Title: Enhancing a Sustainable Pharmacy-based Immunization Program in Two States

NCT number: NCT02615470

Sponsor: Merck & Co.

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Document Date: October 27, 2015

Brief Summary:
The study's aim is to enhance current immunization activities in community pharmacies through targeting the two most commonly available non-seasonal vaccines in community pharmacies, namely pneumococcal and herpes zoster vaccination services. The study will compare the change in the number of pneumococcal and herpes zoster vaccinations administered in pharmacy from the corresponding 6-month period prior to the intervention to the 6-month intervention period between intervention pharmacies and the control pharmacies.

Detailed Description:
Community pharmacies are in a unique position and have potential to help increase immunization rates, especially among those who do not visit their primary care provider regularly. This study seeks to increase the level of pharmacy-based immunization delivery.

The study intervention is designed to increase the current level of pharmacy-based immunization delivery and foster practice change to sustain the intervention effect. Our intervention combines evidence-based strategies for improving immunization coverage and strategies to overcome system barriers to increase sustainability of the intervention over time. The study will focus on pneumococcal and herpes zoster vaccination services.

Specific aims include:

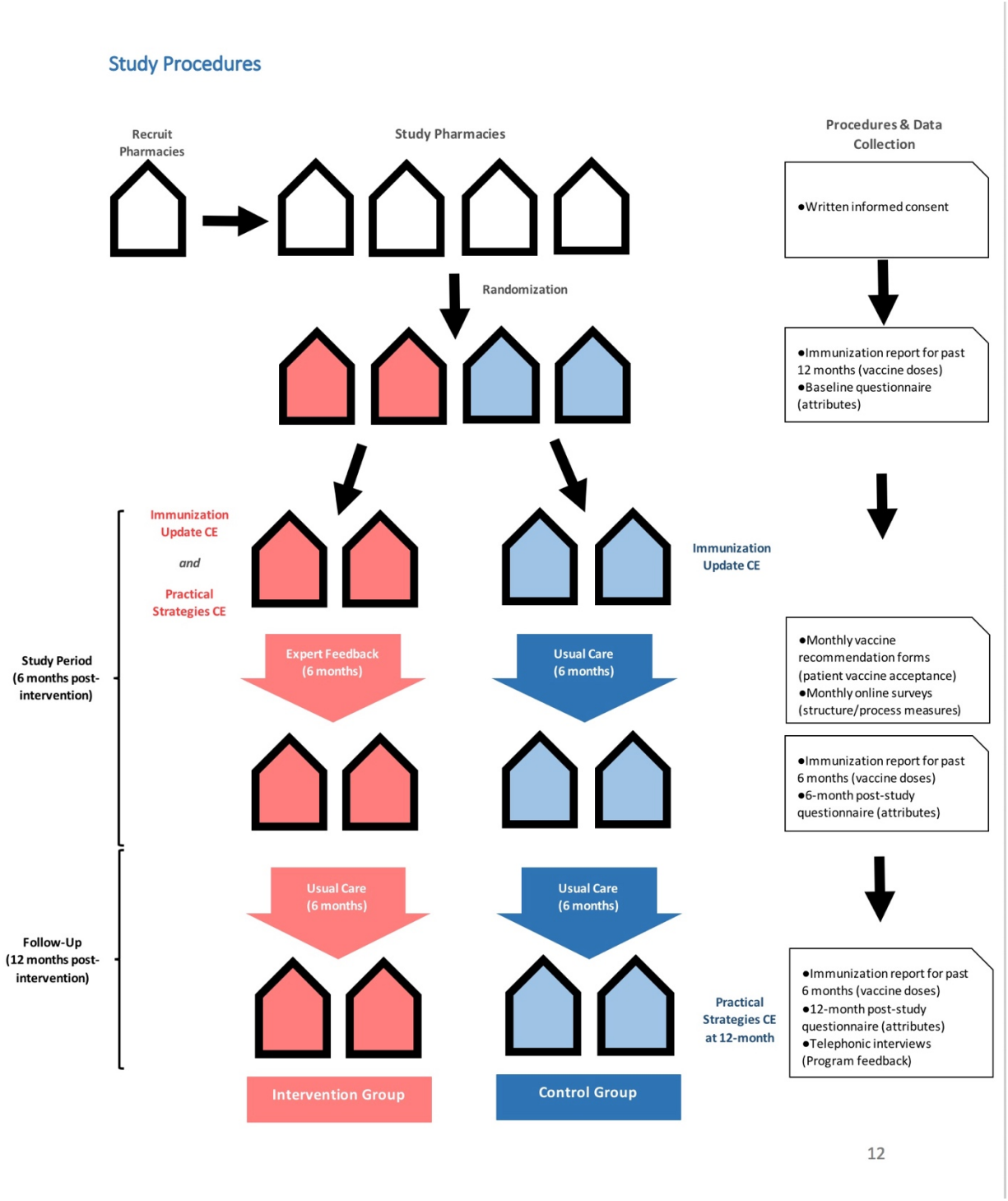
1. To compare the change in the number of pneumococcal and herpes zoster vaccinations administered in pharmacy from the corresponding 6-month period prior to the intervention to the 6-month intervention period between intervention pharmacies and the control pharmacies. The pre-intervention period will correspond to the intervention period.
2. To compare the extent of immunization activity implementation during the intervention period between intervention pharmacies and control pharmacies.
3. To compare the level of sustainability of immunization services over the period of 6 months after the intervention period ends between the intervention group and the control group.
4. To explore facilitators and barriers to implementing immunization services.
5. To explore factors affecting patient acceptance of pharmacist's vaccine recommendations within the intervention pharmacies.

Research Methods:

This study utilized a two-group randomized controlled trial (RCT) design in community pharmacies in Alabama and California beginning in May 2016 to assess the effect of the training program. One group received an enhanced training program and immunization update while the other group (control) only received immunization update. The primary outcome was the change in pneumococcal and herpes zoster vaccine doses during the 6-month intervention period from the baseline period. The unit of analysis was at the pharmacy level.

Community pharmacies in five counties in Alabama (Montgomery, Jefferson, Mobile, Tuscaloosa, Lee) and four counties in California (San Bernadino, Riverside, Los Angeles, San Diego) were identified using Hayes Directory. Given the higher proportion of African Americans and Hispanics in Alabama and California compared to the national average, these states were chosen in order to ensure that pharmacies serving a minority population would be reached. Comparable counties in each state were selected in terms of proportion of adults over age 65 and annual income (after adjusting for cost-of-living). Pharmacies were recruited to participate in the study via telephone with a maximum of five contact attempts, beginning with the first county in each state (Montgomery and San Bernadino) and exhausting the list of pharmacies before moving on to the next county. Pharmacies were eligible to participate if they: 1) provided direct (walk-in) prescription dispensing services; and 2) offered pneumococcal or herpes zoster vaccinations for the previous twelve months. Pharmacies being considered for sale, closure, or relocation in the next twelve months were excluded from participation. A team-oriented approach was used with each enrolled pharmacy contributing one pharmacist-technician pair, with the pharmacist serving as an immunization champion for the site.

Based on a power calculation (effect size= 19.6 doses, SD=35.5, alpha=0.05) [2], it was determined that a minimum sample size of 64 (32 per group) was needed to assess change in number of vaccine doses between groups pre and-post intervention with 80% power.



Data analysis

For the primary outcome (self-reported number of pneumococcal and herpes zoster vaccine doses administered), median change in number of doses from pre- to post-intervention were compared between groups using one-tailed Mann-Whitney U tests.

For the secondary outcome, number of process activities engaged by participants in the two groups were compared using one-tailed Wilcoxon Signed-Rank tests for paired data.