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Implementing an Infusion Program at your Medical Center

Pearls and Pitfalls

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Disclosure

- No disclosures

Objective

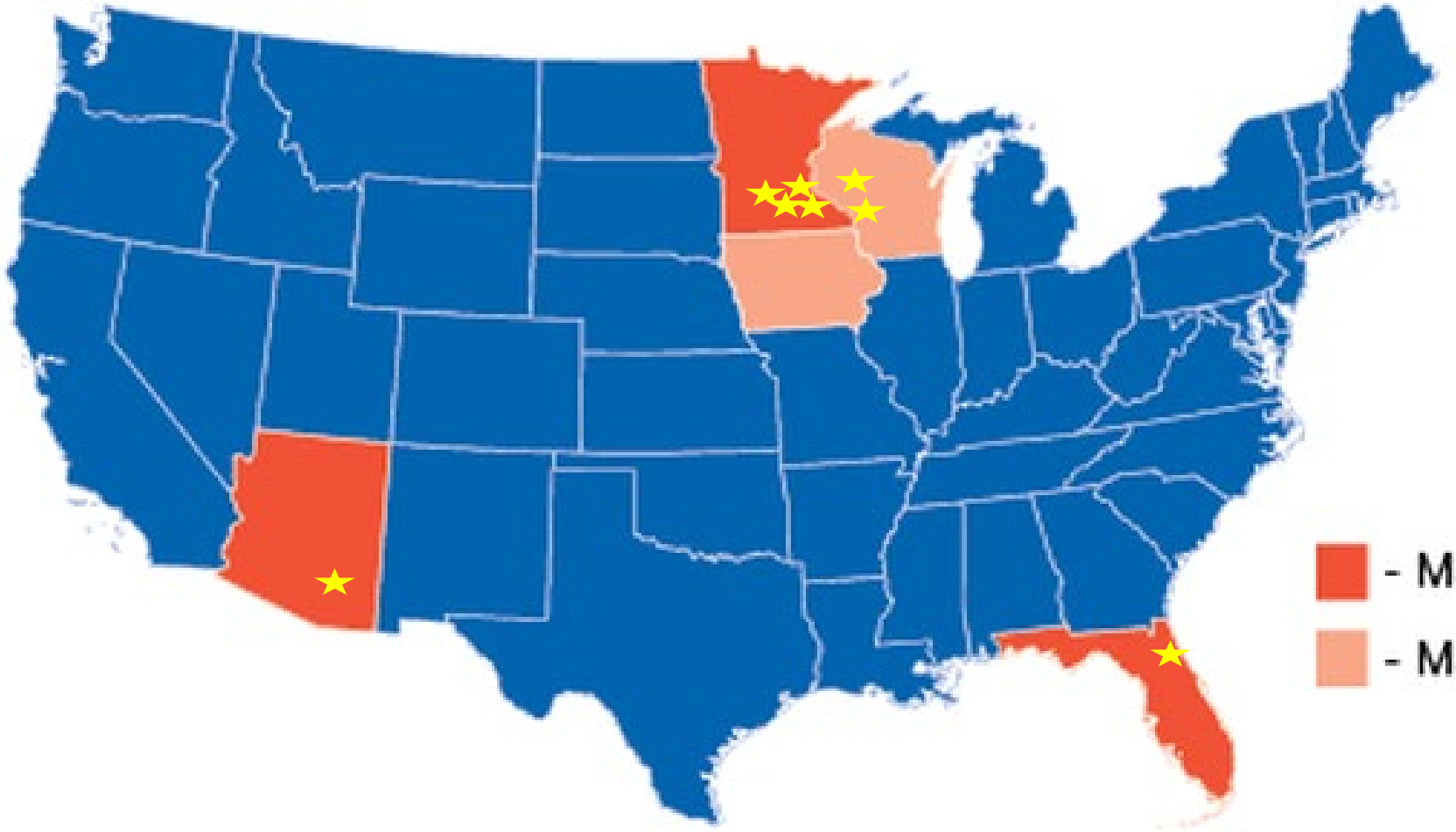
- To identify challenges to implementing a monoclonal antibody infusion program for a highly infectious disease.
- To share lessons learned and techniques used to overcome these challenges.

Our Program

- 8 regions across MN, WI, FL, AZ
  - 12 infusion centers
- >23,000 infusions
- Estimated risk reduction of 25%
  - Almost 6,000 admissions prevented

Dedicated Outpatient Covid-19 Therapy Centers

Rochester. Cannon Falls. Albert Lea. Mankato. Eau Claire. Barron.



La Crosse.

Phoenix.

Jacksonville.

- Main campus sites
- Mayo Clinic Health System sites

Razonable RR et al. Mayo Clinic Proceedings (In press)

Real-World Experience of Spike Monoclonal Antibodies

Challenges: Personnel / Staffing

Create the **MATRx** - Monoclonal Antibody Rx Team

- Multidisciplinary team of clinicians (Infectious Diseases, Internal Medicine, Family Medicine), CFCT, PCCT, ITC, nurses, pharmacists, desk operations, compliance, facilities, engineering, informatics and EHR specialists, medical ethics, legal, administrative operations, administration, many more!

SPECIAL ARTICLE

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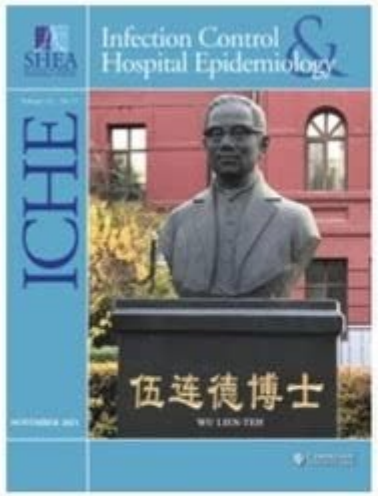
Check for updates

A Framework for Outpatient Infusion of Antispike Monoclonal Antibodies to High-Risk Patients with Mild-to-Moderate Coronavirus Disease-19: The Mayo Clinic Model

Razonable et al, *Mayo Clin Proc*,2021

IPAC was very involved in development



Infection Control & Hospital Epidemiology

Infection prevention and control considerations for safe outpatient monoclonal antibody infusions in patients with coronavirus disease 2019 (COVID-19)

Part of: SARS-CoV-2/COVID-19

Published online by Cambridge University Press: **12 March 2021**

Elena Beam, Molly J. Destro Borgen and Raymund R. Razonable

Show author details

Beam et al, *Infect Control Hosp Epidemiol*,2021

Early problem

- Nursing homes had sick COVID patients
- They did not have the capacity to perform infusions there
- There was also no way to transport these patients to our infusion center.
- These patients were at very high risk for admission and mortality

Solution: Mobile unit

BRIEF REPORT

Journal of the
American Geriatrics Society

A mobile unit overcomes the challenges to monoclonal antibody infusion for COVID-19 in skilled care facilities

Sidna Tulledge-Scheitel MD, MPH[1] | Sarah J. Bell MSN, MHA, RN[2] |
Jennifer J. Larsen MSN, RN, CRNI[2] | Dennis M. Bierle MD[3] |
Paul Takahashi MD[1] | Darcie E. Moehnke MAN, RN[2] |
Molly J. Destro Borgen MA[4] | Donna J. Springer APRN, CNS, MS[5] |
Karen J. Reinschmidt MS[6] | Lori J. Baumbach MBA[1] |
Jennifer A. Matoush APRN, CNS[2] | Alexander Heyliger PharmD, RPh[7] |
Sara N. Hanson DO, MPH[8] | Raymund R. Razonable MD[5] |
Ravindra Ganesh MBBS, MD[3]

Tulledge-Scheitel et al, *J Am Geriatr Soc*, 2021

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Free Press

Early on, patients were declining MAb

Original Research

Influence of Social and Cultural Factors on the Decision to Consent for Monoclonal Antibody Treatment among High-Risk Patients with Mild-Moderate COVID-19

Journal of Primary Care & Community Health
Volume 12: 1–8

DOI: 10.1177/21501327211019282
journals.sagepub.com/home/jpc
SAGE

Dennis M. Bierle[1], Ravindra Ganesh[1], Caroline G. Wilker[2], Sara N. Hanson[3], Darcie E. Moehnke[1], Tammy A. Jackson[4], Priya Ramar[1], Jordan K. Rosedahl[1], Lindsey M. Philpot[1*], and Raymund R. Razonable[1*]

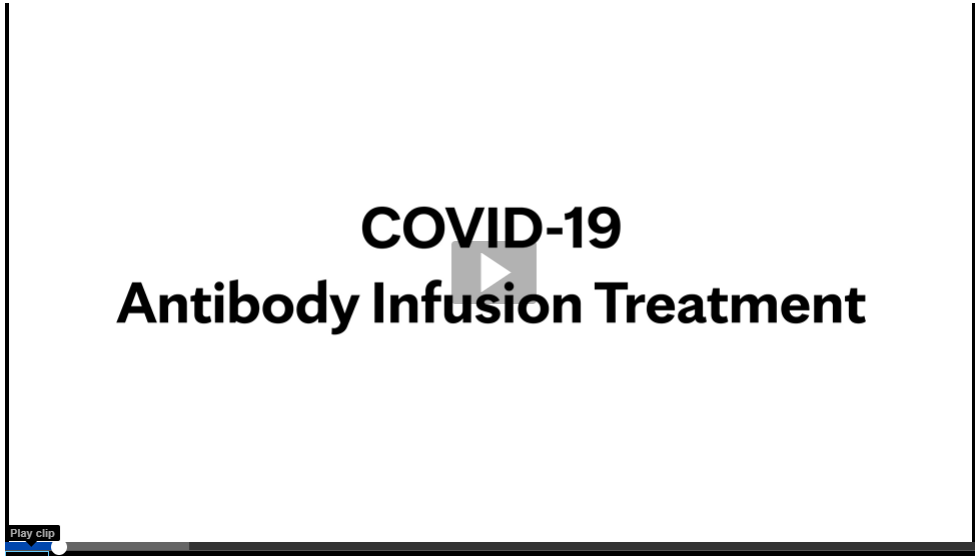
Bierle et al, *J Prim Care Community Health*,2021

Findings

- Patients more likely to decline MAb included
  - Non-White race
  - Non-English speaking
  - Hispanic
  - Lack of social support

Interventions

- Clear explanation of cost
- Video created by a MD and RN to explain the need for MAb



Monoclonal Antibody Screening Score

≥ 65 years of age (2)	≥ 55 years of age	≥ 12 years of age
• No additional requirements	• Cardiovascular Disease (2) • Hypertension (1) • COPD/other chronic respiratory disease (3)	• BMI ≥ 35 kg/m^2 (2) • Chronic Kidney Disease (3) • Diabetes (2) • Immunosuppressive disease or receiving immunosuppressive treatment (4)

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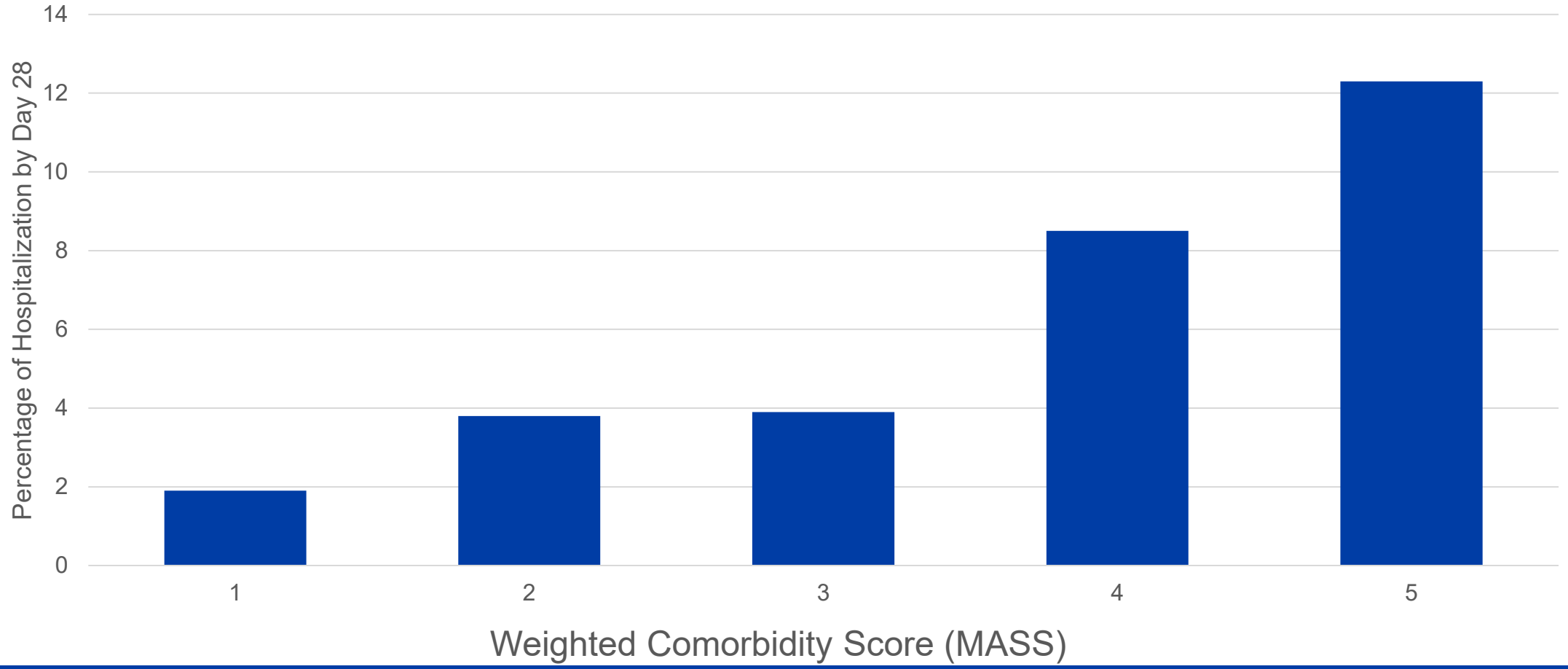
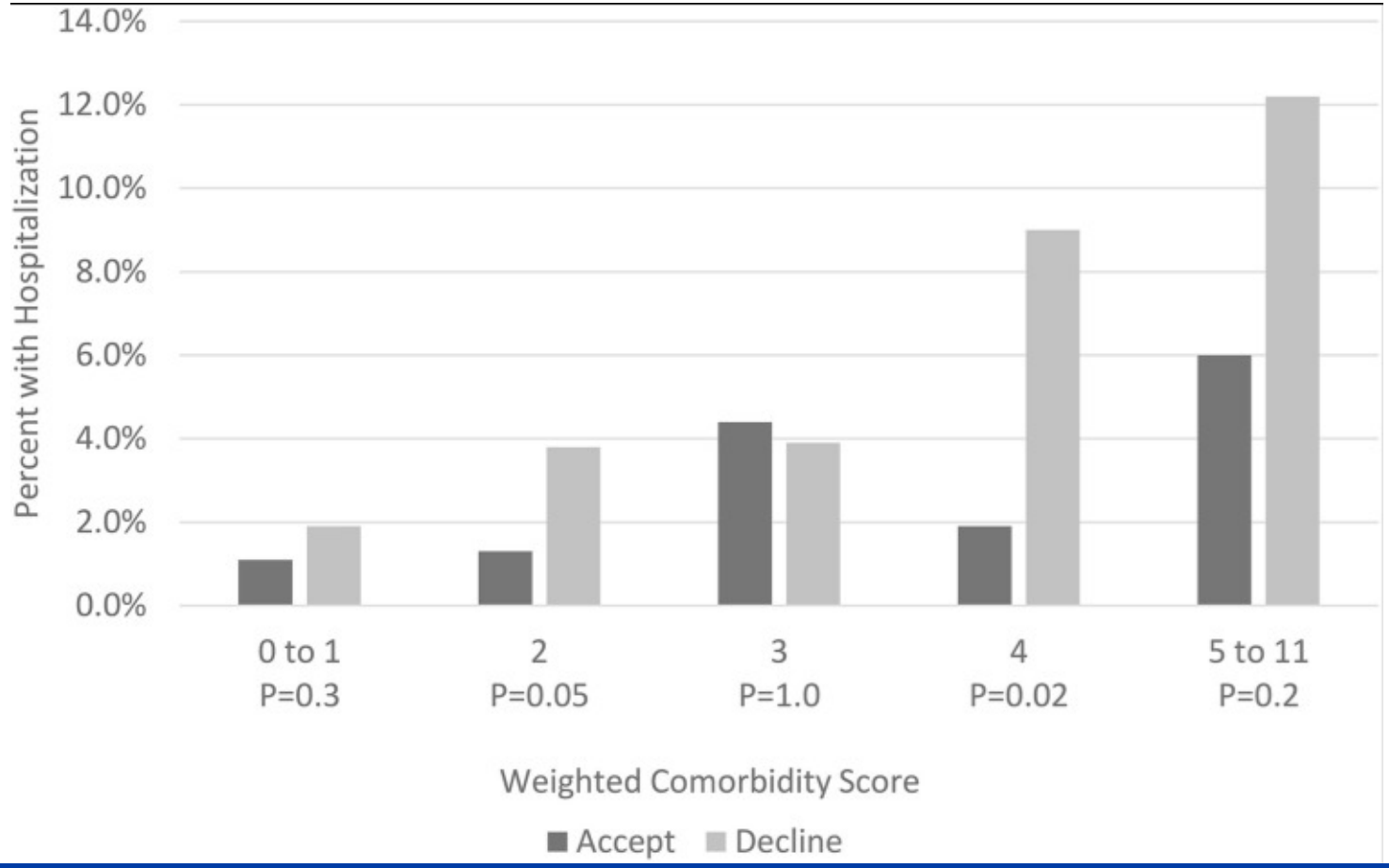
Hospitalization Rates per Monoclonal Antibody Selection Score in Untreated Patients (Declined Monoclonal Antibody Offer)



Early preliminary data: Mayo Clinic (unpublished)

1st publication of our MASS prediction tool



Bierle et al, *J Prim Care Community Health*,2021

Prioritizing MAb in times of scarcity

Mayo Clinic Proceedings
Monoclonal antibody allocation

Table 1. Demographics and clinical characteristics of 1141 patients with COVID-19 at Mayo Clinic in the Midwest, May and June 2021

Characteristics	Casirivimab-Imdevimab Treatment (n=132)	No Antibody Treatment (n=1009)	P value
Age, in years ± standard deviation	55.6 ± 15.9	44.8 ± 18.0	<0.0001
Male gender	50.8%	45.5%	0.25
Body Mass Index, in kg/m^2 ± standard deviation	34.3 ± 8.4	30.9 ± 7.2	<0.0001
Medical comorbidities			
Coronary Artery Disease	9.1%	6.0%	0.18
Congestive Heart Failure	7.6%	3.6%	0.0316
Chronic Kidney Disease	9.1%	5.0%	0.052
Diabetes	21.2%	9.9%	0.0002
Hypertension	45.5%	18.6%	<0.0001
Organ Transplant	3.0%	0.3%	0.0023
Pulmonary disease	15.9%	9.6%	0.0272
Allocation Criteria			
CAST, score ± standard deviation[a,b]	3.1 ± 1.9	1.8 ± 1.8	p<0.0001
MASS, score ± standard deviation[a,c]	3.1 ± 2.6	1.3 ± 2.2	p<0.0001

Clinical Prioritization of Anti-Spike Monoclonal Antibody Treatment of Mild to Moderate COVID-19

Raymund R. Razonable, M.D., Ravindra Ganesh, MBBS, M.D., Dennis M. Bierle, M.D.

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Table 2. Crude all-cause hospitalization rates, by day 28, among 1141 patients with COVID-19 based on clinical eligibility for anti-spike monoclonal antibody therapy as assessed by the original (MASS) and expanded (CAST) FDA EUA criteria, May and June 2021

Score	CAST[a,b]		MASS[a,c]	
	No Treatment	Casirivimab-Imdevimab	No Treatment	Casirivimab-Imdevimab
1	6.4%	3.2%	10.6%	0
2	12.9%	0	13.5%	5.9%
3	13.5%	6.9%	25.3%	3.7%
4	31.0%	4.8%	22.9%	0
5+	46.9%	12.0%	40.7%	16.7%

[a]CAST, COVID-19 Antibody Screening Tool; MASS, Monoclonal Antibody Screening Score

Razonable et al, *Mayo Clin Proc*, 2021

MASS validation

- Validated by MDH
  - AUROC 0.82
  - Did not vary significantly across race
  - Does not account for pregnancy
    - Revised MASS being built to add pregnancy (will get 2 points)

Epic Report

MC HP COVID-19 RST/SEMN/SWMN Monoclonal Antibody Treatment Candidates Report [116830074] as of

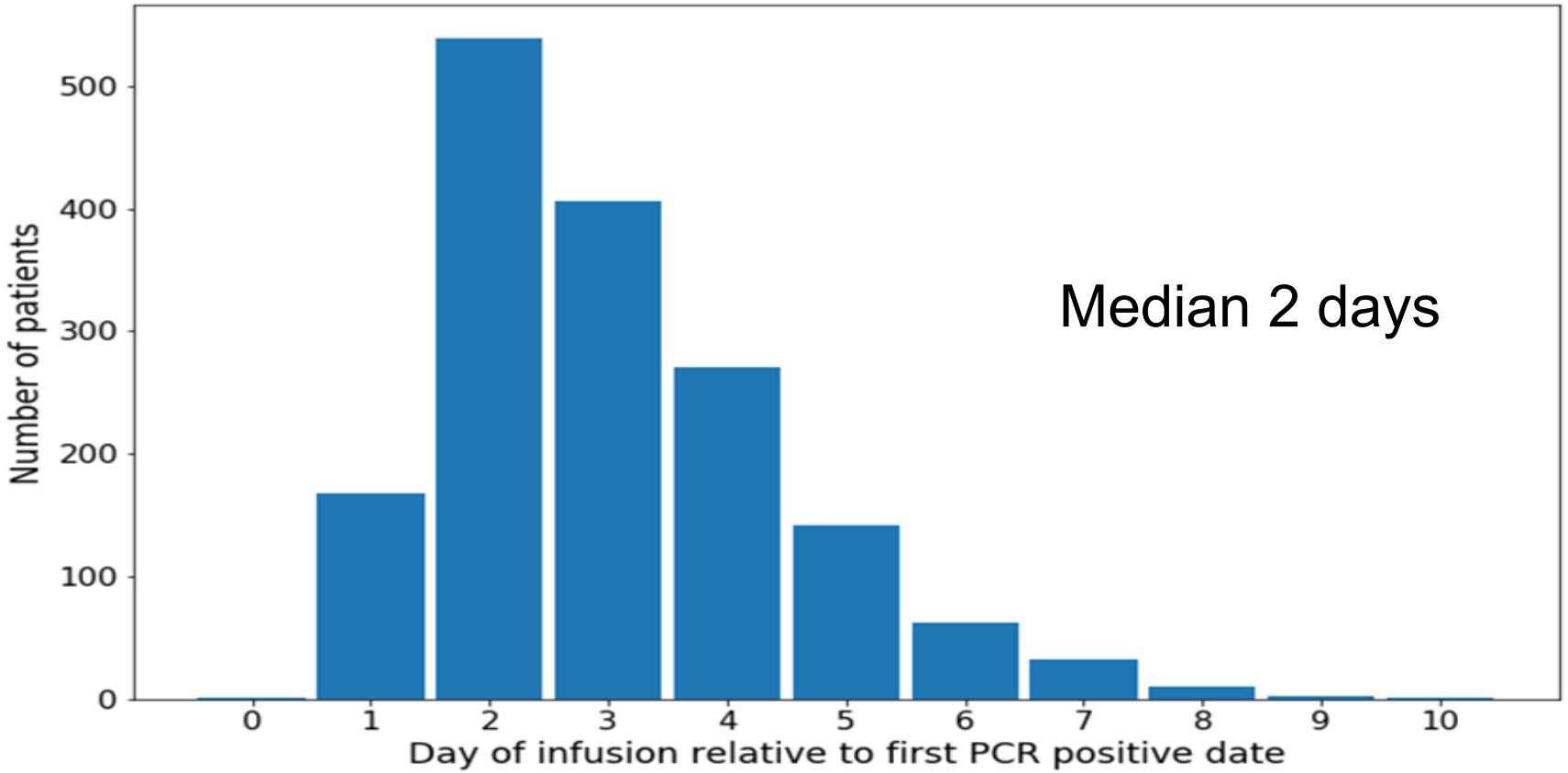
Filters | Options | Re-run Report | Chart | Synopsis | Encounter | Communication | Orders Only | Track Pt Outreach | Episodes of Care | Care Teams | Send Patients Message | Bulk Actions | Registry Prog Forms | Isolations and Infections

Detail | Outreach Tracking Summary

No Tracking Topic | Select All

MRN	Patient	Age	Sex	First Pos COVID Te	Rolling 1st Pos Dat	Active COVID Infection?	County	State	Pat Geo Class	MASS Score	COVID-19	Sx Onset	Bamlanivimab Order Da	Regeneron Order Dt	Last Outrch Dt	Last Outrch Topic
		67 y.o.	Female			Yes	GOODHUE	MN	RST MCHS SE MN	10	5					
		70 y.o.	Female			Yes	FREEBORN	MN	RST MCHS SE MN	4	2					
		59 y.o.	Male			Yes	WASECA	MN	RST MCHS SW MN	4	2					
		73 y.o.	Female			Yes	DAKOTA	MN	RST MCHS SE MN	4	3					
		75 y.o.	Female			Yes	STEELE	MN	RST MCHS SE MN	3	3					
		60 y.o.	Female			Yes	STEELE	MN	RST MCHS SE MN	2	2					
		58 y.o.	Female			Yes	WASECA	MN	RST MCHS SW MN	1	0					
		57 y.o.	Male			Yes	SCOTT	MN	RST MCHS SE MN	1	3					
		50 y.o.	Male			Yes	MOWER	MN	RST MCHS SE MN	1	1					
		33 y.o.	Female			Yes	WASECA	MN	RST MCHS SW MN	1	0					
		57 y.o.	Male			Yes	STEELE	MN	RST MCHS SE MN	1	2					
		35 y.o.	Female			Yes	MOWER	MN	RST MCHS SE MN	1	1					
		46 y.o.	Female			Yes	GOODHUE	MN	RST MCHS SE MN	1	0					

Infusion date relative to PCR date



CONCLUSIONS

- Successful programs require a multidisciplinary and engaged team.
- Constant re-evaluation of program is needed
  - Outcomes data
  - Patient engagement
  - Supply/demand assessment
- Ability to rapidly adapt the process
  - Scarcity
  - Resistance
  - Staffing

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THANK YOU

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