from p8.

When Pfizer's Six-Month Interim Report of Adverse Events (C4591001) revealed a total death count of 38 [35], the number seemed unexpectedly low for a clinical trial involving 44,060 participants amidst a pandemic. To investigate, Michels and colleagues estimated the anticipated deaths based on US mortality rates in 2020, presuming comparability across participating countries [54]. With 132 trial sites in the US and 80% of subjects, they estimated that 222 deaths should have occurred between July 27, 2020, and March 13, 2021, making the observed 38 deaths only 17% of the projected number. Most of the trial sites had fewer deaths than anticipated, possibly attributed to a considerable percentage of "Lost to Follow-up" subjects (4.2% of randomized subjects), including 395 unique subjects within the study period. While some sites recorded negligible losses, others exhibited substantial figures, up to 5% of the site's subjects [54]. These numbers likely contributed to the seemingly low overall death count and should have prompted increased efforts to locate these individuals. Losing track of nearly 400 study participants in the follow-up observation period could have substantially compromised the validity and generalizability of the results. The missing data can produce biased estimates, leading to invalid conclusions. This could result in a distortion of vaccine efficacy and underestimation of SAEs (including deaths), thus misrepresenting the safety profile of the mRNA products. In short, Pfizer's failure to minimize participant attrition seriously undermined the accuracy and reliability of the six-month study's conclusions. — 46

According to a retrospective analysis by Gulbrandsen and colleagues, the Pfizer trial data showed a significant association between the mortality rate and time since the injection in both the vaccine and placebo arms [84]. A minimal number of deaths were recorded during the initial 80 days, but a significant mortality increase was observed around the 100-day mark post-injection, indicating a pattern that cannot be attributed to chance. Remarkably irregular trends are also evident in the cardiac SAEs within the trial. Nearly half of all the cardiac events manifested within the initial 50 days following the injection, despite the constant risk exposure anticipated for the first 140 days. Oddly, a dramatic surge in cardiac SAEs was observed around the 100-day mark from the first injection in both the placebo and vaccine groups, coinciding with the heightened death rate. Examining the predominant medical diagnoses before participation in the trial revealed yet another aberrant trend: all nine of the most prevalent pre-existing diagnoses were more commonly found among participants in the placebo arm. Moreover, there was a notable contrast in the ages of deceased participants between the two groups. These observed patterns were unlikely to occur randomly. The only plausible explanation that aligned with these anomalous trends was that the SAE records among vaccine recipients were altered, relocating them to the placebo arm post occurrence [84]. 47

These concerns are further compounded by revelations concerning substandard research practices and inadequate data management in the pivotal trials. A whistleblower report by a former employee of the contract research organization responsible for enrolling patients in Pfizer's pivotal trial raises significant questions regarding data integrity and the safety of trial participants [85]. Among the trial conduct issues documented were failure to report protocol deviations, improper storage of vaccines, mislabeling of laboratory specimens, and lack of timely follow-up for patients experiencing AEs, possibly leading to underreporting. In terms of regulatory oversight, the FDA inspected only nine out of the 153 study sites involved in the Pfizer trial [86]. 48

Finally, an unblinding of participants occurred early in the trial, potentially on a wide scale across different study sites. Participants were not presented with clear information regarding potential AEs in both trial protocols and consent forms [87]. Some parts of the consent form were misleading and merely intended to elicit participation that might not otherwise have occurred if the volunteers had been made aware that what was promised in theory or "on paper" was unlikely to happen in reality [87]. As a result, participants were not being granted truly informed consent; the potential injuries and AEs most likely to be caused by the vaccinations were never openly stated. 49

This lack of informed consent carried over into the real-world setting following the EUA. For example, not publicly disclosing the Pfizer trial's exclusion of pregnant women is arguably among the CDC's most egregious oversights when asserting the safety of COVID-19 vaccine administration during pregnancy [1]. The Nuremberg Code established patients' rights to voluntary informed consent in the aftermath of World War II [88]. US courts consistently support informed consent as a fundamental right for patients' autonomy [89]. Informed consent procedures must provide clear distinctions between risks that are frequently observed, risks that occur rarely, and the more obvious risk of lack of effectiveness or waning immunity, which is separate from the risk of SAEs. Whether in a clinical trial or free-living real-world setting, informed consent is essential to providing a clear understanding of the potential risks associated with receiving a genetic vaccine. Throughout the pandemic, healthcare workers were duty-bound to provide clear risk-benefit information to patients. In practice, however, informed consent was non-existent, as information sheets were blank [90], and vaccinees were never informed of potential risks beforehand. 50

Shifting narratives, illusions of protection

The ability to halt or greatly limit infection is generally considered essential to vaccine effectiveness. Nevertheless, the registrational trials by Pfizer and Moderna were not designed to address this issue. The endpoint of the trials was the reduction of symptoms associated with COVID-19 [1,2], even though the public was subsequently told by the CDC that the COVID-19 products would stop transmission [91]. Moreover, asymptomatic transmission was shown to be extremely minuscule [92]. Since 2021, the scientific 51