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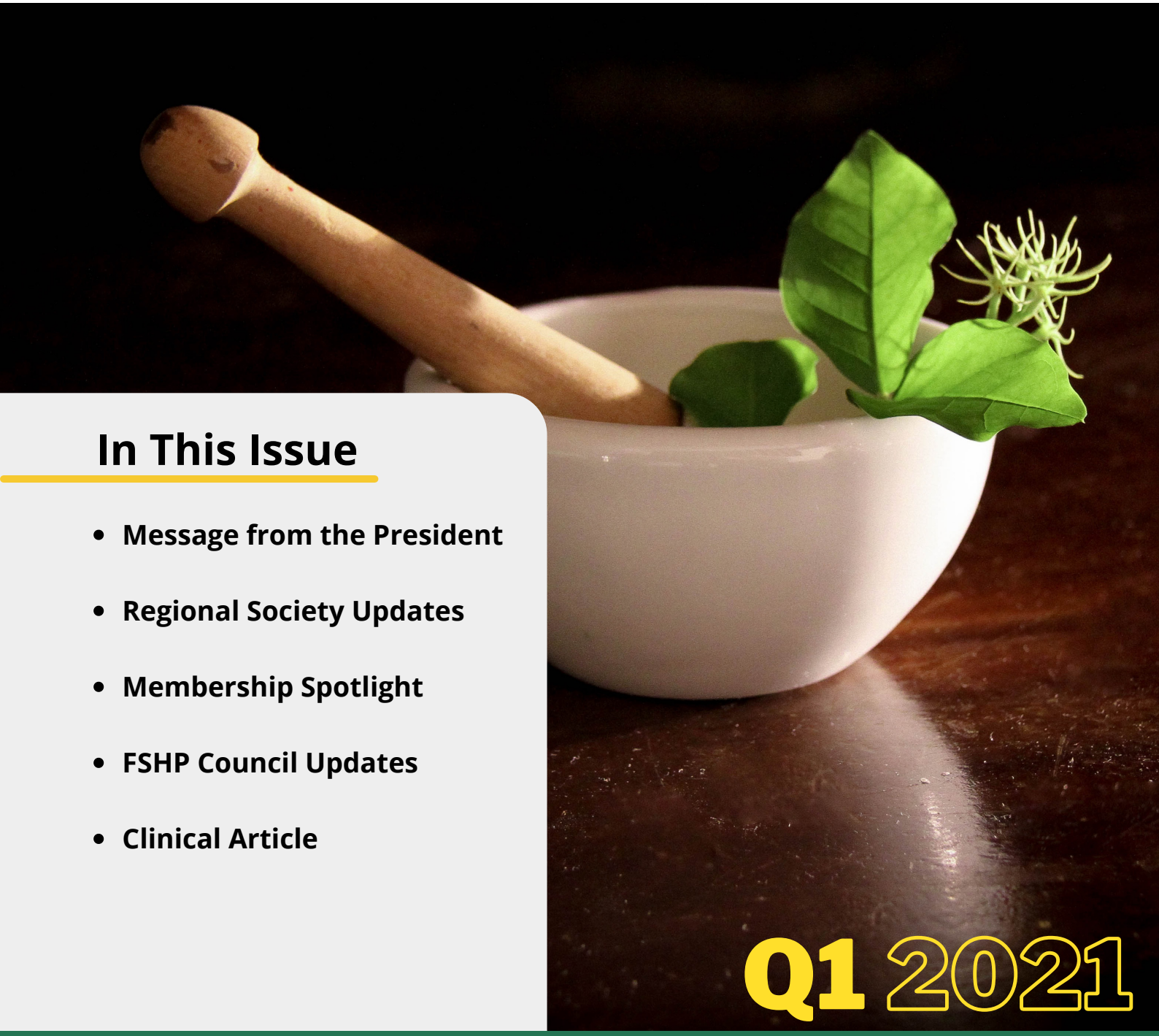
FLORIDA RX TIMES



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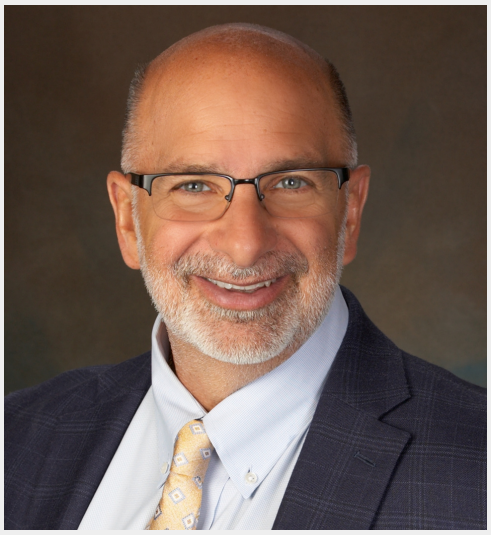
Q1 2021

Quarterly Newsletter from the Florida Society of Health-System Pharmacists (FSHP)

Message from the President



Jeffrey Bush, Pharm.D., CPh
FSHP President

As we maneuver through the first quarter of 2021, our profession continues to be at the forefront of the battle against this pandemic. This first quarter has begun with the release of many medications to fight against the COVID-19 virus through the signing of the Emergency Use Authorization process. This continues to change the footprint of how we practice. We have seen the roll out of now three types of vaccines. The role that pharmacy plays in the administration of the vaccines has been instrumental in the success of vaccinating both healthcare workers, and the most vulnerable population of our communities. There has been an all-out call for all pharmacists and pharmacy interns that are certified to be front and center in our vaccine clinics.

We collaborated with our lobbying firm, Gray Robinson, and the FSHP Legal and Regulatory Affairs Council and participated virtually in Florida Pharmacists Legislative Days on March 9th and 10th. Here are just a few items on our radar: We are tackling both White Bagging and Brown Bagging with the Florida Board of Pharmacy. The Board of Pharmacy will be placing this as an agenda item for the April meeting. We continue to fight for PBM reform. Support for pharmacy technician vaccination administration legislation so that pharmacy technicians can administer vaccines long after the pandemic. Expansion of scope of practice for pharmacists, supporting the HIV Prep/Pep legislation.

We kicked the year off with two virtual Regional Officer training sessions. We had a great turnout with over fifty participants and at least one representative from every Regional Society. Regional Officers are leaders of our Society and they have the direct link to members in their area. Please reach out to your Regional Officers and find out how you can become more involved with the Society. FSHP encourages all who have an interest in Society leadership to think about running for a Regional Officer position, or for those who are currently serving in Regional Officer roles to think about applying for the FSHP Board of Directors. As part of the FSHP Strategic Plan, we have a goal to mentor members and work towards succession planning for leadership roles in FSHP.

Message from the President continued

Our councils continue to be hard at work. The Educational Affairs Council is well underway with planning for this year's in person Annual Meeting. The theme for this year is: A Whole New World: Exploring Uncharted Territory. Our Communications Council continues to impress with this second edition of the FloRxida Times newsletter and their work to increase our Social Media presence, so please FOLLOW, LIKE AND SHARE! Both the Infectious Diseases and Ambulatory Care Forums are gaining interest as they plan to provide resources through their live online communities. The Professional Affairs Council has edited and released the updated Awards, Poster and Fellow criteria, make sure you nominate colleagues, or yourself, for an FSHP Award!

In an effort to keep our members in the know, we are preparing for our second of four Town Hall meetings. The first was well attended and we look forward to you joining us on April 21st at 6:00pm. If you have any ideas, thoughts or feedback please forward them to tamekia@fshp.org
We welcome and appreciate your comments.

In closing, I would like to take this opportunity to thank Tamekia Bennett, FSHP Operations Director, for 21 years of service. Through these 21 years this Society continues to gain strength every year, and much of our success rest solely on the shoulders of Tamekia. Without her dedication and passion, we would not be in the place we are today. So please take a minute and join me and saying… 'Thanks you for all you do!'

Stay safe, and know that I am very proud to be associated with each and every one of you, and honored to represent you as FSHP President.

REGIONAL SOCIETY UPDATES

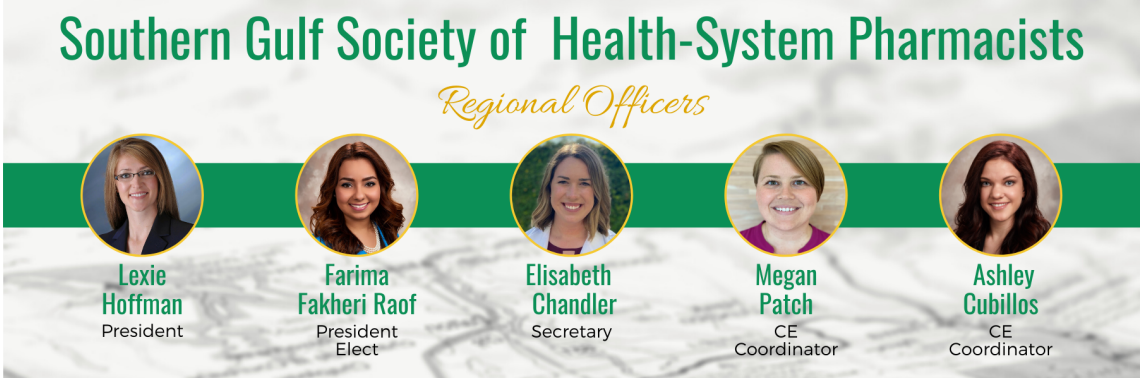
Palm Beach Regional Society

Increased engagement on student and member needs are the focus for the Palm Beach Society this upcoming year. As the President and President Elect are Experiential Directors at NSU and PBA, they have a unique opportunity to reach out to new and different audiences for membership and programming. The first three CE programs of the year have had a COVID focus - mental wellbeing, treatments and managing chronic conditions during a pandemic.

We are planning our annual 6-hour CE June program to include the controlled substance and medication error requirements along with some new topics suggested by our members, diabetes, and transitions of care. Our CE programming is planned remotely for the first half of the year and will resume in person for our September event.

As mentor-mentee events were cancelled in 2020, we are excited to bring this networking event back in October of 2021. We hope to engage P1 through P4 students from Larkin, PBA and NSU as well as preceptors from Miami-Dade, Broward, and Palm Beach. This is something we are looking forward as it's an evening of conversation, education, and fun! We love watching the connections students and pharmacists make which can lead to long lasting mentorship relationships.

REGIONAL SOCIETY UPDATES



Southern Gulf Regional Society

Our Society has always faced challenges in reaching our constituents at live membership and CE events due to the large geographical area we represent. Naples to Port Charlotte is a 75-mile stretch of southwest Florida. Coupled with COVID-19 social distancing practices the 75-mile gap can seem impossible to close. Meeting virtually has become society's new normal platform in everything from office meetings to religious study groups to allow us to remove our masks and be in each other's company screen-to-screen no matter the distance. Perhaps the answer to our Society's problem has been waiting in disguise behind this awful pandemic all along! Thankfully, we decided that virtual socialization and education will allow for the recruitment of members who may have listed distance or health risk as a reason not to participate in the past. What is more, our members will have opportunities to have their knowledge, concerns, and ideas shared locally and statewide through our affiliation with FSHP despite their distance from our meetings.

As such, Southern Gulf had a successful winter Hot Topics Track where we offered 4 hours CE covering Medication Errors, Opioid Stewardship, and Controlled Substance laws and safe practices. The event was offered as a live-virtual hybrid event. Highly solicited, an encore has been scheduled for June in time to meet our September license renewal deadline. Be on the look out for event details and registration link.

Also coming on May 1st is Lee Health's robust resident CE Symposium worth 3 live CE credits. Details TBA.

MEMBER SPOTLIGHT

Christian Calderon, PharmD

Workplace	Putnam Community Medical Center
Location	Palatka, Florida
Fun Fact	EV enthusiast and environmental activist
Alma Mater	University of Florida

Dr. Cauldron graduated from the University of Florida (UF) College of Pharmacy and completed his residency PGY-1 training as the inaugural resident at Putnam Community Medical Center in Palatka, Florida in 2015. He now serves as the Pharmacy Operations Manager and an Informatics Pharmacist for the same hospital. His daily task consists of managing and preparing COVID-19 vaccination clinics, maintaining the MediTech system, and identifying and correcting medication lists and issues. He works with various healthcare disciplines to create new order sets and policies to streamline workflow.

At the age of 16, Dr. Cauldron started his pharmacy career as a pharmacy technician for Walgreens. It was there that he met a pharmacist that inspired him to pursue a career in the field. He then enrolled into UF and had the opportunity to spend three months in Spain working as a student pharmacist thru the UF Global Health Initiative. He is an active member of the Rotary of Palatka where he spearheads initiatives aimed at increasing public health outcomes; the most prominent of which is the "Crush the Crisis" annual health fair where residents of Palatka and the surrounding area are able to receive point of care testing and education about common disease states at no cost. He also serves as the Vice-President of his Gainesville Alumni chapter of Kappa Psi Pharmaceutical Fraternity Inc and president of the NCFSHP.

FSHP COUNCIL UPDATES

Legal & Regulatory Affairs Council

Chair: Kathleen Baldwin, PharmD

Value of Pharmacists Initiative

Lead by Andrea Ledford, Pharm.D.

Many people in the community, our families, and our legislative partners do not understand the role of pharmacists outside the community practice setting. We are asking pharmacists to submit stories showcasing the value of the pharmacist to the interdisciplinary health care team. Our practice settings vary, and so do the patient populations, and disease states that we serve across the state, and we want to showcase this to our legislators.

Our FSHP goal is to create a repository of pharmacist intervention stories in ambulatory care settings. We'd like to create a consultant pharmacist story publication that mirrors our FSHP MTM stories publication: https://cdn.ymaws.com/www.fshp.org/resource/resmgr/l&r/FSHP_MTM_Stories_Booklet.pdf

FSHP will use these stories to educate our legislators and community partners. We need patient medication success stores from across the entire state, including near miss patient safety issues that required pharmacist intervention for resolution from our ambulatory care centers.

An ideal story submission should be:

- 5 sentences or less
- Contain no patient HIPAA information
- Be at a 6th grade reading level (no scientific lingo)
- Be positive and complementary of our health care partner partners.
- Focus on patient outcomes including reduction in 30 days readmission, cost savings, better patient outcomes

Story Example 1:

A cancer patient calls the oncology clinic consultant pharmacist to discuss their new oral chemotherapy medication that the patient began taking at home 2 weeks ago. The patient has begun experiencing diarrhea and rash and this has caused her to miss a day of work. The consultant pharmacist reviews the dosage and works with the oncologist to obtain a dosage reduction.

Outcome: The patient feels better with the new lower dosage and stays on her oral chemotherapy for 9 months. Location: Orlando

FSHP COUNCIL UPDATES

Story Example 2:
A congestive heart failure patient has a follow up consultant pharmacist visit in the clinic. During the visit, the patient complains of feet swelling, coughing, and difficulty breathing. The patient mentions that his prescription bottle of fluid pills spilled down the sink 2 days ago, and he does not have any refills left. The patient wants to know if he should go the emergency room. The consultant pharmacist collaborates with his physician in the clinic, and the patient is given additional refills. The patient is contacted a week later by the pharmacist and feeling much better as the swelling and cough are gone.
Outcome: An emergency room visit is avoided. Location: Daytona Beach
Drop off your stories here: https://www.fshp.org/page/CPA

Consultant Pharmacist Template Initiative
Lead by Paige May, Pharm.D.
Another endeavor is to locate collaborative practice templates used across the country for use in Florida. Since Florida is not the first state to obtain (Consultant) collaborative practice or Collaborative Practice Certification, we have been networking to obtain high quality agreements that can be used in our health systems. Paige May and her team are organizing these templates for placement on our website. More to come.

Here are just a few other highlights from the L & R Affairs Council…

- FSHP Member to Run for House District 5 Representative in 2022. Shane Anderson, BS Pharm and independent pharmacist, wants pharmacists to have a greater voice in legislation.
- If you are interested in learning about Consultant Pharmacist Collaborative Practice Agreements and Collaborative Practice Agreements for Pharmacist Certification for CE, Register Here: https://www.fshp.org/events/EventDetails.aspx?id=1497843

If you missed the previous Legal and Regulatory Affairs update please see the article here: https://www.fshp.org/news/556803/FSHP-Legal--Regulatory-Update--March-2021.htm

The L & R Affairs Council thanks the FSHP membership for their ongoing support in all legislative and regulatory activities and PAC Donations which help us in the legislative process.

FSHP COUNCIL UPDATES

Pharmacy Technician Council

Chair: Tara McNulty

Tara McNulty is a Pharmacy Project Manager III for Envolve Pharmacy Solutions in Tampa FL, focusing on Pharmacy Quality and Clinical Programs since 2012. She started her 25+ year career in pharmacy as a Certified Pharmacy Technician for Eckerd Drugs. In that time, Tara has worked in many diverse settings, which include her expertise in IV chemotherapy, OR anesthesia medication preparation, as well as publisher book reviewer and contributor for technician training materials. She has also been an educator in post-secondary education where she was the Program Director of a Pharmacy Technician program. While in that position, she oversaw the complete revision of the curriculum, procured ASHP accreditation, and grew the student base to over 240 students.

Throughout her career, Tara has continued to be an advocate for the pharmacy profession and the growing roles of pharmacy technicians. She has enjoyed a 12 plus year tenure with Florida Society of Health-System Pharmacists (FSHP) where she helped to increase technician membership to almost 600 technicians and was involved in the development of Technician Education Days, bringing in almost 800 technician attendees. She has served for many years on the Technician Council and House of Delegates and was honored to serve on the FSHP Board of Directors as the technician director. Tara is an active member of ASHP and was elected as an inaugural member of the Pharmacy Technician Executive Committee in 2018 and served as Chair for the 2019/2020 year.

Most recently, Tara was published in the September 2020 edition of the American Journal of Health-System Pharmacy (AJHP) for her collaboration article on addressing the wages, responsibilities, and education of pharmacy technicians. Tara continues her support for pharmacy technician advancement with a goal of focusing her advocacy efforts in having a pharmacy technician serve as a board member on the Florida Board of Pharmacy, in which she is working on with her fellow FSHP council members.

When not working and advocating for pharmacy technicians, Tara is an avid runner that endures long miles in the hot Florida sun. She has run two marathons (New York and Chicago) and countless half marathons.

CLINICAL ARTICLE

Updates on Antithrombotic Therapy for Patients with Atrial Fibrillation Post Percutaneous Coronary Intervention

Marylou Nicolazzo, Pharm.D.

The Treatment Challenge

Atrial fibrillation (afib) is the most common arrhythmia encountered in primary care and affects over 6 million people nationwide. Of these patients, approximately 10% will undergo a percutaneous coronary intervention (PCI) during their lifetime. Afib independently places individuals at increased risk of stroke due to blood pooling and clot formation in the chambers of the heart during prolonged episodes of arrhythmia. Some patients will require lifelong oral anticoagulation therapy based on their annual stroke risk assessment. Similarly, coronary stent placement via PCI requires dual antiplatelet therapy with aspirin and a P2Y12 inhibitor (i.e. clopidogrel, prasugrel, ticagrelor) to prevent stent thrombosis and other coronary complications. It was the previous standard of care to use triple therapy composed of a three-drug regimen of one oral anticoagulant and two oral antiplatelet medications. However, clinical literature now recommends against triple therapy due to increased risk of severe bleeding, morbidity, and mortality.

The advent of the NOAC (non-warfarin oral anticoagulants), which tend to have improved bleeding outcomes, and advancements in stenting technology has necessitated additional research. The question of which combination of antithrombotic agents to use and for how long has been the subject of several clinical trials over the past ten years in an effort to better manage these complicated patients. Current guidelines in both Europe and the United States now suggest a new approach for combination therapy. These new modalities include both time from PCI and tailoring treatment based on an individual's risk for ischemic events weighed against the possibility of having a severe bleed.

Periprocedural Period

Patients who are established on oral anticoagulant therapy will need a washout period prior to elective surgery, typically 24 to 48 hours depending on the medication. When hospitalized, a shorter acting parenteral agent such as unfractionated heparin is most commonly used. Stent types vary between bare metal stents (BMS) which are more quickly endothelialized and drug eluting stents (DES),

which incorporates an anti-proliferative agent and a polymer coating to allow for a slower endothelization process. BMS and early generation DES were associated with an elevated stent thrombosis and myocardial infarction risk during their respective periods of endotheliazation. For BMS, it was observed that the highest risk of early ischemic events occurred in the first 30 days whereas DES (containing either paclitaxel or sirolimus) caused late ischemic events 6 months to 1 year after stenting. Because of this, previous guidelines suggested changing the duration of dual antiplatelet therapy based on the type of stent implanted. Modern DES that contain sophisticated polymer, cobalt-based mesh, and new medications including everolimus and zotarolimus have shown a highly favorable thrombosis profile compared to earlier versions. These new generation DES are the devices of choice and are becoming more prevalent in clinical practice. Because of this, current guidelines do not recommend changing medication therapy or duration based on stent type.

After stenting is completed and the patient has achieved homeostasis, oral anticoagulant therapy can be resumed, and dual antiplatelet therapy can be initiated. The ISAR-TRIPLE trial in 2015 first established the benefits of a shorter duration by comparing 6 weeks of triple therapy to 6 months. The study included the newer generation stents and found that the risk of bleeding and ischemic events was no different between groups.

Current guidelines recommend that triple therapy can be continued during hospitalization for up to one week in the typical patient. This brief period of triple therapy is justified based on the risk of very early stent thrombosis and because additional clinical trials evaluating bleeding outcomes allowed for a variable randomization period that lasted up to 2 weeks. Prior to randomization, patients were typically on triple therapy.

Duration of Antiplatelet Therapy

After discharge from the hospital, oral anticoagulant therapy is continued for cardioembolic stroke prevention. Antiplatelet agent selection and duration of therapy can be variable. For prevention of stent thrombosis in PCI without afib, aspirin and a P2Y12 inhibitor is recommended to be continued for 6 to 12 months followed by lifelong aspirin alone.

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Clinical trials PLATO and TRITON-TIMI suggest that the potent P2Y12 inhibitors prasugrel and ticagrelor have improvements in prevention of cardiovascular mortality compared to clopidogrel. These trials were conducted in patients with acute coronary syndrome (ACS) leading to PCI and there were notably higher bleed rates for the prasugrel group. For patients with afib and PCI, P2Y12 inhibitors are the preferred antiplatelet drug class over aspirin to use in combination with oral anticoagulants. Prasugrel and ticagrelor were used in a very small minority of patients in clinical trials and 90% used clopidogrel. For this reason, although there is evidence supporting ticagrelor and prasugrel in PCI alone, the guidelines only recommend the use of clopidogrel based on limited evidence in the afib/PCI population.

Double therapy was originally evaluated in the 2013 WOEST trial. They found that using a vitamin K antagonist such as warfarin along with a single antiplatelet agent caused significantly fewer bleeding events compared to triple therapy over the course of a year. The duration of double therapy differs depending on if stenting is done emergently due to an ACS or as an elective procedure to facilitate symptom management in stable ischemic heart disease (SIHD).

In ACS, double therapy is continued for 12 months while in SIHD it can be stopped after 6 months. The guidelines emphasize that these durations are flexible and should be based on individual bleeding and ischemia risk. The AFIRE trial, recently published in 2019, evaluated outcomes in patients with afib and PCI due to SIHD, when prolonging double therapy beyond 12 months. Mortality was significantly increased in the group that had prolonged therapy and the trial had to be stopped early. This result strongly supports the recommendation to continue lifelong oral anticoagulant therapy alone without additional antiplatelet agents after one-year post PCI.

The NOAC Trials

Since the WOEST trial, NOACs have become increasingly popular in the United States. With fewer monitoring requirements, drug-drug interactions, and generally improved clinical outcomes, this class of medications are the preferred agents in afib. Between the years 2016 and 2019, rivaroxaban, dabigatran, apixaban, and edoxaban, were each evaluated in its own clinical trial for use in afib post PCI. The PIONEER trial that assessed rivaroxaban was the first to be published and largely set the standard for research design in the subsequent NOAC studies. They compared three groups:

CLINICAL ARTICLE

low-dose rivaroxaban (15 mg) in double therapy, very low-dose rivaroxaban (2.5 mg twice daily) in triple therapy, and standard warfarin in triple therapy. Their primary outcome for bleeding was significantly improved in both groups that used rivaroxaban. However, they were unable to draw conclusions on the efficacy of the therapies because of the low rates of ischemic events and stroke. Based on their estimations, a sample size of over 13,000 patients per group would be required to power a superiority study for efficacy. Similar results were seen in the three remaining NOAC trials where bleed was significantly improved but no study was powered to assess efficacy.

The RE-DUAL trial combined some aspects of the PIONEER trial design with the clinical trial that established dabigatran's efficacy in afib, RE-LY. They compared three groups: dabigatran 150 mg in double therapy, low-dose dabigatran 110 mg in double therapy, and warfarin in triple therapy. In the warfarin group, aspirin was discontinued after 30 days for patients who had BMS and 3 months for DES. Low dose dabigatran was found to be superior to triple therapy for bleed reduction while standard dose dabigatran was non-inferior. However, there were numerically higher instances of MI and stent thrombosis in the low dose group. Comparatively, in the RE-LY trial the higher dose 150 mg was found to have superior stroke reduction over warfarin. Based on the results of these trials together, the guidelines recommend that for typical patients dabigatran 150 mg should be the first line option and 110 mg can be used for patients at a high bleeding risk (HAS-BLED score of at least 3). Aspirin discontinuation in the triple group did not appear to cause increased thrombotic events, paving the way for the next NOAC trial, AUGUSTUS, to further evaluate the effect of aspirin in their trial design.

The AUGUSTUS trial used a 2 by 2 fractional randomization design to compare four groups: apixaban, a P2Y12 inhibitor and aspirin, apixaban, a P2Y12 inhibitor and placebo, warfarin, a P2Y12 inhibitor and aspirin, or warfarin, a P2Y12 inhibitor and placebo. Similarly, to previous trials, they found that apixaban resulted in significantly fewer bleeding events compared to warfarin. The use of aspirin was found to be independently associated with an increased risk of bleeding. This trial supports the guideline recommendations to drop aspirin and to continue double therapy with an oral anticoagulation in combination with a P2Y12 inhibitor.

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The final NOAC trial was ENTRUST AF-PCI which compared standard dose edoxaban 60 mg in double therapy to warfarin triple therapy. The primary outcome, a composite of major and minor bleeding, was found to be non-inferior between groups. Dose reductions in this trial were different compared to the FDA approved doses in afib. In the United States, edoxaban is not recommended for use if renal function exceeds 95 mL/min and the dose should be reduced to 30 mg daily if renal function is between 15 and 50 mL/min. The ENTRUST trial was an international study that included countries in Europe and Asia where the approved doses and reductions are different. The following table summarizes the dose differences between NOACs approved for afib and those studied in afib/PCI.

Medication	Afib		Afib/PCI	
	Standard Dose	Dose Reduction	Standard Dose	Dose Reduction
Rivaroxaban	20 mg daily	CrCl 15-50: 15 mg daily CrCl <15: Avoid use	15 mg daily	CrCl 30-50: 10 mg daily CrCl <30: Not studied
Dabigatran	150 mg twice daily	High bleed risk: 110 mg BID CrCl 15-30: 75 mg twice daily CrCl <15: Avoid use	150 mg twice daily	High bleed risk: 110 mg BID CrCl <30: Not studied
Apixaban	5 mg twice daily	Two of the following: Age > 80, weight < 60 kg, or serum creatinine > 1.5: 2.5 mg twice daily	5 mg twice daily	Two of the following: Age > 80, weight < 60 kg, or serum creatinine > 1.5: 2.5 mg twice daily CrCl <30: Not studied Serum creatinine >2.5: Not studied
Edoxaban	60 mg daily	CrCl >95: Avoid use CrCr 15-50: 30 mg daily CrCl <15: Avoid use	60 mg daily	One of the following: CrCl <50, weight <60 kg, concomitant use of a P-gp inhibitor: 30 mg daily CrCl <15: Not studied

Key Takeaways

Taken together, the recent trials that evaluate NOACs as double therapy show that NOACs are preferred over warfarin for reducing risk of bleeding. While no trial was powered to evaluate ischemic outcomes, stroke rates were similar across groups whereas MI and stent thrombosis tended to be higher in the double therapy groups. Adverse events, which typically included cardiovascular events and mortality, was not significantly different between groups. This seems to indicate that while bleeding risk is reduced, it's effect on mortality is balanced out by the increase in ischemic events. Ultimately, the standard patient should receive triple therapy for up to one week after stenting (regardless of stent type) followed by a period of double therapy that combines a NOAC with clopidogrel for 6 months for SIHD or 12 months for ACS. After double therapy, a NOAC alone should be continued indefinitely. The duration of triple therapy and double therapy must be individually tailored to the individual patient's risk of bleed and thrombosis.

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Thank you to the following council members for your contributions:

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