OHA COVID-19 Webinar Series for Healthcare Providers

Tuesday, May 19th

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Agenda Items

- COVID-19 epi updates
- Reopening update
- Remdesivir
- Pediatric multisystem inflammatory syndrome
- Antibody testing and antigen testing
- General COVID-19 Questions
- Closing



Epidemiology update



The COVID-19 Pandemic Update in Oregon

As of May 18th:

- 3,604 positive COVID-19 cases
- 138 deaths
- 93,628 negative tests
- Test results do not reflect the full impact of COVID-19 in our state



Testing Results Summary through 5/15

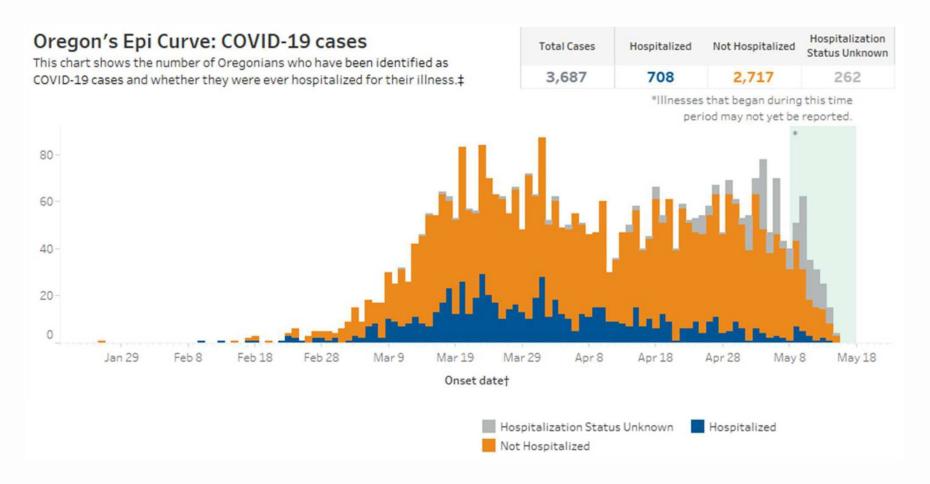
Summary of Oregon test results through 5/15/20

	Pre-	2/29-	3/7-	3/14-	3/21-	3/28-	4/4-	4/11-	4/18-	4/25-	5/2-	5/9-	Total
	2/28	3/6	3/13	3/20	3/27	4/3	4/10	4/17	4/24	5/1	5/8	5/15	to date
Positive	1	12	35	66	348	437	472	414	392	402	453	438	3,470
Negative	3	122	466	1,460	7,050	7,434	9,318	8,683	8,779	12,282	14,028	16,349	85,974
Total results	4	134	501	1,526	7,398	7,871	9,790	9,097	9,171	12,684	14,481	16,787	89,444
% positive	25.0%	9.0%	7.0%	4.3%	4.7%	5.6%	4.8%	4.6%	4.3%	3.2%	3.1%	2.6%	3.9%

As of May 15, Oregon's cumulative positive testing rate has remained fairly consistent at about 3.9% of tests performed. This is considerably lower than the national average of 15.0%. Oregon's decreasing weekly test-positivity rate reflects decreasing numbers of individuals with COVID-19 due to Governor Kate Brown's stay-at-home order and increasing testing statewide, including the tests run at hospital laboratories and commercial laboratories.



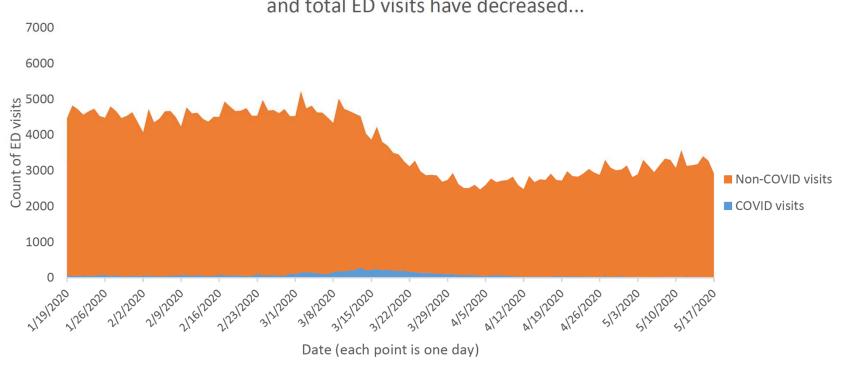
Epidemiologic curve





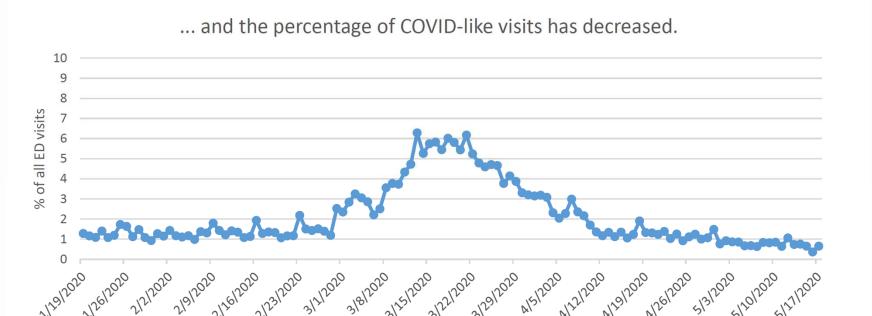
Daily ED visits

COVID-like visits still make up a small proportion of all reported ED visits, and total ED visits have decreased...





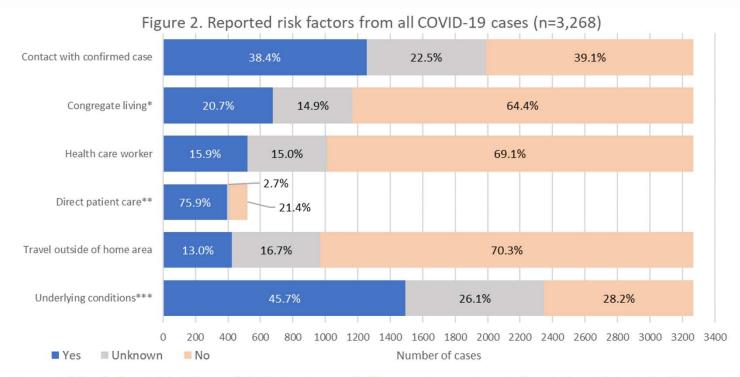
Daily ED visits for CLI



Date (each point is one day)



Reported Risk Factors for All COVID-19 Cases as of May 12



^{*}Congregate living situations include, but are not limited to, long-term care facilities, group homes, prisons, shelters, etc. Data include people with confirmed cases who live or work in congregate living situations.

^{***}Underlying medical conditions include cardiovascular disease, chronic liver disease, chronic lung disease, chronic renal disease, current or former smoker, diabetes mellitus, immunocompromised condition, neurologic/neurodevelopmental condition, obesity, or other chronic diseases.



^{**}Direct patient care is only asked if a case is a healthcare worker or volunteer. The denominator is the number of healthcare workers or volunteers.

Severity by Age Group as of May 12

Table 2. Severity and rates of COVID-19 by age group (n=3,268)

Age group	Cases	% of total cases	Cases per 10,000ª	Deaths	Case fatality (%)	Hospitalized
0-9	24	0.7%	0.5	0	0.0%	5
10-19	102	3.1%	2.1	0	0.0%	1
20-29	457	14.0%	8.2	0	0.0%	25
30-39	558	17.1%	9.6	0	0.0%	44
40-49	559	17.1%	10.3	3	0.5%	83
50-59	574	17.6%	10.7	5	0.9%	112
60-69	463	14.2%	8.6	23	5.0%	161
70-79	302	9.2%	8.9	39	12.9%	134
80+	219	6.7%	13.1	60	27.4%	103
Not available	10	0.3%	n/a	0	0.0%	4
Total	3,268	100.0%	7.8	130	4.0%	672

^aPopulation data were compiled from the 2019 Annual Oregon Population Report which is produced by the Population Research Center, Portland State University



Severity by Race as of May 12

Table 3. Severity and rates of COVID-19 by race (n=3,268)

Table 3. Severity and rates of COVID-13 by race (11-3,200)						
Race	Cases	% of total cases	Cases per 10,000ª	Deaths	Case fatality (%)	Hospitalized
White	1,679	51.4%	5.3	95	5.7%	411
Black	82	2.5%	10.0	5	6.1%	24
Asian	118	3.6%	6.0	7	5.9%	35
American Indian/Alaska Native	57	1.7%	12.2	2	3.5%	10
Pacific Islander	33	1.0%	19.6	1	3.0%	9
Other	879	26.9%	n/a	8	0.9%	133
>1 race	63	1.9%	4.6	2	3.2%	10
Not available	357	10.9%	n/a	10	2.8%	40
Total	3,268	100.0%	7.8	130	4.0%	672

^aNCHS Population Estimates: National Center for Health Statistics (NCHS), Estimates of the resident population of the US by year, county, age, bridged race, Hispanic origin, and sex (Vintage 2018). 2) Census Bureau Population Estimates: U.S. Census bureau, Population Division, Annual Estimates of the Resident Population by Age, Sex, Race, and Hispanic Origin for counties (Vintage 2018)



Severity by Ethnicity as of May 12

Table 4. Severity and rates of COVID-19 by ethnicity (n=3,268)

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Ethnicity	Case count	% of total cases	Cases per 10,000ª	Deaths	Case fatality (%)	Hospitalized
Hispanic	1,004	30.6%	18.0	11	1.1%	154
Non-Hispanic	1,895	57.8%	5.2	102	5.4%	472
Not available	369	11.6%	n/a	17	4.6%	46
Total	3,268	100.0%	7.8	130	4.0%	672

^aNCHS Population Estimates: National Center for Health Statistics (NCHS), Estimates of the resident population of the US by year, county, age, bridged race, Hispanic origin, and sex (Vintage 2018). 2) Census Bureau Population Estimates: U.S. Census bureau, Population Division, Annual Estimates of the Resident Population by Age, Sex, Race, and Hispanic Origin for counties (Vintage 2018)



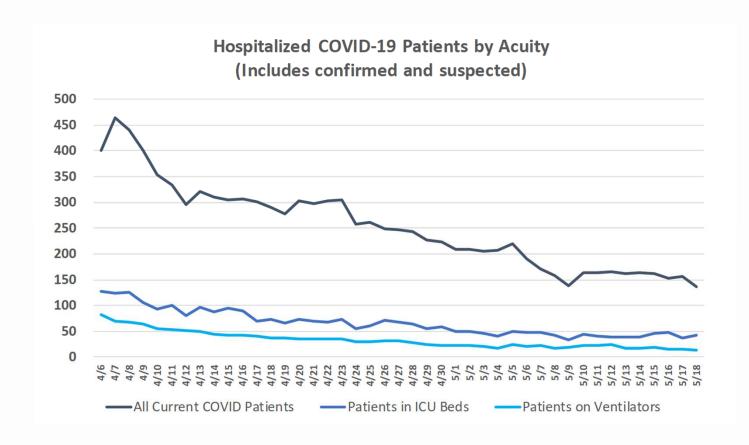
Current COVID-19 Hospitalizations

	Currently Hospitalized COVID-19 Patients*	Currently Hospitalized COVID-19 Positive Patients**
Hospitalized COVID-19 Patients	155	61
COVID-19 Patients in ICU Beds	40	24
COVID-19 Patients on Ventilators	18	12

^{*}Includes both confirmed and suspected COVID-19 patients **Includes only confirmed positive COVID-19 patients

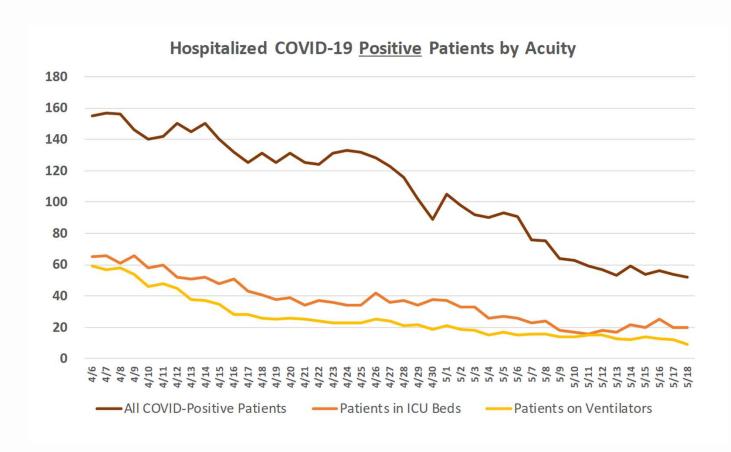


Current COVID-19 Hospitalization Trends: confirmed and suspected cases





Current COVID-19 Hospitalization Trends: confirmed cases only





Reopening Oregon Update



Reopening: Statewide Changes

May 1

 Non-emergency and elective procedures allowed to resume (PPE and hospital capacity dependent)

May 5

 Recreation where physical distancing can be followed (some state park day use areas and boat ramps, option for county/federal campgrounds)

May 15

- Stand-alone retail that was previously closed but can follow OSHA guidelines: furniture stores, art galleries, jewelry shops and boutiques
- Childcare, summer school, camps and youth programs (with limitations and specific guidelines)



Reopening: Phase 1

- Phase I:
 - Local gatherings for local groups only up to 25 (no travel)
 - Restaurants/bars: physical distance spacing, employees wear cloth face or disposable coverings, end all consumption by 10 pm
 - Personal services: by appointment, pre-appointment health check, maintain customer log, six feet physical distancing, face coverings/capes/smocks
- Applications received for Phase 1 reopening from all counties except Clackamas, Multnomah and Washington
- Applications not approved for Marion and Polk counties
- All other 31 counties approved for reopening beginning May 15th

Visit Oregon Reopening Tab and Criteria at: www.healthoregon.org/coronavirus





- On May 12 and May 15, 2020, the Oregon Health Authority (OHA) received allotments from the federal government of remdesivir, an experimental drug for the treatment of COVID-19.
- Remdesivir is a direct acting antiviral that inhibits viral RNA synthesis.
- It is an investigational drug and is not currently FDA approved for any indication.
- On May 1, 2020, the U.S. Food and Drug Administration (FDA)
 announced that it issued an Emergency Use Authorization (EUA) to
 permit the emergency use of remdesivir for COVID-19.



According to an April 29, 2020 NIH news release, preliminary results for the NIAID study involving 1063 individuals with advanced lung disease:

- Patients who received remdesivir had a 31% faster time to recovery than those who received placebo (p<0.001).
- The median time to recovery was 11 days for patients treated with remdesivir compared with 15 days for those who received placebo."
- Differences in mortality rate were not statistically significant, and full results of the study have not been published.
- More information about the results from the NIAID study on remdesivir can be found at https://www.niaid.nih.gov/newsevents/nih-clinical-trial-shows-remdesivir-accelerates-recoveryadvanced-covid-19.



Emergency Use Authorization allows for treatment as follows:

- Patients must have suspected SARS-CoV-2 or laboratory-confirmed SARS-CoV-2 as determined by polymerase chain reaction (PCR)
- Patient is hospitalized
- Patient has severe COVID-19 disease defined by one or more of the following criteria:
 - Documented low oxygen saturation (SpO2) ≤94% on room air
 - Requiring supplemental oxygen
 - Requiring mechanical ventilation or extracorporeal membrane oxygenation

- Starting May 16, OHA began distributing remdesivir to hospitals, upon notification of an eligible patient and receipt of a signed agreement form from the hospital.
- Because remdesivir is experimental, OHA neither recommends nor discourages the use of remdesivir to treat COVID-19 patients.
- The allotments include enough remdesivir for 80 patients to receive a 10-day treatment course, which is sufficient to treat currently hospitalized patients with COVID-19 who meet criteria for eligibility.
- OHA anticipates additional allotments in the future, although the amount and timing are not known.



Remdesivir Resources- OHA

- Hospital Agreement for Receiving Remdesivir through the State of Oregon
- Oregon's Federal Remdesivir Allocation: Patient Criteria and Hospital Distribution
- FDA Fact Sheet for Health Care Providers EUA of Remdesivir
- <u>FDA Fact Sheet for Patients and Parent/Caregivers EUA of</u> Remdesivir For Coronavirus Disease 2019 (COVID-19)
- Remdesivir use for COVID-19 in Oregon: Frequently Asked Questions
- User Guide for Shipping Remdesivir from the Oregon Health Authority to Hospitals
- FDA FAQ on the EUA for Remdesivir for Certain Hospitalized COVID-19 Patients

Pediatric Multisystem Inflammatory Syndrome



Pediatric Multisystem Inflammatory Syndrome—CDC case definition

Case Definition for Multisystem Inflammatory Syndrome in Children (MIS-C)

- An individual aged <21 years presenting with feverⁱ, laboratory evidence of inflammationⁱⁱ, and evidence of clinically severe illness requiring hospitalization, with multisystem (>2) organ involvement (cardiac, renal, respiratory, hematologic, gastrointestinal, dermatologic or neurological); **AND**
- No alternative plausible diagnoses; AND
- Positive for current or recent SARS-CoV-2 infection by RT-PCR, serology, or antigen test; or COVID-19 exposure within the 4 weeks prior to the onset of symptoms



CDC comments

- ⁱFever ≥38.0°C for ≥24 hours, or report of subjective fever lasting ≥24 hours
 - illncluding, but not limited to, one or more of the following: an elevated C-reactive protein (CRP), erythrocyte sedimentation rate (ESR), fibrinogen, procalcitonin, d-dimer, ferritin, lactic acid dehydrogenase (LDH), or interleukin 6 (IL-6), elevated neutrophils, reduced lymphocytes and low albumin
- Additional comments
 - Some individuals may fulfill full or partial criteria for Kawasaki disease but should be reported if they meet the case definition for MIS-C
 - Consider MIS-C in any pediatric death with evidence of SARS-CoV-2 infection



Pediatric Multisystem Inflammatory Syndrome

- Additional CDC information:
 - Healthcare providers who have cared or are caring for patients younger than 21 years of age meeting MIS-C criteria should report suspected cases to their local, state, or territorial health department.
 - It is currently unknown if multisystem inflammatory syndrome is specific to children or if it also occurs in adults.
 - There is limited information currently available about risk factors, pathogenesis, clinical course, and treatment for MIS-C.
- First Reported MIS-C Case in Oregon
 - OHA distributed a press release on 5/13 which can be found here:
 https://www.oregon.gov/oha/ERD/Pages/OHA-announces-1st-case-of-COVID-19-linked-pediatric-condition.aspx
 - A Health Advisory Notice was distributed to Oregon health providers on May 14th

Testing update



- Serology testing, which looks for antibodies in blood, is increasingly available: 12 tests have FDA EUA
 - OHA recommends against using any COVID-19 test that does not have FDA EUA
 - List of all tests with FDA Emergency Use Authorization:
 https://www.fda.gov/medical-devices/emergency-use-authorizations#covid19ivd
- Antibody testing is <u>not</u> recommended for diagnosis or exclusion of COVID-19
- When using antibody testing, notify patients of limitations of the test
 - Still unknown whether antibodies confer full or partial immunity to COVID-19 or for how long.
 - Cross-reactivity with other coronaviruses may be a concern
 - EUA ≠ FDA approval



- OHA is tracking all lab reports from serology tests. Positive serology results are categorized as suspect cases
 - Public health does not follow-up on positive serology; if resources allow LPHA may call provider to ask if molecular test was also done
 - Only confirmed and presumptive cases are included in case counts
- FDA comparison of selected antibody test performance:
 https://www.fda.gov/medical-devices/emergency-situations-medical-devices/eua-authorized-serology-test-performance



Cellex qSARS-CoV-2 IgG/IgM Rapid Test

Developer: Cellex, Inc.

Test: qSARS-CoV-2 IgG/IgM Rapid Test

Technology: Lateral Flow

Antibody	Performance Measure	Estimate of Performance	95% Confidence Interval
Combined	Sensitivity (PPA)	93.8% (120/128)	(88.2%; 96.8%)
Combined	Specificity (NPA)	96.0% (240/250)	(92.8%; 97.8%)
Combined	PPV at prevalence = 5%	55.2%	(39.2%; 69.8%)
Combined	NPV at prevalence = 5%	99.7%	(99.3%; 99.8%)



Roche Elecsys Anti-SARS-CoV-2

Developer: Roche

Test: Elecsys Anti-SARS-CoV-2

Technology: High Throughput ELISA

Antibody	Performance Measure	Estimate of Performance	95% Confidence Interval
Pan-Ig	Sensitivity (PPA)	100% (29/29)	(88.3%; 100%)
Pan-Ig	Specificity (NPA)	99.8% (5262/5272)	(99.7%; 99.9%)
Pan-Ig	PPV at prevalence = 5%	96.5%	(93.9%; 98.1%)
Pan-Ig	NPV at prevalence = 5%	100%	(99.4%; 100%)



Antigen testing

- There is one antigen test with FDA EUA to date: Sofia 2 SARS Antigen FI.
- https://www.fda.gov/media/137885/download
- It is a rapid (results in minutes), point-of-care test that detects SARS-CoV and SARS-CoV-2.
- Specimen: nasal swabs
- Performance data based on small studies from the manufacturer shows a sensitivity of 80% compared to PCR and a specificity of 100%.
 - Higher chance of false negatives, which is problematic
- No cross-reactivity with other respiratory viruses, including human coronaviruses, was found.



Concerns with Abbott ID NOW

- Abbott ID NOW is a platform that allows rapid molecular testing (similar to PCR, but isothermal); results in <15 minutes
- Abbott's small internal performance study showed 100% sensitivity and specificity for their COVID-19 test, but n=50 and it was a contrived study with spiked samples
- FDA issued release on May 14 about data suggesting inaccurate results from the ID NOW COVID-19 test
 - FDA has received 15 adverse event reports about the Abbott ID NOW test that suggest some users are receiving inaccurate negative results
 - https://www.biorxiv.org/content/10.1101/2020.05.11.089896v1.full.pdf
 - NYU study (preprint) compared ID NOW with nasal swabs to Cepheid PCR test with NP swabs



Concerns with Abbott ID NOW

- FDA issued release on May 14 about data suggesting inaccurate results from the ID NOW COVID-19 test
 - In NYU study, ID NOW missed a third of positive samples when using NP swabs in VTM and over 48% when using dry nasal swabs
 - Other studies have showed sensitivity of 85–98%
 - FDA: Negative results may need to be confirmed with a high-sensitivity authorized molecular test"
 - ID NOW machines are in use around the state, but represent a small portion of total testing capacity
 - OHA is reviewing evidence, including types of specimen collection and transport



Clinical Care Questions



When can a patient leave isolation?

- People with COVID-19 who have stayed home (home isolated)
 can leave home under the following conditions:
 - If they have not had a test to determine if they are still contagious, they can leave home after these three things have happened: They have had no fever for at least 72 hours (that is three full days of no fever without the use of medicine that reduces fevers) AND
 - other symptoms have improved (for example, symptoms of cough or shortness of breath have improved) AND
 - at least 10 days have passed since their symptoms first appeared
 - If they have had a test to determine if they are still contagious, they can leave home after these three things have happened:
 - They no longer have a fever (without the use of medicine that reduces fevers) AND
 - other symptoms have improved (for example, symptoms of cough or shortness of breath have improved) AND
 - they have received two negative tests in a row, at least 24 hours apart. Their doctor will follow CDC guidelines

When can a patient leave isolation?

- People who DID NOT have COVID-19 symptoms, but tested positive can leave home isolation under the following conditions:
 - If they have not had a test to determine if they are still contagious, they can leave home after these two things have happened:
 - At least 10 days have passed since the date of their first positive test AND
 - they continue to have no symptoms (no cough or shortness of breath) since the test.
 - If they have had a test to determine if they are still contagious, they can leave home after:
 - They have received two negative tests in a row, at least 24 hours apart.
 Their doctor will follow CDC guidelines.



Answers to Your Questions

- Have there been any concerns or recommendations in post-Covid care?
 - No specific screening or follow up care has been recommended
 - There has been national policy discussions on increasing SNF capacity and in-home post hospital support for rehab
- Why do restaurants and bars have to close at 10PM?
 - To allow thorough cleaning before the next day's service
- What is the transmissibility of COVID-19 out of doors?
 - The CDC notes that is much lower risk of transmission out of doors compared to indoors. People should still maintain a 6 foot distance from others. This is likely sufficient even for higher risk people.



Answers to Your Questions

- What are the recommendations on travel?
 - The CDC is still recommending no non-essential travel within the US
 - The governor is still ordering no non-essential travel for phase 0 counties and recommending limited travel in counties in phase 1 reopening
- What is being done for long term care facilities as far as testing?
 - LTCF should have priority for testing for both patients and staff
 - The current guidance on testing states
 - "When clinical laboratories have sufficient testing capacity, people in [LTCF] settings without symptoms can also be considered for testing if current disease clusters or outbreaks warrant"



Closing and Important Contact Info

OHA Coronavirus Information for healthcare providers http://www.healthoregon.org/coronavirushcp

includes links to these and previous webinar slides

Email your COVID-19 questions here that you want us to address at future informational sessions (*do not expect an individual response and do not send PHI*):

HealthCare.Provider@dhsoha.state.or.us



Oregon COVID-19 Response for Clinicians: Project ECHO

The "Oregon COVID-19 Response for Clinicians"
Project ECHO, a weekly virtual interactive session, will be held on Thursdays from 12-1:00 pm. This is hosted by the Oregon ECHO Network at OHSU and will be staffed by Dr. Hargunani and Dr. Jennifer Vines, Multnomah County Health Officer and other invited content experts. They will provide the latest updates, share COVID-19 clinical cases and answer questions.

For more information see the attached flyer or connect directly on Thursday here: https://zoom.us/j/575366462

