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.

Study Design and Methods We compiled blood transfusion laws and regulations implemented from 1998 to 2019 and official published data on blood donation. Thereafter, we analyzed the impacts of these changes.

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 9.3–35.6% 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.

Conclusion 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.

Introduction

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[1]. Blood without HIV/AIDS, hepatitis C, malaria, and frequent cross infection were common at that time[2, 3]. 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[4, 5]. In the mid-1990s, an outbreak of HIV transmission among paid plasma donors in Anhui Province and Henan Province in China was confirmed[6–8]. 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. 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[9]. China had a total of 459 blood centers in 2010, including 355 specialized blood stations and 104 blood stations in hospitals[10]. The number of blood donations and the volume of blood collection in China have been increasing for 20 consecutive years[11]. 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[12]. 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[13]. 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 [14–19].

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.

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 Fig. 1).
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[1, 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[13]. 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].
| Type                  | Act                                                                 | Legal sources                  | Implementati on Years | Legislature                     | Main points                                      |
|----------------------|----------------------------------------------------------------------|--------------------------------|-----------------------|----------------------------------|--------------------------------------------------|
| Specific Legislations| Regulations on Blood Collection and Supply Institution and Blood Administration | Regulation                     | 1993 (1998 Expired)     | The Ministry of Health\(^a\)   | 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 Implementati on) | Regulation                     | 1998 (2006 Expired)   | The Ministry of Health          | Blood Centre Administration                      |
|                      | regulations on Clinical Use of Blood in Medical Institutions (for Trial Implementati on) | Regulation                     | 1999 (2012 Expired)   | The Ministry of Health          | Clinical Blood Use                               |

\(^a\)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                                      |
|----------------------------------|----------------------------------------------------------------------|---------------|----------------------|--------------------------------------------------|--------------------------------------------------|
| Technical Standards for the Clinical Blood Transfusion | Regulation | 2000 | The Ministry of Health | Corss-Match Test, Blood Transfusion Record |
| Measures for the Administration of Blood Centres | Regulation | 2006 (2009, 2016, 2017 Amendment) | The National Health and Family Planning Commission | 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 | NAT in clinical use |
| Other Relative Legislations | 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 |

*aFrom 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                                                                 |
|-------------------------------|------------------------------------------|---------------|----------------------|-------------------------------------------------|-----------------------------------------------------------------------------|
|                              | Pharmaceutical Administration Law        | Law           | 1984                 | Standing Committee of the National People's Congress | Blood Products Blood Products Cannot Be Commissioned Production and Sell Online |
|                              |                                          |               | (2001, 2002, 2004, 2016, 2017, 2019 Revision) |                                                 |                                                                             |
|                              |                                          |               | (2013 Amendment)     |                                                 |                                                                             |
|                              | Prevention and Treatment Of Infectious Diseases Law | Law           | 1989                 | Standing Committee of the National People's Congress | Ensure the Quality Of Blood And Blood Products To Prevent Transfusion-Transmitted Diseases |
|                              |                                          |               | (2004 Revision)      |                                                 |                                                                             |
|                              |                                          |               | (2013 Amendment)     |                                                 |                                                                             |
| Local Legislation            | Regulations on Voluntary Blood Donation By Citizens Of Beijing | Regulation | 1992                 | Beijing's Standing Committee of the National People's Congress | Promotion of voluntary blood donors |
|                              |                                          |               | (1998 Expired)       |                                                 |                                                                             |
|                              | Regulations on Shenzhen Special Economic Zone on Citizen's Gratis of Blood Donation and Blood Management | Regulation | 1995                 | Shenzhen's Standing Committee of the National People's Congress | Reimbursement of VNBD |
|                              |                                          |               | (2015 Expired)       |                                                 |                                                                             |
|                              | Regulations of Beijing Municipality on Mobilizing and Arranging for Citizens to Donate Blood | Regulation | 1998                 | Beijing's Standing Committee of the National People's Congress | VNBD system |
|                              |                                          |               | (2006 Expired)       |                                                 |                                                                             |

*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 | Implementati on Years | Legislature | Main points |
|------|-----|---------------|-----------------------|-------------|-------------|
| 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 |
| 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 |

aFrom 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.

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[4].

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 Fig. 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[12].

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[12].

**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 Fig. 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 [3].

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[16]. In 2014, the blood test completed by NAT nationwide approached 4.7 million units, which accounted for 36% of the annual blood donation[17]. 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 Fig. 4) 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].

**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

Prior to 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, though it rules the hospital liability exemption in transfusion, the hospital must pay compensation for patients even no error in transfusion for fairness[57].

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. 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].

**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[60, 61]. 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, 62]. The NHC authority expects to reach 15 donors per 1000 population by 2020[63]. 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.[64] 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

The expansive definition of mutual blood donation is allowed and institutionalized in the Blood Donation Law in China. Obviously, there are contradictions and conflicts between the requirements of the NHC in the cancellation of mutual blood donation and the provisions of the Blood Donation Law, which easily leads to the deviation and confusion of medical staff and patients. The notice is merely a departmental regulation formulated within the authority of the NHC, with a lower rank and limited authority. Its legal status and legal effect are lower than the Blood Donation Law, which was deliberated and passed by the Standing Committee of the National People's Congress. Therefore, under the existing legal framework, there are still legal obstacles in terms of the cancellation of FRMBD[65]. 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.

Declarations

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Conflict of interests

None

Contributors

All authors contributed to the project conception, data analysis, manuscript drafting and revision. Each author has approved the final manuscript version and is accountable for all aspects of the work.
References

1. Hong Y, Huang X, Ling H, Liao H: Prevalence and trend of HIV infection among voluntary blood donors in China since implementation of the Blood Donation Law: a systematic review and meta-analysis. Tropical medicine & international health : TM & IH 2012, 17(8):978-988.

2. Adams V, Erwin K, Le PV: Public health works: blood donation in urban China. Social science & medicine (1982) 2009, 68(3):410-418.

3. Chen S, Zhao H, Zhao C, Zhang Y, Li B, Bai G, Liang L, Lu X: Eighteen-year follow-up report of the surveillance and prevention of an HIV/AIDS outbreak amongst plasma donors in Hebei Province, China. BMC infectious diseases 2015, 15:316.

4. Shan H, Wang JX, Ren FR, Zhang YZ, Zhao HY, Gao GJ, Ji Y, Ness PM: Blood banking in China. Lancet (London, England) 2002, 360(9347):1770-1775.

5. Qian HZ, Vermund SH, Wang N: Risk of HIV/AIDS in China: subpopulations of special importance. Sexually transmitted infections 2005, 81(6):442-447.

6. Wu Z, Sullivan SG, Wang Y, Rotheram-Borus MJ, Detels R: Evolution of China’s response to HIV/AIDS. Lancet (London, England) 2007, 369(9562):679-690.

7. Sun X, Lu F, Wu Z, Poundstone K, Zeng G, Xu P, Zhang D, Liu K, Liau A: Evolution of information-driven HIV/AIDS policies in China. International journal of epidemiology 2010, 39 Suppl 2:ii4-13.

8. Wu Z, Rou K, Detels R: Prevalence of HIV infection among former commercial plasma donors in rural eastern China. Health policy and planning 2001, 16(1):41-46.

9. WHO Guidelines Approved by the Guidelines Review Committee. In: Towards 100% Voluntary Blood Donation: A Global Framework for Action. Geneva: World Health Organization Copyright (c) World Health Organization 2010.; 2010.

10. Blood Safety [www.wpro.who.int/china/mediacentre/factsheets/blood_safety/zh/]

11. Yang BC, Shao CP, Zhang YY, Kong L, Xu YP: Two decades of voluntary nonremunerated blood donation in Shenzhen, China. Transfusion 2015, 55(5):1108-1114.

12. Regular Press Conference of National Health Committee on June 10, 2019 [http://www.nhc.gov.cn/yzygj/xxgzdt/201906/14aedfcb64b044a6af5b687257a7e041.shtml]

13. Global Status Report on Blood Safety and Availability 2016. In.; 2017.

14. Shi L, Wang JX, Stevens L, Ness P, Shan H: Blood safety and availability: continuing challenges in China’s blood banking system. Transfusion 2014, 54(2):471-482.

15. Shi L, Wang J, Liu Z, Stevens L, Sadler A, Ness P, Shan H: Blood donor management in china. Transfusion medicine and hemotherapy : offizielles Organ der Deutschen Gesellschaft fur Transfusionsmedizin und Immunhamatologie 2014, 41(4):273-282.

16. Yin YH, Li CQ, Liu Z: Blood donation in China: sustaining efforts and challenges in achieving safety and availability. Transfusion 2015, 55(10):2523-2530.
17. Yu X, Chen W, Liu Z, Huang Y: Safety and current status of blood transfusion in China: an update. *The Lancet Haematology* 2016, 3(2):e60-62.

18. Zhu Y, Xie D, Wang X, Qian K: Challenges and Research in Managing Blood Supply in China. *Transfusion medicine reviews* 2017, 31(2):84-88.

19. Expert Consensus Statement on achieving self-sufficiency in safe blood and blood products, based on voluntary non-remunerated blood donation (VNRBD). *Vox sanguinis* 2012, 103(4):337-342.

20. Tison GH, Liu C, Ren F, Nelson K, Shan H: Influences of general and traditional Chinese beliefs on the decision to donate blood among employer-organized and volunteer donors in Beijing, China. *Transfusion* 2007, 47(10):1871-1879.

21. van der Poel CL, Seifried E, Schaasberg WP: Paying for blood donations: still a risk? *Vox sanguinis* 2002, 83(4):285-293.

22. Erwin K: The circulatory system: blood procurement, AIDS, and the social body in China. *Medical anthropology quarterly* 2006, 20(2):139-159.

23. Zaller N, Nelson KE, Ness P, Wen G, Bai X, Shan H: Knowledge, attitude and practice survey regarding blood donation in a Northwestern Chinese city. *Transfusion medicine (Oxford, England)* 2005, 15(4):277-286.

24. Wen-juan M: Analysis of the Influencing Factors of Blood Disqualification of Individual and Group Voluntary Blood Donors(Chinese). In: *The 14th China Symposium on Integrated Traditional Chinese and Western Medicine Experimental Medicine: 2017; Shandong, China*. 9.

25. Yueguo Z, Wei W, Dakang C: Function and management in group voluntary blood donation(Chinese). *Chinese Journal of Blood Transfusion* 2014, 27(11):1197-1199.

26. Law of the People's Republic of China on Blood donation. In. Edited by Congress SCotNPs, vol. Art 15; 1998.

27. Notice on Doing a Good Job in Medical Safety Management during the 19th National Congress [http://wjw.wulanchabu.gov.cn/information/wsji1418/msg1130857094815.html]

28. Measures for the Administration of Blood Centres (2017 Amendment). In. Edited by NHC, vol. Art41; 2017.

29. Ping H, Xing N: Blood shortages and donation in China. *Lancet (London, England)* 2016, 387(10031):1905-1906.

30. Provisions on Institution of Collection and Supply of Blood and Administration of Blood. 1993, Art3.

31. Measures for the Administration of Blood Stations(for Trial Implementation). In. Edited by Health TMo, vol. Art6; 1998.

32. Provisions on Institution of Collection and Supply of Blood and Administration of Blood. In. Edited by Health TMo, vol. Art2; 1993.

33. Measures for the Administration of Blood Stations(for Trial Implementation). In. Edited by Health TMo, vol. Art27,33; 1998.
34. Law of the People's Republic of China on Blood donation. In. Edited by Congress SCoTNP, vol. Art12,13; 1998.

35. Yu C, Holroyd E, Cheng Y, Lau JT: Institutional incentives for altruism: gifting blood in China. BMC public health 2013, 13:524.

36. National Blood Management Conference (Chinese). Journal of Clinical Transfusion and Laboratory Medicine 2006(02):151.

37. List of countries reported collection of blood from 100% (or almost 100%) voluntary nonremunerated blood donors (in alphabetical order). 2011. 2013.

38. Notice on 2017 national blood safety technical verification. In.; 2018.

39. Jie M: Brief Analysis of Different Blood Donation Models for Voluntary Blood Donation in China from 2009 to 2014(Chinese). Chinese Journal of Blood Transfusion 2017, 30(07):766-768.

40. Circular of the General Office of the National Health and Family Planning Commission on Blood Safety Technical Verification in 2016 [http://www.nhc.gov.cn/yzygj/s7658/201704/5eb5a939a0bd4ba9921f8a3eec46e318.shtml]

41. Jiaxin L, Hongwu G, Jun S: Annual Report on Development of Chinese Blood Collection and Supply Industry 2017 (Chinese). In., 2017 edn; 2017: 55,415.

42. There will be 16 more blood collection points on the streets in Beijing this year [https://new.qq.com/omn/20180213/20180213A0G1QJ.html]

43. Yongjun CRL: Research on the Clinical Application of Mutual Blood Donation System in Blood Source Tension Period(Chinese). Clinical Research 2019, 27(06):7-9.

44. Yun-long H: Try to talk about the confusion and outlet of mutual blood donation(Chinese). Journal of Nanjing Medical University(Social Sciences) 2013, 13(03):219-221.

45. Guo Z, Xiao D, Xu S, He K: Analysis and forecast of the HIV/AIDS epidemic in Mainland China, 1985-2016. Journal of public health (Oxford, England) 2019.

46. Technical operation procedures in blood stations In. Edited by Health TMo, vol. 1997; 1997.

47. Li L, Li KY, Yan K, Ou G, Li W, Wang J, Song N, Tian L, Ji X, Chen Y et al: The History and Challenges of Blood Donor Screening in China. Transfusion medicine reviews 2017, 31(2):89-93.

48. Technical operation procedures in blood stations 2012 Edition. In. Edited by Health TMo, vol. Art4.11; 2012.

49. Cai LN, Zhu SW, Zhou C, Chen BA, Sun J: Analysis on HIV infection status of voluntary blood donors in Chinese Nanjing area from 2003 to 2013. Journal of Experimental Hematology 2014, 22(5):1422-1427.

50. Notice of the General Office of the National Health and Family Planning Commission and the General Office of the Ministry of Finance on Nucleic Acid Test in Blood Stations. In.: NHC; 2015.

51. Technical operation procedures in blood stations 2012 Edition. In. Edited by Comission NH, vol. Art4.2; 2019.
53. Jiang Q: Study on the Relationship between ELISA and NAT in Blood HBV Screening (Chinese). 
Zhejiang Medical Journal 2019, 41(12):1322-1324.

54. Thurn L, Wikman A, Lindqvist PG: Postpartum blood transfusion and hemorrhage as independent 
risk factors for venous thromboembolism. Thrombosis research 2018, 165:54-60.

55. Bolton-Maggs PHB, Watt A: Transfusion errors - can they be eliminated? British journal of 
aematology 2020, 189(1):9-20.

56. Regulation on the Handling of Medical Accidents. In. Edited by Health TMo, vol. Art33,49; 2002.

57. Li H, Zhao X, Li W, Zhao H: Claims and compensation for complications resulting from blood 
transfusions in China from 1998 to 2013. Transfusion and apheresis science : official journal of the 
World Apheresis Association : official journal of the European Society for Haemapheresis 2015, 
53(3):329-336.

58. The function and significance of promulgating and implementing the blood donation law 
[http://www.csbt.org.cn/plus/view.php?aid=6347]

59. Blood safety and availability [https://www.who.int/en/news-room/fact-sheets/detail/blood-safety-
and-availability]

60. Sharma RR, Kumar S, Agnihotri SK: Sources of preventable errors related to transfusion. Vox 
sanguinis 2001, 81(1):37-41.

61. Fastman BR, Kaplan HS: Errors in transfusion medicine: have we learned our lesson? The Mount 
Sinai journal of medicine, New York 2011, 78(6):854-864.

62. Wang Y, Wu Y, Chen Y, Li C, Lu L, AuBuchon JP, Liu Z: The journey toward safer and optimized blood 
service in China: national strategy and progress. Transfusion 2016, 56(12):3112-3120.

63. Opinions on further strengthening blood management [http://www.csbt.org.cn/plus/view.php?
aid=168]

64. Liu Chang q, Shi Xiao f: Study on the revision and improvement of the blood donation law of China: 
From the perspective of the formation of the dilemma of free blood donation and legal response 
(Chinese). Qinghai Social Sciences 2013(05):69-74.

65. Ming-feng Z: Legal Ethics Reflection on Withdawn of Regulation on Mutual Blood 
Donation(Chinese) Medicine & Philosophy 2018, 39(12):23-25.

Figures
Figure 1

Figure 1

[Graph showing the number of donations and volume of blood collected from 1998 to 2018.]

Figure 2

Figure 2
Figure 3

Figure 3

| Year | HBV | HCV | HIV |
|------|-----|-----|-----|
| 1997 | 72  | 22  | 50  |
| 2010 | 59  | 11  | 25  |

Window period (days)

Testing method
- ELISA
- NAT