

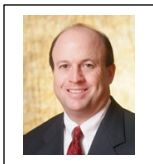
MEDICAL DEFENSE AND HEALTH LAW

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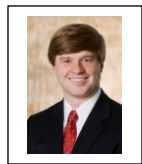
Despite significant advancements in the area of detecting bacterial contamination in platelet transfusions, it still remains the most prevalent transfusion-associated infectious risk. As a result of this technological shortcoming, blood banks are at risk of being named in negligence actions where undiscovered contaminated platelets are transfused. However, the fact that certain bacterial contaminations can exist at levels below a detectable limit should provide blood banks with a viable defense to such claims.

Undetectable Bacteria in Platelet Transfusions: A Viable Defense for Blood Banks



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Despite significant advancements in the area of detecting bacterial contamination in platelet transfusions, it still remains the most prevalent transfusion-associated infectious risk. As a result of this technological shortcoming, blood banks are at risk of being named in negligence actions where undiscovered contaminated platelets are transfused. However, the fact that certain bacterial contaminations can exist at levels below a detectable limit should provide blood banks with a viable defense to such claims.

Transmission of viral infections, such as hepatitis B, hepatitis C, and human immunodeficiency virus, through blood transfusions has dramatically decreased over the past quarter century as a result of donor testing at the time of collection.¹ Bacterial contamination, on the other hand, has proven more difficult to address and remains the most prevalent transfusion-associated infectious risk.²

Bacteria are most often introduced into donated blood from skin flora at the time of phlebotomy; or, less frequently, through asymptomatic donor bacteremia or during processing of the units.³ Transfusion associated bacterial sepsis is caused more frequently in platelets as opposed to red blood cells because they are stored at room temperature under constant agitation to preserve the platelet's function and survival.^{4,5} Consequently, such conditions

provide an excellent environment for bacterial growth and allow ongoing proliferation throughout the platelet's storage period.^{6,7} Although platelets are best used as soon as possible after collection, and required to be used within five days of collection, recruitment of donors and necessary delays associated with testing for the presence of infectious agents, as well as delays in distribution and use, result in many platelets being used when they are four or five days old.⁸

The challenges accompanying the testing of platelet components for bacterial contamination is significantly different from that presented by testing for viral contamination. The risk associated with viral contamination remains constant throughout the lifespan of the component.⁹ There is a low residual risk corresponding to when the component is infectious except at low levels, which cannot be detected by current testing models, and is referred to as the "window period."¹⁰ In contrast, the number of bacteria in a platelet component changes with time due to growth within the platelet component pack, so the probability of a test detecting the contamination changes over the lifespan of the platelet component.¹¹

¹ Palavecino et al., *Bacterial contamination of platelets*, *Transfusion and Apheresis Science*, Vol. 42, Feb. 2010, p. 72.

² *Id.*

³ *Id.*

⁴ Jacobs et al., *Detection of bacterial contamination in prestorage culture-negative apheresis platelets on day of issue with the Pan Genera Detection test*, *TRANSFUSION*, Vol. 51, Dec. 2011, p. 2574.

⁵ The risk of transfusion-transmitted bacterial infections is approximately 1 in 25,000 in platelet transfusions and 1 in 250,000 in red blood cell

transfusions. Rood et al., *Reducing the Risk of Transfusion-Transmitted Bacterial Infections in Platelet Concentrates: Current Status and Developments*, *Labmedicine*, Vol. 39, Sept. 2008, p. 553.

⁶ Jacobs et al., *supra* note 3, p. 2574.

⁷ Rood et al., *supra* note 4, p. 553.

⁸ Jacobs et al., *Relationship between Bacterial Load, Species Virulence, and Transfusion Reaction with Transfusion of Bacterially Contaminated Platelets*, *Clinical Infectious Diseases*, Vol. 46, Mar. 2008, p. 1214.

⁹ Pearce S., Rowe G.P. & Field S.P., *Screening of platelets for bacterial contamination at the Welsh Blood Service*, *Transfusion Medicine*, Vol. 21, Aug. 2010, p. 25.

¹⁰ *Id.*

¹¹ *Id.*

As a result of these challenges, no currently available screening technology is perfectly sensitive and adequately rapid for determining the bacterial contamination status of platelets at the time of transfusion.¹² The main factor associated with failure of culture to detect bacterial contamination near the time of collection is sampling error, which can occur if bacteria are not at a sufficient concentration in platelet units to be consistently present in the culture sample.¹³ Stated differently, the amount of bacteria in some platelet components can be so low at the time of testing, that they cannot be detected. As an unfortunate result, in rare instances cases have occurred in which undiscovered contaminated platelet components have been transfused to a recipient. A common theory of liability in such cases is the pursuit of a negligence action against both the blood bank and the hospital responsible for the transfusion, but the fact that certain bacterial contaminations are at undetectable levels at the time of testing should provide a defense for those defendants.

Generally, to prevail in a negligence case against a blood bank, a plaintiff will be required to establish that the blood bank owed him or her a duty, that the duty was breached, and that as a result of that breach, the plaintiff suffered damages.¹⁴ The primary point of contention in proving these cases is the breach of duty element, which requires identification of the standard of care applicable to the blood bank. Whether a

blood bank is negligent is not measured by a broad, reasonable person standard; instead, a professional standard of care is applied.¹⁵ Typically, this standard is one of “knowledge, skill and care ordinarily possessed and employed by members of the profession in good standing.”¹⁶ In addition, courts often find that the national medical community is considered when establishing the relevant standard of care.¹⁷

The regulations promulgated by various government agencies, including the Food and Drug Administration (FDA), and the standards published by the American Association of Blood Banks (AABB) are considered guides as to the standard of care to which blood banks must adhere when testing blood.¹⁸ The law is clear that when a blood bank follows all required regulations in connection with screening a donor and testing the donor's blood, then the blood bank is entitled to summary judgment on claims that it breached the standard of care in that regard. For example, in *Smythe v. American Red Cross Blood Services Northeastern New York Region*,¹⁹ the court granted the defendant blood center's motion for summary judgment because the undisputed evidence established that the blood center followed all of the promulgated FDA and AABB regulations and performed all the required testing on the blood prior to the transfusion at issue. Similarly, in *Shelby v. St. Luke's Episcopal*

¹² Yomtovian et al., *Evolution of surveillance methods for detection of bacterial contamination of platelets in a university hospital, 1991 through 2004*, *Transfusion*, Vol. 46, May 2006, p. 728.

¹³ Jacobs et al., *Detection of bacterial contamination in prestorage culture-negative apheresis platelets on day of issue with the Pan Genera Detection test*, *TRANSFUSION*, Vol. 51, Dec. 2011, p. 2574.

¹⁴ 57A Am Jur 2d Negligence § 5 (2012).

¹⁵ Pieplow, K., *Aids, Blood Banks and the Courts: The Legal Response to Transfusion-Acquired Disease*, 38 S.D. L. Rev. 609, 629-30. (1993).

¹⁶ *Id.* at 614 (quoting W. Page Keeton et al., *Prosser and Keeton on the Law of Torts* 32, at 187 (5th ed. 1984)).

¹⁷ *Id.* at 634. See *Hawkins v. Carroll*, 676 So. 2d 338, 340 (Ala. Civ. App. 1996).

¹⁸ See *Giorno v. Temple Univ. Hosp.*, 875 F. Supp. 267, 269 (E.D. Pa. 1995); *Barton*, 829 F. Supp. at 1297; *Smythe*, 797 F. Supp. at 153.

¹⁹ 797 F. Supp. 147 (N.D.N.Y. 1992).

Hospital,²⁰ the court granted summary judgment for the defendant blood center on plaintiff's claim of negligent donor screening because the blood center "complied with all federal regulations, all AABB standards, and its own internal procedures"²¹

Per AABB Standard 5.1.5.1, AABB-accredited blood centers are required to employ a method to limit and detect bacterial contamination in all platelet components. To meet this standard, blood centers must use any detection method that has been cleared by the FDA for quality control testing or any other method shown to provide sensitivity equivalent to FDA-approved methods.²² However, even following this procedure, it is possible that blood contaminated with bacteria can ultimately be transfused given the current limitation in technology, which is unable to detect bacteria at low levels. For instance, two commonly utilized, FDA-approved commercial methods applicable for screening—BacT/ALERT and Pall eBDS—have been shown not to detect all contaminated units in clinical use.²³ Moreover, neither blood centers nor hospitals that receive contaminated blood are required to re-test the blood after an initial test reads negative for any bacterial contamination.

Although current advances in medical technology are inching closer towards eliminating all false negatives in the bacterial testing of platelet units, the hard truth is that there exists no way to perfectly detect the presence of bacteria in donated blood. Even if a blood bank were to follow the standards set forth by the AABB, the possibility still

exists that contaminated blood can be transfused. For blood banks, this fact presents a viable defense to negligence claims. As long as a blood bank follows the protocols and procedures in properly testing the donated blood units for bacteria, they are likely to escape liability for the failure to discover undetectable levels of bacteria. There is, unfortunately, no way to completely eliminate the risk of bacterial contamination at this time, and holding blood banks liable for failure to detect bacteria in all circumstances would be requiring them to do the impossible.

²⁰ 1988 WL 28996, *3 (S.D. Tex.).

²¹ See also, *McKee v. Miles Lab, Inc.*, 675 F. Supp. 1060 (E.D. Kent. 1987) (summary judgment granted because the blood center's testing procedures complied with the prevailing practice in the industry).

²² AABB Standard 5.1.5.1.1.

²³ Yomtovian et al., *supra* note 12, p. 728.

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