

Short Note

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Avoidable Intensive Care Resource Use of Unvaccinated COVID-19 Patients: Interpretation and Ethically Defensible Policy Implications

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Abstract: Given that population COVID-19 vaccination does not appreciably reduce SARS-CoV-2 transmission, instead, the potential to reduce hospitalization has been used to justify coercive vaccine passports. We aim to use a recently published research study as an example in order to demonstrate how data can be misinterpreted and result in deriving misleading ethical and policy implications. Bagshaw et al. wrote that unvaccinated patients with COVID-19 in Alberta, Canada "had substantially greater rates of ICU admissions, ICU bed days, and ICU related costs than vaccinated patients did. This increased resource use would have been potentially avoidable had these unvaccinated patients been vaccinated." The authors in Bagshaw et al. then concluded that their findings "have important implications for discourse on the relative balance of increasingly stringent public health protection (restrictions), including mandatory vaccination policies, and the sustainability and function of health system infrastructure and capacity during the ongoing COVID-19 pandemic." Here we show the following. First, the effect of vaccination on intensive care admissions were grossly over-estimated due to several limitations of this and almost all other vaccine studies. Second, an effect of vaccination on access to acute care and on all-cause excess deaths was grossly over-stated due to several more likely causes being omitted from discussion and from the common narrative. Third, policy implications were overstated and at best unclear due to missing consideration of more relevant aspects required to inform policy. Overall, the data cannot support what Bagshaw et al. called "increasingly stringent public health protection (restrictions), including mandatory vaccination policies".

Keywords: COVID-19; Intensive Care Unit; Policy; Resource Use; Vaccination

Given that population COVID-19 vaccination does not appreciably reduce SARS-CoV-2 transmission, instead, the potential to reduce hospitalization has been used to justify coercive vaccine passports [1]. For example, the authors in Bagshaw et al. concluded that unvaccinated patients with COVID-19 in Alberta "had substantially greater rates of ICU admissions, ICU bed days, and ICU related costs than vaccinated patients did. This increased resource use would have been potentially avoidable had these unvaccinated patients been vaccinated ([2] p. 1400)." Using this publication as an example, we aim to demonstrate how data and policy implications can be misinterpreted. This is important for healthcare ethics, as the most ethically defensible policy decisions must first be informed by accurate cost-benefit analysis.

Effect of Vaccination on ICU Admissions Over-Estimated

First, the study by Bagshaw et al. used "publicly available age-stratified aggregate data on COVID-19 infections, vaccination status, and health service use provided by Alberta Health ([2] p. 1401)." A major error in this data was misattribution of vaccination status. Those single- or double-dose vaccinated within 14 days were considered in the unvaccinated or partially vaccinated group respectively. This violates a cardinal principle of interventional studies, the intention to treat principle. Statisticians have shown that this misattribution error alone can account for an apparent

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high placebo-vaccine efficacy for adverse outcomes [3–5]. The effect of this error is exacerbated if a vaccine increases the risk of COVID-19 infection via immunosuppression in those first 2 weeks, which occurs with the mRNA COVID-19 vaccines [6–8]. The effect of this error is further exacerbated if there is delay in reporting of ICU admissions; it is unclear if ICU admission data was backdated for the day of infection, and since this was unlikely, the ICU data was shifted about 1 week from infection date [9,10]. The effect of this misattribution error on causing grossly overestimated COVID-19 vaccine efficacy has been shown using real-world data from Israel and the United Kingdon [11,12]. The data used in the Bagshaw et al. study [2] is no longer publicly available from Alberta Health Services, making correction for these errors impossible.

Second, the study did not report what proportion of ICU admissions with COVID-19 were due to an acute COVID-19 infection. Other reports in North America have found that often 50 per cent of hospitalizations and 25 per cent of ICU admissions with COVID-19 were not due to a COVID-19 infection; that is, the COVID-19 diagnosis was incidental to the reason for admission [13,14].

Third, there was no adjustment for confounding variables. In RCTs (the best method to balance potential confounding variables) of the mRNA COVID-19 vaccines, no effect on all-cause mortality was found; the vaccines reduced COVID-19 deaths but increased other deaths [15]. Confounders such as co-morbidities, community transmission rates, exposure behaviors, and others, were not available so not adjusted for [16]. More difficult to adjust for are clinician behavior biases; for example, unvaccinated patients may be more likely to be admitted to ICU because clinicians believed they were higher risk to deteriorate [16]. Age bias (older people recorded lower infection rates, and were also prioritized for vaccination), and background infection rate bias (vaccine dissemination coincided with a period of decreasing infection rates, leading to unbalanced exposure times between vaccinated and unvaccinated individuals) also can lead to the illusion of high (as high as 50–70%) placebo vaccine efficacy [5]. The healthy vaccinee effect, a type of selection bias where healthier and more health-conscious people obtain the vaccine, was also likely [17,18]. For example, people with symptoms of COVID-19 were told to wait when eligible for vaccine, and so were included in the unvaccinated cohort [19]. Studies finding that VE against non-COVID-19 mortality was over 50% are not plausible unless there was a health vaccinee bias [20]. Adjusting for many confounders has historically, for the influenza vaccine, not been able to correct for the healthy vaccinee bias [21,22].

Fourth, adverse effects of vaccines were not considered for a cost-benefit analysis. Were more vaccinated than unvaccinated patients admitted to hospital or ICU for non-COVID-19 reasons? What was age-stratified population all-cause mortality in those who had been vaccinated compared to unvaccinated? Excess mortality for non-COVID reasons has increased in several highly vaccinated jurisdictions, not clearly due to overwhelmed healthcare capacity [23,24]. Myocarditis in young adult males is caused by mRNA vaccination [25–27], much more than from COVID-19 infection itself [28–30], and may be why EMS calls in Israel for cardiac arrest and acute coronary syndrome increased by 25 per cent in young adults during vaccination rollout [and not during previous COVID-19 waves] [31].

Effect of Vaccination on Access to Acute Care and All-Cause Excess Deaths Unlikely

The authors in Bagshaw et al. wrote that there was "a baseline of 173 funded ICU beds" in Alberta," as asserted by Alberta Health Services later in the pandemic ([2] p. 1402). However, previous publications, by some of the same authors, gave different figures, ranging from 351 to 430 funded adult ICU beds in Alberta [32,33]. In 2015 the authors published an estimate of 268 publicly funded adult ICU beds in the year 2010 [34]. Checking publicly available websites for each ICU in Alberta gave a figure for publicly funded adult ICU capacity of 281 beds (Table 1). It is not clear whether ICU capacity was increased in Alberta during the pandemic; it appears more likely that current ICU resources were simply reallocated in unclear ways. This questions the assertion made in Bagshaw et al. that excess mortality may be attributable to "heart disease, diabetes, and nonrespiratory related disease... related to delayed or impeded access to acute care..." for several reasons ([2] p. 1403).

Table 1. Alberta Intensive Care Unit baseline (pre-pandemic) funded bed capacity.

ICU Name	Location	ICU Type	Hospital Type	Hospital Classification (CIHI) ^a	Funded Adult ICU Beds	Website Where Funded Beds Data Obtained
Foothills Medical Center Multi-Systems ICU	Calgary	Mixed (medical, surgical, neurosurgical, trauma)	Academic	Teaching	28	https://cumming.ucalgary.ca/departments/critical- care/locations/foothills-medical-centre
Foothills Medical Centre CVICU	Calgary	Cardiovascular surgical	Academic	Teaching	22	https://cumming.ucalgary.ca/departments/critical- care/locations/fmc-cardiovascular-intensive-care-unit
University of Alberta Hospital General Systems ICU	Edmonton	Mixed (medical, surgical, trauma, transplant)	Academic	Teaching	28	https://www.ualberta.ca/critical-care/about-us/critical-care-units.html
University of Alberta Neuro ICU	Edmonton	Neurosciences	Academic	Teaching	15	https://www.ualberta.ca/critical-care/about-us/critical-care-units.html
Mazankowski Alberta Heart Institute CVICU	Edmonton	Cardiovascular surgical	Academic	Teaching	24	https://www.ualberta.ca/critical-care/about-us/critical-care-units.html
Peter Lougheed Hospital ICU	Calgary	Mixed (medical, surgical, vascular)	Tertiary	Teaching	18 [plus 4 flex]	https://cumming.ucalgary.ca/departments/critical- care/locations/peter-lougheed-centre
Royal Alexandra Hospital ICU	Edmonton	Mixed (medical, surgical, trauma)	Tertiary	Teaching	25	https://www.ualberta.ca/critical-care/about-us/critical-care-units.html
Rockyview General Hospital ICU	Calgary	Mixed (medical, surgical)	Community	Teaching	17 (7 are CCU)	https://cumming.ucalgary.ca/departments/critical- care/locations/rockyview-general-hospital
South Health Campus ICU	Calgary	Mixed (medical, surgical)	Community	Community large	12 (2 are CCU)	https://cumming.ucalgary.ca/departments/critical- care/locations/south-health-campus
Sturgeon Community Hospital ICU	St. Albert	Mixed (medical, surgical)	Community	Community large	5 [plus 3 High Intensity beds]	https://www.ualberta.ca/critical-care/about-us/critical-care-units.html
Grey Nuns Community Hospital ICU	Edmonton	Mixed (medical, surgical, vascular)	Community	Teaching	8	https://www.ualberta.ca/critical-care/about-us/critical-care-units.html
Misericordia Community Hospital	Edmonton	Mixed (medical, surgical)	Community	Teaching	10	https://www.ualberta.ca/critical-care/about-us/critical-care-units.html
Medicine Hat Regional Hospital ICU	Medicine Hat	Mixed (medical, surgical)	Regional	Community large	10 (2 are CCU)	https://medicinehatnews.com/news/local- news/2021/09/16/icu-struggles-to-keep-up-with-covid- crisis/
Northern Lights Health Centre ICU	Fort McMurray	Mixed (medical, surgical)	Regional	Community medium	6	https://www.fortmcmurraytoday.com/news/not-a-day-we-are-not-busy-icu-doctor-on-fighting-covid-19-at-nlrhc
Chinook Regional Hospital ICU	Lethbridge	Mixed (medical, surgical)	Regional	Community large	14 (probably 4 are CCU)	https://www.albertahealthservices.ca/assets/about/scn/ahs-scn-cc-icu-delirium-ls3-poster-chinook-lethbridge.pdf

Grande Prairie QEII Regional Hospital	Grande Prairie	Mixed (medical, surgical)	Regional	Community large	6	https://everythinggp.com/2021/09/10/qeii-hospital-continuing-to-experience-pressure-from-covid-19-patients/
Red Deer Regional Hospital ICU	Red Deer	Mixed (medical, surgical)	Regional	Community large	18 (6 are CCU)	https://www.albertahealthservices.ca/assets/about/scn/ahs-scn-cc-icu-delirium-ls3-poster-rdrh-icu.pdf
University of Alberta Hospital Burn Unit	Edmonton	Burn	Academic	Teaching	4 [plus 4 High Intensity beds]	https://www.ualberta.ca/critical-care/about-us/critical-care-units.html
TOTAL FUNDED ADULT ICU BEDS	Alberta	All	All	Combined	270 [plus 11 flex or high intensity] ^c	-
FUNDED PICU/PCICU BEDS ^b	Alberta	Stollery Children's Hospital PICU and PCICU, Alberta Children's Hospital PICU	Academic	Teaching	15, 16, and 15 respectively = 46	https://www.ualberta.ca/pediatrics/divisions/critical-care- picu.html; https://cumming.ucalgary.ca/departments/pediatrics/sections/critical-care
TOTAL POTENTIAL FUNDED ADULT ICU BEDS	Alberta	All	All	Combined	327	Combined

Abbreviations: ICU = intensive care unit; PICU: Pediatric Intensive Care Unit; PCICU: Pediatric Cardiac Intensive Care Unit. The table is modified from Supplemental Table 1 in Bagshaw et al. 2022a [30], with the last two columns and last four rows added. a. Hospitals were categorized by Canadian Institute of Health Information (CIHI) by hospital type as follows: teaching (full membership in the Association of Canadian Academic Healthcare Organizations; any size), large (≥200 beds), medium (50–199 beds), and small (1–49 beds) community hospitals. b. These PICU and PCICU beds are capable of caring for young adults [i.e., those that are lower risk for adult-specific diseases, particularly lower risk for coronary artery disease and severe COPD]. c. Compared to the number of adult ICU beds pre-pandemic on the Alberta COVID statistics website of 173 [see: https://www.alberta.ca/stats/covid-19-alberta-statistics.htm#healthcare-capacity (Accessed 13 October 2021)]. This seems to include adult and pediatric ICU beds, given that the tables of ICU admissions on the website include pediatric patients in an ICU. The 'surge capacity' had increased on 14 September 2021, to 297 ICU beds, and by 5 October 2021, to 374 ICU beds [with 69 unoccupied, leaving 305 beds occupied]. Occupied beds on October 5, 2021, were 305/173 = 176% occupancy; however, if there were 327 beds at baseline, this is 305/327 = 93% occupancy.

First, it is more likely that these excess deaths were related to lockdowns causing loneliness, depression, anxiety, unemployment, lack of exercise, poor diet, weight gain, and increased substance use, factors known to significantly increase mortality from these non-communicable diseases (reviewed in [35]). This is important for two reasons. Intensive care for complications of "heart disease, diabetes, and nonrespiratory related disease" is often not successful, and the best outcomes involve primary care that emphasizes avoiding the exact risk factors exacerbated by lockdown policies. Moreover, research has found that lockdowns were not effective at reducing COVID-19 cases in the population, yet had these profound adverse effects (reviewed in [36–38]; see also [39]).

Second, it is more likely that these excess deaths, to the extent they may be related to delayed acute care, were due to fear of COVID-19 inculcated in the population [40], and to cruel hospital visitation policies [41–43], factors that prevented people from seeking healthcare for any condition. These excess deaths were due to policies, and not the COVID-19 pandemic itself.

Third, it is possible that had ICU capacity been increased in Alberta, some of these excess deaths would have been avoided. Working on increased capacity (without simply cancelling what Bagshaw et al. called "non-emergent services including scheduled procedures and surgeries" ([2] p. 1400) was the main priority for public health, Alberta Health Services, and medical experts, or at least it should have been. Making policies such as lockdowns and mandatory vaccination was not their priority, and rather should have been coordinated by Emergency Management Agencies that were trained to consider all costs and benefits of any public policy [38,44]. When the Bagshaw et al. study started [2], on 6 September 2021, there had been seventeen months since the start of the pandemic to prepare needed surge capacity at Alberta hospitals.

Policy Implications at Best Unclear

The authors in Bagshaw et al. concluded that their findings "have important implications for discourse on the relative balance of increasingly stringent public health protection (restrictions), including mandatory vaccination policies, and the sustainability and function of health system infrastructure and capacity during the ongoing COVID-19 pandemic ([2] p. 1403)." We are not so sure.

First, "increasingly stringent public health protection (restrictions)" have not translated into better control of COVID-19 cases nor healthcare infrastructure (reviewed in [36–38], see also [39]). Similarly, "mandatory vaccination policies" in Canada and the United States have not translated into meaningful increases in population vaccination rates (i.e., generally < 1 per cent absolute increases) [45,46]. Policies should be based on transparent and accurate cost-benefit data, yet, as discussed above, the data in Bagshaw et al. [2] was mostly not interpretable, not publicly available (and when publicly available, did not give enough detail to allow an intention to treat analysis), did not consider health costs to mandatory vaccination [25,47,48], and contained no data regarding effects of restrictions or mandatory vaccinations.

Second, policy must be based on more than healthcare information. Considerations include effects on sectors of society other than healthcare, inequality, human rights, and other determinants of population well-being. This detailed cost-benefit analysis requires diverse stakeholders and coordination by an emergency management agency [35,38,44].

Third, if Bagshaw et al. [2] data informs a policy to mandate citizens be vaccinated (because we have concluded that they are using hospital resources due to health decisions we disagree with), then better data suggests this principle should be extended to other disorders. Many health decisions are far more impactful on hospital resource use than is the choice to be unvaccinated. In Canada, there were more hospital admissions due to alcohol use than due to heart attacks—should we enforce no-alcohol mandates [49]? Cigarette smoking was responsible for over 2.2 million days in acute care hospital beds in Canada yearly (at a cost over \$2.5 billion in 2002)—should we enforce no-smoking mandates [50]? Poor diets can lead to diabetes, cardiovascular disease, cancer, obesity, and early death; the WHO has estimated that if all people adopted a vegan diet this would avert approximately 13.7 million deaths by 2030—should we mandate dietary choices [51]? Should we micromanage

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patients' life decisions aiming for "the sustainability and function of health system infrastructure and capacity" ([2] p. 1403)?

Fourth, we suggest that the ICU physician's view can be too skewed to make policy. They daily see rare cases, drawn from a large region and concentrated on their unit. From that point of view, unjustified perceptions of risk can occur. The median infection fatality rate (IFR) from SARS-CoV-2 infection, prior to vaccines, was 0.034 per cent for age 0-59 years, and 0.095 per cent for 0-69 years [52]. The median IFR by age group was a median 0.0003 per cent at zero to nineteen years, 0.002 per cent at twenty to twenty-nine years, 0.011 per cent at thirty to thirty-nine years, 0.035 per cent at forty to forty-nine years, 0.123 per cent at fifty to fifty-nine years, and 0.506 per cent at sixty to sixty-nine years of age [52]. For those under seventy years of age this is 0.33 per cent/0.095 per cent = 3.5 times lower than the case fatality rate in Canada in March, 2021; correcting for this difference between case and infection outcome rates, the infection hospitalization and ICU admission rates for those under seventy years in May, 2021 in Canada were 3.0 per cent/3.5 = 0.86 per cent and 0.7 per cent/3.5 = 0.2percent respectively [38] (and with Omicron variants is now likely three to five times lower) [53,54]. From a public health lens, serious outcomes from SARS-CoV-2 are rare in those under seventy years of age. Adults over age 70 years are at higher risk, with those living in the community having median IFR (before vaccines and Omicron variants) 2.2 per cent [55]; focused protection, especially in those with multiple co-morbidities, should be offered.

What Would We Suggest?

In a public emergency, decisions should be based on the Emergency Management (EM) process, which is coordinated by trained Emergency Management Agencies (EMA), to achieve four simultaneous critical functions: prevention and mitigation of, preparedness for, response to, and recovery from the emergency, regardless of the risk/hazard [38,44,56]. The EM process is the same regardless of hazard, and the steps to follow are shown in Table 2, along with failures during this process that we believe can be attributed to non-EM experts (that is, medical officers of health and medical "experts") leading the response [38,44,57,58]. Others have suggested similar failings without recognizing that their recommendations were already inherent in the EM process [59–61]. We believe the robust EM process would have detected and remedied the errors discussed above.

Table 2. The steps of the Emergency Management process, and suggested failures of this process during the SARS-CoV-2 pandemic.

Emergency Management Step	Ideal	Suggested Failure
1. Identification of the hazard	SARS-CoV-2	-
2. Selection and maintenance of the aim	To minimize the impact of SARS-CoV-2 on the society as a whole in the jurisdiction.	To "flatten the curve", "eradicate the virus", or "protect the medical system from COVID-19" while awaiting a novel vaccine. Eradication of a widespread respiratory virus was not feasible. Protecting healthcare may be an objective in the mission analysis but is not the overall aim. To properly test (in RCTs) a novel vaccine in order to determine safety and efficacy takes far too long to be considered in the overall aim.
3. Establish a Governance Task Force, to provide leadership for all policy, programs, and actions taken	Involve highly diverse stakeholder representation, coordinated, and supported by the EMA, and led by the most senior government official of the jurisdiction.	<u> </u>
4. Risk/Hazard Assessment	Very early it was known that risk was extremely age-dependent (high-risk in older adults with multiple	

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comorbidities), and there were predictable risks to critical infrastructure (including healthcare).

not discriminate". This led to fear, inaccurate individual risk assessment, and extreme responses.

Tasks given (pre-written pandemic response plans) (i) focused protection of those most vulnerable (older people, especially those with multiple comorbidities or in long-term care facilities); (ii) protection of socially vulnerable groups (e.g., temporary housing support to reduce household crowding); (iii) communicate risk in context, difficult trade-offs, and justification for focused protection, (iv) protect critical infrastructure and essential services (e.g., new medical surge capacity, full continued education, continuity of business and economy), (iv) ensure private sector business operations through use of existing business continuity plans to the maximum extent possible, (v) minimize the economic impact on citizens, businesses, and government, and (vi) maximize the use of all resources through efficient use, mutual 5. Mission Analysis to determine aide, and cooperative purchasing, Tasks implied (based on risk assessment): (i) maintain confidence in government (e.g., diminish fear, ensure public has access to a fully written government pandemic response plan with the public

encouraged to provide feedback,

ensure mutual aid, maintain Charter

process to develop a recovery plan

in the SARS CoV-2 virus, to monitor all developing treatments worldwide for SARS CoV-2, and to monitor outbreaks in non-human hosts), (iii) ensure constant communications (e.g., in support of the public, of industry, and of government operations) and iv) maintain a transparent accounting of the financial management of the

Tasks given (pre-written pandemic response plans) seem to have been discarded. This led to distorted objectives, including: (i) fear, which was induced in the population, often to ensure compliance with measures; (ii) inaccurate risk assessment, often presenting raw case counts without denominators, age group and comorbidity, or comparison to other daily risks; (iii) misunderstanding of healthcare surge capacity, which led to creating capacity by sacrificing healthcare for conditions other than COVID-19 (instead of ensuring continuity of the medical system by creating new surge capacity to manage COVID-19 cases); (iv) inaccurate assessment of education as a non-essential service, leading to school closures. Tasks implied: inaccurate risk Rights and Freedoms, demonstrate the assessment led to one predominant distorted objective, to prevent following the pandemic with a defined COVID-19 cases (to the exclusion of operate a Covid-19 specific intelligence all else) by ending social interactions. service (e.g., to monitor developments

what needs to be done: objectives transportation and distribution. in managing the hazard

6. Defining courses open/options to determine how the mission analysis objectives can be met

pandemic response. Determine courses open for each grouping of tasks, as determined by assigning teams with appropriate diverse expertise (to prevent groupthink). Each course open has full 'experts'. Adequate consideration of assessment of cost-benefit to justify

Only courses open for protecting the healthcare system from COVID-19 cases were considered, led by medical officers of health and medical predictable collateral damage was not

	options, and plan for solutions to expected collateral damage. Acknowledge inadequate evidence when this occurs, and, if this leads to implementing an intervention, the intervention is time-limited with robust study of effectiveness. Plans evaluated for each objective, including how to diminish fear; create healthcare surge capacity; maintain continuity of education, business, and	
	economy; implement focused	
	protection; communicate risk; ensure	
	confidence in government.	
7. Public issuing of a written	Forms the basis of confidence in	No plan issued, making both
comprehensive evidence-based	government: transparent	imposition and revocation of rules
Response Plan	demonstrably justified due diligence.	seem arbitrary to the public.
	Seek public feedback. Consider new	Rejected information contrary to the
8. Repeat the ongoing process	information as it accrues (modify	chosen courses open by censoring as
	ongoing steps 3–7 as indicated).	'misinformation'

Conclusions

Although we used Bagshaw et al. [2] as an example, we believe the arguments we make apply in general to similar claims that coercive public SARS-CoV-2 vaccination is warranted to save healthcare capacity. First, the effect of vaccination on intensive care admissions can be grossly overestimated due to misattribution errors, conflating "with COVID" for "from COVID", lack of adjustment for confounders, and not fully considering cost-benefit analysis. Second, an effect of vaccination on access to acute care and on all-cause excess deaths can be grossly over-stated if certain factors are not considered, including the adverse effects of lockdowns, induction of fear in the population, cruel hospital visitation policies, and lack of attention to creating healthcare surge capacity. Third, policy implications can be overstated for several reasons including not considering real-world data on the (lack of) efficacy of increasingly stringent lockdowns and mandatory vaccination policies, full cost-benefit analysis, implications for other medical disorders, and the overall very low risk for serious outcomes from SARS-CoV-2 in people under seventy years old. We believe that these points are extremely important, as accurate empirical data is necessary to inform deliberations about the most ethically defensible policy decisions, and inaccurate data can lead to devastating consequences.

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Compliance with ethical standards: This research did not require ethical approval, using only publicly available published literature.

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References

- 1. Kraaijeveld, S.R. The ethical significance of post-vaccination COVID-19 transmission dynamics. *Journal of Bioethical Inquiry*. https://doi.org/10.1007/s11673-022-10223-6.
- 2. Bagshaw, S.M., Abbott, A., Beesoon, S., et al. (2022). Avoidable intensive care unit resource use and costs of unvaccinated patients with COVID-19: a historical population-based cohort study. *Canadian Journal of Anaesthesia*, 69(11), 1399-1404. https://doi.org/10.1007/s12630-022-02299-w.
- 3. El Gato Malo. (2022, January 12). Bayesian datacrime: Defining vaccine efficacy into existence. How the definitions of "full vaccinated" and now "boosted" are exaggerating (and possibly creating from whole cloth) VE and turning the data into gibberish. *Bad Cattitude, Substack*. Retrieved April 9, 2023, from https://boriquagato.substack.com/p/bayesian-datacrime-defining-vaccine.
- 4. Fenton, N., & Neil, M. (2021, December 1). The impact of misclassifying deaths in evaluating vaccine safety: the same statistical illusion. *Probability and Risk*. Retrieved April 9, 2023, from http://probabilityandlaw.blogspot.com/2021/12/the-impact-of-misclassifying-deaths-in.html.
- 5. Fung, K., Jones, M., & Doshi, P. (2023). Sources of bias in observational studies of covid-19 vaccine effectiveness. *Journal of Evaluation in Clinical Practice*. https://doi.org/10.1111/jep.13839.
- 6. Craig, C. (2021). Covid-19: Stronger warnings are needed to curb socializing after vaccination, say doctors and behavioural scientists. Rapid Response. Thinking beyond behavioural change as an explanation for increased COVID post vaccination. *British Medical Journal*, 372, n783. Available at: https://www.bmj.com/content/372/bmj.n783/rapid-responses.
- 7. El Gato Malo. (2022, January 20). Alberta gets caught palming cards on Covid vaccine efficacy. And we get real quantification on the size of the definitional datacrime. It shocked even me. *Bad Cattitude, Substack*. Retrieved April 9, 2023, from https://boriquagato.substack.com/p/alberta-gets-caught-palming-cards.
- 8. Moustsen-Helms, I.R., Emborg, H.D., Nielsen, J., et al. (2021). Vaccine effectiveness after 1st and 2nd dose of the BNT162b2 mRNA Covid-19 vaccine in long-term care facility residents and healthcare workers–a Danish cohort study. *medRxiv*, Preprint. https://doi.org/10.1101/2021.03.08.21252200.
- 9. Fenton, N., & Neil, M. (2021, November 14). Is vaccine efficacy a statistical illusion? *Probability and Risk*. Retrieved April 9, 2023, from http://probabilityandlaw.blogspot.com/2021/11/is-vaccine-efficacy-statistical-illusion.html.
- 10. Fenton, N., & Neil, M. (2021, December 3). Possible systematic miscategorization of vaccine status raises concerns about claims of Covid-19 vaccination effectiveness. *Probability and Risk*. Retrieved April 9, 2023, from http://probabilityandlaw.blogspot.com/2021/12/possible-systematic-miscategorisation.html.
- 11. El Gato Malo. (2022, December 30). NEJM proves that COVID vaccine study methodologies are rigged. Sometimes a study winds up proving something far more interesting than it intended. *Bad Cattitude, Substack*. Retrieved April 9, 2023, from https://boriquagato.substack.com/p/nejm-proves-that-covid-vaccine-study.
- 12. Neil, M., Fenton, N., Smalley, J., et al. 2022. Official mortality data for England suggest systematic miscategorisation of vaccine status and uncertain effectiveness of Covid-19 vaccination. *ResearchGate*, Preprint. https://doi.org/10.13140/RG.2.2.28055.09124.
- 13. Fillmore, N.R., La, J., Zheng, C., et al. (2022). The COVID-19 hospitalization metric in the pre- and postvaccination eras as a measure of pandemic severity: A retrospective, nationwide cohort study. *Infection Control and Hospital Epidemiology*, 43(12), 1767-1772. https://doi.org/10.1017/ice.2022.13.
- 14. Gutentag, A. (2022, January 30). COVID affects your memory. Masks have never worked. Testing has always been problematic. Kids were never high-risk. The past has never been altered. Welcome to the COVID consensus, circa midterms 2022. *Tablet Magazine*. Retrieved on April 9, 2023, from https://www.tabletmag.com/sections/news/articles/covid-affects-your-memory.
- 15. Benn, C.S., Schaltz-Buchholzer, F., Nielsen, S., Netea, M.G, & Aaby, P. 2022. Randomized clinical trials of COVID-19 vaccines: Do adenovirus-vector vaccines have beneficial non-specific effects. *SSRN*, Preprint. https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4072489.
- Ioannidis, J.P.A. (2022). Factors influencing estimated effectiveness of COVID-19 vaccines in nonrandomized studies. BMJ Evidence-Based Medicine, 27(6), 324-329. https://doi.org/10.1136/bmjebm-2021-111901
- 17. Hama, R. (2021). Rapid response: The risk of vaccination may be higher by considering "healthy vaccinee effect". *British Medical Journal*, 375, e068665. Available at: https://www.bmj.com/content/375/bmj-2021-068665/rapid-responses.
- 18. Watanabe, S., & Hama, R. (2022). SARS-CoV-2 vaccine and increased myocarditis mortality risk: A population based comparative study in Japan. *medRxiv*. Preprint. https://doi.org/10.1101/2022.10.13.22281036.
- 19. Fenton, N., & Neil, M. 2023. The Lancet and the Pfizer vaccine. A case study in academic censorship and deceit in the Covid era. *ResearchGate*. Preprint. https://doi.org/10.13140/RG.2.2.29792.56321.

- 20. Xu, S., Huang, R., Sy, L.S., Hong, V., Glenn, S.C., Ryan, D.S., et al. (2023). A safety study evaluating non-COVID-19 mortality risk following COVID-19 vaccination. *Vaccine*, 41(3), 844-854. https://doi.org/10.1016/j.vaccine.2022.12.036.
- 21. Simonsen, L., Taylor, R.J., Viboud, C., Miller, M.A., & Jackson, L.A. (2007). Mortality benefits of influenza vaccination in elderly people: an ongoing controversy. *Lancet Infectious Diseases*, 7, 658-666. https://doi.org/10.1016/S1473-3099(07)70236-0.
- 22. Remschmidt, C., Wichmann, O., & Harder, T. (2015). Frequency and impact of confounding by indication and healthy vaccinee bias in observational studies assessing influenza vaccine effectiveness: a systematic review. *BMC Infectious Diseases*, 15, 429. https://doi.org/10.1186/s12879-015-1154-y.
- 23. Kuhbandner, C., & Reitzner, M. (2022). Excess mortality in Germany 2020-2022. *Research Gate*, Preprint. https://doi.org/10.13140/RG.2.2.27319.19365.
- 24. Meester, R., Aukema, W., & Schetters, T. (2021). COVID-19 vaccinations and mortality—a Bayesian analysis. *ResearchGate*, Preprint. https://doi.org/10.13140/RG.2.2.34443.21285.
- 25. Bardosh, K., Krug, A., Jamrozik, E., et al. (2022) Covid-19 vaccine boosters for young adults: A risk benefit assessment and ethical analysis of mandate policies at universities. *Journal of Medical Ethics*. https://doi.org/10.1136/medethics-2022-108449.
- 26. Knudsen, B., & Prasad, V. (2023). COVID-19 vaccine induced myocarditis in young males: A systematic review. *European Journal of Clinical Investigation*, 53, e13947. https://doi.org/10.1111/eci.13947.
- 27. Li, X, Lai, F.T.T., Chua, G.T., et al. (2022). Myocarditis following COVID-19 BNT162b2 vaccination among adolescents in Hong Kong. *Journal of the American Medical Association Pediatrics*, 176(6), 612-614. https://doi.org/10.1001/jamapediatrics.2022.0101.
- 28. Karlstad, O., Hovi, P., Husby, A., et al. (2022). SARS-CoV-2 vaccination and myocarditis in a Nordic cohort study of 23 million residents. *Journal of the American Medical Association Cardiology*, 7(6), 600-612. https://doi.org/10.1001/jamacardio.2022.0583.
- 29. Patone, M., Mei, X.W., Handunnetthi, L., Dixon, S., Zaccardi, F., Shankar-Hari, M., et al. (2022). Risk of myocarditis after sequential doses of COVID-19 vaccine and SARS-CoV-2 infection by age and sex. *Circulation*, 146(10), 743-754. https://doi.org/10.1161/circulationha.122.059970.
- 30. Tuvali, O., Tshori, S., Derazne, E., Hannuna, R.R., Afek, A., Haberman, D., et al. (2022). The incidence of myocarditis and pericarditis in post COVID-19 unvaccinated patients—a large population-based study. *Journal of Clinical Medicine*, 11(8), 2219. https://doi.org/10.3390/jcm11082219.
- 31. Sun, C.L.F., Jaffe, E., & Levi, R. (2022). Increased emergency cardiovascular events among under-40 population in Israel during vaccine rollout and third COVID-19 wave. *Scientific Reports*, 12(1), 6978. https://doi.org/10.1038/s41598-022-10928-z.
- 32. Bagshaw, S.M., Tran, D.T., Opgenorth, D., et al. (2020). Assessment of costs of avoidable delays in intensive care unit discharge. *Journal of the American Medical Association Network Open*, 3(8), e2013913. https://doi.org/10.1001/jamanetworkopen.2020.13913.
- 33. Bagshaw, S.M., Zuege, D.J., Stelfox, H.T., et al. (2022). Association between pandemic coronavirus disease 2019 public health measures and reduction in critical care utilization across ICUs in Alberta, Canada. *Critical Care Medicine*, 50(3), 353-362. https://doi.org/10.1097/CCM.00000000000005275.
- 34. Fowler, R.A., Abdelmalik, P., Wood, G., et al. (2015). Critical care capacity in Canada: results of a national cross-sectional study. *Critical Care*, 19(1), 133. https://doi.org/10.1186/s13054-015-0852-6.
- 35. Joffe, A.R. (2021). COVID-19: Rethinking the lockdown groupthink. *Frontiers in Public Health*, 9, 625778. https://doi.org/10.3389/fpubh.2021.625778.
- 36. Allen, D.W. (2023). Lockdown: A final assessment. In D.J. Boudreaux (Ed.), COVID-19. Lessons we should have learned. Collected essays. The Fraser Institute. Retrieved on April 9, 2023, from https://www.fraserinstitute.org/sites/default/files/covid-19-lessons-essay5-lockdown-a-final-assessment.pdf.
- 37. Herby, J., Jonung, L., & Hanke, S.H. (2022). A literature review and meta-analysis of the effects of lockdowns on COVID-19 mortality–II. Studies in Applied Economics (SAE) No.210. Johns Hopkins Institute for Applied Economics, Global Health, and the study of Business Enterprise. Retrieved on April 9, 2023, from https://sites.krieger.jhu.edu/iae/files/2022/06/A-Systematic-Review-and-Meta-Analysis-of-the-Effects-of-Lockdowns-of-COVID-19-Mortality-II.pdf.
- 38. Joffe, A.R., & Redman, D. (2021). The SARS-CoV-2 pandemic in high income countries such as Canada: A better way forward without lockdowns. *Frontiers in Public Health*, 9, 715904. https://doi.org/10.3389/fpubh.2021.715904.
- 39. Vickers, D.M., Baral, S., Mishra, S., et al. (2022). Stringency of containment and closures on the growth of SARS-CoV-2 in Canada prior to accelerated vaccine roll-out. *International Journal of Infectious Diseases*, 118, 73-82. https://doi.org/10.1016/j.ijid.2022.02.030.
- 40. Soutphommasane, T., & Stears, M. (2022). Fear, freedom and political culture during COVID-19. *Monash Bioethics Review*, 40, 110-119. https://doi.org/10.1007/s40592-022-00157-5.

- 41. Chu, C.H., Yee, A.V., & Stamatopoulos, V. (2022). "It's the worst thing I've ever been put through in my life": the trauma experienced by essential family caregivers of loved ones in long-term care during the COVID-19 pandemic in Canada. *International Journal of Qualitative Studies Health Well-Being*, 17, 2075532. https://doi.org/10.1080/17482631.2022.2075532.
- 42. Iness, A.N., Abaricia, J.O., Sawadogo, W., Iness, C.M, Duesberg, M., Cyrus, J., & Prasad, V. (2022). The effect of hospital visitor policies on patients, their visitors, and healthcare providers during the COVID-19 pandemic: a systematic review. *American Journal of Medicine*, 135(10), 1158-1167. https://doi.org/10.1016/j.amjmed.2022.04.005.
- 43. Jones-Bonofiglio, K., Nortje, N., Webster, L., & Garros, D. (2021). A practical approach to hospital visitation during a pandemic: Responding with compassion to unjustified restrictions. *American Journal of Critical Care*, 30(4), 302-311. https://doi.org/10.4037/ajcc2021611.
- 44. Schippers, M.C., Ioannidis, J.P.A., & Joffe, A.R. (2022). Aggressive measures, rising inequalities, and mass formation during the COVID-19 crisis: An overview and proposed way forward. *Frontiers in Public Health*, 10, 950965. https://doi.org/10.3389/fpubh.2022.950965.
- 45. Anato, J.L.F., Ma, H., Hamilton, M.A., et al. (2022). Impact of a vaccine passport on first-dose COVID-19 vaccine coverage by age and area-level social determinants in the Canadian provinces of Quebec and Ontario: an interrupted time series analysis. *MedRxiv*. Preprint. https://doi.org/10.1101/2022.10.18.22281192
- 46. Howard-Williams, M., Soelaeman, R.H., Fischer, L.S., McCord, R., Davison, R., & Dunphy, C. (2022). Association between state-issued COVID-19 vaccine mandates and vaccine administration rates in 12 US States and the District of Columbia. *Journal of the American Medical Association Health Forum*, 3(10), e223810. https://doi.org/10.1001/jamahealthforum.2022.3810.
- 47. Bardosh, K., de Figueiredo, A., Gur-Arie, R., et al. (2022). The unintended consequences of COVID-19 vaccine policy: why mandates, passports and restrictions may cause more harm than good. *British Medical Journal Global Health*, 7(5), e008684. https://doi.org/10.1136/bmjgh-2022-008684.
- 48. Joffe, A.R. 2022. What about the COVID-19 response? Evidence, risk, lockdowns, and vaccine mandates. *Health Ethics Today*, 29(1), 8-12, 14-15. Retrieved on April 9, 2023, from https://www.ualberta.ca/john-dossetor-health-ethics-centre/media-library/health-ethics-today/health-ethics-today-volume29-1-february2022.pdf.
- 49. Canadian Institute for Health Information. (2017). *Alcohol harm in Canada: Examining hospitalizations entirely caused by alcohol and strategies to reduce alcohol harm*. Ottawa, ON: Canadian Institute for Health Information. https://www.cihi.ca/sites/default/files/document/report-alcohol-hospitalizations-en-web.pdf.
- 50. Baliunas, D., Patra, J., Rehm, J., Popova, S., & Taylor B. (2007). Smoking-attributable morbidity: acute care hospital diagnoses and days of treatment in Canada, 2002. *BMC Public Health*, 7, 247. https://doi.org/10.1186/1471-2458-7-247.
- 51. FAO, IFAD, UNICEF, WFP, and WHO. (2020). The State of Food Security and Nutrition in the World 2020. Transforming Food Systems for Affordable Health Diets. Rome: Food and Agriculture Organization of the United Nations. http://www.fao.org/3/ca9692en/CA9692EN.pdf.
- 52. Pezzullo, A.M., Axfors, C., Contopoulos-Ioannidis, C.G., Apostolatos, A., & Ioannidis, J.P.A. (2023). Agestratified infection fatality rate of COVID-19 in the non-elderly population. *Environmental Research*, 216(3), 114655. https://doi.org/10.1016/j.envres.2022.114655.
- 53. Esper, F.P., Adhikari, T.M., Tu, Z.J., Cheng, Y.W., El-Haddad, K., Farkas, D.H., et al. (2023). Alpha to Omicron: Disease severity and clinical outcomes of major SARS-CoV-2 variants. *Journal of Infectious Diseases*, 227(3), 344-352. https://doi.org/10.1093/infdis/jiac411.
- 54. Hani, E., Bertra,n M., Powell, A., Williams, H., Birrell, P., DeAngelis, D., et al. (2023). Significantly lower infection fatality rates associated with SARS-CoV-2 Omicron (B.1.1.529) infection in children and young people: active, prospective national surveillance, January-March 2022, England. *Journal of Infection*, 86(4), 397-398. https://doi.org/10.1016/j.jinf.2023.01.032.
- 55. Axfors, C., & Ioannidis, J.P.A. (2022). Infection fatality rate of COVID-19 in community-dwelling elderly populations. *European Journal of Epidemiology*, 37(3), 235-249. https://doi.org/10.1007/s10654-022-00853-w.
- 56. Redman, D. (2021). An emergency management doctrine and philosophy: the five dimensions. *Preprints*. Retrieved on April 9, 2023 from https://doi.org/10.20944/preprints202102.0367.v1.
- 57. Redman, D. (2021). Canada's Deadly Response to COVID-19. Frontier Center for Public Policy. Policy Series No. 237. Retrieved on April 9, 2023 from https://fcpp.org/2021/07/19/canadas-deadly-response-to-covid-19/.
- 58. Redman, D. (2022). *A Recovery Plan. Canada's post-pandemic COVID-19*. Frontier Center for Public Policy Briefing Note. Retrieved on April 9, 2023 from https://fcpp.org/wp-content/uploads/BriefingNote-COVID_Recovery_PlanFB0922.pdf.
- 59. Zweig, S.A., Zapf, A.J., Beyrer, C., Guha-Sapir, D., & Haar, R.J. (2021). Ensuring rights while protecting health: the importance of using a human rights approach in implementing public health responses to

- COVID-19. *Health and Human Rights Journal*, 23(2), 173-186. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8694292/.
- 60. Schippers, M.C., & Rus, D.C. (2021). Optimizing decision-making processes in times of COVID-19: using reflexivity to counteract information-processing failures. *Frontiers in Psychology*, 12, 650525. https://www.frontiersin.org/articles/10.3389/fpsyg.2021.650525/full.
- 61. Rajan D, Koch K, Rohrer K, Bajnoczki C, Socha A, Voss M, et al. Governance of the Covid-19 response: a call for more inclusive and transparent decision-making. BMJ Global Health 2020;5:e002655. https://doi.org/10.1136/bmjgh-2020-002655.

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