UNIVERSIDAD DE GRANADA
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LA TOMA DE DECISIONES COMPARTIDAS COMO INDICADOR DE CALIDAD EN EL PROCESO ASISTENCIAL CÁNCER DE MAMA.

SHARED DECISION MAKING AS AN INDICATOR OF QUALITY IN THE BREAST CANCER CARE PROCESS.

Programa de Doctorado Internacional en Medicina Clínica y Salud Pública

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Granada, abril 2021

“LA TOMA DE DECISIONES COMPARTIDA COMO INDICADOR DE CALIDAD EN EL PROCESO ASISTENCIAL CÁNCER DE MAMA”

“SHARED DECISION MAKING AS AN INDICATOR OF QUALITY IN THE BREAST CANCER CARE PROCESS”

Tesis Doctoral que presenta **MARTA MAES CARBALLO** para aspirar al título de Doctora con Mención Internacional

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“A good physician treats the disease; the great physician treats the patient who has the disease”.

Unknown

“If you’re always trying to be normal, you will never know how amazing you can be”.

Maya Angelou

“Memoria selectiva para recordar lo bueno, prudencia lógica para no arruinar el presente y optimismo desafiante para encarar el futuro”.

Isabel Allende

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ABSTRACT

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Introduction: The greater therapeutic complexity of breast cancer (BC) requires improving quality care for the diagnosis, treatment and follow-up. Information systems for self-evaluation and improvement opportunities detection must be incorporated to increase patient care results. There is no consensus, so several initiatives have developed specific integrated breast cancer care processes and clinical pathways with their own quality indicators (QIs). Shared decision making (SDM), an approach where the doctor and the patient share the best available evidence, should be considered one of these QIs. In SDM, the patient is supported to consider options and decide based on their own preferences and values. It acquires particular relevance when there are different treatment options associated with a very similar probable outcome, but it can produce very different results depending on the patient's desires and beliefs. BC is a paradigm of this situation. There is currently inadequate evidence on the use of SDM in clinical practice.

Objectives: i) To conduct a review of current studies on SDM, exploring the main facilitators and barriers and the strategies proposed by different authors for its implementation (manuscript 1). ii) To analyse the international BC QIs, measure tools and their compliance standards of care (manuscript 2). iii) To study the Spanish QIs for BC and compare them to the European set of indicators (manuscript 3). iv) To develop a critical evaluation of the quality indicators for BC's diagnosis and treatment. (manuscript 4). v) To investigate the knowledge, attitude and use of SDM in BC management by health professionals (manuscript 5). vi) To spread the results about the SDM knowledge, use and attitude in BC practitioners to a Spanish public (manuscript 6). vii) To analyse the general quality and reporting of clinical practice guidelines (CPGs) and consensus (CSs) on BC screening (manuscript 7). viii) To study the quality and reporting of BC treatment CPGs and CSs (manuscript 8). ix) To systematically review the quality and reporting of SDM on BC screening CPGs and CSs (manuscript 9). x) To analyse the quality and report of SDM in BC treatment CPGs and CSs (manuscript 10).

Methods: For the first objective, we conducted a general review of the literature on SDM. For the second and the third, we did a systematic review (SR) about BC QIs in International clinical pathways and integrated health care processes (manuscript 2) and different Spanish Autonomous Communities quality documents (manuscript 3). Data concerning QIs, measurement tools and compliance standards were extracted from European and North American sources in duplicate. A descriptive statistical analysis was conducted for analysing and classifying the selected QIs. An overarching qualitative synthesis was done to describe the findings. For the fourth one, a prospective observational study was carried out on a series of consecutive BC cases diagnosed and treated during five years in a health care area. A pseudonymised database was designed to analyse the Andalusian Integrating Breast Cancer Care Process indicators' compliance. A descriptive analysis was initially performed: frequency distribution for qualitative variables and central tendency and dispersion measures for quantitative variables and then were stratified by age and year of diagnosis. The percentage of cases meeting each of the indicators and its 95% confidence interval was estimated and stratified by patient characteristics. The results were compared using the Chi-square test to compare proportions (Table 1), a mean comparison test for independent groups (Student T-test) to compare across two categories of variables (Table 2) or analysis of the variance of one route (ANOVA with Bonferroni correction) for variables with more than two categories. Statistical significance was set at $p < 0.05$. The fifth and sixth objectives required to propose a cross-sectional observational study on a convenience sample of BC specialists. An anonymous online questionnaire was designed for self-completion and investigated the knowledge about SDM (questions 1-5), opinion about SDM (questions 6-12), awareness and attitude (questions 13-15) and the degree of current and future application of the SDM (questions 16-23). The variables of interest were measured on a Likert-type scale of 5 responses, 1 being "totally disagree" and 5 "totally agree". For analysing this data, the distribution of responses and the mean values of each question in the questionnaire were studied, stratifying by participant and hospital characteristics. Results were compared using a means comparison test for independent groups or one-way analysis of variance. Statistical significance was set at p

<0.05. Finally, for the rest of the proposed objectives, systematic reviews have been applied following the PRISMA statement and after a prospective registry in Prospero in each case. The CPGs and CSs were searched in various online databases, websites of important professional societies and in specific databases. No language restrictions were applied. Data were extracted in duplicate and independently. Two well-known validated tools were used in the works that analysed the quality and reporting of the guidance documents: AGREE II instrument for quality and RIGHT statement for reporting. The domain quality scores (0-100%) were calculated by summing up reviewers' scores and scaling as a percentage of the maximum possible score according to the formula provided in the AGREE II manual averaging the scores of the two reviewers. For reporting assessment, a numeric score of 1 (reported), 0.5 (partially reported), or 0 (unreported) was assigned to each item. Consistency between reviewers in data extraction was assessed using the intraclass correlation coefficient. To study the quality and reporting of SDM in BC guidance documents, no quality assessment tool has been found, so a new instrument has been developed. Individual quality items were scattered across several tools for guidelines assessment. A 31-item checklist was settled, after a specialist consensus meeting, for evaluation of SDM quality and reporting in guidelines. The greater the percentage of items complied with, the greater the quality for SDM in the CPG or CS assessed. The consensus meeting did not recommend constructing a formal score or a cut point for defining quality.

Results: Our reviews showed no consensus in BC care QIs, and more than half of the clinical pathways and integrated health care processes did not provide a minimum auditable standard of care for compliance. There were no Primary care or patient satisfaction QI provided, and the presence of SDM as a QIs was scarce. A review of the usefulness of these QIs for the improvement of the integrated health care processes and clinical pathways was done. We studied the degree of compliance of these indicators, analysing the variables that influence them and proposing improvement measures. Regarding SDM, the results showed that professionals involved in BC management have a high level of knowledge and a very positive attitude about SDM, although its

application is limited. The main obstacle observed in its implementation was the lack of time. And it was determined that health administrations should facilitate the training, material, and human resources necessary for achieving a useful SDM application. It was also verified that more than half of the CPGs and CSs of BC screening did not meet the minimum standards of quality and reporting. The results, although insufficient, were better in BC treatment guidance documents. Our study suggested that using systematic reviews would improve the quality and reporting of recommendations. The study of the quality and reporting of SDM in BC screening CPGs, although it has eased in recent years, was flawed, and there is a current need for improvement and promotion. Regarding the guidance documents on BC treatment, there is also a necessity to raise the quality and reporting of the recommendations on the use of SDM. More guidelines included SDM in their proposals in recent years, even though it was less reported in those published in medical journals.

Conclusion: There is no consensus about BC QIs, and SDM is not usually shown as one. BC health care and the QIs used to measure it could be improved in various ways. One of the most important would be the active involvement of patients through procedures such as SDM. Although, SDM concept is known and accepted, there are not enough resources or support for its practical application. Furthermore, SDM is scarcely contemplated in CPGs and CSs although it is a vital requirement for a correct implementation in daily clinical practice.

RESUMEN

RESUMEN

Introducción: La creciente complejidad terapéutica del cáncer de mama (CM) exige mejorar la calidad asistencial para el diagnóstico, tratamiento y el seguimiento de la enfermedad. Se deben incorporar sistemas de información para la autoevaluación y detección de oportunidades de mejora para incrementar los resultados en la atención del paciente. No hay consenso, por lo que muchas administraciones y asociaciones sanitarias competentes en el tema han desarrollado diferentes Vías Clínicas o Procesos Asistenciales Integrados del Cáncer de Mama específicos con sus propios indicadores de calidad (ICs). La práctica de la Toma de Decisiones Compartida (TDC), un enfoque en el que el médico y el paciente comparten la mejor evidencia disponible no suele incluirse como uno de estos IC. En la TDC, el médico apoya al paciente para que considere opciones y decida en función de sus preferencias y valores. Adquiere especial relevancia cuando existen diferentes opciones de tratamiento equiparables, pero puede producir resultados muy diferentes según los deseos y creencias del paciente. El CM es un paradigma de esta situación. Actualmente, existen pocos estudios que evalúen la práctica de la TDC en el tratamiento del CM.

Objetivos: i) Realizar una revisión de los estudios actuales sobre la TDC, explorando los principales facilitadores y barreras y las diferentes estrategias propuestas para su implementación (manuscrito 1). ii) Analizar los ICs del CM a nivel internacional y el cumplimiento de sus estándares (manuscrito 2). iii) Estudiar los ICs en España y compararlos con los de Europa (manuscrito 3). iv) Realizar una evaluación crítica de los ICs para el diagnóstico y tratamiento de CM. (manuscrito 4). v) Estudiar el conocimiento, actitud y uso de la TDC en el CM por parte de los profesionales sanitarios (manuscrito 5). vi) Dar a conocer a un público hispano parlante los resultados sobre el conocimiento, uso y actitud ante la TDC en profesionales sanitarios especialistas en CM (manuscrito 6). vii) Analizar la calidad general y el reporte de las guías de práctica clínica (GPCs) y documentos de consensos (DCs) sobre el cribado del CM (manuscrito 7). viii) Estudiar la calidad y reporte de las GPCs y DCs del tratamiento del CM (manuscrito 8). ix) Revisar sistemáticamente

la calidad y reporte de la TDC sobre las GPCs y los DCs de cribado del CM (manuscrito 9). x) Analizar la calidad y reporte del SDM en las GPCs y DCs de tratamiento de CM (manuscrito 10).

Métodos: Para el primer objetivo, realizamos una revisión general de la literatura sobre la TDC. Para el segundo y el tercero, hicimos una revisión sistemática de los ICs en el CM a nivel internacional (manuscrito 2) y en diferentes Comunidades Autónomas españolas (manuscrito 3). La información concerniente a los ICs, herramientas de medida y el cumplimiento de los estándares fue extraída de fuentes europeas y norteamericanas en duplicado. Se realizó un análisis descriptivo para estudiar y clasificar los indicadores seleccionados. Se desarrolló un resumen cualitativo para describir los resultados. Para el cuarto, se realizó un estudio prospectivo observacional sobre una serie de casos consecutivos de CM diagnosticados y tratados durante cinco años en un área sanitaria. Se diseñó una base de datos seudonimizada para analizar el cumplimiento de los indicadores del Proceso Asistencias Integrado Cáncer de Mama de Andalucía. Inicialmente se realizó un análisis descriptivo: distribución de frecuencias para las variables cualitativas y medidas de tendencia central y dispersión para las cuantitativas y luego se estratificó por edad y año de diagnóstico. El porcentaje de casos que cumplieron con cada uno de los indicadores y su intervalo de confianza del 95% se estimó y estratificó por características de los pacientes. Los resultados se compararon mediante la prueba de Chi-cuadrado para proporciones, test de comparación de medias (T-student) para variables con dos categorías y ANOVA para variables con más de dos categorías. La significación estadística se situó en $p< 0.5$. Para el quinto y sexto objetivos se realizó un estudio observacional transversal sobre una muestra de conveniencia de especialistas en CM. Se diseñó un cuestionario online anónimo para autocompletar y se investigó el conocimiento sobre la TDC (preguntas 1-5), la opinión sobre el TDC (preguntas 6-12), la conciencia y la actitud (preguntas 13-15) y su grado de aplicación actual y futura (preguntas 16-23). Las variables de interés se midieron en escala tipo Likert de 5 respuestas, siendo 1 “totalmente en desacuerdo” y 5 “totalmente de acuerdo”. Para el análisis de estos datos se estudió la distribución de las respuestas y los valores medios de cada pregunta

del cuestionario estratificando por características del participante y del hospital. Los resultados se compararon mediante una prueba de comparación de medias para grupos independientes o un análisis de varianza. La significación estadística se estableció en p <0,05. Finalmente, para el resto de los objetivos propuestos, se han aplicado revisiones sistemáticas tras registro prospectivo en Prospero y siguiendo la declaración PRISMA. Las GPCs y DCs se buscaron en diversas bases de datos en línea, sitios web de importantes sociedades profesionales y en bases de datos específicas. No se aplicaron restricciones de idioma. Los datos se extrajeron por duplicado e independientemente. En los trabajos que analizaron la calidad y la presentación de informes de los documentos de orientación se utilizaron dos herramientas validadas reconocidas: AGREE II para la calidad y RIGHT para el reporte. Los puntajes de calidad de cada dominio (0-100%) se calcularon sumando los puntajes de los revisores y obteniéndolos como un porcentaje del puntaje máximo posible de acuerdo con la fórmula proporcionada en el manual AGREE II promediando los puntajes de los dos revisores. Para la evaluación del reporte, se asignó a cada elemento una puntuación numérica de 1 (informado), 0,5 (informado parcialmente) o 0 (no informado). La coherencia entre los revisores en la extracción de datos se evaluó mediante el coeficiente de correlación intraclase. Para estudiar la calidad y reporte de la SDM en los documentos guía del BC, no se encontró ninguna herramienta, por lo que se desarrolló un nuevo instrumento. Se estableció una lista de verificación de 31 elementos, después de una reunión de consenso de especialistas. Cuanto mayor sea el porcentaje de ítems cumplidos, mayor será la calidad de la SDM en las CPGs o CSs evaluados. No se recomendó construir ningún punto de corte para definir la calidad.

Resultados: Nuestras revisiones demostraron que no hubo consenso en determinar una serie de ICs para el CM y que más de la mitad de las vías clínicas y procesos asistenciales integrados no fijaron ningún estándar mínimo de cumplimiento. No se encontraron ICs sobre Atención Primaria o la satisfacción en los pacientes y la presencia de ICs sobre la TDC fue mínima. Se realizó una revisión de la utilidad de estos ICs para la mejora del Proceso Asistencial Integrado Cáncer de

Mama. Estudiamos el grado de cumplimiento de estos indicadores, analizamos las variables que influyen en ellos y propusimos medidas de mejora. En el estudio de la TDC, nuestros resultados mostraron que los profesionales involucrados en el manejo del BC tienen un alto nivel de conocimiento y una actitud muy positiva sobre la SDM, aunque su aplicación es limitada. El principal obstáculo observado en su implementación fue la falta de tiempo y se concluye que las administraciones sanitarias deben facilitar la formación, el material y los recursos humanos necesarios si quieren potenciar el uso de la TDC en el tratamiento del CM. También se verificó que más de la mitad de los documentos guía de cribado no cumplieron con los estándares mínimos de calidad y reporte. Los resultados, aunque insuficientes, fueron mejores en los documentos guía sobre el tratamiento del cáncer de mama. Nuestro estudio sugirió que el uso de revisiones sistemáticas mejoraría la calidad y el reporte de las recomendaciones. El estudio de la calidad y reporte de la TDC en las GPCs y DCs de cribado del CM, aunque ha mejorado en los últimos años, necesita seguir progresando y promocionándose. Con respecto a los documentos guía sobre el tratamiento del cáncer de mama, también existe la necesidad de mejorar la calidad y reporte de las recomendaciones sobre el uso de la TDC. Aunque en los últimos años son cada vez más las GPCs y DCs que incluyen en sus recomendaciones la TDC, la SDM apareció con menor frecuencia en aquellos documentos guías que fueron publicados en revistas médicas.

Conclusión: No hay consenso sobre los ICs del CM y la TDC no está recogida habitualmente como uno de ellos. La atención sanitaria del CM y los ICs utilizados para medirla son mejorables. Facilitar la participación activa de los pacientes en la toma de decisiones podría suponer una mejora importante. Si bien el concepto de la TDC es conocido y aceptado, Los recursos e incentivos para su aplicación son insuficientes. Tampoco está suficientemente tratado ni recomendado en las GPCs y CSs, que podrían tener un papel fundamental en su difusión y promoción e implementación en la práctica clínica diaria.

INTRODUCTION

1. INTRODUCTION

1.1. General concepts

This Doctoral Thesis focuses on the study of quality care for Breast Cancer (BC) and the use of shared decision making (SDM) as a quality indicator (QI) in the integrated breast cancer care processes and clinical pathways. To understand this in-depth, it is necessary to introduce and define some concepts and terms related to the study subject that will appear throughout the work.

BC is the most common neoplasm with an incidence of 2 million cases and the leading cause of cancer death in women, precisely 15% (670,000) of annual cancer deaths worldwide (1-3). Most are diagnosed between 45 and 80 years old, with a peak incidence between 50 and 70 (4). However, there is a large difference in BC survival rates worldwide, with an estimated 5-year survival of 80% in developed countries and below 40% for developing countries (5). This is because most impoverished countries face limitations of resources and infrastructure that hinder timely screening, diagnosis, and treatment (6).

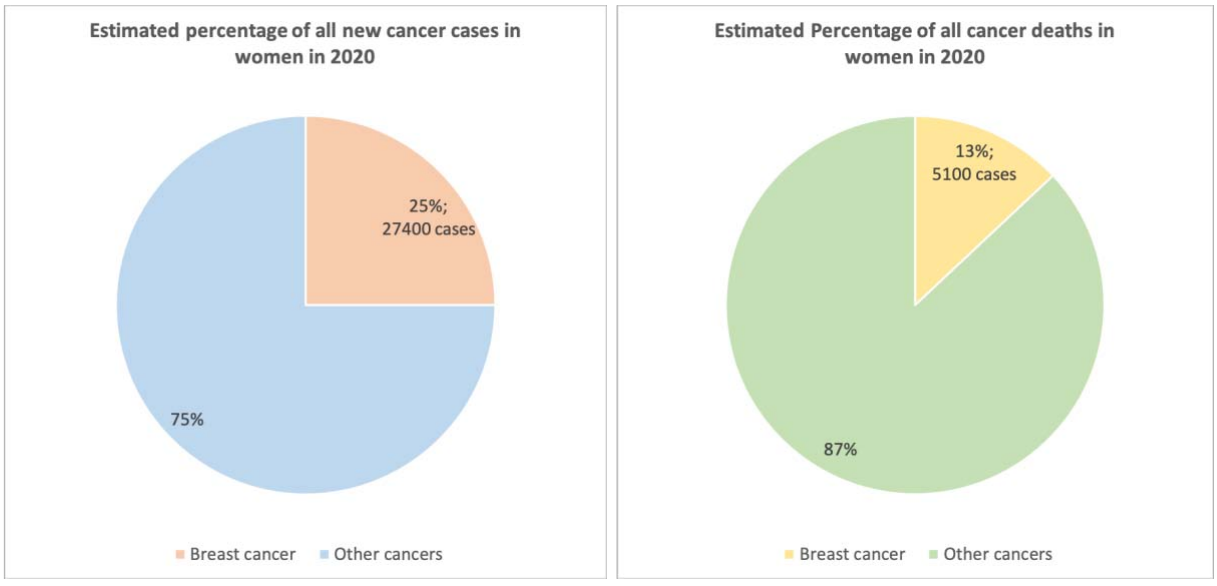

Figure 1 y 2: The estimated global proportion of cancer incidence and mortality in 2020. *Source: Canadian Cancer Society*

Its clinical and histological presentation is varied. Confirmatory diagnosis is pathological and, depending on the result, individualized treatment is prescribed for each patient (7). The main purpose of therapy is to increase disease-free and overall patient survival (4). This treatment has notably improved in the last decades until reaching an overall survival at five years of 76.20% in Spain, one of Europe´s highest (8). This trend can be attributed to early diagnosis in symptomatic patients and women included in screening programs and the selective application of new treatments (4, 9, 10). Simultaneously, the greater efficacy of neoadjuvant therapies and the development of oncoplastic techniques have made it possible to reduce the surgical treatment´s aggressiveness and improve the aesthetic and functional results (11). Consequently, BC treatment is increasingly satisfactory but also more complex. Hence, each case´s ideal approach requires a high degree of individualization, scientific-technical updating, multidisciplinary coordination, and continuous review of results (12, 13).

The ideal strategic plan for the patient will be the one that best meets their needs and expectations. Its design should be based on an accurate diagnosis of their disease and the patient´s circumstances, preferences, and values (4, 14).

1.2. Quality in the breast cancer care process

BC's greater therapeutic complexity requires improving quality care for the diagnosis and treatment of cancer (4). Information systems for self-evaluation and the detection of improvement opportunities must be incorporated for the continuous monitoring and evaluation of results (15). The chosen indicators should allow a simple, objective, and accurate collection of data and its reproducibility, representing the evaluated process. This will enable a thorough analysis of the process and the identification of areas for improvement. Three types of QIs are considered essential for capturing care quality (16). 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) (17, 18).

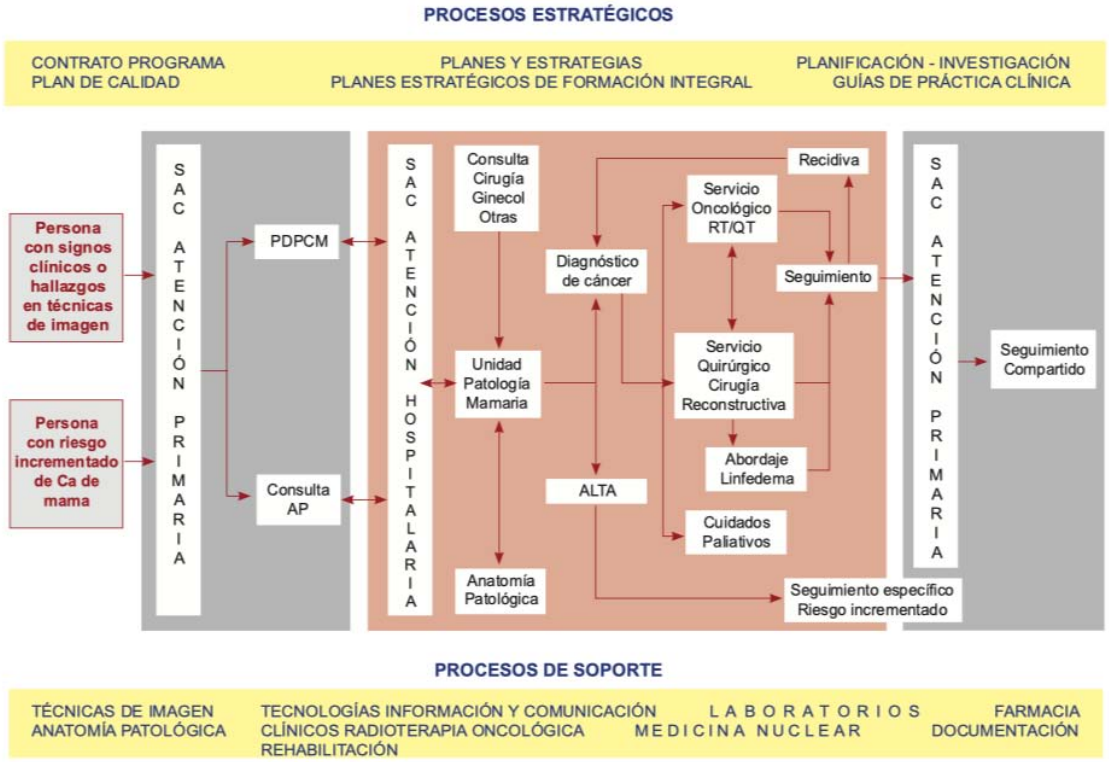

Figure 3: Global summary of the Integrated Care Process for breast cancer (PAICM). *Source: Consejería de Salud Andalucía*

The use of systems to ensure quality has been proven useful to improve patient care results (19-22). Clinical pathways or integrated breast cancer assistance processes, i.e. "preventive, diagnostic, therapeutic, follow-up and care activities, aimed at the comprehensive management of people… with increased risk for breast cancer…" (23) have been deployed to manage and standardise care (24). These include a series of QIs for continuous improvement via maintenance of sociodemographic, clinical and healthcare databases. There are various initiatives for implementing QIs (4, 23, 25) that improve BC care patients. The European Society of Breast Cancer Specialists (EUSOMA) working group indicates that "these 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" (25). In Spain, each area has developed a specific integrated breast cancer care process with its QIs. In Andalusia, for example, the integrated breast cancer care process is defined as the "Set of preventive,

diagnostic, therapeutic, follow-up and care activities, aimed at the comprehensive management of people… with increased risk for breast cancer…" (25). The development of specific indicators for each centre has been proven useful and allows the research to be adapted to the peculiarities of a particular hospital population (26). 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" (27) should be considered a key indicator in care quality management (28-30).

1.3. Screening in breast cancer

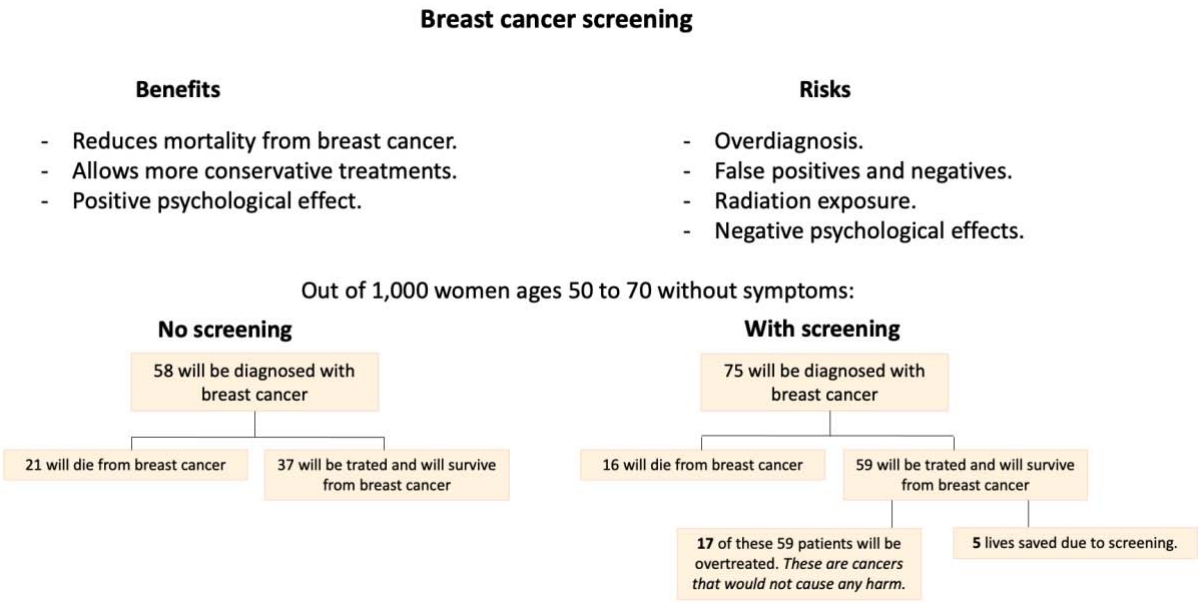

Figure 4: Summary of the risks and benefits of breast cancer screening. *Source: The benefits and harms of breast cancer screening: an independent review. The Lancet 2001; 380 (9855): 1778-1986.*

The early detection of BC allows less aggressive and more effective and efficient treatments, reducing morbimortality (31). The currently recommended technique for breast cancer screening is mammography. Many countries have developed screening programs, but their characteristics vary widely. In Europe, even with different organizational models, the recommendations of the "European quality guide for breast cancer screening and diagnosis" are followed, which indicates as a screening test a biannual mammogram to be performed on all women between 50 and 69

years old (32). In Spain, this test (33) has been included as a benefit in the "Basic Portfolio of Services of the National Health System" since 2014 (34). In the USA, screening is opportunistic, although it is recommended a biannual mammogram in women aged 50 to 74; an individual assessment of its efficacy in women aged 40 to 49 years and not carried out in those over 75 years because its effectiveness is controversial (35).

For years there has been a debate about the efficacy and effectiveness of screening in BC. There are numerous studies in favour (36, 37) and against it (38, 39). In contrast to the benefits obtained from early detection of cancer, allowing less aggressive treatments, BC screening is expensive and annoying (31, 40). It can also carry the risk of false positives and negatives, with subsequent patient stress and the possibility of causing unnecessary procedures and overtreatment (31) and a false sense of security (41, 42). On the other hand, the reduction in mortality is not statistically significant at all ages (43) and the benefit versus harm balance is uncertain (31), so the screening should be adapted to the characteristics such as age, genetic factors and race (43), desires and values of women (44). It should be noted that psychological damage and the woman's preferences are often not considered by health professionals when assessing whether screening can be useful in a patient (45).

1.4. Treatment in breast cancer and its evolution

Breast cancer treatment has undergone a spectacular evolution from more radical to increasingly conservative and individualized throughout history. The first radical mastectomy with amputation of the breast, pectoral removal, and axillary dissection was performed in the XVIII century by J.L. Petit. Along with the XIX century, there were two significant contributions to the BC treatment: the introduction of anaesthesia by W. Morton in 1846 and antisepsis by J. Lister in 1867 (46). In 1890, these two discoveries allowed that in 1890, Halsted and Meeyer, who considered BC a locoregional disease, described the regulated radical mastectomy, which consisted of an en bloc excision with extensive skin excision, removal of the mammary gland and both pectorals and

complete axillary dissection. This treatment prevailed for 100 years (46). In the 20th century, two antagonistic surgical currents appeared. Firstly, Urban's radical mastectomy with en bloc removal of the internal mammary chain. Secondly, Patey's modified radical mastectomy (with the removal of the mammary gland, pectoralis minor, and pectoralis major fascia) and axillary dissection or Madden's modified radical mastectomy (with the removal of the mammary gland without pecs and axillary dissection) (47). The last technique is still currently used when the characteristics of the patient and the tumour require it. Subsequently, the simple mastectomy consisting of removing the mammary gland, without axillary emptying, appeared and later the subcutaneous mastectomy, removing most of the mammary gland, but preserving the skin, areola and nipple. In the 1970s, chemotherapy and radiotherapy gained acceptance as a complement to surgical treatment, so there was a gradual evolution to less aggressive surgeries, making room for oncoplastic and breast-conserving surgery and sentinel lymph node biopsy (SLNB), which, if negative, would prevent axillary emptying (46). This breast-conserving surgery with complete resection of the tumour with a concentric margin of healthy tissue pursues two purposes: local control of the disease and an aesthetic result satisfying for the woman. In the middle of the XX century, numerous studies, such as Veronesi and Fischer's works, reported that lumpectomy followed by radiotherapy in early stages could obtain similar results to classical radical mastectomy (47, 48).

At present, advances in diagnostic imaging methods and molecular classification of BC have allowed the diagnosis of smaller lesions with less lymphatic spread, thus allowing a reduction in the aggressiveness of surgery. The study of the heterogeneity of BC (hormone-sensitive tumours, tumours with Her2 overexpression, and triple-negative tumours) together with the appearance of new neoadjuvant and adjuvant treatments on demand, have made it possible to propose the most suitable agents and the sequence of treatments in each subtype to obtain maximum cancer benefit and thus increase overall survival (49).

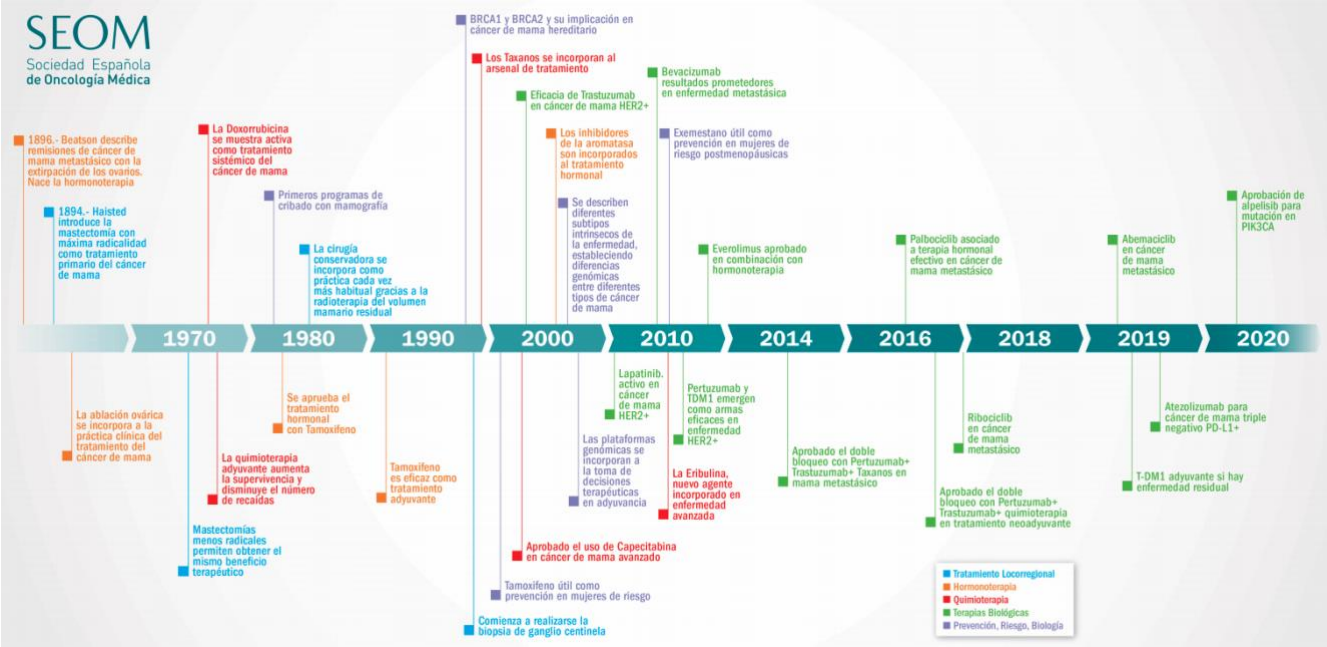

Figure 5: Evolution of breast cancer treatment. *Source: Los avances en Cáncer de Mama. SEOM (Sociedad Española de Oncología Médica).*

1.5. Clinical practice guidelines and consensus in breast cancer

The promotion of high-quality medical care has become a priority in recent years. (50) Even though many published works do not meet the quality criteria to be considered scientifically valid, (51) a more scientific approach can allow health systems to provide a better quality of care and more efficient use of resources (52). This requires developing evidence-based documents that enable medical interventions standardization and improve care quality, such as clinical practice guidelines (CPGs) and consensus statements (CSs). CPGs are defined as "statements that include recommendations aimed at optimizing patient care and which are based on a systematic review (SR) of current evidence and an evaluation of the benefits and harms of the various health care options" (53); while a CSs is developed by an independent panel of experts, generally multidisciplinary, convened to review the evidence-based literature on a specific procedure but with a looser and less strict development methodology (54). CSs are typically intended for controversial breast management areas (where the evidence is still incomplete), and recommendations are based on experts´ perspective. Therefore, they are more likely to have less

editorial independence and endorse a specific product with lower quality and higher bias risks (54).

SRs should be used in CPGs to systematically identify, evaluate, and summarize a clinical issue's current management. These usually require methodological adaptation and innovation for not to lose quality. Therefore, all CPGs must follow a rigorous methodological approach that fits a SR criteria (55). However, SRs that allow synthesis of the existing evidence to transfer it through CPGs are arduous and require much time, which delays the transmission of research to practice. A key point in the last step of the SR for the development of CPGs is to generate GRADE tables to determine the recommendations' strengths (56, 57). These delays may be associated with a loss of benefits for the patient (58) when basing the medical care in outdated CPGs (59), thus decreasing the quality of care provided (60, 61). In this case, the use of tools based on artificial intelligence could accelerate the synthesis of evidence and transmission of knowledge, thus increasing the quality of CPGs and improving medical care (62).

In BC, CPGs and CSs are being promoted to harmonize the provision of adequate health care (63, 64), so it is intended they present a rigorous development and an objective approach to the analysis of the evidence to support the recommendations (64, 65). There are currently various tools to measure this quality and report to analyze each of these qualities' multiple inherent aspects. The instrument usually used to evaluate the quality of the guidance documents is AGREE II (66, 67), while RIGHT is used to assess the report (68, 69).

1.6. Involvement of patients in diagnosis, treatment and follow-up

The doctor-patient relationship has undergone a substantial change, especially since the last decades of the XX century. There are four medical decision-making models according to the role of the person who provides the medical service: paternalistic, informative, interpretive, and deliberative (70, 71). The Paternalistic Model, in which the doctor used his knowledge to choose tests and treatments necessary to restore the health of the patient who was a mere observer,

has given way to models in which the patient takes a more active role in decision-making. Later the Informative Model appeared, which was developed in response to the initial rise of autonomism, in which the doctor has a mere function of informant and the patient manages information and decision-making individually, and the Interpretive Model, in which the doctor maintains an assertive listening and supports the patient, trying not to influence the final decision. Finally, the Deliberative Model appears, which is bidirectional, in which the doctor and the patient establish a dialogue and create a climate that favours the patient choosing the most appropriate option for her characteristics, preferences, and values. The latter is known as SDM (70-72). These relationship models that have developed through history can be valid today under certain circumstances (73).

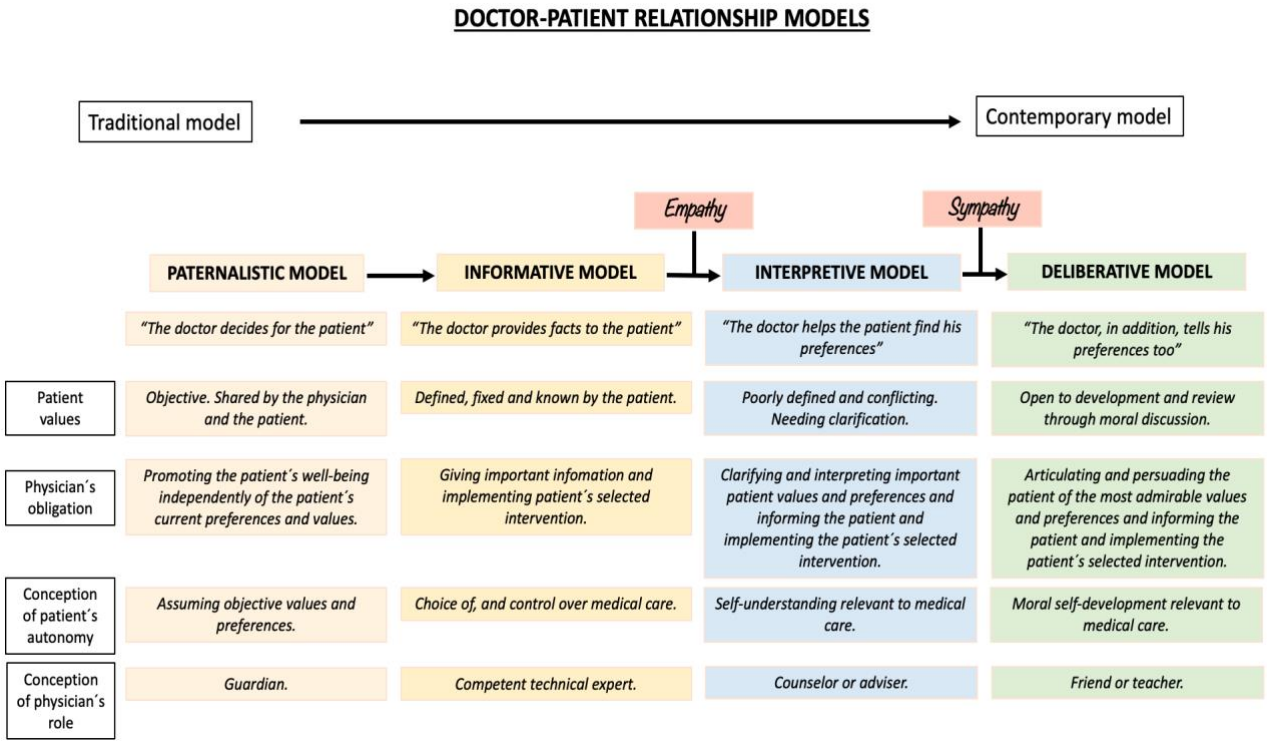

Figure 6: The doctor-patient relationship models: paternalistic, formative, interpretive and deliverative (SDM). *Source: Partially adaptated from "Cuatro modelos de la relación médico-paciente". E.J. Emanuel, L. L. Emanuel.*

1.6.1. Shared decision making, the deliberative model: the concept

SDM is "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" (27). SDM has been globally accepted since its

appearance (74, 75) as it increases the efficiency of the patient care process (28-30). Its use is currently increasing exponentially (76). It acquires special relevance when there are various treatment options with similar potential and probable outcomes but can produce very different results according to the patient's preferences and values (29, 77, 78). It increases patient satisfaction (77), their adherence to treatment (79) and their perception of risk (79, 80). And it is recommended by many medical associations (81-84) and an ethical requirement (85), and a legal obligation (86-89) in many developed countries. Its effective application reduces lawsuits for bad praxis (90). In the USA, for example, it has been adopted as a priority for research by the Patient-Centered Outcomes Research Institute (91).

1.6.2. Shared decision making requirements

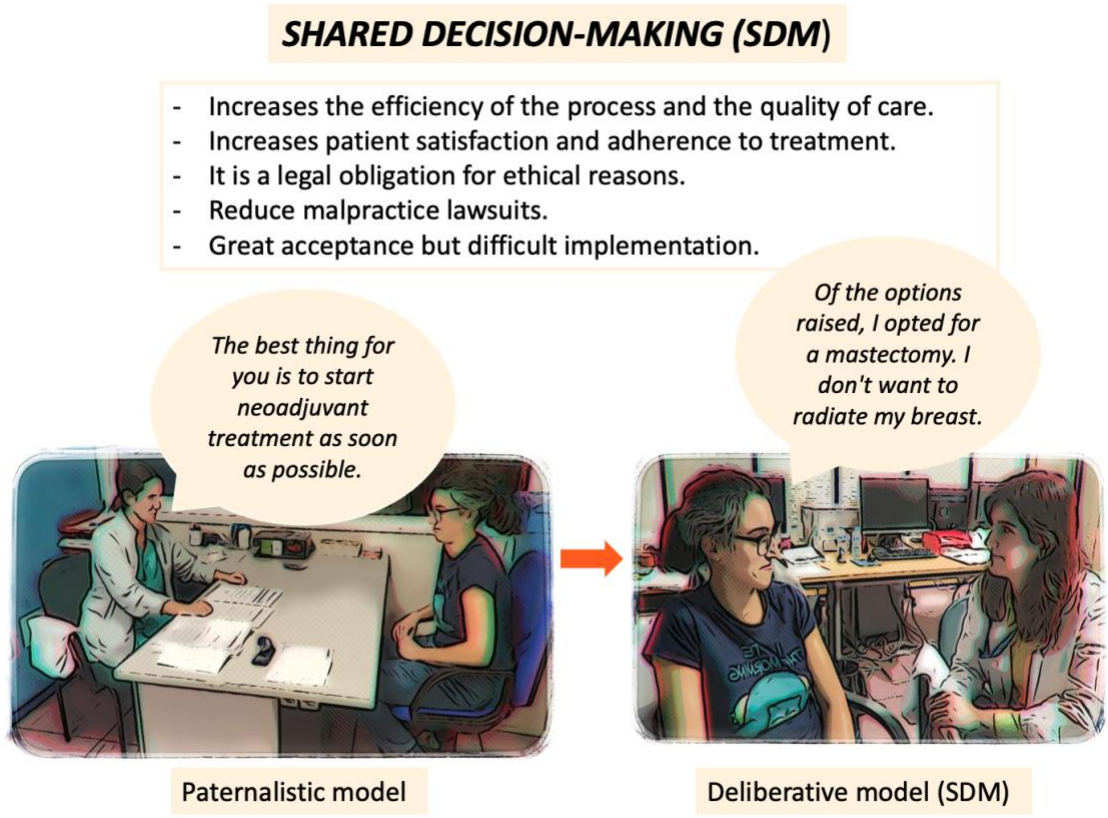

Figure 7: The evolution of shared decision-making (SDM) in the doctor-patient relationship.

SDM has a series of necessary elements to be use it. In the first place, it is essential a good communication with a two-way exchange of information (personal and medical) between the patient and the healthcare professional (92, 93). The physician must clearly and concisely expose

the several treatment options and should be established a relationship of trust between the doctor and the patient. The doctor could use effective conversation techniques that allow the patient to express their values and preferences (94). In this model, it is acceptable for the health professional to give their medical opinion (95). Second, there must be a deliberation between the different options, preserving the principle of autonomy of the patient (96). Third, a consensual decision must be reached, with the patient actively participating in decision-making (97, 98).

1.6.3. Implementation of shared decision making

The main facilitator reported by health professionals for the use of SDM is the perception that putting it into practice will lead to improved outcomes and better medical care (99). However, it currently presents difficulties for its implementation (100-102), so its use is irregular and scarce (103, 104). This critical issue should be adequately studied through systematic reviews and meta-analyses, but its study is still insufficient (60, 105-111). This lack of knowledge is a known barrier to implementation and leaves a great deal of room for improvement in this area. For example, a recent systematic review carried out by our team shows that SDM is poorly addressed in the clinical practice and consensus guidelines of the BC (60). This is surprising given the number of studies demonstrating the benefits of taking this attitude (29, 101). For example, Hack et al. showed that BC patients who had actively participated in SDM during the follow-up of their disease substantially improved their quality of life at the end of the process (76). Among the barriers reported for its correct use are the physicians' lack of training and, especially, the lack of means and resources (112-115). There is no evidence SDM is more time consuming (116, 117), but it should be reserved for decisions highly dependent on the patient's preferences and values (118, 119); or clinical outcomes are uncertainty (120). On the other hand, the lack of professionals' training can prejudge patients' desire to participate actively in SDM (99). For better implementation, it has been demonstrated it is necessary to promote the use of decision-making tools: "interventions that support patients in making decisions, providing information on options and benefits / associated harm, and helping to clarify the congruence between decisions and

personal values and preferences" (93, 121, 122). Studies show that the explanations of risk and benefit indicated by doctors are, in many cases, insufficient (123) but increasing the availability and routine use of decision-making tools help patients to participate more meaningfully in SDM (121).

Numerous authors have proposed strategies for promoting and applying SDM (27, 29, 93, 101, 114, 122). One of the suggested models is based on three steps: informing that there are various options available, provide more detailed information about them, and finally, explore the patient's preferences and encourage them to establish their own goals (29). Another proposal is to set goals following the patient's preferences and translate them into real treatment plans (119). Finally, some of the strategies proposed to encourage its use have been to assume SDM as an indicator of good quality health care (124) and to incentivize professionals to use it (101).

1.6.4. Health impact and the future of shared decision making in breast cancer

SDM may be especially useful in BC management since its diagnosis requires that multiple high-risk decisions be made in a limited period of time and, often, with limited evidence, which enhances the need for more significant patient participation in the decision-making process (125-127). On the other hand, in the last year, COVID-19 has forced changes in medical care, taking into account the application of public health measures necessary to contain the pandemic (128). This has generated an increase in difficult decisions in which it is imperative to involve patients, thus creating a unique role for the SDM too.

The main objective of the SDM is to respect the autonomy of patients without detriment to their benefit, providing quality care under their values and preferences. This implies the development of multidisciplinary teams with a high scientific-technical level, excellent coordination, continuity of care, and communication with the patient, and permanent review of the results within the framework of a continuous improvement program. Even if most patients finally do not want or do not know how to participate very actively in the decision-making process, it does not exempt

us from developing a health system capable of offering this possibility without reducing quality efficiency. The implementation of SDM in BC care is a very demanding path; it requires training, resources, and time, but, above all, it requires a team that is exceptionally trained, committed, and oriented to patient satisfaction. The practice of SDM in cancer care has been proposed as a crucial element to change a system's course in crisis towards excellence and sustainability (77).

JUSTIFICATION

2. JUSTIFICATION

The facts that justify initiating a line of research devoted to SDM as a quality indicator (QI) in BC management care can be summarised in the following points:

2.1. Foreseeable evolution of the health problem.

As explained in the first part of this Doctoral Thesis (introduction section), SDM increases the efficiency of the health care system, and it acquires particular relevance when there are various management options with similar potential and probable development but can produce very different results according to the patient's choices and values. It is a legal obligation for ethical reasons, and it has been demonstrated that the use of SDM increases patient satisfaction, adherence to treatment, and perception of risk.

The aim of SDM is to respect the autonomy of patients without detriment to their benefit, providing high-quality care according to their values and preferences. This implies the development of multidisciplinary teams with a high scientific-technical level, excellent coordination, continuity of care and communication with the patient and permanent review of the results within the framework of a continuous improvement program. Nowadays, most patients probably do not want or do not know how to participate very actively in the decision-making process, but our duty as physicians is to develop a health care system capable of offering this possibility without reducing the quality and efficiency. The implementation of SDM in BC care is a very demanding path, and it requires training, resources and time, but, above all, it requires a team that is particularly trained, committed and oriented to patient satisfaction. The practice of SDM in cancer care has been proposed as a crucial element to achieving the change of a system in crisis towards excellence and sustainability. Nowadays, SDM use remains poor. Therefore, given all the advantages of its use, it could be considered the medicine of the future, a medicine centred on the patient.

2.2. Absence of earlier research.

Leaving aside the above considerations, it is essential to note that our work aims to investigate a wide field of study that is currently shallowly studied. No previous reviews were found about BC management care QIs in clinical pathways or integrated health care processes, and there were no studies in Spain that assess the impact of the analysis of the QIs. However, their evaluation is considered essential for adequate control of the process, to identify areas for improvement and provide possible solutions and improvement plans based on objective data. There were also not prior international studies that assess the level of understanding, attitude and degree of application in clinical practice by health professionals of the use of SDM. Few have been the publications that analyse the quality of BC guidelines. These previous evaluations of guidance were only in BC treatment and have shown that their quality can be heterogeneous (129-131). Moreover, they were only about BC treatment and non-recent, covering guidance documents published between 2009 and 2017. They were limited in their searches and applied languages restrictions to English only (129-131). It has been highlighted that quality and reporting are two distinct aspects that need to be examined separately. The former deals with issues of validity of the recommendations made, while the latter examines the thoroughness of the presentation of the document prepared. In this regard, evidence synthesis's thoroughness and transparency is a crucial guideline feature (132). As there is a requirement for periodic revisions, an updated and comprehensive evaluation of recently published guidance documents was required (133). On the other hand, no studies were identified about the quality and reporting of SDM in BC guidelines, so no SDM assessment tool was developed before. We developed an instrument for evaluating SDM quality and reporting in guidance and analysed BC management guidance documents.

2.3. Clinic Impact of this Doctoral Thesis

Our study will draw attention to BC quality care and SDM as an important QI. We will analyse BC QIs, their measure tools and compliance standards of care in International quality documents (clinical pathways and integrated health care processes), paying special attention to QI related to SDM. We will study the compliance of a set of QI standards in a specific BC population.

Applying and evaluating QIs will allow us to analyze the limitations and specific strengths in a healthcare area as well as analyse what factors influence each indicator and suggest improvement strategies that could be studied a posteriori.

We will investigate the use, knowledge and attitude about SDM for BC practitioners. The clinician and patients´ demands will affect the management of time and processes so that a specific space will be reserved for an adequate implementation of the SDM.

Finally, we will analyse the guidance documents' weaknesses and strengths, which are the main instrument to increase SDM use and implementation in the future. Ideally, the reviews will carry out the clinical practice guidelines (CPG) and consensus (CSs) characteristics. They will be able to highlight any weakness so that future editions of them will solve the problems detected.

HYPOTHESIS

3. HIPOTHESIS

In this research project, we consider several hypotheses closely related to each other and our program to improve the quality of care in breast cancer.

1. The set of breast cancer (BC) quality indicators (QIs) and their compliance standards of care are well-reported in international clinical pathways and integrated health care processes.

2. Shared decision making (SDM) is a valuable QI collected in BC integrated health care processes and clinical pathways.

3. The monitoring of clinical and healthcare data and its periodic analysis is useful for evaluating the integrating breast cancer care process QIs as well as for identifying new indicators of interest and possible improvement actions.

4. SDM is used by healthcare professionals in their usual practice, but barriers may make it difficult to use in the Breast Cancer Care Process.

5. The quality and reporting of BC management CPGs and CSs are adequate.

6. SDM is adequately treated and reported in BC management CPGs and CSs.

OBJECTIVES

4. OBJECTIVES

4.1. Overall aims

To analyze the quality of healthcare through the study (theoretical and practical) of the quality indicators (QI) of the integrated breast cancer care processes and clinical pathways, the quality and reporting in BC guidance documents, and the inclusion of recommendations related to the use of shared decision making (SDM) by healthcare professionals in these guidance documents.

4.2. Specific aims

4.2.1. To conduct a review of current studies on shared decision making (SDM), exploring the main facilitators and barriers, as well as the strategies proposed by the different authors for its implementation.

4.2.2. To explore the international BC QIs, the measure tools, and their compliance standards of care.

4.2.3. To systematically study and compare the different clinical pathways and integrated breast cancer care processes existing in each area of Spain.

4.2.4. To evaluate the BC QIs for diagnosis and treatment in a community and identify areas for improvement.

4.2.5. To investigate the level of understanding, attitude, and degree of application of SDM in BC management clinical practice by health professionals.

4.2.6. To spread the results about the SDM knowledge, use and attitude in BC practitioners to a Spanish public.

4.2.7. To analyze the quality and reporting of clinical practice guidelines (CPGs) and consensus (CSs) on BC screening.

4.2.8. To study the quality and reporting of CPGs and CSs on the treatment of BC.

4.2.9. To carry out a systematic review on the quality and the reporting of SDM in BC screening CPGs and CSs.

4.2.10. To analyze the quality and reporting of SDM on BC treatment CPGs and CSs.

METHODS

5. METHODS

This section describes the global methodology used in this Doctoral Thesis. Each objective/article´s specific methodology will be reported in more detail in each of the manuscripts included as part of the dissertation.

For the first article, we conducted a review of the literature on SDM in general to make it known among health professionals dedicated to the management (screening, diagnosis and management) of BC. In the second and third manuscripts, we did two systematic reviews (SRs) about the quality indicators (QIs) that appeared in the different clinical pathways and integrated health care processes in an international framework and in every Spanish area. In both, 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. We looked for online databases (MEDLINE, Web of Science, EMBASE and Scopus) without retrieving any relevant document. 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. More additional initiatives were searched in the identified publications´ bibliographies to include other essential studies to our review. We included clinical pathways and integrated health care program documents with at least one section dedicated to BC. Three reviewers (MMC, CREL and AR), breast cancer specialists, analysed the potential eligibility of each of the titles from the citations independently. Four reviewers extracted data in a piloted proforma to assess the reporting of BC QIs from the integrated breast cancer assistance processes based on EUSOMA ´s (25). 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).

In the fourth manuscript, a prospective observational study was carried out on a series of consecutive BC cases diagnosed and treated during a period of 5 years in a health care area. The source of information was the medical history. A pseudonymised database was designed to analyse the indicators in Microsoft Excel Version 16.40, continuously updated by two specialists from the Service of General Surgery. The variables collected included demographic information, origin, the reason for entering into the integrated breast cancer care process, and cancer characteristics. Also, a series of variables related to the process were collected: date of diagnosis, the performance of a single act, presentation of tumours in commission, date of decision-making by tumour commission, date of admission to the surgical waiting list, date of intervention, type of adjuvant treatment, date of initiation of adjuvant treatment, type of surgery (conservative or mastectomy), the performance of oncoplastic, the performance of immediate reconstructive surgery, selective biopsy, axillary lymphadenectomy and its reason. Based on these variables, the integrated breast cancer care process´ compliance with the formulas specified in this quality document manual(4) was estimated for each record. A descriptive analysis was initially performed: frequency distribution for qualitative variables and central tendency and dispersion measures for quantitative variables. The sociodemographic, clinical and healthcare variables collected were stratified by age and year of diagnosis. The percentage of cases meeting each of the indicators and its 95% confidence interval was estimated, and it was stratified by year of diagnosis, age group, origin, histological grade and stage. The results were compared by groups using the Chi-square test. Statistical significance was set at $p < 0.05$. All analyses were carried out with the Stata 15.0 statistical package.

In the fifth and sixth works of this Doctoral Thesis, a cross-sectional observational study was proposed on a convenience sample. It was followed the “Checklist for Reporting the Results of Internet E-Surveys” (CHERRIES), which helps to describe the quality of research results from surveys of web environments (134, 135). The reference population were specialists in BC treatment, members of various Scientific Societies related to this process. A questionnaire was

designed for self-completion online, which included brief information on the study's scope and objectives and a warning for those members of several of these societies not to answer it in duplicate. No identifying data was collected. The variables of interest were measured on a polytomous Likert-type scale (136, 137) of 5 responses, 1 being “totally disagree” and 5 “totally agree”. The degree of knowledge about SDM (questions 1-5), opinion about SDM (questions 6-12), awareness and attitude about it (questions 13-15) and the degree of current and future application of the TDC (questions 16-23) were investigated. Finally, three opened questions were included, referring to the advantages, disadvantages and obstacles perceived for its application. The survey was sent to the participants´ emails through the participating Scientific Societies submitted, and it was administered through Google Forms (138) online survey platform. The answer was totally voluntary and without incentives. There was no obligation to answer all the questions, and backtracking was allowed to answer previous questions. There was no random assignment of questions and answers. No identifying data of the participants were stored. No minimum completion time was specified a priori. Partially completed surveys were accepted, provided that at least 10% of the questions were answered, and a manual review was performed to verify abnormal response patterns.

For analysing this data, the distribution of responses and the mean values of each question in the questionnaire were studied, stratifying by sex, age, professional seniority, speciality, type of hospital (public or private) and service (with or without Breast Unit), and the number of patients attended annually, both by the professional and by the hospital. Results were compared using a means comparison test for independent groups or one-way analysis of variance. Statistical significance was set at $p < 0.05$. All analyzes were carried out with the Stata 15.0 statistical package.

For the rest of the proposed objectives, systematic reviews have been applied after a prospective registry in Prospero in each case and following the PRISMA statement (139, 140). The CPGs and CSs were searched in various online databases such as MEDLINE, CDSR, Web of Science, EMBASE,

Scopus, on the websites of important professional societies and in specific databases. No language restrictions were applied. CPGs and CSs on screening or treatment produced by national or international professional organizations and societies or government agencies were included. Randomized controlled trials and observational studies, narrative reviews, scientific reports, discussion articles, conference and poster abstracts, outdated guides replaced by updates from the same organization, and guidance documents for patient education and information were therefore excluded. The eligibility of each of the citations' abstracts and titles was considered independently by two reviewers, both specialists in BC. Full-text versions of potentially relevant citations were obtained to confirm eligibility. A third reviewer helped to resolve disagreements by consensus or arbitration. Duplicate articles were identified and eliminated. When multiple versions were retrieved, the most up-to-date version of the guidelines was included. Data were extracted in duplicate and independently.

Two well-known validated tools were used in the works that analysed the quality and reporting of the guidance documents: AGREE II instrument and RIGHT statement (66-69). According to AGREE II quality was the "reliability that potential development biases had been appropriately addressed and recommendations are internally and externally valid" (66). Data were extracted for its 23 items according to predefined criteria divided into six domains: scope and purpose (items 1 to 3), stakeholder involvement (items 4 to 6), the rigour of development (items 7 to 14), clarity and presentation (items 15 to 17), applicability (items 18 to 21) and editorial independence (items 22 and 23). It was used a 7-point scale to score each item (anchored between 1 or strongly disagree, i.e. when there was no relevant information concerning the item, to 7 or strongly agree, i.e. when the quality of reporting was exceptional, and the criteria were fully met). The domain quality scores (0-100%) were calculated by summing up reviewers' individual scores and scaling as a percentage of the maximum possible score according to the formula provided in the AGREE II manual averaging the scores of the two reviewers (66). A discussion to reach consensus was done to reach consensus and avoid significant deviations in reviewer´. For reporting assessment,

it was used the RIGHT(68) statement's 35 items divided into 7 domains: basic information (items 1 to 4), background (items 5 to 9), evidence (items 10 to 12), recommendations (items 13 to 15), review and quality assurance (items 16 and 17), funding and declaration and management of interests (items 18 and 19), and other information (items 20 to 22). A numeric score of 1 (reported), 0.5 (partially reported), or 0 (unreported) was assigned to each item. Disagreements between two reviewers in the score were discussed, and unresolved matters were addressed by an arbitrator (MMD). Consistency between reviewers in data extraction was assessed using the intraclass correlation coefficient (ICC).

To study the quality and reporting of SDM in BC guidance documents, no quality assessment tool has been found, so a new instrument has been developed. Individual quality items were scattered across a number of tools for guidelines assessment. A long list of items was compiled and presented to a group of BC and SDM specialists in a consensus meeting. A 31-item checklist was settled for evaluation of SDM quality and reporting in guidelines. The greater the percentage of items complied with, the greater the quality for SDM in the CPG or CS assessed. The consensus meeting did not recommend constructing a formal score or a cut point for defining quality.

RESULTS

6. RESULTS

6.1. PLANNING

When presenting the results of this Doctoral Thesis and, consequently, ordering the ten works that have emerged from it, we have chosen to use an order based on the logical sequence with which they should appear and how the objectives have been formulated. However, as the reader could see, this sequence does not precisely coincide with the chronological order in which these works have been done and, consequently, published. Three of them have already been published in first quartile journals, and one has been published in the only breast journal existing in Spain to highlight and spread the importance of SDM in clinical practice. The rest of the works are under review in various indexed journals and have not been published yet. However, following the objectives set out in this work, we have decided to include them to comprehensively address this Doctoral Thesis's main aim: the study of SDM as a quality indicator in BC care.

6.2. Manuscript 1: Maes-Carballo M, Martín-Díaz M, Mignini L. La toma de decisiones compartida: una mirada hacia el futuro de la práctica médica de calidad en el cáncer de mama. Revista de Senología y Patología Mamaria, https://doi.org/10.1016/j.senol.2020.11.008

This article responds to the specific objective 1 of the Thesis. Its primary purpose was to review current studies on SDM, exploring the main facilitators and barriers, the strategies proposed by the different authors for its implementation and the future of SDM in health care and in BC. SDM is a concept universally supported and linked to the quality of care. It is still unknown by many health professionals, which implies that its actual application continues to be deficient. Obstacles to its implementation persist. Our work has reviewed the currently existing evidence on SDM, especially in BC, and our main purpose has been to spread this term among BC specialists.

Publication data:

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- Category: Oncology
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EDITORIAL

La toma de decisiones compartida: una mirada hacia el futuro de la práctica médica de calidad en el cáncer de mama

Shared decision-making: Looking towards the future of high-quality medical practice in breast cancer

El cáncer de mama (CM) es la neoplasia más frecuente y el primer motivo de muerte por cáncer en el sexo femenino. La morbimortalidad ha disminuido en los últimos años debido al diagnóstico temprano y a la aplicación de tratamientos multidisciplinares y personalizados, lo que conlleva sopesar y elegir en cada caso entre un amplio abanico de recursos y esquemas diagnóstico-terapéuticos. El plan estratégico ideal para una paciente será el que mejor satisfaga sus necesidades y expectativas, y su diseño debe basarse en un diagnóstico correcto, no solo de su enfermedad, sino también de las circunstancias, preferencias y valores de esa paciente[1]. Es aquí donde la toma de decisiones compartida (TDC), entendida como «un enfoque en el que el médico y el paciente comparten la mejor evidencia disponible y donde el paciente recibe apoyo para considerar opciones y tomar decisiones sobre el proceso de acuerdo a sus preferencias y valores»[2], adquiere vital importancia. La paciente diagnosticada de CM debe tomar decisiones complejas en un periodo de tiempo limitado y a menudo con evidencias incompletas, pero, además, en este último año, la COVID-19 ha impactado en nuestra sociedad y ha amenazado con desbordar nuestro sistema sanitario, dificultando especialmente la comunicación y la atención personalizada. Esto ha generado un incremento de decisiones difíciles en las que es imperativo involucrar a los pacientes, creando así un papel único para la TDC.

La TDC ha sido globalmente aceptada desde su aparición, ya que aumenta la eficiencia del proceso de atención de los pacientes[2], y actualmente su uso se está incrementando de forma exponencial en la práctica[3]. Adquiere especial relevancia cuando existen diversas opciones de tratamiento, asociadas a un desenlace probable muy similar, pero que pueden producir resultados muy diferentes según las preferencias y valores del paciente.

Se ha demostrado que aumenta la satisfacción del usuario, su percepción del riesgo y su adherencia al tratamiento[4], y reduce las demandas por mala praxis[5]. Además de ser una obligación legal[4], es una exigencia ética y una firme recomendación de las asociaciones profesionales[6,7]. En EE. UU., por ejemplo, ha sido adoptada como una prioridad a investigar por el Patient-Centered Outcomes Research Institute.

Los principales facilitadores reportados por parte de los profesionales de la salud para el uso de la TDC son la percepción de mejora de la calidad de la atención médica y de los resultados tras su puesta en práctica[8]. No obstante, en la actualidad presenta dificultades para su implementación[8], por lo que su uso es irregular e insuficiente. Su estudio mediante revisiones sistemáticas y metaanálisis es aún escaso, y esta falta de conocimiento es una barrera conocida para su implementación. Una revisión sistemática[9] recientemente realizada por nuestro grupo demostró que la TDC está pobremente tratada en las guías de práctica clínica y los consensos de tratamiento del CM, a pesar de que numerosos estudios demuestran sus ventajas. Por ejemplo, un estudio desarrollado por Hack et al. demostró en 205 mujeres diagnosticadas de CM que aquellas pacientes que habían participado activamente en la TDC durante el seguimiento de su enfermedad mejoraban sustancialmente su calidad de vida al final del proceso[3]. Entre las barreras que se han reportado para su correcto uso están la falta de formación de los facultativos y, especialmente, la falta de medios y recursos[8]. No existen pruebas de que, en comparación con la atención habitual, se requiera más tiempo para participar en la TDC, pero, dado que es uno de los principales problemas para su adecuada implementación, varios autores han recomendado que la TDC se reserve para decisiones susceptibles a las preferencias y valores del paciente[10], y otros han propuesto su uso cuando existe incertidumbre

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clínica o similitud en los resultados[11]. Por otra parte, la falta de formación de los profesionales puede hacer que se prejuzgue el deseo de los pacientes de participar activamente en la TDC[8]. Se ha demostrado que para favorecer la implementación de la misma, es necesario fomentar el uso de herramientas de ayuda en la toma de decisiones: «intervenciones que apoyan a los pacientes en la toma de decisiones, proporcionando información sobre las opciones y los beneficios/daños asociados, y ayudando a aclarar la congruencia entre las decisiones y los valores y preferencias personales»[12]. Algunos estudios demuestran que las explicaciones de riesgo y beneficio indicadas por los médicos son en muchos casos insuficientes, pero aumentar la disponibilidad y el uso rutinario de las herramientas de ayuda en la toma de decisiones ayuda a los pacientes a participar de manera más significativa en la TDC[12].

Por otra parte, numerosos autores han propuesto estrategias para la promoción y aplicación práctica de la TDC. Uno de los modelos planteados se basa en 3 pasos: informar de que hay diversas opciones disponibles; proporcionar información más detallada sobre las mismas, y, finalmente, explorar las preferencias del paciente y alentarlo a establecer sus propios objetivos[13]. Otra propuesta se basa en establecer unos objetivos acordes con las preferencias del paciente y traducirlos en planes de tratamiento reales[14]. Finalmente, algunas de las estrategias que se han planteado para incentivar su uso han sido asumir que la TDC es un indicador de calidad de una buena atención sanitaria[15], así como incentivar de alguna manera a los profesionales a utilizarla[16].

En suma, el objetivo de la TDC es respetar la autonomía de los pacientes sin detrimento de su beneficio, brindando una atención de calidad acorde con sus valores y preferencias. Ello implica el desarrollo de equipos multidisciplinares con elevado nivel científico-técnico, excelente coordinación, continuidad asistencial y comunicación con el paciente, y una revisión permanente de los resultados en el marco de un programa de mejora continua. A día de hoy, es probable que la mayoría de los pacientes finalmente no quieran o no sepan participar muy activamente en la toma de decisiones, pero esto en ningún caso nos exime del deber de desarrollar un sistema sanitario capaz de ofrecer esta posibilidad sin disminuir la calidad y la eficiencia. La implementación de la TDC en la atención del CM constituye un camino muy exigente, requiere formación, recursos y tiempo, pero, sobre todo, requiere un equipo particularmente capacitado, comprometido y orientado a la satisfacción del paciente. La práctica de la TDC en la atención del cáncer se ha propuesto como elemento crucial para conseguir el cambio de rumbo de un sistema en crisis hacia la excelencia y la sostenibilidad[2]. Efectivamente, la TDC es un camino muy exigente, pero cabe preguntarse: ¿existe otro camino?

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6.3. Manuscript 2: Maes-Carballo M, Gomez-Fandiño Y, Reinoso-Hermida A, Estrada-López C R, Martín-Díaz M, Khan K S, Bueno-Cavanillas A. Quality indicators for breast cancer care: a systematic review.

This manuscript responds to the precise objective 2 of the PhD work: to systematically review the different clinical pathways and integrate breast cancer care processes worldwide and collect and compare their quality indicators (QIs), the measurement tools and standards of care. Our systematic review has shown that there were no studies that compare QIs for BC care management suggested by different Professional Societies or Health Administrations. The vast majority of QIs identified were process QIs (over three-quarters; 58/77; 75.32%), and these were also found in more documents. They covered all the phases of BC care management from diagnosis (19/77; 24.68%), treatment (30/77; 38.96%), and staging, counselling, follow-up and rehabilitation (9/77; 11.69%). QIs description was heterogeneous, with not a single identical indicator appearing in all the documents analysed. QIs that appeared in more documents were "proportion of BC cases who preoperatively underwent breast and axilla radiology and physical examination" and "proportion of patients with invasive cancer who underwent image-guided axillary staging", both of them indicators related to the process. More than a quarter of the QIs of the process (58/77) and outcome (9/77) did not state a standard (21/67; 31.34%). We observed a minimum variability for "proportion of patients with BC who had a preoperative histologically or cytologically confirmed malignant diagnosis (B5 or C5)" standard; there was consensus in a quarter of the studied manuals. Despite indicating the time required between compliance processes with the indicator, most of the documents did not set a standard of accomplishment. Only one document recognized SDM importance indirectly, but any QIs about measuring SDM use was not found.

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Quality indicators for breast cancer care: a systematic review

--Manuscript Draft--

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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 o : CRD42021228867) relevant documents were identified, without language restrictions, through a systematic search of bibliographic databases (EMBASE, Scopus, Web of Science, MEDLINE) and the World Wide Web in February 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 77 QIs found from 16 selected documents (QI per document mean 15.19 with standard deviation 12.62 and mode 21). The Belgian (38 QIs) and European Society of Breast Cancer Specialists (34 QIs) documents were the ones that best reported the QIs. No QI appeared in all the 16 documents analysed. There were 58/77 QIs covering processes (75.32%), 10/77 structures (12.99%), and 9/77 outcomes (11.69%). There were 19/77 QIs for diagnosis (24.68%), 30/77 for treatment (38.96%), and 9/77 for staging, counselling, follow-up and rehabilitation (11.69%). Of 58 process QIs and 9 outcome QIs, 21/67 (31.34%) did not report a minimum standard of care. Shared decision making was not included as a QI in any document. Conclusion 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.
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Quality indicators for breast cancer care: a systematic review

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7. Funding

7.1. 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.

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

8. Data sharing statement

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

9. Declaration of interest statement:

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

- The quality of breast cancer care has become a preference for health systems.

- There was no established set of quality to harmonise BC quality management's evaluation. A consensus is needed.

- Most of the integrated breast cancer care processes or clinical pathways did not indicate any standard for compliance, a starting point to study how to improve quality.

- No quality indicators specifically related to shared decision making or Primary care were found in our study.

- There is a vast space for improvement, and future studies should pay attention to this issue.

Manuscript Click here to view linked References

Abstract

Objectives: We evaluated breast cancer (BC) care quality indicators (QIs) in clinical pathways and integrated health care processes.

Methods: Following protocol registration (Prospero nº: CRD42021228867) relevant documents were identified, without language restrictions, through a systematic search of bibliographic databases (EMBASE, Scopus, Web of Science, MEDLINE) and the World Wide Web in February 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 77 QIs found from 16 selected documents (QI per document mean 15.19 with standard deviation 12.62 and mode 21). The Belgian (38 QIs) and European Society of Breast Cancer Specialists (34 QIs) documents were the ones that best reported the QIs. No QI appeared in all the 16 documents analysed. There were 58/77 QIs covering processes (75.32%), 10/77 structures (12.99%), and 9/77 outcomes (11.69%). There were 19/77 QIs for diagnosis (24.68%), 30/77 for treatment (38.96%), and 9/77 for staging, counselling, follow-up and rehabilitation (11.69%). Of 58 process QIs and 9 outcome QIs, 21/67 (31.34%) did not report a minimum standard of care. Shared decision making was not included as a QI in any document.

Conclusion: 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.

Keywords: “breast cancer care”, “quality indicators”, “quality care”, “Health Care”.

1. Introduction:

Breast cancer (BC), the most common cancer in women with 2 million cases per year, is the prime reason for female cancer death [1-3]. Its survival rate varies depending on the country, with an 80% estimated 5-years survival in developed countries and below 40% in the developing world [4]. Its treatment is becoming more complex. The greater therapeutic complexity requires an improvement in care quality management. There have been various initiatives to recommend and implement quality indicators (QIs) for BC care [5-8]. Three types of QIs are considered essential for capturing care quality [9]. 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) [10 11].

Clinical pathways or integrated breast cancer assistance processes, i.e. “preventive, diagnostic, therapeutic, follow-up and care activities, aimed at the comprehensive management of people… with increased risk for breast cancer…” [12] have been deployed to manage and standardise care [13]. These include a series of QIs for continuous improvement via maintenance of sociodemographic, clinical and healthcare databases. The European Society of Breast Cancer Specialists (EUSOMA) working group indicates that “these 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” [14]. 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” [15] should be considered a key indicator in care quality management [16-18].

Our primary research has shown that there were no systematic reviews 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 [19]. Many studies have used their own QIs, so comparison between findings of different clinical audits is difficult [6 20-25]. 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 nº: CRD42021228867) and it was reported in line with PRISMA statement (Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols) [26 27].

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) without retrieving any relevant document. 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. More additional initiatives were searched in the identified publications´ bibliographies to include other essential studies to our review.

2.2. Study selection and data extraction

Initiatives encouraging quality measures (clinical pathways and integrated breast cancer assistance processes) in BC care produced by European professional institutions and societies or governmental agencies were included and compared to the EUSOMA working group position paper [14]. 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 [28].

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 third 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, 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.[14] A summary table of EUSOMA QIs in BC care and their characteristics (the definition for each indicator, the type of QI (mandatory or recommended), the minimum and

target standard of care (ST), and the level of evidence) [14] is shown in Appendix B. Other QIs extracted from the analysis of the different integrated breast cancer health care processes and clinical pathways documents studied were collected when no similar QI was found in the EUSOMA´s [14]. 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 (ST) of care. 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) [9] and according to the EUSOMA classification [14] 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 [29]. 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 1472 potentially relevant citations were found; 1397 were from online databases (EMBASE, Web of Science, MEDLINE and Scopus), and 75 were from additional sources (websites of relevant European institutions and the World Wide Web). The selection criteria were not met by 1312 documents, and 131 were found duplicated. Finally, only 16 documents

met the eligibility criterion for the full evaluation. The study selection process is shown in the flow diagram in Figure 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. Table 1 also shows 41 countries with no clinical pathway or integrated health care process found. Most of the quality documents analysed were from Western countries (75%, 12/16).

3.2. General quality indicators assessment

A set of 77 QIs were found from the 16 [30] selected documents [14 30-44]. Thirty-four belonged to the EUSOMA statement [14] (see Appendix B), and the remaining 43 were other indicators derived from the rest of the documents studied that did not appear in EUSOMA. ICC for reviewer agreement was 0.98. Tables 2 showed the different indicators selected and the quality document where they have appeared. The vast majority of the indicators were of the process (75.32%; 58/77), 10/77 (12.99%) were structural indicators, and finally, 9/77 (11.69%) were indicators of outcomes. These indicators cover all steps of BC care management from diagnosis (19/77; 24.68%), treatment (30/77; 38.96%), and staging, counselling, follow-up and rehabilitation (9/77; 11.69%). No QIs specifically related to Primary Care were found in our study.

3.3. Quality indicators comparison between countries

The BC QIs reporting was heterogeneous (Table 2). The mean number of QIs in each document was 15.19 (Standard deviation 12.62), with a mode of 21 QIs reported. The Belgian (38 QIs)[32], the EUSOMA (34 QIs)[14], and the Spanish (28 QIs)[43] documents were those that registered more indicators. Albania[31], Denmark[33], Romania[39], Slovenia[40], Sweden[41] did not present any QIs in their clinical pathways or integrated breast cancer assistance processes.

No indicator was present in all the 16 quality documents analyzed. 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” (62.5%; 10/16) with a ST range from 90-95%, and “proportion of patients with invasive cancer who underwent image-guided axillary staging” (56.25%; 9/16) (ST range 85-100%) [14 35 43]. Moreover, other four QIs, “proportion of patients with BC who had a preoperative histologically or cytologically confirmed malignant diagnosis (B5 or C5)” (ST range 85-90%) [14 35 43 44], “proportion of BC cases for which prognostic and predictive parameters have been recorded” (ST=95%) [14 35], “proportion of BC patients to be discussed pre and postoperatively by a multidisciplinary team (MDT)” (ST range 85-100%)[14 30 43] and “proportion of invasive cancer and clinically negative axilla cases who underwent sentinel lymph node biopsy (SLNB) only, excluding primary systemic treatment (PST) cases” with an appearance of 50% (8/16) (ST range 90-100%)[14 35].

We have compared variations in the same QI in the different documents analyzed in which it appeared. Table 3 and 4 synthetase these differences for the same indicator obtained in the analysis of all the documents. Regarding process and outcome QIs (Table 3 and 4), there were 31.34% of these that did not state a ST (27.59%, 16/58, QIs of the process and 55.6%, 5/9, 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)[14] and 90% (for Irish and Spanish)[35 43]. 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 a narrow range variability for the ST values recommended (Table 3). The QIs of structure, which are yes or no statements, did not establish any ST value.

Concerning QIs of results (Table 4), 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[14]. The percentage of axillar lymphadenectomies that resect more than ten nodes should reach 100%[43]. No specific percentage of BC cases with lymphedema or without recovery of shoulder mobility should be referred to rehabilitation[43]. Finally, the BC survival rate should be more than 50% in patients who have completed treatment[30].

3.4. Quality indicators about timing processes

Table 2 highlights in grey all the QIs related to timing in the BC care management. Most of the documents (58.62%, 17/29), despite indicating the time required between processes for compliance with the indicator, did not set a ST.

3.5. Shared decision-making as a quality indicator

The presence of SDM in the Clinical Pathways and integrated breast cancer assistance processes documents was analysed. Only the integrated breast cancer assistance process manuscript from the USA [30] recognized its importance indirectly (See Table 2). These integrated breast cancer assistance process documents insisted on developing a QI for measuring the quality of the doctor-patient relationship. No indicator of SDM use by the health professionals measure was proposed in any of the documents analysed.

4. Discussion

4.1. Main findings

Our systematic review has shown that there were no studies that compare QIs for BC care management suggested by different Professional Societies or Health Administrations. 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. QIs description was heterogeneous, with not a single identical indicator appearing in all the documents analysed. QIs that appeared in more documents were "proportion of BC cases who preoperatively underwent breast and axilla radiology and physical examination" and "proportion of patients with IC who underwent image-guided axillary staging", both of them indicators related to the process. More than a 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, most of the documents did not set a ST of accomplishment. Only one document recognized SDM importance indirectly, but any QIs about measuring SDM use was not found.

4.2. Strengths and weaknesses

To our knowledge, an evaluation of BC institutional QIs 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 [28]. Over 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). More additional initiatives were searched in the identified publications´ bibliographies to include other essential studies to our review. Therefore, some of these manuals may not have been found due to the difficult search. We have found an already published article [45] that have collected information on the existence of clinical pathways and integrated breast cancer assistance processes in 9 countries (Albania, Bosnia, Bulgaria, Croatia, Serbia, Montenegro, Macedonia, Romania and Slovenia). We did not find the original document of 7 of them (Bosnia, Bulgaria, Croatia, Serbia, Montenegro, Macedonia and Slovenia), although three expert reviewers have done an extensive search. This article has not been added to the study as it did not meet the selection criteria. It was not the type of document studied in our review.

Furthermore, comparing the EUSOMA position paper [14], and the clinical pathways or integrated breast cancer assistance processes studied was limited. EUSOMA´s [14] was only focused on BC care management in specialized 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 better coordinate 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 minimized 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

Our work provides the first current and comprehensive overview of QIs in BC care. We have carried out an extensive search of all the available indicators, highlighting relevant differences between the quality manuals analysed. The use of quality indicators could be extended to all BC care management stages, allowing monitoring processes' evolution over time and could be compared with other centres [6 20-25]. Although several QIs have been proposed to harmonise BC care quality management's evaluation, there is still no consensus between countries [19]. So, the comparison between studies is difficult, reducing the possibility of establishing conclusions that could be extrapolated to other health care areas or hospitals [6 20-25]. The development of QIs in general oncology is complex [46]. 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 related specifically 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 [47]. Further studies should be done to investigate the differences between the indicators according to the country's wealth.

There is still a long way before the achievement of consensus. Current efforts must be required to reach an agreement between institutions [48]. 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.

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 half of the QIs. As it has been remarked in EUSOMA, new researches should be developed, and new manuals would add them in the future [14]. On the other hand, SDM is considered a keystone achieving sustainable, high-quality cancer care, and it should be incorporated its measure in quality assessment.

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.

4.4. Conclusions

There is no established set of QIs to harmonise BC care quality assessment. So, the comparison between studies has been usually difficult, reducing the possibility of establishing conclusions that could be extrapolated. Furthermore, most of the integrated breast cancer assistance processes or clinical pathways did not indicate STs for compliance, a starting point to study how to improve quality. No QIs specifically related to SDM or Primary Care were found in our study.

A consensual set of BC care QIs is needed. Nowadays, there is a vast space for improvement, and future studies should pay attention to these issues.

5. Abbreviations

BC: breast cancer, BCT: breast conserving therapy, CNDO: Coordenação Nacional das Doenças Oncológicas, IKNL: Netherlands comprehensive cancer organisation, MDT: multidisciplinary team, MRI: magnetic resonance imaging, NANDA: North American Nursing Diagnosis Association, NS: not specified, 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, ST: standard.

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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 Centers Standards Manual.	American program	2018	American College of Surgeons	North America/ USA	Review	Yes	Not applicable	Yes
3	The National Cancer Control Program.	Albanian program	2011	National Cancer Control Committee	Europe/Albania	Review	No	No	No
4	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
5	Landsdækkende Klinisk Kvalitetsdatabase for Brystkræft.	Danish program	2005	Danish Breast Cancer Group	Europe/Denmark	Review	Yes	Not applicable	No
6	Optimizing the Quality of Breast Cancer Care at Certified German Breast Centers.	German program	2014	German Cancer Society	Europe/Germany	Review	Yes	Not applicable	Yes
7	Key Performance Indicators Report for Symptomatic Breast Disease Services.	Irish program	2010	NCCP	Europe/Ireland	Review	Yes	Not applicable	Yes
8	The National Cancer Plan for the Maltese Islands (2017-2021).	Maltese program	2007	Ministry of Health	Europe/Malta	Review	No	Yes	Yes
9	Breast Cancer Audit (NBCA) 2019.	Dutch program	2019	IKNL	Europe/Netherlands	Consensus	Yes	Not applicable	Yes
10	Recomendações nacionais para diagnóstico e tratamento do cancro da mama.	Portuguese program	2009	CNDO	Europe/Portugal	Review	Yes	Not applicable	Yes
11	Cancerul mamar.	Romanian program	2010	Ministry of Health	Europe/Romania	Review	Yes	Not applicable	Yes
12	European Guide for Quality National Cancer Control Programmes.	Slovenian program	2015	Ministry of Health	Europe/Slovenia	Review	No	Yes	Yes
13	Bröstcancer.	Swedish program	2020	RCSG	Europe/Sweden	Review	Yes	Not applicable	No
14	Breast cancer. Quality standard.	British program	2011	NICE	Europe/ UK	Review	Yes	Not applicable	Yes
15	Evaluación de la práctica asistencial oncológica. Estrategia en Cáncer del Sistema Nacional de Salud.	Spanish program v1	2013	Sistema Nacional de Salud	Spain	Consensus	No	Yes	Yes
16	Desarrollo de indicadores de proceso y resultado y evaluación de la práctica asistencial oncológica.	Spanish program v2	2006	Sistema Nacional de Salud	Spain	Consensus	No	Yes	Yes

	Countries with no Clinical pathways, Health Care Plans and Integrated Health Care Processes retrieved.		
1	Europe/Andorra	Europe/Liechtenstein	22
2	Europe/Armenia	Europe/Lithuania	23
3	Europe/Austria	Europe/Luxembourg	24
4	Europe/Azerbaijan	Europe/Moldova	25
5	Europe/Belarus	Europe/Moldova	26
6	Europe/Bosnia-Herzegovina	Europe/Monaco	27
7	Europe/Bulgary	Europe/Montenegro	28
8	Europe/Cryprus	Europe/North Macedonia	29
9	Europe/Croatia	Europe/Poland	30
10	Europe/Czechia	Europe/Russia	31
11	Europe/Estonia	Europe/San Marino	32
12	Europe/Finland	Europe/Serbia	33
13	Europe/France	Europe/Slovakia	34
14	Europe/Georgia	Europe/Slovenia	35
15	Europe/Greece	Europe/Switzerland	36
16	Europe/Hungary	Europe/Turkey	37
17	Europe/Iceland	Europe/Ukraine	38
18	Europe/Italy	Europe/Vaticano	39
19	Europe/Kazakhstan	North America/ Canada	40
20	Europe/Kosovo	North America/ Mexico	41
21	Europe/Latvia		

Click here to access/download;Table;210322 Table 2.docx

Table 2: Study of the quality indicators on diagnosis, staging, counselling, follow-up and rehabilitation in the integrated BC health care process and clinical pathways analysed.

			Year of publication	2017	2018	2011	2011	2019	2014	2010	2007	2019	2009	2010	2015	2020	2011	2013	2006	
			Institution	EUSOMA	American College of Surgeons	National Cancer Control Committee	Belgian Cancer Registry	Danish Breast Cancer Group	German Cancer Society	NCCP	Ministry of Health	IKNL	CNDO	Ministry of Health	Ministry of Health	RCSG	NICE	Sistema Nacional de Salud	Sistema Nacional de Salud	
		Type of quality indicator	Title	EUSOMA	American program	Albanian program	Belgium program	Danish program	German program	Irish program	Maltese program	Dutch program	Portuguese program	Romanian program	Slovenian program	Swedish program	British program	Spanish program v1	Spanish program v2	Number of appereance of each QI
1	DIAGNOSIS	STRUCTURAL	There is an Integrated Multidisciplinary Breast Cancer Care Process.															1		1
2		PROCESS	Proportion of patients who time elapsed from the Breast Pathology Unit's referral will not exceed X days.							1										1
3		PROCESS	Proportion of patients with suspected BC who have done radiological studies in a single act.						1	1	1									3
4		PROCESS	Proportion of BC cases who preoperatively underwent breast and axilla radiology and physical examination.	1	1		1		1	1	1		1				1	1	1	10
5		PROCESS	Proportion of patients with BC (different stages) who do/do not undergo baseline-staging tests.	1	1		1					1								4
6		PROCESS	Proportion of BC cases examined preoperatively by MRI (excluding PST´s patients).	1	1					1		1	1				1			6
7		PROCESS	Proportion of BC patients which time elapsed from the request to the mammography will not exceed X days or weeks.								1									1
8		PROCESS	Time elapsed from the beginning of the process to the confirmation of BC diagnosis is X days.				1			1	1	1								4
9		OUTCOME	IC rate.	1														1		2
10		OUTCOME	ISC rate.	1																1
11		PROCESS	Proportion of patients with BC who had a preoperative histologically or cytologically confirmed malignant diagnosis (B5 or C5).	1	1		1			1		1	1					1	1	8
12		PROCESS	Time elapsed from the biopsy to obtain the pathology report will be less than X days.						1	1										2
13		PROCESS	Proportion of BC cases for which prognostic and predictive parameters have been recorded.	1			1		1	1			1				1	1	1	8
14		PROCESS	Proportion of patients with IC who underwent image-guided axillary staging.	1	1		1		1	1		1	1					1	1	9
15		PROCESS	Proportion of benign to malignant diagnoses based on definitive surgical pathology report.	1			1		1	1							1		1	6
16		PROCESS	Proportion of patients with clinical history and /or staging documented.															1		1
17		PROCESS	Time elapse from surgery to final immunohistochemical diagnosis.				1												1	2
18		STRUCTURAL	Standardized content of the pathological anatomy report and BC staging.							1								1		2
19		STRUCTURAL	Standarised initial radiological study report.																	0
20		PROCESS	Proportion of reports with diagnosis, TNM stage, and therapeutic plan in relation to the total of reports issued.				1				1							1	1	4
21		STRUCTURAL	Existence of a MDT.															1		1
22		PROCESS	Proportion of BC patients to be discussed pre and postoperatively by a MDT.	1	1		1			1	1						1	1	1	8
23		STRUCTURAL	Proportion of professionals with participation in the MDT.		1												1			2
24		PROCESS	Time elapsed from MDT decision until the start of the treatment should be 15 days.	1							1									2
25		PROCESS	Proportion of BC cases referred for genetic counselling.	1							1	1					1			4
26	TREATMENT	PROCESS	Diagnostic-therapeutic interval less than 28 days.				1											1	1	3
27		PROCESS	Proportion of BC patients with time elapsed <15 days from the MDT decision to start a treatment.	1																1
28		PROCESS	Proportion of BC patients treated with PST undergoing MRI.	1																1
29		PROCESS	Proportion of BC patients with HER2-positive IC who received PST trastuzumab.	1			1													2
30		PROCESS	Proportion of patients with IBC or locally advanced non-resectable ER-carcinoma who received PST.	1			1						1						1	4
31		PROCESS	Proportion of BC patients who undergo surgery within less than 30 days after the MDT decision.							1								1		2
32		PROCESS	Proportion of BC patients who undergo surgery within less than 30 days after surgical waiting list inclusion.				1												1	2
33		PROCESS	Proportion of BC patients with BCT.		1								1					1		3
34		PROCESS	Proportion of BCT with specification of the resection margin.				1						1							2
35		PROCESS	Proportion of BC patients with IC not greater than 3 cm who underwent BCT as primary treatment.	1	1		1					1	1						1	6
36		PROCESS	Proportion of BC patients with ISC less than 2 cm who underwent BCT.	1			1		1				1						1	5
37		PROCESS	Proportion of BC patients (DCIS only) who received just one operation (excluding reconstruction).	1			1		1	1		1						1	1	7
38		OUTCOME	Proportion of BC patients receiving immediate reconstruction.	1	1					1		1	1					1	1	7
39		PROCESS	Proportion of BC patients with delayed reconstruction time less than 9 months.						1											1
40		STRUCTURAL	Existance of SLNB.										1					1		2
41		PROCESS	Proportion of IC and clinically negative axilla cases who underwent SLNB only (excluding PST cases).	1	1		1		1	1			1					1	1	8
42		PROCESS	Proportion of BC patients with IC who underwent SLNB with no more than 5 nodes excised.	1			1		1									1	1	5
43		PROCESS	Proportion of BC patients with lymphadenectomy.				1		1									1	1	4
44		PROCESS	Proportion of BC patients with up to 3 axillary lymph nodes (pN1) who received post-mastectomy RT (chest wall+non-resected axillary lymph nodes).	1					1											2
45		PROCESS	Proportion of patients with DCIS only who do not undergo axillary clearance	1									1						1	3
46		OUTCOME	Proportions of axillar lymphadenectomy of more than 10 nodes.				1		1				1					1		4
47		PROCESS	Proportion of BC reinterventions in BCT.						1											1
48		PROCESS	Proportion of BCT with specification of the resection margin.						1											1
49		PROCESS	Proportion of BC reinterventions before 6 weeks for margin widening after BCT.				1													1
50		PROCESS	Proportion of BC patients who start adjuvant treatment in less than X days/weeks from the surgical intervention date.							1								1		2
51		PROCESS	Proportion of BC hormone treatment.	1			1		1				1					1	1	6
52		PROCESS	Proportion of BC patients with negative ER (T > 1 cm or N+) IC who received adjuvant chemotherapy.	1	1		1		1											4
53		PROCESS	Proportion of HER2+ IC (T > 1 cm or N+) treated with chemotherapy who received adjuvant trastuzumab.	1	1		1		1		1		1						1	7
54		PROCESS	Proportion of patients with IC (M0) who received postoperative RT after BCT and SLNB.	1	1		1				1									4
55		PROCESS	Proportion of BC patients with less than X days/weeks of delay from the RT indication to its initiation.		1				1	1	1									4
56		PROCESS	Proportion of BC with axillary lymph nodes (>=pN2a) who received post-mastectomy RT to the chest wall and all (non-resected) regional lymph-nodes.	1	1		1		1		1		1							6
57		PROCESS	Proportion of BC patients participating in clinical trials.		1		1													2
58		STRUCTURAL	Number of BC Oncologist by year									1								1
59		STRUCTURAL	Number of BC surgeons by year									1								1
60		STRUCTURAL	Existance of a Plastic Surgeon in the BC Unit.									1								1
61	STAGING, COUNSELLING, FOLLOW-UP AND REHABILITATION	PROCESS	Proportion of BC patients who have direct access to a breast care nurse specialist.	1			1													2
62		PROCESS	Proportion of BC patients referred for nurse counselling after primary treatment.	1	1					1							1			4
63		PROCESS	Proportion of BC patients with immediate access to psychological support.				1											1		2
64		STRUCTURAL	Psychological support access to the patient´s relatives or caregivers.															1		1
65		STRUCTURAL	Existance of fisioterpy consultation.															1		1
66		OUTCOME	Proportion of BC cases with lymphedema or without recovery of shoulder mobility referred to rehabilitation.															1		1
67		PROCESS	Time elapsed from the rehabilitation prescription to beginning will be less than 30 days.				1													1
68		PROCESS	Proportion of BC patients with a single final report with all the oncological strategy of their process.				1													1
69		PROCESS	Proportion of BC patients with a coordinated follow-up.				1													1
70		PROCESS	Proportion of asymptomatic BC with annual mammographic screening and 6/12 months clinical evaluation in the first 5 years after primary surgery.	1			1			1			1							4
71		OUTCOME	Proportion of BC patients with follow-up (data on life status and recurrence rate) for at least 5 years.	1			1			1			1							4
72		PROCESS	Proportion of BC patients included in the palliative care assistance process.														1			1
73		OUTCOME	Recurrence rate				1				1		1							3
74		OUTCOME	Toxic deaths.														1			1
75		OUTCOME	BC Survival rate.		1		1				1						1			4
76		STRUCTURAL	The breast centre must have a data manager responsible for the breast centre data.	1							1							1	1	4
77		PROCESS	Proportion of BC patients participating in shared decision-making.		1															1
			Total of QIs registrated	34	20	0	38	0	21	21	15	12	21	0	0	0	11	28	22	

Click here to access/download;Table;210322 Table 3.docx

Table 3: Differences of the breast cancer (BC) quality indicators (QIs) related to the process between several integrated BC health care processes and clinical pathways. QIs in bold did not state any standard (NS). QIs in grey were related to the timing process in BC care management.

		Abbreviated title	EUSOMA	American College of Surgeons	National Cancer Control Committee	Belgian Cancer Registry	Danish Breast Cancer Group	German Cancer Society	NCCP	Ministry of Health	IKNL	CNDO	Ministry of Health	Ministry of Health	RCSG	NICE	Spanish program v1	Spanish program v2
		Year of publication	2017	2018	2011	2011	2019	2014	2010	2007	2019	2009	2010	2015	2020	2011	2009	2006
		Institution	EUSOMA	American program	Albanian program	Belgium program	Danish program	German program	Irish program	Maltese program	Dutch program	Portuguese program	Romanian program	Slovenian program	Swedish program	British program	Sistema Nacional de Salud	Sistema Nacional de Salud
1		Proportion of patients who time elapsed from the Breast Pathology Unit's referral will not exceed X days.							10 days (ST= 95%)									
2		Proportion of patients with suspected breast cancer (BC) who have done radiological studies in a single act.						NS	90%	NS								
3		Proportion of BC cases who preoperatively underwent breast and axilla radiology and physical examination.	90 %	NS		NS		NS	95%	NS		NS				NS	90 %	NS
4		Proportion of patients with BC (different stages) who do not undergo baseline-staging tests.	95 %	NS		NS					NS							
5		Proportion of BC cases examined preoperatively by MRI (magnetic resonance imaging) ,excluding primary systemic treatment´s (PST) patients.	10 %	NS					NS		NS	NS				NS		
6		Proportion of BC patients which time elapsed from the request to the mammography will not exceed X days or weeks.								6 weeks								
7		Time elapsed from the beginning of the process to the confirmation of BC diagnosis is X days or weeks.				NS			NS	NS	6 weeks							
8		Proportion of patients with BC who had a preoperative histologically or cytologically confirmed malignant diagnosis (B5 or C5).	85 %	NS		NS			90%		NS	NS					90%	90%
9		Time elapsed from the biopsy to obtain the pathology report will be less than X days.						NS	10 days (ST= 95%)									
10	DIAGNOSIS	Proportion of BC cases for which prognostic and predictive parameters have been recorded.	95 %			NS		NS	95%	NS		NS				NS	NS	NS
11		Proportion of patients with invasive cancer who underwent image-guided axillary staging.	85 %	NS		NS		NS	100%		NS	NS					85 %	NS
12		Proportion of benign to malignant diagnoses based on definitive surgical pathology report.	1:04			NS		NS	NS							NS		NS
13		Proportion of patients with clinical history and /or staging documented.															100 %	
14		**Time elapse from surgery to final immunohistochemical diagnosis.**				NS												NS
15		Proportion of reports with diagnosis, TNM stage, and therapeutic plan in relation to the total of reports issued.				NS				NS							100 %	NS
16		Proportion of BC patients to be discussed pre and postoperatively by a multidisciplinary team (MDT).	90 %	85%		NS			NS	NS						NS	100 %	NS
17		Proportion of professionals with participation in the MDT.		> 50%												NS		
18		Time elapsed from MDT decision until the start of the treatment should be 15 days.	90%							NS								
19		Proportion of BC cases referred for genetic counselling.	10 %							NS	NS					NS		
20		**Diagnostic-therapeutic interval less than 28 days.**				NS											90 %	NS
21		Proportion of BC patients with time elapsed <15 days from the MDT decision to start a treatment.	90 %															
22		Proportion of BC patients treated with PST undergoing MRI.	60 %															
23		Proportion of BC patients with HER2-positive invasive cancer who received PST trastuzumab.	90 %			NS												
24		Proportion of patients with inflamatory breast cancer or locally advanced non-resectable ER-carcinoma who received PST.	90 %			NS						NS						NS
25		Proportion of BC patients who undergo surgery within less than 30 days after the MDT decision.							90%								90 %	
26		**Proportion of BC patients who undergo surgery within less than 30 days after surgical waiting list inclusion.**				NS												NS
27		Proportion of BC patients with breast cancer tumorectomy (BCT).		>50%								NS					50-80%	
28		**Proportion of BCT with specification of the resection margin.**				NS						NS						
29		Proportion of BC patients with invasive cancer not greater than 3 cm who underwent BCT as primary treatment.	70 %	NS		NS					NS	NS						NS
30		Proportion of BC patients with in situ cancer less than 2 cm who underwent BCT.	80 %			NS		NS				NS						NS
31		Proportion of BC patients (ductal in situ carcinoma only) who received just one operation (excluding reconstruction).	80 %			NS		NS	NS		NS						NS	NS
32		**Proportion of BC patients with delayed reconstruction time less than 9 months.**						NS										
33		Proportion of invasive cancer and clinically negative axilla cases who underwent sentinel lymph node biopsy (SLNB) only (excluding PST cases).	90 %	NS		NS		NS	100%			NS					NS	NS
34		Proportion of BC patients with IC who underwent SLNB with no more than 5 nodes excised.	90 %			NS		NS									NS	NS
35	TREATMENT	**Proportion of BC patients with lymphadenectomy.**				NS		NS									NS	NS
36		Proportion of BC patients with up to 3 axillary lymph nodes (pN1) who received post-mastectomy (radiotherapy) RT to chest wall and non-resected axillary lymph nodes.	70 %					NS										
37		Proportion of patients with ductal in situ carcinoma only who do not undergo axillary clearance.	97 %									NS						NS
38		**Proportion of BC reinterventions in BCT.**						NS										
39		**Proportion of BCT with specification of the resection margin.**						NS										
40		**Proportion of BC reinterventions before 6 weeks for margin widening after BCT.**				NS												
41		Proportion of BC patients who start adjuvant treatment in less than X days/weeks from the surgical intervention date.							8 weeks (ST= 90%)								6 weeks (ST=90%)	
42		**The delay time from the decision to place the subcutaneous catheter until placement will be less than 7 days.**																NS
43		Percentage of BC hormone treatment.	85 %			NS		NS				NS					100 %	NS
44		Proportion of BC patients with negative ER (T > 1 cm or N+) IC who received adjuvant chemotherapy.	85 %	NS		NS		NS										
45		Proportion of HER2+ invasive carcinoma (T > 1 cm or N+) treated with chemotherapy who received adjuvant trastuzumab.	85 %	NS		NS		NS		NS		NS						NS
46		Proportion of patients with invasive carcinoma (M0) who received postoperative RT after BCT and SLNB.	90 %	NS		NS				NS								
47		Proportion of BC patients with less than X days/weeks of delay from the RT indication to its initiation.		NS				NS	4-12 weeks (ST= 90%)	NS								
48		Proportion of BC with axillary lymph nodes (>=pN2a) who received post-mastectomy RT to the chest wall and all (non-resected) regional lymph-nodes.	90 %	NS		NS		NS		NS		NS						
49		Proportion of BC patients participating in clinical trials.		2%		NS												
50		Proportion of BC patients who have direct access to a breast care nurse specialist.	95 %			NS												
51		Proportion of BC patients referred for nurse counselling after primary treatment.	85 %	NS					NS							NS		
52		**Proportion of BC patients with immediate access to psychological support.**				NS											NS	
53	STAGING, COUNSELLING, FOLLOW-UP AND REHABILITATION	**Time elapsed from the rehabilitation prescription to beginning will be less than 30 days.**				NS												
54		**Proportion of BC patients with a single final report with all the oncological strategy of their process.**				NS												
55		**Proportion of BC patients with a coordinated follow-up.**				NS												
56		Proportion of asymptomatic BC with routine annual mammographic screening and 6/12 months clinical evaluation in the first 5 years after primary surgery.	95 %			NS			NS			NS						
57		**Proportion of BC patients included in the palliative care assistance process.**														NS		
58		**Proportion of BC patients participating in shared decision-making.**		NS														

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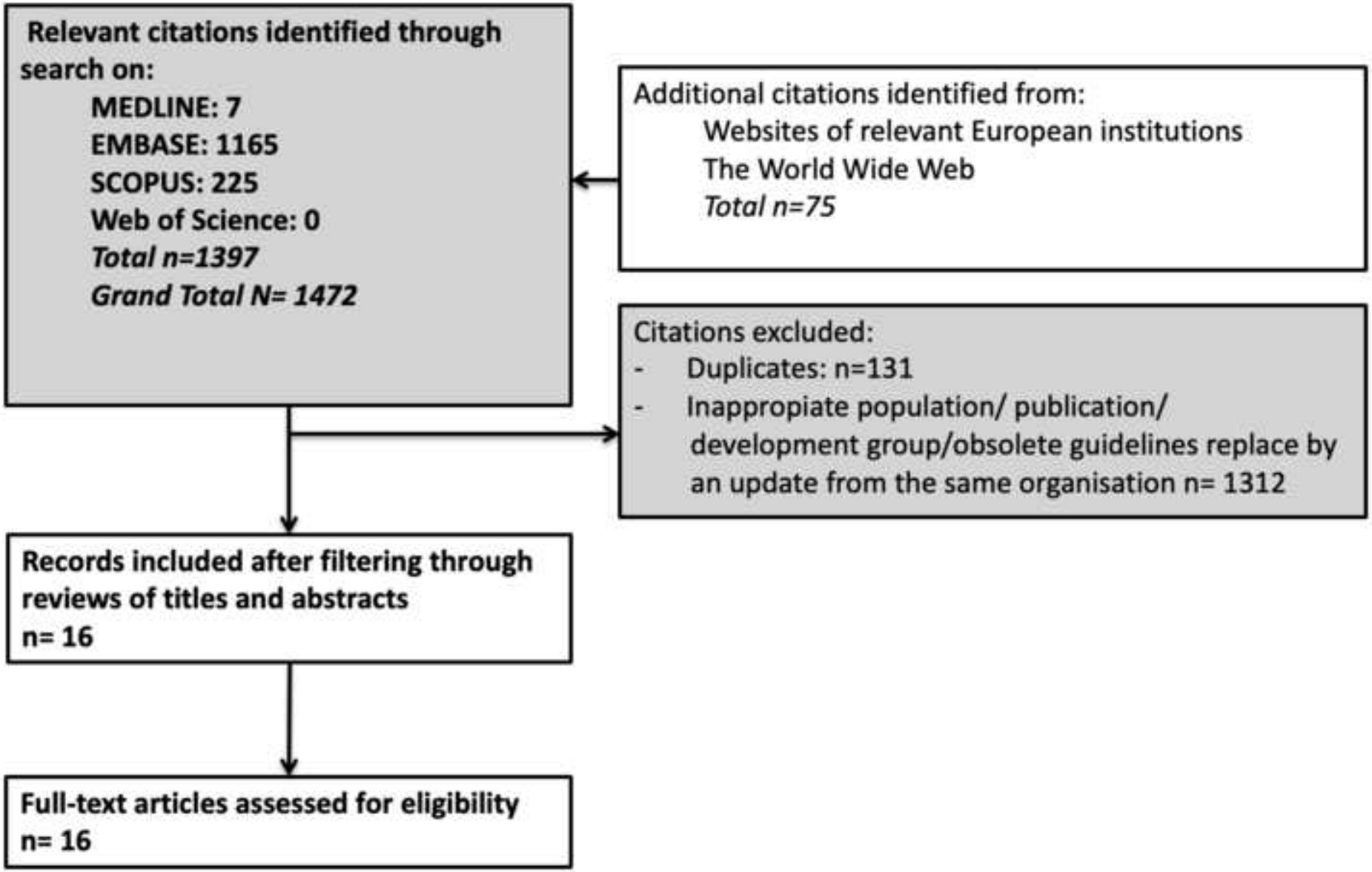
Table 4: Structural and outcome breast cancer (BC) quality indicators and differences between integrated BC health care processes and clinical pathways analysed. QIs in bold did specified no standard (NS).

		Year of publication	2017	2018	2011	2011	2019	2014	2010	2007	2019	2009	2010	2015	2020	2011	2013	2006
		Institution	EUSOMA	American College of Surgeons	National Cancer Control Committee	Belgian Cancer Registry	Danish Breast Cancer Group	German Cancer Society	NCCP	Ministry of Health	IKNL	CNDO	Ministry of Health	Ministry of Health	RCSG	NICE	Sistema Nacional de Salud	Sistema Nacional de Salud
	Type of quality indicator	Title	EUSOMA	American program	Albanian program	Belgium program	Danish program	German program	Irish program	Maltese program	Dutch program	Portuguese program	Romanian program	Slovenian program	Swedish program	British program	Spanish program v1	Spanish program v2
1	STRUCTURAL	There is an Integrated Multidisciplinary Breast Cancer Care Process.															1	
2	STRUCTURAL	Standardized content of the pathological anatomy report and BC staging.							1								1	
3	STRUCTURAL	Existence of a multidisciplinary team (MDT).															1	
4	STRUCTURAL	Existance of sentinel lymph node biopsy (SLNB).										1					1	
5	STRUCTURAL	Number of breast cancer (BC) Oncologist by year.									1							
6	STRUCTURAL	Number of BC surgeons by year.									1							
7	STRUCTURAL	Existance of a Plastic Surgeon in the BC Unit.									1							
8	STRUCTURAL	Psychological support access to the patient´s relatives or caregivers.															1	
9	STRUCTURAL	Existance of fisioterpy consultation.															1	
10	STRUCTURAL	The breast centre must have a data manager responsible for the breast centre data.	1							1							1	1
11	OUTCOME	**Invasive cancer rate.**	NS														NS	
12	OUTCOME	**In situ cancer rate.**	NS															
13	OUTCOME	Proportion of BC patients receiving immediate reconstruction.	40 %	NS					NS		NS	NS					NS	NS
14	OUTCOME	Proportions of axillar lymphadenectomy of more than 10 nodes.				NS		NS				NS					100 %	
15	OUTCOME	Proportion of BC cases with lymphedema or without recovery of shoulder mobility referred to rehabilitation.															NS	
16	OUTCOME	**Proportion of BC patients with follow-up (data on life status and recurrence rate) for at least 5 years.**	NS			NS			NS			NS						
17	OUTCOME	**Recurrence rate**				NS				NS		NS						
18	OUTCOME	**Toxic deaths.**														NS		
19	OUTCOME	BC Survival rate.		≥ 50%*		NS				NS						NS		
		Total (strutural QIs)	1	1	0	0	0	0	1	1	3	1	0	0	0	0	7	1
		Total (outcome Qis)	4	2	0	4	0	0	0	0	0	4	0	0	0	2	4	1

Figure 1: Flow diagram detailing the study selection.

Click here to access/download;Figure;210322 Figure 1.tif



Appendix A: Data sources and search strategy

AA.1 Sample search strategy for MEDLINE

We conducted a systematic search on February 19th, 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: 7 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

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

Indicator					Level of evidence	Mandatory or Recommended	Minimum standard
DIAGNOSIS	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%
	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 tumours, 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%

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

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 0: PRISMA 2009 Checklist

			Page
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

Appendix 0: PRISMA 2009 Checklist

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. doi:10.1371/journal.pmed1000097

6.4. Manuscript 3: Maes-Carballo M, Gomez-Fandiño Y, Estrada-López C R, Reinoso-Hermida A, Martín-Díaz M, Bueno-Cavanillas A., Khan K S. A systematic review of the breast cancer care quality indicators in Spain.

The aim 3 was covered by manuscript 3 of the Doctoral Thesis: to systematically analyse the different clinical pathways and integrating breast cancer care processes in the different areas of Spain and study and compare their quality indicators (QIs), the measurement tools and standards of care. No systematic reviews were found in our primary search comparing Spanish health care QIs collected in integrated health care processes or clinical pathways. In this review, only 11/85 (12.94%) of the indicators appeared exclusively in EUSOMA (25). Despite the high number of QIs, there should be underlined heterogeneity among them. No identical indicator arose in all the documents studied, and there was an enormous variability in their descriptions. A total of 56/74 (75.68%) were QIs dedicated to diagnosis and treatment, and the majority were process-related. The QIs more collected were "proportion of BC patients to be discussed pre and postoperatively by a multidisciplinary team decision (MDT)" and "proportion of invasive cancer and clinically negative axilla cases who underwent to sentinel lymph node biopsy (SLNB) only (excluding primary systemic treatment (PST) cases)". A third part (22/66; 33.33%) of the Spanish process and outcome QIs did not state a standard reference.

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Breast cancer care quality indicators in Spain: A systematic review.

Indicadores del cáncer de mama en España: revisión sistemática.

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Abstract

Objectives: Breast cancer (BC) care quality indicators (QIs) in Spain.

Methods: Prospective systematic search (Prospero no: CRD42021228867) through databases and the World Wide Web in February 2021. Duplicate data extraction with 98% reviewer agreement.

Results: Seventy-four QIs (QI per document mean 11, standard deviation 10.59) were found in 15 documents. The Catalonian 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.

Conclusion: Most of the documents established a BC QI standard for compliance, but the high variability hinders comparing 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 early detection and treatment of breast cancer (BC), and has enhanced overall survival (1). Nowadays, BC management care is more intricate and requires an increment in quality. An initiative to improve quality in BC is registered and studied quality indicators (QIs) (2). The EUSOMA (European Society of Breast Cancer Specialists) working group states that "these 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 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 outcomes (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 believes"(9) have gained importance (10) (11-13). 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's evaluation, but no agreement has been reached (15). In Spain, each of the Autonomous Communities has its own document for BC care quality (clinical pathways or integrated breast cancer assistance Processes). This variability makes comparison of results across populations or hospitals difficult (3, 16-21). Our literature search found no reviews about BC management QIs in health administrations. We appraised the appearance of QIs and their standards systematically, paying special attention to the particular populations to which they are directed and comparing them with those suggested by EUSOMA.

2. Methods

We identified studies through a systematic review of literature following prospective registration (Prospero nº: CRD42021228867) and reported according to PRISMA statement (Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols) (22, 23).

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", "quality care" were combined with other word alternatives to February 2021. The search strategy appears in Appendix 1. Clinical pathways and integrated health care processes are usually not promulgated in medical journals or indexed. A comprehensive manual search of grey literature has been done 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 BC integrated breast cancer care processes and clinical pathways provided by Spanish national institutions. 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 position paper (2) as a reference to compare QIs. Data were

extracted from the selected BC QIs 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 the 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 quality assessment instrument was available for this research topic. We developed a quality scoring system that captured all the QIs and specified the document. Disparities between 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 to Donabedian's framework type (structural, process and outcome indicators) (6).

2.4. Analysis

The interrater agreement (ICC) of the data extraction was calculated to assess reviewers' agreement, and ICC > 0.90 was considered excellent (24). A mediator (MMC) assisted in reaching a consensus and would decide if disagreements. We performed a descriptive statistical study to examining and classifying 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 were evaluated for full-text review (2, 25-38). 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 QIs 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 4 Autonomous Communities from Spain without quality care document (Balearic and Canary Islands, Cantabria, and Castile and La Mancha).

3.2. General quality indicators evaluation

There were collected 85 QIs from the quality care documents analysed. The EUSOMA position paper (2) registered 34/85 QIs (40%). The other 51/85 (60%) QIs that not appeared in EUSOMA´s, were added after a comprehensive analysis of the Spanish documents. Only 11/85 (12.94%) QIs appeared only in the EUSOMA´s. Table 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 the diagnosis (37.84%), the same number (28/74) related to treatment (37.84%), and 18/74 (24.32%) QIs for 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, two 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%). Interrater agreement was 0.98.

3.3. Quality indicators comparison between Spanish areas and Europe

The BC QIs reporting was varied (Table 2). The QIs 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 the EUSOMA´s (2) with 34 QIs, the Catalonian(30) with 30 QIs, and the Government of Spain´s one (25) with 28 QIs. Asturias(28), Extremadura(31), Madrid(34), Basque Country(37) and Valencia(38) did not register any QI.

No indicator appeared in all the 16 documents studied. Of the 51 indicators that only appeared 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 to sentinel lymph node biopsy (SLNB) only (excluding primary systemic treatment or PST cases)" were the two QIs best reported, appearing in appeared in up to 6/15 different documents (25-27, 30, 32, 35).

The variability of the same QI among the diverse Spanish papers analysed was collected in Table 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 (Table 3); the structure indicators do not present standards.

Concerning the diagnosis, "proportion of BC cases who preoperatively underwent breast and axilla radiology and physical examination" appeared in three documents (25, 30, 33) that agree in a standard of 90%. "Proportion of BC cases for which prognostic and predictive parameters have been recorded" should be more than 100% (30), comparing to EUSOMA´s (2) recommendation of 95%. "Proportion of patients with Invasive cancer who underwent image-guided axillary staging" should be in all the cases more than 85% (2, 25, 30, 35) while "proportion of patients with clinical history and /or staging documented" might be 100% (25, 30, 35). "Proportion of BC patients to be discussed pre and postoperatively by a MDT" varied from 90% recommended by EUSOMA(2) and Andalusia(26) to 100% supported by the Spanish National document(25), Aragon(27), Catalonia(30), Galicia(32) and Murcia(35).

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 (25, 26, 30, 35) stated a standard of 50-80% (36). “Percentage of BC hormone treatment” standard was always 100% in the Spanish documents (25, 30, 35) while EUSOMA was 85%. “All the patients with invasive cancer (M0) who received postoperative radiotherapy after breast-conserving surgery and SLNB” might be 100% (32) contrasting with only 90% of the EUSOMA (2).

Analysing outcome QIs, “proportion of BC patients receiving immediate reconstruction” standard was more than 50% in Andalusia(26) versus 40% by EUSOMA (2). Finally, "proportion of BC cases with lymphedema or without recovery of shoulder mobility referred to rehabilitation” should be 80% in Navarra (36) versus 100% in Catalonia (30).

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 Castille and Leon (29) and Navarra (36) admitted its importance (See Table 2). Navarra highlighted the importance of involving at least 15% of the patients in the BC management care decision. No other QIs about SDM use or measures were found.

3.5. Quality indicators about timing processes

Table 3 referred to all the indicators about timing in grey followed with the standard settle by the different quality care documents. Some of them were noteworthy in the following text. The QIs not mentioned were analysed in Table 3. There were 18 QIs about the timing process, and only one (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 (27) or 15 days (32) depending on the quality care document

with a standard that varied from 85 to 100%. “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 (27, 32). “Time elapsed from the biopsy to obtain the pathology report will be less than 5 (32), 7 (30) or 10 (27) days” and the “BC diagnosis should be referral to MDT in less than 30 days” (26, 30, 32) in both cases with a standard of 100%.

Regarding treatment, the “diagnostic-therapeutic interval must be less than 28 days” in more than 80 (30) to 90% (25, 35) of the BC patients. “Proportion of BC patients who undergo surgery within less than 30 days after the MDT decision” QI, although it did not appear in EUSOMA, has reached the highest consensus with a five documents agreement standard of 90% (25-27, 30, 35). Finally, "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(25, 26, 30, 35) standard was 90% in 6 weeks, but Aragon (27) 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 in integrated health care processes or clinical pathways. Only one-tenth of the indicators appeared exclusively in EUSOMA (2), including only four out of ten 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 more collected 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 to 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 beforehand. We undertook a comprehensive systematic review with many expert reviewers studying an important number of integrated BC assistance processes documents 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 between reviewers appeared. The ICC was higher than 98%, denoting an excellent reviewer agreement.

A possible limitation was confronting 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 like BC in the same country. Our findings emphasised the importance and urgency of the need for agreement about this issue. A strong point of this systematic review is that our team included researchers competent in both 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 done to find administrations and official institutions engaged in the 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 have 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 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 remarks relevant discrepancies between the integrated health care processes and clinical pathways studied. 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 the results with other centres so stronger conclusions could be obtained (3).

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, 39). Hence, the 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 (40). Quality is a wide concept that needs a range 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 should be 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 between 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 (27). Evidence indicates that the ideal time to start treatment is 4-8 weeks permitting the recovery from surgery but not giving a longer delay associated with increasing mortality (41). QIs should be based on this evidence.

Further research and consensus regarding the best BC QIs and standards for improving quality is needed and deserves immediate consideration.

4.4. Conclusions

There is no consensus concerning BC care QIs and standards in Spain, and QIs focus on primary care, patient satisfaction and SDM are deficient. Although a majority of the QIs established a standard, they were very varied. These differences made comparisons between different health

care providers arduous, decreasing the chance of making reasonable comprisons. There is an urgent need for establishing an agreed set of BC care QIs.

5. 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 Review and Meta-Analysis Protocols, PST: primary systemic treatment, QIs: quality indicators, RT: radiotherapy, SDM: shared decision-making, SLNB: sentinel lymph-node biopsy.

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7. Funding

7.1. Contributors

Each author certifies that he/she has made a direct and substantial contribution to the conception and design of the review, development of the search strategy, the establishment of the inclusion and exclusion criteria, data extraction, analysis, and interpretation. 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.

7.2. Financial support and sponsorship

None.

8. Data sharing statement

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

9. Conflicts of interest

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

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Table 1: Characteristics of the Clinical Pathways and Spanish Integrated BC Health Care Processes.

	Title	Abreviated 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 oncologico en Castilla y León.	Castille 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

	Countries with no clinical pathways and integrated health care processes retrieved.
1	Europa/ Spain/ Balearic islands
2	Europa/ Spain/ Canary Islands
4	Europa/ Spain/ Castile and La Mancha

Table 2: Appereance 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.*

			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 (QIs)	Title	EUSOMA	Spanish program	Andalusia	Aragon	Asturias	Castille and Leon	Catalonia	Extremadura	Galicia	Rioja	Madrid	Murcia	Navarra	Basque country	Valencia	
1	DIAGNOSIS	STRUCTURAL	There is an Integrated Multidisciplinary Breast Cancer Care Process.		1					1					1				3
2		PROCESS	Proportion of patients who time elapsed from the Breast Pathology Unit's referral will not exceed X days.				1					1							2
3		PROCESS	Proportion of patients from breast cancer (BC) screening.						1				1						2
4		PROCESS	Proportion of patients with suspected BC who have done radiological studies in a single act.			1													1
5		PROCESS	Proportion of BC cases who preoperatively underwent breast and axilla radiology and physical examination.	1	1					1			1						4
6		PROCESS	**Proportion of patients with BC (different stages) who do/do not undergo baseline-staging tests.**	1															1
7		PROCESS	**Proportion of BC cases examined preoperatively by magnetic resonance imaging (MRI), excluding primary systemic treatment (PST) patients.**	1															1
8		PROCESS	Proportion of BC patients which time elapsed from the request to the mammography will not exceed X days or weeks.				1												1
9		PROCESS	Time elapsed from the beginning of the process to the confirmation of BC diagnosis is X days.				1			1							1		3
10		OUTCOME	BC detection rate.										1						1
11		OUTCOME	Invasive cancer rate.	1	1					1						1			4
12		OUTCOME	In situ cancer rate.	1						1						1			3
13		PROCESS	Proportion of patients with BC who had a preoperative histologically or cytologically confirmed malignant diagnosis (B5 or C5).	1	1					1									3
14		PROCESS	Time elapsed from the biopsy to obtain the pathology report will be less than X days.				1			1		1							3
15		PROCESS	Proportion of BC cases for which prognostic and predictive parameters have been recorded.	1	1					1									3
16		PROCESS	Proportion of patients with invasive cancer who underwent image-guided axillary staging.	1	1					1					1				4
17		PROCESS	Proportion of benign to malignant diagnoses based on definitive surgical pathology report.	1															1
18		PROCESS	Proportion of patients with clinical history and /or staging documented.		1					1					1				3
19		PROCESS	Time elapse from surgery to final immunohistochemical diagnosis.							1									1
20		STRUCTURAL	Standardized content of the pathological anatomy report and BC staging.		1					1					1				3
21		STRUCTURAL	Standarised initial radiological study report.							1									1
22		PROCESS	Percentage of reports with diagnosis, TNM stage, and therapeutic plan in relation to the total of reports issued.		1					1			1		1				4
23		STRUCTURAL	Existence of a multidisciplinar (MDT).		1								1		1				3
24		PROCESS	Proportion of BC patients to be discussed pre and postoperatively by a MDT.	1	1	1	1			1		1			1				7
25		STRUCTURAL	Proportion of professionals with participation in the MDT.						1										1
26		PROCESS	Proportion of BC diagnosis with a time elapsed from referral to decision-making by MDT less than 30 days.			1				1		1							3
27		PROCESS	Proportion of BC cases with less than 7 days from diagnosis's pathological confirmation until MDT evaluation.				1												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.	1									1						2
30		PROCESS	Proportion of BRCA genetic determinations performed.										1						1
31	TREATMENT	PROCESS	Diagnostic-therapeutic interval less than 28 days.		1					1					1				3
32		PROCESS	**Proportion of BC patients with time elapsed <15 days from the MDT decision to start a treatment.**	1															1
33		PROCESS	**Proportion of BC patients treated with PST undergoing MRI.**	1															1
34		PROCESS	**Proportion of BC patients with HER2-positive IC who received PST trastuzumab.**	1															1
35		PROCESS	Proportion of patients with inflamatory breast cancer or locally advanced non-resectable ER-carcinoma who received PST.	1															1
36		PROCESS	Time elapsed between PST and surgical treatment.							1									1
37		PROCESS	Proportion of BC patients who undergo surgery within less than 30 days after the MDT decision.		1	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													1
39		PROCESS	Proportion of BC cases referred from the Breast Unit to the Pre-anesthesia consultation in less than 7-10 days.				1												1
40		PROCESS	Proportion of BC patients with breast conservative treatment (BCT).		1	1				1					1	1			5
41		PROCESS	Proportion of BC patients with invasive cancer not greater than 3 cm who underwent BCT as primary treatment.	1															1
42		PROCESS	Proportion of BC patients with in situ cancer less than 2 cm who underwent BCT.	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													1
45		OUTCOME	Proportion of BC patients whose reconstruction (immediate or delayed) is indicated that get a reconstruction.				1												1
46		OUTCOME	Proportion of BC patients receiving immediate reconstruction.	1	1	1													3
47		PROCESS	Proportion of BC patients with delayed reconstruction time less than 9 months.				1												1
48		STRUCTURAL	Existance of sentinel lymph node biopsy (SLNB).		1					1					1				3
49		PROCESS	Proportion of invasive cancer and clinically negative axilla cases who underwent SLNB only (excluding PST cases).	1	1	1	1			1		1			1				7
50		PROCESS	Proportion of BC patients with invasive cancer who underwent SLNB with no more than 5 nodes excised.	1	1														2
51		PROCESS	Proportion of BC patients with lymphadenectomy.		1					1					1				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															1
53		PROCESS	Proportion of patients with ductal in situ carcinoma only who do not undergo axillary clearance	1															1
54		OUTCOME	Proportions of axillar lymphadenectomy of more than 10 nodes.		1					1					1				3
55		PROCESS	Proportion of BC reinterventions in BCT.							1		1							2
56		PROCESS	Proportion of BC reinterventions before 6 weeks for margin widening after BCT.									1							1
57		PROCESS	Proportion of BC patients who start adjuvant treatment in less than X days/weeks from the surgical intervention date.		1	1	1			1					1				5
58		PROCESS	The delay time from the decision to place the subcutaneous catheter until placement will be less than 7 days.				1												1
59		PROCESS	Percentage of BC hormone treatment.	1	1					1			1		1				5
60		PROCESS	**Proportion of BC patients with negative ER (T > 1 cm or N+) invasive cancer who received adjuvant chemotherapy.**	1															1
61		PROCESS	Proportion of HER2+ invasive cancer (T > 1 cm or N+) treated with chemotherapy who received adjuvant trastuzumab.	1															1
62		PROCESS	Proportion of patients with invasive cancer (M0) who received postoperative RT after BCT and SLNB.	1								1							2
63		PROCESS	Proportion of BC patients with less than X days/weeks of delay from the RT indication to its initiation.				1												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															1
65	STAGING, COUNSELLING, FOLLOW-UP AND REHABILITATION	PROCESS	Proportion of BC patients who have direct access to a breast care nurse specialist.	1								1							2
66		PROCESS	**Proportion of BC patients referred for nurse counselling after primary treatment.**	1															1
67		PROCESS	Proportion of BC hospitalized patients with NANDA terminology coded care plan in the discharge report.			1													1
68		PROCESS	Proportion of BC patients with immediate access to psychological support.		1		1						1		1				4
69		STRUCTURAL	Psychological support access to the patient´s relatives or caregivers.		1		1												2
70		STRUCTURAL	Existance of fisioterpy consultation.		1										1				2
71		OUTCOME	Proportion of BC cases with lymphedema or without recovery of shoulder mobility referred to rehabilitation.		1					1						1			3
72		PROCESS	Time elapsed from the rehabilitation prescription to beginning will be less than 30 days.				1												1
73		PROCESS	Proportion of BC patients with a single final report with all the oncological strategy of their process.				1			1									2
74		PROCESS	Proportion of BC patients with a coordinated follow-up.				1												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															1
76		OUTCOME	**Proportion of BC patients with follow-up (data on life status and recurrence rate) for at least 5 years.**	1															1
77		STRUCTURAL	Existance of Palliatiave consultation.													1			1
78		PROCESS	Proportion of BC patients included in the palliative care assistance process.						1										1
79		OUTCOME	BC mortality rate in Palliative Care Unit.										1						1
80		OUTCOME	BC Mortality rate.										1						1
81		OUTCOME	Toxic deaths.			1													1
82		OUTCOME	BC Survival rate.										1						1
83		STRUCTURAL	The breast centre must have a data manager responsible for the breast centre data.	1	1		1			1									4
84		OUTCOME	BC patient satisfaction.										1			1			2
85		PROCESS	Proportion of BC patients participating in shared decision-making.						1							1			2
			Total of QIs registrated	34	28	12	20	0	4	30	0	10	13	0	18	8	0	0	

Table 3: Comparison of the standards of the breast cancer care quality indicators related to the process between the Spanish integrated breast cancer health care processes and clinical pathways analysed. *Abbreviation NS in grey means "standard not specified".*

		Abbreviated title	EUSOMA	Spanish program	Andalusia	Aragon	Asturias	Castille and Leon	Catalonia	Extremadura	Galicia	Rioja	Madrid	Murcia	Navarra	Basquecountry	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	Xuntade Galicia	Gobierno de La Rioja	Comunidad de Madrid	Región de Murcia	Gobierno de Navarra	Gobierno Vasco	Generalitat de Valenciana
1	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%)						
2		**Proportion of patients from breast cancer (BC) screening.**						NS				NS					
3		Proportion of patients with suspected BC who have done radiological studies in a single act.			90 %												
4		Proportion of BC cases who preoperatively underwent breast and axilla radiology and physical examination.	90 %	90 %					90 %			90 %					
5		Proportion of BC patients which time elapsed from the request to the mammography will not exceed X days or weeks.				4 days (ST= 85%)											
6		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%)		
7		Proportion of patients with BC who had a preoperative histologically or cytologically confirmed malignant diagnosis (B5 or C5).	85 %	90%					100 %								
8		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%)						
9		Proportion of BC cases for which prognostic and predictive parameters have been recorded.	95 %	NS					100 %								
10		Proportion of patients with invasive cancer who underwent image-guided axillary staging.	85 %	85 %					85 %					85 %			
11		Proportion of benign to malignant diagnoses based on definitive surgical pathology report.	1:04														
12		Proportion of patients with clinical history and /or staging documented.		100 %					100 %					100 %			
13		**Time elapse from surgery to final immunohistochemical diagnosis.**							NS								
14		Percentage of reports with diagnosis, TNM stage, and therapeutic plan in relation to the total of reports issued.		100 %					NS			NS		100 %			
15		Proportion of BC patients to be discussed pre and postoperatively by a multidisciplinary (MDT).	90 %	100 %	90 %	100 %			100 %		100 %			100 %			
16		**Proportion of professionals with participation in the MDT.**						NS									
17		Proportion of BC diagnosis with a time elapsed from referral to decision-making by MDT less than 30 days.			100 %				100 %		100 %						
18		Proportion of BC cases with less than 7 days from diagnosis's pathological confirmation until MDT evaluation.				100 %											
19		Time elapsed from MDT decision until the start of the treatment should be 15 days.	90%								90%						
20		**Proportion of BC cases referred for genetic counselling.**	10 %									NS					
21		**Proportion of BRCA genetic determinations performed.**										NS					
22	TREATMENT	Diagnostic-therapeutic interval less than 28 days.		90 %					80 %					90 %			
23		Proportion of patients with inflamatory BC or locally advanced non-resectable ER-carcinoma who received primary systemic treatment (PST).	90 %														
24		Time elapsed between PST and surgical treatment.							90 %								
25		Proportion of BC patients who undergo surgery within less than 30 days after the MDT decision.		90 %	90 %	90 %			90 %					90 %			
26		Proportion of BC patients who undergo surgery within less than 30 days after surgical waiting list inclusion.			100 %												
27		Proportion of BC cases referred from the Breast Unit to the Pre-anesthesia consultation in less than 7-10 days.				85 %											
28		Proportion of BC patients with BCT.		50-80%	50-80%				50-80%					50-80%	NS		
29		Proportion of BC patients with invasive cancer not greater than 3 cm who underwent BCT as primary treatment.	70 %														
30		Proportion of BC patients with in situ carcinoma less than 2 cm who underwent BCT.	80 %														
31		Proportion of BC patients (DCIS only) who received just one operation (excluding reconstruction).	80 %	NS													
32		Proportion of BC patients with a surgical safety check-list.			100 %												
33		Proportion of BC patients with delayed reconstruction time less than 9 months.				85 %											
34		Proportion of IC and clinically negative axilla cases who underwent SLNB only (excluding PST cases).	90 %	NS	NS	NS			NS		NS			NS			
35		Proportion of BC patients with invasive cancer who underwent SLNB with no more than 5 nodes excised.	90 %	NS													
36		**Proportion of BC patients with lymphadenectomy.**		NS					NS					NS			
37		Proportion of patients with ductal in situ carcinoma only who do not undergo axillary clearance	97 %														
38		**Proportion of BC reinterventions in breast conserving therapy (BCT).**							NS		NS						
39		Proportion of BC reinterventions before 6 weeks for margin widening after BCT.									< 15%						
40		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%)			
41		The delay time from the decision to place the subcutaneous catheter until placement will be less than 7 days.				85 %											
42		Percentage of BC hormone treatment.	85 %	100 %					100 %			NS		100 %			
43		Proportion of HER2+ invasive cancer (T > 1 cm or N+) treated with chemotherapy who received adjuvant trastuzumab.	85 %														
44		Proportion of patients with invasive cancer (M0) who received postoperative radiotherapy (RT) after BCT and sentinel lymph node bipsy (SLNB).	90 %								100 %						
45		Proportion of BC patients with less than X days/weeks of delay from the RT indication to its initiation.				15 days (ST= 85%)											
46	STAGING, COUNSELLING, FOLLOW-UP AND REHABILITATION	Proportion of BC patients who have direct access to a breast care nurse specialist.	95 %								100 %						
47		Proportion of BC hospitalized patients with NANDA terminology coded care plan in the discharge report.			100 %												
48		**Proportion of BC patients with immediate access to psychological support.**		NS		NS						NS		NS			
49		Time elapsed from the rehabilitation prescription to beginning will be less than 30 days.				85 %											
50		**Proportion of BC patients with a single final report with all the oncological strategy of their process.**				NS			NS								
51		**Proportion of BC patients with a coordinated follow-up.**				NS											
52		**Proportion of BC patients included in the palliative care assistance process.**						NS									
53		**Proportion of BC patients participating in shared decision-making.**						NS							>15%		

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

		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	Castille 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	Standarised initial radiological study report.							1								
4	STRUCTURAL	Existence of a multidisciplinary team (MDT).		1								1		1			
5	STRUCTURAL	Existance of sentinel lymph node biopsy (SLNB).		1					1					1			
6	STRUCTURAL	Psychological support access to the patient´s relatives or caregivers.		1		1											
7	STRUCTURAL	Existance of fisioterpy consultation.		1										1			
8	STRUCTURAL	Existance of Palliatiave 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	**BC mortality rate in Palliative Care Unit.**										NS					
18	OUTCOME	**BC Mortality rate.**										NS					
19	OUTCOME	**Toxic deaths.**			NS												
20	OUTCOME	**BC Survival rate.**										NS					
21	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

Figuras 1: Flow diagram detailing the study selection.

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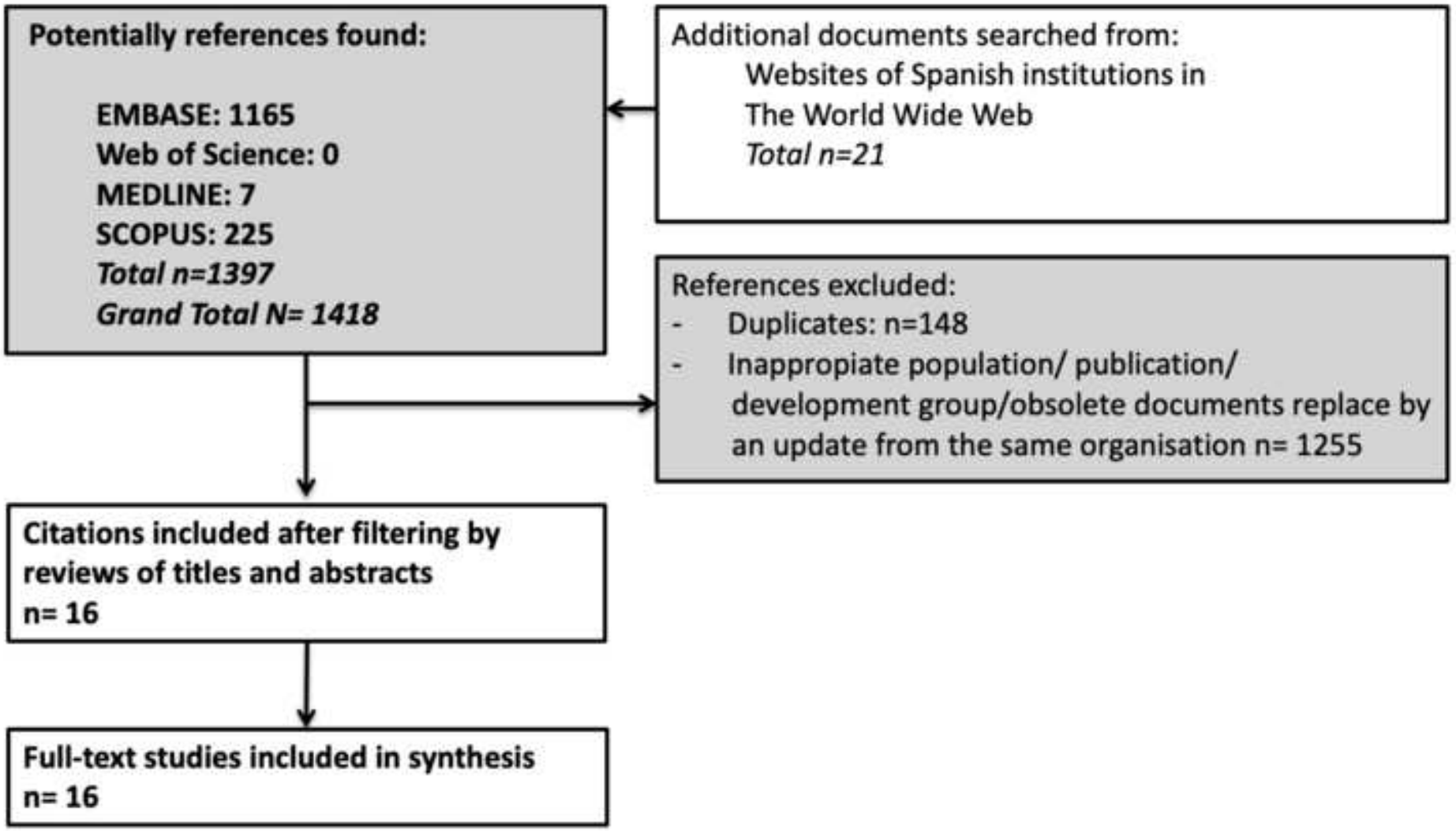


Appendix 1: PRISMA 2009 Checklist

			Page
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	5	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	6	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	7	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 2
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).	4 - 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.	4 - 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.	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.	7

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.	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.	7 - 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]).	7 - 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).	10
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
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.	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. doi:10.1371/journal.pmed1000097

Appendix 1: Data sources and search strategy

A1.1 Sample search strategy for MEDLINE

A systematic search was conducted on February 19th, 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

A1.2 Online databases

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

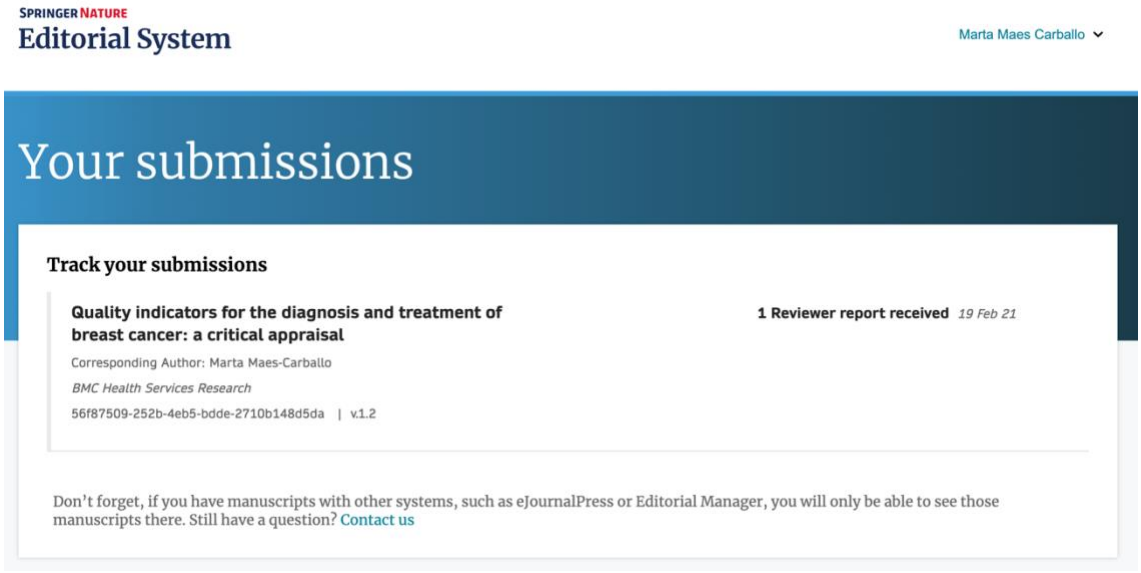
A1.3 Websites of European institutions

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

6.5. Manuscript 4: Maes-Carballo M, Martín-Díaz M, Mignini L, Bueno-Cavanillas A. Quality indicators for the diagnosis and treatment of breast cancer: a critical appraisal.

This manuscript has answered the fourth aim of this Doctoral Thesis: to study the quality indicators for BC diagnosis and treatment and identify areas for improvement. To our knowledge, there are no previous studies in Spain that assess the impact of the analysis of the Integrating Breast Cancer Care Process quality indicators. However, their evaluation is considered essential for adequate control of the process, to identify areas for improvement and provide possible solutions and improvement plans based on objective data. We have carried out a prospective observational study on a series of 508 consecutive cases (487 patients) diagnosed and treated for BC during five years in a healthcare area. A pseudonymized database was designed for the analysis of the indicators, continuously updated by two BC specialists. A descriptive analysis was initially performed, and the indicator´s compliance was estimated and stratified by a series of probably related characteristics. The results showed that four indicators did not meet the standard. The surgical delay after committee indicator (mean 64%, CI (59.6-68.5)) was lower in advanced age (p = 0.027), histological grades (p = 0.019) and early stages (p = 0.008) while the adjuvant delay indicator (mean 55.7%, CI (51.1-60.3)) was lower in advanced patients (p = 0.036) and when there was no reintervention (p = 0.001). The surgical delay after inclusion in the list indicator (mean 83.2%, CI (79.3-87.2)) was lower in low histological grades (p = 0.048). Immediate reconstruction (mean 42.3%, CI (34.0-50.5)) reached 72.34% in young women compared to 11.76% in those older than 70 years (p = 0.001) and was higher in early stages (45.26% vs 36.17%; p = 0.049). It was concluded that the quality indicators' analysis allows evaluating their compliance and studying the variables that influence to propose improvement measures. Not all indicators are equally useful. Some depend on the resources available and others on the mix of patients or the use of complementary treatments. It is essential to identify specific target populations for estimating the indicator or provide standards stratified by the variables that influence them.

(Manuscript under review submitted in BMC Health Services Research)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Quality indicators for the diagnosis and treatment of breast cancer: a critical appraisal

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Abstract

Background: The evaluation of the quality indicators (QI) is considered essential for adequate control of the health care process, identifying areas of improvement and providing possible solutions. This study aims to evaluate the performance of the Integrated Breast Cancer Care Process QIs.

Methods: A series of 487 consecutive breast cancer cases diagnosed from November 1st, 2013, to November 30th, 2019, in a Spanish healthcare area was analysed. We recorded administrative and clinical data for the estimation of the QI.

Results: Four indicators did not meet the standards and were analyzed based on related sociodemographic and clinical variables. The surgical delay after a multidisciplinary team discussion (mean 64%, IQR 59.6-68.5) was lower in elder people (p=0.027), and early histological grades (p=0.019) and stages (p = 0.008). The adjuvant treatment delay (mean 55.7%, IQR 51.1-60.3) was lower in advance stages (p = 0.002) and when there was no reoperation (p=0.001). The surgical delay after inclusion (mean 83.2%, IQR 79.3-87.2) was lower in early histological grades (p=0.048). The immediate reconstruction (mean 42.3%, IQR 34.0-50.5) reached 72.34% in young women compared to 11.76% in older than 70 years (p = 0.001) and it was higher in early stages (45.26% vs 36.17%; p = 0.049).

Conclusions: The study of QIs allowed to evaluate their compliance and analysed the variables that influence them to propose improvement measures. Not all the indicators were equally useful. Some depended on the available resources, and others from the mix of patients or complementary treatments. It would be essential to identify the specific target populations to estimate the indicators or provide standards stratified by the variables that influence them.

Keywords: "breast cancer", "Integrated Healthcare Process", "quality indicators".

1. Introduction and background

Breast Cancer (BC) is the most common type of cancer in women. Annual incidence is 33,000 cases in Spain.[1] Most are diagnosed between 45 and 80 years old, with a maximum incidence between 45 and 70 years old.[2] Its clinical and histological presentation varies depending on the patient.[3] Confirmatory diagnosis is anatomopathological and, depending on the result, individualized treatment is prescribed for each patient.[3] The main purpose of the treatment is to increase disease-free survival and overall survival.[2] This has notably improved in recent decades.[4] This trend can be attributed to early diagnosis in symptomatic patients and women included in screening programs and the individual application of new treatments.[2,5,6] At the same time, the improvement of the diagnosis, the greater efficacy of neoadjuvant treatments and the development of oncoplastic techniques have reduced the surgical treatment's aggressiveness and improved aesthetic and functional results.[7] Consequently, the treatment of BC is every day more satisfactory, but also more complex because the ideal approach to each case requires a high degree of individualization, scientific-technical updating, multidisciplinary coordination and continuous review of results.[8,9]

The greater therapeutic complexity requires improving the quality of cancer diagnosis and treatment.[2] Information systems must be incorporated for the surveillance and continuous evaluation of results. They would allow self-evaluation and detection of opportunities for improvement.[10] To harmonize the evaluation of BC management quality, various QIs have been proposed, but there is still no consensus.[2,11,12] In Spain, each Autonomous Community has developed a Breast Cancer Integrated Care Process. In Andalusia, this Integrated Health Care Process is defined as the "set of preventive, diagnostic, therapeutic, follow-up and care activities, used at the comprehensive management of people ... with increased risk for BC, ...".[12] The Breast Cancer Integrated Care Process includes a series of QIs for the continuous improvement, and their estimation requires the maintenance of a sociodemographic, clinical and healthcare database.

To our knowledge, there are no studies in Spain that assess the impact of the analysis of QIs. Our work aims to evaluate the usefulness of the BC QIs to improve the Integrated Health Care Process and identify areas for improvement.

2. Methods and materials

A prospective observational study was done on a series of consecutive BC cases diagnosed and treated during 5 years, without sex or age exclusions, from November 1st, 2013 to November 30th, 2019 in a health care area. Patients diagnosed with benign breast pathology were excluded.

2.1. Information sources and data collection

The source of information was the patient medical history. A pseudonymised database was designed to analyse the indicators in Microsoft Excel Version 16.40 and continuously updated by two BC specialists, MMC and MMD. The variables collected included demographic information (age and sex), origin, the reason for entering the Integrated Health Care Process and cancer characteristics (clinical examination (palpable nodule in breast or armpit), location (laterality and affected quadrant), type of cancer (in situ or infiltrating and varieties of each), histological grade, tumour stage and existence of recurrence). Besides, a series of variables related to the process were collected: date of diagnosis, the performance of several tests in the same medical consultation, presentation of the case in the multidisciplinary team (MDT) discussion, date of decision-making by the MDT, date of admission to the surgical waiting list, date of intervention, type and date of initiation of adjuvant treatment, type of surgery (tumorectomy or mastectomy), oncoplastic surgery, reconstructive surgery, sentinel lymph node biopsies (SLNB), axillary lymphadenectomy (AL) and its reason. Information was collected from the entire process in most of the cases. Those incomplete cases were not disregarded as they were considered useful in analysing part of the indicators. Table 1 shows the specified formula and the QIs fulfilment.[2]

2.2. Data analysis

A descriptive analysis was initially performed. We have studied the distribution of frequencies for qualitative variables and central tendency and dispersion measures for quantitative variables. The sociodemographic, clinical and healthcare variables collected were stratified by year of diagnosis and age. The percentage of cases that have reached each of the standard indicators and their 95% confidence interval was estimated, and it was stratified by year of diagnosis, group of age, origin, histological grade and cancer stage. The results were compared by groups using the Chi-square test. Statistical significance was set at p-value <0.05. All analyses were carried out with the Stata 15.0 statistical package.

3. Results

3.1. Descriptive analysis of the sample

A total of 487 patients were included, with a mean of 59.57 years old, ranged between 28.78 and 90.12 years. Most patients (98.97%) were women and referred from Primary Care (39.51%) or screening (28.60%). Some of the diagnosed cancers (70.99%) presented a palpable lump in the breast and 9.05% in the axilla. Table 2 presents the main characteristics of the patients studied. The most frequent location was the upper-external quadrant, with almost two-thirds of the cases (66.13%). There were 64 (13.17%) synchronous carcinomas (59.38% multifocal and 35.93% multicentric), and 9 metachronous (1.85%). Most of the patients (81.28%) were diagnosed in the early stages of the disease (Tis, I-II). Regarding the type of cancer, 84.05% were invasive carcinomas (IC), highlighting the invasive ductal carcinoma (IDC) in 80.33% of the cases, and the luminal molecular subtype in 93.91% of the cases. A total of 31.31% were carcinomas in situ (CIS or Tis), highlighting 94.81% of ductal carcinoma in situ (DCIS). Only 2.16% were inflammatory. About 44.73% of the ICs were intermediate grade and 53.25% CIS were high histological grade. Regarding treatment, 65.02% of the surgical interventions were lumpectomies (37.34% of them performed oncoplastic surgery), and 29.42% mastectomies (41.96% of these had reconstruction). We performed 68.93% sentinel lymph node biopsies (SLNB), and only 30.45% of them were positive. The mean number of lymph nodes removed in a SLNB was 2. There were 17.86% of reoperations (82.92% were strategically unforeseen such as amplification of margins, deferred axillary lymphadenectomy (AL) and 17.07% due to morbidities such as hematoma or abscess).

Table 3 shows the stratified analysis according to the year of diagnosis. Differences were observed in the age of onset ($p = 0.043$), with a peak of women under 50 years old in 2017. The percentage of women from the screening decreased significantly from 2016 ($p = 0.010$), showing a minimum value in 2017 (19.19%), and a subsequent increasing trend. The surgical indication exceeded 95% in all years except 2018 ($p = 0.014$), while the neoadjuvant indication increased over the years until reaching 37.89% in 2018, although it decreased in 2019 (15.52%; $p=0.001$). Oncoplastic surgery (mean of 37.46%) progressively increased from 14.06% in 2014 to 60.34% in 2018, and drastically reduced in 2019. Besides, there was an evident decrease in the number of AL in 2019 compared to previous years ($p = 0.025$). Breast

reconstruction was performed between 9 and 10% of patients in all these years except in 2015 when it only reached 3% (p = 0.031). No significant changes were observed over time for characteristics such as sex (p = 0.954), quadrant of the affected breast (p = 0.486) (results not shown), or for the indication of adjuvant treatment (hormone therapy, chemotherapy, biological therapy and radiotherapy).

When stratified by age (Table 4), a lower frequency of CIS was observed in patients older than 70 years (p = 0.023); however, there were no differences by age groups in IC (p = 0.135). The presence of a palpable breast lump at the diagnosis was less usual in those patients in screening age (50-70 years) patients (62.50% of them came from the screening program (p = 0.001)). Conservative surgery (p = 0.001) and oncoplastic surgery (p = 0.010) were more frequent in young women or those in screening age, while mastectomy was more prevalent in old patients (p = 0.001). Reconstructive surgery was performed in 53.62%; 26.58% and 10.04% respectively in each age group (p <0.001). Both chemotherapy (p = 0.001) and radiotherapy (p = 0.001) were more common in young or middle ages. The SLNB was also more usual in younger women (p = 0.001), but there were no significant differences according to age in AL's frequency (p = 0.641).

3.2. Analysis of quality indicators

Table 5 shows the estimates values for the QIs stratified by year of study. Globally, all the indicators were above the minimum standard granted in the Integrated Health Care Process from Andalusia[2] except the surgical delay after the decision of the multidisciplinary team (MDT) or after inclusion in the waiting list, and the delay in adjuvant treatment. The standard for breast reconstruction was also not reached. When stratifying by diagnosis year, significant differences were observed in all the indicators that did not reach the standard, except in breast reconstruction. All these QIs had a general tendency to decrease their values in recent years except the delay in adjuvant treatment that improved. There was a decrease of resolution in a single act, below the standard in 2017 and 2019, and in the MDT decision delay, which did not reach the standard after 2017.

The behaviour of the indicators that did not meet the standards was analysed according to the potentially related sociodemographic and clinical variables (Table 6).

After MDT, the delay in surgical treatment (mean 64%, IQR 59.6-68.5) showed an association with age at diagnosis (p = 0.027). The indicator value increased and approached the standard as age raised. The histological grade in IC was also associated with the percentage of compliance: the lower grade BC, the higher compliance (p = 0.019) and the cancer stage. This QI compliance was lower in advanced tumours (p = 0.008). The percentage of delay compliance in adjuvant treatment (mean 55.7%, IQR 51.1-60.3) was better in women under 50 years old than older (p =0.002), better in advanced stages than in early stages (p = 0.489) and better when no reintervention was necessary (p =0.001), but without the standard being met in any case. Regarding the indicator "immediate reconstruction" after mastectomy (mean 42.3%, IQR 34.0-50.5), the standard was widely exceeded in young women, with 72.34%, much higher than that estimated in the remaining age groups (p = 0.001) and reached 100% in low histological grades of IC or moderate CIS. It was also significantly higher in the early stages than in advance stages (45.26% vs 36.17%; p = 0.049).

4. Discussion

To our knowledge, there were not found similar studies about BC QIs in Spain. However, their evaluation is considered essential for adequate control of the process, identifying areas for improvement and providing possible solutions and improvement plans based on objective data.[2]

The distribution by age and origin of our series, similar to what was described by other authors, [13,14] revealed that most of these were diagnosed early (by screening or by opportunistic screening) of the General Practitioners. There was no doubt that the shorter time spent in the diagnosis, waiting time for surgery and adjuvant treatment, affected patients' well-being and survival, and increased care quality. [15,16] In our study, BC was more frequently located in external quadrants. This was supported by other studies since there would be more glandular tissue in this area.[17] Moreover, our study observed that the number of patients diagnosed in the screening has increased in recent years, suggesting that it has improved its effectiveness and coverage. Although Primary Care was the most frequent origin, more than half of the patients in the age of screening tests came from the screening.

The indication of neoadjuvant treatment has also increased over the years, probably due to the appearance of new advances in management and the approval of new protocols. Likewise, there was an

increase in oncoplastic surgery over time, possibly due to increasing training and qualification of the surgical team, which would allow the performance of more complex surgeries.

Some of these indicators, such as “MDT assessment” of each case, “performance of conservative surgery” and “SLNB”, showed an excellent rate of adherence to the recommendations. Others, such as “delay in surgical treatment after MDT” and “delay in surgical treatment after inclusion in the waiting list”, which in both cases might be less than 30 days, “delay in adjuvant treatment less than 6 weeks” and “immediately reconstruction post-mastectomy” obtained an average compliance rate that did not reach the required quality standards. In the first case, it was necessary to highlight a contrary effect to what expected when stratifying by age, stage or histological grade in IC, which could probably be due to the antecedent or not of neoadjuvant treatment. The frequency of neoadjuvant treatment has increased over the time, particularly in younger women. The mean delay in surgical treatment was longer in women treated with neoadjuvant therapy (150.06 versus 26.94 days; $p < 0.001$; results not shown). This would mean that either the standards were corrected, or the delay indicator was restricted exclusively to women treated without neoadjuvant therapy.

For other indicators, the result was dependent on the available resources, thus, for example, the “adjuvant treatment delay” indicator had improved in 2017 and after, when the availability of oncologists in the hospital has stabilized. The differences observed by age for this indicator suggested that preference was given to younger women in any case.

Concerning immediate reconstruction after mastectomy, the compliance rate was always below standard. This technique, widely recommended nowadays,[18] could be performed using an immediate or delayed prosthesis (by placing a breast expander). There was no current consensus on which would be the best option. [19-21] In our study, reconstruction was performed by placing an expander and delayed prosthesis. Nowadays, there would be a growing tendency to perform conservative surgery. [7,20,22,23] Furthermore, women who have chosen mastectomy would generally have a more advanced stage, with an invasion of adjacent tissues, so the placement of an expander or prosthesis would not always be feasible. Age is also a relative contraindication to reconstruction.[24] The stratification by age showed an excellent result regarding the standard for younger women. However, the Integrated Health Care Process did not

contemplate the data stratification to assess the process's quality. The behaviour of this QIs regarding the preoperative stage has confirmed those mentioned above. The earliest stages were the subsidiary stages of expander or prosthesis placement, and in them, a significantly higher percentage was obtained. After reviewing all the patients who had not been reconstructed, there was at least one relative contraindication criterion for immediate reconstruction in the majority of cases.

Therefore, 50% of cases with immediate reconstruction after mastectomy could be an excessively high percentage; especially since more and more conservative surgery has been indicated with or without oncoplastic surgery and those in which a mastectomy was frequently performed would present relative or absolute contraindications (such as advanced age, invasion of adjacent tissues, or others). Besides, this breast reconstruction QI penalized health areas that would treat older patients and with worse access to screening programs in contrast to other indicators such as surgical delay and single-act diagnosis, which were more independent of the mix of cases and, therefore, more useful to identify deficiencies that could be improved. So, we could consider that this standard was not well defined and that its modification to a lower percentage of compliance should be considered, or its wording should be modified. This quality indicator should refer exclusively to young women in whom radical mastectomy would be performed, and there would not be other contraindication for reconstructive surgery.

5. Conclusions

This is the first study developed in our country that analyzes the QIs´ fulfilment in a Breast Unit. To estimate these indicators, it was required to keep a record of the cancer cases treated, essential for evaluating the entire process. However, not all indicators would be equally useful for improving the Integrated Health Care Process. While some might depend on the available resources and be valued according to them, others would depend on the mix of patients or complementary treatments. In these cases, it would be essential to identify the specific target populations for estimating the indicator or provide standards stratified by the variables that have influenced them, such as age, the use of adjuvant treatment, or the type of surgery. The availability of data from other hospitals will allow us to compare our results and show improvement strategies.

6. Abbreviations

AL: axillary lymphadenectomy, CIS: carcinoma in situ, DCIS: ductal carcinoma in situ, IC: invasive carcinoma, IDC: invasive ductal carcinoma, IQR: confidence interval, MDT: multidisciplinary team, SLNB: sentinel lymph node biopsy, Tis: carcinoma in situ QI: quality indicator.

7. Declarations

Ethics approval and consent to participate

The study was conducted according to the guidelines of the Declaration of Helsinki and approved by the Institutional Review Board of Bioethics Committee from the University of Granada (Ref n. 0922-N-17). All methods were performed in accordance with the relevant guidelines and regulations. Informed consent was obtained from all study participants.

Consent for publication

Not applicable

Availability of data and materials

The datasets used and/or analysed during the current study available from the corresponding author on reasonable request.

Competing interest

The authors declare that they have no conflict of interest.

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Authors´ contributions

Each author certifies that he/she has made a direct and substantial contribution to the conception and design of the study, development of the search strategy, the establishment of the inclusion and exclusion criteria, data extraction, analysis and interpretation. MMC was involved in the design of the study, literature search, data collection and analysis, quality appraisal and writing. MMD was involved in the

design of this study, analysis of data and writing. LM was involved in writing. ABC was involved in the design of this study, data collection and analysis, writing and provided critical revision of the paper. All authors read and provided the final approval of the version to be published.

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Table 1: List of the Integrated Breast Cancer Care Process selected indicators supplemented by their description and standard.

Indicator	Abbreviation	Description	Standard
1. PEOPLE WITH SUSPECTED BREAST CANCER WHO HAVE RECEIVED CONSULTATION IN A SINGLE ACT	**Single act**	Number of people with suspected breast cancer who have undergone more than one test in a single appointment to obtain a diagnosis during the evaluated period / Number of people with suspected breast cancer who have needed more than one test to get a diagnosis in the same period x 100	90%
2. PEOPLE WITH DIAGNOSTICS OF BREAST CANCER WHO ARE ASSESSED BY THE MULTIDISCIPLINARY TEAM DISCUSSION (MDT) BEFORE STARTING TREATMENT	**MDT evaluation**	Number of people diagnosed with breast cancer who have been assessed by the multidisciplinary team discussion / Number of people diagnosed with breast cancer x 100	90%
3. PEOPLE WITH A DIAGNOSIS OF BREAST CANCER IN WHICH THE TIME ELAPSED FROM THE REFERRAL FOR BREAST CANCER TO THE DECISION-MAKING BY THE MULTIDISCIPLINARY TEAM DECISION MEETING IS LESS THAN 30 DAYS	**Decision delay**	Number of people in whom diagnostic-therapeutic decisions are made within less than 30 days from diagnosis / Number of people with breast cancer assessed by the specific MDT x 100	90%
4. PEOPLE DIAGNOSED WITH BREAST CANCER WHO UNDERGO SURGICAL INTERVENTION WITHIN LESS THAN 30 DAYS AFTER DECISION-MAKING BY THE SPECIFIC TUMOR COMMISSION	**Surgical delay after MDT**	Number of people who undergo surgery in less than 30 days from the decision made by the MDT / Number of people diagnosed with breast cancer subsidiary to surgery x 100	90%
5. PEOPLE DIAGNOSED WITH BREAST CANCER WHO UNDERGO SURGICAL INTERVENTION IN LESS THAN 30 DAYS AFTER ENTERING THE SURGICAL WAITING LIST	**Surgical delay after the waiting list**	Number of people diagnosed with breast cancer who undergo surgery in less than 30 days after entering the waiting list / Number of people diagnosed with breast cancer subsidiary to surgery x 100	100%
6. PEOPLE DIAGNOSED WITH BREAST CANCER WHO START ADJUVANT TREATMENT IN LESS THAN 6 WEEKS FROM THE DATE OF THE SURGICAL INTERVENTION	**Delay of adjuvant treatment**	Number of people to whom adjuvant treatment is administered in less than 6 weeks from the date of surgery for breast cancer / Number of people diagnosed with breast cancer under adjuvant treatment x 100	90%
7. PEOPLE WITH A DIAGNOSIS OF BREAST CANCER AND SURGICAL INTERVENTIONS UNDERGOING CONSERVATIVE SURGERY (CONSERVATIVE TREATMENT)	**Conservative treatment**	Number of people diagnosed with breast cancer who have undergone surgery undergoing conservative surgery / Number of people diagnosed with breast cancer and who have undergone surgery x 100	50-80%
8. PEOPLE WITH DIAGNOSIS OF BREAST CANCER UNDER IMMEDIATE RECONSTRUCTIVE SURGERY	**Immediate reconstruction**	Number of people diagnosed with breast cancer who have undergone immediate reconstructive surgery / Number of people with radical mastectomy for breast cancer x 100	90%
9. SENTINEL LYMPH NODE BIOPSY (SLNB)	**SLNB**	Number of people diagnosed with breast cancer who have undergone surgery with selective sentinel node biopsy / Number of people diagnosed with breast cancer and operated on x 100	50%

Table 2: Description of the studied population.

Characteristics		Pacients (n=486)
Age (Mean; Standard deviation)		**59,57 (13.59)**
Sexo Mujer (n, %)		**481 (98.97%)**
Procedencia	Screening	139 (28.60%)
	Primary care	192 (39.51%)
	Other	155 (31.89%)
Palpable breast mass		**345 (70.99%)**
Palpable axilla mass		**44 (9.05%)**
Location in breast	Upper outer quadrant	336 (69.13%)
	Other locations	150 (30.86%)
Synchronous Cancer	**Total**	**64 (13.17%)**
	Multifocal (1)	38 (59.38%)
	Multicentric (1)	23 (35.93%)
	Unknown (1)	3 (4.69%)
Metachronous cancer		**9 (1.85%)**
Cancer stage	Early (Tis, I, II)	395 (81.28%)
	Advance (III, IV)	91 (18.72%)
Types of cancer	**Carcinoma in situ (CIS) (2)**	**154 (31.31%)**
	Ductal carcinoma in situ (DCIS) (3)	146 (94.81%)
	Lobular carcinoma in situ (LCIS) (3)	6 (3.89%)
	Unknown (3)	2(1.29%)
	Infiltrating carcinoma (IC) (2)	**427 (84.05%)**
	Infiltrating ductal carcinoma (IDC)(4)	343 (80.33%)
	Infiltrating lobular carcinoma (ILC)(4)	39 (9.13%)
	Others (4)	41 (9.60%)
	Unknown (4)	4 (0.94%)
	Carcinoma inflamatorio (2)	**11 (2.16%)**
Histological grade of CIS (3)	Low grade	30 (19.48%)
	Moderate grade	39 (25.32%)
	High grade	82 (53.25%)
	Unknown	3 (1.95%)
Histological grade of IC (4)	Low grade	134 (31.38%)
	Moderate grade	191 (44.73%)
	High grade	94 (22.01%)
	Unknown	8 (1.87%)
Molecular subtype of IC (4)	Luminal	401 (93.91%)
	Her 2 positive	24 (5.62%)
	Triple negative	44 (10.30%)
	Unknown	17 (3.98%)
Treatment	**Tumorectomy**	**316 (65.02%)**
	Harpoon-guided lumpectomy (5)	125 (39.56%)
	Oncoplastic (5)	118 (37.34%)
	Mastectomy	**143 (29.42%)**
	Reconstruction (6)	60 (41.96%)
	Sentinel Lymph Node Biopsy (SLNB)	**335 (68.93%)**
	Negative (7)	233 (69.55%)
	Positive (7)	102 (30.45%)
	Average number of lymph nodes removed in each SLNB (Standard deviation)	2.11 (1.06)
	Axillary lymphadenectomy (AL)	**183 (37.65%)**
	Main reason for AL (8)	Positive intra-surgical SLNB 61 (33.33%)
	Hormone therapy	**348 (71.60%)**
	Chemotherapy	**185 (38.07%)**
	Biological therapy	**65 (13.37%)**
	Radiotherapy	**323 (66.46%)**
Reoperations (n=82; 17.86%) (9)	**Strategically unforeseen (10)**	**68 (82.92%)**
	Margins expansion (11)	37 (54.41%)
	Delayed AL (11)	13 (19.12%)
	Margins expansion and delayed AL (11)	6 (8.82%)
	Other(11)	11 (16.17%)
	For morbidity (10)	**14 (17.07%)**
	Hematoma (12)	6 (42.85%)
	Abscess (12)	4 (28.57%)
	Other (12)	4 (28.57%)

(1) Percentage calculated on the total of 64 synchronous cancer patients.

(2) Percentage calculated on the 508 cancers and not on the 486 patients.

(3) Percentage calculated on the 154 patients diagnosed with carcinoma in situ.

(4) Percentage calculated on the 427 patients diagnosed with infiltrating carcinoma.

(5) Percentage calculated on the 316 patients who have undergone conservative surgery.

(6) Percentage calculated on the 143 patients who underwent a mastectomy.

(7) Percentage calculated on the 335 patients who underwent SLNB.

(8) Percentage calculated on the 183 patients who underwent LA.

(9) Percentage calculated on 459 interventions (sum of lumpectomies + mastectomies).

(10) Percentage calculated on the 76 reoperations.

(11) Percentage calculated on the 68 strategically unforeseen interventions.

(12) Percentage calculated on the 14 interventions for morbidity.

Table 3: Stratification by diagnosis year

		2013	2014	2015	2016	2017	2018	2019	Total	**p value**
Age group	< 50 yo	3 (50%)	19 (27.00%)	21 (21.43%)	19 (24.36%)	38 (38.38%)	24 (24.24%)	17 (28.81%)	141 (27.76%)	p = 0.043
	50-70 yo	3 (50%)	33 (48.00%)	52 (53.06)	46 (58.97%)	36 (36.36%)	40 (40.40%)	27 (45.76%)	237 (46.65%)	
	> 70 yo	0(0%)	17 (25.00%)	25 (25.51%)	13 (16.67%)	25 (25.25%)	35 (35.35%)	15 (25.42%)	130 (25.59%)	
	Total	6	69	98	78	99	99	59	508	
Family risk	Habitual	5 (83.33%)	52 (75.36%)	94 (95.92%)	69 (88.46%)	91 (91.92%)	79 (79.8%)	50 (84.75%)	440 (86.61%)	p = 0.023
	Moderate	1 (16.67%)	13 (18.84%)	2 (2.04%)	6 (7.69%)	7 (7.07%)	15 (15.15%)	6 (10.17%)	50 (9.84%)	
	High	0	4 (5.80%)	2 (2.04%)	3 (3.85%)	1 (1.01%)	5 (5.05%)	3 (5.08%)	18 (3.54%)	
	Total	6	69	98	78	99	99	59	508	
Origin	Screening	2 (33.33%)	17 (24.64%)	37 (37.76%)	30 (38.46%)	19 (19.19%)	23 (23.23%)	15 (25.42%)	143 (28.15%)	p = 0.010
	Primary care	1 (16.67%)	29 (42.03%)	30 (30.61%)	25 (32.05%)	38 (38.38%)	45 (45.45%)	25 (42.37%)	193 (37.99%)	
	Other	3 (50%)	23 (33.33%)	31 (31.63%)	23 (29.49%)	42 (42.43%)	31 (31.32%)	19 (32.21%)	172 (33.86%)	
	Total	6	69	98	78	99	99	59	508	
Indication for Surgery	Yes	6 (100%)	67 (97.1%)	95 (96.94%)	76 (97.44%)	97 (97.98%)	87 (87.88%)	56 (94.92%)	484 (95.28%)	p = 0.014
	Total	6	69	98	78	99	99	59	508	
Oncoplastic	Yes	0 (0%)	9 (14.06%)	9 (14.06%)	17 (28.81%)	37 (54.41%)	35 (60.34%)	12 (27.91%)	121 (37.46%)	p = 0.001
	Total	6	64	76	59	68	58	43	374	
Reconstruction	Yes	2 (33.33%)	11 (16.18%)	2 (2.13%)	7 (9.33%)	8 (8.89%)	8 (10.53%)	5 (8.93%)	43 (9.25%)	p = 0.031
	Total	6	68	94	75	90	76	56	465	
Axillary lymphadenectomy	Yes	3 (50%)	26 (40%)	36 (39.13%)	36 (47.37%)	44 (45.36%)	33 (34.38%)	11 (19.30%)	189(38.80%)	p = 0.025
	Total	6	67	92	78	97	99	57	487	
Neoadjuvant	Yes	1 (16.67%)	6 (8.70%)	25 (25.51%)	21 (26.92%)	31 (31.63%)	36 (37.89%)	9 (15.52%)	129 (25.70%)	p = 0.001
	Total	6	69	98	78	98	95	58	502	
Hormone therapy	Yes	6 (100%)	53 (81.54%)	72 (80%)	62 (80.52%)	65 (75.58%)	53 (74.65%)	47 (81.03%)	358 (79.03%)	p=0.734
	Total	6	65	90	77	86	71	58	453	
Chemotherapy	Yes	3 (50%)	53 (81.54%)	25 (39.06%)	35 (46.75%)	35 (41.18%)	29 (42.03%)	28 (48.28%)	191 (42.44%)	p=0.662
	Total	6	64	91	77	86	69	58	450	
Biological therapy	Yes	1 (16.67%)	6 (9.38%)	18 (20.22%)	16 (21.05%)	7 (8.33%)	9 (13.24%)	10 (17.24%)	67 (15.06%)	p=0.174
	Total	6	64	89	76	84	68	58	445	
Radioterapia	Yes	4 (66.67%)	44 (68.75%)	64 (71.11%)	59 (78.67%)	62 (72.09%)	56 (78.87%)	41 (70.69%)	330 (73.33%)	p=0.740
	Total	6	64	90	75	86	71	58	450	

* In gray those results that are significant.
Abbreviation: yo (years old)

Table 4: Stratification by age groups

		< 50 yo	50-70 yo	> 70 yo	Total	**p value**
Carcinoma in situ	Yes	49 (34.75%)	82 (35.04%)	28 (21.88%)	159 (31.61%)	
	Total	141	234	128	503	p=0.023
Infiltrating carcinoma	Yes	127 (90.07%)	200 (85.11%)	119 (91.54%)	446 (88.14%)	
	Total	141	235	130	506	p=0.135
Palpable breast mass	Yes	128 (87.94%)	128 (54.01%)	110 (84.62%)	362 (71.26%)	
	Total	141	237	130	508	p=0.001
Palpable axilla mass	Yes	12 (8.51%)	19 (8.02%)	16 (12.31%)	47 (9.25%)	
	Total	141	237	130	508	p=0.374
Origin	Screening	0 (0%)	135 (62.50%)	8 (7.21%)	143 (32.80%)	
	Primary care	81 (74.31%)	47 (21.76%)	65 (58.56%)	193 (44.27%)	
	Others	28 (25.69%)	34 (15.74%)	38 (34.23%)	100 (22.94%)	
	Total	109	216	111	436	p=0.001
Conservative surgery	Yes	83 (60.58%)	180 (78.60%)	60 (50%)	323 (66.46%)	
	Total	137	229	120	486	p=0.001
Oncoplastic	Yes	40 (39.6%)	66 (34.02%)	15 (18.99%)	121 (32.35%)	
	Total	101	194	79	374	p=0.010
Mastectomy	Yes	51 (37.23%)	49 (21.30%)	54 (43.90%)	154 (31.43%)	
	Total	137	230	123	490	p=0.001
Reconstruction	Yes	37 (53.62%)	21 (26.58%)	7 (10.94%)	65 (30.66%)	
	Total	69	79	64	212	p=0.001
Neoadjuvant treatment	Yes	52 (37.14%)	60 (25.42%)	17 (13.49%)	129 (25.7%)	
	Total	140	236	126	502	p=0.001
Hormone therapy	Yes	93 (75.61%)	177 (80.45%)	88 (80.00%)	358 (79.03%)	
	Total	123	220	110	453	p=0.549
Chemotherapy	Yes	67 (54.47%)	100 (45.66%)	25 (23.15%)	192 (42.67%)	
	Total	123	219	108	450	p=0.001
Biological therapy	Yes	24 (19.67%)	31 (14.22%)	º12 (11.43%)	67 (15.06%)	
	Total	122	218	105	445	p=0.199
Radiotherapy	Yes	89 (73.55%)	184 (83.64%)	57 (52.29%)	330 (73.33%)	
	Total	121	220	109	450	p=0.001
Selective sentinel node biopsy	Yes	105 (74.47%)	173 (73.00%)	71 (54.62%)	349 (68.70%)	
	Total	141	237	130	508	p=0.001
Axillary lymphadenectomy	Yes	55 (39.86%)	84 (36.52%)	50 (41.32%)	189 (38.65%)	
	Total	138	230	121	489	p=0.641

* In gray those results that are significant.
Abbreviation: yo (years old)

Table 5: The compliance rate of quality indicators according to the year of diagnosis and their deviation from the standard (indicated in grey). In **bold**, the three indicators whose mean does not meet the standard.

	Quality indicators	Standard	Mean	2013	2014	2015	2016	2017	2018	2019	p
1	**Single act**	90%	91.4% (88.9-93.9)	100.0% (6/6)	100.0% (68/68)	95.74% (90/94)	92.11% (70/76)	87.10% (81/93)	93.62% (88/94)	74.55% (41/55)	0.001
2	**MDT evaluation**	90%	99.2% (98.3-99.9)	100.0% (6/6)	98.5% (67/68)	98.9% (93/94)	98.7% (75/76)	98.9% (92/93)	100.0% (94/94)	100.0% (55/55)	0.920
3	**Decision delay**	90%	90.9% (88.3-93.5)	83.3% (5/6)	98.5% (66/67)	94.7% (89/94)	92.1% (70/76)	88.2% (82/93)	86.0% (80/93)	87.3% (48/55)	0.081
4	**Surgical delay after MDT**	90%	**64.0% (59.6-68.5)**	83.3% (5/6)	89.1% (57/64)	72.6% (61/84)	53.5% (38/71)	58.0% (51/88)	55.6% (45/81)	76.8% (30/54)	0.001
5	**Surgical delay after the waiting list**	100%	**83.2% (79.3-87.2)**	100.0% (5/5)	96.7% (58/60)	77.9% (60/77)	82.1% (46/56)	81.0% (51/63)	90.6% (48/53)	65.8% (25/38)	0.002
6	**Delay of adjuvant treatment**	90%	**55.7% (51.1-60.3)**	66.7% (4/5)	30.8% (20/65)	23.8% (20/84)	31.0% (22/71)	78.4% (69/88)	98.8% (80/81)	64.8% (35/54)	0.001
7	**Conservative treatment**	50-80%	70.2% (63.7-72.2)	66.7% (4/6)	63.5% (40/63)	76.2% (64/84)	76.1% (54/71)	72.9% (62/85)	60.9% (53/87)	72.2% (39/54)	0.239
8	**Immediate reconstruction**	50%	**42.3% (34.0-50.5)**	100.0% (2/2)	44.0% (11/25)	40.9% (9/22)	33.3% (6/18)	44.0% (11/25)	40.0% (14/35)	46.7% (7/15)	0.732
9	**SLNB**	50%	72.7% (64.8-73.1)	83.3% 2;6	65.1% 42;67	71.4% 65;95	70.4% 52;76	77.7% 69;97	72.4% 70;87	77.8% 46;56	0.651

Table 6: Stratification of the quality indicators by patient characteristics

	Quality indicators	SURGICAL DELAY AFTER MDT	SURGICAL DELAY AFTER THE WAITING LIST	DELAY OF ADJUVANT TREATMENT	IMMEDIATE RECONSTRUCTION
Age group	< 50 yo	57 (55.81%)	62 (89.86%)	88 (68.22%)	34 (72.34%)
	50-70 yo	142 (64.55%)	151 (92.07%)	108 (49.09%)	20 (45.45%)
	> 70 yo	73 (73.74%)	80 (94.12%)	54 (54.00%)	6 (11.76%)
	p valor	p=0.027	p=0.620	p=0.002	p=0.001
Origin	Screening	93 (69.40%)	101 (84.87%)	.	.
	Primary care	112 (63.28%)	113 (81.29%)	.	.
	Others	82 (59.85%)	79 (84.04%)	.	.
	p valor	p=0.251	p=0.723	.	.
Histological grade (Carcinoma in situ)	Low	18 (62.07%)	22 (81.48%)	18 (62.07%)	5 (100.00%)
	Moderate	22 (59.46%)	23 (71.88%)	14 (37.84%)	6 (100.00%)
	High	56 (71.79%)	58 (90.63%)	38 (48.72%)	15 (48.39%)
	p valor	p=0.356	p=0.060	p=0.148	p=0.010
Histological grade (Infiltrating carcinoma)	Low	86 (68.25%)	92 (87.62%)	68 (53.97%)	17 (53.13%)
	Moderate	114 (63.69%)	114 (83.21%)	103 (57.54%)	21 (33.87%)
	High	41 (49.40%)	42 (72.41%)	53 (63.10%)	10 (38.46%)
	p valor	p=0.019	p=0.048	p=0.423	p=0.193
Cancer stage	Early	249 (66.76%)	257 (83.44%)	200 (53.48%)	43 (45.26%)
	Advance	38 (50.67%)	36 (81.82%)	50 (66.67%)	17 (36.17%)
	p valor	p=0.008	p=0.787	p=0.036	p=0.049
Reoperation	Yes	.	.	23 (31.08%)	.
	No	.	.	166 (55.70%)	.
	p valor	.	.	p=0.001	.

* In gray those results that are significant.
Abbreviation: yo (years old)

STROBE Statement—Checklist of items that should be included in reports of ***cross-sectional studies***

	Item No	Recommendation	Page No
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	1
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	2
Objectives	3	State specific objectives, including any prespecified hypotheses	2
Methods			
Study design	4	Present key elements of study design early in the paper	3
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	3
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants	3
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	3
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	*3*
Bias	9	Describe any efforts to address potential sources of bias	3
Study size	10	Explain how the study size was arrived at	3
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	3
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	3
		(*b*) Describe any methods used to examine subgroups and interactions	3
		(*c*) Explain how missing data were addressed	3
		(*d*) If applicable, describe analytical methods taking account of sampling strategy	3
		(*e*) Describe any sensitivity analyses	3
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	4
		(b) Give reasons for non-participation at each stage	4
		(c) Consider use of a flow diagram	4
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	4
		(b) Indicate number of participants with missing data for each variable of interest	4-5
Outcome data	15*	Report numbers of outcome events or summary measures	5
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	4-6

		(*b*) Report category boundaries when continuous variables were categorized	5
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	5
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	5
Discussion			
Key results	18	Summarise key results with reference to study objectives	6
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	7
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	7-8
Generalisability	21	Discuss the generalisability (external validity) of the study results	7-8
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	9

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

6.6. Manuscript 5: Maes-Carballo M, Martín-Díaz M, Mignini L, Khan K S, Trigueros R, Bueno-Cavanillas A. Evaluation of the use of shared decision making in breast cancer: international survey. International Survey. Int. J. Environ. Res. Public Health 2021, 18, 2128. https://doi.org/10.3390/ijerph18042128

This manuscript has answered the fifth objective of this Doctoral Thesis: to assess the level of understanding, attitude, and degree of application of SDM in clinical practice by health professionals. We have carried out a cross-sectional study based on an online questionnaire, prepared ad hoc, which combined demographic and professional data with some items measured on a Likert scale. This survey was disseminated through several prestigious professional societies: AEC (Spanish Association of Surgeons), SESPM (Spanish Society of Senology and Breast Pathology), SAM (Argentine Society of Mastology), SACPER (Argentine Society of Plastic, Aesthetic and Reconstructive Surgery), AOR (Rosario's Oncology Association) and AMAR (Rosario's Mastology Association). The results are supported by the inclusion of a significant number of participants, 459, from different specialities and periods of the professional career. The participation (459/541; 84.84%) and completion (443/459; 96.51%) rates were adequate. In the analysis, participants strongly agreed or agreed in 69.57% (16/23) of the questions. The majority stated that they knew of SDM (mean 4.43; IQR 4.36-4.55) and agreed in the necessity of its implementation (mean 4.58; IQR 4.51-4.64). They highlighted its practice was not adequate due to lack of resources (3.46; IQR 3.37-3.55), and they agreed on policies that improved its implementation (3.96; IQR 3.88-4.04). The main advantage for participants was patient satisfaction (38%), and the main disadvantage was the patients' paucity of knowledge to understand their disease (24%). The main obstacle indicated was the lack of time and resources (40%).

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Article

Evaluation of the Use of Shared Decision Making in Breast Cancer: International Survey

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Abstract: Objectives: To assess shared decision-making (SDM) knowledge, attitude and application among health professionals involved in breast cancer (BC) treatment. Materials and Methods: A cross-sectional study based on an online questionnaire, sent by several professional societies to health professionals involved in BC management. There were 26 questions which combined demographic and professional data with some items measured on a Likert-type scale. Results: The participation (459/541; 84.84%) and completion (443/459; 96.51%) rates were high. Participants strongly agreed or agreed in 69.57% (16/23) of their responses. The majority stated that they knew of SDM (mean 4.43 (4.36–4.55)) and were in favour of its implementation (mean 4.58 (4.51–4.64)). They highlighted that SDM practice was not adequate due to lack of resources (3.46 (3.37–3.55)) and agreed on policies that improved its implementation (3.96 (3.88–4.04)). The main advantage of SDM for participants was patient satisfaction (38%), and the main disadvantage was the patients' paucity of knowledge to understand their disease (24%). The main obstacle indicated was the lack of time and resources (40%). Conclusions: New policies must be designed for adequate training of professionals in integrating SDM in clinical practice, preparing them to use SDM with adequate resources and time provided.

Keywords: shared decision making; breast cancer; use of shared decision making; survey; longitudinal study

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1. Introduction

Breast cancer (BC) is the leading cause of death in women [1]. Improvements in diagnosis, the greater efficacy of neoadjuvant therapies and the development of new oncoplastic techniques and oncological management have reduced the aggressiveness of surgical treatments and improved the aesthetic and functional results [2]. As BC treatment is now more complex, each case's ideal approach requires a high degree of individualization, scientific-technical updating, multidisciplinary coordination, and continuous review of results [3].

The ideal strategic plan for a BC patient will be the one that best meets their needs and expectations. Its design should be based on an accurate diagnosis of their disease and the patient's circumstances, preferences, and values [2,3]. So, shared decision making (SDM), "*an approach in which physicians and patients share the best available evidence when faced with the task of making decisions and where patients are supported in considering options, to achieve decisions following their preferences and values*" [4], is vitally important in BC. Its diagnosis

and treatment requires multiple high-risk decisions made in a limited time period and, often, with incomplete evidence, raising the need for more significant patient support during their decision-making process [4].

SDM is a universally supported concept [5–7] linked to care quality [8,9]. It increases patient satisfaction and their perception of risk [10]. It is a legal obligation in large parts of developed countries [11–14] and reduces malpractice claims [15,16]. However, its actual implementation remains low [17,18]. It is poorly reflected in clinical practice guidelines and consensus [19] and obstacles to its implementation persist [20,21]. Its main objective is to respect patients' autonomy without detriment to their benefit, providing care under their values and preferences. This requires the development of multidisciplinary teams with a high scientific-technical level, excellent coordination, communication with the patient, and permanent review of the results within the framework of a continuous improvement program.

The aim of this work is to assess the level of interest, knowledge and attitude towards SDM, as well as the perception of the degree of application of SDM by health professionals involved in the management of BC (including the entire process screening, diagnosis, treatment and follow-up).

2. Methods

The "Checklist for Reporting the Results of Internet E-Surveys" (CHERRIES) was used for this study, which allows a quality description of the research results from surveys of web environments [22,23]. CHERRIES, used for ensuring complete descriptions of e-survey methodology, is designed to improve the quality of reports [22]. A cross-sectional observational study on a convenience sample of BC specialist was conducted.

2.1. Measurement

A questionnaire was designed by a group of three SDM experts and breast cancer specialist (MMC, MD, LM) with a comprehensive theoretical and practical experience about this deliberative [24,25]. A literature review about SDM was done to elaborate and design a questionnaire to be self-completed online (Appendix A), which included brief information on the study's scope and objectives and a warning to those members of several of these societies not to answer it in duplicate. The survey was constructed in Spanish (Spanish and Argentine variations). Both variants were reviewed by native authors (MMC for Spanish from Spain and LM for Spanish from Argentina). No identifying data were collected. The variables of interest were measured on a Likert-type scale [26,27] with 5 responses, 1 being "strongly disagree" and 5 "strongly agree". The degree of knowledge about SDM (questions 1–5), the opinion about SDM (questions 6–12), the awareness and attitude about SDM (questions 13–15) and the degree of current and future application of SDM (questions 16–23) were investigated. Finally, three open-ended questions were included, referring to the perceived advantages, disadvantages and obstacles to its implementation. An arbitrator (ABC) has reviewed this prototype questionnaire and suggested modifications. Prior to disseminating the questionnaire, a pilot test was carried out on a sample of 15 specialists contacted directly to assess the questions' understanding and relevance. Some modifications for improving understanding of the survey have been done.

We could not estimate the response or participation rate. The completion rate was calculated from those who opened the online link. The real participation rate was impossible due to open distribution dissemination [28,29].

2.2. Period and Scope of the Study

The information was collected during the months of June, July, August and September 2020 in two countries: Spain and Argentina. The reference population was BC treatment specialists, members of scientific societies related to this process (BC screening, diagnosis, treatment and follow-up): Asociación Española de Cirujanos (AEC), Sociedad Española de Senología y Patología Mamaria (SESPM), Sociedad Argentina de Mastología (SAM),

Sociedad Argentina de Cirugía Plástica, Estética y Reparadora (SACPER), Asociación de Oncología de Rosario (AOR) y Asociación de Mastología de Rosario (AMAR). The sample was made up of the members of these societies who received and answered the online survey. Surveys that did not answer at least 25% of the items surveyed were excluded.

2.3. Data Collection

The participating scientific societies sent the survey by e-mail to the partners' list, included a link on their websites and the possibility of sharing this link with other colleagues. Two reminders were sent after the initial invitation; all constructed by the team researcher. The response was entirely voluntary and without incentive. It was administered through Google Forms [30], an online survey platform, from 1 June to 31 October 2020. There was no obligation to answer all the questions, and backtracking was allowed to answer previous questions. There was no random assignment of questions and answers. No data identifying the participants were stored. No minimum completion time was specified a priori. Partially completed surveys were accepted, provided that at least 25% of the questions were answered, and a manual review was conducted to verify abnormal response patterns.

2.4. Data Analysis

The distribution of responses and the average values of each question of the survey were studied, stratifying by sex, age, professional seniority, speciality, type of hospital (public or private) and service (with or without breast unit), and the number of patients attended annually, by the professional and by the hospital. The results were compared using Chi-square test to compare proportions (Table 1), a mean comparison test for independent groups (Student T-test) to compare across two categories of variables (Table 2) or analysis of the variance of one route (ANOVA with Bonferroni correction) for variables with more than two categories. Statistical significance was set at $p < 0.05$. All analyses were performed with the Stata 15.0 statistical package (StataCorp LLC, College Station, TX, USA).

Table 1. Description of the participants stratified according to their nationality.

	Argentina	Spain	Total	*p*-Value
Gender				
Men	121 (51.27%)	97 (44.10%)	218 (47.80%)	
Women	115 (48.73%)	123 (55.90%)	238 (52.19%)	$p = 0.125$
Total	236 (100%)	220 (100%)	456 (100%)	
Age				
<35 yo	130 (54.62%)	80 (36.36%)	210 (45.85%)	
35–50 yo	66 (27.73%)	105 (47.73%)	171 (37.35%)	
51–65 yo	16 (6.72%)	17 (7.73%)	33 (7.20%)	$p = 0.001$
>65 yo	26 (10.93%)	18 (8.18%)	44 (9.60%)	
Total	238 (100%)	220 (100%)	458 (100%)	
Professional career period				
MR	0 (0%)	8 (3.63%)	8 (1.75%)	
MAS	169 (71.00%)	127 (57.73%)	296 (64.63%)	
Head of Service	67 (28.99%)	74 (33.64%)	141 (30.78%)	$p = 0.001$
Other	2 (0.01%)	11 (5%)	13 (2.84%)	
Total	238 (100%)	220 (100%)	458 (100%)	
Speciality				
General Surgery	0 (0%)	126 (56.25%)	126 (27.27%)	
Plastic Surgery	72 (30.25%)	61 (27.23%)	133 (28.78%)	
Mastology *	122 (51.26%)	0 (0%)	122 (26.41%)	$p = 0.001$
Others Speciality	44 (18.49%)	37 (16.52%)	81 (17.54%)	
Total	238 (100%)	224 (100%)	462 (100%)	

Table 1. *Cont.*

	Argentina	Spain	Total	*p*-Value
Kind of service				
Breast Unit	131 (39.70%)	199 (88.83%)	330 (71.42%)	$p = 0.001$
Without Breast Unit	107 (81.06%)	25 (11.16%)	132 (28.57%)	
Total	236 (100%)	224 (100%)	462 (100%)	
Hospital				
Public	94 (39.50%)	172 (76.79%)	266 (57.58%)	$p = 0.001$
Private	144 (60.50%)	52 (23.21%)	196 (42.42%)	
Total	238 (100%)	224 (100%)	462 (100%)	
BC cases/year/hospital				
<100	106 (44.54%)	54 (24.66%)	160 (35.01%)	$p = 0.001$
100–149	52 (21.85%)	41 (18.72%)	93 (20.35%)	
150–199	30 (12.61%)	32 (14.61%)	62 (13.56%)	
200–249	19 (7.98%)	24 (10.96%)	43 (9.40%)	
>250	31 (13.02%)	68 (31.05%)	99 (21.66%)	
Total	238 (100%)	219 (100%)	457 (100%)	
BC cases/year/doctor				
<100	151 (63.44%)	94 (41.96%)	245 (53.03%)	$p = 0.001$
100–149	42 (17.65%)	48 (21.42%)	90 (19.48%)	
150–199	15 (6.30%)	13 (5.80%)	28 (6.06%)	
200–249	12 (5.05%)	14 (6.25%)	26 (5.63%)	
>250	18 (7.56%)	38 (16.96%)	56 (12.12%)	
NSNC	0 (0%)	17 (7.58%)	17 (3.68%)	
Total	238 (100%)	224 (100%)	462 (100%)	
% of use of the SDM				
<33%	49 (20.85%)	19 (8.72%)	68 (15.01%)	$p = 0.001$
33–66%	53 (22.55%)	28 (12.84%)	81 (17.88%)	
>66%	67 (28.51%)	149 (68.35%)	216 (47.69%)	
N/A	66 (28.09%)	22 (10.09%)	88 (19.42%)	
Total	235 (100%)	218 (100%)	453 (100%)	

* Speciality only recognized in Argentina. Abbreviations: BC (Breast Cancer), MAS (Medical Area Specialist), MR (Medical Resident), N/A (no answer), SDM (shared decision-making), yo (years old).

Table 2. Average response values for each survey question.

	Survey Questions	Mean (CI 95%)	Argentina	Spain	*p*-Value
1	I am familiar with the concept and rationale of Shared Decision Making (SDM)	4.43 (4.36–4.50)	4.51 (4.42–4.60)	4.33 (4.22–4.45)	$p = 0.027$
2	The SDM is a necessary survey to provide quality assistance.	4.48 (4.42–4.55)	4.45 (4.36–4.54)	4.51 (4.42–4.61)	$p = 0.289$
3	The importance of SDM increases when there are several treatment options with similar outcomes, where the selection of one or another option depends on the patient's preferences.	4.44 (4.37–4.50)	4.43 (4.34–4.52)	4.44 (4.35–4.54)	$p = 0.741$
4	All physicians should ask their patients exactly how they would like to participate in decision-making.	4.29 (4.22–4.36)	4.32 (4.22–4.41)	4.26 (4.16–4.36)	$p = 0.429$
5	SDM increases patient satisfaction, improves cost-effectiveness and reduces malpractice claims.	4.35 (4.28–4.41)	4.34 (4.25–4.27)	4.36 (4.23–4.44)	$p = 0.708$
6	SDM is a basic element in the physician's relationship with breast cancer (BC) patients.	4.58 (4.51–4.64)	4.79 (4.72–4.85)	4.33 (4.23–4.44)	$p = 0.001$
7	All doctors should inform their patients about the different treatment options available for their health problem.	4.61 (4.55–4.67)	4.57 (4.48–4.67)	4.66 (4.58–4.73)	$p = 0.211$
8	All doctors should explain all treatment options to their patients, including the possibility of not providing any treatment at all.	4.62 (4.56–4.69)	4.79 (4.71–4.84)	4.44 (4.32–4.55)	$p = 0.001$
9	All doctors should explain to their patients the benefits, risks and side effects of possible treatments.	4.72 (4.67–4.78)	4.77 (4.71–4.83)	4.67 (4.58–4.75)	$p = 0.036$

Table 2. *Cont.*

	Survey Questions	Mean (CI 95%)	Argentina	Spain	*p*-Value
10	All doctors should help their patients understand all the information provided to them.	4.52 (4.46–4.59)	4.35 (4.25–4.44)	4.73 (4.66–4.80)	$p = 0.001$
11	All doctors should ask their patients which treatment option they prefer.	4.32 (4.25–4.38)	4.19 (4.11–4.27)	4.46 (4.37–4.55)	$p = 0.001$
12	Most patients feel that the doctor is the best person to decide on the best treatment option.	4.38 (4.31–4.44)	4.57 (4.49–4.65)	4.15 (4.07–4.24)	$p = 0.001$
13	All doctors should give their patients enough time to assess the different treatment options.	4.38 (4.32–4.45)	4.25 (4.14–4.36)	4.54 (4.46–4.62)	$p = 0.001$
14	All doctors should choose the treatment option together with their patients.	4.29 (4.21–4.37)	4.35 (4.24–4.45)	4.22 (4.11–4.34)	$p = 0.135$
15	All doctors should agree with their patients to monitor their process.	3.80 (3.71–3.89)	3.64 (3.53–3.80)	3.98 (3.84–4.11)	$p = 0.001$
16	My Unit has experience in the use of SDM in breast cancer.	3.80 (3.71–3.88)	3.65 (3.54–3.76)	3.97 (3.85–4.09)	$p = 0.001$
17	My Unit has a specific consultation to explain treatment options and facilitate SDM.	3.34 (3.24–3.44)	3.41 (3.29–3.53)	3.26 (3.10–3.42)	$p = 0.179$
18	My Unit has the necessary time to practice the practice of MDS in the care of the BC	3.45 (3.35–3.55)	3.63 (3.50–3.76)	3.24 (3.09–3.40)	$p = 0.001$
19	My Unit has the necessary materials to practice the SDM in the BC	3.46 (3.37–3.55)	3.61 (3.49–3.72)	3.29 (3.15–3.43)	$p = 0.001$
20	My hospital should promote more patient communication and the BC	3.96 (3.88–4.04)	3.98 (3.87–4.08)	3.93 (3.82–4.05)	$p = 0.799$
21	In general, there should be more training on patient communication and BC	4.33 (4.27–4.40)	4.41 (4.33–4.48)	4.25 (4.15–4.35)	$p = 0.023$
22	SDM can be useful for private health care, but it has no application in public health care, the patient cannot decide on the most efficient treatment option.	2.10 (2.00–2.20)	2.49 (2.34–2.64)	1.65 (1.53–1.76)	$p = 0.001$
23	In the future, there will be an increasing application of SDM in BC care.	4.33 (4.27–4.40)	4.34 (4.25–4.42)	4.33 (4.23–4.43)	$p = 0.910$

Abbreviations: CI (confidence interval).

3. Results

A total of 541 doctors viewed the survey, and of these, 459 (84.84%) provided demographic information and answered at least 25% of the questions and one question based on content (participation rate). The majority of participants (443/459; 96.51%) completed all questions (completion rate). There were only 5% of unanswered questions, which was not significant. No pattern to the unanswered questions was found.

3.1. Participants

Table 1 summarised the socio-demographic and professional characteristics of the participants and compared then between countries. There was a similar representation of both sexes, mostly under 50 years old, with various specialities distribution. Most participants belonged to a breast unit (71.42%; $p = 0.001$), but only one third worked in hospitals with more than 200 cases per year (31.06%; $p = 0.001$). When comparing between Argentina and Spain, differences in age (younger professionals in Argentina) and the speciality stand out. A total of 51.26% of Argentine professionals were classified as mastologists, a speciality that does not exist in Spain and which is replaced by 56.25% of general surgeons ($p = 0.001$). It was more frequent in Spain than in Argentina to belong to a breast unit (88.33% vs. 39.70%; $p = 0.001$) and work in a public hospital (76.79% vs. 39.50; $p = 0.001$).

3.2. Global Analysis of the Survey and Comparison between Countries

Table 2 presents the results of the questionnaire. The majority responses were in all cases values 4 "agree" and 5 "strongly agree", except for question 22. The first five questions, about the degree of knowledge of the SDM, obtained a high concordance. Only in the first case, there was a slightly higher score in the Argentine participants (4.51 vs. 4.33), but still statistically significant ($p = 0.027$). The opinion about SDM questions (questions 6-12) revealed a very positive attitude about SDM, which was higher for Argentinean

surgeons in terms of the usefulness of SDM in the relationship with patients (question 6, 4.79 vs. 4.33; $p = 0.001$), also obtaining a higher score in the obligation to explain to patients (question 9, 4.77 vs. 4.67; $p = 0.036$). The Spanish were more willing to help patients understand the information (question 10, 4.73 vs. 4.35; $p = 0.001$) and ask about their expectations (question 11, 4.46 vs. 4.19; $p = 0.001$).

Concerning the questions that measured attitude and awareness about SDM (questions 13–15), question 13, on providing sufficient time, also obtained a high level of agreement, greater in the Spanish practitioners (4.25 vs. 4.54; $p = 0.001$). All these results are presented in Table 2. Question 14, on the joint choice of treatment, also got an enormous agreement but without significant differences between countries ($p = 0.135$). However, when it comes to monitoring the process, question 15, the degree of agreement decreased, particularly in Argentina (3.80 vs. 3.65; $p = 0.001$). Regarding the degree of current and future application of SDM (questions 16–23), the survey obtained the lowest values. Question 17, on the existence of a specific consultation (3.41 vs. 3.26; $p = 0.179$), and questions 18 (3.63 vs. 3.24; $p = 0.001$) and 19 (3.61 vs. 3.29; $p = 0.001$), on the availability of the necessary time and resources respectively, got lower results in Spain. There was high agreement on the need for more training (question 21), significantly higher in Argentina (4.41 vs. 4.25; $p = 0.023$), and on the future growing application (question 23). There was low agreement on Spain's public and private assistance than Argentina (1.65 vs. 2.49; $p = 0.001$).

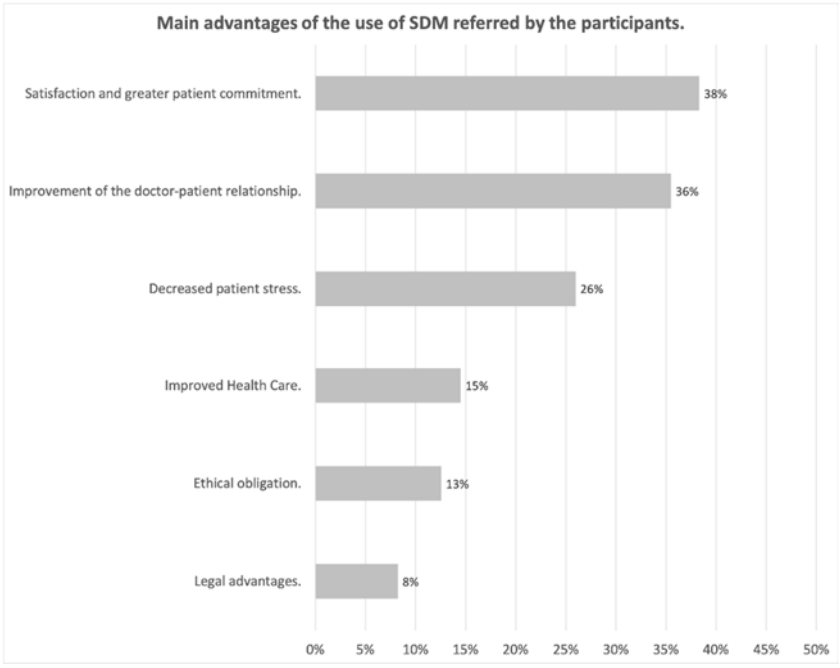
When the responses were stratified by sex, the highest score obtained by women for questions 9 (4.80 vs. 4.64; $p = 0.004$), 10 (4.61 vs. 4.44; $p = 0.007$) and 11 (4.40 vs. 4.23; $p = 0.009$) stood out, revealing a more empathetic attitude on the part of the women, who in turn are more aware of the need for SDM as a quality tool, question 2 ($p = 0.003$). In contrast, men were more likely to consider the doctor the most appropriate person to decide, question 12 ($p = 0.033$). Regarding age, significant differences in favour of younger professionals (doctors more youthful than 50 years old) were observed for questions 6–9, related to attitude, and for that referring to a future application, question 23 (4.41 vs. 4.24; $p = 0.041$).

When analysing the answers by speciality, the highest degree of agreement of the specialists in mastology concerning questions 1 (knowledge of the fundamentals of SDM), 6 (SDM as a basic element of the relationship with the patients), 8 (obligation to explain) and 12 (the patient believes that the doctor should choose the treatment) stood out. Argentinian had more time (question 18) and were more predisposed to recognise differences between public and private care (question 22). Plastic surgeons stood out for the greater agreement regarding the usefulness of SDM when there were several alternatives (question 3) and the need to explain the different treatment options (question 7), their advantages and disadvantages (question 9), and the need for further training (question 21). Finally, the general surgeons claimed the need to help patients understand the information (question 10) and the necessity of time to do so (question 13). Concerning the existence of a Breast Unit, there were few significant differences. However, when there was one, more emphasis was placed on incorporating the patient into the follow-up process (question 15), and the greater experience was highlighted (question 16). On the other hand, when not working in a breast unit, the results were higher for question 6 (SDM as a basic element of the relationship with patients), 8 (obligation to explain) and the need for the joint choice of treatment with patients (question 14), but they also agreed that patients generally consider that it is the doctor who should decide (question 12).

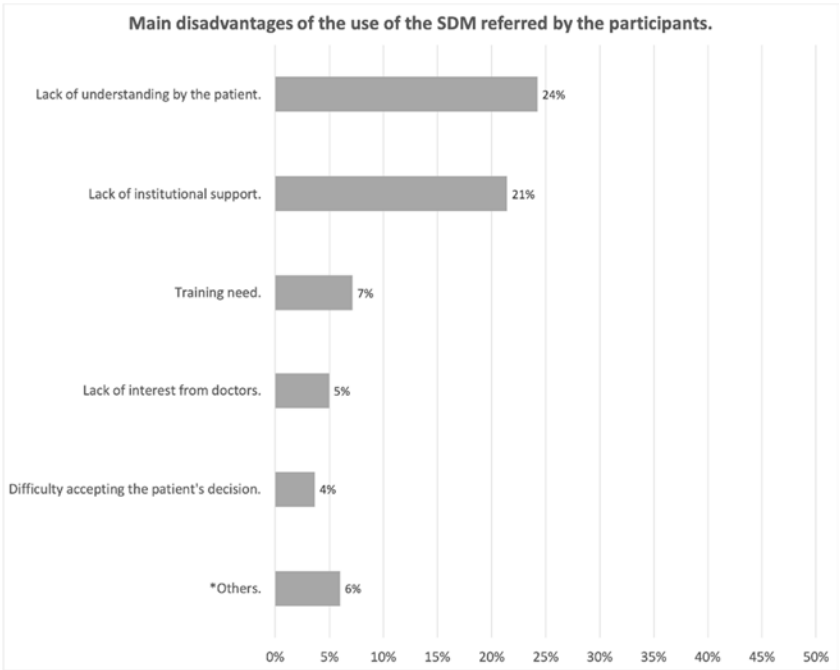
3.3. Advantages, Disadvantages and Main Obstacles to the Implementation of the SDM

Figure 1a and b shows the main advantages and disadvantages of SDM, as reported by participants. The main advantages highlighted were patient satisfaction and greater commitment to treatment (38%), improvement in the doctor-patient relationship, thus increasing confidence in the doctor (36%) and reduction in patient stress by helping them to understand their illness (26%). The main drawback was the lack of patient literacy (24%) followed by the lack of institutional support, lack of means, and time in consultation to

implement it (21%). Concerning the obstacles, Figure 2, widely highlighted the lack of time and resources or materials (a proper SDM consultation available, training courses for practitioners, . . .) for the implementation of SDM, pointed out by 40% of the respondents.



(**a**)



(**b**)

Figure 1. (**a**) Main advantages of the use of the SDM referred by the participants; (**b**) Main disadvantages of the use of the SDM referred by the participants (* Others: lack of universality, delay in the patient's decision and difficult applicability).

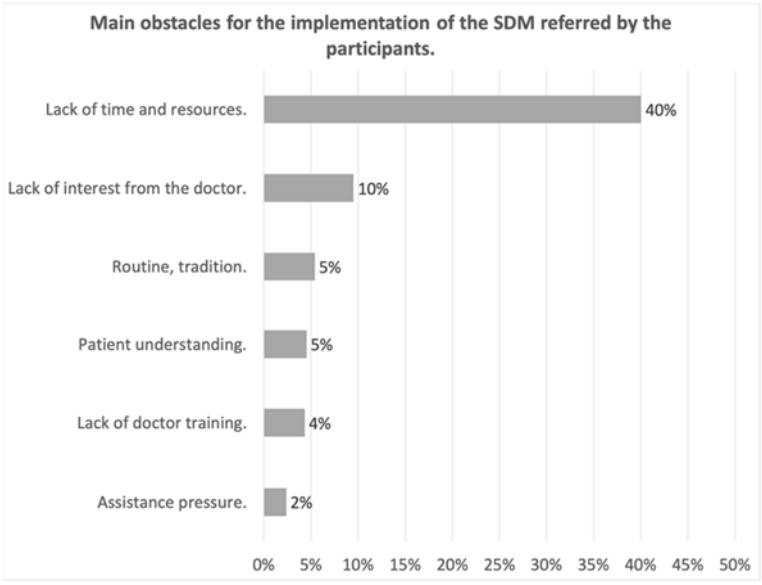


Figure 2. Main Obstacles for the implementations of the SDM.

4. Discussion

Most of the professionals who answered the survey had a broad knowledge and a favourable opinion about SDM. Spanish speaking practitioners were keener to help the patient understand the information process and ask about patient expectations. More Argentineans thought about SDM as an essential element in BC management and an obligation to pursue. Regarding the awareness-raising and attitude about SDM, participants, mainly Spanish, agreed on the necessity of providing enough time to practice SDM and on the joint choice of treatment. Concerning the current and future application of SDM, there was high agreement on the need for more training. The least agreement was observed for the necessity to agree with patients on the process's follow-up and the current and future implementation. This was mainly in the availability of specific consultations or time and resources for SDM in the participant service. On the other hand, participants highlighted patient satisfaction and a more significant commitment to treatment as the main advantage of SDM and the lack of patient preparation to understand their illness as the main drawback. They pointed out the lack of time and resources as the main obstacle.

4.1. Strengths and Limitations

The design and presentation of the study have followed the CHERRIES publication guideline [22,23], so necessary measures have been taken to maintain the quality required in this type of research. The results were underpinned by the inclusion of a significant number of participants, 459, all from different specialities and periods of professional careers in Europe and Latin America, with very different health systems [31].

The lack of established psychometrics of the survey could be considered a limitation. However, this psychometric validation aimed typically to adapt and validate an instrument to measure elements of frequently ambiguous context. In our study, knowledge and attitudes were measured without quantifying or integrating the responses into a complex index.

The main limitation results from the participants' selection bias implicit in online surveys, which possibly leads to responses in favour of SDM. Social desirability bias was inherent to this kind of survey. It could have led professionals to answer based on social expectations rather than their real attitudes towards SDM [32]. Anonymity and confidentiality of the answers were used to reduce it [33]. Therefore, the possible existence of a selection and social-desirability bias further reinforces the results obtained: even among those professionals most likely to use SDM, there is a lack of use, and in particular of time and resources.

On the other hand, sending the survey by open distribution made it impossible to estimate the real response rate [28,29]. E-mail distribution of surveys has a lower response rates than other distribution routes such as telephone surveys [29]. Fortunately, previous reviews identified smaller-than-anticipated differences between physician respondents and non-respondents and between early and late responders [34–36], suggesting low nonresponse bias rates [28]. The completion rate was high, suggesting recognition of the importance of this issue to quality health practice today.

The questionnaire was validated by a pilot test sent to fifteen BC specialist. We were using questions to explore concepts, believes and attitudes. No other tools were found useful to measure these aspects, so we did not have a gold-standard to validate how accurately the selected questions assess every domain (knowledge, opinion, awareness-raising and attitude about SDM, and current or future application of it). Lack of answer variability is problematic in telemedicine surveys because of its harmful effects in responses sensitivity and reliability. This ceiling effect resulted from high satisfaction ratings. Although one presumed solution would be to create a rating scale with more significant discrimination of responses in the continuum scale [37], some studies have found the number of rating points unrelated to cross-sectional reliability [38,39]. There was not enough evidence to support this statement [37]. We have created a 5-point Likert scale that has been demonstrated assurance before [26,27].

Regarding comparisons referring to 23 items as a dependent variable, we could suppose that part of the differences detected might be due only to chance. This was an additional limitation, mainly when the effect of age, sex, size and setting of the hospital and the participant's speciality has been analyzed for each item. Determined patterns have not been appreciated, and the results were interpreted with great caution.

Regarding participants' characteristics, most of the participants did not belong to breast units. This was possibly due to the high requirements necessary to constitute a breast unit [40], which means that there were not too many breast units in hospitals in absolute numbers. A more decisive data were the number of patients treated by each participating physician. A total of 46.97% of the participants treated more than 100 patients per year, a significant number of cases in individual terms and allowed consistency to the findings found in this study.

It has also been shown that participants under 50 years old were opener to SDM. However, it might probably influence that doctors under 50 years of age were more familiar with our survey's distribution networks. However, a more precise analysis could observe that most participants were under 50 years of age because they were the vast majority of active workers in BC today. In the majority of the countries, the retirement age is contemplated from 65 years. Moreover, apart from the fact that this older population would presumably be less interested in updating their knowledge, it was also less interesting for our study since they did not represent active BC management work.

4.2. Implications

To our knowledge, this study was the first international survey of BC specialists on the understanding, attitude and application of SDM. This was surprising as SDM is an essential component of quality health care [8,9] and a legal obligation in most developed countries [11–13]. The practice of SDM in cancer care has been proposed as a crucial element to change a system's course in crisis towards excellence and sustainability [4]. Its implementation in BC care constitutes a very demanding path, which implies the creation of multidisciplinary teams with a high scientific-technical level, excellent coordination, continuity of care and communication with the patient, and a persistent review of the results of a continuous improvement program. Although there are no previous studies of the environmental impact that SDM could cause, it would be logical to think that increasing the efficiency and quality of BC management would reduce the use of resources. This would ultimately be one more foothold to impulse the use of SDM. More studies should be done to support this statement.

As no similar work about SDM in practitioners has been done before, comparisons between researches were impossible to obtain. Therefore, this highlights the importance of this study because the findings were significant in themselves. The study's basis and design were very innovative. Previous surveys done about SDM were about patients' perception and experience [41–43]. All these studies reported a low application of SDM. Moreover, a similar study was done in medical students with similar knowledge results [44]. Still, as they were participants in training and not practitioners, the study was limited since they could not put SDM into practice.

The results refer exclusively to BC, a disease that highlights the importance of SDM in cancer care management. In BC, the different alternatives that exist require an exchange of information between doctor and patient and the inclusion of personal values and preferences for the decision of the best therapeutic option [8,45].

The health administration should promote the application of SDM in normal clinical practice, but it is a slow and challenging process [17,18,46–48]. It requires developing robust, valid and reliable methodological tools, specific training of professionals, and providing the time and environment to be put into practice [4,8,48–50]. The perceived lack of time as a barrier for SDM is not an issue when the consultations are conducted in a structured way towards SDM, and the physicians are trained to do so [47]. Clinical practice guidelines and consensus would play a fundamental role in guiding physicians in practice it [19]. This study identifies a very positive attitude towards SDM on the part of health professionals, who, aware of the usefulness of SDM, and its impact on the quality of care, insist on the need for training, resources and time to be able to put it into practice, with a marked coincidence between professionals from such different social and health contexts as Argentina and Spain. This study has not investigated Argentina and Spain's cultural differences, so it would be necessary to carry out another study. However, we could conclude that Argentine Healthcare seems to be more privatised than Spanish, which could influence a more significant presence of time and resources for SDM in Argentine Healthcare.

5. Conclusions

The professionals involved in treating BC had a high level of knowledge and a positive attitude towards SDM. Its reported application was greater in Spain than in Argentina and in breast units. Lack of time was identified as the main obstacle to its implementation. Health administrations should provide the necessary training and material and human resources for the effective implementation of SDM in the BC care.

Author Contributions: Data curation, M.M.-C., M.M.-D., L.M. and A.B.-C.; Formal analysis, M.M.-C., M.M.-D. and A.B.-C.; Investigation, M.M.-C.; Methodology, L.M., K.S.K. and A.B.-C.; Visualization, K.S.K.; Writing—original draft, M.M.-C.; Writing—review & editing, R.T. All authors have read and agreed to the published version of the manuscript.

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Institutional Review Board Statement: The study was conducted according to the Declaration of Helsinki's guidelines, and approved by the Institutional Review Board (or Ethics Committee) of Bioethics Committee from University of Almería (Ref. 126/2019).

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Data Availability Statement: Not applicable.

Conflicts of Interest: The authors declare no conflict of interest.

Appendix A

Cuestionario sobre la práctica de la toma de decisiones compartida (TDC) en el tratamiento del cáncer de mama (CM).

Instrucciones:

Estimado compañero, estamos analizando el uso de la TDC en el CM. Nuestro objetivo es evaluar los conocimientos y el uso de la TDC en el tratamiento del CM por los profesionales sanitarios, y para ello te pedimos que respondas las siguientes cuestiones. En ningún momento te pediremos ningún dato personal y por supuesto trataremos toda la información de acuerdo con la Ley Orgánica 3/2018, de 5 de diciembre, de Protección de Datos Personales y garantía de los derechos digitales. Asumimos que al contestar el cuestionario das tu permiso para la utilización de la información que proporcionas, y te agradecemos enormemente tu colaboración.

Selecciona la respuesta más acorde.

- ○ Sexo:
  - ○ Hombre.
  - ○ Mujer.
- ○ Edad:
  - ○ <35 años.
  - ○ 36–50 años.
  - ○ 51–65 años.
  - ○ >65 años.
- ○ ¿En qué periodo de su carrera profesional se encuentra?
  - ○ Médico Interno Residente (MIR).
  - ○ Facultativo Especialista de Área (FEA).
  - ○ Responsable de Servicio o Unidad.
  - ○ Otros: _____
- ○ ¿Qué tipo de especialidad tiene?
  - ○ Cirugía General
  - ○ Ginecología y Obstetricia
  - ○ Anatomía Patológica
  - ○ Radiología
  - ○ Oncología
  - ○ Medicina de Familia
  - ○ Otros: _____
- ○ Tipo de Servicio o Unidad donde desarrolla su ejercicio:
  - ○ Servicio de Cirugía General y del Aparato Digestivo o Ginecología y Obstetricia.
  - ○ Servicio de Cirugía General o Ginecología con especial dedicación a la Mama.
  - ○ Unidad de Mama.
  - ○ Otros: _____
- ○ Ámbito donde desarrolla su ejercicio (puede marcar más de una opción):
  - ○ Hospital público o perteneciente al Servicio Sanitario Público.
  - ○ Compañía u Hospital Privado.
  - ○ Otras situaciones: _____

Si señalaste la primera opción, Hospital Público, puedes indicar a que categoría corresponde:

- ○ Hospital regional o de referencia
- ○ Hospital de especialidades
- ○ Hospital de área o comarcal
- ○ Hospital de alta resolución

- ○ Número de casos de Cáncer de Mama atendidos por su Servicio o Unidad al año:
  - ○ <100
  - ○ 100–149
  - ○ 150–199.

- ○ 200–249
- ○ 250 o más

○ Número de pacientes con Cáncer de Mama atendidos en consulta por usted al año:

- ○ <100
- ○ 100–149
- ○ 150–199.
- ○ 200–249
- ○ 250 o más

○ Porcentaje de casos de Cáncer de Mama atendidos en su hospital en los que se realiza una toma de decisiones compartidas

- ○ <33%
- ○ 33–66%
- ○ >66%
- ○ No lo sé

Seleccione la respuesta más acorde con su opinión o experiencia. Intente no dejar preguntas en blanco:

		Totalmente en Desacuerdo	En Desacuerdo	Ni de Acuerdo ni en Desacuerdo	De Acuerdo	Totalmente de Acuerdo
1	Conozco el concepto y los fundamentos de la Toma de Decisiones Compartida (TDC)	1	2	3	4	5
2	La TDC es una herramienta necesaria para proporcionar una asistencia de calidad.	1	2	3	4	5
3	La importancia de la TDC aumenta cuando existen diversas opciones de tratamiento con resultados similares, en las que la selección de una u otra opción depende de las preferencias del paciente.	1	2	3	4	5
4	La TDC aumenta la satisfacción del paciente, mejora la rentabilidad y reduce las demandas por negligencia.	1	2	3	4	5
5	La TDC es un elemento básico en la relación del cirujano con los pacientes con Cáncer de Mama (CM).	1	2	3	4	5
6	Todos los médicos deberían preguntar a sus pacientes exactamente cómo les gustaría participar en la toma de decisiones.	1	2	3	4	5
7	Todos los médicos deberían informar a sus pacientes sobre las diferentes opciones de tratamiento existentes para su problema de salud.	1	2	3	4	5
8	Todos los médicos deberían explicar a sus pacientes todas las opciones de tratamiento, incluyendo la posibilidad de no realizar ningún tratamiento.	1	2	3	4	5
9	Todos los médicos deberían explicar a sus pacientes los beneficios, riesgos y efectos secundarios de los posibles tratamientos.	1	2	3	4	5
10	Todos los médicos deberían ayudar a sus pacientes a entender toda la información que se les proporciona.	1	2	3	4	5

		Totalmente en Desacuerdo	En Desacuerdo	Ni de Acuerdo ni en Desacuerdo	De Acuerdo	Totalmente de Acuerdo
11	Todos los médicos deberían preguntar a sus pacientes qué opción de tratamiento prefieren.	1	2	3	4	5
12	La mayor parte de los pacientes considera que el médico es la persona más adecuada para decidir cuál es la mejor opción terapéutica.	1	2	3	4	5
13	Todos los médicos deberían proporcionar a sus pacientes el tiempo suficiente para que puedan valorar las diferentes opciones de tratamiento.	1	2	3	4	5
14	Todos los médicos deberían escoger conjuntamente con sus pacientes la opción de tratamiento.	1	2	3	4	5
15	Todos los médicos deberían consensuar con sus pacientes el seguimiento de su proceso.	1	2	3	4	5
16	Mi Unidad tiene experiencia en el uso de la TDC en cáncer de mama.	1	2	3	4	5
		Totalmente en Desacuerdo	**En Desacuerdo**	**Ni de Acuerdo ni en Desacuerdo**	**De Acuerdo**	**Totalmente de Acuerdo**
17	Mi Unidad dispone de una consulta específica para explicar las opciones de tratamiento y facilitar la TDC.	1	2	3	4	5
18	Mi Unidad dispone del tiempo necesario para practicar la TDC en la asistencia del CM	1	2	3	4	5
19	Mi Unidad dispone de los materiales necesarios para practicar la TDC en el CM	1	2	3	4	5
20	Mi hospital debería promocionar más la comunicación con el paciente y la TDC	1	2	3	4	5
21	En general, debería haber más formación sobre comunicación con el paciente y la TDC	1	2	3	4	5
22	La TDC puede ser útil para la asistencia sanitaria de carácter privado, pero no tiene aplicación en la asistencia sanitaria pública, el paciente no puede decidir sobre la opción de tratamiento más eficiente	1	2	3	4	5
23	En el futuro se aplicará cada vez más la TDC en la atención al CM	1	2	3	4	5

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6.7. Manuscript 6: Maes-Carballo M, Mignini L, Martín-Díaz M, Khan K S, Bueno-Cavanillas A. Encuesta sobre el uso de la toma de decisiones compartidas en el cáncer de mama.

The sixth objective was pursued in this manuscript: to spread the results about SDM knowledge, use and attitude in BC practitioners. Our team have developed a cross-sectional observational study on a convenience sample through an online survey distributed in various associations of surgeons in Spain and Argentina. The details of this survey were previously published (141). The data analysis showed that the majority of the participants knew the concept of SDM and had a favourable attitude towards its implementation. However, they were not unanimous regarding the need to reach a consensus with the patients on a follow-up of the process, the previous experience of each physician on the subject, or the availability of specific sources for the SDM implementation. The participants globally designated patient satisfaction as the main advantage of SDM, perceiving as the most limiting factor, the difficulty of the patient to understand their disease and as the main obstacle to its implementation, the lack of time and resources.

(Manuscript under review submitted to Cirugía Española)

Cirugía Española

Encuesta sobre el uso de la toma de decisiones compartidas en el cáncer de mama

--Borrador del manuscrito--

Número del manuscrito:	
Tipo de artículo:	Carta científica
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Revisores sugeridos:	yolanda Fandiño, M.D. Surgeon, Complexo Hospitalario de Ourense yfandino@gmail.com Especialista en Cáncer de mama y calidad del cuidado. Es experta en el analisis del proceso asistencial integrado y en la toma de decisiones compartidas.
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Revisores a los que se opone:	

Encuesta sobre el uso de la toma de decisiones compartidas en el cáncer de mama

Survey on the use of shared decision making in breast cancer

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1. Consideraciones éticas

Este estudio sigue las directrices de la Declaración de Helsinki y ha sido aprobado para su realización por el Comité de Ética e Investigación Provincial de Granada.

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3.1. Colaboradores

Todos los autores certifican una contribución sustancial a la concepción y diseño de la encuesta, búsqueda bibliográfica, establecimiento de los criterios de inclusión y exclusión de variables, búsqueda de vías de difusión, así como la extracción, análisis e interpretación de los datos. MMC participó en la concepción y el diseño de la encuesta, la búsqueda bibliográfica, la difusión, la recopilación y el análisis de datos y la redacción. LM participó en la difusión de la encuesta y la redacción. MMD participó en la concepción y el diseño de la encuesta y la redacción de los datos. ABC ayudó en la concepción y el diseño de la encuesta, en el análisis de datos, la redacción y proporcionó una revisión crítica del artículo. KSK proporcionó una revisión crítica del

documento. Todos los autores leyeron y proporcionaron la aprobación final de la versión que se publicará.

3.2. Apoyo financiero y patrocinio

La presente investigación no ha recibido ayudas específicas provenientes de agencias del sector público, sector comercial o entidades sin ánimo de lucro.

4. Declaración del intercambio de material complementario

Se puede acceder al material complementario previa solicitud por correo electrónico a los autores de este estudio.

5. Conflictos de interés

El estudio se realizó en la Universidad de Granada, España. No existen conflictos de intereses.

Carta Científica

La selección del tratamiento adecuado para cada paciente requiere en el cáncer de mama (CM) de un correcto diagnóstico de su enfermedad y sus preferencias[1]. Es esencial en este marco la toma de decisiones compartida (TDC), "un enfoque en el que los médicos y los pacientes comparten la mejor evidencia disponible cuando se enfrentan a la tarea de tomar decisiones y donde los pacientes reciben apoyo para considerar opciones y realizar decisiones de acuerdo con sus preferencias y valores"[2]. Es un concepto universalmente apoyado y vinculado a la calidad asistencial[2], constituye una obligación legal,[3] incrementa la satisfacción del paciente[4] y disminuye las demandas por mala praxis[5]. No obstante, su implementación real continúa siendo deficiente y persisten los obstáculos para su aplicación[6].

Por otra parte, el nivel de interés, conocimientos y actitud hacia la TDC de los profesionales sanitarios es fundamental para su correcta implementación. Nuestro equipo desarrolló un estudio observacional transversal sobre una muestra de conveniencia a través de una encuesta online distribuida en diversas asociaciones de cirujanos de España y Argentina y cuyos detalles han sido previamente publicados[7]. El objetivo fue investigar el nivel de conocimiento y la actitud sobre la TDC, así como el grado de aplicación actual y las expectativas de uso en el futuro (intención de integrar la TDC en la práctica habitual) y las ventajas, inconvenientes y obstáculos percibidos para su aplicación.

El análisis de los datos mostró que los encuestados mayoritariamente conocían el concepto de la TDC y mostraban una actitud claramente favorable hacia el desarrollo de políticas que favoreciesen su implementación, sin embargo, no fueron tan unánimes respecto a la necesidad de consensuar con los pacientes el seguimiento del proceso, la experiencia previa de cada facultativo sobre el tema, o la disponibilidad de consultas específicas y tiempo para la TDC. Los encuestados designaron globalmente como principal ventaja de la TDC la satisfacción del paciente, percibiendo como factor más limitante, la dificultad del paciente para entender su enfermedad y como principal obstáculo para su implementación, la falta de tiempo y recursos. Las Figuras 1 y 2 comparan las principales

ventajas e inconvenientes de la TDC y los principales obstáculos para su implementación referidos en cada país.

La principal limitación de este estudio deriva del sesgo de selección de los participantes, implícito a la realización de una encuesta online, que muy posiblemente fomenta la participación de profesionales favorables a la TDC. El sesgo de deseabilidad social también inherente a este tipo de estudios podría haber llevado a los profesionales a responder en función de las expectativas sociales en lugar de sus actitudes y aptitudes reales hacia la TDC. Se utilizó el anonimato y la confidencialidad de las respuestas para reducirlo. El envío de la encuesta por distribución abierta hizo imposible la estimación de la tasa de respuesta, presumiblemente baja[8] pero revisiones anteriores sugieren un bajo sesgo por falta de respuesta[8,9]. Sí se calculó la tasa de participación y de finalización, ambas elevadas, lo que sugiere el reconocimiento de la importancia que presenta este tema en la actualidad para la práctica sanitaria de calidad. Los resultados de esta encuesta están avalados por la inclusión a nivel internacional de un número importante de participantes, 459 profesionales de distintas especialidades en diversos periodos de la carrera profesional y sistemas sanitarios distintos.

Estos resultados contrastan con la escasa presencia de la TDC en las guías de cribado y tratamiento del CM. Una reciente revisión sistemática[10] realizada por nuestro equipo ha puesto de manifiesto que la TDC está escasamente recogida en guías de práctica clínica y documentos de consensos sobre el tratamiento del CM y en la mayoría de los casos sin que se incluyan recomendaciones específicas para su implementación. Aunque la TDC fue más frecuentemente incluida en documentos guía más recientes, sorprende que aparece en menor medida en aquellos publicados en revistas médicas, hecho que merece atención ya que estas deberían jugar un papel importante en su promoción.

Es fundamental que las administraciones sanitarias faciliten la formación y los recursos materiales y humanos necesarios si se quiere conseguir la implementación efectiva de la TDC en la atención del CM[6]. El hecho de que los profesionales entrevistados señalen la falta de tiempo como principal obstáculo para su implantación revela que este no es el caso ni en el sistema sanitario público

español ni en Argentina, dónde la mayoría de los participantes ejercen la medicina privada. La incorporación de la TDC en la práctica clínica requiere del diseño de políticas innovadoras que integren una formación adecuada de los profesionales con los incentivos y recursos necesarios para que la puedan poner en práctica[2]. La participación de los pacientes es fundamental para el avance de la medicina[2,4]. Es preciso fomentar la investigación sobre las políticas más adecuadas para involucrar pacientes y profesionales en la TDC, con la finalidad de proporcionar una asistencia sanitaria personalizada y participativa y, por lo tanto, de mayor calidad[4,7].

Palabras clave: "toma de decisiones compartidas", "cáncer de mama", "uso de toma de decisiones compartidas", "encuesta", "estudio transversal".

1. Abreviaturas

AEC (Asociación Española de Cirugía), AMAR (Asociación de Mastología de Rosario), AOC (Asociación de Oncología de Rosario), CM (cáncer de mama), SACPER (Sociedad Argentina de Cirugía Plástica, Estética y Reparadora), SAM (Sociedad Argentina de Mastología), SESPM (Sociedad Española de Senología y Patología Mamaria), TDC (toma de decisiones compartida).

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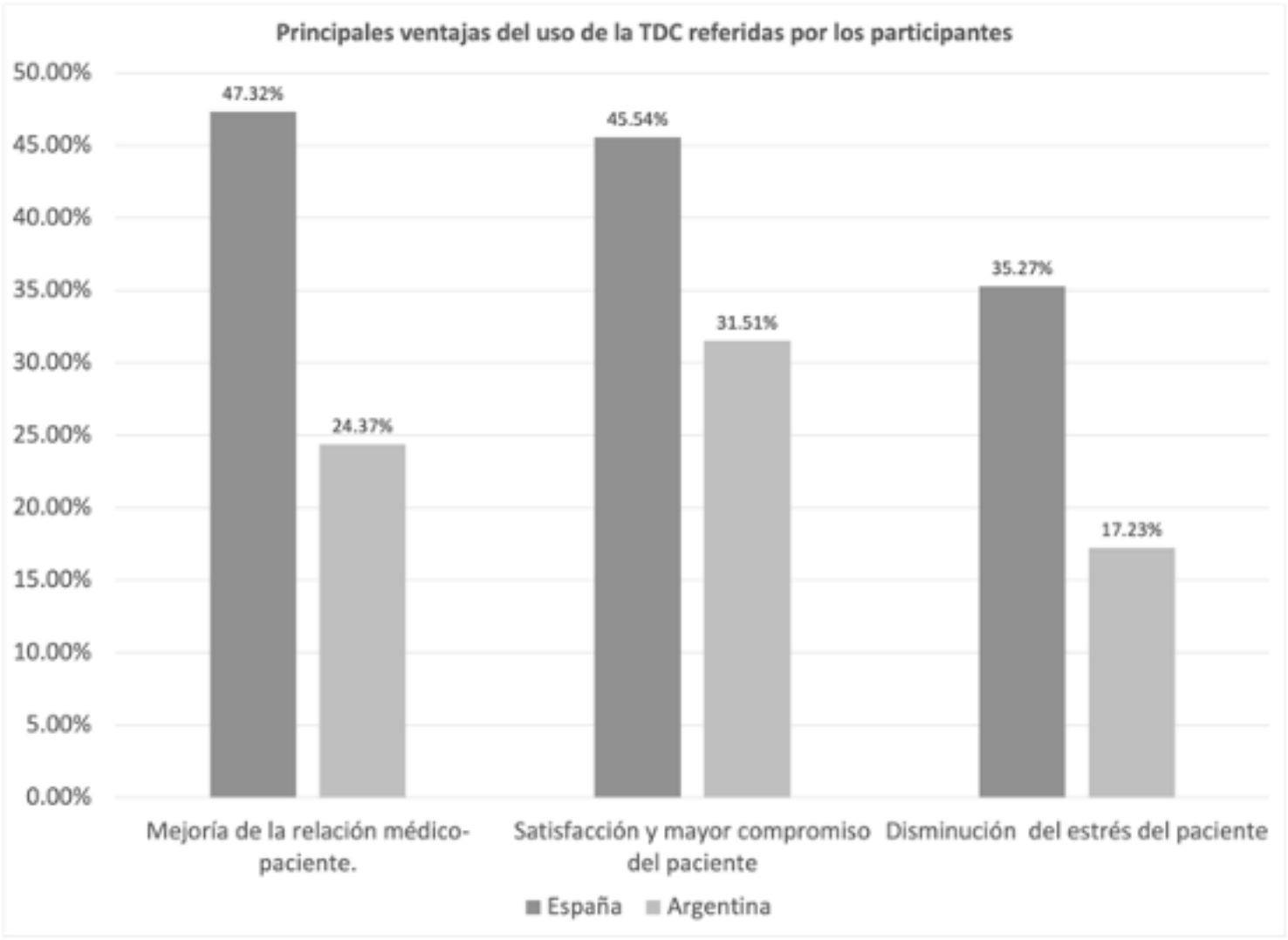
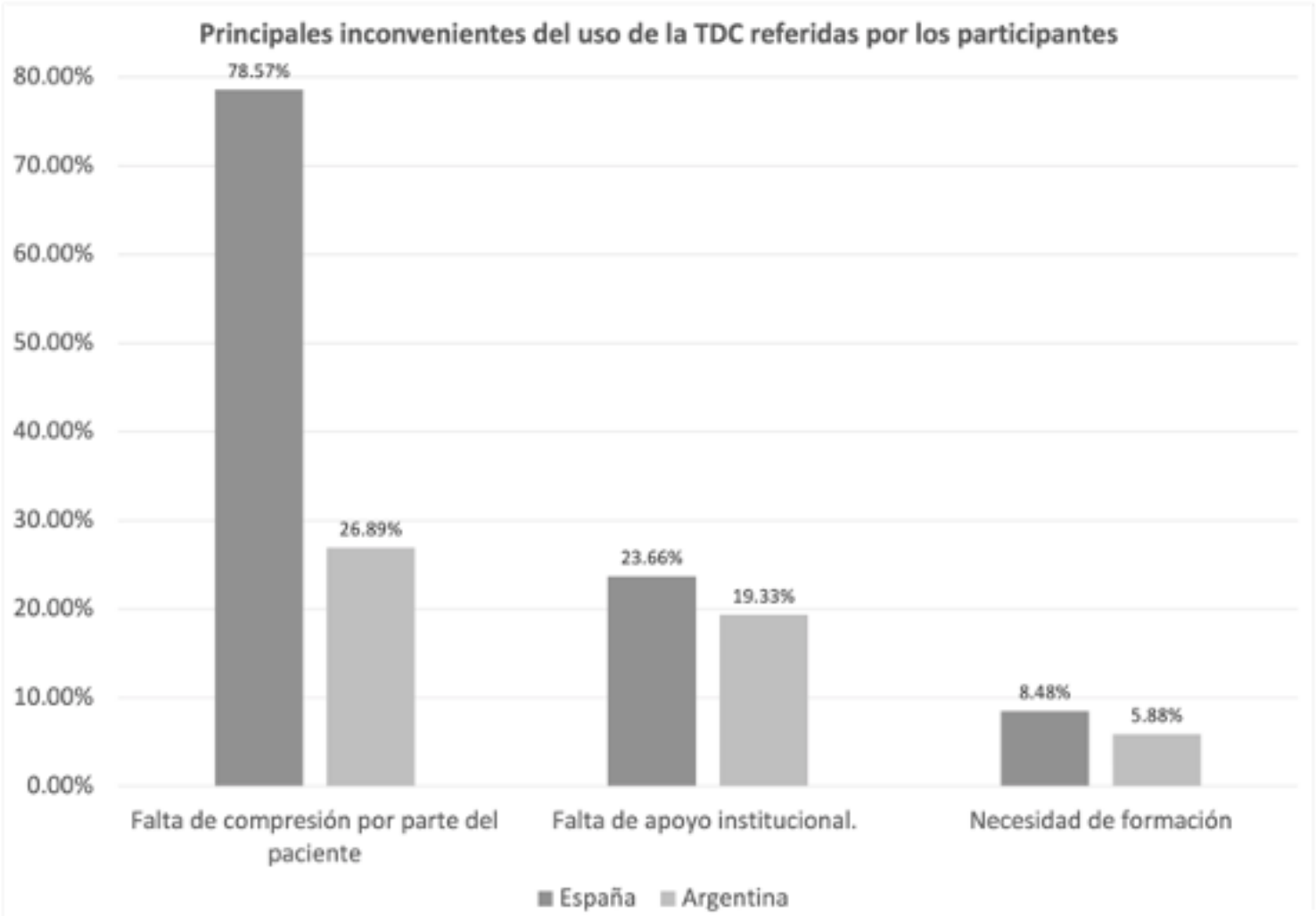
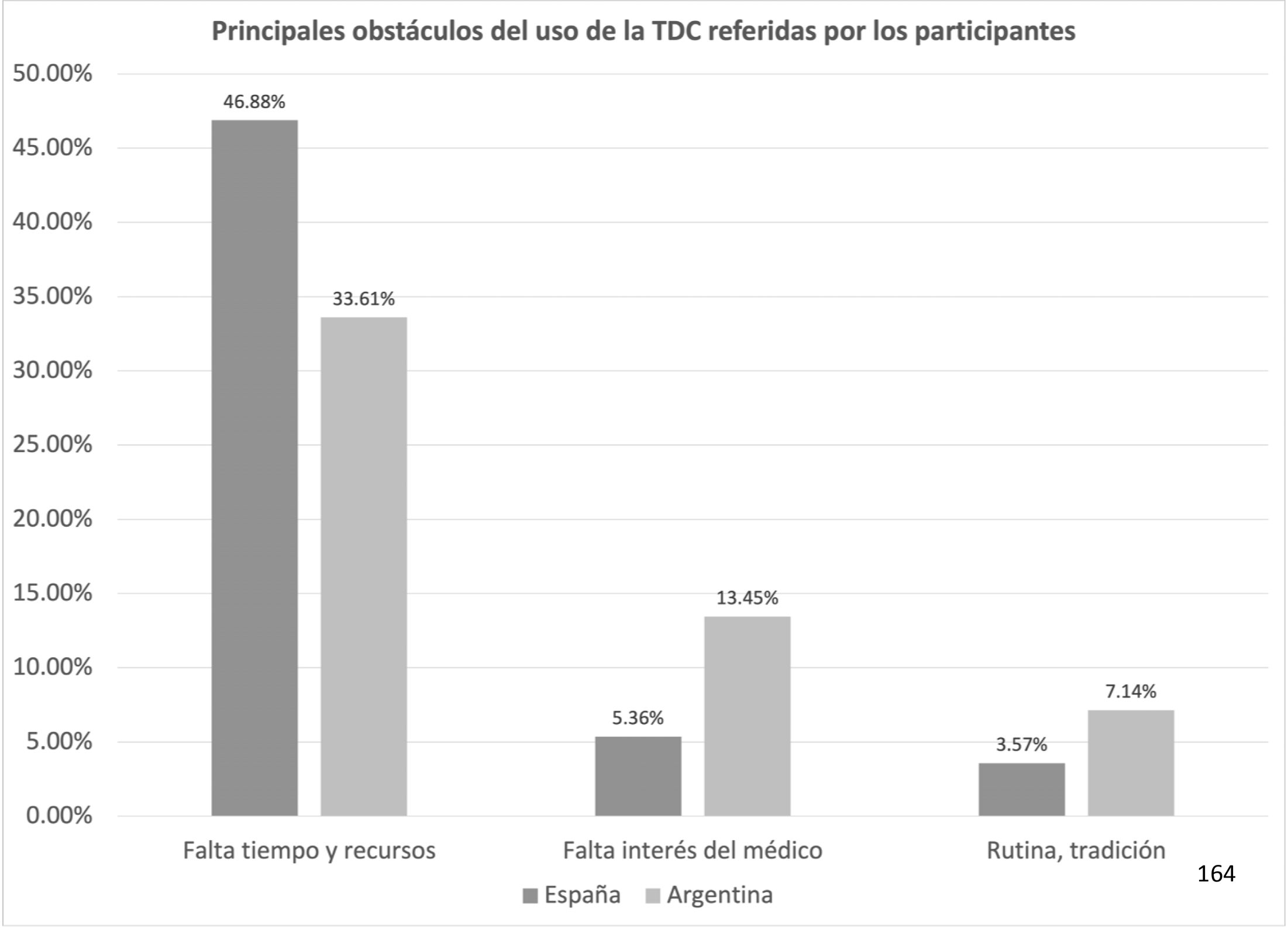

Principales ventajas del uso de la TDC referidas por los participantes
50.00%
45.00%
40.00%
35.00%
30.00%
25.00%
20.00%
15.00%
10.00%
5.00%
0.00%
47.32%
24.37%
45.54%
31.51%
35.27%
17.23%
Mejoría de la relación médico-paciente.
Satisfacción y mayor compromiso del paciente
Disminución del estrés del paciente
España
Argentina


Principales inconvenientes del uso de la TDC referidas por los participantes
80.00%
70.00%
60.00%
50.00%
40.00%
30.00%
20.00%
10.00%
0.00%
78.57%
26.89%
23.66%
19.33%
8.48%
5.88%
Falta de compresión por parte del paciente
Falta de apoyo institucional.
Necesidad de formación
España
Argentina


Principales obstáculos del uso de la TDC referidas por los participantes
50.00%
45.00%
40.00%
35.00%
30.00%
25.00%
20.00%
15.00%
10.00%
5.00%
0.00%
46.88%
33.61%
5.36%
13.45%
3.57%
7.14%
Falta tiempo y recursos
Falta interés del médico
Rutina, tradición
España
Argentina

6.8. Manuscript 7: Maes-Carballo M, Mignini L, Martín-Díaz M, Bueno-Cavanillas A, Khan K S. Clinical practice guidelines and consensus for the screening of breast cancer: a systematic appraisal of their quality and reporting.

This seventh work responds to analyze the quality and reporting of CPGs and CSs on BC screening (objective 7). We appraised the quality and reporting of CPGs and CSs BC screening using AGREE II statement and RIGHT instrument respectively, extracting data in duplicate; reviewer agreement was 98% and 93% respectively. Our study was reported following Prospero protocol registration and PRISMA. CPGs and CSs on BC treatment were identified, without language restrictions, through a wide systematic search of bibliographic databases (MEDLINE, EMBASE, Web of Science, Scopus, CDSR) and online sources (12 guideline databases and 84 professional society websites) from January 2017 to August 2020. There were 40 guidelines with median overall quality and reporting 51% (IQR 39-63) and 48% (IQR 35-65) respectively. Fithty-five (22) and half (20) did not reach the minimum standards (scores <50%). Guidances reporting a tool referral scored better (AGREE II: 72.8% vs 43.1%, p=0.002; RIGHT: 75.0% vs 46.9%, p=0.004) and the guidances deployed systematic reviews had better quality (74.2% vs 46.9%; p=0.001) and reporting (80.5% vs 42.6%; p=0.001). In conclusion, new policies for adequate training of professionals on integrating the SDM in clinical practice are necessary. Quality and reporting would improve if systematic reviews were used to underpin the recommendations made.

(Manuscript under review in Breast Cancer)

Breast Cancer

Clinical practice guidelines and consensus for the screening of breast cancer: a systematic appraisal of their quality and reporting.

--Manuscript Draft--

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Abstract:	Objective Assess the quality and reporting of clinical practice guidelines (CPGs) and consensus statements (CSs) for breast cancer (BC) screening. Methods A search of bibliographic databases (MEDLINE, EMBASE, Web of Science, Scopus, CDSR), 12 guideline databases and 51 professional society websites was performed without language restrictions from January 2017 to June 2020, following prospective registration (Prospero n o : CRD42020203807). AGREE II (% of maximum score) and RIGHT (% of total 35 items) were used for assessing quality and reporting respectively, extracting data in duplicate; reviewer agreement was 98% and 93% respectively. Results There were 40 guidelines with median overall quality and reporting 51% (IQR 39-63) and 48% (IQR 35-65) respectively. Twenty-two (55%) and 20 (50%) did not reach the minimum standards (scores <50%). Studying the methods of evidence analysis, the guidances deployed systematic reviews had better quality (74.2% vs 46.9%; p=0.001) and reporting (80.5% vs 42.6%; p=0.001). Guidances reporting a tool referral scored better (AGREE II: 72.8% vs 43.1%, p=0.002; RIGHT: 75.0% vs 46.9%, p=0.004). Conclusion

	BC screening CPGs and CSs suffered poor quality and reporting as more than half did not reach the minimum standards. Quality and reporting would improve if systematic reviews are used to underpin the recommendations made.
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	Benigno Acea-Nebril, phD Complexo Hospitalario Universitario A Coruña: Complexo Hospitalario Universitario A Coruna Benigno.Acea.Nebril@sergas.es One of the most important Spanish experts in oncoplastic surgery and reputed researcher in breast cancer quality care.
Author Comments:	High-quality, well-reported clinical practice guidelines (CPGs) and consensus statements (CSs) underpinned by systematic reviews are needed for breast cancer (BC). An evaluation of the quality and reporting in guidance documents for BC screening has not been reported previously. We appraised the quality and reporting of CPGs and CSs BC screening using AGREE II statement and RIGHT instrument. Previous evaluations of guidances in BC were only focused on treatment. So our team had released a complementary study (Maes et al. 2020) about analysis of quality and reporting in BC treatment guidelines and both studies have been correlated in the present article. This can be taken as one of the main strengths of this review as it gives a wide perspective of more than 100 BC guidances through the whole process, from diagnosis to treatment.

Clinical practice guidelines and consensus for the screening of breast cancer: a systematic appraisal of their quality and reporting

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Abstract

Purpose: Assess the quality and reporting of clinical practice guidelines (CPGs) and consensus statements (CSs) for breast cancer (BC) screening.

Methods: A search of bibliographic databases (MEDLINE, EMBASE, Web of Science, Scopus, CDSR), 12 guideline databases and 51 professional society websites was performed without language restrictions from January 2017 to June 2020, following prospective registration (Prospero nº: CRD42020203807). AGREE II (% of maximum score) and RIGHT (% of total 35 items) were used for assessing quality and reporting respectively, extracting data in duplicate; reviewer agreement was 98% and 93% respectively.

Results: There were 40 guidelines with median overall quality and reporting 51% (IQR 39-63) and 48% (IQR 35-65) respectively. Twenty-two (55%) and 20 (50%) did not reach the minimum standards (scores <50%). Studying the methods of evidence analysis, the guidances deployed systematic reviews had better quality (74.2% vs 46.9%; p=0.001) and reporting (80.5% vs 42.6%; p=0.001). Guidances reporting a tool referral scored better (AGREE II: 72.8% vs 43.1%, p=0.002; RIGHT: 75.0% vs 46.9%, p=0.004).

Conclusion: BC screening CPGs and CSs suffered poor quality and reporting as more than half did not reach the minimum standards. Quality and reporting would improve if systematic reviews are used to underpin the recommendations made.

Keywords: “breast cancer”, “screening”, “clinical practice guidelines”, “consensus”, “AGREE II”, “RIGHT”.

1. Introduction:

Breast cancer (BC) is the most common cancer in women with an incidence of 2 million cases and 15% (670000) of global cancer deaths per year.[1-3] Morbidity and survival have decreased in the last years due to the early detection with more effective and efficient treatments.[4 5] Nonetheless, BC screening can be irksome and expensive,[4] false negatives could delay BC diagnosis and false positives may conduct to unnecessary procedures.[6 7] These false-positive outcomes have generated a debate about the efficacy of BC screening and overtreatment.[4 7] Doctors often do not take into account wishes and the psychological harm of women in screening.[8]

Clinical practice guidelines (CPG) and consensus statements (CS) are being promoted to provide guidance for high-quality effective healthcare. [9-12] CPGs and CSs should be well informed, implementing factual advances to evidence analysis to build advice.[11 13] We did not find previous reviews of the quality and reporting in BC screening guidelines. However, the necessity of studying the quality and reporting has been spotlighted to identify a worthy guideline.[14] Further, it has been recognized the necessity of examining the quality and reporting as different issues but related.[15] The first handles with questions of the validity of the recommendations made while the second examines the rigor of the presentation of the document prepared. Accordingly, there is a need for evaluation of recently published guidance documents.[16]

The main objective of this systematic review was to assess the quality and reporting of CPGs and CSs for breast cancer (BC) screening, appraising them with validated instruments and focusing on the method utilized for evidence analysis.

2. Methods

A systematic review was developed following Prospero protocol nº: CRD42020203807. It was reported following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement.[17 18]

2.1. Data sources and searches

This systematic literature review included CPGs and CSs published from 2017 until August 23rd, 2020 using MeSH terms "practice guidelines", "guidelines", "consensus", "breast neoplasms", "breast cancer", "screening" and including word alternatives. Important online databases (EMBASE, Web of Science, MEDLINE, Scopus, CDSR, etc.), 84 websites of relevant professional societies, 12 guidance-specific databases, and the Worldwide Website were sought to include guidance met the selection criteria (Appendix S1). We also checked the references of the included CPGs and CSs if there were additional eligible guideline documents. We have chosen a 3-year time window following a recent systematic review of the literature indications; most of the methodological guidance manuals for updating guidelines determined that its update should be done in less than three years.[19] We only incorporated in the analysis of professional societies from countries with a global breast cancer´s scientific yield greater than 0.5%, a decision in line with previous peer-reviewed published studies.[20 21] Scopus was searched on July 10th, 2020 to estimate the scientific production of each country (23,748 "Breast Cancer and Health" documents).

2.2. Study selection and data extraction

Published CPGs and CSs about BC screening, in any language from 2017 onwards, were considered for inclusion. We excluded CPGs and CSs about treatment and diagnosis without screening, old guidelines superseded by updates from the same organization, and CPG and CSs for education and information purpose only. We classified each document a CPG or CS based on its title, subtitle and methods.

Two authors (MMC and LM), both specialists in breast pathology, independently considered titles and abstracts for eligibility. Discrepancies were resolved by consensus between MMC and LM and a third reviewer (MMD). The full-text assessment was then done by MMC and LM. Duplicate articles were identified and removed. The most recent version of the guidelines was incorporated into the review where several updates were found. Duplicated data extraction was obtained independently.

2.3. Assessment of quality and reporting

Two validated appraisal tools, the AGREE II instrument and the RIGHT statement (Appendix S2)[22 23] were used to collect data to assess the quality and reporting of the guidances on a data extraction proforma. The quality was understood as the "reliability that potential development biases have been appropriately addressed and recommendations are internally and externally valid" like in AGREE II.[24] Twenty-three items were fulfilled according to six domains: scope and purpose (items 1 to 3), stakeholder involvement (items 4 to 6), the rigor of development (items 7 to 14), clarity and presentation (items 15 to 17), applicability (items 18 to 21) and editorial independence (items 22 and 23). Each item was scored between 1 (strongly disagree, i.e. when there is no important information of the item) and 7 (strongly agree, i.e. when there is a fantastic description of the item). Two reviewers´ discrepancies on scoring were discussed and unresolved issues were addressed by a referee. The summing up reviewers´ individual scores were used to calculate the 0-100% domain quality scores and to follow the AGREE II formula supplied in the tool manual.[24]

Furthermore, we calculated an overall guideline assessment as the mean scores of the 6 standardized domain, and based on the results, a proposal was made: a CPG or CS was

"recommended" when scored >80%,[25] "recommended with modifications" if scored 50-80%, and "not recommended" if <49%.[26]

The RIGHT[23] statement was used for reporting assessment. Thirty-five items WERE scored in 1 (reported), 0.5 (partially reported), or 0 (unreported) and were classified into 7 domains: basic information (items 1 to 4), background (items 5 to 9), evidence (items 10 to 12), recommendations (items 13 to 15), review and quality assurance (items 16 and 17), funding and declaration and management of interests (items 18 and 19), and other information (items 20 to 22). Disagreements were solved by an arbitrator after the two reviewers' discussion. An overall reporting assessment was calculated based on the rate of the total (score >80%: "well-reported", score = 50-80%: "moderate-reported" and score <50%: "low-reported").[26]

2.4. Data analysis

All analyses were obtained using Stata 15. We have made a descriptive analysis of domain and overall scores. The Kruskal-Wallis test was utilized for comparing results and studying factors that could modify the quality and reporting of guidelines. Statistical significance was fixed in a $p<0.05$. The intraclass correlation coefficient (ICC) was calculated for determining consistency among reviewers and excellent compliance was >0.90.[27]

3. Results

3.1. Study selection

The systematic search retrieved 5803 citations: 5714 from online databases (EMBASE, MEDLINE, Web of Science, SCOPUS and Trip database) and 89 from secondary provenances (guideline specific databases, professional societies, and the Word Wide Web). A total of 5616 publications for not meeting the selection criteria and 146 duplicated guidances were removed. Finally, 35 CPGs[28-62] and 5 CSs[63-67] (40 documents) were included for the final review (Table 1). Four

CPGs and two CSs were in Spanish and the rest in English. Figure 1 detailed the flow diagram with the study selection process. Reviewer agreement (ICC) was 0.98 in AGREE II and 0.93 in RIGHT being their correlation score r=0.92 (Appendix S3).

3.2. Quality assessment

The review of guidances quality demonstrated a heterogeneous and extensive overall score interval (17-90%) and a median overall quality of 51.0% (IQR 39.0 -63.0). Appendix S4 and 5 epitomize all the outcomes. There were only 10% (4) of the guidances classified as "recommended"; 14 (35%) as "recommended with modifications" and 22 (55%) as "not recommended". The domains´ quality was very diverse (Appendix S4). The best-achieved domains (scoring >75%) were 1 (scope and purpose) with 19 (48%) guideline documents and 4 (clarity of presentation) with 18 (45%) CPGs and CSs. Domain 5 (applicability) was the worst explained with only 2 (5%) guidelines scoring >75%. Domain 6 (Editorial independence) was high-scored (>75%) in 10 (25%) CPGs but was very low-scored (<25%) in 16 (40%). The higher quality guidelines were the MHM[32], ACP[49], CFT[51], and Colombian[62] CPGs (Appendix S4 and 6).

3.3. Reporting assessment

The reporting overall score range was varied (17-90%) (Appendix S7 and 8) and the median overall reporting achievement was 48% (IQR 35.0-65.0). Half of the CPGs and CSs (20) were classified as "low-reported". Fifteen (38%) guidelines were "moderate-reported" and only 5 (13%) were "well-reported". The diverse reporting in guidelines was summarized in Appendix S7. The median of the domain scores was 58% (8-53%) for domain 1 (basic information), 63% (25-100%) for domain 2 (background), 50% (0-100%) for domain 3 (evidence), 50% (7-100%) for domain 4 (recommendations), 25% (0-100%) for domain 5 (review and quality assurance), 19 (0-100%) for domain 6 (funding and declaration and management of interests) and 33% (0-100%) for domain

7 (other information). The highest reporting compliance guidelines were the MHM[32], the ACP[49], the CFT[51], the CCO[52], and the Colombian[62] (Appendix S7 and 9).

3.4. Variables related to quality and reporting

Although CPGs scored better than CSs in both quality and reporting assessments, the results were not significant (AGREE II: p=0728; RIGHT: P=0.919). No differences were found between countries (AGREE II: p=0.106; RIGHT: P=0.292), publication year (AGREE II: p=0.841; RIGHT: P=0.106), number of version (AGREE II: p=0.486; RIGHT: P=0.770), or publication in a journal neither. Guidelines based on systematic reviews had better quality (74.2% vs 46.9%; p=0.001) and reporting than consensus (80.5% vs 42.6%; p=0.001). The guidances which reported the following of a quality tool referral scored better than when it was not reported (AGREE II: 72.8% vs 43.1%, p=0.002; RIGHT: 75.0% vs 46.9%, p=0.004). Table 2 summarizes all these results.

3.5. Screening vs treatment guidelines

Analyzing screening vs treatment guidelines, the median overall quality was 45.80% (31.88-62.50) vs 53.98% (35.86-74.27); p=0.096 respectively and the median overall reporting was 49.60% (35.93-68.35) vs 60.93% (44.53-84.37); p=0.043 separately. There was an unequivocal reduction in quality of the screening CPGs and CSs by at least 10% in all domains except domain 5 (for applicability) which have improved although punctuation had not reached minimal requirements. Studying the reporting in both screening and treatment guideline documents, results were more similar. Although domains 1 (basic information), 3 (evidence), and 7 (other information) scored worse in screening CPGs and CSs, Domain 4 (recommendations), 5 (review and quality assurance), and 6 (funding, declaration, and management of interests) were slightly improved. Figure 2 showed a comparison between screening and treatment guidances regarding AGREE and RIGHT tools.

4. Discussion

4.1. Main findings

As in BC treatment guidelines, our current review showed a very diverse quality and reporting between BC screening guidances. More than three-quarters of these guidelines could not be endorsed as it is currently presented so its quality and reporting were even worse than in a complimentary review by our team about the quality and reporting of BC treatment CPGs and CSs.[21] Studying the methods of evidence analysis, the guideline documents that deployed systematic reviews had better quality and reporting. The reporting of the use of a quality tool referral as AGREE II or RIGHT during the guidance elaboration, improved quality, and reporting.

4.2. Strengths and limitations

This non-language-restriction systematic review gave a broad view of the screening scenario guidance literature with a big large number of CPGs and CSs. Being English and Spanish the most widely spoken languages[68]. Most of the Societies[28-31 34 35 58-61 69] presented guideline versions in English and Spanish. One strength of this review is that the authors were fluent in both. Two well-developed assessment tools, AGREE II instrument[22] and RIGHT statement,[23] were used to assess quality and reporting. To our knowledge, there were no other appraisals of BC screening guidelines applying both AGREE II and RIGHT. AGREE II is an instrument to measure the quality of the guidelines while RIGHT study the reporting. However, some of their items overlap. As previously,[21] this review demonstrated a correlation between quality and reporting of the CPG or CSs. As any other tools, AGREE II have inherent limitations. It did not include statement of the patient´s values and preferences and they did not measure the strength of the recommendations, which are also recognized as important components to guideline quality.

The subjective character of the data extraction concerning quality and reporting domains and items can be taken as a possible weakness of our review as it may confer bias. For reducing this

problem, we chose two experienced BC specialist clinicians who studied the appraisal tool manuals and set up a common comprehension of the grading procedure before the duplicate analysis was undertaken. An independent arbitrator was assigned to solve diversions between reviewers within the individual items, although his work was minimal as the reviewer agreement was excellent (ICC>90%).

There is a lack of clear rules on the domain and item weighting in scoring tool manuals[70] so the overall assessments calculated in our review may have limitations. The RIGHT statement[23] indicates avoiding obtaining an average score in each guide since it is not clear that the items could be weighted equitably, and a resume score could reduce the quality of the analysis. However, we find them useful to make a comparison between guides since they facilitate in a simplified way to be able to know in which areas CPGs and CSs have remarkable results and in which they do not. It permits to show if there is a correlation between quality and reporting in each guide. There are no thresholds provided to classify high, moderate, and poor quality and reporting in the AGREE II[22] or RIGHT[23] manuals. However, we have used formerly published cut-offs[25],[26] [21] for easier and powerful analysis. We would recommend caution in interpretation as global scores may vary among recommended guides since the domains don't weigh equally in their contribution towards overall quality and reporting.

The CPGs and CSs included were from 2017 onwards so there is a possibility that some guidelines from distinguished organizations might be excluded. A recent systematic review revealed that updates should be done in less than three years supporting the choice of our search time threshold.[19] Even though we only included CPGs and CSs which met all the inclusion criteria, there was diversity between CPGs and CSs included in our review. This is an important observation and this type of heterogeneity may be inevitable as the guidelines diverge in their development, structure, context, objectives, etc.[71] Therefore, considering the strengths of our

review, the deficient quality, and reporting of the guidance documents, the lack of use of systematic reviews for the synthesis of evidence, as well as the almost non-existent following of tools for quality and reporting improvement during their writing, are powerful observations.

4.3. Interpretation

Quality and reporting in BC screening guidelines have not been systematically analyzed previously. As we have stated before, the classification of documents selected into CPG or CS was based on their titles, subtitles and methods as reported by the authors. CPGs are ideally based on a systematic review of current evidence,[72] though this practice is not universal. A CSs is typically developed by an independent panel of experts, generally multidisciplinary, convened to review the evidence-based literature on a specific procedure but with a lower and less strict development methodology.[73] CSs are generally intended for controversial areas of breast management (where the evidence is still incomplete), and recommendations are based on the perspective of experts. Therefore, they are more likely to have less editorial independence and endorse a specific product with lower quality and higher risks of bias.[73] The avoidance of a systematic review to collate evidence in a CS is a serious methodological deficiency that predisposes them to bias.

This review observed there was a large scope of improvement even for CPGs and CSs with high overall scores as all they have deficient areas. On the other hand, our team had been working in a complementary study[21] about analysis of quality and reporting in BC treatment guidelines so both studies, with more than 100 guideline documents analyzed, have been correlated in the present article. Comparing the screening vs treatment guidelines, there is a clear decrease in quality in all the domains except for domain 5 (applicability) which have improved although punctuation was still poor. Domains 3 (rigor of development), 5 (applicability), and 6 (editorial independence) scored very low. So main goals should be direct to improve all these domains and

especially to provide a clear and efficient procedure for updating the guideline (item 13) and to settle an external review by experts (item 14) (Appendix S10). Regarding the reporting in guidelines, results between treatment and screening CPGs and CSs were more comparable. Besides domain 4 (recommendations), 5 (review and quality assurance), and 6 (funding, declaration, and management of interests) were slightly improved, domains 1 (basic information), 3 (evidence) and 7 (other information) scored worse. New efforts have to be directed to improve these weak areas, particularly describing the selection of all the contributors and their roles (item 9a), specifying the process of formulating a recommendation (item 15), and if costs and resources were considered (item 14b), explaining if there were an external review (item 16) and a quality assessment (item 17), describing the founding sources (items 18a and 18b)and the limitations of the process (item 22) (Appendix S11). Only 5 CPGs and no CSs have specified the following of AGREE II [22 24] instrument in their development, although RIGHT statement[23] was never used. There is still a discussion on the cut-off points to define tolerable scores and weighting of the items and domains. As has been highlighted before, this question should be confronted in future researches. More studies should be also needed to measure the quality of the recommendations. One suggestion to address this issue should be to investigate the similarity of the cited articles supporting the recommendations and compare the differences of direction (favor or against) and strength (strong or weak) of recommendations between guidelines of higher and lower quality and between guidelines and consensus statements. Nowadays, where the search for quality patient care is a must, it could not be permissible or justifiable that some guidances do not even meet the basic quality and reporting criteria. These deficiencies decrease the quality of health care provide.

4.4. Conclusions

CPGs and CSs in BC screening had poor quality and reporting and more than half of them did not reach the minimum standards. Quality and reporting would improve if systematic reviews are

used to underpin the recommendations made. Therefore, it is necessary to make greater efforts to meet the quality and reporting criteria of well-known tools such as AGREE II and RIGHT. This review also found that BC screening CPGs and CSs have slightly worse quality and a significantly lower score for reporting than BC treatment guidances.

5. Abbreviations

Association of breast surgery: ABS; Association of Breast Surgeons of India: ABSI; The American College of Obstetricians and Gynecologists: ACOG; the American College of Physicians: ACP; The American College of Radiology: ACR; The American Cancer Society: ACS; Asociación Española de Cirugía: AEC; Arbeitsgemeinschaft Gynäkologische Onkologie: AGO; The American Society of Breast Surgeons: ASBS; the Brazilian College of Radiology and Diagnostic Imaging: BCRDI; Brazilian Federation of Gynecological and Obstetrical Associations: BFGOA; China Anti-Cancer Association: CACA; Canadian Agency for Drugs and Technologies in Health: CADTH; Cancer Care Ontario: CCO; Canadian Task Force: CTF; clinical practice guidelines: CPGs; consensus statements: CSs; European Society for Medical Oncology: ESMO; Healthcare improvement Scotland: HIS; Instituto de Evaluación Tecnológica en Salud: IETS; Instituto Nacional de Cancerología: INC; Instituto Nacional de Cáncer José Alencar Gomes da Silva: INCJA; Japanese Breast Cancer Society: JBCS; Ministry of Health Malaysia: MHM; Breast Expert Advisory Group/ Northern Cancer Alliance: NCA; Nacional Comprehensive Cancer Network: NCCN; National Clinical Research Center for Cancer: NCRCC; The New England Journal of Medicine: NEJM; National Health Commission of the People's Republic of China: NHCPRC; National Health Service: NHS; National Institute for Health and Care Excellent: NICE; Public Health England: PHE; The Royal College of Radiologists: RCR; Sociedad Española de Anatomía Patológica: SEAP; Sociedad Española de Diagnóstico por Imagen de la Mama: SEDIM; Sociedad Española de Ginecología y Obstetricia: SEGO; Sociedad Española de Medicina Nuclear e Imagen Molecular: SEMNIM; Sociedad Española de Oncologia Médica: SEOM;

Sociedad Española de Oncología Radioterápica: SEOR; Sociedad Española de Senología y Patología Mamaria: SESPM; Secretaría de Salud de México: SSM; University Hospital of Würzburg: UHW.

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7. Authors´ Contributors

All the authors certify a substantial 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. LM was involved in data collection and writing. MMD was involved in data collection and writing. ABC helped in the data analysis and provided critical revision of the paper. KSK was involved in the design of this review, conducted the quality appraisal, in the writing, and provided critical revision of the paper. All authors read and provided the final approval of the version to be published.

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9. Availability of supporting data.

The authors confirm that the data supporting the findings of this study are available within the article and its supplementary materials. Other supplementary materials can be accessed upon request via email to the corresponding authors of this review.

10. Ethics approval and consent to participate

Not applicable.

11. Consent for publication

Not applicable.

12. Conflicts of interest

The review was conducted at the University of Granada, Spain. There are no conflicts of interest.

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Highlights

- Clinical practice guidelines (CPGs) and consensus (CSs) in breast cancer treatment had poor quality and reporting and more than half of them did not reach the minimum standards.
- The quality and reporting of CPGs and CSs should be improved using systematic reviews for settling recommendations.
- AGREE II and RIGHT assessment tools should be followed for assessing high-quality guidelines.

Table 1: Description of the CPGs and CSs (n=40) selected for the systematic review

	Name of the CPG	Abbreviated name	Type of document	Country	Year	Entity	Publication in a Journal	Version	Evidence analysis	Quality tool referral	Last updated date(months)
	Breast cancer screening guideline for Chinese women(26)	CACA BC CPG(26)	CPG	China	2019	CACA, NCRCC	Cancer Biol Med	1	Not reported	Not reported	10
2	Interpretation of breast cancer screening guideline for Chinese women(27)	CACA Interpretation CPG(27)	CPG	China	2019	CACA, NCRCC	Cancer Biol Med	1	Not reported	Not reported	8
3	Chinese guidelines for diagnosis and treatment of breast cancer 2018(28)	Chinese BC diagnosis treatment(28)	CPG	China	2018	NHCPRC	CJCRCN	1	Not reported	Not reported	18
4	The Japanese Breast Cancer Society Clinical Practice Guidelines for Breast Cancer Screening and Diagnosis, 2018 Edition(29)	JBCS screening diagnosis CPG(29)	CPG	Japan	2018	JBCS	Breast Cancer	2	Delphy modified technique	Not reported	12
5	Management of Breast Cancer (3rd Edition)(30)	MHM BC(30)	CPG	Malaysia	2019	MHM	Not published	3	Review	AGREE II	13
6	Early breast cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up(31)	ESMO BC 2019(31)	CPG	Europe	2019	ESMO	Annals of Oncology	3	Not reported	Not reported	14
7	AGO Recommendations for the Diagnosis and Treatment of Patients with Locally Advanced and Metastatic Breast Cancer: Update 2020(32)	AGO LA abd MBC 2020(32)	CPG	Germany	2020	AGO	Breast Care	6	Review	Not reported	3
8	AGO Recommendations for the Diagnosis and Treatment of Patients with Early Breast Cancer: Update 2019(33)	AGO Early BC 2019(33)	CPG	Germany	2019	AGO	Breast Care	5	Review	Not reported	15
9	Diagnosis and Treatment of Patients with Primary and Metastatic Breast Cancer(34)	AGO Primary MBC(34)	CPG	Germany	2018	AGO	Not published	1	Review	Not reported	32
10	The Screening, Diagnosis, Treatment, and Follow-Up of Breast Cancer(35)	Würzburg BC(35)	CPG	Germany	2018	UHW	Dtsch Arztebl Int	1	Systematic review	Not reported	32
11	Cáncer de mama/ Breast Cancer(36)	Fisterra BC(36)	CPG	Spain	2017	Fisterra	Not published	3	Not reported	Not reported	38
12	Cirugía de la Mama(37)	AEC BC(37)	CPG	Spain	2017	AEC	Not published	2	Not reported	Not reported	44
13	Manual de Práctica Clínica en Senología. 4ª Edición. 2019(38)	SESPM(38)	CPG	Spain	2019	SESPM	Not published	4	Not reported	Not reported	20
14	Oncoguía SEGO: Cáncer infiltrante de mama. Guías de práctica clínica en cáncer ginecológico y mamario(39)	SEGO CPG(39)	CPG	Spain	2017	SEGO, SEOM, SEOR,SEAP,SESPM , SEDIM, SEMNIM	Not published	1	Review	AGREE II	38
15	Best practise guidelines for surgeons in breast cancer screening(40)	ABS BC surgeons(40)	CPG	UK	2018	ABS	Not published	6	Not reported	Not reported	31
16	Breast Screening Standards(41)	HIS CPG(41)	CPG	UK	2018	HIS	Not published	1	Not reported	Not reported	14
17	Breast Cancer Clinical Guidelines(42)	NCA BC(42)	CPG	UK	2019	NCA	Not published	2	Review	Not reported	10
18	NHS Breast Screening Programme. Failsafe batch guidance(43)	NHS failsafe batch CPG(43)	CPG	UK	2019	PHE	Not published	1	Not reported	Not reported	19
19	NHS Breast Screening Programme. Guidance for breast screening mammographers(44)	NHS mammographers(44)	CPG	UK	2017	PHE	Not published	3	Not reported	Not reported	33
20	Guidance on screening and symptomatic breast imaging. Fourth edition(45)	RCR breast imaging (45)	CPG	UK	2019	RCR	Not published	4	Not reported	Not reported	10
21	NHS Breast Screening multidisciplinary working group guidelines for the diagnosis and management of breast lesions of uncertain malignant potential on core biopsy (B3 lesions)(46)	RCR NHS B3 lessions(46)	CPG	UK	2018	RCR, NHS	Clinical Radiology	1	Review	Not reported	32
22	Screening for Breast Cancer in Average-Risk Women: A Guidance Statement From the American College of Physicians(47)	ACP BC screening(47)	CPG	USA	2019	ACP	Ann Intern Med	1	Review	AGREE II	25
23	Digital Tomosynthesis for the Screening and Diagnosis of Breast Cancer: Diagnostic Accuracy and Guidelines(48)	CADTH BC screening(48)	CPG	Canada	2019	CADTH	CADTH	1	Systematic review	AGREE II	69
24	Recommendations on screening for breast cancer in women aged 40–74 years who are not at increased risk for breast cancer(49)	CTF 40-74 yo BC screening(49)	CPG	Canada	2018	CTF	CMAJ	1	Systematic review	Not reported	21
25	Magnetic Resonance Imaging Screening of Women at High Risk for Breast Cancer(50)	CCO MRI high-risk BC(50)	CPG	Canada	2017	CCO	Not published	3	Systematic review	Not reported	31
26	Clinical Management Guidelines for Obstetrician–Gynecologists. Breast Cancer Risk Assessment and Screening in Average-Risk Women(51)	ACOG BC screening(51)	CPG	USA	2017	ACOG	ACOG Practice Bulletin.	2	Review	Not reported	37
27	Breast Cancer Screening and Diagnosis. Version 1.2019(52)	NCCN BC Screening(52)	CPG	USA	2019	NCCN	Not published	4	Review	Not reported	16
28	Breast Cancer Screening in Women at Higher-Than-Average Risk: Recommendations From the ACR(53)	ACR High -risk BC(53)	CPG	USA	2018	ACR	JACR	1	Review	Not reported	29
29	ACR Appropriateness Criteria Breast Cancer Screening(54)	ACR Criteria BC(54)	CPG	USA	2017	ACR	JACR	1	Review	Not reported	33
30	Breast Cancer Early Detection and Diagnosis. Can Breast Cancer Be Found Early?(55)	ACS BC detection(55)	CPG	USA	2019	ACS	AJR	2	Not reported	Not reported	10
31	Guidelines for early detection of breast cancer in Brazil. I – Development methods(56)	INC BC Screening I(56)	CPG	Brazil	2018	INC	Cad. Saúde Pública	1	Review	AGREE II	32
32	Guidelines for early detection of breast cancer in Brazil. II – New national recommendations, main evidence, and controversies(57)	INC BC Screening II(57)	CPG	Brazil	2018	INC	Cad. Saúde Pública	1	Review	Not reported	32
33	Guidelines for early detection of breast cancer in Brazil. III – Challenges for implementation(58)	INC BC Screening III(58)	CPG	Brazil	2018	INCJA	Cad. Saúde Pública	1	Review	Not reported	32
34	Breast Cancer Screening: Updated Recommendations of the Brazilian College of Radiology and Diagnostic Imaging, Brazilian Breast Disease Society, and Brazilian Federation of Gynecological and Obstetrical Associations(59)	BCRDI BC screening (59)	CPG	Brazil	2017	BCRDI, BBDS, BFGOA	Thieme Revinter Publicações	1	Review	Not reported	35
35	Guía de práctica clínica (GPC) para la detección temprana, tratamiento integral, seguimiento y rehabilitación del cáncer de mama(60)	GPC Colombia(60)	CPG	Colombia	2017	IETS	Not published	2	Systematic review	Not reported	44
36	Indian Solutions for Indian Problems—Association of Breast Surgeons of India (ABSI) Practical Consensus Statement, Recommendations, and Guidelines for the Treatment of Breast Cancer in India(61)	Indian ABSI CS(61)	CS	India	2017	ABSI	Indian J Surg	1	Consensus method; review	Not reported	38
37	4th ESO–ESMO International Consensus Guidelines for Advanced Breast Cancer (ABC 4)(62)	ABC4(62)	CS	Europe	2018	ESMO, ESO, EUSOMA	The Breast	4	Consensus method, not specified technique	Not reported	25
38	Position Statement on Screening Mammography(63)	ASBS mammography(63)	CS	UK	2019	ASBS	Not published	3	Consensus method; review	Not reported	17
39	Consensus Guideline on Diagnostic and Screening Magnetic Resonance Imaging of the Breast(64)	ASBS MRI(64)	CS	USA	2017	ASBS	Not published	1	Consensus method; review	Not reported	37
40	Consenso Mexicano sobre diagnóstico y tratamiento del cáncer mamario. Octava revisión. Colina 2019(65)	GPC México(65)	CS	México	2019	SSM	Not published	7	Nominal group technique	Not reported	20

Table 2: Variables related to the quality and reporting of CPGs and CSs.

	AGREE II			RIGHT		
Variable	**Median**	**IGQ Range**	**p value**	**Median**	**IGQ Range**	**p value**
Type of document						
CPGs	44.2%	31.2-63.1	p = 0.728	50.0%	35.9-69.5	p = 0.919
CSs	47.1%	46.7-51.1		43.0%	42.1-59.4	
Country						
USA	75.7%	27.5-51.5	p = 0.106	46.5%	35.9-57.8	p = 0.292
Europe	45.1%	39.5-74.3		49.2%	42.2-85.2	
Other countries	55.1%	34.1-63.1		59.4%	35.9-70.3	
Publication Year						
2017	51.1%	30.1-72.8	p = 0.841	71.9%	44.5-90.6	p = 0.106
2018	44.2%	34.1-63.1		60.9%	35.9-76.6	
2019-2020	40.9%	31.7-53.3		58.2%	48.4-83.2	
Publication in a journal						
Yes	51.3%	38.8-63.1	p = 0.248	55.9%	38.3-69.5	p = 0.271
No	38.4%	27.5-53.6		42.6%	33.6-67.2	
Versión number						
1	48.9%	36.7-65.1	p = 0.486	51.2%	35.2-68.4	p = 0.770
2	33.2%	23.9-54.3		43.0%	35.9-50.8	
3 or more	45.1%	30.1-53.6		52.0%	35.9-71.1	
Evidence analysis						
Consensus	46.9%	34.1-51.1	p = 0.001	42.6%	35.9-59.4	p = 0.001
Not reported	27.5%	23.5-31.5		33.6%	25.0-38.3	
Review	52.9%	42.2-62.5		55.9%	48.8-69.9	
Systematic review	74.2%	70.3-76.1		80.5%	75.0-85.2	
Quality tool referral						
Reported	72.8%	70.2-83.0	p = 0.002	75.0%	69.5-89.8	p = 0.004
Not reported	43.1%	31.1-53.6		46.9%	35.9-61.7	

Figure 1: The flow diagram detailing the study selection.

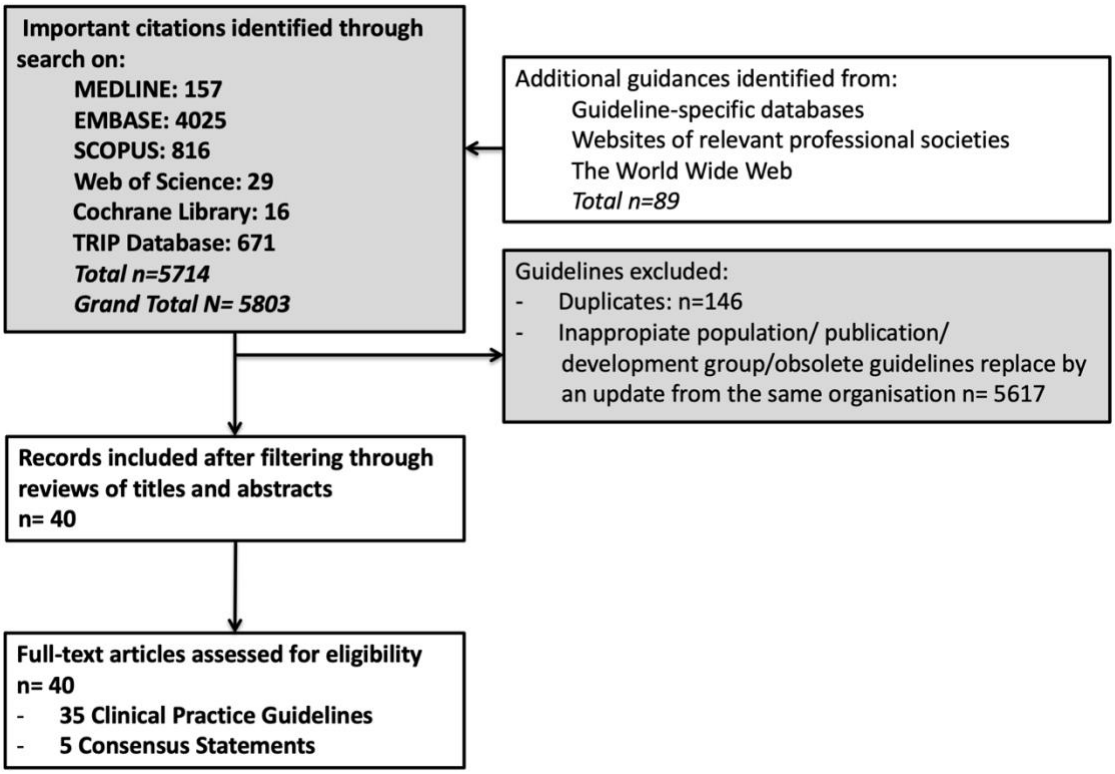
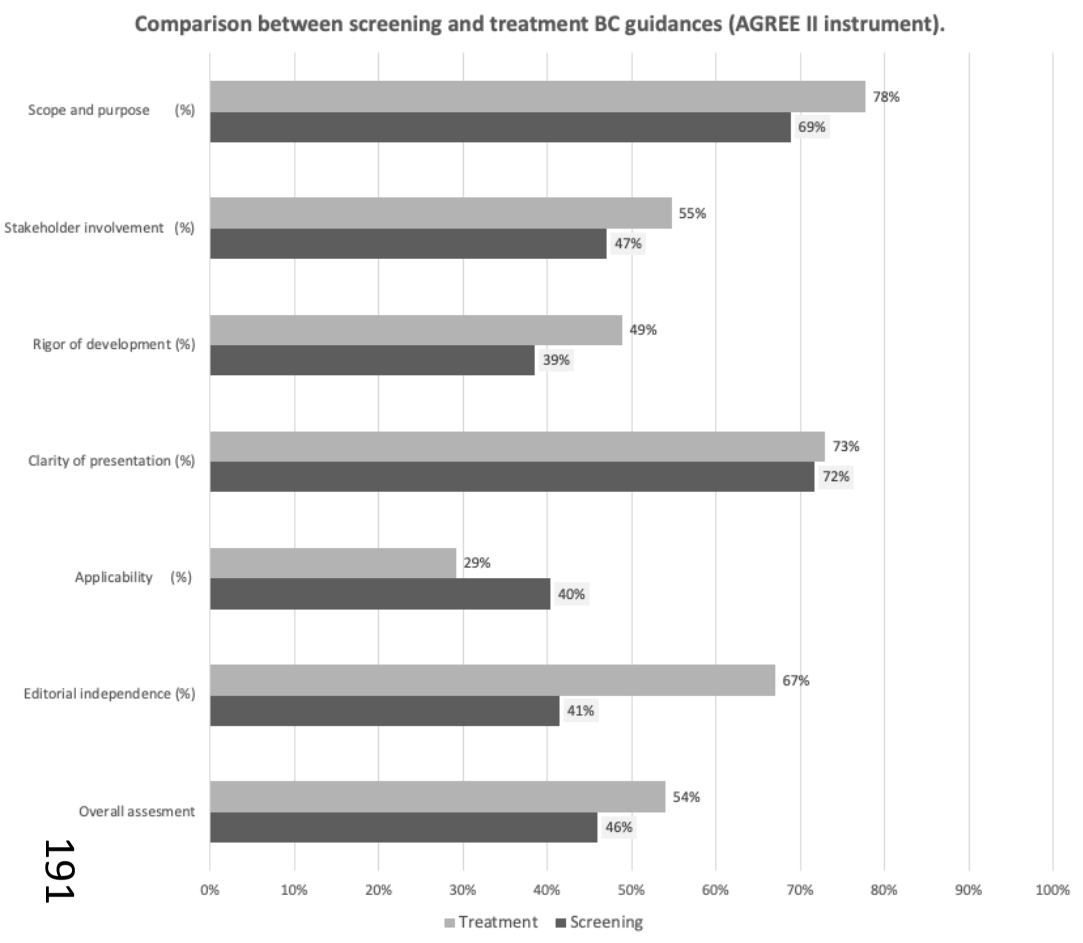
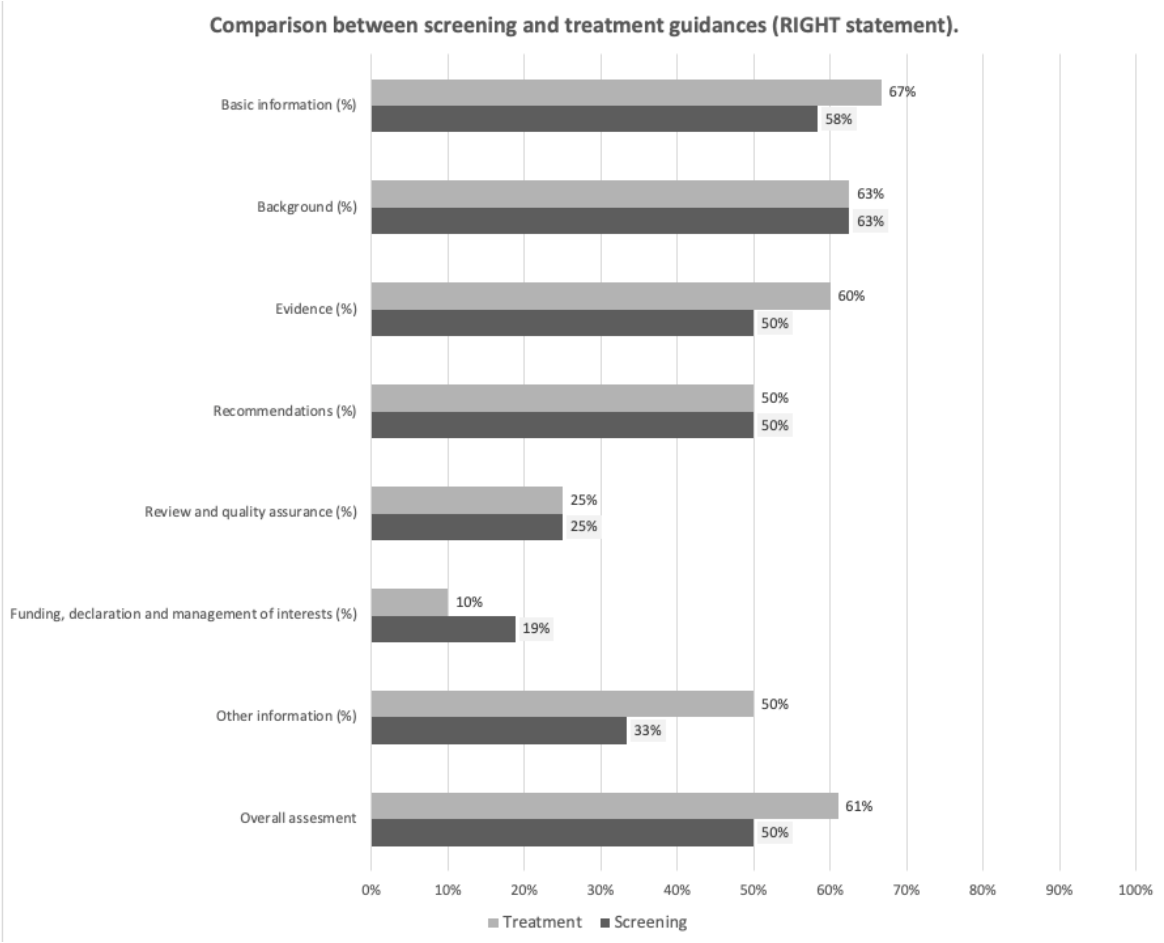


Figure 2: Comparison between screening and treatment guidance documents (next page).


Comparison between screening and treatment BC guidances (AGREE II instrument).
Scope and purpose (%)
78%
69%
Stakeholder involvement (%)
55%
47%
Rigor of development (%)
49%
39%
Clarity of presentation (%)
73%
72%
Applicability (%)
29%
40%
Editorial independence (%)
67%
41%
Overall assesment
54%
46%
0%
10%
20%
30%
40%
50%
60%
70%
80%
90%
100%
Treatment
Screening


Comparison between screening and treatment guidances (RIGHT statement).
Basic information (%)
67%
58%
Background (%)
63%
63%
Evidence (%)
60%
50%
Recommendations (%)
50%
50%
Review and quality assurance (%)
25%
25%
Funding, declaration and management of interests (%)
10%
19%
Other information (%)
50%
33%
Overall assesment
61%
50%
0%
10%
20%
30%
40%
50%
60%
70%
80%
90%
100%
Treatment
Screening

Appendix S0: PRISMA 2009 Checklist

			Page
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.	1
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	1
METHODS			
Protocol and registration	5	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.	1
Eligibility criteria	6	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.	2
Information sources	7	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.	2
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	S2
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).	2-3
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.	2-3
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	3-4
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.	4

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.	4
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.	4-6
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]).	6
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).	7
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).	7-8
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	9-10
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.	1

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. doi:10.1371/journal.pmed1000097

Appendix S1: Data sources and search strategy

S1.1 Sample search strategy for Embase

A systematic search was conducted in Embase on August 23rd, 2020 (from January 2017 to August 2020) using the next combination of free-text terms:

#1 Practice guideline [pt]
#2 Practice guidelines as topic [mesh]
#3 Guideline [pt]
#4 guidelines as topic [mesh]
#5 consensus [mesh]
#6 OR #1-#5
#7 breast neoplasms [mesh]
#8 breast neoplasms [all]
#9 breast cancer [all]
#10 OR #7-9
#11 screening [all]
#12 2017 [pdta] : 3000[pdta]
#6 AND #10 AND #11 AND #12

Results: 4025 articles

S1.2 Online databases

1. MEDLINE
2. EMBASE
3. Web of Science
4. Scopus
5. The Cochrane Database of Systematic Reviews
6. Cochrane Methodology Register
7. ACP Journal Club
8. Database of Abstracts of Reviews of Effects
9. Cochrane Central Register of Controlled Trials (CENTRAL)
10. The Health Technology Assessment

S2.3 Guideline-specific databases

1. NHMRC, Australia
2. CMA Infobase, Canada
3. CPG, Canada
4. GIN, International
5. NZGG, New Zealand
6. NICE, UK
7. Trip Database, UK
8. SIGN, UK
9. Fisterra, Spain
10. HSTAT, USA
11. NCCN, USA
12. NGC, USA

S2.4 Professional societies

1. CECM, China
2. CMH, China

3. NCRCC, China
4. NHCPRC, China
5. CACA, China
6. JBCS, Japan
7. JRG, Japan
8. ABSI, India
9. ICMR, India
10. ICON, India
11. AHS, Canada
12. BCMA, Canada
13. CCM, Canada
14. CCO & Ontario Ministry of Health, Canada
15. CADTH, Canada
16. CMAJ, Canada
17. CTF, Canada
18. QBCF, Canada
19. American Board of Internal Medicine's, USA
20. ASBS, USA
21. ASPS, USA
22. American Society for Radiation Oncology, USA
23. ABS, USA
24. ACS, USA
25. ACOG, USA
26. ASBrS, USA
27. ASBS, USA
28. ASCO, USA
29. ASTRO, USA
30. ACP, USA
31. ACR, USA
32. SSO, USA
33. AMA, USA
34. JACR, USA
35. USPSTF, USA
36. Society of Surgical Oncology Breast Disease, USA
37. ESMO, Europe
38. ESO, Europe
39. ESTRO, Europe
40. EUSOMA, Europe
41. JRC, Europe
42. St. Gallen/Vienna, Europe
43. KCE, Belgium
44. HAS, France
45. ABC3, Germany
46. AGO, Germany
47. DEGRO, Germany
48. IKNL, Netherlands
49. Richtlijnendatabase, Netherlands
50. NCCP, Ireland
51. Lithuanian oncologist, encrinologist and General practicioners, Lithuania
52. SCAN, Singapore
53. AEC, Spain
54. FESEO, Spain
55. SEGO, Spain
56. SEOM, Spain

57. SEAP, Spain
58. SEDIM, Spain
59. SEMNIM, Spain
60. SEOM, Spain
61. SEOR, Spain
62. SESPM, Spain
63. ABS, UK
64. BAPRAS, UK
65. JGBSA, UK
66. RCR, UK
67. SCT, UK
68. HIS, UK
69. NCA, UK
70. RCP, UK
71. RER, UK
72. BBDS, Brazil
73. BCRDI, Brazil
74. BFGOA, Brazil
75. INCJA, Brazil
76. CMCCR, Costa Rica
77. IETS, Colombia
78. INC, Colombia
79. AG, Australia
80. CA, Australia
81. MHNZ, New Zealand
82. IARC, International
83. ESO, International
84. IEP, International

Appendix S2: AGREE II and RIGHT checklists

S2.1. AGREE Checklist

Domain	Item
Scope and purpose	1. The overall objective(s) of the guideline is (are) specifically described.
	2. The health question(s) covered by the guideline is (are) specifically described.
	3. The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described.
Stakeholder involvement	4. The guideline development group includes individuals from all the relevant professional groups.
	5. The views and preferences of the target population (patients, public, etc.) have been sought.
	6. The target users of the guideline are clearly defined.
Rigor of development	7. Systematic methods were used to search for evidence.
	8. The criteria for selecting the evidence are clearly described.
	9. The strengths and limitations of the body of evidence are clearly described.
	10. The methods for formulating the recommendations are clearly described.
	11. The health benefits, side effects and risks have been considered in formulating the recommendations.
	12. There is an explicit link between the recommendations and the supporting evidence.
	13. The guideline has been externally reviewed by experts prior to its publication.
	14. A procedure for updating the guideline is provided.
Clarity of presentation	15. The recommendations are specific and unambiguous.
	16. The different options for management of the condition or health issue are clearly presented.
	17. Key recommendations are easily identifiable.
Applicability	18. The guideline describes facilitators and barriers to its application.
	19. The guideline provides advice and/or tools on how the recommendations can be put into practice.
	20. The potential resource implications of applying the recommendations have been considered.
	21. The guideline presents monitoring and/ or auditing criteria.
Editorial independence	22. The views of the funding body have not influenced the content of the guideline.
	23. Competing interests of guideline development group members have been recorded and addressed.

Appendix S2: AGREE II and RIGHT checklists

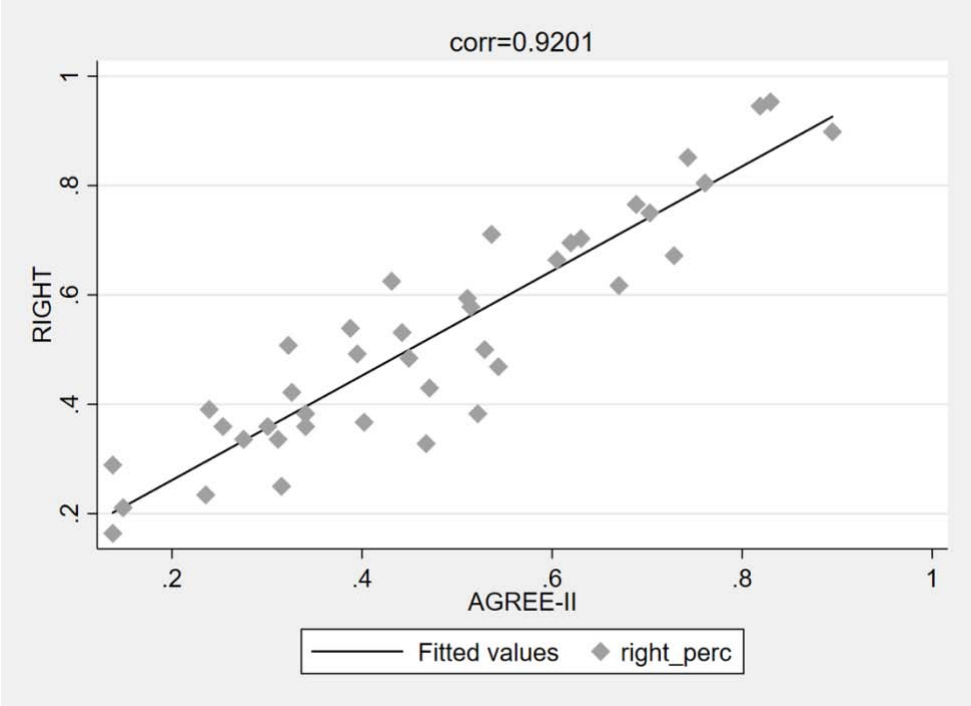
S2.2. RIGHT Checklist

Section	Item
Basic information	
Title/subtitle	1a. Identify the report as a guideline, that is, with "guideline(s)" or "recommendation(s)" in the title.
	1b. Describe the year of publication of the guideline.
	1c. Describe the focus of the guideline, such as screening, diagnosis, treatment, management, prevention or others.
Executive summary	2. Provide a summary of the recommendations contained in the guideline.
Abbreviations and acronyms	3. Define new or key terms and provide a list of abbreviations and acronyms if applicable.
Corresponding developer	4. Identify at least one corresponding developer or author who can be contacted about the guideline.
Background	
Brief description of the health problem(s)	5. Describe the basic epidemiology of the problem, such as the prevalence/incidence, morbidity, mortality, and burden (including financial) resulting from the problem.
Aim(s) of the guideline and specific objectives	6. Describe the aim(s) of the guideline and specific objectives, such as improvements in health indicators (e.g., mortality and disease prevalence), quality of life, or cost savings.
Target population(s)	7a. Describe the primary population(s) that is addressed by the recommendation(s) in the guideline.
	7b. Describe any subgroups that are given special consideration in the guideline.
End- users and settings	8a. Describe the intended primary users of the guideline (such as primary care providers, clinical specialists, public health practitioners, program managers, and policy makers) and other potential users of the guideline.
	8b. Describe the setting(s) for which the guideline is intended, such as primary care, low- and middle-income countries, or in-patient facilities.
Guideline development groups	9a. Describe how all contributors to the guideline development were selected and their roles and responsibilities (e.g., steering group, guideline panel, external reviewer, systematic review team, and methodologists).
	9b. List all individuals involved in developing the guideline, including their title, role(s) and institutional affiliation(s).
Evidence	
Healthcare questions	10a. State the key questions that were the basis for the recommendations in PICO (population, intervention, comparator, and outcome) or another format as appropriate.
	10b Indicate how the outcomes were selected and sorted.
Systematic reviews	11a. Indicate whether the guideline is based on new systematic reviews done specifically for this guideline or whether existing systematic reviews were used.
	11b. If the guideline developers used existing systematic reviews, reference these and describe how those reviews were identified and assessed (provide the search strategies and the selection criteria and describe how the risk of bias was evaluated) and whether they were updated.
Assessment of the certainty of the body of evidence	12. Describe the approach used to assess the certainty of the body of evidence.

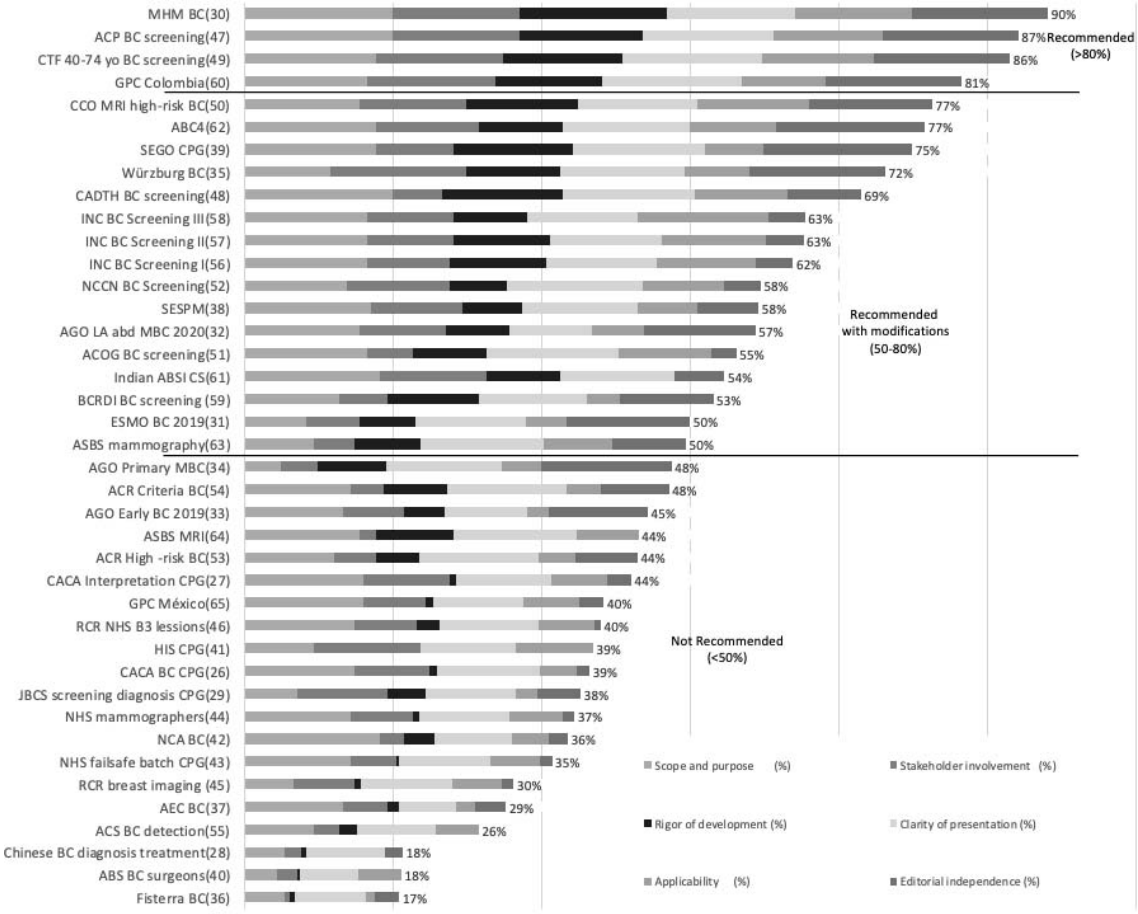
Appendix S2: AGREE II and RIGHT checklists

Recommendations	
Recommendations	13a. Provide clear, precise, and actionable recommendations.
	13b. Present separate recommendations for important subgroups if the evidence suggests that there are important differences in factors influencing recommendations, particularly the balance of benefits and harms across subgroups.
	13c. Indicate the strength of recommendations and the certainty of the supporting evidence.
Rationale/explanation for recommendations	14a. Describe whether values and preferences of the target population(s) were considered in the formulation of each recommendation. If yes, describe the approaches and methods used to elicit or identify these values and preferences. If values and preferences were not considered, provide an explanation.
	14b. Describe whether cost and resource implications were considered in the formulation of recommendations. If yes, describe the specific approaches and methods used (such as cost-effectiveness analysis) and summarize the results. If resource issues were not considered, provide an explanation.
	14c. Describe other factors taken into consideration when formulating the recommendations, such as equity, feasibility and acceptability.
Evidence to decision processes	15. Describe the processes and approaches used by the guideline development group to make decisions, particularly the formulation of recommendations (such as how consensus was defined and achieved and whether voting was used).
Review and quality assurance	
External review	16. Indicate whether the draft guideline underwent independent review and, if so, how this was executed, and the comments considered and addressed.
Quality assurance	17. Indicate whether the guideline was subjected to a quality assurance process. If yes, describe the process.
Funding, declaration and management of interest	
Funding source(s) and role(s) of the funder	18a. Describe the specific sources of funding for all stages of guideline development.
	18b. Describe the role of funder(s) in the different stages of guideline development and in the dissemination and implementation of the recommendations.
Declaration and management of interest	19a. Describe what types of conflicts (financial and non-financial) were relevant to guideline development.
	19b. Describe how conflicts of interest were evaluated and managed and how users of the guideline can access the declarations.
Other information	
Access	20. Describe where the guideline, its appendices, and other related documents can be accessed.
Suggestions for further research	21. Describe the gaps in the evidence and/or provide suggestions for future research.
Limitations of the guideline	22. Describe any limitations in the guideline development process (such as the development groups were not multidisciplinary, or patients' values and preferences were not sought) and indicate how these limitations might have affected the validity of the recommendations.

S3: Correlation between AGREE II and RIGHT scores.



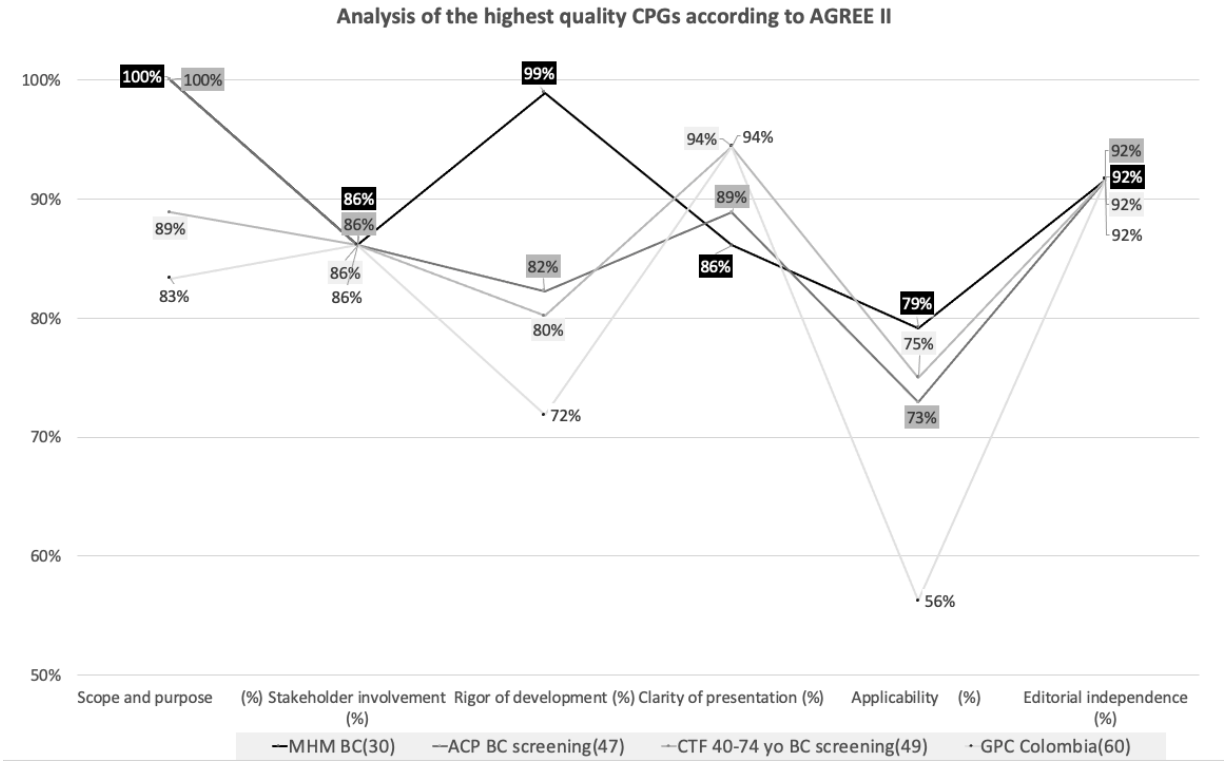
S4: AGREE II overall score of BC CPGs and CSs.



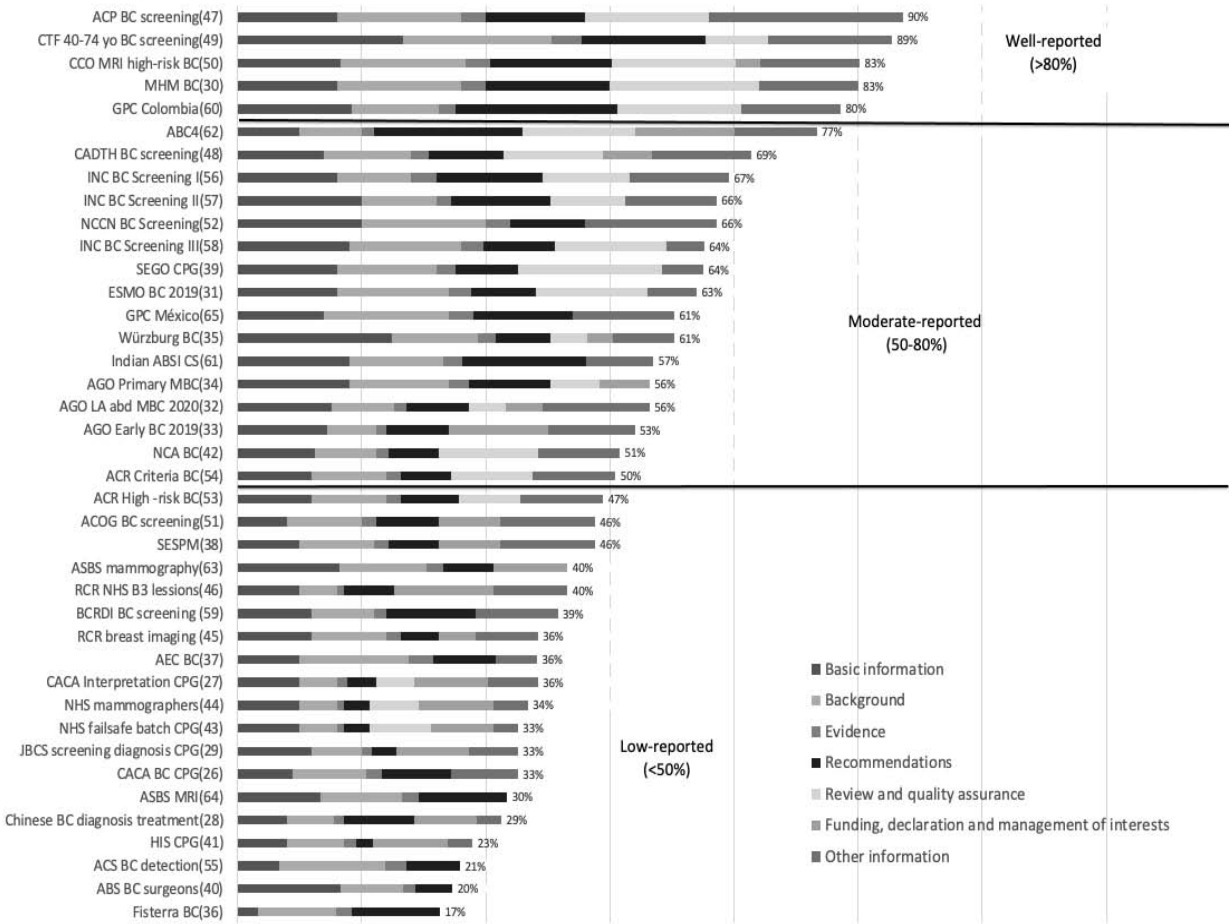
Appendix S5: Adherence to AGREE II by each CPG and CS included (n = 40).

R: recommended
RWM: recommended with modifications
NR: not recommended

		Domain 1	Domain 2	Domain 3	Domain 4	Domain 5	Domain 6			
	Abbreviated name	Scope and purpose (%)	Stakeholder involvement (%)	Rigor of development (%)	Clarity of presentation (%)	Applicability (%)	Editorial independence (%)	Overall Guideline Assessment	Quality score (1 up to 7) of this guideline	Media of total Score (%)
1	CACA BC CPG(26)	75%	50%	5%	69%	25%	8%	NR	3	39%
2	CACA Interpretation CPG(27)	81%	58%	4%	64%	38%	17%	NR	4	44%
3	Chinese BC diagnosis treatment(28)	28%	11%	3%	53%	0%	13%	NR	1	18%
4	JBCS screening diagnosis CPG(29)	36%	61%	25%	61%	15%	29%	NR	3	38%
5	MHM BC(30)	100%	86%	99%	86%	79%	92%	R	7	90%
6	ESMO BC 2019(31)	42%	36%	38%	75%	27%	83%	NR	4	50%
7	AGO LA abd MBC 2020(32)	78%	58%	43%	56%	35%	75%	RWM	4	57%
8	AGO Early BC 2019(33)	67%	42%	27%	56%	15%	67%	NR	4	45%
9	AGO Primary MBC(34)	25%	25%	46%	78%	27%	88%	NR	4	48%
10	Würzburg BC(35)	58%	92%	64%	83%	44%	92%	RWM	6	72%
11	Fisterra BC(36)	28%	3%	4%	47%	6%	17%	NR	1	17%
12	AEC BC(37)	67%	31%	7%	39%	13%	21%	NR	2	29%
13	SESPM(38)	86%	61%	41%	78%	40%	42%	RWM	4	58%
14	SEGO CPG(39)	89%	53%	80%	89%	40%	100%	RWM	6	75%
15	ABS BC surgeons(40)	22%	14%	2%	39%	29%	0%	NR	1	18%
16	HIS CPG(41)	47%	72%	0%	64%	52%	0%	NR	3	39%
17	NCA BC(42)	92%	17%	20%	53%	25%	13%	NR	3	36%
18	NHS failsafe batch CPG(43)	72%	31%	2%	61%	33%	8%	NR	3	35%
19	NHS mammographers(44)	72%	42%	4%	61%	35%	8%	NR	3	37%
20	RCR breast imaging (45)	33%	42%	4%	61%	33%	8%	NR	2	30%
21	RCR NHS B3 lessions(46)	75%	42%	16%	67%	38%	4%	NR	3	40%
22	ACP BC screening(47)	100%	86%	82%	89%	73%	92%	R	7	87%
23	CADTH BC screening(48)	100%	33%	81%	89%	63%	50%	RWM	5	69%
24	CTF 40-74 yo BC screening(49)	89%	86%	80%	94%	75%	92%	R	7	86%
25	CCO MRI high-risk BC(50)	78%	72%	75%	81%	75%	83%	RWM	6	77%
26	ACOG BC screening(51)	83%	31%	50%	89%	63%	17%	RWM	4	55%
27	NCCN BC Screening(52)	69%	69%	39%	92%	54%	25%	RWM	4	58%
28	ACR High -risk BC(53)	61%	28%	29%	81%	25%	42%	NR	4	44%
29	ACR Criteria BC(54)	72%	22%	43%	81%	23%	46%	NR	4	48%
30	ACS BC detection(55)	47%	17%	13%	53%	29%	0%	NR	2	26%
31	INC BC Screening I(56)	83%	56%	65%	75%	67%	25%	RWM	5	62%
32	INC BC Screening II(57)	83%	58%	65%	75%	71%	25%	RWM	5	63%
33	INC BC Screening III(58)	83%	58%	49%	75%	88%	25%	RWM	5	63%
34	BCRDI BC screening (59)	64%	33%	61%	72%	23%	63%	RWM	4	53%
35	GPC Colombia(60)	83%	86%	72%	94%	56%	92%	R	7	81%
36	Indian ABSI CS(61)	92%	72%	49%	78%	0%	33%	RWM	4	54%
37	ABC4(62)	89%	69%	56%	86%	58%	100%	RWM	6	77%
38	ASBS mammography(63)	47%	28%	44%	83%	46%	50%	NR	4	50%
39	ASBS MRI(64)	78%	11%	52%	83%	42%	0%	NR	4	44%
40	GPC México(65)	81%	42%	5%	61%	38%	17%	NR	3	40%
	Median (Range)	69 (22-100)	47 (3-92)	39 (0-99)	72 (39-94)	40 (0-88)	41 (0-100)			46 (17-90)

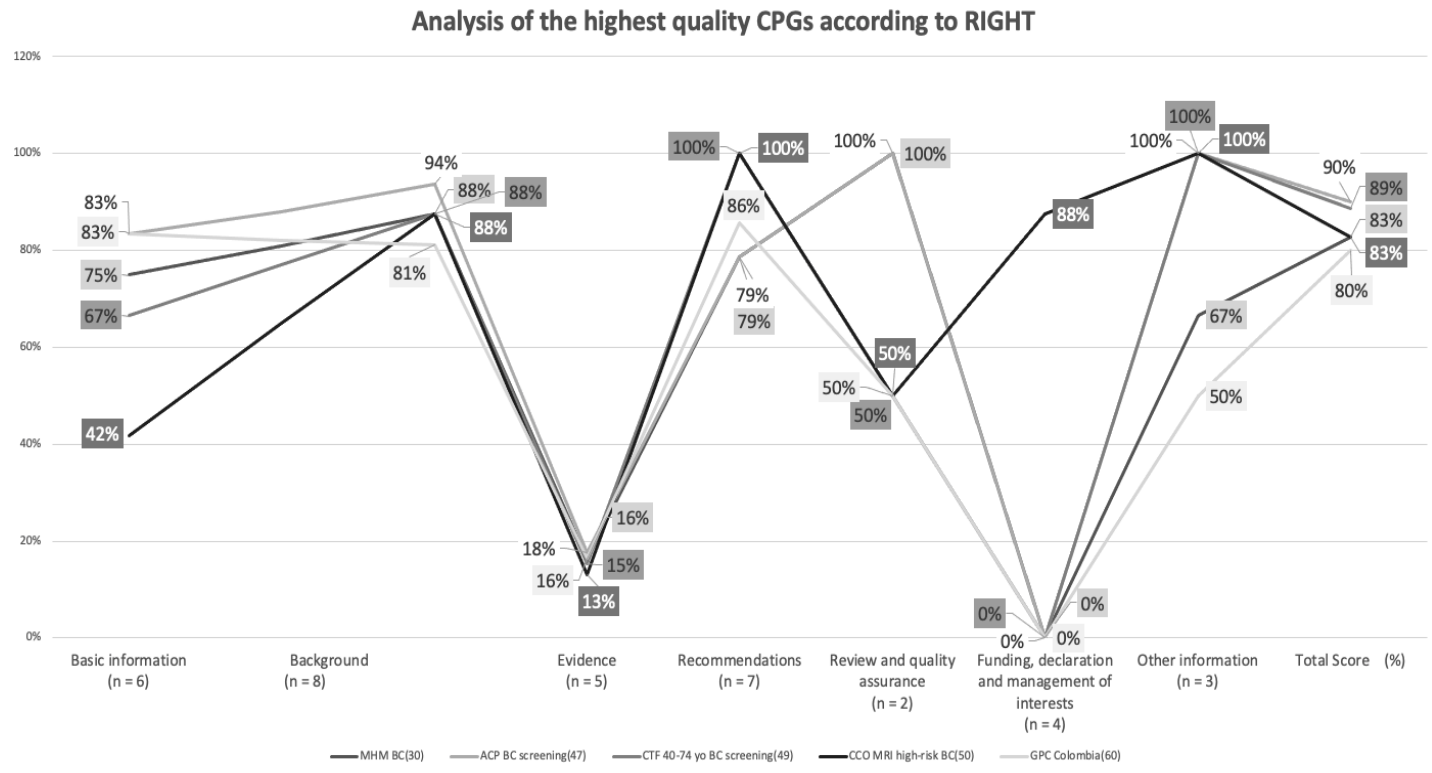


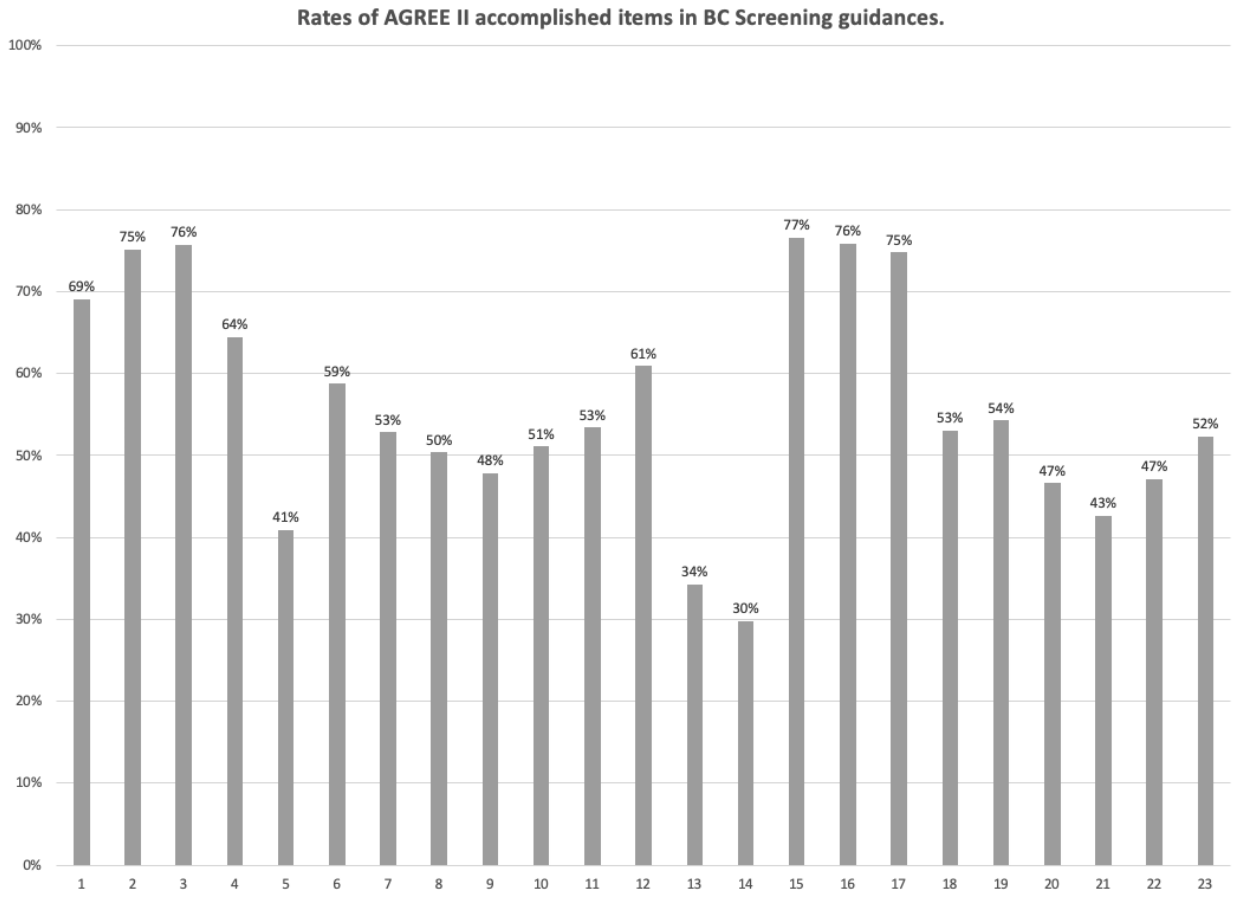
S7: RIGHT overall score of BC CPGs and CSs.



Appendix S8: Adherence to RIGHT Statement items ($n_1 = 35$) by each CPG and CS included ($n_2 = 40$)

		Domain 1		Domain 2		Domain 3		Domain 4		Domain 5		Domain 6		Domain 7			
	Abbreviated name of CPG	Basic information (n = 6)		Background (n = 8)		Evidence (n = 5)		Recommendations (n = 7)		Review and quality assurance (n = 2)		Funding, declaration and management of interests (n = 4)		Other information (n = 3)		Total Score (n= 35)	Total Score (%)
1	CACA BC CPG(26)	2.5	42%	4	50%	0.5	10%	3	43%	0	0%	0	0%	1.5	50%	11.5	33%
2	CACA Interpretation CPG(27)	3.5	58%	4	50%	0.5	10%	2.5	36%	0.5	25%	0	0%	1.5	50%	12.5	36%
3	Chinese BC diagnosis treatment(28)	3.5	58%	2.5	31%	1	20%	2	29%	0	0%	0.5	13%	0.5	17%	10	29%
4	JBCS screening diagnosis CPG(29)	4	67%	3.5	44%	1	20%	2	29%	0	0%	0	0%	1	33%	11.5	33%
5	MHM BC(30)	4.5	75%	7	88%	4	80%	5.5	79%	2	100%	4	100%	2	67%	29	83%
6	ESMO BC 2019(31)	4	67%	4.5	56%	3	60%	4.5	64%	1	50%	4	100%	1	33%	22	63%
7	AGO LA abd MBC 2020(32)	4	67%	4	50%	2.5	50%	3.5	50%	0.5	25%	3	75%	2	67%	19.5	56%
8	AGO Early BC 2019(33)	5	83%	2	25%	2.5	50%	4.5	64%	0	0%	3	75%	1.5	50%	18.5	53%
9	AGO Primary MBC(34)	3.5	58%	4	50%	3.5	70%	4.5	64%	0.5	25%	3.5	88%	0	0%	19.5	56%
10	Würzburg BC(35)	4	67%	5	63%	4	80%	3	43%	0.5	25%	3.5	88%	1.5	50%	21.5	61%
11	Fisterra BC(36)	0.5	8%	2.5	31%	0.5	10%	2.5	36%	0	0%	0	0%	0	0%	6	17%
12	AEC BC(37)	1.5	25%	7	88%	0.5	10%	3	43%	0	0%	0	0%	0.5	17%	12.5	36%
13	SESPM(38)	3.5	58%	7	88%	0.5	10%	3	43%	0	0%	0	0%	2	67%	16	46%
14	SEGO CPG(39)	3	50%	6.5	81%	5	100%	3.5	50%	2	100%	2	50%	0.5	17%	22.5	64%
15	ABS BC surgeons(40)	2.5	42%	3	38%	0	0%	1.5	21%	0	0%	0	0%	0	0%	7	20%
16	HIS CPG(41)	3	50%	3	38%	0.5	10%	0.5	7%	0	0%	0	0%	1	33%	8	23%
17	NCA BC(42)	3.5	58%	4.5	56%	3	60%	3.5	50%	1	50%	0.5	13%	2	67%	18	51%
18	NHS failsafe batch CPG(43)	3.5	58%	4	50%	0.5	10%	2	29%	0.5	25%	0	0%	1	33%	11.5	33%
19	NHS mammographers(44)	3.5	58%	4	50%	0.5	10%	2.5	36%	0.5	25%	0	0%	1	33%	12	34%
20	RCR breast imaging (45)	4	67%	3.5	44%	0.5	10%	3	43%	0	0%	0	0%	1.5	50%	12.5	36%
21	RCR NHS B3 lessions(46)	3.5	58%	5.5	69%	0.5	10%	3.5	50%	0	0%	0	0%	1	33%	14	40%
22	ACP BC screening(47)	5	83%	7.5	94%	4.5	90%	5.5	79%	2	100%	4	100%	3	100%	31.5	90%
23	CADTH BC screening(48)	5	83%	5.5	69%	5	100%	4.5	64%	1	50%	1	25%	2	67%	24	69%
24	CTF 40-74 yo BC screening(49)	4	67%	7	88%	5	100%	7	100%	1	50%	4	100%	3	100%	31	89%
25	CCO MRI high-risk BC(50)	2.5	42%	7	88%	4.5	90%	7	100%	1	50%	4	100%	3	100%	29	83%
26	ACOG BC screening(51)	3.5	58%	5	63%	1.5	30%	4	57%	0	0%	0	0%	2	67%	16	46%
27	NCCN BC Screening(52)	3.5	58%	6.5	81%	3	60%	5	71%	0	0%	3	75%	2	67%	23	66%
28	ACR High -risk BC(53)	4.5	75%	5.5	69%	1.5	30%	2	29%	0.5	25%	1.5	38%	1	33%	16.5	47%
29	ACR Criteria BC(54)	4	67%	5.5	69%	2.5	50%	2	29%	1	50%	1.5	38%	1	33%	17.5	50%
30	ACS BC detection(55)	1	17%	4.5	56%	0.5	10%	1.5	21%	0	0%	0	0%	0	0%	7.5	21%
31	INC BC Screening I(56)	4.5	75%	5.5	69%	5	100%	5	71%	1	50%	1	25%	1.5	50%	23.5	67%
32	INC BC Screening II(57)	4.5	75%	5.5	69%	5	100%	5	71%	1	50%	0	0%	2	67%	23	66%
33	INC BC Screening III(58)	4.5	75%	6	75%	5	100%	5	71%	1	50%	0	0%	1	33%	22.5	64%
34	BCRDI BC screening (59)	3	50%	2.5	31%	1.5	30%	2.5	36%	0	0%	3	75%	1	33%	13.5	39%
35	GPC Colombia(60)	5	83%	6.5	81%	5	100%	6	86%	1	50%	3	75%	1.5	50%	28	80%
36	Indian ABSI CS(61)	4	67%	5	63%	3.5	70%	6	86%	0	0%	0.5	13%	1	33%	20	57%
37	ABC4(62)	4	67%	6	75%	4.5	90%	5.5	79%	2	100%	4	100%	1	33%	27	77%
38	ASBS mammography(63)	3	50%	5	63%	1.5	30%	3	43%	0	0%	1.5	38%	0	0%	14	40%
39	ASBS MRI(64)	2	33%	4	50%	2	40%	2.5	36%	0	0%	0	0%	0	0%	10.5	30%
40	GPC México(65)	2.5	42%	8	100%	4.5	90%	4	57%	0	0%	1	25%	1.5	50%	21.5	61%
	Mode	1		1		0		1		0		0		0.5			
	Median (Range)	58 (8-83)		63 (25-100)		50 (0-100)		50 (7-100)		25 (0-100)		19 (0-100)		33 (0-100)			50 (17-90)


Analysis of the highest quality CPGs according to RIGHT
120%
100%
80%
60%
40%
20%
0%
83%
83%
75%
67%
42%
94%
88%
88%
88%
81%
18%
16%
16%
15%
13%
100%
100%
86%
79%
79%
100%
100%
50%
50%
50%
0%
0%
0%
88%
100%
100%
100%
90%
89%
83%
83%
80%
67%
50%
Basic information (n = 6)
Background (n = 8)
Evidence (n = 5)
Recommendations (n = 7)
Review and quality assurance (n = 2)
Funding, declaration and management of interests (n = 4)
Other information (n = 3)
Total Score (%)
MHM BC(30)
ACP BC screening(47)
CTF 40-74 yo BC screening(49)
CCO MRI high-risk BC(50)
GPC Colombia(60)


Rates of AGREE II accomplished items in BC Screening guidances.
100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%
69%
75%
76%
64%
41%
59%
53%
50%
48%
51%
53%
61%
34%
30%
77%
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52%
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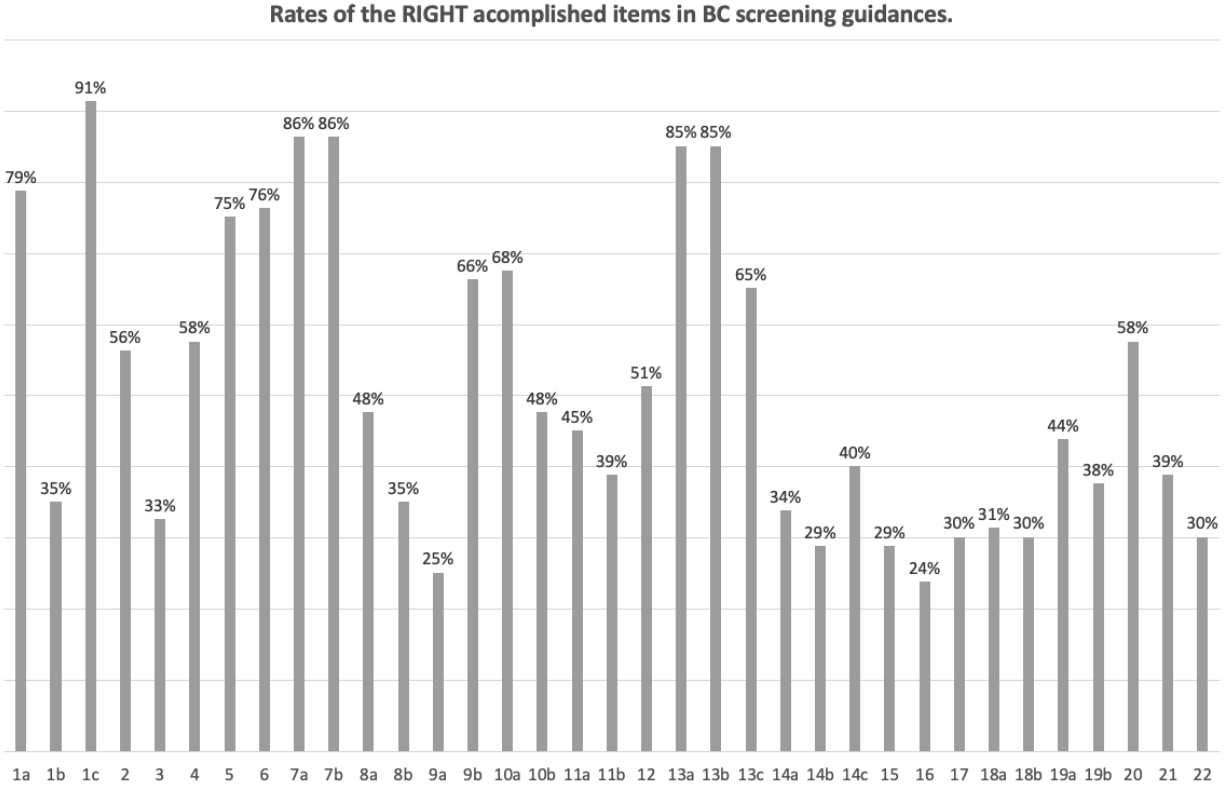
Rates of the RIGHT acomplished items in BC screening guidances.
79%
35%
91%
56%
33%
58%
75%
76%
86%
86%
48%
35%
25%
66%
68%
48%
45%
39%
51%
85%
85%
65%
34%
29%
40%
29%
24%
30%
31%
30%
44%
38%
58%
39%
30%
1a 1b 1c 2 3 4 5 6 7a 7b 8a 8b 9a 9b 10a 10b 11a 11b 12 13a 13b 13c 14a 14b 14c 15 16 17 18a 18b 19a 19b 20 21 22

6.9. Manuscript 8: Maes-Carballo M, Mignini L, Martín-Díaz M, Bueno-Cavanillas A, Khan K S. Quality and reporting of clinical guidelines for breast cancer treatment: A systematic review. Breast. 2020 Oct;53:201-211. doi: 10.1016/j.breast.2020.07.011. Epub 2020 Aug 10.

This eighth work has analysed the quality and reporting of CPGs and CSs on BC treatment (objective 8). We used AGREE II statement and RIGHT instrument to appraise the quality and reporting of CPGs and CSs BC treatment. Analysed documents were identified following Prospero protocol and PRISMA, without language restrictions, through a broad systematic search of bibliographic databases (MEDLINE, EMBASE, Web of Science, Scopus, CDSR) and online sources (12 guideline databases and 51 professional society websites) from January 2017 to December 2019. Data were extracted in duplicate assessing overall quality using AGREE II (% of maximum score) and reporting compliance using RIGHT (% of total 35 items); reviewer agreement was 98% and 96% respectively. Fifty-nine guidance documents (43 CPGs, 16 CSs) were analysed. The median overall quality was 54.0% (IQR 35.9-74.3), and the median overall reporting compliance was 60.9% (IQR 44.5-84.4). The correlation between quality and reporting was 0.9. CPGs had better quality (55.4% vs 44.2%; p ¼ 0.032) and reporting (67.18% vs 44.5%; p = 0.005) than CSs. Compared to subjective evidence analysis methods, guidance documents that used systematic reviews had better quality (76.3% vs 51.4%; p = 0.001) and reporting (87.1% vs 59.4%; p = 0.001). To sum up, the quality and reporting of CPGs and CSs in BC treatment were moderately strong. Systematic reviews should be used to improve the quality and reporting of CPGs and CSs.

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Review

Quality and reporting of clinical guidelines for breast cancer treatment: A systematic review

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"Appraisal instruments"
"Quality of guidelines"

ABSTRACT

Background: High-quality, well-reported clinical practice guidelines (CPGs) and consensus statements (CSs) underpinned by systematic reviews are needed. We appraised the quality and reporting of CPGs and CSs for breast cancer (BC) treatment.

Methods: Following protocol registration (Prospero nº: CRD42020164801), CPGs and CSs on BC treatment were identified, without language restrictions, through a systematic search of bibliographic databases (MEDLINE, EMBASE, Web of Science, Scopus, CDSR) and online sources (12 guideline databases and 51 professional society websites) from January 2017 to June 2020. Data were extracted in duplicate assessing overall quality using AGREE II (% of maximum score) and reporting compliance using RIGHT (% of total 35 items); reviewer agreement was 98% and 96% respectively.

Results: There were 59 relevant guidance documents (43 CPGs, 16 CSs), of which 20 used systematic reviews for evidence synthesis. The median overall quality was 54.0% (IQR 35.9–74.3) and the median overall reporting compliance was 60.9% (IQR 44.5–84.4). The correlation between quality and reporting was 0.9. Compared to CSs, CPGs had better quality (55.4% vs 44.2%; $p = 0.032$) and reporting (67.18% vs 44.5%; $p = 0.005$). Compared to subjective methods of evidence analysis, guidance documents that used systematic reviews had better quality (76.3% vs 51.4%; $p = 0.001$) and reporting (87.1% vs 59.4%; $p = 0.001$).

Conclusion: The quality and reporting of CPGs and CSs in BC treatment were moderately strong. Systematic reviews should be used to improve the quality and reporting of CPGs and CSs.

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Abbreviations: Asian Breast Cancer Cooperative Group, ABCCG; Alberta Health Services, AHS; American Brachytherapy Society, AB; Annals of Surgery, AS; American Society of Breast Surgeons, ASBS; American Society of Clinical Oncology, ASCO; American Society of Plastic Surgeons, ASPS; American Society for Therapeutic Radiology and Oncology, ASTRO; Arbeitsgemeinschaft Gynäkologische Onkologie, AGO; Asociación Española de Cirujanos, AEC; Association of Breast Surgeons of India, ABSI; Association of Breast surgery, ABS; Australian Government, AG; Breast Cancer, BC; Breast Cancer Research Treatment, BCRT; British Journal of Surgery, BJS; Collegio Italiano dei Senologi, CIS; Chinese Journal of Cancer Research, CJCRCN; CPG, Clinical practice guideline; Clinical and Translational Oncology, CTO; Consensus statement, CS; Department of Plastic and Reconstructive Surgery, DPRS; Deutsches Ärzteblatt international, DAI; European School of Oncology, ESO; European Society for Medical Oncology, ESMO; European society radiation oncology, ESTRO; Groupe d'étude des facteurs pronostiques immunohistochimiques dans le cancer du sein, GEFPICS; Instituto de Evaluación de Tecnologías en Salud e Investigación, IETSI; Indian Journal of Surgery, IJS; Instituto Nacional de Colombia, INC; International multidisciplinary expert panel, IMEP; JCO, Journal of Clinical Oncology; JNCCN, Journal of the National Comprehensive Cancer Network; Journal of Plastic, Reconstructive & Aesthetic Surgery, JPRAS; Breast Expert Advisory Group/Northern Cancer Alliance, NCA; CancerCare Manitoba, CCM; Nacional Comprehensive Cancer Network, NCCN; National Health Commission of the People's Republic of China, NHCPRC; National Institute for Health and Care Excellent, NICE; PRS, Plastic and reconstructive surgery; Radiotherapy and Oncology, RO; Sociedad Española de Anatomía Patológica, SEAP; Brazilian Society of Radiotherapy, SBRT; Sociedad Española de Senología y Patología Mamaria, SESPM; Sociedad Española de Oncología Médica, SEOM; Secretaría de Salud de México, SSM; Society of Surgical Oncology, SSO; University Hospital of Würzburg, UHW.

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Contents

1. Introduction

Breast cancer (BC) is the most frequent cancer in women (about 2 million new cases annually) accounting for 15% of global cancer deaths (about 670,000 annually) [1–3]. Recent advances have shown the potential to decrease morbidity and mortality [4–6], but treatment success varies by region and type of hospital [7]. Clinical practice guidelines (CPGs) and consensus statements (CSs) are being promoted to harmonize the provision of effective health care [8–11]. Rigorously developed CPGs and CSs should be well-reported, deploying objective approaches for evidence analysis to underpin the recommendations [10,12].

Previous evaluations of guidance in BC treatment have shown that their quality can be heterogeneous [13–15]. However, these reviews are non-recent, covering CPGs and CSs published between 2009 and 2017. They were limited in their searches and applied languages restrictions to English only [13–15]. They have not had the benefit of recent developments in the assessment of CPGs and CSs [16,17]. It has been highlighted that quality and reporting are two distinct aspects that need to be examined separately. The former deals with issues of validity of the recommendations made while that latter examines the thoroughness of the presentation of the document prepared. In this regard, the thoroughness and transparency of evidence synthesis is a key guideline feature [18]. As there is a requirement for periodic revisions, an updated and comprehensive evaluation of recently published guidance documents is required [7].

In a systematic review, we exhaustively searched for recent CPGs and CSs for BC treatment and appraised their quality and reporting using validated tools, paying special attention to the method used for evidence analysis.

2. Methods

Following prospective registration (Prospero nº: CRD42020164801) a protocol-driven systematic review was performed using currently recommended methods for search and assessment of guidelines and reported using PRISMA statement (see Appendix 1) [1920].

2.1. Data sources and searches

The initial search from 2017 onwards was conducted on April 4th, 2020. A search update was undertaken on June 15th, 2020. We looked for online databases and guideline-specific databases without language restrictions associating MeSH terms “breast cancer”, “breast neoplasms”, “practice guidelines”, “guidelines”, “consensus” and including word alternatives, covering the period January 2017 to June 2020. We have also checked the specific professional society’s websites looking for updated guidelines. We decided to look for CPGs and CSs from 2017 onwards. The main reason for focusing on this 3-year time window was that a systematic review of literature stated that most of the guidance methodological handbooks for updating CPGs determined that the time between updates should be two or three years [21]. By excluding older guidance documents in which new knowledge for good CPG methods has not been incorporated we were able to review the most up-to-date literature. We looked for online databases (MEDLINE, CDSR, Web of Science, EMBASE, Scopus, etc.), 51 websites of important professional societies, and 12 guidance-specific databases (see Appendix 2). The main criterion for searching the websites of professional societies was the contribution of their country of origin to global breast cancer’s scientific production. We included professional societies in countries that produce at least 0.5% of the documents appearing in Scopus about Breast Cancer and Health Care (23,748 document results at July 10th, 2020). Finally, we searched the bibliographies of well-known publications and the World Wide Web to include other important documents in the review.

2.2. Study selection and data extraction

CPGs and CSs about BC management produced by national or international professional organizations and societies or governmental agencies were included. Randomized controlled trials (RCTs) and observational studies, narrative reviews, scientific reports, discussion papers, conference abstracts and posters, CPGs and CSs about screening and diagnosis, obsolete guidelines replaced by updates from the same organization, and CPG and CSs for education and information purpose only were excluded.

The eligibility of each of the abstracts and titles from the citations was considered independently by two reviewers (MMC and LM), both breast cancer specialists. Full-text versions of potentially relevant citations were obtained to confirm eligibility. A third reviewer (MMD) helped to solve disagreements by consensus or arbitration. Duplicate articles were identified and removed. Where multiple versions were retrieved the most updated version of the guidelines was included. Data were extracted from selected CPGs and CSs in duplicate, independently.

2.3. Assessment of quality and reporting

Two reviewers (MMC and LM) extracted data on a piloted proforma to assess the quality and reporting of CPGs and CSs using two validated appraisal tools, the AGREE II instrument and the RIGHT statement (Appendix 3).[16] [17] According to AGREE II quality was the "reliability that potential development biases have been appropriately addressed and recommendations are internally and externally valid" [22]. Data were extracted for its 23 items according to predefined criteria divided into six domains: scope and purpose (items 1 to 3), stakeholder involvement (items 4 to 6), the rigor of development (items 7 to 14), clarity and presentation (items 15 to 17), applicability (items 18 to 21) and editorial independence (items 22 and 23). A 7-point scale was used to score each item (anchored between 1 or strongly disagree, i.e. when there was no relevant information concerning the item, to 7 or strongly agree, i.e. when the quality of reporting was exceptional, and the criteria were fully met). The domain quality scores (0–100%) were calculated by summing up reviewers' individual scores and scaling as a percentage of the maximum possible score according to the formula provided in the AGREE II manual averaging the scores of the two reviewers [22]. To avoid major deviations in reviewers' assessments, we deployed discussion to reach consensus. In addition, an overall guideline assessment was calculated using the mean scores of the 6 standardized domain and a recommendation made: a CPG or CS was "recommended" if the score >80% [23], "recommended with modifications" if it was 50–80%, and "not recommended" if <49% [24].

For reporting assessment data were extracted for the RIGHT [17] statement's 35 items divided into 7 domains: basic information (items 1 to 4), background (items 5 to 9), evidence (items 10 to 12), recommendations (items 13 to 15), review and quality assurance (items 16 and 17), funding and declaration and management of interests (items 18 and 19), and other information (items 20 to 22). A numeric score of 1 (reported), 0.5 (partially reported), or 0 (unreported) was assigned to each item. Disagreements between two reviewers in the score were discussed and unresolved matters were addressed by an arbitrator (MMD). A percentage of the total was calculated to obtain an overall reporting assessment and guidance documents were classified as "well-reported" if the score was >80%, "moderate-reported" if it was 50–80%, and "low-reported" if <50% [24].

2.4. Data analysis

Consistency between reviewers in data extraction was assessed using the intraclass correlation coefficient (ICC), where excellent reliability level was >0.90 [25]. A descriptive statistical analysis was conducted for domains and overall scores. Kruskal-Wallis test was used to compare scores and to evaluate factors that might affect the quality and reporting of CPGs and CSs. All analyses were performed using Stata 16. A value of $p < 0.05$ denoted statistical significance.

3. Results

3.1. Study selection

Of the 7430 potential citations identified, 7334 were from online databases (MEDLINE, EMBASE, SCOPUS, Web of Science, Trip database) and 96 were from additional sources (guideline specific databases, professional societies, and the Word Wide Web). Of them, 168 publications were found duplicated and 7205 did not meet the selection criteria. A total of 59 documents (43 CPGs [26–68] and 16 CSs 42–57 [69–84]) were identified for final evaluation (Table 1). The flow diagram detailing the study selection process is provided in Fig. 1. ICC for reviewer agreement was 0.98 in AGREE II and 0.96 in RIGHT. The correlation between AGREE II and RIGHT scores was $r = 0.90$ (Appendix 4).

3.2. Quality assessment

The analysis of the documents with the AGREE II instrument showed a wide overall score range (16–92%) (Fig. 2 and Appendix 5). The median overall quality was 54.0% (IQR 35.9–74.3). Only 13 (22%) of the CPGs or CSs were "recommended" as presented; the rest were not (19 (32%) "not recommended", 27 (46%) "recommended with modifications"). Quality was heterogeneous in the domains (Appendix 5). In Domains 1 (scope and purpose) and 4 (clarity of presentation) 39 (66%) and 30 (51%) CPGs and CSs respectively scored >75%. In domain 5 (applicability) only 1 (2%) CPG scored >75%. Domain 6 (Editorial independence) related to the bias linked to conflict of interest, scored >75% in 34 (58%) CPGs but it was 0% or almost 0% in five CPGs [26,40,57,63,64,66] and four CSs [72,75,76,78,82]. The ASCO [43–50,52,53], Dutch [31] and Colombian [58] CPGs had the highest quality scores (Fig. 2, Appendix 6). For a better understanding of NICE guidelines, we studied the "Developing NICE guidelines: the manual" [85]. This led to a slight increase in the NICE CPGs scores, although it would be better if the relevant manual content were included in each NICE CPG itself. It is noteworthy that no specific methods are explained in the manual and this made it difficult to analyze the quality of the guidances.

3.3. Reporting assessment

CPGs and CSs reporting was heterogeneous and had a wide overall score range (16–89%) using the RIGHT statement (Fig. 3 and Appendix 7). The median overall reporting compliance was 62.5% (IQR 44.5–84.4). Only 5 (8%) of the CPGs and CSs were "well-reported", 31 (53%) were "moderate-reported" and 23 (39%) were "low-reported". Fig. 3 showed that reporting in domains was heterogeneous. The median of the domain scores was 67% (17–100%) for domain 1 (basic information), 63% (0–100%) for domain 2 (background), 60% (0–100%) for domain 3 (evidence), 50% (0–86%) for domain 4 (recommendations), 25% (0–75%) for domain 5 (review and quality assurance), 0 (0–19%) for domain 6 (funding and declaration and management of interests) and 50% (0–100%) for domain 7 (other information). The ASCO [46,48–50] and Dutch [31] CPGs had the highest reporting compliance (Appendix 8).

Table 1
Description of the CPGs and CSs (n = 167) selected for the systematic review.

	Name of the CPG	Abbreviated name	Entity	Country	Year	Publication in a Journal	Version	Evidence analysis	Quality tool referral
1	Chinese guidelines for diagnosis and treatment of breast cancer 2018[26]	Chinese BC diagnosis treatment[26]	NHCPRC	China	2018	CJCRCN	1	Not reported	Not reported
2	Early breast cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up[27]	ESMO BC 2019[27]	ESMO	Europe	2019	Annals of Oncology	3	Review	Not reported
3	ESO-ESMO 4th international consensus guidelines for breast cancer in young women (BCY4) ([28]	BCY4[28]	ESMO, ESO, EUSOMA	Europe	2020	The Breast	3	Consensus method; review	Not reported
4	AGO Recommendations for the Diagnosis and Treatment of Patients with Early Breast Cancer: Update 2019[29]	AGO Early BC 2019[29]	AGO	Germany	2019	Breast Care	5	Review	Not reported
5	AGO Recommendations for the Diagnosis and Treatment of Patients with Advanced and Metastatic Breast Cancer: Update 2018[30]	AGO Advanced BC 2018[30]	AGO	Germany	2018	Breast Care	5	Review	Not reported
6	Dutch breast reconstruction guideline[31]	Dutch BCR[31]	DPRS	Netherlands	2017	JPRAS	1	Systematic review	AGREE II
7	Cáncer de mama/Breast Cancer[32]	Fisterra BC[32]	Fisterra	Spain	2017	Not published	3	Not reported	Not reported
8	SEOM clinical guidelines in early-stage breast cancer[33]	SEOM early-stage[33]	SEOM	Spain	2018	CTO	2	Consensus method, not specified technique	Not reported
9	SEOM clinical guidelines in advanced and recurrent breast cancer[34]	SEOM advanced BC[34]	SEOM	Spain	2018	CTO	3	Consensus method, not specified technique	Not reported
10	Abemaciclib with fulvestrant for treating hormone receptor-positive, HER2-negative advanced breast cancer after endocrine the therapy[35]	NICE Abemaciclib[35]	NICE	UK	2019	Not published	1	Systematic review	Not reported
11	Ribociclib with fulvestrant for treating hormone receptor-positive, HER2-negativHER2-negative, advanced breast cancer[36]	NICE Ribociclib[36]	NICE	UK	2019	Not published	1	Systematic review	Not reported
12	Early and locally advanced breast cancer: diagnosis and management[37]	Early and locally advanced BC [37]	NICE	UK	2018	Not published	1	Systematic review	Not reported
13	Breast reconstruction following prophylactic or therapeutic mastectomy for breast cancer[38]	AHS reconstruction BC[38]	AHS	Canada	2017	Not published	2	Consensus method; review	Not reported
14	Adjuvant systemic therapy for early stage (lymph node negative and lymph node positive) breast cancer[39]	AHS early BC[39]	AHS	Canada	2018	Not published	4	Consensus method; review	Not reported
15	Performance and Practice Guidelines for the Use of Neoadjuvant Systemic Therapy in the Management of Breast Cancer[40]	ABSB Neoadjuvance BC [40]	ASBS	USA	2017	Not published	1	Consensus method; review	Not reported
16	Evidence-Based Clinical Practice Guideline: Autologous Breast Reconstruction with DIEP or Pedicled TRAM Abdominal Flaps[41]	ASPS DIEP & TRAM[41]	ASPS	USA	2017	PRS	2	Review	Not reported
17	Use of Endocrine Therapy for Breast Cancer Risk Reduction: ASCO Clinical Practice Guideline Update[42]	ASCO Endocrine therapy risk BC[42]	ASCO	USA	2019	JCO	2	Systematic review	Not reported
18	Postmastectomy Radiotherapy: An American Society of Clinical Oncology, American Society for Radiation Oncology, and Society of Surgical Oncology Focused Guideline Update[43]	ASCO postmastectomy RT[43]	ASCO	USA	2017	JCO	2	Systematic review	Not reported
19	Selection of Optimal Adjuvant Chemotherapy and Targeted Therapy for Early Breast Cancer: ASCO Clinical Practice Guideline Focused Update[44]	ASCO treatment for early BC[44]	ASCO	USA	2018	JCO	2	Systematic review	Not reported
20	Systemic Therapy for Patients With Advanced Human Epidermal Growth Factor Receptor 2–Positive Breast Cancer: ASCO Clinical Practice Guideline Update[45]	ASCO systemic therapy EGR2 BC[45]	ASCO	USA	2018	JCO	2	Systematic review	Not reported
21	Recommendations on Disease Management for Patients With Advanced Human Epidermal Growth Factor Receptor 2–Positive Breast Cancer and Brain Metastases: ASCO Clinical Practice Guideline Update[46]	ASCO EGRF2 MBC[46]	ASCO	USA	2018	JCO	2	Systematic review	Not reported
22	Integrative Therapies During and After Breast Cancer Treatment: ASCO Endorsement of the SIO Clinical Practice Guideline[47]	ASCO BC treatment[47]	ASCO	USA	2018	JCO	2	Systematic review	Not reported
23	Role of Bone-Modifying Agents in Metastatic Breast Cancer: An American Society of Clinical Oncology–Cancer Care Ontario Focused Guideline Update[48]	ASCO bone-mod agents MBC[48]	ASCO	USA	2017	JCO	2	Systematic review	Not reported
24	Role of Patient and Disease Factors in Adjuvant Systemic Therapy Decision Making for Early-Stage, Operable Breast Cancer: American Society of Clinical Oncology Endorsement of Cancer Care Ontario Guideline Recommendations[49]	ASCO factors in early BC[49]	ASCO	USA	2019	JCO	2	Systematic review	Not reported
25	Use of Adjuvant Bisphosphonates and Other Bone-Modifying Agents in Breast Cancer: A Cancer Care Ontario and American Society of Clinical Oncology Clinical Practice Guideline[50]	ASCO use bone-mod agents BC[50]	ASCO	USA	2017	JCO	1	Systematic review	Not reported
26	Use of Biomarkers to Guide Decisions on Adjuvant Systemic Therapy for Women With Early-Stage Invasive Breast Cancer:	ASCO biomarkers in early BC[51]	ASCO	USA	2019	JCO	2	Review	Not reported

Table 1 (*continued*)

	Name of the CPG	Abbreviated name	Entity	Country	Year	Publication in a Journal	Version	Evidence analysis	Quality tool referral
	American Society of Clinical Oncology Clinical Practice Guideline Focused Update[51]								
27	Use of Biomarkers to Guide Decisions on Systemic Therapy for Women With Metastatic Breast Cancer: American Society of Clinical Oncology Clinical Practice Guideline[52]	ASCO biomarkers in MBC[52]	ASCO	USA	2019	JCO	2	Systematic review	Not reported
28	Adjuvant Endocrine Therapy for Women With Hormone Receptor-Positive Breast Cancer: ASCO Clinical Practice Guideline Focused Update[53]	ASCO endocrine treatment Her2 BC[53]	ASCO	USA	2019	JCO	2	Systematic review	Not reported
29	Optimal margins for breast-conserving surgery with whole-breast irradiation in ductal carcinoma in situ: Results of the ASTRO, ASCO, and SSO consensus guideline[54]	ASCO, ASTRO, SSO CID[54]	ASCO, ASTRO, SSO	USA	2017	Annals of Surgery	1	Consensus method; review	Not reported
30	Radiation therapy for the whole breast: Executive summary of an American Society for Radiation Oncology (ASTRO) evidence-based guideline[55]	ASTRO RT for whole breast[55]	ASTRO	USA	2018	PRO	2	Systematic review	Not reported
31	Breast Cancer. Version 3.2019[56]	NCCN BC[56]	NCCN	USA	2019	JNCCN	4	Review	Not reported
32	Influencing best practice in breast cancer[57]	Australia BC[57]	AG	Australia	2017	Not published	1	Systematic review	Not reported
33	Guía de práctica clínica (GPC) para la detección temprana, tratamiento integral, seguimiento y rehabilitación del cáncer de mama[58]	GPC Colombia[58]	INC	Colombia	2017	Not published	2	Systematic review	Not reported
34	Guía de Práctica Clínica para el Tratamiento del Cáncer de Mama[59]	GPC Perú[59]	IETSI	Perú	2017	Not published	1	Systematic review	AGREE II
35	The Screening, Diagnosis, Treatment, and Follow-Up of Breast Cancer[60]	Würzburg BC[60]	UHW	Germany	2018	DAI	1	Systematic review	Not reported
36	Cirugía de la Mama[61]	AEC BC[61]	AEC	Spain	2017	Not published	2	Not reported	Not reported
37	Manual de Práctica Clínica en Senología. 4ª Edición. 2019 [62]	SESPM [62]	SESPM	Spain	2019	Not published	2	Not reported	Not reported
38	Linee guida: Neoplasie della mammela [63]	CIS Neoplasia mammella [63]	CIS	Italy	2019	Not published	1	Not reported	Not reported
39	La radioterapia nel carcinoma della mammella. Indicazioni e tecniche [64]	CIS RT mammella [64]	CIS	Italy	2018	Not published	1	Not reported	Not reported
40	Recommandations du GEFPICS pour la prise en charge des prélèvements dans le cadre du traitement néoadjuvant du cancer du sein [65]	GEFPICS Cancer du sein [65]	GEFPICS	France	2019	Annals of Pathologie	1	Not reported	Not reported
41	Breast Cancer Clinical Guidelines[66]	NCA BC[66]	NCA	UK	2019	Not published	1	Review	Not reported
42	The Japanese Breast Cancer Society Clinical Practice Guidelines for systemic treatment of breast cancer, 2018 edition[67]	Japanese systemic BC[67]	JBCS	Japan	2020	Breast Cancer	2	Systematic review	Not reported
43	The Japanese Breast Cancer Society Clinical Practice Guidelines, 2018 edition: the tool for shared decision making between doctor and patient[68]	Japanese SDM BC[68]	JBCS	Japan	2020	Breast Cancer	1	Systematic review	Not reported
44	Consenso Mexicano sobre diagnóstico y tratamiento del cáncer mamario [69]	GPC México[69]	SSM	México	2019	Not published	7	Nominal group technique	Not reported
45	Indian Solutions for Indian Problems—Association of Breast Surgeons of India (ABSI) Practical Consensus Statement, Recommendations, and Guidelines for the Treatment of Breast Cancer in India[70]	Indian ICMR CS[70]	ABSI	India	2017	IJS	2	Delphy modified technique	Not reported
46	4th ESO–ESMO International Consensus Guidelines for Advanced Breast Cancer (ABC 4) ([71]	ABC4[71]	ESMO	Europe	2018	Annals of Oncology	4	Nominal group technique	Not reported
47	St. Gallen/Vienna 2019: A Brief Summary of the Consensus Discussion about Escalation and De-Escalation of Primary Breast Cancer Treatment[72]	St. Gallen 2019[72]	St. Gallen	Europe	2019	Breast Care	4	Nominal group technique	Not reported
48	Biomarkers in breast cancer: A consensus statement by the Spanish Society of Medical Oncology and the Spanish Society of Pathology[73]	SEOM & SEAP[73]	SEOM & SEAP	Spain	2017	CTO	1	Not reported	Not reported
49	Provincial consensus recommendations for adjuvant systemic therapy for breast cancer[74]	CCM 2017[74]	CCM	Canada	2017	Not published	1	Systematic review	AGREE II
50	Consensus Guideline on Accelerated Partial Breast Irradiation[75]	ASBS RT[75]	ASBS	USA	2018	Not published	1	Review	Not reported
51	Consensus Guideline on the Use of Transcutaneous and Percutaneous Ablation for the Treatment of Benign and Malignant Tumors of the Breast[76]	ASBS ablation[76]	ASBS	USA	2018	Not published	1	Review	Not reported
52	Consensus Guideline on the Management of the Axilla in Patients With Invasive/In-Situ Breast Cancer[77]	ASBS axilla[77]	ASBS	USA	2019	Not published	1	Review	Not reported
53	Consensus Guideline on Breast Cancer Lumpectomy Margins[78]	ASBS margins[78]	ASBS	USA	2017	Not published	1	Review	Not reported
54	The American Brachytherapy Society consensus statement on intraoperative radiation therapy[79]	AB intraoperative RT[79]	AB	USA	2017	Brachytherapy	1	Nominal group technique	Not reported
55	ESTRO-ACROP guideline: Interstitial multi-catheter breast brachytherapy as Accelerated Partial Breast Irradiation alone or	ESTRO-ACROP RT[80]	ESTRO	Europe	2018	RO	1	Consensus method; review	Not reported

(*continued on next page*)

Table 1 (*continued*)

	Name of the CPG	Abbreviated name	Entity	Country	Year	Publication in a Journal	Version	Evidence analysis	Quality tool referral
	as boost - GEC-ESTRO Breast Cancer Working Group practical recommendations[80]								
56	ESTRO ACROP consensus guideline for target volume delineation in the setting of postmastectomy radiation therapy after implant-based immediate reconstruction for early stage breast cancer[81]	ESTRO-ACROP postmactectomy[81]	ESTRO	Europe	2019	RO	1	Consensus method; review	Not reported
57	Recommendations for hypofractionated whole-breast irradiation[82]	SBRT RT[82]	SBRT	Brazil	2018	RO	1	Consensus method, not specified technique	Not reported
58	Treating HR+/HER2- breast cancer in premenopausal Asian women: Asian Breast Cancer Cooperative Group 2019 Consensus and position on ovarian suppression[83]	ABCCG BC[83]	ABCCG	Asia	2018	BCRT	1	Consensus method; review	Not reported
59	International multidisciplinary expert panel consensus on breast reconstruction and radiotherapy[84]	IMEP BR and RT[84]	IMEP	Europe	2019	BJS	1	Consensus method; review	Not reported

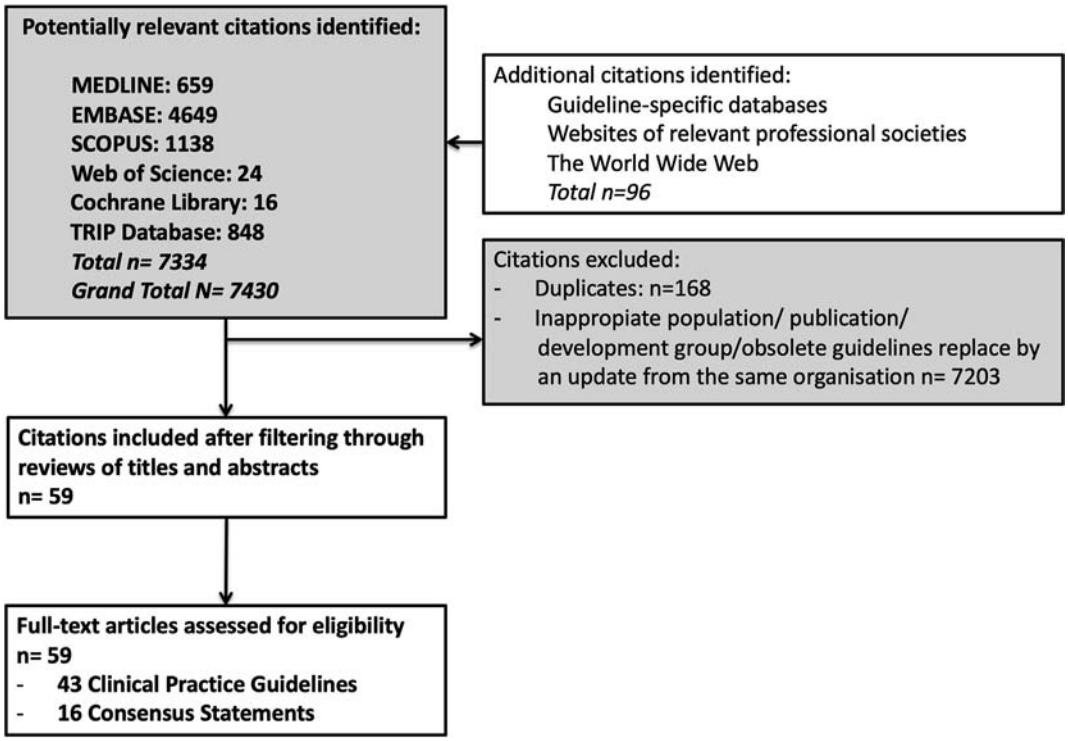

Fig. 1. The flow diagram detailing the study selection.

3.4. Variables related to quality and reporting

As shown in Table 2 CPGs scored better than CSs regarding quality ($p = 0.032$) and reporting ($p = 0.005$). CPGs from the USA had a better score than Europe and the rest of the world (AGREE II 75.7% vs 45.1% vs 55.1, $p = 0.003$; RIGHT 87.1% vs 55.5% vs 59.4, $p = 0.015$). The year of publication did not affect the quality ($p = 0.791$) or reporting ($p = 0.718$). Compared to consecutive updates of the CPG or CS, the second version when published within the review period had better quality ($p = 0.001$) and reporting ($p = 0.002$). Compared to subjective methods of evidence analysis, guidance documents that used systematic reviews had better quality than consensus (76.3% vs 51.4%; $p = 0.001$) and reporting (87.1% vs 59.4%; $p = 0.001$). CPGs and CSs published in a journal showed better quality (66.5% vs 42.0%; $p = 0.001$) and reporting (65.6 vs 50.4; $p = 0.001$) than those unpublished.

4. Discussion

4.1. Main findings

The median overall quality and reporting of CPGs and CSs in BC treatment were poor. Around two-thirds of all guidance documents could not be recommended as written. Over three-quarters of all guidance documents were not well-reported. Compared to CSs, CPGs had better quality and reporting. Compared to subjective methods of evidence analysis, CPGs and CSs using systematic reviews and those published in a journal showed better quality and reporting. Compared to updates, the first iteration CPGs and CSs published within the review period had better quality and reporting.

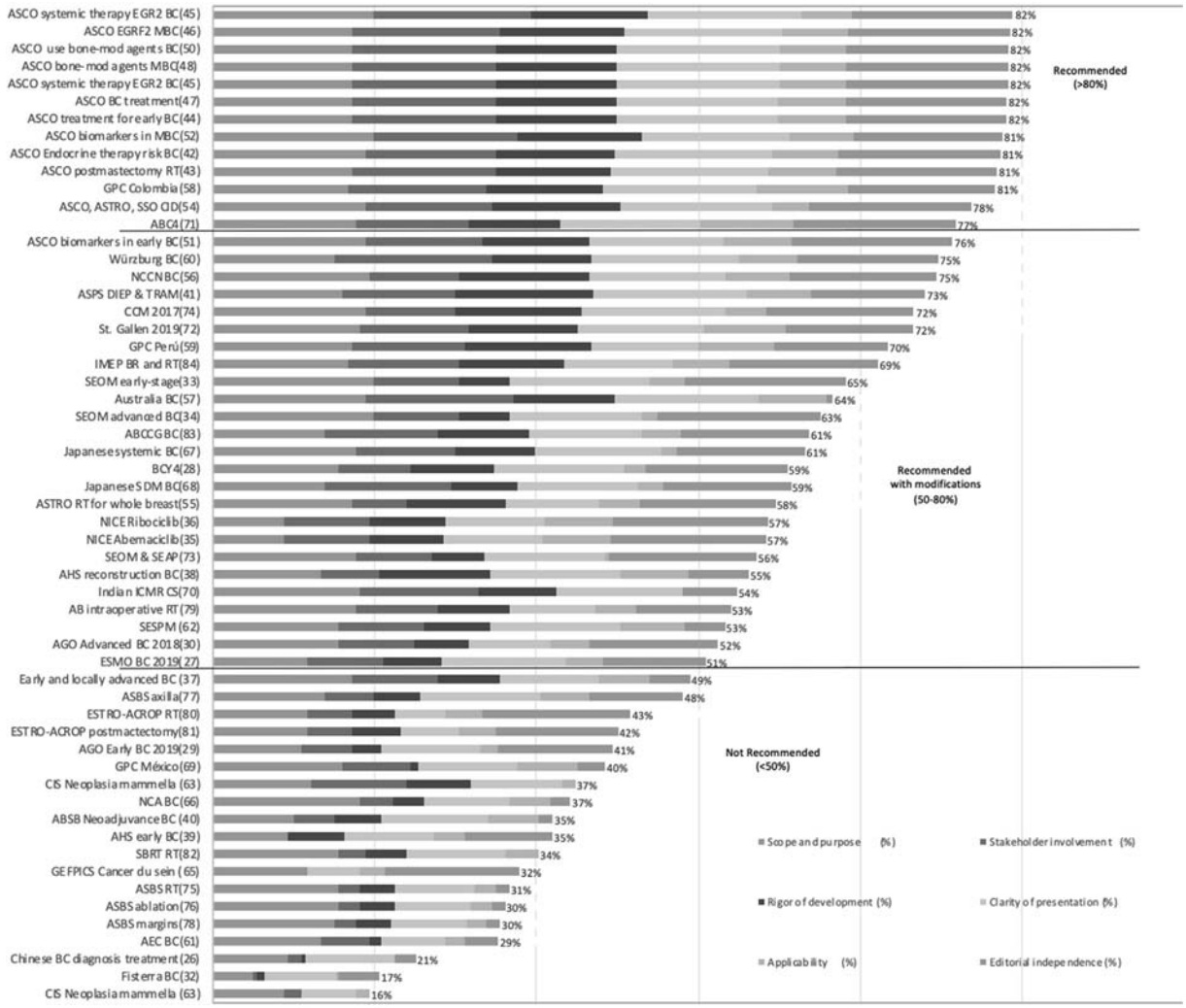

Fig. 2. AGREE II overall score of BC CPGs and CSs.

4.2. Strengths and weaknesses

Our review had a global perspective with a reasonable number of CPGs and CSs identified using a comprehensive search without language restrictions. English and Spanish are the most widely spoken languages [86] and many of the Societies [32–34] present versions in both English and Spanish. One strength of this review is that the authors had command of both languages.

We had a prospective protocol using two well-developed assessment tools, AGREE II instrument [16] and RIGHT statement [17], for as complete an assessment as possible. To our knowledge, an evaluation of guidance documents for BC treatment, using both AGREE II and RIGHT tools, has not been reported previously. While AGREE II instrument addresses different aspects of quality and RIGHT statement is a reporting tool, some items partially overlap. Our results suggest that reporting and quality are correlated. So reporting CPGs or CSs according to the RIGHT recommendations can lead to an increase in the AGREE scores, thus increasing the quality of the guidances. One presumed limitation of this review could be the subjective nature of data extraction concerning quality and reporting items. We minimized this issue by using two experienced BC specialist clinicians who studied the assessment tool manuals to create a mutual understanding of the scoring procedures before duplicate data extraction. Where concerns about major deviations arose, we used reviewer consensus backed by independent arbitration. It was reassuring to note that the reviewer agreement was excellent, with the ICC >95%.

Our main findings have some provisos in that the overall assessments made might be limited because of the lack of clear rules about the weighting of domains and items in the quality and reporting scoring manuals [87]. Although RIGHT statement [17] recommends against deriving a score from the checklist (the items may not be equally weighted, and scores have been shown to be problematic in research synthesis), we found it useful for comparing CPGs and CSs. It also facilitated the comparison of quality with reporting. The AGREE II Consortium [16] and RIGHT team [17] have not preset the thresholds to differentiate between high, moderate, and poor quality and reporting. We used previously reported limits [23,24] to set the cut-offs for our analyses *a priori*. We are, therefore, confident that our main findings concerning poverty of guideline quality and reporting, and the negative impact of lack of systematic review for evidence synthesis are robust. These deficiencies merit urgent attention.

We studied articles published from 2017 onwards. So, we are aware that guidance documents outside our time range from reputable organizations would have been excluded. There was heterogenicity amongst the guidelines included in the review. We only included those guidelines that fulfilled the inclusion criteria.

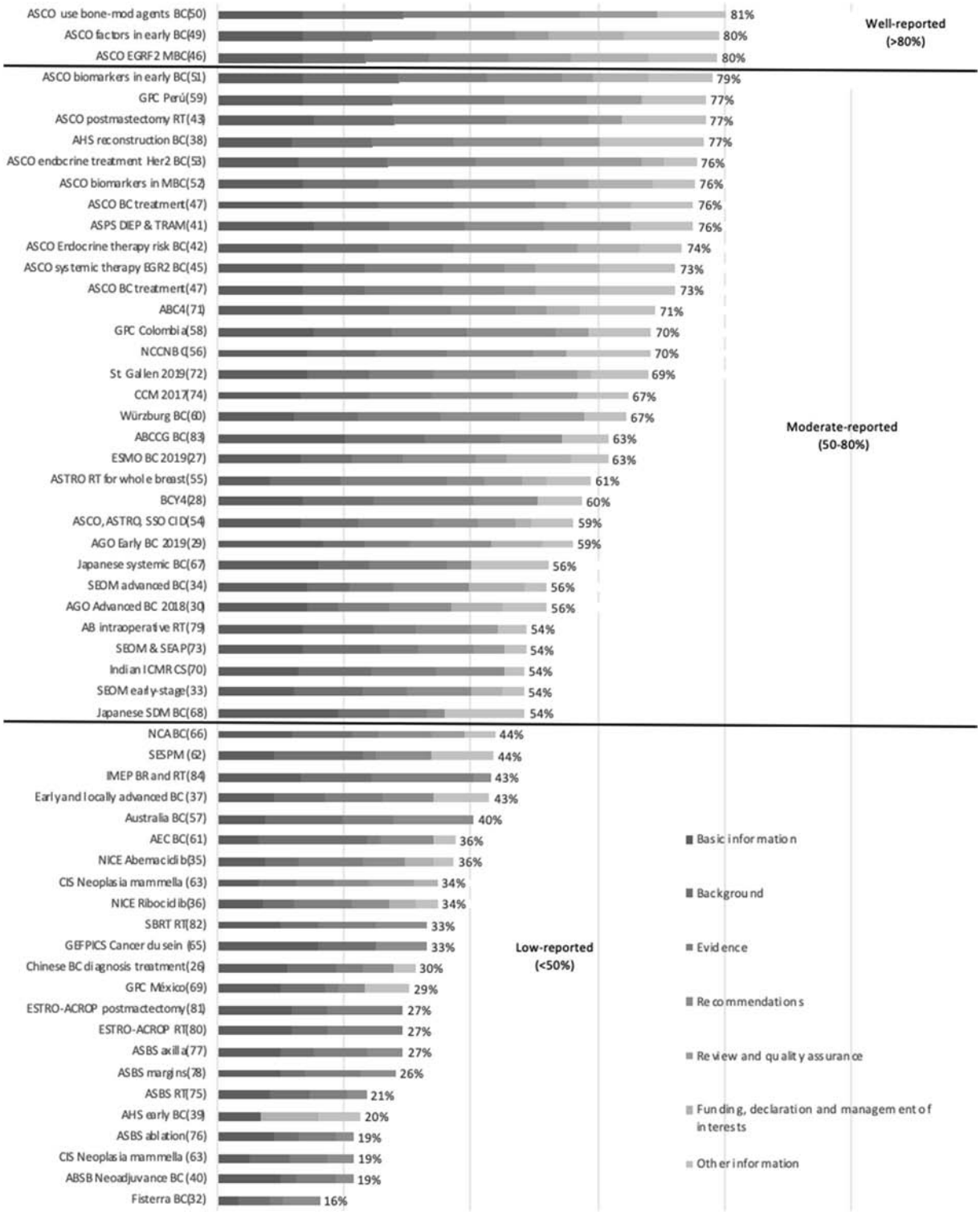

Fig. 3. RIGHT overall score of BC CPGs and CSs.

This formal demonstration of heterogeneity in our review is in itself an important observation that merits consideration as a limitation of the existing guidances. However, this type of heterogeneity may be unavoidable as the guidances differ in their development, structure, context, endpoint definitions, etc. according to target users, both patients and clinicians [88].

4.3. Implications

Our review and analysis highlighted that the quality and reporting of the guidance documents in BC treatment has a wide space for improvement. This is especially obvious in domains concerning applicability and rigor of development in AGREE II. To increase the general quality of CPGs and CSs, there is a necessity of

Table 2
Variables related to quality and reporting of CPGs and CSs.

	AGREE II			RIGHT		
Variable	Median	IGQ Range	p value	Median	IGQ Range	p value
Type of document						
CPGs	55.4%	44.6–76.5		67.18%	50.7–88.2	
CSs	44.2%	32.2–60.9	p = 0.032	44.5%	30.1–63.7	p = 0.005
Country						
USA	75.7%	48.9–76.8	p = 0.003	87.1%	59.3–93.0	p = 0.015
Europe	45.1%	34.4–53.9		55.5%	43.0–66.8	
Other countries	55.1%	45.3–64.5		59.4%	44.5–76.5	
Publication Year						
2017	60.5%	46.4–75.4		71.9%	44.5–90.6	
2018	48.3%	31.9–68.8		60.9%	35.9–76.6	
2019	49.3%	37.0–75.2		58.2%	48.4–83.2	
2020	53.9%	51.8–55.0	p = 0.791	60.9%	59.4–65.6	p = 0.718
Publication in a journal						
Yes	66.5%	48.9–76.5		68.8%	59.4–89.8	
No	42.0%	27.9–52.9	p = 0.001	46.8%	37.5–52.4	p = 0.001
Versión number						
1	45.1%	32.1–60.8		50.4%	30.1–64.8	
2	76.0%	55.8–76.8		87.1%	62.5–91.8	
3 or more	45.3%	33.3–68.8	p = 0.001	65.6%	46.9–70.3	p = 0.002
Evidence analysis						
Consensus	51.4%	35.9–56.5		59.4%	42.2–67.2	
Not reported	38.0%	15.9–45.6		50.0%	28.9–52.3	
Review	42.0%	27.9–72.5		60.9%	30.5–78.1	
Systematic review	76.3%	69.7–77.2	p = 0.001	87.1%	75.0–92.9	p = 0.001
Quality tool referral						
Reported	70.3%	69.2–89.5		83.6%	76.6–97.7	
Not reported	52.5%	35.7–73.7	p = 0.073	60.9%	43.4–82.4	p = 0.065

improvement in considering the potential resource implications of applying the recommendations, presenting monitoring and/or auditing criterion, and providing a procedure for updating the guideline (Appendix 9). In reporting using RIGHT, the domains in need of closer attention are basic information, background, the contrast of evidence of recommendations, and the declaration of interest and funders. There is a need of amelioration in adding new or key terms, a list of abbreviations and acronyms, in indicating whether the draft guideline underwent independent review or whether the guideline was subjected to a quality assurance process (Appendix 10).

CPGs scored higher than CSs due to the fact their methods were better developed, and they more often deployed systematic reviews. Although the terms CPGs and CSs are often used interchangeably, they have differences that need to be highlighted. A clinical practice guideline produces statements that are informed by a systematic review of the evidence and an assessment of the benefits and harms of alternative options. A consensus statement is developed by an independent panel of experts, usually multidisciplinary, convened to review the research literature in an evidence-based manner for the purpose of advancing the understanding of an issuing procedure or method [89]. CSs are more likely to be sponsored by a pharmaceutical company and to endorse a specific product [89]. Unfortunately, transparency of document development was generally poor in both types of documents, and there was infrequent documentation of conflicts of interests, sources of funding, how guideline groups were established and who comprised their guideline development team. CSs are known to score lower than CPGs for scores of the rigor of development and editorial independence [89]. It is also necessary to highlight that CSs are intended for controversial areas of breast management (where the evidence is still incomplete), and the recommendations are based on experts' perspectives. This brings in the notion of lower quality and broader risks of bias [89], which is relevant for the guidance based on consensus.[27,28,81]

It is interesting that only 2 CPGs referred to AGREE II in the development of recommendations. The publication in a journal was associated with better quality and reporting. This could be due to reverse causality; however, every guidance should be submitted for publication in a peer-review journal. Our observations are that there is room for improvement that applies even to CPGs and CSs with high scores as all have some deficiencies. There remains a debate about cut-offs for defining acceptable scores and weighting of the items and domains. These issues should be subject to future research. In the current climate of formality and transparency, it should not be admissible that some CPGs or CSs do not even meet the basic quality and reporting criteria. These flaws will inevitably reduce the possibility of providing the best care to patients.

4.4. Conclusions

This systematic review found that CPGs and CSs for BC treatment insufficiently followed quality and reporting assessment tools. In the future, CPGs and CSs should take AGREE II and RIGHT into account to produce high-quality guidance documents underpinned by systematic reviews to ensure that recommendations are trustworthy. Focus on rigor in guidance development and practical advice concerning the application of recommendations in clinical setting is required for the implementation of evidence-based medicine to improve health outcomes.

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Contributors

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search, data collection and analysis, quality appraisal, and writing. LM was involved in the development of data extraction, analysis, and writing. MMD was involved in the analysis of data. ABC was involved in the design of this review and provided critical revision of the paper. KSK was involved in the design of this review, conducted the quality appraisal, in the writing, and provided critical revision of the paper. All authors read and provided the final approval of the version to be published.

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Data sharing statement

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

Declaration of competing interest

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

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6.10. Manuscript 9: Maes-Carballo M, Moreno-Asencio T, Martín-Díaz M, Mignini L, Bueno-Cavanillas A, Khan K S. Shared decision making in breast cancer screening guidelines: a systematic review of their quality and reporting.

This seventh article has answered the aim seventh. It has carried out a systematic review on the quality and the reporting of SDM in BC screening CPGs and CSs. Seventy-seven CPGs and CSs on BC screening were identified, without language restrictions, through a comprehensive systematic search of bibliographic databases (MEDLINE, EMBASE, Web of Science, Scopus, CDSR) and online sources (12 guideline databases and 51 professional society websites) from January 2010 to August 2020. Data extraction, duplicated, used a 31-item SDM quality assessment tool; reviewer agreement was 98%. The guidances had low quality (mean 2.83 items; p=0.001). SDM appeared only in 37 (48%) (33/68 CPGs, 4/9 CSs). Those specifically mentioning the term SDM (n=12) had higher quality (mean 6.8, IQR 4-9 vs mean 2.1, IQR 0-3; p=0.001). No differences were found in mean quality comparing CPGs with CSs (3 vs 1.6; p=0.634), use of systematic review (4.2 vs 2.9; p=0.929), and publication in a journal (4 vs 1.9; p=0.094). Guidances with SDM were more recently reported (mean 41 vs 57 months; p=0.042). In conclusion, more than half of the guidelines did not meet any quality criteria, although those recently reported had explored more about SDM. There is an urgent need for promoting SDM in guidance documents concerning BC screening issued by institutions, professional associations, and medical journals.

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Shared decision making in breast cancer screening guidelines: a systematic review of their quality and reporting.

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Keywords:	breast cancer screening, clinical practice guidelines, consensus, shared decision making, quality of guidelines

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Shared decision making in breast cancer screening guidelines: a systematic review of their quality and reporting

For Review Only

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For Review Only

Abstract

Background: Shared decision-making (SDM) is a key component of evidence-based and patient-centred care. The aim of this study is to systematically review the quality of SDM proposals in clinical practice guidelines (CPGs) and consensus statements (CSs) concerning breast cancer (BC) screening.

Methods: Guidances were identified, without language restrictions, using a prospectively planned systematic search (MEDLINE, EMBASE, Web of Science,

Scopus, guideline websites) from January 2010 to August 2020. Duplicate data extraction used a 31-item SDM quality assessment tool; reviewer agreement was 98%.

Results: SDM appeared only in 38 (49.4%) (33/68 CPGs, 4/9 CSs) documents (overall compliance with the quality tool: mean 5.74, IQR 3-8). CPGs and CSs specifically mentioning the term SDM (n=12) had higher quality (mean 6.8, IQR 4-9 vs mean 2.1, IQR 0-3; p=0.001). No differences were found in mean quality comparing CPGs with CSs (3 vs 1.6; p=0.634), use of systematic review (4.2 vs 2.9; p=0.929), and publication in a journal (4 vs 1.9; p=0.094). Guidances with SDM were more recently reported than those without it (mean 41 vs 57 months; p=0.042).

Conclusion: More than half of all the guidelines did not meet SDM quality criteria. Those that explored it were more recently reported. There is an urgent need for promoting SDM in guidances concerning BC screening issued by institutions, professional associations, and medical journals.

Keywords: "breast cancer screening", "clinical practice guidelines", "consensus", "shared decision making", "quality of guidelines"

1. Introduction:

Breast cancer (BC) is the most common cancer in women (around 2 million new cases per year) and represents 15% of cancer deaths worldwide (about 670,000 per year).(1) Its local and systemic treatments cause considerable morbidity.(2) Early detection of BC allows less aggressive and more effective and efficient treatments, lowering morbidity and increasing survival.(3) BC screening is costly and bothersome(3), and it entails the risk of false-positives and negatives, which may incur unnecessary stress or procedures and a false sense of security.(4) There is a debate about the effectiveness of BC screening and overtreatment due to false-positive results.(3) The mortality reduction is not statistically significant at all ages,(5) and the benefit versus harm balance are uncertain.(3) So, screening should be tailored to the characteristics (age, genetic factors, race, etc.), desires and values of women.(6) Psychological harms and women´s preferences are not usually emphasised by practitioners in screening.(7)

Shared decision making (SDM), a key component of evidence-based and patient-centred care(8), becomes relevant when there are uncertain risks versus benefits for conducting the screening.(9) It involves bidirectional information flow between the

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clinician and the patient. It has been proved beneficial in situations when more than one screening decision is possible.(9) SDM increases the patient´s satisfaction (10), and reduces medical malpractice claims.(11) It is considered a cornerstone for ensuring high-quality cancer care(10), and it is a legal obligation in developed countries.(12) However, its application in cancer care and screening is still scarce(6), and it faces many difficulties and barriers to overcome.(13) Many models and tools have been proposed for SDM application(14), and Decision Aids and Option Grids could help in the process(15, 16). Governmental and institutional promotion is essential(12), and clinical practice guidelines (CPGs) and consensus statements (CSs) should have strong recommendations about SDM implementation.(17) Fortunately, guidance documents are increasingly recommending it(18). It has been shown that the systematic inclusion of practical issues to inform SDM in CPGs supports evidence-based decisions(19, 20).

This systematic review aimed to assess SDM in BC screening CPGs and CSs, evaluating the quality of recommendations about SDM and the characteristics of guidance documents, including SDM.

2. Methods

A registered systematic review (Prospero nº: CRD42020203854) was accomplished following advocated methods for search, assessment and reporting of guidelines using PRISMA statement (see Appendix 1).(21, 22)

2.1. Data sources and searches

A search for relevant publications from 2010 onwards without language restrictions was undertaken on August 23rd, 2020 using a combined MeSH terms "practice guidelines", "guidelines", "consensus", "breast neoplasms", "breast cancer", “screening” and including word alternatives. We searched online databases (EMBASE, Web of Science, MEDLINE, Scopus, CDSR, etc.), 84 websites of important professional societies, and 12 guidance-specific databases. Details of the search strategy were reported in Appendix 2. The Worldwide Web was explored to include other important documents of professional societies from countries with global breast cancer´s scientific production over 0.5%; 23,748 “Breast Cancer and Health” documents were analyzed from Scopus on July 10th, 2020, to calculate the scientific production of each country.

2.2. Eligibility and inclusion criteria

We included all studies that met the following criteria: eligible guidances about BC screening produced by national or international professional organizations and societies or governmental agencies. We have considered both those guidelines in which screening was the main topic and those in which there was a section dedicated to screening or prevention. We excluded screening program documents, CPGs and CSs about diagnosis and treatment, antiquated guidelines replaced by updates from the same organization, and CPG and CSs for education and information purpose, randomized controlled trials (RCTs), observational studies, narrative reviews, scientific reports, discussion papers, conference abstracts, and posters. Two reviewers (MMC and LM) independently selected potential documents by reviewing titles and abstracts. Finally, the full text was requested for a more detailed evaluation. Disagreements were solved by a third reviewer (MMD) by consensus or arbitration. Articles in duplication were identified and excluded. When several versions of the same guide were found, the most current version was included. Data were extracted from GPC and CS selected independently and in duplicate.

2.3. Guideline quality assessment and data extraction

A published appraisal tool consisting of a 31-item checklist grouped into eleven domains was used by two reviewers (MMC and TMA) to assess the quality and reporting of CPGs and CSs about SDM (Appendix 3).(17) This quality assessment tool was elaborated by a group of BC and SDM specialist in a consensus meeting. This process had several revisions and iterations. It included 68% (n= 21) items from AGREE II statement (23) and 48% (n= 15) from RIGHT instrument.(24) The last four elements were chosen after an expert consensus study of bibliography of interest about SDM.(10, 16, 25, 26) The eleven domains assessing quality and reporting of SDM were: basic information (items 1-4), background (items 5-7), selection criteria (items 8-9), strengths and limitations (items 10-14), recommendations about SDM (items 15-17), facilitators and barriers (items 18-19), implementation (items 20-21), resource implications (items 22-24), monitoring and auditing criteria (items 25-27), recommendations for further research and limitations about these recommendations described (items 28-29) and, editorial independence and declaration of interest (items 30-31).

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According to this SDM assessment tool, each item was examined for compliance. In those guidelines on the management of BC in general, SDM was only considered if addressed in the section that covered screening. The criteria were scored on a dichotomous scale: “0” if the criterion was not met and “1” if the criterion was met. The higher the percentage of completed items, the higher the quality of the SDM in the CPG or CS evaluated. No formal score or cut-off point was established to define quality.(17)

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2.4. Data analysis

The intraclass correlation coefficient (ICC) was used to assess consistency between reviewers in data extraction. A result of more than 0.90 was considered excellent.(27) Data analysis was performed using Stata 16. Our team used the Kruskal-Wallis test to compare scores and stratify for factors that may affect the quality and reporting of SDM in CPGs and CSs. Values were considered statistically significant when $p<0.05$.

3. Results

3.1. Study selection

The searches retrieved 1604 potentially relevant citations; 1470 were from online databases (EMBASE, Web of Science, MEDLINE, Scopus, CDSR, etc.), and 134 were from additional sources (guideline specific databases, professional societies, and the Worldwide Web). We found 346 documents duplicated, and 1181 publications did not meet the selection criteria. Finally, only 77 documents (68 CPGs and 9 CSs) met the full evaluation eligibility criterion. The references of the guides analysed in this systematic review were included in Appendix 4. The study selection process is shown in the flow diagram in Figure 1. ICC for reviewer agreement was 0.98 (Appendix 5).

3.2. Quality and reporting assessment

The characteristics of the CPGs and CSs (type of document, entity, country, year, journal of publication, version and evidence analysis) are synthesized in Table 1. The mean number of items complied with by the documents including SDM was 5.74 (IQR 3-8). Table 2 shows the characteristics of the screening CPGs and CSs regarding SDM. Although CPGs seemed to have a higher number of items complied than CSs, there were no significant differences (CPG's mean 2.97, IQR 0-6 vs CS's mean 1.625, IQR 0-3; p=0.634). None of the guidelines met all quality criteria. More than 50% of the guidelines accomplished 0 items, and only 10% of them scored more than 8 items.

Figure 2 and Appendix 6 resumed the compliance of the items taking into account the SDM quality and reporting analysis tool. The distribution by country of the value of the items analysed with the SDM tool in the BC screening CPGs and CSs was irregular, as shown in Appendix 7. A total of 38 guidances, 34/77 (43%) CPGs and 4/77 (5%), stated about SDM vs 40 guidelines, 35/77 (46%) CPGs, and 5/77 (7%), which did not. Those CPGs or CSs specifically mentioning the term SDM (n=12) had better quality and reporting than those guidances (n=65) that did not mention it (mean 6.8, IQR 4-9 vs mean 2.1, IQR 0-3; p=0.001).

SDM appeared in the executive summary of only 6 (8%) documents, in the table of content of 2 (3%), and in the glossary, abbreviations, acronyms or topic indexes of 5 (7%). The concept, benefits, risk, and limitations were explained in 7 (9%), and the primary population and the subgroups with special consideration were taking into account in 23 (30%) and 20 (26%) documents, respectively. The magnitude of benefit and harms were considered in 4 (5%), and the supporting evidence on SDM was detailed in 7 (9%). Recommendations provided about SDM were clear and precise in 23 guidances (30%), detailing the strength in 5 (7%). Subgroup recommendations were

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indicated in 5 (7%). Facilitators and barriers were described in 6 (8%) and 3 (4%), respectively. Advice on the implementation of SDM was provided in 9 documents (12%), and additional tools were given in 2 (3%). The declaration of the value of SDM was described in 28 (36%), and the professional, financial, or intellectual interest was declared in 5 (7%).

Domains 3 (selection criteria) regarding PICO question and the details of the search strategy for evidence, 8 (resource implications) that specified the cost of SDM implementation, and 10 (recommendations for further research and limitations of the guidance) were accomplished by only one document. Domain 9 (monitoring and auditing criteria) assessing adherence and impact of implementing SDM was not fulfilled in any document. The Canadian Task Force (CTF)(28), the Instituto Nacional de Cáncer José Alencar Gomes da Silva (INCJA)(29), the American College of Obstetricians and Gynecologists(30) (ACOG) and the International Agency for Research on Cancer (IARC)(31) had the highest number of SDM quality and reporting items complied within screening (Appendix 6).

3.3. Study characteristics

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The distribution by countries was uneven regarding SDM (Figure 4). SDM appeared in 38 guidelines (34 CPGs and 4 CSs). Asia developed 5 (13%) from China, Japan, and Malaysia. North America released 8 (21%) guidances (USA: 4, Canada: 2 and Mexico: 1). South America stood out 3 (8%) guidelines (from Brazil). Europe had the amount of 19 (50%) from Germany, Netherlands and the UK. Oceania carried out 2 (5%) from Australia. Finally, one International CPG was also taking into account. There were no differences between guidelines from North America, Europe, and the rest of the world, although North America scored better (mean 3.7 items; IQR 0-6 vs 2.3 items, IQR 0-3 vs 3.2, IQR 0-6; p=0.826) (Table 1).

No differences were found according to the year of publication, but CPGs and CSs released after 2015 stated SDM more often than older guidelines (mean 4.0, IQR 0-7 vs mean 1.9, IQR 0-3; p=0.09). Regarding consecutive updates of the same CPG or CS, versions were not a differential element (p=0.944) (Table 2). The duration from the last update varied regarding the guidance document, and it was summarized in Table 1. The last released CPG was from May 2020 by AGO(32). The update of guidances with SDM was more frequent compared to those without SDM (mean 41 months (range 3 to 104) vs 57 months (range 10 to 116), p=0.042). There were 29% of the CPGs and

CSs about BC screening in general (n=22/77) that did not indicate the month of the last version released but only the year of the issue. Half of these guidances, 14% of the total (n=11/77) reported SDM. CPGs and CSs released in a medical journal scored better (mean 4, IQR 0-7 vs mean 1.9, IQR 0-3; p=0.094) than those unpublished, but it was not significant. Compared to evidence analysis methods, there were no differences between guidelines that used systematic reviews, consensus or reviews, or not reporting (p=0.929).

4. Discussion

4.1. Main findings

To our knowledge, SDM in BC screening CPGs and CSs has not been systematically analysed previously. This review complements one already published about the quality and reporting of SDM in CPGs and CSs about BC treatment.(17) Our current study has also observed that SDM was not widely explored concerning BC screening, and there is an extensive area in need of improvement. Descriptions and recommendations about SDM in BC screening are weak or absent. Although the latest guidelines report better on SDM, there is still not enough as a majority do not even mention it.

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4.2. Strengths and weaknesses

This systematic review provided a wide overview without language limitations about SDM in wide-ranging BC screening CPGs and CSs. Although 71.4% of the methodological guidance handbooks state that the time between guideline updates should be two or three years(33), we decided to search for analysing the evolution of the appearance of SDM during the last decade. This was a crucial point in our review since it permits an exhaustive study of the current use of SDM. Our study has looked for professional societies from countries contributing to global BC's scientific output of more than 0.5%. The main purpose was to focus our work on documents of professional societies of scientifically active countries.

A validated specific SDM quality assessment tool was used in a prospective protocol to assess quality and reporting in the current study. We compared our findings with a similar study about a different aspect of the BC process,(17) allowing examination of SDM in screening versus treatment. As in analogous studies, an observed limitation could be linked to the subjectivity of the data extraction concerning quality and reporting items, but we had dealt with this concern and minimised the problem using duplicate data extraction and arbitration, when it was necessary, by three experienced

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BC specialist clinicians. Furthermore, the reviewer agreement was excellent (ICC> 95%), indicating solid results.

As we have clarified before, “not all the items can have the same relevance and weight”.(17) Our review was not centred on this aspect of tool development. Instead, it was focused on studying the quality and reporting of SDM. Applying a quality assessment instrument, we could identify whether or not SDM was mentioned and which aspects were considered less frequently. Subsequent investigations and researches should direct attention to rating quality. The lack of information about SDM in BC screening CPGs and CSs, the key finding of our review, deserves special consideration in guidance documents. These missing features should be included in the future so that the implementation of SDM could be supported.

4.3. Implications

Our review highlighted that SDM descriptions and recommendations need improvement. SDM, a collaborative process between a healthcare professional and a patient, permits decisions based on informed personal preferences, values, and convictions.(25) It becomes critical when there are questionable risks versus benefits in

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taking part in screening.(9) BC screening is a good field where SDM can be useful regarding different options with similar benefits and harms. It would support decisions related to the patient´s convictions and personal life(34). The development of new abilities and a change of attitudes concerning SDM among doctors could improve patient and clinician satisfaction and contribute to better patient engagement (35).

Despite the importance that SDM has been acquiring in recent years, there is a poverty of coverage and guidance about how to use this relatively new approach in clinical practice routine.(25) It has been shown that the systematic inclusion of practical issues to inform SDM in CPGs could support evidence-based decisions.(20) Recommendations should promote SDM application in screening, but this has proved difficult, and for now, the trust in their usefulness remains unclear. CPGs and CSs would get closer to SDM by using a more fluent wording in language that facilitates dialogue between practitioners and patients.(19)

In our review, CPGs and CSs did not accomplish expectations well, obtaining very poor results. We compared BC screening versus BC treatment results from our team's previous study(17) to give a broader perspective about the current state of SDM in BC

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guidances. The presence of SDM in BC screening guidance documents was slightly better than in BC treatment (49.3% vs 39.5%). The mean number of items accomplished was also higher (2.83 vs 2.47).(17) We have not found differences in guidance updating among the two sets of documents. One possible explanation for the more prominent presence of SDM in screening documents could be that the screening is carried out for healthy women who decide to participate. In comparison, once BC has been diagnosed, the treatment would be an obligatory process, and the emotional impact of the diagnosis may diminish the patient´s decision-making capacity. In both cases, the ideal situation would be to offer SDM universally.

We only found one guidance document that assessed domains 3 (selection criteria) regarding PICO question and the details of the search strategy for evidence, 8 (resource implications) that specified the cost of SDM implementation, and the interval of measurement of these criteria, and 10 (recommendations for further research and limitations of the guidance). Domain 9 (monitoring and auditing criteria) assessing adherence and impact of implementing SDM did not appear in any document. The non-compliance with domains 3, 8, 9 and 10 is probably linked to oversight on the part of guidance writers who have been unable to access any literature concerning

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resources necessary to practice SDM, and the criteria for monitoring and auditing SDM in practice. When the CPGs and CSs included in our review were published, there were no tools capable of measuring the quality and reporting of SDM in guidelines. Our paper will provide hopefully prompt guideline authors to incorporate all vital information concerning SDM in the future.

No differences between screening CPGs and CSs were found, and neither country of origin was relevant. The year of publication, the evidence analysis, or the version of the guideline were not important with respect to SDM. These analyses highlighted that little importance was given to SDM, despite it being a key element for high-quality care.

The last updates of guidelines, which state SDM, have become more specific and focused on SDM in relative terms. This was probably because SDM has been gaining relevance in the last decade. On the other hand, it was obvious to think that a guidance that addresses explicitly “SDM” is more precise, descriptive and achieves better quality and reporting than those that do not state it. More efforts should be made in SDM(6), and future guidelines should play a more important role in SDM implementation(18).

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4.4. Conclusions

This systematic review demonstrated that SDM was inadequately emphasised in BC screening CPGs and CSs, a finding that complements a previous study about BC treatment guidelines.(17) There is a need for improvement in the application of SDM for high-quality clinical prevention and management of BC. SDM was better reported in the recent guidances, but more than half of the analysed documents did not address it at all, and the recommendations were weak when reported. Given these facts, the promotion of SDM needs urgent consideration in CPGs and CSs for BC issued by institutions, professional associations, and medical journals.

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5. Abbreviations

Association of breast surgery: ABS; Association of Breast Surgeons of India: ABSI; The American College of Obstetricians and Gynecologists: ACOG; the American College of Physicians: ACP; The American College of Radiology: ACR; The American Cancer Society: ACS; Asociación española de Cirugía: AEC; Arbeitsgemeinschaft Gynäkologische Onkologie: AGO; American Medical Association: AMA; The American Society of Breast Surgeons: ASBS; the Brazilian College of Radiology and Diagnostic Imaging: BCRDI; Brazilian Federation of Gynecological and Obstetrical Associations:

BFGOA; Cancer Australia: CA; China Anti-Cancer Association: CACA; Canadian Agency for Drugs and Technologies in Health: CADTH; Cancer Care Ontario: CCO; Canadian Medical Association Journal: CMAJ; Colegio de Médicos y Cirujanos de Costa Rica: CMCCR; Canadian Task Force: CTF; clinical practice guidelines: CPGs; consensus statements: CSs; European Society for Medical Oncology: ESMO; European School of Oncology: ESO; European Society of Mastology: EUSOMA; Haute Autorité de Santé: HAS; Healthcare improvement Scotland: HIS; International Agency for Research on Cancer: IARC; Indian Council of Medical Research: ICMR; Instituto de Evaluación Tecnológica en Salud: IETS; Integraal Kankercentrum Nederland: IKNL; Instituto Nacional de Cancerología: INC; Instituto Nacional de Cáncer José Alencar Gomes da Silva: INCJA; Journal of the American College of Radiology: JACR; Japanese Breast Cancer Society: JBCS; Joint Research Centre: JRC; Japanese Research Group: JRG; Belgian healthcare knowledge centre: KCE; Ministry of Health Malaysia: MHM; Ministry of Health from New Zealand: MHNZ; Ministère de la Santé de la Population et de la Réforme Hospitalière: MSP; Breast Expert Advisory Group/ Northern Cancer Alliance: NCA; Nacional Comprehensive Cancer Network: NCCN; National Clinical Research Center for Cancer: NCRCC; The New England Journal of Medicine: NEJM; National Health Commission of the People's Republic of China:

NHCPRC; National Health Service: NHS; National Institute for Health and Care Excellent: NICE; Public Health Agency: PHA; Public Health England: PHE; Quebec Breast Cancer Foundation: QBCF; The Royal College of Pathologists: RCP; The Royal College of Radiologists: RCR; Regione Emilia-Romagna: RER; shared decision making: SDM; Sociedad Española de Anatomía Patológica: SEAP; Sociedad Española de Diagnóstico por Imagen de la Mama: SEDIM; Sociedad Española de Ginecología y Obstetricia: SEGO; Sociedad Española de Medicina Nuclear e Imagen Molecular: SEMNIM; Sociedad Española de Oncologia Médica: SEOM; Sociedad Española de Oncología Radioterápica: SEOR; Sociedad Española de Senología y Patología Mamaria: SESPM; Secretaría de Salud de México: SSM; University Hospital of Würzburg: UHW; The U.S. Preventive Services Task Force: USPSTF.

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6.2. Contributors

Each author certifies that he/she has made a direct and substantial contribution to the conception and design of the review, development of the search strategy, the establishment of the inclusion and exclusion criteria, data extraction, analysis, and

interpretation. MMC was involved in the design of the review, literature search, data collection and analysis, quality appraisal, and writing. LM was involved in the development of data extraction, analysis, and writing. MMD was involved in the analysis of data. ABC was involved in the design of this review and provided critical revision of the paper. KSK was involved in the design of this review, conducted the quality appraisal, in the writing, and provided critical revision of the paper. All authors read and provided the final approval of the version to be published.

7. Conflicts of interest:

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

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9. Data sharing statement

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

10. Key-points

- Shared decision making (SDM) was inadequately emphasized in breast cancer (BC) screening clinical practice guidelines and consensus statements.
- There is a need for improvement in the application of SDM for the prevention and the management of BC.
- There is an urgent need for promoting SDM in guidances concerning BC screening issued by institutions, professional associations, and medical journals.

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12. Figure legends

Figure 1: The flow diagram detailing the study selection.

Figure 2: The compliance of the items with the SDM quality and reporting analysis tool.

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Table 1: Description of the screening clinical practice guidelines (CPGs) and consensus (CSs) (n=77) selected for the systematic review on the quality of reporting for SDM

	Name of the CPG or CS	Abbreviated name	Type of document	Entity	Country	Year	Publication in a Journal	Version	Evidence analysis	SDM named	Last updated date (months)
1	Guide de détection précoce des cancers du sein et du col de l'utérus(1*)	MS Guide(1*)	CPG	MS	Morocco	2011	Not published	2	Not reported	No	116
2	Breast cancer screening guideline for Chinese women(2*)	CACA BC CPG(2*)	CPG	CACA, NCRCC	China	2019	Cancer Biol Med	1	Not reported	No	10
3	Interpretation of breast cancer screening guideline for Chinese women(3*)	CACA Interpretation CPG(3*)	CPG	CACA, NCRCC	China	2019	Cancer Biol Med	1	Not reported	No	8
4	Chinese guidelines for diagnosis and treatment of breast cancer 2018(4*)	Chinese BC diagnosis(4*)	CPG	NHCPRC	China	2018	CJCRCN	1	Not reported	No	18
5	The Japanese Breast Cancer Society Clinical Practice Guidelines for Breast Cancer Screening and Diagnosis, 2018 Edition(5*)	JBCS diagnosis CPG(5*)	CPG	JBCS	Japan	2018	Breast Cancer	2	Delphy technique	Yes	12
6	The Japanese Guidelines for Breast Cancer Screening(6*)	JBCS BC screening CPG(6*)	CPG	JRG	Japan	2016	JJCO	1	Systematic review	No	56
7	Management of Breast Cancer (3rd Edition)(7*)	MHM BC(7*)	CPG	MHM	Malaysia	2019	Not published	3	Review	Yes	13
8	Breast cancer in women: diagnosis, treatment and follow-up(8*)	KCE BC CPG(8*)	CPG	KCE	Belgium	2013	Not published	3	Systematic review	No	85
9	Early breast cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up(9*)	ESMO BC 2019(9*)	CPG	ESMO	Europe	2019	Annals of Oncology	3	Not reported	No	14
10	Prevention and screening in BRCA mutation carriers and other breast/ovarian hereditary cancer syndromes: ESMO Clinical Practice Guidelines for cancer prevention and screening(10*)	ESMO BRCA syndromes(10*)	CPG	ESMO	Europe	2016	Annals of Oncology	1	Review	No	48
11	Primary breast cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up(11*)	ESMO Primary BC(11*)	CPG	ESMO	Europe	2015	Annals of Oncology	1	Not reported	No	61
12	The European Society of Breast Cancer Specialists recommendations for the management of young women with breast cancer(12*)	EUSOMA BC CPG(12*)	CPG	EUSOMA	Europe	2012	EJC	1	Review	No	94
13	European Guidelines for Breast Cancer Screening and Diagnosis - the European Breast Guidelines(13*)	JRC BC CPG(13*)	CPG	JRC	Europe	2016	Not published	1	Systematic review	No	56
14	Guide résumant les recommandations européenes pour lássurance de la qualité dans le despistage et le diagnostic du cancer du sein(14*)	Europa Donna Guide(14*)	CPG	Europa Donna	Europe	2016	Not published	4	Not reported	No	56
15	Actualisation du référentiel de pratiques de l'examen périodique de santé. Dépistage et prévention du cancer du sein(15*)	HAS Guide(15*)	CPG	HAS	France	2015	Not published	1	Not reported	No	58
16	AGO Recommendations for the Diagnosis and Treatment of Patients with Locally Advanced and Metastatic Breast Cancer: Update 2020(16*)	AGO LA abd MBC 2020(16*)	CPG	AGO	Germany	2020	Breast Care	6	Review	Yes	3
17	AGO Recommendations for the Diagnosis and Treatment of Patients with Early Breast Cancer: Update 2019(17*)	AGO Early BC 2019(17*)	CPG	AGO	Germany	2019	Breast Care	5	Review	Yes	15
18	Diagnosis and Treatment of Patients with Primary and Metastatic Breast	AGO Primary MBC(18*)	CPG	AGO	Germany	2018	Not published	1	Review	No	32

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	Cancer(18*)										
19	The Screening, Diagnosis, Treatment, and Follow-Up of Breast Cancer(19*)	Würzburg BC(19*)	CPG	UHW	Germany	2018	Dtsch Arztebl Int	1	Systematic review	No	32
20	Interdisciplinary GoR level III Guidelines for the Diagnosis, Therapy and Follow-up Care of Breast Cancer(20*)	Kreienberg BC screening(20*)	CPG	Kreienberg R et al	Germany	2013	Geburtsh Frauenheilk	1	Review	No	97
21	Breast cancer(21*)	Richtlijnendatabase BC(21*)	CPG	Richtlijnendatabase	Netherlands	2018	Not published	1	Review	No	25
22	Breast Cancer(22*)	IKNL BC(22*)	CPG	IKNL	Netherlands	2012	Not published	2	Review	No	104
23	Cáncer de mama/ Breast Cancer(23*)	Fisterra BC(23*)	CPG	Fisterra	Spain	2017	Not published	3	Not reported	No	38
24	SEOM clinical guidelines in Hereditary Breast and ovarian cancer(24*)	SEOM hereditary BC(24*)	CPG	SEOM	Spain	2015	Clin Transl Oncol	1	Not reported	No	70
25	Cirugía de la Mama(25*)	AEC BC(25*)	CPG	AEC	Spain	2017	Not published	2	Not reported	No	44
26	Manual de Práctica Clínica en Senología. 4ª Edición. 2019(26*)	SESPM(26*)	CPG	SESPM	Spain	2019	Not published	4	Not reported	No	20
27	Oncoguía SEGO: Cáncer infiltrante de mama. Guías de práctica clínica en cáncer ginecológico y mamario(27*)	SEGO CPG(27*)	CPG	SEGO*** (…)	Spain	2017	Not published	1	Review	No	38
28	Protocollo diagnostico terapeutico dello screening per la diagnosi precoce dei tumori della mammella della Regione Emilia-Romagna(28*)	RER CPG(28*)	CPG	RER	Italy	2012	Not published	4	Not reported	No	101
29	Best practise guidelines for surgeons in breast cancer screening(29*)	ABS BC surgeons(29*)	CPG	ABS	UK	2018	Not published	6	Not reported	No	31
30	Breast Screening Standards(30*)	HIS CPG(30*)	CPG	HIS	UK	2018	Not published	1	Not reported	No	14
31	Breast Cancer Clinical Guidelines(31*)	NCA BC(31*)	CPG	NCA	UK	2019	Not published	2	Review	Yes	10
32	Familial breast cancer: classification, care and managing breast cancer and related risks in people with a family history of breast cancer(32*)	NICE familial BC(32*)	CPG	NICE	UK	2013	Not published	1	Not reported	Yes	86
33	The Northern Ireland breast screening programme. Guide for health professionals(33*)	PHA BC screening(33*)	CPG	PHA	UK	2012	Not published	1	Not reported	No	104
34	NHS Breast Screening Programme. Failsafe batch guidance(34*)	NHS failsafe batch CPG(34*)	CPG	PHE	UK	2019	Not published	1	Not reported	No	19
35	NHS Breast Screening Programme. Guidance for breast screening mammographers(35*)	NHS mammographers(35*)	CPG	PHE	UK	2017	Not published	3	Not reported	No	33
36	NHS Breast Screening Programme. Clinical guidance for breast cancer screening assessment(36*)	NHS assesment(36*)	CPG	PHE	UK	2016	Not published	4	Review	No	46
37	Breast cancer screening. Clinical Practice Guideline(37*)	NHS BC screening(37*)	CPG	NHS	UK	2013	Not published	1	Not reported	No	84
38	Interim Quality Assurance guidelines for Clinical Nurse Specialists in breast cancer screening. Fith edition(38*)	NHS Nurse CPG(38*)	CPG	NHS	UK	2013	Not published	5	Not reported	No	93
39	Technical guidelines for magnetic resonance imaging (MRI) for the surveillance of women at higher risk of developing breast cancer(39*)	NHS MRI CPG(39*)	CPG	NHS	UK	2012	Not published	1	Not reported	No	93
40	Guidelines for non-operative diagnostic procedures and reporting in breast cancer screening(40*)	RCP BC screening(40*)	CPG	RCP	UK	2016	Not published	1	Review	No	50

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41	Guidance on screening and symptomatic breast imaging. Fourth edition(41*)	RCR breast imaging (41*)	CPG	RCR	UK	2019	Not published	4	Not reported	No	10
42	NHS Breast Screening multidisciplinary working group guidelines for the diagnosis and management of breast lesions of uncertain malignant potential on core biopsy (B3 lesions)(42*)	RCR NHS B3 lessions(42*)	CPG	RCR, NHS	UK	2018	Clinical Radiology	1	Review	No	32
43	Quality assurance Guidelines for Breast cancer screening radiology. Second edition(43*)	RCR screening radiology(43*)	CPG	RCR	UK	2011	Not published	2	Not reported	No	113
44	Clinical Guidelines for the Management of Breast Cancer(44*)	WMCA BC(44*)	CPG	WMCA BC	UK	2016	Not published	8	Review	No	45
45	Screening for Breast Cancer in Average-Risk Women: A Guidance Statement From the American College of Physicians(45*)	ACP BC screening(45*)	CPG	ACP	USA	2019	Ann Intern Med	1	Review	Yes	25
46	Digital Tomosynthesis for the Screening and Diagnosis of Breast Cancer: Diagnostic Accuracy and Guidelines(46*)	CADTH BC screening(46*)	CPG	CADTH	Canada	2019	CADTH	1	Review	No	69
47	Recommendations on screening for breast cancer in women aged 40–74 years who are not at increased risk for breast cancer(47*)	CTF 40-74 yo screening(47*)	CPG	CTF	Canada	2018	CMAJ	1	Systematic review	No	21
48	Recommendations on breast cancer screening and prevention in the context of implementing risk stratification: impending changes to current policies(48*)	QBCF BC screening(48*)	CPG	QBCF	Canada	2016	Current Oncology	1	Review	No	45
49	Magnetic Resonance Imaging Screening of Women at High Risk for Breast Cancer(49*)	CCO MRI high-risk BC(49*)	CPG	CCO	Canada	2017	Not published	3	Systematic review	No	31
50	Ontario Breast Screening Program (OBSP). Guidelines(50*)	OBSP BC screening(50*)	CPG	CCO	Canada	2015	Not published	1	Not reported	No	58
51	Effective interventions to facilitate the uptake of breast, cervical and colorectal cancer screening: an implementation guideline(51*)	CCO interventions (51*)	CPG	CCO	Canada	2011	Implementation Science	1	Systematic review	No	116
52	Clinical Management Guidelines for Obstetrician–Gynecologists. Breast Cancer Risk Assessment and Screening in Average-Risk Women(52*)	ACOG BC screening(52*)	CPG	ACOG	USA	2017	ACOG Practice Bulletin.	2	Review	Yes	37
53	Breast Cancer Screening for Women at Average Risk 2015 Guideline Update From the American Cancer Society(53*)	AMA BC Screening(53*)	CPG	AMA	USA	2015	JAMA	2	Systematic review	Yes	58
54	Breast Cancer Screening and Diagnosis. Version 1.2019(54*)	NCCN BC Screening(54*)	CPG	NCCN	USA	2019	Not published	4	Review	Yes	16
55	Breast Cancer Screening in Women at Higher-Than-Average Risk: Recommendations From the ACR(55*)	ACR High -risk BC(55*)	CPG	ACR	USA	2018	JACR	1	Review	No	29
56	ACR Appropriateness Criteria â Breast Cancer Screening(55*)	ACR Criteria BC(56*)	CPG	ACR	USA	2017	JACR	1	Review	No	33
57	Breast Cancer Early Detection and Diagnosis. Can Breast Cancer Be Found Early?(57*)	ACS BC detection(57*)	CPG	ACS	USA	2019	AJR	2	Not reported	No	10
58	Guidelines for early detection of breast cancer in Brazil. I – Development methods(58*)	INC BC Screening I(58*)	CPG	INC	Brazil	2018	Cad. Saúde Pública	1	Review	No	32
59	Guidelines for early detection of breast cancer in Brazil. II – New national recommendations, main evidence, and controversies(59*)	INC BC Screening II(59*)	CPG	INC	Brazil	2018	Cad. Saúde Pública	1	Review	Yes	32
60	Guidelines for early detection of breast cancer in Brazil. III – Challenges for implementation(60*)	INC BC Screening III(60*)	CPG	INCJA	Brazil	2018	Cad. Saúde Pública	1	Review	Yes	32
61	Breast Cancer Screening: Updated Recommendations of the Brazilian	BCRDI BC screening (61*)	CPG	BCRDI, BBDS,	Brazil	2017	Thieme Revinter	1	Review	No	35

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	College of Radiology and Diagnostic Imaging, Brazilian Breast Disease Society, and Brazilian Federation of Gynecological and Obstetrical Associations(61*)			BFGOA			Publicações				
62	Manual para la detección temprana del cáncer de mama - Tercera edición(62*)	INC CM Manual(62*)	CPG	INC	Colombia	2015	Not published	1	Review	No	68
63	Guía de práctica clínica (GPC) para la detección temprana, tratamiento integral, seguimiento y rehabilitación del cáncer de mama(63*)	GPC Colombia(63*)	CPG	IETS	Colombia	2017	Not published	2	Systematic review	No	44
64	Early detection of breast cancer(64*)	CA early detection(64*)	CPG	CA	Australia	2015	Not published	3	Not reported	No	68
65	Overdiagnosis from mammographic screening(65*)	CA overdianosis (65*)	CPG	CA	Australia	2014	Not published	3	Not reported	No	80
66	Management of Early Breast Cancer(66*)	New Zealand BC(66*)	CPG	MHNZ	New Zealand	2014	Not published	2	Not reported	No	80
67	Breast-Cancer Screening — Viewpoint of the IARC Working Group(67*)	IARC viewpoint(67*)	CPG	IARC	International	2015	NEJM	1	Review	No	62
68	IARC Handbooks of CanCer PreventIon. Breast Cancer Screening. Volumen 15(68*)	IARC handbooks(68*)	CPG	IARC	International	2016	Not published	1	Review	No	56
69	Indian Solutions for Indian Problems—Association of Breast Surgeons of India (ABSI) Practical Consensus Statement, Recommendations, and Guidelines for the Treatment of Breast Cancer in India(69*)	Indian ABSI CS(69*)	CS	ABSI	India	2017	Indian J Surg	1	Consensus; review	No	38
70	Consensus document for management of breast cancer(70*)	Indian ICMR CS(70*)	CS	ICMR	India	2016	Not published	1	Delphy technique	No	56
71	4th ESO–ESMO International Consensus Guidelines for Advanced Breast Cancer (ABC 4)(71*)	ABC4(71*)	CS	ESMO, ESO, EUSOMA	Europe	2018	The Breast	4	Consensus, not specified technique	No	25
72	International guidelines for management of metastatic breast cancer (MBC) from the European School of Oncology (ESO)-MBC Task Force: Surveillance, staging, and evaluation of patients with early-stage and metastatic breast cancer(72*)	ESO BC CPG(72*)	CS	ESO	Europe	2013	The Breast	1	Consensus; review	No	89
73	Position Statement on Screening Mammography(73*)	ASBS mammography(73*)	CS	ASBS	UK	2019	Not published	3	Consensus; review	No	17
74	Consensus Guideline on Diagnostic and Screening Magnetic Resonance Imaging of the Breast(74*)	ASBS MRI(74*)	CS	ASBS	USA	2017	Not published	1	Consensus; review	No	37
75	Screening for Breast Cancer: U.S. Preventive Services Task Force Recommendation Statement(75*)	USPSTF BC screening(75*)	CS	USPSTF	USA	2016	Annals of Internal Medicine	2	Consensus; review	No	54
76	Consenso costarricense sobre prevención, diagnóstico y tratamiento del cáncer mamario(76*)	CS Costa Rica(76*)	CS	CMCCR	Costa Rica	2016	Not published	1	Not reported	No	53
77	Consenso Mexicano sobre diagnóstico y tratamiento del cáncer mamario. Octava revisión. Colina 2019(77*)	GPC México(77*)	CS	SSM	México	2019	Not published	7	Nominal group technique	No	20

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JJCO: Japanese Journal of Clinical Oncology, EJC: European Journal of Cancer

*** SEGO, SEOM, SEOR, SEAP, SESPM, SEDIM, SEMNIM

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Table 2: Characteristics of the screening clinical practice guidelines (CPGs) and consensus statements (CSs) regarding shared decision-making (SDM).

	SDM tool		
Variable	**Mean (items)**	**IQR Range**	**p value**
Type of document			
CPGs	3.0	0-6	
CSs	1.6	0-3	p = 0.634
Country			
Europe	2.3	0-3	
North America	3.7	0-6	
Other countries	3.2	0-6	p = 0.826
Publication Year			
Before or in 2015	2.2	0-3	
After 2015	3.1	0-6	p=0.432
Publication in a journal			
Yes	4.0	0-7	
No	1.9	0-3	p=0.094
Version number			
1	3.1	0-7	
2	3.2	0-5	
3 or more	2.2	0-3	p=0.944
Evidence analysis			
Systematic review	4.2	0-7	
Consensus or reviews	2.9	0-4	
Not reported	2.4	0-6	p=0.929
SDM specifically named			
Yes	6.8	4-9	
No	2.1	0-3	p=0.001
Variable	**Mean (months)**	**IGQ Range**	**p value**
Last update			
SDM	41	3-104	
No SDM	57	10-116	p=0.042

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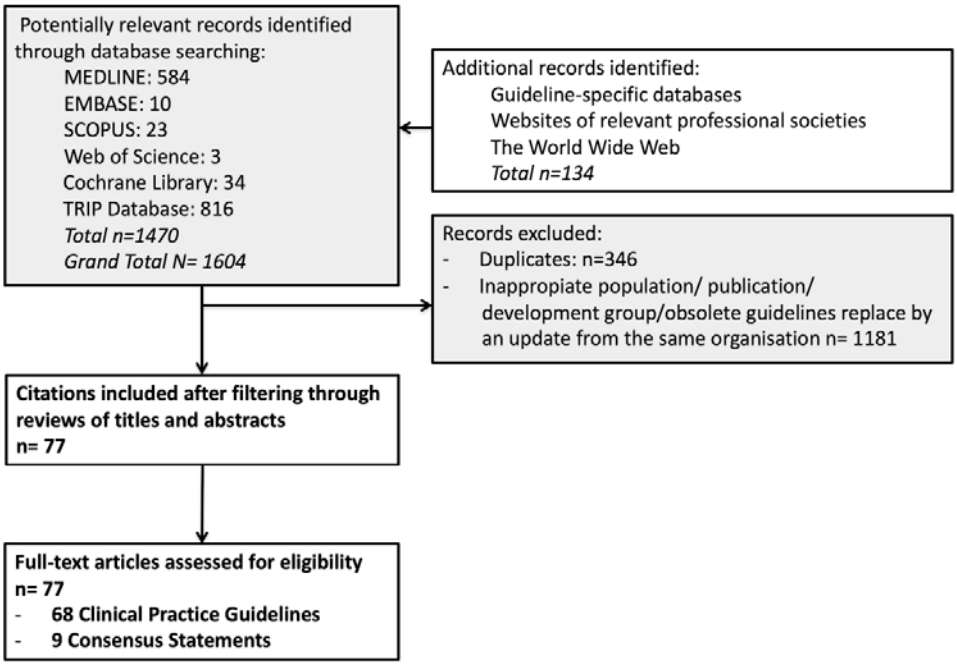
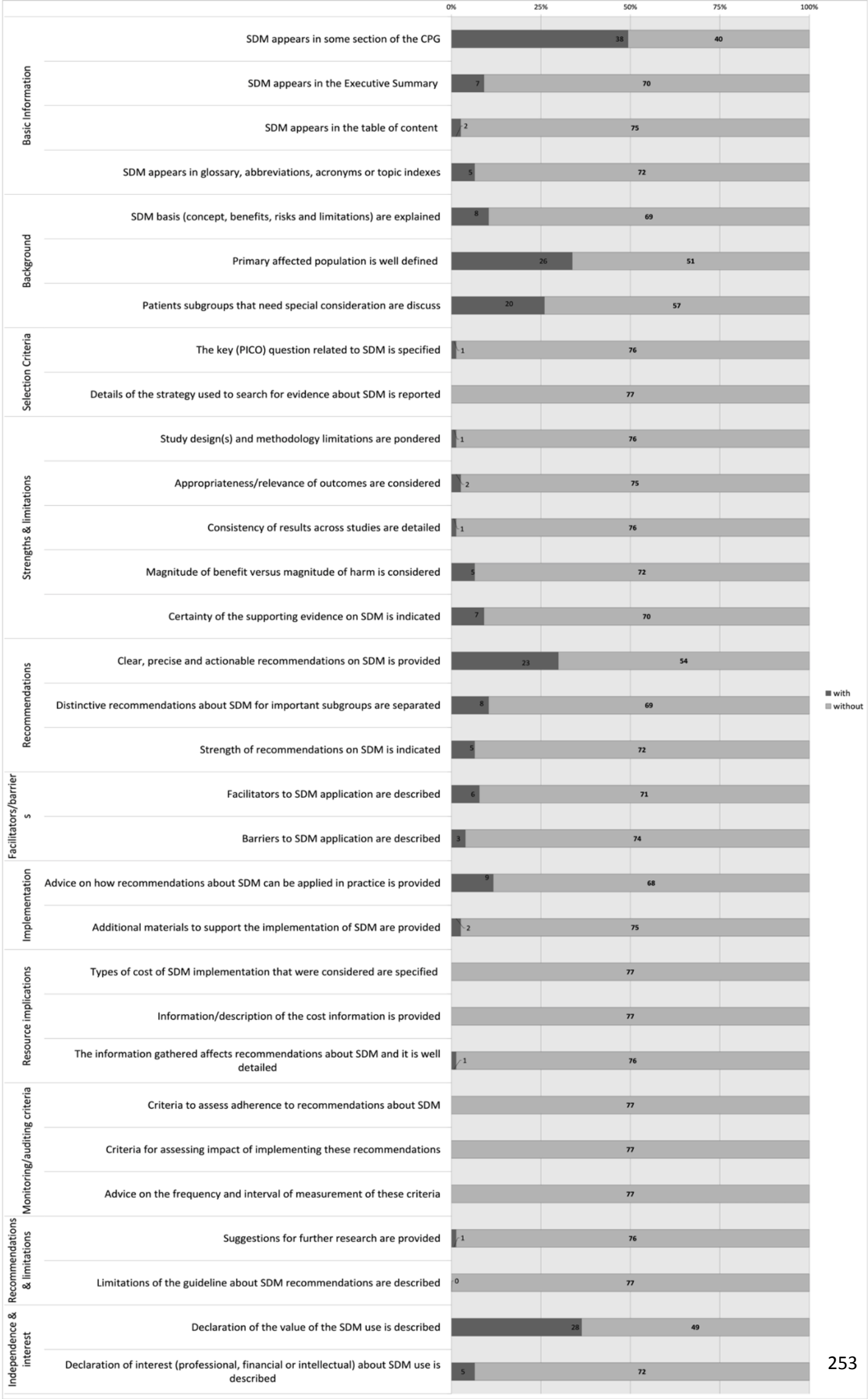


Figure 1: The flow diagram detailing the study selection.

373x261mm (144 x 144 DPI)

Figure 2: The compliance of the items with the SDM quality and reporting analysis tool (next page).


0%
25%
50%
75%
100%
Basic Information
SDM appears in some section of the CPG
38
40
SDM appears in the Executive Summary
7
70
SDM appears in the table of content
2
75
SDM appears in glossary, abbreviations, acronyms or topic indexes
5
72
Background
SDM basis (concept, benefits, risks and limitations) are explained
8
69
Primary affected population is well defined
26
51
Patients subgroups that need special consideration are discuss
20
57
Selection Criteria
The key (PICO) question related to SDM is specified
1
76
Details of the strategy used to search for evidence about SDM is reported
77
Strengths & limitations
Study design(s) and methodology limitations are pondered
1
76
Appropriateness/relevance of outcomes are considered
2
75
Consistency of results across studies are detailed
1
76
Magnitude of benefit versus magnitude of harm is considered
5
72
Certainty of the supporting evidence on SDM is indicated
7
70
Recommendations
Clear, precise and actionable recommendations on SDM is provided
23
54
Distinctive recommendations about SDM for important subgroups are separated
8
69
Strength of recommendations on SDM is indicated
5
72
Facilitators/barriers
Facilitators to SDM application are described
6
71
Barriers to SDM application are described
3
74
Implementation
Advice on how recommendations about SDM can be applied in practice is provided
9
68
Additional materials to support the implementation of SDM are provided
2
75
Resource implications
Types of cost of SDM implementation that were considered are specified
77
Information/description of the cost information is provided
77
The information gathered affects recommendations about SDM and it is well detailed
1
76
Monitoring/auditing criteria
Criteria to assess adherence to recommendations about SDM
77
Criteria for assessing impact of implementing these recommendations
77
Advice on the frequency and interval of measurement of these criteria
77
Recommendations & limitations
Suggestions for further research are provided
1
76
Limitations of the guideline about SDM recommendations are described
0
77
Independence & interest
Declaration of the value of the SDM use is described
28
49
Declaration of interest (professional, financial or intellectual) about SDM use is described
5
72
with
without

Appendix 1: PRISMA 2009 Checklist

			Page
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	5	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	6	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	7	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 2
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).	4 - 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.	4 - 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.	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.	7

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Appendix 1: PRISMA 2009 Checklist

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.	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.	7 - 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]).	7 - 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).	10
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
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.	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. doi:10.1371/journal.pmed1000097

For more information, visit: **www.prisma-statement.org**. Page 2 of 2

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Appendix 2: Data sources and search strategy

A2.1 Sample search strategy for MEDLINE

We conducted a systematic search on August 23rd, 2020 in MEDLINE (via PubMed; from January 2010 to August 2020) using the following combination of free-text terms:

#1 Practice guideline [pt]
#2 Practice guidelines as topic [mesh]
#3 Guideline [pt]
#4 guidelines as topic [mesh]
#5 consensus [mesh]
#6 OR #1-#5
#7 breast neoplasms [mesh]
#8 breast neoplasms [mesh]
#9 breast neoplasms [all]
#9 breast cancer [all]
#10 OR #7-9
#11 screening [all]
#12 2010 [pdta] : 3000[pdta]
#6 AND #10 AND #11 AND #12

Results: 584 articles

A2.2 Online databases

1. MEDLINE
2. EMBASE
3. Web of Science
4. Scopus
5. The Cochrane Database of Systematic Reviews
6. Cochrane Methodology Register
7. ACP Journal Club
8. Database of Abstracts of Reviews of Effects
9. Cochrane Central Register of Controlled Trials (CENTRAL)
10. The Health Technology Assessment

A2.3 Guideline-specific databases

1. NHMRC, Australia
2. CMA Infobase, Canada
3. CPG, Canada
4. GIN, International
5. NZGG, New Zealand
6. NICE, UK
7. Trip Database, UK
8. SIGN, UK
9. Fisterra, Spain
10. HSTAT, USA
11. NCCN, USA
12. NGC, USA

A2.4 Professional societies

1. CECM, China
2. CMH, China

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3. NCRCC, China
4. NHCPRC, China
5. CACA, China
6. JBCS, Japan
7. JRG, Japan
8. ABSI, India
9. ICMR, India
10. ICON, India
11. AHS, Canada
12. BCMA, Canada
13. CCM, Canada
14. CCO & Ontario Ministry of Health, Canada
15. CADTH, Canada
16. CMAJ, Canada
17. CTF, Canada
18. QBCF, Canada
19. American Board of Internal Medicine's, USA
20. ASBS, USA
21. ASPS, USA
22. American Society for Radiation Oncology, USA
23. ABS, USA
24. ACS, USA
25. ACOG, USA
26. ASBrS, USA
27. ASBS, USA
28. ASCO, USA
29. ASTRO, USA
30. ACP, USA
31. ACR, USA
32. SSO, USA
33. AMA, USA
34. JACR, USA
35. USPSTF, USA
36. Society of Surgical Oncology Breast Disease, USA
37. ESMO, Europe
38. ESO, Europe
39. ESTRO, Europe
40. EUSOMA, Europe
41. JRC, Europe
42. St. Gallen/Vienna, Europe
43. KCE, Belgium
44. HAS, France
45. ABC3, Germany
46. AGO, Germany
47. DEGRO, Germany
48. IKNL, Netherlands
49. Richtlijnendatabase, Netherlands
50. NCCP, Ireland
51. Lithuanian oncologist, encrinologist and General practicioners, Lithuania
52. SCAN, Singapore
53. AEC, Spain
54. FESEO, Spain
55. SEGO, Spain
56. SEOM, Spain

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57. SEAP, Spain
58. SEDIM, Spain
59. SEMNIM, Spain
60. SEOM, Spain
61. SEOR, Spain
62. SESPM, Spain
63. ABS, UK
64. BAPRAS, UK
65. JGBSA, UK
66. RCR, UK
67. SCT, UK
68. HIS, UK
69. NCA, UK
70. RCP, UK
71. RER, UK
72. BBDS, Brazil
73. BCRDI, Brazil
74. BFGOA, Brazil
75. INCJA, Brazil
76. CMCCR, Costa Rica
77. IETS, Colombia
78. INC, Colombia
79. AG, Australia
80. CA, Australia
81. MHNZ, New Zealand
82. IARC, International
83. ESO, International
84. IEP, International

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Appendix 3:
Quality assessment tool for shared decision making (SDM) recommendations in breast cancer (BC) management clinical practice guidelines (CPG) and consensus (CS)

Domain		Item
Basic information	1	SDM appears in some section of the CPG
	2	SDM appears in the Executive Summary
	3	SDM appears in the table of content
	4	SDM appears in glossary, abbreviations, acronyms or topic indexes
Background	5	SDM basis (concept, benefits, risks and limitations) are explained
	6	Primary affected population is well defined
	7	Patients subgroups that need special consideration are discuss
Evidence selection criteria	8	The key (PICO) question related to SDM is specified
	9	Details of the strategy used to search for evidence about SDM is reported
Evidence strengths & limitations	10	Study design(s) and methodology limitations are pondered
	11	Appropriateness/relevance of outcomes are considered
	12	Consistency of results across studies are detailed
	13	Magnitude of benefit versus magnitude of harm is considered
	14	Certainty of the supporting evidence on SDM is indicated
Recommendations	15	Clear and precise recommendations on SDM is provided
	16	Distinctive recommendations about SDM for important subgroups are separated
	17	Strength of recommendations on SDM is indicated
Facilitators and barriers	18	Facilitators to SDM application are described
	19	Barriers to SDM application are described
Implementation advice/tools	20	Advice on how recommendations about SDM can be applied in practice is provided
	21	Additional materials to support the implementation of SDM are provided
Resource implications	22	Types of cost of SDM implementation that were considered are specified
	23	Information/description of the cost information is provided
	24	The information gathered affects recommendations about SDM, and it is well detailed
Monitoring/auditing criteria	25	Criteria to assess adherence to recommendations about SDM
	26	Criteria for assessing impact of implementing these recommendations
	27	Advice on the frequency and interval of measurement of these criteria
Recommendations & limitations	28	Suggestions for further research are provided based on the gaps in the evidence encountered
	29	Limitations of the guideline about SDM recommendations are described
Editorial Independence & declaration of interest	30	Declaration of the value of the SDM use is described
	31	Declaration / management of interests (professional, financial or intellectual) about SDM use is described

Appendix 4: References of the guidance documents (68 CPGs(1-68)* and 9 CSs(69-77)*) analyzed in this systematic review.

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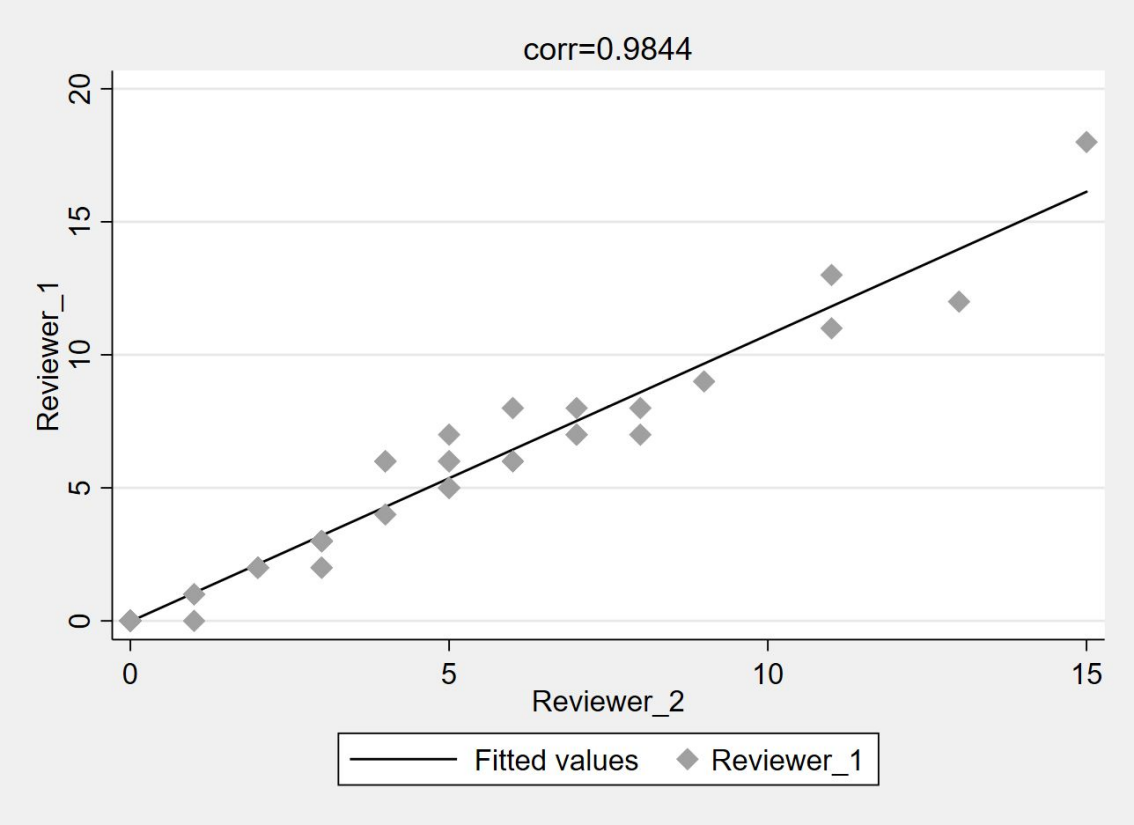
Appendix 4: The intraclass correlation coefficient (Corr) to assess consistency between reviewers in data extraction.



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Appendix 6: Data extraction analysis

					Basic information				Background			Evidence selection criteria		Evidence strengths & limitations						Recommendations			Facilitators and barriers		Implementation advice/tools			Resource implications			Monitoring/auditing criteria						
	Name of the CPG	Entity	Country	Year	SDM appears in any section of the CPG	SDM appears in the Executive Summary	SDM appears in the table of content	SDM appears in glossary or topic indexes	SDM basis are explained	Primary affected population is well defined	Patients subgroups with special consideration are ...	The key (PICO) question related to SDM is specified	Search strategy for evidence about SDM is reported	Study design(s) and methodology limitations are ...	Appropriateness/relevance of outcomes are considered	Consistency of results across studies are detailed	Benefit versus magnitude of harm is considered	Certainty of the supporting evidence on SDM is ...	Clear and precise recommendations on SDM is ...	Recommendations about SDM for subgroups are ...	Strength of recommendations on SDM is indicated ...	Facilitators to SDM application are described	Barriers to SDM application are described	How recommendations can be applied in practice	Support the implementation of SDM	Cost of SDM implementation are specified	Information/description of the cost information is ...	The information gathered affects recommendations	Adherence to recommendations about SDM	Assessing impact of implementing these ...	Frequency and interval of measurement of these ...	Suggestions for further research are provided	Limitations of the CPG about SDM recommendations	Declaration of the value of the SDM use	Professional, financial or intellectual interest about SDM	TOTAL OF ITEMS DISPLAYED IN THE CPG (1)
1	MS Guide(1*)	MS	Morocco	2011																															0
2	CACA BC CPG(2*)	CACA, NCRCC	China	2019	1					1	1							1	1	1															6
3	CACA Interpretation CPG(3*)	CACA, NCRCC	China	2019	1					1	1							1	1	1															6
4	Chinese BC diagnosis(4*)	NHCPRC	China	2018																															0
5	JBCS diagnosis CPG(5*)	JBCS	Japan	2018	1	1												1															1		4
6	JBCS BC screening CPG(6*)	JRG	Japan	2016	1					1	1							1	1	1													1		7
7	MHM BC(7*)	MHM	Malaysia	2019	1					1	1							1	1														1		6
8	KCE BC CPG(8*)	KCE	Belgium	2013																															0
9	ESMO BC 2019(9*)	ESMO	Europe	2019	1		1											1			1		1										1		6
10	ESMO BRCA syndromes(10*)	ESMO	Europe	2016																															0
11	ESMO Primary BC(11*)	ESMO	Europe	2015																															0
12	EUSOMA BC CPG(12*)	EUSOMA	Europe	2012																															0

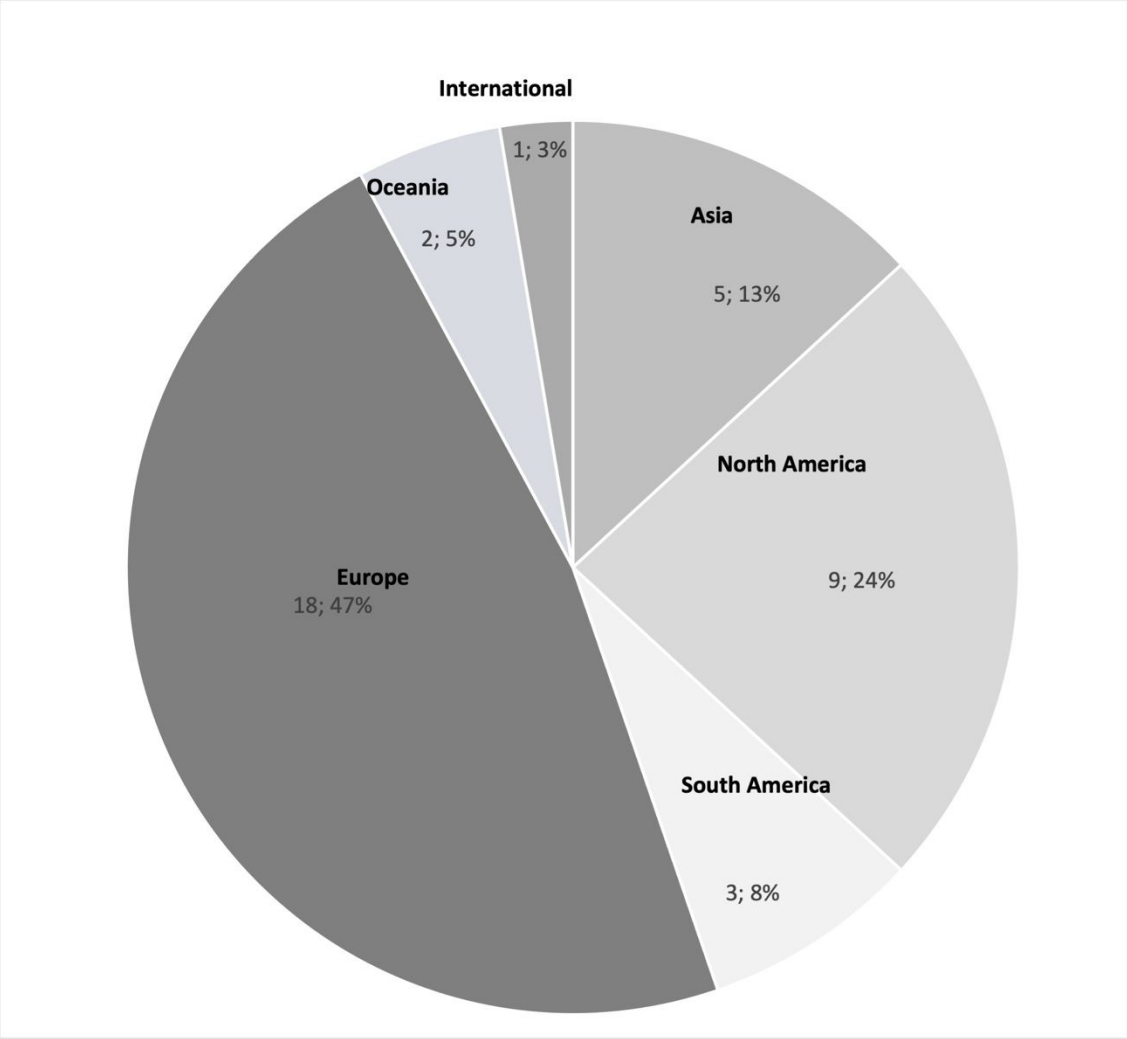
13	JRC BC CPG(13*)	JRC	Europe	2016																																				0
14	Europa Donna Guide(14*)	Europa Donna	Europe	2016	1					1	1								1				1													1				6
15	HAS Guide(15*)	HAS	France	2015																																				0
16	AGO LA abd MBC 2020(16*)	AGO	Germany	2020	1				1	1	1								1			1		1													1				8
17	AGO Early BC 2019(17*)	AGO	Germany	2019	1					1	1																													3
18	AGO Primary MBC(18*)	AGO	Germany	2018	1					1	1																													3
19	Würzburg BC(19*)	UHW	Germany	2018	1					1								1	1																		1				5
20	Kreienberg BC screening(20*)	Kreienberg	Germany	2013	1				1									1	1		1			1												1				7
21	Richtlijnendatabase BC(21*)	Richtlijnendatabase	Netherlands	2018	1																																1				2
22	IKNL BC(22*)	IKNL	Netherlands	2012	1														1																		1				3
23	Fisterra BC(23*)	Fisterra	Spain	2017																																				0
24	SEOM hereditary BC(24*)	SEOM	Spain	2015																																				0
25	AEC BC(25*)	AEC	Spain	2017																																				0
26	SESPM(26*)	SESPM	Spain	2019	1																																			1
27	SEGO CPG(27*)	***SEGO(.)	Spain	2017																																				0
28	RER CPG(28*)	RER	Italy	2012																																				0
29	ABS BC surgeons(29*)	ABS	UK	2018																																				0
30	HIS CPG(30*)	HIS	UK	2018	1		1			1									1	1		1		1													1				8
31	NCA BC(31*)	NCA	UK	2019																																				0
32	NICE familial BC(32*)	NICE	UK	2013	1					1									1			1		1													1				6
33	PHA BC screening(33*)	PHA	UK	2012	1					1									1					1	1												1				6
34	NHS failsafe batch CPG(34*)	PHE	UK	2019																																				0
35	NHS mammographers(35*)	PHE	UK	2017	1						1																														2

36	NHS assesment(36*)	PHE	UK	2016																														0
37	NHS BC screening(37*)	NHS	UK	2013	1	1				1	1				1			1	1														1		8
38	NHS Nurse CPG(38*)	NHS	UK	2013	1																											1		2
39	NHS MRI CPG(39*)	NHS	UK	2012																														0
40	RCP BC screening(40*)	RCP	UK	2016																														0
41	RCR breast imaging (41*)	RCR	UK	2019																														0
42	RCR NHS B3 lessions(42*)	RCR, NHS	UK	2018																														0
43	RCR screening radiology(43*)	RCR	UK	2011																														0
44	WMCA BC(44*)	WMCA BC	UK	2016																														0
45	ACP BC screening(45*)	ACP	USA	2019	1	1		1	1	1	1								1													1	1	9
46	CADTH BC screening(46*)	CADTH	Canada	2019																														0
47	CTF 40-74 yo screening(47*)	CTF	Canada	2018	1	1		1	1	1	1					1	1	1	1	1	1	1	1	1					1		1	1	18
48	QBCF BC screening(48*)	QBCF	Canada	2016																														0
49	CCO MRI high-risk BC(49*)	CCO	Canada	2017																														0
50	OBSP BC screening(50*)	CCO	Canada	2015	1					1	1																							3
51	CCO interventions (51*)	CCO	Canada	2011																														0
52	ACOG BC screening(52*)	ACOG	USA	2017	1	1		1	1	1	1					1	1	1	1													1	1	12
53	AMA BC Screening(53*)	AMA	USA	2015	1			1		1	1								1				1									1		7
54	NCCN BC Screening(54*)	NCCN	USA	2019	1																											1		2
55	ACR High -risk BC(55*)	ACR	USA	2018																														0
56	ACR Criteria BC(56*)	ACR	USA	2017																														0
57	ACS BC detection(57*)	ACS	USA	2019	1																											1		2
58	INC BC Screening I(58*)	INC	Brazil	2018																														0
59	INC BC Screening II(59*)	INC	Brazil	2018	1			1	1	1	1							1														1		7
60	INC BC Screening III(60*)	INCJA	Brazil	2018	1	1			1	1	1					1		1	1		1	1	1									1	1	13
61	BCRDI BC screening (61*)	BCRDI, BBDS,	Brazil	2017	1																													1

	BFGOA																																
62	INC CM Manual(62*)	INC	Colombia	2015																													0
63	GPC Colombia(63*)	IETS	Colombia	2017																													0
64	CA early detection(64*)	CA	Australia	2015	1																										1		2
65	CA overdiagnosis (65*)	CA	Australia	2014	1																										1		2
66	New Zealand BC(66*)	MHNZ	New Zealand	2014																													0
67	IARC viewpoint(67*)	IARC	International	2015																													0
68	IARC handbooks(68*)	IARC	International	2016	1					1	1			1	1	1	1	1	1												1	1	11
69	Indian ABSI CS(69*)	ABSI	India	2017																													0
70	Indian ICMR CS(70*)	ICMR	India	2016																													0
71	ABC4(71*)	ESMO, ESO, EUSOMA	Europe	2018	1														1												1		3
72	ESO BC CPG(72*)	ESO	Europe	2013																													0
73	ASBS mammography(73*)	ASBS	UK	2019	1					1	1																						3
74	ASBS MRI(74*)	ASBS	USA	2017																													0
75	USPSTF BC screening(75*)	USPSTF	USA	2016	1					1	1								1												1		5
76	CS Costa Rica(76*)	CMCCR	Costa Rica	2016																													0
77	GPC México(77*)	SSM	México	2019	1																												1

*** SEGO, SEOM, SEOR, SEAP, SESPM, SEDIM, SEMNIM

Appendix 6: The distribution by countries of the screening clinical practice guidelines (CPGs) and consensus statements (CSs) about shared decision-making SDM)



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6.11. Manuscript 10: Maes-Carballo M, Muñoz-Núñez I, Martín-Díaz M, Mignini L, Bueno-Cavanillas A, Khan K S. Shared decision making in breast cancer treatment guidelines: Development of a quality assessment tool and a systematic review. Health Expectations. 2020;00:1–20. DOI: 10.1111/hex.13112

This manuscript has responded to the eighth aim: to analyse the quality and reporting of BC treatment CPGs and CSs. Information and recommendations about SDM treatment in BC CPGs and CSs have not been systematically analysed previously. Neither did we find a tool to evaluate SDM reporting quality. Our study aimed to collate and evaluate the specific information and recommendations about SDM in CPGs and CSs concerning women's BC treatment. We developed a standardised quality assessment tool for assessing coverage of SDM in recommendation documents to analyse this. This systematic review was carried out following Prospero protocol registration and preferred reporting items for systematic reviews and meta-analyses (PRISMA). CPGs and CSs on BC treatment were identified, without language restrictions, through an exhaustive systematic search of bibliographic databases (MEDLINE, EMBASE, Web of Science, Scopus, CDSR) and online sources (12 guideline databases and 51 professional society websites) from January 2010 to December 2019. One hundred sixty-seven articles were analysed. SDM was reported in only 40% of the studies. and more often in recent publications after 2015 (42/101 (41.6 %) vs 46/66 (69.7 %), p = 0.0003) but less often in medical journal publications (44/101 (43.5 %) vs 17/66 (25.7 %), p = 0.009). In CPGs and CSs with SDM, only 8/66 (12%) met one-fifth (6 of 31) of the quality items; only 14/66 (8%) provided clear and precise SDM recommendations. To sum up, SDM descriptions and recommendations in guidance documents concerning BC treatment need improvement. SDM was more frequently reported in CPGs and CSs in recent years, but surprisingly it was less often covered in medical journals, a feature that needs attention.

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- Ranking in JCR: 13/87
- Category: Health policy & services (SSCI)
- Quartile in JCR: Q1
- Ranking in JCR: 28/171
- Category: Public, environmental & occupational health (SSCI)
- Quartile in JCR: Q1
- Ranking in JCR 2019: 28/102
- Category: Health Care Sciences & Services (SCIE)
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REVIEW ARTICLE

Shared decision making in breast cancer treatment guidelines: Development of a quality assessment tool and a systematic review

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Abstract

Background: It is not clear whether clinical practice guidelines (CPGs) and consensus statements (CSs) are adequately promoting shared decision making (SDM).

Objective: To evaluate the recommendations about SDM in CPGs and CSs concerning breast cancer (BC) treatment.

Search strategy: Following protocol registration (Prospero no.: CRD42018106643), CPGs and CSs on BC treatment were identified, without language restrictions, through systematic search of bibliographic databases (MEDLINE, EMBASE, Web of Science, Scopus, CDSR) and online sources (12 guideline databases and 51 professional society websites) from January 2010 to December 2019.

Inclusion criteria: CPGs and CSs on BC treatment were selected whether published in a journal or in an online document.

Data extraction and synthesis: A 31-item SDM quality assessment tool was developed and used to extract data in duplicate.

Main results: There were 167 relevant CPGs (139) and CSs (28); SDM was reported in only 40% of the studies. SDM was reported more often in recent publications after 2015 (42/101 (41.6 %) vs 46/66 (69.7 %), $P = .0003$) but less often in medical journal publications (44/101 (43.5 %) vs 17/66 (25.7 %), $P = .009$). In CPGs and CSs with SDM, only 8/66 (12%) met one-fifth (6 of 31) of the quality items; only 14/66 (8%) provided clear and precise SDM recommendations.

Discussion and conclusions: SDM descriptions and recommendations in CPGs and CSs concerning BC treatment need improvement. SDM was more frequently reported in CPGs and CSs in recent years, but surprisingly it was less often covered in medical journals, a feature that needs attention.

KEYWORDS

breast cancer, breast cancer treatment, clinical practice guidelines, consensus, shared decision making

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1 | INTRODUCTION

Breast cancer (BC) is the most common cancer in women, with 2.1 million new cases each year (25% of all female cancers), and it also causes the greatest number (about 670000 in 2018, 15%) of cancer-related deaths among women[1,2]. Mortality and morbidity from BC have decreased in recent years thanks to early diagnosis and the combination of new treatments in a growing array of different strategies[3,4]. The best BC treatment must be personalized[4,5], and choosing the ideal approach requires a high degree of specialization, scientific-technical updating, multidisciplinary coordination and patient participation[6-9].

This participation in shared decision making (SDM) is considered a keystone in the achievement of sustainable high-quality cancer care, and it becomes especially important when separate treatment options with overall similar potential can yield very different results depending on patients' preferences[9,10]. In developed countries, SDM is a legal obligation[11-13], and it has been shown to increase the satisfaction of the patient[9], improve cost-effectiveness[9] and reduce malpractice lawsuit[14]. It is claimed to be a keystone to guarantee good quality cancer care[9], and it is highly recommended by medical associations[15-17].

The implementation of SDM has persistent barriers[18-22], and it is still poor[23,24]. Many authors have proposed strategies for promotion and practical application of SDM[10,21,25-28]. A three-step model introducing choice, describing options and exploring preferences has been suggested[10]. Another proposal involves encouraging patients to make their own care goals that clinicians translate into treatment plans[21,25]. Option Grids and other decision aids are thought to make the SDM process easier[26,27]. Measuring SDM as a quality indicator and reimbursing professionals that actually use SDM have been floated as another idea involving incentivization[28].

This important subject should be adequately covered in clinical practice guidelines (CPGs) and consensus statements (CSs), especially in those that are published in a medical journal. The aim of this systematic review was to evaluate the characteristics of CPGs and CSs with SDM compared to those without, to develop an SDM quality assessment tool and to collate the specific information and recommendations about SDM concerning BC treatment in women.

2 | METHODS

This systematic review was carried out following protocol registration (Prospero No: CRD42018106643) and using a prospective protocol developed based on recommended methods for literature searches and assessment of guidelines. During the course of the work, no SDM assessment tool was identified in the literature, so we developed such a tool for data extraction in our work. It was reported according to the preferred reporting items for systematic reviews and meta-analyses (PRISMA)[29,30] (see Appendix 1).

2.1 | Data sources and searches

A systematic search combining MeSH terms "shared decision making", "clinical practice guidelines", "guidelines", "consensus", “breast cancer”, “breast cancer treatment” and including word variants was conducted using MEDLINE covering the period January 2010 to December 2019, without language restrictions. We further searched online databases (EMBASE, Web of Science, Scopus, CDSR, etc.), 12 guideline-specific databases and 51 websites of relevant professional societies (see Appendix). For completeness, we searched on the World Wide Web and the bibliographies of known relevant publications to identify additional studies of relevance to the review.

2.2 | Study selection and data extraction

We included CPGs and CSs about BC management, produced by governmental agencies or national and international professional organizations and societies. We excluded CPGs and CSs about screening and diagnosis, obsolete guidelines replaced by updates from the same organization, and CPG and CSs for education and information purpose only.

Two reviewers (MMC and IMMN) independently considered the potential eligibility of each of the titles and abstracts from the citations and requested full-text versions. Working independently, reviewers assessed the full text to confirm eligibility. Disagreements were resolved by consensus or arbitration by a third reviewer (MMD). Duplicate articles were identified and removed. Where multiple versions of a CPG or CS were retrieved, the most recent version was reviewed. Data were extracted from selected CPGs and CSs in duplicate, independently. The intraclass correlation coefficient (ICC) was used to assess consistency between reviewers in data extraction, and the reliability level was excellent >0.90[31]. Authoritative guidance[32] on systematic review methods recommends inter-reviewer reliability assessment that is designed to compare measurements obtained by two or more reviewers extracting data from the same papers.

2.3 | Guideline quality assessment and data extraction

We conducted a search to identify a quality assessment tool for SDM. No relevant tools were identified, so we constructed one using consensus to create a checklist from a long list of items identified in the literature searches. The quality of CPGs and CSs for SDM to manage patients with BC was independently evaluated by two different reviewers (MMC and IMMN) using a piloted data extraction form. Disagreements between the two authors (MMC and IMMN) over the risk of bias for particular studies were solved by group discussion involving an arbitrator (MMD) who took the final decision.

2.4 | Data synthesis

Two authors (MMC and IMMN) synthesized the data extracted to summarize key information within using a piloted data extraction form concerning characteristics of CPGs and CSs with the SDM information and recommendations contained within them. Rate data were compared using chi-square test to examine whether CPGs and CSs with SDM were different to those without SDM.

3 | RESULTS

3.1 | Study selection

Of the 4116 potential citations identified, a total of 167 documents (139 CPGs[33-171] and 28 CSs[172-199]) were identified for final evaluation (Figure 1). ICC for reviewer agreement was 0.97.

3.2 | Development of a quality assessment tool

Individual quality items were scattered across a number of tools for guidelines assessment [200,201]. A long list of items was compiled and presented to a group of four BC and SDM specialists in a consensus meeting. This process including several revisions and iterations which led to a 31-item checklist grouped into thirteen domains (see Appendix). Of these, 68% (n = 21) were identified from the AGREE[201] and 48% (n = 15) from the RIGHT[200] tools. Only 13% (n = 4) of these items did not appear in any of these two tools. However, the expert consensus advised their inclusion after examining other literature in the bibliography of interest about SDM[9,21,24,25,27]. The consensus meeting following approval of the 31-item checklist recommended that each item be examined for compliance. The greater the percentage of items complied with, the greater the quality for SDM in the CPG or CS assessed. The consensus meeting did not recommend the construction of a formal score or a cut point for defining quality.

3.3 | Study characteristics

The distribution by countries of CPGs and CSs that speak about SDM was irregular (Figure 1). Europe stood out with a total of 25 CPGs and CSs (38%). North America developed 29 (44%) CPGs and CSs (USA: 19 and Canada: 10). South America released six (9%) CPGs and CSs (Colombia, Venezuela, Mexico, Peru and two from Costa Rica). Asia also carried out three (5%) CPGs and CSs (Japan, India and Malaysia). Oceania has developed also three (5%)CPGs and CSs: two from Australia and one from New Zealand. The basic characteristics of the CPGs and CSs including organization, country and year of release are summarized in Table 1. The duration since last update of each CPGs or CSs varied. Some AGO[46,48,49,59], all the NCCN[149-153] and one of the AHS[89] CPGs, and ESMO[178] and the Mexican CS[173] were the most recently updated (highlighted in Table 2). Overall, the last update of the CPGs and CSs with SDM was more recent than that of those without SDM (mean 45 months (range: 3-115) vs 52 months (range: 3-116), $P < .001$). In this comparison, 9% (n = 15/167) did not specify the month of updated but only the year. SDM was reported more often in recent CPGs and CSs published after 2015 (42/101 (42.0%) vs 46/66 (69.7%), $P = .0003$) but less often in CPGs and CSs published in medical journal (44/101 (43.5%) vs 17/66 (25.7%), $P = .009$) (Table 3).

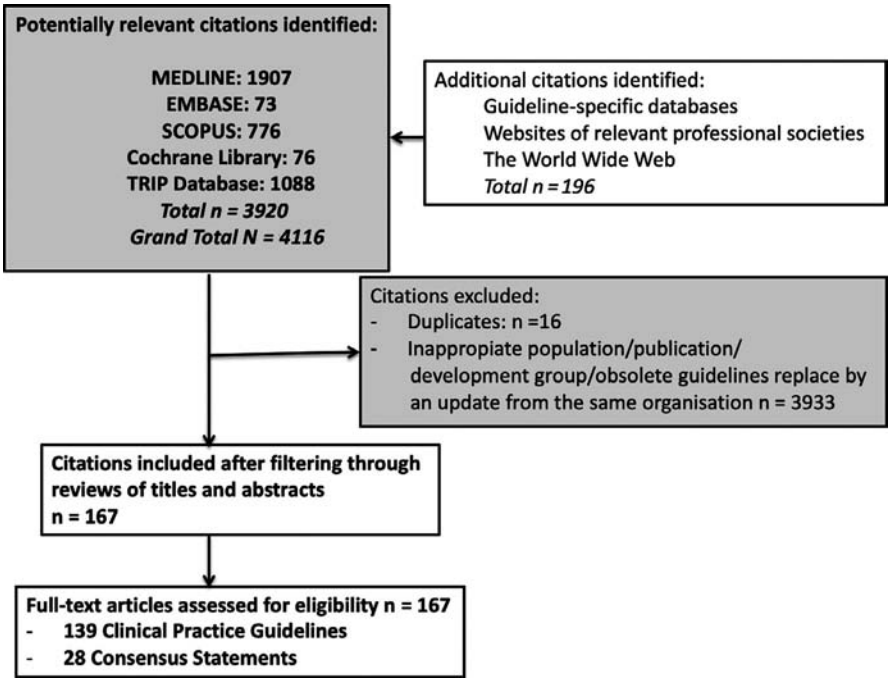

FIGURE 1 Flow diagram for study selection of CPGs and CSs

TABLE 1 Description of the CPGs and CSs (n = 167) selected for the systematic review on the quality of reporting concerning SDM in BC treatment

		Abbreviated name	Entity	Country	Year
	Name of the CPG				
1	Guidelines on the diagnosis and treatment of breast cancer (2011 edition)[32]	Chinese BC CPG[32]	CMH	China	2012
2	Chinese guidelines for diagnosis and treatment of breast cancer 2018[33]	Chinese BC diagnosis treatment[33]	NHCPRC	China	2018
3	The Japanese Breast Cancer Society Clinical Practice Guideline for radiation treatment of breast cancer, 2015 edition[34]	Japanese RT BC CPG[34]	JBCS	Japan	2015
4	The Japanese Breast Cancer Society Clinical Practice Guideline for systemic treatment of breast cancer, 2015 edition[35]	Japanese systemic BC CPG[35]	JBCS	Japan	2015
5	2013 clinical practice guidelines (The Japanese Breast Cancer Society): history, policy and mission[36]	Japanese treatment BC CPG[36]	JBCS	Japan	2014
6	Singapore Cancer Network (SCAN) Guidelines for Adjuvant Trastuzumab Use in Early Stage HER2 Positive Breast Cancer[37]	SCAN early BC[37]	SCAN	Singapore	2015
7	Singapore Cancer Network (SCAN) Guidelines for Bisphosphonate Use in the Adjuvant Breast Cancer Setting[38]	SCAN adjuvant BC treatment[38]	SCAN	Singapore	2015
8	Breast cancer in women: diagnosis, treatment and follow-up[39]	KCE BC CPG[39]	KCE	Belgium	2015
9	Early breast cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up[40]	ESMO BC 2019[40]	ESMO	Europe	2019
10	International guidelines for management of metastatic breast cancer (MBC) from the European School of Oncology (ESO)[41]	ESO MBC[41]	ESO	Europe	2013
11	The European Society of Breast Cancer Specialists recommendations for the management of young women with breast cancer[42]	EUSOMA 2012[42]	EUSOMA	Europe	2012
12	AGO Recommendations for the Diagnosis and Treatment of Patients with Early Breast Cancer: Update 2019[43]	AGO early BC[43]	AGO	Germany	2019
13	Lesions of Uncertain Malignant Potential (B3) (ADH, LIN, FEA, Papilloma, Radial Scar)[44]	AGO uncertain lesions[44]	AGO	Germany	2019
14	Ductal Carcinoma in Situ (DCIS)[45]	AGO DCIS[45]	AGO	Germany	2019
15	Breast Cancer Surgery Oncological Aspects[46]	AGO oncological[46]	AGO	Germany	2019
16	Oncoplastic and Reconstructive Surgery[47]	AGO oncoplastic[47]	AGO	Germany	2019
17	Adjuvant Endocrine Therapy in Pre- and Postmenopausal Patients[48]	AGO adjuvant endocrine[48]	AGO	Germany	2019
18	Adjuvant Cytotoxic and Targeted Therapy[49]	AGO cytotoxic[49]	AGO	Germany	2019
19	Neoadjuvant (Primary) Systemic Therapy[50]	AGO neoadjuvant[50]	AGO	Germany	2019
20	Adjuvant Radiotherapy[51]	AGO RT[51]	AGO	Germany	2019
21	Therapy Side Effects[52]	AGO side effects[52]	AGO	Germany	2019
22	Supportive Care[53]	AGO supportive care[53]	AGO	Germany	2019
23	Breast Cancer: Specific Situations[54]	AGO-specific situations[54]	AGO	Germany	2019
24	Breast Cancer Follow-Up[55]	AGO follow-up[55]	AGO	Germany	2019
25	Loco-Regional Recurrence[56]	AGO recurrence[56]	AGO	Germany	2019
26	Endocrine and "Targeted" Therapy in Metastatic Breast Cancer[57]	AGO endocrine MBC[57]	AGO	Germany	2019
27	Chemotherapy With or Without Targeted Drugs* in Metastatic Breast Cancer[58]	AGO CT MBC[58]	AGO	Germany	2019
28	Osteooncology and Bone Health[59]	AGO osteooncology[59]	AGO	Germany	2019
29	Specific Sites of Metastases[60]	AGO-specific MBC[60]	AGO	Germany	2019
30	CNS Metastases in Breast Cancer[61]	AGO CNS MBC[61]	AGO	Germany	2019

(Continues)

TABLE 1 (Continued)

		Abbreviated name	Entity	Country	Year
31	Complementary Therapy Survivorship[62]	AGO survivorship[62]	AGO	Germany	2019
32	Diagnosis and Treatment of Patients with Primary and Metastatic Breast Cancer[63]	AGO primary MBC[63]	AGO	Germany	2018
33	AGO Recommendations for the Diagnosis and Treatment of Patients with Advanced and Metastatic Breast Cancer: Update 2018[64]	AGO advanced MBC[64]	AGO	Germany	2018
34	DEGRO practical guidelines for radiotherapy of breast cancer VI: therapy of locoregional breast cancer recurrences[65]	DEGRO BC recurrences[65]			2014
35	DEGRO practical guidelines: radiotherapy of breast cancer I. Radiotherapy following breast conserving therapy for invasive breast cancer. [66]	DEGRO RT conserving BC[66]	DEGRO	Germany	2013
36	DEGRO practical guidelines for radiotherapy of breast cancer IV. Radiotherapy following mastectomy for invasive breast cancer[67]	DEGRO RT mastectomy BC[67]	DEGRO	Germany	2014
37	DEGRO practical guidelines: radiotherapy of breast cancer III—radiotherapy of the lymphatic pathways[68]	DEGRO RT lymphatic[68]	DEGRO	Germany	2014
38	Diagnosis, staging and treatment of patients with breast cancer. National Clinical Guideline No. 7[69]	NCCP[69]	NCCP	Ireland	2015
39	Breast cancer[70]	Richtlijnendatabase BC[70]	Richtlijnen	Netherlands	2018
40	Dutch breast reconstruction guideline[71]	Dutch BCR[71]	DPRS	Netherlands	2017
41	Breast Cancer[72]	IKNL BC[72]	IKNL	Netherlands	2012
42	Cáncer de mama/ Breast Cancer[73]	Fisterra BC[73]	Fisterra	Spain	2017
43	SEOM clinical guidelines in early-stage breast cancer[74]	SEOM early stage[74]	SEOM	Spain	2018
44	SEOM clinical guidelines in advanced and recurrent breast cancer[75]	SEOM advanced BC[75]	SEOM	Spain	2018
45	SEOM clinical guidelines in metastatic breast cancer[76]	SEOM MBC[76]	SEOM	Spain	2015
46	SEOM clinical guidelines in Hereditary Breast and ovarian cancer[77]	SEOM hereditary BC[77]	SEOM	Spain	2015
47	Abemaciclib with fulvestrant for treating hormone receptor-positive, HER2-negative advanced breast cancer after endocrine the therapy[78]	NICE abemaciclib[78]	NICE	UK	2019
48	Ribociclib with fulvestrant for treating hormone receptor-positive, HER2-negative advanced breast cancer[79]	NICE ribociclib[79]	NICE	UK	2019
49	Early and locally advanced breast cancer: diagnosis and management[80]	NICE early and advanced BC[80]	NICE	UK	2018
50	Breast cancer[81]	NICE BC[81]	NICE	UK	2011
51	Familial breast cancer: classification, care and managing breast cancer and related risks in people with a family history of breast cancer[82]	NICE familial BC[82]	NICE	UK	2013
52	Breast reconstruction using lipomodelling after breast cancer treatment[83]	NICE lipomodelling[83]	NICE	UK	2012
53	Gene expression profiling and expanded immunohistochemistry tests for guiding adjuvant chemotherapy decisions in early breast cancer management: MammaPrint, Oncotype DDX,X, IHC4 and Mammostrat[84]	NICE gene expression[84]	NICE	UK	2013
54	Pertuzumab for the neoadjuvant treatment of HER2-positive breast cancer[85]	NICE pertuzumab BC[85]	NICE	UK	2016
55	Intraoperative tests (RD-100i OSNA system and Metasin test) for detecting sentinel lymph node metastases in breast cancer[86]	NICE sentinel lymph[86]	NICE	UK	2013
56	Breast reconstruction following prophylactic or therapeutic mastectomy for breast cancer[87]	AHS reconstruction BC[87]	AHS	Canada	2017

(Continues)

TABLE 1 (Continued)

		Abbreviated name	Entity	Country	Year
57	Adjuvant systemic therapy for early stage (lymph node negative and lymph node positive) breast cancer[88]	AHS early BC[88]	AHS	Canada	2018
58	Optimal use of taxanes in metastatic breast cancer (MBC)[89]	AHS MBC[89]	AHS	Canada	2013
59	Adjuvant radiation therapy for invasive breast cancer[90]	AHS RT invasive[90]	AHS	Canada	2015
60	Adjuvant radiation therapy for ductal carcinoma in situ[91]	AHS RT DCI[91]	AHS	Canada	2015
61	Neo-adjuvant (pre-operative) therapy for breast cancer - general considerations [92]	AHS neo-adjuvant[92]	AHS	Canada	2014
62	The Role of Trastuzumab in Adjuvant and Neoadjuvant Therapy in Women with HER2/neu-overexpressing Breast Cancer[93]	CCO trastuzumab Her2 + BC[93]	CCO	Canada	2011
63	Surgical management of early-stage invasive breast cancer[94]	CCO surgical management BC [94]	CCO	Canada	2015
64	Breast irradiation in women with early stage invasive breast cancer following breast conserving surgery[95]	CCO RT[95]	CCO	Canada	2016
65	The role of the taxanes in the management of metastatic breast cancer[96]	CCO taxane MBC[96]	CCO	Canada	2011
66	Vinorelbine in stage IV breast cancer[97]	CCO vinorelbine[97]	CCO	Canada	2012
67	The role of aromatase inhibitors in the treatment of postmenopausal women with metastatic breast cancer[98]	CCO aromatase inhibitor MBC[98]	CCO	Canada	2012
68	Epirubicin, as a single agent or in combination, for metastatic breast cancer[99]	CCO epirubicin MBC[99]	CCO	Canada	2011
69	Adjuvant taxane therapy for women with early-stage, invasive breast cancer[100]	CCO taxane adjuvant therapy BC[100]	CCO	Canada	2011
70	Adjuvant systemic therapy for node-negative breast cancer[101]	CCO sQT for node-negative BC[101]	CCO	Canada	2011
71	Adjuvant ovarian ablation in the treatment of premenopausal women with early stage invasive breast cancer[102]	CCO ovarian ablation early stage[102]	CCO	Canada	2010
72	The role of gemcitabine in the management of metastatic breast cancer[103]	CCO gemcitabine[103]	CCO	Canada	2011
73	The role of trastuzumab (herceptin) in the treatment of women with Her2/neu-overexpressing metastatic breast cancer[104]	CCO trastuzumab MBC[104]	CCO	Canada	2010
74	Capecitabine in stage IV breast cancer[105]	CCO capecitabine[105]	CCO	Canada	2011
75	The role of her2/neu in systemic and radiation therapy for women with breast cancer[106]	CCO her2/neu and RT treatment [106]	CCO	Canada	2012
76	Locoregional therapy of locally advanced breast cancer (LABC)[107]	CCO LABC[107]	CCO	Canada	2014
77	The role of taxanes in neoadjuvant chemotherapy for women with non-metastatic breast cancer[108]	CCO taxane neoadjuvant therapy[108]	CCO	Canada	2011
78	Optimal systemic therapy for early female breast cancer[109]	CCO early BC[109]	CCO	Canada	2014
79	Use of adjuvant bisphosphonates and other bone-modifying agents in breast cancer[110]	CCO bone-modifying agent BC[110]	CCO	Canada	2016
80	The Role of Aromatase Inhibitors in Adjuvant Therapy for Postmenopausal Women with Hormone Receptor-positive Breast Cancer[111]	CCO aromatase inhibitors HR + [111]	CCO	Canada	2012
81	Margin width in breast conservation Surgery[112]	ABS margin width BC[112]	ABS	UK	2015
82	Antibiotic prophylaxis in breast surgery[113]	ABS AB prophylaxis[113]	ABS	UK	2015
83	Management of The malignant axilla In early breast cancer[114]	ABS axila BC[114]	ABS	UK	2015
84	Breast operation note Documentation[115]	ABS BC[115]	ABS	UK	2015
85	Update on optimal duration of adjuvant antihormonal therapy[116]	ABS antihormonal therapy[116]	ABS	UK	2015

(Continues)

TABLE 1 (Continued)

		Abbreviated name	Entity	Country	Year
86	Oncoplastic breast reconstruction[117]	ABS/BAPRAS oncoplastic[117]	ABS, BAPRAS	UK	2012
87	Acellular dermal matrix (ADM) assisted breast reconstruction procedures[118]	ABS/BAPRAS ADM[118]	ABS, BAPRAS	UK	2012
88	Breast Cancer Clinical Quality Performance Indicators[119]	SCT quality indicators[119]	SCT	UK	2016
89	Treatment of primary breast cancer[120]	SIGN[120]	SIGN	UK	2013
90	Lipomodelling Guidelines for Breast Surgery[121]	JGBSA lipomodelling[121]	JGBSA	UK	2012
91	Performance and Practice Guidelines for the Use of Neoadjuvant Systemic Therapy in the Management of Breast Cancer[122]	ASBS NaQT BC[122]	ASBS	USA	2017
92	Performance and Practice Guidelines for Mastectomy[123]	ASBS mastectomy[123]	ASBS	USA	2014
93	Performance and Practice Guidelines for Breast-Conserving Surgery/Partial Mastectomy[124]	ASBS breast conserving[124]	ASBS	USA	2014
94	Performance and Practice Guidelines for Axillary Lymph Node Dissection in Breast Cancer Patients[125]	ASBS ALD[125]	ASBS	USA	2014
95	Performance and Practice Guidelines for Sentinel Lymph Node Biopsy in Breast Cancer Patients[126]	ASBS SLND[126]	ASBS	USA	2014
96	Evidence-Based Clinical Practice Guideline: Autologous Breast Reconstruction with DIEP or Pedicled TRAM Abdominal Flaps[127]	ASPS DIEP and TRAM[127]	ASPS	USA	2017
97	Use of Endocrine Therapy for Breast Cancer Risk Reduction: ASCO Clinical Practice Guideline Update[128]	ASCO endocrine therapy risk BC[128]	ASCO	USA	2019
98	Postmastectomy Radiotherapy: An American Society of Clinical Oncology, American Society for Radiation Oncology, and Society of Surgical Oncology Focused Guideline Update[129]	ASCO postmastectomy RT[129]	ASCO	USA	2017
99	Breast Cancer Surveillance Guidelines[130]	ASCO surveillance[130]	ASCO	USA	2013
100	Selection of Optimal Adjuvant Chemotherapy and Targeted Therapy for Early Breast Cancer: ASCO Clinical Practice Guideline Focused Update[131]	ASCO treatment for early BC[131]	ASCO	USA	2018
101	Systemic Therapy for Patients With Advanced Human Epidermal Growth Factor Receptor 2–Positive Breast Cancer: ASCO Clinical Practice Guideline Update[132]	ASCO systemic therapy EGR2 BC[132]	ASCO	USA	2018
102	Recommendations on Disease Management for Patients With Advanced Human Epidermal Growth Factor Receptor 2–Positive Breast Cancer and Brain Metastases: ASCO Clinical Practice Guideline Update[133]	ASCO EGRF2 MBC[133]	ASCO	USA	2018
103	Integrative Therapies During and After Breast Cancer Treatment: ASCO Endorsement of the SIO Clinical Practice Guideline[134]	ASCO BC treatment[134]	ASCO	USA	2018
104	Chemotherapy and Targeted Therapy for Women With Human Epidermal Growth Factor Receptor 2–Negative (or unknown) Advanced Breast Cancer: American Society of Clinical Oncology Clinical Practice Guideline[135]	ASCO EGFR2 advanced BC[135]	ASCO	USA	2014
105	Role of Bone-Modifying Agents in Metastatic Breast Cancer: An American Society of Clinical Oncology–Cancer Care Ontario Focused Guideline Update[136]	ASCO bone-modifying agent MBC[136]	ASCO	USA	2017
106	Recommendations for Human Epidermal Growth Factor Receptor 2 Testing in Breast Cancer: American Society of Clinical Oncology/College of American Pathologists Clinical Practice Guideline Update[137]	ASCO EGFR2 recommendations[137]	ASCO	USA	2013

(Continues)

TABLE 1 (Continued)

		Abbreviated name	Entity	Country	Year
107	Breast Cancer Follow-Up and Management After Primary Treatment: American Society of Clinical Oncology Clinical Practice Guideline Update[138]	ASCO follow-up/ management BC[138]	ASCO	USA	2013
108	Adjuvant Endocrine Therapy for Women With Hormone Receptor–Positive Breast Cancer: American Society of Clinical Oncology Clinical Practice Guideline Update on Ovarian Suppression[139]	ASCO ovarian suppression BC[139]	ASCO	USA	2016
109	Role of Patient and Disease Factors in Adjuvant Systemic Therapy Decision Making for Early-Stage, Operable Breast Cancer: American Society of Clinical Oncology Endorsement of Cancer Care Ontario Guideline Recommendations[140]	ASCO factors in early BC[140]	ASCO	USA	2016
110	Use of Adjuvant Bisphosphonates and Other Bone-Modifying Agents in Breast Cancer: A Cancer Care Ontario and American Society of Clinical Oncology Clinical Practice Guideline[141]	ASCO use bone-modifying agents BC[141]	ASCO	USA	2017
111	Use of Biomarkers to Guide Decisions on Adjuvant Systemic Therapy for Women With Early-Stage Invasive Breast Cancer: American Society of Clinical Oncology Clinical Practice Guideline Focused Update[142]	ASCO biomarkers in early BC[142]	ASCO	USA	2017
112	Use of Biomarkers to Guide Decisions on Systemic Therapy for Women With Metastatic Breast Cancer: American Society of Clinical Oncology Clinical Practice Guideline[143]	ASCO biomarkers in MBC[143]	ASCO	USA	2019
113	American Society of Clinical Oncology Endorsement of the Cancer Care Ontario Practice Guideline on Adjuvant Ovarian Ablation in the Treatment of Premenopausal Women With Early-Stage Invasive Breast Cancer[144]	ASCO ovarian ablation BC[144]	ASCO	USA	2011
114	American Society of Clinical Oncology/College of American Pathologists Guideline Recommendations for Immunohistochemical Testing of Estrogen and Progesterone Receptors in Breast Cancer[145]	ASCO hormonal BC[145]	ASCO	USA	2010
115	Use of Pharmacologic Interventions for Breast Cancer Risk Reduction: American Society of Clinical Oncology Clinical Practice Guideline[146]	ASCO risk reduction BC[146]	ASCO	USA	2013
116	Endocrine Therapy for Hormone Receptor–Positive Metastatic Breast Cancer: American Society of Clinical Oncology Guideline[147]	ASCO endocrine BC[147]	ASCO	USA	2016
117	Invasive Breast Cancer. Basic resources. Version 1.2019[148]	NCCN invasive BC basic[148]	NCCN	USA	2019
118	Invasive Breast Cancer. Core resources. Version 1.2019[149]	NCCN invasive BC core[149]	NCCN	USA	2019
119	Invasive Breast Cancer. Enhanced resources. Version 1.2019[150]	NCCN invasive BC enhanced[150]	NCCN	USA	2019
120	Breast Cancer. NCCN Evidence Blocks. Version 1.2019[151]	NCCN evidence block BC[151]	NCCN	USA	2019
121	Breast Cancer. Version 3.2019[152]	NCCN BC[152]	NCCN	USA	2019
122	Management of Breast Cancer (2nd Edition)[153]	MHM BC[153]	MHM	Malaysia	2010
123	Influencing best practice in breast cancer[154]	Australia BC[154]	AG	Australia	2016
124	Recommendations for staging and managing the axilla[155]	CA axilla[155]	CA	Australia	2011
125	Recommendations for use of hypofractionated radiotherapy for early operable breast cancer[156]	CA RT[156]	CA	Australia	2011
126	Recommendations for use of Bisphosphonates[157]	CA bisphosphonates[157]	CA	Australia	2011
127	Recommendations for the management of early breast cancer in women with an identified BRCA1 or BRCA2 gene mutation or at high risk of a gene mutation[158]	CA management BC[158]	CA	Australia	2014
128	Guía de Práctica Clínica AUGE Cáncer de Mama[159]	GPC Chile[159]	MSC	Chile	2015

(Continues)

TABLE 1 (Continued)

		Abbreviated name	Entity	Country	Year
129	Guía de práctica clínica (GPC) para la detección temprana, tratamiento integral, seguimiento y rehabilitación del cáncer de mama[160]	GPC Colombia[160]	INC	Colombia	2017
130	Guía de Práctica Clínica del Tratamiento para el Cáncer de Mama[161]	GPC Costa Rica[161]	IHCAI	Costa Rica	2011
131	Guía de Práctica Clínica para el Tratamiento del Cáncer de Mama [162]	GPC Perú[162]	DDSS	Perú	2017
132	Guía para el Cáncer de Mama en Venezuela[163]	GPC Venezuela[163]	SAV	Venezuela	2015
133	Management of Early Breast Cancer[164]	New Zealand BC[164]	MHNZ	New Zealand	2014
134	The Screening, Diagnosis, Treatment, and Follow-Up of Breast Cancer[165]	Würzburg BC[165]	UHW	Germany	2018
135	Breast cancer brain metastases: a review of the literature and a current multidisciplinary management guideline[166]	FESEO brain MBC[166]	FESEO	Spain	2013
136	Cirugía de la Mama[167]	AEC BC[167]	AEC	Spain	2017
137	NCA Breast Cancer Clinical Guidelines[168]	NCA BC[168]	NCA	UK	2019
138	Breast Cancer: Management and Follow-Up[169]	BCMA management and follow-up[169]	BCMA	Canada	2013
139	Clinical Guidelines for the Management of Breast Cancer[170]	WMCA BC [170]	WMCA	UK	2016
	Name of the CS				
140	Consenso costarricense sobre prevención, diagnóstico y tratamiento del cáncer mamario[171]	CS Costa Rica[171]	CMCCR	Costa Rica	2016
141	Consenso Mexicano sobre diagnóstico y tratamiento del cáncer mamario [172]	GPC México[172]	SSM	México	2019
142	National consensus in China on diagnosis and treatment of patients with advanced breast cancer[173]	Chinese BC CS[173]	CECM	China	2015
143	Practical consensus recommendations for hormone receptor-positive Her2-negative advanced or metastatic breast cancer[174]	Indian ICON CS[174]	ICON	India	2013
144	Indian Solutions for Indian Problems—Association of Breast Surgeons of India (ABSI) Practical Consensus Statement, Recommendations, and Guidelines for the Treatment of Breast Cancer in India[175]	Indian ABSI CS[175]	ABSI	India	2017
145	Consensus document for management of breast cancer[176]	Indian ICMR CS[176]	ICMR	India	2016
146	4th ESO–ESMO International Consensus Guidelines for Advanced Breast Cancer (ABC 4)[177]	ABC4[177]	ESMO	Europe	2018
147	St. Gallen/Vienna 2019: A Brief Summary of the Consensus Discussion about Escalation and De-Escalation of Primary Breast Cancer Treatment[178]	St. Gallen 2019[178]	St. Gallen	Europe	2019
148	ESTRO consensus guideline on target volume delineation for elective radiation therapy of early stage breast cancer[179]	ESTRO RT BC[179]	ESTRO	Europe	2014
149	Second international consensus guidelines for breast cancer in young women (BCY2)[180]	BCY2[180]	ESO	Europe	2016
150	Guidelines for diagnostics and treatment of aromatase inhibitor-induced bone loss in women with breast cancer A consensus of Lithuanian medical oncologists, radiation oncologists, endocrinologists, and family medicine physicians[181]	LOEGP[181]	LOEGP	Lithuania	2014
151	Biomarkers in breast cancer: A consensus statement by the Spanish Society of Medical Oncology and the Spanish Society of Pathology[182]	SEOM and SEAP[182]	SEOM	Spain	2017
152	Provincial consensus recommendations for adjuvant systemic therapy for breast cancer[183]	CCM 2017[183]	CCM	Canada	2017

(Continues)

TABLE 1 (Continued)

		Abbreviated name	Entity	Country	Year
153	Postoperative radiotherapy for breast cancer: UK consensus statements[184]	RCR postoperative RT[184]	RCR	UK	2016
154	Consensus Guideline on Accelerated Partial Breast Irradiation[185]	ASBS RT[185]	ASBS	USA	2018
155	Consensus Guideline on the Use of Transcutaneous and Percutaneous Ablation for the Treatment of Benign and Malignant Tumors of the Breast[186]	ASBS ablation[186]	ASBS	USA	2018
156	Consensus Guideline on the Management of the Axilla in Patients With Invasive/In-Situ Breast Cancer[187]	ASBS axilla[187]	ASBS	USA	2019
157	Consensus Guideline on Breast Cancer Lumpectomy Margins[188]	ASBS margins[188]	ASBS	USA	2017
158	Consensus Guideline on Concordance Assessment of Image-Guided Breast Biopsies and Management of Borderline or High-Risk Lesions[189]	ASBS borderline lesions[188]	ASBS	USA	2016
159	Contralateral Prophylactic Mastectomy (CPM) Consensus Statement from the American Society of Breast Surgeons: Data on CPM Outcomes and Risks[190]	ASBS CPM[190]	ASBS	USA	2016
160	Consensus Guideline on Venous Thromboembolism (VTE) Prophylaxis for Patients Undergoing Breast Operations[191]	ASBS VTE prophylaxis BC[191]	ASBS	USA	2011
161	The American Brachytherapy Society consensus statement on intraoperative radiation therapy[192]	AB intraoperative RT[192]	AB	USA	2017
162	The American Brachytherapy Society consensus report for accelerated partial breast irradiation using interstitial multicatheter brachytherapy [193]	AB partial RT BC[193]	AB	USA	2017
163	Society of Surgical Oncology Breast Disease Working Group Statement on Prophylactic (Risk-Reducing) Mastectomy[194]	SSO prophylactic mastectomy[194]	SSO	USA	2016
164	SSO-ASTRO Consensus Guideline on Margins for Breast-Conserving Surgery with Whole-Breast Irradiation in Ductal Carcinoma In Situ[195]	SSO margins [195]	SSO	USA	2016
165	SSO-ASTRO Consensus Guideline on Margins for Breast-Conserving Surgery with Whole Breast Irradiation in Stage I and II Invasive Breast Cancer[196]	SSO–ASTRO invasive BC[196]	SSO - ASTRO	USA	2014
166	Margins for Breast-Conserving Surgery With Whole-Breast Irradiation in Stage I and II Invasive Breast Cancer: American Society of Clinical Oncology Endorsement of the Society of Surgical Oncology/American Society for Radiation Oncology Consensus Guideline[197]	ASCO margin BC CSs[197]	ASCO	USA	2014
167	International expert panel on inflammatory breast cancer: consensus statement for standardized diagnosis and treatment[198]	International expert panel BC[198]	IEP	International	2010

TABLE 2 Characteristics of the CPGs and CSs regarding SDM

Characteristics	CPGs or CSs without SDM (n = 101)	CPGs or CSs with SDM (n = 66)	*P* value
Published after 2015	42 (42.0 %)	46 (69.7 %)	.0003
CPG	83 (82.1 %)	54 (81.8 %)	.95
European guidelines	45 (44.5 %)	25 (37.0 %)	.21
North American guidelines	43 (42.5 %)	28 (42.4 %)	.98
South American guidelines	2 (1.9 %)	5 (7.5 %)	.1
Asia guidelines	9 (8.9 %)	3 (4.5 %)	.15
Oceania guidelines	3 (2.9 %)	3 (4.5 %)	.3
Published in a journal	44 (43.5 %)	17 (25.7 %)	.009

TABLE 3 Update frequency of each CPGs/CSs where SDM appears

		Entity	First year of publication	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019
	CPGs												
3	Japanese RT BC CPG[34]	JBCS	2015						*				
9	ESMO BC 2019[40]	ESMO	2010	*					*				*
11	EUSOMA 2012[42]	EUSOMA	2012			*							
12	**AGO early BC** [43]	**AGO**	**2012**			*	*	*	*				*
14	**AGO DCIS** [45]	**AGO**	**2002**	*		*	*	*	*	*	*	*	*
16	**AGO oncoplastic** [47]	**AGO**	**2012**				*	*	*	*	*	*	*
17	**AGO adjuvant endocrine** [48]	**AGO**	**2012**			*	*	*	*	*	*	*	*
27	**AGO CT MBC** [58]	**AGO**	**2012**			*	*	*	*	*	*	*	*
41	IKNL BC[72]	IKNL	2008			*							
42	Fisterra BC[73]	Fisterra	2011		*						*		*
47	NICE abemaciclib[78]	NICE	2019										*
48	NICE ribociclib[79]	NICE	2019										*
49	NICE early and advanced BC[80]	NICE	2018									*	
50	NICE BC[81]	NICE	2011		*								
51	NICE familial BC[82]	NICE	2013				*						
52	NICE lipomodelling[83]	NICE	2012			*							
53	NICE gene expression[84]	NICE	2013				*						
54	NICE pertuzumab BC[85]	NICE	2016							*			
56	AHS reconstruction BC[87]	AHS	2013				*				*		
57	**AHS early BC** [88]	**AHS**	**2014**					*	*	*		*	
63	CCO surgical management BC [94]	CCO	1996		*				*				
70	CCO sQT for node-negative BC[101]	CCO	1998	*									
71	CCO ovarian ablation early stage[102]	CCO	2010	*									
73	CCO trastuzumab MBC[104]	CCO	1999		*								
76	CCO LABC[107]	CCO	2014					*					
79	CCO bone-modifying agents BC[110]	CCO	2016							*			
86	ABS/BAPRAS oncoplastic[117]	ABS, BAPRAS	2012			*							

(Continues)

TABLE 3 (Continued)

		Entity	First year of publication	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019
88	SCT quality indicators[119]	SCT	2016							*			
98	ASCO postmastectomy RT[129]	ASCO	2001					*			*		
100	ASCO treatment for early BC[131]	ASCO	2016							*		*	
104	ASCO EGFR2 advanced BC[135]	ASCO	2014					*					
105	ASCO bone-modifying agent MBC[136]	ASCO	2000		*						*		
108	ASCO ovarian suppression BC[139]	ASCO	2016							*			
109	ASCO factors in early BC[140]	ASCO	2019										
110	ASCO use bone-modifying agent BC[141]	ASCO	2017								*		
116	ASCO endocrine BC[147]	ASCO	2016							*			
117	**NCCN invasive BC basic** [148]	**NCCN**	**2015**							*		*	*
118	**NCCN invasive BC core** [149]	**NCCN**	**2015**							*		*	*
119	**NCCN invasive BC enhanced** [150]	**NCCN**	**2015**							*		*	*
120	**NCCN evidence block BC** [151]	**NCCN**	**2015**						*	*		*	*
121	**NCCN BC** [152]	**NCCN**	**2015**							*		*	*
122	MHM BC[153]	MHM	2002	*									
123	Australia BC[154]	AG	2016							*			
124	CA axilla[155]	CA	2011		*								
129	GPC Colombia[160]	INC	2013				*				*		
130	IHCAI GPC Costa Rica[161]	IHCAI	2011		*								
131	GPC Perú[162]	IETSI	2017								*		
132	GPC Venezuela[163]	SAV	2015						*				
133	New Zealand BC[164]	MHNZ	2009					*					
134	Würzburg BC[165]	UHW	2018									*	
136	AEC BC[167]	AEC	2007								*		
137	NCA BC[168]	NCA	2019										*
138	BCMA management and follow-up [169]	BCMA	2013				*						
139	WMCA BC [170]	WMCA BC	2016										

(Continues)

TABLE 3 (Continued)

	Entity	First year of publication	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019
CSs												
140	CS Costa Rica[171]	CMCCR	2016									
141	**GPC México**[172]	**SSM**	**1994**	*		*		*		*		*
145	Indian ICMR CS[176]	ICMR	2016						*			
146	**ABC4**[177]	**ESMO**	**2012**		*		*		*		*	
147	St. Gallen 2019[178]	St. Gallen	2015					*		*		*
152	CCM 2017[183]	CCM	2017							*		
154	ASBS RT[185]	ASBS	2018								*	
156	ASBS axilla[187]	ASBS	2019									*
158	ASBS borderline lesions[189]	ASBS	2016						*			
159	ASBS CPM[190]	ASBS	2016						*			
163	SSO prophylactic mastectomy[194]	SSO	2007						*			
164	SSO margins[195]	SSO	2014				*					

3.4 | SDM in CPGs and CSs concerning BC

The analysis of the compliance of the items valued is presented in Figure 2 and Appendix 4. SDM appeared in any section of 66 CPGs and CSs (12/28 (43%) CSs vs 54/139 (39%) CPGs, $P = .69$). SDM appeared in glossary or indexes in only two documents, and only in one, its basis was explained. In general, CSs had higher overall quality than CPGs (CSs' mean 2.833 vs CPGs' mean 1.12 items, $P < .001$) (Appendix).

Overall, 39 (23%) stated the value of SDM as an option in the decision-making process, 14 (8%) provided clear and precise SDM recommendations, 4 (3%) considered benefits versus harms of using SDM, and 4 (2%) identified evidence supporting the use of SDM. Only 9 (5%) of these CPGs and CSs gave advice for the SDM application in practice. The strength of recommendations on SDM was indicated in three (2%). Support for the implementation of SDM was well-detailed in two documents (1%). The information gathered about SDM affected recommendations and was detailed in one (<1%). Limitations of the CPG or CS about SDM recommendations were described in just one of them (<1%).

Only 4 (2%) of these guides emphasized their interest in SDM appearing in the executive summary. Only in three (2%) of the CPGs and CSs, the table of content talked about SDM. Primary affected population with BC was well-defined in 22 (13%) articles, and patients' subgroups with special consideration were discussed in 7 (4%) documents. Appropriateness and relevance of outcomes were considered in only 2 (1%) CPGs. Only one document detailed the consistency of results across studies. Recommendations about SDM for subgroups were separated in only two articles (1%). Facilitators and barriers to SDM application were described in only two articles too (1%).

Ten items (32%) measured in the data extraction instrument were not included in any CPGs and CSs (n = 10/31). The PICO question related to SDM was not specified, search strategy was not reported, the study design and limitations were not pondered, barriers were not described, the cost of SDM implementation was not specified, adherence to recommendations and the impact were not assessed, description of the cost information and suggestions for further research were not provided and finally, professional, financial or intellectual interest about SDM was not described (Figure 2 and Appendix). Finally, there were 101 (61%) CPGs or CSs did not talk about SDM.

All three reviewers categorized that the 'Alberta Health Services'[88], 'Australian Government'[155], 'Ministry of Health from New Zealand'[165] and Costa Rica 'IHCAI'[162] CPGs and 'CMCCR'[172] CS had the highest overall quality in analysing the decision-making process in BC treatment (Appendix). In the United States of America, we highlighted two of the 'American Society of Clinical Oncology (ASCO)'[140-148] guidelines and the last version of NCCN[153], but with a lower mark if you compare with the ones we named before. In Europe, we found the 'European Society for Medical Oncology (ESMO)'[41], the 'Asociación Española de Cirujanos (AEC)'[80] and the 'ABS-BAPRAS'[118] CPGs with a score of 6 as the best paradigm of a guide that talks about SDM.

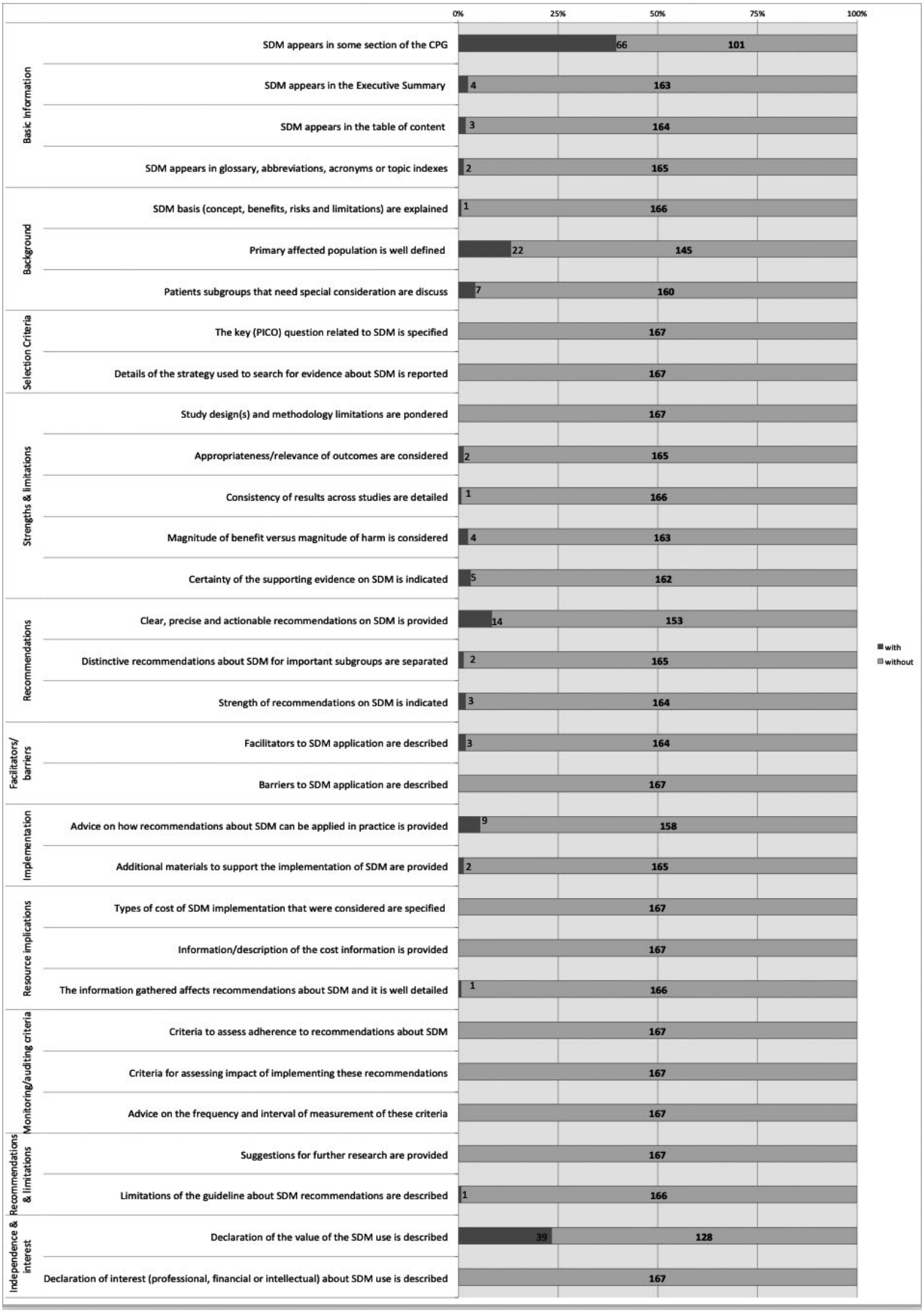

FIGURE 2 The analysis of the compliance of the data extraction items

4 | DISCUSSION

4.1 | Main findings

We developed a standardized quality assessment tool for assessing the coverage of SDM in recommendation documents. Our review and analysis showed that SDM description, clarification and recommendations CPGs and CSs concerning BC treatment were poor, leaving a large scope for improvement in this area. SDM more frequently reported in CPGs and CSs in recent years but surprising SDM was less often covered in medical journals (Figure 3).

4.2 | Strengths and weaknesses

The validity of findings depends on the strength and limitations of methods, which should be understood first before assessing their implications[202]. A key strength of this study was a global perspective with a big number of CPGs and CSs included, without language restrictions or data sources limitations. We developed and deployed a prospective protocol with a specific SDM quality assessment tool incorporating the AGREE II instrument[201], RIGHT statement[200] and other related papers [9,21,24,25,27]. Unfortunately, as there were no other similar studies, we could not compare our results with other findings. There have been evaluations of risk of bias in other papers, but our focus was on examining the reporting of guidance about SDM. One perceived limitation of this study could be related to the subjective nature of the data extraction; however, as we used duplicate data extraction with arbitration, we minimized this methodological issue. Quality assessment tool performance may be a further issue, and we addressed this by following a standard methodology for tool development. Not all quality items can have the same relevance and weight, and future research should focus on scoring them creating a threshold for rating quality. Because the items mainly came from two wide-used indexes[200,201], demonstrably our tool should be considered to have face validity. Therefore, we are confident that our finding of poverty of SDM information in practice recommendations is trustworthy and merits further consideration.

Inter-examiner reliability should be calculated in systematic reviews as the data extracted should be the same by different reviewers[203]. Intra-examiner reliability is a pre-condition for inter-observer reliability, and so was not calculated or reported[31]. In our paper, the inter-examiner reliability score was found to be excellent (ICC = 0.97).

4.3 | Implications

To our knowledge, information and recommendations about SDM in BC CPGs and CSs have not been systematically analysed previously. Neither did we find a tool to evaluate SDM reporting quality. This is surprising because SDM is a legal obligation[11-13] and a key component for high-quality patient-centred cancer care[6-10].

Breast cancer is the paradigm of the situation where a two-way exchange not only of information but also of treatment preferences is needed to find the best option for a particular patient, as different strategies may show a priori similar advantages and disadvantages but possible outcomes are deeply related to the patient's values and personal situation[10,203].

Formal recommendations should promote SDM application in clinical routine practice, but this has proved difficult and slow[18-21,23,24]. It would require changing attitudes, acquiring new skills, developing specific tools and ensuring an environment where communication and sharing perspectives are valued[10,21,25-27]. Effective implementation strategies could be underpinned by SDM detailed in CPGs and CSs as these documents should be expected to provide this specific content[11-13]. Our work has identified a gap that offers an important contribution in directing further research and debate, including assessment of risk of bias in guidelines. It highlights the need for more objective-specific tools for SDM assessment, evaluation of their psychometric properties and promotion in CPGs and

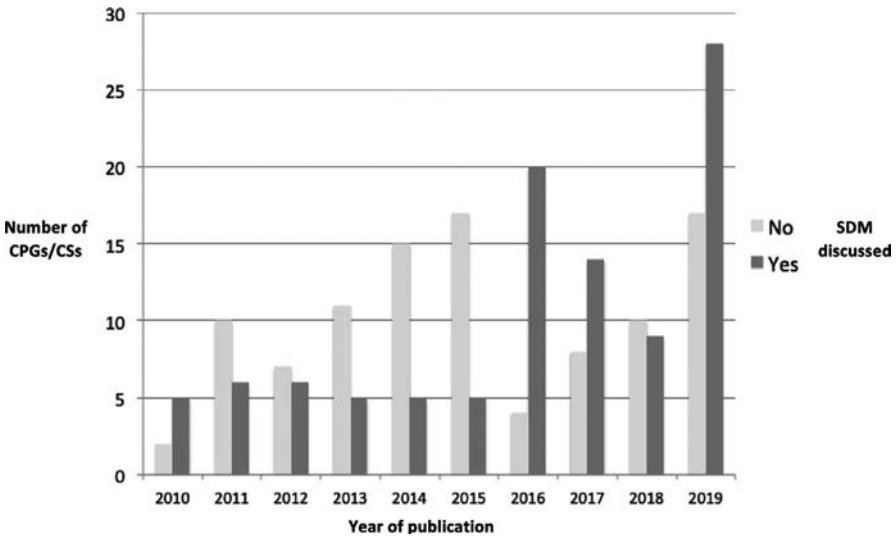

FIGURE 3 Comparison between the year of publication of the guide according to whether or not SDM appearance

CSs for diverse malignancies. Future studies should be required in that direction.

5 | CONCLUSIONS

This systematic review found that BC treatment CPGs and CSs insufficiently addressed SDM. Implementation of this practice is important for high-quality patient-centred cancer care, but lack of knowledge is a known barrier. SDM descriptions and recommendations in CPGs and CSs concerning BC treatment need improvement. SDM was more frequently reported in CPGs and CSs in recent years, but surprisingly it was less often covered in medical journals, a feature that needs attention. In the future, SDM should be suitably explained and encouraged and specific tools should be applied to assess its dealing and promotion in specific cancer treatment CPGs and CSs. Medical journals should play a strong role in promoting SDM in CPGs and CSs they publish in the future.

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CONFLICTS OF INTEREST

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

AUTHOR CONTRIBUTIONS

Each author certifies that he/she has made a direct and substantial contribution to the conception and design of the study, development of the search strategy, the establishment of the inclusion and exclusion criteria, data extraction, analysis and interpretation. MMC was involved in the design of the study, literature search, data collection and analysis, quality appraisal and writing. IMMN was involved in the literature search and data collection. MMD was involved in the design of this study, analysis of data and writing. LM was involved in writing. KSK was involved in the design of this study, conducted the quality appraisal, in the writing, and provided critical revision of the paper. ABC was involved in the design of this study and provided critical revision of the paper. All authors read and provided the final approval of the version to be published.

DATA AVAILABILITY STATEMENT

The authors confirm that the data supporting the findings of this study are available within the article and its supplementary materials.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.

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DISCUSION

4. **DISCUSION**

This Doctoral Thesis has allowed the study of a topic that had not been addressed before: SDM as an indicator of quality in BC management care. We have analysed the quality of healthcare by studying the integrated breast cancer care process QIs, and examining the use of SDM by healthcare professionals nowadays and the quality and reporting in BC guidance documents and spreading its concept among health professionals. The research done has allowed obtaining results presented in each of the publications that make up this work, specifically:

1. To review current studies on SDM and investigate the principal facilitators and barriers, and the strategies propounded by the distinct authors for its execution.

2. To analyse and compare the BC QIs, measure tools and compliance standards of care.

3. To study the integrated breast cancer care process QIs for BC management, identify areas for amelioration, and systematically compare the different Integrating Breast Cancer Care Process of each area of Spain and propose improvement measures.

4. To study the level of understanding, attitude, and degree of use of SDM in BC management by health professionals.

5. To analyse the quality and reporting of CPGs and CSs on BC management (screening and treatment).

6. To carry out a systematic review on the quality and the reporting of SDM in BC management (screening and treatment) CPGs and CSs.

The results obtained in each paper were discussed individually. In this section, the main findings, strengths and limitations will be highlighted. Finally, we will assess the results' practical utility, and explore the new possible research lines.

7.1. Main findings

The most remarkable results that have been obtained are summarised schematically below.

The greater BC therapeutic complexity requires an improvement in care quality management. Clinical pathways or integrated breast cancer assistance processes have been deployed to manage and standardise care. These include a series of QIs for continuous improvement via maintenance of sociodemographic, clinical and healthcare databases. With an emphasis on patient-centred care, the use of SDM should be considered a key indicator in care quality management. Our systematic reviews about International and Spanish integrated health care processes and clinical pathways have shown that no studies that compare QIs for BC care management suggested. The vast majority of QIs identified were process QIs (over three-quarters), and these were also found in more documents. They covered all the BC care management phases from diagnosis, treatment, and staging, counselling, follow-up, and rehabilitation. QIs description was heterogeneous, with not a single identical indicator appearing in all the documents analysed. More than a quarter of the QIs of the process and outcome did not state a standard. Our review did not find QIs about patient satisfaction or Primary Care and SDM was poorly treated.

Furthermore, evaluating these QIs is considered essential for adequate control of the process, identifying areas for amelioration and providing possible solutions and improvement plans based on objective data. Not all indicators are equally profitable. Some depend on the resources available and others on the mix of patients or the use of complementary treatments. It is essential to identify specific target populations for estimating the indicator or provide standards stratified by the variables that influence them.

Regarding SDM, most health care professionals know about it, but its practice is not adequate due to the scarcity of resources. Most of them agree on the necessity of policies that improve SDM implementation. The main advantage pointing out by participants was patient satisfaction,

and the main disadvantage was the patients' lack of knowledge to understand their disease. The main obstacle settled was the lack of time and resources. Professionals should be formed in the use of SDM, and more resources and time should be given to make it into practice.

In this Doctoral Thesis, we appraised the quality and reporting of CPGs and CSs BC screening and treatment. Screening guidances had lower quality and reporting than treatment CPGs and CSs. This quality and reporting will improve if systematic reviews are used to underpin the recommendations made.

Finally, the quality and reporting of SDM in BC screening and treatment guidance documents were also poor. SDM was more frequently reported in CPGs and CSs in recent years, but surprisingly it was less often covered in those published in medical journals. It is urgent to promote SDM in BC screening guidance documents issued by institutions, professional associations, and medical journals.

7.2. The Doctoral Thesis limitations

The validity of findings depends on the methods strength and limitations, so they should be understood first before assessing their implications (142). Very different works have been exhibited in this Doctoral Thesis. This document has limitations inherent to each of the several studies. These limitations must be faced to interpret the results correctly and to design strategies to overcome them.

Regarding the evaluation of the QIs, there have been many initiatives to recommend and implement BC QIs´ use and utility, showing its use improves the results (19, 143, 144). It was a difficult decision on which indicators to choose for analysing the study population. While there are basic indicators that almost all Organisations recognise, others vary. In our work, specifically in manuscripts 2 and 3, we studied and compared the clinical pathways and integrated breast cancer care processes regarding the BC QIs. Most of these quality care documents were not formally published in scientific journals or 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). More additional initiatives were searched in the identified publications´ bibliographies to include other essential studies to our review. Therefore, some of these manuals may not have been found due to the difficult search. Moreover, 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. The reviewer agreement (ICC) was excellent, with more than 90%.

In manuscript 4, we have analysed the BC QIs in clinical practice. We have chosen that set of QIs that we believe could best suit our health area. For this reason, as the study was based on Andalusia´s population, our team chose indicators of this Southern Autonomous Community for the analysis. The estimation of these indicators was based on a prospective registry, maintained thanks to the voluntary and willful dedication of two of the service professionals. Even so, there was a significant amount of missing information, which we tried to alleviate through exhaustive reviews of medical records. Although part of the information necessary for the calculation of the indicators could be contemplated in the "minimum basic set of hospital data", most of it required an exhaustive review of the clinical history that consumes an excessive time, which reduced the validity of the indicators. The modernisation of the information systems is necessary so that the

collection of the variables required for the elaborating QIs is automated so that they can be obtained and compared in an agile, automatic and reliable way (62).

For manuscript 5 and 6, we used an ad hoc questionnaire was used. The main limitation in the document derived from the participants' selection bias, implicit in an online survey, which very possibly favours the participation of professionals pro SDM. It was impossible to estimate the presumably low response rate because of the open distribution of the survey.(145) However, participation and completion rates have been calculated and are both high, suggesting recognition of the importance of this issue to quality health practice today. The possible existence of a selection bias in this study further reinforces the results obtained: even among those professionals most likely to use SDM, there is a lack of training, and in particular of time and resources. Moreover, we followed the CHERRIES checklist, which allows a high-quality description of the research results from surveys of web environments.(134, 135)

Regarding the evaluation of quality and reporting of the guidance documents (manuscripts 7 and 8), a limitation of these two reviews could be the subjective nature of data extraction concerning quality (AGREE II) (66, 67) and reporting (RIGHT) (69) items. We minimised this issue by using two experienced BC specialist clinicians who studied the assessment tool manuals and set up a standard comprehension of the grading procedure before the duplicate analysis was undertaken. Where concerns about significant deviations arose, we used reviewer consensus backed by an independent arbitration. It was reassuring to note that the ICC was excellent, with more than 90%.

There is a known limitation: the lack of clear rules about the weighting of domains and items in the quality and reporting scoring manuals (146). Although RIGHT (69) statement recommends against deriving a score from the checklist (the items may not be equally weighted, and scores have been shown to be problematic in research synthesis), we found it useful for comparing CPGs and CSs. It also facilitated the comparison of quality with reporting. The AGREE II Consortium (67)

and RIGHT team (69) have not preset the thresholds to differentiate between high, moderate, and low quality and reporting. We used previously reported limits (147, 148) to set the cut-offs for our analyses a priori. We would recommend caution in interpretation as global scores may vary among recommended guides since the domains do not weigh equally in their contribution towards overall quality and reporting.

As we studied from 2017 until the year of our manuscripts´ publication, we are aware that guidance documents outside our time range from reputable organisations would have been excluded. A recent systematic review revealed that updates should be done in less than three years, supporting the choice of our search time threshold (59). Even though we only included CPGs and CSs, which met all the inclusion criteria, there was diversity between CPGs and CSs included in our review. This heterogeneity is in itself an important observation that merits consideration as a limitation of the existing CPGs and CSs. However, this type of heterogeneity may be unavoidable as the guidances differ in their development, structure, context and endpoint definitions according to target users, patients and clinicians (149). Therefore, considering the strengths of our review, the deficient quality, reporting of the guidance documents, the lack of systematic reviews for the synthesis of evidence, and the almost non-existent following of quality and reporting improvement tools during their writing are powerful observations.

Finally, for the evaluation of quality and reporting of SDM in the BC guidances (manuscripts 9 and 10), no instrument for measure SDM quality and reporting was found, so we developed and deployed a prospective protocol with a specific SDM quality assessment tool incorporating the AGREE II instrument (67), RIGHT statement (69) and other related papers (27, 77, 103, 114, 122). Unfortunately, as there were no other similar studies to manuscripts 7 and 8, we could not compare our results with other findings. There have been evaluations of the risk of bias in other papers, but our focus was on examining the reporting of guidance about SDM. One perceived limitation of this study could be related to the data extraction´s subjective nature; however, as we used duplicate data extraction with arbitration, we minimised this methodological issue.

Furthermore, the reviewer agreement was excellent (ICC> 95%) in both papers, indicating strong results.

Quality assessment tool performance may be a further issue, and we addressed this by following a standard methodology for tool development. We were aware that not all quality items could have the same relevance and weight, and future research should focus on scoring them, creating a threshold for rating quality. Because the items mainly came from two wide-used indexes (67, 69), demonstrably, our tool should be considered to have face validity. Therefore, we are confident that our finding of poverty of SDM information in practice recommendations is trustworthy and merits further consideration.

7.3. Practical usefulness of the results obtained

From the findings collected in the previous sections, some useful proposals could be made.

Our work provides the first current and comprehensive overview of QIs in BC care. We have carried out an extensive search of all the available indicators, highlighting relevant differences between the quality manuals analysed. The use of quality indicators could be extended to all BC care management stages, allowing monitoring processes' evolution over time and could be compared with other centres (26, 144, 150-154). Although several QIs have been proposed to harmonise BC care quality management's evaluation, there is still no consensus between countries (155). 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.

In addition to conferring control of the sanitary activity done in an area, the estimation of quality indicators allows a detailed evaluation of the process. This is a significant advantage when proposing lines of improvement. Besides, we have verified that not all indicators are equally useful. Some depend on the available resources and must be valued according to them, the mix

of patients, or the use of complementary treatments. Therefore, it is necessary to identify the populations that intervene in calculating the indicator or providing standards stratified by the variables that influence them. In the future, the availability of data from other hospitals will allow us to compare our results and show improvement strategies.

On the other hand, our work has shown that healthcare professionals who care for BC patients have extensive knowledge about SDM. However, they indicate that its use is limited due to the scarcity of time, resources, and professionals´ training. In this way, the Health Authorities have been highlighted as the main future promotor for implementing SDM in cancer care.

Furthermore, we have found that the CPGs and CSs for both treatment and screening have low quality and reporting. A large part of these guidances does not meet the minimum standard. We observe that the quality and the report would improve if SR were used in its preparation. Efforts should be made to follow well-known tools as AGREE II and RIGHT that allow increasing their development rigour.

Finally, we have observed that the quality and reporting on SDM in the BC guidance documents is practically non-existent, and they need to improve their recommendations. Our work team has had to develop and validate a specific tool for quality analysis and reporting in SDM guides since we have not found any. Indeed, SDM is more frequently reported in recent years but surprisingly appears less in medical journals. In the future, medical journals should play a crucial role in promoting SDM in guidance documents and in general. New tools should be developed to encourage and measure their application. All this will allow more and more health professionals to become aware of the vital importance of offering a process of SDM to the patient with cancer.

7.4. Future research strategies

Undoubtedly, the Doctoral Thesis results answer some questions and open new and more complex queries, which invite us to continue deepening in this research line.

It would be interesting to carry out a more comprehensive systematic review. We have only analyzed the indicators collected in North America and Europe. Future research should add the indicators developed in the other continents and suggest which would be the basic indicators that should be fulfilled and those that could be added according to the characteristics of the study population. A study of such disparate populations would allow a much broader understanding of them. Future studies and a reach of consensus in this vital matter would be highly recommended and merit urgent consideration.

It would also be useful to be able to do a multicenter study of the long-term compliance of the QIs and suggest improving and applying them to study the evolution of each indicator and compliance standard of care. It would also be observed if the intervention was effective.

On the other hand, another suggestion for future research could be studying the knowledge, current and future use of SDM in the rest of the continents, thus providing more excellent knowledge and comparing its use according to cultures and technological development of the area.

Nowadays, there is a lack of clear rules on the domain and item weighting in scoring tool manuals (146). The RIGHT statement (69) avoids obtaining an average score in each guidance since it is not clear that the items could be equally weighted, and a resume score could reduce the quality of the analysis. There are no thresholds to classify high, moderate, and low quality and reporting in the manuals, which would be useful for comparing documents. However, we have used formerly published cut-offs (61, 147, 148) for more straightforward and powerful analysis. Our review was not centred on this; instead, it was focused on studying quality and reporting about SDM. Subsequent investigations and research should direct the study in rating quality.

Finally, the paucity of information about SDM in BC screening CPGs and CSs deserved to have special consideration. It is not reasonable to expect that the application of SDM will be prioritized in clinical practice if it is not considered a primary element in the reference CPGs and CSs,

including clear indications for its implementation. Our findings helped to highlight this weak point, and it made us remark which merits urgent attention.

CONCLUSIONS

5. CONCLUSIONS

Globally, the Thesis results suggest that breast cancer (BC) health care and the quality indicators (QIs) used to measure it could be improved in various ways. One of the most important would be the active involvement of patients through procedures such as shared decision making (SDM). Despite the fact that the SDM concept is known and accepted, there are not enough resources or support for its practical application. Furthermore, SDM is scarcely contemplated in clinical practice guidelines (CPGs) and consensus (CSs), although this is vital for a correct implementation in daily clinical practice.

The Doctoral Thesis specific objectives addressed allowed us to conclude:

1. The main purpose of SDM is to respect the patient's autonomy without detriment to their benefit, providing quality care following their values and preferences. The practice of SDM in cancer care has been proposed as a crucial element to achieving a system in crisis towards excellence and sustainability. It implies the development of multidisciplinary teams with a high scientific-technical level, excellent coordination, continuity of care and communication with the patient, and a permanent review of the results within the framework of a continuous improvement program. Nowadays, most patients do not probably want or do not know how to participate very actively in the decision-making process. It is a very demanding path as it requires resources and time. However, health professionals have the duty of developing a health system capable of offering this possibility without reducing quality and efficiency.

2. There is no established set of QIs to harmonise BC care quality assessment. So, the comparison between studies has been usually difficult, reducing the possibility of establishing conclusions that could be extrapolated. Furthermore, some of the integrated breast cancer assistance processes or clinical pathways did not indicate standards of care for compliance, a starting point to study how to improve quality. The standard of each indicator obtained a great variability depending on the document analysed. No QIs

specifically related to patient satisfaction or Primary Care were found in our study. SDM as a QI was poorly addressed and demanded improvement. A consensual set of BC care QIs is needed. Nowadays, there is a vast space for improvement, and future studies should pay attention to these issues.

3. The integrated breast cancer care process and clinical pathways QIs' analysis allowed evaluating their compliance and studying the variables that influence proposed improvement measures. Not all indicators are equally useful. Some depend on the resources available and others on the mix of patients or the use of complementary treatments. It is essential to identify specific target populations for estimating the indicator or provide standards stratified by the variables that influence them.

4. Although the professionals involved in treating BC have a high level of knowledge and a very positive attitude towards SDM, its use is limited. New policies must be designed for adequate training of professionals on integrating the SDM in clinical practice. Professionals should be helped to feel prepared to use SDM, and more resources and time should be given to make it into practice.

5. CPGs and CSs for BC screening and treatment insufficiently followed quality and reporting assessment tools such as AGREE II statement and RIGHT instrument. In screening, CPGs and CSs suffered low quality and reporting as more than half did not reach the minimum standards. In general, they exhibit a slightly worse quality and a significantly lower score for reporting than BC treatment guidances. In the future, CPGs and CSs should take AGREE II and RIGHT into account to produce high-quality guidance documents underpinned by systematic reviews to ensure that recommendations are trustworthy. Focus on rigour in guidance development and practical advice concerning the application of recommendations in the clinical setting is required to implement evidence-based medicine to improve health outcomes.

6. SDM was inadequately emphasised in BC screening and treatment guidance documents. Implementation of this practice is important for high-quality patient-centred cancer care, lack of knowledge is a known barrier, moreover, lack of emphasis is a bigger one. SDM descriptions and recommendations in CPGs and CSs concerning BC management is crucial to prioritise SDM into practice, but it needs improvement. SDM was more frequently reported in CPGs and CSs in recent years, but it is less covered in medical journal published guidance documents, and these probably are which have more diffusion and impact. In the future, SDM should be suitably explained and encouraged, and specific tools should be applied to assess its dealing and promotion in specific cancer treatment CPGs and CSs. Medical journals should play a decisive role in promoting SDM in CPGs and CSs they publish in the future.

ABBREVIATIONS

6. **ABBREVIATIONS**

ABS: Association of breast surgery, AB: American Brachytherapy Society, ABSI: Association of Breast Surgeons of India, ACOG: The American College of Obstetricians and Gynecologists, ACP: the American College of Physicians, ACR: The American College of Radiology, ACS: The American Cancer Society, AEC: Asociación Española de Cirugía (Spanish Association of Surgeons), AGO: Arbeitsgemeinschaft Gynäkologische Onkologie, AHS: Alberta Health Services, AMAR: Asociación de Mastología de Rosario (Rosario Mastology Association), ASCO: American Society of Clinical Oncology, ASTRO: American Society for Therapeutic Radiology and Oncology, ASPS: American Society of Plastic Surgeons, ASBS: The American Society of Breast Surgeons, AOR: Asociación de Oncología de Rosario (Rosario Oncology Association), BAPRAS: British Association of Plastic, Reconstructive and Aesthetic Surgeons, BCMA: British Columbia Medical Association, BC: breast cancer, BCRDI: the Brazilian College of Radiology and Diagnostic Imaging, BCT: breast conserving therapy, BFGOA: Brazilian Federation of Gynecological and Obstetrical Associations, CACA: China Anti-Cancer Association, CADTH: Canadian Agency for Drugs and Technologies in Health, CCO: Cancer Care Ontario, CCM: CancerCare Manitoba, CECM: Chinese expert consensus meeting, CMH: Chinese Ministry of Health, CMCCR: Colegio de Médicos y Cirujanos de Costa Rica, CNDO: Coordenação Nacional das Doenças Oncológicas, CTF: Canadian Task Force, CPGs: clinical practice guidelines, CSs: Consensus, DPRS: Department of Plastic and Reconstructive Surgery, DDSS: Dirección de desarrollo de Servicio de Salud; ESMO: European Society for Medical Oncology, ESO: European School of Oncology, ESTRO: European society radiation oncology, EUSOMA: European Society of Breast Cancer Specialists, FESEO: Federación de Sociedades Españolas de Oncología, DEGRO: German Society of Radiation Oncology, HIS : Healthcare improvement Scotland, ICON: Indian Cooperative Oncology Network, IETS: Instituto de Evaluación Tecnológica en Salud, ICC: intraclass coefficient, IHCAI: International Health Central America Institution; ICMR: Indian Council of Medical Research, INC: Instituto Nacional de Colombia, IKNL: Integraal Kankercentrum Nederland (Netherlands comprehensive cancer

organisation), IEP: International expert panel, INC: Instituto Nacional de Cancerología, INCJA: Instituto Nacional de Cáncer José Alencar Gomes da Silva, JBCS: Japanese Breast Cancer Society, JGBSA: Joint Guidelines from British Surgical Associations, KCE: Belgian healthcare knowledge centre, LOEGP: Lithuanian oncologist, encrinologist and GP, MSC: Ministerio de Salud de Chile, MHNZ: Ministry of Health from New Zealand, MHM: Ministry of Health Malaysia; MDT: multidisciplinary team meeting, MRI: magnetic resonance imaging, NANDA: North American Nursing Diagnosis Association, NS: not specified, NCA: Breast Expert Advisory Group/ Northern Cancer Alliance, NCCP: National Cancer Control Programme, NCRCC: National Clinical Research Center for Cancer, NEJM: The New England Journal of Medicine, NHCPRC: National Health Commission of the People's Republic of China, NHS: National Health Service, NICE: National Institute for Health and Care Excellent, PDPCM: Programs for the Early Detection of Breast Cancer, PhD: Doctor Philosophiae/related to a Doctoral Thesis; PHE: Public Health England, PRISMA: preferred reporting items for systematic reviews and meta-analyses, PST: primary systemic treatment, QIs: quality indicators, RCR: The Royal College of Radiologists, RCSG: Regionalt cancercentrum Stockholm Gotland, RCTs: Randomized clinical trials, RT: radiotherapy, SAM: Asociación Argentina de Mastología (Argentine Society of Mastology); SACPER: Sociedad Argentina de Cirugía Plástica, Estética y Reparadora (Argentine Society of Plastic, Aesthetic and Reconstructive Surgery); SAV: Sociedad Anticancerosa de Venezuela, Singapore Cancer Network: SCAN; SCT: Scottish Cancer Taskforce, shared decision making: SDM; SEAP: Sociedad Española de Anatomía Patológica, SEDIM: Sociedad Española de Diagnóstico por Imagen de la Mama, SEGO: Sociedad Española de Ginecología y Obstetricia, SEMNIM: Sociedad Española de Medicina Nuclear e Imagen Molecular, SEOM: Sociedad Española de Oncologia Médica, SEOR: Sociedad Española de Oncología Radioterápica, SESPM: Sociedad Española de Senología y Patología Mamaria (Spanish Society of Senology and Breast Pathology), SIGN; National Cancer Quality Steering Group Scottish Intercollegiate Guidelines Network, SSM: Secretaría de Salud de México, SLNB: sentinel lymph node biopsy, SR systematic review, SSM: Secretaría de Salud de México,

UHW: University Hospital of Würzburg, WMCA: West Midlands Expert Advisory Group for Breast Cancer.

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APPENDIX

APPENDIX 1: Resume for inclusion in the database for Doctoral Thesis (TESEO)

La creciente complejidad terapéutica del cáncer de mama (CM) exige mejorar la calidad asistencial para su manejo. Se deben incorporar sistemas de información para la autoevaluación y mejora de la atención del paciente. No hay consenso, por lo que muchas administraciones y asociaciones sanitarias competentes en el tema han desarrollado diferentes Vías Clínicas o Procesos Asistenciales Integrados del Cáncer de Mama específicos con sus propios indicadores de calidad (ICs). La práctica de la toma de decisiones compartida (TDC), un enfoque en el médico apoya al paciente para que considere opciones y decida en función de sus preferencias y valores, debería considerarse uno de estos ICs. Adquiere relevancia en el CM ya que existen diferentes opciones de tratamiento equiparables, pero que pueden producir resultados muy diferentes según deseos y creencias. Por lo tanto, los objetivos de esta Tesis fueron: i) Realizar una revisión de los estudios actuales sobre la TDC, explorando los principales facilitadores y barreras y las diferentes estrategias propuestas para su implementación (manuscrito 1). ii) Explorar los indicadores de calidad del CM en España y compararlos con los de la Sociedad Científica Europea (manuscrito 2). iii) Estudiar los ICs en España y compararlos con los de Europa (manuscrito 3). iv) Realizar una evaluación crítica de los ICs para el diagnóstico y tratamiento de CM. (manuscrito 4). v) Estudiar el conocimiento, actitud y uso de la TDC en el CM por parte de los profesionales sanitarios (manuscrito 5). vi) Dar a conocer a un público hispano parlante los resultados sobre el conocimiento, uso y actitud ante la TDC en profesionales sanitarios especialistas en CM (manuscrito 6). vii) Analizar la calidad general y el reporte de las guías de práctica clínica (GPCs) y documentos de consensos (DCs) sobre el cribado del CM (manuscrito 7). viii) Estudiar la calidad y reporte de las GPCs y DCs del tratamiento del CM (manuscrito 8). ix) Revisar sistemáticamente la calidad y reporte de la TDC sobre las GPCs y los DCs de cribado del CM (manuscrito 9). x) Analizar la calidad y reporte del SDM en las GPCs y DCs de tratamiento de CM (manuscrito 10). Para el primer objetivo, se realizó una revisión general de la literatura sobre la TDC. Para el segundo y tercero, se hizo una revisión sistemática de los ICs a nivel internacional (manuscrito 2)

y de diferentes Comunidades Autónomas españolas (manuscrito 3). Para el cuarto, se realizó un estudio prospectivo observacional para el análisis de ICs sobre una serie de casos consecutivos de BC durante cinco años de un área sanitaria. El quintoy sexto objetivo requirieron un estudio observacional transversal (cuestionario online anónimo) para investigar el conocimiento, actitud y aplicación actual y futura de la TDC en especialistas del BC. Finalmente, para el resto de los objetivos propuestos, se han aplicado revisiones sistemáticas. Para el análisis de la calidad y reporte en general de los documentos guía se utilizaron dos herramientas validadas reconocidas: AGREE II y RIGHT respectivamente mientras que para el estudio de la calidad y reporte de la TDC se desarrolló una herramienta por consenso. Nuestros resultados muestran que los profesionales del CM tienen un alto nivel de conocimiento y una actitud muy positiva sobre la TDC, aunque su aplicación es limitada. El principal obstáculo fue la falta de tiempo y se concluyó que las administraciones sanitarias deberían facilitar la formación, el material y los recursos necesarios para lograr una aplicación eficaz. Se realizó una revisión de la utilidad de estos ICs para la mejora del Proceso Asistencial Integrado Cáncer de Mama, proponiendo medidas de mejora. También se verificó que más de la mitad de los documentos guía en BC no cumplieron con los estándares mínimos de calidad y reporte. Nuestro estudio sugirió que el uso de revisiones sistemáticas mejoraría la calidad y el reporte de las recomendaciones, que, aunque ha mejorado, necesita seguir progresando. En conclusión, la atención sanitaria del CM y los ICs utilizados para medirla podrían mejorarse mediante la participación de los pacientes a través de procedimientos como la TDC, sin suficientes recursos para su aplicación y escasamente contemplada en las GPCs y en las DCs.