

A Rebuttal to Orac's Review of the Miller-Goldman Study

by Neil Z. Miller

In 2011, I co-authored a study with Gary Goldman, PhD. We submitted our paper to a credible science journal indexed by the National Library of Medicine. Shortly thereafter, it was peer-reviewed and published. Our main finding was that among developed nations, those requiring the most vaccines for their infants tended to have higher infant mortality rates. A correlation coefficient of $r = 0.70$ ($p < 0.0001$) was found between infant mortality rates and the number of vaccine doses routinely given to infants.

After our paper was published, Dr. David Gorski, a surgical oncologist associated with the Wayne State University School of Medicine, anonymously denounced it on one his internet blogs using the alias, Orac. As a result, some of his followers who believe vaccines are completely safe and effective, falsely claimed that the Miller-Goldman study was “debunked.” (Gorski regularly uses his online forums to minimize the veracity of vaccine studies that have undesirable findings. In contrast, pro-vaccine studies with methodological issues and/or evidence of malfeasance are not critiqued. It should also be noted that Gorski has received funding from the pharmaceutical industry and many people do not consider him an unbiased or objective resource.) In this rebuttal, I will briefly address some of Gorski's concerns in his review of our paper.

Conflicts of interest

Gorski begins his critique by claiming that Goldman and I have conflicts of interest. He believes that I have a conflict of interest because I operate a website promoting informed consent for medical procedures and write about vaccines. He equates this with a pharmaceutical company that conducts its own study touting the benefits of its latest drug or vaccine. This is a false equivalency. By this reasoning, every doctor who writes an article about vaccines and every pediatrician who administers vaccines (and earns a profit), has a conflict of interest, and their research supportive of vaccines should be regarded with suspicion.

Gorski believes that Dr. Goldman has a conflict of interest because he was the president and founder of a medical journal that published scientific papers critical of vaccines. What Gorski failed to mention is that Goldman is an expert on the varicella virus and for 8 years worked as an Epidemiology Analyst for the CDC in collaboration with the Los Angeles County Department of Health (Acute Communicable Disease Control Unit) to help conduct epidemiological studies of varicella disease at one of three surveillance sites in the nation established to monitor the effect of the chickenpox vaccine on the population. Dr. Goldman vaccinated his own children and supported vaccination at the population level during his tenure with the CDC. Goldman has also served as a professional peer-reviewer for numerous medical science journals, including the *Journal of the American Medical Association (JAMA)*, *Vaccine*, *Human and Experimental Toxicology (HET)*, *The American Journal of Managed Care (AJMC)*, *Expert Review of Vaccines (ERV)*, *Epidemiology and Infection*, *The Open Allergy Journal*, *BioMed Research International*, *Epidemiology & Infection*, and *British Medical Journal (BMJ)*. He is included on the Editorial Board of *Research and Reviews in BioSciences*.

Gorski also claimed that our paper was somehow compromised because the National Vaccine Information Center (NVIC) and Michael Belkin (the father of a daughter who died within hours after receiving a hepatitis B vaccine) donated money to pay the journal's Open Access fee. This is not money from a funding source, like when a pharmaceutical company pays researchers to conduct research on their own products. The NVIC and Michael Belkin had no knowledge of or influence over our paper. We did not contact them to solicit a donation until after our paper was written and accepted for publication. While our study was self-funded, the Open Access fee is a hefty sum that journals charge authors if they wish to make their study freely available to everyone without having to pay a \$35 purchase fee.

Data for one year only

Gorski wondered why we only used data for the year 2009. Our paper was published in 2011. We worked on the paper in 2010. Data for 2009 was the most recent available. I agree that our paper could have been strengthened by analyzing multiple years, and that is still possible for anyone wishing to do a followup. However, it does not negate the significance of our findings and their implications. Our paper should not be considered definitive but as a potential warning signal. Our concluding remarks called for more research: *“A closer inspection of correlations between vaccine doses, biochemical or synergistic toxicity, and infant mortality rates, is essential. All nations — rich and poor, advanced and developing — have an obligation to determine whether their immunization schedules are achieving their desired goals.”*

Multivalent vaccines counted as more than one

Gorski claimed that we were “trying to convince people that U.S. infants are ‘overvaccinated’ by artificially pumping up the apparent number of vaccine doses by counting multivalent vaccines as more than one.” But multivalent vaccines ARE more than one. Although MMR is administered as a single injection, the measles, mumps and rubella portions of the vaccine are manufactured separately. They are combined at the end of the process. They are three separate vaccines combined into a single shot. If you go to a bar and order separate drinks of whiskey, gin, and rum then combine them into a single glass, you will still be ingesting the alcohol content from three beverages with their additive and/or synergistic effects.

In addition, an excise tax of \$0.75 per vaccine dose must be paid to fund the U.S. National Vaccine Injury Compensation Program (which has thus far paid out nearly \$4 billion to compensate people who have been permanently incapacitated or died after receiving mandated vaccines). Since DTaP and MMR are each taxed at \$2.25, the federal government acknowledges that these single injections contain three separate and unique vaccines. Gorski and the vaccine industry like to pretend that DTaP and MMR are one vaccine rather than three separate vaccines combined into one syringe because it makes it appear as though children are receiving fewer vaccines than they really are, a tactic to minimize how crowded the vaccine schedule really is.

German immunization schedule

Gorski correctly noted that we made a mistake with the German childhood vaccination schedule. However, the total number of recommended doses during infancy is accurately listed as 18. Two doses of the hepatitis B vaccine were omitted from Table #2 in our paper but Germany recommended only two doses of polio and Hib vaccines (not three, as shown in our table). These mistakes canceled each other out and had no effect on our findings.

Choice of infant mortality data

Gorski complained that we did not use infant mortality rates listed by the United Nations Population Division found in Wikipedia. Instead, we chose data provided by *The World Factbook*, gathered by the Central Intelligence Agency (CIA), also found in Wikipedia. We considered CIA data to be the most authoritative and precise. For example, UNICEF, in collaboration with the World Health Organization, only provides infant mortality rates of all nations rounded to the nearest whole numbers.

Removal of four nations from analysis

Gorski insinuated that we removed four nations — Andorra, Liechtenstein, Monaco, and San Marino — to manipulate our findings. Data was NOT removed to make our findings appear more significant. In our paper, we explained why these four nations were excluded, consistent with biostatistical conventions, because they each had fewer than five infant deaths, producing extremely wide confidence intervals (gross variability) and infant mortality rate (IMR) instability. The remaining 30 (88%) of the data pairs were then available for analysis. It would have been scientifically dishonest for us to have included the four nations in our analysis.

The four excluded nations had/have extremely small populations and just 1 to 5 infant deaths annually. If a single death, for example, is not reported, the IMR is substantially changed. This “noise” and “bias” is not present when IMRs are reported based on a larger number of raw deaths. This is why it would have been improper to include these nations in our analysis. What we did is absolutely consistent with epidemiological guidelines established by many healthcare agencies. It is also noteworthy to mention that when we included the weighted or unweighted contribution of these four countries in our analysis, it produced a negligible effect on the overall reported results. (The raw data is included in the paper for anyone to reproduce.)

Comparison of U.S. infant mortality rates with other nations

Gorski suggests that it is inappropriate to compare U.S. infant mortality rates with rates from other countries. This is simply untrue. Most nations follow standards set by the World Health Organization (WHO). Four nations in our dataset — France, the Czech Republic, the Netherlands, and Ireland — do not report live births entirely consistent with WHO standards. According to the CDC, “*There are some differences among countries in the reporting of very small infants who may die soon after birth. However, it appears unlikely that differences in reporting are the primary explanation for the United States’ relatively low international ranking.*” Furthermore, when the infant mortality rates of France, the Czech Republic, the Netherlands, and Ireland were adjusted for known underreporting of live births and the 30 data pairs retested for significance, the correlation coefficient improved from 0.70 to 0.74 (95% CI, 0.52–0.87).

Here is a summary of how the infant mortality rates of France, the Czech Republic, the Netherlands, and Ireland were adjusted/corrected for known underreporting of live births, and the 30 data pairs retested for significance: Research published in the April 22, 2010 online edition of *Archives of Disease in Children*, **Survival in infants live born at less than 24 weeks’ gestation: the hidden morbidity of nonsurvivors**, showed that of 480,662 live births in northern England between 1993 and 2007, 229 babies (.000476) were born at 22-23 weeks, the “margins of viability.” Of these, 210 died (91.7%). These figures were used to provide an estimate of the number of babies likely to be underreported in nations that count such deaths as stillbirths, rather than as live births and infant deaths. For example, according to the *The World Factbook* published by the CIA, in 2009 France had 796,238 live births and 2,651 infant deaths. These figures were derived from the total population (64,057,792), birth rate (12.43 live births per 1,000 people per year), and infant mortality rate (3.33 deaths per 1,000 live births) provided. By multiplying the number of live births in France x .000476 we determined that about 379 babies would have been born at the margins of viability. About 92% of these babies (349) were likely to have died (but would have been counted as stillbirths). Next, we added these 349 deaths to the original 2,651 deaths for a corrected total of 3,000 infant deaths. We also added these 349 deaths to the original number of live births for a new total of 796,587. Finally, we divided 3,000 infant deaths by 796,587 live births to yield a corrected infant mortality rate of 3.77.

Sudden infant death and reclassifying fatalities

Gorski claimed that we presented no evidence that sudden infant death syndrome (SIDS) is related to vaccines and that vaccine-related deaths may be reclassified as ordinary fatalities. This is untrue. We summarized several peer-reviewed studies that demonstrated a link between vaccines and SIDS. We also provided evidence that doctors who certify infant deaths have reclassified SIDS as suffocation and asphyxia. They must choose from 130 official infant death classifications, yet none of these categories specifies vaccination as a cause of death. This trend toward reclassifying International Classification of Diseases (ICD) data is a great concern of the CDC “because inaccurate or inconsistent cause-of-death determination and reporting hamper the ability to monitor national trends, ascertain risk factors, and design and evaluate programs to prevent these deaths.”

Numerous studies confirm that hexavalent injections (six different vaccines in one syringe) significantly increase the risk of sudden and unexpected deaths in young children. For example, von Kries et al [*Eur J Pediatr* 2005 Feb; 164(2): 61-69] found that in the second year of life, children were significantly more likely to die within one or two days after hexavalent vaccination. According to the authors, “*These findings based on spontaneous reporting... constitute a signal for one of the two hexavalent vaccines which should prompt intensified surveillance for unexpected deaths after vaccination.*” Traversa et al [*PloS One* 2011 Jan 26; 6(1): e16363] found a statistically significant 2-fold increased risk of sudden infant death 0-14 days following the first dose of a hexavalent vaccine (RR = 2.2) or the co-administration of six antigens (RR = 1.9). Kuhnert et al [*Stat Med* 2011; 30(6): 666-77] found that infants had an increased risk of sudden infant death within three days after receiving a second dose of a pentavalent or hexavalent vaccine (risk estimate = 2.56).

A European hexavalent vaccine manufacturer [*GSK Confidential Summary Bridging Report* 2011 Dec 16: 246-49] produced a confidential evaluation on whether the number of sudden deaths reported following receipt of its combination vaccine exceeded the background incidence rate. Sudden deaths reported within 20 days after hexavalent vaccination were tabulated over a 2-year period. There were 67 sudden deaths reported within 20 days after vaccination during the first year of life. Despite the manufacturer’s conclusion that its hexavalent vaccine does not increase the risk of sudden death, Table 36 on page 249 of the confidential report shows that 65 (97%) of the 67 sudden infant deaths occurred in the first 10 days after vaccination and just 2 deaths occurred in the next 10 days.

Zinka et al [*Vaccine* 2006; 24(31-32): 5779-80] documented six cases of sudden death that occurred within 48 hours following the administration of hexavalent vaccination. Autopsies showed abnormal brain neuropathology. There was a 13-fold increase in the risk of sudden death after hexavalent vaccination compared to an earlier period when the multi-dose vaccine was unavailable. Parents and pediatricians should be aware that such fatalities are possible after hexavalent vaccines. In another paper [D’Errico et al. *Forensic Sci Int* 2008 Aug 6; 179(2-3): e25-29] scientists performed an autopsy on a 3-month-old infant who died within 24 hours of receiving a hexavalent vaccine and concluded that the multi-dose vaccination was the cause of death. Matturri et al [*Curr Med Chem* 2014 Mar; 21(7): 941-46] examined several sudden infant deaths that occurred within seven days of hexavalent vaccination. The authors of this paper recommend that all sudden infant deaths occurring soon after hexavalent vaccination should be thoroughly investigated by an expert pathologist to objectively assess the possible role of the multi-dose vaccine in causing SIDS.

Ecological analysis

Gorski claimed that because our paper was an ecological analysis it is somehow invalid. This is patently untrue. In our paper we discussed the potential for ecological bias, which occurs when relationships among individuals are inferred from similar relationships observed among groups (or nations). Most of the nations in our study had 90%-99% of their infants fully vaccinated. We also provided plausible biologic and causal evidence that the observed correlation between IMRs and the number of vaccine doses routinely given to infants should not be dismissed as ecological bias.

Ecological studies provide many advantages. For example, according to Sedgwick [**Ecological studies, advantages and disadvantages.** *British Medical Journal* 2014; 348: g2979] ecological studies “allow an initial examination of the health status and needs of communities. Ecological studies should be seen as a means of generating hypotheses rather than deriving definitive information about associations between risk factors and health outcomes.” According to Schwartz [**The fallacy of the ecological fallacy.** *Am J Public Health* 1994; 84: 819-24] “the ecological study is not a substitute for an individual-level study but an examination of unique variables not measurable on the individual level.” Furthermore, “ecological variables are necessary to examine structural, contextual, and sociological effects on human behavior and disease development.”

According to Wikipedia, “Ecological studies are particularly useful for generating hypotheses since they can use existing data sets and rapidly test the hypothesis.” In addition, “Ecological studies have often found links between risk-modifying factors and health outcomes well in advance of other epidemiological or laboratory approaches.” For example, a study by John Snow in the mid-1800s regarding a cholera outbreak in London “is considered the first ecological study to solve a health issue.” The first paper linking diet to risk of Alzheimer’s disease was a multi-country ecological study. Multi-country ecological studies of cancer incidence and mortality rates with respect to national diets have shown that animal products, sweeteners, and some fats appear to be risk factors for many types of cancer. Wikipedia provides other examples confirming the value of ecological studies.

Independent confirmation of the Miller-Goldman findings

Shortly after the Miller-Goldman study was published, Walter Schumm, PhD, Professor at Kansas State University and chair of the Graduate Faculty in the School of Family Studies and Human Services, further investigated our paper by performing an odds ratio analysis with the countries divided at the median IMR and total vaccine doses, then controlling for the following factors for each nation: (1) child poverty rates, (2) low birth weights, (3) pertussis vaccination rates, (4) breast feeding rates, (5) teenage fertility rates, (6) births out of wedlock rates, (7) age at first marriage, (8) percent of divorces with/without children involved, (9) total fertility rates, and (10) pertussis incidence rates. Although child poverty rates, pertussis vaccination rates, and teenage fertility rates were significant predictors of IMR, none of these factors lowered the partial correlation below 0.62, thus robustly confirming the Miller-Goldman findings.

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Link to the Miller-Goldman study:

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3170075/?tool=pubmed>

Link to another important study conducted by Goldman and Miller:

<http://journals.sagepub.com/doi/full/10.1177/0960327112440111>