# News on Corona mRNA vaccines:

# Concerns about the trustworthiness and meaningfulness of the reported efficacy results.

***A short extract from:***

BMJ

**Peter Doshi: Pfizer and Moderna's "95% effective" vaccines—we need more details and the raw data**

January 4, 2021

**"Suspected covid-19"**

***A rough estimate of vaccine efficacy against developing covid-19 symptoms, with or without a positive PCR test result, would be a relative risk reduction of 19% (see footnote)—far below the 50% effectiveness threshold for authorization set by regulators.*** Even after removing cases occurring within 7 days of vaccination (409 on Pfizer's vaccine vs. 287 on placebo), which should include the majority of symptoms due to short-term vaccine reactogenicity, vaccine efficacy remains low: 29% (see footnote).

***If many or most of these suspected cases were in people who had a false negative PCR test result, this would dramatically decrease vaccine efficacy.*** But considering that influenza-like illnesses have always had myriad causes—rhinoviruses, influenza viruses, other coronaviruses, adenoviruses, respiratory syncytial virus, etc.—***some or many of the suspected covid-19 cases may be due to a different causative agent.***

But why should etiology matter? If those experiencing "suspected covid-19" had essentially the same clinical course as confirmed covid-19, then "suspected plus confirmed covid-19" may be a more clinically meaningful endpoint than just confirmed covid-19.

However, if confirmed covid-19 is on average more severe than suspected covid-19, we must still keep in mind that at the end of the day, it is not average clinical severity that matters, it's the incidence of severe disease that affects hospital admissions. With 20 times more suspected covid-19 than confirmed covid-19, and ***trials not designed to assess whether the vaccines can interrupt viral transmission,*** an analysis of severe disease irrespective of etiologic agent—namely, rates of hospitalizations, ICU cases, and deaths amongst trial participants—seems warranted, and is the only way to assess the vaccines' real ability to take the edge off the pandemic.

**The 371 individuals excluded from Pfizer vaccine efficacy analysis**

Another reason we need more data is to analyse an unexplained detail found in a table of FDA's review of Pfizer's vaccine: 371 individuals excluded from the efficacy analysis for "important protocol deviations on or prior to 7 days after Dose 2." ***What is concerning is the imbalance between randomized groups in the number of these excluded individuals: 311 from the vaccine group vs 60 on placebo.*** (In contrast, in Moderna's trial, there were just 36 participants excluded from the efficacy analysis for "major protocol deviation"—12 vaccine group vs 24 placebo group.)

**Fever and pain medications, unblinding, and primary event adjudication committees**

***That said, the higher rate of medication use in the vaccine arm provides further reason to worry about unofficial unblinding.*** Given the vaccines' reactogenicity, it's hard to imagine participants and investigators could not make educated guesses about which group they were in. The primary endpoint in the trials is relatively subjective making unblinding an important concern. Yet neither FDA nor the companies seem to have formally probed the reliability of the blinding procedure, and its effects on the reported outcomes.

***Nor do we know enough about the processes of the primary event adjudication committees that counted covid-19 cases.*** Were they blinded to antibody data and information on patients' symptoms in the first week after vaccination? What criteria did they employ, and why, with a primary event consisting of a patient-reported outcome (covid-19 symptoms) and PCR test result, was such a committee even necessary? It's also important to understand who was on these committees. While Moderna has named its four-member adjudication committee—all university-affiliated physicians—***Pfizer's protocol says three Pfizer employees did the work. Yes, Pfizer staff members.***

**We need the raw data**

Addressing the many open questions about these trials requires access to the raw trial data. But no company seems to have shared data with any third party at this point.

**Footnote**

Calculations in this article are as follows: 19% = 1 – (8+1594)/(162+1816); 29% = 1 – (8 + 1594 – 409)/(162 + 1816 – 287). I ignored denominators as they are similar between groups.

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Read the full original text here:

https://blogs.bmj.com/bmj/2021/01/04/peter-doshi-pfizer-and-modernas-95-effective-vaccines-we-need-more-details-and-the-raw-data/