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ASHP Debuts Practice Advancement Initiative

Initiative Reflects Pharmacists' Roles as Clinicians, Medication Experts, and Key Members of Interprofessional Teams

Angela R. Thomason, Pharm.D., BCPS, Chair of Practice Advancement Initiative (PAI) Subcommittee of Professional Affairs.

ASHP and the ASHP Foundation recently announced the renaming of the former Pharmacy Practice Model Initiative (PPMI) to the Practice Advancement Initiative (PAI). The name change and debut of an updated website reflect pharmacists' expanding patient care roles in both acute and ambulatory care settings as clinical specialists and generalists. It also focuses more broadly on transitions throughout the continuum of care.

"The initiative's new name and focus reflect the comprehensive nature of this national program as well as the rapid evolution of pharmacists' roles in all patient care settings," said ASHP CEO Paul W. Abramowitz, Pharm.D., Sc.D. (Hon.), FASHP.

Since its start in 2010, the former PPMI has been widely embraced by the profession as a framework to advance the vital roles pharmacists play as clinicians and patient care providers. The new PAI combines the outcomes from the 2010 acute-care-focused Pharmacy Practice Model Summit with those of the 2014 Ambulatory Care Summit. PAI will focus on transforming how pharmacists care for and provide clinical services to patients across the continuum of care.

"We're very excited about this expansion of the initiative's focus, and we believe that pharmacists in all care settings will find value in the kinds of resources we offer on the PAI website," said ASHP Foundation CEO Stephen J. Allen, R.Ph., M.S., FASHP.

The initiative's goals include clinical and healthcare team integration, advancing the roles of pharmacists as clinical specialists and generalists, leveraging pharmacy technicians, elevating the issue of pharmacist credentialing and training, and focusing on technology enhancements that can improve patient safety and outcomes.

The new PAI website features tools and resources for acute and ambulatory care practitioners, including the debut of an Ambulatory Care Self-Assessment tool and "Ambulatory Care Pharmacy Progress Measures," which incorporate recommendations from ASHP's 2014 Ambulatory Care Summit.

The Ambulatory Care Self-Assessment tool helps practitioners see how their practices align with Summit recommendations. Once the multi-question assessment is completed, practitioners can

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develop an action plan that will focus on practice priorities that are individualized to their sites. A list of resources to help implement practice change is also provided with the action plan.

The tool, which was developed by an expert panel, is based on the following principles:

- Every practice stands to benefit from adopting the 2014 ASHP Ambulatory Care Summit recommendations.
- This tool will help practitioners in all outpatient healthcare settings. However, its utility will vary based on various factors, such as the institution's size, geographic location, services provided, and available resources.
- The reports that result from use of the Ambulatory Care Self-Assessment Tool are for internal, peer-review purposes only. In some cases, an assessment question might be applicable to multiple planning categories.

In addition to ambulatory care practice tools, the new PAI website includes acute care pharmacy resources such as the newly revised Hospital Self-Assessment tool and "Hospital Pharmacy Progress Measures," which will replace the former National Dashboard. Updates to the fourth edition of the Pharmacy Forecast report are also coming soon.

Opportunities abound for ASHP members to get involved in PAI activities at the national, state, or local practice levels.

At the national level, members can get involved with PAI in a number of ways:

- Join the PAI Connect community, and participate in online discussions of practice issues.
- Serve on ASHP Sections and Section Advisory Groups working on PAI priorities.
- Participate in ASHP Midyear and Summer meetings sessions on PAI/practice advancement.
- Support ASHP's work to enact provider status by contacting their congressional representatives and supporting the work of ASHP's Political Action Committee.

At the state level, members can participate in PAI committees to address high-priority patient care issues as well as participate in state affiliate planning activities for PAI advancement.

At the local level, members can complete either the Hospital Self-Assessment or the Ambulatory Care Self-Assessment tools. They can educate co-workers on PAI and get them engaged. Members can also engage medical professionals with whom they work in talking about the valuable contributions pharmacists make when they are part of the patient care team.

ASHP state affiliates continue to play a major role in PAI. Many states have utilized the former PPMI recommendations and Hospital Self-Assessment tool as jumping-off points to discuss local practice advancement opportunities. The new Ambulatory Care Self-Assessment tool also now provides similar opportunities for affiliates to get involved in the ambulatory care space.

The Hospital Self-Assessment tool will continue to help members and state affiliates create strategic plans and set patient care priorities; reassessments will help measure progress. Other tools and resources on the PAI website and the state affiliate grant program will help support all of these state affiliate efforts.

The Alabama Society of Health-System Pharmacists (ALSHP) was awarded the ASHP and the ASHP Research and Education Foundation grant for 2016. ALSHP is offering a PPMI/PAI workshop with Steve Rough, M.S., RPh, June 6, 2016 at ALSHP's Summer Clinical Meeting at Point Clear, AL. The workshop will focus on Alabama's needs based on the assessments completed by our pharmacy partners. ALSHP highly encourages our members and non-members to complete both on-line assessments (Ambulatory and Hospital Self-Assessments) before the Summer Meeting. Following the workshop, the ALSHP will accept proposals for up to $2,000 seed grant money to support practice advancement programs in the state of Alabama.

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The SPRINT Study: Will it Prompt Changes in Current Hypertension Guidelines?

William J. Boland, Pharm.D. Candidate 2016, Katelin M. Lisenby, Pharm.D., BCPS
Auburn University Harrison School of Pharmacy

A recently published trial conducted by the National Institutes of Health may soon have a significant impact on the systolic blood pressure (SBP) target recommended by current blood pressure guidelines. At present, the Eighth Joint National Committee (JNC-8) and American Society of Hypertension (ASH) guidelines for the management of high blood pressure each recommend a SBP goal of <140 mmHg for the general population; however, the age at which this goal is recommended differs between the two guidelines. The JNC-8 recommends a SBP goal of <140 mmHg for those in the general population less than 60 years of age, while ASH recommends this goal for those less than 80 years of age.[1,2] There has been some clinical debate in regard to the benefit of treatment with lower blood pressure targets, but high quality data on the subject is limited. A previously published large, randomized, controlled trial (Action to Control Cardiovascular Risk in Diabetes [ACCORD]) investigated whether therapy targeting a SBP of <120 mmHg in patients with type 2 diabetes mellitus would reduce major cardiovascular events and failed to show a significant difference in cardiovascular outcomes. However, the ACCORD trial may have been underpowered due to multiple arms and lower than expected event rates.[3]

The Systolic Blood Pressure Intervention Trial (SPRINT) was a multicenter, randomized, controlled, open-label trial designed to test the hypothesis that a lower SBP goal (<120 mmHg) would reduce clinical events more than the current standard goal of <140 mmHg. The SPRINT study included patients of ≥50 years of age with a SBP of 130-180 mmHg and at an increased risk of cardiovascular events (i.e. clinical or subclinical cardiovascular disease [CVD], chronic kidney disease [CKD], Framingham estimated 10-year risk of CVD of ≥15%, or age of ≥75 years). The trial did not include patients with a prior stroke or diabetes. The primary outcome of SPRINT was a composite of myocardial infarction (MI), acute coronary syndrome not resulting in MI, stroke, acute decompensated heart failure, or death from cardiovascular causes. Secondary outcomes consisted of the individual components of the primary outcome, death from any cause, a composite of the primary outcome or death from any cause, and renal outcomes in patients with and without CKD.[4]

The SPRINT study consisted of a total of 9361 eligible participants, who were randomized into either the standard-treatment group (SBP target of <140 mmHg) or the intensive-treatment group (SBP target of <120 mmHg). Antihypertensive medications from all major classes were provided at no cost to the participants, and the protocol suggested the use of medication classes with the best evidence for reduction in cardiovascular outcomes (e.g. thiazide-type diuretics, loop diuretics in patients with CKD, and beta-adrenergic blockers in patients with coronary artery disease). The protocol also encouraged lifestyle modifications. The trial was designed to last for five years, during which patients were seen monthly for the first three months and then every three months for the remainder of the study. [4]

Baseline characteristics among the participants in the study were similar between the two treatment groups. The majority of patients were white males of nearly 68 years of age with a baseline blood pressure of approximately 140/78 mmHg. About 61% of patients had a Framingham estimated 10-year risk of CVD of ≥15%, around 28% had CKD, and 20% had CVD. The percentage of patients receiving statin therapy was similar between the intensive-treatment group and standard-treatment group (42.6% and 44.7 % respectively) and approximately half of patients were receiving aspirin therapy (51.6% and 50.4%, respectively). The majority of patients were using antihypertensive agents (mean of 1.8 agents per patient) at baseline.[4]

Although the study was planned to last five years, the trial was stopped early due to a significantly lower rate of the primary outcome seen in the intensive-treatment group; the median duration of follow-up was 3.26 years. During this follow-up period, the mean SBP was 121.5 mmHg in the intensive-treatment group and 134.6 mmHg in the standard-treatment group.[4] On average, the intensive-treatment group was receiving one additional antihypertensive medication than the

standard-treatment group (2.8 vs. 1.8 agents). A significant difference was seen in the primary outcome of first occurrence of MI, acute coronary syndrome not resulting in MI, stroke, acute decompensated heart failure, or death from cardiovascular causes between the intensive-treatment group and the standard-treatment group (5.2% vs. 6.8%; HR, 0.75; 95% CI, 0.64 to 0.89; P<0.001). The number of patients needed to treat in order to prevent one primary outcome was 63, and the primary outcome results were consistent amongst all prespecifed subgroups, including those ≥75 years of age. Significant differences between the two treatment groups were also seen in terms of the risk of heart failure, death from cardiovascular causes, and death from any cause in favor of the intensive-treatment group (Table 1). There was no difference in renal outcomes in participants with CKD, but a decrease of 30% or more in the eGFR to a value of less than 60 mL/min/1.73 m^2 occurred more frequently in the intensive-treatment group in those without CKD at baseline (3.8% vs. 1.1%; HR, 3.49; 95% CI, 2.44-5.10; P<0.001). The intensive-treatment group was also more prone to adverse events, such as hypotension, electrolyte abnormalities, and acute kidney injury or failure; although, no significant difference was seen in serious adverse events between the treatment groups (Table 2).[4]

Overall, the SPRINT study was well designed and appeared to have few limitations. The trial consisted of a large, diverse patient population, and while the trial was open-label, an independent data and safety monitoring board was used to monitor both trial results and safety events in an attempt to prevent bias. Limitations of the study included the exclusion of older adults residing in assisted-living facilities and nursing homes, a lower than expected number of patients receiving statin therapy, and the early termination of the trial, which may have resulted in an overestimation of the degree of treatment effect.[4]

The results of SPRINT are promising in terms of reducing cardiovascular events with more intensive control of SBP than recommended by the JNC-8 and the ASH guidelines. However, several factors should be considered in regards to application to patient care. First, only participants ≥ 50 years of age at high risk for cardiovascular events were included and those with diabetes or a history of stroke were excluded. While the results in respect to the primary outcome and several secondary outcomes seem clinically significant, the risks of more intensive therapy were not absent and blood pressure targets should be individualized based on patient specific factors. The higher incidence of acute kidney injury or failure seen in the intensive-treatment group is concerning and, along with potential causes, should be further explored in future studies. Additionally, the effects of a more intensive SBP target on cognition and dementia from SPRINT are still being explored and await publication.[4] The data obtained from SPRINT may trigger changes to SBP recommendations in upcoming renditions of hypertension guidelines, especially in older patients at increased risk for cardiovascular events.

Table 1:

Primary and Secondary Outcomes					
Outcome	Intensive-Treatment (N=4678)	Standard-Treatment (N=4683)	Hazard Ratio (95% confidence interval)	P value	NNT¶
Primary Outcome*	243 (5.2)	319 (6.8)	0.75 (0.64-0.89)	<0.001	63
Secondary Outcomes					
Myocardial infarction	97 (2.1)	116 (2.5)	0.83 (0.64–1.09)	0.19	-
Acute coronary syndrome	40 (0.9)	40 (0.9)	1.00 (0.64–1.55)	0.99	-
Stroke	62 (1.3)	70 (1.5)	0.89 (0.63–1.25)	0.50	-
Heart failure	62 (1.3)	100 (2.1)	0.62 (0.45–0.84)	0.002	125
Death from cardiovascular causes	37 (0.8)	65 (1.4)	0.57 (0.38–0.85)	0.005	167
Death from any cause	155 (3.3)	210 (4.5)	0.73 (0.60–0.90)	0.003	84
Primary outcome or death	332 (7.1)	423 (9.0)	0.78 (0.67–0.90)	<0.001	53

*First occurrence of myocardial infarction, acute coronary syndrome, stroke, heart failure, or death from cardiovascular causes.
¶Number needed to treat

Table 2:

Adverse Events					
Event	Intensive-Treatment (N=4678)	Standard-Treatment (N=4683)	Hazard Ratio	P value	NNH¶
Serious Adverse Event*	1793 (38.3)	1736 (37.1)	1.04	0.25	-
Conditions of Interest					
Hypotension	110 (2.4)	66 (1.4)	1.67	0.001	100
Syncope	107 (2.3)	80 (1.7)	1.33	0.05	-
Bradycardia	87 (1.9)	73 (1.6)	1.19	0.28	-
Electrolyte abnormality	144 (3.1)	107 (2.3)	1.35	0.02	125
Injurious fall	105 (2.2)	110 (2.3)	0.95	0.71	-
Acute kidney injury	193 (4.1)	117 (2.5)	1.66	<0.001	63

*Defined as event that was fatal or life-threatening, that resulted in clinically significant or persistent disability, that required or prolonged a hospitalization, or that was judged by the investigator to represent a clinically significant hazard or harm to the participant that might require medical or surgical intervention to prevent one of the other events listed above.
¶Number needed to harm

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Drug Information Questions: Summary Table

QUESTION	SUMMARY
What data is available for the use of specific antidepressant therapy in stroke patients? Is there evidence for the use of specific antidepressants for patients with focal motor deficit vs. patients with sensory deficit?	Based on evidence from numerous clinical trials, SSRIs appear to be an effective antidepressant class for treatment of depression in stroke patients. Escitalopram and fluoxetine seem to have the most benefit in stroke patients with sensory deficits. Sertraline improves sensory deficits as well as motor performance. Although SSRIs are associated with a low risk of new cardiovascular events, they are associated with increased bleeding risk; therefore, close monitoring is needed when SSRIs are prescribed to stroke patients. Of the common SSRIs featured in the studies, fluoxetine has been shown to have the highest risk of bleeding, therefore recurrent stroke risk. Based on the evidence from the studies, all SSRIs have the potential of increasing the risk of a recurrent stroke. Although the overall risk versus benefit supports their use in stroke patients with depressive symptoms, it is unclear whether their use is justified in non-depressed patients for improvement of motor and sensory deficits.
Can a patient with a neomycin allergy receive the Zostavax® vaccine?	As long as the reaction to neomycin in question was a case of contact dermatitis then the zoster vaccination is not contraindicated. There is risk only if the patient experienced a previous anaphylactic reaction to neomycin.

Drug Information Question: Preferred Antidepressants in Patients with Stroke?

Kelsey Douglas, Pharm.D. Candidate 2016
Bernie R. Olin, Pharm.D., Associate Clinical Professor and Director, Drug Information
Auburn University, Harrison School of Pharmacy

Question: What data is available for the use of specific antidepressant therapy in stroke patients? Is there good evidence for the use of a specific antidepressant for patients with focal motor deficit vs. patients with sensory deficit?

Background: When a stroke occurs, typically brain cells die, thus the ability to control areas such as sensory and/or motor movements may become lost. The requestor inquires about data for the use of specific antidepressants for treatment of depression in stroke patients, as well as if there is evidence for the use of antidepressants for motor versus sensory deficits in stroke patients with or without depression.

Response: Research strategy involved first searching Google Scholar and PubMed. Bibliographies were also utilized. Specific search terms used included antidepressants, stroke, focal motor deficit, and sensory deficit. During research, it was evident that selective serotonin reuptake inhibitors (SSRIs) are commonly used in stroke patients, therefore SSRIs were included in the search terminology.

Depression is a frequently occurring psychiatric condition, affecting nearly half of stroke patients. Depression in poststroke patients negatively affects physical and cognitive recovery, as well as overall survival rates. In poststroke depression, antidepressant therapy is recommended, although the guidelines are not specific as to which particular class should be used. Evidence has suggested that the use of antidepressants, including selective serotonin reuptake inhibitors (SSRIs), tricyclic antidepressants (TCAs), and others, may increase the risk of stroke while other studies have concluded otherwise.[1]

In a large observational case-control study of 19,825 patients surviving a first time stroke, a 41% increase in recurrent stroke for patients with any use of TCAs was observed. Conversely, the study found the use of SSRIs and other antidepressants did not carry the risk.[1] The case-control study did not find an increased risk of bleeding events, including hemorrhagic stroke from SSRIs.[1] The SSRIs used in the study were fluoxetine, sertraline, paroxetine, and citalopram, with fluoxetine having the highest risk (0.7%) and citalopram having the lowest risk (0.4%) of recurrent stroke.[1]

Another study investigating the risk of recurrent stroke associated with SSRIs only found similar results.[2] In a large propensity score-matched population-based follow-up study, SSRI treatment post stroke was associated with lower risk of myocardial infarction (MI) and recurrent ischemic stroke.[2] Although the use of SSRIs were found to carry a significant low risk of stroke, SSRI use was found to be associated with higher risk of major bleedings and death. The increased risk of bleeding with SSRIs is likely due to inhibition of platelet aggregation.[2] Additional research is warranted to ensure optimal patient selection and monitoring of treatment.[2] This study did not define which SSRIs were studied.

There is growing evidence that SSRIs produce neuroplastic changes in the hippocampus, the center of learning, emotion and memory, as well as the cerebral cortex, partially responsible for voluntary muscle movement.[3,4] One study observed increases in proliferation of neuronal precursors in the subgranular zone of the dentate gyrus in the hippocampus in stroke patients with the use of fluoxetine.[4] This suggests that SSRIs may be useful in stroke patients who suffer from motor and sensory losses.

One randomized, double-blind placebo-controlled comparison trial examined the effect of escitalopram (an SSRI) on cognitive outcomes in 120 patients with a history of stroke. The trial concluded that there was improvement in cognitive functioning, specifically in verbal and visual memory function in patients who received escitalopram.[3] Escitalopram was found to be well tolerated, and the frequency of adverse events was not different than that observed in patients receiving placebo.[3]

Fluoxetine has been shown to restore cortical plasticity in the visual system of adult rats, aiding in the recovery of visual function, a sensory function often affected by stroke.[3,5] Sertraline also appears to enhance plastic

changes in the visual cortex.[3,6] Furthermore, sertraline may prevent brain atrophy, improve motor performance, and delay mortality.[3,7] This evidence provides more support for the efficacy of SSRIs in stroke patients.

Based on evidence from numerous clinical trials, SSRIs appear to be an effective antidepressant class for treatment of depression in stroke patients. Escitalopram and fluoxetine seem to have the most benefit in stroke patients with sensory deficits. Sertraline improves sensory deficits as well as motor performance. Although SSRIs are associated with a low risk of new cardiovascular events, they are associated with increased bleeding risk; therefore, close monitoring is needed when SSRIs are prescribed to stroke patients. Of the common SSRIs featured in the studies, fluoxetine has been shown to have the highest risk of bleeding, therefore recurrent stroke risk. Based on the evidence from the studies, all SSRIs have the potential of increasing the risk of a recurrent stroke. Although the overall risk versus benefit supports their use in stroke patients with depressive symptoms, it is unclear whether their use is justified in non-depressed patients for improvement of motor and sensory deficits.

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Drug Information Question: Does neomycin allergy contraindicate receiving neomycin-containing vaccines?

Keith Dasinger, Pharm.D. Candidate 2016
Bernie R. Olin, Pharm.D., Associate Clinical Professor and Director, Drug Information
Auburn University, Harrison School of Pharmacy

Question: Can a patient with a neomycin allergy receive the Zostavax® vaccine?

Background: The patient had a dermatologic reaction in the past that was thought to be due to topical neomycin. The Zostavax® vaccine contains neomycin.

Response: In addition to searching general drug references (CDC.gov, Facts and Comparisons, and Zostavax® [zoster vaccine live] package insert) a primary literature search was done using PubMed. No date limitations were applied. Search terms included Zostavax®, zoster vaccine, neomycin allergy, and hypersensitivity.

Neomycin is an antibiotic that binds to bacterial ribosomes responsible for protein synthesis.[1,2] It is present in the herpes zoster vaccine to prevent bacterial contamination in the manufacturing process.[2] According to the North American Contact Dermatitis Group neomycin is the 3rd most prevalent allergen that manifests as a delayed-type contact dermatitis.[2] Furthermore, contact dermatitis from neomycin is not considered to be a contraindication to immunization with neomycin-containing vaccines.[2,3,5]

In the case of an anaphylactoid reaction attributed to neomycin (in any form), its use is contraindicated and should NOT be given to those individuals.[1,4]

In summary, if the reaction to neomycin in question was a case of contact dermatitis then the zoster vaccination is not contraindicated. There is risk only if the patient experienced a previous anaphylactic reaction to neomycin.

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Submission Guidelines for ALSHP's *InPharmative Quarterly Clinical e-Journal* Publication

The *InPharmative Quarterly Clinical e-Journal* publication provides a forum for communication of relevant information for the practice of pharmacy. The publication encourages manuscripts from pharmacists, non-pharmacist in a pharmacy setting or academia, residents, and students. Types of contributions including original research papers, reviews, program descriptions, and short descriptions of clinical controversies or patient cases. The journal encourages new authors to submit manuscripts, and foster engagement in sharing of expertise.

To ensure that only accurate and substantive articles are included, all manuscripts require an editorial approval prior to acceptance. Submission of a paper to *InPharmative Quarterly clinical e-Journal* publication will be taken to imply that it represents original work not previously published, that it is not being considered elsewhere for publication, and that if accepted for publication it will not be published elsewhere in the same form without the consent of the editors.

Types of Contributions

The journal will publish the following types of communications:

Research papers

Research articles describe experimental or observational investigations that used formal methods for data collection and reporting of results of studies related to pharmacy practice (maximum 2000 words).

Reviews

Reviews are comprehensive, well-referenced descriptive papers on topics directly related to the practice of pharmacy such as new drug updates, disease state reviews or change in practice (maximum 2000 words).

Program Descriptions and Legislative Updates

Program descriptions are descriptive papers outlining specific programs or service descriptions, upgrades and software changes, administrative items, and medication safety issues. To help promote practice development and progress, practice site descriptions and successful strategies implemented are very valuable as the role of pharmacy continues to grow in our state. Legislative updates are also welcomed to help keep members informed of changes affecting pharmacy practice. (maximum 1000 words)

Short descriptions of clinical controversies or patient cases

Short descriptions of controversies or clinical pearls related to pharmacy practice. In addition, authors may submit patient cases with a review section about the problem and solution. (maximum 500 words)

Manuscript Organization

Manuscripts should include title of the article, name of author or authors with credentials, title and institution followed by the body of the manuscript, references, tables and/or figures. References should be cited according to the AMA 10th edition. The telephone and valid e-mail of all authors should be included with an indication of the corresponding author who will check proofs and receive correspondence.

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