

NQF #0559 C0559: Combination chemotherapy is considered or administered within 4 months (120 days) of diagnosis for women under 70 with AJCC T1c, or Stage II or III hormone receptor negative breast cancer.

NATIONAL QUALITY FORUM

Measure Submission and Evaluation Worksheet 5.0

This form contains the information submitted by measure developers/stewards, organized according to NQF's measure evaluation criteria and process. The evaluation criteria, evaluation guidance documents, and a blank online submission form are available on the [submitting standards web page](#).

NQF #: 0559 NQF Project: Cancer Project
(for Endorsement Maintenance Review) Original Endorsement Date: Mar 01, 2007 Most Recent Endorsement Date: Mar 01, 2007
BRIEF MEASURE INFORMATION
De.1 Measure Title: C0559: Combination chemotherapy is considered or administered within 4 months (120 days) of diagnosis for women under 70 with AJCC T1c, or Stage II or III hormone receptor negative breast cancer.
Co.1.1 Measure Steward: American College of Surgeons
De.2 Brief Description of Measure: Percentage of female patients, age >18 at diagnosis, who have their first diagnosis of breast cancer (epithelial malignancy), at AJCC stage T1c, or Stage II, or III, who's primary tumor is progesterone and estrogen receptor negative recommended for multiagent chemotherapy (considered or administered) within 4 months (120 days) of diagnosis.
2a1.1 Numerator Statement: Combination chemotherapy is considered or administered within 4 months (120 days) of the date of diagnosis
2a1.4 Denominator Statement: Women under the age of 70 with AJCC T1cN0M0, or Stage II or III hormone receptor negative breast cancer: <ul style="list-style-type: none"> • Women • Age 18-69 at time of diagnosis • Known or assumed first or only cancer diagnosis • Primary tumors of the breast • Epithelial invasive malignancy only • AJCC T1cN0M0, or Stage II or III • Primary tumor is estrogen receptor negative and progesterone receptor negative • All or part of first course of treatment performed at the reporting facility • Known to be alive within 4 months (120 days) of diagnosis
2a1.8 Denominator Exclusions: Exclude, if any of the following characteristics are identified: Men; Age <18 and >=70; not a first or only cancer diagnosis; non-epithelial and non-invasive tumors; tumor size <=1cm and AJCC pN=0; ERA unknown or positive; PRA unknown or positive; metastatic disease (AJCC Stage IV); not treated surgically; died within 4 months (120 days) of diagnosis
1.1 Measure Type: Process 2a1. 25-26 Data Source: Electronic Clinical Data : Registry, Paper Records 2a1.33 Level of Analysis: Facility 1.2-1.4 Is this measure paired with another measure? No
De.3 If included in a composite, please identify the composite measure (title and NQF number if endorsed):

STAFF NOTES <i>(issues or questions regarding any criteria)</i>
Comments on Conditions for Consideration:

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Is the measure untested? Yes <input type="checkbox"/> No <input type="checkbox"/> If untested, explain how it meets criteria for consideration for time-limited endorsement:
1a. Specific national health goal/priority identified by DHHS or NPP addressed by the measure (check De.5): 5. Similar/related endorsed or submitted measures (check 5.1): Other Criteria:
Staff Reviewer Name(s):

1. IMPACT, OPPORTUNITY, EVIDENCE - IMPORTANCE TO MEASURE AND REPORT

Importance to Measure and Report is a threshold criterion that must be met in order to recommend a measure for endorsement. All three subcriteria must be met to pass this criterion. See [guidance on evidence](#).
Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria. (evaluation criteria)

1a. High Impact: H M L I
(The measure directly addresses a specific national health goal/priority identified by DHHS or NPP, or some other high impact aspect of healthcare.)

De.4 Subject/Topic Areas (Check all the areas that apply): [Cancer, Cancer : Breast](#)
De.5 Cross Cutting Areas (Check all the areas that apply): [Care Coordination, Disparities](#)

1a.1 Demonstrated High Impact Aspect of Healthcare: [Affects large numbers, Frequently performed procedure, Patient/societal consequences of poor quality](#)

1a.2 If "Other," please describe:

1a.3 Summary of Evidence of High Impact (Provide epidemiologic or resource use data):
[There is extensive documentation of the benefit of mutiagent chemotherapy in women with hormone receptor negative breast cancer. Chemotherapy reduces the risk of distant disease recurrence and death by about one-third. The restriction to women under age 70 is because this measure is for the purpose of provider accountability. There are limited data in women over age 70 to guide recommendations and a higher fraction of these women have reasons to omit chemotherapy including co-morbidity.](#)

1a.4 Citations for Evidence of High Impact cited in 1a.3: [1. Early Breast Cancer Trialists Collaborative Group \(EBCTCG\) et al. Comparisons between different polychemotherapy regimens for early breast cancer: metaanalysis of long-term outcome among 100,000 women in 123 randomised trials. Lancet 2012;379\(9814\):4320444. 2. Early Breast Cancer Trialists Collaborative Group \(EBCTCG\) et al. Adjuvant chemotherapy in oestrogen-receptor-poor breast cancer: patient level meta-analysis of randomised trials. Lancet 2008;371\(9606\):29-40. 3. Early Breast Cancer Trialists Collaborative Group \(EBCTCG\). Effects of chemotherapy and hormonal therapy for early breast cancer on recurrence and 15-year survival: and overview of the randomised trials. Lancet 2005;365\(9472\):1687-1717. 4. Hasset MJ, Hughes ME, Niland JC, et al. Selecting high priority quality measures for breast cancer quality improvement. Med Care 2008;46:762-770.](#)

1b. Opportunity for Improvement: H M L I
(There is a demonstrated performance gap - variability or overall less than optimal performance)

1b.1 Briefly explain the benefits (improvements in quality) envisioned by use of this measure:
[Improve the utilization of chemotherapy in women with hormone receptor negative breast cancer.](#)

1b.2 Summary of Data Demonstrating Performance Gap (Variation or overall less than optimal performance across providers):
[For Maintenance – Descriptive statistics for performance results for this measure - distribution of scores for measured entities by quartile/decile, mean, median, SD, min, max, etc.]
[There is literature demonstrating variation in care related to many factors including socioeconomic status, race/ethnicity, and location of services.](#)

1b.3 Citations for Data on Performance Gap: **[For Maintenance – Description of the data or sample for measure results reported**

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in 1b.2 including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included] 1 Morimoto L, Coalson J, Mowat F, O'Malley C. Factors affecting receipt of chemotherapy in women with breast cancer. Int J Womens Health 2010;2:107-22. 2. Bickell NA, Shastri K, Fei K, et al. A tracking and feedback registry to reduce racial disparities in breast cancer care. J Natl Cancer Inst 2008;100:1717-23.

1b.4 Summary of Data on Disparities by Population Group: [*For Maintenance* – Descriptive statistics for performance results for this measure by population group]

Disparities based on race, access, and other factors have been well described.

1b.5 Citations for Data on Disparities Cited in 1b.4: [*For Maintenance* – Description of the data or sample for measure results reported in 1b.4 including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included]

See citations in 1b.3

1c. Evidence (Measure focus is a health outcome OR meets the criteria for quantity, quality, consistency of the body of evidence.)
Is the measure focus a health outcome? Yes No **If not a health outcome, rate the body of evidence.**

Quantity: H M L I Quality: H M L I Consistency: H M L I

Quantity	Quality	Consistency	Does the measure pass subcriterion 1c?
M-H	M-H	M-H	Yes <input type="checkbox"/>
L	M-H	M	Yes <input type="checkbox"/> IF additional research unlikely to change conclusion that benefits to patients outweigh harms: otherwise No <input type="checkbox"/>
M-H	L	M-H	Yes <input type="checkbox"/> IF potential benefits to patients clearly outweigh potential harms: otherwise No <input type="checkbox"/>
L-M-H	L-M-H	L	No <input type="checkbox"/>

Health outcome – rationale supports relationship to at least one healthcare structure, process, intervention, or service

Does the measure pass subcriterion 1c?
Yes IF rationale supports relationship

1c.1 Structure-Process-Outcome Relationship (Briefly state the measure focus, e.g., health outcome, intermediate clinical outcome, process, structure; then identify the appropriate links, e.g., structure-process-health outcome; process-health outcome; intermediate clinical outcome-health outcome):

Process

1c.2-3 Type of Evidence (Check all that apply):

Clinical Practice Guideline, Systematic review of body of evidence (other than within guideline development)

1c.4 Directness of Evidence to the Specified Measure (State the central topic, population, and outcomes addressed in the body of evidence and identify any differences from the measure focus and measure target population):

Directly applicable - randomized trials examining the measure

1c.5 Quantity of Studies in the Body of Evidence (Total number of studies, not articles): Multiple randomized clinical trials

1c.6 Quality of Body of Evidence (Summarize the certainty or confidence in the estimates of benefits and harms to patients across studies in the body of evidence resulting from study factors. Please address: a) study design/flaws; b) directness/indirectness of the evidence to this measure (e.g., interventions, comparisons, outcomes assessed, population included in the evidence); and c) imprecision/wide confidence intervals due to few patients or events): High quality evidence

1c.7 Consistency of Results across Studies (Summarize the consistency of the magnitude and direction of the effect): Strong level of consistency

1c.8 Net Benefit (Provide estimates of effect for benefit/outcome; identify harms addressed and estimates of effect; and net benefit)

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- benefit over harms):

Approximate 33% reduction in risk of distant cancer recurrence and death

1c.9 Grading of Strength/Quality of the Body of Evidence. Has the body of evidence been graded? Yes

1c.10 If body of evidence graded, identify the entity that graded the evidence including balance of representation and any disclosures regarding bias: National Comprehensive Cancer Network (NCCN): Early Breast Cancer Trialists Collaborative Group

1c.11 System Used for Grading the Body of Evidence: Other

1c.12 If other, identify and describe the grading scale with definitions: Level I, IIA, IIB, III

1c.13 Grade Assigned to the Body of Evidence: Level 1

1c.14 Summary of Controversy/Contradictory Evidence: None

1c.15 Citations for Evidence other than Guidelines(Guidelines addressed below):

See 1.b4

1c.16 Quote verbatim, the specific guideline recommendation (Including guideline # and/or page #):

Applies to Tumors > 1 cm or with positive nodes: "Adjuvant Chemotherapy (Category 1)" If HER2 positive: "Adjuvant chemotherapy (category 1) with trastuzumab (Category 1)"

1c.17 Clinical Practice Guideline Citation: NCCN Clinical Practice Guidelines

1c.18 National Guideline Clearinghouse or other URL: www.nccn.org

1c.19 Grading of Strength of Guideline Recommendation. Has the recommendation been graded? Yes

1c.20 If guideline recommendation graded, identify the entity that graded the evidence including balance of representation and any disclosures regarding bias: National Comprehensive Cancer Network (NCCN)

1c.21 System Used for Grading the Strength of Guideline Recommendation: Other

1c.22 If other, identify and describe the grading scale with definitions: Level I, IIA, IIB, III

1c.23 Grade Assigned to the Recommendation: Level 1

1c.24 Rationale for Using this Guideline Over Others: All guidelines recommend chemotherapy with hormone receptor negative breast cancer

Based on the NQF descriptions for rating the evidence, what was the developer's assessment of the quantity, quality, and consistency of the body of evidence?

1c.25 Quantity: High 1c.26 Quality: High 1c.27 Consistency: High

Was the threshold criterion, *Importance to Measure and Report*, met?

(1a & 1b must be rated moderate or high and 1c yes) Yes No

Provide rationale based on specific subcriteria:

For a new measure if the Committee votes NO, then STOP.

For a measure undergoing endorsement maintenance, if the Committee votes NO because of 1b. (no opportunity for improvement), it may be considered for continued endorsement and all criteria need to be evaluated.

2. RELIABILITY & VALIDITY - SCIENTIFIC ACCEPTABILITY OF MEASURE PROPERTIES

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Extent to which the measure, as specified, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. (**evaluation criteria**)

Measure testing must demonstrate adequate reliability and validity in order to be recommended for endorsement. Testing may be conducted for data elements and/or the computed measure score. Testing information and results should be entered in the appropriate field. Supplemental materials may be referenced or attached in item 2.1. See [guidance on measure testing](#).

S.1 Measure Web Page (*In the future, NQF will require measure stewards to provide a URL link to a web page where current detailed specifications can be obtained*). Do you have a web page where current detailed specifications for this measure can be obtained? **Yes**

S.2 If yes, provide web page URL: <http://www.facs.org/cancer/qualitymeasures.html>

2a. RELIABILITY. Precise Specifications and Reliability Testing: H M L I

2a1. Precise Measure Specifications. (*The measure specifications precise and unambiguous.*)

2a1.1 Numerator Statement (*Brief, narrative description of the measure focus or what is being measured about the target population, e.g., cases from the target population with the target process, condition, event, or outcome*):

Combination chemotherapy is considered or administered within 4 months (120 days) of the date of diagnosis

2a1.2 Numerator Time Window (*The time period in which the target process, condition, event, or outcome is eligible for inclusion*):

4 months (120 days)

2a1.3 Numerator Details (*All information required to identify and calculate the cases from the target population with the target process, condition, event, or outcome such as definitions, codes with descriptors, and/or specific data collection items/responses*):

Chemotherapy [NAACCR Item#1390]=82-87 OR; Chemotherapy [NAACCR Item#1390]=3, and Date Chemotherapy Started [NAACCR Item#1220] <=120 days following Date of Diagnosis [NAACCR Item# 340]

2a1.4 Denominator Statement (*Brief, narrative description of the target population being measured*):

Women under the age of 70 with AJCC T1cN0M0, or Stage II or III hormone receptor negative breast cancer:

- Women
- Age 18-69 at time of diagnosis
- Known or assumed first or only cancer diagnosis
- Primary tumors of the breast
- Epithelial invasive malignancy only
- AJCC T1cN0M0, or Stage II or III
- Primary tumor is estrogen receptor negative and progesterone receptor negative
- All or part of first course of treatment performed at the reporting facility
- Known to be alive within 4 months (120 days) of diagnosis

2a1.5 Target Population Category (*Check all the populations for which the measure is specified and tested if any*): **Adult/Elderly Care**

2a1.6 Denominator Time Window (*The time period in which cases are eligible for inclusion*):

Typically a 12 month, calendar year, time period

2a1.7 Denominator Details (*All information required to identify and calculate the target population/denominator such as definitions, codes with descriptors, and/or specific data collection items/responses*):

Sex [NAACCR Item#220]=2; Age at Diagnosis [NAACCR Item#230] < 80; CS Tumor Size [NAACCR Item#2800]= 010 and AJCC pN [NAACCR Item#890]=0, OR AJCC pN [NAACCR Item#890]=1, 2, or 3; AND CS SSF1 (ERA) [NAACCR Item#2880]=020 or 030; AND CS SSF2 (PRA) [NAACCR Item#2890]=020 or 030; AND Surgical Procedure of the Primary Site [NAACCR Item#1290] = 20–90

2a1.8 Denominator Exclusions (*Brief narrative description of exclusions from the target population*):

Exclude, if any of the following characteristics

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are identified:

Men; Age <18 and >=70; not a first or only cancer diagnosis; non-epithelial and non-invasive tumors; tumor size <=1cm and AJCC pN=0; ERA unknown or positive; PRA unknown or positive; metastatic disease (AJCC Stage IV); not treated surgically; died within 4 months (120 days) of diagnosis

2a1.9 Denominator Exclusion Details (All information required to identify and calculate exclusions from the denominator such as definitions, codes with descriptors, and/or specific data collection items/responses):

See: <http://www.facs.org/cancer/ncdb/cp3rv2-measurespecs-1211.pdf>

2a1.10 Stratification Details/Variables (All information required to stratify the measure results including the stratification variables, codes with descriptors, definitions, and/or specific data collection items/responses):

No stratification applied

2a1.11 Risk Adjustment Type (Select type. Provide specifications for risk stratification in 2a1.10 and for statistical model in 2a1.13): No risk adjustment or risk stratification **2a1.12 If "Other," please describe:**

2a1.13 Statistical Risk Model and Variables (Name the statistical method - e.g., logistic regression and list all the risk factor variables. Note - risk model development should be addressed in 2b4.):

2a1.14-16 Detailed Risk Model Available at Web page URL (or attachment). Include coefficients, equations, codes with descriptors, definitions, and/or specific data collection items/responses. Attach documents only if they are not available on a webpage and keep attached file to 5 MB or less. NQF strongly prefers you make documents available at a Web page URL. Please supply login/password if needed:

2a1.17-18. Type of Score: [Rate/proportion](#)

2a1.19 Interpretation of Score (Classifies interpretation of score according to whether better quality is associated with a higher score, a lower score, a score falling within a defined interval, or a passing score): [Better quality = Higher score](#)

2a1.20 Calculation Algorithm/Measure Logic(Describe the calculation of the measure score as an ordered sequence of steps including identifying the target population; exclusions; cases meeting the target process, condition, event, or outcome; aggregating data; risk adjustment; etc.):

See: <http://www.facs.org/cancer/ncdb/cp3rv2-measurespecs-1211.pdf>

2a1.21-23 Calculation Algorithm/Measure Logic Diagram URL or attachment:

URL

<http://www.facs.org/cancer/ncdb/cp3rv2-measurespecs-1211.pdf>

2a1.24 Sampling (Survey) Methodology. If measure is based on a sample (or survey), provide instructions for obtaining the sample, conducting the survey and guidance on minimum sample size (response rate):

2a1.25 Data Source (Check all the sources for which the measure is specified and tested). If other, please describe:

[Electronic Clinical Data : Registry, Paper Records](#)

2a1.26 Data Source/Data Collection Instrument (Identify the specific data source/data collection instrument, e.g. name of database, clinical registry, collection instrument, etc.): [Hospital cancer registry data, reported to the American College of Surgeons, Commission on Cancer, National Cancer Data Base](#)

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2a1.27-29 Data Source/data Collection Instrument Reference Web Page URL or Attachment: [URL
http://www.naaccr.org/StandardsandRegistryOperations/Volumell.aspx](http://www.naaccr.org/StandardsandRegistryOperations/Volumell.aspx)

2a1.30-32 Data Dictionary/Code Table Web Page URL or Attachment:
[URL
http://www.facs.org/cancer/coc/fordsmanual.html](http://www.facs.org/cancer/coc/fordsmanual.html)

2a1.33 Level of Analysis (Check the levels of analysis for which the measure is specified and tested): [Facility](#)

2a1.34-35 Care Setting (Check all the settings for which the measure is specified and tested): [Hospital/Acute Care Facility](#)

2a2. Reliability Testing. (Reliability testing was conducted with appropriate method, scope, and adequate demonstration of reliability.)

2a2.1 Data/Sample (Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included):
This measure has been implemented by the ACoS CoC since 2007 across all CoC-accredited cancer programs, and reports on approximately 14,000 cases per year to almost 1,400 cancer programs.

2a2.2 Analytic Method (Describe method of reliability testing & rationale):
Cancer registry case records reported to the NCDB are reviewed annually, annualized hospital performance rates are provided back to CoC accredited cancer programs via the CoC's Cancer Program Practice Profile Report (CP3R) using the denominator and numerator criteria documented in response to items 2a1.3 and 2a1.7, respectively, in the Specifications section.
(<http://www.facs.org/cancer/ncdb/cp3r.html>)

2a2.3 Testing Results (Reliability statistics, assessment of adequacy in the context of norms for the test conducted):
The mean performance rates across all CoC-accredited cancer programs was 86.3 in 2007 and 84.9 in 2008. The two years available at the time of this writing. Cancer programs in the 75th percentile had performance rates of 100 in each respective year. Even with high aggregate performance rates demonstrated by programs room for improvement across the system of CoC-accredited programs remains, with 6.4% of programs with statistically low outlier performance rates (<44%), SD=22.8%.

2b. VALIDITY. Validity, Testing, including all Threats to Validity: H M L I

2b1.1 Describe how the measure specifications (measure focus, target population, and exclusions) **are consistent with the evidence cited in support of the measure focus** (criterion 1c) **and identify any differences from the evidence:**

2b2. Validity Testing. (Validity testing was conducted with appropriate method, scope, and adequate demonstration of validity.)

2b2.1 Data/Sample (Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included):
See 2a2.1. This measure has been implemented across all CoC-accredited cancer programs and subject to local review by standing committees of these hospitals and site surveyors at the time of accreditation site visits.

2b2.2 Analytic Method (Describe method of validity testing and rationale; if face validity, describe systematic assessment):
Performance rates are reviewed and discussed, randomly selected charts are reviewed by the site surveyor to ascertain the completeness and validity of the data recorded in the local cancer registry and reported to the NCDB and included in the CP3R reporting application.

2b2.3 Testing Results (Statistical results, assessment of adequacy in the context of norms for the test conducted; if face validity, describe results of systematic assessment):
This measure has a high degree of user acceptability, the measure denominator and numerator are viewed by the clinical constituency within these cancer programs as valid and an appropriate reflection of the standard of care described in NCCN clinical guidelines.

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POTENTIAL THREATS TO VALIDITY. (<i>All potential threats to validity were appropriately tested with adequate results.</i>)
2b3. Measure Exclusions. (<i>Exclusions were supported by the clinical evidence in 1c or appropriately tested with results demonstrating the need to specify them.</i>)
2b3.1 Data/Sample for analysis of exclusions (<i>Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included</i>):
2b3.2 Analytic Method (<i>Describe type of analysis and rationale for examining exclusions, including exclusion related to patient preference</i>):
2b3.3 Results (<i>Provide statistical results for analysis of exclusions, e.g., frequency, variability, sensitivity analyses</i>):
2b4. Risk Adjustment Strategy. (<i>For outcome measures, adjustment for differences in case mix (severity) across measured entities was appropriately tested with adequate results.</i>)
2b4.1 Data/Sample (<i>Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included</i>):
2b4.2 Analytic Method (<i>Describe methods and rationale for development and testing of risk model or risk stratification including selection of factors/variables</i>):
2b4.3 Testing Results (<i><u>Statistical risk model</u>: Provide quantitative assessment of relative contribution of model risk factors; risk model performance metrics including cross-validation discrimination and calibration statistics, calibration curve and risk decile plot, and assessment of adequacy in the context of norms for risk models. <u>Risk stratification</u>: Provide quantitative assessment of relationship of risk factors to the outcome and differences in outcomes among the strata</i>):
2b4.4 If outcome or resource use measure is not risk adjusted, provide rationale and analyses to justify lack of adjustment:
2b5. Identification of Meaningful Differences in Performance. (<i>The performance measure scores were appropriately analyzed and discriminated meaningful differences in quality.</i>)
2b5.1 Data/Sample (<i>Describe the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included</i>):
2b5.2 Analytic Method (<i>Describe methods and rationale to identify statistically significant and practically/meaningfully differences in performance</i>):
2b5.3 Results (<i>Provide measure performance results/scores, e.g., distribution by quartile, mean, median, SD, etc.; identification of statistically significant and meaningful differences in performance</i>):
2b6. Comparability of Multiple Data Sources/Methods. (<i>If specified for more than one data source, the various approaches result in comparable scores.</i>)
2b6.1 Data/Sample (<i>Describe the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included</i>):

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2b6.2 Analytic Method (Describe methods and rationale for testing comparability of scores produced by the different data sources specified in the measure):

2b6.3 Testing Results (Provide statistical results, e.g., correlation statistics, comparison of rankings; assessment of adequacy in the context of norms for the test conducted):

2c. Disparities in Care: H M L I NA (If applicable, the measure specifications allow identification of disparities.)

2c.1 If measure is stratified for disparities, provide stratified results (Scores by stratified categories/cohorts):

2c.2 If disparities have been reported/identified (e.g., in 1b), but measure is not specified to detect disparities, please explain:

This measure was not specified to report stratified performance rates, however the CoC's recently released (2011) "real clinical time" Rapid Quality Reporting System (RQRS) (<http://www.facs.org/cancer/ncdb/rqrs.html>) reports back measure-specific performance rates by a number of strata, eg. patient age, sex, ethnicity, insurance status, and area-based SES. RQRS hosts a prospective treatment alert system, and so performance rates are both high and consistent with clinical expectation, however room for potential improvement remains. In a comparative analysis of 16 NCI/NCCCP pilot sites using RQRS with a comparative group of 25 other CoC-accredited cancer programs also using RQRS revealed that across all 41 hospitals 88.1-88.5% of patients (white or African-American) were concordant with receipt of multi-agent chemotherapy, and that 88.9-90.4% of patients, based upon income SES were also concordant, without regard to income status or reporting hospital. Analysis from cases diagnosed 2008-2010.

2.1-2.3 Supplemental Testing Methodology Information:

Steering Committee: Overall, was the criterion, Scientific Acceptability of Measure Properties, met?

(Reliability and Validity must be rated moderate or high) Yes No

Provide rationale based on specific subcriteria:

If the Committee votes No, STOP

3. USABILITY

Extent to which intended audiences (e.g., consumers, purchasers, providers, policy makers) can understand the results of the measure and are likely to find them useful for decision making. (**evaluation criteria**)

C.1 Intended Purpose/ Use (Check all the purposes and/or uses for which the measure is intended): Public Reporting, Quality Improvement (Internal to the specific organization), Quality Improvement with Benchmarking (external benchmarking to multiple organizations), Regulatory and Accreditation Programs

3.1 Current Use (Check all that apply; for any that are checked, provide the specific program information in the following questions): Regulatory and Accreditation Programs, Quality Improvement with Benchmarking (external benchmarking to multiple organizations), Quality Improvement (Internal to the specific organization)

3a. Usefulness for Public Reporting: H M L I

(The measure is meaningful, understandable and useful for public reporting.)

3a.1. Use in Public Reporting - disclosure of performance results to the public at large (If used in a public reporting program, provide name of program(s), locations, Web page URL(s)). If not publicly reported in a national or community program, state the reason AND plans to achieve public reporting, potential reporting programs or commitments, and timeline, e.g., within 3 years of endorsement: [**For Maintenance** – If not publicly reported, describe progress made toward achieving disclosure of performance results to the public at large and expected date for public reporting; provide rationale why continued endorsement should be

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considered.]

This measure is currently in use by ACoS CoC, with performance rates reported back to >1,500 CoC accredited cancer programs since 2007. Over the past five years this measure has been made available primarily for the purposes of QI, however the CoC's 2012 Program Standards (<http://www.facs.org/cancer/coc/cocprogramstandards2012.pdf>) now include expected a minimum performance rate for this measure to be achieved and documented, as well as a commendation recognition for centers that publicly report clinical performance metrics and outcomes. While the CoC anticipates that programs will increasingly self-select to publicly report their own performance rates within the context of the communities they serve, a national public reporting program will require an external mandate (i.e. Federal requirements).

3a.2. Provide a rationale for why the measure performance results are meaningful, understandable, and useful for public reporting. If usefulness was demonstrated (e.g., focus group, cognitive testing), describe the data, method, and results: This measure is based on level 1 clinical evidence. This measure and its specifications have been in use since 2007 though the CoC's CP3R on-line reporting tool (<http://www.facs.org/cancer/ncdb/cp3r.html>) and also included in the more recently released (2011) "real clinical time" RQRS on-line reporting tool (<http://www.facs.org/cancer/ncdb/rqrs.html>). This measure has been easily understood and accepted by the data collection, quality assessment/improvement, and clinical constituents of the >1,500 CoC accredited cancer programs.

3.2 Use for other Accountability Functions (payment, certification, accreditation). If used in a public accountability program, provide name of program(s), locations, Web page URL(s): This measure is currently being considered by the Centers for Medicare and Medicaid Services for inclusion in their public reporting project for PPS-Exempt Cancer Hospitals per the Cancer Hospital Quality Reporting Program (CH QRP) as defined in Section 3005 of the Patient Protection and Affordable Care Act (ACA).

3b. Usefulness for Quality Improvement: H M L I

(The measure is meaningful, understandable and useful for quality improvement.)

3b.1. Use in QI. If used in quality improvement program, provide name of program(s), locations, Web page URL(s):
[For Maintenance – If not used for QI, indicate the reasons and describe progress toward using performance results for improvement].

See response to 3a.1 above.

3b.2. Provide rationale for why the measure performance results are meaningful, understandable, and useful for quality improvement. If usefulness was demonstrated (e.g., QI initiative), describe the data, method and results:

See response to 3a.2 above. In addition, this measure has application in the realm of quality improvement activities, allowing cancer centers to assess and monitor local performance related to the coordination of care and clinical process which are potentially actionable.

Overall, to what extent was the criterion, Usability, met? H M L I

Provide rationale based on specific subcriteria:

4. FEASIBILITY

Extent to which the required data are readily available, retrievable without undue burden, and can be implemented for performance measurement. (**evaluation criteria**)

4a. Data Generated as a Byproduct of Care Processes: H M L I

4a.1-2 How are the data elements needed to compute measure scores generated? (Check all that apply).

Data used in the measure are:

Abstracted from a record by someone other than person obtaining original information (e.g., chart abstraction for quality measure or registry)

4b. Electronic Sources: H M L I

4b.1 Are the data elements needed for the measure as specified available electronically (Elements that are needed to compute measure scores are in defined, computer-readable fields): Some data elements are in electronic sources

NQF #0559 C0559: Combination chemotherapy is considered or administered within 4 months (120 days) of diagnosis for women under 70 with AJCC T1c, or Stage II or III hormone receptor negative breast cancer.

4b.2 If ALL data elements are not from electronic sources, specify a credible, near-term path to electronic capture, OR provide a rationale for using other than electronic sources: The ACoS/CoC implementation of this measure is framed around the feasibility of data collection and reporting considerations. Cancer registries in the United States depend on a multitude of information sources in order to completely abstract case records and be in compliance with State, Federal and private sector accreditation requirements. There is continuing work within the cancer registry and surveillance community, lead largely by the CDC/NPCR program, to help prepare the registries for the universal implementation of EHRs, but until such a time presents itself, registry data will depend upon some level of human review and intervention to ensure data are complete and accurately recorded.

4c. Susceptibility to Inaccuracies, Errors, or Unintended Consequences: H M L I

4c.1 Identify susceptibility to inaccuracies, errors, or unintended consequences of the measurement identified during testing and/or operational use and strategies to prevent, minimize, or detect. If audited, provide results:

This measure, as specified, is susceptible to under-reporting of the adjuvant chemotherapy component appearing in the measure numerator. Due to referral of services, access to patient clinical follow-up with radiation oncology may initially be limited or unavailable. However, CoC accredited programs have demonstrated through retrospective case and chart reviews that significant additional and accurate information regarding treatment provided to patients can be ascertained, resulting in higher and clinically more accurate reflections of the care provided or coordinated through their centers. In addition, at the time of each CoC accreditation survey visit, a chart review of measure eligible cases is conducted on a random selection of as many as 25 cases to ensure the accuracy and validity of the clinical information (focusing on the fact of treatment, the timing of administration of adj. chemotherapy, and whether documentation of consultation and patient refusal occurred) recorded in the registry, reported to the NCDB, and included in the CP3R reporting tool. Additionally, the CoC's 2012 Program Standards (<http://www.facs.org/cancer/coc/cocprogramstandards2012.pdf>) now require direct review and oversight of this measure and the data supporting the denominator and numerator be monitored by an attending physician (Cancer Liaison Physician, CLP) on staff at the center on a quarterly basis.

4d. Data Collection Strategy/Implementation: H M L I

A.2 Please check if either of the following apply (regarding proprietary measures):

4d.1 Describe what you have learned/modified as a result of testing and/or operational use of the measure regarding data collection, availability of data, missing data, timing and frequency of data collection, sampling, patient confidentiality, time and cost of data collection, other feasibility/implementation issues (e.g., fees for use of proprietary measures):

1) The infrastructure to monitor compliance with this measure has been in place since 2005 to assess and feed-back to the >1,500 Commission on Cancer accredited centers performance rates for this measure. CoC accredited cancer programs account for 70-80% of patients affected by this measure. This measure is currently reported to CoC accredited programs through the National Cancer Data Base (NCDB) using the Cancer Program Practice Profile Report (CP3R) web-based audit and feed-back reporting tool. The CP3R is generally described at: www.facs.org/cancer/ncdb/cp3roverview.pdf, and specifications for this measure are provided at: www.facs.org/cancer/ncdb/cp3rmeasurespecs.pdf. In addition, this measure is also reported to over 250 cancer programs participating in its "real clinical time" feedback reporting tool through its Rapid Quality Response System (RQRS). An overview of the RQRS is available at: www.facs.org/cancer/ncdb/qualitytools.html. Both of these reporting tools have been utilized in the cancer registry community and will not produce an undue burden on the data collection network. 2) The data for this measure are key elements already collected in all hospital registries. This measure has been reviewed using cancer registry data. The CoC data demonstrates variation in the measure. Registries have demonstrated the ability to identify gaps in data collection and to correctly identify therapy in the majority of cases. The measure is readily implemented.

Overall, to what extent was the criterion, Feasibility, met? H M L I

Provide rationale based on specific subcriteria:

OVERALL SUITABILITY FOR ENDORSEMENT

Does the measure meet all the NQF criteria for endorsement? Yes No

Rationale:

If the Committee votes No, STOP.

If the Committee votes Yes, the final recommendation is contingent on comparison to related and competing measures.

NQF #0559 C0559: Combination chemotherapy is considered or administered within 4 months (120 days) of diagnosis for women under 70 with AJCC T1c, or Stage II or III hormone receptor negative breast cancer.

5. COMPARISON TO RELATED AND COMPETING MEASURES
If a measure meets the above criteria and there are endorsed or new related measures (either the same measure focus or the same target population) or competing measures (both the same measure focus and the same target population), the measures are compared to address harmonization and/or selection of the best measure before a final recommendation is made.
5.1 If there are related measures (either same measure focus or target population) or competing measures (both the same measure focus and same target population), list the NQF # and title of all related and/or competing measures:
5a. Harmonization
5a.1 If this measure has EITHER the same measure focus OR the same target population as NQF-endorsed measure(s): Are the measure specifications completely harmonized?
5a.2 If the measure specifications are not completely harmonized, identify the differences, rationale, and impact on interpretability and data collection burden:
5b. Competing Measure(s)
5b.1 If this measure has both the same measure focus and the same target population as NQF-endorsed measure(s): Describe why this measure is superior to competing measures (e.g., a more valid or efficient way to measure quality); OR provide a rationale for the additive value of endorsing an additional measure. (Provide analyses when possible):

CONTACT INFORMATION
Co.1 Measure Steward (Intellectual Property Owner): American College of Surgeons, 633 N Saint Clair Street, Chicago, Illinois, 60611-3211
Co.2 Point of Contact: Andrew, Stewart, MA, astewart@facs.org, 312-202-5285-
Co.3 Measure Developer if different from Measure Steward: American College of Surgeons, 633 N Saint Clair Street, Chicago, Illinois, 60611-3211
Co.4 Point of Contact: Andrew, Stewart, MA, astewart@facs.org, 312-202-5285-
Co.5 Submitter: Andrew, Stewart, MA, astewart@facs.org, 312-202-5285-, American College of Surgeons
Co.6 Additional organizations that sponsored/participated in measure development: This measure was harmonized with measure development efforts coordinated between the American Society of Clinical Oncology (ASCO) and The National Cancer Care Network (NCCN) prior to NQF's formal review and consideration of measures submitted in response to its call for measures in 2005 as part of its Quality of Cancer Care Performance Measures project (Desch CE, McNiff KK, Schneider EC, et al. American Society of Clinical Oncology / National Comprehensive Cancer Network Quality Measures. J Clin Oncol 2008;26:3631-3637). The measure, as specified here, has not been altered or changed in any way since harmonization of specifications between these three organizations occurred in the fall of 2006.
Co.7 Public Contact: Andrew, Stewart, MA, astewart@facs.org, 312-202-5285-, American College of Surgeons

ADDITIONAL INFORMATION
Workgroup/Expert Panel involved in measure development
Ad.1 Provide a list of sponsoring organizations and workgroup/panel members' names and organizations. Describe the members' role in measure development.
Christopher Pezzi, MD, FACS (Abington Memorial Hospital, Abington PA); Lawrence Shulman, MD (Dana Farber Cancer Institute, Boston MA); Stephen Edge, MD, FACS (Roswell Park Cancer Institute, Buffalo NY); David Winchester, MD, FACS (Northshore

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University Health System, Evanston IL); Diana Dickson-Witmer, MD, FACS (Christiana Health Care System, Wilmington DE); Kelly Hunt, MD, FACS (MD Anderson Cancer Center, Houston TX); Marilyn Leitch, MD, FACS (University of Texas – Southwestern, Dallas TX); Katherine Virgo, PhD (American Cancer Society)

This panel meets at least once a calendar quarter to review quality measures currently supported and implemented by the ACoS Commission on Cancer and to investigate and consider/review development of possible new measures.

Ad.2 If adapted, provide title of original measure, NQF # if endorsed, and measure steward. Briefly describe the reasons for adapting the original measure and any work with the original measure steward:

Measure Developer/Steward Updates and Ongoing Maintenance

Ad.3 Year the measure was first released: 2007

Ad.4 Month and Year of most recent revision: 06, 2007

Ad.5 What is your frequency for review/update of this measure? Annual

Ad.6 When is the next scheduled review/update for this measure? 05, 2012

Ad.7 Copyright statement:

Ad.8 Disclaimers:

Ad.9 Additional Information/Comments:

Date of Submission (MM/DD/YY): 10/03/2011