

Maine DHHS

COVID-19 Vaccines & Therapies Clinical Updates

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COVID-19 Clinician Discussion

- COVID-19 vaccines - recent updates
- Boosters for all adults
- NEW: Pfizer vaccine booster for 16 & 17yo's
- Implications of omicron
- COVID-19 monoclonal antibody therapies
- NEW: COVID-19 long-acting monoclonal antibodies
- Coming soon: COVID-19 oral antiviral medication(s)
- Q&A

Current COVID-19 Vaccines

Pfizer BioNTech

- mRNA vaccine
- Trial with >44,000 in multp countries
- Efficacy in initial trials 94.5%
- Minimal adverse reactions
- 2nd dose at 21D
- FDA apprvd for ≥16yo
- FDA auth'd for 5-15yo
- **Booster auth'd >16yo**
- Can be refridg'd for 30D

Moderna

- mRNA vaccine
- Trial with >30,000 in US
- Efficacy in initial trials 94.1%
- Minimal adverse reactions
- 2nd dose at 28D
- FDA auth'd for ≥18yo
- Booster auth'd for ≥18yo
- Can be refridg'd for 30D

J&J/Janssen

- Viral vector vaccine
- Trial with >43,800 in multp countries
- Efficacy in initial trials >66.1% overall, 72% US
- Minimal adverse reactions
- Single dose
- FDA auth'd for ≥18yo
- Booster auth'd for ≥18yo
- Can be stored at room temp

COVID-19 Vaccines: Boosters

- FDA EUA & US CDC now recommend **booster dose for individuals with all 3 auth'd vaccines**
- Pfizer & Moderna: give booster at 6+ months
 - Pfizer: for 16yrs & older
 - Moderna: for 18yrs & older
- J&J: give booster at 2+ months for all 18yrs & older
- Any of vaccines can be used for booster vaccination, regardless of vaccine product used for primary vaccination (“Mix & Match”)

COVID-19 Vaccines: Impact of Boosters

- Israeli study of impact of Pfizer booster on 50+yo
- Total 843,208 participants, of whom 758,118 (90%) received booster during 54-day study period
- **Participants with booster at 5+ mos after Pfizer 2nd dose had 90% lower COVID-19 mortality** than participants who did not receive booster

NEJM Dec 9, 2021: BNT162b2 Vaccine Booster and Mortality Due to COVID-19 <https://www.nejm.org/doi/full/10.1056/NEJMoa2115624>

Pfizer COVID-19 Vaccine for 5-11yo's

- FDA authorized, US CDC recommends Pfizer vaccine for 5-11yo's
- Impacts ~28 million youth in US, 96,000 in Maine
- Vaccination was ~91% effective in preventing COVID-19 among children aged 5-11 yo
- Given as reduced dose
- Like adults, given in 2-dose series, 21D apart

COVID-19: Implications of Omicron

- Multiple mutations – unknown implications re:...
 - Transmissibility
 - Disease severity
 - Immunologic “escape”
- Practical implications: ramp up the basics!
 - Masking & distancing
 - Vaccination, vaccination, vaccination
 - Boosters for all

COVID-19 Therapies

- COVID-19 monoclonal antibodies (mAbs):
 - Most effective (70-85%) & currently available
 - Three options: REGEN-COV, bam-ete, Sotrovimab
 - Most effective when given within 10D of symptom onset (sooner is better)
 - Indicated for people at high risk for dev'ing severe COVID – e.g.
 - ≥ 65 yo,
 - BMI > 25
 - Pregnancy
 - Chronic diseases (e.g. diabetes, heart disease, kidney disease, immunosuppressed, COPD)
 - Pts with neurodevelopment disorders (e.g. CP), medical devices (e.g. trach)

Accessing mAb Tx: Issues

- Limited federal supply of doses & increased demand has created shortages
- Some ability to move doses across sites
- Subcu use encouraged, but limited to use with w/ REGEN-COV only
- Goal: give within 10D of symptom onset, but often seeing delays in testing, access to tx
- Providers not widely aware of where & how to send patients for treatment
- List of Maine mAb infusion sites [posted online](#)

Newly Authorized: Long-Acting Antibodies (LAAB)

- Evusheld (AZD7442)
 - Astra-Zeneca product FDA authorized by EUA on Dec 8
 - Long-acting antibody (LAAB) combination for pre-exposure prophylaxis of COVID-19
 - Authorized for adults and certain pediatric individuals with immune compromised systems not expected to mount adequate immune response following vaccination, or for whom vaccination not indicated due to health conditions or history of severe allergic reactions
 - Phase 3 trial of unvaccinated indiv's at increased risk showed 77% reduction in dev of symptomatic COVID
 - Initial supply limited: 216 doses to Maine
 - Distributing through major cancer centers

Coming Soon: Oral Anti-Viral Drugs (AVDs)

Molnupiravir

- Potential FDA EUA by end-Nov/early Dec
- Initial data supports reduced risk of hospitalization or death by ~30% compared to placebo for pts with mild-moderate COVID-19 when given *within 5d of sx onset*
- Inhibits SARS-CoV2 replication
- Treatment as 800mg (4 X 200mg pills), 2x/d for 5 days
- Will require confirmed COVID-19 PCR or antigen test
- Toxicity profile for molnupiravir not yet know, but could require pregnancy testing/counseling
- Supply initially constrained: allocation will be to states, w/ states making local distribution decisions

Coming Soon: Oral Anti-Viral Drugs (AVDs)

Paxlovid (332)

- Pfizer has submitted EUA appln; expect FDA decision by early Jan 2022 & US CDC rec by late Jan – early Feb
- For pts with mild-moderate COVID-19, initial trial data showed reduced risk of hospitalization or death by 89% compared to placebo *when given within 3d of sx onset*; showed 85% reduction *when given within 5d of sx onset*
- Works as protease inhibitor
- Must be given w/ 2nd drug, ritonavir (blocks liver degradation)
- Treatment given as 2 Paxlovid (150mg) + 1 ritonavir (100mg) tabs, 2x/d for 5 days
- Will likely require confirmed COVID-19 PCR or antigen test
- Expect initial supply to be constrained

Oral Anti-Viral Drugs: Access and Administration Challenges

- Initially constrained supply
 - Maine's initial molnupiravir allocation may be only ~1600 courses
 - Feds will allocate doses to states; states select channels
 - Maine will initially distribute via retail pharmacies, unless there are coverage gaps
 - As supply increases, will expand scope of availability
- Need for rapid treatment requires rethinking of current testing and diagnostic workflows
 - Increase use of rapid testing in clinical settings
 - Opportunities to identify pts at high-risk/ candidates for COVID treatments at time of testing

Monoclonal Antibody Tx or Newer Pills?

- Indications for oral AVDs not finalized, but will likely be similar to mAbs (i.e., tx individuals dx'd with COVID at high-risk for severe disease)
- **Given greater efficacy of mAbs and initial limited supply of oral AVDs, recommend use of mAbs whenever possible**
- Particularly recommend use of mAbs for high-risk populations in congregate settings like LTC, correctional facilities
- Toxicity profile for molnupiravir not yet know, but could require pregnancy testing/counseling

Maine DHHS COVID-19 Community Care & Social Support

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How to make a referral - Contact Information

- Online referrals <https://www.maine.gov/dhhs/form/cGvid-19-referral-form>
- Or email DHHS.Covidsocialsupport@maine.gov
- Our website <https://www.maine.gov/dhhs/coronavirus-resources/communitysupports>
- When you forget search Google “Maine DHHS COVID social support” or call 211



“What services do you provide?”

Try us....

Core services are available to all Mainers

- Culturally appropriate food & household supplies
- Cultural Brokering, interpretation, translation
- Information to assist clients to understand reasons and ways to maintain isolation and quarantine
- Housing/shelter (rent relief, quarantine shelters) & heat
- Health Prevention – **testing**, masks, Pulse Ox, thermometers, medical appointments, links to vaccine
- Spiritual and Psychosocial support – Chaplains and mobile crisis
- Transportation to medical care and shelters
- Sustained risk communication in simplified messages on how it's everybody business to stop COVID-19, protect families, communities, society in general.

Process of Community Care for COVID: The Referral

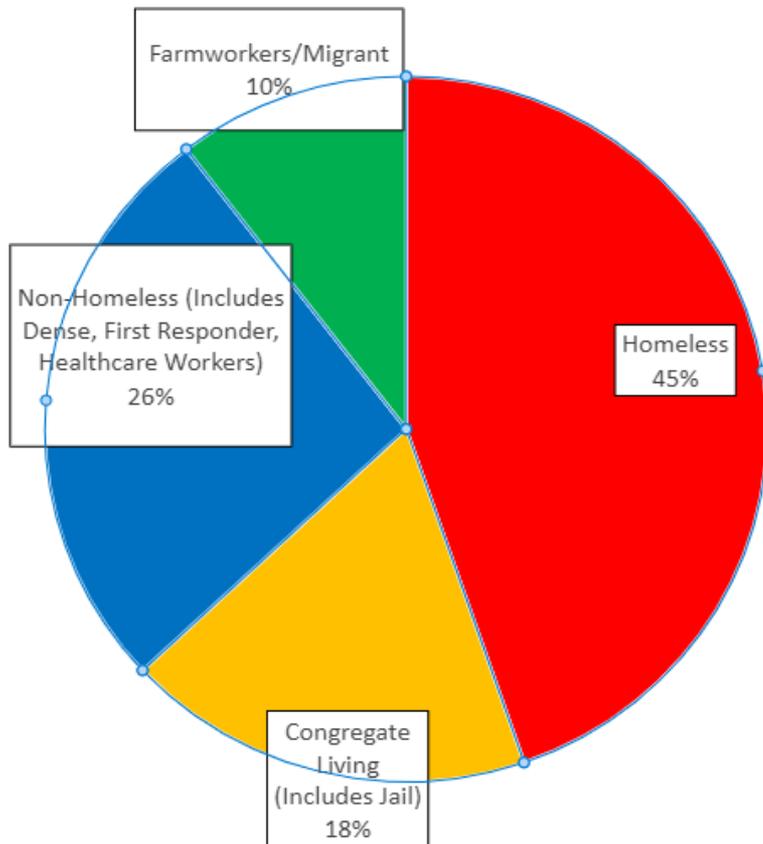
- What happens when a referral is made?
 - Centralized referrals via online form are entered into DHHS database <https://www.maine.gov/dhhs/covid-19-referral-form>
 - Coordination: The DHHS COVID Social Support team and partners MIRC, CCM staff assess incoming referrals and make the best match based on geography, language, and services needed
 - Referral sent to funded partners statewide & local social Service agencies (and cultural brokers) will pick up the referral within 4 hours and begin to contact clients.

Community Care Data: A Summary – June 10, 2020 to December 12, 2021

- 6406 referrals for *approximately* 19,340 Mainers in households, shelters, or outbreaks
 - 300 referrals per week in last 2 weeks
 - 50-95 per day since this surge has started
- The number of referrals for social services depends upon:
 - # cases and # of Contacts in the State – follows geographic trends
 - If referrals are offered and how they are offered.
 - For example, “do you want social services” vs would it be alright if someone called you to check in and make sure you have everything you need or if you have any questions?”
 - Community engagement and outreach- familiarity and trust
 - Outbreaks

Participation by type of housing— June 10, 2020 to December 12, 2021

Quarantine Shelter Use by Housing Type
(since June 2020)



- 61% of all clients are non-homeless
- 14.2 homeless, congregate housing, jail, migrant workers,
- Among those using quarantine shelters - 45% of clients using shelter are homeless

What else do we do?

Health Equity and addressing disparities

Program emphasizes Ethnic Community Based Organizations (ECBO's) and groups likely to have less access or power are a priority

- Success = High vaccination rates among non-white compared to all other groups
- Community engagement with ~37% clients non-English preferred (varies from 20-60%)
- ECBO's services are the vanguard of community services for testing, promotion, and community response.
- Trained outreach testing = 20 groups with ~60 staff
- Vaccine promotion and events

Community Outbreak Detection

- Referrals clue us in to outbreaks that may not be detected otherwise
- Scenario 1: March 2021, a cluster of referrals for social support and outreach testing among Arabic speakers in Augusta. With our partners, we were able to work with community groups to improve the reporting to Maine CDC, initiate vaccine campaigns and a pop-up event, and begin testing and social support.
- Scenario 2: Recovery house clients (Portland and Bangor) with positive tests. Begin serial testing, provide shelter, link to pooled testing, information.

Q&A

- Questions?
- Other issues?

Presenters

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Additional COVID Resources

- [Coronavirus Disease 2019 \(COVID-19\) | US CDC](#)
- [US CDC COVID-19 Vaccines Clinical Considerations](#)
- [Maine COVID-19 Vaccines \(maine.gov\)](#)
- [Maine COVID-19 Vaccines FAQ](#)
- [Maine COVID-19 Vaccination Sites](#)
- [Maine COVID-19 Vaccination Dashboard](#)
- HHS/ASPR Website (mAbs): www.phe.gov/mAbs
- HHS Website (mAbs): <https://combatcovid.hhs.gov/>