Self-examination in the early detection of breast cancer: Memorandum from a WHO Meeting*

Breast self-examination is of interest for the early detection of breast cancer, especially in areas where mammography and regular physical examination of the breasts are not practicable as public health policies. At present, there is insufficient evidence that breast self-examination is effective in reducing mortality from breast cancer. To determine its effectiveness, this method should be applied in a comprehensive programme that provides teaching and guidance on practice of the technique, and facilities for self-referral and diagnosis (when any abnormality is detected) as well as treatment, taking into account the background (economic, social, and cultural) of the country or area concerned. Once the programme has been developed, its effectiveness in reducing breast cancer mortality will have to be assessed in carefully designed research studies. The favoured design for assessment is a randomized controlled trial. Other types of studies, such as quasi-experimental comparisons or a case-control study, are less satisfactory, but may be conducted under strictly specified conditions. Until the effectiveness of breast self-examination has been established, it cannot be recommended as a public health measure for control of breast cancer.

In 1981 a group of experts was assembled by WHO to discuss prevention strategies in cancer and they recommended that careful consideration should be given to the possibility of further testing the efficacy of screening for breast cancer and particularly to breast self-examination. The main reason for selecting breast self-examination (BSE) was that mammography could not be expected to meet the needs of large segments of the world population owing to the cost (1, 2). Further, experience has indicated that physicians are unlikely to perform breast examinations on more than a small proportion of the population, or to do them sufficiently well, for this approach to be adopted as a means of screening for breast cancer (3). The present meeting on breast self-examination was therefore convened to pay attention to the needs of both technically advanced and developing countries.

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* This Memorandum is based on the report of a Consultation on Self-Examination in Breast Cancer Early Detection Programmes, which was held in Geneva on 17-19 November 1983. The names of the participants are given on page 868. Requests for reprints or for the full report should be addressed to the Cancer Unit, World Health Organization, 1211 Geneva 27, Switzerland. A French translation of this Memorandum will appear in a later issue of the Bulletin.


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**EPIDEMIOLOGY AND PRIMARY PREVENTION**

Breast cancer is one of the commonest causes of death in many developed countries and is becoming frequent in developing countries as well, e.g., Egypt, Tunisia, etc. Mortality rates from breast cancer have increased during the past 60 years in every country reporting to the World Health Organization (4), although in most countries with high mortality the rates have been relatively stable over the past 10-20 years. There is a tenfold difference in the age-adjusted incidence of breast cancer between registries in the developed countries and registries in Africa and Asia (5).

Breast cancer is uncommon below the age of 35 years, the incidence increasing rapidly between the ages of 35 and 50. Thereafter in high-incidence areas, the rates continue to rise in successive age groups, although less steeply than before; in low-incidence areas, the rates tend to remain level (5). Migrants who move from a low-incidence country to a high-incidence country gradually acquire the incidence of their host country, suggesting that international differences are due to environmental rather than genetic factors (6).
The risk of breast cancer is related to the duration of ovarian activity (6). Risk is increased for women with an early age at menarche and those with a late menopause and is reduced for those with a surgically induced menopause. An early first full-term pregnancy reduces the risk, but a first pregnancy after the age of 30 is associated with a higher risk compared with nulliparity. Oral contraceptive usage appears to have little overall effect on breast cancer risk, although prolonged use of oral contraceptives before the first pregnancy or before the age of 25 may increase the risk in younger women (7). The risk is high in those with a positive family history, especially if a mother or sister developed breast cancer when premenopausal. There is increasing evidence that breast cancer is associated with high fat in the diet, which suggests one line of approach for primary prevention (8).

TREATMENT AND PROGNOSIS

In recent years many controlled clinical trials have been undertaken in the search for improved therapies. Surgery and radiotherapy are being more rationally applied. Chemotherapy and endocrine therapy have been introduced as adjuvants to surgery in the primary treatment of defined groups of patients. However, no major improvement in survival rates has yet been shown.

There has been some improvement in defining prognosis. The most important determinant of survival is the pathological stage when the cancer is diagnosed. “Early” cancers — i.e., those in which, at the time of diagnosis, the tumour is less than 2 cm in diameter, is not fixed to adjacent tissues, and shows no involvement of lymph nodes — have a very much better prognosis than cases in which the tumour is large and invading local tissues, and shows lymph node involvement and metastatic spread. Such “late” cases may represent over 50% of breast cancers diagnosed in the developing countries.

The growth rates of, and the host’s responses to, breast cancer are very variable, some cases progressing rapidly even if diagnosed at an apparently early stage (9), others surviving for 20 years even after metastatic spread (10). However, in general, the removal of the tumour by treatment early in a cancer’s development is more likely to be curative than removal at a later stage, and this is the rationale for screening apparently well people in order to detect and treat cancers before their presence is realized.

EVIDENCE ON EFFECTIVENESS OF SCREENING

Results are available from the Health Insurance Plan’s trial in the USA, in which 62 000 women aged 40–64 years were randomly allocated either to a study group that was offered screening by physical examination of the breasts and mammography every year for four years, or to a control group that received only conventional care (11). A reduction in the number of women over 50 years old dying of breast cancer in the study group compared with the control group was observed after 5 years and has persisted through 16 years.

In this study the comparison was made between all breast cancer deaths occurring in a stated time period in a population of women offered screening and all breast cancer deaths in a comparable control group that was not offered screening. Thus the number of breast cancer deaths in the population was measured (i.e., mortality) rather than the number of deaths among breast cancer cases (i.e., case fatality). The latter measure is not appropriate for assessing the results of screening because of various biases. For example, screening brings forward the date of diagnosis and extends the interval between diagnosis and death even if the time when death will occur cannot be altered; therefore screening-detected cases will have a longer survival following diagnosis (i.e., they present a lower case fatality in a given time), compared with cases diagnosed without screening. This is called lead-time bias. Secondly, screening detects cases in the preclinical phase and the length of time spent in that phase by different tumours will depend upon their growth rates. Fast-growing tumours will progress rapidly through the preclinical phase and will therefore be less likely to be detected by screening unless this is repeated very frequently. On the other hand, screening at infrequent intervals (e.g., six monthly or annually) will detect a disproportionate number of slow-growing tumours with a good prognosis. This is called length bias. Thirdly, people who accept screening tend to be health-conscious individuals who, if screening were not offered, would present quickly for treatment as soon as any symptoms appeared, so that they would therefore have a better prognosis. This is called selection bias. Fourthly, screening may detect lesions of questionable malignancy that might never have been diagnosed if there were no screening. This is called overdiagnosis bias.

Because of these biases, the survival of screening-detected cases will inevitably be longer than post-symptom-detected cases even if the screening has no influence on mortality. Comparison of the mortality from breast cancer in two exactly comparable populations, except that one has and the other has not been exposed to the offer of screening, will be free from these biases. Although mortality comparisons before and after the introduction of a screening programme in a specified population, or between one district that has screening and another that does not, are of some value, unknown variations between the populations (e.g., selection bias) might account in whole or in part
for any differences that occur.

The Health Insurance Plan's trial, although providing the strongest evidence that breast screening is effective, still leaves some questions unanswered concerning, for example, the effectiveness of screening of women under 50 years old and the relative effectiveness of physical examination and mammography. These matters are being investigated in further randomized controlled trials in Canada (12), Sweden (13), and Scotland (Edinburgh), the latter being part of a non-randomized geographical comparison study in the United Kingdom, in which breast self-examination is also being tested (14).

BREAST SELF-EXAMINATION AS A SCREENING TEST IN EARLY DETECTION PROGRAMMES

Since the middle 1960s when the Health Insurance Plan's trial was started in the USA, most screening emphasis has been placed on developing low-dose mammography systems. However, a careful examination of the trial's results suggests that much of the benefit demonstrated may have been due to detection of small invasive lesions by physical examination. In the screening context, physical examination involves inspection and palpation of the breasts by a trained doctor or nurse, and it is usual to recommend that this examination should be repeated annually.

The purpose of teaching breast self-examination is to train women to examine their own breasts. An advantage of self-examination is that it can be repeated often, and in many countries it may be the only realistic approach to the control of breast cancer. The underlying premise is that regular examination will enable women to become familiar with the appearance and consistency of their own breasts and therefore be able to recognize any change.

However, because in breast self-examination the individual women have to be active, there is a need to:

(a) motivate women in the appropriate age group to undertake this role;
(b) encourage those who find an abnormal sign to have this checked by proper diagnostic measures.

When breast self-examination is a component of an early detection programme, attention should be given to keeping all the elements like information and education, motivation and reinforcement, adequate management and follow-up, etc. close together so as to form a well-balanced entity (16).

The two principal matters connected with breast self-examination are the recommended frequency and the recommended technique. The normally advised frequency of once a month is arbitrary and not supported by evidence on the effects of different frequencies. It is too long an interval for many women to make it an automatic habit, and a reminder (such as a personal, specially devised calendar) may be needed. Premenopausal women are often instructed to relate their "BSE day" to their menstrual cycle, (e.g., 5 or 15 days after the start of the menstrual period). Postmenopausal women are merely told to do their self-examination on a set date of the month.

The rules on technique have been set without knowledge of what is the optimum. The woman is usually recommended to stand and inspect her breasts in a mirror, looking particularly for skin dimpling or asymmetry when the hands are pressed on the hips or raised above the head; she then lies down and systematically palpates every area of each breast using gentle pressure with the finger pads, and similarly palpates into the axilla on each side to detect axillary tail lesions.

The psychological aspects are as important as the technical aspects of performing breast self-examination. The teaching package should therefore include information to ensure that women will feel not just vulnerable to the development of the disease, but optimistic about the outcome if it is diagnosed early (15). Different cultures will vary in their prevailing views about breast cancer and the appropriateness of breast self-examination. Research is required to develop the correct educational message to convince women to adopt this method within their own culture and social framework.

A further most important component of a programme containing breast self-examination is a system for assessment of abnormalities found by self-examination. Women must be given the assurance of rapid, sympathetic, expert advice as well as appropriate investigation. Each woman taught this method should know a doctor or a clinic to which she can go as soon as she is aware of any abnormality (16).

BSE EDUCATION AS PUBLIC HEALTH POLICY

When a method that is successful in persuading women to practise breast self-examination regularly and to refer themselves (when necessary) has been devised, it should be applied to the appropriate target population. Leaving the decision to individual doctors to teach, or individual women to seek to learn about this method may not produce measurable benefits in terms of mortality reduction. A policy decision is therefore required for the implementation of a comprehensive BSE-containing programme based on wide application of breast self-examination as a screening test in the population at risk.

The target population

The first step is to define the target population at
risk. As breast cancer is very uncommon below the age of 35 or 40 years, it would be wasteful of resources to enrol younger women, unless it were shown that early training increased compliance at later ages, or led to an increase in the extent to which older women practised it by diffusion of knowledge from one generation to another. A disadvantage of educating young women is that benign breast disease is common among them and identification of this by self-examination might lead to an unnecessary increase in biopsies.

Apart from age, the other known risk factors, even in combination, do not define a risk group sufficiently well to include most of the breast cancers that will occur (17). Therefore, for practical purposes, the target group should be women above a certain age, usually 40 years.

Methods of BSE education

The various methods of educating women to practise breast self-examination range from general advocacy by poster or media-advertising at one end of the scale to comprehensive programmes at the other. In between are various forms of group teaching, or written instructions to individuals. The method chosen tends to be determined by the resources available but, in general, poster or media-advertising is less effective than more personally directed methods. Advertising may, however, be valuable in reinforcing regular practice of the method by women who have already been taught.

In the assessment of various methods of BSE education it is important to know the proportion of the population who were already practising it before the intervention, so that a “before and after” questionnaire study of an adequate sample of women is desirable.

Use of resources

In some countries breast cancer is frequently discussed in the media, and where health workers are already teaching a method of self-examination to individual patients, the proportion of women already practising it may be high, so that an additional intervention may not have sufficient effect to justify the extra cost. An additional consideration is that in these countries, many women are already subject to regular physical examination of their breasts by their physician, and some are also examined by mammography. It has been suggested that breast self-examination will be most effective under circumstances where other screening tests are not available (18). Nevertheless, breast cancers that appear in the interval between two such screening tests may be amenable to early detection by self-examination. Most studies of BSE practice in these countries suggest that the technique and the regularity of its performance are deficient. However, if it could be established that self-examination, when applied optimally, was an effective method in reducing mortality from breast cancer, then major additional public educational approaches would be justified, though they cannot be advocated at the present time.

In most parts of the world, little BSE education has taken place and there is no immediate prospect of being able to provide resources for annual screening by physical examination of the breasts or mammography. In these circumstances, BSE programmes seem to offer a potentially valuable method of early diagnosis which need not be expensive in resources. Primary health care workers, volunteer group leaders, and others can be trained to teach the technique.

In some countries, however, a major constraint may be in the provision of sufficient resources for definitive diagnosis of any abnormal finding. More than 5% of women over the age of 45 may refer themselves after BSE education for follow-up and up to 1% may require a biopsy to establish the diagnosis. Unless clinics for confirmation of the diagnosis and facilities for treatment are available and accessible to the target population, there is no point in introducing BSE education.

Experience in Finland suggests that a comprehensive programme carried through on a personal and group basis can be applied on a nationwide scale without significantly increasing the work-load of clinics for diagnosis and treatment (16).

Monitoring the effects of a BSE programme

Even after a clear demonstration of benefit it will remain necessary for the health authorities providing BSE programmes to continue to monitor its effects, and make any changes that are appropriate. This calls for a good recording system as described below.

THE EFFECTIVENESS OF DIFFERENT TYPES OF BSE APPROACHES

The effectiveness of breast self-examination has not yet been adequately assessed. In evaluation studies, a distinction must be drawn between those which study the effects of BSE practice (i.e., as a screening test) and those which study the effectiveness of a BSE programme (i.e., as public health policy).

In the former category a number of studies have compared the stage distribution (and, more recently, the survival) of breast cancer cases diagnosed by self-examination, cases diagnosed through symptoms in women practising self-examination, and those diagnosed in women not practising this technique. Some of these studies have shown an apparent
advantage for the BSE-detected cases but the study designs have been unable to correct for lead-time bias, length bias, and selection bias.

The effectiveness of policies to implement BSE-containing programmes is equally uncertain, because no such programme has been widely applied and in operation sufficiently long to demonstrate an effect on mortality. In Finland an apparent increase in breast cancer incidence in the year following the introduction of a comprehensive BSE programme was followed by a decrease when the programme stopped, although this could be accounted for by chance fluctuations from year to year which occur in the absence of any intervention. When such a programme was implemented in a public health care system, a sharp increase in the number of new breast cancer cases was again registered (16).

Need for further research

Evidence of mortality reduction resulting from breast self-examination is needed before this method can be recommended for the control of breast cancer. It must be shown that the mortality from this cancer in a group of women who practise the method is less than that in a comparable group of women who do not; or, before recommendation as a public health measure, it must be shown that the number of breast cancer deaths is less among women who have been influenced by a BSE programme than in a comparable group of women who have not.

As the results will depend on how far women can be persuaded to practise breast self-examination regularly, research into the approaches that will achieve the greatest compliance is very necessary. The complexity of maintaining preventive health behaviours suggests that BSE studies should incorporate the findings previously generated by health behaviour compliance research.

Methods to reach a reasonably high proportion of the target population are already available in some countries so that trials of effectiveness may be carried out now. If these show that BSE programmes are effective, then other countries considering introducing such a programme should undertake the necessary psychosocial research to develop methods of BSE education specific to their own society.

METHODS OF MEASURING EFFECTIVENESS

Criteria for judging effectiveness

The yield of cancers detected by breast self-examination, the stage at which these cancers are diagnosed, and comparisons of the survival or case fatality between persons with BSE-detected cancers and those with post-symptom-detected cancers are inevitably biased. Comparisons of the survival among breast cancer patients in populations offered and not offered a BSE programme do not overcome this problem. However, if one compares, not the percentage distribution, but the cumulative number of advanced cases in a population offered a BSE programme or practising this method and the number in a control population, and the assumption is made that these advanced cases are likely to die of their cancer, then these numbers or the rate per 1000 population may be valid as a surrogate measure for mortality. Furthermore, if a comparison of the survival among cases diagnosed in a group practising self-examination and in a control group is made, and there is no advantage to the BSE group, this is good evidence against the effectiveness of breast self-examination.

Thus, the only unbiased measure of the effectiveness of self-examination as a control measure is a comparison of the mortality from breast cancer.

Methods of studying effectiveness

Time trends. If a BSE programme could be rapidly introduced into a population so that it reached a high proportion of women within a very few years, and if the mortality rate and its trend in that population were known, then a downward trend in mortality starting a few years after the start of this programme might be attributed to the programme. However, this is very indirect evidence because the changes in mortality could be due to changes in incidence, changes in treatment, etc.

Geographical comparisons. Similar considerations apply to comparisons of separate populations, some of which have had a BSE programme and others have not. However, if such studies are done prospectively, and control of the known confounding variables proves possible, more credible evidence of benefit is obtained.

Quasi-experimental studies on an individual basis. In this design, identified individuals are offered participation in a BSE programme in a defined population, and the outcome is assessed in comparison with individuals from another defined population. Such quasi-experimental studies, which are dependent on the collection of data from individuals as distinct from the population as a whole, require to be carried out with much care since selection bias may not be completely eliminated. A study of this type is now in progress in the United Kingdom (14). Comparison is being made between two districts where all women between the age of 45 and 64 years are invited to attend BSE classes, two districts where they are invited to attend screening clinics, and four comparison districts with no intervention. Mortality differentials from this study are not expected for several years.
Randomized controlled trials. This is the optimum method for evaluation, in which individual women or groups of women are identified and allocated at random either to be exposed or not exposed to a BSE programme. Randomization, when applied correctly with the large numbers necessary for evaluation, will tend to result in the confounding variables being equally distributed between the BSE group and the control group.

If randomization were at an individual level, the BSE group would be given the intervention through some form of contact and the control group would not. Since both groups would be drawn from the same population, reinforcement of BSE education by general advertising would dilute the effect because the publicity would reach the control group as well. However, it would be important to study, on a sample basis, the extent to which both groups were practising breast self-examination.

In countries where individual consent is needed prior to randomization, it is unlikely that women would agree to an allocation not to practise self-examination, so that such a trial would probably be impracticable. However, in other countries with suitable sampling frames for identification it would be possible to run a trial by inviting those allocated to breast self-examination to be taught the method while those in the control group would be left ignorant of their status.

For randomization at a group level, the groups might be focused on factories, small districts such as parishes, or women registered with particular doctors or clinics, etc. The groups would be allocated at random, some to be exposed to the BSE programme, others not. It is important that the number of groups should be sufficiently large to prevent random confounding. Both initial education and reinforcement would be done in groups. Contamination of the control group is unlikely but it would be desirable to monitor it.

Case-control (retrospective) studies. The use of case-control studies to evaluate screening is a new approach based on the principle that if screening is effective, a history of previous screening will be found less often among the cases than among the controls. It is a method of assessing the outcome in people exposed to screening, and can only be used in a population where the screening method has been available for several years.

“Cases” in such a study would ideally be women who have died of breast cancer. However, as it might be impossible to ascertain any exposure to BSE education except from the woman herself, advanced cases prevalent in the population may be used as a surrogate for deaths. Controls would be women chosen at random from the population from which the advanced cases came. The control women might by chance include some with early breast cancer, but to deliberately select women with early disease as controls would give a biased comparison. Exposure to a BSE programme could be defined by noting whether the subject had been taught or by questioning cases and controls about their practice of the method. A major problem with such a study would be to allow for all the confounding variables that could bias the results (19). Because the case-control method for evaluating screening is still in an early stage of development, it would be useful to test its validity within the context of a randomized controlled trial (20).

Unfortunately, nearly all the BSE case-control studies conducted to date have been flawed, and only recently, have the methodological issues been discussed sufficiently so that valid studies may be conducted in the future (19–21). Nevertheless, the method, if correctly applied, does provide the opportunity for evaluation in populations where breast-self-examination has been widely promoted, and where randomized controlled trials may be difficult to pursue.

Sample size and duration

Whichever method of evaluation is used, one must take into consideration the size of the population to be studied and the duration of the trial. The sample size depends on the frequency of the outcome (i.e., the frequency of deaths from breast cancer in the absence of a BSE programme) and on the magnitude of the reduction in mortality which the study aims to demonstrate. Additional considerations about the power of the study to detect the predetermined relevant reduction, and about the likely compliance of the population exposed to a BSE programme have to be taken into account. In a randomized trial, the mortality in the control group will initially be lower than that in the general population of the same age, because women already diagnosed as having breast cancer on entry to the trial will be excluded.

The sample size for a BSE trial is likely to be very substantial. Thus if a 20% reduction in mortality was sought, even in developed countries with high mortality from breast cancer, at least 100 000 in each group would be required.

The duration of the trial is decided partly in relation to the feasibility of studying a very large number of women for a few years, or a smaller number of women for a longer period. An important consideration is the time needed for breast self-examination to influence mortality; there is some evidence that women get more efficient at self-examination with practice so that sufficient time for this should be allowed.
Sample size and duration of the trial are usually based on the expectation that a significant mortality difference will be demonstrable at a given point in time after the start of the trial. However, in all trials it is desirable that analyses should continue to be done over a period of many years.

**Information to be recorded**

If it is decided to base evaluation of the effectiveness of BSE programmes on time trends or geographical comparisons only, then the information required will be the mortality from breast cancer in the BSE-exposed population and in the control population.

However, if the studies are based on individuals receiving or not receiving BSE instruction, then more detailed information is required. In such studies it is desirable that the following information should be recorded:

(i) a register of individually identified women in both the BSE programme population and the control populations. If feasible, risk factors on a sample of women in both groups should be included.

(ii) a record of women in both groups who develop breast cancer. It is important that the method of ascertaining cases is similar and complete for both BSE and control groups.

(iii) a record of all women in both groups who die. It is desirable, in the case of breast cancer deaths, that the cause of death should be verified by an independent assessor who does not know whether the woman was in the BSE group or the control group.

(iv) a record of every woman in the BSE programme who was offered some BSE instruction and, if relevant, how often this was reinforced.

(v) information from sample surveys at the beginning and end of the trial on the proportion of women in the control group who are practising breast self-examination.

(vi) a record of consultations for breast disease by women in both BSE and control groups.

**CONCLUSIONS AND RECOMMENDATIONS**

(1) There is evidence that screening has a favourable effect on mortality from breast cancer.

(2) Breast self-examination is a screening method that could be applied in a population of women without requiring a substantial increase in health resources, provided there is a health care delivery system with adequate diagnostic and treatment resources.

(3) There is insufficient evidence that breast self-examination, as applied to date, is effective in reducing mortality from breast cancer. Therefore, BSE screening programmes are not at present recommended as public health policy, although there is equally insufficient evidence to change these programmes where they already exist.

(4) Further research on breast self-examination is needed — on different approaches for promoting its practice, on its effectiveness in reducing breast cancer mortality and, if proved to be effective, on different programme approaches.

(5) Any BSE screening programmes introduced on a public health basis should include plans to evaluate their effectiveness.

(6) The only truly valid criterion of effectiveness is a reduction in the mortality rate from breast cancer in the population being studied, compared with a suitable control population. In certain circumstances, a reduction in the total number (but not the proportion) of cases of advanced breast cancer in the population being studied, compared with a control population, could be used as a surrogate for mortality.

(7) The approaches to evaluating reduction in mortality are:

(i) **Time trends**: comparison of mortality in the same population before and after introduction of BSE programmes.

(ii) **Geographical comparisons**: comparisons of mortality in populations offered BSE programmes, with that in similar but geographically separate populations.

(iii) **Quasi-experimental studies on an individual basis**: comparisons of mortality of identified individuals in groups offered or not offered BSE instruction. It is difficult to avoid selection bias confounding the comparisons in such studies.

(iv) **Randomized controlled trials**: comparison of mortality in populations randomly allocated to be offered or not to be offered a BSE programme. Randomization may be by individuals, or by groups. Randomized trials offer the only possibility by which bias in comparisons is eliminated. Thus every opportunity should be taken to perform such trials in populations where breast self-examination has so far not been introduced. In the context of a BSE programme where it is proposed to reinforce compliance by public education, group randomization (e.g., by factory, or by region) would be inevitable.

(v) **Case-control studies**: comparison of past BSE practice in women who have died of breast cancer or women with advanced breast cancer (cases), with women who have been randomly chosen from the population in which the cases occurred (controls). This method can be used as an assessment of effectiveness in populations already exposed to BSE education for some years.

(8) For all methods of evaluation that involve
The planned BSE programme could utilise the following information:

(i) a register of all women who are in the study and the expected dates of birth.

(ii) a validated record of all women who develop the disease.

(iii) a validated record of the date and cause of death of all women who die.

(iv) a record of all women who have been exposed to the BSE programme. Information on which of them were practising self-examination, as taught, might be assessed by sample surveys.

(v) All the above records must be capable of being linked to one another.

(9) The sample size required for a trial depends on:

(i) the number of breast cancer deaths expected in the control population,

(ii) the expected compliance with the BSE approach taught in the study group, and the degree of dilution of the control group,

(iii) the magnitude of the change in mortality which it is important to detect and which might realistically be expected.

The duration of the trial depends on the expected time it will take for an effect on mortality to become apparent.

(10) Every trial should be preceded by a pilot survey to determine if the planned BSE programme is able to reach a reasonable proportion of the target population and influence their behaviour.

(11) The impact of BSE programmes may vary in different countries according to cultural and psychosocial factors, accessibility and availability of medical care, and the breast cancer incidence and mortality. Each study is specific to its own population and cannot be directly extrapolated to other communities.


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D. Bransfield, Centre G. F. Leclerc Tumour Institute, Dijon, France

J. Chamberlain (Rapporteur), South West Thames Regional Cancer Organization, Sutton, Surrey, England

G. Gastrin, "Mama Programme", Helsinki, Finland

R. Gelman, Harvard School of Public Health, Boston, MA, USA

M. Hakama, Department of Public Health, University of Tampere, Tampere, Finland

J. Howard, Health Promotion Sciences Branch, Division of Cancer Prevention and Control, National Cancer Institute, Bethesda, MD, USA

V. Merabishvili, Department of Biostatistics, Petrov Research Institute of Oncology, Leningrad, USSR

A. B. Miller (Chairman), Epidemiology Unit, National Cancer Institute of Canada, University of Toronto, Toronto, Canada

N. Mourali (Vice-Chairman), Salah Azaiz Institute, Bab Saadoun, Tunis, Tunisia

V. Sagaidack, Cancer Control Department, All-Union Cancer Research Centre, Moscow, USSR

V. Semiglazov, Breast Tumours Department, Petrov Research Institute of Oncology, Leningrad, USSR

Observer

A. Ibrahim, National Cancer Institute, Cairo, Egypt

International Agency for Research on Cancer (IARC)

C. Honing, DOM Project, Preventicon, Utrecht, Netherlands

WHO Secretariat

L. Dobrossy, Cancer, WHO Regional Office for Europe, Copenhagen, Denmark

L. Edouard, Maternal and Child Health, WHO, Geneva, Switzerland

L. Philip, Consultant, Health Education, WHO, Geneva, Switzerland,

K. Stanley, Cancer, WHO, Geneva, Switzerland

J. Stjernsward, Cancer, WHO, Geneva, Switzerland

M. Tschechkovski (Secretary), Cancer, WHO, Geneva, Switzerland

REFERENCES


