

Criminal and Civil Responsibility of the Donor in a Case of Transmission of Malaria by a Blood Transfusion in a Nonendemic Country

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Keywords

Blood transfusion · Liability of donors · Malaria · Transmission

Abstract

Introduction: The blood donation process is strictly regulated by law. The process includes the necessity of a medical history taken to determine if a donor is suitable to donate, which shall guarantee both donor and recipient safety. Supplementary screening for a limited number of infections is performed by antibody (HIV, HCV, syphilis) or antigen (HBV) tests or NAT (HIV, HCV, HBV). **Case Presentation:** With regard to a possible infection due to (sexual) risk behavior or foreign travel, blood donation facilities are predominantly dependent on information provided by the donor. This is especially true for malaria in nonendemic areas such as Europe. Transmission of malaria by a blood transfusion in a nonendemic country that led to fulminant septic shock and death of the patient happened. **Discussion:** From a legal perspective, the donor thus assumes a high level of responsibility with regard to the accuracy and completeness of the information provided on the donor questionnaire. Incorrect information may, as in this Austrian case reported, result in civil or criminal responsibility of the donor.

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Introduction

Malaria transmission through blood transfusion is an accidental but preventable cause of malaria infection and is increasingly becoming a matter of concern for blood transfusion services, not only in endemic but also in non-endemic countries. The Commission directive 2004/33/EC regarding certain technical requirements for blood and blood components (which complements the “Blood Directive” 2002/98/EC) provides eligibility criteria for donors of whole blood and blood components in annex III. For persons with a risk of having contracted malaria, a temporary deferral of the donation is provided for (Annex III., 2.2.1.). Different deferral periods are mentioned: persons who were born or lived in a malaria area, who were diagnosed with malaria, or who have a history of undiagnosed febrile illness during a visit or within 6 months after a visit to an endemic area are deferred as potential donors for 3 years. Asymptomatic visitors to endemic areas have a deferral period of 6 months after leaving the endemic area. These specifications were put into Austrian legislation by the “Blutspenderverordnung” (Regulation on Blood Donors; BSV) with the modification that the 3-year deferral was changed to a permanent deferral (§ 5 para. 1 lit t leg cit). Therefore, only asymptomatic visitors to endemic areas are eligible to donate blood in Austria after a 6-month deferral period (§ 6 para. 2 n. 18 BSV). No malaria-specific testing in order to reduce the deferral period or to release a potential blood donor is performed in Austria. Every donor has to fill out

a questionnaire before donating blood; the questionnaire includes a specific question regarding a stay in an endemic area within the last 6 months under the requirement of being asymptomatic all the time. Additionally, people being in endemic areas usually take drugs to prevent malaria. The donor has to specify this as well according to § 5 para. 1 lit p BSV. In general, the questionnaire asks the donor to report if any symptoms of disease appear within 14 days of donation. The questionnaire has to be signed by both the donor and the medical doctor (§ 9 para. 3 BSV). The donor has the responsibility to provide correct answers, especially in those cases where the questionnaire is the only safety precaution to prevent potential damage to recipients of blood products. It is an act of negligence if the donor makes incorrect answers in order to avoid deferral from the blood donation (see below). The questionnaire does not explicitly refer to the legal responsibility associated with any incorrect answering of the questions and the subsequent signature.

Despite these efforts of blood donation facilities to make blood transfusions as safe as possible, the risk of transmitting infections by transfusion of labile blood products still exists, [1]. Transfusion-transmitted plasmodial infections cause severe malaria infection that is frequently lethal [2]. In nonendemic countries, transfusion-transmitted plasmodial infection is a rare event [3]. Efforts by blood services to reduce the risk of transmitting malaria cannot fully mitigate it [4]. Accidental exposure can therefore still occur.

Coming back to the legal aspects, giving incorrect answers which result in physical harm for blood recipients can have serious legal consequences for the donor, their severity depending on the damage caused by the incorrect or incomplete answer. In this context, a distinction has to be made between criminal liability (which can lead to an indictment by a public prosecutor before a criminal court) and civil liability (which can result in the blood recipient or his/her health insurance suing for damages before a civil court).

From a criminal law perspective, a donor who donates blood infected with malaria can become liable for negligent bodily harm (§ 88 of the Austrian Criminal Code) if he or she, while not knowing about an infection, gave incorrect information about staying in an endemic area or about anti-malaria medication [5]. If the blood recipient becomes infected, this will count as bodily harm which is punishable by up to 3-month imprisonment or a fine of up to 180 daily rates (which are based on the income of the offender).

If the blood recipient dies due to an infection with malaria, the negligent donor can be held liable for the criminal offense of negligent causation of death (negligent manslaughter; § 80 para. 1 of the Austrian Criminal Code) which is punishable by up to a year imprisonment or 720

daily rates [6]. In both cases, the criminal liability derives from the negligent violation of the donor's obligation to completely and correctly answer the questionnaire. Donors are often not aware of the medical importance of the information requested and the potential legal liability resulting from a negligent response. While the negligent causation of bodily harm or death often results in a financial penalty or a suspended prison sentence only, such convictions will nevertheless regularly be entered into the criminal records of the donor, which might have negative consequences on the labor market (e.g., due to doubts concerning a person's reliability) or under foreign immigration regulations.

Furthermore, a donor infected with malaria who gives incomplete or incorrect information might in principle also be held criminally liable under § 179 Austrian Criminal Code for negligent endangerment of humans through communicable diseases (punishable by up to a year imprisonment or up to 720 daily rates). This criminal offense intends to sanction negligent behavior which can lead to the spreading of communicable diseases. However, while sanctions according to this offense can be pronounced in addition to those for negligent bodily harm or causation of death (with the maximum penalty capped according to the more severe sanction), § 179 Austrian Criminal Code is normally understood as requiring the endangerment of a larger number of persons [7]. It is doubtful whether a single donor can, due to the limited amount of blood donated, create such a risk. Still, the general risk of criminal prosecution of a negligent donor transmitting a communicable disease to a recipient due to incorrect or incomplete information given to medical personnel during the donation process should not be underestimated.

A negligent donor may not only face criminal prosecution, but also a civil liability as a tortfeasor toward the recipient if the incorrect or incomplete information given results in the transfusion of malaria-infected blood and, as a consequence, bodily harm or even death. Not only the recipient can act as a plaintiff: If treatment costs were borne by a (public) health insurer, the donor can be held liable by it. If the recipient died as a result of the blood donation, heirs and/or relatives may also sue for damages. As the negligent donor caused bodily harm, damages can be awarded in absence of a contractual relationship between the donor and the recipient. Damages will not only include costs of treatment, but, amongst others, also compensation for pain and suffering or lost income, or, in the case of heirs/relatives, subsistence damage, and, in case of gross negligence, grieving damage. Altogether, the extent of damages can be substantial, in particular, if it is not covered by a donor's liability insurance (which might in particular apply in a case of gross negligence). Possible criminal liability of the physi-

cians or strict product liability of the blood transfusion service according to the Austrian Product Liability Act (PHG) will not be discussed.

Case Presentation

We report a case of an 84-year-old woman, who was admitted for a hip joint endoprosthesis. Increased bleeding was noted during the operation. Due to postoperative anemia and hemodynamic instability the patient received in total 3 units of packed red blood cells. On day 13, the patient developed fever and antibiotics with piperacillin-tazobactam was started. In the following days, the patient suffered from diarrhea and deteriorated clinically, but did not show fever anymore. Three days later, he was admitted to the intensive care unit with a clinical picture of severe septic shock with circulatory failure and lactic acidosis. A blood smear was ordered and the technician detected a high concentration of plasmodia and a rapid test was positive for *Plasmodium falciparum*. The patient received artesunate (2.4 mg/kg i.v.) as soon as the medication was available. Despite all efforts, the patient deteriorated and needed ventilation and hemodynamic support; however, the patient died on the next day.

The patient had no travel history, therefore the suspicion arose that plasmodia were transmitted by the packed red blood cells. A look back process was initiated by the responsible blood transfusion service, including all three donors. One of the donors – with a history of multiple donations – had recently traveled for 1 month to a country where malaria is endemic and obviously contracted malaria without experiencing any symptoms. The donor does not stem from an endemic area being not tolerant to malaria. The blood donation was performed 2 weeks after return from the endemic area. When filling out the questionnaire, the donor did not mention a recent return from an area where malaria is endemic. Furthermore, the donor did not give any information on the intake of drugs for preventing malaria. Therefore, the donor was released to donate whole blood. The donor had general symptoms of illness and fever 1 week after donation. Contrary to the advice in the donor questionnaire to report such symptoms, the donor did not do so. At the same time as the blood transfusion took place (11 days after the donation), the donor himself was diagnosed with malaria in the hospital; however, no information was passed on to the blood transfusion service. It was confirmed that the donor had taken malaria prophylaxis. Thus, after the death of the recipient, the events legally qualified as negligent manslaughter. The donor was indeed confronted with severe legal consequences after the source of the infection and its causality for the death of the recipient had been detected. After an indictment by the public prosecutor, the donor was sentenced to a criminal fine of 280 daily rates (adjusted to her income; in total, slightly over 1.600 EUR) for negligent causation of death (negligent manslaughter; § 81 of the Austrian Criminal Code). According to media reports [8], the judge stressed that while a confession, no prior entries in the criminal records, and the voluntary decision to donate blood could be counted as mitigating circumstances, the criminal conviction should also stress that any information given on one's health and traveling history must be as accurate as possible. The heirs of the deceased blood recipient also sued the donor (and the blood donation facility) for damages before a civil court.

The donor was also convicted under civil law in the first instance and must pay bereavement compensation and funeral expenses. The judgment is not legally binding [9]. To our knowledge, this is the first case emphasizing the legal consequences of the involved donor.

Discussion/Conclusion

In the event of a transmission of pathogens through blood units that leads to serious damage to the health or even death of the recipient, the question of (legal) responsibility always arises. Many players are involved in the entire transfusion chain (from vein to vein) from the donor to the manufacturer and the physician making the indication. Since only a few pathogens are directly detected – but keep the diagnostic window in mind – during testing, the medical history on (sexual) risk behavior and stays abroad remains an important pillar in the prevention of transmissions. A person can be held legally liable if he or she disregarded objective care or even acted intentionally. The donor acts negligently if he or she does not declare an existing illness (sexual) risk behavior, or recent stays abroad. With regard to the stay abroad, there are actually clear rules about which the blood donor service must inform the donors [10]. Thus, misrepresentations, as in this case report, should not actually occur. When it comes to the question of (sexual) risk behavior, this is much more difficult because what a donor sees as risk behavior can vary greatly. Clear, comprehensible, and generally accepted rules are needed here to create legal certainty. We therefore recommend that the legal consequences of negligent or deliberate misrepresentation be explicitly stated in the donor questionnaire. This would help ensure to create legal certainty for altruistic donors. Many multiple donors “skim” the questionnaire, knowing which questions to answer and how. In this context, it could be considered to change the order or the content of the questions from time to time to raise awareness for the content of the questionnaire. In the event of a damage, a distinction must be made between the criminal and civil responsibility of the donor which can both have severe negative personal and/or financial consequences.

While this case report focused on the donor's liability, in general, it is not only him or her who can face legal liability: The manufacturer can be held liable, for example, for not having (correctly) performed the prescribed tests, and doctors or the blood donation facility can be held responsible for not having complied with the state of medical science and experience. Finally, the manufacturer could also be responsible without fault according to the Austrian Product Liability Act (“Produkthaftungsgesetz”).

Statement of Ethics

A written informed consent was obtained from the next-of-kin for publication of the details of their medical case, documented in the case history of the patient. An ethics approval was not required.

Conflict of Interest Statement

The authors have no conflicts of interest to declare.

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Author Contributions

V.S., T.W., K.St, and M.Z. wrote the case report; M.Z. and K.Sc provided data; all the authors approved the final version.

Data Availability Statement

All relevant data are shown in this case report.