EUROPEAN COMMISSION
JOINT RESEARCH CENTRE

Directorate F - Health, Consumers & Reference Materials (Ispra)
Health in Society

European Commission Initiative on Breast Cancer (ECIBC):

European guidelines on breast cancer screening and diagnosis

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QUESTION	
Should a letter vs. nothing be used for informing women who have a negative screening result?	
POPULATION:	women who have a negative screening result
INTERVENTION:	a letter
COMPARISON:	nothing
MAIN OUTCOMES:	Satisfaction; anxiety.
SETTING:	Breast cancer screening programme
PERSPECTIVE:	National health system
BACKGROUND:	Breast cancer screening is a public health initiative that involves a system of informing and offering a defined target population to participate, administering and evaluate the invitation and screening procedure and referral for further assessment, ensuring timely results of the screening test and eventual diagnosis, staging and access to effective treatment with routine evaluation of the process. Breast cancer screening should be viewed as a continuous process encompassing all the components, from invitation to treatment and follow up. The different stages of screening should correspond to different communication modalities and information needs. Therefore, it would be appropriate to provide women with different types of information according to the different screening phases (i.e. invitation, negative results and recall). Women recalled for further assessment might need information about the procedures and on possible outcomes. At this stage it might be appropriate to provide women with additional and more detailed information using different formats. It is crucial that women diagnosed with breast cancer have the opportunity to meet health professionals and be able to discuss various options and outcomes with professionals in a supportive environment. The way and time in which this information is conveyed to women, especially if a further assessment is needed, could have a strong impact on women's anxiety, stress, quality of life and general well-being. Similarly, how negative results are conveyed to women could impact subsequent participation and on women's trust on breast screening initiatives.
CONFLICT OF INTEREST:	Management of Conflicts of Interest (CoI): CoIs for all Guidelines 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: Edoardo Colzani, Markus Follman, Paolo Giorgi Rossi, Axel Gräwingholt and Kenneth Young; Miranda Langendam, as external expert, was also not allowed to vote, according to the ECIBC rules of procedure.

ASSESSMENT

Problem

Is the problem a priority?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ No ○ Probably no ○ Probably yes ● Yes ○ Varies ○ Don't know	Breast cancer screening is a public health initiative that includes a system of informing women about the results of the tests being performed within a timely manner. The way test results are communicated could have an impact on satisfaction, anxiety, stress, quality of life and general well-being.	The GDG prioritised this question for the ECIBC.

Desirable Effects

How substantial are the desirable anticipated effects?

JUDGEMENT

○ Trivial
○ Small
○ Moderate
○ Large
○ Varies
● Don't know

RESEARCH EVIDENCE

Outcomes	№ of participants (studies) Follow up	Certainty of the evidence (GRADE)	Impact
Satisfaction (several communication strategies)	655 (1 observational study)[1]	⨁◯◯◯	In terms of patient´s preferences, the first choice of different methods of communicating mammography normal results was for the physician to call the patient with the result (p<0.001). - 65% of women who received their results by regular mail were 'pleased' or 'very pleased' with the method of telling, as were 72% of those told by their physician in person, and 94% of those called by their physician (based on a 5-point scale: 1 - very displeased; 2 - displeased; 3 - neutral; 4 - pleased; 5 - very pleased)
Anxiety (10 days vs. 5 days to receive written notification)	570 (1 observational study)[2]	⨁◯◯◯ VERY LOW[a]	Shorter time of notification was associated with a more positive “overall satisfaction with results reporting” (p = 0.03) -17.9% poor or fair ratings (10.3days) vs. 6.5% (5days) -62.5% good or very good (10.3days) the mandate vs. 57.1% (5days) -19.6% excellent (10.3 days) vs. 36.4% (5days)

1. Lind SE, Kopans D Good MJD. Patients' preferences for learning the results of mammographic

ADDITIONAL CONSIDERATIONS

The GDG noted that the studies were too indirect and that no comparisons of optimal strategies were provided (studies conducted outside Europe; very low certainty of the evidence; not a real comparison of communication methods was assessed).

The GDG also noted that there may be a number of side benefits (possibility to communicate importance of symptoms; the timing of intervals for new screening rounds; check for mistakes in the system) the magnitude of which is not clear.

examinations. Breast Cancer Research and Treatment; 1992.
2. Priyanath A, Feinglass J,Dolan NC,Haviley C,Venta LA.. Patient satisfaction with the communication of mammographic results before and after the Mammography Quality Standards Reauthorization Act of 1998.. American Journal of Roentgenology; 2002.

a. Downgraded for indirectness because conducted outside Europe

Undesirable Effects

How substantial are the undesirable anticipated effects?

JUDGEMENT

○ Large
○ Moderate
○ Small
● Trivial
○ Varies
○ Don't know

RESEARCH EVIDENCE

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ADDITIONAL CONSIDERATIONS

The GDG noted that the studies were too indirect and that also no comparisons of optimal strategies were provided (studies conducted outside Europe, very low certainty of the evidence, not a real comparison of communication methods was assessed).

The GDG felt that negative health effects are unlikely.

Certainty of evidence

What is the overall certainty of the evidence of effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
● Very low ○ Low ○ Moderate ○ High ○ No included studies		The GDG judged that overall the certainty of the evidence is very low.

Values

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

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Important uncertainty or variability ● Possibly important uncertainty or variability ○ Probably no important uncertainty or variability ○ No important uncertainty or variability ○ No known undesirable outcomes	No systematic review was conducted.	The GDG judged that there may be possibly important uncertainty or variability in how women value the main outcomes.

Balance of effects

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

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ 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		The GDG judged that the balance of effects probably favours the intervention because, despite the studies were too indirect, the undesirable effects are unlikely and there are a number of potential health benefits with an unclear magnitude of effects.

Resources required

How large are the resource requirements (costs)?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Large costs ● Moderate costs ○ Negligible costs and savings ○ Moderate savings ○ Large savings ○ Varies ○ Don't know	No systematic review was conducted.	**Regular mail:** An Italian Technical Report, based on data from four healthcare organisations and investigation of the cost of invitation to screening, reported a median cost of EUR 4.6 per one invited woman (including a letter with the appointment date and the call centre service that manages the appointment dates) (2007 value) (1). The GDG noted that sending a letter appeared to be cheap and that digital letters may be less expensive.

Certainty of evidence of required resources

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

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
● Very low ○ Low ○ Moderate ○ High ○ No included studies		Very low certainty due to the serious indirectness of the evidence.

Cost effectiveness

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

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ 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	No systematic review was conducted.	

Equity
What would be the impact on health equity?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Reduced ○ Probably reduced ○ Probably no impact ● Probably increased ○ Increased ○ Varies ○ Don't know	No systematic review was conducted.	The GDG judged that letters would probably increase equity.

Acceptability
Is the intervention acceptable to key stakeholders?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ No ○ Probably no ● Probably yes ○ Yes ○ Varies ○ Don't know	No systematic review of research evidence was conducted.	The GDG felt that the intervention would probably be acceptable to key stakeholders. The GDG also noted that the majority of the European breast cancer screening programmes surveyed already uses this type of intervention (survey results reported below in the feasibility section).

Feasibility
Is the intervention feasible to implement?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ No ○ Probably no ○ Probably yes ● Yes ○ Varies ○ Don't know	No systematic review of research evidence was conducted. - Survey data (unpublished) from 21 European breast cancer screening programmes from 18 countries (Belgium, Austria, Croatia, Finland, Germany, Latvia, Lithuania, Netherlands, Slovenia, Denmark, Cyprus, Italy, Spain, Norway, Malta, England, Ireland, and Wales) showed that the majority use letters to inform women of a negative result (a total of 28 European countries were reached). These are the findings regarding the content of the letters used by 12 programmes participating in the survey: **Logistic information:** **1. providing information for future screening appointments** All programmes reported information about future appointments. 83% of programmes will send invitation letters again in two years. 17% of programmes will send invitation letters again in three years	The GDG judged that the intervention is feasible to implement because in the majority of the European breast cancer screening programmes surveyed this type of intervention is already in place.

	Background information: **2. Info on what to expect after the screening appointment** 75% of programmes advised women to always check their breasts and to contact their doctor if they notice any anomaly. **Suggestive opening/closing sentences:** **3. Suggestive headlines** Two countries (17%) (Norway, Wales) had suggestive headlines ("Your screening mammogram did not show signs of breast cancer"). **Consequences of screening:** **4. Benefits of screening reported** 25% of programmes mentioned that screening is one way to detect breast cancer early **5. Harms of screening reported/screening limitations** 67% of programmes mentioned that mammography cannot detect all breast cancer.	

SUMMARY OF JUDGEMENTS

	JUDGEMENT						
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 variability	**Possibly important uncertainty or variability**	Probably no important uncertainty or variability	No important uncertainty or variability			No known undesirable outcomes
BALANCE OF EFFECTS	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
RESOURCES REQUIRED	Large costs	**Moderate costs**	Negligible costs and savings	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 comparison	Does not favor either the intervention or the comparison	Probably favors the intervention	Favors the intervention	Varies	**No included studies**
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

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
○	○	○	●	○

CONCLUSIONS

Recommendation

The ECIBC's Guideline Development Group (GDG) suggest using a letter for informing women who have negative screening result (conditional recommendation, very low certainty of the evidence).

Justification

Overall justification

The GDG made a conditional recommendation for the intervention, based on the moderate costs, the probably increased equity and the judgement that the intervention was probably acceptable to key stakeholders and feasible to implement. It did not make a strong recommendation because the studies are too indirect and no comparisons of optimal strategies were provided.

Detailed justification

Desirable Effects

The GDG noted that the studies were too indirect and that also no comparisons of optimal strategies were provided (study conducted outside Europe, very low quality evidence, not a real comparison of communication methods was assessed). It felt that there are a number of benefits the magnitude of which is not clear.

Undesirable Effects

The GDG felt that undesirable effects are unlikely.

Equity

The GDG judged that equity would probably be increased.

Acceptability

The GDG judged that the intervention is probably acceptable to key stakeholders because in the majority of the European breast cancer screening programmes surveyed this type of intervention is already in place.

Feasibility

The GDG judged that the intervention is feasible to implement because in the majority of the European breast cancer screening programmes surveyed this type of intervention is already in place.

Subgroup considerations

None identified.

Implementation considerations

1. The GDG noted that, as evidence coming from the EU Screening Programmes' survey suggests, some countries do not communicate negative results (positive results are followed up anyways), in these cases it needs to be made clear in the invitation letter that no follow up/letter means a negative result.

2. In case of return to sender letters, new addresses need to be identified.

Monitoring and evaluation

None identified.

Research priorities

The GDG recommends conducting RCTs (cluster ideally) on the effect of this intervention.

REFERENCES SUMMARY

1. Mantellini P, Biagi C,D'Angelo D,Falini P,Lippi G,Martello G,. La prevenzione del tumore della mammella. I costi dello screening. Un'analisi in logica activity based.. 2012.