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How is informed decision-making about breast cancer screening addressed in Europe? An international survey of 28 countries

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ABSTRACT

The aim of this study was to develop a typology of approaches towards informed decision-making (IFD) about mammography screening in Europe. All countries collaborating in the European Commission Initiative on Breast Cancer were approached to participate. Experts from 28 European countries responded to a web-based survey providing data on key organisational and policy characteristics of breast screening at the national or regional level. A total of 35 responses were received including data from regionally organised breast screening in several countries. 27 respondents, covering 21 countries, reported the existence of a policy towards IFD and stated that they communicated to women about the benefit and risks. Few countries had attempted to measure the proportion of women making an informed choice. A cluster analysis of the survey responses allowed to identify three categories: countries in a confirmation phase who have adopted a policy specific to mammography screening; countries in an implementation phase with generic polices and limited administrative support dedicated yet to IFD; and countries in a decision phase who are deliberating how to address IFD. To the best of our knowledge, this study is the first to investigate the key policy and organisational characteristics of approaches taken to facilitate IFD in Europe. The results demonstrate a broad adoption of the principle of enabling IFD but indicate heterogeneity of implementation.

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1. Introduction

With 626,679 deaths (15.1% of all cancer deaths) attributed to breast cancer globally in 2018, breast cancer remains the leading cause of cancer mortality in women [1,2]. Organised breast cancer screening has been implemented in many European countries to reduce the burden of breast cancer mortality [3,4]. The 4th edition of the European Code against Cancer advises women in the European Union (EU) to participate in breast cancer screening programmes after being invited by the national or regional programme [5]. This advice was made following a thorough review of the evidence, showing a 25-31% mortality reduction amongst women invited to screening in population-based breast screening programmes [6,7]. However, as with other forms of organised screening, in addition to the potential benefit of decreased mortality risk participation in breast screening carries certain risks or harms, including the risk of overdiagnosis of breast cancer [8,9,10]. Consequently, the general principle is that organised breast cancer screening should only be offered to fully informed women who are asymptomatic at the time of invitation to screening [11].

In accordance with this principle, the World Health Organization affirms that achieving a high uptake of screening should not take precedence over women making informed decisions about screening participation in line with their individual values and preferences [12,13]. Consequently, if making an independent decision is the main ethical consideration, women who are invited to screening must be provided with suitable information to enable them to make an informed decision [14,15]. An informed decision is most commonly defined as being an active choice that is made by a decision-maker consistent with the individual's values, attitudes and personal preferences [16]. Moreover, knowledge is an essential cognitive component of informed decision-making about mammography screening. In order to make an informed decision about participation, knowledge about benefits and risks of mammography screening must be present [13]. In attempts to measure informed choice about screening participation, decisions have been classified as informed if adequate knowledge about the screening was demonstrated and consistency was present between the attitudes and preferences of the individual and their behaviour [17]. Nevertheless, decisions about participation in screening are not based solely on the information provided but also take account of a variety of personal and social factors [13]. Knowledge as an indicator of informed choice is also influenced by health literacy as this demonstrates the ability of an individual to understand and apply information. Consequently, women with lower health literacy levels may have greater difficulties to exer-

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cise an informed decision in comparison to women with high health literacy levels [18]. In respect of these factors, the new European Guidelines for Quality Assurance in Breast Cancer Screening, updated under the auspices of the European Commission Initiative on Breast Cancer (ECIBC), issued a strong recommendation that all women invited to breast screening should receive sufficient information about the desirable and undesirable effects in order to make an informed choice [19].

Whilst research into the effect of specific interventions that are designed to facilitate informed decision-making in breast cancer screening are well reported in the literature [20,21,22,23], to the best of our knowledge, no systematic report has been produced with regard to the key policy and organisational characteristics of approaches taken to facilitate informed decision-making in Europe. The aim of this paper is to address the gap in the literature by mapping the responses taken at national and regional level in Europe and develop a typology of approaches towards the facilitation of informed decision-making about mammography screening in Europe.

2. Materials and methods

2.1. Setting and participants

The study follows a web-based survey design distributed to experts who have been national contact points for the European Commission Initiative on Breast Cancer (ECIBC) or who have provided data to the second implementation report in cancer screening in the EU [24]. Expert contacts were identified following a snowball sample procedure, beginning with the designated national contact points established for each Member State of the European Union and associated countries participating in ECIBC. The ECIBC was used as the basis for selecting the contacts as this initiative is mandated by the European Commission to update the European guidelines for quality assurance in breast cancer screening [25,26]. Plus, each participating country in the ECIBC has nominated a national contact point as a referent to provide feedback and advice based on their expertise regarding their national context.

In the event of non-response or non-completion by ECIBC contact points, a secondary contact list was established for each country. These contacts were either nominated by the ECIBC via direct communication with the authors (in circumstances were the ECIBC contact point felt that a colleague is more qualified to provide the data) or were derived from the data providers to the second report on the implementation status of cancer screening in European Union (hereafter, 'EUSR') published in 2017 [27]. The EUSR is a comprehensive report on the status of cancer screening across the entire EU, containing data on the organisation and performance indicators of organised breast, cervical and colorectal cancer screening programmes. Data for the report was provided by cancer screening programme coordinators with access to the necessary planning, monitoring, and evaluation data for the respective screening programmes [4]. Consequently, data providers to EUSR would be well placed to respond with accurate data. It is important to note that for some countries included in the ECIBC the responsibility for breast screening programme is held by the regional or local authority [4]. For instance, in the United Kingdom, there are in practice four screening programmes for breast cancer in operation, reflecting the four nations of the United Kingdom. The same is true regarding the regions of Belgium, as a further example. This situation has been widely acknowledged as creating difficulties in obtaining comparative data about cancer screening programmes [13]. Consequently, in such instances, it is more appropriate to collect data from the sub-national level. Therefore, regional or local expert contacts derived from data providers to the EUSR were specifically included for countries with sub-national responsibilities for breast screening, as described in the EUSR [27].

A total of 85 individual expert contacts from 36 countries received an email invitation with a unique individual link to complete the survey. This included all 35 countries participating in the ECIBC (27 EU member states and Iceland, Montenegro, North Macedonia, Norway, Serbia, Switzerland, Turkey and the United Kingdom) plus Israel, which had been an observer but not direct participant country of the ECIBC [28]. The survey required a lead respondent who would submit the data and provide their specific contact details and information about their professional profile.

2.2. Data collection

Data was collected via an online questionnaire offered through the Qualtrics survey platform. The survey questions were derived from the typology established in the EUSR and followed the definitions about screening programme coordination outlined in the report [26]. To facilitate an objective and comparable analysis of the data, most questions were closed-ended with categorical variables per question, for example, "Yes/No/Not Applicable." Open-ended comments were available in order to allow the respondent to provide further data or to clarify their response. The survey questions were organised into three distinct sections relating to: (i) policies that are in place to facilitate informed decision-making (e.g. "*Does your country/region have a policy in place for the facilitation of informed decision-making for women offered mammography screening?*"); (ii) enabling informed decision-making in practice (e.g. "*Is the information on the benefits and harms of mammography screening communicated via decision aids?*"); and (iii) evaluating the process for supporting informed decision-making (e.g. "*Which, if any, of the following cognitive variables are measured in your country?*"). The survey flow function of Qualtrics was used to define the sections and apply both skip and branch logic that allowed respondents to provide data relevant to their context of their screening programme. As a result, certain questions were only available to respondents depending on their answers to preceding questions. For instance, if respondents answered "*Yes*" to "*Does your country/region provide written information to women about the benefits and risks of mammography screening …*," further questions would become available to provide additional information about this question. The additional questions would not be available if the respondent answered "*No*" or "*Not Applicable*". Consequently, no respondent could answer every question within the survey.

The initial draft, comprising all possible survey questions, was pre-tested with three external experts in breast cancer screening: a breast screening programme coordinator, an academic with international knowledge in breast screening policy, and a breast cancer patient representative. Following the pre-testing, questions were amended or excluded based on the feedback provided by each expert.

The finalised version of the survey questionnaire was then distributed to the contacts via the email function within Qualtrics. This provided recipients with a structured email invitation with a unique link to complete the survey online. The email invitation explained the aims and objectives of the survey with brief definitions of the key concepts. It also informed the contacted experts that it was possible to refer a more suitable colleague to provide data. In those circumstances, the expert contacts were asked to inform the authors directly.

Additionally, contacts were informed that it was possible to collect a response based on the inputs of a group of colleagues with expertise on the status in their respective country or region. However, a lead respondent would be required to submit their personal information and be contactable for follow up. Overall, one expert respondent per country or region was sought.

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2.3. Data analysis

Data was transferred from Qualtrics to SPSS (version 24.2) and cleaned for missing values and input errors. By way of a descriptive study of the main variables included in the questionnaire, frequencies and percentages of data responses were calculated within SPSS and custom pivot tables developed for each section of the survey.

To identify groups of countries or regions with common organisational characteristics towards enabling informed decision-making, a Hierarchical Cluster Analysis (HCA) of the survey data was performed. HCA groups together objects into distinct, separate clusters according to their similarity. This method was used as HCA has an advantage over other clustering methods in that the HCA does not require a pre-defined number of clusters, thus, it can facilitate a more organic method of developing the typology of approaches to informed decision-making [29]. As categorical data cannot be used directly for the HCA, a Multiple Correspondence Analysis (MCA) was computed as an intermediary step to enable the HCA. MCA identifies inherent structures in nominal or categorical data by visualising the data as points in a low-dimensional space and, as a result, infers relationships between the data providing the numerical values required for the HCA [30]. As the survey flow prohibits respondents from providing data for each question of the survey, specific questions answered by >50% of respondents were selected and used to provide the underlying data for the MCA. The 11 questions included in the MCA, described in supplementary file 2, covered characteristics of informed decision-making policy ($n = 7$), and implementation and evaluation factors ($n = 4$).

Following the MCA computation, the relationship between countries (or regions, in cases were the respondent was active at the regional or local level) was visually represented on a factor map showing the distance along two dimensions. Joint plots of the variables from the survey questions were produced on independent factor maps to represent the distance between the categories according to the individual survey responses. The factor maps were then compared to assess the underlying values contributing to the distance countries or regions for whom an expert submitted data to the survey. Using the object scores produced by the MCA, the HCA was performed using the Ward Agglomerate method to produce clusters of countries and regions. Chi-square tests were applied to assess differences between the clusters.

3. Results

A total of 35 responses were received from experts representing 28 independent countries. 13 responses were received from experts active at the regional or local level in six different countries. As 85 individual experts had been invited to provide data, the participation rate for the survey is 41.2%. The lead respondents of each country or region were most frequently coordinators of the breast screening programme (48.6% of respondents) working within a cancer-specific institute (37.1%). While 40% of respondents were national contacts points for the ECIBC, most respondents had also provided data for the EUSR. Further characteristics of the respondents to the survey questionnaire are shown in Table 1.

An overview of the general characteristics of the countries and regions represented in the survey is provided in Table 2. This table provides information on the status of the population-based screening programme per country or region. The definition of population-based is understood as being a state whereby the eligible target group in a population served by a programme can be identified and invited to each round of screening [4]. Programmes are considered population-based when 90% or more of the eligible target population have been invited at least once, following the precedent of the definition in the second implementation report on cancer screening in the EU [27].

Table 1
Profile of web-based survey respondents ($n = 35$).

Respondent	n	%
ECIBC National Contact Point	14	40%
EUSR data provider	25	71.4%
Position		
Clinician	4	11.4%
Ministry of health medical officer	4	11.4%
Scientific researcher	10	28.6%
Screening coordinator	17	48.6%
Total	35	100%
Affiliations		
Cancer institute	13	37.1%
Clinical centre	5	14.3%
Ministry of health	5	14.3%
NGO	2	5.7%
Public health agency	10	28.6%
Total	35	100%

Countries that had been contacted but from which no response was obtained were: Bulgaria; Estonia; Latvia; Poland; The Netherlands; Serbia; Sweden; Turkey; and, from within the UK, England, Scotland and Northern Ireland. A private communication was received from the contact point in Bulgaria stating the impossibility to provide data as mammography screening had not yet been introduced in the country.

The survey completion ranged from 20% to 60%, with a median of 40%. Due to the survey flow, questions had been posed to respondents based on previous gateway answers, 100% completion of the survey was not possible. Lower completion rates were obtained for countries that do not have widespread systematic breast screening due to insufficient data available at the country level to respond to the questions. Overall, when a question had been shown to a respondent a response was provided by respondents on 90.3% cases. Thus, the missing values for answers when they were expected is 9.7%. Further details on the missing values are provided in annex.

Table 3 summarises the data that were collected regarding the policies to enable informed decision-making in breast cancer screening. Of all respondents, 27 (77.1%) reported that a policy is in place to enable informed decision-making for women about mammography screening. The year of initiation of the policy ranged from 1992 to 2017, with 2015 being the most frequent year of initiation ($n = 4$). Ten respondents indicated that in their country or region the policy regarding informed decision-making applies specifically to mammography screening. For the remaining 17 respondents, the policy in their country or region also applies to cervical ($n = 15$) and colorectal ($n = 12$) cancer screening, and in a few cases, is applied to non-cancer screening programmes ($n = 3$). Amongst the eight respondents who stated their country or region is without a policy towards informed decision-making, three reported that their country or region plans to introduce such a policy in the future.

Table 4 presents data on implementation factors surrounding the informed decision-making process regarding breast cancer screening. As with the presence of a policy for informed decision-making, 27 respondents (77.1%) indicated that their country or region currently provides information to women on the benefits and harms of mammography screening in written form. For those respondents whose country or region does not communicate on the benefits and harms of mammography screening, explanations offered as to why this is the case focused mostly on structural factors, such as the lack of a systematic organised mammography screening programme in place. Nonetheless, four respondents indicated that they are considering communicating information on benefits and harms in the future. As this survey consulted ex-

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Table 2
General characteristics of the countries and regions included in web-based survey (n = 35).

Country (region)	Year of initiation	Population-based screening status	Target Age (years)	Screening interval (years)	Participation 50-69 years (year 2018)	50-69-year-old women estimated target population (x1,000) [1]
Austria	2014	rollout complete	45-69	2	42%	1,140
Belgium (Brussels)	2002	rollout complete	50-69	2	11%	123
Belgium (Flanders)	2001	rollout complete	50-69	2	49%	854
Belgium (Wallonia)	2002	rollout complete	50-69	2	9%	479
Croatia	2006	rollout complete	50-69	2	60%	601
Cyprus	2003	rollout complete	50-69	2	43%	104
Czechia	2002	rollout complete	45+	2	62%	1,417
Denmark	2008	rollout complete	50-69	2	82%	726
Finland	1987	rollout complete	50-69	2	83%	761
France	2004	rollout complete	50-74	2	50%	8,612
Germany	2005	rollout complete	50-69	2	52%	11,443
Greece	NA	no population-based programme	NA	NA	NA	1,421
Hungary	2001	rollout complete	45-64	2	47%	1,374
Iceland	1987	rollout complete	40-69	2	61%	28 [2]
Ireland	2000	rollout complete	50-69	2	74%	499 [2]
Israel	1997	rollout complete	50-74	2	79%	558
Italy (Emilia-Romagna)	1990	rollout complete	45-74	1yr (45–49) 2 yr (50–74)	76%	8,269 [nationwide]
Italy (Piedmont)	1990	rollout complete	45-74	1yr (45–49) 2 yr (50–74)	65%	8,269 [nationwide]
Italy (Tuscany)	1990	rollout complete	50-69	2	70%	8,269 [nationwide]
Italy (Verona)	1990	rollout complete	50-69	2	64%	8,269 [nationwide]
Lithuania	2005	rollout ongoing	50-69	2	40%	419
Luxembourg	1992	rollout complete	50-69	2	61%	66
Malta	2009	rollout complete	50-69	3	60%	59
Montenegro	2014	rollout ongoing	50-69	2	-	81 [2]
North Macedonia (Skopje)	2007	rollout complete	50-69	2	30%	266 [nationwide] [2]
Norway	1995	rollout complete	50-69	2	75%	502 [2]
Portugal	1990	rollout ongoing	45-74	2	73%	1,431
Romania	2015	piloting	50-69	NA	-	2,563
Slovakia	NA	no population-based programme [3]	NA	NA	NA	727
Slovenia	2008	rollout ongoing	50-69	2	71	283
Spain (Basque Country)	1990	rollout complete	50-69	2	80%	5,828 [nationwide]
Spain (Catalonia)	1990	rollout complete	50-69	2	66%	5,828 [nationwide]
Spain (Valencia)	1990	rollout complete	45-69	2	75%	5,828 [nationwide]
Switzerland (Valais)	1999	rollout complete	50-70	2	62%	34 [2]
United Kingdom (Wales)	1989	rollout complete	50-70	3	77%	407

Abbreviations: NA = Not Applicable; "–" = no response.
[1] Data as reported in the second implementation report on Cancer Screening in the European Union (2017). Estimates of age-eligible population based on Eurostat projections for 2016.
[2] Source: Cancer Incidence in Five Continents Vol. X, IARC.
[3] Announced pilot programme in 2019.

perts in breast screening at the national or regional level, the data provided relates to the specific information provided by a screening programme or other official source, such as the Ministry of Health. Nevertheless, other sources of information about breast screening are available to women in Europe. In particular, advocacy groups and non-governmental organisations play a leading role in providing information in both offline and online formats [31].

Eight respondents indicated that their country or region had performed an evaluation of the information that is provided to women about the benefits and harms of mammography screening. This evaluation most frequently covers factors such as women's perception of bias

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Table 3
Characteristics of policy towards facilitating informed decision-making in mammography screening.

Country (region)	Policy exists for informed decision-making	Year of initiation	Policy is for mammography only	If not, other programmes to which it applies	Typology of policy	Professions for whom guidelines are aimed	Team responsible for implementation of policy	Team responsible for oversight of policy
Austria	Yes	2011	Yes	NA	Guidelines for professionals	Cancer nurses; GPs; Gynaecologists; Radiologists.	Yes	Yes
Belgium (Brussels)	Yes	2014	Yes	NA	Guidelines for professionals	Cancer nurses; GPs; Gynaecologists; Radiologists.	No	No
Belgium (Flanders)	Yes	2002	No	Cervical screening; Colorectal screening.	Guidelines for professionals	Communication professionals; Radiologists; Technicians of radiological unit.	No	Yes
Belgium (Wallonia)	Yes	2002	Yes	NA	Statutory instrument	NA	Yes	Yes
Croatia	Yes	2017	Yes	NA	Guidelines for professionals	GPs; Public health professionals; Radiologists.	Yes	Yes
Cyprus	Yes	2008	No	Cervical screening; Colorectal screening.	Guidelines for professionals	GPs; Cancer nurses; Gynaecologists; Radiologists.	Yes	Yes
Czechia	No	NA	NA	NA	NA	NA	NA	NA
Denmark	No	NA	NA	NA	NA	NA	NA	NA
Finland	Yes	-	No	Cervical screening	Non-binding recommendation, decision, or directive.	NA	No	No
France	Yes	1998	Yes	NA	Guidelines for professionals; Non-binding recommendation, decision, or directive; Statutory instrument.	GPs; Gynaecologists; Radiologists.	Yes	Yes
Germany	Yes	2013	No	Cervical screening; Colorectal screening.	Statutory instrument	NA	Yes	Yes
Greece	No	NA	NA	NA	NA	NA	NA	NA
Hungary	Yes	2002	No	Cervical screening	Guidelines for professionals; Non-binding recommendation, decision, or directive.	GPs	Yes	Yes
Iceland	No	NA	NA	NA	NA	NA	NA	NA
Ireland	Yes	2000	No	Cervical screening; Colorectal screening; Diabetic retinopathy screening.	Suite of information leaflets and letters and consent form.	NA	Yes	Yes
Israel	No	NA	NA	NA	NA	NA	NA	NA
Italy (Emilia-Romagna)	Yes	1998	No	Cervical screening	Non-binding recommendation, decision, or directive.	NA	Yes	Yes
Italy (Piedmont)	Yes	2005	No	Cervical screening; Colorectal screening.	Non-binding recommendation, decision, or directive.	NA	Yes	Yes
Italy (Tuscany)	Yes	2015	No	Cervical screening; Colorectal screening.	Guidelines for professionals	Cancer nurses; GPs; Gynaecologists; Radiologists.	Yes	Yes
Italy (Verona)	Yes	2007	No	Cervical screening; Colorectal screening.	Non-binding recommendation, decision, or directive	NA	No	No
Lithuania	No	NA	NA	NA	NA	NA	NA	NA

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Table 3 (*Continued*)

Country (region)	Policy exists for informed decision-making	Year of initiation	Policy is for mammography only	If not, other programmes to which it applies	Typology of policy	Professions for whom guidelines are aimed	Team responsible for implementation of policy	Team responsible for oversight of policy
Luxembourg	Yes	1992	Yes	NA	Guidelines for professionals; Statutory instrument.	GPs; Gynaecologists; Radiologists.	Yes	Yes
Malta	Yes	2017	Yes	NA	Guidelines for professionals	Epidemiologists; Radiologists.	Yes	No
Montenegro	Yes	2015	Yes	NA	Non-binding recommendation, decision, or directive.	NA	Yes	Yes
North Macedonia (Skopje)	Yes	2015	No	Cervical screening; Colorectal screening.	Guidelines for professionals; Statutory instrument.	GPs; Radiologists; Technologists.	Yes	Yes
Norway	Yes	1999	No	-	Guidelines for professionals; Non-binding recommendation, decision, or directive.	Screening staff	No	No
Portugal	Yes	2012	No	Cervical screening; Colorectal screening; Prostate screening; Lung Screening	Non-binding recommendation, decision, or directive; Statutory instrument.	NA	No	No
Romania	No	NA	NA	NA	NA	NA	NA	NA
Slovakia	Yes	2007	No	Cervical screening	Guidelines for professionals; Non-binding recommendation, decision, or directive.	Gynaecologists; Radiologists.	No	No
Slovenia	Yes	2008	Yes	NA	Non-binding recommendation, decision, or directive.	NA	Yes	Yes
Spain (Basque Country)	No	NA	NA	NA	NA	NA	NA	NA
Spain (Catalonia)	Yes	2015	Yes	NA	Non-binding recommendation, decision, or directive.	NA	Yes	Yes
Spain (Valencia)	Yes	2011	No	Cervical screening; Colorectal screening.	Oncological Plan; Statutory instrument.	NA	Yes	Yes
Switzerland (Valais)	Yes	-	No	Colorectal screening.	Guidelines for professionals; Non-binding recommendation, decision, or directive; Statutory instrument.	Programme managers	No	No
United Kingdom (Wales)	Yes	2005	No	Aortic aneurysm screening; Cervical screening; Colorectal screening; Diabetic eye screening, Maternal and Child screening programmes.	Guidelines for professionals	Screening staff	Yes	Yes

Abbreviations: NA = Not Applicable; "–" = no response.

(n = 7), and satisfaction with the information (n = 6). Eight respondents indicated that women who had been offered screening were involved in the evaluation, in addition to health professionals (n = 5) and women in lower socio-economic groups (n = 5). Only one respondent [Switzerland (Valais)] indicated that their programme had measured the proportion of women who have made an informed decision. This was performed in 2017, with 62% of women reported to have made an informed choice about mammography screening.

In respect of how the information on benefits and harms is communicated, ten respondents reported that a decision aid designed to help women make an informed choice about mammography screening was in use in their country or region. These decision aids are mostly in the format of hard copies, i.e. brochures and leaflets (n = 10) but are also provided online in some countries and regions (n = 7). None of the decision aids that were used had the capacity to include an interactive component allowing women to enter their personal details. Reasons that were provided by the respondents as to why specific decision aids for mammography screening were not developed included concerns about the effectiveness of decision aids as a tool to enable informed decision-making (n = 2), and the lack of a standardised best practice (n = 2). It should be noted that at the time of data analysis, respondents in Italy were awaiting the outcome of local investigative trials in

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Table 4
Characteristics of implementation and evaluation of informed decision-making in mammography screening.

Country (region)	Information about benefits & risks communicated	Quantitative data communicated	Qualitative data communicated	Benefits & risks communicated via specific decision aids	Information about benefits & risks has been evaluated	Factors included in evaluation	Programme has measured the proportion of women making informed decision
Austria	Yes	Absolute risk reduction; Natural frequencies; Number needed to screen; Relative risk reduction.	Practitioner testimonials	Yes	Yes	Satisfaction with information; Perception of bias.	No
Belgium (Brussels)	Yes	Relative risk reduction	No such data is provided	Yes	No	NA	No
Belgium (Flanders)	Yes	Absolute risk reduction; Natural frequencies; Relative risk reduction.	Experience of invited women.	No	Yes	Satisfaction with information; Perception of bias; Impact on health equity.	No
Belgium (Wallonia)	Yes	Natural frequencies; Relative risk reduction.	No such data is provided	No	No	NA	No
Croatia	Yes	No such data is provided	No such data is provided	No	No	NA	No
Cyprus	Yes	No such data is provided	No such data is provided	No	No	NA	No
Czechia	No	NA	NA	NA	NA	NA	No
Denmark	Yes	Absolute risk reduction; Natural frequencies	No such data is provided	No	Yes	Perception of bias	-
Finland	Yes	Relative risk reduction	No such data is provided	No	-	NA	No
France	Yes	Absolute risk reduction; Natural frequencies; Number needed to screen; Relative risk reduction.	Practitioner testimonials	No	Yes	-	No
Germany	Yes	Absolute risk reduction; Natural frequencies.	No such data is provided	Yes	Yes	Satisfaction with information; Perception of bias; Impact on health equity;	No
Greece	-	NA	NA	NA	NA	NA	No
Hungary	Yes	Absolute risk reduction	Experience of invited women	No	-	NA	No
Iceland	No	NA	NA	NA	NA	NA	No
Ireland	Yes	No such data is provided	Information leaflets	Yes	No	NA	No
Israel	Yes	-	Testimonials of cancer survivors	No	No	NA	-
Italy (Emilia-Romagna)	Yes	Interval cancer frequency; Sensitivity; Overdiagnosis.	Practitioner testimonials	No	No	NA	No
Italy (Piedmont)	Yes	Absolute risk reduction False positives; False negatives; Interval cancers; Overdiagnosis; Natural frequencies; Recall rate.	No such data is provided	No	Yes	Satisfaction with the information; Perception of bias; Impact on health equity; Impact on uptake.	No
Italy (Tuscany)	Yes	Natural frequencies	No such data is provided	No	No	NA	No
Italy (Verona)	Yes	No such data is provided	No such data is provided	No	No	NA	No
Lithuania	No	NA	NA	NA	NA	NA	-
Luxembourg	Yes	Natural frequencies	No such data is provided	No	No	NA	No
Malta	Yes	Relative risk reduction	No such data is provided	No	No	NA	No

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Table 4 (*Continued*)

Country (region)	Information about benefits & risks communicated	Quantitative data communicated	Qualitative data communicated	Benefits & risks communicated via specific decision aids	Information about benefits & risks has been evaluated	Factors included in evaluation	Programme has measured the proportion of women making informed decision
Montenegro	No	NA	NA	NA	NA	NA	No
North Macedonia (Skopje)	Yes	No such data is provided	No such data is provided	Yes	No	NA	No
Norway	Yes	Absolute risk reduction; Natural frequencies; Number needed to screen; Relative risk reduction.	Experience of invited women	Yes	No	NA	No
Portugal	Yes	Absolute risk reduction; Natural frequencies; Relative risk reduction.	Experience of invited women; Practitioner testimonials; Testimonials of breast cancer patients.	No	-	NA	No
Romania	No	NA	NA	NA	NA	NA	No
Slovakia	No	NA	NA	NA	NA	NA	No
Slovenia	Yes	Relative risk reduction	No such data is provided	Yes	No	NA	No
Spain (Basque Country)	No	NA	NA	NA	NA	NA	No
Spain (Catalonia)	Yes	Absolute risk reduction Natural frequencies	No such data is provided	No	No	NA	No
Spain (Valencia)	Yes	False positive and negative results; Overdiagnosis; Natural frequencies; Number needed to screen; Relative risk reduction.	No such data is provided	Yes	Yes	Satisfaction with the information; Perception of bias; Impact on health equity	No
Switzerland (Valais)	Yes	Absolute risk reduction; Natural frequencies; Relative risk reduction [3]	No such data is provided	No	No	NA	Yes
United Kingdom (Wales)	Yes	Balance sheet; Natural frequencies.	Experience of invited women; Testimonials of breast cancer patients.	No	Yes	Satisfaction with the information; Perception of bias; Impact on health equity	No

Abbreviations: NA = Not Applicable; "–" = no response.
[1]Evaluation is not performed routinely.
[2]For non-population-based screening.
[3]Each canton has some modified versions.

which decision aids are compared to standard practice. Consequently, a decision had not yet been taken about this methodology.

3.1. Cluster analysis

The results of the MCA and HCA support the differentiation of countries according to their approaches towards the policy and implementation of informed decision-making in breast cancer screening. The model summary of the MCA indicates that the two dimensions accounted for a mean variance of 52.9% (Dimension 1: 72.2%; Dimension 2: 33.6%). Discrimination measures of each category from the survey data were calculated for both dimensions. The presence of an administrative team that is responsible for the oversight of the policy towards informed decision-making and a team responsible for its implementation have the largest values on both dimensions (team responsible for oversight, dimension 1 = .939; dimension 2 = .684; team responsible for implementation, dimension 1 = .947; dimension 2 = .825). For dimension 1 additional key discriminating variables included the presence of a policy about informed decision-making, whether this policy is to specific to breast cancer screening, and whether the policy was developed in consultation with stakeholders. For dimension 2, the development of the policy in consultation with stakeholders was also an important factor, along with the level of governance (i.e. regional or national) of the administrative teams responsible for the oversight and implementation of the policy.

Fig. 1 shows the factor map produced as an output from the MCA. This map facilitates the identification of clusters of approaches to supporting informed decision-making in breast cancer screening. Dimension 1 on the map clearly distinguishes between countries and regions that have adopted a policy and communicate actively on the benefits

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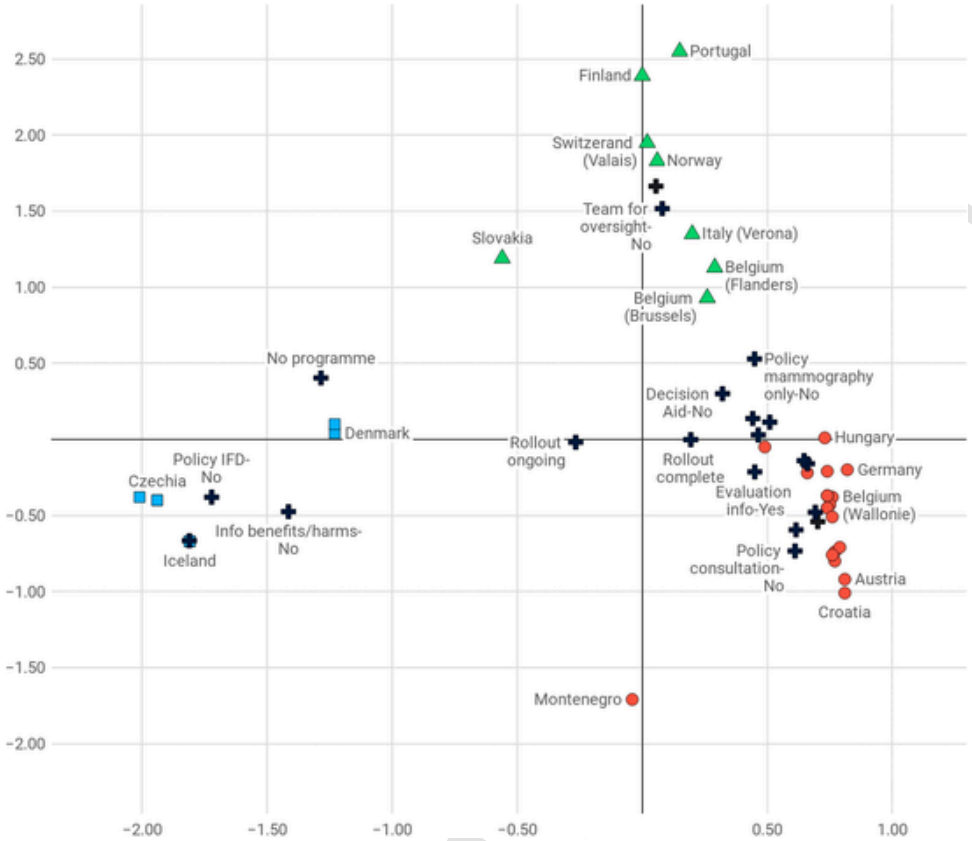

Fig. 1. Multiple Correspondence Analysis Factor Map.X axis = Policy adoption of IFD – (32.4%)Y axis = Implementation of IFD – (72.2%)Bottom right quadrant text box -

Cluster 1

Top right quadrant text box -

Cluster 2

Bottom left quadrant text box -

Cluster 3

The factor map displays the individual object scores of each country or region with similarity depicted through proximity along both dimensions. Thus, the closer the points on the map the more similar the countries or regions are in their approach to informed decision making in breast cancer screening.

- Cluster 1
- Cluster 2
- Cluster 3
- Category

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and potential harms, with the screening programmes in the bottom left quadrant being those without policies for enabling informed decision-making. Following the 'innovation to decision process' proposed by Rogers, which states that innovative ideas and methods of working pass through several stages, from knowledge acquisition to persuasion, before a decision, implementation and confirmation of the innovation [32], dimension 1 can be viewed as depicting the policy adoption of informed decision-making. This would represent the confirmation of adopting specific policies towards informed decision-making as an innovation for mammography screening practice. Dimension 2 helps a develop a typology amongst the countries and regions that have a policy for informed decision-making by demonstrating the discriminating value of organisational characteristics, such as the existence of an administrative team for the oversight and/or implementation of the policy to enable informed decision-making. Following the 'innovation to decision process', dimension 2 can be viewed as representing the organisational status and implementation phase of adopting informed decision-making, which precedes the confirmation phase.

Using the object scores from the MCA, a HCA was performed. Following an iterative process to arrive at the optimal number of clusters informed by a visual inspection of the dendrogram, shown in supplementary file 4, three clusters of programmes were retained.

Table 5 compares the three clusters that were derived from the hierarchical clustering process. Significant differences between clusters were reported for each variable used for the multiple correspondence analysis.

Cluster 1 is by far the largest cluster, containing 19 countries and regions, all of which have a policy for enabling informed decision-making. For most of the countries or regions in this cluster the policy was implemented in the 2010s. These countries also have teams that are responsible for the oversight and implementation of the policy and are predominantly operating at a national scale. All but one of the countries and regions in this cluster provide written information on the benefits and harms of mammography screening, with eight doing so via decision aids. This cluster represent countries and regions in the confirmation phase of adopting policies and practice towards informed deci-

Table 5
Comparison between the clusters of countries and regions according to variables of the Multiple Correspondence Analysis (MCA).

Variables	Cluster 1	Cluster 2	Cluster 3	Total	*p*
	n = 19	*n* = 8	*n* = 8	*n* = 35	
Policy in place for informed decision-making	19 (100%)	8 (100%)	0 (0%)	27 (77.1%)	<0.001
Policy is directed towards to mammography screening only	9 (47.4%)	1 (12.5%)	0 (0%)	10 (28.6%)	<0.001
Policy developed in consultation with stakeholders	9 (47.4%)	2 (25%)	0 (0%)	11 (31.4%)	<0.001
Team in place for the oversight of the policy	18 (94.7%)	1 (12.5%)	0 (0%)	19 (54.3%)	<0.001
Level of oversight team (*national*)	10 (52.6%)	0 (0%)	0 (0%)	10 (28.6%)	<0.001
Level of oversight team (*regional*)	7 (36.8%)	1 (12.5%)	0 (0%)	8 (22.9%)	<0.001
Level of oversight team (*other*)	1 (5.3%)	0 (0%)	0 (0%)	1 (2.9%)	<0.001
Team in place for the implementation of the policy	19 (100%)	0 (0%)	0 (0%)	19 (54.3%)	<0.001
Level of implementation team (*national*)	12 (63.2%)	0 (0%)	0 (0%)	12 (34.3%)	<0.001
Level of implementation team (*regional*)	7 (36.8%)	0 (0%)	0 (0%)	7 (20%)	<0.001
Written information about the benefits and risks provided	18 (94.7%)	7 (87.5%)	2 (25%)	27 (77.1%)	0.002
Benefits and harms communicated via decision aids	8 (42.1%)	2 (25%)	0 (0%)	10 (28.6%)	0.002
Evaluation of information on benefits and harms performed	6 (31.6%)	1 (12.5%)	1 (12.5%)	8 (22.9%)	0.003
Incentives in place for professionals to communicate on benefits and harms	1 (5.3%)	1 (12.5%)	0 (0%)	2 (5.7%)	0.012

Values represent the programmes, in number (percentage), in respect of their specific cluster.

sion-making about mammography screening. Respondents from 6 countries and regions, representing 31.6% of the cluster, reported that they had evaluated the information on benefits and risks of mammography screening that are provided to women. Only one respondent noted that incentives were in place to encourage healthcare professionals to communicate about the benefits and risks of screening. 9 countries in the cluster (47.4%) have nationally organised screening that have completed the roll-out of a population-based programme. This represents the largest group within the cluster according to organisation and status of the screening programme. *Cluster 2* contains 8 countries and regions that also have a policy in place for enabling informed decision making. This policy is not designed solely for breast cancer screening but is oriented towards other screening programmes, such as cervical cancer screening. Unlike cluster 1 these countries and regions do not have specific teams in place to monitor and oversee the policy. All but one of the countries and regions in this cluster communicate to women in the target group about the benefits and harms of mammography screening, but only two use specific decision aids as tools to facilitate informed decision-making in practice. This cluster represent countries and regions in the implementation phase of adopting approaches towards informed decision-making about mammography screening. The countries and regions in this cluster have progressed past the decision phase as their respondents reported a policy in place, albeit more general in focus rather than specific to mammography screening. At present, the respondents noted limited steps towards establishing specific teams for monitoring the policy in practice, which explains a proportion of the difference between clusters 1 and 2. 50% of the cluster is composed of regions who completed the roll-out of a population-based programme.

Cluster 3 contains 8 countries and regions that have no policy for enabling informed decision-making. Nevertheless, two of the countries and regions in this cluster do attempt to communicate about the benefits and harms of mammography screening and use a decision aid to do so. This cluster includes one of the two countries (Greece) participating in the survey that had no organised programme at the time of data analysis.. This cluster represents countries and regions in the decision phase of adopting approaches towards informed decision-making about mammography screening. Therefore, these countries and regions have not yet adopted policies towards informed decision-making, and most do not communicate about benefits and harms of screening to women. 50% of the cluster is comprised of countries who have completed the roll-out of a population-based programme. Two respondents in this cluster reported that only the benefits of mammography screening are communicated to women in their country or region.

4. Discussion

The aim of this study was to develop a typology of approaches towards the facilitation of informed decision-making about mammography screening in Europe. To enable this, an online survey was developed to gather data from key informants, at the national or regional level, on the organisational characteristics of how countries and regions in Europe approach the issue of informed decision-making.

Based on the data provided by 35 respondents from 28 countries, a cluster analysis allowed the identification of three distinct groups: those countries or regions without a defined policy towards informed decision-making; those countries or regions which do have a policy but it tends not to be specific to breast screening and without a team to oversee or implement the policy; and those who do have a policy that is often specific to breast screening and possess a team responsible for the oversight and implementation.

4.1. Results in context

To date, screening for breast cancer is one of only three tumour sites (alongside cervical and colorectal cancer) recommended in Europe on the provision that the screening is offered as part of an organised programme with sufficient resources to ensure high quality [33]. Despite this fact, the debate continues regarding the balance of benefits and harms in breast cancer screening, which emphasises the importance of providing women with necessary information in order to make an informed decision about participation [34,35].

The WHO position paper on mammography screening recommends that breast cancer screening programmes should, therefore, take measures to privilege informed choice over achieving high participation rates [12]. Subsequently, addressing informed decision-making about participation in breast cancer screening has become a priority issue [36]. The corollary of this is the need for screening programmes to define and implement specific policies and initiatives to facilitate informed decision-making in practice. To the best of our knowledge, no systematic overview has yet been performed on how breast screening programmes in Europe address this issue, thus, this study aims to fill an

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important gap in the literature. The results from the survey data demonstrate that policies (explained to survey respondents as including statutory instruments, official recommendations, or specific guidelines for professionals) to facilitate informed decision-making are being put in place by many countries in Europe. Each country or region for whom the expert respondent reported the existence of a policy also noted that their country or region seeks to implement this by communicating the benefits and harms of mammography screening to invited women. The cluster analysis indicates two emergent categories for facilitating informed decision-making: countries or regions with a specific policy and organisational resources towards monitoring and implementing the policy (cluster 1), and countries or regions with a general policy and without organisational resources to oversee and implement the policy (cluster 2). Cluster 1 depicts countries and regions who have adopted a policy specific to mammography screening and are thus in a confirmation phase regarding their approach to informed decision-making. Cluster 2 represents countries and regions with generic polices and limited administrative support dedicated yet to informed decision-making and are thus in an implementation phase. No statistically significant differences in participation rates could be found amongst the two clusters with a policy. Cluster 3 is composed of countries and regions still in a period of deliberation regarding their approach towards informed decision-making, and the communication to women of the benefits and harms of mammography screening. Therefore, this cluster represent countries and regions at the decision phase regarding their approach to informed decision-making.

The survey data also reveals that the nature of the format of the policy adopted by the countries and regions is divergent between and within clusters, including within countries for whom regional data was provided. The specific formats that the policies take cover, on the one hand, specialist guidelines directed at healthcare professionals implicated in mammography screening, whilst on the other, documented principles codified in law or established as non-binding directives. Survey respondents described how the policy can form part of a regional comprehensive cancer plan (for example in Spain [Valencia]); are documented in law through statutory instrument (for example in Germany); or be included in the aggregation of a "suite of information and consent forms" (for example in the Republic of Ireland). This heterogeneity of formats may reflect the variety of organisational characteristics of health systems in Europe. Within cluster one, the respondents from two countries (Republic of Ireland and UK [Wales]) reported that the policy towards informed decision-making was also directed at non-cancer screening programmes. This result may be an outcome of the application of the 'consider the offer' approach that is used in other screening programmes, such as prenatal screening [37].

The MCA factor map demonstrates how the category of screening programme status is distributed along the factor map and is closely bound along dimension 1. This category was a supplementary variable to the cluster analysis, which is included in order to inform the interpretation of the outcome of the cluster analysis rather than the assignment of the clusters themselves. 'Roll-out complete' is the only variable of programme status that appears with a positive value along dimension 1. As this dimension measures principally the presence of a defined policy to facilitate informed decision-making, this result suggests a close association between programme status and the presence of policies towards informed decision-making. Several noticeable exceptions are present in the data, namely Czechia, Iceland and Spain [Basque Country], who are all categorised in cluster 3. The respondent from Czechia noted that the breast screening programme behaves differently to other established programmes in Europe. The programme was described as more "client-oriented" as women are referred to certified screening centres, of the individual woman's choice, via General Practitioners and gynaecologists, with personal invitations reserved to women not participating during the previous three years. This entails that information about mammography to enable informed choice can be provided during the face to face consultation between women and their healthcare providers. Thus, this scenario would be more typically categorised as facilitating a 'shared decision-making' approach, which may help distinguish the countries and regions in cluster 3 from the other clusters. In order to enable women to make an informed decision about mammography participation, decision aids have been developed and widely reported in the literature as a suitable tool for facilitating an informed choice. Decision aids have been defined as evidence-based tools aiming to support people in making specific and deliberated choices among different options in a healthcare setting, such as participation in organised cancer screening [38]. The recently updated European Guidelines on Breast Cancer Screening and Diagnosis recommend that when informing women about the benefits and harms of breast cancer screening, a decision aid explaining the benefits and harms of screening is preferred over a standard invitation letter [39]. Amongst the screening programmes included in this study, the use of decision aids to communicate the benefits and harms of mammography screening was used by ten countries or regions, mostly appearing in cluster 1.

Several aspects could elucidate why a minority of countries reported the use of decision aids in practice despite the recommendation in favour by the new European Guidelines. Whilst many examples of decision aids for breast cancer screening have been developed in research studies, the reported outcomes on women's decision-making confidence is not certain [40,41]. Decision aids, as a tool to facilitate decision-making about participation in screening, should increase knowledge and reduce decisional conflict. However, a recent systematic review on the effects of decision aids tailored to mammography screening reported uncertain results regarding the impact of decision aids on the cognitive components of decisional conflict and decision-making confidence. However, the review evaluated examples of decision aids used in a research context, thus, participants may not be representative of the wider population as they may possess greater commitment towards screening than a typical citizen [40]. Nevertheless, the new European Guidelines acknowledge that the lack of widely available best practices for decision aids for mammography screening is a problem requiring further implementation research to develop and disseminate accepted best practices [42].

The dependency on quantitative information in decision aids to support an informed decision remains a key issue, especially where the objective to avoid exacerbating health inequalities is concerned. A recent clinical trial in Spain noted that providing quantitative information on the benefits and harms of breast screening produces a substantial increase in knowledge and informed choice [23]. However, concern remains about the ability of decision aids to reflect cultural and other intangible factors, which affect women during decision-making [43]. The presentation of the information provided in a decision aid can also influence the extent to which women can make an informed choice. For instance, the use of probabilistic or absolute information can lead to diverging assessment of risk, thereby influencing the ultimate decision of the woman [13]. In the United Kingdom, the review of information provided to women in the target age group for breast screening concluded that some quantitative data can be included in the form of absolute risk reduction [37]. Consequently, considering the ongoing debate about the effectiveness of mammography screening, deciding upon the appropriate form for quantitative data remains open for further investigation [44].Aside from decision aids, programmes typically inform women via an invitation letter to screening or a specific information leaflet. The distinction between a decision aid and an information leaflet is often not clearly delineated and may lead to ambiguity when identifying the communication tools used by the programmes [36]. For example, in the United Kingdom, invited women receive a leaflet with 'balanced information' in order to 'consider the offer' of screening [37]. One subtle difference between an information leaflet and decision

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aid may be the use of pictorial information in place of text. This ambiguity requires further investigation to clarify the terminologies and arrive at best practices for use by women in Europe considering cultural factors and varying levels of health literacy.

The results of our study demonstrate that whilst most countries and regions in clusters 1 and 2 have taken steps to facilitate informed decision-making in mammography screening, few have made attempts to evaluate the effects of the information on benefits and harms. Moreover, only one respondent reported having attempted to measure the proportion of women who had made an informed decision. This is particularly noteworthy given the prioritisation afforded to informed choice above achieving high uptake, which has led to the proposition that the proportion of women making an informed choice should be recognised as a key performance indicator for breast cancer screening [14]. Recent studies that have attempted to measure the extent of informed choice in cancer screening have focused on measuring knowledge, values and behaviour [46], and have indicated that women appear to over-estimate the benefits of breast screening [47]. However, as yet, consensus on the measures and methods to enable the measurement of informed decision-making, and arrive at informed choice is lacking [45]. Consequently, further research is required to examine the impact of methods to communicate the benefits and harms of mammography screening in respect of informed decision-making.

The cluster analysis also reported a third category in the form of countries and regions that have not yet adopted a policy on informed decision-making and mostly do not communicate the benefits and harms of mammography screening (cluster 3). Reasons given included concerns about the potential impact on the uptake on the screening programme, and insufficient evidence to support the development of a policy. The results also suggest that structural issues, at the national and regional level, may act as barriers to providing information on benefits and harms. One respondent observed that, whilst this survey concerns the provision of information from the screening programme or national and regional authorities, information leaflets can be "provided randomly by NGOs and patient support associations, professionals with insufficient knowledge or communication skills." This can lead to conflicting or confusing information for women eligible for mammography screening.

A respondent indicated that the lack of consensus on how to respond to an ongoing negative campaign against mammography screening in their country inhibited the development and implementation of information on the benefits and harms. In other countries, women are invited only if they have visited a family doctor, so that the provision of information comes through primary care, rather than from the programme itself. However, respondents in cluster 3 were mostly ambivalent about informed decision-making, which may explain why several countries and regions with established programmes appear in this cluster. One respondent noted that attendance at mammography screening itself was considered informed consent, thereby seemingly negating the urgency for informed decision-making. A further respondent from this cluster of countries and regions reported that women in their country are provided with "partial information on the benefits of screening". These approaches towards the concept of informed decision-making highlight the importance of countries and regions learning from others within the cluster as they possess a similar stage of adoption regarding informed decision-making about mammography screening. Therefore, the implementation of breast screening in Europe would benefit from a range of options and best practice examples that are tailored towards organisational characteristics.

4.2. Limitations

There are several important limitations to be noted regarding this study. Firstly, countries with important experience, notably the Netherlands and Sweden, did not respond to the survey, despite multiple attempts to engage with the relevant data providers in the respective programmes. In those countries that did respond, the programmes are sometimes de-centralised (e.g. Italy, Spain and the United Kingdom) and not all regions or nations of these countries were reached by the survey.

A key limitation of the survey is that most country or regional responses are the result of the input of a single expert contact. Moreover, as the survey was directed towards experts who in many cases are directly responsible for existing or nascent programmes, a caveat of seeking responses from such professionals is that there could be a professional interest to portray the country or region in a certain direction.

Many of the questions used in the survey questionnaire were closed questions in order to facilitate manageable data gathering and analysis. This may have had the effect of artificially restricting the responses to the questions by the data provider and resulted in a limited data set with which to develop the typologies However, open-ended comments sections were provided for respondents to feedback more qualitative information.

The potential for ambiguity of interpretation by the respondents may have occurred in respect to the definitions of such concepts as 'policy' and 'decision aids'. To mitigate ambiguity, commonly accepted terms and definitions adopted in the second report on the implementation status of cancer screening in European Union were used and explained the introductory email and in the text of the online survey itself. Nonetheless, the possibility that respondents conflated terms such as informed decision-making and informed consent cannot be ruled out.

4.3. Added value

The key strength of this study is that it provides a much-needed overview of the current approaches to facilitate informed decision-making in Europe. That this data was provided by professionals from within the respective screening programmes covering most countries implicated in the ECIBC adds to its value and relevance. Moreover, a high response rate from the competent and qualified professionals working with screening programmes was reported. This demonstrates the interest and relevance of the topic and data provided. Additionally, the cluster analysis of the data provides a basis to promote knowledge exchange between countries and regions with comparable characteristics and stage of adoption of approaches to facilitate informed decision-making about mammography screening. Furthermore, this data can be used by programmes and researchers to propose evidence-informed policy and practice that is tailored to the organisational aspects reflected in the typologies.

5. Conclusions

This study has found that many countries in Europe have adopted a policy to facilitate informed decision-making about mammography screening and make efforts to communicate to women about the benefits and harms associated with participation.

The cluster analysis determined two broad categories of approaches towards facilitating informed decision-making in practice. The largest cluster (cluster 1) typically has a policy specific to mammography screening, and organisational structures in place, in the form of specific teams with the responsibility for the oversight and implementation of the policy. This cluster depicts countries and regions in a confirmation approach towards informed decision-making. The second cluster (cluster 2) has a general policy and is without the organisational teams. The countries and regions in this cluster are in an implementation approach toward towards informed decision-making. A third category (cluster 3) emerged of countries and regions without any policy towards informed decision-making and who tend not to communicate about the benefits

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and harms of mammography screening. These countries and regions are at a decision phase towards informed decision-making, awaiting further evidence or progress in the implementation of organised screening.

The study showed that countries had not yet adopted decision aids to inform women despite this tool now being recommended by the European Guidelines on Breast Cancer Screening and diagnosis over a conventional invitation. Reasons provided for this situation include the lack of validated best practices and the need for results of ongoing research from the field.

Finally, the study also found that the measurement of informed decision-making is rarely conducted in practice thus, remains an area in need of further investigation. Consequently, validated best practices on how to develop, implement and evaluate policies to facilitate informed decision-making, with culturally appropriate and responsive tools for measurement of informed choice, would provide much needed support to help women make an informed decision about mammography screening.

Conflict of interest

NB. No conflict of interest, financial or otherwise, are to be declared by all authors.

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CRediT authorship contribution statement

David Ritchie: Writing - original draft, Software, Formal analysis. **Guido Van Hal:** Supervision, Methodology, Writing - review & editing. **Stephan Van den Broucke:** Supervision, Conceptualization, Methodology, Writing - review & editing.

Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:https://doi.org/10.1016/j.healthpol.2020.05.011.

References

[1] F Bray, J Ferlay, I Soerjomataram, R L Siegel, L A Torre, A Jemal, et al. Global cancer statistics 2018: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries. CA Cancer J Clin 2018;68:394–424. doi:10.3322/caac.21492.

[2] M Arnold, H E Karim-Kos, J W Coebergh, G Byrnes, A Antilla, J Ferlay, et al. Recent trends in incidence of five common cancers in 26 European countries since 1988: Analysis of the European Cancer Observatory. Eur J Cancer 2015;51:1164–1187. doi:10.1016/j.ejca.2013.09.002.

[3] J Ferlay, C Héry, P Autier, R Sankaranarayanan Global Burden of Breast Cancer. Breast Cancer Epidemiol. New York, NY: Springer New York; 2010. p. 1–19. doi:10.1007/978-1-4419-0685-4_1.

[4] P Basu, A Ponti, A Anttila, G Ronco, C Senore, D B Vale, et al. Status of implementation and organization of cancer screening in The European Union Member States—Summary results from the second European screening report. Int J Cancer 2018;142:44–56. doi:10.1002/ijc.31043.

[5] J Schüz, C Espina, P Villain, R Herrero, M E Leon, S Minozzi, et al. European code against cancer 4th edition: 12 ways to reduce your cancer risk. Cancer Epidemiol 2015;39:S1-10. doi:10.1016/j.canep.2015.05.009.

[6] Independent UK Panel on Breast Cancer Screening The benefits and harms of breast cancer screening: an independent review. Lancet 2012;380:1778–1786. doi:10.1016/S0140-6736(12)61611-0.

[7] M Broeders, S Moss, L Nyström, S Njor, H Jonsson, E Paap, et al. The Impact of Mammographic Screening on Breast Cancer Mortality in Europe: A Review of Observational Studies. J Med Screen 2012;19:14–25. doi:10.1258/jms.2012.012078.

[8] B Lauby-Secretan, C Scoccianti, D Loomis, L Benbrahim-Tallaa, V Bouvard, F Bianchini, et al. Breast-cancer screening-viewpoint of the IARC working group. N Engl J Med 2015;372:2353–2358. doi:10.1056/NEJMsr1504363.

[9] E Paci, EUROSCREEN Working Group Summary of the Evidence of Breast Cancer Service Screening Outcomes in Europe and First Estimate of the Benefit and Harm Balance Sheet. J Med Screen 2012;19:5–13. doi:10.1258/jms.2012.012077.

[10] D Puliti, S W Duffy, G Miccinesi, H De Koning, E Lynge, M Zappa, et al. Overdiagnosis in Mammographic Screening for Breast Cancer in Europe: A Literature Review. J Med Screen 2012;19:42–56. doi:10.1258/jms.2012.012082.

[11] The Council of the European Union Council Recommendation of 2 December 2003 on cancer screening. Off J Eur Union 2003;34–38.

[12] WHO position paper on mammography screening, 11; 2015. p. 16–19.

[13] Breast cancer screening/IARC Working Group on the Evaluation of Cancer-Preventive Interventions IARC Handbooks of Cancer Prevention, Volume 15; 2016.

[14] D Strech Participation rate or informed choice? Rethinking the European key performance indicators for mammography screening. Health Policy (New York) 2014;115:100–103. doi:10.1016/j.healthpol.2013.11.012.

[15] A Barratt Evidence Based Medicine and Shared Decision Making: the challenge of getting both evidence and preferences into health care.. Patient Educ Couns 2008;73:407–412. doi:10.1016/j.pec.2008.07.054.

[16] T M Marteau, E Dormandy, S Michie A measure of informed choice. Heal Expect 2001;4:99–108. doi:10.1046/j.1369-6513.2001.00140.x.

[17] P D Mullen, J D Allen, K Glanz, M E Fernandez, D J Bowen, S L Pruitt, et al. Measures used in studies of informed decision making about cancer screening: A systematic review.. Ann. Behav. Med. 2006;32:188–201. doi:10.1207/s15324796abm3203_4.

[18] N S Morris, T S Field, J L Wagner, S L Cutrona, D W Roblin, B Gaglio, et al. The association between health literacy and cancer-related attitudes, behaviors, and knowledge. J Health Commun 2013;18:223–241. doi:10.1080/10810730.2013.825667.

[19] H J Schünemann, D Lerda, C Quinn, M Follmann, P Alonso-Coello, P G Rossi, et al. Breast cancer screening and diagnosis: A synopsis of the european breast guidelines. Ann Intern Med 2020;172:46–56. doi:10.7326/M19-2125.

[20] H van Agt, J Fracheboud, A van der Steen, H de Koning Do women make an informed choice about participating in breast cancer screening? A survey among women invited for a first mammography screening examination.. Patient Educ Couns 2012;89:353–359. doi:10.1016/j.pec.2012.08.003.

[21] L Nekhlyudov, R Li, S W Fletcher Informed decision making before initiating screening mammography: Does it occur and does it make a difference? Heal Expect 2008;11:366–375. doi:10.1111/j.1369-7625.2008.00514.x.

[22] M Reder, P Kolip Does a decision aid improve informed choice in mammography screening? Results from a randomised controlled trial. PLoS One 2017;12:1–19. doi:10.1371/journal.pone.0189148.

[23] M J Pérez-Lacasta, M Martínez-Alonso, M Garcia, M Sala, L Perestelo-Pérez, C Vidal, et al. Effect of information about the benefits and harms of mammography on women's decision making: The InforMa randomised controlled trial. PLoS One 2019;14:e0214057. doi:10.1371/journal.pone.0214057.

[24] Parkinson ZS, Bramesfeld A, Deandrea S, López-Alcalde J, Neamțiu L, Pylkkänen L, et al. Report of a European Survey ECIBC-supporting information for breast cancer care policies and initiatives n.d. https://doi.org/10.2760/070213.

[25] Recommendations from the European Breast Cancer Guidelines n.d. https://ecibc.jrc.ec.europa.eu/recommendations/. [Accessed 10 July 2019].

[26] A Ponti, A Anttila, G Ronco, C Senore Cancer Screening in Report on the implementation of the Council Recommendation on cancer screening. 2017.

[27] International Agency for Research on Cancer, A Ponti, A Anttila, G Ronco, C Senore Cancer screening in the European Union: Report on the Implementation of the Council Recommendation on cancer screening. 2017. doi:10.1016/S0959-8049(00)00311-7.

[28] Governance of ECIBC | ECIBC n.d. https://healthcare-quality.jrc.ec.europa.eu/discover-ecibc/governance. [Accessed 8 January 2020].

[29] G J Szekely, M L Rizzo Hierarchical clustering via joint between-within distances: Extending Ward's minimum variance method. J Classif 2005;22:151–183. doi:10.1007/s00357-005-0012-9.

[30] P S Costa, N C Santos, P Cunha, J Cotter, N Sousa The use of multiple correspondence analysis to explore associations between categories of qualitative variables in healthy ageing. J Aging Res 2013;2013. doi:10.1155/2013/302163.

[31] S Knox The European advocacy perspective on mammography screening. 2011. doi:10.1016/j.breast.2010.07.003.

[32] E M Rogers Diffusion of Innovations. Fifth Edition. 5th ed. New York: Free Press; 2003.

[33] P Armaroli, P Villain, E Suonio, M Almonte, A Anttila, W S Atkin, et al. European Code against Cancer, 4th Edition: Cancer screening. Cancer Epidemiol 2015;39:S139-52. doi:10.1016/j.canep.2015.10.021.

[34] M Broeders, E Paci The balance sheet of benefits and harms of breast cancer population-based screening in Europe: Outcome research, practice and future challenges. Women's Heal 2015;11:883–890. doi:10.2217/whe.15.34.

[35] K J Jørgensen, J Brodersen, O J Hartling, M Nielsen, P C Gøtzsche Informed choice requires information about both benefits and harms. J Med Ethics 2009;35:268–269. doi:10.1136/jme.2008.027961.

[36] H M E Van Agt, I J Korfage, M L Essink-Bot Interventions to enhance informed choices among invitees of screening programmes - A systematic review. Eur J Public Health 2013;24:789–801. doi:10.1093/eurpub/ckt205.

[37] L J L L Forbes, A-J J Ramirez, Expert group on Information about Breast Screening, M Archer, J Cooke, A Coulter, et al. Offering informed choice about breast screening. J Med Screen 2014;21:194–200. doi:10.1177/0969141314555350.

[38] G Elwyn, A O'Connor, D Stacey, R Volk, A Edwards, A Coulter, et al. Developing a quality criteria framework for patient decision aids: online international Delphi consensus process. BMJ 2006;333:417–510. doi:10.1136/bmj.38926.629329.AE.

UNCORRECTED PROOF

[39] Invite and inform women about organised screening programmes | ECIBC n.d. https://healthcare-quality.jrc.ec.europa.eu/european-breast-cancer-guidelines/Invitation-to-screening-and-decision-aid. [Accessed 8 January 2020].
[40] M Carles-lavila, M J Pérez-lacasta, A Pons-Rodríguez, M Garcia, M Martínez-Alonso, M Carles-lavila, et al. Assessment of the effects of decision aids about breast cancer screening : a systematic review and meta-analysis. BMJ Open 2017;7. doi:10.1136/bmjopen-2017-016894.
[41] Jg Zapka, Bm Geller, Jl Bulliard, J Fracheboud, H Sancho-garnier, R Ballard-barbash Print information to inform decisions about mammography screening participation in 16 countries with population-based programs. Patient Educ Couns 2006;63:126–137. doi:10.1016/j.pec.2005.09.012.
[42] Decision aid use for informing women about the benefits and harms of breast cancer screening | ECIBC n.d. https://healthcare-quality.jrc.ec.europa.eu/european-breast-cancer-guidelines/Invitation-to-screening-and-decision-aid/decision-aid. [Accessed 8 January 2020].
[43] L Giordano, Karsa L Von, M Tomatis, O Majek, Wolf C De, L Lancucki, et al. Mammographic screening programmes in Europe: Organization, coverage and participation. J Med Screen 2012;19:72–82. doi:10.1258/jms.2012.012085.
[44] P D Sasieni, R A Smith, S W Duffy Informed decision-making and breast cancer screening. J Med Screen 2015;22:165–167. doi:10.1177/0969141315587344.
[45] K Seaman, P L Dzidic, E Castell, C Saunders, L J Breen A Systematic Review of Women's Knowledge of Screening Mammography. Breast 2018;42:81–93. doi:10.1016/j.breast.2018.08.102.
[46] A Ghanouni, C Renzi, S F Meisel, J Waller Common methods of measuring 'informed choice' in screening participation: Challenges and future directions. Prev Med Reports 2016;4:601–607. doi:10.1016/j.pmedr.2016.10.017.
[47] A G Mathioudakis, M Salakari, L Pylkkanen, Z Saz-Parkinson, A Bramesfeld, S Deandrea, et al. Systematic review on women's values and preferences concerning breast cancer screening and diagnostic services. Psychooncology 2019;28:939–947. doi:10.1002/pon.5041.

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