Patient-centered services to improve specialty medication adherence: results from a prospective randomized controlled trial

NCT03709277
Protocol Date: 09/14/2022

Background

Importance: Medication nonadherence results in poor clinical outcomes and increased healthcare spending. Although specialty pharmacies tend to have high adherence rates, resources are needed to address the unique barriers associated with nonadherence to specialty medications.

Objective: A QI study was conducted to evaluate a service designed to address patient-specific reasons for nonadherence to improve specialty medication adherence at Vanderbilt Specialty Pharmacy. This is a retrospective review of the data collected during the QI study. As results of the QI study were positive and we believe our findings to be generalizable for other specialty pharmacies to implement, we plan to analyze and report the results of the previously collected data.

Design: A quality improvement study using a pragmatic, randomized controlled design, was conducted from May 2019 and August 2021. Eligible patients were randomized 1:1 to usual care or intervention arms and stratified by historical rates of nonadherence in their clinic. Intervention patients underwent a baseline adherence assessment to identify reasons for nonadherence and received patient-tailored interventions and 8 months of follow up from a specialty pharmacist. A Wilcoxon test was used to test the difference in 6, 8, and 12-month post-enrollment PDCs between the intervention and usual care arms.

Main Outcomes and Measures: The primary outcome of the QI study was PDC calculated at 8-months post-enrollment. An exploratory analysis evaluated PDC at 6-months and 12-months post-enrollment. While the QI study was conducted to improve service at Vanderbilt, our findings suggest that any specialty pharmacies could improve adherence with existing resources.

Rationale and Specific Aims

Integrated health system specialty pharmacies provide a high-touch service to their patients at baseline. Our QI study aimed to find out if adding an additional adherence service could identify and address patient-specific reasons for nonadherence to increase adherence to specialty medications at VUMC. Few studies report the reasons for nonadherence to specialty medications. It is commonly accepted that cost is a large reason for nonadherence; however, integrated specialty pharmacies provide financial services to minimize and often remove the impact of cost. In the QI study, we collected each patient's reason for nonadherence by reviewing their chart and by asking the patient (in the intervention arm). Before this study, it was unknown what the reasons for nonadherence were in a broad specialty disease population and if those reasons could be addressed by a pharmacist. The findings of our QI study will be helpful to other specialty pharmacies as it demonstrated that non-labor-intensive interventions could have a significant impact on specialty medication adherence.

Inclusion/Exclusion Criteria

All data will be obtained retrospectively. All nonadherent patients will be included in the QI project and patients with 2 or more refills in the study period will be included in the data analysis.

Study Procedures

This is a retrospective review of data collected under IRB #181452.

Risks

The only potential risk is breach of data which is stored in a HIPAA-secured REDCap and only deidentified data was extracted for analysis. As data has already been extracted and stored in REDCap and deidentified data extracted for analysis, there is minimal risk to the current retrospective review request.

Reporting of Adverse Events or Unanticipated Problems involving Risk to Participants or Others

Adverse events (which may include breach of confidentiality) which are serious, unanticipated, and related (or possibly related) to the research procedures will be reported to the IRB within 7 calendar days of the Investigator's knowledge of the event.

Privacy/Confidentiality Issues

Data was collected as part of the QI study and is already stored in REDCap. No additional data will be collected. All data will remain in the REDCap. Only KSP will have access to the data.

Patient data is stored in the REDCap (a HIPAA-compliant web-based application) and only accessible to KSP. Access is granted as either able to view patient information or not so for example, our statisticians never see any patient-specific information.

Follow-up and Record Retention

Data will be destroyed no earlier than 3 years from the date the research is closed with the IRB.