The MHRA Papers - Part 8

Facilitating Bell's palsy and vaccination in pregnancy with wrong or non-existent data

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SUMMARY: The EWG reaches conclusions on incomplete or no data. But it was a secret anyway.

We continue our review of the minutes of the meeting of the MHRA's Commissio Human Medicines (CHM) COVID-19 Vaccines Benefit Risk Expert Working Grou which took place on 22 December 2020

This was the day after the EMA met and gave conditional market authorisations t PfizerBioNTech's Comirnaty vaccine.

The first topic discussed by the EWG was the risk of anaphylactic reaction after exposure to BNT162b2.

There appeared to be a lot of roundabouts and circumlocutions, and here is some the text:

"The EWG heard about two cases of anaphylaxis reaction on the first day of the U vaccination campaign.

The EWG recalled that polyethylene glycol (PEG) was previously considered a potential causative agent of the two allergic reactions seen in the vaccination campaign".

However, we do not really know much about exposure to PEG in humans, so with of warnings, the discussions petered out with a final appeal to the Yellow Card sys and the statement:

"The EWG was reassured that the signal of anaphylaxis does not appear to be strong".

Next, EWG considered Bell's palsy:

The EWG heard about four reports of facial paralysis in the vaccine arm of BNT16 with zero cases in the placebo arm and one report of facial paresis in the placebo a with none in the vaccine arm.

The EWG heard that the Yellow Card data includes one report of facial paralysis submitted by a healthcare professional and one report of facial weakness submitte a patient".

These facial paralysis events were considered to be within the range of the backgr incidence rate—nothing to see here, then.

However, this statement contradicts the experience of our ophthalmologist reader whose comment on the high incidence of Bell's Palsy following immunisation triggered our Comirnaty series.

> Now, one of our subscribers has written to us telling us the story of the months of 2021-22 when the Covid vaccines were first rolled out. He is an eye doctor, and he sa an abnormally high number of cases of Bell's Palsy. This is a frightening progressive weakness of facial muscles, usually one-sided. Most cases recover, but some do not. How would you like to go around with half your face hanging down and unable to se properly?

The MHRA and Bell's Palsy

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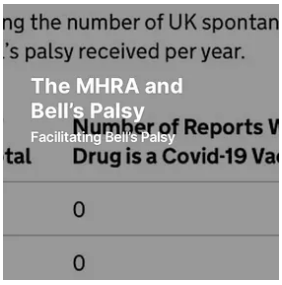

Yesterday, we posted what we thought was a disturbing list of MHRA boarc members. We pointed out that the press had already exposed this state of af with little success. We have already run many posts exposing a long list of problems. We hoped that someone would do something about a public ager that should be on the side of citizens but is manife...

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It also wrongly predicted what happened once the vaccine was rolled out. As with Pandemrix story, one thing is immunising a few thousand people and another is immunising millions.

Please find table below showing the number of UK spontaneous suspect adverse drug reaction (ADR) reports of Bell's palsy received per year.

Year	Number of Reports Total	Number of Reports Where at Least One Suspect Drug is a Covid-19 Vaccine
2018	15	0
2019	22	0
2020	19	7
01/01/2021 - 30/06/2021	784	776
Total	840	783

Why would mortality data by vaccine exposure be withheld from Parliament and Jane/Joe Public?

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Once again, we would like to see the case report forms for the Comirnaty registrat trial as they contradict what actually unfolded. Will the New York Times or the BI launch a campaign for the final full disclosure?

We cannot see from the minutes what data the EWG used when they made such a statement.

Next, the EWG considered vaccine exposure in pregnancy and lactation and statec page 11 of the minute:

5.2 The EWG noted that the degree of reassurance a negative signal in an animal mod reproductive toxicology gives is difficult to translate in terms of relevance to humans. EWG noted that the importance of stating in the product information that the lev knowledge in terms of the interpretation of the reproductive pre-clinical data is limited.

It is limited in rats and non-existent in humans, as we have reported:

Exploring regulatory data sets of the Comirnaty vaccine - 6a

CARL HENEGHAN AND TOM JEFFERSON • 2 MAY 2024

As we anticipated in Cominarty 5, we are reviewing the vaccine's package i of four major regulators: the UK, EU, Canada, and the US, comparing the content by the regulator.

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Even the rat data was open to different interpretations between the EMA and the MHRA.

The EWG heard that the differences arise due to a preclinical reproductive toxicity study th was finalised after the authorisation under regulation 174. The study was conducted female rats with BNT162b2 given by intramuscular (IM) injection prior to mating with an u dosed male; the vaccine was also given on two occasions during pregnancy. The stu design included caesarean section on gestation day 21 which would allow embryo-fet malformations, if present, to be identified. A further group of rats was followed to litter ar the behaviour and features of the offspring observed to post-natal day 21. The EWG hea

However, as per usual at the EWG, all is well

The EWG noted that the UK information mentions that women of childbearing age sho be advised to avoid pregnancy for at least two months after their second dose. The EV heard the two-month period arose due to the time to clearance of the NLPs, but the clini relevance to the embryonic or fetal development remains to be established.

This was on the basis of rat data, which indicated two months as the clearance tim for the lipid nanoparticles. Yet, we now know that they do not stay around the vaccination site and that repeated administration of LNPs is likely to be highly tox

Exploring regulatory data sets of the Comirnaty vaccine - 9c

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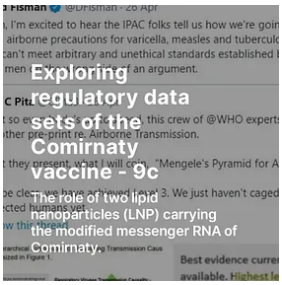

Here, we are taking another look at what is known about the LNPs.

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It assumes animal models are good predictors of human toxicity - they are not. Th lack of correlation between animal models and humans is well documented. While they may be an adjunct to understanding mechanisms, they are no substitute for human trials - under no circumstances should animal models provide reassurance all is well.

The disconnect between animal and human predictors of effect is not new. A thou years ago, the Persian physician Ibn Sina wrote, “Experiments should be carried o the human body. If the experiment is carried out on the bodies of [other animals], possible that it might fail…” (See the James Lind Library). Clearly, the EWG were n students of history or willing to delve into the evidence of what is known about th of animal studies and their limitations in ensuring safety.

The basis on which the EWG was reassured is hard to fathom as there is no menti the RNA clearance. What is the half-life of mmRNA in the elimination phase in different organs, and what happens to the mmRNA in humans in different organs one of our fifteen questions that remain unanswered.

Exploring regulatory data sets of the Comirnaty vaccine - 9e

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The last nine pages of the minutes are devoted to discussions of the ~~Oxford~~ Astra Zeneca and Moderna vaccines.

This post was written by two old geezers who were horrified that women who wer pregnant or in the reproductive age group were pressurised into being vaccinated the basis of XXXXXXXXXX [censored by secret squirrel ltd] data.

Postscript

The two old geezers are still waiting for the publication of the RCT on pregnant women

Exploring regulatory data sets of the Comirnaty vaccine - 7

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Tom Jefferson 6d

Author

Hi Alan, I am swept away by a river of crocodile tears, help!!!!!

An old geezer

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Alan Richards 6d

Liked by Tom Jefferson

Hancock and Whitty knew about the anaphylaxis issue on 9 December 2020. 3 cases out of 400 on day one of the roll-out. That's 0.75% which is close to the SAR rate in the AZ trial.

From the Pandemic Diaries of Matt Hancock as serialised in the Daily Mail

"Much later, I was on my way to bed when my phone rang. Nobody rings at 11.43pm unless it's news, least of all the Prof, whose number was flashing ominously. In that calm, professorial voic he explained that three people had suffered a serious adverse reaction to the vaccine. One had died.

We tried to calculate the statistical risk. If three out of 400 vaccinated today had a massive reac then that's 38,000 out of the whole population. And 38,000 is an awful lot of people.

'Jesus Christ,' I thought, feeling physically sick. We may well have to halt the entire vaccination 'Perhaps all three have a history of anaphylaxis?' I asked hopefully. Still feeling nauseous, I slum bed, knowing I wouldn't get a wink of sleep.

Wednesday, December 9

At 5.30am my phone went. 'All three had a clinical history of anaphylaxis,' said Natasha [head o Hancock's private office].

'[Prof Whitty] recommends that anyone with a history shouldn't take this vaccine, that we intro 15-minute wait after vaccination to monitor people, restrict the rollout to hospitals for the next of days and get on with it,' she said.

I can't remember ever being so relieved in my life."

https://www.dailymail.co.uk/news/article-11502003/Matt-Hancock-reveals-moment-vaccine-approved.html

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