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Barriers to accessing essential breast cancer medicines in sub-Saharan Africa, a scoping review protocol

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ADMINISTRATIVE INFORMATION

Support - None.

Review Stage at time of this submission - Piloting of the study selection process.

Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 21 May 2026 and was last updated on 10 November 2026.

INTRODUCTION

Review question / Objective Overarching Question:
What are the barriers to accessing essential breast cancer medicines in sub-Saharan Africa?
Specific questions:
1. What are the regulatory challenges hindering access to essential breast cancer medicines?
2. What are the health system-related factors impacting access to essential breast cancer medicines?
3. What economic and trade-related obstacles affect the affordability and availability of essential breast cancer medicines?
4. How does the performance of the pharmaceutical system influence access to essential breast cancer medicines?
5. How do reported barriers vary by country, UN M49 subregion (Eastern, Middle, Southern or Western Africa), medicine class and evidence-source type?
6. Which populations, institutions and health-system levels are represented, and which are under-represented?
7. What interventions, policy responses and knowledge gaps are reported?

Rationale Despite policy recognition through the WHO Model List of Essential Medicines (EML), the availability, affordability, and consistent use of essential breast cancer medicines remain highly uneven across SSA. Many countries face persistent challenges related to medicine selection and registration, procurement and supply chain inefficiencies, high prices and limited financing, gaps in health insurance coverage, and broader political and economic constraints. As a result, inclusion of medicines on the WHO EML does not reliably translate into equitable access at the point of care.
Barriers to accessing essential breast cancer medicines in SSA are complex and operate across multiple, interrelated levels of the health and pharmaceutical system, including regulatory

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frameworks, national essential medicines selection processes, procurement and supply chains, pricing and financing mechanisms, health insurance coverage, and wider political and economic contexts. While individual studies, policy reports, and commentaries have examined aspects of these barriers, the evidence base is fragmented and dispersed across peer-reviewed and grey literature.

Given the diversity of health-system contexts within the region, and the mix of empirical studies, policy analyses, and descriptive reports addressing this topic, a scoping review is the most appropriate methodological approach to comprehensively characterise the literature, identify key themes and gaps, and clarify how access barriers are conceptualised and examined.

Condition being studied Background: Breast cancer is the most frequently diagnosed cancer among women globally and a leading cause of cancer related mortality in SSA. Although early-stage breast cancer is highly treatable, survival outcomes in SSA remain substantially poorer than those observed in high income countries. This survival gap is largely attributable to delayed diagnosis, health system constraints, and limited access to effective treatment, including essential medicines.

Access to essential medicines is a core component of the right to health and a cornerstone of universal health coverage. In 2015, the World Health Organization (WHO) undertook a comprehensive, disease-based review of cancer medicines to update the WHO Model EML, prioritising malignancies based on disease burden and the magnitude of clinical benefit. Breast cancer was identified as a priority condition due to its high global incidence and the substantial therapeutic impact of available medicines.

METHODS

Search strategy The search strategy will be constructed following the PCC elements of Population, Concept, and Context. Considering the research questions above the PCC summary is as listed below:

Population - People affected by breast cancer, and institutions, systems or stakeholders involved in access, such as regulators, policymakers, payers, procurement agencies, manufacturers, distributors, healthcare institutions, pharmacists and clinicians.

Concept - A barrier or facilitator directly related to access to at least one eligible essential breast cancer medicine, mapped to the prespecified access and pharmaceutical-system domains.

Context - Any country or territory classified by UN M49 within Eastern, Middle, Southern or Western Africa. Multi-country sources are eligible when SSA findings are separately extractable.

Participant or population People affected by breast cancer, and institutions, systems or stakeholders involved in access, such as regulators, policymakers, payers, procurement agencies, manufacturers, distributors, healthcare institutions, pharmacists and clinicians.

Intervention Concept - A barrier or facilitator directly related to access to at least one eligible essential breast cancer medicine, mapped to the prespecified access and pharmaceutical-system domains.

Comparator Not Applicable.

Study designs to be included Primary empirical studies; evidence syntheses; and documentary evidence containing substantive, attributable and extractable information relevant to medicine access. Eligible documentary evidence may include government or intergovernmental policies, national cancer-control plans, national essential medicines lists, clinical or treatment guidelines, procurement or reimbursement documents, technical or programme reports, theses, dissertations, working papers, committee or institutional reports, policy briefs, annual or project reports, and fact sheets or conference proceedings that report sufficient methods, data, policy provisions, implementation information, or documented barrier or facilitator findings

Eligibility criteria Language - Articles/reports published in English

Time Frame - Articles/reports published from 1 January 2015 to 1 December 2026

Geographic Focus/Context - Studies conducted in/reports concerning sub-Saharan Africa, subregional, country or eligible territory evidence; multi-region sources with separable SSA data.

Information sources Bibliographic databases: PubMed, Scopus, Web of Science, Embase (via the Ovid platform), CINAHL (via EBSCOhost), Global Index Medicus including African Index Medicus, African Journals Online, and Cochrane Library.

Grey literature sources: Google Scholar, the Global Cancer Observatory, the WHO AFRO Data Portal, the WHO AFRO Regional Data Hub, and the WHO Global Health Observatory. The Global Cancer Observatory developed by the International Agency for Research on Cancer (IARC) is an

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interactive, web-based platform that provides comprehensive global data on cancer incidence, mortality, and prevalence to support cancer research, surveillance, and policy-making).
In addition, grey literature sources will be from the following websites: UNDP; UNICEF; World Bank; African Union (AU) and Africa CDC; ministries of health and national medicines regulatory authorities for all eligible countries/territories; national essential medicines lists; national cancer-control plans; public procurement agencies and central medical stores where searchable; Health Action International (HAI); Médecins Sans Frontières (MSF); and Union for International Cancer Control (UICC). Patient and advocacy sources will include the UICC and its relevant member organisations identified for eligible countries through the UICC website. Conference material will be eligible only when a full paper, report or proceedings contribution provides sufficient methods and findings.
The reference lists of included primary studies and relevant reports will also be hand-searched to identify additional eligible sources.

Main outcome(s) This scoping review aims to address the evidence gap on barriers to accessing essential breast cancer medicines in SSA by systematically identifying and synthesising the existing literature. The findings are intended to inform policy-makers, researchers, and other stakeholders by providing an organised overview of current knowledge, highlighting areas where evidence is limited, and supporting further research and health-system strengthening efforts to improve equitable access to life-saving breast cancer treatments in the region.

Data management All retrieved records will be imported into Covidence for de-duplication, screening, and data extraction. Two reviewers will independently screen studies, with discrepancies resolved through discussion or a third reviewer.

Quality assessment / Risk of bias analysis Not Applicable (Secondary research).

Strategy of data synthesis Extracted data will be synthesized using descriptive statistics and framework-guided thematic analysis. Descriptive summaries will characterize included evidence by publication year, country/subregion, study design and source type, medicine/class, stakeholder group, health-system level, and barrier domain, with linked reports treated as a single study family where appropriate. Qualitative findings will be coded deductively using the Joosse pharmaceutical-system processes and prespecified access dimensions, supplemented by inductive subcodes for emerging findings not adequately captured by the framework. Approximately 10% of sources will be independently coded by two reviewers to refine the codebook; remaining sources will be coded by one reviewer and verified by a second. Findings will be compared across countries, UN M49 subregions, medicines/classes, health-system levels, disadvantaged populations, and evidence types using evidence matrices. Empirical, synthesis, and documentary evidence will initially be presented separately before integrative interpretation. Quantitative findings will be presented using tables and graphs, and reporting will follow PRISMA-ScR guidance.

Subgroup analysis Not Applicable.

Sensitivity analysis Not Applicable.

Country(ies) involved South Africa - University of the Western Cape.

Keywords Breast cancer, essential medicines, access to medicines, cancer medicines, sub-Saharan Africa, low- and middle-income countries, low resource settings, barriers to.

Dissemination plans The results of this review will be developed into a manuscript and submitted to a relevant journal for consideration and publication. The results will also be included as part of the corresponding author's doctoral thesis.

Contributions of each author
Author 1 - Tinashe Zigomo - Conceptualization, design, coordination, development of the selection criteria, development of the search strategy, data collection, data management, interpretation of data, writing the protocol.
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