Methods. We identified KTR with COVID-19 between 3/1/2020 and 4/30/2021. Patients were excluded if they had multiorgan transplant or hospital-acquired COVID-19. Data were analyzed by Cox regression with mAb administration as time-dependent variable, and the day of symptom onset as baseline.

Results. We studied 95 KTR; 20 received mAb. Comorbidities and immunosuppression were balanced between the two groups. mAb administration was associated with a significant decrease in hospitalizations or ER visits (15 vs. 76%, P< 0.001). This association remained significant after adjustment for confounders and by analyzing mAb administration as a time-dependent variable (Table: adj. HR 0.2, P=0.04). No KTR who received mAb died or required mechanical ventilation. Black or Hispanic KTR were less likely to receive mAb and more likely to be admitted to the hospital or visit the ER (Table).

Table

Analysis / Parameter	Univariate			Multivariate		
	HR	95% CI	P	HR	95% CI	P
Age (years)	1.022	1.004-1.041	**0.019**	1.023	1.003-1.044	**0.024**
mAb	0.115	0.036-0.368	**0.009**	0.216	0.050-0.929	**0.040**
Chronic kidney disease	2.456	1.243-4.855	**0.010**	2.087	1.043-4.176	**0.038**
Black race	2.168	1.186-3.964	**0.012**	1.881	0.959-3.689	0.066
Hispanic ethnicity	1.701	1.003-2.883	**0.049**	2.029	1.111-3.703	**0.021**

Factors significantly associated with hospitalization or ER visit.

Conclusion. In our KTR population, mAb therapy for COVID-19 may have helped decrease hospitalizations and ER visits. Healthcare inequities, including access to investigational treatments, were exacerbated by the COVID-19 pandemic. Acknowledging the nonconcurrent control group as a limitation, we found a strong signal for benefit from mAb treatment. Antiviral mAb are a promising therapeutic modality for immunosuppressed patients.

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40. Lenzilumab Efficacy and Safety in Newly Hospitalized COVID-19 Subjects: Results From a Phase 3 Randomized Double-Blind Placebo-Controlled Trial

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Session: O-08. COVID-19 Treatment & Diagnostics

Background. Severe coronavirus disease 2019 (COVID-19) often results from the immune-mediated cytokine storm, triggered by granulocyte macrophage-colony stimulating factor (GM-CSF), potentially leading to respiratory failure and death. Lenzilumab, a novel anti-human GM-CSF monoclonal antibody, neutralizes GM-CSF and demonstrated potential to improve clinical outcomes in a matched case-cohort study of patients with severe COVID-19 pneumonia. This Phase 3 randomized, double-blind, placebo-controlled trial investigated the efficacy and safety of lenzilumab to improve the likelihood of survival without invasive mechanical ventilation (SWOV), beyond available treatments.

Methods. Hypoxic patients, hospitalized with COVID-19 (n=520), requiring supplemental oxygen, but not invasive mechanical ventilation, were randomized on Day 0 to receive lenzilumab (1800mg, n=261) or placebo (n=259), and available treatments, including remdesivir and/or corticosteroids; and were followed through Day 28.

Results. Baseline demographics were comparable between groups: male, 64.7%; mean age, 60.5 years; median CRP, 79.0 mg/L. Patients across both groups received steroids (93.7%), remdesivir (72.4%), or both (69.1%). Lenzilumab improved the primary endpoint, likelihood of SWOV in the mITT population, by 1.54-fold (HR: 1.54; 95%CI: 1.02-2.32, p=0.0403). Lenzilumab improved SWOV by 1.91-fold (nominal p=0.0073) and 1.92-fold (nominal p=0.0067) in patients receiving remdesivir or remdesivir and corticosteroids, respectively. A key secondary endpoint of incidence of IMV, ECMO or death was also improved in patients receiving remdesivir (p=0.020) or remdesivir and corticosteroids (p=0.0180). Treatment-emergent serious adverse events were similar across both groups.

Conclusion. Lenzilumab significantly improved SWOV in hypoxic COVID-19 patients upon hospitalization, with the greatest benefit observed in patients receiving treatment with remdesivir and corticosteroids. NCT04351152

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41. Assessing Past vs Present COVID-19 Infection: A Survey of Criteria for Discontinuing Precautions in Asymptomatic Patients

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CDC Epicenters

Session: O-08. COVID-19 Treatment & Diagnostics

Background. COVID-19 patients can remain positive by PCR-testing for several months. Pre-admission or pre-procedure testing can identify recovered asymptomatic patients who may no longer be contagious but would require precautions according to current CDC recommendations (10 days). This can result in unintended consequences, including procedure delays or transfer to appropriate care (e.g., psychiatric or post-trauma patients requiring admission to COVID-19 units instead of psychiatric or rehabilitation facilities, respectively).

Methods. We conducted a structured survey of healthcare epidemiologists and infection prevention experts from the SHEA Research Network between March-April, 2021. The 14-question survey, presented a series of COVID-19 PCR+ asymptomatic patient case scenarios and asked respondents if (1) they would consider the case recovered and not infectious, (2) if they have cleared precautions in such cases, and if so, (3) how many transmission events occurred after discontinuing precautions. The survey used one or a combination of 5 criteria: history of COVID-19 symptoms, history of exposure to a household member with COVID-19, COVID-19 PCR cycle threshold (CT), and IgG serology. Percentages were calculated among respondents for each question.

Results. Among 60 respondents, 56 (93%) were physicians, 51 (86%) were hospital epidemiologists, and 46 (77%) had >10y infection prevention experience. They represented facilities that cumulatively cared for >29,000 COVID-19 cases; 46 (77%) were academic, and 42 (69%) were large (>400 beds). One-third to one-half would consider an incidentally found PCR+ case as recovered based on solo criteria, particularly those with two consecutive high CTs or COVID IgG positivity recovered (53-55%) (Table 1). When combining two criteria, half to four-fifths of respondents deemed PCR+ cases to be recovered (Table 2). Half of those had used those criteria to clear precautions (45-64%) and few to none experienced a subsequent transmission event resulting from clearance.

Conclusion. The majority of healthcare epidemiologists consider a combination of clinical and diagnostic criteria as recovered and many have used these to clear precautions without high numbers of transmission.

Table 1: Assessment of COVID-19 recovery of asymptomatic case scenarios using solo criterion to identify potentially recovered patients for discontinuation of precautions.

SOLO CRITERION			
Asymptomatic Case Scenario	Percent That Believe Case Is Recovered and Not infectious	Percent That Have Used This Criterion to Clear Precautions[1]	Number of Transmission Events Among Those Released from Precautions Using This Criterion[2]
HISTORY OF COVID-LIKE SYMPTOMS Clear history of COVID-like symptoms 1 month ago. Now COVID PCR CT* is 30. COVID IgG* negative.	42%	68%	0
EXPOSURE TO COVID+ HOUSEHOLD/CLOSE CONTACT No history of symptoms. Known household COVID+ contact 5 weeks ago. Current COVID PCR CT is 30. COVID IgG negative.	33%	50%	0
HIGH CYCLE THRESHOLD No history of symptoms or COVID+ contact. Current COVID PCR CT is >35. COVID IgG negative.	37%	45%	1
TWO HIGH CYCLE THRESHOLDS No history of symptoms or COVID+ contact. Current COVID PCR CT is >35 on two separate days. COVID IgG negative.	53%	69%	1
COVID IgG+ No history of symptoms or COVID+ contact. Current COVID PCR CT is 30. COVID IgG positive.	55%	52%	0

[1]Percent calculated among those who believe the case is recovered/not infectious.
[2]Number of known transmission events
*Abbreviations: CT = Cycle Threshold time, IgG – Immunoglobulin G

Table 2: Assessment of COVID-19 recovery of asymptomatic case scenarios using dual criteria to identify potentially recovered patients for discontinuation of precautions.

DUAL CRITERIA			
Asymptomatic Case Scenario	Percent That Believe Case Is Recovered and Not infectious	Percent That Have Used This Criteria to Clear Precautions[1]	Number of Transmission Events Among Those Released from Precautions Using These Criteria[2]
HISTORY OF COVID-LIKE SYMPTOMS + EXPOSURE TO COVID+ HOUSEHOLD OR CLOSE CONTACT Patient with clear history of COVID-like symptoms 1 month ago, known household COVID+ contact 5 weeks ago.	52%	58%	0
HISTORY OF COVID-LIKE SYMPTOMS AND HIGH CYCLE THRESHOLD Patient with clear history of COVID-like symptoms 1 month ago. No COVID+ contact. Current COVID PCR CT is >35. COVID IgG negative.	58%	60%	1
HISTORY OF COVID-LIKE SYMPTOMS AND TWO HIGH CYCLE THRESHOLDS Patient with clear history of COVID-like symptoms 1 month ago. No COVID+ contact. Current COVID PCR CT is >35 on two separate days. COVID IgG negative.	65%	64%	0
HISTORY OF COVID-LIKE SYMPTOMS AND COVID IgG+ Patient with clear history of COVID-like symptoms 1 month ago. No known COVID+ contact. Current COVID PCR CT is 30. COVID IgG positive.	65%	56%	0
EXPOSURE TO COVID+ HOUSEHOLD OR CLOSE CONTACT AND HIGH CYCLE THRESHOLD Patient asymptomatic and no history of symptoms. Known household COVID+ contact 5 weeks ago, current COVID PCR CT is >35. COVID IgG negative.	50%	45%	0
EXPOSURE TO COVID+ HOUSEHOLD OR CLOSE CONTACT AND TWO HIGH CYCLE THRESHOLDS No history of symptoms. Known household COVID+ contact 5 weeks ago. Current COVID PCR CT is >35 on two separate days. COVID IgG negative.	60%	50%	1
EXPOSURE TO COVID+ HOUSEHOLD OR CLOSE CONTACT AND COVID IgG+ No history of symptoms. Known household COVID+ contact 5 weeks ago, current COVID PCR CT is 30. COVID IgG positive.	62%	46%	0
HIGH CYCLE THRESHOLD AND COVID IgG+ No history of symptoms. No known COVID+ contact. Current COVID PCR CT is >35, and COVID IgG positive.	63%	50%	1
TWO HIGH CYCLE THRESHOLDS AND COVID IgG+ No history of symptoms. No known COVID+ contact. Current COVID PCR CT is ≥ 35 on two separate days. COVID IgG positive.	83%	48%	1

[1]Percent calculated among those who believe the case is recovered/not infectious.
[2]Number of known transmission events
*Abbreviations: CT = Cycle Threshold time, IgG – Immunoglobulin G

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