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Bridging the Breast Care Divide: Point-of-Care Ultrasound for all Women with Breast Problems

Richard R. Love[a], Ayrin Aktar Supta[a], Ummay Sani Jahan Rimi[a]

[a]From The Amader Gram Breast Problem Care Center, Khulna, and The Amader Gram Cancer Care and Research Center, Rampal, Bagerhat, Bangladesh

The United Nations current sustainable development goal 3.4 is to reduce premature mortality from noncommunicable disease by one-third by 2030.[1] Among the World Health Organization's target activities directed to this goal is the reduction of premature mortality from improved diagnosis of potentially curable malignancies such as breast cancer.[2] As the National Academy of Medicine in the United States has emphasized, the central issues in primary care— the only health system component or function that has been shown to produce better population health and health equity—are access and quality of care.[3]

Globally, the 10-year breast cancer survival differences between the United States (84%), and India (66%), suggest that reducing the premature mortality for this disease by half (or significantly more than the general target of one-third) should be possible.[4] In low- and middle-income countries (LMICs), advanced stages of breast cancer at diagnosis are more common than in high-income country settings, circumstances which are generally considered a major reason for the long-term survival differences among different countries. Perceived unaffordable access in the International Agency for Research on Cancer (IARC) trial of breast self-examination in the Philippines was a major reason why "early" diagnosis could not be demonstrated effective.[5] The general diagnostic sequence for patients with serious breast problems is: 1) Presentation to a primary care practitioner who may or may not identify the possibility of malignancy; 2) Referral and visit to a surgeon; 3) Referral and visit to a radiologist for imaging with mammography; 4) Follow-up visit with a surgeon who may then perform a fine needle aspiration cytology or core needle biopsy of an examination or mammographically identified abnormality. This whole or partial sequence is inconvenient, and financially and indirectly costly for most women, and thus is understandably associated with delay or absence of prompt diagnosis in LMICs. In a case series of patients presenting with breast cancer in the academic medical center in Khulna, Bangladesh—our community—only 9% of women had potentially curable disease.[6] These observations and experiences call for different health system approaches to increase prompt access and provide impactful quality and practical diagnostic strategies for all women with breast problems, some of which will be breast cancer. How can we bridge the divide in global breast problems and breast cancer diagnostic care to allow higher percentages of women in low- and middle-income countries to be diagnosed with curable stages of breast cancers?

Our answer is a specialty primary care "one stop" service model.

The American Institute of Medicine's six measures of quality of care –efficacy, safety, efficiency, patient-centeredness, timeliness, and equity—are feasibly and sustainably addressable with a specialty service-within-primary care model.[7] Over the last 15 years, we have developed and provided such service to 26,000 Bangladeshi women, none of whom have had any third-party payment coverage. Our Amader Gram Breast Problem Center has these key features:

- All-women clinical staff.
- Screening for ability to pay, and a sliding scale of charges.
- All-inclusive $14 standard visit fee, including bilateral breast ultrasound examinations.

***Address for correspondence:**
Richard R. Love,
2708 Columbia Road, Madison, WI 53705, U.S.A.
Email: richardibcrf@gmail.com

- Bilateral breast examination and ultrasound of all patients by the same physician.
- Immediate interpretation of ultrasound examination by the examining physician and a second ultrasound specialty training physician.
- Sharing and explaining ultrasound images to every patient by the examining physician.
- Arrangements for immediate on-site core needle biopsy for any cancer or historically chronic mass with characteristics of cancer or of uncertain etiology (see footnotes in Table 1). This procedure is done under ultrasound guidance as appropriate, after injection of a local anesthetic and following a minor skin incision, with a 16-gauge biopsy gun. Obtained specimens are immediately placed in 10% neutral buffered formalin. A frozen section procedure is not followed. Overnight fixation is done, and after paraffin block embedding, thin sectioning and formal pathological interpretation of prepared slides; if malignancy is diagnosed, immunohistochemical staining is done for hormonal receptors and Her-2/neu protein expression.
- We have been able to both increase the numbers of women seen daily, and the percentage of women who return for follow-up visits to create a business that is financially sustainable without significant outside monetary support. Our follow-up success is remarkable because in Bangladesh "one-and-done" medical services are the usual model for care.

We were able to conduct a consecutive patient-case series study several years ago documenting the effectiveness of our clinical assessments, summarized in Table 1.[8]

Table 1. Clinical diagnoses with physical and ultrasound exams in a consecutive series of 1085 Bangladeshi women.[8]

Characteristics	Percentage
Breast Cancer	6 (0.6%)
Mass, suspect malignant*	16 (1.5%):11 biopsy positive, 2 biopsy-suspect for malignancy
Mass of uncertain nature#	14 (1.3%)
Fibrocystic changes	733 (67.6%)
Fibroadenoma	128 (11.8%)
Other	188 (17.3%)

* Mass strongly suspected to be cancer: chronic, usually hard, mass, immobile, painless with hypoechoic changes and irregular, angulated borders on ultrasound.

Mass, etiology and nature uncertain: chronic, usually firm, mass with uncertain borders, often associated with some discomfort, with mixed echogenic features on ultrasound with ill-defined borders.

These data show that 36 of 1085 women (3%) had confirmed or suspected/possible malignancy by the criteria noted. Based on these data, our practice is to recommend biopsies in women who have masses that are suspected to be malignant or are of uncertain nature, because high percentages of these turn out to be cancer biopsy-positive.

Over subsequent years in which we have examined several thousand women, we have become aware of no women diagnosed with breast cancer for whom we did not recommend a biopsy. Thus, we believe that our experience is consistent with the high reported sensitivity of ultrasound for diagnosis of breast cancer in a recent meta-analysis.[9] The sensitivity of ultrasound in studies from low- and middle-income countries in that analysis was 89.2%, a figure comparable to the sensitivity of mammography reported in American studies.[10] What is significantly different between mammography and ultrasonography is their specificities. In representative American data, the specificity of mammography is 88.9%, while meta-analysis data for ultrasonography in low- and middle-income countries is 99%.[9,10] While the mammography data are predominantly from screening, the LMIC ultrasonography data are problem-investigation data. However, were mammography to be applied in the LMIC settings for problem assessments, we would expect such a lower specificity rate which would mean that there would be larger numbers of false positive tests, perhaps 1 in every 10 patients. Our experience with ultrasound strongly suggests that the reported research rate for specificity is promising. False positive tests lead to further examinations and costs, which are infeasible and impractical in LMIC settings like ours. For the commonest mass lesion in clinical practice—fibroadenoma (see Table 1), usually seen in younger women, the role and accuracy of mammography are very limited.

As noted in the meta-analysis discussion, studies indicate that ultrasound is effective in diagnosing small invasive cancers in dense breast tissue and has very high sensitivity in women with focal symptoms and in Asian women with denser breast tissue.[9] The three-dimensional component of ultrasonographic imaging may be a significant contributory factor in its

high-performance measures. Unquestionably, more data on the sensitivity and specificity of ultrasonography in LMIC settings are needed to confirm the limited information available, but this need should not prevent us from using this efficacious, safe, and inexpensive technology now.

Beyond these quality measures, point-of-care ultrasonography allows immediate correlation with patient signs and symptoms, is patient-centered in being convenient and allows patient education by viewing the images, and is timely. Of particular note is the value of ultrasonography in specific diagnosis of multiple common breast problems, such as fibrocystic changes and fibroadenoma. In clinical practice, as our experience strongly suggests, the majority of women have clinically important benign conditions. In our practice we have been able to diagnose with confidence 12 different non-malignant conditions.[8] The costs of ultrasonographic machines are much lower than those of mammography equipment, and their necessary special facilities; in our experience, a high-quality ultrasound machine costing $13,000 has performed over 60,000 examinations. Ultrasonography is safer, and the training needed to achieve clinical competence in ultrasonographic interpretation is also much more limited. A further benefit of ultrasonography is that the machine can be used for examinations of the abdomen and pelvis.

The common western, high income country model of breast problem evaluation centered on mammographic imaging in a remote location is inconvenient and impractical in LMIC settings. Screening for breast cancer is not a cost-effective approach in LMIC settings, mainly because of low absolute incidence rates, which we have confirmed in our own country.[11,12] At present, while there is a significant need for further clinical practice data on the performance measures of breast ultrasound as a single evaluation modality or practically as a "one stop tool" together with physical examination as we have done, the available data and our experience strongly suggest the feasibility of point-of-care breast ultrasonography for women presenting with breast problems as a practical approach likely to address constructively, efficiently, and impactfully the common problem of late stage diagnosis of breast cancer in LMIC settings.

By the six standard criteria for quality of an intervention of the Institute of Medicine noted above, ultrasonography is a higher quality test than mammography.[7] This situation is similar to others in medicine in which a new and better technology is developed and replaces a long-held standard of care. Finger oximetry replacement of arterial blood gas assessment, CT scanning and ultrasound replacement of intravenous pyelogram (IVP) testing, and hemoglobin A1c replacement of glucose measurement are a few good examples. The meta-analysis data and consensus reviews have clearly indicated that it is time to promote breast ultrasonography globally for point-of-care assessment of breast problems.[9,13]

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CONFLICT OF INTEREST

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