

# The development of Legal Framework on blood donation and blood safety of China in 24 years

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## Research article

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# Abstract

## Background

This study analyzes the regulations and developments in blood donation from 1996 to 2019 in China, and demonstrate the government's efforts in improving blood safety.

## Results

Since the implementation of the Blood Donation Law in 1998, the number of blood donors in China increased by 275% from 1998 to 2018 (from 4 million to 15 million). The principle of no-fault liability was proposed and has been applied since 2010 to the tort liability related to blood transfusion malpractice. In 2015, mutual blood donation accounts for 4.2% of the national collection. However, in some provinces of China, the percentage of mutual blood donation increased from 9.3% to 35.6% in 2016. The NHC cancelled mutual blood donation in March 2018. Nucleic acid amplification testing (NAT) has become a routine test item for screening blood since 2015.

## Conclusions

The Chinese government institutionalized the voluntary non-remunerated donation principle, enacted regulations for the management of blood transfusion, and adopted advanced blood testing technology to sustain blood supply and ensure blood safety. In spite of increased blood donation, blood shortage persists. Quality and safety of blood collection can be further improved through the cancellation of mutual blood donation and incentive measures for voluntary non-remunerated donation of blood, which needs facilitation by governmental legislation.

## Background

In the 1980s to early 1990s, the shortage of blood and the introduction of new plasma collection technology into China created a big chance for paid donation, which were targeted towards the poor people in rural areas. Blood without HIV/AIDS, hepatitis C, malaria, and frequent cross infection were common at that time[1, 2]. Disorderly pricing, weak supervision, and negligence of tests directly resulted in HBV and HIV epidemics which were transmitted through blood collection and transfusion in some regions[3, 4]. In the mid-1990s, an outbreak of HIV transmission among paid plasma donors in Anhui Province and Henan Province in China was confirmed[5-7]. Blood safety needs more attention and improvements in China. The Chinese government gradually adopted a series of legislations and policies in the improvement of blood safety.

In solving the problem of blood safety, China implemented the Law of the People's Republic of China on Blood donation (Blood Donation Law) in 1998, and institutionalized the principle of voluntary non-remunerated donation of blood (VNRBD) by learning from international experience. VNRBD is an important measure in ensuring blood quality and safety. Blood safety has gone through significant changes in China since 1998. Nowadays, most scholars have reached a consensus regarding VNRBD and its foundation for a safe and sustainable blood supply[8]. In a review published by the World Health Organization (WHO), experts declared that without a system based on VNRBD, no country can provide sufficient blood for all patients who require transfusion[8]. China had a total of 459 blood centers in 2010, including 355 specialized blood stations and 104

blood stations in hospitals[9]. The number of blood donations and the volume of blood collection in China have been increasing for 20 consecutive years[10]. In 1998, the number of unpaid blood donors nationwide was around 4 million, reaching nearly 15 million in 2018. In 1998, the volume of national blood collection was at nearly 5 million units, reaching 25 million units by 2018[11]. According to the *2016 Global Status Report on Blood Safety and Availability of WHO*, apart from increased VNRBD, number of blood donations, and volume of blood collection, the blood Nucleic acid test technology adopted by China has improved blood safety, and the clinical, rational use of blood has likewise significantly improved in China[12]. Despite more than 20 years of continuous improvement, there are still many shortcomings in blood safety in China, such as the increasing need for blood and blood products, the risk of transfusion-transmitted infections that lead to chronic blood shortages, unsafe blood products, and unsound clinical transfusion practices [13-18].

The recent status of blood donation and transfusion in China as per data from 1998 to 2019 is presented in this study. Furthermore, the improvements and developments in blood donation mode, legal framework, policy, screening technology, and government management are demonstrated. The legal frameworks and policies on blood donations and transfusions have been effective intervention mechanisms in ensuring blood quality and safety for more than 20 years. The developments to the blood donation system in China is not only a reference model for other development countries, but also an indicator of blood donation system problems and trends to help improve blood safety and availability in China.

## Method

The laws and regulations related to blood donation and transfusion that were implemented or revised from 1998 to 2019 in China were consolidated to expound on the current legal framework of blood transfusion and the roles of the government, blood stations, and hospitals in the management of clinical blood use. The documents on the laws, regulations and notices were collected from the official websites of the Chinese government, and the data on blood donation were obtained from official reports of the NHC from 1998 to 2019, the Global Database on Blood Safety of the WHO from 1998 to 2011, and the 2016 Global Status Report on Blood Safety and Availability. We used “blood transfusion”, “medical damage liability”, “HBV”, “HIV”, “HCV”, “HCV”, “syphilis” as keywords to search litigation cases on the China Judgement Online. 484 related cases was downloaded, and 301 of them were qualified after screening.

## Result

### **The Change of Blood Donation Modes from Paid and Mobilized Unpaid to Voluntary Unpaid Blood Donation**

In 1998, the Blood Donation Law became the symbol of the VNRBD system in China. VNRBD, family replacement/mutual blood donation (FRMBD), and employer-organized blood donation were the three types of blood donation programs permitted by the Blood Donation Law (see Figure1).

Employer-organized blood donation is an interim policy from paid blood donation to voluntary unpaid blood donation. Employer-organized blood donation, workers blood donation as pre-arranged by the employer and local blood stations, a semi-obligatory and mobilized unpaid mode, was banned by the Chinese government in 2005[19, 20]. The reason for the ban was that those who donate blood, as required by their employer, were exposed to undue pressures and had higher rates of infectious disease markers compared to volunteer

donors[21-24]. In fact, the cancellation of employer-organized blood donation meant that China implemented a voluntary unpaid donation system nationwide, thereby eliminating paid donation by 2005. Of course, group voluntary blood donation, as a mode of VNRBD, is allowed in China, accounting for a large percentage of blood donation. Group blood donation has the advantage of being arranged in advance, making up for seasonal shortage of street blood collection and emergency mobilization[25].

There were three identified types of blood donors in the WHO Blood Safety and Availability Report, such as the voluntary unpaid, family or replacement, and paid[12]. FRMBD, which was concerned with the patients' family members, relatives, and friends, the unit to which he or she belongs in the community, with regard to blood donation for mutual aid, thereby ensuring the supply of blood for citizens' clinical first-aid treatment[26]. FRMBD was widely used for more than 20 years in China. Since 2009, the government of China has been paying much attention to the proportion of FRMBD in blood collection. According to the NHC, the policy of FRMBD was cancelled to improve blood quality and safety in 2018 in most regions[27].

### **Roles of Government, Blood Centers, and Medical Institutions in the Management of Blood Collection and Transfusion**

Blood must be used for official clinical activities. Any form of blood trade has been banned by the Chinese government to assure the quality and safety of blood collected, which were listed in accordance with blood-related laws and regulations (see Table 1). From 1996 to 2013 the national health administration department of China is The Ministry of Health, and it was revoked and replaced by The National Health and Family Planning Commission from 2013 to 2018. Since March 2018, it was replaced by The National Health Commission). Even the importation and exportation of blood was forbidden in 2017[28]. To encourage donation, the government provides voluntary blood donors with a holiday, a nutrition allowance, and priority access to blood transfusion during emergencies[29].

Table 1  
The Outline of Laws and regulations related to Blood Donation and Safety in China

Type	Act	Legal sources	Implementation Years	Legislature	Main points
Specific Legislations	Regulations on Blood Collection and Supply Institution and Blood Administration	Regulation	1993 (1998 Expired)	The Ministry of Health <sup>a</sup>	Permission of The Blood Centre  Blood Donor Registration  Promotion of VNBD
	Detailed Rules for the National Verification of External Immunodiagnostic Reagent for Blood Use	Regulation	1994	The Ministry of Health	Test of HIV, HBV, HCV, Syphilis
	Regulations on Administration of Blood Products	Regulation	1996(2016 Revision)	Instrumentalities of the State Council	Blood Product Administration
	Blood Donation Law	Law	1998	Standing Committee of the National People's Congress	VNBD System; Blood Only for Clinical Use
	Measures for the Administration of Blood Centres (for Trial Implementation)	Regulation	1998 (2006 Expired)	The Ministry of Health	Blood Centre Administration
	regulations on Clinical Use of Blood in Medical Institutions (for Trial Implementation)	Regulation	1999 (2012 Expired)	The Ministry of Health	Clinical Blood Use
	Technical Standards for the Clinical Blood Transfusion	Regulation	2000	The Ministry of Health	Corss-Match Test  Blood Transfusion Record

<sup>a</sup>From 1996 to 2013 the national health administration department of China is The Ministry of Health, and it was revoked and replaced by The National Health and Family Planning Commission from 2013 to 2018. Since March 2018, it was replaced by The National Health Commission.

Type	Act	Legal sources	Implementation Years	Legislature	Main points
	Measures for the Administration of Blood Centres	Regulation	2006 (2009,2016,2017 Amendment)	The National Health and Family Planning Commission <sup>a</sup>	Classification and Management Of Blood Centre  Blood Specimen Restoration  2017 Cancellation of Blood Imports and Exports
	Provisions on Clinical Use of Blood in Medical Institution	Regulation	2012	The National Health and Family Planning Commission	Clinical Blood Use  Emergency Blood Use
	Technical Operating Procedures for Blood Centres (2019 Edition)	Regulation	2019 Edition (2005, 2012, 2015 Edition Expired)	The National Health Commission <sup>a</sup>	NAT in clinical use
<b>Other Relative Legislations</b>	Regulation on the Handling of Medical Accidents	Regulation	2002	Instrumentalities of the State Council	Fault Compensation Liability
	Tort Law	Law	2010	Standing Committee of the National People's Congress	Principle of No-Fault Liability in Blood Transfusion Tort
	Pharmaceutical Administration Law	Law	1984 (2001, 2002, 2004, 2016, 2017, 2019 Revision) (2013 Amendment)	Standing Committee of the National People's Congress	Blood Products Cannot Be Commissioned Production and Sell Online

<sup>a</sup>From 1996 to 2013 the national health administration department of China is The Ministry of Health, and it was revoked and replaced by The National Health and Family Planning Commission from 2013 to 2018. Since March 2018, it was replaced by The National Health Commission.

Type	Act	Legal sources	Implementation Years	Legislature	Main points
	Prevention and Treatment Of Infectious Diseases Law	Law	1989 (2004 Revision) (2013 Amendment)	Standing Committee of the National People's Congress	Ensure the Quality Of Blood And Blood Products To  Prevent Transfusion-Transmitted Diseases
<b>Local Legislation</b>	Regulations on Voluntary Blood Donation By Citizens Of Beijing	Regulation	1992 (1998 Expired)	Beijing's Standing Committee of the National People's Congress	Promotion of voluntary blood donors
	Regulations on Shenzhen Special Economic Zone on Citizen's Gratis of Blood Donation and Blood Management	Regulation	1995 (2015 Expired)	Shenzhen's Standing Committee of the National People's Congress	Reimbursement of VNBD
	Regulations of Beijing Municipality on Mobilizing and Arranging for Citizens to Donate Blood	Regulation	1998 (2006 Expired)	Beijing's Standing Committee of the National People's Congress	VNBD system
	Rules of Guangzhou Municipality on Donation of Blood	Rules	2004 (2015 Amendment)	Guangzhou Municipal People's Government	Mutual Blood Donation
	Regulations of Nanning Municipality on Blood Donation	Regulation	2004 (2012 Revision)	Nanning's Standing Committee of the National People's Congress	VNBD system
	Measures of Beijing Municipality for Administration of Blood Donation	Rules	2009	Beijing Municipal People's Government	VNBD publicity and the service

<sup>a</sup>From 1996 to 2013 the national health administration department of China is The Ministry of Health, and it was revoked and replaced by The National Health and Family Planning Commission from 2013 to 2018. Since March 2018, it was replaced by The National Health Commission.

Type	Act	Legal sources	Implementation Years	Legislature	Main points
	Regulations on Shenzhen Special Economic Zone Blood Donation	Regulation	2015 (2019 Amendment)	Shenzhen's Standing Committee of the National People's Congress	VNBD incentives
	Measures of Nanning for rewarding blood donation	Rules	2017	Standing Committee of Nanning Municipal People's Government	VNBD incentives and rewarding
<p><sup>a</sup>From 1996 to 2013 the national health administration department of China is The Ministry of Health, and it was revoked and replaced by The National Health and Family Planning Commission from 2013 to 2018. Since March 2018, it was replaced by The National Health Commission.</p>					

Blood centers serve as the main institution in the collection and restoration of blood. From 1993 to 1998, the establishment of blood centers have been constantly approved by the Red Cross Society in China[30]. After the *Measures for the Administration of Blood Centre (for Trial Implementation)* were implemented in 1998, the blood center was defined as a non-profit, public welfare organization, and its establishment was thereafter managed by the health administration department of the provincial government[31]. Blood centers provide the necessary health examination and blood collection service for voluntary unpaid blood donors, maintain blood supply for clinical use, and are responsible for restoration and transportation[32]. The blood collected from donors will be tested to avoid quality problems[33].

The medical institution is the only legal institution for the clinical use of blood. The Blood Donation Law stipulated that all blood and blood products must be tested before transfusion in medical institutions to ensure safety[34]. Other regulations and technical standards regarding blood centers and medical institutions are listed in Table 1. These guidelines and regulations have the effect of strengthening the management of blood collected and enhancing the level of blood safe.

### Huge Increase in Blood Collection and Supply

Before 1998, the recruitment of blood donor volunteers was a very challenging endeavor in China. Traditional Chinese medicine holds that the loss of even a small amount of blood was harmful on the health, and it was also why paid blood donation was common at that time[3].

Since 1998, the implementation of the Blood Donation Law and encouragement of unpaid blood donation by laws and policies[35], the number of unpaid blood donors and the amount of blood collected in China have been continuously increasing for 20 years (see Figure 2 Data on 1998, 2010, 2011, 2014, 2015, 2016, 2017, 2018 from National Health Commission of the People's Republic of China (NHC) Data on 2012, 2013 from Global database on blood safety (GDBS). The steady increase in the number of unpaid blood donors and the amount of blood collected has ensured the safe supply of blood from the source[11].

The proportion of unpaid blood donation was only 8% in 1998, which increased to 95.5% in 2005. After 2009, it was realized that all clinical blood came from unpaid donation[36]. In response to the call of The Melbourne Declaration on 100% Voluntary Non-Remunerated Donation of Blood and Blood Components, the Chinese government engaged in efforts to popularize VNRBD donors and entered the list of countries which reported almost 100% blood collection in 2011[37].

Through the establishment of a multi-level alarm mechanism when blood is in short supply and the deployment of resources in different blood centers, seasonal, regional, and partial blood tension problems have been solved to a great extent. In 2015, 1.19 million units of blood were allocated across the country, and it reached 1.54 million in 2017[38]. In 2018, a total of 1.84 million units of blood were allocated across the country, of which 1.585 million units (86.1%) were allocated among the province and 255 thousand units (13.9%) were allocated between provinces. The policy of alarming and deployment of blood effectively ensured the clinical blood demand in blood intensive areas and major public health events[11].

### **The Rise and Fall of Family Replacement/Mutual Blood Donation in VNRBD**

Since 1998, according to Article 15 of the Blood Donation Law, patients' family members, relatives, friends, and their colleagues have been allowed to donate blood for mutual aid in emergency situations. FRMBD is a double-edged sword for blood safety. On the one hand, it can solve the shortage of blood. On the other hand, the risk of blood trade exists in mutual blood donation. The WHO has stressed that when mutual blood donation accounts for more than 5% of unpaid blood donation, there would be a risk of illegal blood trade.

As a specific mode of donation, it was able to relieve the tension and shortage in the clinical blood in China. FRMBD accounted for 0.41% of the national blood collection in 2009 [39]. In 2015, it increased to 4.2% (see Figure 3) nationwide. In some provinces, it was significantly higher, such as in Hainan (35.6%), Guangxi (25.9%), Xinjiang (11.7%), Gansu (9.5%), and Guangdong (9.3%)[40]. Even in the Xinning City of Guangxi Province, it was up to more than 50%[41], while it was 21% in Beijing in 2017[42].

However, the rules on mutual blood donation in the Blood Donation Law are too wide in scope for FRMBD to leave room for criminals to sell blood illegally, thereby increasing the people's distrust regarding voluntary blood donation and lowering the quality and safety of donated blood[43]. Private transactions between donors and recipients cannot be supervised by medical institutions or blood centers.

To ensure the quality and safety of blood collection, NHC issued a government order to cancel FRMBD nationwide, except for some remote areas, by March 2018[27]. At present, most areas have completely stopped FRMBD. It is no doubt that the cancellation of blood donation imposes a burden on the clinical blood shortage in hospitals[44]. In response thereto, VNRBD should be promoted and inter-provincial transfers of blood should be well-allocated to maintain the balance of blood supply and demand.

### **Development of Blood Safety in China**

Blood safety depends on whether the source of blood is safe to a large extent. Ensuring the safety of blood collected is the first step in the whole process. It took the Chinese government 4 years to establish and strictly implement the testing procedures, and continuously improve it over the past two decades.

China's commercial plasma-selling emerged in the early 1980s[45]. Since 1993, blood donors have been required to be tested for HIV, hepatitis B, hepatitis C, and syphilis in order to reduce the infections through transfusion according to Health Examination Standards for Blood Donors[32]. But these regulations was not be fully implemented—HIV-positive individuals could enter the blood plasma collection process without HIV testing. From the end of 1994 to the beginning of 1995, when local outbreaks of the infection occurred first in provinces including Hebei, Anhui, and Henan provinces, the HIV epidemic was subsequently found among plasma donors[45].It was reported that 326 cases from who had donated blood at plasmapheresis centres in Hebei Province were identified as HIV-positive during 1995-2013. These HIV infections were proved to emerge in October 1994 initially[2].

Finally, the Technical Operation Procedures in Blood Stations standardized donor screening has become an essential testing step at blood collection centres since 1997[46]. From then on, each unit of blood must be tested for blood grouping, hemoglobin, alanine aminotransferase(ALT), HBV surface antigen(HBsAg) before collection. Then, donated blood (post-collection) would undergo comprehensive donor testing twice, using different equipment and/or different personnel, including HIV, HBV, hepatitis C virus, ALT, and syphilis[47].

In the next two decades, testing is strictly implemented. Equipment and technology are updated continuously. For blood group, the RhD type were forced to appraise since 2012[48]. For serum markers, colloidal gold strip method was used to detect the markers of HBV in early 1990s. Since 1997, serum markers were tested through enzyme-linked immunosorbent assay (ELISA) reagent[46]. Since 2010, Chinese government has established NAT system in several regions, such as Beijing and Shanghai, covering all types of donations and achieving great progress in improving blood safety[49]. Due to huge operating costs and the shortage of qualified staff of blood centre, NATs were mainly implemented at the provincial level of blood centre in 2013[15]. In 2014, the blood test completed by NAT nationwide approached 4.7 million units, which accounted for 36% of the annual blood donation[16]. About 129 million dollars was invested on the nationwide expansion of NAT in 2015[50]. Eventually, nucleic acid test (NAT) and chemiluminescent immunoassay (CLIA) were formally added to this procedure according to Technical Operating Procedures for Blood Centres (2015 Edition)[51]. In order to simplify the procedure and improve the efficiency, serum markers only need to be detected once by ELISA or CLIA except NAT since 2019[52]. (As showed in Figure4) The window period of HIV, HBV, HCV are shortened by NAT from 50, 72 and 22 days to 25, 59 and 11 days respectively[53].

Through analyzing the litigation cases related to transfusion from 1981 to 2020, we found that the numbers of cases experiences a huge reduction, since the HCV was required to be tested in 1994 (Figure5). Blood transfusion reactions accounted for 5.6% of all documents, HBV infection accounted for 5.3%, HIV infection accounted for 11.0%, HCV infection accounted for 76.7%, syphilis infection accounted for 2.3%. HCV infection took the largest share, of which 55.8% occurred before 1994.

### **Transformation of Liability in Blood Transfusion Malpractice**

Process optimization and technology updates improved blood safety directly but the risk of blood transfusion cannot be eliminated completely for some unpredictable reasons, infections, venous thromboembolism[54], transfusion-related lung injury and transfusion-associated graft-versus-host disease[55]. So it is crucial that who takes this liability.

Before 1993, there was no regulations related to adverse events caused by transfusion. For instance, medical institutions or blood stations would not be held accountable for HIV infection caused by blood transfusion because the antibody of HIV was not required to test until 1993[46]. Between 1993 to 2002, there were no laws or regulations to compensate for the adverse events caused by blood transfusion, leaving the issue to be addressed by civil law. The result of judgements often depended on the opinions of judges and juries.

Between 2002 and 2010, according to Article 33 of the Regulation on the Handling of Medical Accidents, the fault liability principle was deemed applicable in transfusion. It was found that hospitals were not responsible for no-fault transfusion[56]. It means that the hospital will not bear legal responsibility if the whole process met the inspection standards and technical index, even though the unfavorable consequences caused by infections resulting from the quality of blood. What's more, in case of emergency, infections caused by blood transfusion were exempted due to the thought that life extension was more important than long-term quality of life. Then obviously, it was not fair for the patient who get HIV or HBV infectious in transfusion. So in judicial practice, to any cases that the hospital was ordered to pay compensation for patients even no error in transfusion for fairness[57]. Of the 301 cases, 236 hospitals or blood stations in China paid compensation for the infection related to transfusion from 1981 to 2018.

After 2010, according to the Article 59 of the *Tort Law* of China, damage of transfusion was classified as a special no-fault liability tort. It was the first time to clearly point out that patients could claim compensation. This principle shows the protection of the rights and interests of patients. Although the hospital may not be at fault in whole process, they should assume the tort liability for infringing upon a civil right or interest of patient and pay compensation. As showed in Figure5, the numbers of decisions reached its peak in 2015, which has a great deal to do with the *Tort Law* of China. Generally speaking, the trial practice takes three to four years after the prosecution. In one word, the patient has the right to claim for compensation from the blood centre or the hospital, if only he or she suffered any adverse event due to transfusion or infected blood.

## Discussion

### The Legal Framework Promote the Development of VNRBD

The management of blood donation is an essential part of the public health system, and is mainly managed and supervised by government. The laws and regulations play important roles on blood accessibility and safety. Firstly, the legal framework of blood donation, especially the encouragement of VNRBD, assures the supply of clinical blood use. Secondly, the legal framework ensures blood safety for all[58]. The rules on blood collection, blood centers, blood tests, and the standard operating procedures assure the healthy rights of blood donors and blood users. Thirdly, the well-established legal framework promotes the uniform of standards and consistency in the quality and safety of blood and blood products[59].

### Contribution of hospital in improving blood safety

Blood transfusion therapy is of great significance to the treatment of trauma, anemia and blood system diseases. Every recipients' blood group must be determined before transfusion. Application of ABO blood group positive and negative typing and cross matching test helps to avoid acute hemolytic reaction to a great extent. Hemolysis by incompatibility due to anti-erythrocyte antibodies remains the most frequent and most serious immunological risk in the receiver, especially in a transfusional or foeto-maternal context[60]. For some special

patients, Coombs test and an antibody screening test for the detection of irregular antibodies are necessary according to Specification for clinical transfusion technology [61].

### **No-fault Liability Tend in the Protection of Patient's Rights in Blood Transfusion Malpractice**

The principle of no-fault liability actually protects the interests of patients, given that they are a vulnerable group to a large extent, but it brings huge economic burden to public service agencies, such as hospitals and blood centers. The window period of virus and missing detection cannot be avoided completely. Moreover, transfusion infection generally is not found immediately after transfusion. As a result, loss of blood samples or sample collection errors are commonly found during the investigation of cases[62, 63]. Basically, in the absence of conclusive evidence, judges would deduce that the blood or blood product offered by hospitals or blood centers were not qualified and standardized if the patients' family members did not have HCV. Although the restoration of blood specimens has been lengthened for two years after transfusion, which is in accordance with the Measures for the Administration of Blood Centers in 2017, it is still difficult to ensure the integrity of evidence. The final decision depends, on a large extent, on the judge's inference. In brief, the no-fault liability is a strict liability for the hospital, even though the hospital has a right of recourse against the blood center if it fully complies with transfusion standards.

### **Encourage Blood Donation and Save Clinical Blood Use to Solve the Shortage of Blood Supply**

It is evident that China has made significant achievements in increasing blood donation. To achieve a self-sufficient blood supply, the WHO states that a minimum of 20 to 25 donors for a population of 1000 is essential[59]. Even with 15 million donations and a population of 1.39 billion, China has a rate of 11 donors per 1000, far below the WHO recommendation and those of high-income countries (39.2 donors per 1000)[40, 64]. The NHC authority expects to reach 15 donors per 1000 population by 2020[65]. There are two main measures to sustain the supply of blood. First, incentive policies will be introduced to encourage blood donors. Liu's research suggests that, aside from promoting awareness of the public on blood donation, blood traceability during collection, transportation, and storage can increase trust in the relationship between donor and blood center.[66] On the other hand, saving clinical blood is also important to ensure the blood supply; for instance, reducing the number of unnecessary transfusions and increasing the pre-operative autologous blood donation.

### **Suggestion on Abolishment of Mutual Blood Donation in the Blood Donation Law**

In order to prevent blood dealers from profiting from the mutual blood donation, NHC adopted the most direct and effective strategy. Obviously, there are contradictions and conflicts between the requirements and provisions of the NHC in the cancellation of mutual blood donation. The first point is that cancellation of mutual blood donation has imposed a burden on the clinical blood shortage while reducing potential transactions crime between donors, recipients and blood dealers. The second point is that mutual blood donation is allowed and institutionalized by Blood Donation Law, however, NHC tries to cancel it by the notice issued in 2018[27]. The notice is merely a departmental regulation formulated within the authority of NHC, with a lower rank and limited authority. The inconsistency of laws and regulations makes it difficult to judge the legality of mutual blood donation. Therefore, under the existing legal framework, there are still legal obstacles in terms of the cancellation of FRMBD[67]. The Chinese government has noticed this situation and is ready to take measures. In March 2019, the NHC decided to revise the provisions on the clinical use of blood in medical institutions to cancel mutual

blood donation. We can believe that the Blood Donation Law will also be revised to cancel mutual blood donation in the future.

## **Limitation**

Our study on the development of Legal Framework on blood donation and blood safety in China is based on the data collected from Chinese government websites and WHO database, the amount of blood donation in the same year may vary according to different data sources. It is a pity that the data of volume of donations are not obtained in 2002-2008 because they are not publicly available. What's more, the judgements documents related to transfusion was collected on the China Judgements Online. Due to the problems of courts in various regions, there may be some omissions in our data.

## **Conclusions**

The Chinese government institutionalized the voluntary non-remunerated donation principle, enacted regulations for the management of blood transfusion, and adopted advanced blood testing technology to sustain blood supply and ensure blood safety. The numbers of litigation cases related to transfusion has experienced a huge reduction since the legal framework and testing technology were improved. In spite of increased blood donation, blood shortage persists. Quality and safety of blood collection can be further improved through the cancellation of mutual blood donation and incentive measures for voluntary non-remunerated donation of blood, which needs facilitation by governmental legislation.

## **Declarations**

### **Consent for publication**

Not applicable.

### **Availability of data and materials**

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

### **Competing interests**

Each author certifies that he or she has no commercial associations that might pose a conflict of interest in connection with the submitted article.

### **Ethics approval and consent to participate**

This study did not involve any human participants. The data used in our analysis are publicly available. Hence, this study was not considered to require assessment by the ethics review boards of the relevant hospitals.

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### Authors' Contributions

Dajun Gao and Heng Li contributed to the project conception, data analysis. Dajun Gao finished manuscript drafting and revision. Dajun Gao, Heng Li and Wang Kang have approved the final manuscript version.

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Not applicable.

## Abbreviations

NHC: National Health Commission

NAT: nucleic acid amplification testing

HIV/AIDS: human immunodeficiency virus/ acquired immunodeficiency syndrome

HBV: Hepatitis B virus

HCV: Hepatitis C virus

VNRBD: voluntary non-remunerated donation of blood

FRMBD: family replacement/mutual blood donation

GDBS: global database on blood safety

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## Figures

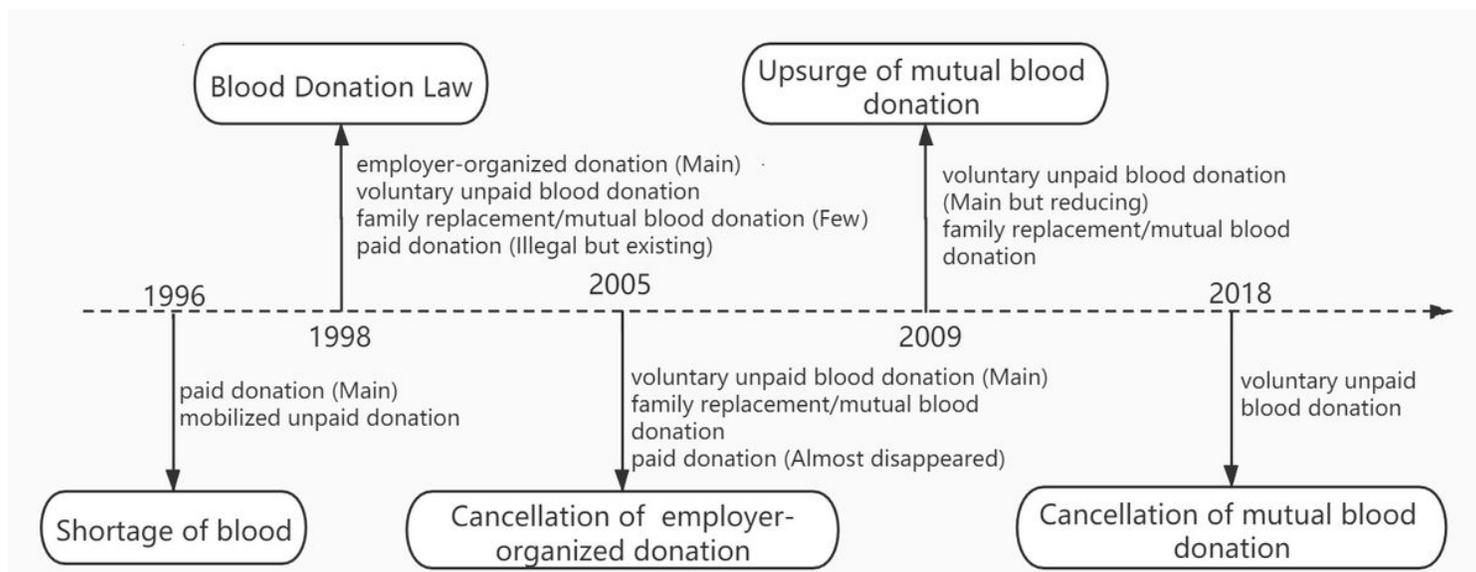


Figure 1

Figure 1

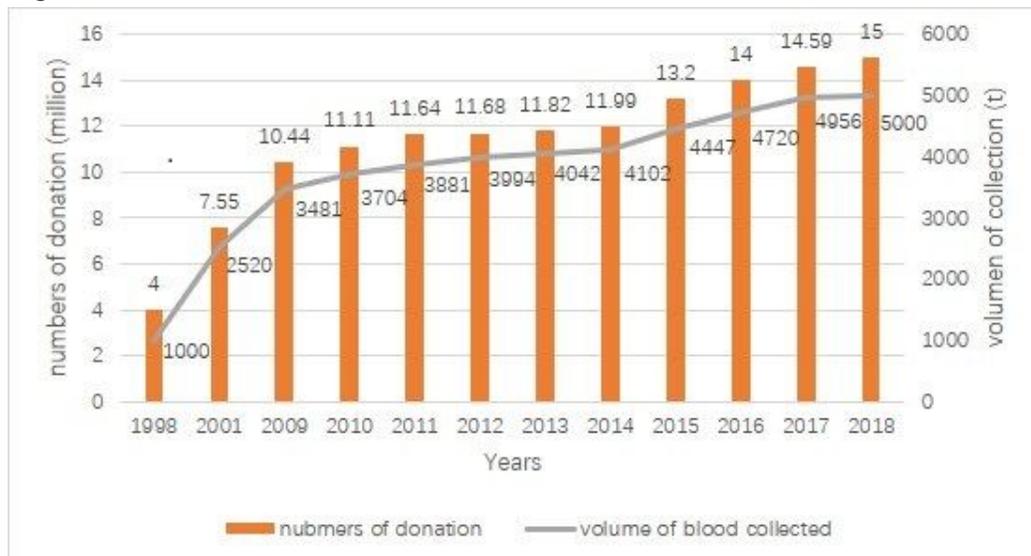


Figure 2

Figure 2

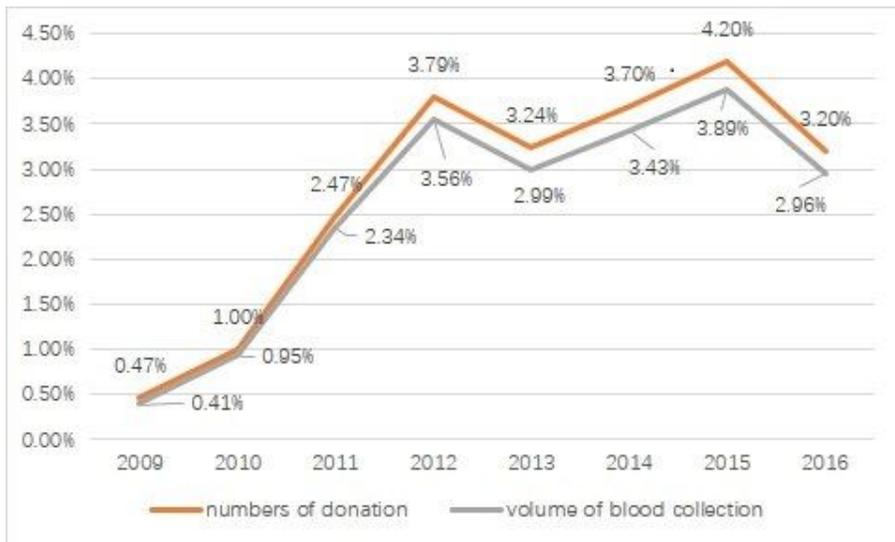


Figure 3

Figure 3

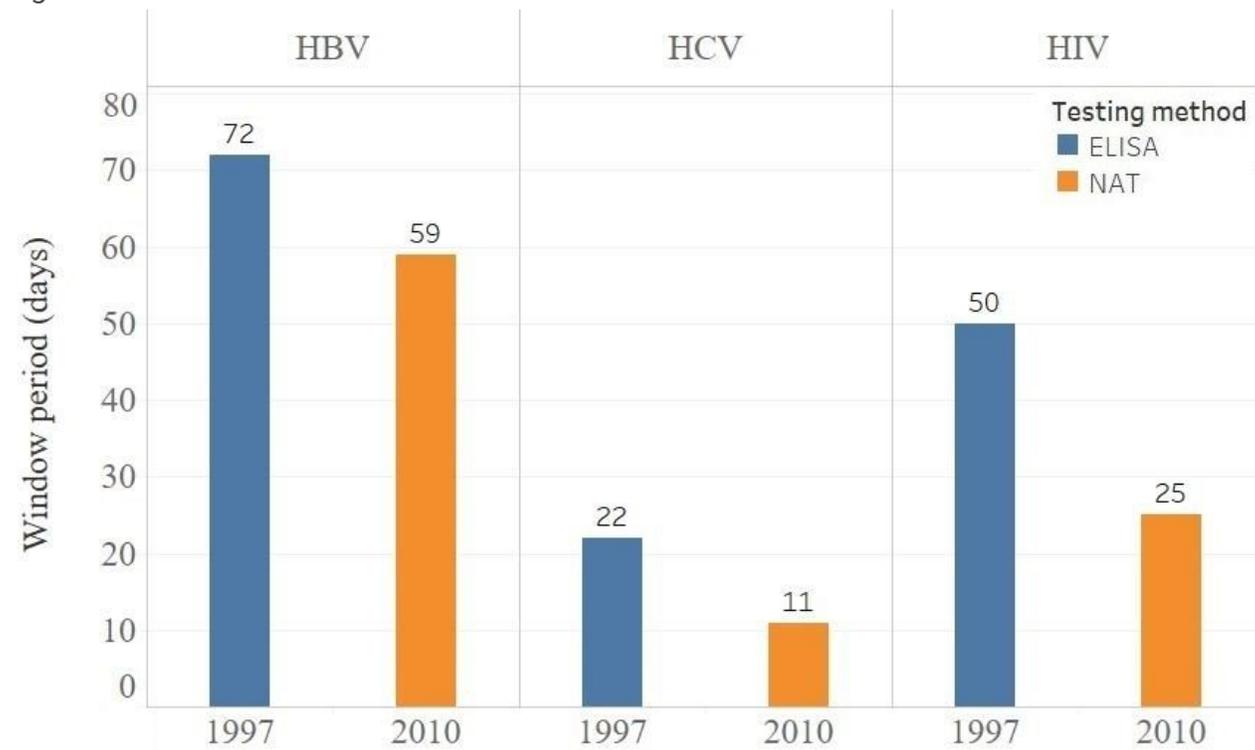


Figure 4

Figure 4

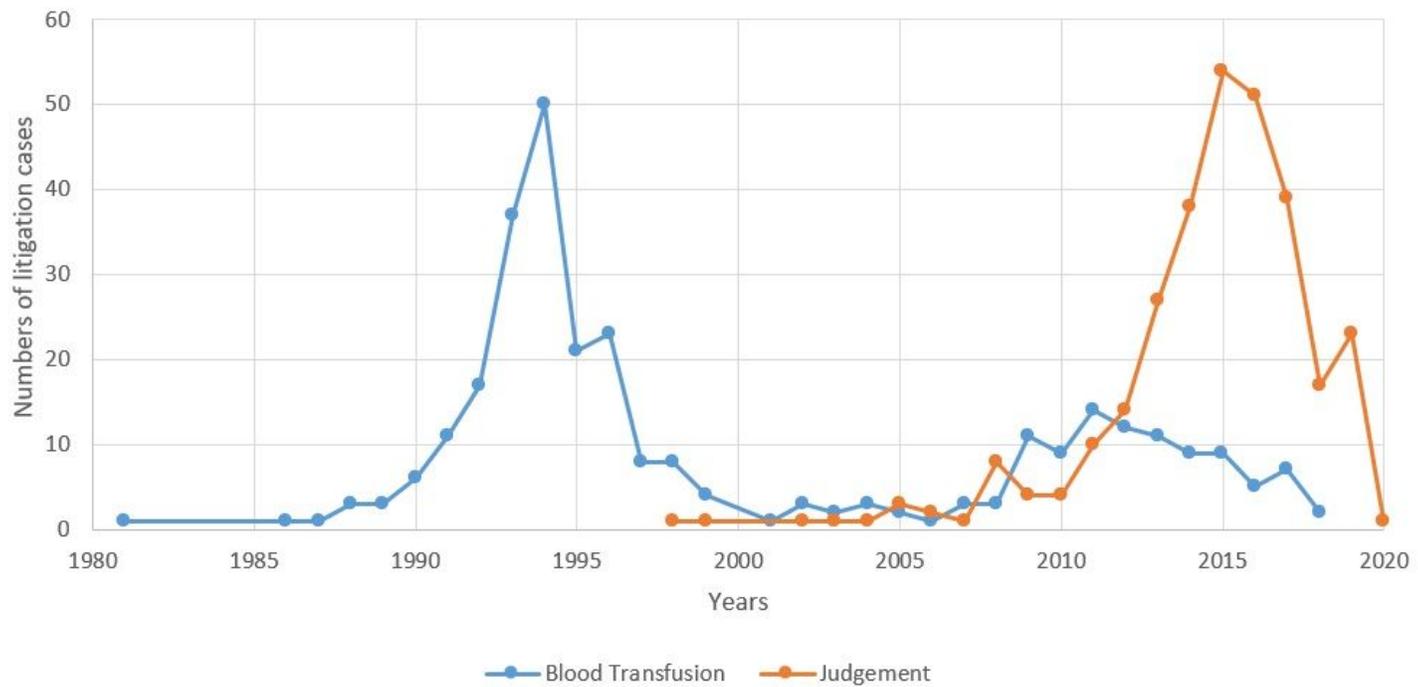


Figure 5

Figure 5