Promoting Early Detection and Timely Breast Cancer Diagnosis in Kenya

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Executive Summary

Objectives

Over 70% of female breast cancer (FBC) diagnoses in Kenya are made at an advanced stage (stage 3 or 4), resulting in high mortality and low survival rates. Culturally sensitive interventions to promote early diagnosis are a priority to improve patient outcomes. The primary aim for the pre-application grant was to facilitate identification, recruitment and involvement of mature patient partners in the prioritization of the research topic and questions; and in the co-creation of a clinical trial to promote early diagnosis of FBC.

Activities

During the pre-application period (January - November 2024), diverse patient partners, including FBC survivors, FBC patient advocates, patient experts, patient organizations, family members, and informal caregivers, were identified and meaningfully engaged in this study. This was achieved by conducting two patient engagement forums, two focus group discussions and two co-creation workshops with mature patient partners.

Outcomes

The involvement of diverse mature patient partners provided insightful ideas that were incorporated into the trial design. While patient partners raised several issues that were incorporated in the trial design, a few of them are highlighted here: 1) prioritization of early diagnosis interventions and questions; 2) identification of an evidence-based intervention; 3) descriptions of contextual drivers of advanced FBC diagnosis; 4) unique role of patriarchal social structures in trial participants' recruitment and retention; 5) culturally-sensitive strategies of optimizing patient partners involvement throughout the clinical trial life cycle.

Challenge

Improving the study design through patient feedback

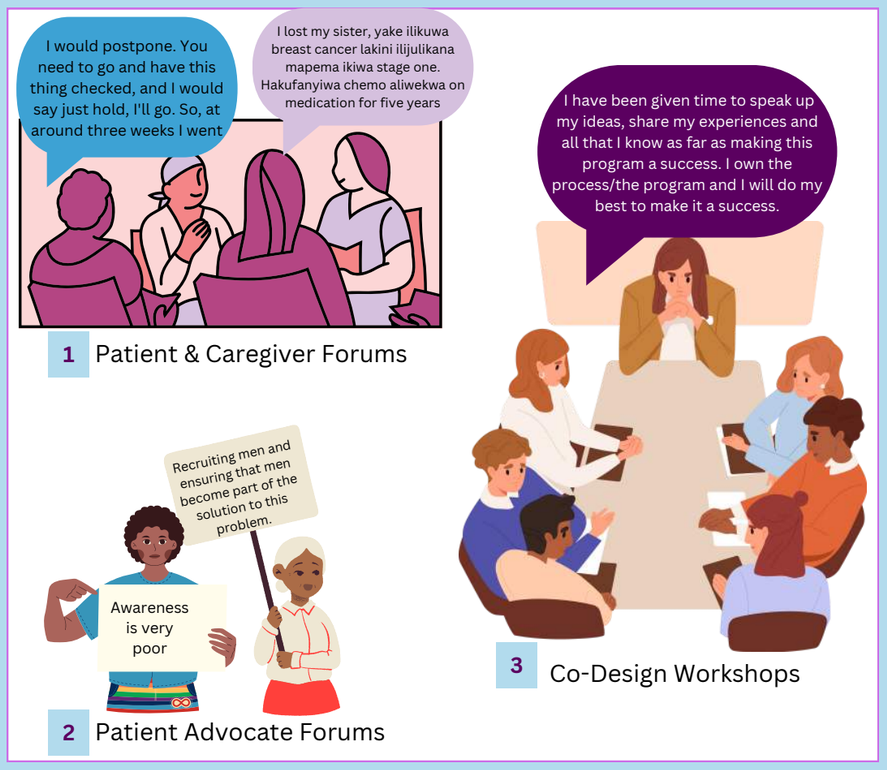
For the first time, the researchers learnt invaluable lessons about the importance of patient involvement in research as portrayed by useful patient feedback about the planned study. The insights informed all phases of the study design. The Rising Tide Foundation for Clinical Cancer Research funding was instrumental in ensuring optimal patient recruitment and engagement.

The idea

Direct Involvement of Patient Experts

A dynamic patient engagement plan was co-created with diverse categories of patient partners to ensure its responsiveness to their current and future needs across the life cycle of the study. Considering patient partners' disease-lived experiences, competencies, diversity, and expected project roles, they were engaged at different levels, including informing, consultations, involvement and collaborations. The engagement plan involved several activities:

- The initial patients identified helped the recruitment of others
- The community advisory board(made of patients and stakeholders) participated in assessing patients' concerns, needs and preferences for incorporation in the study
- Consultative forums to develop and pilot situational analysis tools
- Focus groups, brainstorming sessions and consultative forums were held with patients (as participants) during situation analysis
- Situational analysis report validation workshops helped patients promote contextual sensitivity to the results
- Co-creation workshops were conducted to prioritize the research topic, identify evidence-based interventions, formulate research questions, and design a clinical trial protocol



Incorporating Feedback

Useful insights related to the research topic were gained from the patient partners. From the introduction of the research topic to the development of the protocol for the clinical trial, patients expressed concerns, interests, and preferences that were incorporated into the study. Some of the feedback received and incorporated into the study design include: 1) prioritization of pre-diagnostic interval (patient interval) barriers to symptomatic presentation; 2) unique role of gender power asymmetries/patriarchal systems as barriers to women's help-seeking behaviour; 3) access barriers across different levels of the healthcare system; 4) potential intervention implementation determinants such as patriarchy, transport, and other rurality challenges; and 5) suggestions of intervention implementation strategies.

Impact on Study Design

Contrary to the initial thoughts on the study design, patients' feedback provided insights on several ways of modifying/improving the clinical trial design: 1) The Clinical trial research team was modified to include a breast cancer survivor, patient organisation representative and laypersons as co-investigators to optimize patient involvement; 2) the identification of hardly-considered implementation strategies, such as women's empowerment to mitigate patriarchal negative effects; 3) importance of incorporating women's partners during recruitment of participants to align with the local patriarchal social structures; 4) identification of community health workers as potentially sustainable implementers of the intervention; and 5) formation of a community advisory board to ensure dynamic patient involvement throughout the study life cycle.

Researcher-patient partnerships for patient-centric research

A pre-applicant grant by the Rising Tide Foundation enabled the incorporation of a diverse array of patients in identifying the research topic and questions for a clinical trial to address the high prevalence of advanced-stage diagnosis of FBC in Kenya. A culturally sensitive clinical trial has been designed to promote early FBC diagnosis by leveraging existing community health systems. The patient engagement plan is emergent in that it will be continuously revised based on the results of ongoing assessment of the impacts of patient involvement activities. Lessons learned on patient involvement in clinical trial design and implementation will be disseminated through a publication in a peer-reviewed journal.

1 **Applying for the pre-application grant**

2 **Activities Proposed**

3 **Outcomes & Incorporating them back into endpoint and trial design**

Providing pre-application funding for patient involvement

A new grant mechanism called "pre-application grants" has been launched. These small grants are to close the funding gap for patient experts to provide input to the development of a grant application/ protocol.

We are aiming at supporting patient organizations during this early phase with a budget. The budget should be planned to cover travel costs to preparatory meetings and the work time invested by staff or patient experts. This work should be carried out as a preparation step prior to the submission of a clinical research grant application to RTFCCR

4 **Conclusion**

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