

know how many women, fearing that they had caused harm to their fetus, underwent elective abortions; anecdotal reports suggest that some did.

The decades-long history of doxylamine-pyridoxine emphasizes the importance of making clinical decisions on the basis of scientific evidence. The FDA's approval of Diclegis was based on efficacy and safety data from a randomized, placebo-controlled clinical trial and also took into account the extensive data described above showing that combined treatment with doxylamine succinate and pyridoxine hydrochloride is not teratogenic. These data reveal a favorable risk-bene-

fit profile for Diclegis in the treatment of nausea and vomiting of pregnancy that has been refractory to nonpharmacologic treatment. Although combined doxylamine-pyridoxine treatment is already the single most studied pharmacologic therapy for use in pregnancy, the FDA will continue to carefully monitor postmarketing data related to Diclegis use. The Diclegis story reminds us that reliance on evidence-based practices, with the use of multiple streams of data, is the most appropriate way to evaluate drug safety.

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## Point-of-Care Ultrasound in Medical Education — Stop Listening and Look

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In 1816, the French physician René-Théophile-Hyacinthe Laennec, inspired by children communicating by tapping a pin on one end of a long piece of wood and listening at the other end, rolled a “quire” of paper into a cylinder to listen to the heart of a sick young woman, instead of placing his ear directly on her bare chest. This improvised tool designed to protect a patient's modesty evolved into the wooden instrument that eventually became the modern stethoscope. Nearly 200 years later, the stethoscope is unique among medical devices in that it is used by virtually every type of physician and, with the exception of electronic versions offering amplification and filtering, has changed minimally in style and technol-

ogy. A fixture around the necks of physicians and medical students, it endures as an icon of our profession.

Yet during the past 50 years, diagnostic ultrasonography has replaced auscultation as the primary method of evaluating the mechanics of the heart and peering into the abdomen, vasculature, and uterus without exposing patients or fetuses to ionizing radiation. In cardiovascular medicine, echocardiography is the most used and cost-effective imaging method, despite the development of many other powerful new technologies. Ultrasound machines were once uniformly bulky, cart-like devices that were rolled awkwardly around hospital wards and into cramped patient rooms, but they have shrunk drastically

with the advent of faster microprocessors and improvements in miniaturization. Now, fully functional ultrasound machines are available in the form of laptop computers, and devices with slightly reduced functionality that are not much bigger than a smartphone fit in clinicians' pockets or palms (see photo).<sup>1</sup> Moreover, as these devices become less expensive — they're currently priced under \$10,000 — they're becoming more accessible to physicians and specialists beyond radiologists and cardiologists.

Despite some protectionist attempts to restrict the use of new imaging technologies to professionals with comprehensive training, the broadening use of these devices has served to demystify and universalize ultrasonography.



Harvard Medical School Students Using a Handheld Ultrasound Machine in a Teaching Exercise.

This trend has been led by emergency physicians, whose training now includes basic abdominal, cardiac, and obstetrical ultrasound exams, as well routine use of ultrasonography for procedures such as catheter placement. Intensivists and anesthesiologists have also begun using point-of-care ultrasound devices in intensive care units.

Carefully performed clinical studies have shown that diagnostic ultrasonography can be superior to the physical exam. In one study, first-year medical students using point-of-care ultrasound outperformed board-certified cardiologists using bedside cardiovascular physical examination in identifying cardiac abnormalities, identifying 75% of conditions, as compared with 49% identified by the cardiologists.<sup>2</sup> Another study showed that medical students using point-of-care ultrasound more accurately estimated liver size than did board-certified internists performing a physical examination.<sup>3</sup> The few studies specifically evaluating

handheld devices have generally shown that the information obtained was accurate, though dependent on the operator's skill.<sup>4</sup> As the use of and training in point-of-care ultrasound has grown in medical specialty residencies, medical schools have begun asking whether ultrasound training should be part of standard undergraduate medical education, both as a teaching tool and as a way to instill a diagnostic skill. Direct visualization of organs by ultrasound, correlated with cadaveric examination, atlases, or other imaging modes, can be a powerful adjunct to the traditional teaching of anatomy, physiology, and physical diagnosis. But the use of this technology as a diagnostic extension of the physical exam may represent a transformative change for medical training.

Several U.S. medical schools, recognizing its potential value, now offer ultrasound training early in the undergraduate curriculum. At the University of South Carolina and the University of California, Irvine, ultrasound training now begins during orientation; the technology is then used in classes in anatomy and physiology during the first year and is incorporated into physical diagnosis, problem-based learning, and eventually clinical rotations. Other medical schools have followed suit. This past year, Harvard Medical School introduced a pilot ultrasound curriculum designed to integrate ultrasound into the teaching of physical examination, in which students perform ultrasound and physical exams on their peers and correlate their findings. The Icahn School of Medicine at Mt. Sinai started an extensive, standardized pro-

gram in ultrasound technology. "Forty handheld ultrasound units were made available for use by 140 entering students," according to Jagat Narula and Bret Nelson, who direct the program, "with the expectation that all students will be proficient in identifying normal anatomy during the first year and will be able to differentiate between normal and abnormal in the subsequent years." Mt. Sinai has also distributed handheld units to all the internal medicine interns rotating through various intensive care units and is developing algorithms for the differential diagnoses of presenting symptoms. Although each institution will evaluate students' competence with the technology — at the University of South Carolina, for instance, students are observed performing a 15-minute series of ultrasound scans — widespread incorporation of ultrasonography into the physical examination for the next generation of physicians will most likely require rigorous assessment of the technology's benefit and the reporting of results.

Two major developments need to converge before point-of-care ultrasound is likely to replace the stethoscope. The first is technological: these devices will need to be even smaller and more ergonomic and may need to gain additional functionality, such as the ability to amplify lung or bowel sounds. Second, a generation of physicians will need to be trained to view this technology as an extension of their senses, just as many generations have viewed the stethoscope. That development will require the medical education community to embrace and incorporate the technology throughout the curriculum.

There are, however, several challenges to widespread adoption of point-of-care ultrasound in medical school training. Most new medical technologies tend to be reserved for subspecialists, who then train others in a top-down manner. If medical students begin learning to use this technology, they may show up on rounds feeling more empowered than their teachers, who at best will need to be trained in the new techniques but at worst may resist their adoption. Other practical issues, such as whether findings should be recorded in a hospital's picture archiving and communication system (PACS) and whether physicians should be allowed to bill for these procedures, also require consideration. Most experts believe that these limited exams will serve as screening tools, much as auscultation does currently, but will not substitute for formal ultrasound examinations.

Not everyone agrees that sophisticated imaging devices should be put in the hands of every medical student, intern, and resident. The risk of misdiagnosis is high when diagnostic ultrasound is used by inexperienced practitioners. The amount of training required to perform a competent ultrasound examination is not trivial. Cardiology fellows with a strong background in cardiac anatomy, physiology, and pathophysiology typically require 4 to 6 weeks to learn the basic echocardiographic examination. Although medical students trained in ultrasonography may be able to make relatively crude diagnoses — determining whether ventricular function is normal or reduced, assessing vena cava size,

or detecting gallstones — more sophisticated anatomical assessment will require substantially more training. False positive find-

ings from practitioners steeped in older traditions. Whether ultrasonography becomes as universally used and valued as Laennec's invention

***A generation of physicians will need to be trained to view this technology as an extension of their senses, just as many generations have viewed the stethoscope. That development will require the medical education community to embrace and incorporate the technology throughout the curriculum.***

ings may lead to additional and often unnecessary testing, and false negatives may provide unwarranted reassurance and result in underdiagnosis, especially since greater faith in "high tech" information may lead to the exclusion of other data. A further concern is that these devices distract students from the core principles of physical diagnosis, especially if introduced early in training, and will interpose another layer of technology between doctor and patient.

Such apprehensions have always accompanied the introduction of new medical technologies. In his preface to the English translation of Laennec's "A Treatise on the Diseases of the Chest and on Mediate Auscultation," John Forbes wrote, "Notwithstanding its value, I am extremely doubtful, because its beneficial application requires much time, and gives a good deal of trouble both to the patient and the practitioner."<sup>5</sup> Any new technology requiring training and expertise is met with similar skepticism

will depend on whether training in its use becomes standard for future physicians and whether placing these devices in their hands is shown to improve medical practice at the point of care.

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