

Ebola Convalescent Plasma Trial in West Africa

Clinical Trial Sponsor: Clinical Research Management, Inc. (ClinicalRM)

Presented for IPFA, May 2015
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Purpose (Protocol 1)

Correlate IgG and neutralization titers in Ebola Convalescent Plasma with viral load in treated subjects

Compare survival of subjects treated with and without plasma

Assess safety of treatment with and without plasma

Purpose (Protocol 2)

Pre-qualify potential Ebola Convalescent Plasma donors for donation and collect plasma by apheresis for clinical trials or compassionate use

Assess quantitative and qualitative changes in anti-Ebola virus antibody in survivors over a period of one year

EBOLA IS SERIOUS EBOLA IS A VIRUS

DO **NOT** EAT BUSH MEATS

HOW IT IS SPREAD FROM PERSON TO PERSON:

- Contact with Bodily Fluid from an Infected Person
 - Do Not Touch
 - Do Not Shake Hands or Hug



SYMPTOMS OF EBOLA:

- VOMITING
- DIARRHEA
- BLEEDING

HOW TO PREVENT THE SPREAD OF EBOLA:

- GLOVES • EYE PROTECTION
- GOWNS • MASKS • BLEACH
- ANTIBACTERIAL SOAP
- DISINFECTANT SPRAY
- HAND SANITIZERS



Who?

Clinical Trial Sponsor: ClinicalRM

Funding provided by: Bill & Melinda Gates Foundation

Subject matter experts contracted from:

- SIM and ELWA Hospital: Dr. Jerry Brown, PI
- University of North Carolina; Duke University
- Safe Blood for Africa
- Blood Centers of America, Inc.

Virologic and immunologic analyses provided by: USAMRIID

All clinical work was performed by Liberians

Who? (continued)

HopeMobile: Paul Allen Foundation and the Jim Greenbaum Foundation

**Transportation of equipment provided by:
World Food Programme**

INTERCEPT for PI: Cerus Corp.

Apheresis equipment: Haemonetics

**Protocols approved by: Liberian and US IRBs
Oversight by: Multinational DSMB**



Operational Objectives (Protocol 2)

Deploy outfitted bloodmobile for donor screening, plasma collection, pathogen inactivation

Develop SOPs and Train Staff

Configure and Implement BECS

Develop Processes around handling plasma; freezing, pairing, thawing, distributing

Collect Convalescent plasma from Ebola Survivors

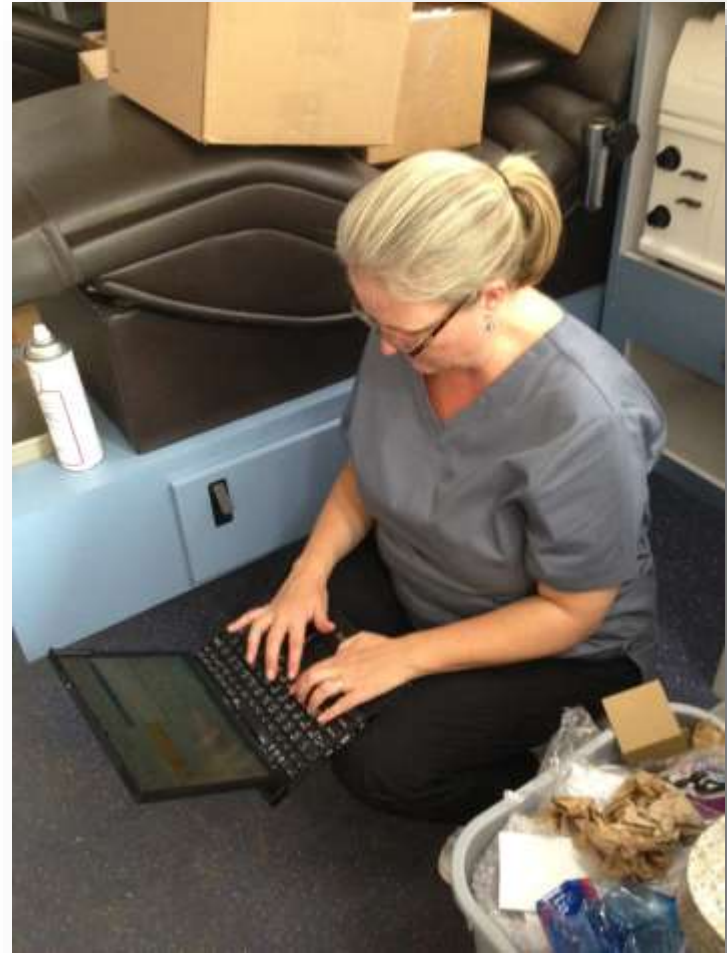


Meeting the HopeMobile November 15

Inside the HopeMobile



Inventory – 3 days in a metal box



Training – PCS2 Collections



Pathogen Inactivation





The Apheresis/Laboratory Team

Darlington Komosee Galakpai Gorvego Uriah Glaybo

Survivors = Donors

On discharge, contact
information collected

Survivors provided with
certificates

Survivors provided with
basic replacement items

- Mattresses
- Clothing
- Etc.





Donor Recruitment

Compensation for Time and Travel

Transportation

Verification of Survivor Status

Health Symposiums/Clinics

Empowerment/Survivor Groups



Donor Protocol

Screen donors with questionnaire

Collect 650ml plasma/samples for IDT

Pathogen Inactivation

Split into 100ml bags

Freeze/Label/Store

IDT using rapid antibody detection tests

Donor Suitability

(first 67 screened donors; 58 collected)

Concerns

Overall Metabolic Status

Low Hemoglobin

Low Weight

High Infectious Disease Rate

High Reaction Rate

Low Total Protein/Albumin

Reality

Only 3 women “in their moon” were deferred for Hgb < 12.0

No deferrals for weight

16 donors permanently deferred (24%)

No reactions/8 QNS (14%)

Currently unable to test for protein

Our First Donor

December 5 – Screening Visit

23yo, female; 52kg

Infected with Malaria
on discharge from ETU

Donated Convalescent
WB previously

Scared of needles

December 8 - Donation



Donor Care

Each offered meal in Cafeteria

Ca+ fortified water during screening

Screened for orthostatic (postural) drop in BP
500 ml Saline replacement end of procedure

Standard snacks on discharge

Multivitamins/Iron given as part of their
Screening “Thank You” package

EMLA cream

Strong Donor Engagement throughout process





Patient Transfusions (1st Protocol)

Protocol Particulars

Assumption that Plasma Availability would be limiting factor

Each patient receives 3 treatments 48 hr apart

- 2, 100ml bags
- 2 donors paired
- Patient gets all plasma from same 2 donors

Allows for A to go to B

EBOV tested in recipients at consent and before and after each txn

6 Patients Enrolled

- Monitored with ISTAT – Chem8+ and INR
- Generally high BUN/creatinine
- 4 Opos (transfused)
- 2 Apos (control group)

NO Apos plasma
available

(Stored plasma is
70% Opos,
20% Bpos,
10% Apos)

- Currently no Patients in Liberia to enroll





Ongoing Work

Stockpiling plasma for future need

Collecting data/samples on Survivors

Exploring partnership for IG fractionation

