



Well Woman Clinic

www.womanscancerfoundation.org

COMBINED SCREENING AND EARLY DETECTION OF CANCERS

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

Aims.....

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

- *COST-EFFECTIVE METHODOLOGY FOR SCREENING AND EARLY DIAGNOSIS*
- *SERVE AS MODEL PROJECTS TO KICK START 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*
- *Existing facilities are over utilized, understaffed and underfunded*
- *An asymptomatic woman is unlikely to make use participate in a screening program in such a setting leading to low compliance rate*

Well Woman Clinic Concept

- Holistic approach of combining a routine health check up with screening and early detection of Breast and Gynecological cancers*

GOALS...

- *To promote the concept of free standing Well Woman's Clinics to improve outcomes from lethal cancers affecting women*
- *The WCF women's 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.*

Global Incidence and Mortality

	<i>ANNUAL NEW CASES</i>	<i>ANNUAL DEATHS</i>
<i>BREAST</i>	<i>700,000</i>	<i>270,000</i>
<i>CERVICAL</i>	<i>450,000</i>	<i>240,000</i>
<i>OVARIAN</i>	<i>125,000</i>	<i>75,000</i>
<i>ENDOMETRIAL</i>	<i>150,000</i>	
<i>TOTAL</i>	<i>1.425 million</i>	<i>5.85000</i>

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*

- *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.*

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*

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

Cervical Cancer

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

EARLY CANCER DETECTION STRATEGY

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

- Ovarian and Endometrial cancer: Age group 45 through 65 years

EARLY CANCER DETECTION STRATEGY

- *BREAST CANCER: Clinical Breast Examination and Breast Ultrasound examination*
- *CERVICAL CANCER: VIA, PAP smear, or HPV DNA testing followed by Cryotherapy or LEEP : Screen and treat approach*
- *Ovarian and Endometrial cancer: Transvaginal ovarian and endometrial sonography in symptomatic women*

SCREENING AND EARLY CANCER DETECTION

STRATEGY: BREAST CANCER

Aim is to downstage cancers from Stage 3 and 4 to Stage 1 and Stage 2 A, reducing mortality from 20-57% (before intervention) to 82-92% (after intervention)

Breast Cancer

Screening Clinical Breast Examination



Screen positive cases



Focused breast ultrasound examination



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

Breast Cancer Screening Strategy

FOCUSSES BREAST ULTRASOUND: SMALL PALPABLE BREAST CANCER



SCREENING AND EARLY CANCER DETECTION

STRATEGY: CERVICAL CANCER

CERVICAL CANCER: SCREEN AND TREAT APPROACH

- *Visual inspection with acetic acid, PAP Smear or HPV DNA Testing*
- *Cryotherapy for screen positive small abnormal lesions*
- *LEEP Procedure for larger lesions*

SCREENING AND EARLY CANCER DETECTION
STRATEGY: OVARIAN CANCER

Ovarian Cancer: Early detection

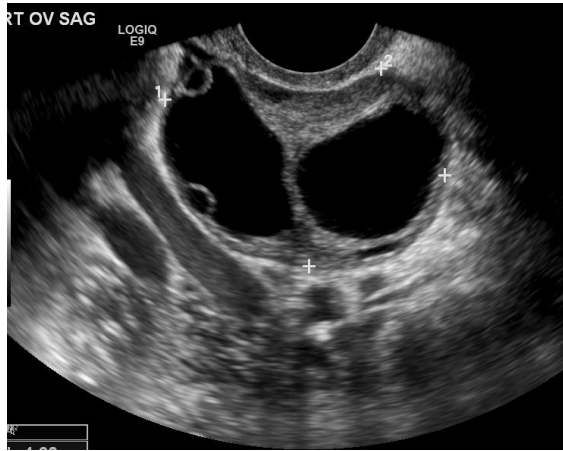
- Goff et al have reported that symptoms that were associated with ovarian cancer were pelvic abdominal pain, urinary frequency/urgency, increased abdominal size and bloating and difficulty eating/feeling full. These symptoms are particularly significant if present for less than year and present > 12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

Ovarian Cancer: Early detection

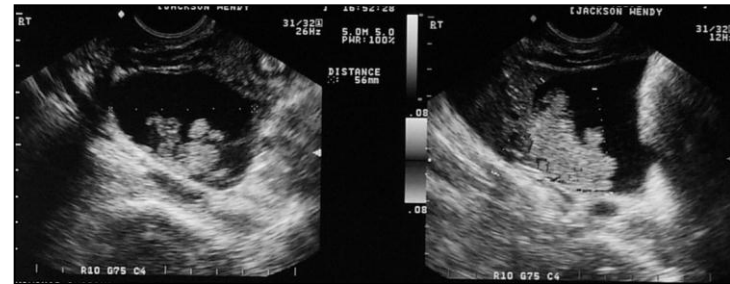
- A symptom index was considered positive if any of the following symptoms occurred > 12 times per month and present for < 1 year: Pelvic/abdominal pain, increased abdominal size/bloating, difficulty eating/feeling full. In the confirmatory sample the index had a sensitivity of 56.7% sensitivity for early disease. Specificity was 90% for women > 50 years*
- All women between 45 and 65 years of age with such symptoms are offered Transvaginal sonographic assessment of the ovaries*

ENDOVAGINAL SONOGRAPHY

NORMAL OVARY



OVARIAN CANCER



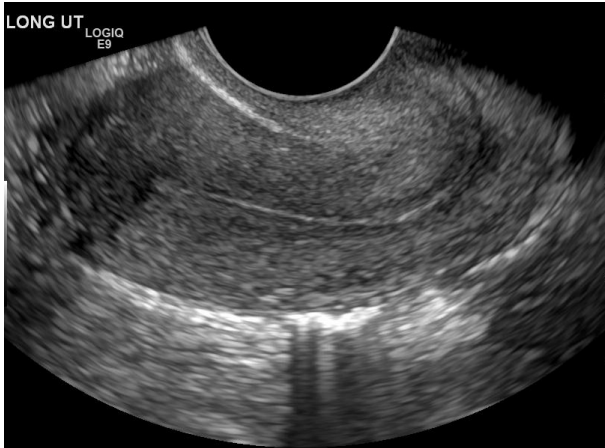
SCREENING AND EARLY CANCER DETECTION
STRATEGY: ENDOMETRIAL CANCER

ENDOMETRIAL CANCER: EARLY DETECTION

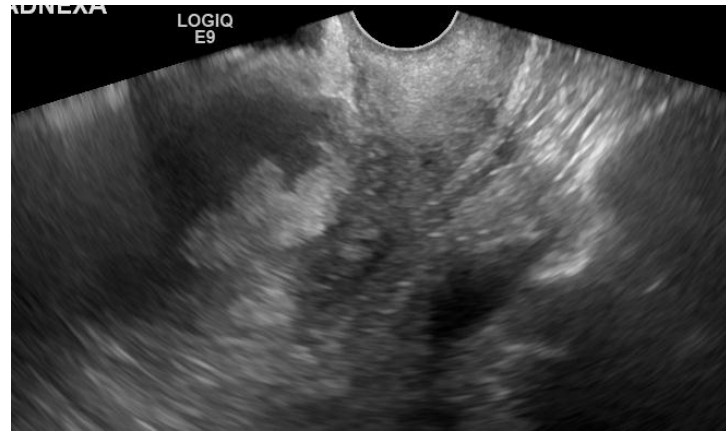
- *Assessment of the endometrial stripe in women with post menopausal bleeding*
- *Those with a abnormal examination are offered Endometrial biopsy during a single clinic visit*

ENDOvaginal SONOGRAPHY

NORMAL ENDOMETRIAL
THICKNESS



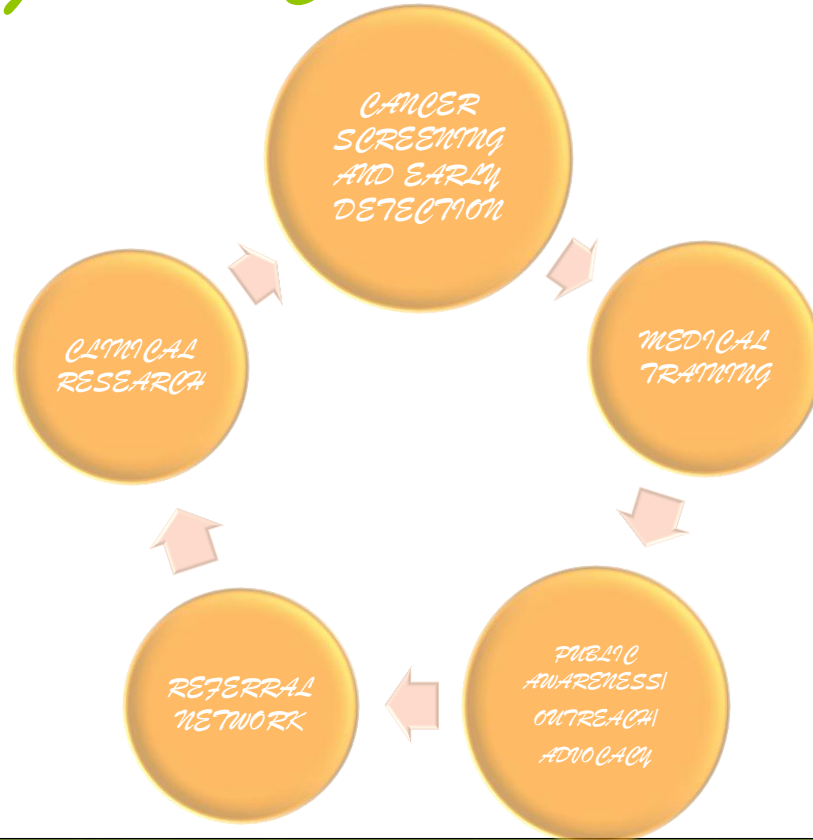
ENDOMETRIAL CANCER



Continuum of care.....is the cornerstone of success

- *Well Woman Clinic Project is always linked to a regional hospital with capacity to manage and treat screen positive cases seen at the clinic*
- *WCF only offers its project plan and assistance to those partners in low resource countries who are able to provide follow up and treatment services to women seen at the clinic*

KEY PROGRAM COMPONENTS



CLINIC OPERATIONS: LAYOUT

RECEPTION | REGISTRATION | EMR:
RECEPTIONIST



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graph TD; A[RECEPTION | REGISTRATION | EMR:  
RECEPTIONIST] --> B[Examination room 1: Well Woman Exam  
Nurse  
Well Woman Examination, CBE, Routine blood tests,  
PAP Smear or VIA or HPV DNA testing]; B --> C[Examination room 2: Diagnostic  
Sonography  
Radiologist  
Diagnostic Breast Ultrasound  
Endometrial Sonography  
Ovarian Sonography]; C --> D[Examination room 3: Minimally Invasive Diagnostic  
Procedures  
Gynecologist [Pathologist referral]  
MAB of Breast masses, Colposcopy and LEEP or  
Cryotherapy];
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Examination room 1: Well Woman Exam

Nurse

Well Woman Examination, CBE, Routine blood tests,
PAP Smear or VIA or HPV DNA testing

Examination room 3: Minimally Invasive Diagnostic
Procedures

Gynecologist [Pathologist referral]

MAB of Breast masses, Colposcopy and LEEP or
Cryotherapy

Examination room 2: Diagnostic
Sonography

Radiologist

Diagnostic Breast Ultrasound
Endometrial Sonography
Ovarian Sonography

CLINIC OPERATIONS: SPECIAL EQUIPMENT/SUPPLIES

OFFICE/RECEPTION
PC/EMR



Examination room 1: Well Woman Exam
Pap Smear kits | HPV DNA Kits



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



Examination room 2: Sonography
Portable Ultrasound System

CLINIC OPERATIONS:

PERSONNEL

- *RECEPTIONIST/CLERK: Patient demographics*
- *NURSE : Clinical duties and Research data*
- *RADIOLOGIST*
- *GYNCOLOGIST [CLINIC DIRECTOR]*
- *MEDICAL SOCIAL WORKER: Public outreach and Public awareness efforts*

*PUBLIC AWARENESS AND OUTREACH BENCHMARK:
TARGET FOR COMPLIANCE*

	<i>TOTAL NO OF WOMEN SCREENED</i>
<i>BREAST CANCER</i>	<i>3000/clinic/year</i>
<i>CERVICAL CANCER</i>	<i>5000/clinic/year</i>
<i>OVARIAN CANCER</i>	<i>500/clinic/year</i>
<i>ENDOMETRIAL CANCER</i>	<i>250/ clinic/year</i>

WCF School of Breast and Gynecological Cancer Diagnosis and Management

- *Training at Site: One week*
- *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

*GYN ECOLOGY
FACULTY*

HPV DNA Testing

Cryotherapy

Loop excision

CBE

*CYTOPATHOLOGY
FACULTY*

FNA techniques

Slide preparation

Interpretation training

Scanning of slide and

Telemedicine

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*

- *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*

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%

*Medical Advisory
Council*

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

Governing Body

*President
Program Manager
Board of Trustees
Patrons*

*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*

Woman's Cancer Foundation Initiatives.....

- Seek partners in low resource countries*
- Provide consultancy services to set up such clinics*
- Oversee implementation of the Combined screening strategy proposed in this project design*

- *Provide on site training for clinic staff on Screening and Diagnostic methods proposed*
- *Provide video-conference continuing medical education training*
- *Telemedicine consultation on cases seen at the clinic*

- *Whenever feasible WCF will donate portable Ultrasound units or other equipment based on a funds available and a need basis*



Future
Strategies...

BREAST CANCER SCREENING

Screening Mammography

Advantages:

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

Screening Mammography: Limitations in Low resource settings

- *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*

*Whole Breast Screening Ultrasound as an
alternate to Screening Mammography*



Future
Strategies...

Breast Ultrasound: Advantages

- *Several large clinical Studies such as the ACRN 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*



Future
Strategies...

Ultrasound: Advantages

Future
Strategies...

- *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 US: Limitations



Future
Strategies...

- *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*

Gynecological Cancer Control



Future
Strategies...

- **CERVICAL CANCER VACCINE.....**
- **USE OF TUMOR MARKERS FOR EARLY DIAGNOSIS OF OVARIAN CANCER.....**



*Future
Strategies...*

Upcoming projects 2012-2013

- *Well Woman Clinic Pilot Project in Nova Andradina, Mata do Sul, in partnership with Barretos Cancer Hospital, Sao Paulo, Brazil*
- *Luanda, Angola*
- *Kolkata, India in partnership with Tata Medical Center, Kolkata*



Thank you!

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