Study Consent Rates and Decline Reasons at the University of Illinois Cancer Center

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Background

To address barriers to clinical trial participation, we want to understand clinical trial participation rates and reasons patients decline participation by time (pre/post-COVID pandemic), gender, and race/ethnicity.

Objectives

The University of Illinois Clinical Trials Office (UICC CTO) analyzed treatment clinical trial participation acceptance rates and reasons for declining clinical trial participation by time, gender, and race/ethnicity. The objectives of this analysis were:

- To understand the demographic make up of the patients that participate in UICC treatment clinical trials and whether there have been any differences over time (pre/post-COVID pandemic).
- To determine potential barriers to treatment clinical trial participation at UICC, and whether these barriers vary by gender, race, or ethnicity and whether they changed over time (pre/post-COVID pandemic).
- To use this information to address barriers to participation, and thereby maximize both the number and diversity of patients participating in treatment clinical trials at UICC.

Methods

In May 2018, the UICC CTO began collecting demographics and reasons for declining study participation for patients approached for treatment trials. Interim findings from May 2018 through December 2021 were analyzed using 1 logistic regression and 1 multivariable regression model to examine participation and reasons for declining by year, gender, and race/ethnicity.

Results

Table 1: Demographics of Patients Approached For Treatment Clinical Trials

	Year				
	2018	2019	2020	2021	Total
Race					
Asian	0%	4%	6%	1%	3%
Black	43%	46%	51%	63%	51%
Hawaiian	0%	0%	0%	1%	0%
Multiple	0%	1%	0%	0%	0%
Native American	0%	1%	0%	2%	1%
Unknown	2%	1%	0%	1%	1%
White	55%	48%	43%	31%	44%
Ethnicity					
Hispanic	18%	23%	23%	19%	21%
Non-Hispanic	80%	76%	77%	80%	78%
Unknown	2%	1%	0%	1%	1%
Gender					
Female	72%	52%	57%	69%	61%
Male	28%	48%	43%	31%	39%

Table 2: Treatment Clinical Trial Acceptance Rates Across Demographic Categories

	Year				
	2018	2019	2020	2021	Total
Race					
Asian		50%	75%	100%	67%
Black	81%	74%	68%	75%	74%
Hawaiian				100%	100%
Multiple		100%			100%
Native American		0%		33%	25%
White	84%	83%	71%	77%	79%
Ethnicity					
Hispanic	94%	87%	74%	74%	81%
Non-Hispanic	80%	74%	68%	75%	74%
Gender					
Female	85%	80%	72%	71%	77%
Male	71%	73%	66%	82%	73%

The demographics of patients approached to enroll in treatment clinical trials over time is shown in Table 1. 579 patients overall were approached to consent to a treatment clinical trial. 61% were female, 39% were male, 21% were Hispanic, 51% were black, 44% were white, and the remaining 4% a mix of other races.

The acceptance rate broken down by race, ethnicity and gender is presented in Table 2. The overall acceptance rate was 75% - 435 patients agreed to participate. Compared with pre-pandemic rates, there was a decline in acceptance rates post-pandemic, 78% vs. 72%, OR = 0.66, 95%CI [0.44, 0.98], p = .04. Gender and racial/ethnic differences were not statistically significant (ps = 0.15-0.81) across gender (female = 77%, male = 73%), race (white = 79%, black = 74%, other = 60%), and ethnicity (non-hispanic = 74%, hispanic = 82%).

Results (Continued)

Among the 144 patients who declined participation, 52% had clinical concerns (e.g., preferred standard treatment, fear of side effects), 27% had concerns of experimentation, and 21% had logistic/unknown concerns (e.g., transportation, time, insurance). Patients were more likely to decline participation due to mistrust post-pandemic relative to pre-pandemic, 30% vs. 23%, OR = 0.47, 95%CI [0.22, 1.00], p = .05. Male patients were more likely to decline participation due to logistic and unknown concerns, 30% vs. 13%, OR = 0.65, 95%CI [0.28, 1.50], p = 0.31.

Conclusions

The UICC CTO treatment clinical trial acceptance rate was relatively high, similar across patient gender, race, and ethnicity, though these rates dipped since the COVID-19 pandemic. Burden of participation was not a significant reason for declining trial participation in this study, perhaps because UICC provides transportation for any clinical trial participants in need of it, and UICC's broad financial assistance policy. New interventions need to be developed to address fears of experimentation and clinical concerns in the post COVID-19 pandemic era.

UICC CTO plans to repeat this analysis annually to assure clinical trial participation barriers are minimized and to monitor the success of efforts to address existing barriers. In the short term, together with community members, we are developing and implementing clinical trial educational modules targeting our patients and the community. These interventions will hopefully help address concerns about clinical trial participation.

Acknowledgements

We would like to thank the University of Illinois Cancer Center for supporting this work, and the patients at the University of Illinois Cancer Center who participated. This analysis was conducted with approval from the University of Illinois at Chicago Institutional Review Board, IRB# 2022-0242.