Providing Access To Monoclonal Antibody Treatment Of Coronavirus (COVID-19) Patients In Rural And Underserved Areas

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Published In/Presented At

Wood DA, Aleem A, Davis D. Providing Access To Monoclonal Antibody Treatment Of Coronavirus (COVID-19) Patients In Rural And Underserved Areas. 2022 May 6. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2022 Jan–. PMID: 34662052.

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Continuing Education Activity

This educational activity is supported by an educational grant from GlaxoSmithKline.

Coronavirus disease 2019 (COVID-19) is an acute viral illness caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). SARS-CoV-2 primarily affects the respiratory system; however, it can affect other major organ systems as well. Initially, the focus of treatment was directed mainly towards hospitalized patients with COVID-19 illness. However, the clinical focus throughout the pandemic has expanded toward combatting this illness early on by reducing the viral load in patients with early disease, thus attempting to halt the disease progression. Monoclonal antibodies are considered a promising approach in managing non-hospitalized patients with mild to moderate COVID-19 who are at high risk of developing severe illness. This activity reviews the evaluation and treatment of COVID-19 with respect to monoclonal antibody administration and highlights the challenges rural and underserved communities face in delivering healthcare to vulnerable populations in those communities. This activity also reviews the current clinical evidence and guideline recommendations for monoclonal antibody treatment for COVID-19, selecting strategies for improving care access for COVID-19 therapy in rural and underserved areas, examines how to address barriers and hesitancy to monoclonal antibody therapy in these communities, and determines how an interprofessional approach to evaluating and treating patients with monoclonal antibodies can improve patient outcomes.

Objectives:

- Evaluate the latest clinical evidence and current guideline recommendations for the use of monoclonal antibodies to treat COVID-19 in rural and underserved areas.
- Select strategies for improving access to care for COVID-19 treatment and prevention in rural and underserved areas.
- Predict potential determinants of monoclonal antibody hesitancy and outline strategies to encourage appropriate usage in at-risk patients in rural communities.
- Determine an interprofessional approach to evaluating and treating COVID-19 patients with monoclonal antibodies in the outpatient setting.

Earn free CME/CE on this educational activity that has been supported by an educational grant from GlaxoSmithKline

Introduction

Coronavirus disease 2019 (COVID-19) pandemic has impacted the world tremendously since the first cases were identified in 2019. COVID-19 was rapidly disseminated globally, with infections identified in most world societies within the first few months of 2020. COVID-19, the illness caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), has had devastating effects on public health and the world economy. In the United States, the earliest and most well-documented areas impacted were large cities and urban communities. Initial efforts to curb the transmission of COVID-19 were largely successful in helping stem continued widespread transmission. As vaccinations for COVID-19 began rollout, authorities eased some of the initial transmission mitigation strategies, and coupled with the increased prominence of COVID-19 variant strains, transmission and infection rates saw an increase throughout the spring and summer of 2021.

Despite their lower population density, rural and underserved areas continue to be especially vulnerable to poor outcomes from SARS-CoV-2. The disparity in healthcare outcomes in these areas is multifactorial. In general, rural and underserved healthcare infrastructure is less developed than its urban counterparts.[1] These residents often have significantly increased distances to travel to access advanced health care facilities. The travel gap often leads to residents not seeking care until the disease has reached advanced stages. Concerning rural and underserved patients, this distance affects all diseases, with cancer often being found after metastasis, diabetes after end-organ dysfunction, hypertension after a stroke or heart attack, and COVID-19 after pneumonia and subsequent hypoxia develop. Additionally, in rural and underserved areas, patient demographics (i.e., tobacco use, hypertension, diabetes, obesity, and older age) often fall in categories associated with a higher risk of mortality and morbidity from SARS-CoV-2 infection.

From a resource standpoint, rural areas have limited availability of intensive care unit (ICU) beds, ventilators, and access to novel medications through clinical trials. Furthermore, rural communities have always been especially vulnerable to supply chain disruptions, and the COVID-19 pandemic exposed some fragilities in our national supply chain. A nationwide shortage of personal protective equipment (PPE), testing devices (e.g., nasopharyngeal swabs, reagents, and test kits), and respiratory ventilators plagued initial efforts to combat COVID-19.[2] The acute shortage of

testing devices made it neither practical nor beneficial to promote universal screening for COVID-19 in rural areas. Perhaps even more disparate, as a country, the USA is experiencing a shortage of trained nurses, allied health providers, and physicians, and rural communities are often the most challenged in providing adequate numbers of health care professionals and, in particular, sub-specialist physicians to care for their residents.[3]

SARS-CoV-2 primarily affects the respiratory system, with most transmission occurring from close contact with pre-symptomatic, asymptomatic, or symptomatic carriers. Since the declaration of COVID-19 as a global pandemic by the World Health Organization (WHO), considerable progress has been made in managing COVID-19 with the development of novel therapeutics and efficacious vaccines that have led to favorable patient outcomes and has helped limit the spread of the virus. A variety of therapeutic options are currently available in the management of COVID-19, including antiviral medications, monoclonal antibodies, and immunomodulatory agents. However, the therapeutic potential and clinical use of these drugs are limited and are specific to the stage of the illness. Further, rural areas have limited resources to provide access to monoclonal antibody therapy. Some strategies to provide options for rural healthcare systems will be discussed here.

The pathogenesis of COVID-19 illness occurs in two distinct phases, an early stage characterized by profound SARS-CoV-2 viral replication followed by a late phase characterized by a hyperinflammatory state induced by the release of cytokines such as tumor necrosis factor-α (TNF α), granulocyte-macrophage colony-stimulating factor (GM-CSF), Interleukin-1 (IL-1), IL-6, interferon (IFN)-γ, and activation of the coagulation system resulting in a prothrombotic state. Antiviral therapy and antibody-based treatments are likely to be more effective if used during the early phase of the illness. Immunomodulating therapies, either alone or in combination with antiviral and antibody-based therapies, may be more effective when used in the later stage to combat the cytokine-mediated hyperinflammatory state that causes severe illness.[4]

Individuals of all ages are at risk for infection and severe disease. However, as noted previously, high-risk individuals are those aged ≥60 years and with underlying medical comorbidities (obesity, cardiovascular disease, chronic kidney disease, diabetes, chronic lung disease, smoking, cancer, solid organ or hematopoietic stem cell transplant recipients) are at increased risk of developing severe COVID-19 infection. The percentage of COVID-19 patients requiring hospitalization was six times higher in those with preexisting medical conditions than those without medical conditions (45.4% vs. 7.6%) based on an analysis by Stokes et al. of confirmed cases reported to the CDC during January 22 to May 30, 2020.[5]

An encouraging approach to address the COVID-19 associated mortality and preventing the increased utilization of healthcare resources is by terminating the progression of viral replication preventing the progression to the hyperinflammatory stage of COVID-19, which causes severe illness in high-risk non-hospitalized patients. Initially, the focus of treatment was directed mainly towards hospitalized patients with COVID-19 illness. However, the clinical focus over the course of the pandemic expanded towards combatting the illness early on by reducing the viral load in patients with early disease, thus attempting to halt the disease progression. Monoclonal antibodies targeting the spike protein of the SARS-CoV-2 have yielded positive in vitro results.[6][7] They are considered a promising approach in managing non-hospitalized patients with mild to moderate COVID-19 who are at high risk of developing severe illness.

Monoclonal antibodies (mAbs) are immune system proteins developed from a single cell lineage that demonstrate a high affinity for their target cell. Monoclonal antibodies were first developed by Köhler and Milstein in 1975 using hybridoma technology.[8] Since then, research has made significant progress in the molecular engineering world that has enabled the establishment of monoclonal antibodies as targeted therapies in various neoplastic conditions, autoimmune, post-transplant immunosuppression, and infectious diseases.[9] When used as antiviral therapies, neutralizing antibodies play an indispensable part in achieving passive antiviral immunity and are also instrumental in preventing or regulating many viral illnesses.

Over the years, passive immunization against many viral diseases was achieved by administering polyclonal sera obtained from convalescent human donors or animals. However, polyclonal antibody preparations are increasingly being replaced by monoclonal antibodies by virtue of their favorable safety profile and target specificity when used in different viral diseases.[10] Palivizumab was the first antiviral monoclonal antibody approved by the US Food and Drug Administration (FDA) for prophylaxis of respiratory syncytial virus (RSV) in high-risk infants.[11]

Over the years, significant developments in antibody engineering, improved understanding of the biology of viruses, and the direct and indirect effect of monoclonal antibodies on viral infections have resulted in the development of many novel monoclonal antibodies. Like other antiviral drugs, monoclonal antibodies, when used as antiviral agents, are also susceptible to developing resistance as a result of alterations in the viral genome which can alter the pathogenic potential of the virus resulting in the emergence of viral escape mutants, which may render the virus-resistant to a specific monoclonal antibody.

To counter this viral escape phenomenon, some monoclonal antibodies were used in combination to complement each other and prevent neutralization escape by targeting multiple viral epitopes. However, as new variants emerged, resistance to multiple previously authorized monoclonal antibodies was noted. Several mAbs had their authorizations revoked in January 2022 by the FDA, with sotrovimab remaining as the only authorized monoclonal antibody that retains its efficacy as the dominant circulating variant of concern, Omicron.

Function

COVID -19 is an acute viral illness caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). SARS-CoV-2 primarily affects the respiratory system; however, it can affect other major organ systems as well. Initially, the focus of treatment was directed mainly towards hospitalized patients with COVID-19 illness. However, the clinical focus throughout the pandemic has expanded toward combatting this illness early on by reducing the viral load in patients with early disease, thus attempting to halt the disease progression. Monoclonal antibodies are considered a promising approach in managing non-hospitalized patients with mild to moderate COVID-19 who are at high risk of developing severe illness.

Mechanism of Action of Monoclonal Antibodies Against SARS-CoV-2

The pathophysiology of COVID-19 is described by the entry of SARS-CoV-2, the causative virus, into the hosts' cells by binding the SARS-CoV-2 spike or S protein (S1) to the angiotensin-converting enzyme 2 (ACE2) receptors expressed abundantly on the respiratory epithelium, such as type II alveolar epithelial cells. This viral entry is mediated by the receptor-binding domain (RBD) on the spike protein followed by priming of the spike protein (S2) by the host transmembrane serine protease 2 (TMPRSS2) that facilitates cell entry and subsequent viral replication.[12] Monoclonal antibodies prevent the viral attachment by binding to a non-overlapping epitope on the surface spike protein RBD of SARS-CoV-2 with high affinity, thereby blocking the binding of the virus to the human ACE2 receptor.

- **Sotrovimab (VIR-7831):** This is a potent anti-spike neutralizing monoclonal antibody that demonstrated *in vitro* activity against all the four VOCs Alpha (B.1.1.7), Beta (B.1.351), Gamma(P1), and Delta (B.1.617.2). Results from a preplanned interim analysis (not yet peer-reviewed) of the multicenter, double-blind placebo-controlled Phase 3, COMET-ICE trial by Gupta *et al.* that evaluated the clinical efficacy and safety of sotrovimab demonstrated that one dose of sotrovimab (500 mg) reduced the risk of hospitalization or death by 85% in high-risk non-hospitalized patients with mild to moderate COVID-19 compared with those receiving placebo. Sotrovimab monotherapy was granted emergency use authorization from FDA in May 2021 for clinical use in non-hospitalized patients with mild to moderate COVID-19 who are at increased risk for developing severe disease and/or hospitalization.

Issues of Concern

Rural and Underserved Area Disparities

Disparities of rural and underserved healthcare go even further than just patient demographics and supply chain disruption. The COVID-19 pandemic has led to a swift increase in virtual connections the world over. Removal of interpersonal physical contact has been a primary and effective approach to minimize transmission of COVID-19. The spatial or social distancing approach has led to virtual connection as the preferred method of meeting for businesses, with many workers choosing to work remotely and many companies choosing to meet virtually. Remote work does not equate to a specific distance but rather refers to a site that is not the traditional office or worksite.

Telehealth systems have also been slowly implemented for many years and are helping to provide access for many patients unable to visit a traditional medical clinic for evaluation. Rural and underserved areas can be severely limited in providing timely, stable, and uninterrupted telehealth access. The existing grid and infrastructure often cannot provide high-speed network access in a reliable, consistent manner, or network access is simply unavailable.[13]

Local health departments continue expansion as technology becomes available and infrastructure is built. These same rural and underserved local health departments rely more on state and federal funding. Unfortunately, this reliance on state and federal funding is vulnerable to state and federal policy change following local, regional, and federal election cycles. Recently several elected officials in states with significant rural populations have highlighted what was termed the "Netflix standard," meaning that if residents can watch their favorite football team or Netflix on-demand in their homes, then we should be able to connect these same residents with healthcare providers. Further complicating the issue of funding is that many times a locale's public health funding is determined by an area's overall wealth and tax base, with rural areas generally lacking a significant tax base as the population density is low and/or much of the land is designated farmland with subsequent tax relief for property in the agricultural designation.

In rural areas, the crisis of the COVID-19 pandemic has been exacerbated by the generally poor patient demographics, as discussed. Residents of these areas have a higher prevalence of comorbidities such as hypertension, obesity, diabetes, and chronic lower respiratory diseases—all of which increase their risk of death from COVID-19. With less funding and staffing, a sicker general population, and, often, a larger geographical area in which to provide services, rural health systems are often not equipped nor staffed to deal with the extreme demands of a global pandemic. COVID-19 has highlighted many areas of inequity and several fundamental flaws in how rural public health is funded and delivered.

Perhaps as germane to the other disparities of rural and underserved communities is the disparate educational levels of the people living in these areas. According to the department of education, in 2019, 39% of residents described as living in an urban community had attained a college degree of bachelor's equivalent versus 21% for those living in rural areas. Further, median household income was 25% higher for those living in urban areas.

And, As the cost of education continues to rise, those living in more urban areas are able to partially mitigate higher educational costs by living at home. With geographically favorable access to many colleges and universities, the cost is even further defrayed. Compared to rural counterparts who often have to travel non-commutable distances and live on/near campus, the overall cost of attendance of higher education can be a significant hurdle for rural students.

Overall, decreased rural educational levels are also associated with a reduced understanding of fundamental physical, mental and sexual health principles and the benefits of healthy food choices and regular physical activity. Succinctly, health literacy is often lacking in these vulnerable populations, contributing to the vicious cycle of poor outcomes associated with public health crises and the COVID-19 pandemic. Educational limitations continue to limit our vulnerable population's ability to gain a substantive understanding of vaccination benefits and monoclonal antibody use, further challenging rural communities in addressing the COVID-19 pandemic.

Additional elements contributing to the disparate rural and underserved health problems identified include:

- Declining population
- Economic stagnation
- Provider shortages
- A disproportionate number of elderly residents
- A disproportionate number of impoverished residents
- Significant numbers of un/underinsured residents
- Higher rates of chronic illness

Simply put, the less healthy the affected population, the more likely SARS COV-2 is to have fatal consequences. Additionally, with a weaker or less developed health system, the more difficult viral containment becomes.

Conceivably though, healthcare costs may still be the most significant issue rural and underserved residents face with a general lack of public health care in these communities. Even with the passage of the *Patient Protection & Affordable Care Act,* 30 million US residents lacked health insurance in the first half of 2020*,* according to estimates from the National Health Interview Survey (NHIS). The US Census estimates that uninsured rates of residents in rural or primarily rural counties outpace urban areas by several percentage points.[14] Patients living in rural areas are disproportionately affected by regulatory and reimbursement changes to Medicare and Medicaid. Therefore, state and federal legislative actions are needed to offset healthcare costs for rural, impoverished residents.

Secondarily, there is growing concern that many hospitals, in particular rural hospitals, may not have the financial reserves to remain fiscally viable. As of this writing, more than 100 rural hospitals have closed since 2010, with over 400 more hospitals at risk of closure.[15] Most rural hospitals rely on high-profit elective services to provide financial stability. With the COVID-19 pandemic, many hospitals have had to cancel profitable services to provide care for the surge in COVID-19 affected patients. Rural hospitals are at greater risk of closure as operating financial margins are much smaller in these communities. A single rural hospital closure could affect a wide catch net of residents. As shown, when these rural hospitals close, the physician workforce also leaves the area, further exacerbating the problem of delivering care in these vulnerable communities and further causing more local economic damage as associated supporting services are simply just not utilized to the same level.[16][17]

Even at baseline, rural areas have a much more significant shortage of subspecialist physicians, including critical care trained clinicians to staff intensive care units. Additionally, The *Patient Protection & Affordable Care Act* (PPACA) of 2010 drastically reshaped healthcare delivery in the United States. The spirit of providing healthcare to all residents in the United States was the driving force for the passage of the PPACA. As has been studied, there have been some unintended consequences of Hospital Value-Based Purchasing (HVBP) and the Hospital Readmission Reduction Program (HRRP) sections of the PPACA. For instance, as has well been established, rural resident demographics fall in several high-risk categories, and those vulnerable patients have a higher likelihood of morbidity and subsequent hospital readmission for their chronic high-risk disease. All hospitals are financially penalized under the HRRP; however, the effect on rural hospitals is greater, given the already slim operating financial margins. The Centers for Medicare and Medicaid Services (CMS) has implemented programs to monitor quality with the goal of quality driving improvement in care. However, many of these programs have some blind spots when applied to rural areas.

Concerns With Monoclonal Antibody Use

Although generally well-tolerated, monoclonal antibody administration carries a risk of immune-mediated reactions, including anaphylaxis, serum sickness, and antibody generation. Besides these immune-mediated reactions, the adverse effects of monoclonal antibodies are also related to their specific targets and are largely unknown due to the limited availability of published literature. Safety data from clinical trials evaluating monoclonal antibodies reported are summarized below.

- The most frequently reported adverse effects with the use of sotrovimab include infusion-related hypersensitivity reactions, rash, and diarrhea.
- Clinical worsening of COVID-19 after monoclonal antibody administration may include but is not limited to fever, fatigue, hypoxia or increased respiratory difficulty, arrhythmias, and altered mental status.

Further, in instances where a patient may experience an adverse side effect, the likelihood of advanced subspecialty care or intensive care in rural areas would also be lacking. As the COVID-19 pandemic runs its course, we must use this opportunity to address public health disparities for our underserved and remote communities. This approach will include audience-appropriate health education, developing clinician-patient relationships in these communities, and addressing concerns and fears, whether real or imagined, in a compassionate and caring manner. Developing relationships with community leaders who can assist with outreach and education is another potential way to address the hesitancy to accept monoclonal antibody therapy in these communities.

Clinical Significance

As per the Fact SheetS for Healthcare Providers provided by the US FDA on granting emergency use authorization (EUA) for the use of sotrovimab, adult and pediatric patients with mild to moderate COVID-19 illness are considered to be at high risk if they meet at least one of the following criteria:

- ≥ 65 years of age
- Have chronic kidney disease (CKD)
- Pregnant women
- Have underlying diabetes mellitus (DM)
- Have underlying immunosuppressive disease
- Are currently on immunosuppressive therapy
- Have a body mass index (BMI) ≥ of 35 kg/m^2
- Cardiovascular disease or hypertension or COPD/other chronic respiratory diseases
- Aged between 12 to 17 years and have a BMI ≥ 85 percentile for that age and gender-based on CDC growth charts, OR
- Have sickle cell disease, or
- Have congenital or acquired heart disease, or
- Have neurodevelopmental disorders, or
- Have dependence on a medical-related technology device (e.g., tracheostomy, gastrostomy, or positive pressure ventilation unrelated to COVID-19, or
- Have underlying asthma, reactive airway, or chronic respiratory disease that requires daily medication for control.

The authorized dosage under the FDA issued EUA is 500 mg of sotrovimab by IV infusion over 30 minutes in adults and pediatric patients (12 years of age and older weighing at least 40 kgs) who have a positive SARS-CoV-2 test and who had symptoms for ten days or less and are at high risk for progression to severe COVID-19 disease

Based on the fact sheet by the FDA EUA sotrovimab is not authorized for use in patients hospitalized with COVID-19, or who require supplemental oxygen therapy due to COVID-19, or who require increasing baseline oxygen therapy due to COVID-19 in those who were previously on chronic oxygen therapy at baseline due to non-COVID-19 related comorbidity. It must not be administered to patients with known hypersensitivity to sotrovimab.

The FDA also cautions against the use of sotrovimab in hospitalized patients with COVID-19 requiring high flow oxygen or mechanical ventilation as it may be associated with worse clinical outcomes.

Patients treated with monoclonal antibody therapies should continue self-isolation measures and follow infection control measures such as wearing masks, practicing social distancing, cleaning and disinfecting surfaces and washing hands frequently according to CDC guidelines.

Enhancing Healthcare Team Outcomes

- Coronavirus disease 2019 (COVID-19), the illness caused by SARS-CoV-2, has had a crippling effect on healthcare systems and economies worldwide.
- The emergency authorization for clinical use of monoclonal therapies in combatting COVID-19 appears promising.
- Limited published data exist regarding the adverse effects and drug-drug interactions with these therapies. Hence its clinical use in patients with COVID-19 illness presenting to the emergency department (ED) who do not require hospitalization but are at high risk of developing

severe illness requires an interprofessional team that includes ED physicians, nurses, and pharmacists; they should be aware of the mechanism of action of these therapies, reported potential side effects, drug-drug interactions, and recommended doses.

- All patients should receive the fact sheet issued by the US FDA about the monoclonal antibody cocktail before receiving the drug.
- Considering monoclonal antibodies are commonly associated with infusion-related reactions, the patient should be monitored closely in the emergency department during the infusion and at least 1 to 2 hours after the infusion is complete.
- There should be close communication between the ordering ED physician, other clinicians, the pharmacist, and the ED nurse.
- Such a holistic approach would lead to the early identification of potential side effects and drug-drug interactions associated with these drugs.
- Lastly, outpatient clinics and healthcare communities should have a plan in place to triage moderate and high-risk patients for additional therapy, such as monoclonal antibodies in the emergency department if clinically indicated.

Nursing, Allied Health, and Interprofessional Team Interventions

According to the CDC, approximately 60 million, or 1 in 5, Americans live in rural or underserved areas of the United States. Every rural and underserved area is as unique as the residents that inhabit those areas, and unfortunately, no blanket strategy can be applied to every situation or community. Continued innovation, modernization, and original thought will be needed to confront the challenges in delivering effective, goal-directed healthcare to vulnerable populations. Many times, communities have disaster plans in place, and reference to these plans would be the first step in developing a rural public health referral network. Reference to the local disaster plan will answer many initial questions posed. However, existing disaster plans are usually designed with a focus on natural disasters or infrastructure breakdowns.

The COVID-19 pandemic has highlighted that these plans should be reviewed to include public health crises as well. As has been established objectively, the current pandemic has caused more cumulative death and economic damage than the entirety of the last decade of natural disasters. Each community will have its own disaster plan review frequency; however, an annual review would be prudent as technology advances rapidly, and systems are changing at a torrid pace. Population shifts across the country have been common since the outset of the current COVID-19 pandemic, and plan review should consider the shifting local demographics and population density.

The following are some basic yet broad ideas to assist in establishing referral systems in rural and underserved areas. These suggestions are the authors' opinion and are not comprehensive nor exclusive to this article and are meant as a starting point in assessing local referral networks and, in particular, referrals for monoclonal antibody treatments.

A first step would be to assess existing local facilities with the ability to provide monoclonal antibody treatment that is adequately staffed with trained nurses and medical professionals. If no such facility exists, what is the next closest facility? Then, a plan can be developed to refer and, if needed, mobilize local residents to these facilities. The following is a suggested framework to develop a logical, sensible plan to establish a referral system for high-risk residents of rural or underserved to get monoclonal antibody treatment.

- **Look at the local public health problem from a broad lens with respect to the local community.**
- - Each local community is different. Consider the unique challenges of the local community, including basic infrastructure.
  - Work to identify why the community is facing challenges.
  - Is public transit available?
    - Is local ride-sharing available? Would partnership with a ride-sharing system make sense?
- **Compile a database of available resources and projected needs.**
- - Human resource needs.
    - Who are the local subject matter experts?
      - Local clinicians
      - Local engineers
      - Others with expertise in respect to the issue at hand
    - Who will keep medical records? How will the integrity and confidentiality of the records be ensured?
    - Will the private sector be involved? If so, who? Have these stakeholders been contacted and brought into decision-making?
  - Resident needs

- Educational content for residents to promote understanding of COVID-19 disease, vaccinations for COVID-19, and monoclonal antibody therapy
- Responsible social media and local municipal informational webpages
- Engagement with local civic and religious leaders with reach to assist with education and information distribution

- Operational Needs

- With the COVID-19 Pandemic, PPE was an early need. Should stockpiles be considered for future use? How might another public health crisis occur, and in what form will it appear?
- Will food, transportation, water, etc., be needed?
- Storage facilities? Mobile operating centers? Mobile resource delivery?

- **Prioritization of goals**.

- What is the overall goal of the plan? Focus on a few specific overall goals rather than a broad array of ideas.
- Align goals with resources availability.

- Is setting up telehealth access sensible if there is no or limited broadband available to the residents.
- Would setting up testing centers for COVID-19 be practical just because tests are available, but no treatment facility exists?

- **Implementation policies that make sense for the local community**

- Establishing public trust at the outset of any plan will increase the chances of public buy-in and successful implementation. A strong argument can be made that establishing public trust should be a continual and primary objective of all local civic organizations.

As always, an interprofessional team will likely be most effective in solving the community's unique challenges as each member will bring a different perspective to the table. This team could include local civic leaders and members of larger organizations with reach, connection, and established trust within the community residents. Local clinicians, allied health providers, and nurses should be included in the problem-solving process concerning public health. Efforts should also be explicitly made to ensure those residents that are the targets of the policy and all vulnerable populations are included in the decision-making process. Thorough, nonjudgemental, and collaborative communication will be key in not only meeting the challenges faced but also in making effective changes in a timely manner so that the local residents may benefit dynamically rather than at some non-explicit point in the future as well as making changes that are sensible and reflect actual needs rather than theoretical ideas of needs.

Change in how healthcare is delivered will be met with skepticism, not all of which is unfounded. A large component of telehealth concern centers around the medicolegal and ethical aspects of healthcare delivery in this way. Practitioners cite concern with malpractice when practicing from "afar." While there are models for teleradiology and tele-neurology that are widely practiced, one of the comforts of these subspecialties is that an actual practitioner is physically present with the patient to ensure the reliability of information gathering and physical exam findings. With the continued rollout of telehealth, safety measures will need to be considered to alleviate practitioner fears of malpractice and ensure the integrity of care.[18] [19] As telehealth secures a more prominent role in healthcare delivery, vigilance is necessary to address ethical concerns and responsible technology use.

Basic ethical tenants to consider are:

- Beneficence - providing services that generally promote good for the individual and community
- Non-Maleficence - doing no harm to the individual or community
- Justice - treating every situation/resident equally
- Autonomy - allowing residents their own choice in care

Consider for a moment an elderly patient who has been contacted via telehealth. The practitioner determines that this patient would benefit from monoclonal antibody therapy. The patient has agreed that treatment may be helpful and wishes to proceed. However, the patient has no transportation. In another scenario, a known more remote part of the community has poor cellphone service and minimal high-speed internet. Yet, a few miles closer, these issues do not exist, and cell phone service is excellent. How would the gap be closed to provide services to both groups? Even more, would residents who are not adequately informed and educated about COVID-19 disease, vaccinations, and monoclonal antibody therapy, really be able to make a truly autonomous decision?

COVID-19 Community Vulnerability Index (CCVI) Tool

Objectively, the COVID-19 Community Vulnerability Index (CCVI) tool is designed after the CDC's Social Vulnerability index.[20] The Idea behind CCVI was to incorporate the latest evidence of COVID-19 risk factors, with data, and dozens of other indicators, into a single score for a population of interest, whether it is a city, county, or state. CCVI considers the seven following indicators when looking at a community's vulnerability index:

- Socioeconomic status
- Minority status and transportation
- Household and transportation
- Epidemiological factors
- Healthcare system factors
- High-risk environments
- Population density

Each of the above themes has its own score of zero, the lowest vulnerability, and 1, the highest vulnerability. Based on these indicators, CCVI can predict why and where there would be worse health, social, and economic outcomes after COVID 19. CCVI offers information for local and state leaders to help understand where there are limited resources. This scoring system helps them identify these areas in need and where to focus interventions such as equipment for healthcare systems, quarantine accommodation, or support for rent payments depending on the community's vulnerability index.

The action-oriented solution that CCVI offers allows one to identify the area of deficit, prepare a plan and address the gaps identified, respond with target-specific interventions and resources, and finally monitor the outcome of the response and how it impacts the vulnerability of the community. Each of the seven indicators incorporated into CCVI has associated interventions that help reduce the community's vulnerability. Below are some listed interventions that could be taken when a deficit is identified in each underlying driver of vulnerability.

- Socioeconomic Status
    - Financial relief for lower-income bracket individuals
    - Free or low-cost testing and vaccines
- Minority Status and Transportation
    - Tailor communication and channels for specific populations if needed
- Household and Transportation
    - Public-private partnerships for access to transportation for testing or healthcare
    - Mobile testing and vaccine sites
- Epidemiological Factors
    - Support stay at home with financial and food support of those at most risk
    - Allow highly vulnerable individuals to avoid contaminated workspaces
- Healthcare System Factors
    - Enact mobile or temporary emergency response facilities
    - Local nonprofit and other community organizations to help fill gaps
- High-risk environments
    - Prisons, Nursing homes
    - Resources for testing, tracing, and isolation of cases
    - Frequent Health inspections of conditions and employment conditions to avoid outbreaks
    - Support self-isolation
    - Continue rapid testing within these high-risk environments
    - Limit capacities within these facilities.
- Population Density
- Mask mandates
- Public area capacity limits
- Minimize non-essential indoor events

Lastly, the CCVI tool allows local and state leaders to identify areas of need and where to delegate resources. This tool also allows these leaders to continue to monitor and see how these changes and resources affect the community's vulnerability. Ultimately, each community is vested in itself and will be the most likely to affect positive change locally; this is especially true for rural areas as these communities are smaller, closer-knit, and not as subject to the bureaucracy known to bog down effective change in larger communities.

In conclusion, the questions and ideas posed are not intended to be answers for any single community. Simply these questions and ideas are posed to generate thought and assist in starting the necessary conversations to develop a plan that will best suit each local communities needs. As demonstrated, rural and underserved communities face a multitude of challenges, and no one-size-fits-all solution is available.

Review Questions

- Access free multiple choice questions on this topic.
- Comment on this article.

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Publication History

Last Update: July 9, 2022.

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Publisher

StatPearls Publishing, Treasure Island (FL)

NLM Citation

Wood DA, Aleem A, Davis D. Providing Access To Monoclonal Antibody Treatment Of Coronavirus (COVID-19) Patients In Rural And Underserved Areas. [Updated 2022 Jul 9]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2022 Jan-.