Conference Abstracts

Patient-centric and Community-engaged Development of a Clinical Trial Summary Tool to Enhance Clinical Trial Communication and Access

Tianci Wang, MS[1], Fabian Robles , MS[2], Emilie Ruiz, BS[3], Zahria Griggs, BS[3], Bob Williams, BS[4], Qian Qin, MD[2], Tian Zhang, MD[2], Heather Kitzman , PhD[3], Changchuan Jiang, MD, MPH[2]

[1] Burnett School of Medicine at TCU , 1651 W Rosedale St, Fort Worth, TX , USA, [2] Division of Hematology and Oncology, Department of Internal Medicine, University of Texas Southwestern Medical Center, 5323 Harry Hines Blvd. Dallas, TX , Dallas, Tx, USA, [3] Peter J. O'Donnell Jr. School of Public Health, University of Texas Southwestern Medical Center, 5323 Harry Hines Blvd, Dallas, Texas, United States, [4] North Texas Prostate Cancer Coalition, 1403 Lexington Pkwy, Colleyville, Tx, USA

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Background

Despite multiple efforts, cancer clinical trials often face low enrollment. The length and complexity of the informed consent form may impede patient comprehension and add additional barriers to clinical trial participation. This study co-developed a patient-centered clinical trial summary tool with patients, caregivers, and stakeholders to improve information sharing, assist informed decision-making, and increase trial participation, especially among underserved populations.

Methods

Using a collaborative approach, we engaged patients with prostate cancer, caregivers, and key stakeholders (clinical research staff, patient navigators, and cancer support organization staff) in 6 semi-structured focus groups. The initial 2 focus groups with patients and caregivers (n=15) identified essential clinical trial information needs from the patient's viewpoint. These findings informed the development of a clinical trial summary framework and a prototype summary for the minority-focused HARMONY prostate cancer trial. 4 subsequent focus groups with both patients/caregivers and stakeholders refined the summary through iterative feedback on content, structure, and language accessibility. Readability and satisfaction were assessed via structured surveys.

Results

The co-development process included 27 participants (52% White, 28% African American, 4% Hispanic), including 16 patients/caregivers and 11 clinical research staff. The final tool featured 7 sections: study goals, design, logistics, key treatment side effects, potential health benefits, and staff contact information refined through 3 feedback-based iterations. Patients preferred a detailed version with comprehensive information in each section, while clinical staff preferred expanded logistics and side effect details but shorter sections on study design and staff contact information. The final document was rated as 'very easy to read' by 100% of patients (n=5) and 90.1% of clinical research staff (n=11), with high satisfaction reported by 92% of patients and 91% of staff.

Conclusion

Our study demonstrated the feasibility of co-developing patient-centered clinical trial summary with patients and stakeholders, providing a replicable framework to potentially enhance diversity in clinical trials. The tool is currently being implemented in the HARMONY trial.