

WOMAN'S CANCER FOUNDATION

Well Woman Clinic

CANCERS TO BE TARGETED



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

AIMS

- **Early detection**
- **Downstage cancer to improve outcomes and reduce mortality**

- ❑ LOW COST METHODS USING MODERN IMAGING TECHNOLOGY
- ❑ WILL SERVE AS A MODEL FOR ESTABLISHING COMMUNITY BASED SCREENING PROGRAMS IN LOW RESOURCE COUNTRIES

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

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

GOALS...



- 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.

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

2008...



- **LOW RESOURCE COUNTRIES ARE BURDENED WITH 50% OF BREAST CANCER CASES AND 60% OF DEATHS DUE TO BREAST CANCER**

	ANNUAL NEW CASES	ANNUAL DEATHS
BREAST	700,000	270,000
CERVICAL	450,000	240,000
OVARIAN	125,000	75,000
ENDOMETRIAL	150,000	
TOTAL	1.425 MILLION	585,000

Global cancer statistics, *CA Cancer J Clin* 2011;61;69-90;

- Breast cancer is the most frequently diagnosed cancer and the leading cause of cancer death among females, accounting for 23% of the total cancer cases and 14% of the cancer deaths.

Breast Cancer

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

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%

Proposed Pilot Project sites



2011

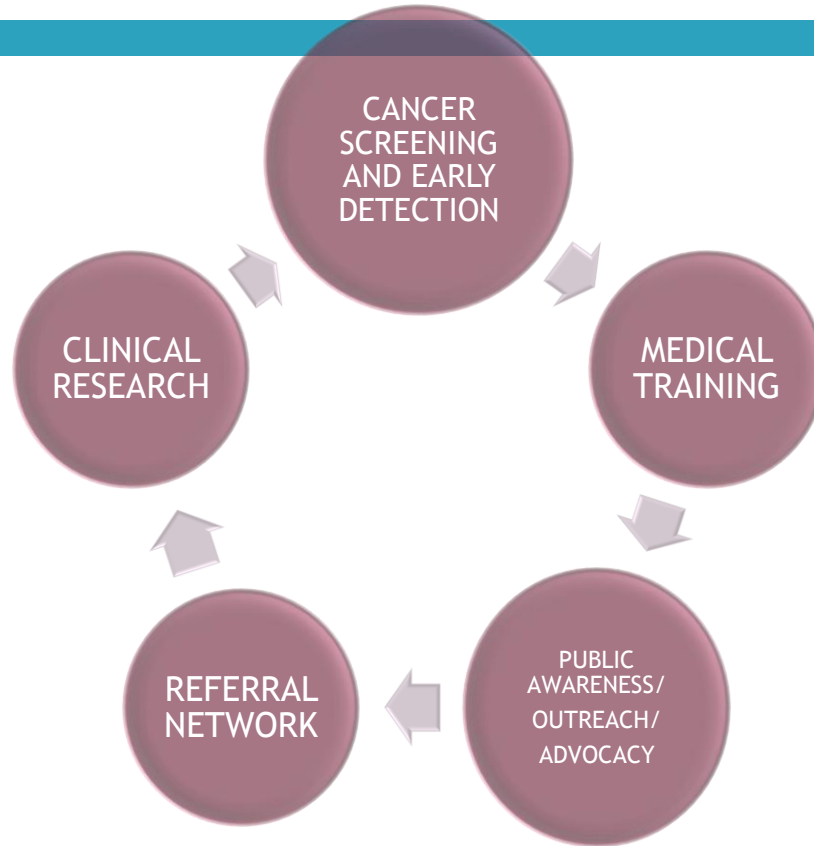
Proposed Clinic locations

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

TARGET POPULATION

- Each clinic would serve an approximate target population of about 9000-15000 eligible women invited to be screened for breast and cervical cancer at three yearly intervals commencing at age 30

KEY PROGRAM COMPONENTS



EARLY CANCER DETECTION STRATEGY

SCREENING EXAMINATION

- Cervical cancer: Age group: 30 through 59 at three year intervals
- Breast cancer: Age group: 30 through 65 at three year intervals

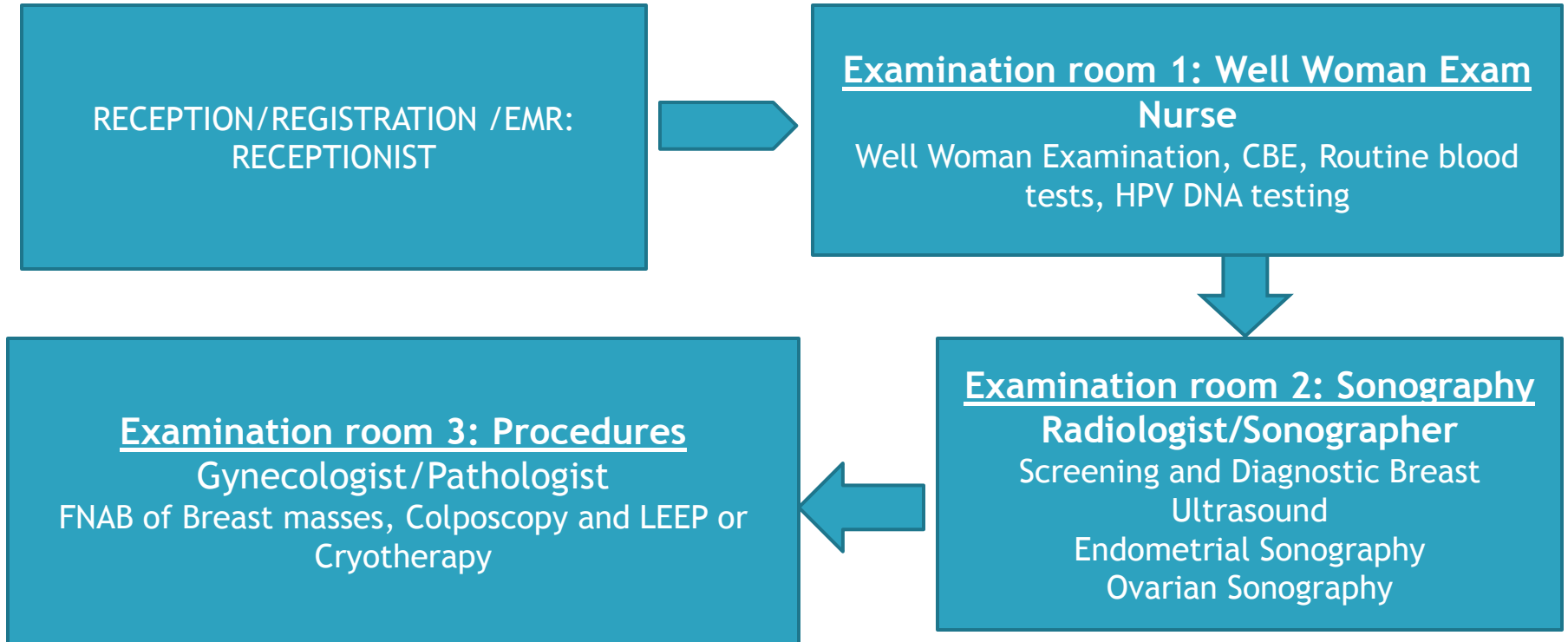
DIAGNOSTIC EXAMINATION

- Ovarian and Endometrial cancer: Age group 50 through 69 years

EARLY CANCER DETECTION STRATEGY

- ❑ BREAST CANCER: CBE and BUS followed by FNAB of screen and Ultrasound positive cases
- ❑ CERVICAL CANCER: HPV DNA followed by Cryotherapy or LEEP : Screen and treat approach
- ❑ Ovarian and Endometrial cancer: Endometrial and Transvaginal ovarian sonography in symptomatic women

CLINIC OPERATIONS: LAYOUT



CLINIC OPERATIONS: SPECIAL EQUIPMENT/SUPPLIES

OFFICE/ RECEPTION
PC/EMR

Examination room 1: Well Woman Exam
HPV DNA Kits

Examination room 3: Procedures
Colposcope, FNAB Kits, Digital Microscope,
telemedicine set up

Examination room 2: Sonography
Portable Ultrasound System

CLINIC OPERATIONS: PERSONNEL

- RECEPTIONIST/CLERK
- NURSE
- RADIOLOGIST
- GYNECOLOGIST [CLINIC DIRECTOR]
- MEDICAL SOCIAL WORKER [RESEARCH DATA COORDINATOR]

CLINIC ADMINISTRATION

- Regional Director
- Clinic Director
- Volunteer Committee: Local community leaders, physicians, NGO's OR
- Partner organization

PUBLIC AWARENESS AND OUTREACH: TARGET

	TOTAL NO OF WOMEN EXAMINED
BREAST CANCER	3000/clinic/year
CERVICAL CANCER	5000/clinic/year
OVARIAN CANCER	500/clinic/year
ENDOMETRIAL CANCER	250/ clinic/year

TRAINING: School of Breast and Gynecological Cancer Diagnosis and Management

- Training at Site
- Videoconference
- Telemedicine consultation

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

- ❑ HPV DNA Testing

- ❑ Cryotherapy

- ❑ Loop excision

- ❑ CBE

- CYTOPATHOLOGY FACULTY

- FNAB techniques

- Slide preparation

- Interpretation training

- Scanning of slide and

- Telemedicine

Clinic Administrative Committee

- To provide space and set up for Training at Clinic sites
- Oversee Telemedicine set up at the clinic

RESEARCH: Clinic Level

- MEDICAL SOCIAL WORKER
- OFFICE CLERK
- NURSE

EMR and Patient data entry

RESEARCH COMPONENT


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.

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SCREENING AND EARLY CANCER DETECTION

STRATEGY: CERVICAL CANCER

CERVICAL CANCER: SCREEN AND TREAT APPROACH

- HPV DNA TESTING
- CRYOTHERAPY FOR SCREEN POSITIVE SMALL LESIONS
- LEEP FOR LARGER LESIONS



SCREENING AND EARLY CANCER DETECTION

STRATEGY: BREAST CANCER

- Screening Clinical Breast Examination



- Screen positive cases



- Ultrasound breast examination



- Fine needle Aspiration of palpable masses that appear suspicious for cancer on utrasoud

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

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SCREENING AND EARLY CANCER DETECTION

STRATEGY: OVARIAN CANCER

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

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SCREENING AND EARLY CANCER DETECTION

STRATEGY: ENDOMETRIAL CANCER

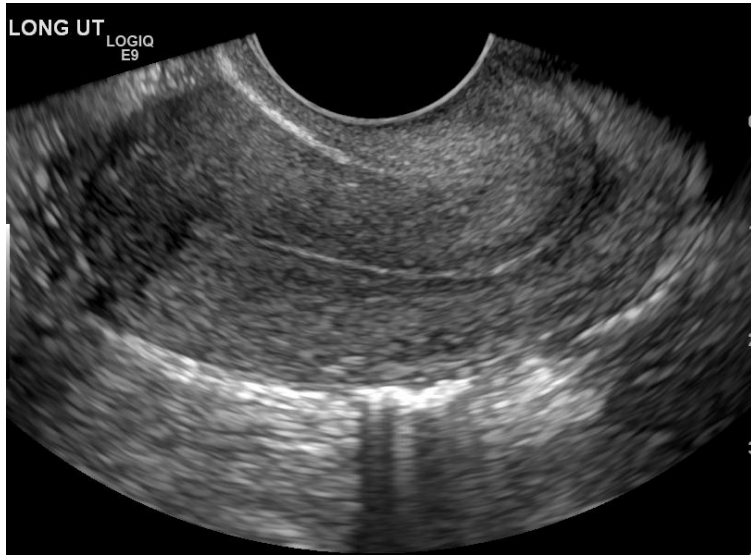
ENDOMETRIAL CANCER EARLY DETECTION



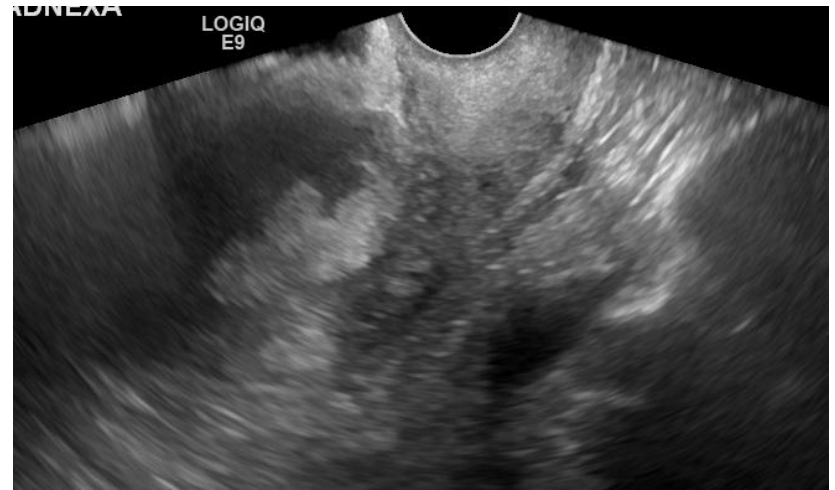
- Assessment of the endometrial stripe in women with post menopausal bleeding

ENDOVAGINAL SONOGRAPHY

NORMAL ENDOMETRIAL LINING



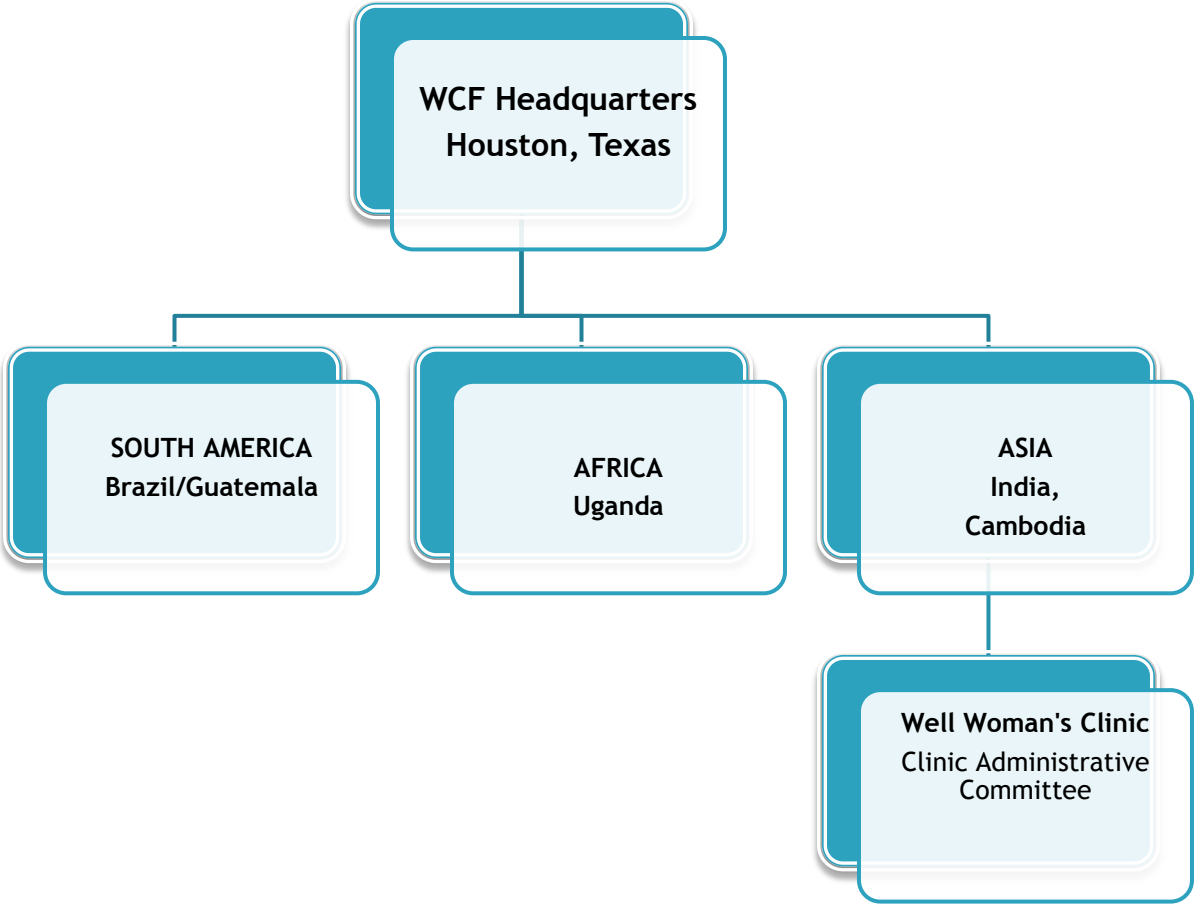
ENDOMETRIAL CANCER



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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

**School of
Breast and
Gynecological
Cancer
Management**

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



Thank you!