Certificate of Need Positron Emission Tomography (PET) Scanner Services
Workgroup Meeting Minutes
Thursday, March 25, 2021

9:30am – 11:30 A.M.

AGENDA

I. Call to Order **Chairperson Brandon Mancini, MD**

- Meeting called to order at 9:33 AM.

II. Charge 1: Review the Oversight Requirements to Initiate Mobile and Fixed Services – Subcommittee Update: Tom Boike, MD (Genesis Care)

- Please see attached supplemental material/slide for an overview of current requirements and proposed change(s).
- Subcommittee met multiple times and looked at the initiation of PET CON Standard 3.1, with some inclusion of 3.2.
    - Discussion regarding Section 3.1 included the evaluation of listed specialties, primarily those (e) through (m) in the current standards, as the receipt and use of radioactive materials is a must. Therefore, need for Nuclear Medicine and other radiologic services involved.
        - Initially wanted to eliminate all (e) through (m) specialties, but concern that these may be included a surrogate for quality, even though may not be the best indicator for quality overall.
            - Keeping a list of specialists/specialties doesn't necessarily increase quality and can become cumbersome.
                - However, concern that elimination of specialty requirement(s) would lead to standard 3.1 not having much robust information.
            - Unanimous that Open Heart Surgery and Psychiatry can be eliminated.
            - Some debate on other specialties.
            - Could consider adding specialties such as Primary Care, Urology, and Gynecologic Oncology.
            - Could combine services into more general specialties/categories.
                - Concern that such a change would then allow the lowest level of a service to then meet the standards.
        - Consider a different approach than requirements related to specialties.
            - Perhaps a requirement that comprehensive care center is available/integrated with PET.
                - Could be a way to ensure quality.

        - Concern that if all specialties removed, no barriers for entry and quality can be compromised.
        - Other diagnostic imaging modalities (i.e. CT or MRI) do not have a specialty requirement list
        - Concern that tying PET to a health system would be difficult.
    - Consider inclusion and/or replacement of specialties with an accrediting body (e.g. American College of Radiology [ACR] or Intersocietal Accreditation Commission [IAC]).
        - PET is useful for a multidisciplinary team to use for the care of a patient, but accreditation would ensure PET scans are conducted with good policies/procedures with high quality for use in radiation therapy treatment planning, etc.
        - A lot of activation energy is required to initiate a PET facility and it would like be at least 6 months until data is available to evaluation for accreditation.
        - For MRI, accreditation is not required, but the standards state that one should follow ACR requirements.
        - For MRT CON, accreditation is required and an institution/facility has 3 years to satisfy the requirement.
        - Include specific language for a commitment to accreditation within a specified period of time.
        - Requirement for board-certified radiologists, technologists, etc.
    - Other CONs have commitment to a volume requirement.
        - Concern that making initiation requirements too lenient may lead to greater difficulty in other facilities satisfying the current volume requirements (e.g. to transition from mobile to fixed services).
            - If too many facilities, this could lead to scans being performed away from hospitals/healthcare facilities with large, robust, high-quality programs.
    - Need to ensure language in standards to prevent rampant proliferation without quality or need.
- For standard 3.2, recommendation is to increase the radius to 50 miles for a host site located in a rural or micropolitan area.
    - Consider removing “hospitals” in exchange for “healthcare entity.”
- If proposed changes to this standard would have an impact on other standards, this is okay to propose to the commission.
    - May also make recommendations for items to be formally addressed within a future workgroup or SAC.

III. Charge 2: Review Minimum Volume Requirement to Convert to a Fixed Service – Subcommittee Update: Alice Pichan (St. Joseph Mercy)

- Subcommittee meeting with the presence of both mobile and hospital-based PET providers.
- Reviewed concerns and history of the charge and found alignment in thoughts of the PET equivalents.

- Agreement that the PET equivalent threshold needs to be reduced.
- Historically, only one facility has been able to convert and there are four facilities in the state nearing 1500 PET equivalents.
  - Concern not to have the threshold too low to allow too many to convert.
- When PET equivalents requirement was raised 10 years ago, skull to mid-thigh scan used a 1.5 conversion rate.
  - The conversion rate was reduced to 1.0 at that time.
    - Idea of retaining current conversion factor of 1.0 for skull to mid-thigh would make sense.
    - This would allow conversion to stay lower, keep equivalents lower.

- Concern that MRI has twice as many sites as PET, but able to convert 17 from mobile to fixed compared to 1 for PET over the same time period.
- If more facilities are able to convert, more access for smaller sites.
  - Availability in rural areas very important.
  - Lowering threshold will keep mobile routes open and allow conversion to fixed more readily.
  - More access is needed for PET.
- Concern that facility numbers may increase due to use of PET in acute cardiac, infection, inpatient, etc.
- Recommendations:
  - Metropolitan: Current standard requires 1700 PET equivalents.
    - Subcommittee proposes to reduce this to 1500 PET equivalents (11.8% reduction).
  - Micropolitan/Rural: Current standard requires 1500 PET equivalents.
    - Subcommittee proposes to reduce this to 1325 PET equivalents (11.8% reduction).
    - Next steps will be to examine how these changes impact cost, quality, and access.
    - Will look at micropolitan centers' volume for review during the next workgroup meeting.

IV. Charge 3: Review if Specific Requirements Should Be Added to the PET Standards for Fixed Novel Whole-Body PET/CT and PET/MR Scanners Located Immediately Adjacent to a Modern Cyclotron-Equipped Radiopharmacy –

Subcommittee Update: Arlene Elliott (Arbor Advisors, LLC)

- See attached presentation/slides.
- Subcommittee met twice and smaller subgroup met separately for a third time.
- Goal of today is to share early concepts, such as definitions, as well as initiation requirements, etc.
- Short half-life radioisotopes is why close proximity is needed (i.e. cannot transport radioisotopes elsewhere).
- There may be a better name than "'Comprehensive' fixed PET referral service."
  - Crux of the issue around the proximity necessary.
- This service would have a large geographic reach and the projection of need compared to standard PET scanner unable to be determined.

    - Propose that the new section be included as a pilot program for a future SAC or workgroup.
        - Use it to inform the methodology within the standards.
        - There is a precedent for pilot programs within CON.
        - Therefore, would not need to project PET data units, as this would be done at a future workgroup/SAC.
- Facility requirements will mirror the definitions from slide #7.
- Pilot Program:
    - How long is the pilot program available to applicants to apply to?
        - Could create a narrow window (6-12 months).
        - Some pilot programs allow years.
    - How long do we report back the data to create a better methodology for the standards?
        - Could require providing data in year one and/or up to 5 years, if desired.
    - Concern for pilot program.
        - There have been issues in the past with such programs making sure enough time is allotted at the front and back end to collect the data.
        - Standards are up for review every three years.
        - In general, the commission has been moving away from pilot programs as a result.
    - Part of the reason for suggesting the pilot program is understanding that we do not have the data necessary to build the appropriate need-based methodology;
        - Including a component about demonstrating need did not seem appropriate.
        - Need to make sure it is clear that the pilot is a time for gathering data instead of a section without demonstrated need.
        - Making a pilot program and setting deadlines for applications to be submitted prevents three full years of passing.
            - Would include a specific window of time for applications and another timeline for data gathering.
- Cost/Barrier of such a program is high and this is a rapidly changing field. Support pilot program and accumulation of data. Excitement regarding access to such a facility in the State of Michigan.

V. Review of Assignments & Next Steps **All**

- Subcommittees will reconvene to further discuss and modify assigned charges and gather data and prepare recommendations for next month's workgroup meeting, as appropriate.

VI. Adjourn

- Meeting adjourned at approximately 11:12 AM.

Future Meetings: April 22, 2021, May 20, 2021, & June 24, 2021

Proposed Changes to PET Standards

Current Requirement	Proposed Change
The existing PET standard section 3.1 lists 12 services that a proposed applicant must provide in order to qualify for PET scanner services.	The workgroup would propose eliminating Open Heart Surgery and Psychiatry from the list as they have little relevance to modern PET.
Section 3.2 requires that organizations providing those contracted services be within the same planning area or within 25 miles of the proposed host site.	The workgroup would propose increasing the distance to 50 miles for a host site located in a rural or micropolitan area. The group also suggested removing the requirement that provider of these services be a hospital.
There are currently no defined quality parameters within either the initiation section or project delivery standards section of the standards.	The workgroup would propose that either the full workgroup or a future SAC be charged to evaluate the inclusion of an accrediting requirement (for example via ACR) within 2 years of the beginning of a new service.
There are currently no volume requirements for initiating a new mobile host site.	The workgroup suggested that this should be put on the agenda for either a future workgroup or SAC.
The current PET data unit methodology needs to be evaluated in light of changing PET usage patterns.	In light of a potential initiation volume requirement, the workgroup suggested that this should be put on the agenda for either a future workgroup or SAC.

Attachment 2

PET CON Workgroup
Charge #3 Subcommittee Report

3/25/2021

CHARGE #3 SUBCOMMITTEE MEMBERS

- Andy McLean
- Anthony Chang
- Arlene Elliott
- Chad Bassett
- David Walker
- Mark Delano
- Melissa Reitz
- Patrick O'Donovan
- Roger Spoelman
- Tom Boike
- Tom Lanni
- Walt Wheeler
- Todd Faasse
- Anderson Peck
- Brandon Mancini
- Brenda Rogers

Full Subcommittee met on 3/9/2021 and 3/23/2021

Small subgroup also met on 3/12/2021

REMINDER: CHARGE

CHARGE #3

- Review if specific requirements should be added to the PET standards for fixed novel whole-body PET/CT and PET/MR scanners located immediately adjacent to a modern cyclotron-equipped radiopharmacy.

CONCERN

The current CON Standards that regulate PET scanners do not account for technological advancements in fixed PET that can serve a broader populations and conditions using a wider range of tracers for both diagnostic and therapeutic purposes, particularly when the fixed PET scanners are adjacent to a radiopharmacy.

THE WORK

Create a new section to the existing PET CON standards that address providers proposing whole body PET/CT and PET/MRI adjacent to a radiopharmacy

- broader population
- conditions
- wider range of tracers
- therapeutic applications
- adjacent to a radiopharmacy

WORKING CONCEPT

- Definitions
- Initiation Requirements
  - Projection of Need
  - Facility Requirements
- Replacement, Expansion and Acquisition Requirements
- Project Delivery Requirements

PROPOSED DEFINITIONS

DRAFT

- “Comprehensive fixed PET referral service“ means a PET scanner service that must include at least one of the following PET scanners, fixed whole-body PET/CT, fixed digital PET/CT scanner, or fixed PET/MRI scanner hybrid and is located immediately adjacent to or in the same facility as a fixed cyclotron-equipped radiopharmacy capable of producing a broad spectrum of radioisotopes, including those with short half lives.

- “Fixed cyclotron” – a fixed particle accelerator used for the production of medical isotopes.

- “Fixed digital PET/CT” scanner” – a fixed PET/CT hybrid with silicon photomultipliers (SiPM) with digital readout for high-resolution image reconstruction

- “Whole body PET/CT scanner” – a fixed PET/CT scanner with an axial field of view of >130cm

PROPOSED INITIATION REQUIREMENTS

1. Projection of Need
   - The current CON projection methodology (Sections 12-16) are based on FDG applications
   - A Comprehensive fixed PET referral service will have different experience from traditional PET
     - Much wider geographic reach
     - Specialized clinical conditions w/novel tracers
     - Theranostic applications

   - The Subcommittee proposes the new standard be created as a Pilot Program for purposes of collecting data to inform a future need-based methodology;
   - Applications to the Pilot Program would not be required to project PET data units using

2. Facility requirements - TBD
   - These will largely mirror the components outlined in the definition of the Comprehensive fixed PET referral service

FUTURE SUBCOMMITTEE WORK

The Subcommittee will continue to work to refine requirements for:

- Initiation
- Replacement
- Expansion
- Acquisition
- Project Delivery

As well as any other recommendations to the CON Commission

DISCUSSION