 doi:10.20944/preprints202206.0240.v1

Article

Bailey's Reanalysis Fails to Debunk, and Inadvertently Supports, Miller-Goldman's Positive Correlation between Number of Vaccine Doses and Infant Mortality Rates

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Abstract: Background—In 2011, Miller and Goldman published a study in *Human and Experimental Toxicology* that found a counterintuitive, positive correlation, $r = 0.70$ ($r^2 = 0.49$, $p < .0001$), demonstrating that as nations require more vaccine doses for their infants, infant mortality rates (IMRs) tend to increase (worsen). The dataset ($n = 30$) included the United States, a nation that required the most vaccines for their infants, and all nations with better IMRs than the United States. Dr. E. Bailey, a professor at BYU, and her students, recently read the Miller-Goldman study and found it "troublesome that this manuscript is in the top 5% of all research outputs" and falsely claimed that its findings were due to "inappropriate data exclusion," i.e., failure to analyze the "full dataset" of all 185 nations. The "Bailey reanalysis," titled *Infant vaccination does not predict increased infant mortality rate: correcting past misinformation*, was posted to the *medRxiv* preprint server on September 10, 2021 (version 1) and October 5, 2021 (version 3) and *Europe PMC* preprint server on September 10, 2021. **Objective**—This present study examines the various claims postulated by the Bailey reanalysis and assesses the robustness of their methodology, analyses, and reported results and conclusions. **Methods**—Data discussed in this paper are based on the previously mentioned study by Miller and Goldman and the Bailey reanalysis. **Results**—Linear regression analysis of IMR and the number of vaccine doses for each country yield a statistically significant positive correlation of $r = 0.70$ ($p < .0001$) for the top nations ($n = 30$) chosen by Miller-Goldman and $r = 0.16$ ($p < .04$) for the "entire dataset" chosen by Bailey et al ($n = 185$). Bailey also conducted linear regression analyses (for the year 2019) of IMRs as a function of vaccination rates for each of eight different vaccines and reported statistically significant inverse correlations for 7 of 8 vaccines over the entire range of vaccination rates. However, Miller and Goldman reanalyzed the Bailey analyses for nations with vaccination rates below 60% and found no statistically significant correlation for six vaccines (DPT, Hib, hepatitis B, polio, rotavirus, and measles) and statistically significant positive correlations for tuberculosis ($r = 0.8$, $p < .005$) and pneumococcal ($r = 0.6$ $p < .023$) vaccines. **Conclusions**—Bailey's reanalysis corroborates a statistically significant *positive* correlation originally reported by Miller and Goldman. However, Bailey's reported correlation ($r = +0.16$, $p < .04$) is small, likely due to poor methodology (failing to account for covariates, i.e., disparities among numerous socioeconomic factors that add uncertainty to their conclusion). The *r*-value reported by the Bailey reanalysis demonstrates an effect size that is about one-fourth (0.16/0.70) that reported by Miller-Goldman—underscoring how critically important it is for Bailey's reanalysis to eliminate confounding variables. Moreover, Bailey's linear regression analyses of IMR as a function of vaccination rates for each of eight different vaccines demonstrate that some countries with low vaccination rates have low IMRs, while other countries with high vaccination rates have high IMRs. Rather than supporting a strong inverse correlation, the Bailey reanalysis demonstrates high vaccination rates are neither necessary nor sufficient to cause low IMR.

Keywords: artifacts; confounders; infant mortality rate; linear regression analysis; vaccination rates; vaccines; vaccine doses; hepatitis B vaccine

 doi:10.20944/preprints202206.0240.v1

1. Introduction

In 2011, Miller and Goldman [1] observed that the United States required more vaccine doses for infants than any other country, yet several nations had better infant mortality rates (IMRs). Thus, the Miller-Goldman study sought to explore the correlation between vaccine doses that these 30 nations—the United States and all nations with better IMRs—routinely give to their infants and their IMRs. Linear regression analysis yielded a coefficient of determination (r^2) of 0.49. The finding of $r = 0.7$ ($p < .0001$) described a positive correlation and revealed a counterintuitive relationship: among the most highly developed nations, those requiring the most vaccine doses for their infants tended to have the highest IMRs. Dr. E. Bailey, a professor at Brigham Young University (BYU), read the Miller-Goldman study and found it "troublesome that this manuscript is in the top 5% of all research outputs." Thus, she and several students (associated with her Bioinformatics Capstone course) reanalyzed the Miller-Goldman study in an effort to "correct past misinformation" and claimed that its findings were due to "inappropriate data exclusion," i.e., failure to analyze the "full dataset" of all 185 nations. The "Bailey reanalysis," titled *Infant vaccination does not predict increased infant mortality rate: correcting past misinformation,* [2] was posted to the *medRxiv* preprint server on September 10, 2021 (version 1) and October 5, 2021 (version 3) and *Europe PMC* preprint server on September 10, 2021.

The Bailey reanalysis explains that "a brief reading" led Bailey and coauthors to question the Miller-Goldman findings. Thus, the Bailey reanalysis sought to achieve two main goals: 1) utilize the "full dataset" of 185 nations, instead of restricting the analysis to the 30 top nations chose by Miller-Goldman, and 2) demonstrate an inverse correlation (the opposite of Miller-Goldman), i.e., as vaccine doses increase, IMR decreases. The Bailey analysis provides two new investigations (not addressed in the original Miller-Goldman study) purporting to show 1) how an inverse correlation exists such that as the percentage vaccination rate of each of 8 different vaccines increase, IMR decreases, and 2) how adding hepatitis B vaccine to the US vaccine schedule did not increase IMR.

The stated rationale behind Bailey's reanalysis and additional new analyses include "correcting past misinformation" and reducing the impact of vaccine hesitancy which "has intensified due to the rapid development and distribution of the COVID-19 vaccine." Bailey et al appear to be targeting the Miller-Goldman study for a potential retraction as well.

This present study examines the various claims postulated by the Bailey reanalysis and assesses the robustness of their methodology, analyses, and reported results and conclusions.

2. Methods

Data discussed in this paper are based on the previously mentioned study by Miller and Goldman [1] and the Bailey reanalysis [2].

3. Results

Linear regression analysis of IMR and the number of vaccine doses for each country yield a statistically significant positive correlation of $r = 0.70$ ($p < .0001$) for the top nations ($n = 30$) chosen by Miller-Goldman and $r = 0.16$ ($p < .04$) for the "entire dataset" chosen by Bailey et al ($n = 185$).

Bailey also conducted linear regression analyses (for the year 2019) of IMRs as a function of vaccination rates for each of eight different vaccines over the entire range of vaccination rates and reports statistically significant inverse correlations for 7 of 8 vaccines (DPT, $r = -0.85$; Hib, $r = -0.81$; hepatitis B, $r = -0.77$; polio, $r = -0.87$; tuberculosis, $r = -0.38$; pneumococcal, $r = -0.42$; measles, $r = -0.79$). However, Miller and Goldman reanalyzed the Bailey analyses for nations with vaccination rates below 60% and found no statistically significant correlation for six vaccines (DPT, Hib, hepatitis B, polio, rotavirus, and measles) and statistically significant positive correlations for tuberculosis ($r = 0.8$, $p < .005$) and pneumococcal ($r = 0.6$, $p < .023$) vaccines.

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4. Discussion

4.1. Bailey's claim of "inappropriate data exclusion" is irrational

Bailey et al erroneously claim that the Goldman-Miller study contains "inappropriate data exclusion" and emphasize, "The most important problem with the [Miller-Goldman] manuscript is that their conclusion could only be reached by omitting >80% of the available data." These statements are demonstrably false. The rationale for Miller and Goldman limiting their analysis to the 30 specific nations with the lowest IMR or for using the United States as the cutoff is perfectly valid (as explained below and in the original study) and no less credible than studies that stratify data using 10-year age categories: 0-9, 10-19, 20-29, etc. This practice is found in many published papers and is not considered random, arbitrary, or unscientific, and it would be biased and irrational to invalidate a study for this reason.

Miller and Goldman observed that the United States required more vaccine doses for infants than any other country yet several nations had better IMRs. Thus, the Miller-Goldman study sought to explore the correlation between vaccine doses that these nations (the United States and all nations with better IMRs) routinely give to their infants and their IMRs. Additionally, all of the nations in the Miller-Goldman study had very high vaccination rates and homogeneity which eliminated numerous confounding variables, including socioeconomic disparities. If instead they had added more countries to the analysis, including Third World nations (as Bailey et al suggested) they would have increasingly introduced confounders due to heterogenicity of socioeconomic factors.

4.2. Minimization of confounders

Prior to contemplating their study, Miller-Goldman knew that compared to all other countries, the US required the greatest number of vaccines. Thus, after inspecting a list of the IMRs reported for all nations arranged in ascending order (from lowest to highest value), Miller-Goldman sought to understand why the US ranked 34th on this list and postulated that a correlation may exist between IMR and the number of vaccine doses required by each of the countries having better (i.e., lower) IMRs than the US. Those countries exhibiting the best (lowest) IMRs were qualitatively recognized as very highly developed countries and, as such, had high childhood vaccination rates (mainly exceeding 90%). Moreover, Miller-Goldman reasoned that such countries likely demonstrate a high degree of homogeneity of socioeconomic factors; or, in statistical terms, an analysis of these countries will have minimal confounding due to 1) difficult or limited access to healthcare, 2) populations experiencing malnutrition, 3) unclean water, 4) unsanitary conditions, 5) widespread poverty, 6) social unrest (fighting/warfare), and 7) variable/inconsistent vaccination coverage rates. Miller-Goldman had no prior knowledge as to whether a relationship between IMR and number of vaccine doses would exist or what type of regression model might fit the data. With confounding minimized due to socioeconomic factors, Miller-Goldman isolated trends due primarily to the varying number of vaccine doses.

4.3. Bailey's reanalysis using a computer simulation generated spurious results

According to Bailey's reanalysis, Miller and Goldman's main finding of $r^2 = 0.49$ after analyzing 30 nations with the top IMRs was "highly improbable." The Bailey computer simulation (see their Figure 2) went through 50,000 iterations of randomly selecting 30 nations from among all 185 nations. This analysis generated spurious results since it failed to consider any covariates. Nearly all the r^2 values were confounded by heterogenicity of socioeconomic factors—especially when Third World nations were randomly grouped with highly developed nations.

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4.4. Bailey's reanalysis of the entire dataset of 185 countries corroborates a positive correlation reported by Miller-Goldman

Table 1 below presents the results of a linear regression analysis independently performed by Miller and Goldman (n=30) and Bailey et al (n=185). Ironically, whether 30 nations or the full dataset of 185 nations are analyzed, both Goldman-Miller and Bailey et al report a statistically significant *positive* correlation coefficient (see Table 1 and Figure 1). As expected, the Bailey correlation coefficient is small—likely due to numerous confounders Bailey introduced into the regression analysis when they inappropriately combined highly developed and Third World nations with large disparities in IMRs and socioeconomic factors. Linear regression analysis using 185 nations yields the best fit equation $y = 4.3 + 1.5x$ (where y is IMR and x is number of vaccine doses); thus, according to Bailey's analysis, *for each dose added to the vaccination schedule, the IMR increases by 1.5 deaths/1,000 births.* Therefore, Bailey et al, instead of invalidating Miller and Goldman's findings, corroborated the counterintuitive trend that as the number of vaccine doses in the immunization schedule increase, IMR tends to increase as well.

Table 1. Comparison of Miller-Goldman and Bailey et al linear regression analyses and resulting positive correlation coefficient (as number of vaccine doses increase, IMR increases).

Parameter	Linear regression analysis performed by	
	Miller-Goldman (n = 30) [1]	Bailey et al (n = 185) [2]
correlation direction	Positive	positive
r correlation coefficient	+0.70 ($p < .0001$)[a]	+0.16[b] ($p < .04$)[a]
r^2 coefficient of determination	0.49	0.026
consistency or uniformity of socioeconomic factors among nations utilized in regression	Homogeneity of nations that are very highly developed and vaccination rates exceed 90%.	Heterogeneity of nations due to mixing of 3rd-world and developed nations.

[a]both Miller-Goldman and Bailey et al report statistically significant, positive correlation coefficients

[b]effect size (based on comparison of r-values) in Bailey et al regression is approximately one-fourth (0.16/0.70) that of Miller-Goldman.

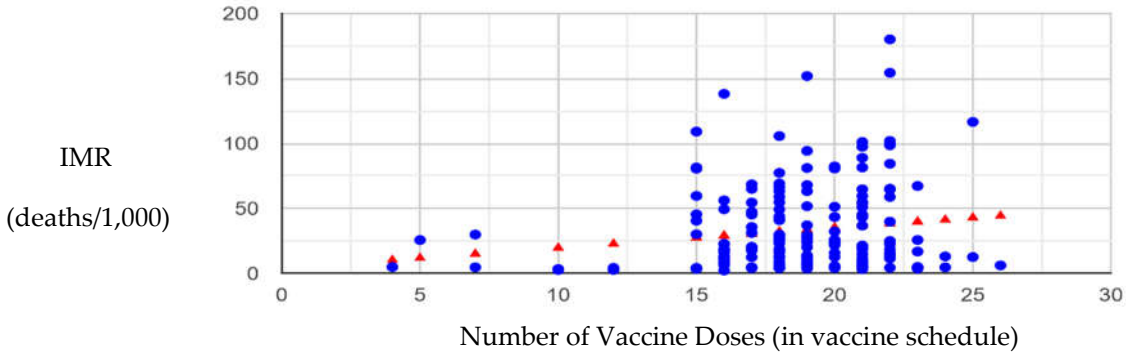

Figure 1. Statistically significant positive linear trend found by Bailey et al using all 185 nations. (Red triangles denote points on best-fit line; Blue circles denote data points for each nation).

4.5. Bailey's reanalysis faults Miller-Goldman for applying proper statistical conventions

Bailey's reanalysis states, "Excluding data to achieve a specific answer is a fraudulent research practice called data dredging that contributes to misinformation in the scientific community." In particular, the Bailey reanalysis criticizes Miller-Goldman for removing four nations—Andorra, Liechtenstein, Monaco, and San Marino—from their analysis, and insinuates that this was done to manipulate the findings to improve the reported correlation. It is noteworthy, that inclusion of these countries had negligible effect on the reported

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results. The Miller-Goldman study explained that the four nations were excluded by following the same guidelines and biostatistical conventions used by the CDC and other epidemiologists in health departments throughout the world.

Since each nation's observed IMR is considered an estimate of the true underlying mortality rate, this estimate is subject to chance variation. If a country has very few births, the observed (i.e., reported) IMR may be very different from the true rate. Prominent biostatistician and epidemiologist, Joel C. Kleinman, PhD, who served in the Office of Analysis and Epidemiology, National Center for Health Statistics, explains:

> "A useful rule is that any rate based on fewer than 20 cases in the numerator [of the infant mortality rate] will have a 95% confidence interval which is about as wide as the rate itself (that is from 0.5*r* to 1.5*r*). Roughly speaking, this means all that can confidently be said about an area [or country] with 20 deaths out of, say 1000 live births, is that the true rate is within 20 ± 10 per 1,000. Clearly this is not precise information." [3]

Following this same convention, Canadian statisticians also suppress rates based on fewer than 20 observations because these data do not meet their requirement for a minimum degree of accuracy (exhibiting a relative standard error or RSE of 50%). [4]

It is concerning and ironic that Bailey and coauthors are unaware of this statistical convention, and their failure to adopt this convention might have confounded their own analysis.

4.6. Bailey's reanalysis fails to address effects of synergistic toxicity

In contrast to the findings in the Miller-Goldman study, the Bailey reanalysis disregarded the effect of *combining vaccines*—and the potential for synergistic toxicity—which the Miller-Goldman study considered by comparing vaccine schedules for each country. Bailey and her coauthors dispute Miller-Goldman's claim that synergistic toxicity may occur when multiple vaccines are administered concurrently, citing four highly selective articles while disregarding a CDC report on mixed exposures to chemical substances and other stressors, including prescribed pharmaceuticals, which found that they may produce "increased or unexpected deleterious health effects." In addition, "exposures to mixed stressors can produce health consequences that are additive, synergistic, antagonistic, or can potentiate the response expected from individual component exposures." [5]

4.7. Bailey's reanalysis reports a new investigation: IMR versus percentage vaccination rates

As demonstrated quantitatively in Table 2 below and shown graphically by the best-fit red line in Figure 2 below, none of the Bailey graphs in the range of vaccination rate <60%, demonstrate a statistically significant negative correlation between vaccination rate and IMR. Rather, polio, rotavirus, and measles vaccines demonstrate small, positive correlations that are not significant; however, both tuberculosis and pneumococcal vaccines demonstrate strong, statistically significant positive correlations, *suggesting that IMRs increase as vaccination rate percentages increase—the opposite of what Bailey et al are attempting to demonstrate.*

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Table 2. Linear Regression Analysis of IMR and Vaccination Rates <60% from Bailey *et al.* Figure 3.

Figure 3 Graph	Vaccine	R-value	R^2-value	P-value
A	DTP	-0.06	0.004	.83
B	Hib	-0.04	0.002	.89
C	Hepatitis B	-0.1	0.01	.70
D	Polio	+0.09	0.008	.77
E	Rotavirus**	+0.07	0.005	.79
F	Tuberculosis	+0.8	0.6	.005*
G	Pneumococcal	+0.6	0.4	.023*
H	Measles	+0.1	0.2	.68

*Statistically significant

** Bailey *et al.* determined that Graph E for Rotavirus vaccine demonstrated no statistically significant correlation over the entire range of vaccination rates.

Bailey's reanalysis reports statistically significant inverse correlations for 7 of 8 vaccines (DPT, r = -0.85; Hib, r = -0.81; hepatitis B, r = -0.77; polio, r = -0.87; tuberculosis, r = -0.38; pneumococcal, r = -0.42; measles, r = -0.79) over the entire range of vaccination rates with a best-fit line represented by the blue line in Figure 2. However, these correlations based on the entire range grossly differ from the correlations obtained for vaccination rates <60%. *This is a strong indicator that a linear model is insufficient or improper for analyzing relationships between IMR and vaccination rates.*

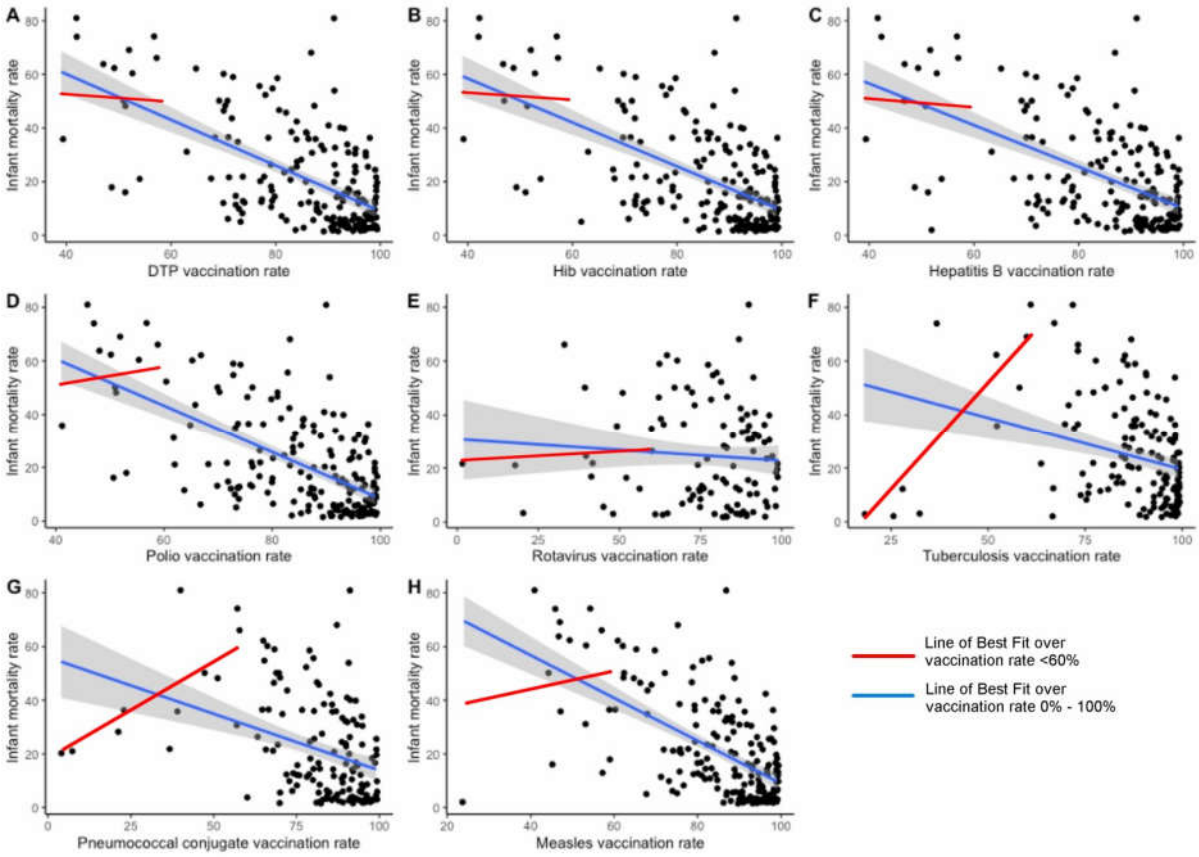

Figure 2. Line of Best Fit for vaccination rates <60% superimposed on Line of Best Fit using all vaccination rates.

Thus, the investigation performed by Bailey shows eight graphs, each of which is a classic textbook example of how a high correlation coefficient does not indicate that the

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fit is good or appropriate even though the deviation of actual points from the fitted points, on average, is small. Demidenko writes, "The p-value can be made as small as desired by increasing the sample size n. The p-value is outdated and does not make sense with big data." [6]

Moreover, of the eight individual vaccines investigated in the Bailey reanalysis, no correlation was found between the IMR and percentage vaccination rate for the rotavirus vaccine (see Bailey reanalysis, Graph E). And oddly, a significant correlation was found for the measles vaccine (see Bailey reanalysis, Graph H) although this vaccine is not administered to infants in most nations throughout the world. The measles vaccine is given *after* the outcome period when IMR is measured.

Observe that numerous data points in all the graphs in Figure 2 (shown above and in Bailey's reanalysis Figure 3) indicate that some countries with low vaccination rates have low IMRs while other countries with high vaccination rates have high IMRs. Yet, the Bailey reanalysis neglected to report that *high vaccination rates are neither necessary nor sufficient to cause low IMR.* Inquiring scientists and researchers would likely want to explore those countries that appear to contradict the prevailing medical presumption that high vaccination rates yield healthier children (e.g., lower IMRs). This is precisely the relationship that Miller-Goldman sought to explore.

4.8. Bailey's reanalysis inappropriately correlates a longitudinal increase in hepatitis B vaccination rates with lowering IMR

The Bailey reanalysis reports that from 1996 to 2019 (a 23-year period), hepatitis B vaccination was "consistently high" and IMR dropped from 8.5% to 6% in males and from 7% to 5% in females. However, this exercise is futile since hepatitis B was never a high risk for infants. In 1996, a single infant death out of 2.9 million births was attributed to this disease [7], so the vaccine could never realistically be expected to contribute to a lowering of the IMR. And from 1960 to 1981 (a 21-year period *before* the hepatitis B vaccine was introduced), the IMR declined 52.7% from 26.4 to 12.5 [8]—a much higher rate than *after* the vaccine was introduced. Obviously, there are multiple reasons for the steady decline in IMR that has occurred since the beginning of the 20th century. The Bailey *et al.* analysis of the hepatitis B vaccine's impact over time on IMR is flawed. The authors acknowledge there are "potential confounding factors" but simply adding this statement is insufficient to justify including this "analysis" in their manuscript. In fact, they seem to be arguing that correlation equals causation. Consider that chronic ailments in childhood and rates of autism *increased* after several new vaccines were added to the immunization schedule. Bailey and her colleagues would be unlikely to weigh this as sufficient evidence of a causative influence, and rightfully so.

4.9. Inappropriate defamatory statements in the Bailey reanalysis

The following is a list of several false and/or defamatory /libelous statements included in the Bailey reanalysis (Version 1):

In the abstract: The findings in the Miller-Goldman study would have been "virtually impossible without data manipulation."

On page 5: The narrative insinuates that Miller and Goldman engaged in "Intentional deception."

On page 9: The finding in the Miller-Goldman study "could only be reached by extensive censoring of the available data."

On page 10: Miller-Goldman excluded data "to achieve a specific answer" and they engaged in "a fraudulent research practice called data dredging that contributes to misinformation in the scientific community."

On page 11: Miller-Goldman engaged in "data manipulation."

On page 13: Findings in the Miller-Goldman study "could only be reached with extensive and intentional censoring of the dataset."

 doi:10.20944/preprints202206.0240.v1

These claims are libelous, outrageous, and mainly serve to reveal the blatant bias of the Bailey reanalysis that demonstrates a misunderstanding and misuse of basic scientific methodologies.

4.10. Funding issues misrepresented

The Bailey reanalysis falsely claims that Miller and Goldman received funding from anti-vaccination organizations. The National Vaccine Information Center (NVIC) is not "anti-vaccine" and did not fund the Miller-Goldman study. The NVIC and Michael Belkin had no knowledge of or influence over the Miller-Goldman study which was self-funded. The NVIC and Michael Belkin only contributed to the Open Access fee. This donation was solicited after the study was accepted for publication. This false information in the Bailey reanalysis appears to be an *ad hominem* slur designed to unfairly discredit Miller and Goldman.

In contrast, Elizabeth Bailey received a salary from BYU while collaborating with her students on their manuscript. This internal funding was not explicitly noted in a conflict of interest or funding statement.

5. Conclusion

Miller and Goldman welcome constructive comments and criticisms of their study but find the Bailey reanalysis invalid and unpublishable due to poor methodology and confounders that add to the uncertainty of their conclusions. Version 1 of the reanalysis contains several false and libelous statements regarding the motives of Miller and Goldman. Although this language has been adjusted in later versions, the retention of data and analyses of the entire dataset of 185 nations without any regard to covariates, i.e., disparities in socioeconomic factors, renders the results and conclusions useless.

Rather than debunking the Miller-Goldman study, Bailey's reanalysis corroborates a statistically significant *positive* correlation that Miller-Goldman initially report. However, Bailey's correlation ($r = +0.16$; $p < .04$) is small due to confounding described in the present paper. The *r*-value reported by the Bailey reanalysis demonstrates an effect size that is approximately one-fourth (0.16/0.70) that reported by Miller-Goldman—underscoring how critically important it is for Bailey's reanalysis to eliminate confounding variables. Therefore, Bailey et al, instead of invalidating Miller and Goldman's findings, corroborated the counterintuitive trend that as the number of vaccine doses in the immunization schedule increase, IMR tends to increase as well.

Moreover, Bailey's linear regression analyses of IMR as a function of vaccination rates for each of eight different vaccines confirms that some countries with low vaccination rates have low IMRs, while other countries with high vaccination rates have high IMRs. Rather than supporting a strong inverse correlation, the Bailey reanalysis demonstrates that high vaccination rates are neither necessary nor sufficient to cause low IMR.

Ironically, the Bailey reanalysis, not the Miller-Goldman study, is problematic and appears to be perpetuating scientific misinformation with a selective presentation of data to support a predetermined goal to debunk the Miller-Goldman study at any cost because it challenges scientific consensus and is "in the top 5% of all research outputs."

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