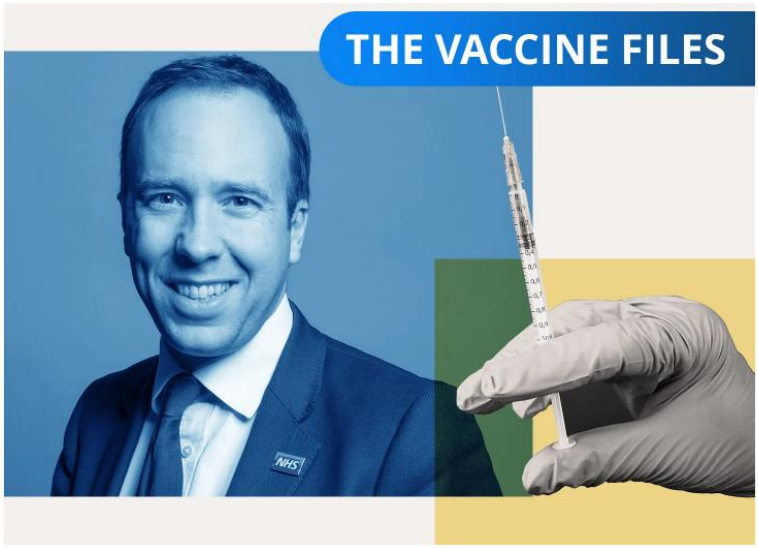
Uit geheime WhatsApp-berichten die zijn vrijgegeven blijkt dat de Britse regering medicijnautoriteit MHRA opdroeg om zorgen over de coronavaccins de kop in te drukken.

https://www.insidetheright.today/p/the-vaccine-files-day-one-how-well

THE VACCINE FILES DAY ONE: HOW WELL DID THE VACCINE WORK?

How Safe was the "Great British" Jab?

ISABEL OAKESHOTT
NOV 28, 2024 · PAID



Graphic created for Inside The Right. Matt Hancock official portrait by UK Parliament.

[09/01/2021, 10:53:05] Matt Hancock: Ara Darzi told me he got the vaccine in December, and then did duty giving vaccinations. He then got covid from a patient after Xmas. He's fine he says. He says apparently it's quite a common story. One that could create a little media anxiety storm.

In the event, while Darzi's experience was not an isolated case, there was no "little media anxiety story." In fairness, nobody had ever claimed that any of the covid vaccines offered instant, 100pc protection from the disease. It would take each patient some time to develop immunity, after receiving the jab.

The question was how long it would take to reach 'peak protection'; how long 'peak protection' would last before a booster was needed; and how effective the vaccines were during each of these stages. These were not conversations ministers were keen to have in public. They certainly didn't want the German newspaper report about the AZ jab 'not working' gaining any traction.

So here's what they did: they put pressure on Medicines and Healthcare Products Regulation Authority (MHRA) to "knock it down." In a highly controversial move, the UK's most senior civil servant, Cabinet Secretary Simon Case, asked Hancock to contact the regulator and ask officials there to have a quiet word with their EU counterparts (the European Medicines' Agency, also supposedly independent from political interference) to help "kill" the story.

Here's his WhatsApp request:

[26/01/2021, 09:15:14] Simon Case: Can you get MHRA to talk to the EMA about these German comments/leaks about AZ efficacy? We obviously need it knocked down authoritatively - and nothing better than a regulator doing it!

Looking at it from the government's point of view, it's quite easy to see the temptation to get the regulator involved. Yet the MHRA is supposed to be independent…..

Throughout the pandemic, the UK government repeatedly emphasised the independent status of the MHRA.

Gates

Onlangs meldden we dat de MHRA en andere toezichthouders een rapport van Pfizer over de veiligheid van de covidvaccins al een half jaar in de la houden.
Het Britse oud-parlementslid Andrew Bridgen wees er eerder op dat de MHRA voor 86 procent wordt gefinancierd door de farmaceutische industrie. "De stroper betaalt de jachtopziener." Ook Bill Gates geeft het medicijnagentschap geld (1).

De Britse medicijnautoriteit MHRA en andere toezichthouders houden een rapport van Pfizer over de veiligheid van de covidvaccins al een half jaar in de la. Voormalig defensieambtenaar Nick Hunt heeft zojuist de samenvatting op internet gevonden (2) en het ziet er niet goed uit, schrijft hij voor The Daily Sceptic (3).
De gevaccineerden hebben minstens 23 tot 40 procent meer kans om hartaandoeningen te krijgen en het risico is groter dan in het vorige rapport van Pfizer. Dat zou betekenen dat het risico mettertijd toeneemt.

Het gaat hier om het 'Interim Report 5' dat dateert van 12 maart 2024. Hunt probeerde het rapport in april via een FOIA-verzoek bij de MHRA boven water te krijgen. Hij kreeg te horen dat de informatie in het vierde kwartaal van 2024 zou worden gepubliceerd.

Weinig haast

Eind augustus diende Hunt nog een FOIA-verzoek in en kreeg dit keer te horen dat het nog niet zeker was of het rapport voor 31 december gepubliceerd zal worden. Ze hebben weinig haast.

Als je de samenvatting leest, wordt al snel duidelijk waarom. Er worden zes aandoeningen genoemd: acuut hart- en vaatletsel, hartritmestoornissen, hartfalen, cardiomyopathie, coronaire hartziekte en myocarditis binnen 21 dagen.

Alleen maar erger geworden

Gevaccineerden hebben bijvoorbeeld 23 procent meer kans om acuut hart- en vaatletsel te krijgen. Daarnaast lopen ze 40 procent meer kans op coronaire hartziekte. De data zijn extreem zorgwekkend, benadrukt Hunt. Sinds Interim Report 4 is het alleen maar erger geworden.

Het is volgens Hunt van groot belang dat we toegang krijgen tot het volledige Pfizer-rapport. Hij vermoedt dat de MHRA, die de prikken heeft goedgekeurd, bezorgd is over de resultaten in het 'Interim Report 5' van Pfizer en het om die reden liever in de la houdt.

(Bijlage 1)

https://www.gov.uk/government/publications/freedom-of-information-responses-from-the-mhra-week-commencing-4-january-2021/freedom-of-information-request-on-emails-with-bill-melinda-gates-foundation-foi-20-534

GOV.UK Menu

Home > Health and social care > Medicines, medical devices > Freedom of Information responses from the MHRA - week commencing 4 January 2021

Medicines & Healthcare products Regulatory Agency

FOI release

Freedom of Information request on emails with Bill & Melinda gates Foundation (FOI 20-534)

Published 24 March 2021

Thank you for your information request, dated 5th December 2020 where you asked for all emails from and to the Bill and Melinda Gates Foundation.

I can confirm that the MHRA has received grant funding from the Bill and Melinda gates Foundation for specific activities. We do hold some of the information that you have requested. However, we have also determined that the information is exempt under Section 12 of the Freedom of Information Act and we cannot process your request any further.

Section 12 of the Act allows public authorities to refuse requests where the cost of dealing with them would exceed the appropriate limit, which for central government is set at £600. This represents the estimated cost of one person spending 24 working hours in determining whether the department holds the information, locating, retrieving and extracting the information.

In order to process your request, we would need to identify all members of MHRA who have had correspondence with the Foundation and search their entire email history, extract these emails and review them for any confidential information and redact as necessary. We consider that this would take longer than 24 working hours to complete.

We advise that you narrow your request by, for example, by asking for details of a particular area of interest and timeframe.

Please note that substantially similar requests made within 60 working days of an original request can be aggregated into one for the purposes of calculating a cost limit, meaning that section 12 could still apply.

If you disagree with how we have interpreted the Freedom of Information Act 2000 with regards to your request, you can ask for the decision to be reviewed. The review would be carried out by a senior member of the Agency who was not involved with the original decision.

If you have a query about the information provided, please reply to this email.

Kind regards,

Pharmacovigilance Service Team Vigilance and Risk Management of Medicines Division Medicines and Healthcare Products Regulatory Agency 10 South Colonnade, Canary Wharf, London E14 4PU Email: pharmacovigilanceservice@mhra.gov.uk Stay connected: mhra.gov.uk/stayconnected

↑ Back to top

NON-INTERVENTIONAL INTERIM STUDY REPORT 5 ABSTRACT

Title: Post Conditional Approval Active Surveillance Study Among Individuals in Europe Receiving the Pfizer-BioNTech Coronavirus Disease 2019 (COVID-19) Vaccine

Date: 12 March 2024

Name and affiliation of the main author: Daniel Weibel, Assistant Professor, University Medical Center Utrecht, Utrecht, The Netherlands (PI); Alejandro Arana, Senior Director Epidemiology, RTI Health Solutions, Barcelona, Spain (Co-PI)

Keywords: Pfizer-BioNTech COVID-19 vaccine; database study; active surveillance study; post-conditional approval safety study; non-interventional study.

Rationale and background: The Pfizer-BioNTech COVID-19 vaccine, tozinameran (Comirnaty®), a novel mRNA-based vaccine, has been authorised for use in several countries including the United States and European Union, for the prevention of COVID-19. Efficient and timely monitoring of the safety of the vaccine is needed. The overall goal of the study is to determine whether an increased risk of prespecified adverse events of special interest (AESIs) exists following the administration of at least one dose of the Pfizer-BioNTech COVID-19 vaccine. This non-interventional study is designated as a Post-Authorization Safety Study (PASS) and is a commitment to the EMA and a Postmarketing Requirement to the Food and Drug Administration (FDA).

Research question and objectives: To determine if there is an increased risk of prespecified AESI following the administration of at least one dose of the Pfizer-BioNTech COVID-19 vaccine.

Study design: This post-authorisation active surveillance study of AESIs following administration of the Pfizer-BioNTech COVID-19 vaccine used a retrospective cohort design comparing the risk in vaccinated and unvaccinated individuals matched by the date of vaccination with data from multiple databases. Additional control for confounding was conducted using propensity score (PS) adjustment. In the final report, comparison with historical controls and a self-controlled risk interval (SCRI) design will also be used.

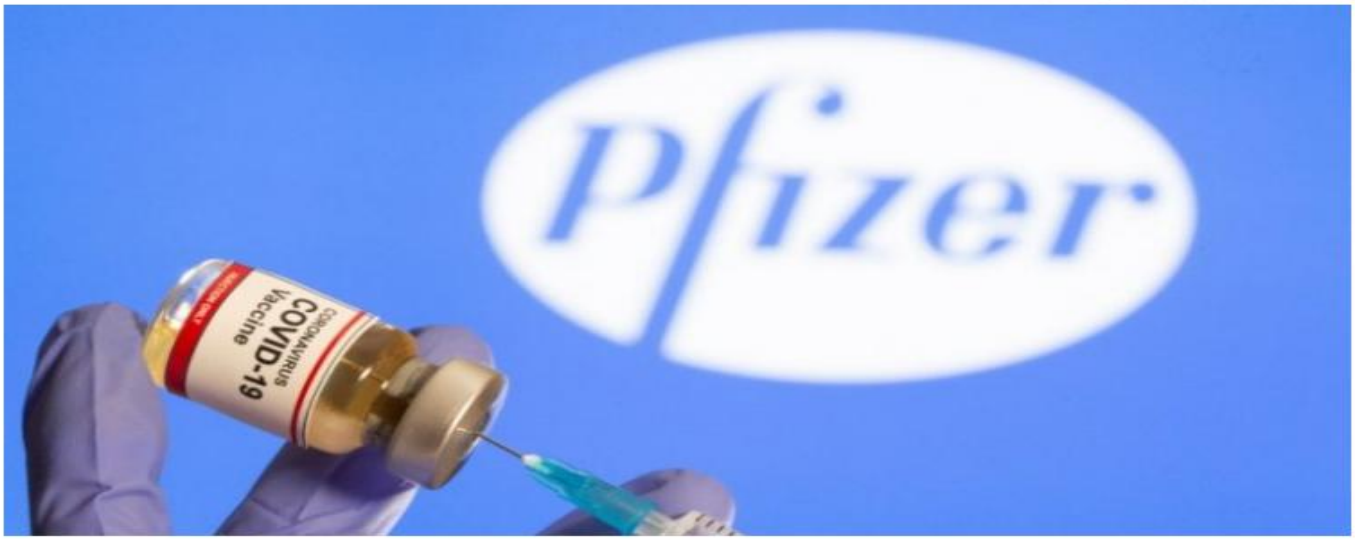
Setting: Data were available from six electronic healthcare data sources in Europe for the objectives of the fifth interim report: Pedianet, IT; PHARMO Institute for Drug Outcomes Research (PHARMO), NL; University of Oslo - Norwegian Health Registries (NHR), NO; EpiChron Research Group on Chronic Diseases at the Aragon Health Sciences Institute (EpiChron), ES; Sistema d'Informació per el Desenvolupament de la Investigació en Atenció Primària (SIDIAP), ES and CPRD (Clinical Practice Research Datalink) Aurum (UK). As per protocol the study originally included two additional electronic healthcare data sources who could not contribute data for the fifth interim report. These were ARS Toscana (Agenzia Regionale di Sanita' della Toscana), a research institute in the Tuscany region of Italy, IT), and Health Search Database (HSD), IT.

(Bijlage 2)

THE DAILY SCEPTIC
QUESTION EVERYTHING. STAY SANE. LIVE FREE.

The Hidden Pfizer Report That Shows Up to 40% More Heart Conditions in the Vaccinated

BY NICK HUNT 8 OCTOBER 2024 7:00 PM SHARE



For six months, the MHRA and other national regulators have been sitting on a Pfizer report about Covid vaccine safety. Worryingly, the abstract which I have just found online doesn't look good at all:

- the vaccinated cohort have at least 23-40% higher risk of some heart-related conditions; and
- the risk is higher than in Pfizer's previous report (i.e., it is increasing over time since vaccination).

The report in question is Pfizer's report C4591021 'Interim Report 5' dated March 12th 2024. It is a Post Authorisation Safety Study (PASS) of Pfizer's Covid vaccine. In summary, national regulators routinely require pharmaceutical manufacturers to conduct PASS studies as a condition of authorisation of most new medicines. The regulators provide data to the manufacturer covering millions of patients registered in national healthcare systems. The manufacturer then conducts analysis to determine whether the medicine has increased the risk of specified health conditions.

I have previously written a couple of articles about Covid vaccine PASS studies. First, in October 2023, to raise awareness of the studies and the fact that most of them were not being published. Second, in January 2024, to report that I had obtained copies of PASS studies by Pfizer, Moderna and AstraZeneca via a Freedom of Information request to the MHRA. In the second article I picked out three health conditions (arrhythmia, heart failure and acute coronary artery disease) from Pfizer's 'Interim Report 4' where there was a higher incident rate in the vaccinated cohort.

Knowing that Pfizer had completed its 'Interim Report 5' in March 2024, in April I submitted FOI 24/075 to MHRA asking for a copy. MHRA applied a Section 22 Exemption: "information intended for future publication." This seemed very odd given that it had sent me previous ones only three months

before. However, helpfully, it stated that it "will be published in the fourth quarter of 2024".

So in late August, I submitted another FOI (24/475) to check that this was still MHRA's intention. Imagine my surprise when it backtracked: "We cannot confirm whether the Pfizer C4591021 Interim Study Report 5 prior to December 31st 2024 is still due to be published. We have contacted the company, who have informed us that the final report is due for submission at the end of 2024 and plans for publication will be decided at this point." I read that as: "We're worried about the results in Interim Report 5, so we've decided to wait for Pfizer's Final Report before deciding if and when to publish either of them."

Imagine my further surprise when I just found an abstract of Pfizer's 'Interim Report 5' online. As I said at the start, it doesn't look good. Here are the first six conditions mentioned in the abstract:

Condition	Hazard Ratio
Acute cardiovascular injury	1.23 *(95% CI: 1.18, 1.27)*
Arrhythmia	1.27 *(95% CI: 1.21, 1.33)*
Heart failure	1.02 *(95% CI: 0.95, 1.09)*
Stress cardiomyopathy	1.30 *(95% CI: 0.53, 3.20)*
Coronary artery disease	1.40 *(95% CI: 1.30, 1.50)*
Myocarditis within 21 days	2.30 *(95% CI: 0.94, 5.66)*

Now, a Hazard Ratio of 1.23 means that the condition is 23% more likely in the vaccinated cohort, and "CI" mean confidence interval, i.e., we can be 95% confident that the 'true' number lies between the following two numbers. So those data are extremely worrying. This is the manufacturer bearing out the numerous anecdotal reports of increasing heart issues since 2020 as well as various independent research reports.

Worse, those data are worse than the corresponding figures in Pfizer's previous 'Interim Report 4'. In other words, the risk appears to be increasing over time since Covid vaccination.

And by the way, none of the above can be attributed to Covid itself: the exposure to Covid will be broadly the same in both the vaccinated and unvaccinated cohorts, which comprise millions of individual patients.

That said, there are potential confounders. The abstract suggests two:

- that for any condition, the seriousness might vary within and between the cohorts; and
- 'healthy vaccinee' bias – the argument that vaccinated individuals are more likely to seek medical attention.

But that's one reason why we need to see the whole Pfizer report – to see the whole dataset, results and argumentation which lead to Pfizer's explanation about confounding.

Even more importantly, we need to see the whole report because the Hazard Ratio will vary by age: younger people are normally much less prone to heart-related conditions than older people. Imagine how surprised I will be if the Hazard Ratios in the full report for younger age groups are even worse than those in the abstract (which are averages across all age groups). Is MHRA sitting on information which actually confirms the many siren warnings that it was reckless for MHRA to authorise, and JCVI to recommend,

Covid vaccination of younger people who were at extremely low risk from Covid when it was known at the time that the Covid vaccines didn't stop transmission and there were no long term safety data?

In summary, if, as I suspect, MHRA is worried by the results in Pfizer's 'Interim Report 5' then no wonder it is sitting on it.

One final thought. The Covid Inquiry Module 4 (Vaccine & Therapeutics) oral hearings are scheduled for January 14th-25th 2025. It would be a travesty if Pfizer's 'Interim Report 5' and 'Final Report' were withheld from the inquiry. Perhaps one of the core participants or their legal representatives will request copies or question MHRA about the data at the oral hearings.

Until Nick retired a few years ago, he was a Senior Civil Servant in the Ministry of Defence responsible for the safety and effectiveness of ammunition used by the Armed Forces. He is co-author of the Perseus Group report on U.K. medicines regulator the MHRA.