Reports of Bleeding and Thrombocytopenia Reported to VAERS after Moderna and Pfizer COVID-19 Vaccinations, Dec 15, 2020, to Mar 12, 2021

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Abstract: Thrombocytopenia has been reported following inoculation with mRNA technology COVID vaccines. The VAERS (Vaccine Adverse Event Reporting System) database was reviewed for cases of overt thrombocytopenia and for bleeding problems—considering that these may represent a less severe form of the same process. Using search words chosen to find such cases, entered between Dec 15, 2020, and Mar 12, 2021, 358 records were retrieved and analyzed. 104 cases of thrombocytopenia were recorded, 90 severe. When documented, the majority of cases in the severe category had platelet counts below 3000. Focal and multifocal brain bleeds, many fatal, were reported 37 times. Even lesser bleeding problems such as nose bleeds were unusual in their presentation. A review of this data suggests a problem with COVID mRNA vaccination involving platelets that may manifest in a variety of ways. Physicians are cautioned to be aware of this potential problem, to check blood counts in any bleeding issue, however minor, in conjunction with this vaccination, and to carefully document in VAERS any bleeding problem occurring within a few weeks of vaccination.

Background

Vaccination with novel mRNA technology began in mid-December 2020. In January 2021, a 56-year-old Florida physician was hospitalized with severe thrombocytopenia, three days after receiving the first dose of the Pfizer vaccine. Despite being treated by a team of physicians, he died two weeks later from a brain hemorrhage, and was reported to have had no platelets. By Feb 10, 2021, 36 other similar cases were reported in the mainstream media.[1]

The Vaccine Adverse Event Reporting System (VAERS) is an open-source searchable database of possible vaccine side effects reported by both medical personnel and patients. According to the CDC website,[2] VAERS is used to detect possible safety problems—called "signals"—that may be related to vaccination. If a vaccine safety signal is identified through VAERS, scientists may conduct further studies to find out whether the signal represents an actual risk.

The main goals of VAERS are to:

- Detect new, unusual, or rare adverse events that happen after vaccination.
- Monitor increases in known side effects, like arm soreness where a shot was given.
- Identify potential patient risk factors for particular types of health problems related to vaccines.
- Assess the safety of newly licensed vaccines.
- Watch for unexpected or unusual patterns in adverse event reports.
- Serve as a monitoring system in public health emergencies.

The CDC acknowledges limitations of the system, including:

- Reports submitted to VAERS often lack details and sometimes contain errors.
- Serious adverse events are more likely to be reported than mild side effects.
- It is generally not possible to find out from VAERS data whether a vaccine caused the adverse event.

Idiopathic (or immune) thrombocytopenic purpura (ITP) of rapid onset most commonly affects children, and generally follows a viral illness. Only 10% of ITP cases occur in adults, who usually present with an indolent form of the disorder, referred to as chronic ITP.[3] Based on the news reports of rapid onset thrombocytopenia and death in an adult population, and the seeming inability in some cases to provide even short-term successful support through the administration of platelets, use of steroids, etc., the cases reported by mainstream media seem to fit the CDC's description of an "unexpected or unusual pattern." The VAERS data was therefore reviewed to determine whether such a pattern exists, to make some preliminary estimate of the frequency of this occurrence, and to look for bleeding problems that may be related.

Methods

The VAERS database was searched using the following key words to identify potential platelet dyscrasia and bleeding problems: platelets, bleeding, hemorrhage, ITP, thrombocytopenia, thrombocytopaenia, bleed, hemorrhagic, spotting, epistaxis, hematuria, stroke, bruise, purpura, hemoptysis, hematuria, pancytopenia, hematologic, and haemotologic. In order to limit the study to products utilizing mRNA technology in general use in the United States for the period of Dec 15, 2020, to Mar 12, 2021, the field was further narrowed to search only for Pfizer and Moderna manufacturers. Cases were then individually evaluated by the author (a physician), categorizing them into diagnostic groups such as "multifocal brain hemorrhage," "subconjunctival hemorrhage," "hematuria," etc. When mentioned, "thrombocytopenia" was used as the primary diagnosis, and these cases were divided into three subcategories: (1) severe thrombocytopenia, for cases in which thrombocytopenia was named and the patient either died, required hospitalization, suffered serious bleeding such as brain bleed or "uncontrolled hemorrhage," or had a very low platelet count (in this category all mentioned platelet counts were less than 3000); (2) mild thrombocytopenia in cases where no hospitalization or serious sequelae were identified, or if platelet count was noted above 50,000, and/or clear resolution was reported; and (3) thrombocytopenic

rash, bruising, or petechiae in the absence of any other information regarding platelet count.

The age and sex of the patients were recorded in the majority of cases, and otherwise were listed as unknown age, unknown sex, or both. Cases that were retrieved from VAERS using the key words but that did not report bleeding or hematologic disorder were excluded. Cases which did not provide enough information to categorize or understand the incident were excluded. In cases where a patient had a diagnosis of thrombocytopenia and significant bleeding (such as a focal brain bleed), this was recorded only as thrombocytopenia, since the platelet issue was likely the probable cause of any secondary bleeding effects.

Results

There were 370 entries retrieved using the search terms above. Five cases were excluded for lack of information to clearly define the issue, and seven were excluded because the cases did not meet inclusion criteria of hematopoietic disorder or bleeding. The remaining 358 entries are listed in Table 1.

Table 1. Cases Retrieved from VAERS

Severe thrombocytopenia	94	Various spontaneous skin bleeding	10
Mild thrombocytopenia	11	Vein bleeding from temple	1
Thrombocytopenic petechial rash/bruising	5	Prolonged surgical site bleeding	3
Severe pancytopenia	2	Severe multifocal bleeding	5
Unknown hematologic problem	1	Severe internal bleeding	5
Multifocal or "massive" brain hemorrhage	20	Severe uncharacterized bleeding	3
Focal brain hemorrhage	29	Bleeding from cancer site liver	1
GI bleed	34	Renal dialysis shunt	1
Severe vaginal bleeding	7	Hematuria	2
Vaginal bleeding	21	Renal bleed	1
Bleeding in pregnancy	6	Tonsillar bleed	1
Bleeding with miscarriage	12	Acute uterine fibroid hemorrhage	1
Irregular menses	4	Nose bleed	32
Oral bleeding	8	Spontaneous splenic hemorrhage	1
Subconjunctival hemorrhage	11	Injection site bleeding	21
Intraocular bleed	4	Arm bruising	1

Most notably there were 105 cases of thrombocytopenia: 94 severe, 11 mild, and there were five cases with petechial rash/bruising only, which did not include platelet counts. Four cases included in the severe category had low platelets in the setting of other broader hematologic disorders: two cases of pancytopenia, a case of Burkitt's lymphoma, and a case of myeloid leukemia, all diagnosed at the time of the report. Four thrombocytopenia cases were in young people aged 18-29: one male and one female in the severe group, and two women in the group only reporting a petechial rash or multifocal bruising. Where the sex was known, 49 patients were female and 55 were male. The ages of patients with severe thrombocytopenia are listed in Table 2.

Table 2. Ages of Patients with Severe Thombocytopenia

Age range	Number Cases
18-29	2
30-39	9
40-49	5
50-59	31
60-64	2
65+	42
Unknown ages	3

In 29 reports, the platelet count was documented. Only six of these patients had platelets more than 15,000, range 28,000-114,000. (The normal range is 150,000 to 450,000 platelets per microliter of blood.) Excluding those, the average platelet count for the remaining 23 records was 2,521. One patient was recorded as having "0 platelets," and another as "1 platelet." (See the full documentation narrative below.)

Brain hemorrhage was reported in 49 people, 29 focal and 20 massive or multifocal. Of these, 25 were female, 24 male. Six of the multifocal bleeds were registered as deaths. Three of the focal bleeds were recorded as deaths. Fifteen cases of brain hemorrhage involved people aged 59 or younger.

Of the 36 gastrointestinal bleeds, 21 were aged 60 or older; 17 were female and 29 were male.

The 28 cases of vaginal bleeding in non-pregnant women, seven "severe," were often accompanied by systemic symptoms—dizziness, blurred vision, lymph node swelling, welts.

In the 36 people who reported nose bleeds, six were either intractable, recurrent, or recorded as having significant blood loss or "profuse." Associated symptoms included photophobia, headache, hives, "sick in bed," brain fog, and face swelling. The youngest patient with a nose bleed was 1-2 years old, who required emergency care.

Unusual skin bleeding was reported—spontaneous bleeding from the legs, one from the scalp, one from an old biopsy site, and one from an old healed "boil" site.

Four women presented with "multifocal bleeding," three of them with other systemic symptoms including "cough, headache, fever, nausea, diarrhea,""cough, headache, vomiting required ambulance," and "severe headache, hematomas on legs, 103 temperature, swollen lymph nodes."

Prolonged post-surgical bleeding was reported. A woman aged between 40 and 49 developed prolonged bleeding after an appendectomy, necessitating re-operation 12 days later. One patient died after a coronary artery bypass graft with prolonged post-operative bleeding. Another physician reported refractory bleeding after multiple skin biopsies in a recently vaccinated person.

Several people clearly had such spontaneous severe bleeding problems that they died before further characterization was possible.

Frank bleeding at the inoculation site occurred 14 times. Some bleeding was momentary, but often the bleeding was difficult to stop, recurrent, and/or persisted after the patient returned home.

Update

Prior to submission, in May 2021 an effort was made to update the report using the latest VAERS numbers. However, by the middle of May, when the database was again searched in identical fashion for vaccination given during the same date range, 6290 entries were retrieved, including 291 deaths. This made reviewing the case reports manually for clarification impossible to complete in a reasonable time. Using the single term "thrombocytopenia" alone, 221 cases of were retrieved, 18 events in persons under 29 years of age. The original numbers are reported here in the belief that these are representative of the bleeding spectrum encountered.

Discussion

Thalidomide is perhaps the most famous example of a pharmacologic disaster. The drug was first was released in 1957 for its sedative effects and was touted as being safe for everyone including pregnant women and children. In 1961, obstetrician William McBride, M.D., recognized its effectiveness for "morning sickness" in pregnant women. Subsequently, he began seeing unusual birth defects in babies born to women for whom he had prescribed the drug.[4] Independently, Dr. Widuking Lenz, a pediatrician in Germany, associated thalidomide with severe and unusual birth defects.[5] By 1962 the drug was taken off the market.

Recognition of thalidomide teratogenicity was made easier by several factors. First was the very unusual presentation of the deformities—hypoplasia or total absence of one or more extremities. Secondly, the physician who first began using the drug for nausea in pregnancy was also the doctor who delivered the affected babies. Thirdly, Dr. Lenz presciently recognized that many less severe deformities, when put into perspective, revealed "gradations of the defect and the biological limits of the syndrome are wider than at first suspected."[5]

The thrombocytopenia reported in the VAERS has features suggesting a different disorder than that encountered in classic ITP: specifically, the ages and sexes involved, and the rapid onset and rapid course to death, which is sometimes refractory to treatment.

Unlike in the case of thalidomide, the lesser degrees of this problem are not easily recognized, being nearly indistinguishable from bleeding issues frequently encountered in an emergency room or doctor's office. For example, a 75-year-old hypertensive man who suffers a brain hemorrhage and dies is not unusual, and the temporal relationship to vaccination may not be explored. Nevertheless, there are unusual features as documented above to which physicians should be alert.

Simply reviewing the numbers of reported deaths and various effects is inadequate. Experts in the field of hematology should take the time to read the reports generated by the search terms above. Here are some examples reproduced as written in the VAERS:

- Female, age 18-29: Patient was seen in in my office on Jan 19, 2021 with complaint of heavy vaginal bleeding. A CBC was obtained which revealed an H/H of 12.2/36.1 and a platelet count of 1 (not 1K, but 1 platelet!). This was confirmed on smear review.
- Female, age 39: Internal brain bleeding 10 days after first dose Covid vaccine; brain damage, confused, suffering memory loss.
- Female, age 30-39: 48 hours after injection developed micro-hemorrhages in her right eye. Symptoms resolved, then recurred, slightly worse than before.
- Male, age 65+: Patient developed significant nose bleed after receiving vaccine. Required two emergency department visits and hospitalization.
- Female, age 65+: Vaccine administered Feb 2, 2021. By Feb 11, patient almost nonverbal, by Feb 15 patient went to the hospital with bruising, sores on her stomach, and clots reported as thrombocytopenia. Deceased by Feb 19, 2021.
- Female, unknown age: "Same day after getting the shot I developed chills. I came home from work and I took a shower and went to bed. Next day I woke up with nausea and headache. Later that day I had a nose bleed. The following day I was so weak, tired, and dark urine."
- Female, age 40-49: Bleeding, myalgia, tingling in the fingers of the right hand; fatigue immediately upon vaccination; bleeding at the injection site, which the employee reports as filling the Band-Aid over the site. When she got home in the evening and took it off, blood ran.

Conclusion

Complications from any new medication are difficult to pick up very early in the "roll out" because of the infrequency of the occurrences, and the geographical separation between cases. In the case of the thalidomide, it was very helpful that the prescribing obstetricians also witnessed the complications. That is rarely true in the case of vaccinations, especially where the patient needs no physician to obtain a vaccine. Furthermore, serious complications present to emergency departments and not in a physician's office where the physician could get a sense of what was happening.

VAERS has the potential to shorten recognition time by trying to spot the "unusual patterns" as recommended by the CDC VAERS program itself. But this requires that physicians be aware of the system, and take the time to enter any suspected

side effect—not just the worst cases. A report previously submitted to the Agency for Healthcare Research and Quality revealed that fewer than 1% of adverse events get reported to VAERS.[6]

The Moderna and Pfizer COVID-19 vaccines employ a mode of vaccination never before used on humans. In previous animal studies, animals succumbed to what was then called "immune enhancement"—now referred to as "antibody dependent enhancement."[7] Problems specifically involving the clotting system, including antibody-mediated platelet damage, have also been reported, and caution has been advised by past researchers.[8-10] Cases of thrombocytopenia by themselves may be considered so rare as to be very low risk. But, as in the case of thalidomide, where Dr. Lenz recognized the gradient of presentation, this review suggests that overt thrombocytopenia is just one manifestation of a larger spectrum of disorders ranging from injection-site bleeding to overt thrombocytopenia with bleeding.

It is incumbent upon physicians who recommend these experimental agents to follow their patients, become familiar with VAERS to document any problems, and employ the precautionary principle.

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AAPS Principles of Medical Policy

Medical care is a professional service, not a right. Rights (as to life, liberty, and property) may be defended by force, if necessary. Professional services are subject to economic laws, such as supply and demand, and are not properly procured by force.

Physicians are professionals. Professionals are agents of their patients or clients, not of corporations, government, insurers, or other entities. Professionals act according to their own best judgment, not government "guidelines," which soon become mandates. Physicians' decisions and procedures cannot be dictated by overseers without destroying their professionalism.

Third-party payment introduces conflicts of interest. Physicians are best paid directly by the recipients of their services. The insurer's contract should be only with subscribers, not with physicians. Patients should pay their physician a mutually agreed-upon fee; the insurer should reimburse the subscriber according to the terms of the contract.

Government regulations reduce access to care. Barriers to market entry, and regulations that impose costs and burdens on the provision of care need to be greatly reduced. Examples include insurance mandates, certificate of need, translation requirements, CLIA regulation of physician office laboratories, HIPAA requirements, FDA restrictions on freedom of speech and physicians' judgment, etc.

Honest, publicly accessible pricing and accounting ("transparency") is essential to controlling costs and optimizing access. Government and other third-party payment or price-fixing obscures the true value of a service, which can only be determined by a buyer's willingness to pay. The resulting misallocation of resources creates both waste and unavailability of services.

Confidentiality is essential to good medical care. Trust is the foundation of the patient-physician relationship. Patient confidences should be preserved; information should be released only upon patient informed consent, with rare exceptions determined by law and related to credible immediate threats to the safety or health of others.

Physicians should be treated fairly in licensure, peer review, and other proceedings. Physicians should not fear loss of their livelihood or burdensome legal expenses because of baseless accusations, competitors' malice, hospitals' attempts to silence dissent, or refusal to violate their consciences. They should be accorded both procedural and substantive due process. They do not lose the basic rights enjoyed by Americans simply because of their vocation.

Medical insurance should be voluntary. While everyone has the responsibility to pay for goods and services he uses, insurance is not the only or best way to finance medical care. It greatly increases costs and expenditures. The right to decline to buy a product is the ultimate and necessary protection against low quality, overpriced offerings by monopolistic providers.

Coverage is not care. Health plans deny payment and ration care. Their promises are often broken. The only reliable protection against serious shortages and deterioration of quality is the right of patients to use their own money to buy the care of their choice.