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Transferring care to enhance access to early-phase cancer clinical trials: Protocol to evaluate a novel program

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ABSTRACT

Involving diverse populations in early-phase (phase I and II) cancer clinical trials is critical to informed therapeutic development. However, given the growing costs and complexities of early-phase trials, trial activation and enrollment barriers may be greatest for these studies at healthcare facilities that provide care to the most diverse patient groups, including those in historically underserved communities (e.g., safety-net healthcare systems). To promote diverse and equitable access to early-phase cancer clinical trials, we are implementing a novel program for the transfer of care to enhance access to early-phase cancer clinical trials. We will then perform a mixed-methods study to determine perceptions and impact of the program. Specifically, we will screen, recruit, and enroll diverse patients from an urban, integrated safety-net healthcare system to open and active early-phase clinical trials being conducted in a university-based cancer center. To evaluate this novel program, we will: (1) determine program impact and efficiency; and (2) determine stakeholder experience with and perceptions of the program. To achieve these goals, we will conduct preliminary cost analyses of the program. We will also conduct surveys and interviews with patients and caregivers to elucidate program impact, challenges, and areas for improvement. We hypothesize that broadening access to early-phase cancer trials conducted at experienced centers may improve equity and diversity. In turn, such efforts may enhance the efficiency and generalizability of cancer clinical research.

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1. Background

Involving socio-demographically diverse populations in early-phase clinical trials is critical to inform therapeutic development. Fewer than five percent of U.S. adults with cancer enroll in clinical trials [1,2]. For under-represented minorities (URM), the likelihood of trial participation is even lower [3]. Black and Hispanic/Latino individuals comprise about 12% and 16% of the U.S. population, respectively. However, these groups are grossly underrepresented in trial enrollment with Hispanic/Latino individuals at 6% and Black trial participants ranging from 0 to 10% depending on the study [4–6].

Achieving diversity is especially important for early-phase cancer trials. Such trials are often quite small, with sponsors, investigators, and regulatory authorities rendering major decisions based on the experience of relatively few non-diverse patients [7]. In a US study of more than 3000 trial participants, Black and Hispanic patients had significantly lower odds of being enrolled in Phase I trials, even after controlling for confounders including travel distance, cancer type, insurance and sex [8]. Scientific data, including pharmacokinetics and pharmacodynamics, collected from non-minority populations are broadly and sometimes inaccurately extrapolated to other populations [9]. Indeed, approximately 20% of new drugs approved from 2010 to 2015 demonstrate differences in exposure and/or response according to patient race and ethnicity [10]. Lack of diversity in prominent early-phase trials can also impair public trust, as exemplified by the Moderna mRNA COVID vaccine phase I study where forty of forty-five trial participants (89%) were White [11]. If early-phase trials (a term that the NCI currently defines as phase 0 [previously referred to as early phase I], I, and II trials) do not include diverse populations, there is a potential risk of skewing medical evidence and innovation towards therapies with understudied efficacy and safety for minority populations [4,12–14].

Over time, cancer clinical trial activation and required procedures have increased in number and complexity [15]. In turn, the rising complexity and cost of cancer clinical trials has exacerbated disparities, particularly for early-phase trials [16]. Such trials often necessitate intensive monitoring, frequent assessments, and additional pharmacokinetic and pharmacodynamic studies—characteristics that may render these studies impractical for many healthcare settings. For instance, safety-net health systems play a key role in providing medical care to low-income and vulnerable populations such as the under- and uninsured, but they may lack the resources to implement and conduct complex trial procedures. In this setting, activation and conduct of early-phase cancer clinical trials can seem impractical and inefficient (Table 1). Because Black and Hispanic individuals each account for almost 40% of the U.S. safety-net patient population [17]—more than twice their representation in the overall U.S. population—challenges to performing clinical trials at these centers disproportionately affect under-represented minority groups. Despite coverage expansions under the Affordable Care Act, the financial viability of safety-net systems is increasingly uncertain [18,19], a trend that will only exacerbate obstacles to clinical research.

Table 1
Reasons for cancer clinical trials not being activated at safety-net clinical sites.

Reason	Number (%)
Sponsor-related	**49 (32)**
Start-up costs	22 (15)
Start-up timelines, approval process	7 (5)
Satellite sites not desired	11 (7)
Perceived inconvenience	9 (6)
Site-related	**77 (51)**
Intervention not available	12 (8)
Study population not seen	2 (1)
Standard of care therapies not on formulary	5 (3)
Required oversight committee not available	5 (3)
Clinic scheduling	2 (1)
Research staffing	5 (3)
Clinician availability	5 (3)
Study procedures (eg, EKGs, PK)	41 (27)
Unknown	**26 (17)**

EKG, electrocardiogram; PK, pharmacokinetics).
Modified from [16].

To address this ongoing challenge—and the broader issue of equitable access and diverse representation to early-phase cancer clinical trials—we have proposed a novel transfer-of-care program to enhance access to early-phase cancer clinical trials. Rather than attempt to bring these trials to patients, we aim to bring patients to the trials. Specifically, we will identify interested and potentially eligible patients in an integrated safety-net healthcare system and offer them participation in early-phase trials available at a neighboring, affiliated university-based cancer center.

2. Methods/design

2.1. Program and study setting

The program and pilot study (NCT05402033) described here are centered at the University of Texas Southwestern Medical Center (UTSW) Harold C. Simmons Comprehensive Cancer Center in Dallas, Texas. The Simmons Comprehensive Cancer Center (SCCC) serves the Dallas-Fort Worth metropolitan area, which has a majority-minority population (43% Non-Hispanic [NH] White, 29% Hispanic, 17% NH Black, 7% NH Asian) and one of the highest uninsured rates in the U.S. (21% vs. 10% nationally)—higher than both Harris County, Texas (Houston), and Bexar County, Texas (San Antonio), the largest counties outside of the Dallas/Fort Worth area in Texas [20]. This number is particularly striking, as Texas ranks last in the U.S. in healthcare access and affordability [21]. In 2019, among Texas adults, 24% were uninsured (versus 10% nationally), 32% had no usual source of care, and 20% were without healthcare because of cost. Among Dallas County residents, 14% live in poverty and poverty is concentrated among the NH Black and Hispanic populations (30%) [22]. Cancer incidence and mortality rates are concentrated in the same areas of poverty; in the region of Southern Dallas **(Supplemental Fig. 1),** an area deemed a "medical desert" due to lack of primary care and specialty services and one where residents face the ongoing legacy of racist housing policy including "redlining" (denial of loans and/or insurance, principally due to race). Because Dallas County is over 99% urban [23], this study does not address specific barriers faced by rural individuals.

Within the SCCC, adult cancer care is provided across two clinical settings: UTSW and Parkland Health (Parkland). Parkland is the integrated safety-net health system for Dallas County, Texas. Through a 982-bed tertiary care hospital, specialty clinics, and 12 community-based primary care clinics, Parkland provides care for more than one million under- and uninsured individuals. UTSW is an NCI-designated cancer center university hospital. At Parkland, oncology clinical care is provided by UTSW oncology faculty and trainees; oncology clinical trials are supported by staff from the SCCC Clinical Research Office.

Patient characteristics differ substantially between the two sites. At UTSW, over 70% are NH White, and more than 95% have private insurance. At Parkland, over 75% are URM, and fewer than 5% have private insurance. For the reasons noted above, cancer clinical trial portfolios also differ between the sites. At UTSW, the majority of patients enrolled in cancer clinical trials participate in phase 1 or 2 trials, with over 20% of patients joining phase 1 trials; by contrast, in recent years at Parkland, fewer than 5% of patients enrolled in cancer clinical trials participate in phase 1 trials (Fig. 1). While multiple factors may contribute to this observation—including stringent eligibility criteria and complex trial procedures—trial *availability* represents a major consideration, as phase 1 cancer clinical trials are significantly less likely to be activated at Parkland than at UTSW [16]. Accordingly, we have designed this program to focus on trial access.

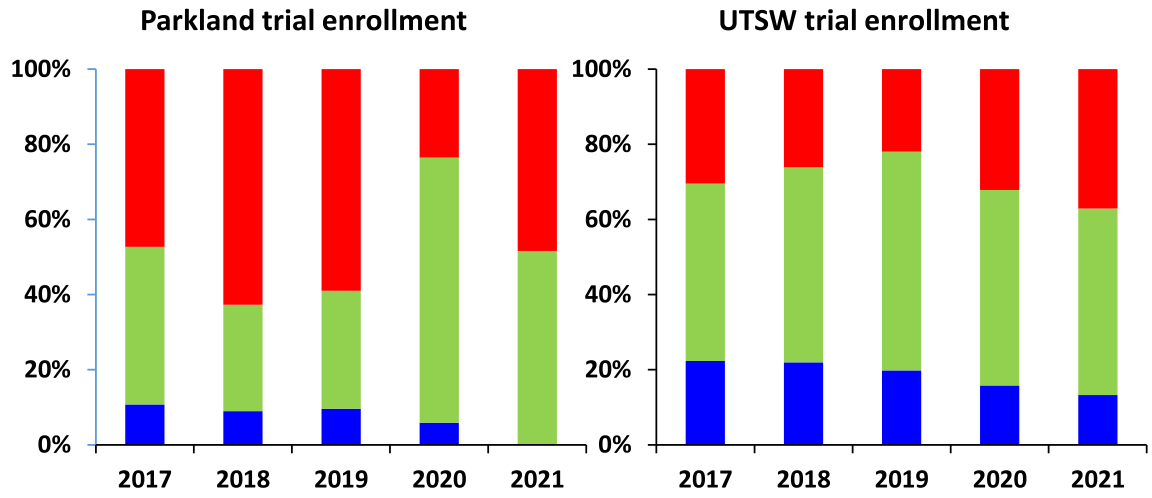

Fig. 1. Phase of trial enrollments across sites. *Blue,* Phase 1; ***Green,*** Phase 2; ***Red,*** Phase 3. (For interpretation of the references to colour in this figure legend, the reader is referred to the Web version of this article.)

2.2. Screening, eligibility, selection, and recruitment of study participants

Eligibility criteria for the proposed program include the following: Adult patients (age 18 years or older) with cancer (any type, any stage) seen in the Parkland oncology clinic regardless of insurance status. Eligibility for individual cancer clinical trials will depend on a trial's inclusion and exclusion criteria. This program excludes pediatric trials, which are conducted at Children's Health. Enrollment to the accompanying program evaluation study will be limited to English- and Spanish-speaking individuals to allow completion of surveys and interviews with study staff fluent in these languages.

2.3. Interventions

The proposed program will support the bidirectional flow of patient care, information on trial availability, medical records, biospecimens,

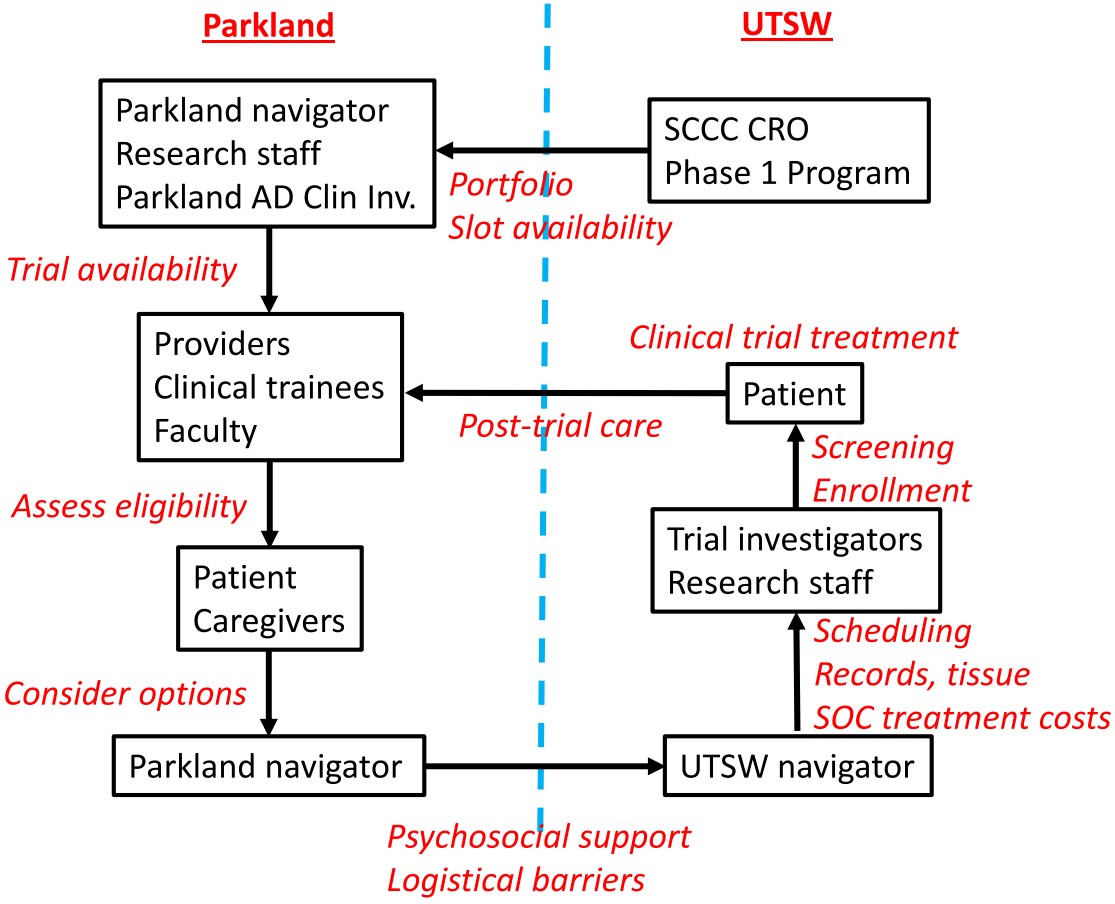

Fig. 2. Program operations supporting information and patient flow across sites. AD, Assistant Director; CRO, Clinical Research Office; SCCC, Simmons Comprehensive Cancer Center; SOC, standard of care.

and navigation services between the Parkland and UTSW clinical sites of the SCCC (Fig. 2). These processes will allow Parkland patients to consider, be evaluated for, and potentially enroll in early-phase cancer clinical trials available only at UTSW. Although the figure depicts these complex steps as occurring sequentially, we anticipate the likelihood of overlap. For instance, psychosocial support and logistical barriers may occur throughout the process. Staff may request and obtain outside patient records and tissue both before and after initial contact with trial investigators and research staff, as these requirements may vary across trials. Given these complexities, it is difficult to project how long the overall process may take for individual patients. For instance, among patients with lung cancer treated at our center, the median interval between trial consent and treatment initiation is 7 days if archival tissue submission is not required and 28 days if tissue is required ($P < 0.001$) [24]. Because early-phase (particularly phase 1) cancer trials have more study requirements than later phase trials [25], and transferring care adds to this complexity, timely patient flow through the proposed process will be critical.

Supporting the feasibility of the proposed program are the following: (1) a broad portfolio of phase 1 and 2 cancer clinical trials at SCCC UTSW that are not activated at Parkland (n = 129 trials in April 2023); (2) an existing relationship and infrastructure between Parkland and UTSW whereby Parkland cancer patients receive standard radiation therapy at UTSW (N = 5911 patients over the past 5 years) because Parkland does not have its own radiation oncology treatment facility; (3) an existing, bilingual clinical research navigator at Parkland (4) an evidence-based [26,27] and FDA-endorsed program providing funds to reimburse non-clinical costs (e.g., transportation, lodging, meals); for patients on trials with household income <700% national poverty rate (funded by the Cancer Prevention and Research Institute of Texas [CPRIT]) [28]; (5) the geographic proximity (1 mile) of Parkland and UTSW outpatient oncology facilities (which are connected via a free shuttle service); (6) financial counselor protocols for requesting provision of free standard-of-care drug therapy from pharmaceutical companies for unfunded or under-insured patients at Parkland and UTSW cancer clinics; and (7) existing relationships between Parkland- and UTSW-based clinicians, clinical research personnel (all of whom are SCCC employees), and clinic staff.

Beyond these established factors, we plan steps specific for implementation of the proposed transfer-of-care program. We will maintain updated lists of active and enrolling early-phase trials at UTSW and provide regular updates to Parkland oncology clinic providers and staff. For trials with limited enrollment (e.g., phase 1 dose escalation trials), we will develop a dashboard to notify Parkland-based teams in real time of trials with available enrollment slots. Parkland clinicians and research staff will pre-screen patients for UTSW-based trials using publicly available data through StudyFinder (the UTSW clinical trials search tool). Potentially eligible and interested patients will be referred and navigated to appropriate UTSW clinical research teams, which will coordinate study-specific screening and clinical trial care at UTSW. Bilingual clinical trial navigators at the UTSW sites will interact with Parkland patients and care teams during the care transfer process. Patients will receive concurrent non-oncology care (e.g., primary care, specialists) and post-trial oncology care at Parkland. We will design and populate a REDCap database [29] for tracking trial availability, referrals, enrollment, surveys, and interviews. We will recognize both referring and receiving clinicians in quarterly practice-wide E-mail program updates.

2.4. Study objectives

To evaluate the proposed program, the accompanying study has two research aims:

Aim 1. *Determine the impact and efficiency of screening, recruiting, and enrolling patients from a safety-net medical system (Parkland) in early-phase cancer clinical trials at an NCI-designated cancer center university hospital (UTSW).* We will track the numbers of patients identified, referred, enrolled, and retained, as well as reasons for non-referral, non-enrollment, and non-retention (Primary Outcome). We will conduct cost analyses of this program (to the institution) to summarize and explore variation in the types of programmatic expenses according to trial characteristics (Secondary Outcome). We hypothesize that, among eligible patients, early-phase trial enrollment and retention rates will be similar between patients transferred from Parkland and those already receiving care at UTSW.

Aim 2. *Determine experience with and perceptions of transferring care to another medical institution for early-phase cancer clinical trials.* We will conduct surveys of patients and caregivers. We will compare findings between Parkland patients transferring care to UTSW for early-phase trials (intervention group) and (1) Parkland patients transferring care to UTSW to receive standard cancer treatment (radiation therapy), and (2) UTSW patients treated on early-phase trials at UTSW (Primary Outcome). These comparisons will allow discernment of the relative effect of changing institutions for care, enrolling on a trial, and experiences and satisfaction with trial participation among Parkland patients compared to UTSW patients (Table 2). We hypothesize the following: (1) Transferring care for an early-phase trial will not pose additional challenges and barriers beyond those associated with transferring care for standard treatment (Table 2 "C" vs. "D"). (2) Parkland patients and UTSW patients will have similar experience and satisfaction with participation in early-phase trials (Table 2 "A" vs. "D"). (3) We will identify facilitators and barriers to hypothetical clinical trial participation among Parkland patients who do not currently have an option for trial enrollment (Table 2 "B"). (4) The Program process map created through iterative semi-structured interviews with staff, research personnel, and clinicians will help assess program efficiencies, impact, and areas for improvement for future sustainability.

2.5. Study assessments

For Aim 1, we will collect and record numbers and characteristics of Parkland patients considered for, screened for, and enrolled in UTSW early-phase cancer clinical trials. Using existing Cancer Center tracking systems, we will compare the numbers and demographics (race, ethnicity, insurance status, ZIP Code median income) of all UTSW and Parkland cancer patients and trial participants. We will compare these descriptive statistics across the samples of Parkland and UTSW cancer patients enrolled in the same early-phase clinical trials at UTSW.

We will also conduct preliminary cost analysis of the program from the perspective of the healthcare system and society, including assessment of implementation, ongoing costs of program management

Table 2
Program schema. We aim to determine the relative impact and perceptions of setting and treatment on experience and feasibility.

	SETTING		
		FAMILIAR	UNFAMILIAR
TREATMENT	UTSW Patients		
	FAMILIAR	SOC therapy at UTSW	–
	UNFAMILIAR	**Clinical trial at UTSW (A)**	–
	Parkland Patients		
	FAMILIAR	**SOC chemotherapy at Parkland (B)**	**SOC Radiation Therapy at UTSW (C)**
	UNFAMILIAR	Clinical trial at Parkland	**SU2C Program at UTSW (D)**

SOC, standard of care; UTSW, UT Southwestern Medical Center; SU2C, Stand-Up-To Cancer.
"Familiar": patients are accustomed to the clinical process and/or care setting that are typical components of their care pathway.
"Unfamiliar": process and/or care settings are new to patients and considered an atypical component of their care pathway.

personnel, and materials/supplies. Using standard approaches in decision analytic modeling, we will construct incremental cost effectiveness ratios to compare the ratio of programmatic costs to health benefits gained (e.g., number of patients screened for and enrolled on trials) with our existing paradigm (Parkland cancer patients enrolled only on trials activated at Parkland) [30]. We will survey key program staff to collect direct measures of costs related to this program. Financial data about treatment, procedural, and overhead costs for various study activities—which are maintained as part of usual fiscal management practices—will be included in these analyses.

To determine participants' experience with and perceptions of the program and to elucidate program impact, areas for improvement, and challenges (Aim 2), we will conduct surveys and interviews with patients and caregivers (Table 3 and **Supplemental Materials**). We will survey caregivers because they represent an integral aspect of support for patients during clinical trials [31–33]. A brief questionnaire (<20 min completion time) based on validated and reliable measures will be used to measure trial participation barriers and facilitators. The survey will include a 17-item measure of medical mistrust; 9 items from a previously developed scale that measure attitudes, knowledge, and prior experience with clinical research [34]; 6 items from a questionnaire on perceived benefits and barriers to trial participation (which measures concerns related to time and trouble with participation, as well as behavioral beliefs about participation); and the validated Research Participant Perception Survey (RPPS) [35]. The RPPS, which is available in English and Spanish, has established internal consistency and reliability. Using feedback from patient advocates and stakeholders, we will adapt questions in the RPPS for caregivers. When feasible, patient surveys will be conducted on the first day of clinical trial treatment (i.e., Cycle 1 Day 1 [C1D1]). We selected this time-point because, while "enrollment" to a trial represents successful completion of trial screening and care transfer, patients may not experience a sense of process completion because enrollment is primarily an administrative phenomenon. However, the start of study therapy marks a tangible step.

To obtain more nuanced and detailed information about the local context and constraints related to the care transfer-of-care program, we will also conduct semi-structured interviews with clinic staff, research personnel, and clinicians. These will provide insights into program processes, workflows, and necessary areas of improvement, with the goal of enhancing the program's success and efficiency. Feedback from these interviews will be analyzed to develop thematic summaries. Interviews will involve the use of open-ended questions and probes to elicit recommendations for program improvement and uncover new domains of interest. We will record interviews, analyze notes, and create thematic summaries. We will develop a Project Process Map (created using Visio, Microsoft) to ensure that program processes and human resources are used efficiently and effectively, and to minimize duplication of effort [36]. The map will be presented to the study team, advocates, and stakeholders for feedback, which will be integrated into ongoing improvement and sustainability.

2.6. Analysis plan

The overall project period is 24 months. Parkland patients will initiate program participation, transfer care, and enroll in early-phase cancer clinical trials at UTSW through month 22, with data analysis planned for months 23 and 24. We will use descriptive statistics to describe differences and test hypotheses, as appropriate based on distributions. For Aim 1, we will compare participation data and costs (obtained using standard clinical research office [CRO] tracking) to test for significant differences from our baseline paradigm. Chi-squared tests and t-tests will compare patients identified, referred, enrolled, and retained into this program as compared to Parkland patients transferred to UTSW Radiation Oncology.

For Aim 2, we will compare outcomes from surveys (e.g., barriers, facilitators, trial satisfaction) using chi-square tests, Fisher's exact tests, or t-tests as appropriate to test (1) whether transferring care for an early-phase trial poses substantial concerns and barriers beyond those associated with transferring care for standard cancer treatment (radiation therapy) (differences between Table 2 groups "C" and "D") and (2) whether Parkland patients and UTSW patients have similar experience and satisfaction with participating in early-phase trials at UTSW (differences between Table 2 groups "A" and "D"). Additionally, we will describe barriers and facilitators to hypothetical trial participation (descriptive statistics for Table 2 group "B") to inform future efforts.

Qualitative interview data will be analyzed using thematic analysis using multiple coders as we have performed in previous studies [37,38]. We will use NVivo 9.0 (QSR International) to collate and analyze interview transcripts [39]. Research staff will audiotape semi-structured interviews for professional transcription by an IRB-approved vendor. Experienced, mixed-method investigators (SM, MM, DEG) will oversee professional qualitative research staff to organize source documents and develop a codebook for deductive analyses following categorical domains laid out in the interview guide. To focus planned inductive analyses, we will develop a matrix of key concepts, including cells featuring brief excerpts of raw text to substantiate claims or interpretations [40]. Indexed data will be grouped to derive collective summaries and to interpret and explain findings.

Because this is a pilot study, it is not powered for formal hypothesis testing, but rather will yield initial information about program

Table 3
Planned surveys and interviews.

Patient/participant and caregiver data collection	Parkland SU2C Program early-phase trial participants	Parkland RT patients	Parkland chemotherapy patients	UTSW clinical trial participants	Parkland, UTSW staff, clinicians
N	N = 15 participants N = 15 caregivers	N = 45 patients N = 45 caregivers	N = 45 patients	N = 45 participants N = 45 caregivers	N = 10 Parkland N = 10 UTSW
Research Participant Perception Survey	***Goal:*** describe program impact	***Goal:*** identify strengths and areas for improvement for Parkland-UTSW patient transfer		***Goal:*** identify challenges facing trial participation among UTSW patients	
Survey about hypothetical clinical trial participation barriers and facilitators		***Goal:*** identify ways to improve trial participation among Parkland cancer patients	***Goal:*** identify ways to improve trial participation among Parkland cancer patients		
Semi-structured exit interview	***Goal:*** identify program strengths and areas for improvement				
Process mapping and process improvement exercise					***Goal:*** identify processes to inform dissemination, improvement

RT, radiation therapy; SU2C, Stand Up To Cancer; UTSW, University of Texas Southwestern Medical Center.

feasibility, impact, efficiency, potential for dissemination, and the needs of our unique populations as they relate to clinical trial participation. Our sample size will be based on the following: (a) the anticipated number of program participants (n = 15); (b) one caregiver per program participant (n = 15); (c) UTSW patients (selected for racial/ethnic representation) enrolled in the same clinical trials as the transfer-of-care program participants (n = 45); and (d) Parkland cancer patients receiving standard-of-care radiation therapy at UTSW (n = 45). (Parkland cancer patients treated on clinical trials at Parkland [not included in our study sample] are participating in similar surveys and interviews through a separate outreach study.)

3. Ethics

This study was approved by the UT Southwestern Institutional Review Board (STU 2021-1144). Study participation is voluntary and can be discontinued at any time. Moreover, participation in the transfer-of-care program is independent of participation in the associated study. That is, deciding not to take part in the study does not affect a participant's access to the program, access to clinical trials, or routine healthcare. We will share participant information only with members of the research team. All members of the research team undergo extensive training in human subject protections and data security.

4. Discussion

The relocation of study participants for clinical trials has previously arisen as a key option for individuals with rare and ultra-rare diseases [41]. While the underlying premise of transferring care to another healthcare system to access clinical trials seems straightforward and logical, numerous real-world factors must be understood and addressed for such an approach to provide meaningful and widespread change:

(1) Unlike non-cancer clinical trials where all treatments and monitoring are often covered by trial budgets (and the trial may therefore be offered to patients regardless of insurance status [42]), therapeutic cancer clinical trials are inherently complex and often rely on a backbone of standard-of-care monitoring and treatment components, which are rarely included in trial budgets. As a result, these costly procedures are billed to patients, precluding participation of patients who lack insurance accepted at the trial site.
(2) Early-phase cancer clinical trials may require frequent and prolonged study visits, exacerbating known financial and logistical challenges (e.g. job loss, missed work) for cancer patients and increasing the gap in access and equity for medically underserved populations [43].
(3) Early-phase cancer clinical trials often have smaller enrollment targets, dynamic cohort definitions, and rapidly changing availability [7], which may make it difficult to enroll patients not already receiving care at the trial site.
(4) Changing clinic locations to participate in a trial could disrupt continuity and communication at a time when patients may be in greatest need of familiarity and comfort [44].

With the goal of increasing access, diversity, and equity, some industry-sponsored cancer clinical trials now feature "fully-loaded" trial budgets (e.g., NCT05461209, NCT04634552, NCT05083169), modeling an approach long taken by the National Institutes of Health (NIH) for trials conducted within the NIH Clinical Center. By covering all clinical costs associated with trial participation (as well as non-clinical costs such as transportation and lodging), NIH trials become available to patients regardless of insurance status. However, NIH-located studies account for only a small fraction of all cancer clinical trials. The goal of the proposed program and pilot study is to operationalize and evaluate a transfer-of-care program for early-phase clinical trials beyond the NIH system.

In addition to patient- and system-level barriers to transferring care for trial access and participation, one must also consider clinician perspective and endorsement. If referring an existing patient to another practice sight is perceived as hindering a longitudinal relationship and/or clinical revenue, physicians may not prioritize such a program. Our planned semi-structured interviews with clinic staff, research personnel, and clinicians are intended to provide insight into such considerations.

Given the complexity of oncology clinical care and cancer trials, we recognize that replication of the transfer-of-care program described here will require some adaptation to render it suitable for a particular population or an organization's setting or program structure. As outcome and process data from this work emerge, we will emphasize its core components and suggest that they are not compromised in the adaptation process.

Relevant to potential replication and dissemination, the geographic proximity and organizational affiliation between Parkland and UTSW resemble those of numerous U.S. NCI-designated cancer centers and safety-net healthcare systems (Table 4). In general, safety-net hospitals are more likely to be teaching sites (almost 30% of safety-net hospitals are members of the Council of Teaching Hospitals, compared with 10% of other urban hospitals), and more than 50% are affiliated with a medical school (compared with 30% of other urban hospitals) [45]. Accordingly, if this project successfully identifies an efficient and effective means of transferring care across affiliated healthcare systems that see highly diverse populations and have large clinical trial portfolios, it may be possible to increase enrollment to and diversity of early-phase cancer clinical trials.

Ethics approval and consent to participate

This study was approved by the Institutional Review Boards of all participating institutions. Informed consent is required for participation. IRB approval includes waiver of written documentation of consent because research participant interactions occur by telephone.

Consent to publish

Consent to publish de-identified information is included in the verbal informed consent process. However, no data is being published at this time.

Availability of data and materials

Not applicable.

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Table 4
Selected major safety-net healthcare systems affiliated with NCI-designated cancer centers.

NCI Cancer Center	Safety-Net	University	Distance (miles)
Anschutz	Denver Health	Univ. Colorado	9.9
Case	MetroHealth	Case Western	6.3
Duncan	Ben Taub	Baylor Univ.	1.3
Norris	Los Angeles Co.	USC	0.7
Perlmutter	Bellevue	NYU	1.0
Simmons	Parkland	UTSW	1.0
Sylvester	Jackson Mem.	Univ. Miami	8.1
Winship	Grady	Emory	6.1

NYU, New York University; USC, University of Southern California; UTSW, University of Texas Southwestern Medical Center.

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CRediT authorship contribution statement

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Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.conctc.2024.101292.

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