Missouri Society of Health-System Pharmacists Bi-Monthly Newsletter

DECEMBER 2014

Diane's Musings

by Diane McClaskey, RPh, BCPS

BRRR!! Who left the freezer door open? Makes me think about when you stand in front of the refrigerator just looking and your parents would tell you to shut the door! Not to worry, folks, your MSHP crew hasn't let the cold slow us down!

Sarah B., Andy, Sara N. and I just got back from attending the ASHP Presidential Officers Retreat in Chicago. (Andy has a funny story to tell about his flight – be sure to ask him!) The keynote speaker was Sheri Jacobs, who has authored a book titled, "The Art of Membership: How to Attract, Retain, and Cement Member Loyalty", and she gave each and every one of us great information on how to make the best of MSHP for you, our members. The four of us are going to compile our notes, give a report to the Board of Directors, and discuss if we can incorporate these strategies into MSHP. Some of them are quite large, and they could be rolled into our next strategic plan. There were over 35 state affiliate leaders at the conference, and one of the highlights is when the Pharmacy Society of Wisconsin shared how they rebranded their organization. Pretty impressive! (They have a video on You Tube, if you want to take a peek.) In addition to Sheri's presentation, we had excellent roundtable discussions on Ambulatory Care, PPMI, and several other topics. We were all tired when we got home; however, it was a great meeting!

I did want to let our members know that we had an external audit completed of our finances. It was a good audit, and we just received the report this week. There are practices that need some fine tuning, and the good folks at Centriq are eager to operationalize these changes to enhance our financial performance. You might, remember that financial performance is on our strategic plan, and we are making great strides into completing those goals and objectives.

A note of celebration! Two of the presidents of our student chapters (Samantha Gripke from UMKC and Stephanie Tackett-Berrong from StLCOP) and Megan Musselman had their poster accepted for Midyear! The poster describes how students can be very helpful in raising awareness regarding PPMI and encouraging facilities to complete the Hospital Self-Assessment. They will present their poster on Tuesday, December 9, from 1130 to 1230. Be sure to stop by and congratulate them for their hard work and successful poster!

Speaking of Midyear, don't forget our Missouri reception, held on Monday, December 8 from 5:30-7pm at the Anaheim Marriott in the Marquis Center Room. Special thanks to St. Louis College of Pharmacy and UMKC School of Pharmacy for their gracious support of this reception. I look forward to seeing you there!

Happy Holidays!
Diane

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Hospital Pharmacy Regulatory Update

by Bert McClary, RPh

Senate Bill 808 became effective on August 28 with several provisions beneficial specifically to hospital pharmacists, relating to a new Class B Board of Pharmacy hospital license, MTS protocols, distribution by hospitals, joint rulemaking by BOP and DHSS, and a BOP hospital advisory committee. DHSS and MSHP requested in May that the Hospital Working Group be re-convened to address implementation of the bill and other topics previously identified by the Working Group.

The August BOP Newsletter contains a summary of the provisions and basic guidance for implementation of SB 808, however, pharmacists have asked questions that are not answered without additional guidance. The Missouri Hospital Association asked the Board to sponsor a webinar to provide more detailed guidance and discussion.

Joint rulemaking is authorized for rules governing medication distribution and MTS provided by a pharmacist within a hospital, and the advisory committee is expected to discuss topics that will be a basis for such rules and make rule recommendations. Representatives to the advisory committee will be selected by MHA, MSHP, MPA, DHSS and BOP. Until the advisory committee is appointed it is expected that a Working Group will be active.

An initial telephone meeting arranged by MHA was held on November 10 to gather questions about implementation issues and determine how to proceed. The invited group of about twenty persons included thirteen pharmacists representing hospitals, health systems and MSHP, and representatives from DHSS, MHA and BOP. Notably, emphasizing the importance of this effort, all invited pharmacists attended.

The following questions/topics were submitted on behalf of MSHP to stimulate discussion. The pharmacists suggested their priority issues and some additional specific topics. Kim Grinston cautioned that during a typical one to two hour webinar, not all topics could be covered, and questions that are based on pending rules cannot be answered by the agencies. Most questions involved the Class B license, MTS, and distribution. A survey will be sent to the group to rank priority topics for the webinar. The webinar is tentatively planned for early in January.

Class B License

- What defines the areas included in a DHSS hospital license and hospital premises, and how can a hospital determine this?
- Is space within a hospital that is leased to a private entity part of the hospital licensed premises, e.g. physical therapy or cardiac cath lab?
- Can a hospital have multiple outpatient prescription dispensing sites within the hospital under a single Class B license?
- Can a hospital have multiple Class B licenses within the hospital if desired for management reasons?
- What defines the Class B "licensed area" in a hospital pharmacy?
- What kind of unique identifiers may be used for prescriptions?
- Are there restrictions on activities or use of common stock for inpatient and outpatient orders and prescriptions?
- Can a clinic that is jointly owned with a non-hospital entity get a Class B license?
- What defines the Class B licensed area in a clinic, infusion center or other non-inpatient area?
- Can a nurse access a clinic Class B area when no pharmacist is on site for medication to administer to a patient or to be dispensed by a physician?
- Can a nurse who is properly trained access a clinic Class B area when no pharmacist is on site to use sterile compounding facilities?
  Consider implications for LTCFs that are health system entities.

MTS

- Is a MT certificate required for a pharmacist to perform routine inpatient "medication order management" procedures?
- Can a nurse or PA issue an order to initiate an inpatient MTS protocol?
- Can a nurse or PA issue an order to initiate an inpatient MTS protocol if the pharmacist is authorized to initiate the protocol independently except in circumstances when confirmation is required by a physician, nurse or PA?

- Can non-employee pharmacists be authorized for hospital MTS protocols, e.g. pharmacists providing remote pharmacy order review and other pharmacy services?
- What basic criteria or topics should be included in a MTS protocol?
- Is credentialing by the hospital medical staff required for MTS pharmacists?
- Can more than one medical staff committee authorize MTS protocols?
- Can a medical staff committee protocol be used in clinics and other outpatient areas?
- Can a single protocol apply to both inpatient and outpatient services?
- Do the BOP protocol rules 6.060, 070 and 080 apply to clinics and other outpatient areas?
- Do the BOP protocol rules apply to clinics that are part of the hospital licensed premises?
- Is a MT certificate required for MTS activities that do not include modifying medications?
- Does the BOP immunization rule 6.040 apply to clinics and other outpatient areas?
- Does the BOP immunization rule apply to clinics that are part of the hospital licensed premises?
- Do the statutory requirements in 338.010.1 and 338.010.12 for immunization apply to hospital licensed premises?
- Is the requirement in DHSS hospital licensing proposed rule language 19 CSR 30-20.100(33)(C) satisfactory or necessary?
- Do Missouri's MTS statutes and rules meet minimum requirements for proposed federal provider status legislation?
- Are there physician groups that still oppose MTS that need education?
- Consider implications for LTCFs that are health system entities.

Distribution

- Can a hospital that does not have a Class B license or drug distributor license distribute to a hospital-owned clinic?
- Can a hospital that does not have a Class B license or DD license fill medication orders for a separate hospital location that operates under the same hospital license?
- If a hospital wishes to maintain a DD license for distribution to non-hospital entities, must the hospital comply with all DD laws and rules regarding distribution when distributing to hospital entities?

Automation

- Inpatient standards of practice for use of automation, e.g. robots, compounders, automated dispensing cabinets.

Administering

- Does the BOP administration rule 6.040 apply to clinics and other outpatient areas?
- Does the BOP administration rule apply to clinics that are part of the hospital licensed premises?
- Consider language proposed for 6.040 submitted by MO Pharmacy Coalition committee in 2012.

Technicians

- Scope of practice for hospital pharmacy technicians who meet required standards for education, training and experience.
- Allowance for technician activities when automation is involved, e.g. automation-check-tech.
- Allowance for on-site remote supervision, e.g. supervision of sterile compounding from outside the sterile compounding area.

Joint rulemaking

- When will Advisory Committee be appointed?
- Can Advisory Committee discuss and advise on possible new rules and other topics, or only advise on proposed rules?
- If Advisory Committee cannot participate in other activities, can we keep the Working Group active?

BOP/DHSS Hospital Pharmacist

- Both BOP and DHSS should fund a full-time hospital pharmacist position.
- Evaluate joint funding/joint position options.
- BOP give preference to pharmacist with hospital background when filling the sterile compounding pharmacist position.

Expanding Board Membership

Gather data re number of practitioners in specialty areas of practice.

- Consider impact of specialty areas on overall patient care.
- Consider knowledge/procedures that are different for specialty areas.

MSHP R&E Foundation News

by Jackie Harris, PharmD, BCPS

With the annual meeting just around the corner, the Research & Education Foundation would like to highlight the great research you are doing throughout the state and those colleagues who deserve recognition for all that they've done throughout their careers. Your donation to the R&E Foundation directly goes to supporting those much deserved awards and recognition presented to members at the annual meeting. In addition, donations have also gone towards supporting Webinars on research-related topics, including Systematic Reviews/Meta-Analysis and Biosimilars. As we strive for 'Every Member Every Year', we encourage you to assist the R&E Foundation in continuing to offer these types of recognition and programming. Contributions are considered charitable contributions and can be deducted from your taxes. Please consider utilizing the online donation form on the MSHP website to donate.

Call for Awards and Research Abstract Submissions

The 2015 ICHP/MSHP Meeting in St. Charles on March 20th- 21st is just around the corner. Deadlines for poster and award submissions (see below) will be here soon. Please don't miss out on this great way to showcase your research project or highlight a deserving colleague for an award! Submissions are due **February 1st**.

Call for Research Abstract Submissions:

Don't miss the opportunity to showcase your great work by presenting a poster or platform!! Submissions are currently being accepted for the categories listed below for presentation/display at the Annual Meeting. All MSHP members and students enrolled in a Missouri School of Pharmacy are eligible to submit abstracts for consideration for presentation.

- Original Research
- Research in Progress
- Encore Presentation
- Student Presentation

Submission Details:

Abstracts will be accepted via the online abstract submission process through February 1, 2015. At least one author on each abstract must be an MSHP member. At least one author is expected to be present at the poster during the poster exhibit session (student must be present for student poster) at the meeting. The presenter must be registered for the meeting.

Submission Deadline: February 1, 2015

Best Practice Award:

The Best Practice Award program recognizes innovation and outstanding performance in a pharmacy directed initiative. The theme for the 2015 award focuses on:

"What innovative practices have health-systems utilized to better manage drug shortages?"

Two health care systems can be recognized with one award presented for a large hospital (average daily census > 100 patients) and one for a small hospital (average daily census ≤ 100 patients). Each recipient will present their project and be honored at the R&E Foundation Breakfast during the 2015 Annual Meeting. In addition, recipients will receive a plaque and a $250 honorarium.

Submission Deadline: February 1, 2015

Thomas J. Garrison Award:

The Garrison award was established in 1985, named after Thomas Garrison for his longstanding support of MSHP (past-president 1974-76), ASHP (past-president 1984) and numerous professional and academic contributions to pharmacy. The Garrison Award is presented each year in which a deserving candidate has been nominated in recognition of sustained contributions in multiple areas:

- Outstanding accomplishment in health-system pharmacy
- Outstanding poster or spoken presentation at a state or national meeting
- Publication in a nationally-recognized pharmacy or medical journal
- Publication in a nationally-recognized pharmacy or medical journal
- Demonstrated activity with pharmacy students from St. Louis or the UMKC Schools of Pharmacy
- Development of an innovative service in health-system pharmacy in either education, administration, clinical services, or distribution
- Contributions to the profession through service to ASHP, MSHP, and/or local affiliates.

Nominee must be a current active member of MSHP. The winner will be selected by the Board of Directors of the MSHP R&E Foundation.

Submission Deadline: February 1, 2015

MSHP R&E Foundation Research Corner

by Paul Juang, PharmD, BCPS

The R&E Foundation is proud to introduce a new section highlighting work from pharmacy researcher within the state of Missouri. The article that we would like to highlight is by Scott Micek, Pharm.D., BCPS, FCCP, Associate Professor of Pharmacy Practice at St. Louis College of Pharmacy. His article, titled "Identifying Critically Ill Patients at Risk for Inappropriate Antibiotic Therapy: A Pilot Study of a Point-of-Care Decision Support Alert" was published in the Critical Care Medicine journal in August of 2014. Please click on the following link to access the interview that I conducted with Dr. Micek regarding his research.

You can view the video at this link or in November 11th Weekly Update:
http://www.moshp.com/research-education-foundation/research-corner/

Member Spotlights

Congratulations to the following members who were ASHP Member Spotlights:

October ASHP Section of Clinical Specialists and Scientists:
Megan Musselman, PharmD, MS, BCPS

October ASHP Section of Ambulatory Care Practitioners:
Cassie Heffern, PharmD, BCACP

MSHP also beat KCHP in the Facebook Border War Challenge in the I "Heart" Health-System Pharmacy during Health-System Pharmacy Week in October!

The PPMI Taskforce has been working on increasing awareness and recognition of PPMI in the state of Missouri. A group of students from St. Louis College of Pharmacy and the University of Missouri-Kansas City School of Pharmacy, along with the current PPMI chair, contacted heath-system pharmacies to discuss PPMI Initiatives and encourage completion of the Hospital Self-Assessment Survey. Highlights of this project will be presented at the ASHP Midyear Clinical Meeting Student Poster Session in Anaheim, CA. **Stephanie Tackett-Berrong, PharmD Candidate 2015** (STLCOP), **Samantha Gripka, PharmD Candidate 2016** (UMKC), and **Megan Musselman, PharmD, MS, BCPS** will present their poster on Tuesday, December 9th from 11:30-12:30 pm.

Pharmacy School Update

by Samantha Gripka, UMKC Doctor of Pharmacy Class of 2016, Student Society of Health-System Pharmacy President

A new academic year began on August 25, 2014, at the University of Missouri – Kansas City (UMKC) School of Pharmacy, bringing with it new students and a new site. The school admitted 143 students into the Class of 2018 from Missouri and 11 other states. UMKC at MU in Columbia also welcomed Dr. Roger Sommi as their new Associate Dean.

This fall, UMKC opened their third pharmacy school site, located at Missouri State University (MSU). Thirty students from the Class of 2018 are the first to attend pharmacy school in Springfield, MO. The new facility consists of a 15,000-square-foot classroom area inside a historic Brick City building in downtown Springfield, not far from MSU's main campus. The satellite campuses in Springfield and Columbia are made possible thanks to videoconference technology that allows students and faculty to communicate in real time during classes and meetings. A new, more reliable system was installed at all three campuses to provide clearer interaction with less technical difficulties. The official opening of the Springfield site was October 29, 2014.

The Springfield area offers many opportunities for students to get involved in the community, gain pharmacy practice experience, and obtain jobs or residencies after graduation. The new site was implemented in hopes of providing more pharmacists to rural areas, especially in southern Missouri.

The new school year is not only exciting for UMKC's newly admitted student pharmacists, but also for the returning students. UMKC held its Professional Dedication Ceremony on September 29, 2014, where 123 second year students received their White Coats. The Class of 2014 graduated 121 students in May. Of those, 35 students were accepted into a PGY-1 residency program. The Student Society of Health-System Pharmacy (SSHP) also hosted their annual Residency Roundtable on September 20, 2014, where representatives from 16 residency programs came to UMKC to give students advice on attending Midyear and applying to residency programs.

Recently, both students and faculty have been honored with state and national awards. At the APhA Annual meeting in March 2014, UMKC's American Pharmacists Association - Academy of Student Pharmacists (APhA-ASP) was recognized as a Chapter Achievement Runner Up (Top 10 in the country). Our APhA-ASP chapter also won the 2013-2014 Region 6 awards for outstanding development and implementation of Operation Immunization, Operation Heart, and Operation Self-Care. Additionally, Dr. Andrew Bzowyckyj, Pharm.D., BCPS, CDE won the Missouri Pharmacy Association (MPA) 2014 Young Pharmacist Award, and Dr. Kelly Cochran, PharmD., BCPS from Columbia won the MPA 2014 Faculty Member of the Year award for UMKC.

UMKC School of Pharmacy is excited for the recent expansion, and we look forward to witnessing our new student pharmacists learn and develop at all three sites. As our graduates continue to impact the health of Missourians, we continue to strive to serve others in an altruistic manner, enriching our community through our leadership and seeking excellence in all that we do.

Featured Article:

Methotrexate-induced Nephrotoxicity and the Role of Glucarpidase

Donald Moore, PharmD, BCPS – Southeast Missouri Hospital

High-dose methotrexate, often defined as greater than 1 gram/m^2 per dose, has been an integral component of treatment regimens for a variety of different malignancies for the past several decades.[1] A variety of supportive care is administered along with high-dose methotrexate in order to prevent toxicities. Despite best supportive care efforts, methotrexate-induced acute kidney injury, considered an oncologic emergency, may still occur in up to 10% of patients.[2] The excretion of methotrexate is dependent on its solubility which is directly proportional to urine pH.[3] Therefore, since methotrexate is a weak acid, in the setting of a low urine pH, methotrexate has the ability to precipitate in the renal tubules and cause a crystal nephropathy. Furthermore, the renal damage that ensues can then reduce the clearance of methotrexate and can increase the duration and degree of exposure to methotrexate which can then create a cycle of precipitation and renal injury.[4] The overexposure to methotrexate than can occur in the setting of methotrexate-induced acute kidney injury can cause toxicities to organ systems besides the kidneys. The most common adverse reactions that can occur in this setting are bone marrow suppression, mucositis, and acute hepatitis.

Supportive care measures such as leucovorin rescue and intravenous hydration are routinely employed in order to help prevent methotrexate-induced toxicities such as acute kidney injury.[4] Urinary alkalinization is also often utilized in order to increase urine pH to promote the excretion of methotrexate and prevent its precipitation. Historically, in the setting of established methotrexate-induced acute kidney injury, such invasive techniques such as high-flux hemodialysis have been employed in order to attempt to manage methotrexate concentrations. However, high-flux hemodialysis may require several sessions a day and can cause hypotension, nausea, leg cramps, fatigue, and chest pain. Also, transient rebound increases in methotrexate levels may occur with hemodialysis.

FDA approved in 2012 under the brand name Voraxaze, glucarpidase is a recombinant carboxypeptidase enzyme indicated for the treatment of toxic plasma methotrexate concentrations, defined as being greater than 1 micromole per liter, in patients with delayed methotrexate clearance secondary to impaired renal function.[5] This recombinant enzyme hydrolyzes the carboxyl-terminal

glutamate residue from methotrexate and folic acid. Glucarpidase will convert methotrexate to its inactive metabolites and will thus provide a non-renal elimination pathway for methotrexate clearance in patients with renal impairment while receiving high-dose methotrexate therapy.

Glucarpidase is available as an intravenous formulation and is to be given as a single 50 unit per kg dose over 5 minutes.[5] In healthy subjects, glucarpidase was found to have a mean elimination half-life of 5.6 hours, a mean systemic clearance of 7.5 mL/min, and a mean volume of distribution of 3.6 L. In patients with severe renal impairment, defined as a creatinine clearance <30 mL/min, the mean elimination half-life was found to be 8.2 hours.

The efficacy of glucarpidase was demonstrated in a single-arm, open label study of patients that had delayed methotrexate clearance secondary to renal insufficiency.[5] Of the 22 patients available for efficacy evaluation in this study, most had osteogenic sarcoma, leukemia, or lymphoma. Patients were to receive one dose of glucarpidase at 50 units per kg; those with pre-glucarpidase methotrexate concentrations >100 micromole/L were given a second dose 48 hours after the initial dose. The primary efficacy outcome measure was the percentage of patients that obtained a rapid and sustained clinically important reduction (RSCIR) in methotrexate plasma concentration. RSCIR was defined in this study as achieving a methotrexate plasma concentration of <1 micromole/L within 15 minutes and this reduction being sustained for up to 8 days. Of the 22 patients evaluated, 10 achieved RSCIR (95% CI; 27-65%). Seven patients had initial methotrexate plasma concentrations >100 micromole/L; six of these seven patients received a second dose. None of the patients that received an additional dose achieved an RSCIR, however there was a greater than 95% rapid reduction in methotrexate plasma concentrations that was sustained up to 8 days in each of these patients.

The effect of glucarpidase on renal function recovery was evaluated in a pooled analysis of efficacy data from four multicenter, single-arm clinical trials.[6] This analysis found there was a 3.5-fold increase in serum creatinine concentrations before methotrexate administration to before glucarpidase was given (0.79 to 2.79 mg/dL). Following glucarpidase administration, serum creatinine continued to rise by a mean increase of 0.24 mg/dL over 3 days and then began to decrease thereafter.

Although glucarpidase has been found to be effective in managing elevated methotrexate levels in the setting of renal impairment, it is still currently recommended to continue with the administration of leucovorin rescue.[5] Also, it is recommended to not administer leucovorin two hours before or after the administration of glucarpidase since leucovorin is a substrate for glucarpidase. In clinical trials, glucarpidase has been found to be relatively well tolerated with the most common adverse events being paresthesia, flushing, nausea, vomiting, hypotension, and headache. Despite being relatively well-tolerated, allergic reactions such as anaphylaxis have been reported; patients should be monitored for serious allergic events following the administration of glucarpidase.

In conclusion, glucarpidase is a safe and effective option in the management of nephrotoxicity secondary to delayed clearance of methotrexate following administration of high-dose methotrexate. Leucovorin and other supportive care options such as hydration and urinary alkalinization should be continued as indicated in addition to the administration of glucarpidase.

References

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3. Abelson HT, Fosburg MT, Beardsley GP, et al. Methotrexate-induce renal impairment: clinical studies and rescue from systemic toxicity with high-dose leucovorin and thymidine. Journal of Clinical Oncology 1983;1:208-16.
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Continuing Education (CE) Article Information:

The Newsletter Committee is happy to announce that the CE articles will be reincorporated back into the newsletter. It will be available as a supplement to the newsletter. Residents from the state have graciously volunteered to tackle the following topics so be on the lookout for these upcoming newsletter articles:

- January/February 2015: Anticoagulation
- March/April 2015: Infectious Disease
- May/June 2015: Oncology
- July/August 2015: Cardiology
- September/October 2015: Transitions of Care

How to Process CE:

Please send completed quizzes to Sara Neiswanger via fax (785-271-0166) or email (acs.saraneiswanger@gmail.com). She will get the information turned in for you. Thanks Sara!

Questions/Comments

If you have any questions or comments about MSHP Newsletter, please don't hesitate to contact the Newsletter Chair, Cassie Heffern, PharmD, BCACP (cassie.heffern@coxhealth.com) or any other newsletter committee member.

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