

## Review Article

# Legal and evidenced-based definitions of standard of care: Implications for code of ethics of professional medical societies

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## Abstract

**Background:** The concept “standard of care” (SOC) is invoked in legal cases, as well as evidence-based, and professional/ethical discussions in medicine and surgery.

**Methods:** We reviewed key legal cases and relevant evidence-based medical articles, and then explored the implications for professional societies seeking to set guidelines for their members testifying as expert witnesses.

**Results:** First, the legal concept of SOC plays a role in malpractice cases in assessing whether a physician’s behavior was “within the SOC.” The concept of SOC has evolved from a “standard of a responsible body of medical opinion” (Bolam case), which implicitly did not allow for multiple SOC, to a more evidence-based approach. Second, according to the evidence-based medical literature, there is more than one SOC in medicine and surgery, including neurosurgery. Third, professional, medical, and surgical societies have evoked the concept of SOC to set ethical guidelines for how their members should behave when testifying as expert witnesses. Specifically, the literature argues societies should avoid abusing singular, self-serving definitions of the SOC to sanction members, typically plaintiff’s experts, who offer alternative SOC in depositions or in court.

**Conclusions:** Recent legal decisions suggest that testimony should be based upon scientific evidence. The scientific evidence indicates that there is often more than one SOC. Thus, any subspecialty society, including the American Association of Neurological Surgeons, that ignores evidence-based medicine and the existence of multiple SOC, risks the appearance of fostering self-interest at the expense of patient care.

**Key Words:** Standard of Care, Definitions, Bolam Test, Medicine, Best Practice, Bolitho, United Kingdom, Guidelines: Neurosurgery

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## INTRODUCTION

The concept “standard of care” (SOC) is invoked in legal cases, as well as evidence-based, and professional/ethical discussions in medicine and surgery. First, legally, the concept of SOC plays a role in malpractice cases in assessing whether a physician’s behavior was “within the SOC.” Second, there is an evidence-based medical literature that evaluates whether alternative methods and procedures are part of the SOC. Third, professional, medical, and surgical societies have evoked the concept of SOC to set ethical guidelines for how their members should behave when testifying as expert witnesses. Ideally, these three approaches should agree. Here, we review key legal cases and relevant evidence-based medical articles, and them explore the implications for professional societies seeking to set guidelines for their members testifying as expert witnesses.

## LEGAL DEFINITIONS OF SOC:A REVIEW OF CASE LAW AND RELATED LITERATURE

The SOC in medicine and surgery has been variously defined in both British and U.S. case law. Here, we summarize landmark decisions.

### Case of *Bolam v Friern Hospital Management Committee (1957)*

The case of *Bolam v Friern Hospital Management Committee* (FHMC) involved a plaintiff who underwent electroconvulsive therapy for mental illness without receiving a muscle relaxant.<sup>[2]</sup> The patient argued the doctor failed to prescribe a muscle relaxant drug, resulting in the patient sustaining a serious fracture. The House of Lords found in favor of the defendant physician; they stated: “...he is not guilty of negligence if he has acted in accordance with a practice accepted as proper by a responsible body of medical men skilled in that particular art....”<sup>[2]</sup> This judgment, labeled the “Bolam test,” established a standard of reasonable care in negligence cases involving skilled professionals (e.g., doctors). That is, “If a doctor reaches the standard of a responsible body of medical opinion, he is not negligent.”<sup>[2]</sup>

### Comments on the Bolam test

In 1999, Hurwitz *et al.* evaluated the English National Health Service definition of the SOC based on *Bolam v FHMC* (1957).<sup>[11]</sup> They warned against adhering to clinical practice guidelines (i.e., a rigid single SOC) over the judgment of individual clinicians. They stated, “It would be wholly inappropriate for clinical guidelines to be used as a means of coercion of the individual clinician, by managers and senior professionals.”<sup>[11]</sup> They also concluded that multiple “schools of thought” should be presented by expert witnesses.

Further, in 2016, Strauss and Thomas criticized the Bolam test for its extension beyond its “intended limits,” allowing the “standard in law to be set subjectively by expert witnesses,” often ignoring plaintiffs’ arguments.<sup>[20]</sup> Specifically, Lord Scarman noted that with Bolam, “...the realm of diagnosis and treatment, negligence is not established by preferring one respectable body of professional opinion to another.”<sup>[20]</sup> Note, in particular, the arguments on behalf of the plaintiffs’ should not be ignored in favor of the SOC set “subjectively by expert witnesses” for the defense.

### 1975 Federal Rules of Evidence

In 1975, the US Congress adopted the 702 Federal Rules of Evidence that better defined the SOC for both sides in medicolegal suits.<sup>[8]</sup> This rule stipulated, in part, “If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.”<sup>[8]</sup> Three provisions were to be incorporated into expert testimony in court. First, testimony had to be evidence-based (e.g., based on scientific knowledge). Second, that knowledge “must assist the trier of fact in understanding the evidence or determining a fact in issue in the case.”<sup>[8]</sup> Third, the “rules expressly provided that the judge would make the threshold determination regarding whether certain scientific knowledge would indeed assist the trier of fact in the manner contemplated by Rule 702.”<sup>[8]</sup> Note, in particular, the need for evidenced-based opinion.

### *Daubert v Merrell Dow Pharmaceuticals, 509 U.S. 579, 589 (1993)*

This Daubert case involved two children; Jason Daubert and Eric Schuller, both of whom were born with serious birth defects.<sup>[7]</sup> The parents sued Merrell Dow Pharmaceuticals Inc., stipulating that the drug Bendectin had caused these defects. Merrell Dow moved for summary judgment, stipulating that there was insufficient scientific evidence to support the claim. Daubert and Schuller themselves submitted their own expert evidence that included the fact that certain “...methodologies had not yet gained acceptance within the general scientific community.”<sup>[7]</sup> The district court granted summary judgment for Merrell Dow. When Daubert and Schuller appealed to the Ninth Circuit, the summary judgment ruling was upheld. Upon review by the US Supreme Court, Justice Blackman later noted; “The inquiries of the District Court and the Court of Appeals focused almost exclusively on “general acceptance,” as gauged by publication and the decisions of other courts. Accordingly, the judgment of the Court of Appeals is vacated and the case is remanded for further proceedings consistent with this opinion.”<sup>[7]</sup> This case thus established the US Federal Daubert standard for “rules of evidence regarding the admissibility of expert

witnesses' testimony. A party may raise a Daubert motion, a special motion *in limine* raised before or during trial, to exclude the presentation of unqualified evidence to the jury." In short, you cannot submit testimony that is not evidence-based.

As Strauss and Thomas pointed out, the Daubert case required that expert testimony must meet two requirements: (1) evidence must constitute scientific knowledge, and (2) the evidence must be relevant to the case.<sup>[20]</sup> In particular, they stated that, "This includes whether the theory or technique has been tested as scientifically valid, whether the idea has been subjected to scientific peer review or published in scientific journals, whether the theory or technique is generally accepted as valid by the relevant scientific community, and whether standards have been circulated to govern the operation of the technique and the known or potential rate of error involved in the technique."<sup>[20]</sup> Again, we note the inclusion of evidence-based criteria, that in this case is defined as "subjected to scientific peer review or published in scientific journals."

### **Bolitho v City and Hackney Health Authority, 4 All Er 771 (1997)**

In 2003, Samanta and Samanta noted a shift from the traditional Bolam test to a test based upon the *Bolitho v City and Hackney Health Authority* case.<sup>[18]</sup> The House of Lords in this case criticized the Bolam principle as too reliant on defense experts and advocated expanding the SOC to include plaintiffs' alternative SOC opinions; "the standard proclaimed must be justified on a logical basis, and must have considered the risks and benefits of competing options."<sup>[3,18]</sup> In short, with Bolitho, the court would more aggressively evaluate medical evidence from both sides in medicolegal proceedings and would more carefully consider the testimony for the plaintiff.

### **Montgomery v Lanarkshire Health Board (2015)**

*Montgomery v Lanarkshire Health Board* (2015 UK) altered the *Bolam test* by emphasizing the "general duty" physicians have to clearly disclose risks of procedures/operations (e.g. providing informed consent) to patients.<sup>[5]</sup> Here, the plaintiff (Montgomery) stipulated the physicians failed to inform her of the risks of a vaginal delivery that included shoulder dystocia that could potentially result in a hypoxic injury, and resultant cerebral palsy. Here, the physicians stated these risks were small, and, therefore, had not recommended a caesarean section. Montgomery sued stating had she been aware of these risks, she would have opted for a caesarean section. The Court of Session ruled that the physician was not negligent based on the Bolam test, and that there was no causation as the patient would not have agreed to a caesarean. The Supreme Court of the United Kingdom (2015) overruled the House of Lord's case (e.g., *Sidaway v Board of Governors of the*

*Bethlem Royal Hospital*), and reassessed the physicians' obligations to a patient undergoing medical treatment. Here, the Supreme Court "affirmed the requirement of 'informed choice' or 'informed consent' for patients undergoing treatment, and that physicians are obligated to appropriately disclose potential risks/complications."<sup>[5]</sup> Again, this is another clear repudiation of the Bolam test.

### **Summary of Legal Precedent re: SOC**

The historical trend is clear. The Bolam test is paternalistic, e.g. the "doctors know best." The SOC was defined as "reasonable practice supported by a responsible body of similar professionals." The Supreme Court in the Daubert case emphasized that experts' testimony had to be evidence-based. Bolitho challenged Bolam, emphasizing the need to hear alternative opinions from witnesses for the plaintiff; "the standard (of care) proclaimed must be justified on a logical basis and must have considered the risks and benefits of competing options." Thus, consideration of SOC arguments now had to include a more balanced input from both the defense and plaintiffs' experts, moving away from long-standing paternalism in favor of greater reliance on evidence-based medicine. Furthermore, bias in favor of "all knowing" defendant physicians had to be challenged as patients were increasingly granted the right to make their own "intelligent" decisions based on a greater preponderance of evidence.

## **SOC AND EVIDENCE-BASED MEDICINE**

Using evidence-based medicine, several studies concluded that there are multiple definitions of the SOC.<sup>[4,6,10,12,14-17,19]</sup> Brenner *et al.* criticized the term SOC as an "inaccurate measure of medical negligence because it is premised on the faulty notion of conformity to norms."<sup>[4]</sup> Alternatively, they proposed; (1) eliminating the term SOC, (2) revising court instructions to jurors, and (3) providing some consensus regarding orthopedic principles of negligence. The key point for our discussion is that the term SOC "...is premised on the faulty notion of conformity to norms." Just because many, or even most physicians do something, does not make it the best option, especially when an individual patient's circumstances are taken into consideration.

### **SOC as applied to Oncology and Medicine**

In 2016, Strauss and Thomas looked at 70 abstracts from the American Society of Clinical Oncology Annual Meeting.<sup>[20]</sup> They defined SOC as "the caution that a reasonable person in similar circumstances would exercise in providing care to a patient."<sup>[20]</sup> They continued: "(The) physician has a duty to exercise the degree of care expected of a minimally competent physician in the same specialty and under the same circumstances." Based on their analysis of the National Institutes of Health Consensus Development Program,

they concluded better assessments were aired when “more objective experts” were involved.<sup>[20]</sup> Indeed, there were multiple SOC relating to medical/therapeutic management strategies substantiated by multiple rather than single studies. They concluded that to avoid bias and self-interest in the future, broader opinions regarding different SOC should be included: “This further prevents investigations or treatment being declared standard of care based on single studies, often not representing the best or highest level of evidence.”<sup>[20]</sup>

### SOC in Dentistry

In dentistry, Jenson *et al.* in 2014 evaluated and compared the medical vs. ethical definitions of the SOC.<sup>[12]</sup> The medicolegal SOC was the “...standard of care (*that*) refers to the set of practices that are accepted as appropriate based on the body of common case law decisions.”<sup>[12]</sup> However, ethical SOC was defined by the; “conscientious application of up-to-date knowledge, competent skill, and reasoned judgment in the best interest of the patient, honoring the autonomy of the patient.”<sup>[12]</sup> In short, a decision that is in the best interest of a particular patient should not be determined by what the majority of doctors are doing.

### SOC in Electronic Fetal Monitoring

Spector-Bagdady *et al.* in 2017 evaluated what was in the best interest of the patient, and simultaneously the “state of the art” SOC for electronic fetal monitoring.<sup>[19]</sup> Their criticism was; “...tort liability is adjudicated based on what most clinicians are doing, not the scientific basis of whether they should be doing it in the first place.”<sup>[19]</sup> Ultimately, they concluded there was no one SOC regarding electronic fetal monitoring, but rather multiple “opinions” and “practices,” which typically led to unnecessary monitoring for patients with routine/healthy pregnancies. In short, the SOC catered to medicolegal concerns rather than to what is in the patient’s best interest.

### SOC in Neurosurgery

In neurosurgery, there are multiple SOC defining the appropriate timing of surgery for acute Cauda Equina Syndrome (CES).<sup>[9,21]</sup> For example, Germon and Ahuja focused on when the SOC requires performing a lumbar MR and subsequent surgery to address an acute CES.<sup>[9]</sup> They specifically weighed the risks/benefits of immediate (early hours of the AM) vs. delayed (e.g., waiting for the next day) surgery, by taking into account the trauma literature which underscores the increased risks/complications of performing major surgery at night. Subsequently, Todd and Dickson (2016) determined the major criteria for performing immediate CES surgery (e.g., whether day or night); the presence of a large central disk herniation with loss of sphincter function warranted immediate surgery, whereas for patients with less severe neurological deficits, surgery

could be scheduled the next day.<sup>[21]</sup> Here, there were multiple expert opinions regarding the optimal SOC for managing CES, offered by caring and competent physicians, and no one opinion was clearly “superior” to the other. Rather, the risk/complications, pros, and cons of different treatment options were being carefully weighed by different experts/neurosurgical professionals.

There also appears to be no single SOC for where spinal cord injury (SCI) patients should be treated.<sup>[13]</sup> In 2016, Maharaj *et al.* asked if the SOC for managing acute SCIs required specialty centers (e.g. specialized trauma/rehab facility) vs. non-subspecialty units (e.g. surgical intensive care units [SICU]).<sup>[13]</sup> They concluded that there was only low-quality evidence supporting admission to SCI vs. SICU (e.g. no direct/sufficient correlation with different complication rates, or reduced LOS), and better quality studies were needed in the future.

The SOC for managing lumbar stenosis/degenerative spondylolisthesis (SDS) has largely focused on instrumented lumbar fusions. However, Abdu *et al.* (2018) in the recent Spine Patient Outcomes Research Trial (SPORT) study documented comparable outcomes for noninstrumented posterolateral, instrumented posterolateral, and 360° fusions (e.g., TLIF [transforaminal lumbar interbody fusions] and PLIF [posterior lumbar interbody fusions]).<sup>[1]</sup> Their study involved 13 centers and compared the 8-year outcomes for patients with lumbar SDS treated nonsurgically vs. those undergoing decompressions with noninstrumented posterolateral fusions, instrumented posterolateral fusions, or 360° instrumented fusions. Patients participated in either the randomized controlled trial (RCT: at 8 years 69% retention) or observational cohort study (OBS: at 8 years 57% retention). They concluded patients with SDS treated nonsurgically had poorer outcomes compared to those managed surgically. Nevertheless, results were the same for patients undergoing any of the three types of lumbar fusion; in short, noninstrumented posterolateral, instrumented posterolateral, and 360° fusions (TLIF/PLIF) had similar outcomes.<sup>[1]</sup>

Outcomes of different spine operations now require valid evidence-based data obtained through randomized controlled trials (RCTs) to document their safety and efficacy. As documented by Abdu *et al.* (2018) in their RCT, no individual neurosurgeon or neurosurgical society can claim any longer that one “fusion” technique is superior to another or is THE SOC. Hence, the SOC is no longer the purview of self-interest or bias, but is rather determined by data.

### IMPLICATIONS FOR PROFESSIONAL MEDICAL SOCIETIES

According to Strauss and Thomas, there are major shortcomings in the definitions of the SOC in different subspecialty societies.<sup>[20]</sup> These included; “self-awarded

either by a group of like-minded individuals or by a specialist society or organization and is a term which can be abused with the intention of providing impact and authenticity to a point of view. At worst it could be considered to be self-promoting.”<sup>[20]</sup> Further, the National Institutes of Health Consensus Development Program found; “Most other scientific and medical conferences rely on content experts to make recommendations; however, this raises the possibility of potential conflicts of interest given the expert’s financial and career ties to the topic.” Finally, they recommended that the multiple SOC can be defined and applied based on RCTs or meta-analyses to avoid following treatments/procedural protocols, considered to be the SOC, but without sufficient supporting evidence.

What are the implications when professional societies set SOC guidelines for their members testifying as expert witnesses? First, guidelines should emphasize that the SOC be evidence-based. Second, it should be explicitly acknowledged that there are multiple SOC and that the appropriate SOC may depend upon the circumstances of an individual patient. Third, they should avoid the appearance of self-interest and place the best interests of the patients first and foremost.

### American Association of Neurological Surgeons (AANS)

As an example of a surgical society that I am most familiar with, let us examine the “Expert Witness Rules and Codes of Ethics” of the American Association of Neurological Surgeons (AANS). These rules do not clearly define what the AANS means by SOC nor whether the AANS thinks the SOC varies based upon the requirements of an individual patient. Further, the rules do not preclude their Professional Conduct Committee (PCC) from taking a narrow interpretation dangerously close to the Bolam test. For example, consider Expert Opinion Rule A.4. “The neurosurgical expert witness shall recognize and correctly represent the full standard of neurosurgical care and shall with reasonable accuracy state whether a particular action was clearly within, outside of, or close to the margins of the standard of neurosurgical care.” The rules do not clearly state, as recommended, that there is not just one SOC, and that the SOC may depend upon the circumstances of a particular patient. Additionally, the rules are not even explicit about the need for evidence-based definitions of the multiple SOC in question. Further, the failure to explore these multiple SOC raises a major concern regarding bias at best, and self-interest at worst.

### CONCLUSION

Recent legal decisions suggest that testimony should be based upon scientific evidence. The scientific evidence indicates that there is often more than one SOC. Thus, any subspecialty society, including the AANS, that ignores

evidence-based medicine and the existence of multiple SOC, risks the appearance of fostering self-interest at the expense of patient care.

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### Disclaimer

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