Proposed New Measures for HEDIS® 2015: Colorectal and Prostate Cancer Appropriateness/Overuse Measures

NCQA seeks comments on the following proposed new measures for inclusion in the HEDIS 2015 measurement set:

1. **Non-Recommended Colorectal Cancer Screening in Older Adults.**
   The percentage of members 86 years and older who were screened unnecessarily for colorectal cancer.

2. **Non-Recommended PSA-Based Screening in Older Men.**
   The percentage of men 70 years and older who were screened unnecessarily for prostate cancer using prostate-specific antigen (PSA)-based screening.

*Note: For both measures, a lower rate indicates better performance.*

These measures represent important areas for quality improvement by assessing the use of services that are not recommended for specific populations. Each is supported by clinical recommendations from the U.S. Preventive Services Task Force (USPSTF) and other national organizations.

Convincing evidence suggests that colorectal cancer screening in the elderly population and PSA-based screening for men at any age are associated with harms that outweigh benefits:

- For colorectal cancer screening, there are risks of serious complications such as perforation and major bleeding from colonoscopies.
- For PSA-based screening, false-positive results are relatively common, leading to harms such as additional follow-up testing, such as biopsies.

NCQA field-tested the measures in a large Medicare claims data set to assess the feasibility of reporting them using administrative data; to understand the impact of exclusions (i.e., justifications for testing); and to assess performance rates.

*Note: A supplemental medical-record study, being completed during this Public Comment period, aims to assess the ability of claims data to reliably identify exclusions and distinguish between tests used for screening vs. diagnostic purposes.*

The claims study revealed that plans had sufficient eligible population for both measures. The average performance rate of non-recommended colorectal cancer screening among plans was 6.1 percent. Among potential justifications for testing in this population, iron deficiency anemia was most frequently documented, followed by gastrointestinal bleeding. The average performance rate among plans for non-recommended prostate cancer screening was 37.7 percent. Among potential justifications for testing, prostate cancer diagnosis and elevated PSA result were the most commonly noted in the claims data.

NCQA’s advisory panels concluded that results to date demonstrate that the measures are feasible and present opportunities for improvement. Stakeholders agree that measure specifications need to explicitly define screening events so that high-risk populations for whom testing is justified and diagnostic tests for follow-up of symptoms are adequately removed from the measures. A hybrid specification that requires medical chart review will allow plans to identify diagnostic tests and other exclusions not captured by claims data.

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1HEDIS® is a registered trademark of the National Committee for Quality Assurance (NCQA).
We request comments on these issues:

1. Although the USPSTF recommends against PSA-based screening in men of all ages, the measure specifies an age range of 70 and older due to advisory panel input noting the clearer lack of benefits of screening and treatment in men of this age group. In addition, the age range aligns with American Urological Association recommendations. We request input on the age range for this measure.

2. NCQA specified that a patient with a history of elevated PSA would be excluded from the measure because both clinicians and patients may request follow-up testing based on an elevated test result (even if the initial result was the result of an inappropriate screening test that might have been performed before guidelines recommended against screening all men). However, several experts on our advisory panels noted that an elevated PSA test should not justify testing in the population of 70 years of age and older because of the lack of benefit and the increased potential for harm. We request input on this issue.

3. In comparison with the PSA-based mean screening rate of 37.7 percent (a lower rate indicates better performance) found in field test, the mean colorectal cancer screening rate was 6.1 percent. Advisory panels noted the rate represents potentially harmful practices, in particular given issues such as colonoscopy perforation rates. Does this rate represent a gap in care?

4. Based on advisory panel feedback, a hybrid method component for both measures was deemed necessary to allow for the identification of exclusions (i.e. justifications for testing) that are not captured by claims data and only found through a medical record review. However, using the hybrid method to identify numerator events may be problematic, as auditing would have to assess whether all events were correctly noted if they occurred. We request input on this issue.

Supporting documents for the proposed measures include the draft measure specifications and associated measure rationale work-ups.

# Non-Recommended PSA-Based Screening in Older Men

## Summary of Changes to HEDIS® 2015

- First-year measure.

## Description

The percentage of men 70 years and older who were screened unnecessarily for prostate cancer using prostate-specific antigen (PSA)-based screening.

*Note: A lower rate indicates better performance.*

## Eligible Population

<table>
<thead>
<tr>
<th>Product lines</th>
<th>Medicare.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ages</td>
<td>Men ages 70 years and older as of December 31 of the measurement year.</td>
</tr>
<tr>
<td>Continuous enrollment</td>
<td>The measurement year.</td>
</tr>
<tr>
<td>Allowable gap</td>
<td>No more than one gap in enrollment of up to 45 days.</td>
</tr>
<tr>
<td>Anchor date</td>
<td>December 31 of the measurement year.</td>
</tr>
<tr>
<td>Benefit</td>
<td>Medical.</td>
</tr>
<tr>
<td>Event/diagnosis</td>
<td>None.</td>
</tr>
</tbody>
</table>

## Administrative Specification

<table>
<thead>
<tr>
<th>Denominator</th>
<th>The eligible population.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Required exclusions</td>
<td>Exclude men with a family history of malignant neoplasm of the prostate, prostate cancer diagnosis, or dysplasia of the prostate (PSA Exclusions Value Set) on or between January 1 of the year prior to the measurement year and December 31 of the measurement year.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Numerator</th>
<th>Screened unnecessarily for prostate cancer. Follow the steps below to identify the numerator.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Step 1</td>
<td>Identify members with a PSA-based screening test (PSA Tests Value Set) performed during the measurement year.</td>
</tr>
<tr>
<td>Step 2</td>
<td>Exclude from the denominator members who had a PSA test with an elevated result during the year prior to the measurement year. Either of the following during the year prior to the measurement year meet criteria:</td>
</tr>
<tr>
<td></td>
<td>- A PSA test with an elevated result (Elevated PSA Value Set).</td>
</tr>
<tr>
<td></td>
<td>- A PSA test (PSA Tests Value Set) where laboratory data indicate an elevated result (&gt;4.0 ng/mL).</td>
</tr>
</tbody>
</table>
Hybrid Specification

**Denominator**
A systematic sample drawn from the eligible population for the Medicare product line.

**Required exclusions**

**Administrative**
Refer to *Administrative Specification* to identify required exclusions from administrative data.

**Medical record**
Exclude men with documentation of any of the following on or between January 1 of the year prior to the measurement year and December 31 of the measurement year.
- Family history of malignant neoplasm of the prostate.
- Prostate cancer.
- Dysplasia of the prostate.

**Numerator**
Documentation in the medical record of PSA-based screening test performed during the measurement year.

**Administrative**
Refer to *Administrative Specification* to identify positive numerator hits from the administrative data.

**Medical Record**
Identify the number of men 70 years of age or older as of December 31 of the measurement year who had a PSA-based prostate cancer screening.

Documentation in the medical record must include a note indicating the date when the PSA screening was performed. A result is not required if the documentation is clearly part of the "medical history" section of the record; if this is not clear, the result or finding must also be present (this ensures that the screening was performed and not merely ordered).

Exclude from the denominator members who had a PSA test where laboratory data indicate an elevated result (>4.0 ng/mL) during the year prior to the measurement year.

**Note**

- Because this measure assesses non-recommended care, organizations may also search the medical record for required exclusions even if the member has an administrative hit. For Hybrid reporting, search the medical record for required exclusions and apply them before determining if the member has a numerator hit.

- During field-testing, organizations generally required an oversample of [TBD] percent to meet the MRSS for this measure.
**Data Elements for Reporting**

Organizations that submit HEDIS data to NCQA must provide the following data elements.

**Table XX: Data Elements PSA-Based Screening in Men**

<table>
<thead>
<tr>
<th>Data Element</th>
<th>Administrative</th>
<th>Hybrid</th>
</tr>
</thead>
<tbody>
<tr>
<td>Measurement year</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Data collection methodology (Administrative or Hybrid)</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Eligible population</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Number of numerator events by administrative data in eligible population (before exclusions)</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Current year’s administrative rate (before exclusions)</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Minimum required sample size (MRSS) or other sample size</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Oversampling rate</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Final sample size (FSS)</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Number of numerator events by administrative data in FSS</td>
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<td>✓</td>
</tr>
<tr>
<td>Administrative rate on FSS</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Number of original sample records excluded because of valid data errors</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Number of administrative data records excluded</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Number of medical records excluded</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Number of employee/dependent medical records excluded</td>
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<td>✓</td>
</tr>
<tr>
<td>Records added from the oversample list</td>
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</tr>
<tr>
<td>Denominator</td>
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<td>✓</td>
</tr>
<tr>
<td>Numerator events by administrative data</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Numerator events by medical records</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Reported rate</td>
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</tr>
<tr>
<td>Lower 95% confidence interval</td>
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<td>✓</td>
</tr>
<tr>
<td>Upper 95% confidence interval</td>
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<td>✓</td>
</tr>
</tbody>
</table>
Non-Recommended PSA-Based Screening in Older Men
Measure Work-Up

Measure Description

The percentage of men 70 years of age and older who were screened unnecessarily for prostate cancer using prostate-specific antigen (PSA)-based screening.

Note: A lower rate indicates better performance.

Topic Overview

Importance and Prevalence

Health importance

Prostate cancer is the most commonly diagnosed form of nonskin cancer among men in the United States (Howlader, 2011; Li, 2012). The current lifetime risk for a male to develop prostate cancer is 15.9 percent (USPSTF, 2012); however, the risk of dying from it is 2.9 percent (Hoffman, 2013).

According to the National Cancer Institute’s Surveillance Epidemiology and End Results data (2005–2009), the median age at diagnosis for men was 67 years of age (Howlader, 2011; Li, 2012; AUA 2009). Since diagnosis is closely linked to screening, the apparent incidence of prostate cancer increases with increasing age until 84, after which it declines, as seen below.

- 0 percent of men were diagnosed under 20 years.
- 0.6 percent between 35 and 44 years.
- 9.6 percent between 45 and 54 years.
- 32.3 percent between 55 and 64 years.
- 35.8 percent between 65 and 74 years.
- 17.7 percent between 75 and 84 years.
- 4.0 percent in 85 years and older.

Although prostate cancer is the fifth leading cause of all cancer deaths in the U.S., the survival rates are relatively high, with 23 deaths per 100,000 per year. Localized prostate cancer has a five-year survival rate of 100 percent, and approximately 81 percent of prostate cancers are diagnosed at the local stage (SEER, 2010).

Screening tests

The primary tests used to screen for prostate cancer are the digital rectal exam (DRE), which allows for physical examination of the prostate, and the prostate-specific antigen (PSA) blood test, which evaluates presence of an antigen in a patient’s blood (CDC, 2013). PSA-based screening is commonly used in lieu of DRE. If results are outside a specified range, providers may perform additional tests to confirm the diagnosis, such as a transrectal ultrasound or a biopsy (CDC, 2013).

Approximately 40 percent–50 percent of men 50 years of age or older have undergone PSA screening (Han, 2013). However, there are a variety of issues associated with PSA-based screening. Research has shown PSA-based screening is not focal, which can result in misdiagnoses and unnecessary performance of diagnostic procedures (AUA, 2009; USPSTF, 2012). Moreover, PSA-based screening is not capable of determining which tumors are fast growing (high grade), which can lead to inappropriate administration of treatment modalities such as radiation (AUA, 2009; USPSTF, 2012). In addition, several unrelated factors can affect PSA levels in a patient’s blood, including current intake of antibiotics, presence of related comorbidities (e.g., prostatitis), select medical procedures (e.g., biopsy), and an enlarged prostate or
systematic infection (AUA, 2009; USPSTF, 2012). The likelihood of PSA tests producing false-positive results is also relatively high, with some studies yielding 80 percent false-positive results when the cut-off range used is between 2.5 and 4.0 ug/L (Schroder, 2009). Men with false-positive results not only experience negative psychological effects such as persistent worrying, but they are also more likely to have follow-up testing in the following year, including one or more biopsies (USPSTF, 2012).

In addition to issues of test specificity and sensitivity, prostate cancer is subject to over-diagnosis, the detection of a condition that would have remained silent and caused no morbidity during a patient’s lifetime (AUA 2009). Two large-scale PSA-based screening studies reveal over-diagnosis rates ranging from 17 percent–50 percent (USPSTF, 2012). The main harms result from complications due to biopsies and treatment that typically follow abnormal results. Studies have shown that, out of 1,000 men screened, 110 (11 percent) would be diagnosed with prostate cancer, and roughly half of those diagnosed experience complications from treatment (NCI, 2012). Complications include erectile dysfunction, urinary incontinence, serious cardiovascular events, deep vein thrombosis, and pulmonary embolism (NCI, 2012).

Research has shown that patients identified early via PSA-based screening had health outcomes that were comparable to patients identified at a later, symptomatic point of development (USPSTF, 2012). Similarly, the mortality rates for those screened compared to non-screened individuals are similar. Five in 1,000 will die from prostate cancer with no screening; 4–5 of 1,000 will die despite having been screened (USPSTF, 2012). Thus, the benefits of PSA-based screening is relatively small: screening is estimated to prevent 0–1 cancer deaths per 1,000 men screened. Watchful waiting on a regular basis is considered a preferable and effective option for low-risk patients, thereby also preventing exposure to side effects associated with testing and treatment (AUA, 2009; USPSTF, 2012).

**Recommended practice**

The United States Preventive Services Task Force (USPSTF) recommends against PSA-based screening for prostate cancer in men in the general U.S. population, regardless of age (D Recommendation, 2012). The USPSTF concludes the overall benefits do not outweigh the associated harms with testing, subsequent diagnosis procedures and treatments. PSA testing will result in little to no difference in prostate cancer-specific mortality and similar length of life. This recommendation updates the previous (2008) USPSTF recommendation against PSA-based screening among men 75 and older. Evidence supporting the performance of screening among men younger than 75 was limited at the time.

**Financial Importance and Cost-Effectiveness**

The cost of a PSA test can range from $70–$400 (Kale, 2013; Korenstein, 2012). Approximately 30 million men undergo PSA testing in the U.S. annually, translating to an estimated $3 billion in associated direct costs (Kale, 2013; Korenstein, 2012). This figure does not account for downstream costs or additional subsequent services such as biopsies, ultrasounds, treatment of irregular screening results or specialist consultation. The Medicare fee-for-service program spent $447 million annually on PSA-based screenings, approximately one-third of which was spent on men older than 75 (Ma, 2013).
Opportunity for Improvement

Gaps in care
Despite the revised guidelines for PSA screening and its questionable benefits, the National Health Interview Surveyed revealed that PSA testing among older men did not change between 2005 and 2010, with 43 percent of 75-year old men receiving a PSA test in both years. In 2011, the PSA screening rate was highest among men 70–74 years of age (45 percent), followed by men 85 and older (25 percent) and men 50 to 54 (24 percent) (Kale, 2013; Drazer, 2011).

Health care disparities
African-American men are disproportionately affected by prostate cancer and are twice as likely to die from it as other men in the U.S. (USPSTF, 2012). There is limited evidence, however, regarding screening rates for this subgroup in particular (ACS, 2012).

References


## Recommendations for Prostate Cancer Screening in Men

<table>
<thead>
<tr>
<th>Organization (Year)</th>
<th>Age</th>
<th>Risk</th>
<th>Recommendation</th>
<th>Rating*</th>
</tr>
</thead>
<tbody>
<tr>
<td>U.S. Preventive Services Task Force (2012)</td>
<td>All</td>
<td>Average Risk</td>
<td>The USPSTF recommends against prostate-specific antigen (PSA)-based screening for prostate cancer. This recommendation applies to men in the general U.S. population, regardless of age.</td>
<td>D grade</td>
</tr>
<tr>
<td>American Cancer Society* (2012)</td>
<td>Starting at 50</td>
<td>Average Risk</td>
<td>This discussion about screening should take place for men who are expected to live at least 10 more years.</td>
<td>No grade listed</td>
</tr>
<tr>
<td></td>
<td>Starting at 45</td>
<td>High Risk</td>
<td>This discussion about screening should take place. This includes African Americans and men who have a first-degree relative (father, brother, or son) diagnosed with prostate cancer at an early age (younger than age 65).</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Starting at 40</td>
<td>Highest Risk</td>
<td>This discussion about screening should take place. Higher risk includes those with more than one first-degree relative who had prostate cancer at an early age.</td>
<td></td>
</tr>
<tr>
<td>American Urological Association (2013)</td>
<td>Under 40</td>
<td>Average Risk</td>
<td>Guideline Statement 1: The Panel recommends against PSA screening in men under age 40 years. In this age group there is a low prevalence of clinically detectable prostate cancer, no evidence demonstrating benefit of screening and likely the same harms of screening as in other age groups. The greatest benefit of screening appears to be in men ages 55–69 years. Additionally, intervals for rescreening can be individualized by a baseline PSA level.</td>
<td>Recommendation; Evidence Strength Grade C</td>
</tr>
<tr>
<td></td>
<td>40–54</td>
<td>Average Risk</td>
<td>Guideline Statement 2: The Panel does not recommend routine screening For men younger than age 55 years at higher risk (e.g. positive family history or African American race), decisions regarding prostate cancer screening should be individualized.</td>
<td>Recommendation; Evidence Strength Grade C</td>
</tr>
<tr>
<td></td>
<td>55–69</td>
<td>Not specified</td>
<td>Guideline Statement 3: The Panel recognizes that the decision to undergo PSA screening involves weighing the benefits of preventing prostate cancer mortality in 1 man for every 1,000 men screened over a decade against the known potential harms associated with screening and treatment. For this reason, the Panel strongly recommends shared decision-making for men age 55–69 years that are considering PSA screening, and proceeding based on a man’s values and preferences.</td>
<td>Standard; Evidence Strength Grade B</td>
</tr>
<tr>
<td></td>
<td>Any</td>
<td>Not specified</td>
<td>Guideline Statement 4: To reduce the harms of screening, a routine screening interval of two years or more may be preferred over annual screening in those men who have participated in shared decision-making and decided on screening. As compared to annual screening, it is expected that screening intervals of two years preserve the majority of the benefits and reduce over-diagnosis and false positives.</td>
<td>Option; Evidence Strength Grade C</td>
</tr>
<tr>
<td></td>
<td>70 and older</td>
<td>Any risk</td>
<td>Guideline Statement 5: The Panel does not recommend routine PSA screening in men age 70+ years or any man with less than a 10–15 year life expectancy. Some men age 70+ years who are in excellent health may benefit from prostate cancer screening.</td>
<td>Recommendation; Evidence Strength Grade C</td>
</tr>
</tbody>
</table>

**Rating Key**

U.S. Preventive Services Task Force  
Grade A. The USPSTF recommends the service. There is high certainty that the net benefit is substantial.  
Grade B. The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.  
Grade C. Clinicians may provide this service to selected patients depending on individual circumstances. However, for most individuals without signs or symptoms there is likely to be only a small benefit from this service.  
Grade D. The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.  
I Statement The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.

**References**

Non-Recommended Colorectal Cancer Screening in Older Adults

Summary of Changes to HEDIS 2015

- First-year measure.

Description

The percentage of members 86 years and older who were screened unnecessarily for colorectal cancer.

Note: A lower rate indicates better performance.

Eligible Population

- Product lines: Medicare.
- Ages: 86 years or older as of December 31 of the measurement year.
- Continuous enrollment: The measurement year.
- Allowable gap: No more than one gap in enrollment of up to 45 days.
- Anchor date: December 31 of the measurement year.
- Benefit: Medical.
- Event/diagnosis: None.

Administrative Specification

- Denominator: The eligible population.
- Required exclusions: Exclude members who met either of the following criteria on or between January 1st of the year prior to the measurement year and December 31 of the measurement year.
  - Colorectal cancer (Colorectal Cancer Value Set).
  - Iron deficiency anemia, lower gastrointestinal bleeding, Crohn’s Disease (i.e., regional enteritis), familial adenomatous polyposis, Lynch syndrome (i.e., hereditary non-polyposis colorectal cancer), inflammatory bowel disease, ulcerative colitis, abnormal findings of gastrointestinal tract, changes in bowel habits or a personal or family history of colorectal cancer (CRC Exclusions Value Set).
- Numerator: One or more screenings for colorectal cancer. Any of the following during the measurement year meet criteria:
  - Fecal occult blood test (FOBT Value Set).
  - Flexible sigmoidoscopy (Flexible Sigmoidoscopy Value Set).
  - Colonoscopy (Colonoscopy Value Set).
- Barium enema (Barium Enema Value Set).
- CT colonography (CT Colonography Value Set).
- Fecal DNA (Fecal DNA Value Set).

**Hybrid Specification**

**Denominator**
A systematic sample drawn from the eligible population for the Medicare product line. Organizations may reduce the sample size using the current year’s administrative rate. Refer to the *Guidelines for Calculations and Sampling* for information on reducing the sample size.

**Required exclusions**

**Administrative**
Refer to *Administrative Specification* to identify required exclusions from administrative data.

**Medical record**
Exclude members with documentation of any of the following on or between January 1 of the year prior to the measurement year and December 31 of the measurement year.

- Colorectal cancer.
- Iron deficiency anemia.
- Lower gastrointestinal bleeding.
- Crohn’s disease (i.e., regional enteritis).
- Familial adenomatous polyposis.
- Lynch syndrome (i.e., hereditary non-polyposis colorectal cancer).
- Inflammatory bowel disease.
- Ulcerative colitis.
- A personal or family history of colorectal cancer.
- Abnormal imaging findings of gastrointestinal tract.
- Change in bowel habits.

**Numerator**
One or more screenings for colorectal cancer. Any of the following during the measurement year meet criteria:

- Fecal occult blood test (guaiac or immunochemical).
- Flexible sigmoidoscopy.
- Colonoscopy.
- Barium enema.
- CT colonography.
- Fecal DNA test.

**Administrative**
Refer to *Administrative Specification* to identify positive numerator hits from the administrative data.
Medical record  Identify the number of members 86 years of age or older as of December 31 of the measurement year who had one or more screenings for colorectal cancer.

Documentation in the medical record must include a note indicating the date when the colorectal cancer screening was performed. A result is not required if the documentation is clearly part of the “medical history” section of the record; if this is not clear, the result or finding must also be present (this ensures that the screening was performed and not merely ordered).

Regardless of the number of samples returned for FOBT tests, both complete and incomplete tests serve as positive numerator hits for this measure.

Note

- Because this measure assesses non-recommended care, organizations may also search the medical record for required exclusions even if the member has an administrative hit. For Hybrid reporting, search the medical record for required exclusions and apply them before determining if the member has a numerator hit.

- During field-testing, organizations generally required an oversample of [TBD] percent to meet the MRSS for this measure.

Data Elements for Reporting

Organizations that submit HEDIS data to NCQA must provide the following data elements.

Table XX: Data Elements for Non-Recommended Colorectal Cancer Screening in Older Adults

<table>
<thead>
<tr>
<th></th>
<th>Administrative</th>
<th>Hybrid</th>
</tr>
</thead>
<tbody>
<tr>
<td>Measurement year</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Data collection methodology (Administrative or Hybrid)</td>
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<td>✔</td>
</tr>
<tr>
<td>Eligible population</td>
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<td>✔</td>
</tr>
<tr>
<td>Number of numerator events by administrative data in eligible population (before exclusions)</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Minimum required sample size (MRSS) or other sample size</td>
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<td>✔</td>
</tr>
<tr>
<td>Oversampling rate</td>
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<tr>
<td>Final sample size (FSS)</td>
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<tr>
<td>Number of numerator events by administrative data in FSS</td>
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<td>✔</td>
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<tr>
<td>Administrative rate on FSS</td>
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</tr>
<tr>
<td>Number of original sample records excluded because of valid data errors</td>
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<td>✔</td>
</tr>
<tr>
<td>Number of administrative data records excluded</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Number of medical records excluded</td>
<td>✔</td>
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</tr>
<tr>
<td>Number of employee/dependent medical records excluded</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Records added from the oversample list</td>
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<td>✔</td>
</tr>
<tr>
<td>Denominator</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Numerator events by administrative data</td>
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<td>✔</td>
</tr>
<tr>
<td>Numerator events by medical records</td>
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</tr>
<tr>
<td>Reported rate</td>
<td>✔</td>
<td>✔</td>
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<td>Lower 95% confidence interval</td>
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<td>Upper 95% confidence interval</td>
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Non-Recommended Colorectal Cancer Screening in Older Adults
Measure Work-Up

Measure Description

The percentage of members 86 years of age and older who were screened unnecessarily for colorectal cancer.

*Note*: A lower rate indicates better performance.

Topic Overview

Importance and Prevalence

**Health importance**

Colorectal cancer is the third most common malignancy and the second leading cause of cancer-related deaths in the United States. The lifetime risk of being diagnosed with cancer in the colon or rectum is about 5 percent. The percentage of new cases is higher in people from 65–84 years of age; the median age of diagnosis is 69 (NCI, 2013). The overall incidence by age for both men and women are as follows:

- 4 percent between 35 and 44 years.
- 13.8 percent between 45 and 54 years.
- 20.8 percent between 55 and 64 years.
- 24 percent between 65 and 74 years.
- 24.1 percent between 75 and 84 years.
- 12 percent in 85 years and older.

The incidence and mortality rates for colorectal cancer are about 35 percent–40 percent higher in men than in women; however, both rates have decreased significantly since 1975 (ACS 2013). The incidence rate declined from 60 cases to 45 cases per 100,000 people, and the mortality rate declined from 28 deaths to 17 deaths per 100,000 people (NCI, 2013).

Declines in incidence and mortality are due, in part, to the routine performance of preventive screening; improved screening is responsible for half of the observed reduction in both rates, while the remaining half derives from changes in the population prevalence of contributing risk factors (NCI, 2013).

**Screening tests**

The two main approaches for colorectal cancer screening are an assessment for blood or DNA in stool and a visual inspection of the colon and rectum for adenomas or early cancer (USPSTF, 2008). Screening blood tests include the fecal immunochemical test (FIT) and fecal occult blood test (FOBT); visual based screening tests are colonoscopy, flexible sigmoidoscopy, double-contrast barium enema (DCBE) and CT colonography (NCI, 2013).

According to the U.S. Preventive Services Task Force (USPSTF), there is limited evidence to assess the benefits and harms of CT colonography and fecal DNA testing, but convincing evidence that screening with any of the three recommended tests (FOBT, sigmoidoscopy, or colonoscopy) reduces mortality in adults 50–75 years (USPSTF, 2008). After the age of 75, however, the risk of harm associated with screening begins to outweigh the benefit of early detection and intervention (Albert, 2008).
For all screening methods, colonoscopy is considered to be a reference standard. Regardless of the screening test used, a positive result requires a follow-up colonoscopy to confirm diagnosis. Visual based screening methods, such as colonoscopy and flexible sigmoidoscopy, however, depend on visual recognition of shape, texture, and other surface alterations of the mucosa of the colorectum (USPSTF, 2008). Consequently, these optical methods can be susceptible to reduced accuracy because they rely on both provider skill and adequate bowel preparation (USPSTF, 2008).

Colonoscopy is associated with serious complications such as perforation, major bleeding, diverticulitis, severe abdominal pain and cardiovascular events (ACS, 2013). Because of its reduced benefits and increased risk of harm, and considering the slow growth of colorectal cancer over 10–15 years, it is reasonable to discontinue screening when a patient’s life expectancy approaches 10 years (75 years for men and 80 years for women) (Albert, 2008).

### Recommended practice

The USPSTF (2008) recommends three screening regimens for individuals 50-75 years of age with average risk:

1. Annual high-sensitivity FOBT.
2. Sigmoidoscopy every 5 years, combined with high-sensitivity fecal occult blood testing every 3 years.
3. Optical colonoscopy every 10 years

For individuals from 76–85 years of age, the Task Force recommends against routine performance of screening unless individuals have not been previously screened, in which case it should be considered in the context of health status and competing risks for each individual (USPSTF, 2008).

For individuals older than 85 years, the Task Force recommends against screening when comparing overall benefits to harms (D Recommendation) (USPSTF, 2008). The Task Force based these recommendations on a systematic review of the literature, supplemented with modeling data (USPSTF, 2008; NCI 2013; USCR, 2011).

For this subgroup, the Task Force concluded that the utility of screening is limited, given the time it takes for a polyp to develop into a clinically observable malignancy (10–26 years) (USPSTF, 2008; NCI 2013; USCR, 2011). Moreover, individuals older than 85 are likely to have multiple comorbidities that influence any potential life-year gain (USPSTF, 2008; NCI 2013; USCR, 2011). They are also at increased risk of suffering from adverse events related to performance of a colonoscopy, with the rate of adverse events being 2.8 per 1,000 procedures and increased by seven-fold if a polypectomy is performed (USPSTF, 2008; CDC 2012; NCI, 2013).

### Financial Importance

The charge for a colonoscopy can range from $1,000–$3,000; Medicare reimbursement covers 75 percent–80 percent of charges. Based on the 2011 U.S. Census, there are currently 8.1 million individuals 85 and older in the U.S. Given this count, regular performance of colonoscopies among this population could result in significant health care spending (not including downstream costs due to subsequent clinical complications) (Goodwin, 2011). The population of individuals 85 years and older is projected to double by 2050; hence, the financial burden related to potentially inappropriate performance of colorectal cancer screening can be expected to increase (Goodwin, 2011).
Opportunities for Improvement

Gaps in care

A retrospective cohort study that evaluated Medicare beneficiaries in Texas showed that the rate of inappropriate colonoscopies for individuals 76–85 and 86 and older were 39 percent and 25 percent, respectively. (Sheffield, 2013).

A recent study suggests that almost one-quarter of Medicare beneficiaries, including a large number of beneficiaries 80 years or older, undergo colonoscopies more frequently than is recommended without a clear indication for an early examination (ACS, 2013). Of these patients, 33 percent had a repeat colonoscopy within seven years (ACS, 2013). Additionally, patients with more comorbidities were more likely to get screening, versus their healthier counterparts.

References


Recommendations for Colorectal Cancer Screening Among Average-Risk Populations

<table>
<thead>
<tr>
<th>Organization (Year)</th>
<th>Age</th>
<th>Recommendation</th>
<th>Rating*</th>
</tr>
</thead>
<tbody>
<tr>
<td>U.S. Preventive Services Task Force (2008)</td>
<td>50–75</td>
<td>Recommends screening for colorectal cancer using fecal occult blood testing, sigmoidoscopy or colonoscopy. The risk and benefits of these screening methods vary.</td>
<td>A</td>
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<tr>
<td></td>
<td>76–85</td>
<td>Recommends against routine screening for colorectal cancer There may be considerations that support colorectal cancer screening in an individual patient.</td>
<td>C</td>
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<tr>
<td></td>
<td>86 or older</td>
<td>Recommends against screening for colorectal cancer</td>
<td>D</td>
</tr>
<tr>
<td>American College of Gastroenterology (2009)</td>
<td>Starting at 50</td>
<td>Cancer prevention tests should be offered first. The preferred CRC prevention test is colonoscopy every 10 years</td>
<td>1B</td>
</tr>
<tr>
<td></td>
<td>Starting at 45</td>
<td>Screening should begin for African Americans</td>
<td>2C</td>
</tr>
<tr>
<td>American Cancer Society (2013)</td>
<td>Starting at 50</td>
<td>Both men and women should use one of the screening tests (see guideline for specific modalities)</td>
<td>No grade listed</td>
</tr>
<tr>
<td>Institute for Clinical Systems Improvement (2012)</td>
<td>50 or older</td>
<td>Colorectal cancer screening is recommended for all patients 50 years of age and older using one of the following methods, based on joint decision-making by patient and clinician (see guideline for specific modalities)</td>
<td>Level I</td>
</tr>
<tr>
<td></td>
<td>45 or older</td>
<td>Colorectal cancer screening is recommended for African Americans or American Indians/Alaska Natives using one of the following methods, based on joint decision-making by patient and clinician (see guideline for specific modalities)</td>
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</table>

Rating System Key*

U.S. Preventive Services Task Force

Grade A. The USPSTF recommends the service. There is high certainty that the net benefit is substantial.

Grade B. The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.

Grade C. Clinicians may provide this service to selected patients depending on individual circumstances. However, for most individuals without signs or symptoms there is likely to be only a small benefit from this service.

Grade D. The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.

I Statement: The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.

American College of Gastroenterology

Grade 1A. Strong evidence, high-quality evidence. Benefit clearly outweighs risk/burden.

Grade 1B. Strong evidence, moderate-quality evidence. Benefit clearly outweighs risk/burden.

Grade 1C. Strong recommendation, low or very-low quality evidence. Benefit clearly outweighs risk/burden.

Grade 2A. Weak recommendation, high quality evidence. Benefit closely balanced with risks/burden.

Grade 2B. Weak recommendation, high quality evidence. Benefit closely balanced with risks/burden.

Grade 2C. Weak recommendation, low or very-low quality evidence. Uncertainty in estimates of benefit, risk, and burden; benefit, risk, and burden may be closely balanced.

Institute for Clinical Systems Improvement: Preventive Services

Level I Clinicians and care systems must assess the need for and recommend these services to every patient. These have the highest value and are worthy of attention at every opportunity.

Level II Clinicians and care systems should assess the need for and recommend these services to every patient. These have demonstrated value, although less than Level I services, and should be provided whenever possible.

Level III Clinicians and care systems could recommend these services to patients, but only after careful consideration of costs and benefits. These are services for which the evidence of effectiveness is currently incomplete or equivocal, or which may have the potential for significant harm. Providing these services is left to the judgment of individual medical groups, clinicians and their patients. Decisions about preventive services in particular should be made based on the principles of shared decision-making.

Level IV These services are not supported by evidence and should not be recommended. They may have insufficient evidence of effectiveness, clear evidence of lack of effectiveness, or the potential for significant harm without any benefit.

References for Recommendations


