**National Quality Forum—Evidence (subcriterion 1a)**

**Measure Number** (*if previously endorsed*)**:** 0210

**Measure Title**: Proportion of patients who died from cancer receiving chemotherapy in last 14 days of life

**IF the measure is a component in a composite performance measure, provide the title of the Composite Measure here:** Click here to enter composite measure #/ title

**Date of Submission**: 2/29/2016

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| **Instructions**  *For composite performance measures:*  *A separate evidence form is required for each component measure unless several components were studied together.*  *If a component measure is submitted as an individual performance measure, attach the evidence form to the individual measure submission.*   * Respond to all questions as instructed with answers immediately following the question. All information needed to demonstrate meeting the evidence subcriterion (1a) must be in this form. An appendix of *supplemental* materials may be submitted, but there is no guarantee it will be reviewed. * If you are unable to check a box, please highlight or shade the box for your response. * Maximum of 10 pages (*incudes questions/instructions*; minimum font size 11 pt; do not change margins). ***Contact NQF staff if more pages are needed.*** * Contact NQF staff regarding questions. Check for resources at [Submitting Standards webpage](http://www.qualityforum.org/Measuring_Performance/Submitting_Standards.aspx). |

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| **Note: The information provided in this form is intended to aid the Steering Committee and other stakeholders in understanding to what degree the evidence for this measure meets NQF’s evaluation criteria.**   1a. Evidence to Support the Measure Focus The measure focus is evidence-based, demonstrated as follows:   * Health outcome: [**3**](#Note3) a rationale supports the relationship of the health outcome to processes or structures of care. Applies to patient-reported outcomes (PRO), including health-related quality of life/functional status, symptom/symptom burden, experience with care, health-related behavior. * Intermediate clinical outcome: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#Note4)that the measured intermediate clinical outcome leads to a desired health outcome. * Process: [**5**](#Note5) a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#Note4) that the measured process leads to a desired health outcome. * Structure: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#Note4) that the measured structure leads to a desired health outcome. * Efficiency: [**6**](#Note6) evidence not required for the resource use component.   **Notes**  **3.** Generally, rare event outcomes do not provide adequate information for improvement or discrimination; however, serious reportable events that are compared to zero are appropriate outcomes for public reporting and quality improvement.  **4.** The preferred systems for grading the evidence are the U.S. Preventive Services Task Force (USPSTF) [grading definitions](http://www.uspreventiveservicestaskforce.org/uspstf/grades.htm) and [methods](http://www.uspreventiveservicestaskforce.org/methods.htm), or Grading of Recommendations, Assessment, Development and Evaluation [(GRADE) guidelines](http://www.gradeworkinggroup.org/publications/index.htm).  **5.** Clinical care processes typically include multiple steps: assess → identify problem/potential problem → choose/plan intervention (with patient input) → provide intervention → evaluate impact on health status. If the measure focus is one step in such a multistep process, the step with the strongest evidence for the link to the desired outcome should be selected as the focus of measurement. Note: A measure focused only on collecting PROM data is not a PRO-PM.  **6.** Measures of efficiency combine the concepts of resource use and quality (see NQF’s [Measurement Framework: Evaluating Efficiency Across Episodes of Care](http://www.qualityforum.org/Publications/2010/01/Measurement_Framework__Evaluating_Efficiency_Across_Patient-Focused_Episodes_of_Care.aspx); [AQA Principles of Efficiency Measures](http://www.aqaalliance.org/files/PrinciplesofEfficiencyMeasurementApril2006.doc)). |

**1a.1.This is a measure of**: (*should be consistent with type of measure entered in De.1*)

Outcome

Health outcome: Click here to name the health outcome

Patient-reported outcome (PRO): Click here to name the PRO

*PROs include HRQoL/functional status, symptom/symptom burden, experience with care, health-related behaviors*

Intermediate clinical outcome (*e.g., lab value*): Click here to name the intermediate outcome

Process: Patients receiving chemotherapy in the last 14 days of life

Structure: Click here to name the structure

Other: Click here to name what is being measured

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**HEALTH OUTCOME/PRO PERFORMANCE MEASURE**  *If not a health outcome or PRO, skip to* [*1a.3*](#Section1a3)

**1a.2.** **Briefly state or diagram the path between the health outcome (or PRO) and the healthcare structures, processes, interventions, or services that influence it.**

**1a.2.1.** **State the rationale supporting the relationship between the health outcome (or PRO) to at least one healthcare structure, process, intervention, or service (*i.e., influence on outcome/PRO*).**

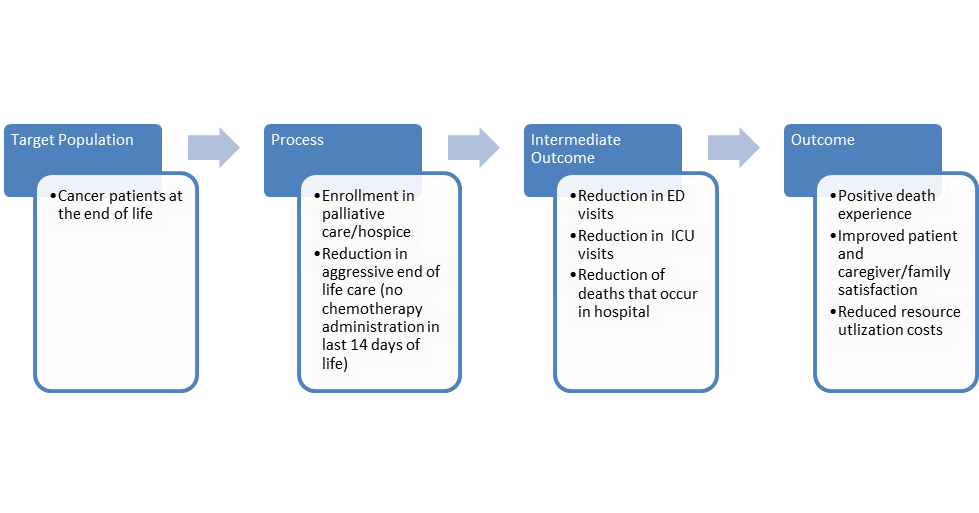
*Note: For health outcome/PRO performance measures, no further information is required; however, you may provide evidence for any of the structures, processes, interventions, or service identified above.*

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**intermediate outcome, PROCESS, or STRUCTURE PERFORMANCE measure**

**1a.3.****Briefly state or diagram the path between structure, process, intermediate outcome, and health outcomes**. Include all the steps between the measure focus and the health outcome.

Use from



There is evidence that demonstrates patients receive unnecessary treatments at the end of life, which can negatively impact the patient and caregiver experience. Patients continue to receive chemotherapy treatments at the end of life even when it is recognized that it is unnecessary. For example, more than 15% of patients with metastatic lung and colorectal cancer received chemotherapy in the last month of life (Mack, 2015). In addition, receipt of chemotherapy at the end of life can increase the potential for hospitalizations and intensive care admissions (El-Jawahri, 2015), which can negatively impact the patient’s and caregiver’s experience.

El-Jawahri, A. R., G. A. Abel, et al. (2015). "Health care utilization and end-of-life care for older patients with acute myeloid leukemia." Cancer 121(16): 2840-2848.

Mack, J. W., A. Walling, et al. (2015). "Patient beliefs that chemotherapy may be curative and care received at the end of life among patients with metastatic lung and colorectal cancer." Cancer 121(11): 1891-1897.

A structural feature: regional availability of hospice, has been shown to correlate with a composite measure of the aggressiveness of cancer care near the end of life that contains this measure. Mostly it is a process measure indicating a possible inadequate focus on palliation and supportive care, that can affect quality of life.

The Process-Outcome link is that continuing chemotherapy near death does not prolong survival (Saito AM, Landrum MB, Neville BA, et al. The effect on survival of continuing chemotherapy to near death. BMC Palliat.Care. 10:14.:14, 2011) or quality of life (Temel JS, Greer JA, Muzikansky A, et al. Early palliative care for patients with metastatic non-small-cell lung cancer. N Engl J Med. 363:733-42, 2010; Greer et al in press J Clin Oncol 2011) and consequently provides only toxicity, inconvenience, and cost in most cases.

In the NIH-funded Cancer Care Outcomes Research and Surveillance Consortium, bereaved family members of 706 lung or colorectal cancer patients rated the quality of end-of-life care their loved one had received. Adjusted for age, sex, marital status, income, education, stage, comorbidity, health system type, census region, and the respondent´s relationship to the patient, respondents were significantly more likely to rate the end-of-life care to have been very good or excellent (86.0 vs 75.7%), with no unmet need for help with anxiety or depression (86.6 vs 78.0%) or breathing (86.3 vs 80.3%), and that they died in their preferred location (77.6 vs 56.3%) if the patient had a composite measure of having spent at least 3 days in hospice, had 1 or fewer hospital admissions in the last month of life, or had an interval of more that 14 days between the last dose of chemotherapy and death(Landrum MB et al, under review).

**1a.3.1.** **What is the source of the systematic review of the body of evidence that supports the performance measure?**

Clinical Practice Guideline recommendation – ***complete sections*** [***1a.4***](#Section1a4)***, and*** [***1a.7***](#Section1a7)

US Preventive Services Task Force Recommendation – ***complete sections*** [***1a.5***](#Section1a5) ***and*** [***1a.7***](#Section1a7)

Other systematic review and grading of the body of evidence (*e.g., Cochrane Collaboration, AHRQ Evidence Practice Center*) – ***complete sections*** [***1a.6***](#Section1a6) ***and*** [***1a.7***](#Section1a7)

Other – ***complete section*** [***1a.8***](#Section1a8)

In 2012: Type of Evidence was selected individual studies (rather than entire body of evidence)

*do not apply.*

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**1a.4. CLINICAL PRACTICE GUIDELINE RECOMMENDATION**

**1a.4.1.** **Guideline citation** (*including date*) and **URL for guideline** (*if available online*):

**1a.4.2.** **Identify guideline recommendation number and/or page number** and **quote verbatim, the specific guideline recommendation**.

**1a.4.3.** **Grade assigned to the quoted recommendation with definition of the grade:**

**1a.4.4. Provide all other grades and associated definitions for recommendations in the grading system.** (*Note: If separate grades for the strength of the evidence, report them in section 1a.7.*)

**1a.4.5. Citation and URL for methodology for grading recommendations** (*if different from 1a.4.1*)**:**

**1a.4.6. If guideline is evidence-based (rather than expert opinion), are the details of the quantity, quality, and consistency of the body of evidence available (e.g., evidence tables)?**

Yes **→ *complete section*** [***1a.7***](#Section1a7)

No **→ *report on another systematic review of the evidence in sections*** [***1a.6***](#Section1a6) ***and*** [***1a.7***](#Section1a7)***; if another review does not exist, provide what is known from the guideline review of evidence in*** [***1a.7***](#Section1a7)

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**1a.5.** **UNITED STATES PREVENTIVE SERVICES TASK FORCE RECOMMENDATION**

**1a.5.1.** **Recommendation citation** (*including date*) and **URL for recommendation** (*if available online*):

**1a.5.2.** **Identify recommendation number and/or page number** and **quote verbatim, the specific recommendation**.

**1a.5.3.** **Grade assigned to the quoted recommendation with definition of the grade**:

**1a.5.4. Provide all other grades and associated definitions for recommendations in the grading system.** (*Note: the* *grading system for the evidence should be reported in section 1a.7.*)

**1a.5.5. Citation and URL for methodology for grading recommendations** (*if different from 1a.5.1*)**:**

***Complete section*** [***1a.7***](#Section1a7)

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**1a.6. OTHER SYSTEMATIC REVIEW OF THE BODY OF EVIDENCE**

**1a.6.1.** **Citation** (*including date*) and **URL** (*if available online*):

Smith TJ, Temin S, Alesi ER, et al. American Society of Clinical Oncology Provisional Clinical Opinion: The Integration of Palliative Care into Standard Oncology Care. J Clin Oncol 2012;30:880-887. Available at: <http://www.instituteforquality.org/asco-provisional-clinical-opinion-integration-palliative-care-standard-oncology-care>.

Gomes, B., N. Calanzani, et al. (2013). "Effectiveness and cost-effectiveness of home palliative care services for adults with advanced illness and their caregivers." Cochrane Database Syst Rev 6: CD007760. Available at: <http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD007760.pub2/pdf>.

**1a.6.2.** **Citation and** **URL for methodology for evidence review and grading** (*if different from 1a.6.1*)**:**

***Complete section*** [***1a.7***](#Section1a7)

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**1a.7. FINDINGS FROM SYSTEMATIC REVIEW OF BODY OF THE EVIDENCE supporting the measure**

*If more than one systematic review of the evidence is identified above, you may choose to summarize the one (or more) for which the best information is available to provide a summary of the quantity, quality, and consistency of the body of evidence. Be sure to identify which review is the basis of the responses in this section and if more than one, provide a separate response for each review.*

**1a.7.1.** **What was the specific structure, treatment, intervention, service, or intermediate outcome addressed in the evidence review?**

A 2012 American Society of Clinical Oncology (ASCO) Provisional Clinical Opinion (PCO) addresses the integration of palliative care (PC) services into standard oncology care at the time a person is diagnosed with metastatic cancer and/or high symptom burden.

A 2013 Cochrane Review, ‘Effectiveness and cost-effectiveness of home palliative care services for adults with advanced illness and their caregivers’, evaluated the impact of home palliative care services on outcomes for adults with advanced illness or their family caregivers, or both. The aim of the review was to quantify the effect of home palliative care services on a patients’ odds of dying at home, examine the clinical effectiveness of home palliative care services on other outcomes such as symptom control, quality of life, caregiver distress and satisfaction with care, and comparing resource use and costs associated with these services.

2012 Submission: The argument is made that because providers cannot predict the future, measures based on decedent cohorts are unfair. However, as described above in 1a.a, the idea is for the measure to be seen as an overall indication of practice style and/or available palliative resources. An individual patient experiencing this process of care has not necessarily received poor quality care. If explanations other than practice style and resource availability, such as unusually poor prognostic ability on the part of the provider or unexpected toxic deaths (whether unavoidable, from overly aggressive treatment, or poor patient selection) are enough to influence the overall aggregate rates, it is still justifiable to consider it a ‘red flag’ that should prompt examination of the care provided.

**1a.7.2.** **Grade assigned for the quality of the quoted evidence with definition of the grade**:

2012 ASCO PCO (p. 881):

The American Society of Clinical Oncology (ASCO) has established a rigorous, evidence-based approach—the provisional clinical opinion (PCO)—to offer a rapid response to emerging data in clinical oncology. The PCO is intended to offer timely clinical direction to ASCO’s oncologists after publication or presentation of potentially practice- changing data from major studies.

The PCO may serve in some cases as interim direction to the membership pending the development or updating of an ASCO clinical practice guideline. As such, the evidence is not graded in a PCO and is a result of expert consensus. A clinical guideline on palliative care integration with recommendations and the associated grading is under development.

2013 Cochrane Review (p. 12):

Two independent reviewers assessed all included studies for methodological quality using the standard criteria developed by the Cochrane EPOC Review Group for RCTs/CCTs, CBAs and ITSs. The checklist for RCTs/CCTs contains seven items qualified as done, unclear and not done for concealment of allocation, follow-up of professionals, follow up of patients or episodes of care, blinded assessment of primary outcome(s), baseline assessment, reliable primary outcome measure(s) and protection against contamination. Blinding and reliability of all outcomes were also assessed.

Each criterion was scored zero (not done), 0.5 (not clear or when scores varied across outcomes) and one (done). Total scores for RCTs/ CCTs ranged from zero to six; studies with a score of 3.5 or above were considered of high quality. Integration of the results of the quality assessment in data analysis was done in addition to meta-analyses with sensitivity analyses including only high quality studies.

**1a.7.3. Provide all other grades and associated definitions for strength of the evidence in the grading system.**

See 1a.7.2 for this information

2012 Submission: Other, does not apply

**1a.7.4.** **What is the time period covered by the body of evidence? (*provide the date range, e.g., 1990-2010*). Date range**:

2012 ASCO PCO: 2004-2012

2013 Cochrane Review: 1950 – November 2012

**QUANTITY AND QUALITY OF BODY OF EVIDENCE**

**1a.7.5.****How many and what type of study designs are included in the body of evidence**? (*e.g., 3 randomized controlled trials and 1 observational study*)

2012 ASCO PCO: 7 randomized controlled trials

2013 Cochrane Review: 5 randomized controlled trials and 2 controlled clinical trials

2012 Submisson: 4 studies were used in the body of evidence

**1a.7.6.** **What is the overall quality of evidence across studies in the body of evidence**? (*discuss the certainty or confidence in the estimates of effect particularly in relation to study factors such as design flaws, imprecision due to small numbers, indirectness of studies to the measure focus or target population*)

2012 ASCO PCO:

This PCO did not provide an assessment of the overall quality of evidence across the studies. This analysis will be completed during the development of the upcoming clinical guideline.

2013 Cochrane Review :

p. 3: The direction of the effect was consistent across all studies but did not reach statistical significance in 3; ORs ranged from 1. 36 (95% CI 0.80 to 2.31) to 2. 86 (95% CI 0.78 to 10.53) Sensitivity analyses showed that exclusion of the 2 CCTs (both of Swedish hospital-based services with a pooled OR 3.44, 95% CI 0.60 to 19.57) and inclusion of only high quality RCTs resulted in a reduction of the OR to 1.28 (95% CI 1.28 to 2.33) and 1.75 (95% CI 1.24 to 2. 47) respectively, with more precision and less heterogeneity.

p. 22:

Pooled data from seven studies (five RCTs, three of high quality, and two CCTs with 1222 participants) showed that those receiving home palliative care had statistically significantly higher odds of dying at home than those receiving usual care (OR 2.21, 95% CI 1.31 to 3.71; Z = 2.98, P value = 0.003; Chi2 = 20.57, degrees of freedom (df ) = 6, P value = 0.002; I2 = 71%). The study population control risk was of 307 home deaths per 1000 deaths; based on this ACR of 0.307, the NNTB was 5 (95% CI 3 to 14), meaning that for one additional patient to die at home five more would need to receive home palliative care as opposed to usual care. Assuming a medium cancer home death rate population ACR of 0.278 (i.e. 278 home deaths per 1000 cancer deaths), the NNTB was 6 (95% CI 3 to 15). This means that for one additional cancer patient to die at home in a population where there are 278 home deaths per 1000 cancer deaths, six more would need to receive home palliative care. NNTB estimates ranged from 9 patients (95% CI 5 to 16) when applied to a low home death rate population such as the one observed in Norway (128 home deaths per 1000 cancer deaths) to 5 patients (95% CI 3 to 13) when applied to a high home death rate population such as the one observed in the Netherlands (454 home deaths per 1000 cancer deaths).

2012 submission: The studies are qualitative and observational using administrative data, consequently there are limitations to the quality of the data.

**ESTIMATES OF BENEFIT AND CONSISTENCY ACROSS STUDIES IN BODY OF EVIDENCE**

**1a.7.7.** **What are the estimates of benefit—magnitude and direction of effect on outcome(s) across studies in the body of evidence**? (*e.g., ranges of percentages or odds ratios for improvement/ decline across studies, results of meta-analysis, and statistical significance*)

2012 ASCO PCO (p. 884):

Seven published randomized trials demonstrate the feasibility of providing various components of PC alongside usual oncology care. There is, however, a dearth of data evaluating the integration of modern PC practices into standard oncology care, especially in concert with ongoing antitumor therapy. Overall, the addition of PC interventions to standard oncology care delivered via different models to patients with cancer provided evidence of benefit.

2013 Cochran Review (p. 22):

The study population control risk was of 307 home deaths per 1000 deaths; based on this ACR of 0.307, the NNTB was 5 (95% CI 3 to 14), meaning that for one additional patient to die at home five more would need to receive home palliative care as opposed to usual care. Assuming a medium cancer home death rate population ACR of 0.278 (i.e. 278 home deaths per 1000 cancer deaths), the NNTB was 6 (95% CI 3 to 15). This means that for one additional cancer patient to die at home in a population where there are 278 home deaths per 1000 cancer deaths, six more would need to receive home palliative care. NNTB estimates ranged from 9 patients (95% CI 5 to 16) when applied to a low home death rate population such as the one observed in Norway (128 home deaths per 1000 cancer deaths) to 5 patients (95% CI 3 to 13) when applied to a high home death rate population such as the one observed in the Netherlands (454 home deaths per 1000 cancer deaths).

2012 Submission: All studies have shown similar results.

As per Ho TH, Barbera L, Saskin R, Lu H, Neville BA, Earle CC.Trends in the Aggressiveness of End-of-Life Cancer Care in the Universal Health Care System of Ontario, Canada. J Clin Oncol April 20, 2011 vol. 29 no. 12 1587-1591, although rates in Canada were lower, trends were similar over time in a comparison with U.S. Medicare patients.

A study examined the frequency and duration of chemotherapy use among Medicare cancer decedents in Massachusetts and California. Researchers found that 9% of Medicare cancer decedents in Massachusetts and California received chemotherapy in the last month of life. No difference was found by geographic region (Emanuel E, Young-Xu Y, Levinsky, N, et al. Chemotherapy use among medicare beneficiaries at the end-of-life. Annals of Internal Medicine. 2003; 138(8): 639-643.).

**1a.7.8.** **What harms were studied and how do they affect the net benefit (benefits over harms)?**

2012 ASCO PCO (p. 884-885):

No harm to any patient was observed in any trial, even with discussions of EOL planning, such as hospice and ADs. Two of five trials measuring change in symptoms, two of five studies measuring QOL, two of three studies measuring patient/caregiver satisfaction, and one of three studies measuring survival found statistically significant improvements with PC. Three of six studies measuring mood, two of five studies measuring resource use, and one of four studies measuring outcomes of advance care planning found statistically significant differences, and one outcome of borderline significance was also found in each of these three areas, Therefore, most trials showed benefits ranging from equal to improved overall survival, reduced depression, improved caregiver and/or patient QOL, and overall lower resource use and cost because EOL hospitalizations were avoided.

2013 Cochrane Review: Discussion of harms was not addressed.

2012 Submission: A shift from aggressive anti-cancer treatment to supportive care can improve the quality of death. There are no known harms to not giving chemotherapy near death.

**UPDATE TO THE SYSTEMATIC REVIEW(S) OF THE BODY OF EVIDENCE**

**1a.7.9.** **If new studies have been conducted since the systematic review of the body of evidence, provide for each new study: 1) citation, 2) description, 3) results, 4) impact on conclusions of systematic review**.

No relevant studies have been conducted and published since the systematic reviews.

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**1a.8 OTHER SOURCE OF EVIDENCE**

*If source of evidence is NOT from a clinical practice guideline, USPSTF, or systematic review, please describe the evidence on which you are basing the performance measure.*

**1a.8.1** **What process was used to identify the evidence?**

**1a.8.2.** **Provide the citation and summary for each piece of evidence.**

2012 Submission: The underlying evidence was obtained by expert consensus, as described in Earle CC, Park ER, Lai B, Weeks JC, Ayanian JZ, Block S. Identifying potential indicators of the quality of end of life cancer care from administrative data. J Clin Oncol. 2003;21(6):1133-8. The panel consisted of oncologists, nurses, palliative care specialists, etc, and used a modified Delphi process to evaluate measures.