Impact of a Local Staple Food Ordinance on Food Choice and Calories Purchased (The STORE Study)

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Table of Contents

I. Project Summary

Improving healthy food availability and decreasing the availability of high calorie, low nutrient products, particularly in underserved communities, has been identified as a leading strategy for local governments to prevent obesity. However, policy action in this area to date has been limited. The purpose of this STORE study, therefore, is to evaluate the impact of a local policy change (i.e., the Minneapolis Staple Foods Ordinance) that establishes minimum stocking criteria for a wide array of healthy foods as a requirement of food store licensing.

In this 4-year study, the impact of the Minneapolis Staple Foods Ordinance will be evaluated by assessing objectively measured changes in: (a) food environments among small and non-traditional urban food stores, including availability, promotion, advertising, quality, price, and placement of both healthy and unhealthy foods and beverages, (b) nutritional quality of consumer purchases at these food stores, including assessment of energy density and calories via customer intercept surveys and direct observation of purchases and (c) home food environments, including availability of healthy and unhealthy foods/beverages and an overall home food obesogenicity score, among households that frequently shop at these stores. These changes will be assessed pre-policy implementation, as well as at 4-, 12- and 24-months post-policy implementation, in two Minnesota cities: Minneapolis and St. Paul (the comparison community). The proposed scope of work in this study is important because it takes advantage of a unique opportunity to evaluate an innovative local policy addressing a recommended action area for obesity prevention that aligns with key recommendations by leading obesity prevention authorities.

II. Background and Significance

Overview of the Problem

In recent years, the Institute of Medicine, Centers for Disease Control and other authorities have identified improving access to healthy foods as a strategy for local governments to help prevent obesity.[1-5] Many communities have limited access to healthy foods.[6, 7] Numerous studies indicate that supermarkets are more likely to be located in high-income and low-minority areas, and convenience stores are more likely to be located in low-income and high-minority areas.[6] Disparities in food access likely contribute to large-scale health disparities, in that better access to supermarkets is associated with healthier diets and reduced risk of obesity, and access to convenience stores is associated with increased risk.[6, 8-12] Supermarkets generally offer a wider variety of healthy, high-quality foods, and small convenience stores carry higher-calorie, processed foods at higher prices.[6, 13-16] Growing evidence suggests that increasing healthy food availability and decreasing high calorie, low nutrient products in convenience stores, or "corner stores," may be a promising strategy for obesity prevention.[1, 2, 4, 17-19] However, much of the work in this area to date has been programmatic in nature (i.e., implemented by working one-on-one with stores via "healthy corner store" programs), which can be time- and resource intensive and have challenges for sustainability.[20] Policy initiatives may be able to expand these efforts by broadening programmatic reach, providing additional incentives for stores, and addressing compliance and enforcement issues.

Potential Action for Research

Although policy work in this area is limited, one potential action area is around the implementation

of health criteria, such as minimum stocking requirements for healthy foods, as a condition of food store licensing.[21] The Minneapolis City Council passed a Staple Foods Ordinance in 2008 requiring stores with grocery licenses to carry specific staple foods, including fresh fruits and vegetables.[22] This ordinance was originally passed as a crime prevention policy (targeting "food stores" that offered little food and served as venues for criminal activity) and contained numerous loopholes. For example, no minimum stocking quantities were specified in the ordinance, the minimum number of varieties mandated for each type of staple food were limited, and most specified foods were not subject to health criteria (i.e., requirements included only general categories like meat, bread/cereal and dairy). In an effort to increase healthy food access, the City of Minneapolis is revising the Staple Foods Ordinance, with implementation of the ordinance expected in April 2015. These revisions include numerous improvements to align the policy with the Dietary Guidelines for Americans and stocking requirements for WIC (Women, Infants and Children) program vendors.[23, 24] Thus, stocking requirements for all eligible stores would increase dramatically across an array of nutrient-rich foods that are low in energy density, including fruits, vegetables, 100% juices, whole grains, and low-fat dairy. If successful, the new ordinance could serve as model legislation for other local governments, particularly those seeking to enhance these efforts by further expanding the scope of the requirements through more rigorous policies.

Knowledge to Be Gained

There is a great deal of knowledge to be gained from this study. The Minneapolis Staple Foods Ordinance is, to our knowledge, the first policy of its kind to be implemented in the United States, and as such, has the potential to substantially improve access to healthy foods in all neighborhoods and communities affected by the ordinance. It will be important to evaluate its impact as well as to identify potential challenges to the implementation, time to compliance, and factors that predict which stores may require support in implementation. Such an evaluation may provide valuable insights for other local governments looking to implement similar or more rigorous policies. Benefits to society greatly outweigh any possible minimal risks, and the impact of this proposed study has the potential to contribute positively to dietary behaviors and weight outcomes of neighborhood and community residents.

Preliminary Studies

- *The role of corner stores in diet and weight outcomes*. In 2009, Dr. Laska and colleagues conducted one of the first systematic reviews on disparities in access to healthy food in the United States.[7] Overwhelmingly, this evidence suggested that residents of low-income and minority neighborhoods are most often affected by poor access to healthful food. Furthermore, Dr. Laska also served as a co-investigator (and later, the Principal Investigator) of Project IDEA, a multilevel 5-year longitudinal cohort study of young people to examine the etiology of adolescent obesity.[25] Our analyses of GIS data indicated that the only attribute of the food environment significantly associated with BMI Z-score and body fat was the presence of convenience stores within 1 mile of adolescents' homes.[26] Sugar sweetened beverage intake was also significantly associated with proximity to convenience stores.[26, 27] In another study of 6th graders attending low-income schools in St. Paul (2008-09), we found that 67% of students bought food at a convenience store in the past week using their own money (Laska, unpublished data). Corner stores were the second most commonly reported location for food purchasing overall, and 71% of students reported spending money on food/ beverages for themselves in a typical day. Similar results have been observed elsewhere,[28] highlighting that corner stores are an important source of excess calories in children.

- *Urban corner stores*. In 2008, Dr. Laska and colleagues conducted store audits to assess food availability in >100 small and non-traditional stores in 4 urban areas (Baltimore, Minneapolis/St. Paul, Oakland, and Philadelphia).[29] Results indicated that availability of healthy food items was notably low, with only 50% having ≥1 type of fresh fruit or vegetable. There was significant cross-site variability in the availability of healthy staple foods and snacks, emphasizing the influence of local contexts on store environments. In analyses of Minnesota-specific data from a larger sample of convenience stores,[30] we again found that a wide range of healthy snack options were typically not available, with many items stocked in <50% of stores, and even fewer stores carrying healthy snacks in single- serving packages. All stores had less healthful impulse items available at or near the cash register (e.g., candy). Only 46% carried healthier impulse items (e.g., fruit). Most stores had food/beverage advertising, and 94% of advertisements were for less healthful, energy-dense products (e.g., soda, beer, chips, prepared foods). These studies demonstrate feasibility in conducting brief, in-store audits over a short time period. In addition, this work was the first of its kind to document the limited availability of healthy foods in small, urban corner stores across multiple regions in the United States. Despite this limited availability, however, we showed that some stores were able to stock and sell healthy foods, thus indicating the capacity for success in improving healthy food availability in these settings. Finally, this work drew attention to less-studied aspects of the retail food environment in small stores, including impulse purchasing displays, in-store advertising and serving size.

- *Challenges in making healthy changes in small and non-traditional food stores*. Dr. Laska and colleagues have also examined barriers faced by small and non-traditional food store owners and the impact of other policy changes. In 2010, Dr. Laska helped lead an effort to assess the impact of the 2009 WIC policy changes across 8 cities in the United States on perceived sales, product selection and stocking habits of small stores.[31, 32] We found that store owners experienced numerous implementation challenges following the policy change, the most common of which were: (a) obtaining a steady supply of healthy, perishable foods, (b) having reliable relationships with healthy food suppliers and (c) working with customers to understand the new regulations. However, most store owners were able to overcome these challenges, and ultimately felt the WIC changes increased their number of customers, sales, and profits. Despite this, many small and non-traditional food stores do not accept WIC, and thus may not currently be stocking a range of healthy foods. Some of the challenges overcome by store owners in our sample could be perceived as insurmountable by others. Dr. Laska and colleagues have also explored challenges among store owners through in-depth case study analyses of lessons learned from corner store programs in 4 U.S. cities.[33] These analyses yielded important insights on establishing relationships with store owners, owner and customer relationships, stocking healthy foods, store evaluations, maintenance of changes in stores, and dissemination of findings. Most importantly, this work enhanced our understanding of the challenges faced by small and non-traditional food stores in providing healthy foods, as well as important factors in working with owners through research and evaluation initiatives.

- *Minneapolis Healthy Corner Store Program*. This program is a city Health Department effort to increase fresh fruit and vegetable access in at-risk areas. It was implemented in 2 phases with a small number of stores (Phase 1: 2010, n=9 stores; Phase 2: 2012, n=30 stores). Stores received low-cost assistance from the Minneapolis Health Department or liaison neighborhood organizations,

including assistance in making produce displays visible and attractive and in hosting in-store events, like taste testings. Our team partnered with the Health Department to evaluate the program. In analyses of sales in 5 intervention and 2 control stores, we detected significant changes in store sales, with intervention stores experiencing a greater increase in fruit/vegetable transactions (146% vs. 11%, p=0.01) and a marginally greater increase fruit/vegetable sales (155% in program stores vs. 22% in control, p=0.057) between baseline (weeks 1-4) and follow-up (weeks 11-14).

III. Specific Aims of the Study

Aim 1: Assess changes in small and non-traditional, urban food stores from baseline to 4-, 12- and 24-months post-policy implementation.
Objective store assessments of healthy and unhealthy food availability, promotion, advertising, quality, price, and placement will allow us to assess the degree of policy implementation, as well as changes in other environmental outcomes not directly specified by the policy. To identify barriers and facilitators associated with implementation, we will also examine patterns of compliance over time (such as "early compliers" vs. "late compliers") and store- and neighborhood-level predictors of these patterns. Our primary hypothesis is that the new policy will result in an increase in healthy food availability in Minneapolis stores at 4-, 12- and 24-months post-implementation, compared to stores in St. Paul, where no policy exists, and that differences in intervention vs. control stores will continue to increase over 24 months.

Aim 2: Assess changes in the nutritional quality of consumer purchases, including assessment of calories and energy density, at small and non-traditional, urban food stores.
We will conduct customer intercept surveys at small and non-traditional stores and assess purchasing via direct observation (i.e., "bag checks"). Our primary hypothesis is that, controlling for any baseline differences, energy density and calories purchased in Minneapolis stores at 4-, 12- and 24-months post-policy implementation will be less than in stores in St. Paul, our control community.

Aim 3: Assess changes in home food availability among households that frequently shop at small and non-traditional, urban food stores.
We will collect objective, longitudinal data among a sub-set of Aim 2 participants from baseline who shop at small and non-traditional stores ≥1 time per week. This will include a staff-administered food inventory to assess the obesogenicity of the home food environment. Inventories will be conducted in participants' homes using a tool that was developed and validated by our team. Our primary hypothesis is that home availability of healthy items, like fruits and vegetables, will be greater and obesogenicity scores will be lower among frequent shoppers in Minneapolis stores, compared to those in St. Paul, at 4-, 12- and 24-months.

IV. Research Design and Methods

Study Population
- *Store-Level (Store Assessment):* Store sample identification will begin by obtaining the total number of stores in Minneapolis and St. Paul with grocery licenses from the Minneapolis Health Department for Minneapolis stores and from the Minnesota Department of Agriculture for St. Paul stores. Stores will be deemed ineligible if they are supermarkets (which we define as places where

someone might regularly do a big shopping trip to feed their household, have grocery carts and not just shopping baskets and have at least three cash registers). Stores will also be ineligible if they accept WIC benefits, because these stores are presumed to already meet minimum stocking requirements, as well as if they have invalid licensing addresses, or if they are located in core downtown commercial districts (because these stores are not expected to stock a wide array of foods). Other stores not reasonably expected to stock a minimal variety of foods will also excluded, including those that have ≤9·29m2 (≤100 ft2) of retail space (such as auto-repair shops selling limited snacks), small vendors in market areas (e.g. produce stands), and liquor or specialty stores (e.g., spice shops).

After applying these criteria and accounting for any errors, the recruitment process will begin with an invitation from our Minneapolis Health Department partners via a letter to eligible stores describing the study and the opportunity to participate. As St. Paul is serving as our comparison community, the invitation letter for these stores will be sent directly from our Principal Investigator, Dr. Melissa Laska. University of Minnesota data collectors will then visit stores in person to request permission to collect data on the stores. Data collectors will request permission at each data collection time point due to the cross-sectional design of the evaluation. The anticipated enrollment is 208 stores.

- *Individual-Level (Customer Intercept Survey):* Customers exiting small and non-traditional food stores after appearing to have purchased a food or beverage item, and who also appear to be 18 years of age or older, will be approached by the study data collection staff members and invited to participate in the study by taking a five-minute survey. Customers are eligible for participation in this survey if they: 1) are 18 years of age or older; 2) purchased a food or beverage item; and 3) speak and understand English. Customers will be excluded only if they do not meet all inclusion criteria. Upon confirmation of eligibility and after the informed consent process is complete, staff will commence with the survey. Health status will not be assessed nor considered for participation. The anticipated enrollment at each measurement time point (i.e., baseline, 4-, 12-, and 24-month post policy implementation) is 424 participants.

- *Individual-Level (Home Food Inventory):* Upon completion of the customer intercept survey (CIS) at baseline, participants who report shopping at small and non-traditional stores an average of at least once per week will be invited to participate in the Home Food Inventory (HFI) segment of this study. Eligible customers' names and contact information will be recorded for future enrollment. As with the CIS, health status will neither be assessed nor considered for recruitment and participation, and the age range for participation is 18 years of age or older. Inclusion and exclusion criteria are identical to the CIS criteria as the HFI participant sample will be drawn from the CIS participant sample. The anticipated enrollment is 68 participants.

Data Collection Handling and Storage

For all STORE study-related measurement data collection aspects, data collectors will be well trained to care for, protect and respect the data while in their possession. Data and signed gift card forms, which are used solely for accounting purposes, will be delivered to the study Project and Evaluation Coordinators on a weekly basis to ensure the safety and integrity of the hard copy data forms. After collection and data entry, hard copy data forms will be stored in locked cabinets at the University of Minnesota's Division of Epidemiology and Community Health offices, and electronic

files of the data will be stored on a secure server housed in the same division. The study's computer programmer is then responsible for formatting the data files so they can be used in data analyses. Data will be provided to only those who require its use. Additional specifics for each study measure are described below.

- *Store-Level (Store Assessment):* Although data to be collected during the assessment of the store food environment is not private and will not require human subjection protections, our study team will take the same precautions to safeguard these data as we do with protected information.

- *Individual-Level (Customer Intercept Survey):* Data will be collected from customers exiting small and non-traditional, urban food stores after having purchased a food or beverage item (subject to study inclusion/exclusion criteria detailed above). The role of the participant will not extend beyond the normal expectations of a consented study participant. Once data are collected, the participant will not be responsible for anything further. CIS participation will be confidential, and participant names will not be attached to or linked to the data or to a study-assigned ID. Participants will sign their names to a gift card form but this form will not be connected in any way to the subjects' data, and is being collected solely for accounting purposes.

- *Individual-Level (Home Food Inventory):* Data will be collected from and at the homes of participants who participated in the CIS and report shopping at small and non-traditional, urban stores an average of at least once per week. The role of the participant will not extend beyond the normal expectations of a consented study participant. As this component of the study is longitudinal in design, the participants will be asked to participate at multiple time points (i.e., at baseline, 4-, 12- and 24-months post-policy). HFI participants will provide protected information (such as name, address, phone number and email address). The participants will also be issued a study ID to which their data will be linked. To ensure the utmost of confidentiality and privacy, participant information will be stored in password-protected electronic files on password-protected computers. All hard copy data forms will be stored in locked cabinets within in our offices at the University.

Confidentiality Protections, Sharing of Data, and Disposition of Data

Study participants will be assured during the informed consent process that all identifying information will be securely protected and stored (as detailed above). An ID number will be assigned to each participant (and store) at the start of the project and this number will be used for record keeping and data analysis. Participants will never see his/her name in any reports or published papers, and data will only be shared in aggregate and only after the grant has ended with appropriate parties, such as study staff and other NIH-funded researchers doing similar work. Participant information will never be shared or used beyond necessary means. Hard copies of data will be kept securely and privately stored for seven years after which time they will be securely destroyed.

Study Timeline

This study was officially funded with a start date of December 1, 2014. Baseline screening for eligibility, enrollment and evaluation measurements began in September 2014 through a pre-award mechanism through the University of Minnesota. We will begin the baseline measures with the Customer Intercept Survey data collection. The original intent was to start with Store Assessment

(and Manager Interviews) followed by CIS and HFI, but to account for the colder temperatures in Minnesota in the late fall and winter, and the fact that CIS will require both staff and participants to stand outside, CIS data will be collected first at the baseline time point only. Both Store Assessment and Home Food Inventory data collection will then follow. Baseline data collection is anticipated to end in early 2015.

The first post-policy measurements will begin in August or September 2015 (i.e., 4-months after policy implementation in April 2015). The second post-policy (12-month) measurement period will begin in April 2016, and the final (24-month) post-policy measurement period will begin in April 2017. At all post-policy time points, data collection will begin with Store Assessment (and Manager Interview) followed by the CIS and HFI data collection.

Enrollment for the HFI data collection will occur at the baseline data collection time point.

V. Data and Safety Monitoring Plan

Study Recruitment and Retention Monitoring

Due to the minimal risk nature of this study, we are following a Data and Safety Monitoring Plan rather than convening a Data and Safety Monitoring Board to oversee this project. This plan/report focuses on close monitoring of study recruitment and retention data and the upholding of participant confidentiality by Dr. Melissa Laska, the study Principal Investigator, in coordination with Ms. Stacey Moe, the study Project Coordinator. Ms. Moe will be responsible for assembling the data and producing this report and for ensuring that Dr. Laska, Dr. Darin Erickson (Study Statistician) and Dr. Susie Nanney (study Safety Officer) all obtain copies of this report after the end of each data collection phase, or four times total for the duration of the study.

As proposed in the NIH-approved Data Safety Monitoring Plan, review of the rate of participant accrual and adherence to inclusion/exclusion criteria will occur quarterly during the active recruitment phases to ensure participants are recruited and enrolled at an acceptable rate. Additionally, recruitment and retention issues will be discussed at weekly staff meetings during the active recruitment phases of the study. The recruitment accrual to be reported in this Data Safety Monitoring Plan include the cross-sectional recruitment for the four time points of the customer intercept surveys and the longitudinal recruitment for the home food inventory sub-study at baseline (which will be monitored by retention reporting for the three follow-up time points). Furthermore, to ensure quality data is being collected, initial waves of basic data cleaning will implemented prior to data entry and additional edit checks will be conducted after data entry has been completed, resulting in a thorough and systematic examination of the data.

Data Safety and Security

Regarding safety and security of STORE study data, the research team will discuss, as the need emerges, any changes to study procedures necessary to ensure that data are kept secure. All study staff have completed trainings in the protection of human subjects and data security. In addition, the study Safety Officer will review data safety and security issues every six months. To help ensure the confidentiality of study participants, data will be linked to participants by their study ID number only. Data collection instruments will include only the ID number of the participant. Files including

the necessary information to link identifying information and study data will be available only to the research staff deemed necessary.

Adverse Event Reporting

In the very rare instance when a possible adverse event might occur, we will document the description of the event, the onset and ending date of the event, the severity and study-relatedness of the event and the outcome of the event. If the event meets the definition of a serious adverse event, we will report the event to the IRB and NIDDK within 15 working days. If the event is life threatening or fatal, we will report the event to the IRB and NIDDK within 5 working days.

VI. Statistical Considerations

Analyses That Will Be Performed

The study design is a 2 (Condition: ordinance, no ordinance) X 4 (Time: Baseline, 4-, 12-, 24-month) quasi-experimental study. The primary hypothesis will be tested using traditional repeated measures modeling as well as growth curve modeling. The unit of analysis is the store, with Time a within-subjects factor and Condition a between-subjects factor. Condition, Time, and their interaction are modeled as fixed effects. The overall test of any difference by policy condition over time is the Time x Condition interaction, a 3 degree of freedom test. Planned contrasts will be used to examine specific hypotheses using single degree of freedom tests, assessing effects at 4-, 12- and 24-month follow-up. Because stores are not randomized to Condition, the statistical models will include a number of potential store-level covariates as additional fixed effects that have been identified from previous work. Covariance pattern modeling implemented by mixed model regression will be used to estimate the repeated measures model; this model allows residuals to correlate to account for the same stores being measured over time.

The repeated measures general linear mixed model includes time as a fixed effect and examines the effect of the policy on the outcome using the Time x Condition interaction. Using a series of planned contrasts, the effects of the intervention at each time point can be estimated (e.g., baseline to 4 months, baseline to 12 months, etc.). This model does not, however, explicitly model change over time. To examine change over time and how this relates to condition, we will augment these analyses with a series of conditional, multilevel models of change (i.e., growth curve models). These models examine inter-individual differences in intra-individual change by fitting a trajectory, with an intercept and slope, to each store. The intercept and slope can be regressed on predictors and covariates of interest.

We will test Aim 1 (to assess changes in food availability pre- vs. post-policy implementation, as well as changes in food price, quality, promotion, and placement) by regressing each outcome variable separately on Time, Condition, and the Time x Condition interaction, as well as a number of potential covariates (store characteristics [e.g., type of store, size, customer base, store owner characteristics] and neighborhood characteristics [e.g., race/ethnicity, household income, poverty, education, employment]). The 3 df Time x Condition interaction is the overall test of the hypothesis; we hypothesize that this estimate will be significantly different from zero. We will conduct a set of single df planned contrasts to isolate effects. Controlling for any baseline differences, we will test differences between Condition (Policy vs. no Policy) at 4-, 12-, and 24-months post policy change. We hypothesize that stores in Minneapolis will show significantly

higher healthy food availability scores at all 3 time points. We will supplement these analyses using growth curve modeling. We will fit individual lines to each store's 4 waves of healthy food availability scores, and regress these intercepts and slopes on Condition and the potential covariates. We hypothesize stores in Minneapolis will show no baseline differences and have significantly larger positive slopes for healthy food availability outcomes over time. We will use growth mixture modeling[34] to examine policy compliance. Growth mixture modeling relaxes the assumption of population homogeneity and tests the presence of heterogeneity in trajectories. These models will identify subgroups of stores that exhibit similar compliance trajectories over time. After determining the optimal number of mixtures (subgroups), we will regress mixture on Condition (Minneapolis vs. St. Paul) and covariates. It is hypothesized that there will be a number of subgroups (e.g., immediate compliers, delayed compliers, non-compliers), Minneapolis stores will be more likely to be in a compliant subgroup (vs. a noncompliant subgroup), and various store and neighborhood characteristics will be associated with subgroup.

We will test Aims 2 (assess changes in nutritional quality of purchases) and 3 (assess changes in home food availability among households that shop at small and non traditional, urban food stores) using similar models. For Aim 2, the data are repeated cross-sections (rather than true panel or longitudinal data) of small store consumers. Although individual change cannot be examined, we will assess aggregate change attributable to the policy change. Each nutritional quality measure (i.e., energy density, calories) will be regressed on Time, Condition, and the Time x Condition interaction, as well as a number of individual-level covariates. We hypothesize that the interaction will be significant, with purchases made in Minneapolis stores showing significantly lower energy density and calories at 4-, 12-, and 24-months post policy. For Aim 3, the data are true longitudinal data of households that frequently shop at small and non-traditional, urban food stores. This uses an identical repeated measures model as Aim 1, now with household as the unit of analysis. We will regress each food availability outcome variable separately on Time, Condition, and the Time x Condition interaction, as well as a number of household-level covariates. We hypothesize that the interaction will be significant, with households in Minneapolis showing significantly higher availability of healthy food and significantly lower availability of unhealthy food at 4-, 12-, and 24-months post policy.

Analyses will be conducted with SAS or MPlus[35, 36] Covariance pattern and growth curve models will be estimated using the SAS v9.3 MIXED procedure, which can estimate a large number of models, including general linear mixed models designed to analyze repeated measures and multilevel change. This procedure has built-in statements for specific planned contrasts. Growth mixture models will be estimated using MPlus v7.[36]

Sample Size Considerations

Because this is a study of a natural experiment, the number of available stores is not controllable. Based on estimates using our inclusion criteria, we expect to have 208 stores at baseline. Using means and variances from a recent study evaluating effects of WIC revisions on HFS scores[37] and setting alpha=0.05 (two-tailed) and power=0.80, we will be able to detect a difference in HFS score of approximately 2.2 points at any one time point. This is approximately 0.4 SD units and is much less than the difference found by Andreyeva and colleagues of approximately 4 points on the HFS score.[37] Even with substantially smaller sample sizes (i.e., <120 stores), we would have sufficient power to detect effect sizes on this order. Factoring in 20% attrition, the detectable effect increases

to approximately 2.4 units. Actual detectable effects will be much smaller given the additional power due to having multiple rounds of data and including covariates. Sample size calculations were also estimated for aims 2 and 3, also setting alpha=0.05 (two-tailed), and power=0.80. For aim 2, using variance estimates from Borradaile et al,[28] 424 intercept surveys at four rounds will allow us to detect a 50-calorie difference (a very small effect size) between conditions over time. For aim 3, 68 households will allow us to detect a 3-point difference (a small effect size) in fruit and vegetable availability and a 4-point difference in obesogenic home food score (also a small effect; variance estimates from Fulkerson et al[38], factoring in 20% attrition.

Quality Control

The first level of control involves monitoring adherence to data collection protocols. The Project Coordinator and Evaluation Coordinator are responsible for training and monitoring staff. All data collectors will receive standardized training, including both office training and subsequent in-field supervised training. For the first two weeks of all measurements, 2 data collectors will complete each set of measures; these will be checked for accuracy and inter-rater reliability. Re-training will be conducted for any problematic items. Frequent communication with data collectors will be used to address issues that arise in the field, to develop a standard procedure or decision rule for those issues, and to maintain consistency in handling those issues. Inter-rater reliability testing will be repeated annually to avoid observer drift. The second level includes monitoring completeness of the data. Once data have been recorded and returned to our research offices, staff will review records to identify empty fields; if incomplete forms are identified, the team will attempt to collect missing data. Next, we will build quality control into data file editing. Out-of-range or questionable values will be identified and corrections will be made using standard protocols. Only approved study team members will have access to files, which will be password-protected and secularly stored. We have very experienced team members who have been responsible for quality control for many large studies.

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