Epidemiology of hepatitis C virus infection among blood donors in Chinese mainland: systematic review and meta-analysis

Running title: HCV infection among blood donors in China

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Abstract

Background
Blood transfusion is one of the most common transmission pathways of hepatitis C virus (HCV). This paper aims to provide a comprehensive and reliable tabulation of available data on the epidemiological characteristics of HCV infection among blood donors in Chinese mainland, so as to help making prevention strategies and guide further research.

Methods
A systematic review was constructed based on the computerized literature database. The summary estimate and 95% confidence interval (CI) of proportions were calculated by fixed or random effects models using the approximate normal distribution model and Freeman-Tukey arcsin transform. Stratified analyses were performed by area, gender, age, period, way of blood donation, and blood type. The Z test was used to assess the differences among the subgroups. Data manipulation and statistical analyses were undertaken using STATA 10.0 and ArcGIS 9.3 was used for map construction.

Results
Two hundred and sixty-five studies met our inclusion criteria. The pooled prevalence of HCV infection among blood donors in Chinese mainland was 8.68% (95%CI: 8.01%-9.39%), and the epidemic was most severe in North and Central China, especially in Henan and Hebei. While a significant low rate was found in Yunnan. Notably, before 1998 the pooled prevalence of HCV infection was 12.87% (95%CI: 11.25%-14.56%) among blood donors, but decreased to 1.71% (95%CI: 1.43%-1.99%) after 1998. No significant difference was found in HCV infection rates between male and female blood donors, as well as among different blood type donors. The prevalence of HCV infection was found to increase with age. During 1994-1995, the prevalence rate reached the highest with a percentage of 15.78 (95% CI: 12.21-19.75), and showed a decreasing trend in the following years. A significant difference was found between HCV infection and blood donor recruitment methods. Plasma donors had a relatively high prevalence than whole blood donors for HCV infection (33.95% vs 7.9%).

Conclusions
The prevalence of HCV infection has rapidly decreased and kept a lower level since 1998, but still relatively high in some province than the general population. It is urgent to make efficient measures to prevent HCV secondary transmission, and the key to reducing the incidence of HCV among blood donors is to encourage true voluntary blood donors, implement strictly blood donation law and avoid cross-infection.

Key words: hepatitis C virus; infection; blood donors; meta-analysis
**Introduction**

Chronic infection with hepatitis C virus (HCV) is a major and growing public health problem, which could easily leads to chronic liver disease, cirrhosis and even hepatocellular carcinoma [1]. The WHO estimated 170 million persons are infected with HCV worldwide and more than 3.5 million new sufferers annually occurred [2]. According to national epidemiological survey of viral hepatitis from 1992 to 1995 [3], anti-HCV positive rate averages 3.2% in the general Chinese population, amounting to more than 30 million infected individuals.

The rapid global spread of HCV is believed to have occurred primarily because of efficient transmission through blood transfusion and parenteral exposures with contaminated equipment [4]. Blood donors, particularly professional blood donors, had a very high prevalence for HCV infection [5]. Recent studies have reported that the current residual risk of transfusion-transmitted HCV infection in China is about in 40,000-60,000 donations, higher than some of the more developed countries [6]. With the implement of Blood Donation Law in 1998, many blood centers relied on various other methods to motivate donors, mostly on employer-organized blood collection, but the donors were not true volunteers as they may be coerced by the employer to some extent. In recent years, the true voluntary donors are gradually becoming the main source of blood in many blood centers in China [7]. Among paid blood donors, the prevalence has reached 5.7% or higher [8]. However, among employer-organized donors and volunteer donors, the prevalence has ranged between 1.1-2.3%, and 0.46%, respectively [7, 9].

The last 20 years have seen a large amount of studies on HCV infection and its associated risk factors among blood donors. However, many of them drew incompatible or even contradictory conclusion and the utilization of these statistics are limited. This paper reviews on the available studies so as to provide a comprehensive and reliable data on the epidemiological characteristics and risk factors for HCV infection among blood donors in China, and help making prevention strategies and guide further research.

**Methods**

**Literature search**

Studies on the prevalence of HCV among blood donors in China were acquired through searching for published articles from PubMed, Embase, CNKI, and Wanfang
Database on July 2010. In order to search and select related studies, we used various combinations of the key words, including hepatitis C virus or HCV, blood donors, and China or Chinese Mainland.

Selection and data abstraction

All the potentially relevant papers were reviewed independently by two investigators through assessing the eligibility of each article and abstracted data with standardized data-abstraction forms, and disagreement was settled by consensus. The data extracted from the literatures mainly include study ID, although some studies did not contain all the information: first author’s name, publication date, study period, province of sample, blood donor recruitment methods (paid blood donors, employer-organized donors, or true volunteer donors), way of blood donation (categorized as plasma donors and whole blood donors), sampling size, the number of subjects infected with HCV, HBV and HIV, or co-infected with two or three of these virus, gender, age, blood type, and detection index of HCV (anti-HCV or HCV RNA), etc. The inclusion criteria were: (1) studies in above-mentioned databases having full text, without limitation of the language of original text; (2) studies reporting anti-HCV positive rates among blood donors in Chinese Mainland; (3) studies using anti-HCV or HCV RNA for detection index of HCV.

The exclusion criteria were: (1) studies without specific sample origin; (2) studies with overlapping time intervals of sample collection from the same origin; (3) studies having number of samples less than 50; (4) studies presenting confusing data or probable errors.

Statistical analysis

Fixed or random effect model and approximate normal distribution model were used for meta-analysis, taking into account the possibility of heterogeneity between studies which was tested with the Q test and the $I^2$ statistic. The summary estimate and 95% confidence interval (CI) of the HCV prevalence were calculated using the Freeman-Tukey arcsin transform to stabilize variances, and after the meta analysis, researchers transform the summary estimate and the CI boundaries back to proportions using sin function[10]. Stratified analyses were performed by study location, gender, age, study period, blood donor recruitment method, way of blood donation, and blood type. The Z test was used to assess the differences among the subgroups. The Beg rank correlation method was used to assess the potential for publication bias. Data manipulation and statistical analyses were undertaken using the
Statistical Software Package (STATA) 10.0 (STATA Corporation, College Station, TX, USA, 2009), and ArcGIS 9.3 (ESRI, Redlands, California, USA) was used for map construction.

**Results**

According to the literature search strategies, 726 studies (90 studies in PubMed, 636 studies in CNKI and Wanfang database) were finally identified, but 461 studies were removed out in view of the inclusion and exclusion criteria. There were 11 studies in English [8-9, 11-19] and 254 studies in Chinese [20-273] of the left 265 studies.

**General information of samples**

A total of 4,519,313 blood donors aged from 18 to 60 years old were involved, with a wide range of blood donation frequency from 1 to more than 50 times. Besides, the duration of blood donation was generally more than 15 years in our study. The majority of blood donors were men, approximately reached 57.72% (101319/175540), while women accounted for 42.28% (74221/175540). The occupation of blood donors was widely distributed. Voluntary blood donors mainly came from college students, health care providers, office worker, and PLA soldiers, while paid blood donors were chiefly consisted of peasants, low wages of workers, and unemployed.

The origin of samples mainly came from blood banks, CDC, and hospitals. The studies of this review have involved in the following regions: Central China (Hunan, Hubei, Henan), North China (Beijing, Hebei, Shanxi, Tianjin, Inner Mongolia), South China(Guangdong, Guangxi), Northwest (Shanxi, Gansu, Ningxia, Qinghai, Xinjiang), Northeast (Liaoning, Jilin, Heilongjiang), Southwest China (Yunnan, Guizhou, Sichuan, Chongqing), East China (Shandong, Jiangsu, Anhui, Zhejiang, Fujian, Shanghai, Jiangxi), a total of 29 provinces and cities were included.

**Prevalence of HCV infection among blood donors in Chinese mainland Region**

As seen in Table 1 and Figure 1-2, the pooled prevalence of HCV infection among blood donors in Chinese mainland from 1990 to 2010 was 8.68% (95%CI: 8.01%-9.39%). Dramatic geographic differences in pooled HCV infection rates among blood donors have been observed. The epidemic was most severe in North and Central China, where the HCV infection rate were 13.45% (95%CI: 11.41%-15.67%), 14.74% (95%CI: 11.06%-18.80%), respectively. The lowest prevalence was in South China with the rate of 2.88% (95%CI: 2.19%-3.64%). Before 1998, the pooled prevalence of
HCV infection was 12.87% (95%CI: 11.25%-14.56%) among blood donors, and the highest rates were found in Henan (35.04%, 95% CI: 23.62%-47.41%), then Hebei (29.26%, 95% CI: 19.63%-39.98%), but the pooled prevalence decreased to 1.71% (95%CI: 1.43%-1.99%) after 1998.

**Gender**

A total of 79 studies have explored the association between the prevalence rate of HCV infection and gender among blood donors. HCV infection rate of male blood donors was 9.87% (95%CI: 8.26%-11.63%), while female blood donors was 9.78% (95%CI: 7.88%-11.89%), and there was no significant statistical differences between male and female (Z=0.6205, \( P = 0.5352 \)).

**Age**

There were 30 studies referring to the association between the prevalence rate of HCV infection and age among blood donors, and blood donors were divided into two groups by the age of 30 years old. HCV infection rate of aged 18-30 was 4.91% (95%CI: 3.89%-6.05%), while the prevalence rate of aged 31-60 was 8.99% (95%CI: 6.86%-11.37%), and there was significant statistical difference between two groups (Z=66.02, \( P = 0.00 \)).

**Time**

As presented in Table 2, 179 studies were divided into 9 groups according to the study period, and Figure 3 was drew on the prevalence of HCV in each group. During 1994-1995, the prevalence rate reached the highest with a percentage of 15.78 (95%CI: 12.21%-19.75%). Since 1995, the rates showed a decreasing trend among blood donors, and even increased to 0.36% (95%CI: 0.09%-0.81%) during 2006-2010.

**Blood type**

As displayed in Table 3, among blood type A, B, AB, and O donors, the HCV infection rates were 8.18% (95%CI: 4.55%-12.77%), 7.58% (95%CI: 4.26%-11.73%), 8.15% (95%CI: 4.64%-12.54%), and 7.85% (95%CI: 4.64%-11.82%), respectively.

**Donation type**

As seen in Table 4, HCV infection rate of voluntary blood donors and paid blood donors were 0.97% (95%CI: 0.79%-1.16%) and 15.53% (95%CI: 13.28%-17.91%) respectively. There was significant statistical difference (Z=325.651, \( P = 0.00 \)). The prevalence of HCV infection among plasma donors and whole blood donors were 7.90% (95%CI: 6.44%-9.51%), 33.95% (95%CI: 29.80%-38.17%), and there was
significant statistical difference ($Z=142.215$, $P=0.00$).

**Discussion**

As a blood-borne pathogen, HCV virus was frequently detected among blood donors in China during the early 1990s [9]. To improve the safety of blood supply and reduce the risk of transfusion-transmitted diseases, the Chinese government has outlawed the use of paid blood donors since 1998. As a result, Chinese blood banks now rely on various other methods to recruit blood donors, mostly on employer-organized donors and true voluntary donors [274]. This transition in the blood donor recruitment methods has been associated with a gradual decrease in the prevalence of anti-HCV among donors. This review shows that the pooled prevalence of HCV infection among blood donors was 8.68% (95%CI: 8.01% to 9.39%) from 1990 to 2010, significantly higher than the estimate of a 3.2% in the general population of China [1]. It’s noteworthy that before 1998 the pooled prevalence of HCV infection was 12.87% among blood donors, but decreased to 1.71% after 1998.

Our results showed significant geographic difference for the prevalence of anti-HCV. Compared with other regions, North and Central China have relatively high anti-HCV positive rates among blood donors, accounting for 13.45% and 14.74%. Meanwhile, the lowest epidemic rate was found in South China with a percentage of 2.88%. Notably, during the period 1990-1998, the prevalence rates were all commonly high among different regions of China. Especially in Henan and Hebei, the rates were even reached 35.04% and 29.26% respectively. After 1998, the epidemic rates have rapidly decreased due to the government banned illegal blood practice by prohibiting the use of paid blood donors. However, by contrast, it still higher in North and Central China. Considering the reason may be because of larger population migration, poor economic condition, higher HCV infection rates among the general populations, and/or limited samples.

According to national epidemiological survey of viral hepatitis from 1992 to 1995, HCV infection rate among the general population increased gradually with ages, but the prevalence rate had no significant difference between male and female [275], which is consistent with our findings that significant difference has found between two age groups but no gender difference for HCV infection rates among blood donors, indicating that HCV infection has nothing to do with gender, but has positive relation to age. Many reasons such as increased blood donation times, longer duration of
blood donation, and more opportunistic infections with advance of age could explain this relationship [35, 61, 65, 153, and 179].

In recent years, the prevalence rate of HCV infection showed a rising trend among blood donors from 1990 to 1995, but significantly decreased from 1996 to 2010 (Figure 3). Our results revealed an outbreak of HCV infection happened among blood donors around 1995. As before1995, many provinces and cities established lots of plasma collection stations. However, the majority was illegal which existed many nonstandard operations such as lacking strict disinfection, exact detection technology of anti-HCV, and even using non-disposable blood collection needles, serious cross-contamination on plasmapheresis was frequently occurred. In some places, the prevalence rate of HCV had even reached as high as 80% [275]. Since 1995, the government implements strict management on blood stations. Besides, the detection technology of anti-HCV got matured in the following years [276], and the sensitivity and specificity of test reagent kit for HCV had also improved. Especially since 1998, with the implementation of Blood Donation Law of China, the true voluntary blood donors constituted the main source of the blood supply in all major blood banks. Reports on the HCV infection among the true voluntary blood donors in China have been rarely found at present.

Our study showed that among blood type A, B, AB, and O donors, the prevalence of HCV infection were 8.18%, 7.58%, 8.15%, and 7.85%, respectively. No significant difference was found between blood types and the epidemic rate of HCV, indicating that HCV infection has no association with blood type. Our finding was consistent with the studies of Lu KQ [52], Zhou ZD [119], and Pu SF [269]. While it was contrary to the study of Ye C [239], who reported that type O blood donors had a higher infection rate, and type AB showed relatively low rate, but in Rui ZL's study, type A blood donors were reported to have a higher rate [131]. However, the mechanism between blood type and HCV infection remained undefined, which may be related to red cell immune adherence function among persons with different blood types, but it need further study.

Numerous researches confirmed that paid blood donors were strongly associated with HCV prevalence, as compared to voluntary blood donors including employer-organized donors and true voluntary donors. Our result showed that HCV infection rate among paid blood donors was significantly high than voluntary blood donors (15.53% vs 0.97%). As most of the paid donors were mainly attracted by high
compensation, and then chose illegal blood stations which could easily cause cross-contamination. Notably, the prevalence rate among plasma donors was significantly higher than whole blood donors (33.95% vs 7.90%), which may be due to lack strict disinfection and normative operation when collecting plasma, so that potential HCV RNA positive plasma donors caused cross-contamination on fingers of health care workers and/or equipments [77]. The implementation of voluntary blood donation and whole blood donation could contribute to the reduction of HCV infection among blood donors.

Several limitations in our study need to be addressed. First of all, the studies were observational and blood donors were not randomly chosen, selection bias and confounding seems inevitable. Secondly, many of our data were extracted from studies written in Chinese, which makes it difficult for non-Chinese reviewers, editors and readers to recheck the original materials. Thirdly, many studies lacked detailed introductions about representativeness of the selected subjects, and some of studies have no effective data on important factors, which limited our ability to assess study quality. Besides, as with all meta-analyses, this study has the potential limitation of publication bias. Negative trials are sometimes less likely to be published. However, our dates were reliable because of the literatures that we researched were mostly on multi-resources and larger sample sizes, which had reduced this bias to some extent.

In conclusion, this meta-analysis provides a comprehensive and reliable data on the epidemiological characteristics and risk factors for HCV infection among blood donors. The pooled epidemic rate of HCV infection has rapidly decreased after 1998, but still higher in some provinces. Long-term, comprehensive and effective interventions and preventions are urgent needed. In particularly, implementing strictly the “Blood Donation Law” and promoting HCV screening, diagnosis, and treatment among blood donors are very important for controlling the transmission of HCV infection. In addition, the key to reducing the incidence of HCV infection among blood donors is to encourage true voluntary blood donation, pay more attention to exclude those high-risk persons from the volunteers and eradicate completely the cross-infection when collecting single plasma, but it warrants in-depth investigation.

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Competing interests
All authors declare that they have no competing interests.

Authors contributions
XFG, QC, XS and RBY were involved in the design, literature searching, assessment of study quality, and drafted the manuscript. JS and RBY revised critically the manuscript. XFG, QC and ZHP performed statistical analysis and critically revised the manuscript. KQD, NL and XC constructed the maps. LW and NW critically revised original study design and the manuscript. All the authors read and approved the final manuscript.

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272. The domestic parts of the anti-HCV positive rate of blood donors in the investigation.


<table>
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<th>Study location</th>
<th>Province of study</th>
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<th>Before 1998</th>
<th>After 1998</th>
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<td></td>
<td>No</td>
<td>Prevalence % (95%CI)</td>
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</tr>
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<td>11.41(6.12,18.07)</td>
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<td>11.31(3.19,23.49)</td>
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<td>8.68(8.01,9.39)</td>
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</table>

IM: Inner Mongolia; CI: confidence interval
### Table 2 Prevalence of HCV infection among blood donors at different study period

<table>
<thead>
<tr>
<th>Study period</th>
<th>No. of studies</th>
<th>Prevalence of HCV % (95%CI)</th>
<th>Heterogeneity I²</th>
<th>P value</th>
<th>Model</th>
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<td>1990-1991</td>
<td>8</td>
<td>13.42(5.79, 23.62)</td>
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<td>1992-1993</td>
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<td>13.66(9.93, 17.87)</td>
<td>99.70%</td>
<td>0.00</td>
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<td>1994-1995</td>
<td>57</td>
<td>15.78(12.21, 19.75)</td>
<td>99.80%</td>
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<td>1996-1997</td>
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<td>7.34(5.40, 9.54)</td>
<td>99.30%</td>
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<td>REM</td>
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<td>1998-1999</td>
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<td>2000-2001</td>
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<td>2002-2003</td>
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<td>99.50%</td>
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<td>REM</td>
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<td>2004-2005</td>
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<td>1.65(0.56, 3.29)</td>
<td>97.40%</td>
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<td>2006-2010</td>
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<td>0.36(0.09, 0.81)</td>
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</table>

REM: random effect model; CI: confidence interval

### Table 3 Prevalence of HCV infection among blood donors of different blood type

<table>
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<tr>
<th>Blood type</th>
<th>No. of studies</th>
<th>Prevalence of HCV % (95%CI)</th>
<th>Heterogeneity I²</th>
<th>P value</th>
<th>Model</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>13</td>
<td>8.18(4.55, 12.77)</td>
<td>98.80%</td>
<td>0.00</td>
<td>REM</td>
</tr>
<tr>
<td>B</td>
<td>13</td>
<td>7.58(4.26, 11.73)</td>
<td>98.80%</td>
<td>0.00</td>
<td>REM</td>
</tr>
<tr>
<td>AB</td>
<td>13</td>
<td>8.15(4.64, 12.54)</td>
<td>94.90%</td>
<td>0.00</td>
<td>REM</td>
</tr>
<tr>
<td>O</td>
<td>13</td>
<td>7.85(4.64, 11.82)</td>
<td>98.80%</td>
<td>0.00</td>
<td>REM</td>
</tr>
</tbody>
</table>

REM: random effect model; CI: confidence interval

### Table 4 Prevalence of HCV infection among blood donors of different donation types

<table>
<thead>
<tr>
<th>Donation type</th>
<th>No. of studies</th>
<th>Prevalence of HCV % (95%CI)</th>
<th>Heterogeneity I²</th>
<th>P value</th>
<th>Model</th>
</tr>
</thead>
<tbody>
<tr>
<td>voluntary donation</td>
<td>73</td>
<td>0.97(0.79, 1.16)</td>
<td>99.60%</td>
<td>0.00</td>
<td>REM</td>
</tr>
<tr>
<td>paid donation</td>
<td>89</td>
<td>15.53(13.28, 17.91)</td>
<td>99.70%</td>
<td>0.00</td>
<td>REM</td>
</tr>
<tr>
<td>whole blood donors</td>
<td>53</td>
<td>7.90(6.44, 9.51)</td>
<td>98.50%</td>
<td>0.00</td>
<td>REM</td>
</tr>
<tr>
<td>plasma donors</td>
<td>64</td>
<td>33.95(29.80, 38.17)</td>
<td>99.40%</td>
<td>0.00</td>
<td>REM</td>
</tr>
</tbody>
</table>

REM: random effect model; CI: confidence interval
Figure 1 The regional distribution of pooled prevalence of HCV infection among blood donors in China before 1998
Figure 2 The regional distribution of pooled prevalence of HCV infection among blood donors in China after 1998
Figure 3 Prevalence of HCV infection among blood donors at different study period