

Centers for Medicare & Medicaid Services
COVID-19 Call: Dialysis Providers and Facilities
Moderator: Jean Moody-Williams
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5:30 p.m. ET

OPERATOR: This is Conference #1796168

Jean Moody-Williams: Thank you so much. Good afternoon everyone. It is truly my pleasure to have this opportunity to speak with you this afternoon and give you a few updates. But always before I do that, I just want to (inaudible) and thank you for the work that you're doing. Never want to take that for granted. A tremendous challenge and all of the new and innovative ideas that you're coming out with to meet that challenge.

We are also trying to support those efforts through a number of the guidances and waivers and flexibilities that we're putting out. We continue to look at what the needs are and continue to release on a slow basis. So we ask that you check our website periodically. We did just release a workforce virtual toolkit.

It's on our website, and we work with ASPR, the planning preparedness response assistant secretary, to develop this new toolkit, and it's really for state and local healthcare decision makers on how to maximize workforce flexibilities as you're working with the 2019 novel coronavirus in the communities.

And so, it includes a full suite of available resources for responsiveness. It includes some of the CMS' waiver -- waivers that we've done to allow maximum practice, scope of practice. It also provides assistance center information exchange and case studies, and some additional peer-to-peer communications that might be helpful, and it's available online.

So, please take a look at that. I'm going to turn just a minute to Dr. Jesse Roach who will give you a few updates today, and then we also have a guest

speaker that I am excited to hear from. And then we will also open up for some questions. So, Jesse.

Jesse Roach: Thank you, Jean. So, just a couple of updates. We've been -- CMS has -- in its capacity is still working, sort of, with the ASPR, from the HHS perspective, and the FEMA task group has become -- we mentioned it last week. We still know about the fluids issues for CRRT. We have identified some avenues to bring those in from either out of the country or from -- to mobilize surpluses in other areas.

We are also looking at avenues for production of more. Unfortunately, a lot of the service lines are maxed out when we talk to manufacturers, but they're our options. Some facilities have been -- some facilities have been creating their own fluid using dialysis machines, and I think our speaker will talk about that. But that's something that we're also working with the FDA for potential guidances on that.

There's nothing forthcoming, but it's something that we're working on. And then also for emergencies, authorizations for other types of fluids that aren't necessarily marketed here. So, that's what we're doing from the perspective of the taskforce. And the -- one of the other things is PPE, so we are -- we're aware that the PPE issue is still out there.

We have sought -- we have formulated a plan where we're -- and we're working with the FEMA taskforce and asked for -- FEMA asked for a taskforce to try to deploy those. And we don't an exact timeline from that, the logistics of it and figuring out where exactly to deploy all of this is complicated, but it's something that's still on our radar.

And one of the other big issues was transportation, and I want to throw that to Shalon Quinn, the Director of the Division of Kidney Health to give us an update on that.

Shalon Quinn: Hi, this is an issue that we're definitely actively triaging right now. We have set up a process with our ESRD networks, so that they can provide us any

information and quantify the disruption in transportation that's occurring in their areas.

So if you are experiencing any transportation issues in your area, please do reach out to your ESRD network for your local service area, and let them know exactly what's going on, what the issue is and how many patients may be affected and they will send that on to us for us to triage.

Jean Moody-Williams: Thank you, Shalon.

Jesse Roach: And then there's one -- I had one other issue, (Jean), sorry. One other issue is, is that we've heard some reports -- we've put out a statement through ASN about -- a couple of weeks ago about (access) being in -- about (access) not being an elective procedure, and that it was important to continue those procedures.

However, if you're hearing stories of -- and have reports of people refusing to do it, because they still consider these things elective procedures. So, fistula graft catheter and PD catheter placements, if you could reach out to your networks as well, we would like to know about those. Thank you, and I'll throw it back to (Jean).

Jean Moody-Williams: Yes. No, thank you very much for that. And so, with that, we'll move to Dr. Michael Heung, the Professor of Medicine and Associate Chief of Nephrology at the University of Michigan. Dr. Heung, are you there?

Michael Heung: Sorry, just had to unmute. Thank you very much for the invitation, it's a real pleasure to come and speak about our experiences. As I was telling the folks on -- the inviters here, you know, we feel like we've learned a lot from other people's experiences. So, happy to share ours and, hopefully, help others that are dealing with the pandemic as we are.

So, just by way of background, I'm a Critical Care Nephrologist at the University of Michigan and, as many of you know, Michigan got hit relatively hard. For a while, we were the third highest state with cases after New York and New Jersey, although it subsided a little bit. And to date, we've had about

122 patients admitted to our ICUs with COVID-19 and many more on the floors as well.

In our experience, we've had about 50 percent of those patients needing renal replacement therapy. This is a lot higher than what's been reported in the literature where -- or there's not much literature, I guess, that's been reported online and anecdotally, which is probably at 20 to 30 percent in many centers.

But keep in mind that we are a referral center, and a lot of our cases are coming from overflow from Detroit area hospitals that were actually hit much harder than we were (inaudible).

But I'll be speaking today about our experience with those patients, including -
- I think it's about 35, 37 patients to date that we've managed on continuous renal replacement therapy, CRRT.

I just wanted to say, that in terms of etiology, what is leading to the renal failure in these patients, predominantly from what we have seen, it appears to be an ATN-type syndrome related to the ARDS and shock, which is what I think has also been mostly reported in the literature.

We have seen pretty significant rhabdomyolysis in the -- a small subset of our patients that could also be contributing, and many of our patients do also have proteinuria and hematuria which has been reported. And in some of our initial pathology from autopsy, we have been able to identify virus in kidney tissue.

So there's a lot more that will need to be understood about that. There was also a paper recently that described some pathology there. But the predominant pathology, at least in what we've seen, is still acute tubular necrosis. So focusing more on our experience with RRT management and, specifically, CRT, one of the things that has been reported out there is that these patients are quite hypercoagulable, and that is consistent with our experience.

We've seen a number of patients that have had DVTs, and we've also had patients clotting off the catheters and dialysis circuits as well. At the University of Michigan, we have a regional situate anticoagulation protocol

that we use on most patients. And actually, that's been very helpful for us. So we actually have had a very good experience so far with maintaining our circuits using our regional anticoagulation.

Talking to other centers, people that are using heparin have also been able to achieve fairly decent circuit patency with the CRRT. But it sounds pretty consistently that if you're trying to do CRRT without any form of anticoagulation, there's going to be a significantly higher risk of clotting.

So that's certainly one of the recommendations that we learned early on. It was already consistent with our practice anyways. And I can say that, with our practice, we've had, again, very good filter lives. In fact, no different than our usual.

One area that was probably unexpected for us in dealing with this is just having to train people on the fly to help run dialysis when we were at our peak business about a week ago.

We were having ICU nurses run CRRT, but did not have as much experience with CRRT. The nurses are not going into the rooms as much to troubleshoot the machines, and so some of our early experiences with premature clotting or other issues probably were -- could be attributed to inexperience.

And I think this really underlines the importance of those strong partnerships at your institution, really good communication being there to support and train people up that are outside their usual comfort zones, which many of us are obviously in this setting. We saw a similar thing with a dialysis catheter placement.

We typically place our own dialysis catheters, but in the setting of the pandemic, the ICU staff have been placing the catheters for us for the most part, since they're already in the room placing other lines.

And we had to make sure that we educated them about the proper sizing of our catheters, the proper location of the tip to ensure adequate flow. And early on, we had a couple of catheters that were placed fairly conservatively

high in the SPC that probably contributed to some issues with flow that we had to correct.

So those were some of the things that we didn't necessarily anticipate, just because people were out of their comfort zone. One other area that has been a pretty significant area for us is scarce resource management, and we are a pretty busy medical center usually. We have 28 PRISMAFLEX CRRT machines, and we have had times where they're fully running.

And so, we had to have a lot of strategic planning early on to determine how we were going to spread out our dialysis resources, and we had a plan to shift from 24/7 CRRT, which is what we typically do, to doing more shift-type therapy with CRRT, such as 24 hours on, 24 hours off, just to share between patients, or even eight to 10 hours on every day to share between patients.

And this -- having this plan in place ahead of time was extremely helpful to avoid the stress of having to make those decisions on the fly. We also quickly realized that it was not just a machine potential limitation, but also disposables, which include filter sets.

In our case with the PRISMAFLEX, the filter sets are proprietary, so it's not as simple as the many dialysis filters that we have for intermittent hemodialysis. So we had to make sure that our supply chain for that was adequate.

And also, our solutions, and that was alluded to earlier. So far, we've been able to maintain our supply chain with the solutions, but we have been exploring alternatives. And just yesterday, after doing some research over the past couple of weeks, we started a protocol where we're able to generate some online dialysate and capture that in CRT solution bags, and we did some testing of those bags to ensure stability and demonstrate that we were achieving the electrolyte concentrations and such that we expected.

So we're pleased that we have a process in place for that. The general idea is quite simple, which is that you run a dialysis machine with the concentrate.

And instead of running a patient on dialysis, you capture the dialysate that is coming through.

But again, there is -- it's a little bit more complicated than that, because you obviously have to worry about sterility. You have to have the right equipment to capture the solution in a sterile way, and you need to be able to have a way to test the solutions to ensure accuracy.

And you need strong biomedical support. So, that's why it took us a little while to get up to speed with that, but that is now an option in our back pocket should we have issues with a supply chain with dialysates. And then the third area, other than machines and other than disposables, that's a really significant potential limiting factor is, of course, personnel.

We have struggled a little bit with our dialysis nursing model. In our health system, we have a fixed number of dialysis nurses. Obviously, they're specialized and they're our key partners in this.

We've had one become ill -- fortunately, not seriously -- with COVID-19. And so, they're a scarce resource and we've been trying to balance how hard we're working them in terms of doing dialysis, where we do dialysis, and ensure that we're keeping them healthy for the long term as well.

So, I think those are some of the key issues and things that we've been dealing with, and have learned about. I'll pause there and happy to take any questions about the AKI, CRRT, or about our experiences with ESRD as well.

Jean Moody-Williams: Great, thank you so much for sharing that information and for the innovation that, obviously, as you're trying to take care of the needs here, and I think that this is going to be very beneficial as others are on the phone. I'm going to open it up for questions that you might have for our speaker, for CMS, but also give you the opportunity to share what's working for you.

I did want to mention as well that this past Sunday we did release -- for those of you that bill Medicare part B, and we added an improvement activity to the Quality Payment Program. And so, if you are participating in any clinical

trials and you are reporting that information, you are able to get credit for an improvement activity.

And if you combine that with another high-weighted activity, you get full credit for that category. So, it's really just a way of continuing to encourage innovation in the field as we all work to see what's working with COVID-19. So operator, with that, if you could please open up the line for questions?

Operator: Sure. At this time, if you have a question you may press star one on your telephone keypad. If you need to withdraw your question, you can press the pound key. Will pause for just a moment to compile the Q&A roster. Your first question comes from the line of Ron Hemming. Ron, your line is open.

Jean Moody-Williams: So, we can't hear.

Bron Hemming: Did you say Bron Hemming. Is that me?

Operator: Yes. Yes.

Bron Hemming: Sorry. Yes, this is Bron Hemming. I have a question for the CMS staff. Has there been any additional thinking with respect to waivers, so that providers can treat AKI patients in SNFs or a nursing facility or other home scenarios, given the issues that we're having with kidney failure and COVID, getting patients out of the hospital, it's been hard to place them, giving the home providers an opportunity to treat those AKI patients in other settings. It would be useful. I mean, I know there's been requests, but I wasn't sure if there's been any further developments on that.

Jean Moody-Williams: Yes, I'm going to turn to (Karen) to see if she has any information on that.

Karen: Hi, thanks very much for your question. We are still in discussions on that. I don't have any final word that I can share with you today, but I do -- it is something that is in active discussion between the quality and safety side, as well as the payment side as well. So hopefully we'll be able to have something for you shortly on that.

Bron Hemming: OK. And then the -- presumably -- I know it's a waiver for dialysis in SNF nursing facilities was for those programs that didn't have a home program, so they used a condition code 71, I would assume, would be inappropriate for a home-only facility. Is that right?

Karen: So this is Karen again. I don't -- I am not able to speak to specific condition code on the -- on the claim. I don't know if there's anybody from payment on the end -- on this end.

Bron Hemming: That's OK, that's not a pressing issue. And then, as part of your discussions on the AKI patients, has there been thought to expanding the locations where home services or dialysis services can happen for other areas, such as assisted-living facilities or is it limited just to nursing facilities and skilled nursing facilities?

Karen: I think we'll have to take a look at that. I think in most cases the assisted-living facilities are considered a home, but let me go -- get back to you on that one if there's -- and we can come back perhaps next week on next week's call on that, or another form. Alina, if you think -- if you want to handle it through email as well, that's fine.

Alina Czekai: Sure thing. And I'll give out our email address. That is covid-19@cms.hhs.gov. And again, we'll also have office hours tomorrow, the 23rd, at 5 p.m. Eastern and we'll be -- we'll have a number of our SMEs online to answer questions then as well.

Bron Hemming: Great. Thank you all very much for this, been very informative.

Jean Moody-Williams: Thank you. How about we take one more question?

Operator: Your next question comes from the line of a phone number that ends in 8001. Caller, your line is open. Please state your name.

Maria Reneri: This is Maria Reneri, we're just doing our modeling for the Dakotas and Minnesota area where we have health systems. We wanted to -- Dr. Heung's experience, we wanted to know what is the average length of time that you are

seeing patients in AKI requiring renal replacement therapy, as well as what is the percent of patients who expire better on renal replacement therapy?

Michael Heung: Sure. I don't have a definite answer for you, because we are still evolving. But I can tell you that it is expected to be a protracted course. So we have had some patients -- we've had many patients discharged from the hospital, but only a couple that were sick enough that were in our ICU and required renal replacement therapies.

We are seeing some patients recover. I'm hoping, just even in these next couple of days, we have some that are leaving the hospital that were on dialysis. But our average course has been at least a week on CRRT and potentially longer. And that's, of course, in the -- in the ones that are surviving.

In terms of our mortality rate, it's somewhere between 40 and 50 percent of these patients. That's actually fairly inline with what we normally see in our severe ARDS patients. So I know some early reports showed very high mortality in patients.

And early on, we had some really sick patients that -- but over time, I don't know if we're getting better with our experience, or the volume has come down, but knock on wood, more recently we've had more success with our patients. And so, I think our mortality rate's going to be around 40 to 50 percent.

Jesse Roach: Is that 40 to 50 -- Mike, this is Jesse Roach. Is that 40 to 50 percent of your patients that require CRRT, or 40 to 50 percent of all comers into the ICU, or ...

Michael Heung: No, sorry. Yes, that's the AKI patients requiring dialysis in the ICU. That's not all comers. Our overall mortality rate for COVID for the institution is 16 percent. But again, keep in mind that we are a referral center, so many of these patients are referred to us from ICUs. These are not predominantly patients that are necessarily just walking in the door.

Jean Moody-Williams: OK. Well, thank you so much for that information, and thank you all for your questions. And we look forward to talking with you next week. Alina, can you ...

Alina Czekai: Yes. Thank you, everyone for joining our call, and I'll give the email out once again. You can continue to direct your COVID-19 questions to our inbox, which is covid-19@cms.hhs.gov. Again, we really appreciate everything that you all are doing for patients and their families around the country. Have a good rest of your night.

End