Implementation of a patient navigation program to increase representative enrollment in cancer clinical trials

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INTRODUCTION

- 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.
- Progress can be made through navigation services, which may help patients learn about trials, identify and overcome barriers, and progress through the care pathway to enrollment and retention.

OBJECTIVE

Evaluate outcomes associated with a patient navigation program to increase diverse enrollment and retention of oncology patients in cancer clinical trials.

METHODS

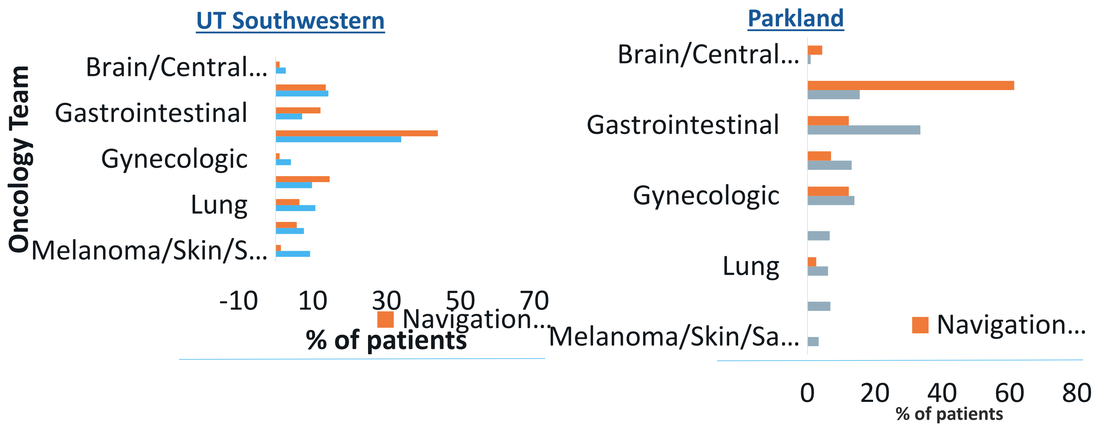
- The study was conducted from July 2023 to July 2024 at two demographically diverse health care systems in Dallas, Texas: UT Southwestern and Parkland Health.
- Evaluation was guided by the Reach, Effectiveness, Adoption, Implementation and Maintenance (RE-AIM) framework and incorporated programmatic data, structured surveys of patients and staff, and qualitative patient interviews.
- Programmatic data included implementation (navigation contacts, content, outcome), clinical and demographic data (from electronic medical record), programmatic data, and patient-reported data (qualitative data on experience with navigation).

RESULTS

Table 1. Characteristics of program participants compared to overall clinic population based on newly diagnosed cancer cases in 2023.

	UT Southwestern			Parkland			Total		
	Program (N = 298) n (%)	Population (N = 7,201) n (%)	P-value	Program (n = 131) n (%)	Population (N = 2,255) n (%)	P-value	Program (N = 429) n (%)	Population (N = 9,774) n (%)	P-value
Minority race	89 (30)	1,584 (22)	<0.01	38 (29)	721 (32)	0.52	128 (30)	2,345 (24)	<0.01
Hispanic	49 (16)	792 (11)	<0.01	83 (65)	1,262 (56)	0.04	132 (31)	2,052 (21)	<0.01
Female sex	116 (39)	3,240 (45)	0.04	102 (81)	1,307 (58)	<0.01	218 (52)	4,691 (48)	0.14
65 years or older	143 (48)	3,600 (50)	0.44	21 (16)	541 (24)	0.03	163 (38)	4,202 (43)	0.01

Figure 1. Adoption of navigation program by oncology teams at the two study sites. Proportion of patients referred to the navigation program compared to oncology teams' relative patient volumes.



The program navigated 429 oncology patients (52% female, 28% Hispanic/Latino (HL), and 16% non-HL Black) across two clinical settings, a university-based tertiary healthcare system and an integrated safety-net healthcare system.

- Compared to the underlying patient population at each clinical setting, 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 were considering 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.
- Qualitative patient-reported data suggested high program acceptability. The mean program sustainability score was 5.5 (out of 7) across both clinical settings.

CONCLUSIONS

- In this study, we found that a patient navigation program to increase enrollment and retention of diverse patients into trials was

  ✓ feasible to implement
  ✓ highly acceptable to patients
  ✓ reached our priority population of patients underrepresented in cancer clinical trials.

- Over a one-year period, the program provided navigation services to more than **400 patients with cancer**, of whom almost **90% 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.

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