Let’s COLLABORATE...

Because of recent regulatory changes, 42 states now have provisions that allow pharmacists and physicians to care for patients under a Collaborative Practice Agreement (CPA). The CPA for a hospital and ambulatory areas would be defined as a practice agreement between one or more physicians and pharmacists who are working within the context of a defined protocol. They are permitted to assume professional responsibility for performing patient assessments, ordering drug therapy related lab tests, administering drugs, and/or selecting, initiating, monitoring, continuing and adjusting drug regimens. The Drug Therapy Management Protocol (DTMP) is a written plan that delegates the legal authority to pharmacists under designated circumstances. The P&T Committee is responsible for establishing programs and procedures that ensure optimum drug therapy from both a quality and cost effective perspective. As part of their responsibility, the P&T members evaluate and approve the protocols for inpatient and ambulatory settings. At The Valley Hospital, an example of this is our use of the Heparin Weight Dose Protocol. This protocol is used extensively in many areas of the hospital.

Meet Pharmacy Supervisors, Sal Ferrito and Nedal Abbassi

Sal Ferrito grew up in Cresskill and has since resided in Old Tappan for the past 28 years. He received a BS degree in Pharmacy and an MS degree in Pharmacy Administration from St. John’s University. In 1982, he began his pharmacy career as a staff pharmacist at Englewood Hospital and Medical Center and was soon promoted to Supervisor. In 1995, he took a position as Pharmacy Manager at Barnert Hospital in Paterson. Then, in 1997, he accepted a position as Director of Pharmacy at Chilton Memorial Hospital where he served until 2009. Sal is now happy to serve The Valley Hospital as the Pharmacy Operation Supervisor.

Nedal Abbassi was born in Jordan where he grew up and finished high school. After high school, he left Jordan to continue his higher education in Italy. Once there, he learned the Italian language in Perugia, a small Italian town in central Italy. After learning the language, he moved up north to Genova, where he attended Pharmacy school and graduated in 1985. “It was a challenge to learn a foreign language and attend pharmacy school in Italy, but, nevertheless, it was achievable and it was an experience of a life time.” In 1985, he immigrated to New York to join the rest of the family, and started working on obtaining his NY Pharmacy License. Since then, he worked in various hospitals in New York. In 2005, he joined the pharmacy team at The Valley Hospital as an evening Pharmacist and, soon after, he was offered a coordinator position. Last year, he was promoted to a supervisory position. “It has been wonderful for me at the Valley Hospital, welcoming staff and supporting the management team. I witnessed so many good changes in the last 6 years. At Valley, I learned a simple philosophy and that is to walk the extra mile and to acknowledge the concerns of our staff and customers. It is a simple philosophy, but it works.”
Learn About Dabigatran (Pradaxa)

In October 2010, the FDA approved Dabigatran Etxilate (Pradaxa, Boehringer Ingelhein), the first oral direct thrombin inhibitor for the prevention of thromboembolic stroke in patients with non-valvular atrial fibrillation. This is the first approval of a new oral anticoagulant in the United States in more than 50 years.

Dabigatran Etxilate is a prodrug and is metabolized by the liver into its active component, Dabigatran. Dabigatran has poor bioavailability and reaches peak levels in approximately 1 to 2 hours after administration. Food will add an additional 1-2 hours onto the time to peak absorption; however, taking Dabigatran with food may be necessary due to its most common side effect: dyspepsia. Its half-life is 12 to 17 hours, which is increased in patients with renal dysfunction.

Approval in the United States was based on data from the Randomized Evaluation of Long-Term Anti-coagulation Therapy (RE-LY) trial, a multinational, randomized study of approximately 18,000 patients. The RE-LY trial was a non-inferiority trial comparing warfarin with a target INR between 2 and 3, Dabigatran 110 mg bid, and Dabigatran 150 mg bid. The results showed that Dabigatran 150 mg bid reduced the annualized risk of stroke and systemic embolism by 34%, compared to warfarin (rate of 1.11% per year in the Dabigatran 150 mg twice daily group, and 1.69% per year in the warfarin group). Based on this, the number needed to treat (NNT) is about 169 patients with atrial fibrillation per year to prevent one event.

The higher Dabigatran dose was associated with a slight, but significant, increased risk of myocardial infarction (a secondary end point); however, when adjusted for confounding variables, the difference was no longer significant. Overall, bleeding risks were similar for warfarin and Dabigatran 150 mg bid; however, Dabigatran showed a higher rate of major gastrointestinal bleeds in patients receiving Dabigatran 150 mg than in patients receiving warfarin. It has been suggested that this may be a reflection of surveillance bias resulting from an increased incidence of dyspepsia in patients receiving Dabigatran. Warfarin showed an increased risk of intracranial hemorrhage.

On the basis of these data, the FDA approved the 150-mg dose. The agency also approved a 75-mg dose for patients with renal dysfunction (CrCl 15-30 mL/min). This dose has not been studied and was determined using the pharmacokinetic profile of the drug.

(Cont. Page 3)
injectable medications used in dialysis and find the least expensive, most effective treatment for patients. This request is for an erythropoiesis stimulating agent that is well known to our dialysis physicians and presents a significant opportunity to lower dialysis costs. This request was produced through a collaborative endeavor by Dr. Kozlowski, dialysis nursing, and a clinical pharmacy specialist in dialysis. The Pharmacy and Therapeutics Committee decision: For the addition of Darbepoetin (Aranesp) to The Valley Hospital Formulary restricted to Dialysis.

Dabigatran (Pradaxa) requested by Dr. Kesselbrenner. The FDA-approved indication is to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation. Dabigatran was approved by the FDA based on the RE-LY study. The RE-LY study was a prospective, open-label, phase III, multicenter, parallel group, noninferiority trial with blinded adjudication of all outcomes. The conclusion of that study was that Dabigatran administered at a dose of 150 mg, as compared with warfarin, was associated with lower rates of stroke and systemic embolism, but similar rates of major hemorrhage. DOSING – 150 mg tablet taken orally twice a day with or without food. For patients with CrCl 15-30 ml/min, use 75 mg twice daily. COST: $3.04/tablet or $6.08/day. The Pharmacy and Therapeutics Committee decision: Approve the addition of Dabigatran (Pradaxa) to The Valley Hospital Formulary to be used according to FDA-approved indications.

Cisatracurium (Nimbex) requested by Dr. Wambold to be admitted into the formulary as a neuromuscular blockade that is independent of hepatic or renal function with much less histamine release. The FDA-approved indication is induction of neuromuscular blockade, adjunct to general anesthesia, to facilitate tracheal intubation, and to provide skeletal muscle relaxation during surgery or mechanical ventilation in the intensive care unit. Doses should be individualized according to patient response. Studied infusion range: Initial 150-200 mcg/kg IV bolus with propofol/nitrous oxide/oxygen induction-intubation technique and Maintenance 30 mcg/kg IV. Maintenance infusion for ICU patients 3 mcg/kg/min (0.5-10.2 mcg/kg/min) Costs for single dose 5 mL vial (2mg/mL) is $11.90, multi dose 10 mL vial (2mg/mL) is $20.83, and single dose 20 mL vial (10 mg/mL) is $226.48 (intended for ICU only). The Pharmacy and Therapeutics Committee decision: For the addition of Cisatracurium (Nimbex) to The Valley Hospital Formulary for use by Anesthesia. (Cont. page 4)

Learn About Dabigatran (Pradaxa) cont.

Additional Advantages of Dabigatran
- Predictable pharmacodynamics profile resulting in a direct correlation between dose and therapeutic efficacy
- No monitoring or monitoring-related dose adjustments required
- Its therapeutic efficacy is unaffected by food, and it has shown few drug interactions to date
- Improved outcomes if current INR control is poor
- Pregnancy Category C (warfarin is Pregnancy Category X)

Potential Treatment Pitfalls
- There is no reversal agent for overdose or severe bleed
- Lack of a way to monitor adherence
- Dyspepsia & twice-daily dosing may lead to adherence problems
- Not recommended for patients with CrCl <15ml/min
- Limited FDA-approved indications to date
- Increased cost

(Cont. Page 4)
Learn About Dabigatran (Pradaxa) cont.

Additional Points
- Dabigatran capsules must be swallowed whole. Opening, chewing, or crushing capsules will result in an increase in absorption (up to a 75% increase).
- Once a bottle of Dabigatran capsules has been opened, the capsules must be used within 30 days.
- Dabigatran should be discontinued before invasive procedures, stopping the medication 1-4 days prior based on bleeding risk and renal function.

P&T Updates cont.

► Sodium Amytal (Amytal) requested by Dr. Walzman. Amytal is an intermediate-acting barbiturate used as a sedative hypnotic. It depresses the sensory cortex, decreases motor activity, and alters cerebellar function, producing drowsiness, sedation, and hypnosis. The FDA-approved indication is used for the short-term management of insomnia, pre-medication for anesthetic procedure, and sedation. Dr. Walzman is requesting Amytal be admitted to The Valley Hospital Formulary to be used to “put the brain under anesthesia” for pre-operative evaluation for tumor disorder. Dosing for Insomnia – short term management is 65-200 mg IM/IV at bedtime, pre-medication for anesthetic procedure is 65-500 mg IM/IV, and Sedation is 30-50 mg IM/IV 2-2 times daily. Common adverse effects include confusion, dizziness, headache, and somnolence. The cost of one 500 mg vial is $94.09. The Pharmacy and Therapeutics Committee decision: For the addition of Sodium Sodium Amytal (Amytal) to The Valley Hospital Formulary for use according to FDA regulations.

► Regadenoson (Lexiscan) requested by Dr. Kesselbrenner. The decision to add Lexiscan should be based upon its comparative cost to adenosine injection. Dr. Kesselbrenner is requesting Lexiscan be restricted to outpatients only based on cost analysis. The FDA-approved indication is Radionuclide myocardial perfusion imaging (MPI) in patients unable to undergo adequate exercise stress. Usual dose: give 5 mL (0.4 mg Lexiscan) by rapid intravenous injection, followed immediately by saline flush and radiopharmaceutical. Cost for 0.08 mg/mL, 5 mL single use syringe is $188.67. The Pharmacy and Therapeutics Committee decision: For the addition of Regadenoson (Lexiscan) to be admitted into The Valley Hospital Formulary to be used according to FDA indications restricted to outpatients.

► Lacosamide (Vimpat) requested by Dr. Nasr to be admitted into the Formulary as a new anticonvulstant drug that is not replaceable by other products currently on the Formulary. The FDA-approved indication is adjunctive therapy of partial-onset seizures in patients > 17 years old. The non-FDA-approved indication is for symptomatic treatment of diabetic neuropathic pain. Vimpat is a new anticonvulstant with a different mechanism of action compared to other antiepileptic agents currently on the market. Adjunctive therapy in partial onset seizures: Initial: 50 mg twice a day, increased at weekly intervals by 100 mg/day in divided doses. Maintenance: 200-400 mg/day based on patient response and tolerability. IV doses should be infused over 30-60 minutes up to 5 days. Cost for a 50 mg tab is $3.75, 100 mg is $5.86, 150 mg is $6.20, 200 mg is $6.21, and Vimpat IV for 200 mg inj. is $33.68 each. The Pharmacy and Therapeutics Committee decision: For the addition of Lacosamide (Vimpat) to The Valley Hospital Formulary.
Alteplase, Recombinant (TPA) 2010 Drug Use Evaluation
Marian Gergis, Pharm D, Sherry Gadalla, Pharm D, Tomas Hicano, RPh.
The Valley Hospital, Ridgewood, NJ

INTRODUCTION/BACKGROUND

The World Health Organization (WHO) has recognized that 15 million people suffer from a stroke each year. Every 40 seconds someone in the United States suffers from a stroke, resulting in approximately 795,000 stroke patients annually. Stroke is not only the third leading cause of death but also, leading cause of serious, long-term disability in the United States. Women seem to be at a higher risk with about 55,000 more women than men suffering from a stroke. Ischemic stroke seems to be the predominant type with an 87% rate, 10% are intra-cerebral hemorrhage, and 3% are subarachnoid hemorrhage.

The Valley Hospital (TVH) has seen a slight increase over the past 4 years in the use of Tissue Plasminogen Activator (TPA) for ischemic stroke. TPA gained its FDA approval for ischemic stroke in 1996 and is currently the only pharmacological treatment for acute ischemic stroke.

OBJECTIVES

With the increasing number of stroke patients TVH pharmacy department has implemented a drug use evaluation of TPA for acute ischemic stroke.

METHODS

<table>
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<tr>
<th>Methods 1</th>
<th>Methods 2</th>
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<tr>
<td>Electronic search was done using TVH medication use system (E-Medtech). search included:</td>
<td>Retrospective chart review was conducted to evaluate the appropriateness of TPA for ischemic stroke.</td>
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<tr>
<td>• Meditech pharmacovigilance TPA (TPA 100mg vials) and TPA (TPA 50mg vials)</td>
<td>• Limited to January 1st – December 31st 2010</td>
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<td>• Time period of 2007-2010.</td>
<td>• Following criteria was used to assess appropriate use of TPA:</td>
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- TVH emergency department stroke protocol was followed.
- TPA was dosed based on current FDA guidelines:
  - 0.5mg/kg (max 90mgq) - 10% given as IV bolus
  - Door to needle time was appropriate (3-4.5 hrs from symptom onset).
- Patient outcome measured using documented NIHSS and Barthel scores.

- Inclusion criteria: Ischemic stroke patients who have been treated with TPA.
- Exclusion criteria: Hemorrhagic strokes, subarachnoid hemorrhage, ischemic stroke patients who were not treated with TPA, and TPA administered for a diagnosis other than ischemic stroke.

RESULTS

Increase in TPA use for ischemic stroke from 2007-2010

Male to Female ratio of TPA patients

Was TVH’s ED stroke protocol followed?

Stoke protocol was appropriately followed for all 42 patients studied
- Initial neuro assessment was positive for stroke.
- Symptom onset was documented.
- Appropriate labs and CT scan performed.
- All patients assessed by ED physician and neurologist.

Table 1

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<tr>
<th>Timeframe</th>
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Male: Female Ratio

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Electronic NIHSS scores documentation

Electronic Barthel scores documentation

TPA cost analysis 2010

CONCLUSION

According to WHO women are at higher risk of having ischemic stroke. At TVH there were 116 females and only 7 males received TPA in 2008 and 101. However in 2007 the male to female ratio was the same and in 2008 it was 21:15.

In 2009 a total of 42 patients received TPA for an ischemic stroke. Upon reviewing patient charts to assess whether a proper diagnosis was made utilizing TVH protocol. 32 patients were excluded from the database due to symptoms resolving and reappearing while in the ED. It is concluded that all patients who received TPA in 2009 had a proper diagnosis of ischemic stroke, made by appropriately following TVH stroke protocol (Table 1).

According to current guidelines, TPA should be administered within 3.5 hours from onset of symptoms. After assessment of each patient, I had patients (21%) received TPA within 3 hours, 7 patients (17%) within 3-4.5 hours, and 1 patient (2%) after the 4.5 hour window. Completed TPA doses were administered in 64 patients (94%) according to the current guidelines. In addition, monitoring using Barthel scores was electronically documented in 41 patients while NIHSS scores were only electronically documented in 38 patients.

The drug use evaluation illustrated that TVH’s ED stroke protocol was followed and likewise TPA was administered appropriately in 2010.

REFERENCES

INTRODUCTION/BACKGROUND

Transformation of ICU (TCU) - The Role of Pharmacists in the Multidisciplinary Team

Introduction of TCU (ICU) - TCU bedside protocols

CONCLUSION

- Antimicrobial stewardship
- Anticoagulation
- Poisoning and toxicology
- Pain management
- Glucose control
- Sedation
- Nutrition
- Blood calculations
- Anticonvulsants
- Opioids
- Antipsychotics
- Mental health
- Renal function
- Infection control
- Blood transfusions
- PDA
- End of life care
- Palliative care
- Pain management
- Paliation
- Pain control
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- Pain management
Antimicrobial Stewardship Revisited
Ryan Miglin, PharmD; Jeeon Varghese, RPh; Ron Krych, RPh
The Valley Hospital, Ridgewood, New Jersey

Introduction
The Center for Disease Control (CDC) has identified stewardship and reducing antimicrobial resistance as one of its top eight priorities. Antimicrobial stewardship programs (ASPs) are recommended by the CDC and the Infectious Diseases Society of America (IDSA). In 2007, the Infectious Diseases Society of America (IDSA) and Society of Healthcare Epidemiologists of America (SHEA) published a joint position paper on antimicrobial stewardship guidelines, and in 2009 a formal antimicrobial stewardship program was implemented at The Valley Hospital (TVH).

Objectives
1. To review the impact of antimicrobial stewardship at TVH, focusing on antimicrobial sensitivity reports and antimicrobial utilization
2. To assess the need for tailored action toward trends signaling the emergence of resistance to otherwise undervalued findings.

Methods
1. In developing antimicrobial stewardship, the Valley Hospital employs a number of strategies to ensure that the treatment of infections includes the most appropriate antibiotics. These strategies include antimicrobial resistance monitoring, drug policy development, daily drug therapy rounds, and education of medical and nursing staff.
2. The stewardship program includes antimicrobial resistance monitoring, drug policy development, education of medical and nursing staff.

Results & Discussion

Figure 1: Most Utilized Antibiotics

- The importance of appropriate antibiotic use has been a longstanding resolution of The Valley Hospital, however optimization of practices directed to employing the most appropriate use of antimicrobial therapy, where excellent patient care is evaluated and limited antimicrobial use guidelines, in 2009 a formal antimicrobial stewardship program was implemented at TVH. The primary objective has been to decrease antimicrobial resistance through education, surveillance, and antibiotic stewardship interventions. The stewardship program focuses on reducing unnecessary antibiotic use, decreasing inappropriate antibiotic use, and improving antibiotic use in accordance with infection control guidelines and evidence-based practice guidelines.

Figure 2: Pseudomonas Aeruginosa Sensitivities

- In 2009, TVH implemented a stewardship program with the goal of reducing unnecessary antibiotic use. The program included education, surveillance, and antibiotic stewardship interventions. The program was evaluated using a combination of microbiological and clinical outcomes.

Figure 3: Vibrio Vulnificus Resistant Enterobacteriaceae

- The stewardship program at TVH was implemented to reduce unnecessary antibiotic use and improve antibiotic use in accordance with infection control guidelines and evidence-based practice guidelines.

Figure 4: MRSA: Methicillin-Resistant Staphylococcus Aureus

- In 2009, TVH implemented a stewardship program with the goal of reducing unnecessary antibiotic use. The program included education, surveillance, and antibiotic stewardship interventions. The program was evaluated using a combination of microbiological and clinical outcomes.

Figure 5: Amplification Resistance in a Bacterial Lactamase Sensitive Market

- The stewardship program at TVH was implemented to reduce unnecessary antibiotic use and improve antibiotic use in accordance with infection control guidelines and evidence-based practice guidelines.

Figure 6: Cephalosporin on SBE, Sensitive Market

- The stewardship program at TVH was implemented to reduce unnecessary antibiotic use and improve antibiotic use in accordance with infection control guidelines and evidence-based practice guidelines.

Figure 7: In the past five years, there has been change in the most frequently used antibiotics at TVH. In 2007 and 2008 there was an increased use of the broad-spectrum antibiotics, ampicillin, sulfonamide, and penicillin. In 2009, the stewardship program was implemented with the goal of decreasing unnecessary antibiotic use. The program included education, surveillance, and antibiotic stewardship interventions. The program was evaluated using a combination of microbiological and clinical outcomes.

Figure 8: The stewardship program at TVH was implemented to reduce unnecessary antibiotic use and improve antibiotic use in accordance with infection control guidelines and evidence-based practice guidelines.

Conclusions
The stewardship program at TVH was implemented to reduce unnecessary antibiotic use and improve antibiotic use in accordance with infection control guidelines and evidence-based practice guidelines. The program included education, surveillance, and antibiotic stewardship interventions. The program was evaluated using a combination of microbiological and clinical outcomes.

References

Disclaimer: This document does not represent any actual finding, testing or hypothesis, or the interpretation of the data.
Heparin Protocol: The Impact of Computerized Order Processing and Evaluation of Monitoring Parameters
Terri Marxen, PharmD, CACP
The Valley Hospital

Introduction
Heparin is on the list of the top 5 drugs reported as a medication error and causing harm. To reduce the risk of errors and patient harm, The Joint Commission requires the use of approved protocols for the initiation and maintenance of anticoagulation therapy.

A new revised heparin protocol was approved at the time the use of computerized provider order processing (CPOE) was rapidly expanding. When revising the heparin protocol, the tandem development of computerized heparin protocol processing presented many unique challenges. The protocol is multifaceted including initial and subsequent laboratory ordering, drug ordering, and dosage adjustment.

A multidisciplinary team comprised of pharmacy, nursing and information systems worked together to identify process improvement steps.

Objective
1. Evaluate the efficacy of using CPOE to manage the heparin protocol
2. Evaluate the clinical target monitoring parameters as a measure of safety

Methods
Efficacy of CPOE
• Identify Heparin protocol process
• Laboratory orders
• Completed laboratory orders collected via electronic medical record prior to protocol implementation from Dec 2009-Jan 2010 and then after protocol implementation from Jan-Feb 2011.

Target Monitoring
• All patients on heparin greater than 24 hours included
• aPTT values collected for first 24 hours
• Compare to protocol
• Determine patients sub-therapeutic, therapeutic and supra-therapeutic

Results
The new protocol adds an option for No initial bolus and No subsequent bolus. The High Dose WITH Bolus decreased 34%.

Discussion/Conclusion
1. Revision of the paper heparin protocol was focused on updating clinical practice based on guidelines and medical staff recommendation
2. Transitioning to CPOE led to missing components in the protocol process.
3. Revised CPOE protocol processing improved baseline lab ordering. However, there was a decrease in subsequent lab orders which still uses a paper based process. This and the question of whether a baseline aPTT is necessary will be further investigated.
4. There is a trend of reaching therapeutic aPTT with both of the NO Bolus protocols, but higher numbers are needed to determine significance.
5. No patients had a supra-therapeutic aPTT using the new High Dose NO Bolus protocol possibly leading to reduced risk of bleeding.
6. Utilizing a multidisciplinary team to identify and integrate the many facets of protocol implementation and execution when using CPOE leads to an improved and safer process.

References