

BACKGROUND

- Medication synchronization, also referred to as the Appointment Based Model (ABM), aligns a patient's monthly chronic medications to a pre-determined pickup date at the pharmacy.
- It was estimated that in the United States in 2014, 10% of independent pharmacies, 6% of stand-alone chain pharmacies, and 11% of other retail pharmacies (primarily mass merchant or grocery store) offered medication synchronization and these numbers continue to increase.²
- Research has demonstrated that community pharmacy-delivered medication synchronization is associated with improved medication adherence.³⁻⁵
- A recent cost benefit analysis model indicated medication synchronization offers payers a positive return on investment, however further research is needed to explore the impact of medication synchronization on costs and outcomes.⁶

OBJECTIVES

The primary objective of this study is to evaluate the association between the ABM and per-member-per-month (PMPM) total healthcare costs in a nationwide sample of Medicare beneficiaries.

Secondary objectives are to evaluate the association between:

- Synchronization and outpatient, inpatient, and emergency department (ED) utilization
- Synchronization and time to first hospitalization and/or ED visit following enrollment in a ABM program
- Synchronization and medication adherence

METHODS: STUDY DESIGN

- This retrospective cohort study will analyze claims data using research identifiable files (RIFs) with data from up to 999,999 Medicare beneficiaries.
- The RIFs used in this study will be purchased from the Centers for Medicare and Medicaid Services (CMS) with the Research Data Assistance Center (ResDAC) facilitating the purchase request.
- The intervention cohort includes beneficiaries first enrolled in a medication synchronization program in 2014. The intervention cohort will be identified through medication claims data when a short-filled Part D prescription was dispensed from a pharmacy offering ABM which resulted in the alignment of chronic medications at the next fill (index date).
- A matched comparison cohort will be constructed using propensity score models of healthcare claims during the previous 12 months.⁷
- Eligible beneficiaries will be followed for 12 months from the index date to determine primary and secondary outcomes.
- All beneficiaries from the pharmacies identified as offering the ABM will be included in the sample. Beneficiaries determined to be receiving medication synchronization will be included in the intervention cohort. A random sample of beneficiaries (up to 999,999) from pharmacies not offering the ABM will be eligible for the matching control cohort.
- The sampling frame consists of 6975 beneficiaries per cohort. This was calculated to ensure 80% power for detecting a 10% lower mean PMPM total Medicare beneficiary cost in the intervention cohort compared to the comparison cohort with a type I error rate (α) of 0.05, employing a two-sided t-test for independent groups.
- The primary outcome will be analyzed using a linear mixed-effects regression model. Multivariate models will be constructed to evaluate secondary outcomes.
 - The model will be adjusted for health behaviors found to be predictive of PMPM overall health cost, using a univariate significance threshold of $p < 0.2$.
 - Overdispersion of count data will also be assessed by fitting negative binomial mixed regression models and comparing goodness of fit for these two distributions.

METHODS: CONCEPTUAL FRAMEWORK

- The conceptual framework for this research is Andersen's Phase-3 Model of Health Services Utilization⁸ which associates three factors responsible for access to and use of health services. (Figure 2.)
- From the below factors, Determinants of Health Behavior will be used for propensity score matching of beneficiaries receiving medication synchronization through an ABM to a control cohort, with Health Behavior defining the cohort, and Health Outcomes being the primary and secondary outcomes.

Figure 2. Study Framework: Andersen's Model and Proposed Study Variables

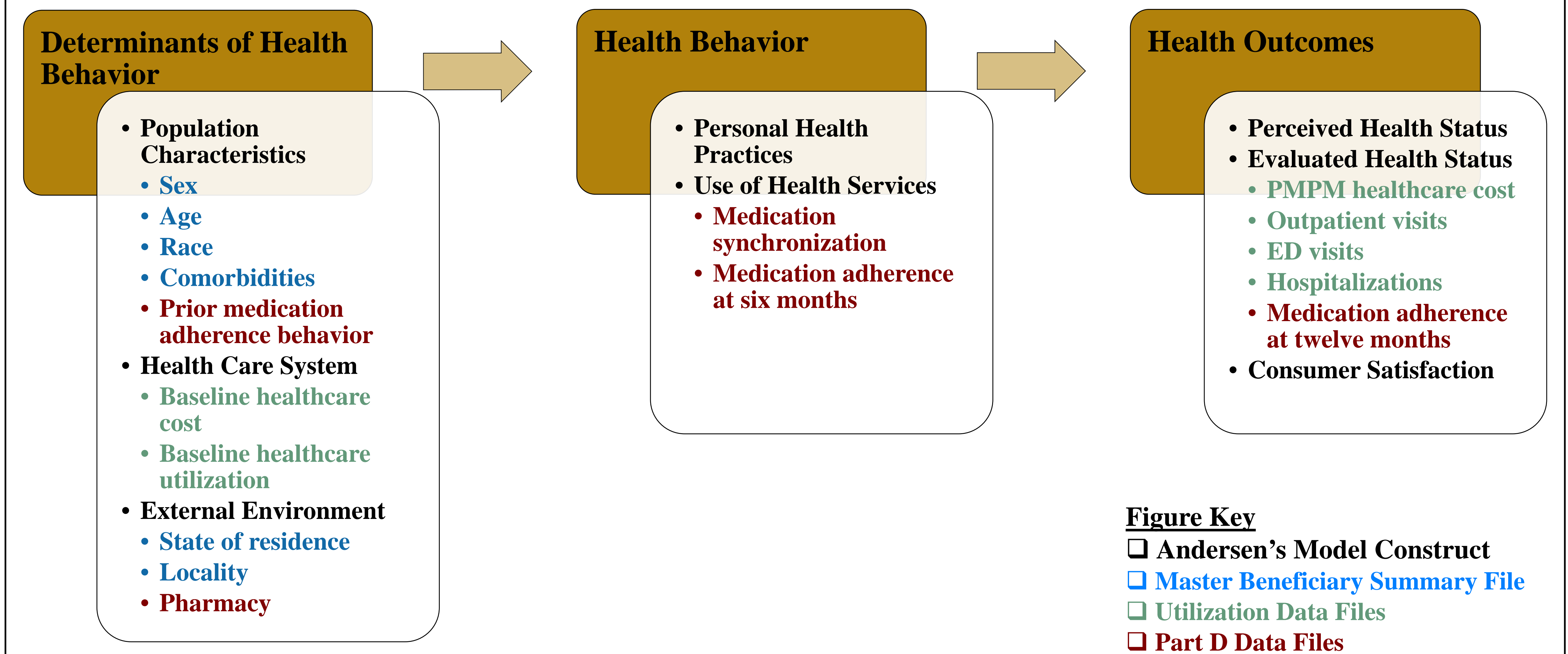


Figure Key

- Andersen's Model Construct
- Master Beneficiary Summary File
- Utilization Data Files
- Part D Data Files

Table 1. Research Identifiable Files Requested	File Years
Master Beneficiary Summary File <ul style="list-style-type: none"> Base Segment Aged/Blind/Disabled Chronic Conditions Other Chronic and Potentially Disabling Conditions Cost and Utilization 	2013 – 2015
Utilization Data <ul style="list-style-type: none"> Inpatient Claims Outpatient Claims Carrier Claims Home Health Claims Skilled Nursing Facility Claims 	2013 – 2015
Part D Data <ul style="list-style-type: none"> Part D Event Data with Drug Characteristics Plan Characteristics Formulary Characteristics Prescriber Characteristics Pharmacy Characteristics 	2013 - 2015

ABM PHARMACY IDENTIFICATION

- A national sample (n=2657) of community pharmacies was obtained (March 2015) from the APhA Foundation *Align my Refills* pharmacy locator webpage.
- From this list, National Provider Identifiers (NPI) were obtained for each of the pharmacies through the National Plan and Provider Enumeration System (NPPES) online registry.
- Student pharmacists made calls to individual pharmacies and corporate headquarters:
 - To confirm the pharmacy was offering medication synchronization services
 - To ascertain when these services began
 - To determine if the pharmacy was delivering these services with the components of the ABM
 - To verify the NPI was correct for each pharmacy

NEXT STEPS

- Paperwork for data purchase is complete and pending review and approval of study by CMS Privacy Board.
 - Paperwork will be sent to CMS Privacy Board once pharmacy variable requested (synchronization indicator) is confirmed
 - Final Data Use Agreement (DUA) will be signed by CMS
- Investigators will submit DUA and study application to the Purdue University Institutional Review Board and purchase a computer isolated from the internet to house the data.
- After receipt of data:
 - Finalization of a "Data Dictionary"
 - Identification of the synchronization cohort
 - Construction of propensity scores and identification of a matched control cohort
 - Construction of linear mixed effects and multivariate models
 - Completion of data analysis using SAS 9.4
- Dissemination of results
- Future research, including a prospective randomized control trial, is needed to examine the economic and health outcome effects of medication synchronization in populations that do not self-select enrollment in the service.

ACKNOWLEDGEMENTS

The authors would like to acknowledge the Community Pharmacy Foundation (Grant #170) and the Purdue University College of Pharmacy Department of Pharmacy Practice for financial support. Additional acknowledgement to the pre-pharmacy and pharmacy students who assisted with NPI look-up and synchronization verification phone calls, Brandon Butram, and the Technical and Executive Advisors at ResDAC.

A portion of Dr. Snyder's effort was supported by the Agency for Healthcare Research and Quality (AHRQ) under award number K08HS022119. The content is solely the responsibility of the authors and does not necessarily represent the official views of AHRQ.

DISCLOSURES

Dr. Snyder has received fees for serving as a consultant for Westat, Inc. Drs. Lantaff, Zillich, Lourens, Murawski, Thomas III, Ott, and Ms. Jaynes report no financial relationships or potential conflicts of interest.

REFERENCES

- Pharmacy's Appointment Based Model. A Prescription Synchronization Program that Improves Adherence. *American Pharmacists Association Foundation*. Accessed March, 6, 2017. [http://www.aphafoundation.org/sites/default/files/ckeditor/files/ABMWhitePaper-FINAL-20130923\(3\).pdf](http://www.aphafoundation.org/sites/default/files/ckeditor/files/ABMWhitePaper-FINAL-20130923(3).pdf).
- Krumme AA, Isaman DL, Stolpe SF, Dougherty S, Choudhry NK. Prevalence, effectiveness, and characteristics of pharmacy-based medication synchronization programs. *Am J Manag Care*. 2016;22(3):179-186.
- Holdford DA, Inocencio TJ. Adherence and persistence associated with an appointment-based medication synchronization program. *J Am Pharm Assoc* (2003). 2013;53(6):576-583.
- Holdford D, Saxena K. Impact of Appointment-Based Medication Synchronization on Existing Users of Chronic Medications. *J Manag Care Spec Pharm*. 2015;21(8):662-669.
- Blackburn DF, Tran D, Quiring C. Evaluation of a refill synchronization program in two community pharmacies. *J Am Pharm Assoc* (2003). 2016;56(6):656-659.
- Patterson JA, Holdford DA, Saxena K. Cost-benefit of appointment-based medication synchronization in community pharmacies. *Am J Manag Care*. 2016;22(9):587-593.
- Stuart, EA. Matching methods for causal inference: A review and a look forward. *Stat Sci*. 2010;25(1):1-21.
- Andersen, R. Revisiting the Behavioral Model and Access to Medical Care: Does it matter? *J Health Soc Behav* 1995, 36(1), 1-10.

STUDY TIMELINE: IN PROGRESS

Figure 1. Timeline of Completed Key Events

