

DIAGNOSTIC BREAST CLINIC MODEL IN A RESOURCE-CONSTRAINED ENVIRONMENT: A QUALITY ANALYSIS

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Introduction:

Breast cancer remains a leading cause of cancer-related illness and death among women worldwide, with early diagnosis essential for increasing survival rates and reducing the burden of advanced disease. In resource-limited settings—particularly in low- and middle-income countries (LMICs)—timely and precise diagnosis often faces challenges due to restricted access to imaging, pathology, trained staff, and coordinated care. Diagnostic breast clinics aim to streamline patient assessment through the triple assessment, comprising clinical examination followed by imaging, and biopsy—ideally carried out in one or as few visits as possible. Although this approach has demonstrated effectiveness in high-resource environments, adapting it for resource-constrained settings requires modifications. Recognising diagnostic delays and understanding the factors behind them are vital for improving the quality and efficiency of breast cancer care in these contexts.

Research of the question / aim of the study:

To evaluate the quality of a diagnostic breast clinic operating in a resource-constrained environment by analyzing diagnostic timelines, identifying factors contributing to delays in diagnosis, and uncovering system gaps that can be addressed to improve efficiency and patient outcomes.

Materials and Methods:

- Study design: Prospective observational study
- Setting and sampling: Groote Schuur Hospital Diagnostic Breast Clinic
- Inclusion and exclusion criteria: All female patients undergoing freehand core needle biopsy of palpable breast lump in the breast clinic from 01 June 2024 to 01 April 2025. Excluded: male patients. Locally advanced breast cancer (T4b, T4c)
- Data collected: Prospective data collection using a RedCap data collection sheet of all female patients undergoing freehand core needle biopsy of palpable breast lump in the breast clinic.
- Data analysis and statistical analysis used: Descriptive statistics were used to summarise the data. Continuous variables were reported as medians with interquartile ranges (IQR). For comparisons between independent numerical variables, the Student's *t*-test was used for two-group comparisons, and the One-way ANOVA test was used for comparisons involving more than two groups. A *p*-value of <0.05 was considered statistically significant.
- Ethical considerations: Ethics approval obtained from UCT HREC Ref 229/204

Results:

A total of 488 female patients with 492 palpable breast lumps were included. All palpable breast lumps on physical examination underwent free-hand biopsy in the same clinic visit, followed by imaging on a later date.

Key demographics:

- Median Age: 47 years (IQR: 37–61)
- Median BMI: 29.2 kg/m² (IQR: 24.3–34.1)
- Median Breast Volume: 448 cc (IQR: 304–657)

Delays Observed

- Patient Delay: 62% (270/433) reported presenting more than three weeks after symptom onset
- Referral to Diagnostic Breast Clinic : Median of 7 days (range: 1–148)

Biopsy outcome				
	Freehand biopsy diagnosis	Repeat biopsy done to make diagnosis	Method repeats	Repeat performed by
Total diagnostic biopsies (n=440)	389 (88.4%)	51 (11.6%)	Freehand 0 Ultrasound 49 (96.1%) Not reported 2 (3.9%)	Surgeon 47 (92.2%) Radiologist 2 (3.9%) Not reported 2 (3.9%)
Benign diagnosis (n=222)	208 (93.7%)	14 (6.3%)	Freehand 0 Ultrasound 13 (92.9%) Not reported 1 (7.1%)	Surgeon 12 (85.7%) Radiologist 1 (7.1%) Not reported 1 (7.1%)
Malignant diagnosis (n=218)	181(83.0%)	37 (17.0%)	Freehand 0 Ultrasound 36 (97.3%) Not reported 1 (2.7%)	Surgeon 35 (94.6%) Radiologist 1 (2.7%) Not reported 1 (2.7%)

- No repeat biopsies were done using the freehand technique.
- In multivariate analysis, no significant association was found between biopsy accuracy and BMI, breast volume, lesion size, or depth from skin.
- **False Negative Impact:** Patients with an initial false negative biopsy experienced a significant delay in diagnosis (mean: 42 days vs. 14 days; $p < 0.05$).
- Sixty-seven patients underwent a biopsy based on clinical findings, with normal subsequent imaging results.

Conclusions:

Despite functioning within a resource-limited environment, the diagnostic breast clinic demonstrated efficiency with a median system delay of only 14 days for 83% of cancer cases. However, delays caused by patients continue to be a significant obstacle. False-negative biopsy results, although rare, substantially contribute to diagnostic delays, highlighting the need for earlier image-guided intervention and potentially more structured protocols for repeat biopsies. Tackling modifiable system inefficiencies and increasing public awareness could greatly improve the timeliness and accuracy of breast cancer diagnosis in LMIC settings.