



Quality Research in Radiation Oncology Process Survey

Executive Summary

Version 1.0

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The Quality Research in Radiation Oncology (QRRO) has the overall goal of improving the care received by cancer patients throughout the USA. To achieve this goal, national surveys will determine structure, process, and outcome of care, emphasizing practice setting, new technologies, and other factors likely to influence outcome.

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Study to be Conducted by: American College of Radiology (ACR)
Study Funded by: National Cancer Institute, grant # CA-065435

Study Summary– National Process Survey:

ACR QRRO has drawn a stratified random sample of radiation oncology facilities in the USA and is asking those facilities to participate in the Process Survey. Information from a Facilities Survey will be used with data collected under the Process Survey to calculate national averages and make statistically valid inferences for national process measures.

The National Process Survey, a two-stage stratified sample of radiation oncology facilities nationwide (first stage) and of eligible cases within those facilities (second stage), includes multiple disease site studies for which data is collected simultaneously. The survey includes samples of patients treated for cancer of the cervix, breast, lung, prostate, and stomach. The time period will vary for different disease site studies from a one-year interval to a three-year interval ending in 2007, depending on the estimated number of cases available and the sample size required to achieve study aims. The survey instruments allow measurement of compliance with quality indicators, as well as other key measures. The survey data will be collected through retrospective patient record review by ACR QRRO Clinical Data Abstractors. The survey instruments are programmed in WebLogic software. Data elements collected relate to eligibility, demographics, diagnosis, staging, history, treatment, outcome and post brachytherapy CT scan of the prostate image data. Only one data element classified as Protected Health Information (PHI) is requested – patient zip code.

Patient Privacy, Protected Health Information (PHI), and Protection of Data:

1. The ACR's Institutional Review Board (IRB) has reviewed and approved this project. The IRB has approved the survey as qualifying for a Waiver of Consent under the Common Rule and a Waiver of Authorization under Health Insurance Portability and Accountability Act (HIPAA):
 - a. The research involves no more than minimal risk to the subjects,
 - b. The waiver will not adversely affect the subjects,
 - c. The research could not be conducted without the waiver, and
 - d. If appropriate, the subjects will be provided with pertinent information after the research.
2. ACR QRRO plan to protect identifiers and PHI:
 - a. ACR-generated case numbers will be used to identify cases in the study dataset. These numbers have no connection to any other patient identification numbers.
 - b. PHI will be seen by the ACR QRRO Clinical Data Abstractor as he/she reviews the subjects' medical record to extract data, including the post brachytherapy CT scan of the prostate. One data element of PHI will be recorded. Because of this:
 - i. Institutions should request a waiver of authorization from their Privacy Board or Institutional Review Board (IRB) representative to ensure compliance with institutional requirements.
 - ii. ACR QRRO Clinical Data Abstractors will sign the Patient Information Access and Confidentiality Agreement.
 - c. Age will be calculated in lieu of use of date of birth.
 - d. Treatment episodes will be recorded as elapsed time events of days or months. Actual dates will not be maintained.
 - e. Zip codes will be collected in order to link survey findings with external data to determine socioeconomic variables. The zip code is the only PHI collected that is necessary to meet the aims of the study. The zip code in and of itself, as the only maintained piece of PHI, does not allow for subject identification.
 - f. Institution chart identification numbers will be used by abstractors only to identify correct charts for abstraction. These identifiers will not be linked to any clinical data. All identifiers will be destroyed after data collection is completed.
3. The confidentiality and anonymity of the data will be scrupulously maintained.

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Study Specific Aims:

1. To define a core set of process measures for selected major cancers in which radiation oncology plays a major role, based on best available evidence that these measures affect outcomes important to patients and providers and, thus measure quality of care. To collect data on those measures from a sample of patients in a survey designed to allow calculation of national averages for all patients treated with RT for the selected cancers. To examine practice setting, treatment technology, patient and disease factors that may influence these measures.
2. To define process of care measures for important emerging advanced technologies based on the best available evidence including expert consensus. To conduct surveys that will allow documentation of process of care and quality assurance in emerging technologies, such as seed implant treatment for prostate cancer, 3D Conformal Radiation Therapy (CRT) and Intensity Modulated Radiation Therapy (IMRT) treatment for prostate, lung, gastric, and breast cancer, and High Dose rate (HDR) brachytherapy for cervical and breast cancer.
3. To document the penetration of results of clinical trials and widely promulgated practice guidelines and appropriateness criteria into use in the national practice providing an overview of quality of care for treatment of each disease.
4. To describe patient and practice-based parameters, such as age, race, ethnicity, geographic region, practice setting, and insurance status in relation to processes of care, disease presentation, disease evaluation, treatment, compliance, and structure of treating facilities,
5. To disseminate information and educate the target audiences, radiation oncologists and other oncologic physicians, health professionals, patients and the public regarding the findings.

Specific Aims – Prostate:

1. Identify specific measures of quality radiotherapy delivery that impact outcome for patients with localized prostate cancer. To assess how frequently these measures are used by US practitioners for the delivery of external beam radiotherapy or brachytherapy to their patients.
2. Identify quality measures for emerging technologies including 3DCRT, IMRT, and ultrasound-guided brachytherapy techniques. To determine how frequently these measures are being used for treatment delivery.
3. Test the feasibility of assessing the quality of brachytherapy delivery in the USA through the use of image transfer technology to enable centralized expert interpretation of post-implant scans and quality of dose delivery to the prostate and surrounding normal tissues. Using this information will better characterize national patterns of quality of treatment delivery in the treatment of prostate brachytherapy patients.
4. Assess differences in the treatment of localized prostate cancer based on age, race and geographic location.
5. Assess the penetration of the results of completed clinical trials into clinical practice and the acceptance of ACR standards and appropriateness criteria for the management of localized prostate cancer.
6. Disseminate information and educate physicians and patients about the findings of the studies.

Specific Aims – Lung:

1. Assess the national adherence to a core set of process measures necessary for optimal radiation treatment of lung cancer derived from evidence based information that such measures yield optimal patient outcomes.
2. Define and analyze a set of process of care measures regarding the emergence of advanced technologies in the radiation treatment of lung cancer.
3. Assess the penetration of results of clinical lung cancer trials into the national practice, particularly regarding use of concurrent chemoRT in stage III NSCLC, as well as use of hyperfractionation and prophylactic cranial irradiation (PCI) in LS-SCLC.
4. Determine the structure and processes of care for patients with lung cancer for different groups based on such factors as age and the presence or absence of co-morbidities.
5. Disseminate information and educate physicians and patients about the findings of the studies.

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Specific Aims – Breast:

1. Determine whether since the 1998 - 1999 survey the process of care for delivering Regional Nodal Irradiation (RNI), as part of either post-mastectomy radiation (PMR) or breast radiation Breast Conservation Therapy (BCT) after lumpectomy, is more consistent with published treatment guidelines and whether adherence to guidelines varies by patient or treatment facility factors.
2. Document if the process of care and delivery of RNI for node positive patients differs after breast conservation versus mastectomy for comparable stage breast cancer patients.
3. Determine if CT-based treatment planning and delivery techniques such as 3DCRT or IMRT are more prevalent processes of care and record how institutions are documenting the quality of the treatment plan.
4. Disseminate information and educate physicians and patients about the findings of the studies.
5. Determine the prevalence of Partial Breast Irradiation (PBI) at surveyed institutions, document the process of care, and determine whether the patient population and method of PBI varies by treatment facility.
6. Document whether the methods used for PBI are technically executed according to prevalent quality assurance (QA) standards established in the clinical trials for PBI.

Specific Aims – Cervix:

1. Define a set of criteria for high quality treatment of carcinoma of the cervix based on published studies and treatment guidelines, including criteria for acceptable pre-treatment evaluation, radiation dose, treatment duration, use of brachytherapy, and application of concurrent chemotherapy.
2. Estimate the rate of compliance with quality care guidelines using data collected on patients treated with radiation for carcinoma of the cervix. Correlate practice parameters with patient and disease factors and practice setting.
3. Assess the use of modern imaging technologies, particularly MRI and PET in treatment planning.
4. Assess the use of emerging brachytherapy techniques particularly high-dose-rate and interstitial brachytherapy.
5. Assess the use of RT with or without chemotherapy for post-operative treatment of cervical cancer.
6. Disseminate information and educate physicians and patients about the findings of the studies through publications, presentations, web announcements, and press releases. In addition, information about compliance with quality parameters in participating facilities will be compared with that from the overall survey group and provided to the participating facilities

Specific Aims – Gastric Cancer:

1. Define nationwide patterns of practice for gastric cancer for the first time and examine penetrance of clinical trial results on those practice patterns.
2. Determine the use of concurrent chemoradiation in the postoperative (adjuvant) and neoadjuvant (preoperative) treatment of stage M0 gastric cancer. Describe the quality and extent of the radiation oncologists' documentation of concurrent chemotherapy and report on the chemotherapeutic regimen used.
3. Examine documentation of the extent of surgery performed, including the presence or absence of residual cancer, and the association of surgical parameters with radiation treatment techniques used, such as volume and dose.
4. Evaluate established guidelines on the use of modern RT technology, treatment planning and techniques.

Additional Information:

1. Survey forms showing the data elements to be collected are available at www.qrro.org.
2. A copy of the research plan from the grant application is available upon request.
3. For questions or additional information please contact Jean Owen, Ph.D., Cheryl L. Crozier, RN or Lisa Morabito at (215) 574-3164 or by email:

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