Evaluation of pharmacist interventions in lipid management for secondary prevention

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Lipids Research Protocol

Title: Second Time's the Charm: Evaluation of pharmacist interventions in lipid management for secondary prevention

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Background/Significance:

Studies have shown prevention of cardiovascular adverse events is directly proportional to percent reduction in LDL.[1] This evidence explains why LDL targets for secondary prevention have continued to be lowered. Cholesterol guidelines have been updated recently and encourage the use of multiple lipid lowering therapies, in addition to statins, for secondary prevention. However, these novel agents can be expensive and difficult to acquire, making prescribing challenging for providers.

This project aims to utilize a pharmacist to evaluate patients for evidence-based therapy and initiate guideline-directed lipid lowering therapy as indicated.

Study Purpose:

The primary objective of this research project is to compare the effect of pharmacist interventions versus usual care in the implementation of guideline directed lipid lowering therapies for secondary prevention.

Study Design: prospective interventional study

Methods/Data Collection

Patient Identification:

- Internal medicine providers and PharmDs will identify patients who are not meeting LDL goals for secondary prevention and could benefit from pharmacist intervention
- SlicerDicer will be utilized to select patients for the control arm as well as potentially for the intervention arm if referrals alone do not meet the sample size goal

Collected data will be stored on a secure Atrium server and de-identified. Data will be analyzed utilizing REDCap. Data collected via EPIC may include:

- Demographic information (age, gender, race)
- Baseline information (recent lipid panel, Lp(a) history)
- Initial hyperlipidemia treatment
- Relevant lab information (renal function, electrolyte values)
- Other co-morbidities (diabetes, CKD, etc)
- Insurance type
- Follow up appointments
- Other relevant patient information for an appropriate hyperlipidemia treatment recommendation

The study period is expected to be 5 months (anticipated November 2024-March 2025).

Inclusion Criteria:

- Age $\geq$ 18 yo
- Diagnosis of coronary artery disease
- Most recent LDL value > 55
- PCP at 1 of 6 identified clinics

Exclusion Criteria:

- Patients who are no longer an active patient of one of the internal medicine practices
- Patients whose cholesterol is managed by another practice
- Women of childbearing age/potential
- Patients residing in hospice/LTC facilities
- End-stage liver disease

Practice Sites:

- Kannapolis Internal Medicine
- Concord Internal Medicine
- Ardsley Internal Medicine – Harrisburg

- Atrium Health Primary Care Cabarrus Family Medicine – Locust
- Atrium Health Primary Care Cabarrus Family Medicine - Midland

In-person, initial visit:

- Perform medication reconciliation and adherence assessment
- Assess recent laps in EPIC profile
- Educate patient on background of project (pharmacist lipid intervention), provide information sheet, future steps/plans
- Adjust hyperlipidemia treatment, which is part of the routine clinical practice under the collaborative practice agreement.
    - CPP is a licensure that is obtained from the NC Board of Pharmacy and is renewed yearly; CPPs must complete an additional 20 hours of continuing education each year
    - A CPP has an established collaborative practice agreement (CPA) with a supervising physician that outlines the role of the CPP
    - Each pharmacist working on this project either practice as a CPP or are under the direct supervision of CPP
- Order appropriate lab work
- Arrange follow-up with patient regarding medication changes (phone visit)
    - Follow up visits will be scheduled every 6-8 weeks as needed based on patient-specific needs
    - Once LDL<55 (controlled), no further follow up will be scheduled with PharmD
- Will also plan to check Lp(a) for patients who have never had this lab assessed
    - Will provide information sheet on this lab and what to do if it comes back as elevated

Follow up visits:

- Repeat lipid panel prior to appointment, review results
- Assess adherence and access to recommended therapy
- Discuss therapy adjustments
- Set up next follow up visits

The initial in-person visit, or a follow-up telephonic phone visit may be completed by another embedded pharmacist within one of the clinics included in study due to schedule availability. Members of the PharmD team will be trained and follow the protocol during their visits. Medications are being adjusted as per the usual care services provided by their PCP office and

PharmD services that are already in place at each practice. Adjustments to medication regimens, comorbidities, and concurrent medications will be made based on national guidelines and evidence-based recommendations that are already allowable by CPP and per our collaborative practice agreement. Any costs/risk associated with medication changes is no additional risk than if they do not participate in the study and would still be subject to these medication changes if they weren't participating in the study. This study and applicable additional intervention are simply offering additional care services provided by a PharmD for closer follow up and offering patients assistance with access to newer therapeutic options.

Control Group:

Patients meeting inclusion criteria will be pulled from SlicerDicer. Any patients previously referred to the project by their provider will be excluded from the control group. Patients included in the report will then be randomized and chosen for retrospective chart review. The goal will be to include 75 patients in both the intervention and control arms. Investigators will perform retrospective chart review for the study period and record the same data as collected for patients in the intervention arm.

Primary endpoint: patients with LDL within goal (<55) (yes/no)

Secondary endpoints:

- Percent LDL reduction (will use baseline LDL and lowest LDL)
- Medication related problems identified and solved
- Medications initiated or titrated
- Number of patients who were provided assistance with access to medication
- Prevalence of elevated Lp(a)

Data and Safety Monitoring:

Principal investigator and co-investigators will meet monthly to re-evaluate patient enrollment and ensure all investigators are adhering to study protocol.

Statistical Analysis:

Data will be analyzed after de-identification using descriptive statistics or inferential statistics as appropriate and will be collected, organized, and stored through REDcap. T-test will be utilized to compare pharmacist intervention versus usual care on the primary outcome. Descriptive statistics will be utilized to report secondary outcomes.

Feasibility of Project:

The anticipated start date for patient enrollment is November 2024. Statistical analysis will be finalized by April 2025. Anticipate presentations/publication in May or June 2025.

Informed Consent:

Participants will be required to provide signed informed consent prior to inclusion in the study.

References:

1. Patel PN, Giugliano RP. Low-density lipoprotein cholesterol lowering therapy for the secondary prevention of atherosclerotic cardiovascular disease. Glob Cardiol Sci Pract. 2020;2020(3):e202039. Published 2020 Dec 31. doi:10.21542/gcsp.2020.39