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The Interlinkage between Blood Plasma Donation and Poverty:
An Examination of the Location of Plasma Centers in the United States

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Introduction

In 2019, plasma centers in the United States received a record 53.5 million paid plasma donations, roughly three times than what was recovered during the Great Recession. (Plasma Protein Therapies Association 2011 and 2019). The number of plasma donation centers has expanded from fewer than 300 in 2005 to over 900 in 2020, supporting a growing industry that was worth $4 billion in 2008, $21 billion in 2016, and is forecast to reach $48 billion by 2025 (Hotchko and Robert 2018, Market Research Engine 2020, Mitchum 2008, U.S. Food Drug Administration 2020, Wellington 2014). Ethnographic research and journalistic accounts suggest a key motivating factor fueling plasma donation in the U.S. is the financial compensation associated with the transaction (Edin & Shaefer 2015, Goldstein 2017, Guendelsberger 2019, Kretzmann 1992, Tirado 2014, Valiente, Abdelmalek, & Pearle 2017).

These accounts suggest paid plasma donation has become a common economic coping strategy among Americans with low incomes, who over the past decades have experienced high rates of poverty and hardship, steep increases in the costs of essential expenses, declines of the cash safety net, and a corresponding rise in extreme poverty (Edin & Shaefer 2015, Valiente, Abddelmalek, & Pearle 2017, Wellington 2014, Woolf, Johnson, & Geiger 2006). Because U.S. Food and Drug Administration (FDA) regulations permit American donors to sell plasma up to twice a week (US FDA 2019), these donations can add a few hundred dollars a month to household income, an important source of economic support for families with very low incomes. During the COVID-19 era, increased demand for blood products and a new recession will likely only intensify this reality.

Despite the large growth in plasma donations since the Great Recession, recent existing literature has not examined the demographic characteristics of the growing number of plasma donors, reportedly Americans with low incomes who are already prone to poor health outcomes (National Center for Health Statistics 2012). Such evidence would hold clear public health implications, particularly given the limited evidence on the impact of plasma donation on donor health. In the absence of publicly available data on the characteristics of plasma donors, this study examines the socioeconomic characteristics of the communities where plasma centers are situated.

Background

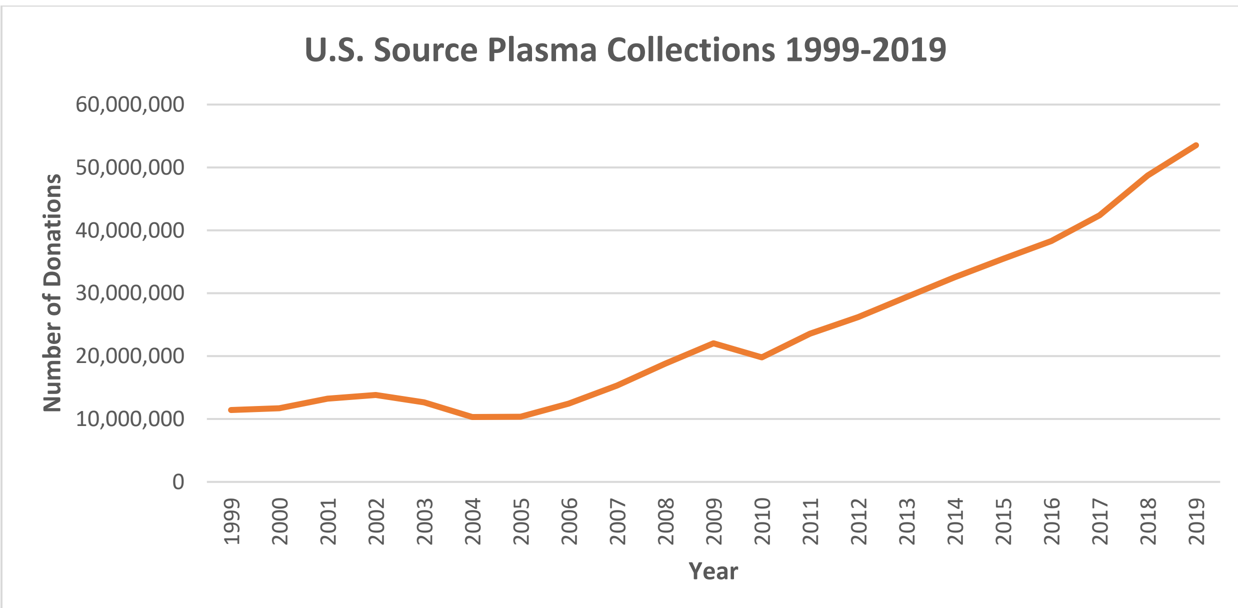
Plasma donation, or plasmapheresis, is a procedure that involves the extraction of plasma from the blood for the use of medical therapies. The plasma exclusively extracted from voluntary donors is known as source plasma, defined by the FDA as the fluid portion of human blood intended as source material for further manufacturing use (US FDA 2019). Plasma is used in medical therapies called plasma protein therapies (PPT) (Market Research Bureau 2018a). These therapies primarily benefit patients suffering from rare diseases, namely antibody deficiencies and hemophiliacs (Farrugia and Robert 2006).

As worldwide demand for plasma-derived therapies has expanded, so has the presence of plasma centers across the U.S. (Hotchko and Robert 2018). The global plasma industry relies heavily on U.S. donors because the U.S. holds the least restrictive plasma regulations in the world (Hotchko and Robert 2018, Robert 2017). A single U.S. donor can yield far more donations than in any other country because most countries limit plasma donation to once every 2 weeks and prohibit paid donation (The Lancet Haematology 2017). In 2016, the United States accounted for 74% of the world’s source plasma supply, while North America accounted for

44% of the demand (Hotchko and Robert 2018, Robert 2017), meaning plasma from U.S. donors is used all across the world.

Figure 1 charts total paid plasma donations in the United States by year, 1999-2019. While the number of donations remained steady between 1999 and 2005 — with some slight counter-cyclical variation — donations began to increase rapidly starting after 2006, quadrupling by 2018.

Figure 1: U.S. Source Plasma Collections 1999-2019



Source: Plasma Protein Therapeutics Association 2011 and 2019.

Health Implications of Plasma Donation

The limited evidence available on the impact of plasma donation on donor health focuses on (1) the linkage between plasma donation and distribution of risk behaviors associated with transfusion-transmissible infections and (2) donor physiological health implications.

In their paper examining the location of commercial plasma centers in the U.S. from the period 1980-1995 relative to geographic distribution of risk behaviors, Robert C. James and

Cameron Mustard found commercial plasma centers were overrepresented in neighborhoods with very active drug economies (James and Mustard 2004). These neighborhoods had high concentrations of households in deep poverty — with incomes below half the official poverty threshold. That this pattern persisted even after contaminated plasma products had infected thousands of patients with HIV and Hepatitis C was an alarming finding (HIV and Hepatitis C testing was not readily available during this time period). Technological advancements since the 1990s that introduced viral inactivation techniques during the production of plasma derivatives manufactured from paid donors have made blood products safer for patients (World Health Organization). However, ethnographic research and journalistic accounts of plasma donors suggest plasma donation is still primarily undertaken by vulnerable populations (Edin & Shaefer, 2015, Valiente, Abdelmalek, & Pearle 2017).

With regards to the impacts of plasma donation on donor health, short-term side effects such as fatigue, tingling sensations, anemia, and blackouts have been chronicled in firsthand accounts published in *The New York Times*, *The Atlantic,* and *Huffington Post* (Greenberg 2019, McCollum 2020, Wellington 2014). Additional physiological implications were examined in a 1994 study that sought to determine whether long-term plasma donation altered plasma proteins or lymphocyte phenotypes (Lewis et al. 1994). The authors found plasma donors had increased percentages of B cells as compared to non-donor controls and whole blood donors. The authors hypothesized that the increase in B cells may be a compensatory mechanism to make more immunoglobulin to replace what was lost in plasmapheresis, suggesting physiological consequences to plasma donation. Another study found performance in exhaustive, severe-intensity exercise was "markedly reduced immediately following the removal of plasma. The only likely explanation is that anaerobic energy pathways must have been compromised" (Hill, Vingren, and Burdette 2013). This study measured time to exhaustion before and after plasma donation at different time intervals. The authors note that while performance declined initially, levels were re-established thereafter. However, because each participant only donated plasma once during this study, possible consequences of repeated withdrawals could not be determined.

A 2010 study investigating the long-term effects of plasma donation in the United States found that high frequency U.S. plasma donors had fewer proteins in their blood when compared to European plasma donors (Hellstern et al. 2011). In this study, all subjects were regular plasmapheresis donors over a period of at least six weeks. The median interval between two plasma donations was five days among U.S. donors and 14 days along German donors. The results indicate plasma collected from frequent donors yielded lower-quality plasma.

In another study that examined the risk of iron depletion among frequent plasma donors, the authors found frequent source plasma donation in the U.S. did not adversely impact iron stores (Schreiber et al. 2018). However, donor samples were taken once at the beginning of the donor's routine plasma donation instead of after, and the period of time between which the donor had last given plasma and the sample was not considered. These factors lead to questions about the validity of the results of this study. It is also important to note the study was a collaborative effort between the Plasma Protein Therapeutics Association and other leaders in the plasma industry.

Data and Statistical Methods

To examine the association between the location of plasmapheresis centers and the demographic characteristics of the surrounding communities, the addresses of active (as of May 2017) FDA-approved plasmapheresis centers were geocoded and analyzed in 2017-2019 in conjunction with census tract level data from the American Community Survey (ACS) (2011-2015 5-year estimates) using ArcGIS. The ACS is a nationally-representative household survey collected by the U.S. Census Bureau that randomly samples addresses in every state, the District of Columbia, and Puerto Rico. The ACS is the primary source of data for the socio-economic characteristics of small units of geography (U.S. Census Bureau 2018). In addition, to provide a population density measure, primary rural-urban commuting area (RUCA) codes classifications were incorporated in our data set. RUCA codes classify U.S. census tracts using measures of population density, urbanization, and daily commuting. Primary codes range from a whole number scale of 1-10 to delineate metropolitan, micropolitan, small town, and rural commuting areas. The RUCA codes used in this study are from the 2010 decennial census.

Plasma center addresses were retrieved from the U.S. Food and Drug Administration's Blood Establishment Registration Database in May 2017 (U.S. Food and Drug Administration 2017). Geocoding these addresses revealed 638 locations throughout the continental United States. Of these centers, eight were nonprofit establishments and one was located in a tract with no population. We dropped these nine centers from the dataset. Our data consist of the remaining addresses of 629 commercial plasmapheresis centers. Data were sorted into two groups, (1) census tracts with plasma centers and (2) census tracts without plasma centers. There were initially 72,065 census tracts in our data set. Of these, 331 tracts were dropped because they had no population, 473 tracts were omitted because they had unreported poverty data, and an additional two tracts were dropped because they were missing data on educational attainment. This left 71,590 census tracts. Of these, 617 census tracts had plasma centers and 70,973 did not.

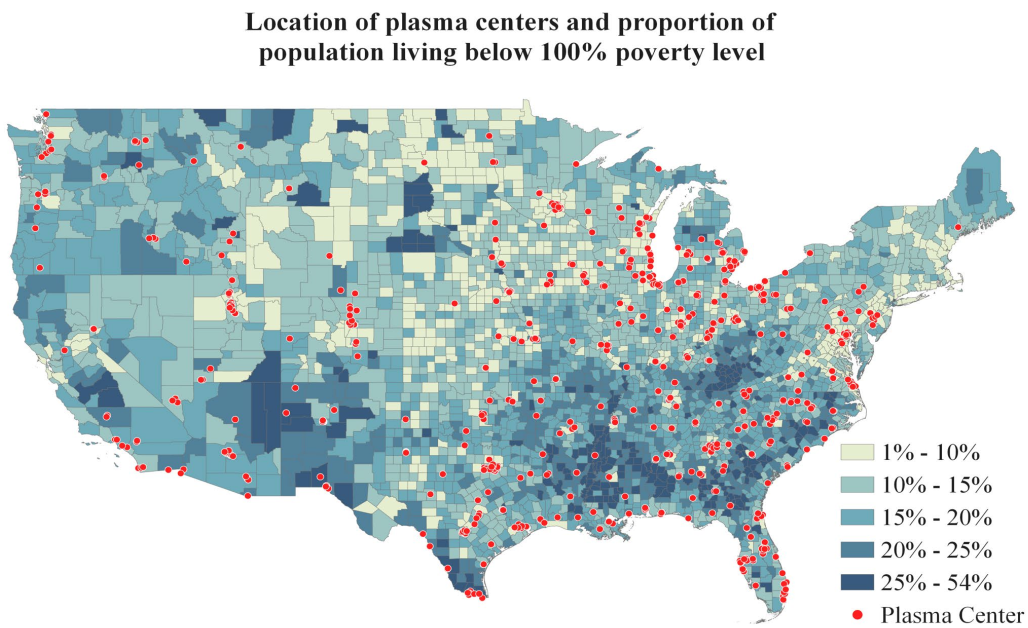
Two sample t-tests were used to assess statistical significance of differences in selected characteristics and logistic regression allowed for multivariate comparison of community characteristics — such as racial and ethnic composition, educational attainment, poverty status, and population density. The outcome variable indicated whether a plasma center existed in the census tract (1=yes, 0=no).

Race and ethnicity were measured using the following variables from the ACS: total percent white alone, total percent non-Hispanic Black, total percent Hispanic, and total percent other (this is the aggregate of all categories other than non-Hispanic Black and Hispanic). The educational attainment variable was measured using the following variables, as a proportion of the census tract population: level of education less than high school, level of education more than high school and some college, and bachelor's degree or more. Poverty was measured by variables of the proportion of people living below cash incomes of 50% of the poverty line, 50-99.9%, and 100-200% of the poverty line. Population density was measured by a dichotomous variable constructed from 2010 RUCA codes. RUCA codes 1-3 denote metropolitan areas, 4-6 denote micropolitan areas, 7-9 denote small towns, and 10 denotes rural areas. We created an urban variable, which categorizes RUCA codes 1-3 as urban (urban=1) and codes 4-10 as not urban (urban=0). Lastly, a variable for state was included in model 3 to control for underlying state characteristics.

Results

Figure 2 plots the locations of commercial plasmapheresis centers in the continental United States. Concentrations of plasma centers exist in the South and Midwest. As per FDA blood establishment registration records, Texas had the highest number of active plasma centers of any state in the United States (84), with many along the southern border, followed by Florida (47). The upper Northeast and West regions exhibited lower concentrations.

Figure 2: Location of plasma centers and proportion of county population living below 100% poverty level



Results from Table 1 (below) indicate 597 census tracts with plasma centers are located in urban areas and 20 are located in rural areas. While 96.8% of plasma centers are located in urban areas, only 82% of all census tracts in the United States are urban. Another primary difference between the two groups of census tracts is in the concentration of racial and ethnic minorities. Non-Hispanic Black people make up almost 21.5% of the population in census tracts with plasma centers, compared to 13.4% of those without plasma centers. The results are similar for Hispanic origin. In contrast, while 50.8% of residents in census tracts with plasma centers are non-Hispanic white, the proportion of non-Hispanic white residents is 12 percentage points higher in census tracts without plasma centers at 62.8%.

The differences are not as striking by educational attainment, although they move in the hypothesized direction. A somewhat larger proportion of residents in census tracts with plasma centers had not graduated from high school (16.8% versus 13.7%), and correspondingly, a somewhat lower fraction had a bachelor's degree (29.0% versus 23.9%). The rates of high school degree attainment and some college are roughly comparable.

Those living in census tracts with plasma centers were also more likely to live in poverty, most noticeably deep poverty, below 50% of the poverty line, and 100% of the poverty line. While on average 7.3% of the population residing in census tracts without plasma centers live below half the poverty line, 12% of those in census tracts with plasma centers did so, a figure 64% higher. The rate of overall poverty was 51% higher in tracts with a plasma center than in tracts without plasma centers.

Table 1: Selected Socio-economic Characteristics for Census Tracts with and without plasma centers (Means)

	No plasma centers		With plasma centers		
Characteristics	Mean	Standard Deviation	Mean	Standard Deviation	t
Urban (dichotomous)	.818	.386	.968	.177	-9.6*
Race and Ethnicity					
Non-Hispanic White	62.8	30.0	50.8	28.6	9.9*
Non-Hispanic Black	13.4	21.7	21.5	25.1	-9.3*
Hispanic	16.1	21.3	20.7	24.7	-5.4*
Other	7.8	10.2	6.9	6.1	2.0*
Educational Attainment					
< High School	13.7	11.0	16.8	11.7	-7.0*
HS, Some college, No BA	57.3	14.3	59.3	10.8	-3.5*
Bachelor's degree +	29.0	18.8	23.9	14.6	6.8*
Income-to-Poverty					
< 50% poverty	7.3	7.0	12.0	10.0	-16.7*
50 to <100% poverty	8.9	7.1	13.4	7.9	-15.6*
101 to 199% poverty	19.0	9.4	23.8	8.3	-12.7*

>200% poverty	64.8	18.9	50.8	18.9	18.4*

* p<0.05 or beyond

Source: Census tract data retrieved from ACS 2011-2015 (5-year estimates) and plasma center addresses retrieved from FDA Blood Establishment Registration Database on May 31, 2017.
Notes: Table 1 compares the socio-economic characteristics for census tracts with and without plasma centers. The table shows statistically significant results at p=0.5 for all selected socioeconomic characteristics.

Table 2 reports the results from three multivariate logistic regression models that estimate the odds a plasma center will reside in a census tract. Census tracts are the unit of observation, and the dichotomous outcome is equal to 1 if there is a plasma center in the census tract, and 0 if there are no plasma centers present. Model 1 includes poverty, race, and ethnicity variables. Model 2 adds educational attainment, and model 3 includes all variables in the previous models, adds a variable indicating urbanicity, and controls for states to adjust for underlying state characteristics. State coefficients have been omitted from the table. In each model standard errors are clustered by state.

Table 2: Odds Ratios From Logistic Regression Models: Predicting the Characteristics of Communities Where Plasma Centers Are Located

Variables	(1)	(2)	(3)
Income-to-Poverty			
Percent Poverty <50%	1.040***	1.043***	1.040***
	(.003)	(.003)	(.003)
Percent Poverty 50-99%	1.032***	1.053***	1.044***
	(.005)	(.006)	(.006)
Percent Poverty 100-200%	1.035***	1.053***	1.045***
	(.006)	(.005)	(.005)
Race and Ethnicity			
Percent Black non-Hispanic	1.001	1.003	1.001
	(.002)	(.002)	(.001)
Percent Hispanic	0.999	1.010	1.013***
	(.006)	(.006)	(.004)
Percent Other	0.997	0.994	1.008
	(.008)	(.009)	(.004)
Education			
Percent HS and/or Some College	---	1.045***	1.033***
		(.006)	(.007)
Percent More than BA	---	1.050***	1.033***

		(.006)	(.006)
Urban/Rural Designation			
Urban	---	---	9.297***
			(2.105)
State controls	---	---	X
Constant	0.002	.00002	.00002
Observations	71,590	71,590	68,372

*** p<0.001, **p<0.01, * p<0.05
Reference category for income-to-poverty is percent poverty >200%
Reference category for race and ethnicity is White non-Hispanic
Reference category for educational attainment is percent < high school
Reference category for urban is percent rural
Robust standard errors are in parentheses

The odds ratios for all the poverty variables (below 50% poverty, 50-99%, and 100-200%) in each model are substantively meaningful and all statistically significant at p<0.01 across all three model variations; the odds of finding a plasma center in census tracts is positively associated with the proportion of individuals living in deep poverty, poverty, and near poverty.

With regard to race and ethnicity, when income-to-poverty variables and race and ethnicity are entered into the same model, the bivariate differences seen by race and ethnicity in Table 1 are not evident. In no model is the percentage of Black non-Hispanic residents associated with greater odds of a plasma center. In model three, the odds of a plasma center are somewhat higher and statistically significant for the percent Hispanic only in model three. Thus, of the inter-related factors of community-level poverty rates and composition by race and ethnicity, poverty appears to be the stronger predictor in these models.

Interestingly, the odds associated with higher levels of educational attainment (percent high school and/or some college and percent more than a bachelor’s degree) are above one, and are statistically significant at above the .001 level. In models two and three, the odds of finding a plasma center in areas where a greater proportion of the population has some college as well as a bachelor's degree are greater when compared to the fraction with less than a high school degree. Thus, after controlling for income-to-poverty and race and ethnicity, the odds of a plasma center locating in a community is positively associated with educational attainment. Finally, given that 96.8% of plasma centers in the U.S. are located in urban census tracts, the odds ratio for the urban variable is large and statistically significant beyond the .001 level.

Discussion

This study establishes there is a clear linkage between the location of plasma centers in the United States — the most important market for the industry — and the presence of disadvantage. Census tracts with the deepest poverty were most likely to have a plasma center. In the absence of the data on the demographic characteristics of the actual people who sell their blood plasma, this study expands our understanding of the characteristics of the people who are most likely to donate plasma — the poor. This finding allows researchers to begin to interrogate the impact of plasma donation on the donor population, an area of research that remains largely unexplored.

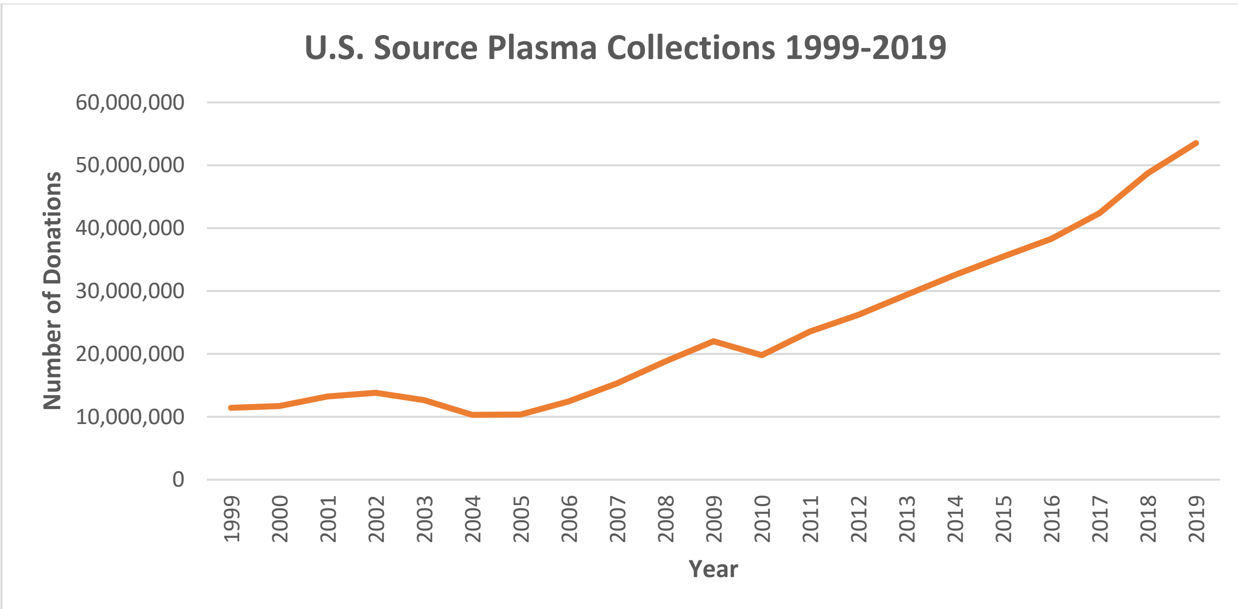
An understanding of the donor population carries compelling public health implications because evidence on the short- and long-term health repercussions experienced by plasma donors is largely absent from the literature. Because likely donors are presumably poor, additional evidence on the impact of plasma donation on vulnerable bodies must be considered. The ongoing COVID-19 pandemic highlights the vulnerability of poor Americans, whose social and environmental circumstances have historically led to worst health outcomes (Abrams & Szefler 2020, Raifman & Raifman 2020). This is due to a range of factors, from decreased access to health care services to an increased likelihood of experiencing chronic health conditions (Adler and Newman 2002).

Pharmaceutical companies that manufacture and profit from the sale of plasma protein therapies have little incentive to investigate this line of inquiry further; their focus is on the patient, not the donor. While there is an abundance of scholarship that examines the benefits of plasma-derived products for patients, deeper examination of how plasma donation affects purveyors of the *raw material* that patients and pharmaceutical companies depend on is equally important. However, the privatized nature of the pharmaceutical industry hinders access to donor data, hampering efforts for independent research in this area. Still, generating this kind of data is paramount to ensuring donors with low incomes are not inadvertently debilitating their bodies in an effort to combat their poverty.

With record unemployment, a massive economic contraction as a result of the COVID-19 pandemic, and expanded access to plasma donation centers across low-income communities, the risk of plasma donation becoming a de facto substitute for a weak safety net for millions of poor Americans is palpable (Schwartz, Casselman, and Koeze 2020, Shaefer et al. 2019, World Bank 2020). In the absence of evidence examining the ramifications of plasma donation to donor health, we encourage policymakers to consider the ethical implications of the reliance of Americans with low incomes on plasma donations. To safeguard the well-being of likely donors, whose hardship has already been amplified by the pandemic, policymakers should expand poverty alleviation policies.

Figure 1: U.S. Source Plasma Collections 1999-2019

Source: Plasma Protein Therapeutics Association 2011 and 2019



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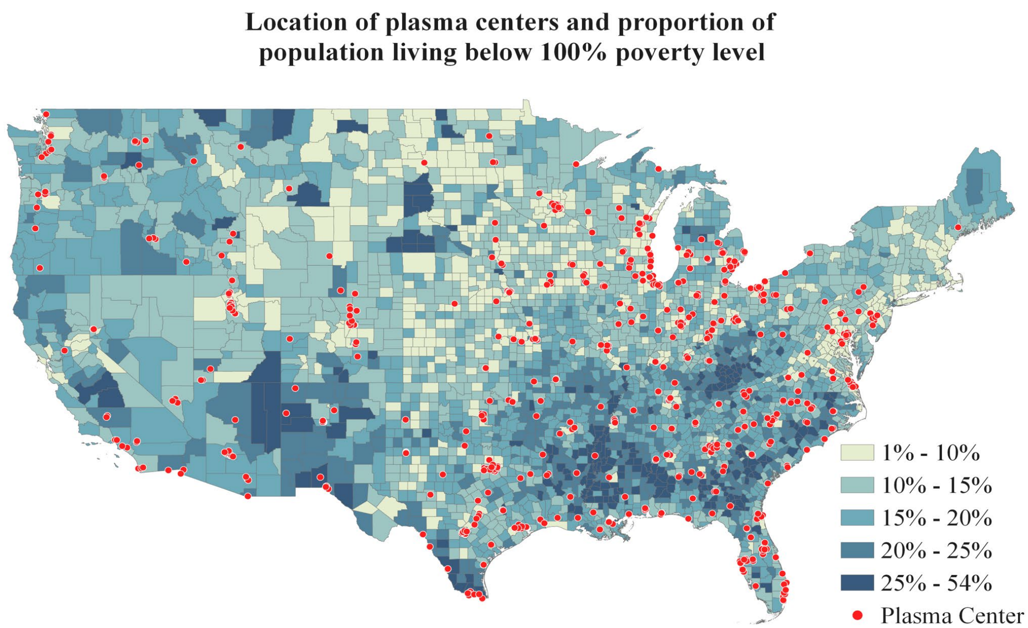

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Urban/Rural Designation			
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			(2.105)
State controls	---	---	X
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Observations	71,590	71,590	68,372

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