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The mission of the Texas Society of Health-System Pharmacists is to support the pharmacist practicing in health systems and other healthcare settings to achieve positive patient outcomes and improved patient equality of life through the provision of pharmaceutical care.

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Legislative/Lobbyist Report...

Texas May Consider a Medicaid Medication Therapy Management (MTM) Pilot Project

In preparation for each Texas legislative session the Legislative Budget Board publishes a report with recommendations on how the State could be more efficient in the services they provide and how those changes will impact revenues and expenditures for future budgets. The 2011 LBB report includes recommendations regarding state employees’ retirement and insurance programs, tax policies, transportation and natural resources policies, business economic development programs and health and human service programs. Many of these recommendations will result in legislation considered during the 2011 legislative session. One such topic may include:

A Medicaid Medication Therapy Management pilot program.
The Texas Health and Human Services Commission estimates that the Texas Medicaid program spent $17.9 million on medication-related adverse events for all Medicaid clients in fiscal year 2009. Medication-related complications increase the risk of hospitalizations, outpatient facility use, and nursing facility admissions. Medication therapy management is a patient-centered service, typically provided by pharmacists in collaboration with physicians and other healthcare providers, that seeks to improve the quality of medication use and results among patients who are at high risk of having adverse reactions from medications. Medications are a common intervention for the treatment and prevention of disease, disability and death; however, they can have many adverse effects on a patient that can range from minor side effects to death. Medication-related adverse events can be caused by a number of factors including a patient receiving a medication they should not have been prescribed, overuse or underuse of medications and inadequate medication adherence.

The report also states that medication therapy management could reduce overall healthcare spending by reducing adverse drug events and related medical costs. In the first year of a MTM program in the Minnesota Medicaid program, 3.1 medication-related complications were resolved per patient and MTM program-related savings exceeded the cost of MTM services by more than 2 to 1.

MTM in Texas
According to the Texas State Board of Pharmacy, MTM has been in development in Texas since 2003. As required by the federal Medicare Prescription Drug, Improvement and Modernization Act of 2003, all Medicare Part D prescription drug plan sponsors offer MTM services to eligible Medicare clients. MTM services may be provided in a retail pharmacy, clinic or hospital setting. In the Texas private sector, various self-insured employer groups or managed care plans provide MTM services for their clients.

The LBB report states that major Texas grocery chains like HEB and Kroger provide MTM services in their pharmacies. HEB in-store pharmacies offer MTM services on behalf of plan sponsors for private and public insurance plan sponsors. HEB pharmacists primarily provide MTM services to Medicare clients, and sessions take place in an isolated counseling area in the pharmacy or in a private office within the store. HEB pharmacies also handle some telephonic MTM cases for other states through a call-center.

The Texas Pharmacy Association (TPA) coordinates a county-funded diabetes MTM program for Williamson County, which has over 2,000 county employees. The program is promoted to all eligible Williamson County employees, and enrollment is voluntary. County employees who participate in the program receive MTM services in addition to diabetes-focused coaching, education and skills training on a six- to eight-week basis. Approximately 15 pharmacists from HEB and Scott and White pharmacies provide services for the program participants. Initial counseling sessions are one hour and follow-up sessions are conducted as needed and are 15 to 30 minutes. TPA contracts with participating pharmacists and provides pharmacist training, a patient documentation and billing platform, patient materials and
coaching session tools. Williamson County pays for the pharmacist services, a data management fee, and they absorb the waived co-pays for diabetes-related medications and glucose testing equipment and supplies as an incentive to participate in the program. Williamson County has not formally evaluated the program, but patient satisfaction survey results indicate that participants are very satisfied with the program. A similar program that combined disease management with MTM in 2008 resulted in improved clinical outcomes and patient adherence to medications. Patients who participated in the program had an increase in drug claims but a decrease in medical claims.

Recommendations
The LBB made two recommendations to the 2011 Texas legislative session:

1. Include a rider in the 2012–13 General Appropriations Bill requiring the Texas Health and Human Services Commission to spend up to $170,000 in General Revenue Funds and $170,000 in Federal Funds to establish a medication therapy management pilot program designed to reduce adverse drug events and related medical costs for high-risk Medicaid clients.

2. Include a rider in the 2012–13 General Appropriations Bill requiring the Texas Health and Human Services Commission to conduct a study to determine the effectiveness of the medication therapy management pilot program established to reduce adverse drug events and related medical costs for high-risk Medicaid clients and submit a report to the Governor and the Legislative Budget Board by December 1, 2012.

Implementing a MTM pilot program in the Medicaid program would require that the HHSC reimburse providers for their services. Factors to consider in developing a pilot program include the following:

- appropriate service area;
- criteria and identification of high-risk clients;
- outreach and retention of potential Medicaid clients and providers;
- provider training needs;
- contractor needs;
- pharmacy compatibility and location;
- billing formulas;
- federal approval, and;
- other state recommendations and best-practices.

With the long-standing policy of TSHP supporting expanded services provided by pharmacists and, in particular, promoting MTM as a cost-effective use of pharmacists’ expertise, we will be working with the Legislature, LBB and other pharmacy organizations to attempt to see that this recommendation is implemented in the budget process this year.

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A Review of Point-of-Care Glycemic Monitoring in the Intensive Care Setting

By Charles E. Janak, Pharm.D.
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Michael G. Liebl, Pharm.D., BCPS

INTRODUCTION
Hyperglycemia in an intensive care unit (ICU) has been associated with increased infections, morbidity, and mortality as well as delayed wound healing. A 2001 study conducted by Van den Berghe and colleagues found that when a tight glycemic control (TGC) protocol was implemented, both morbidity and mortality were reduced in critically ill patients. In contrast to the Van den Berghe study, the NICE-SUGAR trial in 2009 concluded that patients in whom intensive glycemic control was implemented had an increased risk for mortality when compared to patients managed by conventional blood glucose control. The significantly higher frequency of severe hypoglycemia in the intensive control group suggests this was the cause for the increase in mortality.

The results of these two trials highlight glucose monitoring as a very important aspect of glycemic control. While the appropriate blood glucose goal in the ICU is still controversial, one important cornerstone in the management of hyperglycemia is the ability of clinicians to readily and accurately measure blood glucose levels. Many current TGC protocols involve frequent monitoring, often accomplished by point-of-care (POC) devices using blood samples that are obtained via finger sticks or from indwelling venous or arterial catheters. In an ICU, glucose management utilizing insulin drip or sliding-scale insulin protocols rely on multiple measurements throughout the day. These can be taken anywhere from every hour to every eight hours, depending on the level of glycemic control desired. With such frequent measurement desired, bedside capillary monitors have become the standard of care for ICU glucose measurement, with some ICU surveys reporting up to a 95% usage rate. This technology, however, was originally developed to be used for personal assessment of blood glucose in outpatients, without proven efficacy and safety in an ICU population. Newer monitoring options are available, including bedside whole blood analyzers, continuous blood glucose monitoring systems, and closed-loop continuous monitoring systems. Whole blood laboratory analysis is also an option but is not generally utilized in TGC protocols due to the time delay to obtain results. With multiple different monitoring options available, it is appropriate to examine the advantages and disadvantages to determine which is appropriate for the measurement of critically ill patients’ glucose levels.

METHODS OF GLUCOMETER MEASUREMENT
Glucose can be measured using whole blood, plasma, or serum from three potential sites of origin: arteries, capillaries, or veins. Glucose is not distributed equally throughout any sample of blood, mostly present in the plasma portion. Therefore, plasma glucose levels may be higher when comparing them to whole blood glucose levels. Variances within samples, such as decreased hematocrit (HCT) percentage, can potentially magnify this difference. While many different sampling methods are available, the Yellow Springs Instruments’ (YSI) Blood Glucose analyzer – capable of analyzing whole blood or plasma – is currently one of the standards for glucose measurement.

Point-of-care monitors use a sample of capillary whole blood to determine glucose levels, relying on either amperometric or photometric test strips for measurement. Amperometric test strips either use glucose dehydrogenase (GD) or glucose oxidase (GO) to catalyze the oxidation of glucose to gluconic acid. In GD-dependent test strips, the formation of gluconic acid reoxidizes the electron mediator...
(ferrocyanide) and produces electrons. Under the potential of the meter, a current is generated from the electrons that coincides with the glucose level in the blood sample. In GO-dependent strips, the oxidation of electron mediators also produces electrons that generate a current to correlate with blood glucose. Oxygen is not required for these reactions to occur and can compete with electron mediators in the GO-catalyzed reactions. Certain glucometers have the additional ability to retain red blood cells through a filtration system, which allows these devices to measure combined glucose in the plasma and bound to HCT.7

In photometric test strips, oxygen is required to reoxidize GO, producing hydrogen peroxide. This hydrogen peroxide reacts with dye in the test strip to cause color development. The intensity of the color correlates with the amount of glucose present in the sample and the monitor presents a value.7

ADVANTAGES AND DISADVANTAGES OF POINT-OF-CARE GLUCOMETERS
Benefits to utilizing bedside glucometers include small blood samples and rapid results that allow for rapid glucose correction. While some glucometers may require a larger blood sample (1.5 to 3.0 µL), many common brands of glucometers require very little blood (as little as 0.6 µL) to determine a result. This reduces the phlebotomy load of the patient, as many laboratory arterial blood analyzers require anywhere from 3-10 mL of blood volume to determine the results. In addition to lowering sample volumes, the results from bedside glucometers are readily available, making it easier to administer insulin or dextrose if necessary.8

Although there are multiple advantages to the use of glucometers, they are not without their limitations, especially when used in an ICU setting. Many confounding variables are present in critically ill patients that can alter POC glucometer accuracy when compared to laboratory analysis. Because these variables are not commonly present in an outpatient setting, their effects on the accuracy of glucometers have not been extensively studied. Abnormalities such as reduced hematocrit (HCT), altered PO2 levels, and different pH levels may reduce the accuracy of arterial or capillary blood glucose. Also, post-operative patients and those with significant edema and poor peripheral circulation can make collection difficult. Commonly used medications in the ICU setting (e.g. vasopressors and corticosteroids) may interfere with glucometer results.6

LITERATURE REVIEW OF POINT-OF-CARE GLUCOMETER USE IN THE ICU SETTING
Multiple studies have been conducted to evaluate the accuracy and precision of capillary glucometers in comparison with laboratory analyzed arterial blood. Many of these use the Clinical and Laboratory Standards Institute (CLSI) acceptable rates of error for glucometer testing to gauge their accuracy. The CLSI has concluded that 95% of results from POC glucose monitoring systems should coincide with arterial laboratory analysis ± 15 mg/dL at concentrations below 75 mg/dL and within ± 20% of the analysis at concentrations ≥ 75 mg/dL. They also recommend a Pearson’s correlation above 0.9751 to indicate equivalence to laboratory standards.8

Kanji and colleagues conducted a prospective, observational study in a population of thirty mixed medical/surgical ICU patients. The investigators sought out patients with poor perfusion due to vasopressor use, those with significant peripheral edema, or those who required critical care following major surgery. In each patient, blood glucose was analyzed and/or collected by three separate measures: POC glucometer analysis of capillary blood, POC glucometer analysis of arterial blood, and blood gas/chemistry analysis of arterial blood. These measurements were then compared with the institution’s laboratory analysis of glucose. In those samples classified as hypoglycemic (<72 mg/dL), there was a stronger correlation among arterial samples analyzed by chemistry or glucometer (55.6% and 64.9%, respectively) than capillary samples analyzed by glucometer (26.3%). Among non-hypoglycemic samples (≥72 mg/dL), there was not as stark of a contrast seen between the three methods (76.6%, 82.1%, and 71.3%, respectively). Of the three collection methods, only the blood gas/chemistry analysis method met the recommended CLSI correlation coefficient (0.9902 for all readings). When either hypoglycemic or non-hypoglycemic results were analyzed independently, none of the three methods met the CLSI correlation coefficient standard. This indicates that in certain ICU patients glucometer results may not accurately reflect the patient’s true glucose level.10

Another prospective study by Critchell and colleagues compared glucometer results to laboratory analysis in 80 medical ICU patients. Accuracy was evaluated by examining blood glucose values that were not in agreement according to the previously stated CLSI standards. The mean glucose level for samples measured by capillary blood was 129 ± 45 mg/dL and the mean glucose level for samples measured by laboratory analysis was 123 ± 44 mg/dL, yielding a correlation coefficient of 0.9110. In 208 (75%) readings, glucometer analysis overestimated the laboratory results by 15.5 ± 12.2 mg/dL and underestimated the laboratory results by 14.2 ± 19.7 mg/dL in 59 (21%) readings. When paired measurements were examined, the glucometer overestimated the laboratory glucose value 83% of the time. Also, a total of 53 paired values were found not to be in accord, meaning these results did not meet the CLSI threshold of having >95% of values in agreement of another. A subanalysis
of nine paired values in patients with HCT less than 20% showed a 7.5 ± 5.3 mg/dL difference between the two analysis methods. Additionally, the study found that the use of a vasopressor agent (odds ratio 2.81, 95% CI 1.5 – 5.4) and moderate-severe upper extremity edema (OR 2.1, 95% CI 1.05 – 4.19) were associated with an increased probability of inaccurate results.9

With multiple studies demonstrating the effects that low HCT values can have on glucometer accuracy, Mann and colleagues performed a study to determine whether inaccurate glucose levels could be corrected using a mathematical equation. Four separate meters were compared to a laboratory analysis using 196 total samples from mixed ICU populations. Capillary blood was not used, with only venous or arterial samples being taken using standardized collection procedure. Because of the nonlinear effect HCT concentrations have on glucometer accuracy, dual parameter correction factors were used to develop a mathematical correction formula. Multiple data values were used to assure proper correction, even at extreme glucose and HCT levels. The data sets were then analyzed and the formulas were considered valid if the mean error was <1% from the laboratory reference values.

Glucose values ranged from 59-299 mg/dL, with a mean of 129 mg/dL, and the mean HCT was 27.8%. The data from the groups are represented in Table 1. All uncorrected percent error means were significantly different from the reference mean, while all corrected percent error means were not.

After using the correction factor, it was demonstrated that the mean percent of error for all four glucometers when using the correction method was less than ± 5%. After this correction factor was validated, the center started routinely using it in their ICU and realized a 50% reduction in the number of hypoglycemic values in the burn ICU. While these formulas should be further validated in multiple centers, they show that glucometer inaccuracy in the presence of variable HCT values can be corrected for, making glucometer measurement more accurate.5

NEWER OPTIONS FOR GLUCOSE MEASUREMENT
The aforementioned methods of glucose monitoring provide infrequent, and sometimes inaccurate, results about a patient’s glucose control. The means of glucose values measured by such methods were used in major trials2-4 to demonstrate mortality differences based on contrasting insulin administration protocols. While studies showing that higher or lower mean glucose levels may increase mortality, newer studies are indicating that other monitoring parameters may have an impact on mortality rates.

Any ICU patient with hyperglycemia will have variations in their glucose level during their stay. Higher levels of glycemic variability (GV) have previously been identified as a factor that can worsen outcomes in diabetics. In 2008, a retrospective review was conducted consisting of ICU patients managed on a previously initiated TGC protocol to examine the effect that GV would have on mortality. Multiple glucose measurements were taken and standard deviations of glucose values were used as a measurement of GV. In-hospital mortality was measured and modified APACHE II scores were also used to analyze the effects of GV on mortality. The authors found that as mean glucose levels increased, mortality also increased. In addition, ranges of standard deviations (SD) were grouped into quartiles, each representing increased GV. Mortality ranged from 5.9% in the first quartile of GV to 30.1% in the fourth.12 Hermiadis and colleagues elaborated on this and other data based on the theory that SD are not the most appropriate way of determining GV. For instance, two patients could have the same mean glucose value and standard deviations, but could express very different patterns of variability. In a retrospective cohort study using data from 5728 medical/surgical ICU patients, mean absolute glucose (MAG) change per hour and SD were used as measures of GV. Using a MAG change of <7.1 mg/dL/hr as a reference, odds ratios for ICU death increased as MAG change increased, from 1.5 (MAG change 7.1-10.8 mg/dL/hr) to 1.8 (MAG change 10.9-15.8 mg/dL/hr) to 3.3 (MAG change >15.8 mg/dL/hr).13

As this parameter continues to demonstrate clear connections to mortality, it suggests that more frequent and more accurate measurement of glucose is necessary in the critical care setting. Given the information presented above, POC glucometer monitoring is likely not the best option and newer technologies are currently being developed that could benefit glycemic monitoring in the ICU.

One method currently available is to perform continuous glucose monitoring (CGM), a method introduced in the late 1990’s that has since evolved. Earlier systems take subcutaneous glucose readings as often as every ten seconds and record them for retrospective analysis, calculating a mean glucose value every five minutes. These devices lack real-time feedback and were intended for use in the outpatient setting, where a patient uses the device and then the results are uploaded during physician visits. Multiple studies have demonstrated that these systems can provide accurate glucose measurement in an ICU setting, with additional modifications before acceptance.14-15 In addition, newer models are available with the ability to report real-time levels every five minutes, some even sounding an alarm when the level is undesirable. This provision of real-time results overcomes a major problem that investigators had with earlier systems. While these systems have demonstrated accuracy
in the ICU setting, potential disadvantages have been noted in their ability to accurately detect hypoglycemia. Also, using samples from subcutaneous tissue introduces potential sources of error similar to POC glucometers, such as increased or decreased tissue perfusion.\textsuperscript{16}

Other systems are being developed that will utilize a centrally-inserted catheter that will detect glucose from the plasma portion of blood. These products are still in development, but have undergone testing in an ICU setting which has shown they have high levels of accuracy.\textsuperscript{17-20}

As technology advances to increase the amount of monitoring data available, there will be opportunities to make more precise decisions regarding the correction of hyperglycemic values (Figure 1). The increased accuracy of treatment decisions will likely lower GV and theoretically decrease mortality in ICU patients. With new technologies continuing to develop, one of the greatest leaps will be toward the use of a closed-loop system that integrates CGM and administers insulin as needed to correct high values. Such systems are being studied but are still in exploratory stages.\textsuperscript{21}

CONCLUSION

As demonstrated in this review, many options for glycemic monitoring are currently available, with newer technologies being developed at an increasing rate. Whether the choice is made to use TGC protocols or to have less stringent blood glucose control, one thing is clear: Blood glucose monitoring in the ICU needs to be both accurate and timely. Multiple studies have shown that the current standard method of glucose measurement in the ICU is often inaccurate and can result in overcorrection of hyperglycemia as well as underrecognition of hyperglycemia. As more methods for glucose measurement become available, they will need to be validated in an ICU setting before they can be appropriately utilized.

REFERENCES

17. Krinsley J, Hall D, Zheng P, Magarian P. Validation of the


Table 1 – Error rates from the Mann trial, including percent error before and after using the equation to correct glucose values. Modified to include the correction equations used in the study.  

<table>
<thead>
<tr>
<th>Glucometer</th>
<th>Reported Range of Accuracy</th>
<th>Test Method</th>
<th>Enzyme</th>
<th>Uncorrected % Error Mean, SD % (Range; min to max %)</th>
<th>Corrected % Error Mean, SD % (Range; min to max %)</th>
<th>Correction Equation</th>
</tr>
</thead>
<tbody>
<tr>
<td>G1 (SureStep Flexx)</td>
<td>HCT 25-60%</td>
<td>Photometric</td>
<td>Glucose Oxidase</td>
<td>16.0, 7.5 (42; -6.07 to 36.2)</td>
<td>-0.01, 4.8 (30; -14.5 to 15.5)</td>
<td>Glucometer value x 0.2104 x LN(HCT x 3.3249) – 11.3934</td>
</tr>
<tr>
<td>G2 (Accu-Check Inform)</td>
<td>HCT 20-65% (&lt;200 mg/dL)</td>
<td>Amperometric</td>
<td>Glucose dehydrogenase</td>
<td>16.0, 6.7 (41; -3.9 to 37.1)</td>
<td>-0.54, 5.6 (35; -17.2 to 17.7)</td>
<td>Glucometer value x 0.8368 + 1.959 x LN(HCT) – 3.621</td>
</tr>
<tr>
<td>G3 (Accu-Check Advantage)</td>
<td>HCT 20-65% (&lt;200 mg/dL)</td>
<td>Amperometric</td>
<td>Glucose dehydrogenase</td>
<td>16.9, 6.7 (41; -5.4 to 35.9)</td>
<td>-0.6, 5.5 (33; -18.9 to 14.5)</td>
<td>Glucometer value x 0.8248 + 3.3895 x LN(HCT) – 7.6008</td>
</tr>
<tr>
<td>G4 (Precision PCx)</td>
<td>HCT 20-70% (20-600 mg/dL)</td>
<td>Amperometric</td>
<td>Glucose Oxidase</td>
<td>18.7, 10.1 (70; -11.4 to 59.0)</td>
<td>0.2, 8.0 (54; -21.3 to 33.0)</td>
<td>Glucometer value x 0.1866 X LN(HCT x 3.729) – 2.8203</td>
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</tbody>
</table>
Effectiveness of Lactobacillus GG for Prevention of Antibiotic-Associated Diarrhea in the PICU: A Retrospective Chart Review

by: Stephen J. Davis, PharmD, MS; Pharmacy Manager, Department of Pharmacy Administration, Texas Children’s Hospital, Houston, TX

Purpose. The primary purpose of this study is to assess the efficacy of Lactobacillus GG (LGG) for preventing antibiotic-associated diarrhea (AAD) in children in the pediatric intensive care unit (PICU). The secondary purpose of this study is to assess the safety of LGG in children in the PICU.

Methods. A pilot study to evaluate antibiotic-associated diarrhea based on data from patients in the PICU and medical records between January 1, 2007 and December 31, 2007 was conducted at The University of South Alabama Children’s and Women’s Hospital (USACWH). Patients were included in the study if they were admitted in the PICU, if they were between 0-18 years of age, and received antimicrobials and LGG while in the PICU. Patients were excluded from the study if they had any antimicrobial use in the previous four weeks before initiation of LGG. Patients were also excluded if they had gastrointestinal or bowel pathologies.

Results. Of the 51 patients evaluated, 28 were males and 23 were females. The average age of the patients was 3.57 ± 4.67 years old. The average stay in the PICU was 8.35 ± 3.69 days. The average number of stools per day was 2.54 ± 1.74 stools. The average number of antibiotic days per patient was 7.12 ± 3.65 days. The average number of LGG days per patient was 8.71 ± 4.88 days. Six out of 51 patients had ≥ 5 stools which indicated diarrhea by definition. The remaining forty-five patients were controlled with LGG. There was a statistically significant positive relationship between the average stools per day and stay in the PICU. There were no adverse events associated with LGG during this study.

Conclusion. LGG reduces the incidence of AAD, cost associated with treating AAD, and subsequent hospital stay for symptoms of AAD.

Introduction
Diarrhea is defined as the frequency of bowel movements or the consistency (looseness) of stools (normally > 5 stools a day).1 Diarrhea in infants is based on stool volume > 10g/kg and > 200g/day in children older than 3 years of age.2 The incidence of diarrhea in children receiving broad spectrum antibiotics has been reported to range from 11 to 40% between the initiation of therapy and up to two months after cessation of treatment.3 Antimicrobial agents have been shown to disrupt the colonization resistance of gastrointestinal micro flora, which can induce clinical symptoms such as diarrhea.

Antibiotic associated diarrhea (AAD) is the most common cause of diarrhea in hospitalized patients, representing an important source of morbidity, mortality, and cost. Virtually any antimicrobial agent may cause diarrhea, but ampicillin, amoxicillin-clavulanate, cephalosporin, and clindamycin are most often incriminated.3,6 The term antibiotic-associated diarrhea refers to a benign, self-limited diarrhea, following the use of antimicrobials.4 The occurrence of AAD varies greatly and is influenced by multiple factors including nosocomial outbreaks, patterns of antimicrobial use, and individual susceptibility. Typically none or few pathogens are identified and the diarrhea is due to changes in the composition and function of the normal intestinal flora. It is also believed that the use of antibiotics allow opportunistic pathogenic bacteria to take advantage of the alteration in the equilibrium of the normal gut flora, which leads to inflammation and diarrhea.4 Alterations of the intestinal mucosa, gut motility, decreased bile acid metabolism, and decreased metabolism and absorption of carbohydrates by colonic bacteria also are caused by injudicious use of antibiotics.4,5

Antibiotic-associated diarrhea signs and symptoms include frequent watery diarrhea, bloody stools, pus in stools,
abdominal pain and cramping, fever > 101 F, nausea, and dehydration. Signs and symptoms of AAD usually start around five to ten days after initiation of antibiotic therapy, but has been seen as soon as three days after initiation of antibiotic therapy. Prolonged or repeated antibiotic treatment and/or combination antibiotic therapy appears to further increase the risk of AAD occurring. It can be very severe leading to electrolyte imbalances, abdominal pain, acute weight loss, dehydration, and death.

Management of AAD includes discontinuation of the offending antimicrobial therapy as soon as possible in patients in whom clinically significant diarrhea or colitis develops. Antibiotics that are infrequently associated with AAD (e.g., aminoglycosides, macrolides, sulfonamides, tetracyclines, and vancomycin) should be considered when necessary to treat the original infection. However, most patients respond to supportive measures and discontinuation of antibiotics. Lactobacillus rhamnosus GG (LGG) is a non-pathogenic, probiotic lactic-acid bacteria strain intended to benefit the host by re-inoculation and normalization of unbalanced microflora disrupted by the detrimental course of antibiotics. It was discovered by Sherwood Gorbach and Barry Goldin in 1983.

Several studies have shown that oral administration of this strain in >109 colony-forming units (CFUs) per day colonized the intestine, which led to a reduction in the risk and duration of diarrhea. Several studies have also used LGG for various gastrointestinal disorders including diarrhea, inflammatory bowel disease, and gastrointestinal infections. Meta-analyses have also been conducted to evaluate the ability of probiotics to prevent antibiotic-induced diarrhea in the general population. However, few studies have been conducted in intensive care units, where antibiotics that are associated with AAD (e.g., cephalosporins, clindamycin and broad-spectrum penicillins) are frequently used. This study will review the effectiveness of LGG to prevent antibiotic-associated diarrhea (AAD) in pediatric patients in the intensive care unit (PICU).

Purpose
The primary purpose of this study is to assess the efficacy of Lactobacillus GG (LGG) for preventing antibiotic-associated diarrhea (AAD) in children in the pediatric intensive care unit (PICU). The secondary purpose of this study is to assess the safety of LGG in children in the PICU.

Methods
A pilot study to evaluate antibiotic-associated diarrhea based on data from patients in the PICU and medical records between January 1, 2007 and December 31, 2007 was conducted at The University of South Alabama Children’s and Women’s Hospital (USACWH). USACWH is a 152 bed acute care facility that also serves as an academic teaching hospital for The University of South Alabama College of Medicine. Patients were initially identified from the pharmacy’s database of patients who were admitted in the PICU and received LGG between the dates of January 1, 2007 and December 31, 2007. Patients were included in the study if they were admitted in the PICU, if they were between 0-18 years of age, and received antimicrobials and LGG while in the PICU. Patients were excluded from the study if they had any antimicrobial use in the previous four weeks before initiation of LGG. Patients were also excluded if they had gastrointestinal or bowel pathologies (e.g., Crohn’s disease, pseudomembranous colitis, gastroesophageal reflux, lactose intolerance, etc). The data collection form (see Appendix 1) included descriptive statistics such as the patient’s date of birth, gender, race, weight, admission/discharge date, past medical history, disease state, current drug regimen, diet, route of administration (tolerating by mouth), total bowel movements per day, viscosity of bowel movements, and weight/color of stools.

Statistical Analysis
All data were reported as mean or median and range, or number and percentage, as appropriate. Descriptive statistics were used for reporting demographic data. Statistical analysis of the data was completed using Predictive Analytics SoftWare (PASW) 18.0 software, formerly SPSS (Statistical Package for the Social Sciences). The Pearson’s product-moment correlation coefficient and the multiple logistic regression analysis were used for assessing correlations between variables.

Safety Evaluation
The incidence of bacterial sepsis and Lactobacillus bacte remia was obtained to evaluate the safety of LGG therapy. Safety was accessed by reviewing the charts for any documented fevers (e.g., bacteremia, fungemia, sepsis, etc) or gastrointestinal disorders (e.g., diarrhea, pseudomembranous colitis, gastroenteritis, infection, etc) developed during initiation through the discontinuation of LGG therapy. Data were also collected to assess whether documented complications from LGG therapy were treated according to a standard hospital protocol. The responses to treatment were recorded by the nursing staff and documented in the patients’ charts.

Results
A total of 207 charts (see Figure 1) were reviewed. 113 patients were excluded on basis of antimicrobial use in the previous four weeks before initiation of LGG. 43 patients were excluded due to gastrointestinal or bowel pathologies (e.g., Crohn’s disease, pseudomembranous colitis, lactose intolerance, gastroesophageal reflux, etc) during
LGG therapy. Only 51 patients met the inclusion criteria. Of the 51 patients who qualified for analysis, 28 (55%) were males and 23 (45%) were females (see Table 1). A majority of patients were Caucasian (n=24, 47%) while the rest were African Americans (n=22, 43%), Asians (n=2, 4%), Hispanics (n=2, 4%), and Native American (n=1, 2%). The age range was 1 month to 14 years of age with an average age of 3.57 ± 4.67 years old. The average total body weight of the patients was 17.20 ± 18.70 kilograms with a total body weight range from 3.00 kilograms to 82.00 kilograms. The average stay in the PICU was 8.35 ± 3.69 days with a range of 1 day to 22 days. LGG used in the PICU had 1010 CFUs. The average dose of LGG was one capsule per day with a dose range of a half capsule to two capsules per day.

All stools were recorded during the time the patients were in the PICU (see Tables 2). The average number of stools per day was 2.54 ± 1.74 stools. The average number of antibiotics per patient was 2.08 ± 1.05 antibiotics. The average number of antibiotic days per patient was 7.12 ± 3.65 days. 32% and 27% of the patients were on cephalosporins and clindamycin, respectively (see Figure 2). The average number of LGG days per patient was 8.71 ± 4.88 days. Six patients (12%) had greater than five stools, which indicated diarrhea by definition, while on LGG. Forty-five patients (88%) were controlled with LGG. Kale-Pradhan et al. concluded that administration of a Lactobacillus single-agent regimen as a prophylactic agent during antibiotic treatment reduced the risk of AAD compared with placebo in adults, but not pediatric patients. Although the pooled results from the four pediatric studies referenced in their study showed a trend toward reduction of AAD, these results did not reach statistical significance.14 Publication bias may have been due to the disproportionate total number of pediatric and adult patients in their meta-analysis, 585 and 1277 respectively.15

Definitions of AAD and probiotic doses varied in the primary literature. Johnston et al. reported a favorable decrease in stools, but none of statistical significance.8 However, the summary statistics provided a statistical significance (RR = 0.29) for a preventive effect of AAD with the LGG strain. One systematic review identified six randomized controlled trials that involved 766 pediatrics.9 The review found that the treatments with probiotics compared with placebo reduced the risk of AAD from 28.5% to 11.9% (relative risk [RR] 0.44, 95% confidence interval [CI] 0.25 – 0.77, random effect model). It was concluded that probiotics reduce the risk of AAD in children. Turck et al. reported a decrease in the incidence of AAD (28.5% to 11.9%) when compared with placebo.3 It was concluded that for every seven patients that would develop AAD, one fewer would develop AAD when dispensed LGG.

Discussion

There have been numerous studies researching probiotic-
versus patients that did not receive LGG. This study did not analyze the contribution in which diet may have affected the degree of AAD control. However, the external validity of this study is strengthened due to the patients, time, and site of the study. This study also included a strong sample of patients that inferred clinical characteristics to represent our target population of patients affected by AAD in the PICU.

The average cost for 60 capsules of LGG is $8.99. There was no record of the overall costs associated with LGG therapy. It is assumed by this study and meta-analyses that the incidence of AAD, cost associated with treating AAD, and hospital stay for symptoms of AAD are reduced by LGG therapy.1,8,10,11 A study that includes both patients with and without LGG therapy and keeps a record of all costs associated with other AAD associated therapy would yield a cost benefit analyses that would assess any cost effectiveness associated with LGG therapy.

This study would have benefitted if there was a validated primary outcome measure for AAD that was sensitive to change and reflected what stool frequencies and consistencies have importance in the eyes of clinicians, parents, and children. Future studies should include a control group, cost, and outcome data. This would provide information on the cost-effectiveness of this intervention for management of AAD.

Conclusion
Lactobacillus rhamnosus (LGG) is a significant aspect to the treatment of antibiotic-associated diarrhea (AAD). It can be implied from this study and the primary literature that the initiation of LGG reduces the incidence of AAD, costs associated with treating AAD, and subsequent hospital stay for symptoms of AAD. Even with the results of this study and the primary literature, judicious use of antibiotics should be the first step in preventing AAD.9 There were no instances of bacteremia, fungemia, or other adverse effects during the retrospective review. This study generalized that lactobacillus is safe for use of pediatric patients in the PICU. Further study of probiotics, including large, well designed, randomized controlled dose ranging trials, comparative trials, and cost benefit analyses are necessary to access full benefits of lactobacillus therapy.10,14

References
Table 1: Demographics N= 51

<table>
<thead>
<tr>
<th>Gender (%)</th>
<th>M</th>
<th>F</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>28 (55)</td>
<td>23 (45)</td>
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<table>
<thead>
<tr>
<th>Race (%)</th>
<th>Caucasian</th>
<th>African American</th>
<th>Asian</th>
<th>Hispanic</th>
<th>Native American</th>
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<tr>
<td></td>
<td>24 (47)</td>
<td>22 (43)</td>
<td>2 (4)</td>
<td>2 (4)</td>
<td>1 (2)</td>
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</table>

<table>
<thead>
<tr>
<th>Age</th>
<th>Mean Range</th>
<th>Age Mean Range</th>
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<tr>
<td></td>
<td></td>
<td>3.57 – 4.67</td>
</tr>
<tr>
<td>Total Body</td>
<td></td>
<td>1 month – 14yoa</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>17.20 18.70</td>
<td>2.5 – 82.0</td>
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</tbody>
</table>

Table 2: Descriptive Statistics

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<th></th>
<th>Mean</th>
<th>Standard Deviation</th>
<th>N</th>
</tr>
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<tbody>
<tr>
<td>Number of Stools per Day</td>
<td>2.54</td>
<td>1.74</td>
<td>51</td>
</tr>
<tr>
<td>Number of Days in PICU</td>
<td>8.35</td>
<td>3.69</td>
<td>51</td>
</tr>
<tr>
<td>Number of Days on Antibiotics</td>
<td>7.12</td>
<td>3.65</td>
<td>51</td>
</tr>
<tr>
<td>Number of Days on Lactobacillus</td>
<td>8.71</td>
<td>4.88</td>
<td>51</td>
</tr>
</tbody>
</table>

Table 3: Results (Pearson correlations) N= 51

<table>
<thead>
<tr>
<th></th>
<th>Average Stools per Day</th>
<th>Number of Days on Antibiotics</th>
<th>Number of Days on Lactobacillus</th>
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<tbody>
<tr>
<td>Number of Stools per Day</td>
<td>1.000</td>
<td>.199</td>
<td>.275*</td>
</tr>
<tr>
<td></td>
<td></td>
<td>.161</td>
<td>.048</td>
</tr>
<tr>
<td>Number of Days on Antibiotics</td>
<td>.199</td>
<td>.161</td>
<td>1.000</td>
</tr>
<tr>
<td></td>
<td></td>
<td>.366*</td>
<td>.008</td>
</tr>
<tr>
<td>Number of Days on Lactobacillus</td>
<td>.275*</td>
<td>.048</td>
<td>.366*</td>
</tr>
<tr>
<td></td>
<td></td>
<td>.008</td>
<td>1.000</td>
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* Correlation is significant at the 0.05 level (2-tailed).
** Correlation is significant at the 0.01 level (2-tailed).

Table 4: Coefficients^a

<table>
<thead>
<tr>
<th></th>
<th>Standardized Coefficients</th>
<th>t</th>
<th>Sig.</th>
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<tbody>
<tr>
<td>(Constant)</td>
<td></td>
<td></td>
<td>1.290</td>
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<tr>
<td>Number of Days on Antibiotics</td>
<td>.021</td>
<td>.138</td>
<td>.891</td>
</tr>
<tr>
<td>Number of Days on Lactobacillus</td>
<td>.035</td>
<td>.216</td>
<td>.830</td>
</tr>
<tr>
<td>Number of Days in PICU</td>
<td>.380</td>
<td>2.238</td>
<td>.030</td>
</tr>
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</table>

^a Dependent Variable: Number of Stools per Day
Figure 1: Exclusion Flow Chart

207 patients analyzed in retrospective review

113 patients excluded
(Antimicrobial use in previous four weeks)

43 patients excluded
(Lactose intolerance, gastroesophageal reflux, Crohn’s disease, pseudomembranous colitis)

51 patients included in retrospective review

Figure 2: Number of Patients on Common AAD Associated Antibiotics

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—Laura M. Forbes, RPh, Director of Pharmacy Services, Gov. Juan F. Luis Hospital and Medical Center, Christiansted, U.S. Virgin Islands

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Appendix 1
Data Collection Form

Admission Date ___________ SEX ___________________

Discharge Date ___________ AGE ___________________

DOB ___________________ RACE: ☐ African American ☐ Caucasian
☐ Asian ☐ Hispanic
☐ Native American ☐ Other

Diet:
Weight (KG) ___________ HT (CM) ___________________

PMH

Primary DX

<table>
<thead>
<tr>
<th>Current Drug Regimen</th>
<th>Start Date</th>
<th>End Date</th>
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<tbody>
<tr>
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Total Bowel Movements per Day:

<table>
<thead>
<tr>
<th>Total Bowel Movements per Day</th>
<th>Frequency/Viscosity of Bowel Movements</th>
<th>Weight of Stools</th>
<th>Color of Stools</th>
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<tbody>
<tr>
<td></td>
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Evaluation of Drotrecogin Alfa-Activated in Severe Sepsis

by: Sylvia L. Best, Pharm.D., BCPS*; PGY2 Critical Care Resident; The Methodist Hospital, Houston, TX

*At the time of this publication Dr. Best was serving as a PGY2 Critical Care Resident at The Methodist Hospital.

Current Position: Clinical Coordinator; Sentara Williamsburg Regional Medical Center, Williamsburg, Virginia

Abstract
Severe sepsis is a leading cause of intensive care mortality. In 2008, the most recent guidelines for the management of patients with severe sepsis were published. Drotrecogin alfa activated is an anticoagulant and profibrinolytic agent used in severe sepsis. Since its introduction to the market in 2001, additional studies have been published to further clarify appropriate drotrecogin alfa use. Although drotrecogin alfa has been marketed for ten years, questions remain regarding appropriate use, efficacy and safety.

Severe sepsis is a leading cause of intensive care mortality in adults. Approximately 750,000 patients are affected annually. In addition to patient morbidity and mortality, the United States (U.S.) spends 17 billion dollars a year caring for patients with the disease. The 2008 Surviving Sepsis Campaign provides the most current recommendations for managing patients with severe sepsis and septic shock (Table 1). Patients with severe sepsis present with infection, inflammation and exhibit signs of acute organ dysfunction.

Mechanism of Disease
Proteins C and S, antithrombin III, and thrombomodulin are anticoagulants found in the body that regulate the coagulation cascade. When protein C binds to the endothelial protein C receptor, it becomes activated. Activated protein C inactivates Factor Va and Factor VIIIa to reduce further coagulation by inhibiting plasminogen activator inhibitor 1 to promote fibrinolysis and as a result decrease inflammation. In sepsis, an infectious stimuli causes the release of inflammatory cytokines leading to decreased levels of activated protein C in the body and the formation of microvascular thrombi.

Drotrecogin alfa in Initial Studies
In November 2001, Eli Lilly and Company obtained approval from the Food and Drug Administration (FDA) to market drotrecogin alfa-activated (Xigris®, DAA). Drotrecogin alfa is an activated form of protein C with anticoagulant and profibrinolytic properties. It is indicated for the reduction of mortality in patients with severe sepsis that are at an increased risk of death based on an Acute Physiology and Chronic Health Evaluation II (APACHE II) score greater than 25. The APACHE II score is comprised of physiologic variables that are quantified to assess mortality risk and is frequently used in the intensive care setting. Patients with an APACHE II score greater than 25 have a mortality risk more than 50%.

Bernard and colleagues published results from a randomized, double-blind study referred to as the Recombinant Human Activated Protein C Worldwide Evaluation in Severe Sepsis (PROWESS) study. Patients presenting with systemic inflammatory response and acute organ failure were eligible to receive drotrecogin alfa-activated 24 micrograms/kilogram/hour or placebo for 96 hours. 1690 patients participated in the study. The trial was stopped during the second interim analysis. During the subanalysis, FDA discovered additional information after separating patients into groups based on their APACHE II score. Patients with an APACHE II score of 25-29 or greater than 30 were found to have decreased mortality compared to patients with scores less than 24. At 28 days after the beginning of the infusion, patients who received drotrecogin alfa-activated had an absolute risk reduction in death of 6.1% (p=0.005). Data from this study provided information for FDA labeling, contraindications and precautions (Table 2, Table 3).

The Extended Evaluation of Recombinant Human Activated C United States Trial (ENHANCE US) was conducted to gather additional data on safety and efficacy of DAA. 273 patients were evaluated for 28 days or until death. The ENHANCE US trial compared outcomes with the PROWESS trial and the secretory phospholipase A2 inhibitor in severe sepsis trial (sPLA2I) as they had similar inclusion and exclusion criteria. LY315920NA/S-5920 was the drug compound created by Eli Lilly used in the sPLA2I trial. This agent...
failed to improve clinical outcomes or demonstrate survival benefit in septic patients and was never marketed.\textsuperscript{10} Treatment with DAA in the ENHANCE US trial was associated with a 6% reduction in mortality when compared to placebo in other trials. ENHANCE US validated the results from the PROWESS trial. Both studies provided recommendations for DAA treatment in severe sepsis.\textsuperscript{8, 9}

Abraham et al. investigated outcomes in the Drotrecogin alfa-activated for Adults with Severe Sepsis and a Low Risk of Death (ADDRESS) trial. 2613 patients with a low risk of death defined as an APACHE II score less than 25 and single organ failure received DAA or placebo. After 28 days of therapy, patients who received drotrecogin-alfa activated showed no difference in mortality compared to patients with placebo (p=0.31). However, patients who received active therapy were found to have significantly more bleeding events during the infusion period and at 28 days after beginning therapy (p=0.02; p=0.01), respectively. The results of this trial prompted product revisions from the manufacturer and FDA involvement. As a result, patients should not receive drotrecogin alfa-activated if they have a low mortality risk or single organ failure in the presence of severe sepsis.\textsuperscript{11}

**Drotrecogin alfa in Clinical Practice**
Recent data involving DAA described the outcomes of patients in clinical practice. The Xigris Use in the United Sates (XEUS) trial was a prospective, observational study comparing outcomes with the PROWESS study. The outcomes of 548 patients demonstrated that patients who receive DAA are slightly younger as the median age was 58 years in the XEUS study compared to 63 years in PROWESS (p=0.01). Patients in the XEUS trial required more vasopressor support 84.3% vs. 70.3% (p<0.001). There was no difference in mortality at 28 days detected between the trials 36.7% vs. 30.9% (p=0.062). In addition, serious bleeding during the infusion period and at 28 days was not significant. One observation in the study was providers in clinical practice do not frequently utilize the APACHE II scoring system, but rather add DAA therapy based on clinical presentation.\textsuperscript{12}

**Drotrecogin alfa and Coagulation**
Prior to the Xigris and Prophylactic Heparin Evaluation in Severe Sepsis Treated with Drotrecogin Alpha-activated (XPRESS) study, the FDA and the manufacturer suggested that patients receiving heparin concurrently at treatment doses should be advised of potential bleeding risk. Levi and colleagues addressed the issue of using DAA with heparin or enoxaparin for venous thromboembolism prophylaxis. In the XPRESS study, 1994 patients were randomized to receive heparin 5000 units subcutaneously every 12 hours, enoxaparin 40mg subcutaneously daily or placebo with standard dose DAA. There was no difference in mortality at 28 days between groups (p=0.08). Furthermore, there was no difference detected in bleeding events between the groups at the end of the study period (p=0.32). Nevertheless, patients who received heparin with DAA were less likely to experience an ischemic event during active treatment and at conclusion of the 28 days study period (p=0.02, p=0.01), respectively. Therefore, patients on DAA therapy should receive deep vein thrombosis prophylaxis with a low-molecular weight heparin or unfractionated heparin.\textsuperscript{13}

Gentry et al. revisited the initial bleeding baseline precautions from the PROWESS study and compared outcomes in patients with or without precautions at their medical center. A retrospective chart review of all patients who received DAA therapy from 2002-2005 was conducted to investigate the incidence of serious bleeding and mortality at 30 days after initial infusion. Serious bleeding was defined as a decline in hemoglobin of greater than or equal to two grams per deciliter, blood transfusion which required greater than or equal to four units of blood products over 48 hours, objective evidence of bleeding through documentation or physician diagnosis of relevant bleeding. Seventy-three patients were identified in this study. Patients with baseline bleeding precautions experienced a serious bleeding episode 35% of the time compared to 3.8% of bleeding episodes in patients without baseline bleeding precautions (p<0.001). Patients with baseline bleeding precautions also experienced increased mortality rates (65%) when compared with patients without bleeding precautions (24.5%; p=0.01).\textsuperscript{14} The FDA has not concluded if regulatory action will be taken but is considering it due to the outcomes of this study.\textsuperscript{15}

**Conclusion**
The Surviving Sepsis Campaign provides strong recommendations on when DAA should not be used. However, drotrecogin alfa-activated was approved by the FDA nearly ten years ago and there are still unanswered questions of its place in sepsis management.
Table 1: Severe Sepsis and Septic Shock Treatment Recommendations4

<table>
<thead>
<tr>
<th>Fluid resuscitation</th>
<th>Blood product transfusions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antibiotics</td>
<td>Sedation/ Analgesia/ Neuromuscular blockers</td>
</tr>
<tr>
<td>Vaspressors</td>
<td>Deep vein thrombosis prophylaxis</td>
</tr>
<tr>
<td>Inotropes</td>
<td>Stress ulcer prophylaxis</td>
</tr>
<tr>
<td>Corticosteroids</td>
<td>Glucose control</td>
</tr>
<tr>
<td>Recombinant human activated protein C</td>
<td></td>
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</tbody>
</table>

Table 2: Drotrecogin Alfa-activated contraindications5

<table>
<thead>
<tr>
<th>Intracranial bleeding within 2 months</th>
<th>Epidural catheter presence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trauma with life threatening bleeding risk</td>
<td>Intracranial mass or lesion</td>
</tr>
<tr>
<td>Active internal bleeding</td>
<td>Cerebral herniation</td>
</tr>
<tr>
<td>Hemorrhagic stroke within 3 months</td>
<td></td>
</tr>
</tbody>
</table>

Table 3: Drotrecogin Alfa-activated precautions5

<table>
<thead>
<tr>
<th>Concurrent therapeutic heparin use</th>
<th>Thrombolytic therapy within 3 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aspirin &gt; 650mg/day or Clopidogrel within 7 days</td>
<td>Glycoprotein IIb/IIIa inhibitor within 7 days</td>
</tr>
<tr>
<td>Platelets &lt; 30,000 mm3</td>
<td>Antithrombin dose &gt; 100,000 units within 12 hours</td>
</tr>
<tr>
<td>Gastrointestinal bleeding within 6 weeks</td>
<td>Ischemic stroke within 3 months</td>
</tr>
<tr>
<td>International Normalized Ratio (INR) &gt; 3</td>
<td>Chronic severe hepatic disease</td>
</tr>
</tbody>
</table>

References
Speaking of...  
Bird Poop, Jail Cells and PPMI

by Paul F. Davis, R.Ph.
Executive Director

My youngest son came over the other day. Had some things he and his wife had borrowed that needed to be returned. Once done, he suggested we go to lunch, as he often does, mostly figuring I’d buy. I did.

We went to the local Dairy Queen. It was convenient, inexpensive, and quick. We went there a lot when he was in school. He worked there. It’s comfortable.

We pulled in and a parking space was open in a ‘straight shot’ from the street, so we parked, went in and ate. About 30 minutes later we came out and the car was covered... in bird poop!

I don’t mind bird poop. I spend a lot of days being the Pigeon and others being the statue. But I kinda took offense at this herd of Grackles taking it out on MY CAR. Why me? What had I done?

I’d parked under a tree.

Of course we went and washed it off, and life continued pretty much as it had been before the ‘pooping’ imbroglio. Then he left and I turned to writing this column.

Now, I don’t want to put too much into the ‘bird poop’ analogy at this particular point, but it gave me pause, and it related so well to a sermon point that my minister made the following Sunday that I figured it had to be “a message.”

The sermon started off something like this:

Emmet Fox was a minister who lectured and held prayer services for thousands of people in some of the largest auditoriums in New York City in the 1930s and 1940s. He had a happy knack for stating important truth principles clearly and simply, illustrating them with memorable stories. One told about the tale of a prisoner incarcerated in a dungeon for twenty years, alone except for the once-a-day entrance of the jailer into his cell to deliver bread and water. One day, however, he examined his cell door carefully, and discovered that it was unlocked! He walked down the corridor, past several guards who ignored him, and made his way home, where he lived happily ever after. As Fox points out, he could have done this any time through those long years if he had known enough, but he did not. He was a captive, not of stone and iron, but of false belief. He was not locked in; he only thought he was.

Of course this is only a legend, but it is an extremely instructive one. We could all be considered to be living in some kind of prison. Some of us in one kind, some in another; some in a prison of lack, some in a prison of remorse and resentment, some in a prison of blind, unintelligent fear, some in a prison of sickness. But always the prison is in our thought and not in the nature of things.

That prisoner was no more a prisoner than any of us in so many ways. Trapped in a basement? “Confined” by a door of metal or tradition or apathy? Unable to consider a place, practice or activity other than the one you’re ‘chained’ to? Blaming the birds in the tree you happened to park under for all the problems in the world?

It took the prisoner, according to the tale, 20 years to ‘see the light’ and become curious about his situation. Some people, in real life, never test their confines and consequently get pretty much trapped in the cells of their own making. Some never wash the car, just getting madder at themselves and society for the stuff that they have to deal with.

But organizations and leaders every now and then have learned to step back and take a good, hard look at their surroundings, their assumptions and their journey. Occasionally we call that ‘strategic planning’ or ‘visioning.’ In November, 2010 ASHP and a group of about 150 pharmacy leaders from around the county came together in Dallas at what was called the Pharmacy Practice Model Initiative and did just that – considered where health-system pharmacy is and where it’s going – and should be going.
Through an interesting process of developing consensus, both on-site as well as prior to the meeting, the conference developed about 160 recommendations about where we could be/should be/are headed. The outcomes are just now being released and the first tentative steps are being taken.

One of the questions some folks had to get over was the sheer volume of things coming from our national organization these days. They began the 2015 process, a technician initiative, a call for residency training for all pharmacists in health-systems engaged in direct patient care, and more. It seemed that the PPMI might just be the last straw before our collective heads exploded. Instead, it’s turning out to be the package into which all of the initiatives fit, and which gives an overall view and direction for our part of the profession of pharmacy.

A lot of it is not yet ASHP policy – a lot of work needs to be done. Much of it is still conceptual in nature and needs refinement and ‘fleshing out,’ like developing assessment tools and new metrics for use in a future practice setting. It’s definitely not ‘one size fits all.’ Small and large, rural and urban specialty, private and public, and all other variations of hospitals and health-systems will see this like the blind men and the elephant. Some will only see what can’t be done; while others will sit back, digest the vision, and go to work on implementing it in their practices.

It’s going to take time – law changes, mindset changes and some significant paradigm shifts. But we can do it – look at where we’ve come in just the last 40-50 years. Look at what the Hilton Head Conference or Pharmacy in the 21st Century did for changing our view of ourselves, our world and our abilities.

Of course, we could blame the Grackles for our situation, or stay confined unlocked cells.

If you’re just a bit curious about where this all may be headed, I refer you to the ASHP PPMI website: http://www.ashp.org/ppmi?WT.ac=hp%5FPopLinks%5FPPMI or directly to the recommendations and assumptions about our future: http://www.ashp.org/DocLibrary/PPMI/Summit-Recommendations.aspx

(And please, don’t tell Manasse, Zellmer or Diane Ginsburg that I called PPMI ‘bird poop!’ I just hope it got your attention enough to read the message.)