V-safe Technical Report 1 - An Underreporting Factor (URF) of 16

Estimating New Adverse Events (NAEs) in V-safe with a URF of 16.

V-safe asked millions of people how they felt after COVID-19 vaccination. Among them, 337 people described an aortic aneurysm in their own words: 100 thoracic, 92 abdominal and 145 with no site named. Abdominal aortic aneurysms are common, so their known background rate sets a ceiling. That ceiling shows V-safe caught at most about 1 in 16 abdominal cases, an underreporting factor (URF) of 16. Applied to thoracic aortic aneurysms, which are rare, the URF implies about 2,800 diagnoses where about 290 were expected. That is an excess of about 2,500 new adverse events (NAEs) in V-safe, or about 67,000 across the US. The thoracic-to-abdominal proportional reporting ratio (PRR) is 10.11 (8.16–12.52).

By Nicholas Kottenstette, PhD – University of Notre Dame, Electrical Engineering, 2008

Published 11 October 2026 · Revision 1.0 ·

© 2026 Nicholas Kottenstette. All rights reserved.

Published article, data sheets and later reports

- Technical Report 1 (TR1), published X Article: https://x.com/NickKottenstet1/status/2109280153373217216
- V-safe Technical Report 1: aortic aneurysm case file (spreadsheet, Kottenstette 2026b)
- Underreporting-factor sheet (spreadsheet, Kottenstette 2026c)
- V-Safe RSE rate bounds calculator (spreadsheet, Kottenstette 2026d)
- Technical Report 2 (TR2) (report PDF)



In Loving Memory of

Cecilia Louise Kottenstette

June 1, 2012 – August 23, 2022

Federal Appeals Decision Case No. 20-2282

Dedicated to the C-19 injured.

The LORD is my shepherd, I shall not want;
he makes me lie down in green pastures.
He leads me beside still waters;
he restores my soul.
He leads me in paths of righteousness
for his name's sake.
Even though I walk through the valley of the shadow of death,
I fear no evil;
for thou art with me;
thy rod and thy staff, they comfort me.
Thou preparest a table before me
in the presence of my enemies;
thou anointest my head with oil,
my cup overflows.
Surely goodness and mercy shall follow me
all the days of my life;
and I shall dwell in the house of the LORD forever.

On 2 October 2012, Cecilia Louise Kottenstette was four months old. Hours after she received Pentacel and Prevnar, the infantile spasms began. They never stopped. She died on 23 August 2022.

The Federal Circuit affirmed that the injury was vaccine-caused (case No. 20-2282). Her medical trust was established one week before she died and was closed shortly thereafter, arriving too late to be of any help to her.

During the final months with Cecilia in hospice, I would sit by her bedside, inspired to write about the 1976 swine flu vaccine campaign, which was halted because the shots were injuring and ultimately killing many Americans through Guillain-Barré syndrome (GBS) (Kottenstette, 2022a, 2022b, 2022c, 2023). It could have been much worse had the agencies in charge of safety not acted quickly and shut the campaign down after 48 million Americans had been vaccinated (Wade, 1978). What followed was an excellent publication on the attack rate of GBS following the swine flu vaccine (Schonberger et al., 1979). I build on that work as it pertains to the mRNA V-safe data, in order to help those injured by those vaccines.

Data source and methods

What V-safe was. When the first COVID-19 vaccines arrived in December 2020, the Centers for Disease Control and Prevention (CDC) launched V-safe. It was a smartphone program that let people report their health after vaccination (FCDC v. CDC, 2024, pp. 1, 4). It texted each person links to check-in surveys. These came daily for seven days, weekly for five weeks, then at three, six,

and twelve months, and the schedule restarted with each dose (FCDC v. CDC, 2024, p. 4). Each person got an anonymous registrant code, so one person's surveys can be linked without revealing who they are (FCDC v. CDC, 2024, p. 4). Millions of Americans took part (FCDC v. CDC, 2024, p. 1).

Check-the-box data. Most questions were check boxes. The Informed Consent Action Network (ICAN) first asked the CDC for this data under the Freedom of Information Act (FOIA) in June 2021, and sued twice (Siri, 2023). In *ICAN v. CDC* (No. 1:22-CV-481-RP, W.D. Texas), the court entered an order on September 8, 2022 (FCDC v. CDC, 2024, p. 4; Siri, 2023). On September 30, 2022, the CDC released five check-box files. They covered December 14, 2020 to July 31, 2022 (Siri, 2023; CDC, 2022b). ICAN posted them with a public dashboard (ICAN, 2022; ICAN, n.d.).

Free-text data. Each survey also had a free-text box limited to 250 characters, holding about 7.8 million entries (FCDC v. CDC, 2024, p. 5). A doctors' group, the Freedom Coalition of Doctors for Choice (FCDC), asked for them on January 3, 2023. The request covered all free-text entries and each entry's registrant code, for 10/01/2020–12/31/2022 (FCDC v. CDC, 2024, pp. 6–7). In *Freedom Coalition of Doctors for Choice v. CDC* (No. 2:23-CV-102-Z, N.D. Texas, Amarillo Division), the court ordered release on January 5, 2024 (FCDC v. CDC, 2024). Personal details such as names and birth dates had to be removed. The registrant code is not personal information and stayed in (FCDC v. CDC, 2024, pp. 7, 14, 28). Batches were due monthly from February 15, 2024 to January 15, 2025 (FCDC v. CDC, 2024, p. 29). ICAN posted updated copies, marked FOIA 24-01322, that add a survey, response and date field to each entry (ICAN, n.d.). Those are the files we searched.

Other files. The CDC also converted the free text into the Medical Dictionary for Regulatory Activities (MedDRA), a standard medical dictionary, and released about 5 million coded entries (FCDC v. CDC, 2024, p. 5; ICAN, n.d.; MedDRA, n.d.). ICAN also posts the call-center records of the CDC's phone follow-ups (ICAN, n.d.). All of these carry the same registrant code, so we join them person by person. In order not to bias the reader, the codes never appear in this report.

Who counts. A person counts once, at their first report of a new aneurysm. A custom search tool, not yet public, did the matching, and every match was read by hand. MedDRA was used only to find reports the text missed, and only for onsets on or before December 31, 2022.

The first published count was 262 people. A wider text search found 319, and the MedDRA check added 18 more, for 337.

Table 1. People with a new aortic aneurysm report, by site.

Site	People
Thoracic	100
Abdominal	92
Site not named	145
Total	**337**

Of the 100 thoracic, 91 use clear wording (the strict set). The results below hold for 91 as well.

For reference, a further 49 people had a MedDRA aortic aneurysm code dated after the FOIA free-text window (1 October 2020 to 31 December 2022); their first coded check-ins fall between February and June 2023. Of these, 9 were thoracic (7 strict), 11 abdominal and 29 had no site named. They are listed in the case file's "MedDRA after window" worksheet (Kottenstette, 2026b) under separate IDs (TAA-L, AAA-L, AA-L). Because they fall outside the period the analysis covers, they are not part of the counts or estimates and do not change any result.

Three cries for help

This work began with three cries for help, printed by React19 and the Brownstone Institute from the V-safe free text (React19, 2026). V-safe had no checkbox for an aortic aneurysm, so each person had to type it.

Case IDs are our own: TAA- for a thoracic aortic aneurysm, AAA- for an abdominal aortic aneurysm, and AA- for an aortic aneurysm with no site named.

- · First (TAA-1), 23 February 2021. In week 4 after dose 1, she reported a thoracic aortic aneurysm repaired with surgery and a stent on 19 February. Her death on 19 April 2021 was reported in June.
- · Second (AA-1), 13 September 2022. She had reported a severe reaction since week 2 after dose 1 (3 August 2021). After dose 2, her last entry reports that her cardiologist found an aortic aneurysm.
- · Third (AA-2), 26 October 2022. Reporting adverse events since week 4 after dose 2 (18 May 2021), in week 26 after dose 4 she wrote: "Aortic aneurysm … I need your help."

The first came ten weeks into the rollout. A rare, usually silent injury, typed in by hand in the fourth week after a first dose, should have set off an alarm. Nothing followed.

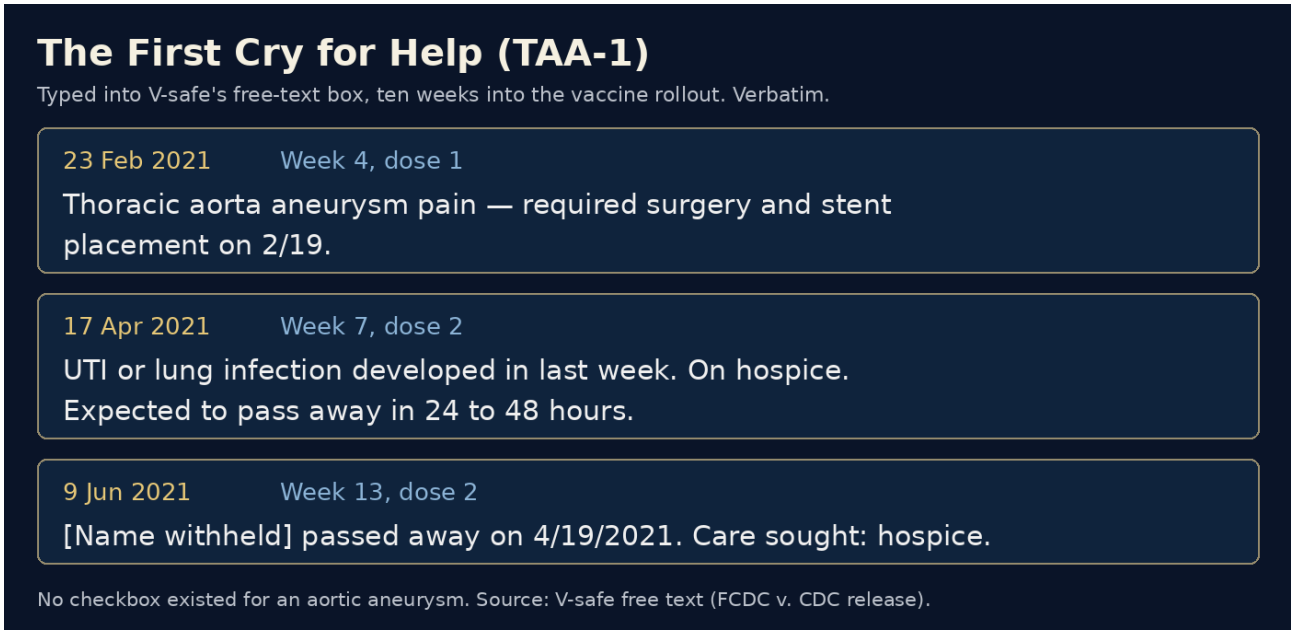


Figure 1. The first cry for help (TAA-1), typed into V-safe's free-text box, verbatim. Name withheld.

Background: thoracic and abdominal aortic aneurysms

The aorta is the body's main artery. It leaves the left ventricle of the heart, runs down through the chest (the thoracic aorta), and continues into the abdomen (the abdominal aorta) (Khan Academy Medicine, n.d.a). An aneurysm is a permanent, localized ballooning of the vessel to at least one and a half times its normal diameter. The thoracic aorta averages about 2.7 cm, so a thoracic aortic aneurysm is one of about 4 cm or more (Khan Academy Medicine, n.d.a). Figure 2 shows a normal aorta, a thoracic aortic aneurysm, and an abdominal aortic aneurysm.

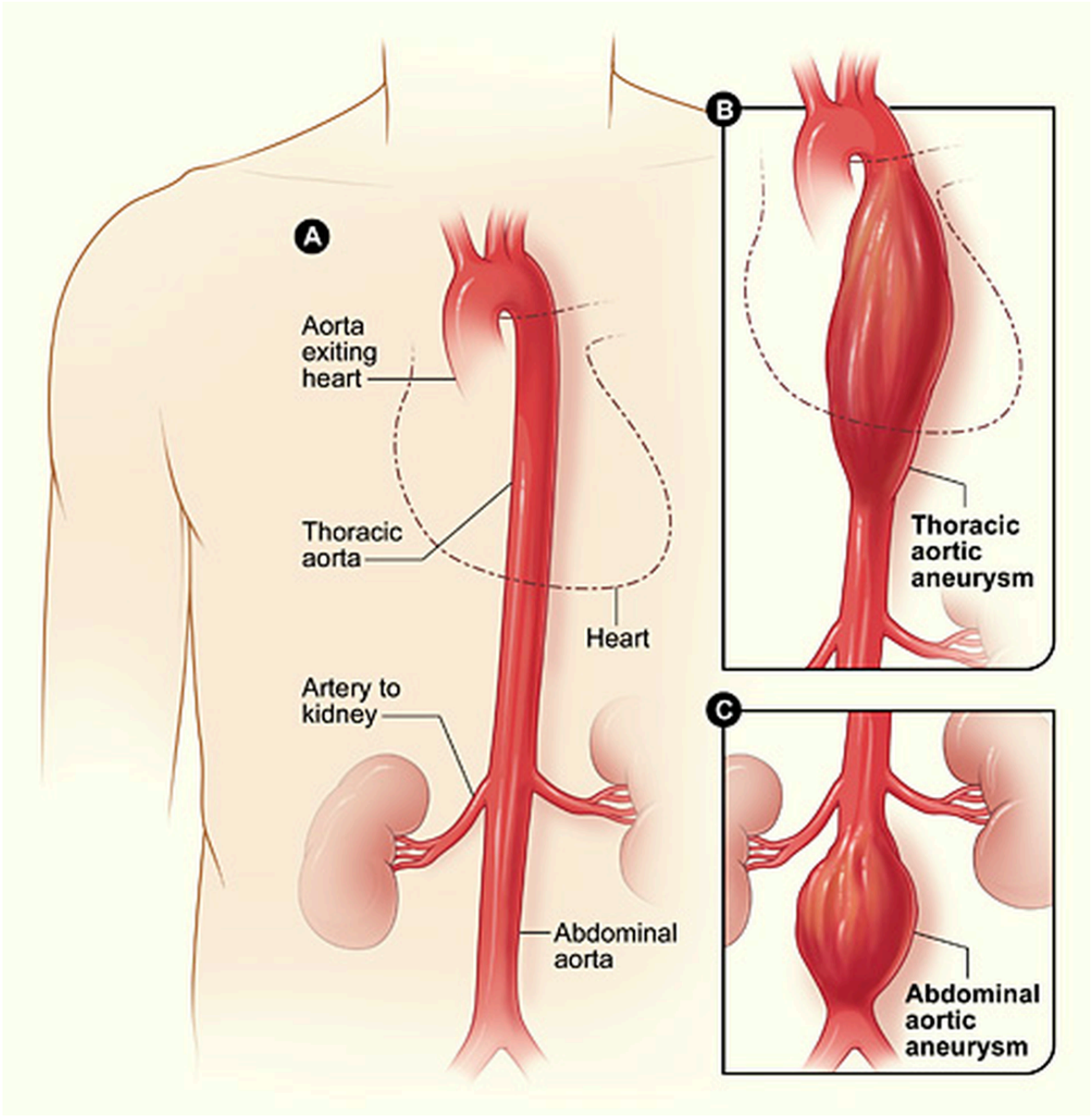


Figure 2. Thoracic and abdominal aortic aneurysms. A: a normal aorta, with the thoracic aorta in the chest and the abdominal aorta below it, past the arteries to the kidneys. B: a thoracic aortic aneurysm, here behind the heart. C: an abdominal aortic aneurysm. Illustration: National Heart, Lung, and Blood Institute (NHLBI, 2022), public domain.

The danger is rupture. A ruptured aneurysm spills blood out of the circulation and is an emergency (Khan Academy Medicine, n.d.a; n.d.b). For a thoracic aortic aneurysm, rupture carries a mortality of 94% to 100% (Gouveia e Melo et al., 2022). A dissection is different: a tear opens between the inner and middle layers of the aortic wall, and blood forces the layers apart, which is also an emergency (Khan Academy Medicine, n.d.c).

Thoracic aneurysms are rare, about 5.3 new cases per 100,000 person-years (Gouveia e Melo et al., 2022). Abdominal aneurysms are about nine times more common, about 49 per 100,000 (a working rate derived from Sampson et al., 2014). That gap is what makes abdominal aneurysms a useful yardstick.

Motivation: from dissections to aneurysms

Immunology predicted an injury to the vessel wall. Palmer, Bhakdi and colleagues argue that cells lining the blood vessels can take up the vaccine's lipid nanoparticles, make spike protein, and then come under immune attack (Palmer et al., 2023). The aorta takes the full pressure of the heart, so a wall weakened by inflammation can tear (a dissection) or rupture.

Pathologists then found it. In autopsies of people who died 7 to 25 days after an mRNA vaccine, Burkhardt found aortic dissection or rupture in three of 29, with spike protein in the dissected aortic wall of one (Palmer et al., 2023, §4.2, §4.3.3). His findings were presented in talks, not peer-reviewed. Peer-reviewed case reports describe fatal aortic dissections about two weeks after vaccination, with an inflamed aortic wall (Takahashi et al., 2022) and spike protein, but no nucleocapsid, in the aortic wall's small vessels (Balbona et al., 2024). In Heidelberg, a peer-reviewed series of 25 unexpected deaths within 20 days of vaccination found vaccine-linked myocarditis in four. That series concerns the heart, not the aorta (Schwab et al., 2023).

The test that tells vaccine from infection already exists: spike protein without nucleocapsid points to the vaccine. Peer-reviewed reviews co-authored by Peter McCullough collect those findings in heart muscle and blood clots (Polykretis et al., 2023; Hulscher et al., 2023; Hulscher et al., 2025). Yet a medical examiner can write "acute aortic dissection" without running it. If no one stains, no one finds it.

So I went to V-safe looking for dissections. The search kept turning up aneurysms instead. Aneurysms are far more often reported, and their abdominal form has a well-known background rate, which gives a yardstick. This report counts the aneurysms. We report the full set of dissections we eventually found in a subsequent technical report.

Sorting by site

Of the 337 people, 145 said "aneurysm" without naming a site. We split them in the same proportion as the 192 who did name one, rounded to whole people: 76 to thoracic (145 × 100/192 = 75.52) and 69 to abdominal (145 × 92/192 = 69.48).

Table 2. Reports by site: named [most likely, after the split].

Site	Named [Most likely]
Thoracic	100 [176]
Abdominal	92 [161]

Source and counting rule

An NRSE is a newly reported side effect: the first report of a search term from a registrant. The term generalizes to any search term. Here, an NRSE is the first aneurysm report from a registrant; a later report is not counted again.

We considered the following NRSEs:

1. New Reported Aortic Aneurysm (NRAortic)
2. New Reported Abdominal Aortic Aneurysm (NRAbdominal)
3. New Reported Thoracic Aneurysm (NRThoracic)

The acronyms are also used for running totals, a slight abuse of notation. In totals:

$$\text{NRAortic} = \text{NRThoracic} + \text{NRAbdominal} + \text{NRUnspecifiedAortic} \qquad (1)$$

Equation (1). The total of new reported aortic aneurysms (NRAortic) is the sum of the new reported thoracic, abdominal, and site-unspecified aortic aneurysm reports.

Splitting the unspecified rows by the named shares gives Most Likely NRThoracic and Most Likely NRAbdominal, so that, in totals:

$$\text{NRAortic} = \text{Most Likely NRThoracic} + \text{Most Likely NRAbdominal} \qquad (2)$$

Equation (2). The same total, split into most likely thoracic and most likely abdominal aortic aneurysm reports.

The unspecified aortic aneurysm reports were distributed in the same ratio as the named reports:

$$\text{Most Likely NRThoracic} = \text{NRThoracic} + \text{NRUnspecifiedAortic} \times \frac{\text{NRThoracic}}{\text{NRThoracic}+\text{NRAbdominal}} \qquad (3)$$

$$\text{Most Likely NRAbdominal} = \text{NRAbdominal} + \text{NRUnspecifiedAortic} \times \frac{\text{NRAbdominal}}{\text{NRThoracic}+\text{NRAbdominal}} \qquad (4)$$

With 100 named thoracic, 92 named abdominal and 145 unspecified reports, this gives $100 + 145 \times 100/192 \approx 175.5$ most likely thoracic and $92 + 145 \times 92/192 \approx 161.5$ most likely abdominal reports, or 176 and 161 in whole people (Table 2).

Aneurysms that are also dissections

A dissection is a tear in the aortic wall. Seven people in the aneurysm count named both an aneurysm and a dissection or its repair, so they are also in the dissection count:

Table 3. Aneurysm reports that also name a dissection.

Case	Site	Week [dose]	What they wrote
AAA-1	Abdominal	13 [2]	Emergency open-heart surgery for a dissection and an aneurysm “in stomach”
AA-3	Site not named	26 [2]	Heart surgery for a dissected aortic aneurysm two weeks after dose 2
TAA-2	Thoracic	26 [3]	Recovering from a stent repair of the thoracic aorta
TAA-3	Thoracic	52 [2]	Dissecting ascending aortic aneurysm
AAA-2	Abdominal	52 [2]	Dissection of an abdominal aortic aneurysm, with aortic valve replacement and a graft
AA-4	Site not named	7 [4]	Surgery for an aortic aneurysm dissection
AA-5	Site not named	13 [4]	A dissecting aortic aneurysm, which the reporter said was not related to the vaccine

Ruptures

A rupture is a burst aneurysm, not a dissection. Three people in the aneurysm count reported a rupture:

Table 4. Aneurysm reports that name a rupture.

Case	Site	Week [dose]	What they wrote
AAA-3	Abdominal	13 [2]	A small rupture of an abdominal aortic aneurysm “in old area”
AA-6	Site not named	26 [2]	Aortic aneurysm rupture
AAA-4	Abdominal	52 [2]	Abdominal aortic aneurysm and a ruptured aorta

The two abdominal ruptures count as abdominal aortic aneurysms, not thoracic ones, and they stand out among the abdominal cases. The rupture “in old area” counts as a new ruptured aortic aneurysm. Ruptures stay in the aneurysm count. They can also enter the dissection count if the report also names a dissection.

What counts and what is set aside

A new event counts, whatever the reporter or a clinician said about whether the vaccine caused it. Two entries in the aneurysm count say it was “not related to vaccine,” and both count. An entry is set aside only when the aneurysm was not new: one the person already had, one being monitored, a scan to rule one out, or a screening. A typical example reads, “Pre-existing condition of ascending aortic aneurysm.” Six entries were set aside this way.

Estimating the underreporting factor

V-safe followed about 5.51 million person-years in its first 52 weeks. At the background rate of 49 per 100,000 person-years, about 2,699 abdominal aortic aneurysms would be diagnosed in that time even with no vaccine effect. V-safe recorded 161 people, most likely, with one: 92 named abdominal plus 69 of the 145 reports that named no site. So at most V-safe captured about 1 in 16.8. We round down to a URF of 16, which keeps every estimate on the low side.

Table 5. Background, expected and reported counts over V-safe’s first 52 weeks.

Measure	Thoracic [Abdominal]
Background per 100,000 person-years	5.3 [49]
Expected in V-safe	292 [2,699]
Most likely reports	176 [161]

The expected ceilings

Gouveia e Melo and colleagues put the thoracic aortic aneurysm rate at 5.3 per 100,000 person-years (Gouveia e Melo et al., 2022). Over the V-safe check-in clock of about 5.51 million person-years, that rate gives an expected ceiling of about 292 thoracic diagnoses.

Sampson and colleagues (2014) give annual abdominal aortic aneurysm incidence per 100,000 by age: in 2010, developed-country rates ranged from under 1 at ages 25–39 to about 150–200 at 65 and over, and global rates were slightly lower. V-safe is not an elderly male screening cohort. According to Myers and colleagues (2023), V-safe participants were 62% female; 69% were ages 25–64, 16.0% ages 65–74 and 5.5% ages 75 or older. (Myers reports ages 18–49 (48.0%) and 50–64 (27.9%); the 69% for ages 25–64 is the author’s estimate after excluding ages 18–24 from Myers’s 18–49 band.) Weighting the Sampson age bands by those shares (under-25s contribute essentially nothing) gives about 51 per 100,000 person-years with the global rates and about 57 with the developed-country rates. We used 49 as the working rate, a round, conservative reading of the global figure. It is conservative because V-safe is more female than the Sampson average, and abdominal aortic aneurysm is much more common in men. The check-in clock of 5.51 million person-years is 55.1 units of 100,000 person-years, so the expected ceiling for diagnosed abdominal aortic aneurysms is:

$$\text{Abdominal ceiling} = 49 \times 55.09 \approx 2,699 \qquad (5)$$

Equation (5). The expected ceiling of diagnosed abdominal aortic aneurysms: the background rate per 100,000 person-years times the V-safe check-in clock in units of 100,000 person-years.

This is the ceiling for diagnosed abdominal aortic aneurysms, not a count of people who would report one.

The underreporting factor

The 176 most likely thoracic reports reached about three-fifths of the thoracic ceiling (176/292). The 161 most likely abdominal reports reached only about 1 in 16.8 of the abdominal ceiling:

$$\text{URF} = 2,699/161 \approx 16.8, \text{ rounded down to } 16 \qquad (6)$$

Equation (6). The underreporting factor (URF): the abdominal aortic aneurysm ceiling divided by the most likely abdominal reports, rounded down.

That 16 is a conservative underreporting factor (URF). It is conservative because the calculation assumes that all of the reported abdominal aneurysms are background reporting only, that is, cases that would have been expected anyway. If any of those reports reflect actual injuries, the URF would be larger. Every choice in this calculation was made to bring the number down. The URF measures how much was missed; it is not a count of extra abdominal aneurysm cases.

How the lower bound and the reporting (upper) bound were created

Both bounds are rates per 100,000 person-years. They use the same numerators, the NRSE counts, but different clocks. Each rate is a running total: the count through week w divided by the person-years through week w. The report weeks are 1–7, 13, 26, and 52.

1. Count NRSEs by report week. For each week, count NRThoracic, NRAbdominal, and NRUnspecifiedAortic. Through week 52, the totals are 100, 92, and 145, or 245 thoracic and unspecified reports together. Weighted by the named thoracic share, 100/192, the unspecified reports add 145 × 100/192 ≈ 75.5 to the thoracic side, for 175.5. Each person counts once, at their first report; people found only through MedDRA are placed at the midpoint of the check-in window before the coded survey.
2. Split the unspecified reports by the named shares (100 + 92 = 192), rounded to whole people: 76 of the 145 go to thoracic (Table 2). The running most likely thoracic count is

$$\begin{aligned}\text{Most Likely NRThoracic}(w) = \text{NRThoracic}(w) \\ + \text{NRUnspecifiedAortic}(w) \times \tfrac{76}{145}\end{aligned} \qquad (7)$$

Equation (7). The running count of most likely thoracic aortic aneurysm reports through report week w, adding the thoracic share of the site-unspecified reports.

and the abdominal count uses 69/145. At week 52, this gives 176 most likely thoracic and 161 most likely abdominal reports.

3. Build the check-in clock. For each interval, multiply the V-safe cohort by the share of check-ins returned and by the interval length in years, then add the intervals up to week w:

$$\mathrm{PY}_{\text{check-in}}(w) = \sum \text{cohort} \times \text{completion} \times \frac{\text{span}}{52} \tag{8}$$

The completion shares are the dose-2 series from the CDC V-safe summary table (Myers et al., 2026, Table 2; Pfizer-BioNTech, adults): 87.5 in week 1, 76.0, 73.6, and the later points. They are not the day-level percentages in Myers et al. (2023) Table 2, which stops at week 6; the 2026 summary table continues to weeks 13, 26, and 52. The 2026 table has no week-7 column, so week 7 reuses week 6's 69.3. The Pfizer-BioNTech series runs slightly below Moderna's in five of nine weeks; we use it because booster uptake and reporting drop off sharply after dose 2, and the difference changes the clock by only a few percent. Week 13 uses the full 10.1 million registrants; for weeks 26 and 52, the lower bound uses the 9.34 million first-year cohort. Late enrollees could not reach a 26- or 52-week check-in inside the FOIA window; that is an enrollment cut that keeps the lower bound a lower bound. The spans are 1 week each for weeks 1–7, then 6, 13, and 26 weeks. Week 1: 10.1 million × 0.875 × 1/52 = 169,952 person-years. By week 52 the clock reaches 5.51 million.

A tighter lower bound would need CDC's full V-safe reporting counts by week, which have not been released. With CDC's full weekly report counts, the lower bound would rise, and the URF would fall by the same factor, because both are tied to the same abdominal ceiling. The excess estimate would stay about the same; only the split between reported cases and underreporting would change.

4. Compute the lower bound:

$$\mathrm{LB}_{\text{Thoracic}}(w) = \frac{\text{Most Likely NRThoracic}(w)}{\mathrm{PY}_{\text{check-in}}(w)} \times 100,000 \tag{9}$$

Week 52: 176 / 5.509 million × 100,000 = 3.19 per 100,000. The abdominal lower bound is 161 / 5.509 million × 100,000 = 2.92. It is a lower bound because it assumes that everyone who returned a check-in could have reported, and that every aneurysm would have been typed.

5. Build the text-field clock. Count person-years only for check-ins in which the person typed something. Each non-empty response contributes its span: 1/52 of a year for a single week, 6/52 for the week-13 bin, 13/52 for week 26, and 26/52 for week 52. The contributions are summed. Most returned surveys had a blank text field, so by week 52 this clock is 579,000 person-years, about one-tenth of the check-in clock.
6. Compute the text-field (ideal reporting) upper bound:

Next we show how to compute an ideal upper bound if there is 100% reporting of adverse events.

$$\frac{\mathrm{UB}(w)}{100,000} = \frac{\mathrm{NRThoracic}(w) + \mathrm{NRUnspecifiedAortic}(w) \times \frac{\mathrm{NRThoracic}}{\mathrm{NRThoracic+NRAbdominal}}}{\mathrm{PY}_{\text{text-field}}(w)} \qquad (10)$$

Equation (10). The text-field upper bound (UB): named thoracic plus weighted site-unspecified reports through week w per 100,000 person-years on the text-field clock, which counts only check-ins with typed text.

The share in Equation 10 uses the week-52 totals, 100/(100 + 92) = 100/192, at every week. Week 52: 175.5 / 579,000 × 100,000 = 30.3 per 100,000. It is an ideal upper bound if there is 100% reporting because it divides by the smallest clock: only the people who reported an adverse event.

The calculations are in the rate-bounds calculator and the underreporting-factor sheet (see References).

Measured against the check-in clock, V-safe's thoracic reports give a lower bound of 3.19 per 100,000 person-years. Multiplied by the URF of 16, that's about 51.1, nearly ten times the background of 5.3. Abdominal reports, scaled the same way, come to 46.8, close to their background of 49, as they should be (Figure 3).

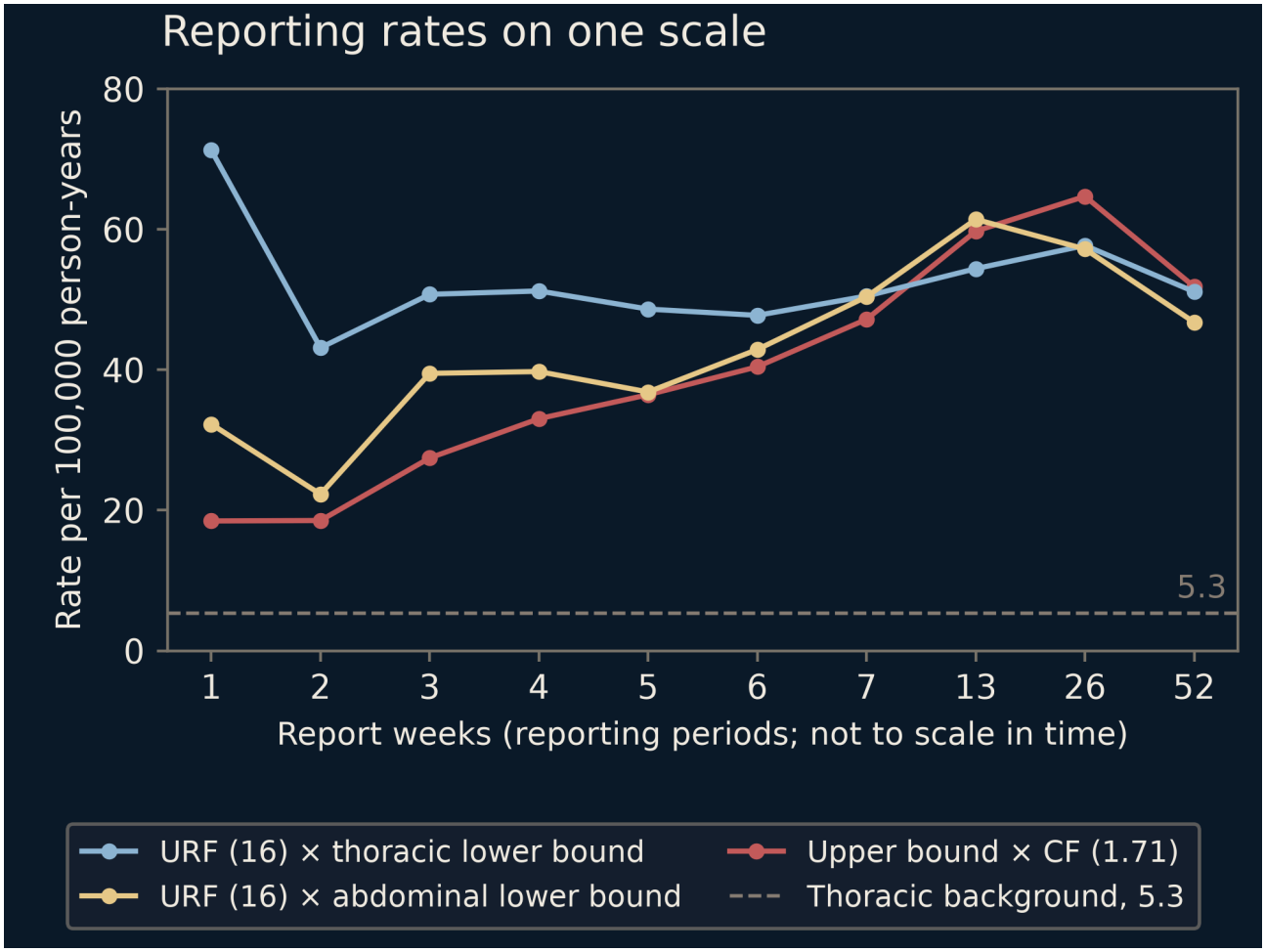


Figure 3. Reporting rates on one scale, per 100,000 person-years, by report week. Four lines: the text-field upper bound (thoracic + unspecified weighted by 100/192) × CF (1.71); URF (16) × the thoracic lower bound; URF × the abdominal lower bound; and, dashed, the thoracic background of 5.3 per 100,000. Each person counts once, at their first report; people found through MedDRA are placed at the midpoint of the check-in window before the coded survey. Report weeks are reporting periods, evenly spaced and not to scale in time.

Computing excess rates with the lower bound and URF, and estimating time-response totals with the reporting bound and the adjustment constant (1.71)

The lower bound gives the size of the excess. The reporting bound gives its timing.

1. Correct the lower bound with the URF (Equation 6):

$$\text{Rate}_{\text{Thoracic}}(w) = \text{URF} \times \text{LB}_{\text{Thoracic}}(w) \qquad (11)$$

Equation (11). The corrected thoracic rate: the underreporting factor (URF) times the thoracic lower bound (LB).

Week 52: 16 × 3.19 = 51.1 per 100,000 person-years. The abdominal line, 16 × 2.92 = 46.8, comes back close to the working abdominal rate of 49; it falls a little short because the URF was rounded down from 16.8. That is a check, not a new result.

2. Subtract the background and convert to a count on the check-in clock:

$$\text{Excess} = [\text{URF} \times \text{LB}_{\text{Thoracic}}(52) - 5.3] \times \frac{\text{PY}_{\text{check-in}}(52)}{100,000} \qquad (12)$$

Equation (12). The excess thoracic aortic aneurysms: the corrected week-52 thoracic rate minus the thoracic background rate, converted to a count on the check-in clock.

Week 52: (51.1 − 5.3) × 55.09 ≈ 2,524, the same as 16 × 176 − 292 = 2,524 (Table 6).

3. Find the adjustment constant. The URF line is reliable only in total, and the text-field line follows the week-to-week timing of the typed reports. Choose the constant CF (the correction factor) that gives the two lines the same span-weighted area across the ten report weeks:

$$\text{CF} = \frac{\sum \text{span} \times \text{URF} \times \text{LB}_{\text{Thoracic}}(w)}{\sum \text{span} \times \text{UB}(w)} = \frac{2,768.8}{1,619.2} \approx 1.71 \qquad (13)$$

Equation (13). The correction factor (CF): the span-weighted area under the underreporting factor (URF) times lower bound (LB) line divided by the span-weighted area under the text-field upper bound (UB) line.

4. Compute the reporting bound: 1.71 × UB(w). Week 52: 1.71 × 30.3 ≈ 51.8 per 100,000 (Figure 3).
5. Turn the reporting bound into running totals on the check-in clock:

$$\text{N}_{\text{Thoracic}}(w) = 1.71 \times \text{UB}(w) \times \frac{\text{PY}_{\text{check-in}}(w)}{100,000} \qquad (14)$$

Equation (14). The running total of implied thoracic aortic aneurysms through week w: the correction factor times the text-field upper bound (UB), converted to a count on the check-in clock.

Week 1: 18.5 × 1.70 = 31. Week 13: 59.7 × 17.82 = 1,065. Week 52: 51.8 × 55.09 ≈ 2,856 (Figure 4). Because both rates are running totals, $\text{N}_{\text{Thoracic}}$(w) is a running total too.

6. Ruptures. Multiply by 20% (Clouse et al., 1998). Week 52: 0.20 × 2,856 = 571. These totals include background (292 by week 52). Subtracting background gives an excess of about 2,564 aneurysms, and 0.20 × 2,564 ≈ 513 excess ruptures.

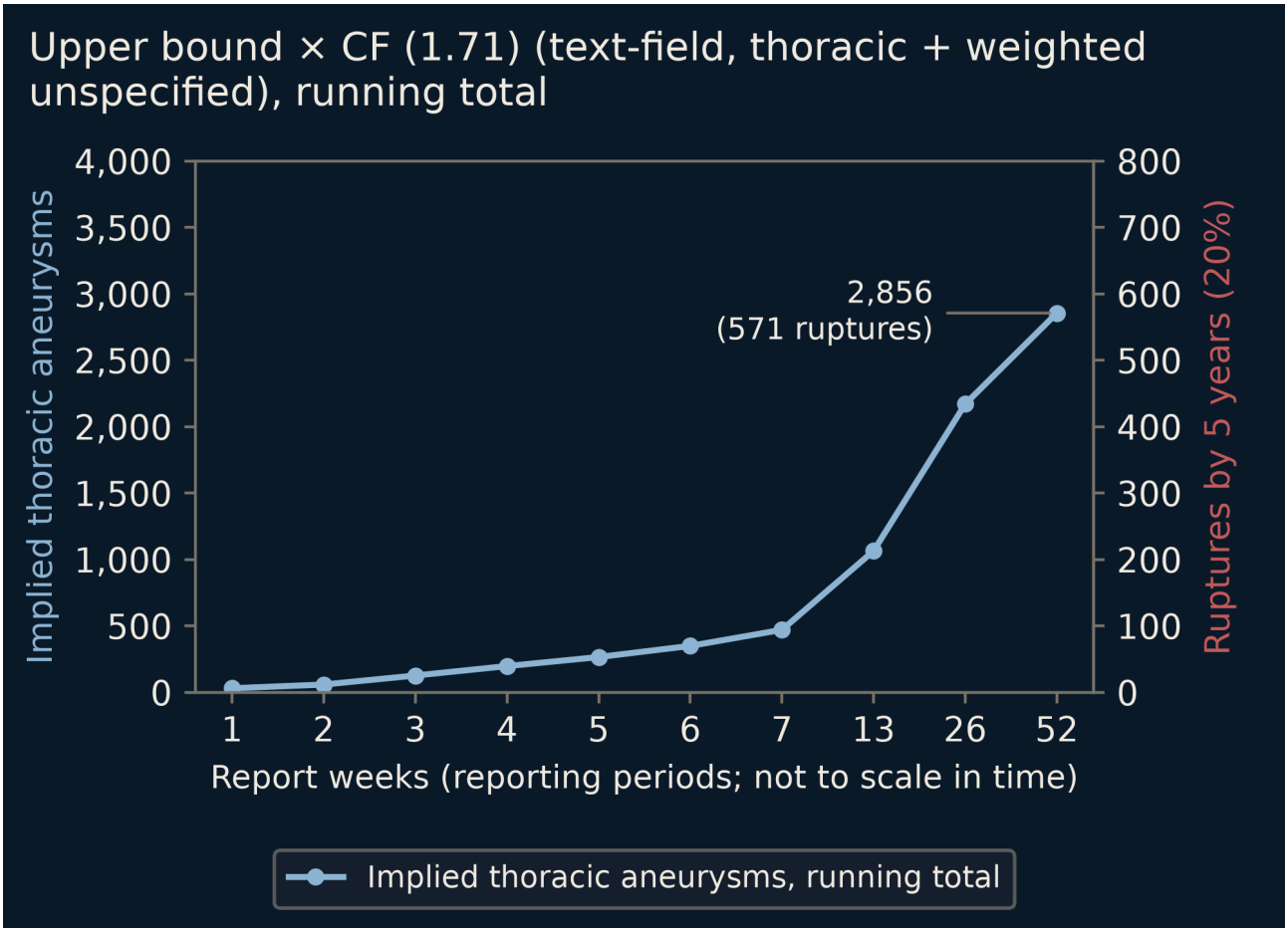


Figure 4. Upper bound × CF (1.71) (text-field, thoracic + unspecified weighted by 100/192), running total by report week: implied thoracic aneurysms (left axis). The right axis is a second scale equal to 20% of the left, with ruptures expected by 5 years; it is not a separate line. These totals include background, so the week-52 values (2,856 implied; 571 ruptures) differ from Table 6, which uses the URF (2,816 diagnoses) and applies the 20% rupture rate to the excess of 2,524 (505 ruptures). Report weeks are reporting periods, evenly spaced and not to scale in time.

A note on the constant. The normalization above is the one used in this report. An alternative scales with both the specific and the unspecified reports of the same category. For an injury counted only from its named reports, the constant becomes CF × (named + weighted unspecified)/named. For thoracic aneurysms, that is 1.71 × 175.5/100 ≈ 3.00, applied to a named-only text-field rate (100 / 579,000 × 100,000 = 17.3 per 100,000 at week 52). It gives the same week-52 total, 3.00 × 17.3 × 55.09 ≈ 2,860, equal to Figure 4 within rounding. Do not apply it to a rate that already includes the unspecified reports; that would count them twice.

The text-field reporting rate reaches nearly the same totals without solving for the URF. Its denominator counts only check-ins in which someone wrote something, because a blank text field carries no information about adverse events. Counting only written reports, against the time of the people who wrote them, already does most of the work the URF does.

The alarm CDC did not run

The CDC's own rule flags a signal when there are at least 3 reports, a proportional reporting ratio (PRR) of at least 2, and a chi-square of at least 4. Comparing thoracic with abdominal reports against their background rates gives a PRR of 10.11 (95% confidence interval 8.16–12.52) and a chi-square of 690. The signal was there from the first week: in the daily check-ins, 6 people named a thoracic aneurysm and 2 named an abdominal one, a PRR of 27.7 and a chi-square of 38.7. That's data the CDC held in 2021.

Thoracic vs abdominal, against background

Background 5.3 vs 49 per 100,000. Expected ratio 0.11.

Count	Thoracic	Abdominal	Ratio	PRR	95% CI	Chi-square
Named (site named)	100	92	1.09	10.05	7.57–13.34	390
Most likely (no-site reports split by named share)	176	161	1.09	10.11	8.16–12.52	690

CDC signal rule: PRR at least 2, chi-square at least 4, and at least 3 reports.

Both rows pass. Thoracic aneurysms are reported about 10 times the abdominal share expected from the published rates.

Figure 5. Thoracic versus abdominal reports, against background (5.3 vs 49 per 100,000 person-years; expected ratio 0.11). Both the named counts and the most likely split pass the CDC's signal rule.

No box, no list, no report

Thoracic aortic aneurysm was not on the Vaccine Safety Datalink list of 23 outcomes (Klein et al., 2021), and V-safe had no checkbox for it. People could report one only in the free-text field. A free-text entry did not become a Vaccine Adverse Event Reporting System (VAERS) report unless the person also checked the follow-up box. So a thoracic aneurysm reported in V-safe had no box, no list, and no automatic report. The later reports in this series start from that gap.

Peter Marks, then director of the Food and Drug Administration's (FDA's) Center for Biologics Evaluation and Research, was shown in early 2021 that a proportional reporting ratio scan of VAERS flagged signals the FDA's empirical Bayesian method missed. According to The BMJ, Marks and his staff declined to change the FDA's method, and the FDA medical officer who proposed an updated algorithm was asked to "cease and desist." The CDC had planned to run proportional reporting ratios on VAERS but did not do so until 2022. Its results were obtained by The Epoch Times under the Freedom of Information Act and first reported in January 2023 (Stieber, 2023; republished by Children's Health Defense). The BMJ later examined them and found that hundreds of adverse event types met the CDC's own signal criteria (Willman, 2026).

The CDC's own Table 5 for adults, dated 29 July 2022, compared COVID-19 mRNA vaccines with non-COVID-19 vaccines from 2009–2022. In it, aortic aneurysm (132 vs 17 reports; PRR 2.85, chi-square 17.3) and aortic dissection (55 vs 2 reports; PRR 10.1, chi-square 14.6) both met the signal rule (CDC, 2022a; Kottenstette, 2026a). A PRR is not a rate, and the background count for aortic dissection is only two reports.

A question, then a halt

A ratio alarm should have started a direct question, and it could have supported a halt. In 1976, two clusters of Guillain-Barré syndrome, seven cases in Minnesota and Alabama, were enough to start active surveillance and then to halt the campaign. The V-safe free-text entries were never read that way.

Estimating the excess

Table 6. Excess thoracic aortic aneurysms at a URF of 16, inside V-safe [scaled to the US].

Thoracic aortic aneurysm	V-safe [US]
Implied diagnoses (176 × 16)	2,816
Expected background	292
Excess (NAEs)	**2,524 [67,474]**
Ruptures within 5 years (20%)	505 [13,495]
Deaths within 5 years (44%)	1,111 [29,689]

US = V-safe × 270 million / 10.1 million. Rupture and death shares from Clouse et al. (1998); deaths are all causes, not a V-safe death count. Using only the 91 strict thoracic reports (163 most likely): excess 2,316 [61,914].

Mechanism, not count

Burkhardt's autopsies supply a mechanism, not the count: they show spike protein in the vessel wall, along with complement and lymphocytes (Palmer et al., 2023). The count comes from the V-safe files.

What should happen now?

- The CDC should call the reporters of an aneurysm, or their next of kin and complete a missing VAERS report.
- For those who died, the CDC should run the published stain for spike protein in the vessel wall.
- For other V-safe reporters of a severe injury whose check-in rate, multiplied by the URF of 16, exceeds its published background, the CDC should file any missing VAERS report.

• • •

Next in this series: the case-study article, with the top 10 thoracic and abdominal cases by onset window. Aortic dissections are covered in their own report. Each builds on the counts and methods set out here.

I once carried Cecilia at the beach, and for that I am blessed. I now write for those who reported their injuries to V-safe and were ignored by the people charged with keeping them safe.

References

Data: V-safe free text, released under the FCDC v. CDC order (ICAN updated files, FOIA 24-01322). Matching was done with a custom search tool (not yet public).

Balbona, E.J., Hudson, H., Mörz, M. and Lindsay, J. (2024) 'Case of myocarditis, pericarditis, and fatal aortic dissection following COVID-19 mRNA vaccination', *Biomedical Science and Clinical Research*, 3(3), pp. 1–8. doi:10.33140/BSCR.03.03.03. Available at: https://www.opastpublishers.com/open-access-articles/case-of-myocarditis-pericarditis-and-fatal-aortic-dissection-following-covid19-mrna-vaccination.pdf

CDC (Centers for Disease Control and Prevention) (2022a) *Table 5: PRR of MedDRA Preferred Terms for COVID-19 mRNA vaccines compared to 2009–2022 non-COVID-19 vaccines, VAERS reports as of 29 July 2022*. Released under FOIA to The Epoch Times; posted 3 January 2023. Available at: https://img.theepochtimes.com/assets/uploads/2023/01/03/Final-7-29-Table5-PRR-of-PTs-for-COVID19-mRNA-Compared-to-2009_2022-NON-COVID19_07.29.2022.xlsx

CDC (Centers for Disease Control and Prevention) (2022b) *FOIA interim response, 30 September 2022 (22-01281-FOIA / 22-00004-LT)*. Hosted by ICAN. Available at: https://icandecide.org/wp-content/uploads/2023/01/22-00004-LT-Interim-release.pdf

Clouse, W.D., Hallett, J.W. Jr, Schaff, H.V., Gayari, M.M., Ilstrup, D.M. and Melton, L.J. 3rd (1998) 'Improved prognosis of thoracic aortic aneurysms: a population-based study', *JAMA*, 280(22), pp. 1926–1929. doi:10.1001/jama.280.22.1926. Available at: https://doi.org/10.1001/jama.280.22.1926

FCDC v. CDC (2024) *Freedom Coalition of Doctors for Choice v. Centers for Disease Control and Prevention*, No. 2:23-CV-102-Z, Memorandum Opinion and Order, ECF No. 40 (N.D. Tex., Amarillo Div., 5 January 2024) (Kacsmaryk, J.). Available at: https://www.justice.gov/oip/freedom-coal-doctors-choice-v-cdc-no-23-102-2024-wl-69084-nd-tex-jan-5-2024-kacsmaryk-j

Gouveia e Melo, R., Silva Duarte, G., Lopes, A., Alves, M., Caldeira, D., Fernandes e Fernandes, R. and Mendes Pedro, L. (2022) 'Incidence and prevalence of thoracic aortic aneurysms: a systematic review and meta-analysis of population-based studies', *Seminars in Thoracic and Cardiovascular Surgery*, 34(1), pp. 1–16. doi:10.1053/j.semtcvs.2021.02.029.

Hulscher, N., Procter, B.C., Wynn, C. and McCullough, P.A. (2023) 'Clinical approach to post-acute sequelae after COVID-19 infection and vaccination', *Cureus*, 15(11), e49204. doi:10.7759/cureus.49204.

Hulscher, N., Hodkinson, R., Makis, W. and McCullough, P.A. (2025) 'Autopsy findings in cases of fatal COVID-19 vaccine-induced myocarditis', *ESC Heart Failure*, 12(5), pp. 3212–3225 (first published online January 2024). doi:10.1002/ehf2.14680.

ICAN (Informed Consent Action Network) (2022) 'V-Safe', 18 October. Available at: https://icandecide.org/article/v-safe/

ICAN (Informed Consent Action Network) (n.d.) 'V-Safe Data' (file listings: check-box files, FOIA 24-01322 free-text files, MedDRA files and call-center records). Available at: https://icandecide.org/v-safe-data/

Khan Academy Medicine (n.d.a) 'Thoracic aortic aneurysms' [YouTube video]. Available at: https://www.youtube.com/watch?v=xHUsdE880so

Khan Academy Medicine (n.d.b) 'Abdominal aortic aneurysms' [YouTube video]. Available at: https://www.youtube.com/watch?v=P1paaFPcdak

Khan Academy Medicine (n.d.c) 'Aortic dissection treatment' [YouTube video]. Available at: https://www.youtube.com/watch?v=JfZ38uHaTEk

Klein, N.P. et al. (2021) 'Surveillance for adverse events after COVID-19 mRNA vaccination', *JAMA*, 326(14), pp. 1390–1399. doi:10.1001/jama.2021.15072. Available at: https://jamanetwork.com/journals/jama/fullarticle/2784015

Kottenstette, N. (2022a) 'An uncontrollable system: and how it impacts your health', Nick's ReFounding America Newsletter (Substack), 11 July. Available at: https://nickkottenstette.substack.com/p/an-uncontrollable-system

Kottenstette, N. (2022b) 'DMED whistleblower data analysis: as it relates to malignant neoplasms and Guillain-Barré syndrome (GBS)', Nick's ReFounding America Newsletter (Substack), 21 July. Available at: https://nickkottenstette.substack.com/p/dmed-whistleblower-data-analysis

Kottenstette, N. (2022c) 'How does the MIL-VAX agency detect GBS?', Nick's ReFounding America Newsletter (Substack), 8 August. Available at: https://nickkottenstette.substack.com/p/how-does-the-mil-vax-agency-detect

Kottenstette, N. (2023) 'Iatrogenic Guillain-Barre syndrome (GBS) case rates in the USA: for the periods i) October 1, 1976 – October 1, 1977; ii) October 25, 2009 – October 25, 2010; and iii) December 13, 2020 – December 13, 2021', Nick's ReFounding America Newsletter (Substack), 3 January. Available at: https://nickkottenstette.substack.com/p/iatrogenic-guillain-barre-syndrome

Kottenstette, N. (2026a) 'Signal. CDC Table 5, aortic dissection, 6 May and 29 July 2022' [X post], 26 September. Available at: https://x.com/NickKottenstet1/status/2104027414808469786

Kottenstette, N. (2026b) *V-safe Technical Report 1: aortic aneurysm case file* [spreadsheet]. Available at: https://docs.google.com/spreadsheets/d/18uirXLm1K3M77jeH_mvdEQueVHcE51T_v6T_Lf3xc3I

Kottenstette, N. (2026c) *Underreporting-factor sheet* [spreadsheet]. Available at: https://docs.google.com/spreadsheets/d/1P-1QXp0O0mkxIBd5EMoqcMgNYyHZHdlR4b1qPHolV7k

Kottenstette, N. (2026d) *V-Safe RSE rate bounds calculator* [spreadsheet]. Available at: https://docs.google.com/spreadsheets/d/1WzoVgx2xXgD0tLZKkgxEq6F0HwCJLT7gGWcZnvRymFw

MedDRA (n.d.) *Medical Dictionary for Regulatory Activities*. International Council for Harmonisation. Available at: https://www.meddra.org/

Myers, T.R., Marquez, P.L., Gee, J.M., Hause, A.M., Panagiotakopoulos, L., Zhang, B., McCullum, I., Licata, C., Olson, C.K., Rahman, S., Kennedy, S.B., Cardozo, M., Patel, C.R., Maxwell, L., Kallman, J.R., Shay, D.K. and Shimabukuro, T.T. (2023) 'The v-safe after vaccination health checker: active vaccine safety monitoring during CDC's COVID-19 pandemic response', *Vaccine*, 41(7), pp. 1310–1318. doi:10.1016/j.vaccine.2022.12.031. Demographics, Table 1.

Myers, T.R., Zauche, L.H., Marquez, P.L., McCullum, I., Hause, A.M. and Shay, D.K. (2026) 'V-safe: summary of findings reported after COVID-19 vaccination to a US CDC active safety surveillance system through June 2023', *Vaccine*, 88, 128725. doi:10.1016/j.vaccine.2026.128725. Dose-2 survey completion (% of eligible surveys completed), Table 2. Available at: https://pmc.ncbi.nlm.nih.gov/articles/PMC13502162/

NHLBI (National Heart, Lung, and Blood Institute) (2022) 'Aortic aneurysm – what is aortic aneurysm?', National Institutes of Health, last updated 24 March. Figure 'Aortic aneurysms' (Figure 2 here); public domain. Available at: https://www.nhlbi.nih.gov/health/aortic-aneurysm

Palmer, M., Bhakdi, S., DesBois, M., Hooker, B., Skidmore, M., Rasnick, D., Holland, M. and Fitts, C.A. (2023) *mRNA vaccine toxicity*, version 2.1, 27 October. Doctors for COVID Ethics. §4.2 and §4.3.3, pp. 56–59. Available at: https://doctors4covidethics.org/mrna-vaccine-toxicity/

Polykretis, P., Donzelli, A., Lindsay, J.C., Wiseman, D., Kyriakopoulos, A.M., Mörz, M., Bellavite, P., Fukushima, M., Seneff, S. and McCullough, P.A. (2023) 'Autoimmune inflammatory reactions triggered by the COVID-19 genetic vaccines in terminally differentiated tissues', *Autoimmunity*, 56(1), 2259123. doi:10.1080/08916934.2023.2259123.

React19 (2026) 'Cries for help buried in V-Safe data', *Brownstone Institute*, 30 September. Available at: https://brownstone.org/articles/cries-for-help-buried-in-v-safe-data/

Sampson, U.K.A., Norman, P.E., Fowkes, F.G.R., Aboyans, V., Song, Y., Harrell, F.E. Jr, Forouzanfar, M.H., Naghavi, M., Denenberg, J.O., McDermott, M.M., Criqui, M.H., Mensah, G.A., Ezzati, M. and Murray, C. (2014) 'Estimation of global and regional incidence and prevalence of abdominal aortic aneurysms 1990 to 2010', *Global Heart*, 9(1), pp. 159–170. doi:10.1016/j.gheart.2013.12.009.

Schonberger, L.B., Bregman, D.J., Sullivan-Bolyai, J.Z., Keenlyside, R.A., Ziegler, D.W., Retailliau, H.F., Eddins, D.L. and Bryan, J.A. (1979) 'Guillain-Barré syndrome following vaccination in the National Influenza Immunization Program, United States, 1976–1977', *American Journal of Epidemiology*, 110(2), pp. 105–123. doi:10.1093/oxfordjournals.aje.a112795.

Schwab, C., Domke, L.M.

Schwab, C., Domke, L.M., Hartmann, L., Stenzinger, A., Longerich, T. and Schirmacher, P. (2023) 'Autopsy-based histopathological characterization of myocarditis after anti-SARS-CoV-2-vaccination', *Clinical Research in Cardiology*, 112(3), pp. 431–440. doi:10.1007/s00392-022-02129-5.

Siri, A. (2023) 'V-Safe Part 5: the fight to get the V-Safe data!', *Substack*, 26 January. Available at: https://aaronsiri.substack.com/p/v-safe-part-5-the-fight-to-get-the

Stieber, Z. (2023) 'EXCLUSIVE: CDC finds hundreds of safety signals for Pfizer and Moderna COVID-19 vaccines', *The Epoch Times*, 3 January. Available at: https://www.theepochtimes.com/health/exclusive-cdc-finds-hundreds-of-safety-signals-for-pfizer-and-moderna-covid-19-vaccines_4956733.html. Republished in *The Defender*, Children's Health Defense, 3 January 2023: https://childrenshealthdefense.org/defender/cdc-safety-signals-pfizer-moderna-covid-vaccines-et/

Takahashi, M., Kondo, T., Yamasaki, G., Sugimoto, M., Asano, M., Ueno, Y. and Nagasaki, Y. (2022) 'An autopsy case report of aortic dissection complicated with histiolymphocytic pericarditis and aortic inflammation after mRNA COVID-19 vaccination', *Legal Medicine*, 59, 102154. doi:10.1016/j.legalmed.2022.102154.

Wade, N. (1978) '1976 swine flu campaign faulted yet principals would do it again', *Science*, 202(4370), pp. 849–852. doi:10.1126/science.715445.

Willman, D. (2026)

Willman, D. (2026) 'US officials knew covid vaccine safety system was flawed—but turned aside the FDA doctor who alerted them', *BMJ*, 394, e100806. doi:10.1136/bmj-2026-100806.