

Effect of COVID-19 Vaccine on Blood Donor Deferral Patterns in PIMS, Islamabad

Farwa Sijjeel¹, Ahmaren Khalid², Muhammad Yousaf Khan³, Nayab BiBi⁴, Aisha Tahir⁵, Zoobia Mushtaq⁶, Basharat Nawaz⁷, Sana Khalil⁸

¹ Assistant Professor, Department of Pathology/Blood Bank (Hematology), PIMS Islamabad Pakistan
Manuscript writing, Data collection

² Associate Professor & HOD, Department of Pathology, PIMS Islamabad Pakistan
Data Analysis

³ Biochemist/Manager, Department of Pathology/Blood Bank, PIMS Islamabad Pakistan
Discussion Writing

⁴ MS Scholar, Department of Biochemistry & Molecular Biology, COMSATS University Islamabad Pakistan
Abstract Writing

⁵ MS Scholar, Department of Biochemistry & Molecular Biology, COMSATS University Islamabad Pakistan
Critical Analysis

⁶ Principal Medical Officer, Department of Gynecology, NDC Medical Center Islamabad Pakistan
Critical Analysis

⁷ Manager, Department of Pathology/ Blood Bank, PIMS Islamabad Pakistan
Data Analysis

⁸ MS Scholar, Department of Biochemistry & Molecular Biology, COMSATS University Islamabad Pakistan
Discussion Writing

CORRESPONDING AUTHOR

Muhammad Yousaf Khan
Biochemist/ Manager, Pathology Department/ Blood Bank, PIMS, Islamabad, Pakistan
Email: yousafqau@gmail.com

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ABSTRACT

Objective: To evaluate the effect of COVID-19 vaccine on overall donor deferral patterns in PIMS, Islamabad. **Study Design:** Cross-sectional descriptive study. **Settings:** This study was carried out at Blood Bank of Pakistan Institute of Medical Sciences (PIMS), Islamabad Pakistan. **Duration:** January 2019 to December 2021. **Methods:** The participants for donation were included in this cross-sectional study on the basis of certain criteria by taking their previous medical history physical examination, COVID-19 vaccination status, and screening results transfusion-transmissible infections (TTIs). All those donors who don't meet the criteria were deferred. On the basis of causes, deferrals were categorized into temporary or permanent. **Results:** This study included a total of 84,669 potential donors during a period of three years (January 2019-December 2021), out of which 82,072 donors met inclusion criteria and donated blood during this period whereas 2597 donors were deferred. The overall deferred rate was 3.2% (n=2,717), out of which 13% (n=342) were deferred permanently and 87% (n=2375) were deferred temporarily. The leading cause of permanent deferral includes hepatitis C (n=142), hepatitis B (n=106) and cardiac diseases (n=94). On the other hand, leading causes of temporary deferrals include COVID-19 vaccination, being under weight, underage, low HB, short gap, fatty veins and fever. **Conclusion:** The identification of deferrals is an important step for safe transfusions and helps to formulate criteria for efficient donor selection. The current study indicates a 3.2% deferral rate for blood donors and demands preventive steps for both donor and patient safety against HBV, HCV and AIDS.

Keywords: Blood safety, Donor deferral, COVID-19 vaccine.

INTRODUCTION

Blood transfusion is a life-saving procedure in which donated blood replaces lost blood due to trauma, surgery and anemia. World Health Organization (WHO) has included blood in the Model List of Essential Medicines, comprising medicines whose availability is important and must be assured of quality.¹ A blood bank is such an establishment that serves the purpose of blood

supply at the time of need to ensure all the safety precautions. Blood establishments maintaining an adequate supply of blood and blood components need an appropriate donor population.²

The screening of blood donors prior to donation is performed with the purpose of maintaining a safe blood supply. Donor selection mostly consists of four steps like Pre-donation information, Donor Health Questionnaire,

Donor interview, and Donor health assessment.³ A deferral usually happens when a blood donor does not meet the eligibility criteria for donating blood. Deferrals help in protecting the health of both donor and the recipient. Similarly, blood donation is not accepted from someone who has recently traveled from pandemic hit areas.⁴

Blood donor deferral can be of two categories, i.e., Permanent deferral and temporary deferral. Permanent donor deferral happens due to multiple reasons including AIDS, epilepsy, intravenous drug abuse, hepatitis B & C, and chronic diseases. Whereas temporary deferral results from a recent viral infection, vaccination, dental extraction, anemia, tattoos, fever, malaria, flue, and short interval between blood donations.⁵

According to World Health Organization (WHO) databases, about 10% of donors are rejected due to anemia worldwide.⁶ Moreover, the WHO database of blood donor deferral reveals that out of 92 million blood unit donations per year from 164 countries, 1.6 million units are deferred.⁷

Infectious diseases are the crucial elements that are taken into account while screening the blood donor population. In December 2019, an infectious disease was discovered in Wuhan China known as Corona virus disease 2019, (COVID-19).⁸ COVID-19 which is characterized by fever, tiredness, cough, and loss of taste requires the patients to be isolated for about 14 days.⁹ COVID-19 structure comprised of spike proteins. The accountabilities of these proteins are to negotiate with host cells and aid COVID-19 to pass through the cell membrane of epithelial cells. The rationale of current study is to analyze the effect of COVID-19 vaccine on donor deferrals patterns in blood bank PIMS, Islamabad.¹⁰

An extensive range of vaccines are accessible in the world. Different vaccines used for COVID-19 are Sinopharm and Sinovac.¹¹ The most common COVID-19 vaccine like Sinopharm is presently accessible. Sinopharm is an inactivated vaccine including the entire virus parts and is sure to be effective in view of a scenario that is becoming more complex because of the rise in variations in the virus put via genetic variations linked to the greater spreading of viruses as well as, some cases, suppressing antibodies escape.¹²

The vaccine like Sinopharm, which is made from a deactivated entire virus, provides a variety of benefits, such as inexpensive production, protection, and the absence of genetic modification. This strategy makes use of technologies that have proved to be very effective, like the vaccines against polio and influenza. The vaccine should be kept at 2 to 8 °C in storage; however, it needs to be shielded by light.¹³

After vaccination blood donors were considered as temporary deferral because the vaccine can induce immune thrombotic thrombocytopenia (VITT) as CBC shows the symptoms like elevated D-dimer, blood clot or bleeding, low platelets, less than $150 \times 10^9 /L$.¹⁴ The aim of this study is to evaluate and analyze the effect of Sinopharm vaccine on blood donor deferral patterns moreover its causes mainly from the COVID-19 affected blood donors in the blood bank of Pakistan Institutes of Medical Sciences (PIMS), Islamabad and to review its influence on blood safety.

METHODS

This cross-sectional study was accomplished for a period of three years from January 2019- December 2021 at Blood Bank of Pakistan Institute of Medical Sciences (PIMS), Islamabad. PIMS is a medical research center of health sciences situated in Islamabad. It is one of the Islamabad main higher-level hospitals containing 22 surgical and medical centers. This blood bank center is dealing with the recruitment of blood donors, screening of blood donors, and collection of blood and supply of donor's blood to the health services in the region. This study was done after taking approval from the Ethical Committee of the PIMS Hospital, Islamabad. All the recorded data and taken information was used only for research purpose.

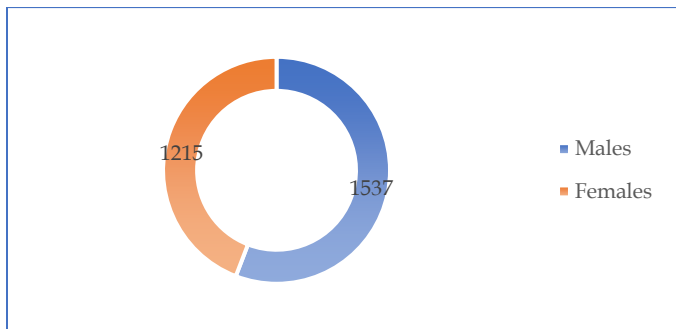
The donors were selected based on inclusion criteria which was age (> than 18 and < than 60 years), weight above 50 kg, hemoglobin (about 12.5g/dl), physical checkup, case history and medical fitness. The exclusion criteria were underage, underweight, anemic, infectious diseases (like Hepatitis B & C, AIDS), chronic diseases (like heart, kidney and liver disease), flu, fever, COVID-19, medication, malaria, recent blood donation history and surgery. The details of blood donor's record taken from PIMS; Islamabad includes donor medicinal history, Performa, physical checkup (like, Hb estimation), Transfusion Transmissible Infections screening results and assessment on the basis of temporary and permanent deferral.

Donors with invisible veins are not able to donate blood and they are not included in the deferral category because they do not have any other disease. The recorded data from blood bank PIMS, Islamabad was shifted to an MS Excel spreadsheet. Later on, analysis of taken data was done via Statistical Package for the Social Sciences (SPSS). Descriptive information has been carried out to examine records and frequency. Cross-tabulation has been drawn and the statistics have been defined in figures and percentages. Pearson Chi-square test was applied to determine the relation between deferral and accepted donors. Results of dissimilarity have been classified as statically significant which shows a p-value less than 0.05.

RESULTS

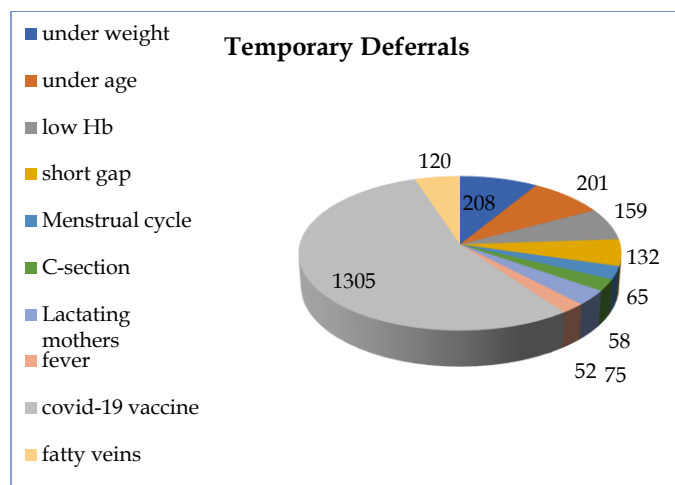
A total of 84,669 potential donors were presented for blood donation during the study period of three years. Out of which 82,072 donors met the inclusion criteria and donated their blood. Remaining 2,597 donors were deferred. The deferral rate of 3.2% represents retrospective whole blood donors deferred among all the donors who reported in PIMS, Islamabad. The donors who donated blood belonged to either the voluntary non-remunerated blood donor (VNRBD) category including 2% (n=1,478) or the replacement donor category including 98% (n=80,594). All the donors included in the current study were between 18 to 65 years. Among the donors, the majority were males 97% (n=79,612) and fewer females 3% (n=2460) because of the menstrual cycle, lactation and C-sections. The percentage of males deferred was 56% (1537) whereas for females were 44% (1215) showing fewer female donations as data represents most of our donors are males as considered strong and they are mostly attendants along with the patients admitted in hospital whereas female donors are quite rare in the above-mentioned case. That's why chances of male deferral are far higher than females as mentioned in our respective data.

Figure 1: Pie chart illustrates more males 1537(56%) were deferred represented by blue color as compare to females 1215(44%) represented by red color



Total combined analysis of deferrals i.e. permanent and temporary is depicted in figures below. Among these deferred patients, 13% (n=342) were permanently deferred whereas 87% (n=2375) were temporarily deferred in which are major portion involved patient deferred due to immediate COVID-19 vaccination. Out of all temporary deferrals, 55% (n=1305) were deferred because of COVID-19 vaccination, 9% (n=208) were underweight, 8% (n=201) were underage, 7% (n=159) due to low Hb, 6% (n=132) due to the short gap (inter-donation interval less than 2 months), 5% (n=120) were deferred due to fatty veins (thickening of underline skin), 3% (n=65) women because of menstruation, 2% (n=58) women's have recently gone through C-section, 3% (n=75) women's were lactating mothers and 2% (n=52) were deferred due to fever.

Figure 2: Pie chart representing multiple causes of temporary deferrals in which COVID -19 was major one before the availability of vaccine in March 2021



The most common cause of permanent deferrals includes Hepatitis C 42% (n=142), Hepatitis B 31% (n=106) and cardiac diseases 27% (n=94).

Figure 3: Pie chart representing causes of permanent deferrals in which hepatitis C (42%) was seen as leading cause followed by hepatitis B (31%) and cardiac diseases (27%)

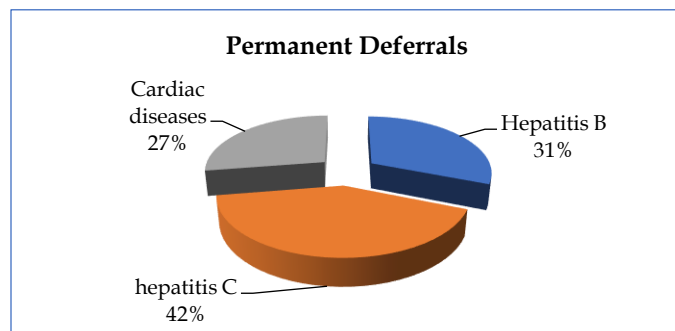
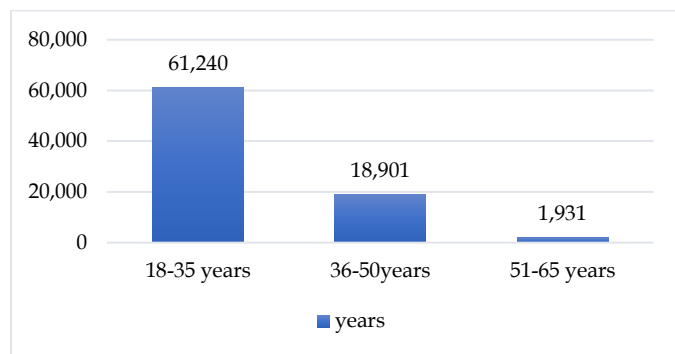


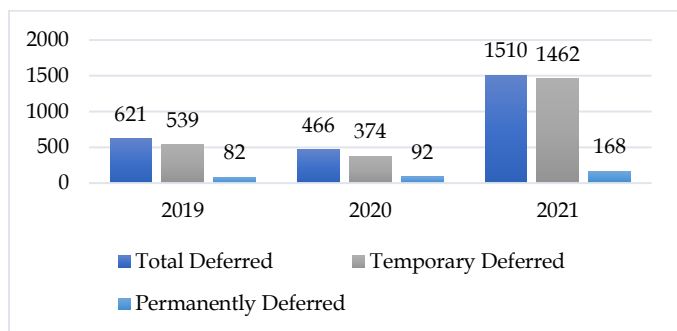
Figure 3: Bar chart showing age wise distribution of donors deferred within a period of three years



The figure below presents the overall deferred rate over the retrospective period of three years i.e., 2019, 2020 and 2021. It shows a certain rise in deferred cases due to the COVID-19 vaccine started in March 2021. In the first two years of the study, percentage of total deferred and

temporary deferral cases were far less than after the introduction of vaccine.

Figure 4: Column chart showing total deferred, temporary deferred and permanent deferred cases over the span of three years from 2019 to 2021



DISCUSSION

Before donation, counseling of donor and screening of certain parameters through a questionnaire is an important process for safe blood transfusion and recruitment of voluntary non-remunerated donors. All the deferred donors were informed about the reason for their deferral.

Deferral patterns in various blood centers around the world are reported from 4.3% to 35.6% whereas it ranges from 7.4% to 25.2% in studies conducted in Pakistan. This difference exists due to different selection criteria in different regions like India, UAE, Tanzania and Nigeria.¹⁵

In the current study conducted over the period of 3 years, deferral rate of blood donors was about 3.2% as compared to other studies carried out in Pakistan ranging from 6% to 25% as given in below Table 2 regions and this study showed lowest recorded deferred rate among all studies conducted in Pakistan.

The leading cause of permanent deferral in our study was hepatitis C (42%) followed by hepatitis B (31%). These results are concurrent with earlier national findings in Rawalpindi¹⁶ and in Mandibahudin,¹⁷ but our results are contradictory with some previous national studies carried out in Peshawar¹⁸ and in Karachi.¹⁹ Contradiction also exists with international findings carried out in Tanzania and Nigeria where Hepatitis B was the leading cause of permanent deferral.

In the current study, major cause of temporary deferral was covid-19 vaccine which was not reported in previous studies. There are various blood deferral periods after covid-19 vaccination recommended by various organizations but we take WHO as the most authentic one and deferral period according to WHO was 28 days after live covid-19 vaccine and 7 days after inactivated covid-19 vaccine.²⁰

Table 1: Deferral percentage with common causes in studies from other countries

| Author and city | % Deferrals | Common causes |
|--|-------------|---|
| Shrivastava <i>et al.</i> , (2016) ²¹ India | 11.5% | History of jaundice (28.2%), low hemoglobin (19.4%) |
| Al Shaer <i>et al.</i> , (2017) ²² UAE | 19.4% | Low hemoglobin (9.29%), high blood pressure (2.22%), medical diagnosis |
| Valerian <i>et al.</i> , (2018) ²³ Tanzania | 12.7% | Hepatitis B (29.6%), low hemoglobin (21.1%), HIV (13.3%), syphilis (9.3%) |
| Okoroiwu <i>et al.</i> , (2019) ²⁴ Nigeria | 8.69% | Hepatitis B (31.71%), anaemia (21.95%), hepatitis C (18.90%) |

Table 2: Deferral percentage with common causes in studies from Pakistan

| Author and city | % Deferrals | Common Causes |
|--|-------------|---|
| Nadeem <i>et al.</i> , (2016) ¹⁶ Rawalpindi | 7.4% | Hepatitis C (28.6%), anemia (24%), hepatitis B (16.8%), syphilis (10.4%) |
| Iqbal <i>et al.</i> , (2020) ²⁵ Multan | 12.9% | Anemia (50.3%), hepatitis C (19.2%), hepatitis B (11.3%), syphilis (8.3%) |
| Saeed <i>et al.</i> , (2020) ¹⁷ Mandi Bahauddin | 25.2% | Hepatitis C (13.3%), hepatitis B (6.1%), syphilis (4.0%), malaria (2.4%) |
| Saba <i>et al.</i> , (2020) ¹⁸ Peshawar | 6.37% | Hepatitis B (30.38%), hepatitis C (21.59%), syphilis (14.16%), low hemoglobin (8.28%) underweight (5.97%) |

In our study major contribution of donors were replacement donors 98%(n=80,594) whereas very few belong to voluntary non-remunerated blood donors which were only 2%(n=80,594). This may happen because of lack of adequate knowledge among our population and also associated myths that after donation one might become weak or may get infection.²⁶ It was contradictory to one of study by Kasraian L *et al* where there was more voluntary donation as compared to replacement donations.¹⁵

The major population of donors included in our study was males about 98% as males were considered more suitable for donations and secondly factors like menstruation, lactation, and anemia were deteriorating factor and led to decrease the number of female donations. It was also reported in study where females were hesitate to donate blood because of multiple reasons like pregnancies, beliefs, anemia and life style.²⁷ This will in turn affect the outcome of the study.

CONCLUSION

This study concluded that deferral rate was lower initially as compared to previous studies conducted but there was a sudden rise in temporary deferrals which in turn has huge impact on overall deferrals. It was due to induction of COVID-19 vaccine during this period.

LIMITATIONS

Limitations faced in study include resemblance of COVID-19 symptoms with common viral flu; therefore donor showing symptoms was temporarily deferred because of flu like symptoms. Other limitation was deferral due to Hepatitis B and Hepatitis C beyond Covid-19.

SUGGESTIONS / RECOMMENDATIONS

Multicenter trials are required to have more generalizable results.

CONFLICT OF INTEREST / DISCLOSURE

None.

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