

NATIONAL STANDARDS FOR BREAST CANCER SCREENING OF WOMEN

Published on July 20, 2004

A. Abstract

1. This document identifies the rules and standards that have to be followed during community based breast cancer screening studies in Turkey. In the course of a community based breast cancer screening study:

a. Target population should be composed of women aged 50-69 years who live in a community the geographical limits of which are defined.

b. The screening intervals should be two years.

c. One with mediolateral oblique (MLO) and the other with cranio-caudal (CC) views, two mammograms for both breasts of the screened women should be taken

d. Mammography films should be evaluated by two radiologists independently and the advices of both should be taken into consideration.

e. Although the basic screening modality is to examine the breast through mammography, each woman participating in the study should also be examined by the physician.

2. Considering that more than seventy percent of the target population should participate in the screening in order for the screening to be effective, i.e. reducing the “breast cancer mortality to thirty percent”, it is compulsory to attach necessary importance to the planning, registry, statistics and evaluation processes of the screening activity.

3. Principles of quality assurance should be followed fastidiously at every phase for the success of the screening.

4. While preparing this document, many scientific publications were scanned, views of many national and international agencies were reviewed and domestic and foreign experts were consulted. However, we

welcome those who wish to contribute to the changes, which may occur in this document in due course, by providing their views and comments in order to meet the needs through forwarding their opinions to kanser@saglik.gov.tr e-mail address.

B. Introduction

1. Importance of Breast Cancer: Breast cancer is a significant public health issue in Turkey.

a. Breast cancer is the most common cancer type among women in Turkey.

b. Turkey is among the countries which has a medium incidence rate of breast cancer in women.

c. Therefore, as part of the breast cancer in Turkey, it would be appropriate to implement community-based programs for the control of breast cancer.

2. The Purpose of the Screening Program: The main purpose of the community based cancer control program in breast cancer in women is to “decrease the mortality rate associated with breast cancer”. Although various modalities were offered to that end, only the effectiveness of “screening with mammography” was proven.

a. It is indicated that the breast cancer incidence rate is low among women who do not smoke, who breast-feed their children and women who are not over-weighted. However, there is not a recommended primary prevention strategy the effectiveness of which has been proved in order to fight at public level against breast cancer in women. In other words there is not a modality to be followed in implementing in the community based programs to prevent the incidence of breast cancer.

b. As a secondary preventive method, there are three modalities offered and extensively practiced with a view to detecting the carcinogenesis process without the appearance of clinical evidences. These are:

i. Encourage woman to do breast self-examination practice at certain intervals through community programs: There is no evidence that breast self-examination programs decreases the mortality of breast cancer.

ii. Clinical Examination by a physician or nurse at intervals: Although there is no sufficient evidence that clinical breast examination as a screening modality decreases the breast cancer mortality rate, it is observed that when applied as an auxiliary method in mammography screenings it increases the selectivity and specificity of mammography.

iii. Regular mammography examination of the breast: Various studies have proved that community based breast cancer screenings conducted through breast mammography process decreases the breast cancer mortality rate by thirty percent, and in spite of different comments and views on this subject, conducting community based breast cancer screening is recommended to the countries by international institutions.

C. Screening Program:

1. Responsibilities of the Screening Center: The center conducting the screening will assume the overall responsibility of the entire planning, implementation and evaluation processes. The Center shall individually execute the following administrative procedures.

- Determination of the target population geographically, identification of the names of the women who residing in the pre-determined regions and who are suitable for participating in the screening, and formation of the name lists

- Invitation of the persons included in the target name list by explaining them one by one,

- Application of screening analysis on healthy women,

- Recall of “suspected cases of cancer”

- Referring the patients to relevant centers for examinations that can not be conducted in the center and in situations necessary for early diagnosis and treatment,

- Follow-up of the patients who are referred to other centers and are included in the “suspected” group and entering their final diagnosis in the data base as “cancer” or not cancer”,

- Registry and storage of the data necessary to evaluate the screening, doing mathematical operations and calculating the measures of valuation,

- Developing and implementing a quality assurance plan that covers all phases of the screening program,

- Composing the interim and final reports.

2. Infrastructure: The infrastructure of the center should have been completed before the planning of the screening process.

a. Physical infrastructure: The center responsible for implementing the project should have mammography and ultrasound devices installed and other tools and equipment that may be needed during the screening.

b. Manpower: The specialist physicians, practitioners, nurses and other staff should be employed in the center to conduct the screening, and relevant staff and connections should be provided for consultations.

c. Training: The initial training of the staff to be employed in the screening should have been completed in the planning process but their in-service training should continue during screening.

d. Quality Assurance: The level of success of the screening should be limited by the one with the lowest quality level among the following aspects:

- i. quality of the devices,
- ii. quality of the consumption materials such as film and development solutions
- iii. quality of the process of mammography scanning
- iv. quality of the process of evaluating the mammography films,
- v. quality of reporting the mammography film

For these reasons, during the planning phase of the screening, the infrastructure should achieve a high quality regarding the tools and equipment as well as manpower and training.

3. Planning Process:

a. Preliminary Phase:

i. Detection of the population to be screened: Befitting to the capacity of the center to execute the screening, a population group should be defined geographically. For that purpose, as long as no other reliable source is found, the Household Registry Forms (ETF) renewed by the health care centers through mid-year population evaluation should be scanned and the population aged between 50-69 years should be taken into consideration. It is advised to take the health care center regions and midwife regions of each health care center as the "population units." In the case that the ETFs are unreliable, the population should be detected before the screening and the persons in the target group aged between 50-69 years should be identified by name.

ii. Flow charts: The following three flow charts should be prepared as part of the planning process:

- Invitation Flow Chart: This flow chart includes information on how the women included in the target group are to be determined whether they are eligible for screening (meaning they are currently residing in the region and they have not been diagnosed with breast cancer) and how they will be invited, whether they take mammography tests at their own discretion and when they took their last mammography test. This chart will also include reasons of women for rejecting, if exists, to take mammography tests and the ways of following those who has made appointments but never come.

-Medical Flow Chart: The administrative and medical procedures to be followed in the centre from the time of presentations to the screening center, how to make recalls and how to monitor the non-comers should be included in this chart.

- Tracing flow chart: The procedures to be followed for the persons referred to institutions other than the screening center and how and which information is to be monitored should be indicated in this chart.

b. Procedures to Refer the Patients: The institution(s) to which the patients are going to be referred should be determined in the preliminary phase and, if necessary, a protocol should be signed with these institutions.

c. Data Collection: During a screening program, data headlines needed both for the execution and evaluation of the program and how to gather and evaluate these data should be determined in the planning phase.

Moreover,

-The headlines of the data to be collected should be selected in a way to be sufficient for calculating the evaluation criteria (See C.5)

- Which measures are to be included in the monthly and yearly maintenance reports and final report should be determined right from the beginning.

- Data should be collected in electronic form

- Confidentiality of the personal information should be guaranteed

- Quality control modalities that will show the reliability of the data should be followed

4. Implementation Process:

In a community based breast cancer screening program to be implemented in Turkey:

a. Two decades Age Range: Women aged between 50-69 years should be included.

b. Two-year Intervals: Community based breast cancer screenings should be carried out every two years.

c. Two mammography films: One with mediolateral oblique (MLO) and the other with cranio-caudal (CC) views, two mammograms for both breasts should be taken

d. Double reading: Mammography films should be evaluated by two separate radiologists uninformed about each others views and the recommendations of both radiologists should be taken into consideration in monitoring the person.

e. Quality Assurance: Since the efficiency of the screening is possible by making quality assurance approach the basic part of the study, quality assurance modalities should be integrated into each of planning, implementation and evaluation phases of the screening process.

5. Evaluation criteria:

a. Short-Term:

i Coverage Rate: It is the rate of women who entered the screening program, among those who are eligible for screening in the target group. This figure is calculated after a single round of screening is completed.

Participants of the Screening Program

$$\text{Coverage Rate} = \frac{\text{Those in the target group who are eligible for screening}}{\text{Participants of the Screening Program}} \times 100$$

ii. Recall Rate: It is the percentage of women who are recalled for medical reasons such as additional shot of mammography, ultrasound review and expert consultation, to the women who entered the screening program. The women who have to come to the center again for technical reasons such as the low quality of the films or administrative reasons such as not coming to the center are excluded from this rate.

Those who are recalled to the center for a medical reason

$$\text{Recall Rate} = \frac{\text{Those who are recalled to the center for a medical reason}}{\text{Participants of the Screening Program}} \times 100$$

iii. Percent of False Positives: It is the percentage of women, who are not diagnosed with cancer among those who are recalled, to the women who entered the screens.

Those who are not diagnosed with cancer among those who are recalled

$$\text{Rate of false positive} = \frac{\text{Those who are not diagnosed with cancer among those who are recalled}}{\text{Participants of the Screening Program}} \times 100$$

iv. Interval Cancer Rate: Cancer cases that are detected in the second round of cancer screens are called "Interval Cancers." The percentage of interval cancers among the total of cancers detected by screens and interval cancers are called "interval cancer rate."

Interval Cancers

$$\text{Interval Cancer Rate} = \frac{\text{Interval Cancers}}{\text{Cancers detected in the screens + interval cancers}} \times 100$$

b. Long-Term: Since the purpose of a long term breast cancer screening program is to decrease the mortality rate of breast cancer among women, it would be advisable to follow the breast cancer mortality rate among women in an area where screening programs are conducted, and to observe the decline in the mortality rate.

Number of women died of breast cancer in a year
Breast cancer mortality rate=.....X100
mid-year population of women

References:

1. European guidelines for quality assurance in mammography screening; Third edition, European Commission; Belgium, 2001.
http://europa.eu.int/comm/health/ph_determinants/genetics/guidelines_toc_en.pdf
2. Evaluation and monitoring of screening programmes; European Commission, Europe Against cancer Programme; Brussels – Luxembourg, 2000.
http://europa.eu.int/comm/health/ph_determinants/genetics/evaluation_toc_en.pdf
3. Breast Cancer Screening, IARC Handbooks of Cancer Prevention, Volume 7, 2002, Lyon – FRANCE.
 - a. <http://www.iarc.fr/pageroot/PUBLICATIONS/hndbks.html>
4. Ulusal Kanser Enstitüsü'nün (ABD) [National Cancer Institute (USA)] "Physician Data Query (PDQ)" adlı veri tabanı. (Data base of the National Cancer Institute named "Physician Data Query")
<http://www.cancer.gov/cancertopics/pdq/screening/breast/HealthProfessional>
5. Council Recommendations on Cancer Screening, Translated by: Feryal Halatçı, Brussels, 5.5.2003.
 - a. http://www.saglik.gov.tr/extras/birimler/ksdb/ABkanser_tarama_tav_kar.doc
6. National Cancer Control Programmes, WHO, Geneva, 2002
<http://www.who.int/cancer/publications/en/#guidelines>

NATIONAL STANDARDS FOR CERVICAL CANCER SCREENING

Published on May 29, 2007

This document identifies the rules and standards that have to be followed during community based cervical cancer screening studies in Turkey.

INTRODUCTION: Cervical cancer screening modalities are one of the few methods the effectiveness of which have been proven and which are considered to decrease the invasive cancer incidence and mortality rate. It should be carried out at advised intervals in order to detect the potential patients at risk. For the patients who are screened and who had abnormal outcomes, thanks to further analyses to be made according to the recommendations, the patients who require treatment are detected and treated accordingly, because the decrease in the incidence and mortality of cervical cancer can be achieved not only through screening but also through necessary treatment.

AIM: Cervical cancer is an important health issue. Due to the presence of pre-invasive lesions and being an easily reachable organ, it allows early detection. For these reasons the basic aim is to apply the target population a national screening program to be developed throughout the country, and to decrease invasive cancer incidence rate, morbidity and mortality rates that are associated with it and by detecting the cervical pathologies at their pre-invasive stages and treating them through effective and simple methods to prevent complicated and expensive treatments that may be needed otherwise

INFRASTRUCTURE OF THE SCREENING PROGRAM: It should be ensured that the infrastructure (physical, manpower, training and material) of the center is ready before the planning is made.

METHOD: Given the infrastructure and capabilities of Turkey, the ideal method is the classical method of “conventional smear”.

TARGET POPULATION, BEGINNING AND TERMINATION AGES OF SCREENING AND SCREENING INTERVALS: The absolute target is to ensure all women aged between 35-40 years have their smears taken at least once. When we consider Turkey’s conditions the ideal target is a community based screening that begins at the age of 35. The population to be screened should be identified by taking the ETFs as a basis and should be repeated at 5-year-intervals through invitation

methods to be developed, and the screening of women at the age of 65 whose last two (2) tests are negative should be terminated.

Special Conditions

▪ **Smear after hysterectomy:** Screening with vaginal cytology is not indicated in women who have undergone total hysterectomy due to benign gynecological reasons (CIN II and III are not considered to be benign). In the cases that have undergone hysterectomy due to CIN II and III, in the presence of **3** documented and technically satisfactory negative cytologies and in the absence of abnormal / positive cytology in the last decade screening should be terminated.

▪ **In the cases diagnosed with HIV infection and / or undergoing immunosuppressive treatment**, smears should be taken two times for the first year, and it should be annually, if the results are negative. For cervical Ca, patients who underwent immunosuppressive treatment (including cases with HIV positive) smear taking should be continued annually until good health conditions are reached.

▪ **PLACE:** These studies can be conducted in Cancer Early Diagnosis and Screening Center (KETEM), Mother and Child Health and Family Planning (AÇSAP) Polyclinics and Health Care Centers. These institutions should periodically forward these results to the Health Directorates for communication to the Ministry of Health Department of Cancer Control. "Screening Registry and Management Units" are created in Health Directorates under the responsibility of the Provincial Cancer Control Coordinator in order to provide the coordination of community based screening activities.

▪ **PROVISION OF THE MATERIALS:** Materials needed for the screening are disposable speculum, special slides on which the name of the patient is written, spray, slide case and smear stick should be acquired in advance through Health Directorates and distributed to the centers against receipt.

▪ **IN COMMUNITY BASED SCREENINGS:** Smear should be taken with conventional methods, the patient should be called in the first stage of menstrual cyclus, disposable speculum, and special slides on which the name of the patient can be written should be used and spray fixatives should be preferred. Slides should be placed in special protective cases which should be sent to pathology laboratories.

▪ **SMEAR TAKING:** Smears should be taken by the practitioners, mid-wives and nurses in the Health Care Centers, Mother and Child

Health and Family Planning (AÇSAP) Polyclinics and KETEMs according to the training they received.

- **EVALUATION OF THE SMEARS:** Evaluation should be made by the pathologists of the State Hospitals with which the evaluation centers are in close connection. If there is a problem in the hospital for pathological inspection (staff, etc), the pathologists in other hospitals in the province may be used. This arrangement in the province is managed through coordination between the Provincial Cancer Control Coordinator, Assistant Director of Provincial Health Directorate and the Assistant Chief Physician who is responsible for cancer control in the hospital.

After completing legal arrangements, Department of Cancer Control establishes cooperation with related vocational organizations for the training of pathologists and cytopathologists, when necessary, to be employed in the evaluation of smear samples. The final goal is the establishment of “Smear Evaluation Centers”

- **INFORMING AFTER EVALUATION:** The center that takes the smear should evaluate and notify the patient of the outcome within one month at the latest. Even if the result is normal, the person should be given notice.

- **MANAGEMENT OF THE PATIENTS WITH ABNORMAL SMEAR RESULTS:** When pathology is detected in the smear, the patient should be referred to the subject-matter experts for the checks of these trained experts of the hospital with which the center has connections. Cooperation is established with related professional organizations and trainings were performed within the framework of the legal arrangements to be made by the Department of Cancer Control for the planning of the obstetricians and medical practitioners to receive their training in colposcopy method to be used for advance inspections of the patients. Patients with definite diagnosis are referred to respective cancer treatment centers.

- **DATA COLLECTION:** During a screening program, data headlines needed both for the execution and evaluation of the program (evaluation criteria) and how to gather and evaluate these data should be determined in the planning phase.

- **CONFIDENTIALITY OF PERSONAL INFORMATION:** Confidentiality of the personal information should be guaranteed at every stage of the screening.

- **TRAINING AND DOCUMENTS:** The training of the staff in the centers in which these services will be provided is realized in accordance with the provisions of the “Regulation on the Arrangement of the Training and Certification of the Staff in the Centers for Early Diagnosis and Detection of Cancer”. Physicians, nurses, midwives and medical technicians working in KETEMs are reliable to receive informative training, and within a feasible program, they will convey this training to the physicians, nurses, midwives and medical technicians serving in AÇSAP and Health Care Centers in their region. The documents covering the information on this subject and educational guide are prepared by the Department of Fight Against Cancer and distributed to all centers participating in the screening program.

- **QUALITY ASSURANCE:** Principles of quality assurance should be followed meticulously at every phase for the success of the screening. (KETEM Quality Standards, Screening Quality Standards, etc)

- **STATE HOSPITALS, TRAINING HOSPITALS AND UNIVERSITIES:** Standards on this issue should be communicated to them; cooperation should be established with them in training an informing the public; planning and treatment of the referred patient requiring advance treatment and the timely and complete feedback of the outcomes should be ensured.

- **PROMOTION:** Campaigns should be organized primarily via printed and visual media for promoting the screening and informing the public, spot films should be shot and making these films broadcasted at convenient times.

CERVICAL PAP SMEAR

Pap smear test is a cytological screening test based on collecting and inspecting smeared cervical cells. Through this cytological screening test, a decline in the mortality and morbidity rate associated with cervical cancer is aimed at by detecting the invasive and early invasive cervical lesions. The Pap smear test was named after George Papanicolaou who first found this test in 1928.

Taking smear is completely a simple and painless procedure. The cervix is inspected after the biggest size disposable speculum is inserted in the vagina during gynecological examination. The clinical appearance of the cervix and any abnormalities, if any, are noted. After making sure that there is no vaginal hemorrhage, samples both from the endocervical channel and from ectocervix should be taken. The received samples are laid out on one or two flat slides and the cells are fixed on the slide by

spraying, as soon as possible, with a hair spray from right angle and from 20 centimeter distance or by keeping it in a case that contains 95% alcohol for at least 10 minutes. This procedure may be applied by using special fixative solutions. Fixing the cells right after the samples are taken prevents the drying and deterioration of cellular samples. Thus, mistakes that may occur in evaluation are prevented.

Conditions to take Smear Test:

- To be on sexual diet at least for 48 hours prior to the examination
- Abstain from vaginal douche at least for 24 hours prior to the examination
- No vaginal medication (crème or other drugs) should be used for at least 48 hours before the examination
- There should be no menstrual bleeding
- If applied, at least 24 hours should pass after a colposcopic inspection during which acetic acid is used

At least 3 months should pass after the last smear taking procedure for taking new smears. Also at least three months should pass after a cervical surgery. The best period for smear test is the days right after the termination of the menstrual bleeding, and the ideal is the mid-term of the cyclus. Because the quality of the preparations is low due to reactive inflammatory changes in this period, taking smear for screening purposes should be abstained during at least 6 to 8 month-period after child birth.

The followings are the conditions that create contraindication for taking smear:

- Total hysterectomy
- Cervical amputation
- Existence of a suspected lesion observed macroscopically in the cervix (in this case colposcopic inspection and / or biopsy is necessary)

These are the factors that affect the smear quality:

- Vaginal infection-inflammation
- Acute genital atrophy (menopause)
- After Pregnancy, post natal and breast-feeding period
- Radiotherapy history

References:

1. Ulusal Kanser Danışma Kurulu, , Erken Tanı ve Tarama Alt Kurulu Raporu (Report of the Early Diagnosis and Detection Commission of the National Cancer Advisory Board)
2. Comprehensive Cervical Cancer Control (A guide to essential practice) WHO 2006
3. American Cancer Society (ACS) Guidelines for the Early Detection of Cancer
4. American College of Obstetricians and Gynecologists (ACOG) Guidelines