Updated Risk Assessment and Testing Considerations for SARS-CoV-2 Transmission in Congregate Care Facilities: Variants and Vaccination

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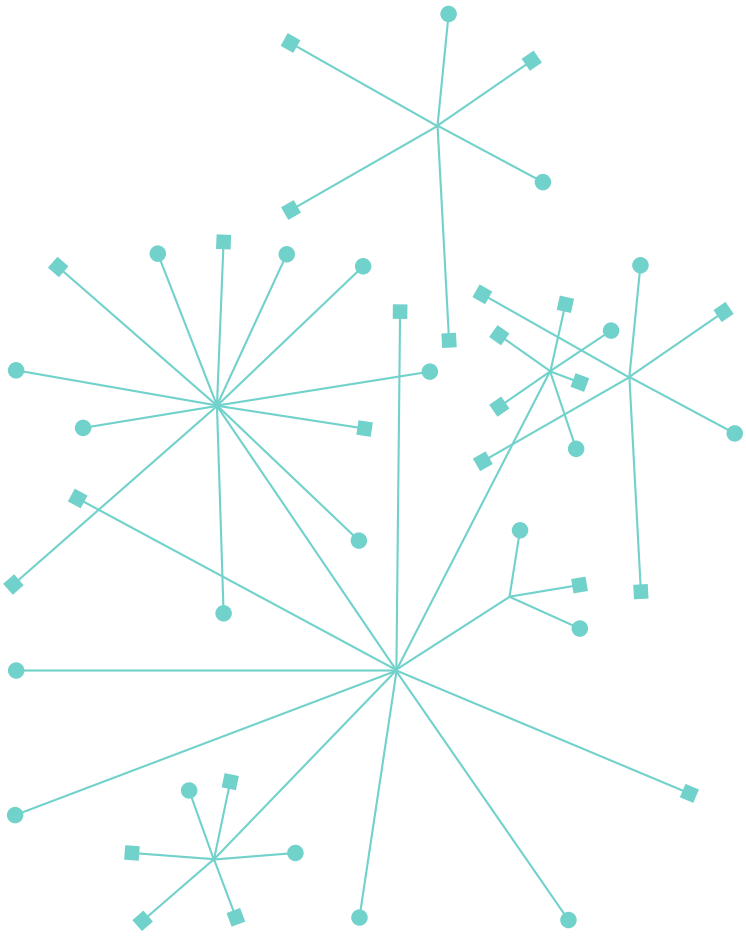
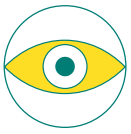


Introduction

The state of the pandemic has changed drastically since its early days, with caseloads dropping dramatically in spring 2021 as vaccinations became more widely available but again surging in many areas in summer 2021, driven by the more contagious Delta variant. This update to the Risk Assessment and Testing Considerations for SARS-CoV-2 Transmission in Congregate Care Facilities is intended to assess these new developments in the context of congregate care facilities (CCFs). We explore how risk has changed over time and discuss when testing can be an effective tool in stopping the spread of the virus. (See Table 1 for the different types of testing strategies that may be deployed, depending on risk.)

TABLE 1 Purposes of Different Testing Strategies

NAME	PURPOSE	TESTING IMPLEMENTATION
Diagnostic 	Confirm or rule-out diagnosis of individuals who have reason to believe they are infected	Testing for symptomatic individuals or unvaccinated individuals with a known exposure. Generally this type of testing is done with highly specific and sensitive molecular (PCR) tests.
Screening 	Identify asymptomatic higher-risk individuals to break chains of transmission	Frequent routine testing (1-2x/week) of asymptomatic individuals can break chains of transmission and reduce spread. Testing can be done via individual PCR, pooled PCR, or antigen tests. Testing frequency should be based on risk; however, it should be noted that testing less than 1x/week moves this strategy from mitigation to surveillance.
Surveillance 	Generate information for pandemic decision-making	Low frequency and/or random samples of a population (either on a county level or within a congregate setting) are tested to track infection rates and support decision-making. Other environmental methods such as wastewater surveillance can also be used to track infection rates.
Outbreak/ Surge Testing[1] 	Rapidly break chains of transmission after a new infection is identified	In the presence of a new infection in a wing or facility, all staff and residents (vaccinated and unvaccinated) are tested every 3-7 days until 14 days pass with no new cases identified. Testing can be done via individual PCR, pooled PCR, or antigen tests.

As discussed more thoroughly in the original report, assessing risk involves weighing 1.) the likelihood of an infection being introduced into a CCF, 2.) the likelihood of an infection spreading within the CCF, and 3.) the consequences of an outbreak in the facility. These three factors have changed with the introduction of widespread vaccination for vulnerable populations as well as differences in the availability and cost of new testing technologies and modalities. At the same time, more transmissible variants of the virus that causes Covid-19 have become dominant. As a result, there are increasing numbers of breakthrough infections in vaccinated people, and previously sufficient mitigation measures are now less protective. Because the pandemic and risks

[1] Interim Final Rule (IFC), CMS-3401-IFC, Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency related to Long-Term Care (LTC) Facility Testing Requirements and Revised COVID-19 Focused Survey Tool; https://www.cms.gov/files/document/qso-20-38-nh-revised.pdf

are changing over time, so should the risk assessment and resulting testing strategies. Ideally, facilities will set up a system that allows them to easily dial testing up and down as risk changes.

Nursing homes and other CCFs have been hardest hit by Covid-19. In the first 8 months of the pandemic, 80% of Covid-19 deaths reported in the U.S. occurred among those 65 and older. Over 40% of Medicare beneficiaries in nursing homes were diagnosed with confirmed or likely Covid-19 in 2020, and in April 2020, excess deaths among this population reached 1,000 per day compared to April 2019. As a result, the elderly were prioritized early in the vaccine rollout. As of August 27, 2021, nearly 92% of people over 65 have received at least one vaccine dose and more than 81% have been fully vaccinated. Death rates have declined from a winter 2021 weekly peak rate of 54 deaths per 100,000 for individuals age 75 or older to 6.3 deaths per 100,000 in mid-August (as reported September 10, 2021). The significant uptake of vaccinations that reduce infection spread and especially reduce serious complications, along with increased availability and diversity of testing modalities, may allow significant modification of testing protocols in communities with lower community spread.

This lower risk of severe disease and death has allowed for changes in testing protocols for vaccinated individuals. The Centers for Disease Control and Prevention (CDC) has recently updated their testing recommendations for nursing homes to account for vaccination. While unvaccinated individuals should still be routinely tested at frequencies based on community risk, vaccinated individuals only need to be tested when symptomatic, when they have a suspected or confirmed exposure to someone with the virus, or as part of surge/outbreak testing if a staff member or resident is infected (see Table 2 for details).

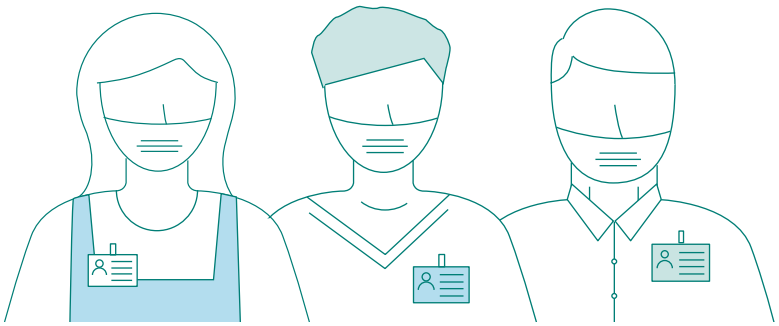
Unfortunately, vaccination rates for direct care workers and employees significantly lag behind the vaccination rate of CCF residents. Complete vaccination for staff is critical for Covid-19 risk management as these individuals circulate in the community and are often the most likely vector for introducing new infections into CCFs, which may lead to significant, negative consequences for even vaccinated residents. This poses particular dangers due to the relatively high prevalence of immunocompromising conditions among CCF residents. Recent Equal Employment Opportunity Commission (EEOC) guidance clarified that employers can require vaccination as a condition for returning to in-person work, as long as they make reasonable accommodations for certain legally protected exemptions. In August 2021, President Biden announced that the administration plans to require nursing home staff to be vaccinated as a condition of continued Medicare and Medicaid funding. Even for long-term care (LTC) facilities not dependent on federal funding, this announcement emphasizes the importance of vaccination in providing a safe environment for residents. The U.S. Food and Drug Administration's (FDA's) full approval of the Pfizer BioNTech vaccine (now marketed as Comirnaty) in August 2021 may also encourage uptake among those initially hesitant to get vaccinated. In locations where vaccine requirements are not feasible, frequent testing for unvaccinated workers should also be considered.

In contrast to vaccines, new variants like the Delta variant, which are more infectious than the original strain, are exacerbating risks for CCFs. While vaccinated individuals with healthy immune systems generally continue to be protected from illness caused by these variants, there are increasing numbers of breakthrough infections in vaccinated individuals. Immunocompromised residents are at particular risk, as they may have insufficient immunity even after vaccination. As such, immunocompromised people must rely on the immunity of those around them. CCFs in regions with high Covid-19 caseloads may want to resume weekly screening testing of even vaccinated staff out of an abundance of caution. In August 2021, the FDA authorized an additional dose of the Pfizer BioNTech and Moderna vaccines for certain immunocompromised individuals, given their increased vulnerability to infection and severe symptoms from Covid-19. Shortly afterward, the U.S. Department of Health and Human Services (HHS) indicated through a joint statement from federal health agencies that the administration is planning to authorize booster shots for all people who have gone more than 8 months since completing their initial course of either two-dose vaccine, with a booster for the single-dose Johnson & Johnson vaccine likely to be authorized as well, pending further data.

TABLE 2 **CDC Recommended Testing Protocols for Nursing Home Workers**

STAFF	DIAGNOSTIC TESTING IF SYMPTOMATIC	DIAGNOSTIC TESTING FOLLOWING EXPOSURE	ROUTINE SCREENING TESTING	OUTBREAK/ SURGE TESTING
Unvaccinated Staff	✓	✓	✓	✓
Vaccinated Staff	✓	✓		✓

Source of recommendations: (CDC) Updated Healthcare Infection Prevention and Control Recommendations in Response to COVID-19 Vaccination. Downloaded August 23, 2021 from https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-after-vaccination.html#anchor_1619116637758



Simplifying Testing Protocols

Routine testing is becoming less expensive and logistically simpler in some ways, especially if a facility's risk level suggests only unvaccinated individuals need to be routinely tested. New testing modalities that have entered the market can also lessen costs and ease administrative complexity for routine testing. Pooled testing has become much more common, in part due to its potential for cost savings relative to individual testing, and many companies have now set up teams to facilitate the logistics of sample collection, transport, reflex testing, and results reporting. In many cases, samples can be self-administered, reducing staff burden. New PCR tests with rapid turnaround times, like the Mesa Accula, can offer high levels of precision without multi-day wait times for results. In addition, the FDA has now approved multiple over the counter (OTC) rapid Covid-19 tests. These rapid tests are slightly less accurate than PCR laboratory tests but are quite sensitive when used routinely. OTC rapid tests can be self-administered and do not require training, nor do they require reporting results to any central repositories (although it is still recommended to report all positive results to public health authorities). Currently, OTC testing is slightly more expensive than the least expensive facility-wide pooled PCR testing, but the decrease in administrative complexity may make OTC testing an attractive choice. Alleviating the need for trained medical personnel could be particularly helpful for testing in CCFs given that they often lack medical directors and on-site medical staff. Setting up a routine testing program also allows an easier "ramp up" to surge testing everyone if an infection is found.

Testing Strategies

Until facility vaccination rates are very high and community case rates are reliably low, routine testing will remain a crucial protective strategy for CCF staff and residents. Testing strategies can and should adapt to changing levels of risk based on factors like community vaccination rates and viral spread but should also account for the protective effect of vaccines on individual risk. Table 3 (below) is a modified version of the testing strategy included in the original report, now accounting for differing vaccination rates.

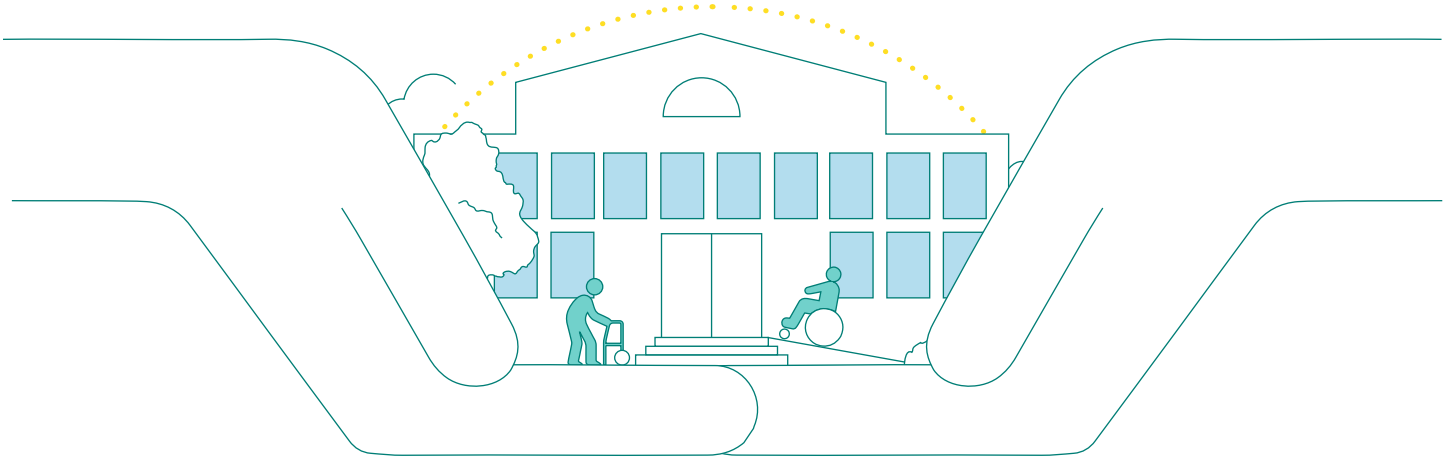
TABLE 3 Example Testing Strategies at Different Risk Levels

RISK LEVEL	EXAMPLE CHARACTERISTICS OF A CCF SETTING	EXAMPLE TESTING STRATEGY
Low	• <1 new daily case/100,000 in local community • 85% + vaccination of staff and residents • 90% + mask wearing compliance (except when eating) • Strong contact tracing program • Good ventilation • Individual rooms	Diagnostic testing for symptomatic and exposed individuals. Outbreak/surge testing if a case is detected.*
Moderate	• <10 new daily cases/100,000 in local community • 80% of residents vaccinated and 50% staff vaccinated • 80% mask wearing compliance (except when eating) • Less effective contact tracing program • Good ventilation	Diagnostic testing for symptomatic and exposed individuals. Screening testing for non-vaccinated staff. Outbreak/surge testing if a case is detected.*
High	• 20 + new daily cases/100,000 in local community • <50% staff vaccinated • <80% mask wearing compliance (except when eating) • No effective contact tracing program • Poor ventilation • Shared rooms	Diagnostic testing for symptomatic and exposed individuals. Screening testing for all staff and non-vaccinated residents. Outbreak/surge testing if a case is detected.*

**Note that outbreak/surge testing is for all individuals, vaccinated and unvaccinated.*

Source: Modification of original Table 2 in Risk Assessment and Testing Considerations for Reducing SARS-CoV-2 Transmission in Congregate Care Facilities

Note that routine testing, in addition to mitigating spread and informing decision-making, can also make a clinical difference for high-risk individuals who are diagnosed early. Monoclonal antibodies and other treatments are most effective when administered early in the disease course. Additionally, FDA has now authorized the monoclonal antibody REGEN-COV to allow post-exposure prophylactic use in high-risk patient groups. Those who have been exposed to the virus can be treated to prevent infection or reduce severity of illness if they are infected. In addition, these drugs can now be given as an injection rather than requiring an infusion.

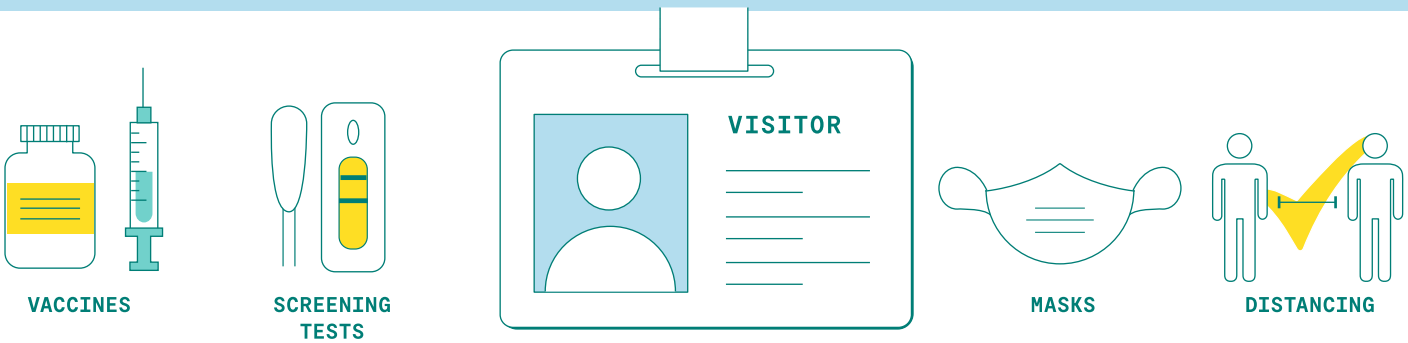


Visitors, family, as well as formal and informal caregivers are critical to maintaining the physical and mental health of CCF residents.

Limited visitation has been shown to be associated with accelerated cognitive decline, increased mental health symptoms, and less access to care for some chronic conditions. Residents are stressed and isolated which can lead to physical, emotional, and mental health declines. As such, CCFs should prioritize allowing residents to visit with caregivers and loved ones. Risk reduction measures can enable more interactions to occur safely. All individuals regardless of their vaccination status should wear masks indoors in counties with high community transmission.

CCF communities can consider these policies that encourage safer visitations, adjusting requirements based on community transmission rates:

- Vaccinated visitors should remain masked indoors but otherwise have no restrictions.
- Non-vaccinated visitors can be asked to either show proof of recent negative test or be tested with a rapid antigen test before entering the CCF. (Non-medicalized facilities can stock OTC rapid tests to give or sell to visitors). All non-vaccinated visitors should be masked and outdoor visits should be encouraged, if feasible.
- Outdoor and distanced visitation can further reduce risk of transmission for all visitors.



Conclusion

Testing will remain an important component of any CCF's Covid-19 risk management practices, but as vaccination becomes more common and new testing options emerge, risk assessments and testing protocols will change.

Data driven and context sensitive testing strategies should lower the burden of testing for CCF residents and staff while enabling safe visitation, appropriate routine medical care, and the fullest enjoyment of life for CCF residents.

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Disclosures

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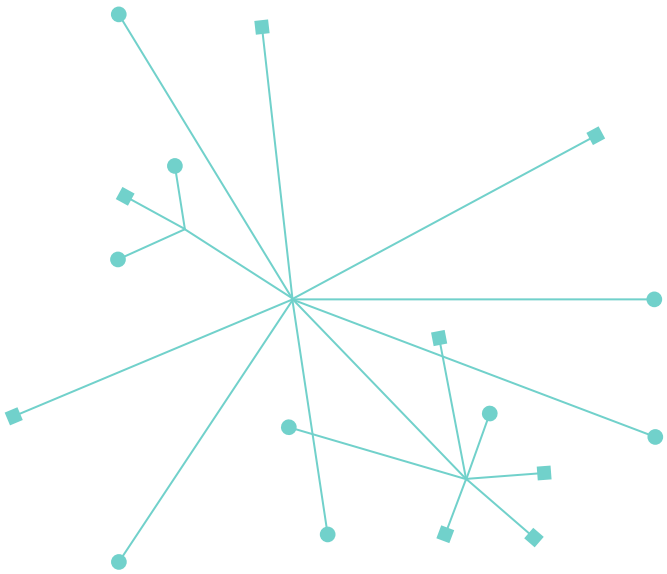

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