EXHIBIT 30

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CLINICAL & RESEARCH

Patients With SMI in the Age of COVID-19: What Psychiatrists Need to Know

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Psychiatrists taking care of people with serious mental illness need information about changed vulnerabilities and unique treatment requirements of this population during the COVID-19 pandemic, as well as what new or changed resources are available to them.

The tsunami of information on COVID-19 has overwhelmed us all. The advisories, guidelines, and directives have, for the most part, been addressing the population as a whole, as well they should be. Those with disabilities have slid to the sidelines with few attending to what issues they face in this pandemic. In this article we look at a population core to the mission of APA, people with serious mental illness (SMI). We examine COVID-19 issues as they impact both inpatients and outpatients, looking at symptoms, service locations, comorbidities, and medications. In addition, we examine how prejudice against those with SMI is impacted by COVID-19 and how some patients are actually showing clinical improvement as a result of the pandemic. Our aim is to heighten awareness of the interfaces between COVID-19 and SMI to facilitate informed treatment of people with SMI during this pandemic, with each hospital and outpatient setting knowingly modifying what it does to meet local needs.

Symptoms

The world's response to COVID-19 needs to be understood in the context of patients' symptoms as the symptoms can significantly alter what has been the general population's response.

Paranoia. Remote forms of communication can increase patients' paranoia as they are required to communicate through electronic tools—seeing their psychiatrist on a screen, for example. The fear experienced by staff is felt by patients whose paranoid thinking can be magnified. Staff: "Those in power are misleading us, particularly in light of the rapidly evolving (or perceived flip-flopping) responses

and parameters to dealing with the pandemic." Patients: "You're pumping the virus through the vents in my room because you want to kill us"; "The staff are all wearing personal protective equipment [PPE] and we patients will die so you can live."

Delusions. Besides beliefs about an evil government or an evil world, some patients have incorporated COVID-19 into their long-held beliefs such as the illuminati being in control of the world pandemic or the world's population deserving to be punished. Another example is a patient who believes she is a physician but is giving misinformed medical advice on COVID-19 to other patients on the unit.

Hallucinations. People with SMI may attribute information they receive to their "voices" or hear the viruses making noises. Most important is the need for the psychiatrist to be sensitive to the fact that auditory hallucinations can interfere with one's ability to communicate by telephone. The patient mixes up all the voices, including the psychiatrist's. The loss of visual cues may seriously compromise communication between doctor and patient that has previously been effective.

Cognitive deficits. Individuals with cognitive deficits may not understand what this is all about, leading to their inability to appreciate the seriousness of the situation. They may not remember what they've been taught about the virus and may require reminders multiple times a day to get them to adopt new habits such as washing their hands more often and practicing social distancing. Individuals with cognitive deficits can be incontinent, leading caretakers to have physical contact with the individual multiple times a day. And patients with cognitive deficits can be agitated, aggressive, and assaultive, again requiring caretakers to have physical contact with the individual multiple times a day. How do staff put someone in a hold or in restraints and maintain social distance? All staff need to be trained how to avoid being spit on by patients during these procedures.

Disorganization. Like those with cognitive deficits, disorganized patients may struggle with following procedures about hand hygiene and social distancing. They may also be confused about their stay in the hospital or why they can't have visitors. Real-time examples include a patient who assents to extend her stay in the hospital, then follows up with "I prefer to be discharged to go visit my family and check on them with this virus thing." Another patient said he had COVID-19, but despite having an unrealistic and incoherent story, this triggered a major staff response due to the potential backlash of ignoring such statements in light of the seriousness of the disease.

Anxiety. Patients with previous trauma symptoms or posttraumatic stress disorder (PTSD), especially complex PTSD, can be triggered by COVID-19 fears: "The hospital is no longer a place of safety"; "My therapist can't even meet with me in person"; "I was told, 'We don't have time for your cutting.' " Symptoms of COVID-19, especially shortness of breath, may compound anxiety and panic attacks that patients experience. This can lead to difficulties in breathing, confusing two origins for poor oxygenation. Anxiety can lead to ignoring early symptoms of the virus or to confabulating symptoms, with or without secondary gain.

Incidence of SMI

During this pandemic, it is reasonable to expect that new cases of SMI will arise and need to be addressed by the current psychiatric workforce. But there is reason to believe there will be additional cases that mimic or may in fact become SMI.

In 1919, Karl Menninger reported that as a result of the Spanish flu epidemic, infected people he saw at the Boston Psychopathic Hospital had psychotic symptoms that appeared to result from their infection (1). One-third of these patients were diagnosed as having schizophrenia (dementia praecox). Of the 50 of 175 cases that could be traced one to five years later, two-thirds had apparently recovered (2). Contemporary extensions of this work have found that "a recent onset of psychotic symptoms was significantly associated with coronavirus exposure as determined by bivariate analysis of quantitative antibody levels and

qualitatively determined seroprevalance" (3). This means that coronavirus exposure may be a comorbid risk factor in individuals diagnosed with SMI (3).

What this will mean in the context of COVID-19 is yet to be seen. Emergency departments (EDs), psychiatric units, and state hospitals might well see psychotic presentations in people with COVID-19 needing treatment, recognizing that these symptoms in all likelihood will not abate when the symptoms of the infection have dissipated. These individuals will need much longer-term follow-up for their psychotic symptoms.

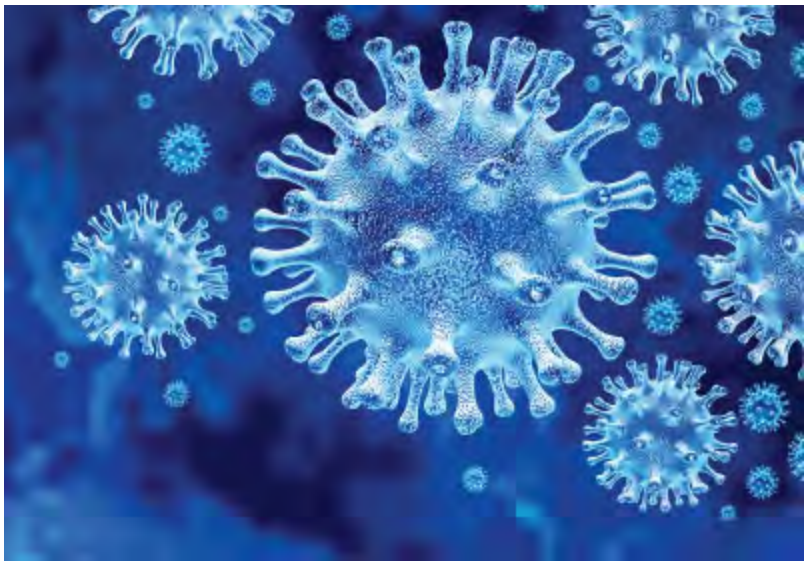
It comes as no surprise that anxiety is at high levels during the pandemic in the United States. One would expect that individuals will present with posttraumatic stress symptoms (PTSS). That is the finding coming from China, where women have experienced higher rates of re-experiencing trauma, negative alterations in cognition or mood, and hyperarousal (4). Many people will need acute treatment for these symptoms, and some will progress to PTSD and require long-term treatment. There is no way to know how many individuals who were coping adequately with PTSS prior to the pandemic will subsequently meet criteria for PTSD.

In health care workers exposed to COVID-19 in China, depression showed a rate of reported symptoms in a sample of 1,257, higher than any symptom other than distress, exceeding anxiety and insomnia (5). As with PTSS, some who develop depressive symptoms will achieve resolution of those symptoms through brief interventions, but others will progress to major depressive disorder and need longer-term treatment.

In addition, beyond fear of, exposure to, or actual infection by coronavirus producing psychiatric symptoms, the act of quarantine and isolation itself induces psychiatric symptoms. Quarantine will not only exacerbate symptoms in those with known SMI, but it also may bring to treatment people with SMI, who were previously undiagnosed and/or untreated due to exacerbation of symptoms.

Settings

Inpatient hospitals. Psychiatric hospitals have followed general hospitals in restricting who is going into the building and in setting up screening of those who enter. Psychiatric hospitals have to enact additional restrictions that limit the movement of patients within the building: In hospitals with multiple units, patients are being restricted to their own unit. Off-unit endeavors, such as group activities and meals, have moved onto the unit. Many of these units, especially those in newly constructed facilities, were never designed to have patients stay on them during the day as the model is off-unit programming. Increased restrictions and overcrowding lead to increased behavioral outbursts, leading to more staff involvement (for example, application of restraints), and hence increased staff exposure. Disrupting patterns of patients' meals increases the risk of choking and medically dangerous confusion of patients' diets. Poor hygiene in hospitals, where no windows are open and the air recycles through a ventilation system, is a heightened risk for, or is perceived by patients and staff to be a heightened risk for, viral transmission.



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Patients in psychiatric hospitals loan, exchange, barter, or steal possessions. These objects have been in the hands and against the faces of patients. Patients often share food despite rules forbidding it.

In states where "patients' rights" are paramount, sometimes at the risk of violating the general rights and safety of others, delayed response in implementing visitor restrictions and restrictions in incoming mail and food increases the risk of exposure throughout the facility. While perhaps not the highest priority, psychiatric hospitals need to have adequate PPE for their staff since the hospital is at high risk not only to have an infection sweep through it, but also to be a center that seeds a community.

Some states are considering or are implementing the placement of all of its coronavirus-positive patients at their public psychiatric hospitals into one of these hospitals. This is available only in states where there is more than one public psychiatric hospital and where geographic distances do not prohibit such an intervention. The challenges of completely isolating the coronavirus-positive patients and the staff who care for them from the hospital's other patients and staff are enormous.

With the outpatient community not able to accommodate discharges as it could before, patients' hospital stays are lengthened. Psychiatrists are making uncharted risk-benefit analyses: Is the patient and others at more or less risk if the patient stays in the hospital or if the patient is discharged with a less-than-optimal discharge plan? For example, should a patient originally planned to be discharged to a residential program be discharged to his parents' home instead because he would be at much lower risk for infection?

While far from extensive, there are some resources available to those working in state hospitals. The Substance Abuse and Mental Health Services Administration (SAMHSA) has a guideline, "Covid-19: Interim Considerations for the State Psychiatric Hospital," but it is cursory and needs to be quickly updated. A valuable resource from the Centers for Disease Control and Prevention is not directed at

state hospitals at all, but rather at correctional facilities: "Interim Guidance on Management of Coronavirus Disease 2019 (COVID-19) in Correctional and Detention Facilities." We make no statement here that state hospitals are like jails and prisons, but these are the best guidelines available that address how to manage a population locked in a facility in close quarters where all the previous day-to-day rules need to be changed. State hospital leaders can take from these guidelines whatever might work for them.

Community. With agencies providing community services operating on skeleton crews and/or with no face-to-face contact, how do individuals who have been dependent on these services for decades survive? What about patients without phones or who know nothing about their phone other than it is an instrument with which to make calls? One temporary change that should make communications easier among those providing services to people with SMI in residences, supported apartments, or in single dwellings is the relaxation of HIPAA standards for sharing information.

In some locations, such as in the greater New York City area, psychiatrists are switching patients they think can manage the change from long-acting injectables to pills so that they do not need to leave their residence to get a shot. Again, we are on a new frontier of risk-benefit analysis. If the result is a substantially greater number of psychotic decompensations, leading to more ED visits, then we have failed. If only a small percentage of those who switched need acute intervention and all the others have stayed home, then we've succeeded. At best we are making an educated guess for each individual.

Residential settings for individuals with SMI are doing preventive interventions, such as having residents spend very little time in common areas of the house, staggering mealtimes, and excluding all visitors. Residents who visit their family must remain with the family until the crisis is over. Some state departments of mental health have set up designated residences where individuals who test positive for the virus but are not in need of hospital care can live.

Shelters need to adjust business as usual: It has long been their practice to put people out during daytime hours; yet, they, too, may be facing problems with overcrowding and the inability to accommodate the same numbers of individuals. Unsheltered homeless people, at least one-third of whom have SMI, represent another problem because they often congregate at night in open-air locations. For example, on Massachusetts Avenue in Boston, homeless people still gather along the street, in close contact with each other and within half a mile (or less) of the Boston Medical Center.

Substance misuse is another problem in the community. The rate of sharing needles and joints may rise as supplies are harder to find. People with limited resources or those turned away because the pharmacy ran out of their medication are taking pills never prescribed for them. Given that care is being channeled to the COVID-19 crisis, to what degree are psychiatrists and others still paying attention to the opioid epidemic and the overdoses that were headlines just weeks ago or to the escalating death rates from benzodiazepines and methamphetamine? And people on opiates and benzodiazepines are at higher risk for respiratory compromise. We hardly need an increase in patients with severe respiratory depression from opiates competing with patients in severe respiratory distress from COVID-19 for the ED staff's attention. We need greater attention to substance misuse at this time, not less. To this end, the Drug Enforcement Administration (DEA), in its statement "Use of Telemedicine While Providing Medication Assisted Treatment," exempted DEA-registered practitioners from the in-person medical evaluation requirement as a prerequisite to prescribing or otherwise dispensing controlled substances. Furthermore, the SAMHSA recently announced increasing the first-year 30-patient limit for qualifying practitioners to a hundred if the need arises to meet demand. SAMHSA also released "OTP Guidance for Patients Quarantined at Home With the Coronavirus" and is permitting states to request blanket exceptions for all stable patients in an opioid treatment program (OTP) to receive 28 days of take-home doses and 14 days for patients who are less stable in their OTP.

Social isolation. For many persons with mental illness, being alone is a terrible burden, far beyond that experienced by many others. The costs of their loneliness are similar to those of many elderly Americans. Loneliness precipitates psychiatric symptoms in those without SMI, let alone those with these disorders. And the message can be quite confusing to the person with SMI: A clubhouse member living at home said, "For years they told me not to isolate myself and to be out with other people. Now they're telling me to stay home and isolate myself. I'm confused."

People in abusive households can be in danger from sources other than the coronavirus. They can be isolated with their abusers; tempers may flare, and violence could ensue. Their abuser may threaten them with eviction if they show symptoms. Among all the other reasons they have feared seeking help, they have a new fear of going outside and contracting COVID-19. Will we see more women with signs of severe physical trauma being pushed into EDs on stretchers? Will we have an increased rate of murder-suicides?

Medical Comorbidities

Physical health. Patients with SMI are particularly vulnerable to COVID-19 due to generally being in worse physical health than the general population. They typically delay seeking medical care for various reasons and have more medical comorbidities such as hypertension and diabetes (6). In addition to the widely recognized risk factors for COVID-19—diabetes, chronic obstructive pulmonary disease (COPD), and cardiovascular disease (CVD)—the American College of Cardiology also identified obesity and hypertension as risk factors for viral respiratory illnesses, including COVID-19 (7). CVD and its risk factors—psychotic illness being an independent risk factor for CVD (8)—are twice as high in patients with schizophrenia than in the general population (9). Likewise, obesity is twice as prevalent (10) and diabetes is at least three times as prevalent (11) in people with SMI compared with the nonpsychiatric population in all age groups.

Additionally, while the rate of smoking in the general population is about 18%, 53% of people with SMI smoke (12), and the rate of COPD is consequently similarly elevated at 22.6% compared with 5% in the general population (13). The medical needs and comorbidities of people with SMI cannot go untreated; otherwise, they will be yet another subpopulation streaming into EDs.

Medications

Antipsychotics. With heart disease and diabetes being major risk factors for severe COVID-19 infection, patients on antipsychotics ought to be considered high risk—a cumulative effect from having an SMI. Long known for their propensity to contribute to obesity, diabetes, and metabolic syndrome (14), antipsychotics also increase risk for hypertension, thrombo-embolic events, QTc prolongations, and change in endothelial function (15).

Additionally, antipsychotics have been linked to respiratory dysfunction and failure (particularly in patients with COPD) likely by causing improper respiratory muscle activity (16) or central respiratory depression (17). First- and second-generation antipsychotics are equal culprits in causing pneumonia, affecting not only elderly individuals, but young patients as well. Smokers, those with chronic respiratory disease, dysphagia, or cerebrovascular disease are particularly at risk. Treatment with multiple antipsychotics further increases the risk for pneumonia. How will those patients fair if they were infected with COVID-19?

Anxiolytics. Even before the COVID-19 pandemic, an increase in the prescription of benzodiazepines by primary care physicians was noted (18). With the rise in anxiety symptoms and diagnosable cases of anxiety disorders such as generalized anxiety disorder and PTSD, an increase in the prescription of anxiolytics followed. Knowing that benzodiazepines contribute to poor respiratory functioning (19), our patients are less able to fight a COVID-19 illness if infected. Alternatively, those unable to fill their long-term prescriptions on time at their pharmacy might either turn to illegitimate ways to obtain them or run the risk of abrupt withdrawal and experiencing seizures.

Side effects. Beyond the physiologic vulnerability to COVID-19 incurred by psychotropics, people with SMI are subject to other side effects that increase their risk of contracting and spreading the virus: sedation and drowsiness may lead patients to put their head on a table and fall asleep, creating face-to-surface contact in common areas. Involuntary movements cause more face touching and contact with others. Drooling from sedation or clozapine-induced sialorrhea (20) can quickly spread the virus over a wide area.

Medication interactions. Experimental drugs are currently used for COVID-19 treatment. Some have unknown side effects, while others can have serious interactions with psychiatric medications and other medications. For example, ritonavir is contraindicated with disulfiram (oral version has 42% alcohol) and decreases metabolism of midazolam and triazolam. Its level is decreased by CYP3A4 inducers such as carbamazepine, and it directly inhibits 3A4 and 2D6 through which several psychotropics are metabolized. The more famous combo hitting the headlines about COVID-19 treatment is made of two QTc prolonging medications: hydroxychloroquine and azithromycin, further increasing the burden on the heart of those on psychotropic medications.

Prejudice (Stigma)

We can anticipate an increased shunning of many people with SMI due to their looking like someone more likely to be infected and their appearance in general. It comes as no surprise that people quickly move away from someone who does not keep usual social distance from them even when there is no pandemic. Most problematic is perceiving people as unable to maintain social distance and handwashing practices just because they have a serious mental illness when, in fact, they are quite capable of doing so. Hospital staff, employers, and family members can be particularly susceptible to this.

Rationing of health care resources is already under discussion (21). Because individuals with schizophrenia have a shorter lifespan than that of the general population, will they be the last to receive treatment if the criteria for prioritizing

treatment "maximizes the number of patients that survive treatment with a reasonable life expectancy" (21)? The Office of Civil Rights of the Department of Health and Human Services has released guidelines saying that states, hospitals, and physicians cannot put people with disabilities at the back of the line for care. But will everyone adhere to that directive?

Benefits

Amid all these concerns during the COVID-19 pandemic, the symptoms and functioning of some psychiatric patients have actually improved when interventions are knowingly framed by their psychiatrist.

Suicidality. A 23-year-old tall, thin woman who has always felt very much alone in the world has been in the hospital since adolescence. She is afraid she'll die in some cataclysmic event. To avoid that, she states she will commit suicide if discharged; once alone on pass she had made a very serious suicide attempt. Her psychiatrist pointed out to her that now the whole world feels just like she does, and she is not alone. She has never functioned better than she has since she understood this.

Delusions. A septuagenarian Korean War veteran, with decades of delusions about federal government deceit and his suffering as a result of its lies, was informed that now a good percentage of the U.S. population also thinks the federal government is lying to them. He was asked if he could put aside his own grievance and take up the national grievance. With all his experience in writing thousands of documents about government deception, would he agree to be a consultant to the national effort? He did agree. He writes less. The national problem is addressed with meetings with his psychiatrist. He's engaged at a time when there's not much to do on the inpatient unit.

Paranoia. A 50-year-old never-married man on disability has, for two decades, gone to supermarkets at off hours to avoid as many people as possible. He goes down aisles when they are empty of people. He keeps his distance from store

personnel in the checkout line. He avoids other shoppers as they enter or leave the store. Now his behavior is normalized, and no one thinks twice about his behavior.

Negative symptoms of schizophrenia. A 62-year-old man who lives alone is a member of a very large Italian family, none of whom had ever moved far from their birthplace. The family gets together almost every week for a holiday or family event, and everyone has to come. Our patient, aware he has no ability to engage in social conversation, hates these gatherings. He describes them as "torture." He has never been more at ease in his life since there are no family get-togethers, and no one knows when there will be another one.

OCD. A 60-year-old woman who became disabled from her teaching job due to OCD symptoms has spent the last decade avoiding touching anything she didn't absolutely have to touch, washing her hands incessantly, and wearing some clothing only outside and other clothing only inside. She had garnered the pity of friends and relatives (which she hated). When she was out in public, people would get impatient with her or stare at her as she hesitated before going through doors or picking up items while figuring out how to minimize her exposure. Now, no one pays her any mind at all. Some people are actually mimicking her well-practiced moves.

Mental health support. As indicated by an APA poll released in March, anxiety about COVID-19 runs high among Americans, as does the sense that coronavirus is having a serious impact on their lives. Health care workers are proving to be especially vulnerable to showing elevated psychiatric symptoms. But while some services have become less available, others have been newly developed: The Texas Health and Human Services created a free, statewide, 24/7 mental health hotline to support Texans struggling with mental health repercussions of the COVID-19 pandemic. Will states that have not done so follow suit? Will individuals who were previously reluctant to seek psychiatric help find this pandemic a good reason to do so?

Conclusion

In this article, we have attempted to provide an overview of what is happening to people with SMI in this pandemic to better equip us all to more effectively deliver care and treatment to this vulnerable population. Like so many others in health care, we now find ourselves in rough waters with one broken oar in a craft that requires two paddles. In this health care crisis, psychiatry, like every other medical discipline, finds itself venturing forth in practice patterns with which we have no experience. We might do well to heed the words of Mahatma Gandhi: "You may never know what results come of your actions, but if you do nothing, there will be no results." ■

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EXHIBIT 31

Commentary: COVID-19

Perspectives on the COVID-19 Pandemic and Individuals With Serious Mental Illness

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Just over a month ago, the World Health Organization declared coronavirus disease 2019 (COVID-19)—the disease caused by the severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2)—a global pandemic.[1] The scale of disruption that the COVID-19 pandemic has had on society has been massive and unprecedented. As of April 16, 2020, the coronavirus has infected more than 2 million people and claimed the lives of 144,341 worldwide.[2] The statistics in the US alone (668,174 cases, 33,931 deaths)[2]—which now overshadow those in the first epicenters such as China, South Korea, Italy, and Spain—are sobering.

The major public health focus at the start of the pandemic was to "flatten the curve," or slow the rate of COVID-19 transmission, with a particular emphasis on protecting the elderly, the immunocompromised, and those with respiratory and other medical conditions that placed them at higher risk of more severe outcomes if infected. However, as we enter the second month of the COVID-19 shutdown and contend with the idea of a new "normal," the impact of the COVID-19 crisis on other vulnerable populations, including individuals with serious mental illness (SMI) such as schizophrenia and bipolar disorder, shifts into greater focus.

Impact of the Coronavirus on People With SMI

Potentially higher risk of coronavirus exposure and infection. Schizophrenia and bipolar disorder are associated with cognitive deficits, including executive dysfunction.[3] In addition, people with SMI comprise a disenfranchised group,[4] with lower educational attainment[5,6] and health literacy,[7–9] on average, compared to the general population. Such factors may make it harder for people with SMI to find accurate information about COVID-19 and to organize, appraise, and translate health information into behavior that reduces risk of exposure and infection. This is especially true given the speed and constantly evolving nature of new information and guidance about COVID-19, as well as the troubling amount of "noise" in the form of misleading or false information circulating in social media and even some mainstream news outlets.[10]

Negative health-related behaviors may also increase infection risk in SMI. Some studies suggest that SMI patients may have lower rates of adherence to treatment for medical conditions[11,12] (though data are mixed; see, eg, Kreyenbuhl et al[13]). Thus, it is possible that patients, especially those who are more acutely ill, may have a harder time complying with protective hygiene measures, stay-at-home orders, and other health guidance during this pandemic. Tobacco use is another adverse health-related behavior that is much more common in SMI (64% in schizophrenia and 44% in bipolar disorder vs 19% in individuals without psychiatric illness).[14] Contact with virus-contaminated fomites is one of the mechanisms of coronavirus infection, and the act of smoking, which involves the hands and possibly contaminated cigarettes and other smoking apparatus coming in frequent contact with the mouth, may elevate risk. In addition, the coronavirus uses the angiotensin converting enzyme II (ACE-2) receptor to gain entry into cells and cause active infection,[15,16] and it was recently found that smokers have higher expression of ACE-2 in bronchial epithelial cells compared to nonsmokers and former smokers.[17] The higher ACE-2 levels in the airways of smokers is thought to predispose smokers to coronavirus infection.

Finally, individuals with SMI face greater risk of contracting exposure and infection because of structural barriers that can hinder their ability to successfully quarantine at home. SMI is associated with higher rates of homelessness and unstable housing.[18] According to one estimate, 20% of schizophrenia and 17% of bipolar disorder patients are homeless.[19] These numbers suggest that a disproportionate number of patients with SMI may lack the basic necessity of a safe and secure location in which to practice social distancing. Furthermore, for patients residing in communal settings, such as shelters, psychiatric units, and group homes, there can be heightened risk of contagion, as occurred in South Korea, where 101 of 103 patients in a psychiatric unit contracted COVID-19 and 7 died.[20] Similarly, in New York, people with disabilities living in group homes were found to be 5.3 times more likely than the general population to develop COVID-19 and 4.9 times more likely to die from it.[21] Psychiatric units and other behavioral health settings are often designed to facilitate social interactions, with patients and staff interacting in close quarters. In contrast to medical floors, psychiatric units are less likely to be equipped with personal protective equipment (PPE), and staff may have less prior training and experience in infection control practices. These factors, compounded by the worldwide shortage of PPE and the ongoing difficulty of accessing testing, create daunting challenges for congregate care settings, where coronavirus infection in just one patient or staff member could spread rapidly and have life-threatening consequences.

Likelihood of poorer outcomes from COVID-19. The coronavirus causes severe illness—with complications such as pneumonia, acute respiratory distress syndrome, septic shock, and acute kidney injury—in approximately 16% of cases, according to data from early in the pandemic.[22] Severe cases are associated with the presence of coexisting conditions, such as diabetes, hypertension, cardiovascular disease, chronic obstructive pulmonary disease (COPD), immunodeficiency, and cancer.[22] Even without factoring COVID-19 into the calculation, SMI patients already have a mortality rate that is 3.7 times that of the general population, with the excess deaths largely attributable to cardiovascular and respiratory diseases.[23] Factors related to both illness (eg, physical inactivity due to negative symptoms) and treatment (ie, metabolic disturbances caused by atypical antipsychotic medications[24]) increase rates of cardiovascular disease and diabetes in patients with SMI. Tobacco use also causes lung disease and reduced lung capacity, increasing the risk of more serious illness. Even before COVID-19, the incidence of pneumonia was higher in schizophrenia,[25] and associated with antipsychotic medications[26,27] and tobacco use, among other factors. Furthermore, clozapine, which is the antipsychotic reserved for treatment-resistant schizophrenia patients, can suppress immune function and increase susceptibility to infections like pneumonia.

The reasons why underlying medical conditions cause more severe COVID-19 illness are not yet fully understood, but ACE-2, the receptor to which SARS-CoV-2 binds to cause infection, are highly expressed in the heart and lungs.[28] The coronavirus is thought to cause acute injury to alveolar and myocardial cells,[29] which may already be compromised in cardiovascular and respiratory diseases. The use of ACE-inhibitor antihypertensive medications, which up-regulate ACE-2, may also play a role in increasing the severity of infections.[29] Whatever the mechanism, the high rate of smoking and comorbid medical conditions in SMI, in combination with the medications routinely used to treat SMI, may create a perfect storm for COVID-19 complications.

Worse outcomes may also result from delays in getting treatment. SMI patients tend to present for medical attention much later in the course of disease. Difficulty recognizing and effectively reporting physical symptoms—whether due to reduced pain sensitivity,[30] anosognosia (impaired awareness of illness), cognitive and motivational impairments, delusional interpretations about the body, and/or denial[31,32]—may contribute. In addition, SMI patients tend to have less financial and other resources, live in poorer neighborhoods with less favorable patterns of use and access to care,[33] and receive lower quality medical care.[34] Unfortunately, in the case of such a highly transmissible virus like SARS-CoV-2, delays in diagnosis and treatment not only impact the health of the affected individual but also have ramifications for public health.

Impact of the Public Health Response on People With SMI

The massive changes in society in response to the COVID-19 crisis—eg, the mandated closure of schools and businesses, and the sight of normally busy urban areas relatively empty of cars and pedestrians—are unsettling and surreal. For people with psychotic disorders, the current circumstances may exacerbate feelings of perplexity, anxiety, and paranoia and may also become integrated into the content of delusions. The lack of clear and consistent messages from the federal and some state governments add to the effects of social media misinformation campaigns and further contribute to confusion and instability in day-to-day life. So much is unknown not only about the new SARS-CoV-2 and the ultimate toll it will exact on human life but also about the scope and duration of mitigation efforts, which continue to be moving targets. The pervasive uncertainty about what to expect and how long the shutdown will last is a major source of distress for many.

While social distancing is necessary to protect public health, it can also have unintended effects. A subset of SMI patients may be less impacted by public health restrictions, having lived "socially distanced" lives for years, with minimal contacts outside of their immediate environment and necessities, whether as a result of symptoms, societal marginalization, or personal choice. But for many others with SMI, isolation measures further reduce and collapse social networks, which are often already tenuous. Social distancing limits access to treatment and support centers, including mental health providers, day programs, clubhouses, and peer-run respites. People in congregate care settings as well as their families and loved ones are now enduring increasingly prohibitive visitor policies. Simple but meaningful daytime routines such as visiting a favorite coffee shop, restaurant, or the library are now impossible.

Finally, the economic toll of the shutdown may be more pronounced for people with SMI. From mid-March to mid-April of this year, over 20 million Americans claimed unemployment.[35] People with SMI are more likely to have jobs that do not provide health benefits or paid sick leave and that are more vulnerable to layoffs and furloughs during the COVID-19 shutdown. While there are now talks about reopening the economy in certain states, the emotional, social, health, and financial impacts of this pandemic could act as traumas with enduring effects that will need continued attention even after the shutdown ends.

Impact of Changes in Health Care Delivery

In response to the pandemic, community-based behavioral health providers have been forced to shift from in-person, face-to-face services to "virtual" visits done by telephone or videoconference. This seismic shift in the landscape of behavioral health care has significant implications for people with SMI. Telehealth approaches have enabled ongoing access to vital services while helping to limit the spread of the virus. Telehealth has generally been found to be feasible and effective in treating mental illness and acceptable to people with SMI.[36,37] Mobile phone ownership (including smartphones) is increasingly common in all populations, including people with SMI, and evidence suggests that concerns regarding patients' ability and comfort using such technology may be unfounded.[38] Still, there will be individuals who will have difficulty or discomfort conveying information by telephone or videoconference. And while videoconferencing can improve the relational connection, there is a sense of "with-ness" that is lost in virtual interactions, and this phenomenon may disproportionately affect people who historically struggle to engage with their treaters. Issues of access and equity will come into play, as some people will not have the resources to obtain phone or Internet service, may lack enough minutes or data on their plans, or may not have the tech-literacy to participate in a video call without assistance. Other access issues to consider include the need to have workflows and technology that allow for the proper use of interpreters, including those for deaf and hard of hearing populations.

Like many others, people with SMI may forgo needed care out of fear of contracting the coronavirus in settings such as emergency departments, hospitals, outpatient laboratories, and pharmacies. Providers may need to reconsider the necessity and frequency of routine laboratory work in order to limit potential community exposure to the virus. Risk-benefit discussions will need to be undertaken with patients in order to assess the value of current monitoring protocols in the setting of a pandemic. The US Food and Drug Administration has released guidance highlighting flexibility in clozapine monitoring requirements during the COVID-19 public health emergency.[39] To ensure medication adherence is not interrupted, patients may need

assistance programs, home deliveries from pharmacies). The prolongation of long-acting injectable medications may also become challenging due to staffing issues and inadequate PPE, necessitating creative problem-solving and possible return to oral medication for a period of time.

Conclusions and Recommendations

The COVID-19 pandemic presents challenges for us all. However, people with SMI may face even greater challenges due to the multiplicity of factors that put these individuals at risk for coronavirus infection and complications, as well as the massive impact of public health measures and associated changes in mental health care delivery. These factors are likely additive and make an already marginalized segment of society even more vulnerable. There is no doubt that this pandemic is causing devastation worldwide, but the pandemic arguably does more to expose problems that already exist. According to historian and writer Frank M. Snowden, epidemics like the coronavirus are "a mirror for humanity."[40] He writes, "Epidemic diseases are not random events that afflict societies capriciously and without warning. On the contrary, every society produces its own specific vulnerabilities."[40] In the case of people with SMI, what is reflected is the profile of a vulnerable population in a health care system that is highly fragmented.

What can we do about this? First, we need to creatively and actively engage and strengthen partnerships with patients, whether through virtual encounters or in-person with the protection of PPE (eg, for congregate care settings) during this period of social distancing. Patients may need increased support to cope with the stress and uncertainty of the pandemic and to manage any exacerbation of symptoms. Importantly, we need to ensure that patients receive clear and accurate information and education about COVID-19 and how to protect themselves and those around them from disease transmission. Health information needs to be presented and represented in clear and accessible ways, tailored to individual strengths and limitations.

Until vaccines become available, close monitoring of physical health and increased access to testing will be critical, while recognizing that treaters may need to advocate for their patients in order to secure appropriate COVID-19 testing. Those living in congregate care settings will need to be supported by staff who have been trained to monitor for signs and symptoms of COVID-19, including the identification of symptoms requiring emergent attention. People with unstable housing will need suitable accommodations to ensure the safety and health of themselves and others. People who are unable or unwilling to follow public health guidance and restrictions such as quarantine or isolation will pose special challenges to the system of care, necessitating supportive and individualized approaches that will hopefully avoid more restrictive or drastic measures that could be undertaken in order to protect the health of the individual and public.

Given the likely increased risks of negative outcomes from COVID-19, as well as the difficulty some individuals have in recognizing and communicating physical symptoms or health needs, people with SMI who are at risk for or have been diagnosed with COVID-19 may need closer medical monitoring if quarantining or isolating outside of a hospital setting. In all these efforts, close collaboration between psychiatry, primary care, and other medical services is needed to reduce poor clinical outcomes in this vulnerable population.

Second, the health care system, and society more generally, needs to not only deal with issues related to COVID-19 but also address the deeper challenges and disparities that people with SMI face. We need to help patients achieve better health outcomes through smoking cessation, improved diet and exercise, more effective medications with better side effect profiles, better access to quality health care, more stable housing, safer neighborhoods, and improved educational and vocational opportunities to increase social capital. We recognize that these goals are ambitious and unlikely to occur overnight. However, if we can use the current crisis to initiate sweeping change, as many clinics and hospitals have been able to do with the rapid transition to telehealth, we may find ourselves facing a less troubling situation in the "mirror" if and when another pandemic occurs.

Last but not least, we need to better understand some of the unique issues facing this population and stay vigilant regarding consequences of our actions or inactions in the months ahead. This will require going beyond making conjectures about potential

risks, as more data in this commentary, to collect data to measure the actual health, emotional, social, and economic impacts of the COVID-19 pandemic on people with SMI.

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EXHIBIT 32

AMEND
CHANGING CORRECTIONAL CULTURE

Berkeley Public Health

Urgent Memo

COVID-19 Outbreak: San Quentin Prison

June 15, 2020

San Quentin California State Prison is experiencing a rapidly evolving COVID-19 (SARS-CoV-2) outbreak with profoundly inadequate resources to keep it from developing into a full-blown local epidemic and health care crisis in the prison and surrounding communities. The urgent resources San Quentin requires range from human capital to environmental risk reduction and rapid testing. Failure to meet these urgent needs will have dire implications for the health of people incarcerated at San Quentin, custody, staff, and the healthcare capacity of Bay Area hospitals. This document provides suggested guidance on immediate actions needed to address the outbreak with emphasis on both the short- and longer-term health of people currently incarcerated at San Quentin.

Background

San Quentin arrives at this tenuous moment with several significant assets including a strong Chief Medical Executive (Dr. Alison Pachynski) and a Chief Physician and Surgeon (Dr. Shanon Garrigan) who have spent the past 3.5 months doing everything in their power to prepare for an unavoidable COVID-19 outbreak. However, these two physicians, even with the enormous assistance they have received from many other healthcare staff, including a strong public health nurse, and a notably excellent partnership with custody leadership (Acting Warden Ronald Broomfield and the recently arrived Health Care Chief Executive Clarence Cryer), is simply not enough to meet the needs at San Quentin. As a result, there are multiple vulnerabilities that we witnessed at San Quentin during our visit on June 13, 2020 which must be urgently addressed to protect the health and safety of the thousands of people incarcerated there as well as staff and surrounding community members.

Although this memo outlines the urgent needs of San Quentin Prison, it is our belief that most – if not all – of these recommendations are important for all California Prisons that are certain to experience an outbreak if they have not already.

Urgent needs and immediate actions required:

1. **Develop a COVID-19 Outbreak Emergency Response Team:** At present, the over-reliance on existing local medical and custody staff to develop an outbreak response plan means that they are tasked with making multiple acute decisions on a daily basis without adequate resources, options, or support to operationalize a centralized plan or long term strategy. This responsibility – overwhelming on its own – is then magnified with the additional necessity of providing

implementation oversight of the ad-hoc outbreak plan. Instead, local leadership should have a team of staff who can implement and recommend adjustments to the overarching central COVID-19 control strategy as needed on the local level. There simply do not appear to be sufficient on-the-ground staff who are not working from home. This daily management of the acute phase of the outbreak has the secondary effect of making the lead physicians less available to coordinate the care and treatment of patients incarcerated at San Quentin who become acutely ill in the facility and also increases the vulnerability of San Quentin to errors with potentially dire consequences. Minimum positions required for such a team are included below. Dr. Pachynski and Dr. Garrigan appear to be personally responsible for all of the tasks described below with insufficient tools to support their success. While there may be some central guidance and support offered, additional human capital is urgently needed to achieve the CCHCS's pandemic response goals.

Minimum Recommended Leadership Team Positions:

- **Environment of Care Leader.** This position would be responsible for evaluating and addressing immediate needs regarding the physical plant of the prison for ventilation, sanitation, path of patient flow (e.g., developing policies and procedures for how people incarcerated at San Quentin who become infected are transferred through and out of the institution for care) and planning for how to reconfigure and reimagine needed space for quarantine, general population, or medical isolation units depending on how the number of affected people increases or decreases over time. This position would also work with plant operations to ensure that all air vents are cleaned and well functioning and would organize the creation of (a) field hospital(s) or quarantine tents as needed.

- **Healthcare – Custody Coordination Leader.** This position would focus on coordinating with Custody (and working closely with the Staff Healthcare Liaison Leader, described below) to review current placement on a daily basis, and to determine the appropriate way to cohort people currently incarcerated at San Quentin, staff, and custody including developing quarantine areas (in partnership with the Environment of Care Leader) to minimize risk of infection. This position would also be responsible for ensuring that all transfers *into* San Quentin are halted and that appropriate and timely testing is done to facilitate transfer out of Medical Isolation and Quarantine within the facility, to the community, and – in certain circumstances - to other facilities if medically necessary.

- **COVID-19 Testing Leader.** This position would be responsible for coordinating with the testing center (at this moment, QUEST Diagnostics) including reaching out through public and private sources and coordinating with the state and local departments of public health to improve testing turnaround time, running the list with medical staff (and the Epidemiologist, described below) on a daily basis to determine who has – and who needs – testing, and coordinating contact tracing in response to testing results and reporting of symptoms throughout the facility.

- **Staff Healthcare Liaison Leader.** This position would work with custody leadership (and Union representatives, as appropriate) to cohort staff/custody, develop plans that eradicate staff/custody working within more than one unit in rapid succession, train and enforce PPE rules, support contact tracing and administrative leave needs among exposed and infected staff/custody, and investigate alternatives to potential staff/custody transmission opportunities such as shared vanpools. This position would also track daily staff movements in order to assist with contact tracing when needed.

- **Epidemiologist Analyst Leader.** This position would be responsible for maintenance of a line listing of all active and resolved cases (people incarcerated at San Quentin and staff) and for all data analysis and reporting. This position would also be responsible for a "patient tracking process" of the facility including daily review of the COVID-19 Monitoring Registry to provide close scrutiny of who has tested positive or is in quarantine – where they are currently located (and were recently located), and the same for those who have tested negative. In addition, this position would assist the Environment of Care leader and the Healthcare – Custody Coordination Leader to manage patient movement to quickly clear people when they have tested negative and return them to the General Population and/or to the community. This position would also manage testing data (e.g., in the Reception Area, some have been tested 3-4 times and test results are coming in at different times).

2. **Address Unsafe Overcrowding.** There are currently 3547 people in total incarcerated at San Quentin, approximately ~1400 of whom have at least one COVID-19 risk factor (as do many, unknown, staff members). This means these individuals are at heightened risk of requiring ICU treatment and/or mortality if infected. We detail the units of most immediate concern below. Given the unique architecture and age of San Quentin (built in the mid 1800s and early 1900s), there is exceedingly poor ventilation, extraordinarily close living quarters, and inadequate sanitation. **We therefore recommend that the prison population at San Quentin be reduced to 50% of current capacity (even further reduction would be more beneficial) via decarceration**; this will allow every cell in North and West blocks to be single-room occupancy and would allow leadership at San Quentin to prioritize which units to depopulate further including the high-risk reception center and gymnasium environments. It is important to note that we spoke to a number of incarcerated people who were over the age of 60 and had a matter of weeks left on their sentences. It is inconceivable that they are still in this dangerous environment.

Housing units of most concern at San Quentin at present time:

- **North Block and West Block** have cells with open-grills, and are each 5-tier buildings with a capacity of 800 persons. Ventilation is poor – windows have been welded shut and the fan system does not appear to have been turned on for years; heat on the far side of the building can be stifling. Over 50% of those incarcerated in these units have at least 1 COVID-19 risk factor, and an alarming ~300 have 4 or more COVID-19 risk factors. An outbreak in North and West blocks could easily flood – and overwhelm – San Quentin as well as Bay

Area hospitals. (For example, see San Francisco hospital capacity: https://data.sfgov.org/stories/s/Hospital-Capacity/qtdt-yqr2/)

- **Reception center** currently has ~500 persons. In the reception Center's "Badger Unit" where people from CIM were transferred, the fear and outrage among the people incarcerated are palpable – people are yelling throughout the housing unit due to discontent about the COVID-19 situation including intake of transfers from CIM and loss of privileges/disruption to daily routine (thereby increasing the risk of COVID-19 spread throughout the tiers via respiratory droplets). It is hard to imagine that as a result of these conditions, that violent incidents will not occur—further threatening the safety and health of the people incarcerated in these units and staff alike.

- **The Gymnasium**, which has been converted to a dorm. There is little to no ventilation in this unit creating high-risk for a catastrophic super spreader event.[1] At a minimum, the gymnasium beds should be spread out more to ensure additional distance between beds, and the second set of doors in the gymnasium dorm must be opened to ensure air turnover. **This unit should be prioritized for closure as a dorm, once sufficient population reduction has been achieved through release.**

- **HVAC – in all units above and in other areas,** there is an immediate need to clean and turn on all fan and HVAC systems immediately (e.g., North Block, Gymnasium, Dorms) in order to maximize air exchange and ventilation as soon as possible. Of note, the exhaust pumps and filters appear dirty on visual inspection, and require clearing and cleaning. Since maximizing air exchange through better ventilation decreases COVID-19 transmission, doors and windows should be opened as much as possible (some have been welded shut and must be remediated). Note that the important aspect is *air exchange*, not the movement of air within the room. Fans that blow air around may help cool people, but they don't decrease rebreathing aerosols unless they filter the air or increase air exchange (diluting the aerosol).

3. **Immediately Improve Testing.** It is inconceivable that in the Bay Area the medical leadership at San Quentin is having to manage an outbreak in their massive antediluvian facilities with PCR tests on a 5-6 day turn-around time. We would argue that there is no higher testing priority for around 100 miles and resources need to be shifted immediately to respond or there will be a massive, uncontrollable outbreak (if it is not too late already). In addition (and this certainly goes without saying), **transfers into San Quentin must be halted immediately**. **Further, priority must be placed on reducing the prison population at San Quentin via decarceration as it will be extremely difficult to ensure the health and safety of all people in this extraordinarily old and**

[1] It is important to recognize that all of our recommendations regarding ventilation in different housing units at San Quentin were based on the observations of a team of public health professionals accompanying San Quentin medical staff. Although incarcerated persons and custody staff shared their understanding of the ventilation systems in the units and their operability, we neither had the opportunity to speak with any of the facilities staff nor were any members of our team experts in HVAC. We would strongly recommend seeking the advice of such experts and monitoring CO2 levels in different parts of the prison as one easy measure of the extent of rebreathing in a housing unit.

complex facility. The following recommendations both support these imperatives and, in some cases, are dependent on their implementation:

- **Liaise with testing laboratory to streamline testing,** including exploring observed self-collection of samples and alternate anatomic sites of testing (e.g. saliva, nares swabs).

- **Improve testing turnaround time at QUEST or go through other laboratories that will be able to improve turnaround time (5-6 days or more is completely unacceptable).** As an example, CMC was able to rapidly respond to their outbreak with a turnaround testing time of 24 hours at some points in the outbreak. Large-scale testing with rapid receipt of results is essential to allow the medical team to minimize community spread. If tests are sent to laboratories other than QUEST, support must be provided to San Quentin to add these results to the EMR as the current process of scanning and manual entry is overly laborious and resulting delays may lead to medical decisions based on outdated data.

- **The California Department of Public Health** should be compelled to prioritize specimens from San Quentin given the potential for super-spreading in that environment.

- **Testing of symptomatic patients must be done with individual testing. Testing of asymptomatic patients to identify people who are shedding virus can be done with pools of samples. Without additional information, pools of 10 should be used.** This approach can be used for frequent retesting of people at especially high risk of spreading the virus (staff/custody and people incarcerated in larger units — i.e. almost all of San Quentin).

- **San Quentin requires on-site testing –** including cartridges and well-trained staff to conduct these (currently they have inadequate staffing to conduct mass swabbing). Sample transport just adds time. San Quentin will need high volume testing for many months, perhaps years. They should have testing capacity on-site and available round-the-clock.

- **Of note, because testing time is so slow, little to no contact tracing can happen. Furthermore, people incarcerated at San Quentin cannot be appropriately transferred within the prison based on test results if results are returned 6 days later and new exposure may have occurred in the interim.** As a result, *entire units are put on lockdown status for the span of a quarantine*. This is not a viable solution. In the long term, as this pandemic will last at least another year and likely longer, this will have profound physical and mental health consequences for the incarcerated population and staff alike.

4. **Develop Additional Medical Isolation and Quarantine Housing.**

Background: It is our understanding that on May 30, transfers from CIM arrived at San Quentin on five buses. Several among those who were transported on Bus 5 tested positive at arrival. While all transfers on Bus 1 and 3 initially tested negative, several later developed COVID-19 symptoms. At the time of our visit, there were no reports of symptoms or positive tests among those who traveled on Buses 2 and 4. At the advice of the local health

department, all individuals from the five CIM buses who tested positive or reported symptoms were placed in the Adjustment Center. Those who either tested negative or did not report symptoms were placed individually and in every other cell on the Reception Area's Badger and Donner Units 4th and 5th tiers (among people who were incarcerated at San Quentin prior to the transfer).

June 13 Visit: As of our visit, those requiring *Quarantine* (i.e., people with a credible exposure to COVID-19 who are asymptomatic) are in the Reception Area's Carson Unit. Those requiring *Medical Isolation* (who have tested positive for COVID-19 **or** who have symptoms suggestive of COVID-19 and are still awaiting testing) are in the Adjustment Center as this is the only unit at San Quentin that has single cells with solid doors. Per our notes, there are ~106 cells in the Adjustment Center, with ~80 occupied at the time of our visit.

Urgent Concerns:

1. A massive outbreak at San Quentin will significantly and quickly overwhelm the availability of these 106 Adjustment Center cells, and there will quickly be nowhere for infectious cases to be moved. Further, we cannot emphasize enough the incredible fear that residents we spoke with expressed about being moved to cells typically used for administrative segregation/punishment or "death row" – potentially resulting in short- and long-term mental health consequences. Especially given that early identification of suspected COVID-19 cases depends on reporting of symptoms, **quarantine strategies relying on the Adjustment Center or cells usually used for punishment may thwart efforts for outbreak containment as people may be reluctant to report their symptoms**. In addition, people with COVID-19 are known to experience rapid physical decompensation; it may therefore be particularly detrimental for a patient with COVID-19 to be behind a solid door in the most secure areas of the prison out of the sight of medical or nursing staff in the case of an emergency. This may be particularly risky if there are structural barriers to communicating distress to staff (e.g., if accomodations are not readily accessible for people with disabilities or who speak other languages, and/or there are multiple security stages to pass through).

Given San Quentin's antiquated facilities, poor ventilation, and overcrowding, **it is hard to identify any options at San Quentin where it is advisable to house high-risk people with multiple COVID-19 risk factors for serious morbidity or mortality**. Again, for these reasons it will be exceedingly hard for medical staff to keep people safe from contracting COVID-19 at San Quentin and, once infected, it will be very hard to ensure that they do not pass the infection on to others with high health risks or experience rapid health declines themselves. **San Quentin is an extremely dangerous place for an outbreak, everything should be done to decrease the number of people exposed to this environment as quickly as possible.**

Our recommendations for Quarantine and Medical Isolation are as follows:

- Immediately create a field hospital by **converting nearby chapels (there are 3) or even the chow hall.** This field hospital can be designated for all people with confirmed COVID-19 ("Medical Isolation Unit") as there are not substantial risks to isolating infected patients together and these patients would then have access to supervising nurses who could regularly check their respiratory status and comfort levels. Such a unit could have different tiers of medical supervision as some people in medical isolation will be asymptomatic and will not require as close medical supervision. The chapels are large rooms with road access for ambulances and other transport. We recognize the plans for assigning units will become increasingly complex as people of multiple security levels require Quarantine or Medial Isolation. **This again reinforces the need for release** and a dedicated team leader (the **Healthcare – Custody Coordination Leader)** who oversees the work of partnering with custody to identify medically appropriate cohorting solutions.

- **For those currently in the Adjustment Center:** As individuals test negative (via recovery or because they never developed infection) they ideally should be moved out of the Adjustment Center as quickly as possible. However, with evidence of community spread at San Quentin, extreme caution must be exercised when moving persons out of the Adjustment Center who test negative for COVID-19 and who are at high risk for poor health outcomes if infected. For these individuals, we strongly recommend that central administration work with medical leaders at San Quentin to identify options for safer placement of individuals leaving the Adjustment Center (perhaps in temporary tents) or in other CDCR facilities (transfers would have to happen with exceptional caution given prior failure with transport including 2 weeks of quarantine on either side of transfer coupled with testing at the outset and end of 14-day quarantine in each site). Alternative housing options outside of San Quentin should also be explored, including nearby hotels or school dorms that can be converted in an effort to save lives. People at the Adjustment Center who test positive should be immediately moved to the new Medical Isolation Unit (e.g., in the converted chapels).

- **Physical and mental health during quarantine and medical isolation must be prioritized with adequate consideration for how need may vary across people incarcerated at San Quentin.** While awaiting testing results, people should receive resources to support their well-being as much as possible during isolation/14-day quarantine period (quarantine should not exceed 14 days after a single exposure). Such resources, at a minimum, should include free access to personal tablets with movies, increased access to free canteen items, personal effects and free phone calls, perhaps on state-owned cell phones, and daily opportunities for yard time. While some of these comforts may seem beyond the normal routine of prisons in California, they are simple, low-cost measures that are essential if there is any hope of minimizing the risk of adverse short- and long-term physical and mental health outcomes of isolation among those who are currently in the Adjustment Center for

quarantine or isolation. Alternatives for isolation or quarantine that do not involve the Adjustment Center must be immediately sought (e.g., quarantine tents or other areas of the prison where significant depopulation can allow for fewer occupied cells). **Ultimately, there are simply too few options for safe quarantine at San Quentin without prioritizing population reduction through release.**

5. **Improve General Prevention efforts throughout the facility.** In particular, we witnessed alarmingly suboptimal mask use by staff, and three "medical pass nurses" sitting in a work room without masks. Moreover, custody work stations are not set up to physically distance, no additional workstations appear to have been built yet. As a result, even with the best of efforts, officers wind up clustered near each other around a central podium. An infection control nurse and environmental assessment would go a long way towards identifying opportunities to partially alleviate these problems.

6. **Staff Cohorting is a necessity.** At present work shift plans are inadequate from a public health perspective. For example, we learned about staff who were working in the Medical Isolation Unit (Adjustment Center) during the shift and were scheduled to work the next shift in the dorms. This is an enormous risk for the spread of COVID-19 between units.

7. **Convene COVID-19 Inmates Council.** To ensure urgent health messaging is comprehensively communicated through trusted paths, we recommend that a COVID-19 Inmates Council be established (if one does not yet exist) in collaboration with any existing leadership groups/councils among people incarcerated at San Quentin. This council should be asked to provide critical feedback regarding all the above recommendations, how they may best be implemented and messaged to the population, and if there are considerations that have not been addressed that will maximize the urgent and long term health needs associated with this outbreak.

8. **Convene COVID-19 Inmate Family Council.** To ensure urgent health messaging is communicated to the families of people incarcerated at San Quentin, we recommend that a COVID-19 Inmate Family Council be established. This council may also provide critical feedback regarding all the above recommendations, how they may best be implemented, and if there are considerations that have not been addressed that will maximize the urgent and long term health needs associated with this outbreak.

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Amend at UCSF is a health-focused correctional culture change program led by experts in medicine, infectious diseases, public health, and correctional health and policy that is providing correctional leaders, policymakers, and advocates the evidence-based tools they need to protect the health and dignity of those who live and work in jails and prisons during the COVID-19 pandemic.

The University of California, Berkeley School of Public Health is working on the leading edge of research, educating the public, and mobilizing to serve California's most vulnerable populations during the COVID-19 pandemic.

For more information:

https://amend.us/covid

EXHIBIT 33

AMEND
CHANGING CORRECTIONAL CULTURE

The Ethical Use of Medical Isolation – *Not Solitary Confinement* – to Reduce COVID-19 Transmission in Correctional Settings

***April 9*, 2020**

David Cloud, JD, MPH, Dallas Augustine, MA, Cyrus Ahalt, MPP, & Brie Williams, MD, MS

What is covered in this brief

This brief clarifies the differences between "medical isolation," "quarantine," and "solitary confinement," and describes the services and benefits that corrections officials should provide to people who are separated for medical isolation or quarantine so that they are not subjected to punitive and traumatizing conditions of solitary confinement. It is intended to provide guidance to departments of correction, prison and jail residents, advocates, and other key stakeholders to help ensure that using medical isolation or quarantine to mitigate the spread of COVID-19 in correctional facilities follow the highest standards of medical ethics.

The distinction between "solitary confinement", "medical isolation", and "quarantine"

- **Solitary Confinement** is the practice of isolating incarcerated people from the rest of the prison population while simultaneously imposing punitive measures such as major restrictions on visitors, phone calls, recreation and outdoor time, and access to personal property.
- **Quarantine** is the practice of separating and restricting the movement of people who may have been exposed to a contagious disease until results of a laboratory test confirm whether or not they have contracted the disease. These individuals may have been exposed to COVID-19, for example, by spending prolonged time in close proximity to someone who has tested positive, or they may have early symptoms of a potential COVID-19 infection.
- **Medical Isolation** is the practice of isolating incarcerated people from the rest of the prison population when they show signs or test positive for COVID-19 in order to stem the risk of COVID-19 transmission throughout the prison.

The ease with which COVID-19 can spread in prisons and jails

The millions of people incarcerated in the U.S. are particularly vulnerable to infection, illness, and death from COVID-19, due to high rates of underlying medical conditions coupled with confinement in crowded and often unsanitary conditions with limited access to personal hygiene products. As the World Health Organization (WHO), Centers for Disease Control (CDC) and many others have emphasized, social distancing, regular handwashing, and frequently sanitizing living spaces are essential to preventing the spread of COVID-19 and "flattening the curve" (or delaying the

transmission of disease in order to distribute the need for life saving healthcare resources over time rather than all at once). **Unfortunately, it is virtually impossible to follow these directives in many correctional facilities**, where hundreds and even thousands of people are confined in overcrowded, often unsanitary conditions—and where people generally lack sufficient access to soap, sanitizer, hot water, and other materials necessary to minimize the risk of COVID-19 infection.

Many public health experts, policymakers, advocates, and community leaders have called for the swift release of as many people as possible from correctional facilities in order to mitigate the accelerated spread of the virus among incarcerated people, correctional workforces, and the larger community. Increasingly, state and local leaders are heeding this call. These actions will surely prevent infections, alleviate suffering, save lives, and help "flatten the curve" inside and outside prisons and jails. However, the number of people released to date has been relatively small. Millions of people will remain in custody as COVID-19 continues to spread. **Some of these individuals will require temporary quarantine or medical isolation to stem the transmission of COVID-19.**

The complexity of using isolation as a tactic to minimize COVID-19 transmission in jails and prisons

1. **Placing people in solitary confinement (punitive isolation) will worsen the COVID-19 crisis.** Many corrections officials lack guidance on how to humanely and effectively separate sick or contagious individuals from the general population. At times, the most feasible and only available housing units in jails and prisons for medical isolation or quarantine of sick patients are those used for punitive solitary confinement in "normal" times (single cells, solid cell doors rather than barred, removed from the main center of the prison). Use of these units for medical purposes, while often necessary, can run the risk of corrections officials falling back on regular policies and procedures governing living conditions in these units that harm the health of those exposed. (see figure for policy differences)
2. **Fear of being placed in solitary will deter people from reporting symptoms to correctional staff.** Experts and advocates are deeply concerned that incarcerated people, many of whom will go to great pains to avoid solitary confinement due to well-established mental and physical health harms associated with the experience, will not come forward when they have symptoms of COVID-19 because they do not want to be placed in such conditions. This avoidance of reporting symptoms or illness will not only accelerate the spread of infection within facilities but also increase the likelihood of prisoner deaths due to lack of treatment.
3. **Preemptive lockdowns may result in failure to detect symptomatic people and cause undue stress to residents.** Some correctional facilities are preemptively placing entire units or facilities on "lockdown" for indefinite amounts of time, meaning that people are confined to a small cell, alone or with another person nearly all the time. Meals, medications, commissary, and other goods are delivered to the cell door. Recreation, programming, educational and religious services are shut down. As a result, interactions with correctional staff and healthcare staff often become less frequent and people with symptoms may go undetected.

During the COVID-19 crisis, medical isolation and quarantine should be used only as medically necessary, and these procedures should result in living conditions clearly distinct from those found in solitary confinement (see figure)

COVID-19 presents daunting public health challenges both inside and outside correctional facilities. **Separating people who become infected is a necessary public health challenge, particularly in prisons and jails. But turning to the punitive practice of solitary confinement in response to the COVID-19 crisis will only make things worse**. Research shows that keeping people socially isolated in a closed cell without a meaningful opportunity to communicate with family, friends, and loved ones or to participate in exercise, educational, and rehabilitative programming (solitary confinement) causes immense, and often irreparable, psychological harm. Emerging evidence suggests that the COVID-19 pandemic will last for at least several more months. Moreover, some people in prison will hide symptoms to avoid being housed in such damaging conditions, even if only temporarily. To minimize the risk of worse health among incarcerated people we recommend the following:

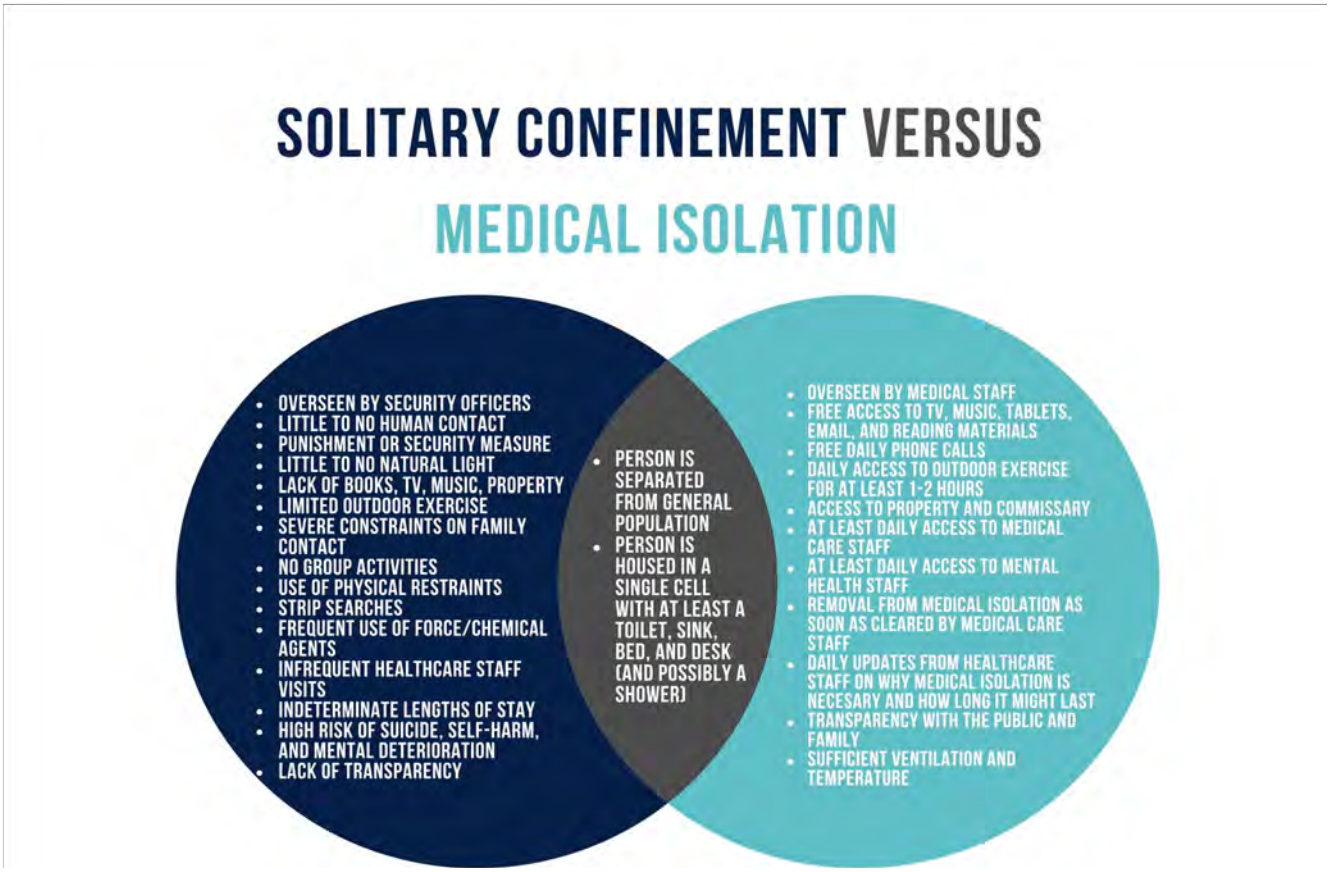
- **The purposes and practices of medical isolation and quarantine should be clearly described** to incarcerated people and their advocates, as well as to the corrections staff that oversees them.

- Corrections officials should only require people on an entire housing unit to stay in their cells ("Lockdown") **if medical professionals determine a symptomatic person resides or works on that unit or contact tracing flags a confirmed or suspected case**.

    - In this event, **time-limitations must be clearly communicated to residents and staff.** Based on current evidence, 5 days is the average time from exposure to symptom onset of COVID-19, and 97.5% of people show symptoms within 11 days. Depending on how evidence emerges in the weeks to come, unit-specific lockdowns could reasonably last 5 to 11 days, but not beyond 14 days, without new evidence of the virus entering the housing unit.

    - All decisions should be documented and communicated with health officials.

Prisons, jails, and other places of detention that are not able to comply with ethical standards of quarantine and medical isolation in the COVID-19 pandemic should urgently implement strategies to release or transfer people to locations that have the capacity to meet community standards of medical care.



Solitary Confinement is defined by the U.S. Department of Justice as:
"[A]ny type of detention that involves: (1) removal from the general inmate population, whether voluntary or involuntary; (2) placement in a locked room or cell, whether alone or with another inmate; and (3) inability to leave the room or cell for the vast majority of the day, typically 22 hours or more."

WHO and CDC define **Medical Isolation** in a correctional context as:
"Confining a confirmed or suspected COVID-19 case (ideally to a single cell with solid walls and a solid door that closes), to prevent contact with others and to reduce the risk of transmission. Medical isolation ends when the individual meets pre-established clinical and/or testing criteria for release from isolation, in consultation with clinical providers and public health officials…In this context, isolation does NOT refer to punitive isolation for behavioral infractions within the custodial setting. Staff are encouraged to use the term "medical isolation" to avoid confusion.

The American Medical Association defines **Quarantine** as: the separation and restricted movement of people who were exposed to a contagious disease while awaiting the results of testing.

Amend COVID-19 Guidance & Tools developed by:

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Amend at UCSF fundamentally transforms culture inside prisons and jails to reduce their debilitating health effects. We provide a multi-year immersive program drawing on public health-oriented correctional practices from Norway and elsewhere to inspire changes in correctional cultures and create environments that can improve the health of people living and working in American correctional facilities.

Amend is currently focused on providing resources, expertise, and support to correctional systems confronting the global COVID-19 pandemic.

For more information: https://amend.us

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EXHIBIT 34

Neurological and neuropsychiatric complications of COVID-19 in 153 patients: a UK-wide surveillance study

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Summary

Background Concerns regarding potential neurological complications of COVID-19 are being increasingly reported, primarily in small series. Larger studies have been limited by both geography and specialty. Comprehensive characterisation of clinical syndromes is crucial to allow rational selection and evaluation of potential therapies. The aim of this study was to investigate the breadth of complications of COVID-19 across the UK that affected the brain.

Methods During the exponential phase of the pandemic, we developed an online network of secure rapid-response case report notification portals across the spectrum of major UK neuroscience bodies, comprising the Association of British Neurologists (ABN), the British Association of Stroke Physicians (BASP), and the Royal College of Psychiatrists (RCPsych), and representing neurology, stroke, psychiatry, and intensive care. Broad clinical syndromes associated with COVID-19 were classified as a cerebrovascular event (defined as an acute ischaemic, haemorrhagic, or thrombotic vascular event involving the brain parenchyma or subarachnoid space), altered mental status (defined as an acute alteration in personality, behaviour, cognition, or consciousness), peripheral neurology (defined as involving nerve roots, peripheral nerves, neuromuscular junction, or muscle), or other (with free text boxes for those not meeting these syndromic presentations). Physicians were encouraged to report cases prospectively and we permitted recent cases to be notified retrospectively when assigned a confirmed date of admission or initial clinical assessment, allowing identification of cases that occurred before notification portals were available. Data collected were compared with the geographical, demographic, and temporal presentation of overall cases of COVID-19 as reported by UK Government public health bodies.

Findings The ABN portal was launched on April 2, 2020, the BASP portal on April 3, 2020, and the RCPsych portal on April 21, 2020. Data lock for this report was on April 26, 2020. During this period, the platforms received notification of 153 unique cases that met the clinical case definitions by clinicians in the UK, with an exponential growth in reported cases that was similar to overall COVID-19 data from UK Government public health bodies. Median patient age was 71 years (range 23–94; IQR 58–79). Complete clinical datasets were available for 125 (82%) of 153 patients. 77 (62%) of 125 patients presented with a cerebrovascular event, of whom 57 (74%) had an ischaemic stroke, nine (12%) an intracerebral haemorrhage, and one (1%) CNS vasculitis. 39 (31%) of 125 patients presented with altered mental status, comprising nine (23%) patients with unspecified encephalopathy and seven (18%) patients with encephalitis. The remaining 23 (59%) patients with altered mental status fulfilled the clinical case definitions for psychiatric diagnoses as classified by the notifying psychiatrist or neuropsychiatrist, and 21 (92%) of these were new diagnoses. Ten (43%) of 23 patients with neuropsychiatric disorders had new-onset psychosis, six (26%) had a neurocognitive (dementia-like) syndrome, and four (17%) had an affective disorder. 18 (49%) of 37 patients with altered mental status were younger than 60 years and 19 (51%) were older than 60 years, whereas 13 (18%) of 74 patients with cerebrovascular events were younger than 60 years versus 61 (82%) patients older than 60 years.

Interpretation To our knowledge, this is the first nationwide, cross-specialty surveillance study of acute neurological and psychiatric complications of COVID-19. Altered mental status was the second most common presentation, comprising encephalopathy or encephalitis and primary psychiatric diagnoses, often occurring in younger patients. This study provides valuable and timely data that are urgently needed by clinicians, researchers, and funders to inform immediate steps in COVID-19 neuroscience research and health policy.

Funding None.

Introduction

In December, 2019, WHO was notified by clinicians in Wuhan, China, of a novel and severe respiratory virus, later called severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). COVID-19, the disease caused by SARS-CoV-2, was recognised as a substantial global

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See Online for appendix

Research in context

Evidence before this study

We searched PubMed on Jan 1, 2020, and May 11, 2020, with no language restrictions, using the search terms "COVID-19 or SARS-CoV2" with "neurological or psychiatric" and identified 133 publications and 371 publications, respectively. A focus on publications that reported data for the onset of new neurological or psychiatric diagnoses in hospitalised patients with confirmed or probable COVID-19 identified a more restricted subset of baseline data. From a neurological perspective, these publications included case reports or series (with less than ten patients) of stroke (six publications), encephalitis (five publications), seizures (one publication), cranial neuropathies (two publications), and posterior reversible encephalopathy syndrome (one publication). A larger series of 214 patients from Wuhan reported neurological symptoms in 78 patients. However, many of these symptoms were vague—for example, dizziness or headache—although a subset of 13 patients had a cerebrovascular diagnosis. A study from France reported patients with COVID-19-related acute respiratory distress syndrome, of whom eight had neurological manifestations, including two with strokes. We identified many publications that addressed the mental health effects of COVID-19 on the general population, health-care workers, and those with pre-existing psychiatric diagnoses. However, cases of new-onset psychiatric diagnoses in hospitalised patients with confirmed or probable COVID-19 were limited to a few case reports. In the large Wuhan study, acute psychiatric diagnoses were not described. In the French study, although a dysexecutive syndrome was reported in 14 patients and 26 were described as confused, little information was available with regard to what the psychiatric diagnoses were, and this cohort represented only the severe end of the respiratory spectrum.

Added value of this study

By working across the clinical neuroscience communities of neurology, psychiatry, stroke, and neurointensive care, we identified acute presentations of new-onset complications of COVID-19, reflecting the spectrum of the burden of disease. Ischaemic stroke was common in our cohort of 153 patients (most of whom were confirmed to have COVID-19). We identified a large group of patients with altered mental status, reflecting both neurological and psychiatric diagnoses, such as encephalitis and psychosis. Altered mental status was identified across all age groups, and many younger patients had this presentation.

Implications of all the available evidence

Our work highlights the importance of interdisciplinary work in the clinical neurosciences field in the COVID-19 era. Clinicians should be alert to the possibility of patients with COVID-19 developing these complications and, conversely, of the possibility of COVID-19 in patients presenting with acute neurological and psychiatric syndromes. These findings should direct future research to establish the role of viral neurotropism, host immune responses, and genetic factors in the development of such complications so that clinical management strategies can be developed.

public health emergency and SARS-CoV-2 was declared a pandemic on March 11, 2020. The neurological community were alerted to the high prevalence of anosmia and dysgeusia in early reports.[1,2,3] Some of these early cohorts also featured non-specific neurological symptoms, such as dizziness and headache.[1] However, severe neurological and neuropsychiatric presentations associated with COVID-19 have become increasingly apparent, including a patient with encephalitis in China in whom SARS-CoV-2 was identified in cerebrospinal fluid (CSF),[4] a patient with acute necrotising encephalopathy in Japan,[5] and cases of cerebrovascular disease.[1,6]

During other pandemics of respiratory pathogens, including severe acute respiratory syndrome, Middle East respiratory syndrome, and H1N1 influenza, there were similar reports of patients with neurological complications,[7,8] either during the acute phase, thought to reflect direct viral cytopathy or a para-infectious cytokine storm, or later as a post-infectious, probably cellular immune or antibody-mediated phenomenon, classically manifested as Guillain-Barré syndrome.[9] Additionally, occasional neuropsychiatric and psychiatric presentations have been reported in severe coronavirus infections,[10] although such presentations could reflect broader socioeconomic implications of the pandemic on mental health. These complications are relatively uncommon, but such patients are often the most severely affected, necessitating protracted intensive care admission and often resulting in poor outcomes.[7]

Most published reports on the neurological complications of COVID-19 are limited to individual cases or small case series.[1,4,5] A few studies showed the benefits of identifying patients with neurological complications across centres.[1,11] However, these studies have largely been limited to two or three hospitals and are restricted by both geography and specialty, therefore not assessing the neurological and neuropsychiatric complications of COVID-19 across the clinical spectrum of neurology, stroke or acute medicine, psychiatry, and intensive care.

Consequently, many important questions remain for neurologists and psychiatrists. How common are neurological and psychiatric complications in patients with COVID-19? What proportion of neurological and psychiatric complications affect the CNS versus the peripheral nervous system, and are novel syndromes emerging? And who is most at risk?

The breadth of early clinical presentations has not been represented in the literature, at least in part because

patients could be primarily managed by physicians with various clinical specialties, including neurologists, stroke or acute medical physicians, psychiatrists, or intensive care physicians. More comprehensive and integrated epidemiological characterisation is crucial to understanding the mechanisms that underlie these presentations, without which it will be impossible to rationally select, evaluate, and use appropriate therapies.

We aimed to collate data through a large-scale, national, dynamic, cross-specialty collaborative structure, to both inform best practice management guidelines and to direct research priorities.

Methods

Case notification

During the exponential phase of the pandemic, we developed an online network of secure rapid-response case report notification portals (CoroNerve platforms) comprising the Association of British Neurologists (ABN) Rare Diseases Ascertainment and Recruitment (RaDAR),[12] the British Association of Stroke Physicians (BASP),[13] and the Royal College of Psychiatrists (RCPsych),[14] in collaboration with the British Paediatric Neurology Association (BPNA),[15] the Neuro Anaesthesia and Critical Care Society (who used the ABN portal), the Intensive Care Society, and key stakeholders. Reporting portals for fully anonymised details were hosted on the web platforms of these collaborating professional bodies and via a novel web portal. Members of these professional organisations were emailed weekly to remind them of the surveillance programmes and were invited to notify the central CoroNerve Group at CoroNerve.com of any cases of COVID-19 associated with any of the clinical case definitions that they had seen through these portals.

Because of the clinical demands of the pandemic, we identified minimum clinical datasets that could be completed in under 5 min to reflect the crucial data required to determine the confidence in the diagnosis of COVID-19, demography, geography, and the nature of the clinical syndrome. Physicians were encouraged to report cases prospectively and we also permitted recent cases to be notified retrospectively when assigned a confirmed date of admission or initial clinical assessment, allowing identification of cases that occurred before notification portals were available. Patients were not randomly assigned. Awareness of the study and notification portals was increased through social platforms during the peak of the pandemic, including professional webinars, recorded online presentations, and social media. The ABN portal was launched on April 2, 2020, the BASP portal on April 3, 2020, and the RCPsych portal on April 21, 2020. Data lock for this report was on April 26, 2020. Given the propensity for hospitalisation with COVID-19 for older demographic groups, older patients were defined as those aged 60 years or older and younger patients as those less than 60 years old.

For a full list of participating hospitals and the number of cases they notified see the appendix (pp 2–3).

Evidence of COVID-19

Evidence of SARS-CoV-2 infection was defined as confirmed COVID-19 if PCR of respiratory samples (eg, nasal or throat swab) or CSF was positive for viral RNA or if serology was positive for anti-SARS-CoV-2 IgM or IgG. Cases were defined as probable COVID-19 if a chest radiograph or chest CT was consistent with COVID-19 but PCR and serology were negative or not done. Cases were defined as possible COVID-19 if the disease was suspected on clinical grounds by the notifying clinician but PCR, serology, and chest imaging were negative or not done.

Clinical case definitions

Broad clinical syndromes associated with COVID-19 were classified as a cerebrovascular event (defined as an acute ischaemic, haemorrhagic, or thrombotic vascular event involving the brain parenchyma or subarachnoid space), altered mental status (defined as an acute alteration in personality, behaviour, cognition, or consciousness),[16] peripheral neurology (defined as involving nerve roots, peripheral nerves, neuromuscular junction, or muscle), or other (with free text boxes for those not meeting these syndromic presentations). Data were collected on the specific clinical case definitions within these broad presentations, as follows: a cerebrovascular event (ischaemic stroke, intracerebral or subarachnoid haemorrhage, cerebral venous sinus thrombosis, or cerebral vasculitis); altered mental status (encephalopathy, encephalitis—defined as encephalopathy with evidence of inflammation in the CNS [CSF white cell count >5 cells per µL, protein >0·45 g/dL, or MRI consistent with inflammation], seizures [clinical or electroencephalographic evidence], and neuropsychiatric syndromes notified through psychiatrists or neuropsychiatrists [psychosis, neurocognitive

For more on the **central CoroNerve Group** see www.coronerve.com

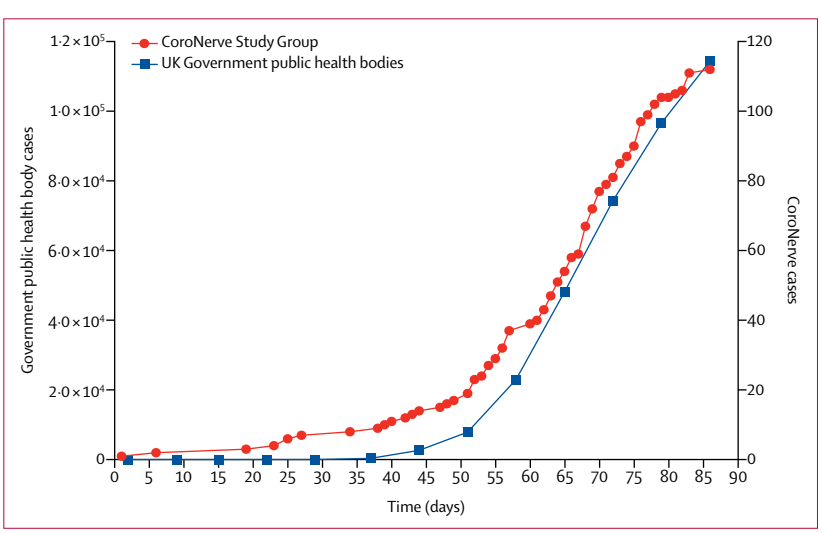

Figure 1: **Temporal distribution of the date of admission or first assessment for cases notified to the CoroNerve Study Group and those identified by UK Government public health bodies**

	All cases (n=153)	Cerebrovascular (n=77)	Altered mental status (n=39)	Peripheral (n=6)	Other (n=3)
Sex at birth					
Male	73 (48%)	44 (57%)	23 (59%)	5 (83%)	1 (33%)
Female	44 (29%)	30 (39%)	14 (36%)	0	0
Not reported	36 (24%)	3 (4%)	2 (5%)	1 (17%)	2 (67%)
Age, years					
≤20	0	0	0	0	0
21–30	4 (3%)	1 (1%)	3 (8%)	0	0
31–40	4 (3%)	1 (1%)	3 (8%)	0	0
41–50	10 (7%)	5 (6%)	4 (10%)	1 (17%)	0
51–60	17 (11%)	6 (8%)	8 (21%)	2 (33%)	1 (33%)
61–70	23 (15%)	16 (21%)	5 (13%)	2 (33%)	0
71–80	31 (20%)	23 (30%)	8 (21%)	0	0
81–90	23 (15%)	18 (23%)	5 (13%)	0	0
≥91	5 (3%)	4 (5%)	1 (3%)	0	0
Missing	36 (24%)	3 (4%)	2 (5%)	1 (17%)	2 (67%)
Median (range; IQR)	71 (23–94; 58–79)	73·5 (25–94; 64–83)	71 (23–91; 48–75)	59 (44–63; 50–62)	54 (54–54)

Data are n (%), unless otherwise indicated.

Table: **Sex and age data for notified patients**

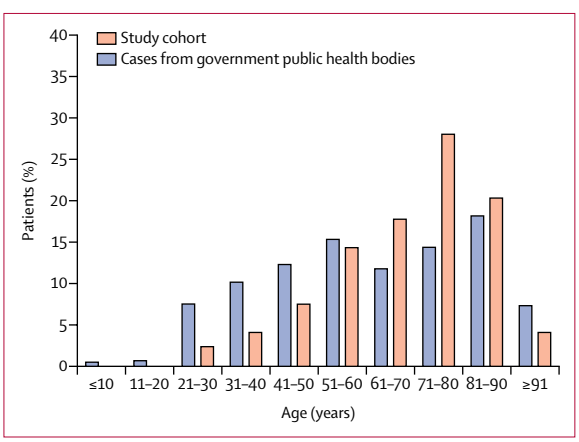

Figure 2: **Age distribution of all cases notified to the CoroNerve Study Group and national data collected by UK Government public health bodies within the first 3 weeks of CoroNerve accepting notifications**

dementia-like syndrome, personality change, catatonia, mania, anxiety or depression, chronic fatigue syndrome, and post-traumatic stress disorder]); and peripheral neurology (Guillain-Barré syndrome, Miller Fisher syndrome, brachial neuritis, myasthenia gravis, peripheral neuropathy, myopathy, myositis—defined as myopathy with evidence of inflammation [eg, by MRI or biopsy of muscle with elevated creatine kinase], and critical illness neuromyopathy).

When patients met more than one specific clinical case definition (eg, seizures and encephalitis), the underlying causal diagnosis was considered primary and complications of that diagnosis considered secondary features (eg, encephalitis would be considered primary and seizures secondary). Where there were discrepancies in classification, these were resolved through discussion with senior authors (BDM, IG, and RHT).

Additional data collection

By asking reporting physicians to submit their contact details at the time of notification (including a National Health Service email address), we established confirmation of the veracity of the data and created a log for subsequent sample collection and longitudinal follow-up studies, through linkage with existing platforms including co-recruitment into the International Severe Acute Respiratory and Emerging Infection Consortium (ISARIC) Clinical Characterisation Protocol, which was also recorded.[17] Data collected were compared with the geographical, demographic, and temporal presentation of overall cases of COVID-19 as reported by national government public health bodies representing each of the regions of the UK (Public Health England, Health Protection Scotland, Public Health Wales, and the Public Health Agency [Northern Ireland]).

The UK Health Research Authority formally confirmed this approach was compliant with regulations regarding anonymised surveillance of routine clinical practice in pandemic conditions, as initiated by the local attending clinician.

Role of the funding source

There was no funding source for this study. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Results

In the first 3 weeks of the submission portals accepting notifications (April 2–26, 2020), the CoroNerve study platforms received notification of 153 unique cases that met the clinical case definitions by clinicians in the UK. Patients were geographically dispersed across the UK, as were overall laboratory-confirmed cases of patients with COVID-19 reported by government public health bodies during the same time period (appendix p 1). Data from the admitting medical units were available for 152 (99%) of 153 patients. 26 (17%) of 152 patients were from tertiary care hospitals, 125 (82%) were from secondary care hospitals, and one (1%) was from primary care. Overall, 75 (49%) of 153 cases were notified through the BASP portal, 53 (35%) through ABN or CoroNerve.com, and 25 (16%) through the RCPsych portal. Cases were reported retrospectively for 24 (16%) of 153 patients and the remainder were reported prospectively. The BPNA surveillance network was not available for notifications, as the portal was not live during the study period. Data on reporting physician specialty were available for 150 patients: 61 (41%) were stroke physicians, 39 (26%) were neurologists, 26 (17%) were psychiatrists or neuropsychiatrists, 23 (15%) were acute medicine or other physicians, and one (1%) was a general practitioner.

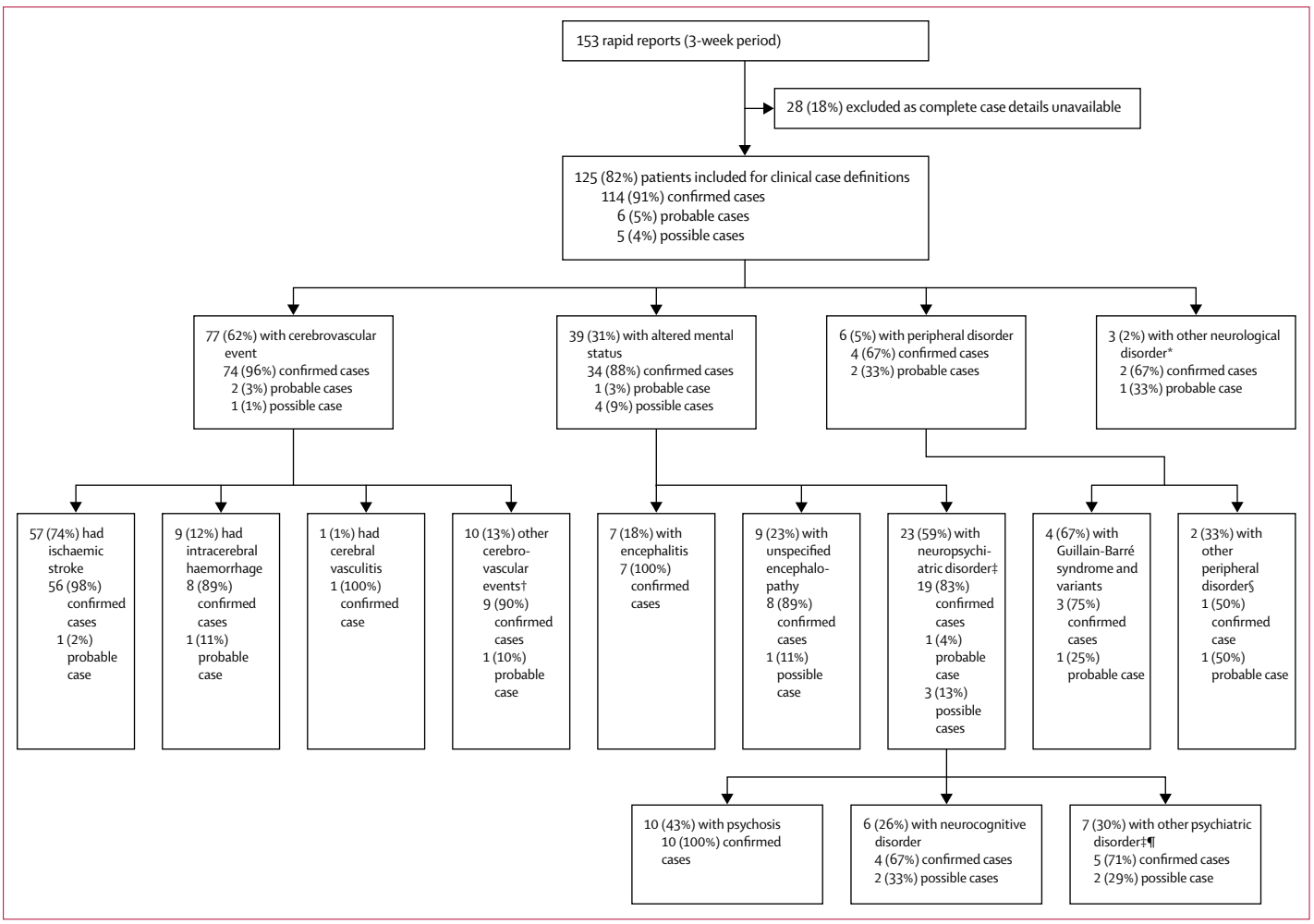

Figure 3: **Number of broad and specific clinical case definitions notified in the dataset, including evidence for severe acute respiratory syndrome coronavirus 2 within each grouping, according to the clinical case definition**

*One patient with opsoclonus-myoclonus syndrome, one patient with sixth nerve palsy, and one patient with seizures. †Two patients with cerebral venous thrombosis, two patients with transient ischaemic attack, one patient with subarachnoid haemorrhage, and five unspecified. ‡1 case with missing SARS-CoV2 data. §One patient with brachial neuritis and one patient with myasthenic crisis. ¶Three patients with depression, two patients with personality change, one patient with catatonia, and one patient with mania.

Complete clinical datasets were available for 125 (82%) of 153 patients. Dates of admission or initial clinical assessment were available for 112 (90%) of 125 patients and correlated with the national case identification data of all laboratory-confirmed patients with COVID-19 reported by government public health bodies over the same time period, reflecting the exponential phase of infection (figure 1).

Data on the sex and age of notified patients are reported in the table. Overall, the median age of 71 years (range 23–94; IQR 58–79) was similar to national data collected through UK Government public health bodies over the same time period, although for some centiles an older population could be overrepresented within the study cohort (figure 2). Data were available for sex for 117 (76%) of 153 patients as this question was not included in the original ABN RaDAR web portal, representing 28 (19%) cases, and this question was not answered in the other portals in eight (5%) cases. Therefore, data regarding sex were available for 117 (94%) of 125 patients for whom these data were requested.

114 (92%) of 125 patients with complete notification data met the criteria for confirmed SARS-CoV-2 infection, five (4%) met the criteria for probable SARS-CoV-2 infection, and five (4%) met the criteria for possible SARS-CoV-2 infection. 77 (62%) of 125 patients presented with the broad clinical syndrome of a cerebrovascular event, of whom 57 (74%) had an ischaemic stroke and nine (12%) an intracerebral haemorrhage. A clinical diagnosis of CNS vasculitis was reported in one (1%) patient with an unusual and otherwise unexplained infarct of the corpus callosum and imaging appearances suggestive of vasculitis; however, the full angiographic report and pathological confirmation were not provided (figure 3). Beyond cerebrovascular events, 39 (31%) of 125 patients presented with altered mental status,

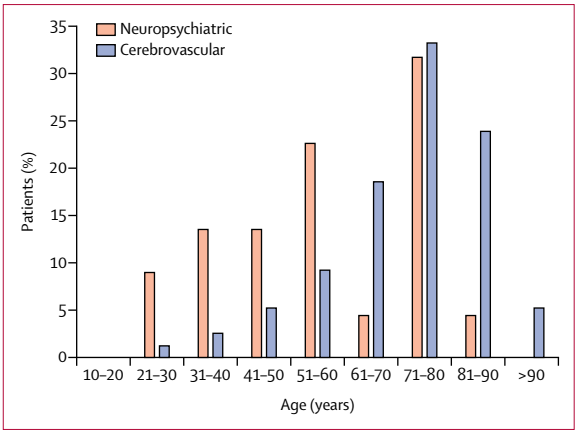

Figure 4: **Age distribution of patients identified through the CoroNerve surveillance study meeting the clinical case definitions for cerebrovascular and neuropsychiatric events**

comprising nine (23%) patients with unspecified encephalopathy and seven (18%) patients with both clinical symptoms or signs of encephalopathy and evidence of CNS inflammation meeting the clinical case definition for encephalitis. All seven patients with encephalitis met the criteria for confirmed SARS-CoV-2 infection. The remaining 23 (59%) patients with altered mental status fulfilled the clinical case definitions for psychiatric diagnoses as classified by the notifying psychiatrist or neuropsychiatrist. Only two (9%) of 23 patients had exacerbations of existing enduring mental illness. Ten (43%) of 23 patients with neuropsychiatric disorders had new-onset psychosis, six (26%) had a neurocognitive (dementia-like) syndrome, and seven (30%) had an other psychiatric disorder, including one case of catatonia and one case of mania.

Age data were available for 74 (96%) of 77 patients with cerebrovascular events and 37 (95%) of 39 patients with altered mental status. 18 (49%) of 37 patients with altered mental status were younger than 60 years and 19 (51%) were older than 60 years, whereas 13 (18%) of 74 patients with cerebrovascular events were younger than 60 years versus 61 (82%) patients older than 60 years (figure 4).

Discussion

To our knowledge, this is the first systematic, nationwide UK surveillance study of the breadth of acute complications of COVID-19 in the nervous system, undertaken through rapid mobilisation of UK professional bodies representing neurology, stroke or acute medicine, psychiatry, and intensive care. Cases notified by the professional membership of these bodies were obtained from across the UK, and an exponential rise in cases of neurological and psychiatric complications of COVID-19 occurred during the exponential rise in overall COVID-19 cases reported by UK Government public health bodies.

Future studies on neurological complications of COVID-19, particularly those assessing genetic and associated risk factors, would benefit from obtaining notification of all cases of infection admitted to every hospital as a denominator, or a cohort of COVID-19 patients without neurological or psychiatric complications as a control group. However, given the time pressure on busy clinical teams during the pandemic, we focused our notification structure on patients with neurological or psychiatric complications of infection. Cases were reported from physicians who spanned various specialties, and almost all cases met the case definition of confirmed SARS-CoV-2 infection.

Cerebrovascular events in patients with COVID-19, which have been well described elsewhere,[1,9] were also identified as a major group within our cohort. However, we identified a large proportion of cases of acute alteration in mental status, comprising neurological syndromic diagnoses such as encephalopathy and encephalitis and primary psychiatric syndromic diagnoses, such as psychosis. Although cerebrovascular events and altered mental status were identified across all age groups, our cohort confirms that cerebrovascular events predominate in older patients; however, these early data identify that acute alterations in mental status were disproportionately overrepresented in younger patients in our cohort. Our rates of neurological and psychiatric complications of COVID-19 cannot be extrapolated to mildly affected patients or patients with asymptomatic infection, especially those in the community, but give a broad national perspective on complications severe enough to require hospitalisation.

Our approach to case ascertainment has the potential for reporting bias and requires validation through detailed prospective clinicoepidemiological data collection. Plans for such studies should be developed in advance of future pandemics, so that they can be mobilised early during disease spread. A more engaged professional membership or those more used to submitting data to surveillance studies through this approach could potentially be overrepresented in our results. However, this study was the first major national investigation to use a data surveillance approach for clinicians, who notified a large proportion of our cohort (ie, BASP and RCPsych). Additionally, the present study included a priori considerations to determine the strength of the evidence for SARS-CoV-2 infection, and data collection was informed by clear clinical case definitions. Moreover, in this cohort, we conclude that this study is unlikely to have had systematic over ascertainment bias for psychiatric or neuropsychiatric presentations. 41% of cases were reported by stroke physicians, and the RCPsych web portal was launched 18 days later than the other neurological, stroke, and intensive care unit or more general portals, yet we observed a large number of psychiatric or neuropsychiatric notifications. Indeed, as many patients with COVID-19 are managed in intensive care units with sedative and paralytic medications, which can both mask and contribute to iatrogenic complications, our cohort might underrepresent the rate of neurological or

psychiatric symptoms.[18] Since we specifically identified moderate to severe complications of COVID-19 as they were reported for inpatient cases by neurologists and psychiatrists, our cohort might underrepresent patients with milder outpatient symptoms, such as reduced taste or smell. Future hypothesis testing studies building on our findings to infer causal relationships between infection and neurological or neuropsychiatric presentations should adhere to basic principles, such as the criteria for causation outlined by Bradford Hill as they pertain to pandemic respiratory infection and effects on the brain.[19]

Many cerebrovascular events were identified in our study, as reported in previous cohorts and case reports of acute COVID-19 complications.[1,20,21] The pathophysiological mechanisms that underlie cerebrovascular events in COVID-19 require further study, but there is a potential biological rationale for a vasculopathy, with a report of SARS-CoV-2 endothelitis in organs outside the cerebral vasculature[22] and cerebrovascular events,[23] in addition to coagulopathy, along with conventional stroke risk during sepsis.[9,24,25] Comprehensive studies with clear control groups, including patients hospitalised with COVID-19 but without cerebrovascular events and patients with cerebrovascular events but who do not have COVID-19, are required to address this issue.

Confirmation of the link between COVID-19 and new acute psychiatric or neuropsychiatric complications in younger patients will require detailed prospective longitudinal studies. Understanding this association will require systematic participant evaluation, characterisation of immune host responses, exploration of genetic associations, and comparison with appropriate controls (including patients hospitalised with COVID-19 who do not have acute neuropsychiatric features).

Altered mental status is common in patients admitted to hospital with severe infection, especially in those requiring intensive care management. However, this symptom typically predominates in older groups, and might reflect an unmasking of latent neurocognitive degenerative disease or multiple medical comorbidities, often in association with sepsis, hypoxia, and the requirement for polypharmacy and sedative medications. In this study, we observed a disproportionate number of neuropsychiatric presentations in younger patients and a predominance of cerebrovascular complications in older patients, which might reflect the state of health of the cerebral vasculature and associated risk factors, exacerbated by critical illness in older patients.[25] The large number of patients with altered mental status might reflect increased access to neuropsychiatry or psychiatry review for younger patients, and increased attribution of altered mental status to delirium in older patients. Nevertheless, the increased recognition of acute altered mental status in patients hospitalised with COVID-19 warrants study. The exclusion of iatrogenic factors, such as sedatives and antipsychotics, should be quantified in future modelling studies. In our study, although most psychiatric diagnoses were determined as new by the notifying psychiatrist or neuropsychiatrist, we cannot exclude the possibility that these were undiagnosed before the patient developed COVID-19.

Our study population represents a snapshot of hospitalised patients with acute neurological or psychiatric complications associated with COVID-19. Larger, ideally prospective, studies should identify the broader cohort of COVID-19 patients both in and outside hospitals, with capture–recapture analysis and health record linkage to determine clearer estimates of the prevalence of these complications and individuals at risk. Additionally, community studies are required to identify those at risk of both COVID-19 and neurological or psychiatric complications, although this strategy will require widespread serological testing.

The importance of data sharing is increasingly recognised as fundamental to facilitate rapidly responsive clinical research and is particularly crucial during an international emergency, such as the SARS-CoV-2 pandemic. The CoroNerve Study Group has been made possible by open collaboration between several UK institutions. We anticipate added value of sharing data more widely, across European and global partners, particularly in low-income and middle-income countries. The Brain Infections Global COVID-Neuro Network is supporting data collection in such countries through freely available case record forms.[26] Wide collaboration is likely to be even more important for characterising rarer or novel COVID-19-associated neurological syndromes. These enriched populations that reflect less common, but nevertheless severe, disease must be studied in close collaboration with larger surveillance efforts, such as the ISARIC Clinical Characterisation Protocol, to identify at-risk groups, determine the strength of relative risk factors, and have adequate controls for mechanistic studies.

Our nationwide, clinician-reported cohort approach provides valuable and timely information that is urgently needed by clinicians, researchers, and funders to inform the immediate next steps in COVID-19 neuroscience-related research and health policy planning. These national data begin to characterise the spectrum of neurological and neuropsychiatric complications that need to be addressed. This multidisciplinary, coordinated approach should be emulated in detailed national mechanistic studies of COVID-19 and the brain, to distinguish the role of the virus and the host inflammatory response versus the broader socioeconomic effects of the pandemic.[27]

Contributors
AV and BDM drafted the initial manuscript and the document was edited and approved by all coauthors.

Declaration of interests
AV is a Medical Research Council (MRC) PhD fellow. MAE is an Association of British Neurologists PhD fellow. MZ reports personal fees from UCB Pharma outside the submitted work. JPC received funding from the National Institute for Health Research (NIHR) Cambridge

BioMedical Research Centre during the conduct of the study. LAB reports funding from GlaxoSmithKline and Research England, outside the submitted work. AC reports personal fees from independent testimony in court on a range of neuropsychiatric topics and as a paid editor of the Journal of Neurology, Neurosurgery and Psychiatry, outside the submitted work. Additionally, AC is planning a rehabilitation trial after COVID-19, which could produce an application that might be associated with intellectual property. CS has received funding from the MRC, NIHR, The Leducq Foundation, and The Stroke Association. MRT reports grants from Motor Neurone Disease Association and My Name'5 Doddie Foundation, and personal fees from Oxford University Press, Oneworld, Karger Publishing, Orphazyme, BMJ Publishing, and GLG Consulting, outside the submitted work. TS reports consultancy for GlaxoSmithKline Ebola Vaccine programme, Siemens Diagnostics Clinical Advisory Board, Siemens Healthineers Clinical Advisory Board, and the Data Safety Monitoring Committee of the GlaxoSmithKline Study to Evaluate the Safety and Immunogenicity of a Candidate Ebola Vaccine in Children GSK3390107A (ChAd3 EBO-Z) vaccine, during the conduct of the study. Additionally, TS has a patent filed for a blood test for bacterial meningitis (GB 1606537.7; April 14, 2016). TS is supported by the European Union's Horizon 2020 research and innovation program ZikaPLAN (Preparedness Latin America Network; 734584). SLP has received funding from the MRC. IG has received funding from the NIHR. RHT reports personal fees from Eisai, GW Pharma, Sanofi, UCB Pharma, Zogenix, Bial, and Arvelle, outside the submitted work. RHT has received funding from the Academy of Medical Sciences (AMS) and Wellcome. BDM has received funding from the MRC, AMS, Wellcome, and the NIHR. BDM and TS are supported by the NIHR Health Protection Research Unit in Emerging and Zoonotic Infections (IS-HPU-1112-10117) and the NIHR Global Health Research Group on Brain Infections (17/63/110). All other authors declare no competing interests.

Data sharing

The authors are committed to open science. The broader data from these studies will be made available at the end of the studies wherever possible, within the terms of participant consent and when not otherwise restricted by intellectual property rights or ongoing collaborative research. To avoid the possibility of identifying individual cases, detailed data are not given in the paper or appendix but are available on appropriate request to the corresponding author.

Acknowledgments

All authors are indebted to the following professional bodies and their membership who contributed cases and form the CoroNerve Study Group: the Association of British Neurologists (Rare Diseases Ascertainment and Recruitment team: Fardousa Musa and Joanne Lawrence), the British Association of Stroke Physicians, the Royal College of Psychiatrists (especially Eileen Joyce and Wendy Burn), the British Paediatric Neurology Association, the Neuro Anaesthesia and Critical Care Society, the Intensive Care Society, and the Faculty of Intensive Care Medicine. BDM, RHT, IG, SLP, RK, AV, MAE, and NT form the CoroNerve study management group.

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EXHIBIT 35

Centers for Disease Control and Prevention

Coronavirus Disease 2019 (COVID-19)

Preparing for COVID-19 in Nursing Homes

Updated June 25, 2020

Print Page

Summary of Changes to the Guidance:

- Tiered recommendations to address nursing homes in different phases of COVID-19 response
- Added a recommendation to assign an individual to manage the facility's infection control program
- Added guidance about new requirements for nursing homes to report to the National Healthcare Safety Network (NHSN)
- Added a recommendation to create a plan for testing residents and healthcare personnel for SARS-CoV-2

Background

Given their congregate nature and resident population served (e.g., older adults often with underlying chronic medical conditions), nursing home populations are at high risk of being affected by respiratory pathogens like COVID-19 and other pathogens, including multidrug-resistant organisms (e.g., Carbapenemase-producing organisms, *Candida auris*). As demonstrated by the COVID-19 pandemic, a strong infection prevention and control (IPC) program is critical to protect both residents and healthcare personnel (HCP).

Facilities should assign at least one individual with training in IPC to provide on-site management of their COVID-19 prevention and response activities because of the breadth of activities for which an IPC program is responsible, including developing IPC policies and procedures, performing infection surveillance, providing competency-based training of HCP, and auditing adherence to recommended IPC practices.

The Centers for Medicare and Medicaid Services (CMS) recently issued Nursing Home Reopening Guidance for State and Local Officials that outlines criteria that could be used to determine when nursing homes could relax restrictions on visitation and group activities and when such restrictions should be reimplemented. Nursing homes should consider the current situation in their facility and community and refer to that guidance as well as direction from state and local officials when making decisions about relaxing restrictions. When relaxing any restrictions, nursing homes must **remain vigilant for COVID-19 among residents and HCP in order to prevent spread and protect residents and HCP** from severe infections, hospitalizations, and death.

This guidance has been updated and reorganized according to **core IPC practices** that should remain in place even as nursing homes resume normal practices, plus **additional strategies** depending on the stages described in the CMS Reopening Guidance or at the direction of state and local officials. This guidance is based on currently available information about COVID-19 and will be refined and updated as more information becomes available.

These recommendations supplement the CDC's Interim Infection Prevention and Control Recommendations for Patients with Suspected or Confirmed Coronavirus Disease 2019 (COVID-19) in Healthcare Settings and are specific for nursing homes, including skilled nursing facilities.

Additional Key Resources:

- Considerations for the Public Health Response to COVID-19 in Nursing Homes
- Interim Testing in Response to Suspected or Confirmed COVID-19 in Nursing Home Residents and Healthcare Personnel

- Considerations for Performing Facility-wide SARS-CoV-2 Testing in Nursing Homes
- Considerations for Memory Care Units in Long-Term Care Facilities
- Infection Prevention and Control Assessment Tool for Nursing Homes Preparing for COVID-19

Core Practices

These practices should remain in place even as nursing homes resume normal activities.

Assign One or More Individuals with Training in Infection Control to Provide On-Site Management of the IPC Program.

- This should be a full-time role for at least one person in facilities that have more than 100 residents or that provide on-site ventilator or hemodialysis services. Smaller facilities should consider staffing the IPC program based on the resident population and facility service needs identified in the facility risk assessment.
- CDC has created an online training course that can be used to orient individuals to this role in nursing homes.

Report COVID-19 cases, facility staffing, and supply information to the National Healthcare Safety Network (NHSN) Long-term Care Facility (LTCF) COVID-19 Module weekly.

- CDC's NHSN provides long-term care facilities with a customized system to track infections and prevention process measures in a systematic way. Nursing homes can report into the four pathways of the LTCF COVID-19 Module including:
  - Resident impact and facility capacity
  - Staff and personnel impact
  - Supplies and personal protective equipment
  - Ventilator capacity and supplies
- Weekly data submission to NHSN will meet the CMS COVID-19 reporting requirements.

Educate Residents, Healthcare Personnel, and Visitors about COVID-19, Current Precautions Being Taken in the Facility, and Actions They Should Take to Protect Themselves.

- Provide information about COVID-19 (including information about signs and symptoms) and strategies for managing stress and anxiety.
- Regularly review CDC's Infection Control Guidance for Healthcare Professionals about COVID-19 for current information and ensure staff and residents are updated when this guidance changes.
- Educate and train HCP, including facility-based and consultant personnel (e.g., wound care, podiatry, barber) and volunteers who provide care or services in the facility. Including consultants is important, since they commonly provide care in multiple facilities where they can be exposed to and serve as a source of COVID-19.
  - Reinforce sick leave policies, and **remind HCP not to report to work when ill.**
  - Reinforce adherence to standard IPC measures including hand hygiene and selection and correct use of personal protective equipment (PPE). Have HCP demonstrate competency with putting on and removing PPE and monitor adherence by observing their resident care activities.
    - CDC has created training modules for front-line staff that can be used to reinforce recommended practices for preventing transmission of SARS-CoV-2 and other pathogens.
  - Educate HCP about any new policies or procedures.
- Educate residents and families on topics including information about COVID-19, actions the facility is taking to protect them and/or their loved ones, any visitor restrictions that are in place, and actions residents and families should take to protect themselves in the facility, emphasizing the importance of hand hygiene and source control.
- Have a plan and mechanism to regularly communicate with residents, families and HCP, including if cases of COVID-19 are identified among residents or HCP.

Implement Source Control Measures.

- HCP should wear a facemask at all times while they are in the facility.
  - When available, facemasks are generally preferred over cloth face coverings for HCP as facemasks offer both source control and protection for the wearer against exposure to splashes and sprays of infectious material from

others. Guidance on extended use and reuse of facemasks is available. **Cloth face coverings should NOT be worn by HCP instead of a respirator or facemask if PPE is required.**

- Residents should wear a cloth face covering or facemask (if tolerated) whenever they leave their room, including for procedures outside the facility. Cloth face coverings should not be placed on anyone who has trouble breathing, or anyone who is unconscious, incapacitated, or otherwise unable to remove the mask without assistance. In addition to the categories described above cloth face coverings should not be placed on children under 2.
- Visitors, if permitted into the facility, should wear a cloth face covering while in the facility.

Have a Plan for Visitor Restrictions.

- Send letters or emails to families reminding them not to visit when ill or if they have a known exposure to someone with COVID-19.
- Facilitate and encourage alternative methods for visitation (e.g., video conferencing) and communication with the resident

- Post signs at the entrances to the facility advising visitors to check-in with the front desk to be assessed for symptoms prior to entry.
  - Screen visitors for fever (T≥100.0ºF), symptoms consistent with COVID-19, or known exposure to someone with COVID-19. Restrict anyone with fever, symptoms, or known exposure from entering the facility.
- Ask visitors to inform the facility if they develop fever or symptoms consistent with COVID-19 within 14 days of visiting the facility.
- Have a plan for when the facility will implement additional restrictions, ranging from limiting the number of visitors and allowing visitation only during select hours or in select locations to restricting all visitors, except for compassionate care reasons (see below).

Create a Plan for Testing Residents and Healthcare Personnel for SARS-CoV-2.

- Testing for SARS-CoV-2, the virus that causes COVID-19, in respiratory specimens can detect current infections (referred to here as viral testing or test) among residents and HCP in nursing homes.
- The plan should align with state and federal requirements for testing residents and HCP for SARS-CoV-2 and address:
  - Triggers for performing testing (e.g., a resident or HCP with symptoms consistent with COVID-19, response to a resident or HCP with COVID-19 in the facility, routine surveillance)
  - Access to tests capable of detecting the virus (e.g., polymerase chain reaction) and an arrangement with laboratories to process tests
    - Antibody test results should not be used to diagnose someone with an active SARS-CoV-2 infection and should not be used to inform IPC action.
  - Process for and capacity to perform SARS-CoV-2 testing of all residents and HCP
  - A procedure for addressing residents or HCP who decline or are unable to be tested (e.g., maintaining Transmission-Based Precautions until symptom-based criteria are met for a symptomatic resident who refuses testing)
- Additional information about testing of residents and HCP is available:
  - CDC Strategy for COVID-19 Testing Nursing Homes.
  - Considerations for Performing Facility-wide SARS-CoV-2 Testing in Nursing Homes

Evaluate and Manage Healthcare Personnel.

- Implement sick leave policies that are non-punitive, flexible, and consistent with public health policies that support HCP to stay home when ill.
- Create an inventory of all volunteers and personnel who provide care in the facility. Use that inventory to determine which personnel are non-essential and whose services can be delayed if such restrictions are necessary to prevent or control transmission.
- As part of routine practice, ask HCP (including consultant personnel and ancillary staff such as environmental and dietary services) to regularly monitor themselves for fever and symptoms consistent with COVID-19.
  - Remind HCP to stay home when they are ill.

- If HCP develop fever (T≥100.0°F) or symptoms consistent with COVID-19 while at work they should inform their supervisor and leave the workplace. Have a plan for how to respond to HCP with COVID-19 who worked while ill (e.g., identifying and performing a risk assessment for exposed residents and co-workers).
- HCP with suspected COVID-19 should be prioritized for testing.

- Screen all HCP at the beginning of their shift for fever and symptoms of COVID-19.
  - **Actively take their temperature*** and document absence of symptoms consistent with COVID-19. If they are ill, have them keep their cloth face covering or facemask on and leave the workplace.
  - *Fever is either measured temperature >100.0°F or subjective fever. Note that fever may be intermittent or may not be present in some individuals, such as those who are elderly, immunosuppressed, or taking certain medications (e.g., NSAIDs). Clinical judgement should be used to guide testing of individuals in such situations.
  - HCP who work in multiple locations may pose higher risk and should be encouraged to tell facilities if they have had exposure to other facilities with recognized COVID-19 cases.
- Develop (or review existing) plans to mitigate staffing shortages from illness or absenteeism.
  - CDC has created guidance to assist facilities with mitigating staffing shortages.
  - For guidance on when HCP with suspected or confirmed COVID-19 may return to work, refer to Criteria for Return to Work for Healthcare Personnel with Confirmed or Suspected COVID-19 (Interim Guidance)

Provide Supplies Necessary to Adhere to Recommended Infection Prevention and Control Practices.

- Hand Hygiene Supplies:
  - Put alcohol-based hand sanitizer with 60-95% alcohol in every resident room (ideally both inside and outside of the room) and other resident care and common areas (e.g., outside dining hall, in therapy gym). Unless hands are visibly soiled, an alcohol-based hand sanitizer is preferred over soap and water in most clinical situations.
  - Make sure that sinks are well-stocked with soap and paper towels for handwashing.
- Respiratory Hygiene and Cough Etiquette:
  - Make tissues and trash cans available in common areas and resident rooms for respiratory hygiene and cough etiquette and source control.
- Personal Protective Equipment (PPE):
  - Perform and maintain an inventory of PPE in the facility.
    - Identify health department or healthcare coalition contacts for getting assistance during PPE shortages. The Supplies and Personal Protective Equipment pathway in the NHSN LTCF COVID-19 Module can be used to indicate critical PPE shortages (i.e., less than one week supply remaining despite use of PPE conservation strategies).
    - Monitor daily PPE use to identify when supplies will run low; use the PPE burn rate calculator or other tools.
  - Make necessary PPE available in areas where resident care is provided.
    - Consider designating staff responsible for stewarding those supplies and monitoring and providing just-in-time feedback promoting appropriate use by staff.
    - Facilities should have supplies of facemasks, respirators (if available and the facility has a respiratory protection program with trained, medically cleared, and fit-tested HCP), gowns, gloves, and eye protection (i.e., face shield or goggles).
  - Position a trash can near the exit inside the resident room to make it easy for staff to discard PPE prior to exiting the room or before providing care for another resident in the same room.
  - Implement strategies to optimize current PPE supply ***even before shortages occur***, including bundling resident care and treatment activities to minimize entries into resident rooms. Additional strategies might include:
    - Extended use of respirators, facemasks, and eye protection, which refers to the practice of wearing the same respirator or facemask and eye protection for the care of more than one resident (e.g., for an entire shift).
      - Care must be taken to **avoid touching the respirator, facemask, or eye protection**. If this must occur (e.g., to adjust or reposition PPE), HCP should perform hand hygiene immediately after touching PPE to prevent contaminating themselves or others.
    - Prioritizing gowns for activities where splashes and sprays are anticipated (including aerosol-generating procedures) and high-contact resident care activities that provide opportunities for transfer of pathogens to hands and clothing of HCP.
      - **If extended use of gowns is implemented as part of crisis strategies, the same gown should not be worn when caring for different residents unless it is for the care of residents with confirmed COVID-19 who are**

cohorted in the same area of the facility and these residents are not known to have any co-infections (e.g., *Clostridioides difficile*)

- Implement a process for decontamination and reuse of PPE such as face shields and goggles.
- Facilities should continue to assess PPE supply and current situation to determine when a return to standard practices can be considered.

- Implement a respiratory protection program that is compliant with the OSHA respiratory protection standard for employees if not already in place. The program should include medical evaluations, training, and fit testing.
- Environmental Cleaning and Disinfection:
  - Develop a schedule for regular cleaning and disinfection of shared equipment, frequently touched surfaces in resident rooms and common areas;
  - Ensure EPA-registered, hospital-grade disinfectants are available to allow for frequent cleaning of high-touch surfaces and shared resident care equipment.
    - Use an EPA-registered disinfectant from List N on the EPA website to disinfect surfaces that might be contaminated with SARS-CoV-2. Ensure HCP are appropriately trained on its use.

Identify Space in the Facility that Could be Dedicated to Monitor and Care for Residents with COVID-19.

- Identify space in the facility that could be dedicated to care for residents with confirmed COVID-19. This could be a dedicated floor, unit, or wing in the facility or a group of rooms at the end of the unit that will be used to cohort residents with COVID-19.
  - Identify HCP who will be assigned to work only on the COVID-19 care unit when it is in use.
- Have a plan for how residents in the facility who develop COVID-19 will be handled (e.g., transfer to single room, implement use of Transmission-Based Precautions, prioritize for testing, transfer to COVID-19 unit if positive).
  - Residents in the facility who develop symptoms consistent with COVID-19 could be moved to a single room pending results of SARS-CoV-2 testing. They should not be placed in a room with a new admission nor should they be moved to the COVID-19 care unit unless they are confirmed to have COVID-19 by testing. While awaiting results of testing, HCP should wear an N95 or higher-level respirator (or facemask if a respirator is not available), eye protection (i.e., goggles or a disposable face shield that covers the front and sides of the face), gloves, and gown when caring for these residents. **Cloth face coverings are not considered PPE and should only be worn by HCP for source control, not when PPE is indicated.**
- Have a plan for how roommates, other residents, and HCP who may have been exposed to an individual with COVID-19 will be handled (e.g., monitor closely, avoid placing unexposed residents into a shared space with them).
- Additional information about cohorting residents and establishing a designated COVID-19 care unit is available in the Considerations for the Public Health Response to COVID-19 in Nursing Homes

Create a Plan for Managing New Admissions and Readmissions Whose COVID-19 Status is Unknown.

- Depending on the prevalence of COVID-19 in the community, this might include placing the resident in a single-person room or in a separate observation area so the resident can be monitored for evidence of COVID-19. HCP should wear an N95 or higher-level respirator (or facemask if a respirator is not available), eye protection (i.e., goggles or a disposable face shield that covers the front and sides of the face), gloves, and gown when caring for these residents. Residents can be transferred out of the observation area to the main facility if they remain afebrile and without symptoms for 14 days after their admission. Testing at the end of this period can be considered to increase certainty that the resident is not infected.

Evaluate and Manage Residents with Symptoms of COVID-19.

- Ask residents to report if they feel feverish or have symptoms consistent with COVID-19.
- Actively monitor all residents upon admission and at least daily for fever (T≥100.0°F) and symptoms consistent with COVID-19. Ideally, include an assessment of oxygen saturation via pulse oximetry. If residents have fever or symptoms consistent with COVID-19, implement Transmission-Based Precautions as described below.
  - Older adults with COVID-19 may not show common symptoms such as fever or respiratory symptoms. Less common symptoms can include new or worsening malaise, headache, or new dizziness, nausea, vomiting, diarrhea, loss of taste or smell. Additionally, more than two temperatures >99.0°F might also be a sign of fever in this population. Identification of these symptoms should prompt isolation and further evaluation for COVID-19.

- The health department should be notified about residents or HCP with suspected or confirmed COVID-19, residents with severe respiratory infection resulting in hospitalization or death, or ≥ 3 residents or HCP with new-onset respiratory symptoms within 72 hours of each other.
    - Contact information for the healthcare-associated infections program in each state health department is available here: https://www.cdc.gov/hai/state-based/index.html
    - Refer to CDC resources for performing respiratory infection surveillance in long-term care facilities during an outbreak.
- Information about the clinical presentation and course of patients with COVID-19 is described in the Interim Clinical Guidance for Management of Patients with Confirmed Coronavirus Disease 2019 (COVID-19). CDC has also developed guidance on Evaluating and Reporting Persons Under Investigation (PUI).
- **If COVID-19 is suspected, based on evaluation of the resident or prevalence of COVID-19 in the community,** follow the Interim Infection Prevention and Control Recommendations for Patients with Suspected or Confirmed Coronavirus Disease 2019 (COVID-19) in Healthcare Settings. **This guidance should be implemented immediately once COVID-19 is suspected**
    - Residents with suspected COVID-19 should be prioritized for testing.
    - Residents with known or suspected COVID-19 do not need to be placed into an airborne infection isolation room (AIIR) but should ideally be placed in a private room with their own bathroom.
        - Residents with COVID-19 should, ideally, be cared for in a dedicated unit or section of the facility with dedicated HCP (see section on Dedicating Space).
        - As roommates of residents with COVID-19 might already be exposed, it is generally not recommended to place them with another roommate until 14 days after their exposure, assuming they have not developed symptoms or had a positive test.
    - Residents with known or suspected COVID-19 should be cared for using all recommended PPE, which includes use of an N95 or higher-level respirator (or facemask if a respirator is not available), eye protection (i.e., goggles or a disposable face shield that covers the front and sides of the face), gloves, and gown. **Cloth face coverings are not considered PPE and should not be worn when PPE is indicated.**
    - Increase monitoring of ill residents, including assessment of symptoms, vital signs, oxygen saturation via pulse oximetry, and respiratory exam, to at least 3 times daily to identify and quickly manage serious infection.
        - Consider increasing monitoring of asymptomatic residents from daily to every shift to more rapidly detect any with new symptoms.
    - If a resident requires a higher level of care or the facility cannot fully implement all recommended infection control precautions, the resident should be transferred to another facility that is capable of implementation**. Transport personnel and the receiving facility should be notified about the suspected diagnosis prior to transfer**.
        - While awaiting transfer, residents should be separated from others (e.g., in a private room with the door closed) and should wear a cloth face covering or facemask (if tolerated) when others are in the room and during transport.
        - All recommended PPE should be used by healthcare personnel when coming in contact with the resident.
    - Because of the higher risk of unrecognized infection among residents, universal use of all recommended PPE for the care of all residents on the affected unit (or facility-wide depending on the situation) is recommended when even a single case among residents or HCP is newly identified in the facility; this could also be considered when there is sustained transmission in the community. The health department can assist with decisions about testing of asymptomatic residents.
    - For decisions on removing residents who have had COVID-19 from Transmission-Based Precautions refer to the Interim Guidance for Discontinuation of Transmission-Based Precautions and Disposition of Hospitalized Patients with COVID-19

Additional Strategies Depending on the Facility's Reopening Status

These strategies will depend on the stages described in the CMS Reopening Guidance or the direction of state and local officials.

Implement Social Distancing Measures

- Implement aggressive social distancing measures (remaining at least 6 feet apart from others):
    - Cancel communal dining and group activities, such as internal and external activities.
    - Remind residents to practice social distancing, use a cloth face covering (if tolerated), and perform hand hygiene

- Remind residents to practice social distancing, wear a cloth face covering (if tolerated), and perform hand hygiene.
- Remind HCP to practice social distancing and wear a facemask (for source control) when in break rooms or common areas.

- Considerations when restrictions are being relaxed include:
  - Allowing communal dining and group activities for residents without COVID-19, including those who have fully recovered while maintaining social distancing, source control measures, and limiting the numbers of residents who participate.
  - Allowing for safe, socially distanced outdoor excursions for residents without COVID-19, including those who have fully recovered. Planning for such excursions should address:
    - Use of cloth face covering for residents and facemask by staff (for source control) while they are outside
    - Potential need for additional PPE by staff accompanying residents
    - Rotating schedule to ensure all residents will have an opportunity if desired, but that does not fully disrupt other resident care activities by staff
    - Defining times for outdoor activities so families could plan around the opportunity to see their loved ones

Implement Visitor Restrictions

- Restrict all visitation to their facilities except for certain compassionate care reasons, such as end-of-life situations.
  - Send letters or emails to families advising them that no visitors will be allowed in the facility except for certain compassionate care situations, such as end of life situations.
  - Use of alternative methods for visitation (e.g., video conferencing) should be facilitated by the facility.
  - Post signs at the entrances to the facility advising that no visitors may enter the facility.
  - Decisions about visitation for compassionate care situations should be made on a case-by-case basis, which should include careful screening of the visitor for fever or symptoms consistent with COVID-19. Those with symptoms should not be permitted to enter the facility. Any visitors that are permitted must wear a cloth face covering while in the building and restrict their visit to the resident's room or other location designated by the facility. They should also be reminded to frequently perform hand hygiene.

- Considerations for visitation when restrictions are being relaxed include:
  - Permit visitation only during select hours and limit the number of visitors per resident (e.g., no more than 2 visitors at one time).
  - Schedule visitation in advance to enable continued social distancing.
  - Restrict visitation to the resident's room or another designated location at the facility (e.g., outside).

Healthcare Personnel Monitoring and Restrictions:

- Restrict non-essential healthcare personnel, such as those providing elective consultations, personnel providing non-essential services (e.g., barber, hair stylist), and volunteers from entering the building.
  - Consider implementing telehealth to offer remote access to care activities.

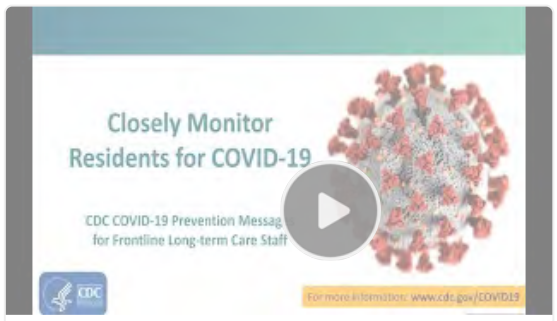
Definitions:

- **Healthcare Personnel (HCP)**: HCP include, but are not limited to, emergency medical service personnel, nurses, nursing assistants, physicians, technicians, therapists, phlebotomists, pharmacists, students and trainees, contractual staff not employed by the healthcare facility, and persons not directly involved in patient care, but who could be exposed to infectious agents that can be transmitted in the healthcare setting (e.g., clerical, dietary, environmental services, laundry, security, engineering and facilities management, administrative, billing, and volunteer personnel).
- **Source Control**: Use of a cloth face covering or facemask to cover a person's mouth and nose to prevent spread of respiratory secretions when they are talking, sneezing, or coughing. Facemasks and cloth face coverings should not be placed on children under age 2, anyone who has trouble breathing, or anyone who is unconscious, incapacitated, or otherwise unable to remove the mask without assistance.
- **Cloth face covering**: Textile (cloth) covers that are intended to keep the person wearing one from spreading respiratory secretions when talking, sneezing, or coughing. They are not PPE and it is uncertain whether cloth face coverings protect the wearer. Guidance on design, use, and maintenance of cloth face coverings is available.

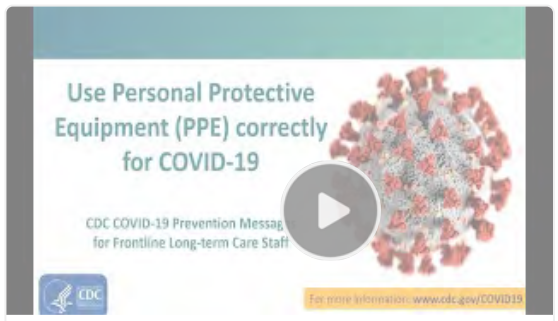
- **Facemask**: Facemasks are PPE and are often referred to as surgical masks or procedure masks. Use facemasks according to product labeling and local, state, and federal requirements. FDA-cleared surgical masks are designed to protect against splashes and sprays and are prioritized for use when such exposures are anticipated, including surgical procedures. Facemasks that are not regulated by FDA, such as some procedure masks, which are typically used for isolation purposes, may not provide protection against splashes and sprays.
- **Respirator:** A respirator is a personal protective device that is worn on the face, covers at least the nose and mouth, and is used to reduce the wearer's risk of inhaling hazardous airborne particles (including dust particles and infectious agents), gases, or vapors. Respirators are certified by the CDC/NIOSH, including those intended for use in healthcare.

Webinar Series - COVID-19 Prevention Messages for Long Term Care Staff

Clean Hands - Combat COVID-19



Closely Monitor Residents for COVID-19



PPE Lessons

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Additional Resources

Sample Notification Letter to Residents and Families: COVID-19 Transmission Identified PDF | DOC

Long-term Care Facility Letter [1 page] to Residents, Families, Friends and Volunteers

CMS Emergency Preparedness & Response Operations

Supporting Your Loved One in a Long-Term Care Facility [472 KB, 1 page]

Infection Prevention Success Stories

Applying COVID-19 Infection Prevention and Control Strategies in Nursing Homes (Recorded Webinar)

Page last reviewed: June 22, 2020

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- More Resources

EXHIBIT 36

Centers for Disease Control and Prevention

Coronavirus Disease 2019 (COVID-19)

People with Developmental and Behavioral Disorders

Updated May 27, 2020

Print Page

Developmental and behavioral disorders are a group of conditions due to an impairment in physical, learning, language, or behavior areas. These conditions begin during the developmental period, may affect day-to-day functioning, and usually last throughout a person's lifetime.[1]

Some developmental and behavioral disorders include:

- Attention Deficit Hyperactivity Disorder (ADHD)
- Autism
- Cerebral Palsy
- Fetal Alcohol Spectrum Disorders (FASDs)
- Fragile X
- Intellectual Disability
- Learning Disorder
- Tourette Syndrome

What do people with developmental and behavioral disorders need to know about COVID-19?

Know who is at risk for severe illness from COVID-19

Most people with developmental or behavioral disorders are not naturally at higher risk for becoming infected with or having severe illness from novel coronavirus (COVID-19). However, people with developmental or behavioral disorders who have serious underlying medical conditions may be at risk of serious illness. Some people with developmental or behavioral disorders may have difficulties accessing information, understanding or practicing preventative measures, and communicating symptoms of illness.

Know how to protect yourself and others

There is currently no specific, Food and Drug Administration (FDA)-approved treatment for COVID-19, and there is currently no vaccine to prevent COVID-19. Treatment is currently supportive. Therefore, the best way to prevent illness is to avoid being exposed to this virus. Advice on preparation for COVID-19 and prevention of exposure to COVID-19 is available.

Continue with your routine care

- Don't stop any medications or change your treatment plan without talking to your healthcare provider.
- Discuss any concerns about your treatment with your healthcare provider.
- Ensure that you are obtaining the tests ordered by your healthcare provider.
- Continue to get your routine immunizations.
- Talk to your healthcare provider, insurer, and pharmacist about creating an emergency supply of prescription medications. Make sure that you have at least 30 days of prescription and over-the-counter medications and supplies on hand in case you need to stay home for a long time. Ask your healthcare provider if it is possible to obtain a 90-day supply of your prescription medications.

- Make or update care plans or an emergency notebook. They typically include important information about a person's medical conditions, how to manage those conditions, how to contact healthcare providers and therapists, allergies, information on medications (names, dosages, and administration instructions), preferences (food and other), and daily routines and activities. This may help you receive consistent care if your Direct Service Providers or family members are unavailable.

> Related: Guidance for Direct Service Providers, Caregivers, Parents, and People with Developmental and Behavioral Disorders

Know how to manage stress and cope during the pandemic

It is natural to feel concerned or stressed as more cases of COVID-19 are discovered and our communities take action to slow the spread of disease. Taking care of yourself, your friends, and your family can help you cope with stress.

Ways to cope with stress

- **Take breaks from watching, reading, or listening to news stories**, including social media. Hearing about the pandemic repeatedly can be upsetting.
- **Take care of your body**.
  - Take deep breaths, stretch, or meditate.
  - Try to eat healthy, well-balanced meals.
  - Exercise regularly, get plenty of sleep.
  - Avoid alcohol and drugs .
- **Make time to unwind**. Try to do some activities you enjoy.
- **Connect with others**. Talk with people you trust about your concerns and how you are feeling.

Click here for information on how to take steps to help yourself cope with stress and anxiety.

Take care of your mental health

Anxiety, depression, and other mental health conditions can be more common in people with some developmental and behavioral disorders. If you are being treated for a mental health condition it is important to continue any therapies or medications.

Look out for these common signs of distress:

- Feelings of numbness, disbelief, confusion, anxiety, or fear
- Changes in appetite, energy, and activity levels
- Difficulty concentrating
- Difficulty sleeping or nightmares and upsetting thoughts and images
- Physical reactions, such as headaches, body pains, stomach problems, and skin rashes
- Worsening of chronic health problems
- Anger or short temper
- Increased use of alcohol, tobacco, or other drugs

If you experience these feelings or behaviors for several days in a row and are unable to carry out normal responsibilities because of them, call your healthcare provider or use the resources below to get help. If you are feeling overwhelmed with emotions like sadness, depression, anxiety, or thoughts of hurting or killing yourself or others:

- Call 911 if you feel like you want to harm yourself or others.
- Visit the Disaster Distress Helpline , call 1-800-985-5990, or text TalkWithUs to 66746.
- Visit the National Domestic Violence Hotline or call 1-800-799-7233 and TTY 1-800-787-3224.
- Visit the National Suicide Prevention Lifeline or call 1-800-273-8255

- Visit the National Suicide Prevention Lifeline or call 1-800-273-8255.

During this pandemic, it is critical that you recognize what stress looks like, take steps to build your resilience and cope with stress, and know where to go if you need help.

More Information

Children and Youth with Special Healthcare Needs

People with Disabilities

Page last reviewed: May 27, 2020

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