Disclosures. **Aisling Caffrey, PhD**, **Merck** (Research Grant or Support)**Pfizer** (Research Grant or Support)**Shionogi, Inc** (Research Grant or Support)

558. Implementation and Outcomes of a COVID-19 Monoclonal Antibody Treatment Program in an Urban Safety-net Community Hospital

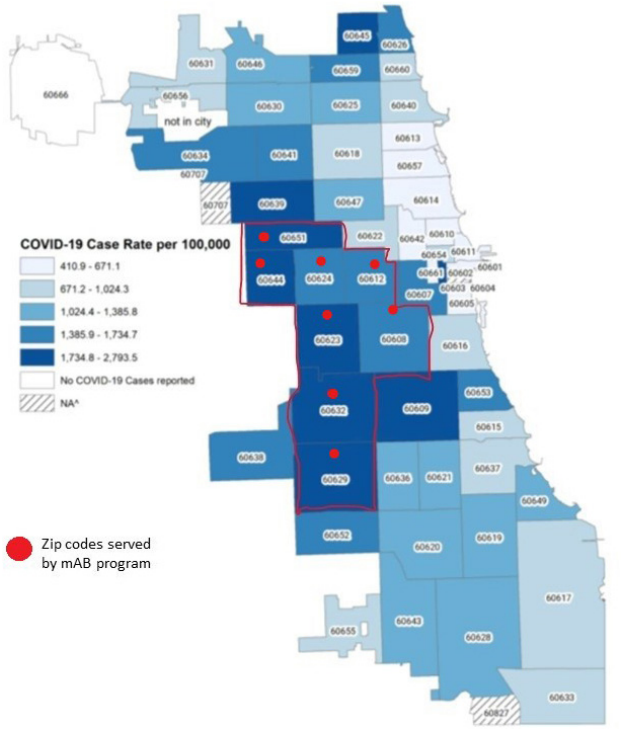
Alfredo J. Mena Lora, MD[1]; Stephanie L. Echeverria, MPH, MBS[2]; Fischer Herald, PharmD[1]; James McSweeney, n/a[2]; Harshil Gumasana, MD[2]; Rodrigo M. Burgos, PharmD[3]; Scott Borgetti, MD[1]; [1]University of Illinois at Chicago, Chicago, IL; [2]Saint Anthony Hospital, Chicago, IL; [3]University of Illinois at Chicago College of Pharmacy, Chicago, IL

Session: P-24. COVID-19 Treatment

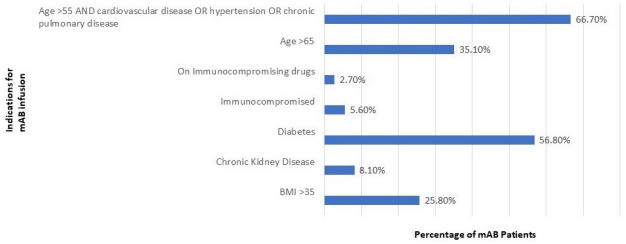
Background. Neutralizing monoclonal antibodies (mAbs) bind to the receptor binding domain of the spike protein of SARS-CoV-2. In November 2020, several mAbs were issued an EUA by the FDA as single-dose intravenous (IV) infusions for treatment of mild to moderate COVID-19. mABs were allocated to local health facilities capable of administering infusions and managing side effects. Creating an outpatient infusion program during the COVID-19 winter surge can be logistically difficult. Our goal was to implement a mAb outpatient infusion program at an urban safety-net community hospital designed to serve communities most heavily impacted by COVID-19.

Methods. The emergency department (ED) fast-track was repurposed for the mAb program with protocols from the infectious diseases physician and antimicrobial stewardship. Education materials with indications for mAbs were distributed in surrounding clinics serving our community. The program was available to all patients meeting criteria outlined in the protocol, 24/7, including but not limited to current ED patients and referrals from facilities in the vicinity.

Results. Between December 1, 2020 and March 1, 2021, a total of 37 patients were treated: 51% male, 57% Hispanic or Latinx, 27% Black, and 95% (35) represented ZIP codes with high COVID-19 burden (Figure 1). Bamlanivimab was used for each instance and all infusions met criteria. Patient indications for mAb infusion are listed in Figure 2. Parenteral antibiotics were given to 10.8% and 35% received oral antibiotics upon discharge. At 30 days post-infusion, 8% (3) required hospitalization and there were no deaths.



Zip codes with high COVID-19 disease burden served by our mAB infusion program



Distribution of patients who received mAB infusions by indication

Conclusion. A mAb outpatient infusion program was successfully deployed in a safety-net community hospital. We believe strengths of the program included the flexible infusion hours and convenient referral site for patients and providers. Of importance, this program was able to provide services to minorities from ZIP codes most heavily impacted by COVID-19. Unfortunately, antibacterial use was common and may reflect broader unnecessary use in COVID-19 patients. Whilst mAb treatment was deemed appropriate in all instances via protocol inclusion criteria, antibacterial stewardship programs may need to expand to ED settings for COVID-19 management.

Disclosures. **All Authors**: No reported disclosures

559. A Nationwide Survey of COVID-19 Management in the Dominican Republic Over the Course of the Pandemic

Alfredo J. Mena Lora, MD[1]; Rita Alexandra Rojas-Fermin, MD[2]; David de Luna, n/a[3]; Stephanie L. Echeverria, MPH, MBS[4]; Yori Roque, MD, MSc[5]; Ruben Calcano, MD[6]; Claudia Blanco, MD[6]; Clevy Perez, MD[6]; Anny Hernandez, MD[6]; Adames Espinal, MD[6]; Carolina Coronado, MD[6]; Michelle Castro, MD[6]; Arelis Batista, MD[6]; Scott Borgetti, MD[1]; Susan C. Bleasdale, MD[1]; [1]University of Illinois at Chicago, Chicago, IL; [2]Hospital General Plaza de la Salud, Santo Domingo, Dominican Republic; [3]Internist-infectologist, Santiago de los cabelleros, Santiago, Dominican Republic; [4]Saint Anthony Hospital, Chicago, IL; [5]Pontificia Universidad Catolica Madre y Maestra (PUCMM), Santiago, Santiago, Dominican Republic; [6]SDI, Santo Domingo, Distrito Nacional, Dominican Republic

Session: P-24. COVID-19 Treatment

Background. COVID-19 was declared a global Public Health Emergency by the WHO in January 2020. Limited treatment options existed early in the pandemic. As COVID-19 spread across the globe and new therapeutics emerged, different interpretations of the literature grew, and major societies relayed conflictive recommendations. There is a paucity of data on COVID-19 management in low- and middle-income countries. As a result, we performed a nationwide survey of local treatment practices in the Dominican Republic (DR).

Methods. We performed an anonymous survey of infectious diseases specialists in the DR and US. The survey collected hospital characteristics and COVID-19 management protocols during different quarters of 2020-21. Management was categorized by drug and disease severity based on supplemental oxygen requirements. A convenience sample in the US representing community and academic sites was surveyed for point comparison between the US and DR.

Results. The survey was completed by physicians from a total of 11 sites located in 4 cities of the DR: Santo Domingo (3), Santiago (4), La Vega (2) and San Francisco (2). These cities were representative of all regions in the country. The survey included 7 (64%) hospitals with < 200 beds, 3 (27%) with 201-300 beds, and 1 (9%) with >400 beds. Seven (47%) were private, 2 (13%) public, and 6 (40%) were teaching hospitals. In the US, 2 academic hospitals with >400 beds and 2 community hospitals with < 200 beds in a major city were surveyed. Management of COVID-19 at sites in the DR and US throughout the pandemic is plotted in Figure 1. Remdesivir use by disease severity is plotted in Figure 2.

Figure 1. Management of COVID-19 at sites in the US and DR throughout the COVID-19 pandemic

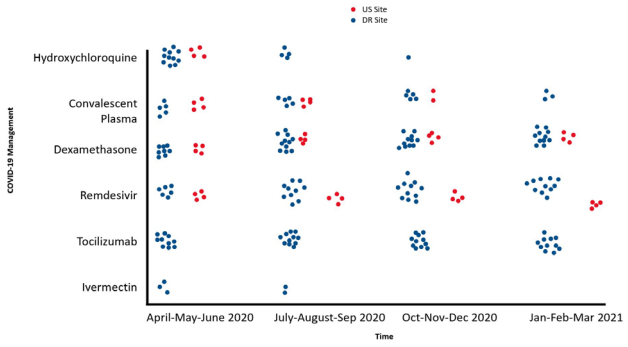
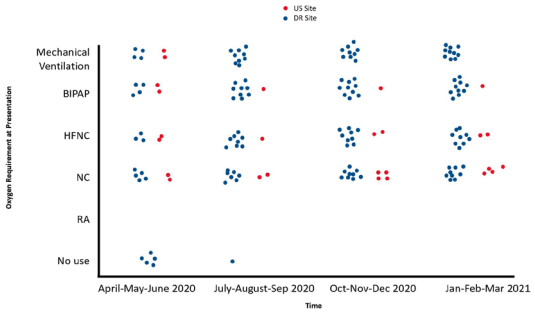


FIgure 2. Remdesivir use by disease severity at sites in the US and DR throughout the COVID-19 pandemic



Conclusion. Throughout the pandemic, as therapeutic options evolved, hospitals and physicians had to adapt to changing guidelines and availability of novel drugs. Variability between countries and sites emerged. The use of hydroxychloroquine and convalescent plasma waned more rapidly in the US. Dexamethasone was widely used at all sites. Tocilizumab and remdesivir were used more liberally in the DR. Antimicrobial stewardship limited these agents at US sites to more narrow therapeutic windows which could explain the discrepancies seen between the US and DR. Uncertainty of benefit in certain disease states, limited availability, and cost may also play a role.

Disclosures. **All Authors**: No reported disclosures

560. Evaluation of Optimal Methylprednisolone Dose in Patients with Covid 19

Jose Luis Lamas Ferreiro, MD[1]; Judith Álvarez Otero, MD[1]; Fernando Maroto Piñeiro, MD[1]; Iolanda Abalde Ortega, Resident[1]; Marta Rodríguez Villar, Resident[1]; Sonia Morón Losada, Resident[1]; Irea Vidal González, Resident[1]; Alejandra Canoa Rico, Resident[1]; Laura Fernández González, Resident[1]; Emilia Fernández Fernández, Resident[1]; Marta Costas Vila, Resident[1]; Ana Sanjurjo Rivo, MD[1]; Francisco Fernández Fernández, MD[1]; Jose Manuel Paz Ferrín, MD[1]; Alexandra Arca Blanco, MD[1]; María Alonso, MD[2]; Javier De la Fuente, MD, PhD[2]; [1]Ribera Povisa Hospital, Vigo, Galicia, Spain; [2]Hospital Povisa, Vigo, Galicia, Spain

Session: P-24. COVID-19 Treatment

Background. Optimal dose of methylprednisolone in patients with moderate or severe COVID-19 is unclear. In our hospital, the use of 250-500 mg/day of methylprednisolone was frequent in the first wave of the pandemic. Lower dose were recommended in our protocol since September 2020. The aim was to evaluate the impact of methylprednisolone dose in the outcome of patients with moderate or severe COVID-19.

Methods. This is a retrospective and observational study. Inclusion criteria: SARS-CoV-2 infection diagnosed by PCR, admission to our hospital between March 2020 and February 2021, SatO2 < 94% or SatO2/FiO2 < 447. Two treatment groups were compared: patients treated with 0.5-1.5 mg/kg/day (group 1) and patients treated with more than 1.5 mg/kg/day (group 2). The primary outcome analyzed was orotracheal intubation (OTI) or death from any cause at 28 days after admission. Differences in demographic, clinical and laboratory characteristics between treatment groups were analyzed. Variables with P < 0.1 were included in a binary logistic regression model, calculating a propensity score for assigning each patient to group 1 treatment. Bivariate analysis was performed to identify variables associated with worst outcome. Finally, Cox regression was performed including treatment group, propensity score as covariate and all the variables with P< 0.05 in the bivariate analysis.

Results. 285 patients were included, 197 in group 1 and 88 in group 2. The median age was 73 years, 52,3% were male. Mortality or OTI at 28 days was 24,9%. There was a higher proportion of patients in group 1 with COPD (9,6% vs 1.1%, P< 0.01), dyspnea (60.4% vs 45.5%, P=0.01), sepsis (22.8% vs 13.6%, P=0.07). Patients in group 2 had more impaired consciousness (18.2% vs 8.6%, P=0.02). The median of lymphocytes count was lower in group 1 (900 vs 1025, P=0.01). There were no differences in the primary outcome between treatment groups (26.1% in the group 2 vs 24.4% in the group 1, P=0.7).

Conclusion. The use of high dose of methylprednisolone compared with intermediate dose is not associated with a better outcome in patients with moderate or severe COVID-19.

Disclosures. **All Authors**: No reported disclosures

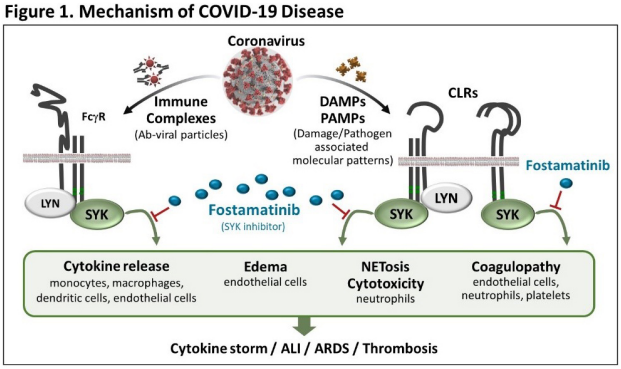
561. Phase 3 Trial of Fostamatinib for the Treatment of COVID-19: Repurposing an Immunomodulatory Drug Previously Approved for Immune Thrombocytopenia

Ziad Mallat, MD, PhD[1]; Suzana Margareth Lobo, MD, PhD[2]; Anuj Malik, MD, MS[3]; Sandra Tong, MD[4]; [1]University of Cambridge, Cambridge, UK; [2]Hospital De Base -FAMERP, São José do Rio Preto, Sao Paulo, Brazil; [3]Ascension St. John Medical Center, Tulsa, Oklahoma; [4]Rigel Pharmaceuticals, Inc., South San Francisco, CA

Session: P-24. COVID-19 Treatment

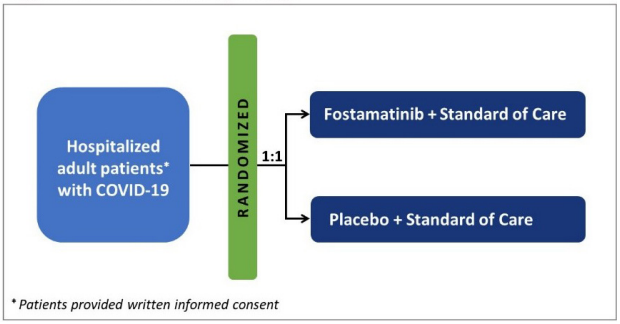
Background. Key pathologies in severe COVID-19 include immune cell activation, inflammatory cytokine release, and neutrophil extracellular trap release (NETosis), which are mediated by spleen tyrosine kinase (SYK) (Figure 1). Fostamatinib, an oral SYK inhibitor approved for chronic immune thrombocytopenia, has shown activity in vitro using plasma from patients with severe COVID-19, by abrogating the hyperimmune response triggered by anti-spike IgG;[1] inhibiting hyperactivation in platelets;[2] and blocking NETosis in neutrophils.[3] R406, active metabolite of fostamatinib, protected against LPS-induced acute lung injury and thrombosis in mice.[4,5] In clinical studies, fostamatinib reduced IL-6 in patients with rheumatoid arthritis.[6] Therefore, a phase 2 study (NCT04579393) evaluated fostamatinib vs. placebo plus standard of care (SOC) in 59 hospitalized COVID-19 patients (manuscript pending). We initiated a phase 3 clinical study (NCT04629703) of fostamatinib for the treatment of COVID-19.

Figure 1. Mechanism of COVID-19 Disease



Methods. A double-blind, randomized, placebo-controlled, adaptive design, multi-center, Phase 3 study (NCT04629703) is underway to evaluate the safety and efficacy of fostamatinib in 308 adult patients with COVID-19 (Figure 2). Hospitalized patients without respiratory failure (with or without supplemental oxygen) were included. Patients with ARDS or using extracorporeal membrane oxygenation (ECMO) were excluded. Patients will receive fostamatinib 150 mg BID or placebo for 14 days; both arms receive SOC. The primary outcome will be progression to severe/critical disease (worsening in clinical status score on the 8-point ordinal scale) within 29 days of the first dose of study drug. Fostamatinib is investigational for COVID-19.

Figure 2. Phase 3 Study Design



Results. Blinded update of trial in progress as of 28 April 2021. 12 patients have been randomized in North and South America. The clinical status score at Baseline was 5 (Hospitalized, requiring supplemental oxygen) in all 12 patients. Five patients had 8 adverse events (AE) (Fig 3). One AE (PE) was serious and is resolving. No deaths have been reported. At least two patients have been discharged (Day 5, Day 13) with continued dosing at home.

Figure 3. Patient Characteristics and Safety

Blinded Data	All Patients (n=12)
Mean age (years)	47.8 (range 30-72)
Sex (male)	8 (67%)
Race, ethnicity (white, Hispanic or Latino)	10 (83%)
Mean BMI	32.4 (range 20-42)
Adverse Events (AE)	5 (42%)
Constipation	2 (17%)
Upper abdominal pain	1 (8%)
Bacterial pneumonia	1 (8%)
Increased alanine aminotransferase	1 (8%)
Pain in extremity	1 (8%)
Insomnia	1 (8%)
Pulmonary embolism (PE)	1 (8%)