



## BRIEF REPORT

# Patient Characteristics and Outcomes among Two COVID-19 Therapeutics Registries in Maine

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## Abstract

This study compared protocolized use of investigational COVID-19 therapies and determined trends among risk factors, disease severity, and outcomes in two patient registries representing 75% of hospitalizations state-wide. Establishing a local pandemic registry provides greater insight into pattern of disease, patient care, and safety of therapeutics during the pandemic.

## Keywords

Coronavirus, Risk factors, Hospitalization, Epidemiology, Pandemic

## Introduction

As of August 2022, the COVID-19 pandemic has been responsible for more than 92.8 million illnesses and 1,032,560 deaths in the United States [1]. The case fatality rate ranges from less than 0.1% to greater than 40%, depending on risk factors (e.g., age, comorbidities) and country specific factors (e.g., testing strategies, health care resources, caseloads) [2-5]. Many promising therapeutic options have been identified throughout the pandemic to treat and to abate the pathophysiologic response to SARS-CoV-2 [4,5]. Given the high mortality in certain risk groups and the emergent nature of the pandemic, off-label use of FDA approved medications with potential efficacy has been employed in the absence of randomized controlled trials to provide confirmatory safety and efficacy data. To this end, Northern Light

Health (NLH), a health system serving communities throughout central, eastern, and northern Maine and Maine Medical Center (MMC) serving communities in southern Maine and northern New Hampshire created prospective multi-center registries to monitor for safety indicators and guide local decision making.

## Materials and Methods

The NLH and MMC registries capture patients with laboratory confirmed SARS-CoV-2 and those with suspected SARS-CoV-2 from emergency and inpatient facilities. Inclusion criteria included patients aged over 18-years-old, laboratory-confirmed SARS-CoV-2 or suspected SARS-CoV-2, CT confirmed lower respiratory disease consistent with SARS-CoV-2 (unilateral or bilateral diffuse or patchy ground glass opacities or dense consolidations), or symptoms consistent with SARS-CoV-2 including cough, fever, dyspnea, and gastrointestinal issues. The registries captured the following elements via retrospective review of qualified subjects: demographics, comorbidities, age, suspected or confirmed COVID-19 diagnosis, labs and clinical status, date of admission, date of discharge, inpatient therapies, and outcomes. Disease severity was defined using the Infectious Disease Society of America categories [6].

These registries were approved by their respective Institutional Review Boards. The study included patients admitted between March 2020 and July 2020. This date range was selected to align with availability of data from



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the MMC registry, which ceased data collection at the end of July 2020. To best describe the patient populations of each registry, descriptive statistics were calculated. Medians and interquartile range (IQR) for continuous variables and proportions for categorical variables were obtained. Statistical analysis was performed using SPSS v.25. Future manuscripts will evaluate the remaining significant amount of data collected the NLH COVID-19 Patient Registry, which houses data through January 2022.

## Results

Table 1 summarizes demographics in each registry.

Patient demographics and outcomes were very similar between both the sites, although there were more African American patients in the MMC registry (11% vs. 1.7%, respectively). While the average BMI matches populations estimates for the area, there are higher proportions of COVID-19 patients in both registries with a history of heart disease, diabetes, chronic obstructive pulmonary disease (COPD) [7]. Overall, the average age was 66 years, and the average length of stay was 7 days. There were 34 deaths (12%) by day 28 (Table 2). Table 3 presents the inpatient therapies.

**Table 1:** NLH and MMC COVID-19 patient registry demographics, comorbidities, severity and baseline status.

	<b>NLH n = 60</b>	<b>MMC n = 228</b>	<b>Total n = 288</b>
<b>Age, median (IQR)</b>	65.5 (54 -81)	66.5 (52-80)	66.0 (52-80)
<b>Male, n (%)</b>	27 (45)	120 (53)	147 (51)
<b>Race, n (%)</b>			
White	48 (80)	183 (80)	231 (80)
Black or African American	6 (10)	26 (11)	32 (11)
Asian	3 (5)	6 (3)	9 (3)
Other	3 (5)	12 (5)	15 (5)
Unknown	0 (0)	1 (0)	1 (0)
<b>BMI, median (IQR)</b>	28.5 (25-34)	29.5 (26 -35)	29.5 (26 -35)
Missing data	2 (3)	8 (4)	10 (3)
< 25	14 (23)	50 (22)	64 (22)
25-29.9	17 (28)	69 (30)	86 (30)
30-34.9	13 (22)	46 (20)	59 (20)
35-39.9	6 (10)	27 (12)	33 (11)
40+	8 (13)	28 (12)	36 (13)
<b>Comorbidities, n (%)</b>			
Atrial fibrillation	7 (12)	20 (9)	27 (9)
Other arrhythmias	7 (12)	26 (11)	33 (11)
Chronic heart failure	5 (8)	25 (11)	30 (10)
COPD/Asthma	11 (18)	42 (18)	53 (18)
Diabetes	18 (30)	65 (29)	83 (29)
Hypertension	32 (53)	105 (46)	137 (48)
On ACE/ARB outpatient	22 (37)	57 (25)	79 (27)
<b>Severity, n (%)</b>			
IDSAs Mild-Moderate	8 (13)	64 (28)	72 (25)
IDSAs Severe	43 (72)	150 (66)	193 (67)
IDSAs Critical	9 (15)	14 (6)	23 (8)
<b>Baseline Status, n (%)</b>			
Died w/in 24 hours	0 (0)	1 (0)	1 (0)
Mechanical ventilation	8 (13)	14 (6)	22 (8)
High-flow nasal cannula	1 (2)	7 (3)	8 (3)
Low-flow oxygen	31 (52)	96 (42)	127 (44)
Room air	20 (33)	106 (46)	126 (44)
Discharged w/in 24 hours	0 (0)	4 (2)	4 (1)

**Note:** NLH: Northern Light Health; MMC: Maine Medical Center; IQR: Interquartile Range; BMI: Body Mass Index; COPD: Chronic Obstructive Pulmonary Disease; ACE: Angiotensin-Converting Enzyme; ARB: Angiotensin Receptor Blocker; IDSA: Infectious Diseases Society of America

**Table 2:** NLH and MMC COVID-19 patient registries outcomes.

Values	NL n = 60	MMC n = 228	Total n = 288
LOS	7 (5-12.25)	7 (4-13.25)	7 (4-13)
<b>Day 7</b>			
Deceased	8 (13)	15 (7)	23 (8)
Mechanical Vent	7 (12)	28 (12)	35 (12)
Hospitalized	25 (42)	75 (33)	100 (35)
Discharged	21 (35)	110 (48)	131 (45)
<b>Day 14</b>			
Deceased	9 (15)	21 (9)	30 (10)
Mechanical Vent	4 (7)	19 (8)	23 (8)
Hospitalized	13 (22)	33 (14)	46 (16)
Discharged	34 (57)	155 (68)	189 (66)
<b>Day 28</b>			
Deceased	11 (18)	23 (10)	34 (12)
Mechanical Vent	0 (0)	6 (3)	6 (2)
Hospitalized	7 (12)	21 (9)	28 (10)
Discharged	42 (70)	178 (78)	220 (76)

**Table 3:** NLH and MMC COVID-19 patient registries inpatient therapies.

Therapy, n (%)	NLH n = 60	MaineMed n = 228	Total n = 288
Antibiotics	45 (75)	139 (61)	184 (64)
Systemic steroids	22 (37)	8 (4)	30 (10)
NSAIDs	7 (12)	11 (5)	18 (6)
ACE/ARB inpatient	11 (18)	3 (1)	14 (5)
Hydroxychloroquine	8 (13)	50 (22)	58 (20)
Convalescent plasma	8 (13)	9 (4)	17 (6)
Tocilizumab	1 (2)	14 (6)	15 (5)
Remdesivir	22 (37)	12 (5)	34 (12)

**Note:** NLH: Northern Light Health; MMC: Maine Medical Center; NSAIDs: Non-Steroidal Anti-Inflammatory Drugs; ACE: Angiotensin-Converting Enzyme; ARB: Angiotensin Receptor Blocker

## Discussion

Use of off-label and investigational therapies in a novel disease, and outside of a controlled clinical trial, presents an ethical dilemma. Both patients and clinicians desire to receive/provide potentially beneficial therapies, yet use outside of clinical trials negates the ability to determine true safety and efficacy. Improvements are often attributed to the drug, while worsening is attributed to the disease [8,9]. This leaves clinicians and the public no better informed.

Selection bias may be present in these datasets. Patients must survive to COVID test results; potentially selecting for less severely ill patients. Misclassification bias may also be present, as respiratory status may be dependent on availability of equipment at time of exposure and not be representative of disease severity. The goal of this study was to augment judicious use of therapies lacking supportive clinical information and ensure patient safety does not suffer. By prospectively capturing use and employing pre-

specified interim analysis of safety indicators, we will be better equipped to identify and respond to concerning safety trends and reduce exposures in our most vulnerable populations. The data from this prospective database will further be maintained for comparative retrospective analysis at a future date.

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## Conflicts of Interest and Source of Funding

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## Author Contributions

All authors designed the study. KM, AK, JT, and KA contributed to research implementation and data analysis. All authors contributed to the interpretation of data and final version of the manuscript.

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