

WOMAN'S CANCER FOUNDATION

Well Woman Clinic

The Need

Rising incidence of cancer in developing Countries which the American Cancer Society describes as a ‘Global Cancer Epidemic’

- ❑ Longer life span
- ❑ Environmental factors, lifestyle changes
- ❑ Cancer causes more deaths than TB, Malaria and HIV combined

- **Early detection is the only ‘cure’ for cancer**
- **Aim is to downstage the cancer to improve outcomes and reduce mortality**

CANCERS TO BE TARGETED



- Breast Cancer
- Cervical Cancer
- Endometrial cancer
- Ovarian Cancer

BREAST CANCER

- ❑ Breast cancer is the most prevalent cancer in the world today. 4.4 million Women are alive today in whom breast cancer was diagnosed within the last five years
- ❑ Over 1 million new cases of Breast cancer will be reported worldwide

2009...

- 45% will be in low resource countries of Asia, Africa and South America
- Half a million women die of breast cancer yearly and
- 55% of breast cancer mortality will occur in underserved countries

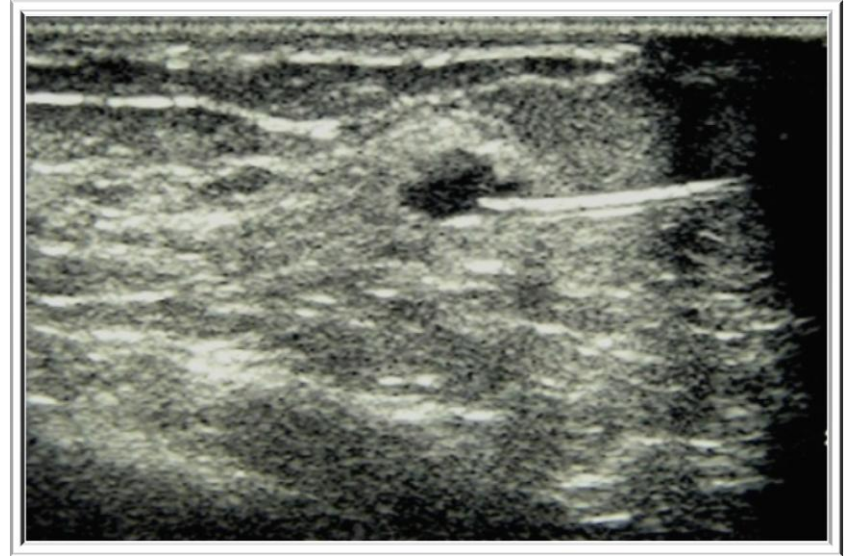
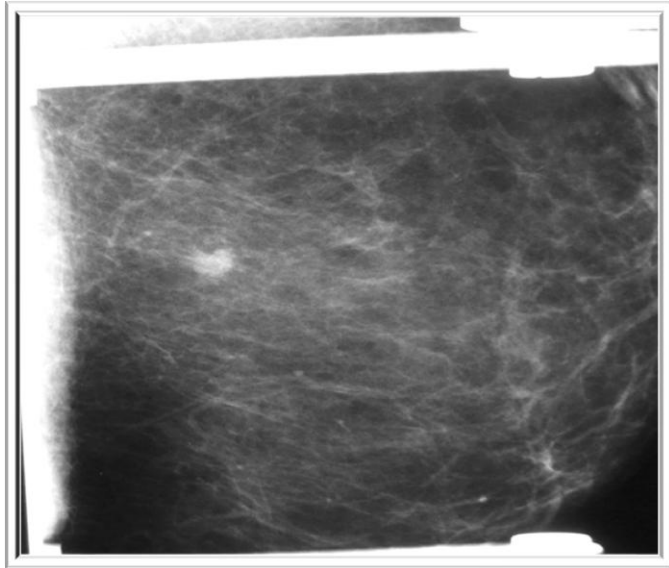
Breast Cancer Staging and Prognosis

Aim is to downstage from Stage 3 and 4 to Stage 1 and 2A to control mortality from cancer

		5 year survival
Stage 0	DCIS	99%
Stage 1	<2cm	92%
Stage 2 A	2-5cm	82%
Stage 3 and 4		14 to 42%

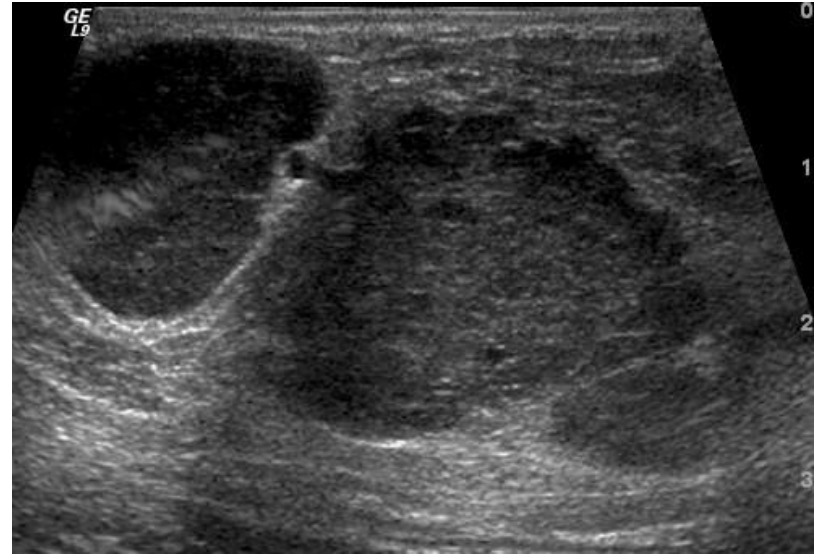
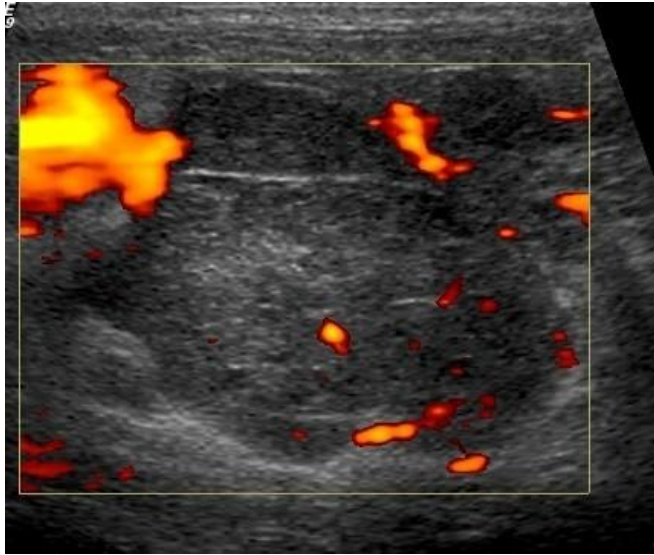
Importance of Down staging Cancer

Small Cancer < 1cm 5 yr survival
> 90%



Importance of Down staging Cancer

Large cancer with metastasis 5 yr survival 15-20%



CERVICAL CANCER

- There are 1.4 million women worldwide with cervical cancer
- 7 million worldwide may have precancerous lesions that need to be identified and treated before they turn cancerous and lethal
- The highest absolute numbers of cervical cancer cases occur in Asia

Cervical Cancer

- Globally nearly 500,000 new cases of cervical cancers are reported yearly with 285,000 deaths, about 85% of these cases occur in the developing countries where screening programs are not established

Cervical Cancer

Aim is to downstage from Stage 3 to 4 to Stage 1 to reduce morbidity and mortality resulting from cervical cancer

		Prognosis: 5year survival
Stage 1 A	Micro invasive	99%
Stage 1 B	Small confined to cervix	80-90%
Stage 3 and 4	Local and distant spread	15 to 40%

Well Woman Clinic Concept

- Holistic approach of combining a routine health check up with screening and early detection of Breast and Gynecological cancers
- Aim is to downstage cancers and improve mortality

- **LOW COST METHODS USING MODERN HEALTH CARE TECHNOLOGY**
- **SERVE AS MODEL PROJECTS TO KICK START COMMUNITY BASED SCREENING PROGRAMS**

Setting up an Integrated Screening Program in existing government run hospitals and Primary health centers: Problems...

- ❑ Health care facilities are not easily accessible to rural poor population
- ❑ Are over utilized, understaffed and underfunded
- ❑ An asymptomatic woman is unlikely to make use of a screening program in such a setting

Objectives...

- To promote the **concept of free standing Well Woman's Clinics** to improve outcomes from lethal cancers affecting women
- The WCF clinic and the strategy adopted for screening should serve as a model for establishment of a chain of similar clinics to be funded by NGO'S and local and national charities.

Proposed Pilot Project sites



Proposed Clinic locations

- Nova Andradina, Mato Grosso do Sul, Brazil
- Phnom Penh, Cambodia
- North Goa, Karnataka ,India

TARGET POPULATION

- Each clinic would serve an approximate target population of about 9000-15000 eligible women who will be invited to be screened for breast and cervical cancer at three yearly intervals

SCREENING EXAMINATION

- Cervical cancer: Age group: 25 through 59 at three year intervals
- Breast cancer: Age group: 35 through 65 at three year intervals

DIAGNOSTIC EXAMINATION

- Sonographic assessment of the Ovaries and Endometrium of symptomatic women. Age group: 50 through 65 years

- ❑ **Examination room 1: [Staffed by an RN or PA]**
 - ❑ Well Woman examination including Clinical Breast Examination [CBE]
 - ❑ HPV DNA testing/PAP /VIA
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- ❑ **Examination room 2: [Staffed by a Sonographer/ Radiologist]**
 - ❑ Breast cancer screening ultrasound
 - ❑ Transvaginal Sonographic ultrasound assessment of the ovaries in symptomatic women
 - ❑ Transvaginal Sonographic diagnostic ultrasound for endometrial cancer in post menopausal women with bleeding
- ❑ **Examination room 3: [Staffed by a Physician] at the Clinic or referral center**
 - ❑ Cryotherapy or LEEP for those testing positive for HPV/VIA
 - ❑ Fine needle aspiration biopsy or core needle biopsy of solid breast masses


Data collection and measurement

- Population registry of the community served to determine number of eligible women in the target population
- **Compliance rate:** To determine potential for effectiveness of the program
- **Prevalence rate** at initial screening for breast and cervical cancer: Provides estimates of sensitivity, lead time and rate of interval cancers, sojourn time and predictive value

- **Stage distribution** of screen detected breast and cervical cancers: Indicates potential for reduction in absolute screen-detected cancers rate of advanced cancers. The same for Endometrial and ovarian cancer in the symptomatic population
- **Rate of advanced breast and cervical cancers:** Early surrogate of mortality. The same for Endometrial and ovarian cancer in the symptomatic population
- **Sensitivity, specificity, Positive predictive value** for each screening method

Confounding variable/study limitations:

- An organized screening program is a novel healthcare intervention in these communities; hence participation of eligible women in the target population is the confounding variable. A screening program which essentially aims to draw in asymptomatic women in a low resource setting will face a challenge of convincing women who are otherwise healthy to attend a health clinic given the social constraints on women with limited financial resources and maternal obligations.

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- The screening strategy has to be adapted to conform to local and national guidelines making it difficult to test efficacy of a similar strategy combined screening program because of inherent differences in methodology of cancer screening necessitated by local and national guidelines'
 - The study design is not that of a randomized clinical trial so mortality reduction cannot be ascertained from implementation of such a screening strategy

Timetables/project management

- The study period will be for a total of six years.
- The investigators will include select members of the Medical Advisory board, Clinic director, a physician from the partner organization
- Project will be managed by local clinic administrative and medical team in consultation with the medical advisory council members who are listed as Clinical Investigators

Performance Indicator	Acceptable outcome
Participation rate	70%
Additional Imaging at time of screening	5%
Pre treatment diagnosis of malignancy	70 %
Insufficient FNA results	25%
Benign to malignant ratio	50 %
Re invitation within specified period	95%



Reporting of findings:

- Initial data will be analyzed at the end of three years and presented at appropriate scientific meetings
- Final data at the end of a six year study period will be analyzed and published in peer reviewed journals.

Screening Mammography

Advantages:

- ❑ Multiple large randomized trials have proven that screening Mammography reduces mortality from Breast cancer
- ❑ Identifies Stage 0 breast cancers

Ultrasound: Advantages

- Several large clinical Studies such as the ACRIN 6666 have shown that US can detect small cancers not seen on mammography due to dense breast tissue
- Cost effective modality: Initial capital expenditure and operational expense is considerably lower than mammography
- Ultrasound can be used for screening and diagnosis of other cancers in Women
- Telemedicine feasible modality

Ultrasound: Advantages

- Portable equipment easy to transport and for use in mobile clinics
- No need to recall for additional imaging evaluation as in mammography
- Sonographic examination of the breast is better tolerated by women due to lack of the need for breast compression
- Fine needle aspiration biopsy feasible: Procedure is cytology based and similar to PAP smears. US is used as the imaging guide to obtain the sample

Screening Mammography: Limitations

- ❑ Expensive to set up
- ❑ Resource intensive modality
- ❑ Poor sensitivity in women with dense breasts
- ❑ Mammographic findings of breast masses and focal asymmetry need additional sonographic evaluation
- ❑ Minimally invasive biopsy procedures for mammographic findings requires stereotactic biopsy equipment which are expensive and time consuming

Screening Mammography: Limitations

- 10-15% or higher recall rate is to be expected for women undergoing screening mammography requiring an additional clinic visit
- Breast compression required for mammography involves patient discomfort, and may be less well tolerated and accepted
- Telemedicine impractical
- FNAB[fine needle aspiration biopsy] is not an option to sample abnormalities detected by this modality

Screening US: Limitations

- Low specificity, False positive rate is high
- Requires a skilled operator, involves an examination time of 15-20 mins per patient
- Mortality reduction resulting from use of sonographic screening for breast cancer is yet to be established in a large scale prospective randomized clinical trial

Ovarian Cancer: Early detection

- Goff and others have reported that symptoms that were associated with ovarian cancer were pelvic abdominal pain, urinary frequency/urgency, increased abdominal size and bloating and difficulty eating/feeling full. These symptoms are particularly significant if present for less than year and present > 12 days per month.

Ovarian Cancer: Early detection

- A symptom index was considered positive if any of the following symptoms occurred > 12 times per month and present for < 1 year:
Pelvic/abdominal pain, increased abdominal size/bloating, difficulty eating/feeling full. In the confirmatory sample the index had a sensitivity of 56.7% sensitivity for early disease. Specificity was 90% for women > 50 years

ENDOMETRIAL CANCER EARLY DETECTION



- Assessment of the endometrial stripe in women with post menopausal bleeding

2011-2014

	TOTAL NO OF WOMEN SCREENED
BREAST CANCER	27000
CERVICAL CANCER	45000
OVARIAN CANCER	3000
ENDOMETRIAL CANCER	3000

Our International Partners

Cambodia: Sihanouk Hospital, Phnom Penh

<http://www.sihosp.org/>

Brazil: Barretos Cancer Hospital. Nova Andradina

<http://www.cliquecontraocancer.com.br/>

India: Manipal Group. North Goa

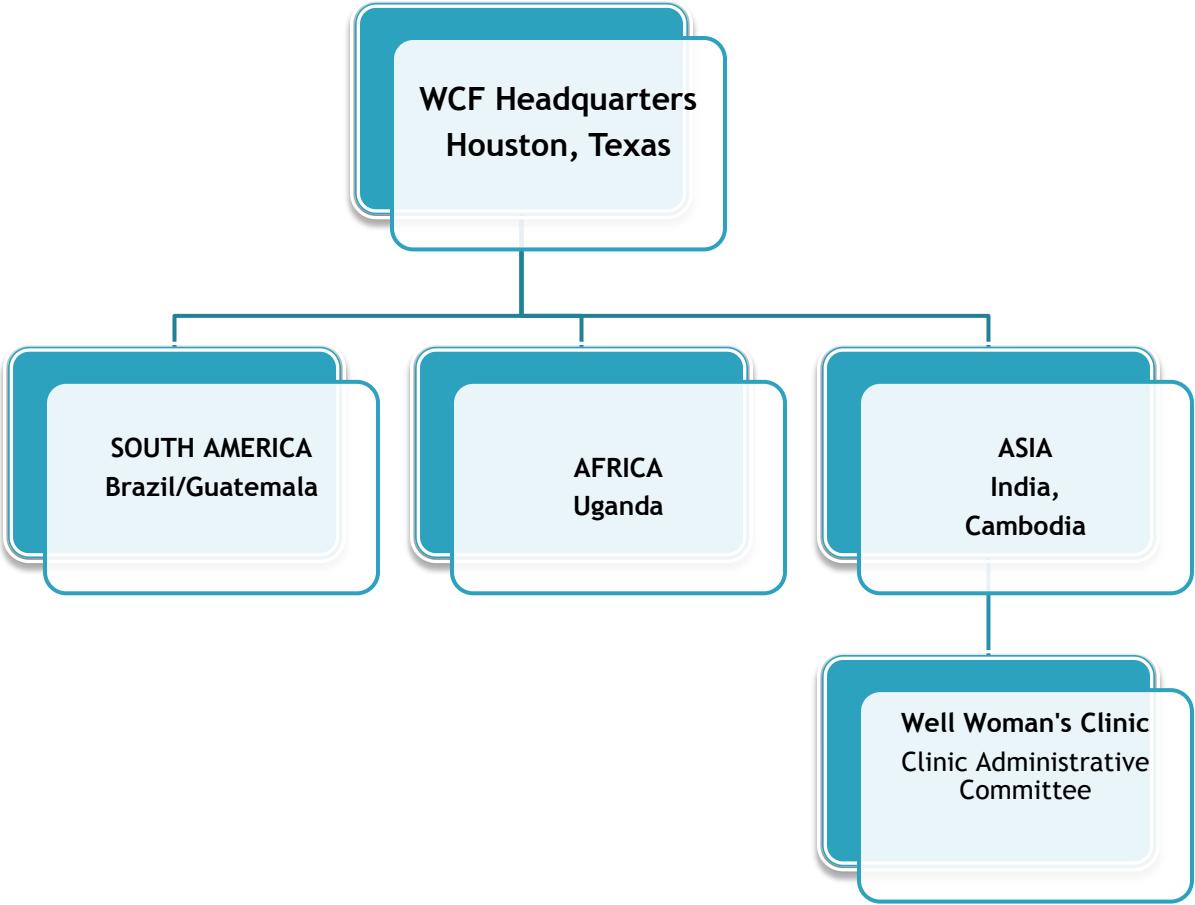
<http://www.manipalgroup.com/>

Breast Health Global Initiative

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Woman's Cancer Foundation

Administrative structure



Governing Body
President
Program Manager
Board of Trustees
Patrons

**Medical
Advisory
Council**

National and
International medical
experts drawn from
fields of Oncology,
Cancer screening and
Public Health

**Public
Awareness
Council:**
Volunteers
and
Supporters

WCF Clinic Administration
Regional Director
Administrative committee:
Partner organization/
Local community &
Clinic Staff

**International
School of
Breast and
Gynecological
Cancer
Management**

Well Woman Clinic Concept: Training Component

- ❑ RADIOLOGY FACULTY
- ❑ Breast Sonography
- ❑ Ovarian Sonography
- ❑ Endometrial Sonography
- ❑ Biopsy guidance

- ❑ SONOGRAPHER FACULTY:
- ❑ Breast Sonography
- ❑ Ovarian Sonography
- ❑ Endometrial Sonography



- ❑ **GYNECOLOGY
FACULTY**

- ❑ VIA/HPV DNA Testing

- ❑ Cryotherapy

- ❑ Loop excision

- ❑ CBE

- CYTOPATHOLOGY
FACULTY**

- FNAB techniques

- Slide preparation

- Interpretation training

- Scanning of slide and

- Telemedicine



Thank you!