HHS/ASPR COVID-19 Outpatient Therapeutics Mini-Series

Session #8— *Regional Approaches to mAb Administration - Operationalizing Partnerships*

Wednesday, February 17, 2021 (12-1 PM ET)

Q/A Sheet

Date	Question	Answer(s)		
17-Feb	With the extensive push to vaccinate LTC patients and staff and the expected immunity achieved…where do you see the future of monoclonal antibody therapy going? If experts are correct, the need should dramatically lesson as vaccine efficacy takes hold.	Live answered.	…you are precisely right and that has been exactly what we are seeing in Utah with a steady tapering off of infusions as our mass vaccination effort in LTCFs draws to close. I was encouraged to see emerging evidence on use of mAb in a more prophylactic way before the diagnosis of COVID-19 and preventing new cases. With new variants I think the future remains uncertain, but I am hopeful for new use cases that improve outcomes for these residents.	
17-Feb	Hi, do you have the education materials posted anywhere to share?	The presentations were linked to the announcement that went out today from Project ECHO (rather than Zoom). For resources and recording from past sessions, please visit the Project ECHO website: https://hsc.unm.edu/echo/institute-programs/covid-19-response/us-covid19/hhs-aspr/miniseries.html Resources and recording from today's session will be available within a few days.		

Date	Question	Answer(s)		
17-Feb	Was vaccination delayed in this LTC population who received monoclonal antibodies per guidelines? How did your team weight the pros and cons?	Live answered.	Additionally, please see CDC guidance for latest on vaccine and mAb timing considerations: https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html. Specifically, see the "*Persons with a current or prior history of SARS-CoV-2 infection*" and "P*ersons who previously received passive antibody therapy*" sections.	
17-Feb	Can we get copies of your protocols and patient handouts you just showed on the slide?	Live answered.	A Resource library with a compilation of standing orders, training guides, SOPS, etc. can be found at https://hsc.unm.edu/echo/institute-programs/covid-19-response/us-covid19/hhs-aspr/miniseries.html	

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17-Feb	"Ineligibility for monoclonal antibody" due to vaccine? This is a first I'm hearing of this. Can you share more specifically?	Per current CDC guidance, "For vaccinated persons who subsequently experience COVID-19, prior receipt of an mRNA COVID-19 vaccine should not affect treatment decisions (including use of monoclonal antibodies, convalescent plasma, antiviral treatment, or corticosteroid administration) or timing of such treatments." https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html		
17-Feb	If a resident has had both vaccinations, but tests positive for COVID (asymptomatic), the antibody is not given?	Currently no, but we are just investigating our first 2 cases of escape infections 2 weeks post-vaccination in Utah using whole genome sequencing. This is definitely something that we are looking at and may be able to adjust our protocols as we learn more.	Additional guidance can be found in CDC's Guidance for latest on vaccine and mAb timing considerations at https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html. Specifically, scroll down to "*Persons with a current or prior history of SARS-CoV-2 infection*" and "*Persons who previously received passive antibody therapy*" sections.	
17-Feb	Guidelines advise waiting 3 months to vaccinate after receiving monoclonal antibodies	Yes, that is correct…thank you.		

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17-Feb	Sorry, I meant the Utah patient education materials, protocols, etc.	Some information (not all of the protocols), including the patient handouts are available on Utah's Coronavirus website at https://coronavirus.utah.gov/noveltherapeutics/	Resources from Utah will be posted on ECHO's Resource Library (compilation of standing orders, training guides, SOPS, etc.) at https://hsc.unm.edu/echo/institute-programs/covid-19-response/us-covid19/hhs-aspr/miniseries.html	
17-Feb	Did you consider COVID vaccination and monoclonal antibody infusion in dialysis facilities with the vulnerable ESRD population?	LTCFs are the second of 3 waves of the monoclonal antibody infusion rollout in our state. We recently started discussions on an expanded model that can include infusion centers and logically dialysis centers as well. Based on our current vaccine supply, those with ESRD that did not meet age-based (we are at 70+ currently) or other priority populations (residents of LTCFs on dialysis) will be qualifying for vaccines in coming weeks.		
17-Feb	Did Utah DOH note the day within the 10-day window the mAbs were infused to correlate with the general outcome?	We have not compiled this data yet.		

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17-Feb	If Bamlanivimab was administered after 1st vaccine but before second (we had this happen this week), would you wait the 90 days before second dose or go ahead on schedule?	Per current CDC guidance, "Currently, there are no data on the safety and efficacy of mRNA COVID-19 vaccines in persons who received monoclonal antibodies or convalescent plasma as part of COVID-19 treatment. Based on the estimated half-life of such therapies and evidence suggesting that reinfection is uncommon in the 90 days after initial infection, vaccination should be deferred for at least 90 days, as a precautionary measure until additional information becomes available, to avoid potential interference of the antibody therapy with vaccine-induced immune responses. This recommendation applies to persons who receive passive antibody therapy before receiving any vaccine doses and those who receive passive antibody therapy after the first dose but before the second dose, in which case the second dose should be deferred for at least 90 days following receipt of the antibody therapy." https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html		

Date	Question	Answer(s)		
17-Feb	What is known about how monoclonal antibodies work against the new variants?	So far the data shows there are effective but more work is underway to study. Certainty a concern and great question!	Also, Regeneron released a press release on Antibody Cocktail effectiveness against SARS-CoV-2 Variants first Identified in the UK and South Africa, go to https://investor.regeneron.com/news-releases/news-release-details/regen-covtm-antibody-cocktail-active-against-sars-cov-2-variants	
17-Feb	Is it possible to elaborate on mAb CareSense pathway that you list on your slides?	It is driven by text with links and bidirectional communication. Pre-procedure with instructions of where to go and what to expect. Then 4 post treatments days 1, 3, 11, and 30. Patient is asked to rate symptoms and if they wanted to speak to a nurse. If yes, the nursing group would get a message and then call the pt. Also, one text asked them to rate the quality of their care		
17-Feb	Do you have any data or information on the incremental FTE necessary in pharmacy for the navigation function between referral placement and scheduling for infusion? Thank you-	It took the pharmacists about 20 min per patient to call the patient, verify their status, and educate them. They then did a warm transfer over to the scheduler.		

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17-Feb	How did you handle patient selection process when demand exceeded capacity?	We gave priority to the pts who had onset of symptoms within the past 7 days, as that is when the drugs are most effective.		
17-Feb	How strongly do you feel about the need for higher level medical services being available post infusion? For instance, if infusion was given at an outpatient unit-separate from any hospital services.	Live answered.		
17-Feb	Did you collect outcomes data from the follow-up communications with patients? Can you share the data?	Nearly 99% of patients would recommend the service to their family and friends, and 95% of patients were confident in the communication between providers.		
17-Feb	For Houston/Methodist: are there any payer / provider restrictions for receiving the infusions? If not, do you coordinate with other organizations like Harris Health (the Co. hospital district)? Any shared learning with other large groups like Memorial Hermann?	No restrictions for payment. We have scheduled and treated everyone regardless of ability to pay. We receive the drug at no cost, and you can receive reimbursement from HHS for the administration for non-resource patients. Memorial Hermann treated patients on a smaller scale than we did. We are now working with 2 FQHCs to share our learnings and transferring drugs to them.		
17-Feb	Was there any push back over the cost of doing this - time for communication, IT resources etc.	Live answered.		

Date	Question	Answer(s)		
17-Feb	What is the staffing model in your outpatient infusion clinics?	When we opened: • New drug being administered – we had many unknowns to patient's response while getting treatment • We budgeted 2.5 hours per patient: 45 mins to check in/prep, 60 mins for gtt, 45 mins for monitoring check out. • Staffed with 2 RNs (10hr shift) and scheduled 8 appointments Current staffing • Significantly more comfortable with drug and administration • Decreased time per patient given lower gtt admin time. • Budget about 1.5 hours per pt. • Staff with 2 RNs + 1 tech and schedule 20 appointments		
17-Feb	What is effect of monoclonal antibodies on the newer variants being introduced nationwide?	So far, the data shows there are effective, but more work is underway to study. Certainty a concern and great question!	Also, Regeneron released a press release on Antibody Cocktail effectiveness against SARS-CoV-2 Variants first Identified in the UK and South Africa, for more information, go to https://investor.regeneron.com/news-releases/news-release-details/regen-covtm-antibody-cocktail-active-against-sars-cov-2-variants	

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17-Feb	Clinical RN Educator - given the delayed symptom reporting that you mentioned, how long do the infusion nurses stay with patients at home?	We are doing infusions in nursing facilities. The infusion team observes for 1 hour following infusion then the facility assumes care and can identify issues after the hour. In our data so far, there have been no delayed symptoms after the hour infusion time.		

17-Feb	There are a lot of outcomes being reported by various speakers at all of these webinars, which is very helpful - is there an effort among providers to collect/share these outcomes, even informally, outside of clinical trials?	I do not know of any efforts to informally share outcomes. Clinical trials have shown the placebo groups have COVID-19-related hospitalization and ED visit rates of 14.6%, 9%, 13.5%, while the intervention groups have a hospitalization rate of 4.2%, 3% and 2.7%, respectively (Chen *et al.*, 2021, *Clinical Trial Results and Supporting Data for EUA*, 2020). Our data is 4.2% hospitalization in our group of patients treated. Here's some references and also there are more recent publications. Chen, P., Nirula, A., Heller, B., Gottlieb, R. L., Boscia, J., Morris, J., Huhn, G., Cardona, J., Mocherla, B., Stosor, V., Shawa, I., Adams, A. C., Van Naarden, J., Custer, K. L., Shen, L., Durante, M., Oakley, G., Schade, A. E., Sabo, J., Patel, D. R., Klekotka, P., Skovronsky, D. M. & Investigators, B.-. (2021). N Engl J Med 384, 229-237. Clinical Trial Results and Supporting Data for EUA, (2020). https://www.regeneroneua.com/clinicaldata. Salazar, E., Christensen, P. A., Graviss, E. A., Nguyen, D. T., Castillo, B., Chen, J., Lopez, B. V., Eagar, T. N., Yi, X., Zhao, P., Rogers, J., Shehabeldin, A., Joseph, D., Leveque, C., Olsen, R. J., Bernard, D. W., Gollihar, J. & Musser, J. M. (2020).	Not that I am aware of but a great idea!	You may find this White Paper published by Duke Margolis helpful at https://healthpolicy.duke.edu/publications/covid-19-monoclonal-antibody-treatments-using-evolving-evidence-improve-care-pandemic.

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		Am J Pathol 190, 2290-2303. Salazar, E., Christensen, P. A., Graviss, E. A., Nguyen, D. T., Castillo, B., Chen, J., Lopez, B. V., Eagar, T. N., Yi, X., Zhao, P., Rogers, J., Shehabeldin, A., Joseph, D., Masud, F., Leveque, C., Olsen, R. J., Bernard, D. W., Gollihar, J. & Musser, J. M. (2021). Am J Pathol 191, 90-107. Sax, P. E. (2020). NEJM Journal Watch. Weinreich, D. M., Sivapalasingam, S., Norton, T., Ali, S., Gao, H., Bhore, R., Musser, B. J., Soo, Y., Rofail, D., Im, J., Perry, C., Pan, C., Hosain, R., Mahmood, A., Davis, J. D., Turner, K. C., Hooper, A. T., Hamilton, J. D., Baum, A., Kyratsous, C. A., Kim, Y., Cook, A., Kampman, W., Kohli, A., Sachdeva, Y., Graber, X., Kowal, B., DiCioccio, T., Stahl, N., Lipsich, L., Braunstein, N., Herman, G., Yancopoulos, G. D. & Trial, I. (2021). N Engl J Med 384, 238-251. Gottlieb RL, et al. JAMA doi 10.1001/jama.2021.0202		
17-Feb	Did you treat any incarcerated, or provide collaboration and communication with their medical staff in the areas?	No, we did not.		

Date	Question	Answer(s)		
17-Feb	Have you had post infusion sx up to 7 days with rash and or arthralgia?	No, we have not.	As part of the EUA, FDA is requiring health care providers who prescribe the mAbs to report all medication errors and serious adverse events considered to be potentially related to the mAbs through FDA's MedWatch at https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program.	
17-Feb	How are the centers mixing the products with the USP 797 restrictions on the number of products that can be used in a mix at the bedside? We are using bam only at this time for that reason	All of the mixing was done in our pharmacies and then delivered to the clinics	We are also only using BAM at this time.	