



Risk Assessment and Testing Considerations for SARS-CoV-2 Transmission in Congregate Care Facilities

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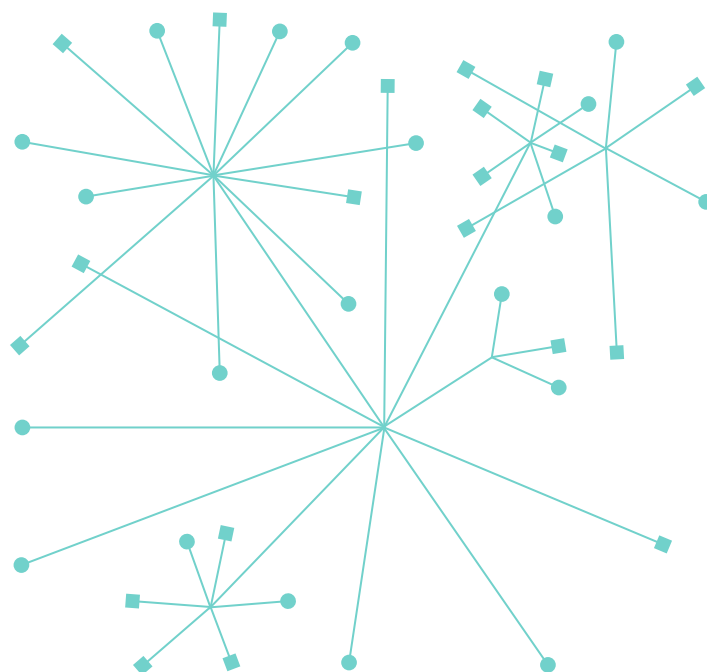
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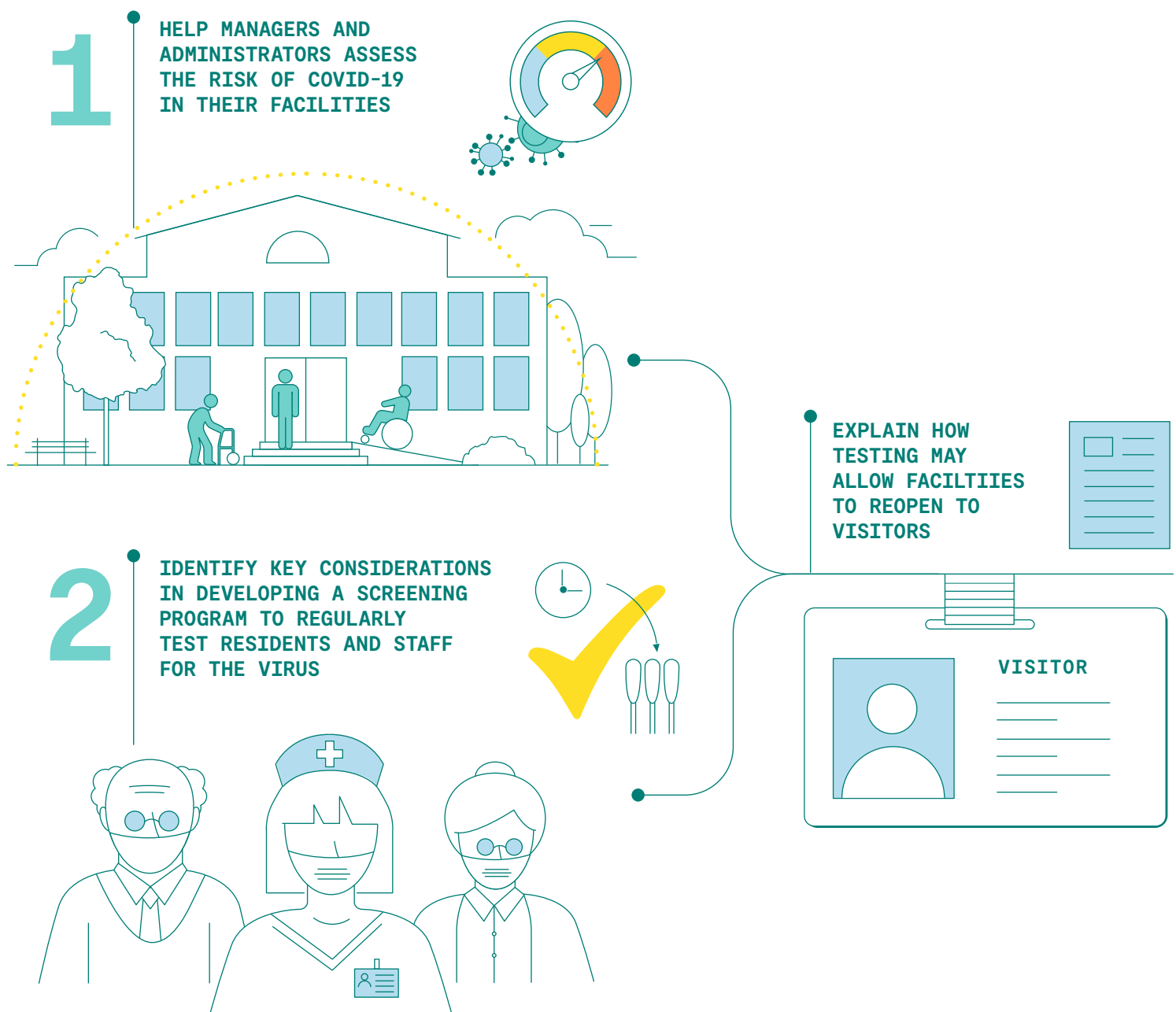
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Objective

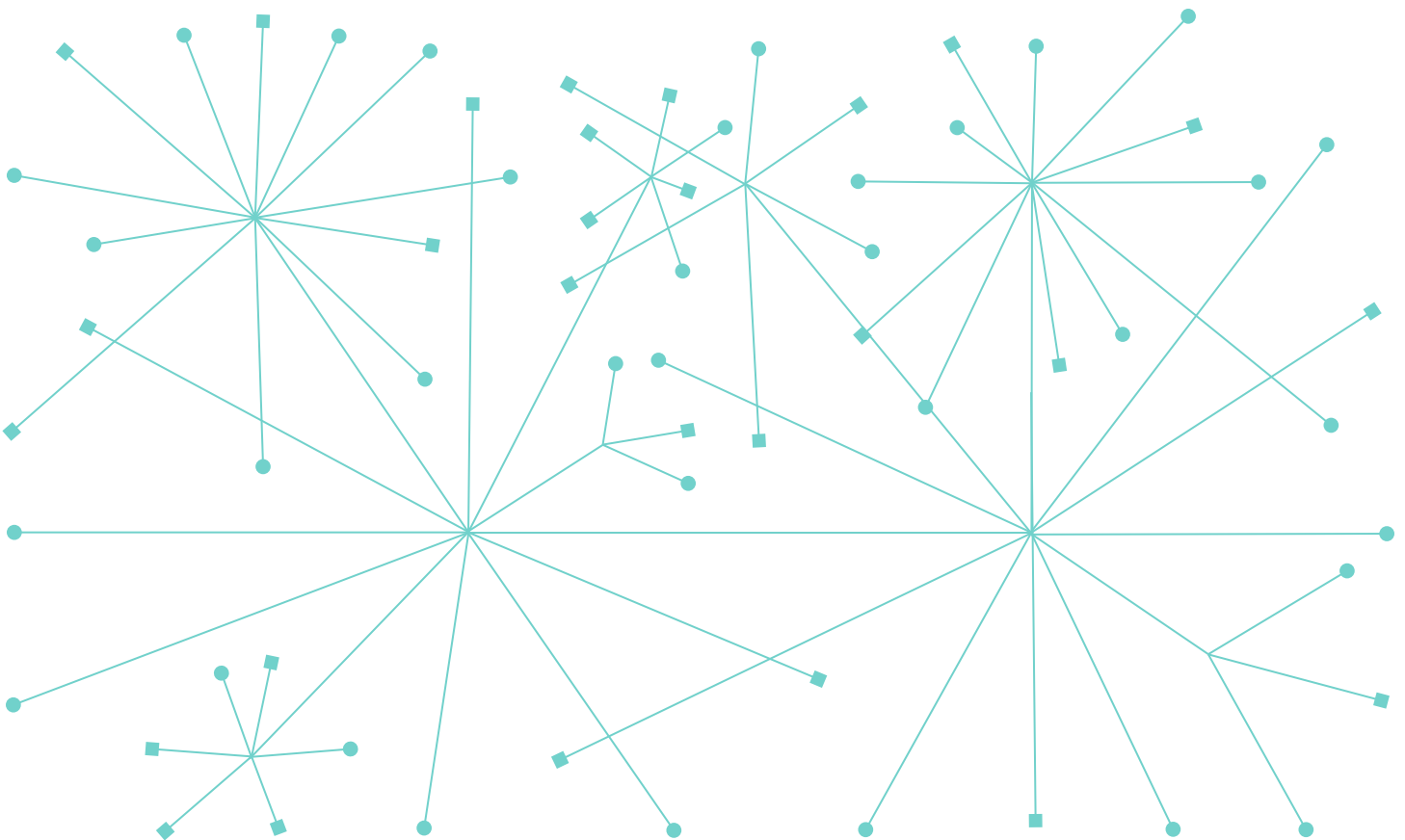
The purposes of this document are to:

1. Help managers and administrators of congregate care facilities (CCFs), such as assisted living facilities (ALFs), memory care units, and federally subsidized senior housing, assess the risk of Covid-19 in their facilities, and
2. Identify key considerations in developing a screening program to regularly test residents and staff for the virus. In addition, because nearly half the states eased visitor restrictions for CCFs at least temporarily by fall of 2020, we offer considerations for testing of visitors.



Introduction

Congregate care facilities (CCFs) are necessary points of care to provide medical and non-medical care for older and disabled adults with functional or cognitive impairment. CCFs, such as assisted living facilities (ALFs), memory care units, and independent living communities, serve populations who are unable or unwilling to live in the community without support but do not need the high level of consistent nursing care provided in nursing homes and skilled nursing facilities (SNFs). Nursing homes and SNFs are also congregate facilities, federally regulated by the Centers for Medicare & Medicaid Services (CMS) (hereafter federally-regulated).



Significant risks for transmission and severe consequences of infection are present in all types of CCFs. Sixteen percent of staff hold multiple jobs, including at other care facilities or in essential worker roles (e.g., grocery store clerks). Residents are likely to have underlying conditions including immunocompromised status, which adds to the consequence of Covid-19 spread in these facilities and the density of the buildings may lead to increased risk of transmission. The early months of the pandemic had disastrous consequences for CCFs, especially nursing facilities and skilled nursing facilities, and the dangers are still present. As of early January 2021, both nursing homes and other CCFs have seen extremely high mortality from Covid-19. Over 140,000, and more than 1,000 staff have died during the pandemic. In December alone, more than 6,400 residents died.

This report focuses on recommendations for CCFs that are not regulated by the federal government, such as the 28,000 ALFs, residential care homes, personal care homes, subsidized senior community living facilities, and memory care units that together serve over one million residents. These types of facilities typically offer meals and assistance with daily activities, with memory care units offering more extensive and intensive custodial care. Testing has slowly increased in these facilities over the course of the pandemic, but still remains challenging. Accelerating use of effective testing protocols will reduce risks and potentially increase freedom for CCF residents by allowing daily activities, communal meals, and visits from family and friends to resume.

We focus on these types of CCFs because, while both CMS and the U.S. Centers for Disease Control and Prevention (CDC) have now released clear screening testing guidance for federally regulated nursing facilities, there is not clear guidance for non-federally regulated CCFs, which may face different infection risks. For context, there are over 15,000 federally-regulated nursing homes and SNFs serving 1.3 million residents. Federally regulated nursing homes and SNFs have very high risk for Covid-19 spread and its consequences. It is common for multiple residents to share a room and for staff to provide close contact care to multiple patients. In addition, there are staffing and reporting requirements related to operations, testing, and Covid-19 mitigation plans.

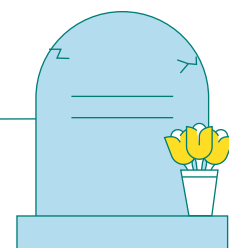
• **SIXTEEN PERCENT OF STAFF HOLD MULTIPLE JOBS**



• **RESIDENTS ARE LIKELY TO HAVE UNDERLYING CONDITIONS INCLUDING IMMUNOCOMPROMISED STATUS**



• **OVER 140,000 RESIDENTS, AND MORE THAN 1,000 STAFF HAVE DIED DURING THE PANDEMIC**

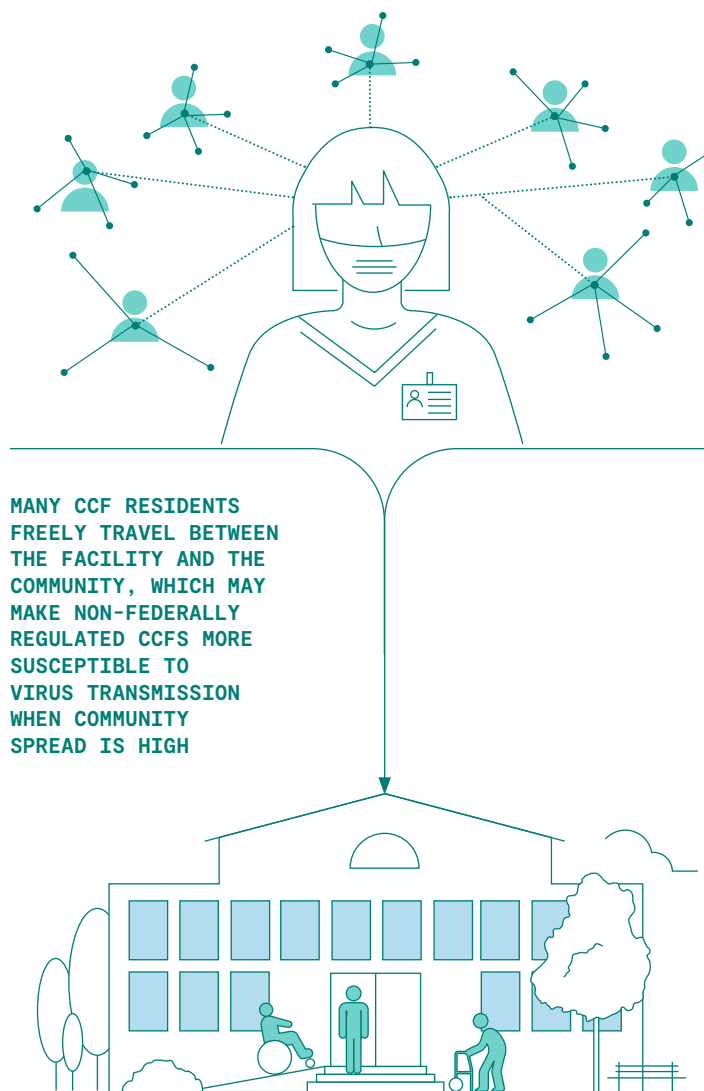


• **ACCELERATING USE OF EFFECTIVE TESTING PROTOCOLS WILL REDUCE RISKS**



Residents in non-federally regulated CCFs have notably different environments and social interaction patterns than those in nursing facilities. Some aspects of these CCFs may decrease risk relative to nursing homes. For instance, most CCF residents live either by themselves or with a single long-term partner, which changes the nature of correlated risk. Nursing homes tend to have shared, semi-private rooms and more amenities that are shared with other residents. Residential care and ALF residents are likely to have their own kitchenette and bedroom even if a communal dining facility is present. Individuals living in memory care units may have private living spaces but generally share more communal spaces than ALF residents. In Section 202 housing (federally subsidized senior housing), residents have their own apartments even as they may share recreational and communal spaces within a building. Individuals who live in these CCFs are, on average, healthier than individuals living in federally-regulated nursing facilities. There is also likely to be less close contact, prolonged caregiving, and therapeutic interactions such as the dispensing of medication. However, some aspects of CCF communities may increase infection introduction risk relative to nursing facilities. For example, CCF residents have significant autonomy. Many freely travel between the facility and the community, which may make non-federally regulated CCFs more susceptible to virus transmission when community spread is high, as there may be greater contact with the general public.

A distinguishing feature of many CCFs, particular ALFs, is that they provide residential and care services but are not inherently medicalized facilities: resident autonomy and choice is highly valued. The culture and regulatory requirements de-emphasize the medical model, which often results in fewer infection control procedures and fewer standing medical resources such as infection prevention coordinators. As a result, ALFs, which do not provide direct medical care to residents but help residents with daily tasks, may be less prepared for Covid-19 outbreaks than are nursing facilities, given they have not been required to comply with nursing home-type reporting requirements or have an up-to-date infection control plan.



Staffing patterns also differ from those of federally-regulated nursing facilities. CCFs are far less likely to have medical directors, registered nurses, or other highly trained medical staff on-site. Individual residents often independently contract with home health aides, physical/occupational therapists, and other service providers. Most of these contracted individuals routinely work in multiple locations over the course of a day and workweek. Residents also commonly visit their own primary care providers off-site. CCFs are unlikely to have Clinical Laboratory Improvement Amendments (CLIA) certifications or waivers, which are required to conduct and analyze most Covid-19 testing on-site.

While less data is available on CCF infections and mortality than for nursing facilities, the overall risk of infection appears significantly lower but still substantial, and risk of hospitalization and death for residents who are infected is still high. Nationally, 78% of federally-regulated nursing facilities have had at least one resident infected with Covid-19. In contrast, in the 39 states that reported data, the CDC has found that 22% of ALFs had at least one Covid-19 positive resident and that mortality was approximately 21% for infected residents. This mortality rate is much higher than in the general population in these states (2.5%). Thus, CCFs like nursing facilities face severe consequences of infection, and relatively high risk of infection compared to the general population. But the fundamental differences in the operations of these environments necessitates tailored strategies to evaluate and mitigate Covid-19 risk, including testing guidance.

Risk to CCF residents remains high even as vaccinations have begun, because, thus far, vaccine distribution has occurred primarily in federally-regulated facilities. Because non-federally regulated CCFs are lower on the vaccination prioritization list than federally-regulated facilities, the consequences of an outbreak remain deadly for these facilities. Although the deployment of vaccines will lower the severity of illness and chance of death, testing at CCFs should continue to be prioritized until we better understand the ability for vaccinated individuals to transmit the virus. CCFs may also be challenged by new, more infectious variants of the virus that increase transmission risk.

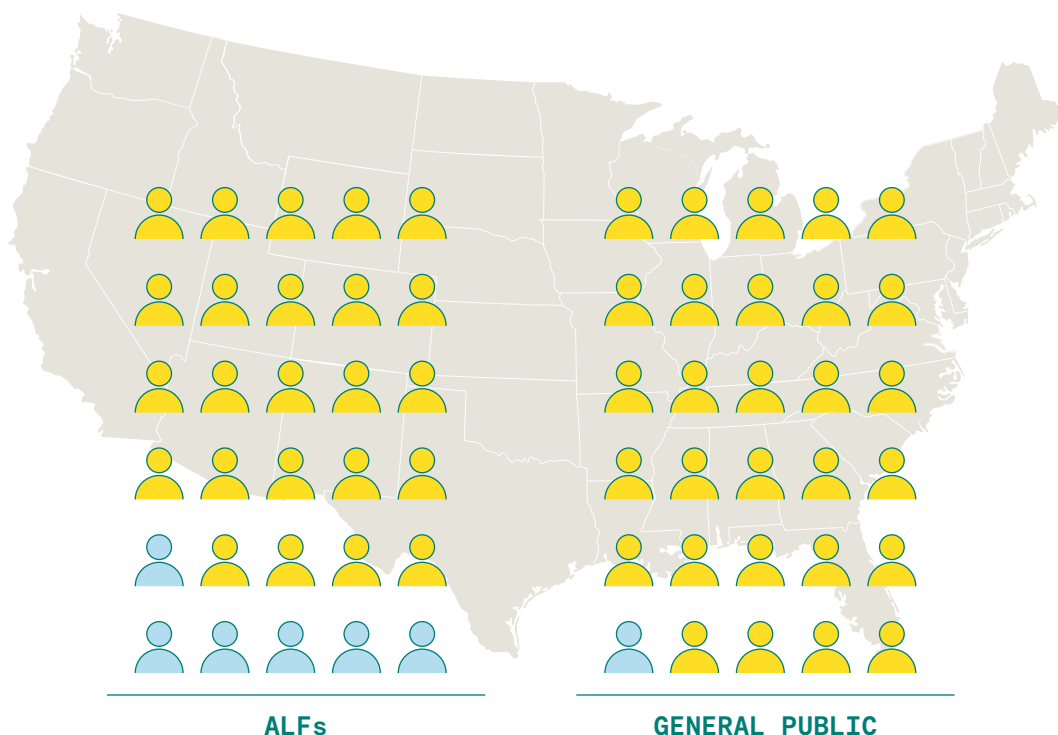
Despite the critical need to for testing, hurdles remain. There are still reports of test shortages and delays in returning results among facilities with testing. Only 17% of federally-certified nursing homes reported returning results to residents in one day and CCFs such as ALFs are likely to face larger barriers. These challenges including test financing, test turnaround time, and staffing capacity, and must be overcome for effective testing strategies to be implemented (see Appendix A).

THE CDC HAS FOUND THAT 22% OF ALFs HAD AT LEAST ONE COVID-19 POSITIVE RESIDENT AND THAT

MORTALITY WAS APPROXIMATELY 21%

FOR INFECTED RESIDENTS.

THIS MORTALITY RATE IS MUCH HIGHER THAN THE GENERAL INFECTED POPULATION IN THESE STATES (2.5%).



 DECEASED  INFECTED

Visitor Restriction Policies

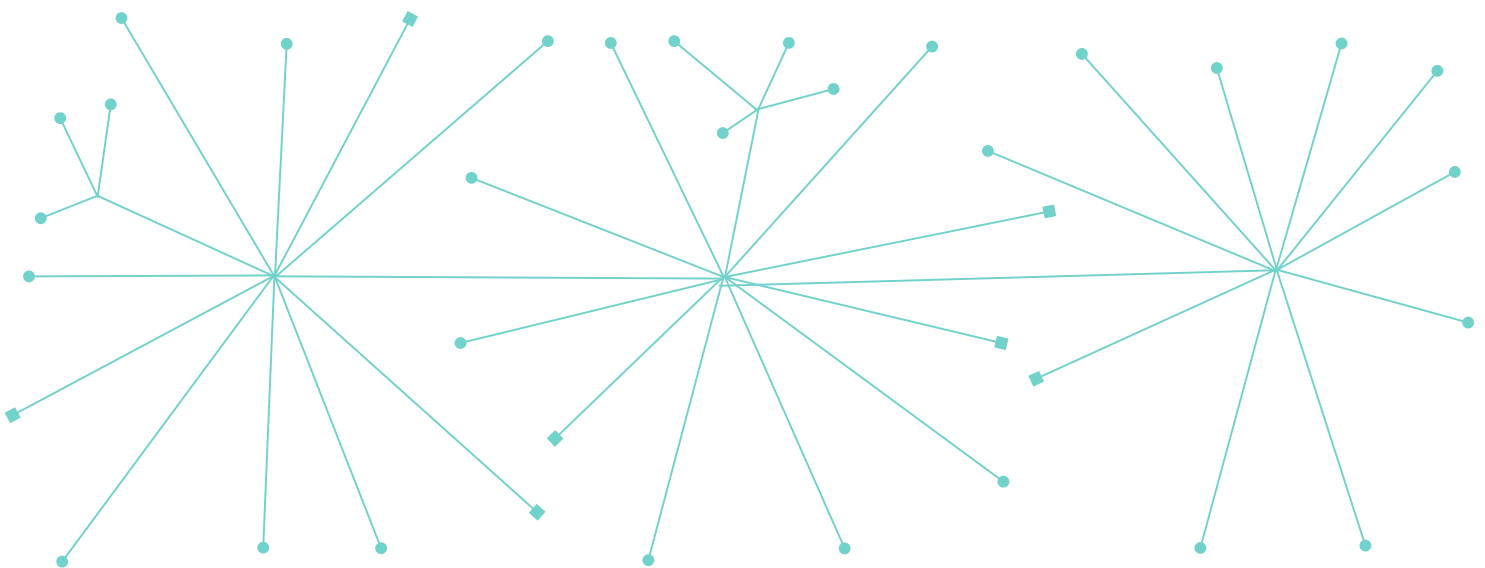
As the combination of vaccinations and social distancing measures reduce community spread, facilitating and increasing testing in CCFs will enable facilities to mitigate infection risk and be more open to visitors.

Many facilities had temporary no-visitor policies from March to September 2020. Half the states loosened restrictions in September-October 2020 and many individual CCFs tightened them again by Thanksgiving 2020, and remain in place as of mid-January 2021. Visitor restrictions are not only distressing for families, who are often serving as unpaid caregivers for residents, they can also be harmful for residents. Evidence has been growing that physical and social isolation of residents has profound negative effects ranging from accelerated aging and advanced dementia to a decrease in the level of tacit and unpaid care that family members and close friends can provide residents. There are few evidence-based practices for visitor policies at this time, even as some states allow family and other non-professional caregivers to be classified as “essential caregivers” for entry purposes.

In order to lift visitor restrictions for CCFs and mitigate future outbreaks, measures to prevent SARS-CoV-2 transmission must be at the forefront

of any discussion. With high documented rates of asymptomatic Covid-19 in nursing homes and similarly high asymptomatic rates expected in other congregate care facilities, a symptom-based screening strategy is insufficient. In addition, visitor policies are not being driven by evidence, so the evidence base around infection risks from visitors needs to be built. A recent rapid review found little scientific evidence of visitors introducing cases into facilities, although this may be because during the first peak of the pandemic very few governments allowed visiting. There is some anecdotal evidence of infections being attributed to visitors before restrictions were enacted, but decisions on visiting have been ad hoc in general.

Testing visitors may be a way to allow family and friends to socialize and care for their loved ones more safely. An example of such a strategy can be seen in Massachusetts where rapid antigen testing kits were allocated to CCFs and long-term care residences to screen visitors.



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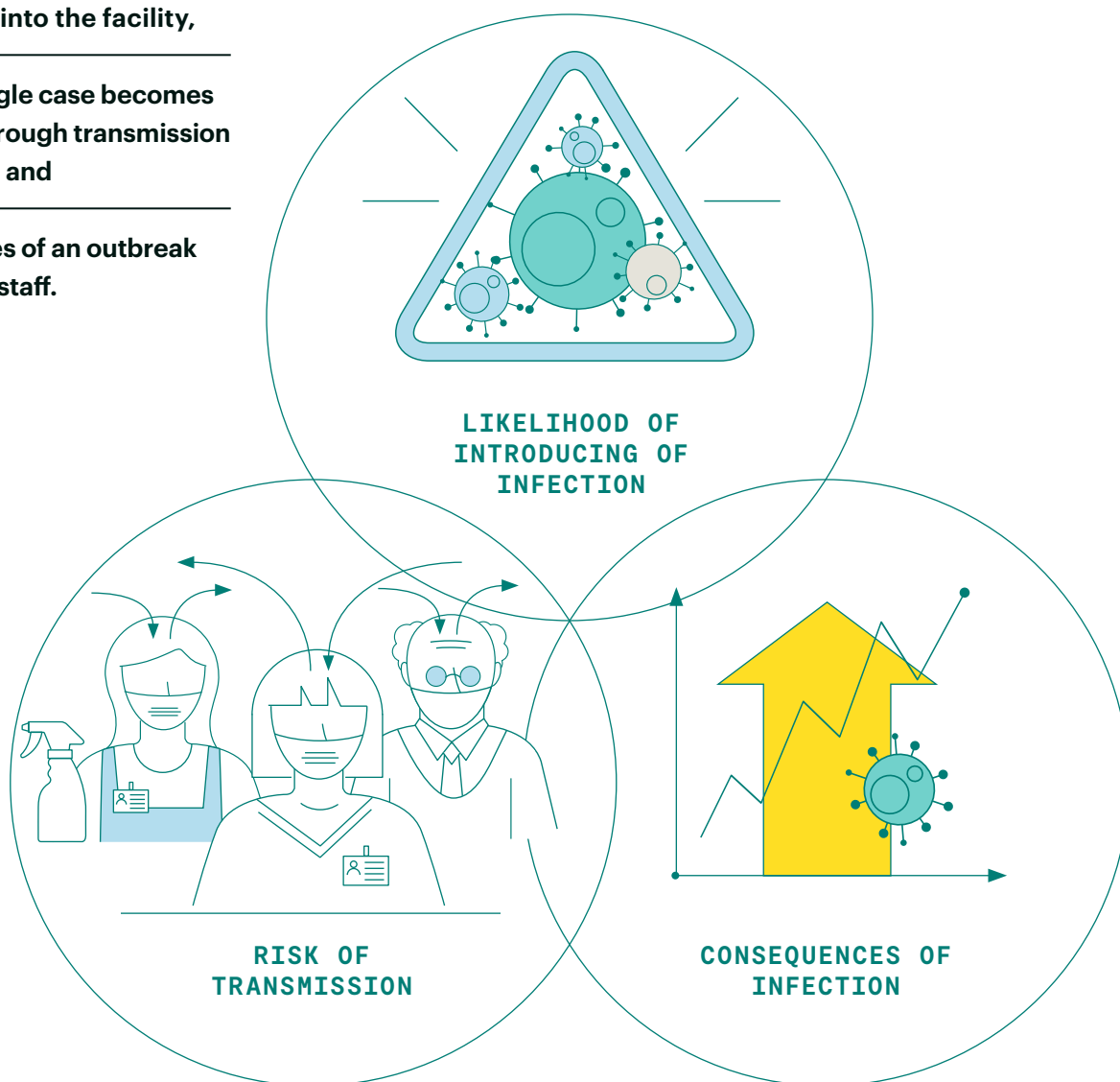
Risk Assessment

The first step when considering implementing a testing strategy is to do a rigorous risk assessment of the facility, residents, and staff.

Risk assessments are composed of three parts:

1. The likelihood of introducing a case of Covid-19 into the facility,
2. The risk that a single case becomes multiple cases through transmission within the facility, and
3. The consequences of an outbreak for residents and staff.

Facilities should assess each of these factors for their own local circumstances and observations as well as consider how vaccination will change the consequences of an outbreak. It may also be useful to consider the staff and residents separately in the risk assessment, especially for facilities where residents are less likely to leave the facility and interact with the general public.



Likelihood of introduction of a Covid-19 case into a Congregate Care Facility

Here we consider the likelihood of a person who contracted Covid-19 outside of a CCF bringing it into the facility.

The likelihood of a Covid-19 case being introduced to a CCF is a direct function of the overall prevalence of Covid-19 cases in the facility’s local surrounding area. Community prevalence drives risk of infection for individuals residing in a CCF, and it will be important for managers and administrators to be aware of local Covid-19 incidence. Tools can then be used to assess a risk “level” with which a facility can start the assessment. For example, a tool from Brown University called “Pandemics Explained” categorizes community risk into four levels. These risk levels are a continuum of the number of daily newly detected infections per 100,000 residents.

As disease incidence increases in a community, the probability that at least one individual in any group is infectious at a given time increases, as shown in Figure 1.

CCF residents and employees have variable degrees of interactions with the general public in their community, so the risk assessment should take this into account. Facilities where residents rarely leave the premises and have barred visitors will have a lower risk of an infection than facilities with significant interactions with the community. Settings with many visitors and traveling or contracted staff (e.g., supplemental healthcare providers like home health aides, beauticians, or other volunteers) may be at higher risk due to the additional contacts and extended interaction networks these individuals have in the community. Another source of elevated transmission risk for residents and staff results from staff who work in multiple CCFs or in other essential worker roles such as grocery store clerks. Individuals who are in broad, loosely connected, high interaction networks may have increased personal infection risk as well as risk of introducing infection to other settings. Importantly, in addition to often having other jobs, direct-care workers in CCFs are commonly unpaid caregivers for their own family members across multiple households.

TABLE 1 Pandemics Explained Community Risk classifications by incidence

Table 1 is modified from Pandemics Explained. All risk assessments should be thought of as a continuum with an eye towards the underlying rates. When possible, changes in mitigation measures based on increasing cases should occur in a continuous manner, rather than sudden, dramatic changes as levels cross a particular threshold.

LEVEL	REPORTED DAILY NEW CASES
Green	<1 PER 100,000 COMMUNITY RESIDENTS
Yellow	1–9 PER 100,000 COMMUNITY RESIDENTS
Orange	10–24 PER 100,000 COMMUNITY RESIDENTS
Red	25 OR MORE PER 100,000 COMMUNITY RESIDENTS



FIGURE 1 Chance of infected individual present within a facility

Figure 1 estimates the probability that at least one person in a group of a particular size is infected with Covid-19. These estimates were made using the [Georgia Tech COVID-19 Event Risk Assessment](#) methodology, assuming a 10-day infectious period and a correction to account for under-reporting and ascertainment bias (multiplier of 5). Note that this may be an overestimation in areas that have low test positivity ratios, meaning that the likelihood of an infected individual within the facility may be lower.

1 DAILY NEW COMMUNITY CASE PER 100,000 PEOPLE	Number of individuals interacting with the general public	10	25	100	500
	Chance of at least 1 infected individual	0%	1%	5%	22%
10 DAILY NEW COMMUNITY CASES PER 100,000 PEOPLE	Number of individuals interacting with the general public	10	25	100	500
	Chance of at least 1 infected individual	5%	12%	39%	92%
25 DAILY NEW COMMUNITY CASES PER 100,000 PEOPLE	Number of individuals interacting with the general public	10	25	100	500
	Chance of at least 1 infected individual	12%	27%	72%	100%
100 DAILY NEW COMMUNITY CASES PER 100,000 PEOPLE	Number of individuals interacting with the general public	10	25	100	500
	Chance of at least 1 infected individual	40%	72%	99%	100%



Likelihood of onward transmission

Here we consider whether a single case in a CCF could cause an outbreak within the facility. Transmission is dependent on mitigation measures. Although we are not yet able to quantify the incremental value of each mitigation measure, guidance by the CDC and others propose a number of measures that, when taken together, can significantly reduce the risk of transmission in a CCF.

Risk of onward transmission is dependent on whether mitigation measures are being effectively implemented and rigorously followed.

All CCFs should have multiple measures and strategies in place to manage risk and provide protection for residents, staff, and visitors. Many different strategies can be used, and while none are perfectly protective, by layering these strategies together the overall protective effect is stronger (see Figure 2). Mitigation steps include increased hand hygiene, mask-wearing, reductions in housing density, social distancing, symptom tracking, and improved ventilation.

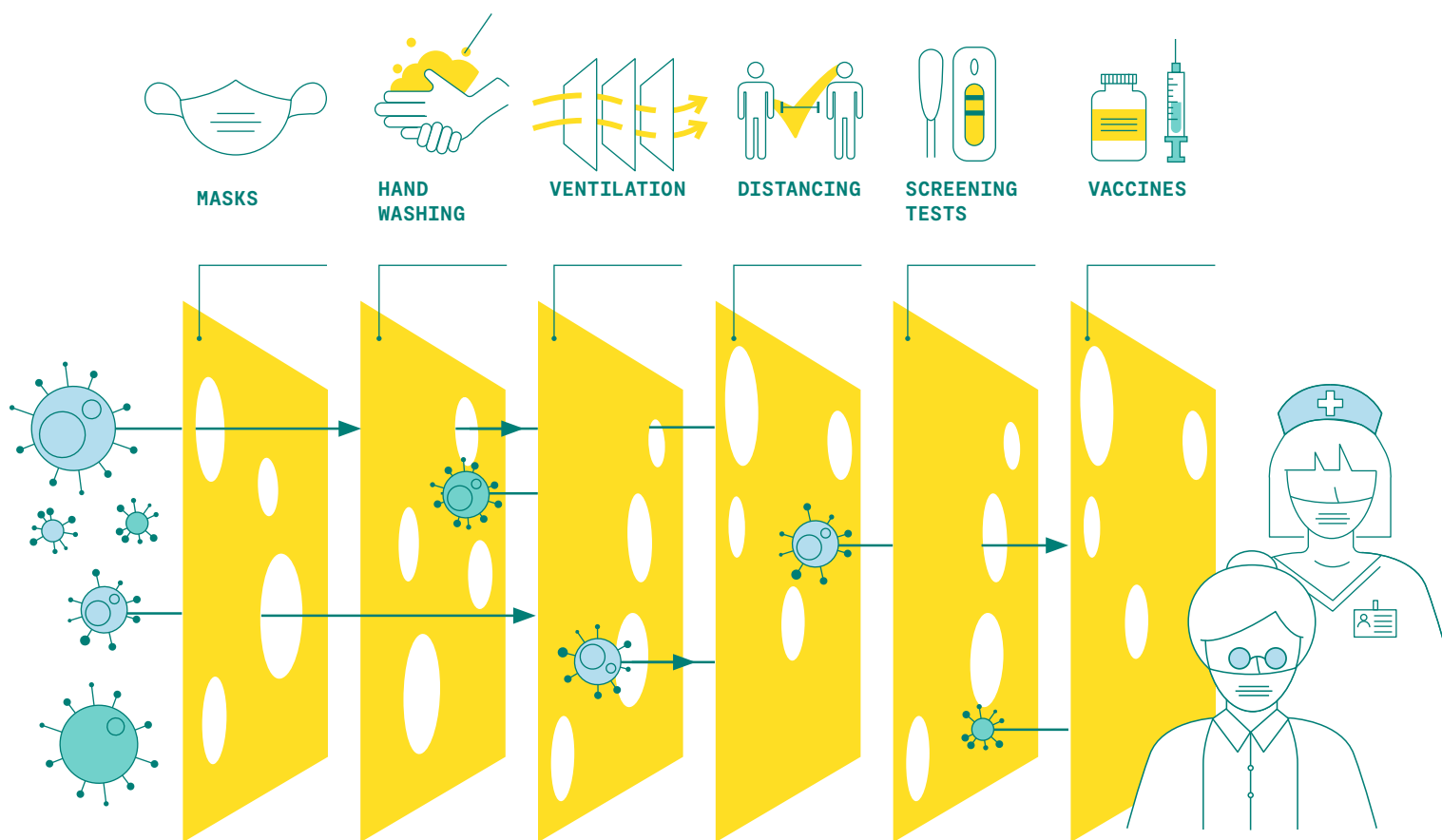


FIGURE 2

Layers of protection that must be taken to ensure Covid-19 spread reduction

Figure 2 illustrates the "Swiss cheese" model of risk mitigation. Multiple types of precautions must be taken in order to effectively reduce Covid-19 spread. As none of these methods are 100% effective, a combination of many layers of protection is needed. Where one method fails (a "hole" in the "Swiss cheese"), another layer may succeed in blocking transmission. Together, the mitigation measures make a more solid and resilient barrier to transmission.



Mask-wearing reduces Covid-19 infection and severity risk to both the mask wearer and the community around them. Social distancing also reduces SARS-CoV-2 viral particle transmission. Staggering meal times, designating hallways and paths as one-way, ensuring frequent handwashing, improving air filtration and ventilation, and holding events outdoors are other techniques that can be used to mitigate transmission risk and protect residents, staff, and visitors.

The risk of onward transmission will be decreased as more mitigation measures such as masking, social distancing, and testing are effectively implemented. Groups that are unlikely or unable to adhere to mitigation measures like social distancing or masking, such as residents that may not be able to remember the importance of such measures or who routinely need care requiring prolonged close contact, may be considered higher-risk subpopulations within CCFs. Some facilities may also have residents who refuse to follow these guidelines. It is critical to assess the real-world adherence of mitigation measures within the facility when doing this portion of the risk assessment.

Lifting visitor restrictions inherently creates new potential opportunities for infected individuals to enter the facility and cause outbreaks, but mitigation steps can limit risk of transmission. In mid-September 2020, CMS announced new guidance to implement safe indoor and outdoor visitation for nursing homes, outlining best practices aimed at reducing risk of SARS-CoV-2 transmission during visits. Outdoor visits are encouraged as they facilitate airflow and social distancing and yet indoor visitation can also be permitted with safeguards in place such as ventilation, glass barriers, hand hygiene, proper masking, and screening of visitors. CCFs are continuing to address how to reduce resident isolation (e.g., through resident activities or video visits with external family) while mitigating risk of Covid-19. Gathering evidence to understand transmission risk posed by visitors is critical given the very real harm to residents' mental and physical health that visitor restriction policies can inadvertently cause. Airlines are beginning to require proof of recent tests for passengers to board some flights; CCFs may wish to consider a requirement that visitors present a recent negative antigen or molecular test to enter the CCF.

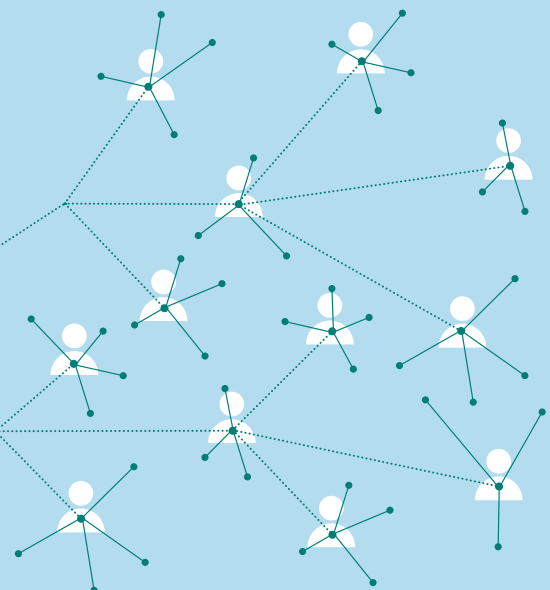
Consequences of transmission

Here we consider consequences of onward transmission to residents and staff of CCFs. Given the age and likelihood of underlying medical conditions in this population, this consideration is particularly important.

Consequences of transmission in CCFs are very high as the mortality risk is very high for CCF residents. CCF residents are likely to be elderly or have underlying health conditions that put them at higher risk of severe Covid-19. Mortality and morbidity risk increases with age, but baseline risk is likely somewhat lower in independent living and ALFs compared to nursing facilities as they house a generally healthier population. Memory care units, however, are more similar to nursing facilities in their risk level; demands for hands-on, close contact care are high in such wings, rooms are often semi-private rather than private, and there is little ability to restrict movement of residents.

Vaccines are a strong risk mitigation tool in Congregate Care Facilities

Older adults, including those living in CCFs, have been prioritized for vaccination efforts, as have frontline healthcare workers. This means that most CCF residents and professional caregivers should be eligible for vaccines very early in 2021. Current evidence shows that vaccination significantly alters the consequence of infection because vaccinated individuals are far less likely to have a symptomatic infection and very unlikely to have a serious infection. CCFs where all residents and staff are vaccinated will have notably different and lower consequence of transmission in morbidity and mortality. However, it is not yet known if vaccinated individuals are still infected at similar rates or if they can transmit the virus. In addition, some facilities may have higher rates of individuals unable or unwilling to be vaccinated. And while frontline healthcare workers have been prioritized for the vaccines, other staff in the facility may not be eligible until later. As such, other mitigation measures including surveillance testing to measure background community prevalence will still be needed until we have a better understanding of the effects of vaccination.



2

Testing Approaches

The choice of a testing protocol will be partially determined by a facility's available resources as well as their specific goals such as allowing for visitation, reducing transmission, or re-starting communal social activities. There are three different types of testing (see Table 2): diagnostic testing, which is used to test individuals who are suspected to be infected; screening testing, which is administered out of precaution to individuals who do not have a known exposure; and surveillance testing, which informs public and community health decision-making. CCF administrators should use the best available evidence as described below for the basis of their actions. As new evidence is generated, it should be incorporated into the decision-making process.

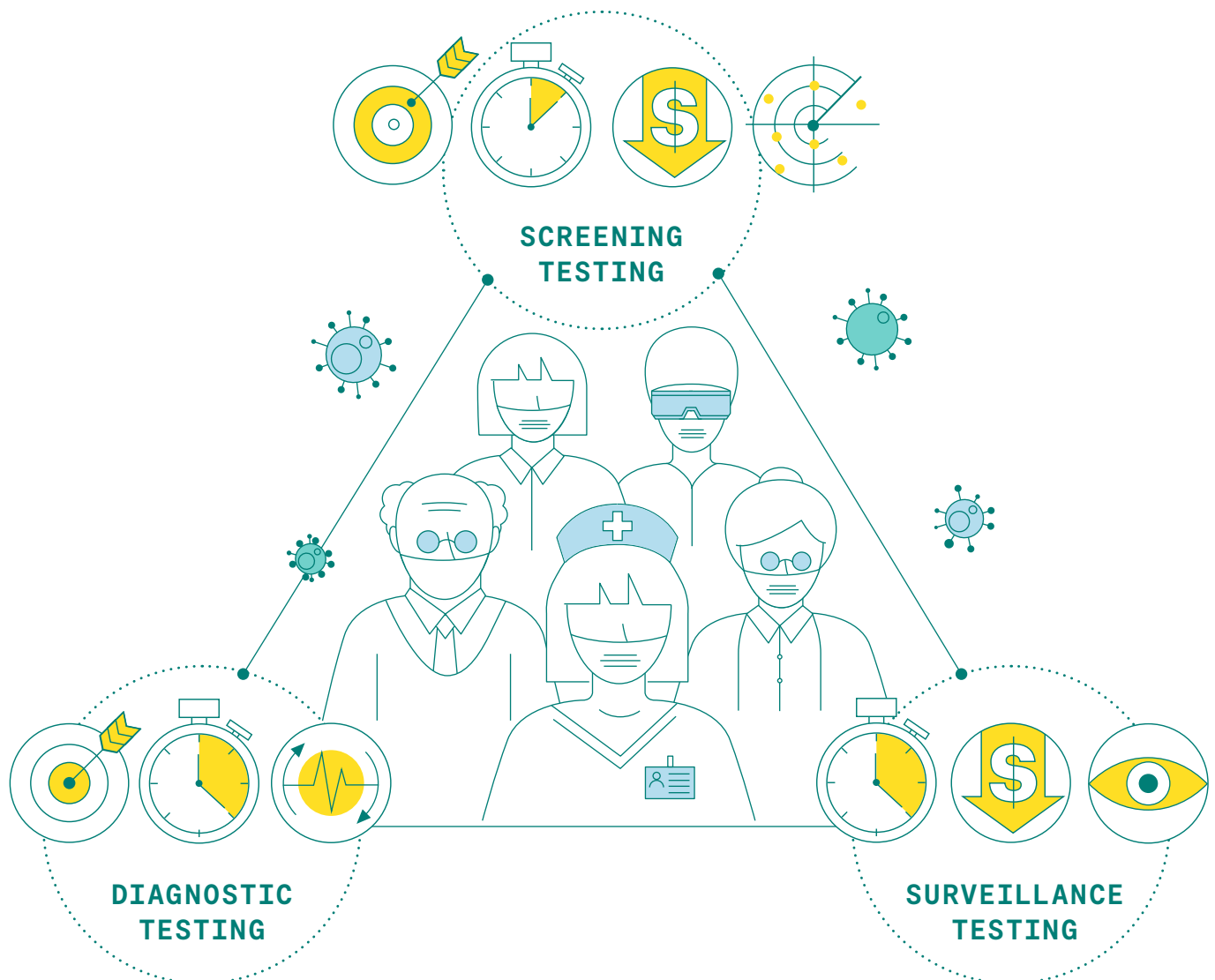


TABLE 2 Testing purposes and characteristics

Table 2 describes the three different types of testing that are conducted with regards to Covid-19 as well as other infectious diseases: diagnostic, screening, and surveillance. It also highlights the unique purposes of these testing types, what testing characteristics must be prioritized to ensure efficacy, and the required levels of accuracy for such tests.

TESTING TYPE	PURPOSE	PRIORITY CHARACTERISTICS	REQUIRED SENSITIVITY AND SPECIFICITY
Diagnostic Testing	Diagnosing symptomatic individuals and close contacts of those infected for clinical and public health decision-making.	Highly accurate results with a short enough time to results for appropriate clinical treatment (if required) and effective isolation and contact tracing.	> 95% Sensitive > 99% Specific
Screening Testing	<p>Routine testing of individuals without symptoms or any history of exposure. The objective of screening is to reduce infection spread by isolating potentially infected individuals faster to protect public health.</p> <p>Screening tests can also be used less frequently or on random subsets of a population to determine prevalence.</p> <p>Screening testing protocols can also be done only in response to an active infection being identified. This is referred to as “surge testing”.</p>	For regular routine screening, frequency of retesting and time to results is more important than highly accurate tests; confirmatory tests may be needed for individual clinical decision-making.	> 70% Sensitive > 97% Specific (higher specificity is required if used in low prevalence settings)
Surveillance Testing	Understanding prevalence in a community to inform workplace, local, or regional policies. Individual results are not returned.	Frequency and time to results should be appropriate to allow timely decision-making and course adjustment.	Because these tests are not used for individual decision-making, less accurate tests can be used if highly validated to allow for appropriate statistical adjustments.

In September 2020, CMS issued guidelines for staff and resident screening test frequency based on test positivity rates in the community (Table 3). For CCFs with similar risk profiles as nursing homes, this guidance may be particularly relevant. However, for CCFs whose risk profile is lower, less frequent testing may be required.

CMS has recommended that facility-specific protocols be put in place to test nursing home and SNF staff (Table 3). Individuals who are symptomatic or in close contact with individuals with a confirmed positive Covid-19 diagnosis should be immediately tested and isolated until results are returned. If there is an outbreak, defined in nursing homes as a single new infection in a facility, surge testing of all individuals, residents, and staff should commence and continue until all tests return negative. While frequency can be adjusted to looser and less frequent testing for individual CCFs, depending on a risk assessment, testing protocols are relevant and needed in all CCFs.

CCFs more generally will need to consider the differences in their structure and risks compared to those of nursing facilities to ascertain whether they want to make adjustments to CMS’s testing guidance. This is particularly the case if their residents are more at-risk of contracting infections from each other or those outside of the CCF setting, rather than from staff. CCFs differ from nursing facilities due to the differing work and social networks within facilities as well as between facilities and the community for medical appointments, religious services, family visits, and other social and economic interactions. CCFs are also likely to have different resource endowments such as small or non-existent medical claims that are reimbursable by the federal or state government, lower profit margins, fewer medical staff and capabilities, and more extensive use of external contractors to provide in-facility services. Additionally, CCF administrators, staff, and residents may have other/additional goals such as the ability to hold physically distanced recreational/social events in common spaces or to re-open communal dining facilities.

TABLE 3 CMS Guidance for Nursing Homes

Table 3 is adapted from CMS’s [Interim Final Rule](#) in response to Covid-19 in nursing homes and frequency assumes <48 hour turnaround for test results.

COMMUNITY COVID-19 ACTIVITY	COUNTY POSITIVITY RATE IN THE PAST WEEK	CMS-GUIDANCE FOR TESTING STAFF* AT NURSING FACILITIES AND SKILLED NURSING FACILITIES (SNFS)
Low	<5%	Monthly
Medium	5%–10%	Once per week*
High	>10%	Twice per week*

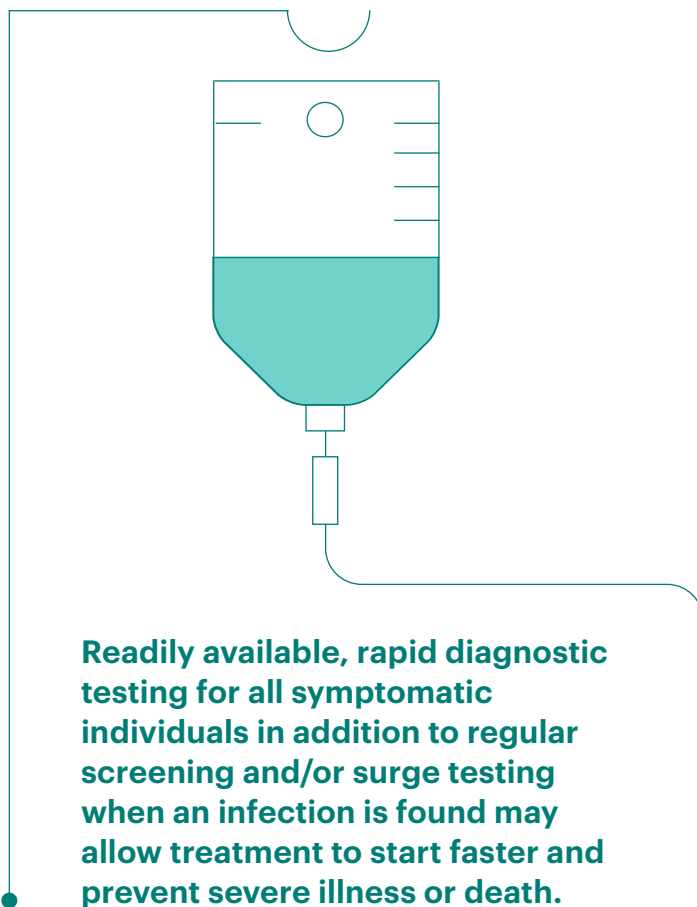


* Residents are recommended to always have diagnostic testing available if symptomatic or exposed to an infected individual. However, CMS does not require routine testing of residents. In response to any new infection in the facility “all staff and residents should be tested, and all staff and residents that tested negative should be retested every 3 days to 7 days until testing identifies no new cases of COVID-19 infection among staff or residents for a period of at least 14 days since the most recent positive result.” This type of testing is referred to as “surge testing”.

Furthermore, facility administrators have many other transmission risk factors to consider such as returns from medical visits, especially from emergency departments and inpatient settings. Risk management must be undertaken as residents move within both the residential setting and broader community. Interactions with heavily tested/protected populations like those in hospitals may not necessitate additional testing. In contrast, interactions with the broader community or susceptible individuals may prompt further testing for both the exposed individual and their contact networks.

Similarly, in addition to community positivity rates, CCF testing protocols need to consider the realities that staff live and face as well as their health and well-being. Staff are likely to work in multiple locations within a community or even in multiple communities. Contracted aides commonly provide daily care, and whereas some paid aides ceased care temporarily or were barred from facilities in early months of the pandemic, contracted aides have generally resumed visits in CCFs, and need to be part of a CCF's testing protocol. At a minimum, this would require documentation of where and when a contracted aide obtained testing and protocols for facilitating testing of aides on-site. Overall, CCF direct-care workers face greater risks of negative consequences if infected too, compared to other essential workers, given their high rates of chronic conditions for their age. For example, over one-third of direct care workers in a large Northeastern nursing home chain, who averaged 40 years of age, reported having at least one chronic condition; 70% of them also agreed or strongly agreed that "when you are sick, you still feel obligated to come into work." Thus, CCF administrators also need to be aware of these pressures when setting minimum frequency of testing strategies.

Finally, congregate care facilities need to consider how early diagnosis and treatment may benefit their residents as new Covid-19 treatments enter the market. Two monoclonal antibody treatments have so far been granted Emergency Use Authorization, specifically for older patients and those with underlying medical conditions, populations often found in CCFs.



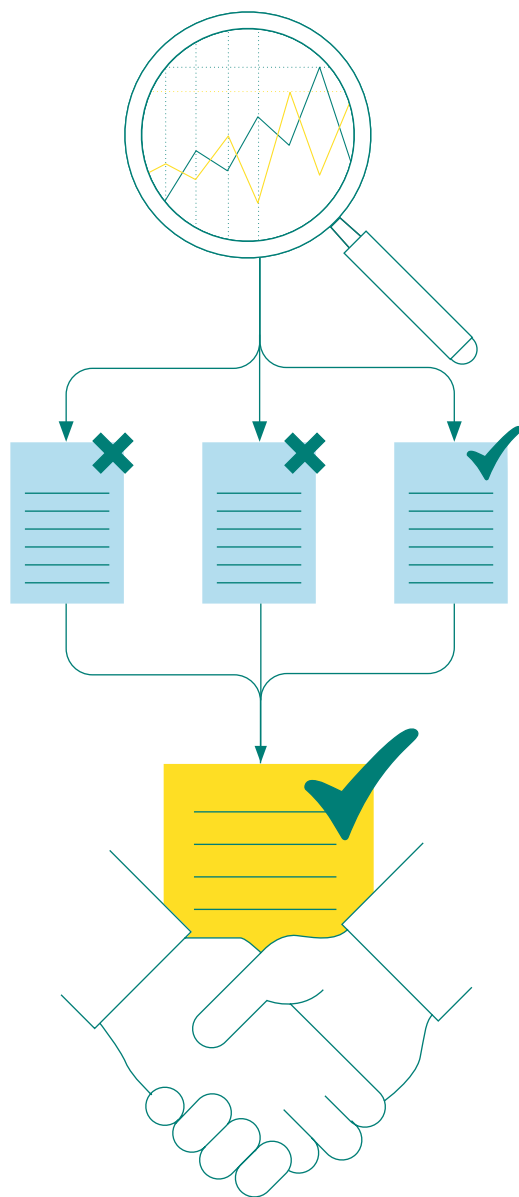
Readily available, rapid diagnostic testing for all symptomatic individuals in addition to regular screening and/or surge testing when an infection is found may allow treatment to start faster and prevent severe illness or death.

These treatments are most effective when given very early in the course of the infection, and recent evidence suggests may even prevent infection in people that have been exposed. Therefore, early identification of new infections now influences clinical decision-making as well as has public health implications. Readily available, rapid diagnostic testing for all symptomatic individuals in addition to regular screening and/or surge testing when an infection is found may allow treatment to start faster and prevent severe illness or death.

Communities have a wide variety of testing options from which to choose. Key trade-offs need to be made between test turnaround time, specificity, and frequency. Additionally, CCFs may have certain sub-populations of residents and workers who are higher or lower risk and may benefit from different testing protocols. As CCFs achieve higher levels of vaccine uptake, testing protocols may change to surveillance testing only to reflect the changing levels of risk.

3

Considerations for designing a testing protocol



Diagnostic testing

The first pillar of every CCF's testing protocol should be ensuring timely and accessible diagnostic testing for any CCF resident or staff showing symptoms of Covid-19 or identified as a close contact of a confirmed case. Symptomatic individuals should be quarantined as soon as symptoms appear. Those who test positive should remain in isolation until all of the following criteria are met: ten days have passed since symptom onset, at least 24 hours have passed since resolution of fever without medication, **and** other symptoms have improved. The CDC does not recommend that people be tested again before leaving isolation because recovered individuals can test positive for several weeks post-recovery without posing an infection risk to others. Individual facilities should also encourage and facilitate diagnostic testing for anyone that was in close contact with an infected person. If they test positive, they should quarantine for the greater of 10 days or the clearance of symptoms. If an individual receives a negative test, they should remain in quarantine for ten days if there is no follow-up testing or seven days if the individual receives a negative result on a test performed on day 5 or later. CDC guidance for critical infrastructure workers suggests that individuals who were in close contact with an infected individual could return to work after baseline and serial testing has commenced. CCFs may consider this approach. This "test-out" capability may increase the effective labor force of some facilities. More risk-averse facilities with adequate staffing may require multiple negative tests, an alternative diagnosis, or a full ten-day quarantine regardless of test result. On the other hand, staff shortages may drive earlier returns for Covid-19 positive patients: in North Dakota, and other states, some direct-care workers during a large outbreak in November 2020 were allowed to return to duty to work in Covid-19 units after being identified as positive but asymptomatic.

Testing is important for close contacts even if the same quarantine is required because it will initiate another round of contact tracing on that person's contacts and guide medical care. It may also allow targeting of antibody treatments early in the patient's disease progression.

Screening and Surveillance

While accessible diagnostic testing is critical, it hasn't been enough to stop outbreaks in CCFs, particularly in communities with high prevalence of the virus. Frequent and rapid screening testing is vital to identify symptomatic and pre-symptomatic individuals before widespread transmission to other residents can occur. Frequent testing with rapid turnaround time is critical. Deaths in nursing homes as a percentage of all deaths due to Covid-19 in the United States have been decreasing as rapid and routine screening testing is implemented, but still represent around one-third of all deaths. At the same time, testing protocols that emphasize frequent surveillance and screening have been shown to be a "safety net" for some universities and other settings and could potentially offer the same benefits for large and/or chain CCFs that can mobilize rapidly. Importantly, testing technology is advancing rapidly, with multiple rapid antigen tests now available. In fact, the U.S. Department of Health and Human Services (HHS) is pilot testing portable, cartridge-based Covid-19 molecular test kits that provide rapid results. These types of tests could be particularly helpful to CCFs, which rarely have medical directors or permanent medical staff. They could ensure faster turnaround times, which are vital to any testing strategy intended to control an outbreak.

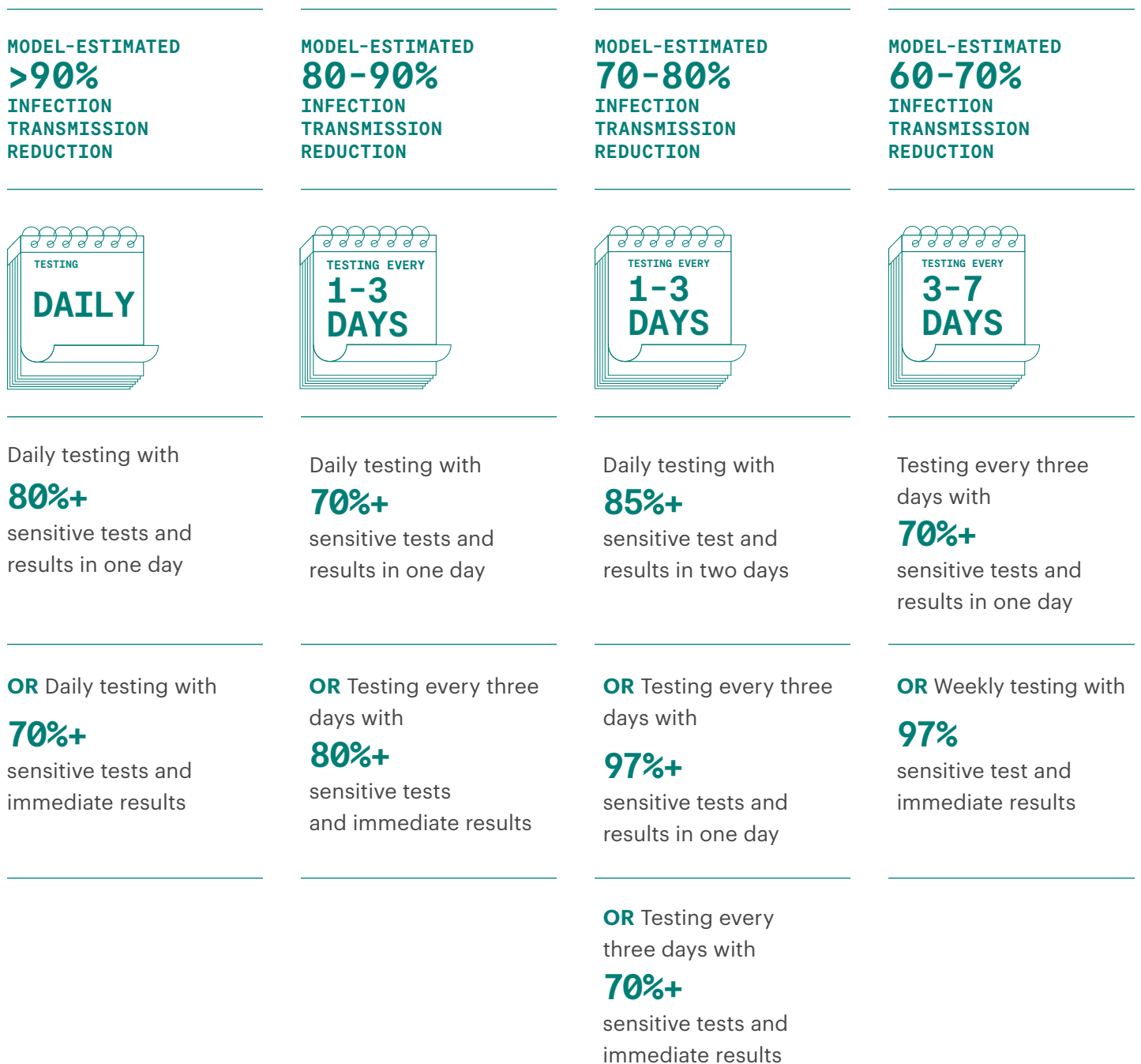
Frequent and rapid screening testing is vital to identify symptomatic and pre-symptomatic individuals before widespread transmission to other residents can occur.

CCFs should plan their screening protocols to be flexible and designed to adjust to changes in the local community infection levels and other risk factors. The objectives of testing and therefore the frequency should shift as community prevalence levels change. Testing twice monthly, for example, does not break chains of transmission effectively, and therefore cannot be relied upon for substantial reductions in transmission. However, in lower-risk settings, such as facilities located in communities with low Covid-19 prevalence, transmission reduction may not be the objective of a routine testing strategy. In this case, twice monthly testing would be useful for surveillance, to understand prevalence, guide more intensive surge testing, and inform decision-making regarding mitigation measures like visitation policies. As discussed above, individuals with symptoms or who have been identified as close contacts should receive diagnostic testing as soon as possible, and not rely on screening test results.

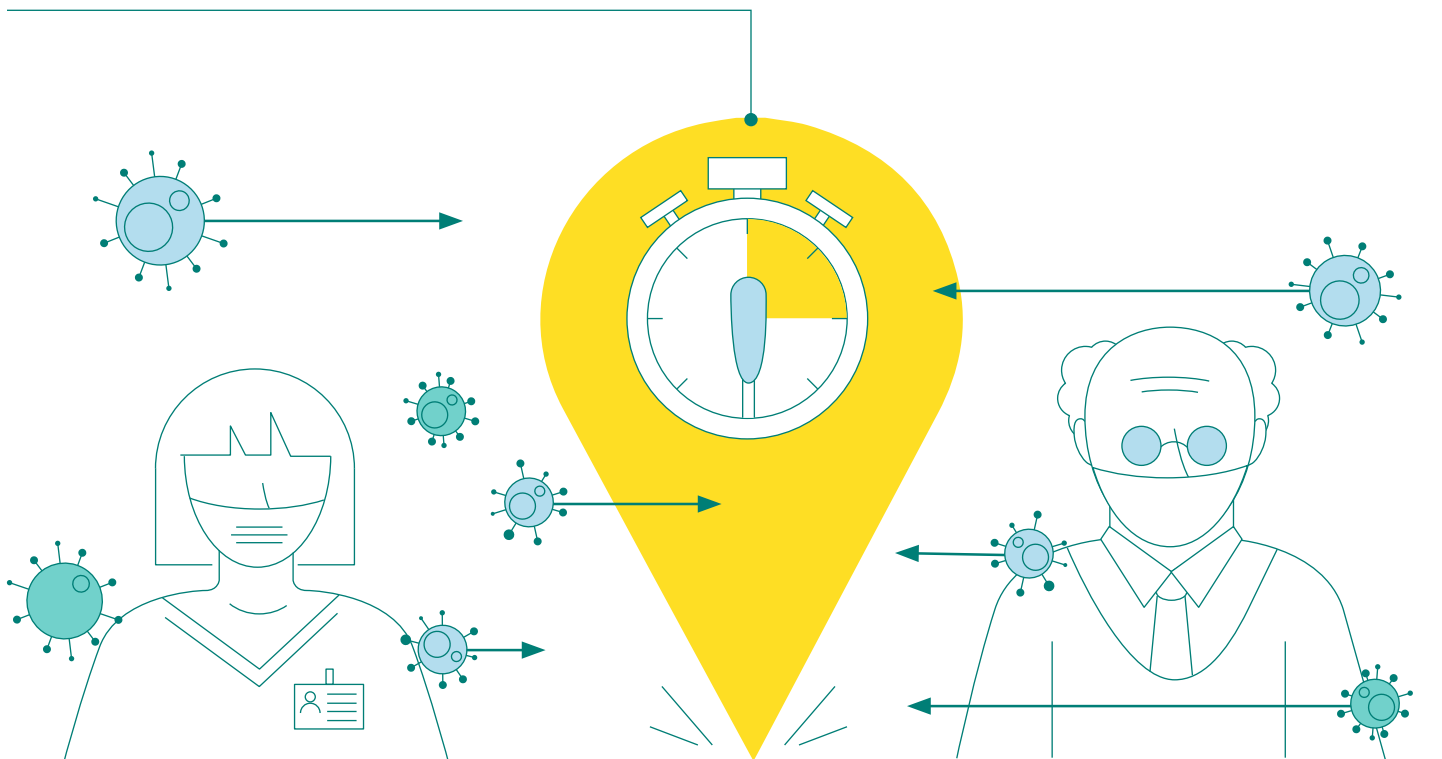


FIGURE 3 Simulated results of testing strategies to reduce SARS-CoV-2 transmission.

Figure 3 illustrates how several alternative testing strategies may achieve similar predicted reductions in SARS-CoV-2 transmission. Components of the simulated testing strategies include test frequency (from daily to every seven days), test sensitivity, and time to result return. Test frequency and time to result return are most influential on projected transmission reduction. These results are based on a simulation model and assume perfect isolation and no further transmission from detected cases. This is a modified figure from “A National Decision Point: Effective Testing and Screening for Covid-19.”



**TO REDUCE TRANSMISSION WITHIN
A CONGREGATE CARE FACILITY,
TESTING FREQUENCY AND TURNAROUND
TIME IS MORE IMPORTANT THAN
A HIGHLY ACCURATE TEST**

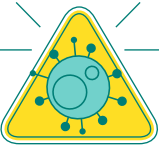
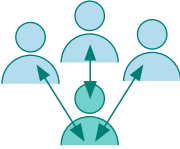
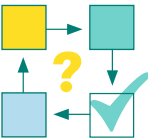


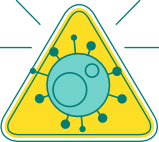








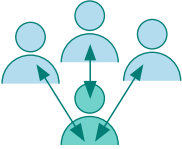
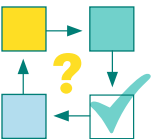
Settings at moderate or high risk, as determined through the risk assessment, would benefit from a regular screening program to prevent infections from spreading within the CCF. Prioritizing direct-care workers and other staff who have contact with residents and then prioritizing new residents, returning residents, and existing residents should be considered. To reduce transmission within a CCF, testing frequency and turnaround time (in addition to reasonable test accuracy) is more important than a highly accurate test, as shown in modeling work by [Larremore et al.](#) Based on a modified version of this model, Figure 3 highlights that different combinations of these attributes can be used to meet the same transmission reduction goals – allowing greater choice for facilities to achieve their testing goals with testing strategies that make sense for their population. Individual facilities can assess test availability, required logistics, and budget to identify a strategy that fits with their CCF’s unique conditions.

However, achieving substantial reduction in transmission requires more frequent testing and shorter lags between test administration and reporting of results, which may be logistically challenging and therefore highlights the importance of maintaining other mitigation measures such as masking and distancing. When combined with other mitigation measures like mask use, ventilation, and social distancing, testing protocols may not need to reduce transmission by 90% or more in order to effectively contain outbreaks. Lower risk environments may also not need such regular screening testing, and very low risk environments may not even require surveillance testing. Therefore, if a CCF’s risks approach those of nursing facilities (e.g., in memory care units where residents have a high dependency and need for assistance from staff), they should consider following the [testing guidelines](#) laid out by CMS and CDC (see Table 3). For CCFs that are lower-risk, less frequent and more targeted testing of [direct-care staff](#) with pooled surveillance testing methods could be adopted (see example testing protocol in Table 4).

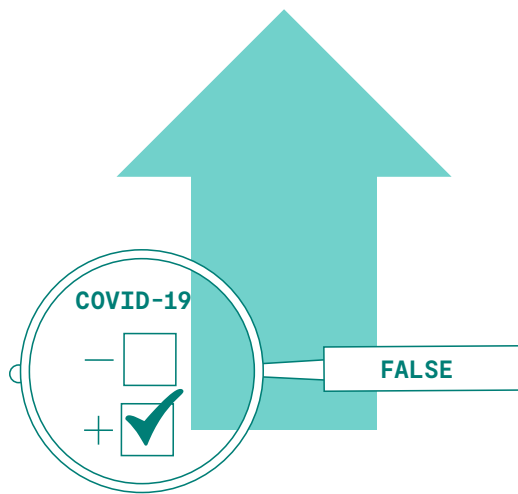
TABLE 4 Example testing strategy for an assisted living facility

Table 4 provides an example testing protocol for an assisted living setting at different risk levels. Testing goals should vary by level of risk. Testing frequency as well as other mitigation strategies should ideally increase as risk level grows. Different settings will have unique strategies depending on factors such as geography, staff/testing capacity, and number of residents, but the general framework of conforming testing goals and strategies to anticipated risk environment is applicable broadly.

	VERY LOW	LOW
Risk level, as determined through the risk assessment 	An example of a facility with a very low risk level may include: <ul style="list-style-type: none"> <3% community test positivity, <1 new daily reported case per 100,000 people in the community, >90% adherence to proper masking and social distancing, and P a strong program to allow rapid contact tracing within the CCF. 	An example of a facility with a low risk level may include: <ul style="list-style-type: none"> <5% community test positivity, <10 new daily reported cases per 100,000 people in the community, >90% adherence to proper masking and social distancing; and P a strong program to allow rapid contact tracing within the CCF.
Goal of testing 	<p>Facilitate accessible diagnostic testing to identify or rule out SARS-CoV-2 infection in residents and staff with Covid-19-like symptoms or recent contact with a confirmed case.</p>	<p>Monitor for an increase in infection rates using surveillance testing.</p> <p>Monitor individuals at higher risk of transmitting the virus using routine screening.</p> <p>Continue to facilitate accessible diagnostic testing.</p>
Testing strategy 	<p>Residents and staff are offered diagnostic testing as needed, with turnaround time less than 48 hours.</p> <p>Continued strict mitigation measures in facility regarding masks, distancing, and hygiene.</p> <p>If a confirmed positive case is found, all individuals in close contact should be quarantined and tested.</p>	<p>Twice a month pooled testing using each residential floor or staff unit to make up the pools. If a pool is found positive, all individuals in the pool should remain in quarantine until individual results are returned.</p> <p>Weekly routine screening for staff in close contact with a significant number of other people throughout the day.</p> <p>Residents and staff are offered diagnostic testing as needed, with turnaround time less than 48 hours.</p> <p>Continued strict mitigation measures in facility regarding masks, distancing, and hygiene.</p> <p>If a confirmed positive case is found, all individuals in the affected pool and any other close contacts should be quarantined and tested.</p>

	MODERATE	HIGH
<p>Risk level, as determined through the risk assessment*</p> 	<p>An example of a facility with a moderate risk level may include:</p> <ul style="list-style-type: none">  community test positivity,  new daily reported cases per 100,000 people in the community,  adherence to proper masking and social distancing, or  a less effective program for contact tracing within the CCF. 	<p>An example of a facility with a high risk level may include:</p> <ul style="list-style-type: none">  community test positivity,  new daily reported cases per 100,000 people in the community,  adherence to proper masking and social distancing, or  no contact tracing program within the CCF.
<p>Goal of testing</p> 	<p>Substantially reduce probability of transmission within the facility.</p> <p>Continue to facilitate accessible diagnostic testing.</p>	<p>Frequent screening testing for all staff and residents in order to monitor for changes in infection rates.</p> <p>Facilitate accessible diagnostic testing to lower community prevalence and allow resumption of operations.</p>
<p>Testing strategy</p> 	<p>Implement a routine screening program of direct care staff, considering the test frequency (at least once a week), test sensitivity and specificity, and time to results that will work best for your facility.</p> <p>Residents and staff are offered diagnostic testing as needed, with turnaround time less than 48 hours.</p> <p>If a confirmed positive case is found, all individual close contacts should be quarantined and tested. Facilities may also consider “surge testing” in the relevant wing(s).</p>	<p>Minimal outside contacts allowed.</p> <p>Implement a routine screening program with direct care staff, considering the test frequency (at least once a week), test sensitivity and specificity, and time to results that will work best for your facility.</p> <p>Residents and staff with less direct contact with residents are offered diagnostic testing as needed.</p> <p>If a confirmed positive case is found, all individual close contacts should be quarantined and tested. Facilities may also consider “surge testing” in the relevant wing(s).</p>

Testing protocols should also conform to the anticipated risk environment. Very frequent testing when the risk level does not justify it runs the risk of the resulting high percentage of false positives undermining the population's trust in the testing protocol. No test is perfectly accurate, and therefore some incorrect test results are expected. The probability of false positives depends on the performance characteristics of the test and community prevalence. Figure 4 shows the number of true and false positives that might be expected in communities with different active infection rates if tests similar to those available today were used to screen 1,000 people. CCF administrators should expect a higher proportion of false positives when the active community infection rate is low. In these circumstances, surveillance testing for CCFs will lower administrative burden and fatigue that could be generated by false positives if using tests with lower specificity. CCFs should also have communication and response plans in place that acknowledge that some false positive results are expected, as false positives can incur both psychological costs on individuals who believe they are infected as well as organizational and potentially financial costs incurred from isolating healthy individuals and conducting follow-up testing.

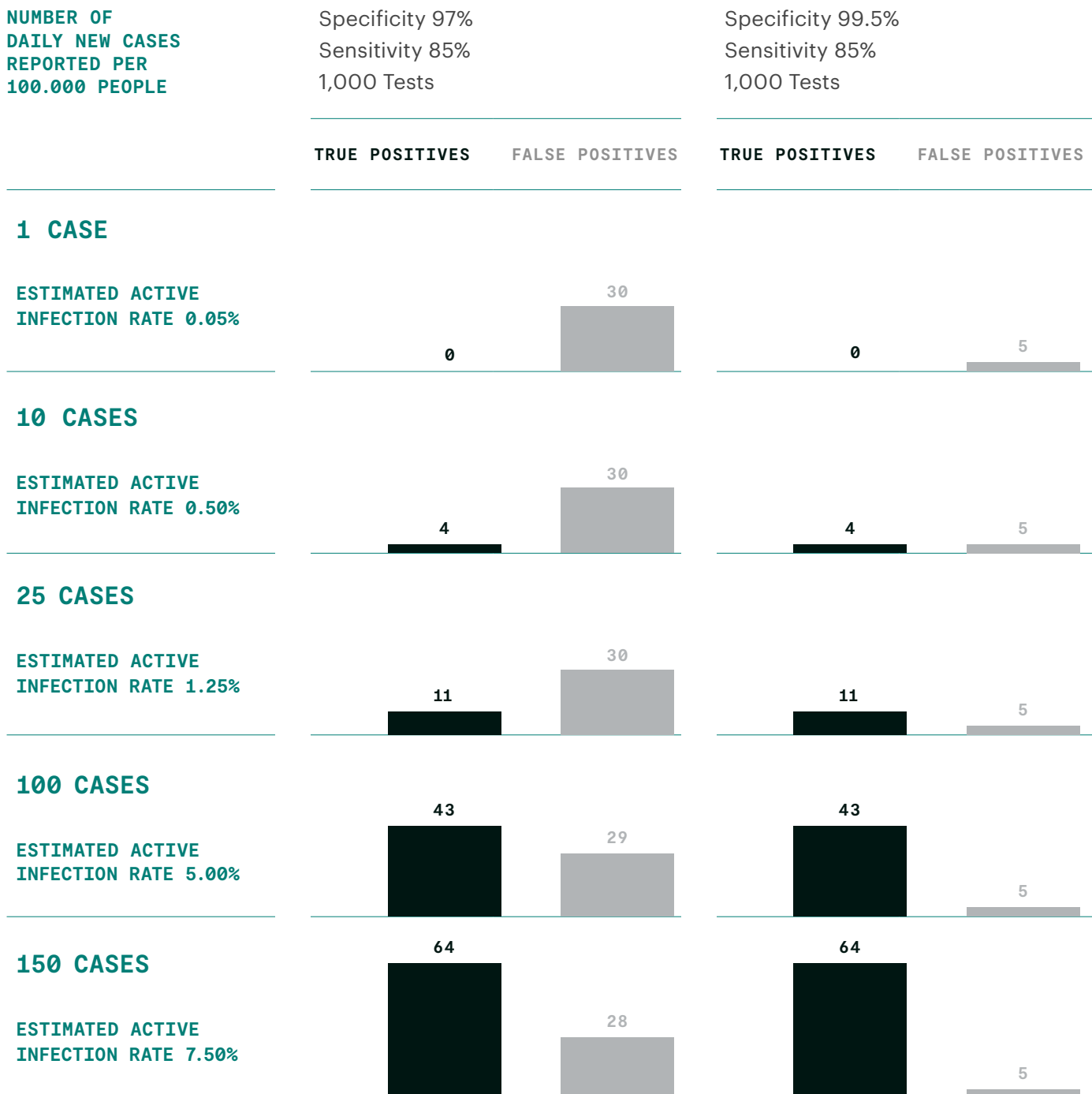


**CONGREGATE CARE FACILITY ADMINISTRATORS
SHOULD EXPECT A HIGHER PROPORTION
OF FALSE POSITIVES WHEN THE ACTIVE
COMMUNITY INFECTION RATE IS LOW**



FIGURE 4 How estimated active infection rate and test specificity affect the ratio of true and false positive test results.

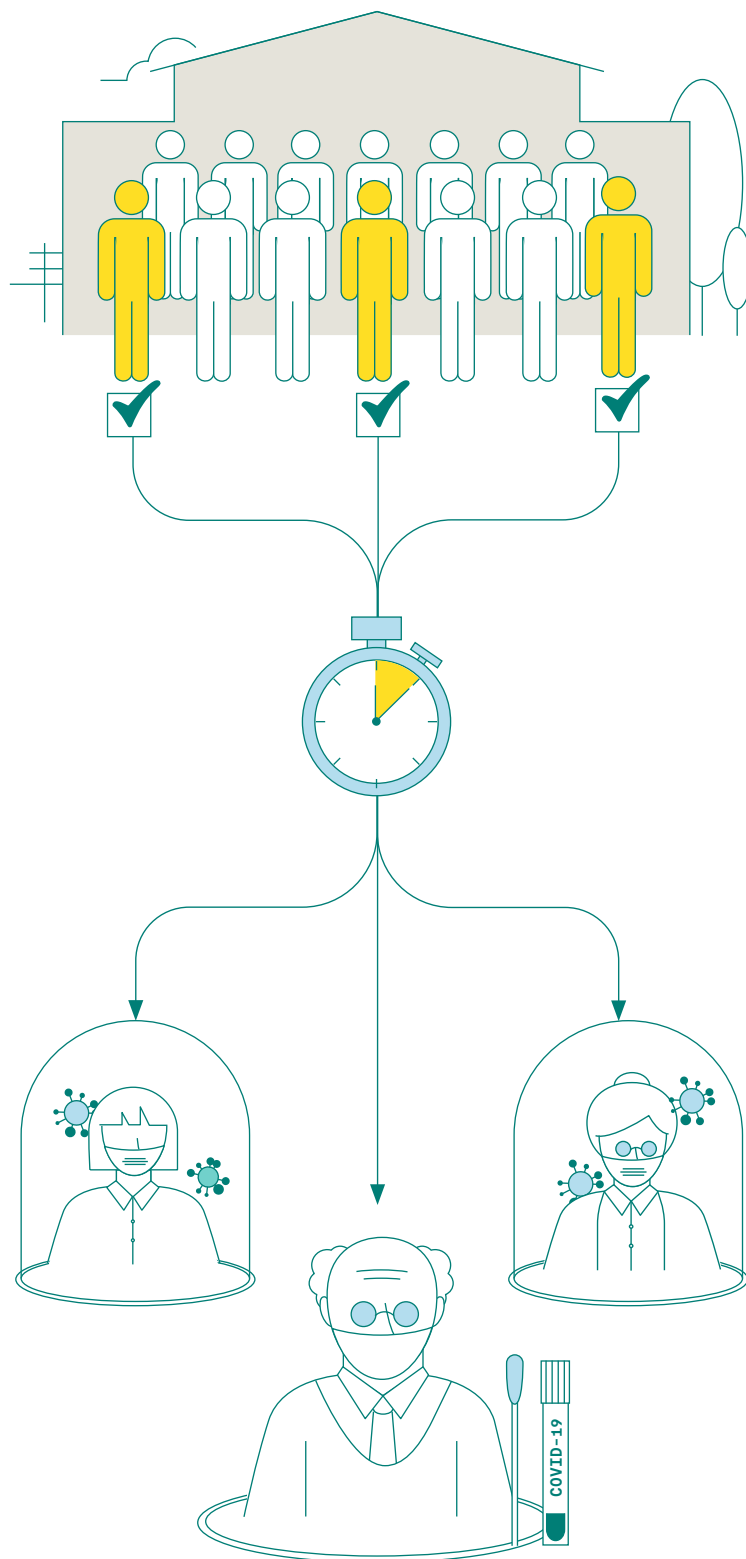
Figure 4 shows the number of expected true and false positives resulting from testing 1,000 individuals at various levels of Covid-19 community prevalence. Estimated active infection rate was calculated using the Pandemics Explained "[Key Metrics for COVID Suppression](#)" framework. The thresholds for the framework's risk levels were utilized, converting new daily cases to active cases over 10 days to represent CDC advice on duration of Covid-19 infectious periods. This 10-day cumulative case load was multiplied by 5 to correct for under-reporting due to ascertainment bias, then converted to percent prevalence. Note that this is likely to be an over-estimation in areas with a low test positivity ratio, meaning that the share of false positives may be higher



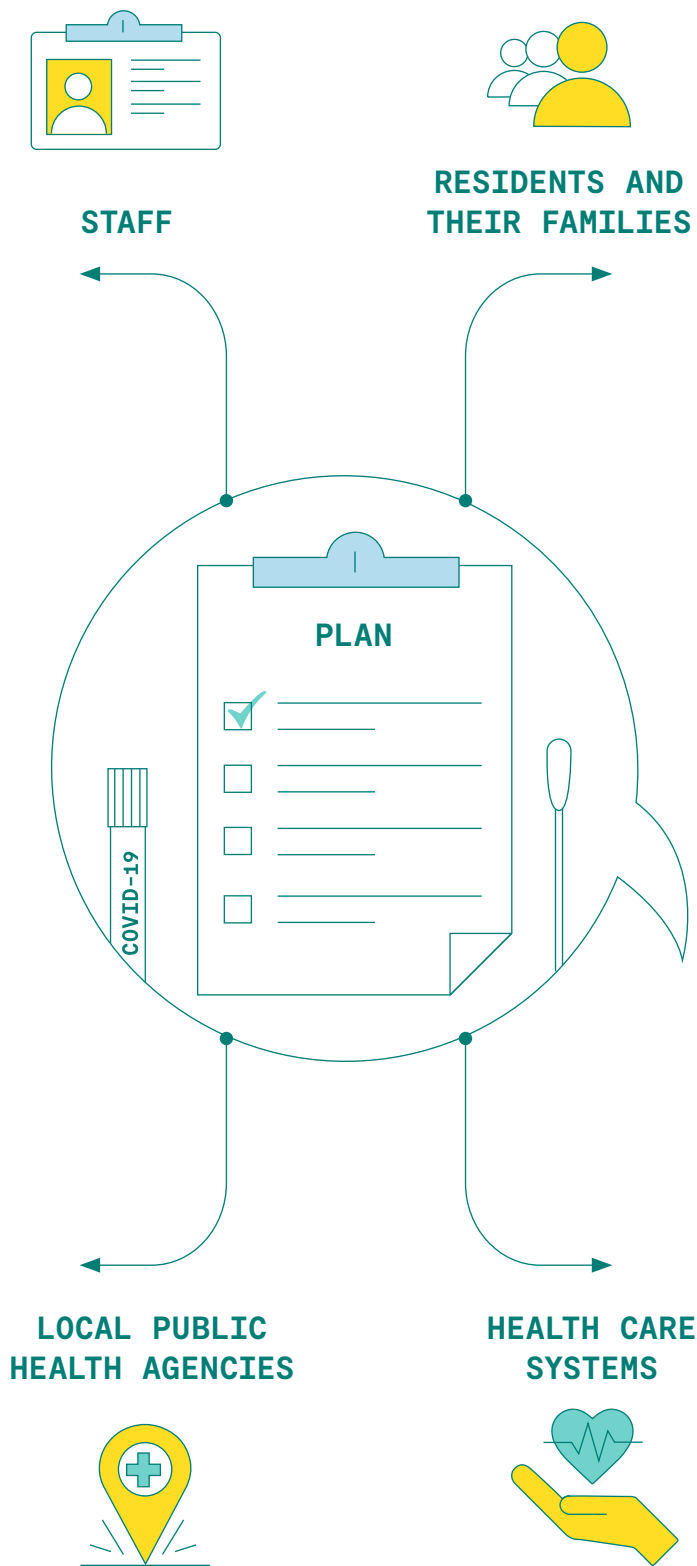
Swift action on testing results.

Swift, isolation of individuals who are presumed or confirmed to be infected is a critical infection control measure. CCFs should have procedures in place to respond to test results quickly, and clearly communicate these plans to staff, residents, and families on a regular basis to keep them up to date and set expectations. Positive results from highly sensitive PCR tests used for diagnostic purposes should lead to the now confirmed infected individual to be isolated immediately. Screening testing strategies that rely on less sensitive tests that create an initial presumption of infection can lead to various options: some communities may seek to isolate presumed infected individuals in special quarantine areas while waiting for confirmation, while others may be able to rapidly confirm a presumed positive with a second, point of care test while the resident waits in the testing area. Individuals should not be moved to any Covid-19 specific wings until a result is confirmed to be positive.

These are challenging decisions based on both available resources and the level of community prevalence. Higher levels of community prevalence increase the probability that a presumed positive test will be confirmed which means that if an individual is isolated in a Covid-19 specific wing, they are less likely to be harmed. Communities that are home to individuals with high care-needs may, if possible, wish to cohort Covid-19 patients needing high levels of care to minimize staff exposure while still meeting residents' needs. Close contacts should also be quarantined for the length of time recommended by public health authorities. Individuals who are not close contacts but had exposure to infected individuals are still at potential risk. Facilities can consider mitigating this risk through serial testing without requiring isolation of these less close contacts.



ISOLATION OF INDIVIDUALS WHO ARE PRESUMED OR CONFIRMED TO BE INFECTED IS A CRITICAL INFECTION CONTROL MEASURE



Clear Communication

Testing protocols are predicated upon trust of a CCF's residents. Trust is built over time by using clear, direct, and honest communication. CCF leadership should outline the objectives, expectations, and limitations of their testing strategy to residents, their families, and staff. Clear acknowledgement of the challenges of false positives should be included in program communication. Language should be locally appropriate and communication methods should be responsive to the needs and capabilities of all residents, staff, and stakeholders such as extended family members. For example, phone, text, and mail communication methods could all be viable options depending on needed urgency of communication and technology access of recipients.

CCFs, including those that have opened up to visitors, should also clearly communicate how they will determine whether the CCF needs to close to visitors or if certain activities (e.g., group dining) must be limited to contain an outbreak. This will primarily depend on assessment by CCF administrators in accordance with existing local/state regulations. A plan will need to be explained to staff, local public health agencies, health care systems, and most importantly residents and their families.

Effective communication around testing is critical and should be tailored to the facility and needs of residents, families, and staff. Facilities should reassure all of these groups that chosen testing protocols are consistent with recommendations from CMS and the CDC but also be transparent that processes may be modified as more evidence develops.

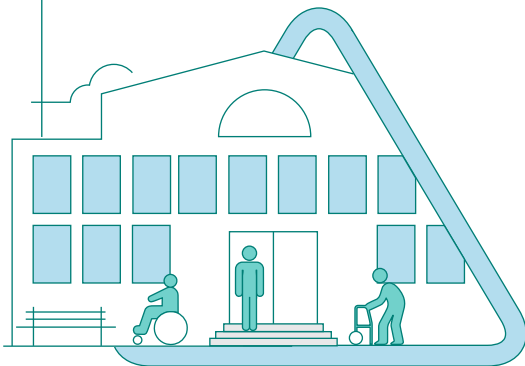
Appendix A: Policy Needs

Over a million Americans reside in Congregate Care Facilities (CCF), which provide housing and some services for individuals who do not need skilled nursing care. CCFs include assisted living facilities, independent living facilities and memory care units. While healthier than nursing home residents, CCF residents face substantial risk of excess death and morbidity from COVID-19.

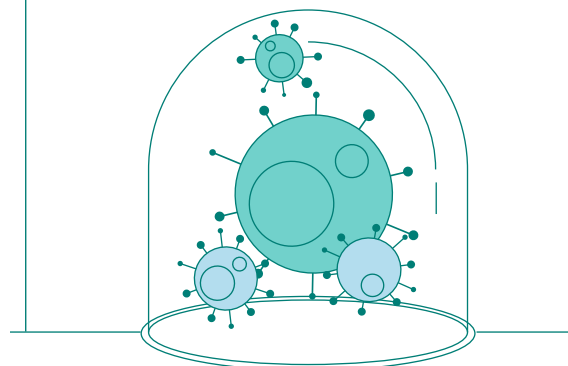
Many residents and staff in these facilities have been vaccinated for Covid-19, and studies on the vaccines have shown that severity of illness and likelihood of death are greatly reduced after vaccination. Some individuals will not be able to take the vaccine for medical reasons, and some staff have been hesitant to get the vaccine. In addition, it is not yet known if vaccinated individuals can transmit infection to others.

Consequently, for some time to come, screening and surveillance test protocols can help reduce the risk of infection and mortality in CCFs. Policy actions can facilitate access and effective use of testing to protect these vulnerable communities until widespread vaccination occurs.

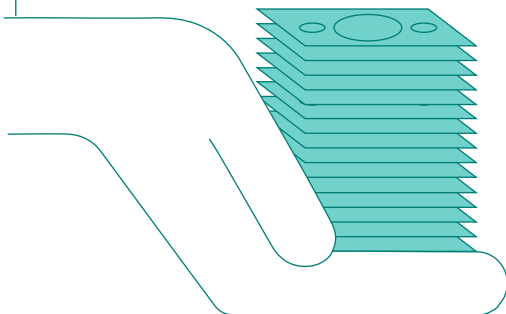
PRIORITIZE CCF SETTINGS FOR FEDERAL AND STATE DISTRIBUTION OF RAPID TESTS



ENSURE RAPID TURNAROUND AND CLEAR UNDERSTANDING OF HOW TO USE RESULTS



SET A PATHWAY FOR PAYMENT



SUPPORT STUDIES TO BETTER UNDERSTAND TRANSMISSION AMONG VACCINATED INDIVIDUALS



Prioritize CCF settings for federal and state test distribution of rapid tests

Rapid testing kits are becoming more common with nearly 100 million tests available per month, and that number is expected to grow throughout 2021. However, there are many competing demands for testing and CCFs do not have a dedicated supply chain. One million CCF residents and 300,000 full time employees being tested twice weekly in a screening program would require 10.8 million tests per month. As manufacturing capacity for antigen and other point-of-care tests rises over the winter, Federal and state distributions should prioritize CCFs as highly at-risk communities. Because many of these facilities do not have high numbers of medical staff and often do not have the required regulatory permission to do point-of-care testing, over-the-counter tests that can be done anywhere and allow self-collection or only light training for administration are preferred. If such tests are not available, the required regulatory permits for testing should be expedited or otherwise facilitated and public health authorities should be encouraged to use standing orders for prescriptions.

Set a pathway for payment

CCFs seldom receive direct reimbursement from Medicare or Medicaid. While there is clarity from CMS that surge testing will be paid for by Medicare and Medicaid for nursing home residents in response to an active infection found within the facility, there is lack of clarity on payment for surge testing at CCFs. Regular screening tests are generally not covered by insurance. Many CCFs that are conducting testing at this time are relying on either reserves, loans or local philanthropy. These are unsustainable funding sources. A clear pathway for payment for this testing should be established, especially for testing required by federal or state authorities and for facilities that serve lower-income populations. The recent COVID-19 emergency relief legislation passed in December allocated \$22.4 billion to the States for “testing, contact tracing, surveillance, containment, and mitigation”.

States should consider putting support for regular testing in these communities high among their priorities, while Congress should consider if additional support may be required.

Ensure rapid turnaround and clear understanding of how to use results

Testing is most effective at reducing infections when turn-around time is rapid. Minimizing the time between when a test is administered and the results are received and acted upon is a critical step in reducing infection spread. While point-of-care tests are designed to return results in minutes to hours, laboratory-based tests will rapidly lose their value as reporting is delayed. Policy makers can encourage the adoption of antigen and other point-of-care tests by providing a straightforward regulatory path for testing and by providing training and technical assistance in administering point of care tests. This includes clear instructions on how to interpret and act on those results, including when confirmatory tests are required and actions to take while awaiting confirmation. However, confirmatory tests and screening methods like pooled testing will still require lab-based tests. Policy makers can encourage rapid return of lab-based results by adding a bonus payment for results returned within a day.

Support studies to better understand transmission among vaccinated individuals

Rapid studies need to be set up to develop evidence on transmission by vaccinated individuals (nursing homes and congregate care facilities could serve as excellent sites for these types of studies). If the evidence shows that vaccinated individuals are not likely to transmit, testing needs may decline substantially in CCFs, which would reduce costs and free up test capacity for other high-risk settings where vaccination may not yet be widely available.

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The Robert J. Margolis, MD, Center for Health Policy at Duke University is directed by Mark McClellan, MD, PhD, and brings together expertise from the Washington, DC, policy community, Duke University, and Duke Health to address the most pressing issues in health policy. The mission of Duke-Margolis is to improve health and the value of health care through practical, innovative, and evidence-based policy solutions. Duke-Margolis catalyzes Duke University's leading capabilities, including interdisciplinary academic research and capacity for education and engagement, to inform policy making and implementation for better health and health care. For more information, visit healthpolicy.duke.edu.

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