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Original Research Article

# Development of an Integrated Ultrasound Predictive Model and Framework for Breast Cancer Diagnosis in Zambia

Oliver Sutherland[1*], Stefan Kafwimbi[2], Jonathan Chinyama[3], Osward Bwanga[4], James Sichone[2]

[1]Evelyn Hone College, School of Applied and Health Sciences, Lusaka, Zambia
[2]University of Zambia, Faculty of Health Sciences, Lusaka, Zambia
[3]University of Zambia/Eden University, Department of Psychology, Lusaka, Zambia
[4]Midland University Hospital Tullamore, Radiology Department, Co. Offaly, Ireland

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**Abstract:** ***Background*:** Developed countries bear a higher burden of breast cancer compared to developing ones. However, they have higher survival rates (80-90%) compared to developing countries (57%). In Zambia, this is compounded by the lack of context-specific integrated predictive model and framework. ***Aim*:** To develop an integrated breast cancer ultrasound predictive model and framework suitable for clinical use in low-resource settings. ***Methods*:** A quantitative analytical cross-sectional study design was used. Participants were selected through systematic random sampling and the breast ultrasound features were documented using the modified BI-RADS Atlas fifth edition. Histology results for the same patients were documented using the modified RCP reporting proformas. Finally, the ultrasound and histology findings were compared for each patient**.** ***Results*:** The findings of this study indicate that productive age, multi-parity, marital status (married), and employment status (employed) are significantly associated with breast cancer (P<0.05). The strength for the associations were 0.6930 and 0.7872 for reproductive age and multi-parity respectively, whereas the strength for the associations of marital and employment status with breast cancer were 0.4455 and 0.4624 respectively. Irregular shape, vertical orientation, hypoechogenicity, complex echopattern, irregular or spiculated margin contours, compression of surrounding tissue, and absence of hyperechogenic spots or a hyperechoic halo or thin capsule were found to be associated with breast cancer (P<0.05). The strength of the association of the preceding ultrasound features with breast cancer was 0.4953, 0.3712, 0.7989, 0.4722, 0.4783, 0.3527 and 0.4540 respectively. Additionally, the study revealed that breast cancer lesions in stage 2 were the most prevalent, and ductal carcinomas were the most common histological type. ***Conclusion***: In countries with limited resources with limited access to imaging diagnostic tools, it is important to closely consider ultrasound findings for potential signs of breast cancer. The patients risk factors and demographics should also be considered. The participants with a high index of suspicion for breast cancer should undergo histology examination. This can help raise suspicion and prompt timely intervention to prevent the development of advanced-stage breast cancer at the point of diagnosis while waiting for confirmation through histology examinations.

**Keywords:** Breast cancer, diagnosis, predictive model and framework, ultrasound, Zambia.



## BACKGROUND

Globally, breast cancer is a leading cause of morbidity (11.6%) and mortality (6.6%) among females (Bray *et al.*, 2018). Developed countries bear a higher burden of breast cancer compared to developing ones, exemplified by new cases in the United States of America (USA) at 15.2% versus 7% in Zambia (National Cancer Institute, 2023; International Agency for Research on Cancer, 2020). Despite higher survival rates (80-90%) in developed nations, attributed to accessible healthcare and early detection tools like mammography and Magnetic Resonance Imaging (MRI) (International

***Corresponding Author:** Oliver Sutherland
Evelyn Hone College, School of Applied and Health Sciences, Lusaka, Zambia

Agency for Research on Cancer, 2020; McKenzie *et al*., 2018), developing countries, including Zambia, exhibit poorer survival (57%) rates due to insufficient diagnostic infrastructure (National Cancer Institute, 2021; Kapambwe, 2015). Approximately 60% of breast cancer deaths occur in developing countries (Siegel *et al*., 2016), emphasising the impact of healthcare disparities on prognosis (NCI, 2021).

In Zambia, breast cancer incidence and mortality are escalating, with the Global Cancer Observatory (GLOBOCAN) estimating 19.9 cases and 9 deaths per 100,000 women, respectively (Ibid). The Zambian Ministry of Health (MoH) acknowledges this high incidence and mortality in its Cancer Control Strategic Plan (2016-2021). Despite efforts to expand screening programs, the lack of accessible early detection tools, especially in public hospitals, persists (Kapambwe, 2015). Bwanga *et al.*, (2021) reported sixteen mammography machines in Zambia, 10 in public and 6 in private hospitals, currently all non-operational in public hospitals except one at Mainasoko medical center. Additionally, only seven MRI machines are available, primarily in Lusaka and the Copper Belt provinces (Bwanga *et al*., 2023), posing accessibility challenges for patients with suspicious lesions.

The current use of BI-RADS in Zambia for sonographic recommendations and data archiving faces limitations, including its inability to substitute personal experience (Kanso *et al*., 2009). Moreover, it lacks a consolidated framework for assigning a high index of suspicion for breast cancer, overlooking factors like demographics and risk factors. Developed in resource-rich settings, BI-RADS may not suit low-resource environments like Zambia, prompting a need for context-specific frameworks, such as the Japanese guidelines (Chisato *et al*., 2016).

This research and write-up proposes and discusses an ultrasound predictive model and framework tailored for Zambia. The model aims to establish an index of suspicion for breast cancer, aiding clinicians in prioritising patients for urgent breast cancer management.

## CONCEPTUALISING THE BREAST CANCER PROBLEM

Breast cancer cases in Zambia must be curbed downwards. Ultrasound is a viable alternative to accomplish this. Figure 1 is a proposed conceptual framework that seeks to explain how ultrasound can be used to curb breast cancer downwards.

### Ideal situation for breast cancer diagnosis

Ideally, breast cancer should be diagnosed at an early stage when it is most treatable (Appleton, 2014). This is evidenced in high-resource countries where there is a high burden of breast cancer but with few morbidities and mortalities. Easy access to quality healthcare services including early detection facilities such as mammography and MRI, and specialized human resources such as radiologists and sonographers, is therefore vital to enhance early breast cancer diagnosis (McKenzie *et al.*, 2018). This would then render prompt and accurate diagnoses of the disease, with minimal delays between breast cancer diagnosis and treatment for breast cancer patients. Further, breast cancer patients should have access to a range of support services, including psychological support and nutrition counselling. This would then culminate in reduced breast cancer morbidity and mortality.

### Prevailing situation for breast cancer diagnosis in Zambia

Breast cancer diagnosis presents significant challenges in low-resource countries like Zambia due to inadequate healthcare infrastructure, which limits access to early diagnostic facilities like mammography, MRI, and histology (Kapambwe, 2015; Bwanga *et al*., 2021). The high cost associated with these diagnostic services and equipment often prevents patients from accessing them, exacerbating the problem. Moreover, a shortage of trained healthcare professionals like radiologists, pathologists, and oncologists in these settings further compounds the issue (Kapambwe, 2015; Bwanga *et al*., 2021). The low level of awareness about breast cancer among the population also contributes to late diagnosis of the disease, which makes treatment more difficult and lowers survival rates.

### Alternative pathway for breast cancer diagnosis in Zambia

The inadequate healthcare infrastructure such as mammography, MRI, and histology that limits access to early breast cancer diagnostic facilities are a matter of policy in Zambia and many other low-resource countries (Bwanga *et al*., 2021). Further, the costs attached to the acquisition of such diagnostic equipment coupled with a shortage of trained healthcare professionals such as radiologists, pathologists, and oncologists in these settings compounds the situation, making it very unlikely that these environments would soon strengthen breast cancer diagnosis using this pathway (Kapambwe, 2015; Bwanga *et al*., 2021). However, an alternative pathway to this is ultrasound which is affordable, non-ionising and readily available in the majority of low-resource countries (Bwalya *et al*., 2022). For ultrasound, to be able to provide the alternative pathway and enhance early breast cancer diagnosis, a strong breast ultrasound reporting framework ideal for low-resource settings is essential. In Zambia, no localised framework is available. Instead, the BI-RADS framework ideal for high-resource environments is used. The preceding framework does not integrate other factors such as the demographics and risk factors of suspected breast cancer patients. It also only classifies individual ultrasound features in terms of the likelihood of diagnosing breast cancer without clustering them. To develop a framework suitable for low-resource countries like Zambia, this study correlated the ultrasound features that suggest breast cancer with histopathology, patients' risk factors and demographics.

The culmination was the establishment of an ultrasound predictive model and framework which would help to denote an index of suspicion for breast cancer and enable clinicians to prioritise patients requiring further and urgent management for breast cancer.

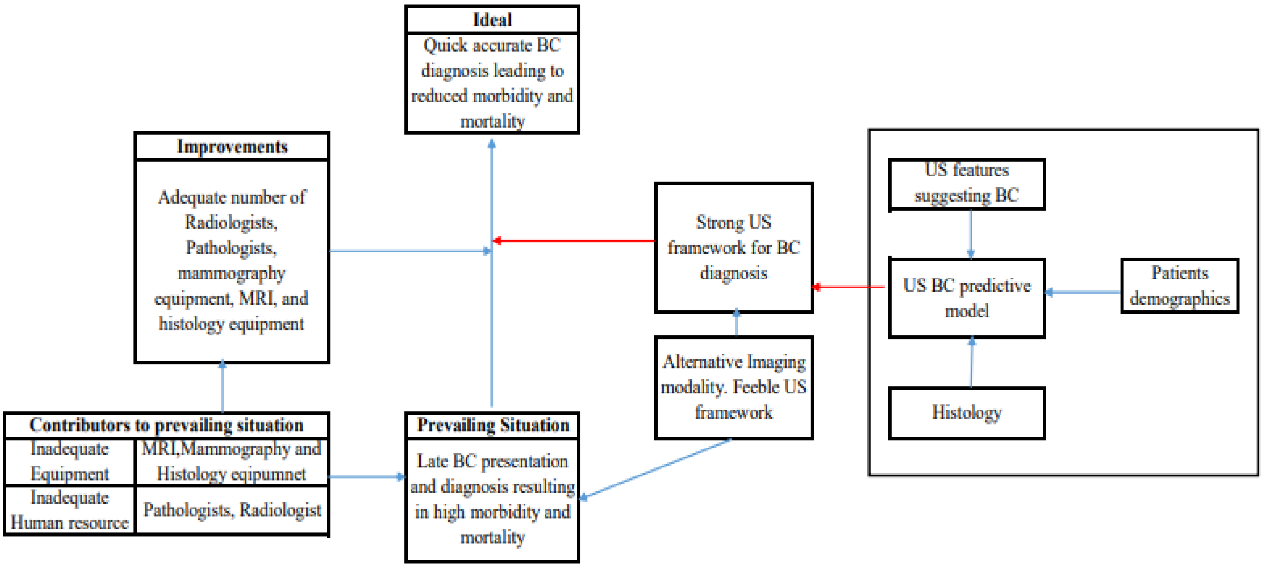


**Figure 1: Conceptual framework**

# METHODS

**Study design**

The study utilised a quantitative analytical cross-sectional study design. Data were collected from July 2021 to June 2022.

**Study Setting**

The study was carried out in the surgical breast clinics and ultrasound departments of the Cancer Diseases Hospital (CDH) and Matero General Hospital (MGH) of Lusaka.

The University Teaching Hospital (UTH)-adult hospital, MGH and CDH, were chosen as study sites, specifically the MGH and CDH breast clinics and ultrasound departments. In the case of UTH-adult hospital, the histology laboratory was used for the examination of breast samples.

CDH is a 252-bed capacity facility and operates 24-hour service. By 2019, the hospital had seen over 21 000 cancer patients over a period time of 13 years (2006 to 2019). In 2018 alone, the hospital attended to 2734 cancer patients with 900 of them being breast cancer patients. This number was expected to increase to over 3000 by the end of 2019 (Banda, 2019). In 2020, 260 outpatient department breast cancer patients were attended to at CDH. The hospital also has well-established laboratory and radiology departments, for easy access to patient's histology data and ultrasound equipment for examining the patient's breasts. UTH is a 1837-bed capacity facility and has a catchment area covering about 1.3 million people. Similarly, UTH has well-established laboratory and radiology departments, for easy access to patients' histology data and ultrasound equipment for examining the patients' breasts.

MGH breast clinic received referrals from District Hospitals within Lusaka, Health centres and Health posts within Lusaka (Songiso *et al.*, 2020). From March 2018 since its inception to April 2019, the hospital's breast clinic attended to 1790 female patients with breast symptoms (Songiso *et al.*, 2020). The participants in the study were patients referred to the breast surgical clinics of these facilities for breast cancer suspicion without confirmation for breast cancer using histology examination. The MGH breast clinic has since been closed due to the non-availability of a breast surgeon. The breast surgeon who used to run the clinic has since been transferred to one of the teaching hospitals within Lusaka.

**Sampling technique**

Systematic random sampling was used for the selection of participants in this study. The sampling interval was calculated by dividing the total patient population size by the calculated sample size. The total population stood at 972 patients (International Agency for Research on Cancer, 2020), while the total calculated sample size was 200. The Cochran formula (1977) was used to determine the sample size at a 5% level of significance. Dividing the patient population size with the calculated sample size yielded a sampling interval of 4.86, rounded off to 5. The researcher then randomly selected the first participant (patient) from between the first patient and the patient falling on the sampling interval of 5 in the patient queue. Once the first participant was selected, the researcher then selected the rest of the participants using a count interval of 5 until the sample size was attained. These were patients that were prescribed histology and breast ultrasound examinations for suspected breast cancer. This sampling technique was applied to both study sites.

**Data Collection Tools**

**Modified American College of Radiologist (ACR) Breast Imaging Reporting and Data System (BI-RADS) and Royal College of Pathologists (RCP) reporting checklists**

The researcher utilised modified piloted checklists to collect data on suspected breast cancer patients, including both histology and ultrasound data. To collect ultrasound data, the researcher adapted and modified the ACR BI-RADS Atlas fifth edition checklist (ACR, 2016), while for histopathology data, the researcher adapted and modified the RCP reporting proformas (checklist) (RCP, 2017).

**High-Frequency Ultrasound Equipment**

The breast ultrasound scans of the research participants at CDH were performed using the Medison Accuvix Vio ultrasound machine, while the Echoson ultrasound machine, model CA 225 was used for scans at MGH. These machines are certified by the International Standard Organization (ISO) under standard number 29821:2018, which focuses on the condition monitoring, diagnostics, and validation of ultrasound machines. A high-frequency linear ultrasound probe with frequencies ranging from 7.5 to 11 megahertz was utilized for scanning the patients' breasts.

**Data Collection Procedures**

Ultrasound departments were used to scan patients while surgical breast clinics were used to recruit patients into the study and access histology results. The ultrasound examination procedure was clearly explained to the patients and they were assured of confidentiality. Firstly, the researcher and his assistants performed a breast ultrasound scan on the suspected breast cancer patients in the ultrasound department to obtain the ultrasound features. The breast surgeons working with the researcher obtained breast samples for histology examination under ultrasound guidance. The histology results for the same patients were then obtained from the UTH histology laboratory or the histology report filed in the patient's medical file after they had done the histology examination. The comparison of ultrasound and histology findings for the same patient was then done.

**Data Management and Analysis**

Data was transferred from the hardcopy collection tools, cleaned and stored in an excel sheet upon completion of data collection. Statistical analyses were performed using Stata SE version 16. The Shapiro-Wilk test for normality of data was performed for continuous data. In this study, continuous data were not normally distributed and as such were presented as medians and Interquartile range (IQR), while categorical data were presented as a percentage frequency distribution.

To assess if there was any significant difference between findings in histology-confirmed breast cancer lesions and histology-confirmed benign breast lesions for continuous data, the Mann-Whitney U test was performed, P=/<0.05, statistically significant at 95% confidence interval. The Chi-square test ($\chi$ 2 test), P=/< 0.05) indicated a significant difference at a 95% confidence interval for categorical data.

The study sample was randomly divided into training and validation data using the ratios of 0.6 to 0.4 respectively to establish the Predictiveness of ultrasound in determining a positive diagnosis of breast cancer. Training data was used for model tuning to fit the data while testing data was used for the evaluation of the prediction models using the cross-validation method. Lasso for prediction and lasso logistic regression (lasso logit) was used in this study for model selection and prediction since it minimises the estimate of the out-of-sample prediction error.

## RESULTS AND DISCUSSION

In this article, instead of presenting individual results for the study, a simplified ultrasound predictive model (Figure 2) and a breast cancer decision making framework (Figure 3) developed from the results is presented. As a result, the model and framework is not just presented, but also discussed. The model and framework have been developed for the prioritisation of patients being managed for breast cancer diagnosis suitable for clinical use in low-resource settings. The research study was titled "UTILISING PREDOMINANT BREAST ULTRASOUND FEATURES OF ZAMBIAN FEMALES IN ESTABLISHING A PREDICTIVE MODEL FOR IMPROVED DIAGNOSIS OF BREAST CANCER IN ZAMBIA". The concepts of the developed framework were then utilised to generate a simplified Microsoft Excel tool, suitable for low-resource environments that can be used to ascertain either a high or low index of suspicion for breast cancer in females.

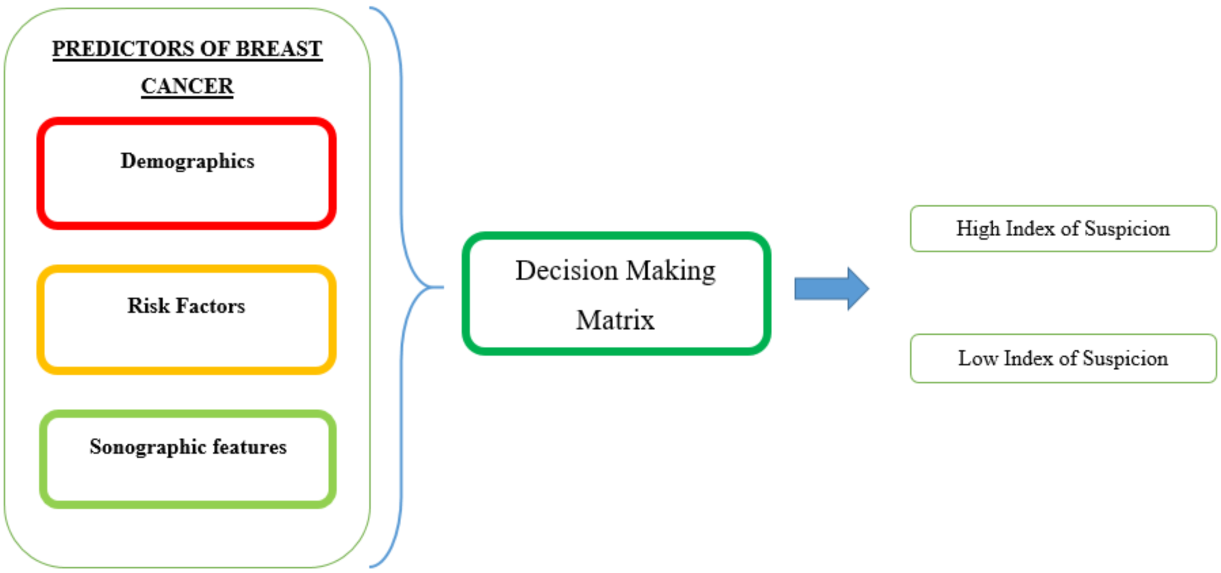


**Figure 2: Simplified low-resource environment integrated ultrasound predictive model for breast cancer**

Overall, the above integrated ultrasound predictive model can help healthcare professionals to identify and differentiate between suspected breast cancer patients with either a high or a low index of suspicion for breast cancer, and potentially improve early detection and treatment of breast cancer. The model is recommended for use in the clinical environment by sonographers, radiographers, breast surgeons and other clinicians involved in breast disease management. It is intended to be used in low-resource environments such as Zambia where early breast cancer detection facilities such as Mammography and MRI, and histology examinations are scarce for prioritising patients who require urgent breast management while awaiting histology confirmation. The utilisation of the model is intended to avoid late-stage breast cancer at the time of diagnosis. The proposed model is a response to the local needs about enhancing breast cancer diagnosis. It integrates and explains multiple variables that point to a high index of suspicion for breast cancer to curtail the scourge of the disease. Further, the model can guide policy formulation regarding breast cancer diagnosis using ultrasound in low-resource environments including Zambia.

Unlike other ultrasound breast cancer models such as the BI-RADS fifth edition (ACR, 2016), which only classifies individual ultrasound features in terms of the likelihood of diagnosing breast cancer, this model, includes clustering of the individual ultrasound features to indicate suspicion of breast cancer. The integration of this model is explained in terms of the demographics of the study participants, the risk factors of study participants, the ultrasound features and the histology findings.

To actualise the recommended simplified and integrated ultrasound predictive model, the breast cancer decision making framework is recommended (Figure 3). The framework is meant to prioritise patients who require urgent breast management while awaiting histology confirmation.

In the framework (Figure 3), it is recommended that when a patient visits a health-care facility with suspicion of breast cancer, the patient's demographics should be considered first. The patients age demographics (35years and above), patients having attained secondary education, multi-parity, the married marital status and habitation in high residential areas should merit a high index of suspicion for breast cancer. The preceding demographics proposed in this framework align with demographic characteristics of breast cancer in low resource regions found by other studies. They include a younger age of between 40 and 50 years (Bekkali and Basu, 2021; Olaogun *et al*., 2020; Shen, 2017; Makanga *et al*., 2013; Hesahm and Alexandra, 2010), secondary education (Liu *et al*., 2017; Sani *et al*., 2016), multi-parity (Makanga *et al*., 2013), married marital status (Olaogun, 2020; Martínez *et al*., 2017), and high residential area habitation (NCI, 2023; Kenzik, 2020).

The framework then proposes that if the patient presents with the risk factors of having previous breast cancer on the contralateral breast and are on contraceptive use for reproductive regulation, a high index of suspicion for breast cancer should be considered in such patients. The other risk factors in this study did not warrant a high index of suspicion for breast cancer. The proposed risk factors in this framework are consistent with findings of some studies regarding the risk factors of previous breast cancer (Manouchehri *et al*., 2022) and contraceptive use (Mørch *et al*., 2017).

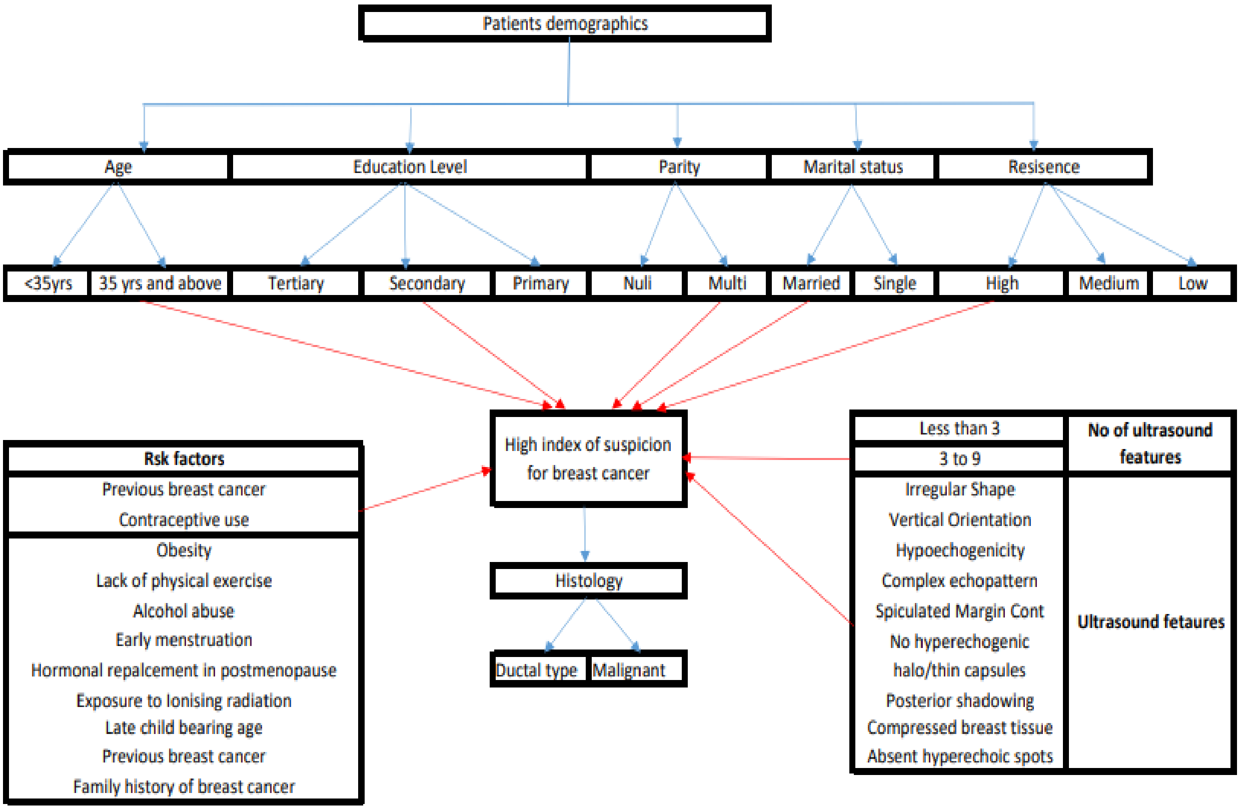


**Figure 3: Breast cancer decision making framework**

A physical examination of the breast is then recommended. This is to assess for the presence of any lumps or changes in breast tissue.

In the preceding framework, the use of high frequency ultrasound as a first-line imaging modality to evaluate suspicious breast lesions is recommended. Mammography and MRI for additional evaluation in certain cases when available is recommended. When the ultrasound features of the irregular shape of breast lesions, vertical orientation of breast lesions, hypo echogenicity of breast lesions, complex echo pattern in breast lesions and spiculated margin contour of breast lesions are noted on ultrasound examination of the breast, a high index of suspicion for breast cancer should be considered. The other ultrasound features of breast lesions which should warrant a high index of suspicion for breast cancer include posterior acoustic shadowing, compressed breast lesion surrounding tissue, breast lesion boundary without hyperechoic halo or thin capsule, and absence of hyperechoic spots. In addition, when 3 to 9 of the cited ultrasound features are found in a single breast lesion, the case for a high index of suspicion for breast cancer is further strengthened.

Some of the proposed ultrasound features indicative of a high suspicious for breast cancer in this framework conform to the findings of some of the previous studies. For example, the findings of irregular shape (Nasser *et al*., 2016; Okello *et al*., 2014; D'Orsi *et al*., 2013; Boujelben *et al*., 2012), vertical orientation (Nasser *et al*., 2016; Okello *et al*., 2014), complex echo pattern (Steven *et al*., 2018), hypoechogenicity (Nasser *et al*., 2016; Wheeler *et al*., 2014; Wojcinski *et al*., 2013), spiculated/irregular margin contour (Gregoria *et al*., 2007) have been found to be associated with breast cancer in previous studies. Other ultrasound features found to be associated with breast cancer include compressed breast lesion surrounding tissue (Gaur *et al*., 2013), absence of hyperechoic spots in breast lesions (Gufler *et al*., 2000) and posterior acoustic shadowing (NCI 2014). Discrepancies between some ultrasound features indicative of a high suspicion for breast cancer in this model and some similar previous studies have been noted. For instance, Okello *et al*., (2014) found breast lesions with hyperechoic halo to be associated with breast cancer, and Gregoria *et al*., (2007) found the complex echopattern to be associated with benign breast lesions. The cause of the discrepancy is unclear and hence raises concern for further investigation. However, the discrepancy may be linked to variations in study settings and populations. Generally, there is a paucity of literature, whether recent or old, on the topic under discussion.

Finally, in this matrix, the histology findings for the breast lesions with a high index of suspicion for breast cancer using the patients' demographics, patients' risk factors, physical examination and ultrasound examination are likely to be positive for breast cancer. The ductal breast cancer type is the most likely breast cancer diagnosis. This is in tandem with findings from literature and other studies (Oncolink wesite, 2022; Olaogun, 2020; Badge, 2017).

Figure 3 above illustrates the breast cancer decision making framework for breast cancer prediction suitable for clinical use in low-resource settings including Zambia.

## CONCLUSION

This article has proposed an integrated ultrasound model and framework that outlines a comprehensive breast cancer decision-making matrix designed for clinical use in low-resource settings, specifically referencing Zambia. The matrix suggests a systematic approach to identifying and assessing patients with a high index of suspicion of breast cancer based on various demographic factors, risk factors, physical examination, and ultrasound features. This would then aid in prioritising patients who require urgent breast management while awaiting histology confirmation to avoid late-stage breast cancer at the time of diagnosis.

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