Chapter 3. Results

Overview

Several perspectives on the results of the systematic review are presented in this chapter. Highlighted first are the results of the literature search and the status of bibliographic records, then full-text articles, as they progressed through the stages of the review. An overview of the numbers and types of quality indicator involved in the relevant quality measurement efforts follows next. The key questions are then answered, with questions organized by the larger categories of diagnosis, treatment (e.g., supportive care), followup, and documentation of this care. Summary tables accompany textual descriptions, and present various attempts at quality measurement organized by subcategory of care (e.g., chemotherapy-related care). Given that a quality indicator pertains to a particular population, questions addressing the identity of the quality indicator, and the population with which it was employed, are answered concurrently. There are a number of instances when a quality measurement, although pertinent to the topic of breast cancer care, does not fit perfectly within the categories of care outlined in the key questions. When available, these data fall under a "general category" placed at the end of a section responding to a given question. The meanings of acronyms and abbreviations used in summary tables appear in the first summary table within each new section of the present chapter.

Results of Literature Search

Regardless of its source, the progress of each bibliographic record through the stages of the systematic review is illustrated in the modified QUOROM flow chart (Appendix D). Ideally, a record included an abstract and key words, in addition to a citation. When a citation was discovered, for example through a manual search of a reference list, its complete bibliographic record was sought (e.g., Pubmed) and then entered into the first level of screening.

Of 3,848 records entered into the initial screening for relevance, 2,937 were excluded. Reflecting the specific eligibility criteria, the reasons for exclusion were: a. not breast cancer in women (n = 928); b. not breast cancer diagnosis or treatment (or followup or reporting/documentation) (n = 1,137); c. not a quality measure/ment, clinical practice guideline, systematic review, or, commentary/editorial (n = 860); and d., not a quality measure/ment (i.e., a clinical practice guideline, systematic review, or, commentary/editorial) (n = 12). The records associated with this last reason for exclusion refer to those rejected via the initial screening of the bibliographic records yielded by the search update, and owing to the narrowed scope of work. All but 16 reports for the remaining 911 records were then retrieved and subjected to a more detailed relevance assessment. Four reports were never retrieved,[93-96] and 12 arrived too late to assess them further before this evidence report was completed.[97-108]

The second relevance screening then excluded 610 reports, with the following noted reasons for exclusion: a. not breast cancer in women (n = 52); b. not breast cancer diagnosis or treatment (or followup or reporting/documentation) (n = 40); and c. not a quality measure/ment, clinical practice guideline, systematic review, or, commentary/editorial (n = 518) (Listing of Excluded

Note: Appendixes and Evidence Tables cited in this report are provided electronically at http://www.ahrq.goc/clinic/epcindex.htm

Studies at Level 2). Required because of the change in the scope of the project, a third level of screening excluded 225 reports for the following reasons: a. not a quality measure/ment (clinical practice guideline) (n = 94); b. not a quality measure/ment (systematic review) (n = 115) and c. not a quality measure/ment (commentary/editorial) (n = 16) (Listing of Excluded Studies at Level 3). In total, 60 reports, describing 58 quality measurement studies, were deemed relevant for the systematic review.[5,109-167]

Two studies were each described by two reports. One study was described by two published reports.[151,166] A second study was referred to by a published report[158] and an abstract.[157] [When more than one author is placed in a row in a summary table, this indicates that more than one report refers to the study.] The latter was the only included abstract, with all other reports having been published as journal articles. Two reports required translation, one from Danish[118] and the other from German.[168] Only the former was included in the final collection of relevant studies. Finally, ASCO decided to wait to share details concerning their quality measures until the results of their developmental process are formally disseminated.

Overview of Quality Indicators Used in Quality Measurement

The 60 relevant reports, describing 58 relevant studies, identified 143 quality indicators used to measure quality (see Appendix E for Evidence Tables and Appendix G for Listing of Quality Indicators Used to Measure Adherence). Other than a small number of studies (n = 11) employing different measures primarily of QOL (n = 12), virtually no validated quality measures were found.[110,113,115,117,123,129,139,148,149,153,156] Thus, almost all efforts in quality measurement entailed quality indicators for which no reference was made, or data reported, indicating that they had been developed scientifically as measures. These quality measures are identified in response to the research questions concerning psychometric properties with respect to each category of care.

Of the 12 validated quality measures, all but one were used with reference to treatment, and all but one assessed quality of life. The Patient Satisfaction Questionnaire was used to investigate the impact of treatment.[148] The breast cancer-specific Functional Assessment of Cancer Therapy Scale (FACT-B, version 3) evaluated the quality of life associated with a diagnosis of breast cancer.[115] The remaining quality of life instruments were used to assess the effects of treatment. Of these, the only breast cancer-specific tool was the European Organization of Research and Treatment of Cancer (EORTC) QLQ-BR23.[148] Generic forms (i.e., not breast cancer-specific) included: the Short Form-36 (SF-36);[113,117,129,139,149] EORTC-C30;[117,153] Medical Outcomes Scale (MOS-20);[129,148] Spitzer Quality of Life Index (QLI);[156] Uniscale;[156] Ferrans Quality of Life scale;[123] Psychosocial Adjustment to Illness Scale (PAIS);[123] Guttman Health Status Questionnaire;[129] and, the Linear Analogue Self-Assessment Scale (LASA).[110] Any adaptations required to employ these generic scales with breast cancer patients were reported as having been achieved. No validated quality measures were described as having been used to assess the quality of followup care or reporting/documentation. The “trajectory of scientific development” scheme allowed us to identify 3 (of 12) validated measures, each assessing quality of life in treatment studies, that failed to report study-related psychometric data despite noting or referencing their psychometric histories: Ferrans Quality of Life scale,[123] the PAIS,[123] and the LASA.[110] All other quality indicators received a grade indicating no history of formal scientific validation (i.e., Level IV).

In the diagnosis category, 26 quality indicators were identified, with most pertaining to the general category (n = 11), followed by breast biopsy (n = 7), pathology staging (n = 3), and diagnostic imaging (n = 2); QOL and patient satisfaction relating to diagnosis were each assessed once. Types of care represented in the task order for which no quality measurements meeting eligibility criteria were found, include: sentinel node biopsy, chest X-ray, bone scan, CT scan, MRI, blood tests, tumor marker status, and genetic testing.

It should be recalled that the general category refers to quality indicators not fitting into the predefined categories established in the task order. The types of care indexed in the general category pertaining to diagnosis, included recommendations that women be seen by specific types of healthcare professional, for specific reasons, and within certain time frames (Summary Tables 5 & 6). The greatest number of studies evaluating any given diagnosis-related quality indicator focused on a recommendation pertaining to the appropriate use of preoperative diagnosis by fine-needle aspiration cytology, needle biopsy or biopsy (n = 4) (Summary Table 2). Other than those involved in the assessment of QOL or patient satisfaction (n = 2), most of the quality indicators referred to the delivery or receipt of indicated diagnostic care (75%: 18/24). Only five quality indicators addressed the quality with which specific diagnostic care was delivered. Virtually all measurements were conducted retrospectively.

Many more quality indicators were employed in the measurement of treatment quality (n = 67). Of these, the most frequently assessed were adjuvant systemic therapy (n = 25), and radiation therapy (n = 16). Other categories were evaluated less often, including the general category (n = 11), QOL relating to treatment (n = 5), patient satisfaction relating to treatment (n = 3), surgery in general (n = 2), breast-conserving surgery (n = 2), mastectomy (n = 1), and (axillary) lymph node surgery (n = 1). Quality measurements were not found relating to two types of treatment, that is, reconstructive surgery, and neodjuvant systemic therapy.

The general category included several perspectives on care that did not fit readily into more narrowly defined categories of quality indicator. For example, the appropriate use of treatment sequences according to guidelines included surgery, radiotherapy, chemotherapy, hormone therapy, initial examination, and followup. This quality indicator was evaluated in four studies (Summary Table 37). The greatest number of studies employing any given treatment-related quality indicator evaluated the appropriate use of breast-conserving surgery (n = 18: Summary Table 8), and the appropriate use of radiotherapy after breast-conserving surgery (n = 19: Summary Table 12). Other than those involved in the assessment of QOL or patient satisfaction (n = 8), most of the quality indicators referred to the delivery or receipt of indicated treatment (70.1%: 47/67). Nine quality indicators assessed the quality with which specific treatment care was delivered, and three referred to a structural variable (e.g., availability of a procedure manual for chemotherapy: Summary Table 29). Virtually all measurements were conducted retrospectively.

Followup care was the focus of efforts to measure quality using five quality indicators. Specific types of care were not predefined in this project for this category. Two studies evaluated the appropriate use of guidelines for followup surveillance of breast cancer (Summary Table 39). Measurements were taken retrospectively.

A considerable number of quality indicators were employed in quality measurement relating to reporting/documentation (n = 45). By far, pathology reporting was the most frequently assessed type of practice (n = 42), with chemotherapy reports (n = 2) and imaging reports (n = 1) barely represented. Neither surgical reporting nor radiotherapy reporting were the focus of quality measurement attempts. Two types of quality indicator were each evaluated in five

studies: reporting the assessment of microscopic margins (Summary Table 53), and reporting histological type (microscopic: Summary Table 55).

Evidence identified in this review is now used to specifically address each of the predefined questions. Adherence rates obtained through quality measurement are presented, yet are de-emphasized. These were not subjected to quantitative synthesis. Supporting data regarding studies may be found in the evidence tables (Appendix E).

Question 1: What measures of the quality of care are available to assess the quality of diagnosis of breast cancer in women, including all foci ranging from appropriate use and quality of diagnostic imaging, to patient-reported QOL and patient satisfaction?

1a: In what patient populations have these quality measures been used? With respect to the topic of the appropriate use and quality of diagnostic imaging (Summary Table 1), McGlynn et al. employed a process quality indicator outlining appropriate care following detection of a palpable breast mass.[5] They collected data via telephone survey and medical records. Data for a small number of women to whom this indicator applied, and drawn from a random sample of women living in 12 metropolitan US areas, indicated an adherence rate of 89.1% to the timely (i.e., within 3 months) completion of at least one of five types of care. Evidence was based on observational studies in addition to expert opinion.

Summary Table 1: Preoperative diagnosis

Author, year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key differences
Appropriate use: If a palpable breast mass has been detected, at least one of the following procedures should be completed within 3 months: fine-needle aspiration, mammography, ultrasound, biopsy, and/or a followup visit[IV]				
McGlynn, 2003, US	Random sample of women living in 12 US metropolitan areas	77	1998-2000	89.1%/NA
Appropriate use of preoperative mammographic evaluation[IV]				
Shank, 2000, US	Random sample women stage I-II invasive BC treated in 1993-1994; ≤3 mo prior mass excision	727	1995-1996	91.5%/NA
White, 2003, US	Convenience sample women BC stage I-II diagnosed in 1994	16,643	1994	88%/Age: <70 y: 88.5%; ≥70 y: 86.2%/ Race/ethnicity: White: 88.4%; Black-H: 86.5%/Payer: Government: 87.7%; Private: 88.7%

KEY: Key differences = regarding age, race, ethnicity, or SES; SES = socioeconomic status; NA = not assessed; BC = breast cancer; NR = not reported; QOL = quality of life ; DCIS = ductal carcinoma in situ; S = significant difference; NS = nonsignificant difference; Mx = mammography; F = followup; b = baseline; HMO = Health Maintenance Organization; H = Hispanic; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Another process indicator was identified whose performance was measured in two different studies conducted in the United States.[162,166] The recommended care pertains to the appropriate use of the preoperative mammographic evaluation, that is, the delivery of this care where it was indicated. Shank et al. specified that mammography take place no more than 3 months prior to the excision of a mass,[162] whereas White et al. did not identify a time frame.[166] Both studies

evaluated data from women with stage I-II breast cancer. Shank et al. selected a random sample of women from their medical records and surveys, whereas White et al. evaluated a convenience sample of women from cancer registries of 842 hospitals. Both studies entailed retrospective review, and employed the standards for breast-conservation treatment jointly developed in 1992 by the American College of Surgeons (ACOS), American College of Radiology (ACR), College of American Pathologists (CAP), and the Society of Surgical Oncology (SSO). The overall adherence rates were similar, although Shank et al.'s 91.5% was associated with a much smaller sample than was White et al.'s 88%.

Cheung assessed adherence to an access (process) indicator recommending that imaging and/or cytology or needle biopsy, if required, be performed at the initial visit (Summary Table 2).[116] The convenience sample included women with operable breast cancer, and a tumor size of <5 cm. Data were collected from the author's medical records using the standards established by the British Association of Surgical Oncology (BASO: 1995). While the measurement period was not reported, it was noted that performance was assessed after the implementation of the guidelines. The overall adherence rate was 0% as the research site did not have a radiology service available at the initial visit.

Summary Table 2: Preoperative diagnosis

Author, year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key differences
Appropriate use of imaging &/or cytology or needle biopsy, if required, to be performed at the initial visit[IV]				
Cheung, 1999, Hong Kong	Convenience sample of women with operable primary BC <5 cm; attended by the author	100	NR	0%/NA
Appropriate use of preoperative diagnosis by fine-needle aspiration cytology, needle histology or biopsy[IV]				
Sauven, 2003, UK	Population-based sample BC women detected by screening in UK, Wales, Scotland & Northern Ireland	43,500	1996-2001	NR (Overall by y (range): 63% - 87%(Minimum: ≥70%; Standard: ≥90%))/NA
Christensen, 2002, Denmark	Convenience sample women with positive mammography screening followed by surgery in Copenhagen	4,111	1991-1997	NA/100%
Cheung, 1999, Hong Kong	Convenience sample women operable primary BC <5 cm; attended by the author	100	NR	82% (Standard: 90%)/NA
McCarthy, 1997, UK	Convenience sample women with operable BC, <70 y treated at Nottingham City Hospital's	83	1994	86.7% (Standard: ≥70%)/NA
Appropriate use: A biopsy or fine-needle aspiration should be performed within 6 weeks either when the mammography suggests malignancy or the persistent palpable mass is not cystic on ultrasound[IV]				
McGlynn, 2003, US	Random sample of women living in 12 US metropolitan areas	33	1998-2000	50.2%/NA
Appropriate use: If a breast mass has been detected on two separate occasions, then either a biopsy, fine-needle aspiration or ultrasound should be performed within 3 months of the second visit[IV]				
McGlynn, 2003, US	Random sample of women living in 12 US metropolitan areas	13	1998-2000	81.6%/NA
Quality of fine-needle aspiration samples from lesions, which subsequently prove to be breast cancer, should be adequate as deemed by the breast pathologist[IV]				
Cheung, 1999, Hong Kong	Convenience sample women with operable primary BC < 5 cm; attended by the author	100	NR	99% (Standard: >90%)/NA

A process indicator relating to breast biopsy was evaluated in four different studies. It refers to the appropriate use of preoperative diagnosis via fine-needle aspiration cytology or needle histology (Summary Table 2). Sauven et al. specified a minimum and a target standard of ≥70 % and ≥90%, respectively.[160] Christensen et al. also included core biopsy among the preoperative diagnosis procedures.[118] Cheung referred to palpable tumors and set the standard at 90%.[116] McCarthy et al. defined the benchmark at ≥70%.[147] The study populations varied slightly, with Sauven et al. including a population-based sample of women with breast cancer detected by mammography screening. Christensen et al. evaluated a convenience sample of women with an abnormal result in the screening mammogram. Cheung selected a convenience sample of women with operable breast cancer and a tumor size of <5 cm. McCarthy et al. only included patients younger than 70 years of age. Sauven et al. conducted a prospective and retrospective review using regional boundaries and medical records in United Kingdom, Wales, Scotland, and Ireland, while employing the surgical standards of the National Health Service Breast Screening Programme (NHSBSP: 1992). McCarthy et al. completed a retrospective review of data from hospital databases using the same standards. Christensen et al. completed a retrospective review of data from patients selected from hospital registries, and utilized the standards of the European Guidelines for Quality Assurance in Mammography Screening (1996) and the Guidelines for cytology and reporting in breast cancer screening (1993). Cheung used the BASO standards (1995). The overall adherence rates ranged from 63% to 100%.

From a random sample of women living in 12 metropolitan US areas, McGlynn et al. abstracted data for two process quality indicators (Summary Table 2).[5] They observed that 50.2% of eligible women had had a biopsy or fine-needle aspiration performed within 6 weeks, either when the mammography suggested malignancy or the persistent palpable mass was not cystic on ultrasound. They also noted that 81.6% of eligible cases had had either a biopsy, fine-needle aspiration or ultrasound performed within 3 months of the second visit if a breast mass had been detected on two separate occasions. Both indicators were supported by data from observational studies and, expert opinion. Cheung employed a process indicator recommending that the quality of fine-needle aspiration samples from lesions, which subsequently prove to be breast cancer, should be adequate as deemed by the breast pathologist.[116] The overall adherence rate was 99%, exceeding the target standard of ≥90%.

Regarding surgical procedures, McGlynn et al. found that, in 100% of very few cases, women had a biopsy performed within 6 weeks if fine-needle aspiration could not rule out malignancy (Summary Table 3).[5] Support for this indicator came from observational studies and expert opinion. McCarthy et al. collected performance data relating to the appropriate use of the first localization biopsy operation to correctly identify impalpable lesions.[147] The target standard (≥95%) was surpassed by the overall, perfect performance (i.e., 100%). Cheung also evaluated a process indicator reflecting the quality of breast biopsy care, whereby a primary operable breast cancer receives a frozen section.[116] The overall adherence rate was 0%, with the target set at <10%.

Summary Table 3: Surgical procedures

Author, year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key differences
Appropriate use: A biopsy should be performed within 6 weeks if fine-needle aspiration cannot rule out malignancy[IV]				
McGlynn, 2003, US	Random sample of women living in 12 US metropolitan areas	2	1998-2000	100%/NA
Appropriate use of first localization biopsy operation to correctly identify impalpable lesions[IV]				
McCarthy, 1997, UK	Convenience sample women operable BC, <70 y at Nottingham City Hospital's	11	1994	100% (Standard: >95%)/NA
Quality of breast biopsy: primary operable breast cancer receives a frozen section[IV]				
Cheung, 1999, Hong Kong	Convenience sample women operable primary BC <5 cm; attended by the author	100	NR	0% (Standard: <10%)/NA
Quality of technique to determine histological node status for all invasive tumors, either by sampling or clearance[IV]				
Sauven, 2003, UK	Population-based sample BC women detected by screening in UK, Wales, Scotland & Northern Ireland	43,500	1996-2001	NR (Overall by y (range): 81%-93%)/NA
Cheung, 1999, Hong Kong	Convenience sample women operable primary BC <5 cm; attended by the author	100	NR	100%/NA
Quality of sampling nodes for invasive breast cancer, to include ≥ 4 nodes[IV]				
Sauven, 2003, UK	Population-based sample BC women detected by screening in UK, Wales, Scotland & Northern Ireland	43,500	1996-2001	NR (Overall by y (range): 89%-95%)/NA
Quality of hormone receptor assay [IV]				
Bickell, 2000, US	Convenience sample women BC stage I-II, receiving definitive surgical treatment in 4 hospitals in NY	723	1995-1996	85%/by hospital: 56-99 %

Three process indicators, relating to pathology staging, were investigated (Summary Table 3). The quality of the technique determining the histological node status for all invasive tumors, either by sampling or clearance, was evaluated by Sauven et al.[160] and Cheung.[116] The former's adherence rates increased from 81% to 93% over time, whereas Cheung's rate was 100%. Sauven et al. assessed adherence to the recommendation indicating that the quality of sampling nodes for invasive breast cancer requires at least four lymph nodes.[160] The adherence rate increased from 89% in 1996/1997, to 95% in 2000/2001. Bickell et al's process indicator pertained to the quality of hormone receptor assays performed.[111] Their convenience sample of women with stage I-II breast cancer was selected from tumor registries from four New York city hospitals. The standards were the Mount Sinai Health Final Guidelines (1994-1995). The adherence rate was 85%, with a range of 56% to 99% across the hospitals.

Northouse et al. conducted a study assessing possible changes in QOL after the diagnosis of breast cancer (Summary Table 4).[115] The instrument employed in a convenience sample of black women was a validated breast cancer specific scale, the 37-item Functional Assessment of Cancer Therapy Scale (FACT-B), version 3. It assesses five factors: physical well-being, family well-being, relationship with the doctor, emotional well-being and functional well-being. The

overall change in the scale, on average, reflected improved QOL. However, women with positive (versus negative) lymph nodes, or women with (versus without) recurrence, experienced a lower QOL after a diagnosis of breast cancer. Any improvement in QOL might reflect the positive impact of relationships with healthcare professionals.

Summary Table 4: QOL and patient satisfaction relating to diagnosis

Author, year, Location	Sample description	No. Eligible	Measurement Period	Results
Change in QOL after diagnosis of breast cancer[Iac]				
Northouse, 1999, US	Convenience sample black women with a confirmed diagnosis of BC who were at least 1 mo post-diagnosis, Southeastern region in Michigan	98	NR	NR (Average: fairly high QOL scale/Variables: Node (+): lower QOL (Mean: 110.8) than node (-) (Mean: 120.7); Recurrence of cancer: lower QOL (Mean: 107.1) than not recurrence (Mean: 118.2))/NA
Women reporting an overall satisfaction with the quality of breast care[IV]				
Haas, 2000, US	Convenience sample women referred for at least 1 visit GP, 1 y prior to Mx; abnormal screening Mx or Mx for a clinical breast concern (lump, thickening, breast pain) in Greater Boston Area	579 (baseline); 447 (followup survey)	1996 -1997	Excellent care: 46.8%(b) 45.8% (F)/Age: < 50 y: 44.4% (b); 46.6% (F); ≥ 50 y: 49.3% (b); 44.9% (F)/Race/ethnicity: White: 51.9% (b); 49.8% (F); Black: 35.9% (b); 35.6% (F); Hispanic: 33.3% (b); 25% (F)/Payer: HMO: 42.9% (b); 42.4% (F); Other: 52.8% (b); 50.7% (F)

A second outcome indicator was used to assess whether patients reported an overall satisfaction with the quality of breast cancer care (Summary Table 4). Haas et al. evaluated women referred for at least one visit to the general practitioner during the year prior to the index mammogram, an abnormal screening result, or receiving a mammogram for a breast complaint (e.g., lump, thickening, or prolonged pain).[133] Data were prospectively collected through patient-reported surveys at baseline, after the mammogram, and then after 7 months. Rated from poor to excellent, patient satisfaction was assessed by a questionnaire based on the Harvard Risk Management Foundation Guidelines (1995). The excellent care rates were 46.8% and 45.8% at baseline and followup, respectively.

A process indicator was identified under the general category (Summary Table 5). It refers to the appropriate use of referrals to a surgeon by a general practitioner according to breast referral guidelines. Cochrane et al. selected a random sample of women with breast complaints (e.g., breast lump, nipple discharge, or breast pain) referred to the Rapid Access Breast Clinic in Cardiff, United Kingdom.[119] The population was selected from the referral databases in a retrospective fashion during 8 months in 1995. The standards were taken from the NHSBSP breast referral guidelines (1995), indicating a short period between the implementation of the standards and the performance measurement. This may account for the adherence rate of 60%.

Summary Table 5: General category

Author, year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key differences
Appropriate use of referrals to surgeon by general practitioner according to breast referral guidelines[IV]				
Cochrane, 1997, UK	Random sample women >35 y breast problems referred to a surgeon by GP, Rapid Access Breast Clinic	2,332 (BC = 147)	1995	60%/Age: <40 y: 54%; >40 y: 64% S
>90% of women with breast cancer detected by screening should attend an assessment center within 3 weeks of mammography[IV]				
McCarthy, 1997, UK	Convenience sample women operable BC, <70 y at Nottingham City Hospital's	75	1994	42.7%/NA
Patients attending for diagnostic purposes seen on at least 1 occasion by a breast specialist surgeon[IV]				
Cheung, 1999, Hong Kong	Convenience sample women operable primary BC <5 cm; attended by the author	100	NR	100%/NA
<10% of all new cases of women with breast cancer should attend the clinic/hospital on > 2 occasions for diagnostic purposes[IV]				
Cheung, 1999, Hong Kong	Convenience sample women operable primary BC <5 cm; attended by the author	100	NR	41%/NA
Urgent referrals of women with breast cancer to be seen within 5 working days[IV]				
Khawaja, 2001, UK	Convenience sample women BC referred by GP to specialist to diagnose: breast lump; suspicion of malignant change; other breast symptoms in Eastbourne	22	3 mo (1998)	82% (Standard: > 80%)/Age: 41-65 y: 27.3%; >65 y: 54.5%
Cheung, 1999, Hong Kong	Convenience sample women operable primary BC <5 cm; attended by the author	100	NR	95% (Standard: >80%)/NA
Women with breast cancer to be seen by specialist in timely fashion post referral for diagnostic purposes[IV]				
Khawaja, 2001, UK	Convenience sample women BC referred by GP to specialist to diagnose: breast lump; suspicion of malignant change; other breast symptoms in Eastbourne	22	3 mo (1998)	100% (Standard: ≥80%)/ Age: >65 y: 18.2%
Cheung, 1999, Hong Kong	Convenience sample women operable primary BC < 5 cm; attended by the author	100	NR	50% (Standard: 70%)/NA

A process/access indicator appraised by McCarthy et al. related to the recommendation that women with breast cancer detected by screening should attend an assessment center within 3 weeks of mammography (Summary Table 5).[147] Taking into account the fact that the target standard was ≥90%, and the overall adherence rate was 42.7%, the system failed to reach the desired level.

The performance of a process/access variable, indicating that patients attending for diagnostic purposes be seen on at least one occasion by a breast specialist surgeon, was measured by Cheung (Summary Table 5).[116] The overall adherence rate was 100%. The same investigator also evaluated the performance of the recommendation that less than 10% of all new cases of women with breast cancer should attend the clinic/hospital on more than two occasions for diagnostic purposes. The overall adherence rate was 41%, indicating a failure to meet the standard.

The urgent referral of women with breast cancer to be seen within 5 working days (process/access) was measured in two studies (Summary Table 5). Khawaja et al. retrospectively collected data from referrals of women with breast symptoms, to the Fast-Access Breast Clinic,[141] whereas Cheung assessed a convenience sample of women with operable breast cancer.[116] The BASO (1995) standards were employed by both authors. Cheung's 95% and Khawaja et al.'s 82% each met the target standard of ≥80%. The same investigators also measured adherence to a standard recommending that women with breast cancer be seen in timely fashion by a specialist, post-referral, for diagnostic purposes (process/access). Based on the BASO (1998) and BASO (1995) standards, Khawaja et al. and Cheung specified timely as within 2 weeks of referral and within 15 working days, respectively. The adherence rate was 100% in Khawaja et al.'s study (target standard: ≥80%), whereas Cheung's rate of 50% failed to reach its standard (70%).

Sauven et al. investigated adherence to the recommendation that the management of cases coming to surgery from the screening program should only be carried out by surgeons with the necessary specialist knowledge (structure) (Summary Table 6).[160] The adherence rate was stratified by year and surgeon screening caseload per annum. The proportion of women treated by a surgeon with a screening caseload of more than 30 patients per annum rose from 63% in 1996/1997, to 72% in 2000/2001. On the other hand, for low caseload surgeons (≤10 patients per annum), the rate did not change significantly from 1996/1997 (8%) to 2000/2001 (5%).

Summary Table 6: General category

Author, year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key differences
Management of cases coming to surgery from the screening program carried out by surgeons who have acquired the necessary specialist knowledge[IV]				
Sauven, 2003, UK	Population-based sample BC women detected by screening in UK, Wales, Scotland & Northern Ireland	43,500	1996-2001	NR (Overall by y & case load range): > 30pts/y, high*: 63%-72%; < 10 pts/y, low: 5%- 8%)/NA
≥90% of women requiring an operation for diagnostic purposes should be admitted within 14 days of the surgical decision[IV]				
Sauven, 2003, UK	Population-based sample BC women detected by screening in UK, Wales, Scotland & Northern Ireland	2,979	1996-2001	NR (Overall by y (range): 52%-60%)/NA
Cheung, 1999, Hong Kong	Convenience sample women operable primary BC <5 cm; attended by the author	100	NR	68%/NA
McCarthy, 1997, UK	Convenience sample women operable BC, <70 y treated at Nottingham City Hospital's	11	1994	45.5%/NA
≥90% of women with breast cancer or with an abnormality requiring diagnostic operation need to be told of this within 5 working days of investigations leading to this diagnosis[IV]				
Cheung, 1999, Hong Kong	Convenience sample women operable primary BC < 5 cm; attended by the author	100	NR	67%/NA
Appropriate use of an evaluation in compliance with guidelines[IV]				
Haas, 2000, US	Convenience sample women referred for at least 1 visit GP, 1 y prior to Mx; abnormal screening Mx or Mx for a clinical breast concern (lump, thickening, breast pain) in Greater Boston Area	579	1996-1997	69.1%/Age: <50 y: 63.8%; >50: 74.5 %/ Race/ ethnicity: White: 71%; Black: 59.5%; Hispanic: 75.8%/Payer: HMO: 73.3%; other: 62%
Appropriate use of initial examination[IV]				
Ray-Coquard, 1997, France	Random sample women with newly diagnosed localized BC (DCIS to nonmetastatic invasive carcinoma) in a cancer center in Rhone Alpes Area	71	1995	86%/NA

Three studies evaluated the process/access variable indicating that women requiring an operation for diagnostic purposes should be admitted within 14 days of the surgical decision (Summary Table 6). Each failed to achieve a target standard of ≥90%. Sauven et al. stratified the results by year of audit and reported a rate of 60% for 1996/1997 and 47% for 2000/2001.[160] McCarthy et al.[147] and Cheung's[116] respective rates were 45.5% and 68%.

Relative to a standard set at ≥90%, Cheung observed an adherence rate of 67% with respect to the recommendation that women with breast cancer or with an abnormality requiring a diagnostic operation should be told of this within 5 working days of the investigations leading to this diagnosis (process/access) (Summary Table 6). Haas et al. observed a 69.1% adherence rate with respect to the appropriate use of an evaluation that was in compliance with guidelines (process).[133] Variations in the rate depended on the type of consultation: women with an abnormal mammography (74%); and, women with a clinical breast complaint (58.8%). Ray-Coquard et al. found that, according to randomly sampled medical records, 85% of women with

newly diagnosed, localized breast cancer had received an initial examination according to practice guidelines developed in 1993 and implemented in 1994 (process).[158]

1b: For what diagnosis-related purposes have these quality measures been used? The evidence is organized according to three broad categories of purpose. The measurements relating to the following quality indicators were undertaken to achieve external quality oversight:

- appropriate use: "If a palpable breast mass has been detected, at least one of the following procedures should be completed within 3 months: fine-needle aspiration, mammography, ultrasound, biopsy and/or a followup visit" (preoperative diagnosis);[5]

- appropriate use: "If a breast mass has been detected on two separate occasions, then either a biopsy, fine-needle aspiration or ultrasound should be performed within 3 months of the second visit" (preoperative diagnosis);[5]

- appropriate use: "A biopsy or fine-needle aspiration should be performed within 6 weeks either when the mammography suggests malignancy or the persistent palpable mass is not cystic on ultrasound" (preoperative diagnosis);[5]

- appropriate use: "A biopsy should be performed within 6 weeks if fine needle aspiration cannot rule out malignancy" (surgical procedures);[5]

- "appropriate use of preoperative mammographic evaluation" (diagnostic imaging);[162,166]

- "quality of sampling nodes for invasive breast cancer, to include at least four nodes" (pathology staging);[160]

- "quality of hormone receptor assay" (pathology staging);[111]

- "appropriate use of referrals to surgeon by general practitioner according to breast referral guidelines" (general category);[119]

- "management of cases coming to surgery from the screening program carried out by surgeons who have acquired the necessary specialist knowledge" (general).[160]

The measurements relating to the following quality indicators were made to afford internal quality improvement:

- "appropriate use of imaging and/or cytology or needle biopsy, if required, to be performed at the initial visit" (diagnostic imaging);[116]

- "quality of fine-needle aspiration samples from lesions which subsequently prove to be breast cancer, should be adequate as deemed by the breast pathologist" (breast biopsy);[116]

- "quality of breast biopsy: primary operable breast cancer receives a frozen section" (breast biopsy);[116]

- "appropriate use of first localization biopsy operation to correctly identify impalpable lesions" (breast biopsy);[147]

- "change in QOL after diagnosis of breast cancer" (QOL);[115]

- "women reporting an overall satisfaction with the quality of breast cancer care" (patient satisfaction);[133]

- "more than 90% of women with breast cancer detected by screening should attend an assessment center within 3 weeks of mammography" (general);[147]

- "patients attending for diagnostic purposes seen on at least one occasion by a breast specialist surgeon" (general);[116]

- "less than 10% of all new cases of women with breast cancer should attend the clinic/hospital on more than 2 occasions for diagnostic purposes" (general);[116]

- "urgent referrals of women with breast cancer to be seen within 5 working days" (general);[116,141]

- "women with breast cancer to be seen by specialist in timely fashion post referral for diagnostic purposes" (general);[116,141]

- "at least 90% of women with breast cancer or with an abnormality requiring diagnostic operation need to be told of this within 5 working days of investigations leading to this diagnosis" (general);[116]

- "appropriate use of an evaluation in compliance with guidelines" (general).[133]

Some studies evaluating the performance of a given quality indicator varied in terms of the diagnosis-related purposes they were intended to achieve. References to studies designed to achieve each purpose are made explicit:

- "appropriate use of preoperative diagnosis using fine-needle aspiration cytology, needle histology, or biopsy" (breast biopsy): external quality oversight[118,160]; internal quality improvement;[116,147]

- "quality of technique to determine histological node status for all invasive tumors, by either sampling or clearance" (pathology staging): external quality oversight;[160] internal quality improvement;[116]

- "at least 90% of women requiring an operation for diagnostic purposes should be admitted within 14 days of the surgical decision:" external quality oversight;[160] internal quality improvement;[116,147]

- "appropriate use of initial examination" (general): both internal quality improvement and external quality oversight.[158]

1c: What quality measures, if any, are available to assess differences in the quality of diagnosis of breast cancer in women related to patients' age, race, socioeconomic status, and ethnicity? The reader is referred to the summary tables provided in response to Questions 1 and 1a. While quality measures to assess any of the above-noted differences have not been developed scientifically to achieve this goal, a number of diagnosis-related quality measurements have been conducted which capture such disparities. Results relating to specific quality indicators are reported from studies having conducted tests of significance to highlight possible gaps in care.

Regarding age, one study observed that, relative to older women, younger women with breast cancer were significantly more likely to receive "a preoperative mammographic evaluation" (diagnostic imaging) (<70 vs. ≥70 years).[166] Yet, two studies reported that, relative to younger women, older women with breast cancer were significantly more likely to receive the following diagnosis-related care:

- "appropriate use of referrals to surgeon by general practitioner according to breast referral guidelines" (general) (<40 vs. ≥40 years);[119]

- "appropriate use of an evaluation in compliance with guidelines" (general) (<50 vs. ≥50 years).[133]

Where a test of significance was performed, one study observed no difference with respect to age for "women reporting an overall satisfaction with the quality of breast care" (patient satisfaction) (<50 vs. ≥50 years).[133]

With respect to race or ethnicity, no studies observed that, relative to white women, black women were significantly more likely to receive specific diagnosis-related care. On the other hand, one study reported that, relative to black women, white women were significantly more likely to "report an overall satisfaction with the quality of breast care" (patient satisfaction).[133] In studies where tests of statistical significance were performed, no difference was observed with respect to race or ethnicity regarding the "appropriate use of a preoperative mammographic evaluation" (diagnosis imaging).[166]

With respect to definitions of socioeconomic status based on healthcare coverage, one study observed that, relative to women with private insurance, women with governmental coverage were significantly more likely to "report an overall satisfaction with the quality of breast care" (patient satisfaction) (HMO vs. other).[133] Conversely, one study reported that, relative to women

with governmental coverage, women with private insurance were significantly more likely to receive "a diagnostic evaluation in compliance with guidelines, when indicated" (general) (<50 vs. ≥ 50 years) (HMO vs. other).[133] A nonsignificant difference between women receiving these two types of coverage was observed with respect to the "appropriate use of the preoperative mammographic evaluation" (diagnosis imaging).[166]

1d: What is the evidence supporting the use of quality measures for the diagnosis of breast cancer in women, exhibited in terms of the scientific evidence demonstrating a linkage to improvement in clinical or patient-reported outcomes? It is assumed that the care captured by each quality indicator included in the present review was identified on the basis of it having been shown to have linkages to improvement in clinical or patient-reported outcomes. And, only associations with improved outcomes observed in the included studies could be described here and in later sections addressing this same issue. However, with respect to the topic of diagnosis, no studies reported having evaluated whether or not those patients having received recommended care experienced improved outcomes relative to those failing to receive this care.

1e: What is the evidence supporting the use of quality measures for the diagnosis of breast cancer in women, exhibited in terms of their psychometric performance (e.g., validity, reliability, sensitivity and specificity, ceiling and floor effects)? Northouse et al assessed QOL after the diagnosis of breast cancer using a validated quality instrument (Summary Table 4).[115] The breast cancer-specific version of the Functional Assessment of Cancer Therapy Scale (FACT-B, version 3) has a sound psychometric history, including evidence for construct validity, internal consistency, and test-retest reliability. The overall (.90) and subscale internal consistency coefficients (.51-.88) observed in their study indicated sound reliability.

Question 2: What measures of the quality of care are available to assess the appropriate use and quality of treatment for breast cancer in women, including all foci ranging from breast-conserving surgery, to patient-reported QOL and patient satisfaction?

2a: In what patient populations have these quality measures been used? Quality indicators relating to treatment are organized by type of care, including surgery (breast conserving, mastectomy, axillary node dissection), radiotherapy, adjuvant systemic therapy, QOL, as well as patient satisfaction with care, and a general category describing care not delineated in the original request for task order.

From a random sample of women living in 12 metropolitan US areas, McGlynn et al. abstracted data for a process quality indicator (Summary Table 7).[5] They observed that 50.2% of eligible women with stage I or stage II breast cancer had been offered a choice of modified radical mastectomy or breast-conserving surgery, unless contraindications to breast-conserving surgery were present. Randomized controlled trial evidence supported this indicator.

Summary Table 7: Surgery

Author, year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key Differences
Appropriate use: Women with stage I or stage II breast cancer should be offered a choice of modified radical mastectomy or breast-conserving surgery, unless contraindications to breast-conserving surgery are present[IV]				
McGlynn, 2003, US	Random sample of women living in 12 US metropolitan areas	13	1998-2000	50.2%/NA
Appropriate use of all surgery[IV]				
Ray-Coquard, 1997, France	Random sample women with localized BC (DCIS to nonmetastatic invasive carcinoma) in a cancer center in Rhone Alpes Area	99	1995	92%/NA
No breast-conserving surgery or mastectomy in metastatic disease[IV]				
Hislop, 2003, Canada	Population-based sample women any stage BC diagnosed in British Columbia	NR (Total = 1,159)	1995	65%/NA

KEY: Key differences = regarding age, race, ethnicity, or SES; SES = socioeconomic status; NA = not assessed; CT = chemotherapy; RT = radiotherapy, BC = breast cancer; BCS = breast-conserving surgery; HT = hormone therapy; NR = not reported; ESBC = early stage breast cancer; QOL = quality of life; Dx = diagnosis; DCIS = ductal carcinoma in situ; S = significant difference; NS = nonsignificant difference; QLI = quality of life index; LCIS = lobular carcinoma in situ; CME = continuing medical education; ALND = axillary lymph node dissection; LN = lymph node; (+) = positive; (-) = negative; ER = estrogen receptor; HR = hormone receptor; RI = Rhode Island; MA = Massachusetts; MN = Minnesota; CMF = cyclophosphamide, methotrexate, 5-fluorouracil; M0 = nonmetastatic; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

A process indicator pertained to the appropriate use of all surgery (Summary Table 7), and was assessed in terms of a random sample of women with newly diagnosed, localized breast cancer (DCIS to nonmetastatic invasive carcinoma) in a cancer center in the Rhone Alpes area of France.[158] Retrospective data were collected by Ray-Coquard et al. in 1995 from medical records, to assess the impact of the implementation in 1994 of a regional practice guideline. No other information was reported about this performance standard. The adherence rate was 92%. Hislop et al. noted that only in 65% of cases of women with metastatic disease was the recommendation not to perform breast-conserving surgery or mastectomy followed.[136]

Eighteen studies evaluated the process indicator referring to the appropriate use of breast-conserving surgery (Summary Table 8). Of these, 12 were conducted in the United States,[111,114,132,140,142-146,150,151,164] three in Canada,[135,136,165], two in Europe,[127,154], and one in Hong Kong.[116] White et al.[166] reported the patterns of local therapy data included in the Morrow et al. publication.[151] Keating et al.[140] and Guadagnoli et al.[132] included a subset of the same patients treated in the states of Massachusetts and Minnesota. Lazovich et al.[143] included the subset of women whose data were analyzed in Lazovich et al.[142] Mandelblatt et al.[145] and Mandelblatt et al.[146] accessed the same data source to investigate data from some of the same patients as well. Fourteen studies involved women diagnosed with Stage I-II breast cancer.[111,114,132,135,140,142-146,150,151,164,166] Tyldesley et al. described their population as women with ductal carcinoma in situ (DCIS) and early stage breast cancer, which included diagnoses of stage I-IIIA.[165] Cheung included a population of women with operable primary breast cancer <5 cm although, with respect to breast-conserving surgery, he focused exclusively on women with tumors <3 cm.[116] Ottevanger et al. analyzed data from premenopausal women with stages II-IIIA, node positive, breast cancer.[154] Both Engel et al.[127] and Hislop et al.[136] evaluated data from any stage breast

cancer, meaning that they evaluated some cases of women for whom breast-conserving surgery was not indicated. In the latter two cases, a complete description of sample sizes was not provided. Inexact or missing age data in reports made it impossible to meaningfully compare studies on this basis. On many occasions, age information referred to ranges of subpopulations (e.g., <70 vs. ≥70 years of age) without specifying the complete range. On the other hand, two studies did stand out for their exclusive focus on older women. Mandelblatt et al. assessed data from women at least 67 years of age with stage I-II breast cancer.[145,146]

Summary Table 8: Surgery

Author, year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key Differences
Appropriate use of breast-conserving surgery[IV]				
Mandelblatt, 2001, US	National random sample, Medicare beneficiaries, ≥ 67 y, newly diagnosed with ESBC 1992-1994; treating surgeons	3,851	1992-1998	35.5%/NA
Mandelblatt, 2002, US	National random sample, Medicare beneficiary women ≥67 y, with newly diagnosed primary, stage I–II BC	1,833	1994	33%/Race/ethnicity: Black: 31%; White: 35%
Bickell, 2000, US	Convenience sample women BC stage I-II, receiving definitive surgical treatment in 4 hospitals in NY	723	1995-1996	59%/NA
Keating, 2001, US	Convenience sample women diagnosed with stage I & II BC at 17 hospitals (MA) & 30 hospitals (MN)	792 (MA); 1,634 (MN)	1993-1995	73.8% (MA) vs. 48% (MN)/NA
Guadagnoli, 1998b, US	Convenience sample women BC stage I or II in hospitals of 2 US states (MA & MN)	1,299 (MA); 836 (MN)	1993-1995	74% (MA) vs. 48% (MN)/ Age (vs. <50 y)(OR): 50-59 y: NS (MA & MN); 60-69 y: NS (MA & MN); 0.7 NS (MN); 70-79 y: NS (MA); S (MN); ≥80 y: NS (MA); S (MN) /Residence (vs. non-urban): Urban: NS (MA); S (MN)/Income: <$40,000: 0.7 NS (MA & MN)/HMO member: NS (MA & MN)/Education (% High school): 70-79: NS (MA & MN); 80-89: NS (MA & MN) ≥ 90: NS (MA & MN)
Lazovich, 1999, US	National population-based sample women stage I-II diagnosed 1983-1995, 9 US regions	109,880	1990-1995	NR/Age: <50 y: 48%; 50-59 y: 49%; 60-69 y: 44.6%; 70-79 y: 39.2%; ≥80 y: 34.7%/Race: White: 44.5%; Non-white: 43.1%
White, 2003, US Morrow, 2001, US	Convenience sample women stage I-II BC receiving their diagnosis and initial course of treatment at any of 842 hospitals	16,643	1994	42.6%/Age: < 70 y: 46%; ≥ 70 y: 34%/ Race/ethnicity: White: 43%; Black + Hispanic: 44%/Payer: Government: 36.9%; Private: 48.4% S
Brenin, 1999, US	National convenience sample women BC, stage I or II treated in 1994, in US hospitals	17,151	1994	44.5%/NA
Hebert-Croteau, 1999, Canada	Random sample newly diagnosed stage I-II BC women ≥50 y treated in Quebec	1,174	1993-1994	NR/Age: 50-69 y: 90.9%; ≥70 y: 80.1%
Lazovich, 1997, US	National population-based sample women ESBC stage I or II diagnosed 1983-1993, 13 western Washington counties	13,541	1990-1993	NR (Stage: I: 54.9%; II: 35.2%) /Age: < 50 y: 52.1%; 50-59 y: 54.9%; 60-69 y: 47.4%; 70-79 y: 39.1%; ≥ 80 y: 31.7%/Education: Lowest tertile: 44.9%; Middle tertile: 49.9%; Highest tertile: 50.9% S

Summary Table 8: Surgery (continued)

Author, year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key Differences
Appropriate use of breast-conserving surgery[IV]				
Mor, 2000, US	Random sample women > 60 y with BC stage I or II diagnosed at 6 hospitals in Providence, RI	350	1992-1997	64.1%/NA
Tyldesley, 2003, Canada	Population-based samples women ESBC eligible for BCS in North American population (DCIS; stage I-IIIA)	NR	NR	NR (Stage: DCIS: 63%; I: 57%; II: 52%; IIIA: 27%)/NA
Cheung, 1999, Hong Kong	Convenience sample of women with operable primary BC < 5 cm; attended by the author. For BCS, tumor size < 3 cm	100	NR	32%/NA
Ottevanger, 2002, Netherlands	Population-based sample premenopausal women, node (+) BC; stages II to IIIA treated from 1988-1992 in 9 hospitals	254	1993-1998	55.5%/NA
Engel, 2002, Germany	Convenience sample women with any stage BC residing in 6 regions in Germany	NR (Total= 8,661)	1996-1998	NR/NA (No breakdown for stages for which BCS is indicated)
Hislop, 2003, Canada	Population-based sample women any stage BC diagnosed in British Columbia.	NR (Total = 1,159)	1995	NR (Incomplete breakdown for M0 invasive pts for whom BCS is indicated)/Age: < 40 y: 42%; 40-49 y: 51%; 50-59 y: 58%; 60-69 y: 50%; 70-79 y: 42%; ≥ 80 y: 41%/By family income: <$35,000: 44%; $35,000-$44,999: 46% $45,000-$54,999: 46%; ≥$55,000: 55%
Lagorreta, 2000, US	Convenience sample women ≥ 21 y with invasive carcinoma; DCIS; stages 0-II; tumor ≤ 5 cm; eligible for BCS, California	748	1994-1996	63%/NA
Solin, 1999, US	Convenience sample women ≥ 65 y, newly diagnosed stage 0-II BC < 5cm	95	1993-1994	65%/NA

Data sources for case identification varied greatly across the 18 studies for the quality indicator pertaining to the appropriate use of breast-conserving surgery. These included national cancer registries (e.g., SEER), Medicare claims data, regional tumor registries, medical records, and various others. Likewise, the sampling strategies exhibited considerable variation, including regional or national random samples, convenience samples, and, population-based samples. The most frequently used performance standard was the NIH Consensus Development Conference (1990). It was employed as the sole source definition of the quality indicator in 11 studies.[114,127,132,135,140,142-146,164] Where overall adherence rates were reported, the appropriate use of breast-conserving surgery ranged from 32% in a random sample of medical records,[116] to 65% in Solin et al.'s convenience sample of data from an HMO claims database supplemented by medical record data.[164] One notable finding with respect to variations in rate linked to variables other than those discussed in relation to Question 2c (below), is the higher rate associated with stage I as opposed to stage II breast cancer.[142,143,165]

Another quality indicator asserted that women undergoing breast-conserving surgery should have no more than two therapeutic operations, likely to spare the patient (Summary Table 9). Examining his own medical records, yet providing no age data regarding this process indicator, Cheung reported 100% adherence to this standard from the BASO guidelines (1995).[116]

Summary Table 9: Surgery

Author, year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key Differences
Appropriate number of therapeutic operations (≤ 2) for women having breast-conserving surgery[IV]				
Cheung, 1999, Hong Kong	Convenience sample of women with operable primary BC < 5 cm; attended by the author. For BCS, only tumor size < 3 cm	100	NR	100% (Standard: 90%)/NA
Appropriate use of mastectomy[IV]				
Ottevanger, 2002, Netherlands	Population-based sample premenopausal women, node (+) BC; stages II to IIIA treated from 1988-1992 in 9 hospitals	254	1993-1998	44.5%/NA
Cheung, 1999, Hong Kong	Convenience sample of women with operable primary BC < 5 cm; attended by the author	100	NR	68%/NA

Two retrospective studies evaluated the appropriate use of mastectomy (Summary Table 9). Neither reported specific age data for this process indicator. Cheung included a convenience sample of women with operable primary breast cancer <5 cm.[116] He assessed his medical records using BASO (1995) guidelines and found a 68% adherence rate. Ottevanger et al. analyzed data from premenopausal women with stages II-IIIA, node positive, breast cancer.[154] Their population-based sample data revealed a 44.5% rate relative to Dutch regional guidelines (i.e., Comprehensive Cancer Center East: CCCE).

Eight studies measured the appropriate use of axillary lymph node dissection, a process quality indicator (Summary Table 10).[111,114,121,126,131,135,146,152] Six were conducted in the United States,[111,114,126,131,146,152] one in Canada,[135] and the last one in Australia.[121] Five involved data from women with stage I-II breast cancer.[111,114,131,135,146] Edge et al. included data from women with stages I-IIIA breast cancer,[126] Craft et al. simply described their convenience sample as including women with newly diagnosed, localized and invasive breast cancer.[121] Nattinger et al. evaluated women at least 30 years of age at the time of first diagnosis of invasive, local or regional, unilateral breast cancer.[152] Mandelblatt et al.[146] and Edge et al.[126] exclusively evaluated older patients (i.e., ≥67 years).

Summary Table 10: Surgery

Author, year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key Differences
Appropriate use of axillary lymph node dissection[iv]				
Craft, 2000, Australia	Convenience sample women newly diagnosed primary localized invasive BC treated in Australian capitol territory	190	1997-1998 (14 mo)	91%/NA
Bickell, 2000, US	Convenience sample women BC stage I-II, receiving definitive surgical treatment in 4 hospitals in NY	723	1995-1996	87%/NA
Guadagnoli, 1998a, US	Convenience sample women ESBC (stage I or II) in 2 states of US (MA & MN)	2,575	1993-1995	81% (MA) vs. 94% (MN)/Age (vs. < 50y) (OR): 50-59 y: NS (MA & MN); 60-69 y: NS (MA & MN); 70-79 y: S (MA &MN); >80 y: S (MA &MN)
Brenin, 1999, US	National convenience sample women BC, stage I or II treated in 1994, in US hospitals	17,151	1994	93.2%/Age: < 70 y: 97%; > 70 y: 86%/Payer: Private vs. Government: OR 1.4 S
Hebert-Croteau, 1999, Canada	Random sample newly diagnosed stage I-II BC women ≥50 y treated in Quebec	1,174	1993-1994	NR/Age: 50-69 y: 82.4%; ≥70 y: 46.9%
Edge, 2002, US	Convenience sample women ≥67 y stage T1-T2 (N0N1) M0, newly diagnosed invasive BC who underwent BCS	464	1995- 1997	63.4%/Age: 67-69 y: 84%; 70-74 y: 73%; 75-79 y: 62%; ≥ 80 y: 33% S/Race/ethnicity: White: 64%; Black: 60% NS/ Education: < high school: 60%; ≥ high school: 66%/Payer: HMO: 64%; Private: 65%
Mandelblatt, 2002, US	National random sample, Medicare beneficiary women ≥67 y, with newly diagnosed primary, stage I–II	1,833	1994	86%/Race/ethnicity: Black: 88%; White: 84%
Nattinger, 2000, US	National population-based sample women ≥30 y at the time of first diagnosis of invasive local or regional unilateral BC	144,759	1995	97.3%/NA

Data sources varied, including hospital or provincial tumor registries, Medicare claims data, and the SEER registries, among others. Sampling strategies ranged from local convenience samples to national population-based samples. Six studies employed the standard from the NIH Consensus Development Conference (1990),[114,126,131,135,146,152] whereas others tended to use regional guidelines. Craft et al.'s was a prospective, longitudinal study.[121] Where overall adherence rates were reported, the appropriate use of axillary lymph node dissection ranged from 63.4% in the Edge et al.[126] study to 97.3% in the Nattinger et al. investigation.[152] As with Mandelblatt et al.'s sample,[146] Edge et al. included only women at least 67 years of age.[126] The Mandelblatt et al. research involved the second lowest adherence rate (86%).[146] The highest rate, found by Nattinger et al., included women at least 30 years of age.[152] They included any-stage breast cancer patients.

Three studies assessed the appropriate use of radiotherapy across various indications (Summary Table 11). Ray-Coquard et al.'s French investigation[158] and Foroudi et al.'s Canadian study[128] each included women with any-stage breast cancer. Solin et al. examined process data

from American women at least 65 years of age, with a diagnosis of stage 0-II breast cancer, and tumors <5 cm.[164] The sampling strategies varied, including Ray-Coquard et al.'s random sample, Solin et al.'s convenience sample, and Foroudi et al.'s synthesis of population-based sample data. Ray-Coquard et al. employed a regional practice guideline to set the standard, whereas Foroudi et al. completed a systematic synthesis based on numerous standards and Solin et al. used the NIH Consensus Development Conference statement (1990). Ray-Coquard et al. reported an adherence rate of 93%, whereas the other two groups of researchers qualified their data. Foroudi et al. observed an adherence rate of 66.4%, with rates of radiotherapy, done initially as opposed to later over the course of the disease, estimated at 57.3% and 9.1%, respectively. Solin et al. found that 60% of women with ductal carcinoma in situ and 91% of those with stage I-II breast cancer appropriately received this care.

Summary Table 11: Radiotherapy

Author, year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key Differences
Appropriate use of radiotherapy[IV]				
Ray-Coquard, 1997, France	Random sample women with localized BC (DCIS to nonmetastatic invasive carcinoma) in a cancer center in Rhone Alpes Area	99	1995	93%/NA
Foroudi, 2002, Canada	Population-based sample women BC eligible for RT from North American population	NR	NR	66.4% (Initial RT: 57.3%; Late RT: 9.1%; Stage: IV, brain metastases at dx: 1.8%; IV; symptomatic bone metastasis at dx: 10%; IV, delayed symptoms bone metastasis: 10.4-21.7%; IV, delayed brain metastasis: 4.8-10%; IV, delayed cord compression: 0.4-0.8%)/NA
Solin, 1999, US	Convenience sample women ≥ 65 y, newly diagnosed stage 0-II BC < 5cm	DCIS: 5 Stage I & II: 57	1993-1994	NR (Stage: DCIS: 60%; stage I & II: 91%)/NA

McGlynn et al.'s random sample of women from 12 metropolitan US areas yielded data indicating 45.3% adherence to a process indicator asserting that women with breast-conserving surgery should begin radiation therapy within 6 weeks of completing either of the following: the last surgical procedure on the breast (including reconstructive surgery that occurs within 6 weeks of primary resection) or chemotherapy, if the patient receives adjuvant chemotherapy, unless wound complications prevent the initiation of the treatment (Summary Table 12).[5] This indicator was supported by observational study data and, expert opinion. Eighteen studies also evaluated process data concerning the appropriate use of radiotherapy following breast-conserving surgery, albeit with fewer details than were described by McGlynn et al.[111,121,126-128,131,135,136,138,142,143,145,146,150,152,154,164,166]

Summary Table 12: Radiotherapy

Author, year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key Differences
Appropriate use: Women treated with breast-conserving surgery should begin radiation therapy within 6 weeks of completing either of the following: the last surgical procedure on the breast (including reconstructive surgery that occurs within 6 weeks of primary resection) or chemotherapy, if the patient receives adjuvant chemotherapy, unless wound complications prevent the initiation of treatment[IV]				
McGlynn, 2003, US	Random sample of women living in 12 US metropolitan areas	10	1998-2000	45.3%/NA
Appropriate use of radiotherapy after breast-conserving surgery[IV]				
Ottevanger, 2002, Netherlands	Population-based sample premenopausal women, node (+) BC; stages II to IIIA treated from 1988-1992 in 9 hospitals	141	1993-1998	100%/NA
Engel, 2002, Germany	Convenience sample women with any stage BC residing in 6 regions in Germany	NR (Total= 8,661)	1996-1998	NR/NA (No breakdown for stages for which BCS is indicated)
Foroudi, 2002, Canada	Population-based sample women BC eligible for RT from North American population	NR	NR	NR (Stage: In situ; moderate risk: 37.7%; I (pN0): 57%; II (pN0): 52.2%; II (pN1): 31.1%; IIIA: 27.8%)/NA
Hislop, 2003, Canada	Population-based sample women any stage BC diagnosed in British Columbia	NR (Total = 1,159)	1995	NR (Stage: M0 invasive: 38% DCIS: 13% [Incomplete breakdown for M0 invasive pts for whom BCS is indicated])/ Family income: <$35,000: 100%; $35,000-44,999: 80%; $45,000-54,999: 89%; ≥$55,000: 82%
Mandelblatt, 2001, US	National random sample, Medicare beneficiaries, ≥ 67 y, newly diagnosed with ESBC 1992 -1994; treating surgeons	3,851	1992-1998	72.1%/NA
Craft, 2000, Australia	Convenience sample women newly diagnosed primary localized invasive BC treated in Australian capitol territory	87	1997-1998 (14 mo)	98%/NA
Bickell, 2000, US	Convenience sample women BC stage I-II, receiving definitive surgical treatment in 4 hospitals in NY	723	1995-1996	81%/NA
Lazovich, 1999, US	National population-based sample women stage I-II diagnosed 1983-1995, 9 US regions	109,880	1990-1995	81.5%/Age: < 50 y: 82.4%; 50-59 y: 86.1%; 60-69 y: 86.6%; 70-79 y: 80.2%; ≥ 80 y: 48.5% S/Race/ethnicity: White: 81.7%; Non-white: 80.7%
Guadagnoli, 1998a, US	Convenience sample women ESBC (stage I or II) in 2 states of US (MA & MN)	2,575	1993-1995	84% (MA) vs. 86% (MN)/Age (vs. < 50 y) (OR): 50-59 y: S (MA); NS (MN); 60-69 y: NS (MA &MN); 70-79 y: S (MA); NS (MN); >80 y: S (MA & MN)

Summary Table 12: Radiotherapy (continued)

Author, year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key Differences
Appropriate use: Women treated with breast-conserving surgery should begin radiation therapy within 6 weeks of completing either of the following: the last surgical procedure on the breast (including reconstructive surgery that occurs within 6 weeks of primary resection) or chemotherapy, if the patient receives adjuvant chemotherapy, unless wound complications prevent the initiation of treatment[IV]				
Guadagnoli, 1998b, US	Convenience sample women BC stage I or II in hospitals of 2 US states (MA & MN)	1,299 (MA); 836 (MN)	1993-1995	84% (MA) vs. 86% (MN)/NA
Hebert-Croteau, 1999, Canada	Random sample newly diagnosed stage I-II BC women ≥50 y treated in Quebec	1,174	1993-1994	NR/Age: 50-69 y: 89.6%; ≥70 y: 59%
Lazovich, 1997, US	National population-based sample women ESBC stage I or II diagnosed 1983-1993, 13 western Washington counties	13,541	1990-1993	94.1%/NA
White, 2003, US Morrow, 2001, US	Convenience sample women stage I-II BC receiving their diagnosis and initial course of treatment at any of 842 hospitals	7,097	1994	85.9%/Age: <70 y: 88.4%; ≥70 y: 78.9%/Race/ethnicity: White: 86.3%; Black-Hispanic: 83.2%/ Payer: Government: 83.3%; Private: 88.6% S
Edge, 2002, US	Convenience sample women ≥67 y stage T1-T2 (N0N1) M0, newly diagnosed invasive BC who underwent BCS	464	1995-1997	77.8%; with ALND: 54.7%/NA
Mor, 2000, US	Convenience sample of women >60 y with BC stage I or II diagnosed at 6 hospitals in Providence, RI	350	1992-1997	70.4 %/Age: 60-69 y: 94%; 70-79 y: 83%; ≥ 80 y: 34% S
Solin, 1999, US	Convenience sample women ≥ 65 y, newly diagnosed stage 0-II BC < 5cm	62	1993-1994	89%/NA
Mandelblatt, 2002, US	National random sample, Medicare beneficiary women ≥67 y, with newly diagnosed primary, stage I–II BC	599	1994	66.6%/Race/ethnicity: Black: 61%; White: 72.2% (S)
Nattinger, 2000, US	National population-based sample women ≥30 y at the time of first diagnosis of invasive local or regional unilateral BC	144,759	1995	65%/NA

White et al.[166] reported the patterns of radiotherapy after breast-conserving surgery data included in the Morrow et al. publication (Summary Table 12).[151] Guadagnoli et al.[131] and Guadagnoli et al.[132] reported the same data with respect to the states of Massachusetts and Minnesota. Lazovich et al.[143] included the subset of women whose data were analyzed in Lazovich et al.[142] Mandelblatt et al.[145] and Mandelblatt et al.[146] accessed the same data source to investigate data from some of the same patients as well. Fifteen studies were conducted in North America, including four in Canada[128,135,136,138] and eleven in the United

States.[111,126,131,142,143,145,146,150,152,164,166] Stage I-II breast cancer was the most frequently established population definition. It was used in eleven investigations.[111,126,131,135,142,143,145,146,150,164,166] Ottevanger et al. included women with stage II-IIIA, node positive breast cancer.[154] Engel et al.[127] as well as Foroudi et al.[128] included data from women with any stage of breast cancer. Hislop et al. evaluated women with nonmetastatic breast cancer,[136] Craft et al. studied those with primary, localized invasive breast cancer,[121] and Nattinger et al. analyzed data from women with invasive, local or regional and unilateral breast cancer.[152] However, in none of these latter three studies were the exact stages of breast cancer indicated. Jackson et al. did not report any information about their population's tumor characteristics.[138] Four studies exclusively assessed women at least 65 years of age.[126,145,146,164] Data sources ranged from regional medical records to large, national registries. Sampling strategies yielded random samples, convenience samples, or population based samples. All but the Craft et al.[121] study were retrospective. Adherence rates ranged from 65% in the very large population-based sample of American women (n = 144,759) assessed by Nattinger et al.,[152] to 100% in the small sample of women in the Netherlands (n = 141) studied by Ottevanger et al.[154]

Jackson et al. reported process data regarding the quality of delivered care indicating that, with reference to the 98.3% of women in their population-based sample having received prescribed care, 95% of the radiotherapy courses had followed guideline recommendations (British Columbia Cancer Agency) (Summary Table 13).[138]

Summary Table 13: Radiotherapy

Author, year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key Differences
Quality of radiotherapy after breast-conserving surgery (following guidelines)[IV]				
Jackson, 1999, Canada	Population-based sample women receiving radical or adjuvant postoperative RT treatments for BC, 3 clinics in British Columbia	9,351	1985-1996	95% (69%-99.5%)/NA
Appropriate use of radiotherapy after mastectomy[IV]				
Engel, 2002, Germany	Convenience sample women with any stage BC residing in 6 regions in Germany	NR (Total= 8,661)	1996-1998	NR (Region: 10.4%-32.2%)/NA
Jackson, 1999, Canada	Population-based sample women receiving radical or adjuvant postoperative RT treatments for BC, 3 clinics in British Columbia	9,351	1985-1996	82.5% (4%-95.5%)/NA
Foroudi, 2002, Canada	Population-based sample women BC eligible for RT from North American population	NR	NR	NR (Stage: I (pN0): 0.6-0.8%; II (pN0): 0.77-0.83%; II (pN1); <4N(+):0. 3%; II (pN1); >3N(+): 5.7-6.1%; IIIA, < 4N(+): 0.24-0.35%; IIIA; >3N(+): 5.1-7.4%; IIIB (pT4 or pN3): 42%)/NA

The appropriate use of radiotherapy after mastectomy was evaluated in three studies, with two undertaken in Canada,[128,138] and the other in Germany (Summary Table 13).[127] Two of these investigations assessed process data from women with any stage of breast cancer,[127,128] whereas the third reported no tumor characteristics data.[138] Data sources varied, including large, population-based registry data and surgery report data. Sampling strategies yielded two population-based samples and one convenience sample. The three studies employed different

performance standards, with one using the NIH Consensus Development Conference statement (1990).[127] Only two studies reported overall adherence data. Jackson et al.[138] observed a rate of 82.5%, whereas Engel et al. reported a range of 10.4% to 32.2% across six regions.[127]

As part of preparations to deliver quality radiotherapy care, White et al. assessed whether or not women in a convenience sample, and diagnosed with stage I-II breast cancer, had their treatment planned on a dedicated simulator (Summary Table 14).[166] The adherence rate was 88.9% when assessed in light of guidelines regarding process, and established by the ACR, ACOS, CAP, and the SSO. Moreover, White et al.'s adherence rate with respect to the process standard of delivering radiotherapy five days per week was 97.4%.

Summary Table 14: Radiotherapy

Author, year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key Differences
Quality of radiotherapy via planning on a dedicated simulator[IV]				
White, 2003, US	Convenience sample women BC stage I-II diagnosed in 1994	16,643	1994	88.9%/Age: <70 y: 89%; ≥70 y: 88.8%/Race/ethnicity: White: 89%; Black-Hispanic: 87.7%/ Payer: Government: 89.1%; Private: 88.8%
Quality of radiotherapy: done 5 days/week[IV]				
White, 2003, US	Convenience sample women BC stage I-II diagnosed in 1994	16,643	1994	97.4%/Age: <70 y: 97.4%; ≥70 y: 97.4%/Race/ethnicity: White: 97.5%; Black-Hispanic: 97.5%/ Payer: Government: 97.1%; Private: 97.1%
Quality of radiotherapy: homogenous dose distribution of radiotherapy[IV]				
Shank, 2000, US	Random sample women stage I-II invasive BC treated in 1993-1994	727	1995-1996	95%/NA
White, 2003, US	Convenience sample women BC stage I-II diagnosed in 1994	16,643	1994	96.6%/Age: <70 y: 96.6%; ≥70 y: 96.8%/Race: White: 96.6%; Black-Hispanic: 96.5% /Payer: Government: 96.7%; Private: 96.7%
Quality of radiotherapy: use of wedges on tangent breast fields[IV]				
White, 2003, US	Convenience sample women BC stage I-II diagnosed in 1994	16,643	1994	93.4%/Age: <70 y: 93.3%; ≥70 y: 93.8%/Race/ethnicity: White: 93.5%; Black-Hispanic: 92.1%/ Payer: Government: 93%; Private: 93.8%
Shank, 2000, US	Random sample women stage I-II invasive BC treated in 1993-1994	727	1995-1996	92.8%/NA

The homogeneous dose distribution of radiotherapy delivered to patients was evaluated in two studies (Summary Table 14). White et al. reported an adherence rate of 96.6%,[166] whereas Shank et al. observed a rate of 95%.[162] The studies analyzed process data from different data sources yet employed the same guidelines established by the ACR, ACOS, CAP, and the SSO. Shank et al. observed an adherence rate of 92.8% with regards to the use of wedges on tangent breast fields. White et al.'s corresponding rate was 93.4%.

The appropriate use of radiotherapy on the axilla following axillary lymph node dissection, and to deal with increased risk of local recurrence (i.e., extracapsular extension; at least four positive lymph nodes), was investigated in three studies (Summary Table 15). However, only one of the three groups provided process data for both indications. Ottevanger et al. did not specify how many of the women with at least four positive nodes received this care.[154] Yet, they reported an adherence rate of 84.7% for women exhibiting extracapsular extension. Brenin et al.

only reported data (53.9%) with regards to at least four positive lymph nodes.[114] Jackson et al.'s data varied widely across both hospitals and years, with an overall rate of 75%.[138] Ottevanger et al. also looked at the appropriate use of parasternal radiotherapy for tumors located in the medial part of the breast, and noted an adherence rate of 49.1%.[154]

Summary Table 15: Radiotherapy

Author, year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key Differences
Appropriate use of radiotherapy on axilla following axillary lymph node dissection, to deal with increased risk of local recurrence (i.e. extracapsular extension; ≥ 4 positive nodes) [IV]				
Ottevanger, 2002, Netherlands	Population-based sample premenopausal women, node (+) BC; stages II to IIIA treated from 1988-1992 in 9 hospitals	85	1993-1998	84.7%/NA
Jackson, 1999, Canada	Population-based sample women receiving radical or adjuvant postoperative RT treatments for, 3 clinics in British Columbia	9,351	1985-1996	75% (3%-92%)/NA
Brenin, 1999, US	National convenience sample women BC, stage I or II, in US hospitals	899	1994	53.9%/NA
Appropriate use of parasternal radiotherapy for tumors located in the medial part of breast [IV]				
Ottevanger, 2002, Netherlands	Population-based sample premenopausal women, node (+) BC; stages II to IIIA treated from 1988-1992 in 9 hospitals	114	1993-1998	49.1%/NA
Appropriate use of palliative radiotherapy for women with progression or recurrence [IV]				
Foroudi, 2002, Canada	Population-based sample women BC eligible for RT from North American population; later RT	NR	NR	NR (Stage: I & II (pN0), postmastectomy: 2.9-4.2%;II (pN1); postmastectomy: 0.5%; e III; postmastectomy: 0.39-0.57%)/NA
Regional recurrence needing further surgery or radiotherapy [IV]				
Foroudi, 2002, Canada	Population-based sample women BC eligible for RT from North American population; late RT	NR	NR	NR (Stage: DCIS: 0.02-0.1%; DCIS, recur with DCIS or invasive carcinoma: 1.2%; I & II (pN0), postmastectomy: 1.3-1.9%; II (pN1); postmastectomy: 1.35%; III; postmastectomy: 1.2-1.7%; LCIS; recur with DCIS or invasive carcinoma: 0.7%)/NA
Cheung, 1999, Hong Kong	Convenience sample of women with operable primary BC <5 cm; attended by the author	100	NR	0% (Standard at 5 y: <10%)/NA

Foroudi et al. did not report overall adherence data with regards to the appropriate use of palliative radiotherapy for the progression or recurrence of breast cancer (Summary Table 15).[128] They did differentiate the process-related rates by stage, with the proportions decreasing as a function of stage (Evidence Table: Appendix E). These authors also obtained performance data relating to an outcome indicator titled regional recurrence needing further surgery or radiotherapy. Again, they only provided data broken down by stage (Evidence Table: Appendix E). Cheung, on the other hand, employed a standard of less than 10% of women requiring further surgery or radiotherapy at 5 years, and reported that no women required such care.[116]

Shank et al. reported a rate of 99.9% relating to the daily treatment of both tangent fields (Summary Table 16). They also observed a rate of 99% with respect to the delivery of 4,500-5,000 cGy total breast dose via 180-200 cGy fractions. Finally, these same investigators noted a 94% rate related to the electron beam radiation of the breast. These last three quality indicators assessed the quality of the care delivered to patients.

Summary Table 16: Radiotherapy

Author, year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key Differences
Quality of radiotherapy: both tangent fields treated daily[IV]				
Shank, 2000, US	Random sample women stage I-II invasive BC treated in 1993-1994	725	1995-1996	99.9%/NA
Quality of radiotherapy: receiving 4,500-5,000 cGy total breast dose given in 180-200 cGy fractions[IV]				
Shank, 2000, US	Random sample women stage I-II invasive BC treated in 1993-1994	725	1995-1996	99%/NA
Quality of radiotherapy: electron beam breast radiation used[IV]				
Shank, 2000, US	Random sample women stage I-II invasive BC treated in 1993-1994	725	1995-1996	94%/NA

The appropriate use of any form of adjuvant systemic therapy (i.e., chemotherapy and/or hormone therapy) was examined in six projects, entailing one random sample from Hebert-Croteau et al.,[135] and convenience samples from each of Mor et al.,[150] Bickell et al.,[111] Craft et al.,[121] Silliman et al.,[163] and Guadagnoli et al.[130] Five studies investigated data from women with stage I-II breast cancer (Summary Table 17).[111,130,135,150,163] Small data sources were most common, including medical records or local cancer registries, for example.[111,121,130,150,163] Adherence rates ranged from 67.3% (n = 303) to 96% in a small number of cases (n = 99).[121]

Summary Table 17: Adjuvant systemic therapy

Author, year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key Differences
Appropriate use of any adjuvant systemic therapy[IV]				
Craft, 2000, Australia	Convenience sample women newly diagnosed primary localized invasive BC treated in Australian capitol territory	99	1997-1998 (14 mo)	96%/NA
Bickell, 2000, US	Convenience sample women BC stage I-II, receiving definitive surgical treatment in 4 hospitals in NY	723	1995-1996	78%/Age: < 50 y: 59-87 %; ≥ 50 y: 65-85 %
Hebert-Croteau, 1999, Canada	Random sample newly diagnosed stage I-II BC women ≥50 y treated in Quebec	1,174	1993-1994	NR/Age: 50-69 y: 74.2%; ≥70 y: 72.1%
Silliman, 1999, US	Convenience sample women ≥55 y newly diagnosed stage I or II BC treated 1 center in Boston	303	NR	67.3% (HT: 76%; CT: 13%; HT + CT: 11%)/ Income: ≤U$14,999: 64%; 15,000 -29, 999: 60%; 30,000-49,999: 77%; ≥50,000: 73%/Education: < high school: 60%; high school: 68%; some college: 64%; college: 72%
Mor, 2000, US	Convenience sample of women >60 y with BC stage I or II diagnosed between 1992 - 1997 at 6 hospitals in Providence, RI	350	1992-1997	81.9%/Age: 60-69 y: 88%; 7-79 y: 82%; ≥ 80 y: 77% S
Guadagnoli, 1997, US	Convenience sample postmenopausal women newly diagnosed ESBC node (+); stage I-II, 30 hospitals in MN	632	1993	71%/Age: 50-59 y: 61%; 60-69 y: 70%; 70-79 y: 81%; >80y: 74% S

McGlynn et al.'s random sample of women from 12 metropolitan US areas yielded data indicating 85.1% adherence to a process indicator asserting that women with invasive breast cancer that is node-positive, or node-negative and primary tumor at least 1 cm, should be treated with adjuvant systemic therapy, including combination chemotherapy (and/or tamoxifen, 20 mg/d) (Summary Table 18).[5] This indicator was supported by randomized controlled trial evidence. Randomly sampling cases by age from the SEER registries, Harlan et al. evaluated the appropriate use of any adjuvant systemic therapy for women with node-positive stages I-IIIA breast cancer, using the NIH Consensus Conference statement (1990) to define its standard.[134] They reported an overall adherence of 70%. Using medical records and interview data seen in light of the Early Breast Cancer Trialist Collaborative Group's meta-analytic results (1992), Guadagnoli et al. observed a rate of 92%.[130]

Summary Table 18: Adjuvant systemic therapy

Author, year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key Differences
Appropriate use: Women with invasive breast cancer that is node-positive, or node-negative and primary tumor ≥1 cm, should be treated with adjuvant systemic therapy to include combination chemotherapy (and/or tamoxifen, 20 mg/d)[IV]				
McGlynn, 2003, US	Random sample of women living in 12 US metropolitan areas	13	1998-2000	85.1%/NA
Appropriate use of any adjuvant systemic therapy in women with node (+) breast cancer[IV]				
Harlan, 2002, US	Random sample from population-based databases women stage I, II & IIIA BC diagnosed in 1987-1991 & 1995	7,724	1987-1991 & 1995	70%/Age: <51 y: 82%; 51-64 y: 73%; ≥65 y: 63%
Guadagnoli, 1997, US	Convenience sample postmenopausal women newly diagnosed ESBC; stage I-II, 30 hospitals in MN	632	1993	92%/Age: 50-59 y: 93%; 60-69 y: 96%; 70-79 y: 89%; >80y: 85% NS
Appropriate use of any adjuvant systemic therapy in women with node (-) breast cancer[IV]				
Harlan, 2002, US	Random sample from population-based databases women stage I, II & IIIA BC diagnosed in 1987-1991 & 1995	7,724	1987-1991 & 1995	53%/Age: <51 y: 45%; 51-64 y: 46%; >65 y: 41% NS/ By Race/ethnicity: White: 44%; Black: 40%; Other: 45%
Guadagnoli, 1997, US	Convenience sample postmenopausal women newly diagnosed ESBC; stage I-II, 30 hospitals in MN	632	1993	62%/Age: 50-59 y: 73%; 60-69 y: 67%; 70-79 y: 56%; >80y: 36% S

Harlan et al. failed to report an overall rate for the appropriate use of any adjuvant systemic therapy for node-negative breast cancers (Summary Table 18) although age-related data are presented in a later section. Guadagnoli et al. found that 62% of node-negative cases appropriately received adjuvant systemic therapy.

Two studies looked at the appropriate use of adjuvant systemic therapy (e.g., chemotherapy and/or hormone therapy) after breast-conserving surgery (Summary Table 19). Edge et al. assessed data exclusively from women at least 67 years of age and reported an overall rate of 70.7%.[126] White at al. observed a higher rate (84.1%) in a much larger sample of cases.[166]

Summary Table 19: Adjuvant systemic therapy

Author, year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key Differences
Appropriate use of adjuvant systemic therapy after breast-conserving surgery[IV]				
Edge, 2002, US	Convenience sample women ≥67 y stage T1-T2 (N0N1) M0, newly diagnosed invasive BC who underwent BCS	464	1995-1997	70.7% (CT: 10.1%; Tamoxifen: 89.9%)/NA
White, 2003, US	Convenience sample women BC node (+) stage I-II diagnosed in 1994	16,643	1994	84.1%/Age: <70 y: 84.9-88.7%; ≥70 y: 72%/Race/ethnicity: White: 85.3%; Black-Hispanic: 78.7%/ Payer: Government: 78.9%; Private: 87.6% S

The appropriate use of tamoxifen was investigated in four studies (Summary Table 20). The two larger ones by Mandelblatt et al.[146] and Guadagnoli et al.[131] observed similar adherence rates of 62% and 59% or 63%, the latter two referring to data from the states of Minnesota and Massachusetts, respectively. In a small sample, Ray-Coquard et al. observed a rate of 94%.[158] A small convenience sample studied by Cheung found adherence to be 28%.[116] Cornfeld et al. used the National Cancer Comprehensive Network guidelines (1999) to assess private practice case data from 11 oncologists, and observed a rate of 100%.[120]

Summary Table 20: Adjuvant systemic therapy

Author, year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key Differences
Appropriate use of tamoxifen[IV]				
Cheung, 1999, Hong Kong	Convenience sample of women with operable primary BC <5 cm; attended by the author	100	NR	28%/NA
Guadagnoli, 1998a, US	Convenience sample women ESBC (stage I or II) in 2 states of US (MA & MN)	2,575	1993-1995	63% (MA) vs. 59% (MN)/NA
Ray-Coquard, 1997, France	Random sample women with localized BC (DCIS to nonmetastatic invasive carcinoma) in a cancer center in Rhone Alpes Area	99	1995	94%/NA
Mandelblatt, 2002, US	National random sample, Medicare beneficiary women ≥67 y, with newly diagnosed primary, stage I–II BC	1,833	1994	62%/Race/ethnicity: Black: 58% (S); White: 66%
Cornfeld, 2001, US	Convenience sample women BC node (+) treated in the private practice of 11 oncologists	220	1999-2000 (9 mo)	100%/NA

Palazzi et al. evaluated data regarding the appropriate use of tamoxifen after breast-conserving surgery in premenopausal women with node-negative, intermediate risk, early stage breast cancer (Summary Table 21).[155] Using data from 12 centers, and appraised according to standards established at the St. Gallen Consensus Conference (1995), they noted an adherence rate of 33%. Palazzi et al's corresponding rate of appropriate use of tamoxifen for postmenopausal women with the same breast cancer characteristics was 59%. Guadagnoli et al.'s estimate (51%) was slightly lower in the same type of women.[130]

Summary Table 21: Adjuvant systemic therapy

Author, year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key Differences
Appropriate use of tamoxifen in premenopausal women with node (-), intermediate risk, breast cancer[IV]				
Palazzi, 2002, Italy	Convenience sample women ESBC, indication of RT after BCS for infiltrating carcinoma & known axillary LN status	1,547	1997	33%/NA
Appropriate use of tamoxifen in postmenopausal women with node (-), intermediate risk, breast cancer[IV]				
Palazzi, 2002, Italy	Convenience sample women ESBC, indication of RT after BCS for infiltrating carcinoma & known axillary LN status	1,547	1997	59%/NA
Guadagnoli, 1997, US	Convenience sample postmenopausal women newly diagnosed stage I-II BC, 30 hospitals (MN)	632	1993	51%/Age: 50-59 y: 52%; 60-69 y: 55%; 70-79 y: 51%; >80y: 34% S
Appropriate use of tamoxifen in postmenopausal women with node (-), high risk, estrogen receptor (+), breast cancer[IV]				
Sawka, 1997, Canada	Population- based women BC node (-) diagnosed in 1991, British Columbia	932	1993- 1998	NR/Age: 50-65%: 62.3%; >65 y: 56.5%
Palazzi, 2002, Italy	Convenience sample women ESBC, indication of RT after BCS for infiltrating carcinoma & known axillary LN status	1,547	1997	59%/NA
Appropriate use of tamoxifen in postmenopausal women with node (+), estrogen receptor (+) breast cancer[IV]				
Engel, 2002, Germany	Convenience sample women with any stage BC residing in 6 regions in Germany	NR (Total= 8,661)	1996-1998	NR (Region: 30.1%-61.5%)/NA
Palazzi, 2002, Italy	Convenience sample women ESBC, indication of RT after BCS for infiltrating carcinoma & known axillary LN status	1,547	1997	40%/NA

The appropriate use of tamoxifen in postmenopausal women with node-negative, high risk, estrogen receptor positive breast cancer was estimated by two groups (Summary Table 21). Palazzi et al. reported a rate of 59%,[155] whereas Sawka et al. noted data stratified by age.[161] Palazzi et al. then examined data from postmenopausal women diagnosed with node-positive, estrogen receptor positive breast cancer.[155] They found a 40% adherence rate. Engel et al. noted that the rate varied between 30.1% and 61.5% across six regions.[127]

The appropriate use of adjuvant chemotherapy and hormone therapy (tamoxifen) was investigated in three studies (Summary Table 22). Engel et al. reported that the rate varied from 9.1% to 32.2% across six regions,[127] whereas Sawka et al. noted a 6.6.% rate.[161] Du et al. primarily evaluated population-based tumor registry data,[125] and found a higher rate of adherence (9.6%) than was observed by Sawka et al.

Summary Table 22: Adjuvant systemic therapy

Author, year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key Differences
Appropriate use of chemotherapy and hormone therapy (tamoxifen)[IV]				
Engel, 2002, Germany	Convenience sample women with any stage BC residing in 6 regions Germany; node (+); HR (+); postmenopausal	NR (Total = 8,661)	1996-1998	NR (Region: 9.1%-32.2%)/NA
Sawka, 1997, Canada	Population- based women BC node (-) diagnosed in 1991, British Columbia	932	1993- 1998	6.6%/NA
Du, 2003, US	Population-based sample women BC ≥20 y stage I-IIIA treated & registered in New Mexico tumor registry	5,101	1991-1997	9.6%/Age: <45 y: 15.8%; 45-49 y: 17%; 50-54 y: 18.5%; 55-59 y: 11.7%; 60-64 y: 8%; 65-69 y: 5.4%; 70-74 y: 4%; ≥75 y: 0.8%
Appropriate use of chemotherapy and hormone therapy (tamoxifen) in premenopausal women, node (+), hormone receptor (+), breast cancer[IV]				
Engel, 2002, Germany	Convenience sample women with any stage BC residing in 6 regions in Germany	NR (Total = 8,661)	1996-1998	NR (Region: 10.3%-57.1%)/NA

Engel et al. reported variations in the rate, from 10.3% to 57.1% across six regions, with respect to the appropriate use of adjuvant chemotherapy and hormone therapy (tamoxifen) in premenopausal women with node-positive, hormone receptor positive breast cancer (Summary Table 22).[127]

Regarding the appropriate use of adjuvant chemotherapy, seven studies were conducted (Summary Table 23). However, Du et al.[125] and Du and Goodwin[124] likely overlap in terms of their population-based cases of breast cancer. The latter studied women at least 65 years of age diagnosed with all stages of breast cancer (I-IV). The former assessed data from women at least 20 years of age diagnosed with stage I-IIIA breast cancer. The adherence rate from the Du et al. study (28.7%),[125] with the wider range of cases defined by age, more than doubled the rate observed with respect to the other study (12.4%).[124] Mandelblatt et al. noted a rate of 9% in women at least 67 years of age.[146] The highest rates were observed in the Guadagnoli et al. study for women from Massachusetts (97%) and Minnesota (94%).[131] DeMichele et al. found that, of 208 chemo-eligible patients, only 74% (n = 156) received a recommendation to receive chemotherapy.[122] Of 132 women who were not eligible to receive chemotherapy, 11% received it.

Summary Table 23: Adjuvant systemic therapy

Author, year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key Differences
Appropriate use of chemotherapy[IV]				
Du, 2003, US	Population-based sample women BC ≥20 y stage I-IIIA treated & registered in New Mexico tumor registry	5,101	1991-1997	28.7%/Age: <45 y: 66%; 45-49 y: 54.9%; 50-54 y: 44.2 %; 55-59 y: 31%; 60-64 y: 18.1%; 65-69 y: 12.3%; 70-74 y: 7.1%; >75 y: 3.4%
Guadagnoli, 1998a, US	Convenience sample women ESBC (stage I or II) in 2 states of US (MA & MN)	2,575	1993-1995	97% (MA) vs. 94% (MN)/NA
Ray-Coquard, 1997, France	Random sample women with localized BC (DCIS to nonmetastatic invasive carcinoma) in a cancer center in Rhone Alpes Area	99	1995	85%/NA
Cheung, 1999, Hong Kong	Convenience sample of women with operable primary BC <5 cm; attended by the author	100	NR	30%/NA
DeMichele, 2003, US	Convenience sample women BC ≥50 y evaluated at UPCC 1993-1997 & eligible for adjuvant CT	Eligible: 208; Non-eligible: 132	1993-1997	74%; Non-eligible received: 11%/Age: 50-59 y: 74%; 60-69 y: 74%; 70-86 y: 70%
Du, 2001, US	Population-based sample women BC ≥65 y; stage I-IV (use of CT within 6 mo of Dx)	5,697	1991-1996	12.4%/Age: 65-69 y: 20.5%; 70-74 y: 13.9%; 75-79 y: 8.7%; ≥80 y: 3.3%
Mandelblatt, 2002, US	National random sample, Medicare beneficiary women ≥67 y, with newly diagnosed primary, stage I –II BC	1,833	1994	9%/Race/ethnicity: Black: 11% S; White: 7%

Palazzi et al. identified a rate of 59% for the appropriate use of chemotherapy in women with node-negative, high risk, estrogen receptor negative breast cancer (Summary Table 24). Du and Goodwin noted a lower rate of 17.9% for these women,[124] whereas Sawka et al. provided no overall adherence data.[161] Du and Goodwin reported a 2% adherence rate regarding the appropriate use of chemotherapy for women with node-negative, estrogen receptor positive breast cancer.[124] These patients were at least 65 years of age.

Summary Table 24: Adjuvant systemic therapy

Author, year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key Differences
Appropriate use of chemotherapy in women with node (-), high risk, estrogen receptor (-), breast cancer[IV]				
Sawka, 1997, Canada	Population- based women BC node (-) diagnosed in 1991, British Columbia	932	1993-1998	NR/Age: <50 y: 78.6%; 50-65 y: 19.1%
Palazzi, 2002, Italy	Convenience sample women ESBC, indication of RT after BCS for infiltrating carcinoma & known axillary LN status	1,547	1997	59%/NA
Du, 2001, US	Population-based sample women BC ≥ 65 y; stage I-IV (use of CT within 6 mo of Dx)	5,697	1996	17.9%/NA
Appropriate use of chemotherapy in women with node (-), estrogen receptor (+), breast cancer[IV]				
Du, 2001, US	Population-based sample women BC ≥ 65 y; stage I-IV (use of CT within 6 mo of Dx)	5,697	1996	2%/NA

Palazzi et al. reported an adherence rate of 55% regarding the appropriate use of chemotherapy for premenopausal women with node-negative, high risk, estrogen receptor positive breast cancer (Summary Table 25).[155]

Summary Table 25: Adjuvant systemic therapy

Author, year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key Differences
Appropriate use of chemotherapy in premenopausal women with node (-), high risk, estrogen receptor (+), breast cancer[IV]				
Palazzi, 2002, Italy	Convenience sample women ESBC, indication of RT after BCS for infiltrating carcinoma & known axillary LN status	1,547	1997	55%/NA
Appropriate use of chemotherapy in premenopausal women with node (+), estrogen receptor (-), breast cancer[IV]				
Engel, 2002, Germany	Convenience sample women with any stage BC residing in 6 regions in Germany	NR (Total = 8,661)	1996-1998	NR (Region: 63.6%-92.3%)/NA
Palazzi, 2002, Italy	Convenience sample women ESBC, indication of RT after BCS for infiltrating carcinoma & known axillary LN status	1,547	1997	90%/NA

Both Palazzi et al. and Engel et al. evaluated the appropriate use of chemotherapy for premenopausal women with node-positive, estrogen receptor negative breast cancer (Summary Table 25). While Engel et al. reported a range, for six regions, of 63.6% to 92.3%,[127] Palazzi et al. found that 90% of these women received the recommended therapy.[155]

Three studies examined data with respect to the appropriate use of chemotherapy for postmenopausal women with node-positive, estrogen receptor negative breast cancer (Summary Table 26). Engel et al. reported rates of 38.5% to 69.6% across six regions.[127] Palazzi et al.[155]

and Du and Goodwin[124] observed rates of 81% and 61.5%, respectively. Du and Goodwin also noted a rate of 27% concerning the appropriate use of chemotherapy in postmenopausal women with node-positive, estrogen receptor positive breast cancer.[124] The latter group included women who were at least 65 years of age.

Summary Table 26: Adjuvant systemic therapy

Author, year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key Differences
Appropriate use of chemotherapy in postmenopausal women with node (+), estrogen receptor (-), breast cancer[IV]				
Engel, 2002, Germany	Convenience sample women with any stage BC residing in 6 regions in Germany	NR (Total = 8,661)	1996-1998	NR (Region: 38.5%-69.6%)/NA
Palazzi, 2002, Italy	Convenience sample women ESBC, indication of RT after BCS for infiltrating carcinoma & known axillary LN status	1,547	1997	81%/NA
Du, 2001, US	Population-based sample women BC ≥ 65 y; stage I-IV (use of CT within 6 mo of Dx)	5,697	1996	61.5%/NA
Appropriate use of chemotherapy in postmenopausal women with node (+), estrogen receptor (+), breast cancer[IV]				
Du, 2001, US	Population-based sample women BC ≥ 65 y; stage I-IV (use of CT within 6 mo of Dx)	5,697	1996	27%/NA

Craft et al. evaluated data with regards to the appropriate use of chemotherapy for women, under the age of 50 years, with node-positive breast cancer (Summary Table 27).[121] They noted a 100% adherence rate in a very small sample (n = 27).

Summary Table 27: Adjuvant systemic therapy

Author, year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key Differences
Appropriate use of chemotherapy in women <50 years of age with node (+), breast cancer[IV]				
Craft, 2000, Australia	Convenience sample women newly diagnosed primary localized invasive BC treated in Australian capitol territory	27	1997-1998 (14 mo)	100%/NA
Appropriate use of chemotherapy &/or ovarian ablation in premenopausal women with node (+), estrogen receptor (+), breast cancer[IV]				
Engel, 2002, Germany	Convenience sample women with any stage BC residing in 6 regions in Germany	NR (Total = 8,661)	1996-1998	NR (Region: 42.9%-84.6%)/NA
Palazzi, 2002, Italy	Convenience sample women ESBC, indication of RT after BCS for infiltrating carcinoma & known axillary LN status	1,547	1997	NR (CT 73%; CT + OA: 18%; OA: 4%)/NA

Palazzi et al.[155] and Engel et al.[127] assessed data regarding the appropriate use of chemotherapy and/or ovarian ablation in premenopausal women with node-positive, estrogen receptor positive breast cancer (Summary Table 27). Palazzi et al provided data by treatment, with 73% of the women receiving chemotherapy, 4% ovarian ablation, and 18% both treatments. Engel et al. provided rates by region (42.9% to 84.6%).

Three studies assessed the adherence to the recommendation not to provide any adjuvant systemic treatment for women with node-negative, low risk breast cancer (Summary Table 28). Palazzi et al.,[155] Sawka et al.,[161] and Harlan et al.[134] reported adherence rates of 69%, 84.9%, and 52.2%, respectively.

Summary Table 28: Adjuvant systemic therapy

Author, year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key Differences
Appropriate decision not to provide adjuvant systemic therapy for women node (-), low risk, breast cancer[IV]				
Sawka, 1997, Canada	Population- based women BC node (-) diagnosed in 1991, British Columbia	932	1993- 1998	84.9%/Age: 50-65 y: 90.3%; >65 y: 85.9%
Palazzi, 2002, Italy	Convenience sample women ESBC, indication of RT after BCS for infiltrating carcinoma & known axillary LN status	1,547	1997	69%/NA
Harlan, 2002, US	Random sample from population-based databases women stage I, II & IIIA BC diagnosed in 1987-1991 & 1995	7,724	1987-1991 & 1995	52.2% (1995)/NA
Appropriate decision not to provide adjuvant systemic therapy for women > 65 years of age with high risk, estrogen receptor (-), breast cancer[IV]				
Sawka, 1997, Canada	Population- based women BC node (-) diagnosed in 1991, British Columbia	932	1993- 1998	82.1%/NA

Sawka et al. also evaluated the adherence to the standard of not providing adjuvant systemic therapy to women over the age of 65 years and diagnosed with node-negative, high risk, estrogen receptor negative breast cancer (Summary Table 28).[161] A rate of 82.1% was observed.

Ottevanger et al. investigated the quality of the delivery of care involving chemotherapy (Summary Table 29).[154] They reported performance data regarding the use of proper doses of chemotherapy, specifically where what is given is at least 85% of both the recommended dose intensity (DI) and the relative dose intensity (RDI) of the cyclophosphamide/methotrexate/5-fluorouracil (CMF) poly-chemotherapy regimen. The adherence to the DI standard was 78.9% and to the RDI, 58.7%.

Summary Table 29: Adjuvant systemic therapy

Author, year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key Differences
Quality of chemotherapy: proper doses administered (≥ 85% dose intensity [DI] & relative dose intensity [RDI]) of CMF[IV]				
Ottevanger, 2002, Netherlands	Population-based sample premenopausal women, node (+) BC; stages II to IIIA treated from 1988-1992 in 9 hospitals	254	1993-1998	78.9% (DI); 58.7% (RDI)/NA
Availability of office procedure manual used for chemotherapy administration[IV]				
Cornfeld, 2001, US	Convenience sample women BC treated in the private practice of 11 oncologists	220	1999-2000 (9 mo)	100%/NA

Cornfeld et al. investigated a structural variable pertaining to the availability of an office procedure manual to be used to administer chemotherapy (Summary Table 29).[120] They noted that all 11 oncologists' private practice offices had such a resource.

Numerous studies measured the QOL of those undergoing treatment for breast cancer. For example, using the validated Medical Outcomes Scale, short form (SF-36), and the Rotterdam symptom check list, Jansen et al. assessed the impact on QOL of post-operative radiotherapy in early breast cancer patients (Summary Table 30).[139] The SF-36 has been used across numerous healthcare domains, including cancer and breast cancer. However, the researchers were particularly interested in whether the internal (i.e., subjective) standards, values, or conceptualizations of the key domains defining QOL (e.g., fatigue) changed over time; and, whether possible shifts in these standards might render meaningless before and after-treatment comparisons of QOL data. The researchers observed the effects of scale recalibration that would have influenced QOL evaluations, leading to underestimation of the impact of radiotherapy on measures of fatigue and overall QOL.

Summary Table 30: QOL and patient satisfaction relating to treatment

Author, year, Location	Sample description	No. Eligible	Measurement Period	Results
Overall changes in QOL over time, before & after radiotherapy[lac]				
Jansen, 2000, Netherlands	Convenience sample women ESBC underwent surgery (BCS or mastectomy)	46	1997-1999	38% (worse); 40% (stable); 22% (improved)/NA
Hassey 2000, US	Convenience sample women ESBC beginning a course of RT after BCS at a hospital in Northeast. 21-45 y; newly diagnosed; not undergoing CT or HT	23	6 mo	NR (NS changes over time in QLI scales)/NA

As measures of QOL, Hassey and Lafferty employed the Ferrans QOL Index (QLI), Cancer version (e.g., psychological/spiritual functioning), the Psychosocial Adjustment to Illness Scale (PAIS: e.g., sexual functioning), and the Adaptation to the Survivorship Experience tool (ASE: e.g., adaptation to the meaning of cancer) (Summary Table 30).[123] The first and third instruments have been used to assess possible changes brought about by cancer treatment. Their results suggested certain changes in QOL, psychosocial adjustment, and adaptation to

survivorship experiences over time in a sample of women receiving radiotherapy following breast-conserving surgery.

Health-related QOL was measured over time by Osoba and Burchmore using the validated European Organization for Research and Treatment of Cancer core QOL Questionnaire (EORTC QLQ-C30) (Summary Table 31).[153] It was used to assess the domains of global QOL, physical, role and social functioning, and fatigue. Respondents were women in treatment with trastuzumab for metastatic breast cancer. The results suggested that trastuzumab was not associated with worsening health-related QOL. Perez et al. performed a longitudinal study of health-related QOL and utility measures (time trade-off).[156] The QOL measures were the Spitzer QOL Index and Uniscale, and both had previously demonstrated construct validity in patients with breast cancer. Participants were women presenting with symptomatic, metastatic breast cancer. Results were expressed only in terms of the relationship of the two key constructs of QOL and time trade-off.

Summary Table 31: QOL and patient satisfaction relating to treatment

Author, year, Location	Sample description	No. Eligible	Measurement Period	Results
Change in QOL in women with metastatic breast cancer[lac]				
Osoba, 1999, Canada & US	Convenience sample women progressive HER-2-overexpressing metastatic BC had been previously treated with CT (phase II) or had not have previous cytotoxic CT (phase III) received trastuzumab	154	32 wks (NR)	100%/Phase of study: Phase II: no apparent worsening of scores; Phase III: NS changes
Perez, 2001, New Zealand UK	Convenience sample women presenting at Dunedin Hospital, NZ, with metastatic symptoms BC	38	1 y (NR)	NR/NA
Women with a significant improvement in QOL in clinical phases of breast cancer[lac]				
Chie, 1999, China	Convenience sample women diagnosed or treated for BC in the breast surgery; RT & oncology outpatients departments; or in general surgical wards of National Taiwan University Hospital	115	1997 (2 mo)	NR/NA
Change in QOL by time and treatment arm in postmenopausal, node (-) breast cancer women who underwent adjuvant therapy[la]				
Bernhard, 1997, Netherlands	Convenience sample pre- & postmenopausal women with operable BC	312	1993-1995	NS in scales of physical well-being; mood; appetite at 1, 3 & 6 mo/NA

Chie et al. utilized the SF-36, QLQ-C30, questions about utility to be responded to using a visual analogue scale, and other instruments examining constructs such as standard gamble and time trade-off (Summary Table 31).[117] Significant differences were observed for most QOL scores among women across various clinical stages of breast cancer. Bernhard et al. employed the Linear Analogue Self-Assessment (LASA) format to assess indicators of QOL, including physical well-being, mood and appetite.[110] This format has been validated for use in studies with

cancer patients. Results indicated nonsignificant changes over time in the indices of physical well-being, mood, and appetite.

Molenaar et al. employed the Medical Outcomes Study 20 (MOS20) QOL tool as well as the EORTC QLQ-BR23 (Summary Table 32), the latter designed to assess breast cancer-specific functioning and symptoms (i.e., body image, sexual functioning, arm symptoms, breast symptoms, systemic therapy symptoms, and future perspective).[148] The psychometric soundness of the breast cancer specific instrument had been demonstrated previously. On some measures (e.g., arm symptoms), it was found that patients exposed to a CD-ROM decision support fared better than controls.

Summary Table 32: QOL and patient satisfaction relating to treatment

Author, year, Location	Sample description	No. Eligible	Measurement Period	Results
Change in QOL over time[lac]				
Molenaar, 2001, Netherlands	Convenience sample women newly diagnosed with stage I & II BC eligible for either BCS or mastectomy in 3 Dutch hospitals	167	1996-1998	Generic QOL scale & specific QOL scale: positive effect (CDROM) 0, 3 & 9 mo; ND/NA
Bower, 2000, US	Convenience sample women ESBC (stage 0-II); diagnosed <5 y; completed adjuvant therapy; currently disease-free; only treated with tamoxifen (cancer survivors)	1,957	1994-1997	NR/Energy/fatigue: 60; Physical functioning: 80.35; Role limitation-physical: 75.80; Emotional well-being: 75; Role limitation-emotional: 77; Social functioning: 86; Bodily pain: 78.60; General health: 73
Frazer, 1998, US	Convenience sample women ESBC diagnosed in 1993 and treated by surgery and HT at MDACCO, Orlando, Florida	70	1993-1996	NS changes over time in all the subscales and overall/NA
Mor, 1994, US	Convenience sample women BC from 2 research trials	262	NR	NR/Age: 24-54 y: 67.6%; >55 y: 71%

In addition to the RAND 36-item Health Survey (MOS SF-36) and a few other instruments, Bower et al. included the Breast Cancer Prevention Trial Symptom Checklist (e.g., symptom intensity) in a study of the occurrence of fatigue in a large sample of breast cancer survivors, compared with general population norms (Summary Table 32).[113] The authors found that, although most women did not experience heightened levels of fatigue relative to women in the general population, a subset of women did experience intense fatigue while being treated with tamoxifen. Frazer et al. used the validated, 39-item, Guttman scaled Health Status Questionnaire to assess breast as well as prostate cancer patients' experience over a three year period while being treated with surgery and hormone therapy.[129] They reported no statistically significant intergroup or intragroup differences between responses of patients with breast cancer and prostate cancer.

Mor et al. collected, then aggregated QOL survey data across two studies from breast cancer patients at various stages of the disease process, to assess the effect of age on women's perceptions of the psychosocial impact of their illness (Summary Table 32).[149] They evaluated psychosocial status using a subscale of the MOS short form General Health Survey (SF-36) called the Mental Health Inventory (MHI-5). A treatment Impact Scale was developed by the

investigators to assess the perceived level of difficulty or disruption that treatment caused in their patients' daily routine and functioning. Overall, the results suggested age-related differences where, despite being advantaged relative to older women in terms of socioeconomic status, social support availability and extent of the disease, younger women experienced the impact of their illness more negatively (e.g., higher levels of perceived emotional and financial distress).

Molenaar et al. also evaluated breast cancer patients' satisfaction with their treatment choice (Summary Table 33).[148] Measures were developed, including two multi-item instruments to assess patients' satisfaction with the amount, clarity, and usefulness of the information they had received, and, to indicate their satisfaction with treatment-specific information (e.g., radiotherapy, local recurrence). In addition, using most of the Decisional Conflict Scale in addition to the full Patient Satisfaction Questionnaire, satisfaction with the decision-making process and with care were measured, respectively. Findings indicated that, relative to those patients not receiving information via a CD-ROM resource, those who did were more satisfied with breast cancer-specific information, the decision-making process, and communication.

Summary Table 33: QOL and patient satisfaction relating to treatment

Author, year, Location	Sample description	No. Eligible	Measurement Period	Results
Satisfaction of women with breast cancer with the treatment choice[Iac]				
Molenaar, 2001, Netherlands	Convenience sample women newly diagnosed with stage I & II BC eligible for either BCS or mastectomy in 3 Dutch hospitals	167	1996-1998	(+) Effect (CDROM) 0, 3 & 9 mo; ND/NA
Keating, 2001, US	Convenience sample women diagnosed with stage I & II BC at 17 hospitals (MA) & 30 hospitals (MN)	792 (MA); 1,634 (MN)	1993-1995	Very satisfied: 80% (MA) vs. 76% (MN)/NA
Participation of women with breast cancer in decision-making as much as they wanted[IV]				
Keating, 2001, US	Convenience sample women diagnosed with stage I & II BC at 17 hospitals (MA) & 30 hospitals (MN)	792 (MA); 1,634 (MN)	1993-1995	83% (MA) vs. 81% (MN)/NA
Received enough information about surgery and radiotherapy[IV]				
Keating, 2001, US	Convenience sample women diagnosed with stage I & II BC at 17 hospitals (MA) & 30 hospitals (MN)	792 (MA); 1,634 (MN)	1993-1995	80% (MA) vs. 80% (MN)/NA

Employing 5-point Likert, as well as other, scales specially developed for their study of women with stage I-II breast cancer in the states of Massachusetts and Minnesota, Keating et al. measured patients' satisfaction with their treatment choice, participation in the decision-making process to the extent they wished, and the amount of information received concerning surgery and radiotherapy (Summary Table 33).[140] The results suggest that collaborative care may benefit early stage breast cancer patients with respect to treatment selection and satisfaction.

Within the general category of quality measurement, Cornfeld et al. assessed adherence to the following structural indicator across the private practices of eleven oncologists: board certified MDs in medical oncology (Summary Table 34).[120] They noted a rate of 100%. These

investigators also performed another measurement concerning structure, observing that all participant oncologists had their documentation of Continuing Medical Education credits for the two-year period preceding an audit.

Summary Table 34: General category

Author, year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key Differences
Board certified medical doctors in medical oncology[IV]				
Cornfeld, 2001, US	Convenience sample women BC treated in the private practice of 11 oncologists	220	1999-2000 (9 mo)	100%/NA
Documentation of Continuing Medical Education credits for the 2 years preceding audit[IV]				
Cornfeld, 2001, US	Convenience sample women BC treated in the private practice of 11 oncologists	220	1999-2000 (9 mo)	100%/NA

Bickell et al. reported a rate of adherence of 64% to the standard that patients with an established diagnosis of at least stage IB breast cancer be referred to an oncologist for treatment (Summary Table 35).[111] Cheung found that all 100 women with breast cancer <5 cm had been given the opportunity to see a nurse specializing in breast cancer.[116] Bickell et al. found varying evidence in tumor registries and other data sources across four hospitals (65% to 100%), indicating that women with stage I-II breast cancer had had a discussion concerning surgical options (mastectomy vs. breast-conserving surgery).[111] Molenaar et al. noted a 100% adherence rate for this quality indicator in their convenience sample of Dutch women newly diagnosed with stage I-II breast cancer and eligible for breast-conserving surgery or mastectomy.[148]

Summary Table 35: General category

Author, year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key Differences
Referral to oncologist for treatment[IV]				
Bickell, 2000, US	Convenience sample women BC stage I-II, receiving definitive surgical treatment in 4 hospitals in NY	723	1995-1996	64%/NA
Women with breast cancer given the opportunity to see a breast cancer specialist nurse[IV]				
Cheung, 1999, Hong Kong	Convenience sample women with operable primary BC <5 cm; attended by the author	100	NR	100% (Standard: 100%)/NA
Evidence of discussion about surgical options[IV]				
Bickell, 2000, US	Convenience sample women BC stage I-II, receiving definitive surgical treatment in 4 hospitals in NY	723	1995-1996	NR (Hospital: 65-100%)/NA
Molenaar, 2001, Netherlands	Convenience sample women newly diagnosed with stage I & II BC eligible for either BCS or mastectomy in 3 Dutch hospitals, patient preference measured	167	1996-1998	100%

Three studies evaluated whether or not women with operable breast cancer were admitted for an operation within 21 days of the surgical decision to operate for therapeutic purposes (Summary Table 36). The standard was established as ≥90% based on BASO's (1992)

guidelines. McCarthy et al.[147] and Cheung[116] reported adherence rates of 90.4% and 93%, respectively. Sauven et al. only provided data by year, observing that the rate decreased from 82% in 1996/1997, to 77% in 1999/2000.[160]

Summary Table 36: General category

Author, year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key Differences
≥90% of women admitted for an operation within 21 days of the surgical decision to operate for therapeutic purposes[IV]				
Sauven, 2003, UK	Population-based sample BC women detected by screening in UK, Wales, Scotland & Northern Ireland	43,500	1996-2001	NR/Overall by y (range): 77-82%
Cheung, 1999, Hong Kong	Convenience sample women with operable primary BC <5 cm; attended by the author	100	NR	93%/NA
McCarthy, 1997,UK	Convenience sample women operable BC, <70 y treated at Nottingham City Hospital's	83	1994	90.4%/NA

Four studies assessed adherence to overall treatment sequences according to guidelines, including the initial examination, surgery, radiotherapy, chemotherapy, hormone therapy, and followup (Summary Table 37). Across two random samples, one population-based sample, and one convenience sample, the rates ranged from 36% to 81%.[136,150,158,159] The two random samples drawn by Ray-Coquard et al. provided the lowest rates, at 36% and 54%.[158,159] When Ray-Coquard et al.'s more recent study evaluated data by category of care, they noted that adherence was highest for surgery (94%) and lowest for radiotherapy (77%).

Summary Table 37: General category

Author, year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key Differences
Appropriate use of treatment sequences according to guidelines (including surgery; radiotherapy; chemotherapy; hormone therapy; initial examination; and followup)[IV]				
Mor, 2000, US	Convenience sample women >60 y with BC stage I or II diagnosed between 1992 - 1997 at 6 hospitals in Providence, RI	350	1992-1997	72.9%/Age: 60-69 y: 89%; ≥80 y: 50% S
Ray-Coquard, 2002, France	Random sample women localized BC (in situ or invasive) treated in the cancer network in Rhone-Alpes region	346	1996	36% (Initial examination: 86%; Surgery: 94%; CT: 78%; RT: 77%; HT: 79%; Followup: 81%)/NA
Ray-Coquard, 1997, France	Random sample women with localized BC (DCIS to nonmetastatic invasive BC) in a cancer center in Rhone Alpes Area	99	1995	54%/NA
Hislop, 2003, Canada	Population-based sample women any stage BC diagnosed in British Columbia	NR (Total = 1,159)	1995	81% (Extent of disease: LCIS: 78%; DCIS: 71%; Metastatic: 73%; M0 invasive: 83%)/NA

Three studies examined data with respect to the appropriate use of definitive locoregional therapy (i.e., total mastectomy plus axillary lymph node dissection, or, breast-conserving surgery plus axillary lymph node dissection and radiotherapy) (Summary Table 38). Nattinger et al.[152] and Silliman et al.[163] observed similar adherence rates of 77.2% and 78%, respectively, in spite of great size differences in their samples. Hebert-Croteau et al. provided no overall data yet age-related figures are presented in response to Question 2c.[135]

Summary Table 38: General category

Author, year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key Differences
Appropriate use of definitive locoregional therapy (total mastectomy + axillary lymph node dissection, or, breast-conserving surgery + axillary lymph node dissection + radiotherapy) IV				
Nattinger, 2000, US	National population-based sample women ≥30 y at the time of first diagnosis of invasive local or regional unilateral BC	144,759	1995	78%/NA
Hebert-Croteau, 1999, Canada	Random sample newly diagnosed stage I-II BC women ≥50 y treated in Quebec	1,174	1993-1994	NR/Age: 50-69 y: 83.5%; ≥70 y: 48.7%
Silliman, 1999, US	Convenience sample women ≥55 y newly diagnosed stage I or II BC treated 1 center in Boston	303	NR	77.2% (Surgery type: BCS + RT: 56%; Mastectomy: 22%)/ Income: ≤U$14,999: 55%; 15,000-29, 999: 85%; 30,000-49,999: 91%; ≥50,000: 87%/Education: < high school: 55%; high school: 75%; some college: 83%; college: 82%
Appropriate use of alternative definitive therapy (radiotherapy after breast-conserving surgery + axillary lymph node dissection or adjuvant treatment) IV				
Hebert-Croteau, 1999, Canada	Random sample newly diagnosed stage I-II BC women ≥50 y treated in Quebec	1,174	1993-1994	NR/Age: 50-69 y: 90.9%; ≥70 y: 60.9%
Silliman, 1999, US	Convenience sample women ≥55 y newly diagnosed stage I or II BC treated 1 center in Boston	303	NR	51.8%/Age: 55-64 y: 50%; 65-74 y: 41%; 75-84 y: 9%
Cases not receiving recommended treatment (radiotherapy after breast-conserving surgery or systemic therapy) due to system failure IV				
Bickell, 2003, US	Convenience sample women ESBC who had treatment underuse; not RT or adjuvant therapy recommended when indicated	44	1998-1999	32%/NA
Appropriate use: Women with metastatic cancer should be offered hormonal therapy, chemotherapy, and/or enrollment in a clinical trial with documentation of informed consent, within 6 weeks of the identification of metastases IV				
McGlynn, 2003, US	Random sample of women living in 12 US metropolitan areas	4	1998-2000	82.6%/NA

Hebert-Croteau et al. and Silliman et al. also examined the appropriate use of alternative, definitive therapy (i.e., radiotherapy after breast-conserving surgery plus axillary lymph node dissection, or, adjuvant treatment) (Summary Table 38).[135,163] Only Silliman and colleagues reported an overall rate (51.8%).[163] Bickell et al. evaluated a convenience sample of early stage

breast cancer patients who did not receive physician recommended treatment (radiotherapy after breast-conserving surgery, or, systemic therapy) due to system failure.[112] They noted that, of 44 women, 32% of cases experienced system failure. Finally, McGlynn et al.'s random sample of women from 12 metropolitan US areas yielded data indicating 82.6% adherence to a process indicator asserting that women with metastatic breast cancer should be offered hormonal therapy, chemotherapy, and/or enrollment in a clinical trial with documentation of informed consent, within 6 weeks of the identification of metastases (Summary Table 38).[5] This indicator was supported by observational study data and expert opinion.

2b: For what treatment-related purposes have these quality measures been used? The evidence is organized according to three broad categories of purpose. The measurements relating to the following quality indicators were undertaken to achieve external quality oversight:

- appropriate use: "Women treated with breast-conserving surgery should begin radiation therapy within 6 weeks of completing either of the following: the last surgical procedure on the breast (including reconstructive surgery that occurs within 6 weeks of primary resection) or chemotherapy, if patient receives adjuvant chemotherapy, unless wound complications prevent the initiation of treatment" (radiotherapy);[5]

- "quality of radiotherapy after breast-conserving surgery" (radiotherapy);[138]

- "appropriate use of radiotherapy after mastectomy" (radiotherapy);[127,128,138]

- "quality of radiotherapy via planning on a dedicated simulator" (radiotherapy);[166]

- "quality of radiotherapy: done five days per week" (radiotherapy);[166]

- "quality of radiotherapy: homogeneous dose distribution of radiotherapy" (radiotherapy);[162,166]

- "quality of radiotherapy: use of wedges on tangent breast fields" (radiotherapy);[162,166]

- "appropriate use of radiotherapy on axilla following axillary lymph node dissection to deal with increased risk of local recurrence (i.e. extracapsular extension; ≥ 4 positive nodes)" (radiotherapy);[114,138,154]

- "appropriate use of parasternal radiotherapy for tumors located in the medial part of breast" (radiotherapy);[154]

- "appropriate use of palliative radiotherapy for women with progression or recurrence" (radiotherapy);[128]

- "quality of radiotherapy: both tangents fields treated daily" (radiotherapy);[162]

- “quality of radiotherapy: receiving 4,500-5,000 cGy total breast dose given in 180-200 cGy fractions” (radiotherapy);[162]

- “quality of radiotherapy: electron beam breast radiation used” (radiotherapy);[162]

- “appropriate use of adjuvant systemic therapy after breast-conserving surgery” (adjuvant systemic therapy);[126,166]

- “appropriate use of any adjuvant systemic therapy in women with node positive breast cancer” (adjuvant systemic therapy);[130,134]

- “appropriate use of any adjuvant systemic therapy in women with node negative breast cancer” (adjuvant systemic therapy);[130,134]

- “appropriate use of tamoxifen in premenopausal women with node negative, intermediate risk, breast cancer” (adjuvant systemic therapy);[155]

- “appropriate use of tamoxifen in postmenopausal women with node negative, intermediate risk, breast cancer” (adjuvant systemic therapy);[130,155]

- “appropriate use of tamoxifen in postmenopausal women with node negative, high risk, estrogen receptor positive, breast cancer” (adjuvant systemic therapy);[155,161]

- “appropriate use of tamoxifen in postmenopausal women with node positive, estrogen receptor positive, breast cancer” (adjuvant systemic therapy);[127,155]

- “ appropriate use of chemotherapy and hormone therapy (tamoxifen)” (adjuvant systemic therapy);[125,127,161]

- “appropriate use of chemotherapy and hormone therapy (tamoxifen) in premenopausal women with node positive, hormone receptor positive, breast cancer” (adjuvant systemic therapy);[127]

- “appropriate decision not to provide adjuvant systemic therapy for women with node negative, low risk breast cancer” (adjuvant systemic therapy);[134,155,161]

- “appropriate use of chemotherapy in premenopausal women with node negative, high risk, estrogen receptor positive, breast cancer” (adjuvant systemic therapy);[155]

- “appropriate use of chemotherapy in women with node negative, high risk, estrogen receptor negative, breast cancer” (adjuvant systemic therapy);[124,155,161]

- “appropriate use of chemotherapy in premenopausal women with node positive, estrogen receptor negative, breast cancer” (adjuvant systemic therapy);[127,155]

- “appropriate use of chemotherapy and/or ovarian ablation in premenopausal women with node positive, estrogen receptor positive, breast cancer” (adjuvant systemic therapy);[127,155]

- “appropriate use of chemotherapy in postmenopausal women with node positive, estrogen receptor negative, breast cancer” (adjuvant systemic therapy);[124,127,155]

- “quality of chemotherapy: proper doses administered (≥85% dose intensity [DI] and of relative dose intensity [RDI]) of CMF” (adjuvant systemic therapy);[154]

- “appropriate use of chemotherapy in postmenopausal women with node positive, estrogen receptor positive, breast cancer” (adjuvant systemic therapy);[124]

- “appropriate use of chemotherapy in women with node negative, estrogen receptor positive, breast cancer” (adjuvant systemic therapy);[124]

- “appropriate decision not to provide adjuvant systemic therapy for women older than 65 years of age with high risk, estrogen receptor negative, breast cancer” (adjuvant systemic therapy);[161]

- appropriate use: “Women with invasive breast cancer that is node-positive, or node-negative and primary tumor $\geq$ 1 cm, should be treated with adjuvant systemic therapy to include combination chemotherapy (and/or tamoxifen, 20mg/d)” (adjuvant systemic therapy);[5]

- “appropriate use of definitive locoregional therapy (total mastectomy with ALND, or breast-conserving surgery with ALND and radiotherapy)” (general);[135,152,163]

- “appropriate use of alternative definitive therapy (radiotherapy after breast-conserving surgery with ALND or adjuvant treatment)” (general);[135,163]

- “referral to oncologist for treatment” (general);[111]

- “evidence of discussion about surgical options” (general);[111,148]

- appropriate use: “Women with metastatic breast cancer should be offered hormonal therapy, chemotherapy, and/or enrollment in a clinical trial with documentation of informed consent within 6 weeks of the identification of metastases” (general);[5]

- “no breast-conserving surgery or mastectomy in metastatic disease” (surgery).[136]

- appropriate use: “Women with stage I or stage II breast cancer should be offered a choice of modified radical mastectomy or breast-conserving surgery, unless contraindications to breast-conserving surgery are present” (surgery);[5]

The measurements relating to the following quality indicators were undertaken to achieve internal quality improvement:

- “women undergoing breast-conserving surgery should have no more than two therapeutic operations” (breast-conserving surgery);[116]

- “availability of office procedure manual used for chemotherapy administration” (adjuvant systemic therapy);[120]

- “appropriate use of chemotherapy in women younger than 50 years of age, with node positive, breast cancer” (adjuvant systemic therapy);[121]

- “overall changes in QOL over time, before and after radiotherapy” (QOL);[123,139]

- “change in QOL in women with metastatic breast cancer” (QOL);[153,156]

- “women with a significant improvement in QOL in clinical phases of breast cancer” (QOL);[117]

- “change in QOL by time and treatment arm in postmenopausal, node negative breast cancer women who underwent adjuvant therapy” (QOL);[110]

- “change in QOL over time” (QOL);[113,129,148,149]

- “satisfaction of women with breast cancer with the treatment choice” (patient satisfaction);[140,148]

- “participation of women with breast cancer in decision-making as much as they wanted” (patient satisfaction);[140]

- “received enough information about surgery and radiotherapy” (patient satisfaction);[140]

- “board certified medical doctors in medical oncology” (general);[120]

- “documentation of Continuing Medical Education credits for the two years preceding each audit” (general);[120]

- “women with breast cancer given the opportunity to see a breast cancer specialist nurse” (general);[116]

- "cases not receiving recommended treatment (radiotherapy after breast-conserving surgery or systemic therapy) due to system failure" (general).[112]

Some studies evaluating the performance of a given quality indicator varied in terms of the treatment-related purposes they were intended to achieve. References to studies designed to achieve each purpose are made explicit:

- "appropriate use of all surgery" (surgery); both internal quality improvement and external quality oversight;[158]

- "appropriate use of breast-conserving surgery" (breast-conserving surgery); internal quality improvement;[116] external quality oversight[111,114,127,132,135,136,140,142-146,151,154,164-166] and both internal quality improvement and external quality oversight;[150,158]

- "appropriate use of mastectomy" (mastectomy); internal quality improvement[116] and external quality oversight;[154]

- "appropriate use axillary lymph node dissection" (axillary lymph node dissection); internal quality improvement[121] and external quality oversight;[111,114,126,131,135,146,152]

- "appropriate use of radiotherapy" (radiotherapy); both internal quality improvement and external quality oversight;[158] and external quality oversight alone;[128,164]

- "appropriate use of radiotherapy after breast-conserving surgery" (radiotherapy); internal quality improvement;[121] external quality oversight[111,126-128,131,132,135,136,142,143,145,146,151,152,154,164,166]; and both internal quality improvement and external quality oversight;[150]

- "regional recurrence needing further surgery or radiotherapy" (radiotherapy); internal quality improvement[116] and external quality oversight;[128]

- "appropriate use of tamoxifen (hormone therapy)" (adjuvant systemic therapy); internal quality improvement;[116,120] external quality oversight;[131,146] and both internal quality improvement and external quality oversight;[158]

- "appropriate use of any adjuvant systemic therapy (chemotherapy and/or hormone therapy)" (adjuvant systemic therapy); internal quality improvement;[121] external quality oversight;[111,130,135,163] and both internal quality improvement and external quality oversight;[150]

- "appropriate use of chemotherapy" (adjuvant systemic therapy); internal quality improvement[116] and external quality oversight;[122,124,125,131,146] and both internal quality improvement and external quality oversight;[158]

- "appropriate use of treatment sequences according to guidelines (including surgery, radiotherapy, chemotherapy, hormone therapy, initial examination and followup)" (general); both internal quality improvement and external quality oversight;[150,158] and external quality oversight;[136,159]

- "at least 90% of women admitted for an operation within 21 days of the surgical decision to operate for therapeutic purposes" (general); internal quality improvement,[116,147] and external quality oversight.[160]

2c: What quality measures, if any, are available to assess differences in the quality of treatment of breast cancer in women related to patients' age, race, socioeconomic status, and ethnicity? The reader is referred to the summary tables provided in response to Questions 2 and 2a. While quality measures to assess any of the above-noted differences have not been developed scientifically to achieve this goal, a number of treatment-related quality measurements have been conducted which capture such disparities. Results relating to specific quality indicators are reported from studies having conducted tests of significance to highlight possible gaps in care.

Regarding age, a number of studies observed that, relative to older women, younger women with breast cancer were significantly (statistically) more likely to receive the following treatment-related care:

- "appropriate use of breast-conserving surgery" (breast-conserving surgery) (<70 vs. >70 years in MN only)[132];(decreasing trend in older groups);[142,143] (50-69 vs. >70 years);[135]

- "appropriate use of axillary lymph node dissection" (axillary lymph node dissection) (<70 vs. >70 years);[114,131] (50-69 vs. >70 years);[135] (decreasing trend in older groups);[126]

- "appropriate use of radiotherapy after breast-conserving surgery" (radiotherapy) (<80 vs. >80 years);[143] (MA: <50 vs. 50-59 & >70 years; MN: <50 vs. >80 years);[131] (50-69 vs. >70 years);[135] (<70 vs. >70 years);[151] (60-69 vs. 70-79 vs. >80 years);[150]

- "appropriate use of adjuvant systemic therapy after breast-conserving surgery" (adjuvant systemic therapy) (< 70 vs. > 70 years);[166]

- "appropriate use of any adjuvant systemic therapy in women with node (-) breast cancer" (adjuvant systemic therapy) (decreasing trend in older groups);[130]

- "appropriate use of tamoxifen in postmenopausal women with node (-), intermediate risk, breast cancer" (hormone therapy) (<80 vs. >80 years);[130]

- "appropriate use of any adjuvant systemic therapy" (adjuvant systemic therapy) (60-69 vs. 70-79 vs. >80 years);[150]

- “appropriate use of chemotherapy” (chemotherapy) (decreasing trend in older groups);[122,125]

- “appropriate use of chemotherapy and hormone therapy (tamoxifen)” (adjuvant systemic therapy) (decreasing trend in older groups);[125]

- “appropriate use of treatment sequences according to Guidelines (including surgery; radiotherapy; chemotherapy; hormone therapy; initial examination; and followup)” (general) (60-69 vs. >80 years);[150]

- “appropriate use of definitive locoregional therapy (total mastectomy + axillary lymph node dissection, or, breast-conserving surgery + axillary lymph node dissection + radiotherapy)” (general) (50-69 vs. >70 years);[135]

- “appropriate use of alternative definitive therapy (radiotherapy after breast-conserving surgery + axillary lymph node dissection or adjuvant treatment)” (general) (50-69 vs. >70 years);[135] (decreasing trend in older groups).[163]

No studies were found to demonstrate that, relative to younger women, older women with breast cancer were significantly more likely to receive specific types of treatment-related care. In studies where tests of statistical significance were performed, no differences were observed with respect to age for the following recommended types of treatment-related care:

- “quality of radiotherapy via planning on a dedicated simulator” (radiotherapy) (<70 vs. >70 years);[166]

- “quality of radiotherapy: done 5 days/week” (radiotherapy) (<70 vs. >70 years);[166]

- “quality of radiotherapy: homogenous dose distribution of radiotherapy” (radiotherapy) (<70 vs. >70 years);[166]

- “quality radiotherapy: use of wedges on tangent breast fields” (radiotherapy) (<70 vs. >70 years);[166]

- “appropriate use of adjuvant systemic therapy after breast-conserving surgery” (adjuvant systemic therapy) (<70 vs. >70 years);[130]

- “appropriate use of any adjuvant systemic therapy in women with node (-) breast cancer” (adjuvant systemic therapy) (<51 vs. 51-64 vs. >65 years);[134]

- “appropriate use of any adjuvant systemic therapy” (adjuvant systemic therapy) (50-69 vs. >70 years);[135]

- “change (improvement) in scales of QOL over time” (QOL) (24-54 vs. >55 years).[149]

With respect to race or ethnicity, a number of studies observed that, relative to white women, black women were significantly more likely to receive these types of treatment-related care:

- "appropriate use of axillary lymph node dissection" (axillary lymph node dissection);[146]
- "appropriate use of chemotherapy" (chemotherapy).[146]

On the other hand, some studies reported that, relative to black women, white women were significantly more likely to receive these types of treatment-related care.

- "appropriate use of radiotherapy after breast-conserving surgery" (radiotherapy);[146,151,166]
- "appropriate use of adjuvant systemic therapy after breast-conserving surgery" (adjuvant systemic therapy);[166]
- "appropriate use of tamoxifen" (hormone therapy).[146]

In studies where tests of statistical significance were performed, no differences were observed with respect to race or ethnicity for the following types of care:

- "appropriate use of breast-conserving surgery" (breast-conserving surgery);[143,146,151,166]
- "appropriate use of axillary lymph node dissection" (axillary lymph node dissection);[126]
- "appropriate use of radiotherapy after breast-conserving surgery" (radiotherapy);[143]
- "quality of radiotherapy via planning on a dedicated simulator" (radiotherapy);[166]
- "quality of radiotherapy: done 5 days/week" (radiotherapy);[166]
- "quality of radiotherapy: homogenous dose distribution of radiotherapy" (radiotherapy);[166]
- "quality of radiotherapy: use of wedges on tangent breast fields" (radiotherapy);[166]
- "appropriate use of any adjuvant systemic therapy in women with node (-) breast cancer" (adjuvant systemic therapy).[134]

Regarding income-related definitions of socioeconomic status, a number of studies observed that, relative to women with lower annual incomes, women with higher annual incomes were significantly more likely to receive the following treatment-related care:

- "appropriate use of breast-conserving surgery" (breast-conserving surgery);[136]
- "appropriate use of any adjuvant systemic therapy" (adjuvant systemic therapy);[163]
- "appropriate use of definitive locoregional therapy (total mastectomy + axillary lymph node dissection, or, breast-conserving surgery + axillary lymph node dissection + radiotherapy)" (general).[163]

No studies were identified wherein, relative to women with higher annual incomes, those with lower annual incomes were significantly more likely to receive specific treatment-related types of care. In studies where tests of statistical significance were performed, no differences were observed with respect to annual income for the "appropriate use of breast-conserving surgery" (breast-conserving surgery).[132]

With respect to education-related definitions of socioeconomic status, a number of studies observed that, relative to women with a lower educational level, women with a higher educational level were significantly more likely to receive treatment-related care.

- "appropriate use of breast-conserving surgery" (breast-conserving surgery);[142]
- "appropriate use of any adjuvant systemic therapy" (adjuvant systemic therapy);[163]
- "appropriate use of definitive locoregional therapy (total mastectomy + axillary lymph node dissection, or, breast-conserving surgery + axillary lymph node dissection + radiotherapy) (general).[163]

No studies observed the converse, however, where women with lower educational levels were advantaged. In studies where tests of statistical significance were performed, no differences were observed with respect to educational level for the following types of treatment-related care:

- "appropriate use of breast-conserving surgery" (breast-conserving surgery);[132]
- "appropriate use of axillary lymph node dissection" (axillary lymph node dissection).[126]

With respect to definitions of socioeconomic status based on healthcare coverage, no studies observed that, relative to women with private insurance, women with governmental coverage were significantly more likely to receive specific treatment-related care. On the other hand, some studies reported that, relative to women with governmental coverage,

women with private insurance were significantly more likely to receive the following types of treatment-related care:

- "appropriate use of breast-conserving surgery" (breast-conserving surgery);[151,166]
- "appropriate use of axillary lymph node dissection" (axillary lymph node dissection);[114]
- "appropriate use of radiotherapy after breast-conserving surgery" (radiotherapy);[151,166]
- "appropriate use of adjuvant systemic therapy after breast-conserving surgery" (adjuvant systemic therapy).[166]

In studies where tests of statistical significance were performed, no differences were observed with respect to healthcare coverage for the following types of care:

- "appropriate use of breast-conserving surgery" (breast-conserving surgery) (HMO member vs. other);[132]
- "appropriate use of axillary lymph node dissection" (axillary lymph node dissection) (HMO vs. private);[126]
- "quality of radiotherapy via planning on a dedicated simulator" (radiotherapy);[166]
- "quality of radiotherapy: done 5 days/week" (radiotherapy);[166]
- "quality of radiotherapy: homogenous dose distribution of radiotherapy" (radiotherapy);[166]
- "quality of radiotherapy: use of wedges on tangent breast fields" (radiotherapy).[166]

With respect to residence-related definitions of socioeconomic status, a number of studies observed that, relative to women living in rural areas, women living in urban areas were significantly more likely to receive this treatment-related care: "appropriate use of breast-conserving surgery" (breast-conserving surgery) (Minnesota only).[132] No studies noted an opposite finding or a null result.

2d: What is the evidence supporting the use of quality measures for the treatment of breast cancer in women, exhibited in terms of the scientific evidence demonstrating a linkage to improvement in clinical or patient-reported outcomes? With regards to the appropriate use of breast-conserving surgery or appropriate use of mastectomy, Ottevanger et al. found that the 5-year overall survival as well as the disease-free survival in patients receiving breast-conserving surgery plus radiotherapy or mastectomy was equivalent, that is, statistically nonsignificant differences were observed.[154] These

investigators also evaluated the locoregional relapse rate in patients who did and did not receive, as indicated, radiotherapy on the axilla following axillary lymph node dissection, to deal with increased risk of local recurrence (i.e. extracapsular extension, ≥4 positive nodes). They observed a statistically nonsignificant difference between the two types of patient. These same investigators also reported a statistically nonsignificant difference in 5-year overall survival for women who did and did not receive radiotherapy on the axilla. Finally, Ottevanger and colleagues assessed the quality of chemotherapy defined in terms of the proper dose of CMF being administered: ≥85% dose intensity and relative dose intensity. They measured the 5-year overall survival and disease-free survival of patients with <65% as opposed to >85% dose intensity, and found that using <65% of the dose intensity was directly correlated with a decrease in each of these outcomes.

2e: What is the evidence supporting the use of quality measures for the treatment of breast cancer in women, exhibited in terms of their psychometric performance (e.g., validity, reliability, sensitivity and specificity, ceiling and floor effects)? Psychometric performance data relating to breast cancer treatment were scarce. The only reported data involved instruments validated to assess patient-centered outcomes such as QOL. These tools had a history of validated use with cancer and breast cancer, yet psychometric data were only reported with respect to their use in the studies of pertinence to the present review. Psychometric data obtained in validating these measures with breast cancer patients were not included in the study reports.

Internal consistency data for the QLI in Hassey and Lafferty's study of changes brought about by radiotherapy after breast-conserving surgery were established using Cronbach's alpha, which ranged from 0.73 to 0.93 (Summary Table 30).[123] The PAIS's Cronbach's alpha was 0.76. Finally, Cronbach's alpha values ranged from 0.71 to 0.81 for the ASE and its subscales.

Chie et al.'s on-study SF-36's Cronbach alpha values exceeded 0.83, while the corresponding datum for the QLQ-C30 was 0.86 (Summary Table 31).[117] In Molenaar et al.'s research (Summary Table 32),[148] modest study-based reliability was observed for the QLQ-BR23 across three (arm, breast, systemic therapy) subscales (0.58-0.65). The satisfactory reliability of the other subscales fell between 0.76 and 0.89. Frazer et al. used the validated, 39-item, Guttman scaled Health Status Questionnaire to assess breast, as well as prostate, cancer patients' experience over a 3-year period while being treated with surgery and hormone therapy (Summary Table 32).[129] Across eight subscales, good reliability was established using Cronbach's alpha (0.85), the Guttman split-half method (0.83), and the Spearman-Brown formula (0.85). Molenaar et al. also evaluated breast cancer patients' satisfaction with their treatment choice (Summary Table 33) using the full Patient Satisfaction Questionnaire and the Decision Conflict Scale.[148] These scales demonstrated satisfactory reliability in this study (i.e., 0.76-0.89).

Question 3: What measures of the quality of care are available to assess the appropriate use and quality of followup for breast cancer in women, including patient-reported QOL, and, patient satisfaction?

3a: In what patient population have these quality measures been used? With respect to followup, the performance of five quality indicators was measured. McGlynn et al.'s random sample of women from 12 metropolitan US areas yielded data indicating 84.6% adherence to a process indicator asserting that women with a history of breast cancer should have a yearly mammography (Summary Table 39).[5] This indicator was supported by randomized controlled trial evidence. Another was a process variable involving the appropriate use of clinical practice guidelines for followup surveillance of breast cancer. Cornfeld et al. selected a convenience sample of women with breast cancer having received treatment in a private setting from eleven clinical oncologists in the United States.[120] Ray-Coquard et al. chose a random sample of women with localized breast cancer, including ductal carcinoma in situ and non-metastatic invasive carcinoma.[158] Both studies abstracted data from medical records, and Cornfeld et al. also utilized a doctor-reported survey. Cornfeld et al. employed the National Comprehensive Cancer Network guidelines (1999), whereas Ray-Coquard et al. employed a regional set of clinical practice guidelines (1993) to define the standard and observed a rate of 80%. Cornfeld et al.'s rates were reported by type of practice, that is, for physical examination (100%), mammography (98%), and gynecology followup (76%).

Summary Table 39: Followup

Author, year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key differences
Appropriate use: Women with a history of breast cancer should have a yearly mammography[IV]				
McGlynn, 2003, US	Random sample of women living in 12 US metropolitan areas	99	1998-2000	84.6%/NA
Appropriate use of guidelines for followup surveillance of breast cancer[IV]				
Cornfeld, 2001, US	Convenience sample women with nonmetastatic BC treated in the private practice of 11 oncologists	110	1999-2000 (9 mo)	NR (Overall by practice: Physical exam: 100%; Mx: 98%; Gynecologic followup: 76% (30%-100%))/NA
Ray-Coquard, 1997, France	Random sample women with localized BC (DCIS to nonmetastatic invasive carcinoma) in a cancer center in Rhone Alpes Area	85	1995	80% (undefined followup)/NA

KEY: Key differences = regarding age, race, ethnicity, or SES; SES = socioeconomic status; NA = not assessed; BC = breast cancer; NR = not reported; DCIS = ductal carcinoma in situ; S = significant; NS = nonsignificant; Mx = mammography; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

Cheung assessed three outcome indicators of quality care using data from his medical records, including the proportion of women with breast cancer who developed a local recurrence within 5 years after breast-conserving surgery (Summary Table 40).[116] In a convenience sample of women with operable breast cancer, and a tumor size of <5 cm, the 0% rate met the standard (<10%). He also reported a lower rate of local recurrence than the standard (<10%) within 5 years after mastectomy (2.6%). Finally, Cheung observed that 2% of women with a high risk of

flap recurrence, including 36% of those having received a mastectomy, appropriately received prophylactic radiotherapy.

Summary Table 40: Followup

Author, year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key differences
Women with breast cancer developing local recurrence within 5 years after breast-conserving surgery[IV]				
Cheung, 1999, Hong Kong	Convenience sample of women with operable primary BC < 5 cm; attended by the author	100	NR	0% (Standard: <10%)/NA
Women with breast cancer developing local recurrence within 5 years after mastectomy[IV]				
Cheung, 1999, Hong Kong	Convenience sample of women with operable primary BC < 5 cm; attended by the author	100	NR	2.6% (Standard: <10%)/NA
Appropriate use of prophylactic radiotherapy in women with high risk of flap recurrence[IV]				
Cheung, 1999, Hong Kong	Convenience sample of women with operable primary BC < 5 cm; attended by the author	100	NR	2% (36% in mastectomy cases)/NA

3b: For what followup-related purposes have these quality measures been used? The evidence is organized according to three broad categories of purpose. The measurements relating to the following quality indicators were undertaken to achieve external quality oversight:

- appropriate use: "Women with a history of breast cancer should have a yearly mammography" (followup);[5]
- "women with breast cancer developing local recurrence within five years after breast-conserving surgery" (followup);[116]
- "women with breast cancer developing local recurrence within five years after mastectomy" (followup);[116] and,
- "appropriate use of prophylactic radiotherapy in women with high risk of flap recurrence" (followup).[116]

Two studies evaluating the performance of a given quality indicator varied somewhat in terms of the followup-related purposes they were intended to achieve: "appropriate use of guidelines for followup surveillance of breast cancer" (followup): internal quality improvement and external quality oversight;[158] and, internal quality improvement alone.[120]

3c: What quality measures, if any, are available to assess differences in the quality of followup of breast cancer in women related to patients' age, race, socioeconomic status, and ethnicity? No studies were identified as reporting data addressing this question.

3d: What is the evidence supporting the use of quality measures for the followup of breast cancer in women, exhibited in terms of the scientific evidence demonstrating a linkage to improvement in clinical or patient-reported outcomes*?* No studies were identified as reporting data addressing this question.

3e: What is the evidence supporting the use of quality measures for the followup of breast cancer in women, exhibited in terms of: their psychometric performance (e.g., validity, reliability, sensitivity and specificity, ceiling and floor effects)? No studies were identified as reporting data addressing this question.

Question 4: What measures are available to assess the adequacy and completeness of documentation of pathology, operative, radiation, and chemotherapy reports?

All of the quality indicators described with respect to the documentation, or reporting, of care of pertinence to the review belong to the process category. Numerous indicators were identified with respect to the adequacy and completeness of the documentation of pathology reports, with Imperato et al. investigating many of these.[137] They randomly selected a retrospective sample of Medicare cases with breast cancer (n = 555) having undergone a mastectomy concomitant with axillary lymph node dissection in four New York State hospitals. Medical records data complemented those from a regional Medicare database, and these were evaluated in terms of standards of care established by CAP and the Association of Directors of Anatomic and Surgical Pathology (ADASP). The standards were developed in 1997 and updated in 2000. Imperato et al. derived adherence rates for the following quality indicators relating to the reporting of the: gross observation of the lesion in mastectomy specimens (60.5%); verification of the tumor size (microscopic: 63%); number of positive lymph nodes (microscopic: 98.6%); nuclear grade (microscopic: 44.3%); mitotic rate (microscopic: 22.5%); and, extent of the tubule formation (microscopic: 19.6%) (Summary Table 41).

Summary Table 41: Pathology reporting/documentation

Author, Year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key differences
Reporting gross observation of lesion[IV]				
Imperato, 2002, US	Random sample Medicare individuals BC total mastectomy + ALND, in NY state hospitals	555	1999	60.5%/NA
Reporting verification tumor size (microscopic)[IV]				
Imperato, 2002, US	Random sample Medicare individuals BC total mastectomy + ALND, in NY state hospitals	555	1999	63%/NA
Reporting number of positive lymph nodes (microscopic)[IV]				
Imperato, 2002, US	Random sample Medicare individuals BC total mastectomy + ALND, NY state hospitals	220	1999	98.6%/NA
Reporting nuclear grade (microscopic)[IV]				
Imperato, 2002, US	Random sample Medicare individuals BC total mastectomy + ALND, NY state hospitals	555	1999	44.3%/NA
Reporting mitotic rate (microscopic)[IV]				
Imperato, 2002, US	Random sample Medicare individuals BC total mastectomy + ALND, NY state hospitals	555	1999	22.5%/NA
Reporting extent of tubule formation (microscopic)[IV]				
Imperato, 2002, US	Random sample Medicare individuals BC total mastectomy + ALND, NY state hospitals	555	1999	19.6%/NA

KEY: Key differences = regarding age, race, ethnicity, or SES; SES = socioeconomic status; NA = not assessed; BC = breast cancer; NR = not reported; DCIS = ductal carcinoma in situ; S = significant difference; NS = nonsignificant difference; Mx = mammography; H = Hispanic; Bx = biopsy; ALND = axillary lymph node dissection; TNM = tumor;node;metastasis state; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data

The frequency of reporting the laterality of the surgical specimen in the gross examination was evaluated in three different studies (Summary Table 42). In addition to Imperato et al.'s work,[137] Appleton et al. selected a convenience sample of pathology reports,[109] and White et al. preferred a convenience sample of cancer registry reports for women with stage I-II breast cancer.[166] They employed the 1997/2000 CAP and ADASP guidelines, NHSBSP guidelines (1991), and the standards for breast-conservation treatment developed jointly in 1992 by ACOS, ACR, CAP and, SSO, respectively. The overall adherence rates obtained by White et al. and Imperato et al. were 98.3% and 99.3%, respectively. Appleton et al. presented results by year of audit, with an increase observed from 1992 (60%) to 1996 (100%).

Summary Table 42: Pathology reporting/documentation

Author, Year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key differences
Reporting laterality of surgical specimen (gross examination) [IV]				
Imperato, 2002, US	Random sample Medicare individuals BC total mastectomy + ALND, 1999 in NY state hospitals	555	1999	99.3%/NA
Appleton, 1998, UK	Convenience sample mastectomy specimens reports of invasive tumor, ALND issued by non-specialist pathologists	30 (10 for each y)	1992-1996	NR (Overall by y (range)): 50 – 100%/NA
White, 2003, US	Convenience sample women BC stage I-II diagnosed in 1994	16,643	1994	98.3%/Age: <70 y: 98.2%; ≥70 y: 98.6%/Race: White: 98.2%; Black-Hispanic: 98.5%/Payer: Government: 98.4%; Private: 98.3%

The reported identification of the affected quadrant in the gross examination was evaluated in four studies (Summary Table 43). Shank et al.[162] and White et al.[166] each employed the ACOS, ACR, CAP and SSO (1992) guidelines, whereas Imperato et al. used the CAP (1997) and ADASP (1997) standards,[137] and Appleton et al. applied the NHSBSP (1991) guidelines.[109] Overall adherence rates obtained by White et al. (21.1%) and Imperato et al. (30.7%) were exceeded by those reported by both Shank et al. (97.8%) and Appleton et al. (80%). The latter's performance data reached 100% by 1996.

Summary Table 43: Pathology reporting/documentation

Author, Year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key differences
Reporting identification of affected quadrant (gross examination) [IV]				
Imperato, 2002, US	Random sample Medicare individuals BC total mastectomy + ALND, in NY state hospitals	336	1999	30.7%/NA
Appleton, 1998, UK	Convenience sample mastectomy specimens reports of invasive tumor, ALND issued by non-specialist pathologists	30 (10 for each y)	1992-1996	NR (Overall by y (range): 60%-100%)/NA
Shank, 2000, US	Random sample women stage I-II invasive BC treated in 1993-1994	727	1995-1996	97.8%/NA
White, 2003, US	Convenience sample women BC stage I-II diagnosed in 1994	16,643	1994	21.1%/Age: <70 y: 21.1%; ≥70 y: 21.3%/Race: White: 20.5%; Black-Hispanic: 26.3%/Payer: Government: 22%; Private: 20.4%

Using convenience samples of women with breast cancer stage I-II, two studies measured the frequency of reporting the orientation of the specimen in the gross examination (Summary Table 44). Wilkinson et al.'s sample of pathology reports (n = 83) was selected from one hospital cancer database and included women who had had an excisional biopsy,[167] whereas White et al. (n = 16,643) collected data from the cancer registries of 842 hospitals.[166] The standards were the CAP (1998) guidelines[167] and the 1992 ACOS, ACR, CAP, SSO (1992) standards for breast conservation therapy, respectively.[166] The overall adherence rate was 25% for Wilkinson et al. and 67.1% for White et al.

Summary Table 44: Pathology reporting/documentation

Author, Year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key differences
Reporting the orientation of the pathology specimen (gross examination) [IV]				
Wilkinson, 2003, US	Convenience sample women stage I-II infiltrative BC referred to Roswell Park Cancer Institute, after excisional Bx	83	1998-1999	25%/NA
White, 2003, US	Convenience sample women BC stage I-II diagnosed in 1994	16,643	1994	67.1%/Age: <70 y: 68%; ≥70 y: 64.9%/Race: White: 67.6%; Black-Hispanic: 64.2%/Payer: Government: 67.5; Private: 67.1%

The frequency with which the size of the pathology specimen obtained in the gross examination is reported was assessed by Wilkinson et al.[167] and Appleton et al. (Summary Table 45).[109] Wilkinson et al. included pathology reports from women with stage I-II breast cancer who had undergone an excisional biopsy, whereas Appleton et al. evaluated the reports relating to specimens obtained via mastectomy. Wilkinson et al.'s overall adherence rate was 91%, whereas Appleton et al.'s figure in both 1992 and 1996 was 100%.

Summary Table 45: Pathology reporting/documentation

Author, Year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key differences
Reporting size of specimen (gross examination) [IV]				
Wilkinson, 2003, US	Convenience sample women stage I-II infiltrative BC referred to Roswell Park Cancer Institute, after excisional Bx. Size in 3 dimensions	83	1998-1999	91%/NA
Appleton, 1998, UK	Convenience sample mastectomy specimens reports of invasive tumor, ALND issued by non-specialist pathologists	30 (10 for each y)	1992-1996	NR (Overall by y (range): 90%-100%)/NA

Four studies evaluated how often tumor size, determined through macroscopic examination, was reported (Summary Table 46). The overall adherence rates for Wilkinson et al.,[167] Shank et al.,[162], Imperato et al.,[137] and Appleton et al.[109] were 40%, 45.9%, 93.5%, and 70-100% over the period from 1992 to 1996. With respect to reporting the tumor size ascertained via the microscopic examination, Wilkinson et al. and Shank et al.'s rates were 90% and 95.3%, respectively.

Summary Table 46: Pathology reporting/documentation

Author, Year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key differences
Reporting tumor size (macroscopic) [IV]				
Wilkinson, 2003, US	Convenience sample women stage I-II infiltrative BC referred to Roswell Park Cancer Institute, after excisional Bx	83	1998-1999	40%/NA
Shank, 2000, US	Random sample women stage I-II invasive BC treated in 1993-1994	727	1995-1996	45.9%/NA
Imperato, 2002, US	Random sample Medicare individuals BC total mastectomy + ALND, in NY state hospitals	336	1999	93.5%/NA
Appleton, 1998, UK	Convenience sample mastectomy specimens reports of invasive tumor, ALND issued by non-specialist pathologists	30 (10 for each y)	1992-1996	NR (Overall by y (range): 70%-100%)/NA
Reporting tumor size (microscopic) [IV]				
Wilkinson, 2003, US	Convenience sample women stage I-II infiltrative BC referred to Roswell Park Cancer Institute, 1998-1999 after excisional Bx	83	1998-1999	90%/NA
Shank, 2000, US	Random sample women stage I-II invasive BC treated in 1993-1994	727	1995-1996	95.3%/NA

Imperato et al.[137] and Shank et al.[162] found that, in 83.7% and 92% of cases, respectively, the presence or absence of lymph nodes in the gross examination had been documented (Summary Table 47). These same investigators found that, in 93.5% and 100% of cases, respectively, the number of lymph nodes present in the gross examination had been reported. In light of regional guideline standards, Ottevanger et al. assessed national cancer registry data for premenopausal women with stage II to IIIA breast cancer, and found that if at least ten nodes were identified as positive, the rate was 59.2%.[154] The value associated with fewer than ten positive nodes was 40.8%.[154]

Summary Table 47: Pathology reporting/documentation

Author, Year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key differences
Reporting lymph node presence/absence (gross examination) [IV]				
Imperato, 2002, US	Random sample Medicare individuals BC total mastectomy + ALND, in NY state hospitals	555	1999	83.7%/NA
Shank, 2000, US	Random sample women stage I-II invasive BC treated in 1993-1994	727	1995-1996	92%/NA
Reporting number of lymph nodes present (gross examination) [IV]				
Imperato, 2002, US	Random sample Medicare individuals BC total mastectomy + ALND, in NY state hospitals	555	1999	93.5%/NA
Appleton, 1998, UK	Convenience sample mastectomy specimens reports of invasive tumor, ALND issued by non-specialist pathologists	30 (10 for each y)	1992-1996	100%/NA
Ottevanger, 2002, Netherlands	Population-based sample premenopausal women, node (+) BC; stages II to IIIA treated from 1988-1992 in 9 hospitals	233	1993-1998	NR (By n nodes: ≥10 nodes: 59.2%; <10 nodes: 40.8%)/NA

Appleton et al. collected adherence data with regards to four quality indicators associated with the documentation of elements of the gross examination in mastectomy cases (Summary Table 48).[109] They reported rates, broken down by year (1992-1996), of 40% to 100%, 30% to 100%, 10% to 80%, and 0% to 20% for the documentation of the nature of the specimen in the gross examination, the distance from the tumor to the nipple, the cut surface of the tumor, and, the description of the skin. However, only with respect to the second last quality indicator did the rate decrease over time, from 80% in both 1992 and 1994, to 10% in 1996. For the three remaining quality indicators, the highest rates were observed in 1996.

Summary Table 48: Pathology reporting/documentation

Author, Year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key differences
Reporting nature of specimen (gross examination) [IV]				
Appleton, 1998, UK	Convenience sample mastectomy specimens reports of invasive tumor, ALND issued by non-specialist pathologists	30 (10 for each y)	1992-1996	NR (Overall by y (range): 40-100%)/NA
Reporting distance of tumor from nipple (gross examination) [IV]				
Appleton, 1998, UK	Convenience sample mastectomy specimens reports of invasive tumor, ALND issued by non-specialist pathologists	30 (10 for each y)	1992-1996	NR (Overall by y (range): 30%-100%)/NA
Reporting description of cut surface of the tumor (gross examination) [IV]				
Appleton, 1998, UK	Convenience sample mastectomy specimens reports of invasive tumor, ALND issued by non-specialist pathologists	30 (10 for each y)	1992-1996	NR (Overall by y (range): 10%-80%)/NA
Reporting description of skin (gross examination) [IV]				
Appleton, 1998, UK	Convenience sample mastectomy specimens reports of invasive tumor, ALND issued by non-specialist pathologists	30 (10 for each y)	1992-1996	NR (Overall by y (range): 0%-20%)/NA

The same investigators reported rates relating to descriptions again concerning aspects of the gross examination (Summary Table 49).[109] An adherence rate of 100% characterized the reporting of the size of the overlying skin. The rate increased from 50% in 1992 and 1994, to 100% in 1996 regarding descriptions of the nipple. The proportion rose from 0% in 1992 and 1994, to 10% in 1996 for reports of the presence or absence of the fascia or skeletal muscle.

Summary Table 49: Pathology reporting/documentation

Author, Year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key differences
Reporting size of overlying skin (gross examination) [IV]				
Appleton, 1998, UK	Convenience sample mastectomy specimens reports of invasive tumor, ALND issued by non-specialist pathologists	30 (10 for each y)	1992-1996	100%
Reporting description of nipple (gross examination) [IV]				
Appleton, 1998, UK	Convenience sample mastectomy specimens reports of invasive tumor, ALND issued by non-specialist pathologists	30 (10 for each y)	1992-1996	NR (Overall by y (range): 50%-100%)/NA
Reporting presence or absence of fascia or skeletal muscle (gross examination) [IV]				
Appleton, 1998, UK	Convenience sample mastectomy specimens reports of invasive tumor, ALND issued by non-specialist pathologists	30 (10 for each y)	1992-1996	NR (Overall by y (range): 0%-10%)/NA

Appleton et al. evaluated three instances of reports of microscopic examinations (Summary Table 50).[109] They noted an increment in the rate of adherence from 40% in 1992, to 80% in 1994 and 1996 for reporting of the involvement of apical lymph nodes. A decrease from 90% in 1992 and 1994, to 80% in 1996, was observed with respect to the description of the background breast. Reports of the size of the concurrent ductal carcinoma in situ (DCIS) reached 100% in 1996 after observations of 38% in 1992 and 33% in 1994.

Summary Table 50: Pathology reporting/documentation

Author, Year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key differences
Reporting involvement of apical lymph nodes (microscopic) [IV]				
Appleton, 1998, UK	Convenience sample mastectomy specimens reports of invasive tumor, ALND issued by non-specialist pathologists	30 (10 for each y)	1992-1996	NR (Overall by y (range): 40%-80%)/NA
Reporting size of concurrent ductal carcinoma in situ (microscopic) [IV]				
Appleton, 1998, UK	Convenience sample mastectomy specimens reports of invasive tumor, ALND issued by non-specialist pathologists	30 (10 for each y)	1992-1996	NR (Overall by y (range): 33%-100%)/NA
Reporting description of background breast (microscopic) [IV]				
Appleton, 1998, UK	Convenience sample mastectomy specimens reports of invasive tumor, ALND issued by non-specialist pathologists	30 (10 for each y)	1992-1996	NR (Overall by y (range): 80%-90%)/NA

There was wide variation in the reporting of the presence or absence of ductal carcinoma in situ based on the microscopic test (Summary Table 51). Wilkinson et al.'s adherence rate was 71%,[167] White et al.'s 43.2%,[166] Shank et al.'s 8.5%,[162] and Appleton et al.'s ranged from 70% to 100%, organized by year of audit.[109]

Summary Table 51: Pathology reporting/documentation

Author, Year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key differences
Reporting ductal carcinoma in situ (DCIS) present/absent (microscopic) [IV]				
Wilkinson, 2003, US	Convenience sample women stage I-II infiltrative BC referred to Roswell Park Cancer Institute, after excisional Bx	83	1998-1999	71%/NA
Shank, 2000, US	Random sample women stage I-II invasive BC treated in 1993-1994	727	1995-1996	8.5%/NA
White, 2003, US	Convenience sample women BC stage I-II diagnosed in 1994	16,643	1994	43.2%/Age: <70 y: 44.8%; ≥70 y: 38.6%/Race: White: 43.3%; Black-Hispanic: 40.8%/Payer: Government: 40.2%; Private: 45.7% S
Appleton, 1998, UK	Convenience sample mastectomy specimens reports of invasive tumor, ALND issued by non-specialist pathologists	30 (10 for each y)	1992-1996	NR/Overall by y (range): 70%-100%

Three groups of investigators evaluated the adherence rates to standards regarding the reporting of the measurements of the macroscopic margins of the carcinoma (Summary Table 52). The largest sample, whose data were examined by White et al., revealed the lowest rate (72.4%)[166] while Cheung[116] and Shank et al.[162] reported percentages of 100% and 96.8%, respectively.

Summary Table 52: Pathology reporting/documentation

Author, Year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key differences
Reporting measurement of macroscopic margins of carcinoma [IV]				
Shank, 2000, US	Random sample women stage I-II invasive BC treated in 1993-1994	727	1995-1996	96.8%/NA
White, 2003, US	Convenience sample women BC stage I-II diagnosed in 1994	16,643	1994	72.4%/Age: <70 y: 72.5%; ≥70 y: 72.1%/Race: White: 72.5%; Black-Hispanic: 73.5%/Payer: Government: 73.1%; Private: 72.3%
Cheung, 1999, Hong Kong	Convenience sample of women with operable primary BC < 5 cm; attended by the author	100	NR	100%/NA

Evaluations of reports of the assessment of microscopic margins revealed variability in adherence (Summary Table 53), with overall percentages of 69.4% to 95.6%,[137,162,166,167] and Appleton et al. observing a range of 90% to 100% by year of audit in small numbers of cases.[109]

Summary Table 53: Pathology reporting/documentation

Author, Year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key differences
Reporting assessment of microscopic margins [IV]				
Wilkinson, 2003, US	Convenience sample women stage I-II infiltrative BC referred to Roswell Park Cancer Institute, after excisional Bx	83	1998-1999	94%/NA
Shank, 2000, US	Random sample women stage I-II invasive BC treated in 1993-1994	727	1995-1996	95.6%/NA
White, 2003, US	Convenience sample women BC stage I-II diagnosed in 1994	16,643	1994	89.5%/Age: <70 y: 90%; ≥70 y: 88.7%/Race: White: 89.7%; Black-Hispanic: 86.8%/ Payer: Government: 89%; Private: 90.2%
Imperato, 2002, US	Random sample Medicare individuals BC total mastectomy + ALND, in NY state hospitals	555	1999	69.4%/NA
Appleton, 1998, UK	Convenience sample mastectomy specimens reports of invasive tumor, ALND issued by non-specialist pathologists	30 (10 for each y)	1992-1996	NR (Overall by y (range): 90%-100%)/NA

Imperato et al.[137] and White et al.[166] assessed the frequency of reports of microscopically confirmed carcinoma (Summary Table 54). Their data revealed rates of 100% and 97.8%, respectively.

Summary Table 54: Pathology reporting/documentation

Author, Year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key differences
Reporting carcinoma confirmed microscopically [IV]				
Imperato, 2002, US	Random sample Medicare individuals BC total mastectomy + ALND, in NY state hospitals	555	1999	100%/NA
White, 2003, US	Convenience sample women BC stage I-II diagnosed in 1994	16,643	1994	97.8%/Age: <70 y: 97.7%; ≥70 y: 97.9%/Race: White: 97.9% Black-Hispanic: 96.7%/Payer: Government: 98.1%; Private: 97.7%

Four studies determined how often the histological type revealed by way of microscopic examination was reported (Summary Table 55). The rates were high, ranging from 95.9% to 100%.[109,137,162,166,167]

Summary Table 55: Pathology reporting/documentation

Author, Year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key differences
Reporting histological type (microscopic) [IV]				
Wilkinson, 2003, US	Convenience sample women stage I-II infiltrative BC referred to Roswell Park Cancer Institute, after excisional Bx	83	1998-1999	100%/NA
Shank, 2000, US	Random sample women stage I-II invasive BC treated in 1993-1994	727	1995-1996	99.7%/NA
White, 2003, US	Convenience sample women BC stage I-II diagnosed in 1994	16,643	1994	98.8%/Age: <70 y: 98.8%; ≥70 y: 98.7%/Race: White: 98.8%; Black-Hispanic: 99%/Payer: Government: 99%; Private: 98.7%
Imperato, 2002, US	Random sample Medicare individuals BC total mastectomy + ALND, in NY state hospitals	555	1999	95.9%/NA
Appleton, 1998, UK	Convenience sample mastectomy specimens reports of invasive tumor, ALND issued by non-specialist pathologists	30 (10 for each y)	1992-1996	100%

Variability characterized adherence to the standards for the reporting of histological grade via microscopic investigation (Summary Table 56). The overall adherence rates were 59.1% for Imperato et al.,[137] 80.6% for White et al.[166] and 90% for Wilkinson et al.[167] Appleton et al.'s rates were expressed by year, with 90% in 1992, 80% in 1994 and 100% in 1996.[109]

Summary Table 56: Pathology reporting/documentation

Author, Year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key differences
Reporting histological grade (microscopic) [IV]				
Wilkinson, 2003, US	Convenience sample women stage I-II infiltrative BC referred to Roswell Park Cancer Institute, 1998-1999 after excisional Bx	83	1998-1999	90%/NA
White, 2003, US	Convenience sample women BC stage I-II diagnosed in 1994	16,643	1994	80.6%/Age: <70 y: 81.1%; ≥70 y: 79.3%/Race: White: 80.5%; Black-Hispanic: 79.7%/ Payer: Government: 80.1%; Private: 81.2%
Imperato, 2002, US	Random sample Medicare individuals BC total mastectomy + ALND, in NY state hospitals	555	1999	59.1%/NA
Appleton, 1998, UK	Convenience sample mastectomy specimens reports of invasive tumor, ALND issued by non-specialist pathologists	30 (10 for each y)	1992-1996	NR (Overall by y (range): 80%-100%)/NA

Reports of lymph-vascular invasion observed microscopically were assessed in three studies (Summary Table 57), with similar results. Imperato et al.'s rate was 45.6%,[137] Wilkinson et al.'s was 47%,[167] and White et al.'s was 53.5%.[166]

Summary Table 57: Pathology reporting/documentation

Author, Year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key differences
Reporting lymph-vascular invasion (microscopic) [IV]				
Wilkinson, 2003, US	Convenience sample women stage I-II infiltrative BC referred to Roswell Park Cancer Institute, after excisional Bx	83	1998-1999	47%/NA
White, 2003, US	Convenience sample women BC stage I-II diagnosed in 1994	16,643	1994	53.5%/Age: <70 y: 54.3%; ≥70 y: 51.5%/Race: White: 52.9%; Black-Hispanic: 54.4%/ Payer: Government: 51.3%; Private: 54.9% S
Imperato, 2002, US	Random sample Medicare individuals BC total mastectomy + ALND, in NY state hospitals	555	1999	45.6%/NA

Shank et al.[162] and White et al.[166] evaluated cases in which the size of the invasive carcinoma, observed microscopically, was reported (Summary Table 58). Shank et al. noted a rate of 8.5% based on a small number of cases, whereas White et al.'s rate was 91.8%.

Summary Table 58: Pathology reporting/documentation

Author, Year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key differences
Reporting size of invasive carcinoma (microscopic) [IV]				
Shank, 2000, US	Random sample women stage I-II invasive BC treated in 1993-1994	727	1995-1996	8.5%/NA
White, 2003, US	Convenience sample women BC stage I-II diagnosed in 1994	16,643	1994	91.8%/Age: <70 y: 91.6%;<70 y: 91.9%/Race: White: 91.7%; Black-Hispanic: 91.2%/Payer: Government: 91.6%; Private: 92%

The same two groups of investigators described similar rates of adherence with regards to reporting estrogen receptor status (Summary Table 59). The figures were 89% in Shank et al.'s study[162] and 91.7% in White et al.'s.[166] Their respective rates of reporting progesterone receptor status were 86.7% and 90.6%.

Summary Table 59: Pathology reporting/documentation

Author, Year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key differences
Reporting estrogen receptor status (microscopic) [IV]				
Shank, 2000, US	Random sample women stage I-II invasive BC treated in 1993-1994	727	1995-1996	89%/NA
White, 2003, US	Convenience sample women BC stage I-II diagnosed in 1994	16,643	1994	91.7%/Age: <70 y: 91.9%; ≥70 y: 91.2%/Race: White: 91.8%; Black-Hispanic: 90.4%/Payer: Government: 91.4%; Private: 92.3%
Reporting progesterone receptor status (microscopic) [IV]				
Shank, 2000, US	Random sample women stage I-II invasive BC treated in 1993-1994	727	1995-1996	86.4%/NA
White, 2003, US	Convenience sample women BC stage I-II diagnosed in 1994	16,643	1994	90.6%/Age: <70 y: 90.9%; ≥70 y: 89.7%/Race: White: 90.7%; Black-Hispanic: 89.6%/Payer: Government: 90.1%; Private: 91.4%

Based on a small number of cases (n = 83), Wilkinson et al. identified three indicators pertaining to documentation (Summary Table 60).[167] They observed a 77% adherence rate for reporting the inking of specimens, 9% for reporting TNM staging, and a 6% rate related to reporting a Bloom Scarf Richardson tumor grade.

Summary Table 60: Pathology reporting/documentation

Author, Year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key differences
Reporting specimen inked (microscopic) [IV]				
Wilkinson, 2003, US	Convenience sample women stage I-II infiltrative BC referred to Roswell Park Cancer Institute, after excisional Bx	83	1998-1999	77%/NA
Reporting Bloom Scarf Richardson scale (tumor grade) (microscopic) [IV]				
Wilkinson, 2003, US	Convenience sample women stage I-II infiltrative BC referred to Roswell Park Cancer Institute, after excisional Bx	83	1998-1999	6%/NA
Reporting TNM staging (microscopic) [IV]				
Wilkinson, 2003, US	Convenience sample women stage I-II infiltrative BC referred to Roswell Park Cancer Institute, after excisional Bx	83	1998-1999	9%/NA

Documenting the distance to the closest margin was evaluated twice (Summary Table 61). Overall adherence rates were 69% in Wilkinson et al.,[167] and ranged from 80% to 100%, by audit year, in Appleton et al.;[109] Shank et al.[162] noted a 99.3% adherence rate pertaining to reports of the pathological extent of the primary tumor.

Summary Table 61: Pathology reporting/documentation

Author, Year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key differences
Reporting distance to the closest margin (microscopic) [IV]				
Wilkinson, 2003, US	Convenience sample women stage I-II infiltrative BC referred to Roswell Park Cancer Institute, after excisional Bx	83	1998-1999	69%/NA
Appleton, 1998, UK	Convenience sample mastectomy specimens reports of invasive tumor, ALND issued by non-specialist pathologists	30 (10 for each y)	1992-1996	NR (Overall by y (range): 80%-100%)/NA
Reporting pathological extent of primary tumor (microscopic) [IV]				
Shank, 2000, US	Random sample women stage I-II invasive BC treated in 1993-1994	727	1995-1996	99.3%/NA

Shank et al. also collected data showing that, in 95.3% and 98.9% of cases relating to the performance of flow cytometry and cytometry ploidy, respectively, reports had been provided (Summary Table 62).[162] In 99.7% of cases, Shank et al. observed that pathology reports were included on the chart.

Summary Table 62: Pathology reporting/documentation

Author, Year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key differences
Reporting having performed flow cytometry (microscopic) [IV]				
Shank, 2000, US	Random sample women stage I-II invasive BC treated in 1993-1994	727	1995-1996	95.3%/NA
Reporting cytometry ploidy (microscopic) [IV]				
Shank, 2000, US	Random sample women stage I-II invasive BC treated in 1993-1994	727	1995-1996	98.9%/NA
Pathology reports on chart [IV]				
Shank, 2000, US	Random sample women stage I-II invasive BC treated in 1993-1994	727	1995-1996	99.7%/NA

Regarding the adequacy and completeness of imaging reports, White et al. noted that, in 47% of cases, the size of the mammographic abnormality had been reported (Summary Table 63).[166]

Summary Table 63: Imaging reporting/documentation

Author, Year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key differences
Size of mammographic abnormality[IV]				
White, 2003, US	Convenience sample women BC stage I-II diagnosed in 1994	16,643	1994	47%/Age: <70 y: 45.9%; ≥70 y: 50.7%/Race: White: 47.5%; Black-Hispanic: 46.3%/Payer: Government: 50.3%; Private: 44.8% S
KEY: Key differences = regarding age, race, ethnicity, or SES; SES = socioeconomic status; NA = not assessed; BC = breast cancer; NR = not reported; DCIS = ductal carcinoma in situ; S = significant; NS = nonsignificant; Mx = mammography; H = Hispanic; Bx = biopsy; ALND = axillary lymph node dissection; TNM = tumor;node;metastasis state; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data				

Two quality indicators relating to the adequacy and completeness of chemotherapy reports were studied by Cornfeld et al. (Summary Table 64).[120] The first is a structural variable relating to the presence of chemotherapy sheets on the active treatment charts. The second is a process indicator indicating the presence of the body surface area calculations on the chemotherapy flow sheets. The overall adherence rates were 99% and 90%, respectively.

Summary Table 64: Chemotherapy reporting/documentation

Author, Year, Location	Sample description	No. Eligible	Measurement Period	Rate (%)/ Key differences
Presence of chemotherapy flow sheets in active treatment charts[IV]				
Cornfeld, 2001, US	Convenience sample women BC treated in the private practice of 11 oncologists	220	1999-2000 (9 mo)	99%/NA
Presence of body surface area calculations on chemotherapy flow sheets[IV]				
Cornfeld, 2001, US	Convenience sample women BC treated in the private practice of 11 oncologists	220	1999-2000 (9 mo)	90%/NA
KEY: Key differences = regarding age, race, ethnicity, or SES; SES = socioeconomic status; NA = not assessed; BC = breast cancer; NR = not reported; DCIS = ductal carcinoma in situ; S = significant; NS = nonsignificant; Mx = mammography; H = Hispanic; Bx = biopsy; ALND = axillary lymph node dissection; TNM = tumor;node;metastasis state; Level Ia = pre-study data indicating consistently sound psychometric properties; Iac = pre- *and* on-study data indicating consistently sound psychometric properties; IV = no pre- *or* on-study psychometric data				

In the sole study providing data regarding possible linkages to outcomes, Ottevanger et al. noted that reporting the number of affected lymph nodes was linked to overall survival and disease-free survival.[154]