Unveiling the Nuances of Cancer Clinical Trial Navigation

Fabian Robles[1,2], D'Angelo Grant[1], Marisol Rojas[1,2], La'Shonda Thomas[1,2], Rebecca Renn[3], Jessica Lee[1], , Erin L. Williams[1], Navid Sadeghi[1,2,4], Nasir Qureshi[1,2], Heather Kitzman[3], Sandi Pruitt[1,3], Sukh Makhnoon[1,3] , David E. Gerber[1,3,4]

1. Harold C. Simmons Comprehensive Cancer Center, UT Southwestern Medical Center, Dallas, Texas, 2. Parkland Health, Dallas, Texas, 3. O'Donnell School of Public Health, UT Southwestern Medical Center, Dallas, Texas, 4. Department of Internal Medicine (Hematology-Oncology), UT Southwestern Medical Center, Dallas Texas.

Background

- Less than 5% of U.S. adults with cancer participate in clinical trials.
- Participation rates are even lower for underrepresented minority (URM) populations.
- Patients face numerous barriers to trial enrollment, including stringent eligibility criteria, increasingly numerous screening and on-study procedures, lack of trial availability, and difficulty understanding lengthy and complex consent forms.
- Clinical trial navigation may address these barriers, but little is known about how such a resource may be implemented.

Project Design/Methods

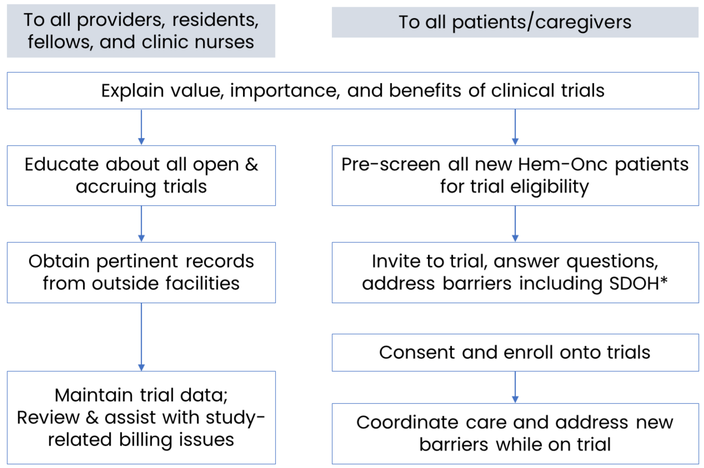
- The navigation components include
  - Explanation of clinical trials' value, importance, and benefits
  - Answering patient questions and addressing barriers
  - Assisting with pre-screening patients for trials
  - Educating clinical staff about trials and navigation programs
- Using a REDCap database, we collected quantitative and qualitative data focused on clinical trial navigation administration and programming for 290 patients from UT Southwestern and Parkland Health, July 2023-April 2024.

Interim Results

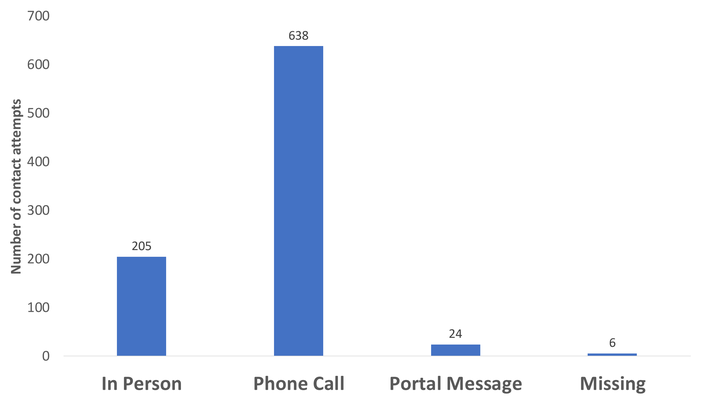
Characteristics of navigated patients (N=290)

Variables	Categories	N	%
Age, years (n=284)	Median (range)	61 (5 – 85)	
Sex (n=281)	Male	147	52.3%
	Female	132	47.0%
	Unknown	2	0.7%
Preferred Language (n=285)	English	213	74.7%
	Spanish	71	24.9%
	Vietnamese	1	0.4%
Race (n=283)	American Indian/Alaska Native	3	1.1%
	Asian	15	5.3%
	Native Hawaiian or Other Pacific Islander	0	0.0%
	Black or African American	38	13.4%
	White	206	72.8%
	Alaska Native	0	0.0%
	Other Race	21	7.4%
	Unknown	0	0.0%
Ethnicity (n=283)	Hispanic or Latino	84	29.7%
	Not Hispanic or Latino	198	70.0%
	Unknown	1	0.4%

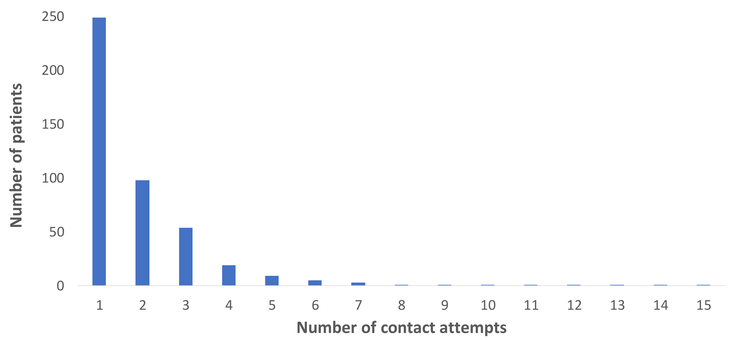
Clinical trial navigation roles



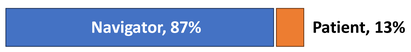
Navigation service by patient contact type



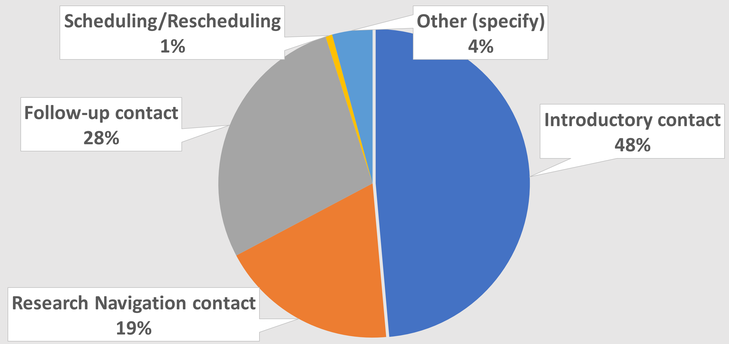
Number of navigation services per patient



Initiation of navigation services



Reasons for navigator contact (N=873 encounters)



Innovation

- **Empirical data:** on nuanced navigation interactions (frequency and content of navigator-patient communication) can help inform implementation of the recent CMS rule on reimbursement for navigation services.
- **Creation of tools** to guide patients participating in clinical trials: REDCap database, templated EPIC note documentation, educational resources (English and Spanish).
- **Quantitative evaluation** of clinical trials navigation to inform the broader adoption of clinical trial navigators.

Implications for Sustainable Practice

- **Impactful Domains:** This project is making a significant impact on the domains of Workflow Integration, Engaged Staff and Leadership, and Monitoring and Evaluation.
- **Supporting Evidence:** Successful integration of navigation question into patient pre-screening questionnaire, EPIC In-basket, engaged staff at two institutions, qualitative, and quantitative data on navigation program.
- **Challenges:** Surprisingly, workflow is also a challenging sustainability domain. While our PNs have been successfully integrated into the clinical flow of several disease-oriented teams at our institution, practice variation across teams poses a challenge for the delivery of coordinated navigation service.
- **Addressing Challenges:** To address this challenge, we are beginning to assess navigation needs among all cancer patients at our institution so navigation services can be delivered as early as possible. We hope to implement a similar system at our partner safety-net county hospital.

Supported by a patient navigation capacity-building grant from the American Cancer Society