

Assessment and Analysis of Morbidity and Mortality Rate Estimates from Vaccine Safety Databases, Corrected for Underreporting Bias

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Running Title: *Assessment of Vaccine Safety Databases*

Abstract

Objectives – To evaluate the utility of two public databases that serve to capture adverse events after routine vaccination.

Methods – Database queries designed to capture temporal trends in mortality and morbidity were conducted and trends analyzed in reference to antecedent events in recommended vaccination practices.

Results and Conclusion - An analysis of trends in mortality and morbidity in two vaccine safety databases, VAERS and VigiBase, reveals a major jump in reported mortality in the VAERS data for vaccines on the CDC pediatric schedule between 2006-2007, and signals for two major events dominate the implied history of morbidity and mortality in VigiBase in

2001 and 2010. Events antecedent to these dominant signals are discussed. The present analysis suggests that post-market surveillance of vaccine safety using databases of passively collected data is not powerful enough to identify hypotheses of serious problems with vaccines. Serious flaws exist in the data capture, data representation, and point-of-care utilization (reporting). The CDC's more comprehensive Vaccine Safety Database (VSD) is not readily available for independent analyses, which severely limits the number, type, design, and reproducibility of VSD studies. Because causality can never be assessed from passive reporting systems, it is therefore concluded that long-term post-market surveillance vaccine safety science does not exist. VSD data should be released for unrestricted analyses, and our society requires mandated, active, automated reporting with penalties to practitioners who fail to report.

Key Words: Vaccines, Adverse Events, database assessment

Introduction

The US Centers for Disease Control and Prevention (CDC) and US Food and Drug Administration (FDA) maintain the Vaccine Adverse Events Reporting System (VAERS)¹, which is described as "a national post-marketing vaccine safety surveillance program of reported adverse events following immunizations administered primarily in the United States" (Halsey and Proveaux, 2017)². Vaccine adverse events are reported worldwide using a similar, passive reporting systems. Patterns of reporting are captured in two publicly accessible resources: the US-based Vaccine Adverse Event Reporting System (VAERS), and VigiBase, an international resource hosted by the World Health Organization-Uppsala Monitoring Centre (WHO-UMC). VigiBase provides temporal reports by vaccine type.

A common complaint levied about these resources is that because they are passive, and anyone can report events to them, they are invalid resources for assessing causality. While reporting in the US at least is required for all health care professionals who administer vaccines, the reporting compliance to these resources is effectively voluntary, as there exist no real consequences to practitioners who fail to report adverse events (AEs). Users who access data from both resources are required to acknowledge that causality cannot be ascertained from the entries. In 2010, the developers of ESP:VAERS, an automated vaccine adverse event reporting system, found that passive reporting captured about 1% of AE's (Lazarus, 2010)⁵.

Previous analyses using VAERS have included detection of an increase in one serious adverse event from one vaccine (1-2 cases of intussusception per 100,000 rotavirus vaccines, Haber et al., 2013³) but the authors noted:

"...firm conclusions about risk could not be derived because of the relatively small number of intussusception cases reported to VAERS at the time and limitations of voluntary reporting to VAERS".

This is an example of a failure to detect, and a failure to discern due to limitations of the instrument of measurement's ability to provide robust evidence. The question of whether VAERS and VigiBase are useful for detecting signals of increases in adverse events for posing and testing hypothesis is a significant one, because limitations that lead to failure to reject a null hypothesis due to design flaw, not due to robust hypothesis testing, could be confused with failure to reject the null hypothesis due to no (real) signal.

Methods

Analysis and Evaluation of VAERS – We conducted a systematic search of adverse events reported for vaccines found on the CDC pediatric schedule. The searches consisted, per vaccine by Trademark (as reported by CDC, 2018a⁴), of all adverse events reported. From the downloaded reports, the following adverse events were considered reflecting “mortality”: *Death, Sudden Death, Sudden Cardiac Death, Cardiac Death, Cardiac Arrest, Death Neonatal, Sudden Infant Death Syndrome, Cardiopulmonary Arrest, Sudden Cardiopulmonary Arrest, Cardio-Respiratory Arrest, Respiratory Arrest, Brain Death, Accidental Death, Terminal State.*

Analysis and Evaluation of VigiBase – As with VAERS, we conducted a systematic search of adverse events reported for vaccines found on the CDC pediatric schedule. VigiBase does not allow a granular search by specific vaccine, nor by adverse event per year, because adverse events reported are stored by type and not separated out for all types or by specific vaccine tradename. Thus, our temporal considerations were restricted to vaccine type. Terms used to reflect “mortality” included: *Autopsy, Sudden Infant Death Syndrome, Apparent Death, Brain Death, Death Neonatal, Sudden Death, Sudden Cardiac Death, Death, Cardiac Death, Cardiac Arrest, Cardiac Failure, Cardiopulmonary Failure, Cardiac Failure Acute, Cardiac Failure Congestive, Cardio-Respiratory Arrest, Respiratory Arrest, Acute Respiratory Failure, and Respiratory Failure.* Morbidity terms included *Coma, and Apparent Life Altering Event,* and by no means reflective of the totality of mortality represented, and therefore should the total score not be taken to reflect total morbidity, and instead only a source of information on trends in mortality.

The overall score per vaccine per year is an arithmetic sum of all reported events from these terms, however, there is no way to interrogate VigiBase to separate mortality and morbidity per year. However, we noticed that for DtaP vaccines, some individual vaccines held reported information separately.

Harvard Pilgrim (HP) Adjustment of Rates – For both resources, adverse event rates were adjusted by multiplying by 100 to bring them into accord with the estimate of underreporting found at Harvard Pilgrim Healthcare, Inc. (Lazarus, 2010)⁵. Data gathered via ESP:VAERS, an automated electronic vaccine adverse event reporting system, for more than three years from 376,452 individuals given vaccines revealed that “fewer than 1% of vaccine adverse events are reported” to VAERS.

VigiBase Mortality and Morbidity Score Per Year by Vaccine Type – For each vaccine type, the total score for all years since release (to market) was calculated (total score/number of years on market). This is a blunt measure because vaccine uptake per year is not readily available in VigiBase, and is not able to provide a measure of number of adverse events of each type per year by vaccine type.

VSD – The Vaccine Safety Datalink (Chen et al., 1997)⁶ a second tool hosted by CDC for tracking adverse events attributable to vaccines, is described as a “model of public health-managed care collaborations in addition to an excellent infrastructure for safety and other studies of vaccines” (Chen et al., 1997)⁶. Unlike VAERS and VigiBase, VSD is not readily available to the public.

Results

VAERS Mortality

Adjusted reported deaths per day showed a general increasing trend over time with high fluctuation from year to year (Figure 1). In total, for the time period studied (1990-2017), there were 198,880 reported deaths (adjusted), providing estimated average of 20.5 deaths

reported per day, or an average of 7501 deaths reported per year. The overall trend in reporting seems to reflect a major increase in reported deaths per day starting in 2006.

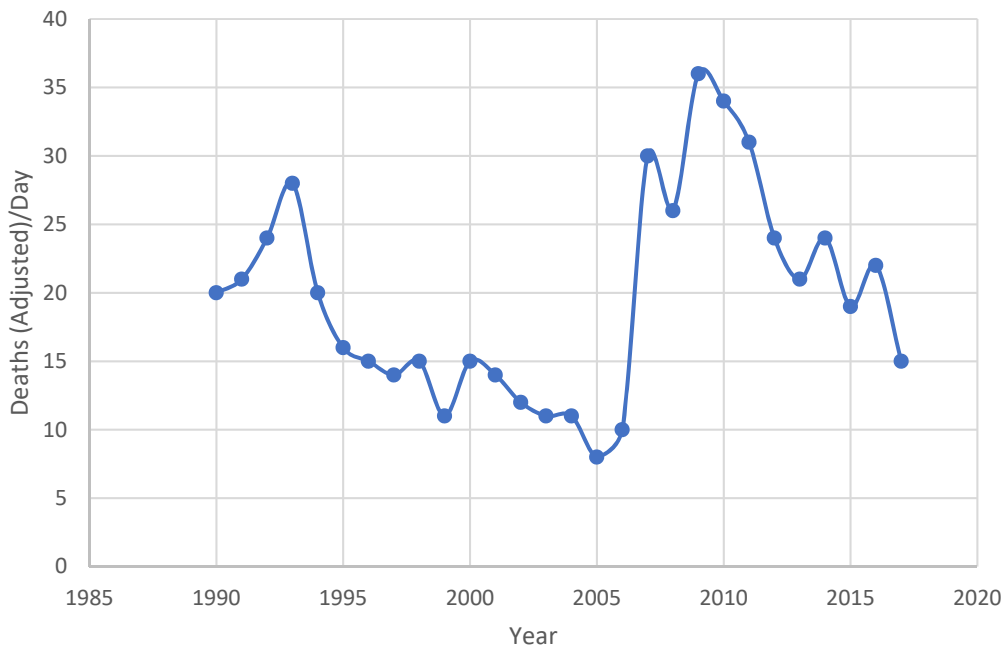


Figure 1. Deaths Reported in VAERS, All Vaccines in CDC Pediatric Schedule, Years 1990-2017.

VigiBase Mortality and Morbidity Score

The patterns of reporting mortality and morbidity in VigiBase are dominated by two main peaks, one in 2001, and the second in 2006 (Figure 2). The increase in morbidity seen in the VAERS reporting is not seen in this graph.

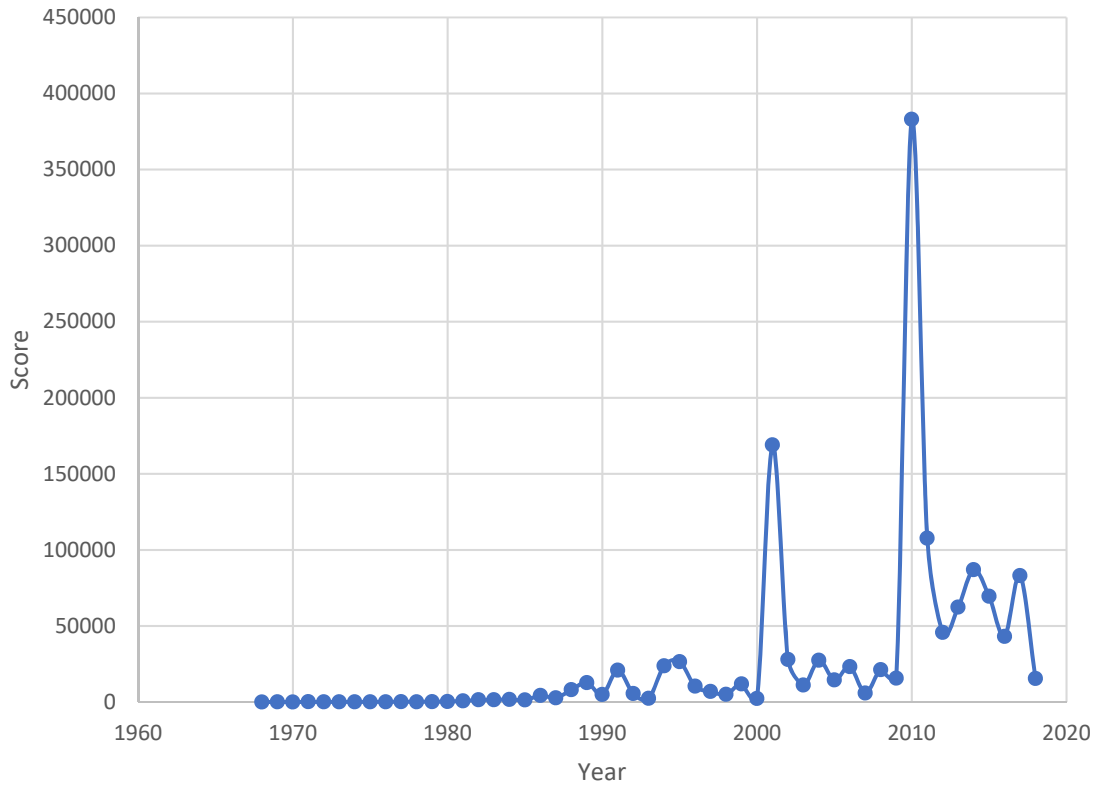


Figure 2 Morbidity + Mortality Score, VigiBase Years 1968-2018.

VigiBase Mortality and Morbidity Score Per Year by Vaccine Type

The Mortality and Morbidity Score by Vaccine Type results showed that HPV vaccine has the highest score, with over 6900 reports per year since coming to market. The score for the rest of the vaccine types are provided (Fig 3).

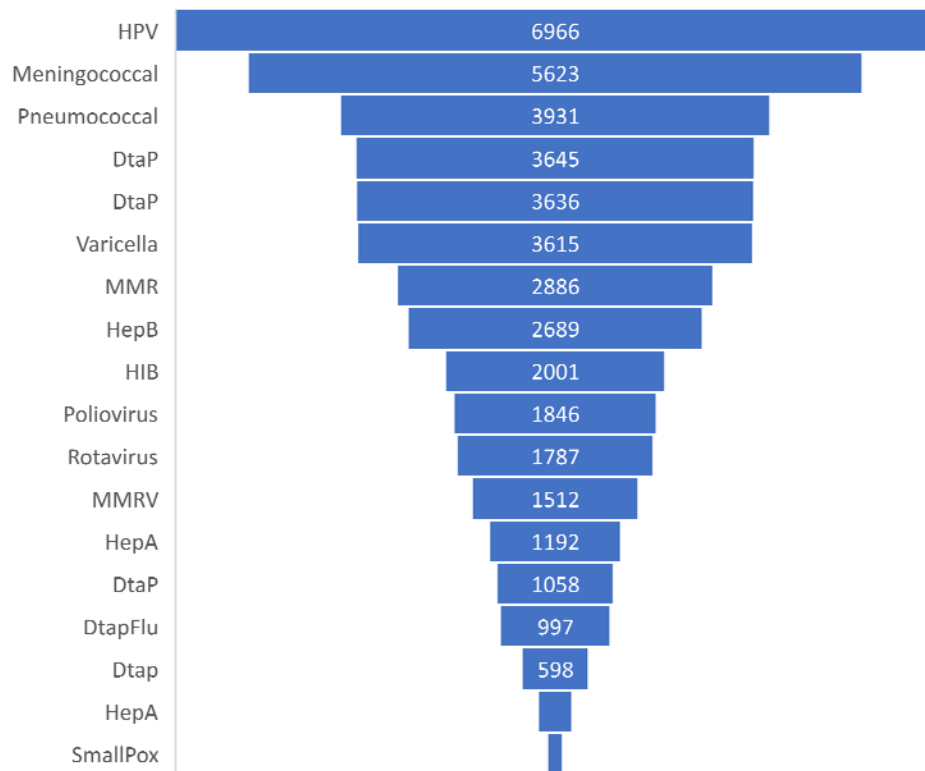


Figure 3. VigiBase Mortality and Morbidity Score Per Year by Vaccine Type. Dtap events are in fact reported separately by Trade Name, thus, the multiple entries.

Example of Extreme Underreporting

Underreporting in VigiBase is so severe that only 11 instances of “rashes at site of injection” were reported for MMRV vaccine across all years – and all countries. In comparison, CDC (2018b)⁷ cites VSD studies that give the rate of rash following MMRV as 1 out of 20. This implies that underreporting of some adverse event may be many orders of magnitude worse than implied by HP.

Discussion

The increase in reported deaths in VAERS in 2006 was concurrent with numerous changes to the CDC schedule. In 2006, CDC "emphasized" universal birth-dose administration of Hepatitis B vaccine; Tdap adolescent preparation was approved in 2005; the meningococcal conjugate vaccine (MCV4) was approved and recommended for children aged 11-12; influenza vaccine was recommend for children >6 months of age; Hepatitis A vaccine was recommended for all children at age 1, and ACIP/CDC allowed that Tdap could be used in lieu of Td for primary catch-up or booster shots⁸.

The dominant spikes in reporting in VigiBase are orders-of-magnitude increases, and are a mystery. The 2006 increase seen in the VAERS-reported morbidity is not present in the VigiBase mortality-morbidity score. Global vaccination patterns may be delayed by 3-4 years following changes in the CDC schedule. Precisely why these two years show spikes in reporting is a mystery, but the spikes are consistent across numerous vaccines. In 2000, FDA licensed the heptavalent pneumococcal polysaccharide-protein conjugate vaccine (PCV), including special recommendations for the immunocompromised (CDC, 2001)⁹.

Some minor changes occurred to the CDC recommendations in 2010, including a shift in the booster timing of the inactivated polio vaccine, and allowance of hepatitis A vaccine for children older than 23 months; a booster of MCV was recommended. One major change was the expansion of the HPV vaccination program to include males aged 9-18 (CDC, 2010)¹⁰.

To our knowledge, CDC did not report detection of these signals of mortality and morbidity in spite of the availability of the data. Also, to the best of available information, CDC has not acted upon the publication of similar findings of the increase in morbidity and mortality detected by Goldman and Miller (2012)¹¹, who also found a correlation between the number of vaccine doses and the rate of hospitalization. Goldman and Miller also reported a

negative correlation between the risk of hospitalization and the age of patients <1 year of age receiving 1-8 vaccines.

As far as available information provides, the CDC pediatric schedule has never been adjusted downward in terms of types or numbers of boosters as a result of post-market surveillance other than the cessation of the recommendation of one type of Rotavirus vaccine. This points to limitations of post-market surveillance, which uses retrospective analyses, primarily the absence of reported mortality and morbidity, which is severely underreported.

Limitations of VAERS and Vigibase

The change in the use of a vaccine for Rotavirus (RV) is sometimes used to point to the usefulness of VAERS and the VSD. According to published report from the Epidemiological Intelligence Service (a branch of CDC), between 1985-1991, the number of pediatric deaths in the US from diarrhea from all causes numbered around 300 per year (Kilgore et al., 1995)¹². The Rotateq™ vaccine was added in 2006 and was followed by 1,206 individual reports of intussusception, and 403 reports of death following its application. In 2007, the pediatric deaths following RV vaccination were changed to “infant deaths”, and there were 413 reported instances of post-vaccination gastritis, duodenitis, and noninfective enteritis and colitis; 68 reported cases of Hernia of abdominal cavity and intestinal obstruction without hernia, and 196 other (all other and unspecified diseases of digestive system). A total of 677 infant deaths from “diseases of the digestive system” was reported, which is more than double the number reported prior to the introduction of Rotavirus vaccine (Xu et al., 2010)¹³. In 2010, there were 316 individual reports of diarrhea and gastrointestinal from infectious origin, 29 reports of gastritis, duodenitis, and non-infective enteritis and

colitis, 51 reported cases of hernia of abdominal cavity and obstruction without hernia, and 124 "other", and a total = 520 infant deaths reported (Murphy et al., 2010)¹⁴.

In spite of the increase in mortality, VAERS failed to provide a detectable signature that after changing vaccine, mortality following RV vaccination increased. These are raw report numbers, not corrected for underreporting. The HP-corrected estimate of the number of infant deaths would be 52,000.

The CDC is aware that VAERS fails to capture at least 99% of serious adverse events, yet they continued with analyses of risk relative to the full population. They consistently find *lower* rates of specific ailments reported in VAERS than in the full population, and this is obviously seriously problematic for interpretation and likely reflects underreporting, not mysterious "added bonus" protective effects of vaccines.

Prior to accessing the VAERS database, users must acknowledge that:

"VAERS data should be used with caution as numbers and conditions do not reflect data collected during follow-up. Note that the inclusion of events in VAERS data does not imply causality" (HHS, 2018)¹.

The number of deaths reported in 2016 to VAERS was 432. Under the HP Correction, that translates to 43,200.

Meaningful, objective public health considerations of the benefits of vaccines and of the disease burden of infectious disease relative to vaccine-related morbidity and mortality cannot be conducted using data from VAERS and VigiBase. VAERS and VigiBase are both completely unreliable research resources for generating or testing hypotheses.

Underreporting is so severe that only a handful of extremely common adverse events are reported per year, when in the US alone, millions of children and adults are vaccinated per year.

Our findings are consistent with those of Halsey and Proveaux (2017)², who found the available resources insufficient for studying adverse events associated with the use of vaccines during pregnancy. These shortcomings are a cause for grave concern. By contrast, a CDC study reported that they did not “identify any concerning patterns” in the one-year analysis of VAERS reports on a quadrivalent live attenuated influenza vaccine (LAIV4; Haber et al., 2015)¹⁵. Haber et al., (2015)¹⁵ did not apply any adjustment for underreporting. Given the limitations of VAERS, one must wonder if instead of not identifying, they failed to detect any concerning patterns.

The CDC does maintain another data and monitoring system which is much more comprehensive than VAERS. The Vaccine Safety Datalink (VSD) system works with several large US health care organizations to gather electronic health records. CDC and VSD researchers have access to this data. Why is VSD data not readily accessible to independent researchers? Instructions for access to VSD at the CDC website read as follows:

“From time to time, scientists (from outside CDC and outside the VSD network) are interested in using data from the VSD to look differently at vaccine safety questions. When possible, CDC tries to accommodate these requests. Depending on the study, interested researchers may be able to access VSD data and data from [VSD publications](#) through [public use datasets](#), the [VSD data sharing program](#), and [collaboration](#) with current VSD investigators.”

The VSD is funded via the US Department of Health and Human Services, which is funded by Congress, and ultimately by the US taxpayers. There is no reason why CDC or “current VSD investigators” should have exclusive or prior or even priority use of and access to this public resource. Restricting access had placed a limit on the number, type, design, and assessment of reproducibility of VSD studies. Scientific integrity in research is built upon transparency through reproducibility. Without it, the validity of any outcomes is called into question.

Limitations of The Current Analysis

The trends and cores herein reflect a correction for underreporting, but because the systems are far too obtuse instruments, the scores cannot be interpreted as sums. Nevertheless, they provide some interesting perspectives on trends in AE reporting that may reflect the history of phasing out thimerosal in some countries that coincided with and was followed by the addition of specific vaccines. Due to limitations of the resource, we can only speculate on the possible causes. The scores may also be of interest for comparing mortality and morbidity that might be occurring as a result of different vaccines or, in the case of VigiBase, types of vaccines, but the inherent limitations prevent a test of causality. No objective, independent and thorough cost-benefit analysis of vaccines can be conducted using these easily accessible databases, and no post-market surveillance results conducted using VAERS or VigiBase can be considered a critical test of causality.

Conclusions

While our analysis of morbidity and mortality from vaccine safety databases, corrected for underreporting, provides some interesting perspectives on trends in AEs that may reflect changes to the CDC schedule, we can draw no causal relationship between the dynamics

and changes in mortality and morbidity due to inherent limitations of the reporting resources. In fact, no analysis can draw any conclusions, for, or against, given the severe limitations of VAERS and VigiBase. Prior analyses using VAERS and VigiBase that report lower rates of conditions in VAERS, or no increase in disease burden compared to the full population rates are unreliable and require further reconsideration.

The ability of independent researchers to obtain accurate assessment of the disease burden caused by vaccines is completely thwarted by reliance on passive VAE reporting. Additionally, passive symptoms suffer from subjectivity and human error. Reporting often only involves “suspected” adverse events, which does not allow for the discovery of non-obvious or previously unidentified events. Any adverse event that occurs after vaccination could, in fact, be due to the vaccine(s). Car accidents and drownings can indicate periods of syncope; non-vaccine-targeted infections can indicate nonspecific effects of any vaccine. Because of the weaknesses of passive reporting systems, Guillan-Barre Syndrome was only added to the Table of Adverse Events¹⁶ in 2017 – over forty years after the first observed cases following the adoption of the universal influenza vaccination program.

As a result of these factors, objective and independent post-market surveillance (so-called “pharmacovigilance”) is therefore reliably uninformed. Because no causality conclusions can be drawn from VAERS, and VigiBase, the public and the medical community are dependent on the results of retrospective post-marketing studies which are subject to unacceptable levels of bias, study design, analysis, and interpretation manipulations, and fraud.

This analysis supports the conclusion that long-term vaccine safety science does not exist in the United States, that new reporting requirements are needed, that the Vaccine Safety Datalink (VSD) should be made universally and freely available for independent use, free of supervision; that VAERS should be replaced by ESP:VAERS; that new requirements for

vaccine adverse events reporting must be drafted; and that failure of pediatric practices to comply with new requirements of vaccine adverse events reporting be subject to fines and restrictions on licenses to practice.

A request to the CDC to release the VSD for independent hosting for public access was given the following response:

"Thank you for your e-mail to the Centers for Disease Control and Prevention (CDC) regarding the Vaccine Safety Datalink (VSD) and other vaccine-related data.

In your message, you requested the complete VSD. Guidelines for requesting data in the VSD, a data-sharing program with the Research Data Center (RDC) at the National Center for Health Statistics, are available at www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vsd/data-sharing-guidelines.html. Information on submitting a proposal to the [RDC](http://www.cdc.gov/rdc/b3prosal/pp300.htm) to summarize your data needs is available at www.cdc.gov/rdc/b3prosal/pp300.htm.

You also requested the total number of U.S. deaths per year following vaccination for the last ten years. CDC does not have precise data on this topic. However, CDC and the Food and Drug Administration (FDA) monitor reports of adverse events, including deaths, following vaccination using the Vaccine Adverse Event Reporting System (VAERS). VAERS is a passive reporting system, meaning it relies on individuals to send reports of their experiences to CDC and FDA. VAERS is not designed to determine if a vaccine caused a health problem but is useful for detecting unusual or unexpected patterns of adverse event reporting that might indicate a possible safety problem with a vaccine. Anyone can report an adverse event to VAERS. For information on reports of deaths following vaccination, please refer to the public VAERS data available at www.vaers.hhs.gov/data.html.

*Evidence supports the safety of vaccines, and studies and scientific reviews have found no association between vaccination and deaths except in rare cases. An article by Miller et al., [Deaths following vaccination: What does the evidence show?](#) *Vaccine*. 2015;33(29):3288-92, provides an overview and specific examples. Additional studies include:*

- Shimabukuro et al., [Safety monitoring in the Vaccine Adverse Event Reporting System \(VAERS\)](#), *Vaccine*. 2015;33(36):4398-4405;
- McCarthy et al., [Mortality Rates and Cause-of-Death Patterns in a Vaccinated Population](#), *American Journal of Preventive Medicine*. 2013;45(1):91-97;
- Moro et al., [Deaths reported to the Vaccine Adverse Event Reporting System \(VAERS\), United States, 1997-2013](#). *Clinical Infectious Diseases*. 2015;61(6):1-8; and
- McCarthy et al., [Vaccination and 30-Day Mortality Risk in Children, Adolescents, and Young Adults](#), *Pediatrics*. 2016;137(3):1-8.

You also asked for estimates of the number of deaths per year for each of the vaccine-preventable infections for which CDC provides [pediatric immunization recommendations](#).

These data, which are based on causes of death reported on death certificates, are accessible via CDC's [Wide-ranging Online Data for Epidemiologic Research](#) platform. Reporting for most vaccine-preventable diseases is straightforward. However, in some cases, such as influenza and rotovirus infections, the complications of the infection (e.g., pneumonia, sepsis, diarrhea) may be reported without specification of the originating infection.

Thank you, again, for your e-mail and your interest in CDC's work. We hope this information is helpful to you."

CDC's "Wide-ranging Online Data for Epidemiologic Research" resource is an XML-based query system for accessing VAERS data with a web-based query interface. Extracting information on mortality and morbidity specifically due vaccines appears to be restricted "acute disseminated encephalomyelitis" caused by vaccines.

This independent analysis shows that VigiBase and VAERS are not reliable source of information on mortality and morbidity due to vaccines, and the CDC's reply demonstrates a lapse in rational inquiry: a lack of association of rare events that may be due to genetic

susceptibility using studies that are designed to detect whole-population effects as correlative association (1) will always fail to provide sufficient evidence of causation, precisely because they are correlational, and (2) cannot be expected to provide a result that may be relevant in a genetic minority of patients unless they specifically consider genotypic or haplotypic information relevant to increased risk of mortality and morbidity from vaccines.

None of the estimates of provided by Shimabukuro et al., (2015)^[17], McCarthy et al. (2013)^[18], Moro et al., (2016)^[19], and McCarthy et al (2016)^[20], all cited by CDC, correct for underreporting, and thus are unreliable. The bias inherent in the view that general epidemiological studies outweigh reports in VAERS reveals logical contortions and rationalization that causes all weight to be placed on epidemiological studies. Consider, for example, the views of Shimabukuro et al (2015)^[17]:

“The relatively rapid increase in numbers of reports to VAERS following the introduction and initial uptake of a new vaccine, an expected occurrence..., has been misinterpreted as actual increases in incidence of adverse events and vaccine related risk. This has been the case with VAERS reports following quadrivalent human papillomavirus (HPV4) vaccination..., which as expected, increased as uptake of HPV4 vaccine increased following licensure in 2006. However, post-licensure epidemiologic studies have consistently demonstrated the safety of HPV4 vaccine..., confirming the limitations of passive surveillance systems like VAERS.”

The rapid increases after uptake of a new vaccine are not expected if the data analyzed corrected for the number of doses given. If there is a subgroup of individuals who are more susceptible to serious adverse events than others, whole-population epidemiological studies are ill-posed. Continued reliance on whole-population epidemiologic studies not stratified by risk factors (familial, genetic, or biomarker-based) that do not fully address risks and that have been reliably underpowered^[21], or manipulated (intentionally biased toward the null)^[22] will prevent the detection of risks that exist in a minority of patients. Further, the

HPV4 post-licensure epidemiologic studies are now at odds with findings of the National Vaccine Compensation Program which recently conceding that plaintiffs have met the burden of proof that Gardasil led to a new case of arrhythmia in a patient causing her death^[23].

McCarthy et al.'s (2013)^[18] reported numbers (from the VSD) lead to 188 deaths/100,000 vaccinated person within 60 days of receipt of vaccination. As this rate is uncorrected for underreporting, the authors concluded that their data reflected a newly invoked (ad-hoc) hypothesis of a "healthy vaccinee effect", never considering that the underreporting bias of mortality and morbidity might drive estimates downward. McCarthy et al. (2016)^[20] similarly found a lower-than-general estimate of mortality, but gave no consideration to underreporting bias. In a highly vaccinated population, such as large bias must be explained by underreporting; however, no estimate of underreporting of events in the VSD has been made available. Moro et al.'s reported noted that over 79% of the child deaths reported in VAERS had received >1 vaccine on the day of vaccination. No issuance of a statement of concern or changed in policy was implemented to reduce the number of vaccines given at one time to reduce the risk of mortality due to the use of multiple vaccines on one day. It is worth noting that Miller^[24] also found increased morbidity and mortality associated with using more than a single vaccine in one day.

Miller et al. (2015)^[25] concluded:

"making general assumptions and drawing conclusions about vaccinations causing deaths based on spontaneous reports to VAERS - some of which might be anecdotal or second-hand - or from case reports in the media, is not a scientifically valid practice."

The current analysis also indicates that VAERS is not reliable for assessing causality, as is VigiBase, and are therefore not reliable resources for assessing post-marketing risks associated with vaccination. The only post-market reporting systems is the VSD, which is not available for public access without intense supervision. VSD should be released to the public for general use without restrictions to allow independent assessment of accuracy and reliability of reporting of mortality and morbidity associated with vaccination. No research on prevention of vaccine-related mortality and morbidity, which is part of public health, can progress until a truly mandatory active reporting system is adopted.

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