

Guidelines for the Appropriate Use of Bedside General and Cardiac Ultrasonography in the Evaluation of Critically III Patients—Part I: General Ultrasonography

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The American College of Critical Care Medicine (ACCM), which honors individuals for their achievements and contributions to multidisciplinary critical care medicine, is the consultative body of the Society of Critical Care Medicine (SCCM) that possesses recognized expertise in the practice of critical care. The College has developed administrative guidelines and clinical practice parameters for the critical care practitioner. New guidelines and practice parameters are continually developed, and current ones are systematically reviewed and revised.

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Dr. Frankel disclosed participation with another healthcare professional organization (ACS and AAST Board). Dr. Kirkpatrick disclosed a relationship with the maker of healthcare product (he received a NanoMaxx ultrasound unit for research purposes from the Sonosite); he received travel assistance from the Lifecell and Syntheses to attend Cadaver laboratories; he served on the Advisory Board for Ultrasound contrast media from the Lanthes over 5 years ago; and he disclosed participation in other healthcare professional organizations (President elect of the WSACS, Scientific Committee Member of WINFOCUS, past Pres of TAC). His institution received unrestricted funding for an RCT of open abdomen Mgt from the KCI. Dr. Elbarbary disclosed participation in another healthcare professional organization (board member and guideline committee chair for WINFOCUS organization). Dr. Blaivas disclosed a relationship with a healthcare provider (consultant for Sonosim) and disclosed participation in other healthcare professional organizations (ACEP, AIUM Third Vice President, SUSME President). Dr. Slonim disclosed consulting for Saint Judes and a relationship with provider of healthcare service (Saint Judes/AHRQ/NSF; ACPE-Board Member). Dr. Breitkreutz disclosed a relationship with makers of healthcare products (Consultant Fujifilm SonoSite, Consultant fees from GE, Ezono), disclosed a relationship with providers of healthcare services (Research Grant recipient, Binz-Stiftung, Ulm, Ultrasound Regional Network in Critical Care, http://www. SonoABCD.org), participates in healthcare professional organizations (DEGUM, WINFOCUS, ESICM, DIVI, and DGINA), disclosed a financial relationship with manufacturers of products/providers of services (consultant Fujifilm SonoSite; served as an expert witness). Dr. Price disclosed a relationship with Medtronic, Educational contract, valvular heart disease; Abbott Medical-medical advisory board MitraClip; board member, European Society of Cardiology Acute cardiac care, Education committee member (ESC); and CPC ESC, education committee British Society of Echocardiography, resuscitation Council UK (all cardiology). Dr. Talmor received research grant support from the Moore Foundation and disclosed participation in other healthcare professional organizations (ATS, ASA). Dr. Levitov disclosed participation in other healthcare organizations (AIUM clinical standard committee SUSME board member). The remaining authors have disclosed that they do not have any potential conflicts of interest.

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Objective: To establish evidence-based guidelines for the use of bedside ultrasound by intensivists and specialists in the ICU and equivalent care sites for diagnostic and therapeutic purposes for organs of the chest, abdomen, pelvis, neck, and extremities.

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Methods: The Grading of Recommendations, Assessment, Development and Evaluation system was used to determine the strength of recommendations as either strong or conditional/weak and to rank the "levels" of quality of evidence into high (A), moderate (B), or low (C) and thus generating six "grades" of recommendation (1A-1B-1C-2A-2B-2C). Grading of Recommendations, Assessment, Development and Evaluation (GRADE) was used for all questions with clinically relevant outcomes. RAND appropriateness method, incorporating modified Delphi technique, was used in steps of GRADE that required panel judgment and for those based purely on expert consensus. The process was conducted by teleconference and electronic-based discussion, following clear rules for establishing consensus and agreement/disagreement. Individual panel members provided full disclosure and were judged to be free of any commercial bias. The process was conducted independent of industry funding.

Results: Twenty-four statements regarding the use of ultrasound were considered-three did not achieve agreement and nine were approved as conditional recommendations (strength class 2). The remaining 12 statements were approved as strong recommendations (strength class 1). Each recommendation was also linked to its level of quality of evidence. Key strong recommendations included the use of ultrasonography for ruling-in pleural effusion and assisting its drainage, ascites drainage, ruling-in pneumothorax, central venous cannulation, particularly for internal jugular and femoral sites, and for diagnosis of deep venous thrombosis. Conditional recommendations were given to the use of ultrasound by the intensivist for diagnosis of acalculous cholecystitis, renal failure, and interstitial and parenchymal lung diseases. No recommendations were made regarding static (vs dynamic) ultrasound guidance of vascular access or the use of needle guide devices.

Conclusions: There was strong agreement among a large cohort of international experts regarding several recommendations for the use of ultrasound in the ICU. Evidence-based recommendations regarding the appropriate use of this technology are a step toward improving patient outcomes in relevant patients. (*Crit Care Med* 2015; 43:2479–2502)

Key Words: critical care; evidence-based medicine; GRADE; guidelines; RAND appropriateness method; sonography; thoracentesis; ultrasound; vascular access

iagnostic and therapeutic ultrasound are a rapidly evolving imaging modality that has achieved greater traction in the ICU environment recently, in part, due to the availability of less expensive and more portable ultrasound machines (1–6). As intensivists and ICU specialists continue to adopt this technology more broadly, there is a need to assure an evidencebased approach in applying these techniques at the bedside.

Guidelines for ultrasound education, credentialing, and competence exist throughout the world. Several organizations have rendered recommendations regarding the use of ultrasound in heterogeneous settings governing a diverse range of applications that are not particular to the ICU (7–11). However, comprehensive, evidence-based guidelines regarding the appropriate clinical use of both general and cardiac ultrasonography specifically in ICU settings are deficient.

To help provide guidance to the ICU practitioner contemplating the use of bedside ultrasound for diagnostic or therapeutic purposes, we established a series of evidence-based recommendations that address the suitability or superiority of bedside ultrasound for a variety of indications as an adjunct to clinical judgment in caring for the critically ill patient (and when additional or alternate imaging is preferable). Unless otherwise specified, these guidelines refer to the adult critically ill or injured patient. Several recommendations are made regarding pediatric patients, as well, when data are sufficient to render these judgments.

Recommendations from these guidelines must be used in context of the clinical picture and should not supersede judgment. This document sets forth recommendations underpinned by evidence of varied quality but does not aim to define the standard of care. This is in spite of the fact that the guidelines do offer several recommendations based on high-quality evidence. Unlike guidelines based on delivering therapy or performing automated diagnostic tests, we acknowledge that the present work addresses the performance of technical tasks by humans with variable degrees of proficiency. In this document, we assume that practitioners of ultrasound, be they intensivists or not, are suitably trained and competent in the technical and interpretative components of the relevant examination. It is beyond the scope to these guidelines to describe in detail the elements of training and competency. The Society of Critical Care Medicine and others have developed language and recommendations to further define parameters for training and competence elsewhere (12). However, we do address the use of ultrasound for novice versus experienced providers where those data exist.

Furthermore, it is clear that the use of ICU ultrasound is quite a dynamic field. We have developed these guidelines based on current evidence. It is quite possible, even probable, that the use of ICU ultrasound (and what diagnostic and therapeutic procedures the intensivist can and should be expected to perform) will continue to evolve.

METHODS

Disclosures

There were no members of the committee from industry nor was there industry input into the development of the guidelines or industry presence at any meetings. No member of the guideline committee received honoraria for participation. Full disclosure of all committee members' potential conflicts at time of deliberation and publication was provided.

Approach

There were two plenary sessions of the writing committee group leaders to establish the content. Then guidelines process followed combined Grading of Recommendations, Assessment, Development and Evaluation (GRADE) and RAND appropriateness method. RAM included modified Delphi method, teleconferences, and several subsequent meetings (including electronically) of subgroups.

Scientific Questions

Clinical questions related to the use of bedside ultrasound were established by the writing group for subsequent discussion, grading of evidence by a methodologist, and then voting on the overall appropriateness of the recommendation. The questions generated statements that constituted draft recommendations during the process of guideline development. (Statements can be approved and become formal recommendations or be disapproved and never reach that stage. Also, during the writing phase, it is possible to combine two or more approved statements into one recommendation.) The questions and statements related to the use of ultrasound exclusive of echocardiography are presented herein as part I of the guidelines; those related to bedside echocardiography form the basis of part II of the guidelines. In areas where the recommendation for the use of ultrasound by any provider (generally a sonographer interpreted by a radiologist) might be discordant with the use of ultrasound by an intensivist or critical care provider per se, separate recommendations were made (e.g., certain abdominal ultrasound examinations and deep venous thrombosis [DVT] screening). The panel recognizes that, over time, as experience with ultrasound by intensivists broadens, this distinction may no longer be necessary. Furthermore, the guiding principle of point of care ultrasound is that it is performed and interpreted by the physician at the bedside.

Systematic Evidence Search

A thorough systematic evidence search was done for each question/statement. This included English and translated literature. Literature related to the use of ultrasound in the ICU setting was the primary focus. If high-quality evidence was present (i.e., randomized controlled trials [RCTs] with large number of patients and no significant downgrading factors), then lower level evidence (i.e., case series) was not included. If no appropriate literature with ICU patients was available, that involving patients in all other appropriate areas such as the emergency department (ED) was considered if patients were considered equivalent. After the comprehensive literature search by the writing committee, the methodologist performed a secondary search and additional articles were included if appropriate.

Expert Panel Formulation

The panel was selected by the chair of the guidelines subcommittee for parts I and II of the guidelines (first author

TABLE 1. Levels of Quality of Evidence

in each). Members were selected to represent the different constituencies of the Society of Critical Care Medicine—i.e., surgical, medical, and anesthesia intensivists. In addition, the panel included an Emergency Medicine physician (M.B.) as much related and relevant literature and clinical experience in general and cardiac ultrasound exists in this field. A methodologist and intensivist (M.E.) supported the groups.

Development of Consensus and Clinical Recommendations

Electronic discussions and meetings occurred among subgroup members to generate the final recommendations presented. GRADE method was used to develop these evidence-based recommendations (13). The process involves two phases: 1) developing the recommendation and 2) determining the level of quality of evidence. Relevant articles with clinical outcomes were classified into three levels of quality based on the criteria of the GRADE methodology (**Table 1**). This was done using GRADEpro Software (http://www.gradepro.org; McMaster University). It assesses nine quality factors including study design with five potential downgraders and three possible upgraders (**Table 2**, section B).

RAM was used within the GRADE steps that required panel judgment and decisions/consensus. RAM was also used in formulating the recommendations based purely on expert consensus. Recommendations were generated in two classes: strong (class 1) or weak/conditional (class 2) based on the GRADE criteria taking into consideration preset rules that defined the panel consensus/agreement and its degree. The transformation of evidence into recommendation depends not only on the level of quality of evidence but also on the panel's judgment on problem priority/importance, benefit/burden balance, and benefit/harm balance, and certainty/concern about four issues: preferences of patients, equity, acceptability, and feasibility as shown in Table 2, section C. Combining the strength of recommendations, strong (1) or conditional/weak (2) with the "levels" of quality of evidence high (A), moderate (B), or low (C) will eventually generate six possible "grades" of recommendations (1A-1B-1C-2A-2B-2C). For example, a 1C recommendation means that although there is a lack of quality of evidence, the recommendation is strong based on expert consensus. Conversely, a 2A indicates a weak recommendation due to consideration of transformative factors (Table 2, section C) despite high-quality evidence.

Level	Points ^a	Quality	Interpretation
А	≥ 4	High	Further research is very unlikely to change our confidence in the estimate of effect or accuracy
В	=3	Moderate	Further research is likely to have an important impact on our confidence in the estimate of effect or accuracy and may change the estimate
С	≤2	Low ^b	Further research is very likely to have an important impact on our confidence in the estimate of effect or accuracy and is likely to change the estimate or any estimate of effect or accuracy is very uncertain (very low)

^aPoints are calculated based on the nine GRADE = Grading of Recommendations, Assessment, Development and Evaluation quality factors (Table 2, section B). ^bLevel C = can be divided into low (points = 2) and very low (points = 1).

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Section A	Critical	Important	Loss important	Not important
Section A	Citical	Important	Less important	
Factor 1 Outcome factor				
Section B	study design as Quality starting factor ^a	Quality of evidence	The 5 downgraders Quality is lowered if:	The 3 upgraders Quality is raised if:
The 9 GRADE quality factors	RCT = 4	A = high = 4 Points	Risk of Bias⁵ −1 Serious −2 Very serious	Large effect + 1 Large + 2 Very large
		B = moderate = 3 Points	<i>Inconsistency</i> −1 Serious −2 Very serious	Dose response + 1 Evidence of a gradient
	Observational studies = 2	C = low ^c = 2 Points	<i>Indirectness</i> −1 Serious −2 Very serious	 Antagonistic bias + 1 All plausible confounding would reduce the effect,
		D = very low ^c = 1 Points	Imprecision -1 Serious -2 Very serious	or + 1 Would suggest a spurious effect when results show no effect
			Publication bias −1 Likely −2 Very likely	
	Total Points			
Section C	Problem priority/ importance	Critical	Important	Less important
The 5 GRADE	Overall quality of evidence	High	Moderate	Low
transformers	Benefit/harm balance	Favorable	Uncertain	Unfavorable
	Benefit/burden balance	Favorable	Uncertain	Unfavorable
	Certainty/Concerns about PEAF (Preference- Equity-Acceptability- Feasibility)	Certain	Uncertain	Concerned

TABLE 2. The 15-Grade Factors

GRADE = Grading of Recommendations, Assessment, Development, and Evaluation; RCT = randomized controlled trials.

^aBased on the design, the evidence will qualify for 4 points (if RCT) or 2 points (if observational) then points will move down by 1 or 2 points (by downgraders) or up (by upgraders) if applicable as indicated in the table.

^bRisk of bias in diagnostic accuracy studies using QUADAS-2 criteria while in diagnostic strategies/effectiveness the risk of bias to be assessed using Cochrane criteria.

°Low and very low levels of quality of evidence can be combined in one level (if total points \leq 2)

^aThe voting on the 5 transformers (from evidence-to-recommendation) and the voting on appropriateness of the draft recommendations to be done using 9-points Likert's scale. More details in *Method* section and Appendix 1.

The RAM process included a modified Delphi method in a consensus conference and several subsequent meetings of subgroups. There were two plenary sessions of the writing committee group leaders to establish the content. Electronic discussions occurred among subgroup members to generate the final grading presented. A strong recommendation is worded as "we recommend," whereas a conditional/weak recommendation as "we suggest" (**Table 3**).

The implication of strong versus weak/conditional recommendation is explained in **Table 4**. The list of the most relevant literature reference is provided for each recommendation and is limited to no more than 10 articles. Differences in opinion were resolved using a set of rules previously described in development of the Surviving Sepsis guidelines (14). Recommendations rendered required more than 70% of committee support. Strong recommendations required at least an 80% majority following the previously validated RAND algorithm (**Fig. 1** and **Appendix 1**) (15).

Guidelines are based on the notion that any bedside ultrasound information is complimentary to physical examination and intensivist clinical judgment and therefore organized around most common suspected ICU diagnoses. Guidelines for repeat examinations are predicated on significance of the change in patient condition or to follow the outcome of a therapeutic intervention.

TABLE 3. Wording Based on Degree of Consensus and Strength of Recommendations

Degree of Consensus	Strength of Recommendation	Wording
Perfect consensus	Strong	Recommend: must/to be/will
Very good consensus	Strong	Recommend: should be/can
Good consensus	Conditional (weak)	Suggest: may be/may
Some consensus	Conditional (weak)	Suggest: may be
No consensus or disagreement	No	No recommendation was made regarding

Rules of RAND appropriateness method that determines the agreement and/or degree of consensus are explained in Appendix 1 and in Figure 1.

TABLE 4. Implications of the Strong and Weak Recommendations in the Grades of Recommendation, Assessment, Development and Evaluation Method

User	Strong Recommendations	Weak (Conditional) Recommendations
Clinicians	Most patients should be offered to receive the recommendation as the most appropriate option	Recognize that different options should be offered as all will be appropriate options for different patients
Policy makers	The recommendation can be adopted as a policy in most situations	Should not be considered as a standard of care
Patient	Most patients in similar condition would accept the recommendation and only a few would not	Expected variability among different patients with your condition to choose or reject the recommendations

RESULTS

Table 5 is the summary of finding (SoF) tables for a few specific recommendations. There are no SoF tables provided for domains based on only expert opinion or for those domains with no recommendations. **Table 6** summarizes the level of evidence and the strength of recommendation for each recommendation. The numbers 1 or 2 indicate the strength: strong or conditional recommendation, respectively; whereas the letters A, B, and C indicate the level of quality of evidence as explained previously.

I. NONCARDIAC THORACIC IMAGING

A. Pleural Effusion

1. Suitability of ultrasound to establish the diagnosis and assist in drainage:

- We recommend that ultrasound should be used to complement physical examination and conventional chest radiography to diagnose and localize a pleural effusion. Grade 1A.
- We recommend that ultrasound guidance should be used to assist in drainage (including needle guidance), particularly of small or loculated effusions compared with landmark technique. Grade 1B.
- We have no recommendation regarding the preference to use of either static or dynamic technique to do so.

Rationale: The sensitivity, specificity, and accuracy of ultrasound to diagnose a pleural effusion are about 84%, 100%, and 94%, respectively, comparable with, or better than, conventional chest radiography noted in a series of surgical ICU patients (16). Thus, the use of ultrasound may be beneficial to rule in but not to rule out or exclude an effusion. Other data

indicate a favorable accuracy (nearly 100%) compared with chest CT (17). Furthermore, complications (pneumothorax, failure to acquire fluid) associated with draining large pleural effusions were decreased from 33 or 50% to 0% when they were drained using ultrasound guidance, further reinforced by a meta-analysis (18, 19). Loculated effusions and empyema may be less amenable to percutaneous ultrasound-guided drainage, but it may be easier to sample small effusions under ultrasound guidance (20–22). It is also possible to use bedside ultrasound to accurately quantify the volume of a pleural effusion (21, 23, 24). Although, in theory, real-time or dynamic imaging may yield better outcomes than static technique, there are no data in the critical care literature to support this contention. Furthermore, we acknowledge that in clear-cut cases of large pleural fluid collections any advantage will be quite small.

The sonographic features of a pleural effusion are basic and objective. Outcome and safety are optimized when imaging is performed in real-time, at the bedside and by the operator of the intervention. Appropriately trained intensivists can perform ultrasound-guided drainage with an acceptable complication profile (i.e., low prevalence of hemopneumothoraces) (21, 23–27). A large, prospective observational trial detailed a 1.3% complication rate in a series of over 200 patients versus 6.5% in a historical control as performed by radiologists (27). Due to the magnitude of this effect, the evidence level was upgraded during deliberation.

B. Diagnosis of Pneumothorax

• We recommend that ultrasound should be used to complement or replace conventional chest radiography to diagnose a pneumothorax, depending on the clinical setting and need for rapid results. Grade 1A.

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Figure 1. Assessment of voting results; algorithm for applying RAND rules on two rounds of voting (modified Delphi technique) for panel decision. Disagreement: if \geq 30% of panelists voted outside the zone of the median (Appendix 1).

TABLE 5. Summary of Findings Tables

We Recomn	We Recommend That Ultrasound Be Used to Complement Physical Examination and Conventional Chest Radiography to Rules In Pleural Effusion. Grade 1A (16–27)										
Quality Assessment Summary of Findings									idings		
Dial. Dublia				Dublication	Overall	Study I	Result				
Participants	of Bias	Inconsistency	Indirectness	Imprecision	Bias	Evidence	Sensitivity	Specificity	Accuracy		
Diagnostic accu	uracy										
140 exam cross- sectional study	No serious risk of bias	No serious inconsistency	No serious indirectness	Imprecision	Undetected	⊕⊕⊕⊕ High	83.6%	100%	94%		

Cross sectional is accepted high-quality design for diagnostic study (qualify four points); risk of bias done by quality assessment of diagnostic accuracy studies-2 criteria for diagnostic testing (28); the recommendation does not apply on ruling-out because the reported sensitivity is only 83.6%.

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We Recommend That Ultrasound-Guidance Be Used to Assist in Drainage (Including Needle Guidance), Particularly for Identification of Small or Loculated Effusions Compared With Landmark Technique. Grade 1B (16–27)											
	Summary of Findings										
	Diala					0	Stud	ly Result			
12 Studies	of Bias	Inconsistency	Indirectness	Imprecision	Publication Bias	Quality of Evidence	With Ultrasound	Without Ultrasound			
Complications											
52 procedures N randomized controlled trial	o serious risk of bias	No serious inconsistency	Indirectness	Imprecision	Undetected	⊕⊕⊕⊝ Moderate	0/19 (0%)	14/33 (24%)			
Rest observational											

Notes on the randomized controlled trial: small sample size and done on large effusion cases.

We Recommend That Ultrasound Be Used to Complement or Replace Conventional Chest Radiography to Diagnose a Pneumothorax, Depending on the Clinical Setting and Need for Rapid Results. Grade 1A (29–39)											
		Qua	lity Assessme	nt			Su	mmary of Fin	dings		
E:-44	Diele					Overall	Stud	y Result			
Studies	of Bias	Inconsistency	Indirectness	Imprecision	Bias	Evidence	Sensitivity	Specificity			
Diagnostic accur	асу										
Randomized controlled trial for strategy Cross sectional for diagnostic accuracy Misanalysis	No risk of bias	No serious inconsistency	No indirectness	No imprecision	Undetected	⊕⊕⊕⊕ High	89% 70%	99% ultrasound vs 96% chest radiograph	Ultrasound has LR 36–153		

When compared with chest radiograph widely reported sensitivities (49–100%), ultrasound was much higher (80–100%). In each of these studies and in the pooled estimate, the sensitivity of ultrasound was significantly higher than chest radiograph. Sonographic specificities were not significantly different from those of chest radiograph.

We Suggest	We Suggest That a Systematic Approach Incorporating Bedside Ultrasound May Be a Primary Diagnostic Modality for the ICU Patient With Respiratory Failure. Grade 2B (40–46)											
			Summary of Findings									
						Overall	Study	Result				
Seven Studies	Risk of Bias	Inconsistency	Indirectness	Imprecision	Bias	Evidence	Sensitivity	Specificity	Accuracy			
Diagnostic accu	iracy											
Cross sectional fo diagnostic accuracy	No risk r of bias	No serious inconsistency	Potential indirectness	No imprecision	Potential	⊕⊕⊕⊖ Moderate	90%	98%	90.5%			

High-quality cross-sectional study compared with CT scan (qualify four points); single group experience. Likely it cannot be reproduced except by highly skilled trained operators; downgraded for potential operator indirectness and potential publication bias.

(Continued)

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We Recommend That Ultrasound Guidance (vs Landmark Technique), Whether Real-Time or Preprocedure, Be Used to Determine the Optimal Location for Performance of Paracentesis. Grade 1B (47–49)											
Quality Assessment Sumn											
						Querell	Study Result				
Three Studies	Risk of Bias	Inconsistency	Indirectness	Imprecision	Publication Bias	Quality of Evidence	With Ultrasound	Without Ultrasound			
Success rate											
1 randomized controlled trial + 2 observational	No risk of bias	No serious inconsistency	No indirectness	Imprecision	Undetected	⊕⊕⊝⊝ Moderate	95%	61%			

Randomized controlled trial had no difference in complication rate. Low baseline risk of complications; downgraded in the outcome of complication for imprecision.

We Sug	We Suggest That Intensivists Not Personally Perform Ultrasound Primarily for the Diagnosis of Acute Cholecystitis. Grade 2B (50–53)											
		Summary of Findings										
	Dials of				Dublication	Overall	Study	Result				
Nine Studies	Bias	Inconsistency	Indirectness	Imprecision	Bias	Evidence	Sensitivity	specificity	Accuracy			
Diagnostic accu	iracy											
Meta-analysis (eight studies) cross sectional	No risk of bias	No serious inconsistency	Indirectness	No imprecisior	Undetected	⊕⊕⊕⊝ Moderate	89.8–96%	88–90%	90.5%			

The emergency department and ICU patient populations (with calculous vs acalculous cholecystitis) are not equivalent to allow for extrapolation. Downgraded for indirectness.

We Recommend That a Focused Ultrasound Technique Using Gray Scale Imaging to Evaluate Vein Compression at the Common Femoral and Popliteal Veins Is Sufficient to Diagnose Most Proximal Deep Venous Thrombosis (Compared With Contrast Venography). Grade 1B (54)										
Quality Assessment Summary of Findings										
	Diale					Overall Quality of Evidence	Study Result			
	of Bias	Inconsistency	Indirectness	Imprecision	Bias		Sensitivity	Specificity		
Diagnostic acc	curacy									
Cross sectional	No risk of bias	No serious inconsistency	Indirectness	Imprecision	Potential	⊕⊕⊕⊖ Moderate	91%	99%		

Downgraded for potential publication bias. No recent studies.

(Continued)

We Recommend That Intensivists Can Reliably Perform a Focused Screening Examination by Ultrasound to Diagnose Lower Extremity Proximal deep venous thrombosis. Grade 1B (55)											
Quality Assessment Summary of Findings											
	Dick				Dublication	Overall	Study Result				
	of Bias	Inconsistency	Indirectness	Imprecision	Bias	Evidence	Sensitivity	Specificity			
Diagnostic accurad	су										
Cross-sectional intensivist vs radiologist	No risk of bias	No serious inconsistency	Indirectness	Imprecision	Potential	⊕⊕⊕⊝ Moderate	86%	96%			

Downgraded for potential publication bias. Single study.

We Recommend That in Most Patients, the Use of Real-Time Ultrasound Is Preferred Over Static Preprocedure Marking. Grade 1B (56, 57)										
Quality Assessment										
Outcomes: no. of punctures, success rate, time, and complications										
No. of Studies	Design	Risk of Bias	Inconsistency	Indirectness	Imprecision	Other	Overall Quality of Evidence	Summary of Findings		
(56)	RCT	No	No	Yes	No	No	⊕⊕⊕⊕ High			
(57)	RCT	No	No	Yes	No	No	⊕⊕⊕⊕ High			

RCT = randomized controlled trial.

Illustrative Comparative				
Outcomes	Real Time Static <i>p</i>		(95% CI) p	Quality of the Evidence
Success rate				
(56)	53	3	< 0.006	High
(57)	100%	74%		

Effect expressed in odds ratio (OR). Large effect (OR = 53) qualifies for upgrading: (56) (adults); success defined as less than 3 punctures: (57) (infants). Overall quality was downgraded for indirectness as (56) was only for internal jugular cannulation and (57) was in infants.

Although	Although There Are Benefits to Visualizing the Vasculature in Both Short- and Long-Axis Images by Ultrasound, We Recommend That the Short-Axis View Be Used During Insertion to Improve Success Rate. Grade 1B (58–61)									
	Quality Assessment									
No of Studies	Design	Risk of Bias	Inconsistency	Indirectness	Imprecision	Other	Overall Quality of Evidence	Summary of Findings		
Outcomes:	no. of punctures, s	success rate, time	e, and complication	ns						
(58)	RCT	No	No	Yes	No	No	High			
(59)	RCT	No	No	Yes	No	No	Moderate			
(60)	RCT (models)	No	No	Yes	No	No	Moderate			
(61)	RCT (models)	No	No	Yes	No	No	Moderate			

RCT = randomized controlled trial.

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	Illustrative C	Comparative				
Outcomes	Short Axis	Long Axis	(95% CI) p	Quality of the Evidence		
Success						
(58)	98%	78%	< 0.006	High		
(59)	95%	85%	95% Cl, 95-100 vs 85-100			
			Pooled $p < 0.05$			
Time	39	46	ho > 0.05	High		
	34	91	p = 0.02			
			Pooled $p < 0.05$			
Complication	1	0	Pooled $p > 0.05$	Moderate		
	3	3				

Downgraded for indirectness as operating room setting and emergency department setting may be different from the ICU setting.

We Re	We Recommend That Conventional B-Mode Imaging to Assist in Vessel Cannulation Is Preferred Compared With Using Audible Doppler Only With No Imaging. Grade 2B (62)									
	Quality Assessment									
Studies	Design	Risk of Bias	Inconsistency	Indirectness	Imprecision	Other	Overall Quality of Evidence	Summary of Findings		
Outcome	Outcomes: no. of punctures, success rate, time, and complications									
(62)	Randomized controlled trial	No	No	Yes	No	No	High			

	Illustrative Comparative					
Outcomes	B-Mode	Doppler	(95% Cl) p	Quality of the Evidence		
Success						
(62): total	96.6%	91%				
(62): total body mass index	97.4%	77%	p < 0.05	High		

High-quality randomized controlled trial but downgraded on basis of indirectness as the large effect was found mostly in obese patients (body mass index > 30).

We	We Suggest That a Detailed Postcannulation Ultrasound Examination May Be Used (vs Conventional Chest Radiography) to Confirm Catheter Location and Exclude a Pneumothorax. Grade 2B (63, 64)									
	Quality Assessment Summary of Findings									
Two Studies	Risk of Bias	Inconsistency	Indirectness	Imprecision	Publication Bias	Overall Quality of Evidence	Study	Result	Accuracy	
Diagnos	tic accuracy	/								
(63)	No risk of bias	No serious inconsistency	Indirectness	No imprecision	Undetected	⊕⊕⊕⊖ Moderate	Positive predictive value, 83%	Negative predictive value, 91%	74–93%	
(64)	No risk of bias	No serious inconsistency	Indirectness	No imprecision	Undetected	⊕⊕⊕⊖ Moderate	Sensitivity, 96% %	Specificity, 93%		

The diagnostic accuracy drops markedly if pre-existing catheter is in place (63); The diagnostic accuracy is enhanced by contrast (64).

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We Recommend That Ultrasound-Guided Internal Jugular Venous Cannulation Should Be Used (vs Landmark Technique) to Improve Success Rate, Shorten Procedure Time and Reduce the Risk of Procedure-Related Complications in Adult Patients. Grade 1A (65–76)

	Summary of Findings						
12 Randomized Controlled Trials and Meta-Analysis	Risk of Bias	Inconsistency	Indirectness	Imprecision	Publication Bias	Overall Quality of Evidence	Relative Risk (95% Cl)
Success rate (important outcome)	No serious risk of bias	No inconsistency	No indirectness	No serious imprecision	Undetected	⊕⊕⊕⊕ High	0.14 (0.06–0.33)
Time	No serious risk of bias	No inconsistency	No indirectness	No serious imprecision	Undetected	⊕⊕⊕⊕ High	Ultrasound 17.1 ± 16.5 min vs no ultrasound 44 ± 95.4 min; $\rho < 0.001$
Complication	No serious risk of bias	No inconsistency	No indirectness	No serious imprecision	Undetected	⊕⊕⊕⊕ High (1)	0.43 (0.22–0.87)

We Recommend That Ultrasound Guidance (vs Landmark Technique) Be Used to Improve the Success Rate and Reduce Complications for Femoral Venous Cannulation. Grade 1A (77–80)

	Quality Assessment							
Randomized Controlled Trials and Observational	Risk of Bias	Inconsistency	Indirectness	Imprecision	Publication Bias	Overall Quality of Evidence	Effect (95% CI)	
Success rate (important outcome)	No serious risk of bias	No inconsistency	No indirectness	No serious imprecision	Undetected	⊕⊕⊕⊕ High	RR, 0.14 (0.06–0.33)	
Time	No serious risk of bias	No inconsistency	No indirectness	No serious imprecision	Undetected	⊕⊕⊕⊕ High	Ultrasound $17.1 \pm 16.5 \text{ min}$ vs no ultrasound $44 \pm 95.4 \text{ min};$ $\rho < 0.001$	
Complication	No serious risk of bias	No inconsistency	No indirectness	No serious imprecision	Undetected	⊕⊕⊕⊕ High	RR, 0.43 (0.22–0.87)	

RR = relative risk.

High-quality randomized controlled trials. Large effect. Meta-analysis reported; benefit more for novice operators.

We Suggest the Use of Ultrasound Guidance (vs Landmark Technique) to Improve the Success Rate and Diminish Complications During Peripheral Venous Catheterization. Grade 2B (81-85) **Quality Assessment Summary of Findings** Study Result Overall Risk Publication Quality of With Without **Five Studies** of Bias Evidence **Ultrasound Ultrasound** Inconsistency Indirectness Imprecision Bias Outcomes: no. of punctures, success rate, time, and complications All in favor of ultrasound Five randomized No risk of No serious No indirectness No imprecision Undetected $\oplus \oplus \oplus \ominus$ controlled bias inconsistency High (1) with significant trial difference in reported outcomes

(Continued)

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	Illustrative	Illustrative Comparative					
Outcomes (80)	Ultrasound	No Ultrasound	(95% CI) P				
Success	97%	33%	< 0.05				
Time (s)	13	30	< 0.05				
Trials (no. of attempts)	1.7	3.7	< 0.05				

Downgraded for indirectness as the technique is mostly useful in difficult patients such as infants, obese, and hemodynamically unstable patients and/or when previous unsuccessful attempts have been performed.

We Suggest the Use of Ultrasound Guidance (vs Landmark Technique) to Improve the Success Rate and Diminish Complications During Arterial Catheterization. Grade 2B (86–91)

Quality Assessment						Summary	of Findings	
						Overall	Study Result	
Six Studies	Risk of Publication Qu s Bias Inconsistency Indirectness Imprecision Bias E	Quality of Evidence	With Ultrasound	Without Ultrasound				
Nine randomized controlled trial 5+4 in meta- analysis	No risk of bias	No serious inconsistency	No indirectness	No imprecision	Undetected	⊕⊕⊕⊕ High	All in favor of u significant d reported out	Iltrasound with ifference in comes

	Illustrative Comparat	ive	(95% CI)
Outcomes	Ultrasound	No Ultrasound	p
Success	Adult: 87%	62%	< 0.05
	Ped: 67%	14%	
Time (s)	136	148	< 0.05
First attempt	71% improvement over control (relative risk, 1.7)		< 0.05

Downgraded for indirectness as the technique is mostly useful in difficult patients such as infants, obese, and hemodynamically patients and/or when previous unsuccessful attempts have been performed.

Rationale: The sensitivity and specificity of ultrasound to diagnose a pneumothorax (by loss of lung sliding and absence of comet tail artifacts and a lung pulse and the presence of a lung point) exceed 85%, compared with approximately 30-75% for conventional radiography in both ED and ICU patients (29-36). Visualization of a comet tail reliably excludes a pneumothorax, whereas demonstration of a lung point without lung sliding invariably confirms the diagnosis. The absence of lung sliding alone can occur with pathology other than a pneumothorax (e.g., atelectasis, consolidation, or lung contusion). The sensitivity of CT scanning to detect small, so-called occult, pneumothoraces (that may not be clinically significant) exceeds that of both ultrasound and chest radiography and is also more helpful in determining the size of the pneumothorax. In a meta-analysis of the use of ultrasound versus chest radiography for pneumothorax detection, Ding et al (35) report a pooled sensitivity of 89% and specificity of 99% for ultrasound performance by nonradiologist clinicians.

The ultrasound examination commonly performed using a linear high-frequency probe (5–12 MHz) with conventional B mode imaging oriented in the long axis starting at the third to fourth intercostal space in the mid-clavicular line moving laterally. Other transducers (e.g., linear array, phased array, and convex) may be chosen based on clinical setting and physician preference. M-mode imaging may also be beneficial.

The sonographic features of a pneumothorax are basic and objective and can be appreciated by intensivists who may perform the examination at the patient's bedside. Intensivists have been shown to perform the examination acceptably with an accuracy exceeding that of chest radiography (36–39). The largest ICU series wherein all enrolled patients (357 hemithoraces) were imaged with both a chest CT scan and an ultrasound revealed a sensitivity of 100% for sonographic loss of lung sliding and a specificity of 100% for the presence of a lung point in establishing the diagnosis of pneumothorax via ultrasound (36).

TABLE 6. Summary of Key Recommendations

Торіс	Overall Grade of Recommendation	Strength of Recommendation	Level of Quality of Evidence
Diagnosis of pleural effusion (ruling-in)	1-A	Strong	А
Guidance of small pleural effusion drainage	1-B	Strong	В
Dynamic vs static technique for pleural effusion drainage	N/A	N/A	N/A
Diagnosis of pneumothorax	1-A	Strong	А
Interstitial and parenchymal lung pathology	2-B	Conditional	В
Ascites (nontrauma setting)	1-B	Strong	В
Acalculous cholecystitis (by sonographer)	2-C	Conditional	С
Acalculous cholecystitis (by intensivist)	2-B	Conditional against	В
Renal failure (mechanical causes)	2-C	Conditional	С
Renal failure (by intensivist)	N/A	N/A	N/A
DVT diagnosis	1-B	Strong	В
DVT by intensivist	1-B	Strong	В
Central venous access			
General	1-A	Strong	А
Real time	1-B	Strong	В
Short axis	1-B	Strong	В
One operator	1-C	Strong	С
Use of Doppler	2-B	Conditional	В
Needle guide device	N/A	N/A	N/A
Postcannulation	2-B	Conditional	В
Access location			
Internal jugular	1-A	Strong	А
Subclavian/axillary	2-C	Conditional	С
Femoral	1-A	Strong	А
Others venous	2-B	Conditional	В
Others arterial	2-B	Conditional	В

DVT = deep venous thrombosis, N/A = not applicable.

Numbers indicate the strength of recommendation, where 1 = strong and 2 = weak/conditional. Letters indicate the level of quality of evidence, where A = high, B = moderate, and C = low.

C. Diagnosis of Interstitial and Parenchymal Lung Pathology

• We suggest that a systematic approach incorporating bedside ultrasound may be a primary diagnostic modality for the ICU patient with respiratory failure. Grade 2B.

Rationale: The sensitivity and specificity of ultrasound to diagnose alveolar consolidation exceed 90% (40). The use of the Bedside Lung Ultrasound in Emergency protocol results in a diagnostic accuracy rate exceeding 90% for the most common etiologies of acute respiratory failure in the ICU (41). The competence and experience of the sonographer are likely to play a role in determining the success of using this protocol.

Others have described a continuum of the normal lung typified by artifactual horizontal "A" lines beyond the pleural line characterizing normal aeration to various pathologic states. These disease states include the interstitial syndrome characterized by multiple vertical "B" lines (comet tails) with well-defined spacing (7 mm apart), irregularly spaced "B" lines consistent with pneumonia and coalescent "B" lines less than 3 mm apart typical of pulmonary edema or confluent bronchopneumonia. They have demonstrated a steep but achievable learning curve and ability to use ultrasound to assess lung recruitment strategies (40–46). Because the supportive body of literature has been contributed largely by a single group, the evidence is graded as "moderate" quality.

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II. ABDOMINAL IMAGING

Ascites (Nontrauma Setting)

1. Suitability of ultrasound to establish the diagnosis to assist in drainage:

• We recommend that ultrasound guidance (instead of the landmark technique), whether real-time or preprocedure, should be used to determine the optimal location for performance of paracentesis. Grade 1B.

Rationale: The complication rate (bowel perforation and bleeding) for non-image-guided paracentesis is reported as less than 1% (47). However, blind paracentesis is typically performed on those with massive ascites. Therefore, the relevant outcome variable with which to compare nonimage versus ultrasound-guided paracentesis may not be complication rate, but, rather, may be success and efficiency rate. Ultrasound can help determine the safest pathway through which to perform a paracentesis (48) by identifying the location of bowel loops and the most accessible path for fluid acquisition. A prospective, randomized emergency medicine (EM) study of 83 patients relates a success rate of 95% versus 61% in image-guided versus blind paracentesis (49). Furthermore, nearly all unsuccessful taps without ultrasound guidance were salvaged using ultrasound. Thus, despite the indirectness of the data (EM patients) and the large benefit being realized in efficiency, the evidence was upgraded to "B" and received a strong recommendation.

B. Acalculous Cholecystitis

1. Suitability of ultrasound to establish the diagnosis

• We suggest that bedside ultrasonography may be used to provide additional valuable information to the clinical presentation to establish the diagnosis of acalculous cholecystitis. Grade 2C.

Rationale: Although calculous cholecystitis may occur in the critically ill, acalculous cholecystitis is a more common ICU disease with subtle and often confusing clinical signs. Sonographic features of acalculous cholecystitis include gallbladder wall thickening (> 3 mm; with many reports suggesting up to 9 mm) and distension (short-axis diameter > 40 mm) and the presence of pericholecystitic fluid, sludge, and a sonographic Murphy's sign (pain when the ultrasound transducer is pressed into right upper quadrant). Nuclear medicine imaging may provide additional information; however, it may not be practical or even diagnostic in a critically ill or injured patient. Both techniques have accuracy rates as high as 95%; however, many sonographic features of acalculous cholecystitis may be routinely present in ICU patients, and it may be difficult to elicit a positive Murphy's sign in those who are intubated and sedated. Finally, although this examination is described as a bedside ICU examination in the literature, it is typically currently performed by ultrasound technicians, not by intensivists (50).

2. Ability of the intensivist to use ultrasound to establish the diagnosis accurately

• We suggest that intensivists/critical care providers should not personally perform ultrasound primarily for the diagnosis of acute cholecystitis. Grade 2B.

Rationale: Although the sonographic features of acalculous cholecystitis are basic and objective and the images are readily acquired, there are no data to suggest that the intensivist can perform the definitive examination. There are no studies specifically describing intensivist-performed right upper quadrant abdominal sonography to establish the diagnosis of acalculous cholecystitis. The emergency medicine literature is rife with studies demonstrating the accuracy of EM-performed right upper quadrant sonography to diagnose biliary pathology. The authors do not believe that the EM and ICU patient populations (with calculous vs acalculous cholecystitis) are equivalent to allow for extrapolation (51–53).

C. Mechanical Causes of Anuria/Oliguria

1. Suitability of ultrasound to establish the diagnosis thereof

• We suggest that ultrasonography may be used to exclude mechanical causes of acute renal failure in the ICU. Grade 2C.

Rationale: Renal ultrasound can readily detect the presence or absence of hydronephrosis-the indicator of obstructive uropathy-the mechanical and treatable cause of acute renal failure in those who are not hypovolemic. In addition, it can detect reduced renal size and echogenicity, features of chronic renal insufficiency and/or failure. In two retrospective studies that included 506 ICU patients, the authors concluded that sonography was a convenient and useful diagnostic tool in this setting. Nonetheless, obstructive uropathy was found in only about 1% of those with acute renal failure, whereas 30-40% of imaged ICU patients had sonographic evidence of chronic renal failure. In 33% of cases of complicated urinary tract infections, sonography revealed abnormalities. Incidental findings not immediately affecting patient care and including ascites and simple renal cysts were identified in 91 patients (92, 93). Our level of quality of evidence assignment, thus, is at the lowest level, driven from mostly the expert opinion or retrospective observational studies. The conditional (class 2) recommendation reflects the degree of uncertainty of the panel regarding the use of ultrasound in this condition.

2. Ability of the critical care provider to use ultrasound to establish the diagnosis accurately

• We have no recommendations regarding this issue due to the paucity of data.

Rationale: Although the sonographic features of mechanical causes of acute renal failure are objective and the images are readily acquired, there are no data to suggest that the intensivist should perform the definitive examination, particularly as this is an unusual occurrence in the ICU. There are no studies specifically describing intensivist-performed renal sonography to establish the diagnosis of obstructive uropathy as the cause of

acute renal failure. Once again, the EM literature is replete with studies documenting EM-provider skill level in this examination, however, in a disparate patient population (94, 95).

III. VASCULAR IMAGING

A. Deep Venous Thrombosis (DVT)

1. Complete versus focused examination of the lower extremities:

• We recommend that a focused ultrasound technique using gray scale imaging to evaluate vein compression at the common femoral and popliteal veins should be used to diagnose most proximal DVTs (compared with contrast venography). Grade 1B.

Rationale: The sensitivity of a focused examination for common femoral and popliteal vein DVT compared with contrast venography was 100% in a prospective study published many years ago (54). This focused ultrasound examination has become the gold standard for DVT screening and detection. These ultrasound examinations, although performed bedside, were conducted by ultrasound technicians, not by intensivists and not necessarily in the ICU. This approach takes advantage of the observation that most DVTs are not found in small isolated vein segments, but in significant portions of the common femoral, deep femoral, superficial femoral, or popliteal veins, thus simplifying the approach. The addition of Colorflow imaging, also known as Duplex, is rarely warranted. Finally, the principal of a focused examination targeted to the area of swelling can even be applied to imaging of the calf and upper extremities if distal DVTs are sought.

2. Accuracy of focused DVT screening by critical care providers

• We recommend that intensivists can reliably perform a focused screening examination by ultrasound to diagnose lower extremity proximal DVT. Grade 1B.

Rationale: A multicenter retrospective study compared matched intensivist-performed focused ultrasound with those performed by certified vascular technicians. The sensitivity and specificity of the ICU-performed studies compared with the technician studies were 88% and 98% versus 85% and 100%, respectively. Furthermore, ICU studies were available real-time compared with a median time delay of nearly 14 hours for the vascular laboratory studies (55). EM data show similar accuracy, but we have not included it because of the uncertainty of patient and operator equivalency. There are no data regarding DVT screening by ultrasound for critical care providers other than intensivists.

B. Imaging to Assist Intravascular Catheter Insertion 1. General consideration

• We recommend that ultrasound guidance of vessel cannulation (compared with landmark technique) should be used to improve the success rate, shorten procedure time and reduce the risk of procedure-related complications such as pneumothorax. Grade 1B.

Rationale: Frequently used sites for the cannulation of central veins include the internal jugular (IJ), subclavian, and femoral veins. We will describe the evidence below by location and general components of the examination regardless of site (96, 97). In the GRADE process, whenever there are multiple outcomes relating to one recommendation, the overall ranking of the level of evidence (as with this global recommendation) is primarily based upon that of the most critical outcome. In case the multiple outcomes are of the same rank of importance, the overall level of evidence is the lowest among them. Therefore, despite some of outcomes for vascular imaging having high level (A) of evidence (such as IJ and femoral cannulation), the global recommendation was ranked B (moderate) due to lower levels of evidence for other sites and outcomes within the context of this general recommendation. Except as noted below, the recommendations regarding ultrasound-guided catheter insertion pertain mostly to adult patients, except if there are sufficient data specific to the pediatric population.

2. Components of the examination

a. Static versus dynamic (preprocedure vs real-time)

• We recommend that in most patients, the use of realtime ultrasound is preferred over static, preprocedure marking. Grade 1B.

Rationale: A preprocedure scan before sterile precautions are secured and can identify thrombi, occlusion and unfavorable anatomy leading to choose another site of insertion, but does not exclude the desirability of using dynamic ultrasound as well. The Third Sonography Outcomes Assessment Project RCT demonstrated a clear benefit of dynamic versus static ultrasound guidance during vascular puncture (56). Dynamic ultrasound was found to have an odds ratio of 53.5 times (6.6–440) higher for success than landmark, whereas static ultrasound had an odds ratio just 3 times (1.3–7) higher for success than for landmarks. This large beneficial effect of dynamic technique may be of particular applicability to novice or inexperience operators as suggested by the authors. No difference in complication rate was reported. In a single, small, underpowered, prospective, randomized trial of pediatric patients, the cannulation and complication rates of preprocedure marking versus real-time ultrasound guidance were not statistically different (100% vs 89%; p = 0.19and 0% vs 7%; p = 0.20). There was a benefit to catheterization time with dynamic ultrasound guidance (57). Nonetheless, the ultrasound paradigm that underlies the subsequent work that will be described in detail below is a preprocedural assessment of the vessels and real-time ultrasound puncture.

b. Long versus short axis

• Although there are benefits to visualizing the vasculature in both short- and long-axis images by ultrasound, we

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recommend that the short-axis view be used during insertion to improve success rate. Grade 1B.

1. Rationale: Although anatomic relationships between contiguous structures are best judged using ultrasound imaging in the short axis, there may also be benefit to visualizing the catheter tip and guidewire in the long axis. These include the ability to observe the guidewire in the vessel and the tip of the needle to minimize the risk of "past pointing." Scanning can be performed in a longitudinal (long axis) and transverse (short axis) plane according to location of the vessel, operator's experience, and anatomic relationships. The short-axis view allows full visualization of small target vessels (i.e., infant veins and arteries) or identification of vital structures close to the target vessels. Although a short-axis view allows visualization of needle entrance avoiding surrounding structures during vascular puncture, a long-axis view may prevent the penetration of the posterior wall of the vein by a continuous visualization of the needle tip. However, the long-axis view may not be possible to achieve and may require additional experience to obtain full proficiency. Four randomized trials were reviewed, of which two were clinical trials and the other two were phantom-based (i.e., simulated) studies. Chitoodan et al (58) reported on 99 patients undergoing cardiac surgery that showed better success rates (98% vs 78% with p < 0.006) using short- than long-axis imaging. The RCT done by Mahler et al (59) enrolled 40 patients in an ED setting and was consistent regarding improved success rate with short-axis imaging. No difference in complication rate was reported. The other two trials with phantoms done by Stone et al (60) and Blaivas et al (61) showed improved skill acquisition using short-axis techniques. Data analysis for level of quality of evidence classification only considered the two clinical trials because the other simulated trials had limitations regarding indirectness and outcome reporting. The panel, therefore, decided to downgrade the level of evidence from high (A) to moderate (B) on the basis of indirectness of the settings.

c. One- versus two-person ultrasound-guided vascular cannulation

• We recommend that one- (rather than two-) person technique is sufficient for ultrasound-guided vascular cannulation. Grade 1C.

Rationale: Only one RCT provided a head-to-head comparison of these two methodologies: a randomized study of 44 patients in the ED that supported the noninferiority of a single operator technique compared with two operators during ultrasound-guided cannulation in terms of overall success rate (59). Because of indirectness, the panel opted to assign this a low evidence level, but a strong recommendation as the default practice in all other studies described herein is a single person technique.

d. The use of Doppler

• We suggest that conventional B-mode imaging to assist in vessel cannulation should be used compared with using audible Doppler only with no imaging. Grade 2B. Rationale: B mode is usually considered the best mode for ultrasound visualization for vessels and subcutaneous structures. Schummer et al (62) demonstrated in a prospective randomized trial that cannulation of the IJ vein was significantly safer using B-mode ultrasound-guided puncture than using audible Doppler only. The success rate of the first needle pass between the two groups was 91% (172/189) with Doppler and 96.6% (144/149) with the B-mode group (p < 0.05). Furthermore, in subgroup analysis, patients with obesity (body mass index \geq 30) in the audible Doppler-only group had a significantly lower first needle pass success rate than in the B-mode ultrasound (Doppler group, 77.1% [27/35] and B-mode group, 97.4% [38/39]; *p* = 0.011). Two prospective studies of subclavian vein cannulation failed to demonstrate any advantage for the use of pulsed wave Doppler imaging in terms of success rate, number of attempts and complications over landmark technique, or conventional B-mode imaging for cannulation guidance (98, 99). The panel decided to downgrade the level of quality of evidence from high to moderate (B) on the basis of indirectness. That degree of uncertainty about Doppler use was also reflected in panel voting that yielded a class 2 (weak/conditional) grade of recommendation.

- e. The use of needle guides
 - We have no recommendation regarding routine use of a device placed on the ultrasound transducer to guide needle placement. This should be left to provider discretion.

Rationale: There are no data to suggest that the use of needle guides improves performance in catheter insertion. However, the guides are inexpensive and introduce no additional risk to the patient. Two prospective studies address the use of the guides by trainees in controlled settings—one in the operating room (OR) and one in a simulation laboratory (100, 101). Although the former study improved first-pass success rate in the OR with junior residents (80.9% vs 68.9%; p = 0.0054), it did not affect the rate of arterial puncture (100). The study of trainees in a simulated environment was unable to demonstrate any advantage (101).

f. Completion examination

• We suggest that a detailed postcannulation ultrasound examination may be used (instead of conventional chest radiography) to confirm catheter location and exclude a pneumothorax in adult patients. Grade 2B.

Rationale: Two prospective studies in adults describe and provide data on the use of ultrasound to determine catheter tip position and technical complications (e.g., hemopneumothorax) of catheterization. The sensitivity for catheter placement ranged from 50% (if pre-existing catheters were present) to 96% and specificity from 93 to 98% (63, 64). The presence of multiple central venous devices may reduce the

accuracy of this study and, at present, a postcatheterization chest radiograph is still considered obligatory.

3. Internal jugular location

• We recommend that *dynamic* ultrasound-guided IJ venous cannulation should be used (instead of landmark technique) to improve success rate, shorten procedure time and reduce the risk of procedure-related complications in adult patients. Grade 1A.

Rationale: In 2002, the U.K. National Institute of Clinical Excellence guidelines recommended the use of ultrasound guidance for the insertion of central venous catheters in the IJ location (65). A meta-analysis (96) including studies of both pediatric and adult patients concluded that real-time ultrasound guidance of IJ cannulation was associated with a lower risk of failure (relative risk [RR], 0.14; 95% CI, 0.06–0.33), complications (RR, 0.43; 95% CI, 0.22-0.87), and first attempt failure (RR, 0.59; 95% CI, 0.39–0.88) and reduced number of attempts (1.5 fewer attempts, 95% CI, 0.39-0.88) (66-72). In mechanically ventilated ICU patients, real-time ultrasound-guided IJ vein cannulation is superior to the landmark technique for several outcome variables (73). It improved overall success rate (100% vs 94.4%; p < 0.001), access time (17.1 ± 16.5 vs 44 ± 95.4 min; p < 0.001), and mechanical and infectious complication rate (74). The first attempt success rate and the arterial puncture rate are equivalent in euvolemic patients between those catheterized with ultrasound guidance versus those using landmark technique only. However, ultrasound guidance improves success rate by both of these parameters in the IJ location in hypovolemic patients (75). On the other hand, when only analyzing pediatric patients, the data are not consistent in supporting the use of ultrasound versus a landmark technique to assist IJ cannulation in infants and children in terms of success rate, complications, and time to insertion in a meta-analysis of 173 procedures, except perhaps for novice operators (76). However, this metaanalysis largely evaluated trials in infants in a surgical setting undergoing cardiac surgery, so the applicability to the ICU setting may be questioned.

4. Subclavian/axillary location

• We suggest that ultrasound dynamic guidance is of limited value for most operators to guide subclavian vein catheterization in adult patients (and that landmark technique is used instead). Grade 2C.

Rationale: ultrasound guidance does not improve the outcome of subclavian vein catheterization over the landmark technique for experienced operators. Ultrasound guidance may be beneficial for novice operators and for cannulation of the axillary vein. It is difficult to interpret the data presented below because of a lack of clarity in whether the authors are referring to the subclavian vein or the axillary

vein. Because the subclavian vein is located beneath the clavicle, the penetration of the ultrasound beam is difficult. The axillary vein, which is the continuation of the subclavian vein lateral to the outer border of the first rib at teres major, can be easily visualized (the vein is caudal to the artery and is smaller and often compressible). The lack of clarity of which vessel is actually being imaged is questioned in a recent editorial (102). A prospective, randomized trial of static ultrasound imaging versus the landmark technique for "subclavian" catheterization found no difference in complication rate (9.7% vs 9.8%) or cannulation failure rate (12.4% vs 12.4%) (103).

On the other hand for inexperienced operators, real-time ultrasound guidance compared with the landmark trainee improved overall success and complication rate and lessened average number of attempts (92% vs 44%; p = 0.0003; 4% vs 41%; 1.4 vs 2.5; p = 0.0007) (104). A recently published RCT of 400 patients undergoing cannulation by experienced operators revealed a 100% success rate using real-time ultrasound guidance compared with 87% with landmark technique (105). There were also fewer complications in the ultrasound group. We would interpret these findings with caution, however, because the baseline complication rate for the authors was high at 16%. More importantly, it is not clear whether or not the subclavian or axillary vein was, in fact, cannulated as noted above. For this reason, we have graded our recommendation as 2C.

5. Femoral location

• We recommend that ultrasound dynamic guidance (instead of the landmark technique) should be used to improve the success rate and reduce complications for femoral venous cannulation although this benefit is mostly realized by novice operators in adult patients. Grade 1A.

Rationale: To date, little data regarding the use of ultrasound in femoral vein cannulation have been reported, compared with other sites. In a prospective trial of 66 patients, first attempt and overall success rate and total procedure time were improved using ultrasound guidance versus the landmark technique for hemodialysis access (92.9% vs 55.3%; *p* < 0.05; 100% vs 89.5%; 45.1 ± 18.8 s vs 9.4 ± 61.7 s; p < 0.05), and arterial puncture was improved from 15.8% to 7.1% in experienced operators (77). In a prospective, randomized trial of 110 patients, although the overall and first attempt success rate, number of attempts, and complication rate were improved by ultrasound guidance, these differences were not appreciated with experienced operators (78). Fewer needle passes $(2.3 \pm 3 \text{ vs } 5.0 \pm 5; p = 0.057)$ and arterial catheterizations (0% vs 20%; p = 0.025) were realized using ultrasound guidance for patients undergoing femoral line placement during cardiopulmonary arrest (79). Finally, in a randomized trial of 48 pediatric patients undergoing femoral venous cannulation in the OR by

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trainees, time to cannulation and first pass success rate were improved by ultrasound guidance versus landmark technique although overall complications and success rate were equivalent (80).

6. Other locations

• We suggest that the use of ultrasound dynamic guidance (instead of the landmark technique) may improve the success rate and diminish complications during peripheral venous (adults and children) and arterial cannulation (adults). Grade 2B for venous and 2B for arterial catheterization.

Rationale: Ultrasound guidance can be useful when peripheral veins are difficult to visualize as in patients with obesity, drug, abusers, and infants. The endpoints to be considered should not only be the success rate but also the time to cannulation and number of attempts. Although several case series exist regarding the use of ultrasound guidance for difficult peripheral intravenous catheterization, a single, small RCT in an ED pediatric population supports the use of ultrasound. Overall success rate (80% vs 64%; p = 0.208), median attempts (1 vs 3; p = 0.004), and time to catheterization (6.3 vs 14.4 min; p = 0.001) were improved with ultrasound guidance (81). There are four additional small prospective studies: three in an adult ED and one in the OR that provides conflicting data in terms of insertion success and patient satisfaction (82-85). One ED study comparing real-time ultrasound guidance with the traditional palpation method revealed that successful cannulation was greater in the ultrasound group (97%) than in the control group (33%) (83). Overall time to cannulation was lower in the ultrasound group (13 vs 30 min) with a reduced number of skin puncture (1.7 vs 3.7). Although the data are not of high quality, the risk/benefit ratio would suggest a role for ultrasound guidance (82-85).

Arterial cannulation is usually performed for hemodynamic monitoring. Preferred sites for arterial cannulation are the radial, brachial, axillary, femoral, and posterior dorsalis pedis arteries. The radial artery is the most commonly used cannulation site given its easy accessibility and palpation. For arterial catheterization, two small RCTs of ultrasound guidance versus the palpation technique indicate that ultrasound is efficacious in improving time to catheterization with fewer attempts (86, 87). A similar study in children (88) did not support the superiority of ultrasound guidance for radial artery catheterization over palpation although one in infants did show improved success with ultrasound guidance (89). Femoral artery access and catheterization can also be improved with ultrasound-guidance although this experience is often reported in patients undergoing cardiac catheterization (90). A meta-analysis of 311 patients-nearly equally divided between palpation technique and ultrasound guidance-demonstrated a 71% improvement in first-pass success rate with the latter (91).

Despite the high quality of evidence (level A) previously described before particularly for arterial cannulation, the use

of ultrasound for arterial and peripheral venous access is useful mostly in difficult patients such as infants, obese, and hemodynamically unstable patients and/or when previous unsuccessful attempts have been performed. Ultrasound use in arterial and peripheral venous cannulation cannot be recommended as a routine practice in the majority of "usual" patients. Therefore, the panel decided to downgrade the evidence to moderate (B) on the basis of indirectness of population that in need of such technique and also made the recommendation as class 2 (conditional), despite the clear favorable benefit /risk ratio for the role for ultrasound guidance.

CONCLUSIONS

Medicine is an ever-changing science and technological advancements are made rapidly in the field of ultrasound. Development of miniaturized imaging systems, intravascular probes, threedimensional imaging, telementored ultrasound, and increasing use of ultrasound contrast agents are some of the examples. Therapeutic use of ultrasound radiation is increasingly entering the field of critical care ultrasonography. We are now at the forefront of the "ultrasound revolution." We believe that these general ultrasound recommendations will evolve rapidly with the field because it undergoes remarkable and unprecedented transformation. These guidelines will be updated regularly when new information is available as is the standard procedure for SCCM materials. The panel of experts will evaluate new data, and additional expertise will likely be sought with creation of the next revision. For example, we suspect that as current practice continues, more definitive conclusions will be possible regarding the appropriate use of ultrasound for both diagnostic and therapeutic purposes in the pediatric patient population.

The authors appreciate that this work has not addressed the very real issues of "turf wars," politics, and the cost of acquiring sufficient equipment and training to implement these guidelines that some providers may encounter. On the other hand, the risks of performing invasive procedures in critically ill and injured patients without image guidance and using alternate diagnostic methods are well described herein. We hope that these guidelines will arm those who care for these patients with the evidence to confront the political and economic challenges of implementing a critical care ultrasound program.

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APPENDIX 1: RAND RULES FOR VOTING

Introduction to RAND Appropriateness Method

In collaboration with clinicians at the University of California at Los Angeles, RAND Heath staff developed the RAND/University of California at Los Angeles Appropriateness Method to synthesize the scientific literature (evidence) and expert opinion on health care topics. This method has become a leading paradigm for quality assessment in medicine. It is also a mechanism for reaching formal agreement about how science should be interpreted in the real world. It makes it possible to set rules for determining best practices-guidelines that, when implemented, increase the value of healthcare management. The method was adopted by the European Commission BIOMED Concerted Action on the appropriateness of medical and surgical procedures and received wide acceptance as a reproducible, validated consensus development method in several countries. The basic concept of RAND appropriateness method is to have structured method in obtaining the panel decisions regarding ranking or regarding agreement on the appropriateness. The method incorporates modified Delphi technique that is performed in a minimum two face-to-face rounds. This achieves the benefits of the interactions between the experts while keeping the benefits of the anonymity through the controlled feedback in the two rounds of anonymous voting. The method establishes the panel judgment based on a reproducible statistical analysis of the panel's voting results, not only to establish agreement/disagreement but also to sensitively measure the degree of the agreement if present.

For those who are specifically interested in gettin into depth of RAND methodology, a full manual can be found at http://www.rand.org/pubs/monograph_reports/MR1269.

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Panel voting following RAND appropriateness method using 9-point Likert Scale

- *Scale*: 1–9
- 9 = extremely appropriate
- 1 = extremely inappropriate
- With three regions/zones:
 - Inappropriate region: 1–3
 - Uncertain region: 4–6
 - Appropriate region: 7–9
- The Likert Scale is used for voting on
 - 1. Judgment about outcome importance (9 = critical; 1 = unimportant)
 - 2. Judgment about the transforming factors evidence-to-recommendation (EtR) or evidence-to-decision table (see EtR table).
 - 3. Judgment about the overall appropriateness of draft recommendation (statement).
- From analysis of voting results the following is determined
 - 1. Presence of disagreement/agreement
 - 2. Degree of consensus
 - 3. Direction of recommendation (with or against)
 - 4. Strength of recommendation (weak or strong or No recommendation)
- Disagreement is defined by more than 30% of panelists have voted outside the three-point region containing the median.
- The degree of consensus is driven from three factors
- 1. Presence or absence of disagreement
- 2. The median score

3. The degree of dispersion of voters around the median (interquartile range and Integer needed to achieve majority percentage)

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Term	Definition
Perfect consensus	All respondents agree on one number between 7 and 9
Very good consensus	Median and middle 50% (interquartile range) of respondents are found at one integer (e.g., median and interquartile range are both at 8), or 80% of respondents are within one integer of the median (e.g., median is 8, 80% respondents are from 7 to 9)
Good consensus	50% of respondents are within one integer of the median (e.g., median is 8, 50% of respondents are from 7 to 9), or 80% of the respondents are within two integers of the median (e.g., median is 7, 80% of respondents are from 5 to 9)
Some consensus	50% or respondents are within two integers of the median (e.g., median is 7, 50% of respondents are from 5 to 9), or 80% of respondents are within three integers of the median (e.g., median is 6, 80% of respondents are from 3 to 9)
No consensus	All other responses. Any median with disagreement

RECOMMENDATION STRENGTH AND DIRECTION

Strong Recommendation

Definition: It has to have all of three conditions:

- 1. no disagreement (voters are \geq 70%) and
- 2. the degree of consensus is at least very good (voters with $\ge 80\%$ at one integer) and

3. median score is not in the undetermined middle zone (median is not in 4–6 zone so it is either in the zone 7–9 or zone 1–3). Two classes of strong recommendations:

- "Strong with" if median score is = 7-9
- "Strong against" if median score is = 1-3

The word *recommend* will be used for strong recommendation The word *must, should or to* depends on the degree of consensus (as shown in the table below)

Conditional/Weak Recommendation

Definition: It has three conditions:

- 1. no disagreement (voters are \geq 70%) and
- 2. the degree of consensus is "good or some consensus" with any median score or median score is 4–6 with any degree of consensus and
- 3. median score is not in the undetermined middle zone (median is not in 4–6 zone so it is either in the zone 7–9 or in the zone 1–3)
- "Weak against" if middle 50% interquartile range = 1 to less than or equal to 3
- *"Weak with"* if middle 50% interquartile range = 4–9

No Recommendation

Definition: either of three conditions:

- 1. disagreement (voters are \geq 70%) or
- 2. no consensus or
- 3. median in the middle region (4–6) with any degree of consensus.

The following table summarizes the relationship between the degree of consensus, the strength of recommendations, and the wording to be used

Degree of consensus	Strength of recommendation	Wording (functionof voting)
Perfect consensus	Strong	Recommend: must/to be/will
Very good consensus	Strong	Recommend: should be/can
Good consensus	Weak/conditional	Suggest: to do
Some consensus	Weak/conditional	Suggest: may do
No consensus	No	No recommendation was made regarding
Disagreement		

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EtR (Evidence-to-Recommendation) table

Panelist code (name is optional)

Round # Domain code

Statement (draft recommendation) code

1. Does the statement address strategy that has clinical outcome? If No then GO DIRCTLY to appropriateness (approval) voting sheet (separate sheet).

2. If YES, then does the statement address a strategy that has more than one outcome?

\Box YES \Box NO^{\dagger}

The 5 Transforming Factors	Voting	Explanation (use additional sheets provided)
1. Problem Priority /Importance Outcome 1its rank is Outcome 2its rank is Outcome 3its rank is List here the previously determined rank of outcome importance and See SoF tables_The more critical is the outcome or the highest the priority of problem, the more likely is a strong recommendation ^{\$} .	Rank of priority/ most important outcome 9 8 7 6 5 4 4 3 2 1	Your notes:
2. Level of Quality of Evidence (LQE) ^{\$} Outcome 1its evidence quality Outcome 2its evidence quality Outcome 3its evidence quality See SoF tables. The higher the quality of evidence, the more likely is a strong recommendation	The overall quality across outcomes High moderate low	If multiple outcomes, overall quality will be based on that of the most important outcome (e.g. of the critical). If multiple equal outcomes (e.g. all have equal importance), then it will have the least estimated quality. <u>Your notes:</u>
3. Benefit /Harm balance The larger the difference between the desirable and undesirable consequences and the certainty around that difference, the more likely a strong recommendation. The smaller the net benefit and the lower the certainty for that benefit, the more likely is a conditional/weak recommendation.	□ 9 □ 8 □ 7 □ 6 □ 5 □ 4 □ 3 □ 2 □ 1	9 =extremely favorable balance 1=extremely unfavorable balance with 3 regions 7-9 favorable, 4-6 uncertain and 1-3 unfavorable <u>Your notes/concerns:</u>
4. Benefit/Burden balance The higher the resource consumed of an intervention or burden related to the decision, the more likely is a conditional/weak recommendation. Are the resources consumed/burden worth the expected benefit?	□ 9 □ 8 □ 7 □ 6 □ 5 □ 4 □ 3 □ 2 □ 1	9 =extremely favorable balance 1=extremely unfavorable balance with 3 regions 7-9 favorable, 4-6 uncertain and 1-3 unfavorable, <u>Your notes/concerns:</u>
5. Certainty/Concerns about PEAF * <u>Preferences/Equity/Acceptability/Eeasibility</u> The greater the certainty around these 4 variables, the more likely is a strong recommendation. The more concerns, the likely is weak/conditional recommendation	$\begin{array}{c} 9 \bigcirc 9 \bigcirc 9 \bigcirc 9 \bigcirc 9 \bigcirc 9 \cr 0 \cr$	9 =extremely certain about PEAF 1=extremely concerned about PEAF with 3 regions 7-9 certain, 4-6 uncertain and 1-3 concerned <u>Your notes/concerns:</u>

Also called **EtD** (Evidence-to-Decision) table. ¹ If No (i.e., one outcome) then please list in column 2 the previously determined level of quality of evidence (LQE) that is presented in Summary of Findings (SoF) table. ⁵ Level of Quality of Evidence (LQE) also described as CEE=Confidence in the Estimate of Effect * Certainty around preferences means expecting average patient will choose this action and minimal variability are expected in patient choices. Concerns means expected wide variability in patient preferences towards this recommendation. Similarly, certainty related to equity (patient accessibility to care), acceptability (by various stakeholders) and feasibility (infrastructure). The more likely the certainty, the more likely is a strong recommendation. The more concerns about any PEAF factors, the likely is weak/conditional recommendation. Use provided additional sheets/space for your notes/concerns