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A Geospatial Analysis of Persons Opting Out of an Exception from Informed Consent Out-of-Hospital Clinical Trial

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Abstract

Study Objective—For trials involving exception from informed consent, some IRBs require that community members be allowed to “opt out” prior to enrollment. We tested for geospatial clustering of opt-out requests and the associated census tract characteristics in one study region.

Methods—This was a retrospective study at a single site of a multicenter exception from informed consent resuscitation trial. We collected and geocoded mailing addresses for persons requesting opt-out bracelets over 16-months, then tested for geospatial clustering using geographic information systems (GIS) analysis. Characteristics for tracts with and without bracelet clustering were compared using univariate tests, multivariable regression, and classification and regression tree (CART) analysis.

Results—We received 395 phone calls requesting 718 bracelets, of which 673 were analyzable. Of 397 census tracts in the region, 208 (52%) had at least one request and 38 (10%) demonstrated clustering. In multivariable models, an increasing proportion of family households (OR .90, 95%CI .85–.93), veterans (OR .91, 95%CI .81–1.02), and renters (OR .96, 95%CI .92–.99) were associated with lower odds of requesting an opt-out bracelet, while census tracts with higher income had higher odds of opting-out (OR 1.07, 95%CI 1.02–1.11). Using CART, the proportion of family households and graduate education identified the majority of opt-out requests by census tracts (cross-validation sensitivity 92%, specificity 56%).

Conclusions—Opt-out requests for an exception from informed consent trial at one study site were geographically clustered and associated with certain population demographics. These findings may help identify key target groups for community consultation in future trials.

Keywords

geographic information systems; census tract; informed consent; ethics; research; U.S. Food and Drug Administration

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1. INTRODUCTION

Opt-out mechanisms have been used in some exception from informed consent trials, yet research examining the opt-out process remains unreported. Because these studies do not allow for individual autonomy via informed consent at enrollment, researchers take extra precautions to protect research subjects (1) and can conduct such research only under highly regulated circumstances (2). Some institutional review boards (IRBs) require that investigators offer community members the option to opt-out of an exception from informed consent trial by wearing a bracelet. The intent of the bracelet is to prevent enrollment in a resuscitation trial, should the wearer become eligible.

Some believe that an opt-out system may be the only method of preserving individual autonomy (1), yet others hold that community knowledge of such trials is so limited (3) that mechanisms for opting-out are not truly available to all and therefore should not be used. The Food and Drug Administration (FDA) does not directly address opt-out mechanisms in the guidelines regulating exception from informed consent trials (4), except in the preamble (5). However, in a 2006 hearing the FDA asked about the utility of opt-out mechanisms in protecting human subjects and whether the use of opt-out bracelets is feasible (6). Although resolutions to such ethical dilemmas have yet to be definitively addressed by the resuscitation research community, (7) opt-out mechanisms are being used in some exception from informed consent trials (8). Characterizing the demographics of persons who opt-out of such trials may be useful for IRBs reviewing these research protocols, for investigators planning consultation and notification processes (9), and to the FDA (10).

In this study, we tested for geospatial clustering of opt-out bracelet requests at one site participating in an exception from informed consent resuscitation trial. We also used census tract information mapped to the mailing address of each request to test associations with opt-out bracelet requests.

2. METHODS

Study Design

This was a retrospective study conducted at a single site using data collected over 16-months (October 1, 2006 through January 31, 2008) during public notification and the first 12 months of an exception from informed consent, out-of-hospital, resuscitation trial. The IRB at Oregon Health & Sciences University approved this study.

Study Setting and Population

The Resuscitation Outcomes Consortium (ROC) is an out-of-hospital resuscitation research network focused on early clinical interventions to improve outcomes for patients with cardiac arrest or trauma (11). The first ROC study involves the use of hypertonic saline (with and without dextran) versus normal saline in patients aged 15 years and older with hemorrhagic shock or traumatic brain injury (8). The current study of opt-out bracelets was conducted at the Portland ROC study site (Portland, Oregon and Vancouver, Washington), which includes all communities served by emergency medical service providers in a four-county region containing urban, suburban, rural, and frontier areas. All U.S. ROC sites offer opt-out bracelets to the community.

At the Portland site, local IRBs requested that opt-out bracelets be available to the public at the start of the public notification phase of the trial (i.e., after community consultation and final IRB approval of the project), several months before the trial was implemented. Availability of opt-out bracelets was widely advertised in all press releases, media coverage, the Portland ROC

website, and community letters distributed during the study notification phase. The time period for this project also included the first 12 months after initiating the clinical trial. The majority of opt-out bracelet requests were received during public notification and the trial implementation phases. After the initial 6 months of the clinical trial, there were, on average, only 2 bracelet requests per month (<1% of total bracelets distributed).

Information about the trial was disseminated to the public during three phases: community consultation (before the trial was approved), public notification (following final IRB approval), and at the start of enrollment. Methods for dissemination included open community meetings in all counties, meeting with community groups and neighborhood associations, announcements on TV and radio stations, multiple publications in local newspapers and community newsletters, as well as mailings to approximately 200 local leaders and neighborhood associations. We attempted to provide trial information to the public (including opt-out bracelet availability) uniformly throughout the study region. Any community member age 15 or older could request an opt-out bracelet for himself/herself and for immediate family members by calling with an address where the bracelet could be mailed via the United States Postal Service first class mail. There was a policy at the study site of providing a maximum of 4 bracelets per caller; individuals were not permitted to request bracelets for general distribution (e.g. to coworkers, neighbors or other groups). The mailing addresses for bracelet requests were tracked, along with the number of bracelets requested at each address and the date mailed (usually within 1–2 days of the request). There were no duplicate addresses for bracelet requests.

The opt-out bracelets are made of stainless steel and designed to look like ‘medical alert’ tags. The bracelets read “NO STUDY”, and all pre-hospital providers were trained to look for the bracelet before enrolling eligible patients in the exception from informed consent trial.

Study Protocol

Bracelet data—All mailing addresses for persons requesting opt-out bracelets during the study period were geocoded using ArcEditor™ (ESRI, Inc., Redlands CA). Addresses not automatically geocoded were manually geocoded using street maps from the Regional Land Information System (Portland Metro™ Data Resource Center, Portland OR). Post office boxes were geocoded to the Zip Code Tabulation Area (ZCTA) centroid (geographic center of a polygon). The number of bracelets requested was aggregated at the census tract level using a “point-in-polygon” overlay procedure.

Census data—A census tract is a geographical region including 4,000 persons with similar socioeconomic and demographic profiles, as defined by the U.S. Census Bureau (12). Census tract demographics have been shown to closely approximate individuals residing there (i.e., homogeneity exists) (12). Twenty-one variables tabulated by the U.S. Census Bureau were used to evaluate census tract characteristics (Table 1). These variables were divided into seven categories: demographics, race/language, family/marriage, education, income, employment, and housing. Variables were coded both continuously and categorically (quartiles).

Outcome—The primary outcome for the geospatial clustering analysis was the prevalence of opt-out bracelets distributed per 1,000 population in each census tract. For univariate and multivariate analyses, the primary outcomes were the presence of geospatial clustering in the census tract and the number of bracelets requested in each census tract.

Data Analysis

To determine geographical clustering, we used the Local Moran’s I function in ArcEditor™ on the prevalence of bracelet requests per 1,000 population in each census tract (13–16). Given

a set of weighted features, in this case the prevalence of bracelet requests per 1,000 population per census tract, Moran's I identifies clusters of features with similar values. A Z-score of ≥ 1.96 was considered significant to determine the presence of clustering. The general and Local Moran's I procedure used the "Inverse Distance" and "Euclidean Distance" parameters for cluster analysis. For polygons, the Moran's I uses the polygon centroid to determine these distances. To determine the cluster distance band for the analysis, a general Moran's I was calculated for the data set at intervals of 25,000 feet from 25,000 feet to 100,000 feet. The maximum Z-score was used to determine the most significant "Distance Band" width for the Local Moran's I analysis.

Non-parametric univariate testing (Wilcoxon signed rank test) was used to compare characteristics between census tracts with and without bracelet clustering. Multivariable logistic regression and negative binomial regression models were used to assess independent predictors of geospatially-identified bracelet clustering (yes/no) and number of opt-out bracelet requests, respectively. To generate the final regression models, we used a non-automated backward stepwise selection process. Selection of variables for the final models was guided by univariate associations of variables between census tracts with and without clustering, magnitude of effect, statistical significance of variables in the models, model fit, and predictors identified in binary recursive partitioning analyses. We tested interaction terms in all models. The Hosmer and Lemeshow goodness-of-fit test was used to assess model fit in logistic regression models; both the Pearson Chi Square test and a visual assessment of observed versus predicted bracelet counts were used to assess model fit in negative binomial models.

To provide an alternative analytic strategy for evaluating important predictors of opt-out bracelets, we also used classification and regression tree (CART) analysis (17). Use of CART analysis in this study provided an opportunity to complement more traditional modeling methods and to further inform development of multivariable models.

Database management and statistical analyses were performed using SAS (version 9.1; SAS Institute, Inc., Cary, NC), Stata (version 10, StataCorp, College Station, TX), and CART (version 5.0; Salford Systems, San Diego, CA). For all analyses, a p value of $< .05$ was considered significant.

3. RESULTS

During the study period, there were 395 phone calls for 718 bracelets. Forty-four bracelet requests were excluded because the caller had an incomplete or undeliverable mailing address, or the address fell outside of the region. Three hundred fifty-one requests for 673 bracelets were analyzed. Of the 397 census tracts included in the study region, 208 (52%) had at least one bracelet request and 38 (10%) had bracelet clustering (Figure 1). Over 90% of opt-out requests were received within the first two months bracelets were available. Census tracts with bracelet clustering were located within more densely populated areas of the study region. The median number of bracelets requested from census tracts without clustering was 0 (IQR 0–2, range 0–12) versus a median of 6 bracelets (IQR 3–8, range 1–17) from census tracts with clustering. Univariate analysis suggested that 9 of the 21 variables were associated with bracelet clustering (Table 2).

Results from the two multivariable models are presented in Table 3. The final logistic regression model included four variables and the final negative binomial regression model included six variables. In both logistic regression and negative binomial regression, family households, veterans, and renters were negatively associated with bracelet counts, while the proportion of households generating more than \$100,000 annually was positively associated with requests to opt-out. In addition to these variables, the negative binomial regression model

included the proportion of high school graduates and Hispanics in census tracts. The final logistic and negative binomial models were well-fit with no significant interaction effects.

In the CART analysis, two variables identified the majority of census tracts with bracelet clustering: the proportion of family households and graduate education (Figure 2). Using specific cut-points within these variables (< 65% family households and >23% with graduate education) yielded a sensitivity 97.4% (95% confidence interval [CI] 85.3 – 100%) and specificity 55.7% (95%CI 50.5 – 60.8%) for identifying census tracts with bracelet clustering; using cross-validation demonstrated sensitivity 92.1% and specificity 56.0%.

4. DISCUSSION

Opt-out bracelet requests for an exception from informed consent clinical trial within this study region were not randomly distributed. Rather, they appeared to be clustered among specific census tracts with characteristic demographic and socioeconomic patterns. These findings suggest that certain populations are more likely than others to object to exception from informed consent research, have better penetration of knowledge about the trial, or are perhaps more likely to discuss concerns with their neighbors. The most consistent independent predictors of opting out of the trial included measures of family households, education, renters, veterans, and higher income.

There was a strong inverse relationship between bracelet requests and the proportion of family households in a census tract. It is unclear whether communities in our area with higher percentages of family households are more accepting of this research, prioritize public health concerns higher than individual autonomy, have lower rates of knowledge about the trial, or have other reasons for being less likely to opt out. Alternatively, people living alone or with unrelated housemates (i.e., census tracts with lower proportions of family households) may be more likely than family units to oppose this research, possibly because they are less supportive of biomedical research, have greater exposure to local media, or are more likely to fear the loss of personal autonomy in a health crisis (without family members to represent their interests). Census tracts with higher proportions of renters were also inversely associated with bracelet clustering, even after adjusting for measures of socioeconomic status. It is possible that these communities reflect students or transient communities that are either more accepting of such research, have less exposure to communication venues describing exception from informed consent trials, or are simply less invested in local issues.

In this region, census tracts with more veterans were also less likely to opt out. Similar to the explanations given for family households and renters, it is unclear whether such communities are more supportive of resuscitation research, have different knowledge dissemination for such trials, or some other explanation. A recent study found that veterans are more likely than the general population to participate in research for altruistic reasons and less likely to participate for personal gain (18), which may also explain our results. Certain segments of the public (e.g., veterans) may believe that the sacrifice of personal autonomy is reasonable to forward scientific knowledge about major public health problems. Our study did not acquire this level of detail.

Census tracts with a higher proportion of households reporting annual incomes over \$100,000 were associated with increased opt-out requests and higher odds of bracelet clustering. Similarly, higher educational attainment (i.e., graduate school) was associated with increased bracelet requests. However, one of the multivariable models demonstrated that census tracts with higher proportions of high school graduates had lower incident rate ratios for opt-out requests. Newspaper readership increases with both increasing income and educational attainment (19,20), which may suggest that such populations were more likely to opt out because they were more likely to receive media coverage about the study. Conversely, if we

assume that the entire study region was equally informed about the trial, then people with higher incomes and higher educational achievement may be more likely to oppose the trial for reasons that are not yet clear. Prior studies about the effects of socioeconomic markers on research participation have generally focused on persons with lower incomes and educational attainment as vulnerable populations needing special protections (21,22). Similarly, IRBs have requested that community consultation and public notification efforts target marginalized populations. While we demonstrate that some disenfranchised populations were less likely to opt out, the explanation for this finding remains unclear.

Hispanic ethnicity was another predictor of opt-out requests, though this association was not consistent across all analyses. No other measures of race, ethnicity or nationality were associated with bracelet requests. Prior studies have demonstrated that people in minority groups lack trust in the medical community (23–26) and that Hispanics self-report fear of participation in research (27), either of which may help explain this finding. However, another study found that minorities are no less likely to participate in research than Caucasians (28), which may offer one reason why the relationship between opt-out requests and ethnicity was not consistent in our study. Nevertheless, investigators planning future exception from informed consent trials may consider giving special consideration to regions with large Hispanic populations during early phases of study design, the community consultation process, and study implementation to ensure that minority perspectives are represented.

Knowing which populations may be more likely to approve or disapprove of an exception from informed consent research study may be advantageous to researchers, IRBs, and other regulatory bodies (e.g., FDA, Office for Human Research Protections) involved with the planning and oversight of such trials. If our results are replicated in other regions, such findings may provide guidance for focusing community outreach and education efforts within certain census tracts during the preparation and implementation of such studies. In this project, we demonstrate that the use of opt-out bracelets is feasible. However, these results deserve further study.

5. LIMITATIONS

One of the assumptions in this study is that the region had equivalent exposure to trial information. If the likelihood of community members learning about the trial was uniform, then the observed demographic and socioeconomic associations may suggest causal or explanatory relationships. However, if knowledge of the trial differed across populations, then such characteristics may serve as surrogate measures for the penetration of trial knowledge. A prospective comparison of penetrance of knowledge about the trial to opt-out requests would add substantially to the literature on this topic.

We used aggregate measures to describe and characterize persons requesting to opt out of the trial, which may lead to an ecological fallacy (the assumption that all members of a group exhibit characteristics of the group at large). While these findings may have been different if evaluated by individuals (rather than by census tracts), census tract information has been shown to be a reasonable proxy for socioeconomic and demographic characteristics of individuals residing within the tract (29,30).

Although some callers requested more than one bracelet, we considered each bracelet as an independent request. Inherent in this analysis is the assumption that each person who received a bracelet would have called to request their own bracelet, had the caller not been allowed to order multiple bracelets. It is possible that our results may have been different if this assumption does not hold. Similarly, we cannot be certain that the bracelets stayed in the same geographical location as the mailing address. For example, a caller requesting two bracelets be sent to his home address, then giving one to family or friends living outside the mailing address, could

result in some bracelet wearers residing in different census tracts than were profiled. We were also unable to account for activists that may have called more than once for bracelets, using secondary addresses or aliases to order additional bracelets, or other means to circumvent the standard processes to limit bracelets to any one caller; however, we are not aware that any such activities occurred. Further, evaluating persons that called to request an opt-out bracelet may not have captured everyone in the community with philosophical disagreements about this research, which is especially relevant when considering that only a small portion of persons in a study region are generally aware of such research (3).

Finally, we studied opting-out of one exception from informed consent clinical trial in a single metropolitan area. Other communities may behave differently regarding opt-out requests. It is difficult to know whether this information can be generalized to other trials and other regions.

6. CONCLUSION

Requests for opt-out bracelets in one site participating in a multicenter exception from informed consent clinical trial were not randomly distributed. These results suggest that persons from communities with higher education and higher income levels are more likely to opt out of such trials, while those living in communities with higher proportions of families, veterans, and renters are less likely to opt out. These findings may help guide resuscitation investigators, IRBs, and federal regulatory bodies when planning future exception from informed consent clinical trials.

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Figure 1.
Geospatial clustering analysis of opt-out bracelet requests by census tract ($n = 397$ census tracts).

* Derivation sample sensitivity 97.4% (95%CI 85.3 – 100%), specificity 55.7% (95%CI 50.5 – 60.8%); cross-validation sensitivity 92.1% and specificity 56.0%.

Figure 2.

Decision tree of sociodemographic characteristics identifying census tracts with clustering of opt-out bracelet requests.*

Table 1
Census tract characteristics.

<u>Dependant variables:</u>	
Bracelets	Total number of bracelets requested in each census tract
Clusters	Census tracts with geospatial clustering of opt-out bracelets
<u>General Demographics:</u>	
Age	Median age within a census tract
Gender	Proportion of female residents in a census tract
Elder	Proportion of residents over age 64 in a census tract
Veterans	Proportion of civilian veteran residents in a census tract. A civilian veteran is 18 years or over who has served, but is not now serving, on active duty in the U.S. military service
Rural	Proportion of territory, population and housing units in a census tract with less than 2,500 persons, outside of urbanized areas
<u>Race/Ethnicity/Language:</u>	
Non-white	Proportion of residents who self-identify as any race other than “White”
Hispanic	Proportion of residents who classify themselves in one of the specific Hispanic or Latino categories listed on the Census 2000 or ACS questionnaire, or in the category of “other Spanish, Hispanic, or Latino”
Foreign born	Proportion of residents in a census tract who are not U.S. citizens at birth
Non-English speaking	Proportion of residents in a census tract who identified themselves as non-English speakers, or persons who speak English as a non-primary language
<u>Family:</u>	
Family Household	Proportion of households in a census tract comprised of two or more people living in the same household who are related by birth, marriage, or adoption
<u>Education:</u>	
High school	Proportion of residents over the age of 25 in a census tract who have a high school diploma or equivalency
College	Proportion of residents in a census tract who attended at least one year of college or technical school
Graduate	Proportion of residents in a census tract who have any degree beyond a bachelor’s degree
<u>Income:</u>	
Income	Median household income within a census tract
Income >100k	Proportion of households in a census tract with combined income $\geq$ \$100,000 per year
Income per capita	Median per capita income within a census tract
Poverty	Proportion of households in a census tract who report combined income at or below the federally-defined poverty line
Public assistance	Proportion of households in a census tract who receive public assistance
<u>Housing:</u>	
Vacant	Proportion of housing units in a census tract that are unoccupied at the time of enumeration, unless its occupants are only temporarily absent
Rental	Proportion of housing units classified as renter-occupied housing units
<u>Employment:</u>	
Unemployment Proportion of unemployed (civilians 16 years old and over who were (1) neither “at work” nor “with a job but not at work” during the reference week, (2) actively looking for work during the last 4 weeks, and (3) available to accept a job) in a census tract	

Table 2
Comparison of characteristics in census tracts with and without geospatial clustering of opt-out bracelets (n=397).

Variables*	Census tracts with clusterin (n = 38)g			Census Tracts without Clustering (n = 359)			p-values
	Median	IQR		Median	IQR		
Family households	55%	(28 – 63)		67%	(59 – 77)		<.0001
Veterans	12%	(9 – 14)		14%	(12 – 16)		.0001
Graduate school degree	15%	(8 – 20)		7%	(4 – 12)		<.0001
College degree	76.5%	(62 – 84)		61%	(53 – 73)		.001
High school degree	92.5%	(86 – 96)		88%	(82 – 92)		.007
Rural housing units	0%	(0 – 0)		0%	(0 – 0)		.004
Housing units for rent	39%	(28 – 75)		33%	(20 – 47)		.02
Per capita income	\$23,189	(19,141 – 32,967)		\$21,605	(18,237 – 26,477)		.05
Below federal poverty line	10%	(6 – 17)		8%	(5 – 13)		.05
Income over \$100,000	6%	(3 – 18)		8%	(4 – 16)		.47
Median income	\$52,251	(40,824 – 73,661)		\$50,287	(41,480 – 59,969)		.16
Median age	37 yrs	(33 – 41)		35 yrs	(32 – 39)		.11
Female	50.7%	(49.0 – 51.9)		50.6%	(49.5 – 51.4)		.90
Age >65 years	10.5%	(8 – 15)		10%	(7 – 12)		.13
Non-Caucasian race	11.5%	(7 – 22)		11%	(6 – 17)		.17
Hispanic ethnicity	4.5%	(3 – 7)		5%	(3 – 8)		.18
Born outside US	9%	(7 – 14)		9%	(6 – 14)		.28
Non-English speaking	12%	(9 – 19)		12%	(8 – 18)		.72
Receiving public assistance	3%	(1 – 5)		3%	(2 – 5)		.68
Vacant housing units	5%	(4 – 6)		5%	(4 – 6)		.51
Unemployed	5%	(3 – 7)		5%	(4 – 7)		.50

*. The value of each variable represents the proportion (range 0 – 100%) of the given characteristic within each group of census tracts, except *per capita income*, *median income*, and *median age*.

Table 3

Multivariable regression models of census tract characteristics associated with opt-out bracelet requests (n = 397 census tracts).^{*}

	Model 1 logistic regression (outcome: bracelet clusters)		Model 2 negative binomial regression (outcome: bracelet count)	
	OR	95%CI	IRR	95%CI
Proportion of family households	.90	(.85 – .93)	.96	(.94 – .98)
Veterans	.91	(.81 – 1.02)	.88	(.83 – .93)
Housing Units for Rent	.96	(.92 – .99)	.98	(.96 – .99)
Income over \$100,000	1.07	(1.02 – 1.11)	1.06	(1.03 – 1.08)
75–100%ile Hispanic			3.25	(1.55 – 6.83)
50–75%ile Hispanic			2.97	(1.59 – 5.53)
25–50%ile Hispanic			2.68	(1.51 – 4.77)
0–25%ile Hispanic				reference
75–100%ile High school graduates			.53	(.28 – 1.01)
50–75%ile High school graduates			.49	(.29 – .81)
25–50%ile High school graduates			.76	(.47 – 1.21)
0–25%ile High school graduates				reference

^{*} OR = odds ratio; IRR = incidence rate ratio; 95% CI = 95% confidence interval.