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# GUIDELINES FOR POINT OF CARE ULTRASOUND UTILIZATION IN CLINICAL PRACTICE

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## Section 1 – Purpose

This document is intended to establish clear and unified guidelines for providers performing clinical ultrasound. The creation and integration of competency-based training, education, and proficiency standards, as outlined here, serves to foster the expanded use of ultrasound by clinicians and better ensure that ultrasound is utilized safely and effectively across the broad spectrum of clinical practice. Recognizing that specialties and societies are increasingly developing education, training, competency, employment, and billing standards for their members, this document is intended to serve as a recommendation for those looking to integrate POCUS into their respective practices where specialty-specific standards are otherwise absent. Adherence to validated standards best ensures POCUS will be safely and effectively employed by all clinicians whose patients can benefit from its employment.

## Section 2 - Introduction / Background

The use of ultrasound has expanded significantly since its early applications in medicine over half a century ago. Advances in technology have led to smaller, more portable machines with better image quality and more intuitive user interfaces, allowing ultrasound to be increasingly and effectively employed by various clinicians at the bedside/point of care.[1-9] Emergency medicine physicians in the '90s were among the first to recognize the value of ultrasound at the bedside of their patients. These physicians keenly spent the subsequent decade validating their safe and effective use of bedside ultrasound, effectively carving a niche that is now known as emergency ultrasound (EUS), a specific category in the overarching realm now known as clinical ultrasound.[10,11] Multiple studies have since validated clinical ultrasound as a safe, expedient, and cost-effective clinical adjunct which improves patient care.[12-16]

Today, bedside ultrasound is utilized across a broad spectrum of medical specialties to diagnose a myriad of conditions, safely guide invasive procedures, as an adjunct to treatment, and to monitor the progress of interventions or changes in a patient's condition. As clinical ultrasound becomes increasingly ubiquitous across the healthcare landscape and through multiple specialties, this technology will be available and beneficial to clinicians and their patients in every practice setting. It is therefore imperative that the role of clinical ultrasound in clinical practice be comprehensively considered, clearly

defined, and outlined, with a clear path established to its safe implementation by well-trained and competent providers across the entire spectrum of their diverse practice settings.

## Section 3 - Definition and Scope of Clinical Ultrasound

Clinical ultrasound (CUS) is defined as a focused ultrasound examination performed and interpreted by the treating clinician, at the point of care, to interrogate a specific clinical question or to guide a procedure. Clinical ultrasonography is a diagnostic modality that provides clinically significant data not obtainable by inspection, palpation, auscultation, or other components of the physical examination, and should be considered complementary to the physical examination. It is a separate entity that adds anatomic, functional, and physiologic information to the care of the patient. [17] Clinical ultrasound, for the purposes of this paper, will be considered synonymous with other terms such as “bedside,” “focused,” and “point-of care-ultrasound (POCUS). Emergency Ultrasound (EUS) is an example of a sub-category of CUS.

CUS is intended to be goal directed and focused with the purpose of answering brief and important clinical questions in an organ system or to query a clinical symptom or sign involving multiple organ systems. It may be performed as a single examination, repeated due to clinical need or a change in condition, or used to monitor physiologic or pathologic changes and assess the response to treatment.

Because CUS is performed, interpreted, and integrated into patient management by the evaluating clinician contemporaneously with the patient's evaluation, it enjoys some unique properties. Real time visualization of critical and pathological anatomy increases the safety of many procedures which have historically been performed without imaging guidance. This includes removal of retained foreign bodies, needle placement, incision and drainage, regional anesthesia, fracture reduction and joint dislocation reduction.

### Comprehensive/Consultative Ultrasound vs Clinical Ultrasound

CUS is not meant to replace comprehensive ultrasound imaging, which is a consultative test performed at traditional imaging centers by non-clinician sonographers, and traditionally interpreted by radiologists. Consultative sonography is intended to comprehensively evaluate anatomy and physiology, while clinical ultrasound focuses on specific, and therefore limited, clinical questions and concerns that the treating clinician may have as it relates to the current clinical encounter, while expediting care.[18]

CUS therefore follows a very different standard of practice compared to consultative ultrasound. Consultative ultrasound exams are broad-based and expected to characterize anatomy and pathology outside of a specific clinical question warranting interrogation. If the clinical question is, "does the patient have an IUP?" the patient should not have the expectation of reporting a cleft palate, gastroschisis, or uterine fibroids, for example.

CUS’s focused nature and limited scope, which seeks to answer a very specific clinical question, should therefore be discussed with the patient to ensure that he/she understands the "focused ultrasound" concept very clearly. For example, a pregnant patient with a small amount of first trimester

bleeding and pain presents for a clinical encounter. The clinical question may be, "does the patient have an intrauterine pregnancy?" This question may be quickly and easily answered by performing a bedside ultrasound. In this example the patient had a bedside ultrasound and was diagnosed with an IUP that appears to be about 9 weeks old with a heart rate of 164 bpm. However, the patient must understand that the purpose of the bedside ultrasound exam was to evaluate her symptoms for the possibility of an ectopic pregnancy. The clinical ultrasound is not intended to replace her scheduled 10 or 20 week consultative ultrasound to evaluate for fetal anomalies, date the pregnancy and assess for signs of a high risk pregnancy or a complicated delivery.

The miniaturization of highly capable ultrasound machines allows clinical ultrasound to be performed, interpreted and shared with the other members of the care team in a multitude of settings. Its versatility across a wide range of practice settings is well documented, thereby highlighting its potential in both well-resourced, and perhaps greater value in resource-constrained settings. These settings include but are not limited to: primary/office-based care settings, outpatient specialty care settings, the emergency department, inpatient setting, the pre-hospital setting, the forward edge of battle, space, urgent care clinics, sporting events, disasters, and remote and frontier settings. [19-27]

## Section 4 - Competency-based Clinical Ultrasound Training

### Core Components of Competency

Achieving competency is vital for clinicians looking to successfully incorporate clinical ultrasound into their clinical practice. The goal of competency-based learning is to ensure that learners have acquired the knowledge and skills deemed essential to successful implementation of ultrasound. Successful implementation of clinical ultrasound requires clinicians to have a strong fundamental knowledge in four key areas. These include:

1. Knowledge related to indications for the exam
2. Image acquisition
3. Image interpretation
4. Integration of findings into patient management

Formal ultrasound educational and training programs with the goal of developing clinicians proficiency in clinical ultrasound should therefore focus on these basic tenets. Bahner, et al. utilized these same tenets to create a simplified approach (known as the “I AIM” model) to be used as both an educational model and clinical tool to improve clinical ultrasound performance.[28] Competency in these four key areas is best achieved with a combination of didactic education and hands-on scanning.

The didactic portion of these tenets can be delivered by attending lectures, clinical rotations, preceptorships, conferences, post graduate and fellowship training programs, through online content and asynchronous education, or through medical school or medical education programs with integrated ultrasound curriculum.

Following the didactic instruction, hands-on scanning is essential to develop requisite psycho-motor skills necessary to capture quality images in a timely manner. The scanning time can be obtained

through one on one scanning, live conferences, remote video conferencing, or through the use of high fidelity ultrasound simulation technologies.

Objective demonstration of competency is vital to any educational or training program. Training in bedside ultrasound is no exception. Demonstration of competency can and should be achieved by various methods. These may include written exams, direct supervision of hands-on scanning, Standardized Directly Observed Tools (SDOTS), Objective Structured Clinical Examination (OSCE) image review sessions, or simulation cases.[29-31]

Demonstration of competency should begin during the didactic portion, Phase I Introductory Training or Practice Based Pathways and should continue into the clinical clerkship phase for students, or for providers in current clinical practice Proctored Scanning Phase II through their home clinical ultrasound programs.

Professional medical organizations such as the American College of Emergency Physicians (ACEP) and Society of Critical Care Medicine (SCCM) have recognized the great potential for ultrasound at the point of care and have taken concrete steps to incorporate formal competency-based educational and training programs for their respective members. ACEP and SCCM have established guidelines outlining the role of bedside ultrasound in their respective specialty clinical practice, as well as made recommendations for training and integration into medical education.([11,31]

In 2007 emergency medicine leaders recognized ultrasound as "a skill integral to the practice of emergency medicine" (EM), as defined by the 2007 Model of Clinical Practice of Emergency Medicine,[33] resulting in the integration of ultrasound into the curriculum of every U.S. EM residency program. This mandate requires every EM resident to complete a didactic clinical ultrasound educational requirement and completion of at least 150-300 proctored, high quality ultrasound scans, and demonstration of competency in EUS in order to successfully complete residency training. This model is now increasingly being adopted by various medical specialties including pediatric, family medicine, and internal medicine residencies.[22,34,35]

Historically, PA education has adopted and mirrored the medical model of education.[36]) A solid foundation of medical knowledge was built with a didactic phase followed by clinical clerkships and rotations in multiple specialties. In many universities, the two disciplines collaborate, share space, resources and coursework. Ideally clinical ultrasound education should be incorporated into both entry-level and post-graduate medical and PA educational programs.

**Integrating Competency-based Training – A Two-Phased Approach**

The following describes a two-phased approach by which clinicians an achieve competency in clinical ultrasound in order to integrate it into their respective clinical practices.

**Phase One – Introductory Training**

**Introductory Training Pathway #1 – Integration into Educational Curriculum**

The American Medical Association (AMA) supports the educational efforts and widespread integration of ultrasound throughout the continuum of medical education.[37] Medical schools began successfully

integrating comprehensive clinical ultrasound training into their UME programs nearly a decade ago.[38] Since that time, CUS is increasingly being integrated into the curriculum of undergraduate medical education (UME) programs across the country. A recent study found 62% of U.S. medical schools surveyed reported they had ultrasound integrated into the curriculum.[39] Many of these same medical schools have adopted a longitudinal approach to ultrasound education. Students start learning ultrasound from day one in their anatomy, physiology, and physical exam courses and continue their learning by integrating information from focused ultrasound exams into patient management during clinical rotations.

Full integration of clinical ultrasound training into the curriculum will provide the richest longitudinal learning experience, therefore training in clinical ultrasound should begin at the earliest point to allow for the progression of skills throughout didactic and clinical training.

Instruction should begin with basic ultrasound physics and instrumentation, followed by a brief introduction to the clinical applications of bedside ultrasound. Ideally, this clinical training would begin during the anatomy and physiology courses. Allowing students to visualize sonographic anatomy (musculoskeletal, abdominal, etc.) and physiology (cardiac, bladder) can greatly complement and enhance their understanding of the human anatomy and demonstrate how pertinent pathology may manifest sonographically.[40]

Although ultrasound is often considered to be a separate entity from the clinical exam, it has the potential to complement the exam by offering otherwise unobtainable and clinically relevant anatomic and physiologic real time information to the scanning clinician. Many UME programs have successfully incorporated clinical ultrasound into the physical exam training.[41-44] Training programs should consider adding clinical ultrasound into the physical exam training as these two clinical skills greatly complement each other.

**Introductory Training Pathway #2 – Practice-Based Pathway**

For practicing clinicians without formalized clinical postgraduate training, or clinicians with formalized clinical postgraduate training without specific clinical ultrasound integration, a comprehensive introductory course covering multiple applications, or a series of short courses covering a single/combination of applications may provide initial training. Short preceptorships with clinical ultrasound training programs may also be valuable in providing fundamental clinical ultrasound skills.

Each of these options available to currently-practicing provides should provide an introduction to ultrasound physics, familiarization with instrumentation, and provide introductory training in the applications the clinician plans to incorporate into practice.

**Introductory Training Pathway #3 - Post Graduate Based Pathway**

For those clinicians who complete a formalized clinical postgraduate training program or fellowship which incorporates formal clinical ultrasound education and training, it is recommended that successful completion of this ultrasound training be accompanied by documentation of training/competency standards that were met along with a list of the applications in which the clinician has demonstrated

competency. This documentation will serve to facilitate future credentialing should the provider pursue privileges in clinical ultrasound at other medical facilities.

The documentation of training for those who complete this pathway should verify that the individuals have simultaneously completed Phase II (Proctored Scanning Phase) during their training and are competent to seek credentialing as clinical ultrasound-proficient staff at their local facilities.

### Phase Two– Proctored Scanning Phase

Clinicians who successfully completed their initial training via Introductory Pathways I and II should not be considered adequately trained to incorporate bedside ultrasound into patient management decisions. Clinicians who complete Phase I Introductory Training, via Pathway I or II, should participate in closely supervised scanning while achieving the appropriate number of proctored scans required for proficiency and credentialing at their home institutions.

For those who receive Phase I training through Introductory Pathway I, (initial clinical training during school), Phase II Proctored Scanning Phase can only begin after the clinician is licensed to practice.

The Proctored Phase II scans should be subject to rigorous quality assurance reviews. Live scanning can be augmented with imaging reviews, simulation training, and competency should be assessed upon completion of this proctored period. Any completed formal training should be accompanied by documentation which outlines the specific topics and applications that were assessed, the total number of training exams completed with expert supervision, and performance assessment measures.

## Section 5 - Proficiency Validation / Certification

Training and proficiency standards should be developed by professional and specialty organizations, and the standards should closely complement well-validated standards set forth previously by other professional medical organizations/colleges. [45,46] In the absence of specialty and practice-specific competency standards, successful deployment of clinical ultrasound by clinicians should parallel and complement the validated standards previously set forth by other professional societies or organizations.

While POCUS can be employed variably depending on specialty and practice setting, it is valuable for professional organizations to develop clinical ultrasound subcommittees as well as administrative and leadership infrastructure to promote clinical ultrasound use among their respective constituencies. It is also valuable for medical professional organizations to work/collaborate with sister specialty organizations to ensure guidelines and efforts are complimentary and parallel.

Certification is a broad term which can encompass both intramural and extramural methods of competency validation. Intramural certification is ideal, due to the fact that it eliminates the financial burden that is typically associated with external / third-party certification, allows local stakeholders to well consider the practice setting, needs, resources, disease burden, and clinician skills, while also

preventing absence of the clinician from his/her practice to take an exam. However, intramural certification requires existence of adequate infrastructure to ensure competency and quality assurance standards are met. This infrastructure may not exist at institutions where clinicians are desirous of integrating POCUS, presenting a challenge to integration.

The role of external (extramural) organizations in certifying proficiency of training has become controversial in recent years. Increased certification testing, escalating costs associated with testing, along with lost productivity spent preparing and taking examinations and the continuing education requirements associated with maintenance of certification, are burdensome. Furthermore, there is little data to support the effectiveness of external certification in demonstrating proficiency which cannot be demonstrate in other ways, or improving patient outcomes.[47]

Because POCUS requires demonstration of competency in image acquisition, image interpretation, and clinical integration, well-designed external POCUS certification methods should encompass each of these skills. Though extramural certification methods exist, often they still require local POCUS skill validation by a peer or supervisor which, in the presence of a POCUS qualified peer or supervisor, might lead one to question the value of extramural certification.

Physician specialty organizations like ACEP, considered pioneers in the implementation of bedside ultrasound, have explicitly rejected the use of external certification as a measure of ultrasound proficiency in favor of a competency based approach.[48] ACEP's competency-based approach has been well-validated since its inception in 2001, leading the organization to unequivocally endorse a competency based pathway and strongly oppose external certification.[10] Clinicians are encouraged to consider ACEP's stated opposition to external certification as a potential barrier to practice that could impede the integration of this critical clinical skill into clinical practice and education, and therefore could adversely affect patient care.

SPOCUS opposes the use of any extramural certification process designed to validate the proficiency of clinicians employing clinical ultrasound that is deemed to be overly burdensome or a barrier to the incorporation of clinical ultrasound in clinical practice. Barriers that certification methods may create include (but are not limited to):

1.) exams or processes which are financially burdensome to the individual clinician
2.) exams that require significant preparation which removes clinicians from their clinical practice environment
3.) processes that require regular monetary fees and testing for maintenance of certification

Clinicians should be wary of certification bodies that claim that their certification methods increase patient safety and demonstrate a commitment to excellence in patient care, without data that demonstrates these claims. Should any external certification body seek to create certification standards for providers utilizing clinical ultrasound, SPOCUS should present the certification method to its constituent organization leaders and SPOCUS members for consideration prior to any endorsement.

It is the responsibility of clinicians utilizing clinical ultrasound to identify and develop minimally burdensome/cumbersome CUS training, education and proficiency standards which increase patient access to ultrasound. Furthermore, clinician professional and specialty organizations are singularly and best qualified to develop, validate, and cultivate those standards. Outsourcing governance of a clinician's professional role or capacity to extramural certification bodies can be tantamount to surrendering the right to professional self-determination, and abdicating the professional responsibility to act as an advocate for what is best for patients and clinical practice.

Further, any such external certification process should not be endorsed or utilized as a requirement for hospital privileges or credentialing, nor for reimbursement by accountable care organizations (ACOs), managed care organizations (MCOs), the Centers for Medicare and Medicaid Services (CMS) or other third-party payers.(48)

## Section 6 - Privileging/Credentialing

These guidelines are intended to outline a fair, proven, cost efficient method of attaining and demonstrating competency, with a clear pathway to credentialing at local institutions.

The AMA House of Delegates in 1999 passed a resolution (AMA HR. 802) recommending hospitals' credentialing committees follow specialty specific guidelines for hospital credentialing decisions related to clinical ultrasound use. The AMA policy states that ultrasound, as an imaging resource, is not the exclusive intellectual property of any one medical specialty.[37] As such, each specialty organization and professional society must decide how to best determine proficiency and create a pathway to credentialing.

Hospital privileging and credentialing processes should be fair and unbiased, and awarded or denied based upon state law, documented training, experience, and current demonstrated competence in clinical practice. Credentialing based on any other factor is contrary to written standards.[49] Credentialing in each ultrasound application relevant to the individual clinician can be pursued in accordance with local hospital credentialing policies.

Although no specific number of clinical ultrasound scans can guarantee individual competence in each ultrasound application, it is recommended that each clinician perform 25 (range 25-50) exams of each application for which privileges are being requested, a minimum of 150-300 general scans, 5% of which should demonstrate pathology.[10,50,51]

During this proctored period, 100% exams should be evaluated by quality assurance by appropriately credentialed providers with advanced training and/or demonstrated competency in ultrasound and should be based on the four basic competencies. This proctored quality review can be performed at the bedside, or remotely. Alternatively, a training portfolio of exams and results may be compared to other diagnostic studies of choice which also answer the clinical question being asked. A final option is to compare clinical outcomes, for example a soft tissue skin infection is drained and improves, a peripheral IV line flushes and draws.

After initial training, continued quality assurance of exams is recommended to document continued competency. Ultrasound-guided procedures should be directly supervised a minimum of five to ten times to ensure competency in each specific ultrasound-guided procedural application.[10]

APPs should follow their collaborating physician specialty specific guidelines or constituent organization guidelines as they relate to credentialing in clinical ultrasound, unless these guidelines are overly restrictive in terms of limiting the employment of a skill in which the APP is trained. In specialties where no credentialing guidelines currently exist, this document should serve as a guideline for outlining proficiency standards to local credentialing bodies.

The pathway in this document will provide local hospital credentialing committees with reassurance that clinicians have met rigorous quality assurance standards, and can safely and effectively employ bedside ultrasound for the benefit of patients without surrendering training and competency standards to external entities which could impede the employment of clinical ultrasound, and thus adversely affect patient care.[10,46]

## Section 7 - Clinical Ultrasound Models of Practice

The model of practice is a description of the role of clinical ultrasound, as employed by individual providers in a particular clinical practice setting. The specific model of practice adopted will therefore depend primarily on the individual clinician's practice setting and the numerous variables that differentiate it from other practice settings.[52] Variables to be considered when defining a model of practice may be static or dynamic. Static variables rarely change or are beyond the control of the provider.

Examples of static variables include:

- state practice laws
- local culture
- the burden of disease
- medical specialty
- patient population

Dynamic variables, conversely, are within the control of the provider performing clinical ultrasound and are easier to influence. Examples of dynamic variables include:

- the skill and the experience of the clinician
- the skill and experience of the collaborating physician
- the relationship of the clinician and collaborating physician, and consultants
- the institutional culture
- the capabilities of the ultrasound equipment
- the availability of practice resources
- the location of the patient
- the patient's condition

A clearly defined model of practice is key to the successful implementation of any clinical ultrasound program. The model should also be clearly understood by all involved parties prior to adoption and implementation of an ultrasound program. The concept of a "model of practice" is not intended to be narrowly described, but rather, it is best described in very broad, over-arching terms at the national level, allowing it to be more specifically defined at the individual practice level by the primary stakeholders. It is at the practice level that clinicians and have the most accurate picture of their practice setting and its variables, and are therefore most capable to create a model of practice which, given the aforementioned variables, best serves their patients.

## Section 8 - Skill Sustainment

Clinical ultrasound is a skill which requires regular performance in order to maintain proficiency.[53] An ultrasound training program must therefore include a system which allows for the sustainment of skills beyond introductory training and proctoring. Once competent, there is no minimum number of ultrasound exams that can guarantee sustained proficiency, therefore clinicians should strive to regularly perform every application the clinician is privileged to perform. Skill sustainment requires all the applications the provider is privileged to perform be a regular part of the clinician's practice, with skills evaluated semi-annually in conjunction with standard two year credentialing re-appointment process. If the infrequently used CUS application remains an underutilized skill, the clinician should not request bedside ultrasound privileging without adequate documentation of performance of exams.

It is recommended that a certain percentage (i.e. 5%) of required continuing medical education (CME) credits achieved per CME cycle be on topics related to point-of-care ultrasound.[10]

## Section 9 - Leadership/Advocacy

Regardless of the size of the facility employing clinical ultrasound or the number of ultrasounds performed, a structured program with designated leadership is needed to drive the process, ensure quality review, mentor participants, and promote education. This formal structure is the Clinical Ultrasound Program (CUSP). The director and deputy director of the institution's CUSP is responsible for executing the day to day operations for the program's overall success.

This includes, but is not limited to, ensuring that appropriate clinical services are provided, continuing educational and credentialing requirements are met, and implementing Phase II Proctored Scanning requirements for providers seeking to attain proficiency. In addition, the director will ensure that support services are sufficient, and that the practice employs an ongoing effective and robust quality assurance program. Leadership is additionally responsible for the maintenance of the equipment, the economic health of the program as well as the development and mentorship of less experienced clinical sonographers in the organization.

In educational settings the CUSP director is the primary point of contact to ensure that the students, dean, educational program director, curriculum committee, and the clinical coordinator have the necessary resources needed to integrate quality clinical ultrasound education into the curriculum

and coordinate ultrasound education with topics that parallel and compliment the traditional core content.

Just as with competency in clinical ultrasound, leadership is often independent of degree or title, and SPOCUS supports the concept that the most experienced and willing ultrasound clinician should be afforded the opportunity to participate in the development and sustainment of the CUSP. Furthermore, and while recognizing the value of interprofessional collaboration, appropriately trained and qualified APPs should be considered for inclusion in the leadership team, and may be suited for the role of director or deputy director of the organization's CUSP. Preparation suited for leadership roles includes mastery of clinical ultrasound applications specific to the organization's practice and a clinical ultrasound leadership course, or completion of a clinical ultrasound fellowship. SPOCUS believes that appropriately-trained APPs may be fully capable to assume leadership positions and champion clinical ultrasound programs in their local facilities and academic programs, particularly in PA programs and undergraduate medical education. APPs who are fellowship trained, experienced in clinical ultrasound through clinical practice or have experience teaching and lecturing on clinical ultrasound topics may be the most experienced sonographers in their organizations, practices, programs and facilities. Practicing APPs who were sonography technologists prior to attending their PA programs may represent an underutilized resource and may help develop clinical ultrasound programs in their facilities. All of these APPs should be actively engaged by the organizational leadership to participate in all efforts which increase patient access to the benefits of clinical ultrasound.

Advocacy, particularly at the national level amongst key organizations, represents an excellent opportunity to eliminate barriers to the integration of clinical ultrasound into medical education and clinical practice. SPOCUS supports and advocates for the concept of implementation of formal bedside ultrasound training for clinicians and for increasing training opportunities for providers, particularly opportunities such as fellowships.

Allowing all clinicians to complete such training will be crucial in the development of leaders in the clinical ultrasound realm who can serve as ambassadors to organizations such as the American Institute of Ultrasound in Medicine (AIUM), The World Interactive Network Focused on Critical Ultrasound (WINFOCUS), The Society of Ultrasound in Medical Education (SUSME) and ACEP. Fostering strong working relationships with such organizations can facilitate the adoption and recognition of policies which are inclusive and supportive of all clinicians utilizing ultrasound. Such policies will be vitally important in supporting ultrasound as a ubiquitous part of clinical practice.

With the goal of competency and a clear path to local credentialing, endorsement by sister organizations as well as support from/collaboration between constituent specialty organizations is key. These organizations are instrumental to the support and development of specialty specific clinical practice guidelines, competency standards and educational goals, as well as future credentialing pathway recommendations. The creation of ultrasound subcommittees within specialty organizations should also be encouraged and supported. The specialty organization ultrasound subcommittees will facilitate communication, the exchange of ideas and provide a channel where clinicians of multiple specialties can easily collaborate.

Lastly, it is imperative that professional organizations foster the development and execution of clinical research which continues to validate safe and effective employment of ultrasound. Rigorous and well-designed studies will be crucial in providing evidence to professional organizations that may be

unsupportive of the integration of bedside ultrasound as a safe and effective tool for all providers to utilize in their clinical practices.

## Section 10 - Quality Assurance/Performance Improvement

Quality control is key to improving standardization and safety of clinical ultrasound applications. In order to ensure quality, facilitate education, and satisfy credentialing pathways, a clinical ultrasound quality assurance (QA) and quality improvement (QI) program should be present. Parameters to be evaluated might include image resolution, anatomic definition, and other image quality acquisition aspects such as gain, depth, orientation, and focus. In addition, the QI system should compare the impression from the clinical ultrasound interpretation to patient outcome measures such as consultative US, other imaging modalities, surgical procedures, or patient clinical outcomes.

The QA program should have a mechanism in place to notify patients of misreads or errors which are discovered during the QA process or by incidental finding from other studies. This includes a mechanism to document the findings in the patient's medical record.

The QI system design places patient safety above all other factors, while maintaining competency and striving to provide timely feedback to clinicians. Balancing quality of review with timely feedback is a key part of QI process design. Any system design should have a data storage component that enables data and image recall. Due to the varieties of practice settings the percentage of scans undergoing quality assurance review should be determined at the practice level by the CUSP director and the facility medical director. While this number can vary, a goal of 5-10% may be reasonable, adjusted for the experience of the providers and newness of the US application in that department.[(10)]

## Section 11 - Value and Safety of Clinical Ultrasound

### Value of Clinical Ultrasound

There is increased concern in today's healthcare environment regarding the adverse effects caused by overutilization of computed tomography (CT). CUS has shown to be an effective tool to minimize radiation exposure in patients with suspected conditions that have been traditionally evaluated with CT, and to decrease patient wait times.12-14 Additionally, in today's world of increased healthcare costs and demand, bedside ultrasound has been shown to be a cost-effective tool in the clinical evaluation and management of patients.[(16)]

### Safety of Clinical Ultrasound

Although ultrasound is associated with increased temperature and cavitation of tissue, these effects rarely occur when ultrasound used at energy levels and lengths of time typical for diagnostic medical sonography. A recent paper suggested a link between autism and exposure to first trimester ultrasound.54 However, this study was poorly designed and no causal link was found, as outlined by the AIUM Bioeffects Committee.[(55)]

Clinical ultrasound is safe when performed only when medically indicated, by properly trained and credentialed clinicians using the ALARA (As Low As Reasonably Achievable) principle. This principle

refers to the lowest energy intensity level and length of scanning time required to make an accurate sonographic diagnosis or to complete an ultrasound-guided procedure.

**Incidental Findings**

An incidental finding is an asymptomatic observation made by the clinician which is outside of the clinical question under interrogation. Such findings may create unnecessary medical burden or even harm as well as the potential for curative benefit. Therefore incidental findings should be communicated to the patient or follow-up provider.[56]The patient should be informed of the risks, and the provided discharge instructions should reflect any specific issues regarding US findings in the context of the diagnosis. If the incidental finding is from a live model teaching session, the scans should be secured and stored for future reference, and the model should be provided with a copy of the images.[57]

## Section 12 -Documentation Requirements

**Medical necessity**

Ultrasounds must have documented medical necessity or study indications, with a written order from the provider, and meet the requirements of completeness for the specific Current Procedural Terminology (CPT) code that is billed.

**Written Interpretation**

Clinical ultrasound exams are immediately interpreted and the findings should be immediately communicated to providers, consultants, and other members of the patient care team by a separate written report. This interpretation should be maintained in the patient's medical record.

The report should include:

1. Date and time of examination.
2. Name and hospital identification number of the patient.
3. Patient age, date of birth, and sex.
4. Name of the person who performed and/or interpreted the study, clinical findings.
5. Indication for the study, the scope (complete vs limited), and if this is a repeat study by the same provider, repeat by a different provider, or reduced level of service.
6. Impression (including when a study is non-diagnostic) and differential diagnosis, as well as the need for follow on exams and incidental findings.
7. Mode of archiving the data (where can the images be found to be viewed).[11]

Expediency in placing handwritten, transcribed, templated, or computerized reports into the medical record facilitates communication within the healthcare team. It also improves patient management and is vital to the peer review and quality assurance process.

In the case of ultrasound guided procedures, the procedure report may be filed as a separate item in the patient’s record or it may be included within the report of the procedure for which the guidance is utilized.

## Image Capture

All clinical ultrasound examinations should have the orienting anatomy labeled and must have permanently recorded images maintained in the patient record. Procedural ultrasounds should have anatomy labeled and the point of interest captured. However, special care should be made to avoid compromising patient safety with the distraction of attempting to capture images while placing a needle in a critical location. Therefore, it is permissible to capture an image when it is safest for the patient, for example an image of an intravenous catheter in the lumen of the vein. The procedure note should reflect the needle was guided under direct visualization of ultrasound.

The stored images do not need to be submitted with the claim, however documentation of the study must be available to the insurer upon request. Images can be stored as printed or digital images. Current practice suggests capturing one image in each orthogonal plane of each relevant structure and/or in the case of echocardiograph, one image of each of the classic windows and levels.[58]

## Section 13- Billing and Reimbursement

Diagnostic and procedural ultrasound performed by clinicians should be coded and reimbursed in the same manner as any other procedure which is performed in the course of the patient's care, using Current Procedure Terminology (CPT) codes. The CPT code and the modifier that most accurately describes the ultrasound exam/procedure performed should be included in the documentation. It is essential to verify each payer's specific payment and coverage policy through the payer or the local CMS representative.

Nearly all payers, including Medicare and Medicaid, cover medical and surgical services provided by APPs, in accordance with state law. The services are submitted/billed under the name of the clinician or under the name of the physician depending on payer policy. It is essential to verify each payer's specific payment and coverage policy for providers.

Specific to PA practice, Medicare pays the PA's employer for medical and surgical services provided by PAs in all settings at 85 percent of the physician fee schedule. These settings include hospitals (inpatient, outpatient, operating room and emergency departments), nursing facilities, offices, clinics, the patient's home and for first assisting at surgery. In certain circumstances, evaluation and management services provided by PAs may be billed under the physician's name and provider number by meeting Medicare's "incident to" or shared visit billing guidelines. Medicare authorizes PAs to personally provide all diagnostic services and requires that those services be billed under the PA.

Commercial insurers do not necessarily follow Medicare policies regarding reimbursement amounts and coverage rules, but are similar to Medicare in that services are billed either under the PA's name or the collaborating physician's name. Always obtain local payer requirements to ensure proper billing.

Generally, clinicians are covered when performing diagnostic ultrasound or using ultrasound guidance during the performance of a procedure, as authorized by state law. Depending on the particular imaging requirement, the location of the service and other factors, there may be a distinction between the technical component (TC) and professional component (PC) of ultrasound utilization. When

appropriate, clinicians may report a global service (PC and TC combined) or either the PC or TC, based on the service(s) delivered.

All clinicians must meet applicable payer guidelines for medical necessity, coverage policy and documentation requirements to obtain reimbursement for their services. In addition, PAs and physicians use the same International Classification of Diseases or ICD codes and Current Procedure Terminology or CPT codes and modifiers to report and describe the services they render.

## Section 14 – Conclusion

Clinical ultrasound represents a bedside adjunct which is increasingly being utilized by a variety of clinicians in multiple care settings, but remains underutilized. Clinical ultrasound is a skill well within the scope of practice of appropriately trained clinicians. Because there are unique advantages that ultrasound offers during the bedside evaluation of patients, SPOCUS will remain vigilant to potential barriers that may impede the safe incorporation of clinical ultrasound into clinical practice, while ensuring that adequate measures are in place to evaluate and ensure providers are competently utilizing clinical ultrasound.

A goal of this document is to provide local hospital credentialing committees with reassurance that clinicians, having met the standards established in this document, can safely and effectively employ bedside ultrasound for the benefit of patients. The utilization of clinical ultrasound has great potential to enhance the care provided by clinicians, contribute to patient safety, reduce unnecessary medical testing, and enhance clinical decision making of providers practicing across the clinical spectrum, and ultimately represents yet another tool that can ensure our patients continue to receive the high-quality and high-value care that they deserve.

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