COVID-19 TherapeuticsProvider Webinar

Hosted by:

Greg Desrosiers Sr.

Acknowledgements:

CRRU Therapeutics Team

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Agenda

- Welcome & Introductions
- COVID-19 Therapeutics Updates
 - Prescribing Guidance
 - Panelist Discussion
 - Q & A
- Closing Comments & Resources
 - Adjourn

Speakers

Greg Desrosiers Sr.Oregon Health Authority,
Outreach Coordinator

Richard Leman, MD
Oregon Health Authority,
Senior Health Advisor

Jason Bradley
One Community Health Hood River,
Site Director

Roxanna Pascual
Ian Clemons, PA-C
Alejandro Lopez
Matt Kelly, RN
Daniel Alvarez-Vargas, PA-C
Virginia Garcia Memorial Health Center





- COVID-19 Therapeutics - Updates





New Developments

FDA authorizes State-licensed Pharmacists to Prescribe Paxlovid with Certain Limitations

- EUA requires pharmacist to evaluate for severe kidney and liver disease, drug allergies, and interactions
- Requires access to recent medical records or consultation with clinician familiar with patient
- Requires access to full list of medications from clinician, pharmacy, or patient



New Developments (cont.)

Paxlovid Rebound

- Post-treatment increases in SARS-CoV-2 RNA shedding (i.e., viral RNA rebound) in nasopharyngeal samples observed in a subset of PAXLOVID and placebo recipients, irrespective of COVID-19 symptoms.
- The frequency of detection of post-treatment viral RNA rebound was generally similar among PAXLOVID and placebo recipients, regardless of the rebound definition used.
- Post-treatment viral RNA rebound wasn't associated with COVID-19related hospitalization or death from any cause through Day 28 following Paxlovid treatment.



Tixagevimab/Cilgavimab (Evusheld)

Redosing

- Long-acting monoclonal antibody combo
- Used for prevention of COVID-19 in patients who
 - are moderately to severely immunocompromised, or
 - have medical contraindications to COVID-19 vaccines
- FDA recently authorized <u>redosing</u> at 6-month intervals



Bebtelovimab

Intravenous monoclonal antibody

- The USG ordered an additional 150,000 doses
- For treatment of lab-confirmed COVID-19 in those at increased risk of severe illness, if started within 7 days of illness onset
- Limited data on clinical effectiveness
- In vitro activity against Omicron BA.4 and BA.5
- Shelf-life extensions authorized by the FDA





Prescribing Guidance





Prescribing Guidance

NIH Guidelines for Therapeutic Management of Non-Hospitalized Adults with COVID-19

Does Not Require Hospitalization or Supplemental Oxygen All patients should be offered symptomatic management (AIII).

For patients who are at high risk of progressing to severe COVID-19, a use 1 of the following treatment options:

Preferred Therapies

Listed in order of preference:

- Ritonavir-boosted nirmatrelvir (Paxlovid)^{b,c} (Alla)
- Remdesivir^{c,d} (Blla)

Alternative Therapies

For use ONLY when neither of the preferred therapies are available, feasible to use, or clinically appropriate. Listed in alphabetical order:

- Bebtelovimab^e (CIII)
- Molnupiravir^{c,f} (Clla)

The Panel recommends against the use of dexamethasone⁹ or other systemic corticosteroids in the absence of another indication (AIII).

Rating of Recommendations: A = Strong; B = Moderate; C = Weak Rating of Evidence: I = One or more randomized trials without major limitations; IIa = Other randomized trials or subgroup analyses of randomized trials; Ilb- Nonrandomized trials or observational cohort studies; III = Expert opinion

NIH Therapeutic Management of Non-hospitalized Adults With COVID-19

ASPR











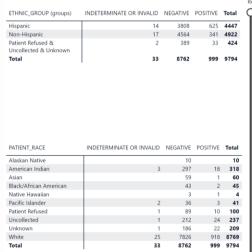
Jason Bradley
Site Director, One
Community Health
Hood River

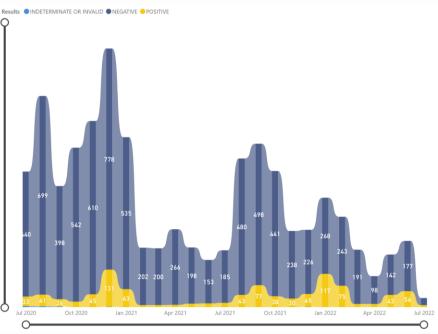




COVID-19 Response

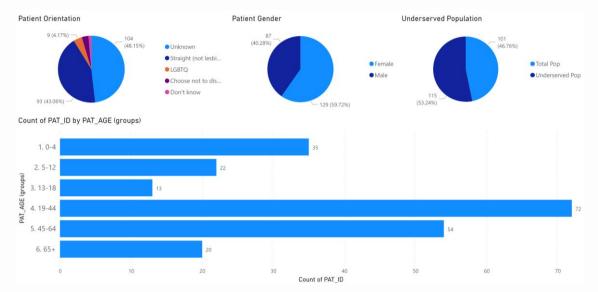
- Performed 9,794 COVID tests with overall 10% positivity rate
- Since pandemic began, 14% positivity rate for Hispanic/Latinx versus 6% for non-Hispanic

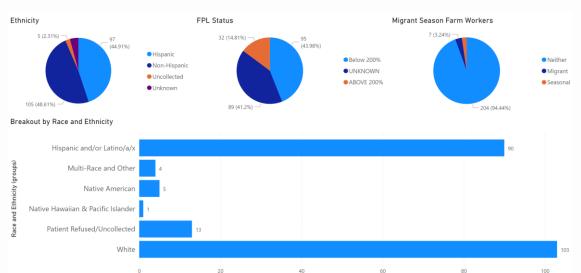












Count of PAT ID

T2T Data

- Starting May 2022
 53% of people seen are underserved
- 30% positivity for Hispanic/Latinx
- 15% for non-Hispanic



One Community Health

Outcome of T2T



- Reduction of PPE burden
- Updated access to testing and vaccines from a few days a week to daily
- Avoided sending patients to ED
- T2T staff increased capacity for PCP staff with inflow of migrant workers
- Educational social media posts, stickers on OTC test kits
- May positivity rate was 23% while Hood River and Wasco Counties are much lower
- Disproportionate positivity rates for people of color, 32/43 people who identify as Latinx tested positive





Roxanna Pascual

Regional Operations Manager

Ian Clemons

Physician Assistant, PA-C

Alejandro Lopez

Core Team Coordinator

Matt Kelly, RN

Core Team

Daniel Alvarez-Vargas

Physician Assistant, PA-C



Virginia Garcia

COVID-19 Data - 7th Avenue Location

Age Group	Immunizations	Tests	Positive Results	Treatments
<18	195	151	53	0
18-21	48	70	30	0
22-40	148	289	106	11
41-65	373	409	162	26
Over 65	205	89	34	8

Ethnic Group	Immunizations	Tests	Positive Results	Treatments
Hispanic	598	625	237	22
Non- Hispanic	273	297	120	20
Unknown	98	86	28	3



Virginia Garcia

Outcome of T2T

- Free take home tests, walk-ups, or by appointment testing and vaccines
- Take home kits with supplies and information about COVID-19
- Following mail distribution appointments doubled from 15-18 patients daily to 30 to 50 daily.
- Text message blast to patients, radio, updated website, flyers to CBOs, social media, signage at new facility
- Increase in:
 - Therapeutics to 3-4 patients a day.
 - Willingness to take therapeutic treatment (education still lacking)
 - COVID-19 positive patients



Testing site at Hillsboro 7th Ave Clinic



Registration area at Test to Treat site

Without the OHA supported staff T2T would be nonoperational











OHA July Events

- COVID-19 Therapeutics Monthly Newsletter Released July 8th
- COVID-19 Community Therapeutics Webinars
 - English July 29th at 12:00pm 1:00pm
 - Link: <u>https://www.zoomgov.com/meeting/register/vJIsduirrDwtHWego28W06qR</u> Ifksz4V0cbY
 - Spanish July 29th at 1:30pm 2:30pm
 - Link:
 https://www.zoomgov.com/meeting/register/vJlsduChpjlqG9hWG5fck-
 Ow0vigqU QnUk
- July Logistics Office Hours
 - Remaining Dates: July 18th and 25th
 - Every Monday from 2:00pm 2:30pm
 - Link sent via GovDelivery Mondays and Fridays (standing invites coming soon!)

We Love Feedback!

We have a quick pop-up poll on the screen. If you would kindly submit your responses, we'd love to hear about your experience.



Question 1: Did you find the updates provided in this webinar on the available COVID-19 therapeutics useful?

Question 2: With the information and resources provided, do you feel more comfortable prescribing therapeutics?

Question 3: What is one thing you would have wanted us to cover that was not discussed?

Questions | Comments| Suggestions

Email us: OHA.therapeutics@dhsoha@state.or.us



Resources

- OHA Provider Monoclonal Antibodies webpage:
 www.oregon.gov/oha/covid19/Pages/monoclonal-antibody-therapy.aspx
- OHA Provider Antivirals webpage: www.oregon.gov/oha/covid19/Pages/antivirals.aspx
- OHA Logistics Office Hours
- Evusheld EUA: https://www.fda.gov/media/154701/download
- Paxlovid EUA: https://www.fda.gov/media/155050/download
- Paxlovid Checklist https://www.fda.gov/media/158165/download
- Federal COVID-19 Therapeutics Clinical Implementation Guide: https://aspr.hhs.gov/COVID-19/Therapeutics/Documents/USG-COVID19-Tx-Playbook.pdf
- CMS Reimbursement Info for mAbs
- CMS Reimbursement Info for Oral Antivirals



Summary of COVID-19 Therapeutics

No Illness

Exposed

Per CDC Close Contact Criteria

Mild to Moderate **Symptoms**

Hospital Admission

ICU Admission

Baseline health status, no

Not hospitalized, with limitations1

Hosp. no act. medical problems

Hospitalized, not on oxygen Hospitalized, on oxygen

Hospitalized, high flow oxygen/ non-invasive ventilation

Hospitalized. mechanical ventilation/ **ECMO**

infection

Not hospitalized, no limitations

> Veklury® (remdesivir, Gilead) and Paxlovid (nirmatrelvir + ritonavir, Pfizer) - Preferred

COVID-19 **VACCINES**

Monoclonal Antibodies for **PrEP**

 Evusheld (tixagevimab + cilgavimab, AZ) None currently authorized for use in any US state or territory.

Oral Antivirals

- · Paxlovid (nirmatrelvir + ritonavir. Pfizer) -Preferred
- · Lagevrio (molnupiravir, Merck) - Alternative

Monoclonal Antibodies for Treatment

Bebtelovimab (Lilly) -Alternative

Please see NIH Current Inpatient Therapies (https://www.covid19treatmentguidelines.nih.gov/therapies/)





