

CONTENT OF OFFICIAL WRITTEN INFORMATION FOR WOMEN ON BREAST CANCER SCREENING IN SPAIN

Sendoa Ballesteros-Peña (1,2) and Enrique Gavilán-Moral (3)

(1) Faculty of Medicine and Nursing, University of the Basque Country (UPV/EHU), Leioa (Bizkaia), Spain.

(2) Nursing Teaching and Research Unit, Bilbao-Basurto Integrated Healthcare Organization, Bilbao, Bizkaia, Spain.

(3) Mirabel Primary Health Center, Mirabel, Cáceres, Spain.

The authors have no conflicts of interest to declare.

ABSTRACT

Background: There are several methods to promote informed decision making before participating in a screening program. This research aimed to analyze the content of official written information on breast cancer screening programs.

Methods: A descriptive study was performed. After a literature review, we drew up a checklist of the information needed to make decisions about participation in mammography screening programs. Various types of official written information on mammography screening used in Spain in 2016 were analyzed by two independent researchers. The inter-rater agreement was assessed and disagreements were resolved by consensus. Absolute and relative frequencies were calculated for each item.

Results: We reviewed 8 invitation and 14 appointment letters, 12 leaflets, 8 brochures and 14 websites, from 18 breast cancer screening programs. The information provided was found to vary considerably between programs. Only a third underlined that participation was voluntary; 8 (44.4%) offered information on what breast cancer is and 7 (38.9%) on the cumulative risk of developing the disease; and 15 (83.3%) explained the objectives of the program and 14 (77.8%) what mammography is. The following benefits of screening were mentioned: less invasive treatment by 14 programs (77.8%), longer survival by 12 (66.7%) and lower specific mortality by 10 (55.6%). Most of the programs did not, however, mention the possibility of false positives (27.8%) or false negatives (38.9%), while only 7 (38.9%) mentioned the possibility of overdiagnosis and 6 (33.3%) of overtreatment.

Conclusions: The information provided varies considerably between breast cancer screening programs and is generally insufficient for informed decision-making.

Key words: Health Communication, Information services, Health Literacy, Mammography, Secondary prevention, Breast cancer, screening, Decision making, Use of scientific information in health decision making.

RESUMEN

Contenido de los documentos informativos dirigidos a las mujeres sobre el cribado de cáncer de mama en España.

Fundamentos: Existen diversos métodos para facilitar la toma de decisiones informada antes de acudir a un programa de cribado. El objetivo de este trabajo fue analizar la información de los documentos oficiales sobre los programas de cribado de cáncer de mama (PCCM).

Métodos: Estudio descriptivo. Análisis del contenido de los documentos informativos de los PCCM vigentes en España en 2016. Se elaboró una lista de comprobación con la información necesaria para la toma de decisiones. Dos investigadores revisaron independientemente los documentos. Se comprobó la concordancia interinvestigador y se resolvieron por consenso las discrepancias. Se calcularon las frecuencias absolutas y relativas de cada ítem.

Resultados: Se revisaron 8 cartas de invitación a participar y 14 de citación, 12 dípticos o trípticos, 8 folletos y 14 webs, procedentes de 18 PCCM. La información resultó ser muy dispar según cada programa. 8 programas (44,4%) informaban sobre qué es el cáncer de mama y 7 (38,9%) sobre el riesgo acumulado de desarrollarlo. 15 (83,3%) explicaban los objetivos del PCCM y 14 (77,8%) en qué consiste una mamografía. 14 programas (77,8%) presentaban como beneficios el cribado los tratamientos menos invasivos, 12 el aumento de la supervivencia (66,7%) y 10 la disminución de la mortalidad específica (55,6%). La mayoría de los programas no informaban sobre la posibilidad de falsos positivos (27,8%) o falsos negativos (38,9%). Sólo 7 (38,9%) mencionaban la posibilidad de sobrediagnóstico y 6 (33,3%) de sobretreatmento.

Conclusiones: La información que facilitan los diferentes PCCM es variable y no contiene información suficiente para la toma de decisiones informada.

Palabras clave: Comunicación en Salud, Servicios de información, Alfabetización en Salud, Mamografía, Prevención secundaria, Cáncer de mama, Cribado, Toma de Decisiones, Uso de información científica en la toma de decisiones en salud.

Corresponding author:
Sendoa Ballesteros-Peña
Facultad de Medicina y Enfermería
Universidad del País Vasco (UPV/EHU)
Campus de Leioa
Barrio Sarriena, s/n
48940 Leioa- Bizkaia, Spain
sendoa.ballesteros@ehu.eus

Suggested citation: Ballesteros-Peña S, Gavilán-Moral E. Content Of Official Written Information For Women On Breast Cancer Screening In Spain. Rev Esp Salud Pública. 2018;92: October 29 e201810076.

INTRODUCTION

Breast cancer screening programs (BCSPs) are based on performing diagnostic tests (mammograms) on apparently healthy women with the aim of distinguishing those who are likely to have breast cancer from those who are not likely not to. This is secondary prevention measure, the goals of which include reducing the number of individuals in whom precancerous lesions are detected who go on to develop invasive disease, as well as avoiding early mortality associated with breast cancer and in general improving the prognosis and quality of life of individuals with the disease⁽¹⁾.

Breast cancer screening programs do, however, have some disadvantages. For example, it has been argued that, as well as the potential adverse effects associated with diagnostic tests and treatment, individuals in whom early detection does not improve their prognosis suffer a longer period of morbidity due to early diagnosis⁽²⁾. In fact, the greatest controversy lies in the possibility that the detection of abnormalities of unknown prognosis or precursor, non-progressive lesions may lead to overdiagnosis and hence overtreatment⁽³⁾, not to mention the potential negative psychosocial and emotional effects of a false positive on an asymptomatic woman⁽⁴⁾. Although BCSPs are generally still recommended, all these disadvantages have fueled debate about the balance between benefits and risks of this and other programs for the early detection of cancer^(5,6), to the point that France and Switzerland are redesigning them or even considering stopping them^(7,8).

In Spain, population BCSPs are run based on performing a mammogram every other year, focused in most autonomous regions on women aged 50 to 69 years old⁽⁹⁾. In order to recruit participants, the BCSPs send a personalized letter accompanied, in many cases, by written information on the program in the form of a leaflet. Additionally, public organizations offer users other materials, in

paper or electronic formats (brochures or websites), in order to support informed decision making concerning whether or not to attend preventative check-ups.

In 2010, the discussion paper working group on population screening of the Spanish Public Health Committee drafted a framework document on population screening which recognized the need for informed decision making in the implementation of population screening programs. For this reason, to enable decisions to be informed, it was stated that people should have access to adequate, high quality, relevant, reliable and easy-to-understand information⁽¹⁰⁾. Additionally, this information should be based on the best available scientific evidence and balanced in relation to the presentation of benefits and risks⁽¹¹⁾.

Earlier, in 2007, a report published in Spain concluded that leaflets were one of the most efficient ways of providing the information necessary to support informed decision making by potential participants in BCSPs⁽¹²⁾. This report also indicated the basic information that should be included in such leaflets, namely, information about the disease itself (breast cancer), the screening program, the target population, the screening interval, the screening test (its nature, aim, procedure, validity, benefits, risks and results), tests for confirming the diagnosis, treatment and how to obtain further information. Nevertheless, comparative analysis of the official written information issued by the BCSPs across Spanish regions yielded disappointing results: at that time, not all the regions offered information leaflets on their BCSPs, and in the case of those that did, they provided limited information on the risks of screening.

A decade after this report, the objective of our study was to analyze the content of official written information available to women on BCSPs in Spain to facilitate informed decision making.

MATERIALS AND METHODS

Study material: the units of analysis were the official written materials available in the first 6 months of 2016 from various different programs for early diagnosis, produced by the regional or provincial departments of health, focused on women eligible for mammograms under the BCSPs.

In order to obtain these written materials, we first contacted the people leading the BCSPs, requesting information on the program's recruitment procedure and copies of written information for women used in the current campaign, such as invitation letters (introducing the program and inviting women to participate in the screening), and appointment letters (giving users appointments for a mammogram specifying the date and time) sent to the homes of women eligible for screening, information leaflets/brochures and websites. If no answer was received after a second request, we contacted healthcare organizations or individual health professionals in corresponding regions requesting the information and materials of interest. In parallel, we reviewed the information available on the official websites of the screening programs or departments of health. We excluded website content that was not intended for the target population.

Content analysis. To analyze the content of the materials, we drew up a checklist, by consensus among researchers, of the types of information considered essential for informed decision making about screening mammograms (Table 1), based on the topics covered in similar studies^(12,13,14,15,16).

Prior to gathering data, we piloted the tool by analyzing the materials from the programs that provided the greatest volume and variety of information (those of Andalusia and Balears), seeking to determine whether any of the checklist items might be

found confusing or ambiguous. Doubts and disagreements were assessed and discussed among researchers and we also sought the opinion of external professionals, until a final checklist was agreed.

Data processing and statistical analysis: Two researchers independently reviewed all the study material to assess, overall, whether each of the types of content referred to in the checklist items was or was not included. The final level of agreement between the two reviewers was assessed using Cohen's kappa coefficient and the corresponding 95% confidence intervals (95% CI), finding a very high level of overall agreement (0.83%, 95% CI 0.80-0.86; $p < 0.001$). Disagreements were discussed and resolved by consensus after reviewing the informative materials.

For the descriptive analysis of data, absolute and relative frequencies were calculated for each of the items studied.

RESULTS

Characteristics of the study material and overall results. We reviewed a total of 56 informative materials (Table 2) offered by 18 BCSPs. We assessed at least one format for delivering the information for each program. The most studied format was the appointment letter (77.8%) followed by websites (72.2%).

Four programs (those of Asturias, Castilla La Mancha and Valencia regions and the Barcelona Public Health Agency, hereon "Barcelona") provided information on 60% or more of the items of the questionnaire, while eight programs (Aragón, Castilla y León, Extremadura, Canarias, La Rioja, Murcia, Navarre and the Basque Country) covered less than 40% of the items. Four programs (Asturias, Barcelona, Castilla La Mancha and the Balearic Islands) included a pictogram summarizing the benefits and

Table 1
Information considered essential for informed decision making about screening mammograms

Domain	Items
Breast cancer	<ul style="list-style-type: none"> • What the disease is • Risk factors • Measures to prevent cancer • Warning signs and symptoms • Natural history of the disease • Incidence and/or prevalence • Estimated lifetime cumulative risk of developing or dying of the disease • Quantitative data on prognosis (mortality, survival and cure rates)
General information on screening: program objectives and characteristics; and organization and logistics	<ul style="list-style-type: none"> • Program objectives • What early diagnosis is • What a screening program is • What a mammogram involves • Target population • Eligible age range • Mention of women outside this age range or at higher risk • Screening intervals • What to do if symptoms develop during this interval • Information on breast self-examination • Pictograms or infographics • Information on appointments (where and when) and how to change them
User rights	<ul style="list-style-type: none"> • Participation being optional and free • Confidentiality • Clarification of the handling of personal data • Mention of controversies about the screening and the risks and benefits it entails
Impact of screening programs	<ul style="list-style-type: none"> • Benefits (possibility of early or less invasive treatment, mention or quantification of the increase in survival and relative or absolute reduction in the risk of death) • Risks (mention of possibility and rates of overdiagnosis, overtreatment and false positives and negatives; effects of radiation; discomfort or pain associated with the mammogram) • Strategies to minimize emotional distress (mention of the fact most tests are negative; information to reduce concerns associated with confirmatory tests, anxiety about results and fear of cancer itself; mention of the availability of effective treatments)
Confirmatory tests	<ul style="list-style-type: none"> • Mention of the possibility of needing confirmatory tests or reasons why they may be necessary • Percentage of women called for confirmatory tests • Identification and description of confirmatory tests, reasons for doing them and potential complications

risks of screening.

General information on breast cancer (Table 3). The majority of the BCSPs provided qualitative or quantitative information on the incidence of breast cancer and listed associated risk factors, and almost half gave information about what breast cancer is and its symptoms. Nevertheless, the cumulative risk of developing the

disease, its natural history and prognosis and preventative lifestyles were less often covered, and none of the BCSPs provided estimates of the lifetime cumulative risk of death due to breast cancer.

Four programs (Extremadura, Canarias, La Rioja and Navarre) did not provide information related to any items in this domain. Three

Table 2
Range of types of material analyzed for each breast cancer screening program

BCSP	Invitation letter	Appointment letter	Leaflet	Brochure	Websites
AR	X	X	X		X
AS		X	X		
CN	X	X		X	X
CB		X	X		
CM		X	X		X
CL		X		X	X
CT (CIO)	X			X	X
B (BPHA)					X
EX	X	X	X	X	X
GA		X			
IB	X	X		X	
RI		X	X	X	X
MD		X	X	X	
MC	X		X		X
NC				X	X
PV	X	X			X
VC		X	X		X
TOTAL n (%):	8 (44.4%)	14 (77.8%)	10 (55.5%)	8 (44.4%)	13 (72.2%)

AN: Andalusia; AR: Aragon; AS: Asturias; ASPB: Agencia Salut Pública Barcelona; B: Barcelona; BCSP: Breast cancer screening program; BPHA: Barcelona Public Health Agency; CN: Canarias; CB: Cantabria; CIO: Catalan Institute of Oncology; CM: Castilla La Mancha; CL: Castilla y León; CT: Catalonia; EX: Extremadura; GA: Galicia; IB: Balearic Islands; RI: La Rioja; MD: Madrid; MC: Murcia; NC: Navarre; PV: Basque Country; VC: Valencia.

programs (Castilla y León, Castilla La Mancha and Valencia) encouraged breast self-examination or sought to teach women how to do it, while two (Asturias and Barcelona) discouraged the practice.

General information on the screening programs:

- Program objectives and characteristics (Table 4). The majority of the BCSPs listed the objectives of the screening program and what early diagnosis means, but only a few explained why healthy women are invited

to participate. Further, most of the programs described what mammograms involve and what to do in the event of noticing symptoms in the interval between screening tests.

- Program organization and logistics. All the programs clearly identified the organization running the campaign, and the majority gave an adequate amount of information on how to contact the people responsible for the program, the date of the appointment and where to go, how to request or change an appointment, the documents to provide,

Table 3
Range of general information on breast cancer provided by each BCSP

BCSP	What breast cancer is	Main risk factors	Age as a risk factor	Other risk factors	Prevention of breast cancer	Warning signs and symptoms	Natural history of the disease	Incidence of the disease (quantitative)	Incidences of the disease (qualitative)	Cumulative risk of the disease	Cumulative risk of mortality	Mortality rate	Survival rate	Cure rate
AN	X	X	X					X	X	X				
AR									X					
AS	X	X	X	X				X	X	X		X		
CN														
CB	X	X	X		X	X		X						
CM	X	X	X	X	X	X		X	X	X		X		
CL			X							X				
CT (CIO)			X	X	X	X			X				X	X
B (BPHA)	X	X	X	X		X	X	X	X			X	X	X
EX														
GA	X	X				X			X	X				
IB	X	X	X	X	X	X		X	X	X				
RI														
MD	X	X	X						X					
MC			X				X		X					
NC														
PV									X					
VC		X	X	X		X		X	X	X		X	X	
TOTAL: n (%)	8 (44.4%)	9 (50%)	11 (61.1%)	7 (38.9%)	4 (22.2%)	7 (38.9%)	3 (16.6%)	7 (38.9%)	12 (66.6)	7 (38.9%)	0	4 (22.4%)	3 (16.6%)	2 (11.1%)

AN: Andalusia; AR: Aragon; AS: Asturias; ASPB: Agencia Salut Pública Barcelona; B: Barcelona; BCSP: Breast cancer screening program; BPHA: Barcelona Public Health Agency; CN: Canarias; CB: Cantabria; CIO: Catalan Institute of Oncology; CM: Castilla La Mancha; CL: Castilla y León; CT: Catalonia; EX: Extremadura; GA: Galicia; IB: Balearic Islands; RI: La Rioja; MD: Madrid; MC: Murcia; NC: Navarra; PV: Basque Country; VC: Valencia.

Table 4
Information on topics related to the objectives of the program provided by each BCSP

BCSP	Objectives	What early diagnosis is	What a screening program is	What a mammogram involves	Target population	Eligible age range	Women outside this range or at high risk	Inviting healthy women	Biennial testing	What to do if symptoms develop during the interval
AN	X	X	X		X	X	X	X	X	X
AR	X			X	X	X			X	
AS	X	X	X	X	X	X	X	X	X	X
CN	X			X	X	X			X	X
CB	X	X		X	X	X			X	
CM	X	X	X	X	X	X	X	X	X	X
CL				X	X	X			X	X
CT (CIO)	X	X		X	X	X	X		X	X
B (BPHA)	X	X	X	X	X	X	X	X	X	X
EX					X	X				
GA	X	X		X	X	X			X	X
IB	X	X		X	X	X			X	X
RI		X		X	X	X			X	X
MD	X	X		X	X	X	X		X	X
MC	X	X		X	X	X			X	
NC	X				X	X			X	X
PV	X				X	X	X		X	
VC	X	X	X	X	X	X	X	X	X	X
TOTAL: n (%)	15 (83.3%)	12 (66.6%)	5 (27.8%)	14 (77.8%)	18 (100%)	18 (100%)	8 (44.4%)	5 (27.8%)	17 (94.4%)	13 (72.2%)

AN: Andalusia; AR: Aragon; AS: Asturias; ASPB: Agencia Salut Pública Barcelona; B: Barcelona; BCSP: Breast cancer screening program; BPHA: Barcelona Public Health Agency; CN: Canarias; CB: Cantabria; CIO: Catalan Institute of Oncology; CM: Castilla La Mancha; CL: Castilla y León; CT: Catalonia; EX: Extremadura; GA: Galicia; IB: Balearic Islands; RI: La Rioja; MD: Madrid; MC: Murcia; NC: Navarre; PV: Basque Country; VC: Valencia.

Table 5
Information on the benefits, disadvantages and risks of breast cancer screening provided by each BCSP

BCSP	Benefits						Disadvantages and risks							
	Early or less invasive treatment	Longer survival	Lower mortality	RRR	ARR	Possibility of over-diagnosis	Rate of over-diagnosis	Over-treatment	Radiation effects negligible or not harmful	Radiation an assumable risk	Not painful for most people	Can be uncomfortable or even painful	False positive rate	False negative rate
AN	X	X	X								X		X	X
AR									X		X			
AS	X	X	X		X	X		X		X		X	X	X
CN	X		X			X		X		X		X		X
CB		X	X						X	X	X	X		
CM	X	X	X			X		X	X	X	X	X	X	X
CL		X							X			X		
CT (CIO)	X	X				X			X		X	X		
B (BPHA)	X	X	X		X	X		X	X	X		X	X	X
EX											X			
GA	X	X	X			X		X	X	X	X	X	X	X
IB	X	X	X			X			X	X	X	X		X
RI	X	X							X	X	X	X		
MD	X	X	X						X	X	X	X		
MC	X									X				
NC	X													
PV	X	X												
VC	X		X		X			X	X			X		
TOTAL: n (%)	14 (77.8%)	12 (66.6%)	10 (55.5%)	2 (11.1%)	1 (5.5%)	7 (38.9%)	0	6 (33.3%)	9 (50%)	6 (33.3%)	9 (50%)	12 (66.6%)	5 (27.8%)	7 (38.9%)

AN: Andalusia; AR: Aragon; ARR: absolute risk reduction; AS: Asturias; ASPB: Agencia Salut Pública Barcelona; B: Barcelona; BCSP: Breast cancer screening program; BPHA: Barcelona Public Health Agency; CN: Canarias; CB: Cantabria; CIO: Catalan Institute of Oncology; CM: Castilla La Mancha; CL: Castilla y León; CT: Catalonia; EX: Extremadura; GA: Galicia; IB: Balearic Islands; RI: La Rioja; MD: Madrid; MC: Murcia; NC: Navarre; PV: Basque Country; RRR: relative risk reduction; VC: Valencia.

Table 6
Information on confirmatory tests under the program provided by each BCSP

BCSP	Mention the need to confirm	Reasons for needing to confirm	% women called for confirmatory tests	Identification of tests to be performed	Description of each test	Reasons for each test	Potential complications of these tests
AN	X	X		X	X		
AR							
AS		X	X		X		X
CN		X	X				
CB		X	X				
CM		X	X				
CL	X			X			
CT (CIO)	X		X	X			
B (BPHA)	X	X	X	X	X	X	X
EX							
GA	X		X	X			
IB	X	X		X			
RI	X						
MD	X	X		X			
MC							
NC	X						
PV	X			X			
VC	X			X	X	X	
TOTAL: n (%)	11 (61.1%)	8 (44.4%)	7 (38.9%)	9 (50%)	4 (22.2%)	2 (11.1%)	2 (11.1%)

AN: Andalusia; AR: Aragon; AS: Asturias; ASPB: Agencia Salut Pública Barcelona; B: Barcelona; BCSP: Breast cancer screening program; BPHA: Barcelona Public Health Agency; CN: Canarias; CB: Cantabria; CIO: Catalan Institute of Oncology; CM: Castilla La Mancha; CL: Castilla y León; CT: Catalonia; EX: Extremadura; GA: Galicia; IB: Balearic Islands; RI: La Rioja; MD: Madrid; MC: Murcia; NC: Navarre; PV: Basque Country; VC: Valencia.

how to prepare oneself for a mammogram and how to find out the results of the test. Only one autonomous region (Castilla La Mancha) underlined the need to sign an informed consent form before the test.

User rights: Only a third of the programs recognized that participation in the screening program was voluntary. The majority of the programs (77.8%) indicated that the test was free of charge but few (11.1%) specified that it was confidential or how personal data were managed (22.2%). The majority did not mention that there is controversy about screening (11.1%), although 44.4% explicitly recognized the presence of both benefits and risks.

Impact of screening programs:

- Benefits of screening (Table 5). Two BCSPs (Aragón and Extremadura) did not give any information on the benefits of screening. Only three programs (Asturias, Barcelona and Valencia) gave some information on reductions in mortality risk thanks to screening.

- Disadvantages and risks of screening (Table 5). Seven programs provided information on the risk of overdiagnosis, although none of them quantified this risk, while six noted the risk of overtreatment associated with screening. Two programs (Navarre and the Basque Country) did not mention any of disadvantages or risks of screening. The majority did not properly describe the rates of false positives and negatives associated with the test, although they mentioned that women might find the test uncomfortable.

- Minimization of emotional distress. Two thirds of the programs analyzed indicated that the majority of screening tests conducted are negative and half of the programs sought to reduce anxiety concerning the results. Only 22.2% of the programs, however, mentioned the availability of effective treatments for breast cancer, while a third sought to provide

data to reduce the fear of cancer. Four programs did not provide any information related to seeking to minimize the emotional distress associated with breast cancer screening.

Confirmatory tests (Table 6). The majority of programs mentioned the possibility of being called for further tests to confirm mammography findings, while less than half set out the reasons for undergoing these additional tests or the probability of this happening. One in two programs mentioned all the types of tests that might be offered, but very few provided further details, explained why they might be necessary or provided information about any disadvantages or potential complications. Three programs (Aragon, Extremadura and Murcia) did not provide any information on confirmatory tests.

DISCUSSION

Although there is notably wide variety in the format and quality of the official information offered to women through the different BCSPs in Spain, in general, the contents tend to place emphasis on the benefits of screening mammograms at the expense of the risks, with a significant lack of information about current areas of controversy and user rights, as well as little to address the emotional distress associated with screening or concerning confirmatory tests. Additionally, around half of the BCSPs did not provide brochures, despite the fact that they may be able to provide more comprehensive information than leaflets.

In Spain, no other studies have recently analyzed and compared the official information provided by different BCSPs. The only study available before ours was conducted by Queiro et al. more than a decade ago⁽¹²⁾. Our findings suggest that the situation has improved in all areas since then, though unevenly: there is moderately more information on the risks of screening (for example, the percentage of programs mentioning the possibility

of overdiagnosis having grown from 0% to 38.9% of the BCSPs) and on the objectives and characteristics of the program (the percentage explaining what early detection is having increased from 16.6% to 66.6%); only marginally more information about confirmatory tests and the benefits of screening; and hardly any improvement in terms of the information addressing emotional distress. Nevertheless, the results of our study and that of Queiro are not directly comparable given that they have been conducted using different assessment instruments. In our case, we have included items that we considered important for informed decision making, and which have been indicated in recent studies^(13,14,15,16), such as information concerning potential complications associated with confirmatory tests, the presentation of absolute numbers and the use of pictograms (graphical representation with greater descriptive and explanatory power than text). Despite the qualitative leap observed in Spain, especially in some BCSPs, we consider that the information provided remains incomplete and that quite a high percentage of the programs do not encourage women to take informed decisions.

The situation in neighboring countries is not markedly better than in Spain. Given the high variability between published studies in the systems for collecting the informative material provided in screening programs and analyzing its content, it is not possible to make direct quantitative comparisons, but we can appreciate trends that seem to follow similar patterns. In countries such as Italy⁽¹⁷⁾ and Finland⁽¹⁸⁾, it seems that adequate information is provided on the objectives, procedures and advantages of screening, but not on risks and disadvantages. A high variability in format and content, a lack of information on areas that are key to enabling informed decision making and a tendency to present the benefits in more detail than the disadvantages and risks of screening, as found in our study, are issues that are common to various comparisons conducted in recent years internationally^(16,19). A recent study was published in

Italy comparing the information provided to users in 2001 and 2014. As in our study, the authors observed a slight improvement regarding information on the risk of overdiagnosis and of false positives and negatives, but pointed out that the information is still far from what could be considered balanced⁽¹⁹⁾. Other authors go as far as suggesting that the bias that tends to be systematically observed in all the studies reflects a clear prescriptive intent, in the sense that it encourages individuals to participate in screening, indicating that healthcare organizations are worried about providing information that could have a negative impact on coverage⁽¹⁸⁾. Nevertheless, a clinical trial conducted in Spain found that providing users with balanced information did not seem to influence whether they decided to participate in the early detection program⁽²⁰⁾.

In Spain, the percentage of women with a reasonable level of knowledge about screening is very low (being estimated to be around 8.4% in our setting)⁽²¹⁾. On the other hand, the information available to users is, in general, incomplete, given that it tends to exaggerate the risk of cancer and overestimate the benefits of early detection⁽²²⁾. Given this, it seems clear that more effort should be made to provide individuals with more balanced and complete information that increases users' knowledge and helps society adopt a more realistic view of the real usefulness of screening.

When women receive more complete information, their level of knowledge grows, but the effect varies considerably with the format. For example, using brochures rather than more limited formats, such as leaflets, women gain knowledge, but only a modest amount and in some areas, namely, those which are the easiest to understand⁽²³⁾. Notably, not even half of the BCSPs in Spain use brochures. Further, decision aids help women gain more knowledge than brochures⁽²⁴⁾. Such tools also seem to increase the percentage of women reaching an informed decision⁽²⁵⁾,

although it is true that an approach focused on maximizing the quantity and quality of information should be based on the combination of different information formats available. On the other hand, it does seem that providing adequate information would not lead to adverse effects such as increases in the levels of concern about cancer or negative emotions⁽²⁰⁾.

The next question that we should be asking ourselves is whether users received sufficient information (taking into account that they do not only obtain information from screening programs but also from other sources such as awareness campaigns, advertisement and news in the media, etc.) for the decision of whether to participate to be taken freely. This is considered a prerequisite for informed decision making, although information alone does not ensure that decisions are independent; for this, it is necessary to confirm that the information has been digested and understood, and that the final choice is made freely and finally reflects personal values and preferences^(26,27). Indeed, it is one thing that information is available and quite another that it is understood, there being sociodemographic and cultural factors that seem to bridge this gap⁽²⁸⁾. On the other hand, people take decisions based not only on facts but also on values, beliefs and personal preferences, and this is reflected in the fact that many people feel overwhelmed by statistics and prefer the advice of other people (close survivors of cancer, health professionals) before making a decision^(20,29,30). Further, asking for advice should not be interpreted as implicitly giving permission to others to make the final decision, since it does not mean that person asking for the advice is not able or does not wish in the end to make an independent decision⁽³¹⁾. Finally, it can be considered striking that contradictory information was provided in material from different autonomous regions within Spain, notably, concerning breast self-examination, a practice that was encouraged in some programs but recommended against in others (on the grounds that according to the current scientific evidence it poses more risks

than benefits), as this may lead to confusion making decisions more difficult and undermining the trustworthiness of the information.

The aforementioned findings have led some countries (such as France, Switzerland and the United Kingdom) to consider alternatives to the current model of decision making, such as shared decision making⁽⁸⁾. Unlike the pattern of decision making prevailing in Spain, in which there is a one-way transfer of information, without the participation of users in the process or provision of personalized information, in shared decision making options are presented and information is personalized, the concerns and goals of each person are assessed and there is help to ensure decisions are in line with personal levels of risk, values and preferences. This process (the implementation of which is not without a certain degree of complexity) should be supported by infographics or pictograms visually illustrating the main results (preferably in absolute terms), vignettes, videos and other aids to support clinical decision making, as well as the organization of face-to-face information sessions. Interventions based on this model of shared decision making have shown to improve people's level of knowledge regarding the usefulness of screening and reduce decisional conflict, without influencing the quality of the decision or the final objective⁽³²⁾. In our study, we found that only four BCSPs included pictograms in the materials they provide and very few provide absolute numbers on the benefits or risks of screening.

The main limitation of our study lies in the difficulty of accessing all the information available in all the autonomous regions across Spain. Despite our efforts to obtain all the up-to-date materials, we may not have collected all the information available. Nevertheless, given the wide variety of documents retrieved, the sample used in this study can be considered representative of the current status of the official written information concerning BCSPs in our country. Another limitation of our study is that we analyzed the information

dichotomously (provided or not), but we did not analyze its quality or whether informed decision making is encouraged, despite tools to assess the quality of the decision support systems now being available⁽³³⁾, nor did we assess the way in which information was presented, when this may be important. It has been demonstrated that individuals' decisions are influenced by the framing of information, in particular, the presenting of information in a schematic way seen to be equivalent to certain values or ideas seeking to promote particular interpretations or motivations and discourage others⁽²⁶⁾. Indeed, the potential power of framing can be seen by comparing which data are and are not given: one example could be underlining the prevalence of breast cancer (given by nearly three-quarters of the BCSPs in our study) but not the estimated lifelong cumulative risk of developing the disease (given by considerably less than half of programs), which could magnify the nature of the problem and lead to a higher rate of participation in the screening.

Future studies should, therefore, assess not only the information itself but also the influence of different focuses in its provision on decisions and on how freely they are taken. Further, greater efforts should be made in the framework of the National Health System to provide the population with the most complete and balanced information possible. Finally, a consensus should be reached on the content of the materials for the target population, as well as the channel and format for presenting it, based on models and tools that have been shown to increase user knowledge and favor informed decision making, and efforts should be made to strengthen mechanisms for monitoring and comparing information resources between BCSPs across the country.

The content of official written information on BCSPs based on mammograms provided in Spain varies between programs and should be improved if we want to encourage women to acquire knowledge and make informed

decisions. More efforts should be made to provide information based on the best available evidence, using simple terms and well-balanced data with absolute numbers on the benefits and risks of screening presented in the form of pictograms, without omitting information related to the characteristics of the disease, the functioning of the program and related tests, and the interpretation of results, as well as their emotional impact.

ACKNOWLEDGEMENTS

We would like to thank the regional coordinators of the breast cancer early detection programs of the regions of Andalusia, Aragon, Cantabria, Castilla y León, Valencia, Extremadura, Galicia, Balearic Islands, La Rioja, Navarre and the Basque Country, as well as of Barcelona (Consorci Sanitari de Barcelona), for their collaboration in providing the documents needed to carry out this study.

REFERENCES

1. World Health Organization. Cancer control. Knowledge into Action. WHO guide for effective programmes. Early detection, Geneva. 2007.
2. Welch HG, Schwartz LM, Woloshin S. Are increasing 5-year survival rates evidence of success against cancer? *JAMA*. 2000;283:2975-8.
3. Welch HG, Prorok PC, O'Malley J, Kramer BS. Breast cancer tumor size, overdiagnosis, and mammography screening effectiveness. *N Engl J Med*. 2016;375:1438-47.
4. Brewer NT, Salz T, Lillie SE. Systematic review: the long-term effects of false-positive mammograms. *Ann Intern Med*. 2007;146(7):502-10.
5. Gøtzsche PC, Jørgensen KJ. Screening for breast cancer with mammography. *Cochrane Database Syst Rev*. 2013;6:CD001877.
6. Esserman L, Shieh Y, Thompson I. Rethinking screening for breast and prostate cancer. *JAMA*. 2009;302(15):1685-92.
7. Arie S. Switzerland debates dismantling its breast cancer screening programme. *BMJ*. 2014;348:g1625.
8. Barratt A, Jørgensen KJ, Autier P. Reform of the national screening mammography program in France. *JAMA Intern Med*. 2018;178(2):177-8.

9. Asuncion N, Delfrade J, Salas D, Zubizarreta R, Ederra R, Red de Programas de cribado de cáncer. Programas de detección precoz de cáncer de mama en España: características y principales resultados. *Med Clin*. 2013;141(1):13-23.
10. Ponencia de Cribado Poblacional de la Comisión de Salud Pública. Documento marco sobre cribado poblacional. Ministerio de Sanidad, Política Social e Igualdad. Madrid; 2010. Available from: https://www.msssi.gob.es/profesionales/saludPublica/prevPromocion/docs/Cribado_poblacional.pdf.
11. Active Citizenship Network. Carta europea de los derechos de los pacientes. Roma; 2002.
12. Queiro Verdes T, Cerdá Mota T, España Fernández S, Coord. Información a usuarias sobre el cribado de cáncer en la mujer: Evaluación de la situación actual y establecimiento de estándares de información basada en la evidencia: 1. Información a usuarias sobre el cribado de cáncer de mama. Plan de Calidad para el Sistema Nacional de Salud del Ministerio de Sanidad y Política Social. Agencia de Avaluación de Tecnologías Sanitarias de Galicia; 2007. Informes de Evaluación de Tecnologías Sanitarias: avaliat N°. 2007/05-1. Available from: https://www.sergas.es/docs/Avalia-t/Avalia-t_Cribado%20Mama_CD.pdf.
13. Geller BM, Zapka J, Hofvind SS, Scharpantgen A, Giordano L, Ohuchi N, et al. Communicating with women about mammography. *J Cancer Educ*. 2007;22(1):25-31.
14. Giordano L, Cogo C, Patnick J, Paci E; Euroscreen Working Group. Communicating the balance sheet in breast cancer screening. *J Med Screen*. 2012;19 Suppl 1:67-71.
15. Slaytor EK, Ward JE. How risks of breast cancer and benefits of screening are communicated to women: analysis of 58 pamphlets. *BMJ*. 1998;317:264-5.
16. Zapka JG, Geller BM, Bulliard JL, Fracheboud J, Sancho-Garnier H, Ballard-Barbash R; IBSN Communications Working Group. Print information to inform decisions about mammography screening participation in 16 countries with population-based programs. *Patient Educ Couns*. 2006;63(1-2):126-37.
17. Giordano L, Rowinski M, Gaudenzi G, Segnan N. What information do breast cancer screening programmes provide to Italian women. *Eur J Public Health*. 2005;15(1):66-9.
18. Saalasti-Koskinen U, Mäkelä M, Saarenmaa I, Autti-Rämö I. Personal invitations for population-based breast cancer screening. *Acad Radiol*. 2009;16(5):546-50.
19. Gummertsbach E, Piccoliori G, Zerbe CO, Altiner A, Othman C, Rose C, et al. Are women getting relevant information about mammography screening for an informed consent? A critical appraisal of information brochures used for screening invitation in Germany, Italy, Spain and France. *Eur J Public Health*. 2010;20(4):409-14.
20. Baena-Cañada JM, Rosado-Varela P, Expósito-Álvarez I, González-Guerrero M, Nieto-Vera J, Benítez-Rodríguez E. Using an informed consent in mammography screening: a randomized trial. *Cancer Med*. 2015;4:1923-32.
21. Rosado P, Baena JM, Quílez A, González M, Expósito I, Nieto J, Benítez E. ¿Qué piensan las mujeres sobre la mamografía de cribado? Encuesta en el programa de diagnóstico precoz de cáncer de mama. *Rev Senol Patol Mamar*. 2018;31:4-11.
22. Black WC, Nease RF Jr, Tosteson AN. Perceptions of breast cancer risk and screening effectiveness in women younger than 50 years of age. *J Natl Cancer Inst*. 1995;87:720-31.
23. Webster P, Austoker J. Does the English Breast Screening Programme's information leaflet improve women's knowledge about mammography screening? A before and after questionnaire survey. *J Public Health*. 2007;29(2):173-7.
24. Reder M, Kolip P. Does a decision aid improve informed choice in mammography screening? Results from a randomised controlled trial. *Plos One*. 2017;12(12):e0189148.
25. Martínez-Alonso M, Carkes-Lavila M, Pérez-Lacasta MJ, Pons-Rodríguez A, García M, Rué M. Assessment of the effects of decision aids about breast cancer screening; a systematic review and meta-analysis. *BMJ Open*. 2017;7:e016894.
26. Jepson R, Hewison J, Thompson A, Weller D. How should we measure informed choice? The case of cancer screening. *J Med Ethics*. 2005;31(4):192-6.
27. Schragger S, Phillips G, Burnside E. Shared decision making in cancer screening. *Fam Pract Manag*. 2017;24(3):5-10.
28. Ghanouni A, Renzi C, Waller J. A cross-sectional survey assessing factors associated with reading cancer screening information: previous screening behaviour, demographics and decision-making style. *BMC Public Health*. 2017;17:327.
29. Hersch J, Jansen J, Barratt A, Irwig L, Houssami N, Howard K, et al. Women's views on overdiagnosis in breast cancer screening: a qualitative study. *BMJ*. 2013;346:f158.

30. Gummersbach E, der Schmitten J, Mortaiefer A, Abholz HH, Wegscheider K, Pentzek M. Willingness to participate in mammography screening. *Dtsch Arztebl Int.* 2015;112:61-8.

31. Ahmed S, Bryant LD, Tizro Z, Shickle D. Is advice incompatible with autonomous informed choice? Women's perceptions of advice in the context of antenatal screening: a qualitative study. *Health Expect.* 2014;17(4):555-64.

32. Lillie SE, Partin MR, Rice K, Fabbrini AE, Greer NL, Patel S, et al. The effects of shared-decision making on cancer screening. A systematic review. VA ESP Project #09-009; 2014.

33. Elwyn G, O'Connor A, Stacey D, Volk R, Edwards A, Coulter A, et al. Developing a quality criteria framework for patient decision aids: online international Delphi consensus process. *BMJ.* 2006;333(7565):417.