Pharmacy & Therapeutics Committee Meeting
Private Dining Room
October 9, 2014 7:00 a.m.

Agenda Items	Individual Responsible
1. Call to Order	Richard Pesce, MD
2. Approval of August, 2014 Minutes	Richard Pesce, MD

3. Therapeutic Interchanges and Formulary Decisions — Page
   - A. Jardiance® (empagliflozin) ..... Patrick Ellis, PharmD 5
   - B. Uceris® (extended release budesonide) 6
   - C. Custodial HTK® (crystalloid cardioplegia) 7
   - D. Fluid Resuscitation – 0.9% NS vs. Balanced Crystalloids ... Eleni Martinez, PharmD ... 8-9
   - E. Azithromycin vs. Erythromycin for Gastroparesis ..... Matthew Russell, Pharm.D ... 10-12
   - F. Levemir – Lantus Formulary Interchange ..... Patrick Ellis, PharmD 13
   - G. Testosterone Replacement Products 14

4. Medication Safety/Quality
   - A. Metformin – IV Contrast Administration ..... Patrick Ellis, PharmD 15-16
   - B. ADR Review 17-18
   - C. VTE Core Measure – data review/discussion ..... Nan Payne, RN 19-22

5. Policy, Procedure & Protocols
   - A. Antibiotic Surgical Prophylaxis ..... Mark Anderson, MD .....
   - B. Unapproved / Unacceptable Abbreviations ..... Patrick Ellis, PharmD 23
   - C. IVP Administration – cefazolin, ceftriaxone, cefoxitin ....

6. Adjournment

Next Meeting will be December 11, 2014 at 7:00am in the Private Dining Room

CATHOLIC HEALTH INITIATIVES
Memorial Health Care System

PHARMACY AND THERAPEUTICS COMMITTEE

DATE: August 14, 2014 CALLED TO ORDER: 7:00 A.M.
LOCATION: Private Dining Room ADJOURNED: 7:54 A.M.

Members Present:		**Members Absent**:	**Guests**:
Richard Pesce, M.D.	Karen Babb, PharmD	Diona Brown, RN	Michael Harper, M.D.
Mark Anderson, M.D.	Michelle Denham, RN	Vickie Burger, Lab	Eleni Martinez, PharmD,
Allen Atchley, M.D.	Patrick Ellis, PharmD	Nathan Chamberlain, M.D.	Matthew Russell, PharmD
Samuel Currin, M.D.	Lila Heet, PharmD	Patrick Hagan, Finance	Megan Whittier, PharmD
David Dodson, M.D.	Brian Jones, RD, LDN	Keith Lockwitz, RN	
Kevin Lewis, M.D.	Melissa Roden, RN	William Oellerich, M.D.	
Nathan Schatzman, M.D.	Sandy Vredeveld, DPh	Nan Payne, RN	
Michael Stipanov, M.D.	Hannah Walker, RN	Beverly Slate, Supply Chain	
		Elvie Smith, RN	
		Danine Watson, RN	

This meeting will be convened under the protection of the Tennessee Statute 63-6-219 and the Health Care Quality Improvement Act of 1986, Public Law 99-660. All information, case reviews, meeting minutes, statistics and correspondence are confidential and protected. Included in that protection are those that are involved in the review of the information. Any discussion of this information outside the realm of Peer Review constitutes a breach and violates the protection of the persons involved in the breach.

AGENDA ITEM	FINDINGS OR CONCLUSION	ACTION, RESPONSIBILITY	STATUS
Minutes	The June 12, 2014 minutes were approved as submitted.		Complete
Therapeutic Interchanges and Formulary Decisions	The following medications were reviewed:		
	1. **Tanzeum® (albiglutide)** – New GLP-1 agonist approved as adjunct therapy for treatment of diabetes mellitus. Recommended to designate this medication non-formulary status along with the other agents in this class since albiglutide is only available as a multi-dose injectable pen.	1. Not Approved	Complete
	2. **Sivextro® (tedizolid)** – Oral/IV antibiotic indicated for treatment of acute bacterial skin and skin structure infections – same therapeutic class as Zyvox® (linezolid). Due to limited data for treatment of respiratory infections and only a marginal price benefit it was recommended to not approve for formulary inclusion at this time. A proposed therapeutic interchange utilizing linezolid was presented.	2. Formulary Interchange Approved	Complete
	3. **Exparel® (liposomal bupivacaine) & Ofirmev (IV APAP)** – The CHI corporate mandate to pause the expansion of use and any new trials until further notice was again discussed. The committee discussed at length the concern over the cost of this therapy and the importance of identifying which cases are most appropriate for use. Dr. Schatzman expressed concern over the need for proper analysis in order to potentially allow expanded use when clinically appropriate situations arise. Melissa Roden recommended that in order to comply with the corporate decision related to Exparel® that a full business review of each requested use/trial be completed prior to considering any further expansion of use. The use of Ofirmev® was also discussed and Dr. Pesce reiterated the previous P&T decision that oral APAP should be utilized at this time due to the cost of IV APAP.	3. Tabled until a full business review can be completed.	Pending
	4. **Dulera® (mometasone/formoterol inhalation)** – Combination inhaled	4. Formulary Interchange Approved	Complete

AGENDA ITEM	FINDINGS OR CONCLUSION	ACTION, RESPONSIBILITY	STATUS
	corticosteroid/Ibeta agonist indicated for treatment of asthma. A new respiratory contract agreement has been signed by the hospital's group purchasing organization that will designate the Merck products (Dulera®, etc.) the preferred combination product in this class of medications. This decision will result in Dulera® being more cost-effective than the current formulary agent Symbicort®. It was recommended to remove Symbicort® from formulary and utilize Dulera® as the corticosteroid/beta agonist agent of choice and interchange all other products in this class to a therapeutically equivalent regimen of Dulera. 5. **Zohydro® (extended reléase hydrocodone)** – Long acting single entity hydrocodone product indicated for patients requiring long acting opioid pain relief. It was recommended to designate this medication non-formulary and therapeutically interchange an equipotent dose of extended release oxycodone for all Zohydro® orders. 6. **Entyvio® (vedolizumab)** – New monoclonal antibody indicated for treatment of uclerative colitis & Crohn's disease who have failed or had inadequate response to conventional therapy. This medication does not yet have a specific HCPS code assigned for outpatient reimbursement at this time and this discussion was tabled until a later date. Patrick expressed the need for a sub committee review of outpatient drugs such as Entyvio® to closely examine the financials (cost, reimbursement, etc.) prior to the clinical P&T review. Melissa Roden agreed and stated that a sub committee will be formed to perform a business review of new outpatient therapies prior to final clinical approval by the full P&T committee. Melissa will work with Patrick to form this committee.	5. Formulary Interchange Approved 6. Not approved / information	Complete Complete
Medication Use Evaluation	• **Kcentra® (PCC) –**Patrick reviewed an MUE evaluating 34 patients who have received PCC since formulary addition last July. The data revealed that when used appropriately (major/life threatening bleeding, reversal for urgent surgical intervention) that PCC was highly effective for reversal of warfarin and also was effective in re-achieving hemostasis in patients treated with the new novel oral anticoagulants. However, the analysis also reviewed the need for further education to ensure that PCC is not utilized for minor bleeding and reversal for non-urgent surgeries. PCC was inappropriately utilized for four situations in which other therapies (Vit K, FFP, etc.) would have been more appropriate and cost effective. Dr. Atchley suggested that pharmacy closely evaluate each order for PCC to ensure appropriateness and intervene when appropriate to recommend other therapies. Dr. Atchley also recommended that PCC use for reversal of the new oral anticoagulants should be monitored closely by pharmacy to ensure that conventional lab tests such as PTT & PT are not used inappropriately to determine a patients need for or PCC dose for reversal.	Information	Complete
Policy, Procedure & Protocols	• **Surgical Prophylaxis Antimicrobial Dosing** – Dr. Anderson updated the committee on upcoming changes to the process for determining antibiotic selection for surgical prophylaxis. The preliminary plan has been presented to the Med-Exec committee and the final policy will be presented at the September meeting for final approval. The policy will clearly define the antibiotic selection based on surgery type and will be executed by the anesthesia staff.	Information	Pending

AGENDA ITEM	FINDINGS OR CONCLUSION	ACTION, RESPONSIBILITY	STATUS
	• **Cefazolin Dose Optimization –** Patrick reviewed a proposal for dose optimization of cefazolin for patients on maintenance therapy to ensure that each patient's dose is appropriate based on their weight and renal function. It was recommended for pharmacy to automatically increase the cefazolin dose to 2 gm Q 8 hrs for all patients > 80 kg and decrease the interval to every 12 hours if CrCl < 30 ml/min.	Approved	Complete
	Metronidazole & Ciprofloxacin Standardized Dosing – It was recommended to automatically adjust all metronidazole orders that are not ordered as 500 mg Q 8 hrs to this dose in order to standardize the dosing for this medication. Additionally, it was recommended to streamline the renal dosing of ciprofloxacin (CrCl < 30 ml/min) to a 500 mg Daily dose which would alleviate the need to maintain stock of the 250 mg (oral) and 200 mg (IV) strengths of ciprofloxacin.	Approved	Complete
Nutrition Support Team	• **Pep-uP Volume Based Feeding Protocol –** Brian reviewed the PEPuP volume based feeding protocol and asked for approval to pilot this protocol in the MICU. IRB approval has been obtained and this will allow our facility to participate in the USPEPuP Collaborative study evaluating the volume based feeding protocol.	Approved	Complete

There being no further business, the meeting was adjourned at 7:54 A.M. The next P&T meeting is October 9, 2014.

Respectfully submitted,

Sandy Vredeveld, D.Ph. Director of Pharmacy
Patrick Ellis, Pharm.D Pharmacy Clinical Coordinator

Approved by,

Richard Pesce, M.D. Chairman

FORMULARY REVIEW

GENERIC NAME: Empagliflozin

PROPRIETARY NAME: Jardiance® (Boehringer Ingelheim and Eli Lilly and Company)

INDICATIONS: Empagliflozin is for use as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

CLINICAL PHARMACOLOGY: Dapagliflozin is a sodium-glucose co-transporter 2 (SGLT2) inhibitor. SGLT2, expressed in the proximal tubules, is responsible for the majority of the reabsorption of filtered glucose from the tubular lumen. By inhibiting SGLT2, empagliflozin reduces reabsorption of filtered glucose and thereby increases urinary glucose excretion.

In patients with type 2 diabetes, empagliflozin lowered fasting and postprandial glucose levels by increasing total glucose excretion, despite a compensatory increase in endogenous glucose production, improving beta cell function, and shifting substrate utilization from glucose to lipid. In patients with type 2 diabetes, increases in urinary glucose excretion have been observed after a single dose, with total glucose excretion increasing 11-fold with a 10 mg dose, 18-fold with a 25 mg dose, and 14-fold with a 100 mg dose compared with placebo. Empagliflozin produced a 36% to 45% inhibition of glucose reabsorption after a single dose and maintained 36% to 48% inhibition after 27 days of daily administration. Fasting plasma glucose was also reduced with the 10, 25, and 100 mg doses compared with placebo.

PHARMACOKINETICS: The mean terminal elimination half-life is 8 to 17 hours. Renal clearance of empagliflozin is dose independent. Approximately 11% to 23% of the dose is excreted unchanged in the urine. Hepatic impairment resulted in a slight increase in empagliflozin peak concentrations and overall exposure; however, dose adjustments are not required.

ADVERSE REACTIONS: Adverse effects have included frequent daytime urination, thirst, nasopharyngitis, urinary tract infections, and genital infections. In pooled data from 4 randomized, placebo-controlled phase 3 studies including 2,477 patients, the incidence of urinary tract infections was comparable in the empagliflozin- and placebo-treated patients (8% to 9%), but the incidence of genital infections was increased in the empagliflozin-treated patients (4% vs 1%).

Empagliflozin is an osmotic diuretic, which may lead to reductions in intravascular volume. In clinical studies, empagliflozin was associated with a dose-dependent increase in the incidence of volume depletion related adverse events (i.e. hypotension). The three factors associated with the largest increase in adverse reactions were the use of loop diuretics, moderate renal impairment (eGFR 30-50 ml/min/1.73m²) and age greater than 65.

DRUG INTERACTIONS: Clinically relevant interactions have not been observed with empagliflozin.

DOSING & COST: 10 mg PO once daily, taken in the morning with or without food. The dose can be increased to 25 mg PO once daily in those who require additional glycemic control.

Patients with renal impairment: eGFR $\leq$ 45 ml/min – Therapy should be discontinued when eGFR is persistently < 45 ml/min and not initiated in patients with eGFR below this threshold.

Cost - $8.59 per day of therapy

CONCLUSION: It is recommended to not add Jardiance (empagliflozin) to formulary at this time.

FORMULARY REVIEW

GENERIC NAME: Budesonide extended release tablet

PROPRIETARY NAME: *Uceris* (Salix Pharmaceuticals)

INDICATIONS: Glucocorticosteroid indicated for the induction of remission in patients with active, mild to moderate ulcerative colitis.

CLINICAL PHARMACOLOGY: Glucocorticosteroid (GCS) that is formulated in an extended release tablet core in order to deliver the drug directly to the site of action in the colon. The tablet core is enteric coated to protect dissolution in gastric juice which delays budesonide release until exposure to a pH $\geq$ 7 in the small intestine. Upon disintegration of the coating, the core matrix provides extended release of budesonide in a time dependent manner throughout the entire colon.

COMPARATIVE PHARMACOLOGY: Entocort is an alternative extended release budesonide product that is also available for treatment of ulcerative colitis. Entocort is designed in an extended release formulation that is designed to protect dissolution until exposure at a pH > 5.5 (normally in the duodenum). This allows for the drug to be most effective for treatment of disease located in the ileum and ascending colon. The Uceris formulation is designed to dissolve at a pH $\geq$ 7 which allows it to be useful for treating ulcerative colitis throughout colon. The delayed release mechanism of Uceris allows it to have greater colonic delivery of the active budesonide ingredient.

ADVERSE REACTIONS: Typical GCS related adverse reactions are possible with the use of Uceris and other similar (Entocort) formulations of budesonide (immunosuppression, hypercorticism and adrenal suppression, etc.). The overall risk of other milder GCS related adverse reactions (insomnia, sleep changes, flushing, flushing, etc.) were not observed to occur at significantly higher rate than those patients treated with placebo during clinical trials. The delayed release mechanism helps to minimize the risk of steroid related adverse reactions.

DRUG INTERACTIONS: Due to its CYP3A4 dependent metabolism use with known 3A4 inhibitors is contraindicated (ketoconazole, itraconazole, ritonavir, indinavir, erythromycin, etc.). Concomitant administration with potent 3A4 inhibitors can lead to up to an eight fold increase of the systemic exposure to oral budesonide.

DOSING & COST: 9 mg Daily with or without food
Cost - $42.36 per day of therapy (Entocort - $38.70 per day of therapy)

CONCLUSION: It was recommended by Dr. Shikoh that Uceris be added to formulary in order to provide continuity of care for patients admitted on this medication as a home medication and also for newly diagnosed patients who could benefit from starting on this medication while hospitalized. Due to the unique pH dependent delivery mechanism Uceris will effectively treat patients with disease located throughout the colon unlike the current formulary agent Entocort. He felt that due to this unique formulation that a formulary substitution with Entocort would not be appropriate. Therefore it is recommended that Uceris be added to formulary without restrictions.

FORMULARY REVIEW

GENERIC NAME: histidine-tryptophan-ketoglutarate crystalloid cardioplegia

PROPRIETARY NAME: *Custodial HTK* (Essential Pharmaceuticals)

*** Requested by Dr. Zellner for trial use in minimally invasive valve repairs ***

INDICATIONS: Custodial HTK is indicated for perfusion and flushing of donor kidneys, liver, and heart prior to removal from the donor or immediately after removal from the donor. The solution is left in the organ vasculature during hypothermic storage and transportation (not for continuous perfusion) to the recipient.

Although it is only indicated for the above clinical scenario it is widely used in other countries as a single dose cardioplegia and is claimed to offer myocardial protection for a period of up to 3 hours, allowing performance of complex procedures without interruption. Due to the single dose administration this is attractive for minimally invasive cardiac surgery (minimally invasive valve repairs, etc.).

CLINICAL PHARMACOLOGY: Custodial is an intracellular crystalloid cardioplegic solution used by some health systems for myocardial protection in complex cardiac surgery and for organ preservations in transplant surgery. It is considered an intracellular cardioplegia due to its low sodium and calcium content. Sodium depletion of the extracellular spaces causes a hyperpolarization of the myocyte plasma membrane, inducing cardiac arrest in diastole. This is a different mechanism of action from conventional extracellular cardioplegic solutions which are high in potassium content and cause arrest by membrane depolarization. The high histidine content buffers the acidosis caused by the accumulation of anaerobic metabolites during the long ischemic period. The ketoglutarate component improves ATP product during reperfusion, tryptophan stabilizes the cell membrane, and the mannitol decreases cellular edema and acts as a free-radical scavenger.

COMPARATIVE EFFICACY: Despite its widespread use in Europe, there is very little data comparing the efficacy of Custodial with conventional blood or crystalloid cardioplegia. A recent systematic review (14 randomized & non-randomized trials) suggests no significant difference between Custodial and conventional cardioplegia for the primary endpoint mortality, or the secondary endpoints used as surrogate markers of myocardial protection during cardiac surgery although data does indicate that the safety is similar. There was a trend for increased incidence of ventricular fibrillation in the Custodial group that did not reach statistical significance. Overall, the results of the available evidence suggest that Custodial offers myocardial protection that is equivalent to that of conventional cardioplegia, however the body of evidence available from which to draw conclusions is limited by the small number of randomized patients.

A single dose cardioplegia does however have some significant benefits for the performance of minimally invasive cardiac surgery and results summarized above support its ongoing trial use in this area. Re-administration of cardioplegia can disturb the technical flow of complex procedures such as minimally invasive surgeries.

ADVERSE REACTIONS: Custodial is a hypotonic solution (sodium 15 mmol/L) and some concerns have been raised about hyponatremia that follows rapid administration of the Custodial solution although none of the available data has specifically evaluated clinical hyponatremia as a data element.

PRODUCT AVAILABILITY & COST:
Product composition: Na – 15 mmol/L, K – 9 mmol/L, Mg – 4 mmol, Ca – 0.015 mmol/L, Histidine – 198 mmol/L, Tryptophan – 2 mmol/L, Ketoglutarate – 1 mmol/L, Mannitol – 30 mmol/L, pH – 7.02
Cost - $122.10 per 1 Liter (Standard cardioplegia - $84.60 - includes induction & maintenance solutions)

CONCLUSION: Based on the available data there is currently insufficient evidence to recommend the routine use of Custodial for use during coronary artery bypass grafting or other simple open cardiac surgical procedures. However, use as a single dose cardioplegia strategy may offer benefits in more complex minimally invasive cardiac surgeries. The pharmaceutical company has offered to supply a limited supply of Custodial HTK to be used as a trial for minimally invasive surgeries to assess the usefulness of this agent for these procedures.

Fluid Resuscitation Literature Summary

Introduction

There has been much debate on which fluid is most beneficial for fluid resuscitation after surgery and in the critical care setting. For many years "normal" 0.9% saline has been used as the standard of care for fluid resuscitation. However, this fluid has not undergone any in-vivo trials proving its safety and efficacy. Recent cohort studies have demonstrated various adverse effects in patients receiving 0.9% saline solution versus balanced crystalloids. Excretion of the salt content in 0.9% saline solution is further complicated by renal insufficiencies. Additionally, since the goal of fluid resuscitation is often to increase glomerular filtration and perfusion to the kidney, choosing the best fluid is of optimal importance.

Pharmacology

The kidney is more easily able to retain salt and water than it is to excrete it. The efficacy of fluid therapy also depends on other factors such as acute illness, chronic disease, and other interacting medications. Fluid resuscitation is often used in the setting of hypotension, illness, and injury. These factors tend to activate the sympathetic nervous system and in turn the renin-angiotensin-aldosterone system. Activation of this system causes release of the antidiuretic hormone and further increases sodium and water retention. Furthermore, hyperchloremia caused by saline infusion causes greater chloride delivery to the macula densa which may activate the tubuloglomerular feedback mechanism and cause afferent arteriolar vasoconstriction resulting in reductions in GFR. Even in patients with normal kidney function, the administration of 0.9% saline solution is more likely to cause water and sodium retention than diuresis. These effects are seen to a much lesser degree with balanced crystalloids such as lactated ringers and Plasma-Lyte that are constituently more similar to human plasma.

	Human plasma	0.9% Sodium chloride	Ringer's lactate	Plasma-Lyte 148
Osmolarity (mOsm/l)	275-295	308	273	295
pH	7.35-7.45	4.5-7.0	6.0-7.5	4-8
Sodium (mmol/l)	135-145	154	130	140
Chloride (mmol/l)	94-111	154	109	98
Potassium (mmol/l)	3.5-5.3	0	4	5
Calcium (mmol/l)	2.2-2.6	0	1.4	0
Magnesium (mmol/l)	0.8-1.0	0	0	1.5
Bicarbonate	24-32			
Acetate (mmol/l)	1	0	0	27
Lactate (mmol/l)	1-2	0	28	0
Gluconate (mmol/l)	0	0	0	23
Maleate (mmol/l)	0	0	0	0
Na:Cl ratio	1.21:1 to 1.54:1	1:1	1.19:1	1.43:1

Effects of fluids on acid-base balance

Numerous studies have been done in humans comparing 0.9% saline solution to balanced crystalloids, namely lactated ringers and Plasma-Lyte, which are very similar in composition. The outcomes of these studies will be discussed below.

In healthy volunteers who received saline solution, persistent acidosis, abdominal discomfort, nausea, and decreased mental capacity to perform complex tasks were seen. These effects were not seen in those who received balanced crystalloids (specifically Hartmann's solution). Urination was significantly delayed due to resulting hyperchloremia. The infused saline solution was also retained for a longer period of time than balanced crystalloid solution. Time to first urination was quicker and urine volumes and sodium excretion were greater with balanced crystalloids than normal saline solution. Blood volume expansion was similar with both fluids but interstitial fluid accumulation was significantly greater with saline solution than with Plasma-Lyte.

Patients undergoing elective surgery, who regularly warrant large amounts of fluid were also compared. Patients who received 0.9% saline solution were found to have a significant decrease in pH and serum bicarbonate concentration and a significant increase in serum chloride concentration during the first 2 hours of infusion. This further proves the point that saline solution infusion causes hyperchloremic acidosis. No significant differences were seen in plasma sodium, potassium, or lactate concentrations in either group. Crystalloid infusions, on the other hand, were associated with a decrease in serum albumin concentration.

Two randomized double-blind controlled trials evaluated the use of 0.9% saline solution versus lactated ringers in the perioperative period. Patients receiving saline solution during abdominal aortic aneurysm repair required significantly greater volumes of packed red blood cells (780 vs. 560 ml), platelets (392 vs. 223ml), and bicarbonate therapy (30 vs 4ml) than those who received lactated ringers. The trial was stopped early for patients undergoing renal transplantation because 19% of patients in the saline group had to be treated for hyperkalemia and 31% had to be treated for metabolic acidosis, compared to none in the group that received lactated

ringers. Patients who received saline solution were also found to have decreased urine output and lower creatinine clearance than those who received lactated ringers.

Patients undergoing major open abdominal surgery were found to have more favorable outcomes when receiving balanced crystalloids than saline solution. In hospital mortality, need for blood transfusions, infectious complications, and dialysis requirements were greater in patients who received saline solution than those who received balanced crystalloids.

Patients with diabetic ketoacidosis were also studied. Those who received balanced crystalloids had a higher bicarbonate concentration which caused a faster resolution of metabolic acidosis. Furthermore, serum potassium concentration was significantly lower (3.4-4.0 mmol/l) in the Plasma-Lyte group than in the saline group (4.1-4.8). Additionally, mean arterial blood pressure and urine output were higher and serum chloride concentrations were lower in patients who received Plasma-Lyte than those who received saline.

Patients in the ICU were studied as well. Patients who received chloride rich fluids, including 0.9% saline solution were found to have larger increases in serum creatinine, higher incidence of AKI, and higher use of renal replacement therapy than those who received balanced crystalloids such as Hartman's solution and Plasma-Lyte.

Based on the above mentioned studies, it has been noted that patients receiving 0.9% normal saline solution tend to develop hyperchloremia more often than those who receive balanced crystalloids. A large study compared the effects of hyperchloremia in surgical patients and found that those with hyperchloremia were at an increased risk of 30-day postoperative mortality, had a longer median hospital stay and were more likely to have postoperative renal dysfunction.

Cost Comparison

It is important to look at the differences in cost together with available data to make the best decision for the hospital. In most of the studies the balanced crystalloids that were used were lactated ringers and Plasma-Lyte 148. Since Plasma-lyte is not on contract, the cost for Normosol-R 7.4 will be evaluated since it is almost the exact same product.

The cost difference between normal saline and lactated ringers is minimal and based on the available evidence lactated ringers provide more favorable outcomes to large variety of patients. Normosol-R 7.4 is significantly more expensive than lactated ringers and was not shown to have more favorable outcomes than lactated ringers.

Solution	**Price per liter**
Normal Saline (1 L)	$0.90
Lactated Ringers	$0.95
Normosol-R 7.4 (1 L)	$ 2.03

Conclusions

This literature review has shown that 0.9% saline solution is not "normal" and its high chloride content often causes hyperchloremic acidosis resulting in unfavorable outcomes. In turn, these changes have not been seen with balanced crystalloids. Some of the adverse effects seen with administration of saline solution in surgical and critically ill patients include increased incidence of acute kidney injury, increased use of buffers to correct acidosis and blood products to compensate for blood loss, increased interstitial fluid resulting in edema, decreased glomerular filtration rate, urine output and sodium excretion, and increased mortality. Based on current data, balanced crystalloids seem to cause less harm to renal function and provide better clinical outcomes. The advantages of using lactated ringers is clearly seen from a clinical perspective as well as cost effective perspective.

THERAPEUTIC REVIEW

Azithromycin vs. Erythromycin – Treatment of Gastroparesis

REVIEW: Azithromycin as a therapeutic alternative for erythromycin for the treatment of gastroparesis

INDICATIONS: Erythromycin is FDA approved for the treatment of microbial infections, including acne, upper and lower respiratory infections, rheumatic fever, gastrointestinal infections, pelvic inflammatory disease, whooping cough, chlamydia, gonorrhea, syphilis, listeriosis, and many others, and has off-label use for the stimulation of gastric emptying in patients with gastroparesis or who are critically ill with feeding intolerance.

CLINICAL PHARMACOLOGY: Erythromycin is a macrolide antibiotic that binds to the 50S ribosomal subunit of microorganisms, preventing bacterial protein synthesis, particularly in gram-positive organisms due to greater penetration compared to gram-negative organisms. Erythromycin and azithromycin also act as a motilin receptor agonist mostly in the gastric antrum and proximal duodenum, causing increased motility during the inter-digestive phase.

Azithromycin is a semisynthetic antibiotic that is similar in structure to erythromycin from the macrolide class of azalides with the same mechanism of action for antimicrobial therapy, but with more activity against gram-negative organisms.

PHARMACOKINETICS: Erythromycin has variable bioavailability from 18-45% when taken orally, but is better absorbed with its' salt forms rather its' base form. Because of its' poor absorption, high concentrations are reached in the large intestine, causing absorption to mostly occur in the duodenum. Erythromycin is both a substrate and inhibitor of the CYP3A4 system and of P-glycoprotein, causing numerous potential interactions. The drug is metabolized hepatically to several inactive metabolites, causing the potential for prolongation of the elimination half-life in the setting of hepatic impairment. Only minuscule amounts of erythromycin are removed by hemodialysis. The oral route of administration is preferred to the parenteral route due to the high occurrence of pain, but may be necessary in cases requiring high blood concentrations.

Azithromycin distributes extensively throughout the body with an absolute bioavailability of 38% for the capsule form, and food can increase the Cmax of the tablet and oral suspension form by up to 23% and 56%, respectively, with no effect on AUC. It has a long half-life of around 68 hours due to its' extensive tissue uptake and slow release, allowing for once daily dosing. Azithromycin is not metabolized and is largely eliminated in the feces, following excretion into the bile, with minimal amounts excreted in the urine. The medication has not been studied in the setting of hepatic impairment and is minimally effected by renal impairment.

COMPARATIVE EFFICACY: Currently, there are no published trials comparing azithromycin with erythromycin for the treatment of gastroparesis in a controlled setting. The results from a phase II, double-blind, randomized, active-controlled trial from the University of Florida directly fulfilling this need were highly anticipated but never published due to early termination of the study (original investigator left institution, replacement investigator retired and study ended with IRB).

An in vivo study published by Sanger et al. in 2012 examined the effects of azithromycin compared to erythromycin on recombinant and naturally expressed motilin receptors in the human stomach to verify motilin receptor binding and activation of the receptors via calcium flux. Results concluded that motilin, erythromycin, and azithromycin all increased intracellular calcium in a concentration-dependent manner in cells expressing motilin receptors with maximal activities being similar for all three comparators. The authors concluded that azithromycin activates human recombinant motilin receptors similar to erythromycin in therapeutically relevant concentrations.

One case report published by Sutera et al. in 2008 delineated an 83-year-old woman with severe gastroparesis, constipation, and vomiting secondary to uncontrolled diabetes mellitus. After 20 days of continuous vomiting that was refractory to initial therapy with osmotic laxatives and prokinetic agents, she received Azithromycin 500mg IV daily for three days, followed by 14 days of azithromycin 500mg PO daily. Three days after the initiation of this regimen, the patient's symptoms abated and she was able to tolerate food.

A retrospective cohort study published by Larson et al. in 2010 assessed 120 patients with gastric emptying scintigraphy (GES)-confirmed gastroparesis. After establishing baseline gastric emptying time, a 250mg IV dose of erythromycin (n=60) or an unspecified dose of IV azithromycin (n=60) was administered, depending on the availability of the medication from the pharmacy. There were no significant differences in baseline characteristics between the groups, including gastric emptying time at baseline, with the exception of a higher number of cirrhotic patients in the erythromycin treatment arm. A similar positive effect on gastric emptying was demonstrated with overall gastric emptying time decreasing from around 170 minutes to around 11 minutes for both treatment

groups. Potential limitations of this study include the observational design with no placebo arm, lack of long-term evaluation of effectiveness, and unspecified doses of azithromycin used.

A case series published in 2010 by Moshiree et al. reviewed 30 patients undergoing antroduodenal manometry (ADM). All individuals received a 250mg dose of IV erythromycin after a 2 hour fed state was accomplished, which was followed 4 hours later by either 250mg (n=15) or 500mg (n=15) of IV azithromycin. Azithromycin 500mg IV was shown to be statistically superior to erythromycin 250mg IV in regards to mean amplitude of antral contractions, duration of highest amplitude of antral contractions, and total duration of antral contractions. There was no significant difference between the two 250mg IV doses. Potential downfalls of the study include the small window allowed for the washout period, possibly leading to an augmented effect due to a residual effect of the erythromycin, lack of disclosure on how patients were allocated to the two doses, and the absence of any long-term symptom assessment.

Another case series published in 2012 by Chini et al. reviewed 21 patients undergoing 24 hour ADM. The study was performed in the same laboratory with the same protocol as the case series mentioned above, except for octreotide being administered at the completion of testing and all patients receiving only a dose of 250mg of IV azithromycin after a 4 hour washout period. The authors reported statistically significant improvement in small bowel and antrum motility with azithromycin versus erythromycin, implying superior applicability for both gastroparesis and small bowel dysmotility, which can commonly occur together. Similar limitations from the previous study apply to this case series.

CONTRAINDICATIONS: Neither azithromycin or erythromycin should be used in a patient with a known hypersensitivity to the medication or macrolide class. Azithromycin is contraindicated in patients with a history of jaundice and/or hepatic dysfunction associated with previous use of the drug.

WARNINGS AND PRECAUTIONS: Both antibiotics are associated with an increased risk of superinfection, pseudomembranous colitis, and potential for causing QT prolongation, and thus should be used cautiously in patients at risk for cardiac arrhythmias. Erythromycin should be used with caution in patients with seizure disorder, myasthenia gravis, or hepatic impairment. Azithromycin should be used with caution in patients with myasthenia gravis, hepatic disease, severe renal impairment (CrCl <10 mL/min), or excessive direct exposure to sunlight.

PREGNANCY AND LACTATION: Both medications are classified by the FDA as pregnancy category B.

PEDIATRIC USE: Neither azithromycin or erythromycin are approved or recommended for the treatment of gastroparesis in pediatrics, but both can be used in children and infants >3 months old for approved indications.

ADVERSE REACTIONS: Nausea, vomiting, abdominal pain, diarrhea, and anorexia are common GI effects of oral erythromycin with similar effects for azithromycin, though commonly less severe. Less commonly, allergic reactions, injection site pain/phlebitis, QT prolongation, erythema multiforme, SJS, toxic epidermal necrolysis, ototoxicity, hepatitis, and pancreatitis have been reported with both drugs.

DRUG INTERACTIONS: Because erythromycin is a strong inhibitor of the CYP3A4 system and of P-glycoprotein, it has a large number of interactions with numerous medications. Grapefruit can increase the plasma concentrations of the medication as well. Azithromycin is not a major substrate or inhibitor of the CYP3A4 system, but some data suggest it is a substrate and inhibitor of P-glycoprotein, and caution should be used when co-administered with other P-glycoprotein substrates and/or inhibitors. Both medications interact with other drugs that prolong the QT interval and should be used cautiously in this setting, particularly when erythromycin is used.

DOSING: Currently there are no dosages approved for either medication for the treatment of gastroparesis. Off-label doses used for erythromycin range from 3mg/kg IV to 500mg PO three times daily before meals. Azithromycin doses that have been previously studied for increasing gastric motility range from 250-500mg IV or PO.

PRODUCT AVAILABILITY:

Erythromycin: Available on formulary at MHCS as 250mg (enteric or regular) or 500mg tablets, 200mg/5mL or 400mg/5mL powder for suspensions, or 500mg or 1000mg powder for injections

Azithromycin: Available on formulary at MHCS as 250mg or 500mg tablets, 100mg/5mL or 200mg/5mL powder for suspensions, or 500mg powder for injection.

PRODUCT COST:
Cost per day of therapy
Erythromycin: $72.87 (250 mg IV Q 6 hrs)
Azithromycin: $5.71 (500 mg IV Q 24 hrs)

CONCLUSION: While there are currently no randomized, controlled trials demonstrating the efficacy of azithromycin for the treatment of gastroparesis, results from retrospective case-control studies indicate its' potential use as a viable alternative to erythromycin for this condition. Limitations of erythromycin therapy include: significant drug-drug interactions that are associated with increased risk of cardiac arrhythmias and sudden cardiac death, more common, severe GI adverse effects, short half-life, tachyphylaxis, and cost/availability. Azithromycin is associated with much lower pro-arrhythmic potential and GI adverse effects, has a much longer half-life allowing for once daily dosing, thus increasing the probability of compliance, and has a clear cost savings compared to erythromycin. Additionally, the IV form of azithromycin can be readily used compared to erythromycin due to the latter's associated injection site pain. More data examining the long-term efficacy of azithromycin for this off-label indication are still needed because of the propensity of erythromycin to induce tachyphylaxis.

RECOMMENDATION: Interchange all orders for erythromycin used for the treatment of gastroparesis or stimulation of gastric motility to orders for azithromycin, using the interchange below:

Drug/Dose written	Drug/Dose interchange
Erythromycin 250-500mg PO q 6-8 hours before meals for gastroparesis	Azithromycin 250mg-500mg PO daily 30 minutes before meal
Erythromycin 250-500mg IV q 6-8 hours for gastroparesis	Azithromycin 250mg-500mg IV daily

John Laramore, M.D. • Mark Heinsohn, M.D. • Arlene Donowitz, M.D. • Michael Wood, M.D.

605 Glenwood Drive
Memorial Medical Plaza
Suite 404
Chattanooga, Tennessee 37404
Phone: 423/629-7220
Fax: 423/629-4091

September 12, 2014

Patrick N. Ellis, Pharm.D.
Chief Clinical Services

RE: Formulary use of Levemir Insulin as a substitution for Lantus Insulin.

Dear Dr. Ellis:

It has come to my attention that patients admitted to the hospital stable on Lantus insulin are having a substitution of Levemir insulin. I understand the need for formulary adherence as a measure for cost containment; however I have some concern as to patients being discharged potentially on two different long acting insulins. Many patients do not understand that Levemir and Lantus insulin should not be taken concurrently. I am concerned that my patients who are stable on Lantus at home and then discharged on Levemir may have inadvertent double dosing of these long acting insulins.

I request, that as possible, individuals who enter the hospital on Lantus be allowed to continue on this long acting insulin. I anticipate that the pharmaceutical manufacturer would be willing to match your price structure for that.

Thanks for your consideration on this matter.

I will send a copy of this note to Dr. Dodson as well.

Sincerely,

Mark E. Heinsohn, M.D.
MEH/tsc/1
File#: WS702597
CC: David B. Dodson, M.D.

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MEMORIAL HEALTH PARTNERS

FORMULARY REVIEW

Topical & Injectable Testosterone Products

Background:

Due to aggressive direct to consumer advertising and the FDA approval of multiple new drug delivery mechanisms, the market for testosterone replacement products has proliferated greatly over the past 3-5 years. As a result, increasingly more patients are admitted to our facilities with testosterone containing products as home medications for treatment of low testosterone. Although the injectable products may be used for indications other than for treatment of hypogonadism these situations are infrequently encountered in the hospital setting.

Testosterone Containing Formulary Products (current):

- Testosterone patch (Androderm®)
- Testosterone gel (Androgel®)
- Testosterone cypionate injectable (Depo Testosterone®)

Additionally, nursing has recently expressed concern regarding the possibility of accidental exposure to topical testosterone formulations (gels, etc.) for female staff that may be pregnant or breast feeding and are unaware that the patient may have these products on their skin. This was in response to a pregnant staff member being inadvertently exposed to a testosterone gel product while caring for a newly admitted patient.

Recommendation:

It is recommended that since topical testosterone products are not a medical necessity for patients to receive while hospitalized that all topical and injectable testosterone products be designated as non-formulary and not dispensed by the hospital pharmacy. Patients can be instructed to resume these products once discharged from the hospital. Additionally, this will alleviate other issues related to controlled substance accountability, disposal, and high cost for the available topical products.

METFORMIN

Hold Parameters for Contrast Administration

Background:

Metformin is a biguanide oral anti-hyperglycemic agent used to treat patients with non-insulin dependent diabetes mellitus. The most significant adverse effect of metformin therapy is the potential for the development of metformin associated lactic acidosis in the susceptible patient. This condition is estimated to occur at a rate of 0 to 0.084 cases per 1,000 patient years. An additional systematic review found the incidence of lactic acidosis to be fewer than 5.1 cases per 100,000 patient years. Although rare, patient mortality in these reported cases is estimated to be approximately 50%. In the absence of acute overdose, metformin associated lactic acidosis rarely develops in patients without comorbidities such as renal or hepatic insufficiency or acute infection.

Metformin is excreted unchanged by the kidneys with the renal elimination accounting for approximately 90% elimination of the absorbed drug within the first 24 hours. Due to the predominant renal elimination of metformin any decrease in renal function is a major consideration for the development of lactic acidosis.

Contrast media & metformin:

Iodinated contrast media are not an independent risk factor for patients taking metformin but are a concern only in the presence of underlying renal dysfunction. Administration of IV contrast media during radiologic procedures has been associated with acute renal dysfunction and may place a patient receiving metformin therapy who previously was at low risk at a higher risk of lactic acidosis. Although no known interaction exists between metformin and contrast media there is concern that should acute renal dysfunction develop, the potential exists for metformin accumulation that can result with subsequent elevations in lactate levels.

Available guidelines for holding:

Prescribing information for metformin indicates, as a contraindication, that metformin should be temporarily discontinued in patients undergoing radiologic studies involving IV administration of iodinated contrast media due to the risk of altered renal function following IV contrast. The specific recommendation in the U.S. package insert states the following: "*Metformin should be temporarily withheld just prior to and for 48 hours after the completion of the procedure and therapy reinstituted only after normal renal function is confirmed."*

American College of Radiology:

Procedure for withholding metformin is dependent upon the patient's renal function and presence of co-morbidities that could also contribute to increased lactate (liver dysfunction, alcohol abuse, cardiac failure, myocardial or peripheral muscle ischemia, sepsis or severe infection).

- Category I (normal renal function & no co-morbidities): no need to discontinue metformin prior to IV contrast, nor is there a need to check creatinine following the test or procedure.
- Category II (normal renal function but with co-morbidities): discontinue metformin at the time of procedure and resume 48 hours following procedure.
- Category III (known renal dysfunction): discontinue at the time of contrast administration and cautious follow up of renal function prior to resuming metformin.

Canadian Association of Radiology:

Patients taking metformin who have an eGFR of less than 60 ml/min should stop taking metformin at the time of contrast administration and not resume until 48 hours after contrast administration if renal function is stable. The same procedure is recommended for patients with eGFR > 60 ml/min if greater than 100 ml of contrast is administered. For patients with eGFR > 60 ml/min the Canadian recommendations do not recommend stopping metformin prior to or after contrast administration.

European Society of Radiology:

Patients with eGFR < 45 ml/min should stop metformin 48 hours prior to contrast administration and should restart 48 hours after the procedure if renal function stable.

Current Practices at MHCS:
Currently much variation exists in regard to the practice of holding and resuming metformin for patients receiving IV contrast.

- Pre-operative Anesthesia Orders
  - *Hold all Metformin drugs 24 hrs prior to surgery*
- Coronary Arteriogram Pre-procedure order
  - *Hold Metformin/Metformin containing products AM of procedure*
- Peripheral Arteriogram Orders
  - *Hold Metformin containing products starting now*

Presently no clear standard protocol is utilized for pre-procedure or post-procedure management of metformin containing products for patients who receive IV contrast agents. The ACR recommendation varies according to renal function and the presence of co-morbidities. **However, given the substantial complexity and challenges in implementing these recommendations it would likely be easiest and most practical to follow the above Category II recommendation (discontinue metformin at the time of procedure and resume 48 hours following procedure).** This would alleviate the need for any patients to have these medications withheld the day prior to procedures and would stop the unnecessary postponement of procedures if these medications were administered the day prior to contrast administration. Additionally, none of the current orders reference withholding metformin drugs following the procedure and this will add an additional layer of protection in the event that patients experience a transient increase in serum creatinine within the 48 hours following contrast administration.

Adverse Drug Reaction (ADR) Summary
4th Quarter (FY14) April-June 2014

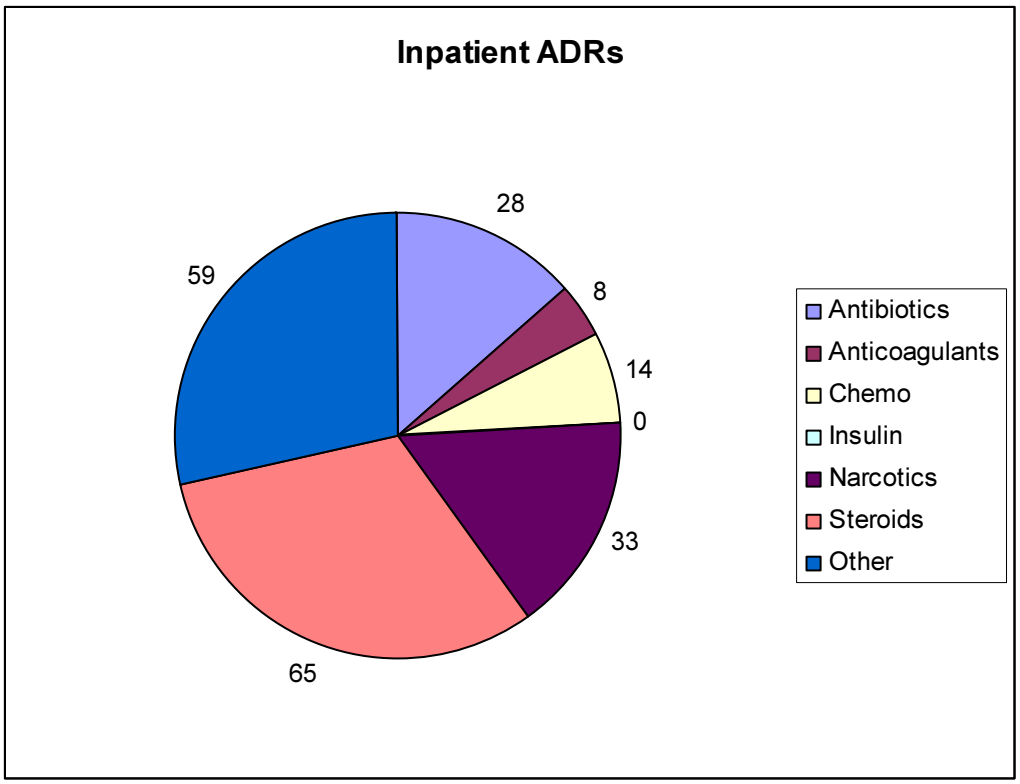
Category 1: Commonly recognized ADR's which are expected and do not result in serious medical consequences or extended hospitalization (e.g. antibiotic rash, nausea, mild hypokalemia).

Category 2: Significant ADR's which extend hospitalization and/or require extensive therapeutic measures (e.g. gastrointestinal bleed secondary to NSAIDs, Aminoglycoside nephrotoxicity.

Category 3: A serious or rare ADR which has abnormal characteristics compared with published reports of the reaction (e.g. heparin induced platelet aggregation resulting in limb amputation). ADR's from this category should be reported to the manufacturer and/or the FDA (MedWatch or the Vaccine Adverse Event Reporting System).

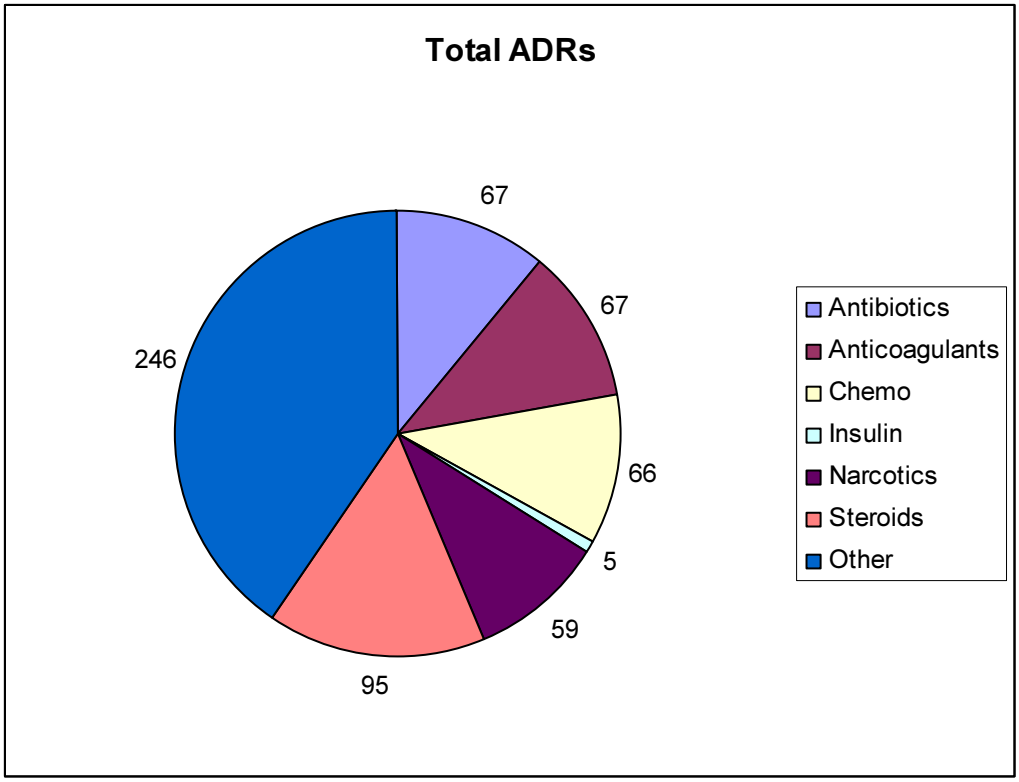
Inpatient: 210 (35%)
Prior to hospitalization: 395 (65%)
Total: 605

Category 1: 436
Category 2: 169
Category 3: 0



Antibiotics: Vancomycin—AKI (28%). Other reactions included rash, diarrhea, and angioedema.
Anticoagulants: Heparin—HIT (50%). Warfarin—Nose bleed, retropharyngeal bleed (25%).
Chemotherapy: Neutropenia, rash, dehydration
Narcotics: Reactions included confusion, nausea, constipation, and respiratory distress.
Steroids: Reaction was hyperglycemia.

Total ADRs:



Antibiotics: Bactrim—AKI, swelling (8%)
Anticoagulants: Warfarin—Various bleeds, (62%)
Chemo: Neutropenia, nausea, vomiting, dehydration
Insulin: Hypoglycemia
Narcotics: Constipation, rash, nausea
Steroids: Hyperglycemia

VTE CORE MEASURES

1. **VTE-1: Venous Thromboembolism Prophylaxis**

Description: This measure assesses the number of patients who received VTE prophylaxis or have documentation why no VTE prophylaxis was given the day of or the day after hospital admission or surgery end date for surgeries that start the day of or the day after hospital admission.

2. **VTE-2: Intensive Care Unit Venous Thromboembolism Prophylaxis**

Description: This measure assesses the number of patients who received VTE prophylaxis or have documentation why no VTE prophylaxis was given the day of or the day after the initial admission (or transfer) to the Intensive Care Unit (ICU) or surgery end date for surgeries that start the day of or the day **after ICU admission (or transfer).**

3. **VTE-3: Venous Thromboembolism Patients with Anticoagulation Overlap Therapy**

Description: This measure assesses the number of patients diagnosed with confirmed VTE who received an overlap of parenteral (intravenous [IV] or subcutaneous [subcu]) anticoagulation and warfarin therapy. For patients who received less than five days of overlap therapy, they should be discharged on both medications or have a Reason for Discontinuation of Overlap Therapy. Overlap therapy should be administered for at least five days with an international normalized ratio (INR) greater than or equal to 2 prior to discontinuation of the parenteral anticoagulation therapy, discharged on both medications or have a Reason for Discontinuation of Overlap Therapy.

4. **VTE-4: Venous Thromboembolism Patients Receiving Unfractionated Heparin with Dosages/Platelet Count Monitoring by Protocol or Nomogram**

Description: This measure assesses the number of patients diagnosed with confirmed VTE who received intravenous (IV) UFH therapy dosages AND had their platelet counts monitored using defined parameters such as a nomogram or protocol.

5. **VTE-5: Venous Thromboembolism Discharge Instructions**

Description: This measure assesses the number of patients diagnosed with confirmed VTE that are discharged to home, home care, court/law enforcement or home on hospice care on warfarin with written discharge instructions that address all four criteria: compliance issues, dietary advice, follow-up monitoring, and information about the potential for adverse drug reactions/interactions.

6. **VTE-6: Incidence of Potentially-Preventable Venous Thromboembolism**

Description: This measure assesses the number of patients diagnosed with confirmed VTE during hospitalization (not present at admission) who did not receive VTE prophylaxis between hospital admission and the day before the VTE diagnostic testing order date.

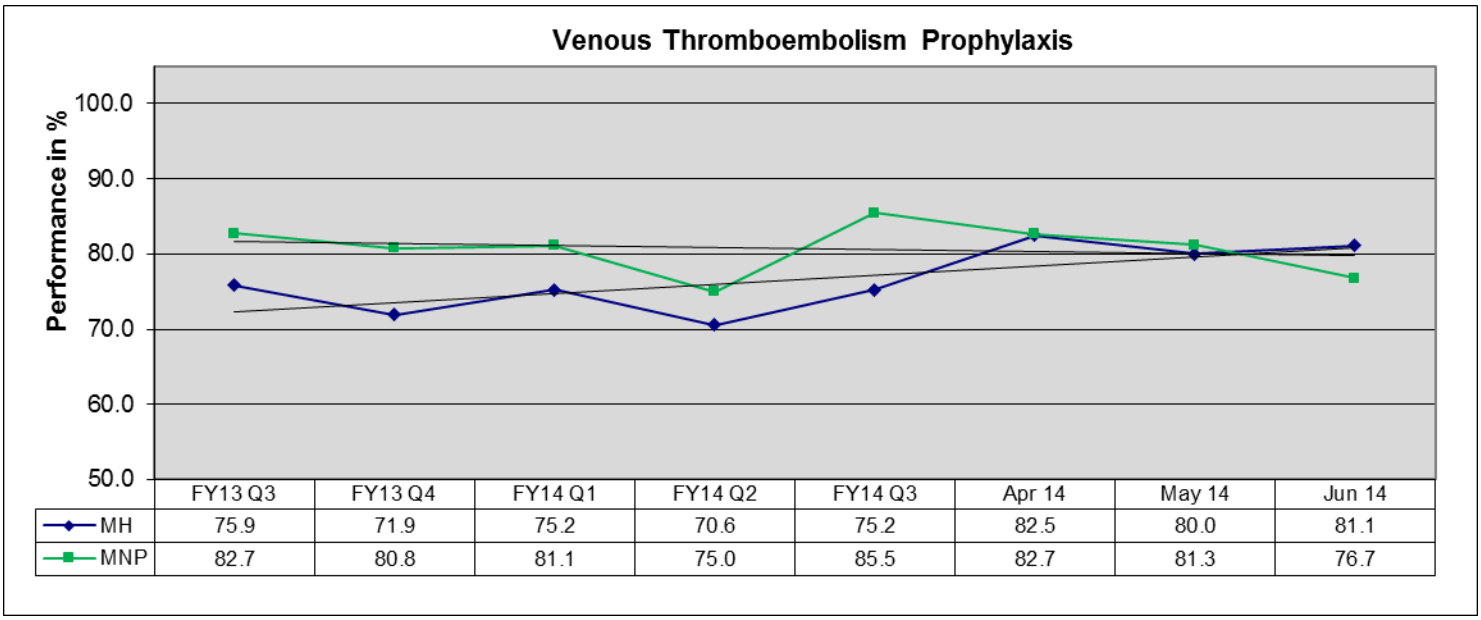
VTE P&T Report

Based on the Premier monthly Core Measure Report

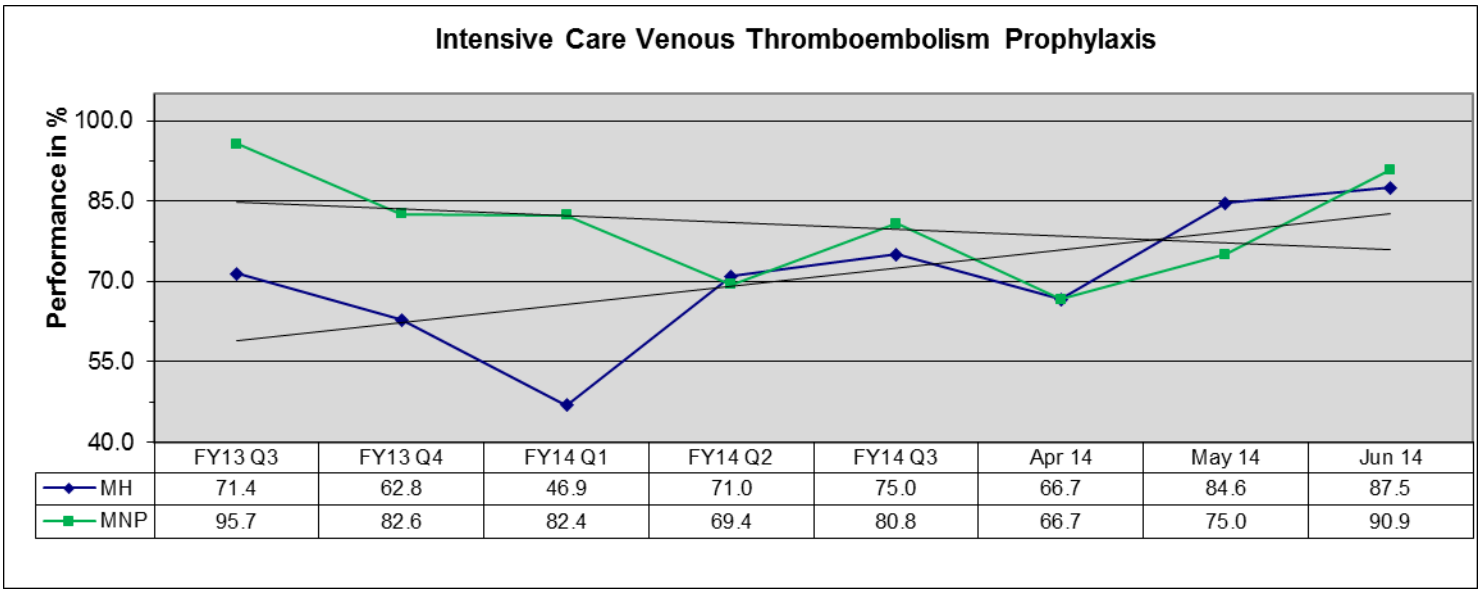
1. Specific Indicator Trends:

Disclaimer: Preliminary data is collected concurrently for reporting in a timely manner and is not absolutely reflective of final patient population submitted externally via vendor (6 months retrospective) and may vary by 1-5% margin based on final coding. The information detailed does not reflect the care of all VTE Patients only those who are required to be submitted via vendor (primary diagnosis).

No VTE Measures are patients who go home without a diagnosis of VTE while in the hospital

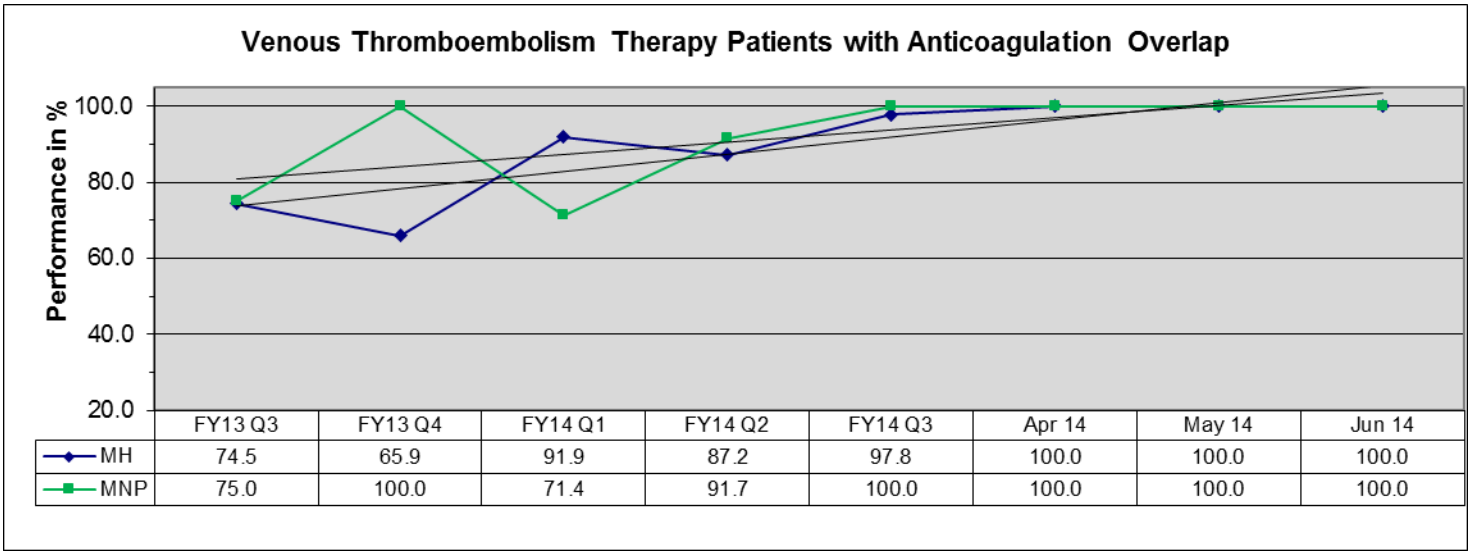


	FY13 Q3	FY13 Q4	FY14 Q1	FY14 Q2	FY14 Q3	Apr 14	May 14	Jun 14
MH	75.9	71.9	75.2	70.6	75.2	82.5	80.0	81.1
MNP	82.7	80.8	81.1	75.0	85.5	82.7	81.3	76.7



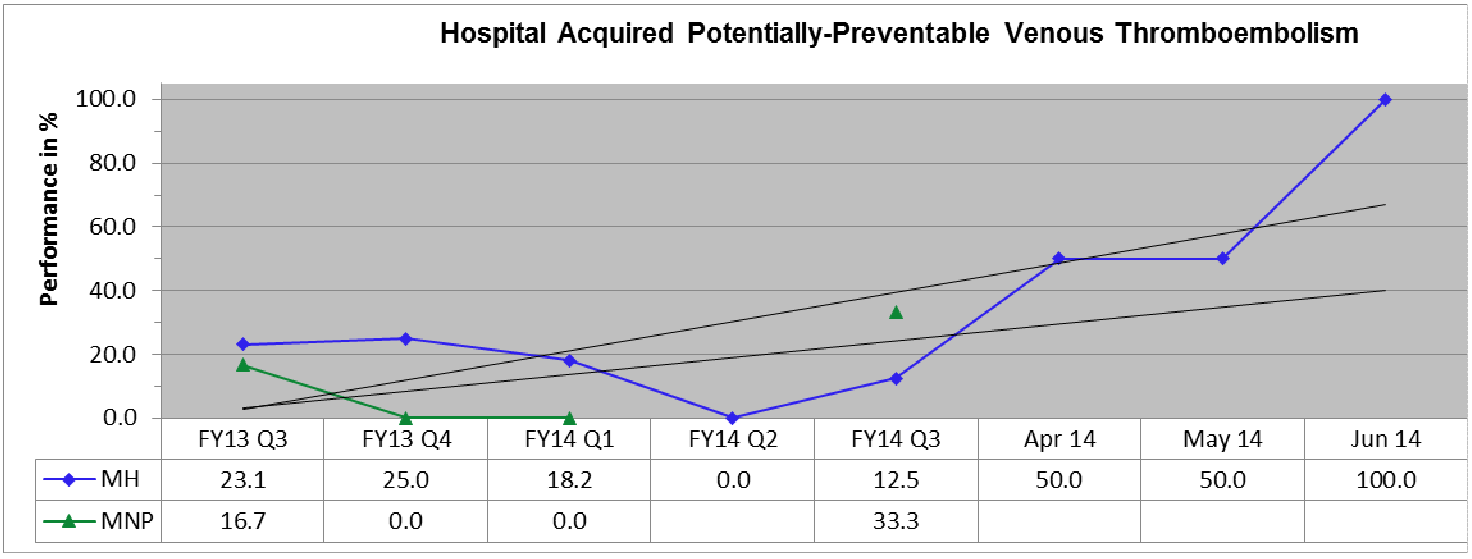
	FY13 Q3	FY13 Q4	FY14 Q1	FY14 Q2	FY14 Q3	Apr 14	May 14	Jun 14
MH	71.4	62.8	46.9	71.0	75.0	66.7	84.6	87.5
MNP	95.7	82.6	82.4	69.4	80.8	66.7	75.0	90.9

Principal & Other Diagnosis VTE



	FY13 Q3	FY13 Q4	FY14 Q1	FY14 Q2	FY14 Q3	Apr 14	May 14	Jun 14
MH	74.5	65.9	91.9	87.2	97.8	100.0	100.0	100.0
MNP	75.0	100.0	71.4	91.7	100.0	100.0	100.0	100.0

Other Diagnosis VTE are patients who come into the hospital without a VTE and later develop a VTE prior to discharge.



	FY13 Q3	FY13 Q4	FY14 Q1	FY14 Q2	FY14 Q3	Apr 14	May 14	Jun 14
MH	23.1	25.0	18.2	0.0	12.5	50.0	50.0	100.0
MNP	16.7	0.0	0.0		33.3			

*All blank fields reflect there were no patients who meet the requirements to be included in the measure.

2. **Findings:**
   - VTE prophylaxis both in and out of the ICU is impacted by both physicians and nurses. It is important for physicians to order prophylaxis or document a reason for not giving prophylaxis (both pharmacological AND mechanical) and for nurses document prophylaxis as given.
   - Overlap therapy is impacted mainly by physicians.
   - Hospital Acquired VTE should ideally be 0%. Volumes for this element are low so even one case could skew us upwards on a monthly basis. Each hospital acquired VTE case is being reviewed for reason and opportunity.

VTE Core Measures are divided into three separate categories:
No VTE are patients who go home without a diagnosis of VTE while in the hospital **Principle VTE** are patients who come into the hospital with a diagnosis of VTE, and **Other VTE** are patients who come into the hospital without a VTE and later develop a VTE prior to discharge.

No VTE has two measure elements:

- VTE prophylaxis
- ICU VTE prophylaxis admitted/transferred to ICU

Principle VTE has three measure elements:

- VTE therapy with anticoagulation overlap if on Warfarin (5 days of overlap required or reason documented for less than 5 days overlap)
- VTE therapy for patients who have UFH and have doses/platelet counts monitored by protocol or nomogram
- Written discharge instructions provided to patients who go home on Warfarin

Other VTE has four measure elements:

- VTE therapy with anticoagulation overlap if on Warfarin (5 days of overlap required or reason documented for less than 5 days overlap)
- VTE therapy for patients who have UFH and have doses/platelet counts monitored by protocol or nomogram
- Written discharge instructions provided to patients who go home on Warfarin
- Hospital Acquired Potentially-Preventable VTE

CATHOLIC HEALTH INITIATIVES

Memorial Health Care System

Chattanooga, Tennessee

POLICY

Title: UNAPPROVED / UNACCEPTABLE ABBREVIATIONS		
	Page 1 of 1	
Policy Number: NPSG-06612	Date Last reviewed/Revised: 1/13	Valid Until: 1/16
Department(s) Affected: All Clinical Areas	Review Period: every 3 years	

OUTCOME:

To provide a list of dangerous abbreviations and dose expressions most often associated with misinterpretation and patient harm and provide a correction to eliminate their use.

POLICY:

The following medications are unapproved / unacceptable abbreviations and dose designations at Memorial Health Care System:

Unacceptable abbreviation	Acceptable order
"u" for units	units
"IU" for international units	units or International units
µg	mcg or micrograms
qd	every day
qid	four times a day
qod	every other day
MS or MSO_4	morphine
MgSO4	magnesium sulfate
.5 mg	0.5mg - - always use zero before decimal
5.0 mg	5mg - - never use trailing zeroes
Nitro / amio / amino	do not use root word - - use whole word

Any variation of the unapproved abbreviation (upper case, lower case, separated by periods, etc.) is not acceptable and must be clarified by the prescriber or covering physician.

Key Contact: Karen Frank, Director Accreditation/Regulatory & Patient Safety
Approved/Reviewed by: Melissa Roden, Exec. Dir,. Quality & Utilization
Reference(s): *JCAHO 2004 Patient Safety Goals and Requirements* / ISMP Medication Safety Alert, May 2, 2001
Date First Effective & Revision/Review dates: 7/01 (1/04) (2/10) (1/13)
Distribution: MHCS Intranet