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What's Inside This Issue?

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New Drug Updates

Edaravone[1] (Radicava®): A free radical scavenger for treatment of amyotrophic lateral sclerosis (ALS) shown to slow decline in the loss of physical function

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ALS is a neurodegenerative disease that affects nerve cells in the brain and spinal cord, resulting in death. As the disease progresses, patients with ALS develop defective motor neurons, in which voluntary movements and muscle controls are progressively affected. This leads to a loss of the ability to speak, eat, move, and breathe. Patients' muscles become weak and eventually this leads to paralysis.[2] Patients with ALS have many symptoms, including weak arm or leg muscles, muscle twitches and spasms, and slow, stiff, or awkward movements. Edaravone is the second novel medication to delay progression of ALS since riluzole was approved in 1995. Patients with ALS have consistent increases in oxidative stress biomarkers. Edaravone is a free radical scavenger, which is believed to relieve effects of oxidative stress, a likely key factor in the ALS onset and disease progression. Most people who are diagnosed with ALS live only a few years after their symptoms begin. There is no cure for ALS, but treating the symptoms can improve the quality of life for those affected.

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Mechanism of Action: The mechanism by which edaravone exerts its therapeutic effect in patients with ALS is unknown, however, it is suspected to reduce oxidative stress by scavenging free radicals.

Clinical Trial: A 6-month, randomized, placebo-controlled, double-blind study was conducted in 137 Japanese patients with ALS who were living independently with normal respiratory function and had disease duration of 2 years or less. In the study, the median age of patients included was 60 years (range 29-75) and 59% were male. Most (93%) of these patients were living independently at the time of screening, and had definite or probable ALS based on El Escorial World Federation of Neurology revised criteria. The study enrolled 69 patients in the edaravone arm and 68 in the placebo arm. Baseline characteristics were similar between the groups. Both groups of patients began the trial with an ALSFRS-R* score of about 42, out of a maximum of 48. The primary endpoint was the difference in scores at the end of treatment between edaravone and placebo. The patients receiving placebo had ALSFRS-R score decline of about 7.5 points, while the edaravone patients had a decline of only about 5.0 points, (95% CI [0.99 – 3.98], p = 0.0013), indicating about a 30% decrease.[3] A 2010 surveys of ALS researchers noted that changes of 20 percent or greater in ALSFRS-R can be considered "clinically meaningful."[3]

Most important risks/adverse events: The most common risks of treatment with edaravone include hypersensitivity reactions (i.e. redness, wheals, and erythema multiforme) and cases of anaphylaxis (i.e. urticaria, decreased blood pressure, and dyspnea); sulfite allergic reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in susceptible people were more common in edaravone-treated patients compared to placebo.[3] If hypersensitivity reactions occur, edaravone needs to be discontinued and the patient monitored until the condition resolves.

Most common adverse events: The following are the most common adverse events reported with edaravone: contusion (15%), gait disturbance (13%) and headache (10%).[4]

Advantages: Edaravone is the first new treatment approved by the FDA for ALS in many years. This medication can potentially improve quality of life for patients affected by ALS, and give patients the ability to complete activities of daily living longer than previously expected. Although there is no cure for ALS at this time, this medication can help patients to retain independence longer. There is no need to adjust the dose of edaravone for patients with renal or mild/moderate hepatic impairments.

Disadvantages: The study used relatively stringent inclusion criteria for patients enrolled. The screening criteria included one of the following: functionality retained most activities of daily living (2 points or better on each individual item of the ALS Functional Rating Scale - Revised); normal respiratory function (defined as percent – predicted forced vital capacity values of [%FVC] $\geq$ 80%; defined or probable ALS based on El Escorial revised criteria or disease duration of 2 years or less.[1] There were only 69 patients enrolled in edaravone arm and 68 in the placebo arm.

Based on the inclusion criteria of the trial, only about 7% of patients with ALS would qualify for treatment with edaravone. The medication is only administered by intravenous infusion, limiting its use for patients living in rural communities or who have difficulty getting to an infusion center. It is likely that few patients will be able to remain adherent to this regimen for a significant length of time. The out-of-pocket costs for treatment are currently up to $20,000 for 12 months, and there are no cost-effectiveness studies.

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Usual dosage: The recommended dosage is 60 mg administered as an intravenous infusion over 60 minutes as follows: initial treatment cycle of daily dosing for 14 days followed by a 14-day drug-free period; subsequent treatment cycle of daily dosing for 10 days out of 14-day periods, followed by 14-day drug-free periods.[1]

Available Products: Injection: 30 mg/100 mL in a single-dose polypropylene bag of clear, colorless aqueous solution.

* ALSFRS-R (ALS Functional Rating Scale-Revised) - 12 questions that evaluated the fine motor, gross motor, bulbar, and respiratory function of patients with ALS.

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Call for Editors

The editors of *Pharmascript* are seeking content reviewers for upcoming editions. Interested Pharmacists, Residents and Students should contact Michael Armahizer (michaelarmahizer@umm.edu) or Vicki Leiman (victorialeiman@umm.edu). Reviewers should note specific areas of expertise or interest in their communications.

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Dolutegravir / Rilpivirine (Juluca®)

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Juluca (dolutegravir 50 mg/ rilpivirine 25 mg) was recently approved by the Food and Drug Administration (FDA) in November of 2017. This is the first two-drug, fixed-dose, complete replacement regimen for the treatment of human immunodeficiency virus type 1 (HIV-1) infection. Juluca is approved for use in adult patients on a stable antiretroviral regimen who have been virologically suppressed (viral load less than 50 copies per mL) for at least six months without history of treatment failure and no known substitutions associated with the individual regimen components.

Two identical Phase 3, multicenter, parallel-group, randomized, non-inferiority trials, SWORD-1 and SWORD-2, evaluated the efficacy and safety of switching to Juluca versus continuation of current, suppressive antiretroviral therapy consisting of two nucleoside reverse transcriptase inhibitors (NRTIs) plus either an INSTI, NNRTI or a protease inhibitor (PI). Pooled data from SWORD 1 and 2 demonstrated that Juluca maintained virologic suppression as effectively as the traditional three drug regimen, 95% (Juluca group n=487; continuation group n=485) of patients in both groups. Rates of virologic failure were slightly less in the Juluca group when compared to continuing regimens, <1% (n=3) and 1% (n=6) participants respectively.

Discontinuation of treatment was higher in the Juluca group, 4% (n=21) compared to the continuation group, 1% (n=5), likely due to adverse effects. The most common adverse effects noted with Juluca were diarrhea and headache, 4% (n=21). Increases in serum creatinine were noted in the Juluca group during the first 4 weeks of treatment with an average change of 0.093 mg/dL, then stabilizing for the remainder of the trial.

Long-term data is warranted to further assess clinical significance of safety and trial findings. The advantages of Juluca over other antiretroviral regimens on the market are that this is a once daily, one tablet, two-drug complete regimen with the potential to limit pill burden and risk for toxicities.

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Technician Corner

Inventory Management from the Frontlines: A Retail Pharmacy Inventory Specialist's Perspective

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Inventory and its associated costs are often the largest expenses for pharmacies. There is a fine line between carrying too little and too much inventory. It is important to balance having the necessary inventory on hand in order to fill prescriptions in a timely manner while avoiding overstocking shelves and risking drug waste due to expiration or changes in prescribing patterns. Adding extra drug volume on the shelves can create a disorganized workspace, as well as decrease workflow efficiency, which may increase the likelihood of incorrect drug selection and medication errors. Some pharmacies consider it "best practice" to stock only about seven days of inventory, but this can vary by setting and site preference. While many of the strategies discussed throughout this article use examples from retail pharmacy, many of the principles apply to all pharmacy settings.

A proactive approach is key to inventory management. This approach creates a more efficient workflow, allowing more time for other pharmacy tasks and ensures the patients consistently receive their prescriptions in a sensible amount of time. Other benefits include reductions in work environment stressors as well as an increased overall profitability.

Appointing an inventory specialist is primary to proactive inventory management. This individual should take the lead for inventory related tasks and issues. The tasks include: monitoring the shelves for gaps and overstock, making corrections to reorder point levels, and returning surplus product to wholesaler. They will also be in charge of rotating stock and ensuring staff clearly mark open bottles as well as soon-to-expire medications.

Secondly, pharmacies should take advantage of perpetual inventory management, offered by most pharmacy computer systems. The key is to make the system work to the benefit of the pharmacy. Regularly spot-checking drug counts to ensure accuracy is the basis for having the system carryout a majority of the inventory workload. Setting appropriate par levels is essential. This will allow the system to generate automatic reorders of products that have a quantity below their established par level. Setting par levels for the pharmacy's inventory can be a daunting task. As a starting point, conduct an initial analysis of the fast moving and high dollar medications, and set applicable par levels for this subsection of the inventory to increase inventory turnover. Establishing reorder points, however, is not a "set it and forget it" task. They need to be maintained and updated at least quarterly by the inventory specialist. After addressing fast movers and high dollar medications, perform an analysis of the remaining inventory. This will allow the pharmacy to identify what is being wasted or no longer dispensed and what are potential items should be relocated, either to another pharmacy site or returned to the manufacturer.

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It is important to keep in mind your vendor's delivery schedule. Most vendors deliver to the pharmacy next day, with the exception of weekends. Using this delivery service to your advantage will give the pharmacy the ability to keep lower levels of inventory on hand. High dollar and low utilization drugs can be ordered upon receipt of a prescription and still have a relatively short turnaround time for the patient. When this occurs, communication with the patient is key.

Another aspect of effective inventory management is monitoring industry trends. Closely monitoring brand to generic release dates and adjusting reorder points as more patients begin to transition to the newly released generic medication is vital. Inventory specialists should continue to monitor these generic releases for 3-6 months to continue to order at the appropriate price point. Monitoring and adjusting to seasonal trends is also helpful. For example, increase par levels of oseltamivir during the fall and winter to anticipate your patients' needs during the flu season. Inventory management not only relates to the physical inventory, but its financial management is also essential. Utilization and optimization of the lowest cost generics is key to increasing the bottom line of the pharmacy budget. Cost should always be a consideration as you establish and modify par levels of your inventory.

Lastly, customer service flourishes with efficient inventory management. Communicating with patients is critical; types of communication may include: informing patients of medications on order and expected arrival dates, offering prescription ready calls, and providing alternative methods of receipt. Being proactive with patients and their prescriptions can save a lot of time and frustration for both pharmacy staff and patients. Implementation of a medication synchronization program is another potential customer-service oriented inventory management strategy. A program like this aligns a patient's maintenance medications to be filled together on a reoccurring basis. For the pharmacy, medication synchronization allows for better inventory management as medications are filled on a predictable schedule.

Pharmacies that effectively address the many factors of inventory management will enable their organizations to improve financial performance, increase adherence to regulatory requirements and reduce risks relating to medication errors and patient safety. Ultimately, the goals are to achieve positive patient outcomes, efficient workflows, and a positive financial bottom line. All of these goals can be achieved with an efficient and well maintained pharmacy inventory.

Deadlines for Upcoming Pharmascript Editions

June 15, 2018 for publication in the July 2018 edition
September 21, 2018 for publication in the October 2018 edition
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March 15, 2019 for publication in the April 2019 edition

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Medication Safety Corner

Weighing the Standards: ISMP's Recommendations on Gravimetric Preparation

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With intravenous (IV) infusion preparation error rates estimated at an average of 9%, the 2016 revised ISMP Guidelines for Safe Preparation of Compounded Sterile Products now recommend that minimally all chemotherapy and pediatric IV preparations are compounded using both barcode scanning and gravimetrics.[1] The use of gravimetrics is also mentioned in ISMP's 2018-2019 Targeted Medication Safety Best Practices for Hospitals.[2] But is your pharmacy gravimetric-ready?

What is gravimetric preparation?

Gravimetric verification of IV preparation incorporates electronic weight balances and the density of solutions to validate appropriate product volume.[3-5] For example, syringes are weighed before and after the drug volume is drawn into the syringe, and the difference in weight is used to calculate the exact volume and dose based on the drug's specific gravity.[4] A similar method is used to calculate the exact volume used to reconstitute medications.[3] This differs from the historical standard of visual verification of volume or the retrospective review of either digital images or the "pull-back" method. Typically, gravimetric verification is used in addition to other methods of verification such as volumetric and barcode scanning.

Why gravimetrics?

There are many limitations to strictly using a volumetric method of preparation and visual verification.[3-5] Reports suggest fewer medication errors and drug waste are incurred with gravimetric preparation as compared to volumetric verification, which has significant cost savings implications.[3] A report by Poppe et al describes a wide deviation range from the intended dose with volumetric verification, with the most significant deviations related to reconstituted drug volumes and small drug volumes.[4] Volumetric measuring has high variability due to differences in user technique as well as the accuracy of syringe demarcations. Indeed, a variance as high as 5% may be seen in syringe demarcation accuracy, and the most deviation with end users is seen with syringe sizes of 10mL or less.[4] In another report by Terkola et al, anywhere from 5.7% to 16.4% of chemotherapy infusions fell outside of the normally tolerated ranges for deviation and would not have been identified had final gravimetric validation not been used.[5] They similarly reported that small drug volumes were correlated with diminished accuracy, particularly with commonly used antineoplastics such as blinatumomab, methotrexate, bortezomib, and vincristine.

Volumetric preparation may also delay preparation if it is necessary to wait for a pharmacist check prior to each addition of volume to a bag or vial or if a volumetric error is identified at the end of the process, requiring the infusion to be re-prepared.[3] Reports have shown a decreased infusion preparation time by using real-time, gravimetric validation in combination with other automated work-flow software.[3] In one report, a 34% decrease in total preparation time (from a mean 9.2 minutes to 6 minutes) was seen, which could have significant implications for labor cost savings.[3]

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There are some limitations associated with gravimetric preparation.[3] Gravimetrics rely on density information of drug products to accurately calculate volume; however, specific gravity information may not yet be readily available for all drug products. Additionally, the use of manual gravimetrics, as opposed to automated gravimetric software, may not see the benefit of decreased preparation time. Lastly, automated gravimetric software is challenged to efficiently communicate with the large variety of electronic health record systems.

How is gravimetric preparation utilized?

Gravimetrics should be incorporated in real-time with each transfer of volume and with the final product verification. Regarding volume transfer, software capabilities may incorporate "hard-stops" on weights, where the user is not able to move forward with preparation until he or she meets the appropriate weight needed for a syringe, vial, or bag. Syringes should be weighed not only at the time of transfer from drug vial to final IV bag but also at the time of vial reconstitution (when transferring from bag to vial or from vial to vial).[3] This allows for better precision of concentration in a reconstituted vial and avoids the assumption that the concentration is the same as the one intended by the manufacturer. Additionally, gravimetric software is able to recalculate the needed drug volume for an intended dose based on the actual drug concentration prepared rather than the intended manufacturer concentration. A final weight of the infusion should be taken just prior to dispensing to act as a final validation that all intended volumes were added to the final product.

Gravimetrics may also be used to help maintain a perpetual inventory of injectable medications.[3] Partial vials can be weighed and a label printed with the appropriate remaining volume and beyond-use-dates. Additionally, it can be used to track wasted volumes, which can be generated into reports that help further streamline that waste.

Conclusion

To conclude, IV infusion preparations verified by conventional volumetric methods are associated with high level of error and a wide deviation from intended doses. It is necessary that pharmacies adopt gravimetric methods for preparation of narrow-therapeutic index drugs like chemotherapy and pediatric infusions to prevent unnecessary under- or overdosing of these medications. Gravimetric preparation may have other benefits as well, including decreased preparation time, decreased drug waste, and the ability to have more accurate perpetual inventories of injectable medications.

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Statistics Corner

Confounding and Multivariable Logistic Regression

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Clinical studies that we read regularly during our clinical practice compare the effectiveness of different medications or interventions using multivariable regression analysis to help deal with the issue of confounding. Confounding occurs when a third variable (often described as a predictor or explanatory variable) distorts the association between your two variables of interest (exposure and outcome). Some degree of confounding is inevitable and cannot be fully accounted for in study design, but efforts should be made to account for the potential distortions caused by confounding.[1] To be a confounding variable, it must have an effect on the outcome (though not directly in the causal pathway) and be unevenly associated with the exposure, often some form of medication in the studies we read regularly, such that it is associated more with either being exposed or not being exposed.[2,3]

Methods to control for confounding with respect to study design include restriction, matching, and randomization.[2] There are also statistical methods to control for confounding, which include regression analysis. By using regression methods, the goal is to determine the causal influence of your exposure variable of interest on your outcome of interest while simultaneously accounting for other variables.[3] Many publications we review for our clinical practices have some form of regression analysis used in their studies; the most common types of multivariable regression models used are linear and binary logistic. Binary logistic regression allows the researcher to control for numerous confounding variables' influence on the outcome of interest, which is a binary outcome such as inpatient mortality (either yes or no). For instance, in a publication examining the clinical outcomes in patients with MRSA bloodstream infection, we compared clinical failure among those treated with vancomycin versus daptomycin, 45.0% versus 29.0%; $P = 0.007$.[4] A direct comparison of these two variables is called a binary analysis, and although it does provide useful information it does not account for confounding, such as whether more patients treated with vancomycin were in the ICU.

Addition of confounding variables into a multivariable model allows for adjustments of associations with respect to all other variables in the model. The straightforward associations (variable of interest and outcome) that result in risk ratios or odds ratios are called unadjusted relations, such as the association between daptomycin versus vancomycin use and clinical failure. The multivariable model will also produce associations; these are termed adjusted relations since they account for the other variables added to the model. For example, our multivariable model contained the following predictor/explanatory variables: treatment with vancomycin (versus daptomycin), acute kidney injury at start of treatment, ICU admission, source of bloodstream infection, and whether the bloodstream infection was complicated. While the bivariate, unadjusted odds ratio for the treatment of MRSA bloodstream infection with vancomycin was 2.05 (95% CI 1.20 – 3.34), the adjusted odds ratio was 2.42 (95% CI 1.35 – 4.35).

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A detailed evaluation of how to build regression models is beyond this brief review but as a peer reviewer and critical reader of medical literature it is part of our due diligence to ensure that these methods are applied appropriately and readily apparent to the final reader to allow for reproducibility. A study in *Medicine* in 2016 reviewed nearly 500 observational studies to evaluate the quality and appropriateness of multivariable models in observational studies published between 2003 and 2014.[5] The authors found that the vast majority (over 60%) did not adequately report methods used to develop the models. Authors should detail the set of predictor variables that are being evaluated for inclusion in their multivariable model. They should state the methods used to evaluate inclusion in to the model and which variables eventually enter the model. Often a *p* value of 0.2 on bivariate analysis between variable and exposure is used for model entry, but this method only evaluates the association with the exposure and not the outcomes and only includes statistically "significant" variables and does not account for biological plausibility.[2]

A common issue is *overfitting* the regression model by adding too many predictor variables, including too much random error to truly assess causal inference. A common rule of thumb states there should be 10 to 20 observations/outcomes per variable being entered in to the model.[6] One last note is the difference between multivariable and multivariate analysis.[7] This review has focused on multivariable analysis wherein numerous predictor variables are entered in to a model to simultaneously assess the causal relationship between the exposure and outcome of interest. Multivariate models, however, refer to models that have two or more outcomes of interest being assessed. These terms are often used interchangeably but are not, in fact, the same.

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BPS Awards 2018 Warren E. Weaver/Richard P. Penna to Johns Hopkins Hospital

The Johns Hopkins Hospital (JHH) Department of Pharmacy was recently named the recipient of the 2018 Board of Pharmacy Specialties (BPS) Warren E. Weaver/Richard P. Penna Award. BPS established the award in 2017 as part of the BPS 40th Anniversary celebration to honor two individuals who were tremendously influential in the evolution and growth of BPS. The award recipient must be an individual or organization who has advanced health quality and/or patient care by promoting the recognition and value of specialized training, knowledge, and skills in pharmacy and the BPS board certification of pharmacists. The JHH Department of Pharmacy has made outstanding voluntary contributions to the advancement of the BPS board certification of pharmacists, and JHH board certified pharmacists are routinely involved in patient care, education, and research consistent with the domains of Pharmacotherapy practice. Furthermore, JHH Board Certified pharmacists have provided service to an array of professional organizations through elected office and committee leadership, including roles on BPS role delineation study task forces and Specialty Councils. For more information about the 2018 recipient and the award, click here. Congratulations to the Johns Hopkins Hospital Department of Pharmacy!