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Claims and compensation for complications resulting from blood transfusions in China from 1998 to 2013

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ABSTRACT

The purpose of this study was to find causes, outcomes, and trends in malpractice litigation involving blood transfusions in China. This study examines 108 claims resulting from transfusion-related complications over a period of 15 years. The primary outcomes associated with these claims included transfusion-transmitted infection (98 cases, 90.8%), transfusion reactions (nine cases, 8.3%), and failures to obtain informed consent (one case, 0.9%). The specialty of obstetrics and gynecology was more likely to be accepted in judgment. As the supreme status of law, Blood Donation Law plays an important role in the blood safety, which results in less HCV infection cases occurred after 1998. Though the 2002 and 2010's rules give opposite liability principle, the fault liability and no-fault liability, the statistics shows that rules do not have an effect on different liabilities in judicial practice. The current study concludes that the risk of serious adverse transfusion reactions may be significantly increased by unnecessary transfusions.

1. Introduction

Blood transfusion is an essential part of modern medicine. Transfusion errors are mistakes that occur in blood production or the clinical supply process and delivery of blood or blood components to the patient, and can lead to the difference between life and death [1]. A focus on the avoidance of transfusion-related error in transfusion practices could significantly reduce morbidity and mortality resulting from mistakes in blood transfusion.

Evidence can be found in published journals of residual risk of transfusion-transmitted infections in other countries [2–5], and in China [6], as well as documentation of near misses [1] and preventable errors [7]. Adverse events related to medical errors are common worldwide, but are largely unreported [8], and, more specifically, reporting on actual transfusion-related error events in China is deficient or lacking. However, these events represent a serious problem within transfusion medicine, potentially causing life-threatening consequences.

Transfusion medicine can serve as an example of lessons learned, with its interdisciplinary intricacies and danger of fatal outcomes [9]. This article reports the results obtained from a study carried out to investigate the causes and outcomes in adverse blood transfusion-related events through a review of transfusion error claims. This study could be helpful for risk management, to improve the quality of blood products and ensure patient safety.

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1.1. Background – legislation in China

The Ministry of Health has enacted a series of legal norms related to blood management, such as Regulations on Blood Stations and Blood Management (which has since been abolished). These regulations required that blood stations test the blood of donors and collect meet certain standards, and were the first regulations requiring the report of blood transfusion adverse reactions to the administrative department since 1993. In addition, the Blood Station Basic Standard and Donor Health Testing Standards of 1993 (also abolished, since that time) contained testing standards for hepatitis C virus (HCV), hepatitis B virus (HBV), human immunodeficiency virus (HIV) antibody, and syphilis. In order to guarantee the supply and safety of blood for clinical application, and protect the health of blood donors and users, the Standing Committee of the National People's Congress (NPC) enacted the Blood Donation Law of the People's Republic of China on October 1, 1998, which, for the first time, set out requirements for a non-paid system of blood donation. The Regulation on Clinical Application of Blood in Medical Institutions (Trial) (now abolished) regulated, for the first time, hospitals' obligation to inform patients and obtain signed transfusion agreements, in 1999. Supporting the Blood Donation Law, many other regulations were enforced to form an integrated blood regulation system since 1998.

Before 2002, there was no regulation on compensation for adverse events resulting from blood transfusions, leaving this to be addressed by civil law. Between 2002 and 2010, according to Article 33 of the Regulation on the Handling of Medical Accidents, hospitals were not responsible for non-fault transfusion errors. After 2010, according to the Article 59 of the Tort Law of China, this was classified as a special non-fault liability tort. If a patient suffered injury due to a defective transfusion, the patient may demand compensation from the blood provider or the medical institution.

2. Methods

2.1. Sample and data collection

This research was designed to be a retrospective study of claims, based on secondary data analyses. A list of malpractice litigation cases involving blood transfusions was retrieved from a computerized legal database that was admitted by the Supreme People's Court of China – Chinese Justice Legal Application Support System (CJLASS) database since 2003. A keyword search was run on "*pkulawclaims*" from September 28, 1998 to June 18, 2013, to identify all claims apparently relating to blood transfusion. First, the keyword "transfusion" was input into the medical malpractice disputes, with 338 results displayed in all 4558 medical malpractice cases. From these results, a total of 108 cases were then selected and confirmed as transfusion-related and available for analysis, complete with the entire contents of judgments.

2.2. Variables

Next, legal information and medical data were obtained from the 108 judgments, most of which contained cases filed for blood transfusion civil litigation in China. Legal information included the type of court, the duration of time from dispute to judgment, and judgment paid. Medical information was also analyzed from these judgments, and included the type of defendant and medical facility, specialties, blood transfusion volumes, transfusion outcomes, duration from transfusion to the time that complications were discovered, and compensation for damages.

2.3. Data analysis

Descriptive statistics included frequency distribution, scatter diagram and contingency table analysis. Chi-square analysis was used for comparison of groups in the cross tabulations. Significance level was set at $P < 0.05$. Data were analyzed by using the PASW statistics software packages, version 18.0.

The amounts discussed herein are estimated based on 1 US $ = 6.17RMB Yuan.

3. Results

3.1. Overview of judgments

Of the 108 total cases, 78 (72.2%) of the plaintiffs–patients' and their families' claims were accepted (Table 1). In the 78 accepted cases, 49 (62.8%) were judged by the Intermediate court or the High court. Thirty cases (27.8%) were rejected, because the defendants (the hospitals or blood centers) won in litigation.

The average duration from time of dispute to judgment was 42.6 months (1.8 years) for the accepted claims, and 22.7 months (0.9 years) for the rejected claims. Thirty claims took less than 1 year (27.8%) to discover injury after transfusion, 30 cases needed 1–10 years (27.8%), and 48 cases took 10–20 years (44.4%) to discover injury. The average payment for all these claims was RMB 4849 ($785).

Hospitals were the defendants in 76 of the cases, while blood centers were in only three cases. Both hospitals and blood centers were sued in the other 29 cases. In particular, 23 of 30 rejected cases (76.7%) involved hospitals only, a much higher number than for the accepted cases (53 cases, 67.9%).

Eighty-five cases accounted for the majority of the medical specialties (69.4%), involved in obstetrics and gynecology (37 cases), orthopedic surgery (21 cases), general surgery (nine cases), and hematology (eight cases). The other 33 cases involved 20 different medical specialties (30.6%). No significant differences were found among cases accepted or rejected. But the specialty of obstetrics and gynecology was more likely to be accepted in judgment, with significant differences noted in the categories of specialties ($P = 0.049$).

3.2. Outcomes and distributions

Claims were associated with three outcomes: transfusion-transmitted infection (98 cases, 90.8%); transfusion reaction (nine cases, or 8.3%); and failure to obtain informed consent (one case, or 0.9%) (Table 1). The transfusion-transmitted

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