

Title: An artificial intelligence point of care ultrasound (POCUS) breast cancer screening program in Gauteng: Improvement of patient referral pathway program

Author: Dr Kathryn Malherbe, University of Pretoria

### **Introduction:**

Breast cancer remains the most common form of cancer among women, worldwide<sup>1-2</sup>. Due to the reported high incidence, technology that improves detection rates needs to be developed.. An alternative approach to screening is being suggested in recent literature<sup>4</sup>, termed as “clinical downstaging”, which is defined as an approach to earlier detection of breast cancer focusing on early-stage cancers of symptomatic women to enhance overall patient prognosis. This approach contrasts with population based, opportunistic screening, focusing on asymptomatic women.

### **Research question and aim of study**

To develop a point of care breast cancer screening program through comparison of clinical breast examination and artificial intelligence breast ultrasound screening in the Gauteng region.

### **Materials and Methods: Study design**

Quantitative comparative descriptive study to be implemented as a research project over 6 months period. The study will be a prospective approach to ensure fair comparison between current and new breast screening methods to be implemented during the study.

### **Materials and methods: Setting and sampling**

Patients included are all women between the age group of 25-85 years, with or without clinical history of breast cancer and symptoms related to breast disease. Patients of any race, socio-cultural background will be included, as per homogenous convenience Daspoort Poli clinic will be the study setting of the 6 month period, including an estimate of 600 women.

### **Inclusion criteria and exclusion criteria:**

Any biologically female patient, between the ages of 25-85 years of age, with or without clinical presentation of a mass/lump/family history will be informed of the study and giving the opportunity to sign informed consent, at their own will and decision. Any patient younger than 25 years or older than 85 years will not be if not willing to participate and sign informed consent will be excluded. However their standard care of practice will not be impeded by the current study.

### **Data collected**

The Breast AI™ application to be used is a registered under SAPHRA. The application is used in conjunction with wireless point of care ultrasound probes (Clarius™) which is an internationally FDA approved system to be used at the Daspoort Polyclinic. Data to be collected will be the incidence rate of suspicious mass findings between CBE, Breast AI and combined use of both methods at Daspoort Poli Clinic. Data will also be collected on the referral network time to surgical intervention using combined method of CBE and Breast AI.

### **Data analysis and statistics**

For objectives the Pearson chi squared and Fisher’s exact test will be used to examine the differences between CBE and use of POCUS and AI for early cancer detection of palpable masses. Means and medians will also be computed for differences in the groups. To examine association to advanced stage, a multivariate logistic regression model will be used. P-values of <0,1 will be prompted in bivariate analysis. Analysis will be performed using STATA 14 software.

### **Ethical considerations**

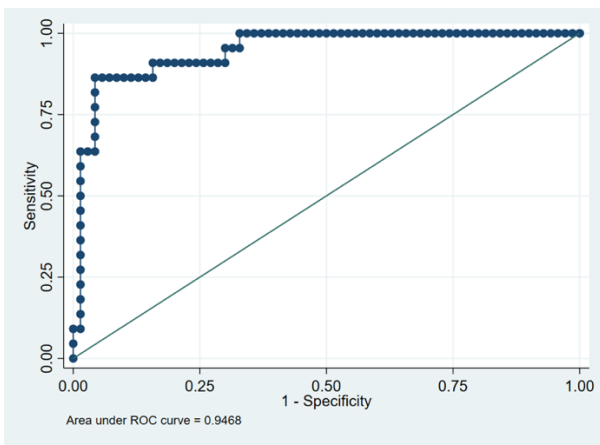
Privacy of patient information will be ensured through use of anonymized data. Dignity will be ensured through the quality of care received at the clinic and respect to their cultural norm, values and beliefs related to disease processes. All information will be secured on the UP Fig share data repository with access only through registered users for research purposes.

### **Results**

Initial results of study in 2022 showed the Breast AI to have a 97,6 % accuracy in predicting the breast cancer subtype as lobular or ductal carcinoma through use of breast ultrasound imaging and the AI algorithm, in comparison to the gold standard of histopathological diagnosis of breast cancer following excision biopsy. The Area Under the Curve AUC was measured as 94,6 during data set training and validation phase of prospective data used in 2021.

### **Conclusion**

The need for adequate patient education at grassroots level is a key motivator for patients to attend their annual mammographic screening. The use of a local breast education program and the AI POCUS system at Daspoort Poli clinic, may potentially allow further employment of youth for data validation and training as the current education sector encourages non-traditional job creation, especially for roles within the fourth industrial revolution.



Picture 1: Note ROC curve comes from the logistic regression model, outcome =  $\log(\text{Odds of being Lobular})$ , predictors = GSM values for cancer and normal tissue. Produces ROC curve with AUC = 0.9468