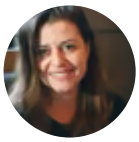
Pfizer's Pregnancy & Lactation Cumulative Review Reveals Damning Data



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Author at Trial Site News | Investigative journalist and broadcaster
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Journalist
Article

A damning 8-page document was recently released, as part of this month's court-ordered Pfizer data dump. I have written many reports for Trial Site News on Pfizer's trove of documents, which both the US Food and Drug Administration (FDA) and the pharmaceutical company wanted to remain hidden from the public until 2096. The links below are for all my analytical reports pertaining to Pfizer's nonclinical and clinical trial documents, including its post-authorization safety report.

https://www.trialsitenews.com/a/fdas-forced-hand-drops-pfizers-bombshell-safety-document

https://www.trialsitenews.com/a/a-first-look-at-the-newly-released-pfizer-papers-part-1-the-errors-and-anomalies-of-the-case-report-forms

https://www.trialsitenews.com/a/first-look-at-newly-released-pfizer-docs-part-2

https://www.trialsitenews.com/a/pfizers-sensitive-document-reveals-alarming-facts-about-trial-subjects-f9d8876c

https://www.trialsitenews.com/a/the-missing-third-death-from-pfizer-biontechs-landmark-article-and-a-

further-look-into-the-anomaly-of-the-non-related-adverse-events-020fab8c

The *Pregnancy and Lactation Cumulative Review* was signed off on 20 April, 2021, just around the same time when there was a strong push by health authorities around the world, including the US Centers for Disease Control and Prevention (CDC) and the UK's National Health Service (NHS), for pregnant and lactating women to receive COVID-19 vaccines. The report is a cumulative review and summary of relevant (pregnancy and lactating) cases reported in Pfizer's pharmacovigilance (Safety) databases **from the time of drug development through to 28 February, 2021** and it contains disturbing data.

673 case (individual) reports were identified in total: 458 cases involved vaccine exposure during pregnancy (mother/fetus) and 215 cases involved exposure during breast feeding. Out of the 458 pregnancy cases, 248 (**more than half**) reported adverse events, see screenshot below.

- Among the remaining 248 cases, the most commonly reported AEs were product use issue (83), off-label use (81), pain (including but not limited to vaccination site pain/pain/pain in extremity)(101), headache (57), abortion spontaneous (51), fatigue (43), pyrexia (26), chills (24), myalgia (23), nausea (22), arthralgia (16), dizziness (15), malaise (12), lymphadenopathy (11) and asthenia (11).

The pregnancy cases

Of the 458 cases involving vaccine exposure during pregnancy, 51 events were reported for spontaneous abortion (miscarriage), abortion (1 event) and abortion missed (1 event).

- There were 53 reports of spontaneous abortion (51)/ abortion (1)/ abortion missed (1) following BNT162b2 vaccination. Of these reports, 4 cases were COVID-19 positive (including suspected), and 13 cases had relevant medical history of endometriosis (1), abortion spontaneous (10), polycystic ovaries (1), menstruation irregular (1). These cases were therefore excluded from the review. One patient had a medical history of COVID-19 (unknown if ongoing) and was excluded from the review. The remaining 39 cases are summarized in Table 1.

According to Pfizer, 53 reports of spontaneous abortion were noted (see screenshot above) but 4 cases were excluded from the review because of COVID-19 (included suspected) and 13 cases were further excluded because of the women's medical history- then there was "one patient" who had a medical history of COVID-19 and was also exlcuded- this should leave 35 remaining cases but Pfizer erroneously writes, "the remaining 39 cases are summarized.."

Of the '39' cases that were reviewed, 38 were actually listed, another reporting error, perhaps? What immediately stands out (where gestational age was known) that all the pregnant women in those cases experienced a miscarriage in their first trimester.

A further 6 disturbing cases out of the 458, involved babies being exposed to the vaccine transplacentally, leading to **premature delivery**. Their cases are described in the screenshot below.

- AER 2021166927 Baby report of fetal tachycardia noted 1 week after the neonate's mother received the second dose of the vaccine. The baby was delivered at 35 weeks and 3 days of gestation due to non-reassuring status during monitoring post vaccination. The baby was hospitalized for 5 days. The clinical outcome of fetal tachycardia was unknown.

- AER 2021015910 Maternal report of a 29-year old female who was pregnant when receiving BNT162B2. She had spontaneous rupture of membranes at 36 weeks of gestation, one day after her 2nd dose of vaccine. Unspecified therapeutic measures were taken as a result of premature rupture of membranes and the mother was recovering.

- AER 2021191405 Baby case of a fetus of unspecified gender who received BNT162B2 transplacentally. The patient's mother received vaccination during the second trimester (13-28 weeks) and experienced premature labor. A live infant was delivered but passed away a day later. Cause of death was cited as extreme prematurity with severe respiratory distress and pneumothorax.

- AER 2021182609 Maternal report (AER 2021193635 associated Baby report) of a 32-year-old female patient received BNT162B2 during the second-trimester (13-28 weeks) and experienced preterm premature rupture of membranes, premature baby/Premature delivery. Outcome of preterm premature rupture of membranes and premature delivery was recovered with sequelae. Concomitant medications included acetylsalicylic acid and dalteparin sodium.

- AER 2021155967 Baby report: A neonate patient's mother (mother was reported as 37-year-old) received BNT162B2 during 13-28 weeks of gestation and experienced foetal exposure during pregnancy, premature baby less than 26 weeks, respiratory distress and pneumothorax. Cause of death for the neonate was premature baby less than 26 weeks and severe respiratory distress and pneumothorax.

- AER 2021203938 Baby report: Patient's 33-year old mother had preterm delivery at 24 weeks and 2 days via emergency caesarean section. The fetus experienced maternal exposure during pregnancy via transplacental route on an unspecified date.

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FDA-CBER-2021-5683-0779747

In two of the premature delivery cases, the babies died because of severe respiratory distress and pneumothorax- both the mothers received the Pfizer-BioNTech mRNA vaccine in their second trimester. In another shocking case, a baby developed foetal tachycardia (heart rate over 160 beats per minute) where "the clinical outcome of the foetal tachycardia was **unknown**."

This bombshell real-world evidence, was known back in early 2021 by the FDA and Pfizer/BioNTech, just before the big push to get pregnant women vaccinated- and it showed significant safety risks to the foetus due to indirect (transplacental) exposure of the Pfizer-BioNTech mRNA vaccine, with spontaneous abortion (miscarriage) being one of the known outcomes.

When I analysed Pfizer's *Cumulative Analysis of* ***Post-Authorization*** *Adverse Event Reports for TrialSite News*, released via court order at the end of 2021, similar alarming data was also observed. Out of 270 post-authorization pregnancy cases, no outcome was provided for 238 cases. Of the remaining 32 cases where the outcome was known: 23 were reported as spontaneous abortion (miscarriage), 2 as premature birth with neonatal death and 2 cases of spontaneous abortion with intrauterine death.

In the biased, retrospective study by Lipkind et al., which formed the 'evidence' for many leading health authorities, such as the CDC, to assure the public that *"COVID-19 vaccination during pregnancy is safe and effective,"* only 1.7% of the roughly 10,000 women received the COVID-19 mRNA vaccine in their first trimester, compared to 61.8% who were vaccinated in their third trimester. This is a significant confounding factor, because 80% of miscarriages (spontaneous abortions) occur in the first trimester. It can be said this bias was an effective way to skew the study's results, making it appear that the mRNA vaccines were safer than they actually were. It's worth reading my report for TrialSite News, *On what basis are pregnant women being encouraged to take the Pfizer vaccine?*

The lactation cases

41 (~20%) of the 215 lactation cases reported adverse events in infants indirectly exposed to the vaccine via the transmammary route (through breast milk). The screenshot below shows an extensive list of adverse events reported in breast feeding infants, ranging from **facial paralysis, lymphadenopathy and blurred vision.**

Table 2. Number of Adverse Events Reported in Infants with 'Exposure via Lactation'

Preferred Term	Number of Events
Pyrexia	9
Off label use	8
Product use issue	7
Infant irritability	5
Headache	5
Rash	5
Diarrhoea	3
Illness	3
Insomnia	3
Suppressed lactation	3
Breast milk discolouration	2
Infantile vomiting	2
Lethargy	2
Pain	2
Peripheral coldness	2
Urticaria	2
Vomiting	2
Abdominal discomfort	1
Agitation	1
Allergy to vaccine	1
Angioedema	1
Anxiety	1
Axillary pain	1
Breast pain	1
Breast swelling	1
Chills	1
Cough	1
Crying	1
Dysgeusia	1
Dysphonia	1
Eructation	1
Epistaxis	1
Eyelid ptosis	1
Facial paralysis	1
Fatigue	1
Increased appetite	1
Lymphadenopathy	1
Myalgia	1
Nausea	1
Paresis	1
Poor feeding infant	1
Poor quality sleep	1
Pruritis	1
Restlessness	1

Table 2. Number of Adverse Events Reported in Infants with 'Exposure via Lactation'

Preferred Term	Number of Events
Rhinorrhoea	1
Roseola	1
Skin exfoliation	1
Vision blurred	1

Pfizer's report concludes that the *"cases reviewed above are **indicative** of what is in the Pfizer safety database as of 28 February 2021. The sponsor (Pfizer/BioNTech) will continue to monitor and report on all pregnancy exposure and lactation cases."*

A study by Hanna et al., published in *JAMA Pediatrics* in September 2022, revealed that researchers found

trace amounts of the COVID-19 vaccine mRNA in the breast milk of lactating women, as soon as one hour after vaccination. They went on to state, "We speculate that, following the vaccine administration, **lipid nanoparticles containing the vaccine mRNA are carried to mammary glands** via hematogenous and/or lymphatic routes."

However, this vitally important information was already known for quite some time by Pfizer and BioNTech, since it was observed in real-world data from Pfizer's own review, signed off on 20 April 2021 and submitted to the Food and Drug Administration (FDA), where 3 days later the CDC began recommending it for pregnant women

Comments (3)

What do you think?

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Publish

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Apr. 23, 2023, 8:08 a.m.

Typo: "4 cases were excluded from the review because of the women's medical history."
It probably should read "14 cases", since 51 + 1 + 1 - 14 = 39.

However it's not easy to check, since the report is neither clear nor exact :

The report claims "There were 53 reports of spontaneous abortion (51)/ abortion (1)/ abortion missed (1) following BNT162b2 vaccination. Of these reports, 4 cases were COVID-19 positive (including suspected), and 13 cases had relevant medical history of endometriosis (1), abortion spontaneous (10), polycystic ovaries (1), menstruation irregular (1). These cases were therefore excluded from the review. One patient had a medical history of COVID-19 (unknown if ongoing) and was excluded from the review. The remaining 39 cases are summarized in Table 1."

Since 53 - 4 - 13 - 1 = 36 (not 39), either there's an error in the report or it failed to explicit that 3 cases cumulated two of the excluding conditions.

Moreover, Table 1 actually lists 38 cases, instead of 39.

Show more (1) Reply

P

partornell

Apr. 27, 2023, 12:05 a.m.

I do not understand. What should the outcome be without vaccine and what is the outcome now and how much higher is it?

Reply

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