

Press Release

The risk-benefit ratio of COVID-19 vaccinations is bad: for 3 lives saved 2 people die of the consequences of the vaccination

COVID-19 vaccinations have been hailed as the best way out of the pandemic. That is why they received fast-track regulatory approval from the European Medicine Agency, the legal regulator in Europe for medications that paves the way for national authorities. This was done without sufficient safety data. This analysis has now been produced by a research group coordinated by Prof. Harald Walach from Poznan University of the Medical Sciences in Poznan, Poland, and University Witten/Herdecke in Germany, Dr. Rainer J. Klement, a medical physicist with Leopoldina Hospital in Schweinfurt, Germany and the data-analyst Wouter Aukema from Holland. It was published in the peer-reviewed online-Journal "Vaccines" on June 24th.

The researchers found that the risk incurred by vaccinating people against COVID-19 with any of the three most widely distributed vaccines, by Pfizer, AstraZeneca, or Moderna, which make up 95% of all vaccines used in the EU, is 4.11 deaths per 100,000 vaccinations received. Roughly 700 persons are reporting side effects per 100,000 vaccinations, 16 of them severe. "Perhaps this would be acceptable, if the vaccines could save enough lives", Prof. Walach says, "but the problem is that although the vaccines are effective relative to their comparisons, no one ever looked at the absolute efficacy. We did that and we see: we need to vaccinate many people to save one life. Precisely how many we need to vaccinate is difficult to gauge. We used the recently released large field study from Israel studying a million people, as well as the large phase 3 studies that were used for regulatory purposes. If you use the data from those studies, you can calculate the "Number Needed to Vaccinate" to prevent one death. This is a clinical effectiveness measure. It depends on the effectiveness of the vaccine on the one hand, but also on the prevalence of the disease on the other hand. Because the prevalence of SARS-CoV2 infections is very low - around 3% of those in the control arm got infected -, and because the Infection Fatality Rate is also comparatively low, we need to vaccinate many to see one death prevented by vaccination," Walach says. The Infection Fatality Rate was 0.5% in the control group of the large Israeli study, which tallies well with a recently published meta-analysis of various studies, the authors write. "Now, if you combine the fact that the prevalence of the infection is low with the Infection Fatality Rate being also low, you need to vaccinate many people until you see one death prevented", explains the medical physicist Rainer Klement who did the maths. "We need to vaccinate between 9,000 and 50,000 people to prevent one death. A good point estimate is about 16,000", Klement says. "This is the figure coming out of the Israeli field study, the largest to date, which tested the BioNTech/Pfizer vaccine. If we use the regulatory data of the other vaccines, we reach somewhat better ratios. But if you compare this with the side effects, the risk-benefit ratio is bad", Prof. Walach seconds. If we vaccinate 100,000 people, we prevent 6 deaths. In the best case the figure rises to 33 deaths prevented by 100,000 vaccinations.

Wouter Aukema - independent data and patterns analyst - analyzed the individual case safety reports of the EMA's adverse reaction database. In order to do that he produced a search-script which he made public on his blog <https://www.aukema.org>. It sorts through each individual report submitted to the EMA. As many reports mention more than one side effect, it is important to separate the cases from the reports. This is exactly what Aukema did. He separated them according to fatal, severe and less severe cases. And he looked at the number of

reports from different countries. He found a very interesting wide range of reporting across the EU. While Holland reports 701 cases with side effects per 100,000 vaccinations, Poland with the lowest number reports only 15. The EU average is 127, with Germany reporting as few as 38 cases, 30% of the EU average. Is the vaccine chauvinist and produces more side effects in some countries than in others? The researchers doubt it. They say that this reflects reporting standards. These are highest in Holland and lowest in Poland.

“Because of these vast differences by a factor of 47, we chose the data from the Netherlands, because this likely reflects the best standard” Wouter Aukema says.

So, he produced the side effect data associated with COVID-19 data. “If you calculate the risk-to-benefit ratio you see that we save the lives of 3 people and kill 2 people by vaccinating them. In the best case we save 8 lives and kill one person,” says Rainer Klement who calculated the figures. As a physicist and data-analyst this is his daily bread. But he adds: “However, the statistical uncertainty also supports more people being killed by vaccination than lives saved, and you also have to consider that probably less than 5% of side effects are officially reported.” “There is no other vaccine around that has such a bad track record as the COVID-19 vaccines”, says Prof. Walach. “We feel that the national authorities should assemble independent groups of scientists to investigate this situation further. Until the results are openly on the table, the vaccination campaigns should be stopped”, he says. “What is especially unacceptable is the fact that children and young people are now targeted. They are not in danger of suffering from severe COVID-19 reactions which was the reason for the vaccination campaign in the first place“, Walach and Klement say in unison. “The danger that a child is hit by a car is much greater than that he or she will suffer from COVID-19”, they say.

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