A Pilot Test of an Innovative New Integrated EMR-Cancer-Registry-Administrative-Claims Data Resource in a Clinical Data Research Network

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Background and Objective
- Much research has been done to understand breast cancer treatments and outcomes. Observational studies often use electronic medical record (EMR) or administrative claims data, each with its own limitations.
- The Greater Plains Collaborative (GPC) recently developed a new data resource: Greater Plains Collaborative Reusable Observable Unified Study Environment (GROUSE), which links EMR, tumor registry (TR), and CMS administrative claims data, covering 19 million beneficiaries across 12 medical centers.
- Our long-term goal is to utilize the richness of the GROUSE environment to tackle pressing patient-centered, real-world issues in the treatment and care of breast cancer patients.
- The objective of this pilot grant is to develop, create, and characterize a single, multi-purpose, breast cancer cohort using GROUSE data for five clinical research projects.

Study Sample
- Women diagnosed between 2011 and 2013 with microscopically confirmed breast cancer as their first primary malignancy at GPC sites across eight states.
- For analyses requiring 2011-2015 CMS administrative claims data, additional inclusion and exclusion criteria will be applied to the cohort.

Overview of Analytic Plan and Teams

Variable Creation Across Projects

One Breast Cancer Cohort, Five Clinical Research Projects

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<td>Indication and contraindications</td>
<td>Chemotherapy: delays and disparity</td>
<td>Cardiac toxicity and cardiovascular events</td>
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Select Objectives
- Compare prescribed with dispensed oral anti-cancer medications and measure adherence to these medications.
- Identify mental health disorders, medication use (specifically selective serotonin reuptake inhibitors and tamoxifen) and CYP450 genetic tests.
- Identify chemotherapy use and potential chemotherapy-related complications (e.g., low white blood cell count, hospitalizations from neutropenic fever).
- Identify exposure to cardiotoxic therapy, cardiovascular (CV) events, and CV disease risk factors (at baseline, post-treatment, & long-term survivorship).
- Identify and categorize UED, and the breast cancer treatments received (specifically breast surgery, nodal dissection, and location of radiation therapy).

Select Hypotheses
- Differences between prescribed and dispensed medications can be explained by patient-level factors, but not differences in prescribing patterns across institutions.
- Concomitant use of selective serotonin reuptake inhibitors and tamoxifen will seldom be accompanied by a diagnosis of mental health disorder or orders for CYP450 tests.
- Differences in chemotherapy delays or discontinuation by sociodemographic characteristics will not be explained by differences in complications.
- Incidence of CV events is higher in the GPC than in published data.
- GROUSE data will identify a substantially lower incidence of UED than patient-reported survey-based data.
- Non-surgical treatments will contribute independently to UED.

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