

Clinical Pathway and Patient Navigation: Research Protocol on the Appropriateness, Timeliness and Support of Women Diagnosed with Breast Cancer in Abia State

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Background: Breast cancer is the second most common malignancy affecting Nigerian women, and contributes the highest cancer-related mortality in this population. Despite the rising prevalence of breast cancer, Nigerian healthcare professionals do not have adequate resources in screening, diagnosing, treating and follow up of women with breast cancer. The objective of this study was to understand how the development and implementation of a state-wide clinical pathway alongside a patient navigation program will impact the care providers and care receiver (breast cancer patients).

Methods: This mixed methods, cross-sectional study will develop and deploy a multidisciplinary clinical pathway focused on breast cancer management. Trained patient navigators will facilitate the implementation of the pathway and to support patients. An electronic medical record system will be deployed to document the use of the pathway. Mixed methods data will be collected periodically, including patient satisfaction, treatment adherence, psychosocial outcomes, and quality of life. Qualitative data will provide contextual details.

Anticipated Result and Discussion: This research will potentially structure the management of breast cancer in a way that optimizes available resources while reducing delays in Abia state, Nigeria.

Introduction

The burden due to cancers is rising in Nigeria and other developing countries. Breast cancer is the second most common malignancy affecting Nigerian women, and contributes the highest cancer-related mortality in this population [1-2]. Despite this rising prevalence Nigerian healthcare professionals do not have adequate skills and resources in screening, diagnosing, treating and following up women with breast cancer [2-4]. The relatively low cancer-related competence is further complicated by the lack of locally-sensitive clinical pathways in most local Nigerian hospitals [4].

Clinical pathways (CPs) are evidence-based multidisciplinary care plans that outline the essential steps needed in the care of patients with a specific clinical problem (e.g. breast cancer). Essentially, CPs seek to link evidence to practice for specific health conditions, thereby optimizing patient outcomes and maximize clinical efficiency [5-6]. They are used to translate more universal clinical guidelines into local protocols which inform clinical practice. Breast cancer clinical

pathways have been shown to reduce hospitalization, improve patient care process, reduce patient anxiety and depression [7], as well as improve overall patient satisfaction [8]. The implementation of clinical pathways requires dedicated, multidisciplinary teams, which are supported by patient navigators.

Meanwhile, a patient navigation program (PNP) is a systematic approach of guiding patients through the complexities of health care systems and removing the barriers to access of health care services. These programs are run by Patient Navigators, who follows patients from screening, through treatment and into survivorship [9]. PNP helps ensure that patients get the most efficient care available locally, without increasing their financial burden. Evidence shows that PNP improves patient outcomes, satisfaction and quality of life [5-6]. It also improves the quality of service provided by physicians [7]. It helps them follow specified clinical pathways and guidelines. Support groups have been shown to improve cancer patients' ability to cope with the disease, their quality of life and adherence to treatment [8]. Developing a patient navigation program is one of the strategies proffered to help sustain the use of clinical pathways. The need for a patient navigation program in Abia State was one of the needs identified during a multidisciplinary course on cancer control [10]. Findings from a Nigerian study [11] that doctors and nurses in Uyo appreciate having navigators as part of their team. The patient navigation program was implemented due to the complexity of the healthcare system and complexity of cancer management.

This project seeks to develop, deploy, and evaluate a robust pathway for breast cancer early detection, diagnosis and treatment in Abia State. The implementation of this pathway will be enhanced by patient navigators, using electronic health record system and patient support groups. The project aims to develop a state-wide program that will decrease unnecessary variation in clinical practice, and assure timely care, and improve outcomes for breast cancer patients. If successful, this pathway will be used as a model for other cancers and in other Nigerian states. This pathway project was informed by needs that were identified through local research [10,12].

The Specific Aim of the Project

The overall goal of this project is to demonstrate how the development and implementation of a state-wide clinical pathway alongside a patient navigation program will impact the care and outcomes for breast cancer patients, as well as the practice experience for primary and oncology care providers (POCP).

The Objectives of this Project are

1. To develop and implement a local clinical pathway for the diagnosis, treatment, and follow-up care of breast cancer patients in Abia State, based on NCCN Harmonized guideline (Sub-Saharan Africa) and other local guidelines
2. To implement a navigation program which will provide psycho-social support for patients, guide providers in implementing the pathway and compliance with the clinical care pathways, using an electronic records system
3. To evaluate the impact of implementing the clinical pathway with patient navigation on provider satisfaction, patient satisfaction, patient-care timelines as well as patient psycho-social outcomes.

Research Rationale

Prior to the project design, a needs assessment survey was conducted with emphasis on determining the best approach to implement the clinical pathway in Abia State. The researchers

explored the need to establish a pilot PNP with support group for breast cancer patients in Abia State, as part of a blended learning course. All the respondents (n=50) agreed that it was necessary to have an operational clinical pathway in the state, as a way of making significant impact on the outcome of breast cancer patients locally. The commonly preferred entry points into the patient navigation program were, during cancer screening (34.7%, 17/50), upon clinical diagnosis (57.1%, 28/50) or at any point during the care process (26.5%, 13/50). Participants suggested the following as focus areas for patient navigators; clinical pathway coordination (59.2%, 29/50), patient education, (49%, 24/50), support group management (42.9%, 21/50), and cancer data management (38.8%, 19/50).

Materials and Methods

This is a mixed-methods, multidisciplinary cross-sectional study having the following components; clinical pathway development and implementation of patient navigation and support groups. Ethics approval has been obtained from Abia State Ministry of Health Human Research Ethics Committee (AB/MH/AD/904/T.190).

Clinical pathway development

The clinical pathways will be developed by a multidisciplinary team, using guidelines from the National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO), and the University of Nigeria Teaching Hospital (UNTH). As versions of the pathways are developed, they will be disseminated to other clinicians from the pool of target participants for feedback, revised as needed until a document that is acceptable to at least 80% of the review panel has been developed. Such iterative steps have been shown to improve adherence to the pathway when it is launched. The final pathways will be printed and distributed widely. Relevant requisition forms will also be developed and printed to facilitate patient referral within the pathway. The pathways will undergo periodic evaluation after implementation to determine whether the pathway is meeting the needs of providers and patients. This approach was also used in developing other pathways [13-15].

The pathways will be developed for early disease (Stages 0-2) and advanced disease (Stages 3 & 4). Each pathway will include the following elements:

- Recommended actions for common scenarios (e.g. primary care, referral hospital)
- Guidelines regarding referrals to specialty services and appropriate timelines
- Guidelines regarding follow-up schedule after completing active treatment and timelines for follow-up surveillance imaging
- Timelines for diagnostic work-up (e.g. mammograms, staging studies, pathology)
- Timelines for treatment (e.g. time from initial diagnosis to initiation of primary treatment)
- Timelines for adjuvant treatment appointments (radiation oncology, medical oncology)

Based on the pathway, each patient who is enrolled in the project will have a unique record in the electronic medical record system that will be managed by the navigators. The records will also contain identifiers for their physicians. The timelines suggested by the pathway will be used to create automatic alert in the records system. This will help the navigator ensure that the patient and providers are on track, to improve treatment adherence. The pathway will be launched using workshops which will be hosted in each of the three senatorial districts in Abia State. The workshops will also be used to remind participants about essential skills required to diagnose and

manage breast cancer (e.g. clinical breast examination, breast ultrasound and breast biopsy). Patient navigators will be deployed to support the pathway after a blended learning training course.

In order to facilitate the adoption of the clinical pathway, we will provide incentives to encourage providers perform recommended actions within timelines suggested in the pathway. The use of financial incentives has been shown to increase compliance with the use of clinical pathways by clinicians [16]. Also, periodic audits of providers will be conducted, and feedback provided to facilitate appropriate use of the pathway. Through the electronic medical records, we intend to use SMS reminders to keep clinicians on track.

Patient navigation and support group

During the development of the pathway, a group of skilled professionals (nurses, community health workers and students from relevant disciplines) will be recruited to participate in a blended learning course on patient navigation. The online version will cover the didactic aspects of patient navigation and support group management, while clinical simulation will be used to acquire hands-on skills. The training will also include the use of the open-source electronic medical record (EMR) system that will be used for the clinical pathway. The navigation program will be delivered to patients through a combination of in-person visits, phone calls and text messages. Furthermore, patients will be recruited into the pathway through referral. It is expected that when a woman is suspected to have breast cancer (e.g. during a community outreach), the individual's screening result will be reported online using the EMR, while being referred appropriately. The EMR system will notify the Navigator to ensure proper patient follow up. These are expected to occur within the intervals recommended by the clinical pathway. If the navigator identifies any challenges with the patient or provider (e.g. missing test results or difficulty in making appointments), the navigator will work to resolve such, thus helping improve adherence to the clinical pathway. The navigators will also liaise with other providers outside the state for services such as radiation therapy.

Meanwhile, each interaction the navigator has with the patient or provider(s) will be documented in the electronic medical records (EMR). Independent contractors will be employed to customize an open source electronic medical records (e.g. OpenEMR) for the project. The secure EMR will host the data for each patient (e.g. diagnosis, treatment, appointments, etc.). This EMR will be integrated into a simple calendar tool (e.g. Google Calendar) so that navigators will receive alerts regarding patients, thus prompting them to check in with the patients and providers. It will also be integrated into a text-messaging system.

We will determine if patients and physicians are fully engaged in the project by the level of compliance with clinical pathways. We will also assess feelings of patient empowerment and patient quality of life using the Health Education Impact Questionnaire and the Medical Outcomes Study 36-Item Short Form (Version 2), respectively, before and after completion of the pathway to determine if these measures improved with the use of the clinical pathways. The navigators will hold monthly support group meetings for cancer patients in each of the three senatorial districts. During these meetings, primary and oncology care providers (POCPs) will discuss issues which are pertinent to cancer survivorship (e.g. sexual intercourse and fatigue). This will potentially encourage the patients through their 'cancer journey', while providing feedback about the functioning of the program.

Target Audience

Providers who are targeted for this project include primary care providers (e.g. family physicians and general nurses), surgeons and resident physicians working at major hospitals in Abia State. This audience was selected as they are most directly involved in the screening, diagnosis and management of breast cancer. There are more than 2,000 individuals in this population of providers. A minimum sample size of 123 patients is required to demonstrate a weak correlation

($r=0.25$) between use of the clinical pathway and reduction the diagnostic interval, with power of 0.8 at 95% confidence level. Participants will be drawn from the three Senatorial districts in Abia State.

Evaluation and Expected Outcomes

Quantitative data will be analyzed by descriptive statistics, chi-square and multivariable Analysis of variance (ANOVA). Qualitative data will undergo thematic analysis for emergent themes. Data for the evaluation of the project will be collected using a mixed- methods approach. Some quantitative outcome measures will be abstracted from the electronic medical records, including 'intervals in accessing different types of care in the health system' (e.g. breast biopsy), and 'treatment adherence by patients.' Surveys will be used to evaluate 'ease of using established clinical guidelines.' Qualitative interviews will show 'stories of change from providers and patients' regarding the impact of the pathway and patient navigation.

Current data shows that most patients wait more than three months to receive treatment (diagnostic interval) and only about 50% complete their treatment (completion rate). Compliance with treatment pathway recommendations will be assessed using patient-level data from the electronic medical record. In the analysis, data will be stratified by the type of facility (e.g. public vs private) where the patients were managed. Patient satisfaction and quality of life surveys will be used to evaluate participants' psycho-social needs as well as the functioning of the patient navigation component. Although there are no baseline data on cancer patient satisfaction and quality of life, we anticipate that most patients who participate in this project will report high satisfaction with good quality of life scores at the end of the study period.

Anticipated Result and Discussion

This project is innovative in the sense of building a new clinical pathway where there was none, especially with input from patients. Typically, projects like this are not developed with the involvement of patients. The integration of patient navigation into the clinical pathway deployment is also an innovative approach, which can help ensure program effectiveness and sustainability. Furthermore, other patient navigation systems that operate in Nigeria are not supported by an electronic medical records system, nor are they integrated into a clinical pathway. Direct beneficiaries of this project are the providers and breast cancer patients. It is also possible that patients with other cancers, e.g. prostate and cervical cancers, will benefit from the project. For instance, they may join the support group, as there is no similar program in Abia State.

Abia State Ministry of Health will also benefit from this project as they would have high quality data about cancer management in the State. Students at a local College of Health will benefit through training on patient navigation. They will also gain practical skills in the use of the OpenEMR ® software, which will be used for data management. It is also anticipated that hospitals which participate in this project will benefit from the practice audits that will be conducted. This will most likely improve overall patient care process at those hospitals. This will be the first project in Nigeria which seeks to structure the management of breast cancer in a way that optimizes available resources, while reducing delays. It is also based on the foundations laid through previous projects on cancer control in Abia State. Through this incremental approach, this is likely to be a sustainable project which will enjoy wide ownership from local stakeholders. Integrated knowledge translation model will be used to disseminate the process and findings from this study.

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