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Health System Success in Delivering Bamlanivimab Within Post-acute and Long-Term Care Facilities

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Keywords: Disaster planning, PALTC, rural, COVID-19, bamlanivimab, health system

Abstract

Objectives: Post-acute and long-term care (PALTC) residents are disproportionately affected by coronavirus 2019 (COVID-19). We describe a health system approach that incorporated PALTC stakeholders to treat residents effectively and efficiently with monoclonal antibodies during the pandemic.

Design: Retrospective observational.

Setting and Participants: Integrated health system headquartered in Sioux Falls, South Dakota, with urban hub and surrounding rural communities. Patients of the health system include PALTC and assisted living (AL) residents of facilities.

Methods: Monoclonal Data Registry captured time to infusion after a positive COVID-19 test, residency (independent or PALTC), and site of infusion (PALTC, hospital outpatient, infusion center). AL residents are included in PALTC data. Registry limited to patients living in SD. Communication and operational resources were tailored to support PALTC infusions. The monoclonal antibody therapy administered to PALTC residents during the first 6 weeks after emergency use authorization (EUA) of monoclonal antibodies was bamlanivimab. The EUA for bamlanivimab was revoked due to lack of effectiveness against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) variants on April 16, 2021.

Results: The results are analyzed for the 6 weeks after bamlanivimab EUA. In PALTC, there was a median of 3 days between positive test and infusion. The total number of monoclonal antibody infusions captured in the registry during this time was 87 PALTC on-site infusions.

Conclusion and Implications: A collaborative approach between health system executives and PALTC experts quickly enabled access to potentially life-saving therapy to a vulnerable population. PALTC settings should be routinely included in health system investment and planning to improve the capacity of the system to achieve optimal outcomes, prevent unnecessary mortality, and preserve health care resources.
The PALTC population, at the height of the US pandemic before vaccinations were available.

This study presents evidence showing that thoughtful infrastructure and resource investments can have a measurable impact on equitable access to novel treatments for residents of PALTC.

**Methods**

This is a retrospective observational study design. The Health System Patient Registry of Bamlanivimab and Casirivimab/Imdevimab for the Outpatient Treatment of COVID-19 Infection protocol was approved by the local institutional review board (IRB) in January 2021. A waiver of informed consent was also obtained from the IRB. The stated purpose was to collect information to assist with evaluating the effectiveness of preventing emergency department visits and/or hospitalization of individuals who have tested positive for COVID-19 and received either bamlanivimab or casirivimab/imdevimab per the Food and Drug Administration's EUA. This registry was also intended to help identify the types and rates of adverse reactions that may be related to the administration of these monoclonal antibodies, as well as the need for associated medical interventions. The original IRB was amended in July 2021 to allow additional analysis of the PALTC data subset, to better understand access to treatment for this population. Patients were included in the registry through query of electronic health records (EHR) for either a bamlanivimab or casirivimab/imdevimab order.

The criterion for inclusion in the PALTC subset was any person within the health system residing in long LTC nursing home, skilled nursing facility, or assisted living (AL) who received an infusion of bamlanivimab or casirivimab/imdevimab in November or December 2020. All health system-affiliated PALTC facilities used a common EHR. Seven nonaffiliated facilities contracted with the health system's LTC pharmacy (LTCPh) did not use the same EHR, but their pharmacy data were accessed through the pharmacy's EHR. Any person who met eligibility and gave valid consent to this treatment was included. However, some patients receiving treatment may have been missed due to nonspecific medication orders in the EHR.

**Health System Infrastructure Elements**

Integrated health system is based in Sioux Falls, SD, and surrounding areas of Minnesota, Iowa, Nebraska, and North Dakota. Services include 7 Prospective Payment System hospitals, 28 Critical Access hospitals (CAH), 215 physician clinics, 15 home care and hospice, 21 PALTC, and 20 AL. Medical directors and providers at the PALTC are a mixture of employed and independent practitioners. The health system has an enterprise pharmacy that serves their hospitals and clinics and rural PALTC affiliated with CAH. A shared services structure provides quality, human resources, marketing/communication, information technology, finance and purchasing support across the enterprise.

The health system LTCPh and Senior Care Telemedicine, are independent entities within the health system that have LTC-dedicated multidisciplinary teams available internally and externally for an additional fee. The LTCPh team includes pharmacists, nurses, account managers, and billing specialists. The telemedicine team of certified medical directors (CMD), geriatrics-trained nurses, practice physicians, pharmacists, social worker, and physicians are embedded with on-site video and peripheral (stethoscope) platform to support most of the health system PALTC staff and residents.

A matrixed structure, with coordination among Enterprise Incident Command, Regional Incident Command, and the PALTC Steering Committee is detailed in Table 1. This structure optimized resources, infrastructure, and expertise available through the health system for the benefit of PALTC.

The health system COVID-19 dashboard imported positive test results from laboratories, as captured by the EHR. These were displayed by community and care setting, promoting transparency, and allowing corporate support to be initiated when positive test results were noted. Nonaffiliated PALTC settings served by the LTCPh were not included on the health system's COVID-19 dashboard.

An enhanced health system communication strategy included daily list-serve updates, a robust COVID-19 hotline, and leadership weekly virtual town halls with all providers and administrative leaders, including PALTC.

**Description of Multicomponent Intervention**

Bamlanivimab received EUA on November 9, 2020. Federal allocation of bamlanivimab was given to the SD Department of Health to distribute to health systems to determine use.

Cases in the health system were identified on the COVID-19 dashboard by the PALTC clinical quality director and a certified nurse executive with system quality and LTC experience (CQD). Nonaffiliated PALTC sites contracted with the LTCPh were identified by LTCPh staff, board-certified geriatric pharmacists, and registered nurses with LTC experience, when facilities asked to modify their standard medication delivery process due to outbreak status. The CQD and LTCPh coordinated with the facility nurse leader to review new positive cases and facilitate discussions with attending physicians to determine eligibility and establish consent for treatment. They also completed a focused facility needs assessment of staffing numbers, capabilities, and community resources. Based on results, tasks were assigned to LTCPh, facility registered nurse, or community resources accessed through Regional Incident Command (ie, local infusion center, home health nurse).

**Table 1**

| Committee | PALTC Steering Committee | Regional Incident Command | Enterprise Incident Command |
|-----------|--------------------------|---------------------------|-----------------------------|
| Scope     | All services delivered to residents of PALTC (including AL) | All health care services delivered in the region | Entire enterprise |
| Function  | Recognize PALTC needs, opportunities, priorities and ensure these are incorporated in enterprise planning | Deliver equitable and high-quality care to all patients in the region | Align resources to support equitable and high-quality care across the enterprise |
| Members   | Multi-professional PALTC experts; quality director (executive registered nurse with LTC experience), LTC pharmacist, CMD physician, administrative executive | Administrative and clinical leaders for each health setting, including PALTC administrators and directors of nursing | Multi-professional health care executives |
|           |                          | During the pandemic, independent healthcare facilities included in communications and invited to access resources |                                |
The pharmacy mixed and delivered the infusion with all necessary supplies. These included protocols for administration and post-monitoring, an emergency response kit, and a registered nurse for on-site consulting with intravenous starts, administering and monitoring if needed.

The corporate CMD participated in national AMDA–The Society for PALTC COVID-19 daily updates and contributed to and accessed resources from their online COVID-19 Resource Center. These resources were streamlined for local PALTC medical directors and providers. The matrixed command structure allowed rapid adaptation to challenges and delivery of services.

Results

The first doses of bamlanivimab were received in the state on November 11, 2020. This health system dispensed the first doses of bamlanivimab on November 13, 2020, to 9 residents of a PALTC facility. During the initial 6 weeks of availability, 87 residents of PALTC in 12 sites received on-site infusion for treatment of early COVID-19. The median time to infusion after a positive test result was 3 days. In the first 2 weeks, most infusions were completed in PALTC with LTCPh support. Additional community resources, such as outpatient COVID-19 infusion centers, were created to allow LTCPh resources to be reprioritized to support COVID-19 vaccination of residents in late December (see Figure 1). This health system received additional federal allocation after recognition at the state and federal levels that it was using the medication effectively.

Discussion

The key finding in our study is the demonstration that it is possible, even when the health care system is under extreme duress, to effectively support and deliver novel treatments to residents of PALTC facilities by engaging PALTC professionals and strategically augmenting resources.

Nationally, it was very difficult for residents of nursing homes to access monoclonal antibody infusions in the first months it was available. During this time, many nursing home residents and staff members were COVID-19 positive, resulting in rampant staffing shortages, one factor directly associated with COVID-19 cases and deaths. Approximately 1 of 6 nursing homes self-reported shortages in staffing during May 2020; those serving higher margin Medicare residents were less likely to suffer staff shortages. The observed barriers to use of monoclonal antibodies can be classified into 4 categories, detailed in Table 2.

Despite these challenges, this health system was able to treat residents with COVID-19 within PALTC settings just 2 days after the first shipment. Policy makers and health care leaders should take note and adapt current disaster management/pandemic planning teams and resources to incorporate PALTC expertise when needed to effectively meet health care needs of the entire population in a community. There are no publicly available data about how many patients received monoclonal antibody infusion, their sites of infusion, or how much was not used. Available data are limited to the amount that was allocated weekly by the federal government to states, territories, and federal entities.

The intervention described in this article was largely successful due to the degree it overcame fear and uncertainty by reducing the need for the facility to initiate the process and providing a “package deal” with targeted information, tools, guidance, and access to additional support that adapted to local conditions. This agile response resulted in medication access for PALTC residents in the critical weeks before infusion centers and teams were created. Some health systems created dedicated infusion centers and/or mobile infusion teams. It is not yet published how successful this approach was at reaching PALTC residents. Preexisting public health infrastructure in some states leveraged academic center partnerships with state departments of health to take a statewide approach to delivery of monoclonal antibody therapy. A shared feature of these successful programs is recognizing and planning for variability of health care support needed, which has been previously published as necessary when implementing programs for residents of care homes.

Early in the pandemic, experts called for regional approaches to systemwide resource allocation, recommending, among other things, involvement of PALTC and geriatric professionals in regional disaster planning and delivery of prophylactic medications in PALTC. Our experience validates the effectiveness of these approaches.

The transformational opportunity is to use the strategies of facility needs assessment and regional support to address long-standing adversities in PALTC medicine, recognizing that challenges, such as access to key supplies (eg, personal protective equipment, specialized tubing), nursing skills, timely medication delivery, on-site medical providers, medical director competence, and engagement, are systemic issues that require collaboration across health systems. In our example, the health system COVID-19 dashboard was a key tool to identify facilities in need of support, but because it did not incorporate nonaffiliated sites, overall usefulness was limited. The state department of health did

![Health System Monoclonal Antibody Infusions in PALTC After Emergency Use Authorization](image-url)
not report information that identified facilities with outbreaks. In contrast, community boards, such as those proposed by MediCaring, that manage and share information can overcome these barriers.17 A national effort to expand the community-level COVID-19 dashboards to include other important indicators of community health, including PALTC-specific data would facilitate population health efforts. A national health care system, such as a National Health Reserve System, modeled after the Federal Reserve System, that is governed and managed by experts using data, experience, evidence, and planning could accomplish similar goals.18

This study has several limitations. The data registry was not originally designed to evaluate access to treatment in PALTC and did not include all positive cases, residents who were positive but ineligible, or outcomes of untreated residents. Data were not structured to identify percentage of eligible residents with COVID-19. Conclusions about impact of treatment on hospitalization and death are not possible from these data. Additional limitations include inconsistent order entry in the EHR, which likely resulted in some treated residents not being included in the registry. Last, degree of impact on access to monoclonal antibodies cannot be quantified because administration in PALTC is not publicly reported.

Conclusions and Implications

This study demonstrates that including PALTC professionals and investing in PALTC data and knowledge infrastructure supports equitable access to novel treatments. With this infrastructure in place, stakeholders can quickly identify gaps, problem solve, and create implementation plans.

Recommendations based on pandemic experience:

1. PALTC professionals, including pharmacists, nursing leaders, administrators, and CMDs, should be heavily involved in regional and national planning efforts for future crisis preparation.

2. Federal allocation, data, and guidance strategies should recognize that health systems and supply chains cross state boundaries and avoid variability between state approaches.

3. Payment for PALTC needs to be included as a key element of health care reform conversations; until equitable payment systems exist, PALTC will struggle to recruit and maintain the staff needed to care for residents.19

4. Hardwire transparency through creation of national and community dashboards (including PALTC populations) rather than relying on proprietary health system data repositories.

5. Invest in technology platforms enabling data integration across care settings without burdening clinicians with nonclinical duties.

Acknowledgments

The authors express appreciation to the extended team of people across the health system who partnered to rise to the challenge of caring for their community members with compassion, creativity, and courage. We especially express gratitude to the LTC pharmacy team members who led the way through extremely long days, weeks, and months without losing their enthusiasm for service. Julia Althoff and the Clinical Intelligence team for their careful listening and adaptation of systems and data queries, the LTC Strategic Business Unit for ongoing support, and the South Dakota Department of Health for the information and resources. Individuals who were particularly helpful include Zachary Muller, the pharmacy resident who created the Registry; Luke Mack, who guided us through key steps of capturing our experience for publishing; and Tobias Meisner and Bing Xu for their assistance with collating the data. Last, but certainly not least, a debt of gratitude to Dr Joanne Lynn and Dr Steve Levenson for inspiration and mentorship.

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Table 2

Barriers to the Administration of Monoclonal Antibodies

| Workforce | Providers | Resident | Logistics |
|-----------|-----------|----------|-----------|
| Staffing shortages in nursing home (preexisting, exacerbated by staff illness) | Provider hesitance to prescribe medication under EUA | Disqualified by declines in health | Inability to transfer medications over state lines |
| Discomfort with managing potential infusion-related emergencies | Unfamiliarity with the medication option | Consent often needed to be given by a family member | Access to specialized tubing |
|  |  |  | Distribution of medication to rural sites |
|  |  |  | Confusion about how to access medication |
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