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Review article

Indian blood donor selection guidelines: Review in the context of the ongoing COVID-19 pandemic



K. Das^a, M. Raturi^{b,*}, N. Agrawal^c, M. Kala^d, A. Kusum^d

^a Department of Pediatrics, Division of Pediatric Oncology and BMT, Himalayan Institute of Medical Sciences, Swami Rama Himalayan University, 248016 Dehradun, Uttarakhand, India

^b Department of Immunohematology and Blood Transfusion, Himalayan Institute of Medical Sciences, Swami Rama Himalayan University, Swami Ram Nagar, 248016 Jolly Grant Dehradun, Uttarakhand, India

^c Department of Pediatrics, Division of Pediatric Critical Care, Himalayan Institute of Medical Sciences, Swami Rama Himalayan University, 248016 Dehradun, Uttarakhand, India

^d Department of Pathology, Himalayan Institute of Medical Sciences, Swami Rama Himalayan University, Swami Ram Nagar, 248016 Jolly Grant Dehradun, Uttarakhand, India

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ABSTRACT

The National Blood Transfusion Services under the aegis of the ministry of health and family welfare, India has recently issued guidelines regarding the blood donor selection criteria and the processing of blood. Care has been taken to make the blood transfusions safer. However, COVID-19 has disrupted the organization of the voluntary blood donation drives, whole blood donations [WBD] and restricted the donors' movement to the blood transfusion centres all across the world. While sickness and the need for transfusions are very much in place, the gap of demand against blood collection has widened. Additionally, with the monsoon season at hand, and the categorical challenges of a dengue outbreak, the subsequent need for blood components especially the platelet concentrates is going to rise. Some of the criteria laid for deferring a blood donor from his or her WBD need a categorical revision, considering these unprecedented times. We, therefore, critically analyzed the blood donor selection criteria and hereby, suggest an updating regarding the pre-donation haemoglobin, sexually transmitted diseases, lactation, pregnancy and many such subheadings. We also suggest collecting smaller blood volumes in the blood bags for the optimal benefit of the recipients both for now and also as a measure of pandemic preparedness for future use.

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1. Introduction

Blood is one of the most widely used drugs in medical practice. With its first documented use in the 18th century, a plethora of advancements and safety measures have been witnessed [1–5]. Safe blood transfusion is a compulsory practice countrywide and the national blood transfusion services under the aegis of the ministry of health and family welfare [MoHFW], India has recently issued guidelines regarding the blood donor selection criteria to streamline this process. Yearly the demand of blood components have shown an increment and the voluntary donations are a norm now, making either the sell or purchase of blood products a punishable offence [6]. However, the latest guidelines available from

the MoHFW-2020 have made the blood donor selection criteria rather more stringent [7]. COVID-19 pandemic has led to a series of interventions targeting its trajectory [8]. Lockdown and staying in-door is widely enforced and promoted. With the minimal public transport facility functional and government advisory, blood donation drives are not being organized like the earlier times. Relatives and voluntary donors are now reluctant to come to the hospital for donations. The donation of blood is being affected significantly [9,10]. WHO advisory regarding readiness for a long haul with this pandemic is a clear indication that similar restrictions will stay, either self-imposed or by the government. Medical practices have also changed in this pandemic, shifting personal visits to telemedicine, deferring non-essential surgeries and postponing stem cell transplants based on guidelines [11,12]. However, a shrinking donor pool is a matter of worry for not just the blood transfusion centres [BTC] but the blood community at large.

* Corresponding author.
E-mail address: manishraturi@srhu.edu.in (M. Raturi).

1.1. Existing donor selection criteria

The gazette notification brought out by the government of India, dated 11th march 2020, has put an elaborated list of exclusion and inclusion criteria for blood donors [7]. Although it looks a robust one to prevent transfusion-transmitted infections [TTI], a balance of deferral against the demand for blood is noticeably uneven. We, therefore, analyzed a few salient points, which we noted to be arbitrarily too stringent in nature. An empirical revision in these is the need of the hour.

1.2. Hemoglobin [Hb] levels

The existing guidelines demand minimum haemoglobin of 12.5 g/dL for a healthy donor to be able to give his or her whole blood donation [WBD]. In India, about 52.9 % of women amid the reproductive age group are in anaemia. Data about males having some anaemia shows a prevalence of 23.2 %. If we analyze these figures critically, the prevalence of female having Hb less than 11 g/dL is 28.2 % and less than 8 g/dL is 2.4 %. Males having Hb less than 11 g/dL is 5.1 % and less than 8 g/dL is 0.5 % [13,14]. Thus the majority of the population in our country falls in the category of some amount of anaemia, with Hb levels ranging from 11 to 13 g/dL and 11 to 12 g/dL in males and females respectively. After a donation of 450 mL whole blood, the average fall in Hb from the baseline is 7 % immediately and 5 % in about two weeks. Complete recovery has been noted in four to six weeks. Although repeated donation puts the RBC mass and serum ferritin losses cumulative, single donation seems quite safe even for a person of borderline fitness [15,16]. Donor studies have noted no side effects of such a fall in Hb levels. Albeit repeat donations have shown a decrease in exercise tolerance and endurance. If we lower the threshold of donation to 12 g/dL from the currently acceptable Hb levels of 12.5 g/dL, the donor pool will increase drastically without putting much danger to the donor's health. In countries such as Japan, the average whole blood collected ranges from 200 to 250 mL with a minimal Hb level of 12 g/dL [17]. From the recipient's point of view, transfusion of packed red blood cell [PRBC] has shown quite a variable increment. Few studies done in the intensive care settings have noted a poor increment with transfusion, average 0.44 g/dL, while another study noted about 1.0 g/dL increment post one unit of PRBC transfusion. It has also been suggested that a lower starting Hb level in the recipient will lead to a greater increment in Hb level with one unit of PRBC, although this may not be a consistent finding in all the recipients' every time [18–20]. However, the majority of transfusion is done in severe anaemia [<8 g/dL] or in a person with moderate anaemia with or without few comorbidities. Even an increment of 1.0 g/dL will be beneficial to the recipient, pushing them from severe to moderate or moderate to mild category. This blood product of donor will nevertheless be lifesaving for the recipient. A smaller whole blood volume collection of about 250 mL is also an alternative for such as observed. Donation of 250 mL WB will cause less fall in Hb to the donor, but, will definitely benefit the recipient in raising his or her hematocrit.

1.3. Physiological state of women

The notification bars women from WBD for six months post-abortion without considering her gestation period and or any blood loss incurred. We, therefore propose a modification in the criteria into two categories of abortions namely, complicated [putting a woman's health in a decompensated situation with compromised Hb levels requiring hospitalization and or blood transfusion] and an uncomplicated one [An abortion in an early trimester, without much blood loss, does not put women at much-decompensated health]. In fact, the literature suggests that body iron stores [BIS]

may be increased in first trimester abortions due to unidirectional iron storage signals [21]. In the uncomplicated abortion category, if the current Hb levels are adequate, the female should be allowed to donate at an earlier interval, such as four months rather than six months. However, the donation period after a complicated abortion needs to be kept at 6 months to help recover the compromised BIS and consequently help in a better fetal development during future pregnancies.

The literature also suggests that haematologically, the postpartum period recovers completely by six months [22]. As per the current Indian guidelines, they are unfit for donation for a year, which looks quite unreasonable. Any female, if having a good Hb status, should be allowed to donate six months post the delivery of her child. Even commission directives [2004/33/EC] of the European Council mentions acceptability of a WBD almost six months post-delivery or termination of pregnancy based on the discretion of the BTC physician [23]. Lactation has also been labelled as an absolute contraindication for WBD. While they may be barred from their WB donation, their apheresis can be done safely. Therefore, these guideline views are too stringent and need a critical review based on not just the scientific evidence rather considering the ongoing pandemic too.

1.4. Surgery

The existing Indian guidelines mention that post major surgery (defined as surgery requiring admission, spinal or general anaesthesia, transfusion after blood loss) a one year gap is needed before making a WBD. This seems too erratic as spinal anaesthesia or admission cannot be taken as criteria of physiological insult. Smaller surgeries such as appendectomy, varicose vein and hernia removal require spinal anaesthesia [24]. While these surgeries are routinely managed as daycare or lesser stay procedure/s, the existing deferral interval of one year is not only unjustified rather it is questionable too [25]. In fact, even the European blood alliance position paper on the existing European council guidelines for donor selection; mention a lower risk of acquiring TTI when it comes to major surgeries [26]. The physiological recovery and adequate blood parameters should be the inclusion criteria before WBD. Similarly, inadvertent cut in the blood vessel during surgery can lead to massive blood loss requiring major transfusion support. But the patients will recover quickly and can be of use as blood donors after a proposed three months post-recovery. The deferral duration should be based on the extent of surgical morbidity rather than the admission or type of anaesthesia given. We, therefore, suggest a three month waiting period after an uncomplicated surgery provided the individual possesses a good Hb level and is not on any anti-platelet medications. Furthermore, the deferral period of about six months after tooth extraction also seems to be completely irrational and needs a major revision [23].

1.5. Infections

While individuals infected with syphilis can have persistent antibodies and they are labelled unsuitable for lifetime WBD, the rationale of simple osteomyelitis who have achieved complete cure, being barred for full one year is simply illogical. Although individuals having chronic osteomyelitis harbour infections for a prolonged period, those with simple acute osteomyelitis, and who have been cured with optimal antimicrobial therapy are healthy recovered subjects. In fact, features of acute osteomyelitis which predict chronicity have been investigated as well [27,28]. With an elaborate assessment, the prediction of recurrence can be done. We, therefore, propose reducing this deferral period to six months after the complete cure of acute osteomyelitis where recurrence probability is less. The chronic osteomyelitis may, however, be accepted

for a WBD after one year of complete cure. Similarly, national guidelines also defer gonorrhoea cases, lifelong while it is a curable disease. The donor selection criteria laid by WHO allows WBD after 12 months of the assessment of high-risk behaviour [HRB] among the individuals [29]. In fact, a similar approach should be incorporated into our national guidelines.

1.6. Gastrointestinal [GI] endoscopy

Indications of GI endoscopy are increasing these days. It has become a routine outpatient department based procedure which is safely done. The rationale of deferral for one year after GI endoscopy is probably an extrapolation from the old era when indications were limited and chances of contamination were considered quite high. Remoortel et al noted in their systemic meta-analysis that all pieces of evidence linking endoscopies with hepatitis B virus [HBV] and hepatitis C virus [HCV] infections are based on low-quality data source. Although an increase in risk for HBV and HCV were noted, it was not sufficient to challenge the European guideline of deferral for four months [30–32]. Additionally, the risk of HIV transmission was also not noticed [33]. Even the European blood alliance position paper on the existing European council guidelines for donor selection; mention a lower risk of acquiring TTI when it comes to endoscopy [26]. We propose, therefore, based on the existing data, a reduction to six months from the existing one year in the donor deferral period.

1.7. Residents of another country

The cut-off of three years of continuous residency in this country is probably quite illogical. The risk factors of getting infections are equal in this country and three-year incubation is not scientifically correct for either of the TTI we know of. Therefore, this deferral period can be reduced to one year considering a longer window period [nearly nine months] of HCV.

1.8. Transgender and MSM

Transgender is barred permanently based on their sexual orientation and HRB. Labelling all transgender at risk of sexually transmissible disease is not only unscientific; it's rather based on a biased opinion. With the changing social structure, transgender people have started accepting all sorts of roles in society. They must

be screened and treated on equal level just like others. Additionally, the ability of transgender to donate should be evaluated based on the Hb level, their sexual practices (multiple sexual partners) and intake of certain drugs such as testosterone and anti-androgens which should contra-indicate donation. A voluntary declaration of HRB rather "truth-telling" should be encouraged, rather than deferring them solely based on their sexual orientation. Studies have shown the same safety level of blood components prepared from the WBD of a transgender if a modified questionnaire and testing were in place [34,35]. Similarly, men having sex with men (MSM) are barred as blood donors while recent study supports a three months sexual abstinence as optimally sufficient to assure safer blood products [36]. In fact, the US-FDA, on April 2nd 2020, announced their interim recommendations regarding the relaxation of its restrictive ban [RB] on men who have sex with men [MSM] from donating blood to a period of three months, which previously demanded twelve months of sexual abstinence before their WBD [37]. Their permanent deferral leads to lesser acceptance of such individuals impacting the blood community at large. Therefore, we also propose adapting a more liberal allowance for transgender and MSM [i.e. an optimal hold of three months as sexual abstinence before their WBD] if they wish to come forward and give their blood.

2. Proposed interventions

2.1. Exclusion criteria for the discussed group

To compensate the gap amid the demand and the collection, especially during this COVID-19 pandemic and so on while the dengue outbreak is going to upsurge, we propose evidence-based acceptance criteria for the WBD. This will help increase the existing donor pool and reduce the burden on the healthcare system (Table 1).

2.2. Smaller volume collections

In a few Asian countries such as Japan, the average whole blood collections range from 200 to 400 mL based on the donors' Hb level of 12 g/dL to 13 g/dL respectively [17]. Similarly, for the Indian population during unprecedented times such as pandemics and wars, a smaller volume of WB collection [around 250 mL] may be allowed at the discretion of the BTC physician. As detailed, this will

Table 1
Proposed modifications for whole blood donor selection criteria in the existing Indian guidelines.

Existing criteria	Proposed modifications	Scientific rationale
Hb level \geq 12.5 g/dL [For both men and women]	Hb level \geq 12.0 g/dL [For both men and women]	No significant physiological impact in a donor after single donation
Abortion/miscarriage – Defer for 6 months	Deferral based on gestation/blood loss/recovery/Hb level. If complicated: 6 months deferral Uncomplicated: 4 months deferral	Uncomplicated abortion/miscarriage has no long lasting physiological impact on the body
Post-partum – defer for 1 year	In extraordinary situations, can be considered after 6 months with good Hb levels	Physiological and hematological compensation usually occurs in 6 months post-partum
Lactation – defer during lactation	In extraordinary situation, can be considered after 6 months	Mild fall in iron levels may not impact infant who is also on top feed apart from breast milk
Osteomyelitis – defer for 1 year after cure	Acute cases- can be taken after 6 months of cure based on predictability score Chronic cases- defer for 1 year	Persistent infections are less likely in acute osteomyelitis with low predictability score
Gonorrhea – defer life-long	1 year deferral and then based on cure assessment, whole blood can be taken	The rationale of life-long deferral is not evidence based
Gastro-intestinal endoscopy – defer for 1 year	Defer for 6 months	Lower risk of acquiring TTI, based on literature and European Council guidelines
Transgender people – defer permanently	Can be taken based on detailed assessment and screening, Hb levels, frequency and pattern of sexual history as well as certain drugs	New literature supports same safety profile as heterosexuals for the transgender blood components
Foreign nationals – defer till 3 years of continuous residency in country	Defer till 1 year of continuous stay in country and then consider them like resident donors	The rationale of prolonged deferral is not evidence based

be helpful not just for the recipients in raising their hematocrit, it would also do lesser to no harm to the donors' health in terms of their BIS.

3. Newer policy proposal

Apart from increasing the donor pool and creating smaller bags of blood components, we propose the following steps to reduce the gap of blood supply and demand:

- indications of transfusion should be made stringent, and the BTC physician must endorse them;
- optimizing haemoglobin using hematinics and treating the underlying cause of anaemia in patients before elective surgeries should be prioritized rather than simply transfusing a pack of allogenic PRBC unit;
- application based blood donor selection and home-based blood collection may be tried as pilot projects.

4. Conclusion

Although the current blood donor selection criteria are robust enough to ensure blood safety and decrease transfusion-related morbidity, given the ongoing pandemic and expected upsurge in the demand of blood components, an updated and liberal donor selection criteria merit immediate consideration. These proposals of modifications need thorough discussion with the experts to frame an effective strategy both for now as well as a measure of pandemic preparedness for future use. Perhaps, the adaptation of donor selection criteria to local context after a critical risk assessment is the need of the hour.

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Disclosure of interest

The authors declare that they have no competing interest.

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