3/29/22 Team 5 Report

Key intelligence question (KIQ) 0022203:
Within this document (https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf), there appears to be a large number of "not recovered at the time of report" and "unknown" case outcomes. As shown in Table 1, these numbers are significant, adding up to 20,761 out of 42,086 "relevant cases." Do we know what happened to them? Has this large number of unknown outcomes and patients who had not recovered at the time of this report been reported anywhere in the press, on the HHS.gov website (FDA, CDC, etc.), or on the Pfizer main website? This number dwarfs the reported deaths number so finding out the eventual outcome is vitally important.

What Happened to Pfizer's Missing Patients?

A great deal of data are missing from Pfizer's analysis of adverse events that were reported after the Pfizer mRNA vaccine was approved by the US Food and Drug Administration ("5.3.6 Cumulative Analysis of Post-Authorization Adverse Event Reports of PF-07302048 (BNT162B2) Received Through 28-Feb-2021," https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf). From the data that are provided, many more questions arise.

- Of the 42,086 cases that Pfizer analyzed, 32,686 (78%) have known outcomes. The outcomes of almost one-quarter (22%) are not known (Table 1, p. 7, https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf). Why are these case reports incomplete?

- Nearly three-quarters (71%) of the 42,086 patients are female; 22% of the patients are male; another 7% have no sex identified (Table 1, p. 7, https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf). Why are so few male patients included in the Pfizer report? This is especially worrying, since the Centers for Disease Control states that it is in male adolescents and young adults that most cases of myocarditis and pericarditis have been reported (https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html). Does this explain why Pfizer does not include myocarditis or pericarditis among the cardiovascular adverse events (Table 7, p. 16, https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf)? Instead, Pfizer buried the myocarditis and pericarditis cases in its review of immune-mediated/autoimmune adverse events (Table 7, p. 20, https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf).

- Sadly, 1,223 (3.7%) of the 32,686 patients with known outcomes died (Table 1, p. 7, https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf). Thus, in 3.7% of the adverse event cases with known outcomes, the Pfizer mRNA vaccine proved fatal. If we knew the number of doses that were shipped worldwide, we could determine the actual mortality rate; unfortunately, Pfizer has redacted that information (p. 6, Section 3.1.1, paragraph 1, https://phmpt.org/wp-

content/uploads/2021/11/5.3.6-postmarketing-experience.pdf). The Centers for Disease Control suggests that the number of deaths should be much less, around 0.003% (paragraph 2, https://www.cdc.gov/mmwr/volumes/71/wr/mm7101a4.htm). What is the actual mortality rate for the injection?

- Four (0.3%) of the 1,223 deaths occurred on the same day the patients received the mRNA vaccine. These patients died of anaphylaxis, although "they all had serious underlying medical conditions, and one individual appeared to also have COVID-19 pneumonia" (Table 4, footnote b, p. 10, https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf). Nonetheless, the Centers for Disease Control advises that "staying up to date with COVID-19 vaccines (getting primary series and booster) . . . is especially important if you are older or have severe health conditions or more than one health condition . . ." (https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html). Is this advice consistent with the deaths from anaphylaxis?

- Pfizer's 3.7% fatality rate for the adverse event cases with known outcomes doesn't include patients that Pfizer said had not recovered at the time of the report (30 April 2021). Of the 32,686 patients with known outcomes, 11,361 (35%) of the patients are listed as not recovered (Table 1, p. 7, https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf). Did those 11,361 patients survive the Pfizer mRNA vaccine?

- Of the 32,686 patients with known outcomes, 19,582 (60%) of the patients are lumped together as recovered/recovering (Table 1, p. 7, https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf). We can assume that recovered cases are free from residual adverse events, but what was the outcome of recovering cases—did they ultimately get well? In reality, recovered and recovering cases should not be combined; instead, coupling not recovered and recovering cases is a more honest way to present the data. By combining recovered and recovering cases, is Pfizer attempting to overcount the number of cases in which the adverse events were resolved?

- Clearly, patients who received the mRNA vaccine weren't adequately tracked, possibly because of the way the mRNA vaccine was named. Pfizer requested a waiver of the standard method for assigning a unique name to the vaccine (p. 4, https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M1_waiver-req-designated-suffix.pdf). The purpose of the unique name is to "secure pharmacovigilance so that the FDA can effectively monitor all biological products in the post market" and to "aid in adverse event report tracking" (paragraph 5, https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-fdas-steps-naming-biological-medicines-balance). Pfizer's waiver request notes that the standard naming method "would be burdensome and redundant" (p. 3, https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M1_waiver-req-designated-suffix.pdf). Did

Pfizer request the waiver knowing it would be more difficult to track and report adverse events experienced by patients?

Pfizer's report raises more questions than it answers. Yet in Pfizer's review of adverse events reported after the Pfizer mRNA vaccine was approved by the FDA, they conclude that their review "confirms a favorable benefit:risk balance" for the mRNA vaccine (p. 29, https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf). With 22% of patients having unknown outcomes, 35% not recovered at the time of the review, and 3.7% dead, Pfizer concludes that the benefits of taking their mRNA vaccine outweigh the risks. So another question arises: how can that conclusion be true?

Even without knowing what happened to the missing patients, the data in Pfizer's analysis of adverse events raise important warning flags. Consider the absolute number of major adverse cardiac events that Pfizer reviewed. In the period from 24 hours to 21 days after receiving Pfizer's mRNA vaccine, there were 394 total cases that included the following.

- Arrhythmia: 102 cases
- Myocardial infarction: 89 cases
- Acute myocardial infarction: 41 cases
- Cardiac failure: 80 cases
- Acute cardiac failure: 11 cases
- Cariogenic shock: 7 cases
- Orthostatic tachycardia syndrome: 7
- Pericarditis: 32 cases
- Myocarditis: 25 cases

Are nearly 400 major adverse cardiac events enough to pause or stop the widespread use of Pfizer's mRNA vaccine?