BrightSpring Health Services Enterprise Outbreak Preparedness Plan

Version 10: October 2021

Update: Summary of Our Response

Since the novel Coronavirus 2019 (COVID-19) pandemic began in early 2020, BrightSpring Health Services has focused on implementing best practices in infection control, visitor management, employee screening, and streamlined reporting and triage protocols to optimally support and protect clients, patients, employees, families and communities. To date, we have experienced an overall infection rate of less than one-half of that of the general population of the United States, and have reported our preparation plan, tactics, experience and data in numerous peer-reviewed research publications, including the below:

1. Supporting individuals with intellectual and developmental disability during the first 100 days of the COVID-19 outbreak in the USA. *Journal of Intellectual Disability Research* 2020, 64: 489-496. https://doi.org/10.1111/jir.12740
2. An Outbreak Preparedness and Mitigation Approach in Home Health and Personal Home Care During the COVID-19 Pandemic. *Home Health Care Management & Practice* 2020. https://doi.org/10.1177/1084822320933567
3. Hydroxychloroquine Sulfate Prescribing Trends and Pharmacist-Led Outbreak Preparedness in Long Term Care Pharmacy During COVID-19. *Journal of the Medical Directors Association* 2020. https://doi.org/10.1016/j.jamda.2020.06.012
4. Home Based Primary Care Led-Outbreak Mitigation in Assisted Living Facilities in the First One Hundred Days of COVID-19. *Journal of the American Medical Directors Association* 2020. https://doi.org/10.1016/j.jamda.2020.06.014

This plan version has been updated to incorporate evolving public health guidance as well as our own experiential best practices as we enter the twenty first month of the COVID-19 pandemic.

Introduction

BrightSpring Health Services ("Company") takes all outbreak threats very seriously. While we have had an organizational disaster and pandemic plan for many years, with the new threat posed by the novel Coronavirus and COVID-19, we have we have adopted additional tactics and committee governance to be able to respond to COVID-19 and other potential outbreaks with agility – to meet both the rapid pace of information being disseminated, and the concerns that people in the community have about COVID-19.

Outbreak Preparedness and Action Committee

We have leveraged the cross-functional expertise of a diverse set of medical, clinical, risk management, human resources, legal, communications and operations leaders throughout our organization and formed an Outbreak Preparedness and Action Committee ("Committee"). The mission of the Committee is to prepare for potential outbreaks and to act when necessary to protect, support and serve our patients, clients and employees. The Committee embodies the principles of preparation, reassurance, evidence-based action, coordination, communication and support. The Committee works with operators and stakeholders to identify areas of patient, client and employee outbreak risk and prepares the organization for such threats. The Committee also serves as a

means of consolidating internal and external communications regarding COVID-19 and other potential outbreaks. Dr. William Mills is Chair of the Committee and serves as the Company's Safety Coordinator. In turn, the Outbreak Committee works with regional and local safety coordinators to implement and monitor the outbreak plan on an ongoing basis. The Committee also oversees and monitors COVID-19 workplace hazard safety assessments to assess and mitigate risks to employees, patients, clients and communities. Input from managers and non-managerial staff is collected and reviewed in an ongoing basis via an "open-door" communication policy, whereby all employees have had the Outbreak Committee and Safety Coordinators contact information made available, and formally provided over 76 times between January, 2020 and present. In addition, the Company's Compliance Line fields COVID-19 related employee concerns, which are communicated to the Committee.

Situation Summary

The virus is named "SARS-CoV-2" (*Figure 1*) and the disease it causes has been named "coronavirus disease 2019" (abbreviated "COVID-19"). Early on, many of the patients in the COVID-19 outbreak in Wuhan, China, had some link to a large seafood and live animal market, suggesting animal-to-person spread. Since, a growing number of patients reportedly did not have exposure to animal markets, indicating person-to-person spread. After implementing travel restrictions and robust infection control, the number of new daily cases of COVID-19 in Wuhan decreased significantly (*Figure 2*).

Figure 1. This transmission electron microscope image shows SARS-CoV-2, the virus that causes COVID-19—isolated from a patient in the U.S. Virus particles are shown emerging from the surface of cells cultured in the lab. The spikes on the outer edge of the virus particles give coronaviruses their name, crown-like. *National Institute of Allergy and Infectious Diseases*

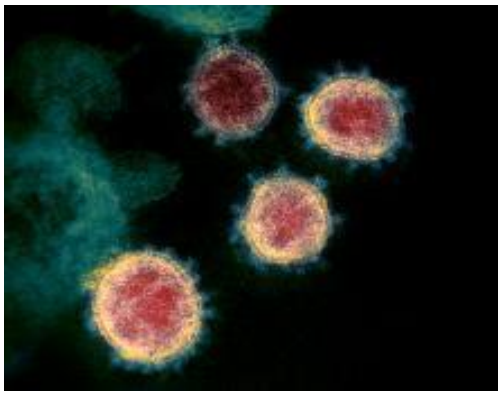
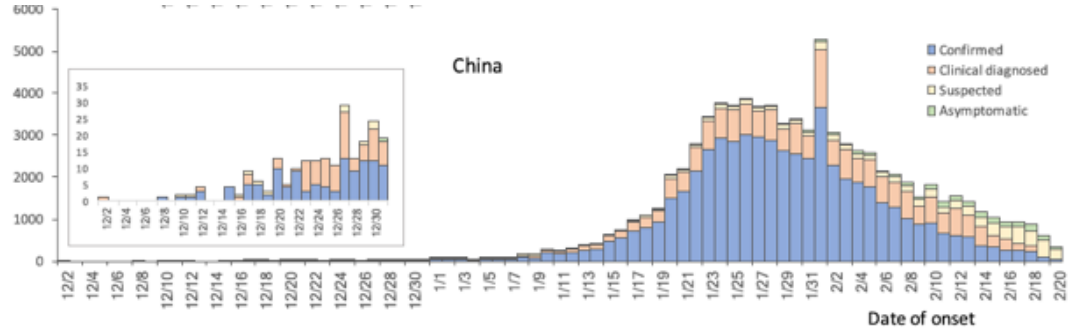


Figure 2. Number of new daily cases of COVID-19 in China steadily decreased since infection control measures and travel restrictions were implemented.



Our organization is using the data that illustrate that the infection control measures taken in China and other countries are working, to sharpen our focus on our own efforts on best practices in infection control and prevention. We are also following the incidence of new daily cases in a number of countries to help inform our trajectory estimate and planning for the situation in the US (*Figure 3a*). We have monitored international and U.S. case rates throughout the pandemic, and at the time of the writing of this Plan update, new daily cases have decreased steadily since vaccinations became available, and as of mid-June 2021, have plateaued at approximately 15,000 per day (*Figure 3b*).

Figure 3a. New daily cases of COVID-19 between January 21, 2020 and July 30, 2020

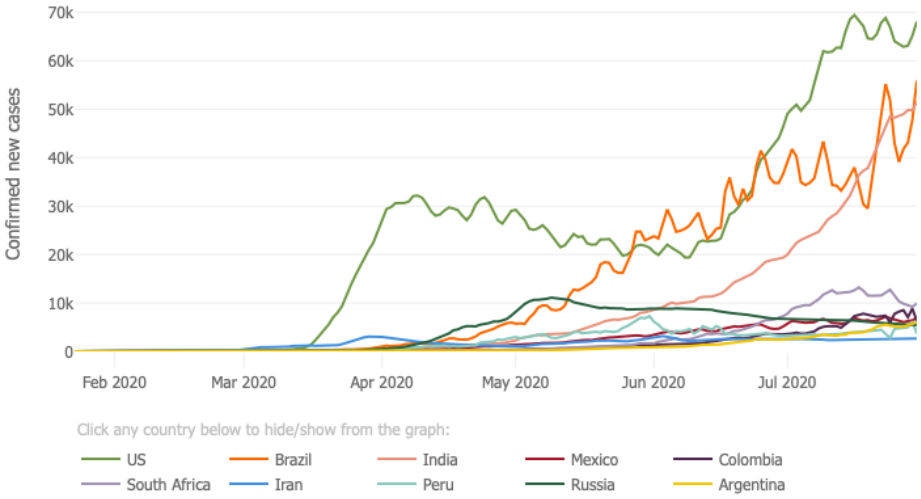


Figure 3b. New daily cases of COVID-19 in the U.S. as of June 14, 2021

Global Situation Summary

The Company is actively monitoring the global situation daily, in order to understand transmission patterns, rate of spread, mitigation tactics, and to highlight geographies that represent high risk travel for employees or family members of employees. Our primary monitoring source is the Johns Hopkins University Coronavirus Resource Center (*Figure 4*), in addition to the Centers for Disease Control and Prevention (CDC) and World Health Organization's (WHO) COVID-19 situation rooms.

Figure 4. Johns Hopkins University Coronavirus Resource Center Dashboard.

Situation in U.S.

The Outbreak Committee monitors the situation rooms from Johns Hopkins University daily, and utilizes "Heat Maps" updated so we can best direct our local operations in markets. These trackers are shown below, for illustrative purposes (*Figure 5a-5b*).

Figure 5a. U.S. State "Heat Map", which shows the new daily COVID-19 case incidence trends by state. The line represents the three day moving average of new cases, and the background color represents the overall trend of new cases in a state (green=downward trend; red=upward trend).

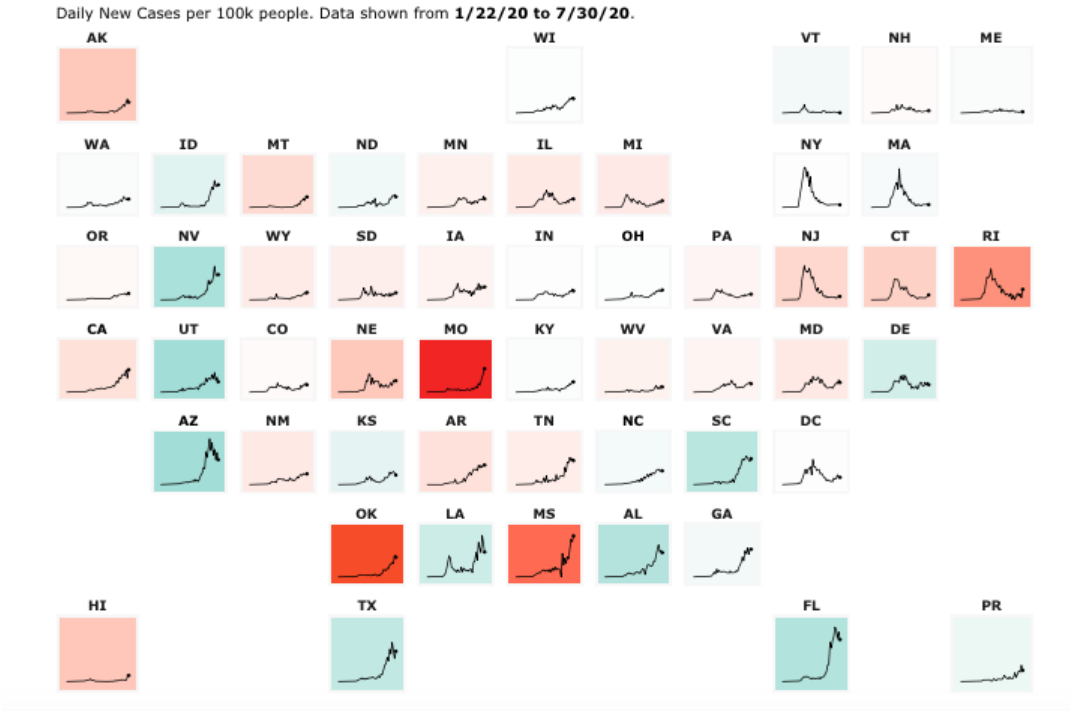
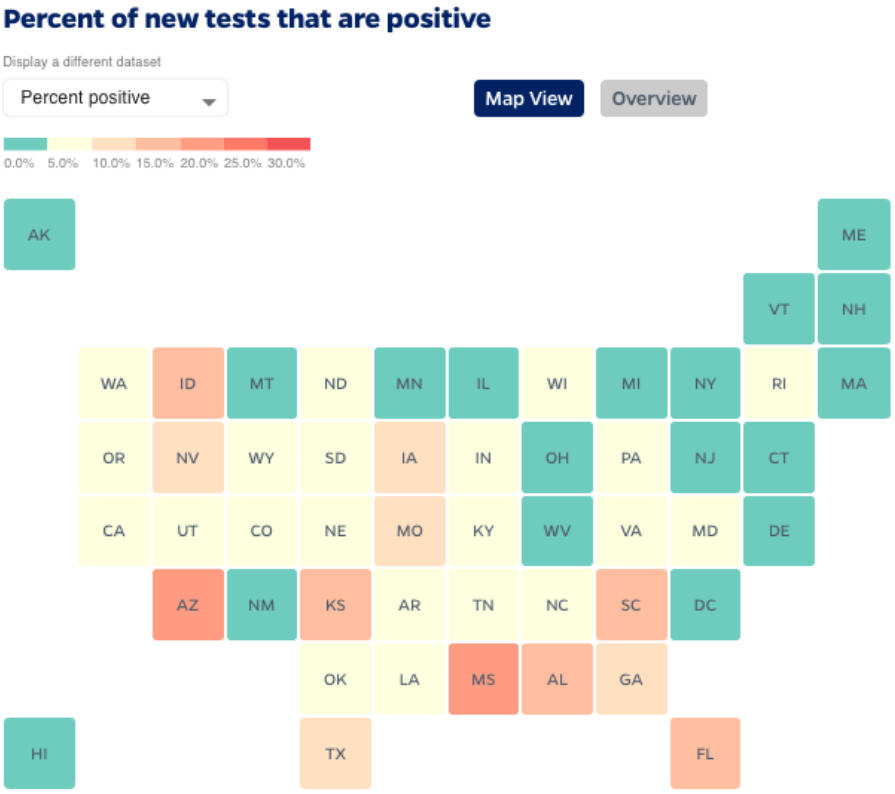


Figure 5b. [Percent of new tests that are positive by state], which shows the COVID-19 positivity rate. This tracker can be used to view transmission trends, which can support social distancing and infection control measures decision making.



Assessment and COVID-19 Case Definition

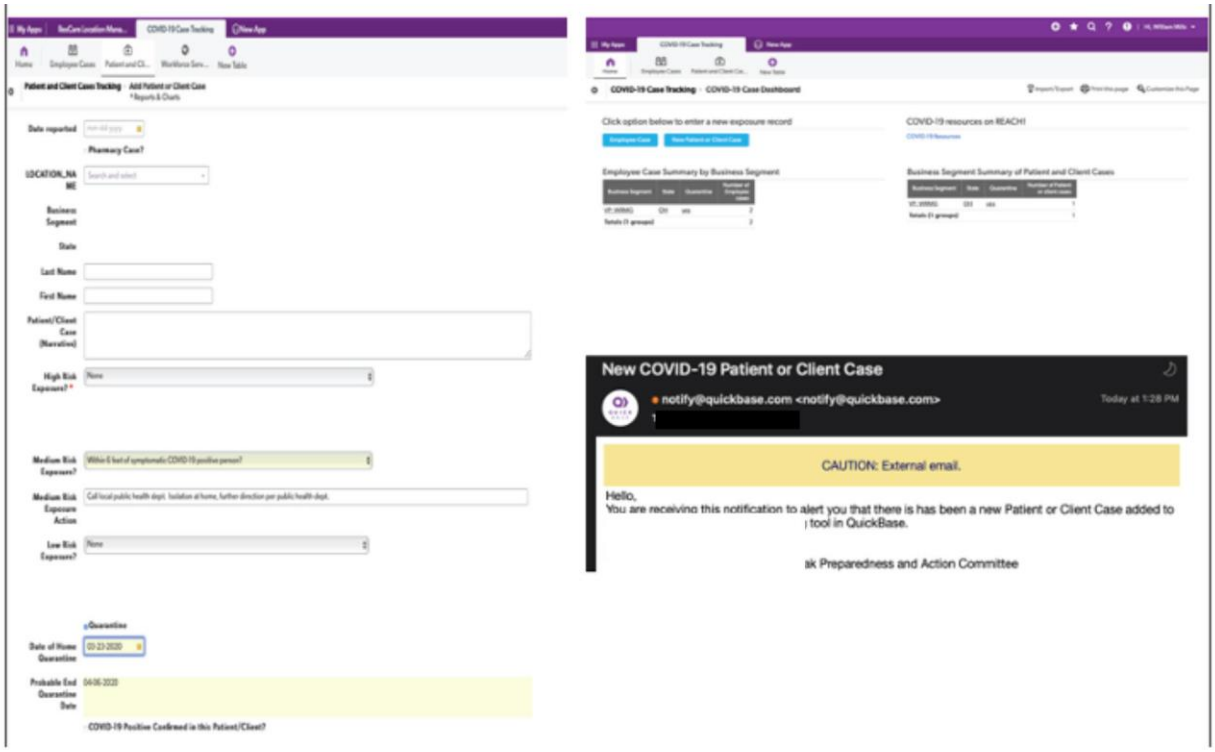
When assessing individuals with a fever and lower respiratory symptoms, such as coughing or shortness of breath, or asymptomatic individuals with potential exposures, [we utilize CDC testing and isolation algorithms.] A positive case is defined as a positive nucleic acid swab / polymerase chain reaction test for SARS-coV-2 RNA.

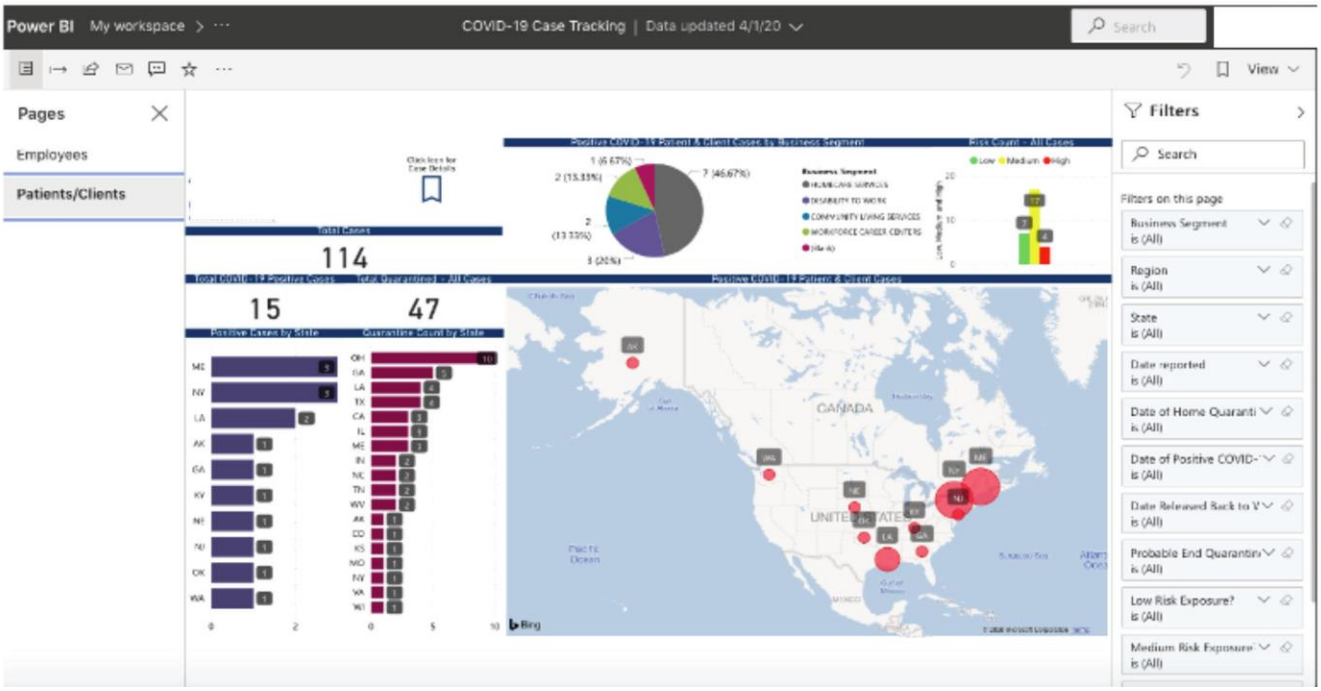
COVID-19 Case Tracking and Visualization Application

In order to streamline COVID-19 case and exposure triage and reporting, we built a secure, cloud-based web application. The application leverages a QuickBase (QuickBase, Inc., Cambridge, MA) data structure to quickly capture confirmed cases as well as potential exposures from our operations sites across the U.S (Figure 6, Panel A). Entry of new patient cases auto-notified of our team of nurses. The nurses then advised the operations team at our local and regional sites to assist with triage and planning. The clinical and operational plan included reinforcement and training on necessary quarantine and isolation procedures, as well as ordering additional personal protective equipment (PPE) supply. Entry of new employee cases or exposures triggered an auto-notification to that location's human resources partner, who then worked with the clinical team and the employee to support triage and assessment. To optimize our ability to visualize COVID-19 positive patients, clients and employees by business segment and geography, we also developed a business intelligence application, leveraging Power BI (Microsoft Corp, Redmond, WA) Figure 6, Panel B. The

clinical, operations, human resources, and executive teams use the visualization tool throughout the day as a “situation room” that enabled us to deploy specific mitigation tactics as cases emerged.

Figure 6. COVID-19 Case Tracking and Data Visualization Application.
Panel A. COVID-19 tracking application that stratifies risk using CDC guidance.
Panel B. COVID-19 case visualization application.





Enterprise Infection Control and Prevention Policy

The Company effectuated a new Enterprise-Wide Infection Control and Prevention Policy, aimed at providing enhanced protection for the patients, clients and employees we serve (*Exhibit A*). Adoption of the policy is optimizing our ability to prevent and control outbreaks in all business segments. Training on the policy has been deployed through a combination of intranet resources as well as on-site and web-based live meetings. The Company has implemented nurse-leader hosted infection control and isolation protocol web meetings, occurring regularly, open to all employees. Hundreds of employees are currently attending these sessions per week.

Supplies

The organization has aggressively acquired PPE in utilizing its large procurement team and approaching many potential global suppliers, attempting to identify reliable sources of PPE. To enable consolidated ordering and distribution of PPE to all Company sites, we formed a new Central Supply distribution center (*Figure 7*). Full PPE kits were assembled and shipped to all locations, in addition to extra allotments of surgical masks, hand sanitizer, cleaning materials, and other items required to effectuate optimal infection. We have implemented the recent recommendations by CDC and the Centers for Medicare and Medicaid Services to use surgical masks for respiratory droplet precautions in non-aerosol-generating situations until the N95 supply chain is restored (*Exhibit B*). We have set up a dedicated email address to streamline requests at PPEsupplyrequests@brightspringhealth.com. Current PPE inventory and order status is communicated daily between Procurement and the Outbreak Committee. PPE kits have been assembled and shipped to locations out of our new Central Supply (*Figure 7*), which has been set up in Louisville as a collaborative effort between the Outbreak Committee and Procurement. All locations have received full PPE kits, and none are currently undersupplied based use scenarios outlined in our Infection Control Policy.

Figure 7. BrightSpring employees sorting PPE for placement into kits for shipping to all locations.

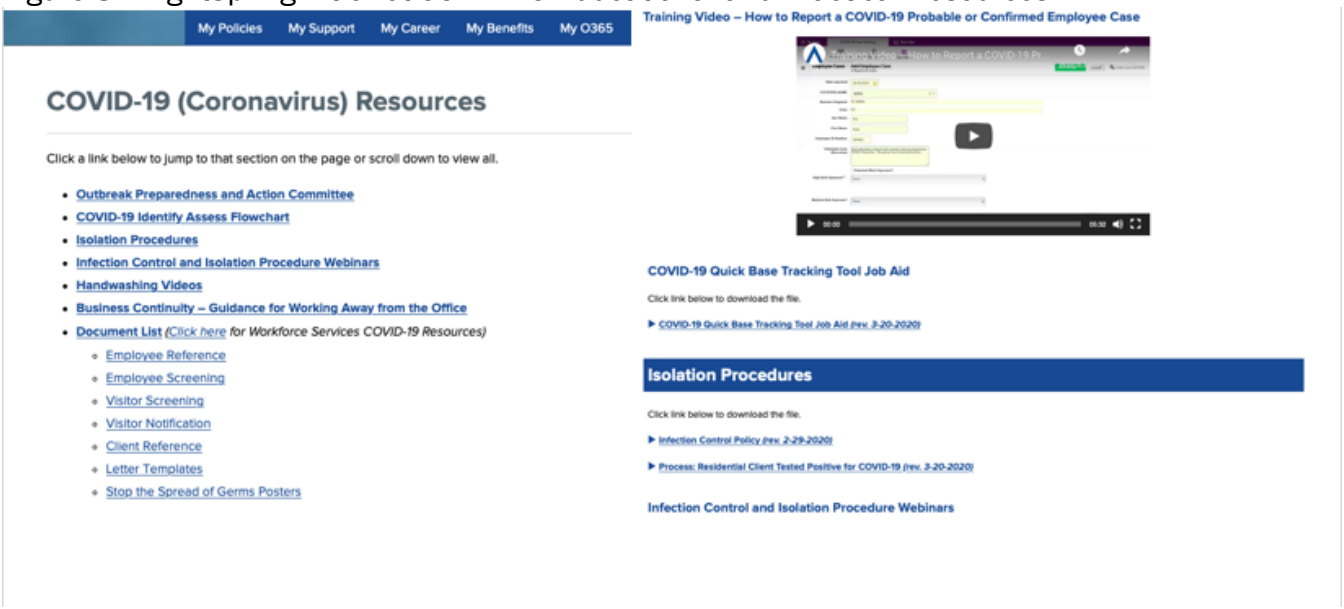
Personal Protective Equipment Conservation

To optimize our supply of PPE, we have provided materials and training to our employees on appropriate steps to conserve equipment where possible. Materials and educational resources are available on our company intranet, and our nurse-led training programs reiterate PPE conservation in real time, daily.

Educational Resources

To enable employees across all locations to have access to the most current information, policies and training materials, we developed and deployed over one hundred COVID-19 and outbreak prevention and action resource materials for employee use. This resource library is available on our organizational intranet (Figure 8), and updates are also communicated by email to the organization three times per week.

Figure 8. BrightSpring Intranet COVID-19 Educational and Practical Resources.



Return to Work Practices and Restrictions

In July, 2020, the CDC updated its guidance regarding return to work for health care workers who have confirmed or suspected (e.g., developed symptoms, but were not tested) COVID-19 infection. In addition to the guidance below, decisions about return to work should consider local circumstances (e.g., rate of new infections in the community), and whether the employee is at high risk, living with or caring for vulnerable persons at high-risk for illness and death if infected.

Except for rare situations, a test-based strategy is no longer recommended in determining when to return to work because in most cases, this results in excluding workers who are no longer infectious. The guidance for return to work falls into one of four categories:

1. Employees with **no symptoms** and who are **not seriously immunocompromised**
2. Employees who experienced **mild to moderate symptoms** and who are **not severely immunocompromised**

3. Employees who experienced **severe or critical illness/symptoms**, or who **are severely immunocompromised**
4. Employees who have **not experienced any symptoms** but who **are severely immunocompromised**

Return to work guidance for each of these scenarios is outlined below. Per the CDC, "Severely immunocompromised" includes:

- Receiving chemotherapy for cancer, untreated HIV infection, combined primary immunodeficiency disorder, and conditions treated with Prednisone (in doses greater than 20mg) for more than 14 days
- Note: factors such as advanced age, diabetes mellitus, or end-stage renal disease may pose a lower degree of immunocompromise
- Ultimately, if there is a question, the employees' treating health care provider will determine whether the employee is immunocompromised

Determination of whether symptoms are "Mild, Moderate, Severe or Critical" is based on the severity of symptoms experienced. This may also be determined by the employees' healthcare provider. Your Director, Clinical Practice can help determine whether there is a need to contact the employee's health care provider

1. Employees with **no symptoms** and who are **not seriously immunocompromised** may return to work when:
    - At least 10 days have passed since the date of their first positive test
2. Employees with **mild to moderate symptoms** and **who are not** severely immunocompromised may return to work when:
    - At least 10 days have passed *since symptoms first appeared* **and**
    - At least 24 hours have passed *since last* fever without the use of fever-reducing medications **and**
    - Symptoms (e.g., cough, shortness of breath) have improved

3. Employees with **severe or critical illness or symptoms,** or **who are** severely immunocompromised may return to work
    - 20 days after symptom onset
    - At least 24 hours have passed since last fever without the use of fever-reducing medications **and**
    - Symptoms (e.g., cough, shortness of breath) have improved

4. Employees who **are** severely immunocompromised but have **not had any symptoms** throughout their infection may return to work:
    - 20 days after the date of their first positive viral diagnostic test (e.g., the "swab" or PCR test).

Return to Work Practices: Upon return to work per the above, employees will:

- Wear a surgical facemask for source control at all times while at work until all symptoms are completely resolved
- After all symptoms have resolved, the employee can revert to using a cloth facemask (per company policy)
- A facemask for source control does not replace the need to wear an N95 mask when caring for clients and patients with suspected or confirmed COVID-19 infection
- Self-monitor for symptoms, and notify their manager if symptoms recur or worsen

Additional information regarding Quarantine

Please note that recommendations for discontinuing isolation in persons known to be infected with COVID-19 (above) may appear to be in conflict with recommendations for when to discontinue quarantine for workers known to have been *exposed* to COVID-19.

The CDC recommends 14 days of quarantine *after an exposure* based on the time it takes to develop illness if infected. It is possible that a person *known* to be infected could leave isolation earlier than a person who is quarantined because of the *possibility* they are infected.

Please contact your Director, Clinical Practice or the Outbreak Committee with questions.

Visitor Management

The Company understands that visitors to care sites represent a potential vector of SARS-CoV-2 transmission. We have enacted a policy that limits visits by people who are sick, and have posted signs, near the entrance of our sites to remind visitors that if they are sick they should not visit until they are free of fever, cough, and shortness of breath for at least 48 hours, and are performing visitor screening at congregate living locations. We have developed letters to inform patients, clients, guardians of the visitor management policy, and have initiated mandatory visitor logs.

Employee Travel

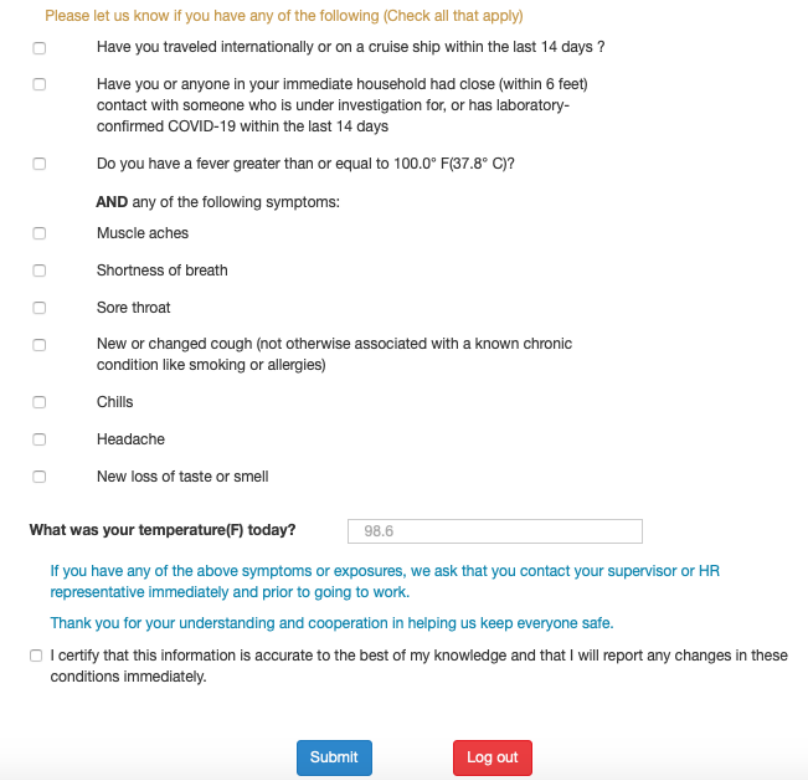
We feel it is our organizational responsibility to do our part in minimizing the spread of the virus for the protection of our patients, clients, those we support, our communities and each other. All non-essential travel has been restricted. Essential travel has been narrowly defined, and requires Executive Committee member approval. In addition, we have provided the following guidance to our employees:

- We have restricted any work-related international travel. Additionally, we strongly discourage any employee from traveling outside of the U.S. for any reason. If an employee or someone who lives in an employee's home still chooses to travel to a destination with significant community transmission of COVID-19 on personal time, the employee is asked to self-quarantine at home for 14 days.
- In-person group meetings are conducted, where possible, via WebEx, phone or video conference. Training and orientation is essential for our business, so when small group in-person meetings are required, we practice social distancing and the meeting space is regularly disinfected.

Employee Screening App Developed

In order to prevent well-intentioned, but ill employees from coming to work sick, the Company developed deployed a symptom-screening app, that can be used on any device – desktop, laptop or mobile (*Figure 9*). All employees are asked to take their own temperature and answer simple screening questions as shown. The app better enables sick employees to stay home, as well as instills confidence in patients, clients, senior communities and referral sources – that we have an organized, scalable, and reportable model for screening employees for illness.

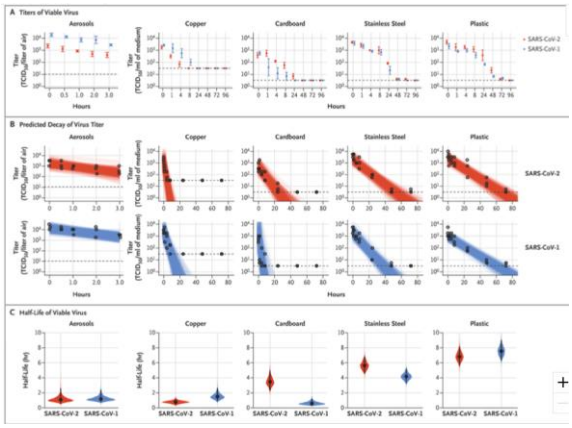
Figure 9. BrightSpring-PharMerica Employee Symptom Screening App.



Cleaning and Disinfection

Evidence suggests that COVID-19 may remain viable for hours to days on surfaces made from a variety of materials – longer on plastics and steel, and shorter viability on cardboard and copper. (*Figure 10*). Cleaning visibly dirty surfaces followed by disinfection is a best practice measure for prevention of COVID-19 and other viral respiratory illnesses in households, clinics, offices and community settings. The Company has implemented additional cleaning and disinfection protocols to limit the spread of COVID-19, and has a number of instructional resources available on our Company intranet.

Figure 10. Doremalen N et al found that SARS-coV-2 is viable for up to 72 hours on plastics, 48 hours on stainless steel, 24 hours on cardboard, 4 hours on copper, and is detectable in aerosols for up to 3 hours. *New England Journal of Medicine, March 17, 2020.*



Therapeutics

We are actively following scientific advancements in potential therapeutics for COVID-19. We follow the Regulatory Affairs Professional Society's therapeutics tracker, which is updated on a weekly basis. More than a year into the pandemic, only a handful of repurposed therapeutics have been approved to treat COVID-19: dexamethasone in the UK and Japan; Avigan (favilavir) in China, Italy and Russia; and Veklury (remdesivir) in the US, UK and Japan.

The US Food and Drug Administration (FDA) has issued emergency use authorizations (EUAs) for a handful of treatments including Eli Lilly and Company's monoclonal antibodies bamlanivimab with etesevimab; Regeneron's casirivimab and imdevimab; and GlaxoSmithKline/Vir Biotechology's sotrovimab. FDA revoked its EUA for bamlanivimab alone on 16 April. Lilly requested the revocation "due to the evolving variant landscape in the U.S. and the full availability of bamlanivimab and etesevimab together," according to a statement. The agency also authorized the use of convalescent plasma and the combination of Gilead's Veklury and Eli Lilly's Olumiant (baracitinib). The South Korea Ministry of Food and Drug Safety has authorized Regkirona (regdanvimab), a human monoclonal antibody.

Several large international trials are underway. The largest, SOLIDARITY, is led by the World Health Organization (WHO). More than 100 countries have joined SOLIDARITY to evaluate high-profile treatment candidates for COVID-19.

Vaccines

The Outbreak Committee follows the Regulatory Affairs Professionals Society COVID-19 Vaccine Tracker. The worldwide endeavor to create a safe and effective COVID-19 vaccine is bearing fruit. More than a dozen vaccines now have been authorized around the globe; many more remain in development. The below focuses on the three vaccines that the U.S. Food and Drug Administration has authorized as of June 14, 2021, and to which employees, patients and clients have access. The Company does not currently require its employees, patients or clients to be vaccinated against COVID-19, but continues to work to educate, encourage and help facilitate access to safe and effective vaccinations as part of our overall COVID-19 outbreak plan.

Pfizer/BioNTech

Background: Comirnaty (formerly BNT162b2) is a nucleoside modified mRNA-based vaccine developed by BioNTech and Pfizer. Fosun Pharma has licensed Comirnaty in China. The vaccine is given as an intramuscular injection in two doses 21 days apart; some countries have modified that schedule. Comirnaty generates an immune response against SARS-CoV-2 by encoding a mutated form of the virus's full spike protein.

Regulatory Actions: On 31 December, WHO issued an emergency use validation for Comirnaty, which supports accelerated approval in other countries. Most authorizations/approvals are in patients aged 16 years and older.

- Australia: Provisional determination granted by TGA on 11 May for individuals 12 years and older.
- Canada: In the context of limited vaccine supply, NACI recommends prioritizing first-dose vaccination with an interval of up to 4 months between doses. On 5 May, authorization was expanded to include adolescents 12-15 years of age.
- EU: In addition to authorization for adults, the vaccine now has conditional marketing authorization by the EMA for use in adolescents aged 12-15 years. EMA's safety committee (PRAC) is currently reviewing Comirnaty for unusual blood clots with low platelets and myocarditis; they have recommended a change for the vaccine's product information to include a low risk of facial swelling in patients with a history of dermal fillers.
- Philippines: EUA expanded on 28 May to include individuals 12 years and older.
- Singapore: The country expanded its emergency use of the Pfizer vaccine to ages 12-15 years on 19 May.
- United Kingdom: Authorization for use expanded by MHRA on 4 June to include individuals 12-15 years old.
- US: Pfizer and BioNTech have begun the rolling submission of a BLA and have requested priority review, the companies announced 07 May. A PDUFA date will be set once the application is complete, they said. FDA expanded emergency use to adolescents 12-15 years old on 10 May, and CDC recommended the vaccine in that age group on 12 May. Effective 25 February, undiluted and frozen vials of Comirnaty can be transported and stored at temperatures found in typical pharmaceutical freezers, according to FDA's reissued EUA. Thawed, undiluted vaccines can be stored in refrigerators for one month. Pfizer and BioNTech plan to submit an EUA expansion for children 2-11 years old in September.

Scores of additional countries have authorized or approved the vaccine for emergency use, and some countries are beginning to expand its use to younger patients. Please see the Authorization/Approval column for hyperlinks to each individual country's announcement.

Trials:

Pre-EUA trials:

Clinical trials evaluating Comirnaty leading up to its emergency use include a pivotal Phase 2/3 trial of more than 43,000 healthy participants around the world (NCT04368728) published in *NEJM*, a Phase 2 trial of 960 participants in China in conjunction with Shanghai Fosun Pharmaceutical (NCT04649021), a Phase 1/2 trial in the US and Germany of 200 healthy participants between aged 18-55 years (NCT04380701), and a combined Phase 1/2 trial of 160 participants (NCT04588480) in Japan.

Phase 3 data of 43,448 participants published in *NEJM* showed Comirnaty was 95% effective. Those results are backed up by Phase 1 data published in NEJM showing similar immunogenicity between Comirnaty and another BNT162 variant developed by Pfizer and BioNTech, but fewer

adverse effects were seen with Comirnaty.

Post-EUA trials:
Pfizer and BioNTech are evaluating the vaccine in a number of additional trials, which include:
- Testing a booster vaccine for participants who received a vaccine dose 6-12 months ago to see how it fares against COVID-19 variants and a formulation of the vaccine that doesn't require cold storage.
- Trials evaluating the vaccine in children under 12 years of age (NCT04816643) and 12 years or older (NCT04368728) are currently underway.
- NIH began a trial in April to examine whether vaccine recipients who are highly allergic are at greater risk for an allergic reaction to the vaccine (NCT04761822).
- Another NIH trial is evaluating the safety and immunogenicity of a booster dose of the Moderna vaccine for individuals who got one dose of the Janssen vaccine, two doses of Comirnaty or two doses of the Moderna vaccine (NCT04889209).
- Pfizer is testing a third shot of Comirnaty together with their 20-valent pneumococcal conjugate vaccine.

Real-world evidence:
In healthcare workers: A decline in hospitalizations has been observed in healthcare workers receiving their first dose in the UK (75%) and among people vaccinated 28-34 days after their first dose in Scotland (85%). Among healthcare workers vaccinated in Israel, the real-world immunogenicity of the vaccine was 92%, according to a study published in *Eurosurveillance*. An interim analysis of 3,950 health care personnel and frontline workers published in CDC's *Morbidity and Mortality Weekly Report (MMWR)* found the Pfizer vaccine was 80% effective ≥14 days after the first dose and 90% ≥14 days after the second dose. Two papers published in *NEJM* on 23 March examining vaccinated healthcare workers in California and in Jerusalem found a reduction in new COVID-19 cases.

Asymptomatic transmission: A study by the Israeli Health Ministry found an 89.4% reduction in transmission for asymptomatic cases and 93.7% for symptomatic cases. A study published in *NEJM* of nearly 600,000 individuals from Clalit, a health maintenance organization covering about half the Israeli population, demonstrated results consistent with Phase 3 clinical trials.

Pregnancy: Preliminary findings published in *NEJM* show there are no "obvious safety signals" for patients who are pregnant and receive an mRNA vaccine.

In older adults: A study of older adults who received the Pfizer vaccine, published in *MMWR* on 28 April, showed the vaccine was 94% effective at preventing hospitalization among patients older than 65 years who were fully vaccinated and 64% for those partially vaccinated. For 172 patients 80 years or older who received the Pfizer vaccine at a standard interval of 3 weeks between doses or an extended interval of up to 12 weeks between doses, there was a 3.5-fold higher antibody response in the extended interval group, according to a pre-print posted to *medRxiv*.

In adolescents: In the study of adolescents ≥12 years old, the Pfizer vaccine had 100% efficacy, according to topline results announced by Pfizer on 31 March.

Previous COVID-19 history: Researchers at Icahn School of Medicine at Mount Sinai and Children's Mercy Kansas City have published letters in NEJM found a single dose of an mRNA vaccine in participants with a previous history of COVID-19 provides a similar or greater response compared

with a two-dose regimen in participants without a COVID-19 history.

Heterologous vaccine schedule: Initial results from the COM-COV study, which is evaluating how patients fare after receiving doses of the AstraZeneca vaccine Vaxzevria and Comirnaty or vice versa, showed an increase in systemic reactogenicity compared with a two-dose series of Vaxzevria alone or Comirnaty alone. Results were published in *The Lancet*.

Evidence in new variants: Results from a pre-print posted to *bioRxiv* also indicate Comirnaty vaccine is effective against the B.1.1.7 variant of SARS-CoV-2 first identified in the UK. In correspondence to the editor published in *NEJM* on 17 February, Comirnaty was found to be approximately two-thirds less effective against the SARS-CoV-2 virus modified to have spike protein mutations similar to the B.1.351 variant. In Qatar, researchers found the vaccine was 89.5% effective against the B.1.1.7 variant and 75.0% effective against the B.1.351 variant, according to correspondence published in *NEJM*. A preprint posted to *bioRxiv* showed the Pfizer vaccine neutralizes the B.1.617.1 variant originating from India, but the variant is "6.8-fold more resistant to neutralization by sera" from the vaccine. Correspondence to the editor published in *NEJM* on 12 May indicates the Pfizer vaccine may neutralize variants originating in New York (B.1.526) and California (B.1.429) as well as the UK B.1.1.7 variant carrying an E484K mutation.

Distribution: Pfizer and BioNTech predict 1.3 billion doses will be available in 2021.

Moderna

Background: Moderna COVID-19 Vaccine (formerly known as mRNA-1273) was developed by Moderna based on prior studies of related coronaviruses. It is a two-dose mRNA vaccine given 28 days apart.

Regulatory Actions: WHO: Emergency use listing (EUL) granted 30 April 2021.

- Canada: On 3 March, the NACI recommended a 4-month interval between doses is appropriate in the context of limited availability. The same day, Health Canada and EMA published the vaccine's full clinical data package. Moderna has filed for authorization of its vaccine for adolescents in Canada.
- EU: EMA's safety committee (PRAC) is currently reviewing the Moderna vaccine for unusual blood clots with low platelets and myocarditis. EMA is currently reviewing the Moderna vaccine for individuals 12-17 years old.
- US: EUA issued 18 December for patients 18 years and older. On 01 April, the FDA revised the EUA to increase the number of vaccine doses available in each vial and authorize a 15-dose vial. Moderna initiated the rolling BLA submission on 01 June.

Trials:
Pre-EUA trials:
- In the pivotal Phase 3 trial of 30,000 participants at high risk for COVID-19, participants received a 100 µg dose of the Moderna COVID-19 Vaccine and another 4 weeks later or placebo injections and then be followed for up to 2 years; results published in *NEJM* demonstrated efficacy of 94.1% (COVE trial; NCT04470427). Moderna posted the full trial protocol for COVE on 17 September.
- A Phase 2 dose-confirmation trial of 600 healthy participants was completed (NCT04405076); preliminary results from that study published in *Vaccine*showed patients in the 50 and 100 ug

groups demonstrated "significant immune responses" to COVID-19.
- A Phase 1 trial (NCT04283461) of 105 healthy participants provided the basis for Moderna's investigational new drug application (IND), which set the stage for Phase 2 testing.

Post-EUA trials:
- Initial analysis of an ongoing Phase 2/3 trial (NCT04649151) testing Moderna's vaccine in 3,225 adolescents aged 12-18 years showed an efficacy rate of 96% in teens without prior COVID-19 who received at least one injection, according to a statement.
- NIH began a trial in April to examine whether vaccine recipients who are highly allergic are at greater risk for an allergic reaction to the vaccine (NCT04761822).
- Another NIH trial is evaluating the safety and immunogenicity of a booster dose of the Moderna vaccine for individuals who got one dose of the Janssen vaccine, two doses of Comirnaty or two doses of the Moderna vaccine (NCT04889209).
- A next-generation version of Moderna COVID-19 Vaccine that is refrigeration stable, named mRNA-1283, is currently being evaluated in a Phase 1 study.
- In March, Moderna and NIAID began evaluating a version of the vaccine, called mRNA-1273.351, that was designed to protect against a variant of SARS-CoV-2 originating in South Africa (NCT04785144).

Real-world evidence:
Real-world data, published in CDC's *MMWR*, showed the Moderna vaccine was 80% effective 14 days after the first dose and 90% effective 14 days after the second dose. The durability of response seems to persist to at least 6 months, according to correspondence to the editor published in *NEJM*.

Previous COVID-19 history: A paper published in *NEJM* found a single dose of an mRNA vaccine in participants with a previous history of COVID-19 provides a similar or greater response compared with a two-dose regimen in participants without a COVID-19 history.

Healthcare workers: Among healthcare workers in California vaccinated with the Pfizer and Moderna vaccines, the number of new COVID-19 cases was deemed "rare," according to correspondence to the editor published in *NEJM*.

Pregnancy: No "obvious safety signals" were observed in pregnant patients who received an mRNA vaccine, according to preliminary findings publishedin *NEJM*.

Effectiveness against variants: In correspondence to the editor published in *NEJM,* investigators from Moderna and NIAID noted the protective effect of the vaccine against the B.1.351 variant was inconclusive and "remains to be determined." Another correspondence to the editor from *NEJM* suggests the Moderna vaccine may be effective against a variant originating in California but less effective against the variant originating from South Africa. Non-peer-reviewed data posted to *MedRxiv* and released by Moderna showed the mRNA-1273.351 booster vaccine induces neutralizing titers against the original SARS-CoV-2, the B.1.351 variant, and the P.1 variant. A pre-print posted to *bioRxiv* showed the Moderna vaccine neutralizes the B.1.617.1 variant originating from India, but the variant is "6.8-fold more resistant to neutralization by sera" from the vaccine.

Janssen Biotech (Johnson & Johnson)

Background: Janssen Biotech, a company owned by Johnson & Johnson, has developed COVID-19 Vaccine Janssen (formerly JNJ-78436735 and Ad26.COV2.S), a single-dose COVID-19 vaccine, using their AdVac and PER.C6 systems, which were also used to develop the company's Ebola vaccine. COVID-19 Vaccine Janssen is a part of Operation Warp Speed.

Status: In April 2021, reports began circulating of very rare instances (6 cases out of 6.8 million vaccinated individuals) of cerebral venous sinus thrombosis (CVST) and thrombocytopenia after receiving COVID-19 Vaccine Janssen. On 13 April, the FDA and CDC recommended that administration of the vaccine be paused in the US while reports were investigated. The CDC's ACIP met on 14 April and deferred a vote on a recommendation until more data were collected; the FDA and CDC lifted the pause on the vaccine after a second ACIP meeting on 23 April. On 20 April, EMA recommended the product information for the Janssen vaccine should be updated to include a "warning about unusual blood clots with low blood platelets" and list it as a rare event. On 7 May, EMA's safety committee (PRAC) concluded their review and reconfirmed that the benefits outweigh the risks for the vaccine.

Some countries decided individually to pause their rollouts, including South Africa, Sweden, and France. A correspondence to the editor, published in *NEJM* by staff physicians at Janssen, said that "evidence is insufficient to establish a causal relationship between these events and the Ad26.COV2.S vaccine." A case report series published in *JAMA* identified 12 cases of CVST in the US, labeling them as "serious events." An accompanying editorial recommended that "US public health agencies and clinicians should consider recommending mRNA vaccines as safer options for those who may be at substantially higher risk for TTS after Ad26.COV2.S vaccination, currently women younger than 50 years."

Regulatory Actions:
- WHO: Listed the vaccine for emergency use and for COVAX rollout. WHO also released interim guidance for use of the vaccine on 17 March.
- Australia: Australia's Therapeutic Goods Administration (TGA) has given the vaccine provisional determination, which is the first step towards approval in the country.
- New Zealand: Medsafe has received a rolling abbreviated application for the vaccine and is seeking additional information from the sponsor.
Many countries have authorized or approved the Janssen vaccine for emergency use. Please see the Authorization/Approval column for hyperlinks to each individual country's announcement.

Trials: Janssen has tested the vaccine in several trials:
- The international Phase 3 ENSEMBLE trial (NCT04505722) (ENSEMBLE Study Protocol)
- The Phase 3 two-dose test of JNJ-78436735 called ENSEMBLE 2 (NCT04614948)
- A randomized, double-blind, placebo-controlled, international Phase 1/2 study (NCT04436276)
- A dose- and range-finding study that was expanded in April 2021 to include adolescents (NCT04535453)
- An NIH trial is evaluating the safety and immunogenicity of a booster dose of the Moderna vaccine for individuals who got one dose of the Janssen vaccine, two doses of the Pfizer vaccine or two doses of the Moderna vaccine (NCT04889209).
- A Phase 1 trial in Japan (NCT04509947).
- J&J is also seeking approval of a Phase 3 trial in India.

In topline Phase 3 data from 43,783 participants announced by press release on 29 January, the company said the vaccine was 66% effective overall, with 72% protection against moderate or severe disease in the United States, 66% in Latin America, and 57% in South

Africa. Documents released ahead of the 26 February VRBPAC meeting indicate the vaccine decreases asymptomatic transmission of SARS-CoV-2 by 74%. Results from the Phase 1/2a study in humans published in NEJM found a single dose of the vaccine showed immunogenicity and a good safety profile, with 90% of participants developing neutralizing-antibody titers against wild-type virus 29 days after receiving the vaccine. Data from the ENSEMBLE trial were published in NEJM, which showed vaccine efficacy was 66.9% at 14 days and 66.1% at 28 days; the vaccine was also effective against severe disease (76.7%, 14 days; 85.4%; 28 days). A study of real-world effectiveness of the Janssen vaccine, posted to the pre-print server *medRxiv*, indicated the vaccine was 76.7% effective.

Distribution: J&J has a memorandum of understanding to provide 500 million vaccine doses to COVAX, and has also agreed to provide 500 million vaccines to Gavi, The Vaccine Alliance. Sanofi has promised manufacturing support to J&J for the production of the vaccine after announcing a similar agreement with Pfizer and BioNTech. Merck has also said it will help produce the vaccine. On 15 March, IDT Biologica said it would use the capacity reserved for Takeda's COVID-19 vaccine candidate to help produce COVID-19 Vaccine Janssen. On 18 May, Biological E announced it would produce COVID-19 Vaccine Janssen alongside its own COVID-19 vaccine candidate.

Government Relations and Advocacy

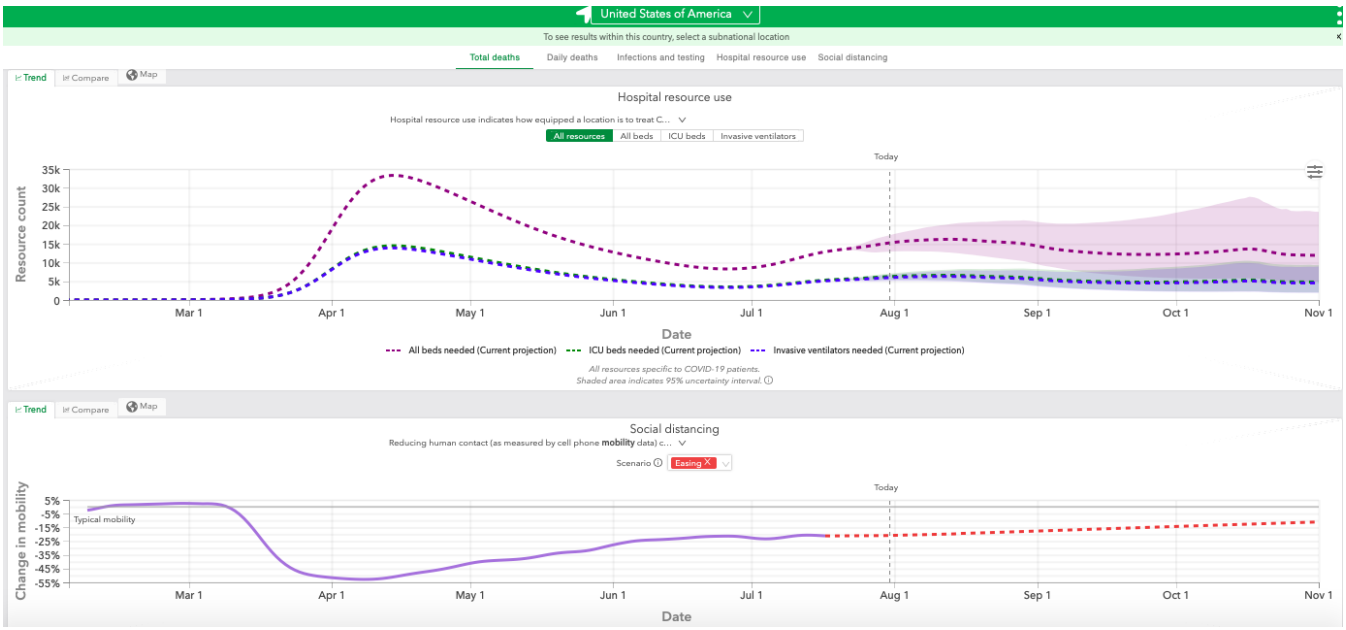
The Company is leveraging its outstanding Government Relations team to advocate for the Company continually being deemed a vital, essential service through our diversified, community-based businesses which provide clinical care, support, medication management, and rehabilitation of the most medically, behaviorally, and socially complex individuals in society. Specific to our outbreak preparedness work, Government Relations has undertaken many initiatives, including:

- Holding a seat on the Company's Outbreak Committee to advise and report on local, state and federal developments impacting the Committee's work;
- Lobbying state and federal lawmakers and appointed officials, including CMS, for the funding, regulatory structures, and flexibility the Company needs to be equipped to answer the challenges of our response to this outbreak;
- Ensuring our services and are workforce are deemed "essential" during any government ordered Stay at Home or business closure periods; and
- Being a leading voice with numerous state and national associations, among other external stakeholder groups, to make our response priorities have broad support.

Business Continuity Planning

The Company has leveraged technology enablers to facilitate remote work for positions that can be effectively performed remotely. The Company has regular executive meetings where census data, COVID-19 cases, and PPE supply and demand are reviewed by business segment. Operational, human resources and governmental relations issues are also discussed. To date, the company has experienced a modest decrease in referrals to some service lines due to the pandemic, and has been working with stakeholders to mitigate effects of the outbreak. We use several COVID-19 case forecast models to best enable national and state-level planning by business segment, including the University of Washington's Institute for Health Metrics and Evaluation predictive model shown below (*Figure 12*).

Figure 12. US-level COVID-19 related resource utilization predictive model (Institute for Health Metrics and Evaluation, University of Washington).



Webinars to Support Our Families

The overall well-being of our team members and their families is very important to us. To help alleviate some of these stressors and provide solutions and support, we are lending the expertise of our Workforce Services division.

Our workforce industry internal experts share information through a series of webinars hosted exclusively to support impacted family members of Company employees. Attendees find out how to access resources, find replacement income opportunities and learn coping skills for dealing with job loss.

Conclusion

BrightSpring Health Services Outbreak Committee reviews COVID-19 epidemiologic data in real time, linking the company's stakeholders to this Plan to ensure optimal preparedness and action. The plan is monitored by the Outbreak Committee, and is adjusted to best serve the needs and safety of the patients, clients, employees and communities we serve.

<table>
<tr><th colspan="3">EXHIBIT A</th></tr>
<tr><td>PROCEDURE: Isolation Precautions and PPE</td><td colspan="2">SUBJECT: Infection Control</td></tr>
<tr><td rowspan="3">PERFORMED BY: DSP, LPT, LVN, LPN, RN, All direct care and support staff</td><td colspan="2">Prepared By: E. Shauen Howard DHA, MSN, RN; VP Clinical Services</td></tr>
<tr><td colspan="2">Approved By: Outbreak Preparedness and Action Committee</td></tr>
<tr><td>Date Written: February 2019
Last Updated February 29, 2020</td><td>Reviewed annually: See below</td></tr>
</table>

GENERAL: When individuals we serve have a known infection, staff must follow specific precautions to reduce the risk of cross contamination to other clients.

World Health Organization—Recommendations for standard precautions:

1. Hand hygiene technique:

- Hand washing (40–60 sec): Wet hands and apply soap; rub all surfaces; rinse hands with warm water and dry thoroughly with a single use towel; use towel to turn off faucet.
- Hand rubbing (20–30 sec): Apply enough hand sanitizer product to cover all areas of the hands; rub hands until dry.

Summary indications:

- Before and after direct individual contact and between individuals we serve; whether or not gloves are worn
- Immediately after removing gloves
- Before handling an invasive device
- After touching blood, body fluids, secretions, excretions, non-intact skin, and contaminated items, even if wearing gloves
- During care, before moving from a contaminated to a clean body site
- After contact with inanimate objects in the immediate vicinity of the individual

2. Gloves:

- Wear when touching blood, body fluids, secretions, excretions, mucous membranes, or non-intact skin.
- Change between tasks and procedures on the same individual, after contact with potentially infectious material.
- Remove after use, before touching non-contaminated items and surfaces, and before going to another individual. Perform hand hygiene immediately after removal.

3. Facial protection (eyes, nose, and mouth):

- (1) Wear a surgical or procedure mask and eye protection (eye visor, goggles)

OR

(2) Wear a face shield to protect mucous membranes of the eyes, nose, and mouth during activities likely to generate splashes or sprays of blood, body fluids, secretions, and excretions.

4. Gown:

- Wear to protect skin and prevent soiling of clothing during activities that are likely to generate splashes or sprays of blood, body fluids, secretions, or excretions.
- Remove a soiled gown as soon as possible and perform hand hygiene.

5. Prevention of needle stick and injuries from other sharp instruments:

- Use care when:
  - Handling and disposing needles and other sharp instruments or devices.
  - Cleaning used supplies.

6. Respiratory hygiene and cough etiquette. Persons with respiratory symptoms should apply control measures:

- Cover the nose and mouth when coughing/sneezing with tissue or mask, dispose of used tissues and masks, and perform hand hygiene after contact with respiratory secretions.

In aggregate care settings:

- With acutely febrile (100.4° F [37.8° C] or greater using an oral thermometer), respiratory symptomatic individuals we serve, place individuals we serve at least 6 feet away from others in common areas, if possible.
- Post signs instructing persons to practice respiratory hygiene/cough etiquette.
- Make hand hygiene resources, tissues, and masks available.

7. Environmental cleaning:

- Provide routine cleaning and disinfection of environmental and other frequently touched surfaces.

8. Linens:

Handle, transport, and process used linen in a manner which:

- Prevents skin and mucous membrane exposure and contamination of clothing.
- Avoids transfer of pathogens to other individuals we serve, staff, or the environment.

9. Waste disposal:

- Ensure waste handling and disposal occurs in a manner, including PPE, which protects staff and individuals we serve from exposure to pathogens.

10. Patient care equipment:

- Handle equipment soiled with blood, body fluids, secretions, and excretions in a manner that prevents skin and mucous membrane exposure, contamination of clothing, and transfer of pathogens to others or the environment.
- Clean and disinfect reusable equipment before used by another individual

PURPOSE: To protect employees and individuals we serve from the spread of infection through contact with blood and/or body fluids in the routine or non-routine course of their job; to practice Standard Precautions in accordance with the State Department of Health rules and OSHA Standards.

EQUIPMENT:
- Gloves
- Gowns
- Masks
- Eyewear

AIRBORNE PRECAUTIONS

Airborne precautions- for individuals we serve known or suspected to be infected with pathogens transmitted by the airborne route (e.g., Coronavirus (COVID-19), tuberculosis, measles, chickenpox, disseminated herpes zoster) will be implemented for this and will include:

- Source control: put a mask on the individual.

Ensure appropriate patient placement in an airborne infection isolation room- (AIIR) constructed according to the Guideline for Isolation Precautions.

In settings where Airborne Precautions cannot be implemented due to limited engineering resources, masking the individual and placing them in an individual room with the door closed will reduce the likelihood of airborne transmission until the individual is either transferred to a facility with an AIIR or returned home.

Restrict susceptible healthcare personnel from entering the room of individuals we serve known or suspected to have measles, chickenpox, disseminated zoster, or smallpox if other immune healthcare personnel are available.

Use personal protective equipment (PPE) appropriately, including a fit-tested NIOSH-approved N95 or higher-level respirator for healthcare personnel.

Limit transport and movement of individuals we serve outside of the room to medically-necessary purposes. If transport or movement outside an AIIR is necessary, instruct individual to wear a surgical mask, if possible, and observe Respiratory Hygiene/Cough Etiquette.

Staff transporting individuals we serve who are on Airborne Precautions do not need to wear a mask or respirator during transport if the individual is wearing a mask and infectious skin lesions are covered.

Immunize susceptible persons as soon as possible following unprotected contact with vaccine- preventable infections (e.g., measles, varicella or smallpox).

DROPLET PRECAUTIONS

Droplet precautions will be implemented for Diphtheria, rubella Streptococcal pharyngitis, pneumonia, scarlet fever, Mycoplasma pneumonia or sepsis, meningococcal pneumonia or sepsis.

This will include private room, mask or respirator (N-95 mask), gown and gloves.

- Source control: put a mask on the individual.

Ensure appropriate individual placement in a single room if possible.

Aggregate Care Settings:

Make decisions regarding individual placement on a case-by-case basis considering infection risks to other patients in the room and available alternatives.

Use personal protective equipment (PPE) appropriately. Apply mask upon entry into the individual room or space.

Limit transport and movement of individual outside of the room to medically-necessary purposes. If transport or movement outside of the room is necessary, instruct individual to wear a mask and follow Respiratory Hygiene/Cough Etiquette.

CONTACT PRECAUTIONS

Contact precautions (direct individual or environmental) will be implemented for multidrug resistant organisms which the such as VRE, MRSA, Clostridium Difficile (C-Diff), and other enteric pathogens, major wound infections, herpes simplex, scabies, varicella zoster.

This will include: private room, gloves and gown, eyewear if splashing is expected.

Ensure appropriate individual placement in a single individual space or room if suspected. Once diagnosis is verified, residential or community settings should make room placement decisions balancing risks to other individuals we serve.

For individuals we serve with suspected Clostridium Difficile (C-Diff) immediate isolation measures should be taken, including use of bedside commode or toilet only to be used by infected individual. Once confirmed, maintain contact precautions for at least 48 hours after diarrhea has resolved.

Restrict any unnecessary personnel from entering the home of individuals we serve known or suspected to have C-Diff.

Use personal protective equipment (PPE) appropriately, including gloves and gown. Wear a gown and gloves for all interactions that may involve contact with the individual or their environment. Donning PPE upon room entry and properly discarding before exiting the patient room is done to contain pathogens.

PROCEDURE:

1. Verify resident's/patient's record and physician order for isolation precautions
   a. Identify specific precaution required
2. Post precaution sign on resident's/patient's door.
3. Protective equipment will be outside of resident's/patient's door.
4. Wash hands before entering room and after leaving room
5. Gather all equipment needed in resident's/patient's room, using resident's/patient's own designated equipment when possible. Keep designated equipment in resident's/patient's room
6. Inform individual that you are entering their room before applying PPE.
7. Apply gown, being sure to cover all outer garments, tie securely at neck and waist.
8. Apply mask next if needed, then eyewear if needed, then clean gloves bring glove cuff over edge of gown sleeves, per specific precaution indicated above
9. If stethoscope is reused, clean ear pieces and diaphragm with alcohol swab.
10. When procedure is completed, dispose of all trash in room.
11. Leave room then remove gloves:
    a. Pinch the outside of the glove about an inch or two down from the top edge inside the wrist.
    b. Peel downwards, away from the wrist, turning the glove inside out
    c. Pull the glove away until it's removed from the hand. Hold the inside-out glove with the gloved hand.
    c. With your gloveless hand, slide your fingers under the wrist of the glove, do not touch the outside of the glove.
    d. Repeat step 3. Peel downwards, away from the wrist, turning the glove inside out.
    e. Continue pulling the glove down and over the first glove. This ensures that both gloves are inside out, one glove enveloped inside the other, with no contaminants on the bare hands.
    f. Dispose of the gloves in a proper bin– this may differ depending on company policies.
12. Dispose of all contaminated items.
13. Wash hands.

Limit transport and movement of individuals we serve outside of the room to medically-necessary purposes. When transport or movement is necessary, cover or contain the infected or colonized areas of the resident's/patient's body. Remove and dispose of contaminated PPE and perform hand hygiene prior to transporting individuals we serve on Contact Precautions. Don clean PPE to handle the individuals we serve at the transport location.

Use disposable or dedicated patient-care equipment (e.g., blood pressure cuffs). If common use of equipment for multiple individuals we serve is unavoidable, clean and disinfect such equipment before use on another individual.

Prioritize cleaning and disinfection of the rooms of individuals we serve on contact precautions ensuring rooms are frequently cleaned and disinfected (e.g., at least daily or prior to use by another individual if outpatient setting) focusing on frequently-touched surfaces and equipment in the immediate vicinity of the individual.

<u>For Individuals we serve diagnosed with C-Diff:</u>

- <u>Complete the Personal Waiver Regarding the use of Chlorine Bleach in a</u>

Residential Home.

- Carefully and thoroughly clean rooms and equipment used for the individuals we serve care with a C. Difficile sporicidal bleach wipe or spray (EPA List K agent).
- Wash all linens separately with an additive of bleach (EPA List K agent) to the laundry soap in hot water.

TRAINING: All staff will be trained in Infection Control & PPE procedures upon orientation and annually. When identified for use, staff will be fitted and trained on respirator (N-95 mask). Competency will be documented. See attachments.

Training by the RN or designated employee will consist of lecture and return demonstration.

POLICY REVIEW: Isolation Precautions

Review Date	Signature	Title
2/29/20		Chair, Outbreak Preparedness and Action Committee

 Description

Medline N95 Qualitative Fit Test Kit feature one kit tests for approximately 100 staff members. It is available as a kit with refills, and is easy to administer and instructions are found within the kit. The Medline qualitative fit test kit is to be used in conjunction with our N95 particulate respirator mask models, NON27501, NON24505, NON24506 and NON24507 as fit testing is required prior to the initial use of a respirator. It is saccharin based qualitative fit test kit that can be used for up to 100 tests.

- Type: Fit test kit
- Material: Latex-free parts
- One kit tests approximately 100 staff members
- Refills are also available
- Saccharin based fit test kit
- Easy to administer and includes instructions
- Available as a Kit, and refills are also available
- Qualitative Fit Test Kit is to be used in conjunction with our N95 particulate respirator masks (NON27501, NON24505, NON24506 and NON24507)
- Fit testing is required prior to the initial use of a respirator
- Test is easy to administer and instructions are found within the kit

Test Numerous Employees

Your staff members have to go through fit testing before they can use respirators, and this Medline N95 qualitative fit test kit provides you with up to 100 tests, so everyone can get done without the need for refills. The test is easy to administer and instructions are included with this kit. Latex-Free Design

Don't worry about employees having allergic reactions to this test; the parts are all latex-free, so you can be sure they're safe. The saccharin-based fit test kit is the ideal choice for all the tests you have to complete. Fits Specific Respirator Masks

Make sure your fit test will work the first time with the Medline N95 qualitative fit test kit and the right respiratory mask. This kit works with the N95 particulate respirator masks with the stock numbers NON27501, NON24506, NON24505, and NON24507 for an accurate test.

Glove Use in Standard Precautions

Wear gloves when anticipating contact with a patient's:

- Blood or body substances (i.e., fluids or solids)
- Mucous membranes (e.g., nasal, oral, genital area)
- Non-intact skin (e.g., wound or surgical incision)
- Insertion point of a patient's invasive or indwelling device

(Siegel JD, CDC Guidelines for Isolation Precaution, 2007)

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

Donning Gloves

Select correct type of glove and size

Extend to cover wrist, over isolation gown if worn

Sequence of PPE donning, gloves are often the last item to be put on

(CDC, Sequence for Personal Protective Equipment, https://www.cdc.gov/hai/pdfs/ppe/ppe-sequence.pdf)

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

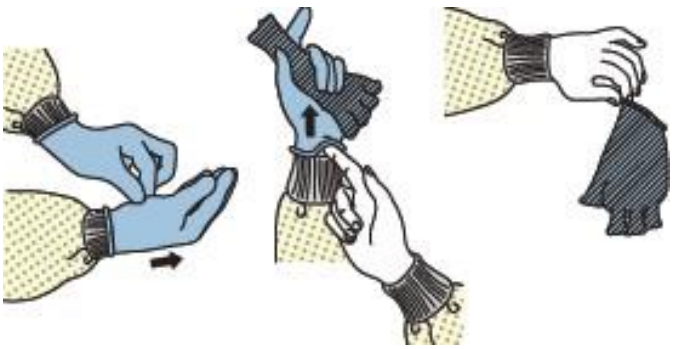
Doffing Gloves

There are a variety of ways to safely remove gloves, one

option is:

- With the gloved hand, grasp the palm area of the other gloved hand and peel off
- Hold removed glove in gloved hand; slide fingers of ungloved hand under remaining glove at wrist, peel off and discard

Sequence of PPE doffing, gloves are usually the first item to be removed



CDC, Sequence for Personal Protective Equipment, https://www.cdc.gov/hai/pdfs/ppe/ppe-sequence.pdf

Gown Use in Standard Precautions

Wear when contact between clothing or skin with patient blood or body substances is expected.

For example:

- Contact with patient's non-intact skin (e.g., wounds)
- During procedures likely to generate a splash or spray of blood or body fluid
- Handling containers or patient fluids likely to leak, splash or spill

(CDC, Sequence for Personal Protective Equipment, https://www.cdc.gov/hai/pdfs/ppe/ppe-sequence.pdf)

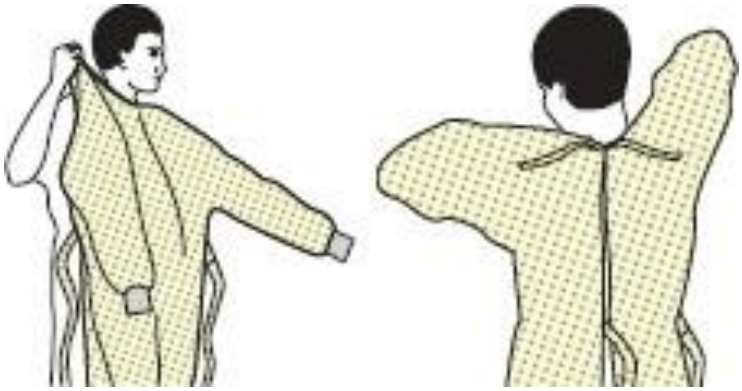
CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

Donning Gowns

Gowns should cover the torso, the legs to the knees, the arms to end of wrist and wrap around the back

Slide gowns on with the opening at the back,

fasten around the back of the neck and the waist



(CDC, Sequence for Personal Protective Equipment, https://www.cdc.gov/hai/pdfs/ppe/ppe-sequence.pdf)

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

Doffing Gowns

Unfasten gown

Pull away from neck and shoulders,

touching inside of gown only

Turn gown inside out

Fold or roll into a bundle and discard

Remove gown and perform hand hygiene before

leaving the patient's environment (e.g., exam room)

Do not wear the same gown between patients

CDC, Sequence for Personal Protective Equipment, https://www.cdc.gov/hai/pdfs/ppe/ppe-sequence.pdf)

Face Mask and Eye Protection Use in Standard Precautions

Wear when anticipating potential splashes or sprays of blood/body substances during patient care

Face Masks–protect nose and mouth

Goggles–protect eyes

Face shields–protect face (i.e., nose, mouth and eyes)

Personal eyeglasses and contact lenses are not considered adequate eye protection

(CDC, Sequence for Personal Protective Equipment, https://www.cdc.gov/hai/pdfs/ppe/ppe-sequence.pdf)

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

Donning a Face Mask or Respirator

Secure ties or elastic bands at middle of head and neck

Flexible band should fit to bridge of nose

Face mask should fit snug to face and

below chin Fit-check respirator

(

CDC, Sequence for Personal Protective Equipment, https://www.cdc.gov/hai/pdfs/ppe/ppe-sequence.pdf)

Doffing a Face Mask or Respirator

Grasp bottom ties or elastics of the face mask/respirator, then the ones at the top, and remove without touching the front

Discard in waste container

(CDC, Sequence for Personal Protective Equipment, https://www.cdc.gov/hai/pdfs/ppe/ppe-sequence.pdf

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

Donning and Doffing Goggles and Face Shield

Don:

- Place over face and eyes and adjust to fit

Doff:

- Remove from the back by lifting the head band over the earpiece
- Place in designated area for reprocessing or disposal

(CDC, Sequence for Personal Protective Equipment https://www.cdc.gov/hai/pdfs/ppe/ppe-sequence.pdf)

Key Points of PPE Removal

The key for PPE removal is to limit opportunities for environment and self-contamination

Outside front of the PPE is the area most likely to be contaminated

Perform hand hygiene after PPE removal

An example sequence of doffing PPE is as follows:

- Gloves
- Face shield/goggles
- Gown
- Face Mask

CDC, Sequence for Personal Protective E

EXHIBIT B

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services 7500 Security Boulevard, Mail Stop C2-21-16 Baltimore, Maryland 21244-1850

Center for Clinical Standards and Quality/Quality, Safety & Oversight Group

Ref: QSO-20-17-ALL

DATE: March 10, 2020

TO: State Survey Agency Directors

FROM: Director
Quality, Safety & Oversight Group

SUBJECT: Guidance for use of Certain Industrial Respirators by Health Care Personnel

Memorandum Summary

- The Centers for Medicare & Medicaid Services (CMS) CMS is committed to taking critical steps to ensure America's health care facilities are prepared to respond to the threat of the Coronavirus Disease 2019 (COVID-19) and other respiratory illnesses.
- The memo clarifies the application of CMS policies in light of recent Centers for Disease Control and Prevention (CDC) and Food and Drug Administration (FDA) guidance expanding the types of facemasks healthcare workers may use in situations involving COVID-19 and other respiratory infections.

Background

CMS is committed to taking critical steps to ensure America's health care facilities are

prepared to respond to the threat of the COVID-19 and other respiratory illness. With this announcement, health care workers in providers and suppliers certified by CMS will have a more expansive range of options to protect themselves and those receiving their care. CMS will continue to explore flexibilities and innovative approaches within our regulations to allow health care entities to meet the critical health needs of the country.

Guidance

The Centers for Disease Control and Prevention (CDC) have updated their Personal Protective Equipment (PPE) recommendations for health care workers involved in the care of patients with known or suspected COVID-19. At this time, these recommendations will be considered by CMS surveyors to determine if Medicare and Medicaid providers and suppliers are complying with infection control protocols:

Based on local and regional situational analysis of PPE supplies, facemasks are an acceptable temporary alternative when the supply chain of respirators cannot meet the demand. During this time, available respirators should be prioritized for procedures that are likely to generate respiratory aerosols, which would pose the highest exposure risk to Health Care Providers (HCP).

- Facemasks protect the wearer from splashes and sprays.
- Respirators, which filter inspired air, offer respiratory protection.

- When the supply chain is restored, facilities with a respiratory protection program should return to use of respirators for patients with known or suspected COVID-19. Facilities that do not currently have a respiratory protection program, but care for patients infected with pathogens for which a respirator is recommended, should implement a respiratory protection program.
- Eye protection, medical gown, and gloves continue to be recommended.
    - If there are shortages of medical gowns, they should be prioritized for aerosol- generating procedures, care activities where splashes and sprays are anticipated, and high-contact patient care activities that provide opportunities for transfer of pathogens to the hands and clothing of HCP.
- Updated recommendations regarding the need for an airborne infection isolation room (AIIR).
    - Patients with known or suspected COVID-19 should be cared for in a single- person room with the door closed. AIIRs should be reserved for patients undergoing aerosol-generating procedures.

- Updated information based on currently available information about COVID-19 and the current situation in the United States, which includes reports of cases of community transmission, infections identified in HCP, and shortages of facemasks, N95 filtering facepiece respirators (FFRs) (commonly known as N95 respirators), and gowns.
- Increased emphasis on early identification and implementation of source control (i.e., putting a face mask on patients presenting with symptoms of respiratory infection).

Additional information on CDC's recommendations above can be found here: https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html

Further, the FDA approved the CDC request for an emergency use authorization (EUA) to allow health care personnel to use certain industrial respirators during the COVID-19 outbreak in health care settings. The FDA concluded that respirators approved by the National Institute for Occupational Safety and Health (NIOSH), but not currently meeting the FDA's requirements, may be effective in preventing health care personnel from airborne exposure, including COVID- 19, which can cause serious or life-threatening disease, including severe respiratory illness.

This action allows the NIOSH-approved respirators not currently regulated by the FDA to be used in a health care setting by health care personnel during the COVID-19 outbreak, thereby maximizing the number of respirators available to meet the needs of the U.S. health care system.

PLEASE NOTE: Due to the updated CDC guidance and current supply demands of these devices (and the discards associated with testing), CMS is directing surveyors not to validate the date of the last FIT test for health care workers in Medicare and Medicaid certified facilities, until further notice.

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