The Breast 59 (2021) 221–231

Contents lists available at ScienceDirect

The Breast

journal homepage: www.elsevier.com/brst

Quality indicators for breast cancer care: A systematic review

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ARTICLE INFO

Article history:
Received 22 March 2021
Received in revised form
18 June 2021
Accepted 27 June 2021
Available online 2 July 2021

Keywords:
Breast cancer care"
"Quality indicators"
"Quality care"
"Health care"

ABSTRACT

Objectives: We evaluated breast cancer (BC) care quality indicators (QIs) in clinical pathways and integrated health care processes.
Methods: Following protocol registration (Prospero n°: CRD42021228867), relevant documents were identified, without language restrictions, through a systematic search of bibliographic databases (EMBASE, Scopus, Web of Science, MEDLINE), health care valuable representatives and the World Wide Web in April 2021. Data concerning QIs, measurement tools and compliance standards were extracted from European and North American sources in duplicate with 98% reviewer agreement.
Results: There were 89 QIs found from 22 selected documents (QI per document mean 13.5 with standard deviation 11.9). The Belgian (38 QIs) and the EUSOMA (European Society of Breast Cancer Specialists) (34 QIs) documents were the ones that best reported the QIs. No identical QI was identified in all the documents analysed. There were 67/89 QIs covering processes (75.3%) and 11/89 (12.4%) for each structure and outcomes QIs. There were 21/89 QIs for diagnosis (30.3%), 43/89 for treatment (48.3%), and 19/89 for staging, counselling, follow-up and rehabilitation (21.4%). Of 67 process QIs and 11 outcome QIs, 20/78 (26%) did not report a minimum standard of care. Shared decision making was only included as a QI in the Italian document.
Conclusion: More than half of countries have not established a national clinical pathway or integrated breast cancer care process to achieve the excellence of BC care. There was heterogeneity in QIs for the evaluation of BC care quality. Over two-thirds of the clinical pathways and integrated health care processes did not provide a minimum auditable standard of care for compliance, leaving open the definition of best practice. There is a need for harmonisation of BC care QIs.

Contents

Abbreviations: ASCO, American Society of Clinical Oncology; BC, breast cancer; BCT, breast conserving therapy; CNDO, Coordenação Nacional das Doenças Oncológicas; IKNL, Netherlands comprehensive cancer organisation; INC, Institute Nacional du Cancer; MDT, multidisciplinary team; MRI, magnetic resonance imaging; NANDA, North American Nursing Diagnosis Association; NS, not specified; NCCN, National Comprehensive cancer Network; NCCP, National Cancer Control Programme; PST, primary systemic treatment; QIs, quality indicators; RCSG, Regionalt cancercentrum Stockholm Gotland; RCTs, Randomized controlled trials; RT, radiotherapy; SDM, shared decision making; SLNB, sentinel lymph-node biopsy; SESPM, Sociedad Española de Senología y Patología Mamaria; ST, standard.

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https://doi.org/10.1016/j.breast.2021.06.013

1. Introduction

Breast cancer (BC), the most common cancer in women with more than 2 million new cases per year, is one of the prime reasons for female cancer death [1]. Its survival rate varies depending on the country, with a 90% estimated 5-years survival for women with non-metastatic invasive breast cancer in developed countries [2]. Its treatment is becoming more complex. The greater therapeutic complexity requires an improvement in care quality management.

Clinical pathways, i.e. methodologies for the mutual decision making and organisation of care for a well-defined group of patients during a well-defined period of time [3], or integrated breast cancer assistance processes, i.e. “preventive, diagnostic, therapeutic, follow-up and care activities, aimed at the comprehensive management of people with BC and those with increased risk of BC” [4] have been deployed to manage and standardise care [5]. The aim of these quality documents is to increase the quality of care, reduce risks, enhance efficiency and improve patient satisfaction. They include a series of QIs for continuous improvement, aiming to guarantee the effectiveness of a clinical care pathway and enhance the quality of care, patient satisfaction and outcome [6,7]. Three types of QIs are considered essential for capturing care quality [8]. They cover structure (includes all the resources involved in the provision of services), process (evaluates the activities carried out during patient care; describes the care that the patient receives) and outcomes (evaluates the final product of care) [9,10].

Our primary research has shown that no systematic reviews were comparing QIs for BC care. Although several QIs have been proposed to harmonise BC care quality management, there is still no consensus among different Professional Societies or Health Administrations [11]. Many studies have used their own QIs, so the comparison between findings of different clinical audits is difficult [12–18]. Thus, they remain disparities in the quality of BC care across areas and hospitals to the detriment of women's health. This review aimed to evaluate systematically the QIs, their measurement tools and their compliance standards of care in clinical pathways and integrated health care processes documents.

2. Methods

A protocol-driven systematic review was performed following prospective registration (Prospero n^{o}: CRD42021228867), and it was reported in line with the PRISMA statement (Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols) [19,20].

2.1. Data sources and searches

A systematic search for relevant published literature was performed without language restrictions associating MeSH terms “breast cancer”, “breast neoplasms”, “quality indicators”, “quality care”, and including word alternatives, covering all the documents published until February 2021. We looked for online databases (MEDLINE, Web of Science, EMBASE and Scopus). Appendix A shows the search strategy. Most of the proposals that measure cancer care quality were usually not formally published in scientific journals and were not indexed in databases. This involved an extensive manual search of grey literature in retrieving recommendations made by European institutions active in this field (QIs of BC care management) on the World Wide Web. We have also contacted more than 200 breast cancer experts from European and American countries to help us in the process. The European Breast Centres Network, Europa Donna (The European Breast Cancer Coalition) representatives from each country, the main hospitals, universities and the specifically Governments, and Ministries of Health of each country have been contacted three or more times waiting for at least one week between emails. More additional initiatives were searched in the identified publications’ bibliographies to include other essential studies in our review.

2.2. Study selection and data extraction

Initiatives encouraging quality measures (clinical pathways and integrated breast cancer integrated processes) in BC care produced by European professional institutions and societies or

governmental agencies were included. We have also added remarkable institutional position papers based on breast quality indicators specifically as the EUSOMA working group's [7]. All these selected documents were compared to EUSOMA's. We included clinical pathways and integrated health care program documents with at least one section dedicated to BC. Those that deal with QIs in general cancer have not been included. Only those that specifically mention BC in a sub-section or even within the text were selected. Randomised controlled trials (RCTs) and observational studies, narrative reviews, scientific reports, discussion papers, conference abstracts and posters, and clinical practice guidelines and consensus were excluded.

We have only included European and North American documents because both areas have the biggest global R&D (research and development) investments and the highest number of publications worldwide [21].

Three reviewers (MMC, CREL and ARH), breast cancer specialists, analysed the potential eligibility of each of the titles from the citations independently. The full-text versions were requested and assessed, working separately to ratify eligibility. A fourth reviewer (YGF) helped to solve disagreements by consensus or arbitration. Duplicate proposals were removed. Where multiple versions were found, the most updated version of the guidelines was included. Data were collected from the selected BC QIs initiatives in duplicate, independently.

2.3. Quality indicators

Four reviewers (MMC, YGF, CREL and ARH) extracted data in a piloted proforma to assess the reporting of BC QIs from the integrated breast cancer assistance processes based on EUSOMA's [7]. A summary table of EUSOMA QIs in BC care and their characteristics (the definition for each indicator, the type of QI (17 mandatory for a EUSOMA breast unit certification), the minimum and target standard of care (ST), and the level of evidence) is shown in Appendix B. Other QIs extracted from the analysis of the different integrated breast cancer health care processes, clinical pathways documents and other remarkable position papers studied were collected when no similar QI was found in the EUSOMA's. Our team considered that two QIs were the same when measuring the same process, even when there were slight differences between population targets and minimum standards of care (ST). We have stated a ST as the level at which the average, prudent provider in a given community would practice. *We have studied the QI ST range as the area of variation between upper and lower limits on a particular scale.* All these differences were reported individually in the Results section of this manuscript. These analysed QIs were classified according to Donabedian's framework type (structural, process and outcome indicators) [8] and according to the EUSOMA classification [7] concerning the intervention they were measuring (diagnosis, treatment, staging, counselling, follow-up and rehabilitation and others).

2.4. Data analysis and synthesis

Reviewers consistency in data extraction was initially studied by the intraclass correlation coefficient (ICC), and the reliability level ">0.90" was considered excellent [22]. However, when disagreements appeared, an arbitrator would help to reach a consensus. If disagreement persisted, this arbitrator would take the final decision. A descriptive statistical analysis was conducted for analysing and classifying the selected QIs. An overarching qualitative synthesis was done to describe the findings. All the analyses were performed with the Stata 15.0 statistical package (StataCorp LLC, College Station, TX, USA).

3. Results

3.1. Study selection

A total of 1615 potentially relevant documents were found; 1397 were from online databases (EMBASE, Web of Science, MEDLINE and Scopus), and 218 were from additional sources (websites of relevant European institutions, health care relevant representatives and the World Wide Web). The selection criteria were not met by 1462 documents, and 131 were found duplicated. Finally, only 22 documents met the eligibility criterion for the full evaluation. Only one document was finally added from online databases for assessing eligibility. The rest of the 21 documents were found in the grey literature after looking for them in the proper European institutions' websites, contacted breast cancer experts from each country to help us in the process, and reviewed the identified documents' bibliography. The study selection process is shown in the flow diagram in Fig. 1. The characteristics of the selected documents (year of publication, institution, continent/country/Autonomous Community, evidence analysis used for QIs assessment, type of document (if it is a specific BC document or not, presence of a specific subsection on BC, the appearance of QIs in the document analysed) are synthesised in Table 1. Based on our selection method, Table 1 also shows 37/59 (63%) countries with no clinical pathway or integrated health care process found. Most of the quality documents analysed were from Western countries (81%, 17/21).

3.2. General quality indicators assessment

A set of 89 QIs were found from the 22 selected documents [7,23–43]. Thirty-four belonged to the EUSOMA statement [7] (see Appendix B), and the remaining 55 were other indicators derived from the rest of the documents studied that did not appear in EUSOMA. ICC for reviewer agreement was 0.98. Appendix C showed the different indicators selected and the quality document where they have appeared. The vast majority of the indicators were of the process (75.3%; 67/89), 11/89 (12.4%) were structural indicators, and finally, 11/89 (12.4%) were indicators of outcomes. These indicators cover all steps of BC care management from diagnosis (21/89; 30.3%), treatment (43/89; 48.3%), and staging, counselling, follow-up and rehabilitation (19/89; 21.4%). No QIs specifically related to Primary Care were found in our study.

3.3. Most common used quality indicators

The BC QIs reporting was heterogeneous (Appendix C). The mean number of QIs in each document was 13.5 (Standard deviation 11.9). The Belgian (38 QIs) [26], the EUSOMA (34 QIs) [7], and the Spanish (28 QIs) [40] documents were those that registered more indicators. Albania [25], Denmark [27], Romania [36], Slovenia [37], Sweden [38] and one of the Irish documents [31] did not present any QIs in their clinical pathways or integrated breast cancer assistance processes.

Only 14 (63.6%) documents collected any BC QI. No indicator was present in all these quality documents analysed. The indicators that appeared more frequently in the analysed documents were "proportion of BC cases who preoperatively underwent breast and axilla radiology and physical examination" (78.6%; 11/14) with a ST range from 85 to 95% [7,23,26,29,30,33,35,39–42], "proportion of patients with BC who had a preoperative histologically or cytologically confirmed malignant diagnosis (B5 or C5)" (71.4%; 10/14; ST range 85–90%) [7,23,26,29,30,34,35,40,42], "proportion of BC cases for which prognostic and predictive parameters have been recorded" (57.1%; 8/14; ST = 95%) [7,26,29,30,33,35,39–41], "proportion of

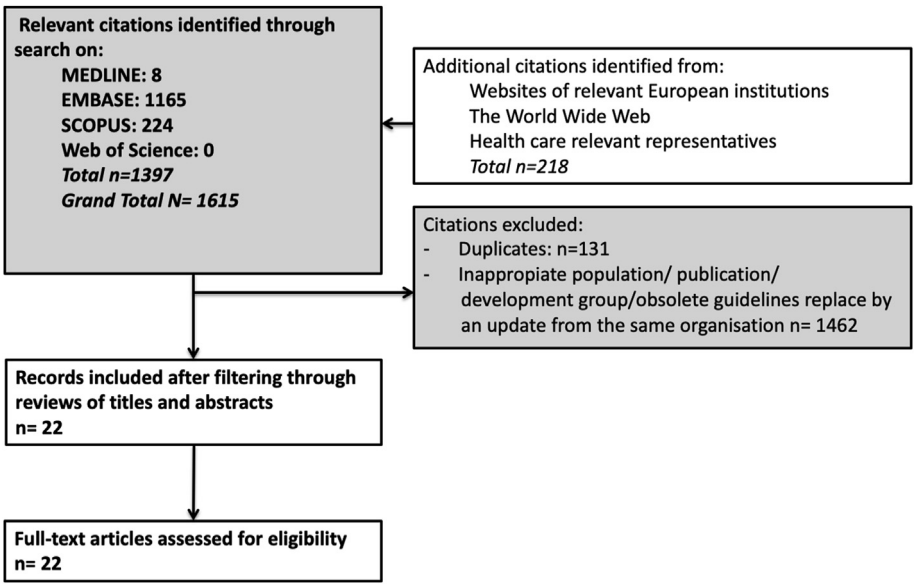

Fig. 1. Flow diagram detailing the study selection.

patients with invasive cancer who underwent image-guided axillary staging" (64.3%; 9/14; ST range 85–100%) [7,23,26,29,30,34,35,40], "proportion of BC patients to be discussed pre and postoperatively by a multidisciplinary team (MDT)" (71.4%; 10/14; ST range 85–100%) [7,23,26,30,32,33,35,39–42], "proportion of BC patients (DCIS only) who received just one operation (excluding reconstruction)" (57.1%; 8/14; ST range 80–90%) [7,26,29,32,33,40,41], "proportion of BC patients receiving immediate reconstruction" (64.3%; 9/14; ST range 40–85%) [7,23,30,32–34,40–42], "proportion of invasive cancer and clinically negative axilla cases who underwent sentinel lymph node biopsy (SLNB) only, excluding primary systemic treatment (PST) cases" (78.6%; 11/14; ST range 90–100%) [7,23,26,28–30,32,35,40–42], and "proportion of HER2+ infiltrating carcinoma (T > 1 cm or N+) treated with chemotherapy who received adjuvant trastuzumab" with an appearance of 57.1% (8/14) (ST range 85–95%) [7,23,26,29,33,35,40,41]. Moreover, other four QIs, "proportion of BC cases examined preoperatively by MRI (excluding PST's patients)" (ST range <10 or <20%) [7,23,30,32,34,35,39], "proportion of BC patients with less than X days/weeks of delay from the RT indication to its initiation" (6–48 weeks; ST range 90%) [23,24,28–30,32,33], and "proportion of BC with axillary lymph nodes (>=pN2a) who received post-mastectomy RT to the chest wall and all (non-resected) regional lymph-nodes" (ST range 90–95%) with an appearance all of them in 50% of the quality documents (7/14) [7,23,26,29,33,35,42].

3.4. Quality indicators minimum standard

We have compared variations in the same QI in the different documents analysed in which it appeared. Appendix C synthetase these differences for the same indicator obtained in the analysis of all the documents. Regarding process and outcome QIs (Appendix C), 26% of these did not state a ST (20.9%, 14/67, QIs of the process and 54.5%, 6/11, QIs of outcomes). The QI for which a ST value was given more frequently was "proportion of patients with BC who had a preoperative histologically or cytologically confirmed malignant diagnosis (B5 or C5)" with values ranging between 85% (for EUSOMA and one of the Spanish documents) [7,42], 90% (for Irish and two Spanish) [30,40,41] or 95% (for French) [28]. This was also the QI for which minimum variability was observed for the ST values of the indicators. "Proportion of BC cases for which prognostic and predictive parameters have been recorded", and "proportion of BC patients who undergo surgery within less than 30 days after the MDT decision", all of them QIs of the process, showed no range variability for the ST values recommended (Appendix C). The QIs of structure, which are yes or no statements, did not establish any ST value.

Concerning QIs of results (Appendix C), BC detection, invasive cancer and in situ cancer incidences, recurrence and mortality rates, "proportion of BC patients with follow-up (data on life status and recurrence rate) for at least 5 years, and patients' satisfaction" did not state any ST. On the other hand, 40% of patients should receive immediate reconstruction according to EUSOMA [7] and 70% according to the Italian program [32]. The percentage of axillar lymphadenectomies that resect more than ten nodes should reach 100% [40]. More than 90% of BC cases with lymphedema or without recovery of shoulder mobility should be referred to rehabilitation [32]. Finally, the BC survival rate should be more than 50% in patients who have completed treatment [23].

3.5. Quality indicators about timing processes

Appendix C highlights in grey all the QIs related to timing in the BC care management. Half of the QIs (52.9%, 9/17) did not set a ST despite indicating the time required between processes for compliance.

3.6. Shared decision making as a quality indicator

The presence of shared decision making (SDM) in the Clinical Pathways and integrated breast cancer assistance processes documents was analysed. Only the integrated breast cancer assistance process manuscripts from the USA [23] and Italy [32] recognized its importance (See Appendix C). American integrated breast cancer process indirectly insisted on developing a QI for measuring the quality of the doctor-patient relationship. An indicator of SDM use by the health professionals measure was only proposed by the Italian document (ST = 100%) [32].

Table 1
Integrated BC health care processes and clinical pathways analysed and their characteristics. Countries with no quality care documents retrieved.

	Title	Abreviated title	Year of publication	Institution	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	National Accreditation Program For Breast Centres Standards Manual.	American program	2018	American College of Surgeons	North America/USA	Review	Yes	Not applicable	Yes
3	American Society of Clinical Oncology/National Comprehensive Cancer Network Quality Measures.	NCCN program	2008	ASCO, NCCN	North America/USA	Consensus	No	Yes	Yes
4	The National Cancer Control Program.	Albanian program	2011	National Cancer Control Committee	Europe/ Albania	Review	No	No	No
5	Developing and measuring a set of process and outcome indicators for breast cancer.	Belgium program	2011	Belgian Cancer Registry	Europe/ Belgium	Systematic review	Yes	Not applicable	Yes
6	Landsdækkende Klinisk Kvalitetsdatabase for Brystkræft.	Danish program	2005	Danish Breast Cancer Group	Europe/ Denmark	Review	Yes	Not applicable	No
7	Cancer du sein: indicateurs de qualité et de sécurité des soins.	French program	2019	INC	Europe/ France	Review, consensus	Yes	Not applicable	Yes
8	Optimizing the Quality of Breast Cancer Care at Certified German Breast Centres.	German program	2014	German Cancer Society	Europe/ Germany	Review	Yes	Not applicable	Yes
9	Key Performance Indicators Report for Symptomatic Breast Disease Services.	Irish program v1	2010	NCCP	Europe/ Ireland	Review	Yes	Not applicable	Yes
10	National Cancer Strategy 2017–2026.	Irish program v2	2017	Ministry of Health	Europe/ Ireland	Not applicable	No	No	No
11	PDTA della Rete Oncologica Veneta per i pazienti affetti da tumore della mammela.	Italian program	2016	Rete Oncologica Veneta	Europe/Italy	Consensus	Yes	Not applicable	Yes
12	The National Cancer Plan for the Maltese Islands (2017–2021).	Maltese program	2007	Ministry of Health	Europe/Malta	Review	No	Yes	Yes
13	Breast Cancer Audit (NBCA) 2019.	Dutch program	2019	IKNL	Europe/ Netherlands	Consensus	Yes	Not applicable	Yes
14	Recomendações nacionais para diagnóstico e tratamento do cancro da mama.	Portuguese program	2009	CNDO	Europe/ Portugal	Review	Yes	Not applicable	Yes
15	Cancerul mamar.	Romanian program	2010	Ministry of Health	Europe/ Romania	Review	Yes	Not applicable	Yes
16	European Guide for Quality National Cancer Control Programmes.	Slovenian program	2015	Ministry of Health	Europe/ Slovenia	Review	No	Yes	Yes
17	Bröstcancer.	Swedish program	2020	RCSG	Europe/ Sweden	Not applicable	Yes	Not applicable	No
18	Breast cancer. Quality standard.	British program	2011	NICE	Europe/UK	Review	Yes	Not applicable	Yes
19	Evaluación de la práctica asistencial oncológica. Estrategia en Cáncer del Sistema Nacional de Salud.	Spanish program v3	2013	Sistema Nacional de Salud	Europe/Spain	Consensus	No	Yes	Yes
20	Desarrollo de indicadores de proceso y resultado y evaluación de la práctica asistencial oncológica.	Spanish program v2	2006	Sistema Nacional de Salud	Europe/Spain	Consensus	No	Yes	Yes
21	Breast cancer clinical pathway.	Spanish program v1	2020	SESPM	Europe/Spain	Review, consensus	Yes	Not applicable	Yes
22	УНІФІКОВАНИЙ КЛІНІЧНИЙ ПРОТОКОЛ ПЕРВИННОЇ, ВТОРИННОЇ (СПЕЦІАЛІЗОВАНОЇ), ТРЕТИННОЇ (ВИСОКОСПЕЦІАЛІЗОВАНОЇ) МЕДИЧНОЇ ДОПОМОГИ РАК МОЛОЧНОЇ ЗАЛОЗИ	Ukranian program	2015	Ministry of Health	Europe/ Ukraine	Review	Yes	Not applicable	Yes

Countries with no Clinical pathways, Health Care Plans and Integrated Health Care Processes retrieved.

1	Europe/Andorra	9	Europe/Croatia	17	Europe/Kazakhstan	25	Europe/Montenegro	33	Europe/Switzerland
2	Europe/Armenia	10	Europe/Czechia	18	Europe/Kosovo	26	Europe/North Macedonia	34	Europe/Turkey
3	Europe/Austria	11	Europe/Estonia	19	Europe/Latvia	27	Europe/Poland	35	Europe/Vaticano
4	Europe/Azerbaijan	12	Europe/Finland	20	Europe/Liechtenstein	28	Europe/Russia	36	North America/Canada
5	Europe/Belarus	13	Europe/Georgia	21	Europe/Lithuania	29	Europe/San Marino	37	North America/Mexico
6	Europe/Bosnia-Herzegovina	14	Europe/Greece	22	Europe/Luxembourg	30	Europe/Serbia		
7	Europe/Bulgaria	15	Europe/Hungary	23	Europe/Moldova	31	Europe/Slovakia		
8	Europe/Cryprus	16	Europe/Iceland	24	Europe/Monaco	32	Europe/Slovenia		

4. Discussion

4.1. Main findings

More than half of the European and American countries have not had any clinical pathway or integrated breast cancer care process to reach the excellence of BC care. QIs description was heterogeneous, with not a single identical indicator appearing in all the documents analysed. Secondly, there were only four comparable QIs that appeared more frequently in the analysed documents: "proportion of BC cases who preoperatively underwent breast and axilla radiology and physical examination", "proportion of patients with BC who had a preoperative histologically or cytologically confirmed malignant diagnosis (B5 or C5)", "proportion of BC patients to be discussed pre and postoperatively by a multidisciplinary team (MDT)", and "proportion of patients with IC who underwent image-guided axillary staging", all of them related to the process. One-quarter of the QIs of the process and outcome did not state a ST. We observed a minimum variability for "proportion of patients with BC who had a preoperative histologically or cytologically confirmed malignant diagnosis (B5 or C5)" ST; there was consensus in a quarter of the studied manuals. Despite indicating the time required between compliance processes with the indicator, half of the documents did not set a ST of accomplishment. Two documents recognized SDM importance, but only Italian collected a QI about measuring SDM use. There were not found QIs related to Primary Care.

The vast majority of QIs identified were process QIs (over three-quarters), and these were also found in more documents. They covered all the phases of BC care management from suspicion, diagnosis, treatment, and staging, counselling, follow-up and rehabilitation.

4.2. Strengths and weaknesses

To our knowledge, an evaluation comparing QIs for BC care management suggested by different Professional Societies or Health Administrations has not been reported previously. Our review gave a comprehensive perspective with a reasonable number of clinical pathways or integrated breast cancer assistance processes documents included using a wide search without language restrictions. This gave a strong global vision on the QIs situation for the whole BC diagnostic-therapeutic-follow-up process.

One possible limitation of this review could be that only European and North American documents were appraised. We have chosen these two continents because both regions have the biggest global R&D (research and development) investments, so they would have the highest number of publications worldwide [21]. More than three-quarters of the documents came from Western countries. Most of the quality care documents analysed were not formally published in scientific journals or were not indexed in databases. This involved an extensive manual search of grey literature in retrieving recommendations made by European and American institutions active in this field (QIs of BC care management) on the World Wide Web. Although our systematic review had no language restrictions, most of the documents studied have not been published in medical journals and were published in the local language of the country, which have made the searching difficult. We have tried to combat this problem by choosing reviewers experts in many languages (English, Spanish, Portuguese, Italian, French and German). To provide an accurate vision of the existing recommendations from European and American countries, we have contacted more than 200 prestigious experts on BC and quality management care by email (at least 3 times with a time lapse of one week per message): European Breast Centres Network and Europa Donna representatives from each country, the main hospitals, universities and the specific Governments, and Ministries of Health. Most of the contacted representatives have admitted that their countries have not had a national clinical pathway or integrated care process and a standard set of QIs and have stated that every region, county, or even hospital has developed their own indicators. ESMO handbooks and NCCN guidelines have been established as some of the most used guidances for a big part of the countries. More additional initiatives were searched in the identified publications' bibliographies to include other essential studies in our review. Therefore, some of these manuals may not have been found due to the difficult search.

Furthermore, comparing the EUSOMA position paper [7], and the clinical pathways or integrated breast cancer assistance processes studied was limited. EUSOMA's was only focused on BC care management in specialised Units, while the rest of the quality documents included all the care management process from the practitioner's referral to follow-up. In addition to the indicators collected in EUSOMA, the other QIs referred to care before and after admission to BC Units and included all the levels as aspects of care in quality assessment. So, incorporating these other documents presents advantages since they allow us to coordinate better communication with other levels and healthcare services, helping to improve compliance by including their singularities and requirements in the QIs measurements.

The level of evidence available on the QIs identified in the scientific literature was variable, and we had to deal with the subjective nature of the data extraction. We minimised the effect of these potential limitations by three experienced BC specialist clinician's analysis. A consensus meeting to unify criteria was done before duplicate data extraction assessment. An independent arbitrator (fourth reviewer) was concerned about the significant deviation that arose and helped reach consensus. It was reassuring to note that the reviewer agreement was excellent, with the ICC >98%.

4.3. Implications

The use of QIs could be extended to all BC care management stages, allowing monitoring processes' evolution over time and could be compared with other centres [12–18]. Although several QIs have been proposed to harmonise BC care quality management's evaluation, there is still no consensus between countries [11]. So, the comparison between studies is difficult, reducing the possibility of establishing conclusions that could be extrapolated to other health care areas or hospitals [12–18].

The development of QIs in general oncology is complex [44]. The concept of quality is broad and requires several indicators to explore different dimensions of the same issue. This could be problematic because similar QIs could not measure the same element. Furthermore, technological advances and the appearance of new treatments are happening fast, so it is a field in constant expansion, and frequent updates are required.

A considerable proportion of the indicators proposed were related to hospital settings because most of the clinical activity for cancer might occur at this level of care. In the QIs set analysed, we did not find any QI explicitly related to Primary Care. However, future reviews should pay more attention to ambulatory care processes if we want to have a comprehensive quality assessment. Most poverty-stricken countries present resource constraints that penalise and result in more poor BC care management [45]. Further studies should be done to investigate the differences between the indicators according to the country's wealth.

With an emphasis on patient-centred care, the use of shared decision making (SDM), i.e. "an approach in which the doctor and

the patient share the best available evidence and where the patient is supported to consider options and reach decisions about the process according to their preferences and values" [46] should be considered a key indicator in care quality management [47–49].

There is still a long way before the achievement of consensus. Current efforts must be required to reach an agreement between institutions [50]. Although the European Commission is currently carrying out an initiative to develop by consensus, indicators for Breast Units that guarantee good practice and excellent patient care, their results are not available yet [51]. Consensus-based quality indicators are needed to allow analysis in a clear, precise and straightforward way. This will allow data to be extrapolated and to be able to evaluate and compare different populations with different requirements. In our review, there were included specific documents about BC QIs such as EUSOMA [7], L'Institut National Du Cancer in France [28], the Belgian Cancer Registry [26], the NICE quality standard [39], the National Health System [41] and the Spanish Foundation of Senology and Breast Disease program [42], which have emphasised the importance of establishing a universal set of QIs. The majority of the countries did not have had any national clinical pathway or integrated breast cancer care process, which is extremely worrying, taking into account that these documents are essential to achieve an excellent quality of care.

The establishment of minimum and optimal quality STs is useful to assess the degree of compliance and the need for improvement of a QI. Currently, there is no ST for more than one-quarter of the QIs. As it has been remarked in EUSOMA, new researches should be developed, and new manuals would add them in the future [7].

Our analysis has identified a gap that offers an essential contribution to further research and debate, including assessing BC quality indicators. There is a broad space for improvement. Future studies and a reach of consensus in this vital matter would be highly recommended and merit urgent consideration.

5. Conclusions

More than half of the countries have not had a national clinical pathway or integrated breast cancer care process to achieve the excellence of BC care. There is no established set of QIs to harmonise BC care quality assessment, and their descriptions are heterogeneous. The comparison between studies has been difficult, reducing the possibility of establishing conclusions that could be extrapolated. Most of the integrated breast cancer assistance processes or clinical pathways did not indicate STs for compliance. Only one document collected the importance of the measurement of the use of SDM in BC, an already demonstrated QI for management care. No QIs specifically related to Primary Care were found in our study. A consensus set of BC care QIs is needed, something that future studies should pay attention to.

Contributors

All the authors certify a relevant contribution to the conception and design of the review, development of the search strategy, establishment of the inclusion and exclusion criteria, extraction, analysis, and interpretation of the data. MMC was involved in the conception and design of the review, literature search, data collection and analysis, quality appraisal, and writing. CREL, ARH and YGF were involved in data collection. ABC was involved in the design of this review, conducted the quality appraisal, in the writing, and provided critical revision of the paper. KSK helped with the writing and provided critical revision of the paper. MMD provided critical revision of the paper. All authors read and provided the final approval of the version to be published.

Financial support and sponsorship

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Data sharing statement

All the supplementary materials can be accessed upon request via email to the corresponding authors of this study.

Declaration of competing interest

The study was conducted in the University of Granada, Spain. There are no conflicts of interest.

Acknowledgments

KSK is a Distinguished Investigator funded by the Beatriz Galindo (senor modality) Program grant given to the University of Granada by the Ministry of Science, Innovation, and Universities of the Spanish Government. We are thankful for the collaboration of the Europa Donna (The European Breast Cancer Coalition) representatives from Belgium Dr Hirsch and Carly, Dr Aleksandrova from Bulgaria, Dr Moldovanova from Russia, Dr Skjoldborg Hansen from Denmark, Dr Egypt from Estonia, Dr Niemi from Finland, Dr Debiais from France, Dr Sartataviciene from Lithuania, Dr Fischbach from Luxembourg, Dr Barilaro from Monaco, Dr Mellem from Norway, Dr Brankovic-Magica from Serbia, Dr Spanić from Slovenia, Dr Bergsten from Sweden, Dr Corbat from Switzerland, Dr Sprengers from the Netherlands, Dr Spittle from the UK, Dr Maistruck from Ukraine and Europa Donna from Portugal. And we would also like to thank Dr Isabel Rubio (EUSOMA and ESSO President) in Spain, Dr Verhoeven at the Breast Centre Voorkempen in Belgium, Dr Ejlertsen, Dr Bohl and Dr Valvere from the Estonian Cancer Society, Dr Espie from the Hôpital Saint-Louis in France, Dr Winkler from the Hungarian League against cancer, Dr Zsuzsanna from the University of Szeged in Hungary, Dr Arnardóttir from the Landspitali University Hospital in Iceland, Dr. Dillenbourg from the Université de Liège in Luxembourg, Dr Daly from the University Hospital Waterford in Ireland, Ms Drochon and Dr Goncharenko from the Institute Nacional du Cancer in France, Dr Jenset from the Swedish Breast Cancer Association, Dr Fredriksson from the Karolinska Institutet in Sweden, Dr Ana Andrijević from the Institute for pulmonary diseases of Vojvodina, Prof Vrancken Peeters from the Dutch Breast Cancer Audit, Dr Verloop and Dr Siesling from IKNL, Prof Ozmen from the Istanbul Florence Nightingale Hospital, Prof Ozaydin from the Turkish Breast Health Society, Dr Lorez from the Swiss Federal Office of Health, the Swiss Cancer League, Dr Mousavi from the Cancer Registry of eastern Switzerland, and Dr Dagmar from the Swiss Office Q-Label. Finally, we are also grateful for the help provided by the Irish Cancer Society, the Norwegian Breast Cancer Association, the MD Anderson Cancer Center in Spain, the Canadian Breast Cancer Network and the Institute of Breast Disease FUCAM in Mexico, the Ministries of Health from Ireland, Georgia, Iceland, Lithuania and Luxembourg.

Appendix 0. PRISMA 2009 Checklist

Section/topic	#	Checklist item	Report Pagee#
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	2
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	3
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	3–4
METHODS			
Protocol and registration	4	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	4
Eligibility criteria	5	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	5
Information sources	4	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	4–5
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	Appendix A
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	5
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	5
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	5–6
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	Not applicable
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	Not applicable
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	6
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	Not applicable
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	Not applicable
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	6–7
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	Not applicable
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	Not applicable
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	Not applicable
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	6–9
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	Not applicable
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	9
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	9–12
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	10–11
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	13–14
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	14–15

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(7): e1000097. https://doi.org/10.1371/journal.pmed1000097.
For more information, visit: www.prisma-statement.org. Page 2 of 2.

Appendix A. Data sources and search strategy

AA.1 Sample search strategy for MEDLINE.

We conducted a systematic search on April 30th, 2021 in MEDLINE (via PubMed) 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: 8 articles.
AA.2 Online databases.

1. MEDLINE
2. EMBASE
3. Web of Science
4. Scopus

AA.3 Websites of European institutions.

1. EUSOMA, Europe
2. Professional institutions and societies or governmental agencies from each European country

AA.4 Health care representatives.

1. EUSOMA (European Society of Breast Cancer Specialists), Europe
2. Europa Donna (European Breast Cancer Coalition), Europe
3. ESSO (European Society of Surgical Oncology), Europe
4. EUBREAST (European Breast cancer Research Association of Surgical Trialists), Europe
5. Breast Cancer Care Network
6. National governments and Ministries of Health
7. Main hospitals from each country

Appendix B. Summary table of EUSOMA Quality Indicators in breast cancer care!

Indicator					Level of evidence	Mandatory or Recommended	Minimum standard
	1	Completeness of clinical and imaging diagnostic work-up			III	M	>90%
	2	Specificity of diagnostic procedures (Benign/Malignant diagnosis ratio)			III	M	1:4
	3	Preoperative diagnosis	A	Proportion of patients with invasive cancer who underwent image-guided axillary staging.	III	R	85%
			B	Proportion of women with breast cancer (invasive or in situ) who had a preoperative, histologically or cytologically confirmed malignant diagnosis (B5 or C5).	III	M	85%
DIAGNOSIS	4	Completeness of prognostic/predictive characterisation	A	Proportion of invasive cancer cases for which prognostic/predictive parameters have been recorded.	II	M	>95%
			B	Proportion of non-invasive cancer cases for which prognostic/predictive parameters have been recorded.	II	M	>95%
	5	Waiting time <6 weeks (from the date of first diagnostic examination within the breast centre to the date of surgery or start of other treatment)			IV	R	80%
	6	MRI availability	A	Proportion of cancer cases examined preoperatively by magnetic resonance imaging (MRI).	IV	R	10%
			B	Proportion of patients treated with primary systemic treatment (PST) undergoing MRI.	III	R	60%
	7	Proportion of cancer cases referred for genetic counselling.			IV	R	10%
SURGERY & LOCOREGIONAL TREATMENT	8	Multidisciplinary discussion.			III	M	90%
	9	Appropriate surgical approach	A	Proportion of patients (invasive cancer only) who received a single (breast) operation for the primary tumour (excluding reconstruction).	II	M	80%
			B	Proportion of patients (DCIS only) who received just one operation (excluding reconstruction).	II	M	70%
			C	Proportion of patients receiving immediate reconstruction at the same time of mastectomy.	III	R	40%
RT	10	Post-operative radiotherapy (RT)	A	Proportion of patients with invasive breast cancer (M0) who received RT after surgical resection of the primary tumour and appropriate axillary staging/ surgery in the framework of breast conserving therapy (BCT).	I	M	90%
			B	Proportion of patients with involvement of axillary lymph nodes who received post-mastectomy RT to the chest wall and all (non-resected) regional lymph-nodes.	I	M	90%
			C	Proportion of patients with involvement of up to three axillary lymph nodes (pN1) who received post-mastectomy radiation therapy to the chest wall and non-resected axillary lymph-nodes, including level IV (supraclavicular), and in medially located tumors, the internal mammary lymph-nodes.	I	M	70%
SURGERY & QUALITY OF LIFE	11	Avoidance of overtreatment	A	Proportion of patients with invasive cancer and clinically negative axilla who underwent sentinel lymph-node biopsy (SLNB) only (excluding patients who received PST).	I	M	90%
			B	Proportion of patients with invasive cancer who underwent sentinel lymph-node biopsy with no more than 5 nodes excised.	I	R	90%
			C	Proportion of patients (BRCA1 and BRCA2 patients excluded) with invasive breast cancer not greater than 3 cm (total size, including DCIS component) who underwent BCT as primary treatment.	I	M	70%
			D	Proportion of patients with non-invasive breast cancer not greater than 2 cm who underwent BCT.	II	M	80%
			E	Proportion of patients with DCIS only who do not undergo axillary clearance.	II	M	97%

(continued on next page)

(*continued*)

Indicator			Level of evidence	Mandatory or Recommended	Minimum standard
Systemic treatment	12 Appropriate endocrine therapy.		I	M	85%
	13 Appropriate chemotherapy and HER2-targeted therapy	A Proportion of patients with ERÀ (T > 1 cm or Nodeþ) invasive carcinoma who received adjuvant chemotherapy	I	M	85%
		B Proportion of patients with HER2 positive (IHC 3þ or in situ hybridisation positive FISH-positive) invasive carcinoma (T > 1 cm or Nþ) treated with chemotherapy who received adjuvant trastuzumab	I	M	85%
		C Proportion of patients with HER2-positive invasive carcinoma treated with neoadjuvant chemotherapy who received neo-adjuvant trastuzumab	I	M	90%
		D Proportion of patients with inflammatory breast cancer (IBC) or locally advanced non-resectable ER-carcinoma who received neo-adjuvant chemotherapy	II	M	90%
STAGING, COUNSELLING, FOLLOW-UP AND REHABILITATION	14 Appropriate staging procedure	A Proportion of women with stage I or primary operable stage II, breast cancer who do not undergo baseline-staging tests (e.g. US of liver, chest X-ray and bone scan)	III	R	95%
		B Proportion of women with stage III breast cancer who undergo baseline staging tests (US of liver, chest X-ray and bone scan)	III	R	95%
	15 Perform appropriate follow-up	A Proportion of asymptomatic patients who undergo routine annual mammographic screening and 6/12 months clinical evaluation in the first 5 years after primary surgery.	I	M	95%
		B Proportion of treated patients for which the breast centre collects data on life status and recurrence rate (for at least 5 years).	III	R	80%
	16 Availability of nurse counselling	A Proportion of patients referred for nurse counselling at the time of primary treatment.	IV	R	85%
		B Proportion of women with a diagnosis of breast cancer who have direct access to a breast care nurse specialist for information and support with treatment-related symptoms and toxicity during the treatment, follow-up and rehabilitation after initial treatment.	IV	R	95%
	17 The availability of data manager		IV	M	Not applicable

The level of evidence was graded according to the short version of the United States Agency for Healthcare Research and Quality (AHRQ).

Appendix C. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.breast.2021.06.013.

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