The MHRA Papers - Part 10

The antibody two-step

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SUMMARY: We secretly discussed the types and quantities of antibodies produ vaccination in trial participants. The only trouble is that we do not know how antibodies correlate to effectiveness, but all is well and secret, of course.

We continue reviewing the minutes of the MHRA's Commission On Human Medicines (CHM) COVID-19 Vaccines Benefit Risk Expert Working Group meet which took place on 29, 31 December 2020, and 3 January 2021.

These secret meetings were devoted to the ~~Oxford~~ Astra Zeneca product, dealing sensitisation issues. The minutes are tedious and complicated and relate to a vac that is no longer available. We will move on to the 13 January meeting, but those interested in each meeting can access the relevant files through the hyperlink.

On 13 January, the EWG examined safety data in those with prior COVID-19 infe recipients of mRNA COVID-19 vaccines, the risk of anaphylaxis with Pfizer/BioI and Moderna COVID-19 vaccines, and got an update on the Safety Data for the Pfizer/BioNTech COVID-19 vaccine.

"[For Comirnaty] The EWG were assured that low levels of lymphadenopathy we observed, and this event is listed in Section 4.8 of the SmPC. The EWG heard the were no cases of appendicitis".

The text does not mention lymphopenia, C-reactive protein (CRP—an aspecific marker of inflammation), or thrombocytopenia. This does not mean the two were discussed, but the minutes did not record them.

Perhaps the most interesting statement can be found on page 4 of the document para 2.5:

> The EWG considered that the correlates or the true biological markers of protection are still unknown. The EWG noted the need for ongoing studies in order to understand if the immune response to each individual batch is the same and a baseline blood sample would be useful to carry this out and to link the subsequent reactions in those with pre-existing antibodies. The EWG considered that such a study might be coordinated by PHE and would likely have a number of individuals with pre-existing antibodies.

Two points stick out:

First, this statement applies to all respiratory virus vaccine trials that rely on ant response as a surrogate marker for field protection and, hence, effectiveness. Regulators have been well aware of this problem for decades but have primarily nothing to address it.

Second, readers will see the interminable discussions around antibody responses they go through the minutes. The validity of these discussions is only relevant to potential harms, as the statement we reported above undermines the significanc antibody responses in vaccines as a marker of effectiveness.

The MHRA were informed that 500 yellow cards concerning the AZ vaccine had received, which they stated did not indicate any signals. While future steps '*indic that the content of the papers and proceedings of the meeting were strictly confidential should not be disclosed,*' not one person around the virtual EWG table bothered to about the inadequacies of the Yellow Card System.

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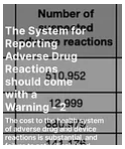

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This post was written by two old geezers who understand why they are never inv safety meetings.

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Tom Jefferson 4d

Author

Hi John and Vivian thank you for your excellent comments. Its is not by chance that EBM has marginalised and infiltrated - just think of the onslaught on the Cochrane review A122 which documented many times. The onslaught is based on the fact that the review does not reach t conclusions.

One more. Everyone in vaccinology knows that antibodes are a hit and miss correlate of prote once asked a PHE (now UKHSA) grandee what the serological correlates were and she answer (referring to antibodies): "the more the better".

These EWG guys (or at least the vaccinologists among them) knew the problem very well, but no trace of discussion as we shall show in Part 13.

Keep supporting us please, we need you.

Best, Tom.

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1 reply

Tom Jefferson 4d

Author

Hi Keith, It's not they do not look for them, they are very rare as we showed in the F word and Connecting the Dots series.

In addition most trials are underpowered and the influenza vaccines registration trials have d surrogate outcomes (antibody responses).

Best wishes, Tom

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