

On the opportunity of extending service screening by mammography to women of 40-49 and 70-74 years of age – Recommendations of a national Italian Consensus Conference

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The question of the optimal age to screen for breast cancer has been a controversial issue since at least since two decades. When recommendations to implement population based organized screening by mammography on a national basis were issued by the Italian Ministry of Health,¹ the opportunity of limiting active invitation to women aged 50-69 years became immediately the object of a fierce debate, which is still ongoing. Although it was evident that most promoters of extending screening before and beyond age 50-69 were limited by a clinical and individual point of view, and missed the cost-effectiveness aspect, a crucial issue when planning population based preventive initiatives, the question of the optimal age to screen has become popular. Criticism against the NHS is raising, pushed by experts or pseudo-experts claiming that current guidelines improperly and unethically exclude a relevant portion of the population from screening benefits. The need for a public authoritative statement on this issue, which might help to get rid of useless and unmotivated polemics, has become evident in the Italian scientific community. With this purpose, the Italian Study Group for Mammography Screening (GISMa) has organized a national consensus conference, inviting a large panel of experts in any field which might be related to the screening issue, with the final aim of producing a consensus statement which might become a reference standard for the nation. A preliminary document describing the rationale for the current guidelines, as well as the evidence causing the existing controversies, was circulated among panelists, discussed and modified, and represented the basis of discussion for the consensus conference which was held in Bologna on May 25-26, 2006. Based on the conference outcomes, a final consensus document was prepared by a writing committee and diffused. The present paper is aimed at presenting the preliminary document and the final consensus document.

Mammography screening of women aged 40-49 years

Consensus document

Existing evidence suggests that offering screening at age 40-49 is associated to a breast cancer specific mortality reduction in the range of 10-15%. This translates into approximately 1-2 saved lives per 10,000 screened women, as compared to 4-5 saved lives for women aged 50-69. Literature estimates suggest cost per life year gained to be 2-3 times higher than for women aged 50-69 years.

Lower efficacy and cost-effectiveness of mammography in this age group may be ascribed to the lower age specific incidence and to the intrinsic limitation of the test, the latter been due to a higher prevalence of radiological dense breast. This translates into a higher frequency of interval cancers. It is worth noting that such a low efficacy might also be ascribed to the design of some controlled trials, adopting an inadequate screening frequency (e.g. biennial) for the predicted duration of preclinical detectable phase. At the same time, analysis based on age “at entry” rather than “at diagnosis” might cause an overestimation of screening efficacy.

The possible use of modelling to identify high risk subgroups and to optimize screening cost effectiveness in this age group represents an important field for research. Unfortunately, currently available models (e.g. Gail) are not easily applicable and would anyhow select a small proportion of incident cancers in this age group.

Evidence on screening diagnostic performance suggest recall rates and benign/malignant surgical biopsy ratios which are comparable to those observed in older women, but the positive predictive value at screening is substantially lower, for the lower age specific incidence and the lower diagnostic anticipation, as confirmed by a lower ratio of cancers detected at screening to cancers expected in absence of screening.

The possibility of improving screening sensitivity with new technologies (e.g. digital mammography, CAD) or associated tests (e.g. ultrasonography, MRI) needs further confirmation from proper controlled studies, as to their efficacy and feasibility.

The risk of radioinduced breast cancer, whatever cautious modelling estimates may be, has to be taken into account, particularly for younger women, although it does not strictly contraindicate the use of mammography in this

age group, if dedicated instruments fulfil international recommended technical and quality assurance standards, and are regularly controlled.

As far breast lesions detected at screening are concerned, identifying the optimal treatment is of paramount importance also in this age group, particularly for “early” lesions (ADH, LCIS, DCIS, pT1a-b), in order to avoid the risk of overdiagnosis and overtreatment.

Recommendations:

1. It is a priority to implement and consolidate properly organized high quality screening for women of 50 years of age or older and to fulfil recommendations provided by law (138/04) and by the National plan for Prevention for the years 2005-2007, that is implementing screening for cervical and colorectal cancer on the whole national territory.
2. Action must be taken to rule spontaneous request for screening in this age group, granting a) the access to integrated and optimised diagnostic protocols, and b) continuous outcome monitoring and quality assurance of diagnostic-therapeutic procedures. Full involvement of Screening and Breast Units is fundamental, as it encourages to use the same protocols, allows for controlling appropriate access criteria and modalities, involving general practices. Agreed diagnostic-therapeutic protocols must be provided, and standards and indicators must be identified which may enable to evaluate performances, similarly to what already exists for screening of women aged 50-69.
3. In order to optimize and qualify diagnostic-therapeutic protocols it is fundamental that existing screening Units, with their know-how and qualified structures, are equipped to manage spontaneous screening demand.
4. Extension of organized screening to resident women aged 40-49 years, though not recommended, may be considered a) in settings where organized screening of women aged 50-69 years has been fully implemented, b) where sufficient resources are available, and c) if priority is given to women aged 45-49 years: in fact, even in absence of significant evidence, screening benefits and a favourable cost-effectiveness balance is likely to concentrate in the latter subgroup.
5. screening of women aged 40-49 years must anyhow fulfil the following conditions:
 - women must receive complete and accurate information, to ensure proper communication and informed consent, also with the involvement of general practices
 - screening should be annual, with two view mammography and double reading
 - accurate monitoring of diagnostic and therapeutic procedures should be provided
 - participation to co-operative prospective studies should be encouraged

Mammography screening of women aged 70-74 years

Consensus document

Limited published evidence provides insufficient evidence on screening efficacy in this age group, but the characteristics of this subgroup (good life expectancy and high cancer incidence and mortality) and of the screening test (expected high sensitivity of mammography), as well as simulation models, may suggest the following recommendations

- Extension of organized to women aged 70-74 years is recommended if resources are available
- Extension of screening beyond age 70 is recommended, as a minimal target, at least in regular screening attenders up to age 69

If screening extension is not feasible, alternative options must be considered to allow screening continuation for regular attenders up to age 69 (e.g. programming last screening invitation after 70th birthday, or facilitating spontaneous access to opportunistic screening within the organized programme).

Careful attention must be paid to the problem of breast cancer undertreatment in elderly women, which often occurs both for surgery, radiotherapy, and chemotherapy, by implementing impact evaluation and monitoring procedures to include the 70-74 years age group.

This document summarizes the conclusions of the Consensus Conference on “Mammography screening in 40-49 and 70-74 years age groups”, organized by the Italian Group for Mammography Screening (GISMa), held in Bologna on May 25-26, 2006,

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