a healthier world through sonographer expertise

Thursday, 21 July 2022

Adjunct Professor Debora Picone AO
Chief Executive Officer
Australian Commission on Safety and Quality in Health Care
GPO Box 5480
Sydney NSW 2001

Via email: diagnosticimaging@safetyandquality.gov.au

Dear Adjunct Professor Picone,

RE: Review of the Diagnostic Imaging Accreditation Scheme standards and model of accreditation

Thank you for the opportunity to provide feedback as part of the Australian Commission on Safety and Quality in Health Care's review of the Diagnostic Imaging Accreditation Scheme (DIAS) standards and accreditation model for diagnostic imaging.

The Australasian Sonographers Association (ASA) is the professional organisation for Australasian sonographers who are the experts in ultrasound. With over 7,000 members, and representing more than 75% of Australasia's sonographers, the ASA's purpose is to foster a sonography profession that delivers high quality ultrasound with a vision to create a healthier world through sonographer expertise.

The ASA, through its Sonographer Policy and Advisory Committee, has considered the consultation questions. We recognise the importance of this review and support the Commission's work to minimise the risk of harm to patients and to improve patient care, by ensuring the DIAS framework is robust and focused on safety and quality improvement.

We agree that the current diagnostic imaging accreditation scheme does not provide a comprehensive safety and quality framework for patients or practices. It does not include a robust clinical governance framework, has limited involvement of consumers, is not risk-based, uses language that reinforces compliance rather than safety and quality improvement, focuses on the on a desktop audit with the preparation of documents rather than in practice requirements, and in some areas duplicates other regulatory or accreditation requirements.

Having considered the current DIAS standards and model of accreditation, the ASA believes there are a number of areas where they could be improved. This includes:

- **Improving safety and quality for patients through** enhanced monitoring of the quality of ultrasound examinations, ensuring policies are in place to support patient-centred communication, and the onsite auditing of patient consent.
- **Recognising the potential for unwarranted variation** in clinical practice due to the operator-dependent nature of ultrasound examinations.
- **Requiring additional data** which demonstrates protocols consider ultrasound examination times, infection control procedures include the tracking of disinfection cycles, ultrasound equipment safety levels have been utilised, as well as auditing of the sonographer's name on reports against their registration.

a healthier world through sonographer expertise

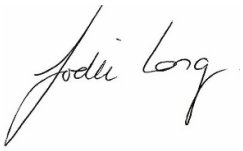
- **Improving the model of accreditation** by incorporating onsite auditing assessments, including assessing the age of ultrasound equipment, and that patients have given informed consent.

The ASA acknowledges the important work the DIAS undertakes to provide a commitment to the community that a diagnostic imaging practice meets expected standards for safety and quality. The commitment is however limited with regards to the expected standards for the safety and quality of sonographer-performed ultrasounds due to sonographers not being a regulated profession, unlike other medical imaging professionals who are regulated under the National Registration and Accreditation Scheme. As a result, there are currently no nationally enforceable standards of practice that set the minimum expectations of ultrasound examinations performed by sonographers in Australia, nor any recency of practice requirements for sonographers.

Our feedback and recommendations are outlined in further detail below.

Thank you for the opportunity to provide input into this review. We look forward to hearing about the outcomes of this consultation. If you have any questions or require additional information, please contact the ASA Policy Officer, Jodie Coulter at policy@sonographers.org or (03) 9552 0000.

Yours sincerely,



Jodie Long

Chief Executive Officer
The Australasian Sonographers Association

Review of the Diagnostic Imaging Accreditation Scheme (DIAS) Standards and Model of Accreditation

Australasian Sonographers Association: Detailed feedback and recommendations

In response to the email received on 16 May 2022, notifying us of the review into the current DIAS standards and model of accreditation, we offer feedback and recommendations in the suggested areas of:

- Safety and quality issues faced by patients accessing diagnostic imaging services
- Areas of unwarranted variation in diagnostic imaging
- Safety and quality data to monitor diagnostic imaging
- A diagnostic imaging model of accreditation.

Background to the sonography profession in Australia

There are currently 7,230 medical sonographers and 1,140 student sonographers in Australia. In 2021, there were 12.1 million Medicare-funded diagnostic ultrasound examinations undertaken; most performed by sonographers.

Unlike other diagnostic imaging professionals, sonographers are not currently regulated, meaning there are no nationally enforceable standards of practice that set the minimum expectations of ultrasound examinations performed by sonographers in Australia, or recency of practice requirements protecting the public and preventing harm.

Sonographers typically work autonomously with patients and undertake examinations in real-time. They view the entire structure of the organ/s to recognise if something is abnormal and capture representative medical ultrasound images so that an accurate diagnosis can be reported by a medical practitioner.

The outcome of the ultrasound examination is directly affected by the competence and expertise of the sonographer. If a sonographer fails to produce quality images or identify pathologies, the report prepared by the medical practitioner is likely to be inaccurate. This impacts on the diagnosis and treatment of the patient, which may include delayed or additional treatment, and patient harm.

1. Safety and quality issues faced by patients accessing diagnostic imaging services

The safety and quality of diagnostic imaging services received by patients can be enhanced through improved monitoring of the quality of ultrasound examinations, ensuring there are polices in place for patient-centred communication, and obtaining patient consent.

1.1. Improved monitoring of the quality of ultrasound examinations

Recommended action:

- Diagnostic imaging practices should be required to demonstrate they have policies and procedures in place to actively and regularly monitor the quality of ultrasound examinations, and implement improvements where required. This requirement should be audited, incorporating assessment by a subject matter expert.

Unlike other medical imaging professionals, sonographers are not currently regulated under the National Registration and Accreditation Scheme (NRAS), meaning there are no nationally enforceable standards of practice that set the minimum expectations of ultrasound examinations performed by sonographers. The outcome of an ultrasound examination is directly affected by the competence and expertise of the sonographer.

Monitoring the quality of examinations is vital to ensuring patients receive a quality and timely diagnosis.

The ASA acknowledges there are already requirements in the DIAS standards (1.1 and 3.1) for practices to have protocols for all routine diagnostic imaging procedures, including for them to submit samples and demonstrate they have been reviewed at least once in the last accreditation cycle.

However, we believe there is currently a gap in the DIAS standards regarding the need to monitor the quality of ultrasound examinations and believe this could be improved through clearer requirements and enhanced auditing including assessment by a subject matter expert.

1.2. Improved communication with patients

Recommended action:

- Diagnostic imaging practices should be required to demonstrate they have policies and procedures in place that promote patient-centered communication. This includes communication protocols for specific events to ensure continuum of care. This requirement should be audited.

Patient-centred care is central to quality outcomes; and a key component of care is communication. Ineffective communication is a significant contributing factor in medical errors, and can lead to missed or misdiagnosis, as well as patient distress and harm. Effective communication improves patient outcomes and reduces the risk of harm.

In their role, a sonographer must communicate with the patient to gather relevant medical history and ensure they understand what will happen in the examination. They must also communicate with the referring and reporting medical practitioners, as well as other team members, to ensure the patient receives an accurate and timely diagnosis.

To improve communication, the ASA believes the DIAS standards should include a requirement for practices to demonstrate they have policies and procedures in place that promote patient-centred communication. This includes communication between health professionals and the patient, including in the event of critical or urgent results.

While it is not usually within a sonographer's scope of practice to communicate details or findings of an examination directly to the patient, there are some settings where this may be appropriate, such as some obstetric examinations (e.g., miscarriage) or where findings are urgent or critical (e.g., DVT). It

is important practices have communication policies in place that outline the protocols in these events to ensure the patients receive continuum of care.

Communication is also essential to obtaining informed consent, by ensuring patients understand why and how the procedure will be performed and the associated risks, costs, and benefits of the examination. More information on our recommendation regarding consent can be found in 4.3 below.

Practices should also be required to demonstrate a commitment to ongoing training for their employees in communicating with patients.

2. Areas of unwarranted variation in diagnostic imaging services

One area of unwarranted variation in diagnostic imaging services includes those in clinical practice – that is, where variations arise in procedures and/or results that do not reflect a difference in clinical needs or preferences of a patient.

In terms of ultrasound examinations, this can be influenced by the operator-dependent nature of examinations – as the outcome of the examination is directly affected by the competence and expertise of the sonographer. This can present a risk to patients.

Examples of unwarranted variations resulting from poor quality sonographer practice may include failure to produce quality diagnostic images, failure to follow protocols and guidelines, failure to identify an abnormality, incomplete examinations or worksheets, and measurement errors.

Ongoing monitoring of ultrasound examination quality is vital for patient health and safety, as outlined in 1.1 above by enhanced auditing including assessment by a subject matter expert.

3. Safety and quality data to monitor diagnostic imaging

We offer several recommendations around additional safety and quality data required to monitor diagnostic imaging, including to; demonstrate protocols consider ultrasound examination times, improve auditing of the sonographer's name on the report with their registration, monitor ultrasound equipment safety levels, and monitor infection control procedures.

3.1. Requirement to demonstrate protocols include ultrasound examination times

Recommended action:

- Diagnostic imaging practices should be required to have a policy and procedure in place to ensure ultrasound examination times are appropriately scheduled to ensure patients receive safe, quality medical diagnostic ultrasound examinations. This requirement should be audited.

The ASA understands there are already requirements around examination protocols but believes there is a gap in the existing DIAS standards and auditing requirements with regards to demonstrating the protocols incorporate ultrasound examination times.

There are many factors that influence examination times including the type and complexity of the study, the expertise of the sonographer, and the age and size of the patient. Additional time is also needed to communicate with the patient, colleagues, and the radiologist or referring physician; as well as prepare and clean the room and disinfect equipment between patients.

We believe protocols for determining ultrasound examination times should consider the different factors that influence examination times and recognise relevant international guidelines.

3.2. Improved auditing of the sonographer's name on the report with their accreditation.

Recommended action:

- The DIAS accreditation process should include an audit of the Medicare requirement for the initial and surname of the sonographer performing the medical ultrasound examination, on behalf of a medical practitioner, to be listed on the report.
- In addition, the Medicare requirement should be cross-referenced against the list of accredited sonographers held by the diagnostic imaging practice as required in DIAS standard 1.2.

DIAS standard 1.2 requires diagnostic imaging practices to hold copies of each sonographer's statement of accreditation on the Australian Sonographer Accreditation Register (ASAR) or a registration number which can be verified on the ASAR register for the purpose of determining registration on the Services Australia Register of Sonographers.

Medicare requires the initial and surname of the sonographer performing the medical ultrasound examination, on behalf of a medical practitioner, to be listed on the report.

However, we believe there is currently no auditing of the Medicare requirement within DIAS or auditing to align the Medicare requirement against the list of accredited sonographers held by diagnostic imaging practice.

We recommend practices be required to submit sample data, so it can be aligned and audited.

3.3. Ensuring appropriate ultrasound equipment safety levels

Recommended action:

- The DIAS standards should be amended to include the requirement to demonstrate the use of appropriate safety levels in ultrasound examinations by ensuring examinations are medically necessary and exposure is as low as reasonably achievable (ALARA). This requirement should be audited.

It is our understanding that the DIAS standards do not currently make reference to ALARA principles in relation to ultrasound examinations. We believe this is a gap, and a potential safety risk to patients resulting from the possible thermal or mechanical effects.

This is particularly important given the use of newer more power technology, and in higher risk examinations such as obstetrics and some paediatric examinations, as well as during higher risk procedures such as eye ultrasounds.

We recommend the DIAS standards include a requirement to demonstrate the use of appropriate safety levels in ultrasound examinations, and that this requirement be audited.

3.4. Improved auditing requirements around infection control

Recommended action:

- The DIAS standards should include clear guidelines and in particular, improved auditing on the processes for ultrasound transducer cleaning and disinfection.

The ASA recognises that standard 1.6 already requires practices providing ultrasound services to have a policy for reprocessing ultrasound transducers that is consistent with national standards and guidelines in relation to disinfection.

However, we believe additional data and improved auditing would enhance patient safety in this area. Specifically, we recommend practices should provide evidence of the tracking of disinfection cycles with the patient's identification, and the person who performed the disinfection cycle. The policy should also include a requirement that audits are performed that successfully match a patient to the cycle and disinfection event.

4. A model of accreditation

The ASA believes that the current model of accreditation focuses on compliance and the preparation of documents, rather than safety and quality improvements. We also believe that the reliance on a desktop audit alone is not robust enough to ensure safety and quality outcomes.

We believe the model of accreditation needs to be improved and that the auditing framework must include some level of onsite assessment. In relation to ultrasound, this should include onsite assessments to determine the age of ultrasound equipment, and to ensure patients are providing informed consent.

4.1. Improved auditing framework to include onsite assessment

Recommended action:

- The DIAS model of accreditation should be improved to include some level of onsite auditing assessment, which should be undertaken by a subject matter expert where the requirement is clinical in nature.

Any auditing requirements should be designed to reduce risk for patients, but not present an unnecessary or unreasonable administrative burden on practices, especially on smaller practices who often have limited resources.

The use of onsite auditing assessments to complement desktop auditing requirements is a reasonable expectation and aligns with accreditation and auditing models used elsewhere. For example, those used in occupational health and safety, and course accreditation for education providers including those that are in place under the Medical Radiation Practice Board of Australia.

4.2. Improved auditing of the age of ultrasound equipment

Recommended action:

- The DIAS auditing process should be improved to ensure equipment used to undertake medical diagnostic ultrasound examinations is not more than 10 years old.

The ASA believes the standards around equipment inventory and servicing requirements are quite robust and extensive, and recognise there are also Medicare incentives that support equipment upgrades.

However, we believe there is a possible loophole that enables older machines to continue to be used in practice. This loophole could be resolved through improved auditing that incorporates onsite checks, matching equipment in use with submitted records.

4.3. Improved auditing in relation to patient consent

Recommended action:

- The DIAS auditing process should be improved in relation to patient consent, to include onsite checks, particularly in relation to diagnostic imaging procedures that are high risk or invasive, such as intracavity examinations.

The ASA recognises DIAS standards 2.2 and 1.1 already include requirements relating to patient consent.

However, we recommend improved auditing, including onsite assessment to make sure consent processes are being adhered to and that patients fully understand what they are consenting to, and why and how the examination is going to be performed, including the risks, costs, and benefits.