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The History and Challenges of Blood Donor Screening in China

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ABSTRACT

Since the establishment of People's Republic of China in 1949, the Chinese government has encountered several catastrophes related to transfusion transmitted diseases. The government's increasing attention to blood safety has prompted the initiation of a series of policies and measures that have enhanced the level of safety for the blood supply and met the basic clinical demands of blood for 1.3 billion people in the country.

Blood donation screening strategies in China predominantly comprise donor screening and donor testing. Donor screening includes selection of low-risk blood donors by the use of a donor history questionnaire, predonation physical examination, and initial rapid donor testing. Donor testing includes direct pathogen detection and serology tests. The year 1998 marked the most transformative change in blood donor selection and screening policies in China. Before 1998, paid donation was the predominant mode of blood donation. Donor screening and donor testing were conducted before donation, and only those who were eligible were allowed to donate. To ensure the safety of blood, donor testing was performed again after donation. After the implementation of the Blood Donation Law in 1998, to promote voluntary and unpaid donation, predonation donor testing was eliminated to reduce the amount of waiting time and to provide a more convenient donation experience for blood donors. However, it is the national requirement that donated blood should undergo 2 rounds of testing using different equipment or reagents, conducted by different personnel. Donor selection has transitioned from paid donation and obligatory donation to voluntary donation with fixed volunteer groups, as the latter mode of donation provides the lowest risks. Donations are currently screened for syphilis, hepatitis C virus, HIV, and hepatitis B virus (HBV). Units, previously typed only for ABO, are now routinely tested for both ABO and Rh(D). Innovations in testing technologies and methods have also brought changes to screening parameters. For instance, screening for HBV pathogens evolved from the early use of hemagglutination method to the later use of radioimmunoassay, independent enzyme-linked immunosorbent assay, and now the widespread application of nucleic acid test (NAT). Since 2010, the Chinese government has established NAT capacity in several blood centers; and in 2015, the government invested 900 million RMB on the nationwide expansion of NAT. Although the Chinese government has worked to enhance blood safety, many challenges remain. Concern exists for rising rates of HIV infection. The existence of occult HBV infection and the transmission of emerging blood-borne diseases continue to challenge the safety of the blood supply.

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Blood safety is an important component of public health. To enhance blood safety, many governments use appropriate laws, regulations, and policies and provide high-level support. Since the establishment of People's Republic of China in 1949, drastic changes have been made in the area of blood safety and availability in China. The first national blood center was established in 1958 by the Chinese Academy of Medical Sciences [1]. In 1983, the People's Liberation Army Hospital formed the first independent Department of Transfusion [2]. Approximately 30 years later, nearly 1000 hospitals have their own transfusion department. In the early 1950s, only whole blood was collected for clinical use. By the 1980s, the use of blood components has increased to 99%. To ensure blood safety, the Chinese government has implemented appropriate blood donor screening strategies. Similar to many other countries, the Chinese government has encountered several mishaps related to transfusion-transmitted diseases. Cases of transfusion-transmitted hepatitis B were reported in the 1980s, and cases of transfusion-transmitted hepatitis C and HIV were reported in the 1990s [3-5]. As the Chinese government began to pay increased attention to blood safety, a series of policies and measures were formulated, resulting in changes to blood donor screening and testing strategies [6,7]. In parallel, advances have been made in pathogen detection technology, as well as related testing methodology. Transfusion risks attributable to infectious diseases have been markedly reduced, leading to enhanced blood safety [8-10]. Blood screening strategies constitute the most important measures to ensure safety for both donors and recipients. China's blood screening strategy is divided into 2 components: donor screening and donor testing. Here, we review the development and challenges confronting blood donor screening strategies in China since 1949.

Blood Donor Screening

Introduction

Chinese blood donor screening mainly consists of 4 components: (1) selection of a blood donation mode, (2) selection of donors, (3) physical examination, and (4) rapid laboratory testing before blood collection.

Donor screening before blood collection aids in selecting low-risk individuals and reduces a variety of risks due to transfusion-transmitted diseases. Donor physical examination (blood pressure, pulse, weight, general status, and others) is in accordance with the new edition of China's *Requirements in Donor Health Examination* [11]. Since the publication of *Technical Operation Procedures in Blood Stations* in 1997 [12], standardized donor screening has become an essential quality control step at blood collection centers. With the advances in science and technology and increased requirements in blood manufacture management, the original donor screening criteria from the 1997 publication no longer fulfilled the needs. Therefore, an expert panel organized by the Ministry of Health rewrote the *Technical Operation Procedures in Blood Stations* [7] in 2012, which requires that donor blood specimens must be collected before blood donation for initial donor testing. Initial donor testing includes ABO typing, hemoglobin, and alanine aminotransferase (ALT) testing, but eliminates predonation rapid testing for hepatitis B virus (HBV) surface antigens. For the current screening strategy, see Fig 1.

Blood Donation Incentives

Incentives for blood donation in China underwent a transition in stages: from paid (remunerated) donation, to obligatory donation, to unpaid donation, to the current practice of nonremunerated voluntary donation.

Before 1978, paid remunerated donation predominated. Incentive of paid remunerated donation carried certain well-known risks [13]. In 1978, to ensure availability of blood and promote blood safety, the State Council of China published an *Announcement on Strengthening the Management of Blood* [14] and authorized obligatory blood donation nationally. As a result, between 1978 and 1998, 2 modes of blood donation coexisted: paid (remunerated) donation and obligatory donation.

In 1998, the *Blood Donation Law in the People's Republic of China* was officially launched and marked a significant transformation in Chinese blood donation practices [15]. The blood donation law openly stated that voluntary blood donation must be implemented nationally. In the beginning phase of implementation, there were not enough voluntary nonremunerated donors to meet demands and nonremunerated family members were encouraged to donate blood for patients. Nowadays, greater than 99% of the Chinese blood supply is provided by voluntary nonremunerated blood donations [16].

Selection of Blood Donors

Informed consent is required before blood collection. According to the regulations written in the 1998 “Blood Donation Law” [15], health consultation and general examination must be performed, and blood donors must accurately fill out the health status form. If a donor's inaccurate information results in adverse transfusion consequences in recipients, then the donor would be penalized legally according to the law. Over time, the donor history questionnaire has evolved from a donor history questionnaire with 32 questions initially [17] to 1 with 58 questions [11]. The early questionnaire focused only on blood safety, whereas the current one emphasizes both blood safety and donor safety. Now before blood donation, donors must fill out the blood donor health status consultation form. Consultation mainly focuses on the donor's history of drug usage, sexual preferences, sexual behaviors, and motivation to donate blood. Donors who purposefully donate blood to find out whether they are infected with HIV (HIV test seeker) are deferred