the Remedi Pulse

NAVIGATING THE PANDEMIC

Remedi SeniorCare EDUCATION Rx

A CLINICAL AND REGULATORY UPDATE FROM REMEDI SENIORCARE

2021 VOLUME 1

Survey Solutions

with William Vaughan, BSN, RN
VP of Education & Clinical Affairs

When CMS met the Novel Coronavirus, It was an Expensive Introduction

Summary of Events

February 2020 began uneventfully for the 120 residents and 170 staff members at the five-star rated skilled nursing facility, Life Care Center of Kirkland, located in Kirkland, Washington. About two weeks later, circumstances began to change when a cluster of febrile respiratory illnesses among their residents was identified. Rapid influenza tests were promptly performed, all of which were negative. By February 23, 14 residents had been diagnosed with facility-acquired lower respiratory infections, including several cases of pneumonia.

On February 26, dozens of residents, visitors and staff attended a Mardi Gras themed party in one of the facility's common areas. That same day, the facility notified the local health department of the spike in illnesses. Admissions were stopped and coronavirus testing, which at the time was not readily available to facilities, was initiated through the health department. By late in the evening on February 28, results confirmed the first documented case of COVID-19 in a resident of a nursing facility in the United States.

Over the next few days, the situation rapidly deteriorated with multiple residents and staff showing signs and symptoms consistent with COVID-19. During the first week of March, with 30% of the staff too ill to work, Kirkland reached out for help from the Department of Health and Human Services writing "... we will agree to whatever it takes to receive federal assistance. Simply stated, we are desperate for licensed nurses and nursing assistants." Help would eventually come, but not before federal surveyors arrived to assess the facility's response to the outbreak. CMS characterized the visit as a complaint survey.

Joining the federal surveyors were staff from the CDC, the local health department and the Washington state survey agency. According to Kirkland's management, between staff interviews and securing thousands of documents demanded by the surveyors, 400 hours of staff time was diverted from resident care to respond to the survey process.

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"By late in the evening of February 28, results confirmed the first documented case of COVID-19 in a resident of a nursing facility in the United States."

FOR MORE INFORMATION
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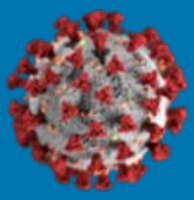

COVID-19 VACCINES AND ANTIBODY THERAPY

Presented by: Erin Foti, PharmD, BCGP, Director of Consulting Services

	Pfizer and BioNTech COVID-19 Vaccine	Moderna COVID-19 Vaccine	Bamlanivimab Monoclonal Antibody
Recipients	Individuals 16 years and older	Individuals 18 years and older	Individuals with mild-moderate COVID-19 who are 12 years and older weighing at least 40 kg and are at increased risk for disease progression
Dosage and Administration	0.3 mL IM in two doses separated 21 days	0.5 mL IM in two doses separated 28 days	700 mg via IV for one dose
Allergies	• Does not contain egg, gelatin, latex • Do not take if allergic to any component within vaccine	• Does not contain egg, gelatin, latex • Do not take if allergic to any component within vaccine	• There is potential for serious hypersensitivity or infusion related reactions • Healthcare provider should have access to emergency medications and protocols
Adverse Side Effects	• Injection site pain (injection site redness/swelling) • Fatigue • Headache • Muscle/joint pain • Chills • Fever • Nausea/Vomiting • Swollen lymph nodes	• Injection site pain (also swelling or redness at injection site) • Fatigue • Headache • Myalgia • Chills • Nausea/Vomiting • Fever • Axillary swelling or tenderness	• Nausea/Diarrhea/Vomiting • Dizziness • Headache • Itching • Chills • Fatigue • Chest Discomfort • Rash • Syncope
Storage	• Must be kept at ultra-cold temperatures (-112 to -76^{o} F) and protected from light	• Unused vials may be stored frozen from -13 to -5^{o} F and protect from light	• Preservative free, should be administered as soon as possible. It may be stored for up to 24 hours refrigerated (36^{o} to 46^{o} F) and up to 7 hours at room temperature
Reporting	• Severe adverse events should be reported to the Vaccine Adverse Event Reporting System (VAERS)	• Severe adverse events should be reported to the Vaccine Adverse Event Reporting System (VAERS)	• Prescriber must report all medication errors or serious adverse events within 7 calendars to FDA MedWatch and Eli Lilly
Additional Requirements	• Recipients should be observed for 15 minutes (30 minutes if history of anaphylaxis)	• Recipients should be observed for 15 minutes (30 minutes if history of anaphylaxis)	• Should be administered as soon as possible following + COVID 19 results and within 10 days of symptom onset

Inclusion Criteria to Receive Medication	• Age 16 years and older
	• Vaccine administration up to individual states
		• Age 18 years and older
		• Vaccine administration up to individual states
			• Patients must meet <u>at least one</u> of the following criteria:
			  • Age ≥ 65
			  • Body mass index (BMI) ≥ 35
			  • Chronic kidney disease
			  • Diabetes Mellitus
			  • Immunosuppressive disease
			  • Receiving immunosuppressive therapy
			• If ≥ 55 years of age AND have cardiovascular disease, OR hypertension, OR COPD/other chronic respiratory disease

Contraindications	Allergies to any vaccine component	Allergies to any vaccine component	• Not authorized for hospitalized patients with COVID-19 • Not authorized for COVID-19 patients requiring supplemental oxygen therapy • Not authorized for individuals who require an increase in baseline oxygen flow rate due to COVID-19

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When CMS met the Novel Coronavirus

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Sanctions

During the survey on March 13th, CMS notified the facility of several immediate jeopardy deficiencies centering on three regulations; F684 (Quality of Care), F713 (Physician Availability for Emergency Care) and F880 (Infection Prevention and Control). As with all IJ level deficiencies, Kirkland was required to immediately develop and implement a plan of correction. By March 16, the CDC had identified 129 cases of COVID-19 involving 81 residents, 34 staff members, and 14 visitors; 23 persons had died. Based on multiple deficiencies, CMS imposed a federal per day civil money penalty of $13,585, effective February 12 through March 27, totaling $611,325. Using the same deficiencies and acting under state authority, Washington imposed a ban on admissions. This marked the first in a series of COVID-19 related sanctions imposed by CMS and state survey agencies on nursing homes across the country in 2020.

Summary of Sanction Related Deficiencies

- The facility failed to have a timely and comprehensive systematic response to the outbreak. To establish the timeline of events and the scope of the outbreak, surveyors relied on various interviews including the following:

During an interview … with the Infection Preventionist (IP) Nurse, she acknowledged having concerns and seeing a cluster with respiratory infections occurring in the facility on approximately 02/12/2020 and had a discussion with Medical Provider 1 (MP1). The IP Nurse stated, "I did not consider calling the Department of Health because it was Flu season and the residents at the facility commonly have Pneumonia. The residents were being treated with antibiotics by the medical providers and being tested for Rapid Flu." She further confirmed all Rapid Flu Tests were negative.

- The failure to contact the health department until 14 days later, as well as the facility's decision continue to admit residents, was strongly criticized. The deficiency statement highlighted several residents who were admitted during this period, became infected with the coronavirus and died.

Resident #118 admitted to the facility on 02/12/2020 with diagnoses of Chronic Obstructive Pulmonary Disease (COPD), Cancer of Bladder, and Chronic kidney disease. The resident was transferred to the hospital on 02/18/2020 with shortness of breath, tested positive for COVID-19 and expired on 2/26/20.

Resident #125 admitted to facility on 02/19/2020 with diagnoses of CHF, Pneumonia (PNA), and COPD. Resident was transferred to the hospital on 02/27/2020 with respiratory distress, tested positive for COVID-19, and expired on 03/04/2020.

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Vaccine and Antibody Therapy

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FREQUENTLY ASKED QUESTIONS

What is an emergency use authorization or EUA?

- **An EUA is a tool used by the Food and Drug Administration (FDA) during an emergency period to authorize medications, testing, and medical supplies outside of completed clinical trials. Their decision to authorize use is based on available evidence in effectiveness and safety. If there is strong evidence available that is beneficial, an EUA can be given**

What is a mRNA vaccine?

- **Contain material from COVID-19 (S-Protein) encoded in genetic material that will give our cells instructions on how to make this protein that is unique to COVID-19. Our bodies will recognize that the protein is foreign and build immunity against it**

Will the COVID-19 vaccine cause COVID-19?

- **No it does not contain a live virus or inactive virus**

Other considerations for COVID-19 vaccination/Bamlanivimab Administration

- **COVID-19 vaccines should be given alone with a minimum interval of 14 days before or after any other vaccines**
- **Persons with current known COVID-19 infection should defer from vaccination until recovery from acute illness if symptomatic AND criteria have been met to discontinue isolation**
- **Persons with prior history of COVID-19 infection should be offered vaccination regardless of symptomatic or asymptomatic infection**
- **Persons receiving antibody therapy for COVID-19 should defer vaccination for at least 90 days to avoid interference with the vaccine-induced response**

"We've worked with Remedi to provide monoclonal antibody therapy to our residents with very positive results and limited adverse reactions."

- Jimmy Harrington
Vice President of Clinical Services
FutureCare Health & Management Corporation

When CMS met the Novel Coronavirus

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Resident #129 admitted to facility on 02/24/2020 with diagnoses of CHF and PNA. Resident was transferred to the hospital on 03/02/2020 with abnormal vital signs, tested positive for COVID-19, and expired on 3/3/20.

- The lack of timely medical evaluations for these and many other residents whose conditions declined was also cited. The surveyors attributed the lack of evaluations to the fact that the facility's Medical Director, who eventually was diagnosed with COVID-19, was the attending physician for more than 90% of the facility's residents. Additionally, when residents were seen by a physician, there were frequently no corresponding notes documented in their medical record. An interview of one physician, who was not the Medical Director, revealed that "with all of the multiple evaluations, treatment decisions, and transfers of residents to hospitals, she was not able to keep up with all of the associated documentation and communications." The facility's Executive Director and other management staff were interviewed on 3/11 and indicated that:

"… [the physician] was still in the process of writing her resident evaluation notes from late February and early March. They stated that during that time, "it was very chaotic" and no written medical provider evaluations would be available because there had been too many residents becoming acutely ill, "We were triaging residents as the residents were crashing, so there wasn't going to be a lot of documentation."

- The nursing and direct care staffs were also criticized for failing to adequately monitor residents, particularly related to the vital signs and oxygen saturation. Interview of the administrative staff indicated:

"[The facility] could not manage their normal processes without leaning on the CDC and Department of Health (who the facility did not notify of the outbreak until 02/26/2020). She also stated, "We lost lots of staff quickly, greater than 30."

Appeals

Kirkland appealed the federal civil money penalty and asked for an expedited hearing, a request supported in writing by The Society for Post-Acute & Long-Term Care Medicine and the American Health Care Association. That "expedited" hearing is currently scheduled for April of 2021. Kirkland simultaneously appealed the state imposed ban on admissions, that hearing took place over four days in June. After hearing testimony and reviewing all of the evidence, the administrative law judge concluded that, while Kirkland had violated some regulations, the state had "abused its discretion" in imposing the ban on admissions. The ban was subsequently reversed.

Discussion

The state and federal response to the outbreak in Kirkland was largely condemned by long-term care providers, and the organizations that represent them, as punitive and counterproductive. Looking beyond the regulatory-related public policy issue, there are still some "on the ground" lessons to be learned.

- In the context of overall infection control requirements, facilities should be well versed in the regulations related to reporting of outbreaks. These are state specific and typically define an outbreak in terms of clinical presentations and suspected organisms. Prior to COVID-19, examples included suspected or confirmed influenza, norovirus and scabies.

- Medical Directors, serving as the attending physician for the majority of residents, create unique regulatory risk. Apart from the availability issue reflected in the Kirkland deficiencies, Medical Directors have an oversight responsibility which obviously can't be fulfilled by evaluating their own care. This conflict is addressed in the guidance to surveyors at F841 and requires the facility to have a process to oversee the Medical Director when he is functioning as the attending physician.

- Federal emergency preparedness regulations stress the need for facilities to develop a plan to meet staffing and equipment shortages. Given the incredible toll the pandemic has taken on healthcare resources across all settings, long-term care facilities should review their individual plans. COVID-19 has exposed system weaknesses that previously could not be imagined.

Lastly, the appropriateness of the regulatory response to the pandemic will be debated for years to come. However, it will not overshadow the sacrifices of long-term care providers and their staffs across the nation, who demonstrated heroic resolve as they advocated for those in their care, often in the face of genuine risk to themselves and their families.

NOTE: Bill was a surveyor with the Maryland State Survey Agency from 1988 until 2001. He became Chief Nurse of the Agency in 2001 and remained in that position until joining Remedi SeniorCare in 2013.

REFERENCES

Kirkland's request for an expedited appeal of federal sanctions:
https://www.hhs.gov/about/agencies/dab/decisions/board-decisions/2020/board-rul-2020-3/index.html

Summary of Kirkland's state appeal of ban on admissions:
https://medicareadvocacy.org/state-administrative-law-judge-largely-clears-lifecare-center-of-kirkland-first-nursing-home-in-country-with-covid-19-outbreak/

Remedi Superstar Nurse

The decision as to who should be this edition's Superstar Nurse was an easy one. Congratulations to our long-term nurse colleagues all across the country, especially those who work in the facilities and communities that are supported by Remedi SeniorCare. We cannot think of a more deserving group of continued appreciation and applause. For the past ten months, you have put yourselves on the front lines to work around the clock serving and protecting your residents from the impact and spread of COVID-19. You have given of your talents tirelessly and selflessly.

You continue to face adversity as you work through the challenges created by COVID-19.

You have mourned losses and celebrated victories.

You have done things you never thought you would or could.

You have been caregivers, but you have also been family and friends during this time.

You embody the true meaning of the word "hero" and remind us just how strong the human spirit can be.

We are so honored to journey alongside you and be your partner in resident care.

Thank you, nurses!

"As COVID-19 keeps our industry in the spotlight, the resilience and determination demonstrated by your teams, especially those on the frontlines, continues to amaze and inspire us. Thank you for your continued trust and partnership as we navigate a new year. We're confident that the light at the end of the tunnel will grow brighter as we work together on behalf of the seniors that we mutually serve."

- Jeffrey M. Stamps, R.Ph.
President and CEO
Remedi SeniorCare

Email your Superstar Nurse nominations to Rebecca.Ogden@RemediRx.com