Checklist

BEFORE the meeting

☐ Invite your participants

☐ Reserve a location

☐ Instruct your PL Journal Club participants to go to PharmacistsLetter.com to print their PARTICIPANT NOTES. Instruct them to search for the keyword “Journal Club” and tell them which month PL Journal Club you intend to use.

☐ Print your copy of PL Journal Club LEADER NOTES, which will be emailed to you from Pharmacist’s Letter

☐ Organize refreshments

DURING the meeting

☐ Announcements

  • Welcome and introductions

  • Pass around attendance sheet

  • Pass out any needed PL Journal Club PARTICIPANT NOTES

  • Announce next meeting time, location, and discussion leader

☐ Discuss any recommendations that you have made, or new information that you have learned or observed based on the discussion at the last PL Journal Club meeting

☐ Proceed to use your PL Journal Club LEADER NOTES to facilitate the PL Journal Club discussion
Patients often don’t realize the risk of stopping aspirin, clopidogrel, or other antiplatelet drugs too soon.

This applies to the many patients with cardiovascular disease on aspirin to prevent a recurrent event...or on aspirin plus clopidogrel for acute coronary syndrome or after a stent.

Stopping these too soon can be catastrophic.

For example, stopping aspirin in patients with a prior heart attack leads to 4 extra heart attacks per 1000 patients per year.

Stopping clopidogrel within 30 days after a drug-eluting stent results in 25% of patients having a stent thrombosis instead of just 1%.

Try to minimize inappropriately stopping antiplatelets.

For stents, recommend aspirin plus clopidogrel (Plavix), prasugrel (Effient), or ticagrelor (Brilinta) for AT LEAST one MONTH after a bare-metal stent...or at least one YEAR after a drug-eluting stent.

But...and this is very important...recommend aspirin INDEFINITELY.

Recommend just 81 mg/day of aspirin...especially for patients on ticagrelor. Higher aspirin doses make ticagrelor LESS effective.

Advise physicians and dentists that antiplatelet drugs usually DON’T need to be stopped for procedures with a low bleeding risk...minor surgery, dental extraction, cataract surgery, endoscopy, etc.

For stent patients, suggest trying to postpone procedures with a high bleeding risk until clopidogrel, prasugrel, or ticagrelor is stopped.

If they can’t wait, suggest continuing the drug through the procedure, if possible...or stopping the drug for a brief time.

Recommend continuing aspirin for all but the riskiest surgery.

If the drug must be stopped, recommend stopping clopidogrel, ticagrelor, or aspirin 5 days prior...and prasugrel 7 days before surgery.

If you’d like to hear our team discussing all this, listen to an excerpt of one of our meetings online...and get our PL Detail-Document, Discontinuing Antiplatelet Drugs, for when to stop them and how to help patients increase adherence.

(For more on this topic, see PL Detail-Document #270903 at PharmacistsLetter.com.)


Discussion Questions

Overview of current therapy

1. What is already known about aspirin discontinuation and subsequent cardiovascular events?

- Aspirin has been shown to reduce the risk of secondary cardiovascular events; however, many patients discontinue aspirin prematurely. Current recommendations are for indefinite treatment.
- Discontinuation of antiplatelet drugs (e.g., aspirin) has been associated with an increased risk of recurrent cardiovascular disease (CVD) in studies in secondary care centers, not in primary care practices.
- This study evaluated the beneficial effects of aspirin in a primary care cohort.
Analysis of new study

2. What type of study was this and how were the patients selected?

- A case-control study evaluating aspirin in subjects with a cardiovascular event (angina, myocardial infarction [MI], stroke, or transient ischemic attack) between January 1, 2000 and December 31, 2007.
- Subjects were identified from the Health Improvement Network database, which contains over 3 million patients receiving primary care in the United Kingdom.
- This was a nested case-control study, which means that both cases and controls were pulled from the same population of 39,513 patients with previous CVD and were started on aspirin.
- Eligible subjects were 50–84 years of age or older and had established care with a physician.
- 3155 subjects with a second MI and 2869 that died during follow-up were reviewed. After a complete review, there were 876 cases classified as having a second nonfatal MI and 346 cases that died from coronary heart disease (CHD). These were randomly matched with 5000 control patients with no MI or death from CHD based upon age, sex, calendar year, and other features.
- Subjects on aspirin received 75–300 mg daily. Aspirin use was classified as recent discontinuation (ended within 31–180 days prior to the second cardiovascular event), distant discontinuation (ended 181–365 days prior), and current (0–30 days prior).
- Reasons for discontinuation of aspirin therapy were delineated.

3. How were the outcomes evaluated?

- Cases were compared to controls with MI and/or death from CHD as the dependent variable.
- The analysis controlled for a variety of clinical and demographic variables including sex, concomitant medications, comorbidities, smoking status, and others.

4. What were the strengths of this trial?

- This study was a case-control design, which has inherent limitations. Case-control studies lack randomization; therefore the possibility for confounding biases is high.
- The investigators used a long list of characteristics to attempt to control for these biases with multivariate logistic regression. The authors also performed sensitivity analyses. However, no degree of control of confounders totally eliminates the possibility of bias.
- The average follow-up period was 3.2 years and it was conducted in primary care patients in the U.K.
- The investigators evaluated the use of OTC aspirin and found it to be protective.

5. What were the results and how did the drug perform in this trial?

- The overall rate of nonfatal MI was 6.67/1000 person-years and the overall rate of death from CHD was 2.71/1000 person-years in this study.
- Recent discontinuers of aspirin had a higher risk of MI or death from CHD (rate ratio = 1.43, 95% CI, 1.12–1.84) compared with current users.
- Distant discontinuation was not associated with an increased risk of nonfatal MI or death from CHD compared with current use.
- Subjects non-adherent to aspirin had a higher risk of events compared with current users.
- When compared individually, nonfatal MIs were increased in recent discontinuers (RR 1.63, 95% CI, 1.23–2.14). Fatal CHD was not statistically significantly increased in recent discontinuers.
- Sensitivity analyses demonstrated results consistent with the main model.
- Use of oral corticosteroids and NSAIDs increased the risk of events; statin use decreased the risk.
- Smoking, recent hospitalization, COPD, and diabetes also showed an increased risk of events.

6. Were there any adverse events that should be noted?

- Specific adverse events were not reported, a weakness of the study.
- Safety concerns were cited as a reason for discontinuation in 1.0% of both the cases and controls.
Other studies have demonstrated that the risk-benefit of aspirin is positive. Low-dose (< 75 mg) appeared to have a greater risk compared with doses 75–300 mg.

7. Were the results expressed in terms we care about and can use?

- Yes. This study provides evidence that patients on aspirin therapy should be counseled to remain on treatment indefinitely.
- The risk of MI or death from CHD appears to be greatest in the first 6 months following discontinuation of low-dose aspirin.

How should the new findings change current therapy?

8. Are the patients studied similar to those you see?

- How many patients do you currently manage who require secondary prevention of CVD?
- This U.K. patient population was reasonably representative of patients cared for in primary care clinics in the U.S; however, Hispanic and African American populations were not included.
- Discuss current management strategies for discontinuing aspirin therapy.

Apply the new findings to the following case

JP is a 62 year-old female recently discharged after a “mild” heart attack. She had a cardiac catheterization showing stenosis of the left anterior descending artery of about 80% and a stent was placed. Her past medical history includes metabolic syndrome. Medical management was recommended.

9. What medications do you recommend JP start or continue after a myocardial infarction?

- Beta-blockers should be started or continued. Beta-blockade after MI prevents recurrent ischemia.
- Statin therapy to lower the LDL to below 70 mg/dL helps prevent recurrent ischemia.
- ACEI or aldosterone is indicated to help with remodeling of the scar tissue.
- Antiplatelet agents are critical after stent placement.
- Diabetes control can be obtained through using conventional medications, but glitazones should be avoided in patients at risk for congestive heart failure.

10. What lifestyle modifications do you recommend?

- If overweight, select a heart healthy diet designed to lose weight. The Mediterranean diet can be beneficial.
- If a smoker, make a date to quit.
- Consume alcohol in moderation. One 6 oz glass of red wine may help prevent further atherosclerosis.
- Begin a physician-supervised exercise program for cardiopulmonary rehabilitation.

11. How can thrombosis be prevented for both bare-metal and drug-eluting stents?

The American College of Cardiology (ACC)/American Heart Association (AHA) recommends for Bare-metal stents:

- Aspirin 162–325 mg daily for at least one month
- Clopidogrel 75 mg daily for at least one month
- Continue dual antiplatelet therapy for 12 months for those who received their stent during PCI for acute coronary syndrome.
- Reduce aspirin to two weeks for high bleeding risk

Drug-eluting stents:

- Aspirin 162–325 mg daily for at least 3 months for sirolimus stents and 6 months for paclitaxel stents
- After initial period, continue aspirin at 75–162 mg indefinitely
- Clopidogrel 75 mg daily for at least 12 months if not high risk for bleeding
12. How can we help patients not discontinue antiplatelet therapy prematurely?

The ACC, AHA, Society for Cardiovascular Angiography and Interventions, American College of Surgeons, and American Dental Association recommend:

- Patient education on the need for 12 months of therapy before stent insertion and prior to discharge.
- Consider a bare-metal stent for those who may need surgery within 12 months.
- Contact their cardiologist before discontinuing antiplatelet therapy.
- Defer elective procedures until after the recommended antiplatelet course of therapy.
- Be aware of factors associated with premature cessation of antiplatelet agents: older age, lower educational level, unmarried, lack of discharge instructions, lack of cardiac rehab referral, anemia, preexisting cardiac disease, lack of health care due to cost.
- Patients who do not fill their prescriptions for dual antiplatelet therapy on the 1st day after discharge had nearly double the chance of death or MI (14.2 vs 7.9 percent, p < 0.001).
- Primary care patients who discontinued their low-dose aspirin for secondary prevention of MI had a statistically significant increase in both nonfatal and fatal events attributed to coronary artery disease.

13. JP’s 72 year-old spouse has well-controlled hypertension, diabetes, and hyperlipidemia. He has heard that he should be taking baby aspirin to prevent a heart attack. Should he be?

- Despite recommendations from the ACC, AHA, and American Diabetes Association, the evidence-based answer appears to be “no” for primary prevention especially in diabetes patients.
- Five recent publications have recommended against aspirin for primary prevention of CVD.
  - The Antithrombotic Trialists’ meta-analysis (BMJ 2002) showed no benefit of aspirin for primary prevention in diabetes.
  - The Primary Prevention Project trial (Diabetes Care 2003) showed no benefit to primary prevention in diabetics without established CVD.
  - A meta-analysis (Heart 2001) concluded that aspirin did not reduce overall mortality and might increase the risk of stroke and bleeding.
  - POPADAD (BMJ 2008) showed no benefit from aspirin for primary prevention in patients at very high risk, namely diabetics with peripheral artery disease.
  - A meta-analysis (BMJ 2009) reached the same conclusion for diabetes patients.
- The American Diabetes Association is considering dropping diabetes as a coronary artery disease risk equivalent due to recent studies that show these patients are at less risk for coronary events.

14. Mr. P wonders if there are any potential risks from taking a low dose of aspirin. After all, if there is a chance it might help, shouldn’t he use it?

- The risks of gastrointestinal and bleeding from other sites from aspirin are real and significant. GI bleeding is associated with NSAIDs in 80% of reported cases. In 87% of those aspirin is the culprit.
- The risk of bleeding with low-dose aspirin (below 100 mg a day) was 1 in 25 in a recent study increasing to 1 in 10 with doses over 300 mg a day.
- “High” risk for CVD based on the Framingham calculations is 10–20% over 10 years. Therefore, the risk of complications from aspirin therapy can at times approach the risk for CVD.
GERIATRICS

You’ll hear about using START and STOPP instead of Beers to evaluate appropriate med use in the elderly.

The Beers list is often used to identify drugs to avoid in the elderly. The START and STOPP criteria take it a step further. They provide more context by listing clinical situations where specific drugs make sense...and where they don’t.

START (Screening Tool to Alert doctors to Right Treatment) lists 22 situations where meds are indicated. It focuses on common quality-of-care indicators...warfarin for atrial fibrillation, ACE inhibitors for heart failure or after a heart attack, metformin for diabetes, etc.

STOPP (Screening Tool of Older Persons’ potentially inappropriate Prescriptions) lists 65 risky drug interactions with diseases or other drugs...plus therapeutic duplications.

For example, it advises not to use benzodiazepines in a patient who has fallen in the past 3 months...or NSAIDs without a PPI or H2-blocker in a patient with a history of ulcers or GI bleeding.

Certain drugs on the Beers list are controversial because they sometimes ARE appropriate in older patients, such as amitriptyline, amiodarone, and naproxen.

STOPP includes some of these, but provides more guidance.

For example, it suggests avoiding tricyclics for patients with glaucoma, cardiac conduction problems, dementia, constipation, or benign prostatic hyperplasia...but NOT neuropathic pain.

Don’t fall into the trap of using these tools as the final word. None of them are appropriate for making formulary decisions or blanket prescribing protocols.

Use them to help identify POTENTIAL problems...and then look at the whole picture. Consider the patient’s medication history, chronic diseases, functional status, and prognosis.

Get our PL Chart, Medications in the Elderly, for potentially inappropriate drugs and alternatives using START and STOPP criteria. (For more on this topic, see PL Detail-Document #270906 at PharmacistsLetter.com.)


Discussion Questions

Overview of current therapy

1. What is already known about decreasing inappropriate prescribing in the elderly?

• Inappropriate prescribing in the elderly is associated with significant morbidity, including hospitalization, increased costs, and other adverse events (e.g., cognitive decline, falls).
• Several interventions have been made to decrease inappropriate prescribing. These include comprehensive geriatric assessment, clinical pharmacy interventions, and provider education programs. Each has limitations.
• Several tools have been developed to evaluate potentially inappropriate prescribing. In addition, the omission of appropriate therapy is, at times, just as important.
• This study evaluates two such tools, STOPP (Screening Tool of Older Persons’ potentially inappropriate Prescriptions) and START (Screening Tool to Alert doctors to Right Treatment). These tools comprise over 80 indicators to improve appropriate prescribing.
Analysis of new study

2. What type of study was this and how were the patients selected?

- Randomized, blinded, controlled trial to evaluate STOPP/START in a geriatric population in Ireland.
- All patients ≥ 65 years admitted at a single tertiary care medical center were eligible.
- Exclusion criteria included admission while under the care of a geriatrician, geriatric psychiatrist, or clinical pharmacologist; need for intensive care; terminal illness; or unwillingness of the patient or their physician to participate.
- Investigators applied STOPP/START and communicated with the physician within 24 hours. Physician then determined whether or not to accept the recommendations.
- STOPP/START have been evaluated for inter-rater reliability; the results demonstrate good reliability.

3. How were the outcomes evaluated?

- Primary outcome was the appropriateness of prescribing as measured by the Medication Appropriateness Index (MAI) and the Assessment of Underutilization (AOU) index, both validated instruments.
- These two indices were evaluated at baseline and at 2-month intervals during the 6-month follow-up.
- Secondary outcome measures included mortality, frequency of health care utilization including provider visits, hospital readmission, and falls in the 6 months after discharge.

4. How were the study groups defined?

- 400 subjects were randomized to “usual care” or STOPP/START. 18 patients died before the first evaluation, leaving a study population of 382, who were followed for the entire 6-month period.
- Median age was ~75 years. 53% were female.
- Other baseline characteristics were equivalent between groups, including comorbidities, cognitive impairment, falls, living arrangements, medication use, proportion of inappropriate prescribing, and proportion of important therapeutic omissions.
- The number of medications with ≥ 1 inappropriate MAI scale ratings were 48% and the number of patients with a prescribing omission was 36% in the study population as a whole.

5. What were the strengths and weaknesses of this trial?

- The trial was designed to detect relatively small differences between the two groups in the primary endpoint, which were established a priori.
- The study was powered to evaluate differences in the MAI and AOU prescribing scales. Unfortunately, the trial was not powered to evaluate important patient-oriented outcomes such as falls, mortality, hospital length of stay, and other important outcomes. This potentially limits the utility of the results.
- It is clear, however, that inappropriate prescribing as measured by the MAI and AOU indices may translate into significant morbidity.
- Because of the interventional nature of the study, it was impossible to maintain blinding.
- The study had an adequate and robust follow-up period of 6 months.
- The authors note that a limitation of the trial was that it was conducted in a single site, limiting the generalizability. In addition, physicians carried out the interventions and this may also impact the generalizability as well as the cost effectiveness of such an intervention.
- The cost associated with the intervention and a pharmacoeconomics analysis were not included, which would have strengthened the results.

6. How did the intervention work in the trial?

- A total of 190 patients received the intervention and there were 192 controls.
- Compared to controls, there was a significant reduction in inappropriate prescribing with the intervention (absolute risk reduction 35.7%, number needed to screen to yield an improvement in MAI = 2.8).
Under-utilization of appropriate medications was also reduced (absolute risk reduction 21.2%, number needed to screen to yield a reduction in AOU = 4.7). These significant improvements were sustained throughout the study period from 2, 4, and 6 months post discharge.

All-cause mortality and falls were lower with the intervention but did not reach statistical significance.

There was no difference in hospital length of stay or frequency of readmission between the two groups.

There was a trend towards fewer physician visits with the intervention during the follow-up period, but this did not reach statistical significance (P = 0.063).

7. Were there any adverse events that should be noted?

There were no adverse events associated with the application of the STOPP/START criteria.

Overall, 91% of the STOPP and 97% of START recommendations were accepted.

The most common issues with STOPP included use of loop diuretics without overt signs of heart failure, use of long-acting benzodiazepines, long-term use of PPIs, and overuse of medications known to increase fall risk.

The most common issue with START included the initiation of cardiovascular drugs (i.e. warfarin for atrial fibrillation or statins for vascular disease) and the use of calcium/vitamin D supplementation for osteoporosis.

8. Were the results expressed in terms we care about and can use?

Yes. In this trial conducted in Ireland, the application of a systematic approach to reducing potentially inappropriate prescribing in the elderly was associated with significant and sustained reductions in indices associated with inappropriate prescribing in elderly patients.

These intermediate outcomes did not translate into statistically significant reductions in patient-oriented outcomes; however, the study was not powered to adequately evaluate these endpoints.

How should the new findings change current therapy?

9. How are the patients studied similar to those you see?

Describe your elderly patient population. How often do you conduct a systematic medication review in these patients?

The subjects appear to be similar to elderly patients seen in the U.S. clinics.

10. Do the results force you to change your practice? How?

This study is part of a growing body of evidence that suggests that programs to reduce inappropriate prescribing in the elderly may result in important outcomes and improvements in well-being.

It is likely that we will see similar efforts in our clinic patients moving forward. In addition, medication therapy management efforts associated with Medicare prescription drug programs are likely to incorporate similar measures and these concepts fit within the medical home model.

Apply the new findings to the following case

JL is a 78 year-old white female brought in for evaluation by her 41 year-old daughter. The daughter is concerned that her mother has fallen twice in the last 6 months.

11. How common are falls in the elderly? Why should you be concerned about the complaint?

Falls are common in the elderly and are a major threat to their continued independent living.

30–40% of community-dwelling elderly over the age of 65 fall each year. 50% of community-dwelling elderly over the age of 80 fall each year.

Men and women fall equally but women have more injuries.
5% of falls in older patients lead to hospitalization.
Falls are the 5th leading cause of death in older adults.
A history of falling is associated with an increase risk for subsequent falls.

12. What are key aspects of her history and physical exam to focus on?

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<th>History</th>
<th>Physical</th>
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<tr>
<td>Previous falls</td>
<td>Postural vital signs</td>
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<td>Medication use</td>
<td>Visual acuity assessment with and without corrective lenses</td>
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<td>Stroke history</td>
<td>Hearing assessment using the whisper test or audiometer</td>
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<td>Dizziness</td>
<td>Extremity examination for bunions, calluses, or deformities from arthritis</td>
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<td>Sensory impairment</td>
<td>Neurologic for sensory neuropathies</td>
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<td>Chronic disease history</td>
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13. JL’s history and exam are normal. You now review her medication list. What classes of medications are associated with falls (PL Detail-Document #270906)?

A meta-analysis evaluated nine classes of medications in association with falls in the elderly.
- Antidepressants had the highest odds ratio at 1.68.
- Neuroleptic agents were next with an odds ratio of 1.59.
- Benzodiazepines are not far behind with an odds ratio of 1.57.
- Sedative/hypnotics are next with an odds ratio of 1.47.
- Finally, antihypertensives had an odds ratio of 1.24.
- Diuretics, beta-blockers, narcotics, and NSAIDs were not associated with an increased risk of falls but have other concerns.

14. JL’s meds include lisinopril/HCTZ, metformin, sertraline, and zolpidem. She also uses OTC diphenhydramine. What changes might you make to help avoid future falls?

- Tapering and discontinuing the sertraline (Zoloft) if able
- Discontinuing the zolpidem (Ambien) if able
- Changing to a nonsedating antihistamine

15. Beers List has been used as a “hit list” for inappropriate meds in the elderly. How might STOPP/START be better than the Beers List?

- STOPP/START were validated in 2008.
- STOPP uses 65 indicators related to drug-drug and drug-disease interactions and therapeutic duplication.
- START incorporates 22 evidence-based indicators of common prescribing omissions.
- Gallagher et al’s RCT shows significant improvement in medical appropriateness and underutilization of medications. However, the study was not powered to evaluate outcomes like falls or adverse drug events.
- With a list of medical conditions and an accurate med history, applying STOPP/START takes a median of 3 minutes, making it an option for both inpatient and outpatient settings.
References

CARDIOLOGY


GERIATRICS


Additional Pharmacist's Letter Resources available at PharmacistsLetter.com


Welcome to PL Journal Club

PL Journal Club gives you insights and guides you to the discoveries that Pharmacist’s Letter researchers and editors uncover. Each month we analyze many new studies and help you discover the answers to the hard questions. “What are the real advantages and disadvantages of new therapies?” “How do they compare with other options?” “What do pharmacists and prescribers need to know?” We look beyond the headlines and promotional materials to interpret the clinical studies and data. Sometimes the marketing spin doesn’t stand up to scrutiny. Sometimes studies do not really prove what they are reported to prove. PL Journal Club helps guide you to the truth and how to apply new findings to patient care.

PL Journal Club builds on Pharmacist’s Letter to provide you with background for your own journal club discussions. We won’t bring up every possible question, but you can...in your own group meetings. If a question comes up, go to PharmacistsLetter.com to find more background. As a PL Journal Club participant, you get access to all of Pharmacist’s Letter. Feel free to call or email us with suggestions or if we can be of assistance...209-472-2240 or PLJournalClub@pletter.com.

Instructions

Go to PharmacistsLetter.com to get the PL Journal Club PARTICIPANT NOTES. Use the search function to look for “Journal Club.” You’ll also get great background materials, including Pharmacist’s Letter and PL Detail-Documents. PL Journal Club functions like a typical group meeting, except that it is organized for you with the expert analysis of important new studies done by the large Pharmacist’s Letter research and editorial staff. Let the questions serve as a springboard for your discussions. Let your own patient cases shape the discussion. Each month PL Journal Club gives you two topics that are also covered in Pharmacist’s Letter. Your group might discuss only one or both topics. You’ll also find a library of previous PL Journal Clubs online for your use.

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AFTER the meeting
☐ File your attendance rosters
☐ Note the next PL Journal Club meeting
☐ Send email invitations and reminders to participants

NOTES
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