Causation in the Face of the 'Psycho-logic'

Dr. Jessica Rose

May 29, 2021

I recently published an analysis of the U.S. Vaccine Adverse Event Reporting System (VAERS) data.[1] VAERS is based on voluntary reporting of individuals who suffer adverse events after having received a vaccination. Although VAERS was not originally designed to determine if a particular vaccine *caused* a health problem, I have provided evidence of causal linkage between the COVID-19 mRNA injections and the adverse events (AEs) reported in the VAERS database using the Bradford Hill Criteria, and the Chi-Square test.[1,2] Ultimately, it is the job of the CDC and the FDA to address and assess possible safety concerns.

In my analysis, I illustrated statistically-significant differences between expected values and observed values by plotting the percentages of each against the amount of time that had passed following the injections (Figure 1). The null hypothesis maintains that if there is no causal link between the injections and the AEs, then the reported percentages of AEs should be equally distributed across days following injection. It follows that there should not be an excess of reports on days 0, 1 and 2. When I plotted the AEs as a percentage against the number days following injection, a clustering of data was observed around 0, 1 and 2 thus negating the null hypothesis - validated by the chi-square test. Since both the Bradford Hill Criteria were satisfied and the null hypothesis negated, there was strong evidence of causation.

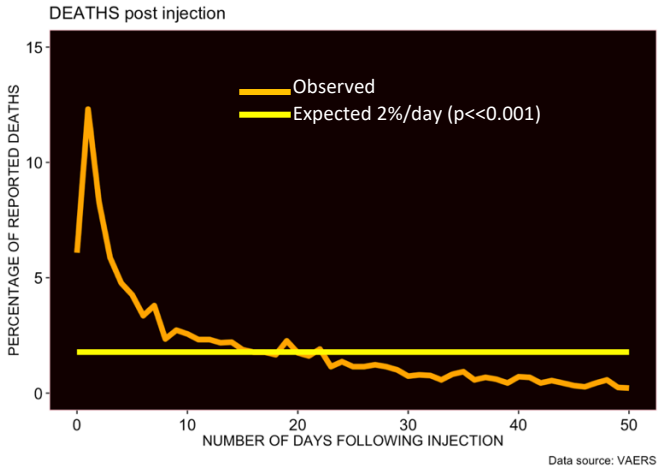

Figure 1: Time series plot showing the percentage of reported Deaths with respect to the amount of time that passed between the date of the injection and the reported adverse event. The orange trajectory are the observed values and the yellow trajectory are the expected values. Figure extracted from [1].

[1] The Bradford Hill criteria, otherwise known as Hill's criteria for causation, are a group of nine principles that can be useful in establishing epidemiologic evidence of a causal relationship between a presumed cause and an observed effect and have been widely used in public health research. They were established in 1965 by the English epidemiologist Sir Austin Bradford Hill.

[2] A chi-square ($\chi 2$) statistic is a test that measures how a model compares to actual observed data. The data used in calculating a chi-square statistic must be random, raw, mutually exclusive, drawn from independent variables, and drawn from a large enough sample. For example, the results of tossing a fair coin meet these criteria.

Since I published this data, I have publicly presented it in the form of a short PowerPoint presentation[3] to many audiences including Vaccine Choice Canada and in every presentation, upon presenting the evidence for causation, I implored the audience to provide alternative explanations for the clustering of data around 0, 1 and 2 if causation was in fact, *not* the reason for this apparent clustering in all AE categories.

1.1 The challenge of the psycho-logic

An alternative explanation has recently been suggested based on the fact that the VAERS system does rely on voluntary reporting. The idea is that the clustering around 0 and 1 may be due to what I am calling 'psycho-logic'. This is a phenomenon that describes when and why individuals report an AE following an injection, for example. The logic is that an individual will take the time to file a report only within a certain time frame temporally close to the injection date. The psychology is based on the idea that they believe there is an association or a link between their AE and their injection, and thus, they take the time to file a report. By extension, individuals who experience an adverse event temporally 'distal' to the injection date will be less inclined to associate or link this event to the injection and thus, will not take the time to file a report. The claim is that the psycho-logic explains the qualitative nature of the distribution of the observed data - that is, the clustering around 0, rather than there being any cause-effect relationship.

If this is presumed to be the case, then there is a burden of proof to establish this with evidence, be it statistical or otherwise, or at the very least, a precedent.

1.2 The evidence against the psycho-logic

I do not deny that the psycho-logic accounts for some trends in reporting patterns – we are human after all, but this does not rule out causation. In my VAERS analysis, in addition to discovering that half of most reports were filed within 48 hours of injection, I also discovered a secondary 'bump' in all AE categories on day 7 and it was most prominent in the immunological AE category (see Figure 2). I had attributed this to normal adaptive immunological responses to the spike protein antigens manifesting as various symptoms that comprise the long list of AEs in the VAERS database. I made this attribution primarily due to the timing - the incubation period for acute respiratory viral infections usually ranges from 1 to 4 days whereby symptoms arise on day 5.[2,3,4] The incubation period for SARS is 2-7 days.[4] In the context of the experimental mRNA products, we are speaking of immunological response time to viral antigens, but the timing is the same and antibody titers peak at day 7.[5] This **directly links** these particular reported AEs to the injection - we expect this immunological response **by design**. Therefore, since these AEs are linked to the injection date, then this is not only further evidence of causation, but a counter-example to the 'psycho-logic' hypothesis. If 50% of people who file reports do so within 48 hours of their injection, and the psycho-logic is responsible for this high percentage, then why would we see

[3] https://rumble.com/vhjgqz-vaers-analysis-summary-of-major-findings.html
[4] https://www.cdc.gov/sars/about/faq.html
[5] Update on COVID-19 vaccines & immune response - THE LATEST ON THE COVID-19 GLOBAL SITUATION & VACCINES. https://www.who.int/docs/default-source/coronaviruse/risk-comms-updates/update52_vaccines.pdf

reports from individuals on day 7? Is a week not distal from the time of injection based on the parameters that describe the psychologic whereby 'individuals who experience an adverse event 'temporally 'distal' to the injection date will be less inclined to associate or link this event to the injection and thus, will not take the time to file a report'? The psycho-logic, if the reason for the clustering, would **not** be able to explain the AEs reported on day 7.

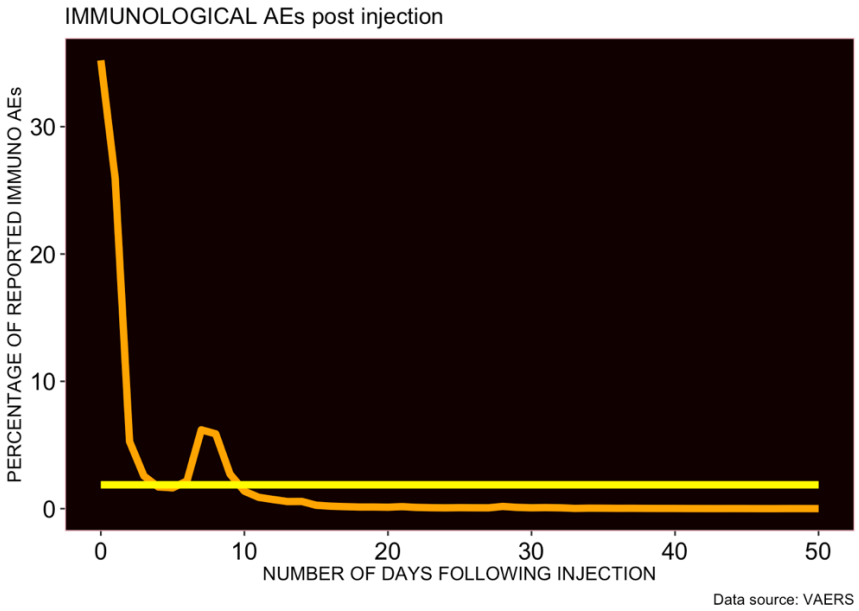

Figure 2: Time series plot showing the percentage of reported Immunological AEs with respect to the amount of time that passed between the date of the injection and the reported adverse event. The orange trajectory are the observed values and the yellow trajectory are the expected values.

The timing of the reports made on ~day 5-7 reflects 2 things: 1. Adverse events were apparent enough for a report to be made around day 7 and 2. The reports were made despite any accepted notion of the 'psycho-logic'. This, to me, proves 2 things. 1. The adverse events were related to the immune response induced by the introduction of the coding material for the antigenic prefusion spike protein and 2. The psycho-logic theory fails in these cases. The bump is highly apparent in every category except in the death category, where it is present but less apparent. This can be explained by the fact that deaths in the context of both SARS and the COVID-19 mRNA products occurs more frequently in the elderly and this is likely due to immune senescence.

1.3 The children

As of May 28th, 2021, children aged 12-18 comprise 3.4% of the total VAERS population with 58% comprising females. Of these 8500 children, 9 (0.1%) have died, 846 (10%) have experienced a severe adverse event resulting in hospitalization or debilitation. 1463 (17%) have experienced cardiovascular AEs, 437 (5.1%) have experienced a neurological AE and 928 (11%) have experienced an immunological AE.

What is most striking about this subset of data is the extremely high percentages of reports made within 24 hours of the injections in the cardiovascular, neurological and immunological AE categories. In each case, over 60% of events occurred and were reported at time 0 following the injections and in the case of cardiovascular AEs, over 80% of events occurred and were reported on the same day as the injections.

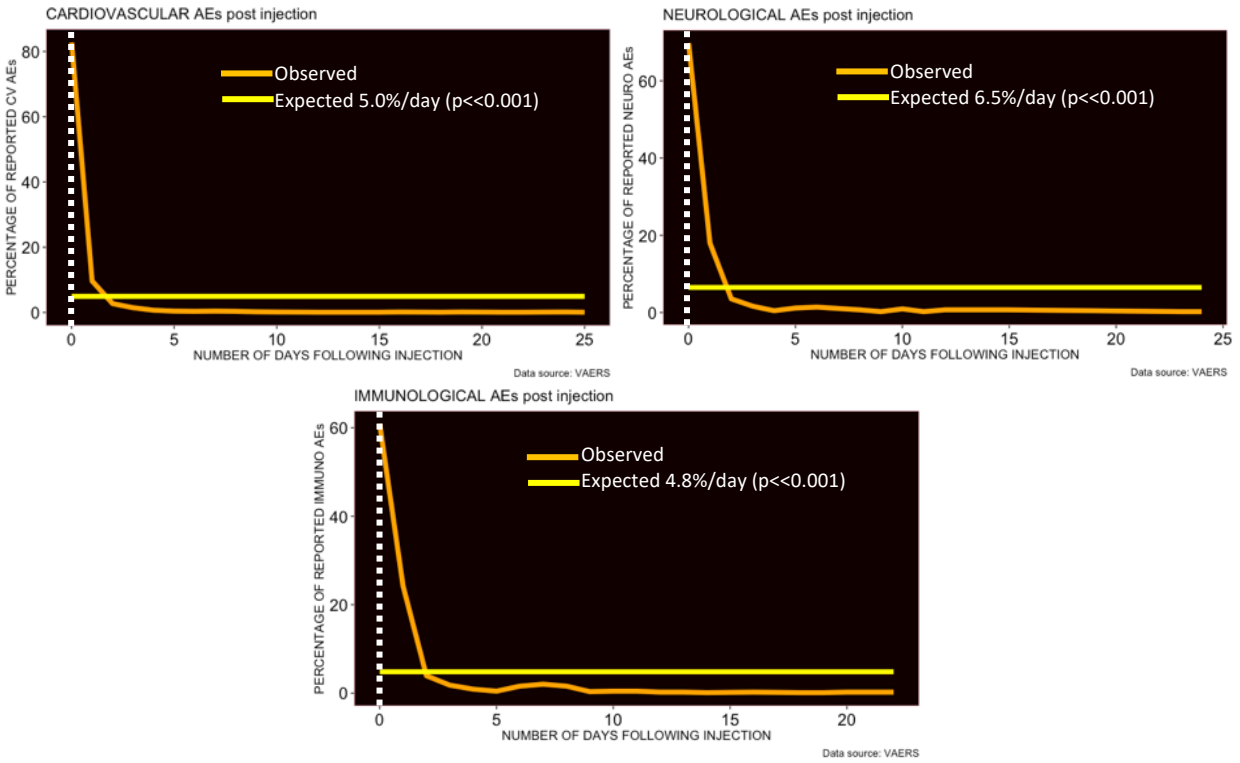

Figure 3: Plots showing percentages of VAERS IDs as per cardiovascular, neurological and immunological AEs against the number of days following injection.

To be clear, a causal effect means that a change in one variable leads to change in another variable. If the cardiovascular AEs, for example, following COVID-19 injections are not causally-linked, then the reported percentages of these AEs should be equally distributed across days following injection according to the null hypothesis: there should not be an excess of reports on days 0, 1 and 2, yet there are. Again, if risk is not accentuated by some immediate factor temporally, then that risk should necessarily plateau or diminish each day.

1.4 A tangential point of interest

The Under-reporting Factor (UF) is a multiplication factor: a number that when multiplied by the reported number of events yields the actual number of events. For example, if the number of Death reports is 100, and the actual number of Deaths is 1000, then the UF is 10. It has been reported that the VAERS under-reporting puts this number at approximately 100[6], but in the

[6] https://vaxopedia.org/2017/08/26/underreporting-of-side-effects-to-vaers

context of COVID-19, we simply don't know the extent or degree of the under-reporting problem. It is likely to be substantial due to the atypically large number of reports filed to date in such a short time period. To put this in context, the number of reports that made it to the VAERS are currently (as of May 28, 2021) 4x larger than the total number of reports filed for last year ***combined***. In my opinion, it would not be extreme to estimate the UF at 1000. This would have to be independently studied and it should be.

Without knowing the value of the UF, it seemed prudent to test a few values in the context of the adverse event data plotted against time. I started with Death as an adverse event. Figure 2 shows the Death data for three different values of UF to represent 33x, 99x and 500x higher values based on level of under-reporting (Figure 2).

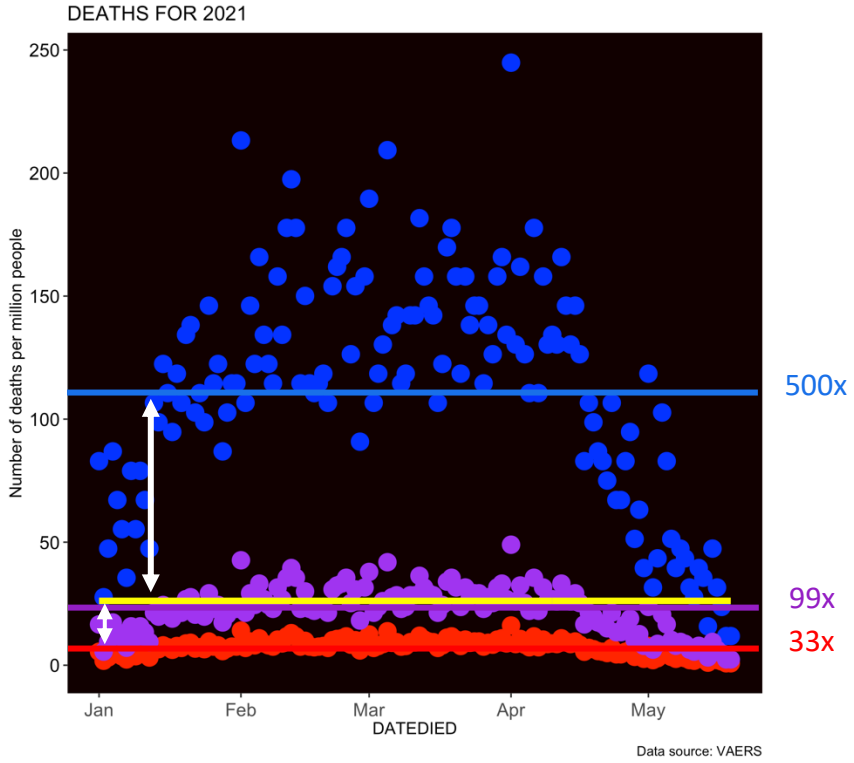

Figure 4: VAERS Death data plotted against date for three values of UF=33x (red), 99x (purple) and 500x (blue) and the All-Cause Mortality (ACM) rate (yellow) normalized to million individuals per day for the fully vaccinated and US populations, respectively.

When comparing the lines of best fit through the Death data, it is clear to see that if the UF is above a certain value, there is an excess of Deaths seen in the difference between the blue line and the yellow line - the rate of Death in the vaccinated population would be on average 5 times greater than the general US population, and presumably attributable to the vaccine itself. If the actual UF value if <99x, then from this vantage point, then there is no excess of Deaths - the vaccinated population mortality rate is equal to or lower than the general U.S. population - and this would support a lack of causation of Deaths by injection. The key here, and another point of

great interest in this study, is the value of the UF. Can we approximate this value from the data to provide further evidence of causation?

Conclusion

Of particular importance in data science, is the correct identification of patterns in data and appropriate use of discoveries, especially in matters of human epidemiology and public health. Although the VAERS system is based on voluntary reporting and perfectly imperfect, it is nonetheless an absolutely invaluable source of data to assess potential clinical problems not detected in pre-market 'testing'. The VAERS was not originally designed to be used to prove causation, but it is also ***not*** the case that the data therein cannot be used to do so if done methodically using the Bradford Hill Criteria and statistical testing.

Furthermore, the idea of 'psycho-logic' has ***not*** been proven to be the reason for the clustering of data at 0, 1 and 2 in this context, and to deny the possibility that it might be a contributing factor would be unscientific. Thus, I explored this idea and found evidence that undermines the psycho-logic idea.

Ultimately, the onus is on the claimants to provide evidence that the clustering of data around 0 is due to the psycho-logic and not causation.

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4. Chaplin DD. Overview of the immune response. *J Allergy Clin Immunol*. 2010;125(2 Suppl 2):S3-S23. doi:10.1016/j.jaci.2009.12.980