

OFFICIAL ANNOUNCEMENT OF FINANCIAL AID BY THE ANDALUSIAN PUBLIC FOUNDATION FUNDACIÓN PROGRESO Y SALUD FOR THE FINANCING OF BIOMEDICAL I+i AND HEALTH SCIENCES OF ANDALUSIA FOR YEAR 2014

SCIENTIFIC-TECHNICAL AND FINANCIAL REPORT _ RESEARCH PROJECTS

MAIN RESEARCHER	
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PROJECT TITLE

Deliberative democracy study on women participating in the screening mammography programme

KEY WORDS

Screening mammography. Community's opinions. Health policy. People's jury.

ABSTRACT

(250 words maximum)

Purpose: Try a method to determine if population, when well informed, would be able to support or reject the political decision on breast cancer early detection. In particular, whether the government of Andalusia should maintain or not the invitation to undergo screening mammography to women aged 50-69.

Design: Development of people's jury-like deliberative democracy methodology.

Subjects and area of study: There will be 12 women selected between 50 and 69 years old who undergo screening mammography in the Bahía de Cádiz-La Janda District. Experts defending the position in favour and against the screening programme will be two epidemiologists who are experts in cancer prevention.

Realization: Study by a people's jury with randomly selected participants. Information is provided to participants via documentation, multimedia presentations, and sessions recording. A final report containing the decision based on votes in favour, against, and abstentions, as well as on women's deliberation, will be prepared.

Factors: contacted women, included in the study, final participants, informed consent, participants' sociobiographic features, qualitative analysis of the deliberation process, votes in favour, against, and abstentions, reasons justifying votes in favour and against, participant's recommendations.



1. SCIENTIFIC-TECHNICAL ASPECTS OF THE PROJECT

1.1 BACKGROUND AND CURRENT STATE OF THE STUDY TOPIC

Knowledge of background and current state of the topic will be assessed. Explain previous works published regarding the project topic, both performed by the research team and by other national or international groups (3 pages maximum)

The controversy related to screening mammography programmes commenced in year 2000 when Peter Gøtzsche (Nordic Cochrane Centre) published in The Lancet his meta-analysis of randomized clinical trials published so far on the efficacy of reduction in breast cancer mortality (1). Pursuant to said author, should methodologically inappropriate trials be excluded, screening mammography does not reduce breast cancer mortality, so it would be unjustified (1). Similar conclusions were reached in the systematic review of the Canadian Task Force on Preventive Health Care (CTFPHC) (2). The Cochrane review (3) concludes that it is unclear that screening mammography causes more benefits than harm and that it seems unreasonable to participate in breast cancer screening.

In 2009, the controversy was intensified again when the U.S. prevention services (USPSTF) decided not to recommend, on a routine basis, screening mammography to women between 40 and 49 years old (4). Such decision, as opposed to the 2002 recommendations (5), was based on a computerised analytical model of 9 randomized and controlled trials carried out in the last century (6-14).

Recently, a new version in the United Kingdom does not shed more light on the controversy (15). The Marmot report concludes on its significant benefits, but it suggests that every woman should make their decisions and, therefore, true information on the benefits and harms (15) must be provided.

The decision taken by every western country to implement and maintain their mammography screening programmes active is based on breast cancer mortality reduction which is estimated, in general, around 20%, with relative risks (RR) near 0.80 (2) (3) (4) (16).

The main risks for a woman who undergoes screening mammography are overdiagnosis, overtreatment, and false positives. There is uncertainty in the quantification of breast cancer detection that would have never been diagnosed and treated if the women would not have undergone mammography. The most certain estimates are derived from calculations performed in proven-quality clinical trials that did not offer mammographies to the control group upon completion of the study. Again, the results vary according to the systematic review, but they vary between 11-19% and 30% in relative terms and in 1 case of overdiagnosis out of 77 to 100 women subjected to screening for 20 years (15) (16) (17) (18) (19). Overtreatment was also assessed in the Cochrane review (3). There were more surgeries (RR 1.31), more mastectomies (RR 1.20) and more radiation therapy (RR 1.24) in women subjected to screening. However, less chemotherapy (RR 0.63) and less hormone therapy (RR 0.81) were employed, without reaching statistical significance. The update of the Canadian trial finds out that after 25 years of follow-up there were 106 overdiganoses out of 484 detected cancer cases (21.9%) (20) (106 out of 44,925 healthy women who underwent screening were diagnosed and treated unnecessarily of breast cancer) (20). Furthermore, the update of this paper does not find any reduction in breast cancer mortality (20), a contrary result conflicting with the mortality reduction of 40% found in the analysis of observational data in 7 out of 12 Canadian provincial screening programmes from 1990 to 2009 (21).

There is more unanimity with respect to other screening programme risks: re-call in 4% of cases to repeat the mammography, and a potential biopsy. Of these women, one out of five will be finally diagnosed with cancer. Of the remaining women, 70% will only need another imaging test and 30% will require biopsy, almost always -90%-with local anaesthetic. All such procedures, as well as the final cancer diagnosis and the pertinent treatment, may have a great psychological impact (22).

Scientific societies continue recommending mammography even as from 40 years old (23) (24) and no western country has dismantled their screening mammography programmes. Only Switzerland has initiated an institutional debate regarding such topic (25) (26). In Andalusia, after an excellent literature review, a report (27) was prepared, which has served as the basis to fix the age for screening mammography between 50 and 69 years old, ceasing to invite women aged 45-49 in districts where they were.

The deliberative democracy methodology is employed to involve citizens in a formal dialogue with the government or other public institutions, in order to provide a solution to complex problems. It includes people's jury, consensus conferences, deliberative surveys, study groups, citizens' meetings, and new online options. Deliberative democracy's primary purpose is to approach opinion and citizens' values to the political decision-making process (28). It is particularly useful for surveys where personal values, ethics, and existing trials on the topic in question are significant. In such issues, citizens need time to understand them fully and to consider all relevant aspects (29). Moreover, an informed consent method representing the community (30) must be considered. There is no consensus on which is the best way for women to be well informed regarding screening mammography and to make informed decisions on this breast cancer secondary prevention method (31), but the point is that women show a very poor level of knowledge and an enthusiastically positive attitude towards mammography (32). The screening mammography programme is a public issue with great relevance because it affects a great volume of the population. The impact of its implementation is morally significant since there exist conflicts as to benefits, harms, autonomy and justice. The decision of its implementation cannot be resolved through scientific evidence given that, as we have already seen, there is no consensus among experts and such decision depends on the values of the women involved, who will probably have different opinions.



In 2007, in New Zealand, 80 women aged 40-49 were randomly selected from the electoral register to participate in a deliberative process regarding the question "Must the government of New Zealand offer free mammographies to women in that range of age?" Out of the 46 contacted women, 17 accepted to participate and out of these, the 12 that first did accept were finally selected for the study. Such 12 women magnified in advance the benefits of screening mammography and all of them supported it, without reservations, within their age range. A Wednesday afternoon the group was provided with information. On Friday, the group met again and listened to experts' presentations, made questions, analysed evidence, and discussed with the support of an independent moderator. During the morning of the following day, without the presence of experts or the moderator, the women expressed their conclusions. The answer: 10 women voted against and 1, in favour (32).

1.2 BIBLIOGRAPHY

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1.3 HYPOTHESIS, RESEARCH QUESTION, OR DESCRIPTIVE STUDY

The relevance and novelty of the hypothesis, research question, or descriptive study will be assessed in relation to the state of knowledge in the scientific-technological area. Expected scientific benefits (advance of knowledge and training of human resources) as well as social benefits (health, environment, industrial, etc.) will be taken into account.

The people's jury-type deliberative democracy methodology is applicable, operative, and useful to provide a favourable or unfavourable answer to citizens on whether the Andalusian public health system must offer screening mammography to women between 50 and 69 years old.

Researchers of this study think it is innovative in the work hypothesis. Although the main contribution of the study is based on citizens' participation in health policies, there is a great potential of high capacity of transfer of result and applicability of results. And this is so because the possibility of disinvestment in the screening mammography programme with new scientific data, whose efficacy is doubtful, is also high. The opinion against screening mammography will provide politicians with a justification and support to perform different ways of disinvestment. The favourable opinion will provide grounds and validity to the political decision of maintaining this way of breast cancer prevention. On the other hand, researchers also find the fact of trying an informed consent method representative of community in an area, like breast cancer prevention, where the informed decision-taking is not resolved, applicable.

1.4 PURPOSES

List briefly, clearly, accurately, in a priority order, and according to the expected project duration, the specific purposes pursued. Clarity, scientifichealth relevance and novelty of purposes will be assessed. Remember that in this section they must only be listed, it being possible to develop them in the next sections.

- 1. Evaluate whether the people's jury-type deliberative democracy methodology is applicable to the Andalusian population.
- Analyse women's deliberative process.
- 3. Know the result of women's deliberation on whether the Andalusian public health system must offer screening mammography to women aged 50 and 69.
- 4. Know the reasons for such decision and the participants' recommendations on the application of screening mammography to women between 50 and 69 years old.



1.5

METHODOLOGY AND WORK PLAN

Detail and justify activities or tasks to be developed, indicating the individual(s) performing each task and a timeline of foreseen scientific milestones (not less than a three-month period or more than a year). Feasibility of the research project will be assessed: adaptation to methodology, design of research, analysis of data and work plan according to purposes (5 pages maximum).

It is a deliberative democracy-type qualitative study to help the pertinent politicians decide on the prescription for screening mammography to women aged 50-69.

<u>Selection of jury members</u>: a sample of 70 women between 50 and 69 years old will be selected from the Screening Programme list. The first telephone contact will occur three months before performance of the study. If after three attempts on different days it is not possible to make contact, the woman will be excluded. In the first telephone contact, they will be provided with information on the features and purposes of the study and, should they accept to participate, contact will be made again one month and one week before it to confirm availability. The goal is to recruit at least 12 women.

Experts selection: they will be chosen to defend the points of view in favour and against the prescription for screening mammography. The experts positioning for and against the screening mammography programme will be Dr. Encarnación Benítez and Dr. Soledad Márquez, both epidemiologists who are experts in cancer prevention. The main researcher of this study (a medical oncologist with expertise in research associated with assistance and with a line of research in screening mammography) will be the neutral moderator and will train experts. Information written with arguments for and against the prescription and presentations on the topic will be prepared jointly with experts and the main researcher. The report recently published by the General Secretariat of Public Health, Social Inclusion, and Life Quality (Márquez S, Lacalle JR. Beneficios y efectos adversos del cribado de cáncer de mama: revisión de la evidencia científica. Secretaría General de Salud Pública, Inclusión Social y Calidad de Vida. Consejería de Salud y Bienestar Social. January 2013) will be used as a guideline for the preparation of the written information and presentations, as well as of a deliberation manual.

<u>Process</u>: Participants will meet a Monday afternoon at a hotel in the city centre. In such meeting, the features and purposes of the study will be reminded, clearing up any doubts, an informed consent will be signed, sheets with participants' features will be filled in, and formal introductions of participants and researchers will take place. Participants will receive written information with arguments for and against screening mammography as well as instructions on how to assess the screening programme. They will also be provided with official information supplied by the Andalusian Public Health System in relation thereto. Participants will be instructed to assess the key benefit of screening programmes (breast cancer mortality reduction) and the main harms (overdiagnosis, overtreatment, and false positives), as well as other benefits and harms.

On Tuesday, experts will submit their presentations on the topic and participants will have the opportunity to make questions. The neutral moderator will promote a debate and discussion in the group.

On Thursday, the jury members will discuss without the presence of experts or the moderator and will reach final conclusions. On the same day, an observing researcher will record and take notes of the deliberation process but will not participate actively. Participants will issue their votes in favour, against, or abstentions. They will state, in writing, the main reasons for their decisions and their recommendations to the relevant politicians.

The entire process will be supervised by an expert in Bioethics, who will collaborate with the group, and who will also be part of the research team.

<u>Case definition.</u> Subjects of the study: Women invited to the breast cancer early diagnosis programme of Bahía de Cádiz-La Janda Health District and who undergo mammographies. Our health area offers a mammography every two years to women aged 50-69, who are invited to participate via a personal letter. As from April 2013, women between 45 and 49 years old are excluded from invitation, although the ones who had already undergone their first mammography are still invited. The group of women not exceeding 50 years old will be excluded.

In compliance with the requirements of inclusion and exclusion, the selection of participants will follow diversity criteria so that there is a fair representation according to age, level of education, social status, working condition, breast cancer family history, acquaintances or friends suffering from breast cancer, number of previous participations, and previous false positives. Extreme cases and convenience cases will be avoided.

Inclusion criteria:

- 1. Women living in the Bahía de Cádiz-La Janda Health District
- 2. Women aged 50-69
- 3. Women invited to the screening mammography programme, whether they participate or not
- 4. Women with a secondary school or university level of education
- 5. Women able to grant their informed consent to participate in the study

Exclusion criteria:

- Women not reaching 50 years old or older than 69 years old
- 2. Women with breast cancer personal history
- 3. Women without any education or with primary-school studies only

Criteria for removal from the study:

Patient's explicit desire to abandon the study

Data collection and analysis: Sessions involving introduction of experts and debate of participants will be recorded.



Participants will be identified as P-1, P-2... P12. The deliberation session will be recorded and notes will be taken by two observing researchers. A literal transcription of recordings of all participants will be carried out. Analysis will be performed following the participants' speech. After successive readings, the main ideas derived from the group deliberation will be extracted. These ideas will be later compared to the reasons for the decision.

Collection of sociobiographic data of participants will occur in data collection notebooks designed to that effect. The first interview with women will occur on a face-to-face basis at the Health District, where mammographies are performed. Deliberation sessions will be at a place different from the health environment (hotel in the city centre). Sample size: Calculation is not applicable. In a group of 36 preselected women, the first 12 will be finally invited to participate and the rest of them will be reserved in case any of the former may revoke their consent or may not participate on any other ground.

<u>Statistical analysis</u>: To process the qualitative study results, it will not be necessary to have a particular digital hardware or statistical analysis, since their usefulness is addressed to the analyses including a big number of interviews. Furthermore, the following variables will be collected: age, level of education, social status, working situation, breast cancer family history, acquaintances or friends suffering from breast cancer, number of previous participations, and previous false positives. A descriptive analysis of such data will be performed, through an estimate of absolute and relative frequencies for qualitative variables and the average and standard deviation for quantitative variables.

Study limitations: Representativeness of the selected group is a common problem in qualitative studies. Women having a low level of education were excluded because, in previous studies of our group, they constitute a part of the population where the degree of knowledge if difficult to modify and it is difficult for them to make an informed decision (Baena-Cañada JM, Rosado-Varela P, Expósito-Álvarez I, González-Guerrero M, Nieto-Vera J, Benítez-Rodríguez E. Women's perceptions of breast cancer screening. Spanish screening programme survey. The Breast 2014, 10.1016/j.breast.2014.09.010). It is also difficult to modify the certainty that the population sample will understand, assimilate, and analyse the information provided and draw appropriate conclusions. Finally, results may depend on the choice of experts, but such limitation is lessened by the preparation, by consensus, of presentations to participants and, since the two presenters are women too, the gender-based influence will be controlled. The population sample including women aged 50 and 69 to whom screening mammography has been offered lessens the representativeness bias. The potential reaction of the main researcher in the participants' deliberation scenario will be impartial and controlled by the expert in Bioethics. Such limitations are common to all deliberative democracy studies and well known (Street J, et al. The use of citizens' juries in health policy decision-making: A systematic review. Soc Sci Med. 2014; 109: 1-9.), so researchers will try to mitigate them.

Work plan: It is a qualitative study, whose original idea comes from the main researcher and will be performed with the cooperation of the Department of Medical Oncology of University Hospital Puerta del Mar, Cádiz, and the Bahía de Cádiz-La Janda Health District. Members of the Provincial Cancer Registry of Cadiz, of the Quality Service and Process of the General Department of Quality, Research, Development, and Innovation of the Department of Equality, Health, and Social Policies of Andalusia will also participate, as well as, finally, of the Bahía de Cádiz Ethics Committee, and a professional having a licentiate in Chemical Sciences, who has a master's degree in clinical trials. Therefore, the professionals involved in the project come from a clearly multidisciplinary group, with members pertaining to the areas of Oncology, Public Health, Nursing, and a professional not related to Health Sciences, most of them being women. The date stipulated for the commencement of participants recruitment will be the first quarter of year 2015 and the deliberation process sessions will be carried out during the second quarter of year 2015. The expert will present their position for and against screening mammography. The main office of the Screening Programme commits to collaborating and making things easier. The oncologist being the main researcher will act as a neutral moderator. Researching oncologists will be responsible for the identification of cases to be included in the study and this will be performed actively through their physical presence at the main office of the screening mammography programme during nonworking hours. Moreover, they will work along with the experts in the preparation of the material to be supplied to participants. A technician specialised in audiovisual media will perform the recording and an oncologist and the expert in clinical trials will take notes on the deliberation process but will not participate actively in it. The nurse expert in Bioethics will give professional advice and supervise the study. A psychologist expert in qualitative research, from the area of Social Psychology of the Department of Psychology of the School of Educational Sciences, University of Cádiz (DPS), Violeta Luque Ribelles, will cooperate with the project.

1.6 PROMOTION AND DISSEMINATION PLAN

The quality of the promotion plan and dissemination of the research project results will be assessed (publications in scientific magazines indexed in JCR, patents, etc.)

As far as we know, there are no similar studies in our country. The research team has informed the management of the Andalusian Oncology Integral Plan of this research project and such Plan has accepted to be mentioned as a promoter interested in it.

We believe the dissemination of results at quality scientific meetings and in magazines with national and international impact is justified (national and international conferences on screening mammography, Medical Oncology, Assistance Quality, national and international Medical Oncology magazines, Cancer Prevention,



Assistance Quality).

The report on conclusions will be made available to the citizenship representatives of the Integral Attention Unit of Cancer at University Hospital Puerta del Mar and interested associations (Asociación Española Contra el Cáncer and Asociación Gaditana de Mujeres con Cáncer de Mama).

A mandatory section of the promotion plan is related to its own nature. It is a deliberative democracy-type qualitative study, where participants will judge the prescription for screening mammography. Deliberation will not only include votes for, against, and abstentions, but also the dissemination of those results to the relevant politicians will take place through the management of the Andalusian Integral Oncology Plan.

1.7 ETHICAL ASPECTS OF THE RESEARCH

The detail of the ethical aspects that must be taken into consideration when performing the project will be assessed.

IMPORTANT: There are three models of management of samples in biomedical research: research project, research collection, research biobank. Advantages and legal requirements associated with the use of each model may be found in the "Use Guide of Samples in Biomedical Research" (http://biobanco.csalud.junta-andalucia.es/salud/biobanco/sites/default/files/Guia_de%20uso_de_muestras_biologicas-Biobanco.pdf). In any case, for the handling of your project it is essential that you have a contingency plan for samples at the time of completion of your project. Should the samples of your project be derived from a research collection, you must provide the registry code of the collection with the ISCIII Catalogue of Collections. Should you use a biobank for the handling of samples required by your project, you must provide the compromise of said Biobank. They will always be biobanks registered with ISCIII.

A woman participating in the screening programme shows an ethical situation completely different from that of a sick person. Individual informed consent is not easily obtained from women who undergo screening mammography and it constitutes a real challenge that women make an informed choice. Although our group has demonstrated that individual informed consent increases the level of knowledge of women invited to screening mammography (Rosado P, Baena JM, Ramírez P, et. al., Using an informed consent in mammography screening: Final result of a randomized trial. Ann Oncol 2014; 25 suppl 4: Iv478 - iv480. doi: 10.1093/annonc/mdu351.3), in the screening context we propose a joint consent derived from a randomised sample of the population to be invited to participate. It is necessary to develop an optimum form to submit information on benefits and risks of the screening mammography programme and to help women make a decision. This study involves an excellent opportunity in that sense, since a sample representing the community involved will be selected and a deliberative process will be performed whose conclusions will not only serve to strengthen or refute the political decision thereon, but which may also be deemed a consent representative of community. Said women will not be subject to any supplementary diagnostic trial or to a treatment different from the usual one. Participation will be voluntary and will involve no cost at all. Every participant will be given a gift with a value not exceeding 30 euros. Should a woman decide to participate and change her opinion later, she is free to do so and is not obliged to provide any explanation. Personal data will be treated as stated in the Spanish legislation in force (Organic Law 15/1999, dated December 13, on Personal Data Protection).

2. MAIN RESEARCHER AND RESEARCH TEAM

2.1 CV OF MAIN RESEARCHER AND OF RESEARCH TEAM

The CVs are attached in the computer Management of Calls

3. AVAILABLE MEANS AND REQUESTED BUDGET

3.1 AVAILABLE MEANS AND RESOURCES TO CARRY OUT THE PROJECT

A) MATERIAL ABLE TO BE INVENTORIED

The amount of infrastructure resources allow for the performance of this study without any special difficulty through the means available at the Bahía de Cádiz-La Janda Health District and at University Hospital Puerta del Mar, Cádiz.

B) BIBLIOGRAPHIC MATERIAL

The Medical Oncology Department has Internet access to perform bibliographic searches and to obtain the necessary bibliographic material. Puerta del Mar Hospital makes the SAS virtual library available to the researches of its centre.

C) PERSONNEL

At the Bahía de Cádiz-La Janda Health District, a sufficient number of women attend in order to recruit the required number of participants. The human resources personnel allows for the performance of this study without any special difficulty. As support for the researching activity, the Medical Oncology department has a research nurse hired by the Foundation *Fundación para la Gestión de la Investigación Biomedica de Cádiz*. Researchers have methodological and statistical assessment by the Preventive Medicine department and the support of the Bahía de Cádiz-La Janda Health District. Likewise, The Andalusian Integral Oncology Plan sponsors this research project.

REQUESTED BUDGET AND JUSTIFICATION.

Every item in the requested budget indicating items, units, unit prices, etc., must be broken down, and if information is available, it is recommendable that supplier be indicated. In case of not matching with the budget stated in the computer application, the one stated therein shall prevail (See annex).

CONCEPT	REQUESTED BUDGET		
	YEAR 1	YEAR 2	TOTAL
Goods and Services: (detail and justification for need)			
Material able to be inventoried			
Portable PC	00.00		
Image and voice recorder	00.00		
Projector	00.00		
Printer	00.00		
Fungible material			
Documentation, folders, and pens for participants' dossier	00.00		
Dissemination of results: (presentation of results in conferences).			
Attendance to National Conference of 2 speakers	1200.00		
Publication of results (publication in open access magazine)	3000.00		



Hiring of external services Translation services		
Translation solvisse	500.00	
Other expenses: (Justification and detail)		
Cafeteria service	00.00	
TOTAL	4700.00	

Comments and details of budget: (indicate items, units, conferences, meetings, etc.)

- 1 portable PC (1000€). Essential for digital hardware in deliberative meetings with participants.
- 1 image and voice recorder (400€). Essential in qualitative studies, since it will be necessary to analyse, *a posteriori*, the participants' comments.
- 1 projector (500€). Useful for the experts' presentation to participants.
- 1 printer (200€). Useful for the preparation of documentation to be submitted to participants.

Documentation, folders, and pens for the dossier to be delivered to participants (300€).

Financing for assisting the two researchers in a national conference where the study results will be presented is also requested (1200€).

Dissemination of results will require translation services for an original document (500€) to be sent to an international English-speaking open access magazine (3000€).

Catering services (300€). The three meetings are expected to last several hours during the afternoon. Cafeteria services are offered to participants as a courtesy.

4. PROJECT APPLICABILITY TO THE ANDALUSIAN PUBLIC HEALTH SYSTEM

4.1 APPLICABILITY

The expectations of transfer of research results to clinical practice, technological innovation, organization, resource management, and health services or health policies will be assessed.

Expected research results are applicable and include improvements to the Health System's usual clinical practice.

Justify your answer and indicate application environment:

Researchers find the fact of trying an informed consent method representing community in an environment, like breast cancer prevention, where informed decision-taking is not resolved applicable.

Knowing the deliberation result of a sample representing community and submitting it to the pertinent politicians has an incomparable potential to include improvements in the usual clinical practice related to screening mammography. In case after the study, with the hypothetical negative vote of participants, some type of disinvestment is chosen, the non-performing of screening mammographies to some women would have, among others, the consequence of preventing overdiagnosis, overtreatment, and false positives, which are the main side effects of screening mammography.

 Expected research results may be transferred to the organization, resources management, health services, or health policies. YES

Justify your answer.

Citizens' participation in health policies will contribute improvements to the Health System. There is a great potential of capacity of transfer of result and high applicability of results. This is so because the possibility of disinvestment in the screening mammography programme, with the new scientific data of doubtful efficacy, is also high. The opinion against screening mammography will provide politicians with a justification and support to perform different types of disinvestment. The opinion in favour will provide grounds and validity to the political decision to maintain this type of breast cancer prevention.

Recommendations to the pertinent politicians will provide value, regardless of their decision. Conclusions obtained in the study will serve, therefore, to guide the resources management and health policies.

Expected research results may lead to the generation of technological innovations, patents, or utility models.



Justify your answer.

Citizens' juries approach, somehow, the deliberative survey technique, which suggests gathering at the same place, in general for 2 days, a sample representing the reference population, to be faced with experts and to make them discuss in small groups, before collecting their informed opinions. Said technique has been employed a dozen times in Great Britain, Australia and the United States. Despite its limited number of applications, such technique may be analysed, not only as an attempt to renew traditional surveys, but also as a symptom of a new link to public opinion in western democracies. Even when the contrast between the method's ambitions and the modesty of its performance is surprising, the emergence of this new way of public action must be taken seriously as a utility model.

The fact that the Integral Oncology Plan of the Andalusian Health Service is an observer interested in the project must be considered a cooperation with a company (in the present case, a public one) for the development of new services which will result in health improvements for citizens.

4) Expected research results may be published in a document having a great impact and commonly used by health professionals, such as the scientific magazines indexed by the Journal Citation Reports of the ISI Web of Science. YES

Justify your answer.

The validity, current nature and original methodology, as well as the significance of results, justify the dissemination at quality scientific meetings and impact magazines, both national and international (national and international conferences on screening mammography, Medical Oncology, assistance quality, national and international magazines of Medical Oncology, cancer prevention, assistance quality). We cannot state accurately in advance the specific magazines and conferences in which results will be published or informed, but their bibliometric impact will always be considered.

5) Expected research results may be transferred through consensus documents, clinical practice guides published, etc., and applicable in the Health System

Justify your answer.

Regardless of women's deliberation results in this study, we believe consensus documents and guides on the application of screening mammography should consider them, being applicable to the Health System.