War Room/DailyClout Pfizer Document Analysis

Post-Marketing Team Micro-Report 17:

Use in Pregnancy and Lactation Review of 5.3.6

SOURCE

https://www.phmpt.org/wp-content/uploads/2022/04/reissue_5.3.6-postmarketing-experience.pdf

5.3.6 AE REPORTING PERIOD:

"Since the first temporary authorization for emergency supply under Regulation 174 in the UK (01 December 2020) and through 28 February 2021."

Adverse Events were reported to Pfizer during a 90-day period, following the December 1, 2020, public rollout of its COVID-19 experimental "vaccine" product.

In the Pfizer 5.3.6 document, these AEs were categorized by System Organ Classes (SOC) – in other words, by systems in the body.

ABBREVIATIONS:

5.3.6 : Pfizer source document

SOC : System Organ Class

AE : Adverse Event

AESI : Adverse Event of Special Interest

EUA : Emergency Use Authorization by FDA

PM : Post-Marketing

BNT162b2 : Pfizer's mRNA COVID-19 vaccine

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Pfizer identified three categories of **Safety Concerns** in Table 3. These were:

1) Important identified risks: Anaphylaxis (Table 4)
2) Important potential risks: Vaccine-Associated Enhanced Disease (VAED), including Vaccine-Associated Enhanced Respiratory Disease (VAERD) (Table 5)
3) Missing Information**: Use in Pregnancy and Lactation**, Use in Paediatric Individuals < 12 years of Age, and Vaccine Effectiveness (Table 6)

Pregnancy Related AESIs *Search criteria: PTs Amniotic cavity infection; Caesarean section; Congenital anomaly; Death neonatal; Eclampsia; Foetal distress syndrome; Low birth weight baby; Maternal exposure during pregnancy; Placenta praevia; Pre-eclampsia; Premature labour; Stillbirth; Uterine rupture; Vasa praevia*	For relevant cases, please refer to Table 6, Description of Missing Information, *Use in Pregnancy and While Breast Feeding*

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Table 6 reports 413 pregnancy and lactation cases, making up 0.98% of the 42,086 cases in the post-marketing data set. Of the 413 cases, 84 were considered serious and 329 non-serious. Of the non-serious adverse effects reported, 262 were exposure to the vaccine. **(It should be noted that BNT162b2 was not recommended for use in pregnancy or with lactation at the time of the post-marketing data set.)**

Three groups are represented in this report:
Pregnancy cases
Breast feeding baby cases
Breast feeding mother cases

Pregnancy cases: 274 pregnancy cases were reported, 270 mothers and four fetus/baby cases.

What happened to these 270 pregnancies?

There were 28 deaths of either a fetus or neonate. These were described as spontaneous abortion (miscarriage) or various other terms which mean loss of the fetus/baby. **No outcome was reported for 238 pregnancies (88%)!** In addition to the 28 deaths, there were five "outcome pending" and one "normal outcome." The numbers add up to more than 270 because a set of twins had different outcomes.

Under Pfizer's Clinical Protocol Document of 11/2020, C4591001, section 8.3.5, "exposure" can mean inhalation or skin contact with the vaccine, contact around the time of conception with a partner who was vaccinated or exposed to inhalation or skin contact, or vaccination. It is not known from 5.3.6 whether these 146 mothers were vaccinated or had other forms of exposure.

One hundred and forty-six of the 270 pregnant women simply noted their exposure to the vaccine. Only a few of these noted the timing during the pregnancy: 15 in the first trimester, seven in the second trimester, and two in the third trimester. Table 6 does not clarify whether "exposure" is the same as vaccination.

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