GREATER NEW YORK NEWS

Greater New York Health Care Facilities Association

FOR THE NEWS THAT MATTERS TO OUR MEMBERS



Facility Recognition

Thank you to Excelsior Care Group for reminding us there is always fun to be had!

You continue to go above and beyond to provide the upmost care for your residents, families, and staff.

Clinical Focus: COVID-19, Influenza, Respiratory Illnesses

Mary Gracey-White, RN, Director of Regulatory Compliance, reminds facilities of continued infection prevention and encourages facilities to stay vigilant in early identification of respiratory illnesses, alongside COVID-19.

Life Safety Review

John Kerney, Life Safety
Consultant, reviews F Tag-584,
an all-encompassing citation,
which requires maintaining a
clean, safe, homelike
environment, and encourages
facilities to review their policies.

Pfizer COVID-19 Licensure Announced

On Monday, August 23, 2021, the U.S. Food and Drug Administration approved the first COVID-19 vaccine. Please find an overview on page 3.

Upcoming Webinar

Save the date for our next webinar in **September 2021**. Please be sure to visit our website at www.gnyhcfa.org for additional information.

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Pfizer COVID-19 Vaccine Licensure Announced

FDA Approves First COVID-19 Vaccine

On Monday, August 23, 2021, the U.S. Food and Drug Administration approved the first COVID-19 vaccine. The vaccine has been known as the Pfizer-BioNTech COVID-19 Vaccine, and will now be marketed as Comirnaty, for the prevention of COVID-19 disease in individuals 16 years of age and older. Comirnaty contains messenger RNA (mRNA), a kind of genetic material. The mRNA is used by the body to make a mimic of one of the proteins in the virus that causes COVID-19. The result of a person receiving this vaccine is that their immune system will ultimately react defensively to the virus that causes COVID-19. Comirnaty has the same formulation as the EUA vaccine and is administered as a series of two doses, three weeks apart.

The vaccine also continues to be available under Emergency Use Authorization (EUA), including for individuals 12-15 years of age, and for the administration of a third dose in certain immunocompromised individuals.

Based on results from the clinical trial, the vaccine was 91% effective in preventing COVID-19 disease. The most commonly reported side effects by those clinical trial participants who received Comirnaty were pain, redness and swelling at the injection site, fatigue, headache, muscle or joint pain, chills, and fever. The vaccine is effective in preventing COVID-19 and potentially serious outcomes including hospitalization and death.

Resources:

https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine

Clinical Focus: COVID-19, Influenza, Respiratory Illnesses Mary Gracey-White, RN, Director of Regulatory Compliance, GNYHCFA

As we transition from summer to fall, we need to continue our infection prevention vigilance, with the early identification of respiratory illnesses, including but not limited to, COVID-19.

Breakthrough COVID-19 infections in vaccinated individuals, as well as increased cases caused primarily by the Delta variant, are challenging but (as of now) not insurmountable. Facilities are well versed in outbreak testing, cohorting, PPE use, and Transmission Based Precautions. With the NYS mandate for HCW vaccination in nursing homes and hospitals, we look forward to not having to test unvaccinated workers, unless there are those who qualify for a medical/religious exemption.

CMS posts data collected from NHSN weekly regarding positivity rates and frequency testing. To access this data, click <u>here</u>.

The FDA approved a modification to the EAU to allow immunocompromised individuals to receive an additional dose of the Pfizer or Moderna vaccine. The CDC differentiates an additional dose and a booster dose. This includes two distinct potential uses for an additional dose of COVID-19 vaccine.

Additional Dose (after an initial primary vaccine series)

 An additional dose of vaccine administered when the immune response following a primary vaccine series is likely to be <u>insufficient</u>. An additional mRNA COVID-19 vaccine dose is recommended for moderately to severely immunocompromised people after an initial 2-dose primary mRNA vaccine series. This can be administered 28 days after the 2nd dose.

Booster Dose

An additional dose of vaccine administered when the initial sufficient <u>immune</u> <u>response to a primary vaccine series is likely to have waned over time</u>. The need for and timing of a COVID-19 booster dose has not yet been established. No booster doses are recommended at this time. This guidance may be updated as more information becomes available.

Through resident medical records, facility Medical Directors and PMD/NPs need to determine which residents qualify as immunocompromised for an additional dose of Pfizer or Moderna mRNA vaccines and arrange for vaccination, which includes consents. At present, the FDA and ACIP have not provided recommendations for an additional dose for those vaccinated with J and J (Janssen) adenovector vaccine.

With nursing homes being a priority, discussions of booster doses for the general population are in process including some preliminary information that people receive the booster dose after having been fully vaccinated 8 months prior. This would place most residents to receive a booster around October, coinciding with the time frame many facilities are administering the influenza vaccination.

The CDC issued guidance on the Coadministration of COVID-19 vaccines with other vaccines. COVID-19 vaccines were previously recommended to be administered alone, with a minimum

interval of 14 days before or after administration of any other vaccines. This was out of an abundance of caution and not due to any known safety or immunogenicity concerns. However, substantial data have now been collected regarding the safety of COVID-19 vaccines currently authorized by FDA for use under EUA.

COVID-19 vaccines and other vaccines may now be administered without regard to timing. This includes simultaneous administration of COVID-19 vaccine and other vaccines on the same day, as well as coadministration within 14 days. It is unknown whether reactogenicity of COVID-19 vaccine is increased with coadministration, including with other vaccines known to be more reactogenic, such as adjuvanted vaccines or live vaccines. When deciding whether to coadminister an(other) vaccine(s) with COVID-19 vaccine, vaccination providers should consider whether the patient is behind or at risk of becoming behind on recommended vaccines, their risk of vaccine-preventable disease (e.g., during an outbreak or occupational exposures), and the reactogenicity profile of the vaccines.

If multiple vaccines are administered at a single visit, administer each injection in a different injection site. For adolescents and adults, the deltoid muscle can be used for more than one intramuscular injection administered at different sites in the muscle.

Best practices for multiple injections include:

- Label each syringe with the name and the dosage (amount) of the vaccine, lot number, the initials of the preparer, and the exact beyond-use time, if applicable.
- Separate injection sites by 1 inch or more, if possible.
- Administer the COVID-19 vaccines and vaccines that may be more likely to cause a local reaction (e.g., tetanus-toxoid-containing and adjuvanted vaccines) in different limbs, if possible.

GNYHCFA has had initial discussion with NYSDOH and will facilitate and disseminate any NYSDOH guidance.

The CDC issued a Health Advisory regarding increased cases of RSV (Respiratory Syncytial Virus). The CDC encourages broader testing for RSV among those presenting with acute respiratory illness who test negative for SARS-CoV-2. RSV can be associated with severe disease in young children and older adults. As we do not know what to expect this fall with Influenza season, planning may include expanding facility capability for point of care testing for Influenza and RSV. Clinical considerations for POC Testing (Insert McKesson info on RSV, Influenza POC testing). Now that staff are competent in POC testing, facilities should consider adding Influenza and RSV to the CLIA waiver to expand current testing capabilities. GNYHCFA reached out to McKesson for information on expanded POC testing and can provide this information, as well as post it on our website. This can aid in early identification/differentiation and treatment of respiratory illnesses to aid in improving clinical care, delays in lab results, and potentially avoiding unnecessary hospitalizations.

Resources:

Interim Clinical Considerations for Use of COVID-19 Vaccines | CDC Considerations for Additional Dose of COVID-19 Vaccine Following a Primary Vaccine Series Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the US CDC Health Advisory: Respiratory Syncytial Virus Activity

Life Safety Review

John Kerney, Life Safety Consultant, GNYHCFA

Survey Focus: Environmental

Over the past 18 months during the Pandemic, it has been very difficult to maintain the facility environment up to the usual standards. Recent surveys have documented this under the FTag-584, which is an all-encompassing citation. This requires maintaining a clean, safe, homelike environment.

Included can be:

- Scratches in paint
- Rust stains in areas
- Dust behind a bed
- Resident daily use items such as wheelchairs can have damage to upholstery or require brake adjustments

Facilities must have documentation in place for requested repairs and need to follow up that repairs are made in a timely manner. It is recommended that a program is implemented for routine room inspections, including both Housekeeping and Maintenance items. Facilities also need to ensure they have policies for special cleaning of rooms and service areas as well as schedules for special room maintenance like painting and wheelchair cleaning.

We recommend facilities conduct a QAPI set up for tracking time to complete requested repairs and see if the time frames are appropriate.

As we have many new surveyors out there, the process has become increasingly focused. In the facility, we are seeing more areas including rooms and closets surveyed for a clean, safe, homelike environment. The survey process regarding environmental issues is likened to previous survey times, when NYSDOH sanitarians came and spent the entire week.

<u>Remember</u> - if you would not accept it in your house, then it should not be in our residents' home.

At GNYHCFA we are here to assist, please contact us if you need more information.