**Table 1**
Demographic, baseline clinical and treatment characteristics of the 54 consecutive patients with severe COVID-19 enrolled in the study.

| Characteristics | Results |
|---|---|
| Median age, years (IQR) | 67 (55.5–73.5) |
| Males/females | 38/16 |
| Male/female ratio | 2.4 |
| Median follow-up, days (IQR) | 270 (261.2–280.5) |
| Coexisting diseases, n (%) | |
| Hypertension | 28/54 (51.8) |
| Obesity | 13/54 (24.1) |
| Cardiovascular disease | 14/54 (25.9) |
| Cerebrovascular disease | 3/54 (5.6) |
| Diabetes | 9/54 (16.7) |
| Cancer | 8/54 (14.8) |
| Chronic kidney disease | 4/54 (7.4) |
| Concomitant therapies, n (%) | |
| Antiviral | 25/54 (46.3) |
| Antibacterial | 54/54 (100.0) |
| Hydroxychloroquine | 38/54 (70.4) |
| Steroids | 13/54 (24.1) |
| Anticoagulant | 51/54 (94.4) |
| Median $P_{AO2}/F_{IO2}$ before first CP transfusion, ratio (IQR) | 150.0 (137.0–183.5) |
| Median interval between hospitalization and first CP transfusion, days (IQR) | 4.7 (2.9–8.4) |
| Viral nucleic acid negative rate[a], *n*/total (%) | |
| Before CP transfusion | 0/54 |
| 72 hours after CP transfusion | 46/54 (85.2) |
| 1 week after CP transfusion | 54/54 (100.0) |
| 1 month after CP transfusion | 54/54 (100.0) |
| At the end of follow-up | 54/54 (100.0) |
| Median anti-SARS-CoV-2 IgG levels at the end of follow-up, U/mL (IQR)[b] | 85 (48.9-103.0) |

IQR: interquartile range; CP: convalescent plasma; $P_{AO2}/F_{IO2}$: partial pressure of arterial oxygen to fraction of inspired oxygen ratio. Severe COVID-19 respiratory distress was defined as follows: > 30 breaths/minute, oxygen saturation < 93% in room air, $P_{AO2}/F_{IO2}$ < 200.

[a] Performed on material collected by nasopharyngeal swab.

[b] Anti-SARS-CoV-2 IgG antibodies were measured using a chemiluminescent immunoassay (LIAISON SARS-CoV-2 IgG, DiaSorin, Vercelli, Italy).

considerations regarding the possibility that *in vivo* CP transfusion could induce mutations in receptor binding and N-terminal domains able to escape from CP neutralizing antibodies, as suggested by *in vitro* studies [5]. In fact, it is somewhat unlikely that this phenomenon could happen in a clinical setting considering the very early suppression of the virus by CP. In other words, findings in experimental studies do not always translate into real-life clinical evidence.

## Disclosure of interest

The authors declare that they have no competing interest.

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## COVID-19 vaccination in the Indian blood donors: Adjudging the impact on the deferral period

Sir,

In December 2019, a novel coronavirus [nCoV] was reported from Wuhan, China [1]. This nCoV is known to cause coronavirus disease 2019 [COVID-19], which has been renamed as Severe acute respiratory syndrome coronavirus 2 [SARS-CoV-2]. Further, the only effective way to provide people with immunity against SARS-CoV-2 is to discover and produce an appropriate vaccine for developing herd immunity to end the current pandemic of COVID-19. With the genetic sequence data of the nCoV already available since January 10, 2020, leading pharmaceutical companies, the world over, in turn, have started working on the clinical trials to produce vaccines against this nCoV. In fact, many vaccines under the Phase III trial have claimed to demonstrate their efficacy to be as high as 95% against the nCoV. In January, the central drugs standard control organization, India had granted the emergency-use authorization [EUA] to two vaccines namely, Covishield (live vaccine, Oxford-AstraZeneca, United Kingdom being manufactured by the Serum Institute of India, Pune) and Covaxin (inactivated vaccine, Bharat Biotech, India). The major difference between these two vaccines is that the Covishield is a live vaccine while Covaxin is an inactivated vaccine. The ultimate aim of blood transfusion services [BTS] is to provide blood that is safe for transfusion. In fact, the pre-donation donor screening is the first and the most important step to ensure the safety of the blood supply. Indeed, screening before donation is the first and most important step in ensuring the safety of the blood supply. This involves the use of a donor questionnaire and a mini-physical examination to ensure both donors as well as the recipient's safety. Blood from a recently vaccinated donor with a live vaccine may contain an infective agent, which can theoretically be transmitted through blood transfusion especially in immunocompromised recipients. Therefore, the World health organisation (WHO) recommends a donor deferral of 28 days after live vaccination [2]. However, killed vaccines do not pose any risk to the recipient of blood and therefore the donor can be accepted for donation without any deferral period. In India, as per amendment in the Drugs and Cosmetics Act, 2020, a temporary deferral of 14 days is recommended for donors with a history of non-live vaccination and 28 days for donors with a history of live vaccination [3]. The national blood transfusion council of India (NBTC) has recently recommended a donor deferral period of 28 days after vac-

**Table 1**
Donor deferral period after COVID-19 vaccination practiced in different countries.

| Name of the country | Donor deferral after live COVID-19 vaccine | Donor deferral after inactivated COVID-19 vaccine |
|---|---|---|
| USA [5] | 14 days | Nil |
| UK [6] | 28 days | 7 days |
| Canada [7] | Nil | Nil |
| European Union [8] | 28 days | Nil |
| Australia [9] | 7 days | 7 days |
| Singapore [10] | 28 days | 3 days |
| India [4] | 28 days | 28 days |

cination against COVID-19 [4]. Depending upon the type of vaccine administered against COVID-19, different countries have adopted different deferral periods [5–10] as enlisted in Table 1. Most of the countries offer no deferral period for the donors who have been administered an inactivated vaccine against COVID-19. However, as per the current protocol in India, both Covishield and Covaxin have a 2-dose regimen, in which the doses are administered 4 weeks apart. Therefore, anyone undergoing vaccination against COVID-19 is essentially deferred for 28 days after the last dose. Now, based on priorities for the high-risk groups of infection and transmission, such as elderliness, healthcare workers, taskforce distribution phase plans, including the government commitment, we have an upcoming mass vaccination program to roll out in India. Hence, the deferral period of 28 days from the last dose could essentially result in a massive reduction in the number of eligible blood donors. This will further compromise the blood supply management, which has already been disrupted due to the COVID-19 pandemic itself [11].

Additionally, the primary route of transmission of COVID-19 is the respiratory route [12,13]. No case of transfusion-transmitted COVID-19 case has been reported thus far. In fact, in a reported case, a recipient was transfused platelet concentrate obtained from a confirmed case of COVID-19 donor and still, the recipient remained negative for the COVID-19 disease [14]. Therefore, in line with current scientific data, the risk of transfusion transmission of COVID-19 is only theoretical. Consequently, the 28-day deferral period adopted by NBTC in India is not only unjustified but also unacceptable. Therefore, we propose a thorough review and modifications of the same, bearing in mind, the discussion with the experts in order to frame an effective strategy, both for now as well as a measure of pandemic preparedness for future use [15]. Another area that warrants immediate attention is the effectiveness of these two vaccines against emerging new variants of nCoV such as, 501Y.V2 (South Africa) and B.1.1.7 (United Kingdom).

## Research involving human participants and/or animals

Human participants.

## Informed consent

As per our department policy an informed consent is obtained from all the donors prior to their whole blood donation in accordance to our standard operating protocol.

## Ethical approval

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional ethics committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

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## Authors' contributions

Naveen Bansal contributed to the literature search, data compilation, manuscript preparation, editing and review, while Manish Raturi contributed to the conceptual design, literature search, manuscript preparation, editing, review as well as being the guarantor who takes the complete responsibility for the integrity of the work done as a whole right from it's inception to the published article.

## Disclosure of interest

The authors declare that they have no competing interest.

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## Application of quality control circle to improve conformity rate of time limits of infusion

Dear Sir,

Temperature control before the completion of infusion is a hinge to avoid bacterial proliferation or loss of function in blood products. WHO has issued guidelines to control the temperature of the whole course and time limits of infusion [1]. In China, National Health Commission of the People's Republic of China has also published standards to standardize the temperature of storage and transportation, but has no relevant mandatory standards about the time limits of infusion. In 2010, our hospital decided to control the last link of the cold chain, and issued regulations about the time limits of infusion, which was in accordance with WHO guidelines. But the performance has never been monitored. As the world-wide spreading of COVID-19, our hospital's transfusion management committee decided to improve the safety in blood transfusion and started to monitor the time limits of infusion and use Conformity Rate (number of transfusion cases meeting the time limits of infusion/total number of transfusion cases × 100%) to local regulations as a quality indicator since January 2020. Because of the lack of supervision over a long term, the initial conformity rate was not satisfactory, and we decided to introduce quality control circle (QCC) to improve it.

Quality control circle (QCC), described by Deming and Juran in 1950s, has been widely and successfully used in medical and healthcare fields [2,3]. QCC refers to a small group of people who share the same professional field, spontaneously form a team to identify, analyze and solve work-related problems to improve the quality of the work [4]. We have established a QCC group with members from administrative department, blood bank, clinical ward, nursing department and information department. The QCC program followed the plan-do-check-act (PDCA) process. An available standard operation procedure (SOP) was issued to standardize the whole course of transfusion, including the time limits of infusion. Data from the information system and personal digital assistant (PDA) were used to monitor the critical time points, including the time of issuing blood products, starting and completion of transfusion. The group met online monthly to analyze the reasons for the low conformity rate from the aspects of personnel, materials, method and environment. A feedback mechanism was also established, non-conforming cases were reviewed and discussed, and improvement measures were implemented. As shown in Fig. 1, the initial conformity rate was only 63.4% (1082/1706) in January 2020. After the QCC program was initiated, the conformity rate has rose sharply up to 75.8% (1229/1621) in February 2020, and kept increasing gradually. During the four rounds of QCC activities, we

**Table 1**
Causes and countermeasures for the low conformity rate.

| Causes | Countermeasures |
|---|---|
| Issuing blood products for excessive number of patients in one ward at the same time | The upper limit of issuing blood products in one ward at the same time is 3 patients. If the limit is exceeded, LIS (Laboratory Information System) will remind blood bank staff to refuse issuing blood products |
| Issuing several packs of blood products for one patient at the same time | The upper limit of blood products is 1 pack per patient at the same time (unless plasma exchange). If the limit is exceeded, LIS (Laboratory Information System) will remind blood bank staff to refuse issuing blood products |
| Patient status is not suitable for transfusion (fever/no intravenous access) | Insert the computer checks for patient status into medical reminder system. Once the blood is request for transfusion, HIS (Hospital Information System) will remind doctors and nurses to check the patient status |
| Low quality of handover | Using nursing PDA and computer system reminders to avoid forgetting. Every link of handover chain will be reminded, if delayed over 10 minutes |

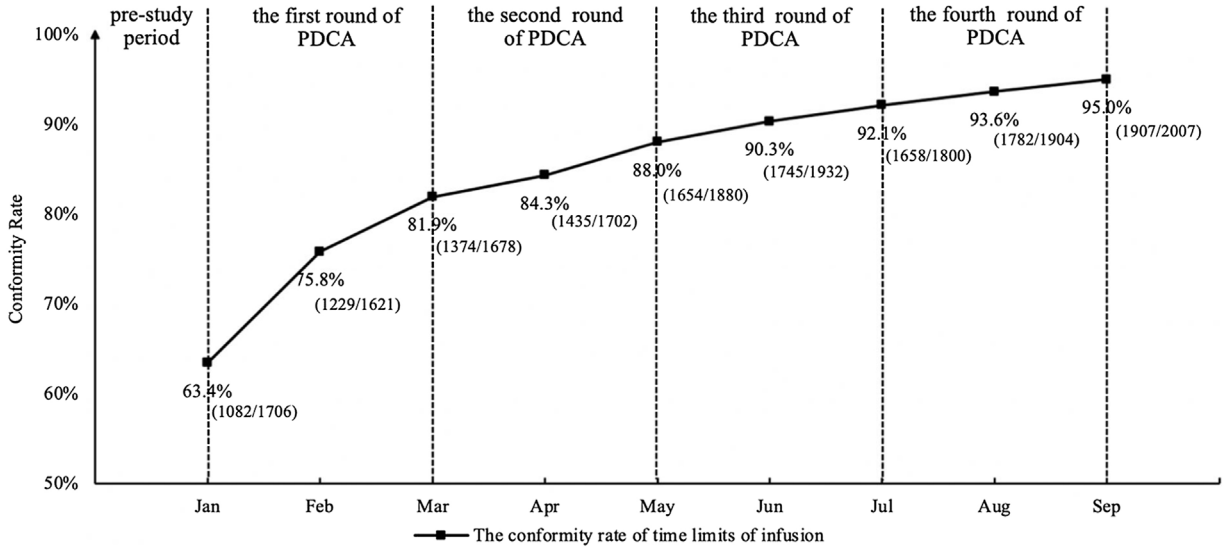


**Fig. 1.** Conformity rate of time limits of infusion.