ACEP ULTRASOUND SECTION: EMERGING TECHNOLOGIES

New Technology – A How to Guide for the Physician

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So, you have finally decided to purchase a hand-held ultrasound for yourself or your department. Congratulations and welcome to the world of highly portable POCUS! Unfortunately, before you take your device to the bedside, you may need to go through some or all of the following steps to obtain institutional approval to use it.

INSTITUTIONAL REQUIREMENTS:

A Business Associate Agreement (BAA)

This is a contract between the vendor and the institution that outlines the terms of engagement between the two entities. This is typically needed when a new vendor enters the market, not when a an already established vendor creates a new product.

Business Service /or Trial Use Agreement

These are contracts between the vendor and the institution typically for research or a product trial. This is not necessary for routine clinical use.

Institutional Legal Team

It will be in your best interest to contact your legal and/or contracts team when bringing a new device into your institution. They can help with the BAA. Some ultrasound devices push images to a 3rd party cloud and image may be downloaded in a HIPAA compliant de-identified format and used for QA and development. Institutional consent documents will need to be clear that patient images may be used for QA/QI and education.

Regulatory:

This may vary state-by-state, and institution by institution, but for new technology clearance by a state Department of Health review is sometimes required.

Medical Informatics

Most institutions have a Chief Medical Informatics Officer. This is typically a high-level "C-Suite" position and this person may be the final arbiter of what technology can be used by providers. We recommend early conversations with this individual when considering integrating new technology.

Information Technology and Information Security

Most institutions have an Information Officer. This individual will assess your device and direct you to the groups and committees you need to interface with to approve your device for quality and safety. This person should also connect you with an individual from radiology information technology so that the device's images can be stored in middleware, PACS, or the EMR. Depending on the device and its platform, images may be stored on the device, in the cloud, on an institutional server, or some combination of the above. Early discussions about image archival, documentation, and electronic medical record (EMR) integration are important.

Supply Chain Approval:
Your institution may have a Supply Chain Committee that reviews capital purchases. The role of this committee is to determine the value of the device or technology compared to the cost to the institution. If individuals are purchasing their own ultrasound device and using personal phones they may not have to go through supply chain. However, for security, legal, and billing purposes, we encourage institutional purchases of technology (this includes both the ultrasound device and the associated tablet or phone).

New Technology Committee:
This committee may exist at your institution. Their role is to assess new technology in terms of safety and scope of use.

System Wide/Enterprise Point-of-Care Ultrasound Committee:
Some institutions have committees of point-of-care ultrasound stakeholders. This group is often involved in providing guidelines on point-of-care ultrasound providers scope of practice, credentialing, device purchasing, image workflow and documentation, training and research. They may be aware of other departments in the hospital integrating the same new technology.

Architectural Review Board:
This committee is designed to evaluate new technology that may require significant information technology (IT) or information security (IS) resources. When significant IT/IS resources/concerns regarding data transfer are needed, this board, or a board with a similar scope, will need to hear about your device and clear it through their vetting team. They will also be the ones to assign you an individual to assist with the IT set up.

Biomedical Engineering:
This team will assess your device for safety for patient use. They may also record your device's serial number and even tag it so that it can be found if lost.

Departmental Equipment Manager:
If you are lucky enough to have a departmental Equipment Manager, you should discuss your device with this individual. They may be able to assist you or your group should the device have a defect or malfunction.

INDIVIDUAL REQUIREMENTS:

Individual Clearances:
If you purchase a hand-held ultrasound device, you may have to meet with certain for clearance similar to the items in the section above. This may include bioengineering, the infection control board, and IT/IS. If it is a departmental purchase, a designated appointee should do this leg work such as the System Wide Clinical Ultrasound Director, Emergency Medicine Ultrasound Director, your medical director or nurse manager.

Legal Requirements for Billing:
We highly recommend that the institution purchases the handheld device if you plan to bill for ultrasound examinations performed on it. Discuss with legal counsel if you plan to personally purchase and then bill for studies with the device. The Stark Law governs physician self-referral and generally prohibits a physician from referring patients for a certain health service to a medical facility in which the referring physician maintains some ownership interest. The Anti-Kickback Statue prohibits any individual from receiving anything of value for purposes of inducing referrals. In some situations, it may be possible to bill for both the professional and technical components.