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Blood Transfusions and Serum Hepatitis

Richard W. Dunn*

ON MARCH 22, 1966, *Look Magazine*¹ published an article titled *Dirt, Infection, Error and Negligence: The Hidden Death Threats in Our Hospitals*. The effect of this article upon the public can be likened, but of course to a lesser degree, to the recent pronouncements of Mr. Ralph Nader² on the failure of the automobile industry to manufacture safe automobiles. The *Look* article referred to comments by a Dr. Leon Sussman, blood specialist at Manhattan's Beth Israel Hospital. Dr. Sussman felt that preventable "human failure" in the hospital accounts for at least 50% of blood transfusion accidents.

Blood and Statistics

Injuries and deaths caused by blood transfusions number in thousands. In 1961³ it was statistically noted that about three and a half million transfusions were administered annually in the United States. Of those, about three thousand resulted in death. Of course, with the population growth over the past six years the number of transfusions could exceed four million per year. The 1965 statistics on the number of deaths resulting from negligence in transfusing blood are not known to this writer. That figure is, however, not significant, since statistics cannot accurately reflect the number of injuries short of death, which were the result of negligence before, during, or after a blood transfusion.

For example, in 1954 Dr. A. S. Weiner estimated that Homologous Serum Hepatitis results in one out of five hundred transfusions.⁴ The death rate from Homologous Serum Hepatitis is statistically not stabilized since death is more prevalent with donees over the age of 40, and many times other complications are involved.

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¹ *Look Magazine*, March 22, 1966, p. 27.

² Nader, *Unsafe at Any Speed* (1965).

³ 11 Am. Jur. Proof of Facts, p. 331 (1961).

⁴ Weiner, Prevention of Accident in Blood Transfusion, 156 J. A. M. A. 1301 (Dec. 4, 1954).

Medical References

Some definitive articles are available which succinctly state the problems and complications involved in the medical analysis and transfusion of blood.⁵ Similarly, general blood transfusion problems and the law applicable to each problem area (sensitization—mistyping—mislabeling—emergency situations—transmission of disease—risks—theories on liability) are represented in many works.⁶

One of the most troublesome of the transfusion-transmitted diseases is homologous serum hepatitis (HSH). The crux of the problem is that the virus of this disease cannot as yet be detected in whole blood. Sole reliance in detecting serum hepatitis must be placed on the reliability of the donor's history. In the case of blood plasma, as distinguished from whole blood, the virus of this disease can be destroyed by storage.⁷

The transfusion of whole blood always is a potentially serious procedure. The "technique" includes pre-transfusion tests and checks to insure that a safe transfusion will be properly administered.⁸

H. S. H. is a form of hepatitis "transmitted by injections of contaminated blood or blood derivative or merely by a needle, lancet or other instrument contaminated and not sterilized."⁹ It should be noted that H. S. H. can be transmitted *through* or *from* the needle. The *only* way H. S. H. can be transmitted is by parenteral routes (through a muscle or vein, or any route other than the alimentary tract).¹⁰ The incubation period of this disease varies among individuals from 6 weeks to 6 months.¹¹ So in those cases where the person receiving contaminated blood contracts the disease following a long incubation period, the trail

⁵ Hemolytic Transfusion Reactions—Medico legal Aspects, 2 J. of Foreign Med. 78 (1955).

⁶ Thoreh, Surgical Errors and Safeguards (J. B. Lippincott Co., 1960); Thomas, Blood Transfusion Liability, 10 Clev-Mar. L. Rev. 469 (1961); notes, 37 Notre Dame Law. 565 (1962); Liability For Blood Transfusion Injuries, 42 Minn. L. Rev. 640 (1958); For tortious aspects of blood donations and blood transfusion, see: 59 A. L. R. 2d 768-787; 5 A. L. R. 2d, Later Case Service, Vol. 5.

⁷ Bowen, Malpractice Actions Involving Blood Transfusions, 9 Defense L. J., 45 (1961).

⁸ Kramer, C., Medical Malpractice, 86 (Practicing Law Inst., rev. ed. 1965).

⁹ Stedman's Medical Dictionary (Unabridged Lawyers Ed., 1961).

¹⁰ 7 Traumatic Medicine and Surgery for the Attorney, 272-273 (1959).

¹¹ *Ibid.*

tends to grow very cold, and with each passing day important evidentiary matter disappears. In many cases the patient does not relate his hepatitis problem to past transfusion exposure.

Cases and Holdings

A case of negligence may be proved, but at too late a date to effect a recovery from the right defendant. In *Hidy v. State*,¹² the plaintiff died of H. S. H., after a transfusion of unirradiated war surplus pooled blood plasma. Plaintiff's suit against the State alleged negligence in that the State failed to irradiate the plasma, as had been made compulsory by The National Health Council. In finding for the defendant, the Court conceded that a warning had been issued concerning pooled plasma and the dangers extant in using it without irradiation, but said there was no negligence by the State in its failure to stop distribution and call in the unused plasma. The Court also indicated that even if the State had been negligent, there was the *independent intervening agency of the physician*, presumably competent, who directed the administration of the plasma to the plaintiff. The plaintiff brought a timely action but against the wrong defendant.

It was held in *Fisher v. Wilmington Gen'l. Hospital*¹³ that there was no duty to warn a patient of the risk of contracting H. S. H. as a result of a transfusion. The Court's rationale was grounded upon its classification of the known risk as one not imposing upon defendant a duty to warn of the possibility of contracting H. S. H. This is one area where the treating physician is "damned if he does and damned if he doesn't." To warn a patient of such a danger might affect the patient psychologically and diminish the chance of success.

Blood and Sales Acts

An H. S. H. victim in Tennessee sued the manufacturer of blood plasma, alleging that the plasma was adulterated and filthy and in violation of the Tennessee Food, Drug and Cosmetic Act.¹⁴ In finding for the defendant, the Court said the

¹² 207 Misc. 207, 137 N. Y. S. 2d 334, affg. 2 App. Div. 644, 151 N. Y. S. 2d 621 (1956).

¹³ 1 Storey (51 Del.) 554, 149 A. 2d 749 (1959).

¹⁴ *Merck and Co. Inc. v. Kidd*, 242 F. 2d 592 (D. C. Tenn. 1957).

plasma was not a filthy substance because impurity could not be discerned microscopically. Since the virus could not be seen, could not be described, and its presence could not be detected, it was not a "filthy substance" within the intent of the statute. When and if research develops techniques of physically detecting H. S. H., and upon proof of the blood being adulterated, the Tennessee Courts would appear to be placed in the position of having to apply their Food, Drug and Cosmetic Act to blood.

In another case the plaintiff based his action for injury from a blood transfusion on breach of implied warranty, and relied on the State Sales Act regulating the sale of deleterious substances not fit for human consumption. The Court said that a blood transfusion was essentially a service and not a sale, and that the Sales Act had no application notwithstanding the fact that the plaintiff was charged \$60¹⁵ for the transfusion. Other jurisdictions¹⁶ have similarly held that the monies paid for blood and blood transfusions are to be construed as service and not a sale.

Specifically, some states have enacted statutes which provide that:

. . . procurement, processing and distribution of blood, plasma, blood products and blood derivatives for the purpose of injecting or transfusing the same or any of them into the human body shall be construed to be and is declared to be, for all purposes whatsoever, the rendition of a service by each and every person, firm or corporation participating therein, and shall not be construed to be, and is declared not to be a sale of such whole blood, plasma, blood products or blood derivatives, for any purpose or purposes whatsoever.¹⁷

The dissenting opinion in *Perlmutter v. Beth David Hospital*¹⁸ is based upon the existence of an implied warranty that drugs are reasonably fit for human consumption, with no distinction being made between drugs and blood, at least as a matter of pleading. The three dissenting judges felt that the

¹⁵ *Perlmutter v. Beth David Hospital*, 308 N. Y. 100, 123 N.E. 2d 792 (1954).

¹⁶ *Koenig v. Milwaukee Blood Center, Inc.*, 23 Wis. 2d 324, 127 N.W. 2d 50 (1964); *Sloncher v. St. Joseph's Hospital*, 233 F. Supp. 105 (D. Colo. 1964); *Whitehurst v. American National Red Cross*, 402 P. 2d 584 (Ariz. App. 1965).

¹⁷ Calif. Health & Safety Code Sec. 1623 (1955); Ariz. Rev. Stats. § 36-1151, added, Laws 1964, Ch. 83 § 1.

¹⁸ *Supra* note 15.

plaintiff should have had the opportunity to present evidence that there was a sale, rather than having her case dismissed for insufficiency in stating a cause of action for implied breach of warranty.

In the vaccine cases,¹⁹ negligence has successfully sounded in implied warranty. Unfortunately the courts have maintained an extraordinary and illogical position in transfusion cases by holding that wholesome blood is no different from blood containing the H. S. H. virus. This reasoning would be acceptable only if the courts said that the intended purpose of a blood transfusion is to propagate H. S. H. among transfusees.

Another point worthy of consideration is that the blood bank or blood distributing agency which sells the blood to the hospital actually does no more than supply blood for a price, yet the sale of that blood is construed as a service. This is true even though the seller or distributor has absolutely no contact with the ultimate donee.²⁰ Why should the blood bank or distributing agency not be held accountable?

When and if a trend starts, whereby plaintiffs begin to obtain awards for damages sustained as a result of negligence in administration of H. S. H. blood transfusions, the impact on medicine may be as dramatic as was the decision in *Mac Pherson v. Buick Motor Co.*²¹ as to manufacturers.

Check List as to Facts

1. Who is the negligent party? (The doctor, the hospital or a specific hospital employee, the supplier, an individual or possibly the donor). Consider joinder statutes, so that the negligent party is not freed by the statute of limitations.
2. What was the transfusion procedure? (both for the hospital, and hospitals in the community, for the doctors, nurses and labs). If there was a deviation from normal procedure, what was the reason for that deviation?
3. Did the donee or donee's family sign a pre-operative or pre-transfusion release? (Was the release fully explained, was there an emergency situation, was the risk involved abnormally great?)

¹⁹ *Gottsdanker v. Cutter Laboratories*, 182 Cal. App. 2d 602, 6 Cal. Rptr. 320 (1960).

²⁰ *Balkowitsch v. Minneapolis War Memorial Blood Bank, Inc.*, 270 Minn. 151, 132 N.W. 2d 805 (1965); *Goely v. J. K. & Susie L. Wadley Research Institute and Blood Bank*, 350 S.W. 2d 573 (Tex. App. 1961).

²¹ 217 N. Y. 382, 111 N.E. 1050 (1916).

4. Was the alleged negligence the proximate cause of the donee's death or injury? (Did the donee have a hepatitis history—would the heart patient have died regardless of the transfusion—was there some intervening cause?)

5. Can the history of the blood transfused be traced from the time of the donation to the time of the transfusion? (Proper storage—contamination—labeling).

6. Is the H. S. H. merely an element of damages caused by some other event? (Injury caused by negligent third party, which injury necessitated a transfusion?)

7. Was gamma globulin considered in light of the age and condition of the patient? Should it have been considered? It has been reliably demonstrated that, in approximately three quarters of transfused persons, gamma globulin from pools of human blood plasma prepared by the ethanol fractionation method has prevented serum hepatitis, . . . In view of . . . developments and the vital importance of the problem in persons over 40 years of age, the routine administration of gamma globulin after blood transfusion should be given serious consideration. . . .²²

8. Was the transfusion necessary? (How much blood was lost? 500-700 cc. loss of whole blood should be able to be comfortably tolerated by an adequately prepared patient.)²³

9. What post and pre-operative and post and pre-transfusion procedures were employed? (Were these procedures in keeping with accepted standards?)

Massachusetts General Hospital, in the attempt to tighten its controls involving blood transfusions, adheres to an inflexible rule in its blood bank; two different technicians use two different blood-matching techniques on each blood sample. Also, to reduce chances of transmitting infection, needles are discarded after one use, as are syringes and plastic bags.

10. Did the injury or death concur in time with the injury or death of other patients who received transfusions? (Either in the same hospital or the same community.)

11. Is the situation such that *res ipsa loquitur* may be invoked? (Was the injury-producing instrumentality within the exclusive control of the defendant?)

By exhausting the possibilities contained in the above listed items, counsel should be well on his way towards establishing a firm foundation for his case.

²² 185 A. M. A. Magazine (No. 13), p. 1037, Sept. 28, 1963.

²³ "Whole Blood Transfusions in Surgical Patients," 39 Magazine of Surgical Clinics of North America (1) (Feb. 1959).

Proof

Once the foundation has been laid, one must consider the evidence required and the need to prove each and every allegation. If a question of a physician's malpractice is the point in issue, one must give thought to obtaining a medical expert who will testify against the defendant. One may also, but to a lesser degree, be confronted with the same problem in establishing the negligence of the hospitals' employees, whereby the negligent act complained of is a deviation from accepted medical standards in the care and treatment of a patient. A nurse's judgment, an incorrect technician's analysis, or perhaps something as minute as hospital house-keeping procedures, are possible considerations.

Other problem areas also arise which at first blush may seem insurmountable. In a case where it was alleged that an unsterile needle was the producing cause of injury, the court held that plaintiff must show by competent evidence, that the *needle* used was, at the time of its use, infected or contaminated, and that such needle was a proximate cause of the injuries. It is not enough that the evidence shows that Mrs. Brown's arm became infected and that she has sustained injuries and damage.²⁴ Plaintiff must prove at what time the infection was introduced into her arm.

Consider, then, the tremendous burden in proving that a needle, tubing, bottle, syringes or any other implement was unsterile or contaminated with H. S. H. This evidentiary problem arises in areas where the medical expert is not required to substantiate the alleged negligence, but where negligence may be shown otherwise.

As to infections resulting from blood transfusions, it was held in *Cox v. Saskatoon*²⁵ that since there was medical testimony indicating that the infectious source could have been external as well as internal, regardless of that which may have caused the disease, the plaintiff had not proved his case.

One must specifically isolate the medical issues of the client's injury, and determine what expert medical testimony can be based on the medical facts to resolve those issues. This can be done only by consulting with medical experts. If after this

²⁴ *Brown v. Shannon West Texas Memorial Hospital*, 222 S.W. 2d 248 (Tex. Civ. App. 1949).

²⁵ 1 West Weekly R., 717, 2 D. L. R. 412 CA (1942).

consultation, it is determined that the medical issues cannot be resolved, one must consider the possibility of applying *res ipsa loquitur*, or in the alternative, allege a breach of implied warranty. Implied warranty is not well taken by the courts in transfusion cases, but this would appear to be the weak area upon which to concentrate.

Procedures employed in transfusions should be closely scrutinized, and although the trial does not begin in the operating room, it may well end there. Answers to the following questions must be secured:

1. Who the donor may have been, and what medical history, if any was taken? (Was there a standard application form for taking the donor's history in conformance with accepted and reasonable procedures? Is the donor or the person who took the blood available to testify?)

If possible, check with the donor personally to determine his history, what history was requested, and what were the physical circumstances surrounding the giving of the blood.

2. How was the blood stored? Where was it stored? Was it whole blood or plasma? Who had access to the storage area? What tests were made prior to storage? Who made those tests?

3. What route did the blood take from the donor to the donee? (Was there a delay in shipment, or any other circumstances which could have affected the blood while it was being transported, and are witnesses able to so testify available?)

4. Were laboratory tests made at the hospital upon the receipt of blood? Who made the tests? What were the qualifications of the testing person? Who was the authority in charge of the testing? What testing and labeling procedures were employed (Labeling, mis-matching?).

5. What were the transfusion techniques employed? Was there, due to unusual circumstances, a short term or even a one-time deviation from the normal technique usually employed?

6. Determine who were involved in the transfusion, and their qualifications.

7. Are the instruments used in the transfusion available? Can their ultimate disposition after the transfusion be determined?

8. Were there any verbal admissions against interest, as to what took place at the time of the transfusion? Is *res gestae* applicable? Were records kept and available?

9. Was there, from the time when the blood was first donated to the time when it was transfused, a violation of any regulation, ordinance, statute, or any other codes or standards of safety issued or sponsored by governmental bodies or voluntary associations providing safeguards for the taking, storage, labeling or the transfusion of whole blood or plasma?
10. Has every discovery tactic been employed to its fullest extent?

Conclusion

It is readily discernible from the foregoing that successful litigation of blood transfusion cases is most difficult. This is an area of the law which, because of its present unacceptable position, requires change. The umbrella of protection which the courts extend to cover the dissemination of deleterious blood and its classification as a service must be removed. This will only be achieved by constant litigation of well-prepared cases by competent men.