BEARING MANY BURDENS
SOURCE PLASMA DONATION IN THE U.S.

Heather Olsen
David Margolius, MD
Anupama Cemballi
Kristin Berg
Sarah Shick
Adam Perzynski, PhD

Patient Centered Media Lab @
Center for Health Research and Policy
Case Western Reserve University & MetroHealth Medical Center
US PDC LOCATIONS AS OF 1.1.2018 (N=664)
STUDY OVERVIEW

- Explore the potential inequity of Plasma Donation Centers (n=664) in the U.S. through micro and macro data sources
- Conduct interviews with plasma donors (N=64) to gauge economic and health impacts of donation
- Analyze state-level federal census and economic data that may correlate with PDC prevalence
1918: Plasma as a blood substitute proposed in the BMJ

1940-1941: Getting whole blood to the front during WWII is problematic due to supply chain issues; physician Charles Drew leads the “Plasma for Britain” initiative to collect and dehydrate U.S. plasma which can be reconstituted with sterile water and infused at the aid station.

1940s: Plasma fractionation with ethanol into 5 components is developed; the current industry is predicated on this advance, and allows batch processing of source plasma

1950s: Immunoglobulins are first used to supplement immune response

1960s: Factor VIII and Factor IX are isolated for treatment of hemophilia

1970s-80s: Reliable Intravenous Immunoglobulin (IVIG) is developed

1990: NIH Consensus Statement on IVIG efficacy

Today: technology includes detergents, large batches and high level of processing into factors and IVIG
U.S. PLASMA BUSINESS EVOLUTION

- 1940s: Widespread volunteer support of plasma donation during WWII, sponsored by Red Cross and Daughters of the American Revolution in U.S.
- 1950s: Demand for plasma remains, but volunteer support dwindles. Paid plasma centers emerge in large cities.
- 1970s: Plasma Donation Centers are primarily “mom and pop” operations who subcontract with fractionators. Hemophilia factors are market drivers.
- 1990s: Major HIV/AIDS settlements cause dissolution and reforming of companies. Industry consolidation and vertical integration with foreign companies beginning to invest in U.S. centers.
- Early 2000s: CJD concerns in UK/Europe drive more production towards U.S. Continued consolidation and increasing production of IVIG; Hemophilia factors no longer driving the market
- Today: 70-80% of the world’s plasma supply comes from paid U.S. donors, $20B USD industry
PARENT CORPORATIONS

Shire

octapharma plasma

CSL Plasma

GRIFOLS

bpl plasma
Plasma Company Consolidation, 1998-2018
METHODS (SURVEY)

- Survey conducted at CSL Plasma, West 25th St, Cleveland, Ohio from Feb-Aug 2017
- Reviewed and Approved by MetroHealth Medical Center IRB
- Funded by Drs. Perzynski and Margolius
- Approached individuals who had donated plasma that day
- 10 minute survey covering demographics, health, and donor experiences based on Pilot Study (Aug 2016)
- Participants given 24 hr transit pass as compensation (value: $5.5 USD)
- Conducted in 1-2 hour blocks over the course of several months on different days of week and time of day, 2-3 interviewers at a time using standard form
SURVEY LOCATION

3203 W 25th St
Cleveland, Ohio

Google, Inc.
AUG 2017
1974: Plasma Alliance at 3204 W 25th certified by FDA (this was the first year certification was issued)

1997: Ownership change to Centeon Bioservices

2000: Ownership change to Aventis Bioservices (FR)

2004: Aventis-Behring becomes ZLB Plasma (GER)

2008: ZLB becomes CSL Plasma (AUS)
DONATION EXPERIENCE

- Twice per week, minimum 48 hrs between donations
- Maximum 104 donations per year
- No appointments (a few exceptions)
- Takes 1.5-4 hours (depending on wait)
- Paid on reloadable debit card, $15-$40 per session depending on donor weight and company
- Paid more for 2\textsuperscript{nd} weekly session, 8\textsuperscript{th} monthly donation to ensure donation frequency
- This location removed chairs from waiting room according to donors

Process:
  - Initial queue – Computer Questionnaire
  - 2\textsuperscript{nd} queue – Vital Signs and Anemia Check
  - 3\textsuperscript{rd} queue – Wait for open donation bed
  - Donation – 45 – 60 min
SURVEY RESULTS (N=64)

DEMOGRAPHICS

- 78% Male / 22% Female
- Ethnicity
  - 84% Black / African American
  - 10% Mixed / Unknown
  - 5% White / Caucasian
- Age
  - Mean: 35.7
  - Median: 35
  - Min: 20
  - Max: 63
- 20% in school (College, Vocational)
- 43% currently employed
SURVEY RESULTS (N=64)

57% will make > 1/3 of their income this month from donating plasma (max $250-300 USD)

70% experienced a side effect after donation (weakness, bruising, dehydration, fainting)

30% use prescription/OTC medicines (asthma, pain relief, HTN, diabetes, antidepressants)

13% have misled plasma center workers in regards to medical conditions in order to donate
HOW DONORS SPEND EARNINGS

# of Respondents

- Food
- General Spending Money
- Gas Money / Car
- Help Out Friends/Family
- Rent / Housing
- Other*
- School Supplies
- Child Care
- Entertainment
- Medical Care / Bills
- Medication
- Street Drugs
- Education

0 10 20 30 40 50 60
RESPONDENT THOUGHTS ON DONATION

LIKE ABOUT DONATING

<table>
<thead>
<tr>
<th>Reason</th>
<th># Respondents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Helping Others</td>
<td>20</td>
</tr>
<tr>
<td>Both Helping &amp; Money</td>
<td>10</td>
</tr>
<tr>
<td>Money</td>
<td>5</td>
</tr>
<tr>
<td>Easy / Convenient</td>
<td>0</td>
</tr>
<tr>
<td>Don't Like It</td>
<td>5</td>
</tr>
<tr>
<td>Staff</td>
<td>0</td>
</tr>
</tbody>
</table>

DISLIKE ABOUT DONATING

<table>
<thead>
<tr>
<th>Reason</th>
<th># Respondents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wait / Time</td>
<td>25</td>
</tr>
<tr>
<td>Needles / Blood</td>
<td>15</td>
</tr>
<tr>
<td>Side Effects</td>
<td>10</td>
</tr>
<tr>
<td>No Complaints</td>
<td>5</td>
</tr>
<tr>
<td>Staff Attitude</td>
<td>0</td>
</tr>
<tr>
<td>Low Pay</td>
<td>5</td>
</tr>
</tbody>
</table>
STATE LEVEL ANALYSIS
METHODS (STATE LEVEL ANALYSIS)

- Correlation analysis between various state level data and plasma donation centers per state

- PDC location data obtained from the FDA Center for Biologics Evaluation & Research (CBER) Database
  - Specialty and Non-Profit source plasma centers excluded from analysis (n=25 PDC, n=27 NPBC)

- State Population and Poverty Data (American Community Survey)

- State Minimum Wage Data (National Conference of State Legislatures)

- Persons Working at or Below Federal Minimum Wage [$7.25 USD / hr] (U.S. Bureau of Labor Statistics)
Correlation of State Minimum Wage with # of PDCs per 1M residents, $R = -.53$
Correlation between minimum wage workers and # PDCs 2018, $R = 0.824$

Correlation between minimum wage workers and # PDCs 2019, $R = 0.866$
Figure 2

Distribution of Adults in the Coverage Gap, by State and Region

Distribution By State

- Other States that Have Not Expanded Medicaid: 34%
- TX: 29%
- FL: 17%
- GA: 11%
- NC: 9%

Distribution By Geographic Region

- South: 89%
- Midwest: 7%
- West: 3%
- Northeast: <1%

Total = 2.2 Million in the Coverage Gap

NOTE: Totals may not sum due to rounding.
CONCLUSIONS

- Donors are using proceeds to pay for basic necessities
- Low income people + minimum wage (or less) jobs + inadequate cash assistance appear to present best opportunity for PDCs to arise
- Insulating factors appear to be increased wages (to some extent) and increased state spending on cash assistance benefits
- Significant numbers of donors who live in states without expanded medical coverage would not be able to afford the lifesaving therapies created by their own plasma contributions
What are the health impacts of very frequent, long term plasma donation?

Are PDCs becoming a barrier to exit for people living in low income neighborhoods?

What role does state and local government play in the proliferation of and dependence on PDCs?

Might increased regulation lead to a more equitable PDC experience?