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EUROPEAN COMMISSION INITIATIVE ON BREAST CANCER

RECOMMENDATIONS



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QUESTION

If you are aged 40 to 44, should you attend an organised mammography screening programme?

RECOMMENDATION

The ECIBC's Guidelines Development Group suggests that women between 40 and 44 years old, who are not at high risk of breast cancer and do not have symptoms, should not have mammography screening.



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ASSESSMENT

| | |
|----------------------|--|
| POPULATION | Women aged 40 to 44 |
| INTERVENTION | organised mammography screening |
| COMPARISON | no mammography screening |
| MAIN OUTCOMES | Breast cancer mortality (short case accrual); Breast cancer mortality (longest case accrual available); All-cause mortality; Other cause mortality; Stage IIA breast cancer or higher; Stage III+ breast cancer or tumour size ≥ 40 mm; Rate of mastectomies; Provision of chemotherapy; Overdiagnosis (long case accrual); Quality of life (inferred from psychological effects); False-positive related adverse effects (psychological distress); and False-positive related adverse effects (biopsies and surgeries) |
| SETTING | European Union |
| PERSPECTIVE | Population (National Health System) |
| BACKGROUND | Although mammography screening has both potential benefits and harms, many countries have organised programmes for women aged 50 or older. However, there continues to be debate about recommendations for mammography screening (Jorgensen 2009, Arie 2014) particularly for women aged 40 to 49 (Petitti 2010). |



JUDGEMENTS

Is the problem a priority?

- No
- Probably no
- Probably yes
- Yes
- Varies
- Don't know

Breast cancer is the second most common cancer in the world and, by far, the most frequent cancer among women with an estimated 1.67 million new cancer cases diagnosed in 2012—accounting for 25% of all cancers (GLOBOCAN 2012). Breast cancer ranks as the fifth leading cause of cancer death worldwide and the second leading cause of cancer-related death in developed regions (GLOBOCAN 2012). In the European Union, 367 090 women were diagnosed with breast cancer and 92 000 women died from the disease in 2012 (Ferlay 2013). Breast cancer ranks fourth among the top five cancers with the highest disease burden (Tsilidis 2016). Annual incidence of breast cancer in the EU, in women aged 40 to 44 is 1.2 per 1 000 and mortality is 0.1 per 1 000 (GLOBOCAN 2012)



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How substantial are the desirable anticipated effects?

- Trivial
- Small
- Moderate
- Large
- Varies
- Don't know

| Outcomes | ? of participants (studies) Follow up | Certainty of the evidence (GRADE) | Relative effect (95% CI) | Anticipated absolute effects* (95% CI) | |
|--|--|---------------------------------------|-------------------------------------|--|--|
| | | | | Risk with no mammography screening | Risk difference with organised mammography screening |
| Breast cancer mortality (short case accrual) for women aged 40 to 44 follow up: mean 16.8 years | 348306 (8 RCTs) | ???? MODERATE ^{a,b,c} | RR 0.89 (0.79 to 1.01) | Low 400 per 100,000 ^d | 44 fewer per 100,000 (84 fewer to 4 more) |
| | | | | High 700 per 100,000 ^e | 77 fewer per 100,000 (147 fewer to 7 more) |
| Breast cancer mortality (longest case accrual available) for women aged 40 to 44 follow up: mean 15.2 years | 348076 (8 RCTs) | ???? MODERATE ^{a,b,c} | RR 0.92 (0.83 to 1.02) | Low 480 per 100,000 ^d | 38 fewer per 100,000 (82 fewer to 10 more) |
| | | | | | |
| Other cause mortality follow up: mean 10.8 years | 290417 (6 RCTs) | ???? VERY LOW ^{a,b,c,f} | RR 1.04 (0.95 to 1.15) | Low 2,500 per 100,000 ^d | 100 more per 100,000 (125 fewer to 375 more) |
| | | | | | |
| Breast cancer stage IIA or higher follow up: mean 13.6 years ^g | 455283 (5 RCTs) | ???? VERY LOW ^{b,c,h} | RR 0.88 (0.78 to 0.99) | Low 380 per 100,000 ^d | 46 fewer per 100,000 (84 fewer to 4 fewer) |
| | | | | | |
| Breast cancer stage III+ or tumour size ≥40 mm follow up: mean 13.5 years ^g | 274219 (4 RCTs) | ???? LOW ^{a,b,c} | RR 0.98 (0.74 to 1.29) | Low 90 per 100,000 ^d | 2 fewer per 100,000 (23 fewer to 26 more) |
| | | | | | |
| Rate of mastectomies | 250479 (5 RCTs) | ???? LOW ^{a,b,i} | RR 1.20 (1.11 to 1.30) ^j | Low 900 per 100,000 ^d | 180 more per 100,000 (99 more to 270 more) |
| | | | | | |
| Provision of chemotherapy | 100383 (2 RCTs) | ???? VERY LOW ^{b,c,i,k,l} | RR 0.86 (0.52 to 1.41) ^j | Low 400 per 100,000 ^d | 56 fewer per 100,000 (192 fewer to 164 more) |
| | | | | | |
| Overdiagnosis (long case accrual) | 0 (1 RCT) | ???? MODERATE ^b | - | 12.4% (95% CI 9.9%-14.9%) ^m | |
| Quality of life | 0 | ???? | - | Systematic review with 54 studies, | |



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| | | | | Risk with no mammography screening | Risk difference with organised mammography screening |
| (inferred from psychological effects) ⁹ | (54 observational studies) | LOW ⁿ | | no meta-analysis (Brett 2005). Mammographic screening does not appear to create anxiety in women who are given a clear result after a mammogram and subsequently placed on routine recall. Mixed results about anxiety in women recalled for further testing: several studies reported transient or long term (from 6 months to 1 year after recall) anxiety, while other studies reported no differences in anxiety levels. The nature and extent of further testing seem to determine the extent of anxiety. | |
| False-positive related adverse effects (psychological distress) ⁹ | 0 (7 observational studies) | ???? LOW | - | RR of psychological distress in women with a false-positive mammogram was compared to those with a normal mammogram 35 months after the last assessment (age of women was not specified). For women that needed further mammography: RR=1.28, 95%CI 0.82-2.00; For women placed in early recall: RR=1.82, 95%CI 1.22-2.72; For women that needed a fine needle puncture aspiration: RR=1.80, 95%CI 1.17-2.77; For women that needed a biopsy: RR=2.07, 95%CI 1.22-3.52. No differences in generic measures of general anxiety and depression were observed at 6 weeks after assessment and 3 months after screening Bond (2013). | |
| False-positive related adverse effects (biopsies and surgeries) ⁹ | 0 (4 observational studies) | ???? VERY LOW ^o | - | Results from literature review (4 studies, 390 000 women aged 50 to 69) show an, overall false-positive screening result of 19.7% in women undergoing 10 biennial screening tests (pooled risk estimate based on 3 studies; range 8 - 21%). This includes 2.9% pooled cumulative risk of an invasive procedure with benign outcome (range 1.8% to 6.3%; based on 2 studies) and 0.9% risk of undergoing surgical intervention with benign outcome (based on 1 study) (Hofvind 2012). Cross-sectional data from the EUNICE Project (women aged 50 to 69): 17 countries, 20 screening programmes, 1.7 million initial screens, 5.9 million subsequent screens; showed that 2.2% and 1.1% of all screening examinations resulted in needle biopsy among women without breast cancer (initial and subsequent screens, | |



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| | | | | respectively). In addition, 0.19% and 0.07% of all screening examinations resulted in surgical interventions among women without breast cancer (initial and subsequent screens, respectively). | |

1. Some studies did use methods that would not be accepted for random allocation today. One study had non-blinded assessment of 'cause of death'. The GDG felt that the CNBSS-1 possibly had issues with achieving prognostic balance. The GDG felt that lack of allocation concealment in this set of studies did not lead to high risk of bias. Given the lack of single trials driving the overall results and similarity in effect sizes (the test for subgroup differences - low vs high risk of bias trials - was non-significant) and overlapping confidence intervals (CIs), the risk of bias was rated as 'not serious'.
2. Trials were conducted more than 20 years ago. Currently, women have higher adherence to breast cancer screening and the quality control of screening and breast cancer care have improved. A large non-randomised study (Hellquist B 2011) showed a reduced risk for breast cancer deaths in women aged 40 to 49 years invited to screening, compared with women not invited (RR=0.74; 95%CI, 0.66-0.83) which is consistent with RCT results. The GDG did not rate downgrade for indirectness for breast cancer mortality but considered it serious for other outcomes.
3. 95% CI probably crosses the clinical decision threshold (as the CI is wide, a different clinical decision regarding the intervention may be taken depending on whether the lower or the higher limit is considered).
4. Median or mean of the control group of the included studies unless otherwise specified
5. Baseline risk calculated from the ITACAN database. <http://itacan.ispo.toscana.it/italian/itacan.htm>
6. Unexplained inconsistency with statistical heterogeneity ($I^2 = 62\%$, $P = 0.02$).
7. Importance of the outcome was lowered from 'critical' to 'important' because the GDG members felt this outcome influenced neither the direction nor the strength of the recommendation.
8. Some studies were sub-optimally randomised and had non-blinded assessment of stage of disease. However, test for subgroup differences - low vs high risk of bias trials - was non-significant.
9. Population included women aged 40-74 years old. Therefore, a much broader age range than the 40-44 age group studied here. Observational studies do not confirm these results, instead they provide opposite results.
10. Due to lead time, there may be greater numbers of cancers to be treated in the screened group, during the period of observation, which may lead to an increased rate of chemotherapy and mastectomies in the screened group
11. Unexplained inconsistency with statistical heterogeneity ($I^2 = 71\%$, $P = 0.06$).
12. Chemotherapy protocols and indications have significantly changed (e.g. node status was not determined in earlier studies).
13. The Independent UK Panel on Breast Cancer Screening (2012) calculated overdiagnosis from the CNBSS-1 trial, in which women in the control group were not offered mammography screening at the end of the trial. Excess cancers as a proportion of cancers diagnosed during follow-up in women invited for screening (population perspective).
14. Unexplained inconsistency for variability in anxiety in the group of women recalled for further testing.
15. Studies included women aged 50 to 69. Estimates for the 40 to 44 age stratum are likely to be higher.

Desirable effects

Eight trials of invitation to mammography screening provided breast cancer mortality data from 347 851 women <50 years (short case accrual). Mammography using short case accrual, compared to no screening, did not significantly reduce the risk of breast cancer mortality (Relative Risk (RR)= 0.89, 95% CI 0.79-1.01; Inconsistency (I^2)=0%, $p=0.48$) (moderate quality evidence). This translates into an absolute effect, using 'short case accrual' with a mean follow-up of 16.8 years of 77 fewer breast cancer deaths per



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100 000 (with a range from 7 more to 147 fewer deaths), and 44 fewer breast cancer deaths per 100 000 (with a range from 4 more to 84 fewer breast cancer deaths), using a 0.7% and 0.4% baseline risk, respectively.

Other methods for calculating absolute effects on breast cancer mortality may be used (more information can be found in the annex accompanying the evidence profile).

With regards to mammography using the 'longest case accrual' available, no reduction in breast cancer mortality was observed (RR=0.92, 95% CI 0.83-1.02; I²=6%, p=0.38) (moderate quality evidence). Mammography, compared to no screening, reduced the risk of stage IIA breast cancer or higher (RR=0.88 95% CI 0.78-0.99; I²=0%, p=0.54; 46 fewer cases of stage IIA breast cancer per 100 000 women during mean 13.6 years of follow up, from 4 to 84 fewer cases) (very low quality evidence). Furthermore, screening did not reduce the risk of all cause mortality (RR=1.01, 95% CI 0.94-1.08; I²=44%, p=0.10) (low quality evidence), other cause mortality (RR=1.04, 95% CI 0.95-1.15; I²=62%, p=0.02) (very low quality evidence), stage III+ breast cancer cases or tumour size \geq 40 mm (RR=0.98, 95% CI 0.74-1.29; I²=0%, p=0.56) (low quality evidence).

Undesirable effects

Although no specific information for this age stratum was identified, women aged 40 to 74 randomised to 'invitation to screening' were more likely to undergo mastectomy (RR=1.20, 95% CI 1.11-1.30; I²=0%, p=0.86; 180 more mastectomies per 100 000 women, from 99 to 270 more mastectomies) (low quality evidence). Estimates of overdiagnosis from one randomised clinical trial (RCT) (CNBSS-1) were 12.4% (95% CI 0.9.9%-14.9%) (moderate quality evidence) from a population perspective (long case accrual). From the perspective of a woman invited to screening, the proportion of overdiagnosed women was 22.7% (95% CI 18.4%-22.7%) (moderate quality evidence).

Mammography screening, compared with no screening, did not increase the number of women aged 43 to 74 treated with chemotherapy (RR=0.86, 95% CI 0.52-1.41; I²=71%, p=0.06) (very low quality evidence).

A systematic review of observational studies (Brett 2005) reported that women who had further testing following their routine mammogram experienced significant short-term anxiety. A systematic review by Hofvind (2012), reported that the estimated cumulative risk of a false-positive screening result in women aged 50 to 69 undergoing 10 biennial screening tests was 19.7%. In addition, the EUNICE Project showed that 2.2% of women had a needle biopsy after an initial screening mammogram. False-positive mammograms are also associated with greater anxiety and distress about breast cancer (Salz 2010). Furthermore, the negative psychological consequences may last up to three years (Bond 2013) (low quality evidence).



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Additional considerations

These studies used an 'intention-to-treat' analysis thus, a per protocol approach would lead to larger absolute effects.

GDG members mentioned that modelling studies describing quality and duration of 'life gained' should be considered.

Long case accrual may dilute the effect of the intervention as for some trials it will include cases diagnosed after closure of the trial when both arms are receiving the same intervention. Therefore, we performed a sensitivity analysis including only studies that reported long case accrual estimates and we observed a small although not significant diluting effect (RR 0.93; 95% CI 0.84 to 1.03).

GDG members agreed that the desirable health effects differ by age group and the age at first screening. For women in the 40 to 44 age group, the GDG agreed these women would have smaller anticipated beneficial health effects compared to older age groups.

Observational data provided supplementary evidence supporting the RCT evidence (see evidence profile).

Test accuracy is poorer in younger women, largely due to mammographic breast density. Digital mammography, which was not in use at the time of most of the studies reviewed here, may result in greater test accuracy in women aged 40 to 44.

In the Sweden Mammography Screening of Young Women (SCRY) cohort, which compared breast cancer mortality between women invited and not invited to screening; RRs of 0.82 (95% CI, 0.67-1.00) and 0.63(95% CI, 0.54-0.75) for the age groups of 40 to 44 and 45 to 49 years were respectively reported. The weighted RR for the 40 to 49 years did not differ from the unweighted estimate of 0.71 (95% CI, 0.62-0.80).



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Desirable effects

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Additional considerations

Overdiagnosis and its magnitude are not greatly influenced by age at first screening.

Overdiagnosis estimates from both CNBSS1 and CNBSS2 may have been overestimated by subsequent screening in the population (both organised and opportunistic) after screening ceased in the CNBSS in 1988. Thus, while at 25 years of follow-up a non-statistically significant excess of all breast cancers was observed in the intervention arm of CNBSS trials (difference 2.6; 95%CI -0.8 to 5.9), the excess rate of in-situ/invasive breast cancers actually increased over the first-years post-screening in the CNBSS1, and dramatically decreased after the 10 years post-screening in the CNBSS2.

Due to lead time (diagnosis time being brought forward with screening), there may be greater numbers of cancers to be treated in the screened group, during the period of observation, which may lead to an increased rate of chemotherapy and mastectomies in the screened group.

False-positive rates have been observed to be higher in women under age 50 than in women aged 50 to 69.

The number of false-positives will depend on the age of first screening. The GDG considered this effect to be large. Radiation risk is higher in younger women.

The radiation exposure and associated risk is dependent on the screening method and frequency that, in turn, will influence the balance of benefits and harms.



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What is the overall certainty of the evidence of effects?

- Very low
- Low
- Moderate
- High
- No included studies

The overall certainty (i.e. quality) of the evidence was considered moderate, as this was the lowest quality among the critical outcomes—namely, breast cancer mortality and overdiagnosis.



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Is there important uncertainty about or variability in how much people value the main outcomes?

- Important uncertainty or variability
- Possibly important uncertainty or variability
- Probably no important uncertainty or variability
- No important uncertainty or variability
- No known undesirable outcomes

A systematic review shows that participants place a low value on the psychosocial and physical effects of false-positive results and overdiagnosis (JRC Technical Report PICO 10-11, contract FWC443094012015; available upon request). Women generally consider these undesirable effects acceptable (low confidence in evidence). However, these findings are of limited value mainly given the significant concerns regarding the adequacy of the information provided to women, in order to make an informed decision about participation. Also, acceptability of false positive results is based on studies of participants who have already received a false positive result. Their preferences may differ from the general population. Another finding is that breast cancer screening represents a significant burden for some participants due to the associated psychological distress and inconvenience (moderate confidence in evidence).

Regarding breast cancer diagnosis, very limited data is available addressing people's views. One of the main themes identified in the literature is that people disvalue highly the anxiety caused by delays in receiving diagnostic results, or by a lack of understanding of the tests due to suboptimal communication with physicians (moderate confidence in evidence). Also, people have a higher overall preference towards more comfortable, brief diagnostic procedures (moderate confidence in evidence). (JRC Technical Report PICO 10-11, contract FWC443094012015; available upon request)



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Does the balance between desirable and undesirable effects favor the intervention or the comparison?

- Favors the comparison
- Probably favors the comparison
- Does not favor either the intervention or the comparison
- Probably favors the intervention
- Favors the intervention
- Varies
- Don't know

Additional considerations

GDG members agreed that the balance of desirable and undesirable health effects for starting screening at age 40 probably favours the comparison (no screening), as the intervention has large undesirable effects and small desirable effects.



European Commission

How large are the resource requirements (costs)?

- Large costs
- Moderate costs
- Negligible costs and savings
- Moderate savings
- Large savings
- Varies
- Don't know

Differences in required resources for mammography screening versus no screening in women aged 40 to 49 in the studies analysed may be related to the inclusion or not of costs related to the screening process, diagnostic techniques, treatment and follow-up of diagnosed women (Madan, 2010 and Sankatsing, 2015).

Based on the results of Sankatsing et al. (2015), the total cost of breast cancer diagnosis, treatment and death in the absence of screening was estimated to be €1 161 008 per 1 000 women, followed over their lifetime. The total cost of extended biennial screening in women aged 40 to 49 would increase to €306 590 per 1 000 women (using a 3.5% discount rate).

Additional considerations

Varies by screening interval and by country and by the presence of opportunistic screening.

GDG members judged the cost to be at least moderate.

However, substantial differences could be observed in European countries without population-based screening programmes or in those programmes with different screening policies.

Estimates refer to organised screening programmes.

Local/regional/country level resource/cost analyses exist or are required to estimate the cost for each setting.



European Commission

What is the certainty of the evidence of resource requirements (costs)?

- Very low
- Low
- Moderate
- High
- No included studies

The certainty of the evidence of resource requirements is low due to the study design of the included study (Sankatsing 2015). This was a modelling study based on observational data from a biennial screening programme using digital mammography. Based on this data, total cost per round of biennial screening in the Netherlands would be €61.3 (value of 2014).

The formal assessment of the certainty in the evidence for cost and resources used was made using GRADE criteria and reported in the Evidence Profile (JRC Technical Report PICO 14-15, contract FWC443094012015; available upon request).

Additional considerations

The study assessed the extension (i.e. starting at age 40 as compared to age 50) of a current population-based screening programme. As previously stated, substantial differences could be observed in European countries without population-based screening programmes or in those programmes with different screening policies.



European Commission

Does the cost-effectiveness of the intervention favor the intervention or the comparison?

- Favors the comparison
- Probably favors the comparison
- Does not favor either the intervention or the comparison
- Probably favors the intervention
- Favors the intervention
- Varies
- No included studies

Based on the evidence provided by Sankatsing et al. (2015), the extension of biennial mammography screening starting at age 40 appears to be cost-effective at a 'willingness-to-pay' of €20 000 per Life Year Gained (LYG) with an Incremental Cost-Effectiveness Ratio (ICER) of €10 826 per LYG starting at age 40 instead of age 45.

Additional considerations

GDG members agreed that cost-effectiveness is likely to vary across European countries, in particular with respect to countries without population-based screening programmes or across programmes with different screening policies.



European Commission

What would be the impact on health equity?

- Reduced
- Probably reduced
- Probably no impact
- Probably increased
- Increased
- Varies
- Don't know

Additional considerations

A systematic review on this topic has not been conducted. However, the utilisation of cancer screening services may largely depend on the availability of national public screening programmes; although European findings highlight that inequalities are larger in countries without population-based screening programmes (Palència, 2010).



European Commission

Is the intervention acceptable to key stakeholders?

- No
- Probably no
- Probably yes
- Yes
- Varies
- Don't know

A systematic review (JRC Technical Report PICO 16-17, contract FWC443094032016; available upon request) found the following barriers associated with breast cancer screening: (a) lack of knowledge and misperceptions regarding preventive medicine and breast health (high confidence in evidence), (b) poor communication skills of healthcare providers (high confidence in evidence), (c) poor accessibility to breast screening, especially among women with disabilities (high confidence in evidence), (d) fear and stress related to the procedure and the possibility of cancer diagnosis (high confidence in evidence), (e) pain and discomfort during the procedure (moderate confidence in evidence), (f) embarrassment and shyness during the procedure (moderate confidence in evidence), (g) lack of support and encouragement from family members, caregivers and social network (moderate confidence in evidence), (h) lack of information regarding the available resources (low confidence in evidence) and (i) low prioritisation of breast cancer screening (low confidence in evidence).

Additional considerations

Some GDG members described some professional groups may find a screening programme not acceptable due to their financial interests.



European Commission

Is the intervention feasible to implement?

- No
- Probably no
- Probably yes
- Yes
- Varies
- Don't know

Additional considerations

A systematic review on this topic has not been conducted. Some countries do not have screening programmes mainly due to lack of resources and/or infrastructure. Given that this recommendation would be additive to screening in older age groups (45 to 69), it was judged as being probably feasible to implement.



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CONCLUSIONS

If you are aged 40 to 44, should you attend an organised mammography screening programme?

| TYPE OF RECOMMENDATION | Strong recommendation against the intervention | Conditional recommendation against the intervention | Conditional recommendation for either the intervention or the comparison | Conditional recommendation for the intervention | Strong recommendation for the intervention |
|--------------------------------------|--|---|--|---|--|
| RECOMMENDATION | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| JUSTIFICATION | The ECIBC's Guidelines Development Group suggests that women between 40 and 44 years old, who are not at high risk of breast cancer and do not have symptoms, should not have mammography screening. | | | | |
| SUBGROUP CONSIDERATIONS | This recommendation does not apply to high-risk women (see recommendations for women with high breast density). | | | | |
| IMPLEMENTATION CONSIDERATIONS | GDG members agreed on the need for additional imaging techniques in this age group, as well as the need for shared decision making. | | | | |
| MONITORING AND EVALUATION | Future monitoring and evaluation of screening services should consider benefits and risks in the context of evolving treatment and management protocols. Monitoring and evaluation criteria are being developed within the ECIBC initiative. | | | | |
| RESEARCH PRIORITIES | 1. Carry out evaluations of the efficacy of the intervention, time intervals, risk factors and stratification of women, as well as context specific cost-effectiveness in this age group. 2. Carry out studies addressing the role of other screening modalities (e.g. MRI) in this population. | | | | |



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Acceptability

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