Michigan Radiation Oncology Quality Consortium (MROQC)

Operating Principles

Section I. Purpose

A. *Mission*: To improve the quality of radiation therapy through patient-centered care
B. *Vision*: To expand access to high value care
C. *Values*:
    a. Patient-centered care
    b. Evidence-based care
    c. Collaboration
    d. Respect
D. *Goals*:
    a. Deliver equitable care
    b. Standardize treatment planning & delivery techniques
    c. Develop best practices
    d. Guide appropriate use of high-cost technology
    e. Sustained growth
    f. Impact policy

Section II. Participation Criteria and Expectations

A. MROQC Site Eligibility Requirements:
    To participate in MROQC, a facility must meet the following eligibility criteria:
    1. Treat a minimum of 150 new breast, lung, and prostate cancer cases per year plus patients being treated for bone metastasis *(with a primary cancer of: breast, lung, prostate, melanoma or renal cell)*
    2. Have an onsite physician champion to act as Clinical Champion.
    3. Have an onsite medical physicist to act as the Physics Lead.
    4. Designate a representative from Physics/Dosimetry to collect dosimetry data for patients enrolled.
    5. Have an administrative champion to act as the Site/Department Administrative Lead.
    6. Have or hire a Clinical Data Abstractor (CDA) to abstract cases into the database.

B. Expectations of a Site:
    To successfully participate in the project, each site will be expected to do the following:

    Identify all eligible **breast** cancer patients presenting to your facility using the following criteria:

    A. Inclusion Criteria
        a. Newly diagnosed female breast cancer patients age 18 years and older
        b. Diagnosed with invasive breast cancer or ductal carcinoma in situ (DCIS)
        c. Patient to be treated with breast conserving surgery and either partial or whole breast radiotherapy
        d. Breast conservation patients treated with neo-adjuvant chemotherapy, concurrent or sequential systemic therapy, and radiation to regional nodes are eligible

e. Patients with metastatic breast cancer are eligible if receiving treatment to the whole breast (breast and lymph nodes)

B. Exclusion Criteria
   a. Patients referred for post-mastectomy radiotherapy
   b. Patients referred for treatment of chest wall recurrences
   c. Any other indication for radiotherapy in a patient who has undergone mastectomy
   d. Patients being treated for synchronous bilateral breast cancer
   e. Patients who have been previously treated with radiation to the thoracic region

Identify all eligible **lung** cancer patients presenting to your facility using the following criteria:

A. Inclusion Criteria
   a. Newly diagnosed, non-small cell, lung cancer patients
   b. To be treated with a curative intent with thoracic definitive radiotherapy
   c. Patients with previous lung surgery not related to their current lung cancer diagnosis or those who have surgery after completing radiation therapy
   d. Patients treated with or without concurrent or sequential chemotherapy are eligible

B. Exclusion Criteria
   a. Patients with metastatic disease
   b. Patients who have been previously treated with radiation to the thoracic region
   c. Small cell lung cancer patients
   d. Post-operative patients, that have had a lung surgery related to their current diagnosis

Identify all eligible **bone mets** patients presenting to your facility using the following criteria:

A. Inclusion Criteria
   a. Patients 18 years or older
   b. Patients with metastatic breast, lung, prostate, melanoma or renal cell cancer, involving bone, to be treated with external beam radiation to a bony site

B. Exclusion Criteria
   a. Patients receiving Xofigo® (radium Ra 223), Metastron (Strontium-89), Quadramet (Samarium 153) within ± 4 weeks of treatment

Identify all eligible **prostate** patients presenting to your facility using the following criteria:

A. Inclusion Criteria
   a. Diagnosis of prostate adenocarcinoma
   b. Patients treated with a curative intent with radiotherapy to at least the prostate or the prostate bed. (includes radiation for intact prostate cancer and post-prostatectomy treatment delivered as adjuvant or salvage radiation with or without hormone therapy).
   c. Localized +/- regional metastatic disease (regional lymph node metastases are still eligible for inclusion, which include obturator, internal iliac, external iliac, and common iliac lymph node stations)

d. Patients without email addresses can still be included if a paper data collection process is in place to collect baseline and follow-up data

B. Exclusion Criteria
   a. Prior pelvic radiation as part of a different treatment course (patients treated with combination therapy of EBRT and brachytherapy at the same institution are eligible)
   b. Prior focal therapy (cryotherapy, HIFU, or focal laser ablation)
   c. Neuroendocrine or small cell prostate cancer confirmed by pathology
   d. The patient refused to complete surveys
   e. Metastatic disease. Metastatic disease is defined as any of the following:
      - Any bone metastasis
      - Any nodal metastasis above the common iliacs (e.g., para-aortic, mediastinal/hilar, supraclavicular)
      - Any visceral metastasis (e.g., lung, liver, brain)
   f. Second active cancer currently receiving therapy or planned therapy within the next 12 months

Contribute case data to the statewide MROQC database(s).

1. Institutional data to be provided annually by practice administrator and physics staff including:
   a. Background information regarding physicians practicing at the participating center
   b. Information classifying each practice as academic, community-based, private, or other
   c. Details regarding treatment planning and delivery systems
2. Provider-Assessed Clinical Data and Outcomes (provided by physicians and CDA)
   a. Data will be collected at baseline (pre-treatment) by the provider or CDA including:
      i. Socio-demographic details
      ii. Clinical history and pre-treatment symptoms
      iii. Pathology and cancer staging
      iv. Treatment information including surgery details, use and types of chemotherapy and hormonal therapy
   b. During radiotherapy, weekly toxicity assessments will be completed by treating physician to track side effects while on treatment for lung cancer.
   c. A comprehensive clinical outcome assessment will be completed during the last week of radiotherapy, and at follow-up visits for breast and lung patients including:
      i. Common toxicity Criteria for Adverse Events
      ii. Customized questions assessing possible side effects of treatment with radiation
3. Patient-Reported Outcomes to Be Collected by Survey Administration
   a. Surveys will be completed pre-treatment, during the last week of radiotherapy, and at specified follow-ups (will vary by cancer type). The questionnaires will ask about acute breast and thoracic symptoms, pain from bone mets treatment, and an overall inconvenience due to treatment (all cancers). Some examples included are:
      i. Excerpted questions from the Brief Pain Index (BPI) and the Breast Cancer Treatment Outcomes Scale (BCTOS)
      ii. Excerpted questions from validated quality of life instruments including FACT-B, FACT-L, the EORTC general, EPIC-26, breast and lung cancer-specific quality of life questionnaires
      iii. Excerpted questions from SkinDex-16

   b. In addition, a weekly swallowing assessment will be completed by patients treated for lung cancer.
4. Physics Data to Be Provided by Physicist/Dosimetrist from Each Institution Including:
   a. Patient-specific treatment planning and delivery information
   b. Patient-specific DICOM-RT data, including CT, RTdose, RTplan, and RTstruct files
   c. Standard beam arrangements for IMRT and non-IMRT plans
   d. Information about linear accelerators, detector equipment, pre-treatment quality assurance process and acceptance criteria

Identify an onsite **Clinical Champion (CC).**

1. The CC will be a physician interested and active in the care of MROQC eligible cancer patients.
2. The CC will ensure maintenance of IRB approval (if applicable), and enrollment of patients as appropriate
3. The CC will champion the MROQC projects and lead the hospital in QI efforts.
4. The CC will participate (in person) in the tri-annual collaborative-wide meetings
5. May be asked to serve on the MROQC executive board or in other governance roles or positions
6. The CC may participate (or assign a delegate) in a Publications Committee that will foster authorship of publications
7. The CC will participate (or assign a delegate) in other ad hoc committees or task forces as appropriate
8. During the ramp-up phase, the CC will work closely with the Program Director and Coordinating Center staff to finalize data to be captured, and identifying and addressing barriers to project implementation.

Identify an onsite **Physics Lead**

1. The Physics Lead will be a medical physicist interested and active in the treatment planning and delivery of care to MROQC eligible cancer patients
2. The Physics Lead will collaborate with the MROQC Co-Director (Physics) and lead the technical aspects of the project at participating sites
3. The Physics Lead will collect and provide feedback to the MROQC Coordinating Center personnel on the Physics and Dosimetry aspects of the program, such as data to be collected, web-based forms, and data accuracy
4. The Physics Lead will oversee the dosimetrist in collecting and submitting data regarding the technical aspects of treatment planning and delivery
5. The Physics Lead will be responsible for working with MROQC Coordinating Center staff in the auditing process
6. The Physics Lead will participate (or assign a delegate) in the tri-annual collaborative-wide meetings
7. The Physics Lead may participate in publications
8. The Physics Lead may participate in other ad hoc committees or task forces as appropriate
9. Designate a Representative from Physics / Dosimetry to This Project
   a. The physics/dosimetry representative will be responsible for providing patient-specific dosimetry data at the completion of treatment.
   b. The physics/dosimetry representative will work with Administrative Lead to complete the annual institutional assessment.
   c. Respond to inquiries from Coordinating Center regarding site-specific technical data.

Identify an **Administrative Lead**.

1. The Administrative Lead will be the administrative contact for MROQC at the facility.
2. This person will also provide institutional support for full project participation.
3. The Administrative Lead will participate in the tri-annual collaborative-wide meetings.

4. Manage IRB-related issues* (*if applicable; MROQC is a non-regulated Quality Improvement project and does not require IRB oversight). This may include initial IRB approval of the project, approval of any amendments to the approved study, and approval of the scheduled continuing reviews.
5. Obtain signatures required for the site's Data Use Agreement, which is to be signed by the site's President/CEO or other person who holds sign-off authority for the hospital, and returned to the Coordinating Center.
6. Coordinate issues related to hospital reimbursement.
7. Hire/assign data collection staff.
8. Partner with Physician lead in working with the Coordinating Center on planning and overseeing Quality Improvement efforts.

Engage and/or hire appropriate **Clinical Data Abstractor (CDA)** support, depending on patient volume.

1. The facility should staff the MROQC project with a CDA who can effectively manage clinical data entry and abstraction on up to 200 eligible MROQC cases per year.
2. The CDA will be responsible for the timely and accurate collection of data and abstraction into the web-based data tables. This will also include screening and enrolling eligible patients based on each project's eligibility criteria.
3. The CDA will be responsible for responding to inquiries from the Coordinating Center regarding clinical data.
4. The CDA will be responsible for working with the Coordinating Center staff in the auditing process.
5. The CDA(s) will participate in project training sessions, the tri-annual Collaborative Meetings, and bimonthly conference calls with the Coordinating Center's Clinical Quality Lead.

- Provide Ample Space and Web-Based Equipment to Support Data Collection / Management Activities

- Collaborate with Coordinating Center.
    1. The participating site staff are expected to respond to Coordinating Center queries and requests in a timely manner.
    2. Retain MROQC-related data documents (i.e. patient surveys) for up to 2 years from the date of radiation treatment end date.
    3. Obtain required IRB approval(s) as indicated by local hospital policy for QI projects, registries, collaborative projects involving data sharing, and other projects developed in the context of this structure.
    4. The facility should actively participate in reporting progress and outcomes.
    5. The institution will work closely with the Coordinating Center and the other sites to develop a Quality Improvement (QI) Agenda for the MROQC program using the aggregate Michigan data.
    6. The institution will work closely with the Coordinating Center to develop a site-specific QI Agenda using data from their own facility in comparison to the aggregate Michigan data.

- Collaborate with other participating sites.
    1. Participation of each site in process improvement is essential to the success of the program, including the sharing of and learning from best practices.
    2. Sites must be willing to share de-identified data.

Section III. Expectations of the Coordinating Center

A. The Coordinating Center provides each participating site with anonymity and will approach the site for permission prior to use or disclosure of site-specific data in meetings
B. BCBSM only has access to de-identified data, typically at the aggregate level
C. Coordinating Center strives at all times to promote a friendly and collegial atmosphere
D. The initiative may use collective data for publication or other data dissemination

Section IV. Payments

A. MROQC participants at hospital-based sites are rewarded annually for participation via the Pay for Performance (P4P) payment mechanism.
B. BCBSM provides reward funding to assist participants in staffing and maintaining this project. The participation model is designed according to the following:
    a. Data Abstraction Payment:
        i. Supports the time and effort involved with abstraction of data and entry of the information into the MROQC database(s).
        ii. BCBSM pays 84% of total projected data abstraction costs for BCBSM, Blue Care Network (BCN), government-insured and uninsured patients.
        iii. Annual payment provided prospectively during every year of participation

Section V. Committees

A. Executive Committee:
    a. Responsibilities (among others):
        i. Oversight
        ii. Establishment of operational policies
        iii. Program evaluation
        iv. Approval of all external sharing of data (including publications)
    b. Terms
        i. Thirteen representatives will serve on the committee at any one time, with no more than two members from the same practice (not including the coordinating center)
        ii. Terms are two to three years, depending on the role of the committee member
        iii. The Coordinating Center is responsible for ensuring that there are a sufficient number of candidates and that there is reasonable geographic equity in the pool of candidates

B. Working Groups:
    a. One working group exists for each MROQC priority
    b. Each working group leadership team is comprised of 2 clinical-leaders (one from the MROQC Coordinating Center, one from a participating site), a physics lead, and a statistician.
    c. All members of the consortium are welcome to participate in the working groups
    d. Goals of the working groups include the following:
        i. Articulate the clinical concern(s)
        ii. Identify measures for assessing opportunities for improvement
        iii. Benchmark QI goal(s) and timeframe for achievement
        iv. Provide input and feedback relative to the actual implementation of relevant QI efforts
        v. Monitor the performance of QI efforts and recommend modifications, as appropriate

Section VI. Publication Authorship

A. First authorship is determined by contribution to the manuscript and is ideally a MROQC radiation oncologist or medical physicist. In the event that a student or resident is serving as the first author on a MROQC-related publication, the goal is for a MROQC radiation oncologist or medical physicist at their institution to serve as the mentor and senior author for the publication. When a MROQC radiation oncologist or medical physicist is neither the first nor the senior author, at least one MROQC radiation oncologist or medical physicist must be included as a co-author.
B. The Coordinating Center is responsible for supporting all MROQC-related publications with the provision of requested data and thus individuals from the Coordinating Center may serve as co-authors, depending on their level of contribution.
C. Blue Cross Blue Shield of Michigan will be made aware of manuscripts being submitted for publication.

Section VII. External Sharing of Data

A. All data will be provided in a de-identified fashion, to protect the confidentiality of MROQC data and the privacy of MROQC participants
B. All external requests for the sharing of MROQC data will be reviewed by the Executive Committee and a majority of the Executive Committee must approve the request before any information is shared outside the collaborative.
C. Data will be shared via the following guidelines:
    a. MROQC participants can share their own MROQC data versus the entire collaborative for internal quality improvement purposes/presentations in their own practice and/or institutions (i.e., hospital or health system). This would include the presentation of the "rankings" data currently available in the MROQC registry, as long as these data are used to motivate, inform, and/or evaluate internal QI activities and not used for marketing or other purposes.
    b. In the event that MROQC participants elect to share their own data outside their own practice and/or for marketing purposes, their own data cannot be presented in comparison to aggregate or practice-level MROQC data. However, individual practices that wish to publicize their own MROQC data for purposes of marketing or other, non-internal quality improvement activities, can present their data in the context of other published and/or national benchmarks.
    c. In instances where another resource within an institution requests the MROQC data, he/she must sign a MROQC attestation form that indicates he/she will not share the data for any type of competitive advantage.

Section VIII. External Funding Opportunities and Scientific Activities

A. It is recognized that MROQC's principal mission is to improve the quality of radiation therapy through patient-centered care. However, giving the unique data and infrastructure provided by the collaborative, it is inevitable that there will be opportunities to examine additional scientific questions related to radiation therapy. Moreover, some of these questions may be sufficiently important to merit external funding by one of several sources, including the state or federal government, private foundations, specialty societies, and/or private industry, among others.
B. As a general principle, MROQC leadership is interested in considering these opportunities and providing its constituent sites with the opportunity to participate in these cutting-edge activities. As such, it is our policy that all requests to use MROQC data and/or infrastructure for scientific activities that involve external funding sources and/or fall outside our direct mission of quality improvement be reviewed first by the Executive Committee. If a majority of the Executive Committee determines that the project is of

sufficient interest and relevance to MROQC sites and radiation oncology, then the MROQC Executive Committee and Coordinating Center will lend its support to the project in word and action. However, final decisions about whether or not to participate in any individual project or grant will be left to the discretion of the constituent practices.

C. We will also require that at least one MROQC radiation oncologist or medical physicist be included as co-author(s) on scientific manuscripts arising from these projects and that investigators present data and findings from MROQC-related projects at our collaborative wide meetings.
D. All publications derived from MROQC-related data must be reviewed by the Executive Committee prior to submission to ensure consistency with our principles around confidentiality, etc.

Section IX. Social Media Policy

A. All information shared will be done in a de-identified fashion, to protect the privacy of all MROQC participants
B. Only those specifically designated can use social media to speak on behalf of MROQC in an official capacity
C. Those designated individual(s) referencing MROQC will exercise personal responsibility whenever they use social media, which includes not violating the collaborative' s core values highlighted in Section I
D. The Coordinating Center will keep record of MROQC-related information shared via social media by those designated individuals