MESSAGE FROM THE CHAIR
Amy Dzierba, PharmD, BCPS, BCCCP, FCCM

I hope this newsletter finds everyone well as we head into autumn! This year, 1,601 abstracts were accepted for the 2018 Congress, a record 81% acceptance rate. I am looking forward to hearing about all the great work generated from the CPP Section at Congress, which will be held in San Antonio, Texas, USA, February 25-28, 2018. As in previous years, Research Snapshot Theaters will be used for abstract presentations; new this upcoming year will be designated areas to “continue the conversation” with the author and abstract viewing stations throughout the exhibit hall. There will also be a number of other exciting new networking and information-sharing opportunities at Congress. There will be roundtable discussions designed to provide information-sharing on a variety of topics from how to become more engaged with the Society to curriculum vitae building. Others include a technology laboratory to learn about the latest and best technologies for personal and professional use, more Crosstalk Theater sessions, and Critical Connections TV, which will stream live sessions for those not able to attend Congress.

The Institute for Healthcare Improvement has developed the Triple Aim framework, which outlines a three-pronged approach to innovation. Ample literature reflects the positive impact of critical care pharmacists toward these three aims. As essential members of the healthcare team, critical care pharmacists have demonstrated influence on reducing healthcare costs, improving the patient experience, and enhancing quality of care. As population health continues to be an area of focus, pharmacy practice models across the nation are evolving by working with healthcare colleagues to identify high-risk patients and reduce modifiable risk factors or care gaps. In the upcoming months, the CPP Section will focus on the future of critical care pharmacy and the evolution of pharmacy practice models. Many of you have already identified opportunities to improve or establish pharmacy services to enhance healthcare in the critically ill and should pursue research that evaluates the impact of this work on patient outcomes. Our profession needs to capitalize on these opportunities and remain engaged with the rising tide of healthcare optimization within the multidisciplinary team.

If you are looking to become involved within the CPP Section or would like to share any ideas or suggestions with me, please feel free to contact me at ald9012@nyp.org.
CPP COMMITTEE CORNER

Communications Committee
Jason Makii, PharmD, MBA, BCPS, BCCCP (chair), and Chris Droege, PharmD, BCCCP (chair-elect)

The Communications Committee is excited to present the second themed newsletter of the year. This issue's member spotlight and pharmacotherapy article focus on a practitioner and topic in the area of pediatric critical care. Also included is an update on the drug shortages everyone is facing and some pointers on how to navigate the institutional review board!

As a reminder, the next issue, coming in December, will have important information as we prepare for the upcoming 2018 Critical Care Congress in San Antonio, Texas, USA.

If you have any questions regarding membership in the Communications Committee or contributions you would like to make to the CPP Section newsletter, please contact Jason Makii (Jason.Makii@UHhospitals.org) or Chris Droege (christopher.droege@UCHealth.com).

Education Committee
Karen Berger, PharmD, BCPS, BCCCP (chair), and Jennifer Cortes, PharmD, BCPS, BCCCP (chair-elect)

The Education Committee is exploring different opportunities for pharmacist-driven education to benefit the section and the society. The committee will be looking at new opportunities to showcase pharmacists and provide education through the use of podcasts. More than 200 Research Snapshot Theater presentations from 2017 Congress have been uploaded to the iRoom. To locate them, log in to the CPP Section iRoom, choose Committee Documents on the left column, then Education Committee, then Congress Posters (2017). They are arranged by abstract number. If you presented an abstract at the 2017 Congress and do not see it in the iRoom, please e-mail it to clgriffiths@wingate.edu and we will upload it for you.

The CPP Journal Club is held on the third Friday of every month at 2:00 p.m. Eastern Time. The committee is working on Accreditation Council for Pharmacy Education accreditation opportunities for the journal club webinars and is using social media to increase audience participation and involvement. Please follow us on Twitter @SCCMCPPJC and join in the discussion by tweeting during our Journal Club webinars using #sccmcppjc. Remember that any SCCM member can register for upcoming Journal Club webcasts for free through the SCCM store. Subscription to Journal Club On Demand is automatic once you are registered; this can be accessed any time by logging in to MySCCM and navigating to MyLearning.

If you have questions or would like to be involved in the Education Committee, please contact Karen Berger (karenberger7@gmail.com) or Jennifer Cortes (jccortes0801@gmail.com).

Research and Scholarship Committee
Joe Swanson, PharmD, BCPS, FCCM (chair), and Megan Rech, PharmD, MS, BCPS, BCCCP (chair-elect)

We are excited to continue supporting research-related resources available to all CPP members:

- **Online research discussion forum:**
  - Provides a place for CPP members to discuss research ideas or find collaborators
Please register for the forum and post any research-related questions or comments you may have
- Register and access the forum at http://cppresearchforum.icyboards.net/
- The forum also houses the research funding database and the formal research consult service. So, if you are looking for funding sources or would like a formal review of a grant proposal, please visit the forum for more information

Research funding opportunities:
- Identifies grants available from professional organizations, industry, and government
- Funding from SCCM and CPP awards at various levels
- Found at http://cppresearchforum.icyboards.net/
- The link to the research forum is also available in the iRoom in the Research and Scholarship Committee folder

Research consultation for any aspect of your study design or analytical plan:
- All questions are welcome, from power calculations to appropriateness of statistical tests to outcome definitions. We are available for both simple and complex consults!
- You can utilize the Research Consult Service by inquiring at http://cppresearchforum.icyboards.net/

Critical Care Pharmacotherapy Literature Updates (CCPLU):
- Remain up to date with summaries of clinical trials and guidelines encompassing critical care pharmacotherapy from over 40 scientific journals
- There are multiple ways to receive monthly updates!
  - Review the literature updates monthly in the iRoom under Committee Documents > Research and Scholarship Committee > Literature Updates
  - Join our mailing list! E-mail CPP_CCPLU@gmail.com
  - Like us on Facebook: https://www.facebook.com/Critical-Care-Pharmacotherapy-179309855414314/

Manuscript or grant pre-peer review:
- Have your manuscript or grant reviewed by an expert prior to a formal submission
- Contact Joe Swanson (jswanson@uthsc.edu) or Megan Rech (mrech@lumc.edu) for more information

Another area of emphasis for the committee is developing and facilitating multiple research projects. We currently have numerous ongoing multicenter surveys and retrospective reviews. If your goal is to get involved in research but don’t know how to get started, consider volunteering for the Research and Scholarship Committee (specifically Charge 1, conducting research)

- Our goal for 2018 Congress is to have available a list of potential research projects for Charge 1 for you to review as you sign up for committees. We hope this will help identify researchers interested in this charge.

If you would like further information about any of these activities or would like to get involved in the Research and Scholarship Committee, please contact Joe Swanson (jswanson@uthsc.edu) or Megan Rech (mrech@lumc.edu).

Programming Committee
Todd Miano, PharmD, MSCE (chair), and Laura Zane, PharmD, BCCCP (chair-elect)
The Program committee has had a very productive year so far, with all of the 2018 programming content complete and the 2019 content planning nearly complete! In this update, we’d like to give a brief snapshot of two programs that are available to our members.

Visiting Clinical Professor Program
Are you trying to grow your critical care pharmacy program? If so, the Visiting Clinical Professor (VCP) Program may be able to help! The VCP program matches CPP members with a visiting professor based on their specific needs. The visiting professors are nationally recognized faculty in their fields. The VCP visits for one to two days to interact with pharmacy and medical colleagues, share knowledge and experience, and provide guidance and advice for forward movement of practice. If you are interested in applying, the application can be found under the Program Committee Documents section in the CPP iRoom at http://www.sccm.org. The application process is continuous throughout the year. If you’d like to learn more about the VCP Program, please contact Patricia Lynch (Patricia.Louzon@flhosp.org) or Todd Miano (Todd.Miano@uphs.upenn.edu) for more information.

Recruitment Exchange
The CPP Recruitment Exchange will be held again at Congress in San Antonio! This no-charge, informal event allows institutions with available critical care pharmacy positions to meet prospective candidates. This past year we had over 45 candidates seeking positions at the live event. All information is also posted in the iRoom for easy access after Congress. If you would like to advertise a critical care position, please e-mail SCCMPPExchange@gmail.com by February 9, 2018. The committee would like to ask all CPP members to share this information with their institutions.

And for CPP members who are residents: This is a great opportunity for you to meet your future employer and to see what critical care positions are available! More details on date, time, and room location to come!

Patient Safety Committee
Andrew Fritschle-Hilliard, PharmD, BCPS, BCCCP (chair), and Siu Yan Amy Yeung, PharmD, BCPS (chair-elect)

The CPP Patient Safety Committee continues to provide the Patient Safety Pearl for the quarterly newsletter. In this issue, the focus is on drug shortages and their implications. The authors share management strategies that they are implementing at their own institutions and provide considerations and challenges for preventing shortages from becoming critical. We welcome any suggestions other members may have on the Listserv as well as ongoing discussion on this topic as we all work together to ensure the safety of the critically ill during these challenging times.

The Patient Safety Committee, in partnership with the Education Committee, will host two patient safety-related journal articles in the 2017-2018 academic year. The first of these will be presented in January 2018. Please watch your e-mail for future communications regarding registration and participation in the January CPP Journal Club.

Other initiatives for the committee include conducting patient safety-related research. If you are interested in joining the Patient Safety Committee or have a desire to learn more about these initiatives or others that our committee is undertaking, please contact Andrew Fritschle-Hilliard (andrew.fritschlehilliard@eskenazihealth.edu) or Siu Yan Amy Yeung (syeung@umm.edu).
Membership Committee
Tara Holt, PharmD, BCPS, BCCCP (chair), and Meghan Caylor, PharmD, BCPS (chair-elect)

SCCM Congress Buddy Program
The CCP Membership Committee will again be offering the Congress Buddy Program at the annual Congress in San Antonio. This program pairs first-time attendees with experienced members to ensure that first-time attendees maximize their Congress experience. Stay tuned for further details.

SCCM Congress First-Time Attendees Orientation
The Membership Committee would like to welcome new members or first-time Congress attendees to attend an orientation that will provide insight into various CPP Section programs as well as activities occurring during Congress. This orientation is typically held prior to the CPP member reception and is a great opportunity to meet fellow section members. Additional details will be distributed as they are known.

Mentor-Mentee Program
The Membership Committee continues to offer the CPP Section Mentor-Mentee Program, which connects pharmacists at all levels of training, with the goal of furthering clinical practice, research, teaching skills, and/or SCCM and CPP involvement. While we are always interested in having new mentees, we are in need of mentors with all types and years of experience to sustain the program. Mentee experience levels range from PGY2 residents to those with multiple years of experience who are transitioning to a different practice area or looking for mentorship in a specific area, such as research or CPP involvement. If you are interested in participating, please contact Tara Holt (tholt4@iuhealth.org) or Meghan Caylor (meghan.caylor@uphs.upenn.edu) for more information.

Pharmacotherapy Article
Pediatric Plastic Bronchitis: Approaches to Treatment
Thomas Moran, MS, PharmD, BCPS, and Gretchen Sacha, PharmD, BCCCP

Plastic bronchitis is a rare disorder that can affect all age groups, with fewer than 500 cases reported in the literature prior to 2008. Specifically in pediatrics, one institution described a prevalence rate of 6.8 cases per 100,000 patients. Due to unfamiliarity with the disorder, its true prevalence is unknown; many cases are not diagnosed until autopsy and can be misdiagnosed as other syndromes that result in mucus plug formation. Plastic bronchitis is characterized by the expectoration of extensive bronchial casts that are often full impressions of the patient’s tracheobronchial tree. Patients with plastic bronchitis can present with a range of symptoms from mild respiratory symptoms to life-threatening respiratory failure due to airway obstruction. An additional finding on presentation is partially occluded airways termed *bruit de drapeau*, likened to the sound of a flag snapping, which can be heard during respiration. Due to the condition’s rarity, mortality rates reported in the literature vary greatly, ranging as high as 50%. It is important to note that plastic bronchitis is a consequence of many different disease processes and not of one disease. The most common diseases associated with pediatric bronchial cast formation are congenital and structural heart disease (particularly after surgical correction, including Fontan surgery for single-ventricle physiology), with estimated prevalence rates of 4% to 14%, and influenza, asthma, allergies, and sickle cell acute chest syndrome.
Historically, there have been two classifications of plastic bronchitis based on the histology of the mucus plug. Type I bronchial casts are said to be inflammatory in nature, and the casts are composed mostly of fibrin with small areas of mucin and a dense eosinophilic inflammatory infiltrate. Type II bronchial casts are said to be acellular in nature, composed mostly of mucin with small areas of fibrin and no acute inflammatory infiltrate. Patients with type II casts frequently have congenital cyanotic heart disease and have had palliative surgical correction. These patients appear to have higher mortality rates compared to patients with type I casts.

Recently, plastic bronchitis cases have not fit well into this classification scheme, and new schemes have been proposed that include both disease association and cast histology. Brogan et al described three groups of patients presenting with plastic bronchitis categorized based on their underlying illness. Group I patients were described as those with cast formation due to asthma or allergic histories, group II had underlying cardiac abnormalities, and group III had neither cardiac disease nor asthma. The most recently proposed classification scheme combines cast histology and underlying disease, grouping patients into one of 6 categories: 1) structural heart disease with mucinous casts, 2) structural heart disease with mucinous casts with inflammatory cells, 3) structural heart disease with casts with mucin and fibrin, 4) nonstructural heart disease with lymphatic abnormalities/chylous casts, 5) nonstructural heart disease with atopic disease/eosinophilic casts, and 6) sickle cell acute chest syndrome with fibrinous casts.

There is debate regarding the pathophysiologic origin of cast production; a mechanism has not been fully elucidated. It is suggested that patients with type II casts or structural heart disease typically have an abundance of mucin production resulting in mucus accumulation in the airways, leading to cast formation. Theories about the cause of mucus hypersecretion include elevated pulmonary pressures resulting in an exaggerated response of the pulmonary epithelium and excessive mucus secretion or an underlying host factor that is stimulated after cardiac surgery or inherited with congenital heart disease. In patients with Fontan physiology, it is theorized that there may be either abnormal drainage, production of pulmonary fluid, or a pronounced inflammatory response due to prolonged exposure to chest tubes. Other pathophysiologic processes implicated in the development of plastic bronchitis are impaired lymphatic drainage in the pulmonary lymphatics resulting in the buildup of chyle in the airways and inflammatory reactions resulting in buildup of inflammatory cells such as neutrophils and eosinophils, with subsequent cast formation. Overall, all proposed mechanisms of cast formation remain theoretical.

Treatment of plastic bronchitis in the literature varies and tends to include medical management of the condition’s source (optimizing the pulmonary venous pressures and decreasing inflammatory states), surgical removal of the source (transplantation or embolization), and management of the casts themselves (bronchoscopy to remove the casts, respiratory therapy and inhaled medications to help clear formed casts). Surgical procedures that have demonstrated efficacy in treating plastic bronchitis include embolization of the specific regions of the lymphatic system and heart transplantation.
In a case report from the Children’s Hospital of Philadelphia, Dori et al described a 6-year-old child with a hypoplastic left heart who presented with casts despite aggressive medical management including saline nebulizations, albuterol, acetylcysteine, dornase alfa, sildenafil, and steroids. The patient underwent comprehensive imaging and mapping of the lymphatic system, including lymphatic flow. The imaging studies showed dilated lymphatic ducts, which allowed abnormal lymphatic flow patterns. Selective embolization of the ducts to help reduce the aberrant flow followed. After the procedure the patient had improved oxygen saturation and was able to be discharged after 3 days. It is reported that the patient was able to discontinue use of inhaled therapies within 2 weeks of the procedure and has remained cast-free for at least 5 months.\textsuperscript{11}

Gossett et al described 10 patients with plastic bronchitis who underwent heart transplant surgery. Three of them did not survive 1 month post-surgery due to complications unrelated to plastic bronchitis. In the 7 surviving patients, however, there were no casts reported after a median of 5.7 years post-surgery. The authors acknowledge the considerable risks associated with heart transplantation but have shown that it can lead to a resolution of plastic bronchitis in the studied population.\textsuperscript{12}

While medical and surgical management to avoid the production of casts may be ideal, optimizing the complex hemodynamics of palliative cardiac surgeries can be difficult at best, and surgical management comes with its own inherent risks. There are numerous case reports and small case studies in the literature describing treatment regimens for plastic bronchitis; however, patients frequently receive multiple medications, and it can be difficult to assess the true effectiveness of each individual therapy.\textsuperscript{9} Currently described medical interventions include corticosteroids,\textsuperscript{13} dornase alfa\textsuperscript{2,14}, \textit{N}-acetylcysteine (NAC),\textsuperscript{15,16} and inhaled tissue plasminogen activator (tPA).\textsuperscript{2,17,18,19}

Onoue et al described an 8-year-old boy with dextrocardia and single-ventricle physiology who presented with plastic bronchitis. He underwent a bronchoscopy to remove a large cast and then was treated with NAC and beta-2-agonists but continued to produce casts. The casts stained positive for activated eosinophils using an antibody marker, resulting in the initiation of oral prednisone (2 mg/kg/day) and inhaled beclomethasone (600 µg/day). The day after starting steroids the patient stopped producing casts and remained cast-free for 3 years even after tapering off the steroid.\textsuperscript{13}

Alternatively, Kunder et al described a 1-year-old boy with a history of cardiac surgeries and chronic lung disease who presented with casts and was treated with inhaled dornase alfa in addition to albuterol, budesonide, and azithromycin, all of which were used to manage the condition on an outpatient basis. Unfortunately, because the histology of the casts was unavailable, it was difficult to know which therapy was directly effective.\textsuperscript{2} A more simplified approach was reported by Tzifa et al, in which they used dornase alfa in a 3-year-old Fontan patient who had casts removed via bronchoscopy. Histology of the casts showed moderate numbers of macrophages, but the patient failed to respond to inhaled steroids and antibiotics. Upon introduction of dornase alfa, lung function improved, and the patient was cast-free for at least 8 months with continued treatment.\textsuperscript{14}
NAC is frequently used as a respiratory treatment for a variety of indications including plastic bronchitis.\textsuperscript{15} Mateos-Corral et al described incubating a type II cast that was removed from a cystic fibrosis patient via bronchospy in NAC (200 mg/mL), NaCl (5%), 2.5 mg of dornase alfa, and normal saline. The only effect seen was partial dissolution of the cast with NAC. The patient was started on NAC, 400 mg twice daily, but again developed respiratory distress from cast formation; however, the obstruction could be removed via a flexible bronchoscopy with suction alone. The NAC was continued and no further casts were reported for at least 18 months.\textsuperscript{16}

The medication tPA is also frequently reported to treat plastic bronchitis.\textsuperscript{2,17,18,19} In several reports the cast histology was examined and revealed that the casts contained fibrin. In 2011 Heath et al looked at spontaneously expectorated casts from 4 pediatric patients with congenital heart disease. The casts were treated with phosphate-buffered saline (PBS) or tPA. Cast weight and production of fibrin D dimer were measured to assess the effectiveness of tPA versus PBS. The use of tPA significantly decreased the weight of the casts and increased the D dimer levels detected. As previously mentioned, the histology showed that the casts were primarily composed of fibrin and contained lymphocytes.\textsuperscript{19} In the literature, the dosing of tPA varies, ranging from a de-escalating regimen described by Costello et al to 5 mg inhaled 3 to 4 times daily.\textsuperscript{17,18,20}

In conclusion, plastic bronchitis is a rare and potentially fatal complication of several disease states with a predominant number of those affected having an underlying cardiac or pulmonary diagnosis. The treatments for plastic bronchitis vary wildly in the literature, with evidence suggesting that the cast type is fundamental in terms of which topical or respiratory medical treatment the patient will respond to best.

\textbf{References}
Member Spotlight: Kristine Parbuoni, PharmD, BCPPS
Susan Hamblin, PharmD, BCPS, BCCCP

Kristine Parbuoni, PharmD, BCPPS, is an assistant professor at Loma Linda University (LLU) School of Pharmacy, with a busy practice site in the pediatric cardiac ICU at LLU Children’s Hospital, a 343-bed hospital with over 13,000 children visiting annually. It is the only level 1 trauma center in the Inland Empire of California and has pioneered advanced care in neonatal heart transplantation. Dr. Parbuoni received her doctor of pharmacy degree from the University of Maryland School of Pharmacy. Following pharmacy school, she completed her PGY1 pharmacy practice residency and PGY2 pediatric specialty residency at the Johns Hopkins Hospital in Baltimore, Maryland, USA. During her active career, she has practiced as a pediatric ICU clinical specialist, as well as clinical manager at the University of Maryland Medical Center before transitioning into academia. With this career transition, she particularly enjoys the ability to interact with students and residents, providing mentorship and guidance in her current role.

Kristine became interested in pediatric critical care after spending a day with the pediatric ICU clinical specialist on an introductory pharmacy practice experience at Children’s National Health Center in Washington, DC, USA. She was particularly impressed by the clinical specialist’s dedication to her patients and knowledge of the literature. Kristine later completed a full advanced pharmacy practice experience at this institution that confirmed her increasing interest in pediatric critical care.

Kristine has contributed to the training of young pharmacists through residency, in previous positions as well as her current position. She served as the residency academic coordinator and preceptor before her most recent transition to residency program director. She undertook the task of developing the PGY2 pediatric residency program at LLU in 2014 and has remained program director ever since. She has provided oversight to three PGY2 residency graduates from this program since its inception.

Her dedication to the profession of pharmacy through active involvement in committee and task force work is readily apparent. She is an active member of the American Association of Colleges of Pharmacy, Pediatric Pharmacy Advocacy Group, and American Society of Health-System Pharmacists. She has been actively involved in SCCM’s CPP Section through numerous committees, including the Patient Safety, Membership, and Communications Committees. She has been involved in transitions of care research and the review committee for the Patient Safety Award. She has also led the New Member Orientation on multiple occasions, in addition to numerous other functions within CPP Section committees. She is proud of her involvement on the Pediatric Sepsis Task Force and Drug Shortage Task Force through SCCM. Kristine finds involvement in SCCM particularly collegial, as anyone with a desire to increase involvement can do so while feeling supported by CPP leadership.

With over a dozen publications, Kristine has been involved in research and guideline development. Her research interests center around pediatric sedation and pharmacokinetics in the ICU. She not only provides education for the school of pharmacy, but has experience teaching nursing staff, medical residents, and pediatric critical care fellows. While these activities keep Kristine on the move, she does reserve time to watch the University of Southern
California play football. She also enjoys visiting Disneyland and recently ran a 5K there as an outlet to balance her busy professional career.

**Safety Clinical Pearl: Drug Shortages**

Janet Bush, PharmD, BCPS, BCCCP; Brian Kopp, PharmD, BCPS, FCCM; Meagan Latham, PharmD, BCPS, BCCCP; Andrea Sikora Newsome, PharmD, BCPS, BCCCP, Siu Yan Amy Yeung, PharmD, BCPS, and Andrew Fritschle-Hilliard, PharmD, BCPS, BCCCP

During the past 10 years, drug shortages have greatly impacted patient care. In recent months a surge of new shortages have directly impacted the critical care setting. Pharmacists are in a unique role of developing and implementing drug shortage management strategies; however, this task can often pose a challenge when limited options are available. Members of the Patient Safety Committee have shared a few strategies as responses to recent shortages.

Communication is imperative for providing optimal patient care during a drug shortage. In particular, proactive communication that alerts providers early in the process to prevent shortages from becoming critical can decrease the incidence of stressful patient care situations. Routine communication with providers and clinicians through e-mail, newsletter, and hospital intranet to provide updates on shortage statuses and guide alternative therapies can help streamline conservation strategies and enforce prescribing restrictions.

Here are some examples:

**Epinephrine Emergency Syringe:**
- Evaluate par levels in emergency kits and code carts and decrease to safest possible minimum par level.
- Remove all epinephrine syringes from the automated dispensing cabinets (ADCs).
- Provide prebuilt alternative kits (Fig. 1) with epinephrine and sodium chloride for dilution, as well as preprinted label for instructions on preparation in code carts, emergency kits, and ADCs.
- If possible, consider including one prefilled epinephrine syringe in code cart for first-dose administration, allowing approximately 3 minutes for preparation of next dose via syringe shortage alternative kit.

![Figure 1. Prebuilt alternative kit with epinephrine and sodium chloride for dilution](image)

**Sodium Bicarbonate Emergency Syringe:**
• Check for alternative suppliers of drug (e.g., prefilled sodium bicarbonate syringe from compounding pharmacies).
• Evaluate par levels in code carts and emergency kits (e.g., malignant hyperthermia kit) and decrease to safest possible minimum par level.
• Use central pharmacy to store and allocate syringes.
• Evaluate sodium bicarbonate continuous infusion used in the ICU setting versus alternative strategies, such as oral sodium bicarbonate or hemodialysis.

**Calcium Chloride and Calcium Gluconate:**
• Evaluate calcium repletion thresholds and consider adjustment.
• Develop an alternative strategy for regional anticoagulation instead of citrate for continuous renal replacement therapy.

**Sodium Phosphate:**
• Use enteral supplementation in patients who have functioning gastrointestinal tracts.
• If possible, recommend potassium phosphate instead of sodium phosphate.

One of the most effective approaches to the development of a drug shortage strategy is knowledge-sharing. The Patient Safety Committee encourages members to utilize the CPP Listserv to share your drug shortage management strategies.

**Research Pearl: Navigating the Institutional Review Board**
**Mathew Johnson, PharmD, and Todd Miano, PharmD, MSCE**

Because a large portion of research conducted by pharmacists involves patients or other human subjects, it is important for all pharmacist researchers to be familiar with the institutional review board (IRB). Understanding IRB rules and regulations is important because research generally cannot begin until IRB review has occurred, and many medical journals require evidence of IRB approval or review for manuscript publication. It is also important to understand how to navigate the IRB process in order to minimize delays in reviewing and prevent unnecessary patient harm.

The ultimate purpose of an IRB is to protect the interests of subjects who participate in research. IRBs must ensure that researchers work to minimize the risks taken by study participants while also aiming to maximize the benefits of research to participants and society in general. The guiding principles of most IRB regulations are based on the Belmont Report, published in 1979. It is based on three ethical principles: respect for persons, beneficence, and justice. A set of federal regulations called the Common Rule was subsequently created to govern human subject research. Many of the criteria that IRBs use for reviewing research projects are found here.

Most IRBs require investigators to complete human subject research training, typically through the Collaborative Institutional Training Initiative. Other requirements may include additional training on the Health Insurance Portability and Accountability Act (HIPAA) and/or additional research modules on good clinical practices (GCPs), research ethics, or multiculturalsim. Pharmacists who are principle investigators (PIs) must be particularly attentive to IRB policies and procedures. The PI may be the only person able to submit information to the IRB or make subsequent changes to an IRB
protocol. Consequently, many IRBs require the PI to have more comprehensive training.\(^1\)

Pharmacist researchers may wonder whether their projects must be submitted for IRB review at all. Although the specific requirements for submission vary by institution, the general rule is that all projects that are considered “research” must be submitted for review. This distinction can be confusing for clinicians involved in quality improvement projects, which may involve the collection of data on human subjects but may not be considered research. A good rule of thumb to use in this context is: “If the goal is to publish the results of the project, then the work is considered research and must be reviewed.” In contrast, if data are collected solely for in-house quality improvement initiatives, IRB review may not be required. Other projects may be exempt from IRB review because the research involves no risk to subjects (e.g., projects that use publicly available data). Importantly, only the IRB can make this determination. Thus, even if an investigator is confident that a project will be deemed exempt, submission to the IRB for review is still required.\(^1,4\)

Materials typically required for IRB submission include an institution-specific submission form, the research proposal, curricula vitae, conflict-of-interest forms, data collection forms, and, if necessary, recruitment materials and informed consent forms. The submission must be written in language that is clear, specific, and easy to understand, since the IRB consists of both scientist and nonscientist members.\(^4\) Aspects of the research project that the IRB considers include study design, subject selection, risks posed by the research and the methods employed to minimize them, potential benefits of the research, confidentiality, compensation, informed consent, and access to protected health information (PHI). Research that involves only minimal risk to participants (e.g., retrospective studies) can include a waiver or alteration of informed consent and HIPAA authorization. If a waiver or alteration is sought, it is important to detail in the IRB submission why the research involves only minimal risk to the subjects. Retrospective studies must also include a detailed plan that specifies how PHI (e.g., identifiers, names, dates) will be collected, stored, and destroyed to ensure that it is not improperly used or disclosed. There should be a clear process for data de-identification and the use of encrypted storage platforms if PHI is required for research conduct (e.g., manual chart review).\(^1\) Fortunately, if the initial IRB protocol is rejected, the majority of IRBs will assist in making appropriate revisions.\(^5\)

It is important to begin working on IRB submission early in the planning stages of the project because work on the research project (e.g., data collection) cannot begin until it has been approved by the IRB. Once initial approval has been obtained, the IRB must review the research on at least an annual basis.\(^1\) It is important for investigators to know the local IRB continuing review policy and what information will be required for continuing review, such as a summary of the protocol and an update on the study’s progress.\(^9\) If changes to the research protocol are needed, they cannot be initiated without IRB approval. These changes will need either an expedited or full IRB review, depending on the magnitude of the changes.\(^1\) Investigators are also required to report to the IRB any unanticipated problems, such as the loss of a laptop that contains patient health information.\(^4\)
Successfully completing the IRB review process is an important step for all research projects. Pharmacist researchers should thus utilize all resources at their disposal. This may involve seeking a review from a peer or mentor who is familiar with the IRB process. Some IRBs offer consultation before IRB submission in order to prevent reviewing delays. Maintaining communication with the IRB office will keep the project on track and ensure a smoother navigation process. 

References


Communications Committee members are charged with publishing the newsletter. Thank you to the following members:

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Marilyn Bulloch  
Payal Gurnani  
Brianne Ritchie

Featured CPP Resources

- Are you stuck on a research-related question? Consider reaching out to the experts in the CPP Research Committee by visiting the CPP Research Forum.
- Do you have a manuscript or grant that you would like to have reviewed by a content expert? If so, e-mail the Research Committee chair at piche.shannon@mayo.edu.

Upcoming SCCM Congress Meetings – Save the Date!

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<td>February 25–28</td>
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