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## Standard of Care

The previous chapter addressed the question, “To whom does the healthcare provider owe a duty?” This chapter asks “What kind of duty is owed?”

In negligence law, the duty that is owed is the duty of due care, or what a reasonably prudent person would do under the circumstances. Stated more formally, negligence is “*conduct which falls below the standard established by law for the protection of others against unreasonable risk of harm.*”<sup>88</sup> The standard is, therefore, an objective one — as judged by the reasonably prudent person, which means the jury. If the conduct of the tortfeasor, i.e., wrongdoer, falls below this standard, then a breach of duty is said to have occurred.

This standard is somewhat modified for medical professionals who are alleged to have caused injuries to patients. It has long been recognized that the average layperson was incapable of judging what the acceptable level of medical care ought to be. The law, therefore, has taken the position that the standard is that level of care expected of the reasonably competent doctor, rather than the reasonably prudent person. Alabama, for example, has held that physicians must “*exercise such reasonable care, diligence, and skill as reasonably competent physicians*” would exercise in the same or similar circumstances.<sup>89</sup> An Illinois court used similar words: “[a] *physician must possess and apply the knowledge, skill, and care of a reasonably well-qualified physician in the relevant medical community.*”<sup>90</sup>

Occasionally, injuries sustained in a healthcare setting may be judged by the reasonably prudent person standard. While the professional standard pertains to injuries arising out of healthcare, the reasonable person standard

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<sup>88</sup>Restatement (second) of Torts §282 (1965).

<sup>89</sup>*Keebler v. Winfield Carraway Hospital*, 531 So.2d 841 (Ala. 1988).

<sup>90</sup>*Purtill v. Hess*, 489 N.E.2d 867 (Ill. 1986).

governs non-healthcare activities such as falls on slippery hospital floors. Unfortunately on occasion the distinction is unclear. As one author put it, “Sometimes it is difficult to differentiate bad housekeeping and bad medical care, as where rats in a hospital repeatedly bit a comatose patient.”<sup>91</sup>

## LOCALITY RULE

In the past, courts would use the standard of the particular locale where the tortious act took place, invoking the so-called ‘locality rule.’ This was based on the belief that different standards of care were applicable in different areas of the country, e.g., urban or rural. However, this rule has been largely abandoned in favor of a uniform standard, because medical training and board certifications all adhere to a national standard. Telemedicine has further propagated this uniformity.

With the erosion of the locality rule, courts now readily allow out-of-state experts to testify on behalf of the opposing parties. This has been especially helpful for plaintiffs who are far less likely to be able to secure willing experts from the local community.

Geographical considerations are not entirely irrelevant. Where the local medical facilities lack state-of-the-art equipment or specialists, courts will look at the existing circumstances. However, there is always the duty to refer and transfer to an available specialist, and the failure to do so may form the basis of liability.

## SETTING THE STANDARD OF CARE

An allegation of malpractice is not about the physician’s bad judgment, bad faith, or intentional malfeasance. It is about breaching an objective standard of medical practice. As a rule, expert testimony is required to establish the custom of the profession. Both the complaining patient and the defendant doctor are required to produce experts to legally establish what constitutes standard as opposed to substandard care. Experts, by virtue of their skills, knowledge, experience or education — supported by authoritative texts and

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<sup>91</sup>Dobbs, DB. *The Law of Torts*, Chapter 14. West Information Publishing Group, 2000, referring to *Lejeunee v. Rayne Branch Hospital*, 556 So.2d 559 (La. 1990).

treatises as necessary — then articulate the standard as it applies to the particular case. In reaching their verdict, the jurors listen to all the evidence and decide which expert, and therefore which of the parties, is the more credible (see Chapter 7: Expert Testimony).

A plaintiff who attempts to sue a practitioner without the assistance of an expert witness is likely to have the case thrown out at an early stage. The law generally prohibits a lay person from setting the standard of care in professional negligence disputes; the plaintiff cannot simply refer to a book or article to support his or her case. In many ways, therefore, this is the biggest stumbling block for the plaintiff, as it is not always an easy or inexpensive matter to secure the services of an expert witness who is willing to testify against a doctor. Experienced plaintiff law firms, however, count on reliable medical contacts to review the case.

In legal proceedings addressing the standard of care, the doctor is judged according to his or her specialty. A general practitioner (GP) will not be held to the same standard of care as a specialist. The surgeon will be judged according to the community standard of the ordinarily skilled surgeon, and the GP to that of his fellow GPs. But there is a separate duty to refer to a specialist if the case is outside the doctor's field of expertise. If the standard of care is to refer to a specialist, the GP who undertakes to treat the patient within that specialty will be held to that higher standard. In *Simpson v. Davis*,<sup>92</sup> a general dentist performed root canal work and was therefore held to the standard of an endodontist.

Inexperience is not a defense. This seems particularly harsh to the trainee who cannot be expected to perform at the level of a fully trained or experienced practitioner. Yet, the trend is to hold medical trainees to the same standard as a qualified doctor in that specialty (see Chapter 16: Medical Trainees).

## RESPECTABLE MINORITY RULE

The standard of care does not have to be a unanimous community standard. In medicine, there is frequently a minority view of how things ought to be

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<sup>92</sup> *Simpson v. Davis*, 549 P.2d 950 (Kan. 1976).

done. So long as this minority view is held by a respectable group of doctors, the law will accept it as a legitimate alternative.

What can this mean in practice? If an expert presents a 'respectable minority' view, then the court or jury may find in favor of the defendant even if there are other acceptable ways of diagnosing or treating the patient. However, this does not mean that any 'on-the-fringe' publication on an issue will rise to the level of the respectable minority. Even if the information is allowed into evidence, the jurors may choose not to accept it.

A minority view may simply be considered reflective of a different approach to the same problem, but the care rendered must still comply with the standard of care of the minority view. In one Texas case, the court was not concerned with whether the practice was that of a 'respectable minority' or a 'considerable number' of physicians, but whether it met the standard. The case involved an augmentation mammoplasty procedure that resulted in silicone leakage. A number of qualified physicians had used that procedure, and this satisfied the court that the standard had been met.<sup>93</sup>

## **PHYSICIANS' DESK REFERENCE (PDR) AND MANUFACTURERS' PACKAGE INSERTS**

The PDR lists all approved prescription drugs and provides detailed information covering, among other things, indications, contraindications, side-effects and warnings. Manufacturers of medical devices or equipment likewise provide detailed information governing the use of their products. These instructions are termed 'package inserts.' Some courts have chosen to accept package inserts as setting the standard for drug or device use, and will hold a physician liable if it can be shown that the product used by the patient was contrary to issued instructions. This approach was adopted by a Minnesota court in a wrongful death claim against a physician for using repeated doses of the drug chloromycetin to treat an ear infection. The patient died from aplastic anemia, a known complication of the drug. The court held that "*drug manufacturer's instructions concerning use of its product governed profession in prescribing treatment. . . sufficient to make out a prima facie case of liability.*" This is now widely known as the Mulder Rule.<sup>94</sup>

<sup>93</sup> *Henderson v. Heyer-Schulte Corp. of Santa Barbara*, 600 S.W.2d 844 (Tex Civ. App. 1980).

<sup>94</sup> *Mulder v. Parke Davis & Company*, 181 N.W.2d 882 (Minn. 1970).

Other jurisdictions do not go as far, and merely accept the PDR as evidence to be considered. Hawaii is a jurisdiction that rejects the Mulder Rule. In its seminal case on the issue, a 21-year-old woman underwent breast augmentation surgery, and subsequently noticed hardening of the right breast. Dr. Peebles, the defendant, diagnosed capsular contracture and performed closed capsulotomy, which unfortunately led to implant rupture. The plaintiff argued that the 'common knowledge' exception transformed her malpractice lawsuit into an ordinary negligence case, thus obviating the necessity of expert testimony to establish the applicable standard of care. She asserted that the 'common knowledge' exception applied because of specific information contained in the manufacturer's package insert.

However, the Hawaii court held that *"a manufacturer's package insert, in and of itself, may not establish the relevant standard of care in a medical negligence action. The inserts may be considered by the fact finder along with expert testimony, but may not alone define the standard of care."* It drew attention to the fact that the American Medical Association, while recognizing package inserts as one useful source of information, has maintained that inserts are an inadequate standard for medical practice, as they serve inconsistent purposes such as advertising for the manufacturer, regulation by the government, and information for the doctor.<sup>95</sup>

This same position was taken by a California Court in the case of a patient who sustained spinal cord injury following the injection of Sodium Urokon during translumbar aortography. The manufacturer's package insert recommended 10–15 ml, whereas the defendant used the customary dose of 50 ml. The plaintiff asserted that this spoke for itself as proof of negligence, but the Court held otherwise: *"Thus, while admissible, it cannot establish as a matter of law the standard of care required of a physician in the use of the drug. It may be considered by the jury along with the other evidence in the case to determine whether the particular physician met the standard of care required of him."*<sup>96</sup>

Doctors sometimes treat a condition with drugs that have not been approved by the FDA for use in that specific condition. This is called 'off-label'

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<sup>95</sup> *Craft v. Peebles*, 893 P.2d 138 (Haw. 1995).

<sup>96</sup> *Salgo v. Leland Stanford Jr. Univ. Board of Trustees*, 317 P.2d 170 (Cal. 1957).

use. Whether such 'off-label' use amounts to negligence will depend on the community standard of practice as articulated by medical experts.

## PRACTICE GUIDELINES

In recent years, various medical specialty organizations and governmental and commercial enterprises have issued practice guidelines that purport to define the best evidence-based medicine. The courts have tended to use these guidelines as reflective of current medical standards because they are usually arrived at by consensus of an objective authoritative body of clinicians such as the American College of Surgeons.<sup>97</sup> Some states such as Maine have passed legislation that allows doctors to elect to be covered by practice guidelines, with such compliance constituting evidence against an allegation of negligence.<sup>98</sup> Kentucky's statute presumes that the doctor has met the appropriate standard of care when the treatment has been in compliance with these guidelines.<sup>99</sup> On the other hand, other states such as Maryland, have ruled that practice guidelines are inadmissible as evidence in courts of law.<sup>100</sup>

## EXCEPTIONS TO THE NEED FOR EXPERT TESTIMONY

An occasional case of medical negligence may not need the testimony of an expert to establish the standard of care. The defendant's own testimony can sometimes be sufficient. Criminal defendants have a fifth Amendment right against self-incrimination, but civil defendants do not. Theoretically, the plaintiff can call the defendant to state the requisite standard of care, but it is unlikely that the testimony will be what the plaintiff seeks given that the defendant is an 'adverse or hostile witness.' The two most common exceptions to the requirement for expert testimony are *res ipsa loquitur* and violation of statutes.

***Res Ipsa Loquitur:*** The doctrine of common knowledge, more technically called *res ipsa loquitur* or 'the thing speaks for itself,' holds that where "the plaintiff's evidence of injury creates a probability so strong that a lay juror

<sup>97</sup> *Pollard v. Goldsmith*, 572 P.2d 1201 (Ariz. App. 1977).

<sup>98</sup> Me. Rev. Stats. Ann. §2975.

<sup>99</sup> Ky. Rev. Stat. §342.035.

<sup>100</sup> Ann. Code Md., Health-Gen. §19-1606.

can form a reasonable belief," a plaintiff may be entitled to a waiver of the requirement of expert testimony.<sup>101</sup> This doctrine is rarely invoked, usually in obvious examples of medical injuries such as amputation of the wrong limb, lung puncture following routine shoulder injection, or removal of the wrong vertebral disc. In one not so obvious example, the court allowed the case to go to the jury without the benefit of expert testimony on the basis of common knowledge. The case involved the severance of a patient's ureter during a complicated hysterectomy.<sup>102</sup> On the other hand, an Illinois court disallowed a plaintiff from claiming that it was common knowledge that someone should be referred to a cardiologist for a heart condition.<sup>103</sup>

*Res ipsa loquitur* had its genesis in the classic 1863 English case where a barrel of flour fell upon the plaintiff from a window above a shop. Despite no other evidence, the Court ruled for the plaintiff, opining that the circumstances constituted *prima facie* evidence of negligence (A *prima facie* case means the plaintiff has met the burden of going forward with evidence on the legal issue):

*"I think it apparent that the barrel was in the custody of the defendant who occupied the premises, and who is responsible for the acts of his servants who had control of it; and in my opinion the fact of its falling is prima facie evidence of negligence..."*<sup>104</sup>

The *res ipsa loquitur* doctrine is most useful when the plaintiff has insufficient evidence of what caused the negligent act, but circumstances clearly indicate that the defendant was negligent. It is applicable only when three conditions are met:

- (1) The event, under the circumstances of the case, ordinarily does not occur in the absence of someone's negligence.
- (2) The event must be caused by a means within the exclusive control of the defendant.
- (3) The plaintiff did not contribute to the event.

<sup>101</sup> *Gordon v. Glass*, 785 A.2d 1220 (Conn. App. 2001).

<sup>102</sup> *Cangemi v. Cone*, 774 A.2d 1262 (Pa. Super. Ct. 2001).

<sup>103</sup> *Evanston Hospital v. Crane*, 627 N.E.2d 29 (Ill. App. 1993).

<sup>104</sup> *Byrne v. Boadle*, 2 H. & C. 722, 159 Eng. Rep. 299 (Court of the Exchequer 1863).

In most jurisdictions, *res ipsa* permits the jury to infer that a negligent act had taken place, but the defense may still be able to rebut the evidence. Courts are usually hostile to the use of the *res ipsa* doctrine in medical malpractice, unless the circumstances clearly warrant the application of the doctrine such as in the case of foreign bodies that are left within body cavities following surgery. On the other hand, dysuria in association with a deformed penis was not sufficient evidence by itself to indicate negligent circumcision.<sup>105</sup>

In the well known California case of *Ybarra v. Spangard*, the court permitted the use of the *res ipsa* doctrine against multiple defendants in the operating room after the plaintiff developed shoulder injuries following an appendectomy.<sup>106</sup> Since the plaintiff was unconscious, the Court felt it was appropriate to place the burden on defendants to explain how the shoulder injury occurred. The *res ipsa* doctrine was also allowed in a case where the plaintiff sustained injuries to the peroneal and tibial nerves after knee surgery.<sup>107</sup>

Courtroom eloquence concerning *res ipsa* was at its best in *Cassidy v. Ministry of Health*, an English case from the 1950s. In *Cassidy*, a patient suffered significant deformity of his hand following surgery for Dupuytren's contracture. His attorney asserted: "At the outset, only two of the plaintiff's fingers were affected; all four are now useless. There must have been negligence — *res ipsa*." The Court of Appeal agreed, Lord Denning taking the position that it raised a *prima facie* case against the hospital. However, Lord Denning also indicated that the doctrine could only be invoked against a doctor in extreme cases.<sup>108</sup>

The use of *res ipsa* is governed by statutes in some states. Georgia and North Dakota, for example, disallow the use of *res ipsa* in medical negligence cases.

**Violation of Statutes:** If a healthcare provider violates a statute or regulation, and a patient incurs harm from this violation, the patient may have a good case to assert a breach of duty. The conduct has to affect the class of victims of which the plaintiff is a member, and be the type of injury that the statute was intended to protect. An example is where negligence is alleged against

<sup>105</sup> *Walker v. Skiowski*, 529 So.2d 184 (Miss. 1988).

<sup>106</sup> *Ybarra v. Spangard*, 154 P.2d 687 (Cal. 1944).

<sup>107</sup> *Hale v. Venuto*, 137 Cal.App.3d 910 (Cal.App. 1982).

<sup>108</sup> *Cassidy v. Ministry of Health*, 2 KB 343 (1951).

a practitioner without a valid medical license. Court opinions have differed, depending on whether the license had innocently lapsed,<sup>109</sup> or whether the practitioner was unqualified.<sup>110</sup>

In some jurisdictions, violation of a statute can amount to negligence *per se* (also termed statutory negligence), which means that there is no need for expert testimony. However, the plaintiff will still need an expert witness to prove causation. An example is the case of *Landeros v. Flood*. In *Landeros*, an emergency room physician failed to diagnose battered child syndrome, and discharged the child who subsequently suffered additional injuries at home. An existing statute mandated reporting of child abuse, and the doctor's breach of his statutory duty created a basis of liability for the missed diagnosis and injuries.<sup>111</sup>

If a statutory violation amounts to a rebuttable presumption of negligence, this may allow the plaintiff to get to the jury which can then accept or reject the presumption of fault.<sup>112</sup>

## JUDGE-MADE STANDARDS

Medical standards are issues of fact that are ultimately determined by the jury after listening to the experts. It is rare therefore for a judge in a jury trial to decide on what constitutes the proper community standard. But in 1974, the Supreme Court of Washington did just that.<sup>113</sup> It held, as a matter of law, that tonometry or the measurement of intraocular pressure to diagnose glaucoma should be performed on all patients regardless of age. The standard of care at that time was to obtain such measurements only in those past the age of 40 because glaucoma is rare in younger patients. The case involved a 32-year-old woman who became blind because of the failure over a five-year period of various treating ophthalmologists to measure her intraocular pressures. The Court decided that it would institute its own standard in the name of public safety, since tonometric measurements are easy to perform

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<sup>109</sup> *McCarthy v. Boston City Hospital*, 266 N.E. 2d 292 (Mass. 1971).

<sup>110</sup> *Stahlin v. Hilton Hotels Corp.*, 484 F.2d 580 (7th Cir. 1973).

<sup>111</sup> *Landeros v. Flood*, 551 P.2d 389 (Cal. 1976).

<sup>112</sup> *Martin v. Herzog*, 228 N.Y. 164 (1920).

<sup>113</sup> *Helling v. Carey*, 519 P.2d 981 (Wash. 1974).

and may be sight-saving:

*“Courts must in the end say what is required; there are precautions so imperative that even their universal disregard will not excuse their omission . . . Under the facts of this case reasonable prudence required the timely giving of the pressure test to this plaintiff. The precaution of giving this test to detect the incidence of glaucoma to patients under 40 years of age is so imperative that irrespective of its disregard by the standards of the ophthalmology profession, it is the duty of the courts to say what is required to protect patients under 40 from the damaging results of glaucoma.”*

Some seven years earlier, the same court had held that to permit a surgical operation in an anesthetized patient without a supervising doctor in the operating room amounted to *“negligence as a matter of law.”*<sup>114</sup>

There has not been a proliferation of cases where judge-made standards supplanted the traditional medical standard of care established by expert testimony. Allowing judicial weighing of risks versus utility was however at work in several cases of HIV transmission through infected blood products that could have been more thoroughly screened.<sup>115</sup> In one of these cases, the court wondered whether the then prevailing professional standard of care itself constituted negligence.<sup>116</sup>

<sup>114</sup> *Pederson v. Dumouchel*, 431 P.2d 973 (Wash. 1967).

<sup>115</sup> *United Blood Services v. Quintana*, 827 P.2d 509 (Colo. 1992); *Snyder v. Am. Ass'n of Blood Banks*, 676 A.2d 1036 (N.J. 1996).

<sup>116</sup> *Advincula v. United Blood Servicers*, 678 N.E.2d 1009 (Ill. 1996).

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# SUMMARY POINTS

## STANDARD OF CARE

- Breach of duty of care means falling below the standard of care. In medical malpractice, an ordinarily skilled practitioner in that specialty, not one with exceptional or the highest skills, is used as the standard. The standard can usually be satisfied as long as there is a respectable minority with that view.
- An expert witness is generally needed to articulate this standard.
- In most jurisdictions, PDR warnings can be used as evidence of the standard of care, but they are not dispositive of the issue, and expert testimony is still required.
- Where negligence can be inferred, e.g., foreign bodies left within body cavities, the plaintiff can invoke the doctrine of *res ipsa loquitur*, which does not require expert testimony, to win the case.
- A defendant will usually be found negligent if there is a violation of a statute or regulation enacted to protect victims such as the plaintiff against such kind of harm.