Category: Community Outreach and Engagement & Health Equity – Work in Progress

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

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1. Background

Cancer clinical trials often face low enrollment despite multiple efforts to recruit and work with potential participants. We hypothesized this could be, at least in part, due to the length and complexity of the informed consent form, causing low patient comprehension, and therefore, participation in clinical trials. This study, co-developed as a patient-centered clinical trial summary tool with patients, caregivers, and stakeholders, intended to improve information sharing, assist informed decision-making, and increasing trial participation, especially among underserved populations.

2. Goals

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 seven sections: study goals, design, logistics, key treatment side effects, potential health benefits, and staff contact information, refined through three feedback-based iterations. Patients preferred a detailed version with comprehensive information in each section. In contrast, 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 percent of patients (n=5) and 90.1 percent of clinical research staff (n=11), with high satisfaction reported by 92 percent of patients and 91 percent of staff.

3. Solutions and Methods

Using a collaborative approach, we engaged patients with prostate cancer, their caregivers, and key stakeholders (clinical research staff, patient navigators, and cancer support organization staff) in six semi-structured focus groups. The initial two 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. Two 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.

4. Outcomes

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 now being implemented.

5. Learned and Future Directions

Expanding its application across diverse cancer types, evaluating its impact on actual trial enrollment rates, and exploring digital adaptations to improve accessibility will be essential. Additionally, sustained collaboration with patient advocacy groups and research staff will be essential to continuously refine the tool and ensure it remains relevant to the needs of diverse patient populations.