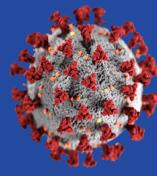


Chapter 13

Therapeutics

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Version History

Version #	Date	Notes
0.1	11/14/2023	First Draft submitted to CPR Team
0.2	8/14/2024	Final Draft revised per Expert SME review
0.3	11/6/2024	Final Draft revised per CPR Leadership review

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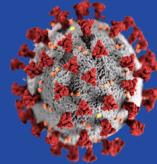
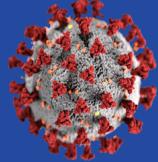


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13. Therapeutics

Public Health Emergency Preparedness and Response Capabilities: Community Preparedness; Medical Countermeasure Dispensing and Administration; Medical Material Management and Distribution.

Related CDPH AAR Chapters: Logistics, Distribution and Warehousing; Vaccines; Policy Development and Guidance; Data and Reporting.

In this chapter, some abbreviations may be used interchangeably with their respective full spellings for ease of reading.

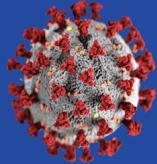
Chapter Summary

Overview

This section provides a high-level overview of milestones and activities related to this chapter.

During the pandemic, therapeutic treatments played an important role in reducing morbidity and mortality from COVID-19. Inpatient treatments for patients hospitalized with COVID-19 were available earlier in the pandemic and helped improve patient outcomes, and outpatient treatments that were available later in the pandemic helped reduce the risk of hospitalization and death if taken soon after symptom onset. While vaccines were always recommended as the first line of defense against COVID-19, therapeutics were another useful form of clinical care for people who could not or would not take vaccines, and there is evidence that these medicines helped reduce the risk of hospitalization and death even in vaccinated individuals. There was also early evidence that COVID-19 therapeutics might reduce the risk of developing long COVID-19 (which a subsequent study in early 2024 did not confirm).

Some therapeutic treatments, like Evusheld, were recommended for immunocompromised individuals before exposure to COVID-19 to help reduce the likelihood of becoming sick. Other treatments could be taken within five to seven days of COVID-19 symptom onset to reduce the risk of hospitalization and death. There were two forms of COVID-19 therapeutics treatments: antivirals and monoclonal antibodies. Antivirals worked by stopping the virus that causes COVID-19 from making copies of itself in the body. One antiviral, Evusheld, was administered via intramuscular injection, while two antivirals, Paxlovid and Lagevrio, were taken orally. Monoclonal antibodies mimicked the body's own



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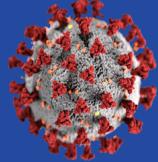
antibodies to help prevent the virus from infecting more cells. This treatment was administered to patients through an infusion or injection delivered in an appropriate health care setting by a healthcare practitioner.

The first therapeutic developed specifically for COVID-19 was Veklury, an intravenous (IV) antiviral that received emergency use authorization (EUA) in May 2020. The federal government purchased the national supply from the manufacturer for allocation to the states. In California, CDPH established a therapeutics work group to devise a systematic ordering process to distribute the State's allocation equitably among the Local Health Jurisdictions (LHJs), which then determined the sub-allocations to the healthcare providers within their jurisdiction. The work group continued its activities until October 2020 when Veklury received FDA approval to be sold in the commercial marketplace. The federal government then stopped purchasing the antiviral and the State no longer received allocations.

From November 2020 to May 2021, three monoclonal antibody treatments received EUAs, but were not allocated to the states until late summer 2021. The decision to start allocating to the states was spurred by the rapid spread of the COVID-19 Delta variant, leading to a significant uptick in utilizing monoclonal antibody products across the country.

In anticipation of the federal government's allocation of monoclonal antibody products to the states, CDPH transformed the therapeutics work group into the Therapeutics Task Force in October 2021. The Therapeutics Task Force ramped up to provide clinical guidance, oversee the allocation and ordering process, and conduct outreach to healthcare providers and the public. Shortly after CDPH established the Therapeutics Task Force, two oral antivirals, Paxlovid and Lagevrio, received EUAs and the federal government began allocations to the states.

While the U.S. Food and Drug Administration granted EUAs for five different monoclonal antibody treatments during the pandemic, by the end of 2022 all of the authorizations were revoked due to their ineffectiveness against the COVID-19 Omicron variant. At that time, the two remaining oral antivirals, Paxlovid and Lagevrio, were the primary treatment options allocated to the states until their commercialization in November 2023. The sequential ineffectiveness of monoclonal antibodies was expected as the mechanism of actions of this therapy are much more susceptible to changes in variants.



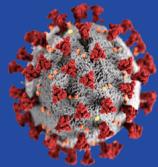
Antivirals, on the other hand, have mechanisms of action that likely work against multiple variants of a virus.

With this shifting landscape of treatment options and frequent revisions to recommended usage, there was a critical need for accurate and up-to-date information. The Therapeutics Task Force proactively developed and disseminated extensive clinical guidance, health alerts, and other communication and educational materials, to assist providers in making informed treatment decisions and to assist the public in understanding the importance of seeking treatment within symptom onset as soon as possible. The Therapeutics Task Force directed several initiatives that successfully expanded options in disadvantaged communities and for the public to get tested, obtain a prescription, and receive treatment all at one convenient location (“Test-to-Treat”).

This chapter focuses on the allocation and administration of medical countermeasures for COVID-19 treatment, which includes monoclonal antibodies and oral antiviral treatments, commonly referred to as COVID-19 therapeutics. For a discussion of the allocation, distribution, and administration of vaccines for COVID-19 prevention, see the Vaccines chapter of this AAR. For a discussion of the allocation and distribution of non-pharmaceutical countermeasures, see the Logistics, Distribution, and Warehousing chapter of this AAR.

Timeline and Key Milestones

2020	
Spring 2020	<ul style="list-style-type: none">▶ March: CDPH activated the Operational Plan and Procedures for Receiving and Distributing Medical Countermeasures (MCM)▶ March: CDPH established work group to implement Operational Plan and Procedures▶ March – April: First Surge (Skilled Nursing Facility [SNF] Surge)▶ May: Veklury (remdesivir) received EUA for use in hospitalized patients with severe COVID-19
Summer 2020	<ul style="list-style-type: none">▶ June – August: Second Surge (Hospital Surge)▶ August: Veklury (remdesivir) EUA expanded to include hospitalized adults and pediatric patients with suspected or confirmed COVID-19, irrespective of severity of disease

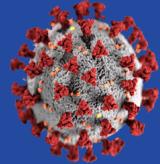


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Fall 2020	<ul style="list-style-type: none">▶ October: Veklury (remdesivir) received commercial use approval▶ November: REGEN-COV (casirivimab and imdevimab) received EUA
2021	
Winter 2020/2021	<ul style="list-style-type: none">▶ December – February: Third Surge (Winter Surge)▶ February: Federal government discontinued control of national supply of Veklury (remdesivir)▶ February: Bamlanivimab and etesevimab (administered together) received EUA
Spring 2021	<ul style="list-style-type: none">▶ April: First case of the Delta variant detected in California▶ May: Sotrovimab received EUA
Summer 2021	<ul style="list-style-type: none">▶ August: Beginning of Delta variant surge
Fall 2021	<ul style="list-style-type: none">▶ September – November: Fourth Surge (Delta Variant)▶ September: Federal government began managing the national supply of monoclonal antibody and oral antivirals▶ October: CDPH established Therapeutics Task Force
2022	
Winter 2021/2022	<ul style="list-style-type: none">▶ December – February: Omicron variant surge▶ December: Evusheld (tixagevimab co-packaged with cilgavimab) received EUA▶ December: Paxlovid (nirmatrelvir and ritonavir) received EUA for use in adult and pediatric patients with mild-to-moderate COVID-19▶ December: Lagevrio (molnupiravir) received EUA▶ December – February: Fifth Surge (Omicron Variant)▶ January: Omicron Variant Surge peaked▶ January: FDA revoked EUA for bamlanivimab and etesevimab (administered together), and REGEN-COV (casirivimab and imdevimab) due to ineffectiveness against the COVID-19 Omicron variant▶ February: FDA revoked EUA for sotrovimab due to ineffectiveness against the COVID-19 Omicron variant▶ February: Bebtelovimab received EUA
Spring 2022	<ul style="list-style-type: none">▶ March: Therapeutics Task Force received funding to expand public and provider communications▶ March: Federal government launched nationwide Test-to-Treat initiative▶ April: CDPH released Request for Information (RFI) for a State-funded telehealth provider▶ May: Optum Serve began to convert 146 testing sites to Test-to-Treat sites

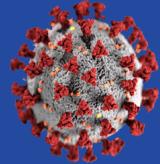


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Summer 2022	<ul style="list-style-type: none">▶ July: Therapeutics Task Force released the Test-to-Treat Playbook▶ July: CDPH launched telehealth services (SesameCare)▶ July: FDA authorized pharmacists to prescribe Paxlovid to patients
Fall 2022	<ul style="list-style-type: none">▶ October: CDPH began awarding Test-to-Treat Grants to safety net healthcare providers to increase access to COVID-19 therapeutics▶ October: Therapeutics Task Force released updated Test-to-Treat Playbook▶ November: FDA revoked EUA for bebtelovimab
2023	
Winter 2022/2023	<ul style="list-style-type: none">▶ December: CDPH launched multilingual multimedia campaign to inform the public about the importance of seeking COVID-19 therapeutics after testing positive▶ January: FDA revoked EUA for Evusheld due to ineffectiveness against circulating COVID-19 variants▶ January: Optum Serve Test-to-Treat sites close▶ January: CDPH launched COVID-19 Therapeutics provider warmline to provide clinical consultation▶ February: FDA no longer required COVID-19 positive test for oral antiviral prescriptions▶ February 28: California's State of Emergency for COVID-19 ended
Spring 2023	<ul style="list-style-type: none">▶ May: FDA expanded EUA for Paxlovid to adults who are at high risk for progression to severe COVID-19▶ May: Federal Public Health Emergency ends
Summer 2023	<ul style="list-style-type: none">▶ June 30: Therapeutics Task Force demobilized and transitioned to a transitional skeleton team in the new Medical Countermeasures Unit in the Office of Infectious Disease Preparedness and Response



Main Strengths and Successes

This section describes the Main Strengths and Successes, including findings and corrective actions, related to this chapter. Further elaboration and a more detailed discussion of these strengths and successes can be found in the Analysis of Activities section.

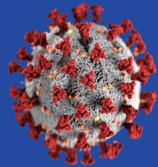
1. CDPH effectively supported LHJs and healthcare providers to triage, prescribe, and dispense COVID-19 therapeutic treatments.

Throughout the pandemic, COVID-19 therapeutics treatment options continuously changed. New treatments received emergency use authorization, while others were revoked due to their lack of efficacy against emerging virus variants. As a result, prescribing guidelines underwent frequent revisions, and it was critical that LHJs and healthcare providers received the most accurate and current information. In a notable achievement, the Therapeutics Task Force, particularly the collaborative efforts of the clinical and the communications teams, created an extensive array of clinical guidance, educational materials, and tools that assisted LHJs and healthcare providers in their treatment decisions. This support included weekly provider webinars, a weekly newsletter, a dedicated [website](#), and numerous [COVID-19 therapeutics toolkits](#). These tools provided straightforward, actionable guidelines and checklists to help healthcare providers seamlessly integrate new treatment protocols into their existing operations.

Finding/Corrective Action: CDPH has the opportunity to plan, develop, and deliver a comprehensive set of therapeutic resources to influence and inform LHJs and healthcare providers. (ID: Therapeutics 1)

2. CDPH enabled a Statewide telehealth service to provide same-day access to prescribers at no cost to Californians.

One of the major obstacles associated with COVID-19 therapeutics was ensuring that Californians had timely access to a provider who could assess them and then prescribe COVID-19 therapeutics (if warranted) within five to seven days of symptom onset. In July 2022, CDPH launched a Statewide telehealth service at no cost to Californians with prioritized



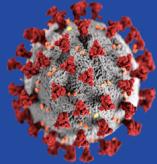
focus on communities least likely to have timely access to healthcare including: farmworkers, tribal communities, rural communities, and the underinsured or uninsured. The service remained free to Californians until February 2024, after which Californians could still access the service via Sesame Care, a telehealth provider.

Finding/Corrective Action: CDPH recognized the need for timely access to a provider and implemented a Statewide telehealth service to provide same-day access. This model can be leveraged in future pandemic responses. (*ID: Therapeutics 2*)

3. CDPH implemented creative public communications campaigns with a focus on priority populations, which successfully increased levels of public awareness of the availability and effectiveness of COVID-19 treatment among priority populations.

The communications team collaborated with an external communications and marketing agency to develop and execute a comprehensive \$30 million multilingual public awareness campaign about COVID-19 treatments across various platforms with a focus on priority populations facing disproportionate burden of COVID-19. These campaigns, which portrayed a positive, empowering tone, centered around the theme "Test It. Treat It. You Can Beat It." The ads addressed key barriers to awareness and utilization to engage the public by featuring authentic, relatable people from various backgrounds, joyfully dancing in homemade-style videos. The campaign utilized a range of media, including television, radio, newspaper, digital, video and audio streaming, social media, billboard, and bus shelter ads. With the goal of tailoring the campaign to three major ethnolinguistic groups in California (English, Spanish, and East Asian language-speaking) three sets of advertisements were developed with similar messaging and storylines but different languages, casting, and creative execution. The team launched a free multilingual call center and webpage to provide accessible information on COVID-19 treatments.

In addition to traditional media, the team diversified their outreach by partnering with community-based organizations and social media influencers popular among specific demographic groups, such as both



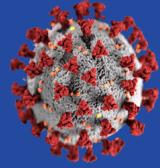
younger and older audiences, Latino and Black/African American communities, and other target populations. Influencers were given creative freedom to tailor content for platforms like TikTok and Instagram, effectively disseminating crucial public health messages in culturally relevant and engaging ways. The team also conducted public relations activities including publishing press releases and op-eds, conducting multilingual press briefings, participating at community events via informational booths, and broadcasting, pre-recorded interviews with trusted healthcare leaders. To measure the potential effect of the campaign on statewide levels of awareness and treatment-seeking behaviors, the team surveyed over 1,500 Californians representative of the target populations. Metrics demonstrated that the campaign significantly increased levels of awareness of COVID-19 treatments and intentions to seek COVID-19 treatments among the target populations.

Finding/Corrective Action: Concerted investment in a communications campaign was critical to raising awareness of COVID-19 treatments. The Therapeutics Task Force's public communications strategy for therapeutics provides an effective model to be used in future pandemics. (ID: Therapeutics 3)

4. CDPH successfully developed and implemented Test-to-Treat initiatives that expanded COVID-19 therapeutic options.

CDPH successfully implemented the State's Test-to-Treat initiative, modelled after the federal government's program, to enhance public access to therapeutic treatment for COVID-19. Test-to-treat facilities allowed individuals to go to one location to undergo COVID-19 testing, consult with healthcare providers about treatment options if they tested positive, and leave with medication in-hand. This approach improves the chances of timely treatment since therapeutic medications need to be administered within five to seven days of symptom onset. Test-to-Treat sites were especially important for equitable access since they reduced the number of steps needed to get a test, talk to a doctor, and get a prescription.

In April 2022, CDPH added a dedicated team to the Therapeutics Task Force to develop the State's Test-to-Treat policies and implement targeted strategies. One strategy focused on transforming the State's

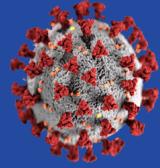


existing testing contractor's testing sites into 146 Test-to-Treat facilities in underserved areas, to help ensure that approximately 90% of the state's population lived within a 30-minute drive of the sites. These locations offered comprehensive services, encompassing testing, telehealth prescribing for COVID-19-positive patients, and on-site dispensing of therapeutics. The on-site dispensing component involved getting a specialized dispensing waiver from the California State Board of Pharmacy. In addition, CDPH created a comprehensive [Test-To-Treat Playbook](#), which served as an in-depth guide for LHJs and healthcare providers that were either implementing or making improvements to their test-to-treat operations. Furthermore, CDPH launched a virtual telehealth service to improve access to healthcare consultations and therapeutic prescriptions for symptomatic individuals who tested positive. Additionally, CDPH awarded \$67 million in COVID-19 Test-to-Treat Equity Grants to 176 safety net providers caring for communities disproportionately affected by COVID-19. CDPH also partnered with long term care associations and developed toolkits to promote workflow changes for more rapid clinical assessment and COVID-19 therapeutics prescriptions for those with symptomatic COVID-19 in long term care facilities. Taken all together, these strategies promoted expansive systems changes to the delivery of healthcare to enable easier and more equitable access to these time-sensitive medications.

Finding/Corrective Action: A multi-pronged approach is necessary to promote systems changes in healthcare to enable more equitable access to care. CDPH has the opportunity to replicate and expand upon the successful Test-to-Treat model for future pandemics. (ID: Therapeutics 4)

5. CDPH used an innovative data analytics approach to better allocate therapeutics in disadvantaged communities.

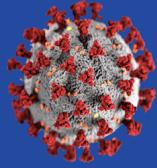
Until November 2021, data was not available on COVID-19 therapeutics utilization rates. The sole available data prior to that was limited to the order requests CDPH received from LHJs, which were maintained in Excel spreadsheets. When the federal government implemented the Health Partner Ordering Portal (HPOP), CDPH gained access to ordering and shipping data of all COVID-19 therapeutic products coming into the State. In addition, due to federal mandates, COVID-19 therapeutic



providers were required to report daily in HPOP, providing details on the number of treatment courses administered and inventory on-hand by product type. CDPH staff used this data to calculate the overall percentage of product utilization.

However, CDPH did not have patient-specific data on who received treatment, which could have informed equity considerations. To address this issue, the Therapeutics Task Force devised an innovative approach, which involved cross-referencing shipping data with provider-reported administration data at the local level. This methodology allowed the team to evaluate therapeutic utilization by zip codes categorized within Healthy Places Index (HPI) quartiles, revealing valuable insights into gaps in therapeutic administration across California. Moreover, this qualitative data allowed CDPH to measure allocation levels and identify opportunities. CDPH then worked with the large pharmacy chains to redistribute allocations or activate new store locations in disadvantaged communities.

Finding/Corrective Action: CDPH developed a successful data-driven model to monitor equitable access to therapeutic treatment and make adjustments, as necessary, which should be incorporated as early as possible in future responses. (ID: Therapeutics 5)



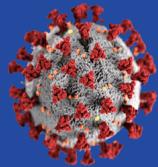
Main Challenges and Lessons Learned

This section describes the Main Challenges and Lessons Learned, including findings and corrective actions, related to this chapter. Further elaboration and a more detailed discussion of these challenges and lessons learned can be found in the Analysis of Activities section.

6. The Therapeutics Task Force was not adequately resourced, which hindered CDPH's ability to adequately respond when the federal government began distributing newly authorized treatments mid-way through the pandemic.

In March 2020, CDPH established the therapeutics work group to oversee the allocation and administration of medical countermeasures, including COVID-19 treatment drugs. Initially, the work group managed the allocation of Veklury (remdesivir) when it received emergency use authorization in May 2020, but the work group lacked a dedicated communications team to disseminate information and guidance about the drug. The work group's role in therapeutics allocation diminished as the drug became commercialized in October 2020 and their work phased out in February 2021 when federal control over the national supply ended. Subsequently CDPH significantly scaled back its therapeutics activities and handed it off to the COVID-19 clinical team to serve as subject matter experts.

In the summer of 2021, the federal government abruptly resumed allocations for newly authorized monoclonal antibody treatments without advance notice to the states. The subsequent 6 months were challenging as the clinical team was not resourced to handle this sudden influx of logistics, allocations, and supply chain issues around drug shipping and receiving. Consequently, the work group was reconvened with many of the same personnel who had assisted with Veklury. Recognizing the need for a more active role in providing clinical guidance, improving equity in distribution, and communicating therapeutic benefits, CDPH then created a new Therapeutics Task Force in late 2021. The Task Force needed to ramp up its activities but did not have the commensurate level of resources compared to other COVID-19 task forces, such as a dedicated communications team. In mid-2022 the Task Force received additional resources to improve LHI, provider,



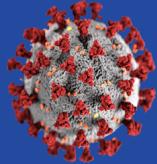
and public communication and outreach. However, this should have been done sooner according to SMEs.

Finding/Corrective Action: In future pandemics, CDPH should apply lessons learned from the Therapeutics Task Force to anticipate, plan, and devote adequate resources (such as communications) for response activities that can be scaled up quickly due to changing circumstances. (ID: Therapeutics 6)

7. CDPH was limited in its ability to affect systems change with its healthcare partners that could have successfully socialized the presence of the new COVID-19 therapeutics medical countermeasure and ensured equitable access.

It takes approximately ten to seventeen years for health research and/or drug discoveries to reach and change clinical practice. In the case of COVID-19 therapeutics, the expectation and need was that this transformation to clinical practice needed to happen within months to 1-2 years in order to have meaningful impact for a global pandemic crisis. Two audiences that needed to undergo significant changes in order for COVID-19 therapeutics to be optimally used and accessed were the public and the healthcare community. In order for COVID-19 therapeutics to be accessed equitably by the public, healthcare delivery systems and payers needed to be aligned in enabling that access.

CDPH was limited in its position, authority, and influence on the healthcare delivery system. Early efforts of the COVID-19 therapeutics Task Force, in part due to limited resources, were on provider education. However, education often is not enough to change clinical behavior. Quality improvement initiatives in healthcare spaces often requires concerted investment and effort in process changes to achieve the desired outcome, which, in this case, was expedited triaging of symptomatic patients to be tested for COVID-19 and if positive, expedited process flow to a prescriber and dispensed medication. The Therapeutics Task Force attempted in multiple ways to engage healthcare systems change with some success. These strategies included clinical playbooks, best practice guidance aimed at healthcare systems and payers, collaboration with healthcare partners, and funding and technical assistance to safety-net providers to promote



Test-to-Treat clinical workflows. However, the main levers for change in healthcare—financial incentives, disincentives, requirements—were not in CDPH's purview and hence the ability to reform the system that distributes COVID-19 therapeutics was limited.

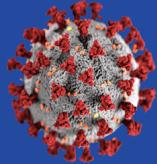
Finding/Corrective Action: Future efforts should prioritize healthcare systems change earlier and include more effort to foster partnership with healthcare providers and payors. (*ID: Therapeutics 7*)

8. The federal government launched a new therapeutics ordering system quickly, creating challenges for CDPH, LHJs, and healthcare providers to initially manage the allocation and ordering process.

In November 2021, the federal government introduced the Health Partner Ordering Portal (HPOP) to automate the process for managing orders of COVID-19 therapeutic products. Although CDPH continued to oversee orders, this new federal system brought changes in order processing and enabled LHJs and healthcare providers to directly track their therapeutics orders and shipments. The transition to HPOP unfolded over a four-month period during which CDPH staff navigated both the new and old ordering systems, as drugs were phased into HPOP. By February 2022, CDPH was managing orders for eight authorized COVID-19 therapeutic products, significantly increasing the workload. However, HPOP proved less user-friendly than expected. This transition posed challenges not only for CDPH but also for LHJs and healthcare providers due to its swift launch, minimal coordination, and limited training. CDPH staff learned the system simultaneously with LHJs and providers while facing ongoing system issues. The federal government's HPOP helpdesk directed callers back to CDPH for support, making CDPH staff the de facto local-level support for the federal HPOP system.

Finding/Corrective Action: Since the federal government will utilize HPOP for medical countermeasures ordering and inventory tracking for future pandemics, CDPH should identify staff to receive training and become proficient users of the system for future activations. (*ID: Therapeutics 8*)

9. The Therapeutics Task Force would have been more effective if the pandemic response functions encouraged cross-task force initiatives.

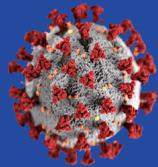


The lack of robust coordination and communication among the various CDPH and Governor's task forces on cross cutting policies during the COVID-19 response hindered the Therapeutics Task Force's ability to perform some of its activities. For instance, when CDPH initiated the Test-to-Treat program, which encouraged healthcare providers to provide end-to-end testing, prescription, and dispensing services, there was a missed opportunity for collaboration between the Testing Task Force and the Therapeutics Task Force to synchronize guidance. Each task force independently developed and implemented its own policies without necessarily informing the other task forces of important initiatives.

Additionally, efforts to engage the healthcare system would have likely been more coordinated and potentially more impactful if the Vaccines, Testing, and Therapeutics Taskforces were more unified in their approach to healthcare delivery systems and healthcare payors. All three Taskforces worked to change norms in how healthcare approached and enabled access to vaccines, testing, and therapeutics but the strategies used by these three Taskforces were independently crafted and executed.

Another example involved the Therapeutics Task Force's desire to adopt successful practices from the Vaccinate All 58 (VA58) public communications campaign, which implemented robust communication strategies and effective community outreach pathways. The Therapeutics Task Force team made attempts to foster partnership and collaboration with the VA58 team with the goal of aligning messaging/dissemination strategies and learning from their best practices. The VA58 team eventually reciprocated engagement, such as by inviting the Therapeutics Task Force to participate in their monthly community-based organization webinars. However, the Therapeutics Task Force wanted more frequent and meaningful opportunities to collaborate to leverage best practices, venues for messaging, and opportunities for partnership with the network of CBOs that VA58 collaborated with.

Finding/Corrective Action: To enhance future pandemic responses, CDPH should establish a structured process to facilitate coordination and collaboration among task forces, ensuring alignment of policies, decisions, and communications. (ID: Therapeutics 9)

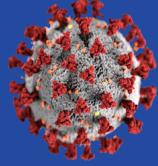


10. Therapeutics data limitations hampered CDPH's ability to conduct comprehensive equity analyses.

While CDPH developed an innovative methodology to evaluate therapeutic utilization, revealing valuable insights into gaps in therapeutic administration across California, data limitations prevented more robust analyses. Up to 30% of providers failed to comply with the federal government's semi-weekly therapeutics reporting requirements, leaving a substantial data gap, although the Therapeutics Task Force worked with LHJs to shrink this number to 5-10%. Also, reporting rates varied among provider types, with chain pharmacies exhibiting higher reporting rates than local health clinics. Moreover, providers were not required to report details about the recipients of therapeutic treatment, resulting in the unavailability of patient demographic data. Since it is not standard practice to collect demographic data for any prescription in general, it is not surprising that data collection proved to be a problem in the case of COVID-19 therapeutics.

These challenges limited CDPH's efforts to conduct more comprehensive data analysis for decision-making, for evaluation of equity in treatment, and for establishing a dashboard that accurately portrayed therapeutics utilization. To address these challenges in the future, SMEs recommended that CDPH explore alternative data sources and analytical methods to enhance reporting capabilities. For example, collecting data from patients before a telehealth visit could help measure equitable access. Several SMEs expressed the need for more resources dedicated to therapeutics data analysis and dissemination, comparing it to the robust data and reporting mechanisms established for vaccines. However, CDPH will always be limited somewhat by what systems the federal government opts to put into place. The data accessible for therapeutics was not nearly as detailed as data collected by the California Immunization Registry (CAIR) for vaccines.

Finding/Corrective Action: CDPH has the opportunity in future pandemics to devote specific resources to therapeutics data analytics to identify data sources, develop appropriate analytical methodologies, and create and maintain a therapeutics dashboard. (*ID: Therapeutics 10*)



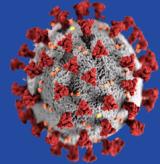
11. The Therapeutics Task Force communications team was initially hampered due to organizational challenges.

The Therapeutics Task Force's communications team initially faced challenges that prevented them from responding quickly to the continually changing therapeutics environment. Unlike the VA58 team, which used a streamlined messaging approval process through the Governor's Office and often separate from CDPH's content approval process, the therapeutics communications team adhered to the lengthier traditional CDPH approval process. For example, PDF documents to be published on the CDPH website often involved several rounds of review and remediation over several weeks to months, especially related to challenges with designing for ADA compliance. This was less than ideal as there were so many rapid changes to therapeutics given the changing variant resistance patterns. Thus, the CDPH website was typically out of date due to the lengthy approval process making it virtually impossible to communicate timely information to those who needed it most. Most providers and patients started to turn to social media platforms such as Twitter or the general news to obtain current information, rather than from trusted resources. To improve preparedness for future pandemics, SMEs recommended streamlining the therapeutics communications review and approval process to help ensure timely information dissemination.

Finding/Corrective Action: For future pandemics, CDPH has the opportunity to establish a therapeutics communications approval process that identifies responsibilities for approval, sequence of approvers, and timeframe for approval. (*ID: Therapeutics 11*)

12. There was a missed opportunity to identify barriers and develop appropriate messaging to address misconceptions about therapeutics administration earlier in the pandemic.

In early 2022, the data reflected a gap in the amount of therapeutics ordered versus the amount that was being prescribed. To better understand the low uptake in COVID-19 treatment and impediments to prescribing, the Therapeutics Task Force conducted a needs assessment survey of LHJs to gauge healthcare provider awareness and to obtain input on potential ways to remove the barriers. The results revealed an



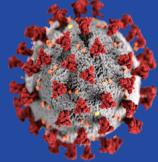
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“artificial concern” that promoting therapeutics would discourage people from getting vaccinated, according to one SME. Also, some healthcare providers were hesitant to prescribe treatments that were under emergency use authorization. In addition, several myths persisted, namely there was not enough therapeutics supply for all who needed it, the drugs were difficult to access and/or expensive, and that only the sickest, oldest or those with multiple clinical issues could qualify. The Therapeutics Task Force found the survey information very useful to understand the “systemic issues,” which subsequently assisted them in finding “ways to remove barriers in order to move the needle.” Furthermore, several SMEs noted that, in retrospect, if they had known this information earlier in the pandemic, they could have developed and implemented communication strategies that would have addressed these misconceptions much sooner.

Finding/Corrective Action: CDPH has the opportunity to establish information feedback loops with LHJs and healthcare providers to identify barriers and misinformation and begin developing effective communication strategies to address issues earlier in future emergencies. (ID: Therapeutics 12)



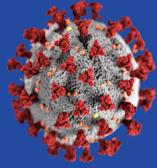
Analysis of Activities

This section elaborates and provides more detail on the findings, corrective actions, and lessons learned that are presented in the Main Strengths and Successes and the Main Challenges and Lessons Learned sections.

Ordering, Allocation, and Distribution

CDPH Activated its Emergency Preparedness Plan for Medical Countermeasures

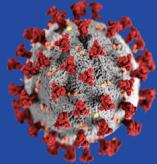
- During the initial stages of the pandemic, healthcare providers began experiencing shortages of essential medical supplies and formulary drugs, which were crucial for treating COVID-19 patients in healthcare settings. To respond to this urgent need, CDPH activated its existing *Emergency Preparedness Office Operational Plan and Procedures for Receiving and Distributing Medical Countermeasures (MCMs)*. MCMs include the following items: 1) biological products, such as vaccines, blood products, and antibodies; 2) drugs, such as antimicrobial and antiviral drugs; and 3) devices, such as personal protective equipment (PPE), respirators, face masks, and ventilators. The plan and associated procedures define the mechanisms for requesting and activating needed MCM, including those from the Centers for Disease Control and Prevention (CDC), commonly referred to as the Strategic National Stockpile (SNS).
- In March 2020, CDPH formed a therapeutics work group to oversee the implementation of the plan and procedures, including the management of key clinical and operational aspects of drugs used to treat COVID-19. Led by a CDPH pharmacist and supported by a dedicated logistics team, the work group efficiently handled the logistics of drug supplies. They worked in collaboration with LHJs and other stakeholders to assess needs and allocate drugs accordingly. To address supply shortages, the work group proactively engaged with the SNS and drug manufacturers to secure additional stock. Furthermore, the team developed comprehensive guidelines, policies, and communication protocols for the appropriate use of COVID-19 medical countermeasures. The work group operated with a similar structure as the other Governor's COVID-19 task forces, albeit without the equivalent resources and support, and provided clinical guidance, statewide allocation and distribution policies, and promoted equity.



- This chapter focuses on the allocation and administration of monoclonal antibodies and oral antiviral treatments, commonly referred to as COVID-19 therapeutics. For a discussion of the allocation, distribution, and administration of other MCMs, see the Logistics, Distribution, and Warehouse chapter of this AAR.

Allocation and Ordering Process Developed for First COVID-19 Authorized Treatment

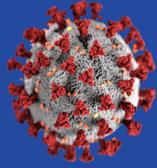
- When the first therapeutic for COVID-19, the antiviral treatment Veklury (remdesivir), obtained federal Emergency Use Authorization (EUA) in May 2020, the U.S. Department of Health and Human Services, Administration for Strategic Preparedness and Response (HHS/ASPR) purchased the national supply from the manufacturer for allocation to the states. In California, the work group devised a systematic ordering and allocation process to distribute the State's allocation fairly among local jurisdictions.
- Every week, California's Regional Disaster Medical Health Coordinators (RDMHC) and Medical Health Operational Area Coordinators (MHOAC) submitted spreadsheets to CDPH containing the number of hospitalizations and ICU utilization in their respective jurisdictions, along with their order requests. CDPH staff consolidated this information and developed a master spreadsheet with algorithms to portion out the State's allocation to the LHJs. These algorithms took into account key factors, including hospital population, disease burden, and new cases, to calculate each county's allocation in relation to the overall allocation given to the State. This approach equitably distributed Veklury to all regions within the State, based on their specific needs and circumstances.
- The work group also placed orders on behalf of the local jurisdictions. CDPH staff transferred the allocation information in the master spreadsheet to an ordering form. The form was then emailed to the third-party distributor, AmerisourceBergen, to process and ship the order. In the fall of 2020, AmerisourceBergen implemented an online portal through which CDPH staff input orders, but staff still maintained the Excel spreadsheets to track and calculate allocations.
- The State's role in managing allocations of Veklury was relatively brief. With the drug's commercialization in October 2020, the State's involvement in allocation and ordering diminished, and in February 2021, stopped



altogether when HHS/ASPR ceased control of the national supply. LHJs and health care providers could then order Veklury directly from the third-party distributor, AmerisourceBergen. As a result, the work group's activities significantly scaled down to focus primarily on developing therapeutics policy and guidance and to monitor the federal government's authorization of new COVID-19 treatments.

CDPH Reinstated Allocations for Newly Authorized Therapeutics

- From November 2020 to May 2021, the federal government granted EUAs for three additional monoclonal antibody treatments including bamlanivimab plus etesevimab, casirivimab plus imdevimab, and sotrovimab. These therapeutics were not allocated to the states until late summer of 2021. In late summer 2021, the rapid spread of the COVID-19 Delta variant led to a significant uptick in the utilization of monoclonal antibody products across the country. A few months later, in December 2021, two oral antivirals, Paxlovid (nirmatrelvir co-packaged with ritonavir) and Lagevrio (molnupiravir), and another monoclonal antibody, Evusheld (tixagevimab co-packaged with cilgavimab), received EUAs, which the federal government also started sending to the states.
- The federal government's decision to restart therapeutic allocations in late summer 2021 caught the states, including California, off guard. Since the therapeutics work group had previously scaled back its activities, CDPH was not prepared for the logistical challenges of allocating and distributing multiple monoclonal antibody and oral antiviral products.
- CDPH leadership recognized that with multiple COVID-19 therapeutic products receiving EUAs and additional therapeutics likely to receive authorization in the future, CDPH needed to take a larger role to provide clinical guidance, promote equitable allocation and distribution, and communicate the benefits of therapeutics to healthcare providers and the public. Consequently, the work group ramped up its activities. Given that there were now multiple treatments available, the work group re-evaluated its processes for determining allocations. In addition, the workload substantially increased because the work group now maintained a separate spreadsheet for each therapeutic drug and managed allocations for the various authorized treatments. Furthermore, AmerisourceBergen had made changes to its ordering system, which required states to enter orders separately on behalf of each LHJ and provider.



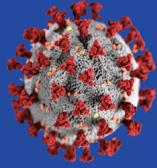
- The work group updated its roles and responsibilities and developed an organizational structure to manage allocating and ordering COVID-19 therapeutics. A project manager and dedicated staff were resourced to manage clinical guidelines, communications, data analytics to inform equity considerations, allocation methodologies, ordering, logistics, and media inquiries. One leader highlighted the pivotal role of project management, along with twice-weekly meetings and centralized document management, stating that these were "responsible for a lot of our success in keeping the ball rolling." This team was officially recognized as the Therapeutics Task Force in October 2021.

CDPH Selected Two Federal Retail Pharmacy Therapeutics Program Partners

- In fall 2021, the federal government announced the Federal Retail Pharmacy Therapeutics Program (FRPTP) for COVID-19 therapeutics, which was a public-private partnership to equitably increase therapeutics access across the country. The program was a collaboration between the federal government, state and local health departments, and 20 national and independent pharmacy networks. The FRPTP was modeled after the Federal Retail Pharmacy Program (FRPP) for COVID-19 vaccines.
- In December 2021, CDPH selected CVS and RiteAid as its FRPTP partners after concluding that these two partners covered most of the State and reached more of the State's priority equity areas than other combinations of partners. Unlike in the vaccine rollout, the two pharmacies did not receive their own separate allocations. Rather, the LHJs designated a portion of their allocation to the two pharmacies. Based on this LHJ input, CDPH determined how much of the State's overall allocation to apportion to the two pharmacies. CVS and Rite-Aid then allocated their therapeutics by prioritizing stores with drive through service, testing sites, with specific inventory systems and storage capacity, and within locations in disadvantaged communities.

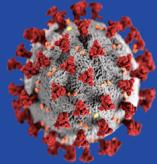
Ordering Process Transitioned to HPOP, the Federal Government Portal

- In November 2021, HHS/ASPR launched the Health Partner Ordering Portal (HPOP). While CDPH still continued to manage the orders, this new federal system changed how orders were processed and allowed LHJs and healthcare providers to monitor their therapeutics orders and shipments.

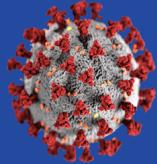


HHS/ASPR phased in the drugs available for order through HPOP over a four-month period. Initially, HPOP was used only for Evusheld (a monoclonal antibody) orders. Next, the authorized oral antiviral medications were incorporated into the system in December 2021. By February 2022, the remaining monoclonal antibodies were added to HPOP. During this four-month period, CDPH staff managed therapeutics ordering in two systems; if the drug had not yet been added to HPOP, then it was ordered through the third-party distributor's system. By the time all the drugs had been added to HPOP in February 2022, CDPH was managing the ordering for eight different authorized COVID-19 therapeutics. This transition to HPOP significantly increased the workload because staff had to maintain the existing allocation spreadsheets for the different products and then input that same information into HPOP.

- HPOP proved to be less user-friendly than anticipated and CDPH staff frequently encountered issues with processing orders accurately. As one SME noted, "HPOP wouldn't do what it's supposed to do," forcing them to devise alternative methods to complete the ordering process correctly. Adding to the complexity, AmerisourceBergen, the third-party distributor, directly pulled orders from HPOP, making it imperative that the information within the system be precise. As a result, CDPH staff engaged in meticulous and time-consuming quality assurance checks to minimize the risk of errors during the ordering process.
- The transition to HPOP was not only challenging for CDPH, but for the LHJs and healthcare providers as well. Because HHS/ASPR required users to set up an account in the system, CDPH took on the responsibility to enroll providers in HPOP. This required CDPH staff to work with the LHJs to identify the provider sites. Then CDPH staff had to make a "mad scramble" to go in and manually add, set up, and adjust permissions for approximately 3,000 provider sites, recalled one SME. The other complicating factor was that, once enrolled, CDPH and the LHJs had to onboard the healthcare providers so they became familiar with using HPOP. One requirement was that healthcare providers had to activate their accounts by confirming their site address and hours of operation. Often, providers did not understand how to activate their account and CDPH staff spent considerable time troubleshooting and assisting them.



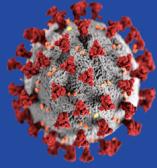
- According to several SMEs, the challenges that CDPH, LHJs, and providers experienced can be attributed to the swift launch of HPOP (with only three weeks' notice) and the lack of coordination or training. CDPH staff were learning the system at the same time as the LHJs and healthcare providers, all while simultaneously using the system. According to one SME, "just as we would learn something, we would send notices" to the LHJs so that they could inform the providers. Furthermore, the HHS/ASPR HPOP helpdesk referred LHJs and providers requesting assistance back to CDPH instead of assisting them directly. Consequently, CDPH staff became the de facto support for the federal HPOP system at the local level.
- When HHS/ASPR launched a direct ordering feature in April 2022 that allowed healthcare providers to order therapeutic products directly in HPOP, the State decided to opt out. Instead, CDPH continued its existing allocation and ordering procedures because CDPH leadership concluded that implementing direct ordering at the local level would not be operationally feasible. Equity, a long-standing focus for CDPH, would have been particularly difficult to maintain under a direct ordering system. By managing allocations to LHJs and healthcare providers, CDPH could target allocations to specific disadvantaged areas, using the Healthy Places Index (HPI) quartiles, and adjust product distributions to improve equitable access. CDPH would have lost its ability to take this targeted approach if direct ordering had been implemented. LHJs would also have lost valuable insights into which providers within their jurisdictions were requesting products and where those products would be available. Operational challenges were another concern. Enabling a direct ordering system would have required CDPH staff to make manual adjustments in each provider's record. Every order submitted by providers would have needed to be individually reviewed and either approved or denied by CDPH, creating a substantial workload.
- CDPH required providers using HPOP to consistently report their therapeutic supplies inventory. If this reporting was not completed, inventory levels for these providers would be inaccurately inflated, making it difficult for CDPH to validate new order requests. To tackle this issue, CDPH launched a communication campaign in June 2022 underscoring the critical need for providers to keep their inventory levels current in HPOP. As a further measure, CDPH began withholding orders from providers who neglected to report their inventory. Although these steps resulted in some improvements, providers continued to require ongoing reminders to update their inventory records.



- HPOP was originally designed to enable states, LHJs, and healthcare providers to order, distribute, and track inventory of COVID-19 medical countermeasures. In 2023, HHS/ASPR enhanced HPOP to order other federally supplied medical countermeasures and other resources needed for future public health response operations, as needed. Since HPOP has been designated as the primary system for ordering medical countermeasures for future responses, CDPH will need to maintain knowledge of how to use the system. One SME suggested that CDPH designate a full-time position, with technology expertise, "who will have the muscle memory to fire HPOP back up in the event of a new emergency."

Emergency Use Authorization Revoked for Monoclonal Antibody Treatments

- In early spring 2022, the Federal government revoked the emergency use authorizations (EUAs) of several monoclonal antibody treatments, including bamlanivimab and etesevimab (administered together), REGEN-COV (casirivimab and imdevimab), and sotrovimab due to their ineffectiveness against the COVID-19 Omicron variant. This was followed by the revocation of the last authorized monoclonal antibody drug, Evusheld, in January 2023. Consequently, by early 2023, the State was only allocating two oral antiviral medications authorized for emergency use, Paxlovid and Lagevrio.
- CDPH utilized an allocation strategy rooted in both population metrics and health equity to distribute the two oral antiviral medications. The State's supply was divided into two equal portions. One half was allocated based on each county's proportion of COVID-19 cases recorded over the prior two-week period. The remaining half was allocated according to population characteristics, giving greater weight to populations residing in lower health equity quartiles. LHJs were then allowed to order up to their allocated threshold. Sometimes LHJs would not order their full amount, a circumstance that occasionally arose due to the complexities with prescribing outpatient COVID-19 treatments at the local level.
- LHJs managed all the COVID-19 therapeutic provider sites within their jurisdictions. If a provider wanted a new site to distribute oral antiviral medications, it submitted a request to the LHJ for vetting. Following successful approval, the LHJ forwarded the site's details to CDPH for enrollment in HPOP.

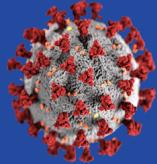


- Each week, LHJs received their allocation totals and completed an ordering sheet to distribute specific quantities to their various site locations. Thus, LHJs essentially determined the volume of products allocated to each site in their jurisdiction, except for the large chain pharmacies that participated in the federal government's Test-to-Treat initiative that launched in December 2021. Originally, both CDPH and LHJs played a role in prioritizing the distribution to pharmacy locations based on equity considerations. However, when the federal government made allocations for Test-to-Treat, these major pharmacy chains determined the distribution of oral antiviral medications to their individual store locations. They committed to maintain a robust inventory in locations that had been previously identified by CDPH and LHJs as equity priorities.

Clinical Guidance

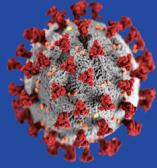
Therapeutics Clinical Workstream Established

- In the summer of 2021, health care providers began to receive their State allocations of monoclonal antibody treatments. These COVID-19 treatments were administered intravenously or by injection in outpatient healthcare settings, which required monitoring patients closely for adverse reactions. When arranging the infusion space, the health care provider took into account several factors, including patient entry/exit patterns, patient flow within the facility, ventilation, and the potential risk of exposing other patients to COVID-19. Consequently, these health care providers needed clinical and operational guidance on proper therapeutic administration.
- To meet the need for clinical guidance, CDPH established a clinical workstream to develop and disseminate comprehensive guidance that addressed the complexities of monoclonal antibody treatments. Members of CDPH's clinical team embarked on a thorough review of the prescribing guidelines. This team developed generalized guidance for monoclonal antibody treatment for providers and facilities as well as fact sheets with treatment guidelines for each of the monoclonal antibody drugs.
- When the Therapeutics Task Force was established in late 2021, it incorporated the existing clinical workstream into its activities, at which point the clinical role expanded with the designation of the therapeutics clinical team. The therapeutics clinical team conducted literature reviews and made presentations on clinical topics to CDPH leadership, LHJs, and healthcare



providers. This team also collaborated extensively with the Therapeutics Task Force's communications team on provider and public outreach, including providing the clinical perspective on therapeutics messaging and participating as SMEs in the weekly LHJ and provider webinars. When CDPH received reports that some providers mistakenly believed that Paxlovid caused a high COVID-19 rebound rate, the clinical team wrote a [health advisory](#) highlighting facts around this.

- Throughout 2022, the landscape of COVID-19 therapeutics was in a constant state of flux. At one point, three oral antiviral and five monoclonal antibody treatments were authorized for emergency use. However, as the scientific evidence evolved, the monoclonal antibody treatments proved to be ineffective against the emerging COVID-19 variants and their EUAs were revoked. Consequently, by early 2023, only two oral antiviral treatments, Paxlovid and Lagevrio, were authorized for emergency use. Veklury, another antiviral treatment, was already available through the commercial market, since it had received commercial use approval in October 2020.
- This shifting landscape of treatment options and prescription guidelines generated confusion among healthcare providers. CDPH received numerous reports detailing issues such as providers' unfamiliarity with new medications, challenges in identifying contraindications and potential drug interactions, and instances where treatment was denied to eligible patients. In an effort to mitigate these issues, the clinical team prepared guidance that was issued in a [health advisory](#) in December 2022, which urged healthcare providers to evaluate all symptomatic individuals who tested positive for COVID-19 for COVID-19 treatment. This was a frame shift from previous messaging with monoclonal antibodies, which had focused on reserving treatment for those with the most severe underlying conditions and/or severity of disease. Antivirals were much more widely available than monoclonal antibodies, so providers had become accustomed to reserving treatment only for the most at-risk individuals. The advisory aimed to reduce obstacles to prescribing therapeutics, with particular attention given to populations disproportionately affected by COVID-19, such as communities of color, low-income neighborhoods, and residents of long-term care facilities. Following the release of the advisory, SMEs observed a noticeable increase in the utilization of therapeutics.

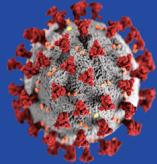


Test-to-Treat

Federal Government Launched Test-to-Treat Initiative

- In December 2021, when the oral antiviral drugs Paxlovid and Lagevrio obtained EUA designation, supplies were initially limited. By early March 2022, production accelerated and supplies started to increase. Concurrently, healthcare systems encountered significant challenges to facilitate streamlined testing and treatment. This resulted in the public experiencing difficulties in accessing COVID-19 oral antiviral drugs promptly. Timely administration is extremely important as the effectiveness of these drugs relies on starting treatment within five to seven days of symptom onset.
- The federal government launched the COVID-19 Test-to-Treat initiative to expand options for the public to receive free treatment. Test-to-treat facilities are locations where individuals can get tested for COVID-19, prescribed COVID-19 therapeutics if appropriate, then have the medication dispensed at the same location. By allowing patients to obtain a therapeutic prescribed and dispensed at the same location, the likelihood of getting on-time treatment increased, especially for patients with limited mobility or modes of transportation. The federal COVID-19 Test-to-Treat initiative did not replace the existing direct allocation system of therapeutics in California.
- HHS/ASPR designated federally qualified health centers, existing pharmacy partners participating in the Federal Retail Pharmacy Therapeutics and the Federal Pharmacy Partnership for Long-Term Care programs, and long-term care facilities as Test-to-Treat facilities. These providers received their therapeutic allocations from the federal government rather than from the State's allocation. These healthcare providers were required to provide rapid testing, provide in-person or telehealth prescribing capabilities, and to dispense COVID-19 oral antivirals according to California state law. Ideally, testing, prescribing, and dispensing services were housed in the same facility, but HHS/ASPR allowed clinics and pharmacies to co-locate in proximity to each other to offer services. HHS/ASPR created a [Test-to-Treat locator webpage](#), available in English, Spanish, and Chinese, for the public to locate Test-to-Treat facilities. HHS/ASPR also provided a toll-free number to assist patients in finding Test-to-Treat sites.

Therapeutics Task Force Expanded to Implement Test-to-Treat

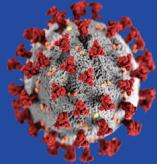


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- In April 2022, CDPH added a team to the Therapeutics Task Force to increase the number of Test-to-Treat providers in California. This new team created the State's Test-to-Treat policies, guidelines, and communications. The team also developed detailed criteria that a qualified healthcare provider needed to meet to become a Test-to-Treat location, including:
 - Offer services to all individuals, regardless of insurance status or ability to pay;
 - Have hours of operation and language translation services that accommodated local community needs;
 - Provide comprehensive end-to-end testing, evaluation for treatment, and prescription-dispensing services for a seamless patient experience;
 - Conduct rapid COVID-19 testing (result available at time of visit) on-site or provide an evaluation of at-home testing results;
 - Provide timely and thorough assessment and discussion relevant to treatment option(s), consistent with FDA requirements regarding these therapeutic options;
 - Readily dispense oral medications to eligible patients; if necessary, direct prescriptions to pharmacies that have expedited home delivery services; and
 - Have a plan to refer patients to a provider able to offer infusion services should oral medications be contraindicated, and the patient needs to receive either a monoclonal antibody (e.g., bebtelovimab) or IV remdesivir.
- Test-to-treat providers could also request federal support for testing, contracting, and reimbursement. The provider had to also meet the federal government's eligibility criteria, which included providing end-to-end test and treat services on-site (this could include telehealth accessed on-site), offering services to all individuals regardless of insurance status, accepting Test-to-Treat patients for priority same-day or next-day visits, providing services at no charge to patients, and being located in counties with high Social Vulnerability Index (SVI) scores. LHJs coordinated with their MHOAC to request federal support for sites in their area.
- CDPH and LHJs encouraged healthcare providers that wanted to become a Test-to-Treat site to create operational workflows that facilitated patients'

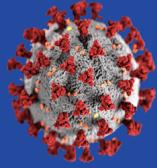


connection to a prescriber and a prescription if they tested positive for COVID-19. While some sites offered a full range of testing, prescribing, and dispensing services, some locations only dispensed the product. This meant that in order to access Paxlovid or Lagevrio, patients needed to first obtain a prescription from a healthcare provider and then take it to a dispensing location that had COVID-19 therapeutics on-hand. Healthcare providers were urged to examine their workflows to minimize the number of places a patient had to go to access medications. This included ensuring patients were able to receive same-day consultation (in-person or via telehealth) and were accurately directed to pharmacies carrying oral COVID-19 therapeutics. To assist healthcare providers in identifying pharmacies, the federal government established a [locator for sites that dispensed oral antiviral medications](#) or administered monoclonal antibody infusions, which was a separate website from the federal Test-to-Treat locator.

- CDPH and LHJs urged sites that offered testing, prescribing, and dispensing to contact their LHJs to get added to the federal Test-to-Treat locator. Increasing the number of providers in the federal Test-to-Treat locator helped patients who could not access therapeutics through their regular healthcare provider to identify Test-to-Treat locations in their area, thereby closing equity gaps in therapeutics access.
- Despite these efforts, many clinics serving disadvantaged groups, specifically low-income individuals, BIPOC (Black, Indigenous, and People of Color), the uninsured, and the underinsured either did not implement Test-to-Treat procedures nor participate in the Test-to-Treat locator. As a result, these vulnerable populations, particularly those experiencing homelessness or residing in remote rural areas distant from licensed pharmacies, continued to face disproportionate hurdles in accessing COVID-19 therapeutics.

Testing Sites Converted into Test-to-Treat Facilities

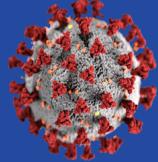
- In May 2022, CDPH engaged Optum Serve, a contractor already providing testing services, to convert its facilities to 146 Test-to-Treat sites in high-need, low-access areas of the State to help address ongoing inequities in therapeutics access. Once the testing sites converted, approximately 90% of the State's population lived within a 30-minute driving distance from a Test-to-Treat site. The Optum Serve Test-to-Treat sites offered an end-to-end service with antigen testing, telehealth prescribing for COVID-positive patients, and on-site Paxlovid and Lagevrio dispensing.



- CDPH utilized the existing contract for testing services, which the Testing Task Force continued to manage, while the Therapeutics Task Force managed the Test-to-Treat operations. While this arrangement could have provided the opportunity for the task forces to collaborate on the Test-to-Treat initiative, in reality there was limited coordination between the two task forces, according to several therapeutics SMEs. Each task force made policy and allocation decisions independently. In hindsight, if the two task forces coordinated more on their daily operations the Test-to-Treat initiative would have been more effective, according to several therapeutics SMEs.
- Prior to converting to the Test-to-Treat model, the Optum Serve sites were not enrolled in the HPOP system since testing services did not dispense medications. When the sites converted to Test-to-Treat facilities, however, the Therapeutics Task Force asked Optum Serve to register its sites in HPOP. Also, since Optum Serve received 10% of the State's therapeutics allocation and did not have to coordinate its orders with the LHJs and MHOACs, the Therapeutics Task Force requested that the sites process and manage their own orders in HPOP. However, Optum Serve did not comply with either request because the Therapeutics Task Force did not manage their contract and lacked the authority to amend and/or enforce the agreement. Consequently, the Therapeutics Task Force team members enrolled and ordered for the 146 Optum Serve sites.
- Throughout Optum Serve's Test-to-Treat operations, the Therapeutics Task Force fielded complaints from both site personnel and patients. Site managers and pharmacists frequently reported a shortage of supplies, which was a byproduct of the Optum Serve sites not managing their orders directly in HPOP. Several SMEs noted that patients would also encounter issues, such as the unavailability of healthcare professionals authorized to prescribe therapeutics and/or a lack of medications on hand at the sites.
- In early 2023 when the California State Board of Pharmacy terminated the waiver that allowed drug dispensing at Optum Serve locations CDPH and Optum Serve mutually agreed to shut down their Test-to-Treat sites.

Test-to-Treat Playbook Released

- While the Therapeutics Task Force communicated regularly with LHJs and healthcare providers through the weekly webinars and newsletters, these stakeholders needed a comprehensive resource on the State's policies and

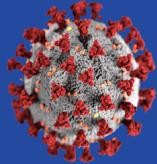


procedures for therapeutics administration. To meet this need, the Therapeutics Task Force created a comprehensive [Test-To-Treat Playbook](#) in July 2022, a significant achievement that was accomplished in a tight timeframe. The playbook was primarily designed for LHJs, healthcare providers, pharmacists, healthcare delivery systems, and health plans that were implementing Test-to-Treat initiatives. It specifically addressed the administration of Paxlovid and Lagevrio, two antiviral medications integral to the Test-to-Treat program.

- The playbook served as an in-depth guide and covered various facets of COVID-19 therapeutic management, including clinical guidelines, allocations, distribution and logistics, and best practices for improving access. Key sections of the playbook encompassed testing, prescriptions, dispensing, and data reporting procedures. It provided billing and reimbursement guidance for the insured, under-insured, and non-insured. Additionally, it included federal and State legal and regulatory requirements on who could prescribe and dispense therapeutics, and alternatives for e-prescriptions.
- Shortly after the playbook was published, the California State Board of Pharmacy issued the [waiver](#) that allowed pharmacists to independently prescribe Paxlovid to patients. This significantly increased the number of COVID-19 therapeutic prescribers in the State. For example, large health systems with integrated pharmacies could now train their pharmacist staff to prescribe Paxlovid to patients. Also, in rural locations where healthcare providers were not readily accessible, pharmacists could fill gaps in COVID-19 therapeutics access. Subsequently, the Therapeutics Task Force updated the playbook in October 2022 to ensure that the stakeholders had the most current information at their disposal.

Telehealth Contractor Provided Virtual Triage and Prescription Services

- In July 2022, CDPH launched a telehealth service to complement its COVID-19 Test-to-Treat initiative. This service aimed to increase timely access to healthcare consultations and therapeutics prescriptions. It targeted symptomatic individuals who tested positive but could not connect with a healthcare provider within 24 hours of receiving a positive test result or developing symptoms. Initially, the telehealth initiative focused on those who received COVID-19 tests at community-based organizations' (CBO) testing

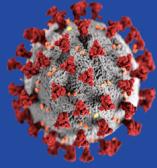


locations. However, the program eventually expanded to serve all Californians over the age of 12.

- These virtual visits, conducted by video or telephone, allowed eligible patients to communicate with a healthcare provider who could appropriately prescribe same-day delivery of a prescription or schedule an appointment for an infusion. Patients made their appointments via phone call, the [designated website](#), or QR code. The visits were free of charge and available without the need for insurance or other documentation. English and Spanish speaking doctors were available as well as a translator for other languages. By offering an alternative to in-person visits for triage, the telehealth program helped to remove barriers for patients needing therapeutic treatment.
- The Task Force promoted use of the telehealth program through the Testing Task Force's CBO partners, Equity Grant awardees, LHJs, and public-facing media campaigns.
- The telehealth program was initially a temporary solution to fill the gap until California health systems, physician offices, clinics, managed care organizations, and health plans developed robust Test-to-Treat pathways for their patient populations. However, due to the program's success, CDPH extended the service through February 2024.

Test-to-Treat Equity Grants Promoted Access to Treatment

- CDPH awarded COVID-19 Test-to-Treat Equity Grants to improve access to therapeutics in communities disproportionately impacted by COVID-19 and with the greatest barriers to care. Grants between \$50,000 to \$500,000 were offered to “safety net” clinics, which included federally qualified health centers, community clinics, rural health clinics, free clinics, regional clinic networks, and Indian Health Services (IHS)/Tribal Health clinics. Grants between \$250,000 to \$1 million were provided to clinics operated by city or county hospitals and other public health care systems. Grant recipients also received technical assistance to develop workflows, processes, and communications to expedite each step of COVID-19 care delivery including improvements to dispensing on site, offering telehealth, developing surge capacity, supporting mobile clinics, expanding urgent care, and coordinating care.

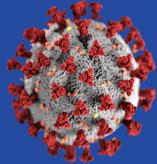


- In December 2022, CDPH offered a second grant round to entities that received the original Test-to-Treat Equity Grants. The COVID-19 Treatments Community-Clinical Linkages Grants supported equitable access to COVID-19 treatments via partnerships with CBOs and faith-based organizations (FBOs). Grant recipients could request up to \$100,000 per partnership to foster and support a robust community-clinical linkage with 90% of the funds allocated directly to the CBO or FBO partners for outreach and/or education.
- While CDPH oversaw the grant program it partnered with the non-profit Physicians for a Healthy California (PHC) to administer the grants. PHC established a [dedicated website](#) for grant program resources, including frequently asked questions (FAQs), grant guidelines, grant application details, reporting instructions, and outreach and social media toolkits. PHC managed the grant-related communications and evaluated grant applications. Grants were rejected if the applicant did not indicate how it was going to contribute to equity or did not specify sufficient plans or activities on how it would improve its test-to-treat capabilities. CDPH also partnered with the Center for Care Innovations to provide technical assistance and coaching to grant recipients, which included a [COVID-19 Clinical and Therapeutic Resource Hub](#). This partnership also provided grant recipients the opportunity to participate in a peer learning community with other clinics launching and improving COVID-19 therapeutics services.
- Between October and December 2022, CDPH awarded \$67 million to 176 organizations with a total of 1,452 clinic site locations across 36 counties in California. The grantees reported serving over 10 million patients. The grant program successfully reached disadvantaged communities as 74% of the grantee organizations that received approximately \$50 million in grant awards had over 50% of their sites located in HPI Q1 or Q2 locations.

Data Analytics

Initial Therapeutic Data was Limited

- Prior to November 2021, utilization rate data was not available for COVID-19 therapeutics. The only available data during that period was order requests received from LHJs, which were maintained in Excel spreadsheets. CDPH did not have access to shipping and delivery information as that was maintained in the third-party distributor AmerisourceBergen's system. Furthermore, as



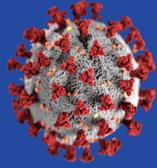
monoclonal antibody treatments required intravenous administration and were predominantly prescribed in clinical or hospital settings, the availability of monoclonal antibody data was very limited.

Data Used to Identify Needs for Pharmacy Locations

- The Therapeutics Task Force established a data analytics workstream and dedicated a staff member to the effort. Initially, analysis focused on identifying the need for therapeutics provider locations in disadvantaged communities. The staff member mapped providers to HPI quartiles to determine gaps in coverage. This analysis, conducted in winter 2021-22, allowed the Task Force to work with the large chain pharmacies to activate sites in disadvantaged communities to fill the gaps in underrepresented zip codes.

Datasets Created to Analyze Utilization

- Following the implementation of HHS/ASPR's Health Partner Ordering Portal (HPOP) in November 2021 and data access enhancements to the AmerisourceBergen system, CDPH had the ability to analyze ordering, shipping, and delivery information. Therapeutics Task Force staff created the Therapeutics Shipping and Ordering Dataset, which integrated ordering information from HPOP and shipping information from AmerisourceBergen. The dataset included ordering and shipment data for all COVID-19 therapeutic providers (i.e., pharmacy chain locations and federal entities as well as state- and LHC-coordinated sites) and contained a complete record of all COVID-19 therapeutic products coming into the State.
- Task Force staff also created a second dataset on utilization information. With the implementation of HPOP, the federal government required all COVID-19 therapeutics providers to report in HPOP each day they were open the number of courses administered by product type and the number of courses available by product type. HHS/ASPR used this information to populate where product was available on the [HHS therapeutics locator site](#). CDPH used this data to create its Therapeutics Utilization Dataset. CDPH then used the two datasets to compare the amount of product shipped to the number of courses administered to calculate the percentage of product that was utilized.
- The accuracy of the Therapeutics Utilization Dataset was dependent on providers adhering to the reporting requirements, but unfortunately many did



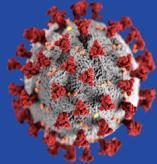
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not. As of May 2022, just 70% of therapeutics providers reported their utilization data, which results in a large data gap. According to one SME, reporting rates tended to be higher for chain pharmacies and lower for State- and LHJ-coordinated sites like local health clinics. This difference in reporting rates among different types of providers made utilization data difficult to accurately analyze. Moreover, providers were not required to report on who received treatment, so no patient demographic data was available. To promote better data reporting, the federal government established incentives. For example, if a provider reported on courses administered and courses on-hand, they could stay active on the therapeutics site locator. Also, CDPH would approve a provider requesting a larger supply than previous weeks if they entered their inventory information.

- In the absence of patient demographic data, in order to assess equitable access to therapeutic treatment, the Therapeutics Task Force developed an innovative approach to its data analysis. By cross-referencing the shipping data with provider-reported administration data at the local level, the team evaluated the utilization of therapeutics within different HPI quartiles. The results of this analysis provided valuable insights into gaps in therapeutic administration throughout California. Additionally, the data offered qualitative evidence to measure allocation levels and identified opportunities to expand access points for providers, particularly in hard-to-reach HPI quartile 1 populations.
- As of November 2023, HHS/ASPR demobilized the federal government's COVID-19 Therapeutics Distribution Program due to the commercialization of Paxlovid and Lagevrio. Once a COVID-19 therapeutic drug commercializes, the federal government no longer controls the national supply or requires providers to report utilization, making data that was previously reported to HPOP no longer available. After these drugs were commercialized, one SME observed that the "drug manufacturers had more information than CDPH did." Another SME noted that the "lack of data and lack of specificity" hindered CDPH's ability to perform more robust data analysis to drive equity policies and decisions.
- In the future, the SMEs suggested that CDPH investigate other data sources and analytical methods to create more robust reporting capabilities. For instance, since the inception of the telehealth vendor's contract, CDPH has been reporting on telehealth visits and the therapeutic prescription rates that



result from those visits. The vendor collects some data from patients in a pre-visit intake form, which could potentially be analyzed to determine equitable access.

- As the Task Force prepared to demobilize at the end of the public health emergency, the staff member responsible for analytics also took on the allocation process. At demobilization, the allocation process transitioned to the CDPH Center for Preparedness and Response, Pharmaceutical Warehouse Team leaving a gap when it came to therapeutics data analysis.

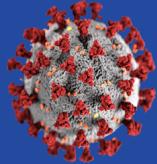
Partner and Public Engagement

Communications Efforts Limited Initially

- When the first COVID-19 therapeutic drug, Veklury, received emergency authorization in May 2020 and the federal government began allocating supplies to the states, the Therapeutics Work Group did not have a dedicated communications team to issue information or guidance about the drug. Rather, the work group members collaborated to draft informational materials for stakeholders' use and made the information accessible via a SharePoint site. According to several SMEs, informational materials primarily consisted of FAQs, but were "very ad hoc." As more therapeutic drugs received emergency authorization, information about the treatments changed quickly and it was difficult to create, maintain, and revise the FAQs to keep them current. Consequently, the work group "couldn't keep up" with issuing FAQs, one SME noted. Communications efforts ceased altogether between February 2021 to September 2021 when HHS/ASPR stopped controlling the national supply and CDPH no longer managed allocations to the LHJs and healthcare providers.

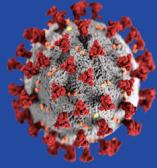
Communications Ramped Up to Promote Uptake in COVID-19 Therapeutic Treatments

- In fall 2021, the therapeutics work group evolved into the Therapeutics Task Force. Since the first types of treatments available required infusion by a qualified health care provider, communications to the public occurred primarily through healthcare providers. By February 2022, several additional emergency use authorizations expanded treatment options to include oral antiviral treatments. This meant that the Therapeutics Task Force needed to design additional communications for the general public, community-based



organizations, and LHJs (in addition to health care providers) to drive demand for treatment. Messaging up to that point in the pandemic had set the norm that there was no treatment to be pursued unless someone was severely ill or had severe medical conditions; thus, the public was unaware they should be seeking medical evaluation for treatment when diagnosed with symptomatic COVID-19. To educate LHJs and healthcare providers with clinical guidance on the available treatment options and operational guidance, in early 2022 the Therapeutics Task Force added dedicated communications team members to engage with the LHJs and providers. This team presented therapeutics updates in the Vaccine Task Force's weekly LHJ and provider webinars as well as disseminated new guidance through a therapeutics newsletter.

- The expanded communications team then concentrated their efforts on enhancing external communication with LHJs, healthcare providers, pharmacies, and the public. Aimed at tackling the issue of low therapeutic utilization, the team undertook a coordinated initiative to broaden its communication channels. In collaboration with the CDPH clinical team, they updated the guidance information for healthcare providers available on the CDPH website. They also developed and published information and social media graphics on the CDPH webpage to educate the public about COVID-19 treatments. Additionally, with dedicated resources, the team was now able to regularly update FAQs to disseminate important information about the use of therapeutics to stakeholders.
- In early 2022, data analysis revealed a significant gap between the volume of therapeutics ordered and the actual prescriptions being made for COVID-19 treatment. To investigate this issue and identify obstacles to prescription, the Therapeutics Task Force surveyed LHJs. The survey results unveiled concerns that promoting therapeutics might deter vaccination efforts and hesitancy among healthcare providers to prescribe treatments under emergency use authorization. Persistent myths included the scarcity of therapeutics, difficulty in obtaining them, and strict, limited eligibility criteria. This survey proved instrumental in uncovering systemic issues and guiding efforts to eliminate barriers. In hindsight, some SMEs recognized the potential for earlier development of communication strategies to combat these misconceptions during the pandemic.

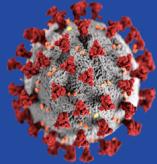


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- In September 2022, the team engaged with local public health leaders to solicit their perspective on how to best tailor the team's communication strategies. These local experts indicated that a prevailing public misconception was that COVID-19 therapeutics were only applicable to very immunocompromised and/or elderly populations, thereby fostering a sense of ineligibility among the public. Other prevailing misconceptions were that COVID-19 therapeutics should be started only if the illness had already become severe (rather than while the illness is still mild within the first 5-7 days of symptoms) and that all therapeutics were very expensive and/or difficult to access. They also expressed observations that the public was exhausted by COVID-19 and had become numb to and disinterested in public health messaging, especially messaging that emphasized the severity of COVID-19. Communications research in October 2022, including surveys and focus groups of the public, revealed that across demographic groups, participants responded more positively to hopeful, empowering messaging with emphases on availability and responded less positively to messaging that emphasized the severity and seriousness of COVID-19.
- Recognizing the unique challenge posed by misconceptions about COVID-19 treatments and growing public apathy, the team realized that traditional communication methods would likely be insufficient to effectively engage the public and increase levels of awareness and utilization. The CDPH team also decided to refrain from emphasizing eligibility criteria in communications and instead encouraged the public to consult their healthcare providers for personalized guidance on COVID-19 treatment options. This strategic shift aimed to broaden the understanding of who could potentially benefit from available therapeutic treatments.
- The therapeutics paid media budget was small compared to the corresponding budget of the Statewide COVID-19 vaccination campaign. Furthermore, with quickly approaching wintertime COVID-19 surges predicted, CDPH determined that the need to rapidly increase levels of public awareness and utilization of COVID-19 therapeutics was high.
- The Therapeutics Task Force faced other challenges that hindered its ability to communicate rapidly. Unlike the VA58 team, which had a streamlined review process to approve content that could be completed in just a few hours, the therapeutics communications team navigated the traditional content approval process, which could take several weeks to obtain

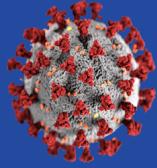


approval on messaging. Additionally, the team did not have many examples of public health communication campaigns on COVID-19 treatments to draw best practices from. To the team's knowledge, there was only one other media campaign in the U.S. on COVID-19 treatments that was launched by a public health department.¹

Provider Communications Aimed at Comprehensive Messaging

- By mid-2022, the therapeutics communications team undertook a comprehensive review of existing provider communication strategies to ascertain both effective messaging and conspicuous gaps. The team's composition was notably enriched by including a contractor team member who was a registered nurse seasoned in large clinical operations. This contractor provided valuable insights into clinical operations and served as a vital bridge to the clinician community. This expertise was instrumental in crafting messages that resonated with healthcare professionals, thereby facilitating a more effective communication strategy.
- The therapeutics communications team developed a multi-faceted approach to expand the messaging reach and support healthcare providers, which included weekly webinars, weekly newsletters, a dedicated [website](#), and [COVID-19 therapeutics toolkits](#). These platforms offered easily accessible information and tools that could be shared with partners. In addition, the communications team continued to participate in the weekly webinars that included SMEs to discuss therapeutics equity, education, clinical updates, storage and handling, and other timely and relevant topics. To bolster healthcare providers' preparedness for potential COVID-19 surges, the team created specialized [COVID-19 Therapeutics Toolkits](#) and a [COVID-19 Therapeutics Best Practices Checklist](#) that includes guidance on testing, prescribing, and dispensing. These tools provided guidelines and checklists to help healthcare settings seamlessly integrate new treatment protocols into their existing operations.

¹ New York State Governor Kathy Hochul (2022, July 12). Governor Hochul Announces New COVID-19 Treatment Public Awareness Campaign to Educate New Yorkers Who Test Positive for COVID-19 [Press release]. <https://www.governor.ny.gov/news/governor-hochul-announces-new-covid-19-treatment-public-awareness-campaign-educate-new-yorkers>

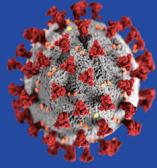


- Starting in fall 2022, the therapeutics communications team focused its efforts on long-term care facilities (LTCFs). The team reached out directly to the medical directors of these facilities and the advocacy organizations that represent the small, large, and private chain LTCFs. One particularly effective tactic was featuring medical officers in webinars to share their experiences. In addition, a few LHJs had built effective relationships with LTCFs in their localities, and they disseminated their best practices during the LHJ webinars. Such cross-sharing of experiences was met with appreciation and respect among the LHJ community. As time progressed, CDPH became a “trusted voice” for treatment information within the long-term care sector according to SMEs. The team could see “the needle really start to move” when deaths in these facilities decreased and prescribing rates steadily increased from approximately 25% share of cases treated with therapeutics per week in September 2022 to over 40% per week by January 2023, according to one SME. These outcomes were attributable to the team’s ability to reach long-term care facilities “from 360 degrees,” according to one SME.

Public Communications Conveyed Positive Messaging

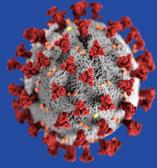
- The communications team contracted with an external communications and marketing agency to create and implement multi-platform public awareness campaigns. These campaigns aimed to inform and engage the public through a variety of channels, including the web, social media, billboards, newspapers, music streaming platforms, television, and radio, and were designed to be positive and uplifting. The urgency to develop these campaigns was heightened by the successive outbreaks of the flu, respiratory syncytial virus (RSV), and a winter surge in COVID-19 cases in early 2023.
- The agency crafted a series of multilingual media campaigns using the theme, “Test It. Treat It. You Can Beat It,” with a cast that represented a range of backgrounds to engage the audience and convey that eligibility criteria for COVID-19 treatments included the majority of American adults.²

² Centers for Disease Control and Prevention (2020, June 25). CDC updates, expands list of people at risk of severe COVID-19 illness [Press release]. <https://archive.cdc.gov/#/details?url=https://www.cdc.gov/media/releases/2020/p0625-update-expands-covid-19.html>



Designed with an empowering, upbeat tone, an ear-catching jingle, the slogan “Test it. Treat it. You Can Beat It,” and homemade-style videos that captured people joyfully dancing, the campaign was designed to be distinct from other public health messaging campaigns on COVID-19 to penetrate through public apathy and “pandemic information fatigue.” Messaging emphasized the availability of COVID-19 treatments, efficacy, the importance of seeking treatment promptly after symptom onset, and how to seek COVID-19 treatment, such as via the free CDPH COVID-19 treatment telehealth service. Messaging also referred to COVID-19 treatments as “COVID-19 medications” and “prescription COVID-19 medications” rather than “COVID-19 treatments” or “COVID-19 therapeutics” to inform that most COVID-19 treatments were available in oral pill form and could be taken at home rather than as intensive inpatient treatments.

- The CDPH team developed an informational webpage and a free, multilingual COVID-19 treatment-specific call line within the CDPH Call Center, and all ads directed the public to those resources.
- These ads resonated well, particularly in the Spanish-language TV commercials. These ads, set in the heart of Hispanic neighborhoods—from bustling fruit markets to lively laundromats—struck a chord with the community, according to one SME. The English-language commercials, while “campier,” stood out with its bold colors and distinct styling, one SME noted. With a strategic launch during wintertime COVID-19 surges in January and February 2023, the campaign raised awareness that treatment was readily available and captured public attention.
- In a bid to sustain and broaden the scope of public awareness across diverse segments of California’s population, the communications team diversified their outreach platforms beyond traditional media. Recognizing the need for a multi-pronged approach, the team collaborated with a variety of social media influencers who had significant followings among specific demographic groups. These included younger and older audiences, and Latino and Black/African American communities. To ensure authenticity and resonance, the influencers drafted their own content that was verified by CDPH, specifically tailored for platforms such as TikTok and Instagram. This initiative disseminated key public health messages through channels that were both culturally relevant and highly engaging, augmenting the reach and impact of the public awareness campaign.

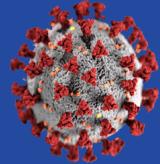


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- The team also made optimizations to further increase the effectiveness of the campaign among target audiences. For example, in response to lower approval ratings of the ads among rural audiences than urban audiences, the team conducted A/B message testing with 100 respondents who had low income, resided in rural counties, were older than 50 years, and were politically conservative. The results informed the team's use of additional radio broadcasting and new radio messaging for rural regions.
- In an effort to leverage the credibility of trusted community and health leaders within California, the team conducted public relations activities including holding a multilingual press briefing, publishing a press release, publishing op-ed pieces in collaboration with community leaders in community newspapers and broadcasting pre-recorded interviews designed for multi-platform dissemination, including radio, television, and YouTube. Notably, the California Surgeon General's participation significantly amplified the message about the efficacy and availability of treatments. While metrics were not available to quantitatively assess the success of the public communications campaign, CDPH received anecdotal feedback that its messaging was well-received, underscoring the effectiveness of utilizing a variety of creative methods to enhance public engagement and awareness.
- The team also conducted community-based outreach to further disseminate messaging, including developing a network of over 150 statewide government and community-based organizations representing priority populations. The team collaborated with some of the organizations, such as the CA Dept of Aging and CA Department of Corrections and Rehabilitation (CDCR) to develop and disseminate tailored communications toolkits to specific priority populations. The team also gave webinar and in-person presentations at different organizations' meetings and partnered with many organizations to disseminate messaging to their broader networks.
- While the public communication campaign achieved its goals, collaborating with the advertising and marketing agency posed challenges. Due to the urgency to address the winter surge in COVID-19 cases, there was insufficient time to pre-test the ads for their effectiveness. The CDPH team was uncertain whether some of the ads would resonate well with the public, but this could not be confirmed due to tight timeframes. The therapeutics communications team lacked experience in advertising, marketing, media markets, and targeting audiences. Consequently, the team relied on the agency's



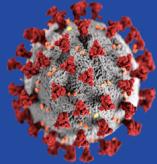
expertise for the media management as well as assistance from a CDPH retired annuitant who had expertise in tobacco media campaigns. By January 2023, the team addressed these gaps by adding advertising, public relations, and community outreach specialists to enhance their overall expertise.

- With varying degrees of success, the team initiated collaborations with other task forces and workgroups within the emergency response structure to increase dissemination of messaging on COVID-19 treatments. One notable example was the VA58 campaign for vaccines, which conducted robust messaging and substantial engagement with CBOs. The therapeutics team sought to replicate the successful practices of VA58 but with a smaller budget and less resources. The therapeutics communications team suggested that for future pandemics, CDPH widen the scope of its campaigns to encourage and support collaboration on holistic communications, exchanging of best practices, and seamless alignment of messaging.

Equity

This section describes equity considerations specific to this chapter.

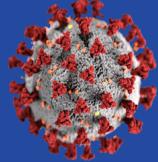
- The Therapeutics Task Force incorporated equity into all its policies, decision making, and work streams, including developing the healthcare provider therapeutic treatment network, making allocations to LHJs and providers, using data to evaluate equitable access to treatment, implementing Test-to-Treat initiatives that prioritized and expanded treatment options in disadvantaged communities, and designed a multilingual, multi-media campaign to drive understanding and demand of the importance of seeking COVID-19 treatment.
- For a detailed discussion of the equity considerations within the therapeutics workstreams, see the Analysis of Activities section above.



Data and Technology

This section describes data and information technology specific to this chapter.

- CDPH, in coordination with the LHJs, used Excel spreadsheets to calculate allocations and determine orders. This ordering data was the only therapeutics-related information available from March 2020 through November 2021.
- In November 2021, the federal government launched the Health Partner Ordering Portal (HPOP) for CDPH to use for entering site-level therapeutics orders for all State- and LHJ-coordinated therapeutics sites. CDPH staff still maintained the Excel spreadsheets, however, to calculate the allocations and then entered this information into HPOP.
- While HPOP was the tool used to order and report inventory and utilization, the federal government uses an analytics platform, Tiberius, to view the data collected in HPOP. Tiberius provided the analytical dashboard to HPOP users.
- AmerisourceBergen maintained its own system to track therapeutic shipments. The company pulled ordering data from HPOP and then processed the orders and shipments in its system. By November 2021, the company made enhancements to its system, which allowed CDPH and LHJs to access shipping information.
- As discussed in the Analysis of Activities above, CDPH created two datasets using information from HPOP and AmerisourceBergen. The first dataset contained ordering and shipping data cross-referenced from the two systems. The second data set contains utilization information pulled from provider reporting in HPOP. In June 2022, CDPH provided LHJs access to the two therapeutics datasets in Snowflake using their preexisting accounts.
- For further discussion of Snowflake see the Data and Reporting chapter in this AAR.



Communications

This section describes communications specific to this chapter.

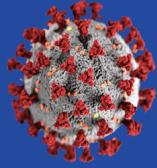
External

Communicating with LHJs

- The Therapeutics Task Force had frequent communications with LHJs to discuss, clarify, and confirm allocations and suballocations to the healthcare providers in their jurisdictions.
- A multi-prong approach was used for additional communications with LHJs. The LHJs were granted access to CDPH's SharePoint site to view orders during the first year of the pandemic, until this capability was provided in the federal government's ordering portal. Eventually, Therapeutics Task Force members participated in the weekly Vaccine LHJ webinars to provide clinical insights and operational updates. Furthermore, the therapeutics communications team leveraged the LHJ communications process managed by the Local Coordination Team to share information. For example, the therapeutics communications team presented updates on the communications campaign at webinars attended by LHJs, such as the weekly "CDPH Check-In Call." For further discussion of the Local Coordination Team, see the County Monitoring and Local Coordination chapter of this AAR.

Communicating with Healthcare Providers

- The Therapeutics Task Force established the therapeutics communications team to create and disseminate critical communications to healthcare providers via weekly provider webinars, a weekly newsletter, a dedicated website, and numerous COVID-19 therapeutics toolkits. These tools included updates, guidelines, and checklists to help healthcare providers integrate new treatment protocols into their existing operations.
- The Therapeutics Task Force also leveraged the California Health Alert (CAHAN) system to release health advisories about COVID-19 therapeutics. These advisories proved to be an impactful mechanism to reach providers and let them know the importance of prescribing COVID-19 treatments. The advisories were also used to dispel myths and misinformation about therapeutics and to reduce hesitancy in prescribing.

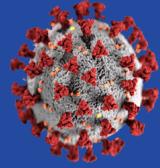


Communicating with the Public

- The Therapeutics Task Force's communications team contracted with an advertising and marketing agency to develop and execute comprehensive public awareness campaigns about COVID-19 treatments across various platforms. Public advertising campaigns ran throughout California from September 2022 to March 2023 and from October 2023 to March 2024, with the largest push during the 2022/2023 winter surge. The team disseminated ads on television, radio, billboards, newspapers, the web, music streaming, flyers at CBOs and events, social media, and YouTube to create awareness to the public that if you have COVID-19 there are treatments available.
- The team also reached the public through a multilingual press briefing, a press release, op-eds published in local newspapers, and broadcasted TV and radio interviews with public health leaders such as the CA Surgeon General.
- The team further expanded reach through outreach efforts, including collaborations with government and community organizations on tailored communications toolkits for specific priority populations, presentations, and messaging dissemination.

Communicating with Other State Departments

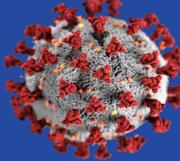
- In an effort to inform all Californians of COVID-19 treatment options and how to seek care and prescriptions, CDPH partnered with the California Department of Health Care Services (DHCS) to reach MediCal Providers (MCPs) through an All Plan Letter ([APL 22-009](#)) and other communications. CDPH also partnered with the Department of Managed Healthcare (DMHC) to issue a [similar APL to managed healthcare plans](#). The Therapeutics Task Force provided input in the Expedited Access to Therapeutics section of the APL to encourage MCPs to prioritize symptomatic COVID-19 patients to gain access to care and treatment. The APL encouraged MCPs to refresh their therapeutics processes and communications, as well as their websites, to expedite COVID-19 treatment.
- The Therapeutics Taskforce also collaborated with EMSA to provide strategic and clinical guidance on EMSA's mAb infusion centers across the State.



Internal

Communicating with COVID-19 Task Forces

- The Therapeutics Task Force struggled to fully collaborate with other COVID-19 task forces on cross-functional initiatives and public messaging. Several SMEs reported that overall, the task forces operated in silos. Furthermore, there were no incentives, sufficient time, or adequate resources to synchronize policies, decisions, and activities across task forces. For future pandemics, the SMEs suggested that CDPH establish a structured process to improve coordination and collaboration among the task forces, to better align policies, decisions, and communications. For further discussion of task force challenges, see the Operational Organization chapter in this AAR.
- For additional discussion on LHJ, provider, and public communications within the various workstreams, see the Analysis of Activities section above.



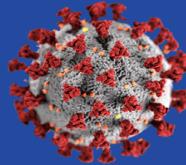
Workplan

This section is designed to be used as a workplan for future pandemics.

Definitions:

- **Phase:** The phase of the response in which the major tasks should be conducted (Planning; Initial start-up, Ongoing operations, or Close-out).
- **Major Tasks:** The tasks and activities that have to be conducted as part of the public health emergency response to a respiratory pandemic.
- **Success Criteria:** Criteria used to assess whether a task has been achieved successfully.
- **Considerations Based on COVID-19 Response:** Things to consider, including pitfalls, risks, and lessons learned, based on the COVID-19 response.
- **Finding ID:** The ID(s) from the related Finding/Corrective Action (where applicable).
- **Lead:** The lead person(s) responsible for task completion.

Phase	Major Tasks	Success Criteria	Considerations	Finding ID	Lead
Planning; Initial start- up; Ongoing operations	Form Task Force to oversee the therapeutics program	<ul style="list-style-type: none">• The Therapeutics Task Force is comprised of the appropriate SMEs and leaders, including physicians, pharmacists, logistics specialists,	<ul style="list-style-type: none">• Determine appropriate workstreams for the therapeutics program, define roles and responsibilities, and create/maintain an	<ul style="list-style-type: none">• Therapeutics 6, 9, 11	

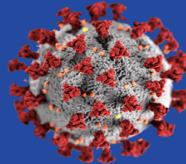


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Phase	Major Tasks	Success Criteria	Considerations	Finding ID	Lead
		<p>communications specialists, and others to operationalize a statewide therapeutics program.</p> <ul style="list-style-type: none">The Therapeutics Task Force coordinates and collaborates with other task forces on cross-functional initiatives.	<p>organizational chart.</p> <ul style="list-style-type: none">Anticipate and plan for adequate resources for response activities.Designate a small project management office to track issues, risks, facilitate key meetings, and manage cross workstream special projects.Build communication mechanisms to inform and coordinate with other task forces and workgroups.Orient all team members to organizational structure,		

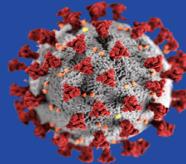


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Phase	Major Tasks	Success Criteria	Considerations	Finding ID	Lead
Planning; Initial start-up; Ongoing operations	Establish robust LHJ, provider, and public communication channels and processes	<ul style="list-style-type: none">Establish robust communication channels and processes.	<ul style="list-style-type: none">Establish a communications team as soon as possible to plan and initiate messaging.Assess resource needs and develop communications plans, with predictability in updates (e.g., every week).Ensure there is advertising and marketing experience within the team.Develop creative messaging and deployment strategies that resonate with the public.	<ul style="list-style-type: none">Therapeutics 1, 3, 11, 12	

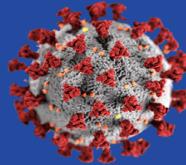


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Phase	Major Tasks	Success Criteria	Considerations	Finding ID	Lead
			<ul style="list-style-type: none">• Create a designated website for therapeutics information and links to resources.• Identify trusted messengers and other partners who can help disseminate messaging to communities.• During the declared emergency streamline the approval process for messaging.		
Planning; Initial start-up; Ongoing operations	Develop guidance, tools, and educational resources	<ul style="list-style-type: none">• LHJs and providers have resources to rely on that supports therapeutics administration.• The public has access to current information to make informed	<ul style="list-style-type: none">• Refresh guidance on authorized treatment options as evidence of effectiveness becomes available.	<ul style="list-style-type: none">• Therapeutics 1, 2, 3, 6	

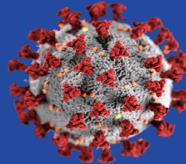


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Phase	Major Tasks	Success Criteria	Considerations	Finding ID	Lead
		decisions related to treatment options.	<ul style="list-style-type: none">Utilize online platforms to disseminate information.Use multi-media formats to develop content.Obtain clinician input on educational and marketing materials.Create educational fact sheets, tools kits, and a playbook for providers. Incorporate equity considerations to reach the widest audience possible.		
Planning; Initial start-up; Ongoing operations	Use data-driven strategies to promote equitable access	<ul style="list-style-type: none">Equity is formally incorporated into all therapeutics workstreams and initiatives.	<ul style="list-style-type: none">Understand the patient journey from initial diagnosis to treatment compliance to	<ul style="list-style-type: none">Therapeutics 5, 7, 10	

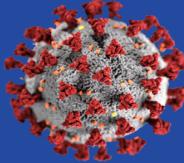


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Phase	Major Tasks	Success Criteria	Considerations	Finding ID	Lead
		<ul style="list-style-type: none">• CDPH, in partnership with LHJs, deploys innovative strategies to promote equitable access.	<ul style="list-style-type: none">• Identify equity barriers in the process and opportunities for intervention.• Continue to improve data collection methods and analytical approaches for therapeutics utilization.• Use Healthy Places Index and develop additional therapeutics equity metrics, as appropriate.• Make data accessible 24/7, including establishing a dashboard, to diverse audiences, including the public,		

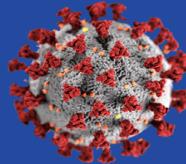


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Phase	Major Tasks	Success Criteria	Considerations	Finding ID	Lead
			leadership, LHJs, and healthcare providers.		
Planning; Initial start-up; Ongoing operations	Streamline allocation and ordering therapeutics processes	<ul style="list-style-type: none">LHJs can allocate supplies effectively to healthcare providers in their jurisdictions.Providers receive amount of drug supply that best meets their supply and demand needs.The public has access and can promptly obtain treatment.	<ul style="list-style-type: none">Create an allocation plan, including strategies and calculation formulas to address changes in therapeutics supply and demand.Survey LHJs and providers to identify potential improvements.Revise processes to accommodate changes in supply and demand.	<ul style="list-style-type: none">Therapeutics 8, 9	
Planning; Initial start-up;	Identify initiatives to support healthcare	<ul style="list-style-type: none">Providers are incentivized to deploy strategies to support end to	<ul style="list-style-type: none">Partner with non-profit health care organization(s) to	<ul style="list-style-type: none">Therapeutics 2, 4, 7, 9	



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Phase	Major Tasks	Success Criteria	Considerations	Finding ID	Lead
Ongoing operations	providers to improve their operations and reach underserved communities	end testing, prescription, and treatment. <ul style="list-style-type: none">• Disadvantaged communities have more options for test-to-treat services.	administer grant programs. <ul style="list-style-type: none">• Maintain and update the Test-to-Treat playbook.• Consider establishing a virtual telehealth service.		