

Commentary

mRNA Vaccines for SARS-CoV-2 are “95% Effective”: What Does That Mean?

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In a recent paper, Polack et al. [1], who are members of the C4591001 Clinical Trial Group, stated that the Pfizer vaccine for SARS-CoV-2 is 95% effective. The Clinical Trial Group and their paper are funded by BioNTech and Pfizer. The statement that the mRNA vaccines for SARS-CoV-2 manufactured by Pfizer and Moderna are 95% effective has been made countless times in the media and by the heads of the CDC and NIAID and other physicians and public health authorities. But what does “95% effective” actually mean? It is a relative risk number. What are the raw data reported by Polack et al. [1]? In their trial, 21,720 participants received the active vaccine and 21,728 received placebo. Altogether, 162 participants in the placebo group developed COVID-19 illness compared to 8 in the vaccine group; 9 participants in the placebo group developed severe COVID-19 disease compared to 1 in the vaccine group. This is a reduction in COVID-19 illness of 95% (the rate of illness in the vaccine group was $8/162 = 5\%$ of the rate in the placebo group). There were no deaths in either group. This means that there is no evidence that mRNA vaccines reduce the risk of death from COVID-19 illness.

Doing the arithmetic on the raw data, the risk of severe illness in the vaccine group was $1/21,720 = 0.00005$, while it was $9/21,728 = 0.0004$ in the placebo group: expressed as percentages, the risks for severe illness were 0.005% in the vaccine group and 0.04% in the placebo group. That is, the absolute reduction in risk of severe illness conferred by the vaccine was 0.035%, less than one tenth of one percent. These results by themselves are a very remarkable finding: less than 1 in 2000 individuals in the placebo group developed a severe COVID-19 illness and none died.

If we assume that the population of the United States is 330,000,000 people and we assume that the vaccines are equally effective in children, and if we assume that 10% of the population has been infected, this means that there are 33,000,000 currently or previously infected individuals in the country. If we then assume that the vaccine reduces the risk of getting severe disease by 0.035%, this means that the number of cases of severe illness in the country would have been reduced by $0.00035 \times 33,000,000 = 11,500$ cases if everyone got vaccinated in January, 2020. However, that number is much higher than reality, because the rates of serious COVID-19 illness are

extremely low in children: the Pfizer trial enrolled only people 16 years of age or older. Polack et al. [1] state that the vaccine efficacy was the same when they controlled for age, sex, race, ethnicity, baseline body-mass index, and the presence of coexisting conditions. This means that the effectiveness of the vaccine is no higher in certain racial or ethnic groups than in others, nor is it higher in certain age groups or weight categories than others.

It is impossible to generate a precise number, but, based on the data, one must conclude that the mRNA vaccines, if administered to everyone in the United States, could prevent only a few thousand cases of serious COVID-19 illness over the next year. From the data, we know that the vaccines can prevent death in fewer than one in 21,000 people. This means that your risk of death if you get the vaccine is reduced by less than $1/21,000 = 0.00005$ or less than 0.005%. None of these numbers have anything to do with being pro or anti-vaccine. They are just the facts. An assessment of the cost-benefit from COVID-19 mRNA vaccines should be balanced against their costs in terms of side effects, financial costs, and diversion of resources from other social and public health needs. Telling the public that the mRNA vaccines for COVID-19 are 95% effective leads to a false sense of safety and security, much like stating that face masks are effective for reducing viral transmission in public [2]. There is no evidence that mRNA vaccines reduce the rate of coronavirus transmission in public: if they do not, or do so by only a tiny amount, then it is not socially irresponsible to decline to take the vaccine. It is irresponsible not to practice social distancing and not to quarantine if symptomatic, but there is no evidence that declining the vaccine will increase anyone else's risk of serious illness or death to a meaningful extent. Public health policies should be based on these facts, not on scare tactics, a false sense of security, or political ideology distorting the data and the science.

References

1. Polack FP, Thomas SJ, Kitchin N, Absalon J, Gurtman A et al (2020) Safety and efficacy of the BNT162b2 mRNA Covid-19 vaccine. *New England Journal of Medicine* 383: 2603-2615 [[crossref](#)]
2. Ross CA (2020) Differences in evaluation of hydroxychloroquine and face masks for SARS-CoV-2. *Journal of Neurology and Neurocritical Care* 3: 1-3.

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