Monoclonal Antibodies (mAbs)

COVID-19 Therapeutic Interventions

VDH Partner Call

4/9/2021

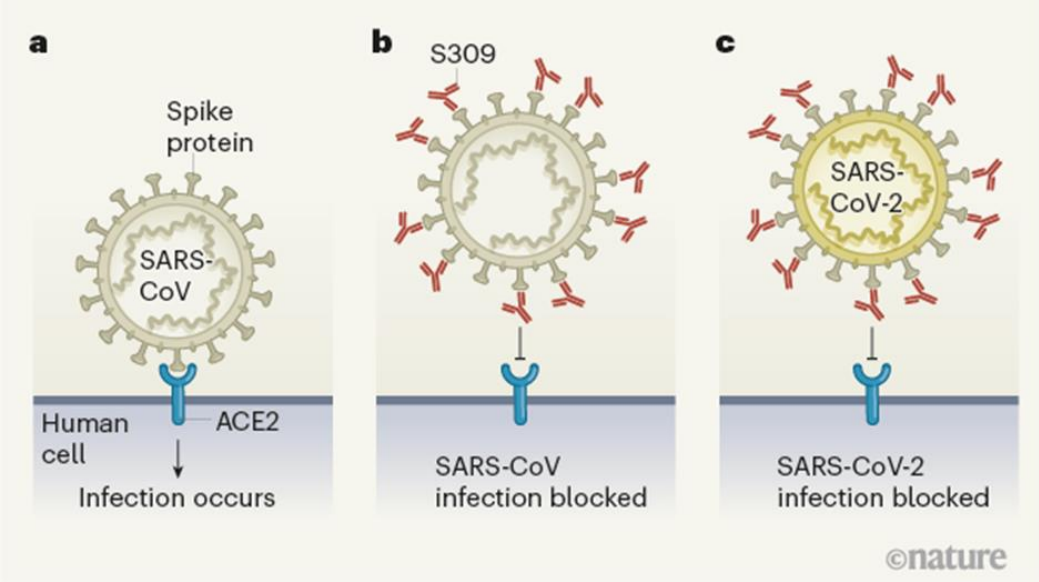
Clinical Background

Monoclonal antibodies (mAbs) directly neutralize the COVID-19 virus and are intended to **prevent progression of disease**

mAbs likely to be most effective when **given early in infection**

Product delivered via **single administration (e.g., IV infusion)**

Early evidence suggested promise of mAb products in outpatient settings



Emergency Use Authorizations (EUAs) for bamlanivimab and casirivimab/imdevimab

1. Positive direct SARS-CoV-2 test (e.g., PCR, rapid antigen test)
2. As soon as possible after positive test, within 10 days of symptom onset
3. In patients at high risk
4. Provider reviews EUA fact sheet; patient/caregiver provided with EUA fact sheet
5. Administered in a setting where HCPs have direct access to medications to manage severe reactions

Emergency Use Authorizations
High-Risk Criteria

- All Patients (who meet at least 1 of the following criteria):
  - BMI ≥35
  - Chronic kidney disease
  - Diabetes
  - Immunosuppressive disease
  - Receiving immunosuppressive treatment
  - Age ≥ 65 years
  - Age ≥ 55 years AND have any of the following
    - Cardiovascular disease
    - Hypertension
    - COPD/other chronic respiratory disease

- Adolescents (Age 12-17 years) who meet at least 1 of the following criteria:
  - BMI ≥85th percentile for age/gender
  - Sickle cell disease
  - Congenital or acquired heart disease
  - Neurodevelopmental disorders (e.g., cerebral palsy)
  - Medical-related technological dependence [e.g., tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID-19)]
  - Asthma, reactive airway, or other chronic respiratory disease that requires daily medication for control

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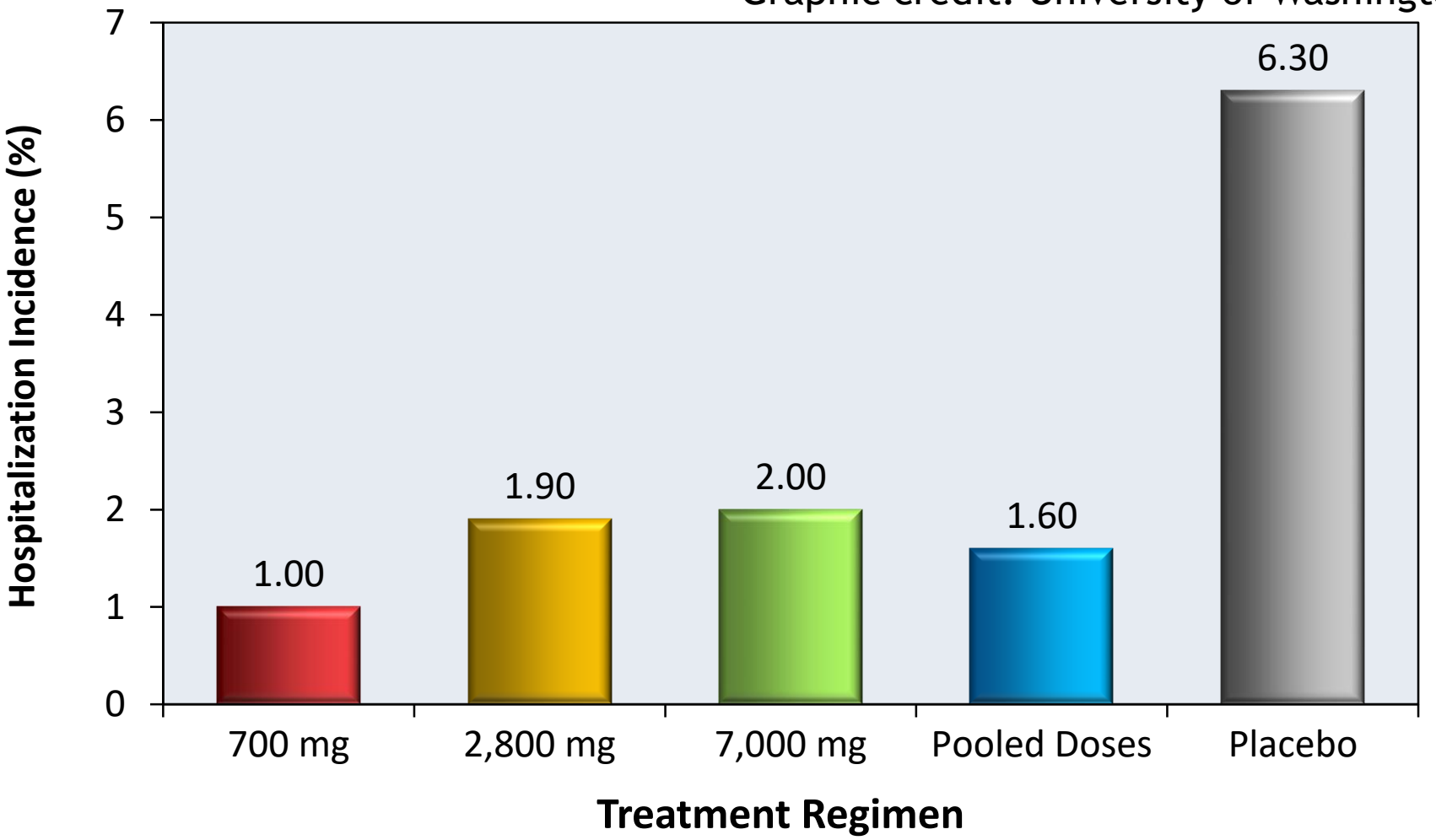
SARS-CoV-2 Neutralizing Antibody LY-CoV555 in Outpatients with Covid-19: Hospitalization Incidence

Graphic credit: University of Washington

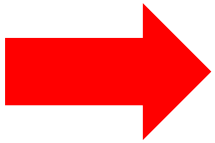


Source: Chen P, et al. N Engl J Med. 2020 Oct 28. doi: 10.1056/NEJMoa2029849849

Monoclonal Antibodies Treatment Effects

Individual

- Reduces viral load
- Reduces admission rate
- Reduces ED return rate
- No proven mortality reduction



Population

- Reduces rate of transmission
- Reduces inpatient burden
- Reduces ED crowding
- Fewer cases → Fewer deaths

For 10,000 pts: ***No drug:*** ***630 admissions & ED visits***

With drug: ***170 admissions & ED visits***

Cost

- The federal government has bought hundreds of thousands of doses.

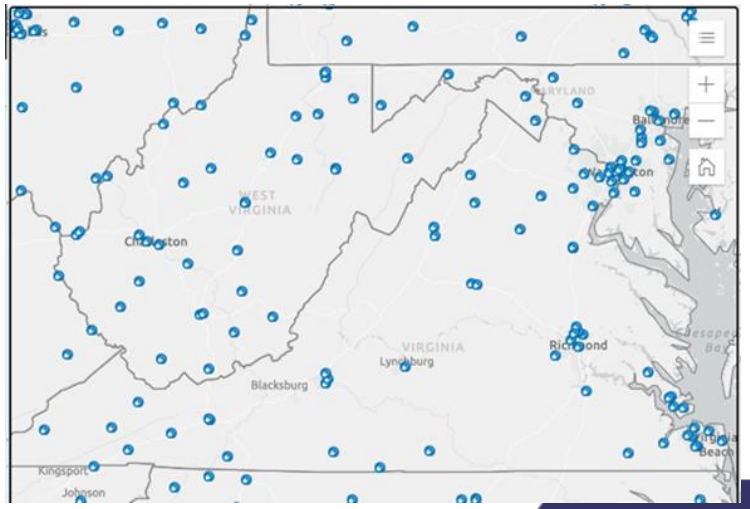
- Patients are not charged for the drug, but they may be charged for their clinic visit/infusion services.

Program Success to Date

- Nearly all Virginia Hospital systems across the Commonwealth have established infusion operations for ambulatory or emergency department patients.

Largest Consumers
Inova Fairfax Hospital
Carilion Roanoke Memorial Hospital
Sentara Norfolk General Hospital
Inova Mount Vernon Hospital
Chesapeake General Hospital

- Several dialysis centers and skilled nursing facilities also administering these therapeutics.



- Number of Unique Facilities: 66
- Number of Doses Used: 12,695

Program Goals

- Maximize utilization of the allocated drugs within the appropriate medical indications for use for to reduce the impact on patients and inpatient hospital systems

- Ensure access of these agents throughout all geographic regions of the Commonwealth, however, demographic data is not collected by the HHS database.

  - **Next Steps:** Work with stakeholders / healthcare facilities to see how this data can be collected within the Commonwealth.
  - South Carolina/Texas shared on national call on 3/23 their in-state strategies in conducting outreach to vuln populations.

From March 17, 2021 HHS Presentation

Update: Allocation and Distribution of COVID-19 Therapeutics

MARCH 17, 2021

Office of the Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services

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→ *Potential site-based solutions in green*

Understanding a patient's journey and potential barriers to treatment

*Patient decides to **contact** healthcare facility*

*Facility **diagnoses and refers** patient with mAb site*

Patient

Potential barriers pre-diagnosis

- Undiagnosed based on improved symptoms, etc. → *provide patient education ahead of illness; post mAb info (i.e., digital toolkit) on website*

Healthcare facility

Potential barriers post-diagnosis

- Unaware of treatment options → *post mAb info (i.e., digital toolkit) on website*
- Unwilling to participate → *provide patient and provider-focused education*
- Unable to navigate HC system/find treatment location → *direct patients to resources, post mAb info on website*
- Provider unwilling or doesn't know where to refer → *provide provider-focused education*

mAb infusion site

Potential barriers post-referral

- Treatment/scheduling barriers → *provide dedicated phone line for COVID-19*
- Unable to access treatment → *provide transportation support / help patient find closest infusion location*

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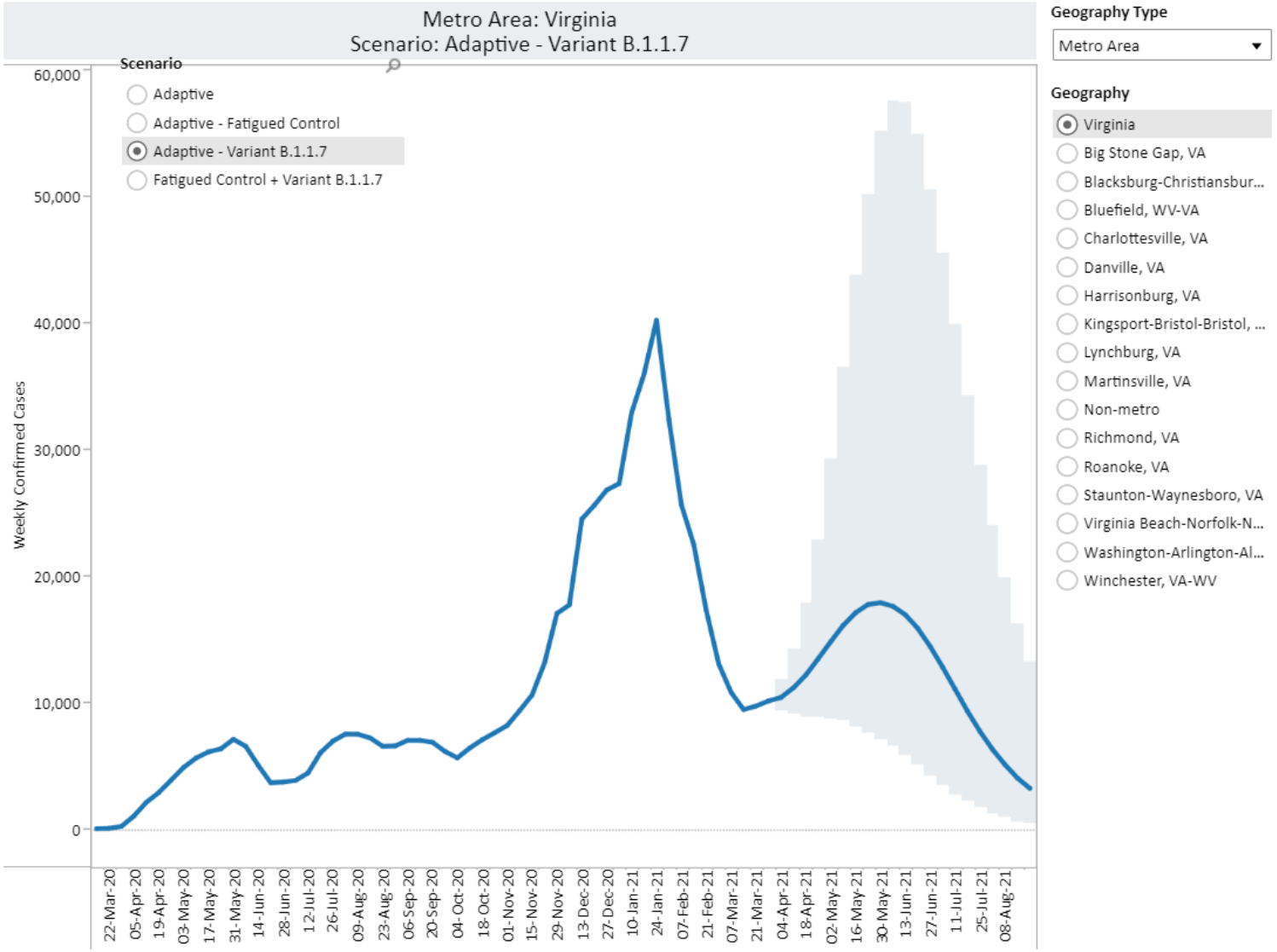
Why is this still important?



Vaccination of the Medically Fragile and Homebound

VDH Partner Call

4/9/2021

Drake Well
Titusville, PA – 1859

69.5 feet deep

Drake Well
Titusville, PA – 1859

69.5 feet deep

Deep Water Horizon
Gulf of Mexico – 2010

35,050 feet deep
50 miles offshore
Under 4,132 feet of water.

Medically Fragile and Homebound Residents

- **Problem Statement:**
  - Homebound, medically fragile, and medically complex Virginia residents need access to vaccination either at home or at sites that provide accommodations.
- **Program Plan**
  - VDH, in coordination with DMAS, DARS, and DBHDS, will establish a strategic plan to safely vaccinate the medically fragile, medically complex, and their in-home caregivers.
  - This effort will culminate in a network of local providers and care coordinators that, together, will provide all necessary accommodations to safely vaccinate the target populations.

Defining Fragile and Homebound Patients

- These residents:
  - Are usually significantly disabled
  - Have impaired mobility
  - Often have caregivers
- Example: DMAS Commonwealth Coordinated Care Plus Waiver program
  - Meet the NF level of care criteria (i.e., they are functionally dependent and have a medical nursing needs); or
  - Individuals who are dependent upon technological support and require substantial, ongoing skilled nursing care

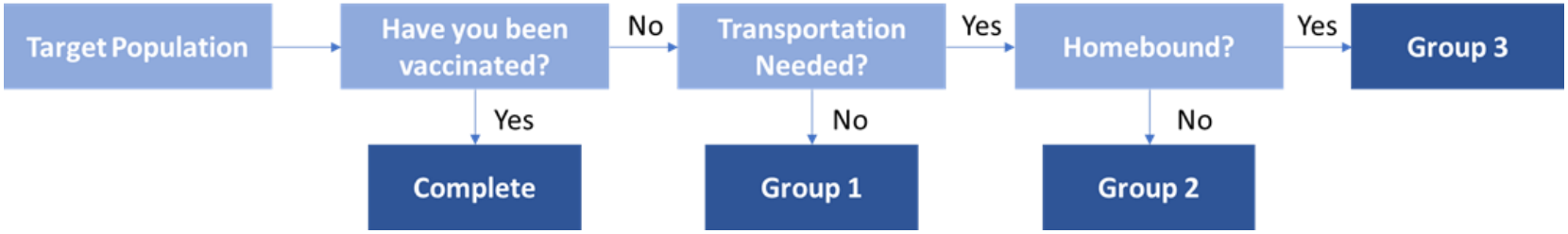
Defining and Locating Vulnerable Residents

- Collaborative effort with other agencies to identify medical fragile and homebound patients
  - DMAS
  - DBDHS
  - DARS
  - DSS
  - Meals on Wheel
- Significant overlap with DMAS group
- Data sharing agreements required

Target Population Size

Target Population	Total Population
TOTAL DMAS POPULATION > 16 years	1,137,318
All CCC Plus members (non-institutionalized)	233,044
DD/IDD waiver	14,443
CCCP Waiver	33,619
Dual Eligible	195,873
Homebound	1,678
PACE	1,508
Medallion 4.0	721,804
FFS	164,630

Determining Tactics

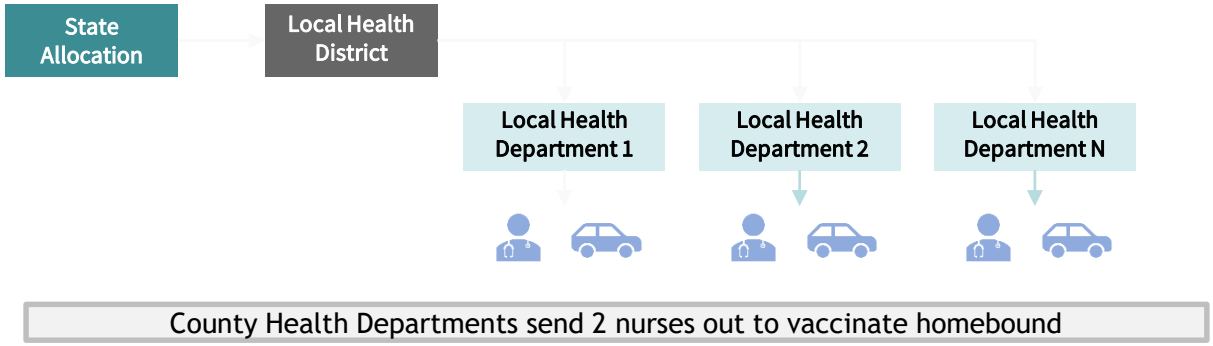


- **Medically Fragile Target Population**: DMAS-identified CCCP members who are unvaccinated, > 16 years
  - Pharmacy:
    - Network of pharmacies holding private clinics for the high-risk population.
    - MCO care coordinators (500+) call these members to directly schedule them using the site locator tool.
  - CVC:
    - MCO CCs will use spreadsheets to schedule members into CVC sites. In the long-term, VDH will obtain consent from the broader CCCP population and upload their information to receive direct links for scheduling.
    - Lynchburg CVC and Norfolk FEMA Site

Homebound Population Vaccination Strategy: Two-Pronged Approach

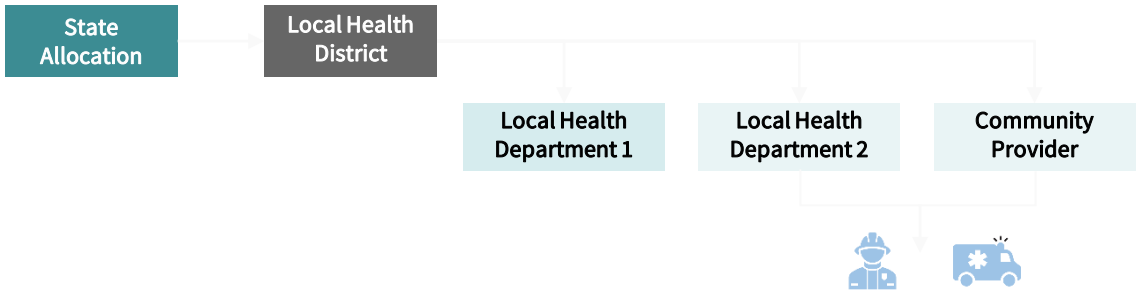
Current DMAS-identified homebound population totals 1597 patients

1 Local Health District Approach



County Health Departments send 2 nurses out to vaccinate homebound

2 EMS / Fire Department Approach



Health Departments partner with local EMS or Fire Department to vaccinate homebound population

Key Decisions or Assumptions:

- Established **threshold for LHD** approach (e.g., < 100 homebound per district)
- Vaccine recorded under **VIIS and VTrcks ID of Local Health Department**
- **Additional allocation provided** to LHD to send to health departments within purview
- Throughput: **10 homes a day**, 15-20 vaccinations
- **A cold chain member (vaccinator or driver) and EMS / Fire Department (vaccinator or driver) ride together to serve homebound population**
- Local Health Department may send nurses if homebound population within its county is small
- Vaccine recorded under the local health department or community provider's **VIIS and VTrcks ID**
- **Additional allocation provided** to Health Department or community provider

Results - So Far…..

		Received At Least One Dose				
Target Population	Total Population	3/30/2021	3/30/2021	4/6/2021	4/6/2021	Δ
TOTAL POPULATION > 16 years	1,137,318	162,767	14%	212,053	19%	4%
All CCC Plus members (non-institutionalized)	233,044	49,304	21%	62,757	27%	6%
DD/IDD waiver	14,443	6,888	48%	7,824	54%	6%
CCCP Waiver	33,619	9,499	28%	11,898	35%	7%
Dual Eligible	195,873	57,411	29%	70,192	36%	7%
Homebound	1,678	117	7%	281	17%	10%
PACE	1,508	632	42%	728	48%	6%
Medallion 4.0	721,804	59,122	8%	87,149	12%	4%
FFS	164,630	41,917	25%	50,047	30%	5%

For Questions or More Information

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