ASTRO/APEx

Accreditation Program for Excellence

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Goal for today

- To dissect APEx assessment evidence indicators into three sources of data and build understanding of its process from surveyor's as well as preparer's perspective.

APEx Assessment

- Ensures radiation oncology practice (ROP) has *appropriate* systems and processes in place (systems, personnel, policies and procedures)
- Built on specific standards of performance derived from white papers and consensus practice guidance of radiation oncology

APEx Standards -16 standards in 5 pillars

- The process of care (1-3)
  - Patient evaluation, Tx planning, patient specific safety interventions
- RO team (4-6)
  - Staff roles and responsibilities, qualifications, safe staffing
- Safety (7-9)
  - Culture, radiation safety, emergency preparation
- QM (10-13)
  - Facility and equipment, Information system, Tx procedures and modalities, peer review
- Patient centered care (14-16)
  - Patient consent, education, performance measurement and outcome reporting

APEx Evidence Indicators (EIs)

- 63 EIs and their sub EIs measured by
  - Medical record abstraction
  - Document upload
  - Facility visit/Site interview
- Mandatory EIs
- Primary and secondary measurement methods

Outline

- Data source 1: Documentation upload
- Data source 2: Medical records abstraction
- Data source 3: Site interview
- A preparer and surveyor's experience and tips

Data Source 1: Documentation upload

- Standard 3: Patient-Specific Safety Interventions and Safe Practices in Treatment Preparation and Delivery
  - 3.1.1 The ROP verifies patient identity
  - 3.4.1-3.4.12 The ROP follows written standard operating procedures (SOPs) for each treatment modalities *(Mandatory)*
- Standard 4: Staff Roles and Accountabilities
  - 4.1.1a-4.2.1 The ROP has job descriptions
- Standard 5: Qualifications and ongoing training of staff
  - 5.1.1-5.1.6 All team members possess or eligible for licensure and/or certification
  - 5.2.1 For each discipline the ROP defines a process and a timeline for individuals not certified *(Mandatory)*
- Standard 6: Safe Staffing plan (6.1.1-6.5.1)

Data Source 1: Documentation upload

- Standard 7: The ROP has a patient safety program (various SOP requirements)
- Standard 8: Radiation Safety program
  - 8.1.1 Requirements by the NRC, Agreement State and /or locality *(Mandatory)*
  - 8.2.1 Radiation exposure monitoring system *(Mandatory)*
  - 8.3.1 Annual radiation safety training *(Mandatory)*
  - 8.4.1 Pre-and post-treatment radiation surveys for brachytherapy procedures *(Mandatory)*
  - 8.5.1 Imaging protocols for simulation and treatment
- Standard 9: Written plan for emergencies
- Standard 10: The ROP provides radiation shielding, simulation SOP, and infection control SOP
- Standard 11: Information system map and SOPs

Data Source 1: Documentation upload

- Standard 12: QM of Treatment Procedures
  - 12.2 Processes for maintaining system
    - 12.2.1 Routine PMI
    - 12.2.2 SOP for reinstating clinical use status
    - 12.2.3 SOP when data deviates from expected findings
  - 12.3 Record review and trend analysis
  - 12.4 External validation of machine output accuracy *(Mandatory)*
    - 12.4.1 Prior to clinical use
    - 12.4.2 At least annually for photons and protons and every two years for electrons

Data Source 1: Documentation upload

- Standard 13: Peer Review of Clinical Processes
  - Peer review program *(Mandatory)*
- Standard 14
  - 14.1 Patient consent *(Mandatory)*
  - 14.2 Communication with patient
- Standard 15: Patient Education
- Standard 16: Performance Measurement and Outcomes Reporting
  - Patient complaints

Outline

- Data source 1: Documentation upload
- Data source 2: Medical records abstraction
- Data source 3: Site interview
- A preparer and surveyor's experience and tips

Data Source 2: Medical Record Abstraction

- Standard 1: Patient evaluation, care coordination and follow up
  - 1.1 Patient evaluation is documented by the radiation oncologist prior to initiation of treatment *(Mandatory)*
    - 1.1.1 History
      - Patient history
      - Current medication name and dose
      - Implantable cardiac devices (ICD): type, implant date and plan of care pertaining Tx and the ICD
      - Pregnancy status
      - Allergies
      - Previous radiation therapy history
    - 1.1.2 Review of systems
    - 1.1.3 Physical examination findings

Data Source 2: Medical Record Abstraction

- Standard 1: Patient evaluation, care coordination and follow up
  - 1.1 Patient evaluation is documented by the radiation oncologist prior to initiation of treatment (Mandatory)
    - 1.1.4 Pathology review
    - 1.1.5 Staging and metastatic disease
    - 1.1.6 Laboratory findings
    - 1.1.7 Imaging studies
    - 1.1.8 Pain intensity assessment
      - Pain management plan
    - 1.1.9 Initial plan of care
    - 1.1.10 Radiation oncologist's signature and date

Data Source 2: Medical Record Abstraction

- Standard 1: Patient evaluation, care coordination and follow up
  - 1.2 Patient direct evaluation is provided by the radiation oncologist at least once every five patient treatment
    - 1.2.1 Review of cumulative interim dose delivered; 1.2.2 Patient examination; 1.2.3 Assessment of tolerance and response to treatment; 1.2.4 Pain intensity assessment and pain management plan and 1.2.5 Radiation oncologist's signature and date
  - 1.3 Post treatment summary
    - 1.3.1 Site of treatment; 1.3.2 Dose per fraction; 1.3.3 cumulative dose delivered. 1.3.4 Treatment data range; 1.3.5 Concurrent systemic therapy; 1.3.6 Assessment of tolerance and response to treatment; 1.3.7 Pain management plan; 1.3.8 Follow-up plan and 1.3.9 Radiation oncologist's signature and date
  - 1.4 Coordination of care and communication
    - The ROP communicates with other involved providers (within four weeks)
  - 1.5 Patient follow up (within four months)

Data Source 2: Medical Record Abstraction

- Standard 2: Treatment Planning
  - 2.1 The treatment planning process is based on the data from a simulation procedure
    - 2.1.1 written simulation directive of a radiation oncologist
    - 2.1.2 simulation directive includes patient positioning, immobilization
      - Verification of accurate information transfer from simulation to TPS
  - 2.2 Documented, patient-specific planning directive
  - 2.3 (Mandatory) Formal treatment prescription that includes
    - 2.3.1 Anatomic treatment sites. 2.3.2 Type and method of radiation treatment delivery. 2.3.3 Energy. 2.3.4 Total dose. 2.3.5 Dose per fraction. 2.3.6 Number of fractions. 2.3.7 Frequency of treatment. 2.3.8 Imaging guidance to be used during the course of radiation treatment. 2.3.9 Radiation oncologist's signature and date prior to initiation of treatment

Data Source 2: Medical Record Abstraction

- Standard 3: Patient-Specific Safety Interventions and Safe Practices in Treatment Preparation and Delivery
  - 3.2 (*Mandatory*) Timeout prior to every patient procedure (Secondary: Interview)
    - 3.2.1 Verification of patient identity using at least two patient specific identifiers
    - 3.2.2 Verification of patient treatment site
    - 3.2.3 Verification of patient positioning
    - 3.2.4 Verification of treatment delivery parameters
  - 3.3 A medical physicist performs an end-of-treatment review within one week

Data Source 2: Medical Record Abstraction

- Standard 3: Patient-Specific Safety Interventions and Safe Practices in Treatment Preparation and Delivery
  - 3.5 (*Mandatory*) A medical physicist initial review before treatment
    - 3.5.1 Plan compared to prescription
    - 3.5.2 Verification of dosimetric results
    - 3.5.3 IMRT QA
  - 3.6 (*Mandatory*) A medical physicist performs periodic checks at least every five fractions
    - 3.6.1 Accuracy of treatment delivery
    - 3.6.2 Accuracy of treatment setup parameters

Data Source 2: Medical Record Abstraction

- Standard 14: Patient Consent
  - 14.1 (*Mandatory*) Informed patient consent
    - 14.1.1 Information regarding risks and benefits of radiation therapy
    - 14.1.2 Obtaining consent before the simulation
    - 14.1.3 Verifying consent is within 60 days prior to treatment
    - 14.1.4 Date and signature from the radiation oncologist
- Standard 15: Patient Education
  - 15.1 Assesses patient education needs before treatment begins and at least one time during the course of treatment
  - 15.2 The ROP educates patients on
    - 15.2.1 Treatment options; 15.2.2 The intent of treatment and what to expect in the treatment process; 15.2.3 Management of treatment side effects (pain, skin care, weight loss and self care)

Outline

- Data source 1: Documentation upload
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- Data source 3: Site interview
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Data Source 3: Site Interview

- Standard 1: Patient Evaluation, Care Coordination and Follow-up *(team)*
  - 1.4.3 *Multidisciplinary review program, such as tumor board (Mandatory)*
- Standard 3: Culture of Safety
  - 3.2 Mandatory components of a timeout prior to every patient procedure *(Mandatory) (team)*
    - 3.2.1 Verification of patient identity using at least two patient specific identifiers
    - 3.2.2 Verification of patient treatment site
    - 3.2.3 Verification of patient positioning
    - 3.2.4 Verification of treatment delivery parameters
      - Describe your timeout process
  - 3.3 End of treatment review of medical record within one week of the completion of therapy *(physicist)*
    - *What steps do you take to close out a treatment records*

Data Source 3: Site Interview

- Standard 3: Culture of Safety
  - 3.4 written clinical/patient treatment SOPs for each treatment modality *(Mandatory) (physicist and team)*
    - 3.4.1-3.4.12 2D/3D, IMRT, IGRT, IORT, SRS, SBRT, Brachytherapy, Electronic brachytherapy, Unsealed radioactive sources, Hyperthermia, Proton, All others
      - *Who is responsible for daily QA?*
      - *How do you know that the daily QA has been performed and passed*
- Standard 5: Qualifications and Ongoing Training of Staff *(team) review the documentation*
  - 5.6.1 Initial training, orientation and job-specific competency testing process for reach team member *(Mandatory)*

Data Source 3: Site Interview

- Standard 5: Qualifications and Ongoing Training of Staff *(team) review the documentation*
  - 5.7 Ongoing staff training and competency testing
    - 5.7.1 Annual staff training and competency testing
    - 5.7.2 New equipment and/or procedures
    - 5.7.3 Training and competency testing on the use of treatment machine
    - 5.7.4 Training for patients with special needs

Data Source 3: Site Interview

- Standard 7: Culture of Safety *(team)*
  - 7.1 Policy and procedure on patient safety (Mandatory)
    - *What do you do if you have a safety concern?*
    - 7.1.1 Articulates the ROP's approach to patient safety
    - 7.1.2a Specifies the patient safety incidents are to be reported and tracked within the ROP
    - 7.1.2b Specifies the near-misses are to be reported and tracked within the ROP
    - 7.1.3 Identifies methods for staff to report patient safety events and unsafe conditions (including reporting anonymously)
    - 7.1.4 Encourages timely reporting
    - 7.1.5 Specifies periodic reporting back to staff
    - 7.1.6 Specifies that procedures are not started until all questions and/or concerns are resolved.
    - 7.1.7 Provides assurances that there will be no reprisals
    - 7.1.8 Identifies a role for patients
    - 7.1.9 Accountability within the practice leadership

Data Source 3: Site Interview

- Standard 7: Culture of Safety *(team)*
  - 7.2 Interdisciplinary safety round
    - *Which professional disciplines are presented*
    - *How does your ROP review patient safety event data*
    - *How does your ROP proactively assess its structure and processes to promote safety?*
    - *Describe a recent plan to improve safety at your ROP*
  - 7.4 Patient safety organization (PSO)
    - *Does your ROP participate in a patient safety organization?*

Data Source 3: Site Interview

- Standard 8: Radiation Safety *(physicist)*
  - 8.4.1 The ROP conducts radiation surveys pre- and post-treatment for brachytherapy and radiopharmaceutical procedures *(Mandatory)*
    - *When are radiation surveys performed on patients*
  - 8.5.1 The ROP utilizes imaging protocol for simulation and treatment
    - *How to you know what protocols to follow when performing imaging procedures on patients?*
- Standard 9: Emergency preparation and planning *(team)*
  - 9.1.1 The ROP has a written plan for patient clinical emergencies
    - *How do you respond to a patient clinical emergency?*
  - 9.2.1 The ROP identifies and plans for power failure
    - *What do you do in the event of a power failure?*

Data Source 3: Site Interview

- Standard 9: Emergency preparation and planning *(team)*
  - 9.2.2 The ROP identifies and plans for information system failure
    - *What do you do if your information system is not functional?*
  - 9.2.3 The ROP identifies and plans for radioactive material release
    - *What steps do you take in the event of a radioactive material release from your ROP?*
  - 9.2.4 The ROP identifies and plans for external threats
    - *What external threat is most concerning to your ROP?*
    - *What do you do in the event that it happens*
- Standard 10: Facility and Equipment *(physicist and team)*
  - 10.1 The ROP provides radiation shielding for each radiation area
    - *How was the current workload calculated, and how does it compare with what was initially used to design the shielding*
    - *Review shielding calculation documents*
    - *Review radiation survey documents*

Data Source 3: Site Interview

- Standard 10: Facility and Equipment *(physicist and team)*
  - 10.2 The ROP provides functional audio and video patient monitoring system in all treatment rooms *(Mandatory)*
  - 10.3 The ROP performs radiation therapy simulations, including at a minimum CT simulation
    - *How to you ensure that patient positioning from simulation to treatment is reproducible?*
    - *What staff is required to perform a radiation simulation?*
    - *What patient-specific considerations do you need to be aware of before starting a radiation simulation*
    - *How would you know if a patient received previous radiation therapy?*
  - 10.4 The ROP has an infection control program *(Mandatory)*
    - *What steps do you take to control the risk of infection between treatment of patients?*
    - *What happens to non-custom patient positioning devices between patients*

Data Source 3: Site Interview

- Standard 11: Information System
  - 11.2 The ROP designates authorized users *(team)*
    - *How are access rights to information systems differentiated among types of users?*
    - *How is unauthorized access to information systems prevented?*
  - 11.3 The ROP conducts a QA program for each information system *(physicist)*
    - *Acceptance testing*
    - *Commissioning*
    - *Ongoing QA*
    - *Verify the fidelity of information transfer between systems*
  - 11.4 The ROP ensures staff receives training *(physicist)*
    - *Review documentation of staff training*
  - 11.6 The ROP enables optional software to improve safety *(physicist and team)*

Data Source 3: Site Interview

- Standard 12: QM of Treatment Procedures *(physicist)*
  - 12.1 Equipment QA *(Mandatory) review documentation*
    - 12.1.1 EBRT QA: dosimetry checks, mechanical checks, safety checks, and respiratory management checks
    - 12.1.2 Brachytherapy QA: dosimetry checks, mechanical checks, safety checks,
    - 12.1.3 QA of measurement equipment
    - 12.1.4 Acceptance testing , clinical commissioning and clinical release
    - 12.1.5 End-to-end dosimetry system testing
    - 12.1.6 Simulation QA: dosimetry checks, mechanical checks, safety checks, and respiratory management checks
  - 12.2 Maintaining systems: PMI and reinstating clinical use status
    - *Mechanical systems, electronic systems, software systems*
  - 12.3 Trend analysis: machine calibration, QA results, downtime and service reports

Data Source 3: Site Interview

- Standard 13: Peer Review of Clinical Processes *(team) (Mandatory)*
  - 13.1.1 Objective of peer review program
  - 13.1.2 Frequency of peer review
  - 13.1.3 Number, type and frequency of cases for peer review
  - 13.1.4 Professional feedback and future learning
- Standard 15: Patient Education *(team)*
  - *Who is responsible to provide patients about the cost of treatment, and what process do they follow to obtain and provide the information*
  - *Review written and online education materials*
  - *What therapeutic interventions do you provide to manage side effects, and what do you refer to another specialists?*
- Standard 16: Performance Measurement and Outcomes Reporting *(team)*
  - 16.1.1 The ROP measures and evaluates, at least annually, the patient experience

Outline

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APEx-Preparer's perspective

- City of Hope National Medical Center
  - A comprehensive cancer center designated by NCI, including Beckman Research Institute, Helford clinical research hospital and a biomedical graduate school, resides and 110 acre of land northeast of Los Angeles, with 5,000 employees.
  - Department of Radiation Oncology has 1,200 new start patients annually
- Self Assessment Process
  - Medical records abstraction: 20 charts, 94% Level 1 and 76% Level 2
    - Current medication, pregnancy status, communication to outside providers, treatment planning directive…
  - Document upload: 87% Level 1 and 90% Level 2
    - SOP SRS, Xoft IORT, physicist/dosimetrist staffing level, tracking PHI changes, QMP trend analysis
  - Interview preparation: 97% Level 1 and 100% Level 2
- Preparer's Perspective
  - ROP will improve through the self-assessment process

APEx-Surveyor's perspective

- 5 facility visits (2 in 2016, 1 in 2017 and 2 in 2018)
  - Facility A: a major academic radiation oncology department
  - Facility B: a regional community cancer centers with 5 locations
  - Facility C: a national recognized top radiation oncology program with proton modality
  - Facility D: a regional academic radiation oncology department
  - Facility E: a regional community cancer centers with 5 locations
- APEx physics retreat (2017)
  - Three physics surveyors were invited to attend with APEx committee members to discuss minimum requirements
- Surveyor's perspective
  - A medical physicist should play a leading role in preparation for APEx
  - Each evidence indicator should be addressed in the self-assessment process

Summary

- APEx uses document upload, medical record abstraction and onsite interview to assess ROP to ensure *appropriate* systems and processes are in place.
- A medical physicist should play a leading role in APEx preparation.
- ROP will improve through self-assessment process. Working at each and every evidence indicator will get the ROP ready for accreditation.