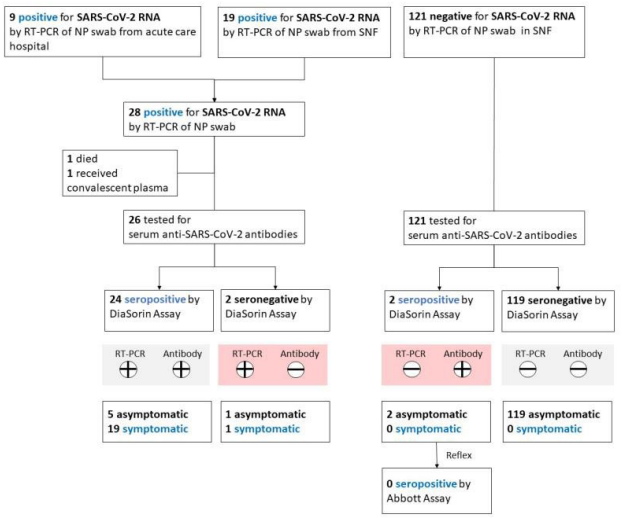
serological test results in a cohort of SNF residents who had been repetitively screened for SARS-CoV-2 infection by nasopharyngeal swab PCR.

Methods: In late March 2019, we identified symptomatic SARS-CoV-2 PCR positive residents at a SNF. In response, all remaining SNF patients were serially screened, and all SARS-CoV-2 PCR positive patients were transferred to the acute care hospital or cohorted in a separate COVID Recovery Unit (CRU) in the SNF. In early June, all SNF residents (SARS-CoV-2 PCR positive and negative) underwent serologic testing for SARS-CoV-2 Spike (S1/S2) IgG (DiaSorin). DiaSorin IgG-positive results for patients that were SARS-CoV-2 PCR-negative were reflexed to nucleocapsid IgG (Abbott). Antibody testing occurred a median of 69 days (63–70 IQR) after PCR positivity.

Results: Nineteen SARS-CoV-2 PCR positive residents were identified from the outbreak and an additional 9 were transferred from the acute care hospital to the CRU; 1 died and 1 received convalescent plasma leaving 26 SARS-CoV-2 PCR positive residents, including 6 who were asymptomatic, that were eligible for serologic testing. Twenty-four of the 26 were positive for IgG by the DiaSorin assay; one seronegative resident was one of the asymptomatic residents. There were an additional 121 residents in the SNF whose SARS-CoV-2 PCR was negative at least once. Among these 121 SNF residents with negative SARS-CoV-2 RT-PCR, all but two were seronegative by the Diasorin assay. The two seropositive residents had no nucleocapsid antibodies when reflex tested by the Abbott assay.

Figure 1. Cohort Diagram



Conclusion: In a limited sample of SNF residents with SARS-CoV-2 PCR positivity, the sensitivity of the Diasorin assay was 92% (24/26) and the specificity was 98% (119/121). None of the residents with negative SARS-CoV-2 PCR had *confirmed* positive antibody results using reflex testing (DiaSorin/Abbott). Despite high risk exposure in congregate living facilities, we found no evidence of additional SARS-CoV-2 exposure, reinforcing the importance of serial surveillance SARS-CoV-2 testing and early cohorting in SNF settings.

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71. Use of Intravenous Immunoglobulin Therapy Reduces Progression to Mechanical Ventilation in COVID-19 Patients with Moderate to Severe Hypoxia

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Background: The majority of COVID-19 morbidity and mortality occurs in patients who progress to mechanical ventilation. Therefore, therapeutic interventions targeting the mitigation of this complication would markedly improve outcomes and reduce healthcare utilization.

Methods: Patients with COVID-19 from two hospitals in San Diego, California were randomized at a 1:1 ratio to receive standard of care (SOC) plus intravenous immunoglobulin (IVIG) at 0.5 g/kg/day x 3 days with solumedrol 40 mg 30 minutes before infusion (IVIG group) versus SOC alone. The primary composite endpoint was receipt of mechanical ventilation or death before receiving ventilation. Patients were followed until discharge to home or up to 30 days from time of enrollment.

Results: Sixteen patients received IVIG plus SOC and 17 SOC alone. The median age was 54 years for SOC and 57 years for IVIG. Median time from hospital admission to study enrollment was 1 day (range 0–4) for SOC and 2 days (range 0–8) for IVIG. APACHE II scores and Charlson comorbidity indices were similar for IVIG and SOC (median 8 vs 7 and 2 for both, respectively). Seven SOC patients achieved the composite endpoint (6 ventilated, 1 death) versus 2 IVIG patients (2 ventilated), p=0.12, Fisher exact test. Among the subgroup with an estimated A-a gradient of >200 mm Hg at time of enrollment, the IVIG group showed a lower rate of progression to the composite endpoint (2/14 vs 7/12, p=0.04 Fisher exact test), shorter median hospital length (11 vs 24 days, p=0.001 Mann Whitney U), and shorter median intensive care unit (ICU) stay (3 vs 13 days, p=0.005 Mann Whitey U).

Conclusion: This small, prospective, randomized, open-label study showed that when administered to hypoxic non-ventilated COVID-19 patients with an A-a gradient of >200 mm Hg (corresponding to a requirement of 6 liters O_2 via nasal cannula to achieve an SpO_2 of 92%), IVIG significantly decreased the rates of progression to mechanical ventilation, ICU length of stay, and total hospital length of stay. A Phase 3 prospective, randomized, placebo-controlled, multicenter trial is underway to further validate these findings.

Disclosures: **George Sakoulas, MD**, **Octapharma** (Grant/Research Support, Scientific Research Study Investigator)

72. Remdesivir vs Standard Care in Patients with Moderate covid-19

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Session: O-14. COVID-19 Therapies

Background: Remdesivir (RDV) shortens time to recovery time in patients with severe COVID-19. Its effect in patients with moderate COVID-19 remains unclear.

Methods: We conducted an open-label, phase 3 trial (NCT04252664) involving hospitalized patients with confirmed SARS-CoV-2 infection, evidence of pulmonary infiltrates, and oxygen saturation >94% on room air. Patients were randomly assigned 1:1:1 to receive up to 5d or 10d of RDV with standard of care (SoC), or SoC alone; patients could be discharged prior to completing per-protocol assigned treatment duration. RDV was dosed intravenously at 200 mg on d1, 100 mg daily thereafter. Patients were evaluated daily while hospitalized, and via telephone if discharged. The primary endpoint was clinical status on d11 assessed on a 7-point ordinal scale. Results regarding the primary endpoint are expected to be published before IDWeek 2020; we plan to present d28 results at the meeting.

Results: In total, 584 patients underwent randomization and started their assigned treatment (191, 5d RDV; 193, 10d RDV; 200, SoC). By d11, ^{3} 2 point improvement on the ordinal scale occurred in 70% of patients in the 5d arm, 65% in the 10d arm, and 61% in the SoC arm. Patients in the 5d RDV arm were significantly more likely to have an improvement in clinical status than those receiving SoC (odds ratio [OR], 1.65; 95% confidence interval [CI], 1.09–2.48; P=0.017); OR of improvement for the 10d RDV arm compared to SoC was 1.31 (95% CI, 0.88–1.95]; p=0.183). This improvement in the 5-day arm over the SOC arm was noted from d6 through d11. We observed a peak of discharges corresponding with the assigned treatment duration of RDV, with increased discharges at d6 in the 5-day arm and at d11 in the 10-day arm. A worsening of clinical status of $\geq$ 1 point in the ordinal scale was observed more commonly in the SoC am (n=19, 10%) versus the 5d RDV (n=7, 4%) and 10d RDV (n=9, 5%).

Conclusion: RDV for up to 5 days was superior to SoC in improving the clinical status of patients with moderate COVID-19 by d11. We will report d28 outcomes at the meeting.

Disclosures: **Francisco M. Marty, MD**, **Allovir** (Consultant)**Amplyx** (Consultant)**Ansun** (Scientific Research Study Investigator)**Avir** (Consultant)**Cidara** (Scientific Research Study Investigator)**F2G** (Consultant, Scientific Research Study Investigator)**Kyorin** (Consultant)**Merck** (Consultant, Grant/Research Support, Scientific Research Study Investigator)**New England Journal of Medicine** (Other Financial or Material Support, Honorarium for Video)**Regeneron** (Consultant, Scientific Research Study Investigator)**ReViral** (Consultant)**Scynexis** (Scientific Research Study Investigator)**Symbio** (Consultant)**Takeda** (Scientific Research Study Investigator)**United Medical** (Consultant)**WHISCON** (Scientific Research Study Investigator) **Prashant Malhotra, MD**, **Gilead Sciences Inc.** (Scientific Research Study Investigator) **Robert L. Gottlieb, MD**, **Gilead Sciences Inc.** (Scientific Research Study Investigator) **Karen T. Tashima, MD**, **Bristol-Myers Squibb** (Research Grant or Support)**Gilead Sciences Inc.** (Grant/Research Support, Scientific Research Study Investigator)**GlaxoSmithKline** (Research Grant or Support)**Merck** (Research Grant or Support)**Tibotec** (Research Grant or Support)**Viiv Healthcare** (Research Grant or Support) **Massimo Galli, MD**, **Gilead Sciences Inc.** (Grant/Research Support, Scientific Research Study Investigator, Advisor or Review Panel member, Other Financial or Material Support, Personal fees) **Louis Yi Ann Chai, MD**, **Gilead Sciences Inc.** (Scientific Research Study Investigator) **Devi SenGupta, MD**, **Gilead Sciences Inc.** (Employee, Shareholder) **Robert H. Hyland, MD**, **Gilead Sciences Inc.** (Employee, Shareholder) **Hongyuan Wang, PhD**, **Gilead Sciences Inc.** (Employee, Shareholder) **Lijie Zhong, PhD**, **Gilead Sciences Inc.** (Employee, Shareholder) **Huyen Cao, MD**, **Gilead Sciences Inc.** (Employee, Shareholder) **Anand**

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73. Geographical Disparities in Clinical Outcomes of Severe COVID-19 Patients Treated with Remdesivir

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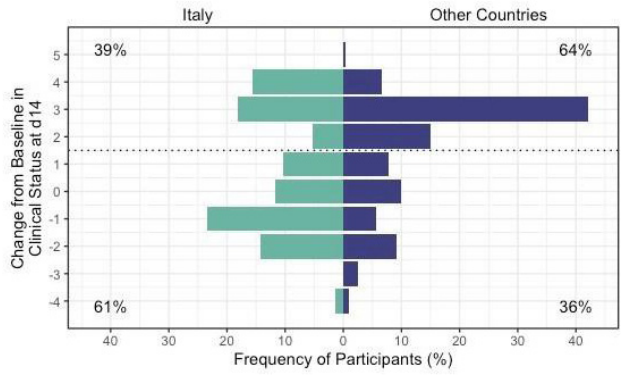
Session: O-14. COVID-19 Therapies

Background: Remdesivir (RDV), a RNA polymerase inhibitor with potent in vitro activity against SARS-CoV-2, is the only treatment with demonstrated efficacy in shortening the duration of COVID-19. Here we report regional differences in clinical outcomes of severe COVID-19 patients treated with RDV, as part of an open-label, randomized phase-3 trial establishing RDV treatment duration.

Methods: Hospitalized patients with oxygen saturation ≤94%, a positive SARS-CoV-2 PCR in the past 4 days and radiographic evidence of pneumonia were randomized 1:1 to receive 5d or 10d of intravenous RDV. We compared d14 clinical outcomes of patients from different geographical areas, as measured by mortality rates, change in clinical status from baseline (BL) on a 7-point ordinal scale and change in O2 requirements from BL. Based on previous analyses in compassionate use data showing region as an important predictor of outcome, Italy was examined separately from other regions.

Results: 397 patients were treated with RDV, of which 229 (58%) were in the US, 77 (19%) Italy, 61 (15% in Spain), 12 (3%) Republic of Korea, 9 (2%) Singapore, 4 (1%) Germany, 4 (1%) Hong Kong and 1 (< 1%) Taiwan. BL clinical status was worse in Italy compared to other regions (72% vs 17% requiring high-flow oxygen delivery or higher), and Italian patients were more likely to be male than patients from other regions (69% vs 63%). Overall results showed 5d RDV was as effective as 10d. Mortality at d14 was higher in Italy (18%) compared to all other countries except Italy (7%). Similarly, clinical improvement at d14, measured as ≥2-point increase in the ordinal scale, was lower in Italian patients (39%) compared to all other countries combined (64%). (Fig.1).

Figure 1. Change from Baseline in Clinical Status (measured on a 7-point Ordinal Scale) at d14.



Conclusion: Overall, our results demonstrate significant geographical differences in the clinical course of severe COVID-19 patients treated with RDV. We observed worse outcomes, such as increased mortality and lower rate of clinical improvement, in patients from Italy compared to other regions.

Disclosures: **George Diaz, MD**, NO DISCLOSURE DATA **Jose Ramon Arribas, MD**, **Alexa** (Advisor or Review Panel member, Speaker's Bureau, Other Financial or Material Support, Personal fees)**Gilead Sciences Inc.** (Scientific Research Study Investigator, Advisor or Review Panel member, Speaker's Bureau, Other Financial or Material Support, Personal fees)**Janssen** (Advisor or Review Panel member, Speaker's Bureau, Other Financial or Material Support, Personal fees)**Merck** (Advisor or Review Panel member, Speaker's Bureau, Other Financial or Material Support, Personal fees)**Viiv Healthcare** (Advisor or Review Panel member, Speaker's Bureau, Other Financial or Material Support, Personal fees) **Jose Ramon Arribas, MD**, NO DISCLOSURE DATA **Philip A. Robinson, MD**, NO DISCLOSURE DATA **Anna Maria Cattelan, MD**, NO DISCLOSURE DATA **Karen T. Tashima, MD**, **Bristol-Myers Squibb** (Research Grant or Support)**Gilead Sciences Inc.** (Grant/Research Support, Scientific Research Study Investigator)**GlaxoSmithKline** (Research Grant or Support)**Merck** (Research Grant or Support)**Tibotec** (Research Grant or Support)**Viiv Healthcare** (Research Grant or Support) **Owen Tak-Yin Tsang, MD**, **Gilead Sciences Inc.** (Scientific Research Study Investigator) **Owen Tak-Yin Tsang, MD**, NO DISCLOSURE DATA **Yao-Shen Chen, MD**, **Gilead Sciences Inc.** (Scientific Research Study Investigator) **Yao-Shen Chen, MD**, NO DISCLOSURE DATA **Devi SenGupta, MD**, **Gilead Sciences Inc.** (Employee, Shareholder) **Elena Vendrame, MD**, NO DISCLOSURE DATA **Christiana Blair, MS**, **Gilead Sciences** (Employee, Shareholder) **Anand Chokkalingam, PhD**, **Gilead Sciences** (Employee) **Anu Osinusi, MD**, **Gilead Sciences** (Employee) **Diana M. Brainard, MD**, **Gilead Sciences** (Employee) **Bum Sik Chin, MD**, **Gilead Sciences Inc.** (Scientific Research Study Investigator) **Bum Sik Chin, MD**, NO DISCLOSURE DATA **Christoph Spinner, MD**, **AbbVie** (Advisor or Review Panel member, Other Financial or Material Support, Travel)**Bristol-Myers Squibb** (Grant/Research Support, Advisor or Review Panel member, Other Financial or Material Support, Travel)**Gilead Sciences Inc.** (Grant/Research Support, Scientific Research Study Investigator, Advisor or Review Panel member, Other Financial or Material Support, Travel)**Janssen** (Grant/Research Support, Advisor or Review Panel member, Other Financial or Material Support, Travel)**MSD** (Grant/Research Support, Advisor or Review Panel member, Other Financial or Material Support, Travel)**Viiv Healthcare** (Grant/Research Support, Advisor or Review Panel member, Other Financial or Material Support, Travel) **Gerard J. Criner, MD**, **Gilead Sciences Inc.** (Scientific Research Study Investigator)**Regeneron** (Scientific Research Study Investigator) **Gerard J. Criner, MD**, NO DISCLOSURE DATA **Jose Muñoz, MD**, NO DISCLOSURE DATA **David Chien Boon Lye, MD**, **Gilead Sciences Inc.** (Scientific Research Study Investigator) **David Chien Boon Lye, MD**, NO DISCLOSURE DATA **Robert L. Gottlieb, MD**, **Gilead Sciences Inc.** (Scientific Research Study Investigator)

74. Empiric Antibiotic Therapy and Community-onset Bacterial Co-infection in Patients Hospitalized with COVID-19: A Multi-hospital Cohort Study

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Session: O-14. COVID-19 Therapies

Background: Antibiotic therapy has no known benefit against COVID-19, but is often initiated out of concern for concomitant bacterial infection. We sought to determine how common early empiric antibiotic therapy and community-onset bacterial co-infections are in hospitalized patients with COVID-19.

Methods: In this multi-center cohort study of hospitalized patients with COVID-19 discharged from 32 Michigan hospitals during the COVID-19 Michigan surge, we describe the use of early empiric antibiotic therapy (within the first two days) and prevalence of community-onset bacterial co-infection. Additionally, we assessed patient and hospital predictors of early empiric antibiotic using poison generalized estimating equation models.

Results: Between 3/10/2020 and 5/10/2020, data were collected on 951 COVID-19 PCR positive patients. Patient characteristics are described in **Table 1**. Nearly two thirds (62.4%, 593/951) of COVID-19 positive patients were prescribed early empiric antibiotic therapy, most of which (66.2%, 393/593) was directed at community-acquired pathogens. Across hospitals, the proportion of COVID-19 patients prescribed early empiric antibiotics varied from 40% to 90% (**Figure 1**). On multivariable analysis, patients were more likely to receive early empiric antibiotic therapy if they were older (adjusted rate ratio [ARR]: 1.01 [1.00–1.01] per year), required respiratory support (e.g., low flow oxygen, ARR: 1.16 [1.04–1.29]), had signs of a bacterial infection (e.g., lobar infiltrate, ARR: 1.17 [1.02–1.34]), or were admitted to a for-profit hospital (ARR: 1.27 [1.11–1.45]); patients admitted later were less likely to receive empiric antibiotics (April vs. March, ARR: 0.72 [0.62–0.84], **Table 2**). Community-onset bacterial co-infections were identified in 4.5% (43/951) of COVID-19 positive patients (2.4% [23/951] positive blood culture; 1.9% [18/951] positive respiratory culture).