Satellite Meeting of the IEA/ 1999 IBSN biennial meeting
Progress of Breast Cancer Screening in the World:
Quality evaluation of breast cancer screening:
August 30-31, 1999
Florence, Italy

TITLE: ORGANIZATION OF QUALITY ASSURANCE FOR SCREENING MAMMOGRAPHY: A COMPARISON AMONG 22 COUNTRIES

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KEYWORDS: Screening Mammography, Quality Assurance, Health Services Organization

BACKGROUND: Implementation of population-based screening mammography and recognition of the importance of assuring high-quality screening examinations as well as the complexity of the screening process have prompted development of quality assurance activities for mammography.

OBJECTIVE: In 1998, the IBSN sponsored an assessment of quality assurance policies and practices among its members. The purpose of the assessment was to define the scope of quality assurance activities for screening mammography across IBSN countries.

METHODS: A questionnaire was developed and mailed to IBSN representatives in 23 countries. The questionnaire covered the organization of quality assurance activities, whether countries have in place mechanisms for site visits and accreditation, requirements for quality control and data systems, and inclusion of treatment, follow-up, and program evaluation in quality assurance activities.

RESULTS: The 22 responding countries vary in their approaches to implementing quality assurance for screening mammography, although all monitor the quality assurance components of structure, process, and outcome. Nearly all have in place laws, surveillance mechanisms, or standards for quality assurance. In all countries, quality assurance activities extend beyond the technical aspects of the screening mammography exam. Few differences in the comprehensiveness of quality assurance activities were noted among countries.

CONCLUSIONS: The quality assurance assessment has enhanced understanding of the organization of screening mammography across IBSN countries, as well as the comparability of screening mammography data. All countries have established mechanisms for assuring the quality of screening mammography in population-based programs, although these mechanisms vary across countries.

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TITLE: QUALITY CONTROL PRACTICES IN MAMMOGRAPHY SCREENING PROGRAMS IN 22 COUNTRIES

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Objective: To assess current quality control (QC) practices within population-based breast cancer screening or surveillance programs internationally.

Methods: The International Breast Cancer Screening Network (IBSN) conducted an extensive survey of quality assurance (QA) activities in developed countries known to have population-based breast cancer screening or surveillance programs. Twenty-three countries were sent questionnaires that included items about QA and QC requirements at screening sites, guidelines followed, minimum frequencies of QC test performance, and personnel responsible for performing QC tests.

Results: Twenty-two countries responded with completed questionnaires between July and October 1998. Responses indicated a pattern of strong quality control practices among population-based breast cancer screening and surveillance programs. All countries but one reported requiring QC of equipment used in screening mammography, by law in 9 countries and by practice standards or the screening program in 12 countries. All countries responded positively to routine performance of processor sensitometry, screen-film contact, kVp accuracy/reproducibility, and automatic exposure control (AEC) tests. Most countries perform each of the following tests on a regular basis: collimation assessment, cassette cleaning, and beam quality measurement. All but two countries routinely perform phantom image quality, compression force, and beam entrance exposure tests. Variation among countries in the personnel responsible for performing different QC tests was observed.

Conclusions: QC practices among population-based breast cancer screening and surveillance programs are highly evolved, with the great majority of responding countries following prescribed QC protocols.

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TITLE: QUALITY ASSURANCE IN FOLLOW-UP AND TREATMENT IN BREAST CANCER MASS SCREENING PROGRAMS

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KEYWORDS: Screening Mammography, Quality Assurance, Follow-up, Treatment

BACKGROUND: Many factors contribute to the success of a screening program. The quality of all steps in the screening process, from mammography testing to treatment of screen-detected cancers, must be assured to achieve optimal benefit.

OBJECTIVE: To investigate how the breast cancer mass screening programs in 22 countries ensure that women with abnormal mammograms are not lost to follow-up. In addition, to determine the quality assurance activities involved in establishing a diagnosis following a positive screening mammogram and in the treatment of screen-detected cancers.

METHODS: A detailed questionnaire covering all aspects of quality assurance in screening mammography was mailed to IBSN representatives in 23 countries in late May 1998. Completed questionnaires were returned by 22 countries. Responses were summarized in a Microsoft Access database.

RESULTS: Twenty-one countries reported that screening programs are responsible for assuring that women with abnormal mammograms receive appropriate follow-up investigations. Fifteen countries have guidelines or policies that specify what is to be done following an abnormal result. Seventeen countries have implemented a set procedure for the review of abnormal screens initially determined to be breast cancer. Slightly over half of countries set and monitor a time limit for performing additional investigations following an abnormal screen. A minority of countries require accreditation of the cytology and pathology laboratories used by the screening program. Two-thirds indicated that data on chemo-, radiation, and hormonal therapy can be accessed, although access is with some difficulty for many.

CONCLUSION: In most countries, quality assurance activities extend to monitoring to ensure that women with abnormal mammograms are not lost to follow-up. However, few countries also have in place mechanisms to monitor the quality of diagnostic care and treatment.

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TITLE: INTERNATIONAL COMPARISON OF QUALITY ASSURANCE FOR DATA TO EVALUATE SCREENING MAMMOGRAPHY PROGRAM PERFORMANCE

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KEYWORDS: Screening Mammography, Quality Assurance, Data Collection

BACKGROUND: The ultimate goal of screening mammography is to reduce mortality from breast cancer in defined populations. To demonstrate attainment of this goal, population-based screening programs must gather high-quality data on all aspects of the screening process, from identification of eligible women to calculation of program performance parameters such as participation rates, cancer detection rates, and cost-effectiveness ratios.

OBJECTIVE: This study documents the administrative and clinical data for screening mammography that are gathered by IBSN countries, the nature of the procedures that countries have developed to ensure that these data are of high quality, and the performance parameters they use to assess program impact.

METHODS: A detailed questionnaire covering all aspects of quality assurance in screening mammography was mailed to IBSN representatives in 23 countries in late May 1998. Completed questionnaires were returned by 22 countries. Responses were summarized in a Microsoft Access database.

RESULTS: IBSN countries collect a wealth of administrative and clinical data; many of these data elements are maintained in a computerized rather than manual form. In most countries, designated staff are responsible for data quality assurance. All provide staff training as well as have documentation requirements for the collection of mammography data. Most have in place one or more procedures to maintain confidentiality of patient-level data. There is diversity in the extent to which countries currently gather and assess data to monitor screening program performance.

CONCLUSION: Assuring the quality of data collection for screening mammography is an important and evolving area for IBSN countries.

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TITLE: ADAPTING QUALITY ASSURANCE TO COUNTRY SPECIFIC NEEDS: CANADA

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Since 1988, population based provincial and territorial organised screening programs have been gradually implemented in Canada. As of today, all provinces and territories have implemented organised breast cancer screening programs. Recognizing the diversity but also the need for monitoring, outcome evaluation and a focus on quality, Health Canada has established with the provinces a National Committee on Breast cancer Screening. To support the establishment of quality assurance programs , the committee undertook the development , revision and updating of national guidelines in such areas as participation, film interpretation, follow-up process and other issues related to screening.

Following the publication in 1997 of the first edition of "*Quality Determinants of organized breast cancer screening programs*", a survey regarding the practices of quality assurance in the provincial and territorial programs was conducted in 1998. The results show that programs differ in some areas and in the degree of implementation of quality assurance activities but also have some common ground as a result of working together to develop quality determinants guidelines.

Those results can help identify the factors that influence the adoption of quality assurance programs in breast cancer screening in the context of provincially based programs. It also facilitates the setting of priorities for future quality assurance activities at the national level.

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TITLE: SERVICE SCREENING WITH MAMMOGRAPHY IN SWEDEN: EVALUATION OF EFECTS ON THE BREAST CANCER MORTALITY IN THE AGE GROUP 40-49 YEARS

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Based on results from the randomised controlled trials there is now consensus that mammography screening reduces the breast cancer mortality in the age group 40-69 years. The interesting question is if the results from the randomised controlled trials can be repeated within the nationwide screening programmes.

The aim of the study was to evaluate the effect on the breast cancer mortality of the nationwide service screening program with mammography in the age group 40-49 years in Sweden.

Population-based screeing was in Sweden introduced in 1986 and had in 1997 been started in all 27 counties. In half of the counties suitable for evaluation the lower age limit for screening was 40 years and in the other half it was 50 years. In 1988 the number of female subjects in these populations 40-49 years of age were 202,152 and 237,279, respectively. Counties with a lower age limit at 40 years (study population) were compared with those who had 50 years as lower age limit (control population) with regard to the breast cancer mortality in the study period 1986-1994. To adjust for geographical differences a reference period 1976-1984 was considered.

The follow-up was measured from the month of start of invitation to screening in each study area and a corresponding starting time for the control areas. In the control group the follow-up time was nine years while in the study group it varied from 2 to 9 years (Mean 7.0 years). The cumulative breast cancer mortality per 100,000 was 92.8 and 125.6 for the study and control group in the study period and 84.8 and 109.2 in the reference period resulting in a relative risk was 0.95 (95 % confidence interval 0.61 to 1.47). Thus, there was no statistically significant difference in breast cancer mortality between the study and control populations.

At seven years of follow-up there was no significant effect of mammography screening on the breast cancer mortality. Considering both the lead time bias and the inclusion of an unknown number of cases diagnosed before invitation to screening during the first round it can be conluded that the mortality reduction is at least 5% and in accordance with what was achieved in the overview of the Swedish randomised trials.

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TITLE: NATIONWIDE SURVEY OF QUALITY ASSESSMENT OF MAMMOGRAPHY AND PERSPECTIVE OF MAMMOGRAPHIC SCREENING FOR BREAST CANCER IN JAPAN

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KEY WORDS: Breast Cancer Screening, Mammography, Quality Assessment

BACKGROUND: In Japan, clinical breast examination (CBE) was conducted as a screening modality in 1989. Recently we have demonstrated by a case control study that CBE would lack its effectiveness (OR=0.93), although it might be effective for asymptomatic population (OR=0.56). Now, it is necessary to consider an introduction of mammographic screening to reduce breast cancer mortality in Japan.

OBJECTIVE: To establish the breast cancer screening system using mammography, we performed a nationwide survey of glandular tissue doses and image quality.

METHODS : RMI-156 phantom and glass dosimeters were sent to 104 mammography sites. Glass dosimeters were exposed together with a phantom on the protocols described in the mammography Quality Control Manual. Average glandular doses were estimated from the beam qualities and the entrance surface exposures. Phantom images were read by means of ACR method. The readings were performed by four radiological technologists who have experience in mammography.

RESULTS: In 91 facilities, the average glandular doses were less than 2mGy. The mean dose and the standard deviation were 1.48mGy and 0.52mGy, respectively. The doses ranged from 0.5 to 3.7mGy. The phantom image in 77 facilities was satisfactory. The phantom image in 10 facilities was almost satisfactory.

CONCLUSIONS: The results of this survey showed that QC practices for mammography in Japan have made a significant improvement for the past decades. To establish mammographic screening in Japan, the study group "Quality Control of Breast Cancer Screening with Mammography" was organized from the Ministry of Health and Welfare in 1995. The essential issues have been analyzed including cost-effectiveness analysis and risk-effectiveness analysis, in comparison among CBE with SMG, CBE, or SMG alone. In this meeting the new direction in the organization of the delivery of screening that differs from the current program will be presented.

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TITLE: THE NON-CENTRALIZED, NATIONWIDE BREAST CANCER SCREENING PROGRAMME IN LUXEMBOURG: RESULTS OF 1992-1997

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KEY WORDS : Breast cancer, mammography, screening, European quality standards in a non-centralized health system

Background : Nationwide breast cancer screening at biennial intervals, with 2 views and double reading, started in Luxembourg in 1992 for women aged 50-65. A political decision was made in 1991 to perform the screening mammograms in the existing radiological units in the ten hospitals operating in Luxembourg. The alternative of opening 2 specialized screening units for a target population of 34.000 women was rejected. All radiologists performing mammograms (20) are working in hospital radiological units.

Objective: To reduce the mortality rate from breast cancer for women in Luxembourg by means of achieving European quality standards (European Guidelines for QA in mammography) on each element in the mammographic chain.

Methods: Seven years after the start of the Programme Mammographie (PM) the participation rate is about 52%. Of the eligible women 10% are covered by opportunistic screening. In a non-centralized system it is essential to set up a co-ordination centre, which in Luxembourg is based at the ministry of health. Its role includes 1) management of the screening campaign, 2) organization of the second and third readings of the mammograms, 3) training of radiographers (31) and 4) implementation of a standardized quality assurance programme in the 10 hospitals. These are the key elements for achieving the set objectives.

Results: Prior to implementation of the PM, the coverage rate was 9%. By 1997, the coverage rate had increased to 62%. Women are invited by the social security funds, updated by the national population register. One national cancer register exists in Luxembourg. In the PM, the 74% node negative cancers (92-97) and the 29.5% infiltrative tumours less than 15mm (96-97) correspond to the European recommendations(respectively > 70% and 25 %).

Conclusion: A quality assurance programme in a non-centralized health system is able to achieve results corresponding to the European recommendations if each element in the mammographic chain is monitored on a regular basis by a co-ordination centre.

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[4] Programme Mammographie, Service des Statistiques.

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TITLE: EVALUATION OF A PILOT QUALITY ASSURANCE PROGRAMME FOR BREAST CANCER SCREENING IN THE BRUSSELS AREA: THE REFERENCE CENTER FOR BREAST CANCER SCREENING

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KEY WORDS: Quality assurance, mammographic screening, double reading, early indicators, evaluation.

BACKGROUND: A pilot quality assurance project for breast cancer screening was set up in the Brussels area in 1994. This paper aims to assess the performance of this programme after 4 years of activity, and the specific impact of consensual double reading of mammograms.

OBJECTIVE: Evaluation of a quality assurance pilot programme for breast cancer screening in the Brussels area.

METHODS: Each screening mammogram of women aged 50-69 years was submitted to a consensual dual reading. Results of readings were registered with standardized forms. Follow-up data were traced for every positive mammogram.

RESULTS: 15,624 mammograms were performed in 12,239 women; recall rate at first round was 7.8%, open biopsy rate was 1%, cancer detection rate was 5.8%, positive predictive value of biopsy recommendation was 53.4%, benign to malignant biopsy ratio was 0.87:1, small size (less or equal to 10 mm) cancer proportion was 40%, proportion of cancers free of nodal involvement was 65%. Double reading yielded a 6% gain in sensitivity, while recall rate dropped from 8.1% to 7.8%.

CONCLUSIONS: Apart from a too high recall rate, screening performance was comparable with other published results in the same context; performance indicators ranged within norms recommended by "Europe against cancer". However, impact of dual reading was weak and should be reevaluated in the future perspective of a larger scale organized programme.

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TITLE: STANDARDIZING REPORTS OF BIOPSY YIELD

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KEY WORDS: PPV, biopsy yield, screening mammography

BACKGROUND: Positive Predictive Value (PPV - biopsy yield) is the number of true cancers divided by the number of tests called positive for cancer. PPV varies in the literature from 10 – 68% [1,2]. It is difficult to compare published data because the definition of how biopsy yield has been derived and a description of the population studied are often missing from papers.

OBJECTIVE: To show the variation in PPV (biopsy yield) when different methods are used to derive the PPV.

METHODS: The data from the Vermont Mammography Registry are used to vary the methods five different ways to derive the PPV. Variations will be:

1. Reporting only women ages 40 - 49 and 50 -70;
2. Including only diagnostic mammograms vs. only screening mammograms;
3. Including and excluding FNA's and core biopsies as biopsies;
4. Reporting prevalent and subsequent screening separately;
5. Changing the denominator to include those that were recommended for biopsy vs. those that went to biopsy.

RESULTS: From 52,244 screening and 9,649 diagnostic mammograms, there are 4,133 prevalent screening mammograms. There are 43 true positives (TP) and 164 false positives (FP) for women 40-49, 102 TP and 200 FP for women 50-70 from screening. There are 13 TP and 75 FP for prevalent and 190 TP and 375 FP for subsequent screens. There are 233 TP and 358 FP for diagnostic mammograms. The biopsy yield for the variations are:

1. Ages 40-49 = 21%; ages 50-70 = 34% (screening only)
2. Diagnostic mammograms = 39%; screening mammograms = 31%
3. (removing FNA and core biopsies is not calculated at this time)
4. Prevalent screening = 15%; subsequent screening = 34% (screening only)
5. Recommended for biopsy = 21% (screening only)

CONCLUSIONS: Variation in the definition of PPV (biopsy yield) changes the outcome. The population that the data represents influences the PPV and must be adjusted for or described. It is important to provide readers with the definitions for the measure as well as the TP and FP data to enable readers to recalculate, if necessary, their own data for comparison purposes.

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TITLE: CHARACTERISATION OF TUMOURS DETECTED IN THE NORWEGIAN BREAST CANCER SCREENING PROGRAMME

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KEY WORDS: first screening round, early quality indicators, breast cancer

BACKGROUND: About 127 000 women aged 50-69 nave been examined in the first screening round. The detection rate was 6.8 women with cancer per 1000 screened women. The Positive Predictive Value based on positive mammograms was 0.16. The characteristics of the detected tumours are important indicators on whether the screening programme will achieve the desired mortality reduction or not.

OBJECTIVE: The objective of the presentation is to describe the screening detected tumours and to compare the characteristics with the early quality indicators defined in the quality assurance manual of the programme.

METHODS: The data are reported to the Cancer Registry of Norway (CR) as copies of the original cytology or histology reports. The data are coded and registered in a central screening database at the CR.

RESULTS: 51 percent of the tumours were less than 15 mm in diameter, and the median tumour size was 14 mm. Only 19.8 % of the women with cancer had axillary lymph node metastasis. Approximately 47 % of the cancers were histologically classified as grade 1, 42 % grade 2 and 11 % grade 3. About 89 % were found to be oestrogen receptor positive and 66 % progesteron receptor positive. The tumours of grade 1 were more likely to be small and hormone receptor positive.

CONCLUSIONS: The results are in accordance with the early quality indicators defined in the literature and in the quality assurance manual of the programme.

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TITLE: MAMMOGRAPHY SCREENING AND DIFFERENCES IN TUMOR STAGING BY RACE/ETHNICITY

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KEY WORDS: ethnic groups; incidence case; prevalence cases; tumor stage

BACKGROUND: Tumor stage differentials are noted among Black, Hispanic, and White women diagnosed with breast cancer in Colorado. It has been hypothesized that the larger percentage of advanced stage breast cancer among both Black and Hispanic women is related to less screening use
OBJECTIVE: This study examines the association of ethnicity on breast cancer distribution at the time of diagnosis in Hispanic, Black and White women participating in periodic mammography screening in Colorado.
METHODS: The CMAP and CDC database were combined to examine women residing in the Denver area with respect to distribution of ethnicity, age, cancer incidence, and the stage distribution. Each ethnic cohort's breast cancer incident cases (women with at least one mammogram in the two years prior to diagnosis, excluding the detection mammographic sequence) were examined to determine if there were differences in the distribution of tumor staging.
RESULTS: The registry database contains over 200,000 women. Over 4700 cancers were detected. Sixteen hundred (1/3) were classified as incident cancers. Thirty four percent of White women were classified as having an incident cancer compared to 23% for Hispanic women, and 31% for Black women. Overall, 72% were SEER Summary Stage 0 or 1 and 24% regional staged cases. Among the cases classified as incident cancers, 75.9% were stage 0 or 1 compared with 70.5% of the prevalent cases. Among Hispanics, 77% of the incident cases were early stage compared with 71% for the prevalent ones, 76.2% and 70.8% respectively, for Whites and 68.3% and 60.7% for Blacks. Thirty seven percent of the Hispanic cases were under 50 and over 90% of the incident cases were stage 0 or 1 compared to Whites with 29% under 50 and 69% stage 0 or 1; and for Blacks, 32% were under 50 and 75% of the incident cancers stage 0 or 1.
CONCLUSIONS: Screening lowered the stage of diagnosis by approximately 5% regardless of ethnic group. The CDC subgroup data suggests that screening may not mediate stage distribution in minority women. More detailed analyses will be presented examining the impact of DCIS and comparisons in cases matched for more extensive screening history.
REFERENCES: Cancer in Colorado 1998; the Colorado Central Cancer Registry; Colorado Department of Public Health and Environment.

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TITLE: EFFECT OF HORMONE REPLACEMENT THERAPY ON MAMMOGRAPHY FINDINGS

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BACKGROUND: Bi-annual breast cancer screening for women ages 50-74 with mammography has been underway since the end of 1996. Of a total of 82,675 screening tests in 1997, 63,635 were done in postmenopausal women. Breast cancer was detected in 468 of the screened women (16.6% of 2814 women detected with breast cancer in Israel in 1997).

OBJECTIVES: To evaluate if women on Hormone replacement therapy (HRT) have a different mammography detection profile than women not on HRT.

Methods: All women diagnosed with a new primary breast cancer in 1997 in Israel were investigated. HRT-use status was available for 1081 post/peri-menopausal women of the total of 2814 women with breast cancer detected that year in Israel. The women were divided into those detected through screening (418), those missed by screening (50), those detected through clinical mammography (548) and those missed by clinical mammography (65). HRT use was further evaluated in two duration groups (1-5 years, 6 years and over)

RESULTS: Women on HRT were more often missed during mammography screening than women not on HRT (17.9% vs. 9.7% correspondingly, p=0.059). Women on HRT who were detected by screening mammography were diagnosed more often with DCIS (27.9%) than screened women not on HRT (13.1%, p=0.013). DCIS rate was higher with longer periods of reported use of HRT. HRT users were also found at screening mammography to be more node negative than non-users (19.4% vs. 27.4%, n.s.). With longer periods of use the nodal status became even more favorable in the HRT users. Size of invasive tumors did not differ between HRT users and non-users. Screen missed tumors in women on HRT were of similar histological distribution and size, but were more often with positive nodes than screen missed tumors in women not on HRT (44.4% vs. 13.3%).
The high miss rate and the low lymph node involvement were also noticed among the HRT users who were diagnosed by clinical/diagnostic mammography.

CONCLUSIONS: Women on HRT seem to be missed in the screening process more often than women who are not on HRT. Screen detected tumors in HRT users seem to carry a better prognostic profile. These results call attention to major changes in screening mammography performance in the world, as more women go on HRT.

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TITLE: SCREENING MAMMOGRAPHY PERFORMANCE ON SINGLE VS. INDEPENDENT DOUBLE READING

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Objective: To identify the average change in screening mammography interpretive performance afforded by independent double reading among 31 radiologists, practicing in three American College of Radiology accredited facilities.

Methods: We assessed interpretive performance on a test set of screening mammograms selected by stratified random sampling among 21,567 examined women followed for two years to identify cancers. The set included 30 women with cancer and 83 without. Cases were weighted to include an increased proportion of difficult films compared to usual practice. Radiologists read the films in isolation and were blind to each other's assessments and any clinical information. We measured performance for radiologists and radiologist-pairs in the following way: 1) proportions of each of 5 assessment categories assigned to women, 2) weighted and unweighted kappa statistics among all 465 pairs of radiologists, and 31,465 unique pairs of radiologist-pairs, and 3) average sensitivity, specificity, diagnostic likelihood ratio positive (DLR+) and negative (DLR-), and area under the receiver operating curve (AUC) for readers and pairs. To identify the assessment for paired readings we assigned the maximum examination rating across the two radiologists or the available rating when only one was present. We calculated change scores by taking the difference between each reader's individual accuracy and average accuracy across that reader's 30 paired observations.

Results: Average sensitivity, specificity, DLR+ and DLR-, and AUC for individual readers was 79%, 81%, 5.53 and 0.26, 0.88 respectively. The mean kappa statistic among radiologists for cancer cases increased with paired readings from 0.59 to 0.71, and for non-cancer cases from 0.30 to 0.33. Paired reading resulted in an average increase of 7% in sensitivity, a decrease in specificity of 11%, a decrease DLR+ of 2.35, and DLR- of 0.06, and an increase in AUC of 0.015.

Conclusions: Individual performance as measured by the area under the receiver operating curve was relatively unchanged by paired readings. If double reading is to be widely instituted more should be done to evaluate the implications of consensus reading, because blinded reading results in a decline in specificity that may not be compensated by the gain in sensitivity.

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August 30-31, 1999
Florence, Italy

TITLE: INTERVAL CANCERS IN THE DUTCH BREAST CANCER SCREENING PROGRAMME

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KEY WORDS: breast cancer, interval cancer, relative incidence, population-based screening, evaluation

Background: The nation-wide breast cancer screening programme in the Netherlands providing a biennial mammographic screen examination to all women aged 50-69 years. The programme started in 1989 and was fully implemented in 1997.

Objective: To assess the occurrence and stage distribution of interval cancers in women screened during 1990-1994.

Methods: Records of nearly 1.2 million screened women were linked to the regional cancer registries yielding a follow-up of at least 2.5 years. Age-adjusted incidence rates and relative incidences of the underlying incidence were calculates by tumour size including DCIS for screen-detected and interval cancers, and cancers in not (yet) screened women.

Results: Totally 2,103 interval cancers were identified in the first two year after screening, resulting in 0.97 and 0.94 interval cancers per 1,000 women-years of follow-up after initial and subsequent screens, respectively. In the first year after initial screening interval cancers amounted to 26% (25% after subsequent screens) of underlying incidence, and in the second year to 48% (51%). Generally, interval cancers had a more favourable tumour size distribution than breast cancers in not (yet) screened women.

Conclusions: Taking into account a slight underregistration of interval cancers, the observed occurrence was quite the same as expected and in line with published results from the UK breast screening programme. Nevertheless, efforts should be made to improve further the screen-detection of breast cancer, particularly in subsequent screens.

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TITLE: THE COST EFFECTIVENESS OF BEGINNING SCREENING AT AGE 40 AND ITS RELATIONSHIP TO THE PROGRESSION OF DCIS

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KEY WORDS: DCIS, microsimulation, cancer progression

BACKGROUND: There is substantial debate about whether women should begin mammography screening at age 40. Several randomized clinical studies and non-randomized studies, including microsimulation and decision models, have failed to demonstrate that this strategy is beneficial. However, the beneficial effects of early screening may be found outside the observable time-frame of the randomized clinical studied, and may depend on attributes of DCIS progression and treatment costs that are not suitably represented in the non-randomized studies. By DCIS progression we mean the fraction of DCIS detected by screening that would have progressed to an invasive state in the absence of screening.

OBJECTIVE: We compare the cost effectiveness of beginning screening at age 40 compared to age 50, and consider both the costs and effects accrued over a woman's entire lifetime. In particular, we investigate the role of DCIS progression on the long term cost effectiveness.

METHODS: A microsimulation (computer) model that represents screening protocols, breast density, tumor progression (including DCIS), and treatment costs are used to simulate population screening programs. By varying the rates of DCIS progression we assess the cost effectiveness of detecting DCIS with screening on the later development of invasive cancer and its costs. The model's representations of treatment costs and DCIS cancer progression make it uniquely suited to assess this question. The model is validated with mammography registry data, cancer registry data (SEER), and clinical trial data, and so our predictions are consistent with those data sources.

RESULTS: The long term cost effectiveness of screening young women is highly dependent on the behavior of DCIS. If a high proportion of DCIS cases detected by screening would have progressed to an invasive stage had they not been screened, then early detection of DCIS can prevent invasive cancer in older women. This can reduce mortality and avoid the high cost of treating invasive cancer. For example, we find that progression rates of 70% down to 30% give a marginal discounted cost per years of life saved from $15,000 to $40,000, respectively. Thus, although short-term effects may not provide a compelling case for early screening, the long-term effects may, depending on the behavior of DCIS. These long-term effects cannot be observed by cancer screening trials due to their short follow up, and so our findings do not contradict them.

CONCLUSIONS: Screening for breast cancer by mammography may be more cost-effective in women aged 40-49 than previously thought if DCIS detected by mammography would otherwise have progressed and been diagnosed as invasive cancer. The debate over early screening should consider the long-term effects of screening in addition to the shorter-term benefits measured by randomized clinical studies. The behavior of DCIS progression has a central role in this debate.

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TITLE: COMPARISON OF RECALL RATES AMONG INTERNATIONAL SCREENING PROGRAMS

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BACKGROUND: Recall rates are often used as indicators of screening performance. It is known that these rates differ among international screening programs. What is not known is the reason for the variation in rates: whether it is because the practice of screening is different, or that definitions used and calculation of these rates vary sufficiently to result in different results. The International Breast Cancer Screening Network was formed to enable sharing of information among screening programs around the world. This has created the opportunity to examine this important question.

OBJECTIVE: The main objective of this study was to gather data from screening programs who are members of the IBSN to determine if definitions of recall could be standardized, such that recall rates could be compared among programs.

METHODS: A questionnaire was developed to gather data from the various international screening programs for the purpose of determining the feasibility of collecting rates that would be comparable. Data are presently being gathered on who is screened, how screening is defined, how data are collected, and the definitions used to determine both recall for further radiologic work-up and recall for invasive procedures following a screening mammogram.

RESULTS: This questionnaire has been finalized, and will be sent to screening programs in the countries that are members of the IBSN including: Australia, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Israel, Italy, Japan, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, United Kingdom, United States, and Uruguay.

Results will be analyzed and ready for presentation in August.

CONCLUSION: This will be an important study, as it will lay the foundation for future work to compare screening performance and outcomes internationally. The results of this survey will identify which countries will be able to calculate rates that can be compared and how these rates should be calculated so they can be compared.

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TITLE: **PILOT MAMMOGRAPHY SCREENING PROGRAM IN THE UKRAINE: RECALL RATES AND POSITIVE PREDICTIVE VALUES OF BIOPSY RECOMMENDATIONS**

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KEY WORDS: Screening mammography in developing countries, recall rates, positive predictive value of biopsy recommendations.

BACKGROUND: In 1996 USAID awarded a cooperative agreement to a non-profit organization, PATH (Program for Appropriate Technology in Health), to enhance breast cancer services in Ukraine, with specific attention to Chernobyl-affected women. Following the equipment acquisition and training phases of the project, a pilot screening mammography program was initiated targeting a district bordering the Chernobyl zone.

OBJECTIVE: To compare audit data of a pilot screening mammography program in Ukraine to the recommended goals published by the U.S. Agency for Healthcare Policy and Research (1), with special attention to recall rates and positive predictive value (PPV) of recommendations for biopsy.

METHODS: Audit data was analyzed for the first 6 months of the screening program (July 1, 1998 to January 1, 1999). Screening exams consisted of bilateral, single-view mediolateral oblique (MLO) mammograms. Recall rate was defined as percentage of patients screened who were recommended for further evaluation. PPV for recommendation for biopsy was defined as malignant biopsies/number of cases recommended for biopsy. The percentage of all tumors that were detected at stage 0 to 1 was calculated. All outcome measures were compared to recommended goals published by the U.S. Agency for Healthcare Policy and Research (1).

RESULTS: Percent of Stage 0 to 1 cancers was 52%, consistent with a published "desirable goal" of >50%. The recall rate was 70%, compared to a published recommendation of 6-10% (for two-view mammography) (1). Most recalls were for one additional mammographic view (craniocaudad, to complement the single MLO taken for the standard screen). PPV for biopsy was 18%, compared to the recommended goal of 25-40%.

CONCLUSIONS: Three factors were considered important to explain the high recall rate: 1) relative inexperience in interpreting screening mammograms, 2) single-view mammography, 3) lack of comparison films (no prior screening mammograms existed). Establishing sustainable screening mammography programs in developing countries presents unique challenges. Beyond equipment provision and initial training, ongoing support and continued education is essential to meet desirable goals. Current training in this program is targeted at reducing recall rates and improving PPV of recommended biopsies without decreasing the percentage of early cancers detected.

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TITLE: PASSING FROM A LIMITED BREAST CANCER SCREENING PILOT PROJECT TO A REGIONAL AND NATIONAL ONE. QUALITY ASSURANCE DIFFICULTIES AND STRATEGIES

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KEY WORDS: breast cancer, quality assurance

BACKGROUND: The frequency of breast cancer in Uruguay is among the highest in the world (among the first ten countries). In 1992 a breast cancer screening pilot project was initiated, which actually is on an expansion stage.

OBJECTIVE: To analyze the difficulties of spreading the Quality Assurance (QA) from a pilot model project to a regional or national program.

METHODS: Comparison of the QA policies and results of the pilot project (which are consistent with the ones the IBSN evaluates) with the actual stage of regional implementation.

RESULTS: Difficulties and problems arise at the present stage of expansion. Analysis of their causes show that they are multifactorial, being one of the most important in our experience the lack of a "High Quality Assurance culture" in our country.

CONCLUSIONS: The importance of education and permanent evaluation and promotion of QA is highlighted.

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TITLE: PERSPECTIVES ON FUTURE PRIORITIES IN MAMMOGRAPHY SCREENING FROM THE AMERICAN CANCER SOCIETY

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KEY WORDS: mammography, screening, interpretation, training, evaluation, infrastructure

Breast cancer screening has been successfully introduced in the U.S. during the last 15 years. While the elements necessary for high quality screening exist in the U.S., in most geographic areas they are not integrated into a system, and thus the fullest potential of organized screening is not being met. Further, in addition to remaining challenges, screening in the U.S. faces new challenges, namely an increase in the size of the population at risk, anecdotal reports of declining interest in providing mammography due to regulatory oversight, low reimbursement and high malpractice exposure, weak standards for experience in screening, and limited opportunities for training in screening and performance feedback. In June, 1999, the ACS convened the Workshop on Interpretative Skills in Mammography to address these and other challenges related to insuring the availability of high quality screening in the U.S. into the next century. Four workgroups were organized: (I) Test Development; (II) Continuing Education and Skills Enhancement Tools; (III) Residency Training and Fellowship Opportunities; and (IV) Organizational Strategies to Improve Interpretive Skills. Key recommendations from the Workshop included: (1) the need to accelerate research and development on evaluating radiologists' screening and diagnostic skills; (2) the need to create opportunities for testing, feedback, and corrective education; (3) investigate the potential for a centralized mammography training institute, academic detailing, mini-fellowships, and new CME models (home study, internet, etc.); (4) establish new criteria for residency training, and strengthen testing criteria on the board certification exam; (5) increase post-residency fellowship opportunities and re-establish fellowship standards; and (6) create new incentives to strengthen mammography infrastructure in the U.S., including criteria for "centers of excellence," increased reimbursement for mammography, higher standards for interpreting physicians, and development of regional mammography databases linked to tumor registries for surveillance and on-going performance feedback..

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TITLE: BREAST CANCER TRENDS AND THE INFLUENCE OF PRIMARY PREVENTION AND SCREENING

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BACKGROUND: Around 1990 cancer of the breast was the most common cancer in women world-wide[1]. In western countries it is still the most common cause of death from cancer in women[2], in spite of the steady improvement of prognosis observed in the more advanced economies in recent years. Available incidence data suggest fairly generalised increases in risk up to the late 70s in both developed and developing countries[3-6]. The increase is generally better explained by a birth cohort effect, successive generations being at higher risk from early age throughout their lives. This phenomenon is the basis of the shape of the age-specific curve, the well-known two-slope monotonically increasing curve of high-risk countries appearing as a decline in risk around age 40-50 years in low-risk countries. The increase in risk is generally attributed to reduced fertility and changing dietary habits however the possibility that other unidentified factors play a role should not be dismissed.

Percent annual changes in incidence over the 15-year period 1975-1990 for populations represented in volumes IV and VII of Cancer Incidence in 5 Continents, give a general picture of increase, with only 4 out of 70 populations recording an average change less than .5% per year. Steep increases of the order of 3-5% per year are recorded in Asian countries, (Japan, Singapore, Israel), Asian migrants to the U.S. (Japanese, Chinese and Filipinos) and Southern Europe (Spain). Incidence data in more recent years are available from individual publications, in some high-risk countries. Most indicate continuing increases (Finland[7], Denmark[8], The Netherlands[9], Sweden[10], East Anglia- UK[11], Slovenia[12]), in others rates seem to have reached a plateau (US[13], England and Wales[14]). In some of these countries a clear change in the speed of increase can be linked to the introduction of mass screening which occurred at different times in different countries, e.g. early 80s in the U.S., 87-88 in England and Wales[14], early 1989-90 in The Netherlands[15]. That mammography is the main determinant of these sudden increases is confirmed by trends in the incidence of *in situ* cancers[10,11,13].

Trends in mortality have not consistently paralleled incidence trends everywhere; in fact, in some developed countries, mortality has been rather stable even with incidence on the increase. No overall declins in mortality were observed before the 80s, since when a smooth change of trend has been reported in some countries of Europe, North America and Australia. But the most remarkable observation is the drastic fall of mortality observed in the U.K.[14] and North America[16] in the early 90s. The fall occurs too soon after the widespread availability of mammography to be its consequence; widespread use of Tamoxifen as adjuvant therapy is likely to be the major cause of the reverse trend[17]. In addition, Tamoxifen was administered in case of recurrence of the disease even before it became a standard adjuvant. Even a modest efficacy but generalised to a large number of prevalent cases, together with simultaneous "downstaging" due to mammography, might have translated into the sudden decline of mortality. If this is the case one may predict further reduction of mortality in these populations towards the end of the century. That the impact of mammography may not be complete is suggested by trends of incidence of *in situ* cancer which, in 1995, was still on the increase in the US[13].

In addition to these phenomena it is important to recognise a further factor likely to have contributed to the diverging trends of incidence and mortality - the general shift towards earlier stages at diagnosis which was occurring in most countries well before the introduction of proper mass screening. Indirect evidence that increased women's awareness and improved accessibility to health services have contributed to the observed trends, comes from the analysis of mortality in young women, who have not been the target of screening. In the U.S., breast cancer mortality in women below 40 years has being decreasing since 1973 while incidence has been slightly increasing[13]. Secular trends of incidence by extent of the disease would be extremley helpful but are very limited. Such data could also help to clarify trends in risk of the disease from the effects of screening. This is so important as to justify *ad hoc* retrospective studies.

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TITLE: THE IBSN SURVEY: QUALITY ASSURANCE IN PRACTICE IN 22 COUNTRIES

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KEYWORDS: Screening Mammography, Quality Assurance, Health Services Organization, Technical Measures, Data Collection

BACKGROUND: To facilitate understanding and the comparison of the impact of international population-based screening mammography the International Breast Cancer Screening Network, a voluntary organization developed in 1988 to compare results from population-based screening mammography, undertook an assessment in 1998 of quality assurance policies and activities for screening mammography in its 23 member countries.

OBJECTIVE: The assessment defined the scope of quality assurance activities with detailed data collected on organization, technical measures, and data systems for program evaluation and limited data collected on diagnostic follow-up and treatment.

METHODS: The questionnaire was mailed to IBSN representatives in 23 countries and covered the organization of quality assurance activities, whether countries have in place mechanisms for site visits and accreditation, requirements for quality control and data systems, and inclusion of treatment, follow-up, and program evaluation in quality assurance activities.

RESULTS: Nearly all countries have laws, surveillance mechanisms, or standards for quality assurance that extend beyond the technical aspects of the screening mammography exam. In general high caliber quality control practices exist among population-based breast cancer screening and in associated surveillance programs. All countries but one require QC of equipment used in screening mammography with some variability noted in the tests required. All countries require that mammography programs ensure that women are notified of required diagnostic evaluation. In a few countries, quality assurance criteria for treatment of screen-detected breast cancers have been developed. A minority of countries currently assess such aspects of screening program performance as case fatality, deaths prevented and cost effectiveness. However, most indicated that they plan to do so in the future.

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TITLE: BREAST CANCER SCREENING OF HIGH RISK POPULATIONS

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BACKGROUND: Bi-annual breast cancer screening for women ages 50-74 with mammography has been underway since the end of 1996. Women of younger age are eligible for a free-of-charge mammography examination if they have a family history of a first degree relative with breast cancer. Of a total of 82,675 screening tests in 1997, 14,722 women (17.8%) reported any family history of breast cancer. Most women (9456) were over the age of 50, but 5266 (35.8%) were under that age. Breast cancer was detected in 468 of the screened women (16.6% of 2814 women detected with breast cancer in Israel in 1997).

OBJECTIVES: To evaluate if women with family history of breast cancer have a different mammography detection profile than women without family history.

METHODS: All women diagnosed with a new primary breast cancer in 1997 in Israel were investigated. Family history was available for 1081 post/peri-menopausal women of the total of 2814 women with breast cancer detected that year in Israel. The women were divided into those detected through screening (418), those missed by screening (50), those detected through clinical mammography (548) and those missed by clinical mammography (65).

RESULTS: Among the women with family history 67 breast cancers were detected through mammography screening and another 122 through clinical/diagnostic mammography. Detection rates were similar in all age groups between the women with and without family history. Recall rates were significantly higher among the women with family history than among those without family history, mainly in the older women, but only in the prevalence round. Women under the age of 50 with a family history of breast cancer tended to be missed more often by screening mammography than women of the same age without family history (30.8% vs. 15.6%, n.s.). The same was true for young women in the clinical set up (29.3% miss vs. 12.3% respectively, p=0.003). Nodal status was similar between women with and without family history, but tumor size tended to be larger in young women with family history. One third of the screen-detected tumors in women under 50 with family history were DCIS, compared to only 12.5% in those without family history.

CONCLUSIONS: Mammography in women with a family history of breast cancer seems to miss tumors more often, to call for more evaluation tests and to yield a higher proportion of tumors in the DCIS stage.

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TITLE: MONITORING AND EVALUATION OF A BREAST CANCER SCREENING PROGRAMME

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The effectiveness of breast cancer screening has been demonstrated by randomised trials, and a number of countries are now establishing population screening programmes.

It is important that a system for monitoring and evaluation of a screening programme should be designed from the outset. This will help ensure good quality data collection from the outset; completeness of data collection is a priority.

Initially, monitoring of the programme performance should include coverage of the target population, uptake of screening invitations and later the percentage re-invited within the recommended interval.

Screening outcome measures will include referral rates for assessment, biopsy rates and cancer detection rates, (both in-situ and invasive). Expected rates will vary according to whether they are for prevalent and incidence screens, and for the incident screen will depend on the screening interval. Standards or expected rates for some outcome measures can be established on the basis of experience elsewhere, but will need to take account of the setting of the particular programme: i.e. population age-structure, age-range to be invited, background incidence rates, screening frequency etc. Ideally, information on incidence and mortality rate and stage distribution of breast cancers should be available for a number of years prior to the introduction of screening.

Although the primary outcome measure of a breast screening programme is the effect on breast cancer mortality, this can be difficult to evaluate for a population based programme. Rates of interval cancers (occurring after a negative screening test) can also give an indication of the effectiveness of screening, but again completeness of data collection is essential for such rates to be meaningful.

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TITLE: QUALITY ASSURANCE IN BREAST CANCER SCREENING PROGRAMMES

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In 1985, the European Commission initiated the Europe Against Cancer (EAC) programme with the aim of reducing cancer mortality in Europe with 15% from the expected level in the year 2000. One of the most important issues was to reduce breast cancer mortality. It was therefore decided to set up one pilot mammography screening programme in each member state to learn how to perform the most optimal way of screening in the different health care environments present in the different countries. The benefits of a European Breast Screening Network include the pooling and dissemination of knowledge and expertise and a practical basis for the decision should governments consider the implementation of a national breast screening programme. To facilitate these efforts, the EAC programme established the EUropean Network of REFerence Centres for Breast Screening (EUREF) in 1993. Its office in Nijmegen, The Netherlands, is charged with the responsibility of responding to and co-ordinating quality assurance requirements in the programmes funded by the EAC programme. EUREF's main tool in standardising procedures, increasing quality assurance and improving reporting of results among the participating programmes is the implementation of the European Guidelines for Quality Assurance in Mammography Screening. This set of guidelines, prepared by working groups for each group of health care professionals involved in a breast screening programme, is currently under major revision. The third edition which will take us into the new millennium is expected in January 2000.

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TITLE: A WORLDWIDE PERSPECTIVE ON CANCER SCREENING

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Screening/early detection has been attempted as a means of reducing mortality for 10 of the 12 most common cancers, and for 6 there are ongoing programmes or randomised trials in progress.

Stomach cancer screening is carried out mainly in Japan, though there are also projects in Korea and some S. American countries. No RCT has been performed, but observational studies suggest a moderate efficacy. The reason that implementation remains limited elsewhere is the doubt concerning cost-effectiveness (low specificity of tests, and high follow up costs, for a declining cancer).

Breast cancer screening (with mammography) is widely implemented, with programmatic variation with respect to type of mammography, ages and frequency. Breast cancer is nowhere rare, and there is pressure for screening programmes in many countries. The high cost of mammographic screening has prompted research into alternatives (BSE and PE), but the relative efficacy and costs remain unclear.

Colon/Rectum cancer screening (by FOB tests) has been demonstrated to be effective in RCTs, and widely implemented in some countries (Japan, Germany). Wider implementation has been slow, because of doubts concerning cost-effectiveness of mass screening, and the possibility of better alternative methods (notably sigmoidoscopy).

Prostate cancer screening (with PSA) has been wildly popular in the USA, and the consequences in terms of a huge surge in Aincident@ cancers are well known. It seems there may now be some decline in mortality rates. No organised screening programme has yet been proposed, and it will be interesting to see if public opinion will force the issue before the results of the ongoing RCTs are available.

Cervix cancer screening, the longest established approach, works well in organised programmes or even (though very wasteful) when opportunistic screening is very intense. Most experience in low-income countries (at highest risk) has been disappointing; the reasons are technical and logistical. Two new approaches offer potential improvement; Aided Visual Inspection (VIA) and HPV testing. Both are undergoing intensive field testing in a wide range of countries.

Oral cancer screening has been a bit neglected, though implemented in a few countries (occasionally as a national programme). A formal trial of efficacy is in progress in India.

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TITLE: CERVICAL CANCER SCREENING: CURRENT PROGRAMS AND EMERGING TECHNOLOGIES

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Cervical cancer remains the second most common cancer among women, with approximately 500,000 new cases per year. A limited number of sexually transmitted human papillomavirus (HPV) types (mainly HPV 16, 18, 31 and 45) are considered necessary but not sufficient causes of cervical cancer. Cervical disease evolves from initial HPV infection to a series of cellular abnormalities called cervical intraepithelial neoplasia (CIN), which in most instances regress spontaneously. However, in a small proportion of the cases, these lesions can progress over several decades to increasingly severe lesions and cancer. Before progressing to invasive cancer, CINs are 100% curable and detectable in exfoliated cells from the cervix for many years. Periodic mass screening with pap smears has produced a major decline in the incidence and mortality from cervical cancer in several developed countries. However, it has been generally impractical or inefficient in developing regions, where mortality remains elevated and where 80% of cervical cancers still occur. Mass screening programs with cytology are limited as they require strict quality control of laboratories and thorough follow-up for treatment of lesions. Current research is aimed at developing simpler and more effective screening methods. For developing countries, visual inspection with acetic acid with or without magnification devices has recently proven to be a promising alternative. For developed countries, potentially useful techniques include automated or semi-automated cytology, liquid-based cytology with monolayer preparations, cervicography and HPV testing (either as a primary screening tool or as an adjuvant to cytology). The development of a successful program requires extensive resources and programmatic efforts, regardless of the screening method. Vaccine trials with HPV are underway and are expected to constitute the best alternative for control of cervical cancer in the future.

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TITLE: **ADAPTING QUALITY ASSURANCE TO COUNTRY SPECIFIC NEEDS: CANADA**

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Since 1988, population based provincial and territorial organised screening programs have been gradually implemented in Canada. As of today, all provinces and territories have implemented organised breast cancer screening programs. Recognizing the diversity but also the need for monitoring, outcome evaluation and a focus on quality, Health Canada has established with the provinces a National Committee on Breast cancer Screening. To support the establishment of quality assurance programs , the committee undertook the development , revision and updating of national guidelines in such areas as participation, film interpretation, follow-up process and other issues related to screening.

Following the publication in 1997 of the first edition of "*Quality Determinants of organized breast cancer screening programs*", a survey regarding the practices of quality assurance in the provincial and territorial programs was conducted in 1998. The results show that programs differ in some areas and in the degree of implementation of quality assurance activities but also have some common ground as a result of working together to develop quality determinants guidelines.

Those results can help identify the factors that influence the adoption of quality assurance programs in breast cancer screening in the context of provincially based programs. It also facilitates the setting of priorities for future quality assurance activities at the national level.

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TITLE: QUALITY CONTROL PRACTICES IN MAMMOGRAPHY SCREENING PROGRAMS IN 22 COUNTRIES

AUTHORS: R. Edward Hendrick, Ph.D. [1], Carrie Klabunde, Ph.D.[2], Rachel Ballard-Barbash, M.D., M.P.H. [2] for the IBSN Quality Assurance Working Group

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Objective: To assess current quality control (QC) practices within population-based breast cancer screening or surveillance programs internationally.

Methods: The International Breast Cancer Screening Network (IBSN) conducted an extensive survey of quality assurance (QA) activities in developed countries known to have population-based breast cancer screening or surveillance programs. Twenty-three countries were sent questionnaires that included items about QA and QC requirements at screening sites, guidelines followed, minimum frequencies of QC test performance, and personnel responsible for performing QC tests.

Results: Twenty-two countries responded with completed questionnaires between July and October 1998. Responses indicated a pattern of strong quality control practices among population-based breast cancer screening and surveillance programs. All countries but one reported requiring QC of equipment used in screening mammography, by law in 9 countries and by practice standards or the screening program in 12 countries. All countries responded positively to routine performance of processor sensitometry, screen-film contact, kVp accuracy/reproducibility, and automatic exposure control (AEC) tests. Most countries perform each of the following tests on a regular basis: collimation assessment, cassette cleaning, and beam quality measurement. All but two countries routinely perform phantom image quality, compression force, and beam entrance exposure tests. Variation among countries in the personnel responsible for performing different QC tests was observed.

Conclusions: QC practices among population-based breast cancer screening and surveillance programs are highly evolved, with the great majority of responding countries following prescribed QC protocols.

References: Ballard Barbash R, Taplin S, Yankaskas B, et.al. Breast Cancer Surveillance Consortium: a national mammography screening and outcomes database. *Am. J. Roentgenology* 1997;**169**:1001-1009.

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TITLE: QUALITY ASSURANCE IN BREAST CANCER SCREENING PROGRAMMES – IBSN PANEL

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In 1985, the European Commission initiated the Europe Against Cancer (EAC) programme with the aim of reducing cancer mortality in Europe with 15% from the expected level in the year 2000. One of the most important issues was to reduce breast cancer mortality. It was therefore decided to set up one pilot mammography screening programme in each member state to learn how to perform the most optimal way of screening in the different health care environments present in the different countries. The benefits of a European Breast Screening Network include the pooling and dissemination of knowledge and expertise and a practical basis for the decision should governments consider the implementation of a national breast screening programme. To facilitate these efforts, the EAC programme established the EUropean Network of REFerence Centres for Breast Screening (EUREF) in 1993. Its office in Nijmegen, The Netherlands, is charged with the responsibility of responding to and co-ordinating quality assurance requirements in the programmes funded by the EAC programme. EUREF's main tool in standardising procedures, increasing quality assurance and improving reporting of results among the participating programmes is the implementation of the European Guidelines for Quality Assurance in Mammography Screening. This set of guidelines, prepared by working groups for each group of health care professionals involved in a breast screening programme, is currently under major revision. The third edition which will take us into the new millennium is expected in January 2000.

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TITLE: STATE OF KNOWLEDGE ON PSA SCREENING

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Prostate cancer is a leading cause of death in developing countries. The widespread introduction of early detection or screening by Prostate Specific Antigen (PSA) has changed deeply the epidemiology of this type of cancer. In the USA a slight and stable increase in incidence till 1986 was observed, afterwards there was a sharp slope up to 1992-1993 (mainly due to the increased rate of localised tumours) which was followed by a reverse trend. To be effective screening for cancer requires a valid and acceptable test capable of detecting a high proportion of cancers in the detectable pre-clinical test, and a treatment for the detected pre-clinical neoplasm more effective at this time in the cancers' natural history than later. The PSA testing is undoubtedly capable of detecting asymptomatic disease. The first problem arises as far as the effectiveness of treatment of early detected cancers is concerned. Treatments believed to be potentially curative are radical prostatectomy and radiotherapy but it is still unknown if those treatments are more effective than conservative therapy (watchful waiting). Two trials are currently ongoing in the USA and in Scandinavia to evaluate this issue. The curative treatments can be associated with severe side effects (urinary incontinence, impotence, bowel dysfunction, perioperatory deaths). The most controversial problem is connected with the problems of over-diagnosis and over-treatment i.e. the risk that screening will detect and subsequently will treat cancers which would have never appeared. The over-diagnosis depends on the adopted cut-off for PSA and the type of screening protocol. The estimate of the magnitude of over-diagnosis is a crucial element and a complex exercise. Simple estimations seem to indicate it as a relevant problem; with the current protocols we would expect an increase in incidence of prostate cancer of more than 50%. The risk of over-diagnosis (and of over-treatment) is an obvious consequence of screening but it could be accepted in view of greater benefits and/or of limited side effects. The only established mechanism to evaluate the efficacy of screening is the randomized controlled trial. At the moment we are not able to establish the benefit of a screening for prostate cancer. Two large trials on the effectiveness of prostate screening are currently ongoing and the results will have to be carefully evaluated. In the absence of any scientific evidence of screening benefits (if any) screening should not be recommended as a current practice.

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TITLE: MICROSIMULATION MODELS FOR THE EVALUATION OF CANCER SCREENING PROGRAMS

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Modeling techniques have been found useful in the interpretation of cancer screening trials and the evaluation of cancer screening programs and the impact of these program on population-based cancer statistics. A variety of modeling approaches have been used for these purposes. Microsimulation modeling is one approach that has a number of advantages. Microsimulation models can be constructed to be detailed and flexible. This class of models easily accommodates the introduction of costs and quality-of-life parameters and is particularly well suited for the simulation screening program dissemination in the context of demographically realistic population assumptions. For these reasons microsimulation models can be used in calibration and validation studies with a greater degree of precision than is possible with many other classes of models.

In this presentation the general activities of the National Cancer Institute in supporting the development of microsimulation models for the analysis of cancer screening programs in population-based context will be described. For illustrative purposes, MISCAN-COLON, a specific microsimulation model designed to evaluate colorectal cancer screening, will be discussed. This model has been developed by the Department of Public Health at the Erasmus University, the Netherlands, with support and collaboration by NCI. The following aspects of model development will be discussed: Determination of model logic and structure; initial model parameter estimation; evaluation of model consistency; model calibration; and model validation.
Potential uses of MISCAN-COLON will be illustrated with reference to unresolved screening program and policy issues in the United States regarding colorectal cancer screening.