# InPharmative Quarterly

ALSHP's Clinical e-Journal Quarterly Publication

February 2017, Volume 3, Issue 1


## Standardize 4 Safety

*By: Charles Durant, PharmD and Emily Lambert, PharmD Candidate 2017*

Standardize 4 Safety is the first initiative of its kind, aimed at producing and implementing national standardized concentrations for both intravenous (IV) and liquid oral medications. ASHP was awarded a 3-year contract from the FDA's Safe Use Initiative to develop these standards. The ultimate goal of the initiative is to use standardization as a means to decrease medication errors, as well as improve transitions of care.

Partners with ASHP to develop these national standardized medication concentrations included national organizations such as: the Pediatric Pharmacy Association (PPAG), the Institute for Safe Medication Practices (ISMP), the Association for the Advancement of Medical Instrumentation (AAMI), as well as regional and local healthcare organizations. An interprofessional panel consisting of a pharmacist, nurse, and physician experts in a variety of disciplines are working together to develop these standards.

It is important to note that Standardize 4 Safety is a guideline and implementation is not mandatory; however, the vision of ASHP is that organizations nationwide will adopt these proposed concentrations in order to work toward better standardization within healthcare across all settings in the interest of patient safety.

This initiative has been broken down into 3 phases for the IV project, each to be completed within a year's time starting in 2016. Phase I focused on standardizing adult continuous infusions, while Phase II targets pediatric continuous infusions. Phase III will work towards normalizing IV intermittent and PCA/epidural medications. Throughout the project standard doses for oral liquid medications and oral chemotherapy agents, as well as concentrations for compounded oral liquid medications, will be developed.

To date, Phase I of the initiative has been completed. A finalized list, referred to as Version 1.01, is published and is comprised of 32 of the most commonly used or high-alert medications administered as an intravenous continuous infusion in adults.

To view the list, compare your intravenous solutions to the proposed national standards, or to learn more about the Standardize 4 Safety initiative, visit the link below. Additionally, at this link you contribute comments regarding future phases of this initiative.

http://www.ashp.org/DocLibrary/Policy/Standard-4-Safety/ASHP-IV-Adult-Continuous-Infusion-Guiding-Principles.pdf

### IN THIS ISSUE:

# Creating a More Effective Pharmacy and Therapeutics Committee

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### *Introduction*

Many small hospitals and healthcare systems struggle with the production of true change and quality improvement. This can be compounded when charged with standardizing a system of hospitals with different cultures. This article will describe one tactic that a small healthcare system used to address standardization of medication management.

The healthcare system, consisting of two hospitals, a cancer center, and multiple off-site clinics, including a pain clinic, wound clinic, imaging centers, and ambulance services, was merged under one provider number. One year after the merger, the system was surveyed by an accrediting organization. In the exit interview, the surveyors noted that the system functioned more like separate parts than one entity. The management of the system knew this must be addressed prior to the next accreditation survey.

To address medication management issues, the system utilized a combination of local and system Pharmacy and Therapeutics Committees (P&T). The Directors had already begun the process of standardizing processes, policies, standing orders, and other issues, but started running into resistance to change which slowed the process. After much early success, even small changes became a struggle.

### *Changing the Process and Structure of the P&T model*

In an effort to accelerate the standardization process, the CEO, in consultation with the Pharmacy Directors, suggested changing the P&T model. The new committee consists of: (1) physicians selected by the Directors of Pharmacy, (2) Directors of Pharmacy, and (3) the CEO of the system. The physicians included hospitalists from each facility and the primary private practice groups, active private practitioners, and an Emergency Department physician.

There are no hospital departments except the pharmacies represented on the committee. Ad hoc inclusion of department directors or other physicians may be added when warranted. The rationale to exclude other department members was based on ineffective meetings due to tangible conversations, turf discussions, and time management issues. Reducing these distractions should help the members fulfill the primary charge of the committee – "selecting best available practices when discussing an issue" and removing the conversations of individual past practices.

The group decided to move data not requiring approval to a 'consent agenda' thereby increasing committee time to focus on the physicians' priorities. The first meeting was spent brainstorming what the physicians thought should be addressed. This information was organized into two project groups, indirect issues outside the P&T committee and direct issues addressed by the committee.

The first group included issues outside the scope of the committee (indirect issues). These concerns were forwarded to departments that would lead each process of quality improvement. Though not undertaken by the committee, the committee was apprised of improvement progress for each P&T indirect issue. Much improvement has been seen on this front, including areas of improvement not under prior consideration by the P&T committee.

The second group included direct issues that could be addressed by the committee. These were organized into line items, upon which the physicians were polled via an online voting site. Each physician ranked the importance of each of topics the committee might undertake. After voting, completed results were presented, and the committee selected which direct issues to focus their time and attention.

The process of each meeting is simple. An agenda is prepared based on medical staff requests and accrediting organization requirements. An executive summary is prepared for committee members, addressing outliers noted in the consent agenda and discussion topic summaries. A packet is prepared and distributed to the members including information addressing the consent agenda, other information that may be needed during the meeting, the agenda, and the executive summary. Post-meeting, a highlights newsletter is emailed to the medical staff. The complete Medical Staff Summary is placed on the intranet and minutes are prepared.

### *One Year Later*

The committee approved system-wide admission orders for adults and pediatrics, admission orders for our top ten diagnoses, standardized anticoagulant prophylaxis and treatment processes, and multiple changes in the reconciliation process.

Active projects include medication reconciliation in cooperation with the University of Alabama Huntsville, oxygen-saturation monitoring in patients receiving opiates, and standardized therapeutic interchange across the system. Indirect issues addressed outside of P&T include four completed Nursing projects and one Laboratory project.

### *Example of an initiative*

An example of the quality improvement with P&T was the standardization of anticoagulant therapy. Standardization of the treatment and prophylactic process were both ranked within the top 5 priorities by the committee. This was an emotional issue between facilities. Nursing administration had previously been charged with standardization of this process, but there had been no movement for two years. In one facility, scoring for prophylaxis was done by the physician with multiple forms being placed in the patient's chart upon initiation of anticoagulant therapy. Another facility utilized a single form for all anticoagulants (except heparin), which was placed under an anticoagulant tab on all adult charts for the physicians to address. In addition, nursing was utilized to complete the required scoring prior to the physician addressing venous thromboembolism prophylaxis needs assessment for the patient. The committee reviewed each facility's process (including paper forms) involved, and developed a standardized, simplified process. After years of work with little to no result, a collaborative decision was made in five minutes.

### *Utilization of Technology*

Further progress in the P&T initiative involved the use of the intranet to make decisions between meetings. For example, two projects high on the priority list were preparation and approval of standard system admission orders (adult and pediatric) and admission orders for the system's top 10 diagnoses. The committee is on a quarterly meeting schedule, so this project would have taken many meetings to complete. Utilizing proprietary software, the P&T committee was able to post documents/issues for review, discussion, and voting related to the issues surrounding the admission order sets. Utilizing technology has allowed us to continue our work on processes and issues between meetings and making virtual meetings possible, if necessary. The P&T committee did conduct one business meeting virtually. The meeting ran the same as face-to-face meetings, but all voting was done via the intranet platform.

### *Conclusion*

The changes made to the P&T Committee have been very successful for the healthcare system. The committee has made advances in the standardization process in a relatively short time that could have taken years. Much of this is attributed to the reduction of the committee to a core group that functions more efficiently and support from the system's physicians of the committee. With strategic organization and committed support, this is progress that could be made in any system or single facility.

# 2016 ALSHP New Practitioners' Research Forum Abstracts

## Acute kidney injury associated with vancomycin and beta-lactams: Piperacillin-tazobactam versus cefepime

Tied for 1st Place

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**Purpose/Background:** Recently published retrospective data demonstrates at least a two-fold higher incidence of acute kidney injury (AKI) with the combination of vancomycin and piperacillin-tazobactam (VPT) compared to both vancomycin monotherapy and the combination of vancomycin and cefepime (VC). Our study aims to further investigate the incidence of AKI between these two beta-lactam combinations and to identify independent risk factors for AKI.

**Methods:** This single-center, retrospective chart review compared patients who received VPT between April and August 2014 and patients who received VC between April and August 2015. Adult patients who received either VPT or VC for at least 48 hours with study drugs initiated within 48 hours of each other were included. Patients with creatinine clearance less than 15 mL/min or renal replacement therapy (RRT) at baseline, AKI prior to study drug initiation, study drugs initiated at another facility, active cancer undergoing intravenous chemotherapy, or pregnancy were excluded. The primary endpoint was AKI, defined as an increase of either at least 0.3 mg/dL from baseline within 48 hours or at least 1.5 times baseline within 7 days. AKI was considered to be related to the study drugs if it developed either during combination therapy or within 72 hours of discontinuation of combination therapy or until discharge, whichever occurred sooner. Key secondary endpoints included time to AKI, status of AKI status at discharge, hospital and ICU lengths of stay (LOS), and all-cause mortality. Potential independent risk factors were compared between the patients who developed AKI and those who did not.

**Results:** A total of 60 patients were included in the VPT group and 55 patients were included in the VC group. A low percentage of patients had CKD stage 3 or 4 at baseline, 8.3% in VPT and 3.6% in VC. The primary outcome, incidence of AKI, was 23.3% with VPT and 10.9% with VC (p=0.08). Nearly all patients in each group who developed AKI qualified by having an increase in serum creatinine by at least 0.3 mg/dL from baseline within 48 hours. More patients were either improving or resolved at discharge with VC than VPT (67% versus 50%, respectively); however, time to AKI, hospital LOS, ICU LOS, and all-cause mortality were similar between groups (p>0.05). In the analysis of possible risk factors associated with AKI, only vasopressor use and the receipt of at least two other nephrotoxins were found to be independent predictors of AKI.

**Conclusions:** The rates of AKI between VPT and VC from this study are consistent with those seen in previous studies. VC may be associated with a higher rate of improvement and resolution than VPT. Larger studies should be performed to further investigate the incidence of AKI between VPT and VC, and a multivariate analysis should be completed to compare the effects of combinations of potential risk factors on the development of AKI between VPT and VC.

## Identifying risk factors for viral reactivation after solid organ transplant in a pediatric population

**Tied for 1st Place**

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**Purpose/Background:** The complications of viral reactivation in pediatric patients post-transplant can be severe and can lead to allograft injury, organ rejection, or graft loss. With new advances in the medications used for immunosuppression, episodes of acute rejection have decreased while episodes of viral reactivation have increased especially in the pediatric population. Data identifying specific potential risk factors for viral reactivation after a solid organ transplant in pediatrics is lacking, making early identification and prevention a difficult task. This project will aim to identify risk factors associated with viral reactivation so that it may be possible to provide better screening to identify patients at higher risk, develop protocols to reduce the likelihood of viral reactivation, and prevent viral reactivation from occurring.

**Methods:** This study is a retrospective chart review of pediatric transplant patients who received a solid organ transplant between 2010 and 2014 at Children's of Alabama. The purpose of the study is to identify risk factors for reactivation of BK virus, Cytomegalovirus (CMV), and Epstein-Barr virus (EBV) in children 18 years of age or younger after a kidney, liver, or heart transplant. Patient demographic data, underlying disease state, patient serology, donor serology, induction treatment, pre- and post-transplant immunosuppression regimens, rejection episodes and treatment regimens, viral development and treatment regimens, and other pertinent data were collected from patient charts. A case-control statistical analysis of the data was performed. Categorical variables were compared using chi-square tests unless one or more cells had an expected $N < 5$, for which Fisher's exact tests were used. A Student's t-test was used to test for significant group differences for mean age, and a Kruskal-Wallis test was used to test for significant group differences for median age. An alpha of 0.05 was set for significance.

**Results:** No statistical differences in baseline demographics were found between the group that developed virus and those that did not develop virus. Overall, 50.3% (N=82) developed one or more virus within one-year of transplant. EBV was the most common of all viral infections within one-year of transplant (81.7%), followed by BK (31.7%) and CMV (19.5%). At time of transplant, a greater proportion of these patients were seropositive for CMV. There were no significant differences between the two groups for immunizations before transplant; however a relationship between the pneumococcal vaccine and an increase in virus development was present. Data analysis is still ongoing.

**Conclusions:** With the lack of literature regarding specific risk factors to assist in identifying those patients more likely to experience viral reactivation, the frequency of viral reactivation in pediatric solid organ transplant, and the serious complications associated with viral reactivation, our group hopes to develop a protocol when data analysis is complete that includes a scoring system to identify those patients at higher risk for developing viral infections post-transplantation in order to provide better and more frequent screening for virus development and possibly higher antiviral medication doses for a longer duration.

## Evaluation of bivalirudin in patients undergoing percutaneous coronary intervention by duration of infusion

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**Purpose/Background:** Stent thrombosis is a potential complication of stent placement within 30 days following percutaneous coronary intervention (PCI). Several clinical trials consistently show treatment with bivalirudin

resulted in higher incidents of stent thrombosis compared to unfractionated heparin. There is limited but promising data to suggest prolonged infusion may reduce this incidence.

**Methods:** A retrospective chart review of one-hundred patients was conducted to determine the composite of cardiovascular outcomes (revascularization, AST, myocardial infarction, or death) within 24 hours following PCI, and readmission at 30 days, length of hospital stay, and bleeding events between dosing strategies. The study criteria include all patients >19 years of age who received bivalirudin during PCI and coronary stent placement at DCH Health System from January 2015 to August 2015. One out of every three patients who qualified for the study was categorized to either receiving bivalirudin as a bolus dose followed by an intraprocedural infusion (infusion that ended with the procedure) or an extended infusion (infusion lasting beyond the procedure). Fifty patients were collected in each category.

**Results:** Two patients receiving intraprocedural infusion experienced a cardiovascular outcome compared to one patient receiving extended infusion. At 30 days, twelve patients in the intraprocedural infusion group experienced a cardiovascular outcome or readmission versus ten patients in the comparative treatment arm. Eight patients with extended infusion compared to ten patients in the comparative group experienced a bleeding event.

**Conclusions:** Extended infusion does not appear to reduce the incidence of cardiovascular outcomes and bleeding events at 30 days.

## Nephrotoxic injury negated by just-in-time action in a level IV neonatal intensive care unit

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**Purpose/Background:** Drug-induced nephrotoxicity is a common cause of acute kidney injury (AKI). Renal damage is commonly seen in preterm neonates, as nephrogenesis is not complete until 36 weeks gestation. Nephrotoxicity due to medication exposure is perhaps the most potentially avoidable cause of AKI. The quality improvement initiative, Nephrotoxic Injury Negated by Just-in-time Action (NINJA), has been implemented in non-ICU settings at eleven children's hospitals nationwide. This study examines the efficacy of NINJA in the Neonatal Intensive Care Unit (NICU) at Children's of Alabama. The purpose of this study is to assess the effectiveness of closely monitoring nephrotoxic medication and serum creatinine in relation to the occurrence and duration of AKI in critically ill neonates.

**Methods:** This is a case study of a performance improvement initiative. The pre-intervention portion of the study was from March 1, 2015 to August 30, 2015. After a one month wash-out period, the post-intervention portion of this study was conducted from October 1, 2015 to December 31, 2015. Per the national NINJA protocol, NICU pharmacists conducted daily assessments of the patients' medication regimen, specifically looking for three or more predefined nephrotoxic medications being ordered at the same time or IV aminoglycoside therapy for three or more consecutive days. For patients meeting this criteria, pharmacists recommended daily serum creatinine monitoring. The primary endpoint is duration of AKI, using the RIFLE classification. The secondary endpoints include the rate of highly nephrotoxic medication exposure and AKI occurrence rate. Statistical analysis was performed using t-test and chi-square analysis, as appropriate.

**Results:** The duration of AKI in the NICU increased from 6.48% of exposure days spent in AKI, to 6.98%, after NINJA implementation ($p=0.5114$). The pre-intervention exposure rate to highly nephrotoxic medication was 15.86 per 1,000 NICU patient days, which increased in the post-intervention era to 25.33 per 1,000 NICU patient days ($p<0.0001$). The incidence of AKI in patients who were exposed to highly nephrotoxic medications increased from 14.29% to 17.14% ($p=0.541$) after the implementation of NINJA.

**Conclusions:** NINJA implementation did not decrease the rate or severity of AKI in NICU patients exposed to highly nephrotoxic medications. Increased monitoring of serum

creatinine has led to increased identification of AKI, indicating patients who need further follow-up and perhaps treatment modifications in the future. Alterations to the nationwide NINJA protocol should be made to better adapt to the unique patient population of critically ill neonates.

## Integrating clinical pharmacist services into an inpatient pediatric psychiatric unit

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**Purpose/Background:** Pharmacotherapy is one of the most important aspects of acute psychiatric care. Particularly in the pediatric subset, there is a lack of data on the value and cost-savings associated with including a clinical pharmacist on the inpatient psychiatric multidisciplinary team. In a 2015 position paper, the College of Psychiatric and Neurologic Pharmacists (CPNP) highlighted the myriad of ways that clinical pharmacists can be utilized. Adult studies comparing psychiatric services with and without a pharmacist have shown that including a pharmacist can reduce the workload of psychiatrists, provide cost-savings for the institution, improve patient satisfaction surveys, increase medication adherence rates, and improve patients' clinical response. This study's purpose is to provide evidence in support of including clinical pharmacists on the inpatient pediatric psychiatric multidisciplinary team.

**Methods:** The interventions made by a pharmacy resident on a 34-bed pediatric behavioral health unit over a one-month time period were collected using Sentri7 computer software. This online program interfaces with hospitals' electronic medical records and can export data collected to run quantitative reports. The behavioral health unit does not currently have a clinical pharmacist as a part of the healthcare team. All patients between 5 and 18 years old admitted over a one-month time period were included in the study. Examples of interventions performed include medication reconciliation, medication order clarification, drug information requests, lab and drug level recommendations, and patient counseling.

**Results:** A total of 74 interventions were performed over an 18-day time span with the most common interventions being medication reconciliation and medication order clarification. Based upon the cost savings pre-defined in the Sentri7 computer program, these interventions collectively saved at least $4,620.00. The computer program is only able to calculate the cost savings of the interventions that have published average cost-savings data available and therefore, only 29 of the 74 interventions are accounted for in the above total. The cost-savings per hour calculated using the total number of hours the pharmacy resident was on the unit is $48 per hour.

**Conclusions:** This study provides evidence that utilizing a pediatric clinical pharmacist as a part of the multidisciplinary team on pediatric behavioral health units can provide substantial cost savings to institutions. A cost-savings of $48 per hour approaches the median salary of hospital pharmacists in the United States ($58.15). Limitations of the study include the limited time frame and the lack of knowledge of the behavioral health unit staff of the role of a clinical pharmacist. Areas for further research include involvement in the outpatient psychiatric clinic setting and transition of care from the Emergency Department to the psychiatric unit, as well as developing standardized discharge medication counseling.

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

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

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

## Types of Contributions

The journal will publish the following types of communications:

### Research papers

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

### Reviews

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

### Program descriptions and legislative updates

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

### Short descriptions of clinical controversies or patient cases

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

## Manuscript Organization

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

## Submission

Manuscripts should be submitted electronically to Allison Helmer or an editorial board member as noted below.

The Editorial Board looks forward to reading and publishing the innovative programs, review articles, clinical controversies, and research that is happening across the state!

# Editorial Board