COVID-19 Evidence Accelerator Collaborative

Lab Meeting # 39

Thursday, August 19th, 2021, 3 - 4 pm ET

Call Summary

<u>**Overview of Lab Meeting 39**</u>

During Lab Meeting 39 of the COVID Therapeutics and Vaccines Accelerator we heard two presentations about using real world data to plan for distribution and track use of monoclonal antibodies (MAbs) to treat COVID. First, Dr. Brandon J. Webb of Intermountain Healthcare discussed how data was used to prioritize patients and select sites for infusion of MAbs for COVID in the state of Utah. Next, we heard from Dr. Ravindra Ganesh & Dr. Lindsey M. Philpot of the Mayo Clinic about how they utilized data from the COVID registry to identify patients eligible for MAbs and track outreach and outcomes data. The meeting closed with the data visualization of the week which shows the distribution of MAb infusion sites in states with two of the highest COVID infection rates.

<u>**MAb Therapy for Early COVID-19**</u>

Dr. Brandon J. Webb, Intermountain Healthcare

Efficacy and Safety of monoclonal antibodies (MAbs) for Early COVID

- Two trials studied the efficacy and safety of MAbs and lead to subsequent emergency use authorizations for two MAbs for COVID:
    - BLAZE-1 (Bamlanivimab)
        - 6.3% vs. 1.6% hospitalizations, RR .26 (NNT = 21.2)
        - High-risk strata: 7/48 (15%) vs. 4/95 (4%), RR .29 (NNT = 9.1)
        - 2.3% infusion reaction
    - SPIKE (Casirivimab/Imdevimab)
        - Medically attended visits: 6.5% vs. 2.8%
        - 72% relative reduction in high-risk strata
        - 1.5% infusion reaction
- Best when given early in symptom course (both trials enrolled within first 7 days of symptoms)

Questions about using MAbs

- **Safety and efficacy of MAbs in the real world:** How well do MAbs work in the real-world? Real-world safety profile and infusion experience? What is the ideal target population?
- **Capacity and logistical challenges of using MAbs:** What logistical limitations on infusion capacity exist? Are there behavioral barriers to delivery and equity? How do we deal with the gap between demand and capacity? Cost and cost-effectiveness? Scalability?
- Unique role in a hybrid healthcare/public health model

Logistical Challenges

- **Common barriers:** limited clinical resources for infusion, infection control issues, safety, infusion prep and time
- **Delivery Options & Unique Challenges:**
  - Infusion centers – limited access to these and infection control issues for oncology and autoimmune patients
  - Homecare – risk of anaphylaxis
  - Emergency departments (EDs) – not cost-effective and prohibitive surge volumes
  - Clinics and Urgent Care – reconstitution, volumes, infection control
  - Stand-up site – limited resources and staffing

Patient Selection & Identification

- *How to identify patients with the highest probability of benefiting from MAbs?*
- *Early* patient identification (recruitment within 7 days, emergency use authorization (EUA) gave 10-day window)
- High-risk patient selection
- Referrals versus proactive – identifying patients based on referral is inequitable because many times patients are not connected to referring provider (first point of contact is for test)
- Stewardship and coordination
- Leveraged screening platform from pragmatic HCQ trial – allowed us to identify patients where their test positive, using informatics addended clinical and demographic data which allowed identification of patients by age, comorbidities

Risk-Based Prioritization

- The EUA identified a broad patient population (about 27% of all positive cases) but the capacity to infuse all these patients was not available
- Prioritized infusions by risk because the number needed to treat (NNT) to prevent one hospitalization is lower among high-risk groups
- Able to prevent an equal number of hospitalizations with fewer infusions and less resource use
- Worked with the State of Utah Crisis Standards of Care Scarce Medications Committee to develop a tool for estimating the risk of hospitalization and mortality in ambulatory and ED patients with COVID
  - Informed thresholds for eligibility to help prioritize transfusions for highest-risk patients
  - Helped understand state's capacity to transfuse

Infusion Site Selection

- Strategic demographic placement (most of Utah's population is within a 60 min drive of an infusion center) based on case density, equity, and goal to preserve clinical access.
- Partnered with hospital-based infusion centers, urgent care centers, and emergency departments.
- Adjusted scheduling to avoid risk of non-COVID transfusion patients coming in contact with COVID patients receiving a transfusion.

MAb Squad: Stewardship, Access, & Equity

- Redeployed providers who worked to proactively to contact patients based on eligibility for transfusions, field referrals, discuss and triage care for patients, provide language and transportation services, coordinate with transfusion sites, etc.
- Focused on access and equity spotlighted by HHS.

Metrics and Data

- Reporting to HHS
- Drug usage and allocation
- Supply and demand matching to understand capacity to treat
- Recruitment efficiency
- Time to infusion
- Symptoms and time to symptom onset
- Social determinants of health
- Vaccine status
- Safety events
- Outcomes – ED visits, hospitalizations, mortality
- Subgroup effectiveness
- Value based care
- Post-acute COVID symptoms

Future Directions

- Impact of variants of concern
- Effect on long post-acute COVID symptoms
- Delivery efficiency

Data Handling for the Monoclonal Antibody (MATRX) Team

Dr. Ravindra Ganesh & Dr. Lindsey M. Philpot, Mayo Clinic

Using Reports to Harness the COVID Registry

- All patients testing positive for COVID within the Mayo System included in registry
- Used registry to populate reports on new positive COVID tests with multiple data fields
- Built & implemented several scoring systems:
- "Scores" were used identify patients in the registry who met the criteria in the EUA for MAbs for COVID:
  - Score was assigned based on factors such as age, hypertension, cardiovascular disease, chronic respiratory disease, diabetes, immune function, etc.
  - Scores adjusted based on expanded criteria in EUA
- Tracked patient outreach when a patients score made them "eligible" for MAb treatment
  - Tracked by county to understand where additional resources might be needed for outreach/infusions
- Tracked infusion data through Epic tool built to track EUA data

Pitfalls

- External testing
  - Support state of MN with outside referrals, difficult to incorporate these data
  - Requires manual access and entry of records
  - Does not populate the registry so some patients are lost/ become "invisible" to the system which makes it difficult to analyze data and outcomes
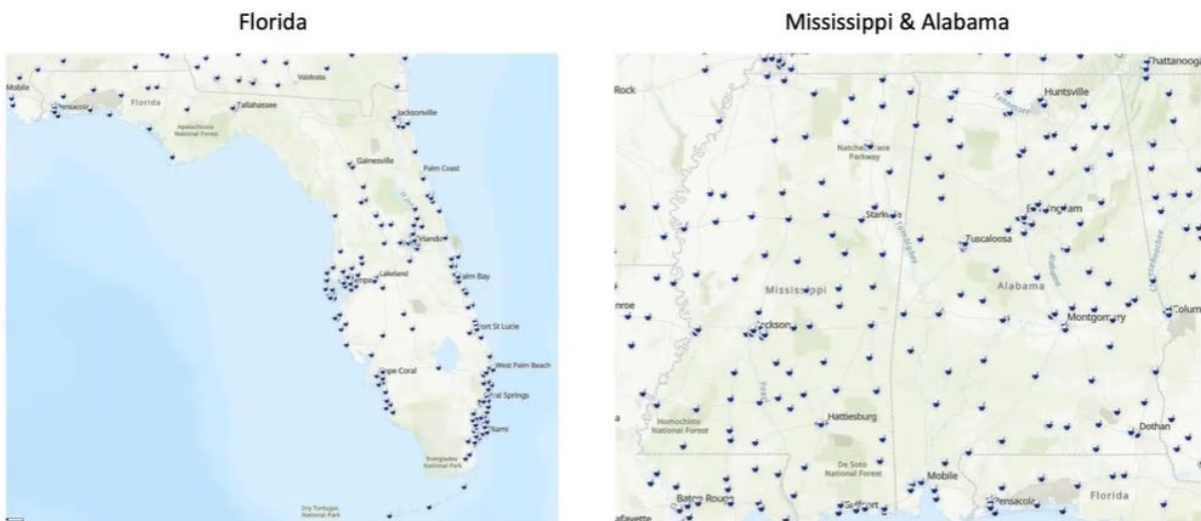
Assessing Outcomes

- Patient and clinical factors for conduction outcomes analyses
  - MAb status, MAb score – Epic MAb screening report
  - Symptom onset date – Epic Clinical Flowsheets
  - COVID testing date(s) and results – Labs
  - Mental health screening, primary language spoken, translation services, other demographic information – Patient provided information from patient registration
- Patient outcomes
  - Hospitalization, ED Visit, ICU Admission – Admission/ Discharge/ Transfer
  - Ventilator Use – Epic Clinical Flowsheets

<u>Data Visualization of the Week</u>

- Availability of MAbs in states with high COVID infection rates.

Availability of Antibody Treatments

Florida   Mississippi & Alabama

Source: HHS Protect Public Data Hub. Found at https://protect-public.hhs.gov/pages/therapeutics-distribution