An Effective Model for Establishing a Collaborative for the Treatment of COVID-19 in the Rio Grande Valley

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Abstract: The DHR Health Institute for Research and Development spearheaded a region-wide initiative to establish a Rio Grande Valley (RGV) Collaborative for early diagnosis, prevention, and treatment of COVID-19. The Collaborative was established on March 23, 2020, to conserve resources and provide the best clinical care in the face of an imminent regional health crisis in an underserved community, predominantly of Hispanic heritage with some of the highest rates of chronic diseases in the United States. The use of plasma obtained from convalesced SARS-CoV-2-infected donors was approved by the FDA and the RGV Collaborative took this as its initial challenge. To date, over 2,200 patients with severe and life-threatening COVID-19 have successfully received transfusion of convalescent plasma in various health care facilities in the RGV. The RGV Collaborative is a unique model for creating an effective public health strategy for the delivery of quality clinical care, especially in underserved communities.

Key words: COVID-19; convalescent plasma; SARS-CoV-2; expanded access; emergency use authorization, Rio Grande Valley.

The first case of the coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) was identified in Wuhan City, Hubei, China, in December 2019.[1–4] In the United States, the first reported case of SARS-CoV-2 infection was found on January 19, 2020, in Snohomish County, Washington.[4] On March 11, 2020, the World Health Organization (WHO) declared COVID-19 a pandemic.[5] On September 09, 2020, there were over 27 million confirmed cases of

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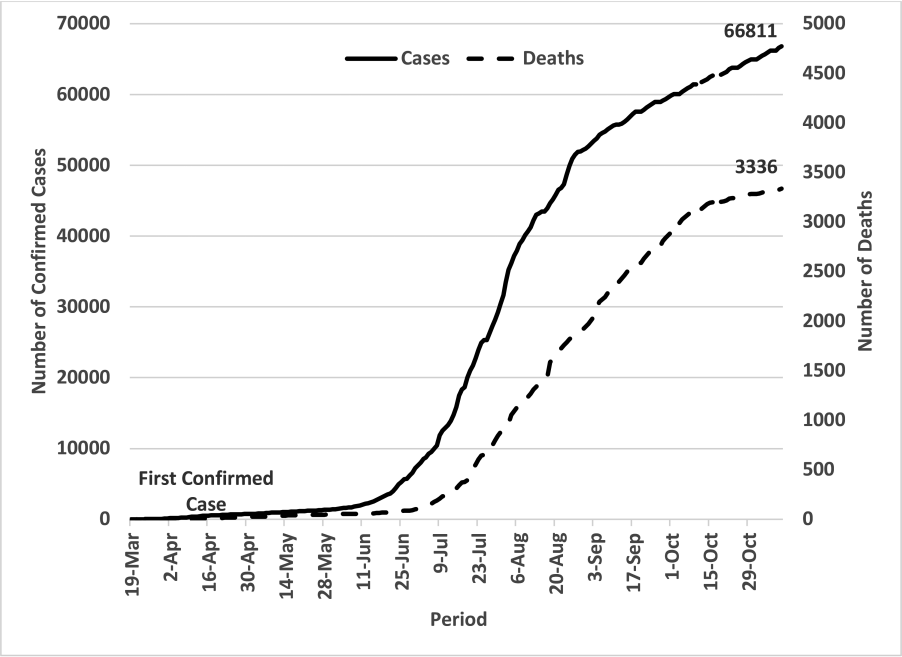

Figure 1. Number of confirmed COVID-19 positive cases (by rT-PCR) and deaths in the four (4) counties in the Rio Grande Valley from March 19, 2020–October 29, 2020.

COVID-19 worldwide, of which more than 6.2 million were in the United States and over 630,000 in the State of Texas.[6]

The Rio Grande Valley (RGV) is located along the U.S.-Mexico border in South Texas and has a population of over 1.4 million people. Over 90% of its residents are of Hispanic origin, with some of the highest rates of chronic diseases in the nation.[7–8] The first case of COVID-19 was confirmed in the RGV on March 19, 2019.[9] Since then, the RGV has witnessed a gradual increase in confirmed cases of COVID-19 as well as in deaths related to its complications (Figure 1). As anticipated, there was a concomitant increase in hospitalization of patients with severe and life-threatening SARS-CoV-2 infection. (Figure 2).

The use of plasma obtained from convalesced SARS-CoV-2 infected donors was considered as an investigational therapeutic intervention due to the lack of treatments approved by the FDA for patients with severe and life-threatening COVID-19. On April 08, 2020, in partnership with the Mayo Clinic, the FDA approved the use of convalescent plasma for the treatment of patients with COVID-19 as an Expanded Access Program (EAP).[10] Given the impending threat in the RGV, DHR Health Institute for Research and Development established a comprehensive system of convalescent plasma donation and distribution, which resulted in the treatment of over 2,200 patients with severe and life-threatening COVID-19. The partnerships with Vitalant, a regional blood bank provider, the health departments of four counties (Hidalgo, Cameron, Starr, and Willacy), and 11 local health care facilities were essential to this undertaking. The success of this program underscores the need to create such collaboratives across hospital systems and

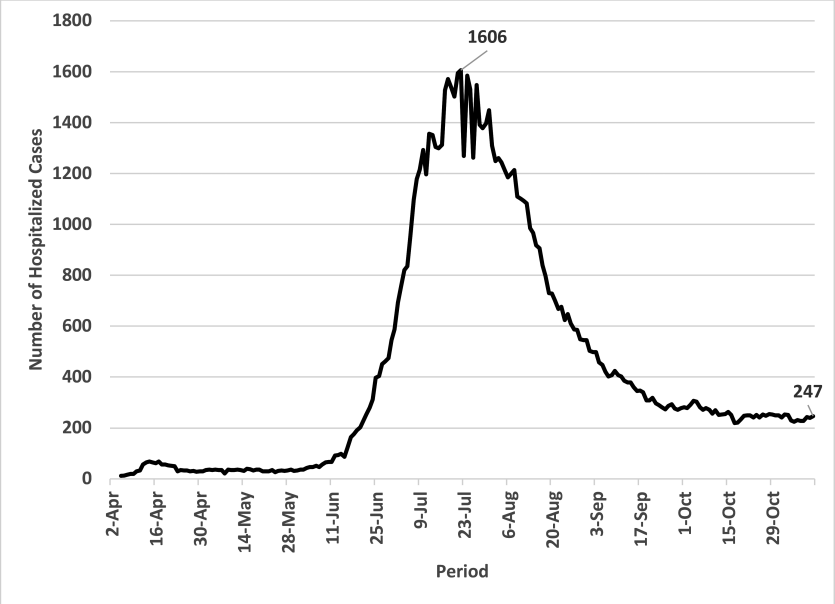

Figure 2. The number of hospitalized patients in various regional hospitals in the Rio Grande Valley (April 02, 2020–October 29, 2020).

county health departments, particularly in regions with medically underserved populations, to maximize the utilization of available assets and infrastructure in combating a pandemic such as COVID-19. Additionally, a productive and mutually beneficial partnership with the regional blood bank(s) is indispensable for the success of such a collaborative program. Establishment of the RGV Collaborative was predicated on the collective understanding that its inception would allow us to: serve the community most effectively; conserve limited resources; prevent duplication of efforts; help raise local awareness of the disease; and create a model for future collaborations in areas of public health interest.

Methods

Formation of the RGV Collaborative. As the COVID-19 pandemic started to involve the community in the RGV, it became evident that the use of convalescent plasma was perhaps the only therapeutic option available at that time to treat patients with COVID-19. However, despite this realization, there existed no mechanism to organize a large-scale project for collection and timely distribution of convalescent plasma for patients in various health care facilities in the RGV. As a consequence, discussion was initiated by the President and Chief Executive Officer of the DHR Health Institute for Research and Development with chief medical officers of regional hospitals, medical directors of the four county health departments, and a regional blood bank to establish a collaborative with the goal to provide this service to patients in health care facilities in the RGV. With the support and engagement of key stakeholders in the region, RGV Collaborative for the Early Diagnosis and Treatment of Patients with COVID-19 was established. All regional hospitals in the Valley were approached and invited to par-

Box 1.

THE STRUCTURE, ROLES, AND RESPONSIBILITIES OF COVID-19 RESEARCH TASK FORCE

	Plasma Donation Team	Plasma Distribution Team
Members	Plasma Donation Call Center Clinical Research Scientist Clinical Research Fellow Clinical Research Coordinators Data Analysts	24/7 Service Hotline Clinical Research Fellow Clinical Coordinator Convalescent Plasma Nurses
Tasks	Liaison with Vitalant Screen Potential Donors Obtain Electronic Consent via DocuShare Referral to Vitalant Arrange Plasma Donation Drives Donor Follow-up Maintain Inventory of Donated Convalescent Plasma	Enroll hospitals and physicians in Mayo Expanded Access (MEA) website (www.uscovidplasma.org) Enroll individual patient in MEA website and obtain code Release ABO compatible convalescent plasma to various hospitals in the RGV Share weekly updates and other relevant information with members of RGV Collaborative

ticipate in this initiative and ultimately 11 health care facilities expressed their interest in becoming active members of the RGV Collaborative (Box 1).

To make this collaborative a success, many other logistical steps were taken, including developing and implementing a robust system for identification, recruitment, consent from, and final approval of all potential donors, cataloging and maintaining all regulatory documents for donors and recipients, registration of sites, physicians, and plasma recipients on the Mayo Clinic website, organizing plasma donation drives, and coordination of plasma distribution to regional health care facilities. As a 501(c)(3) non-profit organization with a comprehensive infrastructure for clinical research, the DHR Health Institute for Research and Development was in a unique position to take the lead in the regional administration of the convalescent plasma program.

Formation of the COVID-19 Research Task Force. On March 23, 2020, DHR Health Institute for Research and Development established a COVID-19 Research Task Force with the explicit purpose of developing and executing a region-wide strategy to deal with the emerging threat posed by SARS-CoV-2 infection. To facilitate this process, two teams were set-up with distinct structures, roles, and responsibilities (Box 2).

Donor recruitment. The DHR Health Institute for Research and Development, with an established clinical research unit, had built extensive experience in patient recruitment in clinical trials and biobank initiatives. This experience and expertise which is

Box 2.

THE ELEVEN (11) REGIONAL FACILITIES THAT AGREED TO PARTICIPATE IN FORMING THE RGV COLLABORATIVE

County	Facility
Hidalgo	DHR Health Rio Grande Regional Hospital Edinburgh Regional Hospital Edinburg Regional Hospital—Heart Mission Regional Medical Center McAllen Medical Center
Cameron	Valley Baptist Medical Center—Harlingen Valley Baptist Medical Center—Brownsville Valley Regional Medical Center Solara Hospital, Harlingen
Starr	Starr County Memorial Hospital

specific to the RGV, provided the staff in the DHR Health Institute for Research and Development a distinct advantage to successfully lead the convalescent plasma donor program.

The success of this venture was predicated on our deep understanding of the community. We were aware that the residents of the Rio Grande Valley will be more than willing to participate or volunteer for research studies if: the research benefits the participant, their family, or future generations; that there is a tangible benefit to them and/or their community; and that participating does not take too much time or interfere with their clinical care. With these key facts in mind, we developed a protocol that would benefit both the donor and the recipient.

Multiple incentives were put in place to encourage local convalescent plasma donation. To confirm presence of anti-SARS-CoV-2 antibodies, each potential donor was subjected to a blood test. This was particularly valuable during the initial months when patients had symptoms indicative of the SARS-CoV-2 infection but were not able to get tested due to lack of widespread availability of the same. DHR Health Institute for Research and Development provided anti-SARS-CoV-2 antibody test to any individual who had COVID-19 symptoms confirmed during a telephone interview. Additionally, each potential donor was screened for blood type and cross-match. The benefits of undertaking this process were two-fold. The results of these tests were provided to the potential donors which, was yet another advantage in the recruitment process. Equally valuable for the Collaborative was to identify appropriate donors for recipients awaiting transfusion during the early months when the infection rate with SARS-CoV-2

was relatively low in the Valley. Recovered COVID-19 patients who tested positive for anti-SARS-CoV-2 antibodies were processed further for plasmapheresis.

At the DHR Health Institute for Research and Development, all participants who volunteered to serve as plasma donors were financially compensated for their time and effort. This was of particular value in this community which is socioeconomically disadvantaged. Financial compensation was provided in the form of a $50 gift card which was offered to the donors at the time of plasmapheresis or mailed to their home address that was provided at the time of enrollment.

For the clinical requirements of convalescent plasma donation, the donor eligibility criteria from FDA guidelines were adopted.[11] Plasma donation was carried out following a protocol that was developed and subsequently approved on April 07, 2020 by the DHR Health Institute for Research and Development Institutional Review Board.

Marketing and messaging approach. Social media (including Facebook, Twitter, and LinkedIn), regional print, and digital media outlets were used to encourage recovered SARS-CoV-2 infected patients to consider donating plasma.[12–14]

All four counties that make up the RGV are designated as medically underserved communities. This moniker is used frequently and residents in the RGV recognize that advanced clinical care is limited in this community. Residents were also well aware that therapeutic options to treat patients with COVID-19 were non-existent. It was, therefore, donors' strong desire that the donated convalescent plasma be retained for use for patients in the community.

Initially, finding the right messaging outlet was a challenge. Flyers were placed in the hospital clinics and information regarding the convalescent plasma program was added to the DHR Health Institute for Research and Development website, but it did not generate the level of engagement that was anticipated. Radio news interviews were more helpful but they also did not yield the desired outcome. The most effective media outlet was local television stations. In June 2020, when cases began to rise exponentially in the RGV, televised interviews and advertisements became the primary messaging outlet. All flyers and radio and televised interviews were then posted to Facebook© for widespread dissemination. Subsequently, COVID-19 recovery groups were formed in the RGV on Facebook© where information and flyers were reposted by members of the community.

Working in partnership with Vitalant, numerous plasma donation drives were also organized in the region to facilitate plasma donation in geographical locations most convenient for potential donors (Figure 3). An online portal was also established for potential donors to register prior to these plasma donation drives.

Additionally, partnerships with health departments and local primary care physicians in the four counties in the RGV were also very critical. The county health departments and regional physicians provided lists of potential donors for screening and encouraged them to donate. All potential donors were screened by telephone prior to obtaining electronic consent using Xerox® DocuShare®. The donors were subsequently referred to Vitalant for plasmapheresis.

Hospital and physician registration on Mayo Clinic website. All regional hospitals in the Valley were approached and invited to participate in this initiative. Ultimately

Figure 3. A sample flyer for plasma donation drive in Starr County.

11 health care facilities expressed their interest in becoming active members of the RGV Collaborative (Box 1). Additionally, a total of 89 physicians in various regional hospitals became part of this initiative. DHR Health Institute for Research and Development assisted with the registration of local hospitals and physicians in the Mayo Clinic Expanded Access (MEA) website (www.uscovidplasma.org) to participate in this protocol. Although registration could have been done by each hospital and/or physician independently, there were many who were unfamiliar with the process. The President and Chief Executive Officer, DHR Health Institute for Research and Development, a Clinical Research Scientist and a Clinical Research Fellow served as 24/7 virtual help desk for any hospital, physician, or community member that needed information regarding the convalescent plasma program.

Plasma distribution process. A communication network involving the Plasma Distribution Team at DHR Health Institute for Research and Development and Vitalant was established to ensure the timely release of ABO-compatible convalescent plasma. The team worked around the clock (including weekends) to distribute plasma on a first-come-first-serve basis. Facilities either registered their patients on the MEA website or provided relevant patient information to the Plasma Distribution Team at

DHR Health Institute for Research and Development to register the patient and obtain the appropriate code. Information about the patient, along with the relevant code and blood group, were ultimately shared with Vitalant's Hospital Services Department in order to release convalescent plasma promptly.

Transition from Expanded Access to Emergency Use Authorization. On August 23, 2020, the FDA issued an Emergency Use Authorization (EUA) allowing the use of convalescent plasma for the treatment of COVID-19 in hospitalized patients.[15] This transition from EAP to EUA was effective as of 12:00 a.m. EST on Saturday, August 29, 2020. With this transition, the requirement to register patients on the MEA website was eliminated while the rest of the process for plasma collection and distribution remained unchanged. Members of the RGV Collaborative were provided with a draft informed consent form that complied with the requirements of the FDA to assist with the transition from EAP to EUA. Additionally, in some facilities, a local code was generated using a similar process to the one previously used for MEA registration. This latter process was implemented to assist with the identification of patients receiving specific units of convalescent plasma for future reference.

Results

Practical approaches and lessons learned. The establishment of the COVID-19 Research Task Force and the Plasma Donation and Distribution teams was critical in the successful donation and distribution of convalescent plasma within the RGV. Defining the distinct roles and responsibilities of the teams was vital in managing this complex process most effectively (Box 2).

Transparency was crucial to the development of a working partnership with Vitalant, all four county health agencies, hospital facilities, and prospective donors. These partnerships were essential to ensure access to potential donors as well as the timely recovery and distribution of convalescent plasma. Since the inception of the convalescent plasma program, data were shared on a weekly basis with all concerned parties who described how many donors were screened; how many potential donors completed plasmapheresis; how many units of plasma were collected; and how many units of plasma were transfused at each individual facility. This level of transparency was extremely important to gain and retain the trust of all involved in this process. These data were also shared through email with local public health officials, county health agencies, and physicians participating in the protocol and through Facebook© for the community's perusal.

Indispensable to the attainment of our goals and objectives was the creation of a 24/7 hotline that was available to both the medical community and residents of the RGV for plasma donation. This service was crucial in recruiting potential donors and securing informed consent from the patients or their legally authorized guardians. The availability of this 24/7 hotline was important as it provided the prospective donors the opportunities to seek information and donate at times that accommodated their working schedules. Family members of hospitalized patients also used this resource to gain more information about the benefits of convalescent plasma therapy. For the medical community, this service provided timely registration of patients and allocation

Table 1.

DATA CONCERNING POTENTIAL PLASMA DONORS, UNITS OF CONVALESCENT PLASMA OBTAINED AND TRANSFUSED IN HOSPITALIZED PATIENTS WITH SEVERE AND LIFE-THREATENING COVID-19 (AS OF NOVEMBER 27, 2020)

Plasma Donors (*n*)			Plasma Units (*n*)[a]		Plasma Recipients (*n*)				
Screened	Consented	Procedures	Donated	Transfused	EAP		EUA[b]		Total
					1,520		725		
1,804	1,314	1,126	3,636	2,847	One Unit 1,240	Two Units 280	One Unit 372	Two Units 353	2,245

Notes:
[a]Plasma units were also obtained from Vitalant's National Stockpile.
[b]Since August 29, 2020.

of available ABO-compatible convalescent plasma for hospitalized patients with severe and life-threatening COVID-19.

Since the inception of the RGV Collaborative and as of November 27, 2020, over 1,800 potential plasma donors have been screened with 1,314 consented to donate convalescent plasma (Table 1).

In the face of social distancing, the use of electronic consenting process was essential to accomplishing this outcome. Of the consented donors, there have been 1,126 successful procedures yielding 3,636 units of convalescent plasma (Table 1). The remaining consented donors are scheduled to donate in the coming days/weeks. Organization and coordination of four plasma donation drives in various locations in the RGV were also successful, particularly for donors who were unable to travel to distant places to donate convalescent plasma. Another success factor was the assurance provided to the donors that the donated plasma would be retained in the RGV for use on patients hospitalized in local health care facilities with severe and life-threatening COVID-19. The provision of a $50 stipend to donors who had completed the process also facilitated this process.

With the transition from EAP to EUA on August 29, 2020, the need to register patients in the MEA website was eliminated. This transition, however, did not alter the plasma donation and distribution process, which continued without any interruption. An informed consent template was developed and shared with health care partners in the Consortium to continue to obtain required informed consent from the patients or their legally authorized representatives. Of the recovered plasma, over 2,800 units have been transfused in over 2,200 patients with severe and life-threatening COVID-19 in various health care facilities in the Valley (Table 1). Over 1,600 patients received transfusion of a single unit, whereas over 600 patients with severe or life-threatening COVID-19 received two units of convalescent plasma during their hospitalization.

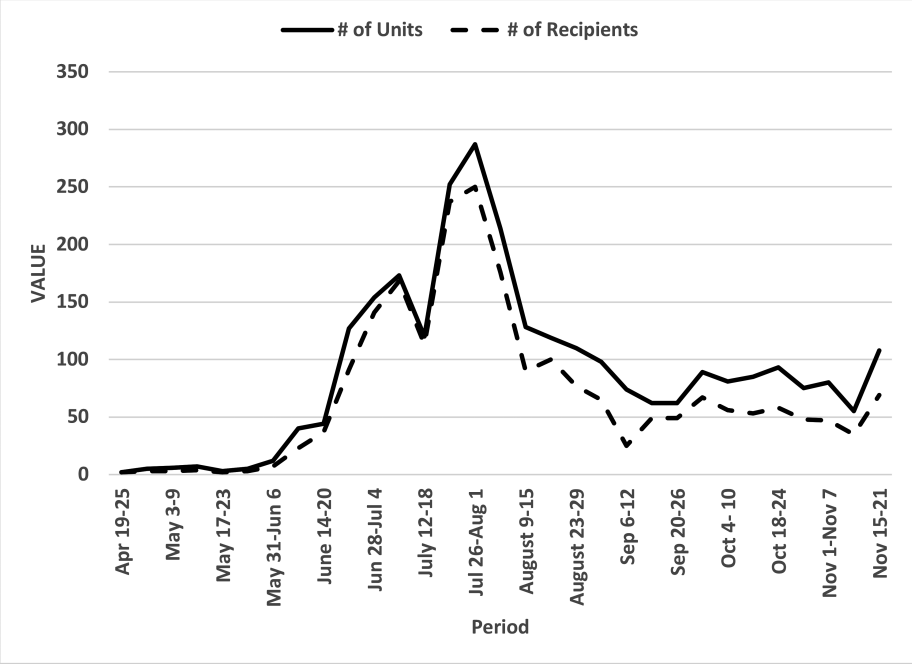

Figure 4. The gradual increase and subsequent decline in the number of patients with severe and life-threatening COVID-19 requiring convalescent plasma therapy in the Valley.

At the peak of the COVID-19 pandemic in the RGV (July 26–August 01, 2020), the Collaborative provided 287 units of convalescent plasma to treat 250 patients with SARS-CoV-2 infection (Figure 4).

Discussion

The RGV Collaborative is a unique model for creating a functional public health strategy for collection and distribution of convalescent plasma for the treatment of patients with COVID-19. Such a model can be replicated for the delivery of quality clinical care, especially in communities that are underserved with predominantly minority population. The continued success of such collaboration hinged on creating a model that is built on common goals and outcomes. To effectively work across various corporate systems and launch such a Collaborative, it was vital to establish mutual trust and create and sustain an environment of openness with information. Members of the Collaborative appreciated the value and purpose of such an endeavor, the outcome of which was to conserve resources and best serve the needs of the patients in the community. It was equally important to engage community leaders, civic organizations, regional print, and media outlets to support such a collaborative. Finally, for its enduring success, the support of the public was essential. The community not only appreciated the significance of such a venture but proactively extended their support, an outcome that was forthcoming once the impact of the community-wide effort was realized.

Declarations

Ethics Approval and Consent to Participate: The DHR Health Institute for Research & Development Institutional Review Board approved the protocol for the donation and collection of convalescent plasma. The administration of plasma to patients with COVID-19 was approved by the Mayo Clinic Institutional Review Board and endorsed by the local Institutional Review Board. Convalescent plasma was administered under FDA Expanded Access Program and Emergency Use Authorization.

Consent for Publication

All authors have significantly contributed, reviewed, and approved the final version of this manuscript.

Availability of Data and Materials

All data used for the current manuscript has been depicted in the figures and tables. Additional details may be requested in writing to the corresponding author.

Competing Interests

None of the authors have any competing financial interests.

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