

Trend Analysis of Hepatitis C Seroreactivity in Voluntary Blood Donors at a Stand-Alone Blood Centre: A Retrospective Study

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Abstract

Background: Hepatitis C virus (HCV) is a major transfusion-transmitted infection and remains an important public health concern. Blood donor screening is essential for ensuring blood safety. This study aimed to determine the seroprevalence of HCV and analyse its temporal trend among voluntary blood donors at a standalone blood centre in Ahmedabad district, Gujarat, over a six-year period.

Methods: A retrospective record-based study was conducted at stand-alone blood centre in Ahmedabad District, Gujarat, India, over a six-year period from January 2020 to December 2025. Data from all voluntary blood donors who successfully donated blood during the study period were included. Donor blood samples were initially screened for anti-HCV antibodies using a third-generation Enzyme-Linked Immunosorbent Assay (ELISA). Initially reactive samples were retested and confirmed using Chemiluminescent Microparticle Immunoassay (CMIA). The collected data were analysed to calculate annual and overall HCV prevalence and to observe changes across the study years.

Results: A total of 332,639 blood donations were analysed. Overall, 230 donations were confirmed HCV reactive, giving a prevalence of 0.069%. Annual prevalence ranged from 0.039% to 0.111%. The highest prevalence was observed in 2025. While the overall prevalence remained low, an increase in HCV-reactive donations was observed during 2024 and 2025.

Conclusion: The findings demonstrate that HCV seroreactivity among voluntary blood donors remained consistently low over the six-year study period, reflecting the effectiveness of existing blood safety measures. The late increase in seroprevalence highlights the need to monitor local donor demographics and evaluate whether supplementary testing methods like nucleic acid testing (NAT) should be integrated to reduce window-period risks.

Keywords: Hepatitis C virus, Voluntary blood donors, seroprevalence, ELISA, CLIA, transfusion-transmitted infections

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Manuscript Body

Introduction

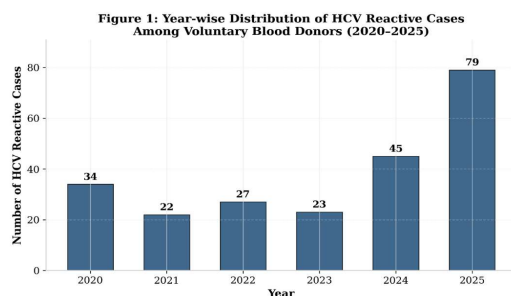
Hepatitis C virus (HCV) is a blood-borne pathogen responsible for causing both acute and chronic hepatitis worldwide. Hepatitis C continues to be an important public health problem worldwide. World Health Organization (WHO) estimating that approximately 58 million people live with chronic hepatitis C, and about 1.5 million new infections occur annually ^[1]. The virus is predominantly transmitted through exposure to infected blood, with parenteral routes including unsafe injection practices, needle sharing among people who inject drugs, unsafe healthcare procedures, and transfusion

of unscreened blood and blood products representing the principal modes of spread ^[2].

Although blood donor screening has improved considerably over the years, transfusion-transmitted infections continue to remain a concern in donor screening technologies and the implementation of stringent selection protocols. It continues to remain an important challenge, particularly in resource-limited settings. ^[3,4]

Gujarat, a western Indian state with a population exceeding 60 million, has a well-established network of blood centres; nevertheless, data on HCV seroprevalence among blood donors from this

Trend Analysis of Hepatitis C Seroreactivity in Voluntary Blood Donors at a Stand-Alone Blood Centre: A Retrospective Study



region remain sparse. Ahmedabad district, being the most populous district in the state and an industrial hub, attracts people from different regions, which may influence the pattern of infectious diseases among blood donors. Standalone blood centres, which operate independently, cater to a substantial proportion of voluntary donors and play a crucial role in the regional blood supply chain [5].

This study evaluated HCV seroprevalence among voluntary blood donors at a standalone blood centre in Ahmedabad over a six-year period (2020–2025). Secondary objectives included analysing temporal trends in seroprevalence, evaluating year-to-year variations, and comparing the prevalence between the first and second halves of the study period.

Materials and Methods

This is a retrospective, cross-sectional study conducted at a standalone blood centre located in Ahmedabad district, Gujarat, India. The study period encompassed six consecutive calendar years, from January 2020 to December 2025. The study population included all voluntary blood donors during the specified period. Donors were screened through a structured pre-donation questionnaire, physical and medical examination. Only donors who fulfilled the eligibility criteria and consented to blood donation were included in the analysis.

Method

All blood samples collected from eligible donors were screened for mandatory transfusion-transmitted infections, including HCV. All donor samples were initially tested for the presence of anti-HCV antibodies using a third-generation ELISA kit used routinely in the blood centre. All ELISA-reactive samples were subsequently subjected to confirmatory testing using the chemiluminescence immunoassay (CLIA) method.

Ethical Consideration

This study involved the retrospective analysis of anonymised data routinely collected during mandatory donor screening at a standalone blood centre. No direct patient interaction, intervention, or identifiable information was used. All data were fully de-identified before analysis, ensuring complete donor anonymity and confidentiality.

Results

HCV Seroprevalence

During the six-year study period, a total of 332,639 voluntary blood donors were screened for HCV

infection at the standalone blood centre. Annual donations increased by 77.2% over the study period, rising from 40,224 units in 2020 to 71,262 units in 2025. Of the 332,639 donors screened, 230 were confirmed to be HCV reactive. The overall seroprevalence of HCV among voluntary blood donors was calculated as 0.691 per 1000 donors, which translates to 0.069% of the total donor population. (Table 1)

Table 1: Year-wise Data of Blood Donations and HCV Seroprevalence (2020–2025)

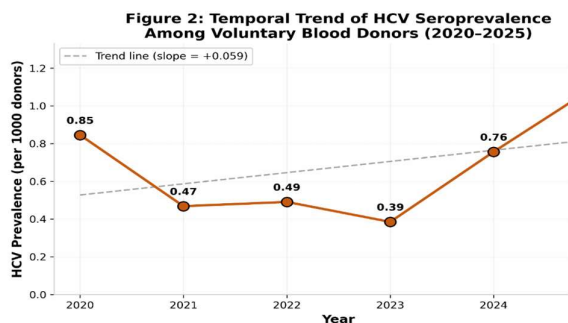
Year	Total Donors Screened	HCV Reactive Cases	Prevalence (per 1000)	Prevalence (%)
2020	40,224	34	0.845	0.085
2021	46,963	22	0.468	0.047
2022	54,997	27	0.491	0.049
2023	59,701	23	0.385	0.039
2024	59,492	45	0.756	0.076
2025	71,262	79	1.109	0.111
Total	332,639	230	0.691	0.069

The year-wise seroprevalence showed year-to-year variation over the study period. The highest prevalence was recorded in 2025 (1.109 per 1000), followed by 2020 (0.845 per 1000) and 2024 (0.756 per 1000). The lowest prevalence was observed in 2023 (0.385 per 1000). The mean annual prevalence was 0.676 per 1000, with a standard deviation of 0.277.(Figure 1)

Trend Analysis of Hepatitis C Seroreactivity in Voluntary Blood Donors at a Stand-Alone Blood Centre: A Retrospective Study

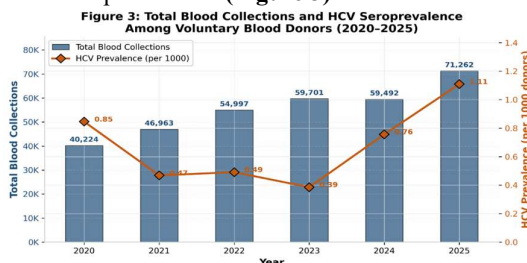
Temporal Trends

Linear regression analysis revealed a slight increasing trend of +0.059 per 1000 donors per year, indicating a gradual increase over time in HCV seroprevalence over the six-year period. However, this trend did not reach statistical significance ($r = 0.400$, $R^2 = 0.160$, $p = 0.432$), indicating that year alone explained only 16% of the variance in prevalence. Despite the non-significant linear trend, the chi-square test across all six years yielded a highly significant result ($\chi^2 = 34.367$, degrees of freedom = 5, $p < 0.001$), confirming that the observed variations in HCV reactivity were statistically significant across the study period. (Figure 2)



Period-wise Comparison

To compare temporal trends, the data were divided into two three-year periods (2020–2022 vs. 2023–2025), the first half (2020–2022) recorded 83 reactive cases out of 142,184 donors (0.584 per 1000), whereas the second half (2023–2025) recorded 147 reactive cases out of 190,455 donors (0.772 per 1000). The two-proportion z-test revealed a statistically significant difference between these periods ($z = -2.042$, $p = 0.041$), indicating that the latter triennium experienced a significantly higher HCV seroprevalence. (Figure 3)



Year-over-Year Changes

The most dramatic shifts occurred during the final two years of the study. Between 2023 and 2024, the prevalence surged by 96.3% (from 0.385 to 0.756 per 1000), and between 2024 and 2025, it rose by an additional 46.6% (from 0.756 to 1.109 per 1000). Conversely, the period between 2020 and 2021

witnessed a 44.6% decline in prevalence (from 0.845 to 0.468 per 1000).

Discussion

Among more than 332,000 voluntary blood donations screened over six years, only 230 were confirmed positive for HCV, corresponding to an overall seroprevalence of 0.069%. This low prevalence suggests that the donor selection process and routine screening programme are working effectively. This finding is comparable with findings reported in other Indian studies from India that have documented HCV seroprevalence among blood donors in the range of 0.05% to 0.15% [06,07].

The most notable finding of this study is the significant rise in HCV seropositivity during 2024 and 2025. After recording the lowest prevalence in the series (0.385 per 1000) in 2023, the centre showed almost a two-fold increase in 2024 (0.756 per 1000) and a further 46.6% rise in 2025 (1.109 per 1000). The statistical comparison between the first and second triennia confirmed that this increase was not a random fluctuation ($p = 0.041$).

From a transfusion safety perspective, our findings reinforce the importance of maintaining vigilant donor screening practices. Even with a seroprevalence below 0.1%, the absolute number of HCV-infected units entering the blood supply—if undetected—may increase the risk to recipients. The window period of HCV infection, during which antibodies are not yet detectable, continues to be a challenge with serological screening alone [08]. Although nucleic acid amplification testing (NAT) is not universally implemented in Indian blood centres due to cost constraints, its introduction in high-throughput centres could further reduce the residual risk of transfusion-transmitted HCV [09].

Conclusion

This six-year retrospective analysis of 332,639 voluntary blood donors at a standalone blood centre in Ahmedabad district showed an overall HCV seroprevalence of 0.691 per 1000 donors, which is consistent with national benchmarks for voluntary donor populations. However, the statistically significant increase in seroprevalence observed during 2024 and 2025—from 0.385 per 1000 in 2023 to 1.109 per 1000 in 2025—should be monitored closely and explored further. The reason for this increase is not clear and may be related to changes in donor characteristics or community prevalence.

Blood centres must continue to enforce rigorous donor selection protocols, continue using sensitive screening methods such as the ELISA-CLIA combination, and maintain meticulous surveillance of seroprevalence trends. Maintaining strict donor screening protocols and exploring supplementary testing strategies will be essential to further improving blood safety in this population [10,11].

References

Trend Analysis of Hepatitis C Seroreactivity in Voluntary Blood Donors at a Stand-Alone Blood Centre: A Retrospective Study

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