Background

Disruptive Innovation? Portable Ultrasound Systems

Technological advances over the past 2 decades have made ultrasound equipment quite portable, with functionality and image quality similar to high-end ultrasound systems used in dedicated imaging laboratories.¹ Echocardiography and vascular laboratories are using these portable ultrasound machines to perform studies on patients who are unable to travel to the imaging laboratory. The same equipment now enables other healthcare providers to perform ultrasound examinations at the point of care (POC), that is, ultrasound examinations performed and interpreted at the bedside in real time. At present, the most commonly used devices for POC ultrasonography include portable, cart-based machines that are smaller and lighter than traditional systems, while offering the same features as larger ultrasound systems.² The cart-based machines are often equipped with batteries and have bootup times as short as 15 seconds. Although a wide range of cart-based ultrasound systems is currently available, these systems have demonstrated adequate image quality to answer focused POC questions, even in patients with obesity or chronic obstructive pulmonary disease.³,⁴

More recently, pocket-size ultrasound devices have been developed by various vendors. These devices have sizes approaching those of smart phones and are equipped with a battery and a single transducer. Although these devices currently do not have advanced features such as spectral or tissue doppler, they allow for gray-scale imaging (B-mode) and color-flow Doppler and are capable of recording both still images and video clips.¹ These attributes, along with their low cost, allow providers to use these devices like a stethoscope of the future and arguably places them in a disruptive technology category.¹⁵ In a recent study comparing the accuracy of a pocket-size ultrasound device with high-end ultrasound systems in 349 patients, concordance with respect to regional wall motion, ejections fraction, and left ventricular (LV) dimensions was very good between the 2 systems, raising concerns regarding training, documentation, and reimbursement.⁶,⁷

Current Role of Point-of-Care Echocardiography

Although diagnostic ultrasound has been used in medical practice for more than 5 decades, it has only been used by US clinicians at the patients’ bedside during the past 15 years.⁸ In this short period of time, POC ultrasonography has become an indispensable diagnostic tool for clinicians from various specialties in the assessment and management of patients in the acute care setting and is used to examine almost all organs of the body, including heart, lungs, intrabdominal organs, and blood vessels. For example, multiple studies have demonstrated that clinician-performed ultrasound is reliable in detecting free intraperitoneal fluid in trauma patients and has thus replaced diagnostic peritoneal lavage at many trauma centers.⁹,¹⁰ In central line placement, ultrasound guidance confers a significantly lower complication rate and is rapidly becoming standard of care.¹¹–¹³ The latter is one of the reasons why portable ultrasound systems are now available throughout many hospitals.

POC echocardiography has been proven equally beneficial, in the detection of pericardial effusions or the determination of cardiac activity in patients with pulseless electrical activity.¹⁴–¹⁶ In parallel with the improvement of image quality and provider skills, more advanced assessments, including global LV function, right ventricular dilatation, and inferior vena cava diameter have been adopted.¹⁷ Furthermore, European critical care physicians and cardiologists expanded on the sonographic assessment of the chest beyond the detection of pleural effusions and identified the usefulness of ultrasound artifacts in the assessment of pneumothoraces and extravascular lung water (pulmonary edema).¹⁸–²⁰ Pulmonary ultrasonography as an adjunct to echocardiography is gaining increasing interest among US clinicians and is the focus of ongoing research efforts.²¹,²²

In many European and other countries, acquisition and interpretation of sonographic images is exclusively performed by physicians. In these countries, the main differentiation

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between comprehensive and POC ultrasonography is usually based on the question whether the physician performing and interpreting the study is directly involved in the care of the patient who is being imaged or functions on a consultative basis. In these countries, clinicians from various specialties commonly perform their own ultrasound studies, for example, obstetricians (fetal ultrasonography) and cardiologists (echocardiography). In the United States, however, ultrasound studies are typically performed by sonographers and interpreted by physicians.

Although the use of POC echocardiography allows for more rapid and less costly sonographic imaging, it has led to a more distinct differentiation between comprehensive and POC ultrasonography. It has also resulted in controversial debates on who should (and should not) be permitted to perform sonographic examinations, what the training requirements and credentialing process should be, and whether POC imaging should be reimbursed.

Regulatory Aspects
Various accreditation groups, including the Joint Commission, mandate that all health professionals have delineated clinical privileges, and these privileges are regulated within the institution. Several professional societies have also adopted specific guidelines for ultrasound imaging: for example, the American Medical Association passed a resolution on ultrasound imaging in 1999 acknowledging that ultrasound imaging lay within the scope of practice of appropriately trained physicians, that a broad and diverse use and application of ultrasound imaging technologies exists in medical practice, and that privileging of the physicians to perform ultrasound studies in a hospital setting should be a function of hospital medical staff.

Since then, several other professional organizations have developed guidelines outlining appropriate ultrasound applications, training, and documentation standards. With respect to POC echocardiography in the United States, comprehensive guidelines have been published by the American College of Emergency Physicians and the American Society of Echocardiography. The American Society of Echocardiography published a consensus statement on “Focused cardiac ultrasound in the emergent setting” outlining clinical applications, training, image archival, and report generation. A similar position statement has recently been published by the European Society of Echocardiography focusing on the use of pocket-size imaging devices.

Reimbursement and Controversies
Despite the existing regulations and guidelines by the professional organizations of several specialties, many clinicians who seek privileges to perform POC ultrasonography within their hospitals are struggling to have these granted. In some instances, concerns may be centered around competency, ongoing quality improvement programs, and adequate documentation; frequently, however, controversies arise when the discussion involves billing for POC ultrasonography examinations. Unfortunately, these discussions are rarely focused on the question, What is the most expeditious, safe and cost-effective way of diagnosing a condition in order to improve patient outcomes? but rather which imaging studies and tests are best reimbursed and who should bill for them.

Given the current payment structure in the United States, it comes as no surprise that literature on cost analysis data for POC echocardiography is sparse and stems mainly from Europe. It has been demonstrated that improved diagnostic accuracy at the patients’ bedside because of POC echocardiography and, with that expedited, and earlier proper management of cardiac conditions leads to improved quality of care and likely cost reduction. Moreover, normal POC echocardiograms in low-risk patients may reduce the need for comprehensive studies. Razi et al found that POC echocardiography performed by internal medicine residents was able to identify LV systolic dysfunction in patients with acute decompensated heart failure with superior accuracy compared with clinical, physical examination, laboratory testing, and electrocardiographic findings, and an average of 22 hours sooner than comprehensive echocardiograms.

Several other studies have demonstrated improved diagnostic accuracy of POC echocardiography over the physical examination, echocardiography, chest radiography, and biomarkers in patients with cardiovascular disease that would lead to earlier identification and correct diagnosis of pathologies. Similarly, in a study of 238

Table 1. Medicare Reimbursement for Comprehensive Versus POC Echocardiography and Lung Ultrasound Applications

<table>
<thead>
<tr>
<th>Application</th>
<th>Common Assessment</th>
<th>CPT Code</th>
<th>Nonfacility Medicare Reimbursement, $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Echocardiography; transthoracic; real time with image documentation (2D); includes M-mode recording; when performed; complete with spectral Doppler echocardiography; and with color-flow Doppler echocardiography</td>
<td>LV and RV function; regional wall motion; valvular anatomy and function</td>
<td>93306</td>
<td>238.24</td>
</tr>
<tr>
<td>Echocardiography; transthoracic; real time with image documentation (2D); includes M-mode recording; when performed; follow-up or limited study</td>
<td>Cardiac activity; pericardial effusion; global LV function; RV dilatation; IVC diameter</td>
<td>93308</td>
<td>114.26</td>
</tr>
<tr>
<td>Ultrasound; chest (includes mediastinum); real time with image documentation</td>
<td>Pleural effusion; pneumothorax; B-lines (extravascular lung water)</td>
<td>76604</td>
<td>99.84</td>
</tr>
</tbody>
</table>

POC indicates point of care; 2D, two-dimensional; LV, left ventricle; RV, right ventricle; CPT, current procedural terminology; and IVC, inferior vena cava.

*Based on 2012 Medicare payment for current procedural terminology codes for metropolitan Boston, MA [https://catalog.ama-assn.org/Catalog/cpt/cpt_search.jsp?_requestid=761540].

The listed Medicare reimbursement rates do not include facility fees.
patients with penetrating chest injuries, surgeon-performed POC echocardiography yielded 100% sensitivity and 96.7% specificity for the detection of pericardial effusions.31 In another study of 49 patients with penetrating chest injuries, the survival was 100% in the group that underwent immediate POC echocardiography versus 57.1% in the group that did not.32 The average time to diagnosis and disposition for surgical intervention was 15.5 minutes for the POC echocardiography group and 42.4 minutes for the non-echo group.

Normal POC echocardiograms in low-risk patients may also reduce the need for comprehensive studies and with that decrease costs and, potentially, wait times for indicated echocardiograms.3,27 In a study from the United Kingdom, trainee cardiologists performed POC echocardiograms using a portable ultrasound device. Of 157 patients scanned, POC echocardiograms recorded 46 (29%) with completely normal findings, which could translate into cost savings of up to £30 367 (£47 965) per year, if these patients did not require subsequent comprehensive echocardiograms. Another study from the United Kingdom found that screening subjects at high risk for LV systolic dysfunction with POC echocardiography in the community could translate into 63% cost savings (£650 Euros/$860 per case) compared with comprehensive echocardiography.28 Although reports on long-term effects of POC echocardiography on echocardiographic laboratories were not identified by the authors, early performance of bedside echocardiographic studies could potentially lead to improved workflow and productivity for sonographers in imaging laboratories.25

With the proposed changes from the current fee-for-service system toward bundled reimbursement for integrated care within an accountable care organization (ACO), healthcare organizations will soon favor processes and diagnostic tests that allow for quicker diagnosis and proper treatment with the least costly resources. This environment will likely promote POC echocardiography and other POC ultrasound examinations by a broad range of providers in the near future.

Accountable Care Organizations—What Would Change?

New Structures, New Incentives

ACOs are currently being proposed as part of the healthcare reform efforts in the United States in an attempt to decrease cost while improving quality of health care. An ACO is defined as a local healthcare system and its associated providers who are held accountable for both cost and quality of care provided to a defined population.35 Several different ACO models will be offered, ranging from independent practice associations to integrated delivery systems.35,36 The means by which the ACO would be held accountable for their care would primarily be through novel provider payment systems offering financial incentives for low-cost, high-quality care. Under this new payment system, providers and healthcare organizations would face new incentives to reduce cost while meeting certain quality measures. Specifically, ACOs could achieve savings on the care of the assigned Medicare population by reducing hospital inpatient admissions or readmissions, by reducing the provision of specialty care, and by reducing imaging studies and other tests.

Over the past years, the rapid growth of medical imaging technology has contributed substantially to the exponential increase in healthcare expenditures in the United States.27 In US emergency departments alone, there was a 4-fold increase in advanced imaging performed between 1996 and 2007.38 It has been proposed that both the availability of imaging technology and current reimbursement incentives foster the use of this technology, often despite a lack of robust evidence supporting its use and high cost.39 Accordingly, a reduction in imaging-related costs will be a main target for cost reduction in health care, and new strategies are needed.

Perspectives: Organizations, Providers, Patients

Although in the past the focus was on which imaging studies were reimbursed best, healthcare organizations will need to change their strategy in the new reimbursement environment from high-volume, high-margin diagnostic studies and procedures to high-quality care provided at low cost, with likely an overall reduction in imaging studies. Although in the current system a comprehensive outpatient transthoracic echocardiogram receives higher reimbursement than the same study performed during an inpatient encounter, with the new incentives, a simple POC echocardiogram performed and interpreted by the provider may be more cost-effective, depending on the clinical indication. With respect to the care of patients with cardiac disease, organizations will need to identify the following:

- Which imaging studies allow rapid and reliable identification of relevant cardiovascular and pulmonary conditions at low cost?
- Which group of patients would benefit from these imaging studies?
- At which point in the patient encounter would the patient benefit most from the imaging studies?
- What are the necessary qualifications that allow providers to perform and interpret POC ultrasound studies safely?
- What is the optimal documentation of POC ultrasound studies that improves communication between providers and reduces duplication of testing?

An overview of specific aspects that should be considered by ACOs with respect to the implementation of POC echocardiography programs is provided in Table 2.

Similarly, providers who are accustomed to frequently ordering high-cost imaging studies will need to change their practice and understand not only the indications but also the inherent costs of imaging studies. A recent European study assessed the utility of POC echocardiography with a pocket-size device during initial outpatient cardiology consultation. They found that performance of POC echocardiography caused no significant increase in duration of consultation (≈3 minutes), yet it was diagnostic in 75% of patients, and resulted in 20% of patients being discharged without the need for comprehensive echocardiography.23 Ongoing research efforts will provide additional data regarding the utility and potential limitations of this new diagnostic tool.
Lastly, it is conceivable that patient satisfaction will increase with the use of POC echocardiography, as long as these studies result in more rapid and efficient diagnosis and management of their condition.

### Health Policy Considerations

#### Training and Continuous Quality Improvement

To assure appropriate study quality by clinicians who are performing and interpreting POC ultrasound examinations, including focused echocardiography training, documentation, and quality improvement programs will play an important role. A few specialty boards have recognized this need and integrated POC ultrasound training into their curricula. For instance, the certifying body for emergency physicians, the American Board of Emergency Medicine, considers POC ultrasonography, including basic echocardiography, a core skill for emergency medicine residents. Although recent emergency medicine graduates may be proficient in these skills, more senior practitioners from this or other specialties, such as internal medicine, critical care, or even cardiology may have lost their echocardiography skills over the years or may have never been trained. With the currently available technology and the pressure on organizations and providers to reduce cost and improve quality of care, it will be important that both hospitals (or future ACOs) and providers recognize the need for adequate training of providers along with ongoing quality improvement initiatives for POC echocardiography. Although minimum training standards have been published by professional organizations, it is ultimately up to the individual departments and hospital credentialing committees to implement these in their organizations. As midlevel providers play an essential role in many acute care settings where they are being trained in the use of POC echocardiography, POC ultrasound privileges should be included in their hospital credentials, provided they practice under a credentialed physician. Training of midlevel providers is feasible as demonstrated in a small study where nurses were trained in POC echocardiography and subsequently assessed LV systolic dysfunction with a sensitivity of 100% in a group of 63 patients with multiple cardiovascular risk factors. As with other noncardiac and cardiac imaging studies, the final interpretation of POC echocardiograms performed by midlevel providers could be made by supervising physicians in real time, through an overread mechanism or remotely via telemedicine.

For physicians, current guidelines vary with respect to recommended minimal training criteria for POC echocardiography. It seems feasible to tailor training to clinically relevant information that can be gathered from a focused POC echocardiogram (Table 2; Clinical applications). In practice, didactic and hands-on training in POC echocardiography has been imparted during residency, in the form of ultrasound fellowships or through dedicated curricula for practicing clinicians. For instance, during emergency medicine residency, training for POC ultrasound takes place in form of didactic training and dedicated ultrasound rotations. Many academic centers require their residents to complete a certain number of studies followed by written and practical examinations (objective standardized clinical examination) to assess both knowledge and skill acquisition.

For practicing clinicians, learning new skills presents a greater challenge because they need to complete the training in parallel to clinical work and other professional responsibilities. Potential solutions include traditional continuing medical education ultrasound courses or blended learning courses, which include web-based didactics followed by hands-on training. Didactic training duration for POC echocardiography reported in the literature ranged from 2 to 30 hours, including review of normal and pathological studies, with subsequent performance of proctored examinations. Depending on the extent of training and imaging goals, focused training resulted in moderate to excellent test accuracy (Table 3). To assure knowledge retention and skill improvement, the initial training must be followed by ongoing practical training, ideally with proctoring or feedback from more experienced sonographers. This could take place through a dedicated ultrasound rotation, for example, in an echocardiography laboratory, or through ongoing training and quality improvement measures within their own department. Despite a wealth of POC ultrasound textbooks, DVDs, online resources, ultrasound simulators, and even built-in training modules on ultrasound systems, how to provide sufficient hands-on training in POC echocardiography for practicing clinicians remains a challenge. For credentialing purposes, both

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**Table 2. Overview of Technical and Regulatory Aspects in the Implementation of POC Echocardiography**

<table>
<thead>
<tr>
<th>Equipment</th>
<th>Desirable equipment features:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Size and mobility: easy to maneuver, light weight, durable</td>
<td></td>
</tr>
<tr>
<td>• Short boot up time; battery</td>
<td></td>
</tr>
<tr>
<td>• Platform: user-friendly for multiple users</td>
<td></td>
</tr>
<tr>
<td>• Sufficient image quality and imaging modes (B-mode, M-mode, color Doppler); measuring capability (caliber)</td>
<td></td>
</tr>
<tr>
<td>• Archiving options: storage and versatile output of video clips and still images</td>
<td></td>
</tr>
<tr>
<td>• Reporting: text function for study/patient identification</td>
<td></td>
</tr>
<tr>
<td>• Infection control: easy to clean transducers and system</td>
<td></td>
</tr>
<tr>
<td>• Service contract: responsive technical support; coverage of accidental damage</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Clinical applications</th>
<th>Focused POC echocardiography goals:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Assessment of pericardial effusion</td>
<td></td>
</tr>
<tr>
<td>• Assessment of global cardiac function</td>
<td></td>
</tr>
<tr>
<td>• Identification of marked right ventricular and left ventricular enlargement</td>
<td></td>
</tr>
<tr>
<td>• Intravascular volume assessment</td>
<td></td>
</tr>
<tr>
<td>• Assessment of extravascular lung water (B-lines)</td>
<td></td>
</tr>
<tr>
<td>• Guidance of pericardiocentesis</td>
<td></td>
</tr>
<tr>
<td>• Confirmation of transvenous pacing wire placement</td>
<td></td>
</tr>
</tbody>
</table>

| Training | Ongoing continued education and quality improvement initiatives, including didactic training and performance assessment |

| Documentation | Image archival and written report generation |
written and practical competency assessment (through objective standardized clinical examinations) are feasible, although time and resource consuming. Before the implementation of POC echocardiography, staff, resources, and costs for training and competency assessment of providers, as well as an internal quality assurance system should be considered.

**Accreditation**

In the United States, there are several national echocardiography certification programs offered both for image acquisition by sonographers (eg, Registered Diagnostic Cardiac Sonographer) and for image interpretation by cardiologists and anesthesiologists (National Board of Echocardiography). However, with respect to POC echocardiography, there is no formal certifying organization today. If such a certification is offered in the future, it should ideally be developed as a joint effort of those specialties that intend to use this certification for competency assessment of their providers. Specialty-specific modules or different levels of certification would be desirable, similar to the National Board of Echocardiography examinations or certifications for sonographers. Such a test should include both assessment of image acquisition and interpretation knowledge and could provide a basis for organizations to verify basic competence of their providers in conjunction with ongoing CME requirements.

It will be essential to recognize that POC echocardiography is limited and intended to only answer focused, usually dichotomous questions, such as: “Is a significant pericardial effusion present? Yes/No,” rather than: “What is the degree of aortic stenosis?” Martin demonstrated, in a study of 10 hospitalists who performed POC echocardiograms on 354 general medical inpatients, that adding ultrasound to the physical examination improved hospitalists’ assessment of LV function, cardiomegaly, and pericardial effusion. It, however, failed to improve their assessment of valvular pathology. Although the potential benefit of POC echocardiography is substantial, its limitations bear the risk of misinterpretation both by the operator and other clinicians involved in the patient’s care. If physician A evaluated a patient for a pericardial effusion and then reported to a colleague: “I performed a POC echo on Mr. Smith, which was normal,” physician B may interpret this as “there were no regional wall motion or valvular abnormalities.” Thus, providers, credentialing, and accreditation committees should be aware of these limitations and the need for alternative testing to answer more complex questions. Moreover, more research is needed to evaluate the long-term implications of POC echocardiography by various healthcare providers and in different settings.

**Documentation**

To prevent repetitive testing and to improve communication between providers, another important aspect of POC echocardiography is standardized documentation. Newer portable and pocket-size ultrasound systems can store images and video clips in digital format that can be exported via DVD, universal serial bus (USB), or wirelessly to a network, but do not necessarily connect within hospital imaging-archiving systems. Some systems allow for report generation directly on the ultrasound screen; other solutions include individual documentation in paper-based or electronic medical records, as well as dedicated imaging software with templates for report generation. Whatever the documentation system may be within a given healthcare organization, standardization of POC echocardiography reports could prevent miscommunication between providers regarding the focused nature and results of the examination and ultimately improve patient care.

**Conclusions**

In summary, technological advances over the past 2 decades have made ultrasound devices portable with functionality

<table>
<thead>
<tr>
<th>Study</th>
<th>Participants</th>
<th>Prior TTE Training</th>
<th>Training</th>
<th>Imaging Goals</th>
<th>Accuracy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Longjohn et al56</td>
<td>Pediatric emergency physicians (n=2)</td>
<td>Minimal</td>
<td>2 hours didactic training; 15 practice POC TTEs</td>
<td>LV function (normal or diminished); IVC collapsibility; pericardial effusion</td>
<td>Agreement with cardiologist: LV function κ=0.87; IVC collapsibility κ=0.73; pericardial effusion κ=0.77</td>
</tr>
<tr>
<td>Razi et al6</td>
<td>Internal medicine residents (n=3)</td>
<td>None</td>
<td>Image review (DVD with 50 sample TTEs); 20 practice POC TTEs</td>
<td>LV systolic dysfunction (LVEF&lt;40%)</td>
<td>Sensitivity 94%; Specificity 94%</td>
</tr>
<tr>
<td>Lucas et al4</td>
<td>Internal medicine hospitalists (n=8)</td>
<td>None</td>
<td>27 hours didactic and hands-on training;34 practice POC TTEs</td>
<td>LV systolic dysfunction; severe mitral regurgitation; moderate/severe left atrial enlargement; moderate/severe LVH; pericardial effusion; IVC dilatation</td>
<td>LV systolic dysfunction; sensitivity 84%; specificity 87%; pericardial effusion: sensitivity 100%; specificity 95%</td>
</tr>
<tr>
<td>Croft et al50</td>
<td>Internal medicine residents (n=9)</td>
<td>None</td>
<td>15 hours didactic training (including image review); 15 hours hands-on training</td>
<td>LV size; global/regional LV systolic function; valvular abnormalities; LVH; pericardial effusion</td>
<td>Diagnostic images obtained: 94%; Images interpreted correctly: 93%; Correct identification of major TTE findings: 92%; and minor findings: 78%</td>
</tr>
</tbody>
</table>

POC indicates point of care; TTE, transthoracic echocardiogram; LV, left ventricle; EF, ejection fraction; LVH, left ventricular hypertrophy; and IVC, inferior vena cava.
and image quality similar to high-end ultrasound systems, enabling healthcare providers to perform ultrasound examinations at the point of care. POC echocardiography represents a safe, low-cost imaging technology with the potential to expedite and improve patient care. The establishment of ACOs with the introduction of bundled payments will likely result in a shift of incentives favoring lower-cost imaging studies, including POC echocardiography. When introducing POC echocardiography, healthcare organizations, department leaders, and providers must consider implications of its use with respect to training, credentialing, continuous quality improvement, accreditation, and documentation.

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Disclosures

None.

References


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