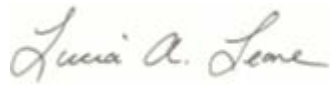# Statistical Analysis Plan (SAP)

Effectiveness and Implementation of a Research Tested Mobile Produce Market Designed to Improve Diet in Underserved Communities

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ABBREVIATIONS

BMI   Body Mass Index

F&V   Fruits and Vegetables

MM   Mobile Market

RFP   Request for Partners

SAP   Statistical Analysis Plan

SNAP   Supplemental Nutrition Assistance Program

TANF   Temporary Assistance for Needy Families

VV   Veggie Van

WIC   Special Supplemental Nutrition Program for Women, Infants, and Children

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1. Introduction

The goal of the Veggie Van (VV) study is to evaluate the effectiveness of mobile produce markets using the VV mobile market (MM) model through a 12-month cluster-randomized controlled trial in 33 communities.

This statistical analysis plan (SAP) will describe the endpoints of the study and the analyses to evaluate our main outcomes.

2. Study design

We utilized a request-for-partners (RFP) process to recruit organizations as study partners; nine organizations were selected as partners and asked to implement the Veggie Van model at new mobile market sites and facilitate recruitment of mobile market customers for the study and data collection activities. Each study partner organization was asked to partner with four community sites that serve as potential locations for the mobile market program, known as community sites.

Partner organizations will choose two sites they would start working with first based on timeline and readiness. These two sites will be paired for the purposes of randomization; one will be randomized to the mobile market site (intervention) and the other to the planning site (control). The same process will be used for the remaining pairs of sites as applicable. Partner organizations will run a mobile market following the Veggie Van model for at least one year at community sites randomized to the mobile market intervention. Planning sites partake in a year-long food access planning process to help determine if the surrounding community would benefit from a mobile market at that location. After one year, the partner and the planning site can decide to implement a mobile market, or another food access program based on community feedback gathered through the planning activities. Two months prior to the launch date of both the mobile market site and the planning site activities, partner organizations work jointly with community sites to engage the community to raise awareness of the mobile market and to recruit potential customers to participate in the Veggie Van Study.

Partner organizations will identify individuals who are interested in learning more about a mobile market in their community. To facilitate recruitment to the Veggie Van study, the partner and community site will utilize interest forms or sign-up sheets to collect community member contact information. If community members indicate interest in participating in the Veggie Van Study, the research team will contact them to screen, provide consent, and enroll into the study. The goal is to recruit at least 30 participants at each of 32 proposed mobile market sites (960 total). Eligible individuals include those at least 18 years old, ability to speak English and/or Spanish, are the primary grocery shopper for their household, and live near or otherwise regularly frequent the community site. A threshold was established to ensure that market sites will be serving a predominantly lower-income community and that the study team is sampling from the appropriate target population. At least 60% of eligible sign-up forms are required to be from individuals that self-identity as receiving government assistance such as: the Supplemental Nutrition Assistance Program (SNAP), the Special Supplemental Nutrition Program for Women,

Infants, and Children (WIC), Temporary Assistance for Needy Families (TANF), Medicaid, Work First, and/or housing assistance.

The intervention is an evidence-based model intended for mobile markets, the Veggie Van model. Informed by the social cognitive theory, the Veggie Van model was designed to address the multiple dimensions of access to fresh produce for lower-income and underserved communities: acceptability, availability, affordability, accessibility, and accommodation. The VV program also includes a cooking and nutrition education component to improve self-efficacy for finding, purchasing, and preparing fruits and vegetables (F&V). Lastly, acceptance of SNAP and participation in local incentive programs further increase affordability.

Data collection will take place at baseline (prior to market launch and planning activities) and approximately 12-month follow-up while the market is still in operation and the planning site has not yet started a market. Data will be collected from market and planning site participants through surveys, 24hr-dietary recalls, and an in-person data collection event (where available). Baseline and 12-month follow-up surveys will include dietary-related psychosocial measures. These surveys will be administered over the phone. The main individual-level outcome, change in F&V intake at 12 months, will be measured through four 24-hour recalls (2 at baseline and 2 at 12 months), which will be administered over the phone by trained interviewers. One recall at each time point will be from a weekday and the other from a weekend day. Recalls will be collected using the Nutrition Data Systems for Research (NDSR) computer-based software application. A participant will receive The Food Amounts Booklet via mail after the baseline survey to have as a visual reference for the 24-hour recalls. In addition to survey data, body mass index (BMI) and dermal carotenoids will be measured at in-person data collection events at baseline and 12 months. Figure 1 illustrates a flowchart of the sequence of study events including partner selection, site randomization, and participant study activities.

Figure 1: Study sequence and data collection events
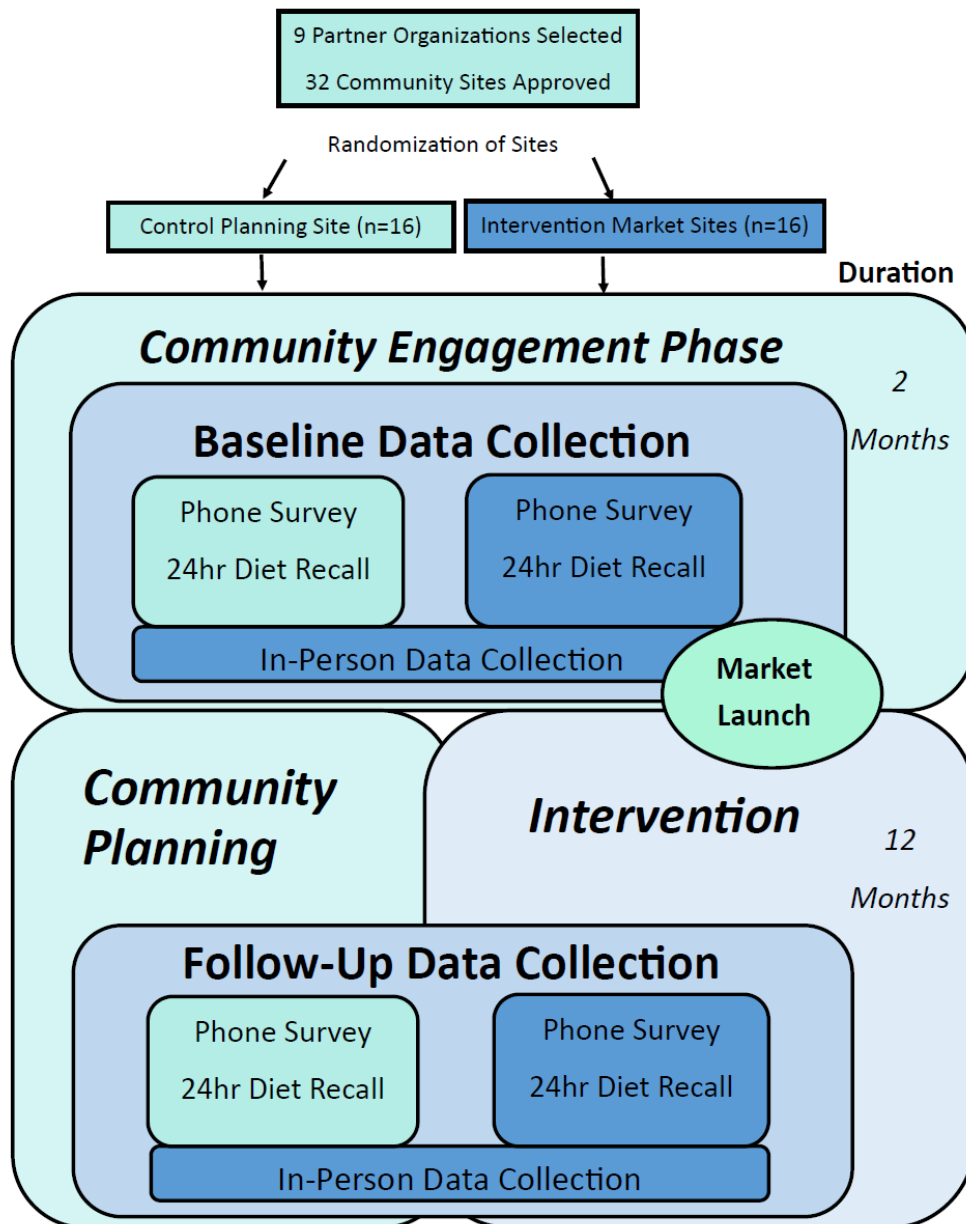
2.1 Sample size calculation

Our primary outcome is change in F&V intake (cups/day) at 12 months using the 24-hour recall, thus, we will compare the difference in mean changes in F&V between intervention and comparison group participants. In the sample size and power analyses, we considered similarity in changes in F&V among participants within a site (intra-class correlation, ICC), and the fact that the intervention is at the site level (54, 55). Based on a previous cluster RCT, we estimated the ICC for change in F&V intake to be 0.08 (SD 2.7); We expect the MM program to increase the F&V intake by at least 1 cup/day (effect size of approximately 0.4). Using one-sided tests of

significance at p=0.05, an ICC = 0.08, and cluster size = 21 participants per site, 12 sites per group will provide at least 80% power to detect the anticipated change in F&V consumption. To account for possible attrition or extended delays on the part of the organization, we will over-recruit (i.e., select more organizations than needed as part of the RFP process). While we need 6 organizations (24 MM sites) to achieve the desired power (Table 4), we will recruit 8 organizations (32 sites). We expect participant attrition to be no more than 30% based on previous work, so we will plan to recruit about 30 participants per site.

Table 1: Power Calculation

Actual Power (1-β)	Difference in Mean Change in F&V	No. of Sites Per Study Group	No. of Participants per Site	Sample Size Per Study Group	Sample Size Per Group with 30%
0.80	1.0	12	21	252	328
0.81	1.0	16	11	176	229
0.80	1.0	20	8	160	200
0.80	.75	20	45	900	1285

3. Aims and objectives

To measure MM effectiveness at sites randomized to implement a MM for 1 year versus a planning (control) condition. Measure MM effectiveness at improving the following outcomes between baseline and 1-year follow-up: 1.) self-reported diet measured via two 24-hour dietary recalls, 2.) BMI based on in-person height and weight measurements; 3.) an objective indicator of F&V consumption (dermal carotenoids measured via finger scan) and 4.) Social Cognitive Theory diet-related constructs including self-efficacy and food environment.

4. Outcomes

This section will present outcomes investigated in the RCT to answer the above study aims and objectives.

4.1 Primary Outcome

Consumption of fruits and vegetables (F&V) will be measured at baseline and 12 months. Change in F&V intake (cups/day) at 12 months will be calculated from four 24-hour recalls (2 at baseline and 2 at 12-months) which will be administered over the phone by trained interviewers (in English or Spanish). One recall at each time point will be from a weekday and the other from a weekend day. The 24-hour dietary recalls will be collected using the Nutrition Data Systems for Research (NDSR) computer-based software application developed at the University of Minnesota Nutrition Coordinating Center (NCC); NDSR uses a five pass interview approach with interview prompts in English and Spanish (49). The NCC Food and Nutrient Database serves as the source of food composition information in NDSR (50). When a participant completes their in-person data collection, participants will receive The Food Amounts Booklet to have as a visual reference during the 24-hour recall. This booklet is compatible with the NDSR program.

4.2 Secondary Outcomes

Body Mass Index (BMI)

BMI will be calculated at baseline and 12 months from weight measured using a Seca 876 digital scale (maximum capacity of 250 kg) and height measured to the nearest 1/8 inch using a Seca stadiometer. Weight and height will be combined to report BMI in kg/m^2.

Dermal Carotenoids

Dermal Carotenoids will be measured at baseline and 12 months using a finger scan technology called the "Veggie Meter" which relies on pressure mediated Raman Spectroscopy (RS) and is thought to be a valid indicator of changes in skin carotenoids in response to dietary carotenoid consumption.

4.3 Other Outcomes

Psychosocial measures – Self-efficacy

Self-efficacy to purchase, prepare and eat fresh F&V and will be measured with a 10-point Likert scale using a selection of items adapted from a study of shoppers where self-efficacy was shown to be correlated with nutrition behaviors and will serve as a comprehensive assessment of the effect of the educational intervention.

Psychosocial measures - Benefits (expectations)

Benefits (expectations) and barriers to eating F&V will be measured using a 4-point Likert scale (strongly agree, agree, disagree, strongly disagree) previously tested in lower-income adults which reflects common benefits/barriers found in the literature.

Psychosocial measures will be measured at baseline and 12 months.

5. Population to be Analyzed

To be eligible for the study, individuals had to be at least 18 years old, able to speak English and/or Spanish, be the primary grocery shopper for their household, and live near or otherwise regularly frequent the site. Individuals were ineligible if they were planning to leave the area or stop frequenting the site within the next year. To ensure that sites were predominantly serving lower-income community members and that the study team was sampling from the appropriate target population, a goal was set that at least 60% of eligible sign-ups are from individuals who self-report utilizing assistance programs (e.g., SNAP, WIC, TANF, Medicaid, Work First, and/or housing assistance).

6. Analyses

In order to test the impact of the VV intervention on change in F&V intake, we used generalized linear mixed model (GLMM) with random intercept to control for clustering within sites. In order to further explore the intervention effect, we fit GLMMs that adjust for (1) baseline dietary intake and (2) race and baseline income due to significant differences between groups at baseline

(race p=.01; income: p=0.02). Including the baseline values as a covariate in an analysis of covariance (ANCOVA) is known to be a more powerful test than a group comparison of baseline to post-intervention change (42, 43). ANCOVA is not distorted by regression towards the mean bias, whereas a change analysis is subject to that bias (42, 43). We also conducted a sensitivity analysis excluding extreme F&V reporters, defined as participants who had a change (increase or decrease) greater than 10 servings of F&V per day based on generating histograms and identifying outliers in the data distribution. We conducted additional analyses comparing change in F&V intake for those who reported ever purchasing from VV (VV users) to those who did not report shopping at VV (VV non-users), including delayed-intervention control participants. Due to major disruptions to VV operations in the beginning of the study period (2020), we also looked for differences among a sub-sample of sites that launched after the peak of COVID-19 related closures defined as launching in 2021 or later (i.e., post-covid sites). All secondary outcome analyses were conducted using GLMMs and controlled for baseline covariates of interest and clustering within sites.

Additional analyses by question set can be found below:

Question Set	Answer options	Variable Creation	Analysis Plan *For all main outcomes we need to control for site and relevant demographic variables*
Demographics (13) *Weight is asked again at follow-up*	various	Will combine categories with small numbers of respondents BMI: created from height and weight	1. Descriptive 2. Will test for differences between Ix and Control groups and include any variables that differ as co-variates in outcome analyses 3. BMI is Aim 1 outcome- compare intervention and control at 6 and 12 months. We expect BMI to stay the same for intervention at 6 months and decrease at 12 months whereas control will increase over time.

NCI F&V Screener (11)*	Frequency (per day, week or month) plus Portion Size	See below for scoring	Aim 1 Outcome. We hypothesize an increase in F&V consumption for intervention compared to control at 6 months.
F&V 2-question*	Servings per day	Continuous	Aim 1 Outcome. We hypothesize an increase in F&V consumption for intervention compared to control at 6 months and that differences will be maintained at 12 months. We want to compare the 2 F&V measures and possibly combine them as was done in NC Strides and other projects
NHANES FFQ-Sweets (7)*	Frequency (per day, week or month)	1. Convert all answers to per day or per week depending on which seems more reasonable. 1 month=4.348 weeks 1 week=7 days 2. Sum all 7 questions to get a combine servings per (week or day) score	Aim 1 Outcome. We hypothesize a decrease in sweet consumption for intervention compared to control at 6 months.
Barriers to F&V (12)*	Strongly agree (1) Agree (2) Disagree (3) Strongly disagree (4) Don't know (5)	Answers 5, 6 and 7 will be treated as missing If answers are normally distributed, we will combine 1&2 and 3&4 and create a dichotomous variable. If answers are weight to one end or the other,	Descriptive Correlate with F&V consumption at each timepoint Mediator of F&V consumption

	Skip refuse (6) N/A (7)	we will look at them as 4-category variables or combine categories as is appropriate	
Shopping Behavior (10)* *2 questions repeated at follow-up*	Various	Will combine categories with small numbers of respondents (q65) - mark 6 and 7- skip/refuse as missing for baseline and follow-up - for everyone else, subtract follow-up from baseline - If number is positive then re-categorize as 1= shopping more often - If number is negative then re-categorize as 2= shopping less often - if number is 0, re-categorize as 3= shopping the same frequency	Descriptive at baseline For questions available at follow-up: (q65) Percent of people who shop more often, less often or the same at each type of store - Compare intervention vs. control percentages (q66 follow-up) calculate percent of people who answer "Veggie Van" as one of the stores they most shop at- compare intervention vs. control percentages
Importance to buy/make/eat F&V (1)*	5- point likert scale	If answer= 6 (don't know) or 7 (skip/ refuse), categorize as missing and treat remaining as continuous variable	Descriptive Correlate with F&V consumption at each timepoint Mediator of F&V consumption
Cooking at home (1)*	Days per week	Create a continuous variable If they choose 1 then the number they enter is the days per week	For baseline, we will just look at descriptive – i.e. days per week cooking at home For follow-up we will look at the percent of people who

		If they chose 2 (never) then enter as 0 days per week If they choose 3 or 4 (don't know or skip/refuse) then treat as missing - for everyone else, subtract baseline from follow-up - If number is positive then re-categorize as 1= cooking more often - If number is negative then re-categorize as 2= cooking less often - if number is 0, re-categorize as 3= cooking the same frequency	cook more often, less often or the same at each type of store at follow-up - Compare intervention vs. control percentages (chi-sq??)
Self- Efficacy Cooking F&V (7)*	5- point likert scale	If answer= 6 (don't know) or 7 (skip/ refuse), categorize as missing and treat remaining as continuous variable Need to complete factor analysis with pilot data to see if questions should be used as a scale or individual	Aim 1 Outcome. We hypothesize an increase in self-efficacy for intervention compared to control at 6 months Additional analyses: - Correlation between F&V consumption and self-efficacy at baseline - Correlation between changes in F&V consumption and changes in self-efficacy at follow-up

			- If correlated at follow-up we will complete mediation analysis.
Self- efficacy Eating Veg (9)*	5- point likert scale	If answer= 6 (don't know) or 7 (skip/ refuse), categorize as missing and treat remaining as continuous variable Need to complete factor analysis with pilot data to see if questions should be used as a scale or individual	Aim 1 Outcome. We hypothesize an increase in self-efficacy for intervention compared to control at 6 months Additional analyses: - Correlation between F&V consumption and self-efficacy at baseline - Correlation between changes in F&V consumption and changes in self-efficacy at follow-up - If correlated at follow-up we will complete mediation analysis.