

## 2007 QRRO Clinical Performance Measures (CPM)

### Radiation Oncology – Gastric

**Measure #G\_CM1:** Use of postoperative (adjuvant) chemoradiotherapy

**Type of Measure:** This measure is appropriately used as a quality improvement measure.

<b>Clinical Performance Measure</b>
<b>Quantifiable Measure:</b> Percentage of patients with Stage IB – IV (non-metastatic) gastric cancer who receive adjuvant chemoradiotherapy after an R0 surgical resection.
<b>Numerator:</b> Patients with Stage IB – IV (non-metastatic) gastric cancer who receive adjuvant chemoradiotherapy after an R0 surgical resection.
<b>Denominator:</b> All patients with Stage IB – IV (non-metastatic) gastric cancer who undergo an R0 surgical resection.
<b>Denominator exclusions:</b> <u>Documentation</u> of any of the following reasons: 1. Medical comorbidities 2. Patients treated with pre-operative chemoradiation
<b>Rationale for the measure:</b> Adjuvant chemoradiation was shown in the Gastric Surgical Adjuvant Trial (Intergroup 0116) to improve both disease-free and overall survival, presumably by sterilizing occult regional microscopic disease. <sup>1</sup> This was a large phase III, randomized trial of surgery alone versus surgery followed by 5-FU/leucovorin and radiation therapy (45 Gy). These results led to the adoption of postoperative chemoradiation as the standard of care in the US for resected gastric cancer patients.
<b>The following clinical recommendation statements are quoted verbatim from the referenced clinical guidelines and represent the evidence base for the measure:</b> In selected patients with T2, N0 tumors along with high-risk features (poorly differentiated or higher grade cancer, lymphovascular invasion, neural invasion, or age younger than 50 years) adjuvant chemoradiation therapy is recommended. The panel recommends that all patients who have T3, T4, or any T, N+ cancer should be offered radiotherapy (45 to 50.4 Gy) plus concurrent 5-FU-based radiosensitization (preferred) plus 5-FU with or without leucovorin following R0 resection. (NCCN guidelines <sup>2</sup> ) (Category 1)
<b>QRRO Survey Form Questions:</b> I1 - 56, 57, 59, 79, 140, 141, 142, 151, 152, 161, 162, 171, 172 and 200 – 223

References

1. Macdonald J S, Smalley S R, Benedetti J et al. Chemoradiotherapy after surgery compared with surgery alone for adenocarcinoma of the stomach or gastroesophageal junction. N Engl J Med 2001; 345: 725–30.
2. National Comprehensive Cancer Network (NCCN). Clinical Practice Guidelines in Oncology: Gastric Cancer. Version 2.2007. Available at: [www.nccn.org/professionals/physician\\_gls/default.asp](http://www.nccn.org/professionals/physician_gls/default.asp).

## 2007 QRRO Clinical Performance Measures (CPM)

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### Radiation Oncology – Gastric

**Measure #G\_CM2:** Completion of planned RT course within the prescribed time frame

**Type of Measure:** This measure is appropriately used as a quality improvement measure.

<b>Clinical Performance Measure</b>
<b>Quantifiable Measure:</b> Percentage of patients with gastric cancer receiving adjuvant chemoradiotherapy after an R0 surgical resection who complete radiotherapy within 33 to 45 days.
<b>Numerator:</b> Patients with gastric cancer who receive adjuvant chemoradiotherapy after an R0 surgical resection and complete radiotherapy within 33 to 45 days.
<b>Denominator:</b> All patients with gastric cancer who receive adjuvant chemoradiotherapy after an R0 surgical resection.
<b>Denominator exclusions:</b> None
<b>Rationale for the measure:</b> Completion of radiotherapy without prolonged treatment breaks has been associated with better clinical outcomes for several tumor sites, including head and neck, cervical and anal canal carcinomas <sup>1-5</sup> . Adjuvant chemoradiotherapy for gastric cancer can be associated with large radiation fields and significant acute toxicity <sup>6</sup> . In the Intergroup 0116 trial, completely resected gastric cancer patients received adjuvant radiation using AP-PA fields and 41% of patients reported grade 3 or 4 toxicity, with 17% unable to complete the protocol radiation course. Improved planning techniques to spare normal tissue are now being introduced and fewer patients should require prolonged treatment breaks or discontinuation of radiotherapy.
<b>The following clinical recommendation statements are quoted verbatim from the referenced clinical guidelines and represent the evidence base for the measure:</b> Guidelines are pending.
<b>QRRO Survey Form Questions: I1 - 56, 57, 59, 79, 140, 141, 142, 151, 152, 161, 162, 171, 172, 249</b>

References

1. Weber DC, Kurtz JM, Allal AS. The impact of gap duration on local control in anal canal carcinoma treated by split-course radiotherapy and concomitant chemotherapy. *Int J Radiat Oncol Biol Phys* 2001; 50:675-80.
2. Petereit DG, Sakaria JN, Chappell R, et al. The adverse effect of treatment prolongation in cervical carcinoma. *Int J Radiat Oncol Biol Phys* 1995; 32(5):1301-1307.
3. Fowler JF and Lindstrom MJ. Loss of local control with prolongation in radiotherapy. *Int J Radiat Oncol Biol Phys* 1992; 23:457-467.
4. Taylor JM, Whithers HR, Mendenhall WM. Dose-time considerations of head and neck squamous cell carcinomas treated with irradiation. *Radiother Oncol* 1990; 17(2):95-102.
5. Yalman D, Aras AB, Ozkok S, et al. Prognostic factors in definitive radiotherapy of uterine cervical cancer. *Eur J Gynaecol Oncol* 2003;24:309-14.
6. Macdonald J S, Smalley S R, Benedetti J et al. Chemoradiotherapy after surgery compared with surgery alone for adenocarcinoma of the stomach or gastroesophageal junction. *N Engl J Med* 2001; 345: 725-30.

## 2007 QRRO Clinical Performance Measures (CPM)

### Radiation Oncology – Gastric

**Emerging Measure #G\_EM1A:** Use of CT-based simulation and treatment planning

**Type of Measure:** This measure is appropriately used as a quality improvement measure.

Clinical Performance Measure
<b>Quantifiable Measure:</b> Percentage of patients with Stage IB – IV (non-metastatic) gastric cancer receiving adjuvant chemoradiation who undergo CT-based simulation and treatment planning.
<b>Numerator:</b> Patients with Stage IB – IV (non-metastatic) gastric cancer receiving adjuvant chemoradiotherapy who undergo CT-based simulation and treatment planning.
<b>Denominator:</b> All patients with Stage IB – IV (non-metastatic) gastric cancer who receive adjuvant chemoradiation.
<b>Denominator exclusions:</b> None
<b>Rationale for the measure:</b> CT-based radiotherapy simulation and planning techniques improve the precision of the irradiation of cancerous tissue and should be employed for all patients receiving adjuvant radiotherapy for gastric cancer to minimize the normal tissue irradiated. Dosimetric analyses of AP/PA versus CT-based 3D conformal radiotherapy (3DCRT) plans have shown reduced doses to the kidneys using 3DCRT. <sup>1</sup> Clinical studies have demonstrated a decrement in renal function after adjuvant radiotherapy for gastric cancer which may be reduced by using 3-dimensional treatment planning techniques. <sup>2</sup>
<b>The following clinical recommendation statements are quoted verbatim from the referenced clinical guidelines and represent the evidence base for the measure:</b> Guidelines for CT-based planning for gastric cancer are pending.
<b>QRRO Survey Form Questions:</b> I1 - 56, 114, 140

References

1. Leong T, Willis D, Joon DL, et al. 3D conformal radiotherapy for gastric cancer--results of a comparative planning study. *Radiother Oncol.* 2005 Mar;74(3):301-6.
2. Jansen EP, Saunders MP, Boot H, et al. Prospective study on late renal toxicity following postoperative chemoradiotherapy in gastric cancer. *Int J Radiat Oncol Biol Phys.* 2007 Mar 1;67(3):781-5.



## 2007 QRRO Clinical Performance Measures (CPM)

### Radiation Oncology – Gastric

**Emerging Measure #G\_EM1B:** Use of image-guided tools, other than computed tomography scans, for radiation therapy (RT) target delineation.

**Type of Measure:** This measure is appropriately used as a quality improvement measure.

<b>Clinical Performance Measure</b>
<p><b>Quantifiable Measure:</b> Percentage of patients treated with chemoradiation for gastric cancer whose radiation therapy target delineation or treatment delivery includes image-guided tools, other than computed tomography scans.</p>
<p><b>Numerator:</b> Patients receiving chemoradiation for gastric cancer whose radiation treatment planning or delivery is aided by image-guided tools, other than computed tomography scans.</p>
<p><b>Denominator:</b> All patients who undergo chemoradiation for gastric cancer.</p>
<p><b>Denominator exclusions:</b> None</p>
<p><b>Rationale for the measure:</b> Advances in imaging modalities such as MRI and functional imaging allow for more precise delineation of the GTV + CTV. Tumor localization using 4D CT and treatment delivery using real-time on-board image guidance and respiratory gating allow for more conformal treatment fields. Increasing the precision of treatment and reducing uncertainties allow for decreased normal tissue toxicity and ability for dose escalation as well as delivery of a single fraction of high dose radiation. Image-guided radiotherapy is emerging as an important area of investigation in radiation oncology and its application for the treatment of gastric cancer is not well defined.</p>
<p><b>The following clinical recommendation statements are quoted verbatim from the referenced clinical guidelines and represent the evidence base for the measure:</b> Guidelines for the use of image-guided tools for the planning and delivery of radiotherapy for gastric cancer are pending.</p>
<p><b>QRRO Survey Form Questions:</b> I1 - 56, 127, 128, 129, 130, 140</p>

## 2007 QRRO Clinical Performance Measures (CPM)

### Radiation Oncology – Gastric

**Emerging Measure #G\_EM2:** Use of Dose volume histograms (DVH) to evaluate normal tissue doses to the kidneys and liver.

**Type of Measure:** This measure is appropriately used as a quality improvement measure.

Clinical Performance Measure
<b>Quantifiable Measure:</b> Percentage of patients receiving adjuvant chemoradiation whose treatment planning included the generation of dose volume histograms (DVH) to evaluate normal tissue doses to the kidneys and liver.
<b>Numerator:</b> Patients receiving adjuvant chemoradiation whose CT based simulation and treatment planning included the generation of dose volume histograms (DVH) to evaluate normal tissue doses to the kidneys and liver.
<b>Denominator:</b> All patients receiving adjuvant chemoradiation who underwent CT-based simulation and treatment planning.
<b>Denominator exclusions:</b> None
<b>Rationale for the measure:</b> CT-based radiotherapy simulation and planning techniques improve the precision of the irradiation of cancerous tissue and should be employed for all patients receiving adjuvant radiotherapy for gastric cancer to minimize the normal tissue irradiated. Dosimetric analyses of AP/PA versus CT-based 3D conformal radiotherapy (3DCRT) plans have shown reduced doses to the kidneys using 3DCRT. <sup>1</sup> Clinical studies have demonstrated a decrement in renal function after adjuvant radiotherapy for gastric cancer which may be reduced by using 3-dimensional treatment planning techniques. <sup>2</sup> Dose volume histograms are used to evaluate normal tissue doses and to limit the doses to surrounding organs based on the known radiation tolerance doses of these organs.
<b>The following clinical recommendation statements are quoted verbatim from the referenced clinical guidelines and represent the evidence base for the measure:</b> Guidelines for CT-based planning for gastric cancer are pending.
<b>QRRO Survey Form Questions:</b> I1 - 56, 114, 115, 116, 118, 140

References

1. Leong T, Willis D, Joon DL, et al. 3D conformal radiotherapy for gastric cancer--results of a comparative planning study. *Radiother Oncol.* 2005 Mar;74(3):301-6.
2. Jansen EP, Saunders MP, Boot H, et al. Prospective study on late renal toxicity following postoperative chemoradiotherapy in gastric cancer. *Int J Radiat Oncol Biol Phys.* 2007 Mar 1;67(3):781-5.

## 2007 QRRO Clinical Performance Measures (CPM)

### Radiation Oncology – Gastric

**Emerging Measure #G\_EM3:** Use of preoperative (neoadjuvant) chemoradiotherapy

**Type of Measure:** This measure is appropriately used as a quality improvement measure.

Clinical Performance Measure
<b>Quantifiable Measure:</b> Percentage of patients with non-metastatic gastric cancer receiving pre-operative (neoadjuvant) chemoradiation for gastric cancer.
<b>Numerator:</b> Patients receiving pre-operative (neoadjuvant) chemoradiation for gastric cancer.
<b>Denominator:</b> All patients who undergo surgical resection for non-metastatic gastric cancer.
<b>Denominator exclusions:</b> <i>Documentation of any of the following reasons:</i> 1. Medical co-morbidities
<b>Rationale for the measure:</b> Preoperative has become standard for many gastrointestinal malignancies, most notably for rectal cancer, where there is clearly a benefit to preoperative chemoradiotherapy for both toxicity and local control <sup>1</sup> . This may also hold true for gastric cancers since the diverse and widespread patterns of direct extension and lymphatic drainage oblige the radiation oncologist to treat very large fields to cover areas of potential relapse <sup>2,3</sup> . Preoperative treatment facilitates tumor downstaging prior to resection and allows adjuvant treatment to be delivered when local tissue has been surgically undisturbed. Phase II data from MD Anderson Cancer Center have demonstrated excellent R0 resection rates with preoperative treatment for gastric cancer <sup>4</sup> . Early results suggest promising preliminary outcomes and toxicity profiles. Pathologic response rates following preoperative chemoradiation is predictive of overall survival in gastric cancer <sup>5</sup> .
<b>The following clinical recommendation statements are quoted verbatim from the referenced clinical guidelines and represent the evidence base for the measure:</b> Guidelines for CT-based planning for gastric cancer are pending.
<b>QRRO Survey Form Questions: I1 - 56, 57, 59, 140, 141, 142, 151, 152, 161, 162, 171, 172, 200 – 223</b>

References

1. Sauer R, Becker H, Hohenberger W et al. Preoperative versus postoperative chemoradiotherapy for rectal cancer. N Engl J Med 2004; 351: 1731–40.
2. Gunderson L. Adenocarcinoma of the stomach: areas of failure in a re-operation series (second or symptomatic look) clinicopathologic correlation and implications for adjuvant therapy. Int J Radiat Oncol Biol Phys 1982; 8: 1–11.
3. Smalley S R, Gunderson L, Tepper J et al. Gastric surgical adjuvant radiotherapy consensus report: rationale and treatment implementation. Int J Radiat Oncol Biol Phys 2002; 52: 283–93.
4. Ajani JA, Mansfield P F, Janjan N et al. Multi-institutional trial of preoperative chemoradiotherapy in patients with potentially resectable gastric carcinoma. J Clin Oncol 2004; 22: 2774–80.



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5. Lowy A M, Mansfield P F, Leach S D, Pazdur R, Dumas P, Ajani J A. Response to neoadjuvant chemotherapy best predicts survival after curative resection of gastric cancer. *Ann Surg* 1999; 229: 303–8.