The Tuskegee Syphilis Study, IRBs, and the Standard of Care

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"There are four aspects that a plaintiff must prove in order to be successful in a malpractice claim against a physician. These are often called the 4 "D's": Duty to care, Dereliction of duty, Damages (i.e., injuries), and a Direct Cause between the dereliction and the damages."

There are four aspects that a plaintiff must prove in order to be successful in a malpractice claim against a physician. These are often called the 4 "D's": **D**uty to care, **D**ereliction of duty, **D**amages (i.e., injuries), and a **D**irect Cause between the dereliction and the damages. Dereliction of duty is generally claimed by a plaintiff expert witness who opines that the accused physician did not meet the "standard of care" while providing services to the newborn. The standard of care is usually defined as the care a reasonably prudent physician would provide in the same or similar circumstances. In a subspecialty such as neonatology, the standard of care is often a national standard and not primarily influenced by the local environment in which the care occurred. Moreover, most jurisdictions will only allow a physician in the same subspecialty to opine on the standard of care. Thus, a pediatrician could not give standard of care testimony for or against a neonatologist or obstetrician.

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However, the interpretation of the standard of care is often quite subjective. There is no high or low standard of care, and often many different methods to treat the same patient can all meet the standard of care. Expert witnesses for both plaintiff and defense will cite guidelines published by the American Academy of Pediatrics (AAP) to support their opinions or refer to standard textbooks in the field. However, it should be noted that the AAP puts a disclaimer in front of every published guideline and clinical report that states:

> *"The guidance in this report does not indicate an exclusive course of treatment or serve as a standard of medical care. Variations taking into account individual circumstances may be appropriate."*

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Standard textbooks are often 2-4 years out of date when published, so they must be viewed in that context. An expert will often cite "Up-to-Date" or published studies which support his/her opinion. But "Up-to-Date" is not subject to the same peer review as manuscripts submitted to peer-reviewed journals, and one study does not define a standard of care. Often subsequent studies will not substantiate the findings in the initial study for a variety of reasons. Moreover, the development of Institutional Review Boards (IRBs) after the exposure of the Tuskegee "Study of Untreated Syphilis in the Negro Male" (1) brings another aspect to the standard of care debate.

The Tuskegee Study, conducted by the U.S. Public Health Service between 1932 and 1972, recruited 399 poor and mostly illiterate African American men with known syphilis into a longitudinal and observational study on the progress of the disease. The subjects were promised free medical care, burial insurance, and other incentives, but most could not read and did not understand the consent forms they signed. When penicillin became the standard treatment for syphilis in 1947, the study was continued, and the surviving subjects were not offered antibiotic therapy. In the 1960s, a story was leaked to the press, which led to a national outcry, congressional hearings, and eventually reparations to the surviving subjects and their families. The Congressional hearings which reviewed this unethical study led to the National Research Act of 1974. A commission was created to develop regulations governing human experimentation. The resulting Belmont Report (2) established standards for human experimentation, including

the creation of Institutional Review Boards (IRBs) at each organization doing human research with special consideration for subjects who were poor, illiterate, pregnant, children, and prisoners. The report stated that human experimentation with treatment and control groups must not be approved unless there was true scientific equipoise (i.e., substantial uncertainty) regarding whether the treatment or control groups would benefit most from the study. Thus, it would be against Federal law to conduct a prospective randomized controlled trial of a particular treatment if a standard of care existed regarding the use or non-use of that therapy.

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Although this principle seems to be helpful for the defense of malpractice actions, such rules may prevent medical advancement when the standard of care is not based on good science. Examples of this effect in neonatology are studies that had difficulty getting US IRB approval due to a mostly historical standard of care and care practices not based on sound science. The practice of intubating all newborns born through meconium was first promulgated in the 1970s, and for his study to challenge this practice, Dr. Thomas Wiswell had to recruit many institutions outside the U.S. to allow vigorous newborns not to be intubated and compare their outcomes to the standard intubation approach. (3) A similar story regarding the use of 100% oxygen to resuscitate depressed newly born infants resulted in the initial studies being performed in Norway, Spain, and India. Because of the findings of these prospective studies, the use of room air to start resuscitation and non-intubation of vigorous meconium-stained newborns have subsequently become routine practice in the U.S. Thus, for the scientific advancement of care for newborns, historical practices which become the standard of care and bad science are worse than no science at all.

In a recent malpractice suit against a neonatologist, the plaintiff claimed that the failure to close a patent ductus arteriosus (PDA) in a 27-week gestation, 900-gram premature male led to periventricular leukomalacia (PVL). Plaintiff's expert neonatologist and cardiologist stated that the "standard of care" was to close a "clinically significant" PDA, first pharmacologically, and if that failed, to refer the patient to the local Level 4 hospital for transcatheter or surgical closure. The defense expert neonatologist argued that numerous IRB-approved studies were ongoing at the time the care was provided regarding the treatment of PDA, including all types of treatment and observation only. Thus, there could not be a standard of care since IRB-approved studies were still trying to determine the best course of management. The defense also presented numerous other potential etiologies for the development of PVL. The case was settled prior to trial. Nonetheless, the principle remains intact. There cannot be a recognized standard of care if human IRB-approved clinical trials are ongoing in which there are treatment and control arms (indicating that an IRB considered there was scientific equipoise regarding the outcome).

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Disclosures: *There are no reported disclosures*

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