COVID-19 Convalescent Antibody Testing in Donors

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Background

➢ Novel coronavirus SARS-CoV-2 discovered Dec. 2019 during unusual pneumonia outbreak in Wuhan City, Hubai Province, China

➢ Causes a disease called COVID-19

➢ Reported to WHO on Dec. 31, 2019

➢ Spread rapidly internationally

➢ Jan. 30, 2020 WHO declared outbreak to be a Public Health Emergency of International Concern

➢ March 11, 2020 WHO declared a global pandemic

➢ Does not appear transfusion-transmissible, but is infectious person-to-person via respiratory route
As of May 25, 2020 there were over 5 million cases globally with more than 340,000 deaths

As of May 25, 2020 in the U.S. there were over 1.6 million cases and close to 100,000 deaths

Clinical symptoms:
- Fever, chills, dyspnea, fatigue, body aches, headache, loss of smell/taste, sore throat, sniffles, nausea, vomiting, diarrhea

Mild to life-threatening disease

Potential for overwhelming healthcare system capacity

No specific treatment, no vaccine

Use of COVID-19 convalescent plasma shows promise
On March 23, 2020, the FDA authorized use of CCP for treatment of severe COVID-19 via 3 pathways:

- eIND
- Mayo Clinic EAP
- Traditional IND

FDA requirements for CCP donor intake for eIND and EAP:

- Had a positive diagnostic test (e.g., nasopharyngeal swab) at the time of illness or,
- Had a positive serological test for SARS-CoV-2 antibodies after recovery or, had a physician attestation that this testing was performed and
- had complete resolution of symptoms for at least 28 days initially (later changed to 14 days) before the donation and
- meet all allogeneic donor requirements

Sample retention for neutralizing antibody titers to be performed later
Challenges

At the time of the FDA announcement, many areas of the U.S had a large backlog of need for CCP

Blood centers have no ready access to lists of persons recovering from CCP

There were no blood center processes in place to screen or collect CCP donors

There were no blood center staff trained to collect CCP donors

There were no dedicated facilities for collection of CCP donors

There were shortages of PPE – particularly masks

There were local shortages of plasma collection kits

Some centers had furloughed staff due to decreased collections

How to ramp up production of this novel product?
# Considerations

- **How to identify and recruit CCP donors**
  - Dedicated facilities needed?
  - Level of PPE?
  - Dedicated staff?

- **How to collect them**
  - Confidentiality HIPAA
  - Handling directed donations

- **How to maintain traceability of units if done manually**

- **Recordkeeping for donors**
  - Confidentiality HIPAA
  - Handling directed donations

- **Physician and family communication**

- **Media and public communications**

- **Cost**

- **Prioritization of recipients**

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**Considerations**
One Large Blood Center’s Approach

IRB approval (for potential research)

Engage Project Management Office

Phased strategy
- Manual
- Automated
- Global blood donor testing

Approach
- Deploy Medical Directors for screening/intake
- Deploy extra staff from collections
- Use mobiles for dedicated collection sites
- Full PPE per CDC recommendations
Phase 1: Manual Donor Intake and Getting the Word Out

Website
1-800 number with staff assisted manual form completion

Encrypted email with blood center MDs screening donors

When calls received asking for a CCP unit, a qualified donor was requested from the caller

Manual scheduling and collection - Drove mobiles to donor

White glove distribution – one courier/one product to hospital with manual handoff

Social Media
Letter to hospitals
Meetings with state Medical Association
Meetings with FDOH
Meetings with Governor’s office

Output weeks 1 & 2 = 2-6 units per day
Phase 2: Automated Process

Registered CCP donors through website using CRM software

Fill out forms, upload lab results

Scheduling software – small drives scheduled

BloodHub for inventory and distribution

Cleared backlog

Began to build inventory
CCP Donor Intake

494 CCP Donors Presented

44 CCP Donors Deferred

450 CCP Donors Collected

345 CCP Donations Available for Transfusion

105 CCP Donations Discarded Positive Test Results

196 CCP Donations Not Tested for SARS-CoV-2 Antibodies Released for Transfusion

139 CCP Donations Tested Reactive for SARS-CoV-2 Antibodies Released for Transfusion

10 CCP Donations Tested Nonreactive for SARS-CoV-2 Antibodies Not Released for Transfusion*

*current criteria
Discussion & Questions
Heather Moulder
Director of Marketing & Public Relations

THE BLOOD CONNECTION
Your Community Blood Center
First - Consult Your Donors

• Have your donors been asking?
• Find ways to ask your donors about what they think
  • Survey (Email or Phone)
  • Focus Groups
  • A/B Testing
• Talk to ALL donors
  • Current
  • Lapsed
  • Super-lapsed
The Launch - Things to Consider

- No ordinary marketing campaign
- Many, many meetings
- Ensure all affected departments are included in planning
- Take into consideration all that must be done to make the change
External Promotion

- Think outside the norm for promoting this program
- Reaching current donors
  - Emails
  - Texts & Cloud Calls
  - Social Media Pages
- Reaching potential donors
  - Social media ads (targeting specific areas and interests)
  - Every-door direct mail
  - Press Releases
  - Local media contact
Internal Communication

• This **cannot** be an afterthought
• Early – Clear – Concise
• ALL forms of internal communication
  • Employee Newsletter
  • Intranet Posting
  • Internal Talking Points
  • Time clock posters
• Be ready for **ANY** questions!
Support Materials

- Signs
- Brochures
- Flyers
- Website
- ALSO – Support Staff
  - Phone Bank
  - Online Community Managers

Free COVID-19 Antibody Testing for all Donors
Lessons Learned

• Be upfront about timing
• Beware of internet trolls
• One thing to remember...

"If someone hadn’t donated blood, I wouldn’t have this life that I love."
– Emma, Recipient