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BMJ INVESTIGATION

US officials knew covid vaccine safety system was flawed—but turned aside the FDA doctor who alerted them

US officials embraced an algorithm for detecting signals of harm from mRNA covid-19 vaccines that they knew was broken and suppressed efforts to fix it. **David Willman** reports

David Willman *investigative journalist*

Before covid-19 vaccines were rolled out to Americans in December 2020, the US Centers for Disease Control and Prevention (CDC) assured healthcare providers that the agency was on the lookout for any harmful reactions. A key part of the CDC's strategy was its Vaccine Adverse Event Reporting System (VAERS), which receives such reports after vaccination.

"It is the nation's frontline system for monitoring vaccine safety and the early warning system for detecting possible vaccine safety problems," said Tom Shimabukuro, deputy director of CDC's Immunization Safety Office, on 30 October 2020.

Millions of people were to be vaccinated each week, and the CDC would rely on statistical "data mining" of the VAERS database to quickly identify any safety signals in need of further probing.

Two well recognised, separate algorithms were to be used. The first involved calculating "proportional reporting ratios" (PRRs), which sought to identify types of reactions reported to VAERS disproportionately or more frequently than background rates. The second data mining technique, called "empirical bayesian," was to be provided by the Food and Drug Administration (FDA), which operated VAERS jointly with the CDC, and the two agencies planned to share and discuss results.[1]

But in a little noticed September 2022 letter, CDC director Rochelle Walensky said that the agency did not perform PRR analyses for signals until 2022. This was more than a year into the vaccine rollout and was intended, she wrote, "to corroborate" the FDA's approach. Instead of using the PRR and empirical bayesian methods jointly during the pandemic, Walensky explained that both the CDC and FDA instead "chose to rely" on empirical bayesian, which she characterised as "a more robust technique."

The BMJ, however, has found that the FDA's algorithm was mathematically compromised by the deluge of covid vaccine adverse event reports—resulting in a near total loss of signal detection sensitivity for the new mRNA vaccines made by Pfizer and Moderna. Top FDA officials were warned internally of this problem in early 2021, and the official who headed its pharmacovigilance division for vaccines commented more than two years later to his CDC and FDA colleagues: "We were aware of this [data mining] limitation before and during the pandemic." Government documents also show that CDC officials were informed during rollout of the vaccines—on multiple occasions.

Yet instead of fixing the safety deficiency—or shutting down the unreliable signal detection system—officials continued to rely on the FDA's broken algorithm. The officials also cited the absence of signals when assuring clinicians and the public of the vaccines' safety.

At the FDA, managers went a step further by silencing the career drug safety officer who had repeatedly brought the deficiency to their attention and had offered an updated algorithm intended to fix it. As a result, Americans received unfounded assurances of the safety of the most widely used covid vaccines and were denied prompt warnings of potential harms, *The BMJ*'s investigation found.

Years after the pandemic, questions persist about what steps were taken to safeguard public health from any unintended consequences of the population-wide vaccination rollout. This account is based on newly available internal government emails released under the Freedom of Information Act and in response to US Senate investigators, as well as *The BMJ*'s exclusive interviews with public health officials and other scientists.

"I'm perplexed that myocarditis isn't alerting"

In late February 2021, CDC and FDA officials received notice of "a large number of reports of myocarditis, particularly in young people," after vaccination. The warnings of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the pericardium) came from the Israeli Ministry of Health. In a private meeting five weeks later, the Israelis informed a CDC convened covid vaccine safety committee that two of the 77 vaccinated people with myocarditis or pericarditis had died.

The next week, the same committee heard from the Pentagon's Defense Health Agency, which reported a "cluster of cases" of myocarditis among male US military members.

US public health officials remained sceptical of a link to the new mRNA vaccines. "We have not seen a signal [for myocarditis], and we've actually looked intentionally for the signal in the over 200 million doses we've given," CDC director Walensky told reporters.[2]

By May 2021, VAERS had received hundreds of reports of myocarditis and pericarditis after covid vaccinations, and the CDC began alerting healthcare professionals. While the agency was still unsure of a causal relationship, it decided to alert physicians more broadly through a "clinical considerations" web posting.

But oncologist Peter Marks, who as director of the FDA's Center for Biologics Evaluation and Research was the agency's top covid vaccine regulator, objected. He questioned the CDC's imminent website announcement, emailing Walensky directly, highlighting the lack of any safety signal from the government's own surveillance: "We still have concerns here [at the FDA] if myocarditis and pericarditis have not actually signaled . . . Can you help me understand why we are doing this when pediatricians and others in the community already seem to be aware?"

Patients experiencing tinnitus had received a similar message from officials at the CDC. Vaccinologist Gregory Poland, who headed vaccine research at the Mayo Clinic and was editor in chief of *Vaccine*, developed severe ringing in his ears about an hour after his second covid vaccination. He asked the CDC for information about other reported cases, while noting that he had received "a large number of emails regarding others with tinnitus post-mRNA vax."

The agency told Poland that no signal had been found in VAERS to indicate linkage between the vaccines and tinnitus. Indeed, weekly FDA data mining reports during this period, seen by *The BMJ*, show that the algorithm never signalled for myocarditis, pericarditis, or tinnitus.[3]

Still, VAERS reports continued to mount, with myocarditis attracting the greatest attention. In a June 2021 public presentation, the CDC's Shimabukuro showed that, for young males (age 12-24), VAERS had received between 29 and 347 times more myocarditis and pericarditis reports than the agency expected based on background incidence rates. In a public statement that day, the CDC dubbed myocarditis an "extremely rare side effect."

Government records show that, the day before his presentation, Shimabukuro had received the FDA's latest data mining report—and it continued to show no signal. "I'm perplexed that myocarditis isn't alerting for either of the mRNA vaccines," Shimabukuro emailed a colleague.

Early warnings

The BMJ can reveal that the FDA's algorithm failed to signal a potential relationship between mRNA covid vaccination and myocarditis, pericarditis, Bell's palsy, tinnitus, and other reported disorders owing to a flaw in the detection methodology—a flaw that senior officials declined to address.

The problem arose because, in the first year of the rollout, almost all the reports coming into VAERS—more than 90% of 1.1 million—were for the mRNA covid shots, dwarfing vaccines for all other diseases.[4] This meant that analysing the safety of one vaccine, for example Pfizer's product, involved comparing it to other vaccines, which were overwhelmingly limited to Moderna's product. But if both mRNA vaccines elevated the risk of an adverse event like myocarditis in roughly equal amounts, the "observed" frequency and "expected" frequency would be similar, resulting in no automated alert.[5] The statistical phenomenon is known as "masking."

The concern had made its way to Marks, FDA's top official overseeing the covid vaccines, in early 2021. And it came from a career medical officer in the FDA's centre for drugs, not vaccines: Ana Szarfman, a doctor with a PhD in microbiology and immunology. She worked for decades on drug safety data mining at the FDA and had a lead role in modernising the agency's approach.[6 7]

Szarfman had built a years long professional association with an accomplished statistician, William DuMouchel, who devised the particular bayesian data mining algorithm that the FDA began using more than 15 years before the pandemic.[6]

Szarfman and DuMouchel, who earned his PhD at Yale and by 2010 became chief statistician at Oracle Health Sciences, judged that the unique circumstances of the pandemic meant that the FDA's approach was missing safety signals. The pair initially made suggestions for improving vaccine safety studies with FDA officials during a presentation on 23 December 2020, lauding the "new potential interventions for containing the pandemic." After the *New York Times* reported in February 2021 that the government was struggling to launch various pharmacovigilance systems aside from VAERS,[8] Szarfman took additional action—reaching outside the chain of command by emailing Marks directly.

"Regarding the NYT article, I am quite concerned," Szarfman emailed Marks two days later. She wrote that the agency should be "clamoring to fix this problem." Szarfman concluded, "Let me know if you want Bill DuMouchel and I to discuss our proposal for more effective monitoring, including the need to use an updated algorithm by DuMouchel for data mining spontaneous reports."

Marks scheduled a meeting, and two weeks later a video conference was held. Szarfman's presentation included a slide of adjoining heatmaps showing how different algorithms performed on the VAERS data. The PRR analysis lit up red with safety signals (fig 1). "Highlights almost everything," her slide observed. But the bayesian approach used by the FDA was displayed as green, identifying virtually no safety signals. "You are not getting useful information with such low counts."

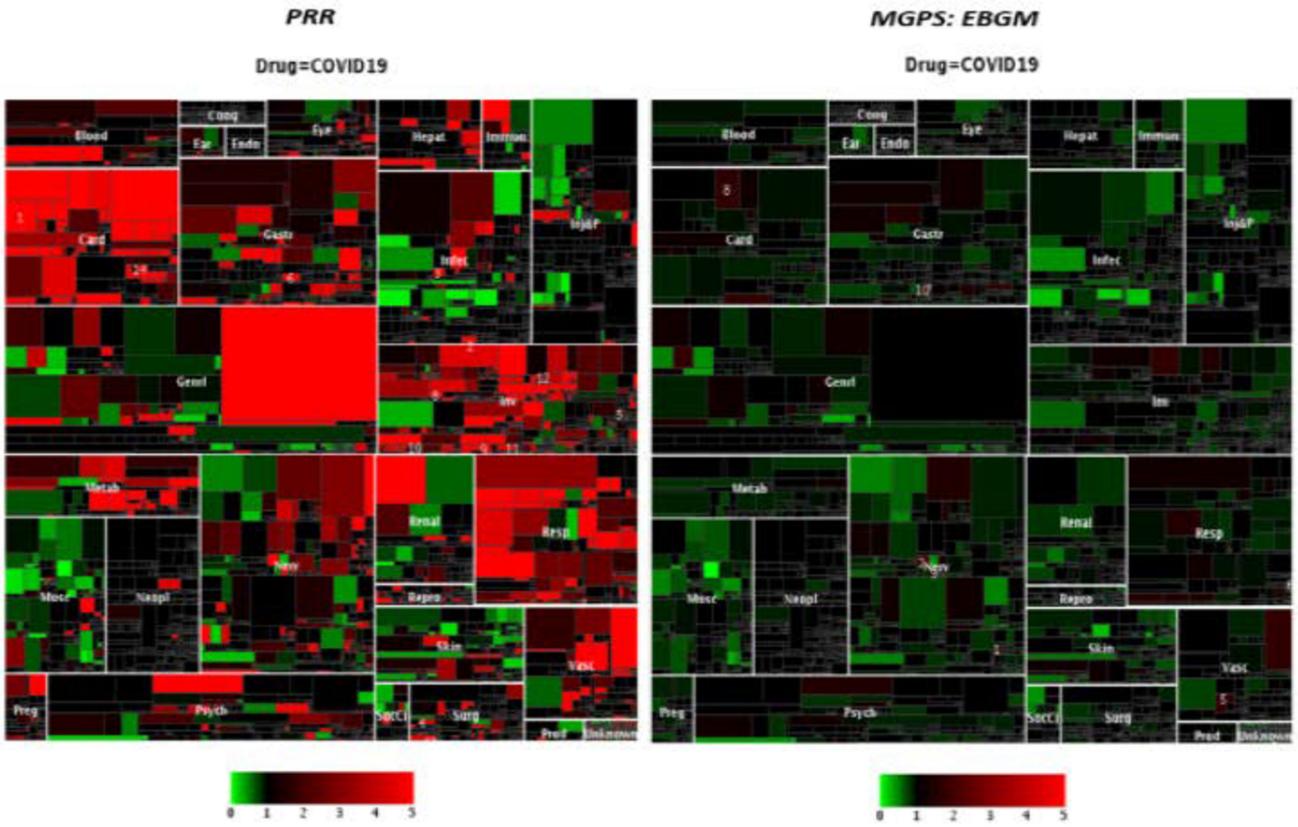

Fig 1 | FDA medical officer Ana Szarfman's presentation on 29 February 2021 included a comparison of signal detection using the PRR (left) and empirical bayesian (right) algorithms

Szarfman encouraged Marks's staff to adopt the updated algorithm, which DuMouchel had originally published in 2012.[9] Her presentation showed that the proposed, updated method had detected signals—but not as many as PRR—suggesting a more manageable load for investigating further. "Looks more informative for follow-up evaluation."

Muzzling the messenger

Marks and his staff, however, declined to alter the FDA's existing approach—and agency officials did not publicly warn of the deficiency with finding safety signals. When Szarfman continued to press the matter, she was told, with diplomatic flourish, to back off.

That email, sent on 7 May 2021, by Craig Zinderman, associate director for medical policy in FDA's Office of Biostatistics and Epidemiology, began: "Good Afternoon Ana, Thank you again for talking with us back in March about your work exploring new data mining approaches . . . We are writing to kindly ask you to please hold off on creating and sending data mining reports and analyses using covid-19 vaccine AE [adverse event] data."

Zinderman told Szarfman that potential problems such as blood clotting and heart attacks were "already under close observation" through other safety systems, such as the CDC's Vaccine Safety Datalink (VSD). Unlike VAERS, the VSD uses clinical records from participating healthcare organisations to evaluate adverse events.

While Zinderman projected faith in the other approaches, the fallibility of those systems was already evident: VSD analyses, for example, reported finding "no" signal for myocarditis in April 2021, despite intentionally looking for one. (Even in August 2021, two months after US officials had acknowledged a causal relationship between the Pfizer and Moderna mRNA vaccines and myocarditis, VSD did not signal.[10])

"We understand that exploring new approaches might improve the methodology and is of interest to you," Zinderman told Szarfman. "However, from our perspective, the approach employed during a period of intense, high profile surveillance should be standard, predictable, and road tested. Results from adjusting parameters that raise or lower sensitivity of the alerts as the vaccination campaign is underway could lead to confusion and have unintended consequences (eg, regarding vaccine confidence)." His citing of a potential effect on "vaccine confidence" highlighted that the US health agencies were not solely focused on the safety of the covid vaccines.

Zinderman's email ended by reiterating the FDA's request to Szarfman: "Please hold off on creating and sending data mining results for covid-19 vaccine AE [adverse event] data." Zinderman could not be reached for comment.

Szarfman pledged to comply. "I will only deliver analyses when I am specifically requested to do so, and only to the reviewer making such requests." Recalled DuMouchel: "I do know that Ana was frustrated . . . She did tell me that someone told her to stop working on it."

But by July 2021, Szarfman again sounded an alarm over a "strong signal" for "death and sudden death" that she said DuMouchel had identified using the updated algorithm. She shared the findings

with a colleague, Richard Forshee, a deputy director for biostatistics and pharmacovigilance, who worked under Peter Marks. Forshee expressed his doubts about the analysis to Szarfman and wrote to Marks: "Ana Szarfman called me . . . She said that she and Bill DuMouchel had found an increased risk of mortality following covid-19 vaccination using data mining methods.

"I am very concerned that whatever association they think they have identified is spurious based on the way the covid-19 vaccination program prioritized individuals and the required and stimulated reporting we are seeing with the covid-19 vaccines. . . . Please let me know how you would like us to proceed."

Government emails show that Szarfman continued to raise concerns with the FDA's vaccine regulators. She wrote to agency officials managing the algorithm in September 2021, again urging adoption of the updated technique, which she said was "much, much better at unmasking signals . . . It automatically identifies and corrects for confounders. This is an important function to have, given the pandemic situation."

On 15 September 2021, Marks wrote to his counterpart in the FDA's Center for Drug Evaluation and Research (CDER): "One of the CDER statisticians, Ana Szarfman, has decided on her own to do vaccine analyses using VAERS as part of her work at FDA. She is, however, not doing this in collaboration with our [vaccine centre] statisticians, and quite to the contrary, has been asked to cease and desist, because the strategy that she is using could create erroneous conflicts that feed in to anti-vaccination rhetoric. This is creating an issue . . . This issue came up previously during the pandemic and . . . it seemed to go away, but it is now back. Can we catch up about this sometime?"

Less than three weeks later, over Zoom, Marks addressed a group of people who had been experiencing prolonged, severe neurological symptoms after receiving covid vaccines. Marks said that FDA officials would query their databases for "a neurologic signal." When he met with the same group three months later, he reported that his staff members had "looked for various signals," but "we have not found a rate . . . that is higher than would be expected in the population." Marks, who resigned from the FDA last year, did not respond to requests for comment.

Concerns outside the FDA

Former CDC director Rochelle Walensky also did not respond, and it's unclear if she knew that the FDA's bayesian data mining technique was unsuitable for analysing the covid vaccines' rollout. But emails released following a Senate subpoena, and reviewed by *The BMJ*, show that senior CDC staff members were informed.

One official who informed the CDC was FDA medical officer David Menschik. Elaborating in emails to a CDC epidemiologist with whom he and other officials were coauthoring a scientific article, Menschik made clear that the lack of automated empirical bayesian data mining alerts was no guarantee of safety, explaining that the government's "data mining has blind spots."

In the article, which had first been posted as a preprint, the authors ultimately described the problem with data mining as a "limitation."[11] Peer reviewers, however, were less charitable.

One anonymous reviewer for the *Lancet Infectious Diseases*, where the paper was published, seemed perplexed that the federal vaccine safety specialists had treated the bayesian data mining analysis as valid: "The authors reported in the limitation [section] that . . . the great majority of [total VAERS] reports was for the vaccines of interest. If this proportion is over 90%, the possibility of identifying a signal was likely close to zero. So, why performing [sic] such an analysis?"

The journal's editors told the CDC-FDA team that it wasn't sufficient to report the bayesian analysis with a simple disclaimer about its "limitations." They said the coauthors should either justify its inclusion—or remove it. Menschik and his FDA coauthor told CDC colleagues that they agreed with the criticism: "There is a considerable bias toward the null when using our data mining efforts." The analysis was removed from the paper, and the two FDA officials withdrew as authors, as their only contribution had been the bayesian analysis.[12]

"I think that they were wrong"

In justifying her agency's decision to suspend the PRR analyses it had publicly pledged to conduct, CDC director Walensky said that the agency briefly performed PRRs in 2022, "to corroborate" the bayesian results from the FDA. "Notably, results from PRR analysis were generally consistent . . . revealing no additional unexpected safety signals."

The results, however, challenged that conclusion.

The agency's PRR analyses—examined by *The BMJ*—show that hundreds of types of adverse events met the agency's criteria for a signal. In fact, the CDC identified myocarditis, pericarditis, Bell's palsy, and tinnitus as a "vaccine safety signal" in all 13 consecutive weekly PRR reports comparing mRNA covid vaccines to non-covid vaccines between 6 May and 29 July. The FDA's bayesian approach, on the other hand, triggered no such alerts.

In October 2023, the FDA's pharmacovigilance chief acknowledged in an email to colleagues that the agency knew—as the vaccines had rolled out more than two years earlier—of the detection deficiency. The official, physician Narayan Nair, did not respond to messages seeking his comment.

For his part, the statistician William DuMouchel said that he had only wanted to help the FDA examine the most precise data, not create controversy. "I wasn't interested in kind of figuring out who to blame or something. I was just trying to understand better what data was available and what you could do with it," he recalled in an interview with *The BMJ*.

Nor was DuMouchel opposed to vaccines, saying he regarded them as "one of the most remarkable medical innovations of the past thousand years." He'd been twice vaccinated with Moderna's shot.

But while reflecting on the events, DuMouchel said that he could not explain the government officials' resistance. "It's really hard to know what they really had in their mind," he said. "Or whether to believe or to accept their excuses for not wanting to switch to a new method . . . I think that they were wrong."

Approached by *The BMJ*, Szarfman insisted that she had not sought to undermine public support for the covid vaccines. She recalled her efforts with what seemed to be resigned frustration. "Very few people understand the statistics," she said. "That's the problem."

Over lunch near his residence in Miami, Florida, DuMouchel voiced regret that FDA officials had rebuffed Szarfman's attempts to overhaul the deficient approach with VAERS. "If they had paid attention to Ana, they would have done better."

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