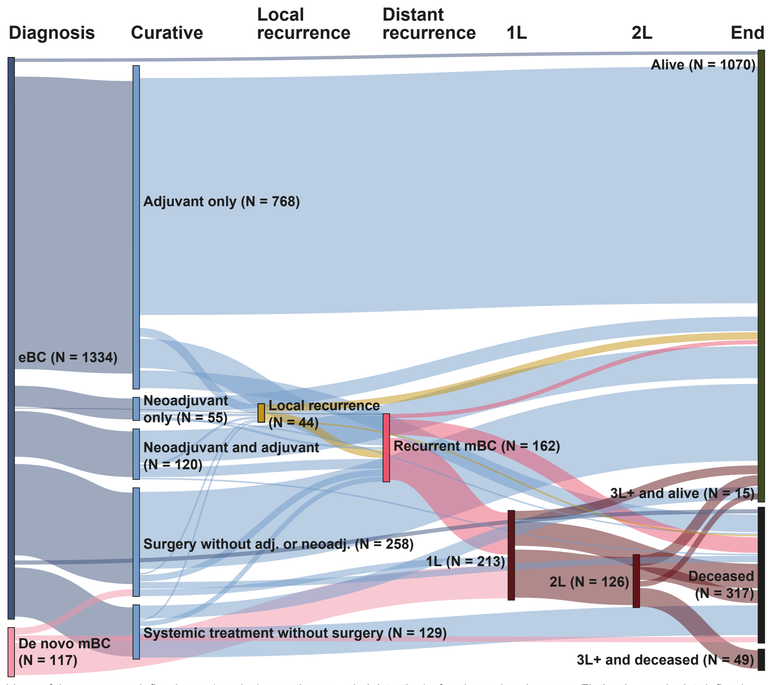
Table 1. Patient Characteristics

	Overall				Metastatic			
	Overall (n = 1451)	TNBC (n = 153, 11%)	HR+/HER2− (n = 1070, 74%)	HER2+ (n = 228, 16%)	Overall (n = 279)	TNBC (n = 52, 19%)	HR+/HER2− (n = 174, 62%)	HER2+ (n = 53, 19%)
Mean age (SD), years	63 (13)	61 (14)	63 (13)	61 (14)	64 (15)	64 (15)	65 (15)	60 (16)
Female	1438 (99)	153 (100)	1060 (99)	225 (99)	275 (99)	52 (100)	173 (99)	50 (94)
eBC/mBC diagnosis								
Not metastatic at diagnosis	1334 (92)	139 (91)	991 (93)	204 (89)	-	-	-	-
Metastatic at diagnosis	117 (8)	14 (9)	79 (7)	24 (11)	117 (43)	14 (27)	79 (45)	24 (45)
Recurrent	-	-	-	-	162 (58)	38 (73)	95 (55)	29 (55)
Disease stage at diagnosis[a]								
Stage I	567 (39)	45 (29)	458 (43)	64 (28)	17 (6)	NA[b]	NA[b]	NA[b]
Stage II	369 (25)	43 (28)	271 (25)	55 (24)	56 (20)	NA[b]	34 (20)	NA[b]
Stage III	147 (10)	19 (12)	99 (9)	29 (13)	59 (21)	NA[b]	36 (21)	NA[b]
Stage IV	117 (8)	14 (9)	79 (7)	24 (11)	117 (42)	14 (27)	79 (45)	24 (45)
Unknown/not documented	251 (17)	32 (21)	163 (15)	56 (25)	30 (11)	NA[b]	NA[b]	NA[b]
ECOG PS[c]								
0	40 (3)	NA[b]	12 (1)	NA[b]	22 (8)	NA[b]	12 (7)	NA[b]
1	29 (2)	NA[b]	16 (1)	NA[b]	41 (15)	NA[b]	26 (15)	NA[b]
2+	26 (2)	NA[b]	23 (2)	NA[b]	29 (10)	NA[b]	23 (13)	NA[b]
Unknown/not documented	1356 (93)	138 (90)	1019 (95)	199 (87)	187 (67)	39 (75)	113 (65)	35 (66)
Median follow-up (IQR),[d] months								
From initial diagnosis	43.7 (23.8-66.0)	40.0 (19.3-59.3)	45.4 (24.5-67.5)	42.3 (25.1-63.2)	29.8 (19.2-50.4)	23.4 (10.5-37.4)	31.9 (21.6-54.0)	30.6 (19.2-48.2)
From mBC diagnosis	-	-	-	-	13.3 (3.6-29.4)	3.9 (1.7-10.4)	18.2 (5.5-34.2)	16.5 (6.3-30.3)

Data are n (%) unless otherwise noted. [a]Pathologic stage supplemented with clinical stage due to missingness (patients with stage IV disease at diagnosis are not affected). [b]Not reported where ≤ 10 patients or where this number could be back-calculated due to low numbers. [c]Record of ECOG PS closest to and within ± 30 days of BC diagnosis date. [d]Time from BC diagnosis date to death or last activity. In patients with mBC, follow-up is additionally computed from date of mBC diagnosis to death or last activity.
BC, breast cancer; eBC, early BC; ECOG PS, Eastern Cooperative Oncology Group performance status; HER2, human epidermal growth factor receptor 2; HR, hormone receptor; IQR, interquartile range; mBC, metastatic BC; SD, standard deviation; TNBC, triple-negative BC.

- Treatment patterns are presented in **Figure 2**
- The most common treatment pattern in patients with eBC was adjuvant treatment only (58%), and most patients with mBC received first-line therapy
- Most patients remained alive at the end of the study period

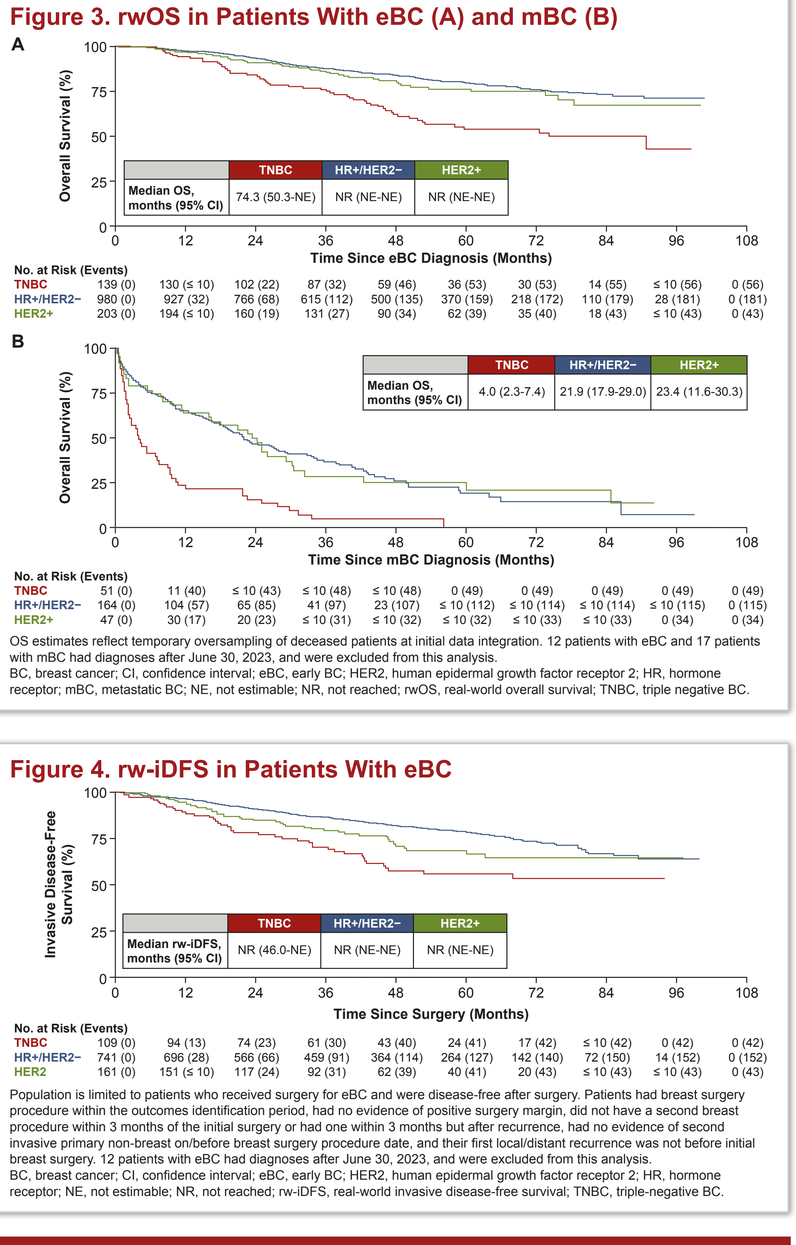
Figure 2. Treatment Patterns in Patients With eBC and mBC



Lines of therapy were defined as ≥ 1 cycle (or continuous administration) of a planned regimen per Flatiron's oncologist-defined, rule-based methodology. Patterns were assessed in both curative and metastatic settings, encompassing systemic treatments (monotherapy and combination therapy), surgery, and radiation.
1L, first line; 2L, second line; 3L, third line; adj; adjuvant; eBC, early breast cancer; mBC, metastatic breast cancer; neoadj, neoadjuvant.

- Median rwOS was 74.3 months for patients with early TNBC and was not reached for patients with HR+/HER2– and HER2+ eBC (**Figure 3A**)
  - rwOS rates for eBC at 1, 3, and 5 years were was 96%, 85%, and 76%, respectively
- Median rwOS was 4.0 months for patients with metastatic TNBC, 21.9 months for patients with HR+/HER2– mBC, and 23.4 months for patients with HER2+ mBC (**Figure 3B**)
  - rwOS rates for mBC at 1, 3, and 5 years were 57%, 29%, and 17%, respectively
- Among patients with eBC who were disease-free after initial surgery, median rw-iDFS was not reached in any subtypes (**Figure 4**)
  - rw-iDFS rates for eBC at 1, 3, and 5 years were 95%, 83%, and 74%, respectively

Figure 3. rwOS in Patients With eBC (A) and mBC (B)



OS estimates reflect temporary oversampling of deceased patients at initial data integration. 12 patients with eBC and 17 patients with mBC had diagnoses after June 30, 2023, and were excluded from this analysis.
BC, breast cancer; CI, confidence interval; eBC, early BC; HER2, human epidermal growth factor receptor 2; HR, hormone receptor; mBC, metastatic BC; NE, not estimable; NR, not reached; rwOS, real-world overall survival; TNBC, triple negative BC.

Figure 4. rw-iDFS in Patients With eBC

Population is limited to patients who received surgery for eBC and were disease-free after surgery. Patients had breast surgery procedure within the outcomes identification period, had no evidence of positive surgery margin, did not have a second breast procedure within 3 months of the initial surgery or had one within 3 months but after recurrence, had no evidence of second invasive primary non-breast on/before breast surgery procedure date, and their first local/distant recurrence was not before initial breast surgery. 12 patients with eBC had diagnoses after June 30, 2023, and were excluded from this analysis.
BC, breast cancer; CI, confidence interval; eBC, early BC; HER2, human epidermal growth factor receptor 2; HR, hormone receptor; NE, not estimable; NR, not reached; rw-iDFS, real-world invasive disease-free survival; TNBC, triple-negative BC.

Limitations

- This study has limited generalizability since the patients were from only 1 NHS Trust; future studies based on this dataset include an increased number of NHS Trusts
- At the time of evaluation, the database did not include any information on patient comorbidities; thus, this was not evaluated to characterize the study population
- This analysis was conducted as a pilot, and further assessments of the data source (eg, representativeness) are in progress[5]
- OS estimates reflect temporary oversampling of deceased patients at initial data integrations; this bias has been resolved in more recent updates of the dataset
- ECOG performance status was not available for most (93%) patients

References: **1**. National Cancer Audit Collaborating Center. National Audit of Primary Breast Cancer (NAoPri). Accessed October 28, 2025. https://www.natcan.org.uk/audits/primary-breast **2**. National Audit of Primary Breast Cancer (NAoPri) State of the Nation Report 2025. London: National Cancer Audit Collaborating Centre, Royal College of Surgeons of England, 2025. Accessed October 28, 2025. https://www.natcan.org.uk/wp-content/uploads/2025/09/NAoPri-State-of-the-Nation-Report-2025.-V02.pdf **3**. Barclay NL, et al. *Sci Rep*. 2024;14:19069. **4**. Flatiron Health. Database Characterization Guide. Flatiron.com. Published March 18, 2025. Accessed October 8, 2025. https://flatiron.com/database-characterization. **5**. Adamson B, et al. *ESMO Real World Data Digit Oncol*. 2025;7:100113.

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Disclosures: **PM**, **KN**, **NS**, and **MH** are employees of and own stock in Gilead Sciences, Inc. **AS** and **BA** are employees of Flatiron Health, Inc. – an independent member of the Roche Group –and own stock in Roche.

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