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Vulnerable Household Women's Health Assessment (VH-WHAT): Protocol Design and Implementation

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Abstract

Background: The gender-based approach can identify women's health problems on the basis of biological differences and their social, familial and individual roles. Unequal power relationship between men and women, fewer chances of education and employment, repeated pregnancies, longer life-spans, a greater proportion of the world's poor, inappropriate familiarity with their health risks increase their need to better benefit from primary healthcare. As determinants of health, poverty and social class indicate that women and especially deprived women require a greater focus on their health. This study attempts to identify modifiable health risk factors of these individuals.

Methods: The women-headed households under cover in 11 provincial centers were included in the study. Medical consultation, general physical examination, fasting blood sugar level, blood cell count, lipid profile and systematic examinations, specific examinations of breast, pelvis, mammography and Pap Smear were performed according to the protocol. As a pilot study, 2730 individuals were assessed and their demographic features were obtained.

Results: The mean age of participants in the pilot study was 47.6±10.2 years ranging from 22 to 88 years of age.

Conclusion: We expect that the study's findings would provide the opportunity to compare the differences of the special subgroups of vulnerable women with the data available in the country, and if necessary implement changes suitable with the vulnerable groups' health status.

Keywords: Gender-based, Household women,Health, protocol, Iran

Introduction

Women health status has always been one of the major health concerns particularly in developing countries. Despite significant improvements in primary and secondary health care in recent decades, women still encounter various health issues worldwide and biological and gender differences contribute significantly to their health status and issues.[1,2] Gender differences play important role in health inequity and disparities in women.[2,3] In fact gender is a social construct that is described under the influences of family, culture, politics, economy, rights and opportunities and interactions between men and women.[4]

Women constitute over 50% of the world population and even though they contribute to more than 66% of working hours worldwide, they merely receive 15% of the overall income. Furthermore, with each pregnancy they undergo a high risk situation that can lead to burdens of morbidity or mortality and as the primary provider of children's welfare, they have become increasingly vulnerable to several important health issues and disease.[5,6] On the other hand, as women have a longer life span and fewer possessions

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compared to men, they face greater security threats with aging.[7,8]

Additionally with the longer life span of women the incidence of non-communicable disease is rising significantly in women and this heralds the need for improvement of screening systems.[4,9]

The important role of socioeconomic status in one's accessibility to health care services cannot be denied and it is considered as one of the major determinants of health both in men and women.[6,10] Poverty and low socioeconomic status restricts women's access to healthcare and further forces them to live in an unhealthy and substandard condition with poor nutrition and exposure to psychological stress. These are all associated with poor health outcome.[11,12] Maternal mortality rate is estimated to be nearly three times higher among women in low socioeconomic groups than that in other women.[4]

Furthermore, it is demonstrated that poverty has a deeper impact on women and girls compared to men in regard to adverse health outcomes.[11]

Incidence of non-communicable diseases is continuing to rise and they are posing a great burden on both health care system and individuals including women.[13] Fortunately, most of these diseases are preventable or at least they can be diagnosed early by screening tests and this significantly favors the outcome and might reduce morbidity and mortality.

Health care protocols are designed to prevent or diagnose diseases in the early stages in which interventions can effectively reduce the costs and burdens and increase quality of life. Currently, most of the screening tests such as biochemical tests to check cholesterol levels and radiologic tests like mammography or tests like Pap smear are approved based on their ease of access and cost-effectiveness,.[14,15]

These screening tests should logically target the common and prevalent diseases in the community along with those which exert a great burden on health sector. In Iran the three main causes of disease burden and mortality are accidents, cardiovascular diseases and malignancies respectively.[16]

Although various programs have been designed and implemented by the national health system for several communicable and non-communicable diseases, particular subgroups of the society especially vulnerable household women might have been neglected or not benefiting sufficiently from such national health services.

There are currently several supporting and health insurance systems active in Islamic Republic of Iran. The "Imam Khomeini Relief Foundation (IKRF)" was established in 1980 with the purpose of delivering supportive social and cultural services to the deprived and poor subgroups of the society to secure their self-reliance, empowerment and human dignity. The "State Welfare Organization (SWO)" is a public organization that aims to provide the basic needs of the deprived and disabled. Both of these organizations cover a considerable proportion of the lower socioeconomic groups of the society.[17]

Vulnerable Household Women's Health Assessment (VH-WHAT) has been designed in an attempt to determine the modifiable risk factors for public health issues, cardiovascular diseases and gynecological malignancies and other major diseases that pose the greatest burden on the household women under coverage of IKRF or SWO as one of the major susceptible groups facing health burdens. Furthermore, VH-WHAT's objective is to design timely and appropriate interventions to reduce the burden of vulnerable household women under the protection of IKRF and SWO along with facilitating a proper gender approach in health sector toward an appropriate policy to cover lower socioeconomic and high risk groups in the community.

Primary objectives of VH-WHAT include: i) Assessment of general health status of vulnerable household women, ii) Early detection of modifiable risk factors such as hypertension, etc., iii) Early detection of breast masses and early intervention, iv) Establishment of a health registry for each household woman and v) Case report of important health issues in household women to IKRF and SWO on a regular basis.

Materials and Methods

The VH-WHAT was conducted in 11 province capitals during a 2 year period from 2007 to 2009 to evaluate the status of vulnerable household women in their urban populations.

Participants Recruiting and Samplings

Located in the Middle East region with an over 70 million population, Islamic Republic of Iran consists of 30 provinces with Tehran as its capital and a population of more than 10 million. Along with Tehran, 10 more province capitals including Shiraz, Mashad, Kerman, Kermanshah, Bushehr, Qom, Isfahan, Gorgan, Rasht and Yazd were included in this trial. The statistics and number of vulnerable household women

was obtained from the provincial public service organizations (IKRF and SWO). The population size of VH-WHAT in each province capital was determined according to its population and the allocated budget.

Health Assessment Protocol

VH-WHAT protocol comprises a stepwise process of call-recall of eligible household women, registration of the participants and a comprehensive general health examination package. The package includes a detailed history taking, review of system and a complete physical examination of each participant, breast examination, mammography, gynecologic examination and Pap smear sampling along with paraclinical work-ups such as blood tests for Complete Blood count (CBC), Erythrocyte sedimentation rate (ESR), Fasting blood sugar (FBS), Triglyceride (TG), Cholesterol, BUN, Creatinine (Cr), LDL and HDL and finally biopsy or Fine needle aspiration if necessary (Figure 1).

Call and Recall of Participants

A complete list of all eligible women with their full address and telephone number will be obtained from each public service or insurance organization (IKRF and SWO) in all 11 provinces. The sample size will be determined on the basis of budget allocation and the number of population under coverage in each region which is estimated overall to be approximately 30,000 women. Then all subjects will be called and explained the goals and objectives of the VH-WHAT and an appointment will be made for each individual to attend and formally enroll and participate in the trial. Those who do not attend the meeting will be recalled again in order to increase the participation rate to the maximum. Furthermore, each household woman will be informed of the need for an 8 hour fasting before the appointment to increase the accuracy of some lab tests along with other considerations regarding their menstruation (for clinicians in order to be able to perform Pap smear and vaginal examination) and the need to bring any kind of medications they take or previous lab readings regarding their history of any special disease or health issue.

Insurance companies were previously informed of the name and location of the health service delivery centers in which VH-WHAT will be conducted. All eligible household women will then receive a referral letter from these insurance companies and with assistance of the designated project coordinator in each IKRF or SWO center, the participants will be introduced to each health service delivery center (HSDC) in provincial capitals.

Registration

Participants will then refer to the HSDCs on the day of appointment with their referral letters. The registry in-charge will check their identity and referral letter and a personal code will be assigned to each subject. Detailed information regarding the process of the trial and its objectives and services will be provided and after obtaining a written consent, subjects are introduced to the first phase of the process which is to be visited by a general practitioner.

General Health Assessment

During the appointment session inclusive information regarding the objectives of the trial along with the necessity of routine checkups and screening tests and the meaning and importance of positive and negative screening test results will be explained by an expert physician at each center. Thereafter a detailed history taking and a complete physical examination will be performed and presence of risk factors such as lifestyle, insufficient or unhealthy nutrition, hypertension, etc. will be assessed and the information will be recorded in each participant's file.

Clinical Measurements

Blood pressure (mmHg) will be measured using a manual sphygmomanometer in 2 occasions with 10 minutes interval after the patient sits in a comfortable position for at least 5 minutes. Each subject's height will be measured using a portable measuring tape with the participant standing with her shoes off and in a straight position. Weight will be measured afterwards using a digital portable weighing scale. The devices will be checked for accuracy and calibration on a regular basis by project observers.

Laboratory Work-ups

After applying a tourniquet at about 4 inches above the sampling site, 10 cc of blood will be drawn in a syringe and transferred to the specified laboratories to be tested for CBC and differentiation, ESR, BUN, Cr, TG, Chol, LDL and HDL.

Breast Examination and Mammography

Prior to implementation of VH-WHAT, selected gynecologists and surgeons will attend educational workshops to be oriented towards the principles of a concise breast examination. Then on the appointment day a gynecologist or surgeon will perform a complete breast examination to detect any lump or mass along with axillary lymph node exam. All participants

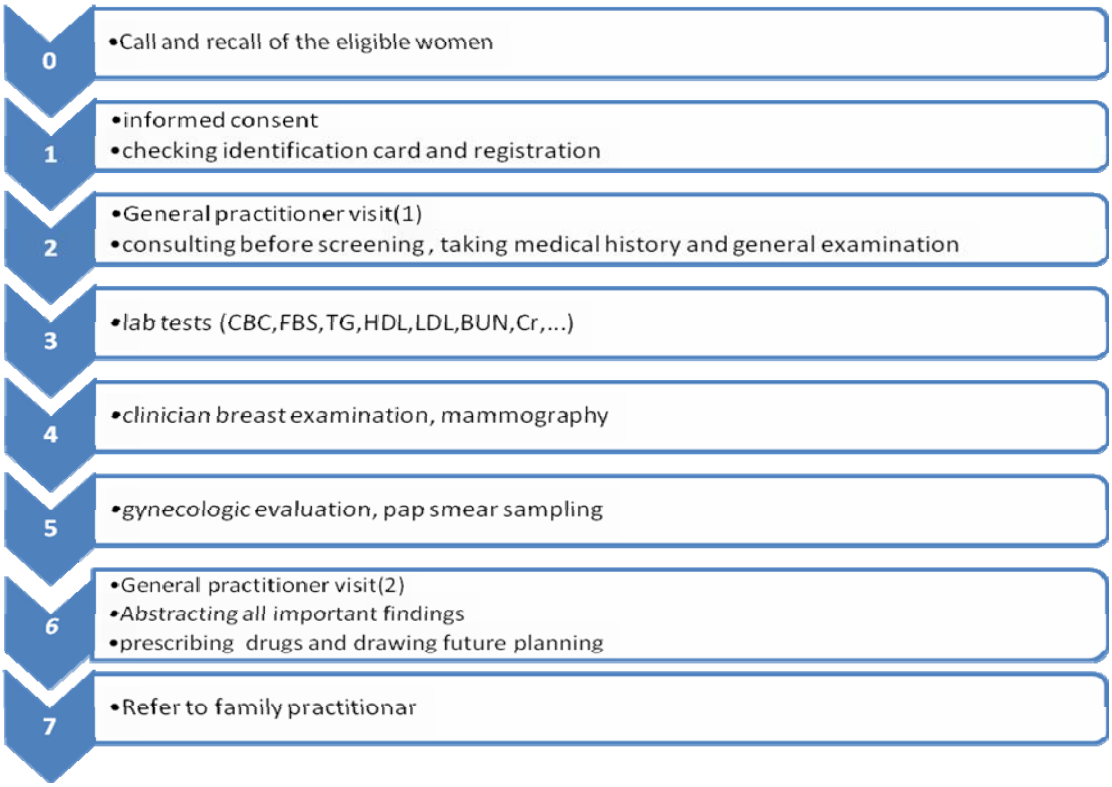

Fig.1A: Schematic view of the stepwise process of Vulnerable Household Health Assessment Trial

Fig. 1B: Geographical distribution of provinces (1.Tehran, 2. Razavi-Khorasan, 3. Fars, 4. Esfahan, 5. East Azarbaijan, 6. Kerman, 7. Yazd, 8. Golestan, 9. Kermanshah, 10. Gilan and 11.Qom)

in the range of 35 to 60 years will then be referred to designated radiology centers for mammography based on current guidelines.[18] For those women above 60 or below 35 years of age mammography will be performed according to physician's opinion and the results of breast examination.

All subjects will be asked to remove any necklace or metallic accessories that can affect the accuracy of

mammography results. The participants will then stand in front of the X-ray machine in upright position and at each time one breast will be held against the plane surface of the X-ray plate. The compressor will further gently press against the breast tissue and X-ray films will be taken at different angles.

In some cases with suspicious results of mammography a breast ultrasonography will be performed to evaluate any abnormal mass or lumps. If a cystic lesion is detected, it will be aspirated with needle. All suspicious breast masses will be biopsied for detection of malignant lesions. All information regarding breast examination and mammography results will be recorded in each participant's file for further reference.

Gynecologic Examination

In the last step of the VH-WHAT process, all women will undergo a thorough pelvic examination by a gynecologist in a gynecologic position. During the pelvic examination, external genitalia, signs of pelvic or vaginal infections and anatomical disorders will be checked and in the end a Pap smear sampling will be done and the sample will be sent to a laboratory for pathological and cytological study according to the latest WHO guidelines.[19]

Definitions

Anemia: A blood hemoglobin level of less than 12 g/dl in women is considered the threshold for diagnosis of anemia. Lipid profile: Total cholesterol level is classified into <200, 200-250, 250-300 and >300 mg/dL. LDL normal range is defined as levels below 131 mg/dL and HDL value is categorized into <35, 35-50 and >50 mg/dL levels. Triglyceride level is categorized into <200, 200-400 and >400 mg/dL.

Diabetes Mellitus: Based on WHO criteria for diagnosis of diabetes mellitus a fasting blood sugar of 126 mg/dL or higher after 10 hours of fasting confirms the diagnosis of diabetes.[20]

Hypertension: A blood pressure of more than 140/90 mmHg at two occasions in otherwise healthy adults and a blood pressure of more than 130/80 mmHg in those with high risk factors such as diabetes, heart or kidney disease. Obesity: after measurement of height and weight of each individual, her body mass index will be calculated as weight (Kg)/height^2 (m^2). A person with a BMI of more than 30 kg/m^2 is considered obese.

Quality Control

Staffing and Trainings

The execution of the project is performed by two major groups: A: Senior management of the project including senior experts of Ministry of Health and Medical Education (MOHME), senior experts at IKRF and SWO, chancellors of universities of medical sciences under whose jurisdiction the project is implemented and hospital directors and managers. B: Executive authorities MOHME experts, executive authorities at IKRF and SWO, a general practitioner in-charge of the project at each provincial level, a gynecologist, a general surgeon, radiologist, pathologist, laboratory specialist, an experienced midwife, executive staffs of gynecology and surgical clinics, radiology departments, clinical and pathological labs and IKRF and SWO insurance representatives at each designated hospital at provincial levels. Training workshops are held for both groups for orientation of individuals regarding the goals and objectives of the trial and methodology.

Pilot Study

A pilot study was conducted in 1000 household women in Tehran's Imam Hossein Hospital prior to the main study to evaluate the overall process including call-recall, feasibility and pitfalls, transportation to specified centers, registration process, health assessment team's performance and initial data gathering and analysis.

Ethical Consideration

The current VH-WHAT protocol has been ethically inspected and approved by the following authorities: Research Committee of Women's Affairs Unit, MOHME's Deputy of Health and Ethical Committee of MOHME.

During the project, participants are familiarized with the main objectives and overall stages of the study via phone contact and further information and details of each stage and procedure will be described on the registration day. All participants are reassured of the secrecy of their information and that the results of lab tests and paraclinical work ups will be handed over to them for future follow-up.

Subjects will not be charged for any of the services mentioned in the protocol and they can withdraw from the trial at any time during the process.

Data Entry and Statistical Analysis

A personal file and data sheet with an exclusive

code will be designated to each participant from the time their names and contacts are derived from the insurance agency and following the registration on the appointment day all data regarding history and physical examination along with all lab data and radiologic and pathologic reports will be summarized and entered in each subject's data sheet. After all forms and sheets are filled out, all files and data will be collected by IKRF and SWO representatives and will be presented to the organization and each participant's family physician in order to be recorded in their files. Incomplete forms will be returned to the project observers to be completed and all data and paraclinical results will be entered into the trial's main database.

Results

A pilot study was implemented in Tehran Province on approximately 2730 household women to evaluate the feasibility and pitfalls of the protocol.

The mean age of participants in the pilot study was 47.6±10.2 years ranging from 22 to 88 years of age. Table 1 demonstrates the basic demographic features of the participants.

Discussion

VH-WHAT is to be implemented in almost 30,000 household women that are under coverage of insurance and public supporting companies like IKRF and SWO for assessment of their general health status in a descriptive manner. It is expected that the results will portray a clearer image on current health status in lower socioeconomic classes and will demonstrate the need for modification of general health policies, e.g., educating such groups on the necessity of routine checkups and screening tests as well as increasing the awareness of health policy makers and government officials on the health burdens of lower socioeconomic groups. Considering the special characteristics of the population of this trial we hope that based on the results and analysis of the collected data in this study more appropriate interventions and more suitable models will be implemented for these susceptible groups.

Table 1: Demographic features of participants in the pilot study

Demographic features	Number (%)
Occupation:	
- Housewife	- 2234 (81.7%)
- Teacher	- 265 (9.7%)
- Other	- 231 (8.6%)
Marital status:	
- Married	- 618 (22.6%)
- Single	- 46 (1.7%)
- Divorced or widow	- 2070 (75.7%)
Education:	
- Illiterate	- 987 (36.1%)
- High school	- 1508 (55.1%)
- College or higher	- 239 (8.7%)
Cigarette smoking:	
- Recent	- 3 (0.1%)
- Remote	- 2 (0.1%)
- Never used	- 2725 (99.8%)
History of oral contraceptive pills use:	
- Never	- 1083 (41.8%)
- Started from 20 years of age	- 1269 (49%)
- Started after 30 years of age	- 237 (9.2%)
Number of pregnancies:	
- None	- 89 (3.3%)
- One	- 253 (9.3%)
- Two	- 500 (18.3%)
- Three or more	- 1888 (69.1%)
Family history of breast cancer	181 (6.6%)
Family history of ovarian cancer	78 (2.9%)
Age (mean±SD)	47.6±10.2 (Min:22, Max:88)
Age of Marriage (mean±SD)	17.8±4.7 (Min:12, Max:45)
Age of Menarche (mean±SD)	13.3±1.5 (Min:9, Max:17)

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Conflict of interest: None declared.

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