	with a potential increase in mortality, serious adverse effects, and very low certainty of the evidence. For patients with extensively drug-resistant (XDR) tuberculosis and limited, if any other options, the desirable effects probably outweigh the undesirable effects.
Subgroup considerations	Bedaquiline is only suggested for patients with extensively drug-resistant MDR TB under the specified conditions.
Implementation considerations	• A process to ensure informed decision-making by patients should be established. • Equipment for baseline testing and monitoring for QT prolongation and development of arrhythmia should be available. • Monitoring of cardiac and liver disease should be available.
Monitoring and evaluation	• Spontaneous reporting of adverse drug reactions should be reinforced at country level and active pharmacovigilance should be established among patient groups treated with the drug. • Resistance to bedaquiline should be monitored. • Resistance to other anti-TB drugs should be monitored following WHO recommendations.
Research priorities	• Phase 3 clinical trial(s) of safety and efficacy of bedaquiline, with particular attention to mortality (including causes of death), in the treatment of MDRTB should be accelerated • Pharmacokinetics, safety and efficacy studies in specific populations (paediatrics, HIV patients, alcohol and drug users, elderly, pregnant women, extrapulmonary TB, persons with diabetes) • Safety studies, including type, frequency and severity of adverse events (short term and long term) • Drug-drug interactions, including with other existing and newly developed TB drugs and ARVs • Impact on mortality (including cause of death) • Acquisition of resistance to bedaquiline and to other TB drugs • Duration and dosing of treatment • Patients' values • Further research on the validity of culture conversion as a surrogate marker of treatment outcome

6. WHO Interim policy recommendations

In view of the aforementioned evidence assessment and advice provided by the EG, WHO recommends that ***bedaquiline may be added to a WHO-recommended regimen in adult patients with pulmonary MDR-TB (conditional recommendation, very low confidence in estimates of effects).***

Given the limited data available on bedaquiline and its use under the various situations that may be encountered in different clinical settings, adequate provisions for safe and effective use of the drug must be in place. Consequently, countries are advised to follow a phased approach to bedaquiline implementation, ideally through observational

5. **Pharmacovigilance and proper management of adverse drug reactions and prevention of drug–drug interactions.**
    a. Special measures need to be put in place to ensure the early detection and timely reporting of adverse events using active pharmacovigilance methods, such as 'cohort event monitoring'. Any adverse drug reaction attributed to bedaquiline should also be reported to the national pharmacovigilance centre as part of the spontaneous reporting mechanism in the country. As for any other drug in the MDR-TB regimen the patient should be encouraged to report to the attending health worker any adverse event that occurs during the time the drug is being

Acknowledgements

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- The Cochrane Qualitative and Implementation Methods Group

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- The Research Council of Norway
- The Cochrane Methods Innovation Fund

GRADE

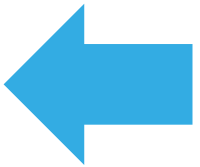
GRADE CERQual

Breast Cancer screening recommendations for different age groups by the European Commission

For asymptomatic women aged **40 to 44** with an average risk of breast cancer, the ECIBC's Guideline Development Group (GDG) **suggests not implementing mammography screening** (conditional recommendation, moderate certainty in the evidence).

For asymptomatic women aged **45 to 49** with an average risk of breast cancer, the ECIBC's Guideline Development Group (GDG) **suggests mammography screening** over no mammography screening, in the context of an organised screening programme (conditional recommendation, moderate certainty in the evidence).

For asymptomatic women aged **50 to 69** with an average risk of breast cancer, the ECIBC's Guideline Development Group (GDG) **recommends mammography screening** over no mammography screening, in the context of an organised screening programme (strong recommendation, moderate certainty in the evidence).



For asymptomatic women aged **70 to 74** with an average risk of breast cancer, the ECIBC's Guideline Development Group (GDG) **suggests mammography screening** over no mammography screening, in the context of an organised screening programme (conditional recommendation, moderate certainty in the evidence).

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Question

Should organised mammography screening vs. no mammography screening be used for early detection of breast cancer in women aged of 50 to 69?

Population: Women aged of 50 to 69

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. A reassessment of the evidence for screening women aged 50 to 69 is appropriate considering advances in diagnosis and treatment of breast cancer.

Management of Conflicts of Interests (CoI): CoIs of all Guideline Development Group (GDG) members were assessed and managed by the Joint Research Centre (JRC) following an established procedure in line with European Commission rules. GDG member participation in the development of the recommendations was restricted, according to CoI disclosure. Consequently, for this particular question, the following GDG members were recused from voting: Mireille Broeders, Roberto d'Amico, Jan Danes, Patricia Fitzpatrick, Axel Gräwingholt, Elsa Pérez Gómez, Ruben van Engen, Cary van Landsveld-Verhoeven, and Kenneth Young.
For more information please visit: http://ecibc.jrc.ec.europa.eu/gdg-documents

Assessment

	CRITERIA	JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
PROBLEM	**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 for25% 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 (citation). 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).	

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Question

Should organised mammography screening vs. no mammography screening be used for early detection of breast cancer in women aged of 50 to 69?

Assessment

	CRITERIA	JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
PROBLEM	**Is the problem a priority?**	○ No ○ Probably no ○ Probably yes ◉ Yes ○ Varies ○ Don't know Detailed judgements	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 for25% 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 (citation). 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 among women aged 50 to 69 is 2.7 per 1 000 and mortality is 0.5 per 1 000 (GLOBOCAN 2012)	
	How substantial are the desirable anticipated effects?	○ Trivial ○ Small ○ Moderate ◉ Large ○ Varies ○ Don't know Detailed judgements	**Desirable effects** Six trials of invitation to mammography screening provided breast cancer mortality data from 249 160 women aged 50 to69 (short case accrual). Mammography (using short case accrual), compared to no screening, reduced the risk of breast cancer mortality (Relative Risk (RR)=0.76, 95% CI 0.64-0.90; Inconsistency (I2)=52%, p=0.06) (high quality evidence). This translates into an absolute effect of 144 fewer breast cancer deaths per 100 000 women invited to screening over 18 years (range: 60 to 216 fewer deaths). Mammography screening also reduced breast cancer mortality using 'longest case accrual available' (RR=0.78, 95% CI 0.67-0.90; I2=54%, p=0.05; resulting in 167 fewer breast cancer deaths per 100 000 women over 17.3 years, from 76 to 251 fewer) (high quality evidence) and stage III+ breast cancer or tumour size ≥ 40 mm	These studies used an 'intention-to-treat' analysis thus, a per protocol approach would lead to even larger absolute effects. Estimates from observational studies were similar to those described here (see evidence profile). As there was disagreement among GDG members regarding whether the effects were large or moderate, voting took place among the 18 GDG members: 15 GDG members voted that the effects were large. Two GDG members voted that the effects were moderate. One

UNDESIRABLE EFFECTS	**How substantial are the undesirable anticipated effects?**	○ Large ◉ Moderate ○ Small ○ Trivial ○ Varies ○ Don't know Detailed judgements	overdiagnosis from two randomised clinical trials (RCTs) were 10.1% (95% CI 8.6%-11.6%; I2=0%, p=0.61) (moderate quality evidence) from a population perspective (long case accrual). From the perspective of women invited to screening, the proportion of overdiagnosed women was 17.3% (95% CI 14.7-20.0; I2=10%, p=0.29) (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 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).	
TY OF EVIDENCE	**What is the overall certainty of the evidence of effects?**	○ Very low ○ Low ◉ Moderate ○ High	The overall certainty (i.e. quality) of the evidence was moderate, as this was the lowest quality (corresponding to the quality of the evidence for overdiagnosis) of the two critical outcomes—namely, breast cancer mortality and overdiagnosis.	Effects of chemotherapy and mastectomy were not considered to change the recommendation, and thus did not critically influence the overall certainty in the evidence.

VALUES

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

Detailed judgements

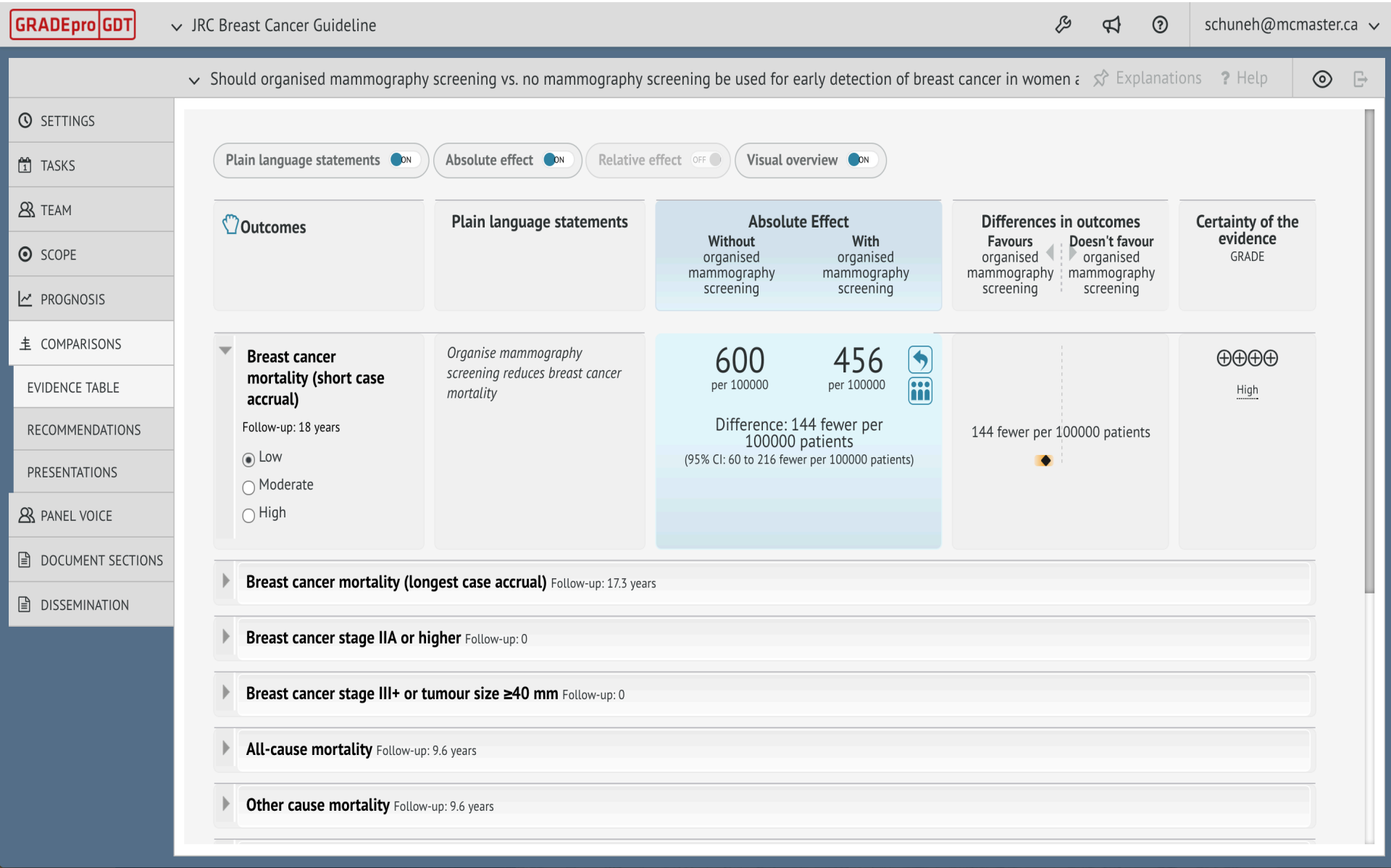
A systematic review (JRC Technical Report PICO 10-11, contract FWC443094012015; available upon request) shows that women placed little value on the psychosocial and physical effects of false-positive results and overdiagnosis. However, women generally consider these undesirable effects acceptable (low confidence in evidence). These findings are of limited value mainly given the significant concerns regarding the adequacy of the information provided to the participants, in order to make an informed decision. Another finding is that breast cancer screening represents a significant burden for some women due to associated psychological distress and inconvenience (moderate confidence in evidence).

Also, acceptability of false-positive results is based on studies of patients who have already received a false-positive result and, whose preferences may differ from the general population.

Regarding breast cancer diagnosis, very limited data is available addressing patients' views. One of the main themes identified in the literature is that patients have a high disregard for anxiety caused by delays in receiving diagnostic results from or by a lack of understanding of the tests due to suboptimal communication with physicians (moderate confidence in evidence). Also, women have a higher overall preference towards more comfortable, brief diagnostic procedures (moderate confidence in evidence).

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 Detailed judgements	**The relative importance of the outcomes is as follows:** **Pulmonary embolism: 0.63-0.93** **Deep vein thrombosis: 0.64-0.99** **Deep vein thrombosis patients' own current health: 0.95 (Time trade off)** Patients highly value the benefits of VTE risk reduction of VTE prophylaxis; patients would like to avoid adverse events but most of them are "not afraid of" the adverse events. For patients using mechanical methods to prevent VTE, in general patients would like to continue with the same methods. However, discomfort with the mechanical methods is a major complaint with this intervention. Most patients prefer knee-length stockings rather than thigh-length stockings.	The tolerability of the stockings was described as very good with no complaints of side effects. None of the other trials reported adverse effects of wearing the stockings (**Clarke et al., 2016**). For patients using any mechanical methods to prevent VTE, in general, they would like to continue with the same methods. Most patients prefer knee-length stockings rather than thigh-length stockings.

The panel evaluated the effects of screening



In asymptomatic women with average breast cancer risk between the ages of 40 to 44, the ECIBC's Guideline Development Group suggests not implementing mammography screening (conditional recommendation, moderate certainty in the evidence).

Background | Subgroup considerations | Justification | Detailed justification | Summary of findings

Plain language statements ON | Absolute effect ON | Relative effect OFF | Visual overview ON

Outcomes	Plain language statements	Absolute Effect: Without organised mammography screening	Absolute Effect: With organised mammography screening	Differences in outcomes: Favours organised mammography screening	Differences in outcomes: Doesn't favour organised mammography screening	Certainty of the evidence GRADE
not have breast cancer (over-diagnosis population perspective)			have it (from 9 900 to 14 900).			

56 fewer breast cancer deaths per 100,000 women

but

12,400 false positives per 100,000 women with related consequences

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diagnostic procedures (moderate confidence in evidence).

BALANCE OF EFFECTS

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

Detailed judgements

Two GDG members disagreed.

How large are the resource requirements (costs)?

- ○ Large costs
- ◉ Moderate costs
- ○ Negligible costs and savings
- ○ Moderate savings
- ○ Large savings
- ○ Varies

Arrospide et al. (2016) found that the total screening cost for more than 400 000 women aged 50 to 69 followed for 15 years was €1 126.6 million (using a 3% discount rate). The incremental cost for a breast cancer screening programme was €36.4 million compared to no screening.

Sankatsing et al. (2015) reported the total costs related to diagnosis, treatment and death in the absence of screening were estimated at €1 161 008 per 1 000 women aged 50 to 74 followed over their lifetime (using a 3.5% discount rate). The incremental

Although costs were considered moderate, these costs differ by country and they are influenced by the presence of opportunistic screening.

CERTAINTY OF EVIDENCE OF REQUIRED RESOURCES

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

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

Detailed judgements

The certainty of the evidence of resource requirements is low due to the study design. On the one hand, parameters used in the model of Arrospide et al. (Arrospide 2016), Sankatsing et al. (Sankatsing 2015), Carles et al. (Carles 2011), de Gelder et al. (de Gelder 2009), Wang et al. (Wang 2001), Leivo et al. (Leivo 1999) and Norum et al. (Norum 1999) were based on data from a biennial screening. On the other hand, parameters used in Pharoah et al. (Pharoah 2013) and Roijnik et al. (Rojnik 2008) were from a triennial screening. Only the model of Arveux et al. (Arveux 2003) used parameters from an annual screening. The studies of Arrospide (2016), Sankatsing (2015), Pharoah (2013), Carles (2011), de Gelder (2009), Arveux (2003), Leivo (1999), Norum (1999) reported costs of screening, diagnosis, and treatment. In Wang et al. (2001), the cost per screen included cost of invitation, screening and diagnostic work-up until a final benign/malign diagnosis, but not treatment. Roijnik et al. (2008) did not report cost components.
The formal assessment of the certainty in the evidence for cost and resources used was made following the GRADE criteria and informed in the Evidence Profile (JRC Technical Report PICO 14-15, contract FWC443094012015; available upon request).

CTIVENESS

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

Arrospide et al. (2016) found that the screening programme during the 15-year period for women aged 50 to 69 is related to an Incremental Cost-Effectiveness Ratio (ICER) below the threshold of €30 000 per Quality Adjusted Life Year (QALY). The programme proved to be cost-effective during the evaluation phase. Based on the evidence provided by Sankatsing et al. (2015), the screening programme for women aged 50 to 74 was associated with an ICER that was below the cost-effectiveness threshold (£20 000 / €24 000). Pharoah et al. (2013) recalculated the incremental cost of screening against the change in QALYs for each of the 5000 model runs under the base case scenario. The probability that the breast screening programme was cost effective compared with no screening was 45% (2260 scenarios) at a threshold of £20 000 per QALY. In 588 (12%) model runs, the screening programme was associated with a reduction in QALYs. Furthermore, Carles et al. (2011) selected the biennial strategies for women aged 50 to 69 as cost-effective for both effect measures, life year gained (LYG) and QALY. The findings

Cost-effectiveness probably favours the intervention in different countries or settings but varies across them.

Differences in the cost-effectiveness results could be explained by the differences in screening policies, settings, outcomes and types of technology used.

Sankatsing et al. (2015) reported the ICER per LYG, Pharoah et al. (2013) and Roijnik (2008) considered the ICER per QALY. Whereas, Carles et al. (2011)

Cost effectiveness

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

Judgement | Research Evidences | Additional Considerations

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.

On the contrary, based on the evidence provided by Madan et al. (2010), the extension of triennial mammography screening in women aged 47 to 49 does not appear to be cost-effective at a 'willingness-to-pay' of £20 000 per Quality Adjusted Life Years (QALY). The probability of being cost-effective at this threshold was low (29%). The ICER per QALY gained for triennial screening was £27 400.

Decision | Comments

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
○	○	○	◉	○	○	○

Relevance of values in EtDs

- Is there important **uncertainty about or variability** in how much people **value** the main outcomes?
  - From value exercises
- Does the balance between desirable and undesirable effects favour the option or the comparison?
  - Integrating values with effects on outcomes
- Does the **cost-effectiveness** of the intervention favour the option or the comparison?
  - How much does it cost to achieve the outcomes when we know their value and is it considered worth it?

Should organised mammography screening vs. no mammography screening be used for early detection of breast cancer in women aged of 50 to 69?

Explanations | Help

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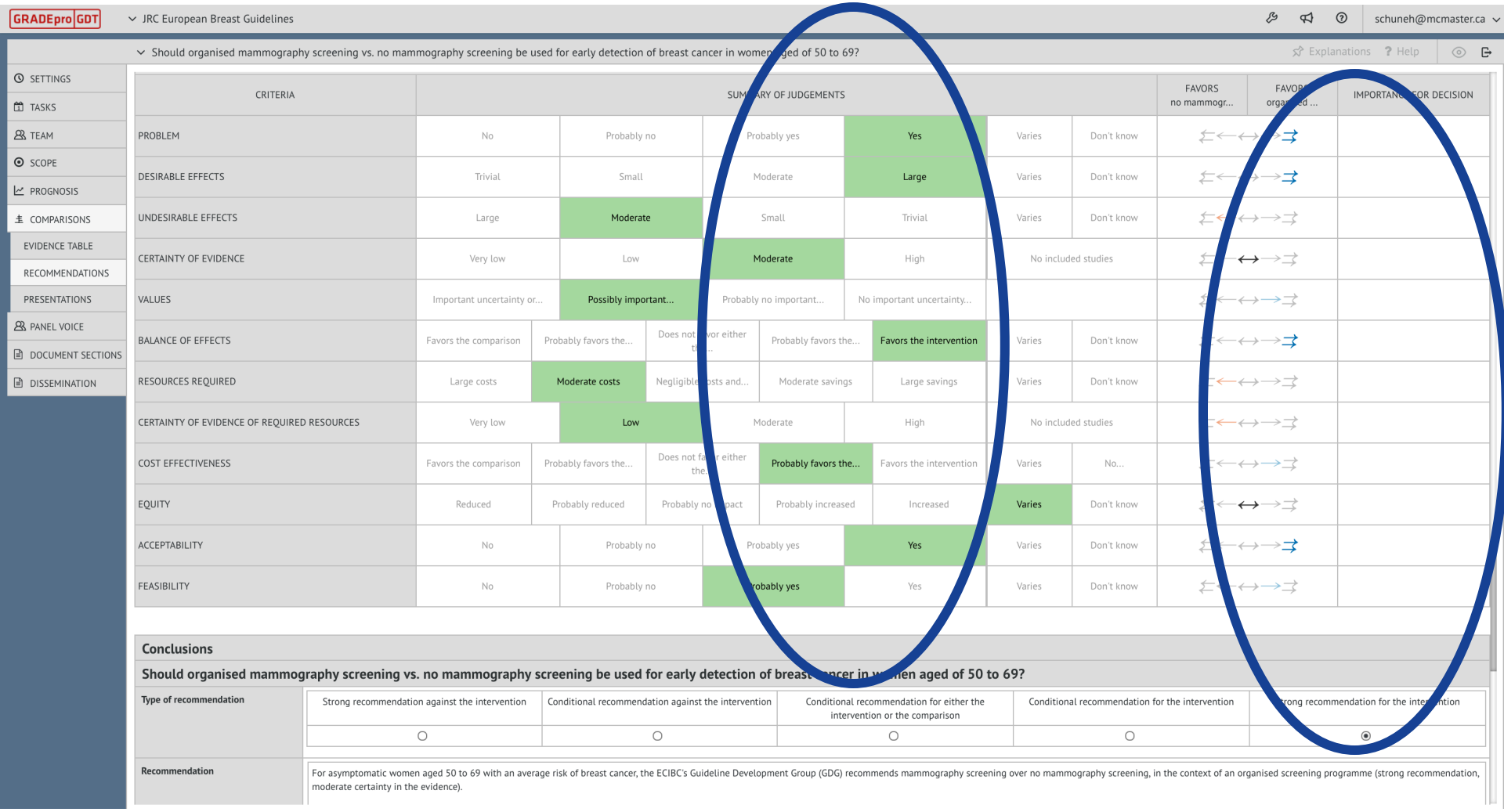
EQUITY	**What would be the impact on health equity?**	○ Reduced ○ Probably reduced ○ Probably no impact ○ Probably increased ○ Increased ◉ Varies ○ Don't know Detailed judgements		A systematic review on this topic has not been conducted. However, the utilisation of cancer screening services may largely 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).
ACCEPTABILITY	**Is the intervention acceptable to key stakeholders?**	○ No ○ Probably no ○ Probably yes ◉ Yes ○ Varies ○ Don't know Detailed judgements	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).	Some GDG members described that some professional groups may find a screening programme not acceptable because of their financial interests.
FEASIBILITY	**Is the intervention feasible to implement?**	○ No ○ Probably no ◉ Probably yes ○ Yes ○ Varies ○ Don't know Detailed judgements		A systematic review on this topic has not been conducted. Some countries do not have organised screening programmes in place and may not be able to implement them mainly due to lack of resources and / or infrastructure.

Summary of judgements

CRITERIA	SUMMARY OF JUDGEMENTS						FAVORS no mammogr...	FAVORS organised ...
PROBLEM	No	Probably no	Probably yes	**Yes**	Varies	Don't know		
DESIRABLE EFFECTS	Trivial	Small	Moderate	**Large**	Varies	Don't know		
UNDESIRABLE EFFECTS	Large	**Moderate**	Small	Trivial	Varies	Don't know		
CERTAINTY OF EVIDENCE	Very low	Low	**Moderate**	High	No included studies			
VALUES	Important uncertainty or...	**Possibly important...**	Probably no important...	No important uncertainty...				
BALANCE OF EFFECTS	Favors the comparison	Probably favors the...	Does not favor either the...	Probably favors the...	**Favors the intervention**	Varies	Don't know	
RESOURCES REQUIRED	Large costs	**Moderate costs**	Negligible costs and...	Moderate savings	Large savings	Varies	Don't know	
CERTAINTY OF EVIDENCE OF REQUIRED RESOURCES	Very low	**Low**	Moderate	High	No included studies			
COST EFFECTIVENESS	Favors the comparison	Probably favors the...	Does not favor either the...	**Probably favors the...**	Favors the intervention	Varies	No...	
EQUITY	Reduced	Probably reduced	Probably no impact	Probably increased	Increased	**Varies**	Don't know	
ACCEPTABILITY	No	Probably no	Probably yes	**Yes**	Varies	Don't know		
FEASIBILITY	No	Probably no	**Probably yes**	Yes	Varies	Don't know		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FAVORS no mammogr...
IMPORTANCE FOR DECISION
PROBLEM
No
Probably no
Probably yes
Yes
Varies
Don't know
DESIRABLE EFFECTS
Trivial
Small
Moderate
Large
UNDESIRABLE EFFECTS
Large
Moderate
Small
Trivial
CERTAINTY OF EVIDENCE
Very low
Low
Moderate
High
No included studies
VALUES
Important uncertainty or...
Possibly important...
Probably no important...
No important uncertainty...
BALANCE OF EFFECTS
Favors the comparison
Probably favors the...
Probably favors the...
Favors the intervention
RESOURCES REQUIRED
Large costs
Moderate costs
Moderate savings
Large savings
CERTAINTY OF EVIDENCE OF REQUIRED RESOURCES
COST EFFECTIVENESS
Probably favors the...
Favors the intervention
EQUITY
Reduced
Probably reduced
Probably increased
Increased
ACCEPTABILITY
FEASIBILITY
Conclusions
Should organised mammography screening vs. no mammography screening be used for early detection of breast cancer in women aged of 50 to 69?
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
Recommendation
For asymptomatic women aged 50 to 69 with an average risk of breast cancer, the ECIBC's Guideline Development Group (GDG) recommends mammography screening over no mammography screening, in the context of an organised screening programme (strong recommendation, moderate certainty in the evidence).