

Case Study: Varicella Vaccine and the Suppression of Data

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This article is based on Neil Z. Miller's interview of Gary S. Goldman, Ph.D., concerning his experiences with the Centers for Disease Control and Prevention (CDC), with regard to the varicella vaccine.¹ The CDC is a U.S. public health agency trusted to provide accurate information about important health-related issues. Goldman, a computer scientist who taught statistics, digital logic design, and switching theory as an associate professor at California State University, Fullerton, considered CDC to be the gold standard for objective science. Thus, in 1995 he welcomed the opportunity to serve as a research analyst on the CDC-funded Antelope Valley Varicella Active Surveillance Project (VASP). Gradually, however, his views changed, and after serving eight years at his post, he resigned to avoid participating in what he perceived was research fraud.

Goldman's numerous published studies on chickenpox and shingles demonstrate his advocacy for impartiality and accountability in public health. His claims that the CDC suppressed or disallowed deleterious vaccine data from being published and engaged in other acts of questionable scientific integrity are substantiated with compelling evidence in the full interview,¹ which can only be excerpted here. The full interview includes legal correspondence, tables, and figures.

Neil Z. Miller (NM): How did your work with the CDC as an expert on varicella-zoster get started?

Gary Goldman, PhD (GG): In January 1995, I was hired by *Vestex Human Resource Systems* on behalf of the Los Angeles County Department of Health Services, Acute Communicable Disease Control Unit, to serve as the sole research analyst on the CDC-funded Antelope Valley Varicella Active Surveillance Project (VASP). This project's mission was to perform epidemiological studies and monitor the effects of the universal varicella vaccination program on the 300,000 residents comprising the study population, principally in two cities, Lancaster and Palmdale, in California.

NM: What were your responsibilities?

GG: I designed and implemented VASP's database of demographic and clinical variables and developed programs to perform all statistical and data analyses associated with the project. From the project onset, I was encouraged by the co-principal investigators to pursue any analyses and studies that might be suitable for publication. In fulfillment of this directive, I authored and co-authored studies that highlighted positive aspects of the varicella vaccination program. These studies were quickly approved by CDC/VASP and subsequently presented and/or published.²⁻¹² However, my investigation of herpes zoster (HZ) incidence rates and other deleterious findings were either suppressed or disallowed.¹³⁻²¹

NM: Do you believe that the CDC engaged in scientific misconduct?

GG: The CDC obscured the immunologically mediated link between universal varicella (chickenpox) vaccination and HZ (shingles) epidemiology, especially concerning increased HZ incidence rates among individuals with a history of natural varicella. The CDC perpetuated a false narrative regarding the role that universal varicella vaccination played in reducing exposures to wild-type varicella, which provide natural immune boosts helping to prevent or postpone the reactivation of the varicella-zoster virus as HZ.

NM: Chickenpox is a relatively harmless disease. Yet, in 1995 the chickenpox vaccine was licensed by the Food and Drug Administration (FDA) and recommended by the CDC for universal use in the U.S. Was that a good idea?

GG: The varicella vaccine was licensed despite prior concerns that exogenous exposures to wild-type varicella provided subclinical immune boosts to inhibit the reactivation of varicella-zoster virus as HZ in people who had previously contracted varicella. In fact, this was acknowledged in the Summary for Basis of Approval Agreement between the FDA and Merck (the varicella vaccine manufacturer): "There is... concern that universal vaccination might result in increased rates of herpes zoster in vaccinated and unvaccinated individuals."²²

NM: If there were legitimate concerns that a universal chickenpox vaccination program might increase shingles rates, how was this vaccine approved?

GG: Despite concerns acknowledged by the FDA, Merck, and other health authorities regarding the overall effect that a loss of exogenous boosts following universal varicella vaccination might have on rates of HZ, universal varicella vaccination was adopted in the U.S. primarily based on the cost savings from parental time lost from work to care for a child with chickenpox.²³

NM: That doesn't seem to be a sufficient or sound rationale. Regarding your claim that undesirable findings were suppressed, do you have evidence of malfeasance, research bias, or scientific misconduct?

GG: Yes. When the Los Angeles County Department of Health Services, Acute Communicable Disease Control Unit, entered into a cooperative agreement with the CDC, no directive existed for VASP to initiate active surveillance of HZ, so only data on varicella was initially collected *with no corresponding baseline HZ incidence data for the Antelope Valley study region during the early varicella vaccine post-licensure years 1995 through 1999*. I recommended that collecting cases of HZ be adopted as part of active surveillance at the close of VASP's first five-year grant cycle. Although CDC approved HZ active surveillance starting Jan 1, 2000, a lack of HZ surveillance from the inception of this project is suggestive of either

incompetence or misconduct by health authorities, especially considering that FDA scientists were fully aware that HZ rates were likely to increase following universal varicella vaccination. Thus, *active surveillance of HZ should have been initiated at the start of the universal varicella vaccination program concurrent with active surveillance of varicella.*

NM: How did you inform the CDC about your concerns related to HZ?

GG: On Nov 28, 2000, I informed Dr. Jane Seward, CDC varicella chief, that the HZ incidence rate among children aged less than 10 years with a history of varicella was approaching the high HZ incidence rate reported in older adults (aged 50-59). I also noted that, as vaccination programs continue to reduce the incidence of varicella, adults will increasingly fail to receive natural immune boosts normally obtained from wild-type varicella circulating in the community. I alerted Dr. Seward of my concern that *“there will be dramatic increases in zoster among adults as mandatory varicella vaccination programs are instituted.”*²⁴

NM: How did the CDC varicella chief respond to your concern?

GG: Dr. Seward claimed that *“internal boosting, not external boosting, maintains immunity,”*²⁵ despite prior evidence that exogenous exposures play the dominant role in boosting immunity, as shown in studies by Arvin et al.,²⁶ Terada et al.,²⁷ Gershon et al.,²⁸ and Solomon et al.²⁹ Later studies³⁰⁻³² provided additional evidence that exogenous exposures are the most significant factor. Seward asserted that the data I reported was inconclusive and premature for evidence of an increase in HZ, and, *“unfortunately, we do not have baseline data to use for interpreting the incidence.”*³³

NM: But isn't that because the CDC initially failed to undertake collection of baseline shingles data?

GG: Yes. This statement by the CDC's varicella chief was true only because *the CDC itself was negligent in not requiring VASP to collect baseline HZ data at the start of the project in 1995.*

NM: How did lack of baseline data on shingles affect your analyses?

GG: A lack of baseline HZ data did not affect my analyses of the relative age-specific HZ incidence rates reported by VASP in 2000 and thereafter. Children aged 1-9 years with a history of varicella were afflicted with HZ at a rate 16 times greater than vaccinated children. Additionally, VASP HZ case reports among adults aged 20-69 years increased 28.5 percent from 2000 to 2001.^{12,20}

NM: So, shingles rates were starting to increase as suspected. Did you have enough data to publish your findings?

GG: HZ data collected by VASP from the Antelope Valley study population had a sample size and observation times comparable to other historical studies reporting HZ incidence rates,³⁴⁻³⁷ so it was suitable for publication despite its *unfavorable* findings. Seward claimed that VASP HZ data (2000-2002) were too preliminary for publication, yet she sought to publish preliminary VASP data showing *favorable* trends in declining varicella incidence. The *New England Journal of Medicine* rejected Seward's study on the grounds

that it did not contribute anything substantially new to the current understanding of varicella.

NM: So, your unfavorable data on rising shingles rates was rejected by Dr. Seward for publication because it was considered preliminary yet she sought to publish favorable preliminary data on the declining incidence of chickenpox. How did you respond?

GG: In February 2001, I reached out to Dr. Philip R. Krause, lead research investigator at the FDA Center for Biologics Evaluation and Research. On Feb 28, 2001, Dr. Krause stated that *“the most intriguing zoster-related issue is the one that [Goldman] is working on, which is the question of how continuous re-exposure influences zoster rates.”*³⁸ Krause had more to say on this topic: *“If exogenous exposures contribute heavily to maintenance of immunity, there is the potential [as a result of universal varicella vaccination] to see an increase in wild-type shingles in the unimmunized—and potentially also the immunized—as wild-type exposures decrease.”*³⁸

Yet, Dr. Seward had previously stated to VASP co-principal investigators that questions related to the effects of the varicella vaccination program on HZ were not designed to be answered by Antelope Valley VASP. I did not agree with this logic since I had previously proposed HZ surveillance for that very purpose.

NM: Did you stop pursuing publication of your findings?

GG: No. On May 4, 2001, Dr. John Glasser, the CDC disease modeler with whom I had collaborated on the relationship between varicella, high ambient air temperature, and clustering of students in schools,^{2,3} indicated that he would review the methods section of the HZ paper that I was preparing for publication.³⁹ Dr. Glasser had previously expressed his interest in modeling HZ disease and suggested that such a model could be confirmed through data collected by Antelope Valley VASP. However, on the following day he wrote that the conclusions are premature, *“for which reason neither Carol [VASP co-principal investigator], nor Jane [CDC varicella chief], will clear any manuscript on zoster for years.”*⁴⁰ At this time, Dr. Glasser also rebuked me for not being a compliant “Boy Scout.”

NM: How did you react?

GG: I was concerned that data and analyses regarding rising HZ rates were being suppressed, so I contacted Dr. Krause once again, requesting his feedback on whether to continue pursuing publication now or drop the issue and pursue publication in another 5 or 10 years (as implied by my superiors). Dr. Krause responded:

I would hope the CDC doesn't want to be in a position where they are preventing publication without even reading the manuscript. (Some pharmaceutical companies have been severely criticized for over-enforcing these types of agreements.) *This would create the impression that they are trying to manipulate the scientific data to prevent publication of data that could adversely influence immunization rates, regardless of the potential public health consequences [emphasis added].*⁴¹

NM: Dr. Krause seemed supportive of your dilemma. How did events proceed?

GG: On May 9, 2001, during a VASP conference call between Dr. Seward and VASP staff, I learned that my HZ manuscripts were in the process of being reviewed. However, the following day, when I asked Teresa Maupin, Antelope Valley VASP project director, for permission to phone-interview 10 individuals who had experienced recurrence of shingles in the Antelope Valley, I was instructed not to contact them—and later, in 2002, *not to pursue any further HZ studies.*

NM: That must have been disappointing.

GG: By the end of December 2001, I had analyzed two complete years of HZ data. Case reports among adults showed a statistically significant increase of 28.5 percent.¹² Rates among children with a history of varicella were unusually high, approaching the rate typical of older adults, while the rate among vaccinated children was low as expected and served as a control indicating that cases of HZ were not being misdiagnosed or over-diagnosed. I also worked on determining the increased costs associated with a higher incidence of HZ in adults. *These additional costs, such as excess hospitalizations for pain and suffering, are a direct deleterious consequence of the universal varicella vaccination program, which had reduced opportunities for natural, periodic exogenous boosts to immunity.*¹⁷

NM: Did your papers get published?

GG: By October 2002, 17 months had passed with no word regarding any progress on my HZ manuscripts that were supposedly under review. Nearly three years of HZ incidence data had been collected, and it was now apparent that Dr. Glasser was correct when he asserted that the CDC would not clear for publication “any manuscript on zoster for years.” And it seemed especially unlikely for any manuscript to be approved if the findings showed evidence of deleterious effects associated with the universal varicella vaccination program. Not desiring to be a participant in what I perceived was research fraud, I resigned on Oct 18, 2002.

NM: Did you provide a reason for your resignation?

GG: I stated, “When research data concerning a vaccine used in human populations is being suppressed and/or misrepresented, this is very disturbing and goes against all scientific norms and compromises professional ethics.”

NM: I commend you for your integrity.

GG: Now that I was free from CDC/VASP sponsor bias, I felt a moral obligation to publish all of the varicella and HZ data I had analyzed.¹³⁻²¹ Since VASP was funded by the CDC, the data collected by VASP was available to any citizen through the Freedom of Information Act.¹² Upon finalizing several papers for publication, I contacted VASP and CDC to determine whether those associated with VASP wanted to be recognized as co-authors.

NM: As a professional courtesy?

GG: Yes, but on Apr 10, 2003, I received from the Los Angeles County Legal Department a notification to “cease and desist” in any effort to publish or disseminate any information gathered as part of my employment with VASP (Letter 1).¹ Consequently, I retained an attorney whose reply seemed to

resolve any legal issues (Letter 2).¹ Subsequently, three of my studies were published in the Oct 1, 2003, issue of *Vaccine*, a well-respected European medical journal.¹³⁻¹⁵

NM: Congratulations. I summarized some of your published papers in my book, *Miller’s Review of Critical Vaccine Studies*.⁴² Were there other experts in the field who realized what was happening?

GG: Yes. In 2002, Marc Brisson and W. John Edmunds, infectious disease experts associated with the Immunization Division of the Public Health Laboratory Service Communicable Disease Surveillance Centre in London, wrote a letter⁴³ to the editor of the *Journal of the American Medical Association* in which they criticized Dr. Seward and her colleagues for reporting that the incidence of varicella in the U.S. declined markedly following the introduction of varicella vaccination *without also discussing how this decline “might lead to a significantly increased incidence of HZ over the next 50 years.... Seward et al. report only half the story: trends in the annual age-specific incidence of HZ should be presented alongside the varicella data to show the full impact of the vaccination program on varicella-zoster virus disease.”*

NM: Apparently, other experts were aware that the CDC was promoting *benefits* of the chickenpox vaccine program while dodging a discussion of potential *detriments* associated with the program. How did you determine the true rates of shingles in vaccinated versus unvaccinated populations?

GG: To properly calculate HZ incidence in a community with moderate varicella vaccination coverage required a different methodology than the approach utilized in historical studies conducted prior to implementation of the universal varicella vaccination program. Those studies simply reported crude incidence rates by combining all children into a single cohort. This was an acceptable approach during the pre-varicella vaccine period. However, after the vaccine was licensed in 1995 and vaccine coverage rates rapidly increased in subsequent years, calculation of a crude (or population) rate was no longer an acceptable method for tracking trends in HZ incidence. Thus, I implemented an approach that stratified children into two separate cohorts: 1) those who received the varicella vaccine, and 2) unvaccinated children who had previously contracted wild-type varicella.¹⁶ Thus, the diverse HZ incidence rates could be separately tracked in each of these distinct cohorts.

NM: So, before the chickenpox vaccine was introduced, it was acceptable to combine all children of the same age into one group to calculate the incidence of shingles. However, after the chickenpox vaccine was licensed in 1995, shingles rates had to be calculated separately in children that had received the vaccine and in unvaccinated children who had previously contracted chickenpox naturally.

GG: Yes. By 2000, with approximately 50 percent of the child population vaccinated, opportunities for unvaccinated children with a history of varicella to gain exogenous boosts to their immunity were greatly diminished. The incidence of HZ in this group of children would be much higher than HZ rates in vaccinated children—and *greater than HZ rates during the pre-vaccine era*. Yet, the CDC advocated the calculation of a single *crude* HZ incidence rate among children aged less than 10 years.⁴⁴ The CDC/VASP’s fundamental approach was

to combine into a single cohort 1) vaccinated children, and 2) unvaccinated children who had previously contracted wild-type varicella. This approach yielded a single mean HZ incidence rate of a bimodal distribution. This mean rate did not represent either of the two widely divergent HZ incidence rates. More concerning, *this had the effect of concealing the importance of exogenous boosts while masking a significantly higher HZ incidence rate (post-varicella vaccine licensure versus pre-licensure) in children with a history of varicella.*

NM: Has the loss of exogenous exposures to the natural (or wild) chickenpox virus caused any other undesirable effects?

GG: Yes, the chickenpox vaccine was losing its efficacy. Table 4¹ shows the “honeymoon” effect during 1997–1999 during which vaccine efficacy increased from 87 percent to 96 percent, augmented due to vaccinees receiving exogenous exposures (natural immune boosts) from children infected with wild-type varicella (i.e., contagious children shedding varicella-zoster virus). This augmentation of vaccine efficacy would only occur during the early years of the universal varicella vaccine program as varicella remained endemic. However, as more children were vaccinated and the widespread circulation of wild-type varicella declined, exogenous exposures became rare in 2000 and beyond. Single-dose vaccine efficacy plummeted, causing increased cases of breakthrough varicella (outbreaks of chickenpox in varicella-vaccinated people). Apparently, exogenous exposures to wild-type varicella not only 1) subclinically boosted cell-mediated immunity to postpone or prevent the reactivation of varicella-zoster virus as HZ in people who had previously contracted varicella (as discussed earlier), but they also 2) augmented efficacy of the varicella vaccine. *Ironically, the “success” of the varicella vaccine at reducing cases of wild-type varicella contributed to the failure of the single-dose vaccine to maintain adequate efficacy to prevent varicella in vaccinated individuals.*

NM: How did the industry respond to this finding?

GG: In 2006, a booster dose of the varicella vaccine was recommended for children aged 4 to 6 years.

NM: Please discuss epidemiological studies that may provide false information when improper methodologies are utilized.

GG: In 2009, when the CDC finally published age-specific HZ incidence rates among children and adolescents annually for 2000 through 2006, CDC and VASP authors compared VASP *unadjusted* HZ incidence rates to rates reported in other studies using methodology with more exhaustive case collection.^{45,46} Such comparisons were problematic and misleading. Since application of capture-recapture indicated a 50 percent underreporting of HZ cases to VASP,^{14,15} *ascertainment-corrected age-specific HZ incidence rates among children aged 1-9 years and adolescents aged 10-19 years were two-fold higher than the CDC’s published unadjusted rates.*

NM: So, the CDC was publishing unadjusted data that was misleading. How did this influence other scientists who trusted the CDC data?

GG: The CDC’s promotion of *unadjusted* age-specific HZ incidence rates, rather than ascertainment-corrected rates, created an unfortunate cascading effect in subsequent publications by other researchers (who presumed CDC data

were reliable), resulting in wide variability in published age-specific HZ incidence rates.

NM: Nearly 20 years have passed since you resigned from your work with the CDC-funded VASP. Have other studies confirmed your findings?

GG: Yes. For example, a study by Yawn et al., sponsored by the Mayo Clinic, utilized data from the Rochester Epidemiology Project (REP) and found a 5.6 percent average annual increase in HZ incidence (during the early post-varicella vaccine period) among adults aged ≥ 22 years. This study recognized that “vaccination may reduce opportunities for varicella-zoster virus immunity boosting from exposure to natural varicella, leading to...increased incidence of HZ in older adults.”⁴⁷

NM: Have any studies contradicted your findings?

GG: Yes. Merck, the varicella vaccine manufacturer, sponsored a retrospective study (Wolfson et al.) of HZ incidence rates from 1991-2016 that concluded: “The annual incidence of HZ in adults increased at approximately the same rate...in the years before and after childhood varicella vaccination took effect.”⁴⁸ However, this study has several weaknesses or limitations that create uncertainty regarding the authors’ conclusion. For example, the study authors acknowledged that HZ incidence rates during the pre-vaccine period from 1991-1995 were estimates rather than actual rates, and the MarketScan databases⁴⁹ that were utilized for the study did not reflect the true HZ incidence rates of the population.

NM: I’m not surprised that a study sponsored by the chickenpox vaccine manufacturer found that their vaccine did not cause increased rates of shingles.

GG: In 2016, a CDC-sponsored study by Kawai et al.⁵⁰ used the same REP data utilized by Yawn et al. and found that there was “no change in the rate of increase before versus after the introduction of the varicella vaccination program.” However, Kawai et al. failed to show an increasing trend because *widely divergent HZ rates between two distinct cohorts—vaccinated and unvaccinated populations—were combined in a misleading and unscientific methodology to effectively mask the increase in adult HZ incidence rates.*

NM: So, a study sponsored by the Mayo Clinic reported an annual increase in shingles incidence that was higher than the pre-licensure rates—which supported the increasing trend that you reported from VASP—while a CDC-sponsored study using the same database contradicted those findings.

GG: Yes.

NM: Since 1995, the chickenpox vaccine was recommended by the CDC for universal use in the U.S. Thus, if CDC data were to show evidence that it causes deleterious effects (i.e., a negative cost/benefit ratio), the agency would lose credibility. I wonder whether this influenced or biased their decisions.

GG: Perhaps, but whatever hidden agendas or unknown motives might have existed, my concern was simply to report the surveillance data as accurately and objectively as possible.

NM: Of course. Were there other studies that contradicted your findings?

GG: Yes. In 2018 and 2019, several CDC-sponsored studies⁵¹⁻⁵⁴ reported a constant increase in adult HZ incidence that remained unchanged in the periods before and after varicella vaccine licensure. These studies extracted data from large administrative databases that were subject to the same confounders and limitations previously described for MarketScan. Clearly, multiple confounders and methodological limitations in CDC-sponsored retrospective studies of HZ incidence rates—and obfuscation of deleterious data—have prolonged the specious controversy regarding the well-documented significance of exogenous exposures to inhibit reactivation of the varicella-zoster virus as HZ.⁵⁵ (See Figure 1¹ for additional details regarding the Merck and CDC studies.)

NM: There are ethical issues associated with introducing a vaccination program that could advance the health of one population group (reduced cases of chickenpox in children) at the expense of another (increased cases of shingles in adults).⁵⁶ Considering your lengthy relationship with the CDC, do you believe it's a trustworthy public health agency?

GG: Dr. Julie Gerberding served as director of the CDC from 2002 until her resignation in 2009 to become president of Merck's vaccine division. I do not know whether conflicts of interest between CDC and the varicella vaccine manufacturer played a role in concealing the importance of exogenous boosting and censorship of deleterious outcomes associated with the universal varicella vaccination program. However, due to blatant biases such as those described in this interview, CDC/VASP seemed to serve as a commercial enterprise marketing a product rather than as an impartial national public health agency reporting on the true impact that universal varicella vaccination had on the U.S. population.

NM: What do you conclude about the health impact of the universal varicella vaccination program and the implications for public health policy?

GG: The U.S. universal varicella vaccination program reduced cases of chickenpox but also caused a significant increase in adult HZ incidence rates. Excess medical costs for pain and suffering are a direct deleterious consequence of the program. The CDC reported all positive findings while negative data were either suppressed or misrepresented to make unfavorable outcomes appear less concerning than they actually were. When public health agencies fail to remain impartial—whether inadvertently or by design—health authorities lose their credibility, our confidence in the veracity of scientific research is diminished, and large populations may be exposed to increased rates of adverse health consequences. Finding ways to improve vaccine safety and increase CDC accountability must be top priorities.

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