

Handheld Point-of-Care Ultrasound: Safety Considerations for Creating Guidelines

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Journal of Intensive Care Medicine
2022, Vol. 37(9) 1146-1151
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DOI: 10.1177/08850666221076041
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Abstract

Background: Compared to traditional ultrasound machines, emerging handheld point-of-care-ultrasound (HPOCUS) systems exhibit superior portability and affordability. Thus, they have been increasingly embraced in the intensive care setting. However, there is scarce data on patient safety and current regulatory body guidelines are lacking. Here, we critically appraise the literature with a focus on the merits, concerns, and framework of existing POCUS guidelines. Subsequently, we provide recommendations for future regulatory guidelines. **Methods:** A comprehensive literature review was conducted using the PubMed database employing the key words “point-of-care/handheld/portable ultrasound” and “guidelines” alone, in combination, and using thesaurus terms. Eligible articles were scrutinized for description of potential benefits and concerns of HPOCUS, especially from a patient safety perspective, as well as currently existing POCUS practice guidelines. Data was extracted, reported thematically using a narrative synthesis approach, then subsequently used to guide our proposed guidelines. **Results:** The most widely reported benefits of HPOCUS include superior portability, affordability, imaging, facilitation of expedited diagnosis and management, and integration with medical workplace flow. However, major barriers to adoption include device security/patient confidentiality and patient safety. Furthermore, except for a policy published by the American College of Emergency Physicians (ACEP) in 2018, there are few other national regulatory guidelines pertaining to handheld POCUS. In light of this, we propose a framework for HPOCUS guideline development to address these and other concerns. Such guidelines include training and credentialing, bioengineering approval, and strategic integration with electronic medical record systems. **Conclusion:** HPOCUS can be a powerful tool for expedited diagnosis and management guidance. However, there is limited data regarding patient safety and current regulatory body guidelines are lacking. Our assessment illuminates that there remain many unsolved problems about HPOCUS, and in turn, we propose guidelines to address safe regulation and implementation.

Keywords

handheld point-of-care ultrasound (HPOCUS), regulation, guidelines, patient safety

Introduction

Historically, medical ultrasound has been dominated by traditional cart-based systems located predominantly in hospitals, imaging centers, and physician clinics. As physicians strive to constantly refine and improve our clinical decision-making, ultrasound technology has advanced in response to these evolving contemporary needs. Over the last five years, a new development in ultrasound technology has emerged: handheld point of care ultrasound (HPOCUS). Designed to address the limitations of currently available cart-based ultrasound, HPOCUS excels in two key areas: size and affordability. Akin to the paradigm shift in medicine that followed development of the stethoscope centuries ago, many are hopeful that such ultrasound technology may become the modern physician’s new personal universal examination tool. New handheld devices are smaller, more portable, and more intelligent than ever before, setting HPOCUS up to be a powerful tool in improving universal access to medical imaging.¹ HPOCUS examination

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Received May 4, 2021. Received revised January 1, 2022. Accepted January 10, 2022.

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provides immediate diagnostic information at the bedside, simultaneous with ongoing diagnostic and therapeutic interventions and thus facilitating more efficient, effective care for critically ill patients.² Such a development has vast implications for nearly all medical specialties, especially those which require evaluation of critically ill or injured patients, such as in emergency and intensive care, the perioperative environment, and pre-hospital settings. Not unlike the early 19th century with René Laennec's development of the stethoscope, this new era of HPOCUS devices may usher in another paradigm shift in medicine, allowing increased diagnostic and treatment interventions by providers in an effort to improve patient care.

Such a shift has been recognized in the past several years with the advent of several high-quality, low-cost handheld ultrasound units available from a variety of companies. New advancements in performance, size, and interface usability have enabled users to perform exams more efficiently in comparison to cart-based ultrasound with minimal compromise. Decreasing costs of these systems has led to increased access to ultrasound exams for rural medicine and low resource settings. Currently, there is a significant gap in medicine with respect to regulation of traditional imaging devices and that required to address novel issues related to HPOCUS devices. As more physicians and facilities are investigating the feasibility of HPOCUS, an important new question has emerged in the duty of physicians to uphold patient safety: How will we ensure safe and standardized care surrounding HPOCUS in the patient care setting? Here, we highlight the advantages and complications of this new technology, review current existing POCUS guidelines, and provide subsequent recommendations for future regulatory guidelines. Features of some currently available commercial handheld HPOCUS devices are described in Table 1.

Merits of POCUS

One significant benefit of handheld ultrasound is the ability to help temporally expedite clinical care. HPOCUS involves considerably less time than that required to use a cart-mounted machine, and thus, can decrease time to diagnosis and improve care efficiency. In one study, two hours were saved per patient on average when POCUS was used in comparison to traditional ultrasound in post-operative follow-ups of patients who underwent a pyeloplasty.² Similarly, when POCUS was compared to traditional ultrasound methods, time to diagnosis was significantly reduced from 186 minutes (± 72 minutes) to 24 minutes (± 10 minutes).³ Trauma teams across the country are already using POCUS to expand their toolbox, as reflected in the eFAST exam. One study found that in adult trauma patients, the use of eFAST has increased over the last decade while abdominal computed tomography (CT) use has declined, saving patients money by reducing unnecessary diagnostic intervention, providers' time, and reducing unnecessary radiation exposure.⁴ For intensivists, ultrasound is an invaluable tool in the placement of peripheral and central lines. This is especially helpful in patients with difficult intravenous access

(DIVA). A study investigating the impact of ultrasound guided IVs identified "significant delays" in care when comparing patients with DIVA to patients without, with DIVA patients nearly taking 1.46 the time to draw labs compared to patients without DIVA.⁴ Such increases in time are associated with poorer clinical outcome.⁵ In procedures such as central venous cannulation, studies have found that ultrasound guidance lowers the rate of both overall and first attempt failure compared to the landmark technique.⁶ The same findings have been noted for placement of arterial lines.⁵

In addition to facilitating procedures, ultrasonography is also a powerful diagnostic tool. Point of care transthoracic echocardiographic (TTE) ultrasound allows providers to quickly detect cardiac pathologies and assess cardiac function. Ultrasound is also heavily utilized in trauma assessment to rapidly identify free fluid in the chest and abdomen, known as the Extended Focused Assessment with Sonography in Trauma (eFAST) exam. Handheld POCUS has been increasingly demonstrated to show diagnostic value in combating COVID-19.⁷ Accumulating literature has advocated POCUS' merits in rapid assessment of evolving lung pathology in COVID-19 (more sensitive than chest x-ray) patients as well as detection of early signs of COVID-19 patient deterioration, such as lower extremity deep vein thrombosis⁷⁻⁹. Additional research investigating the role of POCUS in combating the COVID-19 pandemic found that point of care lung ultrasound (POCLUS) was able to identify signs of COVID-19 in patients that initially tested negative multiple times before testing positive via RT-PCR. This study highlights the possibility of increased sensitivity provided by POCLUS when compared to RT-PCR testing in identifying and diagnosing COVID-19.⁹ Other literature has advocated for POCUS' role in minimizing chest x-rays and CT scans, thereby reducing patient movement and maintaining isolation protocols, while leading to reduced radiation exposure for patients and clinicians.¹⁰

The most striking advantage of handheld POCUS is its footprint. New handheld devices are significantly smaller than conventional cart-based ultrasound machines and are now compact enough to be carried in a white coat pocket. The portability of HPOCUS appeals to those practicing in fast-moving environments, such as intensive care, military medicine, pre-hospital settings, as well as remote care/low-resource settings, where access to electricity may not be readily available or dependable.

The exceptional affordability of HPOCUS is another attraction. Prices are considerably lower than cart-based ultrasound systems, with a traditional system costing between 10 to 30 times more than a handheld system. As seen in Table 1, devices can be purchased for \$2000 USD. In contrast, most new cart-based hospital ultrasound machines cost in the \$20,000 - \$75,000 range, which is significantly more expensive. The affordability of HPOCUS could translate to smaller, rural community hospitals being able to purchase more units, so that more patients in those communities can have increased access to ultrasound imaging in the effort to improve patient care. Improved access through reduced cost is a central

Table 1. Comparison of Current Handheld POCUS Devices.

	Kosmos Torso-One	Butterfly iQ +	Clarius HD	GE Vscan Extend	Philips Lumify
Cost	\$8500	\$1999 + \$420/yr	\$4900 +	\$4995 +	~\$10,000
Probe type	3-in-1 single probe (linear, curvilinear, phased array)	3-in-1 single probe (linear, curvilinear, phased array)	Separate linear, curvilinear, phased array probes	Dual probe (linear, curvilinear)	Separate linear, curvilinear, phased array probes
Imaging modes	2D, M, CDI, PW	2D, M, CDI, PDI	2D, M, CDI, PW, PDI	2D, M, CDI	2D, M, CDI
Operating system	Proprietary tablet included	Android/iOS	Android/iOS	Android/Linux	Android
Scan/ Recharge time	90 to 120 min scan time, 3 hr recharge time	120 min scan time, 5 hr recharge time	60 min scan time, 90 min recharge time	60 min scan time, 75 min recharge time to 90% battery	N/A (Powered by connected device)

*CDI – Color Doppler Imaging, PW – Pulsed Wave, PDI – Power Doppler Imaging.

attraction of handheld POCUS; one company producing HPOCUS devices has partnered with global health organizations and projects across the world to bring high-quality imaging to underserved communities.

Concerns of POCUS

Handheld POCUS has many merits; however, device security/patient confidentiality and patient safety are main points of scrutiny. Some security questions that must be answered are: Who would be able to operate pocket ultrasound machines? What qualifications would need to be placed? Who would enable the credentialing process and who would be in charge of oversight? In terms of software itself, what would be the difference in security between ultrasound devices operated in Android versus iOS operating systems? How safe are HIPAA locally/cloud-based storages from a breach? What happens if there is a breach to the cloud storage? Who is responsible for securing patient data? Similar to security concerns, patient confidentiality must also be scrutinized. Firstly, who would have access to patient records and how do we ensure confidentiality with a larger network of people? Secondly, whose device would the handheld ultrasound be connected to (hospital's tablet/smartphone or clinician's smartphone)? HPOCUS also raises the question: Should there be a possible cut-off for age of device for personal devices to ensure compatibility and performance? Lastly, concerns regarding data ownership and duration of ownership would surely arise.

Patient safety is the other concern, and ensuring proper infection control protocols, prevention of the transfer of pathogens between patients, and minimization of over/under diagnosis all must be addressed. For several handheld POCUS machines, manufacturers provide brief instructions on how to properly disinfect and clean the probe. Consequently, hospital and national guidelines on HPOCUS storage, cleaning, and disinfecting must be addressed. There are multiple publications that review sanitation techniques for cleaning traditional ultrasound probes, which can in theory be applied to HPOCUS as well, as the construction of the probes is similar in build and design, including a set of guidelines by ACEP for transducer

cleaning and disinfection.¹¹ One article of note pointed out that the use of glass-sealed control panels for POCUS devices significantly reduced bacterial contamination and aided in cleaning.¹² Besides biological safety, electrical and electromagnetic safety have not been adequately addressed. More guidelines on patient safety specifically pertaining to handheld POCUS devices should be implemented.

Given the merits and concerns of this new technology it begs the question: Is there an improvement in patient outcome when using handheld POCUS compared to cart-based ultrasound? In the clinical setting, the need to improve systems and streamline operations is increasingly important as the pressure increases to see patients more quickly and cost-effectively, especially in the setting of the current COVID-19 pandemic. Point of care testing, and by extension – POCUS, has been shown to be a potential strategy. Increasing literature has shown that POCUS improves patient throughput and satisfaction, while decreasing cost and need for additional diagnostic testing.¹ The potential benefits of new handheld POCUS devices are attractive. However, we must be cautious. Where are the proper rules and regulations which one must abide by if they wish to use this technology? For that matter which organizations should set these guidelines and what must be included in them? As time continues to produce newer technology, proper guidelines must be established to guide the future generations of HPOCUS users into the unknown.

Current Literature

Even though ultrasound technology has proven to play important roles in diagnostic and procedural medicine, the global community has inadequately addressed training and competence checks for acquiring and maintaining HPOCUS competencies. As per Coker and Zimmerman and a review article written by McCormick *et al.* there is currently little consensus in the anesthesiology specialty regarding the basic training one must receive to be certified in POCUS handling.^{13,14} To date, there is only one publication that explored acquiring and maintaining POCUS competence for anesthesiologists.¹⁴ Given that HPOCUS utilization is growing, we propose that

guidelines should address HPOCUS image acquisition and interpretation as core competencies in medical school and dependent on specialty, subsequent residency training. There are few published guidelines on the safe use and regulation for both POCUS and HPOCUS. In 2017, the American College of Emergency Physicians (ACEP) published guidelines for POCUS.¹⁵ In those guidelines they recommend that to educate providers, training should be fully integrated into emergency medicine residency programs, and to ensure proper continued clinical use, thorough quality assurance programs must be in place.¹⁵ This will require a clinical director to oversee policy development, equipment purchase, training, competency assessment, as well as credentialing.¹⁵ Furthermore, competency must require recognizing indications, contraindications, obtaining suitable images, interpreting images, and applying this interpretation into management of the patient.¹⁵ In 2020, ACEP published a set of ultrasound machine and transducer cleaning guidelines.¹¹ Besides guidelines issued by the European Society of Paediatric and Neonatal Intensive Care (ESPNIC) and the European Association of Cardiovascular Imaging (EACVI),^{16,17} there are no other national society guidelines for POCUS in current literature.

Proposed Guideline Framework for Safe HPOCUS

Large social media and electronic manufacturer conglomerates have demonstrated that technological advancement can outpace regulation. Healthcare is no different. The landscape of HPOCUS continues to evolve every year making access to devices easier than ever, but without full consideration of the impact they are having on patient care and clinical outcomes. Moreover, because HPOCUS is applicable to so many medical specialties, timely oversight of this technology by one governing body presents an additional challenge. Specialty specific guidelines accounting for specialty specific variabilities employing a uniform framework maybe more appropriate. We commend the American Society of Echocardiography and the ACEP for making initial efforts to regulate HPOCUS; however, in a rapidly advancing environment such as HPOCUS, practice guidelines should continue to evolve to complement this progress. While there are HPOCUS guidelines, they are limited, resulting in little evidence to date of their impact on care. As defined by The Institute of Medicine (IOM), guidelines are “systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances”.¹⁸ Guidelines employ best evidence where they exist and at a minimum, minimize variation in clinical practices so that outcomes may be benchmarked against guideline-based care and/or processes.¹⁹ Guidance developed in accordance with that promoted by the IOM, with constant appraisal, will enhance effectiveness and efficiency of patient care in employing HPOCUS while maintaining safety and privacy standards. We propose the following framework for guideline development:

1. Usage
 - (a) HPOCUS devices are classified as, and are to be used as medical devices, only by licensed health-care professionals. They should be used only for its intended purposes and governed as such by existing hospital/clinic/group/institution policy pertaining to medical equipment.
 - (b) Examinations performed with HPOCUS should be treated similar to those performed with cart-based ultrasound systems. The information obtained should not be solely relied upon to complete a diagnostic examination. Rather, it should augment patient history and physical examination, along with any other relevant examinations.
 - (c) Some reasons for integrating HPOCUS into clinical workflow may include increasing availability of ultrasonography for patient care and decision-making (especially in low-resource settings and underserved communities), expediting acquisition of images, improving patient outcomes, reducing radiation exposure from unnecessary x-rays and CT scans, aid with isolation protocols and telemedicine, and improving patient safety.
 - (d) Information obtained from HPOCUS should be archived and documented similar to current practices for cart-based ultrasound machines. Exportation of patient data to the camera roll/phone should be prohibited. Similarly, there should not be exports to a computer manually. Rather, direct information flow from the POCUS device to a medical image archiving and communications system, interfacing with the electronic patient medical record should be required.
 - (e) Billing and reimbursement should resemble current practices for other ultrasound devices.
2. Security and Safety
 - (a) Existing hospital policy for medical equipment should govern the purchase (if hospital owned), inventory, inspection, and repair of HPOCUS devices. If the device is privately purchased and owned, the device must go through the same initial vetting process as other medical devices, as governed by hospital policy and thereafter, to ongoing inspections as would pertain to hospital-owned devices.
 - (b) HPOCUS devices should be cleared by both the hospital’s information technology and biomedical engineering departments for safe use on patients.
 - (c) Devices should not be operated if any part of their system is known or suspected to be defective or incorrectly adjusted, until repaired. Devices should be structurally and functionally intact. Safety devices should never be removed, modified, or overrode.
 - (d) Operation of HPOCUS devices should be immediately stopped if the patient complains of heat or other device-related discomfort.

- (e) HPOCUS should only be permitted in medical settings if equipped with HIPAA regulated software that demonstrates unique user identification, automatic log-off after inactivity, and encryption/decryption of patient information. In the unlikely event of a data breach in which the HPOCUS software is compromised, affected patients should be promptly notified, all applicable hospital regulations and state/federal laws regarding disclosure should be followed. A systems response to security breach that mitigates potential adverse consequences of said breach should be pursued that prioritizes the interests of patients above those of providers and medical institutions.
 - (f) Probes, device units, smartphones, and tablets should follow cleaning guidelines as issued by the manufacturer or as proposed by ACEP or as outlined by hospital policy. All components should be disinfected in between use for different patients.
3. Training and Credentialing
- (a) Devices should not be operated until the operator is adequately and properly trained on its safe and effective operation.
 - (b) Competency should be achieved by completion of a specialty-dependent curriculum, which includes didactics, access to an archive of images, and hands-on supervised simulation training as an essential component of residency training. Furthermore, we believe practicing physicians should be able to obtain training through equivalent post graduate training programs, and that competency must be maintained through clinical practice with quality assurance. This can be accomplished by a clinical director to oversee policy development, equipment purchases, training, credentialing, and initial and ongoing competency assessment.

Conclusion

Handheld POCUS can be a powerful tool to enhance clinical practice through expedited diagnosis and management guidance, and already physicians among numerous specialties in various clinical settings are taking advantage of the technology. Subsequently, as a leader in medicine in patient safety and effective patient care, critical care should be at the forefront of this new frontier. To continue our mission of continuous innovation so that we may advance patient care, we must step forward and embrace new technology but do so in a safe way. HPOCUS has the exciting potential to improve the physician's toolbox with its speed, affordability, portability, precision, and accuracy. As much value as this new technology brings, with its benefits come numerous unsolved safety concerns which must be addressed. In keeping with the ever-relevant topic of patient safety, we should always be vigilant

of new changes to come. By utilizing existing hospital infrastructure in regulating equipment oversight and expanding training in both medical education and post graduate medical education, we believe HPOCUS has the potential to improve patient care through multiple specialties. In closing, we propose that proper protocols and guidelines be created by the professional association for each medical specialty that may use handheld POCUS in an effort to mitigate complications while maximizing patient safety in taking advantage of new medical technology.

Author Contributions

All authors contributed equally.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.


Funding


The author(s) received no financial support for the research, authorship and/or publication of this article.

Ethical Approval

Not applicable, because this article does not contain any studies with human or animal subjects.

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