



FEATURE

US government website for collecting adverse events after vaccination is inaccessible to most users

Peter Doshi asks why no one seems to have noticed that the website isn't working properly and what it says about the state of pharmacovigilance

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For over three weeks, the website of the US government Vaccination Adverse Reporting System (VAERS) has been inaccessible to most users. The website address, www.vaers.hhs.gov, is printed on the vaccine information statements (VISs), short documents listing the benefits and risks of vaccines that are required by law to be distributed with every vaccine dose administered in the US.¹

But the website link leads anybody using the web browsers Chrome, Firefox, and some versions of Internet Explorer to a warning page. "Your connection is not private," it says in large font on my screen (fig 1⇓). "Attackers might be trying to steal your information from www.vaers.hhs.gov (for example, passwords, messages, or credit cards)." The only browser that seems to consistently connect properly is Safari, used by only around a quarter of people accessing government sites.²

I can't speak for others, but I suspect most people will respond to such a warning by closing their browser and moving along. The adverse event will go unreported. Few will realize that connecting to vaers.hhs.gov (that is, dropping the "www.") takes you to the intended website.

Technically, the website is not down. It is just misconfigured such that the website address advertised to millions is not working, and hasn't been working for at least three weeks.

When vigilance is not vigilant

If anyone was looking for a good illustration of how little respect pharmacovigilance gets in the US healthcare system, this might be it. It's not known how long this problem has been going on, but I informed the US Department of Health and Human Services, which runs the VAERS program, on 25 April. After not hearing back, I sent another email on 2 May. I then received a call from Elisa (she wouldn't provide her last name out of a concern for confidentiality), who said the information technology staff were working on it. Presumably they're still working on it as the problem isn't fixed.

The term pharmacovigilance remains a boutique word, mostly known only to those with an interest in the subject. This is unfortunate at best, and dangerous at worst, considering that when medical products enter the marketplace we have a rather crude and limited understanding of their possible side effects. Pharmacovigilance is the information gathering superstructure that's meant to fill in the blanks, to offer a balanced view of a medicine's benefits against its harms.

Or at least so went the theory. For decades, the importance of postmarketing surveillance has been recognized, and medical and pharmacy training has taught healthcare professionals to report suspected side effects through schemes like VAERS and the Yellow Card in the UK, but estimates suggest that no more than 10% of adverse events get reported.³ My colleague at University of Maryland, pharmacoepidemiologist Julie Zito, described postmarketing surveillance as the "neglected stepchild of federal research for more than 50 years."⁴

Neglected it is. When the US government website for purchasing individual insurance plans, HealthCare.gov, had connectivity problems, it made the national news. But I could not find a single media story on the VAERS outage.

To be sure, there are other ways to report suspected vaccine related harms. VIS pamphlets also list a toll-free number people can phone. But if public health officials believed pharmacovigilance was important, it is hard to imagine a website connectivity problem would last this long.

Adding insult to injury

Last month, the non-profit organization National Foundation for Infectious Diseases ran a massive social media campaign to promote vaccination,⁵ reaching over 750 000 people.⁶ The centerpiece of the campaign was four infographics headlined, "Vaccines are safe." One of the graphics depicts the VAERS system as a pillar of vaccine safety. But at the time of the campaign, the VAERS website was inaccessible.

Presumably, the information technology staff will have the website restored before too long. But the fire will be far from out. The VAERS outage shows the lack of serious attention paid to understanding the harms profile of medical products. Without greater attention, pharmacovigilance will be nothing more than a hollow pillar of the supposed knowledge base—a fig leaf allowing us to think we are monitoring things we are not.

And if some powerful people have their way, drugs may soon start coming to the market with even less evidence of benefit and harm.⁷ Supposedly, we'll figure all this out once they are being prescribed. Will we? Of course we won't. But what we will do is continue to lure ourselves into believing that if a medicine's approved, then the benefits outweigh the harms. Who needs pharmacovigilance?

Competing interests: See <http://www.bmj.com/about-bmj/editorial-staff/peter-doshi>

Provenance and peer review: Commissioned; not externally peer reviewed.

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Figure

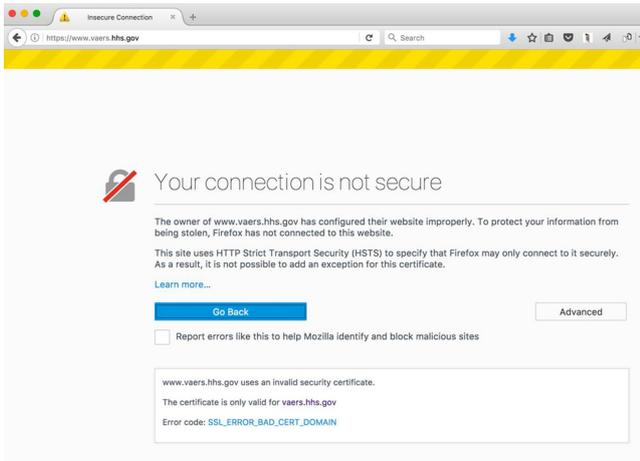


Fig 1 Screenshot of attempt to access VAERS website