

Challenges in Establishing a Coronavirus Disease 2019 (COVID-19) Convalescent Plasma Donation Program in a Multicultural Environment

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• **Context.**—In the face of the coronavirus disease 2019 (COVID-19) pandemic response, it was worthwhile to test the safety and efficacy of COVID-19 convalescent plasma (CCP) transfusion.

Objective.—To establish a CCP donation program based on the availability of recovered COVID-19 patients and the practical limitations in recruiting clinically valid donors in a multicultural setting.

Design.—From March to June 2020, we developed a program for collection of COVID-19 CCP as part of the treatment options for patients affected with COVID-19. From an initial population of 3746 candidates, only those with positive polymerase chain reaction results in at least 2 separate tests were considered. This filter reduced the eligible donor pool to 488 patients. After other exclusions were applied, such as language barrier, age, accessibility to donation, and comorbidities, the final count was 267

potentially eligible donors, which represented only 54.7% (267 of 488) of preselected candidates.

Results.—Eighty donors were called. Approximately a third of the calls provided additional challenges as outlined by the following 4 reasons: limited functional understanding of English; schedule availability due to rotating work timetables; transportation restrictions since public transport services were severely restricted during lockdown; and lost to follow-up. Finally, a total of 38 valid donors participated, upon whom 45 apheresis procedures were performed.

Conclusions.—As a summary of our experience, we can conclude that despite the limitations we were able to establish an effective program. A total of 90 units of CCP were collected before the pandemic curve began to flatten toward the end of June 2020.

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During the past century, serum therapies were used successfully to treat many infectious diseases, a majority of which were stopped with the arrival of antibiotics; however, in current practice, specific immunoglobulins derived from humans and animals are important

therapies for a variety of conditions (eg, parvovirus infection, cytomegalovirus infection, hepatitis A and B, rabies, botulism poisoning). In the modern era, there are also several precedents for the use of convalescent plasma (CP) from recovered patients with viral infections, such as the Spanish flu of 1918,^{1,2} Argentine hemorrhagic fever,³ and the 2009 influenza A H1N1⁴ pandemic. More recently in 2014, CP from patients recovered from Ebola virus disease was recommended by the World Health Organization as an empirical treatment during outbreaks,⁵ and a protocol was established for the use of CP in the treatment of Middle East respiratory syndrome coronavirus (MERS-CoV) in 2015.⁶

During the initial outbreak of coronavirus disease 2019 (COVID-19), owing to the absence of available vaccines for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), large populations of susceptible people were affected and became ill. Management was mainly focused on infection prevention, detection, monitoring, and supportive care, since no specific anti-SARS-CoV-2 treatment had been recommended owing to the absence of evidence.⁷ In the face of the pandemic response, it was advisable to look for other therapeutic interventions; thus, it was worthwhile to test the safety and efficacy of COVID-19 convalescent plasma (CCP) transfusion therapy in SARS-CoV-2-infected patients.

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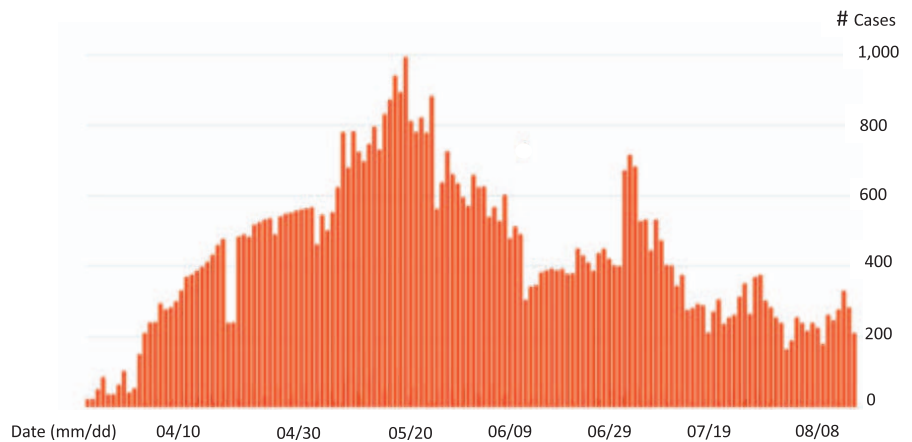
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Figure 1. Number of daily new cases in the United Arab Emirates from April to August 2020.



The United Arab Emirates (UAE) is a unique example of diverse convivence, with more than 200 nationalities represented within the country. Emirati citizens constitute only 11.5% (1.15 million [M] of 9.99M) of the population, with expatriates making up the remaining 88.5% (8.84M of 9.99M). This extraordinary cultural diversity creates a model of social cohesion, resulting in difficulties for those who are not fluent in either Arabic or English.

In this article, we describe the experience of Cleveland Clinic Abu Dhabi (CCAD; Abu Dhabi, United Arab Emirates) in establishing a Convalescent Plasma Donation Program based on the availability of recovered COVID-19 patients and the practical limitations in recruiting clinically valid donors in a multicultural setting.

CORONAVIRUS HITS THE UNITED ARAB EMIRATES

The first reported case of COVID-19 in the Emirates was in January 2020, with the first COVID-19–related mortality on March 20, 2020. By the end of March, the volume of cases had progressively increased; with the beginning of April, 150 newly infected cases were being confirmed daily (Figure 1). In response, CCAD began studying the possibility of establishing a program to obtain immune plasma from convalescent patients. To do this, several measures needed to be implemented, such as obtaining a valid source of potential donor candidates (people who had tested positive by polymerase chain reaction [PCR] and were now recovered with antibodies); acquisition and validation of laboratory tests to determine qualitatively and quantitatively immunoglobulin G (IgG) antibodies; creating and presenting a research protocol for the use of plasma, including informed consent for donation, to the Ethics and Institutional Research Board for approval; collaboration with the Abu Dhabi Blood Bank (ADBB), outlining the donor selection policy regarding the status of infection, determination of PCR tests, and frequency of donations; and designing and producing the labeling for new products, using ISBT128 codes, specifically including documentation of their experimental use and adapting our Laboratory Information System and Healthcare Information and Management System (HIMS) for the traceability of new products from the donor to the recipient.

DONOR CANDIDATE RECRUITMENT

From March to June 2020, we developed a program for collection of COVID-19 convalescent hyperimmune plasma as part of the treatment options for patients affected with

COVID-19. The process of determining which patients would become potential donors involved a collaboration between the blood bank caregivers who provided inclusion and exclusion criteria; clinical intelligence who developed the abstract of discrete data points from the electronic medical record, which allowed quick exclusion of patients; and lastly, clinical abstractors to manually filter those cases for which automation was unable to definitively determine exclusion or inclusion parameters.

Both the Table and Figure 2 show the effect of different filters in the selection of candidates.

The initial population of single positive PCR-tested males and nulligravid females was 3746 patients. The first filter applied captured patients who had at least 2 positive PCR test findings, resulting in the remaining eligible donor pool of 488 patients. We further identified patients residing outside the Emirate of Abu Dhabi who were unable to access the Emirate, as the borders were closed at the time the CCP program was active; this reduced the pool to 479. ADBB donation guidelines restrict the donation of blood products from donors who either originated from or lived in France, Ireland, or the United Kingdom for 3 months or more from January 1, 1980, through December 12, 1996⁸; after this filter was applied, the residual pool was 473. Informed consent documents are only available in Arabic and English, and therefore patients unable to functionally read or speak Arabic or English were excluded, which reduced valid donors to 386. Owing to public transportation limitations during lockdown, patients who lived within the Emirate yet outside the city limits of Abu Dhabi were excluded. Additionally, those residing in shared accommodations within workers' compounds were excluded, as these patients had rotating work schedules and were typically off duty during curfew hours, which made travel without appropriate government issued permits prohibited.

This left 330 potential candidates. Patients younger than 18 years and those older than 60 years were ineligible to donate as per donation guidelines, leaving 283 candidates. Patients identified as visitors to the UAE as well as those with a history of specific comorbidities were excluded. After these exclusions were applied, the final count was 267 potentially eligible donors.

THE CALL EXPERIENCE

Once the list of eligible plasma donors was filtered, the next task was to contact potential candidates by phone. Figure 3 describes the workflow used to assess eligibility of

Exclusion Criteria in Donor Candidate Recruitment and Accumulative Percentage of Losses				
Exclusion Criteria	Excluded	Single Reduction Factor, %	Cumulative Reduction, %	Volume Remaining
Initial number – male and nulligravid female only				3746
PCR positive (>1)	3258/3746	86.9	86.9	488
Location	9/488	1.8	1.8	479
Country of origin (exclude: France, Ireland, UK)	6/488	1.2	3.0	473
Language (exclude: other than English or Arabic)	87/488	17.8	20.8	386
Accessibility (exclude: camps)	56/488	11.4	32.2	330
Age, y (include: >18 / ≤60)	47/488	9.6	41.8	283
Residency status and comorbidity (exclude: visitor, transplant, and other)	16/488	3.2	45.3	267
Final	3479/3746	-	92.8	267

Abbreviations: PCR, polymerase chain reaction; UK, United Kingdom.

patients for the COVID Convalescent Plasma Donation Program (CCPDP).

Before initiating calls, a script was developed with 3 goals: follow-up on COVID-19-positive patients to ensure that they were well and recovering following their diagnosis; educate candidates regarding COVID-19 antibodies, the donation process, and what they could expect if they chose to participate; and obtain agreement to participate in donation and secure a commitment for a date and time to meet at the blood bank.

While most candidates eagerly agreed to donate, there were a minority who refused without providing a reason.

Approximately a third of the calls provided additional challenges as outlined by the following 4 reasons.

The first of these challenges was the language barrier. Although English may have been listed as a candidate's primary language in the electronic medical record, many had extremely limited functional understanding of English. The ADBB from the onset of the pandemic offered the donation questionnaires and informed consent in Arabic and English only. Therefore, non-Arabic- and non-English-speaking candidates were excluded as they would be unable to give full informed consent. During the early days of the pandemic, multiple language translation resources were not

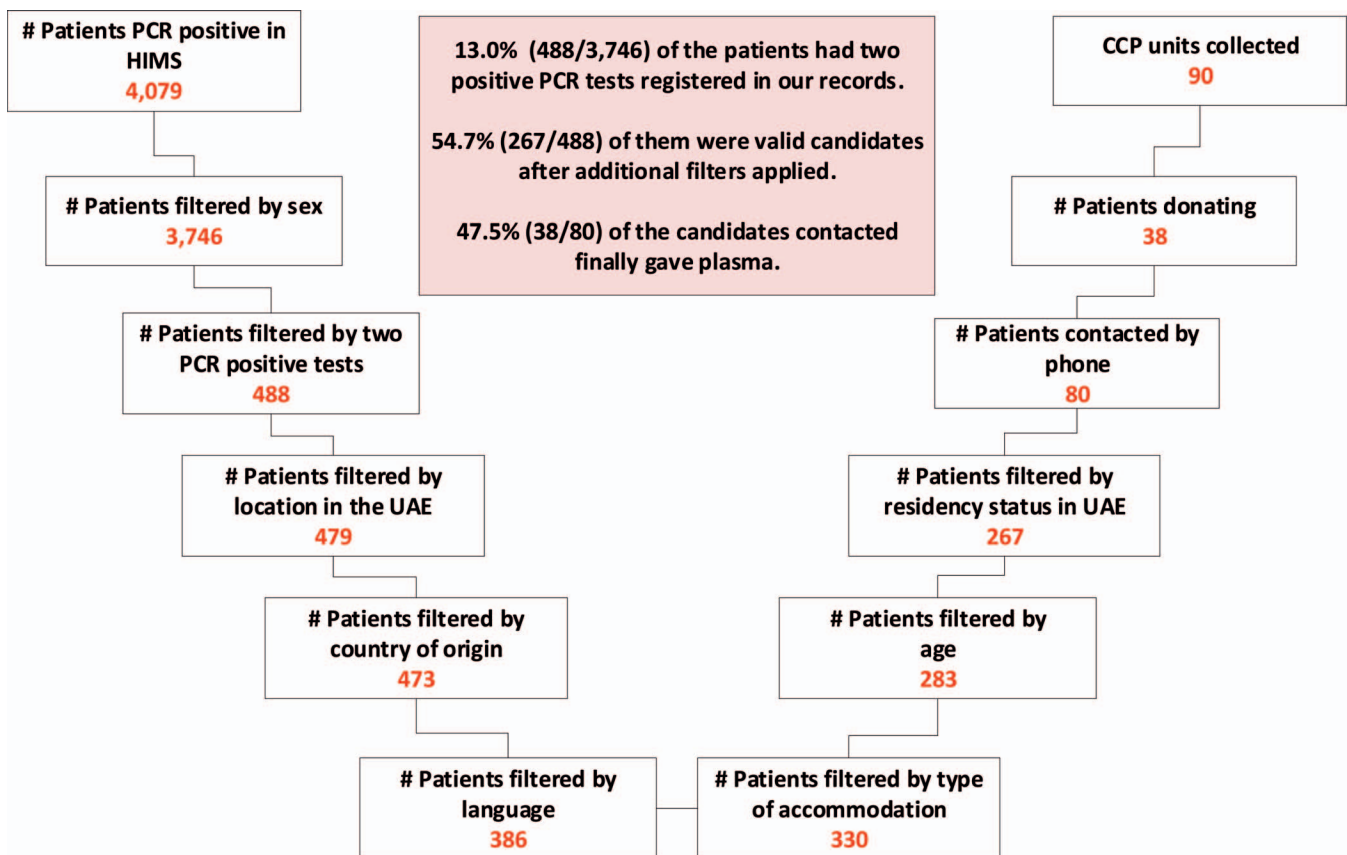


Figure 2. Filter of candidates. Red numbers show the valid candidates remaining after the filter was applied. Abbreviations: CCP, convalescent COVID-19 plasma; COVID-19, coronavirus disease 2019; HIMS, Healthcare Information and Management System; PCR, polymerase chain reaction; UAE, United Arab Emirates.

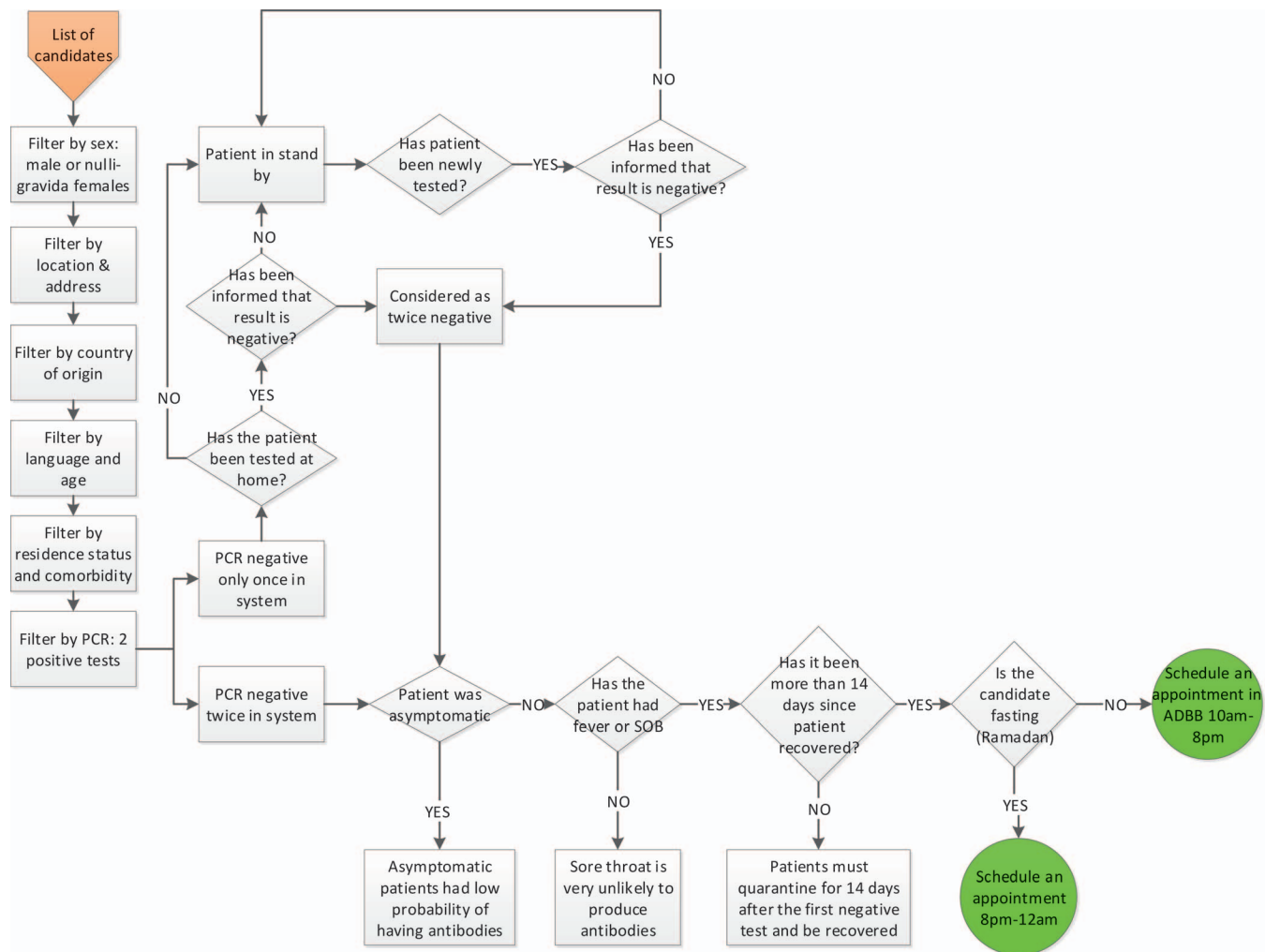


Figure 3. Workflow used to assess eligibility of patients to enter the Coronavirus Disease 2019 Convalescent Plasma program. After filters were applied, 2 negative PCR test results were requested on different days before donation; symptomatic patients were prioritized; and an appointment was scheduled regarding the fasting or nonfasting options during the holy month of Ramadan. Abbreviations: ADBB, Abu Dhabi Blood Bank; PCR, polymerase chain reaction; SOB, short of breath.

available to produce health questionnaires, plasmapheresis educational materials, and informed consent forms, which require finesse to ensure patient rights are protected and legalities are satisfied. To thoughtfully draft, review, finalize, and approve documents for donor use would have required an exhaustive amount of time and resources on the part of the CCAD and ADBB, which circumstances at the time would not allow. It is reasonable to propose to the leadership of CCAD and ADBB that in the future they consider including educational materials and consents in the most frequently spoken languages to better serve the majority and thus the community as a whole.

Schedule availability was another challenge; many candidates were willing to donate but could not commit to a date or time owing to rotating work schedules.

The third major challenge was public transportation restrictions; many individuals rely on public transport and services were severely restricted during lockdown.

The fourth reason was lost to follow-up. Those who were phoned 3 or more times without answering were ultimately excluded from the pool of potential donors.

Confirmed candidates were forwarded for physician second contact via email or mobile phone. The physician then reached out to explain the informed consent and donor medical questionnaire, as well as set a date and time to meet at the blood bank to review forms and sign consent forms.

Two additional situational challenges were identified in coordinating times for meeting with the donor at the blood bank. A local lockdown with curfew restrictions was implemented mid-March 2020 in response to the pandemic to combat virus transmission within the community. Citizens and residents were asked to remain home, and nonessential businesses were closed from mid-March through the end of June with only essential services remaining open to ensure supply chain and the population's needs were met. People who needed to leave their homes during the curfew of 8 PM to 6 AM daily were required to obtain a government-issued permit to travel between curfew hours. The second issue identified was that the CCPDP was coincidentally initiated during the holy month of Ramadan, which took place from April 23 through May 23. Ramadan is a time in which Muslims fast from sunrise to sunset. In respect to fasting participants,

ADBB modified donation hours from 8 PM to 12 AM to accommodate those who had completed their fast for the day, thus likely avoiding untoward postdonation events. Nonfasting donors had a larger window between 10 AM to 8 PM.

COLLECTION OF THE PRODUCT

CCAD CCPDP was part of a full-design clinical trial to assess the efficacy of CCP. This trial was approved by the Hospital Research Committee and regulatory authorities (REC No.: A-2020-029), whereby all donors signed an informed consent before plasma collection. Selection criteria for donors included all the requirements for the prevention of transfusion-transmitted diseases⁹; additionally, donors had to have complete resolution of symptoms at least 14 days before donation, as well as 2 negative results for COVID-19 either from nasopharyngeal swab specimens or by a molecular diagnostic test from blood collected on different days. Furthermore, to guarantee safety for donors, no more than 2 collections of a maximum of 600 mL (500 mL if <80 kg of weight) were allowed to be carried out separated by an interval of at least 2 weeks.

Apheresis procedure (plasmapheresis) is currently the preferred method for plasma collection. It allows collection of larger volumes per session, as well as the potential for more frequent donations without impact on donor hemoglobin levels because of the reinfusion of red blood cells. To minimize the risk of transfusion-related acute lung injury, only males and nulligravid females were selected as the plasma sources.

Plasma collection and preparation was performed at the ADBB, which is a community-based blood center serving 44 facilities and collecting 50 000 blood products per year. The ADBB is certified in accordance with international guidance and accredited by the American Association of Blood Banks. CCP products thus obtained at ADBB were frozen during the first 8 hours of collection in accordance with good manufacturing guidelines. Fresh frozen plasma was transported to CCAD, maintaining its solid state, stored at -20°C , and thawed at 37°C for immediate transfusion. Because the efficacy of convalescent plasma is still unproven, the products were labeled by using ISBT128 codes as “for experimental use only.”

A total of 38 valid donors participated, upon whom 45 apheresis procedures were performed, with no significant side effects reported. Ultimately a total of 90 convalescent plasma units were collected and 43 patients were treated in acute care and intensive care units.¹⁰

ANTIBODY DETERMINATION

The methodology used was to plan apheresis plasma collection of filtered donors, and later to determine the antibody status in a sample of the donated plasma kept frozen at -20°C until the IgG antibody assay was validated.

In some of the collected products, the determination of antibodies was negative. These donors were rejected for further collections and their remaining units still in inventory were discarded. This happened with 8 donors at the beginning of the program; 6 of 8 were asymptomatic and had only 1 positive PCR result. Owing to these findings, the strategy to collect products was updated so only symptomatic donors who had at least 2 PCR positive test results were selected to enter the donation program.

Antibodies were determined by LIAISON SARS-CoV-2 S1/S2 (DiaSorin, Italy) IgG, which uses chemiluminescence immunoassay technology for the quantitative determination of anti-S1- and anti-S2-specific IgG antibodies to SARS-CoV-2 in human serum or plasma samples. According to the manufacturer, a cutoff above 15 AU/mL is considered positive, whereas a value below 12 AU/mL is considered negative. Values between 12 and 15 AU/mL are considered equivocal or in seroconversion phase. The assay is intended as an aid in the diagnosis of COVID-19, and to support the study of the immune status of infected patients by providing an indication of the presence of neutralizing IgG antibodies against SARS-CoV-2. Therefore, cutoff values above 80 AU/mL on this assay have been described to have concordance with a neutralizing antibody titer of 1:160 on the Plaque Reduction Neutralization Test¹¹ according to a recent publication.

DISCUSSION

The UAE was the first country in the Middle East to report a COVID-19-infected patient, with the first confirmed case documented on January 29, 2020. The UAE is a federation of 7 emirates established in 1971. The current population is 9.99 million and is an international model of social cohesion and cultural diversity, as more than 200 nationalities are represented within the country. According to 2021 demographic analysis of the UAE population, Emirati citizens represent 11.5% (1.15M) and expatriates (non-Emirati) comprise 88.5% (8.84M) of the population.¹² Taking into consideration the multicultural makeup of the country and the humanitarian nature of most of our COVID-19 admissions, most of these consisted of various ethnic groups and social strata for whom neither Arabic nor English was their first language. Roughly 54% (5.39M of 9.99M) of the total UAE population originates from the Indian subcontinent (India, Pakistan, Bangladesh, Nepal, and Sri Lanka), resulting in potentially 22 or more different languages and or dialects spoken. However, the persons conducting the phone calls to potential donors spoke either Arabic or English only, thus limiting effective communication with most candidates. CCAD does employ caregivers who speak many of the various languages; however, these caregivers were not available to assist in donor recruitment owing to concurrent mass mobilization of all clinical and ancillary support of inpatient, outpatient, and emergency department services to meet the immediate needs of the community.

This demographic provided challenges owing not only to communication limitations but also to bridging cultural gaps due to individual cultural concepts relating to egalitarian and hierarchal preconceptions, which had been developed and reinforced over a lifetime, resulting in contradictory perceptions¹³ in relation to the concepts and acceptance of donation.

Cleveland Clinic Foundation (Cleveland, Ohio) is a surgery-intensive organization that is ranked as the number 2 hospital across the United States.¹⁴ CCAD is the first international extension of an American hospital outside the United States, providing a “Cleveland Clinic model of care” in the UAE. CCAD opened its doors in March 2015 as a quaternary-tertiary care hospital. Cleveland Clinic’s “Patients First” principal core value seeks to provide the best possible outcome for every patient. Based on this core value, those clinically affected with COVID-19 were admitted independently of their insurance coverage at CCAD.

Admitted patients were classified into 3 categories: patients compassionately admitted who were unable to effectively isolate in their homes, as their primary residence consisted of shared accommodation; moderately/severely sick patients who required acute or critical care; and patients referred from other hospitals for advanced life-saving therapies such as extracorporeal membrane oxygenation.

We confirmed at least 2 positive PCR test results to establish initial diagnosis in the selection of individuals as possible CCP donor candidates. In our program, of the 3746 potential candidates, 3258 (86.9%) had to be excluded on the basis of absence of 2 PCR positive test results. Many of these candidates did not have a secondary PCR test in our HIMS for 3 primary reasons: they were transferred to another facility for further treatment and it was not possible to investigate whether secondary testing was performed; they had not reached the recommended timeframe for retesting by the time the extract was generated; or they were stable patients who were tested in the emergency department and discharged to quarantine at home without subsequent follow-up. In each scenario, the potential for missed donors was high. The successive filters removed 221 from the eligible pool of 488 (45.3%): language barrier removed 87 of 488 (17.8%); older than 60 years, 47 of 488 (9.6%); accessibility to donation, 56 of 488 (11.4%); comorbidities, 16 of 488 (3.2%); and other circumstances, 15 of 488 (3%). Therefore, the final population eligible to donate among those with confirmed diagnosis was 267 of 488 (54.7%), which is in line with other publications.¹³ In comparison with similar studies, an estimation published in 2007, after counting for donor exclusion factors, suggested that only 38% of the US population would be eligible to give blood.¹⁵ The inclusion of individuals 65 years and older had the single largest impact on the pool of eligible blood donors, increasing it to 62.6% in 2020.¹⁶ However, we could not accept individuals 60 years and older, since apheresis requires younger donors, making our final rate of 54.7% (267 of 488) for eligible donors very realistic and aligned with previous reports. Additionally, differences in donor eligibility rate have been associated with ethnicity; specifically, 42% of African Americans, 57% of Hispanics, and 62% of whites were estimated to be eligible donors in a recent study in the United States.¹⁷ All these differences published confirm that our 54.7% donor eligibility rate is suitable in our multicultural environment.

In respect to our calling experience, we found our results similar to those reported by other investigating teams.¹⁸ In a Hong Kong Red Cross Blood Transfusion Service study,¹⁹ a total of 9101 people who were confirmed to have recovered from influenza A (H1N1) were contacted and only 786 attended donation screening, which represents 8.6% of the total calls. In our study, which is of a much smaller scale, we contacted 80 eligible donors, of which 45% presented to the apheresis plasma donation appointment within the following 2 weeks. We believe that the positive response was due to the impact of the pandemic on society. Like all blood donation programs around the world, identification, selection, and recruitment of potential donors is not a simple task. But in the case of the COVID-19 pandemic, the general population was informed of the absence of preexisting specific treatments and protocols, and thus that their plasma

could be used as a therapeutic tool to aid in the recovery of active infection. In our opinion, these aspects facilitated the development of a CCP program and helped potential candidates in committing to donate.

As a summary of our experience, we can conclude that despite the limitations we faced at the beginning of the pandemic, where the serologic assays were not fully developed and donor conditions were still evolving, an effective program for CCP donation was established. A total of 90 units of CCP were collected, which permitted us to treat 43 patients before the pandemic curve flattened in the UAE, toward the end of June 2020.

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