



Systematic Review

# Breast Cancer Care Quality Indicators in Spain: A Systematic Review

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**Abstract:** Breast cancer (BC) management care requires an increment in quality. An initiative to improve the BC quality care is registered, and quality indicators (QIs) are studied. We appraised the appearance of QIs and their standards systematically in Spain. A prospective systematic search (Prospero no: CRD42021228867) for clinical pathways and integrated breast cancer care processes was conducted through databases and the World Wide Web in February 2021. Duplicate data extraction was performed with 98% reviewer agreement. Seventy-four QIs (QI per document mean: 11; standard deviation: 10.59) were found in 15 documents. The Catalanian document had the highest number of QIs ( $n = 30$ ). No QI appeared in all the documents. There were 9/74 QIs covering structure (12.16%), 53/74 covering process (71.62%), and 12/74 covering outcome (16.22%). A total of 22/66 (33.33%) process and outcome QIs did not set a minimum standard of care. QIs related to primary care, patient satisfaction, and shared decision making were deficient. Most of the documents established a BC QI standard for compliance, but the high variability hinders the comparison of outcomes. Establishing a consensus-based set of QIs needs urgent attention.

**Keywords:** breast cancer care; quality indicators; quality care; health care; Spanish quality care

## 1. Introduction

Technological advancement has improved the early detection and treatment of breast cancer (BC) and has enhanced overall survival [1]. Nowadays, BC care management is more intricate and requires an increment in quality. An initiative to improve the quality of BC care is registered, and quality indicators (QIs) are studied [2]. The EUSOMA (European Society of Breast Cancer Specialists) working group states that “BC QIs provide a set of metrics to allow centres to follow patients over time in a standardised manner, and easily recognise when attention is required to improve particular areas of healthcare delivery” [2]. These must be explained in quality documents for the standardisation of care as clinical pathways or integrated breast cancer care processes elaborated by official institutions [3–5]. There are three types of QIs [6]: indicators of structure (evaluates all the sources used during the provision of services), process (appraises the actions done during patient care), and outcome (studies the results of patient care) [7,8]. In recent years, patient-centred care and shared decision making (SDM) (i.e., “a communication process in which clinicians and patients work together to share the best available evidence, consider options, and reach decisions about care according to their choices and beliefs”) [9] have gained importance [10–13]. Thus, there should be QIs focused on the evaluation of SDM [14].

Numerous authorities have suggested their own sets of QIs to establish BC quality management evaluation, but no agreement has been reached [15]. For example, in Europe, EUSOMA [2] has published a compilation of QIs that could be embraced by breast centres to provide standardised auditing and quality support and to establish an acceptable minimum standard of care. In Spain, the BC organisation varies among the 16 autonomous communities. Basic services are respected in all of them, but they establish specific health plans and adapt resources to the needs of the assigned population [16]. Every autonomous community has its own document for BC care quality (clinical pathways or integrated breast cancer assistance processes). These are quality documents deployed to manage and standardise BC care for a well-defined group of patients during a period of time and establish structured criteria for quality of care. The variability of this type of documents makes comparisons of results across populations or hospitals difficult [3,17–22]. There is also no legal obligation or incentives to report BC care management in public health. Therefore, BC care quality data analysis is heterogeneous [23].

Our literature search found no reviews about BC management QIs in health administrations in Europe or Spain. We appraised the appearance of QIs and their standards of care in Spanish quality documents systematically, paying special attention to the particular populations to which they are directed and comparing them with those suggested by EUSOMA [2].

## 2. Methods

We identified studies through a systematic review of the literature following prospective registration (Prospero no: CRD42021228867) and reported according to the PRISMA statement (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) [24,25].

### 2.1. Data Search and Selection

Eligible studies included clinical pathways and integrated health care processes from Spanish administrations. The research was performed without language limitations on online databases (Medline, Web of Science, Embase, and Scopus). The MeSH terms “breast cancer”, “breast neoplasms”, “quality indicators”, and “quality care” were combined with other word alternatives in February 2021. The search strategy appears in Appendix A. Clinical pathways and integrated health care processes are usually not promulgated in medical journals or indexed. A comprehensive manual search of grey literature was conducted to find these BC quality documents elaborated by Spanish institutions on the World Wide Web. We also explored the bibliographies of the papers added to incorporate other crucial studies to our analysis.

### 2.2. Study Selection and Data Extraction

Three reviewers (YGF, ARH, and CREL) independently selected studies for inclusion in the review. The inclusion criteria were integrated breast cancer care processes and clinical pathways provided by Spanish national institutions. These are quality documents disposed to guide and standardise BC care for a well-defined group of patients during a period of time [26] and set structured criteria for quality of care [27]. We only collected documents that explicitly mentioned BC in a section of writing. We rejected observational studies, narrative reviews, scientific reports, discussion papers, conference abstracts and posters, randomised controlled trials (RCTs), clinical practice guidelines, and consensus. Full-text versions of conceivably relevant citations were obtained to confirm acceptability. A fourth reviewer (MMC) assisted in solving disagreements by consensus or arbitration. Where multiple versions were retrieved, the most updated version of the guidelines was incorporated. Duplicate articles were identified and deleted. We considered the EUSOMA working group’s position paper [2] as a reference to compare QIs. Data were extracted from the selected BC QI initiatives in duplicate and independently using standardised data extraction forms specifically created for this review and subsequently entered into a database. All data entry was double-checked.

### 2.3. Quality Assessment

The reporting of BC QIs from EUSOMA's position paper [2], the Spanish integrated cancer care processes and clinical pathways, was independently appraised by three different reviewers (YGF, CREL, and ARH) using a piloted data extraction form. No suitable data extraction form was available for this research topic. We developed a descriptive quality scoring system that captured all the QIs and specified the document. These QIs collected in our review have already been validated in the quality documents (clinical pathways and integrated breast cancer care processes) where they belong. Disparities among the authors over the risk of bias for particular manuals were solved by group discussion, requiring a mediator (MMC) who decided when no consensus achieved. Two QIs were recognised as the same when they measured the same process, even when there were scanty differences between population targets and minimum standards. All these deviations were reported individually in the Results section of this paper. These studied QIs were classified according to the EUSOMA classification [2] concerning the intervention they were measuring (diagnosis, treatment, staging, counselling, follow-up, and rehabilitation) and Donabedian's framework type (structural, process, and outcome indicators) [6].

### 2.4. Data Analysis

The inter-rater agreement (ICC) of the data extraction was calculated to assess the reviewers' agreement, and ICC >0.90 was considered excellent [28]. A mediator (MMC) assisted in reaching a consensus and would decide in case of disagreements. We performed a descriptive statistical study to examine and classify the selected BC QIs using the Stata 15.0 statistical package (StataCorp LLC, College Station, TX, USA).

## 3. Results

### 3.1. Study Selection

We identified 1418 relevant references (1165 from databases and 21 from the World Wide Web and Spanish institutions). Of them, 148 were duplicated reports, and 1255 did not satisfy the selection criteria. Finally, only 15 Spanish quality documents and the EUSOMA position paper were evaluated for full-text review [2,29–42]. A PRISMA flow diagram is synthesised in Figure 1. The study characteristics are reported in Table 1 (year of publication, organisation, region, evidence analysis used for QI evaluation, type of document (specific BC document or not), the presence of a specific section on BC, the appearance of QIs in the document analysed). Table 1 also shows four autonomous communities from Spain without a quality care document (Balearic and Canary Islands, Cantabria, and Castile and La Mancha).

### 3.2. General Quality Indicator Evaluation

There were 85 QIs collected from the quality care documents analysed. The EUSOMA position paper [2] registered 34/85 QIs (40%). The 51/85 (60%) QIs that did not appear in the EUSOMA position paper were added after a comprehensive analysis of the Spanish documents. Only 11/85 (12.94%) QIs appeared only in the EUSOMA paper. Figure 2 shows all the integrated health care programs and clinical pathways studied and the QIs appearing in them. From the Spanish documents, there were 28/74 QIs related to diagnosis (37.84%), the same number (28/74) related to treatment (37.84%), and 18/74 (24.32%) QIs to staging, counselling, follow-up, and rehabilitation. Nine of these Spanish QIs were structural (12.16%), 53/74 were related to the process (71.62%), and 12/74 were outcome QIs (16.22%). Analysing EUSOMA indicators that did not appear in any of the Spanish documents, 2 were related to diagnosis (18.18%), 6/11 related to treatment (54.54%), 1/11 to counselling (9.09%), and 2/11 to follow-up (18.18%). Inter-rater agreement was 0.98.

### 3.3. Quality Indicator Comparison between Spanish Areas and Europe

The BC QI reporting was varied (Figure 2). The QI mean in each document was 11.00 (standard deviation: 10.59), ranging from 0 to 30 QIs reported. The clinical pathways

or integrated breast cancer care processes that collected more QIs were EUSOMA's [2] with 34 QIs, Catalonia's [34] with 30 QIs, and the government of Spain's [29] with 28 QIs. Asturias [32], Extremadura [35], Madrid [38], Basque Country [41], and Valencia [42] did not register any QI.

Comparing the Spanish quality documents and the EUSOMA position paper [2], all the clinical pathways and integrated cancer care processes that collected any BC QI had at least one EUSOMA QI included. The national Spanish program [29] was the document that collected more EUSOMA QIs (12 QIs), followed by the Catalanian program [34] with 10 QIs.

No indicator appeared in all the 16 documents studied. Of the 51 indicators that appeared only in the Spanish documents, "proportion of BC patients to be discussed pre- and postoperatively by a multidisciplinary team (MDT)" and "proportion of invasive cancer and clinically negative axilla cases who underwent sentinel lymph node biopsy (SLNB) only (excluding primary systemic treatment or PST cases)" were the two QIs best reported, appearing in up to 6/15 different documents [29–31,34,36,39].

The variability of the same QI among the diverse Spanish papers analysed is registered in Figures 3 and 4. A total of 22/66 (33.33%) process and outcome QIs (12/53; 22.64% related to the process and 10/13; 76.92% outcome QIs) did not express any standard (Figure 3); the structure indicators do not present standards.

Concerning diagnosis, "proportion of BC cases who preoperatively underwent breast and axilla radiology and physical examination" appeared in three documents [29,34,37] that agree with a standard of 90%. "Proportion of BC cases for which prognostic and predictive parameters have been recorded" should be more than 100% [34], compared with EUSOMA's [2] recommendation of 95%. "Proportion of patients with invasive cancer who underwent image-guided axillary staging" should be in all the cases at more than 85% [2,29,34,39], while "proportion of patients with clinical history and/or staging documented" might be 100% [29,34,39]. "Proportion of BC patients to be discussed pre- and postoperatively by a MDT" varied from 90% recommended by EUSOMA [2] and Andalusia [30] to 100% supported by the Spanish national document [29], Aragon [31], Catalonia [34], Galicia [36], and Murcia [39].

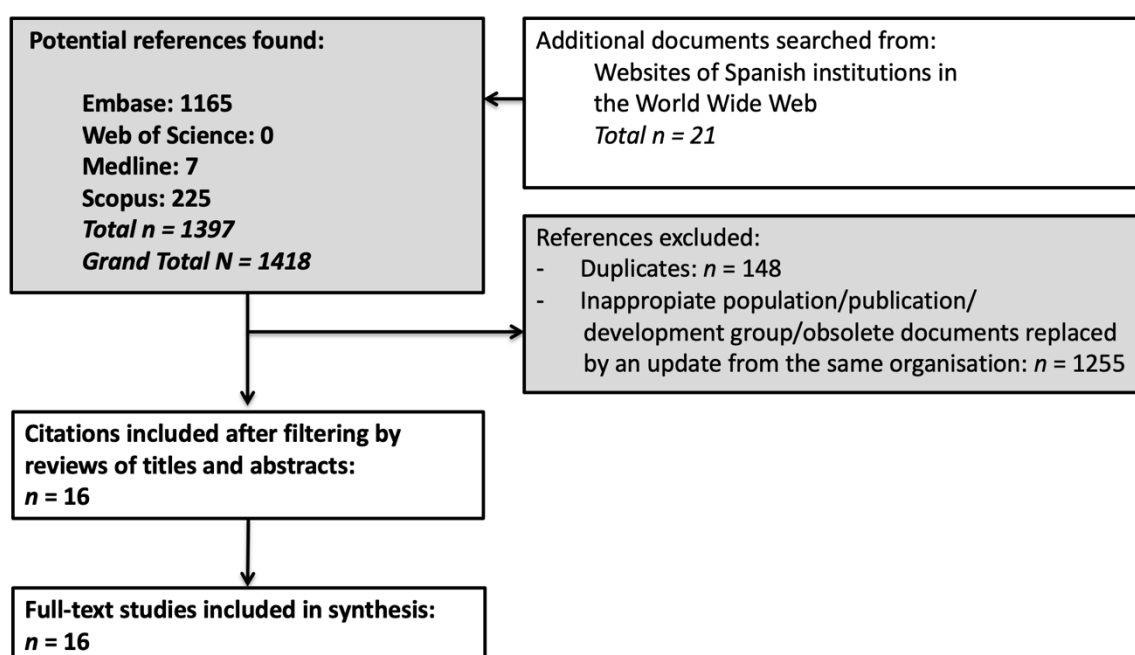


Figure 1. Flow chart of the literature search.

**Table 1.** Characteristics of the clinical pathways and Spanish integrated BC health care processes.

	Title	Abbreviated Title	Year of Publication	Organisation	Region (Continent/Country/Autonomous Community)	Evidence Analysis for Quality Indicators (QIs)	Specific Breast Cancer Document	Subsection with Specific Information on Breast Cancer	Appearance of Quality Indicators (QIs)
1	Quality indicators in breast cancer care: An update from the EUSOMA working group.	EUSOMA	2017	EUSOMA	Europe	Review, consensus	Yes	Not applicable	Yes
2	Evaluación de la práctica asistencial oncológica. Estrategia en Cáncer del Sistema Nacional de Salud.	Spanish program	2013	Sistema Nacional de Salud	Spain	Consensus	No	Yes	Yes
3	Proceso Asistencial Integrado Cáncer de Mama (PAICM).	Andalusia	2011	Junta de Andalucía	Europe/Spain/Andalucía	Review	Yes	Not applicable	Yes
4	Proceso de Cáncer de Mama. Criterios de implantación.	Aragon	2006	Sistema de Salud de Aragón	Europe/Spain/Aragón	Consensus	Yes	Not applicable	Yes
5	Programas clave de Atención Interdisciplinar.	Asturias	2019	Gobierno del Principado de Asturias	Europe/Spain/Asturias	Not applicable	No	No	No
6	Estrategia regional del paciente oncológico en Castilla y León.	Castile and Leon	2019	Junta de Castilla y León	Europe/Spain/Castile and Leon	Review	No	No	Yes
7	Desarrollo de indicadores de proceso y resultado, y evaluación de la práctica asistencial oncológica.	Catalonia	2006	Generalitat de Catalunya	Europe/Spain/Catalonia	Review, consensus	No	Yes	Yes
8	Plan integral contra el cáncer en Extremadura.	Extremadura	2017	Junta de Extremadura	Europe/Spain/Extremadura	Not applicable	No	No	No
9	Proceso asistencial integrado de cancer de mama.	Galicia	2014	Xunta de Galicia	Europe/Spain/Galicia	Not specified	Yes	Not applicable	Yes
10	III plan de Salud La Rioja (2015–2019).	Rioja	2015	Gobierno de La Rioja	Europe/Spain/ La Rioja	Based on the Nation Plan of Healthcare	No	No	Yes
11	Plan integral de control del cáncer de la Comunidad de Madrid.	Madrid	2007	Comunidad de Madrid	Europe/Spain/Madrid	Not applicable	No	No	No
12	Esta garantizada la calidad de la atención al cancer de mama.	Murcia	2012	Región de Murcia	Europe/Spain/Murcia	Based on the Nation Plan of Healthcare	Yes	Not applicable	Yes
13	Plan de Salud de Navarra.	Navarra	2014	Gobierno de Navarra	Europe/Spain/Navarra	Not applicable	No	No	No
14	Plan oncológico de Euskadi.	Basque country	2018	Gobierno Vasco	Europe/Spain/Basque Country	Not applicable	No	No	No
15	Estrategia contra el cancer de la Comunitat Valenciana 2019–2022.	Valencia	2019	Generalitat Valenciana	Europe/Spain/Valencia	Not applicable	No	No	No

		Year of publication																2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030				
		Institution																EUSOMA	Sistema Nacional de Salud	Junta de Andalucía	Sistema de Salud de Aragón	Principado de Asturias	Junta de Castilla y León	Generalitat de Catalunya	Junta de Extremadura	Junta de Galicia	Gobierno de la Rioja	Comunidad de Madrid	Región de Murcia	Gobierno de Navarra	Gobierno Vasco	Generalitat Valenciana			
Type of quality indicator (QIs)		Title																EUSOMA	Spanish program	Andalucía	Aragón	Asturias	Castile and Leon	Catalonia	Extremadura	Galicia	Rioja	Madrid	Murcia	Navarra	Basque country	Valencia			
1	STRUCTURAL	There is an Integrated Multidisciplinary Breast Cancer Care Process.																																	3
2	PROCESS	Proportion of patients who time elapsed from the Breast Pathology Unit's referral will not exceed X days.																																2	
3	PROCESS	Proportion of patients from breast cancer (BC) screening.																																2	
4	PROCESS	Proportion of patients with suspected BC who have done radiological studies in a single act.																																1	
5	PROCESS	Proportion of BC cases who preoperatively underwent breast and axilla radiology and physical examination.																1	1															4	
6	PROCESS	Proportion of patients with BC (different stages) who do/do not undergo baseline-staging tests.																																1	
7	PROCESS	Proportion of BC cases examined preoperatively by magnetic resonance imaging (MRI), excluding primary systemic treatment (PST) patients.																																1	
8	PROCESS	Proportion of BC patients which time elapsed from the request to the mammography will not exceed X days or weeks.																																1	
9	PROCESS	Time elapsed from the beginning of the process to the confirmation of BC diagnosis is X days.																																1	
10	OUTCOME	BC detection rate.																																1	
11	OUTCOME	Invasive cancer rate.																																4	
12	OUTCOME	In situ cancer rate.																1	1															3	
13	PROCESS	Proportion of patients with BC who had a preoperative histologically or cytologically confirmed malignant diagnosis (B5 or C5).																																3	
14	PROCESS	Time elapsed from the biopsy to obtain the pathology report will be less than X days.																																3	
15	PROCESS	Proportion of BC cases for which prognostic and predictive parameters have been recorded.																																3	
16	PROCESS	Proportion of patients with invasive cancer who underwent image-guided axillary staging.																1	1																4
17	PROCESS	Proportion of benign to malignant diagnoses based on definitive surgical pathology report.																																1	
18	PROCESS	Proportion of patients with clinical history and/or staging documented.																																3	
19	PROCESS	Time elapse from surgery to final immunohistochemical diagnosis.																																1	
20	STRUCTURAL	Standardized content of the pathological anatomy report and BC staging.																																3	
21	STRUCTURAL	Standardised initial radiological study report.																																1	
22	PROCESS	Percentage of reports with diagnosis, TNM stage, and therapeutic plan in relation to the total of reports issued.																															4		
23	STRUCTURAL	Existence of a multidisciplinary (MDT).																																1	
24	PROCESS	Proportion of BC patients to be discussed pre and postoperatively by a MDT.																1	1	1	1													7	
25	STRUCTURAL	Proportion of professionals with participation in the MDT.																																1	
26	PROCESS	Proportion of BC diagnosis with a time elapsed from referral to decision-making by MDT less than 30 days.																																3	
27	PROCESS	Proportion of BC cases with less than 7 days from diagnosis's pathological confirmation until MDT evaluation.																																1	
28	PROCESS	Time elapsed from MDT decision until the start of the treatment should be 15 days.																1	1															2	
29	PROCESS	Proportion of BC cases referred for genetic counselling.																																2	
30	PROCESS	Proportion of BRCA genetic determinations performed.																																1	
31	PROCESS	Diagnostic-therapeutic interval less than 28 days.																																3	
32	PROCESS	Proportion of BC patients with time elapsed <15 days from the MDT decision to start a treatment.																																1	
33	PROCESS	Proportion of BC patients treated with PST undergoing MRI.																																1	
34	PROCESS	Proportion of BC patients with HER2-positive IC who received PST trastuzumab.																																1	
35	PROCESS	Proportion of patients with inflammatory breast cancer or locally advanced non-resectable ER-carcinoma who received PST.																1	1															1	
36	PROCESS	Time elapsed between PST and surgical treatment.																																1	
37	PROCESS	Proportion of BC patients who undergo surgery within less than 30 days after the MDT decision.																1	1	1	1													5	
38	PROCESS	Proportion of BC patients who undergo surgery within less than 30 days after surgical waiting list inclusion.																																1	
39	PROCESS	Proportion of BC cases referred from the Breast Unit to the Pre-anesthesia consultation in less than 7-10 days.																																1	
40	PROCESS	Proportion of BC patients with breast conservative treatment (BCT).																																5	
41	PROCESS	Proportion of BC patients with invasive cancer not greater than 3 cm who underwent BCT as primary treatment.																1	1															1	
42	PROCESS	Proportion of BC patients with in situ cancer less than 2 cm who underwent BCT.																1	1															1	
43	PROCESS	Proportion of BC patients (ductal in situ carcinoma only) who received just one operation (excluding reconstruction).																1	1															2	
44	PROCESS	Proportion of BC patients with a surgical safety check-list.																																1	
45	OUTCOME	Proportion of BC patients whose reconstruction (immediate or delayed) is indicated that get a reconstruction.																1	1															1	
46	OUTCOME	Proportion of BC patients receiving immediate reconstruction.																1	1															3	
47	PROCESS	Proportion of BC patients with delayed reconstruction time less than 9 months.																																1	
48	STRUCTURAL	Existence of sentinel lymph node biopsy (SLNB).																																3	
49	PROCESS	Proportion of invasive cancer and clinically negative axilla cases who underwent SLNB only (excluding PST cases).																1	1	1	1													7	
50	PROCESS	Proportion of BC patients with invasive cancer who underwent SLNB with no more than 5 nodes excised.																																2	
51	PROCESS	Proportion of BC patients with lymphadenectomy.																																3	
52	PROCESS	Proportion of BC patients with up to 3 axillary lymph nodes (pN1) who received post-mastectomy radiotherapy (RT): chest wall + non-resected axillary lymph nodes.																																1	
53	PROCESS	Proportion of patients with ductal in situ carcinoma only who do not undergo axillary clearance																																1	
54	OUTCOME	Proportions of axillary lymphadenectomy of more than 10 nodes.																																3	
55	PROCESS	Proportion of BC reinterventions in BCT.																																2	
56	PROCESS	Proportion of BC reinterventions before 6 weeks for margin widening after BCT.																																1	
57	PROCESS	Proportion of BC patients who start adjuvant treatment in less than X days/weeks from the surgical intervention date.																																5	
58	PROCESS	The delay time from the decision to place the subcutaneous catheter until placement will be less than 7 days.																																1	
59	PROCESS	Percentage of BC hormone treatment.																1	1															5	
60	PROCESS	Proportion of BC patients with negative ER (T > 1 cm or N+) invasive cancer who received adjuvant chemotherapy.																																1	
61	PROCESS	Proportion of HER2+ invasive cancer (T > 1 cm or N+) treated with chemotherapy who received adjuvant trastuzumab.																																2	
62	PROCESS	Proportion of patients with invasive cancer (MO) who received postoperative RT after BCT and SLNB.																																1	
63	PROCESS	Proportion of BC patients with less than X days/weeks of delay from the RT indication to its initiation.																																1	
64	PROCESS	Proportion of BC with axillary lymph nodes (≥pN2a) who received post-mastectomy RT: chest wall and all (non-resected) regional lymph-nodes.																																1	
65	PROCESS	Proportion of BC patients who have direct access to a breast care nurse specialist.																																1	
66	PROCESS	Proportion of BC patients referred for nurse counselling after primary treatment.																																2	
67	PROCESS	Proportion of BC hospitalized patients with NANDA terminology coded care plan in the discharge report.																																1	
68	PROCESS	Proportion of BC patients with immediate access to psychological support.																																1	
69	STRUCTURAL	Psychological support access to the patient's relatives or caregivers.																																2	
70	STRUCTURAL	Existence of fisioterapy consultation.																																2	
71	OUTCOME	Proportion of BC cases with lymphedema or without recovery of shoulder mobility referred to rehabilitation.																																3	
72	PROCESS	Time elapsed from the rehabilitation prescription to beginning will be less than 30 days.																																1	
73	PROCESS	Proportion of BC patients with a single final report with all the oncological strategy of their process.																																2	
74	PROCESS	Proportion of BC patients with a coordinated follow-up.																																1	
75	PROCESS	Proportion of asymptomatic BC with annual mammographic screening and 6/12 months clinical evaluation in the first 5 years after primary surgery.																																1	
76	OUTCOME	Proportion of BC patients with follow-up (data on life status and recurrence rate) for at least 5 years.																																1	
77	STRUCTURAL	Existence of Palliative consultation.																																1	
78	PROCESS	Proportion of BC patients included in the palliative care assistance process.																																1	
79	OUTCOME	BC mortality rate in Palliative Care Unit.																																1	
80	OUTCOME	BC Mortality rate.																																1	
81	OUTCOME	Toxic deaths.																																1	
82	OUTCOME	BC Survival rate.																																1	
83	STRUCTURAL	The breast centre must have a data manager responsible for the breast centre data.																1	1															4	
84	OUTCOME	BC patient satisfaction.																																2	
85	PROCESS	Proportion of BC patients participating in shared decision-making.																																2	
		Total of QIs registered																34	29	12	20	0	4	30	0	10	13	0	15	8	0	0	0		

**Figure 2.** Appearance of the quality indicators (QIs) on diagnosis, staging, counselling, follow-up, and rehabilitation and others in the integrated BC health care process and clinical pathways analysed. QIs in bold were just published in EUSOMA. QIs in grey appeared in the Spanish documents analysed but not in the EUSOMA position paper.

Abbreviated title		EUSOMA	Spanish program	Andalusia	Aragon	Asturias	Castile and Leon	Catalonia	Extremadura	Galicia	Rioja	Madrid	Murcia	Navarra	Basque country	Valencia
Year of publication		2017	2009	2011	2006	2019	2019	2006	2017	2014	2015	2007	2012	2014	2018	2019
Institution		EUSOMA	Sistema Nacional de Salud	Junta de Andalucía	Sistema de Salud de Aragón	Gobierno del Principado de Asturias	Junta de Castilla y León	Generalitat de Catalunya	Junta de Extremadura	Xunta de Galicia	Gobierno de La Rioja	Comunidad de Madrid	Región de Murcia	Gobierno de Navarra	Gobierno Vasco	Generalitat de Valenciana
DIAGNOSIS	Proportion of patients who time elapsed from the Breast Pathology Unit's referral will not exceed X days.				3 days (ST= 85%)					15 days (ST= 100%)						
	Proportion of patients from breast cancer (BC) screening.					NS					NS					
	Proportion of patients with suspected BC who have done radiological studies in a single act.			90 %												
	Proportion of BC cases who preoperatively underwent breast and axilla radiology and physical examination.	90 %	90 %					90 %			90 %					
	Proportion of BC patients which time elapsed from the request to the mammography will not exceed X days or weeks.				4 days (ST= 85%)											
	Time elapsed from the beginning of the process to the confirmation of BC diagnosis is X days or weeks.				7-14 days (ST= 85%)			10 days (ST=90%)						15 days (ST=90%)		
	Proportion of patients with BC who had a preoperative histologically or cytologically confirmed malignant diagnosis (B5 or C5).	85 %	90%					100 %								
	Time elapsed from the biopsy to obtain the pathology report will be less than X days.				10 days (ST=100%)			7 days (ST=100%)		5 days (ST=100%)						
	Proportion of BC cases for which prognostic and predictive parameters have been recorded.	95 %	NS					100 %								
	Proportion of patients with invasive cancer who underwent image-guided axillary staging.	85 %	85 %					85 %						85 %		
	Proportion of benign to malignant diagnoses based on definitive surgical pathology report.	1.04														
	Proportion of patients with clinical history and/or staging documented.		100 %					100 %						100 %		
	Time elapse from surgery to final immunohistochemical diagnosis.						NS									
	Percentage of reports with diagnosis, TNM stage, and therapeutic plan in relation to the total of reports issued.		100 %				NS				NS			100 %		
	Proportion of BC patients to be discussed pre and postoperatively by a multidisciplinary (MDT).	90 %	100 %	90 %	100 %			100 %		100 %				100 %		
	Proportion of professionals with participation in the MDT.					NS										
	Proportion of BC diagnosis with a time elapsed from referral to decision-making by MDT less than 30 days.			100 %				100 %		100 %						
	Proportion of BC cases with less than 7 days from diagnosis's pathological confirmation until MDT evaluation.				100 %											
	Time elapsed from MDT decision until the start of the treatment should be 15 days.	90%								90%						
	Proportion of BC cases referred for genetic counselling.	10 %									NS					
	Proportion of BRCA genetic determinations performed.										NS					
TREATMENT	Diagnostic-therapeutic interval less than 28 days.		90 %					80 %						90 %		
	Proportion of patients with inflammatory BC or locally advanced non-resectable ER-carcinoma who received primary systemic treatment (PST).	90 %														
	Time elapsed between PST and surgical treatment.							90 %								
	Proportion of BC patients who undergo surgery within less than 30 days after the MDT decision.		90 %		90 %			90 %						90 %		
	Proportion of BC patients who undergo surgery within less than 30 days after surgical waiting list inclusion.			100 %												
	Proportion of BC cases referred from the Breast Unit to the Pre-anesthesia consultation in less than 7-10 days.				85 %											
	Proportion of BC patients with BCT.		50-80%	50-80%				50-80%						50-80%	NS	
	Proportion of BC patients with invasive cancer not greater than 3 cm who underwent BCT as primary treatment.	70 %														
	Proportion of BC patients with in situ carcinoma less than 2 cm who underwent BCT.	80 %														
	Proportion of BC patients (DCIS only) who received just one operation (excluding reconstruction).	80 %	NS													
	Proportion of BC patients with a surgical safety check-list.			100 %												
	Proportion of BC patients with delayed reconstruction time less than 9 months.				85 %											
	Proportion of IC and clinically negative axilla cases who underwent SLNB only (excluding PST cases).	90 %	NS	NS	NS		NS		NS				NS			
	Proportion of BC patients with invasive cancer who underwent SLNB with no more than 5 nodes excised.	90 %	NS													
	Proportion of BC patients with lymphadenectomy.		NS					NS					NS			
	Proportion of patients with ductal in situ carcinoma only who do not undergo axillary clearance	97 %														
	Proportion of BC reinterventions in breast conserving therapy (BCT).						NS		NS							
	Proportion of BC reinterventions before 6 weeks for margin widening after BCT.															
	Proportion of BC patients who start adjuvant treatment in less than X days/weeks from the surgical intervention date.		6 weeks (ST=90%)	6 weeks (ST=90%)	10 days (ST=85%)			6 weeks (ST=90%)						6 weeks (ST=90%)		
	The delay time from the decision to place the subcutaneous catheter until placement will be less than 7 days.					85 %										
	Percentage of BC hormone treatment.	85 %	100 %					100 %			NS			100 %		
	Proportion of HER2+ invasive cancer (T > 1 cm or N+) treated with chemotherapy who received adjuvant trastuzumab.	85 %														
	Proportion of patients with invasive cancer (M0) who received postoperative radiotherapy (RT) after BCT and sentinel lymph node biopsy (SLNB).	90 %								100 %						
	Proportion of BC patients with less than X days/weeks of delay from the RT indication to its initiation.				15 days (ST= 85%)											
STAGING, COUNSELLING, FOLLOW-UP AND REHABILITATION	Proportion of BC patients who have direct access to a breast care nurse specialist.	95 %								100 %						
	Proportion of BC hospitalized patients with NANDA terminology coded care plan in the discharge report.			100 %												
	Proportion of BC patients with immediate access to psychological support.		NS		NS						NS		NS			
	Time elapsed from the rehabilitation prescription to beginning will be less than 30 days.					85 %										
	Proportion of BC patients with a single final report with all the oncological strategy of their process.				NS		NS									
	Proportion of BC patients with a coordinated follow-up.				NS											
	Proportion of BC patients included in the palliative care assistance process.						NS									
	Proportion of BC patients participating in shared decision-making.						NS								>15%	

**Figure 3.** Comparison of the standards of the breast cancer care quality indicators related to the process among the Spanish integrated breast cancer health care processes and clinical pathways analysed. NS in grey means “standard not specified”.



		Year of publication	2017	2013	2011	2006	2019	2019	2006	2017	2014	2015	2007	2012	2014	2018	2019
			Institution														
			EUSOMA	Sistema Nacional de Salud	Junta de Andalucía	Sistema de Salud de Aragón	Principado de Asturias	Junta de Castilla y León	Generalitat de Catalunya	Junta de Extremadura	Xunta de Galicia	Gobierno de La Rioja	Comunidad de Madrid	Región de Murcia	Gobierno de Navarra	Gobierno Vasco	Generalitat Valenciana
	Type of quality indicator	Title	EUSOMA	Spanish program	Andalusia	Aragon	Asturias	Castile and Leon	Catalonia	Extremadura	Galicia	Rioja	Madrid	Murcia	Navarra	Basque country	Valencia
1	STRUCTURAL	There is an Integrated Multidisciplinary Breast Cancer Care Process.		1					1					1			
2	STRUCTURAL	Standardized content of the pathological anatomy report and breast cancer (BC) staging.		1					1					1			
3	STRUCTURAL	Standardised initial radiological study report.							1								
4	STRUCTURAL	Existence of a multidisciplinary team (MDT).		1								1		1			
5	STRUCTURAL	Existence of sentinel lymph node biopsy (SLNB).		1					1					1			
6	STRUCTURAL	Psychological support access to the patient's relatives or caregivers.		1		1								1			
7	STRUCTURAL	Existence of fisioterpy consultation.		1										1			
8	STRUCTURAL	Existence of Palliative consultation.													1		
9	STRUCTURAL	The breast centre must have a data manager responsible for the breast centre data.	1	1		1			1								
10	OUTCOME	BC detection rate.										NS					
11	OUTCOME	Invasive cancer rate.	NS	NS					NS						NS		
12	OUTCOME	In situ carcinoma rate.	NS						NS						NS		
13	OUTCOME	Proportion of BC patients whose reconstruction (immediate or delayed) is indicated that get a reconstruction.				NS											
14	OUTCOME	Proportion of BC patients receiving immediate reconstruction.	40 %	NS	50 %												
15	OUTCOME	Proportions of axillar lymphadenectomy of more than 10 nodes.		100 %					100 %					100 %			
16	OUTCOME	Proportion of BC cases with lymphedema or without recovery of shoulder mobility referred to rehabilitation.		NS					100 %						80 %		
17	OUTCOME	Proportion of BC patients with follow-up (data on life status and recurrence rate ) for at least 5 years.	NS														
18	OUTCOME	BC mortality rate in Palliative Care Unit.										NS					
19	OUTCOME	BC Mortality rate.										NS					
20	OUTCOME	Toxic deaths.			NS												
21	OUTCOME	BC Survival rate.										NS					
22	OUTCOME	BC patient satisfaction.										NS			NS		
Total (strutural QIs)			1	7	0	2	0	1	5	0	0	1	0	5	1	0	0
Total (outcome QIs)			4	4	2	1	0	0	4	0	0	5	0	1	4	0	0

**Figure 4.** Quality indicators of structure and outcome in the Spanish breast cancer integrated health care processes and clinical pathways analysed.



Regarding treatment, “proportion of BC patients with breast-conserving therapy (BCT)” did not arise in EUSOMA, but it was treated in a third part of the Spanish quality care papers (5/15). All of these documents except one [29,30,34,39] stated a standard of 50–80% [40]. The “percentage of BC hormone treatment” standard was always 100% in the Spanish documents [29,34,39], but 85% in the EUSOMA position paper. “All the patients with invasive cancer (M0) who received postoperative radiotherapy after breast-conserving surgery and SLNB” might be 100% [36], in contrast with only 90% in EUSOMA [2].

Analysing outcome QIs, the “proportion of BC patients receiving immediate reconstruction” standard was more than 50% in Andalusia [39] versus 40% in EUSOMA [2]. Finally, “proportion of BC cases with lymphedema or without recovery of shoulder mobility referred to rehabilitation” should be 80% in Navarra [40] versus 100% in Catalonia [34].

### 3.4. Shared Decision Making as an Essential Quality Indicator

We studied the appearance of SDM in the integrated cancer care processes and clinical pathways analysed. Only Castile and Leon [33] and Navarra [40] admitted its importance (see Figure 2). Navarra highlighted the importance of involving at least 15% of the patients in the BC care management decision. No other QIs about SDM use or measures were found.

### 3.5. Quality Indicators about Timing Processes

Figure 3 refers to all the indicators about timing in grey, followed by the standard established by the different quality care documents. Some of them are noteworthy in the following text. The QIs not mentioned are analysed in Figure 3. There were 18 QIs about the timing process, and only 1 (0.05%) did not state any standard.

Concerning diagnosis, “proportion of patients who time-elapsed from the breast pathology unit’s referral should not exceed 3 days [31] or 15 days” [36] depending on the quality care document with a standard that varied from 85% to 100%. The “time elapsed from the beginning of the process to the confirmation of BC diagnosis should be 7–14 or 10 days” standard varied from 90% or 85%, respectively [31,36]. “Time elapsed from the biopsy to obtain the pathology report will be less than 5 [36], 7 [34], or 10 [31] days”, and the “BC diagnosis should be referral to MDT in less than 30 days” [30,34,36] in both cases with a standard of 100%.

Regarding treatment, the “diagnostic–therapeutic interval must be less than 28 days” in more than 80% [34] to 90% [29,39] of the BC patients. The “proportion of BC patients who undergo surgery within less than 30 days after the MDT decision” QI, although it did not appear in EUSOMA, reached the highest consensus with a five-document agreement standard of 90% [29–31,34,39]. Finally, the “proportion of BC patients who start adjuvant treatment in less than a specific date from the surgical intervention date” QI had an enormous variability. Four quality care documents’ [29,30,34,39] standard was 90% in 6 weeks, but Aragon’s [31] clinical pathway stated 85% in 10 days.

## 4. Discussion

### 4.1. Main Findings

No systematic reviews were found in our search for Spanish health care QIs collected from integrated health care processes or clinical pathways. Only one-tenth of the indicators appeared exclusively in EUSOMA [2], including only 4 out of 10 of the QIs identified. There was heterogeneity among the QIs. No single indicator appeared in all the documents studied, and there was an enormous variability in QI descriptions. Over three-quarters were QIs dedicated to diagnosis and treatment, and the majority were process related. The QIs collected mostly were “proportion of BC patients to be discussed pre- and postoperatively by an MDT” and “proportion of invasive cancer and clinically negative axilla cases who underwent SLNB only (excluding PST cases)”. A third of the process and outcome QIs did not state a standard for reference.

#### 4.2. Strengths and Weaknesses

To our knowledge, a collation of BC care management QIs has not been published before. We undertook a comprehensive systematic review with many expert reviewers studying an important number of integrated BC assistance processes and clinical pathways. This review provided a powerful insight into the state of QIs for the whole BC care management process, including diagnosis, treatment, and follow-up.

The data extraction's subjective character was addressed using three qualified and trained BC specialist clinicians. The reviewers held a consensus meeting to consolidate criteria before duplicate data extraction appraisal. A fourth reviewer arbitrated the work to get a consensus when a meaningful deviation among the reviewers appeared. The ICC was higher than 98%, denoting an excellent reviewer agreement.

A possible limitation was to compare the Spanish clinical pathways or integrated breast cancer assistance processes versus the EUSOMA position paper [2]. The Spanish documents covered all the phases required in the BC care management process, from the general practitioner's referral to the follow-up, while the European document was directed to the specific BC unit of care. However, this could be considered an advantage as including these Spanish manuals has shown the necessity for adding all levels and aspects of care in BC quality assessment.

One limitation could be geographical in that only Spanish documents were assessed in this review. However, our main objective was to highlight the level of consensus when choosing QIs of an important disease such as BC in the same country. Our findings emphasised the importance and urgent need for agreement about this issue. A strong point of this systematic review is that our team included researchers competent in both the English and Spanish languages. There was no need to use external translations to interpret any report.

Most of the studied papers were not academic articles in scientific journals or indexed in databases. Although it was not easy, a comprehensive manual search of grey literature was conducted to find administrations and official institutions engaged in BC care management quality on the World Wide Web. We engaged expert reviewers in this clinical field to ensure that we captured the totality of the relevant literature. We also searched in the identified publications' bibliographies to incorporate more studies into our review. An interesting observation is that we did not find any document in order to analyse QIs in only three Spanish areas.

#### 4.3. Implications

Our systematic review offers a crucial contribution to BC care quality assessment. It presents an extensive study of all the available BC care QIs in Spain and highlights relevant discrepancies among the studied integrated health care processes and clinical pathways. It provides a global overview of the current situation of the QIs by identifying areas in need of urgent improvement. Medical improvements are occurring quickly, so continuous development and periodic updates are needed. The BC care process's control and progress could be made by analysing a single set of QIs and would help correlate results with other centres so stronger conclusions could be obtained [3].

The physical environment or structure is imperative in influencing the health care delivery process and outcomes. This physical environment will require supporting staff plus a healing environment to conclude better quality care finally [43].

Nowadays, even though diverse institutions have published different indicators to assess BC care quality, there is yet no consensus on BC QIs even in the same country [15,44]. Hence, correlation among studies is challenging, and this reduces the feasibility of comparing outcomes among different hospitals or health care areas [3]. Sometimes the same QIs could be interpreted as measuring different aspects of care [45]. Quality is a wide concept that needs a range of QIs to analyse various dimensions of care.

Even though only a few indicators have appeared exclusively in EUSOMA [2], it should be noted that the Spanish documents have not collected indicators about the use of

magnetic resonance imaging in BC care, nurse counselling, and follow-up. These EUSOMA indicators should be reviewed and added to them in the next updates. On the other hand, the Spanish documents provided many indicators that EUSOMA did not collect, but no indicators were found about primary care or patient satisfaction. The European position paper [2] indicates that more studies are necessary to establish satisfaction indicators, but it does not consider indicators related to primary care. Obtaining QIs at all breast cancer care levels should be highlighted as an important point of improvement to control and improve cancer quality care and not only focus on breast units. All the links in the chain are important to obtain excellent results. Besides, SDM, a recognised pillar of high-quality cancer care, was vaguely included in only two documents. Forthcoming reviews should give deep consideration to primary care, patient satisfaction, and SDM.

A minimum standard of quality care is beneficial to evaluate compliance and the necessity for improvement. In this review, we found proposed standards for two-thirds of the process and outcome indicators, but there was high variability among documents. For example, most of the documents proposed that adjuvant treatment should start in 6 weeks in 90% of the patients, but only one document set 10 days in 85% of the patients [31]. Evidence indicates that the ideal time to start treatment is 4–8 weeks, permitting recovery from surgery. A longer delay could be associated with worse outcomes and increased mortality [46] due to the rapid growth of micrometastasis following the removal of the primary tumour [47]. Therefore, all the QIs should be evidence based.

Further research and consensus regarding the best BC QIs and standards for improving quality is needed and deserves immediate consideration. There is an urgent need for a compendium of common QIs and their standards of care for all the autonomous communities in Spain. Each region should design specific QIs, taking into account the particular characteristics of its population. Thus, a set of common and specific QIs should be developed to allow a homogeneous analysis of the BC quality of care and comparisons among regions.

## 5. Conclusions

There is no consensus concerning BC care QIs and standards in Spain, and QI focus on primary care, patient satisfaction, and SDM is lacking. Although a majority of the QIs established a standard, they were very varied. These differences made comparisons among different health care providers arduous, decreasing the chance of making reasonable comparisons. There is an urgent need for establishing an agreed set of BC care QIs. Common and specific QIs should be developed to allow a homogeneous analysis of the BC quality of care and comparisons among regions.

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## Abbreviations

BC: breast cancer, BCT: breast-conserving therapy, EUSOMA: European Society of Breast Cancer Specialists, ICC: intraclass coefficient, MDT: multidisciplinary team, MRI: magnetic resonance imaging, NANDA: North American Nursing Diagnosis Association, NS: not specified, PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses, PST: primary systemic treatment, QIs: quality indicators, RT: radiotherapy, SDM: shared decision making, SLNB: sentinel lymph node biopsy.

## Appendix A. Data Sources and Search Strategy

### Appendix A.1. Sample Search Strategy for Medline

A systematic search was conducted on 19 February 2021 in Medline (via PubMed, to February 2021) using the following combination of free-text terms:

#1 breast cancer (all)  
 #2 breast neoplasms (all)  
 #3 quality indicators (all)  
 #4 quality care (all)  
 #5 2010 (pdta): 3000 (pdta)  
 # #6 AND #10 AND #11 AND #12  
 Results: 7 articles

### Appendix A.2. Online Databases

1. Embase
2. Scopus
3. Web of Science
4. Medline

### Appendix A.3. Websites of European Institutions

1. EUSOMA, Europe
2. Professional institutions and societies or governmental agencies from Spain

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