

Discussion Paper: Definition of Point of Care Ultrasound (POCUS)

Purpose

ASUM is seeking to develop a position paper on POCUS which would set down ASUM's views about the training and credentialing requirements for providers of these services. As part of this exercise a definition of POCUS is needed.

The Government is seeking to establish a definition of POCUS that distinguishes it from other uses of US but this has proven difficult for a variety of reasons. ASUM is in a position to influence the development of such a definition.

The purpose of this discussion paper is to provide background to Government/stakeholder efforts to develop a definition and to present some definitions already in the public domain to inform consideration by ASUM of an agreed definition of POCUS that will be accepted more broadly by Government and other stakeholders.

Background

In March 2013 the Government asked members of Diagnostic Imaging Advisory Committee (DIAC) to consider "how the distinction between point of care and diagnostic ultrasound could be made."

At that time it was suggested that there is a significant difference between protocol driven services and quick examinations and that quick services should not be rebated the same; that a requirement for a report to be produced was an appropriate requirement to draw a rebate; that ultrasound is now seen as the stethoscope of the 21st century and there may not need to be a rebate where it is used as an adjunct to a clinical examination. The issue of Medicare rebates for point of care ultrasound was also discussed, noting that equipment is not the major cost, and that cost is driven by the other aspects of providing a quality service.

It was agreed that further work was required clarify the difference between point of care and diagnostic ultrasound, as well as determining what qualifications are appropriate.

In July 2013 the Department produced a paper outlining a range of issues related to how fully diagnostic ultrasound could be defined and differentiated from point of care ultrasound. In this paper the Department cites the view of the Society of Diagnostic Medical Imaging that ultrasound can be used by a range of practitioners for "point of care clinical investigations, which unlike traditional diagnostic ultrasound aid ordinary clinical assessment and are secondary to a consultation or procedure". It also refers to a report in 2011 (not referenced) which distinguished "specialist diagnostic ultrasound from ultrasound for procedural assistance and ultrasound for diagnostic assistance (point of care)". Discussion within DIAC indicated that imaging services exist on a spectrum ranging from comprehensive, fully diagnostic services; to very brief services to support a consultation.

Given the challenges in establishing a precise definition, the paper suggested it may be more practical to use indicators to identify when a service should be considered diagnostic. Indicators could then be combined into a comprehensive framework or definition.

A number of indicators that could be used to define an ultrasound as diagnostic were proposed by various stakeholders:

- The presence of a request (potentially including a self request)
- The presence of a clinical indication
- The conduct of a comprehensive examination



- The conduct of a protocol driven examination
- The service is a stand-alone service
- The production of a formal report for the requesting practitioner or the patient record
- Provision by a qualified provider.

When the strengths and weaknesses of each of these indicators were considered, none of the indicators was sufficiently robust to use as a sole indicator of diagnostic status. The potential to combine several indicators into an integrated framework or definition so that the strengths of one indicator offset the weaknesses of another was then explored.

One option proposed would require diagnostic ultrasound services to:

- Be requested for a specific/specified/relevant clinical indication
- Be comprehensive and appropriate for the specified indication
- result in a formal report which contains all relevant measurements, images and interpretation necessary for diagnosis, treatment, or monitoring of the clinical indication.

The following approach to implementing this type of framework was suggested:

- 1. Define appropriate DIST ultrasound services as 'fully diagnostic';
- 2. Clarify and enhance the regulatory requirements for reporting;
- 3. Introduce specific qualification requirements for fully diagnostic services.
- 4. Establish alternative treatment mechanism for point-of-care services.

The paper suggested the following definition of the term "fully diagnostic" for use in

A diagnostic imaging service which is clinically necessary, which investigates, provides an image and reports on the relevant anatomy with sufficient detail for a treating practitioner to make an informed diagnosis or assessment of the patient's current condition and appropriate treatment options, and is provided by a suitably qualified professional.

DIAC members agreed that the issue was complex and noted that inserting the proposed definition would not prevent practitioners from asserting that their services met the indicators. Suggestions about what might be required for a service to meet the definition of a diagnostic imaging ultrasound included: the qualifications of practitioners; protocol examination; scope of the written report; provided in an accredited practice and brevity of the examination. It was further suggested that the features and quality of the ultrasound equipment used would also be a distinguishing feature.

At the following DIAC meeting In November 2013, the Government presented the following potential package of regulatory changes for DIAC discussion ahead of a proposed broader consultation process and potential consideration by Government.

1: Introduce a definition of diagnostic ultrasound

This element would introduce a requirement into the *Health Insurance (Diagnostic Imaging Services Table) Regulation* 2013 that would require all ultrasound services, except where otherwise specified, to be comprehensive diagnostic services. This would be defined as:

An ultrasound service which is clinically necessary, which investigates, provides imaging and reports on the relevant anatomy with sufficient detail for a treating practitioner to make an informed diagnosis or assessment of the patient's current condition and appropriate treatment options, and is provided by a suitably qualified professional using equipment that is appropriate to the service and meets quality and safety standards.



2: Introduce credentialing arrangements for ultrasound into the Diagnostic Imaging Accreditation Scheme (DIAS)

- 3: Introduce minimum equipment standards
- 4: Enhance existing requesting requirements
- 5: Enhance existing reporting requirements

While it was agreed that a definition would be useful, members agreed the definition provided was not enough to delineate between diagnostic and point-of-care (POC) ultrasound. There was recognition that creating a definition of point of care ultrasound was difficult.

Views of ASUM

Adrian Goudie provided a number of comments in response to the proposed package of regulatory reforms presented at DIAC in November 2013. The following points relating to terminology have been extracted from these comments to provide some guidance in current efforts to develop a clear definition of POCUS:

- Medical ultrasound use can be divided into 3 broad categories:
 - Therapeutic such as for tissue heating (in general use by physiotherapists), coagulation (currently experimental) and to control drug delivery (also experimental).
 - Diagnostic used to contribute information to the making of a diagnosis
 - Intervention imaging used to guide interventional procedures.
- A plethora of terms has been used to try and characterize the range of examinations that are performed. The different terms are confusing, often inherently illogical and frequently based upon historical and geographical patterns of practice (which differ between countries and regions due to historical variation rather than intrinsic requirements or value). Terms have often been coined to create pejorative implications and defend traditional business models rather than viewing the spectrum of uses from the perspective of either the patient or an efficient medical system.
- ASUM recommends discarding terms that create confusion. These include:
 - "Diagnostic" Other than therapeutic and interventional guidance, all ultrasound is performed with the aim of progressing towards a diagnosis. The distinction is thus fundamentally flawed. To use a phrase such as "fully diagnostic" is even more confusing, as it implies these examinations will give a single, definitive diagnosis without requiring the integration of clinical information or further testing, which is incorrect.
 - "Adjunctive clinical examination" is undefined and suffers the same problems as the terms above. From a patient's perspective (and a system that is aiming for efficient, quality medical care) all tests, regardless of complexity, are adjuncts to the clinical evaluation.
 - Geographically based terms such as 'bedside' and 'point of care' should be abandoned. All ultrasound is performed by an operator who is in contact with the patient. The patient's location (e.g. in an imaging suite or elsewhere) is also irrelevant as the required skill and quality of an examination does not change based upon where a patient is.
 - "Clinician performed" as many specialist imaging providers also practice as 'clinicians' (for example cardiologists and obstetricians & gynaecologists) this term is confusing. The required skill and quality of a scan are determined by the patient's needs, not the background of the practitioner.



- ASUM recommends the terms "comprehensive ultrasound", "limited ultrasound" and "focused ultrasound" be used to capture the differences in the range of ultrasound examinations (these terms were introduced by the American Society of Echocardiography, J Am Soc Echocardiogr 2013;26:567-81). Please note that while ASUM recommends the terms introduced by the ASE, it does not agree with the use of some of the confusing phrases listed above in the ASE's description of focused examinations and recognizes that the driving force for some of the descriptions is financially based in the US setting.
 - Focused = used in specific clinical settings to recognize a narrow list of potential diagnoses. As such, these examinations may have lower requirements for training and equipment and can often be performed more quickly.
 - Limited = an examination performed using the skill and equipment suitable for a comprehensive examination, but not undertaking the full protocol of a comprehensive examination.
 - Comprehensive = following a recognized protocol to obtain good quality images that are interpreted by a physician who has undertaken advanced training in ultrasound. Usually would be associated with a comprehensive report.
- Unless otherwise specified, referred examinations will usually be of the comprehensive type, but the referrer may request only a limited or focused examination in appropriate clinical circumstances.
- Non-referred examinations may be of any type, depending on the clinical requirement of the patient.

Definitions of Point of Care Ultrasound - Review of Available Literature

Local efforts to clearly characterise and distinguish the range of US examinations have proven difficult.

While it has been suggested above that terms such a 'point of care' are confusing and should be abandoned on the basis that all ultrasound is performed by an operator who is in contact with the patient, Internet searching suggests there is widespread use of the term "Point of Care Ultrasound" and several attempts have been made to define/scope it as follows:

1. Source: Article by ASUM in AHHB, The Speed of Ultrasound, July 20131

The use of ultrasound has undergone dramatic changes in the last decade as a result of technological advances. As the cost and size of ultrasound machines have decreased, the ability to perform diagnostic quality ultrasound has spread rapidly. Ultrasound is now widely available outside imaging departments and is being performed by an ever growing range of specialties. This use is generally limited in scope to answering specific clinical questions or guiding procedures and is referred to as clinician performed or 'point of care' ultrasound (POCUS).

Many allied health practitioners use ultrasound as part of their daily practice, and in some cases ultrasound has become the standard of care for their counterparts overseas. Examples include midwives who use ultrasound to monitor fetal wellbeing, vascular access nurses who perform central venous cannulation and PICC (Peripherally Inserted Central Catheter) line insertion, and defence force medics who assess wounded personnel in the field.

¹ http://www.hospitalhealth.com.au/content/nursing/article/the-speed-of-ultrasound-1151044715



2. <u>Source: ASUM Response by Adrian Goudie to DIAC discussion papers on Diagnostic</u> Ultrasound, 2013

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- Focused = used in specific clinical settings to recognize a narrow list of potential diagnoses.
 As such, these examinations may have lower requirements for training and equipment and can often be performed more quickly.
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- Comprehensive = following a recognized protocol to obtain good quality images that are interpreted by a physician who has undertaken advanced training in ultrasound. Usually would be associated with a comprehensive report.

3. Source: RANZCR, Position on the Provision of Medical Ultrasound Services, June 2013 2

Ultrasound technology has developed rapidly and its medical application has continued to evolve. It is now a widely utilised diagnostic and clinical tool. More recently, the increasing portability, ease of use, increasing medical applications and advent of simple, low-cost ultrasound equipment have resulted in many clinicians utilising ultrasound in the course of their clinical consultations. This has resulted in two distinct medical applications of ultrasound: the specialist diagnostic ultrasound examination, and the point of care ultrasound examination.

Specialist Diagnostic Ultrasound Examination

The sonologist performs the ultrasound examination either by him/herself or in conjunction with a sonographer, who is a dedicated ultrasound technologist. The study is interpreted by the sonologist, who issues a specialist medical opinion in the form of a written report. The sonologist may be a radiologist (medical imaging specialist) or another medical specialist who has specific ultrasound training and qualifications. The specialist diagnostic ultrasound examination is preferably performed on referral from another clinician using dedicated diagnostic ultrasound equipment which produces high resolution diagnostic images.

Crucial components of the diagnostic ultrasound examination are ultrasound images forming a complete diagnostic examination and retained for subsequent correlation or comparison, and a written report communicating the sonologist's specialist medical interpretation. These will contribute to the clinical management of the patient by the referring doctor and/or any other clinicians who may be involved in the patient's care.

Point of Care Ultrasound

² http://www.ranzcr.edu.au/component/docman/?task=doc_download&gid=2569



Point of care ultrasound is performed by a medical practitioner who uses ultrasound equipment to enhance and extend their own clinical examination of the patient. In this scenario, the use of the ultrasound transducer is a tool of the clinical examination, analogous to the stethoscope. In point of care ultrasound usually there are few or no images retained for correlation or follow-up, and no written report of the ultrasound study to be used by other clinicians involved in the patient's care – as such, the examination is useful only to the clinician performing it.

Relevant ultrasound features of the examination are recorded as part of the patient's clinical record. As such, point of care ultrasound will usually be a limited and directed ultrasound examination, relevant to the clinician's scope of clinical practice. The equipment required may be uncomplicated but suitable for the limited scope of the examination. The patient may still be referred for a comprehensive specialist diagnostic ultrasound examination.

4. Source: RANZCR Position Statement on the Definition of Diagnostic Ultrasound, (July 2015)3

Ultrasound technology has developed rapidly and its medical application has continued to evolve. It is now widely used as a diagnostic and clinical tool. Recent advancements in ultrasound technology have resulted in a divergence between highly complex and more rudimentary examinations. A greater range of equipment types, with some ultrasound machines becoming smaller, simpler to use and portable, has allowed non-specialist clinicians to use ultrasound in the course of their consultations. Two distinct medical applications of ultrasound have become apparent: specialist diagnostic ultrasound examination; and point of care ultrasound examination.

This position statement is intended to assist the Australian Government Department of Health in determining how to differentiate between diagnostic ultrasound and point of care examinations and to ensure that high quality imaging is provided through the Diagnostic Imaging Services Table (DIST). There are six essential components to a diagnostic ultrasound examination which demonstrate its comprehensive nature. These components ensure that structures relevant to the patient's symptoms are fully assessed and documented thereby allowing the patient and referring clinician to be confident that the scan can be used to direct their case management. We submit that any ultrasound examination which does not include all six components listed below should not be considered a comprehensive diagnostic ultrasound examination and should not be funded under the DIST.

1. REFERRAL AND SERVICE

A diagnostic ultrasound service is a service initiated by a request or referral from a medical health care provider to investigate clinical signs or symptoms. It provides a comprehensive visualisation of the relevant anatomy to identify any pathology associated with the clinical indication(s) for the examination.

2. QUALIFICATIONS AND EQUIPMENT

The service is provided by a sonologist (i.e. radiologist or other medical specialist with subspecialty ultrasound training) or a sonographer acting on the behalf of a sonologist. A sonographer is a medical imaging professional who is registered as an accredited sonographer by ASAR (Australian Sonographer Accreditation Registry) and has the training and skills to perform and document the ultrasound examination. Specialist ultrasound equipment is used that meets all quality and safety

 $^{^3 \, \}underline{\text{http://www.ranzcr.edu.au/documents-download/document-library-2/document-library-4/4179-20150726-} \\ \underline{\text{definition-of-diagnostic-ultrasound-position-statement}}$



standards1 and has the capacity to evaluate all accessible anatomical structures. The practice and practitioners providing the service undertake ongoing quality assurance activities.

3. PROTOCOL

Diagnostic ultrasound services have standard protocols in place for performing the various types of scans that are requested in the referral. The sonologist's background of specialist medical imaging training allows them to modify the scan protocol, where appropriate, by collating the information given in the referral, reviewing the current ultrasound scans and any previous imaging and on occasion by talking to the patient and referring doctor.

4. PERFORMING THE ULTRASOUND SCAN

The sonographer and sonologist act as a team, each bringing the attributes of their background and training to optimise the ultrasound study. The sonologist may scan the patient, either performing the whole or part examination. If the sonographer scans the patient, the sonologist may subsequently, after reviewing the findings with the sonographer, attend and personally scan any areas of concern.

5. EVALUATION AND REPORT

The sonologist provides a written comprehensive report describing and interpreting the ultrasound examination in the clinical context. A diagnosis or a list of differential diagnoses to guide the referrer in assessment of the patient's condition is integral to the ultrasound report. If appropriate, further imaging tests or other tests such as blood tests may be suggested. The report is a specialist medical opinion and cannot be delegated; it reflects the sonologist's expertise as a medical practitioner.

6. IMAGE STORAGE

The ultrasound images are recorded as a series of digitally captured images of all assessable anatomical structures in the area of the examination. This digital image file is stored and available to the referrer and, where appropriate, other healthcare professionals managing the patient's care.

CONCLUSION

These six components must feature in the regulations which govern the provision of diagnostic ultrasound under Medicare arrangements. Any ultrasound examination which does not include all of these components would not be considered a comprehensive diagnostic ultrasound examination and should not be funded under the DIST.

5. <u>Source: Canadian Association of Radiologists</u>, *Position Statement on Point of Care Ultrasound*, (2013)⁴

Point of Care Ultrasound (POCUS) is an ultrasound examination provided and performed by the primary care physician (or their designate), usually as an adjunct to the physical examination, to identify the presence or absence of a limited number of specific findings. POCUS is considered a different examination than a comprehensive or limited sonographic evaluation of a patient performed in a dedicated imaging facility or department in a consultative process between the physician providing primary or specialty care for the patient and the consulting imaging specialist. POCUS can at times be invaluable at the point of care to clarify uncertain findings of the physical

http://www.car.ca/uploads/standards%20guidelines/point of care ultrasound position statement 20140527.pdf



exam, identify important conditions in the context of acute care of the unwell patient, or provide image guidance that improves the success and safety of many procedures in the acute care setting, particularly when time saving for diagnosis or treatment is absolutely critical.

POCUS can also be performed in various settings and can be performed for diagnostic purposes or interventional procedure guidance. Typically, the assessment is goal orientated to add immediate information to the clinical examination. Various medical specialists may use POCUS at the bedside directly relevant to their area of expertise to efficiently diagnose certain conditions in patients presenting with particular symptoms and signs. POCUS can potentially be used in remote communities where access to diagnostic sonography by certified imaging specialists is limited, however it should not be used in this role as a substitute for a comprehensive or limited consultative sonographic examination.

It is important to distinguish the POCUS examination from the imaging consultant's examination, which is usually carried out at the request of a non-imaging primary care or specialist physician. The consultative sonographic exam aims to systematically map out normal and disordered anatomy, assess function and dysfunction in the body or provide guidance for a wide range of interventional procedures. Necessary components for a consultative sonographic exam include: a professional mastery of the imaging technology, a systematic approach that results in a thorough diagnostic imaging assessment of the patient to include image recording and an interpretation of the exam provided in a well documented and recorded report of the findings and conclusions. Consultative sonographic examinations may involve comprehensive or limited diagnostic examinations depending on the referral question. Fundamentally, the limited consultative sonographic examination is distinctly different from the POCUS examination whose purpose is to identify the presence or absence of one or several specific findings.

6. Source: NEJM, Point of Care Ultrasonography, (2011)⁵

Point-of-care ultrasonography is defined as ultrasonography brought to the patient and performed by the provider in real time. Point-of-care ultrasound images can be obtained nearly immediately, and the clinician can use real-time dynamic images (rather than images recorded by a sonographer and interpreted later), allowing findings to be directly correlated with the patient's presenting signs and symptoms. Point-of-care ultrasonography is easily repeatable if the patient's condition changes. It is used by various specialties in diverse situations allowing findings to be directly correlated with the patient's presenting signs and symptoms [see Table below] and may be broadly divided into procedural, diagnostic, and screening applications.

Procedural Guidance

Ultrasound guidance may improve success and decrease complications in procedures performed by multiple specialties, including central and peripheral vascular access, thoracentesis, paracentesis, arthrocentesis, regional anaesthesia, incision and drainage of abscesses, localization and removal of foreign bodies, lumbar puncture, biopsies, and other procedures.

Procedural guidance may be static or dynamic. With static guidance, the structure of interest is identified, and the angle required by the needle is noted, with the point of entry marked on the skin. In dynamic procedures, ultrasonography visualizes the needle in real time. Static guidance may

⁵ **Point-of-Care Ultrasonography,** Christopher L. Moore, M.D., and Joshua A. Copel, M.D. N Engl J Med 2011; 364:749-757<u>February 24, 2011</u>DOI: 10.1056/NEJMra0909487



initially be easier to perform, but properly performed dynamic guidance provides more accurate guidance and is generally preferred by experienced users.

Diagnostic Assessment

The concept of a focused ("limited," or "goal-directed") examination is important in point-of-care ultrasonography. Clinicians from diverse specialties can become very adept at using ultrasonography to examine a particular organ, disease, or procedure that is directly relevant to their area of expertise, whereas imaging specialists typically perform more comprehensive examinations [See Table below]

Point-of-care ultrasonography may involve the use of a series of focused ultrasonographic examinations to efficiently diagnose or rule out certain conditions in patients presenting with particular symptoms or signs, such as hypotension, chest pain, or dyspnoea. In patients with trauma, this approach is known as FAST (focused assessment with sonography for trauma). Point-of-care ultrasonography allows immediate, dynamic, and repeated assessments in these situations and has the potential for detecting conditions such as pneumothorax in which ultrasonography was traditionally thought to be unhelpful.

Screening

Screening with ultrasonography is attractive because it is noninvasive and lacks ionizing radiation. Ultrasonography has been described as a screening test for cardiovascular and gynecologic disease, and compact ultrasonography has been incorporated into "mobile screening labs." However, the benefits of screening must be weighed against the harms, particularly false positive findings that lead to unnecessary testing, intervention, or both.

Point-Of-Care Ultrasonography in Other Settings

Point-of-care ultrasonography is increasingly being used in resource-limited settings. The World Health Organization states that plain radiography and ultrasonography, singly or in combination, will meet two thirds of all imaging needs in developing countries. Ultrasonography has been used at the Mount Everest base camp to diagnose high-altitude pulmonary oedema, and ultrasonography is the only diagnostic imaging technique used on the International Space Station, where astronauts obtain images that are interpreted on earth. The use of hand-carried ultrasonographic devices has been described in prehospital settings, including ambulance and disaster settings, as well as in battlefield medicine (the scenario for which hand-carried ultrasonography was initially developed). The e-FAST examination for internal bleeding and pneumothorax has been the most extensively described application in the prehospital setting.



Table 1 Selected	Applications of	f Point-of-Care I Iltrasonography	According to Medical Specialty.*
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Specialty Ultrasound Applications

Anesthesia Guidance for vascular access, regional anesthesia, intraoperative monitoring

of fluid status and cardiac function

Cardiology Echocardiography, intracardiac assessment

Critical care medicine Procedural guidance, pulmonary assessment, focused echocardiography

Dermatology Assessment of skin lesions and tumors

Emergency medicine FAST, focused emergency assessment, procedural guidance Endocrinology and endocrine surgery Assessment of thyroid and parathyroid, procedural guidance

General surgery Ultrasonography of the breast, procedural guidance, intraoperative assessment

Gynecology Assessment of cervix, uterus, and adnexa; procedural guidance

Obstetrics and maternal-fetal medicine Assessment of pregnancy, detection of fetal abnormalities, procedural guidance

Neonatology Cranial and pulmonary assessments

Nephrology Vascular access for dialysis

Neurology Transcranial Doppler, peripheral-nerve evaluation

Ophthalmology Corneal and retinal assessment
Orthopedic surgery Musculoskeletal applications

Otolaryngology Assessment of thyroid, parathyroid, and neck masses; procedural guidance

Pediatrics Assessment of bladder, procedural guidance

Pulmonary medicine Transthoracic pulmonary assessment, endobronchial assessment, proce-

dural guidance

procedural guidance

Rheumatology Monitoring of synovitis, procedural guidance

Trauma surgery FAST, procedural guidance

Urology Renal, bladder, and prostate assessment; procedural guidance

Vascular surgery Carotid, arterial, and venous assessment; procedural assessment

7. Health Management, Point-of-care-ultrasound-Potential-and-Limitations Feb 2015⁶

POCUS is a modality, not an application. The scope of practice differs by specialty. POC ultrasound examinations differ from complete studies in that they are:

- Limited in scope, designed to achieve specific procedural aims (eg, direct the needle to the correct location) or answer focused questions (eg, does my patient have ascites?).
- Performed by the same care provider who will be using the information to direct immediate patient care management at the bedside.

POCUS cannot supplant all aspects of the physical examination. However, if used appropriately, it is an extension of the physical examination, which can provide more rapid and accurate assessments.

^{*} FAST denotes focused assessment with sonography for trauma.

⁶ https://healthmanagement.org/c/imaging/news/point-of-care-ultrasound-potential-and-limitations



FOR DISCUSSION

While there may be other definitions of POCUS that are not publicly accessible, the material provided above covers the range of issues involved and provides a basis for a robust discussion about the definition of POCUS and how it is differentiated from other uses of US. This exercise presents an opportunity to come up with definitions that are acceptable to ASUM but at the same time provide a framework for addressing broader issues around MBS remuneration etc which will ultimately be part of the government/other stakeholder agenda going forward.