Review Article

Impact of COVID-19 on transfusion care of patients with hemoglobin disorders in India

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Abstract: As we navigate the first pandemic of our generation, we've been learning and adapting ourselves to this viral infection and its consequences. It's been more than two years since the World Health Organization (WHO) declared coronavirus disease 2019 (COVID-19) pandemic, and the virus has crippled the healthcare services in almost all the countries of the world. The healthcare systems in various parts of the world are still in the phase of recovery from the effect of the pandemic, as each country is witnessing the emergence of various variants causing multiple waves of infection. As an important part of the health care system, blood banks were one of the affected services. Most of the blood centers in India reported a significant reduction in blood donation during the COVID-19 pandemic. As transfusion services constitute a crucial backbone for the management of transfusion-dependent patients with hemoglobinopathies, the substantial reduction in the timely blood supply drastically affected these patients. All major healthcare centers in India were designated as COVID-19 care centers, which left very few options for these patients to visit for their routine care. Every country managed this acute blood shortages and developed unique strategies to support patients requiring blood transfusion. This manuscript aims to provide a snapshot of the challenges faced by the blood banks and transfusion services in India in the care of patients with hemoglobinopathies, and the mitigation strategies that were adopted.

Keywords: Coronavirus disease 2019 pandemic (COVID-19 pandemic); hemoglobin disorders; transfusion; blood supply

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Introduction

The coronavirus disease 2019 (COVID-19) pandemic has posed many unprecedented challenges to the healthcare systems worldwide. The World Health Organization (WHO) declared the COVID-19 pandemic in March 2020. Most countries struggled to contain the infection and treat the infected individuals. Strategies adopted included travel restrictions and lockdowns, resulting in significant challenges for the care of non-COVID patients (1). The reduction in blood donation and challenges in transfusion

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care were reported by many regions of the world (2-8). A multi-center survey run by the Thalassemia International Federation (TIF), including 42 countries, showed moderate to severe blood shortage during the COVID-19 pandemic, specifically in developing nations, while the impact in western countries was mild to nil despite initial blood shortages (9). The same survey showed a drop in pretransfusion hemoglobin (Hb) levels up to 5g/dL or lower in beta-thalassemia patients in developed countries during the pandemic (9).

In India, patients suffering from chronic illnesses, such as malignancies and Hb disorders, were among the most affected (3,10,11). Aside from travel restrictions, the significant decrease in blood donations made it difficult to receive regular transfusions. A tertiary care institute from India reported a 56% reduction in total transfusion sessions to patients with Hb disorders during the early phases of the pandemic in 2020 (April to June) compared to the same period in 2019 (12). This article aims to provide an overview of the challenges faced by the blood banks and transfusion services in India caring for patients with Hb disorders and the mitigation strategies adopted to overcome them.

The Hb disorders

Hb disorders are broadly classified into two; caused by quantitative defects such as α-thalassemia (α^+ α^0 thalassemia, Hb H and Hb Bart's) and β-thalassemia (β thalassemia minor/intermedia/major), and caused by point mutations in the β globin genes, resulting in Hb variants such as sickle cell disease (SCD) (Hb S; S/β thalassemia; Hb S/C), Hb E and Hb D (13,14).

These disorders are prevalent in tropical and subtropical regions of the Mediterranean region, South Africa, South and Southeast Asia, the Middle East, and the Pacific islands (14). With increasing migration, Hb disorders are now seen in more than 71% of countries (14). The 2008 WHO survey estimated that 5.2% of the world population carry a significant Hb variant (Hb S/C/D/E, β thalassemia, α^0 thalassemia), with 40% being Hb S trait. In addition, 20% of the world population carries an α^+ Hb variant. About 1.1% of couples worldwide are at risk of giving birth to a child carrying a significant Hb disorder, and 3.4% of early mortality (under 5 years of age) is due to Hb disorders (14). SCD is one of the commonest inherited Hb disorders that present with well-described complications such as acute chest syndrome (ACS), vaso-occlusive crisis (VOC), chronic hemolysis, priapism, and stroke (15).

The Hb disorders in India and their burden

Earlier reports reported a 1.2 per 1,000 births (accounting for approximately 32,400 annual births) prevalence rate of significant Hb disorders in India (16). α-thalassemia, β-thalassemia and sickle cell disorders outnumber the other Hb disorders. The average prevalence of α-thalassemia and carriers of β thalassemia is 10–25% and 3–4%, respectively, with a maximum of 1–9% in Maharashtra and Gujrat states (17,18). Several ethnic groups have a much higher prevalence of these disorders due to consanguineous marriage and the natural selection pressure due to malaria prevalence (19,20). Hb S is common in tribes and communities in specific parts of the country with a prevalence rate of 5–35% (17). Hb E is common in the Northeastern states with a carrier frequency of 3–50% (17). Blood transfusion is required as a cornerstone in managing patients with Hb disorders. However, such a huge patient load causes a significant burden on transfusion services in the country.

Blood banks and transfusion services in India and challenges faced during COVID-19 pandemic

Government of India defines a "Blood Centre" as a premise in an organization or institution, authorized for carrying out all or any of the operations including collection, apheresis, processing, storage, and distribution of blood drawn from donors or received from another licensed Blood Centre and for preparation, storage, and distribution of blood components. For this review the term "Blood Centre" and "Blood Bank" are used interchangeably. Blood banks and transfusion services in India have their unique challenges. These challenges were further augmented during the COVID-19 pandemic, besides the new challenges due to the nature of the pandemic (*Table 1*).

Organizational challenges

India has a very diverse and decentralized system of blood establishment/blood bank services, with more than 3,300 blood centers across the country, collecting approximately 12.2 million units annually (21-23). These blood centers function independently and differ in organization type [hospital-based (teaching/non-teaching institutions) or stand-alone] and annual blood collection numbers (from

Table 1 Challenges for blood centers and transfusion services in India during the COVID-19 pandemic

Existing challenges (pre-COVID-19 era) that were augmented during the pandemic
Decentralisation of blood establishments/blood banks
Non-availability of large pool of voluntary blood donor base
Non-availability of centralized component preparation facilities
Variabilities in TTID testing methods
Lack of adequate/standard transfusion facilities in some hospitals
Lack of patient blood management program
Unique new challenges during the pandemic
Motivating and mobilizing voluntary blood donors
Inventory management
Consumable and logistic supply chain
Ensuring donors and staff safety

COVID-19, coronavirus disease-19; TTID, transfusion transmitted infectious disease.

less than 5,000 to as high as >80,000 donations per year). Decentralization has also led to a wide range of quality and performance variations depending on each center's geography (rural *vs.* urban) and infrastructure.

Most of the blood transfusion facilities are in either cities or district headquarters, while many far-off rural areas of the country lack blood transfusion services or blood centers with manufacturing facilities. Home transfusions are not practiced in India, limiting this option to patients with Hb disorder. Therefore, visiting a hospital/transfusion center is required to receive a transfusion. With the sudden cessation of routine out-patient care during COVID-19 pandemic, it was difficult for patients with Hb disorders to get their blood transfusions at the required frequency.

Decline of blood donations

Blood centers in India largely depend on replacement or family donations. Due to the lower proportion of voluntary donations, a regular supply of blood and blood components for chronically transfused patients, such as patients with Hb disorders and cancer, is challenging. During the COVID-19 pandemic, the Government of India granted permission to all blood centers (governmental, private, and stand-alone) to organize blood donation campaigns to increase voluntary blood donation in the country. Despite the growth of the recruitment programs for voluntary blood donation during the pandemic, a huge decline in the blood donation rates due to the inherent fear of acquiring the infection during blood donation was reported (4).

Inventory management

Inventory management during the COVID-19 pandemic was very challenging due to the sudden decrease in blood supply. The government allowed the transfer of surplus blood and components from one blood centre to another, but the country's significant geographical diversity made it difficult. In addition, non-uniform component preparation procedures in different blood collection facilities further complicated inventory management and component distribution. According to the National AIDS Control Organization (NACO) report, 34% (1,131 out of 3,311) of blood centers in India are government-supported and process 78% of the total collection into components such as packed red blood cells, platelet concentrates, and fresh frozen plasma, owing to the limited resources (23).

Variabilities in testing methods on donated blood across the country

Blood donor testing for human immunodeficiency virus (HIV)-1 & -2, hepatitis C virus (HCV), hepatitis B virus (HBV), Malaria, and Syphilis is mandatory in India. However, owing to the decentralization and variable resources, testing methods vary from rapid antigen/antibody tests to enzyme-linked immunosorbent assay (ELISA), chemiluminescence tests, and nucleic acid amplification tests (NAT). Due to this variability, transfusion-transmitted infections (TTIs) have been reported in patients with Hb disorders in India. Many studies from India reported TTI seroprevalence rates in this group of patients of 2.2–5.1%, 1.2–7.4%, and 0–9% for HCV, HBV, and HIV viruses, respectively (24-26).

Blood grouping and cross match methods in India range from manual tube/slide to fully automatic testing. Previous studies reported higher alloimmunization and autoimmunization rates in SCD and thalassemia patients (27-30). The use of immediate spin crossmatch (IgM testing) without screening for rare alloantibodies, may contribute to alloimmunization and hemolytic transfusion reactions.

As most of the reagents used in blood banking in India are manufactured abroad and have a short shelf life, it

was very challenging to maintain a regular and adequate supply of testing reagents and consumables during the COVID-19 pandemic due to the lockdowns and restrictions of international flights. In addition, apart from consumables supply, equipment services provided by the vendors for preventive maintenance, calibrations, and repairs were also affected.

Patient blood management program

Patient blood management is a relatively new concept in India and is not universally practiced (31). This resulted from the lack of enough expertise in transfusion medicine and the lack of transfusion medicine undergraduate and post-graduate education and training. Only a few institutions in the country have adequate training facilities for transfusion medicine specialists. Inadequate/inappropriate transfusion is also exacerbated by a lack of national guidelines for the transfusion of patients with Hb disorders. As a result, clinicians order blood based on their knowledge or international standards, which may not apply in our country. However, some centers could adopt patient blood management principles to support the blood requirements during periods of reduced supply, such as starting patients with nutritional anemias on hematinics (32).

Challenges faced for transfusion management of patients with Hb disorders during COVID-19 pandemic

During the pandemic, an advisory from the Ministry of Health and Family Welfare in India instructed states to continue the provision of all essential health services (33). This included blood transfusions for thalassemia and SCD and emergency care. One of the centers in India reported a drop in blood collection to as much as 1/6th to 1/9th when compared to previous years (34). Adaptation to COVID-19 restrictions such as social distancing, staying at home, avoiding non-essential travel, and strict lockdown posed by the government were limiting factors (35). Late presentation of patients to the hospital with life-threatening complications (such as anemia, splenomegaly etc.) due to lockdown and lack of appropriate health care was seen. Some patients feared contracting the virus either during travel or in the hospital (36).

Various factors predispose patients with Hb disorders to infections, such as a history of splenectomy or functional asplenia, oxidative stress due to iron overload, and organ damage, including the adrenal glands (37,38). SCD patients infected with COVID-19 have a higher risk of hospitalization and development of pain and pneumonia as compared to individuals without SCD or trait, although case fatality rates were not significantly different (39).

In a meta-analysis, the incidence of COVID-19 among patients with thalassemia and SCD were 1.34 and 17.22 per 100,000 person-day, respectively and the mortality was around 1.07 per 1,000-day (40). Black SCD patients with COVID had a higher risk of hospitalization, development of pain, and pneumonia as compared to blacks without SCD or trait, although case fatality rates were not significantly different (39).

Mitigating strategies adopted in India during the pandemic

To overcome the challenges in managing these patients, many mitigation strategies were adopted by healthcare centers and transfusion services (*Table 2*).

Table 2 Mitigation strategies adopted by the blood establishments/blood donation centers in India to manage the transfusion support to patients with hemoglobin disorders

Potential challenges	Mitigative strategy adopted
Patient blood management	Introduction and application of principles of PBM
	Use of drugs to reduce the need of transfusions
	Revising the transfusion thresholds and policies (wherever possible)
	Avoiding iatrogenic blood loss
Clinical care and transfusion	Batching the day care transfusion services (to reduce crowding)
	Near-home transfusions
	Transition to Tele-care

Table 2 (*continued*)

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Potential challenges	Mitigative strategy adopted
Increasing blood supply	Motivation
	Social media engagement
	Regular call for donors via media
	Collaboration with NGOs
	Recruitment and travel
	Providing travel pass for donors to reach the donation centres
	Providing safe transport during lockdowns (by the blood centres for donors)
	Providing certificate/photo of donation (for social media promotion)
	Tele counselling and screening for basic requirements for blood donations (hence avoiding travel if not eligible)
	Voluntary donors register
	Maintaining list of donors living in area near the donation centre
	Health care workers who are eligible for donation
	Donor safety
	Pre-registration (for less time in donation centre)
	Appointment-based visits to donation centre
	Use of *Aarogya Setu* Mobile App
	Screening of donors for temperature upon arrival
	Providing masks and hand sanitization
	Social distancing in the waiting or donation area
	Avoiding outdoor donation campaigns/sessions in crowded area
	Rare donor registry
	Contacting donors on a case-to-case basis based on the needs
Inventory management	Maintain a buffer stock of additional units (1–2 weeks)
	Preparation of required components
	Considering apheresis platelets collection and use
	Demand-based collection and component preparation
	Reduce wastage
	FIFO policy
	Use of ABO compatible units (may not be ABO matched)
	Transfer of units to other blood centres
	Education of clinicians for appropriate use
	Regular audits for appropriate utilization
	Consideration of frozen and fractionated blood products
Staff and donor safety	Donor safety
	Pre-registration (for less time in donation centre)
	Appointment-based visits to donation centre
	Use of *Aarogya Setu* Mobile App
	Screening of donors for temperature on arrival
	Providing mask and hand sanitization
	Social distancing in the waiting or donation area
	Avoiding outdoor donation campaigns/sessions in crowded area

PBM, patient blood management; NGO, non-government organizations; FIFO, first-in, first-out.

Patient blood management

Medications

To manage transfusion needs in these patients, many medications were adopted, such as hydroxyurea and Luspartacept. Low dose hydroxyurea therapy (10 mg/kg/day) reduces the need for regular monitoring of blood counts in patients with SCD and thalassemia (41). The role of Luspartacept (erythroid maturation agent) in thalassemia and Voxelator (a Hb stabilizer that prevents Hb S polymerization) in SCD was also explored (42,43). Luspartacept is launched in India but is not routinely used due to its high cost, while Voxelator is not available.

Revised transfusion strategies

Some centers relaxed transfusion thresholds in patients without any cardiac comorbidity to increase the interval between transfusions. As a result of the inability to travel to hospitals and attain proper care, a center reported a median pre-transfusion Hb concentration of 5.8 g/dL (range, 1–8.5 g/dL) for transfusing thalassemia patients, significantly lower than the usual threshold of 9 g/dL for transfusion (12). For SCD patients on chronic automated red cell exchange, a study reported setting of the target hematocrit (Hct) 5% higher (maximum of 36% Hct) at the end of exchange procedure (44).

Avoiding iatrogenic anemia

Reducing the iatrogenic blood loss through the appropriate collection of samples (volume and type vacutainer) was emphasized during the pandemic and played an important role in pediatric patients (45). Elective surgeries were postponed during the pandemic.

Clinical care and transfusion

Batching day-care services

Scheduling fewer patients for transfusions in the daycare was adopted to help maintain adequate social distancing. Appointment slots were prescheduled in batches during the day to ensure adequate staffing. Early communication with blood centers for blood supply and special transfusion needs (e.g., phenotyped red cells and rare blood groups) was practiced (12).

Near-home transfusions

For patients who must travel long distances to reach a transfusion center, arrangements to transfuse patients in local medical centers near their homes helped immensely (46). Logistic support was also provided by many non-governmental organizations (NGOs).

Transitioning to tele-care

Most centers treating patients with Hb disorders have adapted to teleconsultation services to avoid hospital visits except in emergencies (46,47). Telemedicine consults reduce hospital visits and the risk of exposing the patient to potential infections, thus reducing the burden on an already strained healthcare system. During these teleconsultations, advice on regular care, the prevention, and treatment of COVID-19, and dosing of medicines were delivered.

Increasing blood supply

Media campaigns to motivate donors were carried out to overcome blood shortages. Examples were highlighting the blood shortage, the safety of coming to attend blood banks with prior appointments and attending mobile donation campaigns/units near the vicinity of their homes (48). Along with many NGOs, the blood centers provided safe travel options for donors during the travel restriction periods.

Inventory management

Inventory management was one of the most challenging parts, as it involved planning with a high degree of uncertainty. Each blood centre developed its own unique protocol/ plan to maintain a buffer stock depending on the type of medical emergencies or chronically transfused patients they were supporting. The risk of shortage of blood units and the risk of a higher degree of discard due to the cessation of routine surgeries were considered. Actions encouraged included rationalizing the type of components to be prepared (platelets to be made or not) from whole blood donations, use of first-in-first-out (FIFO) policy, considering apheresis platelets collections and considering the options of ABO compatible (non-identical) platelet transfusions.

Conclusions

In conclusion, the COVID-19 pandemic brought up challenges and different mitigation strategies for transfusion care of patients with Hb disorders in India. Maintaining the continuity of blood banks and transfusion services during viral pandemics is vital for this group of patients, among

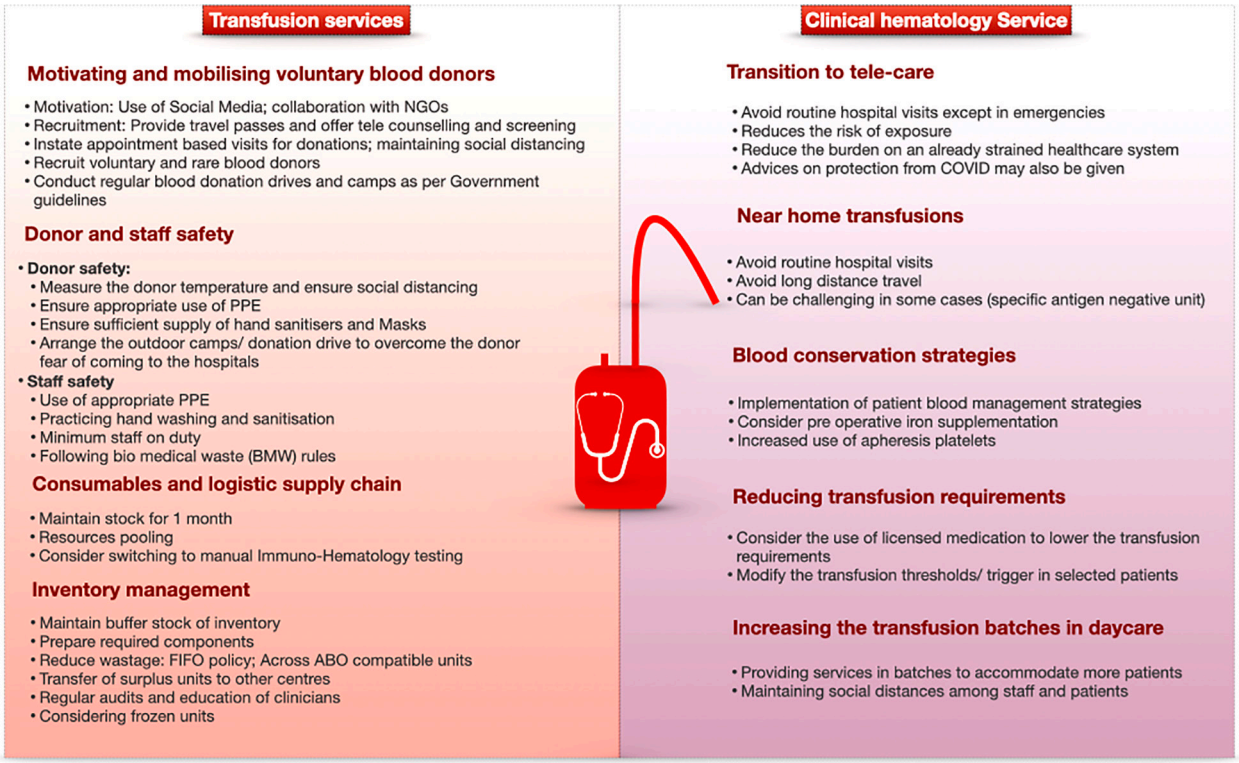

Figure 1 Points to consider for transfusion and clinical hematology services in India to manage the transfusion support to patients with hemoglobin disorders. NGO, non-government organizations; PPE, personal protective equipment; FIFO, first-in, first-out; COVID, coronavirus disease.

others. Blood banks and transfusion services should develop strategies to maintain blood supply during such pandemics. A team-approach is very important to overcome the challenges faced.

To ensure continuity of care during these challenging times, there is a need for closer communication between the blood center and transfusion services. We summarize here points to consider in facing similar pandemics the future (*Figure 1*). Local guidelines and policies on the continuity of care of this group of patients in future pandemics are required. Development for patient blood management and home transfusion policies is recommended.

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