STATISTICAL ANALYSIS PLAN

The COVID-19 Vaccine Acceptance Study (CoVAcS)

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The Statistical Analysis Plan (SAP) is a living document and will be modified as necessary up to final data lock and before study unblinding. Only the blinded statistician will modify the SAP. This plan focuses only on the quantitative aspects of this trial.

ClinicalTrials.gov Identifier: NCT05027464

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1. STUDY SYNOPSIS

Title	The COVID-19 Vaccine Acceptance Study (CoVAcS)
Study Design	The design is a hybrid type 2 (implementation-effectiveness) study. It consists of a pragmatic cluster randomized controlled 2-arm superiority trial with unit of randomization Veteran Healthcare System (VAHCS) (Aim 1); a survey (Aim 2) and qualitative interviews using purposive sampling (Aim 3).
Study Duration	3 years
Trial Sites	VISN 21 and VISN 16 VA facilities
Objectives	Conduct a one-year pragmatic cluster randomized trial to determine the effectiveness of a vaccine acceptance intervention (VAI) training for healthcare providers and staff in increasing the uptake of any COVID-19 vaccination dose in Veterans; conduct a survey to identify predictors of vaccine acceptance/hesitation.
Number of Participants	10 trial sites in VISNs 16 and 21 (including approximately 90,000 -100,000 (Expected); 338,000 (Actual) Veterans Survey completed: 450 (Expected) Veterans; 224 (Actual) Veterans.
Main Inclusion Criteria	Belonging to either VISNs 16 or 21: Aim 1 Trial: Veterans included in the analysis have had one or more primary care visit(s) at a participating VA facility within the past year at the start of site-level randomization. Aim 2 Survey: Veterans eligible for the trial and who (1) had not started the COVID-19 vaccination and (2) received their most current dose of the primary COVID-19 series in the prior 150 days from when they were contacted and without ICD-10 diagnostic codes indicating dementia and have received primary care at their study site since the study start date at their site.
Intervention	VAI training for health care providers and staff, which includes the use of Motivational Interviewing to promote vaccine acceptance.
Duration of Intervention and Follow-up	Intervention (Provider VAI training): 12 months; Follow-up 12-months.
Blinding	Study statistician, study evaluators, and Veterans will be blinded to study arm.
Primary Outcome	Aim 1: Receipt of at least one dose of the COVID-19 vaccine.
Primary Analysis	All analyses will be according to intent to treat. The difference in proportion of Veterans receiving any dose at 12 months will be compared between treatment groups using a multi-level model that accounts for the hierarchical clustering and adjusts for baseline vaccination rate at the VAHCS facility, region (VISN), age, race/ethnicity, gender, and health care utilization one year prior to the start of the trial. The difference will be tested at the 0.05 level of significance (two-sided).
Heterogeneity of Treatment Effect (HTE) Analyses	We will describe the variation in treatment response on the primary outcome by the following variables: seasonality, sex, rural vs. urban, and age groups.

Secondary Outcomes	Aim 1: Completion of the COVID-19 primary vaccine series.
Exploratory Outcomes	Aim 1: Receipt of COVID-19 booster; receipt of seasonal flu vaccination.
Interim Analysis	No interim analyses were proposed.

2. BACKGROUND, STUDY OBJECTIVES AND SPECIFIC AIMS

2.1 Background

The COVID-19 pandemic has resulted in significant loss of life with total case and death counts increasing daily. COVID-19 vaccines are effective in preventing symptomatic disease, severe disease, disease transmission, and death. Despite the efficacy and safety of COVID-19 vaccines, many people remain hesitant about vaccination with increased hesitancy among younger individuals (less than 50 years old), Black and Hispanic adults, and those living in rural areas. Recent surveys of Veterans indicate that approximately 35% are unsure whether they will receive a vaccine, highlighting the critical need for evidence-based motivational interventions to increase COVID-19 vaccine acceptance in this population who, without vaccination, remain at risk of severe adverse outcomes and death. The overall objective of this study is to implement and test a COVID-19 vaccine acceptance intervention that is responsive to the needs of Veterans and VA healthcare providers and staff. VA healthcare providers and staff are consistently identified by patients as trusted sources of vaccine information, thereby best suited to initiate vaccine acceptance discussions with patients.

2.2 Study Objectives

The COVID-19 Vaccine Acceptance Study (CoVAcS) is a hybrid type II effectiveness-implementation study with a cluster randomized clinical trial (CRCT) of 10 Veteran Healthcare Systems (VAHCS) within 2 Veteran Health Administration (VHA) regions (VISNs) aimed at improving COVID-19 vaccine uptake through use of a vaccine acceptance intervention (VAI). The objectives of this study are:

1) Conduct a one-year pragmatic CRCT of the COVID-19 VAI to increase uptake of any COVID-19 vaccine (primary outcome) and secondarily, to increase completion of the primary COVID-19 vaccine series in 10 VAHCS compared to usual care. As an exploratory outcome, we will compare rates of the seasonal flu and COVID-19 boosters between intervention and control sites.
2) Survey Veterans with recent primary care visits from intervention and usual care VAHCS who did and did not receive COVID-19 primary vaccination to identify correlates of COVID-19 vaccine acceptance/hesitation.

2.3 Specific Aims

The specific aims are as follows:

Aim 1: Examine the effectiveness of a Vaccine Acceptance Intervention (VAI) versus usual care on Veterans' vaccination rates in a one-year cluster randomized control trial.

Aim 2: Survey Veterans to understand what factors are associated with the decision to accept or not accept COVID-19 vaccination.

3. RANDOMIZATION

Aim 1 randomization was stratified by VHA region and covariate constrained by baseline vaccination rate [Greene EJ. (2017); Moulton LH. (2004)].

4. BLINDING

All decisions about changes to the Statistical Analysis Plan will be made by a blinded statistician who will communicate with study leadership. Study evaluators and Veterans will be blinded to study arm. No other blinding was possible in this study.

5. OUTCOMES

5.1 Aim 1

5.1.1. Primary Outcome

The primary outcome is receipt of at least one dose (one of primary series or booster) of COVID-19 vaccination in Veterans who had one or more primary care visit(s) at a VA facility participating in the trial within the past year.

5.1.2 Secondary Outcome

The secondary outcome is completion of COVID-19 primary vaccination series by a previously unvaccinated Veteran with one or more primary care visit(s) at a participating VA facility within the past year.

5.1.3 Exploratory Outcomes

Flu vaccination: Receipt of seasonal flu vaccination in all Veterans with one or more primary care visit(s) at a participating VA facility within the past year.

COVID-19 First Booster: Receipt of first COVID-19 booster by those eligible for the booster within 3 months prior to the end of the study period. This includes Veterans who were eligible and had one or more primary care visit(s) at a participating VA facility within the year prior to study period, but unboosted at the start of the trial, as well as those who completed their primary series during the trial and became eligible for the booster.

5.2 Aim 2

5.2.1 Survey

Our survey contained items from the World Health Organization (WHO) Behavioral and Social Drivers Vaccination (BeSD) Model [Brewer et al., 2017]. The BeSD model included four domains: What People Think and Feel, Social Processes, Motivation, and Practical Issues.

Other survey item domains are seasonal flu vaccine acceptance, VA primary care experience, health status, and socio-demographics.

6. SAMPLE SIZE

6.1 Aim 1

6.1.1 Primary Outcome

6.1.1.1. Original Design Assumptions

Of the 16 VAHCS in VHA region 16 and 21, 10 VAHCS agreed to participate in the study, with an average of 9 to 10 clinics per VAHCS, and an average of at least 1,000 Veterans per clinic. These numbers were based on conservative projections of the number of Veterans at the time of randomization and account for missing vaccination (i.e., misclassification) status for Veterans who may have been vaccinated outside of the VA. We hypothesize that the larger proportion of Veterans will get vaccinated (both first and fully) within 12 months in the VAI arm compared to usual care. Calculations were conducted with PASS 19 (Kaysville, Utah) using sample size for mixed models for two sample proportions with a 3-level hierarchical design assuming an intra-cluster correlation (ICC) of 0.07 for individuals within a clinic and an ICC of 0.02 for clinics within a VAHCS [Elley CR, et al. (2005)]. With a type I error rate of 0.05 (two-sided) we will have at least 90% power to detect between a 9.6% and 14.6% difference in vaccination rates assuming a rate in the usual care group ranging from 5% to 20% and a total sample size of 90,000 to 100,000. **Table 1** shows details of different scenarios.

Table 1: Detectable difference for comparing 2 proportions in a hierarchical model assuming 5 VAHCS per arm with on average 9-10 clinics per VAHCS and on average 1000 individuals per clinic, 90% power, type I error of 5% (two-sided) and level 1 ICC of 0.07 and level 2 ICC of 0.02

Total Sample Size	Clinics VAMC*	Rate in Usual Care	Detectable difference
90,000	9	5%	9.7%
100,000	10	5%	9.6%
90,000	9	10%	12.0%
100,000	10	10%	11.8%
90,000	9	15%	13.5%
100,000	10	15%	13.3%
90,000	9	20%	14.6%
100,000	10	20%	14.4%

6.1.1.2 Actual Design Parameters

Of the 16 VAHCS in VHA region 16 and 21, 10 VAHCS agreed to participate in the study (5 per arm), with median number of 9 clinics per VAHCS (range: 4 to 12) with total sample size of 338,718 (Usual Care: 190,427; Intervention: 148,291) eligible Veterans at the start of the study at each VAHCS.

6.1.2 Secondary Outcome

Power calculations for the primary outcome (any dose) apply to the secondary outcome (completion of primary series). Since there is only one secondary outcome, no multiple testing procedures will be applied, and a type I error rate of 5% (two-sided) will also be used for the secondary outcome.

6.2 Aim 2

6.2.1 Survey

6.2.1.1. Original Design Assumptions

Each month we will enroll 25 Veterans; roughly 20 of whom are vaccinated and 5 of whom are unvaccinated (total: 360 receiving vaccine; 90 not receiving vaccine). We will oversample recently vaccinated Veterans to ensure an adequate sample size to attempt to describe the impact of the VAI on COVID-19 vaccine acceptance after considering other factors using purposive sampling. This is primarily a descriptive aim as there is no *a priori* data to guide sample size/power calculations.

6.2.1.2 Actual Design Assumptions

We were unable to reach the target sample size of 450 and were only able to enroll 228 individuals with 224 eligible surveys: 139 (62.1%) vaccinated and 85 (38.9%) unvaccinated individuals.

7. INTERIM MONITORING

There is no planned interim monitoring for this study.

8. DATA COLLECTION AND DATA FREEZE

8.1 Aim 1

Data from Aim 1 will be obtained from the VA Corporate Data Warehouse (CDW) and supplemented with data from other VA administrative data (e.g., VA COVID-19 Shared Data Resource, Medicare data). Table 2 provides the study initiation for each site and the last day of 12-month follow-up for eligible participants. In the subsequent Project Modification, we added two additional follow-up timepoints of 15 and 18 months after study site initiation. The last follow-up for any participant will be 10/19/2023 – at which point the trial database will be closed/frozen and be considered ready for final analysis.

Table 2: Study initiation and follow-up completion by study site

Study Site	Initiation Date	Follow-up Completion Date
Little Rock, AR	02/14/2022	02/13/2023
Fayetteville, AR	02/14/2022	02/13/2023
Las Vegas, NV	03/08/2022	03/07/2023
Reno, NV	03/08/2022	03/07/2023
Palo Alto, CA	03/21/2022	03/20/2023
Northern CA, CA	03/21/2022	03/20/2023
Honolulu, HI	03/23/2022	03/22/2023
Fresno, CA	03/23/2022	03/22/2023
New Orleans, LA	04/20/2022	04/19/2023
Houston, TX	04/20/2022	04/19/2023

8.2 Aim 2

8.2.1. Survey Data

Aim 2 survey data were collected from 5/25/2022 to 8/7/2023.

9. ANALYSIS PLAN

This section describes the analysis of the primary, secondary, and exploratory outcomes for Aims 1 and 2. The analytic plan will be modified as necessary up to final data lock and before study unblinding. Results will be reported to clinicaltrials.gov within one year of obtaining all data necessary to analyze the primary outcome on the last patient. The trial has been registered on clinicaltrials.gov: NCT05027464. Data analysis will be performed by the unblinded statisticians. Current versions of SAS and R will be used for all analyses.

9.1 Aim 1

9.1.1 General Approach

Analyses will be based on the intent to treat principle, that is any Veteran at the start of the trial who receives VHA primary care services at a participating site within one year of the study start date (Aim 1) will be considered in the denominator of the vaccination rate regardless of whether they received the intervention. Randomization was stratified by VISN and constrained based on baseline vaccination rate; therefore, all analyses will adjust for VISN and baseline vaccination rate. Since randomization was conducted at the site level, but analyses will include individual level data, we will assess the adequacy of the randomization by comparing baseline characteristics of participants between the two groups. No statistical tests will be used to assess these comparisons. Variables will be summarized using descriptive statistics. Nominal and ordinal categorical variables will be summarized using frequencies and percentages. Continuous variables will be summarized with the following descriptive statistics: N, mean, standard deviation, median, minimum, maximum, interquartile range, and range. We will also use plots (e.g., box and whisker) to explore the distribution of the data. Both the primary and secondary outcome will be tested with an alpha of 0.05 (two-sided). All other outcomes will be considered exploratory and will not be subject to corrections for multiple testing.

9.1.2 Comparability of Baseline Characteristics

We will present baseline site and participant characteristics (mean, standard deviations, medians, and quartiles for continuous variables; frequency and percentages for categorical variables) by treatment group and use the summary statistics to assess for adequate balance of relevant confounders; no inferential statistics will be used. Given that the randomization was conducted at the site level and analyses will be conducted at the individual level, variables that appear to be different between the VAI and usual care arms will be adjusted for in sensitivity analyses. Study results will be reported according to the Consolidated Standards of Reporting Trials (CONSORT).

9.1.3 Background of Vaccination Records Ascertainment

The uncertainty in vaccine records ascertainment is pertinent to discuss prior to describing how we will analyze the primary, secondary, and exploratory outcomes with standard and sensitivity analyses. There will be Veterans who receive their COVID-19 vaccinations outside of the VA system or from venues not currently captured in VA databases (i.e., State fairs, shopping malls etc.). This could inflate our denominator of unvaccinated Veterans at the start of the trial (i.e., false negatives – Veterans are actually vaccinated). It could also decrease our numerator during the trial because we could miss Veterans who received COVID-19 vaccines during the study follow-up period at non-VA sites not captured in VA data. There are two main avenues to supplement missing vaccine information in VA records; however, both have important limitations.

First, we will supplement VA vaccination records with Medicare claims data. While the federal government paid for the vaccine product, providers were permitted to bill for the cost of administering the vaccines. Based on analyses from the VA Information Resource Center (VIReC) in 2021, linking Medicare data substantially improved ascertainment. There are a few limitations. First, due to a lag, claims data will not be available for the complete study period. For Veterans enrolled in traditional Medicare fee-for-service, which account for approximately 70% of Medicare-enrolled Veterans, we anticipate data being available through 2022 [Centers for Medicare and Medicaid Services (2021)]. For Veterans enrolled in Medicare Advantage (i.e., managed care programs), data will only be available through 2021. Second, during the early phases of vaccine rollout in 2021 when mass vaccination clinics had been common, Centers for Medicare and Medicaid Services estimated that claims were never submitted for as many as half of Medicare-age people.

Second, VHA has been developing a health information exchange with state Immunization Information Systems (IIS) in partnership with CDC to query and report Veteran immunization records. This exchange, known as the IZ Gateway, began querying state registries for 9 of the 10 study sites during July and August of 2023. Unfortunately, VHA does not plan to query state registries retrospectively for all Veterans. Instead, VHA will query individual Veterans' records when they receive VA health services. Accordingly, we anticipate differential vaccine ascertainment in which Veterans who receive care from the time the Gateway was activated in their home state until the final data lock for this study will have near-complete vaccine ascertainment; in contrast, Veterans who do not receive care during this period will have less-complete ascertainment. Vaccine records populated through the Gateway can be identified which will help us to evaluate potential biases resulting from the timing of the Gateway rollout. For the main analyses, records populated through the IZ Gateway are being removed from the analytic dataset to avoid differential bias.

Due to limitations of the IZ Gateway and Medicare data, we will utilize one or more of several methods to ascertain the missing vaccination records and its impact on our estimates. These include comparison of our rates to those published by state and federal authorities for our VISNs or comparison of our rates to those reported by national and local VA dashboards. Alternatively, to estimate population levels of underreporting, we may need to utilize survey sampling methodology and probability weighting to randomly survey Veterans with no documentation of COVID vaccination. In sum, primary analyses for Aim 1 will utilize only VA electronic health data to ascertain Veterans' vaccination status. We will also conduct sensitivity analyses that incorporate all available data sources (e.g., electronic health records; Medicare; state-level records; IZ Gateway).

9.1.4 Analysis of the Primary Outcome

To analyze the primary outcome (receipt of any COVID vaccination), we will use a multi-level model that considers the hierarchical clustering [Guo et al. (2000)] for a binary outcome and adjusts for region (VISN) and baseline vaccination rate to estimate the difference in proportion of vaccinated Veterans at 12-months between VAI and usual care. The model will also be *a priori* adjusted for the following participant level covariates: age, race/ethnicity, gender, health care utilization one year prior to the start of the trial. We will report the difference in rates between the VAI and usual care arms and 95% confidence interval.

Sensitivity Analyses

9.1.4.1 Expanding Analyses to Include Vaccination Records from Medicare/Medicaid and IZ Gateway

We plan to incorporate the vaccination records from Medicare/Medicaid and the IZ gateway and run sensitivity analyses for the primary outcome. These supportive analyses will provide variation in the estimated intervention effect related to incorporating external sources of vaccination records. On account of the IZ Gateway querying state IIS records on a prospective basis, these sensitivity analyses will focus on Veterans who have received care since the IZ Gateway was activated in their home states, which for the study sites happened during July or August of 2023. The specified statistical model is identical to that laid out in Section 9.1.4.

9.1.4.2 Missing Outcomes/Misclassification of Vaccination Status

We will conduct sensitivity analyses with a Bayesian form of multi-level logistic regression that uses the same core hierarchical model in Section 9.1.4 [Polson et al. (2013)]. Bayesian methods estimate parameter values (e.g., odds ratio of vaccine uptake between intervention arms) by summarizing sequentially drawn values from probability distributions with parameters updated jointly by the observed data (vaccination counts, clinic, and VAMC characteristics, etc.) and updated values of other model parameters. For our needs, the Bayesian logistic regression will incorporate a *multiple imputation* step that corrects the observed vaccination rates in two different ways. We can correct the total number of eligible Veterans, i.e., the denominator at each facility due to misclassifying them as unvaccinated prior to study start. Second, we can correct the count of observed vaccinations over the course of the study at each study site, i.e., the numerator, due to imperfect vaccination records ascertainment.

For the primary aim, we assume no uncertainty in Veteran eligibility since we will be using all Veterans with at least one primary care visit. This entails not subtracting a modeled probabilistic number of Veterans from the denominator of the rate of vaccination per facility, whereas the multiple imputation adds a *random quantity* to the count of instances of any vaccine dose (i.e., the numerator) to represent the unknown vaccinations over the course of the study that, if ignored, would be labeled as unvaccinated in the eligible sample.

Each clinic's corrected quantity will be equal to a probabilistically modeled rate of misclassified vaccinations multiplied by the count of those Veterans labeled as unvaccinated according to the available data. The distribution for each timepoint's rate of misclassified vaccinations will be assumed to follow a truncated Beta distribution with a lower bound estimated from available Medicare data from 2021-2022, upper bound, mode (most likely value), lower and upper percentile values determined by investigators. The Bayesian framework then updates the model's parameters with these corrected vaccination counts instead of the observed vaccination counts. We will assess changes in the parameter estimates across a range of assumptions for the two misclassification rates and summarize the results with posterior probabilities of a non-null intervention effect, 95% credible intervals, and posterior means and medians.

9.1.5 Analysis of Secondary Outcome

We will use the same hierarchical, multi-level method for binary outcomes to analyze the secondary outcome of primary series completion in Veterans reported to not have initiated or completed the COVID-19 primary series at randomization. The model structure and adjustments are identical to that

for the primary outcome in Section 9.1.4. No multiple testing will be considered since there is only one secondary outcome. We will report the difference in rates between the VAI and usual care arms and the 95% confidence interval.

Sensitivity Analyses

9.1.5.1 Expanding Analyses to Vaccination Records from Medicare/Medicaid and IZ Gateway

We plan to incorporate the vaccination records from Medicare/Medicaid and the IZ gateway and run sensitivity analyses for the secondary outcome. The motivation and analysis model are identical to that laid out in Section 9.1.4.1. We will include Veteran records provided by these additional data sources who were not reported to have completed or initiated the primary series at randomization.

9.1.5.2 Missing Outcomes/Misclassification of Vaccination Status

We will use the Bayesian multiple imputation model described in Section 9.1.4.3 for the secondary outcome for the same motivations described therein. Due to the uncertainty in the definition of the eligibility, that is, knowing with 100% certainty that a Veteran did not complete the vaccine primary series prior to study start, the total count of eligible Veterans at each clinic (i.e., the denominator) will be reduced by a *random* quantity to represent the count of Veterans who were misclassified as having not completed the primary series at or before baseline. Thereafter, we will correct the count of observed primary series completions by adding a *random* value to represent the unknown primary series completions over the course of the study that, if ignored, would be labeled as incomplete primary series in the eligible sample. Analytical summaries will be identical to those laid out in Section 9.1.4.2.

9.1.6 Analysis of Exploratory Outcomes

No control for multiplicity will be performed for exploratory outcomes. We will use the same methods proposed to analyze the primary and secondary outcomes to analyze receipt of a booster vaccination and flu vaccination. We will adapt methods presented by Sinclair et al. (2012) to estimate the spill-over effect of the intervention by analyzing receipt of seasonal flu vaccination. CDC guidelines on the minimum length of time between COVID-19 primary series completion and booster eligibility decreased during the study period. We will use the most recent guideline in effect during our study period, which was a minimum of 60 days from primary series completion to receipt of the first booster. In instances where a third mRNA vaccine dose was administered prior to 60-days following the second mRNA dose, that is classified as an additional primary series dose per CDC guidelines for Veterans with immunosuppression, and the date of that vaccination is defined as the date of primary series completion. Due to difficulties ascertaining which Veterans have immunosuppression, and the relatively loose guidelines for which conditions qualify, third doses have been defined empirically based on vaccination dates.

Because of evolving guidance on COVID vaccinations (products, dosing, etc.) in the context of fluctuating background COVID-19 prevalence at different VAHCS sites combined with seasonal flu vaccination in the Fall and Winter months, we expect temporal and site trends. Therefore, we plan to conduct the following exploratory analyses: (1) adjust for time-dependent variables; and (2) perform analyses stratified by time period and site.

9.2 Aim 2

9.2.1 General Approach

We will use descriptive statistics--nominal and ordinal categorical variables will be summarized using frequencies and percentages while continuous variables will be summarized with the following descriptive statistics: N, mean, standard deviation, median, minimum, maximum, interquartile range, and range, to describe the populations surveyed.

9.2.1 Survey Data

Aim 2's primary outcome is receipt of vaccination, and we will explore characteristics that may be associated with the decision to receive the vaccine. This case-control design will use generalized linear mixed models that account for clustering by VAHCS to model vaccine receipt and estimate differences between those who were and were not vaccinated. We will present estimates and 95% confidence intervals.

9.2.1.1 *Missing Data*

We will use complete case analysis as we expect the missing data rate to be low. We will describe any differences in participant characteristics between those who do and do not have missing data.

REFERENCES

Brewer NT, Chapman GB, Rothman AJ, Leask J, Kempe A. Increasing Vaccination: Putting Psychological Science Into Action. *Psychological Science in the Public Interest.* 2017;18(3):149-207.

Centers for Medicare and Medicaid Services. *Assessing the Completeness of Medicare Claims Data for Measuring COVID-19 Vaccine Administration*.; 2021. Accessed September 19, 2023

Elley CR, Kerse N, Chondros P, Robinson E. Intraclass correlation coefficients from three cluster randomised controlled trials in primary and residential health care. *Aust N Z J Public Health.* 2005;29(5):461-467.

Greene EJ. A SAS Macro for Covariate-Constrained Randomization of General Cluster- Randomized and Unstratified Designs. *J Stat Softw.* 2017;77(Cs1).

Guo G, Zhao H. Multilevel Modeling for Binary Data. *Annual Review of Sociology.* 2000;26(1):441-462.

Moulton LH. Covariate-based constrained randomization of group-randomized trials. *Clin Trials.* 2004;1(3):297-305.

Polson, N. G., Scott, J. G., & Windle, J. (2013). Bayesian inference for logistic models using Pólya–Gamma latent variables. *Journal of the American statistical Association*, *108*(504), 1339-1349.

Sinclair B, McConnell M, Green DP. Detecting Spillover Effects: Design and Analysis of Multilevel Experiments. *American Journal of Political Science.* 2012;56(4):1055-1069.