Covid-19 Webinar for Critical Access Hospitals and Outpatient

Presented in collaboration with Nebraska ICAP, Nebraska DHHS HAI Team, Nebraska Medicine, and The University of Nebraska Medical Center

Special Guest:
Scott Bergman, PharmD, BCPS, BCIDP

Presented by Kate Tyner
Moderated by Mounica Soma

Panelists:
Dr. Salman Ashraf, MBBS
Angie Vasa, RN, BSN
Kate Tyner, RN, BSN, CIC
Margaret Drake, MT(ASCP),CIC
Teri Fitzgerald RN, BSN, CIC

Guidance and responses were provided based on information known on 5/12/2020 and may become out of date. Guidance is being updated rapidly, so users should look to CDC and jurisdictional guidance for updates.

Questions and Answer Session

Use the QA box in the webinar platform to type a question. Questions will be read aloud by the moderator

If your question is not answered during the webinar, please either e-mail it to NE ICAP or call during our office hours to speak with one of our IPs

A transcript of the discussion will be made available on the ICAP website

https://icap.nebraskamed.com/coronavirus/
https://icap.nebraskamed.com/covid-19-webinars/

Panelists today are:

Dr. Salman Ashraf, MBBS	salman.ashraf@unmc.edu
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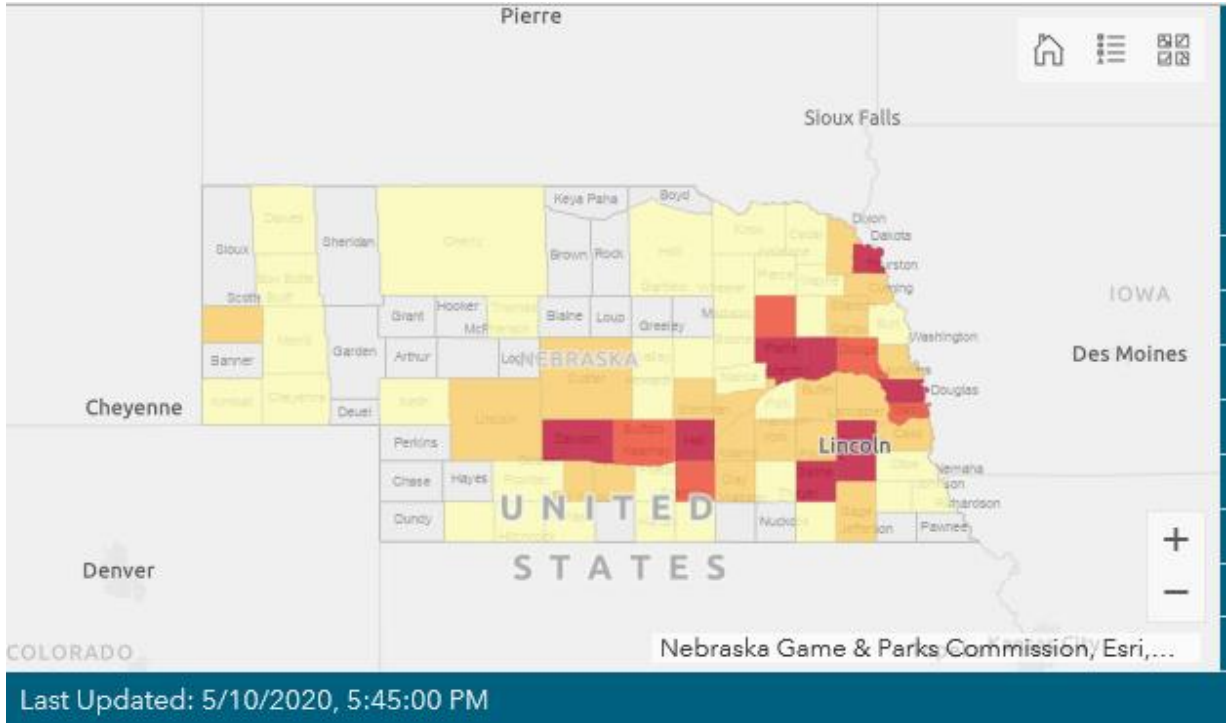
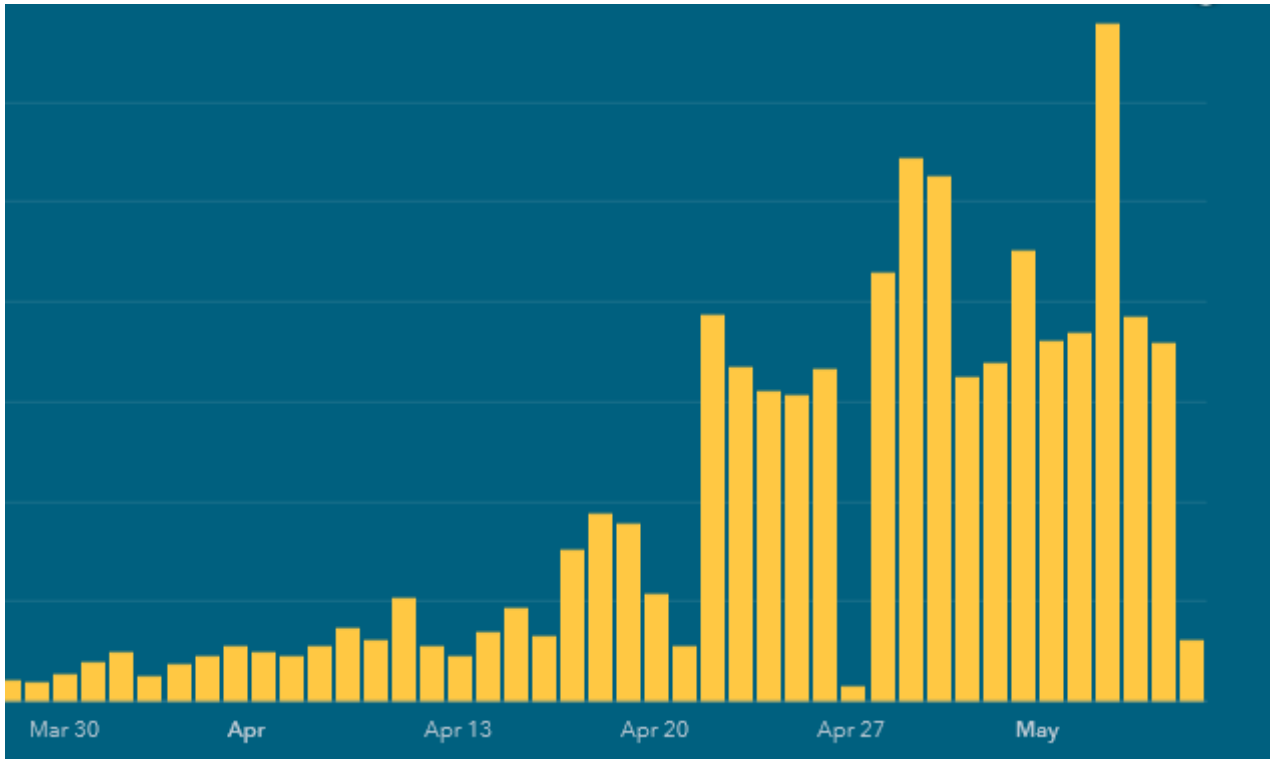
DEPT. OF HEALTH AND HUMAN SERVICES

Nebraska Case Update

Coronavirus COVID-19 Nebraska Cases



New positive cases by date results were received



https://nebraska.maps.arcgis.com/apps/opsdashboard/index.html#/4213f719a45647bc873ffb58783ffef3

Treatment of COVID-19: Focus on Remdesivir

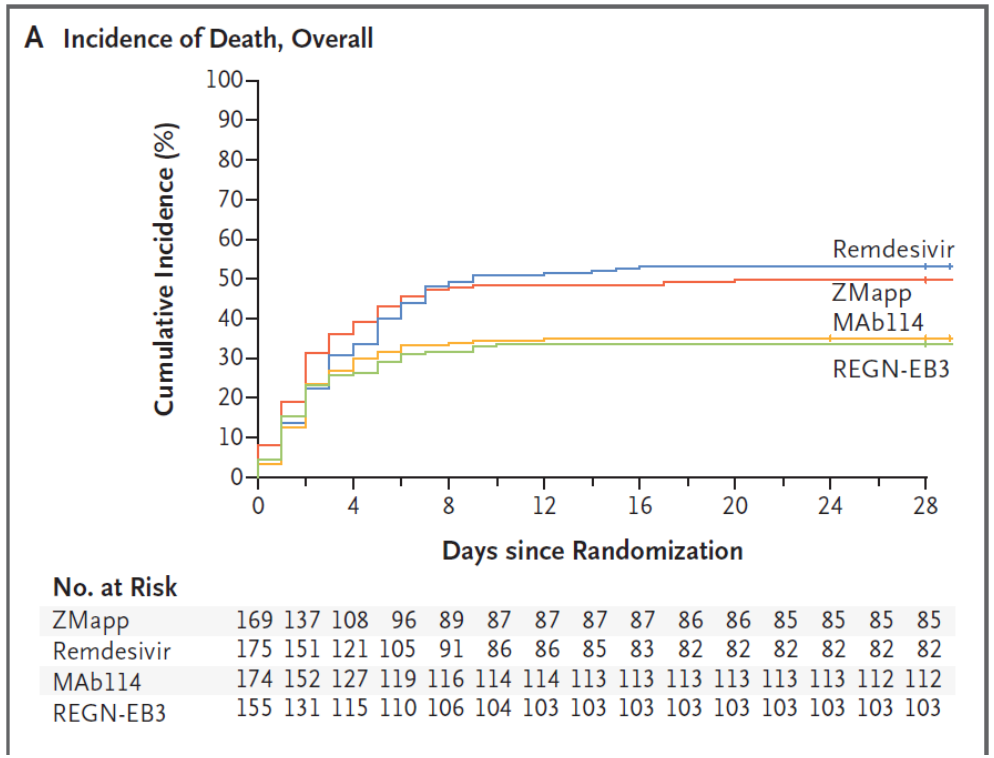
Scott Bergman, PharmD, BCPS, BCIDP, FCCP, FIDSA

Pharmacy Coordinator, Antimicrobial Stewardship - Nebraska Medicine

Clinical Associate Professor, UNMC College of Pharmacy

Remdesivir

- Mechanism: Nucleoside analogue that interferes with RNA-dependent RNA polymerase and leads to premature termination of viral RNA transcription
- Studied for Ebola virus disease



Mulangu. NEJM. Dec 12, 2019

Adaptive COVID Treatment Trial (ACTT)

- Began Feb 25, 2020
  - 68 sites, 47 in U.S.
- Randomized, placebo-controlled study
  - Initial goal: 400 patients
- Inclusion: Adults with pneumonia, $SpO_2 \leq 94\%$
  - Illness of any duration, but test positive ≤ 72 hours prior
- Exclusion: eGFR < 50 ml/min
  - ALT/AST > 5 times upper limit of normal

https://www.nih.gov/news-events/news-releases/nih-clinical-trial-remdesivir-treat-covid-19-begins

Primary Endpoint: Day of Recovery

1. **Not hospitalized, no limitations**
2. **Not hospitalized, limitations on activities and/or home oxygen**
3. **Hospitalized, no supplemental oxygen or on-going medical care required**
4. Hospitalized, not on supplemental oxygen but requires on-going medical care
5. Hospitalized, requiring supplemental oxygen
6. Hospitalized, on high-flow/Non-invasive positive pressure ventilation
7. Hospitalized, on Mechanical ventilation or ECMO
8. Death

Remdesivir Efficacy

- First phase closed on April 19
  - >600 assessed improvements
- Remdesiver 200mg x1, then 100mg daily
  - Up to 10 days of therapy while hospitalized
- Treated group had 31% faster time to recovery
  - 11 vs 15 d ($p<0.001$)
- Similar mortality
  - 8% vs 11.6% ($p=0.056$)

https://www.nih.gov/news-events/news-releases/nih-clinical-trial-shows-remdesivir-accelerates-recovery-advanced-covid-19

Remdesivir Efficacy

- Another randomized-placebo controlled trial was conducted in hospitalized patients in China
- 237 enrolled between Feb 6-Mar 12, 2020
  - 158 remdesivir, 79 placebo
    - R: 82% on supplemental oxygen + 18% on high-flow
    - P: 4% no oxygen, 83% oxygen, 12% high-flow, 1% vent

Wang. Lancet. Apr 29, 2020.

Remdesivir Efficacy = 2 point Improvement

1. Discharged (alive)
2. Ambient Air
3. Low-flow supplemental oxygen
4. High-flow/Non-invasive positive pressure ventilation
5. Mechanical ventilation/ECMO
6. Death

Wang. Lancet. Apr 29, 2020.

Remdesivir Efficacy

- Treatment not associated with time to clinical improvement
  - 21d vs 23d = Hazard ratio 1.23 [95% CI 0.87-1.75]
- Mortality on day 28 **if** started ≤10d from symptoms:
  - 11% vs 15% [-3.6 (95% CI -16.2 to 8.9)]

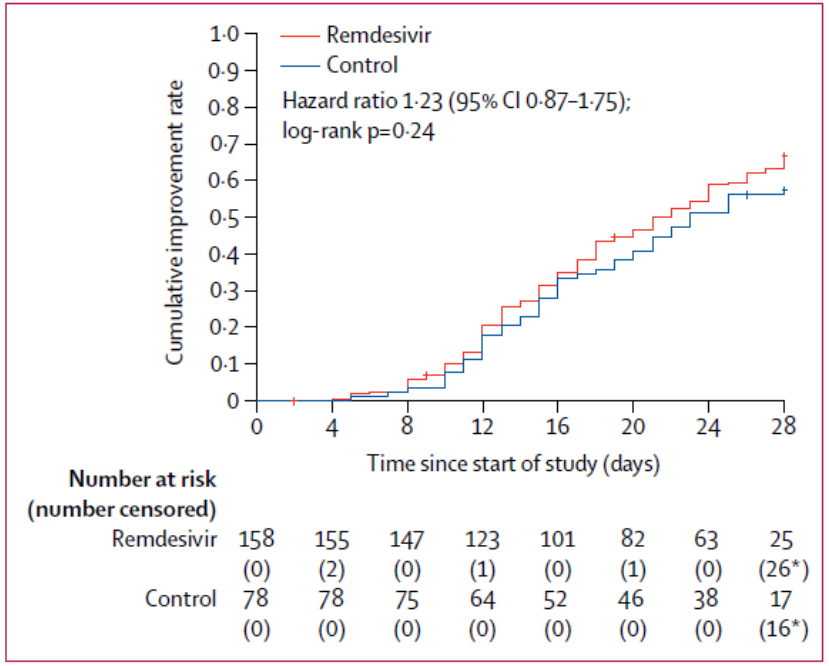


Figure 2: **Time to clinical improvement in the intention-to-treat population**
Adjusted hazard ratio for randomisation stratification was 1·25 (95% CI 0·88–1·78). *Including deaths before day 28 as right censored at day 28, the number of patients without clinical improvement was still included in the number at risk.

Wang. Lancet. Apr 29, 2020.

Safety and Monitoring

- Remdesivir was adequately tolerated and no new safety concerns were identified

Adverse Effects	Remdesivir – (%)	Placebo – n (%)
Any	102 (66)	50 (64)
AST elevation	7 (5)	9 (12)
Thrombocytopenia	16 (10)	5 (6)
Rash	11 (7)	2 (3)
Constipation	21 (14)	12 (15)
Serious	28 (18)	20 (26)
Acute Kidney Injury	1 (1)	0 (0)
Requiring Discontinue	18 (12)	4 (5)
ALT elevation	2 (1)	0 (0)
ARDS/resp. failure	7 (5)	1 (1)

Wang. Lancet. Apr 29, 2020.

Emergency Use Authorization

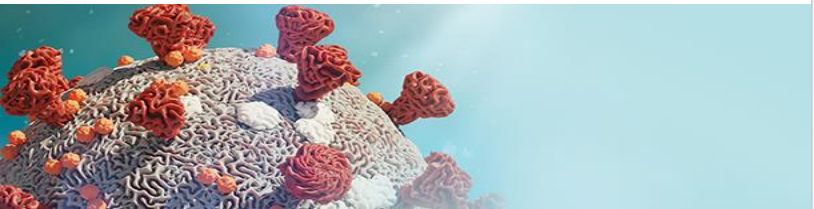
- On May 1st, FDA started to allow remdesivir to be used temporarily during the pandemic without approval
- Gilead donated doses to government*
  - FEMA began issuing allocations to states this week based on case load
- Shipment is coming today for Nebraska
  - 400 vials, approximately 50 treatment courses (same for Iowa)
- Contact your Department of Health and Human Services

*1.5 million doses donated, 600,000 to U.S.

https://www.hhs.gov/about/news/2020/05/09/hhs-ships-first-doses-of-donated-remdesivir-for-hospitalized-patients-with-covid-19.html

Resources

https://www.nebraskamed.com/for-providers/covid19/other-protocols-and-resources



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Revision Date: 4/29/2020

COVID-19 Antiviral and Pharmacotherapy Information

Supportive therapy is the cornerstone of treatment. No antiviral therapy option can currently be recommended in addition to supportive care, nor should any be considered comparatively superior for SARS-CoV-2 given the available data. Recent IDSA and NIH guidelines reinforce this general approach to pharmacological treatment[32,40]. It is also currently unclear whether multidrug regimens provide any additional benefit in the treatment of COVID-19. Given the current lack of data over monotherapy regimens and the added toxicity of multidrug regimens, it is very unlikely that multidrug combinations will produce a favorable risk/benefit ratio.

Antiviral therapy should only be considered in patients with confirmed infection. Therapies below have been tiered based on the available data, current availability, toxicity profile, and practical considerations specific to the Nebraska Medical Center. Updates are expected during this fluid situation.

Preferential (clinical trial enrollment):

» **Remdesivir Clinical Trial** (NCT04280705) – The remdesivir phase of the NIAID adaptive trial has completed enrollment. This trial will be unavailable for enrollment for a few weeks while data are analyzed and the next phase is prepared with baricitinib.

- Dosing: 200mg IV once, then 100mg IV daily for duration of hospitalization or up to 10 total days
- Adverse Effects: Generally mild severity - GI intolerances, LFT abnormalities, infusion-related reactions
- Inclusion Criteria: Age ≥18, PCR confirmed SARS-CoV-2 infection within past 3 days, one of: 1) infiltrates on chest imaging 2) requiring supplemental oxygen or mechanical ventilation 3) respiratory physical exam findings and $S_pO_2 \leq 94\%$ on RA
- Exclusion Criteria: AST or ALT >5x ULN, eGFR<50 or on dialysis, pregnancy or breast feeding, anticipated discharge within 3 days

Situational (alphabetical order): Risk/benefit ratio may favor use in selected patients. ID consultation required.

» **Remdesivir Expanded Access** (NCT04323761) – This is an IRB-approved medication expanded access program. The UNMC Clinical Research Center (llarson@unmc.edu) can be contacted for the latest status.

- Dosing: 200mg IV once, then 100mg IV daily for up to 10 total days
- Adverse Effects: Generally moderate severity – GI intolerances, LFT abnormalities, infusion-related reactions
- Inclusion Criteria: Age ≥18, PCR confirmed SARS-CoV-2 infection or known contact of a confirmed case with PCR pending, requiring mechanical ventilation
- Exclusion Criteria: AST or ALT >5x ULN, eGFR<30 or on dialysis, pregnancy, multi-organ failure, requiring vasopressor support

Situational (alphabetical order): Efficacy unproven and toxicity risk noteworthy; do not generally use outside of a clinical trial

Treatment of COVID-19: Focus on Remdesivir

Scott Bergman, PharmD, BCPS, BCIDP
scbergman@nebraskamed.com

Tips and reminders from the field

Staff training

When considering where to start with staff training needs, you will be best served if you start observing staff in their work environment.

Go out with a specific practice or practices to observe – hand hygiene, PPE donning and doffing, mask use, gown use, and environmental cleaning….note competency of staff in their performance of these practices

Once you have identified areas of concern, you may wish to engage some of your staff to become **super users**, and enlist their help in helping others. They may need some initial training on proper steps of procedure, how best to observe, and how to approach staff to help them correct any inappropriate practices.

Staff training – hand hygiene

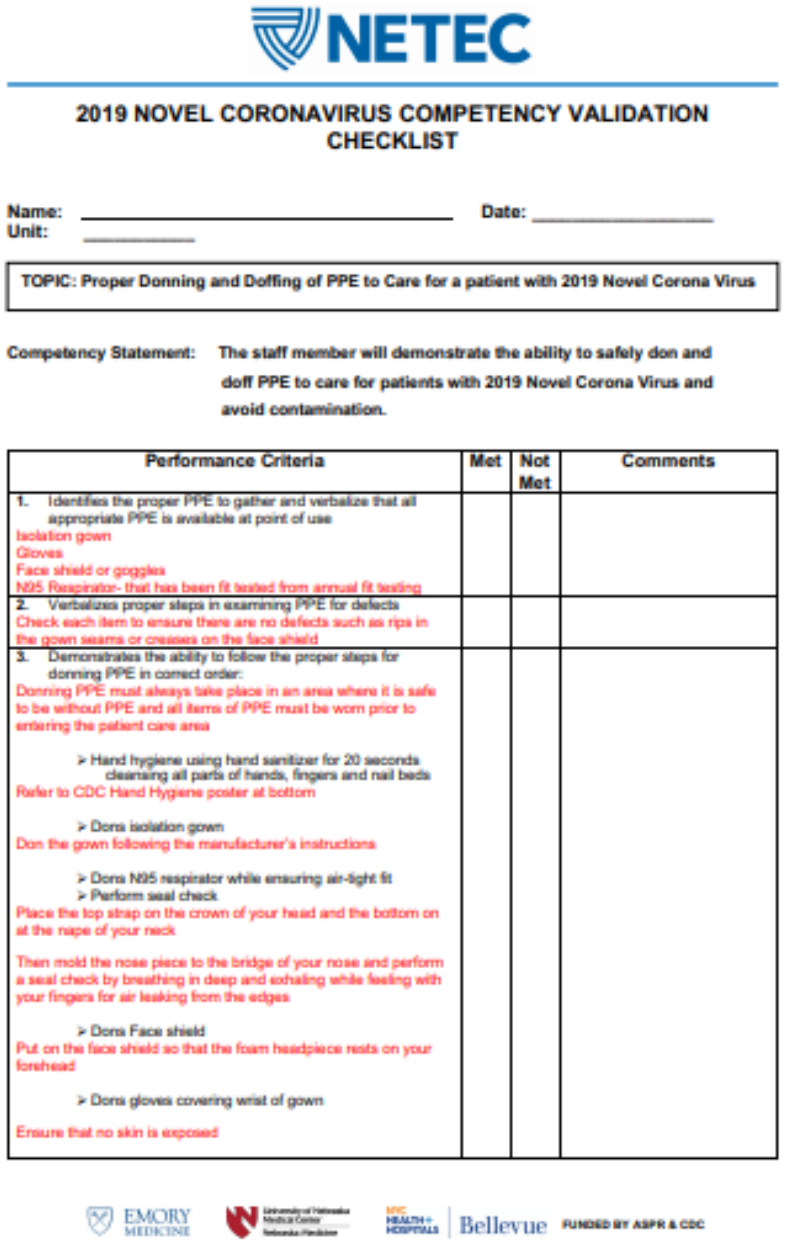
First, let's discuss hand hygiene, as HH is a basic infection control practice that ensures we have clean hands before donning PPE, and during doffing of PPE. Staff should know how to perform correctly in each situation.

- What is the facility expectation for performance of hand hygiene? Perform in sinks only? Or is ABHR available?
- Do you have ABHR available throughout your facility?
- Do you routinely observe HH performance and give feedback to staff?

Staff training: Barriers & Ideas

Barrier	Idea
Not enough time	Designate a “training extender” per shift
No team members feel comfortable giving feedback	• Utilize checklists • Round in teams • Script feedback “I care about you and want you to be safe.”
Team members don’t handle criticism well	• Phrase feedback in a way that doesn’t feel like criticism • Offer feedback when good practice is observed
Care happens behind a closed door	• Use 2-person tasks for audit and feedback • Shadow staff and use time to check in with residents

Staff training - PPE



NETEC

2019 NOVEL CORONAVIRUS COMPETENCY VALIDATION CHECKLIST

Name: _____ **Date:** _____
Unit: _____

TOPIC: Proper Donning and Doffing of PPE to Care for a patient with 2019 Novel Corona Virus

Competency Statement: **The staff member will demonstrate the ability to safely don and doff PPE to care for patients with 2019 Novel Corona Virus and avoid contamination.**

Performance Criteria	Met	Not Met	Comments
1. Identifies the proper PPE to gather and verbalize that all appropriate PPE is available at point of use Isolation gown Gloves Face shield or goggles N95 Respirator- that has been fit tested from annual fit testing			
2. Verbalizes proper steps in examining PPE for defects Check each item to ensure there are no defects such as rips in the gown seams or creases on the face shield			
3. Demonstrates the ability to follow the proper steps for donning PPE in correct order: Donning PPE must always take place in an area where it is safe to be without PPE and all items of PPE must be worn prior to entering the patient care area ➢ Hand hygiene using hand sanitizer for 20 seconds cleansing all parts of hands, fingers and nail beds Refer to CDC Hand Hygiene poster at bottom ➢ Dons isolation gown Don the gown following the manufacturer's instructions ➢ Dons N95 respirator while ensuring air-tight fit ➢ Perform seal check Place the top strap on the crown of your head and the bottom on at the nape of your neck Then mold the nose piece to the bridge of your nose and perform a seal check by breathing in deep and exhaling while feeling with your fingers for air leaking from the edges ➢ Dons Face shield Put on the face shield so that the foam headpiece rests on your forehead ➢ Dons gloves covering wrist of gown Ensure that no skin is exposed			

EMORY MEDICINE | Bellevue | FUNDED BY ASPR & CDC

https://repository.netecweb.org/files/original/b1abd8f26ee3739f72e62718691f663b.pdf

Staff training – environmental cleaning

Here are the links to the Environmental Cleaning Videos. These are available in 4 languages.
https://icap.nebraskamed.com/practice-tools/educational-and-training-videos/draft-environmental-cleaning-in-healthcare

CDC Environmental Checklist for Monitoring Terminal Cleaning[1]

Date:	
Unit:	
Room Number:	
Initials of ES staff (optional):[2]	

Evaluate the following priority sites for each patient room:

High-touch Room Surfaces[3]	**Cleaned**	**Not Cleaned**	**Not Present in Room**
Bed rails / controls			
Tray table			
IV pole (grab area)			
Call box / button			
Telephone			
Bedside table handle			
Chair			
Room sink			
Room light switch			
Room inner door knob			
Bathroom inner door knob / plate			
Bathroom light switch			
Bathroom handrails by toilet			
Bathroom sink			

https://www.cdc.gov/hai/pdfs/toolkits/environmental-cleaning-checklist-10-6-2010.pdf

Anticipate findings

- A protocol has been updated and this teammate on night shift wasn't notified - *Is our communication process working for all shifts?*

- Ask for staff input *"I see that this is difficult for you. How can we work together to make the process easier to follow?"*

- Let them know your thoughts as well – *"When we designed or implemented the workflow, we didn't think of this barrier. Let's take it back to the team to think through the best way to deal with this issue."*

New and interesting resources

Infectious Diseases Society of America Guidelines on Infection Prevention in Patients with Suspected or Known COVID-19

- N95s and Respirators
- Double vs. Single Glove (Routine Patient Care)
- Shoe Cover vs. No Shoe Covers (Routine Patient Care)
- N95 Respirators vs. Surgical Masks (Aerosol Generating Procedures)
- Reuse/ Extended Use of N95 Respirators vs. Surgical Masks (Aerosol Generating Procedures)
- Face Shield/ Surgical Mask + N95 Respirator (Aerosol Generating Procedures)

https://www.idsociety.org/practice-guideline/covid-19-guideline-infection-prevention/

How Reliable Are COVID-19 Tests? Depends Which One You Mean (NPR Shots)

- **Diagnostic or PCR test**
- **Antibody test**
- **Antigen test**

- What it does
- How it works
- How accurate is it
- How quick is it

https://www.npr.org/sections/health-shots/2020/05/01/847368012/how-reliable-are-covid-19-tests-depends-which-one-you-mean

CDC Updates

CDC Worker Safety and Support (5/11/2020)

https://www.cdc.gov/coronavirus/2019-ncov/community/worker-safety-support/index.html

- Recognize the symptoms of stress you may be experiencing
- Tips to cope and enhance your resilience
- Know where to go if you need help

•National Suicide Prevention Lifelineexternal icon

Toll-free number 1-800-273-TALK (1-800-273-8255)

The online Lifeline Crisis Chatexternal icon is free and confidential. You'll be connected to a skilled, trained counselor in your area.

•National Domestic Violence Hotlineexternal icon

Call 1-800-799-7233 and TTY 1-800-787-3224

If you feel overwhelmed with emotions like sadness, depression, or anxiety:

•Disaster Distress Helplineexternal icon

Call 1-800-985-5990 or text TalkWithUs to 66746

Self-Care And Mental Health

NOTE: *All outside links and PDFs open in a NEW browser window.*

Resiliency, well-being and mental health – Health Providers

- NETEC Resources
- SAMSA Disaster Distress Helpline
- Nebraska Disaster Behavioral Health System
- Psychological First Aid

Resources and support for those in isolation

- Coalition to End Social Isolation & Loneliness
- SAMHSA – Tips for Social Distancing, Quarantine and Isolation

http://dhhs.ne.gov/Pages/Self-care-and-Mental-Health.aspx

When should I seek help?

- Intrusions (nightmares, flashbacks, intrusive thoughts)
- Avoiding reminders of a traumatic event
- Hyper-arousal (anxiety, insomnia, irritability, etc.)
- Avoiding feelings by using substances
- Feeling numb, spaced out or like things aren't real
- Daily functioning is affected

https://repository.netecweb.org/files/original/0cedfcdf6b03dd905b3ff7aa83905e6a.pdf

IP Office Hours

Monday – Friday

7:30 AM – 9:30 AM Central Time

2:00 PM -4:00 PM Central Time

Call 402-552-2881

ICAP

Infection Control Assessment and Promotion Program

Questions and Answer Session

Use the QA box in the webinar platform to type a question. Questions will be read aloud by the moderator, in the order they are received

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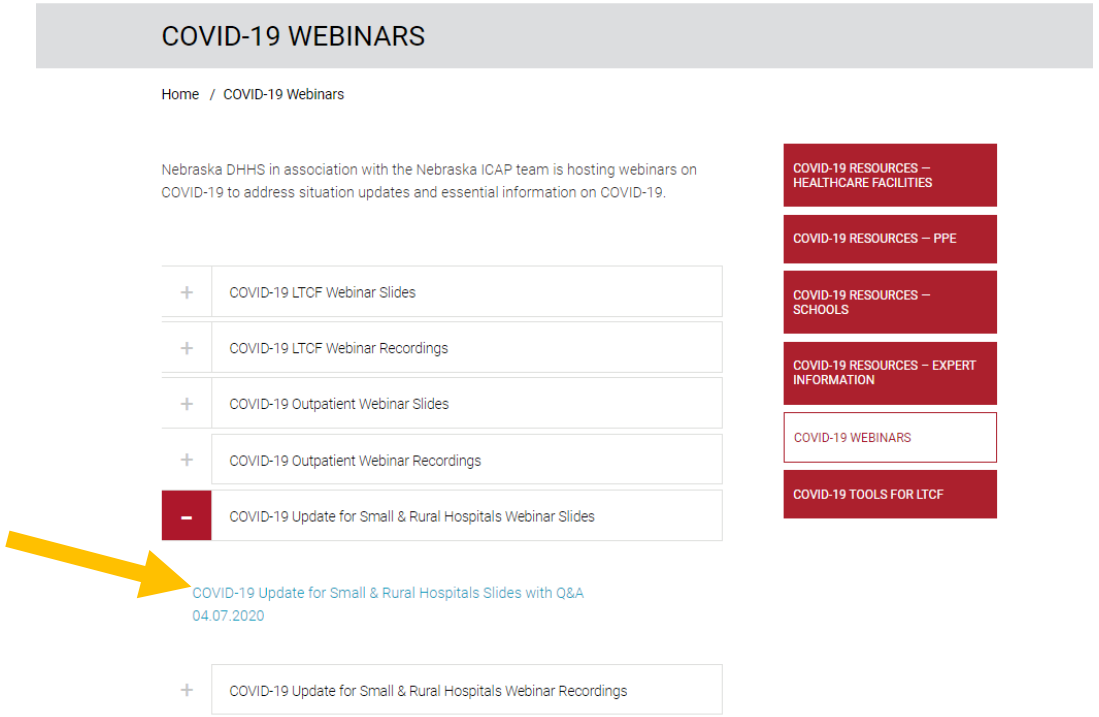

https://icap.nebraskamed.com/resources/

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NETEC – NICS/Nebraska DHHS HAI-AR/Nebraska ICAP
Small and Critical Access Hospitals-Outpatient Region VII Webinar on COVID-19 5/12/2020

1. **A local LTC with an active outbreak is outsourcing COVID-19 testing to a lab in Colorado that reportedly does not have a requirement to report to the state of Nebraska. Is this allowable?**
   All facilities getting Medicare/Medicaid patients are subject to the regulatory and licensure requirements for the State of Nebraska. Those requirements include reporting to local public health as well as the regulatory division. The long-term care facility may be incorrectly assuming that the lab is reporting on their behalf through the electronic lab reporting and that is not a good assumption. Contact the long-term care to be sure they are aware of the additional reporting elements. You could involve your local public health department and ask them to work with the public health department in the other state to try to determine how the reporting gap is happening and to try to work it out. Facilities have to report themselves to the licensure and not rely on the labs to report to the state. The labs will report but the facility should not rely on that alone. It is not required that the facilities only need to report to certain labs.

   How are cases such as this tracked if they are not reported to the state or local health department? As the nearest Critical Access Hospital to this facility, we are not able to be well prepared due a severe lack in awareness of the local situation.
   See above answer. When you report to the state licensure, the information gets to the state. It is collated at the state health department. The state is looking at multiple data sources, but ICAP will double check on this.

2. **Should we still self-quarantine if we travel out of state? Is it different if you travel by car versus public transportation (plane/train)? Thinking about what to do with summer vacation.**
   The state still has a list of places (on their website) that if you have traveled there, you should self-quarantining for 14 days on your return. If you are traveling by plane, that is a higher risk exposure because you are coming in contact with many people in the close spaces of the plane. You need to be careful of where you are going and if there is community transmission in that area. Social distancing needs to be maintained. Even people traveling by car, depending on your destination, distance from home, how many stops you need to make, how many places you need to stay along the way, all factor into that. Be very careful in planning your summer vacations. CDC updated their traveler guidance slightly over the weekend. They noted that with spotted openings in certain states, you can't count on nation-wide guidance. We recommend you tell your employees that only essential travel should be done for their safety.

   There is a page on the DHHS website for travelers returning to Nebraska and that will give more guidance. It was updated on March 25 and that is the latest update to that. Healthcare worker situations are specifically mentioned on that document.

3. **What is the link to today's slides?** https://icap.nebraskamed.com/covid-19-webinars/

4. **If Test Nebraska says we should get a test, do we need to get it done? I am concerned that someone with no symptoms will get a false positive and not be able to work for 2 weeks.**
   TestNebraska is not a mandate. Everyone who thinks they may be exposed has it available to it. This helps identify if people are asymptomatically affected, so it is best to find them and isolate them. This gives more people the ability to determine if they have contracted the virus and are carrying it asymptomatically.

5. **Do you know if they are working towards tracking recovery rates?**
   As far as nursing home, they are providing information to the state on the number of patients who are testing positive and how many deaths there have been, along with recovery data. ICAP will check on the hospitals and report back soon.

6. **Has there been updated guidance on providing universal testing within long-term care facilities or assisted living facilities? Where all staff and all residents are tested?**
   So far, in long-term care and assisted living, if there is a suspicion of wide-spread transmission there with positive residents and staff, there have been time when all were tested. It can be scaled back to a specific unit or floor, including staff that work in those areas. More recently the White House has suggested we might need to test every single patient in every long term care facility in the nation. The CDC guidance is that if there is a suspected or confirmed case on a floor or the whole facility, you can do point-prevalence testing of staff and residents.

7. **Do you have any suggestions on getting to tests to long-term care facilities? So they could test immediately if they believe they may have a case?**
   Long-term care facilities have recommendations to contact their local health department. They have been issued a few test kits in some cases to use to test immediately if a case comes in. That is especially true when they have seen a positive case in their facility, then the local health department may have given the facility test kits to keep on hand. It is a bigger problem in some assisted living facilities if they don't had a nursing staff to administer the testing. That can cause a delay where you have to find someone to come in and give the test.

8. **If there are no COVID-positive residents or workers at a facility, do residents need to wear a mask when out of the room in the facility?**
   Yes, they do need to wear a mask. Universal masking doesn't depend on whether you know a case. It is based on the fact that there is asymptomatic transmission happening in the community. It could be residents or staff who don't show any signs. We cannot assume that. There are some residents who can't keep them on; who don't understand why they need them on, etc. We should be on the safe side as much as possible.

9. **If an acute care facility in Nebraska is trying to request Remdisivir, is there someone they should contact? Is there a protocol in development? How do we know the right person to contact?**
   Nebraska Medicine is working on criteria for use and how many doses can be allocated. Scott Bergman explained there is a committee meeting today to decide on distribution to facilities. He favors getting the doses into the hands of the facilities for them to decide on any use of the drug. Right now the DHHS and Dr. Anthone are leading this effort, so you those would be the

contacts – public health. He believes there will be waiting lists developed and recommended criteria to budget the supplies. We want to make the best use of the supply on hand.