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Comparison of Sampling Strategies for Tobacco Retailer Inspections to Maximize Coverage in Vulnerable Areas and Minimize Cost

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Abstract

Introduction: In the United States, tens of thousands of inspections of tobacco retailers are conducted each year. Various sampling choices can reduce travel costs, emphasize enforcement in areas with greater noncompliance, and allow for comparability between states and over time. We sought to develop a model sampling strategy for state tobacco retailer inspections.

Methods: Using a 2014 list of 10,161 North Carolina tobacco retailers, we compared results from simple random sampling; stratified, clustered at the ZIP code sampling; and, stratified, clustered at the census tract sampling. We conducted a simulation of repeated sampling and compared approaches for their comparative level of precision, coverage, and retailer dispersion.

Results: While maintaining an adequate design effect and statistical precision appropriate for a public health enforcement program, both stratified, clustered ZIP- and tract-based approaches were feasible. Both ZIP and tract strategies yielded improvements over simple random sampling, with relative improvements, respectively, of average distance between retailers (reduced 5.0% and 1.9%), percent Black residents in sampled neighborhoods (increased 17.2% and 32.6%), percent Hispanic residents in sampled neighborhoods (reduced 2.2% and increased 18.3%), percentage of sampled retailers located near schools (increased 61.3% and 37.5%), and poverty rate in sampled neighborhoods (increased 14.0% and 38.2%).

Conclusions: States can make retailer inspections more efficient and targeted with stratified, clustered sampling. Use of statistically appropriate sampling strategies like these should be considered by states, researchers, and the Food and Drug Administration to improve program impact and allow for comparisons over time and across states.

Implications: The authors present a model tobacco retailer sampling strategy for promoting compliance and reducing costs that could be used by US states and the Food and Drug Administration (FDA). The design is feasible to implement in North Carolina. Use of the sampling design would help document the impact of FDA's compliance and enforcement program, save money, and emphasize inspections in areas where they are needed most. FDA should consider requiring probability-based sampling in their inspections contracts with states and private contractors.

Introduction

Since 2010, Food and Drug Administration (FDA) contractors have conducted over 660,000 compliance checks at retailers that sell tobacco products to enforce tobacco sales and marketing regulations.[1] These compliance inspections, authorized under the Family Smoking Prevention and Tobacco Control Act of 2009 (FSPTCA),[2] are designed to reduce underage purchase of tobacco products and enforce advertising/labeling provisions such as restrictions on self-service for tobacco products and bans on the sale of single cigarettes. The FDA contracts with states, territories, and some private organizations to enumerate tobacco retailers and develop a sampling strategy for inspections.[3] FDA advises that sampling strategies should take into consideration areas where youth smoking rates are higher, youth access is greater, if the retailer is near a school, and "regions with lower socioeconomic populations (historically associated with market targeting)" (p. 15).[3] Additionally, the FDA requires states to ensure inspection coverage in racial/ethnic minority communities.[3]

There is no requirement for states to use probability-based sampling strategies for FDA inspections, but FDA has the power to approve sampling plans.[3] Previous recommendations regarding tobacco retailer inspections have not discussed sampling and have noted a wide variation in state approaches to implementing youth access programs.[4–6] Visiting tobacco retailers can be expensive. Law enforcement, youth staff, and travel routes must be efficiently coordinated because public health budgets are limited. However, even among researchers, the sampling of tobacco retailers does not typically consider cost-saving efficiencies from clustered sampling. A 2014 systematic review found that while a substantial proportion of research-related audits of tobacco marketing at tobacco retailers used random sampling (ie, 45% of those reporting a sampling strategy) or conducted censuses (41%), fewer than 10% mentioned strategies for stratified or cluster sampling.[7]

Sampling strategies can be used to maximize scarce enforcement resources by oversampling areas where noncompliance is highest. The distribution of both underage sales and advertising/labeling violations are not random.[8,9] In national FDA data from 2015, likelihood of sale to a minor is positively associated with neighborhood lower socioeconomic status; greater segregation of American Indian, African American, and Hispanic residents; and, the proportion of American Indian, African American, and Hispanic residents.[9] Smaller studies confirm these disparities, showing more noncompliance in areas with greater population density,[10] areas with greater Hispanic population,[11] areas with greater African American population,[12,13] and areas with greater foreign-born population.[10] Similarly, single cigarette sales, another FSPTCA violation, are not distributed evenly across neighborhoods, with greater presence of single cigarettes in neighborhoods with a higher proportion of African American residents.[14,15]

We aimed to examine three sampling strategies (simple random sampling; stratified, clustered sampling at the ZIP code; and stratified, clustered sampling at the census tract) designed to (1) improve inspection program impact by emphasizing inspections in areas with greater noncompliance, (2) create cost savings, and (3) generate data for public health surveillance. We hope these could provide a model for states' proposed strategies to FDA. We compare sampling strategies by the neighborhood poverty of selected retailers, the racial/ethnic neighborhood characteristics of sampled retailers, proportion of retailers near schools, average distance between all sampled retailers (a proxy for travel costs), average distance to the nearest neighbor (a proxy for travel costs), design effect (ie, how much less statistically efficient the sampling strategy is than simple random sampling), and expected margin of error of the violation rate (ie, the range around the sample estimate that the true population estimate is likely to fall if all sites were inspected).

Methods

We used a list of likely tobacco retailers in NC in 2014. As NC does not have tobacco retailer licensing, the list was constructed using methods previously validated in NC.[16] Briefly, we identified and deduplicated likely tobacco retailers from ReferenceUSA business listing service and alcohol sales licenses for off-premise consumption. We geocoded stores to a latitude and longitude using Texas A&M University's Geocoding service (http://geoservices.tamu.edu/Services/Geocode). An earlier version of this service was validated with ground truthing and reported a >99% match rate.[17] Past research from NC has shown use of ReferenceUSA store lists results in >90% of tobacco retailers being geocoded to the correct census tract.[16] After list cleaning and geocoding, this resulted in 10,161 likely tobacco retailers. We calculated a 305 m (1,000 foot) buffer around the school points in NC State Plane Projection, using data from the North Carolina OneMap GeoSpatial Portal to identify stores near schools.[18,19] This distance has been suggested in US policy debates about restrictions on tobacco retailing.[20,21] This approach identified 806 retailers as being near schools. Using Census Bureau American Community Survey, 5-Year Estimates, 2008–2012, we calculated ZIP code and census tract Black racial composition (% of residents identifying as Black/African American alone or in combination with other races), Latino/Hispanic ethnic composition (% of residents identifying as Latino/Hispanic of any race), and poverty (% of residents living below the poverty line). We defined high-poverty areas as those above the 75th percentile of percent of residents living below the poverty line (ie, above 24.20% in ZIPs, 27.16% in tracts). Maps of poverty strata for a given sample are available online in Supplementary File 1. Phi coefficients between retailers being near schools and high poverty designation were weak for ZIP codes, 0.02, $p = .13$, and tracts, 0.03, $p = .01$.

Based on FDA requirements to conduct compliance checks for at least 20% of retailers,[3] we wished to achieve a final sample of 20% of the frame (2,032 retailers). To allow for retailers who were out of business, closed, or impossible to find, we adjusted our sample size to 2,184 given an anticipated eligibility rate of 93.1%, which was based on the 2016 NC Synar data.[22] Design 1 was a simple random sample where we selected the sample of 2,184 retailers from the frame, giving each retailer equal probability of selection.

To better achieve FDAs goals of oversampling in low income areas and retailers near schools, Designs 2 and 3 were stratified, cluster designs, also known more formally as stratified probability proportional to size cluster sampling with oversampling of high poverty neighborhoods. Cluster designs also have the benefit of reducing travel distances between sampled retailers as two stages are used in the sampling. Retailers selected in the second stage are selected only within areas selected in the first stage. Thus, selected retailers are located in more limited areas, which can reduce travel costs. Stratified designs allow retailers or areas to be classified in a category (ie, a stratum), such as high or low poverty. Sampling can then disproportionately select from one stratum over another. In this way, for example, one can oversample retailers in high-poverty areas giving them a greater probability of selection than those in low-poverty areas. Sampling weights are applied to adjust estimates of the state's violation rate for the sampling strategy used.

NC has 808 5-digit ZIP code tabulation areas, and 685 ZIP codes had a tobacco retailer present (tobacco retailers per ZIP code: mean = 33.3, SD = 21.1). In Design 2, clusters were defined as ZIP codes. That is, ZIP codes served as the primary sampling units (PSUs), which are selected in the first stage of a cluster design. First, ZIP codes were stratified based on their poverty rate into high-poverty and low-poverty areas, classifying the 25% of ZIP codes with the highest poverty rates as high poverty and the remaining ZIP codes as low poverty. Second, 250 ZIP codes were selected (172 from high-poverty areas and 78 from low-poverty areas) using a probability proportionate to size with minimal replacement[23] method that selects PSUs proportional to their size (in this case, the count of retailers in the ZIP code). This stratification and allocation approach maximized the percent of sampled retailers in high-poverty areas while controlling the statistical efficiency of the sample. In the second stage of sampling, within selected PSUs, retailers were selected based on a stratified simple random sample, with a target sample of nine retailers selected within each PSU and with retailers near schools sampled at a rate three times greater than retailers not near schools.

NC has 2,184 census tracts of which 1,861 had a tobacco retailer present (tobacco retailers per census tract: mean = 8.57, SD = 5.04). Design 3 was identical to Design 2, except that PSUs were census tracts, and 350 tracts were selected (238 from high-poverty areas and 112 from low-poverty areas), with a target sample size of seven retailers per cluster. The stratification and allocation approach was similarly designed to maximize the percent of sampled retailers in high-poverty areas while controlling statistical precision in the resulting sample. The additional clusters for the census tracts were needed because census tracts are smaller than ZIP codes and this larger sample of clusters allowed us to achieve the desired sample size while maintaining statistical efficiency.

We compared the three designs based on anticipated statistical characteristics, neighborhood characteristics, and retailer proximity to compare the statistical efficiency, oversampling success, and potential for cost savings across the three designs. We compared the comparative level of precision (reporting the anticipated design effect and the expected margin of error on the violation rate, defined subsequently), coverage, and retailer dispersion in each sampling strategy.

The design effect quantifies statistical inefficiencies in the cluster designs due to oversampling of retailers in high-poverty areas and near schools and due to the clustering by either ZIP code or census tract. That is, clustering retailers in a ZIP code or tract reduces the available information as each retailer's characteristics can be partially predicted by neighboring retailers, assuming retailers near each other are more similar than retailers far from each other. A design effect is relative to the statistical precision in a simple random sample, so a design effect of 2 would indicate that the design is half as statistically efficient as a simple random sample.[24] We calculated the overall design effect ($DEFF_O$) for each of the three designs as the product of the design effect due to clustering ($DEFF_C$) and the design effect due to weighting ($DEFF_W$), as follows:[25]

$$DEFF_O = DEFF_C * DEFF_W, \text{where}$$

$$DEFF_C = 1 + ICC(\bar{c} - 1), \text{and } DEFF_W = \frac{n\sum WT^2}{\left(\sum WT\right)^2}$$

The ICC is the intraclass correlation, which represents the similarity of retailer violation rates within clusters (ZIP codes or tracts). For the two stratified cluster designs, we estimated the ICC with 2016 NC Synar data.[22] $\bar{c}$ represents the average cluster size, or the number of retailers in the final sample divided by the number of clusters (2,032/250 = 8.1 for ZIP codes and 2,032/350 = 5.8 for census tracts). n represents the overall sample size (2,032), and WT represents the weight of each retailer, or its inverse probability of selection. Because it is dependent on the specific sample of retailers selected, $DEFF_O$ was calculated for each simulated sample and the average was computed across all 1,000 replicate samples for each design.

The anticipated margin of error is a measure that estimates the true proportion of violations that exists in the population of all tobacco retailers based on the sampled retailers. The margin of error is the range around the sample estimate in which the true population estimate is likely to fall if all sites were inspected. The anticipated margin of error applies the design effect to the estimated violation rate, 15% based off of national data,[9] with a 95% confidence interval, calculated as follows.

$$MOE = 100\% * 1.96 * \sqrt{\frac{DEFF_O * p(1-p)}{n}}$$

Where $DEFF_O$ is as defined previously for each simulated sample, 1.96 is the critical value for a 95% confidence interval, p is the assumed violation rate (15%), and n represents the overall sample size (2,032). It is important to note that the assumptions in our simulation are reasonable for the state of NC, and should be reviewed and revised, as appropriate, when applied to other states. The resulting utility of the three designs might change depending on these assumptions.

To quantify the effectiveness of our oversampling, we also assess the tract characteristics expected with each sampling approach: average poverty rate, percent of the sample in clusters that are in high-poverty areas, percent Black residents, and percent Hispanic residents. We further examine oversampling by comparing the percent of the sample located within 305 m of schools for each of the three designs. Finally, we calculate the average distance between selected retailers and the average nearest neighbor distance using SAS's GEODIST function. The GEODIST function, available in SAS 9.2 and newer editions, provides the straight-line distance between two sets of latitude and longitude coordinates using the Vincentry distance formula.[26]

The average distance between selected retailers and nearest neighbor metrics serve as indicators of potential cost savings associated with each design, as shorter distances would indicate lower travel costs for conducting the inspections.

We used PROC SURVEYSELECT commands in SAS 9.3. Appendix A contains example SAS code for selecting a sample based on each of the three designs. To control for random variation that would be observed in a single sample, we conducted a simulation where we selected 1,000 samples for each of the three designs and averaged the observed characteristics across the 1,000 samples. We present the results of the simulation study in Table 1. As no human subjects were involved in this research, IRB approval was not sought.

Results

As shown in Table 1, each of the three sampling strategies was feasible for sampling of tobacco retailers. The statistical precision of the simple random sample as indicated by the estimated margin of error was superior. Because simple random sampling does not include any oversampling, the pooled characteristics of retailers selected in simple random sampling are similar to the characteristics of the entire sampling frame. Simple random sampling used alone, therefore, does

Table 1. Design Comparison

Sampling approach	Size (retailer n)[b]	Percent poverty[c]	Percent >75th percentile poverty[c]	Percent Black[c]	Percent Hispanic[c]	Percent near schools (305 m)	Average distance between retailers (km)	Average nearest neighbor (km)	Anticipated design effect	Anticipated MOE (%)[d]
Design 1: Simple Random Sample[a]	2,184	20.7	25.1	27.9	9.3	8.0	191.5	2.8	1.0	1.5
Design 2: Stratified, Cluster Sample (ZIP codes, n = 250)[a]	2,146	23.6	34.0	32.7	9.1	12.9	181.9	1.3	2.8	2.5
Design 3: Stratified, Cluster Sample (Census Tracts, n = 350)[a]	2,124	28.6	53.7	37.0	11.0	11.0	187.7	2.1	2.2	2.2
Frame (all retailers)	10,161	20.7	25.0	27.9	9.3	7.9	191.4	1.5	-	-

[a]Values are averages across 1,000 simulated samples.
[b]Sample sizes for Designs 2 and 3 are lower than the number of clusters multiplied by the sample size per cluster (250 × 9 = 2,150 for Design 2 and 350 × 7 = 2,450 for Design 3) because many clusters on the frame had fewer retailers than the number selected per cluster.
[c]Estimated based on retailer's neighborhood (census tract) characteristics from the 2008-2012 American Community Survey. These serve as indicators of oversampling success in Designs 2 and 3.
[d]Anticipated margin of error (MOE) based on a 95% confidence interval with an expected violation rate of 15%.

not provide the cost savings and ability to target specific areas that stratification and clustering provide.

Compared to simple random sampling, both ZIP and tract stratified, clustered sampling showed advantages, respectively, in average distance between retailers (relative reduction of 5.0% and 1.9%), in nearest neighbor (relative reduction of 54% and 25%), percent Black residents in sampled neighborhoods (relative increases of 17.2% and 32.6%), percent Hispanic residents in sampled neighborhoods (relative decrease of 2.2% and increase of 18.3%), percentage of sampled retailers located near schools (relative increases of 61.3% and 37.5%), and poverty rate in sampled neighborhoods (relative increases of 14.0% and 38.2%). We note that the small reduction in travel distance could be substantial over time. Yet, these improvements came at a cost of statistical precision, raising the design effect to 2.8 and 2.2, respectively. Figure 1 shows an example of each strategy.

Discussion

Principal Findings

Policy makers will need to decide the appropriate balance between ensuring greater numbers of inspections where there are likely to be more violations, travel costs, and statistical precision. Simple random sampling provides the smallest margin of error. However, the two stratified, cluster sampling approaches may maximize program impact by emphasizing inspections in areas with inequalities in health and lower retailer compliance. They do so while also reducing the distance between inspection locations. These sampling strategies are suitable for advancing the work of tobacco retailer regulators, including their focus on addressing disparities in compliance rates. Importantly, these can be implemented in ways that also allow for tracking violation rates over time and comparing violation rates between states. Stratified, clustered sampling strategies are feasible to implement at the state level. When oversampling by poverty and retailers near schools, we found that, in NC, the inspections also oversampled areas that have historically been associated with greater noncompliance.[9] This has important implications for ensuring the racial or ethnic identity of neighborhood youth does not predict easier access to regulated tobacco products.

Our stratified, clustered sampling designs addressing both area characteristics and retailer-level characteristics represent a useful strategy that may be emulated by other states and should be considered by the FDA. Without inspection and enforcement, regulations alone will have little effect on youth access.[27] Stratified, clustered designs may be particularly useful to improving compliance in targeted areas as inspections can have an effect on nearby retailers,[28] and more frequent inspections promote compliance.[6] Given the likely use of nonprobability sampling approaches, FDA inspection results cannot currently be compared across time, between states, or with other inspection programs. However, use of probability-based sampling could help document program outcomes and inform quality improvement efforts.

We believe the stratified, clustered at the tract design is superior to simple random sampling as having precise estimates of violation rates is likely a lower priority for FDA's compliance and enforcement program than is ensuring that inspections are being conducted in areas where they are needed most. Indeed, the margin of error and design effect may matter less given the minimum of 20% of retailers being inspected in a given year. Reducing cost is also an important consideration for government programs. The ZIP code approach did slightly better in increasing the percent of retailers near schools than did the tract-based approach. However, it does not perform as well in reaching high-poverty areas. ZIP codes, which are larger area units, often consist of both high- and low-poverty areas making it harder to select PSUs that will yield retailers in high-poverty neighborhoods. This is consistent with long-standing evidence as one modifies the area unit of study, extremes in smaller areas may be attenuated.[29] Geographers term this the modifiable area unit problem,[30] and it explains how the use of a larger area unit (ZIP codes) may perform less well in targeting inspections than the smaller area unit (tract) in this study. Nonetheless, both design 2 and design 3 outperform the simple random sample in design 1 with respect to targeting inspections where compliance is likely lower while also reducing the distance between retailers.

Strengths and Weaknesses

This study is strengthened by use of a simulation to show differences across repeated samples and use of a validated[16] approach to

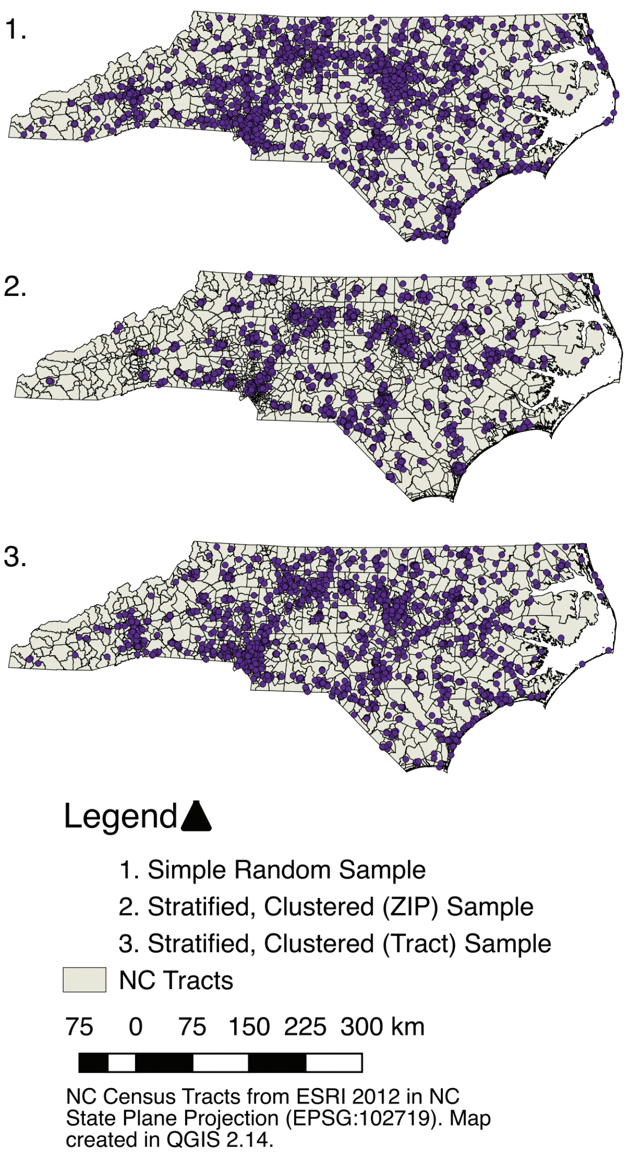

Figure 1. Examples of three sampling approaches, North Carolina.

enumerate tobacco retailers. However, there are important limitations. Our sampling plan is specific to NC, and other states may find the same process yields different results given different demographic patterning of race, ethnicity, schools, and poverty. NC does not have tobacco retailer licensing; there may be some measurement error in the creation of our sampling frame. Tobacco retailer licensing could improve the quality of the sampling frame. We cannot directly calculate costs saving associated with clustered sampling, and our metrics of distance do not reflect real world travel costs; future research should examine travel optimization strategies and use actual travel distances from street networks. We did not exhaust all possible approaches to sampling and different approaches may be feasible or superior for other states.

Unanswered Questions and Future Research

Further optimizations of this sampling strategy can likely be identified based on correlates of noncompliance that help target inspections in areas with greatest noncompliance. Our sampling strategy decreases the average distance between inspections; however, it does not address how to most efficiently assign inspections. Nor does it address a potential challenge with clustered designs: the possibility that retailers advise neighboring retailers of an inspection team in the area.

States also participate in youth inspections requiring a probability-based sampling strategy required under the Synar Amendment and reported to Substance Abuse and Mental Health Services Administration.[5] These are used for tracking trends and evaluating state efforts to reduce youth access. In addition to use of clustered sampling for inspections, this approach may also be useful for state Synar sampling. As states could lose federal funding if violation rates are reported to be over 20%, states have an incentive to underreport violation rates and to adopt protocols that minimize the identification.[4] Use of probability-based sampling in FDA inspections also could help assess the validity of Synar inspection results. However, this would still be subject to the validity of FDA's unpublished inspection protocols. Many inspection protocols used likely do not reflect real-world purchase attempts and thus underestimate youth access.[31,32]

Conclusion

Probability-based sampling offers advantages that should be considered by FDA and state contractors. Stratified, cluster sampling strategies can reduce the cost of conducting state FDA compliance check inspections by reducing the average distance between inspections and can do a better job focusing enforcement resources in areas with more vulnerable populations, such as youth and populations that are racially and ethnically diverse. FDA has the power to review and approve state sampling plans.[3] This power could—and we would argue should—be used to require probability-based sampling strategies in ways to allow for comparisons between states and across time while also advancing a regulatory agenda of targeting inspections to areas where violations are most common.

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Declaration of Interests

KMR serves as an expert consultant in litigation against cigarette manufacturers. JGLL and KMR have a royalty interest in a store mapping and audit system owned by the University of North Carolina at Chapel Hill, but these systems were not used in this study.

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