

International Evidence-Based Recommendations for Focused Cardiac Ultrasound

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Background: Focused cardiac ultrasound (FoCUS) is a simplified, clinician-performed application of echocardiography that is rapidly expanding in use, especially in emergency and critical care medicine. Performed by appropriately trained clinicians, typically not cardiologists, FoCUS ascertains the essential information needed in critical scenarios for time-sensitive clinical decision making. A need exists for quality evidence-based review and clinical recommendations on its use.

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Methods: The World Interactive Network Focused on Critical UltraSound conducted an international, multi-specialty, evidence-based, methodologically rigorous consensus process on FoCUS. Thirty-three experts from 16 countries were involved. A systematic multiple-database, double-track literature search (January 1980 to September 2013) was performed. The Grading of Recommendation, Assessment, Development and Evaluation method was used to determine the quality of available evidence and subsequent development of the recommendations. Evidence-based panel judgment and consensus was collected and analyzed by means of the RAND appropriateness method.

Results: During four conferences (in New Delhi, Milan, Boston, and Barcelona), 108 statements were elaborated and discussed. Face-to-face debates were held in two rounds using the modified Delphi technique. Disagreement occurred for 10 statements. Weak or conditional recommendations were made for two statements and strong or very strong recommendations for 96. These recommendations delineate the nature, applications, technique, potential benefits, clinical integration, education, and certification principles for FoCUS, both for adults and pediatric patients.

Conclusions: This document presents the results of the first International Conference on FoCUS. For the first time, evidence-based clinical recommendations comprehensively address this branch of point-of-care ultrasound, providing a framework for FoCUS to standardize its application in different clinical settings around the world. (J Am Soc Echocardiogr 2014;27:683.e1-e33.)

Keywords: Cardiac sonography, Echocardiography, Cardiac ultrasound, Crit Care echocardiography, Emergency ultrasound, Critical ultrasound, Point-of-care ultrasound, Guideline, RAND, GRADE, Evidence-based medicine

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The history of echocardiography began with the collaboration of Drs. Edler and Hertz in Lund in 1954.¹ It has since evolved into a highly sophisticated and powerful tool. Comprehensive standard echocardiography provides information on virtually all aspects of heart morphology and function, disclosing numerous derangements in cardiovascular physiology. However, image acquisition and interpretation of comprehensive standard echocardiography require extensive training. Until recently, this technology was provided only to stable patients able to reach an echocardiography laboratory.

With the advent of mobile, portable, and pocket-sized ultrasound machines, this imaging modality is now readily available in emergency and critical care settings in time-sensitive scenarios in which it is immediately needed. Ease of use, availability of diagnostic information within a short time, high-quality imaging in most patients, and low complication rates have led to the widespread use of echocardiography in the perioperative, critical care, and emergency medicine environments. For many years, the scientific community has affirmed that ultrasound imaging is within the scope of practice of

| Abbreviations |
|--|
| ALS = Advanced life support |
| ASE = American Society of Echocardiography |
| ECG = Electrocardiographic |
| ED = Emergency department |
| ESM = Electronic Supplementary Material |
| FAST = Focused Assessment with Sonography in Trauma |
| FoCUS = Focused cardiac ultrasound |
| GRADE = Grading of Recommendation, Assessment, Development and Evaluation |
| ICU = Intensive care unit |
| IVC = Inferior vena cava |
| LV = Left ventricle |
| 2D = Two-dimensional |
| WINFOCUS = World Interactive Network Focused on Critical UltraSound |

multiple medical specialties. Indeed, American Medical Association Resolution 802 states that “the privileging...training and education standard [be] developed by each physician’s respective specialty.”²

In these settings, realizing the benefit of echocardiography in the management of critically ill or injured patients, a different, simplified, clinician-performed application of this technology has also been developed: focused cardiac ultrasound (FoCUS). This sonographic evaluation of the heart is limited in comparison with comprehensive standard echocardiography, and it is conducted by appropriately trained clinicians, typically not cardiologists, to ascertain only the essential information needed in critical scenarios and time-sensitive decision making. Generally, a FoCUS examination is brief and addresses a few clinical questions, mainly in a dichotomous (yes or no) fashion (e.g. “Is the patient hypotensive because of se-

vere dysfunction of the left ventricle or not?” “Is the cause of shock cardiac tamponade or not?”).

Interestingly, FoCUS was derived for nonechocardiography specialists for two different reasons, two journeys that coalesced at the same end point:

- Emergency, critical care, and prehospital physicians have been eager to expand the use of smaller and portable ultrasound equipment in critical settings, where the modality has been underused, and thus developed focused scanning protocols,³⁻⁹ which can be mastered by practitioners with appropriate training.
- Simultaneously, cardiologists have urged other specialists to decrease the inappropriate use of comprehensive standard echocardiography for mere screening purposes for cardiac pathology in specific populations¹⁰⁻¹⁶ and mostly in asymptomatic high-risk patients.¹⁶⁻²¹ To attain these goals, limited scanning protocols for practitioners with focused training have been proposed.^{15,21-23}

These groups of physicians have ended up at the same point: FoCUS.

Several scientific bodies have previously provided guidelines and recommendations for comprehensive standard echocardiography,²⁴⁻²⁸ critical care echocardiography,²⁹⁻³¹ and a few on emergency echocardiography.³¹⁻³³ Labovitz *et al.*³² published jointly with the American College of Emergency Physicians and the American Society of Echocardiography (ASE) a consensus statement on FoCUS in emergency medicine. Spencer *et al.*³⁴ produced an expert consensus statement for the ASE in 2013.

The use of clinician-performed ultrasound is specialty specific. The specialists using this technology have the responsibility to determine the training, imaging criteria, accreditation of training programs, and quality management of the use of FoCUS. A need exists for quality evidence-based review and clinical recommendations. Therefore,

the World Interactive Network Focused on Critical UltraSound (WINFOCUS) conducted an international, multispecialty, evidence-based, and methodologically rigorous consensus conference on FoCUS.³⁵ The recommendations that follow represent a framework for FoCUS intended to standardize its application around the world and in different settings.

METHODS

Recommendation-Building Methodology

The evidence-based statements and recommendations presented in this document were developed using a rigorous methodologic regimen, previously described, starting with the Grading of Recommendation, Assessment, Development and Evaluation (GRADE) method.³⁶ This approach entails: (1) a preliminary determination of the quality of available evidence and (2) the subsequent development of the recommendations. All articles concerning the conference object were ranked into three levels of quality according to the GRADE methodology for guideline and recommendation development (Table 1). Second, evidence-based panel judgment and consensus were collected by means of the RAND appropriateness method,³⁷ which incorporates a modified Delphi technique carried out in a minimum two face-to-face rounds of debate and voting. The RAND appropriateness method was also applied to formulate recommendations based exclusively on expert consensus, such as the ones concerning terminology. On the basis of the GRADE criteria, recommendations were generated in two classes (strong and weak or conditional), according to preset rules defining the panel’s agreement and consensus and its degree, as illustrated in Figure 2 of Appendix 1 in the Electronic Supplementary Material (ESM). That in turn determined the wording of each recommendation. Phrasing of strong recommendations used “we recommend” (or the verb “must” or “should”), while weak or conditional recommendations used “we suggest” (or the verb “may”), as shown in Table 4 of Appendix 1 in the ESM. Implications deriving from the strength of recommendations are illustrated in Tables 5 and 9 of Appendix 1 in the ESM. The conversion of evidence into recommendation depends on its evaluation by the panel as concerns quality of evidence, outcome importance, benefit/burden and benefit/harm balance, and finally the degree of certainty about similarity in the values and preferences of average patients, as applicable.³⁶ Final grading of recommendations, on the basis of their strength and on level of evidence, is described in Table 2. A detailed description of the GRADE and RAND appropriateness methodology used, as already published,^{38,39} is provided in Appendix 1 in the ESM. The clinical practice guidelines development process that we followed aimed at fulfilling the 2011 Institute of Medicine of the National Academies report of the eight standards for trustworthy guidelines.⁴⁰ Great attention was paid to meet these standards, to overcome the shortcomings of similar guidelines previously published in this field. Because some of them did not meet more than a small portion of these standards, these guidelines created controversies and received variable degrees of acceptance and therefore had limited applicability. We believe that the more guidelines are robust in methodology, by meeting these eight standards, the greater will be the chance for them to be universally accepted and hence widely applied.

The entire consensus conference process was funded by WINFOCUS, nonprofit scientific organization devoted to education, evidence-based research, and international networking in the field of point-of-care ultrasound.⁴¹

Table 1 Level of evidence quality

| Level | Points* | Level | Interpretation |
|----------------|-----------------|----------|--|
| A | ≥4 | HIGH | Further research is very unlikely to change our confidence in the estimate of effect or accuracy |
| B | 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 |
| C [†] | ≤2 [†] | LOW | 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 (low), OR any estimate of effect or accuracy is very uncertain (very low) |

*Points are calculated on the basis of the nine GRADE quality factors,⁴² as shown in Table 2 of ESM Appendix 1.

[†]Level C includes additional sublevels: low (2 points) and very low (≤1 point).

Modified from Guyatt G, Rennie D, Meade M, Cook D. *Users' Guide to the Medical Literature: A Manual for Evidence-Based Clinical Practice*. New York: McGraw-Hill; 2008.

Panel Selection

Criteria adopted for panel selection were multiple. The major one was met either by the authorship of a peer-reviewed article on the conference topic in the past 15 years or by being an internationally acknowledged educator in the specific field of FoCUS. To take into consideration the transversal application of FoCUS through several medical disciplines, a multispecialty composition of the panel was expressly sought and included representatives from anesthesiology, cardiology, critical care medicine, emergency medicine, pediatric cardiology, and pediatric emergency medicine. Additionally, further input was obtained by asking various international cardiologic, echocardiographic, critical care, and emergency medicine societies to provide representatives, matching the above criteria. Finally, methodologists with expertise in guideline development and evidence-based methodology completed the panel. (A complete list of panelists with affiliations and their roles in the consensus conference process is available in ESM Appendix 2).

Conflict of Interest

The corresponding author formally requested a declaration of possible conflicts of interest from each of the panel members. Conflicts of interest at the organizational and individual levels are detailed in ESM Appendix 1.

WINFOCUS assumed the role of the main promoter and facilitator and supported the development of these guidelines and recommendations by providing the infrastructure and logistics for the process. The funds invested by WINFOCUS in this process were pooled from unconditioned donations to WINFOCUS from multiple resources, including commercial and industrial funding. The organization could use these pooled funds at its discretion, either for guideline development or for any other purpose. By having the role of main promoter and facilitator, WINFOCUS was able to ensure working and scientific independence for the members of the panel. All sessions were controlled continuously to avoid external influence. Thereby, no attempt of commercial or industrial interference and no information leakage were noticed or reported.

No direct sponsorship of any kind was provided by any kind of commercial or industrial source. No honoraria were given to any of the panel members.

Literature Search Strategy

The literature search was conducted in two independent tracks. The first track resulted from searches by the expert panelists themselves,

with more than one expert search to avoid selection bias. The second search track was carried out by an epidemiologist assisted by a professional librarian. English-language articles published from January 1980 to June 2012 were included in the search. Updates of the literature were performed in January and September 2013. Search databases, terms, and Medical Subject Headings used are reported in Table 3. The two bibliographies were compared for completeness and consistency and then merged.

Panel Meetings and Voting

The panel of experts had four face-to-face meetings, in New Delhi (November 2011), Boston (May 2012), Milan (May 2012), and Barcelona (October 2012). A Web-based system allowed active live participation in each session to those who were unable to attend in person. Before the conferences, the panelists produced draft statements to serve as a foundation for the subsequent debate. Each domain of the conference was assigned to a working group within the panel. Different domains of the conference were debated and voted on at different meetings. At each plenary meeting, potentially controversial issues and batches of draft statements and recommendations were submitted by a representative of each working group. Face-to-face debates were held in two rounds using a modified Delphi technique. Anonymous voting took place after each round, after assessment of GRADE transformation factors (Table 2 of Appendix 1 in the ESM), either in the meeting venue or through a secured electronic distance voting system. The evidence-based medicine committee subsequently applied to each voting result the RAND standardized methodology for determination of the agreement or disagreement and the degree of agreement, as shown in Figure 2 of Appendix 1 in the ESM. On this basis, a grade of recommendation (weak or conditional vs strong) or no recommendation was attributed to each statement. As shown in Figure 2 of Appendix 1 in the ESM, establishing a recommendation required at least 70% agreement. A strong recommendation required 80% agreement.⁴²

RESULTS

Literature Search Results

The complete literature search was then screened for clearly nonpertinent findings; the final bibliography was consistent with the definition of FoCUS and agreed on by the panel. A total of 293 articles

Table 2 Final grading of evidence-based recommendations

| Grade of recommendation | Clarity of risk/benefit | Quality of supporting evidence | Implications |
|--|--|---|--|
| 1A. STRONG recommendation (1), HIGH QUALITY evidence (A) | Benefits clearly outweigh risk and burdens, or vice versa. | Consistent evidence from well performed randomized, controlled trials or overwhelming evidence of some other form. Further research is unlikely to change our confidence in the estimate of benefit and risk. | Strong recommendations, can apply to most patients in most circumstances without reservation. Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present. |
| 1B. STRONG recommendation (1), MODERATE QUALITY evidence (B) | Benefits clearly outweigh risk and burdens, or vice versa. | Evidence from randomized, controlled trials with important limitations (inconsistent results, methodologic flaws, indirect or imprecise), or very strong evidence of some other research design. Further research (if performed) is likely to have an impact on our confidence in the estimate of benefit and risk and may change the estimate. | Strong recommendation and applies to most patients. Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present. |
| 1C. STRONG recommendation (1), LOW QUALITY evidence (C) | Benefits appear to outweigh risk and burdens, or vice versa. | Evidence from observational studies, unsystematic clinical experience, or from randomized, controlled trials with serious flaws. Any estimate of effect is uncertain. | Strong recommendation, and applies to most patients. Some of the evidence base supporting the recommendation is, however, of low quality. |
| 2A. WEAK/CONDITIONAL recommendation (2), HIGH QUALITY evidence (A) | Benefits closely balanced with risks and burdens. | Consistent evidence from well performed randomized, controlled trials or overwhelming evidence of some other form. Further research is unlikely to change our confidence in the estimate of benefit and risk. | Weak recommendation, best action may differ depending on circumstances or patients or societal values. |
| 2B. WEAK/CONDITIONAL recommendation (2), MODERATE QUALITY evidence (B) | Benefits closely balanced with risks and burdens, some uncertainty in the estimates of benefits, risks and burdens. | Evidence from randomized, controlled trials with important limitations (inconsistent results, methodologic flaws, indirect or imprecise), or very strong evidence of some other research design. Further research (if performed) is likely to have an impact on our confidence in the estimate of benefit and risk and may change the estimate. | Weak recommendation, alternative approaches likely to be better for some patients under some circumstances. |
| 2C. WEAK/CONDITIONAL recommendation (2), LOW QUALITY evidence (C) | Uncertainty in the estimates of benefits, risks, and burdens; benefits may be closely balanced with risks and burdens. | Evidence from observational studies, unsystematic clinical experience, or from randomized, controlled trials with serious flaws. Any estimate of effect is uncertain. | Very weak recommendation; other alternatives may be equally reasonable. |

Final grading results from presence and degree of consensus (strength of recommendation) and from level of the quality of evidence. Modified from GRADE guidelines.⁴²

(as of June 2012) were retrieved by the two search tracks. Two additional searches were performed over a 15-month period (June 2012 to September 2013), reaching the final number of 382 articles (Appendix 3 in the ESM). These were individually appraised on the

basis of established methodologic criteria to determine the initial quality level. The final judgment about the quality of evidence-based recommendations was done only after assigning the articles to each statement or question.

Table 3 Literature search terms used

| Medical Subject Heading | Terms |
|-------------------------|---|
| SONOGRAPHY | (sonography OR echography OR ultrasound OR ultrasonography OR ultrasonic) |
| ECHO | (echocardiography OR Cardiac OR cardiologic OR cardiological echocardiography OR echocardiographic OR chest OR heart) |
| EM/CCM | (bedside OR limited OR focused OR emergency OR emergent OR urgent OR urgency OR anesthesia OR intensive care OR critical OR critically ill OR critical care OR shock OR hypotension OR hypotensive OR unstable) |
| TRAUMA | (trauma OR traumatic OR injury OR injured OR injuries OR blunt OR penetrating) |
| OTHER | (accuracy OR accurate OR sensitivity OR sensitive OR specificity OR specific OR predictive OR predict) |
| COST | (cost OR effective OR effectiveness OR efficacy OR efficacious OR efficient OR efficiency OR benefit OR value) |

Search databases: Books@Ovid September 2, 2013; Journals@Ovid full text September 2, 2013; Your Journals@Ovid; AMED (Allied and Complementary Medicine) 1985 to September 2013; CAB Abstracts Archive 1910 to 1972; Embase 1980 to 2013 week 41; ERIC 1965 to September 2013; Google Scholar to September 2013; MEDLINE via PubMed January 1970 to September 2013; Health and Psychosocial Instruments 1985 to September 2013; Ovid MEDLINE In-Process & Other Non-Indexed Citations and Ovid MEDLINE 1948 to present; Ovid MEDLINE 1948 to 2013 week 41; Social Work Abstracts 1968 to September 2013; NASW Clinical Register 14th Edition.

Conference Results

The overall number of statements proposed and examined by the 33 experts at the four meetings was 108. Statements for which there was no agreement or consensus numbered 10. The number of recommendations receiving final approval was 98, presented in Table 4, together with their respective degrees of consensus and quality levels of evidence. Each recommendation is attributed an alphanumeric code including the domain's number and a progressive number.

Specific results, represented by the evidence-based recommendations produced by the conference, are described and commented on in subsequent sections of this report.

Domain 1: TERMINOLOGY

1. The name of this cardiac sonographic examination is focused cardiac ultrasound (FoCUS).

[1C: Strong Recommendation, with Very Good Agreement; Level C Evidence]

Comment. Literature in the past 10 to 15 years has coined different names and acronyms for a variety of focused bedside cardiac ultrasound protocols, with the result being a nonuniform and somewhat confusing definition of this form of point-of-care ultrasound application, including but not limited to focused assessment with transthoracic echocardiography,³ focused echocardiographic evaluation in life support,⁴³ focused echocardiographic evaluation in resuscita-

tion,⁴⁴ bedside limited echocardiography by the emergency physician,⁴ goal-directed transthoracic echocardiography,⁵ goal-oriented hand-held echocardiography,⁶ goal-directed echocardiography,⁴⁵ cardiovascular limited ultrasound examination,¹⁵ focused critical care ultrasound study,⁴⁶ focused cardiovascular ultrasound,⁷ bedside echocardiographic assessment in trauma,⁸ rapid assessment with cardiac echocardiography,⁴⁷ intensivist bedside ultrasound,⁴⁸ focused intensive care echocardiography,⁴⁹ focused rapid echocardiographic examination,⁵⁰ and limited transthoracic echocardiography.⁵¹

Other bedside ultrasound protocols proposed an integration of focused heart scanning with ultrasound applications beyond heart sonography: rapid ultrasound in shock,⁵² abdominal and cardiac examination with sonography in shock,⁵³ undifferentiated hypotensive patient protocol,⁵⁴ and echocardiography-guided life support.⁵⁵ Moreover, the Focused Assessment with Sonography in Trauma (FAST) protocol,⁵⁶ with its evocative name suggesting a quick bedside ultrasound examination, is sometimes used as misnomer for a cardiac ultrasound examination, although limited to the detection of free pericardial, peritoneal, and pleural fluid in the context of trauma.

The cardiac ultrasound examinations described in these publications were performed in different populations and in diverse clinical settings, with a prevalence (though not exclusively) of emergency and critical care scenarios.

With this preliminary statement, the panel identified the name "focused cardiac ultrasound" (FoCUS) as appropriate to define the cardiac ultrasonographic practice object of this international conference and variously studied and published in the literature. Its features are specified in recommendations 2 and 3 and further characterized in domain 3. The panel strongly agreed in identifying a term neutral enough to be "universally" applied to a form of point-of-care cardiac ultrasound investigation, unrelated to any specialty (e.g., emergency medicine, critical care medicine, anesthesiology, cardiology, emergency surgery, internal medicine, general practice, pediatrics), ultrasound machine used (from high-end to pocket-sized devices), or specific clinical scenario (prehospital, emergency department [ED], resuscitation suite, trauma bay, perioperative setting, intensive care unit [ICU], medical and surgical wards, remote or austere scenarios).

At the same time, the panel desired a term specific enough to recall the two major distinctive features of this point-of-care ultrasound application. "Focused" defines its limited scope: to answer specific clinical questions in specific clinical contexts (mostly regarding a symptomatic patient). "Cardiac ultrasound" (as opposed to "echocardiography") clarifies that "focused" does not refer to a circumscribed diagnostic objective regardless of the potential complexity of the cardiac ultrasound technique used; rather, it addresses a basic, simplified approach, clearly distinct from a comprehensive standard echocardiographic examination. Limited echocardiographic studies may also be performed, incorporating only some components of a comprehensive standard examination,²⁵ but differ from FoCUS in terms of complexity of cardiac ultrasound modalities used and competence required.

This terminology helps address the boundary with the full-spectrum application of cardiac ultrasound technique (comprehensive standard echocardiography), as defined by scientific societies,^{24,25} and in line with recommendations specific to the field of emergency and critical care medicine.^{29,31} The same terminology was proposed by a recent ASE and American College of Emergency Physicians consensus document³² and an ASE position paper.³⁴

The present document refers only to the transthoracic cardiac ultrasound technique.

Table 4 Summary table of the grade of recommendations with their levels of evidence and degrees of consensus

| Recommendation N | Statement Code | Recommendation strength | Degree of consensus | Level of evidence |
|---------------------------------------|----------------|-------------------------|---------------------|-------------------|
| Domain 1: TERMINOLOGY | | | | |
| 1 | ICC1.D1.S1 | Strong | Very good | C* |
| 2 | ICC1.D1.S2 | Strong | Very good | C* |
| 3 | ICC1.D1.S3 | Strong | Very good | C* |
| Domain 2: TECHNOLOGY | | | | |
| 4 | ICC1.D2.S1 | Strong | Good | C |
| 5 | ICC1.D2.S2 | NO = disagreement | NO | C |
| 6 | ICC1.D2.S3 | NO = disagreement | NO | C |
| 7 | ICC1.D2.S4 | NO = disagreement | NO | C |
| 8 | ICC1.D2.S5 | Strong | Very good | B |
| 9 | ICC1.D2.S6 | Weak/conditional | Some | B |
| Domain 3: TECHNIQUE | | | | |
| 10 | ICC1.D3.S1a | Strong | Very Good | B |
| 11 | ICC1.D3.S1b | Strong | Very Good | B |
| 12 | ICC1.D5.S15 | Strong | Very Good | B |
| 13 | ICC1.D3.S2a | Strong | Good | B |
| 14 | ICC1.D3.S2b | Strong | Very good | C |
| 15 | ICC1.D3.S2c | Strong | Good | C |
| 16 | ICC1.D9.S8b | Strong | Very Good | C |
| 17 | ICC1.D9.S8c | Strong | Very Good | C |
| 18 | ICC1.D3.S3 | Strong | Good | C |
| 19 | ICC1.D3.S4 | Strong | Very Good | C |
| 20 | ICC1.D3.S5 | Strong | Very Good | C |
| 21 | ICC1.D3.S6 | Strong | Very Good | B |
| 22 | ICC1.D3.S7 | Strong | Very Good | B |
| 23 | ICC1.D3.S8 | Strong | Good | C |
| 24 | ICC1.D3.S9 | Strong | Very good | C |
| 25 | ICC1.D3.S10 | Strong | Very good | C |
| Domain 4: CLINICAL INTEGRATION | | | | |
| 26 | ICC1.D4.S1 | Strong | Very Good | B |
| 27 | ICC1.D4.S2 | Strong | Very Good | B |
| 28 | ICC1.D4.S3 | Strong | Very Good | A |
| 29 | ICC1.D4.S4 | Strong | Very Good | A |
| 30 | ICC1.D4.S5 | Strong | Very Good | B |
| 31 | ICC1.D4.S6 | Strong | Very Good | B |
| 32 | ICC1.D4.S7 | NO = disagreement | NO | C |
| 33 | ICC1.D4.S8 | Strong | Very good | B |
| Domain 5: CLINICAL OUTCOMES | | | | |
| 34 | ICC1.D5.S1 | Strong | Very good | A |
| 35 | ICC1.D5.S2 | Strong | Very good | A |
| 36 | ICC1.D5.S3 | Strong | Good | B |
| 37 | ICC1.D5.S4 | NO = disagreement | NO | C |
| 38 | ICC1.D5.S8a | Strong | Good | B |
| 39 | ICC1.D5.S8b | Strong | Very good | A |
| 40 | ICC1.D5.S5 | Strong | Very good | B |
| 41 | ICC1.D5.S6 | NO = disagreement | NO | C |
| 42 | ICC1.D5.S7 | Strong | Very good | A |
| 43 | ICC1.D5.S9 | Strong | Very good | A |
| 44 | ICC1.D5.S13a | Strong | Very good | A |
| 45 | ICC1.D5.S13 b | Strong | Very good | C |
| 46 | ICC1.D5.S13c | Strong | Good | B |
| 47 | ICC1.D5.S14 | Strong | Very good | B |
| 48 | ICC1.D5.S11 | Strong | Very good | A |
| 49 | ICC1.D5.S12 | Strong | Good | B |
| 50 | ICC1.D2.S16 | Strong | Good | A |
| 51 | ICC1.D5.S10a | Strong | Very good | A |
| 52 | ICC1.D5.S10 b | NO = disagreement | NO | C |
| 53 | ICC1.D5.S10c | Strong | Good | B |
| 54 | ICC1.D5.S10 d | NO = disagreement | NO | C |
| 55 | ICC1.D2.S17 | Strong | Good | B |

(Continued)

Table 4 (Continued)

| Recommendation N | Statement Code | Recommendation strength | Degree of consensus | Level of evidence |
|--|----------------|-------------------------|---------------------|-------------------|
| Domain 6: RISKS | | | | |
| 56 | ICC1.D6.S1 | Strong | Very good | A |
| 57 | ICC1.D6.S2 | Strong | Very good | A |
| 58 | ICC1.D6.S3 | Strong | Good | B |
| 59 | ICC1.D6.S4 | Strong | Very good | B |
| 60 | ICC1.D6.S5 | Weak/Conditional | Some | B |
| Domain 7: COST-EFFECTIVENESS AND SOCIO-ECHONOMICS | | | | |
| 61 | ICC1.D7.S1 | Strong | Very good | B |
| 62 | ICC1.D7.S2 | Strong | Good | C |
| 63 | ICC1.D7.S3 | Strong | Good | C |
| 64 | ICC1.D7.S4 | Strong | Good | B |
| 65 | ICC1.D7.S5 | Strong | Good | C |
| 66 | ICC1.D7.S6 | Strong | Very good | C |
| 67 | ICC1.D7.S7 | Strong | Very good | B |
| 68 | ICC1.D7.S8 | Strong | Very good | B |
| 69 | ICC1.D7.S9 | Strong | Very good | B |
| 70 | ICC1.D7.S10 | Strong | Very good | B |
| 71 | ICC1.D7.S11 | Strong | Very good | C |
| 72 | ICC1.D7.S12 | Strong | Very good | C |
| Domain 8: EDUCATION | | | | |
| 73 | ICC1.D8.S1a | Strong | Very good | B |
| 74 | ICC1.D8.S1b | Strong | Very good | C |
| 75 | ICC1.D8.S1c | Strong | Very good | B |
| 76 | ICC1.D8.S1d | Strong | Very good | C |
| 77 | ICC1.D8.S2 | Strong | Very good | C |
| 78 | ICC1.D8.S3 | Strong | Very good | C |
| 79 | ICC1.D8.S4 | Strong | Very good | C |
| 80 | ICC1.D8.S5 | Strong | Very good | C |
| 81 | ICC1.D8.S6 | Strong | Good | C |
| 82 | ICC1.D8.S7 | Strong | Very good | B |
| 83 | ICC1.D8.S8 | Strong | Good | C |
| Domain 9: CERTIFICATION OF PRACTITIONERS AND ACCREDITATION OF TRAINING PROGRAMS | | | | |
| 86 | ICC1.D9.S3a | Strong | Very Good | C |
| 87 | ICC1.D9.S3b | Strong | Very Good | C |
| 88 | ICC1.D9.S3c | Strong | Very Good | C |
| 89 | ICC1.D9.S4 | Strong | Very Good | B |
| 90 | ICC1.D9.S5 | Strong | Very Good | C |
| 91 | ICC1.D9.S6 | Strong | Very Good | B |
| 92 | ICC1.D9.S7 | Strong | Very Good | C |
| 93 | ICC1.D9.S8a | Strong | Very Good | C |
| Domain 10: PEDIATRICS | | | | |
| 94 | ICC1.D10.S1a | Strong | Very Good | B |
| 95 | ICC1.D10.S1b | Strong | Very Good | B |
| 96 | ICC1.D10.S1c | Strong | Very Good | B |
| 97 | ICC1.D10.S3a | Strong | Very Good | B |
| 98 | ICC1.D10.S3b | Strong | Very Good | B |
| 99 | ICC1.D10.S3c | Strong | Very Good | B |
| 100 | ICC1.D10.S3d | Strong | Very Good | B |
| 101 | ICC1.D10.S3e | Strong | Very Good | B |
| 102 | ICC1.D10.S4a | NO = disagreement | NO | B |
| 103 | ICC1.D10.S4b | NO = disagreement | NO | B |
| 104 | ICC1.D10.S5 | Strong | Very good | B |
| 105 | ICC1.D10.S2a | Strong | Good | C |
| 106 | ICC1.D10.S2b | Strong | Very good | C |
| 107 | ICC1.D10.S7 | Strong | Very good | B |
| 108 | ICC1.D10.S6 | Strong | Good | B |

Once statements (indicated here also with the original alphanumeric code used at the conference) passed the voting, they became recommendations.

*Level evidence C implies a low or very low level of quality of evidence. In domain 1, on terminology, this indicated expert opinion only.

FoCUS Definition. What does the term “focused cardiac ultrasound” identify? What are the features of this ultrasound application?

2. *The definition of FoCUS entails the following features:*

- Goal-directed
- Problem oriented
- Limited in scope
- Simplified
- Time sensitive and repeatable
- Qualitative or semiquantitative
- Performed at the point of care
- Usually performed by clinicians

[1C: Strong Recommendation, with Very Good Agreement; Level C Evidence]

Comment. The statement clarifies the essence of the FoCUS practice and obtained high agreement within the panel. FoCUS is a cardiac ultrasound examination, dictated by a patient’s symptoms (problem oriented) and centered on the search of an answer or solution (goal directed) to a clinically relevant question or problem (e.g., Why is the patient hypotensive? Might the patient benefit from fluid loading? Is there major left ventricular [LV] systolic dysfunction responsible for the shock state?). It is not exhaustive, being focused on elucidating the underlying pathophysiology of a cardiovascular or respiratory critical state (simplified, qualitative), without necessarily aiming at establishing a final diagnosis. It fulfills the needs of critically ill patients (rapid, bedside, available anytime, and repeatable) or in the context in which it is applied (e.g., as a screening tool in more stable patients). It is performed at the point of care and generally by the same physician who manages the patient. The panel identified these as common features of the FoCUS protocols and curricula described in the literature.^{3-8,15,44,46-50,53-55,57}

The technical issues related to this definition were further characterized in domain 3.

3. *FoCUS is a point-of-care application potentially capable of providing information, including physiologic status, that may be critical for patient management in all clinical settings.*

[1C: Strong Recommendation, with Very Good Agreement; Level C Evidence]

Comment. This statement highlights additional characteristics of FoCUS. FoCUS is targeted at obtaining information that is critical for patient management. Similar to all other point-of-care ultrasound applications,⁵⁸ FoCUS is a diagnostic tool tightly integrated into the decision making process, providing information that orients the physician at the key junctions of clinicotherapeutic algorithms.⁵⁹ In this context, the adjective “critical” refers to the patient’s compromised vital parameters but may also allude to the discrepancy between the patient’s needs and available resources, that is, the clinical scenario being critical (e.g., a remote or scarce-resource setting where patients deserve immediate critical decisions about their management and/or transport,⁶⁰ or mass casualty scenarios, where patient screening for triage purposes can be the critical issue).⁶¹ Indeed, screening for relevant cardiac disease in symptomatic but not severely ill patients^{22,62} or in asymptomatic patients^{13,15,17} may also represent a “critical” issue in specific populations such as ED patients or medical clinic outpatients, respectively.

This led the panel to agree on the concept that FoCUS is potentially suitable for all clinical settings in which an answer concerning a patient’s cardiovascular or respiratory status is needed at the point of

care, this is crucial for the patient’s management, and the answer is obtainable by means of a simplified cardiac ultrasound examination.

Domain 2: TECHNOLOGY

Performance and Minimum Requirements of Current Ultrasound Equipment for the Execution of FoCUS. Are mobile, portable, pocket-sized devices equivalent to high-end ultrasound machines for FoCUS performance? What are the minimum requirements of ultrasound machines for FoCUS performance?

4. *FoCUS with current ultrasound machines provides essential information for clinical decision making.*

[1C: Strong Recommendation, with Good Agreement; Level C Evidence]

Comment. The recent availability of smaller, more portable ultrasound machines, meaning hand-carried, pocket-sized,⁶³⁻⁶⁵ and light-cart devices, facilitated the development and diffusion of FoCUS (similarly to other point-of-care ultrasound applications). The panel strongly agreed on the suitability of this type of equipment, when FoCUS is performed, for the provision of critical information for patient management. Numerous studies of FoCUS have successfully assessed the performance of this class of ultrasound platform, regardless of the operator and the setting.^{11,18,20,21,66-92}

5. *FoCUS is equally accurate when done with current ultrasound machines compared with high-end machines in detecting cardiac abnormalities.*

[NO Agreement, NO Recommendation; Level C Evidence]

Comment. Hand-carried and pocket-sized devices use simpler technology and thus present relevant technical and diagnostic limitations in comparison with full functionality platforms (light-cart machines were not included in these comparisons). When echocardiography was performed by experienced operators with comparatively high-end machines and portable devices, results varied according to the targets of the examination considered, ranging from a good agreement (for simple targets such as LV enlargement and systolic dysfunction)^{20,78,80,93,94} to significant superiority of stationary high-end systems (significant number of missed diagnosis by portable machines for nonsevere valve disease and regional wall motion abnormalities).^{76,84,90} Factors related to an intrinsic lack of complex image enhancement and artifact reduction capabilities, to limited acquisition modifications possibility, and to smaller and lower resolution of the screen⁶⁴ may potentially affect the quality of information obtained with FoCUS and its interpretation. This may be relevant in situations in which suboptimal patient echogenicity poses a challenge. Therefore, the panel adopted a cautious judgment and considered inappropriate the equivalence between current hand-carried and pocket-sized devices and fully equipped ultrasound platforms. Awareness of the limitations of portable ultrasound machines by FoCUS practitioners is important: the capability of a careful assessment of image quality and reliability should be part of any FoCUS competency-based training (see recommendation 90).

6. *Current ultrasound machines need to include M-mode imaging to be effectively used for FoCUS.*

[NO Agreement, NO Recommendation; Level C Evidence]

Comment. As detailed in the commentary on recommendation 11, FoCUS does not require any echocardiographic application beyond

two-dimensional (2D) and M-mode imaging (such as Doppler-based techniques). From a technical point of view, this waives the requirement for fully equipped cardiologic platforms. Although many hand-carried devices support M-mode imaging, pocket-sized ones currently do not. The panel believed that the ease of use of pocket-sized devices in the resuscitation setting was more beneficial than the lack of M-mode imaging in these devices and did not want to prescribe their use. The panel agreed that although M-mode imaging may be useful for the evaluation of certain aspects of cardiac function and pathology,⁹⁵ and indicated as an additional scanning modality by current recommendations on echocardiographic studies,²⁸ sufficient analogous information can be garnered in the simplified goal-oriented FoCUS approach through 2D interrogation. This statement was therefore considered inappropriate. M-mode imaging can represent an additional valuable feature of the FoCUS examination, but the lack of M-mode functionality should not represent a criterion for considering ultrasound equipment inadequate for FoCUS.

7. *Current ultrasound machines need the ability to synchronize imaging with electrocardiographic (ECG) tracings to be effectively used for FoCUS.*

[NO Agreement, NO Recommendation; Level C Evidence]

Comment. Current echocardiography guidelines recommend electrocardiographically gated acquisition as a minimum quality standard for echocardiography laboratory operations.^{25,27} Just a minority of hand-carried and no pocket-sized devices currently allow ECG acquisition. For the purpose of FoCUS, which does not require Doppler study and targets only severe morphologic and functional abnormalities, the correct timing of cardiac events does not usually require electrocardiography. This statement was therefore considered inappropriate. Should any interpretative doubt relevant to diagnosis and concerning cardiac event timing arise, referral for comprehensive standard echocardiography is strongly advocated, as part of the customary FoCUS approach (see ICC.D3.S1 a-b).

8. *Current ultrasound machines used for FoCUS should be able to store images.*

[1B: Strong Recommendation, with Very Good Agreement; Level B Evidence]

Comment. Consistent with recommendation 23, the panel strongly recommends, with very good agreement, that ultrasound devices be capable of image archiving. Despite the different goals and content of the two practices, FoCUS shares with comprehensive standard echocardiography the need for image storage^{25,27,28,31,32} for the purpose of consultation and information sharing, quality assurance and education, and medicolegal documentation.

9. *A phased-array transducer is suggested for FoCUS, although adequate images may be obtained with other probes.*

[2B: Weak/Conditional Recommendation, with Some Agreement; Level B Evidence]

Comment. Transthoracic comprehensive standard echocardiography demands the use of phased-array probe(s) supporting the full range of echocardiographic applications.^{25,28} Because FoCUS uses primarily 2D and M-mode imaging, it may theoretically be performed with other types of probes, provided suitable frequencies and adequate machine settings are used. This has traditionally been quite common in the emergency setting⁹⁶ and is often practiced when FoCUS is performed as part of a whole-body ultrasound examination^{56,59} with a single probe.⁹⁷ With special reference to scarce-resource settings,

the panel expressed consensus in not precluding the use of alternative probes. "Cardiac" phased-array probes are, however, recommended by the panel as the first choice (weak or conditional recommendation), when available, as they provide a better image resolution.

Domain 3: TECHNIQUE

FoCUS Goals and Limitations. What are the practical goals of a FoCUS examination? Which cardiac ultrasound modalities does FoCUS entail? What is within FoCUS's diagnostic purview? Who should perform FoCUS?

10. *FoCUS aims to gather sufficient information to assess physiologic status and essential differential diagnoses.*

[1B: Strong Recommendation, with Very Good Agreement; Level B Evidence]

Comment. This statement was meant to define the overall scope of FoCUS and to highlight the principles of FoCUS practice common to all point-of-care ultrasound applications.^{58,59,98} The panel identified as primary goals of FoCUS the understanding of patients' cardiovascular physiology and pathophysiology and the "reduction of diagnostic uncertainty." The first goal represents the "physiologic rationale" of FoCUS use. The second, its capability of narrowing the range of viable diagnoses, provides the major added value of FoCUS in clinical practice^{7,9,43,99-103} and a surrogate primary outcome in studies on FoCUS effectiveness.¹⁰⁰

The term "sufficient information," despite its apparent vagueness, defines the framework of this simplified approach: the search for gross pathologic cardiovascular findings consistent with the clinical picture to enhance the diagnostic process, even when used in a rule-in/rule-out fashion. It sets a clear boundary when compared with comprehensive standard echocardiography, which is aimed at conclusive diagnoses and monitoring of cardiac diseases. Thus, FoCUS is conceived as a targeted diagnostic test rather than as comprehensive diagnostic test and should trigger consideration of referral to comprehensive standard echocardiography when findings are not conclusive and/or fall beyond the boundaries of the technique.³⁴

Consistent with recommendation 3, care was taken by the panel to leave the statement's phrasing so as to apply not only to cardiac ultrasound practice in critically ill patients but also to a wider medical praxis potentially entailing all specialties in which cardiovascular clinical assessment is performed.

11. *FoCUS is carried out to facilitate decision making mainly in a binary (yes or no) fashion.*

[1B: Strong Recommendation, with Very Good Agreement; Level B Evidence]

Comment. The essence of FoCUS is mainly a dichotomous interpretation of the findings to answer questions that are crucial to the clinical decision-making process. The diagnostic approach of FoCUS is qualitative or semiquantitative.¹⁰⁴ Consistent with the FoCUS definition in recommendation 2, the examination is conducted without the requirement of performing specific measurements. Qualitative appreciation of sizes and function (e.g., the right ventricle is dilated or non-dilated, normokinetic or hypokinetic) or semiquantification of ranges of function (e.g., the left ventricle is hyperkinetic, normokinetic, hypokinetic, or severely hypokinetic) represents the modus operandi of FoCUS. Evidence in the literature shows good agreement between data obtained by this qualitative approach and comprehensive standard echocardiography on selected diagnostic targets.^{7,74,80,104-106}

The magnitude of the target pathologic findings of FoCUS, their context-sensitive interpretation in selected areas of the clinical workup, and clear knowledge of its limitations represent the prerequisites for both FoCUS diagnostic accuracy and feasibility with focused training.

Modalities other than 2D and M-mode imaging were not addressed by the panel. At this time, there is insufficient information to determine their role in FoCUS. It is recognized that these modalities might require training beyond that currently attained by most practitioners of FoCUS and may be fraught with the burden of greater potential pitfalls.

Although the visual use of color Doppler could be applied in specific clinical conditions to address patients toward comprehensive standard echocardiographic examination, there are only scarce data on the use of Doppler modalities for FoCUS examinations¹⁰⁷⁻¹¹⁰; the majority of validation studies of the FoCUS technique and previously published international guidelines have been limited to 2D and M-mode modalities.^{3-6,15,44,47,48} Indeed, the previous guidelines do not consider color Doppler a basic cardiac ultrasound technique³² or simply cautiously recommend it as a screening tool.^{30,34,111}

12. *FoCUS should be performed by appropriately trained clinicians treating the patient.*

[1B: Strong Recommendation, with Very Good Agreement; Level B Evidence]

Like other point-of-care ultrasound applications,⁵⁸ FoCUS is a clinician-performed, limited diagnostic test. It is conceived as an aid to patient management and is expected to be performed by the clinicians attending the patient.^{3-8,15,44,46-50,53-55,57} As detailed in domain 9, competence in FoCUS, achieved by means of adequate training, is the prerequisite for its practice.

FoCUS Diagnostic Targets. Which are the specific diagnostic targets of a FoCUS examination? When should FoCUS trigger comprehensive echocardiography referral?

13. *The aim of a FoCUS examination is to establish etiologies, which may include assessment of*

- *LV dimensions and systolic function*
- *Right ventricular systolic function*
- *Volume status*
- *Pericardial effusion and tamponade physiology*

[1B: Strong Recommendation, with Good Agreement; Level B Evidence]

14. *The aim of a FoCUS examination is to establish etiologies, which may include*

- *Detection of gross signs of chronic cardiac disease*

[1C: Strong Recommendation, with Very Good Agreement; Level C Evidence]

15. *The aim of a FoCUS examination is to establish etiologies, which may include*

- *Detection of morphologic clues toward gross valvular disease*
- *Detection of gross intracardiac masses*

[1C: Strong Recommendation, with Good Agreement; Level C Evidence]

Comment. These three linked statements define the specific targets of a FoCUS examination, further characterizing the boundaries of FoCUS practice with respect to comprehensive standard echocardiography and outlining a suggested core content of a FoCUS curricu-

lum. Indeed, acute LV and right ventricular dysfunction, hypovolemia, and tamponade represent major underlying causes of shock and dyspnea and potentially treatable mechanical causes of cardiac arrest. A number of publications in the domains of educational and clinical research suggest that these are appropriate targets of simplified cardiac ultrasound approaches, especially in the emergency and critical care settings.^{4,5,8,9,11,18,20,23,44,47,48,53,57,112-115} This is also consistent with position statements and recommendations issued by several scientific societies, both in the cardiology and critical care fields,^{29,31,32,116} and with several curricula for critical care ultrasound currently proposed.^{29,30,46,59,117} The identification of FoCUS diagnostic targets listed in recommendation 13 obtained strong agreement in the panel.

Additionally, screening for gross signs of cardiac disease (i.e., major LV dilatation or severe hypertrophy, right ventricular hypertrophy, major atrial dilatation), again in a qualitative fashion, was believed to be an essential part of a FoCUS examination. Recommendation 14 was more problematic despite the final very good agreement. Agreement was reached thanks to the acknowledgment of the relative ease in diagnosing these conditions with focused training^{6,50,107,118-122} and of the relevant consequences of neglecting to assess for gross signs of chronic cardiac disease. In the context of critical care, missing the chronic nature of right ventricular dysfunction, for example, may lead the unaware FoCUS practitioner to misdiagnose chronic cor pulmonale as acute cor pulmonale. Similarly, searching for a hyperdynamic small left ventricle as a criterion for diagnosing hypovolemia in a patient with dilated cardiomyopathy may be highly misleading.

There was considerable debate over whether to consider valvular disease as part of the FoCUS examination. The panel acknowledged that the assessment of cardiac valves is complex, entailing pulsed- and continuous-wave Doppler as well as color Doppler techniques,¹²³⁻¹²⁵ requiring full comprehensive standard echocardiography training, and thus is well beyond the scope of FoCUS. However, appreciation of the potential role of severe valvular dysfunction in shock and heart failure can undoubtedly be lifesaving.¹²⁶ Given a critical scenario, FoCUS may include the assessment of gross valvular findings (i.e., leaflet or cusp flail, evident disruption or thickening of the valvular apparatus, or masses attached to valves). Recognition of major valve disease on the basis of simple morphologic findings has been demonstrated as feasible with pocket-sized devices^{74,80,119,127} and by non-cardiologists,¹¹⁹ as well as by operators with limited training.¹²⁷⁻¹²⁹ The panel acknowledged that, distinct from the diagnosis of other causes of shock, evidence in this area is not well established. Nevertheless, the recommendation was felt necessary because of the clinical relevance of the issue and the common experience of panelists. Care was taken in defining an appropriate target for FoCUS to include only “clues toward gross valvular disease,” to emphasize the limited role of the FoCUS examination in this regard: to appreciate suspected valve dysfunction and in an appropriate time frame recommend additional evaluation by comprehensive standard echocardiography.

The panel agreed that all these targets of the FoCUS examination (Table 5), in addition to their clinical relevance in the critical patient, share the features of being detectable with a simple technique and of attaining proficiency with focused training. They are suitable not only to the critical setting but also in a context of disease screening in asymptomatic patients with a view to ongoing referral,^{23,111,130} and to complement the clinical examination.^{64,131} A “pattern recognition” interpretation is the basis for this simplified approach: recognizing a few distinctive features of the cardiac ultrasonographic picture, whose combined detection is highly likely to be associated

Table 5 Suggested targets of the FoCUS examination

| |
|---|
| LV dimension, systolic function |
| RV systolic function* |
| Volume status |
| Pericardial effusion, tamponade physiology† |
| Gross signs of chronic heart disease‡ |
| Gross valvular abnormalities§ |
| Large intracardiac masses |

LV, Left ventricular; RV, right ventricular.

*RV size is considered an intrinsic element of RV systolic function evaluation (i.e., a failing right ventricle will initially dilate).

†Cardiac tamponade physiology assessment refers to the observation on two-dimensional imaging of basic signs of compression of right-sided chambers (systolic collapse of the right atrium, diastolic collapse of the right ventricle) rather than Doppler-based study of intracardiac flows.

‡Signs of chronic heart disease are considered as relevant LV or left atrial dilatation, relevant right atrial dilatation, marked LV or RV hypertrophy (RV dilatation can occur acutely or be consequence of a chronic process). Assessment of heart chamber size and myocardial thickness is proposed as qualitative assessment, consistently with FoCUS methodology.

§Valvular abnormalities recognizable with FoCUS (without the use of Doppler-based techniques) entail leaflet or cusp massive disruption or marked thickening, flail, or anatomic gaps.

||Refers to large valve vegetations or visible intracardiac or inferior vena cava thrombi.

to the suspected pathophysiology. Explicative FoCUS patterns are detailed in Appendix 4 in the ESM and [Videos 1 to 12](#) (available at www.onlinejase.com).

16. *Given the limitations of FoCUS, patients with abnormalities detected by FoCUS that are beyond the scope of the examination should be referred for comprehensive standard echocardiographic evaluation.*

[1C: Strong Recommendation, with Very Good Agreement; Level C Evidence]

17. *Given the limitations of FoCUS, patients in whom there is suspicion of undetected cardiac pathology should be referred for comprehensive standard echocardiographic evaluation.*

[1C: Strong Recommendation, with Very Good Agreement; Level C Evidence]

Comment. The expert panel acknowledged that FoCUS is not intended to be a comprehensive standard echocardiographic examination, that not all cardiac pathology may be detected by FoCUS, and that not all detected pathology may be fully examined or elucidated with FoCUS. The panel therefore strongly recommended that all patients in whom pathology is detected that falls out of the scope of FoCUS, or in whom pathology undetected by FoCUS is suspected, should be referred for formal comprehensive standard echocardiographic evaluation.^{29,116,132,133}

FoCUS Technique. Which echocardiographic views should be part of a FoCUS examination? Which scanning approach should be adopted? Should FoCUS examinations be reported and archived?

18. *A FoCUS examination does not require the execution of all the views of a comprehensive standard echocardiographic examination. A limited num-*

ber of views, such as subcostal long axis, subcostal inferior vena cava (IVC), parasternal long axis, parasternal midpapillary short axis, and apical four chamber, can suffice to allow confirmation of findings. More than one view is to be obtained if required and clinical status allows.

[1C: Strong Recommendation, with Good Agreement; Level C Evidence]

Comment. The statement suggests that the simplified nature of the FoCUS examination is characterized not only by the cardiac ultrasound modalities applied but also by the limited number of views deployed in contrast to comprehensive standard echocardiography ([Figure 1](#)). Validation studies, published protocols on bedside limited cardiac ultrasound,^{4-6,8,9,23,44-48,53,57,112,134} and guidelines³⁰ suggest the use of a limited number of views. This serves the crucial purpose of fitting the examination to time-sensitive scenarios. The statement clarifies that this is valid as long as a diagnosis is made but should prompt extension to additional views as required. Whenever possible, a combination of views should be obtained, although not all of them may be achievable with the same ease in the critical setting.^{68,135} Ideally, each target structure should be visualized in at least two different views to confirm the findings, provided the patient's condition allows it. The set of views indicated in the statement was selected on the basis of this concept. When time permits, a FoCUS standard acquisition protocol should entail the aforementioned views. In extreme situations with the greatest time sensitivity (such as cardiac arrest), even a single view may suffice⁴⁴: accuracy in identifying major cardiac arrest causes will be reasonably maintained by such an approach because of the expected magnitude of pathologic findings.^{43,101,136}

19. *A systematic approach with FoCUS, going through multiple views in a protocolized approach, is recommended.*

[1C: Strong Recommendation, with Very Good Agreement; Level C Evidence]

Comment. The panel expressed consensus in favor of a systematic approach for the FoCUS examination, in line with recommendation 18 and to increase the accuracy of FoCUS. Although this remains unproven, it is reasonable to think that going through most or all views of a FoCUS examination in a standardized way increases its screening capabilities for the various shock-related abnormalities. Furthermore, specific studies on FoCUS describe a protocol-based approach^{9,23,44,53,54,57,112}: the protocolized approach is preferred to promote correct integration within the clinical diagnostic workup, respecting the patient's needs dictated by the clinical picture. Again, FoCUS is not intended as a complete diagnostic evaluation but rather as a bedside diagnostic and management tool to be integrated into the existing clinical and resuscitation protocols.

The importance of a protocol-based approach is further stressed in domain 4, in which the issue of advanced life support (ALS) compliance is discussed.⁴³

20. *When performed for serial examinations, FoCUS can be simplified by assessing only a single or few targets of interest.*

[1C: Strong Recommendation, with Very Good Agreement; Level C Evidence]

Comment. With this statement, a specific and not at all infrequent situation in emergency and critical care practice was taken into consideration by the panel: when recognition of the reason(s) for cardiovascular failure has already been achieved, observation over

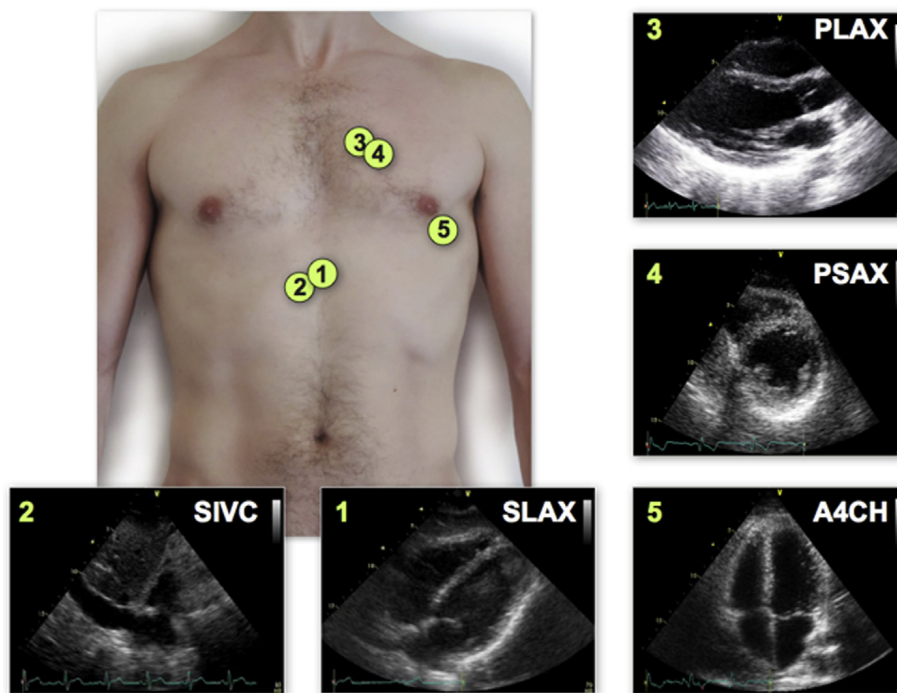


Figure 1 Ideal standard set of views for FoCUS: (1) Subcostal long axis (SLAX), (2) subcostal inferior vena cava (SIVC), (3) parasternal long axis (PLAX), (4) parasternal short axis (PSAX), and (5) apical four chamber (A4CH).

time may be required (e.g., severe hypovolemia has been detected and is now being treated). The panel agreed that for this purpose, there may be no need to repeat a complete FoCUS examination but rather to limit it to the specific target.^{103,137} This addresses the concept of sequential assessment for monitoring clinical evolution and therapy efficacy, again from a patient-management rather than from a merely diagnostic perspective. Provided this remains within the domain of FoCUS (see recommendations 3, 10, 11, and 13–15 regarding FoCUS features and content), this can be accomplished in an abbreviated examination. As in comprehensive standard echocardiography, the best technique for comparing serial changes in FoCUS findings is to use the same view, machine settings, and sector size and, when possible, to perform side-by-side comparisons on the screen.²⁸

21. *In nonshockable rhythm cardiac arrest, FoCUS should be performed in an ALS-conforming manner, following a specific protocol.*

[1B: Strong Recommendation, with Very Good Agreement; Level B Evidence]

Comment. The performance of FoCUS in cardiac arrest scenarios is subject to obvious time constraints and to the need not to hinder in any way the execution of resuscitative maneuvers. ALS guidelines emphasize as priority with relevant prognostic implications¹³⁸ the limitation of “no-flow” intervals exclusively to pulse-check pauses, with the goal of maximizing overall perfusion time.¹³⁹ This renders the need for a systematic, protocol-based approach for FoCUS even more compelling than in shock states. Protocol-based ALS-compliant cardiac ultrasound use, such as in the focused echocardiographic evaluation in life support procedure,^{44,140} has proved to be feasible and associated with adequate image quality yield,⁴³ no additional chest compression interruption time,^{43,44} and relevant diagnostic information capable of affecting management.⁴³ The panel thus strongly recommends, with very good agreement, that the use of FoCUS in nonshockable rhythm cardiac arrest should be preceded and fol-

lowed by high-quality cardiopulmonary resuscitation, timed to perfectly fit into the 10-sec pulse check, within an effective, standardized, algorithmic execution scheme.⁴⁴

22. *For patients in cardiac arrest, the subcostal view may be attempted first. If not sufficient to image the heart, the apical four-chamber view or parasternal long-axis view may be attempted next, as long as conforming to ALS protocol.*

[1B: Strong Recommendation, with Very Good Agreement; Level B Evidence]

Comment. A number of scanning protocols were reviewed by the panel for patients in cardiac arrest. Although there have not been detailed assessments of each protocol in a prospective and comparative manner, the consensus of this panel was that it is reasonable to start with the subxiphoid view in arrest patients⁴⁴ so as not to interrupt chest compressions given the emphasis of current resuscitative guidelines on continuous compressions. If acceptable images are not obtained in the subcostal plane, the panel agreed that either the apical four-chamber or the parasternal long-axis view could be assessed during a pulse check, again as long as the acquisition of images does not delay standard resuscitation protocols. There is some evidence that this can be done with training.¹⁴¹

23. *It is recommended that FoCUS examination images and videos be stored.*

[1C: Strong Recommendation, with Good Agreement; Level C Evidence]

Comment. With this statement, the panel advocates that FoCUS studies be recorded and stored for subsequent analysis, review, and comparison of findings. In the context of the simplified cardiac ultrasonographic approach within the FoCUS technique, as a diagnostic tool and complement to the physical examination, the panel believed

that image and video archiving serves multiple objectives relevant to quality assurance of this practice: case retrieval for confirmation of findings, information sharing for better patient care, robust clinician feedback, and, as needed, referral to higher competence, sequential patient assessment purposes, and medicolegal documentation.^{28,31,32} The issue of the choice of storage medium was judged moot by the panel, given that ultrasound machines currently used for FoCUS are nearly always devices with digital storage capacity rather than analogue videotape storage systems. Furthermore, almost all ultrasound machines, from stationary high-end systems to miniaturized devices nowadays offer digital storage capabilities.

24. *Whenever FoCUS is performed, the findings of the examination should be appropriately documented. FoCUS examination reporting can be effectively accomplished by means of simplified, standardized forms.*

[1C: Strong Recommendation, with Very Good Agreement; Level C Evidence]

Comment. The issue of reporting examinations is addressed in recommendations by echocardiography societies.²⁸ For the purpose of quality assurance, these mandate not only a minimal standard acquisition and storage protocol (minimum data set of views, modalities, and measurements) but also standardized reporting. The panel acknowledged that these recommendations cannot be applied (in terms of specific content) to FoCUS, which is a simplified form of cardiac ultrasound, different in scope and technique from comprehensive standard echocardiography. But as with image storage, keeping a record of what was diagnosed with FoCUS, ideally in a report, is essential for the purpose of proper medical documentation,²⁸ case review, and patients' information sharing. FoCUS documentation was therefore judged as mandatory. Because FoCUS examination findings are often acted on contemporaneously, reporting must be completed in a timely fashion, as with all documentation of the specific episode of care, and should not be excessively time consuming. For this reason, the panel suggested the use of simplified standardized report forms, with box checking and minimal free text consistent with the brevity of the FoCUS examination. FoCUS reports should ideally be organized in different sections, including demographics data, minimal clinical data, findings, summary, date, and signature. Examples of these FoCUS-specific report forms can be found in ESM Appendix 5 (focused echocardiographic evaluation in life support, focused assessment with transthoracic echocardiography, and FoCUS report forms).^{29,112,142} Description of findings and summary should be consistent with goals and targets of FoCUS as outlined in recommendations 10 to 15. Referral for consultation by a more experienced operator or for comprehensive standard echocardiography should be an option explicitly provided for in the report.

25. *There are multiple, well-established standards of image orientation. Practitioners may receive training in any of these standards and may adopt conventional views used by the trainer.*

[1C: Strong Recommendation, with Very Good Agreement; Level C Evidence]

Comment. This statement acknowledges that there are a variety of different ways to perform cardiac ultrasound, in terms of probe orientation and corresponding display of the image and the indicator on the screen.^{9,23,25,28,29,31,48,96,112,143,144} This reflects different imaging conventions in the practice of clinician-performed ultrasound across the various medical specialties: differences are encountered between emergency physicians, intensivists, and cardiologists. Regardless of these differences, all these training and examination

approaches may be equally valid in their educational output and in achieving proficiency in clinical practice. The crucial issue is maintaining internal consistency within the individual system of standard views adopted.

Domain 4: CLINICAL INTEGRATION

FoCUS Clinical Utility. What are the clinical conditions for which FoCUS has the potential to provide information useful for patient management? What is the added value of FoCUS in the clinical setting?

26. *In the prehospital setting, FoCUS can help triage patients to appropriate care centers.*

[1B: Strong Recommendation, with Very Good Agreement; Level B Evidence]

Comment. There has been increasing interest in training prehospital medical personnel in point-of-care ultrasound techniques over the past decade, partly because having diagnostic information in a resource limited setting can be useful in focusing efforts on fewer potential diagnoses.¹⁴⁵ One of the challenges when evaluating the evidence behind this effort globally is that not all prehospital settings are staffed with the same level of provider, and the evidence for prehospital ultrasound does not always separate point-of-care ultrasound applications into cardiac and non-cardiac examinations. However, there is increasing evidence that training in focused cardiac applications can be successful both in systems that primarily are staffed by paramedics^{146,147} and in those that are primarily staffed by physicians.¹⁴⁸ There are a few studies, in addition, suggesting that FoCUS with limited goals (cardiac activity present or absent) in a specific subset of patients (cardiac arrest) can predict patient outcomes and may have a role in the decision to transport or not to the hospital.¹⁴⁹ Technology has broadened the user base for prehospital FoCUS examinations as evidence has grown that remote image guidance or "teleradiology" can help novice users acquire adequate images successfully and expediently.¹⁵⁰

Therefore, the panel agrees that the incorporation of the FoCUS examination into the prehospital evaluation of patients has enough evidence in specific patient care scenarios to make this a strong recommendation.¹⁵¹

27. *FoCUS identifies patients who may benefit from fluid loading.*

[1B: Strong Recommendation, with Very Good Agreement; Level B Evidence]

Comment. There has been a consistent effort to define what ultrasound findings (indeed what ultrasound applications) can be helpful in determining fluid responsiveness over the past decade. The literature on this topic has proliferated in the past few years, such that multiple techniques have been suggested to help guide this omnipresent decision for care providers managing shock states. The challenge here is that the literature on vena cava indices, stroke volume variations, global end-diastolic volume indices, aortic flow peak velocity, and many other dynamic techniques has often been applied to a heterogeneous population of shock states. When the evaluation is limited to a FoCUS examination, however, there are distinct parameters for which there is some evidence supporting a FoCUS assessment of volume status, especially in the early stages of shock, and thus by extrapolation a diagnosis of clinically relevant hypovolemia (intended as a condition of pronounced cardiac preload defect, with an expected beneficial clinical response to fluid loading). The presence of a small

hyperkinetic LV cavity that obliterates during systole has been demonstrated to correlate with marked volume depletion.¹⁵² This can be confirmed with the detection of a small, collapsible IVC^{137,153} and small right ventricle.¹⁵⁴ Other authors have defined a population of septic patients on mechanical ventilation with no respiratory effort who have an increase in cardiac output when the IVC distends from 12% to 18% with the respiratory cycle.¹⁵⁵⁻¹⁵⁷ These articles generated much enthusiasm, and the concept of a distensible venous system that is not at full capacity continues to inspire research efforts.

In conditions other than passive mechanical ventilation (spontaneous breathing, assisted and noninvasive ventilation) when the passive leg-raising technique is combined with an ultrasound assessment of venous capacitance or cardiac output, the evidence is more robust, and this can be a helpful predictor of the need for volume.¹⁵⁸⁻¹⁶⁰ But this requires the use of pulsed-wave Doppler.

There have been studies in trauma patients demonstrating that a small, collapsible, IVC—even with negative results on a FAST examination—is a strong predictor of hemorrhagic shock that will respond to volume.¹⁰³ Accuracy of IVC size and collapsibility may, however, be limited in early stages of hemorrhage.¹⁶¹ A screening look at the IVC in a multitrauma or disaster scenario has been advocated to help triage patients.¹⁶² Finally, technical caveats in IVC size and behavior assessment should not be neglected,^{163,164} and conflicting results on IVC collapsibility should be taken into account.¹⁶⁵

28. *FoCUS is useful to narrow the differential diagnosis in patients with undifferentiated shock.*

[1A: Strong Recommendation, with Very Good Agreement; Level A Evidence]

Comment. Several studies have used focused ultrasound protocols to assess patients in undifferentiated shock states to good effect. Often, these protocols incorporate other point-of-care ultrasound applications (lung ultrasound, IVC assessment, FAST screening) in addition to FoCUS, but almost uniformly, they have demonstrated utility in enabling the clinician to rule out and rule in potential causes of the shock state. For example in Jones *et al.*'s¹⁰⁰ randomized trial assessing diagnostic thinking effectiveness, clinicians who performed ultrasound immediately in the evaluation of patients with undifferentiated hypotension in the ED narrowed their potential diagnoses list by almost 50% compared with those who followed a delayed ultrasound evaluation protocol. The FoCUS examination was management changing or supplementary in more than half of the patients in whom the examination was performed in an ICU setting.³ This narrowing of differential diagnoses is also supported by two studies^{43,166} conducted in very different settings, but in both cases, the diagnostic narrowing translated into a change in management.

29. *During pulseless electrical activity cardiac arrest, FoCUS identifies patients with myocardial mechanical activity and those with none.*

[1A: Strong Recommendation, with Very Good Agreement; Level A Evidence]

Comment. Several large observational studies have looked at using FoCUS in pulseless electrical activity arrest to identify those patients with some myocardial mechanical activity because of the survival benefit this confers on an otherwise undifferentiated population of arrest patients. If myocardial activity is seen, FoCUS can also be useful to help look for reversible causes of the shock state (pericardial effusion, massive pulmonary embolus, and pneumothorax) and can expedite treatment.¹⁶⁷⁻¹⁶⁹ In contrast, those patients in whom there is no cardiac

activity have a much lower survival rate, and as such, several studies have looked at whether there are specific patient populations (patients who arrive in the ED with ongoing resuscitation, for example) in whom the FoCUS examination could be used to guide in which patients resuscitative efforts should be continued.^{170,171} Because of this level of consistent evidence, the evaluation with FoCUS to look for mechanical activity was strongly supported by the panel.

30. *FoCUS risk-stratifies patients with pericardial effusion.*

[1B: Strong Recommendation, with Very Good Agreement; Level B Evidence]

Comment. There is good evidence that pericardial effusions can be detected with high accuracy by clinicians trained in FoCUS techniques.^{120,172} There is emerging evidence that in patients with hemodynamic instability or shock states, the identification of an unexpected pericardial effusion can lead to a more directed diagnostic approach identifying critical illness (aortic dissection, new metastatic disease) and more expeditious interventions (urgent drainage, volume resuscitation).¹⁶⁷

31. *FoCUS directs the management of patients with LV systolic dysfunction.*

[1B: Strong Recommendation, with Very Good Agreement; Level B Evidence]

Comment. There has been good evidence that clinicians can be trained in the global assessment of systolic function.^{105,173} It is also well established that visual estimations of global function approximate formal quantitative methods in trained observers.¹⁰⁴ In fact, transthoracic echocardiography provides similar information to pulmonary artery catheters.¹⁷⁴

It follows that if FoCUS can rule in or rule out categories of shock and the clinician can be guided toward a more directed resuscitation, the effort to train in FoCUS would be effective. For example, among ED patients with nontraumatic undifferentiated symptomatic hypotension, the presence of a hyperdynamic left ventricle on FoCUS is highly specific for sepsis as the etiology of shock and had a likelihood ratio of 5.3 for predicting sepsis.⁹⁹ Moreover, the assessment of cardiac function in patients presenting to the ED with cardiac-related symptoms had prognostic value, as the age-adjusted prevalence of major cardiac events was >8 times greater in patients with depressed LV function.¹⁷⁵

32. *FoCUS directs the management of patients with LV diastolic dysfunction.*

[NO Recommendation, NO Agreement; Level C Evidence]

Comment. There was no agreement on this statement, and there was no recommendation to incorporate this into a guideline for FoCUS applications. Insufficient evidence exists on the diagnosis of diastolic dysfunction and elevated LV filling pressures by minimally trained physicians.¹⁷⁶ The assessment of patients with diastolic dysfunction was thought to require more training and a greater facility with Doppler than what is generally considered to be the skill set for clinicians using the FoCUS examination.

33. *FoCUS is an essential part of the initial assessment of patients with cardiopulmonary instability.*

[1B: Strong Recommendation, with Very Good Agreement; Level B Evidence]

Comment. There is growing evidence that in patients with shock, FoCUS can help narrow the differential diagnosis, rule in or rule out categories

of shock, identify reversible causes of hypotension, and guide therapeutic interventions if reversible causes are found. This is not a new body of literature, and it has been slowly added to over the past 30 years. Twenty-five years ago, the suggestion that FoCUS could influence resuscitation and expedite treatment for critically ill patients was made in a study looking at ED patients.¹⁷⁷ More than 20 years ago, there was evidence that a screening assessment of LV function could have prognostic implications for major cardiac events and could identify patients who were at high risk for such events from the ED.¹⁷⁵ Furthermore, the identification of organized cardiac activity during resuscitation has a predictive value for return of spontaneous circulation. Sufficient studies have evidenced that FoCUS to look for myocardial activity should be a standard step in cardiac resuscitation.¹⁷⁸ Current research has looked more at narrowing of potential causes for shock^{52,100} and integrating a FoCUS assessment into a resuscitation protocol.⁴⁴

Domain 5: CLINICAL OUTCOMES

Comment. It seems like common sense that a diagnostic test that provides clinicians with timely information about cardiac structure and function will lead to better management and clinical outcomes, especially in critically ill patients. However, it is difficult to prove that diagnostic information improves clinical outcomes, and evidence for the use of many common diagnostic tests is lacking.¹⁷⁹⁻¹⁸¹ The ideal method to demonstrate how FoCUS improves clinical outcomes would be a randomized study of FoCUS versus no FoCUS in a group of critically ill patients; however, randomizing patients to no FoCUS in 2014 would likely be unethical. In situations such as this, when a randomized trial is impractical, expert opinion and consensus using the Delphi method may be the only reasonable approach.

Cardiac Arrest. Does FoCUS improve diagnostic accuracy when used in cardiac arrest? Does the use of FoCUS affect patient management and outcome in cardiac arrest?

34. *In the setting of cardiac arrest, FoCUS is more accurate than electrocardiography for determining mechanical cardiac function.*

[1A: Strong Recommendation, with Very Good Agreement; Level A Evidence]

35. *In the setting of cardiac arrest, FoCUS changes management.*

[1A: Strong Recommendation, with Very Good Agreement; Level A Evidence]

36. *In the setting of cardiac arrest, FoCUS improves the clinician's ability to predict outcome.*

[1B: Strong Recommendation, with Good Agreement; Level B Evidence]

37. *In the setting of cardiac arrest, FoCUS improves outcome.*

[NO Recommendation, NO Agreement; Level C Evidence]

38. *In the setting of cardiac arrest, FoCUS is more accurate than the physical examination for diagnosing the cause of cardiac arrest.*

[1B: Strong Recommendation, with Good Agreement; Level B Evidence]

39. *In the setting of cardiac arrest, FoCUS is more accurate than the physical examination for assessing cardiac function.*

[1A: Strong Recommendation, with Very Good Agreement; Level A Evidence]

Comment. In the setting of cardiac arrest, several large observational trials have revealed that FoCUS helps clinicians rapidly determine the cause of cardiac arrest, changes management, and predicts outcomes. More than 25 years ago, clinicians realized that FoCUS could provide rapid and accurate diagnostic information about cardiac structure and function, which was especially useful for managing patients in cardiac arrest.^{177,182,183} In 2010, Breitkreutz *et al.*⁴³ published the results of a prospective trial in which FoCUS was used during cardiac arrest resuscitation in 204 patients. Images of diagnostic quality were obtained in 96%. In 35% of those with ECG diagnoses of asystole, and 58% of those with pulseless electrical activity, coordinated cardiac motion was detected and associated with increased survival. Most important, FoCUS changed the management of cardiac arrest in 89% of these patients.⁴³ Blaivas and Fox,¹⁷¹ Salen *et al.*,¹⁷⁸ and Aichinger *et al.*¹⁴⁹ demonstrated that the presence or absence of kinetic cardiac activity by FoCUS predicts cardiac arrest outcomes. Prosen *et al.*¹⁸⁴ used FoCUS to modify their ALS algorithm.¹⁸⁴ In pulseless patients who had organized cardiac activity by FoCUS, they prolonged the compression pause pulse check for 15 sec and administered an additional 20 IU vasopressin. They managed 16 cardiac arrest patients using this approach and reported 94% recovery of spontaneous circulation and 50% survival with good neurologic outcomes, significant improvement compared with a historical cohort with 8% survival with good neurologic outcomes.¹⁸⁴

This large pool of consistent evidence has shown that FoCUS can differentiate between those with electromechanical dissociation and those with organized myocardial activity. It is the detection of electromechanical dissociation that is the most relevant clinical question and where the greatest value is added by FoCUS in this most critical scenario.

Penetrating Cardiac Injury. Does FoCUS improve diagnostic accuracy when used in penetrating cardiac injury? Does the use of FoCUS affect patient management and outcome in penetrating cardiac injury?

40. *In patients with suspected cardiac injuries from penetrating trauma, using FoCUS rather than relying on clinical signs and symptoms decreases mortality.*

[1B: Strong Recommendation, with Very Good Agreement; Level B Evidence]

41. *In patients with suspected cardiac injuries from penetrating trauma, using FoCUS rather than relying on clinical signs and symptoms improves neurologic outcomes.*

[NO Recommendation, NO Agreement; Level C Evidence]

42. *In patients with suspected cardiac tamponade (after potential penetrating cardiac injury), FoCUS is as accurate as comprehensive standard echocardiography for identifying a pericardial collection.*

[1A: Strong Recommendation, with Very Good Agreement; Level A Evidence]

Comment. In 1992, Plummer *et al.*¹⁸⁵ published a review of patients with penetrating cardiac injuries using a longitudinal study design, which demonstrated that FoCUS was associated with decreased mortality. They compared the time to diagnosis and mortality from penetrating cardiac injury before and after FoCUS was introduced into their clinical practice. They reported outcome data on 49 patients presenting with penetrating cardiac injuries. Of these, 28 received immediate FoCUS in the ED (echocardiography group) and 21 did not (nonechocardiography group). Time to diagnosis and disposition for

surgical intervention was 15 min for the echocardiography group and 42 min for the nonechocardiography group, survival was 100% in the echocardiography group and 57% in the nonechocardiography group, and neurologic outcomes were better in the echocardiography group,¹⁸⁵ (although in terms of FoCUS's benefit on neurologic outcomes, there was no agreement within the panel). In 1999, Rozycki *et al.*¹⁸⁶ published the results of a prospective multicenter trial of FoCUS in 261 patients with potential penetrating cardiac injuries. They reported sensitivity of 100%, specificity of 97%, and accuracy of 97% for diagnosing cardiac injury using FoCUS. This pool of consistent evidence, derived from examinations conducted by surgeons, cardiologists, and emergency physicians at six centers, led to strong recommendation by the panel.

Shock and Hemodynamic Instability. Does FoCUS improve diagnostic accuracy when used in shock and hemodynamic instability? Does the use of FoCUS affect patient management and outcome in shock?

43. *In the setting of shock, FoCUS accurately assesses global LV systolic function, when compared with comprehensive standard echocardiography.*

[1A: Strong Recommendation, with Very Good Agreement; Level A Evidence]

44. *In the setting of shock, FoCUS narrows the differential diagnosis.*

[1A: Strong Recommendation, with Very Good Agreement; Level A Evidence]

45. *In the setting of shock, FoCUS changes management.*

[1C: Strong Recommendation, with Very Good Agreement; Level C Evidence]

46. *In the setting of shock, FoCUS improves outcomes.*

[1B: Strong Recommendation, with Good Agreement; Level B Evidence]

47. *FoCUS should be part of the initial assessment of a hemodynamically unstable patient.*

[1B: Strong Recommendation, with Very Good Agreement; Level B Evidence]

Comment. There are many large observational studies and one randomized trial of diagnostic thinking effectiveness demonstrating the impact of FoCUS by showing that it improves diagnostic accuracy or changes clinical management. These studies do not directly prove that FoCUS leads to better clinical outcomes, but it is reasonable to conclude that a test that provides more accurate diagnostic information or improves clinical management will result in improved clinical outcomes.

In the setting of shock, there is good evidence that FoCUS narrows the differential diagnosis and changes management.^{43,99,177,182,183,187,188} Jones *et al.*'s¹⁰⁰ randomized trial of diagnostic thinking effectiveness showed that goal-directed ultrasound allowed clinicians to correctly diagnose the etiology of shock in 80% of patients, compared with 50% when ultrasound was not used. Breitkreutz *et al.*⁴³ reported that management changed in 66% of unstable patients as a result of FoCUS. Indeed, FoCUS is beneficial in guiding therapy of trauma patients, with particular emphasis on volume resuscitation⁵¹. Finally, FoCUS has been shown to increase emergency physicians' certainty in the hemodynamic management of septic

patients¹⁸⁹. The use of FoCUS during the initial assessment of all hemodynamically unstable patients is rapidly becoming, and should become, the standard of care³³, as there is increasing evidence that this approach has the potential to improve clinical outcomes. This large pool of consistent evidence led to strong recommendations by the panel.

FoCUS Compared with Physical Examination. Is FoCUS superior to the physical examination in the assessment of cardiac function?

48. *FoCUS is more accurate than the physical examination for assessing LV systolic function.*

[1A: Strong Recommendation, with Very Good Agreement; Level A Evidence]

49. *FoCUS is more accurate than the physical examination for detecting valvular disease.*

[1B: Strong Recommendation, with Good Agreement; Level B Evidence]

Comment. One of the best ways to demonstrate the clinical utility of FoCUS is to show that it improves diagnostic accuracy compared to the physical examination and electrocardiography. Visualization of cardiac structure and function is the essence of FoCUS, so it is not surprising that FoCUS is more accurate than the physical examination for assessing LV systolic function and for detecting valvular disease.^{128,190,191} Also, there is significant evidence showing that FoCUS is more accurate than ECG for determining mechanical cardiac function^{43,149,177,178,183,192,193} (refer to recommendation 34). Furthermore, there is good and consistent evidence from several large observational trials that clinicians using FoCUS with substantial accuracy assess LV function and identify pericardial fluid collections in critically ill patients, compared with comprehensive standard echocardiography^{4,5,77,83,105,167,185,186,194,195} (refer to recommendation 42 and 43)

50. *FoCUS with current ultrasound machines for the detection of cardiac abnormalities is superior to the physical examination alone.*

[1A: Strong Recommendation, with Good Agreement; Level A Evidence]

Comment. Several studies have compared the diagnostic yield of FoCUS with that of the physical examination, providing data showing superiority of FoCUS. This was proved regardless of who was performing the examination, either inexperienced (residents, medical students, clinicians with minimal FoCUS training)^{62,128,196-198} or experienced clinicians.^{131,145,199,200} Adding to the physical examination, this limited diagnostic test increases the number of diagnoses of several cardiac conditions,^{62,128,197,199} in different clinical settings, and predicts hemodynamic variables.^{198,201} This consistent evidence derived from a large pool of observational trials is consistent with the panel's experience and led to a strong recommendation.

Estimating Central Venous Pressure, Diagnosing Hypovolemia, and Predicting Fluid Responsiveness. What is the usefulness of FoCUS in the assessment of volume status?

51. *In spontaneously breathing patients in shock, FoCUS can accurately identify patients with low central venous pressure.*

[1B: Strong Recommendation, with Very Good Agreement; Level B Evidence]

52. *In spontaneously breathing patients in shock, FoCUS can accurately identify patients with high central venous pressure.*

[NO Recommendation, NO Agreement; Level C Evidence]

53. *In spontaneously breathing patients in shock, FoCUS can accurately identify patients who may benefit from fluid loading.*

[1B: Strong Recommendation, with Good Agreement; Level B Evidence]

54. *In ventilated patients in shock, FoCUS can accurately identify patients who may benefit from fluid loading.*

[NO Recommendation, NO Agreement; Level C Evidence]

Comment. Using FoCUS to detect low central venous pressure, diagnose clinically relevant hypovolemia, and predict fluid responsiveness in acute care is popular but often misunderstood, especially as concerns IVC assessment. Part of the available evidence derives in fact from studies not performed in critical care settings,^{137,202} in inhomogeneous populations as concerns the respiratory modality,^{203,204} and influenced by different technical approaches.²⁰⁵⁻²⁰⁷

Measurement of an end-expiratory small IVC size can identify spontaneously breathing patients with low central venous pressure^{103,162,202,204,208,209} or rule out the presence of elevated central venous pressure.²⁰² However, low central venous pressure does not necessarily correlate with fluid responsiveness.^{210,211} Conversely, ultrasound assessment of IVC size cannot accurately identify high central venous pressure in ventilated patients.²¹²

In spontaneous respiration, a small end-expiratory size of the IVC (<10 mm) is associated with hypovolemia in blood-depleted volunteers,²⁰⁸ and it is significantly small in hypotensive ED patients²¹³ and hypovolemic trauma patients in early shock^{103,162,214}; a moderate level of evidence supports the concept that IVC diameter is consistently low in hypovolemic patients.¹⁵³ Furthermore, detection of a FoCUS pattern characterized by a "flat IVC" and small hyperdynamic ventricles leads to better fluid management of shocked trauma patients.²¹⁵ Conflicting results exist as concerns the reliability of IVC respiratory variations in spontaneous respiration (IVC collapsibility or "caval index") as diagnostic of hypovolemia or fluid responsiveness,^{165,205,213,216} and this index should be cautiously interpreted.

In mechanically ventilated patients, the IVC end-expiratory diameter shows large overlapping between fluid-responder and non-fluid-responder groups in septic shock.¹⁵⁵ Fluid responsiveness (including states of preload defect milder than in hypovolemic shock at onset) can be accurately predicted in passively ventilated patients, with M-mode measurement of IVC distensibility to detect subtle variations during the respiratory cycle, as resulting from studies in septic shock and subarachnoid hemorrhage.^{155-157,212} However, ultrasound assessment of the IVC cannot estimate fluid responsiveness when mechanical ventilation is performed with assisted ventilation modalities.²⁰⁶

Fluid responsiveness can be accurately predicted in both spontaneously breathing and mechanically ventilated patients by measuring changes in stroke volume with passive leg raising, but this requires pulsed-wave Doppler flow measurements,^{159,160,217-222} beyond the scope of FoCUS.

The "hypovolemic FoCUS pattern" (represented by small hyperdynamic ventricles and a small IVC at end-expiration) was altogether considered by the panel as sufficiently accurate for the diagnosis of clinically relevant hypovolemia in spontaneously breathing shocked patients: this led to a result of good agreement. No agreement was conversely found as concerns the full applicability of this pattern to me-

chanically ventilated patients (intended as a general category including patients ventilated with assisted modalities or noninvasive ventilation).

Screening for Cardiovascular Disease. Does FoCUS show any utility in screening for cardiovascular disease?

55. *FoCUS with current ultrasound machines is useful in screening patients at risk for cardiovascular disease.*

[1B: Strong Recommendation, with Good Agreement; Level B Evidence]

Comment. FoCUS has shown promise in detecting unexpected relevant cardiac abnormalities when used as a screening tool in asymptomatic patients for cardiovascular disease.¹⁰

Indeed, several studies on FoCUS, performed in settings other than emergency and critical care medicine, identified specific cardiac ultrasound findings indicating increased cardiovascular risk and mortality within asymptomatic populations. These included clinical ward patients,^{20,23} hypertensive patients,^{17,223} clinic outpatients,^{18,23,115} community practice patients,¹⁶ underserved minority clinical center patients,¹⁴ medical service inpatients with cardiovascular risk factors,¹⁹ patients at risk for coronary artery disease submitted to stress tests,²²⁴ as well as, potentially, athletes¹³ and schoolchildren.¹²

In these populations, FoCUS accurately detected LV systolic dysfunction,^{11,20,23,225} LV dilatation,¹⁸ left atrial enlargement,^{18,20,23,115,226} and LV hypertrophy,^{11,13,17,227} markers of cardiovascular disease with established prognostic value, in patients who can benefit from treatment at a preclinical phase. Weaker evidence exists in favor of the screening of rheumatic disease-related valve morphologic abnormalities.¹² The recognition of regional wall motion abnormalities²²⁴ may pose a greater challenge to a FoCUS practitioner.

The use of FoCUS for cardiovascular disease screening may have cost-effectiveness implications and contribute in the future to the design of alternative screening strategies.^{16,225} Provision of cost-effective cardiovascular disease screening by means of FoCUS to underserved populations¹⁰ or to populations in scarce-resource settings^{12,227} may represent a step forward toward more equitable health care.

Domain 6: RISKS

Biohazard. What are the risks related to ultrasound physical properties for patients undergoing FoCUS?

56. *Given the limited nature of FoCUS, tissue thermal generation is negligible.*

[1A: Strong Recommendation, with Very Good Agreement; – Level A Evidence]

57. *Given the limited nature of FoCUS, tissue mechanical effects are negligible.*

[1A: Strong Recommendation, with Very Good Agreement; Level A Evidence]

Comment. The biohazard associated with ultrasound exposure is generally minimal when considering the field of diagnostic ultrasound. Although tissue exposure to ultrasound may be accompanied by thermal, mechanical, acoustic-cavitation, radiation-pressure, and gas-body effects,²²⁸ the amount of tissue exposure to ultrasound energy is small with frequencies and times of insonation applied in normal scanning practices.²²⁹ As in comprehensive standard echocardiography, and even more, the consecutive time of ultrasound emission with the probe

kept still in the same place during FoCUS examinations does not exceed a few dozen seconds. And in both practices, being the target organ deep in the mediastinum and the frequencies of ultrasound emission low, superficial tissues further attenuate the energy delivered. Specific risks associated with the use of gas-bubble contrast agents, or transcranial insonation, do not apply to the practice of FoCUS. The panel rendered these strong recommendations on the basis of two large review articles published by recognized expert societies.

Inappropriate FoCUS Application. Does any risk related to FoCUS misuse exist?

58. *Close adherence to image acquisition techniques is needed to ensure quality image attainment.*

[1B: Strong Recommendation, with Good Agreement; Level B Evidence]

59. *Careful integration of sonographic findings into clinical decision making is needed to ensure appropriate use.*

[1B: Strong Recommendation, with Very Good Agreement; Level B Evidence]

60. *Lack of appreciation of the limitations of FoCUS carries a significant risk for neglecting relevant pathologic conditions other than the ones defined in recommendations 13 to 15 as specific goals of the FoCUS examination (such as diastolic dysfunction).*

[2B: Weak/Conditional Recommendation, with Some Agreement; Level B Evidence]

Comment. With this group of linked statements, the panel wanted to address what is perceived as the real potential risk concerning the use of FoCUS: inadequate skill and competence on one hand and practice beyond its intrinsic limitations (see recommendations 13–15) on the other. Insufficient competence can potentially manifest as a lack of appreciation of the inadequacy of images obtained (e.g., a right ventricle judged as dilated when it erroneously only appears so because of an off-axis, nonconventional view) or as incorrect interpretation of true findings (e.g., detection of acute cor pulmonale in a hemodynamically stable patient assumed to be diagnostic for massive pulmonary embolism, as it might be in cardiac arrest).

The panel also reached consensus, with some agreement, on stigmatizing the risks related to an unaware use of FoCUS beyond its scope: the “visual gratuity” of the images obtained and the simplified approach may lead an inadequately trained FoCUS practitioner to overestimate the diagnostic potential of the limited FoCUS approach (e.g., ruling out cardiogenic pulmonary edema on the basis of the simple detection of a normal LV systolic function and absence of gross valve abnormalities, neglecting as potential cause diastolic dysfunction or milder forms of valve disease, conditions to which FoCUS is blind). As emphasized by recent guidelines,^{29,31} awareness of the boundaries between comprehensive standard echocardiography and FoCUS is a prerequisite for this practice.

Domain 7: COST-EFFECTIVENESS AND SOCIOECONOMICS

General Comments. Cost-effectiveness is an elusive concept, difficult to study directly, and, generally, documented by circumstantial or inferential evidence.^{178,179,228} The statements presented were specific to four clinical scenarios: cardiac arrest, shock or hemodynamic instability, and traumatic and atraumatic pericardial effusion. The panel

was asked to weigh the “reasonable additional cost” of FoCUS against the diagnostic, therapeutic, and clinical effectiveness of FoCUS in each of the four scenarios, thus yielding 12 statements.

Evidence for the incremental costs of FoCUS was derived from adding the anticipated expenses of machines, training, quality management, and maintenance of proficiency divided by the number of examinations expected to be conducted and presumed to modest.²³⁰ The diagnostic accuracy and the therapeutic and clinical benefit are well supported in the literature and were debated in the earlier domains (several from domains 4 and 5).

Cardiac Arrest. Is the use of FoCUS in cardiac arrest cost effective?

61. *In the setting of cardiac arrest, FoCUS provides diagnostic accuracy with reasonable additional cost and, therefore, is cost effective.*

[1B: Strong Recommendation, with Very Good Agreement; Level B Evidence]

62. *In the setting of cardiac arrest, FoCUS provides therapeutic benefit with reasonable additional cost and, therefore, is cost effective.*

[1C: Strong Recommendation, with Good Agreement; Level C Evidence]

63. *In the setting of cardiac arrest, FoCUS provides overall clinical benefit with reasonable additional cost and, therefore, is cost effective.*

[1C: Strong Recommendation, with Good Agreement; Level C Evidence]

Comment. In cardiac arrest, the panel had very good consensus with respect to diagnostic effectiveness, but given the limited success of resuscitation, was less consistently in agreement with therapeutic or clinical effectiveness.^{43,101,148,165,167,169,176,182,190}

Shock and Hemodynamic Instability. Is the use of FoCUS in shock and hemodynamic instability cost effective?

64. *In the setting of shock or hemodynamic instability, FoCUS provides diagnostic accuracy with reasonable additional cost and, therefore, is cost effective.*

[1B: Strong Recommendation, with Good Agreement; Level B Evidence]

65. *In the setting of shock or hemodynamic instability, FoCUS provides therapeutic benefit with reasonable additional cost and, therefore, is cost effective.*

[1C: Strong Recommendation, with Good Agreement; Level C Evidence]

66. *In the setting of shock or hemodynamic instability, FoCUS provides overall clinical benefit with reasonable additional cost and, therefore, is cost effective.*

[1C: Strong Recommendation, with Very Good Agreement; Level C Evidence]

Comment. In shock, there was less consistency with diagnostic and therapeutic effectiveness but very good consensus regarding clinical benefit.^{52-54,100,102,103,172,186,187}

Pericardial Effusion. Is the use of FoCUS for pericardial effusion assessment cost effective?

67. *In the setting of suspected traumatic pericardial effusion, FoCUS provides diagnostic accuracy with reasonable additional cost and, therefore, is cost effective.*

[1B: Strong Recommendation, with Very Good Agreement; Level B Evidence]

68. *In the setting of suspected traumatic pericardial effusion, FoCUS provides therapeutic benefit with reasonable additional cost and, therefore, is cost effective.*

[1B: Strong Recommendation, with Very Good Agreement; Level B Evidence]

69. *In the setting of suspected traumatic pericardial effusion, FoCUS provides overall clinical benefit with reasonable additional cost and, therefore, is cost effective.*

[1B: Strong Recommendation, with Very Good Agreement; Level B Evidence]

70. *In the setting of suspected atraumatic pericardial effusion, FoCUS provides diagnostic accuracy with reasonable additional cost and, therefore, is cost effective.*

[1B: Strong Recommendation, with Very Good Agreement; Level B Evidence]

71. *In the setting of suspected atraumatic pericardial effusion, FoCUS provides therapeutic benefit with reasonable additional cost and, therefore, is cost effective.*

[1C: Strong Recommendation, with Very Good Agreement; Level C Evidence]

72. *In the setting of suspected atraumatic pericardial effusion, FoCUS provides overall clinical benefit with reasonable additional cost and, therefore, is cost effective.*

[1C: Strong Recommendation, with Very Good Agreement; Level C Evidence]

Comment. In both traumatic and atraumatic pericardial effusion, with concern for the deleterious consequence of cardiac tamponade, both agreement and consensus were high for diagnostic, therapeutic, and clinical effectiveness.^{32,102,135,165,172,178,183,184,186,187,193}

The notion that the additional costs of a new technology such as FoCUS may outweigh its benefit over conventional management has been a justifiable concern.²³¹ It is important not to confuse comprehensive standard echocardiography, which is significantly more costly than FoCUS, while delivering valuable clinical information at the point of care. Moreover, in marked contrast to comprehensive standard echocardiography, FoCUS can be performed by most clinicians with appropriate training, requiring less time and resources.

With the advent of newer, more powerful ultrasound probes and devices with improved resolution and an increased body of experience among clinicians, other more expensive interventions may no longer be essential, especially in critical scenarios in which transport is difficult or dangerous. The diagnostic accuracy of FoCUS is well supported, lending support to the idea that FoCUS alone is adequate to make many diagnoses and provides the information necessary to make decisions regarding further diagnostics and management. In the first Sonography Outcomes Assessment Program trial,²³² a randomized, controlled trial of the FAST examination for trauma patients (which includes cardiac ultrasound), the difference between mean hospital charges was assessed, including multivariate analyses that

controlled for age, gender, institution, injury severity, and final diagnoses. Mean hospital charges for the FAST versus non-FAST patients were \$16,100 (95% confidence interval, \$3,200) and \$31,500 (95% confidence interval, \$7,400), respectively, with a mean difference of \$14,000 per patient. Trauma patients evaluated with FAST had significantly lower hospital charges compared with well-matched patients not evaluated with FAST.

Future research will be needed to assess the value of the additional access to care provided by FoCUS in austere, remote settings as well as prehospital, tactical, and disaster medicine.

Domain 8: EDUCATION

FoCUS Training and Curricula. How should FoCUS training be structured? What components should it include? Should FoCUS training be part of undergraduate and postgraduate medical curricula?

73. *Adequacy of training in FoCUS should be determined by competency-based assessment.*

[1B: Strong Recommendation, with Very Good Agreement; Level B Evidence]

Comment. The panel debated whether recommendations should be made on training and education in FoCUS on the basis of a prescribed course of training with a minimum number of studies and found that the literature was so varied on the subject^{29,107,117,120,233-236} that a more logical and consistent approach should be adopted. The literature refers to the number of studies performed or the number of hours spent to acquire FoCUS skills, without consistently defining the competencies that constitute FoCUS examinations. To overcome this difficulty, it was agreed that training adequacy be determined by competency-based assessment and that this complex subject be addressed in several substatements.

74. *The training process should include image acquisition and interpretation through personally performed and supervised studies from an appropriate case mix.*

[1C: Strong Recommendation, with Very Good Agreement; Level C Evidence]

Comment. It is important to embrace the concept that FoCUS is performed and interpreted by physicians themselves practicing specialties other than cardiology.² Proper image acquisition can be learned only through continuously improving and mastering the technique. Besides this technical competency, a sufficient knowledge base can be built if exposure to all relevant pathologies is ensured for the purpose of training. The following expert opinion adopted for one specialty makes sense: for all "minimum" training numbers, it is essential that the trainee have acquired and interpreted ultrasound images that represent the full range of diagnostic possibilities for that training level. Therefore, both FoCUS and comprehensive standard echocardiography trainees are required to have case mixes of positive and negative studies that include the breadth of pathology expected to be recognized by a given level of training.³²

75. *A minimum number of studies should form the basis of training depending on the requirements of respective specialties.*

[1B: Strong Recommendation, with Very Good Agreement; Level B Evidence]

Comment. Although it is difficult to agree on a minimum number of studies to achieve competence in FoCUS in general, it may appear easier to recommend such number that would prepare the practicing

physicians in their respective specialties. At the present time, such numbers are available for comprehensive standard echocardiography, but research is required to fill in this gap for FoCUS.

76. *The competency assessment should be an ongoing process during the course of training, as described in recommendation 74 on the training process.*

[1C: Strong Recommendation, with Very Good Agreement; Level C Evidence]

Comment. In a graded fashion, competencies can be assessed as part of an ongoing training process that runs parallel to the training in the respective specialty. The competencies are being defined for different specialties, and it is clear that what an intensivist needs to learn is somewhat different from what an emergency medicine physician, a surgeon, or an anesthesiologist needs to learn.

77. *Only appropriately trained practitioners should practice FoCUS. The exact specifications of competencies should be in line with the recommendations of their respective specialties.*

[1C: Strong Recommendation, with Very Good Agreement; Level C Evidence]

Comment. Different specialties through their colleges and societies have started to publish detailed lists of competencies to be acquired, and even structured examinations are being contemplated for the extent of cardiac ultrasound knowledge and skills sets required for their specialists. Anesthesiologists took the lead among noncardiologists for training and examinations in transesophageal echocardiography as a result of collaborative work under the auspices of the ASE, the Society of Cardiovascular Anesthesiologists, and the European Association of CardioThoracic Anesthesiologists. Fellowship in cardiac anesthesiology now includes transesophageal echocardiography training and examinations administered respectively by the National Board of Echocardiography and by the European Association of CardioThoracic Anesthesiologists (jointly with the European Association of Cardiovascular Imaging). For FoCUS, however, the recognition for such recommendations was delayed, primarily because of different needs of various specialties. The American College of Chest Physicians published a comprehensive standard document on echocardiography and lung ultrasound,³⁰ followed by a consensus statement of the ASE and the American College of Emergency Physicians³² and an ASE expert statement³⁴ clarifying the role of FoCUS, and limited versus comprehensive standard echocardiography, and also setting standards for competencies.

78. *Training in FoCUS should include blended learning using e-learning and self-teaching in addition to formal face-to-face didactics.*

[1C: Strong Recommendation, with Very Good Agreement; Level C Evidence]

Comment. The role of e-learning and Web-based education has been shown to be beneficial as an adjunct to face-to-face learning in different specialties of medicine.²³⁷⁻²³⁹ Similar benefits can be achieved in ultrasound²⁴⁰ and echocardiography.²⁴¹ The Web sites of different societies and organizations have instructional material and libraries of video clips and images, and the use of these aides is encouraged for knowledge building. Template matching tools have been successfully used to train even medical students.¹⁰⁶ Trainees should complement their learning and enrich their knowledge by using a library of educational cardiac ultrasound cases that depict the various pathologies.³²

79. *Education and training in FoCUS should use terminology as defined in "Domain 3: Technique."*

[1C: Strong Recommendation, with Very Good Agreement; Level C Evidence]

Comment. To avoid any confusion in reading the literature published on FoCUS and to adopt a common language already in use by cardiologists, the terminology to be used in FoCUS reporting and research publications should be the same as defined in "Domain 3: Technique."

80. *Education and training in FoCUS should include the standard views as defined in "Domain 3: Technique."*

[1C: Strong Recommendation, with Very Good Agreement; Level C Evidence]

Comment. Of all the standard views used in comprehensive standard echocardiography, some selected views that have maximum diagnostic yield are to be taught for use in FoCUS. It is also understood that the performance of FoCUS requires standards consistent with the quality assurance processes for all diagnostic imaging performed within the hospital.³²

81. *Education and training in FoCUS may be integrated into medical school curricula.*

[1C: Strong Recommendation, with Good Agreement; Level C Evidence]

Comment. At least two examples of ultrasound as part of the medical school curriculum^{242,243} were used to make the above statement. The panel felt that although for medical students, broad knowledge of ultrasound is very appropriate, an introduction to FoCUS would suffice at that level. The interest in incorporating ultrasound in the medical school curriculum is growing rapidly, and many medical schools across the world have already done so.

82. *Education and training in FoCUS should be integrated into postgraduate training programs.*

[1B: Strong Recommendation, with Very Good Agreement; Level B Evidence]

Comment. Two clear examples of specialty-specific recommendations to support the statement strongly have been cited above. They pertain to the documents produced by the American College of Chest Physicians and La Société de Réanimation de Langue Française³⁰ and the American College of Emergency Physicians and the ASE.³²

83. *In the context of periresuscitation care of patients, ALS-compliant protocols may be included in the training programs of FoCUS.*

[1C: Strong Recommendation, with Good Agreement; Level C Evidence]

Comment. After a prospective study⁴³ that looked at the outcomes of resuscitation of patients in whom treatable causes were detected in a number of patients who would have otherwise been declared as having pulseless electrical activity, the panel has considered training in this context as important. Other publications by the same group^{142,244} concluded that novice cardiac ultrasound performers could obtain knowledge and skills relevant to ALS-compliant periresuscitation echocardiography using a range of educational techniques, including 1-day courses. The participants felt strongly that making the above statement would not be premature and that incorporating such training in the courses would constitute as a strong recommendation.

Domain 9: CERTIFICATION OF PRACTITIONERS AND ACCREDITATION OF TRAINING PROGRAMS

FoCUS Proficiency and Certification. How can FoCUS proficiency be obtained and documented? Who should provide FoCUS certification?

84. *Clinicians can be proficient in FoCUS if they fulfill the training requirements and competency assessments as outlined by their respective governing specialty societies.*

[1C: Strong Recommendation, with Very Good Agreement; Level C Evidence]

Comment. Although there is limited evidence with regard to any specific pathway to the achievement of competency in FoCUS, there is little doubt that noncardiologist clinicians can be proficient in these skills.^{2,46,132,235,245} The panel strongly endorsed the concept and utility of noncardiologist performed emergency FoCUS, not only as a complement to the clinical examination but as a separate skill that requires training and certification above normal specialist or subspecialist education,⁴⁹ certainly when practiced at a level beyond basic skills.²³⁵ This competency in FoCUS can be achieved by a clinician by means of undergoing an appropriate, accredited training program that culminates in a multicomponent examination on which the candidate is required to show proficiency.^{29,116} The details of this process are dealt with more specifically in subsequent statements in this domain. Because FoCUS may be used by emergency physicians, intensivists, anesthesiologists, and physicians from other disciplines, and because the requirements of each discipline might differ as to the scope and application of FoCUS,^{246,247} each discipline should establish its own training and certification requirements.²⁴⁸ This is also discussed in more detail in subsequent statements in this domain.

85. *Proficiency in FoCUS should be demonstrated by competency-based assessment before it is used by a clinician for clinical decision making.*

[1C: Strong Recommendation, with Very Good Agreement; Level C Evidence]

Comment. There was strong expert consensus that it is not sufficient for a clinician to undergo training in FoCUS alone without a culmination in successful demonstration of his or her competency in the practical and theoretical aspects that are required for the successful application of FoCUS in clinical practice.^{235,249} This is important to maintain an appropriate level of care²⁵⁰ and for medicolegal protection.²⁵¹

There was further strong expert consensus that all clinicians using FoCUS should be fully credentialed before doing so.^{252,253} A clinician undergoing the training process should not rely on echocardiographic findings obtained during patient management until he or she is fully credentialed, unless the scans have been supervised by an approved credentialed clinician within an appropriate clinical governance system.^{32,49,59,247} Certification should also be viewed as part of a quality assurance and quality improvement process.²⁵⁴

86. *Competency criteria and required components of FoCUS may differ between disciplines and should be determined by the appropriate specialty-specific organization or national regulatory bodies.*

[1C: Strong Recommendation, with Very Good Agreement; Level C Evidence]

Comment. The expert panel acknowledged that the difference between the applications of FoCUS in different disciplines makes it impossible to provide a global recommendation with regard to the

content and format of training and competency assessment. Nonetheless, the consensus panel strongly recommended that each discipline that makes use of FoCUS must have a detailed syllabus describing the repertoire of required ultrasound skills and must have formal competency criteria that must be satisfied for a clinician to be credentialed.^{246,248} An example of FoCUS curriculum for critical care adult patients is provided in Appendix 6 in the ESM.

87. *Different training pathways may be taken to qualify for competency assessment, which should be approved by the appropriate specialty-specific organization or national regulatory body.*

[1C: Strong Recommendation, with Very Good Agreement; Level C Evidence]

Comment. Because there is no good evidence to support any particular training methodology or program, the expert panel further acknowledged that different training pathways may be taken to qualify for competency assessment in FoCUS. This has been recognized for other aspects of echocardiography.^{255,256} These training pathways, however, must be approved by the body responsible for accrediting training programs and conducting competency assessments. The level of training required to achieve competency has not yet been fully elucidated.⁴⁶

88. *Each trainee should have one or more designated supervisors who possess a higher training standard and should be approved by the appropriate training body.*

[1C: Strong Recommendation, with Very Good Agreement; Level C Evidence]

Comment. The expert panel further strongly recommended that each candidate must have a designated supervisor or mentor to oversee his or her ultrasound training because the majority of learning in FoCUS will most likely occur at the bedside as part of ordinary clinical practice. The supervisor must have a higher level of training and competency than the candidate, and the supervisor must be approved by the body responsible for conducting the competency assessments.^{249,257}

89. *An appropriate number of supervised and unsupervised scans (with both normal and abnormal findings) should be logged before a competency assessment may be triggered.*

[1B: Strong Recommendation, with Very Good Agreement; Level B Evidence]

Comment. There is insufficient evidence to recommend a definite number of scans that will allow a candidate to achieve competency in any form of cardiac ultrasound.^{120,235,258,259} The variation in clinical application of FoCUS between disciplines and the variation in the individual skills of ultrasound users makes this impossible.²⁵² Nonetheless, a minimum number of scans that document both normal findings and common pathology should be specified in each individual training program; evidence suggests that this number is less than that required for certification in formal echocardiography.^{46,59,117,120,235,248,260} Of particular note is the strong recommendation of the consensus committee that a sufficient number of scans with the full spectrum of abnormal findings be obtained.^{29,32,49} Only once these scans have been acquired should a candidate be permitted to attend a competency-based assessment, and the completion of a certain number of scans should not in itself be considered to constitute competency without a formal assessment thereof.^{254,261}

Competency Assessment. How should competency in FoCUS be assessed?

90. A competency assessment should evaluate proficiency in

- The appropriate use of the ultrasound machine
- The ability to obtain standard FoCUS views
- Critical evaluation of reliably interpretable images
- Identification of cardiac chambers and structures
- Pattern recognition of structural abnormalities and pathology
- Clinical integration of ultrasound findings
- The use of ultrasound information in guiding patient management

[1C: Strong Recommendation, with Very Good Agreement; Level C Evidence]

Comment. Although this statement is fairly specific and detailed, the expert panel spent some time in discussion about the importance of an appropriate competency assessment in ensuring that candidates are proficient in FoCUS. The panel strongly recommended that competency assessment must be comprehensive and must include an assessment of knowledge, practical skills, and the ability to use the cardiac ultrasound findings to appropriately guide patient management. Thus, the competency assessment should evaluate technical skills in image acquisition and optimization, recognition of normal and abnormal anatomy, as well as the ability to incorporate the findings and any technical inadequacies in to the clinical decision matrix.^{29,30,59,132} Any competency assessment examination should have a blueprint containing these elements (see an example of a detailed FoCUS curriculum in ESM Appendix 6). Training in echocardiography itself does not necessarily provide the understanding of cardiovascular pathophysiology required for the implementation of FoCUS,²⁶² and the certification assessment must therefore ensure that a successful candidate can fully integrate FoCUS into clinical management. The details of the competency assessment process are covered in subsequent statements.

91. A wide range of tools should be included in performing a competency assessment, including

- Observation of image acquisition
- Review of documented ultrasound experience (a logbook of acquired images)

[1B: Strong Recommendation, with Very Good Agreement; Level B Evidence]

92. There are a variety of tools that can be used to assist in the competency assessment of theoretical and practical ultrasound knowledge, which may include evaluation of a logbook, an objective structured clinical and practical examination, and medical simulation tools.

[1C: Strong Recommendation, with Very Good Agreement; Level C Evidence]

Comment. There is insufficient evidence to support the recommendation of any particular method of performing a competency assessment. The expert panel made a strong recommendation, however, that the assessment process should include a review of the candidate's ultrasound experience (which should be archived, e.g., in a logbook and should document the required number of scans, the number of normal findings, and the number and details of abnormal findings), and the actions undertaken on the basis of these findings.^{29,116} The assessment should further involve the observation of image acquisition by the candidate to ensure that he or she can perform technical skills that are required for proficiency in FoCUS.^{59,252} The assessment of the candidate's theoretical knowledge and ability to assimilate the ultrasound findings into the clinical decision matrix may be performed using medical simulation, an objective structured clinical and practical evaluation, or other appropriate assessments of compe-

tency.^{30,46,254,263} A comprehensive standard competency evaluation will ensure that FoCUS trainees have been exposed to an appropriate variety of ultrasound images and pathologies and have the skills and insight to safely and effectively make use of FoCUS in clinical practice.

Limits of FoCUS Competency. How does FoCUS competency relate to competence in comprehensive echocardiography?

93. Clinicians practicing techniques beyond the scope of FoCUS should acquire additional training.

[1C: Strong Recommendation, with Very Good Agreement; Level C Evidence]

Comment. The expert panel strongly recommended that clinicians performing echocardiographic examinations beyond the scope of FoCUS, as defined by their own discipline-specific professional regulatory bodies, should acquire appropriate training and, as appropriate, additional certification.^{29,46,59,235} A clinician should be able to demonstrate competency in whichever echocardiographic skills he or she uses in clinical practice.

Continuous Quality Improvement to Maintain and Expand Skills.—Continuous quality improvement to maintain and expand FoCUS skills is required.^{29,33} Continuing medical education and ongoing training specific to FoCUS must be completed and can be done so in a wide variety of ways, including but not limited to any of the following: conference attendance, online educational activities, preceptorships, teaching, research, hands-on training, administration, quality assurance, image review, in-service examinations, textbook and journal readings, and morbidity and mortality conferences inclusive of FoCUS cases. Certified physicians should have an amount of the above continuing medical education activities designated by their respective specialty societies; it should be related to the frequency of use and the further development of FoCUS. Continuous quality improvement must include review of selected FoCUS examinations for both technical and interpretative skills. Feedback, both formative and summative, as well as any remedial training must be formally documented.

Domain 10: PEDIATRICS

General Comments. FoCUS is an ideal point-of-care diagnostic tool to evaluate infants and children with suspected cardiac pathology. Images often have better resolution relative to those obtained in adults. A complicating factor here is due to the higher prevalence of congenital heart disease than in the adult population. This carries a potential burden of complexity in interpreting the morphologic and functional findings that may well go beyond the capability of the simplified application of echocardiography that FoCUS represents.

Imaging orientation standards and the spectrum of disease differ between adult and pediatric echocardiographic views.²⁶⁴ For these reasons, with reference to recommendation 25, it is recommended that practitioners adopt a pediatric orientation or adult transesophageal echocardiography orientation for FoCUS, where possible, with the image apex at the bottom of the screen. This serves the purpose to demonstrate structures in their correct anatomic orientations and has particular relevance because of the wide range of anatomic variations frequently seen in patients with congenital heart disease. Practitioners who care for both children and adults may prefer an adult imaging orientation for problems for which congenital heart disease is not a concern (e.g., simple pericardial effusion).

Cardiac Arrest. What is the potential role for FoCUS use in pediatric cardiac arrest?

94. *FoCUS should be considered to identify potentially treatable causes of a cardiac arrest.*

[1B: Strong Recommendation, with Very Good Agreement; Level B Evidence]

95. *In cardiac arrest, FoCUS should be used when appropriately skilled personnel are available.*

[1B: Strong Recommendation, with Very Good Agreement; Level B Evidence]

96. *In cardiac arrest, the benefits of FoCUS should be carefully weighed against the known deleterious consequences of interrupting chest compressions.*

[1B: Strong Recommendation, with Very Good Agreement; Level B Evidence]

Comment. The 2010 international pediatric basic life support and ALS recommendations state that "FoCUS may be considered to identify potentially treatable causes of a cardiac arrest when appropriately skilled personnel are available, but the benefits must be carefully weighed against the known deleterious consequences of interrupting chest compressions."²⁶⁵ The panel affirms these recommendations with very good consensus.

FoCUS Diagnostic Targets. Which are the specific diagnostic targets of FoCUS in pediatrics and neonatology?

97. *FoCUS in critically ill or injured children can assess pericardial effusion.*

[1B: Strong Recommendation, with Very Good Agreement; Level B Evidence]

98. *FoCUS in critically ill or injured children can assess gross discrepancy in chamber size.*

[1B: Strong Recommendation, with Very Good Agreement; Level B Evidence]

99. *FoCUS in critically ill or injured children can assess gross cardiac systolic function.*

[1B: Strong Recommendation, with Very Good Agreement; Level B Evidence]

100. *FoCUS in critically ill or injured children can assess volume status.*

[1B: Strong Recommendation, with Very Good Agreement; Level B Evidence]

101. *FoCUS in critically ill or injured children can assess gross valvular abnormalities.*

[1B: Strong Recommendation, with Very Good Agreement; Level B Evidence]

Comment. FoCUS detects significant and/or life-threatening cardiac pathology in children, such as pericardial effusion, cardiac tamponade, severe hypovolemia, marked enlargement and disproportion in cardiac chamber size, and infective endocarditis, which have been described in a number of case reports and series.^{4,266-274} FoCUS has been shown to be effective assessing gross valvular abnormalities, in particular rheumatic heart disease.^{12,275}

102. *FoCUS is to be used to rule in patent ductus arteriosus in neonates.*

[NO Recommendation, NO Agreement; Level B Evidence]

103. *FoCUS can assist in the assessment and management of patients with patent ductus arteriosus in the neonatal ICU.*

[NO Recommendation, NO Agreement; Level B Evidence]

104. *FoCUS is insufficient to rule out congenital heart disease.*

[1B: Strong Recommendation, with Very Good Agreement; Level B Evidence]

Comment. FoCUS was acknowledged by the panel to have a potential role in ruling in patent ductus arteriosus²⁷⁶ in preterm neonates and in assisting in the assessment and management of hemodynamic instability of these patients in the neonatal ICU.²⁷⁷⁻²⁷⁹ But the panel was unable to reach consensus on the basis of these promising but preliminary data. However, as agreed upon strongly and stated in recommendation 106, the role of FoCUS is not to rule out congenital heart disease or its complications. This is the role of comprehensive standard echocardiography.

FoCUS Limitations. What are the FoCUS limitations in pediatrics and neonatology?

105. *FoCUS in children is limited in scope and is not intended to definitively rule out pathology compared with comprehensive standard pediatric echocardiography.*

[1C: Strong Recommendation, with Good Agreement; Level C Evidence]

106. *FoCUS in neonates is limited in scope and does not contain all elements of comprehensive standard or targeted neonatal echocardiography.*

[1C: Strong Recommendation, with Very Good Agreement; Level C Evidence]

107. *FoCUS can identify patients who may require more comprehensive standard cardiologic evaluation.*

[1B: Strong Recommendation, with Very Good Agreement; Level B Evidence]

Comment. Consistently with 2010 international pediatric basic life support and ALS recommendations,²⁶⁵ with adult recommendations,^{31,32} and with statements in domains 1 and 3, the panel agreed that in children, FoCUS is a cardiac ultrasound application limited in scope and is not intended to definitively rule out pathology compared with comprehensive standard pediatric echocardiography²⁶⁴ or to contain all elements of targeted neonatal echocardiography.²⁸⁰ The panel wanted here to highlight again the limitation of FoCUS in comparison with comprehensive standard echocardiography, clarifying the boundaries of its appropriateness of use in the pediatrics setting.

108. *Technology can facilitate real-time consultation with pediatric cardiologists for pediatric health care providers performing FoCUS.*

[1B: Strong Recommendation, with Good Agreement; Level B Evidence]

Comment. Use of technology to facilitate real-time tele-echocardiography/FoCUS consultation from novice FoCUS pediatric health care providers to distant pediatric cardiologists in critical care or emergency scenarios may be a sustainable solution in underdeveloped or remote areas of the world.^{156,281,282}

KNOWLEDGE GAPS AND FUTURE RESEARCH DIRECTIONS

The lack of adequately powered outcome-based studies to prove benefit of use of FoCUS in the various specific clinical settings is certainly the major knowledge gap. Exhaustive data on the cost-effectiveness of FoCUS use should also be acquired, especially in the critical care scenario. Validation of integrated clinical ultrasound protocols for FoCUS-driven patient management should be studied. Impact evaluation of FoCUS-based early goal-directed management of septic shock, cardiogenic shock, trauma management, and dyspnea is an area worthy to explore.

The heterogeneity of publications evaluating the accuracy of non-echocardiography specialists in obtaining diagnostic images (different training schemes, different scanning protocols, and different medical backgrounds of trainees) also demands further studies on minimum training standards for FoCUS competence achievement, tailored to the specific needs of the respective specialists. FoCUS is reshaping cardiovascular assessment (as in general other point-of-care ultrasound applications have for other clinical entities): sustainable dedicated training programs could and should be incorporated widely into both pregraduate and postgraduate curricula by academic institutions.^{242,243,283}

The evaluation of diagnostic accuracy (and subsequently of impact) of FoCUS use in isolation versus in combination with other point-of-care ultrasound application, has just recently begun being addressed^{23,100,284-290} and deserves further investigation.

The development of sustainable tele-ultrasonography FoCUS technology, training programs and protocols,^{156,281,282,291} either for the purpose of telementoring as a quality assurance tool, or for diagnosis by minimally trained health care allies in underserved population of remote, austere, scarce-resource settings is another research frontier to target. Assessment of potential adverse events related to FoCUS use (inappropriate, out-of-scope application; misdiagnosis; missed diagnosis; failure to use; omitted referral to a comprehensive standard examination; delayed access to appropriate diagnostics) may also be promoted to develop better standards of training and of patient care.

Access is an important concept in the study of how to organize, finance, and deliver health care services as well as an important political symbol and policy goal. Theories of access accept that it is a dynamic process that includes the potential for health care providers to learn and modify their behavior and must be explored in empirical research of access to health care. Researchers should consider these aspects of access as they attempt to understand how to improve health care delivery systems and use these access models to direct the formulation of better health policy. Therefore, additional research is needed to define the relationship of FoCUS to access.

Most work in this area has been conceptualized as access to physician services or particular types of settings such as hospital care, not as access to point-of-care testing. Gaps in evidence may include (1) the effect of regional market factors (such as poverty), (2) the lack of a critical analysis of outcome research, (3) measures of utilization and access specific to FoCUS in a variety of settings, and (4) the need for more and better data to evaluate equipment acquisition, clinician training, and effectiveness.

Furthermore, where evidence of a mortality advantage or prevention of nonfatal outcomes or disabilities is established, the incremental cost-effectiveness ratios of FoCUS for each additional quality-adjusted life-year should be calculated.²⁹²

Finally, as FoCUS is going to become part of the standard of care in medical evaluation, the current gap in legislation on medicolegal is-

ues related to the use of FoCUS²⁵¹ should be carefully studied. These data will allow scientific and academic organizations to aid health care institutions in the process of implementation of FoCUS into their standard practices.

Guideline Update Plan

Previous reports²⁹³ indicated that there is a drop in the relevance of the results of systemic reviews after 2 years and a marked drop by 4 years. Thus, a maximum of 4 years is preset for the next update. However, the emergence of new evidence that may contradict any of the statements and recommendations will be monitored by means of two independent procedures. A professional librarian will run an annual search using the same search terms that served for preparation of these guidelines and will send any new publications (from 2013 onward) to the first author (chairperson). Similarly, each member of the panel will be encouraged to forward to the chairperson any paper that may provide new evidence to the subject matter of the conference.

CONCLUSIONS

The primary impetus for the development and promulgation of FoCUS is to increase access to this important diagnostic tool.

Multiple converging sources of evidence support the fact that FoCUS is a diagnostic tool; its use determines diagnoses contemporaneously with treatment and management and mitigates diagnostic uncertainty. Like all diagnostics, the expectation of FoCUS is to facilitate patient care and, thereby, improve outcomes. FoCUS requires archiving, reporting, and, where relevant, reimbursement.

Access to high-quality health services is possible only if there are an adequate number and distribution of qualified health care providers with the necessary skills and equipment. FoCUS, by its very nature, is a multispecialty phenomenon, and neither the specialty of the practitioner nor the size of the equipment is relevant. Consistent with Resolution 802 of the American Medical Association,² training parameters, image acquisition criteria, and archiving and reporting requirements must be defined by the multiple respective specialty societies.

Training must involve theory, image acquisition, recognition, and interpretation and documentation of proficiency and competency. An appropriately trained FoCUS practitioner possesses all the skills needed to complete a focused evaluation of symptomatic cardiac patients, as well as screening of high-risk asymptomatic patients, and guide definitive care as indicated.

Continuous quality management of FoCUS practitioners should include timely image review with documentation of formative and summative feedback and any remediation required.

SUPPLEMENTARY DATA

Supplementary data related to this article, including video materials, can be found at <http://dx.doi.org/10.1016/j.echo.2014.05.001>.

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