### Outbreak or pseudo-outbreak? Integrating SARS-CoV-2 sequencing to validate infection control practices in an end stage renal disease facility

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#### ABSTRACT

**Background:** The COVID-19 pandemic of 2020 poses a particularly high risk for End Stage Renal Disease (ESRD) patients and led to a need for facility-wide control plans to prevent introduction and spread of infection within ESRD facilities. Rapid identification of clusters of contemporaneous cases is essential, as these may be indicative of within-facility spread. Nevertheless, in a setting of high community COVID-19 prevalence, a series of ESRD patients may test positive at around the same time without their shared ESRD facility being the nexus for disease spread. Here we describe a series of five cases occurring within an eleven-day period in November 2020 in a hospital-based 32-station ESRD facility in southwest Wisconsin, the subsequent facility-wide testing, and the use of genetic sequence analysis of positive specimens to evaluate whether these cases were linked.

**Methods:** Four patient cases and one staff case were identified in symptomatic individuals by RT-PCR. Facility-wide screening was initiated at the request of local public health and conducted using Abbot BinaxNOW antigen tests. SARS-CoV-2 genome sequences were obtained from residual diagnostic test specimens using an amplicon-based approach on an Ion Torrent S5 sequencer.

**Results:** Residual specimens from 4 of 5 cases were available for sequence analysis. Each sequence was very clearly genetically distinct from the others, indicating that these contemporaneous cases were not linked. Facility-wide screening of 47 staff and 107 patients did not identify any additional cases.

**Conclusions:** These data indicate that despite the outward appearance of a case cluster, the facility did not experience within-facility spread nor serve as the epicenter of a new outbreak, suggesting that the enacted rigorous infection control procedures (screening, masking, distancing) practiced stringently by patients and staff were sufficient to permit dialysis to proceed safely in a very high-risk population under pressure from increasing community spread. These data also demonstrate the utility of rapid turnaround SARS-CoV-2 sequencing in outbreak investigations in settings like ESRD facilities.

#### INTRODUCTION

A global pandemic of novel coronavirus, SARS-CoV-2, was declared by the World Health Organization on March 11, 2020. The first reported death from COVID-19 in the United States was an End Stage Renal Disease (ESRD) patient (1). Accumulating data show that ESRD patients are at higher risk of adverse outcomes when infected with the virus (2, 3); however, they still depend on regularly scheduled treatments to maintain their health. Detailed guidance on optimal control measures to contain COVID-19 in dialysis is available and emphasizes staff and patient education, early screening of patients, managing patients with symptoms or illness, managing resources and managing the workforce (4-6). There are limited protocols and procedures in place to guide facility-wide testing efforts, and some suggest transferring these patients to designated COVID-19 facilities or hospitals in response to identification of cases (4).

Because of the risk of COVID-19 to ESRD patients and the risk of subsequent spread to other vulnerable populations (7), rapid detection and prevention of COVID-19 spread within dialysis facilities is of critical importance. In Wisconsin, two cases occurring within seven days in an ESRD facility is considered an outbreak warranting public health investigation (8). As cases in the community become more widespread, the probability of two or more unrelated cases utilizing the same ESRD facility increases. Efficiently distinguishing such "pseudo-outbreaks" from true cases of intra-facility spread may allow more efficient use of both infection control and public health staff resources, as well as providing reassurance to both staff and patients about the actual effectiveness of infection control measures employed.

Here we describe a series of five cases occurring within an eleven-day period in a hospitalbased 32-station ESRD facility in southwest Wisconsin, the subsequent facility-wide testing, and the use of genetic analysis of positive specimens to unambiguously demonstrate that these cases were not linked to spread of a commonly circulated virus within the facility.

#### MATERIALS AND METHODS

*SARS-CoV-2 testing:* Each of the five cases defining the potential cluster was diagnosed by RT-PCR from nasopharyngeal specimens at Gundersen Health System laboratories. Facility-wide surveillance testing was performed using anterior nares swabs with the Abbott BinaxNOW antigen test kit.

*SARS-CoV-2 sequencing and analysis:* cDNA was generated from residual RNA from diagnostic specimens using ProtoScript II (New England Biolabs, Ipswich, MA). The Ion AmpliSeq SARS-CoV-2 Panel (Thermo-Fisher, Waltham, MA) was used to amplify 237 viral specific targets encompassing the complete viral genome. Libraries were sequenced and analyzed as we have previously described (9). For phylogenetic inference (i.e. to determine the hierarchy of case relationships), sequences were integrated with associated metadata and aligned on a local implementation of NextStrain (10) using augur and displayed via a web browser using auspice. Cases sequenced in this study were analyzed against a background collection of 1,120 SARS-CoV-2 genomes sequenced at Gundersen Health System between March and December 2020.

*Ethical approval:* Specimens were analyzed in this study under a protocol approved by the Gundersen Health System Institutional Review Board (#2-20-03-008; PI: Kenny) to perform next-generation sequencing on remnant specimens after completion of diagnostic testing.

#### RESULTS

To protect patient privacy, we will not disclose precise diagnosis dates but instead provide a numbered timeline centered on the date of the first diagnosis in the apparent cluster. The first patient case of COVID-19 in this investigation was diagnosed on a date between Nov 1-15, 2020, which we designate "Day 0". One additional patient was diagnosed on day 1, two more followed on day 3 and a staff member was diagnosed on day 10. Hemodialysis patients typically utilize the facility once every two days, and all four COVID-19-positive patients shared the same alternate day schedule. These details and the treatment location for each individual are summarized on the facility map (Figure 1).

The facility administrator and manager contacted local public health officials after the second, third and fifth cases. After the fifth case (day 10), health officials requested facility-wide testing of all patients and staff. This was performed on days 12 and 13 using the BinaxNOW antigen test. In the facility-wide testing 47 of 47 employees and 107 of 107 patients tested were negative. One patient refused testing and two patients were not present on either testing day.

The COVID-19 sequencing team was notified of the potential cluster on day 10. Of the five positive cases, four residual specimens were available for sequencing. Sequencing was

completed on day 14. Genomes from each investigated specimen were compared to each other, and to a total of 1,120 genomes sequenced by the team from this region between March and December 2020. Each of the four samples analyzed was clearly genetically distinct from the others (Figure 2), unambiguously demonstrating that within-facility spread did not give rise to this apparent five case cluster.

Antigen testing (with confirmation by isothermal amplification for any positive cases) was chosen for the facility-wide screening for pragmatic reasons, most significantly (1) same-day result, preventing the need for patients or staff to isolate while results were pending, (2) the anterior nares swab was more acceptable to patients than the nasopharyngeal swab used for RT-PCR testing, (3) testing capacity constraints (154 additional RT-PCR tests in a single day was close to half of the daily throughput of the hospital's laboratory) and (4) cost (an allowance of test kits provided at no-cost by the state of Wisconsin was used in this instance, obviating any delays due to potential disagreements on how screening costs should be assigned). Nevertheless, the false negative rate associated with antigen-directed testing among asymptomatic individuals (11) was concerning so we carefully monitored the ESRD facility in the following weeks to identify cases or spread that may have escaped surveillance using this particular assay. In the 14 days following the facility-wide testing, no additional staff cases were identified. Two patient additional cases were identified on days 26 and 28. Residual specimens were available for sequencing from these two cases, and analysis confirmed that they were distinct from each other and from the other cases described in this study.

#### DISCUSSION

In this study, we demonstrate the contribution that rapid turnaround SARS-CoV-2 genome sequencing can make to infection cluster investigation. In this ESRD facility, five cases occurred within an eleven-day period, exceeding Wisconsin's threshold for conducting a facility-wide investigation. The shared dialysis schedule and the proximity of the treatment stations for several of the affected individuals gave rise for additional concern about within-facility spread. While antigen testing of all patients and staff subsequently showed that SARS-CoV-2 infection was limited to only those individuals comprising the putative outbreak, the genomic analysis of the four available specimens conclusively demonstrated that these viruses each possessed distinct genomic lineages, and therefore could not have originated from a spread of a single viral

substrain occurring within the limited window this cohort spent in the dialysis facility, as would be expected in a common source outbreak. Showing that SARS-CoV-2 spread had not occurred between the sequenced individuals in the facility refuted this presumptive cluster and provided staff and patients with reassurance that existing infection control procedures were working well.

We cannot exclude the possibility that the sample that was unavailable for sequencing (P2) might have matched one of the sequenced specimens. However, in the context of the otherwise negative facility-wide screening, the physical separation between P2's treatment station and the nearest station used by a COVID19-positive individual (P4, Figure 1), the universal masking practiced in the facility, and P2's other exposure risk factors (P2 lives in a congregate setting and requires care for complex medical needs), we considered it more likely than not that P2's COVID-19 infection was unconnected to the other individuals.

When the first case of this investigation was identified (day 0), the county in which the facility is located reported a 7-day rolling average test positivity of 27% among symptomatic patients, with a known active case burden (cases identified within the previous 14 days) of 101 active cases per 10,000 residents. By day 11 when the fifth case was identified, the county's level 7-day rolling average test positivity remained little changed at 29%, while the known active case burden had increased to 154 cases per 10,000 residents. In the presence of such widespread community activity, ESRD patients and staff may commonly acquire infections outside of the dialysis facility. While this places other patients at risk if institutional infection control procedures are weak, it may also lead to considerable over-burdening of institutional and public health resources investigating apparent clusters of cases that lack a common infection source.

The facility had implemented progressively more stringent face masking protocols beginning in April, and all patients and staff were masked at all times since July. During this investigation, it was determined that one of the positive patients who, had passed through screening multiple times, reported having had a "cough for a few weeks" when tested. This led to re-education of staff on the importance of diligent use of the screening tools at the entrance to the facility. Despite this screening failure, the absence of detected COVID-19 transmission from this individual in the facility over multiple visits underlines the value of educating patients and staff about mask use and enforcing these rules.

Nationwide, outbreaks in ESRD facilities have resulted in adverse impact to patients (morbidity and mortality among infected individuals, as well as disruption in dialysis schedules/locations for others). Public health recommendations include additional surveillance testing at weekly intervals for up to 28 days until there is a 7-day period of no positive cases. Using sequence data allowed us to demonstrate that this collection of cases was not a cluster of linked infections and therefore, the facility avoided the need for further rounds of surveillance screening of staff and patients. Although genetic analysis subsequently confirmed that these cases were not linked (three days after the decision to implement facility wide testing was taken), a more rapid demonstration that these cases were truly unlinked might have prevented the need for such extensive testing. Given the community case burden at the time of this study, it is likely that weekly surveillance testing may have continued to identify occasional sporadic cases, creating the false impression of a possible ongoing within-facility outbreak.

Though the risks of COVID-19 to ESRD patients are considerable, it is important to account also for the considerable resources involved in monitoring dialysis facilities during putative outbreaks. In our case, the rationale for performing facility-wide screening was clear and concordant with public health guidance. We posit that quicker access to sequencing data, and rapidly demonstrating the lack of a credible genetic and epidemiologic link in the cases in question, may spare the expenses of subsequent rounds of screening in instances similar to our own. Estimating using Medicare reimbursement rates, a single round of screening in a facility of this size would cost \$7,700 (antigen testing) or \$15,400 (RT-PCR). Conversely, sequencing costs per specimen (five each) amounted to approximately \$200 dollars. In this proportion, the speed, cost, and surety provided by sequencing are compelling features that support its more regular inclusion in outbreak investigations as a way to conserve healthcare resources. Moreover, because resource shortages (e.g. PPE, testing capacity) have been an ongoing hallmark of the COVID-19 pandemic in the US, the public health response will likely benefit from redirection of such resources toward higher yield activities.

An adequate, trained and willing workforce as well as robust infection control training and procedures are recognized as key elements in institutional resilience against infectious disease outbreaks (12). Studies of healthcare workers who delivered care during the first SARS pandemic demonstrated long term adverse impacts (13), an experience that will likely be recapitulated at much larger scale in the current SARS-CoV-2 pandemic. Accordingly, it is important for staff to know that not every "outbreak" represents a collective failure to control

disease spread. By demonstrating that this set of cases was not linked and did not lead to intrafacility spread, the genetic data strongly underlined the value of the infection control procedures that were practiced by both staff and patients. They confirm that the ESRD facility was a safe place in which to work and to receive care. Conversely, if the data had indicated some evidence of within-facility spread, the more granular nature of the genetic data may have led to the provision of targeted interventions to mitigate specific risk factors that would have been more challenging to identify from simply a numerical cluster of cases.

In conclusion, the exclusion of a true outbreak in our dialysis facility by way of robust genetic sequencing data validates the integrity of refined infection control practices in these critically important facilities, enabled provision of uninterrupted safe care to vulnerable patients in the midst of accelerating community spread, and highlighted the value of an interconnected network of nimble players in infection control, nursing, public health, and scientific laboratories. We anticipate that the benefits of this collaboration will serve as a model for the increasing use of rapid genomic sequencing data to shape institutional as well as public health responses in future outbreak scenarios in facilities of all sizes. As technology and expertise permit, we anticipate that the tools to quickly differentiate true outbreaks from pseudo-outbreaks will disseminate further into the healthcare landscape, and provide tangible benefits in other congregate settings.

### ACKNOWLEDGEMENTS

This work was supported by the Gundersen Medical Foundation. PAK holds the Dr. Jon & Betty Kabara Endowed Chair in Precision Oncology.

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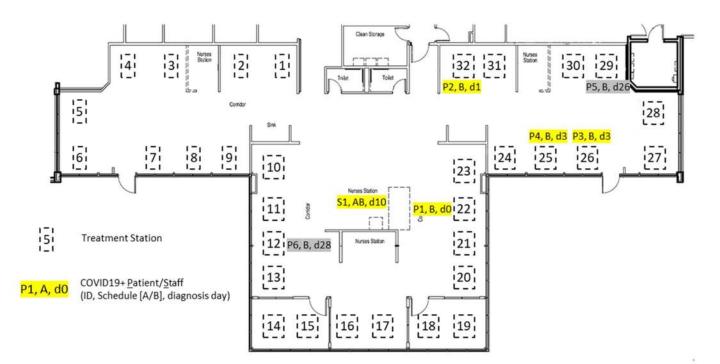
#### FIGURE LEGENDS:

# Figure 1. Schematic representation of the ESRD facility showing the location of treatment stations used by COVID-19-positive individuals.

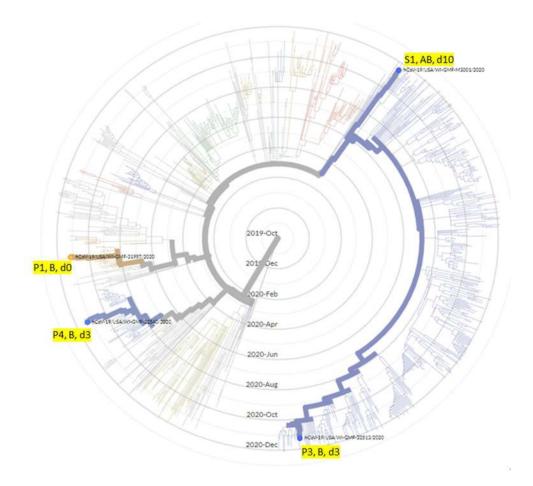
Cases are identified by an ID (P = Patient, S = Staff), which of two non-overlapping dialysis schedules was utilized (A or B) and the date of diagnosis relative to the diagnosis date of the initial patient of this cluster investigation. The five cases comprising the current cluster investigation are highlighted in yellow. Two cases that were detected subsequent to the current investigation are shown in gray.

# Figure 2. Four genetically distinct viral genomes sequenced from patient and staff in this ESRD cluster investigation.

Radial phylogenetic tree representing 1,120 SARS-CoV-2 genomes sequenced at the Gundersen Health System between March – December 2020, with cases relevant to this cluster investigation highlighted. The tip of each branch represents a case and more genetically similar genomes cluster together. Specimens are identified using the code described in Figure 1.



### Figure 1



### Figure 2

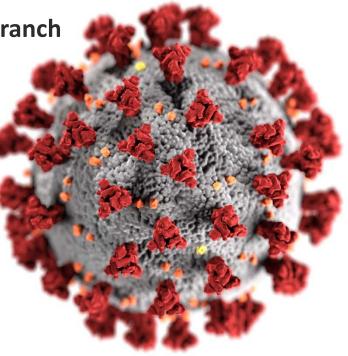
### CDC's COVID-19 Activities in the Dialysis Setting

Dialysis Safety Team, Prevention and Response Branch Division of Healthcare Quality Promotion Centers for Disease Control and Prevention

Annual Dialysis Conference

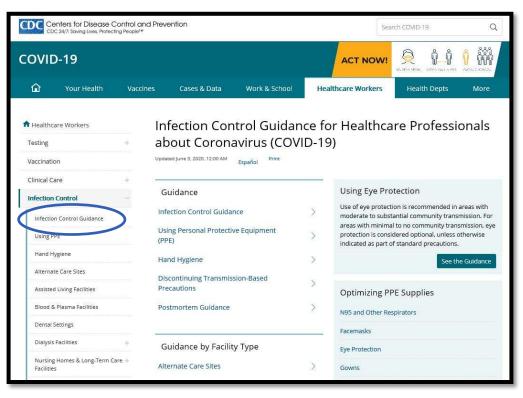
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cdc.gov/coronavirus

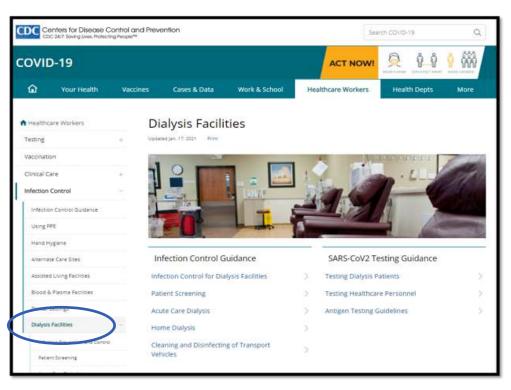
## **CDC Guidance on Infection Control for COVID-19**





https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html

## **CDC Guidance on Infection Control for COVID-19**





https://www.cdc.gov/coronavirus/2019-ncov/hcp/dialysis/infection-prevention-control.html

### **COVID-19 Dialysis Guidance**

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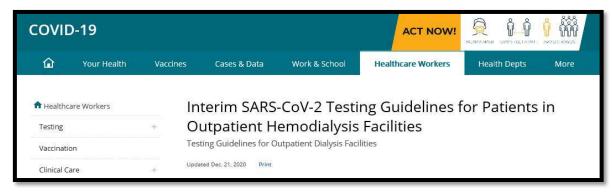
### **COVID-19 Dialysis Guidance**

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# **Testing Guidelines**



- Testing patients with signs and symptoms of COVID-19
- Testing asymptomatic patients with known or suspected exposure to an individual infected with SARS-CoV-2, including close and expanded contacts (e.g., there is an outbreak in the facility) to control transmission
- Testing to determine resolution of infection



https://www.cdc.gov/coronavirus/2019-ncov/hcp/dialysis/testing-patients.html

## **Testing Guidelines (Cont.)**

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Testing conducted at dialysis facilities should be implemented in addition to recommended infection prevention and control (IPC) measures.

Not all dialysis facilities can perform on-site testing; however, all facilities should have a plan for testing patients for SARS-CoV-2 (e.g., identify where patients will be referred to for testing if the dialysis facility cannot perform on-site testing).

Testing Asymptomatic Patients with Known or Suspected Exposure to an Individual Infected with SARS-CoV-2, including Close and Expanded Contacts (e.g., there is an outbreak in the facility) to Control Transmission

- Consider testing all patients and healthcare personnel (HCP) in the facility or at least all patients and HCP of the same shift.
- Identifying transmission within a dialysis facility can be challenging:
  - SARS-CoV-2 infections among HCP or patients with epidemiological links and no other exposures suggest transmission may have occurred within the facility.
  - Transmission within the facility should be considered an outbreak.
- Testing all patients as soon as transmission is suspected will allow:
  - Quick identification of infected patients
  - Clinical management of patients



Rapid implementation of IPC interventions

https://www.cdc.gov/coronavirus/2019-ncov/hcp/dialysis/testing-patients.html

Testing Asymptomatic Patients with Known or Suspected Exposure to an Individual Infected with SARS-CoV-2, including Close and Expanded Contacts (e.g., there is an outbreak in the facility) to Control Transmission

- Facility leadership should be prepared to continue to provide dialysis and isolate patients as needed.
- HCP should also be tested.
- The following website has considerations on performing broad-based testing for SARS-CoV-2 infections in congregate settings: <u>https://www.cdc.gov/coronavirus/2019-ncov/hcp/broad-based-testing.html</u>
- Notify local public health authorities of suspected or confirmed outbreaks in the dialysis facility.



https://www.cdc.gov/coronavirus/2019-ncov/hcp/dialysis/testing-patients.html

### Discontinuation of Transmission-Based Precautions for Patients with Confirmed SARS-CoV-2 Infection

The decision to discontinue <u>Transmission-Based Precautions</u> for patients with confirmed SARS-CoV-2 infection should be made using a symptom-based strategy as described below. The time period used depends on the patient's <u>severity</u> <u>of illness</u> and if they are severely immunocompromised.<sup>1</sup> Meeting criteria for discontinuation of Transmission-Based Precautions is not a prerequisite for discharge from a healthcare facility.

A test-based strategy is no longer recommended (except as noted below) because, in the majority of cases, it results in prolonged isolation of patients who continue to shed detectable SARS-CoV-2 RNA but are no longer infectious.

Symptom-Based Strategy for Discontinuing Transmission-Based Precautions.

Patients with mild to moderate illness who are not severely immunocompromised:

- · At least 10 days have passed since symptoms first appeared and
- · At least 24 hours have passed since last fever without the use of fever-reducing medications and
- · Symptoms (e.g., cough, shortness of breath) have improved

Note: For patients who are **not severely immunocompromised**<sup>1</sup> and who were **asymptomatic** throughout their infection, Transmission-Based Precautions may be discontinued when at least 10 days have passed since the date of their first positive viral diagnostic test.

Patients with severe to critical illness or who are severely immunocompromised":

- · At least 10 days and up to 20 days have passed since symptoms first appeared and
- · At least 24 hours have passed since last fever without the use of fever-reducing medications and
- · Symptoms (e.g., cough, shortness of breath) have improved
- Consider consultation with infection control experts



https://www.cdc.gov/coronavirus/2019-ncov/hcp/disposition-hospitalized-patients.html

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https://www.cdc.gov/coronavirus/2019-ncov/hcp/disposition-hospitalized-patients.html

## **Defining Severely Immunocompromised**

<sup>1</sup>The studies used to inform this guidance did not clearly define "severely immunocompromised." For the purposes of this guidance, CDC used the following definition:

- Some conditions, such as being on chemotherapy for cancer, being within one year out from receiving a hematopoietic stem cell or solid organ transplant, untreated HIV infection with CD4 T lymphocyte count < 200, combined primary immunodeficiency disorder, and receipt of prednisone >20mg/day for more than 14 days, may cause a higher degree of immunocompromise and inform decisions regarding the duration of Transmission-Based Precautions.
- Other factors, such as advanced age, diabetes mellitus, or end-stage renal disease, may pose a much lower degree of immunocompromise and not clearly affect decisions about duration of Transmission-Based Precautions.
- Ultimately, the degree of immunocompromise for the patient is determined by the treating provider, and preventive actions are tailored to each individual and situation.



https://www.cdc.gov/coronavirus/2019-ncov/hcp/disposition-hospitalized-patients.html

#### Coronavirus Disease 2019 (COVID-19) Outpatient Dialysis Facility Preparedness Assessment Tool



			2. P
COVID-19 as p ntext of an esc ID-19.	art of rou alating o	utine utbreak.	Faci
nt areas CDC rec	commend:	5	4. Tra
personnel (	HCP):		
Completed I	n Progress	Not Started	
			Facilit equip suppl
luding:			
			8. Mo
			Facilit
			perse
gov/co	rona	virus	
	f are trained, 4 alysis facility. correct dialysis cOVID-19 as p text of an esc D-19, terral comme tareas CDC rec trained completed tareas CDC rec trained completed tareas CDC rec tareas	fare trained, equipped alysis facility. correct dialysis facility : cOVID-19 as part of rou itext of an escalating o ID-19, ternal communication at areas CDC recommend: Completed In Progress Completed In Progress Co	COVID-19 as part of routine text of an escalating outbreak. ID-19. ternal communication related Int areas CDC recommends Personnel (HCP): Completed In Progress Not Started

#### . Process for rapidly identifying and isolating patients with confirmed or suspected COVID-19:

Completed In Progress Not Started

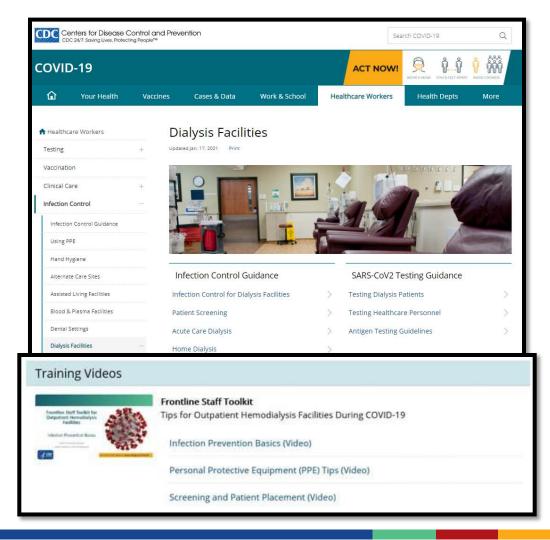
Facility has notified patients to call ahead and report fever or symptoms of respiratory infection.

4. Transmission-Based Precautions:			
	Completed	In Progress	Not Started
Facility has a procedure for assessing supply (inventory) of personal protective equipment (PPE) and other infection prevention and control supplies (e.g., hand hygiene supplies).			

8. Monitoring and managing HCP:			
	Completed	In Progress	Not Started
Facility has sick leave policies that are non-punitive, flexible and allow ill healthcare personnel (HCP) to stay home.			



https://www.cdc.gov/coronavirus/2019-ncov/downloads/COVID-19-outpatient-dialysis.pdf





## **Frontline Staff Toolkit: Infection Prevention Basics**



Infection Prevention Basics Tips for Outpatient Hemodialysis Facilities during COVID-19

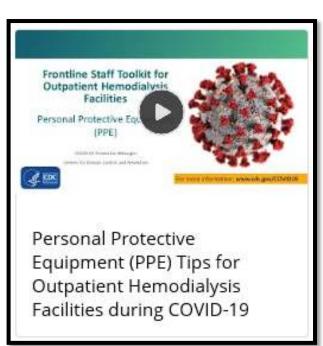
- Basic infection prevention steps
- Hand hygiene and environmental cleaning and disinfection help prevent the spread of COVID-19



https://www.cdc.gov/coronavirus/2019-ncov/hcp/dialysis.html

https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2

## **Frontline Staff Toolkit: Personal Protective Equipment**

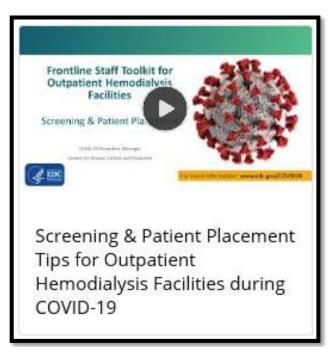


- Personal protective equipment (PPE) used in dialysis facilities
- Correctly using PPE helps prevent the spread of COVID-19



https://www.cdc.gov/coronavirus/2019-ncov/hcp/dialysis.html

## **Frontline Staff Toolkit: Screening & Patient Placement**



- Steps for screening patients before dialysis treatments
- Appropriate patient placement can help prevent the spread of COVID-19



https://www.cdc.gov/coronavirus/2019-ncov/hcp/dialysis.html

### **COVID-19 Dialysis Resources**

We are training staff about proper use of

personal protective equipment for COVID-19.

You may see a change in the personal

gloses) that staff are asked to want.

protective equipment (i.e. governe, masks

We are limiting non-essential staff entry

We are restricting visitor access to only

those who are essential for the patient's

rate the distyras facility by exploring ways to provide care to patients remotify (e.g., using

We are continuing our routine deaning and disinfection

procedures as these procedures are recommended for protecting patients from CDVID-19 in dialysis settings.

Any surface, supplies, or equipment located within the

within 6 feet of an ill patient is distributed or discarded

We are limiting staff and visitors coming into the diabait

care. Visitors will be screened for fever and symptoms of

COVID-19 prior to entry. Visitors will be asked to wear

their cloth lace covering and limit their movement in the

a related to COVID-19

We are encouraging patients and staff to share all

Don't he afraid to use your yours. It is play

to askstaff questions about treatment

changes and waysto protect yourself and

patient station will combinue to be distrilected or discarded.

We will ensure any surface, supplies or equipment located

#### How our facility is keeping patients safe from COVID-19

Our outputient dialysis facility is prepared for the possible arrival of patients with coronavirus disease 2019 (COVID-19). We are committed to keeping patients safe and are taking the following steps to reduce the risk of COVID-19 in our patients and staff:

facility

factity.

(anotice of leaded

We are providing extra training for staff and education for patients about the importance of hand busians far amasks respiratory hygiene, and cough etiquette. Threase, alcohol-based hand sontfiner, and

trash cans will be provided in the southing area and treatment area. Soon and water will continue to be available at all handscobing sinks and in the restrooms.

We are monitoring all staff for symptoms of COVID-19.

We are instructing staff who have symptoms of COVID-19 (e.g., fever, cough, shortness of breath, sore throat, muscle aches, redness) to stay home and not come to work

#### We are monitoring patients on dialy and visitors for symptoms of COVID-19,

Call abased if you have favor, more courth som throat, thechess, much aches or shortness of breath. This allows us to plan for your arrival and take infection mention steps to keep you safe



#### We are prepared to quickly identify and separate patients with symptoms of COVID-19.

All patients will be acrossed upon entry to the facility and trainacted to continue wearing their doth face towering (or offered a facemask, if waitable). Patrents with symptoms of COVID-19 will be treated in a separate area or at a corner or end of row station, away from the main flow of traffic.

This may affect your chair location, treatment inter or day or you may need to be transformed to another factity based on symptoms or diagnosis of COVID 19.

We are staying up-to-date with the latest information from CDC's COVID 19 web pager www.odc.gov/coronavirus. Thank you for everything you are doing to keep yourself and your loved ones safe. We will keep you informed about any new precautionsise think are tocessary. Please feel free to contact us with additional questions.



#### Coronavirus Disease 2019 (COVID-19) **Keeping Patients on Dialysis Safe**

#### What is COVID-19?

COVID-19 is a respiratory illness that can spread from person to person. similar to influenza.

#### Take Everyday Precautions

- Wash your hands often with soap and water for at least 20 seconds or use hand sanitizer with at least 60% alcohol.
- Avoid touching your face.
- Everyone should wear a cloth face cover in public setting where other social distancing measures are difficult to maintain.
- Avoid close contact with people who are sick.
- Avoid crowds and keep at least six feet of space between yourself and others if COVID-19 is spreading in your community.
- If you are in a private setting and do not have on your cloth face covering, remember to always cover your mouth and nose with a tissue when you cough or sneeze or use the inside of your elbow.
- » Throw used tissues in the trash and immediately clean your hands.
- Routinely clean and disinfect surfaces you often touch, such as cell phones, computers, countertops, handles, and light switches.

#### Preparing the Facility

You may see changes as the dialysis facility prepares to keep you safe during treatment. This may include:

- Signs with special instructions for patients with symptoms of COVID-19.
- Additional education about hand hygiene and cough etiquette.
- Waiting areas will be divided for patients with symptoms and patients without symptoms
- A change in patient chair locations, treatment times, or days.
- A change in the gowns, facemasks, and eye protection that the staff wear
- Patients, visitors and staff will all be wearing a cloth face covering or facemask the entire time they are in the facility.



### **Preparing Outpatient** Hemodialysis Facilities for COVID-19 April 13, 2020





https://www.cdc.gov/coronavirus/2019-

For more information: www.cdc.gov/COVID19

cdc.gov/coronavirus



ncov/hcp/dialysis/home-dialysis.html

https://www.cdc.gov/coronavirus/2019-ncov/downloads/healthcare-facilities/316158-A FS ProtectSelfAndFam.pdf

https://www.cdc.gov/coronavirus/2019-ncov/downloads/healthcare-facilities/316157-A FS KeepingPatientsSafe.pdf





### **General IPC Guidance**

	Infection Control	-
<	Infection Control Guidance	>
	Using PPE	
	Hand Hygiene	
	Postmortem Guidance	
	Post-Vaccine Considerations for Healthcare Personnel	
	First Responders	
	Exposure in Healthcare Settings	+
	Optimizing PPE Supplies	+
	Facility Planning & Operations	+
	Non-Hospital Settings	+
	FAQs	

Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 (COVID-19) Pandemic

Updated Feb. 10, 2021 Print

#### Summary of Recent Changes

Updates as of February 10, 2021

#### As of February 10, 2021

- Updated the Implement Universal Use of Personal Protective Equipment section to expand options for source control and patient care activities in areas of moderate to substantial transmission and describe strategies for improving fit of facemasks. Definitions of source control are included at the end of this document.
- Included a reference to <u>Optimizing Personal Protective Equipment (PPE) Supplies</u> that include a hierarchy of strategies to implement when PPE are in short supply or unavailable.

#### View Previous Updates

Table of Contents

https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control.html



~

### **Outreach via Partners Webinars and Meetings**

- Making Dialysis Safer for Patients (MDS)
- Dialysis Patient Citizens (DPC)
- American Association of Kidney Patients (AAKP)
- Standardized Care to Improve Outcomes in Pediatric End stage Kidney Disease (SCOPE) collaborative
- National Kidney Foundation (NKF)
- American Society of Nephrology (ASN)
- National Coordinating Center (NCC)





# CMS.gov Centers for Medicare & Medicaid Services

### U.S. Department of Health & Human Services

Office of the Assistant Secretary for Preparedness and Response







SATION IN

RECOVERY

KCER

#### National Healthcare Safety Network (NHSN)

CDC > NHSN > Materials for Enrolled Facilities > Outpatient Dialysis Facilities

### (f) 💟 🛅 🎯

#### n NHSN

NHSN Login	
About NHSN	+
Enroll Here	+
Change NHSN Facility Administrator	
Materials for Enrolled Facilities	-
COVID-19 Information	+
Ambulatory Surgery Centers	+
Acute Care Hospitals/Facilities	+

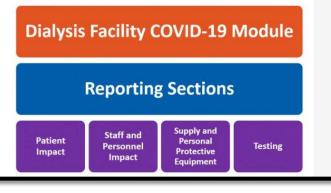
### Dialysis COVID-19 Module

<u>CDC's NHSN</u> provides healthcare facilities, with a customized system to track infections and prevention process measures in a systematic way. Tracking this information allows facilities to identify problems, improve care, and determine progress toward national healthcare-associated infection goals.

The NHSN Outpatient Dialysis Component is supporting the nation's COVID-19 emergency response with a COVID-19 module designed to collect data pertaining to in-center dialysis, home dialysis, and peritoneal dialysis patients.

The COVID-19 Module has a single data entry page with four sections:

- Patient Impact
- Staff and Personnel Impact
- Supply and Personal Protective Equipment
- Testing





https://www.cdc.gov/nhsn/dialysis/covid19/index.html

## NSHN: Reporting Healthcare Personnel (HCP) COVID-19 Vaccination

- Facilities participating in NHSN can report weekly COVID-1 vaccination data through the Healthcare Personnel Safety (HPS) Component
- Weekly reporting is currently optional
- Facilities can use the data to obtain a better picture of COVID-19 vaccination at their facility
  - Monitor vaccination rates over time
  - Identify HCP groups with lower vaccination rates
  - Improve vaccination tracking
  - Data from the HCP vaccination module
  - can inform decision-making

NATIONAL HEALTHC SAFETY NETWOR	ARE K							Decemb	er 2020
3 Pages 'required for saving	Healtho			VID-19 Vacci J-Term Care F			Summary	0	
"Facility ID#:									
"Vaccination type: COVID-18	9				2				
"Week of data collection (Mo	nday – Sunda	1	11		'Date Last M	odified: _/_/			
			Cun	nulative Vaccination	Coverage				
				Chies and Charles and Charles	ersonnel (HCi	P) Categories			
	*All HCP (Total)	Environmental services	Nurses*	Medical assistants and certified nursing assistants	Respiratory therapiets	Pharmacists and pharmacy technicians	Physicians <sup>5</sup>	Other licensed Independent practitioners <sup>4</sup>	Other HCP
<ol> <li>"Number of HCP that were eligible to have worked at this healthcare facility for at least 1 day during the week of data collection</li> </ol>									
2. Cumulative number of H	CP in Question	#1 who have rece	eived COVI	D-19 vaccines at this	facility or elsev	where:			55
2.1. <u>'Only</u> dose 1 of Pfizer-BioNTech COVID-19 vaccine									ć
2.2. *Dose 1 and dose 2 of Pfizer-BioNTech COVID-19 vaccine									
2.3. "Only dose 1 of Moderna COVID-19		-							1



# A point prevalence survey was implemented at four dialysis facilities in the metro Atlanta area.





### ~640 dialysis patients in-center

#### Decreasing but high community spread No suspected outbreak or transmission in the facilities







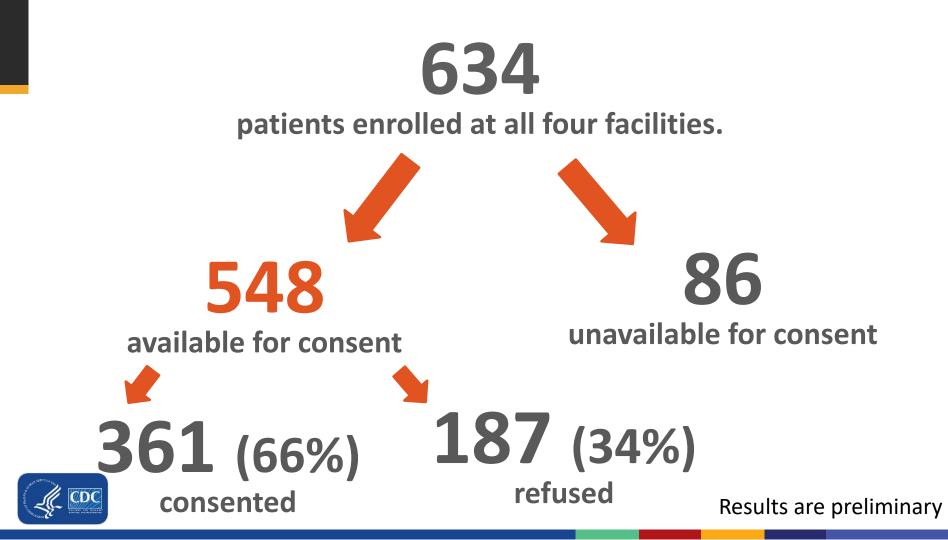




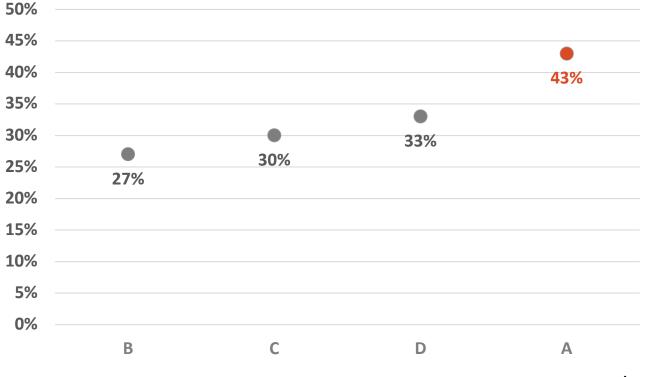
# Of the 86 unavailable patients, **51 (59%)** patients did not have a reason for missing dialysis.

		1	í	1	1
Reasons for Unavailability	Α	В	С	D	All Facilities
Sick or Hospitalized	2	4	2	3	11
Hospice	0	1	0	0	1
Cognitive Impairment	4	4	1	4	13
Dialysis Schedule Change	2	0	0	1	3
Too late to sample (night shift)		0	0	4	4
Deceased		0	2	1	3
No Show	25	9	8	9	51
Total	33	18	13	22	86





# Refusal rates ranged from 27 - 43% depending on the dialysis facility.





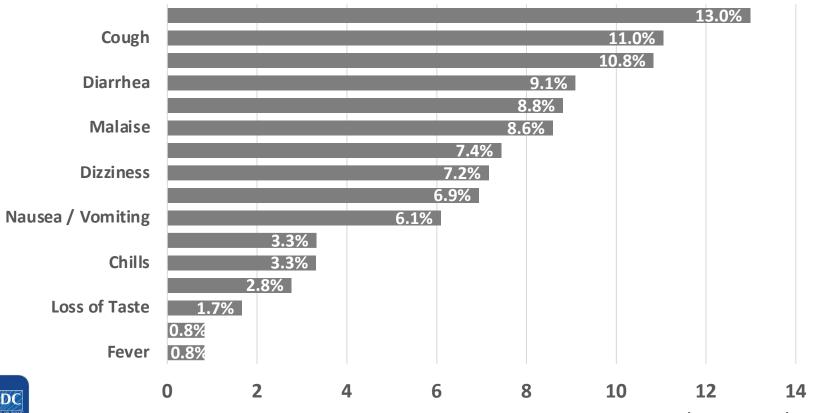
# Of the 187 patients who refused, nearly **1 in 4** were likely to refuse because of testing in recent weeks.

					All
Reasons for Refusal	Α	В	С	D	Facilities
					43
Previously Tested	9	3	12	19	(23%)
Did not want to alter dialysis schedule	0	1	0	1	2
Getting tested soon	1	2	0	5	8
Distrust (CDC, testing, etc.)	1	1	1	7	10
Fear of result or of procedure	0	3	1	8	12
Asymptomatic	1	1	0	6	8
Other	2	0	2	0	4
Total *(+ those with no reason listed)	64	34	26	63	187

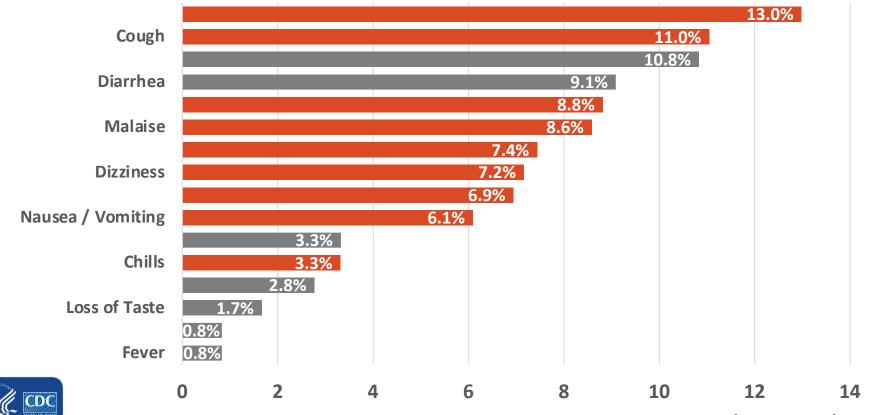


Results are preliminary

# Among the **361** participants, **165** (46%) reported symptoms in the last 14 days.



# Some of the most reported symptoms may be frequently encountered in ESRD patients.



Among the **361** patients who participated, few reported high-risk exposures.

2% had close contact to a person with COVID-19 at home or in the community



# **1%** lived in a nursing home





# Among the **361** patients who participated, few reported high-risk exposures.

# **1%** worked in a healthcare setting



**6%** attended gatherings >10 people in the past 2 weeks





### Among the **361** patients who participated,

## **Zero** were positive for SARS-CoV-2.



Heightened infection control practices were already in place.

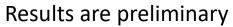


**Universal Masking** 





### COVID-19 Dialysis Cohort





Facility-wide testing may be more useful when specific indicators of are present.



**Increasing community spread\*** 



# Suspected transmission within a dialysis facility



\*=increasing cumulative incidence or % test positivity in the past 7 days

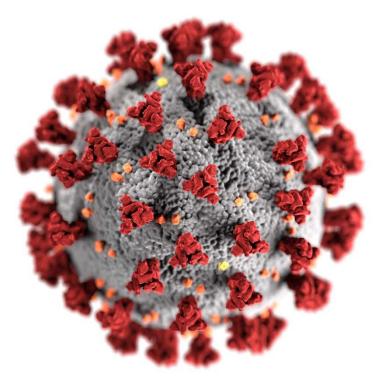
### Thank you!

### dialysiscoalition@cdc.gov

For more information, contact CDC 1-800-CDC-INFO (232-4636) TTY: 1-888-232-6348 www.cdc.gov

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.



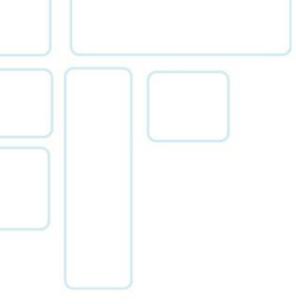




## Best Practices on Preventing the Spread of Infections During the COVID-19 Pandemic and Beyond

Megan Meller, Gundersen Health Dr. Shannon Novosad, CDC Sanford Health Caprice Vanderkolk, University of Minnesota





# Objectives

- Identify 2 ways the pandemic changed infection control in dialysis.
- Describe the CDC's role in the pandemic.
- Review the interface between dialysis and the skilled nursing facilities in a pandemic.
- Describe 2 ethical considerations for COVID care during the pandemic.



## Infection Control

- Incident Command
- Training
- New workflows





•••••

## New phrases...









### **Patient Care**

- N95, PAPR
- Special Precautions
- Surge Capacity
- Facility Surveys

## **PPE & facilities**





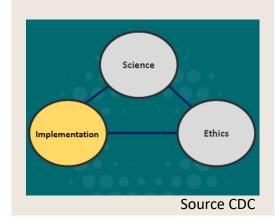


Delivery date stock on hand fills projected need through mid-January stock on hand fills projected need through May. On hand lasts to May. MFG ALLOCATION Stock on hand fills need through May. 3500 GOWNS ON HAND, PLANNING 2X DAILY LAUNDERING
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Stock on hand fills need through May. 3500 GOWNS ON HAND, PLANNING 2X DAILY LAUNDERING
3500 GOWNS ON HAND, PLANNING 2X DAILY LAUNDERING
stock on hand fills projected need through early February
stock on hand fills projected need through December. Weekly
allocation is not replacing demand. Size risks.

Stock on hand fills need through early May. Purchase orders are complete. Stock on hand fills need

- Tracking inventory
- Redesign facilities for social distancing

### Vaccination











## **Dialysis Facility Plans**

Guidelines for Infection Control and Prevention of COVID-19 in Dialysis Facilities

#### Early recognition and isolation of patients with respiratory infection

- 1. Identify patients with signs and symptoms of respiratory infection prior to the patient entering the treatment area.
  - a. Instruct patients to call ahead to report fever or respiratory symptoms so the facility can be prepared for their arrival or triage them to a more appropriate setting.
  - b. Patients should notify staff of fever or respiratory symptoms immediately upon arrival at the facility.
    - i. All patients should wear a facemask into the building and keep it on until they leave the facility.
    - ii. Patient screener will be at the door screening for COVID 19 symptoms including but not limited to: New cough onset, new shortness of breath onset, or fever.
    - iii. If asymptomatic, patient is taken to "well waiting room."
    - iv. If symptomatic, patient is taken to "ill waiting room" and RN notified immediately.



To our valued patients and partners,

We have all been learning about COVID together. As we continue to progress through this pandemic, we want to assure you that we are following best practices at this time to prevent it from spreading to others if identified in our facilities.

Renal managers are in the process of connecting with each patient to discuss the expectation of face covering. All patients are required to have a face covering over their nose and mouth while in the dialysis building. If a face covering is not properly over the nose and mouth, the patient will receive a reminder. If that patient is, again, seen with his or her mouth or nose showing, the patient will be sent home and may return the following scheduled dialysis treatment. We appreciate your cooperation in helping us control the spread.

Staff may wear N95's or Purified Air Purifying Respirators (PAPRs) at times to care for patients. All patients will continue to have their temperature taken and be screened for symptoms of COVID. In addition, we will be posting weekly COVID case numbers on our website (<u>https://www.gundersenhealth.org/locations/renal-dialysis-centers/</u>). The number will include a total number of staff and patients impacted by COVID each week.

We have been in close contact with the local health departments in the areas we serve. Our Medical Director and Leadership Team have been working extensively to investigate cases and support contact tracing. We will alert anyone we feel has been exposed to COVID in our facilities, but our practices of universal masking should minimize any risk while at dialysis.

#### Covid-19 Dialysis audits



#### 5 audits monthly

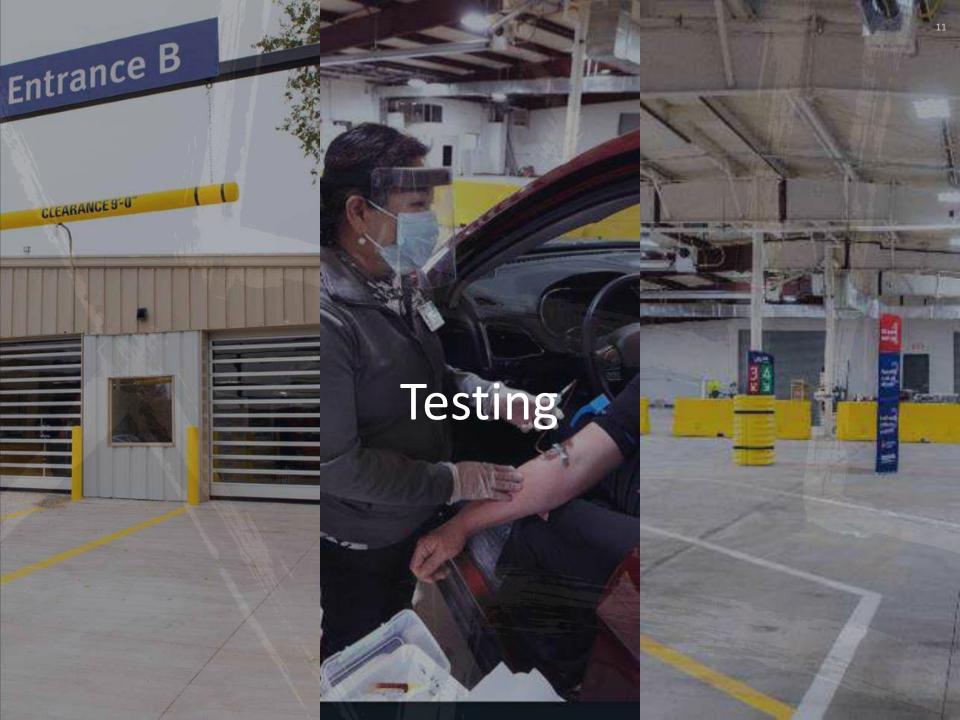
Date	Staff	Staff was able to verbize how to identify	F/U education provided
		and isolate suspected COVID 19 cases	

#### 5 audits monthly

Date	Staff	Staff was able to verbalize who should be notified if there is a suspected case?	F/U education provided

#### 5 audits monthly

Date	Staff	Staff can explain respiratory etiquette	F/U education provided



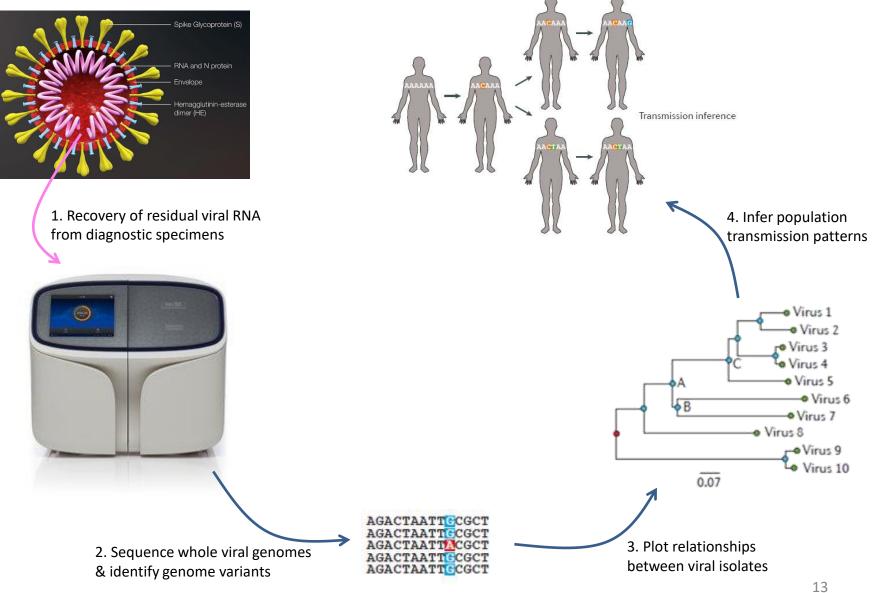
# Testing

## Antigen

PCR

## **Genetic Analysis**

#### Gundersen's COVID19 genomic epidemiology program (March 2020 – ongoing)



Gundersen's COVID19 genomic epidemiology program (March 2020 – ongoing)



#### Key Benchmarks

- 15<sup>th</sup> US-based laboratory to start reporting COVID19 sequencing (3/28/2020)
- Over 1,400 viral genomes sequenced (30% of all cases diagnosed at Gundersen)
- Conducting broad regional surveillance across 21 counties in WI, MN & IA, but the priority has been monitoring transmission risks among healthcare works and between patients and staff.
- Key research publications have identified risks associated with viral transmission:
  - Within meatpacking plants and from the plant workers to the surrounding region
  - Among college students, with detection of transfer to skilled nursing facilities
- Current focus on detection of emerging variants of concern
  - Detected third US case of "Brazilian" P.2 substrain (1/8/21)
  - Detected a newly emergent Spike:E484K lineage in Minnesota (12/30/20)

#### WISCONSIN DEPARTMENT of HEALTH SERVICES

#### COVID-19

#### Weekly Verification for Data on DHS Facility-Wide Investigations COVID-19 Page

Beginning on Wednesday, August 24, <u>facility-wide investigations</u> will include a new category, "Educational facility." Educational facilities include schools, colleges, universities, and child day care centers. During previous weeks these facility types were included in the "Other setting" category. The updated setting descriptions below will be reflected on our facility-wide investigations <u>webpage</u> when data are updated on Wednesday at 2pm.

A single confirmed case in the following setting initiates a facility-wide public health investigation:

 Long-term care facilities include skilled nursing facilities (nursing homes) and assisted living facilities (community-based residential facilities and residential care apartment complexes).

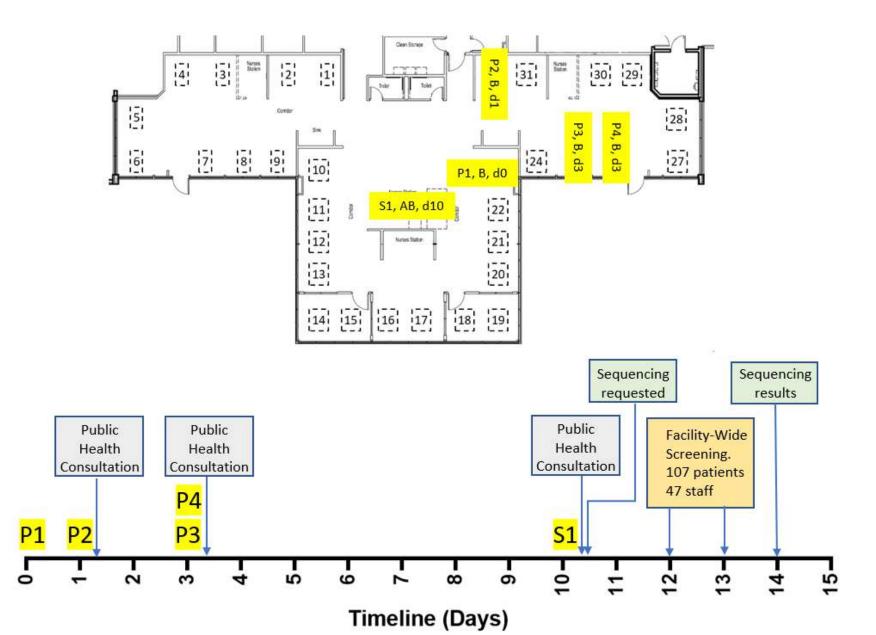
Two or more confirmed cases in the following settings initiate a facility-wide public health investigation:

- Group housing facilities include correctional facilities, homeless shelters, dormitories, and group homes.
- · Health care facilities include hospitals, clinics, dialysis centers, hospice, and in-home care.
- Workplace (non-health care) settings include manufacturing and production facilities, distribution facilities, offices, and other indoor workplaces.
- · Educational facilities include schools, colleges, universities, and child day care centers.
- Other settings include adult day care centers, restaurants, event spaces, and religious settings.

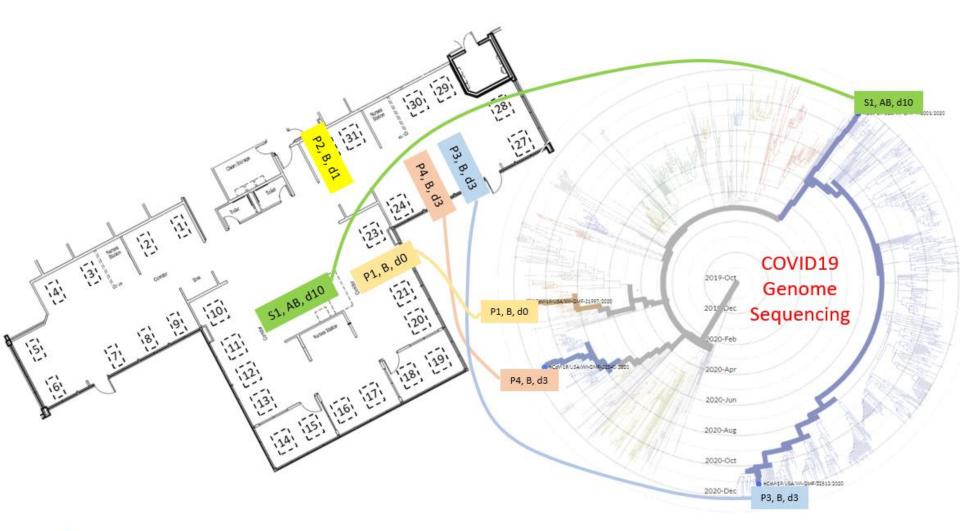
https://content.govdelivery.com/accounts/WIDHS/bulletins/29ca76c

#### Outbreak investigation in an ESRD facility

- Four patients sharing the same schedule, diagnosed within four days
- A staff member diagnosed six days later.



Sequencing of four available COVID19 specimens confirmed cases unrelated to each other



#### medRχiv

Outbreak or pseudo-outbreak? Integrating SARS-CoV-2 sequencing to validate infection control practices in an end stage renal disease facility

Bridget L. Pfaff, Craig S. Richmond, Arick P. Sabin, Deena M. Athas, Jessica C. Adams, Megan E. Meller, Kumari Usha, Sarah A. Schmitz, Brian J. Simmons, Andrew J. Borgert, Paraic A. Kenny

medRxiv 2020.12.30.20249062; dOI: https://doi.org/10.1101/2020.12.30.20249062



#### Summary

- Anticipate regulatory changes.
- PPE works in the dialysis center.

### Dr. Novosad

Rationing Care: Decision-making Strategies and Ethical Considerations

Dr. Sabin



This Photo by Unknown Author is licensed under CC BY

The New York Times

= Q Popular Latest

Sign In

#### HEALTH

#### The U.S. Is Repeating Its Deadliest Pandemic Mistake

More than 40 percent of all coronavirus deaths in America have been in nursing homes. Here's how it got so bad, and why there might still be more to come as cases surge in the Sun Belt.

OLGA KHAZAN JULY 6, 2020



At the start of 2020, the Life Care Center of Kirkland nursing home in Kirkland, Washington, cared for roughly 120 residents with 180 staff members. Although this facility has the highest rating of 5 stars on the federal government Nursing Home Compare website, it received a deficiency during its most recent inspection <u>survey</u> in April 2019 for failing to provide and implement an infection control program. The deficiency was considered less serious because it was associated with "minimal harm or potential for actual harm."

WORLD COUNTRIES U.S.A. STATES TESTING

#### More Than 40% of U.S. Coronavirus Deaths Are Linked to Nursing Homes

By The New York Times Updated July 15, 2020



**9%** OF ALL U.S. CASES 316,000+

At least 57,000 residents and workers have died from the coronavirus at nursing homes and other long-term care facilities for older adults in the United States, according to a New York Times database. As of July 15, the virus has infected more than 316,000 people at some 14,000 facilities.

Nursing home populations are at a high risk of being infected by -



## Landscape of SNFs & ALFs

### Facility factors:

- Congregate setting in indoor spaces
- Shared rooms & bathrooms
- Memory care units with wandering
- Staffing shortages therefore limitations in infection control practices
- Staff perform very close, intimate cares for residents
- Staff often work in multiple facilities in community
- Visitors

## Surge Capacity

FULL COVID PPE MUST BE WORN BEYOND THIS POINT: Gown Gloves Face Shield N95

STOP





#### RESIDENTS: DO NOT LET ANYONE IN THE BUILDING

THIS IS THE JOB OF RECEPTIONIST OR CARE STAFF

> Per LaCrosse County Public Health, we are out of the "Red Zone."

> > We are now in the ORANGE ZONE -









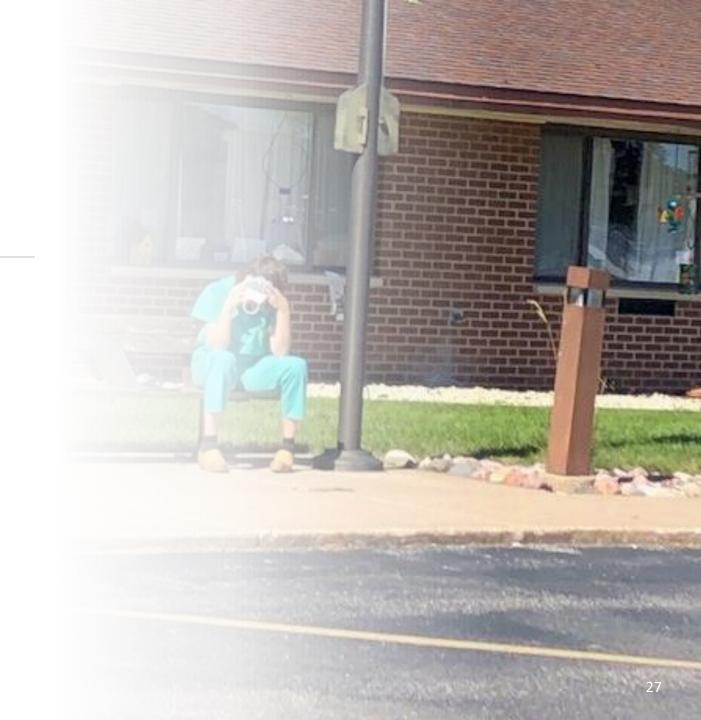
## Reflections



TH

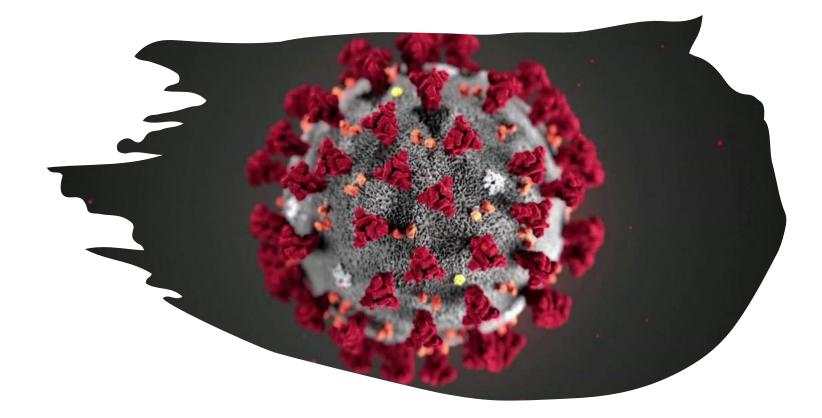
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### Compassion Fatigue



# A Shot of Hope





## Panel Q&A