

THE QUARTERLY CONNECTION

Quarterly from Pharma-Care, Inc. / Creative Care Consulting / The Rasa Group

First Quarter 2024

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Increased Rate of Multi-Resistance *Klebsiella* a New Focus for Infection Control Specialists

National Institutes of Health scientists this fall discovered new “hypervirulent” multi-drug resistant strains of centuries-old *Klebsiella pneumoniae*, an opportunistic bacterium highly dangerous to nursing home patients. *Klebsiella pneumoniae* belongs to the *Enterobacteriaceae* family and is described as a gram-negative, encapsulate, and non-motile bacterium. Virulence of the bacterium is provided by a wide array of factors that can lead to infection and antibiotic resistance. *Klebsiella pneumoniae* is one of a handful of bacteria that are now experiencing a high rate of antibiotic resistance secondary to alterations in the core genome of the organism *K. pneumoniae*. Carbapenem resistance has been linked to an up-regulation in efflux pumps, alteration of the outer membrane, and increased production of ESBL enzymes in the organism-(National Library of Medicine. Ashurst, Dawson 7/20/23)

Klebsiella may cause many types of healthcare-associated infections, including UTIs, pneumonia, bloodstream infections, wound or surgical site infections, and meningitis. *Klebsiella* bacteria are normally found in the human intestinal flora. In healthcare settings, *Klebsiella* infections commonly occur among patients who are receiving treatment for multiple conditions. Patients whose care requires devices such as ventilators or intravenous catheters, and patients who are taking long courses of antibiotics are most at risk for *Klebsiella* infections.

In healthcare settings, *Klebsiella* bacteria may be spread through person-to-person contact or, less commonly, by contamination of the environment.

To prevent spreading *Klebsiella* infections between patients, healthcare personnel must follow specific infection control precautions. These precautions may include strict adherence to hand hygiene and wearing gowns and gloves when they enter rooms where patients with *Klebsiella*-related illnesses are housed. Healthcare facilities also must follow strict cleaning procedures to prevent the spread of *Klebsiella*.

Antimicrobial resistance has been found in every U.S. state and country. Addressing this threat requires continued aggressive action to:

- **Prevent infections** through diligent practice of infection control procedures, staff inservicing on appropriate handwashing, continued practice of antibiotic stewardship
- **Stop the spread of infection** if it does develop through proper infection control procedures
- **Improve antibiotic and antifungal** use to slow the development of resistance by appropriate use for the appropriate duration of treatment
- **Appropriate selection of antimicrobial agents based on susceptibility**

Overview of Currently Available Treatments for COVID-19

Paxlovid (nirmatrelvir/ritonavir) 150mg/100mg oral tablets

Dose and administration: 300mg nirmatrelvir (2 150mg tablets) + 100mg ritonavir. Three tablets taken together every 12 hours for 5 days. Tablets may be taken with or without food and **cannot be crushed, broken or chewed.**

Dosing adjustment required for moderate renal impairment (GFR of 30ml/min-59ml/min): 150mg of nirmatrelvir+ 100mg ritonavir. Two tablets taken together every 12 hours for 5days.

Paxlovid is not recommended with severe renal impairment GFR < 30ml/min or with severe hepatic impairment.

Treatment should be started as soon as symptoms are noted but may be started up to 5 days of symptoms.

May be used for children and adults 12 years or older with mild to moderate symptoms who are at risk for severe complications.

Paxlovid is a strong CYP3A inhibitor and as such has multiple drug interactions. Review Medication regimen before initiation

Efficacy per CDC: 86% reduction in hospitalization/death.

Lagevrio (molnupiravir) 200mg Oral capsules

Dose and administration: 800mg(4 capsules) orally every 12 hours for 5 days with or without food.

Capsules may be opened and administered through an NG or G-tube. Capsules must be opened and contents added to 40mls of room temp water in a container with a cover. Shake for 3 minutes (contents may not completely dissolve)

May be used for Adults 18 years or older at high risk for severe complications and for whom other therapies are not available or are not appropriate.

Not recommended if pregnant. Not to be used if patient is hospitalized due to Covid symptoms. No drug interactions identified at this time, but data is limited.

A recent observation study done by the Cleveland clinic and published in JAMA Network Open found the effectiveness of molnupiravir to be as high as 77% in lowering the risk of death as compared to no treatment.

Efficacy per CDC: 30% reduction in hospitalization/death

Veklury (Remdesivir) IV infusion

Dose and administration: IV once daily for 3 days

For Hospitalized or non-hospitalized Adults and pediatric patients 28 days of age or older and

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Do Genetics Affect Users Response To Meds?

Pharmacogenetics is the field of research that studies how a person's individual genome will affect their response to certain medications. Its long term goal is to aid in the selection of the medication and dose that will have the highest efficacy in a particular person. It is part of the field of precision medicine that aims to treat each person individually. Today the Food and Drug Administration (FDA) includes pharmacogenomic language in the package inserts of many commonly prescribed psychiatric medications.

The GeneSight Psychotropic Test is a pharmacogenomic test that evaluates a person's DNA to determine how they may metabolize or respond to certain medications. The results of the test show which medications may require dose adjustments, may be less likely to work, or may have an increased risk of side effects¹ based on a patient's genetic results. The GeneSight test provides pharmacogenomic information for antidepressants, anxiolytics & hypnotics, antipsychotics, mood stabilizers, and stimulants & non stimulants used to treat ADHD.

The clinical utility of the GeneSight Psychotropic Test has been extensively studied. Improved outcomes were observed for patients whose clinicians had access to GeneSight testing compared to treatment as usual in multiple studies, including the two largest pharmacogenomic randomized controlled trials in mental health, the Prime Care (n=1944)² and GUIDED (n=1167)³ trials. These trials showed significantly improved remission rates for patients with depression. Additionally, a meta-analysis of 4 GeneSight studies found significant improvement in symptoms, response, and remission rates.⁴ Furthermore, greater improvement in remission rates was seen in patients taking medications with gene-drug interactions⁵ and the elderly population⁶.

To order the GeneSight test, the health care provider simply places an order on www.mygenesight.com, collects the patient's DNA sample using a buccal swab or sends a sample collection kit to the patient's home, and then the sample is sent to Myriad's laboratory for analysis. The test results are typically returned to the clinician two days after the sample is received in our lab. The GeneSight lab is CLIA (Clinical Laboratory Improvement Amendments), and CAP (College of American Pathologists) accredited.

If you are interested in learning more about the GeneSight Psychotropic Test, please visit www.genesight.com or reach out directly to your local molecular sales consultant, Barbara Gilgallon at Barbara.gilgallon@myriad.com. If you have any scientific or clinical related questions, please reach out to the Medical Information team at Myriad at medinfo@genesight.com or call 855.891.9415.

1. Maher RL, et al. Expert Opin Drug Saf. 2014
2. Oslin DW, et al. JAMA. (2022)
3. Greden JF, et al. Psychiatr Res. (2019)
4. Brown L, et al. Pharmacogenomics. (2020)
5. Thase ME, et al. J Clin Psychiatry. 2019
6. Forester BP et al. Am J Geriatr Psychiatry 2020

Overview of Currently Available \ Treatments for COVID-19

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weighing at least 3 pound 18 or older with mild to moderate symptoms at risk for severe complications.
Start treatment as soon as symptoms are identified or within 7days of onset.
Efficacy per CDC: 87% reduction in hospitalizations and deaths

COVID-19 Convalescent Plasma

Plasma from donors who have recovered from COVID-19 (regardless of vaccination status) may contain antibodies to SARS-CoV-2 that could help suppress viral replication. In August 2020, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for COVID-19 convalescent plasma (CCP) for the treatment of hospitalized patients with COVID-19. The EUA was subsequently revised. The current EUA limits the authorization to the use of CCP products that contain high levels of anti-SARS-CoV-2 antibodies (i.e., high-titer products) for the treatment of outpatients or inpatients with COVID-19 who have immunosuppressive disease or who are receiving immunosuppressive treatment. The testing criteria used to identify high-titer CCP products was also revised. (WHO 11/2/23).

STATE SURVEY TRENDS



- F658** – Services Provided Meet Professional Standards: Oxygen tubing not dated; Missing order for frequency of Oxygen tubing changes; Order for disinfectant solution was not transcribed onto TAR for wound
- F755** – Pharmacy Services: Narcotic given without signing countdown sheet; Duplicate order for OTC item; Charting omissions throughout MAR
- F759** – Medication Errors: late administration of medications; medication not available during med pass; incorrect OTC stock formulation administered (Senna vs Senna-S)
- F761** – Med storage: Insulin pen not dated; glucose test strips undated; Med room was open with the refrigerator unlocked; E-kit with seal broken; expired tubing in med room; nurse forgot to put Gabapentin liquid back in refrigerator after removing it to give to a patient that day
- F657** – Care Plan Timing and Revision
- F694** – Parenteral Fluid: No order to flush PICC line or change dressing weekly
- F695** – Respiratory Care: Missing order for Oxygen
- F698** – Dialysis: permcath was not checked; Dialysis patient did not have order to check access site
- F842** – Medical Records: Missing documentation for change in condition for a resident sent to ER
- F880** – Infection Control: Nurse did not wash hands between patients; insulin pen in drawer without putting top on it; Nurse did not wash hands after taking off gloves; CNA entered Covid room without proper PPE and did not use hand hygiene after exiting room; Covid positive resident's room missing signage on front of door
- F883** – Influenza and Pneumococcal Immunizations: patients with no pneumonia vaccine record on file.

New Drugs In the Spotlight

Airsupra (albuterol-budesonide inhaler) - the first SABA/ICS asthma rescue inhaler FDA-approved to treat symptoms and inflammation. A dose of AIRSUPRA is 2 inhalations (puffs) as needed, with a maximum of 12 puffs (which equals 6 doses) within a 24-hour period. AIRSUPRA is not to be used as a maintenance treatment for asthma. Discard AIRSUPRA 12 months after you open the foil pouch or when the dose indicator reaches zero "0", whichever comes first.

Jesduvroq (Daprodustat) - Jesduvroq is a hypoxia-inducible factor prolyl hydroxylase (HIF PH) inhibitor used to treat anemia caused by chronic kidney disease (CKD) in adults who have been on dialysis for at least 4 months. It works differently from erythropoiesis-stimulating agent (ESA) injections and iron supplements because it helps the body make its own erythropoietin (EPO). JESDUVROQ is taken once daily with or without food, and may be taken with iron supplements or phosphate binders, if necessary. JESDUVROQ must be swallowed whole, it cannot be cut, crushed, or chewed.

Xcopri (Cenobamate) - XCOPRI is indicated for the treatment of partial-onset seizures in adult patients and is a Schedule V controlled substance. It has a multimodal mechanism of action by inhibiting voltage-gated sodium currents, as well as acting as a positive allosteric modulator of the GABA_A ion channel. XCOPRI can be prescribed as monotherapy or adjunctive therapy and is usually titrated to effective dose at 2-week intervals.

Caplyta (Lumateperone) - CAPLYTA is indicated in adults for the treatment of schizophrenia and depressive episodes associated with bipolar I or II disorder (bipolar depression), as monotherapy and as adjunctive therapy with lithium or valproate. Lumateperone is an oral atypical antipsychotic that has a dual action as a serotonin 5-HT_{2A} receptor antagonist and a dopamine modulator. As with all antipsychotics, lumateperone carries a boxed warning for increased mortality in elderly patients with dementia-related psychosis.

Changes to USP-797

USP-797 has been fully adopted as of November 2023. The guidelines have become less stringent from the 1 hour rule for spiking IV bags and pre-drawn syringes to 4 hours. The FAQs section of USP-797 has taken the view that:

"The immediate-use CSP provision was revised to allow up to 4 hours for beginning administration to balance the need for ensuring CSP quality with timely access to medication in a variety of healthcare settings. The allowance of up to 4 hours was based on the 4-to-6-hour lag phase of microbial growth, during which potential bacterial cells are adjusting to their environment and change very little, and they do not immediately start reproducing.¹ In the event bacterial cells were inadvertently introduced into a CSP during compounding, replication is unlikely and therefore there is a window of time in which a CSP can be held prior to administration"

So far, AAAHC will "recognize" the 4 hour rule, the recommendations of each will and should prevail.

APIC has not yet taken a position that we are aware of.

Facilities should ensure if they adopt the 4 hour change then the facility policy and procedures need to be amended. Additionally, should the drug insert state otherwise then we recommend following the manufacturer instructions unless it exceeds the 4 hours (797) or center policy.

Issues regarding increased use of GLP-1 Agonists for diabetes and weight loss.

With the widespread use of GLP-1 Agonists, there have been relevant concerns regarding the safety of this medication in relation to surgical procedures due to delayed gastric emptying. Recently, the American Society of Anesthesiologists issued a statement addressing this very concern. Prominent examples of GLP-1 Agonists include Ozempic® (semaglutide), Mounjaro (tirzepatide) and Trulicity® (dulaglutide).

The recommendations are as follows:

DAY OR WEEK PRIOR TO PROCEDURE

- Hold on day of procedure for patients who take daily.
- Hold a week prior for patients who take medication weekly. Consider consulting with endocrinologist **

DAY OF PROCEDURE

Consider delay if patient has GI symptoms such as nausea/vomiting. Review with surgeon/anesthesia/procedurist as GI symptoms may have patient more prone to regurgitation.

If no GI symptoms, and meds were not held, use precautions assuming full stomach.

We recommend:

1. Share this memorandum with all staff who make preoperative/procedure calls. Have them enquire if these medications are part of the patient's current drug regimens.
2. Consult with your anesthesia and medical providers and add to the medical executive committee agenda.

For additional information on Pharma-Care's and Creative Care Consulting's services to both the Ambulatory Surgery Centers and Dialysis Centers contact Cheryl Bruno, Director. Call 732-574-9015, extension 253



Pharma-Care continues to support The Rasa Group family with a new Nursing Notables quarterly, along with Quarterly Connections as Page 5 and available on Pharma-Care's Website.

E.P.I.C. Corner

ELECTRONIC PHARMACIST INFORMATION CONSULTANT
(MEDICATION REVIEWS WITHIN 48 BUSINESS HOURS)

Phone: 732-943-3573

Email: epic@pharmacareinc.com

Avoid re-writing orders and save nursing time!

Common EPIC reasons recommendations are made

- Classification of medication, instead of diagnosis listed, i.e. *Eliquis for anticoagulant*.
- Pain and laxative PRN indications not sequenced or overlapping, i.e. *Tylenol for mild pain, Percocet for pain*.
- BP/pulse not being documented with BP/pulse hold parameter order. *Make sure supplementary documentation is attached to order*.
- Two indications for PRN orders, i.e. *Tylenol PRN for pain or fever*. i.e. *morphine for SOB and pain*.
- Certain antibiotics not scheduled correctly. Interactions with certain supplements and probiotics.
 - Please refer to Pharma-Care's provided Antibiotic Administration Times handout prior to plotting the Times for antibiotics.

Note: Antibiotics MAY be given and scheduled with probiotic Florastor, saccharomyces boulardii.

REMINDER: Please do not send completed EPIC reviews back to us. The completed EPIC review is ideally placed in the resident's chart or if facility is chart-less scanned into their EMAR system.

Please make sure your fax machine is sending over legible information. Many times, EPIC receives requests with blank lines going through the pages which makes it difficult to read. If your not sure, send a fax from one device to another device at your facility and review.

EPIC has 4 fax numbers:

732-574-3469 - 732-574-3926 - 732-943-3571 - 732-943-3572



Annual Non-Perishables Collected

Employees' donated various food items at their annual Year-End Meeting to be distributed to several Pantries in the area: Food Pantry of St. Theresa in Kenilworth and the Soup Kitchen of St. John's in Newark. Pictured left to right, Pharmacy Consultants Belinda Cella, Kathy Batchelor and Melissa Lang.

FDA requiring Labeling updates for Levetiracetam and Clobazam

The FDA has issued an alert for levetiracetam (Keppra) and Clobazam (Onfi) regarding a rare but serious, life threatening drug hypersensitivity reaction. Drug reaction with eosinophilia and systemic symptoms (DRESS), may start as a rash but quickly progress, causing injury to internal organs, requiring hospitalization. If not caught and treated promptly, DRESS may result in death.

Signs and symptoms include skin rash, fever, eosinophilia, lymph node swelling, face swelling, thrombocytopenia/Leukopenia, and atypical lymphocytes. Injured organs may include liver, lungs, GI tract, Kidneys and gallbladder.

Time range for onset for Levetiracetam was 7 to 170 days; for clobazam time range was 7 to 103 days. In the majority of treated cases, discontinuation of the offending agent resulted in resolution of symptoms. Care givers and patients should be educated to stop these medications and notify the prescribers immediately if symptoms are noted.

The FDA is requiring that DRESS be added to the prescribing information and patient medication guides for these medications.

How many copies of your Consultant Pharmacist's Monthly Report, EPIC Service Reviews and IMRR do you receive?

At the end of a visit from your Pharma-Care, Creative Care or Rasa Group consultant pharmacist generate a Summary Report. The Report contains important suggestions, information, comments, summaries and recommendations for your nurses and physicians in regards to resident care. Many facilities receive between 5 and 10+ copies of each report, is the distribution listing correct for your facility?



How many staff members actually review the reports in a timely manner?

In a recent three month study conducted by our technical services department on the emailing of reports the results indicated the following average for the period of September 2023-November 2023.

32,765	32,437	19,7867	655
Emails SENT	99% DELIVERED	61% OPENED	2% DROPPED

The results of this study has show that 12,650 were never opened by the recipient. The 655 emails dropped were mainly caused by email address that no-longer existed.



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Health Care Consultation Specialists

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Nursing Notables

Polypharmacy...



Definition:

Using multiple medications to treat a single condition or coexisting conditions:

Potential Negative Outcomes:

- ✓ Decreases patient quality of life
 - Increased pill burden
 - Increased cost
 - Excessive monitoring (fingersticks, labwork, blood pressure, etc.)
 - Adverse events and side effects
- ✓ Slows medication pass
- ✓ Drug-drug interactions
- ✓ F-tag 757 citation (unnecessary medication)

Examples of Polypharmacy: (All medications should be reassessed periodically for need)

- ✓ Therapeutic interchange drug-Original drug ordered is not discontinued when interchanged drug is received from pharmacy
- ✓ Antipsychotic or sedative/hypnotic should have a trial reduction due to evidence of behavior resolution
- ✓ Appetite stimulant is continued after goal weight is reached, ineffective, or surpassed
- ✓ PPI, H2-blocker, and Carafate used long-term for indication of GERD
- ✓ Antihistamines used long-term for indication of seasonal allergies
- ✓ Several laxatives used when constipating drugs are discontinued or condition resolves
- ✓ Vitamins and supplements are continued once the deficiency has been resolved
- ✓ Drugs are added to regimen before behavioral interventions have been tried
- ✓ Midodrine used with other medications that have an antihypertensive indication



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Minimize meds & maximize outcomes!



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