The MHRA Papers - Part 9

Rats to you

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SUMMARY: Having previously drawn reassuring conclusions from animal studi now the EWG think perhaps they are of unknown relevance to human beings

We continue our review of the minutes of the meeting of the MHRA's Commissi Human Medicines (CHM) COVID-19 Vaccines Benefit Risk Expert Working Gro which took place on 24 December 2020

The secret squirrel's considered evidence from three vaccines: ~~Oxford~~ ASTRA ZENECA'S AZD1222 Deployment Model, Quality assessment AND NON CLINI reproductive toxicity focus, PfizerBioNTech's BNT162b2 dose interval and a non clinical assessment for Moderna's vaccine

For the AZ product, The EWG discussed the reproductive toxicity and the precautionary text that should go into the SmPC as the animal data is incomplet whether the text should be aligned with that for the Pfizer/BioNTech vaccine.

> The EWG agreed with the wording 'The full relevance of animal studies to human risk vaccines for COVID-19 remains to be established.'

SmPC stands for Summary of Product Characteristics in EMA speak and it tells what the product is, how it works and how it should be used.

So, we don't know much about the thorny issue of reproductive toxicity based on and nought based on humans. We know the rat stuff isn't generalisable to *Homo Sapiens*. There was mix up with doses in the AZ trial, so we are not sure how efficacious the stuff is, but let's move on - THE EWG was - as per usual - reassur

On the BNT162b2 front, we are glad to report that the EWG agreed that the vacc efficacy reported by Pfizer of 52% is likely to be underestimated since little prote is expected within 14 days of the first dose.

Although this is likely to be an underestimate as

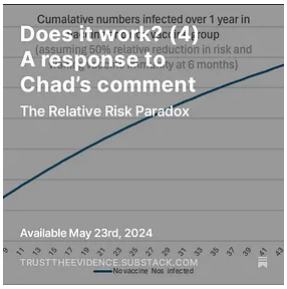
6.4 The EWG also reviewed a Tabled Paper submitted by PHE on an independent anal the full Pfizer data. This analysis found a VE of 89% (CI 52, 97) from day 15 to day 2 the first dose based on 2 COVID-19 cases on vaccine compared to 18 COVID-19 ca placebo. The VE increased to 91% (CI 74, 97) from day 15 to day 28 based on 4 CO cases on vaccine compared to 42 COVID-19 cases on placebo. The EWG agreed th suggest there is no decline in the level of protection at 28 days and that there biologically plausible reason to expect that it would decline rapidly. Immunological prir and experience with other types of vaccines suggest that immunogenicity may be imp with more prolonged intervals between doses in the primary immunisation series.

This is the first and last time we found mention of an independent analysis, altho PHE the predecessor to UKHSA can hardly be called "independent". The non de in the level of protection is incompatible with persistent lymphopenia. As we hav access to the PHE analysis we cannot comment further.

Note the absence of any absolute measure of effect; it is an omission. However, ir placebo-controlled trial, if you have the data (as any regulator should have), you c quickly get the Risk Difference and, from there, calculate the number needed to vaccinate and the number needed to be vaccinated to harm. This gives a complet picture. This stuff is so easy to calculate that even Tom can do it.

Does it work? (4) A response to Chad's commen

CARL HENEGHAN AND TOM JEFFERSON • 22 MAY 2024



Chad's comment to the "Does it Work 2" post asked, 'Is it correct to say tl relative risk is more useful where you expect close to 100% of a populatio exposed to a pathogen?' We set out how to think about this issue. If you b with us and follow our estimates, you'll end up with a different viewpoint relative effects in the context of r...

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Back to the topic of vaccinating pregnant women or those in the reproductive ph their lives,

> The EWG agreed that for pregnant women where the risk of not having the vaccine is gr than the risk of having it, a clinical decision will need to be made.

With the systematic subversion of the precautionary principle underway, that pr means all of this age group. The statement also reinforces the concept of pregna a dangerous disease and not a physiological process (if doctors can keep their ha off pregnancy and labour unless in dire need of an intervention, of course).

However, you'll be reassured by the conflict of interest policy for Invited experts

> **Invited experts**
>
> - May hold current personal interests in one or more companies associated with the development of COVID-19 vaccines
> - May currently be or have previously been involved in the development of COVID-vaccines

The Invited experts May be invited to all meetings, receive all the papers and presentations and are permitted to participate in discussions when asked by the However - somehow - the expert "does not contribute to conclusions and recommendations. "

This post was written by two old geezers who are reassured that "all is well" base sketchy rat data and no data on humans.

53 Likes · 5 Restacks

Discussion about this post

Comments Restacks

Write a comment...

Tom Jefferson 5d

Author

Dear Brian, thanks for your comment. Just the other night I noticed 1-2 apparent strange thin clinical study report dated 20 November. As soon as I have a mo I'll get the other old geezer this with me and we'll respond. I swear I'll do it on Matt Hancock's head.

If I forget please remind me as it's really important stuff.

Best, Tom.

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Brian Finney 5d

Are people aware of Prof Norman Fenton's Cheap Trick illusion wrt to VE?

Basically, any occurrence of Covid in the first 15 days (ONS use 21 days) in the vaccinated gro moved to the unvaccinated group, which would account for only 2 covid cases in the vaccinat covid cases in the unvaccinated.

https://www.youtube.com/watch?v=6hHKr9Ig36E

Of course, in real life I'm vaccinated from day 1 which is what should be measured to replicat world conditions, not some academic BS to inflate VE.

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