Well Woman Clinic Concept: An Integrated Approach for Screening and Early Diagnosis of Breast and Gynecological Cancers in Developing Countries

17

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Abstract

A vertical delivery of an integrated healthcare intervention to decrease mortality from breast and gynecological cancers is proposed for implementation through a Well Woman Clinic. The operations and logistics of such a clinic are discussed in this chapter. The pros and cons of horizontal and vertical delivery of healthcare services and the benefits of an integrated approach to screen for cancers in women are outlined. The methodology proposed is to screen for breast and cervical cancer and to diagnostically test symptomatic postmenopausal woman so as to detect endometrial and ovarian cancers at an early stage. The healthcare personnel required to carry out these tasks and the training and telemedicine support to ensure quality and consistency of services provided also are discussed. The need to have a robust and enforced referral system in place to provide a continuum of care for those women who are tested positive for malignancy and need definitive treatment and or surgery is emphasized. The methodology may need modifications for adaptation to individual countries and resources available; the core principle, however, of this proposal is integration of a well woman exam with screening and early diagnosis of multiple commonly occurring cancers affecting women. Some variation in the screening methodology, particularly for cervical cancer, is expected from one country to another and will be influenced by factors such as existing national or professional body guidelines or resource limitations.

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Introduction

An integrated approach of providing a well woman examination in combination with screening for breast and cervical cancer as well as testing of symptomatic women for early diagnosis of ovarian and endometrial cancer is proposed.

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While such a concept is applicable to a majority of women in low- and mid-resource countries with limited access to cancer screening and treatment residing in rural areas, the same may not apply to more affluent women residing in urban areas of mid-resource countries where a more robust cancer screening and early diagnosis approach may be available. These women then avail themselves of quality care based on personal resources.

A vertical program to deliver such an intervention is likely to be more effective than a horizontal delivery program through existing healthcare facilities that may not have the infrastructure needed for implementation of a cancer screening program in resource-poor settings. A well woman clinic can be set up as a free-standing clinic, as an addition to an existing primary healthcare center, or as a mobile clinic serving remote populations in low-resource countries who have only limited or no access to healthcare services.

Vertical Versus Horizontal Programs for Delivery of Healthcare Services [1, 2]

Horizontal programs are those that are implemented through existing health systems and receive funding through the government. These may include primary healthcare centers and/or regional hospitals and healthcare facilities. Incorporating a cancer screening service through a horizontal program has the theoretical advantage of using established facilities that are staffed to provide healthcare services to the population served. However, for such horizontal programs to succeed in implementing newly launched initiatives, the health system infrastructure has to be strong, well-funded, and well-staffed as is the case in developed countries. In resource-poor settings, healthcare facilities are often nonfunctioning and have poor infrastructure, making it nearly impossible to use them as a means to deliver new healthcare interventions. Vertical programs on the other hand are those that focus on a specific disease, and such programs are carried out in addition to primary care services. These programs are usually funded by an external donor for a finite period of time. There has been increased emphasis in recent years on vertical programs because they show quick results and are easier to operate than horizontal programs. Such programs have the best chance of being effective for cancer screening and early diagnosis interventions. Policy makers sometimes see vertical programs as draining and diverting limited personnel and financial resources in low-resource countries; they consider horizontal programs more sustainable and easier to manage. While this may hold true for providing basic services such as immunizations, cancer screening services are much more complex and would represent a challenge for successful implementation through an existing healthcare facility. Vertical programs on the other hand are more likely to be effective in low-resource countries. Sustainability of such vertical programs may be the greatest challenge due to funding requirements, and this needs to be addressed by policy makers and stakeholders.

Integrated Approach to Screening for Cancers in Women

A cost-effective strategy is a critical prerequisite of any new healthcare intervention in developing countries. Developing a strategy to diagnose multiple cancers afflicting women at a single site is a sensible approach to the integration of healthcare intervention services. This serves both the provider as well as the women in the target population well. The efficacy of integration of health services has been studied before. The Program for Appropriate Technology in Health (PATH) is a global health nonprofit that has advocated for and implemented integrated solutions for healthcare problems in developing countries [3]. The integration of HIV care services with maternal and child health in Kenya, HIV/AIDS with TB diagnosis in Tanzania, diarrheal disease and child nutrition in Vietnam, and the linking of agriculture and nutritional health in pregnant women in Kenya are some of the projects that have been very successfully implemented by PATH [1]. Such an approach is a departure from the usual traditional emphasis on specific health issues vs. attempting

to provide a range of services to an individual. It makes practical sense to maximize the value of a woman's visit, particularly in rural settings, by addressing multiple healthcare concerns during a single visit. Such an approach makes sense both from a cost-effectiveness point of view as well as in terms of in maximizing compliance and participation in a cancer screening program. We propose an integrated approach for screening and early diagnosis of breast, cervical, endometrial, and ovarian cancer combined with a well woman examination that would involve providing a physical examination and routine blood/urine tests to assess the nutritional and general health status of women attending the cancer detection clinic. To date, such an approach has not been proposed or studied. There have been several reports on the benefit of combining breast and cervical cancer screening. Combined screening for breast and cervical cancer delivered through mobile clinics traveling to remote parts of Brazil has been reported with great success by the Barretos Cancer Hospital mobile cancer screening program, discussed in depth in Chap. 10 [4]. A study conducted in South Africa found that combining cervical and breast screenings led to an increase in cervical screening uptake [5].

Methodology and Rationale

Breast Cancer (Fig. 17.1)

The proposed strategy and rationale for screening for breast cancer are discussed in detail elsewhere in this book. A brief description is provided here. Annual screening commencing at 40 years of age and continuing until 69 years of age is suggested. As part of a well woman examination, screening for breast cancer is done by utilizing clinical breast examination that is performed by a nurse trained in CBE. There is considerable indirect evidence from studies that CBE can be recommended as an effective method for early detection of breast cancer. The examination is inexpensive, needs no special equipment, is easy to perform, is tolerated well by women, and healthcare professionals can be trained to perform it. CBE has been recommended as part of any global program for early detection of breast cancer [6].

CBE has never been studied in a randomized clinical trial such as has been done for mammography in order to prove mortality rate reduction. However, the effectiveness of CBE in breast cancer

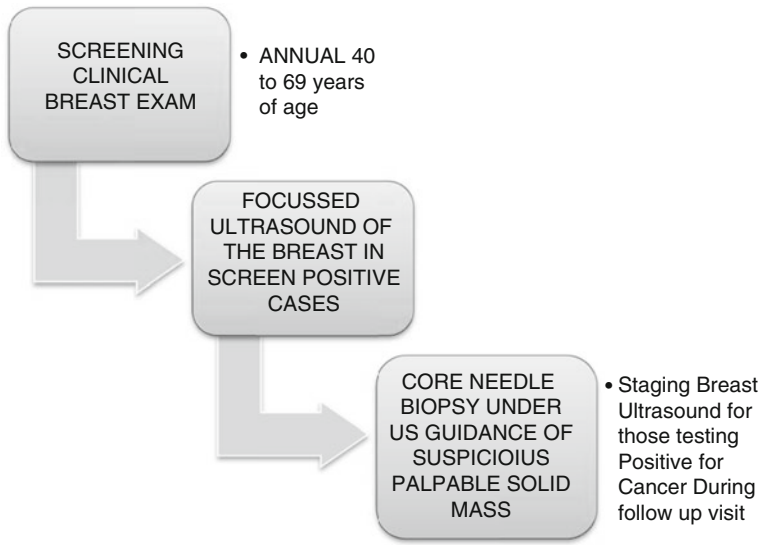

Fig. 17.1 Flowchart outlining methodology for breast cancer screening for breast cancer, single visit approach

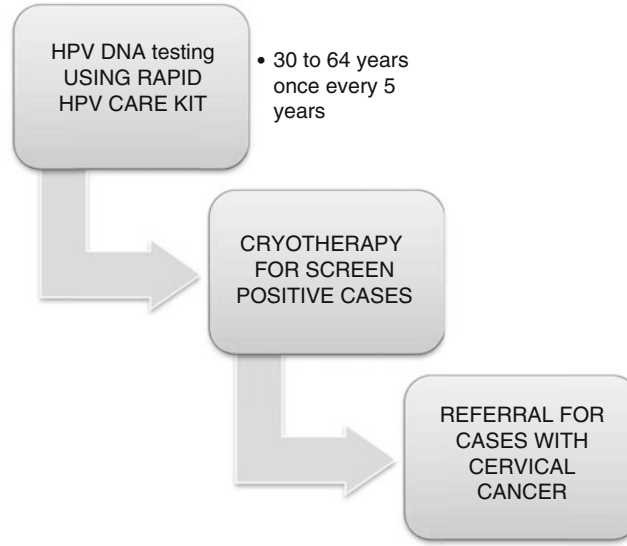

Fig. 17.2 Flowchart for cervical cancer screening, screen-and-treat approach, single clinic visit

screening and its role in reducing mortality from breast cancer have been reported in nonrandomized studies. A study conducted in Japan measured the effectiveness of breast cancer screening using CBE [7]. The change in the age-adjusted death rate from breast cancer for the period of 1986–1990 to 1991–1995 in the high coverage rate municipalities and comparable controls was studied. It was found that reduction of age-adjusted death rate was statistically significantly greater in those screened with clinical breast examination than those in the control group, suggesting that mass screening by physical examination contributed to the reduction of mortality from breast cancer [7]. The cost-effectiveness of CBE as a breast cancer screening modality has also been studied. It has been estimated that the mortality rate reduction was the greatest for programs that target women 40–60 years of age. Biannual CBE was expected to reduce breast cancer mortality by 16.3 %. Annual CBE, what we propose, is expected to be nearly as efficacious as biennial screening mammography for reducing breast cancer mortality at a fraction of the cost [8]. In the NHSS breast cancer screening program involving over a million women between 50 and 64 years of age screened with mammography, 60 % of the 5,000 cancers found were greater than 1 cm and therefore potentially detectable on CBE. In the US breast cancer detection demonstration project, 39 % of cancers under 1 cm in size were detected on CBE [9–11]. Following a CBE, all screen-positive women, i.e., women who have an abnormal finding on physical examination, are directed to the ultrasound examination room to undergo a focused sonographic examination of the palpable finding in the breast. In those with a solid mass demonstrating suspicious morphologic features, an ultrasound-guided core needle biopsy of the mass is performed. Patients with a malignant diagnosis are recalled for a staging breast ultrasound (BUS) and set up for referral to a regional hospital for definitive treatment.

Cervical Cancer (Fig. 17.2)

In developing countries, screening for cervical cancer is generally recommended to commence at the age of 30, as the maximum impact of screening has been shown to occur when women are screened in their thirties [12–14]. Screening of women in their 30s allows for identifying cancers in the preclinical phase, thereby maximizing the benefits of screening [13]. The optimal age

group to be targeted for cervical cancer screening appears to be 30–59 years. Data published recently from a cluster randomized trial of 137,461 women studied in India demonstrated that even a single round of testing with HPV (Human Papilloma Virus) DNA resulted in significant reductions in the number of cases of advanced cancer and mortality from cervical cancer [12]. This study examined the efficacy of a single round of screening using visual inspection with acetic acid (VIA), cytology testing (PAP smear), and HPV DNA testing on the incidence of cervical cancer and associated death rates [13]. Women with a positive screening test were evaluated by means of colposcopy, and doctors reported the results as normal findings, inflammation, probable low-grade or high-grade precancerous lesions, or invasive cancer. Women with colposcopic findings of low-grade or high-grade lesions were offered immediate cryotherapy, if all the following criteria were met: the lesion could be covered by the cryoprobe and involved three quadrants or less of the cervix with no extension into the endocervix or vaginal walls; the squamocolumnar junction was fully visible; there was no suspicion of invasive cancer. Loop electrosurgical excisional procedure (LEEP) was offered to women with CIN lesions that were unsuitable for cryotherapy. Women with suspected invasive cancer were referred to the NDMCH or to the hospital of their choice for investigations and treatment with surgery, radiotherapy, or both [13]. Based on this large clinical trial and other previous studies, HPV DNA testing has been recommended for implementation as a method for cervical cancer screening in low-resource countries [14]. The cost-effectiveness of such a strategy has also been previously published. The most effective strategy—in terms of lives saved—was use of a single lifetime HPV test, followed by cryotherapy for women who tested positive. Such an approach demonstrated that the cost per year of life saved was $14, and the reduction of cervical cancer incidence was 32 % [15]. Although a single lifetime testing shows significant reduction in mortality, more frequent testing adds to the benefit of screening. Testing for HPV every 3 years has also been shown to be very cost-effective in saving lives [15]. HPV DNA testing can be undertaken in two-step processes, where during the initial clinic visit the test is administered and test-positive women are recalled for colposcopy. At colposcopy, women with abnormal findings undergo biopsy followed by treatment by means of cryotherapy or LEEP, depending on the size of the abnormality. Alternatively, use of single visit strategy may be adopted, which may be more beneficial in terms of cost savings, ensure better patient compliance, and minimize the risk of loss to follow-up. Single visit strategies are made possible by using HPV testing of self-collected samples or rapid processing of clinician-collected samples. A simple, affordable, and accurate HPV test (CareHPV™ test, Qiagen, Hilden, Germany) provides results within 3 h and was recently evaluated in China; in this study, the accuracy was found to be similar to that of the Hybrid capture 11 test, with a higher sensitivity than VIA. In the near future, this test kit should be available for use in low-resource countries. These two studies clearly demonstrate the appropriateness of using HPV testing as a primary screening method in low-resource countries [16]. The most cost-effective approach would involve use of HPV DNA testing and refer those women who test positive for cryotherapy. A randomized clinical trial of 6,555 nonpregnant women aged 35–65 recruited through community outreach and conducted between June 2000 and December 2002 at ambulatory women's health clinics in Khayelitsha, South Africa, clearly showed that such an approach was very effective [17]. Noncytology-based screening and treatment of positive cases, bypassing colposcopy, is a tremendous advantage in low-resource situations. When HPV rapid result kit is used, there is an opportunity for a screen-and-treat approach during a single clinic visit since results of the test are available in 2.5 h.

Endometrial and Ovarian Cancers (Figs. 17.3 and 17.4)

Unlike breast and cervical cancer screenings, the benefits of screening for ovarian and endometrial cancers have not been shown. These screenings are

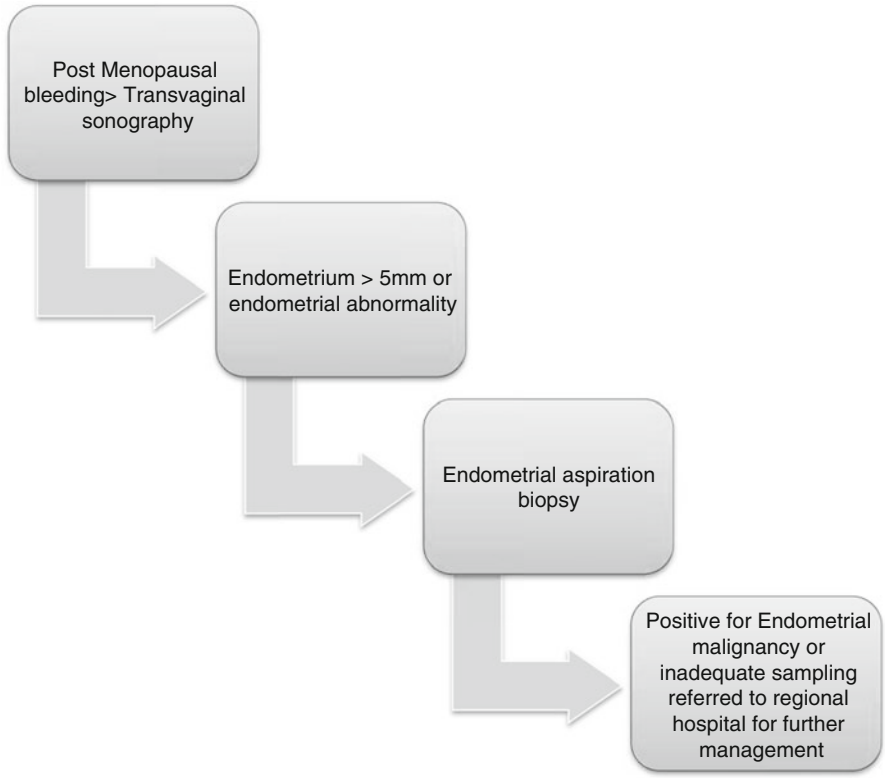

Fig. 17.3 Flowchart outlining methodology for early diagnosis of endometrial cancer

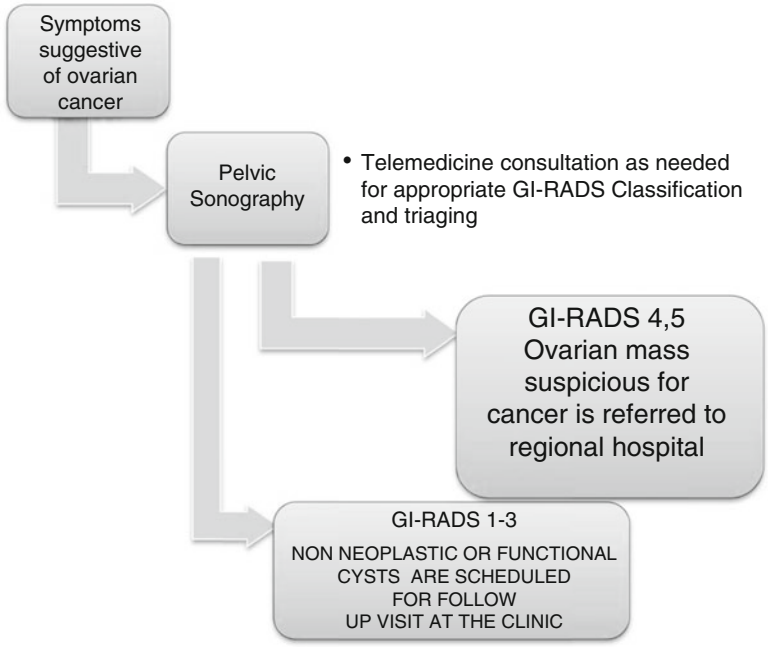

Fig. 17.4 Flowchart outlining methodology for early diagnosis of ovarian cancer

Table 17.1 Gynecologic imaging report and data system (GI-RADS) classification system for adnexal masses

GI-RADS grade	Diagnosis	Est. prob. malignancy (%)	Detail
1	Definitive benign	0	Normal ovaries identified and no adnexal mass seen
2	Very probably benign	<1	Adnexal lesions thought to be of functional origin, e.g., follicles, corpora lutea, hemorrhagic cysts
3	Probably benign	1–4	Neoplastic adnexal lesions thought to be benign, such as endometrioma, teratoma, simple cyst, hydrosalpinx, paraovarian cyst, peritoneal pseudocyst, pedunculated myoma, or findings suggestive of pelvic inflammatory disease
4	Probably malignant	5–20	Any adnexal lesion not included in GI-RADS 1–3 and with one or two findings suggestive of malignancy[a]
5	Very probably malignant	>20	Adnexal masses with three or more findings suggestive of malignancy[a]

[a]Thick papillary projections, thick septations, solid areas and/or ascites, defined according to IOTA criteria, and vascularization within solid areas, papillary projections, or central area of a solid tumor on color or power Doppler assessment. Est prob: estimated probability

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not appropriate in countries with limited resources. However, there may be a potential to detect these cancers at an earlier stage by selectively examining postmenopausal women with symptoms suggestive of ovarian and/or endometrial cancers as part of a well woman examination. We recognize that the yield may still be low given the relatively low prevalence of these cancers; however, one has to keep in mind that performing these additional evaluations suggested next adds very little cost to the envisaged program and may have the potential to reduce the high mortality from being diagnosed at advanced stages of ovarian and endometrial cancers. It has been shown in several retrospective studies that the majority of women with ovarian cancer are symptomatic, even though some of these may be non-gynecologic in nature [18, 19]. Goff and coworkers have studied the value of using a symptom index to help in the early diagnosis of ovarian cancer. Women with ovarian cancer experienced symptoms more frequently, and these symptoms were of higher severity and of more recent onset than women with benign masses or those in the control population. A combination of bloating, increased abdominal size, and urinary symptoms was found in 43 % of those with cancer compared to 8 % of those without cancer presenting to primary care clinics. The authors of this study concluded that women with more frequent, more severe, and more recent onset of symptoms warranted further diagnostic investigation because they were more likely to be associated with both benign and malignant ovarian masses [18]. In another study, Goff and colleagues reported that symptoms 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. A symptom index was considered positive if any of the following symptoms occurred >12 times per month and were 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 % for early disease. The specificity was 90 % for women >50 years [19]. Based on these studies, we propose using the Goff symptom index to identify women who need additional diagnostic evaluation. Women in the age group of 50–69 with symptoms indicating increased risk for ovarian cancer may benefit from a pelvic examination followed by endovaginal sonography to assess the ovaries (Table 17.1).

Ultrasound evaluation of the endometrial thickness is the accepted method to assess endometrial abnormalities in postmenopausal women. About 10 % of postmenopausal women with abnormal bleeding are diagnosed with endometrial carcinoma. About 75–80 % of women with endometrial carcinoma will present with abnormal postmenopausal bleeding. In these patients, performance of transvaginal ultrasound for assessment of the endometrium identifies an abnormality in most women with endometrial cancer [20–24]. A large clinical study reported that 96 % of endometrial carcinomas will be detected in symptomatic postmenopausal women if additional procedures are performed only in those with an endometrial thickness of >4 mm [23, 24]. A thin and regular endometrial lining is very reliable for the exclusion of endometrial carcinoma in a postmenopausal patient with abnormal bleeding [24]. We recommend use of transvaginal sonography (TVS) in postmenopausal women with abnormal bleeding to identify those women who will need endometrial biopsy. An abnormal endometrium in a postmenopausal woman with bleeding detected on sonography is an indication for endometrial biopsy. As with screening methods for breast and cervical cancers, diagnostic assessment for early detection of endometrial and ovarian cancers can be accomplished during a single visit. Endometrial sampling is considered the gold standard as described in Chap. 8. Endometrial aspiration biopsy is easily performed as an outpatient procedure using a cannula. It is recognized that such a procedure may have limitations when abnormality as shown by ultrasound is focal; in such cases when endometrial aspiration biopsy fails, the patient can be referred for dilatation and curettage in a hospital setting.

Clinic Operation and Patient Flow

A typical floor plan of a well woman clinic is shown in Fig. 17.5a, b. The patient examination section of the clinic will require two rooms or cubicles: one for physical examination and obtaining samples from uterine cervix and a second room for procedures and biopsy as discussed next. The following sequence is suggested. Women would as a first step undergo a clinical evaluation including a well-performed CBE followed by a physical examination of the nutritional status and general well-being. Blood samples for CBC (Complete Blood Count) testing are then obtained. This is followed by cervical sampling for HPV DNA. Subsequently, those women with an abnormal finding on CBE then proceed to the procedure room for a focused BUS. Those who are triaged during clinical evaluation to receive TVS necessitated by symptoms indicative of either endometrial or ovarian cancer will undergo TVS in conjunction with the BUS. Endometrial biopsy is performed when an endometrial abnormality is identified. Those women in whom there is a solid suspicious breast mass on sonographic evaluation of a physical finding will undergo core needle biopsy under ultrasound guidance. Women who are tested positive for HPV DNA will undergo cryotherapy in the procedure room on the same day. Such a screen-and-treat approach has been studied and shown to be highly cost-effective; performing screening and treatment on the same day also serves to maximize compliance since a second visit is not required [11, 12]. Women undergoing breast biopsy will be advised to return for follow-up in 1 week. Those women with a malignant diagnosis will undergo a staging ultrasound; then they are set up to receive definitive treatment at a regional hospital with which the clinic has a preexisting affiliation in place for referral. Similar referrals to the regional hospital are to be arranged for women who may have a sonographic assessment that is suspicious for ovarian cancer or those who are diagnosed with endometrial cancer following an endometrial biopsy. The funding of the clinic should include provision for financial aid to enable the women to travel to the regional center and obtain treatment. Such arrangements should include transport, lodging, and meals for the patient and a member of her family, as the case may be. A preexisting agreement with a regional cancer hospital to treat patients diagnosed with cancer at the clinic should be in place when the well woman clinic commences its program. The downstream support is a critical component of this integrated strategy.

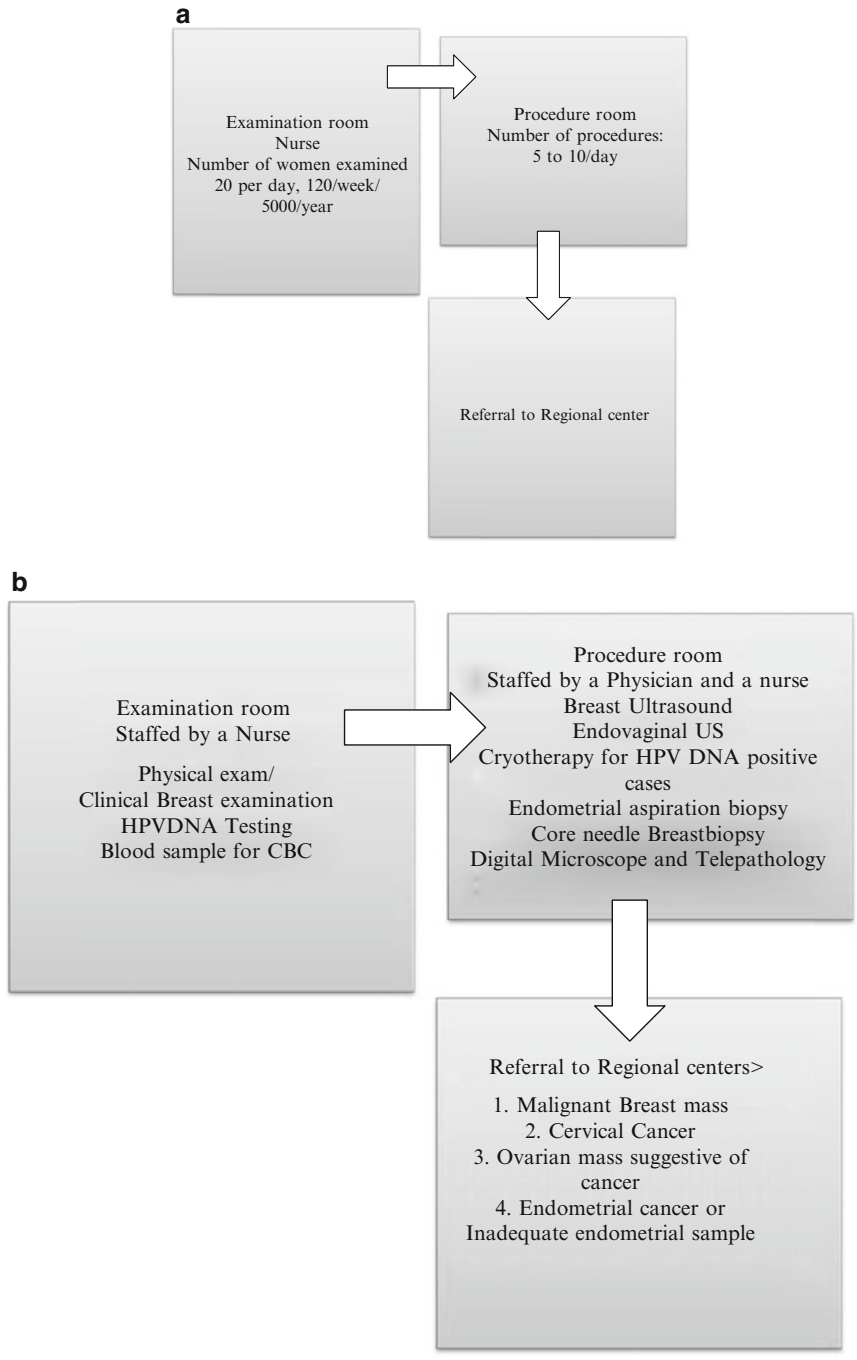

Fig. 17.5 (**a**, **b**) Flowchart outlining the operations of the well woman clinic

Resources Required for the Well Woman Clinic

Personnel Requirements

The following personnel are needed at a fully staffed well woman clinic:

- A receptionist who would be responsible for appointments and patient demographics data entry.
- A medical social worker to handle public outreach, coordinate follow-up visits for patients, and act as a liaison with referral hospitals and pathology labs.
- A physician who would perform BUS examinations, and breast and endometrial biopsy procedures.
- A nurse who would be trained to perform physical examinations, clinical breast examinations, and cervical swabs for HPV DNA testing.
- A nurse in the procedure room trained to perform cryotherapy for those testing positive for HPV DNA and also serve as an assistant to the physician when he or she is performing procedures.
- A clinic manager, who would oversee the operations of the clinic and is responsible for budgeting, funding, and would ensure collection of data for research.

Equipment Requirements

Apart from the standard requirements of a clinic, the following additional items are needed for a well woman clinic:

- An ultrasound machine with Doppler capabilities, with a high frequency probes for performing BUS as well as an endovaginal probe for endometrial and ovarian sonography.
- A digital microscope and a telepathology setup allowing for remote reads of histology specimens.
- Disposable core biopsy needles for percutaneous biopsy of breast masses.
- Endometrial aspiration biopsy cannula for endometrial biopsy.
- HPV DNA kits, including cervical samplers for obtaining cervical brush specimens.

Training of Clinic Healthcare Staff

The success of the cancer screening program will, to a great extent, depend on the skill and expertise of the healthcare providers carrying out the proposed screening and diagnostic studies. Initial rigorous training on site or off site will have to be supplemented with periodic continuing medical education training. The role of telemedicine and training in early detection of breast cancer is discussed at length in Chaps. 14 and 15.

As far as breast cancer screening is concerned, since the core of the proposed methodology is screening by clinical breast examination, training nurses and physicians at the clinic to perform consistently high quality CBEs is critical. There are three components of such a training program: a didactic presentation, a visual presentation, and practice with feedback. The didactic presentation should include teaching of the anatomy and physiology of the breast, background information on common breast health and disease processes, and the steps in performing a CBE (such as obtaining a clinical history, performing a visual inspection, the technique of palpation, and training to interpret and report abnormal findings). The visual presentation consists of watching a real-time performance of CBE. Finally, trainees need to practice performing CBEs on models and obtaining feedback from experienced examiners. For this portion of the training, live models provide the most realistic clinical experience. Measuring and demonstrating sensitivity and specificity of breast lump detection should also be a part of the training [25]. CBE training can improve sensitivity of breast lump detection and reduce false-positive rates. A program that studied effectiveness of a self-study manual and a 1.5 h skills-based curriculum reported an increase from 59 to 94 % in physicians detecting 60–100 % of lumps. The false-positive rate declined to 59 % of the pretest rate [26].

Quality assurance checks to monitor the screening methodology will determine the need and frequency of additional training. A telemedicine set up at the clinic is the best way not only to deliver periodic refresher course training but also to provide second opinion on test findings. Such a link is best established with regional referral hospitals or cancer centers and would need reliable Internet

Table 17.2 Measures of monitoring

Measure	Type of evaluation provided
Participation (compliance) rate	Indicates potential for effectiveness of screening program
Prevalence rate at initial screening test and rate of interval cancers	Provides estimates of sensitivity, lead time, sojourn time and predictive value
Stage and size distribution of screen-detected cancers	Indicates potential for reduction in absolute rate of advanced cancers
Rate of advanced cancers	Early surrogate of mortality
Breast cancer death rate	Final evaluation

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access as well as video conference capabilities. When local pathology lab support is not available, an additional investment in the purchase of a digital microscope is recommended with the capacity to remotely read the slides prepared by the nurse. Nurses are trained to process core biopsy or fine-needle aspirate samples and to mount the specimen slides on the digital microscope. A digital microscope and telepathology capability represent cost-effective solutions in the long run that help overcome the shortage of locally available pathologists or clinics in remote locations.

Referral System

A critical prerequisite of this program is an affiliation and/or an agreement with a regional hospital that has the capacity to perform additional testing of and treating of cancers diagnosed at the clinic. The medical social worker at the clinic and the clinic administrator should rigorously ensure that all women who are tested positive for breast, cervical, or endometrial cancers are treated at regional hospitals. Women should be provided with all and any assistance that is needed to ensure compliance and follow-up at facilities that provide definitive care. Women who are diagnosed with ovarian masses considered to be suspicious and those who have focal endometrial abnormalities with inadequate endometrial sampling and are in need of D & E will need to be referred to a specialist at the regional hospital. The overall success of this program depends on the existence of a robust and efficient system of referral for those who need treatment or additional testing. A clearly defined referral system for women with positive screen results and a system that ensures women receive appropriate treatment and follow-up should be in place and monitored. Any financial barrier to referral, treatment, and follow-up of women testing positive has to be overcome.

Monitoring Performance Metrics

A cancer screening program consists of a process that starts with identifying the target population, then invites women to participate, and ends with a negative examination or diagnosis and treatment of cancer, with outcomes documented. An attempt to follow up negatives and determine false-negative rate whenever feasible is also desirable. In the long term, observational studies will have to be conducted in a large patient population followed over many years in order to test the effectiveness of the program; however, in the short term, there are several indicators that can be monitored to determine effectiveness of the program. These are outlined in Tables 17.2, 17.3, and 17.4 [27]. During the first year of screening, performance benchmarks are expected to be lower than in subsequent years, due to existence of a greater proportion of advanced stage cancers in a previously unscreened population. For instance, the breast cancer detection rate is expected to be three times the incidence rates. A higher percentage of cancers will be diagnosed at a more advanced stage of the disease, and there will be fewer node-negative small cancers. As noted previously, a factor affecting performance metrics will be the skill level of the clinical staff, which is anticipated to improve over time. The success of the program is also critically dependent on the compliance and

Table 17.3 Indicators for assessing performance of a breast cancer screening program for women aged 40–69

Performance indicator	Acceptable (%)	Goal (%)
Participation rate	70	75
Pretreatment diagnosis of malignant lesions	70	90
Positive predictive value for biopsy		
Initial screen	50	50
Subsequent screen	75	75
Reinvitation rate within screening interval	95	100

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Table 17.4 Early surrogate indicators for monitoring effectiveness of screening for breast cancer 40–69 years

Surrogate indicator	Acceptable	Desirable
Interval cancers rate/background Incidence		
First year	30 %	
Second year	50 %	
Breast cancer detection rate		
Initial screening	3× incidence rate (3 per 1,000 women screened)	
Subsequent screen	1.5× incidence rate (1.5 PER 1,000 women screened)	
Stage >II/total cancers detected at screening		
Initial screening	25 %	<25 %
Subsequent screens	20 %	<20 %
Node-negative cancers/total cancers detected at screening		
Initial screening	70 %	>75 %
Subsequent screens	75 %	>75 %
Invasive cancers/total cancers detected at screening	100 %	100 %

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participation rate of the target population, and there are benchmarks to be monitored to ensure satisfactory compliance (Table 17.2).

Summary

Integrated screening of multiple cancers in women carried out in conjunction with a well woman examination and delivered through a vertical approach via free-standing clinics or through independently functioning additions to existing primary healthcare facilities may be a cost-effective solution to decreasing the mortality from breast and gynecological cancers in resource-poor countries. In reality, this may manifest itself as a mobile clinic in areas where access may be an issue due to remote locations.

Utilizing methods that are the least expensive and that are not resource intensive will help keep costs down. The challenges anticipated in implementation of this methodology will be funding for a vertical healthcare delivery system, sustainability, and availability of trained healthcare professionals to carry out the integrated clinical services outlined previously. Ensuring participation of the target

population is yet another major challenge. A model clinic is being proposed to test the efficacy and practicality of such an approach; a Houston-based nonprofit organization, the Woman's Cancer Foundation (womanscancerfoundation.org), is leading this effort. Sustaining this challenge for the long term may necessitate that such projects be eventually integrated with existing healthcare facilities. The efficacy of such an approach requires validation through large-scale observational studies so as to demonstrate a case for widespread implementation of such an approach to reduce existing high mortality from breast and gynecological cancers in developing countries.

Appendix: Design, Layout, and Construction of a Well Woman Clinic in a Developed Country

Jennifer C. Garza

Introduction

The well woman clinic concept described previously may also be useful to help the underserved and/or indigent population in large cities of developing countries. The logistics of constructing a clinic in such a setting is described in this appendix. This description is in contrast to the bare bones approach outlined previously, keeping in mind that a clinic in a developed nation utilizing the same project design will have to meet certain minimum standards, and the funding available is significantly higher than in resource-poor settings (Fig. 17.6).

Constructing a Well Woman Clinic

There are various factors to take into account when designing and building such a project. Building one from scratch, often called a "Greenfield" project, involves many steps. This appendix is designed to familiarize the reader with the various steps in the process. The process will vary depending on resources available at each specific clinic location.

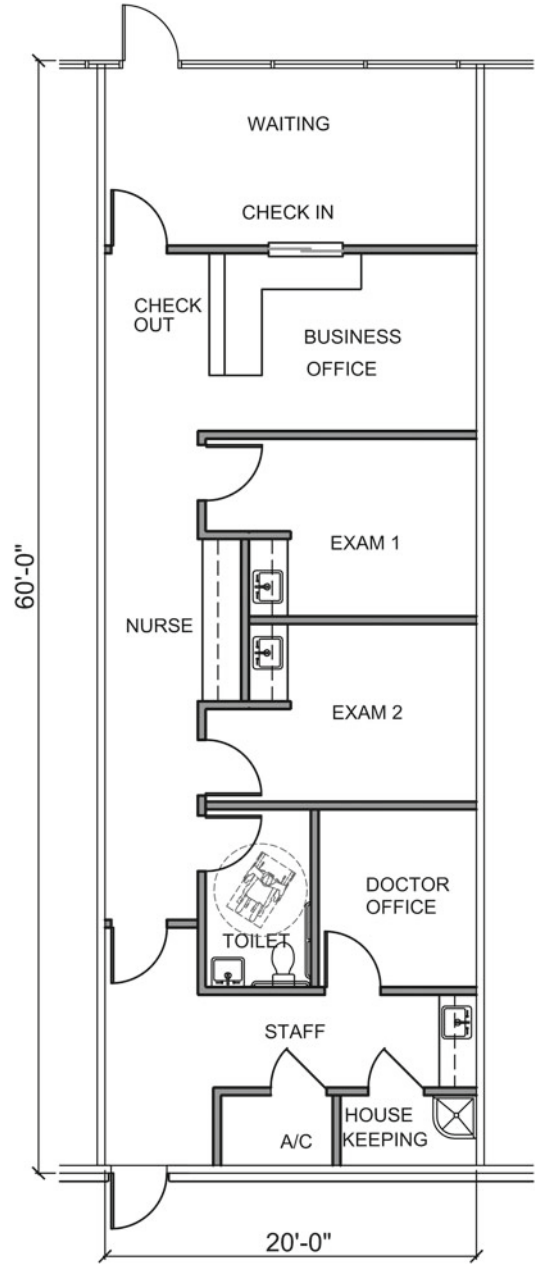

Fig. 17.6 Floor plan of a typical well woman clinic (Design by Robert Mason, Director, Architect, HCA/Gulf Coast Division, Houston, TX. Used with permission.)

Choosing a Location

It would be preferable to find a shelled out space in an existing building if one does exist. Also, an easily identifiable location will ensure the patient's ability to find the clinic and will ensure

success. It is recommended to establish contact and work with local authorities to determine if land could be donated, if the determination is to build a free-standing clinic.

Cost to Build the Clinic

The cost for construction varies greatly and depends on the location, labor availability, and material availability. In US dollars, constructing medical office building space can range anywhere from $160 to $220/square feet in metropolitan areas. It will be important to determine what types of constraints will be present at the location, but it will also be important to speak with local architects and contractors to show you examples of completed work done along with cost to determine an average cost for the well woman clinic.

Budget for the Clinic Space

The budge for a well woman clinic space would include:

- Architect and Engineering Fees
- Land
- Contractor Fees for Construction and Build-out
- A 20 % contingency budget
- Furniture, Fixtures, and Equipment

Selecting an Architect

If possible, it is important to select an architect who is familiar with the location where the clinic will be built. Knowing the local building requirements will speed up the permit process. The architect familiar with the local area will also be aware of any constraints present in the market. For example, if certain materials are not permitted as part of the construction, the architect can make changes to the design specifications to allow for that. If certain utilities are not readily available, the architect can redesign the space to take into account these constraints. Architects also usually can recommend engineers for the project if necessary.

Architectural Design Process

There are several phases in the architectural design process. To cut down on costs, researching medical office floor plans and selecting one to base the clinic space upon will be beneficial. Many floor plans can be found on the Internet, and several should be provided to illustrate the medical office layout that should suffice for the well woman clinic. For purposes of the well woman clinic, most of the programming and schematic phases have been completed.

Programming

Programming is the activity of determining the set of needs the building or space needs to fulfill. In this part of the process, you define what exactly is needed; for example, the number of exam rooms, the lobby, the physician's office, etc.

Schematic Phase

Schematic phase is the first step in the design process for planning the clinic space. The architect will typically sketch out the space in this phase. This is a high-level design for the space and will generally specify the dimensions of the different components in the space. It will also show doorways and egress, and will allow you to look at the "flow" of the space.

Design and Development

During design and development, the scheme is refined into the final design. During this portion of the process, different sets of drawings for mechanical, electrical, and communication are designed and specified. For example, an issue that will be addressed will be the number of electrical outlets needed. Communication drawings show where data lines will be located or "dropped" in the various work spaces. Also, keep in mind the logistics of patients, family members, equipment, and personnel in the space when designing the different areas.

Construction Documents

The purpose of the various sets of drawings is to specifically spell out everything that is needed in order to construct the space. Construction documents typically are submitted to permit authorities. These authorities typically review the documents, and, in most cases, they will add comments and will prescribe required revisions to the design before the permit is granted. If the

architect is familiar with the location, there will more than likely be a faster turnaround time to securing the permit.

Selecting a Contractor to Build the Well Woman Clinic

Before final construction documents are created, it is important to begin to identify a construction company or a contractor that will build-out the clinic. The contractor is in charge of procuring all the different trades needed for the project. For example, trades needed typically include flooring work, masonry, plumbing, electrical work, painting, cabinetry, etc. It is very important that a good working relationship exist with the contractor. It is suggested that one interviews several contractors. It is also important for them to demonstrate various completed projects. If possible, physically travel to locations where work was completed by these contractor candidates to determine the quality of their work.

Bidding Out the Project

If possible, the project should be bid out to at least three reputable contractors. The architect firm should be responsible for setting the "rules" for the bid. They should specify when the bid is due and the specific items that need to be addressed on the bid. For this part of the process, make sure contractors are as detailed as possible in the bid. Make sure all items have been addressed. If one contractor's price is significantly different from the others, it is more than likely that a component of the project was missed in the proposal. Other topics to take into consideration are the time it takes to order and receive supplies. It also is important to ask for an estimated time frame or schedule for construction completion. It is common to request a project timeline with key milestones identified. After questioning contractors and deciding on the price, it is customary to formally award the project to the contractor selected for the project in the form of written communication. In this communication, it is important to reference the project number if one was assigned and the total dollar amount that was agreed to. It is also customary to let the other contractors know by written communication that they were not selected for the project.

Change Orders

Change orders are changes requested after the original scope of the project has been agreed to. An example of a change order would be if it was decided to go with finished concrete for the flooring vs. ceramic tile flooring as bid originally. In this case, there very well may be a savings to the project because of the change in materials. If there is a savings, then a credit for the price specified in the original bid is due. Most projects have several change orders. Make sure both parties agree to a change order and sign off as well as date the change order. Adherence to this process will prevent any misunderstandings and arguments later. It is also important to decide how change orders will be paid and credited as the project progresses. This should be negotiated before the project commences.

Payment to Contractors

Usually, there is a payment at the beginning of the project in order for the contractor to procure supplies and labor. Generally, as the project goes through completion, there are different payment stages. It is important to negotiate the payment terms and schedule before the project is started. Again, proper documentation of these terms should be completed prior to the project commencing.

Contingency Budget

It is typical in a construction project that unanticipated issues previously not identified in the design process arise. For example, in an existing building, a wall may be demolished and then it is discovered that the plumbing will have to be rerouted or replaced due to its age. For this purpose, it is important to determine a contingency budget. It should be based on the overall project cost and can range from 10 to 20 % depending on the unknown conditions.

Well Woman Clinic General Layout

We provide schematics for typical clinic space with dimensions in the sections that follow. Sometimes, contractors can work with as little as this information to begin renovations or work. Again, it is important to know building code requirements in the local area. Generally speaking,

the clinic should range from 1,000 to 2,200 square feet (Fig. 17.6).

Waiting Room Space

The waiting room space should be the first space that you walk into in the clinic. The size of the waiting room will be determined by the anticipated needs of the patients. If a large amount of family will accompany the patient, then it may be wise to develop a waiting porch area outside the clinic. "Gang" seating is also preferable. These types of chairs are connected to each other and make it difficult for visitors to rearrange the layout. A waiting room can be efficiently used and can be relatively small at 200 square feet. At 200 square feet, it could hold ten patients waiting at one time. At 400–500 square feet, the waiting room could hold well over 20 people at one time.

The patient would walk up to the check-in counter. The reception desk should consist of a walk-up counter. It could be enclosed or partitioned off with a transparent type of window, or it could be open to the public but partitioned off from the waiting room by the counter itself.

Exam Room [2]

Exam rooms should measure from 100 to 150 square feet. Exam rooms of this size should be large enough to fit a basic obstetrics exam table, an ultrasound machine, one or two seats, a counter with sink, and cabinets above the sink.

The clinic should have two exam rooms. One will be used for well woman examinations and various testing. The second exam room will be used for sonography and procedures.

Procedure Room [1]

The procedure room could be built larger than the exam rooms if necessary. For example, the waiting room could me made smaller so that one of the exam rooms could be made larger for use as a procedure room. This room would be used for cryotherapy and other clinical procedures.

Other Spaces

Other spaces to be included and planned are Office for Physician/Practitioner, Small Break Room/Lounge, and Closets.

Materials to Consider When Building the Clinic

Using durable materials is important for ensuring that the clinic hold up to patient use and possible harsh environmental factors. For the flooring, the sealed concrete floor should be sufficient. Ceramic tile throughout would also be a good choice. Walls should be built to local standards. Epoxy paint on cinder block will suffice for all areas. For a more decorative, yet cost-effective approach, ceramic tile could also be installed along the perimeter of the wall. This could serve as wall protection. For counters with sinks, it is highly recommended that a solid surface countertop be installed. Corian is a type of solid surface material that can be made for counters that will withstand water and is durable. Sometimes you will find laminate used in clinics, but laminate has a tendency to chip or warp with age. Another consideration is to pour out concrete countertops and seal them. This will be very durable and will be easy to clean in the long term.

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