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March 22, 2022

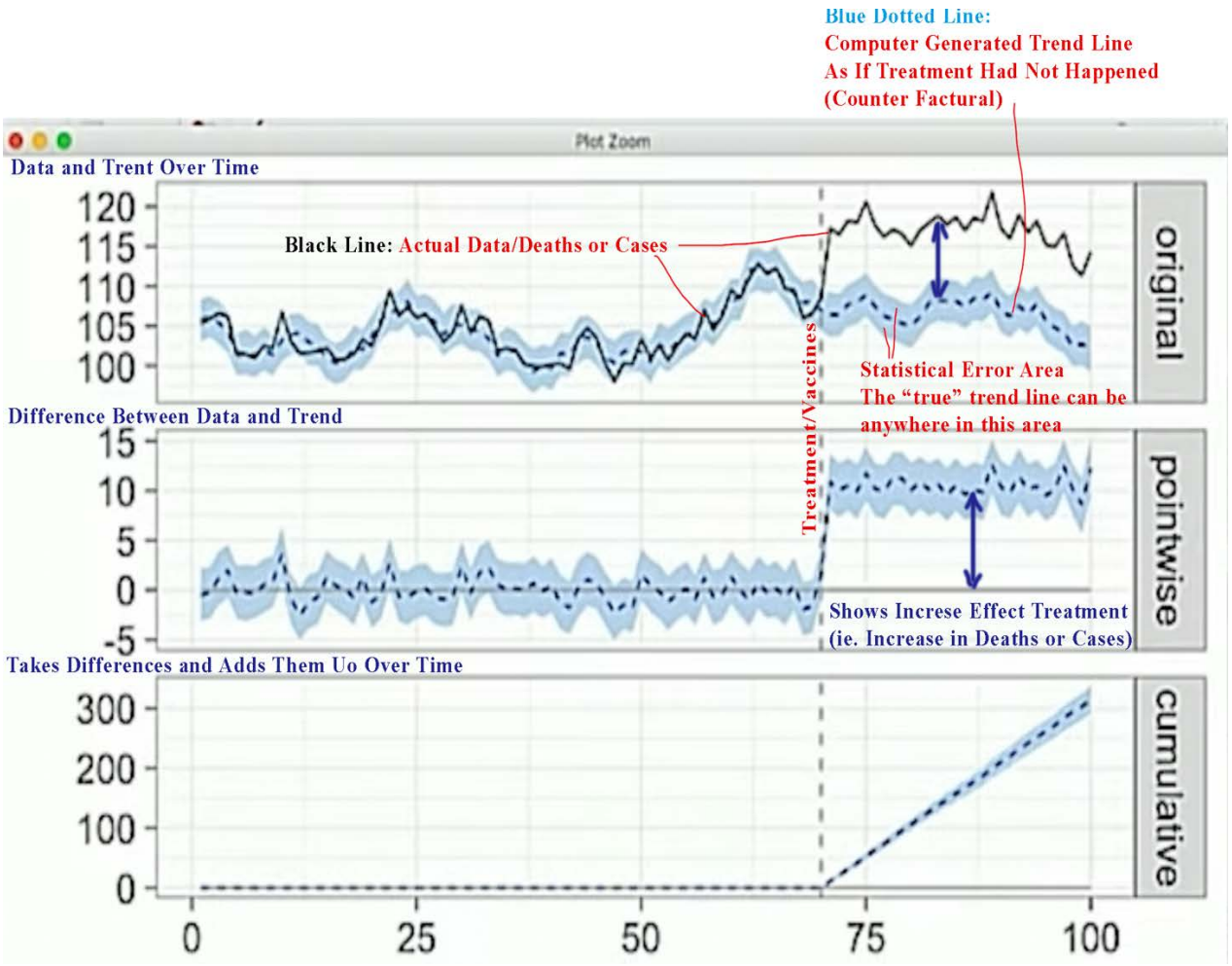
To: Kyle Beattie, Ravalli County Board of Health (Montana, United States of America)

Subject: REVIEW OF Worldwide Bayesian Causal Impact Analysis of Vaccine Administration on Deaths and Cases Associated with COVID-19: A BigData Analysis of 145 Counties — A Preprint
By Kyle A. Beattie
Department of Political Science
University of Alberta

Dear Mr. Beattie,

I learned something. Having taken statistics in the late '60s, learning about Markov, Linear Algebra in the 70's, and occasionally using Bayesian methods imbedded in some of the sensor software I worked in the 70's, 80's, and 90's, this review has led me to learn some more. My two-day excursion into the *CausalImpact* package, introduced by Google in 2015 I believe. Since I am working on a project on COVID-19 this will be useful for me and drew me into this review.

Here is an annotated graph from am video featuring Google's Kay Brodersen at the BigData Conference in 2016 as he described *CausalImpact* (Brodersen 2016). I am hoping to help the people reading your paper in Ravalli County with the graphs in your paper which present these three types of graphs.



It may be unfortunate that your paper that you put out for review on Research Gate as a Preprint has gotten into the political domain so that critiques may become more public. But your paper is here, now, in Ravalli County. Your paper has a number of significant issues which I believe should be corrected before being published or used in a public setting. I will take these up in this review, both to deal with a scheduled Health Board Presentation using your paper and as an attempt at a peer-review input. The key message of the review below is that I suggest that you need to understand the nature of your data, a lesson I have learned, sometimes the hard way, in my engineering career and time as a grassroots activist.

Ravalli County Politics.

According to statements made by a member of the Ravalli County Board of Health a week or so ago, the paper above was sent to the board a few months ago. One of the board members said he contacted you and is currently scheduled to make a presentation based on this paper in April. While the board members, in their discussions, assured each other that it would not be "political," saying they were exhausted by the politics, a presentation on this subject is unavoidably political. It is political simply because it has been put into the public square of the county in which I live, possibly having larger implications if the press shows up.

In your abstract, it is clear that this study is for the purpose of changing political behavior — "sold to the public as the 'key to gain back our freedoms.'… people have a right to know…" (Beattie 2022). This, in addition to your statement in page 57 of your paper about vaccine mandates, puts this paper squarely in the middle of our politics.

So, before getting into your analysis, I will say a few things about ethics, as we have a history of people protesting the idea of vaccine mandates even before there was any attempt to implement them in the United States. I agree that vaccine mandates are bad policy. But some have taken it further, saying that the government "cannot tell them what to do," in a county that, a couple of decades ago had this logic taken to a threatening extreme over a traffic ticket by a self-appointed militia (AP 1995, Bethel 1995).

About the Reviewer. Let me introduce myself before we go on. I have been around for a while, a laborer, engineer, manager, business owner, activist, and author. You can see my resumé at www.JamesROlsen.com. If you look at the detailed resumé button, you will see I have been involved in programs for *Transport Canada Civil Aviation* and have met with them once or twice in the past. While the political history and some aspects of the theory of government differ between the United States and Canada, I think a discussion of ethics and rights from the viewpoint of the American legal system should translate.

You will also see in my resumé that my activities include taking on Dr. Anthony Fauci's organization to task to make one of his planned BSL-4 labs safer than planned, a lab that was put in and continues to operate a few blocks from my house. I am familiar with reviewing the underlying literature in several fields, in addition to the engineering systems on which I have worked.

Ethics Introduced by the Paper.

Why start with ethics? It is very likely to pique the interest of people in our community. And it is the apparent motivation for your paper:

> 9.3 Vaccine Mandates:
> If they ever were ethical, which this author disagrees with strongly based on scientific, medical, and research ethics that regard the patient rights to informed consent and non-prejudcial refusal of treatment or experimentation as iterated and agreed to under the Nuremberg Code (Code 1998), Helsinki Accords (Association and others 2009), and the

> Human Rights Declaration on Bioethics (UNESCO 2019) as inalienable, essential, and non-negotiable, vaccine mandates under these conditions and results are beyond unethical at this point, they are clearly discriminatory and likely criminal, a determination courts and lawyers will ultimately decide. ” (Beattie 2022, p. 57).

Purpose of paper confusing. It is surprising to see this in a research paper submitted to Research Gate for review when it does not relate to the stated purpose of the paper, which is: “Has this policy [worldwide rollout of vaccines] produced the desired effect?” (Beattie 2022, p. 1). In this context, 9.3 is made to seem more like a political rant that has nothing to do with the question asked. I believe you can fix it easily.

It would be more to the point if you change the purpose of the paper to make your point: “Are vaccine mandates ethical?” Then proceed. Examining this question thoroughly would be very interesting. In any case, I suggest dropping “beyond ethical” as a phrase in a research paper.

Nuremberg Code (legality). I am familiar with the unethical and horrifying medical experiments done during World War II, not only by the Nazi Regime in Germany, but by the Japanese because of my research for another book project. The Americans pushed this envelope as well in the *Tuskegee Study of Untreated Syphilis in the Negro Male*, military members during nuclear blast tests, exposure to Agent Orange during the Vietnam War, and Military Burn Pits in recent conflicts.

The issue with the *Nuremberg Code* is the definition of “experiment.” In the United States, there are two levels of approval for medicines by the agency tasked with approval, the Food and Drug Administration (FDA). They are “Emergency Use Authorization” (EUA) and final approval. Legally, an approved drug is unlikely to be seen as an experiment — though the FDA did require an informed consent for anyone taking the vaccine in the EUA approval. Even so, certain private institutions did require vaccines when vaccines were EUA approved (Johnson 2021) — so far, private business vaccine mandates have not been struck down by the U.S. courts.

When at least one mRNA vaccine was given final approval by the FDA, the government got involved in mandates. The current U.S. federal administration issued an order to large private businesses to require vaccines — this was stayed by the U.S. Supreme Court (U.S. Supreme Court 2022), even though the Supreme Court had previously upheld a vaccine mandate in 1905.

On difference between the cases is that, in the 1905 case, the risks and rewards were not presented in court, just a straight claim that the U.S, Constitution prohibited such a mandate (U.S. Supreme Court 1905). The 2022 case provided evidence to the court that the societal rewards did not sufficiently outweigh the risks to the individual.

Even so, the government has put out vaccine mandates on other groups that are dependent upon their funding — a common method in the United States to provide pressure for state and local governments to comply with their will. This includes federal workers, federal contractors, and other groups.

It would seem under the laws of the United States, that a drug approved by the FDA is not experimental in a legal sense. However, when I look at a number of the FDA approvals for medicines (Olsen August 2020) and for vaccines, especially for children, I believe FDA approval process is often flawed and the risks and rewards are not appropriately weighed. But, in the legal environment of the United States, vaccine mandates are not illegal by definition, but can be when the societal risks do not significantly outweigh individual rights.

Nuremberg Code (ethics). As to the events when the *Nuremberg Code* was written, and the imprecise language used in the code in the face of those events, are so different from current events that they do not translate well enough to merit a useful comparison.

Declaration of Helsinki (legal and ethics). This declaration is clearly directed toward clinical experiments, not approved vaccines (World Medical Association 2013 note that this is a different source than Beatie — a complete English language text).

Human Rights Declaration on Bioethics (legality). As to the *Human Rights Declaration on Bioethics* (UNESCO 2019), I don't believe the United States has given up its sovereignty to be bound by this declaration — I suspect Canada has not done so either, so one must look to the rights persevered in our countries' and provinces/states' constitutions and laws.

Human Rights Declaration on Bioethics (ethics). Looking to the *Human Rights Declaration on Bioethics* as an Ethical Mandate, it must be taken whole. This code has a strong consent clause in Article 6:

> Any preventive, diagnostic and therapeutic medical intervention is only to be carried out with the prior, free and informed consent of the person concerned, based on adequate information. The consent should, where appropriate, be express and may be withdrawn by the person concerned at any time and for any reason without disadvantage or prejudice. (UNESCO 2005).

But, Article 6 comes in a package that brings social living standards in Article 14 and biodiversity in Article 17 to the same ethical level — the latter in the United States being embedded in a number of environmental laws. If one cites one article of the declaration, one cites them all. Given our long history of environmental discussion, conflict, and consensus in Ravalli County, I suspect many who are concerned about vaccine mandates won't want to swallow the *Human Rights Declaration on Bioethics* whole.

Vaccine mandates on its own merits (ethics). In the end, an ethical discussion about medical consent and vaccine mandates should stand on their own merit and need not rest on either of these citations. Given the history of Ravalli County, I have often have this conversion and will try to get to a baseline:

- Societies must govern themselves — to keep people from doing violence upon each other is the first order of business.
- Societies also govern themselves to do cooperative efforts — common defense, public infrastructure such as rails and roads and rules for fair commercial trade.
- Western societies have recognized, since ancient times, including in Biblical scripture, that societies have the right to intervene to stop infectious diseases through quarantine — a large imposition on an individual's rights.
- Involuntary medical treatment for apparent mental conditions has a long history and is still practiced today in the United States for people judged to be a "danger to themselves or others." Other involuntary commitments having been ruled as a violation of civil rights. (U.S. Supreme Court 1975).
- Involuntary medical treatment in other cases is a subject seems appropriate for COVID-19, both ethically and legally.

In a contentious meeting of the Health Board on October 26, 2021, numerous people weighed in on this subject (Ravalli County Health Board Special Meeting, (Video) 2021). I presented my case that vaccine mandates make no sense in a presentation at that meeting (Olsen "COVID Presentation" 2021). Since it is not posted on the County Archives, a pdf copy is attached.

Turning to a review of the paper's BigData analysis:

Understanding the nature of the data being analyzed is essential.

It is unfortunate that the word "Causal" is used since no statistical method really identifies a cause-and-effect relationship. Even though the U.S. CDC will say, "Smoking causes cancer" (CDC 2022), "causality" is still not proven as far as a thorough researcher is concerned (Causality 2022). The causal analysis is really a correlation, which, if it has a high statistical confidence, *and is properly designed*, can suggest a cause and effect — that is one can say with high confidence that the cause always produces the effect — but is never perfect. Even so, the actual real-live cause may still be hidden.

A thought experiment might be the case of migrating geese. One may see a high correlation between month of the year and average latitude as they migrate seasonally. Then, seeing that the migration pattern is affected by winter temperatures, one may notice that they may stay longer if it doesn't cool off as fast as and hang around longer. If one ran *CausalImpact* to show a causal relationship between winter temperature and migration, one might find a causal impact with high confidence — let's assume this is the case. But the real "cause," when one looks at it from the Goose's viewpoint, is more likely to be the availability of food.

The problems with assumptions about cause-and-effect are pretty common. I have seen this in real life in engineering systems. I have seen this in highway safety as well — the perception, versus the institutional bias, versus the data, when I was involved with the Department of Transportation when they were in the process of expanding U.S. Highway 93, which runs down the middle of our valley. The project was to expand from two lanes to four lanes.[1]

In analysis method chosen for this paper is laid out by Brodersen et. el. in "Inferring Causal Impact Using Bayesian Structural Time-Series Models." Brodersen uses examples dealing with market interventions, such as introducing a new product (Brodersen 2015). In the video presentation by Brodersen during a BigData Conference he uses a examples of introducing new products and initiating google-ad campaigns in his before-and-after observational studies. (Brodersen 2016). The data used in his examples:

- Is known to be accurately counted.
- Has characteristics and influences that are understood by the user.

It is clear in both his paper and presentation the Brodersen assumes the user of the *CausalImpact* software package *has an understanding of the data* they are dealing with. This is evident when he talks about the baseline pattern predicting the "counterfactual" trend line, showing how the "before trend" would continue if the treatment (vaccines) had not been deployed. When Brodersen uses "competitors" as a baseline in his example he is assuming the user understands the nature of their business in order to know which competitors to select. Brodersen also discusses the seasonal ups and downs of retail sales as being part of that baseline trend, again, indicating that understanding the data is an important factor in using *CausalImpact*. This need to reflect an understanding of the data is also embedded in the math in the transformation matrices in Brodersen's paper as well.

Using Bayes, or nearly any other statistical method for that matter, also demands in understanding to the statistical nature of the data. The original Bayes conditional probability theory rests on an assumption of statistically independent probability functions.

This comment is not unique to this review or your paper. This misunderstanding and mischaracterization of the nature of the data and apparent non-statistical, unrecognized biases is surprisingly frequent in peer-reviewed medical journals that I have reviewed (a list of which is on my website).

The bottom line is that one cannot simply crunch the numbers and assume something useful will come out of it no matter what; one must understand the data.

The Data Source itself that the paper uses has errors that are not accounted for in the resulting graphs. This may be a fatal flaw that needs to be corrected. The issue begins with the four countries selected for Synthetic Control, DRC (Democratic Republic of Congo), South Sudan, Chad, Burkina Faso. *These four countries have no requirement to actually count deaths (Shveda 2021)*, a problem noted by an MD on the Ravalli Republic Board of Health during my presentation while I was speculating on why most African countries have low death counts — upon further research he was proven correct as far as I am concerned.

Selecting data with low variance/sample deviations is something I have learned to raise questions about. It may be flawed or even cooked. An example is the Russian COVID-19 data which is too neat and does not match the expected probability density function (Kobak 2022).

I didn't educate myself well enough on the programming language to be sure how the data from these four countries plays into the program, but, if it is part of the pattern for the counterfactual trend for other countries, then all of the data in the paper is tainted.

Further, COVID-19 deaths are counted differently from country to country and even county by county in the United States. So merging all of this data induces errors in the data itself and variances in the data itself that are not reflected in the results.

At some of our Health Board Meetings, we have heard the Public Health Nurse/Director describe her method of adjudicating death certificates. The very nature of the death is the proximate cause, the heart stops beating. The decision as to if it is related, or not, to the presence of SARS-CoV-2 is made by someone based criteria that varies and is often subjective. There is plenty of controversy in the United States about whether or not to count all positive-test COVID-19 cases as COVID caused — something which does not happen in Ravalli County.

Of course, I recognize that you suggest excess deaths as a better way to do it in your narrative. But, the assumption that death rates among all countries are apples-to-apples seems like a large stretch.

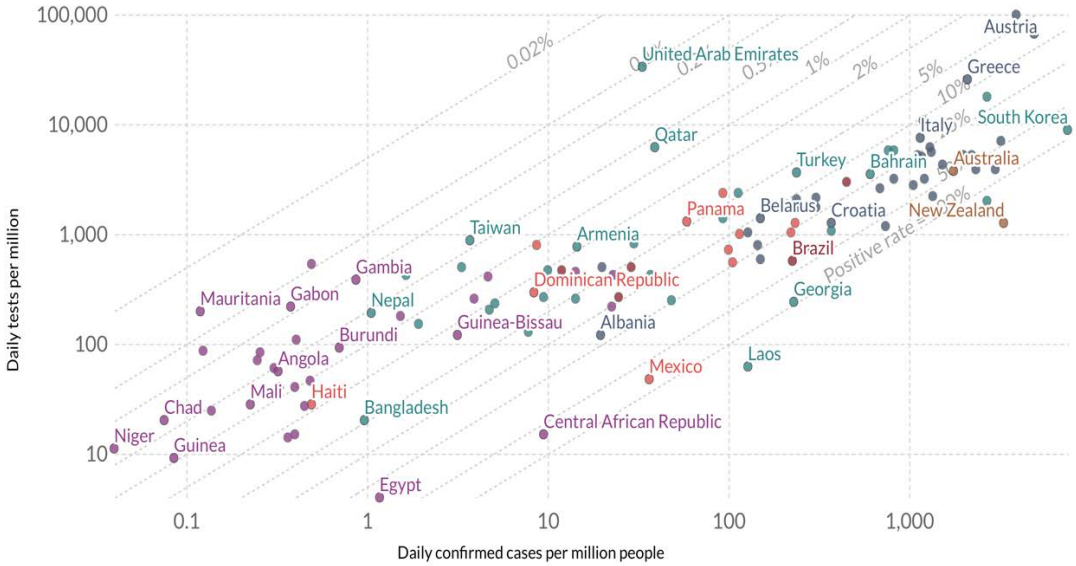
Correlation with case rates is unlikely to be valid. Except in limited and rare circumstances where universal test are applied and verified to a population under study, case rates do not reflect actual infections very well or in a way that is tractable. The way cases are determined vary from place to place and over time. To have a case requires:

- There are test kits available.
- The criteria for being eligible for a test is met — which has changed dramatically in the United States over time.
- The person or their physician decides to get a test — this has varied by perceived availability, actual availability, the person's own mind set, whether motivated by having symptoms, how worried they are, and political outlook.
- The quality for the test.

• Whether or not a combination of factors, such as symptoms, tests, and test followup are a criteria for counting a case.

The first letter I sent to the county official on COVID-19 dealt with the data being used for public health decisions and the challenges in understanding how to interpret the news (Olsen March 2020). It is a real problem, the government, people, and the new media reacting to data when the hear it and see it, while not taking into account the factors that drive it, nor the delay between what is measured and the data. While this is par for the course in Operations Research and modeling systems, most people are not aware of it. Even if you know about feedback delays, it is hard not to react to information as if it is current at the time you see it. This, over course, underlies the data the paper is processing.

The correlation of cases to these government policy and personal choice factors is so confounding that I have trouble finding any correlation of an intervention with cases useful. As you can see in the following chart, there appears to be loose correlation between tests and cases in a scattergram which one would assume would have no correlation at all if case rates reflected only actual infection rates

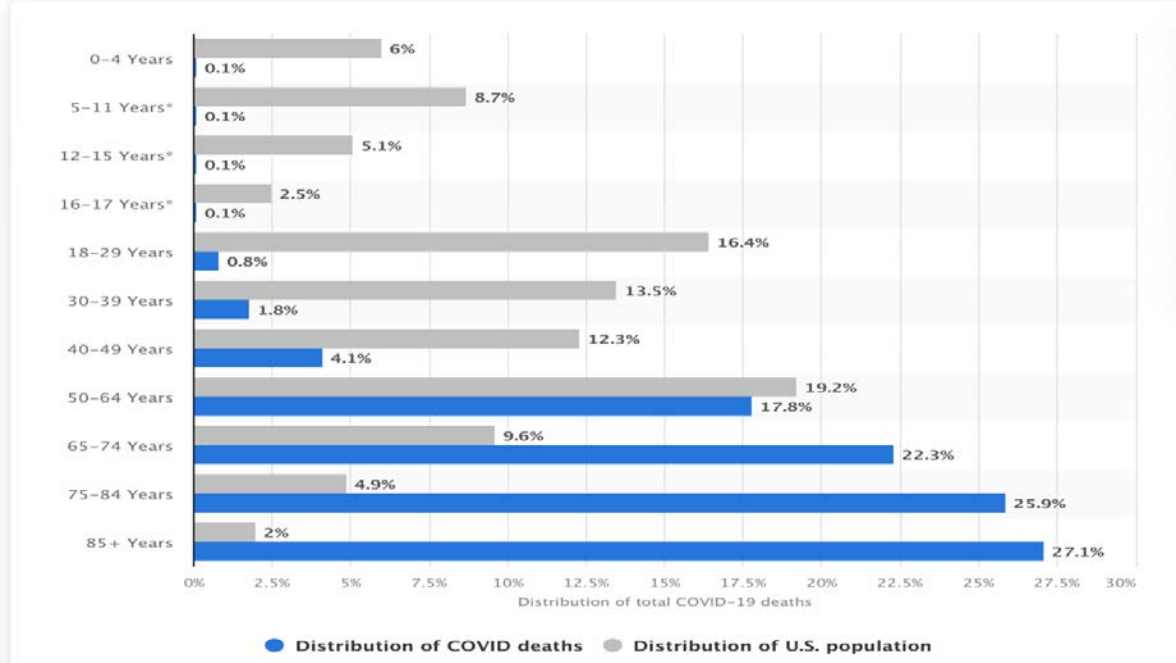


The Paper should incorporate basic principles of Epidemiology

The BigData analysis in the paper, its big problem is that it ignores all of the years of learning and extensive literature of the paper's subject, epidemiology. Epidemiology is the study of the nature and control of diseases, the very subject on which your paper deals with.

The problem with this approach is that epidemiological problems have so many interdependencies and confounding factors — all of which are ignored by this paper and taken into account on nearly all other peer reviewed COVID-19 papers. While a general correlation may be noted, the approach used does not show a "causal" relationship. I recommend a general reference such as (Woodward, *Epidemiology: Study Design and Data Analysis* 2014) that deals with the analysis methods of epidemiology that should underpin the methods used. There is a whole chapter on Confounding and Interaction which would be well worth reading.

The first letter I sent to the county official on COVID-19 dealt with the problematic data and the challenges in understanding how to interpret the news, (Olsen March 2020).



In most of the epidemiological literature, the nature of the data is accounted for. For example, most papers do an "age adjusted" of the statistic when comparing their sample population with norm. The age distribution across counties varies quite a bit, so that an apples-to-apples must account for the nature of COVID-19 deaths which is highly correlated with age.

The death rate is affected by other government interventions that vary over time and by county. This non-random input cannot be ignored. There is evidence, which I won't cite here, that lockdowns work, mask mandates don't. But mask mandates change the texture of many people's interactions, some going to crowded stores less often and so on. This is a sophisticated subject that, at its core, involves the texture of human behavior in response to information that they are exposed to, most of it flawed from whatever source or side it comes from.

Some examples of interventions that affect the data at least as much as any vaccine program. One example is China. China has a Zero-COVID policy so that after the Wuhan, lockdown, even a few cases has gotten a rather draconian shutdown, though it is not clear that this policy is going to work in the long run. (Lee 2022). It seems more likely that the population of China has less exposure to COVID-19, fewer asymptomatic exposers which would lead to a higher proportion of people with antibodies than in the United States or Canada. So the correlation of vaccines in China with death rates is confounded and may be quite different that the United States or Canada.

The Paper should discuss related studies in the literature

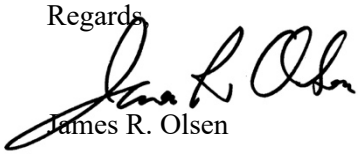
Finally, a survey of the literature would be useful, other than simply citing papers that used similar methods. There are a number of papers that provide evidence of reduced hospitalizations for people who are vaccinated (Two examples: Jucker 2022, Washington Dept of Heath 2022). Of course, one must be careful to compare the percent of hospitalized patients who are vaccinated with the vaccination rate of the entire population. Or better, do an age-adjusted comparison to match vaccination rates by age group with vaccination status in the hospital.

Doctor Mercola, in a column in the *Epoch Times*, cited a UK study where he ignored that comparison, saying "9 in 10 COVID Deaths Are in Vaccinated People: Report." (Mercola 2022). That shocking headline came from a UK report he cited (which had a hyperlink in the *Epoch Times* a practice I wish all news medias would practice). The UK report contains data that well over 90% of the older population had been vaccinated. It also shows decreasing vaccine effectiveness over time, confirming one of your statements. (UK Health Security Agency 2022). As I was going to comment in the social media side bar that "99% of automobile accidents are caused by gasoline power cars" someone beat me to it.

The very attempt at look only at vaccine policy does not seem to be a valid application of the statistical method used. At best it can only suggest a possible correlation and cannot claim a causal effect.

I think I will stop here. On the one hand I feal obliged to comment to our local government on your paper, on the other I hope this provides some help. I applaud your stated desire to focus on corruption and think it could lead to fascinating and useful research.

Regards,



James R. Olsen

ENDNOTES

[1] After agreeing to help a grassroots group get organized around a highway expansion from 2 to 4 lanes, I got hooked when I saw the engineering. The Highway industry showed an institutional bias to expanding capacity — that's OK with me until it biases the literature. It is common in DOT literature to look at accident statistics for particular stretches of highway, writing studies about how highway design features related to safety. Invariably the standard for a characterizing the safety performance of a highway is a polynomial curve fit, using features familiar to the industry such as lane width, shoulders, turning movements, and average daily traffic.

One of the issues was, "Is an undivided 4-lane safer than a 2-lane?" At one point DOT handed me a draft study from a university professor that said, among other things, that if you increase capacity by adding lanes the highway is safer. There, sitting in the polynomial curve fit equation is a negative Average Daily Traffic exponent. In other words, a curve fit improved safety if the capacity went down. After being blown off by DOT, I wrote to the Dean as the university. It didn't make any difference in our political argument, but the final paper did change.

Many people had "Pray for me I drive 93" bumper stickers on their cars. The assumption was that it was one of the, or the most, dangerous roads in the country. The data showed otherwise, performing a bit better that average for 2-lane roads in the U.S. And when I compared the risk metric – accidents per mile driven — it performed much better than the average county road.

When I thought about this, two things became clear.

1) Because there is more traffic on the Highway 93 arterial, there are more accidents. Thus, more people would see an accident on 93 than a fatal roll over on a back country road.
2) When you get ready to pass on a two lane when there is an oncoming car, your attention rises, your heart rate increases, your hands grip the steering wheel a little tighter — you focus on avoiding the calamity of a head on collision. So, it is experienced as a dangerous situation — it seems natural to associate a dangerous situation with more accidents. But, in 5 years of traffic reports, there was not a single passing accident. The few head-ons were drunk drivers or drivers asleep. Most accidents were cars going in different directions.

What is important here, in terms of COVID-19, is 1) that the data does not necessarily match the fear, and 2) people modify their behavior, such as paying extra attention when passing, to avoid risk.

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