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# Becoming the Standard: How Innovative Procedures Benefitting Public Health Are Incorporated into the Standard of Care

*Jalayne J. Arias*

Physicians' resistance to implementing innovative medical procedures due to a perceived risk of liability can adversely affect the public's health. This resistance prevents public access to procedures that could better treat communicable or chronic diseases. Innovative procedures, for the purpose of this article, are medical practices that require physicians to modify current clinical approaches to treating or diagnosing a patient's condition and incorporate: (1) newly developed tests, treatments, drugs or devices (e.g., genetic screening to identify drug sensitivities to reduce adverse drug reactions<sup>1</sup>); or (2) novel methods not commonly used by a majority of physicians (e.g., partner delivered therapy to treat an intimate partner for a communicable disease<sup>2</sup> or advanced prescription of naloxone to patients prone to an opioid overdose<sup>3</sup>). Innovative procedures do not include treatments provided during clinical research or those beyond a physician's scope of practice.

A physician's choice to use any medical procedure is informed, in part, by a perceived risk of liability. Liability risks increase where a procedure is not currently within the standard of care, including most innovative procedures. However, a physician may mitigate liability risks by demonstrating that the procedure benefits the patient, without an increased risk of harm, as compared to the current standard clinical practice. It is less clear whether a physician can similarly mitigate liability risks by demonstrating that the procedure benefits public health, where the patient is neither at a greater risk of harm nor likely to experience signifi-

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*Jalayne J. Arias, J.D., is a fellow/faculty associate with the Public Health Law and Policy Program at the Sandra Day O'Connor College of Law, Arizona State University; and Deputy Director, Public Health Law Network - Western Region, Arizona State University.*

cant benefits. Despite the impact of perceived liability, public health is not currently a factor in determining the standard of care underlying physician liability. Therefore, innovative procedures benefiting the public's health may be underused in clinical practices.

This article addresses the legal standard of care underlying medical malpractice liability and its connection to the adoption of innovative procedures to improve public health. First, the article demonstrates that physicians' liability concerns can impede adoption of innovative procedures into practice, adversely affecting public health. Next, the article reviews the process of determining physician liability through the standard of care and how innovative procedures are incorporated into the standard. The final section addresses public health benefits as a method of mitigating heightened liability risks associated with innovative procedures.

## **Perception of Liability as a Barrier to Innovative Procedures**

Perceived liability risks can impede adoption of innovative procedures regardless of the actual risk of liability associated with a procedure.<sup>4</sup> While physicians consider other factors during clinical decision-making, the potential risk of liability is pivotal. According to a study published by the *Journal of the American Medical Association (JAMA)* in 2005, 93% of responding physicians admitted to using defensive medicine practices.<sup>5</sup> Survey results published by HealthLeaders Media in 2010 reported 33% of its respondents cited fear of lawsuits as a major influence on decision-making when ordering tests or procedures.<sup>6</sup>

Defensive medicine practices manifest as assurance or avoidance behaviors among clinicians. Assurance behaviors contribute to the inefficient and overuse of

tests and treatments and are detrimental to public health outcomes (e.g., antibiotic resistance).<sup>7</sup> Similarly, avoidance behaviors result in a lack of patient access to beneficial medical procedures (e.g., a reduction in the number of high-risk obstetric patients accepted).<sup>8</sup> Avoidance behaviors include resistance to practices deemed risky, like innovative procedures.<sup>9</sup>

Liability risks associated with innovative procedures are generally higher because physicians lack experience with these procedures and may not know or understand their medical risks.<sup>10</sup> The legal standard of care, which is the foundation for determining medical malpractice liability, is a double-edged sword for implementing innovative procedures. The standard requires physicians to be knowledgeable of, and to use, advancements in medicine for patients' benefits.<sup>11</sup> However, failure to adhere to the standard of care can lead to successful liability claims when patients are injured or killed.<sup>12</sup> As a result, physicians are often hesitant to implement innovative procedures.

Physicians' natural reluctance may be compounded when innovative procedures benefit the public's health, while offering only minimal benefits to a patient. For example, in 2006 the Centers for Disease Control and Prevention endorsed and issued guidance on expedited partner therapy (EPT) for sexually transmitted diseases (specifically chlamydia and gonorrhea).<sup>13</sup> EPT allows physicians to provide treatment (in the form of prescription medication) to a patient for the patient's sexual partner, without first physically examining the partner. Despite evidence of its efficacy in preventing recurring and future infections, EPT has not been fully implemented even in states where it is expressly legally authorized. Physician and health care provider concerns related to liability have impeded implementation.<sup>14</sup> Similar barriers are apparent in physicians' resistance to provide advanced prescriptions for naloxone or to provide genetic screening for markers indicating a patient's likelihood of responding to a prescription drug.

### **Establishing Physician Liability through the Standard of Care**

A physician may be found liable for medical malpractice when a patient's injuries result from medical treatment that does not meet the legal standard of care. While the standard of care varies across the United States, a growing number of states use the "reasonable physician" standard, requiring physicians to provide the same level of care as a reasonable physician in the same specialty in similar circumstances. This standard differs from the traditional "custom of practice" stan-

dard, requiring physicians to act within the custom of the same or similar locality.<sup>15</sup>

Pursuant to a state's legal definition of the standard of care, physician liability is assessed based on the factual circumstances leading to the malpractice claim by a patient. Generally, a jury is asked to determine whether the physician's actions are within the standard of care. Expert testimony is introduced to provide guidance to jurors, or other fact finders, as to the complexities of medical practice and identify actions that would likely fulfill the standard.<sup>16</sup> Expert testimony regularly introduces evidence as to what a typical physician would do in a similar circumstance. To the extent they exceed the norm, innovative procedures may conflict with the prevailing standard of care identified by an expert. This conflict contributes to an increased risk of liability associated with implementing an innovative procedure.

Countervailing legal doctrines, however, may protect a physician's decision to implement innovative procedures, assuming they are properly administered. First, under the custom of practice standard, a procedure may be within the standard of care even though it is not the primary method of treatment in the locality. The "two schools of thought" doctrine, also known as the "respectable minority" rule, allows a physician to use discretion in choosing a course of treatment without liability, so long as the action complies with an accepted medical opinion.<sup>17</sup> An innovative procedure may be considered within the standard of care via this doctrine where a physician can demonstrate that the procedure qualifies as a "second school of thought." This could be accomplished with evidence of established medical opinion favoring the procedure (e.g., use of the procedure in a comparable community).

Second, the standard of care necessarily evolves with medical advancements. In some states the standard of care includes a duty to stay current on medical advancements.<sup>18</sup> In these states, the duty may serve as a factor in establishing that adoption of an innovative procedure was reasonable based on the circumstances. Third, under the "reasonable physician" standard, a physician may support adoption of an innovative procedure as reasonable, and mitigate liability risks, by receiving training, learning the potential medical risks of varied procedures, and obtaining proper advance informed consent from the patient.<sup>19</sup> Additionally, a physician's choice to implement an innovative procedure may be reasonable if he or she can justify the procedure as benefitting the patient, either because of lower costs or improvement of outcome, without an increased risk of harm.<sup>20</sup>

## Connecting Innovative Procedures and Public Health with the Standard of Care

Whether a physician can use an innovative procedure that primarily benefits the public's health (instead of the patient) is questionable. Incorporating public health benefits, similar to patient benefits, as a factor in establishing the standard of care could reduce liability risks and physicians' concerns and improve the rate of physicians adopting innovative procedures. A number of procedures, like advanced distribution of naloxone to prevent opioid overdose, offers primary benefits to patients, while also addressing a public health concern. Conversely, some procedures may have public health benefits that are greater than the benefit to the patient. For example, while a patient may benefit from EPT because she may avoid reinfection with a sexually transmitted disease from her partner, the primary benefit is the reduction of the spread of the disease stemming from the partner's treatment (particularly where the partner and patient are not in a monogamous relationship). Similar public health benefits may exist where a physician administers the Human Papillomavirus (HPV) vaccine series in a male patient, who may contract or carry HPV without ever developing related diseases, to reduce the rate of infections from the virus.<sup>21</sup>

Current case law does not indicate that a public health benefit has been previously considered as a factor in establishing the standard of care. However, public health concerns have a history of being incorporated in physician liability through the duty owed to third parties largely established by *Tarasoff*.<sup>22</sup> This duty has been extended to protect third parties from contracting communicable diseases.<sup>23</sup> However, the duty is limited to third parties (1) directly injured by the physician's patient; and (2) at a foreseeable risk due to a familial or intimate relationship with the patient. This duty does not require physicians to protect the general public from the potential spread of communicable diseases. Yet, it could provide a foundation for a physician's decision to use innovative procedures to benefit the public's health.

Concerning EPT, a physician could demonstrate that implementing the practice fulfills a duty to a third party, the known sexual partner, who is at a foreseeable risk. However, the physician can meet the same duty by instructing the patient to refrain from unsafe sexual behaviors to prevent spreading the sexually transmitted disease. Additionally, the extension of the duty owed to third parties does little to support procedures which have public health implications but do not offer protection to third parties against communicable diseases or similar risks (e.g., genetic screening for drug sensitivities to reduce the rate of adverse drug

reactions). In these cases, a physician is left to rely on the "respectable minority" doctrine and the duty to stay informed of medical advancements as mitigating factors within the standard of care to support his or her use of innovative procedures. However, these factors may not be sufficient.

The inclusion of public health as a factor in establishing the standard of care could address the impact of physicians' resistance to implementing innovative procedures. Liability concerns could be narrowed if physicians had the opportunity to provide evidence of a procedure's public health implications (e.g., the reduction of the spread of a communicable disease). This inclusion would not fully protect (or shield) physicians from liability, because a jury must still determine whether a physician was reasonable or acted within the custom of practice. However, the impact of clinical practices on public health would be more fully incorporated into the legal system which provides for physician liability.<sup>24</sup> This may encourage physicians to similarly incorporate public health benefits in decision-making regarding innovative procedures.

## Conclusion

The development and use of innovative procedures offers potential benefits to improve public health. These benefits, and implementation of innovative procedures, are limited by physicians' liability and prevalent understandings of what constitutes the legal standard of care. Established legal doctrines may mitigate liability risks associated with innovative procedures. However, without the consideration of public health as a factor of the standard of care to curb physicians' perception of liability risks, innovative procedures may not be fully implemented to benefit communal health despite their known efficacy. Additional scholarship may more fully review the potential methods of successfully incorporating public health as a factor in the standard of care to encourage physicians to use innovative procedures that are effective in improving public health.

## Acknowledgement

The author would like to acknowledge Andrew Sorensen, Legal Researcher, Public Health Law and Policy Program, Arizona State University; and Andrew White, Arizona State University, for their guidance and review.

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  7. See Coleman, *supra* note 4.
  8. See Studdert et al., *supra* note 5 (one-third of specialists reported avoiding certain procedures or clinical interventions because of liability concerns).
  9. The American Congress of Obstetricians and Gynecologists, *ACOG Releases 2009 Medical Liability Survey*, Press Release, September 11, 2009, available at <[http://www.acog.org/from\\_home/publications/press\\_releases/nr09-11-09.cfm](http://www.acog.org/from_home/publications/press_releases/nr09-11-09.cfm)> (last visited December 15, 2010).
  10. M. D. Greenberg, “Medical Malpractice and New Devices: Defining an Elusive Standard of Care,” *Health Matrix: Journal of Law-Medicine* 19 (2009): 423-444.
  11. See Pennsylvania Suggested Standard Civil Jury Instructions, *Medical Malpractice – Standard of Care*, 11.01 (2010).
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  17. See Peters, *supra* note 12.
  18. See Pennsylvania Suggested Standard Civil Jury Instructions, *supra* note 12 (“a physician must also keep informed of the contemporary developments in the medical profession”).
  19. See Greenberg, *supra* note 10 (These measures are beneficial in “reasonable physician” and “custom of practice” jurisdictions to reduce the risk of potential harm to a patient).
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  22. *Tarasoff v. The Regents of the Univ. of Cal.*, 551 P.2d 334 (Cal. 1976) (The physician was held liable for the death of a third party caused by his patient when the physician should have known the third party was at risk).
  23. *DiMarco v. Lynch Homes-Chester County, Inc.*, 583 A.2d 422, 562 (Pa. 1990); *Troxel v. A.I. Dupont Institute*, 675 A.2d 314, 319 (Pa. Super. Ct. 1996).
  24. A similar proposal for the consideration of community health in the standard of care has been suggested in the emergency setting. See J. G. Hodge and B. Courtney, “Assessing the Legal Standard of Care in Public Health Emergencies,” *JAMA* 303, no. 4 (2010): 361-362.