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# Real-word utilization of the 21-gene assay for guiding treatment decisions in patients with HR+/HER2- early breast cancer in the US

Gebra Cuyun Carter[1], Jennifer Racz[1], Ning Yan Gu[1], John Bennett[1], Quang Le[1], Monal Kohli[2], Jensy Rodriguez-Silva[2], Yazid Barhoush[2], Lakshmi Batchu[2], Yara Abdou[3]

1. Exact Sciences, Madison, WI; 2. STATinMED LLC., Dallas, TX ; 3. Division of Oncology, University of North Carolina, Chapel Hill, NC

## BACKGROUND

**The Assay:** The 21-gene Oncotype DX® assay is the only genomic assay proven to be both prognostic of distant recurrence and predictive of chemotherapy (CT) benefit in patients with early-stage, HR+/HER2- node-negative or node-positive breast cancer (BC).

**Study Focus:** This study analyzes real-world data in the U.S. to assess the 21-gene assay on CT decisions and treatment patterns across diverse populations.

## METHODS

**Study Design and Data Sources:**

Retrospective study used de-identified data linking Exact Sciences (ES) clinical lab database and STATinMED RWD Insights, an all-payer medical & pharmacy claims dataset.

**Patient Selection Criteria:**

- Females 18+ with ≥2 inpatient or outpatient BC claims between January 1, 2015, and November 30, 2023.
- First BC diagnosis was defined as the index date with patients required to have data 12 months pre- and 30 days post-index date.
- HR+ & HER2- status was from ES clinical lab database.
- Patients were excluded if index date occurred after the testing date, were pregnant, treatment in the baseline period, or had other cancers.

**Data Analysis and Stratification:**

- Key variables: Recurrence Score® (RS) result and nodal status from ES clinical lab database, and CT use and racial/ethnic data from STATinMED RWD Insights. CT use was defined as any CT use within 12 months of index date
- Descriptive analyses were conducted in the overall population and by RS result category, nodal status and racial/ethnic group.

## FIGURES & TABLES

**Table 1. Demographics by nodal status**

| Demographcis | Node Positive (N=21,706) | Node Negative (N=97,677) |
|---|---|---|
| | N (%) | N (%) |
| **Age (mean, SD)** | 63.4 (10.3) | 63.2 (9.9) |
| **Race/ethnicty* (N, %)** | | |
| Non-Hispanic White | 11,916 (54.9) | 55,190 (56.5) |
| Non-Hispanic Black | 1,351 (6.2) | 5,970 (6.1) |
| Asian | 412 (1.9) | 1,961 (2.0) |
| Hispanic | 2,076 (9.6) | 8,836 (9.0) |
| **Geographic Region* (N, %)** | | |
| Northeast | 3,922 (18.1%) | 18,500 (18.9%) |
| North central | 5,169 (23.8%) | 23,440 (24.0%) |
| South | 8,065 (37.2%) | 36,943 (37.8%) |
| West | 4,543 (20.9%) | 18,738 (19.2%) |
| **Payer Channel (N, %)** | | |
| Commercial | 7,030 (32.4%) | 33,428 (34.2%) |
| Other | 113 (0.5%) | 608 (0.6%) |
| Medicaid | 3,535 (16.3%) | 14,215 (14.6%) |
| Medicare | 11,028 (50.8%) | 49,426 (50.6%) |
| **Urbanicity* (N, %)** | | |
| Rural | 719 (3.3%) | 2,812 (2.9%) |
| Urban | 20,972 (96.6%) | 94,742 (97.0%) |
| **Patient-reported Education* (N, %)** | | |
| Less than High School | 108 (0.5%) | 436 (0.5%) |
| High School/Equivalent | 8,117 (37.4%) | 36,340 (37.2%) |
| College graduate | 4,817 (22.2%) | 22,734 (23.3%) |
| Post Graduate | 2,393 (11.0%) | 11,249 (11.5%) |
| **Patient-reported Income* (N, %)** | | |
| <=$25,000 | 6,244 (28.8%) | 26,555 (27.2%) |
| $25,001 - $50,000 | 5,277 (24.3%) | 24,972 (25.6%) |
| $50,001 - $75,000 | 1,670 (7.7%) | 7,901 (8.1%) |
| $75,001 - $100,000 | 1,945 (9.0%) | 9,282 (9.5%) |
| >$100,000 | 1,425 (6.6%) | 7,222 (7.4%) |
| **Quan Charlson Comorbidity Index (N, %)** | | |
| 0 | 14,820 (68.3%) | 68,720 (70.4%) |
| 1 | 2,254 (10.4%) | 9,983 (10.2%) |
| 2 | 2,129 (9.8%) | 9,170 (9.4%) |
| ≥3 | 2,503 (11.5%) | 9,804 (10.0%) |
| **Menopausal status (N, %)** | | |
| Premenopausal | 4,475 (20.6%) | 20,056 (20.5%) |
| Postmenopausal | 17,231 (79.4%) | 77,621 (79.5%) |
| **Recurrence Score** | | |
| RS 0-10 | | 25,407 (26.0) |
| RS 11-25 | | 59,626 (61.0) |
| RS 0-25 | 18,686 (86.1) | |
| RS 26-100 | 3020 (13.9) | 12,644 (12.9) |

*Numbers won't equal 100% due to unknown/missing

**Figure 1. Chemotherapy Use in N0 patients by race/ethnicity, stratified by RS Result**

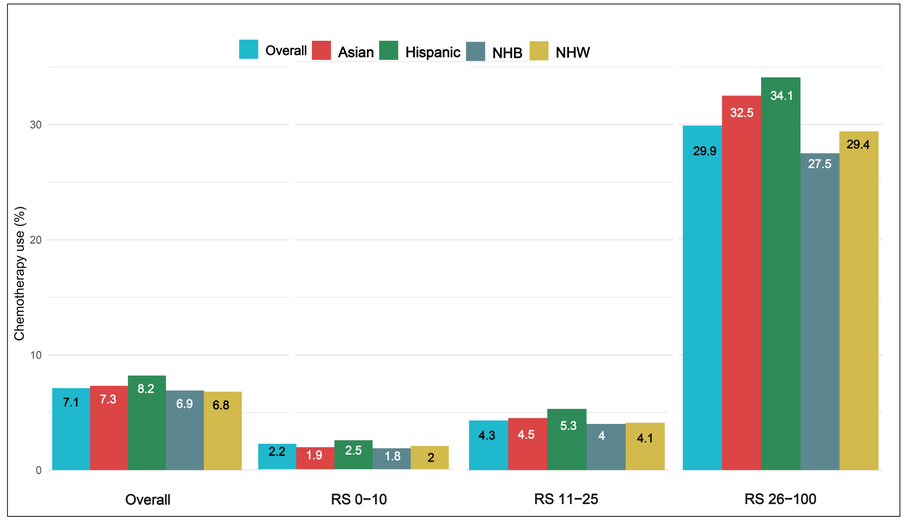
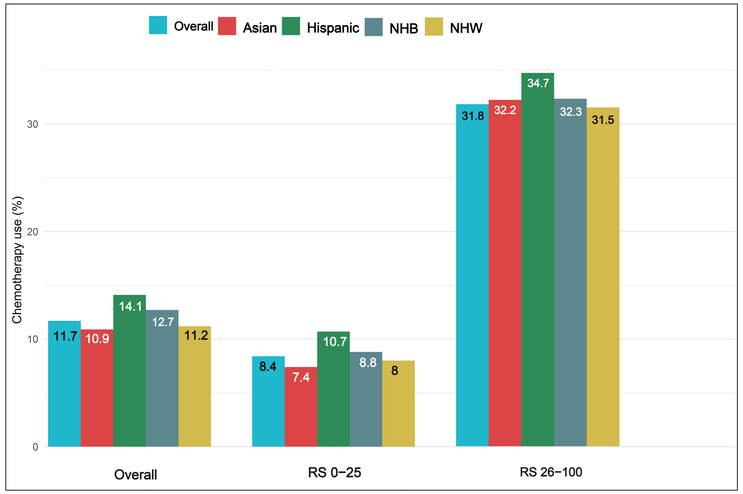



**Figure 2. Chemotherapy Use in N1 patients by race/ethnicity, stratified by RS Result group**




## RESULTS & DISCUSSION

- In the N0 cohort, most patients had low (0-10; 26.0%) or intermediate (11-25; 61.0%) RS results, while 12.9% had high (26-100) RS results. The distribution was similar in the N1 cohort with 86.1% in the low/intermediate risk group (0-25), and 13.9% in the high risk (26-100) group (Table 1).
- The proportion of patients with a high RS result was numerically higher among NHB patients in both the N0 (14.9%) and N1 (16.5%) cohorts compared with NHW (12.7%, 13.8%), Asian (12.5%, 14.3%), and Hispanic (12.9%, 14.2%) patients.
- Across both N0 and N1 cohorts, CT use increased with higher RS category overall and within each racial and ethnic group (Figures 1 and 2).
- There were no apparent differences in CT use by race or ethnicity.
- An inherent limitation of using claims data is incomplete clinical information; however, this was partially mitigated by leveraging linked data.

## CONCLUSIONS

**This large real-world analysis of patients with early-stage HR+/HER2- BC shows that CT utilization increases appropriately with higher RS results, consistent with guideline-based care. Importantly, CT use was generally consistent across racial and ethnic groups, suggesting equitable application of RS-guided treatment recommendations.**

This research was sponsored and funded by Exact Sciences Corporation. Contact: Gebra Cuyún Carter, Exact Sciences; Email: gcuyuncarter@exactsciences.com