

# Development of Quality Indicators in the Management of Breast Cancer: A Systematic Review

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## Research Article

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## Abstract

## Background

Breast cancer is one of the leading causes of cancer-related death. Current evidence suggests a gap between what is understood to be standard breast cancer management and what happens in clinical practice. The development and implementation of breast quality indicators (QIs) for breast cancer management is one way to achieve better care. This systematic review aimed to identify QIs developed for the management of breast cancer and to summarize characteristics and range of measures uncovered.

## Methods

Studies related to the development of QIs for management and monitoring of breast cancer care were systematically searched, extracted and reviewed using four electronic databases (MEDLINE, EMBASE, CINAHL and Cochrane Library) following a Prospero Protocol Registration (CRD42020207945). The study was reported using the Preferred Reporting Items for the Systematic Review and Meta-analysis (PRISMA). This review reported on the development of QIs in the management of breast cancer and Donabedian's framework was adopted as the analytical framework.

## Results

Out of 1161 potentially relevant articles identified, eight studies met the inclusion criteria and were directly concerned with QI development for breast cancer care. These included two papers from China and one each from; The Netherlands, Belgium, Scotland and Canada. The remaining two were a collaboration among the European Society of Breast cancer Specialists (EUSOMA). The methods used by these studies to identify and develop QIs included a comprehensive literature review, medical records review, clinical guidelines, and Delphi consensus using an expert panel discussion. A total of 38 QIs were identified and classified as: structure (n = 3); process (n = 30); and outcome (n = 5). Structure indicators included: the availability of Multi-Disciplinary Team Meeting (MDT), medical records and breast cancer research infrastructure. Process indicators included eight diagnostic QIs, 22 treatment QIs and seven follow-up QIs. The outcome indicator focused mainly on the overall five-year survival statistics.

## Conclusions

The development of QIs appears relevant to monitor clinical management and performance but is currently limited to higher income countries. Development and implementation of QIs in LMICs countries will improve practice.

## Background

Breast cancer is one of the most common cancers affecting women and is a leading cause of cancer-related deaths worldwide (1, 3). Despite the high incidence and mortality related to breast cancer, there has been some improvement in care and survival due to the development of new treatments (2). A collaborative multidisciplinary approach aimed at minimizing recurrence, and reducing treatment-associated morbidity and limiting mortality is essential (4). However, the intended treatment is frequently not achieved as many errors of both commission and omission by health professionals can occur that are often overlooked (5). There is evidence suggesting that the development and implementation of quality indicators (QIs) may help close the gap between the realities of clinical practice and desired standard of breast cancer care (6).

High-quality evidence has been produced in many studies of breast cancer that must be incorporated into practice to ensure improvement in care (7). Quality indicators (QIs) can be developed systematically and used as a measurement tool for breast cancer care management (8) but quality measurement in cancer is generally challenging to achieve. Wasif and colleagues define the quality of cancer care as the overall management of cancer (9). Additionally, Birkmeyer and team proposed that quality of care can be divided into three distinct areas of structure, process, and outcome (10). The structure is described as the measurable institutional characteristics which comprise the staff or professional-patients ratio, the number of hospital beds, and other infrastructure (9, 10). Birkmeyer and team defined process indicators as the actual characteristics of care delivered by providers, while outcome indicators describe the metrics commonly represented as mortality and morbidity (10). Quality cancer care, therefore, comprises the entire pathway of process, structure, and outcome events. The National Initiative for Cancer Care Quality (NICCCQ) was started by the American Society of Clinical Oncology (ASCO) in 2000 for the efficient evaluation of quality care (7). Existing diagnostic and treatment guidelines and protocols can be evaluated together with QIs to measure the extent to which practice conforms to the established indicators in order to guide future improvement. A recent publication reveals more countries are now requiring an established clinical pathway for breast cancer care to achieve quality and excellence of care (11).

Using QIs for quality assessment represents an important approach to documenting the quality of care (12). The aim of this systematic review was to identify QIs developed for the management of breast cancer and to summarize their characteristics. This was done to inform the development if

QIs in a country where these are not currently in use.

## Methods

This systematic review is reported in accordance with the Preferred Reporting items for the Systematic review and Meta-analysis (PRISMA) statement. The protocol for this review was registered with PROSPERO (CRD42020207945).

### Sources of information

Four electronic databases were searched, namely: MEDLINE, EMBASE, CINAHL and The Cochrane Library. In addition, a manual search of the reference lists of included studies was performed.

### Search strategy

Databases were searched from December 2020 to May 2021 and subsequently updated in December 2021. The search strategy included terms related to breast cancer, quality indicators care, and management. Medical subject headings, keywords and free text terms were combined using "AND" or "OR" Boolean operators. The initial search strategy was developed using MEDLINE and was slightly adapted for the other databases (Appendices 2, 3 & 4).

### Study selection

Two authors (VD and AD) independently screened titles and abstracts of all citations retrieved for inclusion in the review. A third reviewer (PA) was available to independently screen articles where there was a discrepancy. Studies were excluded if they did not meet the pre-determined inclusion criteria. Discrepancies were resolved through discussion to achieve consensus. Full texts of all studies included during the title and abstract screening were obtained.

### Eligibility criteria

This review included studies published in English within peer-reviewed journals, conducted in any country and that reported on the development of QIs in the management of breast cancer. Letters, comments, editorials, opinion pieces and studies in languages other than English were excluded.

### Data extraction and quality assessment

Full-text data extraction was performed by three authors (VD, AD and PA) using an electronic data extraction form developed for the study. The extracted data was subsequently reviewed, and disagreements were resolved through discussion to achieve consensus. The data extracted included general information such as study eligibility, setting, study aim, design, and data collection, the number of indicators, results, and conclusion. The study findings on the developed QIs was extracted and classified using Donabedian's framework based on structure, process, and outcome indicators. Again the two reviewers (VD and AD) independently assessed the quality of the included studies according to the appropriate Joanna Briggs Institute (JBI) Critical Appraisal Checklist for quantitative studies. JBI appraisal enabled the assessment of the methodological quality of the study and helped to determine the extent of possible bias in its design, conduct and analysis (13). Discrepancies among the reviewers were resolved by a third reviewer (PA) through discussion to avoid the risk of bias.

### Data analysis and synthesis

Donabedian's framework was adopted as the analytical framework for this review. This approach considers three components for evaluating the quality of care; including the structure, process and outcomes which are interrelated and suitable for effective measurement (15, 29). The individual studies had different methodologies and analytic approaches (systematic and non-systematic) in the development of the indicators. Due to the heterogeneity of the studies, a meta-analysis was not feasible, and a narrative analysis of the data was therefore conducted.

## Results

The electronic database searches resulted in 1158 potentially relevant articles with three articles identified through the search of the reference lists for a total of 1161 articles. After duplicates were excluded (266 articles), title and abstract screening by the team yielded 101 possible articles and therefore 101 full-text articles were finally screened for eligibility. There were 93 articles excluded for the following reasons: adherence to rather than the development of QI measures (69), breast cancer management guidelines (16), indicator measure for other cancer types and incomplete information (4), non-cancers (3) and non-English articles (1). A total of eight articles were included in the final review (see Figure 1).

[Insert Figure1]

### Characteristics of included studies

The main characteristics of the studies included are presented in Table 1a. The supplementary Table 1b briefly describes the main methodological approaches utilized. Studies included consisted of two papers from China and one each from the Netherlands, Belgium, Scotland, and Canada. The further two emanated from a collaboration between the European Society of Breast Cancer Specialists (EUSOMA). Of note is that one paper was an update on an earlier publication. It was agreed through consensus to include both versions to identify the updated information and any other relevant characteristics of the studies. Most of the studies included used a combination of literature review and consensus, such as the Delphi consensus methods to create the final set of QIs. Two of the studies focused on assessing care for patients with invasive breast cancer or ductile carcinoma in-situ (DCIS) (16,17) whilst one study focused on QIs for vulnerable elderly patients with breast cancer (18).

**[Insert Table 1a and 1b]**

### **Quality indicators**

The QIs developed ranged from eight (17) to thirty-two (16) items within the studies reviewed. Overall, a total of 38 QIs were identified and summarized (Appendix 1) which were classified as: structure (n = 3); process (n = 30); and outcome (n = 5) (see Figure 2).

### **Structure indicators for breast cancer care**

Seven studies reported on structure indicators for breast cancer care. These included: the availability of multidisciplinary team (MDT) meetings (8,18,19-23); information system and medical records for documentation (18); and breast cancer research infrastructure (20).

### **Process indicators for breast cancer care**

Most of the QIs identified were process-related (30 QIs). These were classified under three domains: diagnosis (8), treatment (15), and follow-up (7) (Figure 2)

### **Outcome indicators for breast cancer care**

The outcome indicators for breast cancer was reported by three studies (8,20,21). This indicator was focused on the overall five-year survival of breast cancer, 5-year survival by stage, disease-free 5year survival by stage, 5-year local recurrence rate after curative surgery and 5-year survival for BC presenting symptomatically.

**[Insert Figure 2]**

### **Diagnostic QIs for breast cancer care**

A total of 8 QIs were identified and classified as relating to diagnosis including medical imaging (mammography/MRI/USG – 4QIs) and medical laboratory (histopathology/ cytology – 4QIs). Medical imaging diagnosis indicators emerged in all studies except in the study conducted by Bao and team (8). The diagnostic indicators focused on the assessment of breast cancer patients and the completeness of clinical and imaging diagnostic workup using mammogram, ultrasound, physical examination, breast MRI (16-22). The other three indicators included: the complete evaluation of comorbid illness and overall performance status (18), the performance of a bone scan to detect locally invasive early breast cancer (18) and radiological reporting using BI-RADS classification (16).

One of the studies reported all four QIs related to histopathology and cytology (8). Seven studies focused on the completeness of prognostic or predictive characterization involving the performance of human epidermal growth factor receptor 2 (HERS 2), Oestrogen (ER), Progesterone receptor status (PgR) testing histological type, grading, pathological stage, tumor size and margins (8,16,18-22). The evaluation of pathology report status for a surgical margins indicator was identified in two studies (8,20) whilst the evaluation of the number of breast lymph nodes and axillary lymph nodes dissected and staging indicators were identified in four studies (8,19,20,22).

### **Treatment QIs for breast cancer care**

The treatment domains identified within the review included radiotherapy, systemic therapy, and surgery. Overall, 15 QIs were identified constituting radiotherapy (4), systemic therapy (5) and surgery (6) respectively.

### **Surgery**

Breast cancer surgical indicators covered a wide range of surgical procedures including sentinel lymph node biopsy (SLNB), mastectomy and lumpectomy. Surgical indicators emerged from seven out of the eight studies. Patients undergoing conserving surgery for DCIS or early-stage invasive disease emerged as an indicator from seven studies (16–22). The four QIs concerning mastectomy emerged in all the studies whilst lumpectomy indicators were identified in two (17,18).

### **Systemic therapy**

There were five systematic therapy-related QIs identified. Receiving intravenous chemotherapy (adjuvant or neoadjuvant chemotherapy); was one of the indicators that was identified in seven studies (8,16,18–22). Other indicators identified included: women who received neoadjuvant or adjuvant systemic therapy (18,20); women with hormone receptor-positive invasive breast cancer or DCIS who received adjuvant endocrine treatment (Tamoxifen/AI) or hormonal therapy or chemotherapy or aromatase inhibitor treatment (8,18–20,22); women treated by trastuzumab in whom cardiac function was monitored every three months (8,20) and women with metastatic breast cancer and lytic bone metastases who received bisphosphonates (18,20).

### **Radiotherapy**

Radiotherapy QIs were identified within seven studies (8,16,17,19-22). Women who received a standard dose of radiotherapy after breast-conserving surgery, mastectomy and axillary lymph node dissection (ALND) were identified in four studies (8,16,19–22). The QIs identified in only a single study included; women patients who received adjuvant radiotherapy to the chest wall after mastectomy (8) and radiotherapy for locally advanced breast cancer (excluding T3N0) following mastectomy (16). Radiation oncology referral after lumpectomy and surgical resection for postoperative radiotherapy emerged in three studies (17,19,22)

### **Follow-up**

Seven QIs related to follow-up were identified in the studies. The QI on clinical evaluation and rehabilitation was identified in four (8,19,20,22). Two studies (19,22) focused on staging procedures for patients who may or may not undergo baseline staging tests (US of liver, chest x-ray and bone scan), administrative management and a data manager being responsible for breast centre data and genetic counselling for referrals. The follow-up indicator on communication, availability of information and counselling among breast cancer patients were also identified (21). Another follow-up QI that emerged was the transit times of less than or equal to five weeks between various breast cancer managements. This included transit times of  $\leq 5$  weeks between each diagnosis and the start of neoadjuvant chemotherapy or primary surgery (without immediate reconstruction) or transit time  $\leq 5$  weeks between final operation and the start of radiotherapy etc. (19).

## **Discussion**

This systematic review was conducted to identify QIs developed for the management of breast cancer based on Donabedian's conceptual framework of structure, process, and outcome. The study reviewed articles published in English that focused on the development of QIs using a systematic approach. Overall, 38 QIs were identified, which included three structure, 30 process and 5 outcome measure of breast cancer management. It was evident that less attention has been paid to the structure and outcome of breast cancer care as stated QIs; although studies showing the importance of these two QI concepts (25).

Measures of structure usually involve and reflect variables and a system in which care is delivered. They may also measure staff expertise, or equipment availability (10). The three QIs for structure identified revolved around the formation of a multidisciplinary team (MDT) for rigorous discussions of individual cases, availability of information and documentation and clinical research. Discussion and documentation of information for the patient before the management plan is formulated is an essential step towards achieving quality within the system to ensure consistent cancer care delivery based on the available evidence (26). Cowpli-Bony and colleagues revealed a positive relation between MDT and adherence or compliance to breast cancer management and guidelines (28).

The outcome indicators that were identified focused on the overall survival of the patient and emerged from three studies (8, 20, 21). This entailed survival at five years according to 1) disease stage at diagnoses, 2) specific breast disease, 3) disease presenting symptomatically, 4) disease-free survival by stage, and 5) local recurrence after curative surgery.

Michailovich and Gaisenko also identified five outcome indicators in their systematic review focusing on the quality of life, survival and disease-free outcome (28) .

Most of the studies in this review focused on the development of process indicators (16–19, 22). In contrast to structure indicators, many process indicators are readily actionable and describe the actual care assessed and received by the patient (10). The 30 process QIs identified in this review (8 diagnoses, 15 treatments, 7 follow-ups) and their respective domains relate to diagnosis (4 imaging and 4 histopathology) and treatment (5 surgery, 4 radiotherapy and 6 chemotherapy) (Fig. 2). This finding is similar to a recent study by Maes-Carballo et al., (2021) which also identified a majority of process indicators(11).

In six of the studies, developing QIs was the first step in assessing breast cancer care (8, 16–18, 20, 21). In the other two studies; EUSOMA published a position paper for the first time in 2010; describing a set of benchmark quality indicators (QIs) adopted by breast centres for standardization auditing and quality assurance (22) which was subsequently updated by the EUSOMA working group to incorporate new knowledge in the field and to establish an agreed minimum standard of care (19). These were concerned with: the structure, process and outcome of breast cancer management which are in agreement with the Donabedian classical theoretical model (29). Breast cancer guidelines management requirements are described as including diagnosis, treatment and follow-up or review (30, 31). Most indicators focused on breast cancer

management from referral to follow-up. This is supported by Mburu and his colleagues that management of breast cancer requires a holistic approach consisting of early detection, diagnosis through treatment, consistent follow-ups and review (32).

The study also identified different strategies and pathways in the development of QIs. In general, information for the identification and development of QIs can be derived based on a systematic or non-systematic method. The systematic method requires clear scientific evidence and a stakeholder perspective interspersed with clinical guidelines and clear scientific evidence whilst the non-systematic method may be in a form of case studies without any scientific evidence (33).

All the eight studies in this review applied a systematic method to the development of the QIs. These included a review of literature, the use of clinical practice guidelines, medical records data and expert opinion of stakeholders through a panel consensus. Seven of the eight studies employed a literature search to identify existing quality indicators (8, 17,18, 19,20,22,23 ). One of the studies combined the literature search with clinical practice guidelines and medical records to identify existing QIs (20). In the development and measuring of a set of indicators to monitor the quality of Breast Cancer care, Stordeur and team reviewed the Belgian clinical practice guideline using a clinical expert panel to evaluate the reliability, relevance, interpretability and actionability of each indicator (20). Although Bao and team focused on a comprehensive literature review search, their selection criteria were also based on scientific evidence, utility, interpretability, validity, preventability and data availability evaluated on a 5-point scale to identify potential indicators (8) The use of the Delphi method to establish consensus was evident in two of the papers reviewed (8, 17).

All the studies employed a multidisciplinary team as an expert panel which included surgeons, medical oncologists, radiation oncologists, pathologists etc. Experts were required to review the appropriateness of each indicator based on defined criteria. For instance, 24 experts within the EUSOMA working group reported the definition, the minimum and target standard, the motivation for selection, and the level of evidence of each indicator (19).

Overall the studies suggested that QIs will help bridge the gap between clinical practice and standard performance by making explicit monitoring of quality service (35, 37).

## Strengths And Limitations Of This Study

This review highlights the importance of a process for developing QIs for the management of breast cancer and the application of a systematic method that requires clear scientific evidence and a stakeholder perspective together with clinical guidelines. However, only one study referenced the Donabedian theoretical framework (8). This systematic review had a language restriction due to the unavailability of a language expert reviewer. Almost all documents were published in English language medical journals (25). In contrast, a systematic review in Spain conducted without language restriction identified 89 QIs from 22 selected documents concerning not only QIs development but the measurement tools and compliance standards or adherence for breast cancer.

More processes indicators were identified suggesting that studies should focus on identifying more structure and outcome indicators. At the same time overall there is limited research regarding quality indicators in breast cancer care. There is also a need for studies relating to Low and Middle-Income Countries (LMICS) due to the differences in technologies and treatment available worldwide. Another limitation is the reproducibility of the developed QIs especially with the different constitutions of expert panels and methods used. A re-evaluation of the literature on QIs will be necessary after a period of technological advancement resulting in the improved care of breast cancer patients.

## Conclusions

QI on the process, structure and outcome of breast cancer management have been identified from this review. More processes indicators were identified suggesting that studies focused on identifying the structure and outcome indicators are required. Overall, there is limited research regarding QIs in breast cancer care. Recording accurate and comprehensive data is key to the development of QIs to monitor the management of care. QIs must be updated periodically to encompass new technologies and practices if they are to be instrumental in producing better care.

## List Of Abbreviations

QI: Quality Indicator,

BC: Breast Cancer

PRISMA: Preferred Reporting Items for Systematic Review and Meta-Analysis

DCIS: Ductile Carcinoma in Situ

## Declarations

## Ethics approval and consent to participate

The PRISMA guideline for reporting systematic and meta-analysis was followed. The article is based on a secondary analysis of the existing literature and does not contain any studies with human participants or animals.

## Consent for publication

NA

## Availability of data and materials

The datasets that support this finding are available from the corresponding author on reasonable request.

## Competing interests

I declare that the authors have no competing interests as defined by BMC, or other interests that might be perceived to influence the results and/or discussion reported in this paper.

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## Author's Contributions

V.D. coordinated the systematic review, drafted the manuscript, screened and verified all information, was the corresponding author.

A.D. and P.A. assisted in data extraction, screening articles, literature search and review of the document.

E.K., P.E., M.G., J.Y. and M.B. collaborated in literature search, document review and manuscript approval.

K.T. and E.D. provided content expertise and finalization of the manuscript. All authors read and agreed to the final submission of the manuscript

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## Tables

**Table 1a: Characteristics of included studies**

Authors	Year of publication	Aim	Evidence or Design for QI	Country	Sample Size	BC category	No of Final QIs	Key results/ summary
1.  Bao et al., 2015	2015	To develop a set of quality indicators to measure and improve the quality of breast cancer care	<b>Review</b> (literature search)  <b>Consensus</b> (A modified Delphi process implemented)  <b>Review</b>	China	A 16-member expert panel was assembled (10 medical oncologists, 5 surgical oncologists and 1 radiation oncologist)	General	31	A set of QIs systematically developed for BC quality measurement
2. (Naeim, Sawhney, MacLean, & Sanati, 2007	2007	Identify potential QIs used to assess the treatment of VEs with BC, reviews evidence in support	Review  Consensus	China	Expert Panel involved in validating the indicators	Vulnerable Elders	23	QI identified for VEs with breast cancer
3.  Stordeur et al., 2012	2012	To develop and measure a set of indicators to monitor the quality of BC care	Review (registry data)	Belgium	Expert panel involved	General	32	Study demonstrates feasibility of developing multidisciplinary set of QIs for BC Using national cancer registry data
4.  Van Bommel et al., 2017	2017	Review (audit data)	Review (Clinical characteristics)	Neitherlands	—	Invasive breast cancer or ductile carcinoma in situ	32	QIs measuring care structure, processes and outcomes evaluated over time and compared between hospitals.
5.  (Government, 2016)	2016	To develop a framework, and foster a culture of, continuous quality improvement.	Review	Scotland	A committee (task force)	General	15 QIs	
6.  (Chin-Lenn et al., 2013	2013	To define performance measures for the treatment of DCIS for measuring “quality” of treatment in patients diagnosed with DCIS	Review (practice guideline).  Consensus (Delphi)	Canada	—	DCIS	8 QIs	Performance measures for DCIS can be assessed with the developed QIs
7.  Rosselli Del Turco et al., 2010	2010	To define a set of QIs that should be routinely measured and evaluated to confirm that the clinical outcome reaches the requested standards	Review (literature)  Consensus  Review	Italy	24 expert panel	General	17	QI developed to improve standard clinical outcome.

Authors	Year of publication	Aim	Evidence or Design for QI	Country	Sample Size	BC category	No of Final QIs	Key results/ summary
8.  (Biganzoli et al., 2017)	2017	A position paper, describing a set of benchmark QIs that could be adopted by breast centres to allow standardised auditing and quality assurance	Review (literature)  Consensus  Review	Italy	A working group of European experts in the different disciplines met to update the original articles	General	17 QIs	QI developed for breast units in Europe to monitor

TABLE 1b. Methodological approaches to developing QIs

AUTHOR	FINAL SET QI	LITERATURE REVIEW	EVIDENCE BASE CLINICAL GUIDELINES	CLINICAL DATA/REGISTRY	EXPERT PANEL CONSENSUS	NUMBER OF PROCESS INDICATORS	NUMBER OF OUTCOME INDICATORS	NUMBER OF STRUCTURE INDICATORS
1. Bao et al., 2015	31	yes	no	no	yes	28	2	1
2. Naeim, Sawhney, MacLean, & Sanati, 2007	23	yes	no	no	yes	22	-	1
3. Stordeur et al., 2012	32	yes	yes	yes	no	26	5	1
4. Van Bommel et al., 2017	32	no	no	yes	no	31	-	1
5. Government, 2016	15	yes	yes	no	yes	12	2	1
6. Chin-Lenn et al., 2013	8	no	yes	no	yes	8	-	-
7. Rosselli Del Turco et al., 2010	17	yes	no	no	yes	16	-	1
8. Biganzoli et al., 2017	17	yes	no	no	Yes	16	-	1

## Figures

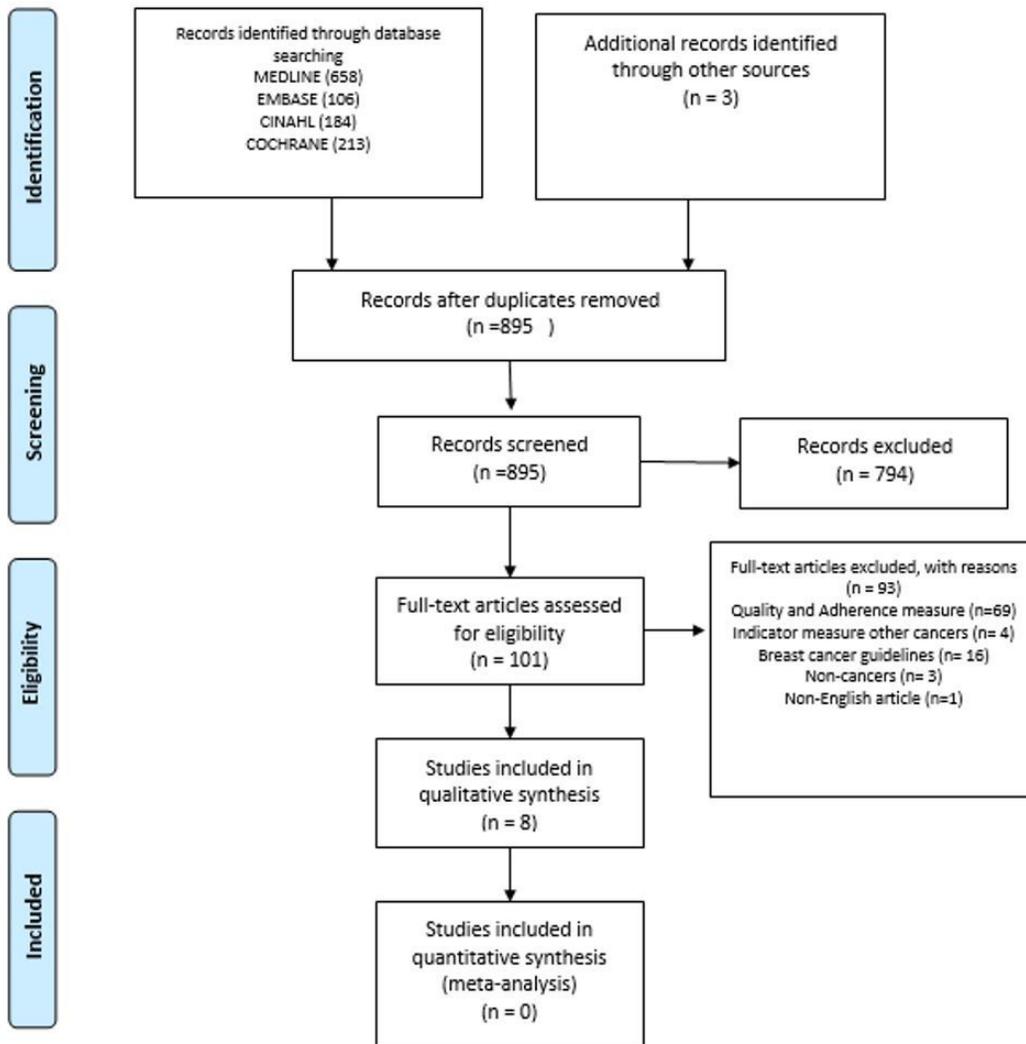


Figure 1  
PRISMA flow diagram

