Establishing Requirements for Breast Centers in Low- and Middle-Income Countries: A South African Perspective

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DOI https://doi.org/10.1200/GO-25-00168

ABSTRACT

PURPOSE In South Africa, breast care lacks governance and standardization, necessitating urgent improvements in patient outcomes. Quality improvement initiatives are urgently needed in low- and middle-income countries (LMICs), but requirements for breast centers in lower resource settings remain undefined and must be tailored to local environments. This consensus document outlines the role and requirements of breast centers in LMICs and presents a step-by-step implementation plan.

METHODS The literature was systematically reviewed, and the primary review team tabulated international accreditation standards alongside the 2018 South African Clinical Guidelines for Breast Cancer Control and Management from the South African National Department of Health, along with proposed South African standards. The broader consensus panel consisted of 29 clinical experts and representatives from societies, advocacy, and funders.

RESULTS We categorized requirements into eight broader categories and achieved unanimous consensus on all requirement components, except for 1 abstention in the general specialist and expertise category. We were unable to reach consensus on the patient volume requirements for radiologists as well as for medical and clinical/radiation oncologists. Volume requirements for clinical and radiation oncologists were later provided by the South African Society of Clinical and Radiation Oncology (SASCRO), along with the volume requirements submitted by the participating radiologists. We also achieved unanimous consensus for the Breast Interest Group of Southern Africa (BIGOSA) to house the initial project implementation. This consensus document is endorsed by BIGOSA, SASCRO, and the Cancer Association of South Africa.

CONCLUSION We emphasize the importance and necessity of breast centers in resource-constrained environments, outline the first set of requirements for breast centers tailored to LMICs in sub-Saharan Africa, and present a feasible and detailed plan for initial implementation.

Accepted May 21, 2025
Published June 18, 2025

JCO Global Oncol 11:e2500168

INTRODUCTION

Breast cancer is the most common cancer among women in South Africa and most countries worldwide.[1,2] Numbers are steadily increasing in low- and middle-income countries (LMICs), and mortality rates are disproportionately higher, reflecting weaker health care infrastructure and late-stage presentation among multifactorial barriers to care.[2,3] The provision of care, such as access to optimal therapies or waiting times, accounts for approximately one third of survival differences; however, lack of guidelines, quality control, and regulatory framework may also account for up to a quarter of survival differences.[4]

The global disparities in breast cancer outcomes are a major challenge, and significant focus has been placed on the strengthening of care in LMICs where implementable quality improvement initiatives are urgently needed.[5,6] In South Africa, breast cancer survival is considerably lower than in high-income countries but better than in many other countries in sub-Saharan Africa, and survival seems to reflect the Human Development Index of countries.[7-9]

The available resources and health care spending vary widely across LMICs and are relatively better in South Africa compared with other sub-Saharan countries.[7,10] South Africa has a highly unequal, dual health care system in which over

CONTEXT

Key Objective
What are the requirements for breast centers in low- and middle-income countries (LMICs), and how can they be effectively implemented?

Knowledge Generated
This consensus document describes the tailored requirements for breast centers in LMICs and their relevance in resource-constrained settings and provides a step-by-step implementation plan.

Relevance
Breast centers have been widely adopted in some high-income countries; however, their standards are not universally applicable, and accreditation remains unaffordable, hindering widespread adoption in LMICs. The tailored center requirements present a feasible intervention that will strengthen health care systems and enhance clinical capacity.

80% of the population relies on the lower resourced public sector and less than 20% have access to the private sector.[11] Access to high-quality breast services is limited in South Africa and depends on the patient's geographical location and socioeconomic situation. At present, we estimate that there are <10 specialized high-volume multidisciplinary breast care services in the public sector and less than 10 in the private sector, serving a population of over 62 million.

Breast centers condense multidisciplinary expertise and resources with improved patient outcomes including survival, guideline-adherent care with appropriate use of multidisciplinary treatment modalities, and increased cost efficiency.[12] The process of internal and external audits and accreditation processes have been shown to improve the quality of care over time.[13,14]

There are several set requirement and accreditation systems, most prominently European Society of Breast Cancer Specialists (EUSOMA) in Europe,[4] National Accreditation Program for Breast Centers (NAPBC) in the United States,[15] and Onkozert from Deutsche Krebs Gesellschaft (DKG) in Germany.[16] Although accreditation with all three is available internationally, their standards are not uniformly appropriate in the LMIC setting, and the international accreditation process is not affordable and, therefore, not widely reproducible. This has left a gap for providers in LMICs where implementation of quality initiatives is particularly relevant; however, it is essential that the processes are pragmatic and involve systematic, sequential steps for implementation.[17]

Although sub-Saharan countries vary, this South African perspective reflects diverse resource levels and offers a consensus for South Africa and a pragmatic implementation approach for a quality improvement initiative applicable to all LMICs. This document intends to provide a consensus on the required structures and processes, describes the role of the centers, and offers a step-by-step plan for initial implementation. These are intended to be achievable with appropriate expertise and effort, widely reproducible and affordable while elevating the overall standard of care, fostering transparency, and protecting the public.

METHODS

The consensus process is illustrated in Figure 1. The literature was reviewed, and international accreditation standards of EUSOMA, NAPBC, and DKG, as well as the 2018 South African Clinical Guidelines for Breast Cancer Control and Management from the South African National Department of Health (NDoH), were compiled in a table with recommended South African requirements tailored to our setting. Our primary review team included all authors, and the final tables and base documents were circulated to the broader consensus team for review before the meeting. The consensus meeting was held virtually in August 2024, and the discussion was moderated by S.N. and P.R. The consensus meeting had 29 participants comprising 10 clinical experts from the executive committee of the Breast Interest Group of Southern Africa (BIGOSA); 1 representative each from the South African Society of Medical Oncology (SASMO), the South African Society of Clinical and Radiation Oncology (SASCRO), and the Association of Surgeons of South Africa (ASSA); five further current heads of academic breast units; seven further clinical experts with particular academic seniority; 1 representative for advocacy from the Cancer Association of South Africa (CANSA), as well as private sector funder representatives from Discovery Health and Medscheme, two of South Africa's largest private health care administrators. The NDoH was invited to participate, but no response was received.

RESULTS

We categorized the requirements into eight broader categories. During discussion in the roundtable meeting, we achieved unanimous consensus on all requirement components, except 1 abstention in the general specialist and

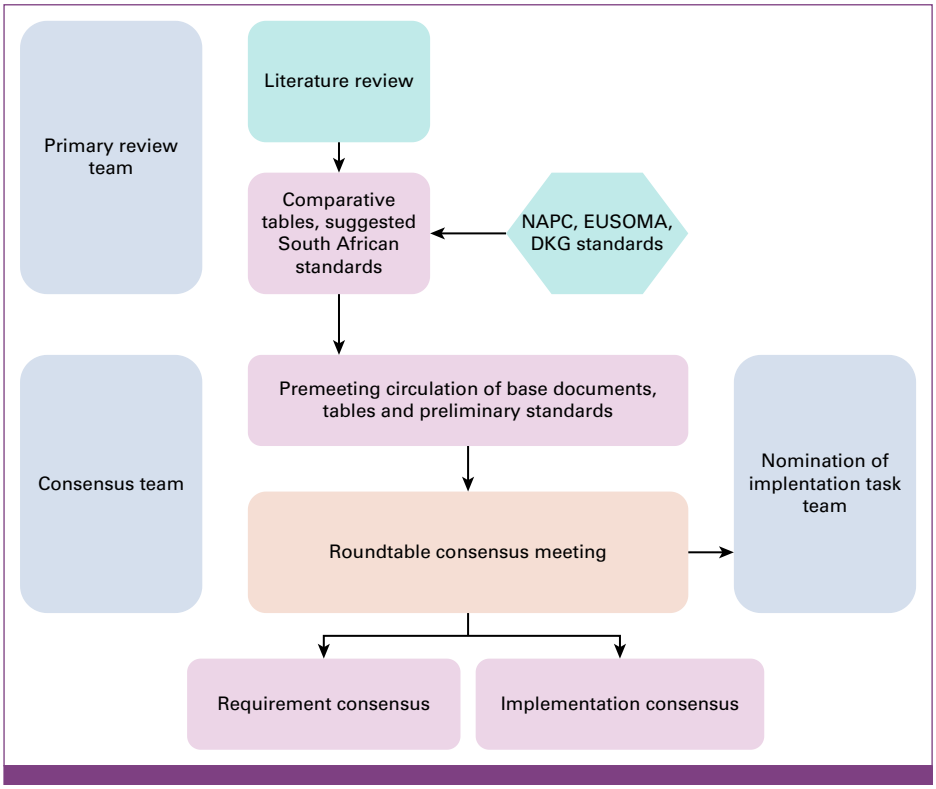

FIG 1. Consensus process.

expertise category (consensus 96%), and we were unable to reach a consensus on the volume requirements for radiologists, as well as medical and clinical and radiation oncologists. Volume requirements for clinical and radiation oncologists were received by SASCRO, and the participating radiologists provided volume requirements, which were included. Treating advanced metastatic breast cancer with systemic therapies is complex and often involves multiple therapy lines, making volume requirements challenging to assess in medical oncology.

The consensus on the implementation was unanimous in supporting BIGOSA as a means to assist in the initial project implementation with South Africa. At the time of writing, this consensus document had received official endorsement by BIGOSA, SASCRO, and CANSA.

Center Governance and Administration

A breast center is a structured team of specialists in breast cancer who work as a multidisciplinary team (MDT) with access to all necessary resources and treatments. Although single-location centers are preferable, multiple locations can cooperate through agreements and shared treatment protocols.

The center needs a governance document outlining the organization, team members, and resource locations, which should be publicly accessible along with treatment protocols. Local guidelines should be followed where applicable. Cooperation agreements between participating practices should be in place and updated annually.

A director should be appointed, who can be a specialist from any specialty on the MDT core team. The steering committee, which should include three specialists from other core specialties, supports the director, and together, they are responsible for MDT participation, data collection, and internal review and audit of the center's performance.

Specialist Expertise and Resource

The team's mandatory core specialties include radiology, pathology, breast surgery, plastic surgery, and medical and clinical and radiation oncology. A dedicated breast nurse and clinical navigators improve patient outcomes, and the center should have at least 1 breast nurse or trained navigator.[18,19]

Ideally, the extended team should include nuclear medicine, human genetics, psychologic support, palliative care, rehabilitation, dieticians, and fertility preservation. However, these services are often unavailable in LMICs, but are important to highlight, especially the advantages of the availability and early engagement of palliative care.

Ideally, there should be at least two members from each core specialty to enhance treatment options, encourage discussion, and prevent dominance in decision making. However,

resource constraints may necessitate accepting 1 member from each specialty.

For breast radiology, the participating radiologists should spend a significant portion of their time working in breast imaging. In terms of resources and expertise, the radiology center should have tomosynthesis digital mammography, high-resolution ultrasound and must be able to perform ultrasound-guided core biopsies and localizations. Within South Africa, which is relatively well resourced, breast magnetic resonance imaging (MRI) and stereotactic biopsy (and localization) should be available, or there must be an established referral system. Imaging and reports should be stored digitally, and reporting must be standardized and follow the Breast Imaging Reporting and Data System classification.

Pathologists are scarce in South Africa and even more so in other sub-Saharan African countries, leading to a lack of specialized breast pathologists.[20] However, breast center pathologists should meet international volume criteria and have specific experience in breast disease. EUSOMA and NAPBC suggest a mandatory internal review of every pathology performed outside of the center. This is not feasible in LMICs; instead, we recommend that the report must be reviewed in the MDT meeting, and a formal tissue review can be requested if there is clinical concern or discordance.

The breast surgeon must dedicate most of their working time to treating breast disease, meet the volume criteria, and ideally, have completed at least 12 months of post-qualification training or academic experience in breast surgery. There is compelling evidence for improved patient outcomes with specialization, including a reduction in the relative risk of death at 5 years of up to 33% compared with low-volume nonspecialized surgeons.[21] Given the scarcity of breast surgeons and lack of formal national training programs, this is a recommended but not a mandatory requirement. Nevertheless, the operative skill set for a specialized center in South Africa must include the appropriate performance of axillary dissection, sentinel node biopsy and targeted axillary surgery, localization techniques for impalpable tumors, breast-conserving and oncoplastic procedures, and all types of mastectomies (including nipple-sparing and skin-reducing techniques). This skill set is only achievable with specific training, and it is therefore critical that fellowships in breast surgery are recognized and offered in LMICs.

Plastic and reconstructive surgeons should fulfill the volume criteria. The center should be able to offer a wide range of advanced oncoplastic techniques, immediate and delayed implant-based and autologous reconstructions.

Medical oncologists (or clinical oncologists) should have specific experience in treating breast cancer. They must lead the decisions on and oversee all systemic therapies including endocrine therapy, chemotherapy, targeted therapy, and immunotherapy and provide follow-up information.

The radiation oncologists (or clinical oncologists) should equally have specific experience in the treatment of breast cancer. They should be competent in all breast radiation techniques, including 2D radiotherapy, 3D conformal radiotherapy, intensity-modulated radiotherapy, volumetric modulated arc therapy, image-guided radiotherapy, respiratory motion management techniques, stereotactic radiotherapy, and palliative care techniques. They must be skilled in breast cancer contouring and encouraged to complete an online course every 5 years to stay current. Breast radiotherapy protocols should be regularly updated and include dose-planning objectives for target volumes and organ-at-risk constraints for different fractionation schedules. Breast radiotherapy planning and peer-review meetings should involve at least two clinical and radiation oncologists, planning radiotherapists, treating radiotherapists, and medical physicists to review cases and assess treatment strategy, fractionation schedule, contours, and dose-volume histograms. Adverse event data should be documented weekly, and follow-up data should be collected once patients have completed treatment. Furthermore, national radiation control regulations and their quality assurance must be followed.

Patient Volumes

A critical volume is necessary to build and maintain expertise in some of the core specialties and justify the additional resources and costs for a center.[22,23] The center must manage a minimum caseload of 100 newly diagnosed or referred patients annually. In addition, each breast surgeon should operate on at least 50 primary breast cancers, and plastic surgeons should perform at least 50 postmastectomy reconstructions or advanced oncoplastic procedures. The systemic treatment of breast cancer is complex and frequently necessitates multiple treatment lines, complicating volume assessment. Clinical and radiation oncologists should aim to create at least 50 new oncology treatment plans. To ensure adequate breast imaging expertise, participating radiologists should report at least 300 mammograms per year, perform at least 200 breast ultrasounds per year, perform at least 36 biopsies or localizations a year, and, for those reporting breast MRI, they should report at least 36 per year.

Multidisciplinary Meetings

Multidisciplinary meetings foster interdisciplinary care and adherence to guidelines; reduce overservicing, overtreatment, and futile care; and improve breast cancer survival.[24-26] The center must have at least bimonthly multidisciplinary meetings. Attendance is mandatory and must include the core team members. All newly diagnosed patients, postoperative patients, and patients with disease

recurrence or distant disease progression must be discussed with clear documentation of team recommendations and treatment pathways. Radiology imaging should be available and viewed at the meeting. Patients who had their imaging outside of the breast center should have this reviewed by the center radiologists. Decisions and recommendations from the team must be communicated to the patient. In principle, these recommendations are binding, and if there is a deviation from the clinical treatment plan, the reasons must be discussed and documented.

Patient Care Principles

Figure 2 shows the patient care principles and pathway. Breast care should be standardized and evidence based with shared decision making. These choices must be within the constraints of available resources. MDT recommendations must be shared with the patient. Ideally, patients should have written information on treatment options and the treatment pathway.

Access to care should be streamlined. A diagnosis and referral to an appropriate center should take no longer than 4 weeks from when the patient noticed symptoms or a screening-detected abnormality was found. Treatment should be timely, but patients must not be rushed. They should commence treatment no earlier than a week after diagnosis, but ideally within 4 weeks of diagnosis.[27] Patients must be allowed to seek a second opinion without fear of disadvantage.

Treatment costs are particularly important in LMICs, and emphasis must be placed on both cost and value of care. High-cost treatment do not necessarily translate to better outcomes and high-cost drivers with little impact on value are well described.[28] Although more complex to implement, in the longer term, breast centers across LMICs should adopt the concept of value-based care.[28,29]

Electronic Data Records

A well-functioning and fit-for-purpose electronic record is preferable for a breast center and forms the basis for research, audit, and quality control. Initial key data should include stage, tumor biology, age, time lines, and treatments received.

Outcome indicators are more laborious to document and would require data or research assistants, resources not commonly available in either health care sector in South Africa.

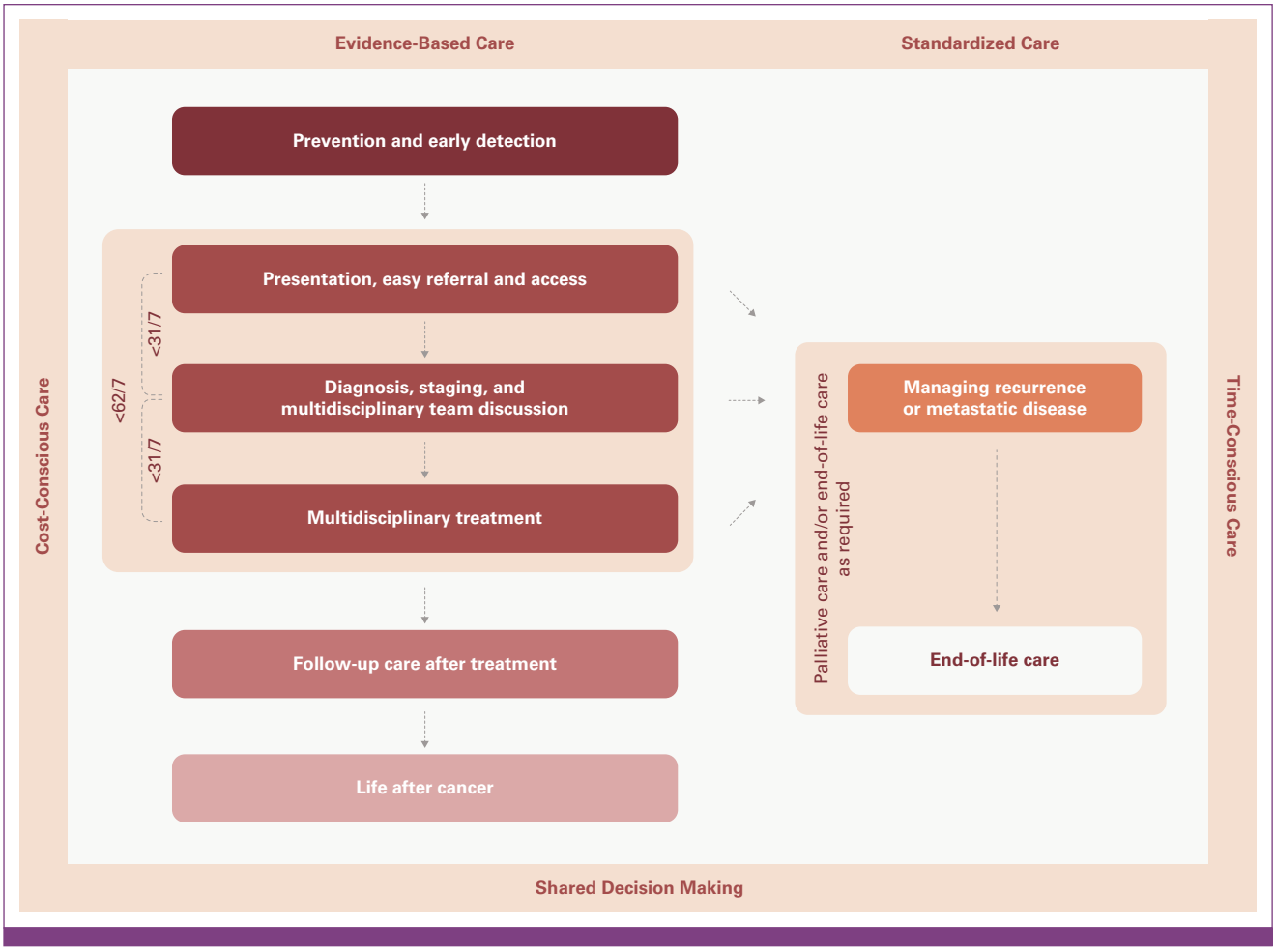

FIG 2. Patient pathway and care principles.

Table 1. Initial Quality Indicators

Quality Indicators
Timeliness of care, with documentation of time from presentation to MDT discussion, to treatment modality dates
Rate of discussion of newly diagnosed patients at MDT
Rate of breast-conserving surgery
Rate of sentinel lymph node biopsy in clinically node-negative patients
Rate of postmastectomy immediate reconstruction
Rate of radiation receipt after breast-conserving surgery
Rate of hypofractionation
Rate of systemic therapy received for patients with ER-negative tumors
Rate of HER2 targeted therapy received in patients with HER2-positive tumors

Abbreviations: ER, estrogen receptor; HER2, human epidermal growth factor receptor 2; MDT, multidisciplinary team.

Nevertheless, we recommend recording patient-reported outcome measures[17] and conducting survival follow-up for a minimum of 5 years where possible. The center should appoint a data manager to ensure data completeness and extract data for research and audits wherever feasible. The electronic database must ensure data security and confidentiality.

Audit and Quality Control

The breast center ought to conduct annual audits to identify gaps, followed by a minimum of two interventions as quality improvement initiatives. Data sets can be adapted to local resources and are easily expandable; however, we recommend the following initial quality measurements to achieve a broad quality overview (Table 1).

Research and Training

Breast centers must engage in research and training to enhance clinical practice, especially in LMICs where training of specialists is critical. In South Africa, academic units meet this demand, often in challenging conditions. Private centers should support this effort by participating in research and aiding academic training programs. We advocate for national collaborations between academic and private centers, emphasizing private sector support for academic programs.

DISCUSSION

We propose an implementable stepwise approach to build breast centers in Southern Africa, which may be applicable throughout other LMICs. We recognize that some categories may not be achievable in low-resource settings, but argue that the stepwise approach, the systematic documentation of resources and gaps in care, and the process of internal or external audit would improve the quality of care over time, transparently and timeously inform on the status of care and build breast care capacity in Southern Africa. At present, minimum targets for quality indicators are unsuitable in LMICs, where participation in quality improvements must be encouraged across all resource levels. The initial data collection should first identify and address existing gaps, but may establish benchmarks over time.

Within South Africa, we urgently need to expand breast cancer capacity with well-supported breast centers across health care sectors that provide standardized and safe care over a broad geographical area. A careful balance should be established between creating high-quality centers and still providing broad access, potentially with support of peripheral services through a hub-and-spoke system.[17] In a region with relatively scarce oncology services, the focus is not on a single site but on improving multiple sites with the goal of increasing capacity over time. No overall cancer control policy is in place in South Africa but three documents were published by the NDoH for breast, cervical, and lung cancers. Breast centers were part of the NDoH 2017 breast cancer control policy, which flagged breast cancer as a national priority.[30] The document described the importance of these centers but implementation is yet to happen and existing breast academic units remain largely underresourced with no new centers established to date. In view of this, we propose this consensus as a clinician-based initiative to increase capacity by forming public-private partnerships for implementation. Establishing collaborative centers would improve integration across health care sectors. At present, specialists are primarily trained in academic hospitals; private sector exposure would enhance training for all subspecialties, but it generally produces less research, has poor data collection, and lacks transparency. Affiliating with academic centers would improve documentation and transparency, may reduce patient overservicing, and increase research capacity. Besides assisting with training, supportive collaboration could include funding data management, aiding trainee examinations, and financing shared trainee positions.

Voluntary participation and self-reporting of audits is a well-described and appropriate step in the first implementation phase of breast centers.[31] The document offers a step-by-step plan to facilitate the implementation process (Fig 3), and in principle, appropriate multidisciplinary services can implement these steps independently at a low cost. Any new center must add value and build capacity; there must be a need for a center and willingness to collaborate, transparently share audit results, and participate in training and research. The clinicians can then form the appropriate teams and resources, with established patient volumes and MDT meetings. Once these clinical prerequisites are met, the next implementation steps should be taken to cover governance and electronic record-keeping requirements. These will create additional administrative workload and commitments and require institutional support. Within Southern Africa, new centers could register themselves after 3 months of clinical data collection with BIGOSA.

Key data and indicators, along with their intervention plans, should be shared collaboratively. Reviews must be anonymous

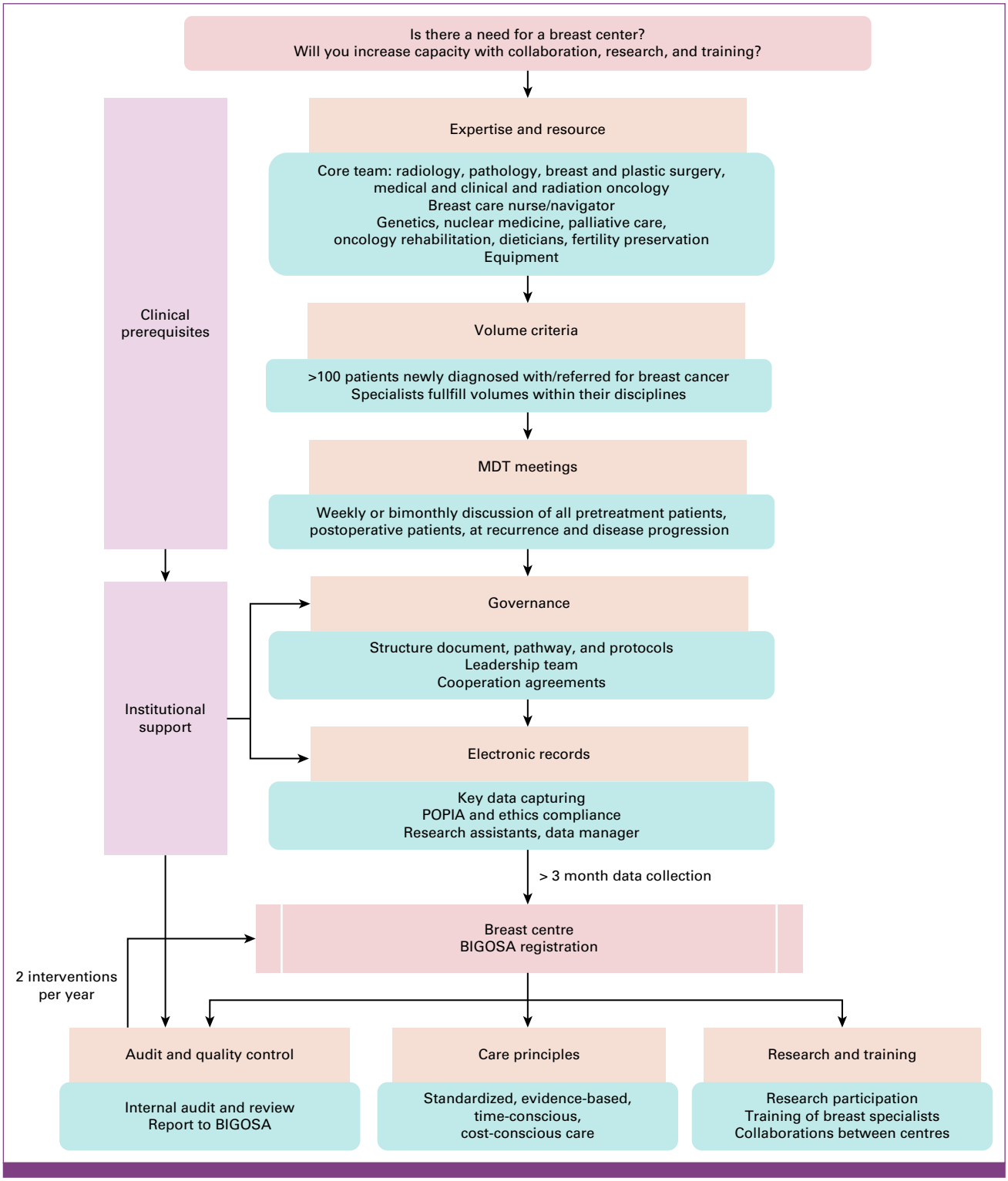

FIG 3. Breast center implementation steps. BIGOSA, Breast Interest Group of Southern Africa; MDT, multidisciplinary team; POPIA, Protection of Personal Information Act.

and nonpunitive, with compliance status attained through active participation and transparent data sharing.

The implementation of quality improvement initiatives is complex across health care environments, particularly in LMICs.[32] BIGOSA is presently not equipped and experienced to collate multisite audit results, and this will require funding and data management support. Initial key data and indicators will hopefully be expanded over time. Formal accreditation was intended in the 2018 NDoH document and

may be a possible future step after initial benchmarking. There are appropriate third-party accreditors available in South Africa who could fulfill this role, but this would need the involvement and support of statutory bodies and further funding. The BIGOSA executive committee will create a working group to address implementation phases, secure funding, support academic centers and affiliations, address ethics, and gain statutory support.

In conclusion, we have provided an initial framework and implementation guide for breast centers in Southern Africa. Participation in the registration as a breast center and audits should be voluntary and nonpunitive, and results will be collated and presented annually by BIGOSA. The implementation of the initial steps will assist to standardize care, build capacity, and improve overall quality of breast cancer care in Southern Africa.

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AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

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Research Funding: MSD (Inst), Janssen Oncology (Inst), Roche (Inst), AstraZeneca (Inst), Novartis (Inst), Pfizer (Inst), AbbVie (Inst), ImmunityBio (Inst), HUYA Bioscience International (Inst)

No other potential conflicts of interest were reported.

ACKNOWLEDGMENT

We thank the members of the consensus panel for their contribution to this work. The panel included Dr Ines Buccimazza, Dr Sharon Čačala, Prof Herbert Cubasch, Dr Marcel de Kock, Prof Georgia Demetriou, Prof Jenny Edge, Prof Paul Goldberg, Prof Jane Harries, Dr Sheree Koonin, Prof Francois Malherbe, Dr Dikeledi Mokone, Dr Nivashini Murugan, Dr Ettienne Myburgh, Dr Sudeshen Naidoo, Dr Aaron Ndhluni, Dr Noluthando Nematswerani, Dr Edward Ngwenya, Dr Jenni Noble-Luckhoff, Dr Rushen Padayachee, Dr Sumi Padayachee, Prof Boitumelo Phakathi, Dr Duvern Ramiah, Dr Peter Schoub, Ms Sandhya Singh, Prof Jacqueline Smilg, Dr Keorapetse Tabane, Dr Mariza Tunmer, Dr Eunice van den Bergh, and Dr Ronwyn van Eeden.

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