Category: Community Outreach and Engagement & Health Equity – Completed project

Implementation of a Patient Navigation Program to Increase Representative Enrollment in Cancer Clinical Trials

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1. Background

Insufficiently diverse patient representation compromises the generalizability of clinical trial findings and remains a persistent issue in oncology. Achieving diverse enrollment may reduce the efficacy-effectiveness gap and identify pharmacologic, efficacy, and safety differences across populations. Yet despite much attention to the issue, there remain few evidence-based approaches that increase accrual diversity. Among these, it appears that progress can be made through navigation services, which may help patients learn about cancer clinical trials, identify and overcome barriers, and progress through the care pathway to enrollment and retention.

2. Goals

To evaluate outcomes associated with a patient navigation program designed to increase diverse enrollment and retention of oncology patients into cancer clinical trials.

3. Solutions and Methods

We implemented a patient navigation program, a multicomponent evidence-based intervention including four lay clinical trial navigators, to increase diverse enrollment and retention of patients into cancer clinical trials. A study was conducted from July 2023 to July 2024 at two demographically diverse health care systems in Dallas, Texas: an integrated safety-net healthcare system and an NCI-designated comprehensive cancer center. Dallas County has a population of 2.6 million (42% Hispanic, 22% Black), of whom 14 percent live in poverty and 21 percent lack health care coverage. Evaluation was guided by the Reach, Effectiveness, Adoption, Implementation and Maintenance (RE-AIM) framework and incorporated programmatic data, structured surveys of patients and staff, and qualitative patient interviews.

4. Outcomes

Navigators supported 429 oncology patients (52% female, 28% Hispanic/Latino (HL), and 16 percent non-HL Black) across two clinical settings, a university based tertiary healthcare system and an integrated safety-net healthcare system. Navigators provided education and addressed barriers to trial participation. Compared to the underlying patient population of the clinical settings, program participants were more likely to be Hispanic (31% vs 21%; P<0.01), female (52% vs 48%; P=0.01) and from a minority race (30% vs 24%, P<0.01). Of the patients who considered trial participation at the time of referral, 325 (92%) received financial navigation to support trial enrollment and retention. Among the remaining 83 patients not enrolled in a cancer clinical trial at the time of referral, all received navigation and 39 (47%) expressed interest in participating in a clinical trial in future. Referrals were received from

nine oncology teams. While referral volumes generally corresponded to oncology team's patient volume, referrals were relatively higher for genitourinary team and lower for gynecologic and melanoma/cutaneous oncology teams. Qualitative patient-reported data suggested high program acceptability. The mean program sustainability score was 5.5 (out of 7) across both clinical settings.

5. Learned and Future Directions

We found that a patient navigation program to increase enrollment and retention of diverse patients to trials was feasible to implement, highly acceptable to patients, and reached our priority population of traditionally underrepresented patients. Over a one-year period, clinical trials navigators provided services to more than 400 patients with cancer, of whom almost 90 percent were historically under-represented in clinical trials. To our knowledge, this is the first program to provide and evaluate clinical trial navigation across cancer types, populations, and clinical settings.
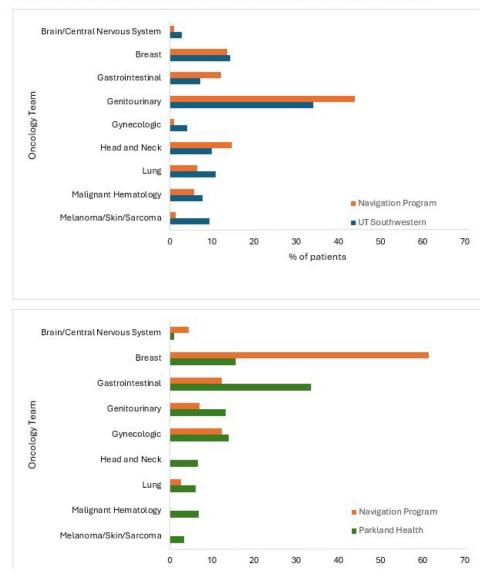
Figure 1. Adoption of navigation program by oncology teams at the two study sites.