Australasian Association of Nuclear Medicine Specialists

- For discussion without prejudice -

DISCUSSION PAPER: REVIEW OF SUPERVISION REQUIREMENTS FOR NUCLEAR MEDICINE SERVICES UNDER MEDICARE

August 2022

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 (No. 2) 2020* (DIST), made under the *Health Insurance Act 1973* (the Act). These rules are reviewed from time-to-time to ensure that they are contemporary and align with best practice.

In July 2020, the Department of Health (the department) developed and released the *Review of supervision of nuclear medicine imaging, including positron emission tomography (PET) services under Medicare Discussion Paper* (the discussion paper). The discussion paper aimed to obtain stakeholder views about current and alternative arrangements on several topics, including whether the rules which apply to supervision of nuclear medicine services should be amended.

Nineteen submissions were received in response to the discussion paper from state and territory health departments, peak bodies, private providers, and individuals.

In addition, during the COVID-19 pandemic the requirements for personal supervision have been relaxed to allow supervision to take place remotely where required. This has enabled medical practitioners to comply with social distancing requirements and has now been in place since mid-2020. It is therefore an opportune time to review personal supervision requirements for nuclear medicine services.

This paper addresses whether the supervision requirements for PET and non-PET services should be amended. It sets out the department's preliminary proposed approach and is intended to support the department in seeking further feedback from stakeholders.

Questions to guide the provision of feedback are provided on page 5 and a template for responses is provided on page 6.

PET services

Current supervision requirements for PET services

The current rules which apply to the supervision of Medicare funded PET services are set out in clause 2.4.3 of the DIST, as below:

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)

Note: Clause 2.4.2 referred to in this provision states that PET services can only be claimed where certain requirements are met. It references clause 2.4.3 among other clauses.

The term 'personal supervision' is not defined in the DIST. Historically, 'personal supervision' has been interpreted to mean that the physical presence of a specialist at some time during each component of the service is required.

Potential future approach

Based on feedback received, the department has developed a potential draft change to the supervision requirements for PET and non-PET services for stakeholder consideration. It attempts to balance the need to maintain quality and safety with accessibility for patients.

The proposed approach would encompass the amendment of clause 2.4.3 for supervision of PET services to allow for remote supervision to take place in some circumstances, as follows:

DRAFT CHANGE FOR CONSIDERATION

1. For the purposes of clause 2.4.2, the service must be performed by or under the supervision of a PET credentialled specialist other than the requesting practitioner where:
    a) the PET credentialled specialist responsible for the service performs or personally supervises the service on site; and
    b) the service is reported by a PET credentialled specialist.
2. If paragraph (1) cannot be complied with:
    a) in an emergency; or
    b) in a location in a Modified Monash 3 – 7 area.
3. Where a service is performed under the conditions stated in paragraph (2):
    a) The service is performed under the remote supervision of the PET credentialled specialist responsible for the conduct and report of the examination; and
    b) the PET credentialled specialist supervises the service in real time and from a location within Australia; and
    c) A medical practitioner is available on site to attend in emergency situations; and
    d) the service is reported by a PET credentialled specialist.

Note: 'PET credentialled specialist' would be defined to include both the 'credentialled specialist' currently defined in the DIST and medical practitioners who meet the requirements in the current paragraph 2.4.3(1)(b).

Rationale

The proposed approach seeks to provide additional flexibility for the provision of remote supervision while ensuring that controls continue to be in place to support the delivery of safe and quality services.

It enables the provision of remote supervision in any areas where there is an emergency, and in Modified Monash (MM) 3 – 7 areas. The requirements set out in proposed paragraph 2.4.3(3) seek to ensure that remote supervision is performed by the reporting specialist and in real time. This is to ensure that the specialist is available to monitor the examination and provide advice to the patient and nuclear medicine technologist in a timely fashion to ensure the quality of the service. It also seeks to ensure that a qualified medical practitioner is available to attend in emergency situations.

The Modified Monash Model (MMM) is proposed for use in determining whether a service can provide services under remote supervision. The MMM classifies areas by considering both rurality and population. Further information about the MMM can be found on the department's website: https://www.health.gov.au/resources/publications/modified-monash-model-fact-sheet.

In the draft change for consideration, the department has proposed enabling remote supervision to be performed in MM 3 – 7 areas. Figure 1 below shows the distribution of population and PET machines by MM area, while Figure 2 provides an indication of extent to which patients who reside in one MM area travel to another MM area in order to access a PET service. Note that there are currently no PET machines in MM 4 – 7 locations.

Figure 1: PET providers and population size by MM area.

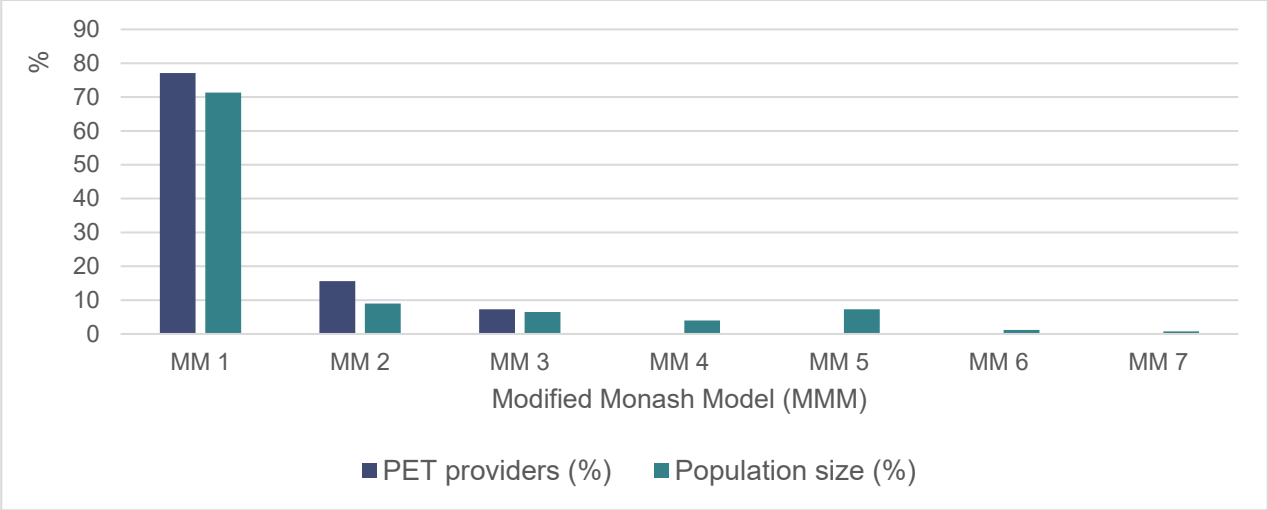

Figure 2: PET services per 10,000 residents, by patient and provider location (2020-21)

Figure 1 shows that the location of PET providers aligns to some extent with the distribution of patients by MM areas. Figure 2 shows that patients in MM areas 3-7 are more likely to travel to MM1 areas to receive a PET service than any other location, including the MM area the patient lives in. It also shows that a significant number of patients will travel to MM2 areas for PET services.

The department is seeking advice from professional bodies regarding whether remote supervision should be available in MM 2 areas.

The department recognises that changes to the supervision requirements for PET services will have flow on effects for the nuclear medicine sector. Advice is sought on the impacts of this proposed change. See the questions provided on page 5.

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Non-PET services

Current supervision requirements for non-PET services

The requirements for the supervision of nuclear medicine imaging services other than PET are set out in clause 2.4.1 of the DIST, as follows:

2.4.1 Nuclear scanning services (other than PET nuclear scanning services) and adjunctive services

An item in Subgroup 1 or 3 of Group I4 applies only if:

a) the performance of the service does not involve the use of positron-emission radio-isotopes or a PET scanner; and

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 Credentialling 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 department recognises that in many cases the estimation and administration of the radiopharmaceutical can be performed by a nuclear medicine technician supported by protocols, meaning that subclause 2.4.1(c) is not always reflective of current clinical practice.

Potential future approach

The department proposes minor changes to increase clarity and align with clinical practice:

DRAFT CHANGE FOR CONSIDERATION

An item in Subgroup 1 or 3 of Group I4 applies only if:

1. the performance of the service does not involve the use of positron-emission radio-isotopes or a PET scanner; and
2. the service is performed by or under the supervision of a nuclear medicine credentialled specialist; and
3. the final report of the service is compiled by a nuclear medicine credentialled specialist.

Note: 'Nuclear medicine credentialled specialist' would be defined as 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.

Rationale

The proposed change seeks to align the requirements with current clinical practice by recognising that the nuclear medicine credentialled specialist does not always perform the estimation and administration of the radiopharmaceutical.

The proposed change also removes the requirement for the final report of the service to be compiled by the specialist or consultant physician who performed the service and replaces it with a requirement that the service is reported by a nuclear medicine credentialled specialist. Feedback is sought on the proposed change. See the questions provided on page 5.

No other changes are proposed as feedback from stakeholders indicates that this supervision requirement remains broadly appropriate.

Comprehensive facility requirements

The original discussion paper of 2020 also sought feedback on whether the comprehensive facility requirements for PET services should be amended.

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The recent introduction of an item for PET for the diagnosis of Alzheimer's Disease renders the requirements for PET facilities to be collocated with medical, radiation and surgical oncology less relevant for some items. The department recognises that this means the current definition of comprehensive facility will require review.

It is proposed that any changes to supervision requirements are implemented and monitored for 12 months before changes to comprehensive facility requirements are considered. This will enable the impact of changes to supervision requirements and subsequent potential implications for comprehensive facility requirements to be evaluated before action is taken.

Questions for discussion

The department is seeking feedback to understand whether this change would be supported and what the potential impacts may be.

In particular, feedback is sought on the following questions:

1. In your view, what should the requirements for the supervision of PET and non-PET services under Medicare be?
2. Do you support the proposed approach for the supervision requirements for PET and non-PET services?
3. Are there any amendments you would suggest? If so, why?
4. Should MM 2 areas be included in remote supervision arrangements for PET services? If so, why?
5. Should the reporting of PET and non-PET services be performed by the specialist or consultant physician who performed or supervised the service?
6. Are the proposed changes to supervision arrangements for PET and non-PET services likely to impact the number of service providers? If so, how?
7. Are the proposed changes to supervision arrangements for PET and non-PET services likely to impact service volumes? If so, how?
8. Are there any other comments or observations that you wish to provide?

How to provide feedback

Submissions should be emailed to Radiology@health.gov.au by **Friday, 29 April 2022.**

A template is provided overleaf to aid the provision of feedback.

Please direct any enquiries regarding this paper to Radiology@health.gov.au.

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DISCUSSION PAPER: REVIEW OF SUPERVISION REQUIREMENTS FOR NUCLEAR MEDICINE SERVICES UNDER MEDICARE

AANMS Response

August 2022

Organisation	AANMS
Date of response	19 August 2022

Discussion questions
1. In your view, what should the requirements for the supervision of PET and non-PET services under Medicare be?

The AANMS believes that the best practice remains to have a nuclear medicine specialist in attendance for all PET and non-PET nuclear medicine services.

Background:

The current requirements for provision of nuclear medicine services have been in place for many years and are well understood by the imaging community. There have been extensive changes since the implementation of these regulations in terms of technology, as well as patient expectations. Consideration of the ongoing usefulness of these requirements is appropriate, however, any suggested change should be demonstrated to be clearly beneficial to the patient and imaging communities over the status quo.

Perhaps the best approach is to consider why these provisions are in place and what goals they were set to achieve.

The overriding goal was the ***provision of safe and high quality nuclear medicine services*** to the Australian population. The approach aimed to balance equitable access to these technologies with ensuring that studies were performed at sites which had optimal equipment and appropriately qualified staff. The staff must be capable of performing detailed assessment of the appropriateness of the indication (in particular consider the appropriateness of the administration of ionising radiation, as per the Medical Exposure Code requirements), correlating any relevant clinical history with the scan findings, and producing a report that encapsulates not only the imaging findings but also provides ***specialist*** level advice as to the patient's clinical management. We strongly consider that any changes made to the requirements should continue to facilitate this goal being readily achieved by all sites performing nuclear medicine services.

It is understandable that parallels may be drawn between other imaging modalities and Nuclear Medicine services to clarify why Nuclear Medicine services require a higher level of personal supervision than another imaging modality (eg. CT). There is no doubt that every modality benefits to some degree from greater interaction with the supervising specialist however the relative cost benefit needs to be considered. Predominately anatomic imaging modalities (like CT) are less affected by patient-specific factors, such as what the patient had for breakfast, whether they are diabetic or what medications they are taking, which affects the physiological aspects of Nuclear Medicine imaging. The quality of functional studies, as are the norm for Nuclear Medicine services, as well as accuracy of interpretation of findings is profoundly impacted by many variables. The Nuclear Medicine Specialist must not only be aware of these but needs to actively intervene on occasion to modify these variables or the study parameters prior to radioactive tracer administration to patients, to ensure that the most accurate test result is provided.

PET/CT in particular benefits from a close working relationship between referring clinician and Nuclear Medicine Specialist (NMS). A comprehensive understanding of where the patient is in their disease journey, the ease of communication with referrers to

clarify issues and alert to concerns, and involvement in local multidisciplinary meetings all greatly enhance the quality of the report allowing optimal integration of this information with the patients overall current status.

General benefits of personal supervision for Nuclear Medicine and PET:

Benefits.

- ease of timely clinical review where required
- ease of intervention for scan/protocol optimisation, side-effects' management or other complications
- immediate feedback to staff as to issues with quality or potential improvements in technique as images are brought for review
- minimisation of the risk of inappropriate administration of ionising radiation and minimisation of the need for additional administration of ionising radiation on a separate occasion for the same indication optimisation of scan quality by modification of administered radiopharmaceutical dose in difficult cases,
- optimisation of radiation protection and compliance with Medical Exposure Code for children, pregnant people and members of the public
- higher likelihood of close partnerships with referrers and other members of the multidisciplinary team
- higher likelihood of commitment to local community

Risks of no supervision:

- The outcome of an incorrect study or an incomplete study involving ionising radiation is less than ideal and may have several impacts, including patient management and care, as well as increased costs due to the need for a repeat or additional studies.
- Similarly, insufficient clinical assessment due to remote supervision may result in incorrect interpretation with potential errors and/or unnecessary additional investigations, increasing radiation doses for patients and adding to health care cost.
- Pressure from managing multiple sites may lead to a reduction in (or absence of) time spent with patients and overall reduction in time spent on each report.
- It places significant responsibility on the nuclear medicine technologists (NMTs) who are not trained in the clinical aspects of the disease.
- Regular interaction between the NMT and NMS is ideal for best practice. NMTs working continuously in isolation may get less feedback and day to day quality control may deteriorate without timely feedback and intervention. Protocol drift and lack of implementation of updated practices are also risks.

PET Supervision

At the time of the introduction of PET services in Australia, there were limited facilities and limited expertise in providing the services. Concentrating the services at a reduced number of sites was beneficial in rapidly developing sites of excellence who could then disseminate these skills through teaching and other educational activities more broadly in the nuclear medicine community. It would be fair to say that this has been achieved.

PET scanning is a specialist-referred service and hence usually involves the assessment and management of patients with potentially complex disorders or those that will require long-term oversight of their treatment regime and disease process. Up till now, and still true for the majority, these referrals have related to cancer and cancer related illnesses. PET involvement in these services typically relates to initial staging and treatment monitoring.

Initial staging remains the simplest of these areas in that the patient typically is treatment-naive and therefore scan interpretation is relatively straightforward unless complex prior medical history is present. Patients referred for staging scans typically have only limited prior imaging to review. Clinical assessment at the time of the PET scan is focused on evaluation for unexpected sites of symptoms (which may lead to identifying unexpected sites of disease) or intercurrent illnesses that may affect scan interpretation.

Monitoring of treatment is a large component of current PET services. This is where the situation becomes more complex by an order of magnitude. To report the study to the highest quality, one needs to have:

- in-depth knowledge of the therapy being provided so as to have a clear understanding of expected and unexpected findings with this particular treatment,
- access to prior PET imaging,

- access to ancillary imaging and their reports,
- access to non-imaging test results and clinical information (e.g. blood tests, operative reports)
- and last, but not least, a good relationship with the referring specialists to allow both easy access to relevant but often unprovided clinical information as well as prompt feedback of relevant or urgent findings. This is facilitated by regular involvement in appropriate multidisciplinary meetings (MDM) though clearly, no one specialist can attend every MDM across the entire gamut of oncological services. Regular involvement in any MDM provides good experience and understanding of the role of PET imaging even if details may differ from say lung cancer therapy to colorectal cancers. If the reporting specialist is present at the same campus on a regular basis, relationships with the common referrers will be developed and the experience from one multidisciplinary meeting can be then applied more broadly to PET reporting.

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 inferior to directly speaking to the patient in terms of clinical result but clearly saves time, and a cost/benefit balance needs to be reached. Telehealth measures could be used to try and bridge this gap. We have reservations whether they would be employed in all cases and whether they would provide a similar benefit compared to a real-life interaction. Telehealth certainly provides an additional option, however, if there is no additional rebate for performing telehealth interactions, we have reservations about whether investment of resources money into required infrastructure and, more critically, investment of the time of centrally located reporting specialist would be perceived as a cost benefit. This would also preclude any physical examination of the patient, which, on rare occasion, can be important aspect of providing optimal PET service.

Does the nuclear medicine specialist need to see every patient?
Through the use of both patient and technologist worksheets, standard key information can be obtained without direct clinician involvement. These should be encouraged as both time saving and a solid method to routinely obtained and record relevant data. While there is likely an incremental benefit in seeing every patient, the cost benefit of this would be limited and hence we see no reason to mandate this. We would recommend that the specialist has reviewed the referral and the worksheets prior to patient injection, particular for patients not having initial staging allowing them to confirm when a face to face interaction is clinically necessary

Does the nuclear medicine specialist need to be on-site at some point during the patients imaging? While it may be that for many patients the worksheets will be sufficient, what would be the process if this system breaks down or if the technologist feels clinician interaction is required. If the nuclear medicine specialist is on-site, clearly it is straightforward for them to attend patients who require clinical review. If they are not on-site, then the options would be:

- some form of telehealth interaction,
- review by a non-nuclear medicine specialist who is on-site or
- it may fall ultimately to the nuclear medicine technologist to make the clinical decision as best they can.

These workarounds are considered to be suboptimal.

Proponents for reduced supervision maintain that the option of telehealth interaction would be the mainstay and equivalent to direct contact, however, the AANMS considers it likely that when at a different site, the responsible NMS will have competing clinical demands that may prevent immediate response to requests from subsidiary sites performing unsupervised imaging. Review by a non-NMS clinician will be sufficient for general medical issues but not specialty-specific issues, and this underlines why we have specialists in fields rather than generalists. Finally, defaulting to the NMTs to make clinical and specialty decisions is beyond the scope of their training and registration and may create medicolegal issues if there are suboptimal outcomes. In addition, the role of supervising radiological practitioner cannot be legally conferred on a NMT, as per the relevant radiation protection laws.

Specific Issues with PET Imaging:

- Diabetic patients may require insulin to get optimal scan results, and this requires an on-site clinician with understanding of how insulin will affect the timing and interpretation of the PET study, as well as the ability to clinically manage the risks associated with insulin administration
- Claustrophobia requiring sedative administration
- Paediatric imaging requiring specialised positioning or administration of sedation
- Patients with difficulty lying in standard positions
- Patients who don't fit standard protocols
- Unexpected findings requiring urgent management or communication with referrers (prior to patient leaving the premises)

- Unexpected illness -usually related to the primary diagnosis

Having a Nuclear Medicine Specialist (NMS) on site allows for the most effective intervention in these occurrences. If there was an acute issue and the nuclear medicine specialist was unable to be contacted due to being offsite, then the performance of the study could be compromised and patient safety and outcomes may be impaired. A non NMS could certainly provide cover medically but not for NMS specific issues.

What we don't want to see:
We are certainly against a model where patients scans are reported remotely by specialists who are interstate or even in a different country, with minimal, if any, interaction with the local site. This model would encourage, particularly as these are often volume-based models, reporting at the basic level where lesions will be listed albeit with accuracy, but where the relevance of these in the patient's cancer journey is ignored. It is fair to say that this already occurs even with the current provisions in place, however, we would have an expectation that this would become more common where the reporting specialist has no local MDM involvement, no local connection and no local oversight of the PET procedure. We already see examples of this at MDMs where external studies reported in the absence of full clinical background require in depth review to place the findings into appropriate clinical context. This is a labour intensive process and impacts the local health service due to the time and resources required. We are concerned that adopting a non-supervision model would exacerbate this problem several-fold.

Is any remote supervision acceptable?
There are some practices which for commercial reasons, open subsidiary PET sites within a short distance of their main facility. These may be acceptable if:

- Their specialists rotate on a regular basis through all sites
- They have a good understanding of the capabilities of each site.
- As they are regionally co-located, they support the same referring specialists
- There is an experienced imaging specialist on site (Non NMS)

These specialists can fulfil most the aims of personal supervision. Hence there may be an argument that PET sites that are co-located within, say for arguments sake, 5 km of each other and where the reporting nuclear medicine specialists fulfil the above criteria could be considered a single site for the purposes of supervision. However, we are concerned that this would set a precedent which would lead to further dilution of standards.

Another concern with facilitating a centralised model is that they will undercut services provided by local groups leading to a loss of local specialists in nuclear medicine and hence lack of local availability. We are concerned that remotely operated sites will focus on providing services with the best remuneration. Focusing on these studies would shift the burden of the less profitable tests on to local practices who maintain a commitment to providing comprehensive service to their local community. This combined with loss of the more lucrative services, may make them financially unviable leading to an overall reduction in the range of services and local closures. These specialists currently contribute to MDMs, their loss would be to the detriment of the overall quality of delivered services.

What about rural patients?
As part of the proposal from the Department of Health we note the proposal to allow an exemption for supervision to modified Monash 3 to 7 areas and we are *generally* supportive of this. We do note that some large towns fall into modified Monash 3, for example Lismore and Dubbo. These sized towns could justify a "fly in fly out" (FIFO) service. It would be our preference to see a mechanism introduced that allowed **and** encouraged "FIFO" services to be performed in larger regional centres as needed, thereby maintaining quality over a blanket exemption in these regions. This would require a regional item number covering "personal supervision in a MM3-7 site" that reflected the higher cost of providing personal supervision. Sites providing the higher service level could then bill this additional fee to offset the FIFO costs. It is unfair to insist on a higher cost model without adequate recompense.

We remain uncomfortable with the concept of allowing less optimal performance of nuclear medicine imaging to minimise patient inconvenience. Many of these patients (and this in part was the rationale behind the PET comprehensive facility structure) will need to come to a larger centre to see and receive their oncology therapy anyway, and they can (and do) arrange their imaging to be performed at the same time minimising their inconvenience.

Allowing unsupervised PET services at small sites would have both commercial and logistic difficulties as economies of scale would be difficult to achieve.

- For discussion without prejudice -

Personal supervision for general Nuclear Medicine (non-PET)

Most of the points made for PET are equally applicable to general nuclear medicine however there is a greater proportion of general practice referral in which the complexity of the case is often less. For example, scans such as gated heart pool scans are relatively standard and rarely require intervention. although the occasional patient with a difficult rhythm may benefit from specialist intervention. If the site is providing the full range of nuclear medicine tests such as diuretic renography, therapies such as radioactive iodine or cardiac perfusion imaging then clearly a nuclear medicine specialist must be in attendance. Bone scans range from extraordinarily simple e.g., query metatarsal fracture to complex assessments of pain post-multiple surgical interventions, which requires detailed understanding of complex medical history including the timing and indication for each of the surgical procedures (this is rarely documented sufficiently on the request form).

Assessing each patient for test appropriateness and justification of ionising radiation administration by a responsible nuclear medicine practitioner is a legal requirement, as per the Medical Exposure Radiation Code. Being available to modifying the test in the event of an unexpected finding or issue clearly allows for the best possible result for the patient. Adjusting, on the fly, to unexpected issues are all facilitated by an on-site nuclear medicine specialist.

2. Do you support the proposed approach for the supervision requirements for PET and non-PET services?

Overall yes, but **see 1 and 3 for detail.**

3. Are there any amendments you would suggest? If so, why?

Suggestions for PET.

1. The addition of the exemption for an emergency is understandable and sensible however the definition of an emergency should be tightly defined. For example, there may be some who would consider the doctor being on leave and inability to obtain locum cover “an emergency” and therefore feel that the use of this exemption was reasonable. We completely support the concept that if a doctor who had planned to be available on the day is unable to attend due to unforeseen circumstances such as motor vehicle accident or sudden illness, this should not be allowed to impact on patients who have scans booked and for which delaying the scan could impact on their treatment. However, these instances should be infrequent and hence there should be a mechanism in place if such an exemption is given to ensure that it is used as intended. This could be potentially by limiting the numbers of days per year that you can claim an emergency or by simply giving the clarification of what constitutes an acceptable emergency. We would suggest that an annual limit of 5 days per site be imposed.
2. Ideally, the supervising NMS should report the PET though we acknowledge this is not always practical. A reasonable criteria could be agreed on for what percentage of PET studies should be reported by the supervising NMS to strike the balance between best practice and reasonable flexibility.

See bolded changes below.

DRAFT CHANGE FOR CONSIDERATION

4. For the purposes of clause 2.4.2, the service must be performed by or under the supervision of a PET credentialled specialist other than the requesting practitioner where:
   c) the PET credentialled specialist responsible for the service performs or personally supervises the service on site; and
   d) the service is reported by the supervising PET credentialled specialist in ***over 80% of services per annum***
5. If paragraph (1) cannot be complied with:
   c) in an unforeseeable emergency ***(such as motor vehicle accident or sudden illness) limited to 5 days/year/site;*** or
   d) in a location in a Modified Monash 3 – 7 area ***(See suggestions to support FIFO model).***
6. Where a service is performed under the conditions stated in paragraph (2):

e) The service is performed under the remote supervision of the PET credentialled specialist responsible for the conduct and report of the examination; and

f) the PET credentialled specialist supervises the service in real time and from a location within **the same state (preferred) or Australia (alternative option)**; and

g) A medical practitioner is available on site to attend in emergency situations; and

h) the service is reported by a PET credentialled specialist.

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For non-PET services we would suggest the following wording:

2.4.1 ***Nuclear scanning services (other than PET nuclear scanning services) and adjunctive services***

An item in Subgroup 1 or 3 of Group I4 applies only if:

1. the performance of the service does not involve the use of positron-emission radio-isotopes or a PET scanner; and
2. the service is performed by or under the personal supervision of a nuclear medicine credentialled specialist; and
3. the final report of the service is compiled by the nuclear medicine credentialled specialist ***who clinically assessed the patient on the day of the examination in over 80% of services per annum except in the setting of studies that span several days.***

4. Should MM 2 areas be included in remote supervision arrangements for PET services? If so, why?

As we noted above larger MM 2 centres should be able to utilise a FIFO model. The arguments made above for large towns is even more applicable to MM2.

We remain uncomfortable with the concept of allowing less optimal performance of nuclear medicine imaging in an attempt to minimise patient inconvenience, when patient safety is paramount. Many of these patients (and this in part was the rationale behind the PET comprehensive facility structure) will need to come to a larger centre to see and receive their oncology therapy anyway and can arrange their imaging to be performed at the same time minimising their inconvenience.

Patients in MM2 locations are more likely to seek services in MM2 communities. The reports own figures demonstrate that MM2 is well serviced for these studies with the majority of MM2 patients having PETs in an MM2 location (see fig 2 chart). By allowing remote supervision we undermine established local practices currently providing these services and who are more likely to be involved in their local communities, hospitals and MDMs.

5. Should the reporting of PET and non-PET services be performed by the specialist or consultant physician who performed or supervised the service?

Overall yes. The clinical impression obtained when talking to a patient can make the difference between overinterpreting uptake due to treatment side-effects versus underreporting a clinically significant finding. It is true that in nuclear medicine there are some studies that take more than one day, Gallium-67 scanning and large bowel transit scanning for example. It is not practical to try and ensure that the doctor who saw the patient is available at the end of imaging to do the report in these limited cases and we accept that some flexibility is desirable. See suggested amendments above.

6. Are the proposed changes to supervision arrangements for PET and non-PET services likely to impact the number of service providers? If so, how?

Our comments on the proposed changes are relatively modest and are unlikely to cause major impact in service providers, if adopted.

7. Are the proposed changes to supervision arrangements for PET and non-PET services likely to impact service volumes? If so, how?
Any change that allows expansion of services by allowing centres to be set up without a nuclear medicine specialist being available on site may lead to increased volumes as increased availability may capture a small number of patients who currently defer to more locally available modalities. We do not believe that there is a significant untapped demand for nuclear medicine services and that the growth in PET services simply reflects increasing approved indications and expansion of the available PET radiopharmaceutical armamentarium leading to its use in a wide range of conditions. This remains under MSAC control.
8. Are there any other comments or observations that you wish to provide?
When considering any change to an existing process, it is important to identify exactly what we are hoping to achieve with the changes. We do not perceive any significant failings of the current system acknowledging that it would be ideal to allow people to bill in good faith during rare emergency situations and for multi-day services where it is difficult to comply with the requirements of the doctor on Day 1 performing the report at the completion of the study. Regional access is always difficult issue and, as noted, we are happy to investigate mechanisms of improving access while maintaining equivalent quality of service. Care should be taken not to prioritise the commercial benefits of change and relaxation of requirements over the provision of quality patient care services. Otherwise we would simply note that if "*it ain't broken, don't fix it".* Under **Comprehensive facility requirements**, it is suggested that these proposals regarding supervision be allowed 12 months to "bed down" before considering what changes to facility requirements are appropriate. The Comprehensive facility requirements are also a mechanism to promote best practice and therefore overlap in intent with personal supervision. Hence we concur in delaying this decision as the changes finally implemented to personal supervision for PET will impact our recommendations for facility requirements. Many of the existing requirements may be no longer required if the goal of best practice is achieved under the PET supervision requirements. As noted in our earlier discussion paper, the rationale behind the comprehensive facility definition was to ensure that specialty PET reporting was maintained with the reporter being a regular attendee of MDMs, bringing with them the experience required to understand how the PET study fits into the staging, restaging and therapy monitoring of the patient, as well is how the various treatments, particularly novel therapies such as immunotherapy and radionuclide therapies, can affect the appearance and interpretation of the study. While not every PET needs to be individually reviewed at an MDT, active MDT involvement allows one to be aware of potential issues and makes it much more likely that the reporting specialist is abreast of current issues. We have previously acknowledged that surgical oncology services are not an integral on-site requirement. Having no site requirements would then increase the risk that the current high quality of PET reporting would be undermined, however, having **strong and enforceable** on-site requirements for the reporting nuclear medicine specialist would at least prevent centralised bunkers. One of the major demands of quality PET reporting is access to and correlation with other imaging and investigation findings. This can be more challenging for a standalone practice than a comprehensive practice where other modalities may be readily available. Most comprehensive sites have mechanisms in place for accessing correlative imaging and other results. As was noted on the recent task force review, removing site requirements may lead to a proliferation of PET camera installations. It is a practice at many sites to subsidise PET scanner installations by performing diagnostic CT studies eligible for an MBS rebate in association with the PET study. Not all of these studies are clinically required. The cost and medical radiation exposure implications of multiple ancillary CT studies should be considered.