**Vaccination history assessment during comprehensive medication review in an independent pharmacy setting**

**Background:**

During the 2016-2017 influenza season, it is estimated the influenza vaccine prevented 5.29 million influenza illnesses, 2.64 million influenza associated medical visits, and 84,700 influenza associated hospitalizations.1 In the population aged between 18 and 64 years, prevalence of invasive pneumococcal disease decreased from 16 cases per 100,000 to 7 cases per 100,000 between 1998 and 2015.2 In the same time period, a decrease in prevalence of invasive pneumococcal disease decreased from 59 cases per 100,000 to 23 cases per 100,00 in the adults aged 65 and older population.2

HealthyPeople2020 is a government initiative that aims to improve the health and wellness of the US population. Originally started in 1979 by the Office of the Surgeon General, the fifth rendition of this series is currently managed by the Office of Disease Prevention and Health Promotion (ODPHP).3 The Healthy People initiatives set quantifiable 10-year goals and objectives aimed at health promotion and disease prevention.3 In 2018, only 37.1% of adults in the US aged 18 and older and 32.6% of adults in Indiana aged 18 and older received the annual influenza vaccine.4 The target annual influenza vaccination rate set by HealthyPeople2020 in this population is 70%.5 In 2016, 66.9% of adults aged 65 and older in the US had received a pneumococcal vaccination.6 In 2016, 65.4% of the same population in Indiana had received a pneumococcal vaccination.6 HealthyPeople2020 has set a target pneumococcal vaccination rate of 90%. 5

Pharmacists are at an advantageous position for providing education and vaccination recommendations due to their accessibility in most communities. The ability of pharmacists to administer vaccinations has been shown to increase vaccination uptake, which aligns with the goals of the HealthyPeople2020 initiative.7,8 Before a pharmacist is able to administer vaccinations, they must undergo specific training provided by an Accreditation Council for Pharmacy Education (ACPE) accredited provider and meet all requirements of their state.9 This training prepares pharmacists for patient education, identifying appropriate vaccines based on age and medical history, and safe vaccine administration.10

Alongside vaccination training, pharmacists are becoming more involved with patient care services, such as medication therapy management (MTM). MTM is a large umbrella that encompasses a broad variety of patient care services including, but not limited to, adherence assistance, therapy gaps, education on medications and disease states, medication reconciliation, and comprehensive medication review (CMR). A CMR is an interactive discussion, performed either in person or via telehealth.11 CMRs are designed to provide an environment where patients can receive consultation from a pharmacist on all medications, including over-the-counter (OTC) medications, herbal therapies, and dietary supplements.11 Provision of CMRs has been shown to provide benefits, such as reducing medication-related problems and decreasing use of high-risk medications.12,13 CMR eligibility requirements differ between each individual patient plan, but follow guidelines set forth by the Center for Medicare and Medicaid Services (CMS). In 2018, the Medicare requirements were: a minimum number of chronic conditions (2 or 3), a minimum number of Part D medications (between 2 and 8), and an annual cost threshold for Part D medications of $3,967.14

**Objectives:**

The objective of this study was to model the association between utilization of a vaccination history assessment during CMRs and a change in vaccination rates.

**Methods:**

*Study Design*

This retrospective, cross-sectional chart review compared data between two time periods, the pre-intervention period (July 1 – December 31, 2017) and the intervention period (July 1 – December 31, 2018). The intervention period is the first six months after implementation of vaccination history assessment in the CMR process. The pre-intervention period is the identical six-month time frame from the previous year, without inclusion of vaccination history assessment in the CMR process. The number of completed CMR cases performed during the study periods determined the sample size. This study was granted institutional review board (IRB) approval.

*Setting*

Vaccination history assessment was implemented during the CMR process at this independent pharmacy on July 1, 2018. The pre-intervention process was to perform face-to-face CMRs with all eligible patients, utilizing the OutcomesMTM and MirixaPro platforms to determine eligibility. All CMRs included collection of past medical history and current active prescriber information. Patients’ prescription and over-the-counter medications were discussed, along with any herbal or dietary supplements they may have been taking. The intervention added vaccine history assessment prior to medication discussion. The assessment included guided discussion for patients to provide their vaccination history followed by verification in the onsite prescription dispensing system and the Indiana vaccination registry, Children and Hoosier Immunization and Registry Program (CHIRP).

*Study Participants*

To be eligible for this study, participants must have completed a CMR at this pharmacy during the pre-intervention period and/or the intervention period and have been eligible to receive at least one of the three vaccinations included in this study. The three vaccinations included were the annual flu vaccine, PPSV23, and PCV13. There was no minimum age requirement to participate in this study.

*Data Collection*

The following data was collected through chart review of CMR records, the onsite prescription dispensing system, and CHIRP: CMR completion date, vaccination history, and administration status of the three included vaccinations. Participants were given a 14-day period post CMR completion to receive one of the included vaccinations to reduce potential for factors outside of the CMR to contribute to change in vaccination status. Data collection began on January 15, 2019. This ensured that any participants receiving a CMR on the final eligible date for the intervention period would have the same allotted 14-day period to receive their vaccinations. Age, sex, race, and insurance provider were collected to characterize the patient population.

*Data Analysis*

For the purpose of this study, vaccination history assessment was set as the independent variable (did not receive vaccination history assessment versus received vaccination history assessment) and vaccination status was set as the dependent variable (unvaccinated versus vaccinated). Fisher’s exact test was used to compare administration rate data between the pre-intervention period and the intervention period. 31 patients were found to be eligible for the study out of 43 patients who received CMRs during the two combined time periods. A chi-square test was originally selected to analyze the data, but due to the small sample size and pre-intervention period results less than 5, Fisher’s test was utilized.

**Results:**

Of the 43 completed CMRs between the two time periods, 31 CMRs were eligible to receive at least one of the included vaccinations. 17 of the eligible CMRs occurred during the pre-intervention period and 14 occurred during the intervention period. Of the 17 included pre-intervention period CMRs, 3 patients (17.65%) received at least one of the three included vaccinations within two weeks of CMR completion. Of the 14 included intervention period CMRs, 7 patients (50%) received at least one of the three included vaccination within two weeks of CMR completion. This depicts a 32.35% increase in vaccination status, with a p-value of 0.0626.

**Table 1: Baseline Characteristics**

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| **Baseline Characteristics** |
| **Characteristic** | **Pre – Intervention** **n = 17** | **Intervention** **n = 14** | **Total** **n = 31** |
| **Age (SD)** | 59.41 (15.87) | 60.14 ± 15.47 | 59.74 ± 15.43 |
| **Sex (%)** |
|  **Female** | 11 (65) | 7 (50) | 18 (57) |
|  **Male** | 6 (35) | 7 (50) | 13 (43) |
| **Race (%)** |
|  **White** | 16 (94) | 14 (100) | 30 (97) |
|  **Black** | 1 (6) | 0 (0) | 1 (3) |
| **Ins. Provider (%)** |
|  **Medicare** | 3 (18) | 4 (29) | 7 (23) |
|  **Medicaid** | 14 (82) | 10 (71) | 24 (77) |

**Table 2: Intervention Results**

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| **Intervention Results** |
|  | **Pre – Intervention****n = 17** | **Intervention** **n = 14** | **Difference** | **p-value** |
| **Received vaccination within 2 weeks of CMR (%)** | 3 (17.65) | 7 (50) | 4 (32.35) | 0.0626 |

**Discussion:**

The aim of this study was to model an association between performing vaccination history assessment during the CMR process and a change in vaccinations rates. An association was not confirmed. This study was limited by the small available sample size. This reduced the study’s ability to determine statistical significance with minimal possibility of a type II error. The single-site nature of this study contributed to the small sample size and the lack of demographic diversity. Both the single-site nature of this study and the lack of demographic diversity have a negative impact on the generalizability of the results of this study. While not statistically significant, an increase in vaccination status of 32.35% shows potential for pharmacist involvement in vaccine education to have a clinically significant impact on vaccination rates. There are currently no other studies specifically investigating the inclusion of the vaccine history assessment in CMRs, however, other studies have shown the benefits on vaccination rates of involving pharmacists in vaccine administration as well as the positive impact of CMRs on addressing medication-related problems.7,8,12,13

**Conclusion:**

Although study results did not show statistical significance, probable clinical significance of an increase in vaccination rates warrants further investigation. The authors of this study recommend further research include a larger patient sample size. This could be achieved by performing a multisite study, with an emphasis on sites with large CMR populations. Future research would benefit from including sites from multiple states as this could be beneficial in determining if state vaccination laws have any effect on results as well as increasing demographic diversity. At this pharmacy, the increase in vaccination rates with vaccine history assessment resulted in its permanent incorporation into the standard procedure for CMRs.

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