CRITICAL CARE

VIEWPOINT

Do we need a critical care ultrasound certification program? Implications from an Australian medical-legal perspective

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Abstract

Medical practitioners have a duty to maintain a certain standard of care in providing their services. With critical care ultrasound gaining popularity in the ICU, it is envisaged that more intensivists will use the tool in managing their patients. Ultrasound, especially echocardiography, can be an 'easy to learn, difficult to manage' skill, and the competency in performing the procedure varies greatly. In view of this, several recommendations for competency statements have been published in recent years to advocate the need for a unified approach to training and certification. In this paper, we take a slightly different perspective, from an Australian medical-legal viewpoint, to argue for the need to implement a critical care ultrasound certification program. We examine various issues that can potentially lead to a breach of the standard of care, hence exposing the practitioners and/or the healthcare institutions to lawsuits in professional negligence or breach of contract. These issues, among others, include the failure to use ultrasound in appropriate situations, the failure of hospitals to ensure practitioners are properly trained in the skills, the failure of practitioners to perform an ultrasound study that is of a reasonable standard, and the failure of practitioners to keep themselves abreast of the latest developments in treatment and management. The implications of these issues and the importance of having a certification process are discussed.

Introduction

Although ultrasound has been used in various settings for decades, it is only in the past 10 to 15 years that critical care physicians have increasingly become aware of its usefulness. For example, critical care echocardiography was initially used in patients following cardiac surgery; soon it expanded to include diagnosis and monitoring in the ICU [1,2].

While critical care ultrasound is seen as an indispensable tool in the ICU nowadays, proper training and assessment modules are still lacking in many countries. The level of competency of practitioners varies greatly - some are very experienced and knowledgeable, while others have little practical experience. International statements (guidelines) specifying the requirements for different levels of competency and the scope of knowledge have been published [3,4]. These statements acknowledge the need for establishing a unified training pathway, the rationale of which mostly rests on improving the clinical skills of the physicians, hence the management and care of patients.

This article examines the need for establishing a proper training and assessment program but from a medical-legal perspective. The competency of healthcare providers and the provision of a reasonable standard of healthcare service are inter-related, and the failure of either one has not only legal but also cost and psychological implications for healthcare providers and patients. While this article is written from an Australian legal perspective, similar principles can be found in many other jurisdictions.

Legal principles

Duty of doctor

Australia is a common law country. Under the common law system a medical practitioner owes two different duties to patients: contractual and tortious. Breach of these duties not only renders the practitioner liable for breach of contract and negligence, respectively, but also exposes him/her to unsatisfactory professional conduct or professional misconduct under legislation [5].

Contractual duty

A contract is established when a patient pays the service fee and the doctor or hospital accepts it. Upon accepting the fee, the doctor has a contractual duty to provide a

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service, namely diagnosis, advice and treatment, to the patient with reasonable skill and care [6]. There is an implied term in the contract where the doctor is to exercise 'reasonable skill and care' in the provision of professional advice and treatment. There is also a duty to warn the patient of any material risk inherent in the proposed treatment or procedure. However, there is no warranty that the treatment will succeed, unless a contract was entered into with such an intention [7].

Tortious duty - duty under the law of tort

A 'tort' in law means civil wrong. Tort law is primarily concerned with compensating a person suffering from injury or damages for another's wrongful acts or omissions, such as through negligence. Tort arises as a result of a breach of a duty imposed by law. These laws are mostly laid down by judges over time in common law countries (for example, Australia, UK, India, USA, Canada), but are codified (legislated) in countries with a civil law system (most European countries).

The largest area of tort law is the law of negligence, which requires that a person must take reasonable care to avoid acts (or omissions) that he/she could reasonably foresee would be likely to injure his/her neighbours [8]. Note that 'neighbours' has taken a broad meaning to include anybody that the person may have a professional relationship with. In the case of a doctor-patient relationship, the patient is the doctor's 'neighbour' and the doctor must act reasonably to avoid any foreseeable risks that may cause harm to his/her patient. When a hospital accepts a patient, the hospital (including the treating doctors) automatically inherits a tortious duty owed to the patient who is now its 'neighbour'.

While there is no obligation for a doctor to provide professional service in every instance, those who choose to act must do so carefully to avoid inflicting harm on patients. Similar to contractual duty, there is a duty on the doctor's part to exercise reasonable care and skill in the provision of advice and treatment, and a duty to warn the patient of any material risk inherent in the proposed treatment or procedure [9].

Breach of duty

Breach of duty is the failure to meet the duty imposed under a contract or tort law. In a doctor-patient relationship, it is the failure to provide the required professional service (in the form of diagnosis, advice or treatment); or the failure to provide such service at a reasonable standard. A wrong diagnosis or errors in treatment do not by themselves establish a breach of duty, provided that the process of arriving at those decisions is carried out with reasonable skill and care - a standard reasonably expected of a practitioner with an equivalent level of training and experience [9].

Before the Tort Law Reform in Australia, the standard of care to be observed by medical practitioners was not to be determined solely or even primarily by medical practice. It was for the court to judge what standard should be expected from the medical profession [9,10]. In other words, the doctor's conduct has to conform to the standard of reasonable care demanded by the law [11]. Following the Tort Law Reform and enactments of the Civil Liability Acts (or its equivalents) in most Australian states between 2002 and 2003, the standard of care is taken to be a standard that conforms with the opinion that is widely held by a significant number of respected or competent practitioners in the field, unless the court considers that opinion is irrational or unreasonable [12]. This is similar to the approach adopted in the UK, and has the effect of avoiding unacceptable results where small pockets of medical opinion might otherwise determine the standard, even where the great majority of medical opinion would take a different view [13]. The qualifier for the approach is the 'rationality' or 'reasonableness' of the opinion. If an opinion is deemed irrational or unreasonable, even if it is opined by most practitioners as acceptable or reasonable practice, it will not be accepted by the court (Box 1).

Standard of care

The requisite standard of care is reasonable skills and care reasonably expected of a practitioner with the same standing. The standard of care is different in cases of diagnosis and treatment, and in cases of giving advice and information. In the former case responsible professional opinion will have an influential, often decisive role to play. The latter case, where the patient has been given all the relevant information to choose between undergoing or not undergoing the treatment, is not dependent upon medical standards or practices [10]. In treatment and diagnosis cases, the training, qualifications and the practice of a practitioner will be examined closely to decide if a practitioner has failed to provide the required standard of care.

Qualifications and experience

A practitioner is expected to have the relevant qualifications and experience when performing a particular procedure or treatment. He/she will be expected to meet the same general standard as his/her experienced colleagues (Box 2) [9]. The purpose is to protect the public from doctors performing procedures they are not familiar with, and to avoid doctors from invoking 'inexperience' as a defence to an action for professional negligence [14,15]. On the other hand, specialists, or doctors who hold themselves out as having special skills, may be required to meet the standard of a doctor with those special skills or a higher standard than the ordinary

Box 1. *Hucks v Cole* [1993] 4 Med L R 393

In *Hucks v Cole*, a pregnant woman presented to her general practitioner (GP) with septic spot but was given no treatment. The woman gave birth 3 days later but developed more spots. The GP prescribed and continued tetracycline despite pathology results showing that the bacteria was sensitive to penicillin. The woman later developed fulminating septicaemia and was seriously ill. At the trial, although a number of distinguished medical experts gave evidence that they would not give penicillin, the GP was found to have been negligent nevertheless. The court found the medical expert opinion unreasonable because the risk of causing grave danger could have easily and inexpensively been avoided [21].

Box 2. Hypothetical scenario of an inexperienced practitioner performing an echocardiography

A doctor with little experience and training in echocardiography decides to perform an echocardiogram on a patient with acute onset dyspnea and hypotension. The findings are reported to be normal and later the patient dies of tamponade. While a missed or wrong diagnosis itself is not necessarily a breach of duty, a 'substandard' procedure is. In this case, as soon as the doctor holds the transducer, he/she is professing to be fluent in the technique. Others, thinking that he is experienced in the field, may not doubt his skills and may rely on his findings in managing the patient.

practitioner. Therefore, where ultrasound is applied, it is expected the practitioner will possess the relevant skills and experience in that particular application.

A healthcare institution or employer has a duty to ensure that the doctor provided is adequately qualified to carry out the procedure in question [16]. In *Brus v ACT* [16], the defendant hospital was held negligent in permitting a registrar to perform a vaginal hysterectomy that was beyond the capacity of the registrar in question. As a result of poor surgical skills, the patient's fallopian tube was entrapped in the suture line and later prolapsed into her vagina, causing sustained pain. The hospital, as employer, was held liable for negligence. In the context of critical care ultrasound, hospitals and employers have a duty to ensure doctors performing ultrasound are properly trained to perform such procedures.

Continuing education and up-to-date information

As part of a duty to exercise reasonable skills and care, there is a duty on a doctor in certain circumstances to inform themselves of up-to-date information concerning a proposed treatment or procedure. Clinical practice changes over time as new evidence emerges. A failure to keep abreast of the latest developments in clinical practice that results in an adverse outcome to a patient may be seen as professional negligence in some cases (Box 3) [17].

Box 3. *SESAHS v King* [2006] NSWCA 2

In *SESAHS v King*, a pediatric oncologist acted in accordance with an outdated overseas protocol involving an experimental and controversial procedure to treat a 13 year old with a tumour in the spine. At the time, it was known that the procedure carried considerable risk of complications in the central nervous system (including paraplegia), and an update of the treatment regime was published subsequently. The oncologist was not aware of the change and continued treating the child according to the outdated protocol. As a result, the child became quadriplegic. The hospital was found liable for damages due to negligence [17]. It is the duty of doctors to ensure they are in a good position to receive up-to-date information.

Failure to take further action: further investigation, risk minimisation and referral

'Ultrasound, biopsy and referral were all available as reasonable options in the circumstances. It was a breach of duty in the circumstances not to utilize the available option' was the comment given by a medical expert and was accepted by the court in the case of *Boehm v Deleuil* [18]. In that case, two general practitioners (GPs) practicing in the same medical centre were held to be in breach of their duty by performing inadequate examinations and misdiagnosing malignant fibrous histiocytoma for lipoma in the popliteal fossa. As a result, the patient's left leg was amputated above the knee. The argument point of that case was not centred upon the misdiagnosis but on the poor standard of the service provided by the two doctors. It was found by expert evidence that, by not performing further investigations, the two doctors fell short of a professional standard that was reasonably expected of a doctor of their experience.

Where there is a possibility to guard against a foreseeable risk (no matter how small, provided it is not remote or fanciful) by adopting a means involving little difficulty or expense, the failure to adopt such means will, in general, be professional negligence (Box 4) [19]. For example, in *Halverson v Dobler* [20], a young patient visited his GP on a number of occasions over a number of years for syncopal events, but the GP failed to perform a single electrocardiogram on the patient despite negative neurological investigations. When the patient was 18 years old, he had another episode of syncope that left him with hypoxic brain damage. It was found later that the patient had long QT syndrome, which could be easily picked up by electrocardiogram. The GP was held liable for professional negligence [20]. Deliberately (or perhaps recklessly) taking a risk of grave danger, when that risk could be avoided relatively easily with little expense or risk, will amount to negligence (Box 5) [21].

In some cases, a practitioner may breach his/her duty if he/she does not realize his/her limitations and fails to

Box 4. *Sherry v Australasian Conference Association & 3 Ors* [2006] NSWSC 75

In *Sherry v Australasian Conference Association & 3 Ors* [2006] NSWSC 75, Mr Sherry underwent minimally invasive direct coronary arterial bypass, and was admitted to ICU on completion of the procedure. There was ample evidence that the patient was suffering from hypovolaemia, possibly blood loss, the next day. The patient also complained of chest pain and, on examination, decreased air entry on the left chest. The intensivist-in-charge made a provisional diagnosis of pneumothorax without performing a simple percussion test. X-ray revealed the patient in fact had haemothorax, which the intensivist-in-charge had failed to diagnose in time. The patient was left in a shock state and later died. The intensivist-in-charge was found to have been negligent. The court, with the support of expert evidence, held the view that if the intensivist-in-charge had performed a percussion test, he would have been alerted to haemothorax rather than pneumothorax and would have taken appropriate action. The hospital was also found to have been negligent in this case for providing poorly qualified nursing staff because the nursing staff failed to recognize the vital signs of hypovolaemia and also failed to alert the intensivist-in-charge.

refer patients to a specialist [22]. In *Tran v Lam* [22], the defendant GP found a lump in the plaintiff's left breast. Examination by mammography and ultrasound did not suggest the presence of malignancy. Needle biopsy was not carried out. Instead, the GP attempted to excise the lump in the surgery. This attempt was thwarted by excessive bleeding. The patient was referred to a surgeon only after 2 months, and the lumpectomy performed by the surgeon revealed the lump was malignant. Although denied by the defendant, the court considered the delay in referral was to avoid the opprobrium associated with the botched procedure. The cancer had metastasized and the plaintiff later died as a result. The court accepted that the delay in diagnosis meant the patient lost the chance of a full recovery or at least a longer life. The contentious point was again not the missed diagnosis but the standard of skill and care provided by the GP. The duty to refer is now recognized as part of the reasonable skill and care expected from a doctor. Where ultrasound has been applied and the practitioner is uncertain of the findings, it behoves that practitioner to refer the patient to a more skilled sonographer. For example, if a basic (or level 1) echocardiogram is provided in the acute situation and the operator identifies unexplained abnormalities, then he/she should refer the patient for a full echocardiographic study.

Failure to diagnose

Failure to diagnose and misdiagnosis *per se* are not evidence of breach of the standard of care. The law of negligence in Australia recognizes the limitations of doctors, and does not require doctors to be perfect [23]. The law is not concerned with absolute scientific accuracy in making diagnoses, but it does require a doctor with ordinary competence to exercise reasonable skill and care in reaching a diagnosis [24]. In doing so, he/she must show the standard of his/her practice is concordant with a competent practitioner of his/her experience (Boxes 6 and 7) [25-27].

Box 5. A scenario of blind versus ultrasound-guided pericardiocentesis

Blind pericardiocentesis is still commonly practiced nowadays. However, when ultrasound is easily accessible, the failure to use echocardiogram to guide pericardiocentesis may amount to negligence because the benefits of using such a method far outweigh the risks involved.

Damages and injury

For a breach of duty (or contract) to be actionable, the sufferer (patient) needs to show he/she suffered damages (for example, loss of income, unnecessary and extra medical bills) or injury (either physical or psychological) as a result of the breach and that these were reasonably foreseeable.

Implications for practitioners and hospitals

The legal duty for a medical practitioner is to ensure the services he/she provides are of reasonable skill and care as expected of a practitioner with the same level of training and experience. In order to achieve this, medical practitioners have the responsibility to: ensure he/she is properly trained in the procedure he/she is performing; keep himself/herself up-to-date in the area he/she is practicing, or in the procedure he/she is performing; recognize his/her own limitations and know when to refer a case to more experienced colleagues or specialists; and perform further investigations or procedures where appropriate to minimize treatment risks and misdiagnosis.

Therefore, an intensive care practitioner may easily find himself/herself in breach of duty of care if he/she: performs critical care ultrasound that is below the standard expected of a competent (medical practitioner) sonographer; applies out-of-date knowledge or criteria to his/her study, or fails to realize and apply the latest criteria or measurement methods in his/her studies; does not seek help from more experienced colleagues in difficult cases; and fails to perform ultrasound when it is easily available in his/her setting.

The hospital is also liable for breach of duty by any of its employee practitioners. The employer hospital has a duty to ensure its staff who perform critical care ultrasound are competent and qualified.

Box 6. Not negligent for failure to diagnose

In *Walton-Taylor v Wilson*, a patient in her third trimester complained of severe abdominal pain to her GP. The GP induced labour and the neonate was healthy. It was later found that the pain was due to a perforated appendix, and the patient subsequently required sub-total hysterectomy due to the complications. The GP was found not liable for failure to diagnose because the management plan adopted by the GP was appropriate [25]. Similarly, in *Holliday v Curtin*, a GP was held not liable for failure to diagnose breast cancer on a young female based on the fact that the doctor had showed reasonable skill and care, and there was insufficient evidence of a persisting abnormality to have alerted the GP that he should order further investigations [26].

Box 7. Negligent for failure to diagnose

In *O'Shea v Sullivan*, a GP and a pathology laboratory were held liable for failure to detect cervical cancer in a patient who complained of intermenstrual bleeding and post-coital bleeding [27]. The initial examination made by the GP was less than reasonably thorough. In a subsequent visit, the GP examined the patient's cervix and mistook the malignancy for an erosion or small ectopic columnar epithelium. The GP did not pursue the case further and failed to refer the patient to a gynaecologist. Although pap smear examination was carried out, the pathology laboratory incorrectly reported the findings to be 'mild squamous atypical cells possibly due to inflammation' rather than CIN3/ micro-invasive cancer cells. Given the marked difference between mild atypia and CIN3, the wrong assessment could not be explained by an acceptable difference in interpretation. Both the GP and the pathology laboratory were found to have provided a substandard professional service leading to missed diagnosis.

Role of certification of critical care ultrasonography

In order to avoid incurring liability while performing critical care ultrasound, intensivists should ensure they are properly trained and competent in the procedure. The best way to acquire competency in critical care ultrasonography is to complete a well-structured accreditation or certification program. While the certificate itself does not render a practitioner immune from professional negligence, the attainment of the recognized level of competency means there is less chance of breaching the standard of care. Another important benefit of having a certification process is that it allows other practitioners or employers to identify those who are competent to perform critical care ultrasound, thereby providing better patient care by allowing the procedure to be performed by only those who are qualified.

In Australia, the launching of a two-tiered critical care echocardiography certification program is on its way. The level 1 certification aims for a minimum level of training and experience to perform basic critical care echocardiography. Certification can be attained by attending workshops and by submitting a required number of case studies. A more advanced level (level 2) certification provides a qualification (Diploma in Diagnostic Ultrasound in Critical Care Ultrasound) by examination to practitioners. To avoid variability in standards, both certification processes are provided by a single professional body that is well-recognized and widely accepted in Australia and New Zealand, the Australasian Society of Ultrasound in Medicine.

Conclusion

Medical practitioners owe a duty of care, arising from contract and/or tort laws, to their patients. The duty of care demands the practitioner provides a professional service with reasonable skill and care - a standard of care that is expected of a competent practitioner in the same position. By providing a service that is below the expected standard of care will result in a breach of duty and render a practitioner liable for breach of contract or negligence. In some cases, it may amount to professional misconduct.

Breaches of standard of care come in various forms. With the costs of ultrasound equipment decreasing and the advancement in ultrasound technology and knowledge, it is inevitable that ultrasound will become an indispensable tool in the next few years. In fact, many ICUs nowadays have an ultrasound machine available in their units, or at least accessible in the hospitals. Considering the benefits it confers on patients, it is unacceptable and almost inexcusable in some cases not to utilize ultrasound in the management of patients, for example, ultrasound-guided pericardiocentesis and vascular access. Practitioners, on the other hand, have to ensure they have the required skills and experience to enable them to perform and interpret the studies competently. They should also keep themselves up-to-date with knowledge, realize their own limitations and seek help from more experienced colleagues if necessary.

A structured certification program is probably the best approach to equip practitioners with the necessary skills and knowledge. However, it should be remembered that, at least in Australia, the certificate *per se* does not protect medical practitioners from legal action. It is professional skills and knowledge that do.

Abbreviations

GP = general practitioner.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

SJH and ASM both drafted the manuscript.

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Published: 8 June 2010

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doi:10.1186/cc8968
Cite this article as: Huang SJ, McLean AS: **Do we need a critical care ultrasound certification program? Implications from an Australian medical-legal perspective.** *Critical Care* 2010, **14:**313.