The New England Journal of Medicine, or New England Journal of Misinformation? How COVID Vaccine Injuries are Being Under-Reported

A woman injured during a U.S. COVID vaccine trial claims the New England Journal of Medicine (NEJM) considered one of the most prestigious journals in the world, published clinical trial results from a pharmaceutical company that purposely omitted adverse event data. When it was pointed out to the editor-in-chief that the journal had done so, they refused to issue a correction.

In addition, COVID vaccine manufacturers, who have complete control over study design and analysis of data, are excluding people from clinical trial results who experienced adverse events, including deaths, to make their vaccines appear safe.

During testimony on Nov. 2 at an event held by Sen. Ron

Johnson (R-WI), Brianne Dressen, who suffered an injury after receiving her first dose of AstraZeneca, said her adverse event was excluded from the published trial data. Another participant on the panel, Maddie De Garay, a 12-year-old girl severely injured during Pfizer's clinical trial, said her adverse event was also excluded by Pfizer's trial results, also published in the NEJM.

After the hearing, Dressen contacted the NEJM. Below is her correspondence with Dr. Eric Rubin, editor-in-chief of NEJM and member of the U.S. Food and Drug Administration's (FDA) vaccine advisory panel.

Brianne Dressen's letter to the NEJM

"I was a participant in Astra-Zeneca's Covid-19 vaccine trial. I suffered serious and severe adverse effects after the first dose of AZC1222, was disabled and remain so today. I write to request inaccuracies in the trial publication be corrected, and to demand complete reporting of the trial publication and results.

The authors state that 180 AZD1222 recipients "withdrew" and "all serious adverse events will be recorded from the time of informed consent through day 730." This is inaccurate. During hospitalization due to my adverse events, the trial investigators unblinded me, saw that I had received AZD1222 and recommended that I not receive the second dose.

The trial smartphone app was subsequently disabled on my phone. I did not withdraw. I was withdrawn, and AstraZeneca chose to stop collecting my data after 60 days despite the fact that I remain with persistent symptoms one year later.

The trial publication lacks complete reporting of my adverse events, and readers are not informed that the trial smartphone

app did not allow study participants to record adverse events in their own words.

The authors state that "No new vaccine-related safety signals were identified" but this may be an unreliable conclusion due to test clinics and the study sponsor neither recording nor reporting adverse events that did occur in study participants like myself.

Brianne Dressen, Clinical Trial Participant, Founder react19.org

Conflicts of interest: AstraZeneca has provided me $590 for my participation in the trial. They have not paid for any of my medical bills."

Responses from NEJM

Rubin almost immediately responded to Dressen's letter:

From: NEJM Letter <onbehalfof@manuscriptcentral.com>
Date: November 15, 2021 at 10:13:27 AM MST
To: Brian n Bri Dressen
Subject: New England Journal of Medicine 21-17934
Reply-To: letter@nejm.org

Dear Mrs. Dressen:

I am sorry that we will not be able to publish your recent letter to the editor. The space available for correspondence is very limited, and we must use our judgment to present a representative selection of the material received. Many worthwhile communications must be declined for lack of space.

Sincerely,

Eric J. Rubin, MD, PhD
Editor-in-Chief
New England Journal of Medicine

From: Brian n Bri Dressen
Date: November 15, 2021 at 2:45:40 PM MST
To: letter@nejm.org, erubin@nejm.org
Subject: Re: New England Journal of Medicine 21-17934

Dear Dr. Rubin,

I am sorry to hear that you will not publish my letter. Apart from the letter itself, the far more important issue is the problems I wrote about. Will the NEJM be issuing any corrections to the Falsey et al. trial publication (https://www.nejm.org/doi/full/10.1056/NEJMoa2105290)? My letter documented how the article omitted key safety data in my case (I am aware of at least one other trial participant who suffered a similar reaction and is also missing from the AZ report) I have documentation proving trial participation as well as diagnosis of vaccine injury from the National Institutes of Health. The other injured participant also reported to the NIH. Omission of adverse reactions is a violation of a key tenet of clinical trial reporting.

Best regards,

Brianne Dressen

From: "Rubin, Eric" <erubin@nejm.org>
Date: November 15, 2021 at 2:53:52 PM MST
To: Brian n Bri Dressen , Letter <letter@nejm.org>
Subject: Re: New England Journal of Medicine 21-17934

Dear Ms. Dressen,

We rarely publish case reports and we have no investigative powers. I suggest that you use standard reporting mechanisms (though, if the diagnosis was made at the NIH, they should report) and follow up with the FDA and/or CDC which can actually investigate.

Eric

From: Brian n Bri Dressen
Date: Monday, November 15, 2021 at 5:16 PM
To: Rubin, Eric <erubin@nejm.org>
Cc: Letter <letter@nejm.org>
Subject: Re: New England Journal of Medicine 21-17934

Dear Dr. Rubin,

I think there has been a misunderstanding. I did not ask to publish a case report, nor have I called for an investigation. I am reporting errors in the NEJM trial publication that require correction, and my understanding is that the journal is the place to report errors in a publication. Will you be taking action?

Regards,

Brianne

From: "Rubin, Eric" <erubin@nejm.org>
Date: November 15, 2021 at 3:19:37 PM MST
To: Brian n Bri Dressen
Cc: Letter <letter@nejm.org>
Subject: Re: New England Journal of Medicine 21-17934

Dear Ms. Dressen,

The best we could do is forward your letter to the manufacturer. Only they are in a position to see the primary data. But you can do that yourself and I would encourage you to do so. Only you can provide the information that they can use to investigate.

Eric

From: Brian n Bri Dressen
Date: November 15, 2021 at 4:01:52 PM MST
To: "Rubin, Eric" <erubin@nejm.org>
Cc: Letter <letter@nejm.org>
Subject: Re: New England Journal of Medicine 21-17934

Dear Dr. Rubin,

It is troubling to see that only the manufacturer is in a position to see the primary data. I think I understand what you mean, but I am not sure I fully agree. As I mentioned in my original letter, AstraZeneca stopped recording data on me at day 60, so they do not have all the data on my severe and serious adverse events that persist to this day which is beyond one year. The publication claims "serious adverse events will be recorded from the time of informed consent through day 730" and I am evidence that this is not the case.

At any rate, thank you for your offer to forward my letter to the manufacturer. I would welcome that and look forward to hearing from you what they say. I have read the NEJM publication and am confident in what I have described to you as errors in the publication which require correction. I suggest starting with a query asking whether the participants they describe as "withdrawing" actually "withdrew". As I explained, I did not withdraw, I was withdrawn and the trial app on my phone was disabled.

Best,

Brianne

From: "Rubin, Eric" <erubin@nejm.org>
Date: November 15, 2021 at 4:35:00 PM MST
To: Brian n Bri Dressen
Cc: Letter <letter@nejm.org>
Subject: Re: New England Journal of Medicine 21-17934

Dear Ms. Dressen,

I'm sorry, I wasn't clear. Our correspondence with authors is all confidential so you would not get any reply. That's why I'd suggest that you write to them directly. You can also write to the FDA, the only agency with the capability of independently investigating claims of trial misconduct. I'm

afraid that our writing about a single patient, without our being able to provide documentation, in a trial with tens of thousands of participants would not have any effect.

Rubin's ties to the FDA

Two weeks prior to Dressen's email, Rubin voted as part of the FDA's vaccine advisory panel to approve Pfizer's COVID vaccine for 5 to 11 year-olds. During the meeting, he stated, "we are never going to learn how safe this vaccine is unless we start giving it."

The very next day, he published an article in the NEJM on Pfizer's COVID vaccine and adverse events – information that he knowingly withheld from the FDA's safety committee when they were assessing Pfizer's data.

Scientist says adverse events are under-reported

Data on adverse events is vital for effective decision-making by regulators, policymakers, doctors and patients, Maryanne Demasi, a medical scientist and investigative journalist wrote in a blog post. "But there are serious concerns about publication bias or selective omission of data, whereby adverse events are less likely to be published than positive results.

For example, a systematic review in PLOS journal analyzed 28 studies and found that adverse events were less likely to appear in published journal articles than unpublished studies. Experts now suggest that the pivotal clinical trials on COVID vaccines may have under-reported adverse events in published trial data.

Demasi explained:

> *"In the Pfizer and AstraZeneca vaccine trials, participants were given digital apps to record adverse events remotely – a more convenient, time-efficient and cost-effective way of gathering patient data.*
>
> *"A major problem however, is that the pre-determined options on the digital apps have a narrow focus on particular adverse events. For example, the app only allows a participant to record what the company deems as 'expected' events such as fever, pain at injection site, temperature, redness, swelling, fatigue, headache, diarrhea, chills, muscle and joint pain.*
>
> *But if they experience a serious adverse event like myocarditis or early signs of transverse myelitis, Guillain-Barre Syndrome, a myopathic disorder, myocarditis or thrombosis, there is no option for them to record it on the app."*

Demasi said, "if vaccine manufacturers selectively withdraw subjects who experience serious adverse events, as was the case with Brianne Dressen and others, it may explain why the trials mostly found "statistically significant" increases in minor adverse events (fever, chills, headaches) but not in serious harms."

Demasi said something similar happened with Pfizer's vaccine trial. "When Pfizer recruited 12-15-year-olds for its mRNA vaccine trial, the published data in the New England Journal of Medicine, stated that there were "no serious vaccine-related adverse events," Demasi said.

De Garay volunteered for the Pfizer vaccine trial when she was 12. On Jan. 20, she received her second dose of the Pfizer COVID vaccine as a participant in the clinical trial for 12- to 15-year-olds and is now in a wheelchair and uses a

nasogastric tube.

De Garay's vaccine adverse reaction has been completely ignored by the FDA, Centers for Disease Control and Prevention (CDC), Pfizer and the mainstream media. Instead of taking De Garay's vaccine injury seriously, doctors referred her to a mental health facility, citing a "predisposition to hysteria" as the root cause of her sudden paralysis and onset of severe symptoms.

Dr. David Healy, a psychiatrist, scientist, psychopharmacologist and author conducted an extensive review of De Garay's medical records and interview with her family, and found no history of pre-existing conditions or mental illness.

"This trial designation is not just wrong, but quite unbelievable," said Healy, who feared the erroneous diagnosis would jeopardize De Garay's treatment and progress.

"It is perhaps even sociopathic as it appears that, in order to maintain Pfizer's position, this young woman is not getting the treatment that would be ordinarily indicated for the kind of problems she has. Instead based on a claimed 'functional disorder', she has been directed to a mental health facility," said Healy.

"If there is any chance that you have a pre-existing condition, then they do not blame the vaccine," Healy said. "And so they can claim there were no serious vaccine-related events because they do not believe her reaction was 'vaccine-related.' It is quite unbelievable."

Healy said he has seen this before when looking at SSRI studies, where he discovered participants were being dropped from clinical trials due to supposed "intercurrent illnesses."

“Intercurrent illnesses” used to exclude vaccine injuries from trial results

According to Healy, if someone is dropped from a trial because of an “intercurrent illness,” the investigators do not have to write up a narrative explaining why this patient was dropped from the trial.

“This may well be a sink-hole into which deaths from the vaccine have vanished,” Healy said. Patients with strokes, heart attacks or thrombotic events may have all vanished here, the justification being that they must have had a dodgy heart or another pre-existing [or intercurrent] illness.”

According to Demasi, when Astrazenca published deaths from their clinical trial, investigators excluded deaths that occurred immediately after the first dose of the vaccine, up to 14 days after the second dose.

“In other words: 1) first injection, 2) wait for three weeks before having second injection, 3) wait a further two weeks. That is a total of five weeks where deaths were not published.”

Investigators said it was because participants are not “fully immune” until two weeks after their second dose, which is true, but “ignoring deaths in that five-week period fails to capture any deaths that might be caused by the vaccine,” Demasi said.

“Randomised controlled trials are not supposed to allow decisions like this. All deaths should be reported. The company can say that they do not think the deaths were caused by the vaccine, but we need a chance to know how many there were and decide if these need further investigation,” said Healy.

According to the CDC, as of June 25, the majority of reported deaths after receiving a COVID vaccine, occur within the first 30 days.

This surveillance data cannot establish a causal link with the vaccine, but the signal is considered significant, especially if deaths are not being captured in the controlled trials, Demasi said.

According to Astrazeneca's Phase 3 clinical trial to assess safety and efficacy of its COVID vaccine, "deaths that were adjudicated as not related to COVID-19 were treated as intercurrent events and therefore censored at the date of death."

"Given that deaths on the vaccines happen within two weeks of a dose – first or second – and given there are thousands been reported to regulators with reasonable estimates of up to 150,000 in the U.S. alone, more than half of which happen in this two week period, this is a quite extraordinary state of affairs," said Healy.

COVID vaccine trials are controlled by Pharma companies

Thus far, reports of serious, life-threatening adverse events linked to COVID vaccines have not been found in "gold standard" controlled trials, yet there are almost a million adverse events reported to the CDC's Vaccine Adverse Event Reporting System (VAERS). Historically, VAERS has been shown to report only 1% of actual vaccine adverse events.

"If all COVID vaccine trials are funded, designed, conducted and analysed by the manufacturers – which is known to distort the results to favour the sponsor's aims – then more should be done to gain access to the data to allow for independent scrutiny," Demasi said.