Exhibit 1

THE LANCET

High Mortality Rates Among Mechanically Ventilated COVID Patients Treated in New York Public Hospitals

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Summary

Background- The mortality rates are unknown for mechanically ventilated patients with SARS-CoV-2 ("COVID") infections treated in New York State public hospitals. New York State and New York City have not made those data accessible. This paper now provides them.

Methods- Retrospective cohort study of COVID patients exposed to mechanical ventilation by any of the 11 New York public hospitals versus the 239 other non-public New York hospitals during 2020, which was the first year that the COVID pandemic became known to the public. The primary outcome variable was mortality (total and per 100) among mechanically ventilated COVID patients treated in one of the 11 New York public hospitals.

Findings- During three-months early in the COVID outbreak (i.e., March, April, and May of 2020), within the 11 public hospitals in New York, patients diagnosed with COVID and placed on mechanical ventilation died before being discharged from the ICU at mortality rates of at least 2-times greater than the months before and after those three months (i.e., in March- 257/291, or 88% mortality, in April- 1286/1569, or 82% mortality, and in May- 281/498, or 56% mortality, with surrounding-month mortality rates averaging only 24% mortality for ventilated patients). Annually, the all-cause mortality for hospital deaths of the 250 private and public hospitals in New York State, for the year 2020, totaled 81,047, which was a year-over-year increase of 31% in mortality. In contrast, the all-cause hospital deaths for just the 11 New York State public hospitals totaled 7,604, for a year-over-year increase of 81% in mortality. Most ventilator-associated deaths occurred in patients over age 50 (86%), were non-white (83%, Black, Asian, Hispanic, Other), and males outnumbered females by over 2 times.

Interpretation- The mortality rate for mechanically ventilated COVID patients treated by one of the 11 New York public hospitals spiked in March, April, and May of 2020, then dropped sharply. Changes in ventilator management are a possible explanation for this aberrant rise and fall. If the COVID infections alone caused the worse outcomes among the ventilated, then one might expect to see overall hospital admissions to have increased, which was not the case. The sharp drop in deaths is also inconsistent with the increasing spread of COVID at the time. Moreover, nurse whistleblower accounts implicated the public hospital ventilator management protocols. Even assuming that human error was not the cause of the high death rates, the use of mechanical ventilation for the COVID infected population should be critically analyzed compared to other means of oxygenation available as alternatives, such as nasal canula oxygen, extracorporeal membrane oxygenation (ECMO), and red blood cell transfusion.

Funding- These data were exclusively obtained by the authors from the New York City Health + Hospitals after a Freedom of Information Law request was made. A similar records request was made of the New York State Department of Health and is still being challenged in court. The legal work was provided *pro bono* by author Dellaportas. The time spent preparing this paper was donated by author Greer.

Introduction

The SARS-CoV-2 ("COVID") outbreak became recognized as an outbreak in the United States around January of 2020. Having started on the West Coast (i.e., Washington State[1,2]) in January of 2020, the virus rapidly spread to the East Coast in New York. However, rather than the virus spreading evenly, New York greatly exceeded every other state in infections, comprising 30% of the national cases by April.[3]

In April of 2020, a medical report was published[4], along with social media accounts by nurses acting as whistleblowers[5,6], of high mortality rates among the mechanically ventilated COVID patients. Due to the novelty of COVID, it was unknown whether the high mortality rates were due to the virulence of the novel virus or other factors, (e.g., unique vulnerabilities of the urban New York City patient demographic, human error, or a multitude of those factors). The New York State and New York City agencies in possession of the patient data had not released them until now.

Methods

Study design and participants

The New York Statewide Planning and Research Cooperative System (SPARCS) does not detail mortality rates of mechanically ventilated COVID patients or give hospital-by-hospital death data. Therefore, authors Greer and Dellaportas filed Freedom of Information Law (FOIL) requests from the New York Department of Health regarding ventilator data. The requests were mostly stonewalled. An official lawsuit was filed and that case is still underway.[7]

Meanwhile, the same documents and data were requested via a New York City Health and Hospitals FOIL. Unlike New York State, that city agency did provide the data that are published here.

Procedures

New York City Health and Hospitals Corporation provided Microsoft Excel spreadsheets with data from the 11 New York public hospitals controlled by Governor Andrew Cuomo at the time. Those data included yearly total number of deaths from 2016 to 2022. Also, monthly data from 2020 and 2022 on ventilator use, death, and discharge-alive were provided in aggregate for the entire HHC hospital system, but not by individual hospitals. Data on the number of patients receiving antiviral therapies, by each hospital, were also provided. "Monoclonal antibody", "convalescent plasma", and "remdesivir" were tracked.

In addition to data from the city agency, The New York State Health Department did provide some data as well. The total number of deaths by individual hospital from 2016 through 2022, for all of

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the 250 hospitals tracked in the state, were provided. No data on individual patient health status or demographics were provided. The causes of death were not provided either.

We examined the number of ventilator patients, deaths among ventilator patients, and the mortality rate of ventilator patients (expressed as deaths per 100 patients on ventilators) by age group, sex, and race/ethnicity.

Outcomes

We calculated the total number and rate of COVID-diagnosed ventilator deaths (expressed as deaths per 100 admissions) from January 2020 through December 2022. The annual number of all-cause deaths in New York Public Hospitals was compared to non-Public New York Hospitals for 2016 to 2020.

Statistical analysis

To compare changes in deaths in public sector hospitals between 2019 and 2020, a chi-square test was performed. The number of deaths by year between 2020 and 2022 was calculated for each of the public hospitals. Mortality rate ratios were examined using Poisson regression with a log-link in SAS Version 9.3. We also calculated total deaths and ventilator deaths per admissions for 2020.

Results

Table 1 shows demographic characteristics of patients on ventilators and deaths on ventilators in March, April, and May 2020. Patients over age 50 accounted for the majority of ventilator patients and deaths. Mortality rates for these patients were significantly elevated compared to ventilator patients less than 18 to 29 years old. Males also accounted for the majority of ventilator patients and deaths. However, mortality rates were not significantly different between males and females. Finally, non-White patients account for over 80% of ventilator patients and deaths, but mortality rates were not significantly different according to race, with the exception of Hispanic patients having a lower mortality rate.

Table 1: Demographics of Ventilated Patients in 11 New York Public Hospitals							
Age group	n (deaths)	% (deaths)	n (on ventilator)	% (on ventilator)	Deaths per 100	Mortality Rate Ratio (95% CI)	P-value
Age < 18 to 29 (ref)	27	1.4	69	2.5	39.1		
Ages 30-49	250	12.6	453	16.3	55.2	1.41 (0.95, 2.10)	0.0896
Ages 50-64	648	32.6	950	34.3	68.2	1.74 (1.19, 2.56)	0.0047
Age 65+	1064	53.5	1301	46.9	81.8	2.09 (1.43, 3.06)	0.0002
Total	1989	100.0	2773	100.0	71.7		
Gender							
Female (ref)	651	32.7	925	33.4	70.4		
Male	1338	67.3	1848	66.6	72.4	1.03 (0.94, 1.13)	0.5529
Total	1989	100.0	2773	100.0	71.7		
Race/ethnicity							
White (ref)	191	9.6	255	9.2	74.9		
Non-white	1655	83.2	2333	84.1	70.9	0.95 (0.82, 1.10)	0.4768
Asian	146	7.3	195	7.0	74.9	1.00 (0.81, 1.24)	0.9971
Black	536	26.9	745	26.9	71.9	0.96 (0.81, 1.13)	0.6328
Hispanic	210	10.6	419	15.1	50.1	0.67 (0.55, 0.81)	<0.0001
Other	763	38.4	974	35.1	78.3	1.05 (0.89, 1.23)	0.5795
Missing	143	7.2	185	6.7	77.3	1.03 (0.83, 1.28)	0.7759
Total	1989	100.0	2773	100.0	71.7		

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Figure 1 shows the total number of COVID-positive ventilator deaths increased rapidly in early 2020, reaching a peak of 1,286 deaths in April of 2020, before rapidly falling. Ventilator deaths began increasing again in late 2020 with a second peak of 183 deaths in February 2021, albeit far less in absolute number than April. Ventilator deaths again began to increase in late 2021 peaking at 233 deaths in January 2022.

Figure 1

Figure 1. Total COVID Ventilator Deaths for 11 New York Public Hospitals
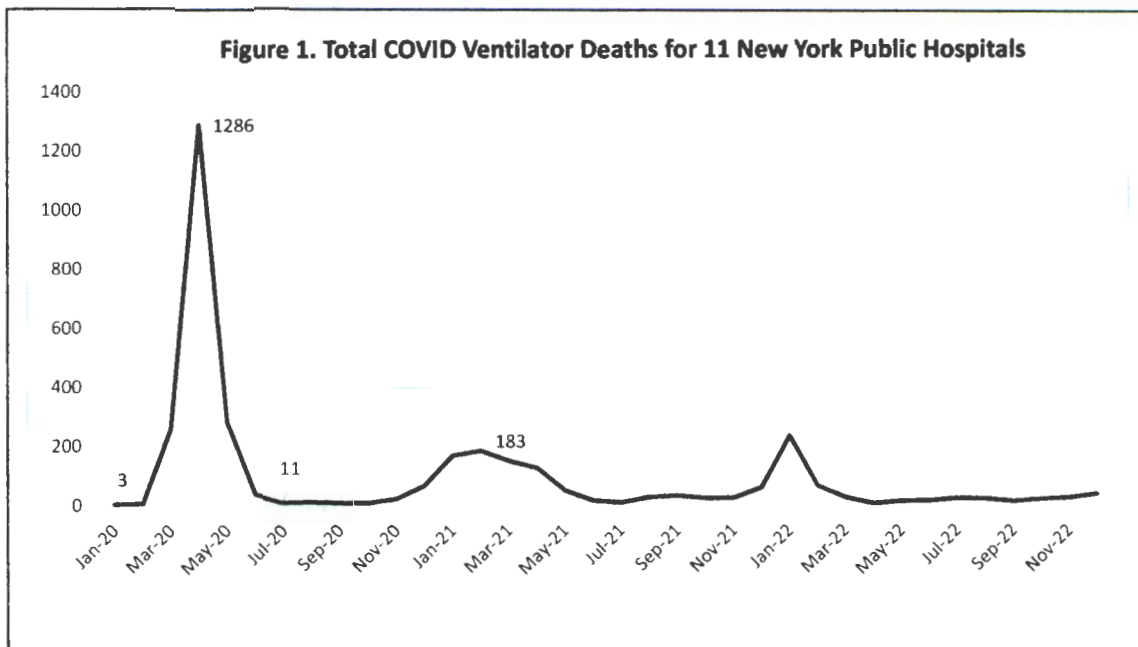
Figure 2 shows when deaths rates per 100 ventilated patients. A more complicated pattern than Figure 1 emerges. Although the peaks observed for the ventilated deaths per 100 ventilated patients are similar temporarily to the peaks observed for total deaths (March 2020: 88, January 2021: 78; December 21: 71), unlike with the total deaths in Figure 1, the magnitude of these death rates peaks were similar throughout the period considered. For the total ventilator death graphs, the second and third peaks were much lower than the initial peak in early 2020. Additionally several 'sub-peaks' of death rates are noted in September 2020, May 2022, and December 2022.

Figure 2

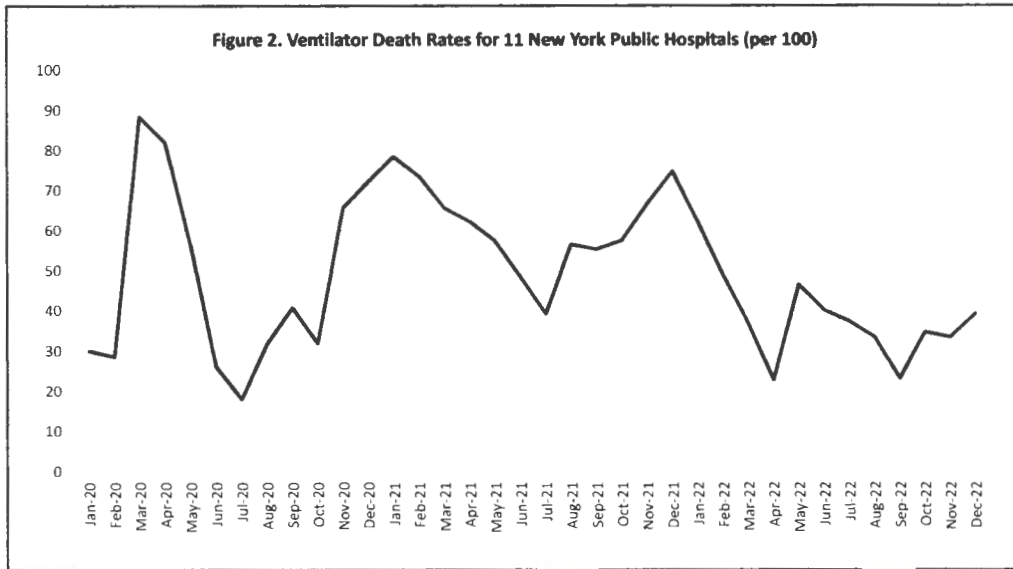Figure 2. Ventilator Death Rates for 11 New York Public Hospitals (per 100)

Figures 3 shows total all-cause mortality (i.e., not death rates) for the 11 New York public hospitals. The portion of deaths from ventilated COVID patients, from 2020 to 2022, is detailed (white-hash sections of bars) for perspective as to the contribution to total deaths.

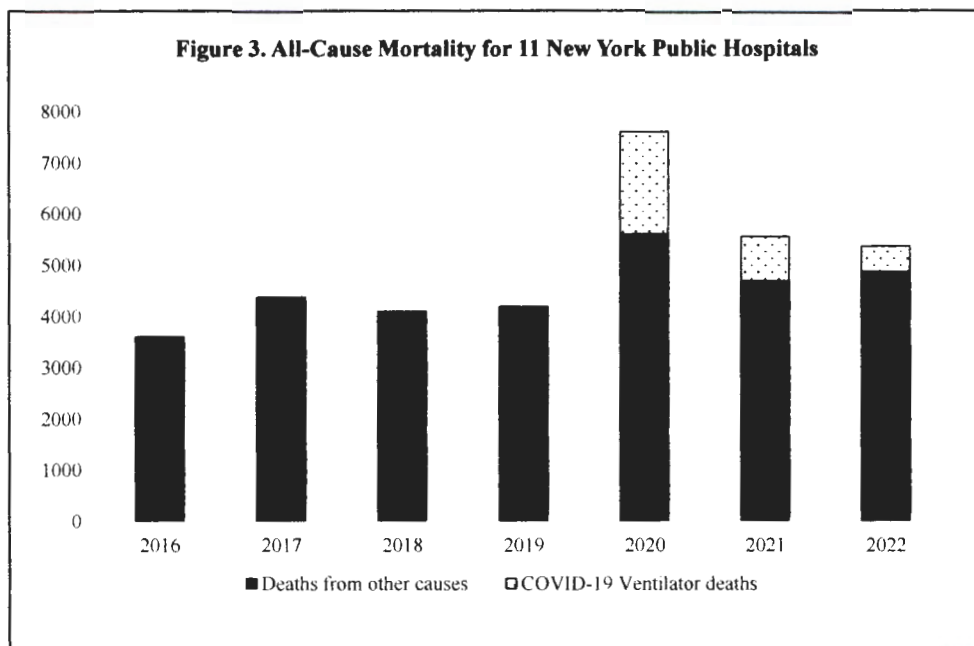Figure 3. All-Cause Mortality for 11 New York Public Hospitals

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Figure 4 compares the year-over-year percentage increases in death between the public and nonpublic hospitals. While the absolute number of deaths is much higher in the non-public hospitals due to there being many more non-public hospitals (i.e., 239 versus only 11), the y-o-y percentage increase in public hospitals was much greater than the increase in non-public hospitals (81.3% vs 27.3 %, p<0.0001).

Figure 4

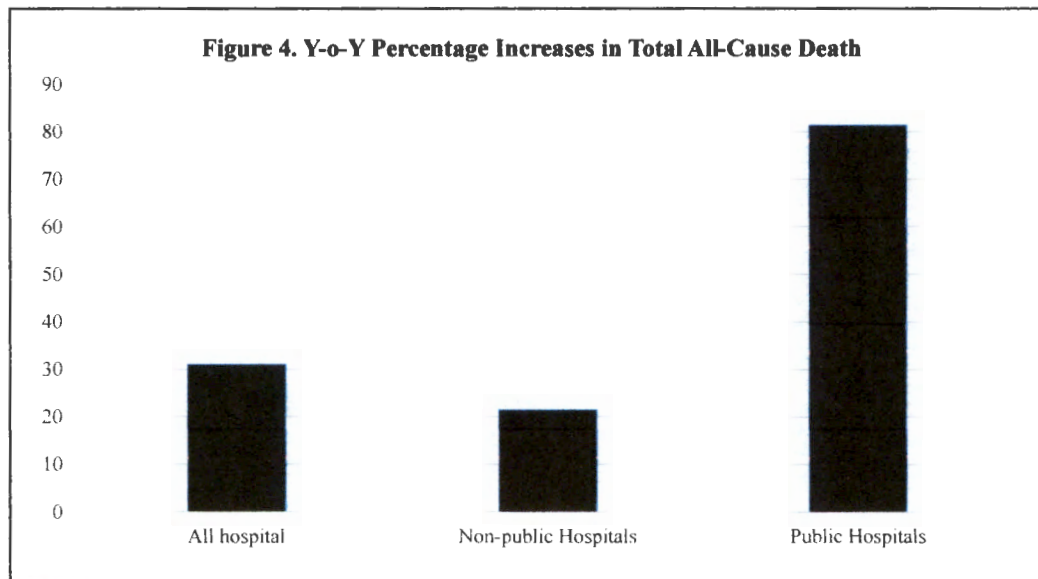Figure 4. Y-o-Y Percentage Increases in Total All-Cause Death

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Figure 5 shows all-cause mortality for each of the 11 New York public hospitals by year (from 2020 through 2022). The highest numbers of deaths were observed, as expected, in the largest institutions of Coney Island Hospital Center, Elmhurst Hospital Center, and Jacobi Medical Center. All hospitals had fewer deaths in 2021 compared to 2020, but three hospitals had more deaths in 2022 compared to 2021: Harlem Hospital Center, Elmhurst Hospital Center, Queens Hospital Center

Figure 5

Figure 5. All-Cause Mortality of Each of the 11 New York Public Hospitals

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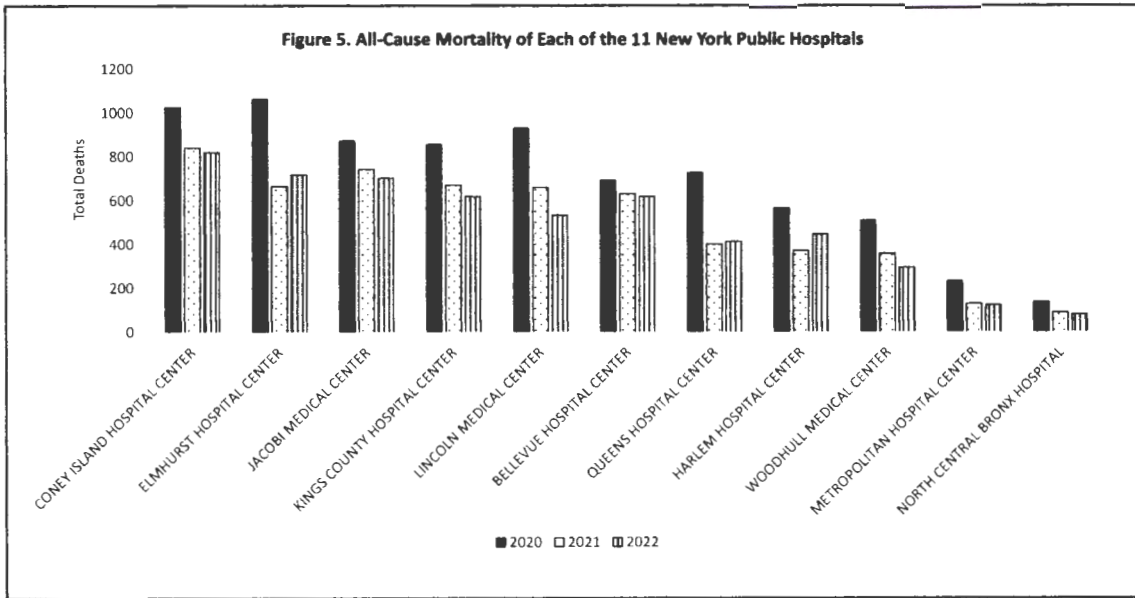
Discussion

All-cause mortality increased more (2019/2020 y-o-y) in New York public hospitals (81.3%) compared to non-public hospitals (21.5%). From January of 2020, when COVID became a new diagnosis, the number of patients with COVID who were place on mechanical ventilation and died increased from 3 to 1,286 in April (for an 82% death rate), then dropped sharply to a low of 7 in October of 2020 (for only a 31% death rate).

During March, April, and May of 2020, the mechanically ventilated COVID-positive patients who died were 68% male and 86% were over the age of 50. By race, 83% were non-white (i.e., Black, Hispanic, Asian, or Other). In fact, more than half (58.6%) of the y-o-y increase in 2020 of all-cause mortality was comprised of COVID ventilated patients.

Numerous findings indicate that a unique problem existed within the New York public hospitals generating these outlier death statistics. The deaths were correlated with the type of care administered to the COVID patients in the ICU with mechanical ventilation (causation cannot be determined by the data we obtained).

Firstly, the combination of much greater all-cause mortality and increase in total COVID-ventilator deaths is a signal for possible sentinel-event medical error related to protocols for ventilation management. To place in historical perspective, far less dramatic changes in death rates, in the single-digit range, have been flagged by the New York SPARCS safety monitoring program and hospital divisions have been shut down.[8]

Secondly, the all-cause and total COVID ventilator deaths in the public hospitals sharply dropped after May of 2020 when nurse whistleblowers came forward[9] and a paper was published in April in JAMA[4], *inter alia*. The total number of patients placed on mechanical ventilation dropped abruptly after May for unknown reasons. Changes in overall hospital admissions or severity of the COVID virus do not explain the sudden reduction in ventilator deaths after May of 2020.

Thirdly, even when the total number of COVID patients ventilated and total deaths decreased after May of 2020, the death rates among the COVID ventilated fluctuated back into the highly abnormal range of 80% when historical death rates in the ICU ventilator setting have been in the 30% range or lower, depending on the reasons for placing the patient on mechanical ventilation. A 2002 JAMA study from Spain showed a 31% ICU mortality rate when the reason was acute respiratory distress.[10] This signals a unique and lethal ventilator management strategy was used by the public hospitals.

Fourthly, no whistleblowers or medical reports described problems in the other private hospitals within New York. Anecdotes and case reports in the media implicate only the public hospitals.[5,6]

There are no published reports to date that allow these New York ventilator death data to be compared to other regions of the country or world. Several publications in JAMA, Lancet, etc. were short-term and many patients were still in the ICU at the time of publication. Therefore, mortality rates were not accurately published.[4,11,12] The Lancet authors from Columbia University published

a letter updating their data with 97% follow-up, showing a 44% COVID ventilator death rate in their non-public hospital in Manhattan.[13])

One explanation for the disparities in mortality rates could be that only the public hospitals were willing to treat COVID patients at the time. Indeed, it is well documented that many hospitals were openly refusing to admit COVID patients.[14] Also, those patients seeking care in public hospitals might also have been sicker and with more comorbidities than patients in private hospitals.

However, evidence opposing that theory is the inexplicable drop in all-cause mortality, ventilator total deaths, and ventilator death rates. The pandemic was only getting more severe and widespread at the time, in early 2020, and it is implausible that patient demographics suddenly changed.

The limitations of this study are that the data did not come from a comprehensive electronic medical record system. Patient-by-patient comorbidities and demographics are unknown. Also, COVID was not a well-recognized diagnosis prior to 2020. Therefore, no COVID ventilator data are available prior to 2020.

However, it should be emphasized that this is not a typical retrospective study drawing from easily obtainable hospital electronic records. The COVID ventilator death data were obtained only through years of extraordinary litigation by authors Greer and Dellaportas against the State of New York. Because these data are still being withheld by New York, and this paper has produced the mortality data for the first time, the limitations of this study need to be put in perspective to the importance of the publication of these data.

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Conclusion

In the initial months of the COVID pandemic in 2020 (i.e., March, April, and May), the 11 New York State public hospitals under the control of Governor Andrew Cuomo increased usage of mechanical ventilators with a corresponding large increase in deaths rates among the COVID-positive ventilated patients compared to the preceding two months (2.7 times greater ventilator death rate in March-May compared to February). The all-cause mortality of the 11 public hospitals also increased to a degree far larger than surrounding time periods (4.9-times increase in number of deaths in March and April compared to January and February).

Then, as abruptly as they rose, those death statistics fell sharply after May of 2020. Changes in ventilator management are a possible explanation. If the COVID infections alone had caused the worse outcomes among the ventilated, then one might expect to see overall hospital admissions to have increased, which was not the case. The sharp drop in deaths is also inconsistent with the increasing spread of the COVID virus at the time. Moreover, whistleblower accounts clearly implicated the public hospital management.

The patients who died while on mechanical ventilators were overwhelmingly from the non-White communities (83%). Data on comorbidities, such as COVID infection status, diabetes, or obesity were not provided despite litigation underway by the researchers against the New York State Department of Health.

The ventilated COVID patients were, for the most part, not receiving monoclonal antibody or convalescent plasma. Remdesivir was administered more often. However, details are lacking in the data obtained to make proper inferences on drug therapies. (Note to peer-reviewers: We are leaving out the data on this because it opens up a can of worms unrelated to the objectives of this paper.)

Assuming *arguendo* that human error was not the cause of the high death rates, then the use of mechanical ventilation for the COVID (i.e., SARS-CoV-2 virus) infected population should still be critically analyzed compared to other means of oxygenation available as alternatives, such as nasal canula oxygen[15], extracorporeal membrane oxygenation (ECMO)[16], and red blood cell transfusion).[17]

Further investigation is required to determine why total all-cause mortality and COVID ventilator mortality spiked for only a three consecutive months in early 2020, and whether or not human error was the cause. The entirety of the data held by the State of New York will likely be revealed at some point. This study could expedite that release for other researchers.

Word count = 2,645 not including references and abstract sections

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Steven E. Greer, MD is now an independent researcher and journalist. His medical degree is from *The Ohio State University College of Medicine* with surgery training from *Jackson Memorial Hospital* in Miami, *Bellevue Hospital* in New York, *The Manhattan VA*, and the private hospital of *New York University*. His surgery research training is from NYU under the supervision of Michael Longaker, MD. Greer has also been a journalist for *The Wall Street Journal, Reuters,* and *Fox News*, among others.

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John Dellaportas, JD is the Co-Chair of the law firm *Emmet Marvin's* litigation department. He attended undergrad college at *Yale* and then law school at *Columbia University*. His father and sister are medical doctors in Ohio.

Greer, Pronovost, Dawkins, and Dellaportas had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

Concept and design: Greer, Pronovost, Dellaportas

Acquisition of data: Greer, Dellaportas

Analysis and interpretation of data: Greer (with help from Devan Hawkins, see below)

Critical revision of the manuscript for important intellectual content: Greer, Pronovost, Dellaportas

Statistical analysis: Devan Hawkins, paid consultant, biostatistical expert and Assistant Professor of Public Health at Massachusetts College of Pharmacy and Health Sciences

Obtained funding: Dellaportas contributed legal work *pro bono*. Greer volunteered his time and paid for the statistical analysis service.

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References

1. Holshue ML, DeBolt C, Lindquist S, et al; Washington State 2019-nCoV Case Investigation Team. First case of 2019 novel coronavirus in the United States. *N Engl J Med*. 2020;382(10):929-936. doi:10.1056/NEJMoa2001191

2. Arentz M, YimE, Klaff L, et al. Characteristics and outcomes of 21 critically ill patients with COVID-19 inWashington State. *JAMA*. 2020. doi:10.1001/jama.2020.4326

3. Centers for Disease Control and Prevention. Coronavirus disease 2019 (COVID-19): cases in US. Accessed March 25, 2020. https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/cases-inus.html

4. Richardson, S, et al. Presenting Characteristics, Comorbidities, and Outcomes Among 5700 Patients Hospitalized With COVID-19 in the New York City Area. *JAMA*. 2020;323(20):2052-2059

5. Forrester, K. 'WORSE THAN A WAR ZONE' Coronavirus epicenter nurse writes bombshell whistleblower book & demands federal investigation into New York hospital. *The Sun*. August 28, 2020. https://www.the-sun.com/news/1357963/new-york-nurse-coronavirus-book-investigation-elmhurst-hospital/

6. Gould, M. "It's a horror movie." Nurse working on coronavirus frontline in New York claims the city is 'murdering' COVID-19 patients by putting them on ventilators and causing trauma to the lungs." *Daily Mail*, April 27, 2020

7. *Cortex Television v. New York State Dept Health*, Index No. 318612 (Sup. Ct., Albany Cnty. 2022)

8. Lovett, K, "2 City Hospitals Rank Worst in Heart-Bypass Death Rates", *New York Post*, February 14, 2001

9. Gould, M. "It's a horror movie." Nurse working on coronavirus frontline in New York claims the city is 'murdering' COVID-19 patients by putting them on ventilators and causing trauma to the lungs." *Daily Mail*, April 27, 2020

10. Esteban A, et al. Characteristics and Outcomes in Adult Patients Receiving Mechanical Ventilation: A 28-Day International Study. *JAMA*. 2002;287(3):345–355. doi:10.1001/jama.287.3.345

11. Karagiannidis C, et al. Case characteristics, resource use, and outcomes of 10,021 patients with COVID-19 admitted to 920 German hospitals: an observational study. *Lancet Respir Med*. 2020 Sep;8(9):853-862. doi: 10.1016/S2213-2600(20)30316-7.

12. Wunsch H. Mechanical Ventilation in COVID-19: Interpreting the Current Epidemiology. *Am J Respir Crit Care Med*. 2020 Jul 1;202(1):1-4. doi: 10.1164/rccm.202004-1385ED. PMID: 32402207; PMCID: PMC7328308.

13. Cummings, M. et al. Study of critically ill patients with COVID-19 in New York City – Authors' reply. *Lancet* 2020, October 396:1064. https://doi.org/10.1016/S0140-6736(20)32072-9

14. Fitzgibbons, T. "I Almost Died From COVID. A Medical Advocate Saved My Life." *Real Clear Politics* website. January 11, 2021.

15. Ramirez GA, et al. "Outcomes of noninvasive ventilation as the ceiling of treatment in patients with COVID-19." Panminerva Med. 2022 Dec;64(4):506-516.

16. Byrne JJ, Shamshirsaz AA, Cahill AG, et al. Outcomes Following Extracorporeal Membrane Oxygenation for Severe COVID-19 in Pregnancy or Post Partum. *JAMA Netw Open*. 2023;6(5):e2314678. doi:10.1001/jamanetworkopen.2023.14678

17. Ejigu T, Patel N, Sharma A, Vanjarapu JMR, Nookala V. Packed Red Blood Cell Transfusion as a Potential Treatment Option in COVID-19 Patients With Hypoxemic Respiratory Failure: A Case Report. Cureus. 2020 Jun 1;12(6):e8398. doi: 10.7759/cureus.8398. PMID: 32637278; PMCID: PMC7331927.

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