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## RESEARCH PAPER

# The US Public Health Service "treating tobacco use and dependence clinical practice guidelines" as a legal standard of care

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**Background:** The important factors in evaluating the role of clinical practice guidelines (CPGs) in medical malpractice litigation have been discussed for several years, but have focused on broad policy implications rather than on a concrete example of how an actual guideline might be evaluated. There are four items that need to be considered in negligence torts: legal duty, a breach of that duty, causal relationship between breach and injury, and damages.

**Objective:** To identify the arguments related to legal duty.

**Results:** The Treating Tobacco Use and Dependence (revised 2000) CPG, sponsored by the US Public Health Service, recommends effective and inexpensive treatments for nicotine addiction, the largest preventable cause of death in the US, and can be used as an example to focus on important considerations about the appropriateness of CPGs in the judicial system. Furthermore, the failure of many doctors and hospitals to deal with tobacco use and dependence raises the question of whether this failure could be considered malpractice, given the Public Health Service guideline's straightforward recommendations, their efficacy in preventing serious disease and cost-effectiveness.

**Conclusion:** Although each case of medical malpractice depends on a multitude of factors unique to individual cases, a court could have sufficient basis to find that the failure to adequately treat the main cause of preventable disease and death in the US qualifies as a violation of the legal duty that doctors and hospitals owe to patients habituated to tobacco use and dependence.

The use of clinical practice guidelines (CPGs)—sets of suggestions reflecting informed opinion on how to treat illnesses or conditions generally derived from scientific studies comparing the effectiveness of various clinical approaches<sup>1-2</sup>—as evidence to support expert testimony in medical malpractice litigation or as legal standards of care approved by the court has been discussed for several years.<sup>3-11</sup> These discussions have focused on broad policy implications, such as simplifying medical malpractice trials, eliminating expert witness bias or reducing doctors' practice of defensive medicine, rather than giving concrete examples of how actual guidelines might be evaluated by courts.

Despite the strong evidence that a doctor's intervention is an effective form of smoking cessation treatment,<sup>12-14</sup> in 2003, only 63.6% of US smokers who had a routine check-up that year were advised by a doctor to quit smoking.<sup>15</sup> Furthermore, although treatment of nicotine addiction is often considered to be "prevention", there is growing evidence that it should be considered to be "treatment", as smoking cessation as a treatment is as effective or more effective than other treatments recommended for heart failure.<sup>16-20</sup> This failure of many doctors and hospitals to deal with tobacco use and dependence despite the availability of effective treatment raises the question of whether this failure could be considered malpractice. An important element of answering this question requires an analysis of a clinician's duty to adequately treat a patient who smokes.

## MEDICAL MALPRACTICE AND THE STANDARD OF CARE

Cases of medical malpractice are generally brought under the theory of a negligent tort (a private or civil wrong or injury). As in all negligence torts, a plaintiff claiming medical malpractice must show: (1) a legal duty owed to the plaintiff

by the defendant; (2) a breach of that duty; (3) a causal relationship between the breach of duty and the incurred injury; and (4) damages.<sup>21</sup> The distinguishing element between common negligence and medical malpractice torts is the determination of the standard of care. In cases not involving professional malpractice, the standard of care is "that degree of care which a reasonably prudent person should exercise in same or similar circumstances."<sup>21</sup> In cases of malpractice, the standard of care is a measure of professional competence. It should be noted that although the general public often thinks of a doctor's "legal duty of care" as synonymous with "malpractice" this is not the case. Identifying one's legal duty, the specific element considered by this paper, is only one element in establishing a finding of malpractice. In medical malpractice, the duty of care is generally formulated as that degree of reasonable care and skill expected of members of the medical profession under the circumstances in the same or similar communities.<sup>22</sup> The normal practices or customs of the medical profession in similar circumstances are often used as evidence to establish the appropriate standard of care by showing what other doctors have previously done. However, evidence of professional custom is not dispositive, and some courts have found that following a custom may itself be found to be negligent.<sup>23</sup> The Supreme Court of Washington concluded as such in the often cited 1974 case *Helling v Carey*, ruling that doctors may be guilty of negligence even though he or she adheres to the common practices in the field, if reasonable prudence requires a higher degree of care.<sup>24-25</sup> This principle was succinctly expressed by the US Supreme Court in the 1903 case, *Texas and Pacific Railway Co v Behymer*<sup>26</sup>:

**Abbreviations:** CPG, clinical practice guidelines; PHS, Public Health Services

“What is usually done may be evidence of what ought to be done, but what ought to be done is fixed by a standard of reasonable prudence, whether it usually is complied with or not.”<sup>26</sup> Although the reasonableness standard applied in *Helling* is rarely used in comparison to the more common medical custom standard, other more recent cases have recognised a reasonableness standard when a medical custom standard is “unreasonably deficient by not incorporating readily available practices and procedures substantially more protective.”<sup>27</sup> Thus, guidelines such as the Public Health Service (PHS) tobacco treatment CPG can be used either as evidence of reasonably prudent treatment that is actually practised by medical professionals, or to show what constitutes reasonably prudent treatment regardless of the actual practice of medical professionals.

## CURRENT USE OF CPGs IN MEDICAL MALPRACTICE LITIGATION

Although most discussion surrounding CPGs and medical malpractice litigation deals with potential policy changes that could result if courts recognised them as a presumed standard of care, CPGs already have a major role in traditional malpractice litigation. In the ordinary course of a medical malpractice case, the appropriate standard of care is determined through adversarial expert witnesses hired by opposing parties who present testimony on what doctors usually do or typically think in such cases on the basis of their accumulated professional experience, knowledge and training.<sup>28</sup> In this traditional method of determining a standard of care, CPGs can be introduced as evidence by an expert witness to support his or her opinions, although juries can reject such evidence.<sup>29</sup> Use of CPGs as evidence to support expert witness testimony has become increasingly important, with research showing that attorneys across the US viewed CPGs as a growing factor in medical malpractice cases during the 1990s.<sup>30 31</sup>

As CPGs are hearsay (out-of-court statements offered to prove the truth of the matter asserted), they are inadmissible unless the party introducing them shows that they qualify as an exception to the hearsay rule. The most common hearsay exception used for CPGs is the “learned treatise” rule,<sup>4</sup> which, under the Federal Rules of Evidence (Fed R Evid 803(18)), is:

To the extent called to the attention of an expert witness upon cross-examination or relied upon by the expert witness in direct examination, statements contained in published treatises, periodicals, or pamphlets on a subject of history, medicine, or other science or art, established as a reliable authority by the testimony or admission of the witness or by other expert testimony or by judicial notice. If admitted, the statements may be read into evidence but may not be received as exhibits.

Establishing a CPG as a learned treatise of “reliable authority” requires a showing that the “body which created the guidelines is a well-respected medical authority and that the process through which the guidelines were developed and updated was sound.”<sup>4</sup>

In applying the “reliable authority” standard to the PHS CPG for Treating Tobacco Use and Dependence, there is little difficulty in concluding that it should be found by a court to be a learned treatise of reliable authority. The PHS CPG<sup>14</sup> (an updated version of the 1996 Agency for Health Care Policy and Research Smoking Cessation Clinical Practice Guideline<sup>32</sup>) was sponsored by a consortium of seven federal government and non-profit organisations: the Agency for Healthcare Research and Quality, Centers for Disease Control

and Prevention, National Cancer Institute, National Heart, Lung, and Blood Institute, National Institute on Drug Abuse, Robert Wood Johnson Foundation and University of Wisconsin Medical School’s Center for Tobacco Research and Intervention.<sup>14</sup> A panel of 30 representatives from these organisations identified effective, experimentally validated, tobacco dependence treatments and practices. A draft of the guidelines was peer-reviewed before publication, and the comments of 70 external reviewers were incorporated in the final document.<sup>14</sup> It would be difficult to find more well-respected medical authorities than those that sponsored the PHS CPG or find fault in its review process.

Once a CPG is recognised by a court as a learned treatise, an expert witness could use it to show that a purported standard of care was reasonably prudent, which should be bolstered by additional evidence showing that the recommendations were actually used by doctors and hospitals. For example, an expert witness testifying to the proper treatment for smokers in Northern California hospitals could point to the PHS CPG recommendations as the basis for the tobacco dependence programme implemented by hospitals of Kaiser Permanente Northern California (consisting of 17 medical centres and additional medical offices<sup>33</sup>), to show that the PHS recommendations were both recognised by respected national medical authorities and actually used by doctors and hospitals in the community. Similarly, expert witnesses testifying to standards in national hospital systems might point to the Veterans Health Administration system (consisting of 158 hospitals nationwide), which provides a Smoking and Tobacco Use Cessation Program<sup>34</sup> that implements the PHS CPG.<sup>14</sup>

## PROPOSALS OF CPGs AS A LEGAL STANDARD OF CARE

Although CPGs can already be introduced in trials of medical malpractice to support expert witness testimony, there have been proposals to give CPGs the status of a rebuttable presumptive standard in certain cases of alleged medical negligence through “judicial notice”, rather than simply allowing CPGs as “a tool for expert witnesses”, which a jury is not obligated to accept.<sup>23</sup> In the judicial notice CPG model, a judge (with the help of a court-retained medical expert) in a particular case would identify a CPG and the field to which it applies, and recognise it as a presumed standard of care, thus relieving the plaintiff of the burden of establishing the doctor’s duty.<sup>4 29 35</sup> Other proposals have called for the use of binding CPG standards of care as evidentiary tools to be used only as affirmative defenses by doctors or through contractual agreements between patients and health plans agreeing to a certain set of practice guidelines that would then apply to any forthcoming claims of malpractice.<sup>4</sup> These various proposals have identified factors that should be considered in determining which CPGs are appropriate for legal standards of care.<sup>4 23</sup> Among the factors regularly mentioned are the complexity of medicine considered by the CPG, whether the CPG is clear and specific enough to establish a standard of care usable by juries, which CPG to apply when there is more than one guideline for a specific condition or procedure, and the amount of scientific information supportive of the CPG. The Treating Tobacco Use and Dependence PHS CPG meets these standards.

## Complexity of medical treatment and specificity of the CPG

The complexity of some medical treatments and procedures is a regularly mentioned concern of using CPGs as legal standards of care, since highly complex areas of medicine “may require a more sophisticated set of guidelines with numerous options with different characteristics”, especially if

the condition is one in which "patients with the same general category of disease symptoms may be treated differently according to the gravity of the symptoms, the general health of the patient, the nature of any other medical problems ... and other characteristics."<sup>11</sup> As such CPGs present several options or give alternative recommendations based on sophisticated assessments, they could be difficult to apply as a legal standard.

Use of CPGs in areas of less complex medicine have been acknowledged as appropriate for judicial use: "practice parameters that address clinical problems that can be expressed as limited or simple set of guidelines may be readily used as a potential standard of care."<sup>11</sup> The Tobacco Use and Dependence Treatment CPG is a straightforward, and therefore suitable, legal standard of care. Among its recommendations, the PHS CPG states that "it is essential that clinicians and health care delivery systems ... institutionalize the consistent identification, documentation, and treatment of every tobacco user seen in a healthcare setting."<sup>14</sup> Or, as phrased by then-Assistant Secretary of Health, David Satcher, the guideline calls on clinicians and healthcare institutions to ask "Do you smoke?" and "Do you want to quit?", then follow the recommendations for tobacco treatment in the guideline.<sup>14</sup> The PHS recommendations are straightforward and widely applicable, stating that "every patient who uses tobacco should be offered at least one of these treatments."<sup>14</sup> These recommendations are divided into two categories comprised of easily applicable steps. For those willing to attempt quitting, there are five steps (table 1). As with all medical care, the patient can decline the offered treatment. For those unwilling to attempt quitting, it is recommended that clinicians use brief interventions that educate, reassure and motivate the patient to quit.<sup>14</sup> Although the CPG specifies that primary care clinicians should be particularly prepared to intervene with tobacco users, inquiries of tobacco use should be performed by all doctors. This practice could be implemented by expanding routinely checked vital signs (such as blood pressure, pulse, weight, etc) to include tobacco use.<sup>14</sup>

Specificity of recommendations is another important consideration in determining the appropriateness of a CPG-based standard of care. "To be effectively predictable and consistent, practice guidelines as prescriptive standards of care would need to be clear and specific enough to be usable

by juries in malpractice cases and by physicians in making defensible clinical decisions."<sup>8</sup> In examining whether a CPG covers a complex topic of medicine that necessitates sophisticated professional discretion or gives relatively straightforward recommendations that can be generally applied, the PHS tobacco treatment guideline provides a good example of a CPG in the second category that would be easily understood by a jury.

### Multiple CPGs covering the same treatment

Another important consideration when deciding whether to apply a CPG standard of care is which guideline to apply if several cover a specific condition or procedure,<sup>29</sup> although the problem of multiple CPGs is of less concern if their recommendations are in general agreement, as appropriate treatments would essentially be the same regardless of which CPG the court recognised. Considerations regarding multiple guidelines are relevant in tobacco treatment, because, as noted in the PHS CPG,<sup>14</sup> there are other guidelines on the topic.<sup>34-38</sup>

Although the existence of alternative guidelines is a valid concern in deciding whether a court should implement a CPG-based standard of care, the issue does not complicate the example of tobacco treatment. The various tobacco dependence treatment guidelines from other medical organisations either predate the 2000 revised PHS guideline and the original 1996 AHCPH guideline that it updates,<sup>36</sup> or give similar recommendations to it, at times even citing it as a source.<sup>34-37</sup> Furthermore, research comparing guidelines on reducing tobacco use shows that "there is uniform agreement on the effectiveness of the clinical interventions."<sup>38</sup> Consequently, there is little concern that multiple CPGs on tobacco use treatment would cause confusion for a judge deciding whether to adopt the PHS guideline, as it is regularly referred to by alternate guidelines, and "[t]here is broad agreement, based on strong evidence, about what constitutes effective treatment of tobacco use and dependence. Physicians should routinely identify patients' smoking status and readiness to quit, advise and assist smokers to quit, and offer pharmacotherapy to help them quit."<sup>39</sup>

### Amount of scientific information

The amount of scientific information available when a CPG was created is another important factor in determining its appropriateness as a legal standard of care. A lack of sufficient scientific information and clinical research would probably produce a range of recommendations, as well as differing opinions between different guidelines covering the same treatment or procedure. Similar to problems that arise in highly complex areas of medicine, clinicians would need to make sophisticated decisions regarding which recommendations to follow, or even which guideline (assuming they conflicted) to follow. Differences of opinions among doctors in disputed aspects of medicine would also require testimony from opposing expert witnesses before a jury could decide whether a doctor or hospital acted appropriately, creating a problematic process similar to that seen in traditional litigation on medical malpractice.

Although CPGs covering topics of medical uncertainty would be difficult to apply as presumed legal standards of care, there are some areas of treatment where sufficient information exists to make a CPG highly specific. "When there is sufficient scientific information, clinical experience, or another basis for certainty about how to handle a given problem, the practice parameter for the problem might be a highly specific set of prescriptive principles that should always be followed."<sup>11</sup>

The PHS CPG is based on a large amount of scientific information, resulting in highly specific recommendations.

**Table 1** The five major steps (the "5As") to intervention in the primary care setting for patients willing to quit

Ask: systematically identify all tobacco users at every visit	Implement an officewide system that ensures that, for EVERY patient at EVERY clinical visit, tobacco-use status is queried and documented
Advise: strongly urge all tobacco users to quit	In a clear, strong and personalised manner, urge every tobacco user to quit
Assess: determine willingness to make a quit attempt	Ask every tobacco user if he or she is willing to make a quit attempt at this time (eg, within the next 30 days)
Assist: help the patient in quitting	Help the patient with the quit plan; provide practical counselling (problem solving/skills training); provide intratreatment social support; help the patient obtain extratreatment support; recommend the use of approved pharmacotherapy, except in special circumstances; provide supplementary materials
Arrange: schedule follow-up contact	Schedule follow-up contact, either in person or via telephone, soon after the quit date. A second follow-up contact is recommended within the first month after the quit date

The tobacco treatment guideline explains that it “is based on two systematic reviews of the available scientific literature”, with the first review conducted for the creation of the original 1996 guideline and the second review conducted for the updated 2000 guideline,<sup>14</sup> resulting in the identification of 6000 papers on tobacco published between 1975 and 1999.<sup>14</sup> Thus, the PHS tobacco treatment CPG serves as an example of a guideline based on sufficient information resulting in specific recommendations that are widely agreed on.

### **COST OF TOBACCO USE AND DEPENDENCE CPG AS A LEGAL STANDARD OF CARE**

Implementing appropriate CPG-based legal standards of care has often been cited as a way to cut costs of both health services and medical malpractice litigation. Clear prescriptive standards would reduce the type of costly defensive medicine practised by doctors unsure of their legal duties and would simplify litigation by making cases more predictable, in turn reducing the number of frivolous claims.<sup>8–29</sup> The potential benefit of using a CPG as a presumed standard of care is thought to be highest when (like the PHS CPG) it gives straightforward recommendations that do not conflict with other guidelines in the practice.<sup>4–8</sup>

In addition to the financial benefits that would generally occur from using a CPG as a presumed legal standard of care, recommendations in the PHS CPG have specifically been found to be both clinically effective and cost effective.<sup>40</sup> The rate of smokers successfully quitting is increased markedly when PHS guideline recommendations are used,<sup>40</sup> and the cost of tobacco cessation treatment is low when compared with other widely accepted medical practices, such as treatment for hypertension or periodic mammograms.<sup>12–40–43</sup> Given the numerous illnesses prevented by treating tobacco dependence (including heart disease, several cancers, pulmonary disease and delayed healing<sup>40</sup>), the favourable cost effectiveness of cessation programmes<sup>12–41–43</sup> further strengthens the assertion that such treatments should be a universally recognised standard of care.

In terms of medical malpractice litigation, the cost-effectiveness analysis of a medical procedure or treatment is also a factor in deciding whether treatment is reasonably prudent. In *Helling v Carey*,<sup>24</sup> an ophthalmologist was found negligent for not testing a patient <40 years of age for glaucoma after he complained of eye discomfort, even though such tests were not routinely given by ophthalmologists under similar circumstances. In explaining its finding of negligence despite the defendant’s adherence to professional standards, the court pointed out that the glaucoma test was simple, inexpensive and harmless, and that the consequences of not testing resulted in irreversible blindness. The *Helling* ruling holds relevance to the discussion of relatively inexpensive tobacco cessation treatments that can prevent long-term, often irreversible, disease. It should also be noted that the smoking assessment recommendations in the PHS guidelines are probably even simpler than the glaucoma test at issue in *Helling*, and that the probability of the *Helling* plaintiff having glaucoma (1/25 000<sup>24</sup>) was much smaller than the probability of developing various health problems from smoking.

### **CONCLUSION**

The PHS Treating Tobacco Use and Dependence CPG forms a strong basis for a legal duty, whether it is used as a tool to support expert witness testimony in traditional litigation or as a judicially noticed presumptive standard of care under a litigation reform model. Given the PHS guideline’s straightforward recommendations, the broad agreement regarding the efficacy of its treatments, its cost effectiveness and the recognised ability of smoking cessation to prevent serious

### **What this paper adds**

- Despite well-established treatment protocols for smoking cessation and strong evidence of efficacy and cost-effectiveness, many doctors and hospitals still do not incorporate the treatment of nicotine dependence into their routine practices.
- The presence of a widely recognised clinical practice guideline in this area may provide a judicial standard of care that could be used in cases of malpractice brought against healthcare providers who do not treat patients who smoke.

disease, a doctor or hospital might be hard pressed to defend against a failure to properly treat tobacco use dependence. Evidence that smoking cessation as a treatment is as effective or more effective for patients with heart disease as other recommended treatments further reinforces the proposition that tobacco dependence treatment should be a widely recognised standard of care.<sup>16–20</sup> The importance of smoking cessation treatment is also reflected by the Joint Commission on Accreditation of Health Care Organizations<sup>44</sup> measures, which requires hospitals to provide smoking cessation counselling, albeit loosely defined, to patients diagnosed with acute myocardial infarction, congestive heart failure and community-acquired pneumonia,<sup>45–46</sup> and Medicare’s decision to provide coverage for beneficiaries diagnosed with illnesses caused or complicated by tobacco use (such as heart disease, lung disease, weak bones, blood clots and cataracts) or who are taking drugs for being affected by tobacco use.<sup>47–48</sup>

The growing number of healthcare institutions providing smoking cessation treatment based on PHS recommendations further solidifies tobacco use treatment as a reasonably prudent standard of care that should be provided to patients who smoke. A 1999 survey showed that 60% of responding Health Maintenance Organizations in California used the PHS guideline in the design and development of treatment for smokers,<sup>49</sup> and a 2002 survey showed that most of the healthcare plans widely accepted the PHS recommendation for coverage of repeated, intensive tobacco dependence counselling and pharmacotherapy, and used internally developed guidelines that required providers to carry out the “5 As” in accordance with the PHS guideline.<sup>50</sup>

The PHS guideline recommendations are simple, inexpensive tobacco-use treatments sponsored by government agencies and national medical organisations that are practised consistently and effectively. Each case of medical malpractice depends on a multitude of factors unique to individual cases (including proving all the elements of a tort: duty, breach, causation and damages). The increasing scientific evidence supporting the benefits of tobacco-cessation treatment and the growing number of doctors and hospitals providing such treatment go a long way in strengthening the PHS CPG recommendations as a widely recognised medical standard of care, and thus establishing a legal duty on doctors to provide a certain level of treatment. A court could have sufficient basis to find that the failure to adequately treat the main cause of preventable disease and death in the US qualifies as a violation of the legal duty that doctors and hospitals owe to patients habituated to tobacco use and dependence.

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