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Unlocking the Potential of Vacuum Assisted Breast Biopsy for South African Breast Cancer Diagnosis

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Contents

Executive Summary

Breast cancer is the most common cancer in South Africa, with rising incidence and mortality rates affecting both women and men, and an alarming increase among younger women. With 1 in 27 women in South Africa expected to be diagnosed with breast cancer in their lifetime, the disease represents a major public health concern. Despite its prevalence, the country faces significant barriers to early detection and effective diagnosis, including the absence of a national screening programme, workforce shortages, urban-rural disparities, and fragmented care pathways. Most diagnoses occur at advanced stages, limiting treatment options and reducing survival rates.

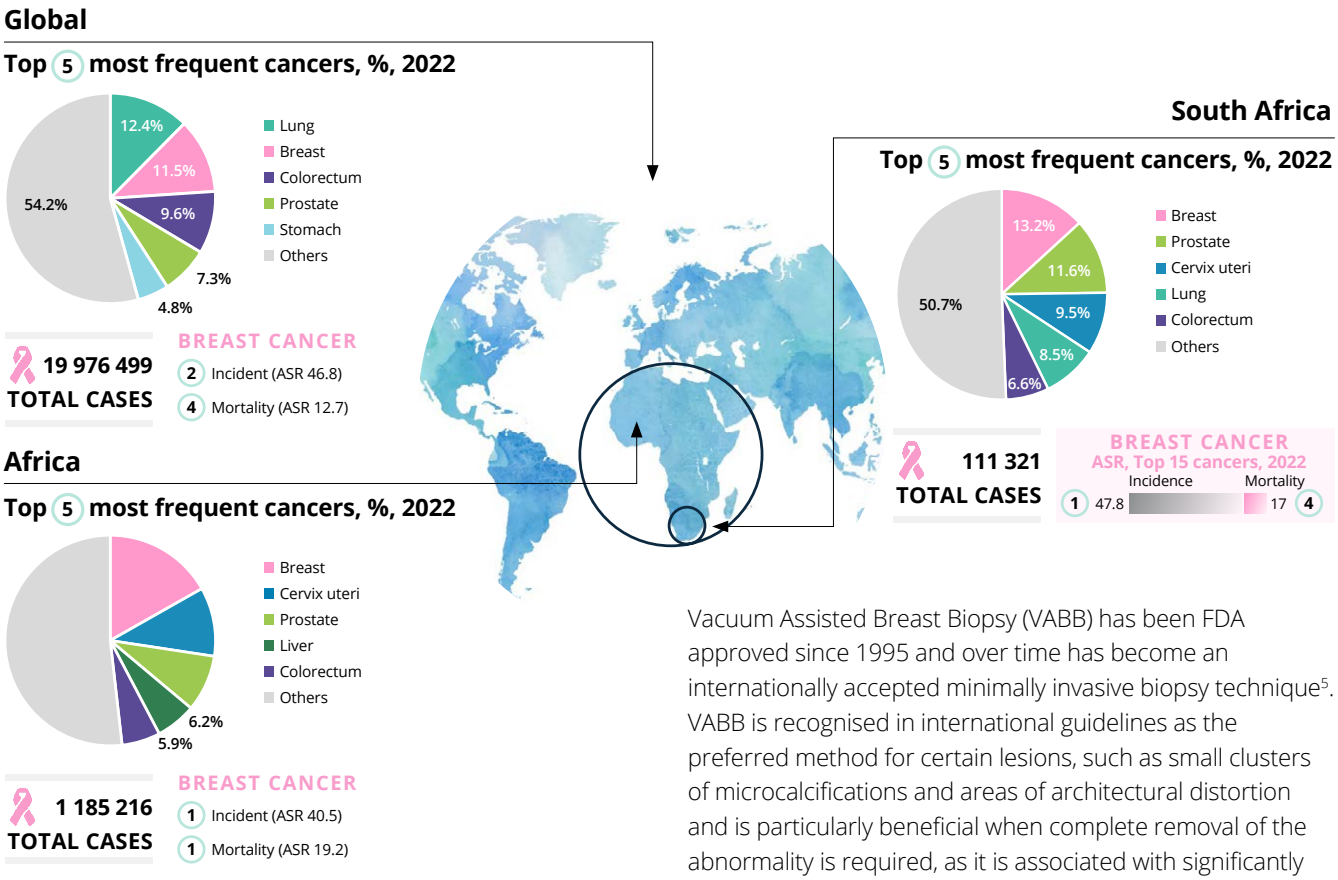
Vacuum Assisted Breast Biopsy (VABB) represents a critical advancement in breast cancer diagnostics, offering a minimally invasive, highly accurate method for sampling complex or indeterminate lesions. VABB outperforms traditional biopsy techniques in sensitivity and specificity, reduces the need for repeat procedures, and supports more timely and reliable diagnoses. However, its adoption remains inconsistent across provinces due to resource constraints, lack of standardised protocols, and limited training opportunities.

This paper calls for a national commitment to integrating VABB into standard breast cancer diagnostic pathways. Key strategic priorities include establishing clear national guidelines, ensuring VABB is covered in National Health Insurance (NHI) benefit packages, investing in workforce training, and embedding VABB within multidisciplinary teams at Breast Centres of Excellence, which are specialised healthcare facilities dedicated to providing comprehensive, high-quality breast cancer care. Public-private partnerships, evidence-based advocacy, and robust sustainability planning are essential to expand access and drive equity.

By standardising the diagnostic pathway and ensuring routine access to VABB where clinically indicated, South Africa can improve early detection, reduce mortality, and provide equitable, high-quality care for all patients, regardless of geography or socioeconomic status. Through collaborative efforts and sustained investment, the burden of breast cancer can be significantly reduced and outcomes transformed for future generations.

Introduction

Breast cancer remains the most prevalent cancer in both Africa and South Africa, with rising mortality rates among both women and men[1,2]. According to the Global Cancer Observatory (2022), breast cancer accounts for 16.8% of all cancer cases in Africa and 13.2% in South Africa, making it the leading cancer among women and a significant contributor to cancer-related deaths[1,2]. Notably, the incidence is increasing in younger women, with cases now frequently seen in those under 40 years of age[3].



Early detection and accurate diagnosis are critical to improving breast cancer survival. However, South Africa's diagnostic landscape is challenged by the absence of a national screening programme along with significant disparities in access, resources, and operational efficiency. Most diagnoses are symptom-driven, often occurring at advanced stages when treatment options are more limited and outcomes poorer.

Current diagnostic pathways involve a triple assessment, clinical examination, imaging, and traditional biopsy techniques. Some biopsy techniques are limited by reduced accuracy of certain lesion types and reoccurring need for repeat procedures[4]. These challenges can lead to delays in diagnosis, more invasive interventions, and ultimately poorer patient outcomes.

Vacuum Assisted Breast Biopsy (VABB) has been FDA approved since 1995 and over time has become an internationally accepted minimally invasive biopsy technique[5]. VABB is recognised in international guidelines as the preferred method for certain lesions, such as small clusters of microcalcifications and areas of architectural distortion and is particularly beneficial when complete removal of the abnormality is required, as it is associated with significantly lower risk of underestimating the pathology[6]. While VABB has proven clinical value for sampling specific lesion types, it remains a relatively recent advancement in breast biopsy technique in South Africa. VABB is used to achieve earlier and more accurate diagnoses, particularly with complex or indeterminate lesions, however, the adoption has been inconsistent across provinces, reflecting broader systemic challenges[7]. Expanding access to such advanced diagnostics is central to the goals of early detection, equity, and improved survival outlined in the National Cancer Strategic Framework[8], National Health Insurance reforms[9] and Breast Cancer Control and Management Guidelines[10].

This paper aims to promote consistent, high-quality breast cancer diagnostic pathways in South Africa by evaluating the adoption of VABB across South Africa, standardising protocols, and ensuring its routine use.

Overview of the Breast Cancer Diagnostic Pathway in South Africa

In South Africa, the breast cancer diagnostic journey is shaped by the interplay of healthcare infrastructure, resource allocation, and patient access. Early and accurate diagnosis is essential for improving patient outcomes, yet the absence of a standardised national screening programme means most diagnoses are symptom driven and often occur at an advanced stage[11].

Patients typically enter the public health system at primary healthcare clinics, where a clinical breast examination is performed by nursing staff. If a suspicious mass is detected, the patient is referred to a medical officer or general practitioner, who may then initiate referral for diagnostic imaging.

Imaging is a critical step in the diagnostic process. Mammography is generally the first line imaging modality, particularly for women over 40, while ultrasound is preferred for younger women due to higher breast density or is used to further characterise lesions detected on mammography. Magnetic resonance imaging (MRI) may be used in selected high-risk cases or when other imaging is inconclusive[12].

Accurate diagnosis and effective treatment planning for breast cancer depend on obtaining high-quality histological and/or cytological samples from suspicious lesions. The choice of biopsy technique is primarily determined by a lesions BI-RADS characteristics such as size, visibility, type, and positioning, with patient factors considered secondary.

When a lesion is identified on ultrasound, the standard of care is an ultrasound-guided core needle biopsy (CNB) as CNB is suitable for most palpable masses as it provides adequate tissue for a definitive diagnosis, tumour staging, and receptor analysis. Fine needle aspiration (FNA) is primarily reserved for cystic lesions and suspicious axillary lymphadenopathy, as it yields cytological material which has limited tissue analysis qualities[12].

In selected cases, image-guided vacuum-assisted breast biopsy (VABB) may be indicated, as it provides a larger and more representative tissue sample, improving diagnostic accuracy[13] and lowering underestimation risk.

Both CNB and VABB specimens provide sufficient tissue for comprehensive histopathological evaluation. However, VABB should be reserved for clinically necessary cases due to risk of complications.

These tissue samples are sent to the National Health Laboratory Service (NHLS) for analysis, where malignancy, tumour staging, and hormone receptor status are assessed.

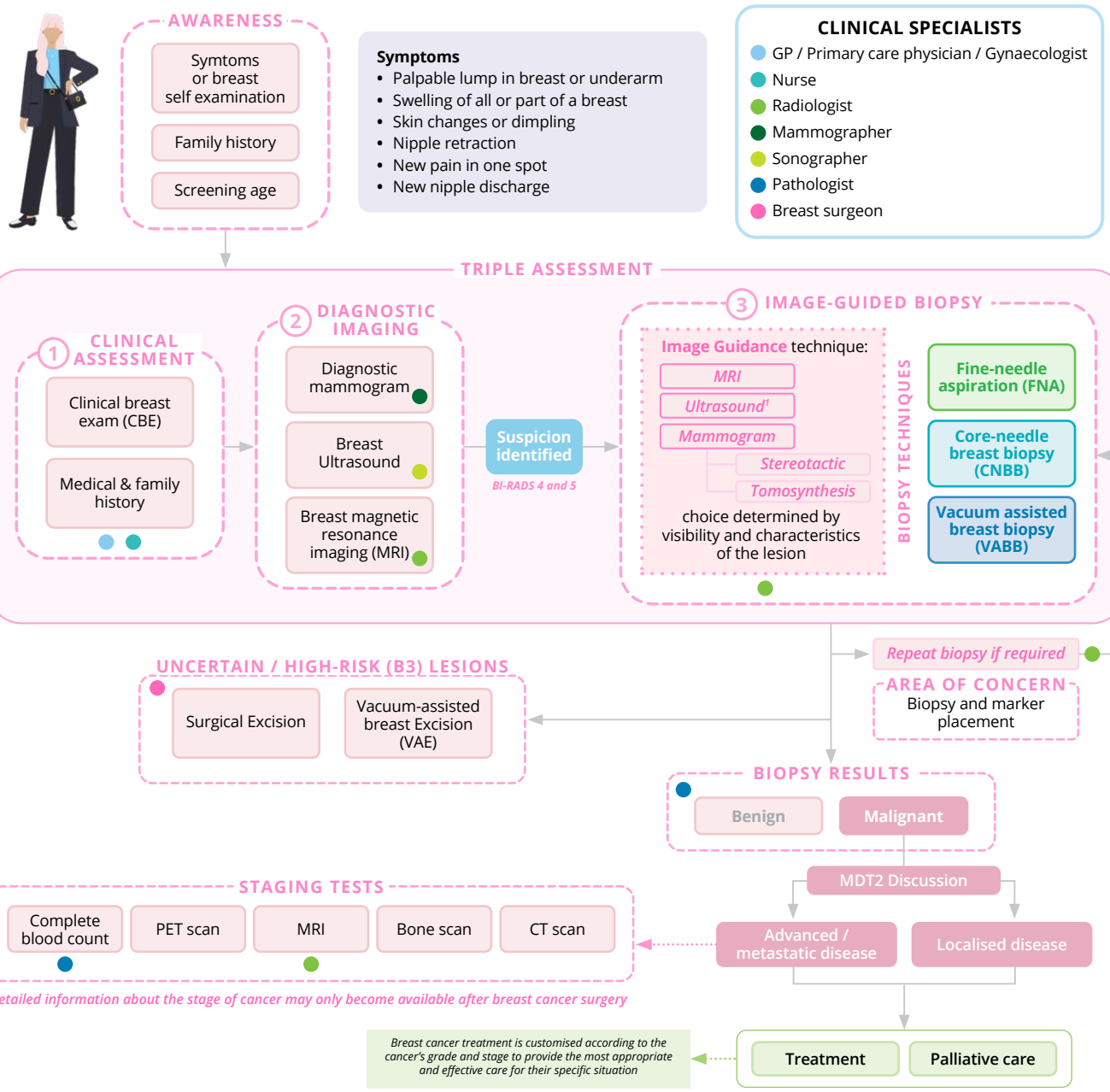
The "One-Stop" Clinic Advantage

Where available, one-stop-shops or rather clinics enable same-day imaging and biopsy, reducing diagnostic delays and patient anxiety. However, this model is generally reserved for Breast Centers of Excellence (BCoE) and is not yet widely adopted across South Africa.

Diagnosis and treatment planning is reviewed by a multidisciplinary team (MDT) to ensure coordinated, patient-centred care. MDT involvement is linked to improved adherence to evidence-based guidelines, better survival rates, and a higher standard of care[14].

Equitable access to multidisciplinary expertise is essential to improving outcomes for all patients, regardless of geographical location or socioeconomic status.

Example of a typical breast cancer patient journey



Systemic Barriers and Fragmentation in the Diagnostic Pathway

In South Africa, the diagnostic pathway for patients with suspected breast cancer is hindered by several systemic issues at every stage, from initial presentation to final diagnoses[11,15]. Diagnostic delays begin with limited patient awareness of breast cancer symptoms and the absence of a national screening programme, leading to missed or delayed diagnoses. Low awareness of symptoms, socio-economic status and stigma are further reasons why a patient will delay initial examination ultimately delaying a definitive diagnosis.

Although the Clinical Guidelines for Breast Cancer Control and Management stipulate that all healthcare workers, including nurses, should be trained to perform clinical breast examination (CBE) and to recognise symptoms of breast cancer[10], implementation of these requirements remains inconsistent. Many healthcare professionals who lack adequate training are unfamiliar with appropriate referral pathways. Leading to missed or delayed diagnosis and suboptimal patient management[15].

Resource constraints are acute. According to the National Cancer Registry (NCR), 1 in 27 women in South Africa will be diagnosed with breast cancer[11] and the countries incidence-to-mortality ratio of 3.3:1[16], highlights the high disease burden. The health system has only 60.5 radiologists per 10 000 cancer patients[17], meaning each radiologist is responsible for approximately 165 cancer patients, 13.1% of whom have breast cancer. This results in unsustainable workloads, increased risk of diagnostic errors, and reduced capacity for MDT collaboration and patient counselling. Similar shortages exist for pathologists, surgeons, and oncologists, particularly in rural areas.

Geographical disparities in access to breast cancer care are significant. Most tertiary hospitals, along with imaging and biopsy equipment and specialist staff, are concentrated in urban centres, resulting in clustered care in these regions. Patients, particularly those from rural areas, often travel significant distances, sometimes up to 100 kilometres, for specialist care, which can delay presentation, complicate follow-up and contribute to later stage diagnoses and challenges in maintaining continuity of care.

For example, the Northern Cape, which is the largest province by area, has only one tertiary hospital, while Gauteng, the smallest province by area, has six[18]. This uneven distribution means rural patients must travel long distances, incur additional costs, and face greater inconvenience and delays in accessing care. In contrast urban patients benefit from faster access to high-quality services. The distance required to reach a tertiary hospital varies widely across provinces, and not all tertiary hospitals are designated Breast Centers of Excellence (BCoE), which further exacerbate disparities in timely and comprehensive care. Geographic constraints further underscore the importance of high-quality diagnostic pathways; in regions where patients must travel long distances to access specialist care. The absence of robust, standardised protocols increases the risk of inconclusive results and re-biopsies, compounding delays, costs, and patient hardship.

Biopsy availability is further restricted by the need for fully functional ultrasound and/or mammography machines, adequate consumables, available procedure rooms, and skilled medical personnel. If any of these components are lacking the ability to perform the biopsy technique is severely limited. Even after a biopsy is performed, further delays frequently arise from backlogs in pathology analysis and inefficient communication of results to clinicians and MDTs, which can postpone treatment decisions and impact patient outcomes.

Finally, the absence of a standardised national reporting platform for cancer diagnoses leads to frequent data loss and repeat biopsies, further delaying a definitive diagnosis. This lack of uniformed data collection also prevents authorities from accurately assessing the true burden and prevalence of breast cancer in South Africa.

Key Barriers to Consistent Care

- Lack of national screening programme
- Urban-rural inequities
- Workforce shortages
- Delays in histopathologic analysis and reporting
- Communication delays and loss to follow-up at clinic level
- No standardised national cancer registry

The Value Proposition of VABB in Modern Breast Cancer Diagnosis

Vacuum-Assisted Breast Biopsy (VABB) represents a significant advancement in the diagnostic pathway for breast cancer in South Africa. As a minimally invasive, image-guided diagnostic procedure, VABB utilises larger gauge needles (typically 7-12G) and a vacuum mechanism to obtain more substantial and representative tissue samples than traditional core needle biopsy (CNB) which uses 12-18G needles[4].

The technical advantages of VABB translate into improved diagnostic performance. Studies report VABB specificity of 92–99%, sensitivity greater than 97%, and accuracy above 93.2%. These metrics consistently outperform core needle breast biopsy in complex cases, where CNB specificity range from 80–100%, sensitivity from 81–100%, and accuracy from 82.8–100%[19]. While CNB remains appropriate for many routine scenarios, VABB delivers distinct advantages in challenging or indeterminate cases.

VABB is particularly valuable for sampling microcalcifications, architectural distortions, lesions smaller than 5mm, complex cystic lesions with small solid components and for re-biopsy in cases where previous CNB pathology results are discordant with imaging findings[4,20] or if a high-risk lesion is identified from histological analysis requiring a larger sample for further characterisation.

In these contexts, VABB reduces the likelihood of repeat procedures, minimises false negatives, and lowers the risk of underestimating lesion severity[21]. By providing larger, more representative samples and reducing diagnostic uncertainty, VABB supports more consistent and actionable pathological results. Potentially shortening the time from initial presentation to definitive treatment, ultimately improving patient outcomes[19].

The decision to use VABB should be guided by clear clinical indications, as it offers several patient benefits over surgical biopsies, due to its minimally invasive approach while achieving comparable diagnostic results. VABB should be considered an alternative to CNB for certain lesions, as it provides greater diagnostic accuracy, reduce the risk of histological underestimation, and the fact that it helps avoid unnecessary surgical procedures[5].

However, VABB is not without limitations. The procedure samples a larger portion of tissue from the breast, which can increase the risk of haematoma and bleeding. Patients with a known bleeding tendency, blood coagulation disorders, or related haematological abnormalities should not undergo VABB due to the increased risk of haemorrhagic complications, and those taking coumarin derivates (e.g. Warfarin) should be advised to discontinue use 48 hours prior to the procedure to minimise this risk.

VABB is also more resource-intensive, requiring specialised equipment, consumables, and skilled personnel, and typically occupies mammography suites for longer periods than CNB. As such, VABB should be reserved for clinically indicated cases where CNB is less effective for first line diagnosis or re-biopsy procedures post initial CNB procedures.

Given the complexity of some cases, the decision on biopsy technique is not always straightforward. Multidisciplinary team (MDT) review at a Breast Centre of Excellence (BCoE) is invaluable for complex presentations, enabling expert input and tailored decision-making to optimise patient outcomes [22].

Ideal Candidates for Vacuum Assisted Breast Biopsy (VABB)

- Suspicious microcalcifications that are not visualised on ultrasound, including isolated microcalcifications or those situated outside a defined mass.
- Architectural distortions identified on imaging.
- Small masses less than 5 mm, or larger masses requiring repeat biopsy when core biopsy is inconclusive.
- Discordant findings between imaging and histopathology.
- High-risk histopathological findings (such as atypical ductal hyperplasia) where more tissue is needed for diagnosis.
- Complex cystic or intraductal lesions that are difficult to sample with standard techniques.
- Lesions detected only on contrast-enhanced imaging that require targeted biopsy.

Implementation Considerations for VABB Adoption

1

Establishing Breast Centres of Excellence (BCoEs) and Multidisciplinary Teams (MDTs)

Multidisciplinary teams (MDTs) are essential for delivering coordinated, patient-centred care and ensuring the appropriate use of VABB within the diagnostic pathway. Ideally situated within Breast Centres of Excellence (BCoE), MDTs could include radiologists, surgeons, pathologists, oncologists, nurses, mammographers, psychologists or counsellors, and genetic counselling services. While a fully staffed MDT provides the greatest benefit, a minimum standard MDT comprising of a mammographer, breast radiologist, breast surgeon, and pathologist remains effective in supporting high-quality clinical decision-making.

2

Resource Requirements

Although VABB machines are available in most tertiary hospitals, the essential consumables such as needles and tubing used in combination with the primary equipment are often limited due to budget and procurement constraints. Workforce shortages, particularly among skilled radiologists, mammographers, and breast surgeons, further constrain the ability to deliver VABB services consistently.

3

Scheduling and Workflow Management

Operational planning is required to integrate VABB procedures into existing diagnostic workflows. VABB procedures typically require mammography rooms to be booked for extended periods, which can limit access for other imaging needs and create scheduling bottlenecks. Effective coordination with imaging and pathology services is necessary to minimise delays and ensure efficient patient flow. In practice, VABB procedures may not be feasible on the same day as initial imaging, even in facilities with a one-stop clinic model, due to resource and staffing constraints.

4

Training and Workforce Development

The absence of national training protocols for VABB is a key barrier to consistent, high-quality service delivery. Ongoing professional development for radiologists, mammographers, and surgeons is essential to ensure procedural competence and adherence to best practice. The shortage of experienced mammographers is particularly acute, as their expertise is crucial for patient positioning, safety, and management of complications. Structured training programmes and certification pathways are needed to build and maintain a skilled workforce capable of supporting VABB adoption nationwide.

5

The Need for Standardised Protocols and Guidelines

Currently, the lack of national standardised protocols for VABB leads to variability in clinical practice, operational inefficiencies, and inconsistent patient experiences. In the absence of unified guidelines, individual hospitals develop their own protocols, resulting in fragmented service delivery and disparities in care quality. Standardised, evidence-based national protocols are essential to ensure that VABB is used appropriately, resources are optimally allocated, and all patients receive equitable access to high-quality breast cancer diagnostics. Clear protocols also facilitate procurement planning, streamline training requirements, and support continuous quality improvement across the health system.

Strategic Priorities for National Implementation and Sustainability of VABB in Breast Cancer Diagnosis

National Guidelines and Policies: National breast cancer diagnostic guidelines should mandate the use of VABB as the first-line biopsy technique for suspicious microcalcifications and complex lesions, replacing less accurate methods where evidence supports its superiority.

Benefit Packages: The Essential Diagnostic Benefit Package under National Health Insurance should explicitly list VABB as a covered service for indicated breast lesions, ensuring reimbursement and eliminating out-of-pocket costs to patients.

Evidence-Based Advocacy: Advocacy initiatives should present local data on VABB's higher diagnostic accuracy in selected cases, reduced need for repeat biopsies, and improved patient outcomes to policymakers and funders, supporting its prioritisation in resource allocation.

Public-Private Partnerships (PPPs): PPPs should be established to optimise the utilisation of both financial and human resources for procuring, maintaining, and distributing VABB machines and consumables in public hospitals. These partnerships should also provide technical support and training in collaboration with device manufacturers.

Professional Societies: The Radiological Society of South Africa and Breast Imaging Society of South Africa should set national VABB competency standards, accredit training centres, and require VABB proficiency for breast imaging certification.

Training and Professional Development: All radiologists, breast surgeons, and relevant allied health professionals should undergo certified hands-on VABB training, including ultrasound- and stereotactic-guided techniques, as part of both initial qualification and ongoing CPD requirements.

Referral Pathways and Communication: Referral protocols should require that patients with imaging findings of suspicious lesions are referred directly to centres equipped with VABB. Protocols must include clear guidance on transfer arrangements and the use of standardised communication templates to expedite scheduling and reporting.

Integration with Multidisciplinary Teams (MDTs): Ensure VABB results are seamlessly integrated into MDT discussions, with clear pathways for follow-up and treatment planning.

Sustainability Planning: Develop long-term plans for the financial and operational sustainability of VABB services, including budgeting for equipment replacement, consumables and ongoing training.

Conclusion

Improving breast cancer outcomes in South Africa requires decisive and unified action. Vacuum Assisted Breast Biopsy offers a significant opportunity to achieve earlier and more accurate diagnosis, reducing the need for repeat procedures and improving care for patients with complex or indeterminate lesions. Realising the full benefits of VABB depends on national commitment to standardised protocols, equitable resource distribution, and comprehensive training for healthcare professionals. Integrating VABB into multidisciplinary teams, inclusion in benefit packages, and ensuring its availability at all Breast Centres of Excellence will help achieve earlier detection, better treatment, and lower mortality rates. By making VABB a central part of breast cancer diagnostics, South Africa can ensure that every patient, regardless of location or background, receives the highest standard of care. The strategic priorities outlined in this paper provide a clear path for sustainable and nationwide implementation, creating a future where breast cancer is detected sooner, treated more effectively, and survival is improved for all.

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