

Development of evidence-based clinical recommendations and consensus statements in critical ultrasound field: why and how?

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While ultrasound (US) has been used in medicine for several decades, its use in critical care and emergency medicine is relatively new. Clinician-performed ultrasound brings an essential imaging capability to the point-of-care in a manner that represents a true paradigm shift in the art and science of physical examination and diagnosis. The performance of ultrasound by clinicians in critical settings, “Critical Ultrasound”, has created new challenges that must be addressed by the medical community.

Why we need critical US evidence-based clinical recommendations (CR) and consensus statements (CS)?

Numerous new challenges have emerged with the appearance of “Critical Ultrasound”, but one can recognize eight major domains. The first challenging domain may be *definition and nomenclature*. One can find several names or terms for a single sign such as the B-lines that were also called comet tail artifacts ultrasound lung comets, multiple B-line pattern, indicated as lung rockets or B-plus [1–3]. This is seen in many new signs that are given different names by various investigators resulting in a degree of confusion or at least difficulty in scientific communication. The second domain is the *technology*. This domain is particularly challenging as it is rapidly and continuously

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evolving and is affected by huge industrial funding and advertisement. To keep current with technology and decide which specific aspects or features are clinically useful to the patient and cost effective is quite challenging. This third domain of *cost-effectiveness* is not only restricted to new technology assessment, but also covers the whole strategy of this new US enhanced management in comparison with other conventional diagnostic and management strategies. The fourth domain is the *technique* itself. We observed the progress of the original FAST technique to e-FAST (extended FAST, including pneumothorax assessment) [4–6], to the FASTER (FAST, including extremities and respiratory tract) [7], up to the FAST-ABCDE (FAST including airway-breathing-circulation-disabilities and exposure) [8], with an increase from the initial three abdominal windows (suprapubic, peri-splenic and peri-hepatic) to several integrated windows over different body districts. Similarly, there is great variability in definition of lung zones that should be covered during lung ultrasound scanning [9–13]. Having consensus on the basic technique will facilitate the diagnostic process, patient management and clinician training. The fifth domain: “training, education and credentialing” is extremely important. It critically impacts not only practice privileging, patient management and outcome, but also has legal and financial consequences. The sixth domain deals with *clinical outcomes* or endpoints where it examines specific clinical conditions with clear patient-oriented endpoints related to mortality, morbidity and quality of life in comparison to conventional management (such as in the case of pneumothorax) [14]. This domain also addresses certain clinical scenarios that may be encountered in critical settings. Many examples can be listed under this domain such as acute respiratory failure, lung ultrasound-guided fluid therapy, focused ECHO in shock management, ultrasound in resuscitation, lung ultrasound in monitoring alveolar recruitment [12, 15–18].

Critical ultrasound, as most topics in medicine, is not without risks. Concerns have been raised regarding infection, technology dependency, time and resource consumption. It may be necessary to devote a seventh domain for *potential risks*, to address these legitimate concerns and propose solutions or at least develop recommendations to minimize these risks. Finally, the eighth domain that needs consensus and recommendations is the domain of *future research*. It becomes obvious that there are new challenges and heralds emerging every day in the field of Critical Ultrasound. The only way to face these challenges and overcome the heralds is scientifically sound, well-conducted and clinically relevant research. We need to set up the priorities according to the patient’s best interest. We need to direct the researchers to what really is needed. We, as clinicians and patient advocates, need to direct the

industry and not be driven by their own agenda. We should be the master of technology not the reverse. The alternative is detrimental because “when technology becomes the master, disaster will come faster”.

It is also important to stress the multi-disciplinary nature of this consensus guideline creation process. Unilaterally created guidelines from single societies often conflict with guidelines issuing from different specialties and may make little impact outside of that particular society. It is the mission of WINFOCUS to provide guidelines that can be used all over the world, especially given that 80% of the world’s population lives outside of Europe and North America.

How WINFOCUS is developing evidence-based CR and CS in Critical Ultrasound?

The World Interactive Network Focused on Critical Ultrasound (WINFOCUS) made a commitment to address these challenges by establishing an array of International Liaison Committees (ILC) to evaluate the evidence for specific applications of Critical Ultrasound and ultimately generate series of documents that address the above-mentioned eight domains. Despite that these eight domains were judged by WINFOCUS-ILC to be essential, the ILC are empowered to add domains as they deem appropriate. Realizing the potential impact of such sensitive documents in critical medical settings, WINFOCUS decided to adopt well-defined clinical epidemiological methodologies in the process of developing its CR and CS. The ILC are supported by clinical epidemiologists and experts in the process of evidence-based CR and CS development. A great effort was made to avoid the methodological shortcomings found in recommendations generated by societies that do not adhere to strict evidence-based criteria. The need to optimize methodological processes and avoid previous pitfalls by following strict evidence based criteria was clearly recognized during the first ILC, at which time the International Liaison Committee for Lung Ultrasound was established.

This leading committee is composed of 25 members from 8 Countries. Their background includes a diversity of specialties (Emergency Medicine, Intensive Care, Trauma Care, Pulmonology, and Internal Medicine). Each expert has made significant contributions and published in this field particularly in the last 15 years. Moreover, most of the selected experts published on more than one of the main fields of lung ultrasound (interstitial syndromes, pleural effusions, pneumothorax, lung consolidations, pediatric and neonatology). This committee held three consensus conferences that addressed several domains and questions in the field of lung US. For the development of valid CR and

CS, we incorporated the GRADE Method [19, <http://www.gradeworkinggroup.org/index.htm>] and RAND Appropriateness Method [20, http://www.rand.org/health/surveys_tools/appropriateness.html, http://www.rand.org/pubs/monograph_reports/MR1269/index.html]; both rigorously validated evidence-based methodologies.

The GRADE Method assures a systematic review of evidence, a structured process for judging its quality, and most importantly, provides a clear pathway for transforming the evidence into clinical recommendations. It includes considerations of the benefit/harm ratio, the benefit/risk ratio, the potential variability in preferences and the importance of different outcomes. The RAND Appropriateness Method gives surety that the panel judgment is assessed in an objective and valid manner; minimizing bias and avoiding domination or suppression by incorporating the modified Delphi technique in 2-rounds of face-to-face debate and voting. It also allows an accurate measurement of the degree of consensus based on a reproducible statistical analysis of the outcome of voting using Likert's scale, which subsequently is reflected in the way recommendations or statements are finally phrased.

The work of International Liaison Committee for Lung Ultrasound will be published soon. This will be followed by the work of International Liaison Committees for: US guided vascular access, US guided airway management, Focused ECHO, FAST exam, US in resuscitation, US in neonatal & pediatric care, US in medical education, and others. It is expected that the product of this series of unique committees will re-shape the future practice and knowledge of this widely expanding, important and sensitive field: "Critical Ultrasonography". The final goal of this process is to develop comprehensive guidelines covering multiple critical ultrasound applications that empower ultrasound-guided resuscitation and bring point-of-care ultrasound to every bedside around the world where it may improve patient care. There are many reasons for continuing to create state of the art evaluations of current management and capability of point-of-care ultrasound in a variety of settings and applications. These applications will benefit patients worldwide, but not without rigorous assessment, classification and publication so this critical information is available to all clinicians. In addition, expert consensus statements may be of great aid as clinicians in developing portions of the world, where ultrasound at the bedside may be a new tool, to convince authorities, allies and opponents of the utility of these applications in their settings.

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