Pharmacy & Therapeutics Committee Meeting
Private Dining Room
April 10, 2014 7:00 a.m.

Next Meeting will be June 12, 2014 at 7:00am in the Private Dining Room

CATHOLIC HEALTH INITIATIVES

Memorial Health Care System

PHARMACY AND THERAPEUTICS COMMITTEE

DATE: February 27, 2014 CALLED TO ORDER: 7:00 A.M.
LOCATION: Private Dining Room ADJOURNED: 8:00 A.M.

Members Present:			**Members Absent**:		**Guests**:
Richard Pesce, M.D.	Karen Babb, Pharm.D.	Brian Jones, RD, LDN	Nathan Chamberlain, M.D.	Sandy Vredeveld, DPh	Darrin Majors, Pharm D Resident
Mark Anderson, M.D.	Vickie Burger, Lab	Keith Lockwitz, RN	William Oellerich, M.D.	Danine Watson, RN	Sarah Smith, Pharm D Resident
Allen Atchley, M.D.	Patrick Ellis, Pharm.D.	Melissa Roden, RN	Michelle Denham, RN		Megan Whittier, Student
David Dodson, M.D.	Rodney Elliott, CPT	Hannah Walker, RN	Deb Moore, RN		
Samuel Currin, M.D.	Patrick Hagan, Finance		Nan Payne, RN		
Kevin Lewis, M.D.	Lila Heet, Pharm.D.		Beverly Slate, Supply Chain		
Nathan Schatzman, M.D.			Elvie Smith, RN		
Michael Stipanov, M.D					

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 October 10, 2013 minutes were approved as submitted.		Complete
Therapeutic Interchanges and Formulary Decisions	The following medications were reviewed: 1. **Arzerra ® (ofatumumab) –** Mononoclonal antibody used for treatment of patients with refractory chronic lymphocytic leukemia (CCL) refractory. Infusion related reactions discussed and the need for pre-treatment. Two patients have received year to date.	1. Approved.	Complete
	2. **Exparel® (bupivacaine liposomal)** – Liposomal formulation of bupivacaine. The trial for Intercostal nerve block did show efficacy in comparison to bupivicaine and dexamethasone. Recommended to add to formulary for intercostal nerve block s/p thoracic surgery. Dr. Schatzman discussed Dr. Hartley's request to utilize Exparel during total knee replacement procedures. The plan is to use a multi-model approach using bupivacaine with epinephrine and Exparel in order to help decrease opioid usage and decrease length of stay. Dr. Schatzman felt that its usage in joints was appropriate for a trial to gauge its effectiveness. The committee recommended to approve the trial of twenty patients and to review the following outcomes: narcotic usage, pain control (VAS scores) and length of stay. Dr. Nelson's request for hemorrhoidectomy use was considered and committee recommended having him discuss the formulary addition at the next meeting.	2. Added to formulary with restriction to cardiothoracic usage and limited trial in orthopedics. Patrick to follow up.	Ongoing
	3. **Ofirmev® (IV acetaminophen) –** Continue to receive requests for IV acetaminophen. Dr. Morrison is using currently to improve weaning patients off the vent. IV acetaminophen does have a quicker onset and a higher peak. Committee discussed giving oral or rectal pre-operatively may negate the need for administering the IV formulation.	3. Keep Ofirmev restricted to cardiothoracic cases. Continue to review as appropriate.	Complete
	4. **Combivent® Formulary Interchange -** Due to the newer formulation of Combivent, it is not able to be utilized via the common canister. Dr. Mull and Dr. Pesce agreed prior to meeting to automatically substitute to albuterol and atrovent nebulizer treatments.	4. Approved.	Complete Ongoing

AGENDA ITEM	FINDINGS OR CONCLUSION	ACTION, RESPONSIBILITY	STATUS
	5. **Tudorza® (aclidinium for inhalation) –** A long-acting inhaled antimuscarinic showing similar efficacy to Spiriva®. Current pricing indicates a possible cost savings opportunity if Tudorza® is utilized in place of Spiriva®. The hospital's group purchasing organization (GPO) is currently evaluating the respiratory market and updated pricing contracts will be released in March. It was recommended to declare these agents therapeutically equivalent and once the pricing situation becomes clearer a therapeutic interchange will be implemented for the most cost effective agent.	5. Pending. Patrick to re-evaluate once GPO finalizes contract.	Complete
	6. **Inhaled Cortiscosteroid/β-Agonist – Formulary Interchange –** A new agent (Breo Elipta®) has now been FDA approved and it was recommended to add this drug to the existing Symbicort® formulary Interchange.	6. Approved for formulary substitution.	

Medication Safety	• **ADR Review –Medication Error Review –** 5 month summary.
	  • One Category 3 ADR reviewed.
	  • Category 1 & 2 statistics reviewed.
		Information	Complete

	Patrick presented information on 3 category 2 ADR's related to enoxaparin that occurred in elderly patients with normal renal function. The safety of low molecular weight agents was discussed. Anti-xa assays are obtainable within the hospital. Vicki Burger explained that the processing time will become faster as we increase the ordering of anti-xa assays. The committee recommended that pharmacy automatically order anti-xa assays for patients on treatment dose enoxaparin that are ≥ 70 yrs of age to help ensure appropriate dosing in elderly patients.	Approved – *Anticoagulation Management Policy* will be edited to reflect this recommendation	
	Dr. Atchley requested that pharmacy automatically adjust the new oral anticoagulants (Xarelto®, Eliquis®, Pradaxa®) per renal function and notify the prescriber when an adjustment is warranted.	Approved	Approved
Medication Use Evaluation	• **Vitamin K – Warfarin Reversal -** MUE reviewing six months usage of Vitamin K indicated a need for physician education. A trend was noted in using subcutaneous Vitamin K for reversal of warfarin in patients	Information.	Complete
	• A trend was noted in using subcutaneous Vitamin K for warfarin reversal which is no longer recommended per the CHEST guidelines. Two patients with life threatening major bleeding (intracranial hemorrhage) received Vitamin K Subscutaneously. Of the 47 patients who received Vitamin K to aid in the reversal of warfarin reversal for surgery, 40% of them experienced a delay in surgery >24 hours. All of the delays were experienced in those patients who received the subcutaneous route. It was recommended to encourage the use of IV vitamin K when urgent warfarin reversal is needed (surgery, active bleeding, etc.).	Physician Education Needed on current guidelines.	
	• Recommended to flag prescribers when subcutaneous formulation ordered. Subcutaneous is less effective than oral and IV administration and can lead to delays in anticoagulation reversal or need for more expensive agents such as Kcentra to be used prior to surgery.	Approved for pharmacists to contact prescribers when SQ route is ordered and recommend IV formulation if need for reversal is urgent or oral vitamin K for non-urgent reversal.	
Policy, Procedure & Protocols	• **Pneumonia Standing Orders -** Discussed the need to change the standing orders due to worsening fluoroquinolone resistance against *Pseudmonas aeruginosa*. Tobramycin will be added to HAP/HCAP regimen with pharmacy dosing and each patient will be reviewed to ensure	Approved	Complete

AGENDA ITEM	FINDINGS OR CONCLUSION	ACTION, RESPONSIBILITY	STATUS
	prolonged courses of tobramycin are not inappropriately continued to minimize the risk of tobramycin associated kidney injury. The use of tobramycin for patients with mild to moderate renal dysfunction was discussed and it was recommended to still include an option for a fluoroquinolone containing regimen for patients with preexisting renal dysfunction. Committee approved protocol with the addition of fluroquinolones for the patients with severe renal impairment.		
	• **Tamiflu® (oseltamivir) – Automatic Stop Proposal –** Proposed to institute a 5 day automatic stop for oseltamivir when used for non-critically ill patients and a 10 day automatic stop of critically ill ICU patients. It is also recommended to allow this drug to be automatically adjusted in patients with impaired renal function in accordance with the Renal Dosing Adjustments policy.	Approved	Complete
	• **IV to PO – IV Synthroid® -** It was recommended to add this to IV to PO policy due to an ongoing shortage of the IV formulation.	Approved	Complete
	• **Sterile Compounding Outsourcing –** Patrick explained to the committee that the hospital uses two different compounding companies for the preparation of certain sterile products that are not compounded by the hospital pharmacy. One is Cantrell, which is an FDA approved outsourcer and supplies MHCS with drug shortage items that are unable to be obtained from other drug manufacturers as well as some PCA's and epidurals. The second is Surgery Pharmacy Services in which individual prescriptions are obtained per patient and is accredited by the Pharmacy Compounding Accreditation Board. Dr. Anderson asked if periodic site visits to the local compounding pharmacy could be performed by pharmacy leadership to help ensure ongoing compliance with sterile compounding regulations. The committee agreed that we are in compliance and agreed to continue to document compliance and have documentation readily available.	Information: Quarterly quality reports available and annual site visit performed to local compounding site.	Complete
Nutrition Support Team	**Pivot 1.5 – addition to nutrition formulary –** Brian reviewed new high protein product. **Enteral Nutrition – Order Set & Policy Revision -** Brian reviewed an updated, streamlined tube feeding order set. This order set has been approved by nursing practice council. He also reviewed the updated process for implementing the Enteral Nutrition Adult Order set.	Approved Approved	Complete Complete
Other	• **Octagam (IVIG) patients –** Patrick updated the committee on new data that shows we can infuse at a faster rate. The plan is to pursue the faster administration rate and begin conversion of our outpatient IVIG patients to Octagam 5% once provider notification is completed over the next 4-6 weeks.	Approved	Ongoing

There being no further business, the meeting was adjourned at 8:00 A.M. The next P&T meeting is April 10, 2014.

Respectfully submitted,

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

Approved by,

Richard Pesce, M.D. Chairman

SUMMARY REVIEW

GENERIC NAME: DAPAGLIFLOZIN

PROPRIETARY NAME: FARXIGA (Bristol-Myers Squibb / AstraZeneca)

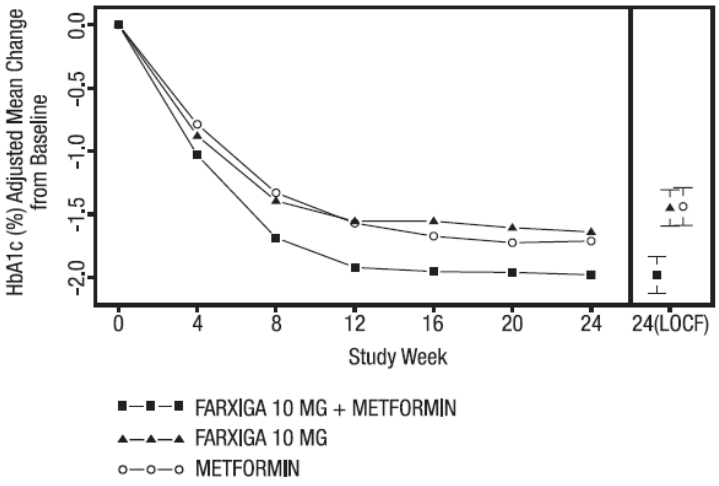
INDICATIONS:
Dapagliflozin was approved by the FDA in January 2013 as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

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, dapagliflozin reduces reabsorption of filtered glucose and thereby increases urinary glucose excretion.

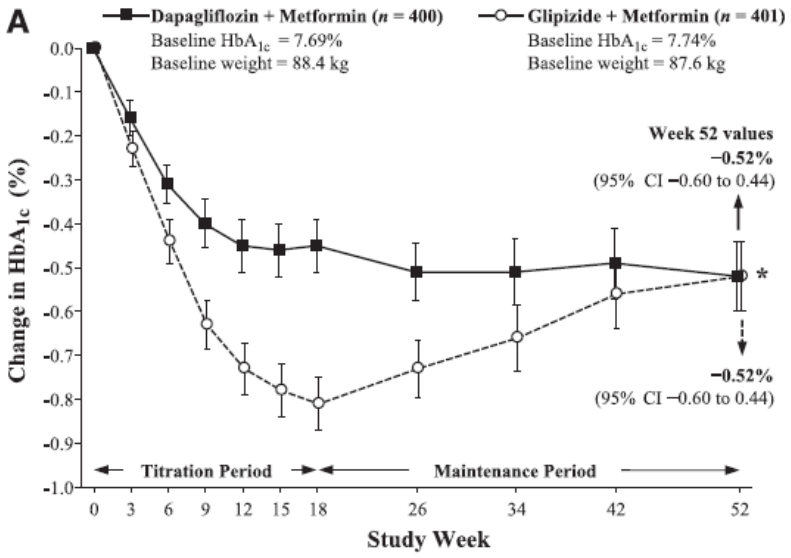
COMPARATIVE EFFICACY:
Dapagliflozin has been studied as monotherapy and in combination with metformin, pioglitizone, glimepiride, sitagliptin (with or without metformin), or insulin (with or without oral antidiabetic therapy). The efficacy of dapagliflozin has been compared to glipizide as add-on therapy to metformin in clinical trials. To date there have been no studies comparing dapagliflozin to canagliflozin, the other FDA approved SGLT2 inhibitor. In a monotherapy trial after 24 weeks of therapy, HbA1c was reduced by 0.77% to 0.89% in the dapagliflozin group compared to placebo in type 2 diabetics inadequately controlled with diet and exercise.

In a 24 week, randomized, double-blind, three arm trial dapagliflozin plus metformin, dapagliflozin alone, and metformin alone were studied. The primary efficacy endpoint was HbA1c change from baseline. The combination of dapagliflozin plus metformin provided statistically significant improvements in HbA1c compared with either of the monotherapy treatments.

Figure 2: Adjusted Mean Change from Baseline Over Time in HbA1c (%) in a 24-Week Active-Controlled Study of FARXIGA Initial Combination Therapy with Metformin XR



In a 52 week, randomized, double-blind, active-controlled noninferioriy trial dapagliflozin plus metformin was compared to glipizide plus metformin. The primary end point, adjusted mean HbA1c reduction with dapagliflozin (-0.52%) compared with glipizide (-0.52%) was statistically noninferior at 52 weeks.



PHARMACOKINETICS:

Absorption	T_{max}: 2 hours Oral bioavailability: 78%
Distribution	91% protein bound in plasma Protein binding is not altered in patients with renal or hepatic impairment
Metabolism	Mainly metabolized by by O-glucuronidation, primarily by UGT1A9 CYP-mediated metabolism is a minor clearance pathway
Elimination	Excreted in urine (75%) and feces (21%) Elimination $t_{1/2}$: 12.9 hr for the 10mg dose

ADVERSE REACTIONS:
Most common adverse effects (>2%) *of twelve 12 to 26-week placebo controlled trials*
Female genital mycotic infections (6.9-8.4%), urinary tract infections (4.3-5.7%), nasopharyngitis (6.3-6.6%) increased urination (2.9-3.8%), and male genital mycotic infections (2.7-2.8%)

Dapagliflozin is an osmotic diuretic, which may lead to reductions in intravascular volume. In clinical studies, dapagliflozin 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 30-60 ml/min/1.73m², and age greater than 65.

DRUG INTERACTIONS:
Overall, dapagliflozin is unlikely to affect the pharmacokinetics of concurrently administered medications that are P-gp, OCT2, OAT1, or OAT3 substrates. Of all tested coadministered medications, dapagliflozin did not meaningfully affect the pharmacokinetics of the coadministered drugs.

DOSING:
The recommended starting dose is 5 mg once daily, taken in the morning, with or without food. The dose can be increased to 10 mg once daily based on tolerability and need for additional glycemic control.

Assess renal function before initiation. Do not initiate if eGFR < 60 and discontinue if eGFR falls persistently below 60.

PRODUCT AVAILABILITY and STORAGE:

	30 day supply	**Cost per dose**
Farxiga 5mg & 10mg	**$275.53**	**$9.18**
Invokana 100mg & 300mg	**$275.53**	**$9.18**
Januvia 100mg	**$270.12**	**$9.00**

CONCLUSION:
It is recommended to not add Farxiga (dapagliflozin) to formulary at this time.

FORMULARY REVIEW

GENERIC NAME: OBINUTUZUMAB

PROPRIETARY NAME: Gazyva (Genentech)

INDICATIONS: Obinutuzumab is indicated for co-administration with chlorambucil in patients with previously untreated chronic lymphocytic leukemia (CLL).

CLINICAL PHARMACOLOGY: The cell surface antigen CD20 is commonly expressed on B-cell precursors and mature B cells, making them an ideal target for malignancies in this hematopoietic cell lineage. However, in the course of treatment of indolent B-cell malignancies, patients typically fail to achieve complete response or relapse and become refractory to current therapy, including specific type I anti-CD20 monoclonal antibodies. Obinutuzumab is a novel glycoengineered type II anti-CD20 monoclonal antibody intended to have improved efficacy over previous type I monoclonal antibodies. In general, anti-CD20 antibodies induce apoptosis through varying degrees of activation of the complement-dependent cytotoxicity (CDC), antibody-dependent cellular cytotoxicity (ADCC), and direct cell death.

PHARMACOKINETICS: Obinutuzumab appears to have linear pharmacokinetics, with area under the curve (AUC), maximum serum concentration, and serum trough concentration increasing proportionally with dose and decreasing after cessation of the drug. Obinutuzumab appears to be eliminated through 2 pathways: a linear clearance pathway and a time-dependent nonlinear clearance pathway. With prolonged obinutuzumab treatment, the impact of the time-dependent pathway diminishes, which may suggest target-mediated drug disposition. Terminal clearance is 0.09 L/day, terminal half-life is 28.4 days, and the volume of distribution is 3.8 L. Both distribution volume and clearance increased with body weight. However, no dose adjustment is recommended based on changes in these parameters. Obinutuzumab has not been studied in CrCL below 30 ml/min and hepatic impairment.

ADVERSE REACTIONS: The most common adverse reactions reported with obinutuzumab therapy include infusion reactions, neutropenia, thrombocytopenia, anemia, pyrexia, cough, and musculoskeletal disorder. Of the patients receiving obinutuzumab, 38% experienced infection (similar rate in the chlorambucil arm), 17% experienced musculoskeletal disorders (13% in the chlorambucil arm), two percent experienced grade 3 or 4 tumor lysis syndrome (none in the chorambucil arm).

DRUG INTERACTIONS: There is no published information regarding drug interactions with obinutuzumab.

DOSING: Cycle 1: 100 mg IV on day 1, 900 mg on day 2, and then 1000 mg on day 8 & 15; Cycles 2-6: 1000 mg IV on day 1 every 28 days x 5 doses.

PRODUCT AVAILABILITY AND STORAGE: Obinutuzumab was approved by the Food and Drug Administration on November 1, 2013.(21) Obinutuzumab is available as preservative-free, single-use vials of 1,000 mg per 40 mL (25 mg/mL).

COST: $5,160 per vial; $41,280 per complete regimen (cycles 1-6)

CONCLUSION: Obinutuzumab is a unique glycoengineered type II anti-CD20 monoclonal antibody. Differences in fucose content of the Fc region increase obinutuzumab's apoptotic ability through ADCC and direct cell death but decrease CDC activity compared with type I anti-CD20 antibodies. Obinutuzumab is currently approved for previously untreated CLL in combination with chlorambucil. However, results from phase 1 and 2 studies may show promise when obinutuzumab is applied in relapsed or refractory CD20+ non-Hodgkin lymphoma. A recent study (NEJM – March, 2014) evaluated chlorambucil + obinutuzumab vs. chlorambucil + rituximab in patients with previously untreated CLL. Patients in the obinutuzumab arm achieved a median PFS of 26.7 months compared with 15.2 months for those in the Rituxan arm (HR 0.39, CI 0.31-0.49, $P<0.0001$). Additionally, obinutuzumab treated patients also had a higher rate of complete response (20.7% vs. 7.0%, hazard ratio, 0.39; 95% CI, 0.31 to 0.49; P<0.001) as compared to the patients treated with the rituximab containing regimen. Infusion-related reactions and neutropenia were more common with obinutuzumab–chlorambucil than with rituximab–chlorambucil, but the risk of infection was not increased. The time point for overall survival has not been reached yet in these patients.

Based on the above data it is recommended to add obinutuzumab to formulary. Cost is comparable when compared to usual dosing of rituximab for the same indication.

FORMULARY REVIEW

GENERIC NAME: Bupivacaine Liposomal

PROPRIETARY NAME: Exparel (Pacira)

Requested for use by Dr. Brzezienski for use in breast surgery

INDICATIONS: Exparel is a liposome injection of bupivicaine, an amide local anesthetic, indicated for single-dose infiltration into the surgical site to produce postsurgical analgesia.

CLINICAL PHARMACOLOGY: Local anesthetics block the generation and the conduction of nerve impulses presumably by increasing the threshold for electrical excitation in the nerve, by slowing the propagation of the nerve impulse, and by reducing the rate of rise of the action potential. In general, the progression of anesthesia is related to the diameter, myelination, and conduction velocity of affected nerve fibers.

PHARMACOKINETICS: Local infiltration of EXPAREL results in significant systemic plasma levels of bupivacaine which can persist for 96 hours. The rate of systemic absorption of bupivacaine is dependent upon the total dose of drug administered, the route of administration, and the vascularity of the administration site. Systemic plasma levels of bupivacaine following administration are not correlated with local efficacy. For the FDA approved indications the difference in pain intensity when compared to placebo occurred only during the first 24 hours following study drug administration. Between 24 and 72 hours after study drug administration, there was minimal to no difference between liposomal bupivacaine and placebo on mean pain intensity.

ADVERSE REACTIONS: Nausea, Constipation, and Vomiting were reported in greater than or equal to 10% of the patients.

DRUG INTERACTIONS: Do not admix with lidocaine or other non-bupivacaine-based local anestheics.

DOSING: Is intended for single-dose administration only. The recommended dose is based on the surgical site and the volume required to cover that area:

Surgery	**Dose of EXPAREL**	**Volume of EXPAREL**
Bunionectomy	106 mg	8 mL
Hemorrhoidectomy	266 mg	20 mL

CONTRAINDICATIONS: Do not use in obstetrical paracervical block anesthesia.

WARNINGS AND PRECAUTIONS: Monitoring of cardiovascular and neurological status, as well as vital signs should be performed during and after injection. It is metabolized by the liver, so use with caution in patients with hepatic disease. It is substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function.

Bupivacaine liposome injectable suspension must NOT be mixed with or come in direct contact with non-bupivacaine-based local anesthetics, including lidocaine. These products may cause an immediate release of bupivacaine from the liposomes. Bupivacaine hydrochloride products if injected immediately before bupivacaine liposome injectable suspension may alter the pharmacokinetic and/or physicochemical properties of the drugs if the dose of bupivacaine hydrochloride solution exceeds 50% of the bupivacaine liposome injectable suspension (Exparel) dose.

MAMMAPLASTY STUDY RESULTS:
To date only one clinical trial has been published outlining the use of Exparel for patients undergoing breast surgery. The trial was a double-blind, randomized trial in which patients were randomized to receive either a single dose of Exparel 300 mg or bupivacaine 200 mg into each implant pocket at the conclusion of surgery. The study was terminated early due to "administrative reasons" and was thus underpowered to detect statistically significant differences in treatment groups. Assessments of cumulative pain score and opioid usage trended in favor of Exparel, however neither reached a *P* value of less than .05. Numerically lower pain intensity scores were observed for Exparel at 8 hrs and 12 hrs, however the scores were not significantly different at the other timed assessments. Overall, due to the early termination of this trial it is difficult to draw accurate comparisons between treatments.

COST: $285/20 ml

FORMULARY REVIEW

GENERIC NAME: CLEVIDIPINE BUTYRATE INJECTABLE EMULSION

PROPRIETARY NAME: *Cleviprex* (Medicines Company)

INDICATIONS: Clevidipine butyrate injectable emulsion is indicated for the reduction of blood pressure when oral therapy is not feasible or not desirable. Other agents used for the acute intravenous (IV) management of hypertension include sodium nitroprusside, nitroglycerin, fenoldopam, hydralazine, esmolol, labetalol, and nicardipine.

CLINICAL PHARMACOLOGY: Clevidipine is an ultrashort-acting dihydropyridine L-type calcium channel antagonist. Clevidipine is structurally related to felodipine, with the inclusion of an ester group in the structure that causes it to undergo rapid hydrolysis by esterases in the blood and extravascular tissue to an inactive metabolite. Clevidipine is poorly soluble in water and has been formulated in a 20% lipid emulsion with the same constituents as *Intralipid*.

PHARMACOKINETICS: Clevidipine pharmacokinetics are linear. Steady-state arterial clevidipine levels are reached within 2 minutes. Steady-state venous concentrations are reached within approximately 10 minutes. Clevidipine is rapidly metabolized by blood and tissue esterases to inactive metabolites. The initial half-life is less than 3 minutes, and the terminal half-life is 4 to 21 minutes (15 minutes according to the product labeling). The primary metabolites are the carboxylic acid metabolite and formaldehyde formed by hydrolysis of the ester group. The carboxylic acid metabolite is inactive. It has a terminal half-life of 9.5 hours. The primary metabolite undergoes further metabolism prior to excretion.

COMPARATIVE EFFICACY: In 3 open-label, randomized trials with cardiac surgery patients, clevidipine was compared to nitroglycerin and sodium nitroprusside pre-, peri-, and post-operatively and to nicardipine post-operatively only. Compared to nitroglycerin, nicardipine, and sodium nitroprusside, clevidipine was not associated with statistically significantly differences in the pre-, peri-, or post-operative periods in regards to the primary outcomes of death, MI, stroke or renal insufficiency within 30 days after surgery. Clevidipine was associated with a significantly greater BP control versus nitroglycerin and sodium nitroprusside. Blood pressure was comparable between clevidipine and nicardipine.

ADVERSE REACTIONS: The most common adverse reactions, occurring in more than 2% of clevidipine-treated patients, include headache, nausea, and vomiting.

DRUG INTERACTIONS: At clinically relevant concentrations, clevidipine does not induce or inhibit CYP-450 isozymes.

DOSING: Clevidipine is administered as a continuous IV infusion via a central or peripheral line. The dose is titrated to achieve the desired blood pressure reduction and individualized depending on the blood pressure response and goal blood pressure. The infusion is initiated at 1 to 2 mg/h (2 to 4 mL/h), with the dose doubled at 90-second intervals initially. As the blood pressure approaches goal, the dose should be increased by less than doubling, and the time between adjustments should be increased to every 5 to 10 minutes. Severe hypertension may require higher doses. Because of lipid load restriction, no more than 1,000 mL or an average of 21 mg/h is recommended per 24-hour period. There is little experience with dosing beyond 72 hours. The 1 to 2 mg/h initiation dose is appropriate for use in patients with abnormal hepatic function or moderate to severe renal function impairment.

PRODUCT AVAILABILITY and STORAGE: Clevidipine butyrate injectable emulsion received Food and Drug Administration approval in August 2008. It is available as a 0.5 mg/mL emulsion in single-use, premixed, ready-to-use 50 and 100 mL vials. Clevidipine is insoluble in water and is available in a lipid emulsion similar to propofol. The vial should be inverted gently several times before use to ensure uniformity of the emulsion prior to administration. Clevidipine vials should be stored in the refrigerator (2° to 8°C [36° to 46°F] and protected from freezing. Once the vial is punctured it must be used within 12 hrs and any unused portion should be discarded and replaced with a new bottle if continued administration is

necessary.

COST:	Clevidipine:	$61.65 / vial (25 mg vial); $123.90 / vial (50 mg vial)
	Nicardipine:	$16.19 / vial (25 mg vial)
	Nitroglycerin:	$4.51 / bottle (50 mg/250 ml)
	Nitroprusside:	$204.67 / vial (50 mg vial)

As seen in clinical trials, administration of clevidipine at a median rate of 3.1 mg/hr for a median of 6.4 hours will result in an estimated cost of $61.65 per patient (cardiac surgery patients).

CONCLUSION: Cleviprex is a short-acting dihydropyridine calcium channel blocker for acute management of hypertension when oral therapy is not appropriate. Clevidipine, like propofol, is formulated in a lipid emulsion, which also appears milky white. Both products are available in 50 ml glass bottles and are used in the ICU/OR/ED settings. Due to product similarities, a major potential for "look-alike" confusion between the two products exists. Staff must be informed of the potential "look-alike" confusion between propofol and cleviprex.

Pancrelipase					
Product	**Lipase (u)**	**Protease (u)**	**Amylase (u)**	**Cost (per unit dose)**	**Equivalent Cost of pancrelipase**
Creon	3,000	9,500	15,000	$0.94	N/A
Creon	6,000	19,000	30,000	$1.08	$0.60
Creon	12,000	38,000	60,000	$2.03	$1.20
Creon	24,000	76,000	120,000	$3.98	$3.00
Creon	36,000	114,000	180,000	$6.27	$4.20
Zenpep	3,000	10,000	16,000	$1.01	N/A
Zenpep	5,000	17,000	27,000	$0.96	$0.60
Zenpep	10,000	34,000	55,000	$1.91	$1.20
Zenpep	15,000	51,000	82,000	$2.75	$1.80
Zenpep	20,000	68,000	109,000	$3.74	$2.40
Zenpep	25,000	85,000	136,000	$4.63	$3.00
Pancreaze 4	4,200	10,000	17,500	$0.80	$0.60
Pancreaze 10	10,500	25,000	43,750	$2.00	$1.20
Pancreaze 16	16,800	40,000	70,000	$3.21	$1.80
Pancreaze 20	21,000	37,000	61,000	$3.99	$2.40
Pertzye	8,000	28,750	30,250	$1.52	$1.20
Pertzye	16,000	57,500	60,500	$3.04	$1.80
Ultresa	13,800	27,600	27,600	$2.39	$1.20
Ultresa	20,700	41,400	41,400	$3.54	$1.80
Ultresa	23,000	46,000	46,000	$4.34	$3.00
Viokace	10,440	39,150	39,150	$2.32	$1.20
Viokace	20,880	78,300	78,300	$4.57	$2.40
Formulary					
Pancrelipase	5,000	17,000	27,000	$0.60	N/A

* Dosing is based on LIPASE units

Formulary Substitution	
ORDERED	**SUBSTITUTION**
Creon 3,000 units	Pancrelipase 5,000 - 1 capsule
Creon 6,000 units	Pancrelipase 5,000 - 1 capsule
Creon 12,000 units	Pancrelipase 5,000 - 2 capsules
Pancreaze 4 (4,200 units)	Pancrelipase 5,000 - 1 capsule
Pancreaze 10 (10,500 units)	Pancrelipase 5,000 - 2 capsules
Pancreaze 16 (16,800 units)	Pancrelipase 5,000 - 3 capsules
Pancreaze 20 (21,000 units)	Creon 24,000 - 1 capsule
Pertzye 8,000 units	Pancrelipase 5,000 - 2 capsules
Pertzye 16,000 units	Pancrelipase 5,000 - 3 capsules
Ultresa 13,800 units	Pancrelipase 5,000 - 3 capsules
Ultresa 20,700 units	Creon 24,000 - 1 capsule
Ultresa 23,000 units	Creon 24,000 - 1 capsule
Viokase 10,440 units	Pancrelipase 5,000 - 2 capsules
Viokase 20,880 units	Creon 24,000 - 1 capsule
Zenpep 3,000 units	Pancrelipase 5,000 - 1 capsule
Zenpep 5,000 units	Pancrelipase 5,000 - 1 capsule
Zenpep 10,000 units	Pancrelipase 5,000 - 2 capsules
Zenpep 15,000 units	Pancrelipase 5,000 - 3 capsules
Zenpep 20,000 units	Pancrelipase 5,000 - 4 capsules
Zenpep 25,000 units	Creon 24,000 - 1 capsule
* Units expressed in LIPASE content	

FORMULARY REVIEW

GENERIC NAME: ICOSAPENT ETHYL (Vascepa)
OMEGA-3-ACID ETHYL ESTERS (Lovaza)

PROPRIETARY NAME: Vascepa (contains EPA)
Lovaza (contains EPA and DHA)

INDICATIONS: Vascepa and Lovaza are indicated as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe hypertriglyceridemia (500 mg/dL or more).

CLINICAL PHARMACOLOGY: There are 3 omega-3 fatty acids: alpha-linolenic acid, eicosapentaenoic acid (EPA), and docosahexaenoic acid (DHA). Only 2 of these omega-3 fatty acids, EPA and DHA, are found in fish oils. Most fish contain approximately 1 g of omega-3 fatty acids per 100 g of fish. The pharmacologic effects of EPA and DHA on lipids appear to be different. From studies using rats, it was thought that EPA was primarily responsible for the TG-lowering effects of fish oil. However, clinical trials in humans have shown that both EPA and DHA are able to decrease serum TGs when used as monotherapy. Additionally, DHA increased serum high-density lipoprotein cholesterol (HDL-C) concentrations and increased low-density lipoprotein cholesterol (LDL-C) particle size. Icosapent ethyl is an ethyl ester of the omega-3 fatty acid EPA. EPA is thought to inhibit hepatic very-low-density lipoprotein (VLDL) TG synthesis and/or secretion and enhance the clearance of TGs from circulating VLDL particles.

PHARMACOKINETICS: Following oral administration, these are de-esterified in the gut to the active metabolites. Peak plasma concentrations of EPA are reached approximately 5 hours following oral administration. In clinical trials, icosapent ethyl was administered with or following a meal and the manufacturer recommends that it be taken with meals. The plasma elimination half-life of EPA is approximately 89 hours. Greater than 99% of EPA is bound to plasma proteins. EPA does not undergo renal excretion, but is metabolized by the liver via beta-oxidation. The beta-oxidation splits the long carbon chain of EPA into acetyl coenzyme A, which is converted into energy via the Krebs cycle. Cytochrome P450–mediated metabolism is also a minor metabolic pathway of EPA.

ADVERSE REACTIONS: Fish oil supplements are generally well tolerated and associated with minimal adverse effects. The product labeling for omega-3-acid ethyl esters has postmarketing reports of anaphylactic reactions and hemorrhagic diathesis.

DRUG INTERACTIONS: Prolongation of bleeding time has been reported with omega-3 fatty acids. However, the prolongation of bleeding time has not exceeded normal limits and did not produce clinically significant bleeding episodes. Clinical studies have not been done to thoroughly examine the effect of icosapent ethyl and concomitant anticoagulants. Until such trials are conducted, patients requiring treatment with drugs affecting coagulation (eg, antiplatelet agents) should be monitored periodically throughout therapy.

DOSING: The daily dose of either product is 4 g/day in addition to appropriate nutritional intake and physical activity.

PRODUCT AVAILABILITY: Vascepa was approved in July 2012 and Lovaza (previously Omacor) was approved in 2004. Both are supplied as 1 g soft gelatin capsules.

COST: Vascepa ($1.55/1gm) Lovaza ($1.66/1gm) Promega (0.03/1gm)

RECOMMENDATION:
Currently only a generic fish oil product is stocked by the pharmacy (generic Promega). The generic product that is currently stocked is a 1 gm gel cap that consists of a mixture of both EPA and DHA which compares closely to the composition of Lovaza although the exact amounts of each fatty acid differ slightly between products. Due to the significant cost advantage of the generically available products it is recommended to automatically substitute Promega for Vascepa and Lovaza on a mg/mg basis.

THERAPEUTIC REVIEW
Clostridium difficile

Vancomycin dosing, use of cholestyramine & anti-diarrheals

VANCOMYCIN DOSING:
Recent guidelines (IDSA, American College of Gastroenterology) have attempted to more clearly define the appropriate Vancomycin dosage for the treatment of *Clostridium difficile* infection (CDI). Both guidelines recommend the use of Vancomycin 125 mg Q 6 hrs for mild, moderate and severe CDI and only a higher dose of 500 mg Q 6 hrs for patients with complicated CDI with ileus or toxic mega colon. The lower dose strategy (125 mg Q 6 hrs) is encouraged in both guidelines based on stool concentration studies which have demonstrated that the Vancomycin stool concentrations far exceed *C. difficile* MIC values in the stool. However, until recently true clinical data have been lacking to clinically evaluate doses exceeding 500 mg per day versus the standard low dose dosing strategy. A recent study demonstrated a statistically equivalent clinical response (85% vs. 86%) as well as no other significant differences observed between a high dose or low dose strategy (mortality, readmission rates, etc.). Due to similar efficacy it is recommended to automatically substitute the 125 mg dose when the 250 mg Vancomycin dose is ordered. Doses of 500 mg Q 6 hrs will not be adjusted when used in patients with suspected ileus or mega colon. This substitution also has the potential to decrease CDI treatment costs (inpatient and outpatient) as well as potentially decreasing the risk of developing Vancomycin resistant *Enterococci.*

CHOLESTYRAMINE:
Bile acid binders such as cholestyramine are occasionally ordered as an adjunctive therapy for treatment of CDI. Neither guideline recommends the use of bile acid binders as there is currently no convincing evidence for efficacy of these agents for the treatment of CDI. Additionally, these drugs can bind Vancomycin and render its antibacterial activity ineffective further complicating CDI treatment. Due to the above rationale it is recommended to automatically discontinue the use of bile acid binders in patients actively undergoing treatment of CDI.

ANTI-DIARRHEAL AGENTS:
It has generally been recognized that antimotility agents should be avoided for diarrheal disease caused by viral or inflammatory pathogens to prevent potentiation of local bacterial proliferation and worsening clinical outcome. Currently there are no published studies evaluating the use of antimotility agents for symptomatic relief related to the treatment of CDI. Despite a lack of definitive literature in this area caution is still deemed necessary when administering antimotility agents to patients with CDI due to case reports of worsening disease when these agents are used. Therefore, it is recommended to discourage and discontinue the use of antimotility agents in patients actively undergoing treatment of CDI.

Medication-Use Evaluation: Relistor (methylnaltrexone)

Completed by: Karen Babb and Megan Whittier
Facility: Memorial Health Care System

Presented to P&T Committee: April 10, 2014

MUE Objectives:

1. Promote optimal medical therapy with Relistor
2. Prevent medication-related problems and improve patient safety
3. Evaluate the effectiveness of Relistor therapy
4. Enhance opportunities, through standardization, to assess the value of innovative medication-use practices from both patient-outcome and resource-utilization perspectives
5. Minimize costs of medication therapy
6. Meet or exceed internal and external quality standards

Background:

Relistor received FDA approval for the treatment of opioid-induced constipation in April 2008. As a result of its mechanism of action, Relistor has specific effects on constipation that can be attributed to opioid use. The drug acts as an antagonist of gastrointestinal (GI) *mu*-opioid receptors, thereby inhibiting opioid-induced delay of GI transit. The package insert states that Relistor "is indicated for the treatment of opioid-induced constipation in patients with advanced illness who are receiving palliative care, when response to laxative therapy has not been sufficient." Frequency is Q 48hrs PRN. Dosage is
<38kg; 0.15mg/kg day SC
38-61kg; 8mg/day SC
62-114kg; 12mg/day SC
>114kg; 0.15mg/kg/day SC

Cost: $56/12mg vial

In 2008, the drug was added to our formulary with its use restricted to Oncology, Hospice, Surgery, and ED. From July 1, 2013 through December 31, 2013, there were 336 doses dispensed on the Glenwood campus. This MUE was completed to determine whether there was adherence to the labeled indication.

Methods: We conducted a single-center, restrospective chart review of 25 patients who received Relistor from July 1-December 31, 2013. The pharmacy informatics database was used to identify patients who had received at least 1 dose of Relistor during this time-frame.
Data collected included patient's age, weight, renal function, reason for prescribing, dose, correct dose for weight or renal function, number of doses administered, was the medication stopped after bowel movement, and prescribing service.
To determine adherence to the label's indication, data was collected on opioid use, constipation, and if a laxative was used first.

Definitions:

We defined constipation as any documentation of constipation with no prespecified number of days since the last bowel movement.

Laxative use was defined as therapy with such agents as stimulants, osmotic laxatives, or stool softeners of any duration before methylnaltrexone administration.

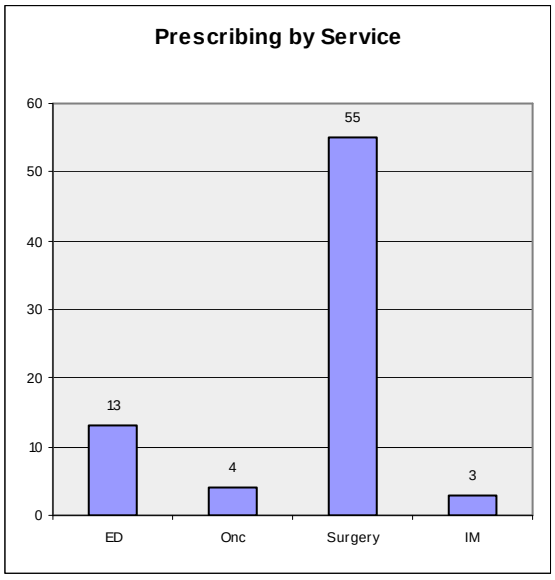
Opioid use was defined as the inpatient or outpatient administration of any opioid agent (e.g., morphine, propoxyphene, or hydromorphone) scheduled or as needed, with no minimum dose or duration.

We defined renal dysfunction as an estimated creatinine clearance (CrCl) of 30 mL/minute or less, using the Cockcroft–Gault equation to make our calculations.

Results:
We evaluated 25 patients to determine appropriate use. A total of 75 doses were administered. The average age was 59 years. Of the 75 doses, 64 (85%) were written with the correct dose.

Of the 11 (14%) doses that were written with the incorrect dose, 1 was incorrect because of a failure to adjust the dose for renal dysfunction and 10 were inappropriate for the patient's weight. Seventeen (22%) orders were written within the prescribing schedule of once or every-other-day dosing; however, 58 (77%) doses were prescribed for scheduled daily administration.

Relistor was prescribed by Emergency Department (17%), Surgery (72%), Oncology (7%), and Internal Medicine (4%) physicians. See Table 1.



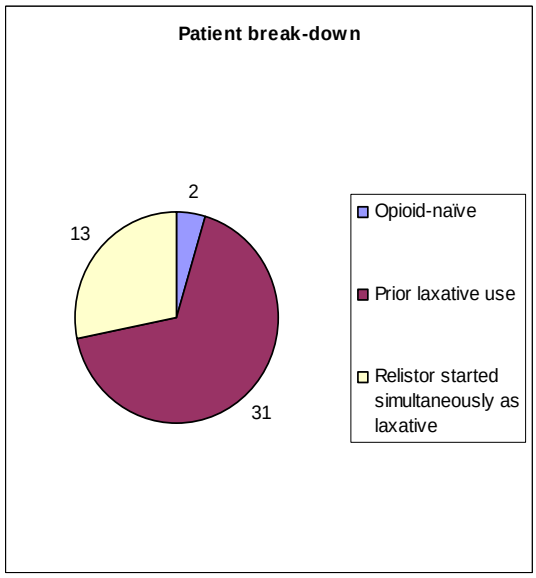


Table 1 Table 2

Two (2%) doses were written for patients without any history of opioid use. Thirty-one (41%) doses were written for patients without a history of prior laxative use. Thirteen doses (17%) were started at the same time as a laxative. See Table 2. Twenty-three (30%) doses were given for possible ileus versus 52 (70%) for constipation. See Table 3.

Fifty (66%) doses were given and not discontinued after a bowel movement was achieved. Table 4.

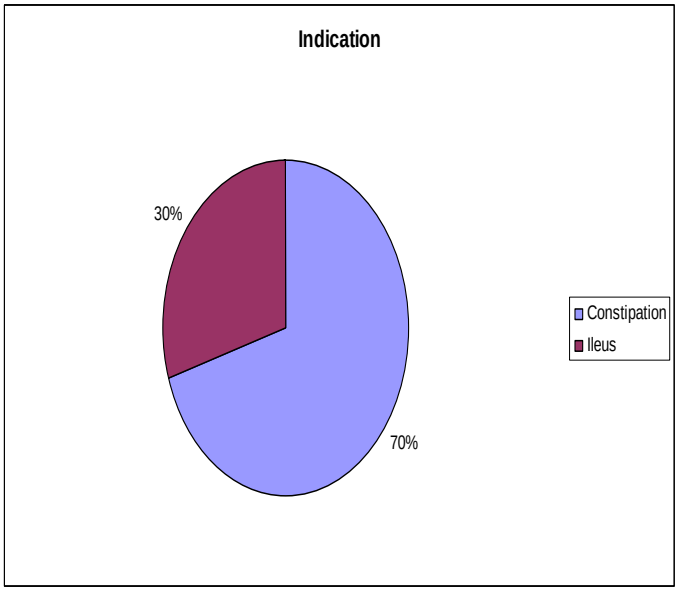


Table 3

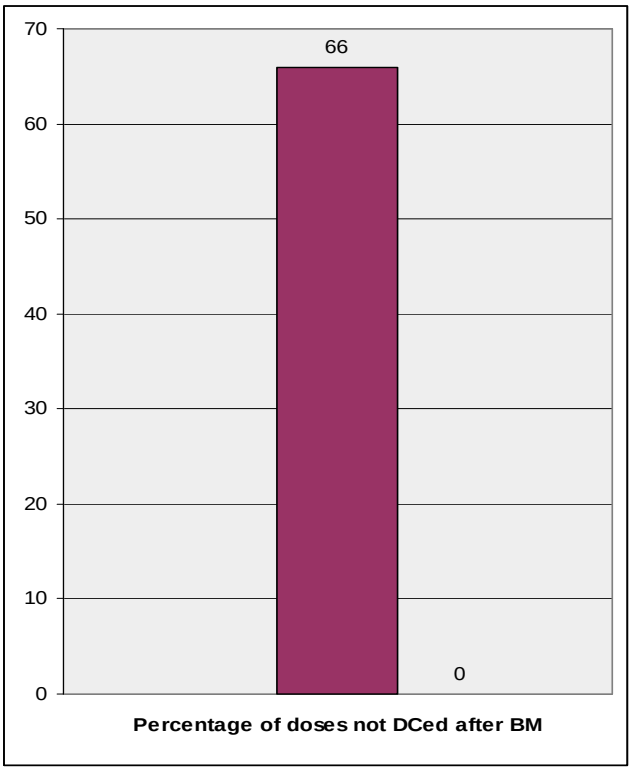


Table 4

Conclusions: In our patient population, we found that Relistor is not being used in accordance with its labeled indication. The off-label use of Relistor suggests that there might be situations, such as for ileus, in which the drug could be suitable.

Recommendations: If more than 1 dose at a time is ordered, such as 12mg SC daily x 3 doses, pharmacy will automatically discontinue the medication upon first sign of flatus or bowel movement. Based on the 50 doses that were given post flatus or BM, this offers an estimated cost savings of approximately $10,000 annually.

ANTIMICROBIAL PROPHYLAXIS IN SURGERY
Dosing changes to standard prophylaxis regimens

BACKGROUND: In February 2013, new clinical practice guidelines for antimicrobial prophylaxis in surgery were published. These guidelines reflect substantial changes from the previous guidelines published in 1999 and those changes are outlined below.

CHANGES:
Preoperative-dose timing: These guidelines outline a more specific time frame for administration than the previous recommendation time, which was "at induction of anesthesia." The optimal time for administration of preoperative doses is **within 60 minutes before surgical incision**. The administration of antimicrobials that require longer infusions (i.e. vancomycin) should begin within 120 minutes before surgical incision.

Dosing changes: The new guidelines place a larger emphasis on weight-based dosing than previous recommendations. This is attributable to obesity being linked to an increased risk for surgical site infections (SSI). Key dosing changes include:

- **Cefazolin (Ancef®)**: <80 kg = 1g; 80-120 = 2 g; >120 = 3 g
- **Vancomycin**: 15mg/kg: < 80 kg = 1g; 80-120 = 1.5g; >120 kg = 2 g
- **Gentamicin**: 5mg/kg (dosing weight): <50 kg = 240 mg; 50-80 kg = 320 mg; > 80kg = 400 mg
- **Cefoxitin**: 2 g
- **Clindamycin**: 900mg

Duration of prophylaxis: The duration of antimicrobial prophylaxis should be **less than 24 hours for most procedures** and evidence is mounting that postoperative antimicrobial administration is not necessary for most procedures. Cardiothoracic procedures for which a prophylaxis duration of up to 48 hours has been accepted without evidence to support the practice is an area that remains controversial.

REFERENCE:
Bratzler DW, Dellinger EP, Olsen KM, et al. Clinical Practice Guideline for Antimicrobial Prophylaxis in Surgery. *Am J Health-Syst Pharm*. 2013;70:195-283

Pharmacist Ordering of Lab Values
Proposed Additions

Background:
As part of the *Medication Orders – Pharmacist Review* policy, pharmacists are authorized to initiate the ordering of necessary laboratory tests in consideration of patient safety and improved patient care. The laboratory tests that may be ordered are as defined by the Pharmacy and Therapeutics committee.

Previously approved laboratory tests/drug levels: theophylline, serum creatinine, INR, phenytoin, vancomycin, anti-Xa assays (LMWH), platelet count

Proposed additions:
Recent patient safety events have highlighted the need for additions to this P&T managed protocol. The following are the proposed additions to this policy/protocol:

- Aminoglycoside levels (gentamicin, tobramycin, amikacin)
  - *patients not being managed by pharmacokinetic service*

- Procalcitonin, CBC*, PTT*
  **as previously designated in the Anticoagulation Management Policy, Warfarin Dosing – Pharmacy Policy*

Title: VENOUS THROMBOEMBOLISM (VTE) PREVENTION		
Page 1 of 2		
Policy Number: PC	Date Last Revised: 3/14	Valid Until: 3/17
Department(s) Affected: All Clinical Areas	Review Period: every 3 years	

OUTCOME:
To reduce the likelihood of patient harm due to preventable venous thromboembolism (VTE) for all adult patients through the use of evidence-based interventions and practices.

DEFINITIONS:
- **DVT (Deep Vein Thrombosis):** a condition in which a blood clot (thrombus) forms in one or more of the deep veins in the body.
- **LIP (Licensed Independent Practitioner):** any practitioner permitted by law and by the organization to provide care and services, without direction or supervision, within the scope of the practitioner license and consistent with individually assigned clinical responsibilities.
- **VTE (Venous Thromboembolism):** a disease that includes both deep vein thrombosis (DVT) and pulmonary embolism (PE).

POLICY:
1. All patients are assessed for risk of developing a VTE upon admission, change in level of care, prior to discharge, and when clinically indicated.
   a) Risk assessment at admission: All patients admitted are screened for risk of VTE. A numerical value of the patient's individualized VTE risk score is calculated using an evidence-based scoring system. The calculated risk score is then populated on the Adult DVT Prophylaxis Assessment and Orders form, which is placed in the patient's chart for review by the admitting physician or other LIP. Refer to policy **ADMISSION OF PATIENT (ADULT/ADOLESCENT) (PC-07006).**
   b) Risk assessment upon change in level of care, prior to discharge: All patients will be re-screened daily using the same risk assessment tool as is used upon admission. Upon completion, instructions for obtaining orders for appropriate preventative measures are communicated to the nurse electronically if the patient's risk score is 1 or greater.

2. Utilize evidence based interventions and practices for preventing VTE's.
   a) An evidence-based risk scoring system is used for the purpose of calculating an individualized VTE risk score for all patients. The Adult DVT Prophylaxis Assessment and Orders outline the most appropriate treatments and interventions based on each patient's calculated risk assessment score.

3. Provide patients with education on admission and prior to discharge regarding the risk for developing a VTE, signs and symptoms of a VTE, treatment/prophylaxis for a VTE, and the importance of early and frequent ambulation.
   a) Patients with a VTE risk score indicative of at least moderate risk (≥ 2) upon admission will be educated using Mosby's Nursing Consult handout "Venous Thromboembolism (VTE) Prevention". Patient education is documented in the Education: Interdisciplinary intervention. Refer to policy **PATIENT EDUCATION PROGRAM (PC-07230).**
   b) Patients with a VTE risk score indicative of at least moderate risk (≥ 2) upon discharge will have "Blood Clot Education" included in the Patient Discharge Instructions.

4. Per facility standards, assess patients for bleeding who are receiving pharmaceutical prophylaxis for VTE and provide clinically indicated intervention(s) if bleeding occurs.
   a) Nursing will assess the patient for signs/symptoms of bleeding using the following nursing interventions:
      1. Shift Assessment: head-to-toe assessment completed once per shift for Medical/Surgical/Telemetry units and every four hours for Intensive Care units
      2. Assess/Monitor interventions: focused nursing assessments for specific body systems that may be performed at any time as warranted by patient condition or nursing judgment
      3. Intake & Output: documentation of intake and output including tube and drain output
      4. Vital Signs/Hemodynamics Monitor: documentation of vital signs including blood pressure, pulse, respiratory rate, temperature, and oxygen saturation. Frequency of vital signs will be determined

by unit specific standards/routine, or as directed by the nurse, physician, or as patient condition warrants

b) Refer to policy **DOCUMENTATION – DAILY NURSING: FREQUENTLY USED INTERVENTIONS AND PLAN OF CARE (RC-04519)**.

POLICY

Title: VENOUS THROMBOEMBOLISM (VTE) PREVENTION		
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Policy Number: PC	Date Last Revised: 3/14	Valid Until: 3/17
Department(s) Affected: All Clinical Areas	Review Period: every 3 years	

5. Education of Healthcare Workers

a) Upon hire, nursing staff (including RNs and LPNs) will be assigned the eCRS skill **ANTIEMBOLIC STOCKINGS AND SEQUENTIAL COMPRESSION DEVICES**.

b) Education regarding anticoagulation therapy is provided as stated in the policy **ANTICOAGULATION MANAGEMENT (MM-05401)**.

Key Contact: Patrick Ellis, Pharm. D.; Michelle Denham, RN, Clinical Informaticist/Nursing - Pharmacy Liaison
Reviewed by: Nursing Professional Practice Council, Danine Watston, Interim Chief Nurse Executive
Joint Commission Chapter: Provision of Care (PC)
References:

CHI Evidence Based Practice Toolkit

Date First Effective: 3/14
Distribution: MHCS Intranet

POLICY

Title: DIET ORDERS		
Page 1 of 3		
Policy Number: PC-07017	Date Last Revised: 11/13	Valid Until: 11/16
Department(s) Affected: Nutrition Services, Nursing Services	Review Period: every 3 years	

OUTCOME:
The food provided on the patient meal tray will follow the prescribed diet as defined in the approved diet manual.

SUPPORTIVE DATA:
DOWNTIME AND INTERRUPTIONS - INFORMATION SYSTEMS (IM-010103)

POLICY:
Diet orders are recorded in the patient's medical record by the physician before any diet is served to the patient.

PROCEDURE:
The diet order must be a diet(s) from the current approved diet manual and must specify modifications and/ or enteral feedings. Diet orders as written by the physician, will be accurately transcribed from the patient's medical record and sent to Nutrition Services Department via computer. Nursing will sign the physician order sheet confirming that the correct order was sent by the unit clerk.

1. Patients who are not receiving a tray must still have an order sent, i.e. "NPO (Nothing per Oral)", a tube feeding order, or notification of TPN initiation, for Nutrition Services to monitor and provide appropriate care/service.

2. The Nutrition Services Department is notified of any new diet order in order to maintain a record of all current diet orders in the patient nutrition cardex.
   - An "NPO" diet order cancels all previous diet orders. When a patient is able to eat again, a new written order must be issued.
   - A "HOLD" order cancels meal or nourishment delivery until a "RELEASE TRAY" is received.

3. No tray will be served to a patient without a confirmed diet order sent to Nutrition Services following established procedures.

4. In the case of computer malfunctions, computer downtime procedures will be followed for communication of diet orders/changes. Orders will be keyed into the system once computer functions are restored.

5. If a patient requires a diet with a softer texture than that ordered, the dietitian may communicate this to the diet office without further physician order. Documentation in the patient's medical record will state the reason why this change has been made. This will in no way alter the Physician Ordered Therapeutic Diet but only downgrade the texture of said diet per the expressed desire/need of the patient.

6. A Registered Dietitian may restrict a diet from Regular to Low Salt/ Diabetic diet for patients who request these restrictions.

7. The term "diet" as in "diet order" refers to the food the patient consumes. In order to most effectively achieve the appropriate nutrient intake of the patient and to honor food preferences within the therapeutic diet order, the dietitian may add snacks or other foods (i.e. Ensure, Glucerna) that are consistent with the ordered diet without further orders by a physician. Any snacks or other foods requested that are not clearly consistent with the diet must be ordered by the patient's physician.

If a licensed independent practitioner orders a tube feed diet and then delegates authority by placing an order in the chart for the registered dietitian to "manage" the tube feed, the dietitian may change the

POLICY

Title: DIET ORDERS		
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8. formula, strength or rate of the tube feed without further physician order. Additionally, if the licensed independent practitioner orders “tube feeds per dietitian” or “dietitian for tube feeds” it will be interpreted as an order to manage the tube feeding unless otherwise specified.

9. If a licensed independent practitioner orders tube feeding goal per dietitian, the dietitian will write the order for the tube feeding goal, but not assume continued management of the feeding unless otherwise ordered.

10. Patients with GI bleeds will be identified by Nursing. Nursing will notify Nutrition Services via diet order for “no red Jell-O or juice”.

10. On the Oncology Unit (4 East) a decision tree will be utilized by nursing (RN) to quickly administer nutrition supplementation (Ensure, Glucerna Shake and Suplena) to those patients who are appropriate. Patients must receive a $\geq$2 on the Malnutrition Screening Tool (found in the Adult Database Part 1) in order to qualify for nutritional supplementation. When the nurse administers the initial supplement they will also key in a diet order reflecting this so supplementation can continue at all meals. The Registered Dietitian will review this order within 48 hours to alter or discontinue as needed (*Decision tree attached*).

11. To combat skin breakdown, any patient with a Braden score of $\leq$13 will have a medically appropriate oral nutrition supplement added to their diet. Based on a Meditech generated report, the diet clerk will add the appropriate supplement using a decision tree (attached) and the Registered Dietitian will follow up to review appropriateness and acceptability with the patient per screening and assessment guidelines. The RD can then adjust the supplement or d/c as needed. If no supplement is medically compliant to the patient’s diet, the RD will address nutritional inadequacies during their nutritional assessment.

12. When unclear diet orders written by a physician are received in the diet office, the following diets will be used.

Non-Specified Diet Ordered	Diet Selected/Sent
Low Sodium	2000-3000 mg (2-3g) sodium
Low Salt	4000 mg (4g) sodium
No Added Salt	4000 mg (4g) sodium
AHA	Fat/cholesterol controlled; 3000 - 4000 mg sodium
Cardiac	Fat/cholesterol-controlled, 3000 – 4000 mg sodium
ADA (with no specified calorie level) Diabetic (with no specified calorie level)	No Concentrated Carbohydrates
Weight Management	1600 calories for women/1800 calories for men or as determined by RD

Low Fat	50 gm fat
Low Protein	50 gm protein
Low Potassium	2000 - 3000 mg potassium

POLICY

Title: DIET ORDERS		
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Policy Number: PC-07017	Date Last Revised: 11/13	Valid Until: 11/16
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Renal	80 gm Protein, 2 gm Sodium, 2 gm Potassium
Renal Diabetic	80 gm Protein, 2 gm Sodium, 2 gm Potassium No concentrated carbohydrates
Liquid	Full liquid
Hepatic Diet:	
Without encephalopathy	1.5 gm protein / kg / day
With encephalopathy	40 – 50 gm protein / day or 0.5-0.7 gm /kg /day

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Key Contact: Nutrition Services-Brian K. Jones MS, RD, LDN-CNM; Dori Neufeld- RD
Approved/Reviewed by: Nutrition Services, Nursing Professional Practice Council
Reference(s): ADA Nutrition Care Manual
Joint Commission Standard: Provision of Care Chapter (PC) PC 02.02.03
Attachment(s): None
Date First Effective/Revisions: 1/89, (5/10), (5/12) (11/13)
Distribution: MHCS Intranet