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Call for Articles

The editors of *Pharmascript* are seeking articles related to ASHP recommended Practice Advancement Initiatives, student or resident research, MSHP committee updates, new drug updates and clinical reviews. Interested writers are encouraged to submit articles as a clinical review (1,000 words), a research project manuscript (2,000 words), or a new drug update (250 words). Other article topics will be considered. Articles should be submitted to Michael Armahizer at <u>michaelarmahizer@umm.edu</u> by December 16th, 2016 to be published in the January edition of MSHP's *Pharmascript*. See the newsletter deadlines in this edition for subsequent issues.

Call for Editors

The editors of *Pharmascript* are seeking content reviewers for upcoming editions. Interested Pharmacists and Residents contact Michael Armahizer at <u>michaelarmahizer@umm.edu</u>. Reviewers should note specific areas of expertise or interest in their communications.

Medication Safety Corner:

ISMP Best Practices Update

Agnes Ann Feemster, PharmD, BCPS Assistant Dean, Experiential Learning Program University of Maryland School of Pharmacy Medication Safety Officer for Oncology at the Johns Hopkins Hospital

The Institute for Safe Medication Practices (ISMP) recently released the "2016-2017 Targeted Medication Safety Best Practices for Hospitals." This version includes revisions to two existing best practices and incorporates five more recommendations to reduce errors in hospitalized patients. ISMP encourages concentration on the first six recommendations before moving on to the new best practices. The first six best practices are consistent with the 2014-2015 best practices guidelines.

Important revisions of the 2014-2015 best practices were made to the two practices involving oral methotrexate (Best Practice 2) and patient weights (Best Practice 3). Previous guidelines required hard stop verification of an appropriate oncologic indication for all daily oral methotrexate orders. This recommendation is still in effect,

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but this year's update to Best Practice 2 contains two clarifications. Because some electronic order entry systems currently do not allow hard stops, the revised description states that clinicians must clarify all daily orders for methotrexate for patients with no documented oncologic diagnosis and should work with the software vendor to implement this critical feature. Another revision to Best Practice 2 involves patient education. Given that education for patients discharged on oral methotrexate can be effectively provided by a nurse, pharmacist, or physician, the second best practice no longer limits this function to a pharmacist. This revised best practice also extends the need for education to all oral methotrexate discharge orders and is not limited to weekly orders. The third best practice states that patients should be weighed as soon as possible rather than using a stated, estimated, or historical weight. Use of the metric system to measure and document weight is a continued recommendation.

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The following five additional best practices are suggested to promote patient safety in hospitals:

1. Segregate, sequester, and differentiate all neuromuscular blocking agents (NMBs) from other medications, wherever they are stored in the organization. NMBs should be secured in patient care areas and labeled with "Warning: Paralyzing Agent- Causes Respiratory Arrest."

2. Administer high-alert intravenous (IV) medication infusions through a programmable infusion pump using dose error-reduction software. This practice applies to inpatient and outpatient hospital settings and in all situations in which high-alert medications are infused by the IV route, including anesthesia use and patient-controlled analgesia.

Additionally, health systems should:

- Ensure that dose error-reduction software is employed on all smart pumps.
- Verify that drug libraries are built and installed and ensure staff is using the error-reduction software.
- Require periodic maintenance, updating, and testing of the software.
- Evaluate alerts regularly.

3. Ensure all appropriate antidotes, reversal agents, and rescue agents are readily available. Furthermore, standardized protocols and directions for use and administration should be easily accessible in all clinical areas where these agents are used.

4. Eliminate 1000-mL bags of sterile water labeled for injection, irrigation, and inhalation from all areas outside of the pharmacy. Instead, health-system pharmacists should use alternatives in patient care areas, such as two liter bags or vials.

5. When compounding sterile preparations, perform an independent verification to ensure that the proper ingredients are added, including confirmation of the proper volume of each ingredient prior to its addition to the final container. Proxy methods (e.g., the "syringe pull back method") of verification for compounded sterile medication preparations should be eliminated.

At a minimum, health-system pharmacists should ensure that ingredients are confirmed prior to addition to the final container for:

- All high-alert medications, such as chemotherapy and parenteral nutrition
- All pediatric and neonatal preparations
- Pharmacy-prepared source and bulk containers
- Drugs administered through high-risk routes of administration, including intrathecal, epidural, and intraocular.

For more information, please see the following link: <u>http://www.ismp.org/tools/bestpractices/TMSBP-for-hospitals.pdf</u>.

Acknowledgements and Awards

MSHP Preceptor of the Year Award

Dr. Melinda Ortmann was honored as the 2016 MSHP Preceptor of the Year.

Medication Safety Award

Dr. Emily Heil will receive the 2016 MSHP Medication Safety Award for her work on the Implementation of an Infectious Disease Fellow Led Penicillin Allergy Testing Consult Service.

Purdum Award Announcement

Dr. Jill Morgan is the 2016 MSHP W. Arthur Purdum Award recipient.

MSHP awards will be presented during the MSHP Awards and Medication Safety CE Dinner on November 17th.



Student Leadership Update Developing Pharmacy Leaders: Student Leadership Workshop

Denise Fu, PharmD, BCACP Clinical Programs Manager, Johns Hopkins Outpatient Pharmacy

Sujin Lee Weinstein, PharmD, BCPP Clinical Pharmacist, Psychiatry, the Johns Hopkins Hospital

For the second year, pharmacy students gathered at MedStar Harbor Hospital in Baltimore, Maryland to attend the Student Leadership Workshop sponsored by The Johns Hopkins Hospital in conjunction with the Maryland Society of Health-System Pharmacists.

The all-day program included presentations by local pharmacist leaders listed below and certified Gallup StrengthsFinder coach, Lana Hailemariam.

- Bonnie Levin, Pharm.D., M.B.A., Corporate Assistant Vice President, Pharmacy Services, MedStar Health
- Joseph Mattingly, Pharm.D., M.B.A., Assistant Professor, University of Maryland School of Pharmacy
- Brent N. Reed, Pharm.D., BCPS-AQ Cardiology, FAHA, Assistant Professor, University of Maryland School of Pharmacy
- William H. Vanderpool, M.S., R.Ph., Director of Pharmacy, MedStar Harbor Hospital
- Hannah Vanderpool, Pharm.D., M.A., Vice President, Member Relations, American Society of Health-System Pharmacists

In the morning, students learned about methods for staying active as leaders within the profession as they continue through their training and as new graduates from Drs. Reed and Mattingly. Mr. and Dr. Vanderpool presented on striving towards work-life balance. Additionally, students had the opportunity to share their own individual leadership activities in a collaborative poster presentation and identify opportunities to develop new pharmacy programs to take back to their respective schools. The speakers above and Pharmacy Leadership Group, which consists of Directors of Pharmacy from the area who were attending their own annual meeting, were invited to lunch with the students to promote networking. The afternoon session was led by Ms. Hailemariam, who taught students how to focus on and utilize their strengths as they progress through their career.

Students enjoyed the event, commenting "The speakers were excellent and made me really think about changes I could implement in my own schedule". "I thought the speakers were incredibly engaging and the topics were extremely relevant".

For more information about next year's program, please check back in the spring of 2017.



Participants of the Student Leadership Workshop pose for a group photo



Summer intern Shannon Parkey presents her poster to University of Maryland student Zemen Habtemariam and discuss methods to fundraise.





Husband and wife team, Mr. and Dr. Vanderpool share their experiences with work-life balance.



Students listen intently to Dr. Levin during her welcome.



Drs. Reed and Mattingly grab the attention of the students during their presentation.



Renewal Reminder

Individual members of MSHP are reminded to renew their memberships. Membership includes weekly updates, *Pharmascript* subscription (4 issues / year), discounts on MSHP programming, access to the MSHP online community, opportunities to volunteer on MSHP committees and more!



Residency Spotlight

Creating an Investigational Drug Services Residency

Molly Wascher, PharmD PGY2 Health-System Pharmacy Administration Resident at Johns Hopkins Hospital

Background

The Investigational Drug Services (IDS) are responsible for supporting clinical trial research and contributing to the institutional strategic priority to provide high quality care to patients enrolled in clinical trials. Pharmacists and pharmacy technicians play a vital role in clinical research; roles include assistance with protocol development, management and preparation of investigational products, monitoring clinical parameters for both standard of care and research, patient education and medication adherence monitoring, facilitation of electronic order set development and maintenance, and Institutional Review Board (IRB) membership and regulatory compliance.^{1,2} As described in the Food and Drug Administration's (FDA) statement on the 21st Century Cures Act³, clinical trials continue to increase in complexity and diversity. This presents an opportunity for the advancement of pharmacy practice in the area of Investigational Drug Services (IDS). IDS pharmacy practitioners have increasing direct patient care responsibilities to meet the needs of the patients and to assure that all patients receive the same high quality standards of care.

Currently, there are no specialty residency training programs focused in IDS. Only a small proportion of pharmacy students have access to training in IDS via limited classroom instruction and the elective nature of an IDS advanced practice experience. The goal of the IDS residency is to meet the increasing need for expertise in this specialty area of practice akin to that seen with other newly developed residency training programs such as informatics and pain and palliative care. This new residency-training program will meet the needs of an evolving area of the profession of pharmacy.

Development Process: Utilization of an Expert Panel

As part of the residency development process, a multi-disciplinary expert panel was recruited consisting of 22 members both internal and external to the institution. Internal representation consisted of research leadership, pharmacy leadership, principal investigators, and regulatory expertise, in addition to IDS pharmacists. External representation included key stakeholders in clinical research; the National Institutes of Health (NIH) including the National Cancer Institute (NCI), FDA, a life-sciences company, and IDS leadership from an outside institution. The panel met for a one day meeting on January 11th, 2016. The majority of the day's discussion concentrated on four proposed residency competency areas; (1) patient care, (2) research protocols and regulations, (3) leadership and management, and (4) teaching, education, and dissemination of knowledge.

The overall outcome of the meeting was an overwhelming support for the development of an IDS focused residency program. There was also strong support for developing a resident with the knowledge and skills necessary for expanding IDS roles and responsibilities. The discussion at the meeting provided valuable information to support the development of the PGY2 IDS Competency Areas, Goals, and Objectives.

Residency Program Structure

The IDS Residency will be a combined PGY1 and PGY2 program where the resident will receive a PGY1 Pharmacy certificate and a PGY2 IDS certificate. Below are the PGY2 Investigational Drug Services Rotations Offered:



Core rotations

- IDS Operations Rotations (2)
- Clinical Research Office
- Johns Hopkins Office of Human Subjects Research
- Drug Development (2)
- Longitudinal Outpatient clinic
- Patient Care Team (ex: Hematologic Malignancy service, HIV Service, or Pediatric Oncology)
- IDS Leadership and Management
- Research Medication Safety and Clinical Decision Support

Elective rotations

- FDA: Office of Clinical Pharmacology
- NIH: National Cancer Institute, Pharmaceutical Management Branch
- Drug manufacturer: Pharmaceutical Industry, Drug Discovery and Development

Application Process:

Upon completion, the resident will be prepared for a position as an IDS pharmacist or other opportunities within clinical research. For interested candidates, participation in Personnel Placement Service at the Midyear Clinical Meeting is recommended. Candidates interested in the program should apply online through the Pharmacy Online Residency Centralized Application Services (PhORCAS), deadline is January 1st, 2017. For additional information about our pharmacy residency programs, please visit our website at http://www.hopkinsmedicine.org/pharmacy/residents/.

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- 1. ASHP guidelines on clinical drug research. Am J Health-Syst Pharm. 1998; 55: 369-76.
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- 3. Woodcock J. 21st century cures: modernizing clinical trials and incorporating the patient perspective. FDA. July 2014.

Upcoming Events and Continuing Education Opportunities

MSHP Fall Seminar – Friday, October 14, 2016 at the Hilton Baltimore. Registration is available until October 14, 2016. <u>Register Here!</u>

Fall Residency Showcase – Saturday, October 15, 2016 at the Johns Hopkins Asthma and Allergy Clinic. Registration is available until Saturday, October 8, 2016. The event is free of charge for student members of MSHP and \$10 for non-member students. <u>Register Here!</u>

Maryland Society for Parenteral and Enteral Nutrition (MSPEN) CEU Opportunity – Thursday, October 6, 2016 at the Hotel at Arundel Preserve from 5:30-8:30 pm. For more information, please visit the <u>MSPEN Flyer</u> in the <u>ASPEN Calendar of Events</u>. <u>Register Here!</u>

Technician CE and Networking Event – Saturday, October 15, 2016 at the Johns Hopkins Bayview Asthma and Allergy Center. <u>Register Here!</u>



New Drug Update

New Drug Update: Pimavanserin (Nuplazid™)

Brenna Baals, PharmD Candidate 2017, Shenandoah University Bernard J. Dunn School of Pharmacy Kathryn Dane, PharmD, PGY-2 Pharmacotherapy Resident, the Johns Hopkins Hospital Sujin Weinstein, PharmD, BCPP, Clinical Pharmacist, the Johns Hopkins Hospital

In April 2016, the Food and Drug Administration (FDA) approved pimavanserin (NuplazidTM), an atypical antipsychotic indicated for the treatment of hallucinations and delusions in Parkinson's disease psychosis (PDP).¹ Although motor symptoms in Parkinson's disease remain the primary focus of therapy, non-motor symptoms have been reported in at least 60% of patients, and often require medication management.² Prior to the FDA approval of pimavanserin, therapeutic options targeting PDP symptoms included clozapine, olanzapine, quetiapine, and risperidone, the use of which are limited by variable therapeutic benefits and prevalent adverse effects.³ Unlike other currently available antipsychotic agents, pimavanserin exerts its therapeutic effects via inverse agonism at serotonin-2A (5HT2A) receptors.⁴ This unique mechanism effectively alleviates psychotic symptoms, and results in a favorable adverse effect profile. Pimavanserin lacks significant activity at receptors responsible for the orthostatic, anticholinergic, sedating, and extrapyramidal effects characteristic of the antipsychotic class.⁴ Additionally, pimavanserin administration is devoid of the monitoring requirements and access challenges associated with clozapine use.⁴

The efficacy and safety of pimavanserin were evaluated in a six-week, multi-center, randomized, double- blind, placebo-controlled trial. Patients were eligible to participate if they had been diagnosed with Parkinson's disease at least one year prior to study entry and experienced sustained hallucinations and/or delusions.⁵ Patients were randomly assigned to treatment with pimavanserin 34 mg daily (n = 95) or placebo (n = 90). The primary outcome was the change in key symptoms of PDP from baseline to day 43, as measured by the Scale for Assessment of Positive Symptoms in Parkinson's Disease (SAPS-PD) score.⁵ Pimavanserin use was associated with a significant reduction in PDP symptoms versus placebo (37% vs. 14%, p = 0.0014). The most commonly reported adverse effects included urinary tract infections (13%), falls (11%), and peripheral edema (7%).⁵ Notably, no extrapyramidal adverse effects occurred with pimavanserin administration. In addition, patients receiving pimavanserin experienced a mean increase in QTc of 7.3 ms from baseline.⁵

Preliminary evidence evaluating the therapeutic efficacy of pimavanserin is promising, and the tolerability of this agent appears favorable. Yet, pharmacists should note the following warnings and precautions when involved in the treatment of patients receiving this medication.⁶ Due to the mild QTc prolongation associated with pimavanserin use, caution is warranted when administered with concomitant QTc-prolonging medications or in high risk patients.⁶ As with all antipsychotic agents, pimavanserin carries a black box warning for increased mortality risk in elderly patients with dementia-related psychosis, and should only be used in this population after careful assessment of potential benefits and risks. Additionally, pimavanserin undergoes metabolism via cytochrome P450 3A4, and therefore, pharmacists should be vigilant in identifying potential drug interactions in patients receiving this medication. The recommended dose of pimavanserin for PDP treatment is 34 mg daily, and will be supplied as 17 mg tablets, with an anticipated wholesale acquisition cost of \$1,950 for 60 tablets.^{6,7}

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- 2. Hacksell U, Burstein ES, McFarland K, et al. On the discovery and development of pimavanserin: a novel drug candidate for Parkinson's psychosis. *Neurochem Res.* 2014;39(10):2008-2017.
- 3. Zahodne LB, Fernandez HH. A review of the pathophysiology and treatment of psychosis in Parkinson's disease. *Drugs Aging*. 2008;25(8):665–682.
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- 5. Cummings J, Isaacson S, Mills R, et al. Pimavanserin for patients with Parkinson's disease psychosis: a randomised, placebo-controlled phase 3 trial. *The Lancet*. 2014;383(9916):533-540.
- 6. NUPLAZID[™] [package insert]. San Diego, CA: ACADIA Pharmaceuticals Inc; 2016.
- 7. Personal Communication. Yi P, Director, Patient Access and Channel Operations. ACADIA Pharmaceuticals. 15 June 2016. E-mail correspondence.



Legislative Update

A Summary of Policy Positions Passed at the 2016 ASHP Summer Meeting: Implications for Hospital Practice

Brian Heilbronner PharmD Candidate, 2017 Ohio Northern University

The House of Delegates (HOD) of the American Society of Health-Systems Pharmacists (ASHP) presides as the ultimate authority over the passing of ASHP professional policy positions. Meeting annually at the ASHP Summer Meetings and virtually in March and November, the HOD approves policies that address various issues pertaining to pharmacy practice. Policies typically originate from proposals by ASHP councils throughout the year, highlighting issues from a variety of areas in pharmacy practice, including therapeutics, pharmacy management, education and workforce development, and public policy.¹

During the 2016 ASHP Summer Meeting, the HOD approved twenty-four policy positions, many of which are amendments to previously approved policies.² Summarized below are four of the twenty-four policies approved at the 2016 ASHP Summer Meeting on June 12 and 14, including potential implications for hospital practice

Ban on Direct-to-Consumer Advertising for Prescription Drugs and Medication-Containing Devices (Policy 1624)

The HOD approved a policy advocating that Congress ban direct-to-consumer advertising (DTCA) for prescription drugs and medicationcontaining devices, repealing its former, more lenient stance on the issue. There is a growing body of evidence that DTCA may lead to rising healthcare costs, the overuse of prescription drugs, less appropriate prescribing, and an intrusion of the patient-physician relationship.³⁻⁶ ASHP contends that the risks of DTCA outweigh its potential benefits. ASHP expresses its commitment to providing additional evidence of the potential negative impacts of DTCA on the healthcare system.

With regards to hospital practice, pharmacists play a vital role in fully understanding and evaluating the evidenced-based risks and benefits of medical therapies frequently advertised by DTCA as well as educating prescribers on these benefits and risks. Prescribers who are completely educated on the benefits and risks of medical therapies advertised via DTCA may feel less pressured to fulfill inappropriate DTCA-prompted patient requests for prescriptions, ultimately avoiding inappropriate prescribing and the continued overuse of prescription drugs.

Timely Board of Pharmacy Licensing (Policy 1621)

The HOD also approved a policy advocating that the National Association of Boards of Pharmacy (NABP) collaborate with state boards of pharmacy to streamline the licensure process and timeliness of application approval for pharmacists. Emphasizing that pharmacists often face many logistical barriers to securing licensure in new jurisdictions efficiently, ASHP promotes that pharmacists in good standing be granted up to six months of temporary licensure while permanent licensure is processed.

Slow delays in the issuance of pharmacy licensure pose potential problems for pharmacists relocating to new jurisdictions, especially new pharmacy graduates transitioning to out-of-state residency programs. Because workforce productivity is lost during delays in licensure transfer and reciprocity, ASHP urges NABP to assemble a task force to identify areas in improving timeliness and access of licensure. Increased awareness, advocacy, and assessment of areas for improvement at the state level will help contribute to the larger conversation of approaches to streamlining the process of pharmacy licensing.



Pharmacy Technician Training and Certification (Policy 1609)

The HOD approved a policy advocating that Pharmacy Technician Certification Board (PTCB) certification be required for and maintained by all pharmacy technicians, effectively reinstating a policy from 2014 that had been previously amended to remove the requirement of maintenance of PTCB certification. Presently, ASHP has partnered with the Accreditation Council for Pharmacy Education (ACPE) to develop an accreditation standard for pharmacy technicians programs, aiming to institute a requirement that all pharmacy technicians be graduates of an ASHP-ACPE accredited program in order to test for PTCB licensure, by the year 2020. ASHP emphasizes that the shift in requiring ASHP-ACPE accredited education prior to licensure for pharmacy technicians mirrors that of the pharmacy profession.

As the anticipated demand for enrollment in ASHP-ACPE accredited programs is expected to increase by the year 2020, ASHP cites concern for having the necessary resources to expand the number of ASHP-ACPE accredited programs. Hospitals, especially large academic medical centers, have an opportunity to use their educational resources to establish such programs and meet the growing demand for ASHP-ACPE accredited pharmacy technician programs.

Patient Experience (Policy 1616)

The HOD approved a policy advocating that pharmacists and other pharmacy personnel be educated about the relationship between patient satisfaction and positive health outcomes with medication therapy. Furthermore, ASHP encourages that pharmacists continually develop and adopt tools that will help engage patients and improve their overall satisfaction. Highlighting that current research suggest a clear correlation between positive patient satisfaction and improved patient outcomes, ASHP stresses the importance of pharmacists identifying ways to promote patient satisfaction through the coordination of team-based care.

The hospital setting presents a unique environment for patients to receive care for an extended length of time, depending upon their duration of admission. As a result, there exists numerous opportunities for pharmacists to intervene and facilitate positive patient experiences along the continuum of inpatient care. For example, pharmacists can play an active role in providing quality patient education about newly initiated high-risk medications in the hospital, such as insulin, anticoagulants, and inhalation devices. Additionally, pharmacists can coordinate with other multidisciplinary healthcare professionals to identify new methods of facilitating positive patient experiences.

While the HOD approved numerous additional policy positions at the 2016 ASHP Summer Meeting, these four policies highlight particular challenges facing the future of hospital practice, specifically regarding public policy, pharmacy management, and education and workforce development. State-level chapters of pharmacy organizations, such as the Maryland Society of Health-System Pharmacy, are well suited to engage with nationally driven efforts by ASHP to develop solutions to the many issues facing hospital practice. A complete list of all twenty-four policies is available on the ASHP website.²

References:

- 1. Introduction: ASHP Policy Positions. xix-xxi. Available from: <u>http://www.ashp.org/DocLibrary/BestPractices/BPIntro.aspx</u> accessed 2016 Aug 24)
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Announcements

MSHP Pharmacy Technician Training Task Force

MSHP is excited to announce the establishment of an MSHP Pharmacy Technician Training Task Force. The Task Force will monitor national initiatives, support MSHP member initiatives dedicated to technician training and implement collaborative strategies with the Maryland Pharmacy Coalition, Maryland Pharmacists Association, the Colleges of Pharmacy and the Maryland Board of Pharmacy. The Task Force is seeking a diverse representation including pharmacists, pharmacy technicians and pharmacy technician educators. Interested participants should contact Dan Ashby: <u>dashby@jhmi.edu</u>; (410) 955-6249.

Article Submission Deadlines for Upcoming Newsletters

December 16th, 2016 for the January 2017 Edition March 17th, 2017 for the April 2017 Edition June 16th, 2017 for the July 2017 Edition September 15th, 2017 for the October 2017 Edition