

Hospital Pharmacist Monthly

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Welcome to the current issue of *Hospital Pharmacist Monthly*.

- A letter titled **“Need for specific-gravity values in adopting gravimetric measurement in sterile compounding”** (*Am J Health-Syst Phar.* 2017;74(12):871-872) was reviewed. It is noted that in one observational study the volumetric method of compounded sterile product (CSP) production resulted in a 9% error rate and in a study of over one thousand hazardous CSPs prepared using the volumetric method found a 0.53% negative variance from the expected product weight, with individual variances ranging from negative 65% to positive 94%! Potential errors associated with the volumetric method of preparation can be eliminated through the use of gravimetrics. The 2016 ISMP Guidelines for Safe Preparation of CSPs state that gravimetrics should be used for the preparation of all chemotherapy and pediatric CSPs. The authors found that implementing a gravimetric workflow system was impeded by the lack of availability of specific-gravity values. They sent out 287 inquiries to manufacturers for specific-gravity information and only obtained 27 responses. The authors are recommending that specific-gravity data be required to be included in Safety Data Sheets and that the FDA require drug manufacturers to provide that information for all sterile drug products on the market. We concur with this need and hope that ASHP and ISMP can help bring this to fruition.
 - **HPM Recommendation – As more hospitals move to gravimetrics for CSPs, the demand for specific-gravity data will rise. Hopefully, this won’t continue to be a stumbling block for implementing this technology.**
- The recently published **“ISMP Guide to Building a Smart Infusion System Drug Library”** (<http://www.ismp.org/docs/Building-Smart-Infusion-System-Drug-Library.pdf>) was reviewed. ISMP has published a very useful tool to help you with the process of building and implementing a drug library for your smart infusion pumps. The process is broken down into 3 phases – design, drug library configuration and testing. A 4th phase – EHR integration is included for facilities that have that functionality. A key success factor for a well-built library is collaboration with a broad group of stakeholders. The suggested group includes: pharmacy drug library leader, nursing drug library leader, pharmacy admixing representative, clinical pharmacist from each clinical care setting, a pharmacy P&T representative, pharmacy and nursing informaticists, prescriber from critical care and a general medicine unit and an IT resource. The next steps of the design phase include: formalize the process, define the scope and collect relevant information (all standard order sets for each medication or therapy, list of IV medications mixed by pharmacy, list of IV medications mixed by nursing, medications administered by IV syringe pump, medications administered by PCA, hospital formulary and hospital IV manual, drug library/formulations/drug label and data from IV workflow system, and many more). The configuration phase is the most critical phase and includes: drug setup, care areas setup, general pump settings, and review/verify/document all activities. The testing phase is critical and must include end-users to help identify issues not considered by the build team. EHR integration is becoming more common and recommendations for successful integration are provided.
 - **HPM Recommendation – Even if your library is already built, we recommend that you review this document to identify opportunities to improve your library and processes involved in managing the library. This is a must review if you are preparing to build a library.**

- An article titled **“Safe Parenteral Nutrition Prescribing and Order Review”** (*Pharm Purch & Prod. 2017: June; 2-4*) was discussed. This is the first of two articles on the topic of the safe use of parenteral nutrition (PN). The second article will focus on the compounding and administration phases of PN and this one focuses on prescribing, order review and verification. ASPEN consensus recommendations on prescribing call for standardization – this includes a policy, documentation of indications for PN, and the use of standard electronic order form, with clinical decision support, for prescribing PN, and having an interface between the EHR and the automated compounding device. For adults PN should be ordered in amounts/24 hours and in neonatal and pediatric patients in amounts/kg/24 hours. Electrolytes should be ordered as complete salts and not as ions. PN reorders should always be ordered in its entirety. ASPEN recommendations with regards to order review and verification include: the process for verification should be included in policy and should include process to take if doses are out of range or potential incompatibilities are identified. Other steps in the verification process include: proper indication, osmolarity is appropriate for route of administration, macronutrient, micronutrient and non-nutrient medications are clinically appropriate, laboratory data is reviewed and the admixture compatibility and stability are in order. The use of automated compounding devices is recommended as they have been shown to decrease compounding errors.
 - **HPM Recommendation – This is a good review of safe prescribing, order review and verification of TPN. Compare these recommendations to your practices and update as necessary.**
- An article titled **“An Organizational Framework to Reduce Professional Burnout and Bring Back Joy in Practice”** (*The Joint Commission Journal in Qual and Patient Safety. 2017;43:308-3137*) was reviewed. The authors are physicians and the primary focus of the article is to bring joy back to the practice of physicians, but we feel that the points made apply to pharmacists as well. The 6 evidence-based actions that leaders can take to bring back Joy in Practice include: Design Organizational Systems to Address Human Needs; Develop Leaders with Participative Management Competency; Build Social Community; Remove Sources of Frustration and Inefficiency; Reduce Preventable Patient Harm and Support Second Victims; and Bolster Individual Wellness. A couple of key points in the Design of Organizational Systems section are: Humans like to be part of the decision-making process and when decisions are autocratically made and communicated, the Joy in Practice declines; and what organizations measure and pay attention too (e.g. financials over clinical outcomes) matters and forcing staff to focus on metrics that are not aligned with their passions leads to an unsatisfied work force. A workplace with leaders that exhibit participative management skills will help to create more Joy in Practice. We see one of key actions is removing frustration and inefficiencies in the workplace. We need to make our work environments operationally effective and remove unneeded burdens that adversely impact the workers. Good leaders ask their staff what is bothering them most (“what is the pebble in your shoe?”) and try to find ways to address these issues while still delivering cost efficient care, that is safe and regulatory compliant.
 - **HPM Recommendation – Review this article and think about how it applies in your pharmacy department and what you can do to change things. Don’t forget to check on how your department is impacting nurses and how simple things like optimizing your ADCs can decrease nurses’ frustration about the difficulty in performing a med pass.**
- The Joint Commission recently released **“Prepublication Requirements – Standards Revisions Related to Pain Assessment and Management”** was reviewed. These new standards are effective (https://www.jointcommission.org/prepublication_standards_%E2%80%93_standards_revisions_related_to_pain_assessment_and_management/) January 1, 2018. A new leadership standard (LD.04.03.13) created is: “Pain assessment and pain management, including safe opioid prescribing, is identified as an organizational priority for the hospital.” The first element of performance for this standard is: “the hospital has a leader or leadership team that is responsible for pain management and safe opioid prescribing and develops and monitors performance improvement activities.” EP 6 requires the hospital to facilitate practitioner and pharmacist access to the prescription drug monitoring program (PDMP) in states that have such a program. Another EP in this new leadership standard is #7 – “hospital leadership works with its clinical staff to identify and acquire the equipment needed to monitor patients who are at risk for adverse outcomes from opioid treatment” (think end-

tidal CO₂ monitors). There are changes in the patient care standards and performance improvement standards related to pain management as well.

- **HPM Recommendation – If you are TJC accredited, we recommend that you create a PI team (or equivalent) to review these new standards/revisions and work to ensure compliance.**

- An article titled **“The Joint Commission’s Medication Compounding Certification Program”** (*Pharm Purch & Prod. 2017: June; 24-29*). The Joint Commission (TJC) recently announced that they offer a Medication Compounding Certification Program. In a Q&A format, this article presents information on the program as provided by Robert Campbell, a PharmD, TJC surveyor. TJC Medication Compounding certification is a voluntary certification for hospitals and home care agencies and TJC accreditation is not required to obtain this certification. Standards for the program were developed by working closely with USP and the FDA and for the most part, mirrors the requirements outlined in USP <795> (non-sterile) and <797> (sterile compounding). When USP <800> becomes effective on July 1, 2018, the program will cover those requirements as well. The Michigan Board of Pharmacy requires licensed pharmacies performing compounding to be accredited and TJC program is approved as one of the eligible certifying bodies. A copy of the standards is available on TJC website and any organization considering certification should prepare for survey by downloading the standards and assuring that all required standards and elements of performance are in place. Dan noted that he has downloaded these standards and if you are following USP<797> or the requirements in California from the CA BOP, you should be generally prepared for this survey. We anticipate that hospitals that are required to have some certification by an approved organization, like in Michigan, will consider this certification, but it is unlikely that hospitals will opt to have this certification on top of being licensed by their state BOP.
 - **HPM Recommendation – Information on the new medication compounding certification program from TJC. Review the article and download the standards if you are considering TJC certification.**

- A news article titled **“Attention turns to nonpharmacy sterile compounding activities”** (*Am J Health-Syst Pharm. 2017;74(13):954-955*) was reviewed. In response to an outbreak of fungal infections in 17 patients in New York City, the FDA inspected an oncology clinic that was a site of care for all the infected patients. They found egregious practice conditions including the preparation of a one-liter heparin-antimicrobial bag that was used for flush syringes until empty, which could be up to 8 weeks! The biological safety cabinet was last tested in 2014 and had failed inspection at that time. The FDA acknowledged that they are only inspecting physician practices when complaints are received and that they have been talking to state medical boards, the National Association of Boards of Pharmacy and the CDC to devise a process to increase inspections of these areas. A Government Accountability Office (GAO) survey in 2015 identified that only 9 states have laws, regulations or policies that apply to compounding activities by healthcare practitioners who are not pharmacists.
 - **HPM Recommendation – Make sure that if there are sterile compounds prepared under your hospital license, anywhere outside of the oversight of the pharmacy department, that safe compounding practices are in place. You don’t want to be in the headlines.**

- An article titled **“Ensure Compliant Vaccine Waste Disposal”** (*Pharm Purch & Prod. 2017: June; 6-8*) was reviewed. Proper vaccine storage is critical to ensure the product is effective and there are many resources to provide information on this topic. What is not commonly discussed is appropriate vaccine waste disposal. Expired or compromised vaccine doses may be returnable for credit. Check with the manufacturer or immunization program. As many facilities are about to start disposing 2016-2017 flu vaccine, the author puts special emphasis on this topic. A table is provided that lists all of the various products distributed last year. All the MDVs contain sufficient thimerosal to reach the threshold for categorization as hazardous waste and must be disposed of as RCRA waste. Single-dose injections may be disposed of as pharmaceutical waste. As FluMist (nasal spray) is a live virus, it must be disposed of as biohazardous waste (in Sharps container). It is also mentioned that most empty vaccine vials are not usually considered hazardous or pharmaceutical waste, but that empty

rotavirus dispensing tubes or oral applicators are considered medical waste and disposed of in either a Sharps container or a red biohazard container.

- **HPM Recommendation – Good review of vaccine waste disposal, just in time for the flu vaccine that is starting to expire. Make sure you are following the guidelines.**

- An article titled **“Results of the 2015 National Certified Pharmacy Technician Workforce Survey”** (*Am J of Pharmaceutical Education. 2017;74(13):981-991*) was discussed. A survey was sent to over 5,000 certified pharmacy technicians (CPhTs) and 516 CPhTs currently working as pharmacy technicians responded to the survey. Questions differed for CPhTs in community settings versus health systems and we will focus on the health system results. Respondents were frequently participating in maintaining floor stock and dispensing cabinets, repackaging activities and unit inspections. There was less involvement in dispensing medications with remote video supervision, order entry and assisting with medication assistance programs. For each activity, the respondents were asked to rate their perceived importance of the task and their perceived importance to employers. The biggest gaps between self-ascribed and perceived importance of employer were for sterile compounding and supervising other technicians and in both instances the CPhTs felt the employer rated the importance lower than they did. CPhTs in the community setting had slightly lower levels of satisfaction with the level of stress in their workplace (3.30 vs. 3.45 on a scale of 1 to 6). The community CPhTs reported a higher level of satisfaction with their co-workers (both pharmacists and other technicians) than the hospital based CPhTs. Overall, it was concluded that CPhTs had moderate job satisfaction coupled with somewhat high stress levels.
 - **HPM Recommendation – This is a good article to review to get a snapshot on the pulse of CPhTs in the country. Use this information to better relate with your technicians and to identify ways you may improve their work environment.**

- An article titled **“ACCP Clinical Pharmacist Competencies”** (*Pharmacotherapy. 2017;37(5):630-636*) was reviewed. This paper provides an update to the American College of Clinical Pharmacy (ACCP) clinical pharmacist competencies that were first published in 2008. The ACCP expectations are that clinical pharmacists be competent in six domains: direct patient care, pharmacotherapy knowledge, systems-based care and population health, communication, professionalism and continuing professional development. Within each domain there are 4 to 6 elements of the competency and this is all laid out nicely in Table 1. The ACCP believes that clinical pharmacists engaged in direct patient care should be board certified (or board eligible is a BPS certification does not exist in their area of practice) and have established a valid collaborative drug therapy management (CDTM) agreement or have been formally granted privileges by the medical staff. We discussed this expectation and wondered what percentage of pharmacists in clinical roles are board certified. We suspect the answer is <10% and perhaps <5%.
 - **HPM Recommendation – Review this article (and the next one too) and assess whether your expectations for your clinical staff match those of ACCP and then adjust based on your determination of what works best for your organization.**

- An article titled **“ACCP Template for Evaluating a Clinical Pharmacist”** (*Pharmacotherapy. 2017;37(5):e21-e29*) was discussed. This is a companion article to the one just discussed. The ACCP has provided a template evaluation tool for clinical pharmacists that is based on the elements of competency as described above. Each domain contains two or more tasks that should be measured to assess competency within that domain (direct patient care, pharmacotherapy, etc.). They also provide suggested examples of performance evaluation for each task. In addition, to provide further edification on the process, they provide sample criteria to define success for 2 suggested tasks (document an accurate complete list of medications and appropriately assess patient data). ACCP suggests that this document could be used in its entirety or, if appropriate, sections of the template can be added to an existing institution-specific tool.
 - **HPM Recommendation – Review this article (and the one before too) and assess whether your expectations for your clinical staff match those of ACCP and then adjust based on your determination of what works best for your organization.**

- An article titled **“Maximizing Automation in the IV Compounding Process”** (*Pharm Purch & Prod. 2017; June; 10-16*) was discussed. The author describes the sterile compounding technology implemented at the University of Rochester Medical Center (URMC) over the last 3 years. Matching the ISMP recommendations for safe sterile compounding for: bar code verification of ingredients, digital image capture of compounding processes and steps and gravimetric verification of added components, they have deployed: a non-hazardous IV compounding robot, a hazardous IV compounding robot, IV workflow automation and human-assist robotics. Key challenges identified during this journey were: difficulties in integrating the new technologies with the EMR, extensive training requirements for technicians and pharmacists on the use of the robots, challenges in gravimetric checking due to lack of specific gravity data and label formatting. The number of fully robotic doses produced has gradually increased and they are now producing approximately 4,000 doses/month through this equipment. Hazardous drug preparations with the robot are up to about 200 doses/month as of early 2017. URMC has a goal of increasing the utilization of the non-hazardous robot to prepare 12,000 doses per month and increasing hazardous compounding from 12/day to about 40/day.
 - **HPM Recommendation – This is the wave of the future. If you have not yet brought in robots for your sterile compounding needs, it’s time to at least explore the variety of equipment available at the next big meeting you attend.**
- An article titled **“Implementation of a proton pump inhibitor stewardship program”** (*Am J Health-Syst Pharm. 2017;74(12):932-937*) was discussed. Due to the overuse of proton pump inhibitors (PPIs) and the increasing recognition of the adverse effects associated with their use, The VA Medical Center in Lexington, Kentucky initiated a PPI stewardship program. The PPI stewardship team includes 2 pharmacists and a hospitalist with a gastroenterologist consulted as needed. The team started by identifying the scope of the project. There are approximately 250 patients admitted to the internal medicine services each month and approximately half of them are taking PPIs regularly. The team defined appropriate use criteria for PPIs: stress ulcer prophylaxis in critically ill patients, patients with Barrett’s esophagus and those with acid-related complications (upper GI bleed, erosive esophagitis, ulcers) diagnosed within 8 weeks before admission, patients with persistent GERD symptoms, patients with hypersecretory disorders, patients with previous esophageal or gastric surgery, and patients receiving a PPI as part of a *Helicobacter pylori* infection treatment regimen. All patients admitted to the service were evaluated for appropriateness of PPI therapy and if the patient did not meet the appropriate use criteria, the PPI was discontinued and order for PRN for 2 acid-suppressive therapies (first choice antacids, second choice H₂ – receptor antagonists) were placed. Attending physicians were notified when the PPI stewardship team made these changes. There was no data provided as to the effectiveness of the program in decreasing PPI use, decreasing adverse events associated with PPI use, cost savings or attending physician acceptance of the program.
 - **HPM Recommendation – The authors provide good information on the development and implementation of a PPI stewardship program, but no results are provided. This article will help you in developing criteria if you are considering on implementing a similar program at your facility.**
- An article titled **“Emerging roles for pharmacists in performance-based risk-sharing arrangements”** (*Am J Health-Syst Pharm. 2017;74(13):1007-1012*) was discussed. In the ambulatory care setting, a newer model of payment is paying for positive healthcare outcomes. One model in place is a performance-based risk-sharing arrangement (PBRSA). PBRSA are an opportunity for pharmacists to provide value to the healthcare system. There are many different types of PBRSA and no two are alike. The basic premise is that the level of payment or reimbursement for a given drug is based on whether or not the intended outcomes are achieved. Manufacturers promote the use of PBRSA when there are questions on the effectiveness and safety of new agents as compared to low-cost standard therapies. A PBRSA incentivizes payers to adopt the use of the new agent while minimizing the financial risk in doing so. The U.S. healthcare system has been slower to implement PBRSA than European health systems. One reason cited for this slow adoption is the

fragmented healthcare systems in the U.S. and the increased efforts, resources and infrastructure required to effectively implement record-keeping systems needed for PBRsAs. The authors suggest that pharmacists can play key roles in PBRsAs by contributing to the design, implementation, provision of care and evaluation of the PBRSA.

- **HPM Recommendation – Discuss this topic with your managed care contracting people to determine if PBRSA opportunities exist in your organization and, if so, get your pharmacists involved.**

- A CPO perspective article titled **“Ambulatory care pharmacy: Realizing the potential for patient access and operational excellence”** (*Am J Health-Syst Pharm.* 2017;74(13):1013-1019) was reviewed. The authors describe the expansion of ambulatory pharmacy services at the University of Kentucky Health Care (UKHC) as part of a conscious effort to expand access and generate net income for the organization. The program included: optimization of contract pharmacy services provided in conjunction with the 340B drug pricing program; optimization and expansion of retail pharmacy services; creation of a prescription delivery service for patients being discharged; optimization of employee prescription benefits; and the creation of a specialty pharmacy in collaboration with specialty clinics. Before embarking on any expansion efforts, UKHC fortified the compliance aspects of the 340B program and put in place multiple analysts to audit the 340B program on a weekly basis. Hospital based retail pharmacy services were expanded and a new pharmacy located in the hospital lobby initiated a med-to-bed discharge prescription medication program. 340B split-billing software was added to the retail settings and this allowed for filling prescriptions for walk-in business. This provided the opportunity to offer employees the opportunity to have their prescriptions filled on-site. An effort to increase 340B contract pharmacy opportunities was very successful and UKHC went from having 1 to 75 contract pharmacies over a 4-year period. UKHC estimated potential revenue from specialty pharmacy services to be over \$200 million and implemented a plan to add a specialty pharmacy. By 2016 the UKHC specialty pharmacy was filling over 2,000 prescriptions per month. Over a 5-year period, the UKHC ambulatory pharmacy services increased prescription volume from 223,000 to 430,000 per year and increase profit margins by over 500% over baseline.
 - **HPM Recommendation – This is a compelling story about the benefits of expanding ambulatory care pharmacy services in a 340B participating institution. Review the article carefully and determine how much of this success that you may be able to replicate in your institution.**

- A Perspective article titled **“Accelerated Approval and Expensive Drugs – A Challenging Combination”** (*N Engl J Med.* 2017;376(21):2001-2004) was discussed. Since the 1990s the FDA has been approving drugs for serious or life-threatening disease based on surrogate end points that “reasonably likely to predict clinical benefit”. This accelerated pathway requires the manufacturer to perform post approval trials to confirm the efficacy for the indication, but there is often-times a significant time lag for these studies to be completed. Meanwhile, the drug is prescribed and Medicaid and Medicare are basically required to automatically approve the use for any FDA approved indications. Multiple examples of drugs that cost over \$100,000/year are provided and Eteplirsen (Exondys 5.1) is a drug in this category that costs over \$300,000/year. The authors propose policy changes to address this issue. 1. Manufacturers could be required to offer additional price concessions to public insurance programs until the confirmatory trials are completed. 2. The FDA needs to do more to ensure that the confirmatory trials are completed in a timely fashion. The FDA already has the authority to assess financial penalties or withdraw an accelerated-approval drug from the market if the manufacturer fails to execute due diligence in completing the trials, but this authority is rarely exercised. 3. All drugs that approved through the accelerated-approval pathway and cost over \$100,000 per year should be the subject of formal economic impact analyses after 1 to 2 years on the market.
 - **HPM Recommendation – Primarily an FYI article, but good food for thought related to the accelerated-approval pathway.**

- An article titled **“Healthcare utilization and costs for patients initiating Dabigatran or Warfarin”** was reviewed. This manufacturer (Boehringer Ingelheim (BI)) sponsored study (*Health and Quality of Life Outcomes*. 2017;15(128):1-9 - <https://hqlo.biomedcentral.com/articles/10.1186/s12955-017-0705-x>) compared the health care resource utilization, mean pharmacy costs, mean medical costs and mean total costs in 1,110 patients initiated on dabigatran therapy for non-valvular atrial fibrillation with corresponding patients initiated on warfarin. While the pharmacy costs were significantly higher in the dabigatran group, the overall total costs on a per member per month basis were similar between the two groups. We caution about reading too much into the results of this manufacturer sponsored study. Over half of the 10 authors are either employed by BI or have other financial ties to the company. Furthermore, this is not a journal that is highly respected by the medical establishment.
 - **HPM Recommendation – As noted above, be cautious in accepting these results on face value alone. We include this article in the anticipation that Pradaxa reps will begin using this information to promote this drug to prescribers and you should be aware.**

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Drs. Dan Ross and Amy Gutierrez do not have (nor do any of their immediate family members have) a vested interest in or affiliation with any corporate organization in the past 12 months offering financial support or grant money for this continuing education activity, or any affiliation with an organization whose philosophy could potentially bias their presentation.