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Protecting Scientific Integrity and Public Policy Pronouncements on COVID-19*

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Abstract

The SARS-CoV-2 virus and the associated COVID-19 disease is a pandemic that has rocked the world in terms of public health and medical issues, business, economics and finance. Interesting and topical discussions regarding risk management of COVID-19 have been reported in leading business, economics, finance, and medical journals, as well as information and misinformation, intended or not, in the mass media. In this context, protecting the integrity of public policy pronouncements relating to the conduct and outcomes of scientific clinical trials. In terms of protecting the scientific integrity of clinical trials of COVID-19 patients, it is intentional to determine whether imperfectly collected data on clinical trials are more useful than having no data at all.

Keywords: COVID-19; SARS-CoV-2; scientific integrity; public policy pronouncements; medical research; business, economics and finance.
JEL: D81, G32, H12, L82.

1. Introduction

A pandemic that has rocked the international community in terms of public health and medical issues, business, economics and finance is the SARS-CoV-2 virus that causes the COVID-19 disease. In addition to substantial information and misinformation about COVID-19 in the mass media, important scientific research about the virus and associated disease has also been reported in leading medical, public health, business, economics and finance journals.

Interesting and topical discussions regarding risk management of COVID-19 have been reported in Yang et al. (2020) on risk management of COVID-19 by universities in China, in McAleer (2020) on prevention being better than the cure, in Chang and McAleer (2020) regarding alternative global health security indexes for risk analysis of COVID-19, in Chang, McAleer and Ramos (2020) on a charter for sustainable tourism after COVID-19, and in Chang, McAleer and Wong (2020) on risk and financial management of COVID-19 in business, economics and finance.

Recent research in medicine includes, among others, a study by Cheng, Wong and Yuen (2020) on accurate estimation of coronavirus disease 2019 infection risk in health care workers. Comparisons were made of infection rates across different studies, but no assumptions were made regarding the likely independence of the samples, and the underlying statistical distributions. Although the estimated infection rates are numerically different, they are nevertheless point estimates. In the absence of standard deviations or any other measure of dispersion, any inferences as to why the infection rates might differ across the three groups are problematic as the detailed numerical comparisons, and accompanying explanations regarding the differences in infection rates, cannot be tested statistically.

Klein, Ferrer and Kaufman (2020) on whether people "think" about cancer risk, and why that matters. Impending mortality can clear and focus the mind, though the good fortune to have access to excellent private health insurance, skilled surgeons, talented oncologists, devoted nursing staff, and state-of-the-art hospital facilities, cancer treatments, new therapies, and genetic screening, as well as family and close friends, can perform modern-day miracles. The presence of COVID-19 has led to increased risk management and health security for protection against exposure of immune-challenged patients undergoing cancer treatment. Simple and

informative recommendations can lead to effective behavioural changes in advance of contracting cancer.

Liang, Liang and Ou et al. (2020), develop and validate a clinical risk score to predict the occurrence of critical illness in hospitalized patients with COVID-19. The score, which is based on data from China from 21 November 2019 to 31 January 2020, is a composite measure of whether COVID-19 hospital patients will be admitted to an ICU, will need invasive mechanical ventilation, or will die. A logistic regression model was used to construct a predictive risk score to estimate the risk that a hospitalized patient with COVID-19 will develop critical illness. In order to enhance the accuracy and usefulness of the innovative clinical risk score, it would be helpful to examine additional samples based on a larger sample of patients from a wide range of countries to establish an unbalanced dynamic panel data set, extending the data set of patients beyond 31 January 2020, using samples from different countries comprising younger patients, using samples from different countries comprising older patients with comorbidities, using samples from different countries according to low, moderate and high risk categories of patients, testing the statistical validity of the logistic regression model using functional form tests, testing the significance of omitted variables, validating the predicted critical illnesses using the mortality rates of critically ill patients, checking the sensitivity of the estimates from the logistic regressions used in the clinical risk score, using a larger data set to determine how the estimates of the LASSO and logistic regressions change dynamically over time, and using a larger data set to check the accuracy of the predicted critical illnesses according to different rates of confirmed COVID-19 cases.

Shah (2020) discussed cancer and COVID-19, each of which can lead to the destruction of body tissue and death. Unlike cancer, where members of the general public free of the disease are seemingly not concerned about possible infection, the SARS-CoV-2 virus that causes the COVID-19 disease would almost certainly be on the minds of every human being, especially as the chances of infection and transmission are far from negligible. Cancer patients have diminished immune systems, and so are more susceptible to contracting COVID-19, and suffering severely from such an infection. Whether cancer patients with COVID-19 are more likely to transmit the disease to healthy humans does not yet seem to have undergone serious clinical trials.

Starr (2020) uses controlled trials to resolve key unknowns about policy during the COVID-19 pandemic, and provides factual evidence through controlled trials for effective minimization of the spread of COVID-19, which are preferable to the current arbitrary policies based on preconceived and prejudicial ideas, frequently of a political nature. There are numerous key unknown effects of policies that need resolution for the desired control and mitigation of COVID-19, where the alternative is the status quo. Although public policy decisions based on arbitrary political priorities should not dominate scientific controlled data-based outcomes regarding the reopening of the economy and of schools, informed policy requires accurate information on infections, for which the data are sadly lacking.

Williams and Cooper (2020) evaluate COVID-19 and health equity as a new kind of "herd immunity", and re-interprets herd immunity, which is associated with intended or unconscious government policy to allow a large percentage of a population to catch a disease to develop immunity against its spread. The detailed and illuminating discussion focuses on research that demonstrates systemic inequities (or biases) in health, specifically shorter life spans, greater illnesses, and death rates, according to ethnic, racial, economic, and social differences. Although adverse lifelong environmental, social, economic and geographic factors impact public health, such differences seem to have been exacerbated in, among others, the treatment of patients and testing, or lack thereof, for COVID-19. Three important and prescient strategies are suggested to raise awareness of, and to improve, the inherent ethnic, racial, economic, and social inequities in public health, namely acknowledgement of the problem, clarifying the reasons for such inequities, and the elimination of racial stereotyping. The observed herd immunity is not independent of ethnic, racial, economic, and social categorization, with disparities leading to the burden of herd immunity falling heavily on the inherently disadvantaged in society, namely those who need public health assistance the most.

Berwick (2020) provides a foundation for careful public policy decision making regarding a fair distribution of wealth, security, and opportunity, as well as access to quality health care facilities and hospitals, in a COVID-19 world. Time heals all wounds, and leads to a more balanced and patient process than expedient short term effects, which are frequently based on political rather than scientific considerations. The author proposes 6 properties of care for lasting change in a world dominated by COVID-16, namely: the speed of learning and implementation of new practices, which should not be confused with accuracy; the value of standards, which should not be rushed, otherwise quality can be compromised; protecting the

workforce, which should also not be rushed as it will affect safety; virtual care can be convenient, but bedside manner might disappear, especially for those who need it most; readiness to face threats, both known and unknown; and unequal treatment of the marginalized and disadvantaged everywhere, including the poor and unemployed. Returning to a world before COVID-10 would discard many expected and unexpected gains that have been made, and lead to a legacy that is far from optimal.

Fischoff (2020) argues that reopening all or parts of the economy are critical cost-benefit decisions that must be taken by governments at all levels in virtually every country based on prevailing science, as mentioned in Starr (2020). In many countries, administrative and public policy decisions are made at the federal, state, provincial, prefectural or regional levels, which renders consistent decision-making onerous or impossible. Moreover, individuals who lack sufficient information for considered decision making can face bewildering choices. It is essential that there be minimal adherence to technical, statistical and quantitative analysis of estimates of unknown parameters of models that are used in decision making. Informed cost-benefit public policy decisions based on scientific data-based outcomes should dominate ill-informed and arbitrary decisions by administrators and individuals at all levels, even if accurate and precise risk metrics might not yet be available.

Gill and DeJoseph (2020) provide a detailed and informative analysis of accurate death certification provided by health care professionals, nursing homes, and hospitals, as being informative for public health policies, and timely evaluation and optimal risk management of the disease. Probable contributing conditions leading to death include starvation and associated illnesses in many less developed countries, where government subsidies for the poor and unemployed arising from COVID-19 range from minimal to non-existent. Any deaths caused by temporary or permanent unemployment and poverty because of the pandemic, and a lack of availability of welfare payments to enable access to hospitals, nursing homes, and health care facilities, are also contributing conditions for death that are associated with COVID-19, even if the cause of death is determined to derive from specific medical conditions, including comorbidities. This is especially the case where testing for COVID-19 is not performed on patients after death for a variety of reasons. Inaccurate and imprecise determination of the medical causes provided by physicians on death certificates, especially in the absence of laboratory-confirmed infection, will compromise the true COVID-19 death count, and hence associated optimal public policy.

Gilchrist, Howard, Akinyemiju, et al. (2020) investigate the sedentary behaviour of cancer mortality in middle-aged and older US adults. The authors used accelerometers to determine movement patterns in a cohort of 8002 middle-aged and older US adults, of which 3668 were males with a mean age of 69.8 years. The key finding for public health is that decreasing sedentary behaviour and increasing physical activity is associated with reducing the risk of cancer death in a cohort of adults aged 45+ years, in a study for a one-year period from 18 April 2019 to 21 April 2020. Although not considered by the authors, it would be invaluable to cancer patients, oncologists, and health care providers to extend the analysis to examine the effects of accelerometry on: sedentary females; younger cohorts of males and females; different health categories of males and females; extending the accelerometry period beyond 7 days; varying intensity levels of accelerometry; an alternative set of healthy lifestyle choices; different types of cancer; duration of diagnosed cancer; different comorbidities; different treatments for cancer, including radio and chemo therapies; examining genetic associations; and analysing the effects of stress induced by COVID-19. Certain types of cancer are seen as immutable, but it is striking that the quality of life of cancer patients can be alleviated through even mild forms of exercise.

Gostin and Salmon (2020) examine the dual epidemics of COVID-19 and influenza in terms of vaccine acceptance, coverage, and mandates. The authors investigate the connection between COVID-19 and the seasonal flu, and the likely impact of the co-epidemics (or pandemic-epidemics) after the summer of 2020 in the absence of a vaccine for SARS-CoV-2. Despite a vaccine being available for the seasonal flu, it is surprising that fewer than one-half of the adult population avails itself of the vaccine. As the effectiveness of the flu vaccine differs according to age, health status, and season, among others, it is essential that any vaccine for COVID-19 is clinically tested according to similar factors, though seasonal effects will not be possible until several years after the development of a vaccine. The evident awareness of COVID-19 among vast segments of the population is likely to ensure that there will be a greater acceptance of an effective, safe, timely, and affordable vaccine, especially for high risk groups in the community. Moreover, in the absence of a vaccine for COVID-19, it is not possible to determine the comingled effects of infection from both COVID-19 and seasonal flu. How a vaccine might be distributed throughout the population of any country, let alone the international community, especially the coverage in poorer countries with problematic health care and hospital systems, remains to be seen.

Tolles and Luong (2020) analyse the modelling of epidemics on the basis of compartmental models, specifically the susceptible-infected-recovered (SIR) model, for the legion of researchers and health care professional who rely on sophisticated technical procedures to guide them in predicting the number of patients who are susceptible to infection, are infected through transmission, and ultimate recovery from infection. As in the case of all models, stringent assumptions are imposed. The SIR model is simple and straightforward, with only two parameters to analyse three mutually exclusive and sequential groups, or compartments, namely S, I and R, based on disease status. The two parameters are the effective contact rate (β), in transitioning from S to I, and the rate of recovery or mortality (γ), in transitioning from I to R, where the transmission durations are assumed to be immediate. The purported recovery to a noncontagious state includes both immunity from the disease and death. The basic reproduction number (BRN) is the ratio between β and γ, with a decrease in the BRN leading to a "flattening of the curve". The JAMA Guide lists a number of limitations of the model, including identical probabilities of community contact and social distancing, and alternative guesses (guesstimates?) of the two model parameters, leading to a range of future trajectories. This is a serious imperfection in SIR models as such guesses incorporate (possibly large) measurement errors that will lead to biased forecasts and their associated standard errors in obtaining interval estimates of infection rates. Moreover, a lack of a distributional foundation to estimate the unknown parameters, and a lack of statistical diagnostic checks of the underlying assumptions, will make it impossible to determine the robustness of the empirical estimates and associated forecasts.

Continuing the medical theme, Fleming, Labriola and Wittes (2020) provide a useful and interesting discussion regarding conducting clinical research during the COVID-19 pandemic, with an emphasis on protecting scientific integrity. The authors admit that some informative data on clinical trial patients is missing, which could lead to biased estimates and analysis.

The purpose of the remainder of the paper is to analyze how to protect the scientific integrity of clinical trials of COVID-19 patients, as well as protecting the integrity of public policy pronouncements relating to the conduct and outcomes of scientific clinical trials in order to avoid and counteract distortions, intentional or otherwise, that can arise in any quarter. Another strategy for protecting and enhancing scientific integrity and public policy pronouncements

would be through the use of more powerful statistical methods in evaluating the content of clinical trials and diagnoses, including the use of incomplete data.

The next section examines whether imperfectly collected data are more useful than having no data at all, as well as superior statistical methods to evaluate clinical trials and asking the right questions.

2. Discussion of the Previous Literature

The penetrating analysis by Fleming, Labriola and Wittes (2020) goes to the heart of protecting scientific integrity during the COVID-19 pandemic, and at all other times, with respect to conducting clinical trials and predicting confirmed cases, deaths, interventions, and overall health care risk in the period after COVID-19, if and when that might occur.

Several prescient caveats about conducting and maintaining the scientific integrity of clinical trials are presented, including:

(1) minimizing risks to patients;
(2) proper statistical analyses;
(3) mitigating against missing observations;
(4) excluding patients from trials until the SARS-CoV-2 virus and COVID-19 disease burdens are low;
(5) minimizing the confounding effects of clinical treatment on the primary safety and efficacy outcomes;
(6) adhering to prescribed drugs that are consistent with clinically achievable levels in pre-COVID scenarios;
(7) improving methodology for collecting critical outcome assessment data;
(8) maintaining a data set of patients whose participation in clinical trials has been compromised;
(9) clear documentation of data management, including modification of trials;
(10) monitoring and controlling data quality;
(11) application of advanced statistical techniques and sensitivity analysis to protect data integrity and interpretation;

(12) pre-specification of clinical trial outcomes.

The invaluable contribution and warnings by Fleming, Labriola and Wittes (2020) include the following significant statement:

"Some data, even though imperfectly collected, usually are more useful than no data."

Missing observations in business, economics and finance include latent data on expectations, rationality, fundamentals, thresholds, risk, volatility, talent, ability, and general unobserved data, among others.

As a commentary on the critical statement given above, it would be useful to conduct in sensitivity analysis and evaluate alternative deterministic and stochastic methods of imputing and extrapolating data to evaluate the robustness of the statistical analysis of critical missing observations that might compromise the scientific integrity of any diagnoses relating to patient treatment.

In addition to protecting the scientific integrity of clinical trials of COVID-19 patients, protecting the integrity of public policy pronouncements relating to the conduct and outcomes of scientific clinical trials, as well as any implications for business, economics and finance, is also imperative to avoid and counteract distortions, intentional or otherwise, that can appear from any direction and at any time, including from the highest administrative positions in the world.

Another strategy for protecting and enhancing scientific integrity and public policy pronouncements would be through the use of more powerful statistical methods in evaluating the content of clinical trials and diagnoses, as well as asking the right questions.

Wu and McCoogan (2020) evaluate the pursuit of diagnostic excellence, but do not cover all the attendant issues, including the likelihood of generating false positives or false negatives, and the possibility of re-infection after supposed recovery from COVID-19 and how quickly this might occur.

Centor, Geha and Manesh (2019) are concerned with estimating the probability of a diagnosis to enable more accurate medical advice. A point estimate is a random variable, and so has an associated sampling distribution and higher moments. Making any medical decisions based only on a point estimate ignores probabilistic considerations about the more revealing interval estimates, based on standard errors, which should lead to more accurate medical diagnoses. Moreover, a diagnostic check provides a formal test of the underlying assumptions of a model that generate the estimates of any moments. Such diagnostic checks lead to more robust statistical inferences regarding an estimated model, and hence to estimates of the probability of a diagnosis that would be less sensitive to any changes in the underlying assumptions.

The discussion presented in the prescient papers demonstrate that protecting the integrity of public policy pronouncements in business, economics, finance and public health policy relating to the conduct and outcomes of scientific clinical trials on COVID-19 is a difficult, demanding, and ongoing process.

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