

**REVIEW OF SUPERVISION OF NUCLEAR
MEDICINE IMAGING, INCLUDING
POSITRON EMISSION TOMOGRAPHY
(PET) SERVICES UNDER MEDICARE**

Discussion paper

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1 Introduction

The current rules which apply to the provision of Medicare funded diagnostic imaging services, including nuclear medicine imaging services, are set out in the [Health Insurance \(Diagnostic Imaging Services Table\) Regulations 2020](#) (DIST), made under the [Health Insurance Act 1973](#) (the Act). These arrangements are reviewed from time-to-time to ensure that they are contemporary and align with best practice.

In view of the sector's investment in digital solutions to modernise service delivery so that it is more effective and efficient¹, the Department has been asked by a provider of positron emission tomography (PET) services to consider whether the current rules which apply to the provision of these services could be more flexible.

The Department has taken this opportunity to additionally consider:

- whether the requirements for PET to be provided in a comprehensive practice should be reconsidered; and
- the current requirements for non-PET nuclear medicine imaging services.

This discussion paper has been developed to seek stakeholder views on the effectiveness of the current arrangements, as well as potential proposed changes, including the impact of any changes on access to and the quality of, nuclear medicine imaging services. Your views will help inform advice to Government about any regulatory change

2 PET supervision

2.1 Current PET supervision requirements

The requirement for PET services to be personally supervised by a credentialed PET specialist is set out in clause 2.4.3 of the DIST:

2.4.3 PET nuclear scanning services—performance under personal supervision

- (1) For the purposes of clause 2.4.2, the service must be performed on a person by or under the personal supervision of:
 - (a) a credentialed specialist other than the requesting practitioner; or
 - (b) a medical practitioner other than the requesting practitioner if the medical practitioner:
 - (i) is a Fellow of the RACP or RANZCR; and
 - (ii) has reported 400 or more studies forming part of PET services for which a Medicare benefit was payable; and
 - (iii) is authorised under State or Territory law to prescribe and administer to humans the PET radiopharmaceuticals that are to be administered to the person; and
 - (iv) met the requirements of subparagraphs (i), (ii) and (iii) before 1 November 2011.
- (2) In this clause:
requesting practitioner has the same meaning as in paragraph 2.4.2(1)(a).

¹ From Australia's National Digital Health Strategy <https://conversation.digitalhealth.gov.au/australias-national-digital-health-strategy>

2.2 Definition of ‘personal supervision’

As the DIST does not define ‘personal supervision’, policy guidance has relied on historical advice from the Australasian Association of Nuclear Medicine Specialists (AANMS), which requires the physical presence of the specialist at some time during each component of the service, as well as the ordinary dictionary definition of personal, meaning ‘in person’.

The Department’s current position is that PET services are required to be supervised in person to ensure better imaging outcomes and improved patient care.

2.3 Recent review

As part of the recent Medicare Benefits Schedule (MBS) Review Taskforce (Taskforce) processes, the current rules around who can supervise PET services were considered². The review acknowledged that Australia currently has high standards of requirements for PET and that this should continue to be the case.

The review concluded that current PET supervision rules remain appropriate and the rule stating all doctors reporting PET scans must be specifically trained for this purpose also remains appropriate. It was acknowledged that the current ‘grandfathering’ provision on paragraph 2.4.3(1)(b) of the DIST would gradually become redundant.

2.4 Sectoral standards

In relation to its own voluntary accreditation program that assesses nuclear medicine practices against the *Australasian Association of Nuclear Medicine Specialists Standards for Accreditation of Nuclear Medicine Practices*, which were jointly developed with the Royal Australian and New Zealand College of Radiologists (RANZCR), AANMS³ explains:

3. What are the requirements for personal supervision/specialist attendance?

The *Standards* document (pp 8 - 9, Standard 3, *Explanation and Guidelines in Relation to Personal Supervision*) states in part:

"Although each component of the nuclear medicine service requires personal supervision this does not imply direct physical attendance by the specialist during the entirety of each component.

For every patient the specialist must complete the report on site, and there must be consultation with the patient. The specialist must take responsibility to ensure that each of the other components is completed satisfactorily. Mostly this will require the physical presence of the specialist at some time during each component, although this will vary from patient to patient, and from study to study. The attending specialist will be required to take these matters into consideration and take responsibility for whatever decision he or she takes in a particular case."

² MBS Review Taskforce, *Final Report on the MBS Items for Nuclear Medicine 2018*, pp28

[https://www1.health.gov.au/internet/main/publishing.nsf/Content/BEB6C6D36DE56438CA258397000F4898/\\$File/Final%20Report%20on%20the%20MBS%20Items%20for%20Nuclear%20Medicine.pdf](https://www1.health.gov.au/internet/main/publishing.nsf/Content/BEB6C6D36DE56438CA258397000F4898/$File/Final%20Report%20on%20the%20MBS%20Items%20for%20Nuclear%20Medicine.pdf)

³ https://www.aanms.org.au/index.php?option=com_content&view=article&id=16:frequently-asked-questions-on-accreditation&catid=1:main-content&Itemid=22 (Question 3)

2.5 Possible alternative approach

PET is required to be provided in a comprehensive facility (discussed further below), which includes computed tomography (CT) (among other services). In addition, all modern PET scanners have both PET and CT capabilities.

Diagnostic CT scans provided on a PET/CT scanner are required to be reported by specialist radiologist. In addition, such scans need to be provided under the supervision of a specialist radiologist (not necessarily the reporting radiologist) who is available to monitor the diagnostic quality of the examination and personally attend during the scan if necessary (clause 2.2.1 of the DIST⁴).

A proposal has been put forward that, if accepted would allow PET-credentialed nuclear medicine specialists (PET NMS) unable to be on site, to supervise the services remotely in real time if necessary. Under the proposed arrangement:

- the qualified nuclear medicine imaging technologist (NM technologist) would consult with the off-site PET NMS in real time in accordance with current protocols for on site practitioners;
- the PET NMS would review and report the scans by teleradiology; and
- a radiologist would be available on site (in line with the comprehensive facility and CT professional supervision requirements) to attend the patient if medically necessary.

Under the proposal, PET NMS could remotely supervise a number of PET sites.

2.6 Discussion

More flexible ways of working may have their advantages, but quality patient outcomes must be a priority. Patients should be provided with the same quality of services whether the PET NMS is on or off site.

The proposal would mean that the NM technologist is providing all of the service, without any personal attendance by the PET NMS, with the radiologist available in case of medical necessity.

Presumably, the PET NMS would review the request off-site and determine any changes to the radioisotope dosage protocol, which would be prepared and administered by the NM technologist. The NM technologist would capture the images, in real time consultation with the PET NMS if needed, and the PET NMS would report the service.

The radiologist would be required to be on site for all the patient interaction elements of the procedure, i.e. the administration of the radioisotope and the scan. There would be no discretion for the radiologist to be on site only if necessary.

⁴ Health Insurance (Diagnostic Imaging Services Table) Regulations 2019, <https://www.legislation.gov.au/Details/F2019L00563>

Having a radiologist on site in metropolitan areas is consistent with the joint RANZCR and Australian Diagnostic Imaging Association (ADIA) Quality Framework⁵, and RANZCR's Teleradiology Standards⁶.

However, under the 'by or under the behalf of' provisions in subsection 3(17) of the Act, a medical practitioner cannot delegate his or her responsibility to another medical practitioner, or be under the supervision of another medical practitioner.

The responsible PET NMS is the one who would claim a Medicare benefit.

2.7 Benefits of the proposal

Benefits of the proposal include:

- it would make PET services more available in regional areas where radiologists are working, and it could reduce the travel distances for remote patients
- may reduce pressure on state-funded transport schemes⁷
- it would assist with workforce management of the PET NMS by allowing the supervision of multiple PET sites
- it would make best use of available technology
- it may lead to better outcomes for patients as an on site radiologist can advise on radiology procedures⁸ the costs to provide services are reduced, which potentially reduces patient out-of-pocket costs⁹

2.8 Disadvantages/risks with the proposal

Disadvantages and risks of the remote supervision proposal include:

- the off-site provider may not be available in real time due to connectivity problems, competing priorities involving patients from other sites for which the provider is also providing off-site supervision, or other circumstances
- it needs regulation change

2.9 Other PET supervision options

2.9.1 No change

This option would mean that the current PET supervision rules would continue to apply.

⁵ Quality Framework <https://www.ranzcr.com/search/quality-framework-for-diagnostic-imaging>

⁶ RANZCR Teleradiology Standards, <https://www.ranzcr.com/search/media-release-new-standards-for-teleradiology> (Principle 3)

⁷ *Smarter Cancer Care: Giving all Australians access to specialist diagnostic imaging services*, Qscan Group, pp3

⁸ *Smarter Cancer Care: Giving all Australians access to specialist diagnostic imaging services*, Qscan Group, pp6

⁹ *Smarter Cancer Care: Giving all Australians access to specialist diagnostic imaging services*, Qscan Group, pp3

Advantages

- patients have access to a PET NMS on site
- no changes need to be made to existing regulations

Disadvantages

- provides reduced flexibility for some business models
- may not make the most of new and developing technologies
- may not make best use of available workforce

2.9.2 Relax rules for non-metropolitan areas only

This option would allow for supervision to be undertaken off-site only for non-metropolitan areas.

Advantages

- it would make PET services more available in regional areas, and it could reduce the travel distances for remote patients
- may reduce pressure on state-funded transport schemes
- it would assist with workforce management of the PET NMS by allowing the supervision of multiple non-metropolitan PET sites.
- it would make best use of available technology, in non-metropolitan areas

Disadvantages

- the off-site provider may not be available in real time due to connectivity problems, competing priorities involving patients from other sites for which the provider is also providing off-site supervision, or other circumstances
- it may not assist may with workforce management of the PET NMS in metropolitan areas
- needs regulation change

2.10 PET supervision consultation questions

Consultation question 1

What are the benefits of having a PET NMS on site?

PET is a highly specialised modality requiring active and considered medical input to achieve optimal results. The patients are often receiving a multitude of therapies and these can have multiple effects on the performance of the scan and its interpretation. While a checklist can be provided to the patient, this is an inferior substitute to directly speaking to the patient and obtaining information first hand. Telehealth measures could be used to try and bridge this gap. We have reservations that they would be employed in all cases and that they would provide a similar level of detail compared to a real-life interaction. This would also preclude any physical examination of the patient, which, on occasion, is an important aspect of providing optimal PET service.

As the scan progresses, patients may have issues with claustrophobia, lying supine or other issues related to their primary diagnosis. Having a Nuclear Medicine Specialist (NMS) on site allows for the most effective intervention in these occurrences.

When the scan is completed, the NMS will review the images and advise the technologist that the scan is complete or whether additional imaging is required. Having the NMS offsite may lead to a breakdown in this process due to the workload of the doctor working remotely or telecommunication issues compromising image quality.

We refer to our comments listed below on the numerous disadvantages and risks to highlight why onsite supervision is recognised best practice and delivers optimal patients' outcomes and safety and quality of care.

Consultation question 2

What are the risks or detrimental effects of not having a PET NMS on site?

As personal supervision is the accepted standard for diagnostic CT scans, the proposal that the NMS not be required to be onsite for PET is contradictory and could be viewed as not supporting best practice standards for diagnostic PET scans. The established standards for a diagnostic CT scan as established in clause 2.2.1 in the Diagnostic Imaging Services Table – available at <https://www.legislation.gov.au/Details/F2019L00563>

Under the proposal, a radiologist would be required to be on site for all the patient interaction elements of the procedure, i.e. the administration of the radioisotope and the scan. All the clinical decision making regarding dosage and appropriateness of the test must be made by the qualified NMS. If there was a communication outage or the offsite NMS was unavailable for another reasons, the PET scan should be deferred until the NMS was available as the untrained radiologist could not substitute for the NMS in this role. However, there would be significant pressure for the scan to be performed regardless with the patient in attendance, expensive

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radiopharmaceutical with a limited lifespan having been procured and technologist and camera time having been allocated.

Additional disadvantages and risks include:

- The outcome of an incorrect study being performed involving radiation, or an incomplete study being performed, would impact on patient management and result in further increased radiation dose due to the need for a repeat study.
- Insufficient clinical assessment due to remote supervision may result in incorrect interpretation with potential errors and/or unnecessary additional investigations, adding to the health care cost and increased radiation dose.
- Pressure from managing multiple sites may lead to a reduction in time spent with each patient and overall reduction in time spent on each report.
- Places significant responsibility on the nuclear medicine technologist (NMT) who are not trained in the clinical aspects of the disease, although they typically work under the direct supervision of the NMS.
- Reliance on network infrastructure may delay reporting if there is an outage, which can impact on patient management
- Regular interaction between the NMT and NMS is ideal for best practice. NMT working continuously in isolation may get less feedback and day to day quality control may deteriorate.

Consultation question 3

Is there a shortage of PET NMS? If so, please quantify/provide rationale.

From what the AANMS knows and understands anecdotally there is currently not a shortage of PET NMS. We frequently are a conduit for advertising vacant positions, and we know of no vacant positions at this time. Workforce analysis and quantification is a significant task to undertake and one which a volunteer organisation such as ours lacks adequate resourcing and capacity to undertake. This is the type of work is the role of Government to undertake or fund to ensure correct data and information is included and appropriate decisions made. We would be concerned if a decision to reduce supervision was based on others anecdotal comments.

Consultation question 4

Should there be minimum information technology requirements, for example internet speed, computing capacity etc, for remote PET supervision to optimise quality patient outcomes?

There should be in any circumstance as this is about optimising quality patient outcomes. Given metropolitan practices regularly suffer from infrastructure failures and encounter difficulties with IT requirements, this would likely be even more so in regional and remote areas.

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These infrastructure costs in obtaining higher end reporting equipment are relatively minor in comparison to the imaging equipment and most sites would have state of the art systems at set up.

Consultation question 5

Are there any other safety and quality standards relating to PET supervision that should be considered?

State and Territory Environmental Protection Agency (EPA) regulations currently guide Nuclear Medicine and this should continue to be the case. Any practices currently undertaking PET should be complying with relevant state regulations, many of which have supervision requirements for the administration of unsealed radioisotopes.

Consultation question 6

What are the patient outcome implications of each of the options presented?

There is no evidence to support some of the benefits listed for patients in under section 2.7. The claim that it would reduce travel distances for patients and reduce pressure in state/territory-funded transport schemes is not supported by any other information in the discussion paper, and in addition there are a range of factors that are incorporated in such schemes so this claim is somewhat simplistic. Patients often co-ordinate their trips to see their specialists, get necessary imaging and attend to other aspects of the care not readily available in regional areas. A standalone PET facility in a remote area (which would become potentially possible if there are changes made to site requirements) would require a co-located for modality radiology practice otherwise any abnormality identified on the PET study requiring further imaging would still result in the patient travelling to the nearest comprehensive facility.

The balance between providing a convenient service with the best service is what needs to be achieved. A more readily accessible, second rate test is to no one's benefit.

Travel per se should not be a critical issue as long as patients can do so in a relevant timeframe and with acceptable level of cost. It is rare that a patient requires a PET scan of sufficient urgency that it would require being performed within 48 hours. A patient requiring an urgent study are typically inpatients.

Consultation question 7

What are the business implications of the each of the options presented?

The main focus on any proposal should be patient outcomes not business outcomes.

We note that there may be many large practices that will see workflow advantages and higher profitability by having a centralised system. They could concentrate the reporting and limit the number of NMS they need to employ. There is a risk here that they will focus on the higher profitability areas of Nuclear Medicine, specifically PET. This will make comprehensive nuclear medicine services less viable as the more profitable areas of their business are undermined. The whole range of general nuclear medicine procedures would then become less available as a result and this would impact other patients care and increase their travel times.

Consultation question 8

Are there any other issues that should be considered in relation to PET supervision?

We would simply reiterate that any change should be driven by the desire to improve patient outcomes without compromising patient safety and scan quality.

3 Comprehensive practice requirements for PET

3.1 Current requirements

Currently, PET must be located in a facility that has comprehensive cancer care services. The number of facilities that offer these services outside of major cities is limited¹⁰.

Part 3 of the DIST defines a comprehensive facility, below:

3.1 Dictionary

comprehensive facility means a facility where all of the following services are performed (whether or not other services are also performed):

- (a) PET;
- (b) computed tomography;
- (c) diagnostic ultrasound;
- (d) medical oncology;
- (e) radiation oncology;
- (f) surgical oncology;
- (g) X-ray.

The intention is that PET services should be provided in a comprehensive facility in a single location so that the patient has access to high quality, multidisciplinary services required for cancer diagnosis and treatment, the records of which can be available readily through a

¹⁰ *Smarter Cancer Care: Giving all Australians access to specialist diagnostic imaging services*, Qscan Group, pp5

single network. Historically, the definition included that buildings could be joined by a covered walkway as some hospitals did not have all of these services available in one building. However, that requirement was removed because covered walkways were not always available. Despite this amendment, the Department's policy position is still that these services are hospital or cancer centre-based, and not provided by separate entities within close geographical proximity and with no formal network of patient care.

3.2 Recent review

The Taskforce also recently reviewed PET arrangements. It had concerns that relaxing the comprehensive facility definition would result in low-quality PET services. An extract from the Taskforce's Final Report on Nuclear Medicine¹¹ is:

The Committee considered the current definition of a 'comprehensive facility' outlined in the DIST and whether this should be updated or removed.

- △ Section 2.4.2 of the DIST requires that Medicare-funded PET services are rendered in a 'comprehensive facility'. A comprehensive facility is defined in [the then] Clause 3 of the DIST (Part 3 – Dictionary) as follows:

A building or part of a building, or more than one building, where all of the following services are performed: PET, computed tomography, diagnostic ultrasound, medical oncology, radiation oncology, surgical oncology and x-ray.

The Committee agreed removal of the requirement may result in the proliferation of PET services without access to the multidisciplinary services complex cancer patients would require. The Committee discussed possible approaches to revising the definition. The Committee agreed on the imperative that the clinician reporting on the test possesses a thorough understanding of cancer care. However, it was acknowledged the definition may need to be refined to include a professional network of multidisciplinary health professionals rather than a physical facility as physical proximity to other services has become less relevant in modern practice. It was agreed patients need access to the full scope of multidisciplinary services. However, these would not necessarily be accessed on the same day and so may not need to be in close physical proximity to one another.

The Committee considered the following options:

- △ Remove the comprehensive facility definition entirely;
- △ Modify the current definition of a comprehensive facility for PET with the requirements to align with those for magnetic resonance imaging;
- △ Otherwise modify the definition of a comprehensive facility; or
- △ Retain existing requirements but review the situation again in three years.

The Committee acknowledged as there is currently good access to high-quality PET services in Australia, any changes to the standards should be undertaken with caution. The current requirements inhibit the proliferation of low-quality PET services without

¹¹ MBS Review Taskforce, *Final Report on the MBS Items for Nuclear Medicine 2018*, pp30
[https://www1.health.gov.au/internet/main/publishing.nsf/Content/BEB6C6D36DE56438CA258397000F4898/\\$File/Final%20Report%20on%20the%20MBS%20Items%20for%20Nuclear%20Medicine.pdf](https://www1.health.gov.au/internet/main/publishing.nsf/Content/BEB6C6D36DE56438CA258397000F4898/$File/Final%20Report%20on%20the%20MBS%20Items%20for%20Nuclear%20Medicine.pdf)

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appropriate cancer service provision. The Committee agreed that PET should be performed in a hospital setting with the involvement of an oncologist where appropriate.

At the conclusion of its deliberations, the Committee decided to retain the current definition of a 'comprehensive facility' outlined in the DIST.

The Committee agreed that this matter should be reviewed in three years.

In the context of consultation on potential changes to PET supervision, the Department considers it appropriate to bring forward the review of the definition of a comprehensive facility.

3.3 Discussion

The original intent of the comprehensive facility requirement was to ensure that Medicare-funded PET services were rendered at facilities equipped to respond to the results of the scan. The combination of required services was intended to ensure that patients would have access to a multidisciplinary team (MDT) for ongoing cancer treatment and management.

However, the way in which these services are provided has evolved, through the use of teleradiology/telehealth and through models of service delivery which can take place across multiple clinical campuses. There are facilities which may provide some components of diagnosis, monitoring and treatment at differing physical locations.

In its deliberations, the Diagnostic Imaging Clinical Committee (DICC) of the MBS Review Taskforce's review of the comprehensive facility requirement, acknowledged that services sharing a campus would not always have integrated patient management systems. However, a fundamental requirement would need to be that services were appropriately networked with the necessary cancer services and that PET services were provided as part of a MDT. An operational definition of MDT, including what appropriately networked means, would be necessary in this circumstance.

It was noted that PET is currently mainly cancer specific and that its role is frequently not in the early diagnosis of cancers but in the appropriate management of the malignancy after diagnosis. However, other diagnostic imaging modalities are also often used in the diagnosis and management of cancer, with many of those patients then requiring multidisciplinary care. It would seem therefore that MDTs still function as required without the need for the radiological services to be at the same location as the MDT services or the need for regulations to enforce this. However, it is still essential that imaging providers are involved in MDTs.

There was also discussion about the potential risk of proliferation of PET facilities should the comprehensive facility requirement be relaxed or removed. Given the costs associated with the equipment, the need to attract and maintain highly specialised staff, and the requirement to access radioisotopes, the risk of proliferation may not be realised. However, this cannot be quantified.

It is uncertain under current arrangements whether the demand for PET significantly outweighs supply, or whether the establishment of new facilities would redistribute existing

patients. It could be argued that redistributing patients away from existing facilities would create potential workforce issues and financial harm to those facilities. Business owners would make their own decisions about the viability of establishing a PET facility in a particular location.

3.4 Comprehensive facility options

3.4.1 No change

This option would mean that the current comprehensive facility definition would continue to apply as per the Taskforce recommendation.

Advantages

- will ensure that services are provided where there is access to multi-disciplinary care
- there would be no need for regulatory change

Disadvantages

- patients do not have access to Medicare rebates for PET services provided at facilities that do not meet the current definition and may need to travel to access these services

3.4.2 Modify the current definition of a comprehensive facility for PET with the requirements to align with those for magnetic resonance imaging

Currently, Medicare-funded magnetic resonance imaging (MRI) services are required to be carried out in a facility which meets the definition in the DIST of 'comprehensive practice'.

This differs from the definition of a 'comprehensive facility' in that a 'comprehensive practice' means a medical practice, or radiology department of a hospital, which provides x-ray, ultrasound, and CT services in addition to MRI. The definition applies to any facility, including hospitals that also provide services to non-admitted patients. The intention of this requirement is so that there are a range of services available to the radiologist, if an MRI is deemed not the most appropriate.

This enables MRI to be provided in the community or in a hospital-based location. For PET services, the current inclusion of oncological services (particularly surgical oncology services), in the list of required modalities under the definition of a comprehensive facility means that PET services need to be provided in a hospital environment. Given that PET services are usually used to assist with the management of the malignancy after diagnosis, urgent surgical intervention required immediately after the scan is unlikely to be common, and arranging this with a nearby hospital (not technically on site) would probably not be detrimental for the care of the patient.

Aligning the definition requirements for PET services with those for MRI services would provide flexibility for cancer centres to offer differing models of service delivery and at the same time ensure that all imaging modalities are available for use as needed, which is most likely already the case.

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As the aim is to ensure that PET/CT is part of a comprehensive facility that can provide all required alternative imaging options, MRI could be included in the list of modalities required to be on site.

The safeguard whereby the service must be requested by the patient's treating specialist would still be in place. The treating specialist, would, as they do now, be responsible for co-ordinating the patient's ongoing care and treatment, including MDT meetings as required.

Advantages

- PET could be provided in a community or hospital based location
- would still allow for multi-disciplinary care
- allows for more flexible delivery arrangements

Disadvantages

- patients would not have access to Medicare benefits for PET provided at facilities that do not meet the definition
- would require regulation change

3.4.3 Modify the definition of a comprehensive facility - MDT

This option would modify the definition of a comprehensive facility for PET services to expressly state that the practice must demonstrate involvement in a MDT (either physically or through teleradiology/telehealth). A possible definition could be:

Comprehensive facility means a medical practice, or imaging department of a hospital, which has direct access to and active engagement with multidisciplinary cancer care whether at the same location or elsewhere.

This differs from the current definition, which is simply a listing of diagnostic imaging and treatment modalities, without necessarily requiring interaction between each of the specialists involved in those modalities.

While this might ensure MDT involvement continues for PET services, it is still inconsistent with other imaging modalities used for oncology diagnosis or management, that do not need legislative requirement for MDT for it to occur. While it could be argued that MDT arrangements should apply to all imaging modalities, it would be an impractical imposition, as not all services imaging services are cancer related.

Advantages

- PET could be provided in a community or hospital based location
- would still allow for multi-disciplinary care
- allows for more flexible delivery arrangements

Disadvantages

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- patients would not have access to Medicare rebates for PET services provided at facilities that do not meet the definition
- monitoring compliance may be difficult
- would require regulation change

3.4.4 Remove the requirement for PET to be provided in a comprehensive facility

This option would align with other imaging modalities (except MRI) where there are no restrictions on where equipment can be located.

It would recognise the intent of the DIST to create the framework under which Medicare-funded diagnostic imaging services are rendered, rather than to influence business decisions about the actual model under which these services are delivered. The same kinds of requirements are not applied to other diagnostic imaging modalities in the DIST, even when used for cancer diagnosis or monitoring.

Medicare-funded PET services would still need to be requested by a specialist or consultant physician and the PET NMS providing the service must compile a report for the requesting practitioner.

As most PET scans are cancer related, it would be likely that the PET service would be requested in the context of a MDT environment, but this would not be legislated.

There remains the concern that some physicians not participating in MDTs may order scans. This concern would be true, regardless of whether the service was provided at a comprehensive facility under the current definition.

Advantages

- it would provide full flexibility as to where equipment is located
- it would remove current administrative burden on providers to provide a statutory declaration that the equipment is part of a comprehensive facility

Disadvantages

- there is a risk that the number of PET machines may proliferate
- there is no control of whether or not practices would be providing multi-disciplinary care, which may impact health outcomes for patients

3.5 Comprehensive facility consultation questions

Consultation question 9

What implications would supervising remotely as discussed under section 2 have on the options regarding the comprehensive facility definition?

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If the requirement for personal supervision was removed, the impetus for site requirements (ensuring that the PET is reported as part of a comprehensive oncology service) remains. The remote reporter of regional PET services would need to facilitate engagement with the local oncology service providers to arrange a method of attending their multidisciplinary meetings and provide evidence that they were otherwise engaged in multidisciplinary processes.

If the remote PET camera was situated in a regional hospital that provided on-site cancer services then the specific requirements (perhaps with the removal of the surgical component) of the comprehensive facility definition could still be largely met. However such a regional hospital may be of sufficient size to justify their own nuclear medicine facility regardless, and therefore not require remote supervision.

A PET camera as a standalone service or in conjunction with limited other radiology services clearly would not (and should not) fulfil the comprehensive facility definition.

Consultation question 10

Is it best practice for PET results to be reviewed in an MDT? Are there specific situations where MDT review is unnecessary?

While not every individual PET scan requires review at a local MDT, involvement of the reporting specialists in this process is an important mechanism for allowing the reporting specialist to keep abreast of the rapidly changing therapeutic environment from which these patients originate. Modern oncology is rapidly progressing with multiple new targeted therapies being available. Their impact on the timing of the PET scan, interpretation of the PET scan and the potential to create false positive or negative findings cannot be underestimated. The referring specialist, it could be argued, has a responsibility to providing the reporting specialist with all relevant information. However, this is not practical and it is incumbent upon the reporting specialist to remain abreast of the many changes that are occurring in this field. At a MDT, different cases will be presented, offering everyone the opportunity to understand how their component of patient management interacts and integrates with the care provided by their colleagues.

So while one could find many individual patients where the MDT review is unnecessary in that specific instance, there is no simple way to identify which patients will or won't benefit from the MDT interaction. Education of attendees of the MDT benefits the interpretation of all patients that are reported or otherwise managed by members of that MDT.

Obtaining the kind of information that assists with PET scan interpretation without attending an MDT is possible. It would require diligent maintenance of their continuing education, covering the gamut of specialist publications in the areas covered, frequent interaction with referring doctors to understand where the PET study sits in regards to the

patients ongoing management, as well as to get clear feedback on current management trends at a local level and potential impacts of these on the PET service.

Consultation question 11

Is it necessary for surgical oncology services to be available at the same location as PET?

It is considered that the surgical oncology services requirement can be safely removed as long as there are local surgical services for emergencies, and access to experienced surgical oncology services available.

Consultation question 12

What are risks of removing the comprehensive facility definition? Would the introduction of a comprehensive practice definition (per MRI) mitigate these risks?

Firstly, there is the risk that the current high level of quality PET reporting will be undermined as reporting shifts to centralised centres producing bulk output. PET remains a complex modality. One may find individual cases where the scan interpretation is simple but there are many cases, particularly in oncology, where placing the PET scan in context of the patient's current position in their cancer journey requires review of all their prior PET studies (which may be numerous) and an understanding of the therapy that was in play at the time of each of the studies. There is also comparison with contemporaneous other imaging, as well as clinical history, which would ensure that the most accurate report is issued. Hence, it can be seen that reporting one of these patients carefully can take a substantial period of time as well as focused concentration.

Secondly, as was noted on the recent task force review, removing this requirement may lead to a proliferation of PET camera installations. It is common practice at many sites to subsidise PET scanner installations by performing diagnostic CT studies in association with the PET study. The cost and radiation implications of both the hybrid PET/CT study itself as well as multiple ancillary CT studies should be considered. It is essential that patients who require a PET/CT study for appropriate management of their illness should have access available in a reasonable timeframe. It is anticipated that the use of PET/CT will steadily increase as newer radiopharmaceuticals are developed and indications and applications broaden. This will see PET scanner business case models become more robust and a natural diffusion of PET/CT into the community should ensue.

Thirdly, as per the MRI definition, standalone PET/CT cameras may make it more difficult to access ancillary imaging as required. It would be pointless for example for a patient to have a rural PET/CT that demonstrates the need for an MRI study that then would require the patient to travel to obtain. Hence, we would certainly suggest that PET/CT at the least be located within a comprehensive imaging facility that includes MRI as well as CT, ultrasound and other diagnostic imaging.

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We note the suggestion that telehealth could be used to maintain MDT exposure. This is certainly a potential alternative however monitoring compliance of this will be difficult, and not to the best interest of the patient's management, as outlined above.

Consultation question 13

What other options regarding rules for the location of PET equipment are there?

If one were to remove the current definitions regarding to oncology services, these would need to be replaced with a mechanism that allows and ensures the reporting specialist is maintaining their knowledge of the complexities of cancer management. This may require further specialist accreditation as well as specific or expanded maintenance of professional standards and site accreditation to ensure that oncology services while not on site are located within a reasonable distance. The additional cost of these would need to be covered through some mechanism.

PET remains largely an oncology-based modality and as such is best reported by specialists who are working within oncological centres and therefore have the best experience in managing and reporting the studies.

Consultation question 14

What are the patient outcome implications of each of the options presented?

Option 1 - No change:

As noted, no change will continue to provide quality PET/CT management outcomes. This does come at the cost of increased travel requirements for rural patients, but the rationale for this has been outlined.

Option 2 - Modify the definition to be similar to MRI:

This will certainly address the issue of ancillary imaging services being readily available.

Potentially this would allow PET/CT services to occur in an environment without ready access to oncological services and may undermine the MDT environment. The impact to patient from this have been outlined above and would include inaccurate scan interpretation, inaccurate scan performance and the potential for repeat or additional imaging to clarify findings resulting in unnecessary radiation exposure to the patient and increased healthcare costs. This would not address the issue of patients who subsequently need to travel for their oncological services. It would be rare for a patient to be referred for a PET scan that did not require follow up by the referring specialist and hence if both are not available in the same location, travel will not be avoided, unless a robust mechanism for telehealth provision of oncological services was also in place.

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Option 3 - Modify the definition of a comprehensive facility to specifically require involvement in an MDT:

In isolation, this would allow for the reporting nuclear medicine specialist to maintain their appropriate level of knowledge of PET and their role in patient management.

The combination of option 2 and option 3 with telehealth oncological services could be an acceptable solution.

Consultation question 15

What are the business implications of the each of the options presented?

We would preface this response by stating that the business implications are considered secondary to patient outcomes and safety. As a clinical organisation, business implications are not our primary focus.

Option 1 - No change:

The current status quo would persist. Expansion of services to some rural areas would be restrained. Current quality reporting would persist.

Option 2 - Comprehensive requirement as per MRI:

A limited increase in PET/CT services would become available.

Option 3 - modify the definition of a comprehensive facility to specifically require involvement in an MDT:

1. We believe that formal MDT affiliation with a tertiary centre is required.
2. We believe documented audited attendance with this MDT system should be a requirement for a NMS specialist to claim MBS rebates for PET in this scenario.

Consultation question 16

Are there any other issues that should be considered in relation to PET in a comprehensive facility?

Nothing that has not already been covered.

4 Nuclear medicine imaging services (non-PET)

4.1 Current requirements

The current requirements for the supervision of nuclear medicine imaging services other than PET are set out in paragraphs 2.4.1(b) and (c) of the DIST, restated as follows:

- (b) the service is performed:
 - (i) by a specialist or consultant physician whose name is included in a register, given to the Chief Executive Medicare by the JNMCAC, of participants in the Joint Nuclear Medicine Specialist Credentialing Program of the JNMCAC; or
 - (ii) by a person acting on behalf of a specialist or consultant physician mentioned in subparagraph (i); and
- (c) the final report of the service is compiled by the specialist or consultant physician who performed the preliminary examination of the patient and the estimation and administration of the dosage of radiopharmaceuticals.

The JNMCAC referred to in the above provisions is the Joint Nuclear Medicine Credentialing and Accreditation Committee of the Royal Australasian College of Physicians (RACP) and RANZCR.

There are no specific requirements around supervising the imaging procedure. This is because the rule explicitly requires the reporting credentialed nuclear medicine specialist (NMS) to undertake a preliminary examination and administer the radiopharmaceutical. Administration of the dose clearly cannot be done remotely.

From time-to-time, the Department receives enquiries from providers about whether they can supervise nuclear medicine imaging procedures (other than PET) off-site. Given that the radiopharmaceuticals needs to be administered in person by the NMS, there is no room for misinterpretation about personal supervision of that component of a non-PET nuclear medicine imaging service.

This provision differs from the PET supervision requirements in that the supervising and reporting practitioners for PET are not required to administer the radiopharmaceutical.

However, similar issues around the implications for the credentialed practitioner workforce arise as they do for PET supervision and there may be similar potential impacts on business arrangements for nuclear medicine imaging.

4.2 Options for non-PET requirements

4.2.1 No change

This option would mean that the current rules would continue to apply.

Advantages

- patients have access to a credentialed NMS provider on site
- no changes need to be made to existing regulations

Disadvantages

- would provide lesser flexibility in business models
- may not make the best use of workforce

4.2.2 Remove the requirement for a credentialed nuclear medicine specialist to be on site – non-metropolitan areas only

Under this option, a credentialed NMS would need to be on site in metropolitan areas only, but would not need to personally administer the radiopharmaceutical.

Advantages

- it would make services more available in regional areas, and it could reduce the travel distances for remote patients
- reduced pressure on state-funded transport schemes
- it would assist with workforce management of the PET NMS by allowing the supervision of multiple nuclear medicine imaging sites
- it would make best use of available technology

Disadvantages

- the off-site provider may not be available in real time due to connectivity problems, competing priorities involving patients from other sites for which the provider is also providing off-site supervision, or other circumstances
- it may assist may with workforce management of the PET NMS in metropolitan sites
- it would need regulation change

4.2.3 Remove the requirement for a credentialed nuclear medicine specialist to be on site

This option would still retain the need for a NMS to estimate the radiopharmaceutical dose and report on the service. However, a history could be obtained from patient remotely and the administration of the dose would be undertaken by the nuclear medicine imaging technologist. No physical examination would be possible.

Advantages

Advantages of the proposal include:

- it could make some nuclear medicine imaging services more available in regional areas, and it could reduce the travel distances for remote patients

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- may reduce pressure on state-funded transport schemes
- it would allow the supervision of multiple non-metropolitan PET sites by one NMS
- it would make better use of available technology
- it may lead to better outcomes for patients as an on site radiologist can advise on radiology procedures
- the costs to provide services are reduced, which potentially reduces patient out-of-pocket costs

Disadvantages

Disadvantages and risks of the remote supervision proposal include:

- a different medical practitioner would need to be on-site in case of an adverse reaction or other medical emergency
- the off-site provider may not be available in real time due to connectivity problems, competing priorities involving patients from other sites for which the provider is also providing off-site supervision, or other circumstances

4.3 Nuclear medicine imaging (non-PET) consultation questions

Consultation question 17

Is it essential for the credentialed NMS to estimate the radiation dose or can this be done by the nuclear medicine imaging technologist by protocol? What are the risks this would create?

The majority of studies are performed under protocol with the activity being prescribed within that protocol (dose is not the appropriate terminology as dose refers to the absorbed radiation dose to the patient not to the activity administered in conjunction with the active radiopharmaceutical).

However, there are occasions where the dose is varied based on specific patient factors (eg. patient body habitus, pain, pregnancy, etc). These are only apparent once the nuclear medicine specialist has spoken to and, on occasion, examined the patient. These specific interventions may be lost by a strict protocol driven process.

The estimation of the activity is only one component of the prescribing. The actual process involves ensuring that the appropriate test is being performed while utilising the best radiopharmaceutical and altering the administered activity to account for patient specific factors.

Consultation question 18

Is it necessary for the credentialed NMS to administer the dose, or could this be done by the nuclear medicine imaging technologist under protocol? If so, are there any safety concerns (if so, please elaborate).

Many of the standard radiopharmaceuticals can be administered by a credentialed nuclear medicine technologist under appropriate supervision. However not all can be done by the technologist. For example cardiac studies require an intervention which needs to be supervised by the medical specialist. Some agents need to be specifically injected into the correct site. In a situation where the nuclear medicine specialist was not available, these specific studies would not be able to be performed.

Nuclear medicine therapies require the specialist to be on-site and would not be able to be performed at site acting without a nuclear medicine specialist in attendance.

Other points to note: if the nuclear medicine specialist was not on-site or available in real time for some reason, the study would need to be deferred which would impact patient care, or the nuclear medicine technologist would be under pressure to proceed without adequate medical supervision, which is not best practice.

Consultation question 19

What are the benefits of having a credentialed NMS on site?

In addition to the matters discussed under question 18, having the nuclear medicine specialist on-site for at least a component of the procedure allow significant benefits. This primarily relates to the initial interaction with the patient where clinical history and physical examination can be undertaken. For anxious patients, discussion with the medical specialist is often reassuring and knowing that the specialist is on site to deal with any issues of comfort.

Less commonly, a finding that becomes apparent during imaging may require the nuclear medicine specialist to have further discussion or targeted examination of the patient to allow for accurate interpretation of an unsuspected or unusual finding. Clinical examination could not be mitigated using telehealth initiatives. These unexpected results and relevance to patient status would need to be relayed to the referring doctor in real time, and best patient management might ensue with the patient seeking emergent care for the unexpected result.

As previously noted, having the specialist on-site allows for regular feedback and interaction with the nuclear medicine technologist allowing them to ensure that their work practices remain optimal.

Consultation question 20

What are the risks of not having a credentialed NMS on site, e.g. who would be available for emergencies?

Medical emergencies related to nuclear radiopharmaceuticals are exceedingly rare. Medical risks would be limited to patients receiving therapy or myocardial perfusion studies. It would be impossible to perform these latter 2 procedures remotely. For more generic medical emergencies, any medical practitioner on-site would be sufficient.

Consultation question 21

Is there a shortage of credentialed NMS? If so, please quantify.

As per our comments in the PET section, the AANMS anecdotally believes there is currently not a shortage of NM NMS. We frequently are a conduit for advertising vacant positions, and we know of no vacant positions at this time. Indeed, we believe the opposite to be true-that there is a small number of NMS who are looking to increase their

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workload. Should changes be made to centralise provision of nuclear medicine services, there would be reduced opportunities in the workforce and a potential lack of employment for some nuclear medicine specialists.

Workforce analysis and quantification is a significant task to undertake and one which a volunteer organisation such as ours lacks adequate resourcing and capacity to undertake. This is the type of work is the role of Government to undertake or fund to ensure correct data and information is included and appropriate decisions made. We would be concerned if a decision to reduce supervision was based on others anecdotal comments.

Consultation question 22

Should there be minimum information technology requirements, for example internet speed, computing capacity etc, for remote supervision of nuclear medicine imaging (non-PET) procedures?

As for PET, there should be in any circumstance as this is about optimising quality patient outcomes. Given metropolitan practices regularly suffer from infrastructure failures and encounter difficulties with IT requirements, this would likely be even more so in regional and remote areas.

These infrastructure costs in obtaining higher end reporting equipment are relatively minor in comparison to the imaging equipment and most sites would have state of the art systems at set up.

Consultation question 23

Are there any other safety and quality standards relating to the supervision of nuclear medicine imaging (non-PET) procedures that should be considered, or other requirements that should be imposed?

No

Consultation question 24

What are the patient outcome implications of each of the options presented?

Option 1 – No change:

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We are unaware of any particular issues with access to nuclear medicine services at the moment and hence do not see there is a need for change since patient care is currently optimal.

Option 2 – Remove on-site requirements for rural areas:

This is again a balance between delivering best quality service and the inconvenience of travel. If there were robust telehealth options available, a hybrid model could be developed where the nuclear medicine specialist was available on a few days each week to allow performance of specific procedures and to administer therapies. The other days could be scheduled to contain less complex procedures and telehealth could be used to provide an overview of the patient's history. While there would be some loss of quality, this balance may well be a reasonable compromise in the rural setting.

Option 3 – Complete removal of on-site requirements:

There is no rationale to allow this in metropolitan areas where there is adequate access already available in situations that allow optimal practice. Anything else would lead to a reduction in quality nuclear medicine service provision and suboptimal patient care.

Consultation question 25

What are the business implications of each of the options presented?

The real issue here is what kind of diagnostic imaging service we wish to provide to the Australian public. Will it be the current system where a specialist is available to oversee and ensure best practice, quality outcomes and maximum safety? Or are we willing to compromise to allow centralised reporting which will maximise profits and could be used to make provision of rural services easier. We do not see rural access as being only solved by centralised reporting. As suggested above, there are a number of limited compromises that could be made to ensure that axis is maintained without major impact on quality.

Option 1 – no change:

Providers of nuclear medicine services need to have a NMS available for NM procedures to be performed. Businesses need to consider carefully opening new sites to ensure there is adequate workload to justify the cost of the equipment and the NMS resources required.

Option 2 – remove on-site requirements for rural areas:

As noted above in question 24, this would potentially improve regional access however whether the nuclear medicine specialists is the rate limiting step in provision of the services would need to be more carefully assessed. The business would need to investigate equipment costs, pharmaceutical costs and other staff costs to ensure the workload was sufficient. If there is sufficient workload, this will tie up the nuclear

medicine specialist for the day and hence there is no real reason why they could not be on-site.

Option 3 – complete removal of on-site requirements:

The lack of Medicare indexation over many years has reduced the profitability of medical imaging across the board. This has meant that there are strong drivers for minimising cost wherever possible. While cost minimisation is always desirable, this must be carefully managed to prevent impacts on quality service delivery. We would argue that complete removal of on-site requirements within metropolitan areas would lead to centralised reporting where the reporting specialist would be expected to report in excess of a reasonable day's work otherwise there would be no cost advantage. While this could perhaps be done safely to a degree, at some point, this would lead to reduction in report quality and subsequent additional healthcare costs due to misdiagnosis or additional investigations being required.

Consultation question 26

Are there any other issues that should be considered in relation to nuclear medicine (non-PET) supervision?

As a more general comment on the removal of on-site provisions, this is often put forward by corporate sites as it would allow them greater flexibility in rostering. We acknowledge that manpower is a significant cost in the provision of nuclear medicine services. Current nuclear medicine services cover a wide range of items, for many of which, the currently available rebate is insufficient to justify the provision of the service in isolation either due to the high cost of the radiopharmaceutical or the significant time commitment of both technical and medical staff to perform the procedure. Provision of the services is often underwritten by profits in other areas of the nuclear medicine service.

Purely profit driven motives would see these less common and less well remunerated services disappear leading to targeted nuclear medicine service provision and reduced access to studies for the small number of patients that require these specific procedures, resulting in suboptimal patient care.

Consultation question 27

Are there any other comments or observations that you wish to raise?

None to raise.

5 Consultation

The following organisations are being consulted.

- AANMS
- RANZCR
- Australian Radiation Protection and Nuclear Safety Agency (ARPANSA)
- Australian Society of Medical Imaging and Radiation Therapy (ASMIRT)
- Australian Diagnostic Imaging Association (ADIA)
- Qscan
- Healius
- Australian and New Zealand Society of Nuclear Medicine (ANZSNM)
- Rural Alliance in Nuclear Scintigraphy (RAINS)
- State and territory governments
- Consumers Health Forum (CHF)

6 Consolidated consultation questions

1. What are the benefits of having a PET NMS on site?
2. What are the risks or detrimental effects of not having a PET NMS on site?
3. Is there a shortage of PET NMS? If so, please quantify/provide rationale.
4. Should there be minimum information technology requirements, for example internet speed, computing capacity etc, for remote PET supervision to optimise quality patient outcomes?
5. Are there any other safety and quality standards relating to PET supervision that should be considered?
6. What are the patient outcome implications of each of the options presented?
7. What are the business implications of the each of the options presented?
8. Are there any other issues that should be considered in relation to PET supervision?
9. What implications would supervising remotely as discussed under section 2 have on the options regarding the comprehensive facility definition?
10. Is it best practice for PET results to be reviewed in an MDT? Are there specific situations where MDT review is unnecessary?
11. Is it necessary for surgical oncology services to be available at the same location as PET?
12. What are risks of removing the comprehensive facility definition? Would the introduction of a comprehensive practice definition (per MRI) mitigate these risks?
13. What other options regarding rules for the location of PET equipment are there?
14. What are the patient outcome implications of each of the options presented?
15. What are the business implications of the each of the options presented?
16. Are there any other issues that should be considered in relation to PET in a comprehensive facility?
17. Is it essential for the credentialed NMS to estimate the radiation dose or can this be done by the nuclear medicine imaging technologist by protocol? What are the risks this would create?
18. Is it necessary for the credentialed NMS to administer the dose, or could this be done by the nuclear medicine imaging technologist under protocol? If so, are there any safety concerns (if so, please elaborate).

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19. What are the benefits of having a credentialed NMS on site?
20. What are the risks of not having a credentialed NMS on site, e.g. who would be available for emergencies?
21. Is there a shortage of credentialed NMS? If so, please quantify.
22. Should there be minimum information technology requirements, for example internet speed, computing capacity etc, for remote supervision of nuclear medicine imaging (non-PET) procedures?
23. Are there any other safety and quality standards relating to the supervision of nuclear medicine imaging (non-PET) procedures that should be considered, or other requirements that should be imposed?
24. What are the patient outcome implications of each of the options presented?
25. What are the business implications of each of the options presented?
26. Are there any other issues that should be considered in relation to nuclear medicine (non-PET) supervision?
27. Are there any other comments or observations that you wish to raise?

7 Submissions

Submissions to this discussion should be emailed to Radiology@health.gov.au by 18 September 2020.

Please direct any enquiries to Radiology@health.gov.au and we will call you if required.

It is intended that submissions will be published on the Department's website. Please identify any commercially sensitive information in your submission so that the information can be redacted from your submission prior to publication.