Internacional Meeting on Breast Cancer Screening

April 16th and 17th Rio de Janeiro

1st day - April 16th

9h00 - 10h00	Opening ceremony
10h00 - 11h45	Plenary session: Breast cancer screening 1. Fundaments breast cancer screening – Andrew Coldman (BCCA – Canada) 2. Implementation of breast cancer screening in the EU: the role of international cooperation and collaboration in developing and implement quality assurance guidelines – Lawrance von Karsa (IARC)
11h45 - 12h00	Coffee break
12h00 - 13h00	Discussion 1. Chair: Ellyete Canella 2. Debaters: Luiz Cláudio Santos Thuler e Rodrigo Cericatto
13h00 - 14h00	Lunch
14h00 - 14h40	Plenary session: Breast Cancer Screening – National Programmes 1. Canada – Verna Mai 2. Italy – Alfonso Frigerio
14h40 -15h20	Discussion 1. Chair: Carlos Frederico de Freitas Lima 2. Debaters: José Antonio Marques e Sérgio Koiffman
15h20 - 16h00	Plenary session: Breast Cancer Screening – National Programmes 1. The Netherlands – Mireille Broeders 2. Norway – Berit Damtjernhaug
16h00 - 16h20	Coffee break
16h20 - 17h00	Discussion 1. Chair: Roberto Vieira 2. Debaters: Luiz Carlos Zeferino e Luciano de Melo Pompei

2nd day - April 17th

9h00 - 11h00	Plenary session: Economic aspects of breast cancer screening – national experiences 1. Canada – Verna Mai 2. Italy – Alfonso Frigerio 3. The Netherlands – Mireille Broeders 4. Norway – Berit Damtjernhaug
11h00 - 11h15	Coffee break
11h15 - 12h30	Discussion 1. Chair: Cláudio Pompeiano Noronha 2. Debaters: Rosângela Caetano, Fabíola Vieira e Antônio Frasson
12h30 - 14h00	Lunch
14h00 - 15h10	Plenary session: Breast cancer control in low and middle income countries 1. Resource-stratified guidelines for breast cancer control – Benjamin Anderson (USA) 2. Brazilian and Chilean strategies on breast cancer screening – Ana Ramalho (Brasil) e Marta Pietro (Chile)
15h10 - 16h10	Discussion 1. Chair: Liz Maria de Almeida 2. Debaters: Suzanne Serruya e Armando Henrique Norman
16h10 - 16h30	Coffee break
16h30 - 17h30	Closing ceremony – INCA

Divisão de Comunicação Social - INCA / 2009

Organização Pan-Americana da Saúde · Alianza América Latina y Caribe para Control del Cáncer · INCA · SUS · Ministry of Health · Brasil Brazilian Government

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Programme

Divisão de Comunicação Social - INCA / 2009

Seminário internacional sobre câncer de mama

Instituto Nacional de Câncer, INCA, promoveu debate de políticas de rastreamento populacional da doença.

O Instituto Nacional de Câncer (INCA) promoveu, nos dias 16 e 17 de abril de 2009, o Seminário Internacional sobre Rastreamento de Câncer de Mama. Foram dois dias de debates sobre evidências científicas disponíveis e as experiências com rastreamento populacional do câncer de mama realizado por sistemas públicos de saúde na América do Norte e Europa. Participaram do debate gestores de saúde, representantes de organizações da sociedade civil que atuam nessa área, sociedades e associações médicas, universidades e institutos de pesquisa, além de alguns dos maiores especialistas em rastreamento do Brasil, Canadá, Estados Unidos, Holanda, Itália e Noruega.

A partir da discussão de experiências internacionais bem sucedidas, o INCA vai elaborar material técnico para subsidiar o Ministério da Saúde na regulamentação da Lei 11.664, de 29 de abril de 2009, que dispõe sobre as ações de saúde integral da mulher. Ao determinar que todas as mulheres têm direito à mamografia a partir dos 40 anos, a nova lei suscitou uma discussão sobre a idade adotada para rastreamento populacional de câncer de mama. O rastreamento é uma estratégia de monitoramento das mulheres sem sintomas, com a realização de exames regulares, com a finalidade de diagnosticar precocemente possíveis casos da doença na faixa etária de maior risco e incidência.

No Brasil, o Consenso de Mama (documento elaborado em 2004 por gestores, ONGs, sociedades médicas universidades) recomenda como estratégia de controle da doença o exame clínico anual das mamas em mulheres de 40 a 49 anos, além da realização de mamografia para a faixa etária de 50 a 69 anos, repetida a cada dois anos. Também faz recomendações específicas para mulheres pertencentes a grupos populacionais com risco elevado de desenvolver câncer de mama, que são exame clínico e mamografia anual a partir dos 35 anos.* Hoje, o Sistema Único de Saúde realiza mamografia para todas as mulheres que tenham indicação médica de fazer o exame, sem limite de idade.

Esse seminário foi mais uma atividade no âmbito da Aliança da América Latina e Caribe para o Controle do Câncer, apoiada pela Organização Pan-Americana de Saúde (OPAS), e contou com a participação de representantes dos países que compõem a Aliança da América Latina e do Caribe para Controle do Câncer (México, Cuba, Argentina, Chile, Peru, Uruguai e Colômbia).

** Nesse caso estão mulheres com história familiar de pelo menos um parente de primeiro grau (mãe, irmã ou filha) com diagnóstico de câncer de mama antes dos 50 anos; com história familiar de parente de primeiro grau com diagnóstico de câncer de mama bilateral ou câncer de ovário, em qualquer faixa etária; com história familiar de câncer de mama masculino; e mulheres com diagnóstico histopatológico de lesão mamária proliferativa com atipia ou neoplasia lobular in situ.*

Seminário Internacional sobre rastreamento de câncer de mama
Data: 16 e 17 de abril
Local: Hotel Novo Mundo
Praia do Flamengo, 25, 3º andar - Flamengo - Rio de Janeiro - RJ

Screening for breast cancer: Experiences from The Netherlands

Mireille Broeders, PhD

The Dutch experience with population-based breast screening programmes dates back nearly 35 years, when the first pilot programmes in the cities of Utrecht and Nijmegen were launched in 1975. The favourable results of these non-randomised pilot programmes and detailed outcomes of the Swedish randomised controlled trials, combined with an extensive cost-effectiveness analysis, led to the decision to implement a nationwide breast cancer screening programme in 1989.

The Dutch screening programme offers biennial mammography for all women aged 50-74 years (50-69 years until 1998). The main characteristics of the programme are the centralised organisation including centralised technical and medical quality control and audit, the 2-year interval between examinations, and the eligible age of 50-74. The programme is financed by the Ministry of Health, Welfare and Sport, but coordinated by the National Institute for Public Health and the Environment. The actual execution of the screening however is organised regionally. There are 9 screening regions which coincide with the regions covered by the Comprehensive Cancer Centres. The 9 regional organisations operate a total of 64 screening units of which 57 are mobile to improve attendance. The personal data of the eligible women are provided by the municipal population register which is fully computerised. Every 2 years, women get a personal invitation letter with a fixed appointment for a screen examination in one of the screening units. Non-responding women are issued a reminder after 2-3 months. At the initial screen, 2-view mammography is performed; at subsequent screens, medio-lateral-oblique (MLO) views are standard. Additional cranio-caudal (CC) views are performed on indication which include dense glandular tissue, postoperative changes, implants and whenever abnormalities are suspected by the radiographer. At present, an additional CC view will be performed in about 50% of cases at subsequent examination. Films are processed on site in the mobile units so that additional views and/or repeats for technical reasons can be made immediately. X-rays of previous examinations are also available for the radiographer for comparison. There is no radiologist present at the SU. Physical examination is not part of the screening. X-rays are transported daily to 21 central reading units (30 reading stations) where they are read independently by 2 radiologists. A decision on recall for further assessment is made usually on the basis of consensus. In some units, the second reader decides whether the woman will be recalled. All examined women receive the results in writing; in the event of a positive result (referral for further examination), the general practitioner is informed in advance.

The National Expert and Training Centre for Breast Cancer Screening was set up in Nijmegen. Its responsibilities include training radiographers, radiologists and pathologists who are participating in the screening programme and monitoring the technical and medical quality of the programme. The professional associations agreed that targeted training and continuing education are a necessary precondition for qualitatively acceptable screening. Only professionals certified by the National Reference Centre are allowed to participate in the screening. One of the instruments of quality control of the medical performance of the Dutch mammographic screening is the regular audit visit of the professional staff of the National Reference Centre to the 21 central reading units of the regional screening organisations. The frequency of the visits is once every 3 years. At these site visits, the performance of the screening radiologists and radiographers is monitored and the technical and positioning quality of the mammograms are checked. Performance data of 2 screening rounds of a 4-year period are presented and compared to desirable target values and to the mean national performance values.

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The National Evaluation Team for Breast Cancer Screening monitors the programme annually, collecting regional tabulated data on invitations, attendance, screen examinations, referrals, assessment and screen-detected breast cancers including tumour stage. Data on interval cancers and breast cancer incidence and therapy are obtained after linkage of the regional files of screened women to the files of the regional cancer registry. Statistics Netherlands provides data on breast cancer mortality annually.

Currently, in the Dutch screening programme, the attendance rate is 82%, and 900 000 women are examined annually. The main results in 2007 are 18 referrals for clinical assessment per 1000 women screened, 8.2 biopsies and 5.5 breast cancers detected. The stage distribution of detected cancers is favourable with 67% either in situ or T1 tumours of at most 20 mm, and 73% axillary lymph node negativity. In the past years, the referral rate has slowly increased from around 1% for the early period 1990-1997 to the current 1.8%. This increase follows the outcome of a review study indicating that the low referral rate was the most likely reason for a lower than expected number of screen-detected cancers and a higher than expected number of interval cancers. The present recommendation of the National Expert Centre is to increase the referral rate to 2% or above, by referring more women with subtle mammographic abnormalities.

The National Evaluation Team uses the MISCAN (Microsimulation Screening Analysis) model to predict age-specific breast cancer mortality rates (in the presence and absence of a screening programme) and annually compares these rates to the observed breast cancer mortality rates in The Netherlands. The model simulates individual life histories in the absence of screening and calculates the changes after introduction of a screening programme in terms of mortality, life-years gained and cost-effectiveness. After 20 years of nation-wide screening breast cancer screening, breast cancer mortality in women aged 55-74 is now 28.7% lower in 2007 than before the start of the screening programme. This is very close to the reduction predicted by MISCAN in the presence of screening. Since 2002, breast cancer mortality declines significantly in all age groups, including women aged 75-84. The total cost of the programme was 48.7 million Euro in 2007, including training, audits, evaluation and all management costs, equal to 53.36 Euro per screen examination.

The fact that the breast cancer screening programme is one of the best prepared, systematically executed and documented facilities in the Dutch health care system allows a number of lessons to be derived from this. The first concerns the need for continuous assessment of the effect of the programme, even after evidence-based implementation of the facility. The second lesson learned is that intensive quality and outcome control are worth the effort. A third lesson is that the concern expressed by some at the implementation of the screening programme, namely that it would draw away attention and resources from the clinical treatment of breast cancer, has not materialized. On the contrary, the screening programme has served to stimulate the spread of quality care in diagnosis and treatment of breast cancer.

After 20 years, the Dutch breast cancer screening programme can be regarded an effective health care intervention at reasonable costs. A new challenge for the Dutch screening programme is the current transformation of analogue to digital screening. This transition goes far beyond replacement of the analogue mammographs by digital equipment, since a nation-wide digital infrastructure is being created for archiving, soft-copy reading, and reporting. The digital framework with on-line access to the screening outcomes for 1,000,000 women invited yearly is an unprecedented opportunity to design studies in order to further optimize the performance of the breast cancer screening programme.

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Economic aspects of screening for breast cancer: Experiences from The Netherlands

Mireille Broeders, PhD

Nearly 30 years ago, when the screening projects in Utrecht and Nijmegen were launched, the Netherlands became one of the first European countries to run an experimental population-based screening programme. In light of the favourable results yielded by these pilot projects and following an extensive cost-effectiveness analysis, it was decided to establish a nationwide screening programme in the Netherlands. In 1989, the gradual implementation per municipality of a national screening network for women aged 50 to 69 got underway, a project that was completed by the end of 1997. Simulation models subsequently showed that breast cancer screening could be cost-effective in women above 69 years, assuming equal efficacy of screening. In 1998, the Dutch government decided to include women aged 70-75 in the nation-wide breast screening programme, implying 3 additional screening rounds.

Before the political decision to implement breast cancer screening was taken, a study was conducted to assess the likely benefits and risks, the consequences for the health care system, and the financial and staffing implications of a national screening programme. The conclusion was that, if women between the ages of 50 and 70 were screened for breast cancer every other year in the context of a national programme, the effects would on balance be positive, and that the benefits of such a programme would justify the costs. The consequences for health care were estimated based on generally accepted assessment and treatment policies. The number of assessment procedures for non-palpable lesions would increase by 12% per year in the build-up period, and would remain slightly higher. The total number of biopsies in a real population was expected to decrease. Screening would lead to a shift in primary treatment modalities, as 15% of mastectomies will be replaced by breast conserving therapy. The temporary increase in the demand for primary treatment in the first years would be followed by a decrease in the demand for treating women with advanced disease. Favourable effects outweigh the inevitable unfavourable effects, assuming a high quality screening and an appropriate invitation system. In summary, it was concluded that breast cancer screening could also be recommended after considering other consequences than mortality reduction alone. Moreover, cost per death prevented or per life-year saved is much lower than for most other medical interventions for which cost-effectiveness ratios are known, screening for cervical cancer included.

The above estimates were derived from the Microsimulation Screening Analysis (MISCAN) model. The MISCAN model was developed to estimate the costs and effects of the introduction of a nation-wide screening programme in the Netherlands and has been described in detail in the literature. In the model, individual life histories are generated as a Markov process of stages and transitions. The natural history of breast cancer is modelled as progression through four invasive, screen-detectable, preclinical stages or transformation into a clinical stage. It is assumed that the majority of the invasive cancers are preceded by ductal carcinoma in situ (DCIS). Without screening, a preclinical cancer may either become clinically diagnosed or progress to the next preclinical stage. Screening will result in earlier detection and treatment and, as a consequence, improved prognosis for some (but not all) women. The output of the model yields a number of estimates of the effect of screening and subsequent outcome. The output also includes the stage distributions of all breast cancers, and the number of breast cancer treatments. Moreover, the model calculates the number of breast cancer deaths and life-years lost due to cancer. Cost-effectiveness is calculated by adding a profile of diagnostic and treatment costs over time to each disease state.

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In the Netherlands, the National Institute for Public Health and the Environment coordinates the screening programme. The National Expert and Training Centre in Nijmegen is responsible for the technical and medical quality control and the National Evaluation Team in Rotterdam for the data collection evaluation and annual reporting of the performance results. The nine screening regions are responsible for performing the screens in 64 (2007), predominantly mobile screening units. The personal data of women qualifying for screening are provided by the municipal population registers. All women in the target group receive a personal invitation every 2 years for mammography. Women failing to respond are sent a reminder after 2 or 3 months. At initial screens, two-view mammography is performed, whereas at subsequent screens in a minority of cases only the mediolateral oblique view is taken. All mammograms are independently reviewed by two radiologists who must reach mutual agreement (consensus) before referring a woman for further diagnostic assessment. All women examined receive the result of the screening in writing; in the event of a positive result, the general practitioner is informed in advance. The effectiveness of screening is dependent on the assessment, and if necessary further clinical treatment and follow-up, which in terms of organization does not come under the auspices of the screening programme. This underlines the need for adequate clinical breast care for women referred to hospital on the basis of a positive screening examination. Adequate feedback to the screening radiologists on results of investigations indirectly plays a huge role in maintaining the performance and quality of the screening programme. This requires optimum communication between the screening and clinical environment, as is emphasized and prescribed in the new CBO (Dutch Institute for Healthcare Improvement) guideline on screening and diagnosis of breast cancer. The strict separation of screening from health care is also reflected in different types of funding: taxes versus health care premiums.

The aggregated results of the Dutch programme are favourable. Between 1990 and 2007, 14.4 million invitations were issued and 11.4 million examinations performed (a participation rate of 80%), 144,300 women have been referred for further assessment (12.7 per 1,000) and 56,200 breast cancers detected (4.9 per 1,000). The total cost of the programme was 48.7 million Euro in 2007 (preliminary figures), which constitutes about a quarter of the national budget for prevention. This is equal to 53 Euro per screen examination, including 3 Euro for training, audits, evaluation and all management costs. When adjusted for the increasing number of screen examinations, the creation of financial reserves for the forthcoming digitalising and for deflation, total costs remain rather stable since 2002, and costs per screen (after correction for inflation) even show a slight decrease since 1997.

After 20 years, the Dutch breast cancer screening programme can be regarded as an effective health care intervention at reasonable costs. In addition, continuous monitoring of the screening programme has further contributed to its effectiveness, as a consequence of which the screening programme is in all likelihood one of the few facilities of which the costs have remained within the margins forecast over 10 years ago.

The current challenge for the Dutch screening programme is the transformation of analogue to digital screening. It is estimated that the national costs for digitization will amount to 3,6 Euro per screening examination. This includes the costs for 64 digital mammographs, 30 reading stations and 57 mobile units. Whether digital screening performance may change the overall balance between effects and costs in the programme remains to be seen, but the first results are positive.

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Breast cancer control in low and middle income countries (LMCS): resource-stratified guidelines for breast cancer control

Benjamin O. Anderson, M.D.

Among women, breast cancer is the most common cause of cancer-related death worldwide, with case fatality rates highest in low and middle income countries (LMCs). Globally, breast cancer is the most common cancer among women, comprising 23% of all female cancers that are newly diagnosed in more than 1.1 million women each year.[1] Over 411,000 deaths each year result from breast cancer annually, accounting for over 1.6% of female deaths from all causes.[2] Projecting to 2010, the annual global burden of new breast cancer cases will be 1.5 million and an ever-increasing majority will be from LMCs.[3] Approximately 4.4 million women diagnosed with breast cancer in the last five year are currently alive, making breast cancer the single most prevalent cancer in the world.1 Despite the common misconception that breast cancer is predominantly a problem of wealthy countries, the majority of breast cancer deaths in fact occur each year in developing rather than developed countries.[3]

Guideline development. Evidence-based guidelines outlining optimal approaches to breast cancer detection, diagnosis, and treatment have been well-developed and disseminated in several high resource countries.[4,5] These guidelines define optimal practice, and therefore have limited utility in LMCs. Optimal practice guidelines may be inappropriate to apply in LMCs for numerous reasons, including inadequate personal resources, limited health care infrastructure, lack of pharmaceuticals and cultural barriers. Hence, there is a need to develop clinical practice guidelines oriented towards LMCs, specifically considering and adapting to existing health care resources.

Co-sponsored by the Fred Hutchinson Cancer Research Center and Susan G. Komen for the Cure, the Breast Health Global Initiative (BHGI) strives to develop evidence-based, economically feasible, and culturally appropriate guidelines that can be used in nations with limited health care resources to improve breast cancer outcomes. The BHGI held three Global Summits to address health care disparities (Seattle 2002),[6] evidence-based resource allocation (Bethesda 2005)[7] and guideline implementation (Budapest 2007) as related to breast cancer in LMCs. Modeled after the approach of the National Comprehensive Cancer Network (NCCN), BHGI developed and applied an evidence-based consensus panel process now formally endorsed by the Institute of Medicine[8] to create resource-sensitive guidelines for breast cancer early detection,[9,10] diagnosis,[11,12] treatment,[13,14] and health care systems,[15] as related to breast health care in LMCs. The BHGI guidelines are intended to assist ministers of health, policymakers, administrators, and institutions in prioritizing resource allocation as breast cancer treatment programs are implemented and developed in their resource-constrained countries.

Guideline dissemination and implementation (D&I) research. The dominant paradigm even now in the medical community is that good research and publication should be sufficient to ensure the translation of scientific findings into general practice.[16] Unfortunately, a landmark Institute of Medicine (IOM) report from 2001 clearly identified the failure of much scientific innovation to be translated into practice.[17,18] More recently, Rubenstein and Pugh separated the IOM's second translational block - clinical research to practice - into two parts: 1) clinical research to guidelines and 2) guidelines to practice.19 D&I researchers maintain that the process is complex and have begun to identify factors and processes critical to the adoption of new technologies and practices.[20] While there has already been some D&I work on assessing readiness for change, it has usually focused on just one component, such as providers or health units, or has focused on intention without considering self-efficacy or environment. As a conclusion in her extensive review of the implementation literature, Greenhalgh notes the need for more research on system readiness for innovation and for more studies evaluating implementation of specific interventions.[21]

A review of available information strongly suggests a crucial role for research in applying the experience and knowledge of high income societies to the challenges of women and breast cancer throughout the world. A recent

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survey of oncology experts from Latin American countries found that 94% of the surveyed experts consider clinical-epidemiologic research development on breast cancer insufficient in their country. The main reasons identified were insufficient economic retribution and lack of available time.

Very little research on guideline implementation has been done in LMCs. It is necessary to see whether the basic frameworks and instruments being described in high-income countries apply in these very different environments and what adaptation is needed to make them both valid and feasible. A systematic program of research to develop appropriate readiness assessment instruments and identify effective implementation strategies is now needed in a variety of LMCs. As we move forward to support the adoption, implementation, and maintenance of the new evidence-based principles embodied in the BHGI guidelines, it is critical that careful evaluation be incorporated in the efforts, to ensure that lessons about effectiveness and efficiency are captured. It is precisely because resources are scarce in these countries, that it is even more imperative for LMCs to adopt effective practices as quickly as possible, and that implementation approaches are designed with limited resources in mind.[16]

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The Norwegian Breast Cancer Screening Program

The Cancer Registry of Norway, Institute of Population-based Cancer Research, was established in 1951. It is one of the oldest national cancer registries in the world. This, combined with the unique personal identification number used in Norway, makes the Cancer Registry's data suitable, also internationally; by establishing new knowledge through research and spreading information on cancer.

All medical doctors in the country are instructed by law to notify new cancer cases. Cancer must be notified in case of cancer suspicion, even without a verified cancer diagnosis, and also if cancer is first diagnosed by autopsy. In case of doubt, a notification must be sent.

Cancer information comes from several independent sources, thus securing a high grade of completeness. The Cancer Registry receive each year ca 225 000 notifications related to cancer illness. Of these, almost 25 000 are newly diagnosed.

The Cancer Registry is responsible for the national screening programs: Breast Cancer Screening Program and Cervical Cancer Screening Program. The goal is to prevent cancer death by discovering cancer or pre cancerous lesions as early as possible.

The Norwegian Breast Cancer Screening Program was initiated as a pilot project in four counties in 1995/96. It was gradually expanded until it became nationwide in 2004. A quality assurance manual was created before the pilot project started and is regularly revised. The administration of the NBCSP is localized to the Cancer Registry in Oslo. The target population is women from 50 to 69 years of age, about half a million women at the time beeing. Every second year they get a personal invitation letter with place and time for attendance. There are totally 32 screening units all over the country, of which there are 4 mobile units. The mammography is a two-view examination, read by to radiologists independently. Recall examinations take place in a breast center, of which there are totally 17, almost one in each county. Here is the administration of the program in the actual area, the interpretation, the consensus and work up, in addition to performance of clinical mammography. These centers are placed at University or county hospitals, thus the treatment and follow up usually take place at the same hospital as the recall examination. All activities are reported on standardized forms to the Cancer registry. Every breast center is connected to the Cancer Registry in a closed IT-network, where they are able to review only their own data. If the woman doesn't want to participate in the program, she might do a reservation. If she doesn't attend, without having made a reservation, she will have a reminder within a few months.

The aim is to reduce the mortality from breast cancer with 30% among the invited. There are some intermediate indicators developed to measure effect of performance on the service screening programs: Attendance rate, recall rate, detection rate, stage and morphological characteristics and interval cancer. The quality manual requests a minimal attendance of 75%. Total attendance in NBCSP is 76.6%, with somewhat higher attendance in the rural areas than in the cities, higher on the mobile units and lover among the youngest women. 20-40% of ordinary invited women have a reminder, which increase the participation rate by 4.5%.The recall rate is higher in the prevalent round than in subsequent rounds, totally 4.4%. Total detection rate is 5.8 per 1000 screened women, rate of DCIS is 17%. Researcher at the Cancer Registry, Solveig Hofvind et al. has written an article, Incidence and tumor characteristics of breast cancer diagnosed before and after implementation of a population-based screening-program Hofvind S, Sorum R, Thoresen S. Acta Oncol. 2007 Sep 12;:1-7, a comparison between tumor size and characteristics before and after screening. This article states that tumors are smaller and of lower grade after screening.

There are also negative consequences of screening; one is interval cancers. An interval cancer is a cancer that is detected between two screening rounds or within 24 months after the last round. The interval cancers tend to be of higher grade than the screening detected cancers, they are larger and there is a lower percentage that is

node negative. Interval cancers tend to appear in the latter part of the interval. Breast conserving therapy has been increasing since the start of the Norwegian Breast Cancer Screening Program, and is now the surgery of choice. From the start in 1995 until July 2008 totally 565 212 women had participated in the program and 1 653 582 screens had been taken. There are about 28 000 total reservations.

The Norwegian Breast Cancer Screening Program will now be evaluated by 7 research groups. Focus will be on mortality reduction, but there are also projects that will evaluate overdiagnosis, cost-effectiveness and women's perspective.This work is calculated to last for three years, so until then we have to rely on our good results concerning intermediate indicators.

Fundamentals of Breast Cancer Screening

Andrew Coldman, PhD

Principles have been developed to evaluate screening tests before they are adopted into the population at large. These principles provide a framework within which different screening approaches can be considered and alternatives assessed. Despite the widespread adoption of mammography screening many question remain about how to make appropriate use of this technology.

In this talk I will discuss these principles and show how they relate to the planning of breast cancer screening services. Much information is available from the scientific literature but also much relies upon the specific context for screening. The incidence and mortality rates of cancer influence the efficiency of screening. The frequency of screening also influences the effectiveness and efficiency of the use of services. The age range of women to be screened will also influence the magnitude of resources to be used and the overall effectiveness and efficiency of the screening program. Finally the choice of screening tests used will also influence the ultimate outcomes and costs. I will discuss some alternatives and present estimates of the relative effectiveness and efficiency of different approaches. Examples will use data from Canada and from the world literature.

Final decisions on screening approaches used in different countries are dependent upon resources available and the potential alternative uses of these resources.

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Implementation of breast cancer screening in the EU
The role of international cooperation and collaboration in developing and implementing quality assurance guidelines

Lawrence von Karsa

Introduction

Both in Brazil and in the European Union, breast cancer is the most frequent cancer and the most frequent cause of cancer deaths in women. Due to current demographic trends, substantial increases in the burden of breast cancer can be expected in Brazil in the coming years. In some regions of the country, breast cancer rates already surpass those observed in a number of EU member states. The European experience in implementation of breast cancer screening programmes may therefore provide insight into future prospects for mutual cooperation and collaboration to improve control of breast cancer.

The current status of breast cancer screening in the EU has been documented in the first report on implementation of the Council Recommendation on Cancer Screening. This unanimous recommendation of the EU Health Ministers spells out fundamental principles of best practice in early detection of cancer and invites EU Member States to take common action to implement national cancer screening programmes with a population-based approach and with appropriate quality assurance at all levels, taking into account European Quality Assurance Guidelines for Cancer Screening, where they exist. In order to put the current situation in the EU in perspective, the rationale of the Council Recommendation which specifies evidence-based tests for breast (mammography for women 50-69 years according to EU Guidelines), cervical (3-5-yearly Pap smear beginning no later than 20-30 years) and colorectal cancer screening (FOBT for men and women 50-74 years), as well as the main results and conclusions of the first report will be presented; and those aspects of particular relevance to breast cancer screening will be highlighted.

Methods

A written survey of the 27 EU Member States was conducted in 2007. By May 2008 questionnaires were received from 22 EU Member States. For the remaining five Member States, information on the status of cancer screening programmes was provided by official and authoritative sources.

Results

In 2007 more than 59 million women in the EU were of the target age for breast cancer screening based on mammography specified in the Council Recommendation (50-69 years). Four out of 10 women in this age group in the EU (41%) were targeted for breast cancer screening by 11 Member States in which nationwide rollout of population-based programmes was complete in 2007. A slightly higher proportion of the women in this age group in the EU (44%) was targeted for breast cancer screening by the seven Member States in which nationwide rollout of population-based breast screening programmes was ongoing in 2007. Non-population-based programmes were running in five Member States, one of which was also piloting population-based programmes. No screening programme based on mammography was running or being established in only one Member State in 2007.

Women outside the age range 50-69 years were also eligible to attend breast screening programmes in a number of Member States in 2007. In the Member States which have adopted a population-based approach for breast cancer screening, the smallest target age range is 50-59 years and the largest age range is 40-74 years. The limits of the target age for breast cancer screening in the EU varied between 40 and 75 years in 2007. The lowest

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age targeted was less than 50 years in 8 Member States; the highest age targeted was over 69 years in the same number of Member States. In 2007, over 64 million women in the EU were targeted for, and approximately 12 million women attended breast cancer screening programmes based on mammography.

Whereas over 90% of the minimum target population recommended in the EU for breast cancer screening resides in Member States which are running or establishing breast screening programmes based on mammography with a population-based approach, this only applies to 50% of the respective target population for cervical cancer screening, and 43% for colorectal cancer screening. Furthermore, 97% of the approximately 12 million examinations currently performed per year for breast cancer screening are provided in population-based programmes, whereas only 25% of the approximately 32 million cervical cancer screening, and only 30% of the approximately 12 million colorectal cancer screening examinations are provided in population-based programmes.

Discussion and Conclusions

Adequate quality assurance requires substantial efforts, due to the complexity of the screening process which extends from identification and invitation of the target population, to performance of the screening test and, if necessary, diagnostic work-up and treatment of screen-detected lesions; and aftercare. The European screening networks have shown that a population-based approach provides the organisational framework essential to monitoring and maintaining high quality at every step in the screening process. Nationwide implementation of population-based screening programmes makes services performing to the high standards accessible to the entire population eligible to attend screening. Large numbers of professionals undertake further specialisation in order to meet the screening standards. Consequently, these nationwide efforts also contribute to widespread improvement in diagnosis and management of cancers which are detected outside of screening programmes.

A long-term translational phase is essential to successfully plan, pilot and rollout population-based cancer screening programmes across an entire country, and particularly also across several countries. The time frame depends, to a large extent, on the professional and organisational capacity which must be developed to successfully perform, monitor and evaluate high quality services integrating all steps in the screening process. This activity not only entails coordination of complex communication and training, but also integration of multidisciplinary teams into the diagnosis and treatment of screen-detected lesions, and integration of cancer registration and cancer registries into the monitoring and evaluation of programme performance. Even in countries with relatively small target populations, the magnitude of the task can be substantial, compared to initially available resources. Successful preparation and completion of the nationwide implementation process may require ten years or more. It is for this reason that international cooperation and collaboration is essential in the planning and piloting phases and in order to effectively control screening quality during programme rollout across a country or region.

Even though the number of individuals currently attending cancer screening programmes in the EU is still far from the level which can be achieved in the future (more than 100 million per year), the expenditure in human and financial resources is already considerable. The scale of these resources and the challenge of maintaining an appropriate balance between benefit and harm of screening call for an effective strategy to ensure that appropriate quality is maintained at each step in the screening process. Development and piloting of a voluntary EU-wide accreditation/ certification scheme mandated by the member states and based on EU quality assurance guidelines would encourage programmes throughout the EU to take the initiative to continuously improve performance and would help consumers to recognise which services achieve the EU standards. International cooperation and collaboration in developing and testing such protocols for breast cancer screening has the potential to accelerate improvements in breast cancer control in the coming years and will provide a model for improvement in control of other chronic disease.

Economic aspects of breast cancer screening - National Programmes - Italy

Alfonso Frigerio, Paolo Giorgi Rossi*, Marco Rosselli Del Turco**, Nereo Segnan, Marco Zappa***

There is evidence that in Italy organized mammography screening offered to women 50-69 years old is largely cost-effective. Evaluations on the possibility of screening younger women show that this age-group may be some 3 times less convenient.

Organized screening in Italy is on the whole of good quality, however it fails to reach the coverage of the entire target population, This may - to a large extent - be due to a situation where, alongside with well monitored organized screening programmes producing over 1 million screening tests per year, there is a huge amount of mammographies (some other 4 millions per year), many of which probably answer a diffuse request of spontaneous, non-organized tests both from physicians and women.

Individual prevention, as compared to organized screening, tends to be largely less cost-effective than its organized counterpart. This depends on organizational and managing issues; to diagnostic protocols that aim to the maximum sensitivity with little consideration of specificity; to the lack of a monitoring and QA context.

This situation leads to a waste of resources, thus contributing to maintain inequalities of access to care based on socio-economic factors.

One of the main problems that Italy's screening providers are facing right now is to try and reset the system in order to get all of early diagnostic activity in asymptomatic women within the boundaries of a well-monitored, high quality screening project, working according to well-defined protocols, within a QA and training setting, aiming at a sensible balance of sensitivity and specificity.

Most important, such an organized system can actively guarantee equity of access to all the target population, irrespective of any socio-economic or geographic difference.

Within this setting, the opportunity of extending the screening offer to age-groups over 70 and below 50 will be discussed.

One relevant focus in this re-organization of early diagnostic activities is the strict cooperation with all the professionals involved, as well as a finely-devised communication strategy aimed to both the population and the health providers themselves.

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Breast cancer screening - National Programmes - Italy

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In Italy, Health Care is mainly provided by a national public system (NHS).

There are National Laws, Recommendations, Guidelines and funding from the central Government, yet the actual Health System is managed at a Regional level.

Breast cancer screening is recommended as an essential health procedure for which a number of National Recommendations and Laws have been issued and funds provided in order that Regional Health Authorities could set up and run Regionally based organized screening projects.

In Italy, breast screening programs are completely free of charge for attending women.

Most Regional Projects - as recommended - address the 50-69 ys age group (women are actively invited). Some extend coverage to 45-49ys old and 70-75 ys old, but in these age-groups women should request to have the test.

Screening test is "mammography every 2 years" (every 12 months for 45-49 old).

Breast cancer screening is included in the list of LEA (Essential Health Procedures).

Minister of Health states minimum standards for monitoring breast screening projects.

Indeed, organized screening projects are very well monitored in Italy, with attention to both indicators of population participation and performance indicators of diagnosis and treatment.

On a National basis, 3.8 millions women have been invited to screening in the biennium 2005-2006 and 2.2 millions were screened (57% attendance).

Population coverage is indeed a critical point, with only 81% of Italian women living in areas with active screening programs and only 62% actually receiving an invitation in year 2007. However, a relatively large activity of spontaneous, non organized screening contributes to a wider coverage of the target population. Coverage problems are in fact particularly critical in the Southern Regions of Italy.

Performance indicators in 2005-2006 were very satisfactory: 6.3% recall rate, 10168 cancers detected, of which 1215 were in situ lesions and 2892 small invasive cancers of no more than 10mm; overall standardized cancer detection rate was 4.7 per thousand.

Organized screening in Italy could also prove its effectiveness, as shown by a number of papers produced by the "Gruppo Impatto" (Group coordinator: E. Paci), demonstrating significant mortality reduction from breast cancer in women screened in the organized setting, as well as a significant reduction of mastectomy rates.

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