

Geographic Location of Commercial Plasma Donation Clinics in the United States, 1980–1995

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The contamination of fractionated plasma products led to an epidemic of infection with human immunodeficiency virus (HIV) and hepatitis C virus (HCV) in the worldwide hemophilia community in the early years of the 1980s.^{1,2} The consequences of that epidemic are well known. The World Federation of Hemophilia has reported that nearly half of individuals with hemophilia worldwide are infected with HCV, and 10% are infected with HIV.3 In North America, approximately 65% of recent mortality among hemophiliacs has been related to HIV.4,5 The prevalence of HCV, which is associated with hepatocellular carcinoma, nears saturation in older hemophiliacs.6,7

The underlying causes and context of this epidemic have been the subject of controversy and civil litigation.^{8,9} Responses have ranged from public inquiries in Canada and the United States, to criminal convictions in France, to civil litigation in many countries. There has also been widespread reorganization of many transfusion services over the last 2 decades, including the termination of the Canadian Red Cross Society's role in the provision of blood collection and distribution activities in that country.¹⁰

The degree to which blood and plasma donors carry, or are at risk for acquiring, transfusion-transmissible infectious agents is an important determinant of the overall safety of blood products. Minimizing the risks associated with blood products is therefore a critical regulatory objective for blood collection and manufacturing agencies. A long-standing criticism of American source plasma collection-where plasma rather than whole blood is procured-is that risk is not minimized. Specifically, it has been suggested that commercial source plasma clinics (which pay donors for plasma) attract high-risk donors,11-13 and that commercial source plasma clinics are located near areas with a high prevalence of illicit drug use.¹⁴

Objective. We examined the location of commercial plasma donation centers in the United States over the period 1980 to 1995 relative to the geographic distribution of risk behaviors associated with transfusion-transmissible infections.

Methods. The census tract locations of commercial source plasma clinics were described by measures of neighborhood social disadvantage and the prevalence of illicit drug use and active local drug economies.

Results. Depending on the measure of social environment used, commercial plasma clinics were 5 to 8 times more likely to be located in census tracts designated high-risk than would be expected by chance.

Conclusions. Commercial source plasma clinics were overrepresented in neighborhoods with very active local drug economies. These patterns persisted after the links between human immunodeficiency virus and hepatitis C virus infections and plasma products had been established and may present risks to blood system safety. (*Am J Public Health.* 2004;94:1224–1229)

Although very limited data are available on infection rates of commercial donors, there is some information indicating higher seropositivity among commercial plasma donors relative to volunteer donors. In a secondary analysis of information submitted by plasma manufacturers in support of viral testing techniques, the US General Accounting Office (GAO) has reported that "test-positive rates for commercial plasma donors were substantially higher than those of volunteer whole blood donors, ranging from 2 to 20 times higher on the different tests."11(p7) The GAO proposed that these higher infection rates arise because "monetary incentives such as those offered by commercial plasma-collection centers may be tantalizing to some of those who are known to be at risk for infectious diseases, such as intravenous drug users and prostitutes,"^{11(p7)} but offered no evidence to support these arguments. Yet, the GAO statement is consistent with published studies of paid blood/plasma donation in cohorts of injection drug users conducted in South Florida¹⁴ and Baltimore¹⁵ that observed high rates of commercial blood donation in cohorts of street-recruited illicit drug users.

In addition to the risk of commercial donation attracting high-risk donors, concerns have been raised about the location of paid blood donation centers in high-risk areas.¹⁴ Donor recruitment in areas of high prevalence of transfusion-transmissible pathogens presents risks to blood safety arising from false-negative results in donation screening and from the transmission of pathogens for which no screening procedure is available. Although a number of commentaries have suggested that paid blood and plasma clinics are overrepresented in disadvantaged socioeconomic settings, no formal study of the geographic organization of commercial donation sites has been published.^{12,16,17}

The objective of this study is to describe the geographic location of commercial source plasma centers in the continental United States over the period 1980 to 1995. We examine evidence for the hypothesis that during the period 1980 to 1989, source plasma clinics were disproportionately located in areas with high rates of risk behaviors that are related to illicit drug use and associated with transfusion-transmissible infections. In addition, we consider whether location practices may have changed in the period 1990 to 1995.

In describing current location practices in the commercial plasma industry, this work is

relevant for evaluating the effectiveness of self-regulation by the plasma industry and also of governmental regulation of source plasma collection in the United States. This work may also have important international implications, as the United States is the chief supplier of source plasma and plasma-derived pharmaceuticals in the world market.

METHODS

Sample

Inclusion criteria. All source plasma clinics regulated by the US Food and Drug Administration (FDA) and operating in the continental United States, Hawaii, or Alaska in the period 1980 to 1990 and in 1995 were eligible for inclusion in this analysis. Addresses were obtained from the trade publication of the American Blood Resources Association,¹⁸⁻²⁷ which approximately once per year publishes a list of addresses of FDA-licensed source plasma clinics. We obtained addresses from 1980 through 1990, and for 1995 (addresses were not available for 1984, 1985, or 1991 through 1994). Commentary included with these lists suggests that the information was gathered through Freedom of Information Act requests filed by the journal with the FDA, the regulating body for US blood and plasma collection.

Exclusion criteria. Several types of plasma clinics were excluded from our analysis. Clinics operated by the American Red Cross were excluded because these did not offer payment for blood or plasma donations. However, a limited number of community-based blood collection agencies that would not have offered payment remain in our sample as they could not be reliably distinguished from commercial operations.

Plasma clinics operating within penal institutions also were excluded, even though viral hepatitis, drug abuse, and sexual behaviors associated with parenteral disease transmission were recognized to be common in penal institutions.^{28–30} Our rationale for excluding these penal clinics was that standard interpretations of census data to characterize neighborhoods would not apply to penal institutions.

We further excluded those plasma clinics for which the reported address was not suitable for geocoding. This exclusion applied to addresses where the mailing address was given as a postal box, or where the address was a building name, a functional description of a building (e.g., "bus depot"), or otherwise not a street address.

Geocoding

Unique addresses were identified by manual comparison of addresses across years, and all nonexcluded addresses were submitted to geocoding. The list of unique plasma clinic addresses was linked with either the 1980 or 1990 US Census tract geography for that address, or both. A census tract is the second smallest areal unit for which census data are publicly reported; it is intended to have a mean population of approximately 4000 individuals and to be socially homogeneous.³¹ The census tract is commonly used to operationalize the concepts of neighborhood in US sociology and urban ecology literature.³²

The 1980s addresses were geocoded by GDT (Lebanon, NH) and used the 1980 census geography. For those addresses with active clinics in the 1990s, Maptitude Geographic Information System Version 4.0 was used (Caliper Corp, Newton, Mass). This package uses US Census Bureau Topologically Integrated Geographic Encoding and Referencing System base maps to determine the 1990 census tract that contains the address.³³

Once the 1980 and/or 1990 census tract for a given address was known, data from the 1980 and/or 1990 Summary Tape File (STF) 3A census files^{33,34} was linked, and the census tract containing the clinic was classified according to 3 neighborhood typologies, described below.

Neighborhood Classification

In this study we applied 3 neighborhood classification schemes (Table 1). All 3 measures were operationalized at the census tract level. Two of the 3 neighborhood classifications were defined by previous work: the US Census Bureau's "extreme poverty areas" designation,³¹ and the "underclass areas" designation, proposed by researchers at the Washington, DC-based Urban Institute.³⁵ The US Census defines extreme poverty areas as those census tracts where the poverty rate is greater than 40%.³¹ The "underclass areas" designation does not use poverty as part of the classifying algorithm, but rather identifies high rates of 4 measures of social "deviance." Although neither the associated agencies nor the measures themselves were specifically designed to identify areas with high rates of drug use, extreme poverty areas have been correlated with social problems,³⁷ and the "underclass areas" definition is specifically designed to find areas with high rates of social problems.35

A third classification scheme was developed by the authors to identify areas with high rates of social disorganization and reflected 2 dimensions: economic deprivation and residential instability.^{38,39} Neighborhoods with low economic resources and high residential mobility were proposed to be centers of social problems, including illicit drug use. A factor analysis of 14 measures from the US Census, structured to reflect these 2 dimensions, resulted in the definition of 9 neighborhood types.³⁶ The subset of census tracts with the lowest economic resources and concurrently the highest levels of residential mobility

TABLE 1—Neighborhood Types, by Characteristics

| | Characteristics | | | | | |
|---|---|--|--|--|--|--|
| Extreme Poverty Areas ³¹ | Household poverty rate greater than 40%. | | | | | |
| Underclass Areas ³⁵ | Concurrent high rates for female-headed households, receipt of welfare, high school dropouts, and adult male nonparticipation in the workforce. High rates are | | | | | |
| | defined (for both 1980 and 1990 census years) as greater than the 1980 mean plus one 1980 standard deviation for the measure. All 4 metrics had to be "high" in order to meet the definition. | | | | | |
| Socially Disorganized Areas ³⁶ | All US census tracts were stratified into 1 of 9 neighborhood types based on factor analysis of 14 common census variables, independently estimated for 1980 and 1990. Socially disorganized areas had the highest levels of residential mobility and concurrently the highest levels of economic deprivation. | | | | | |

were labeled "socially disorganized" areas. We expected that socially disorganized areas, extreme poverty areas, and underclass areas would show high rates of illicit drug use and active local drug economies.

Neighborhoods and Illicit Drug Activity

To characterize these 3 classes of neighborhoods in terms of their association with illicit drug use, we have elsewhere described the geographic distribution of drug practices and drug choices that have either been linked directly to infectious disease transmission (heroin, crack, PCP, needle use) or that reflect socially proscribed behaviors (selling drugs) suggestive of active local drug economies.⁴⁰ That analysis was performed on a special geocoded version of the 1993 National Household Survey on Drug Abuse (NHSDA). The NHSDA is the standard reference survey for population-based studies of drug use in the United States.³⁶ This survey is a representative sample of householddwelling adults aged 12 years and older, and uses a multistage sampling design.

Our analyses were restricted to the 1993 survey, with a sample size of 26 489, and focused on neighborhood drug activity, availability of "hard" drugs (i.e. cocaine, heroin, LSD, and PCP), and personal drug use. By special arrangement with the Substance Abuse and Mental Health Services Administration, the 3 neighborhood classification schemes were integrated with the 1993 NHSDA public use file,³⁶ linking public use file data to specific neighborhoods. This augmentation of the public use file did not compromise the anonymity of respondents.

Selected results from our analysis of the 1993 NHSDA—organized by neighborhood type—are reported in Table 2. As compared with respondents outside of these neighborhood types, residents of extreme poverty areas, underclass areas, and socially disorganized areas all reported rates for drug activity that were higher than the rates reported at the national level. The rate ratios (not shown) varied widely from 2- to 8-fold higher than those reported at the national level (detailed analyses are available from the authors).

Evidence from the NHSDA suggests that these 3 neighborhood types are characterized by very active drug selling and very ready availability of a broad range of "hard" street drugs, as compared with national rates (measures that others have labeled as "drug visibility"). Evidence of substantially higher personal drug use among residents of these neighborhood types was not found in our analysis, a finding that is consistent with recent evidence from an independent survey.⁴¹

TABLE 2—Respondents' Self-Report of Drug Use and Drug Availability Characteristics, by Neighborhood, and National Rates⁴⁰

| Response | National | Underclass Areas | Extreme Poverty Areas | Socially Disorganized Areas |
|---|----------|---------------------|-----------------------------|-----------------------------------|
| Self-reported use of crack cocaine in the last year | 0.5% | 1% | 0.6% | 1.6% |
| Self-reported use of cocaine in the last year | 2.2% | 3.4% | 1.9% | 3.4% |
| Self-reported use of heroin in the last year | 0.1% | 0.5% | 0.3% | 0.4% |
| "Very frequent" drug sales in neighborhood | 5.6% | 46.7% | 24.9% | 32% |
| "Very frequent" observation of intoxicated | 11.5% | 49.3% | 41.1% | 43% |
| individuals in neighborhood | | | | |
| "Very easy" access to cocaine | 20% | 41.9% | 29.2% | 40.8% |
| "Very easy" access to heroin | 11.9% | 30.1% | 17.4% | 28.6% |
| "Very easy" access to LSD | 11.4% | 24.4% | 13.9% | 25.2% |
| "Very easy" access to PCP | 9.9% | 24.3% | 12.8% | 25.4% |
| Lifetime history of injection drug use | 1.4% | 1.8% | 1.3% | 1.9% |
| Self-reported drug selling in last year | 0.8% | 1.1% | 1.5% | 1.6% |

Note. By special arrangement with the Substance Abuse and Mental Health Services Administration, the 3 neighborhood classification schemes were integrated with the 1993 National Household Survey on Drug Abuse public use file.³⁶ This augmentation of the public use file did not compromise the anonymity of respondents.

On balance, this analysis provides evidence for a marked concentration of drug sales and some evidence of higher drug use in these populations. On the basis of this evidence, we defined US Census tracts included under any of these 3 designations as high-risk areas for transfusion-transmissible diseases.

Statistical Analysis

Characteristics of census tracts with clinics and of all census tracts in 1980 to 1989 were determined based on the 1980 STF 3A census file, and those of census tracts in 1990 and 1995 were based on the 1990 STF 3A census file. Analyses of the distribution of clinics in the 3 neighborhood types were compared with the national distribution of these neighborhood types from the appropriate census year, and the proportion of clinics in each neighborhood type was compared with the proportion of the total census tracts in that neighborhood type. Statistical testing of the resulting rates was accomplished with Stata Version 6.0 (Stata Corp, College Station, Tex) using exact binomial distribution.

RESULTS

A total of 3962 plasma clinic addresses were reviewed, from which a total of 915 unique addresses were identified. Among the 712 unique addresses from the 1980s, 16 were American Red Cross sites, 16 were penal institutions, and 11 were unsuitable for geocoding. A total of 601 addresses (89.8%) were successfully geocoded, and of these geocoded addresses, 20 failed to link to the 1980 census tract data. A total of 581 unique addresses were available for analysis.

With respect to the 1990-era addresses, a total of 588 unique addresses were identified. Of these, 36 were operated by the American Red Cross, 9 were penal institutions, and 9 were inappropriate for geocoding. The geocoding success rate was 91.9%. All 491 geocoded addresses were linked to a 1990 census tract and associated census data. These geocoding rates are consistent with other studies.^{42,43}

Table 3 describes the distribution of commercial source plasma clinics with respect to the 3 classifications of neighborhoods—extreme poverty areas, underclass areas, and socially

| Num of Year Clini | | Extreme Poverty Areas | | | Underclass Areas | | | | Socially Disorganized Areas | | | | |
|-------------------------|-------------------------|--|---------------------------------|---|------------------|---|--------------------------------|--|-----------------------------|--|---------------------------------|---|-----------------|
| | Number of Clinics | Proportion of All Census Tracts Defined as EPAs (A) | Number of Clinics in EPAs | Proportion of Clinics in EPAs (B) | Ratio (B/A)* | Proportion of All Census Tracts Defined as UAs (C) | Number of Clinics in UAs | Proportion of Clinics in UAs (D) | Ratio (D/C)* | Proportion of All Census Tracts Defined as SDAs (E) | Number of Clinics in SDAs | Proportion of Clinics in SDAs (F) | Ratio (F/E)* |
| 1980 | 342 | 4.36% | 77 | 22.5% | 5.16 | 2.01% | 37 | 10.82% | 5.38 | 3.0% | 84 | 24.56% | 8.19 |
| 1981 | 321 | 4.36% | 73 | 22.7% | 5.22 | 2.01% | 33 | 10.28% | 5.11 | 3.0% | 72 | 22.43% | 7.48 |
| 1982 | 299 | 4.36% | 68 | 22.7% | 5.22 | 2.01% | 30 | 10.03% | 4.99 | 3.0% | 64 | 21.40% | 7.13 |
| 1983 | 288 | 4.36% | 68 | 23.6% | 5.42 | 2.01% | 32 | 11.11% | 5.53 | 3.0% | 63 | 21.88% | 7.29 |
| 1986 | 319 | 4.36% | 75 | 23.5% | 5.39 | 2.01% | 33 | 10.34% | 5.15 | 3.0% | 65 | 20.38% | 6.79 |
| 1987 | 335 | 4.36% | 80 | 23.9% | 5.48 | 2.01% | 38 | 11.34% | 5.64 | 3.0% | 69 | 20.60% | 6.87 |
| 1988 | 324 | 4.36% | 77 | 23.8% | 5.45 | 2.01% | 35 | 10.80% | 5.37 | 3.0% | 65 | 20.06% | 6.69 |
| 1989 | 324 | 4.36% | 75 | 23.1% | 5.31 | 2.01% | 34 | 10.49% | 5.22 | 3.0% | 62 | 19.14% | 6.38 |
| 1990 | 392 | 5.6% | 156 | 39.8% | 7.11 | 1.51% | 44 | 11.22% | 7.43 | 3.9% | 114 | 29.08% | 7.46 |
| 1995 | 367 | 5.6% | 136 | 37.1% | 6.62 | 1.51% | 34 | 9.26% | 6.14 | 3.9% | 93 | 25.34% | 6.50 |

TABLE 3-Number of US Commercial Source Plasma Clinics by Neighborhood Type

Note. EPA = extreme poverty area; UA = underclass area; SDA = socially disorganized area. Over the period 1980 to 1995, 5% to 10% of clinics could not be associated with a neighborhood type because of missing values for 1 or more of the covariates that set the underlying factor analysis. All rates are estimated with the total number of clinics as the denominator, thereby assuming that none of the clinics not assigned to any of these 3 neighborhood types were at high risk.

*P<.001 (exact binomial).

disorganized areas. The degree to which source plasma clinics were disproportionately located in these areas was persistent across all years and all classification schemes, and typically represented at least a 5-fold increased representation over what would have been expected had plasma clinics been allocated randomly across census tracts.

Extreme poverty areas represented 4.36% of all 1980 census tracts and 5.6% of all 1990 census tracts, but represented the location of between 22.6% and 39.8% of all source plasma clinics in the years studied during the period 1980 to 1995. The underclass areas told a similar story: these areas represented approximately 2% of 1980 census tracts and 1.5% of 1990 census tracts, but between 9.3% and 11.3% of all source plasma clinics were located in these areas. Finally, the socially disorganized areas also showed a pattern of overrepresentation of source plasma clinics. Three percent of 1980 tracts and 3.9% of 1990 tracts could be designated as socially disorganized areas, but between 19.1% and 29% of all source plasma clinics were found in these neighborhood types, representing a 6.4- to 8.2-fold excess over what would have been expected by chance alone. All differences between the expected and the observed proportion of clinics

in these areas were tested against the binominal distribution, with P values consistently less than .001.

The proportion of all census tracts defined as disadvantaged increased between the 1980 and 1990 censuses on the measures of extreme poverty and social disorganization. Additionally, in both 1990 and 1995, the concentration of clinics increased in extreme poverty areas, underclass areas, and socially disorganized areas relative to concentrations observed over the period 1980 to 1989.

DISCUSSION

Our results show that source plasma clinics were disproportionately overrepresented in areas characterized by socioeconomic disadvantage, residential mobility, and active drug sales throughout the period 1980 to 1995. For all 3 measures of neighborhood circumstance, in all years studied, source plasma clinics were more likely to be located in extremely disadvantaged types of neighborhoods.

The number of source plasma clinics operating in extreme poverty areas grew from 77 clinics to 136 clinics during this period, which represented a change from 22.5% of all clinics in 1980 to 37.1% in 1995. For underclass areas, the proportion dropped from

10.8% in 1980 to 9.3% in 1995. With respect to clinics operating in socially disorganized area, the proportion of all clinics was 24.6% in 1980 and 25.3% in 1995. The difference in results between extreme poverty areas and socially disorganized areas (where marked increases in the proportion of clinics are seen) and the results from underclass areas (which decline slightly in the proportion of clinics) suggests some strategic redeployment of clinic resources over this period. Reasons for the marked single-year increase in the overall number of operating clinics in 1990 and why this year should also represent the consistent peak for location of clinics in high-risk areas are unclear and merit further investigation.

There are potential limitations to our study arising from possible errors in classification and measurement. For example, not all clinics were fully geocoded, and those that were not coded may have represented a less-risky pool of clinics. Similarly, some fraction of clinics may have been misallocated to a neighboring census tract. However, because the types of tracts that we have designated as high-risk represent a very small minority of all tracts, the consequence of such an error would be to reduce the proportion of clinics located in high-risk tracts. Overall, potential classification

and measurement errors will have produced a conservative bias in the reported results.

These data clearly suggest that the location of commercial source plasma clinics is markedly nonrepresentative of the spectrum of neighborhood socioeconomic circumstances and social environments in the United States, at least over this 15-year period. The observation that US source plasma clinics were disproportionately located in high-risk areas in the early 1980s is not unexpected, and reflects well-recognized historical strategies for locating these clinics.^{15–17}

What is surprising is that such clinics continued to operate in these areas well after the epidemiologies of HIV and HCV and the links between drug use, infection, and blood product infection were established. That these clinics remained in these areas as late as 1995 is inconsistent with epidemiologic evidence that locating commercial source plasma clinics—which provide cash compensation for plasma donation in the midst of active drug markets and poverty—represents a risk to blood system safety.

Regulatory responses to these findings could adopt a multifaceted approach. Clinics could be discouraged from establishing in high-risk areas, but regulation on this point is likely to become embroiled in definitions of high-risk areas. Public accountability mechanisms could also be considered: clinic-specific performance indicators including risk behaviors, third-party drug use surveys of donors, and seroreactivity rates for known pathogens could be required annually on a clinicspecific basis, and this information could be made publicly available by regulatory agencies. Vigorous regulatory oversight could be directed at clinics with poor performance on these indicators.

A potential secondary effect of such clinicspecific performance indicators could be to create a market organized around plasma quality rather than plasma price. Consistently high performance on quality indicators would allow clinics to demand higher return for their plasma. Arrangements should be made to ensure that plasma arising from inferior clinics is not available to non-FDA-regulated international markets.

In our view, the lack of routinely available seroprevalance information for source plasma

donors and the absence of monitoring of the geographic location of commercial source plasma clinics together suggest that existing efforts by government agencies lack critical information on which to guide regulation of the safety of domestic and international blood products. Our study documents a systematic and enduring pattern in the location of source plasma centers in nonrepresentative—and high-risk—locations within the United States during the years 1980 to 1995. ■

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Contributors

R. James conceived of the study and conducted the analysis. R. James and C. Mustard designed the study and participated in the writing of the article.

Human Participant Protection

This protocol was approved by the health research ethics board of the University of Manitoba Faculty of Medicine.

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