

Evaluation of a Pharmacist-Driven Ambulatory Aspirin Deprescribing Protocol

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Background: Recent guidelines indicate that aspirin affords less cardiovascular protection and greater bleeding risks in adults aged > 70 years. Deprescribing potentially inappropriate medications is particularly important in older adults, as this population experiences a high risk of adverse effects and polypharmacy. Limited data are available regarding targeted aspirin deprescribing approaches by pharmacists. The objective of this study was to implement and evaluate the success and feasibility of a pharmacist-led aspirin deprescribing protocol for older adults in a primary care setting.

Observations: This prospective feasibility study in a US Department of Veterans Affairs ambulatory care pharmacy setting included veteran patients aged ≥ 70 years with documented aspirin use. We reviewed 459 patient records and determined that 110 were eligible for deprescribing. A pharmacist-initiated telephone call was attempted for each eligible patient to discuss the risks and benefits of

deprescribing aspirin. The primary outcome was the proportion of patients reached for whom aspirin was discontinued. Secondary outcomes included patient rationale for declining deprescribing and the time to complete the intervention. Of 94 patients reached, 45 (48%) agreed to aspirin deprescribing, 3 (3%) agreed to dose reduction, and 29 (31%) declined the intervention. An additional 17 (18%) had previously stopped aspirin, which led to a medication reconciliation intervention. Pharmacists spent about 2 minutes per record review and 12 minutes on each encounter, including documentation.

Conclusions: Implementing a pharmacist-driven aspirin deprescribing protocol in a primary care setting led to the discontinuation of inappropriate aspirin prescribing in nearly half of older adults contacted. The protocol was well accepted by collaborating physicians and feasible for pharmacists to implement, with potential for further dissemination across primary care settings.

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The use of low-dose aspirin for the primary prevention of cardiovascular disease (CVD) morbidity and mortality continues to be controversial, particularly for older adults. Recently published, robust randomized controlled trials have revealed less cardiovascular benefit from aspirin for primary prevention compared with previous trials; additionally, an increased risk of major bleeding events has been notably more prevalent in older adults.¹⁻⁵ These trials have suggested that preventative aspirin use in older adults confers less benefit than other therapies for decreasing atherosclerotic CVD (ASCVD) risk, including blood pressure (BP) control, cholesterol management, and tobacco cessation.^{1,6}

A recent meta-analysis indicated a composite cardiovascular risk reduction in patients aged 53 to 74 years taking aspirin vs no aspirin; however, this benefit was offset with an even greater increased risk of major bleeding.⁷ This trend was consistent regardless of stratification by 10-year ASCVD risk or presence of diabetes mellitus (DM) diagnosis.^{7,8} Additionally, the recently published Aspirin in Reducing Events in the Elderly (ASPREE) trial studied the impacts of aspirin use in healthy adults aged ≥ 70 years and

aged ≥ 65 years among Black and Hispanic adults.⁴ The study concluded that the risk of major bleeding with aspirin use was even higher vs the potential cardiovascular benefit in older adults.⁴

With this emerging evidence, guidelines have been updated to represent the need for risk vs benefit considerations regarding aspirin use for primary prevention in older adults.^{1,9,10} The most recent guideline update from the American College of Cardiology and American Heart Association (ACC/AHA) recommends against the routine use of aspirin in patients aged > 70 years or those with bleeding risk factors.¹ The guideline recommends considering aspirin use for patients ages 40 to 70 years only after a patient-specific risk vs benefit discussion.¹ Furthermore, the 2020 American Diabetes Association guideline recommends considering aspirin use for primary prevention in adults with DM between ages 50 and 70 only after a risk vs benefit discussion of patient-specific bleeding risk factors and ASCVD risk-enhancing factors.¹⁰

Despite the demonstrated risks for bleeding with the routine use of aspirin, studies indicate that aspirin continues to be used commonly among older adults, often when unnecessary. In the 2017 National

TABLE Patient Demographics^a

Characteristics	Total (N = 94)	Deprescribed (n = 45)	Not deprescribed (n = 29)
Age, mean (range), y	75 (70-93)	75 (70-87)	78 (71-93)
Male sex, No. (%)	94 (100)	45 (100)	29 (100)
Race, No. (%)			
White	87 (93)	41 (91)	27 (93)
Other/not specified ^a	10 (11)	4 (9)	2 (7)
Daily aspirin dose, No. (%)			
81 mg	83 (88)	41 (91)	28 (97)
> 81 mg	9 (10)	4 (9)	0
As needed	2 (2)	0	1 (3)

^a Patient may select 'other' as a category option.

Health Interview Survey, about 23% of adults aged > 40 years in the United States without CVD used aspirin daily, and 23% of these did so without recommendation from a health care professional.¹¹ Furthermore, nearly half of adults ages ≥ 70 years and nearly one-quarter of adults with a history of peptic ulcer disease used aspirin daily.¹¹ Although the most recent guidelines from the ACC/AHA do not recommend a 10-year ASCVD risk threshold for therapy, one study illustrated that 12% of older adult patients were inappropriately prescribed aspirin for primary prevention despite a 10-year ASCVD risk of < 6%.^{1,12} These studies highlight the large proportion of individuals, particularly older adults, who may be inappropriately taking aspirin for primary prevention.

DEPRESCRIBING PROGRAM

Deprescribing potentially inappropriate medications (PIMs) is particularly important in the older adult population, as these individuals experience a high risk of adverse effects (AEs), polypharmacy, cognitive decline, and falls related to medication use.^{6,13-17} Evidence suggests that mortality outcomes are improved with the implementation of targeted deprescribing efforts based on patient-specific factors.¹⁸ Additionally, deprescribing unnecessary medications may improve adherence to other essential medications and reduce financial burdens.¹⁹ Pharmacists play a crucial role among health care professionals in the implementation of deprescribing practices, and studies have shown that physicians are highly accepting of pharmacists' deprescribing recommendations.^{13,20-22}

Despite the evidence for the benefits of

deprescribing, limited data are available regarding the impact and feasibility of a targeted aspirin deprescribing approach by nonphysician practitioners.²³ The objective of this study was to implement and evaluate the success of a pharmacist-driven aspirin deprescribing protocol for older adults in a primary care setting.

This aspirin deprescribing protocol was developed by ambulatory care clinical pharmacist or clinical pharmacist practitioners (CPPs), at the William S. Middleton Memorial Veterans Hospital in Madison, Wisconsin. Within the US Department of Veterans Affairs (VA) health care system, CPPs work under a broad scope of practice with the ability to independently prescribe and monitor medications. The protocol was reviewed by physician stakeholders in both primary care and cardiology and a list was generated, including patients from 2 primary care panels aged ≥ 70 years with aspirin on their medication list, either as a prescription or over-the-counter medication, using the VA Information System Technology and Architecture. A CPP or supervised pharmacy intern identified patients from this list who were appropriate for risk/benefit discussions regarding the discontinuation of aspirin. Patients were excluded from the intervention if they had a history of clinical ASCVD, including myocardial infarction (MI), stable or unstable angina, coronary artery disease (CAD), coronary or other arterial revascularization, cerebrovascular accident (CVA), transient ischemic accident (TIA), or peripheral artery disease (PAD), or another documented indication for aspirin use, including pain, flushing (with niacin use), venous thromboembolism prophylaxis, valvular heart disease, or acute or recurrent pericarditis.

After identifying eligible patients, a CPP or pharmacy intern contacted patients by telephone, following a script to guide conversation. All patients were screened for potential appropriate aspirin indications, particularly any history of MI, CAD, CVA, TIA, PAD, or other clinical ASCVD. The patient was asked about their rationale for taking aspirin and patient-specific ASCVD risk-enhancing factors and bleeding risk factors and educated them on lifestyle modalities to reduce ASCVD risk, using the script as a guide. ASCVD risk-enhancing factors included family history of

premature MI, inability to achieve BP goal, DM with the inability to achieve blood glucose or hemoglobin A_{1c} goal, tobacco use, or inadequate statin therapy. Bleeding risk factors included a history of gastrointestinal bleed or peptic ulcer disease, concurrent use of medications that increase bleeding risk, chronic kidney disease, or thrombocytopenia.

Through shared decision making with careful consideration of these factors, we reached a conclusion with each patient to either continue or to deprescribe aspirin. Each discussion was documented in the electronic health record (EHR) using a standard documentation template (Appendix). The patient's medication list also was updated to reflect changes in aspirin use. For patients who declined deprescribing, the CPP or pharmacy intern asked the patient for their primary reason for preferring to continue aspirin, which was subsequently categorized as one of the following: no prior concerns with bleeding, concerns about a future cardiovascular event, wishing to discuss further with their primary care practitioner (PCP), or identifying an appropriate use for aspirin not evident through record review. For the patients who wished to further discuss the issue with their PCP before deprescribing, the patient's PCP was notified of this preference by a record alert to the note documenting the encounter, and the patient was also encouraged to follow up about this issue. A voice-mail was left if the patient did not answer requesting a call back, and a second attempt was made within 2 weeks.

Data Collected

We collected data to assess the proportion of patients for whom aspirin for primary prevention was discontinued. For patients who declined deprescribing, we documented the rationale for continuing aspirin. Additionally, the feasibility of implementation was assessed, including pharmacist time spent on each record review and intervention. Descriptive statistics were generated to evaluate baseline characteristics and intervention outcomes. The time to completion of these tasks was summarized with descriptive statistics.

We reviewed 459 patient records, and 110 were determined eligible for risk/benefit discussions. The mean (range) age of the patients contacted was 75 (70-93) years

(Table). Telephone calls were attempted to these 110 patients, resulting in an 86% reach rate. Of the 94 patients reached, 45 (48%) agreed to aspirin deprescribing and 29 (31%) declined deprescribing. Seventeen (18%) patients had previously stopped taking aspirin, which required medication reconciliation to remove aspirin from the medication list. Three (3%) patients preferred to stay on aspirin and agreed to stay on aspirin on reduced dosage.

Patients had various reasons for declining deprescribing, including 8 (28%) who had no prior concerns with bleeding while on aspirin and 6 (21%) who were concerned about a future cardiovascular event. Of those who declined aspirin deprescribing, 6 (21%) wished to further discuss the issue with their PCP. In 9 patients (31%) an alternative appropriate indication for aspirin was identified through discussion. In these cases, the indication for aspirin was documented and updated in the EHR.

Most patients contacted (87%) reported taking low-dose aspirin 81 mg daily, while 10% reported taking higher doses (range, 162-325) and 3% on an as-needed basis. In all 3 patients who agreed to dose reduction, the initial dose of 325 mg daily was reduced to 81 mg daily.

Results of the time-study analysis for each intervention indicated that a pharmacy intern or pharmacist spent about 2 minutes reviewing the record of each patient to determine eligibility for risk/benefit discussions. The 110 patients identified as eligible were 24% of the 459 records reviewed. An average (range) of 12 (6-20) minutes was spent on the telephone call plus documentation for each patient contacted. Additionally, we estimated that CPPs and pharmacy interns spent an approximate combined 12 hours in the development and review of materials for this program, including the protocol, script, and documentation templates. This also included about 1 hour to identify appropriate parameters for, and generate, the eligible patient list.

DISCUSSION

The implementation of a pharmacist-driven aspirin deprescribing protocol for older adults in a primary care setting led to the discontinuation of inappropriate aspirin use in nearly half of older adults contacted.

Furthermore, opportunities were identified to update medication lists to reflect previously self-discontinued aspirin for older adults. Just over one-quarter of those contacted declined to discontinue or reduce their aspirin dose. It is hypothesized that with these targeted deprescribing interventions, overall risk reduction for bleeding and polypharmacy will be observed for older adults.¹

In addition to deprescribing aspirin, CPPs used shared decision making to initiate risk/benefit discussions and to educate on targeted lifestyle modifications to lower ASCVD risk. While not all patients agreed to discontinue aspirin, all were provided education that may empower them to engage in future discussions with PCPs regarding appropriate aspirin use. Previous pharmacist-led deprescribing initiatives for proton pump inhibitors and other PIMs have indicated that a large percentage of patients who opt to further discuss a deprescribing concern with their PCPs ultimately resulted in deprescribing outcomes.^{24,25} Additionally, a recent trial examining pharmacist-led deprescribing of 4 common PIMs in older adults compared the impact of pharmacists leading educational interventions directly to patients with pharmacists making deprescribing recommendations to physicians. Deprescribing was more successful when patients were involved in the decision-making process.²⁶

Limitations

Although this quality improvement initiative resulted in the deprescribing of inappropriate aspirin for many older adults, a limitation is the small sample size within a single institution. The population of male veterans also may limit generalizability to nonmale and nonveteran older adults. As the protocol was initiated within a limited number of primary care teams initially, future implementation into additional primary care teams will increase the number of older adults impacted by risk/benefit discussions regarding aspirin use. This work may not be generalizable to other health care systems. Many patients within the VA receive both their primary and specialty care within the system, which facilitates communication and collaboration between primary and specialty practitioners. The protocol may require

workflow adjustments for patients receiving care within multiple systems. Additionally, although the deprescribing protocol was created in collaboration with physicians, CPPs within the VA work under a broad scope of practice that includes independent medication prescribing, deprescribing, and monitoring. This may be a consideration when implementing similar protocols at other sites, as collaborative practice agreements may need to be in place.

Future Directions

The time required to complete these interventions was generally feasible, though this intervention would require some workflow alteration to be incorporated routinely into a CPP's schedule. The telephone calls were completed as isolated interventions and were not incorporated into existing scheduled primary care appointments. In the future, the aspirin deprescribing protocol could be incorporated into existing pharmacist-led primary care appointments. Based on the outcomes of this study, CPPs are leading an initiative to develop an aspirin deprescribing clinical reminder tool, which may be quickly inserted into a progress note within the EHR and may be incorporated into any primary care visit led by a CPP or PCP.

CONCLUSIONS

This study demonstrates that a pharmacist-led aspirin deprescribing protocol in the ambulatory care pharmacy setting was successful in the discontinuation of unnecessary aspirin use in older adults. The protocol also provided opportunities for education on ASCVD risk reduction in all older adults reached. These findings highlight the role of pharmacists in deprescribing PIMs for older adults and identifying opportunities to further streamline risk/benefit discussions on aspirin deprescribing potential within primary care visits.

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Ethics and consent

This project did not meet the federal definition of research pursuant to 45 CFR §46. The University of Wisconsin-Madison Quality Improvement Program Evaluation Self-Certification Tool was used to confirm this project did not require institutional review board approval.

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APPENDIX Standard Documentation Record Template

|PATIENT NAME| is a |PATIENT AGE| |PATIENT SEX| contacted by phone today to discuss risk vs benefit of aspirin use for primary prevention.

Past Medical History: |ACTIVE PROBLEMS LIST|

Subjective:

Today, patient agreeable to risk vs benefit discussion of aspirin use. Patient (denies/identifies) history of MI, CVA, PAD, angina, or other ASCVD.

Current aspirin dose:

After risk/benefit discussion:

- Patient agreeable to aspirin deprescribing
 - Will stop aspirin
 - Will decrease aspirin dose
- Patient declines aspirin deprescribing with the following rationale:
 - Concerned about experiencing cardiovascular event
 - No previous bleeding concerns
 - Would like to further discuss with PCP
 - Other use for aspirin identified:
 - Other:
- Patient no longer on aspirin therapy—removed from medication list

Objective:

|blood pressure|
|hemoglobin A_{1c}|
|lipid panel|
|complete blood count|

Assessment:

Per 2019 ACC/AHA primary prevention guidelines, risk of bleeding likely outweighs benefit in patients aged > 70 years using aspirin for primary prevention. Based on shared decision making, patient preference to (continue/discontinue) aspirin.

Plan:

1. Medications:
 - (STOP aspirin/no change)
2. Education:
 - Discussed potential risks and benefits of aspirin use
 - Reviewed patient-specific ASCVD risk-enhancing and bleeding risk factors
 - Encouraged healthy lifestyle to minimize ASCVD risk
 - Encouraged to call clinic with questions or concerns
3. Follow-up:
 - With PCP as scheduled

Time Spent:

Abbreviations: ACC/AHA, American College of Cardiology and American Heart Association; ASCVD, atherosclerotic cardiovascular disease; CVA, cerebrovascular accident; MI, myocardial infarction; PAD, peripheral artery disease; PCP, primary care practitioner.