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"The case definition is very simplistic. It means, at the time of death, it was a COVID positive diagnosis. That means, that if you were in hospice and had already been given a few weeks to live, and then you also were found to have COVID, that would be counted as a COVID death. It means, technically even if you died of [a] clear alternative cause, but you had COVID at the same time, it's still listed as a COVID death." - Dr. Ngozi Ezike, director of Illinois Department of Public Health

"If someone dies with COVID-19, we are counting that as a COVID-19 death." – Dr. Deborah Birx

""It would be foolish, I think we would all agree, if somebody died in a car accident who had tested positive for COVID-19, and we would say that's a COVID-19 death. That's a car accident death …" – Dr. Thomas Gilson

"New York City, already a world epicenter of the coronavirus outbreak, sharply increased its death toll by more than 3,700 victims on Tuesday, after officials said they were now including people who had never tested positive for the virus but were presumed to have died of it." – David Goodman and William K. Rashbaum

Based on definitional and testing irregularities, there is controversy about the SARS-CoV-2/COVID-19 death count. Even under normal circumstances, initial or raw fatality numbers and estimates for a pathogen require further analysis to get a better handle on pathogen associated or caused death. For example, in 2018 the CDC estimated that there were some 80,000 flu related deaths and that the estimate was "not expected to go down". As of this writing, the CDC has revised its estimate for the 2017/2018 season to 61,000 flu associated deaths. In terms of deaths directly attributable to the flu, a recent study put the number at 4,000 in the US for 2017.

What follows below is a preliminary analysis of the CDC's official COVID-19 death and comorbidity statistics with the goal of estimating SARS-CoV-2/COVID-19 caused or contributed deaths. As of September 2nd, 2020 the CDC is officially reporting 169,044 COVID-19 involved or associated deaths. That is to say, the CDC is reporting that as of September 02, 2020 169,044 deaths were associated with non-specific cold and flu systems. Moreover, official CDC comorbidity data includes car accident, gunshot and poisoning victims among the COVID-19 associated deaths. It is thus indubitably clear that further analysis is required to arrive at a reasonable estimate for the number of deaths attributable to SARS-CoV-2/COVID-19 as a causal or contributing factor. It is important the conversation be moved beyond the media's CDC number of COVID-19 associated deaths to a more scientifically meaningful number of SARS-CoV-2/COVID-19 caused or contributed deaths that will hopefully provide a more solid basis for fruitful scientific research and rational public policy.

A concise review of SARS-CoV-2/COVID-19 pathophysiology will be helpful. Briefly, SARS-CoV-2 is the corona virus that is said to cause the medical disease COVID-19, which basically manifests itself in patients as non-specific cold and flu symptoms like fever, dyspnea, muscle aches, sore throats, etc. In a small fraction of patients, a SARS-CoV-2 upper respiratory tract infection will cause COVID-19 symptoms which will then cause a lower respiratory tract infection leading to pneumonia, acute respiratory distress and ultimately death. Not surprisingly, according to the CDC, expert opinion, published scientific research, and main stream media reports, the canonical or normative death certificate for a SARS-CoV-2/COVID-19 death should record COVID-19 as the underlying cause of pneumonia which, in turn, should be recorded as the intermediate cause of acute (adult) respiratory distress syndrome (ARDS) which should be recorded as the immediate cause of a patient's death. Indeed, the very acronym "SARS" – which stands for severe acute respiratory syndrome – implies a dominant role for ARDS as the immediate cause of death in COVID-19 patients with fatal outcomes. ARDS as the immediate cause of death in COVID-19 patients also helps to explain all the talk and even panic about the availability and use of ventilators during March and April of 2020. Hence, the dominant death pathway for COVID-19 patients should be COVID-19/pneumonia/ARDS.

Importantly, the CDC reports statistics on COVID-19 comorbidities and, in particular, on ARDS as a condition that contributes to COVID-19 deaths. As of this writing, the CDC is officially reporting that from February 2020 to September 2, 2020 exactly 22,747 COVID-19 death certificates listed ARDS as a contributing cause to COVID-19 deaths. This implies that from February 2020 to September 2, 2020 a maximum of 22,747 people died according to the canonical COVID-19/pneumonia/ARDS death pathway. Put differently, 13.5% (22,747 / 169,044) of COVID-19 linked or associated deaths conform to the expected casual death sequence for COVID-19.

It is not known how other comorbidities or coinfections may have contributed to or caused the deaths of the 22,747 COVID-19/pneumonia/ARDS patients. Indeed, it is not known how many of the COVID-19 diagnoses are supported by laboratory confirmation of a SARS-CoV-2 infection. A straightforward excess ARDS death analysis using CDC mortality data from 2000 (2,185 ARDS deaths) suggests that SARS-CoV-2 contributed to or caused approximately 20,562 deaths. However, it must be remembered that definitional and testing abnormalities, unprecedented lockdown measures that may increase microbial infection risk and other risks, mass fear and panic, novel diagnostic challenges, aggressive ventilator usage and the like complicate the picture in 2020 and warn against prematurely assigning SARS-CoV-2 as the etiological agent. As such, an analysis of the published literature is called for to develop a better model estimate of deaths that may have been caused or contributed to by SARS-CoV-2 infection. Two publications provide insights into the role viral or microbial coinfections may have played in causing or contributing to fatal outcomes in COVID-19/pneumonia/ARDS patients and the rate of SARS-CoV-2 laboratory confirmation for COVID-19 patients. According to a paper by Lai et al., complicating viral, bacterial or fungal coinfections may be present in 50% of COVID-19 fatalities; another article by Davis and co-workers suggests co-infections are present in as many as 16.8% of cases. The important role of bacterial coinfection is also suggested by meta-analyses of COVID-19 patients which have identified elevated procalcitonin levels as a significant risk factor for severe disease and adverse outcomes in COVID-19 patients. Publications by Huang et al. and Petrilli and co-workers report that 69% and 48.2%,

respectively, of patients with clinically suspected COVID-19 test positive for SARS-CoV-2. Taken together, the 50% coinfection rate and 48% and 69% laboratory confirmation rates, respectively, when applied to the 22,747 ARDS deaths imply that 5,460-7,848 COVID-19/pneumonia/ARDS deaths are "clean" or coinfection free and are supported by a laboratory confirmed SARS-CoV-2 infection. As such, it can be tentatively proposed that approximately 3.2%-4.6% of COVID-19 deaths were of the type SARS-CoV-2/COVID-19/pneumonia/ARDS and free from confounding coinfections.

Future research will be required to sharpen the above preliminary estimate and sort out the roles lockdown measures, and community, health care and nursing home acquired coinfections and secondary infections played in producing fatal outcomes. While a detailed analysis is beyond the scope of this paper, another important factor to consider is the role medical treatment, particularly the use or non-use of antibiotics, corticosteroids, and mechanical ventilation of COVID-19/pneumonia/ARDS patients, may have played in contributing to or causing COVID-19/pneumonia/ARDS deaths. Indeed, several studies from Germany, Philadelphia and Detroit point to mechanical ventilation as a significant risk factor for death among hospitalized COVID-19 patients. The failure to use medications like hydroxychloroquine in an appropriate manner may also have contributed to the mortality burden. Finally, the roles comorbidities like diabetes, obesity, cardiovascular disease, hypertension and cancer may have played in contributing to or causing COVID-19/pneumonia/ARDS deaths also requires further investigation.

Out of 169,044 deaths reported by the CDC as involved or associated with COVID-19, an upper limit of 22,747 deaths conform to the most logical death sequence of COVID-19/pneumonia/ARDS. Based on a naïve excess death analysis some 20,562 deaths plausibly conform to the SARS-CoV-2/COVID-19/pneumonia/ARDS death pathway. Based on published SARS-CoV-2 testing confirmation rates of 48% and 69%, between 10,919 and 15,695 deaths conform to the logical death pathway of SARS-CoV-2/COVID-19/pneumonia/ARDS. Based on a published estimate of a 50% coinfection rate among COVID-19 fatalities, between 5,460 and 7,848 deaths conform to the SARS-CoV-2/COVID-19/ pneumonia/ARDS and are coinfection free. Hence, it can be tentatively concluded that SARS-CoV-2 caused or contributed to between 5,460 and 15,695 deaths, respectively, in the US during the period February 2020 to September 2, 2020 according to the canonical SARS-CoV-2/COVID-19/pneumonia/ ARDS death pathway. For context, a recent study concluded that some 4,000 deaths in the US were directly attributable to seasonal influenza caused lower respiratory tract infections. Importantly, that figure is significantly smaller than CDC reported influenza associated deaths which can be as high 61,000. Applying the influenza causation/association ratio (6.5%) to COVID-19 associated deaths suggests that ≈ 11,156 deaths are attributable to SARS-CoV-2 caused lower respiratory tract infections, a figure that is almost exactly midway between the 5,460-15,695 range calculated above.

It is possible that SARS-CoV-2 infection can contribute to or cause death in the absence of ARDS. A recent meta-analysis and systematic review by Qiu et al. indicates that ARDS is a highly significant risk factor for death and that some 90% of deceased COVID-19 patients experienced ARDS as a complication and that 10% died without ARDS. A Spanish study of critically ill COVID-19 patients also reported ARDS as significant risk factor for death and that 95% of non-survivors had ARDS as a complication and that 5% did not. Assuming 10% of COVID-19 patients die without ARDS entails 1,744 additional deaths for a total

of 17,439 ARDS and non-ARDS deaths. And while it strains credulity to think that the number of SARS-CoV-2 caused or contributed deaths free from ARDS would totally exclude a pneumonia diagnosis and exceed 15,695, doubling the number of ARDS deaths implies a hard upper limit of 31,390 on the number of deaths that SARS-CoV-2/COVID-19/pneumonia caused or significantly contributed to in the total absence of ARDS. This hard upper limit leaves the true non-SARS-CoV-2 casual pathways for 137,654 COVID-19 associated deaths unaccounted for. A simple analysis of CDC comorbidity data immediately suggests that roughly 5,424 COVID-19 associated deaths were probably caused by things like automobile accidents, gunshots, and poisonings. Clearly, further research is required to elucidate more accurate non-SARS-CoV-2 death pathways for the remaining 132,230 COVID-19 associated deaths.

In conclusion, there is significant controversy surrounding the COVID-19 death count. Based on CDC death certificate standards, official CDC COVID-19 fatality and comorbidity data, expert opinion, main stream media reports and results obtained from the peer reviewed literature, for the period February 2020 to September 2, 2020 in the US the following key points can be tentatively concluded:

1) The all-important and logical sequence of COVID-19/pneumonia/ARDS accounts for 22,747 deaths

2) The logical sequence of SARS-CoV-2/COVID-19/pneumonia/ARDS accounts for 10,919 to 15,695 deaths

3) The logical sequence of SARS-CoV-2/COVID-19/pneumonia/ARDS with no coinfections accounts for 5,460 to 7,848 deaths

4) Thus, between 5,460 and 15,695 deaths were caused or contributed to by a SARS-CoV-2 infection that culminated in ARDS as the immediate cause of death

5) Points (1) through (4) make sense in light of a recent study which estimated that 4,000 deaths in the US were directly attributable to influenza caused lower respiratory tract infection deaths in 2017, despite an initial CDC estimate of 80,000 flu associated deaths

6) Future research will have to sort out how lockdown measures, hospital, community and nursing home acquired infections, the use of mechanical ventilation, antibiotics and corticosteroids, failure to use hydroxychloroquine, comorbidities, and other factors may have contributed to or caused other COVID-19 ARDS deaths

7) While it is possible that SARS-CoV-2 caused or contributed to the COVID-19 death toll in the total absence of ARDS, it is highly unlikely that pneumonia would be totally excluded as a diagnosis and that the number would exceed an additional 15,695 deaths. This implies a hard upper limit on the SARS-CoV-2/COVID-19/pneumonia caused or contributed death count of 31,390

8) Point (7) suggests that SARS-CoV-2 did not cause or significantly contribute to as many as 137,654 of the COVID-19 involved deaths reported by the CDC. Indeed, analysis of the CDC comorbidity data suggests that as many as 5,424 of the COVID-19 associated deaths may be attributable to external trauma or injury through such things as automobile accidents, gunshot wounds and poisonings. Future

research should focus on identifying accurate death pathways for the 132,230 (≈ 81%) of CDC reported COVID-19 associated deaths in which SARS-CoV-2 infection probably played a non-contributory role.

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