



Evaluation of the accuracy, completeness, and compliance of current summary reporting of adverse events to the Food and Drug Administration using the manufacturer and user facility device experience (MAUDE) database: cross sectional study

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ABSTRACT

OBJECTIVES

To evaluate the accuracy and completeness of adverse event summary reports for medical devices and compliance of the reports with the Food and Drug Administration (FDA) requirements.

DESIGN

Cross sectional study.

SETTING

The FDA manufacturer and user facility device experience (MAUDE) database.

PARTICIPANTS

All adverse event summary reports filed in MAUDE from July 2019 to June 2025.

MAIN OUTCOME MEASURES

Identification of device problem codes, appropriate identification as summary reports in the submission form, concordance between the number of events data field and the report narrative, and compliance with FDA reporting deadlines.

RESULTS

6308 summary reports were submitted to MAUDE containing 159 503 adverse events. Use of summary reports increased from 808 to 1757 between 2020

and 2024, a factor of 1.21 per year ($P<0.001$). Most (91%) adverse events in summary reports were for class 3 high risk devices. Summary reports lacked descriptions of potential device related problems: 57% of reports denoted an “adverse event without identified device or use problem” and 38% of reports selected “insufficient information” in the device problem code data field. Manufacturers incorrectly checked “N” (no) in the summary report (Y/N, reporting yes/no) field for 694 summary reports (11%) and erroneously listed “n=1” under the number of events field for 423 summary reports (7%), causing an undercount of 11 902 adverse events. The majority (55%) of summary reports failed to comply with the FDA reporting deadline of 30 days after the manufacturer became aware of the adverse event.

CONCLUSIONS

Adverse event summary reports in MAUDE are frequently incomplete, inaccurate, and delayed. Improvements are needed to ensure timely identification of device safety signals and uphold FDA transparency standards.

Introduction

Each year, the United States Food and Drug Administration (FDA) authorises thousands of medical devices with the goal of improving patient care.¹ Most devices reach the market without any clinical studies.² Even high risk devices are approved based on small, non-randomised studies with short follow-up duration, sometimes despite failing to meet pivotal study primary endpoints.³⁻⁵ The FDA total product lifecycle approach emphasises reliance on robust surveillance data after the device has been marketed to compensate for deficiencies in premarket data and ensure the ongoing safety and effectiveness of medical devices.

The FDA manufacturer and user facility device experience (MAUDE) database is the primary resource for postmarket device surveillance in the United States.⁶ The database plays a critical role in early signal detection, transparency, and independent oversight of all medical devices.⁶ Certain device related adverse events are subject to mandatory reporting by manufacturers and device user facilities, among others, while patients and individual doctors are considered voluntary reporters.⁷ MAUDE receives medical device reports almost entirely from manufacturers. The reporter identifies the type of adverse event being submitted and classifies the event as a death, serious injury, or device malfunction. MAUDE is used by a wide range of individuals and entities, including regulators,

WHAT IS ALREADY KNOWN ON THIS TOPIC

The Food and Drug Administration (FDA) manufacturer and user facility device experience (MAUDE) database is the foundation of postmarket surveillance infrastructure in the United States, serving as the primary repository for medical device adverse event data and informing recalls and regulatory actions. MAUDE requires complete and accurate reporting to be effective; earlier programmes, notably the Alternative Summary Reporting programme, permitted manufacturers to submit millions of adverse events as bulk summaries rather than as individual reports.

The Alternative Summary Reporting programme was terminated in 2019 because of concerns that the programme structure obscured the identification of safety signals; however, similar methods of gaining other summary reporting exemptions remain in use.

WHAT THIS STUDY ADDS

Ongoing use of similar summary reporting programmes following termination of the Alternative Summary Reporting programme has not been closely examined; yet, patient safety information continues to be obscured because of the use of summary reporting exemptions.

Most adverse events (91%) contained in summary reports from 1 July 2019 to 30 June 2025 were associated with class 3 high risk devices, and summary reports often failed to identify potential device problems or device use problems, and failed to comply with FDA timely reporting requirements.

researchers, manufacturers, and clinical care teams, many of whom are trained in interpreting complaint data.⁸

Safety signals identified through the MAUDE database typically prompt downstream consideration of potential regulatory action.⁷ Entries in MAUDE do not establish a causal relationship between a medical device and an adverse event, and MAUDE is not a comprehensive measure of device safety. Rather, MAUDE serves as an essential mechanism for early warning and transparency within a broader surveillance system, and patterns found in adverse event reports can prompt the investigation of possible safety signals through the use of additional data sources, including device registries and studies after product approval.⁶⁻⁸ While the FDA may have access to non-publicly disclosed information, MAUDE remains the primary resource by which researchers, clinicians, and patients can independently evaluate device safety signals, providing external transparency and oversight, comprehensive coverage, real time reporting, and public accessibility. Thus, the accuracy and completeness of adverse event reports filed in MAUDE are essential for surveillance after the product is marketed.

The FDA applies a least burdensome approach to medical device regulation—a principle aimed at minimising regulatory burden on manufacturers—which extends to postmarket adverse event reporting requirements.⁹ For example, the Alternative Summary Reporting programme, which began in 1997, permitted manufacturers of certain medical devices to submit quarterly summary reports rather than file individual adverse event reports in order to “reduce the burden on industry.”¹⁰⁻¹¹ These summary reports were not publicly available through MAUDE, which medical experts rely on to identify safety risks.¹² A pivotal Kaiser Family Foundation investigation found that millions of adverse events were being hidden in summary reports.¹² In June 2019, following the Kaiser Family Foundation report, former FDA Center for Devices and Radiological Health director Jeffrey Shuren announced the termination of the Alternative Summary Reporting programme “in the spirit of promoting public transparency.”¹⁰⁻¹²⁻¹³ A former FDA official, speaking on the dangers associated with the programme, stated “doctors relying just on the public reports—and unaware that many incidents may be omitted—can easily reach the wrong conclusion about the safety record of a particular device.”¹² The FDA created the Voluntary Malfunction Summary Reporting programme when ending the Alternative Summary Reporting programme. The Voluntary Malfunction Summary Reporting guidance explicitly limits summary reporting to certain device malfunctions, with individual reporting still required for deaths and serious injuries.¹⁴

However, other summary reporting pathways with the same shortcomings and lack of transparency, such as the summary reporting programme examined in this study, continue to be used after the termination of the

Alternative Summary Reporting programme.¹² The FDA has continued to grant various reporting exemptions to manufacturers on a case-by-case basis, with the stated intention of expediting the identification of safety signals.¹⁴⁻¹⁵ According to FDA spokeswoman Deborah Kotz, exemptions from standard adverse event reporting requirements were created without any regulations or public notice.¹² One such exemption allows manufacturers to submit a summary report comprising aggregated data on adverse events sourced from prespecified, approved registries in lieu of submitting individual medical device reports. The summary reporting exemptions currently used for moderate risk to high risk medical devices share weaknesses with the defunct Alternative Summary Reporting programme; for example, manufacturers are allowed to submit summary reports for deaths and serious injuries under summary reporting exemptions. Consequently, summary reporting exemptions allow manufacturers to circumvent the stricter requirements of the Voluntary Malfunction Summary Reporting programme, which only allows reporting of malfunctions. Deborah Kotz acknowledged that “data in registries often falls short of the level of detail that the FDA seeks for more thorough death reports that device makers are required to file” and confirmed that “any device manufacturer can request an exemption from its reporting requirements” through this summary reporting exemption pathway.¹²⁻¹⁵

Because of the concern that the currently used summary reporting exemptions share weaknesses with the terminated Alternative Summary Reporting programme, we aimed to evaluate the accuracy and completeness of current summary reporting exemptions. We hypothesised that summary reports for moderate risk and high risk medical devices may underestimate serious adverse events and provide insufficient clinical context of safety risks.

Methods

In this cross sectional study, we identified all adverse event reports submitted to the MAUDE database, from the termination of the Alternative Summary Reporting programme in June 2019 until 30 June 2025. The standard adverse event report form has many data fields that reporters are instructed to complete, including the date on which the manufacturer became aware of the adverse event, the date the FDA received the adverse event report, the type of report, the company name, and the device name. Reporters also complete free text to provide additional clinical context.⁷⁻¹⁶⁻¹⁷ Under summary reporting exemptions, manufacturers are required to complete the data fields contained in the standard FDA report form Form 3500A (MedWatch Adverse Event Mandatory Reporting Form) (supplementary appendix), select “Yes” under the summary report (Y/N) field, and indicate the number of events aggregated to make summarised safety data readily apparent.¹⁵⁻¹⁷

We used Device Events (a proprietary software platform that interfaces directly with the MAUDE

database, retrieving adverse event reports in their original, unmodified form)¹⁸ to query and extract medical device reports filed in MAUDE. The software does not alter the underlying data, but provides a structured interface that facilitates systematic querying, filtering, and export of reports that would otherwise require manual retrieval from MAUDE. Each report extracted through Device Events is linked to its corresponding MAUDE entry, allowing for direct verification of the source data. Device Events has been used in earlier peer reviewed research to analyse MAUDE data.^{19 20}

We used Device Events to query all adverse event reports that were received by the FDA between 1 July 2019 and 30 June 2025. Our search parameters were reporter country code “US” or blank, and search term “exemption” or any reports with exemption numbers included in the exemption number data field. Upon approval of a summary reporting exemption, the FDA assigns a unique exemption number, which manufacturers use when submitting summary reports under that exemption.

Our approach captured all reports submitted as exemptions in the appropriate data field (exemption number) as well as reports that did not list an exemption number in the exemption number data field but mentioned a reporting exemption and exemption number in the free text submission in the report narrative. We reviewed all resulting adverse event reports that met these criteria, and exemption numbers were determined for all reports based on details included in the report narrative or the exemption number submitted under the exemption number field. Each report narrative was reviewed to identify all exemptions containing language reflecting summary reporting (eg, this report . . . summarises adverse events) and to exclude exemption numbers associated with revoked Alternative Summary Reporting exemptions and other types of reporting exemptions. All adverse event reports associated with the final list of summary reporting exemption numbers were compiled for analysis. We then reviewed report narratives to ascertain the number of adverse events contained in each summary report (eg, this device may be related to (number) adverse events, this report summarises (number) adverse events).

Our analysis distinguishes the following layers of summary reporting: summary reporting exemptions (FDA granted approvals permitting a manufacturer to submit summary reports for a specific device), summary reports (individual reports filed under each exemption number), and adverse events (individual events aggregated within each summary report). We conducted our analyses at the report level and the event level, depending on the outcome of interest. Report level analyses were used for outcomes that were characteristics of the reports themselves, such as correct identification as a summary report in the summary report (Y/N) field, accuracy of the number of events field, and proper identification of device problem codes (representing issues pertaining to the

device itself) using the device problem field, as these reflect reporting practices at the level of the individual submission. We also performed analysis of compliance with reporting deadlines at the report level. The FDA requires that manufacturers submit adverse event reports within 30 days of becoming aware of death, serious injury, and malfunction events.²¹ Event level analyses were used for outcomes pertaining to the adverse events aggregated within each report, including the total number of each type of adverse event contained in summary reports (eg, death, serious injury, or malfunction), the type of device involved (eg, cardiac, vascular, etc), the device class, and the device manufacturer. The device class is a three tiered, risk based classification system, with class 3 referring to the highest risk products, including those that are life sustaining, implanted, or present an unreasonable risk of illness or injury.²²

Statistical analysis

We used descriptive statistics including counts and percentages to characterise summary reporting patterns and device level adverse event data. Negative binomial regression was used to assess annual trends in summary reporting over the full study years (2020–24), consistent with previously published methods for analysing MAUDE adverse event data.²³ Device level negative binomial regression analyses were performed for each device across five outcomes—total adverse events, total summary reports, serious injuries, deaths, and device malfunctions—to evaluate whether observed trends were consistent across individual devices or driven by specific devices entering or leaving the summary reporting system during the study period. Leading zeros were excluded for devices whose exemptions were not yet active at the start of the study period. Devices with fewer than three data points were considered to have insufficient data for trend analysis, and the partial years 2019 and 2025 were excluded from trend analyses. All statistical analyses were performed using R version 4.5.3. Statistical significance was set at $P < 0.05$.

We defined submission time as the number of days between the date the manufacturer was notified of the adverse event and the date the report was submitted to the FDA. Mean, median, and standard deviation (SD) of submission time were calculated across all summary reports in the study period, regardless of whether they exceeded the required 30 day regulatory reporting window.

Our study used deidentified public data and was therefore exempt from institutional review board approval in compliance with University of California, San Francisco guidance.

Patient and public involvement

The research question was informed by priorities of patients and the public after informal discussions of their awareness of adverse event reporting. Although patients and members of the general public were not directly involved in the design or conduct of our

study owing to lack of funding, the study relied on public reporting of adverse event data to the MAUDE database. Media reports have highlighted potential harm to patients as a result of the continued use of summary reporting exemptions.¹²

Results

MAUDE received approximately 42 000 adverse event reports that were submitted under FDA exemptions during the six year study period following the termination of the Alternative Summary Reporting programme. These reports comprised 125 unique exemption numbers, of which 14 were identified as summary reporting exemptions based on details provided in the report narratives, such as stating “per summary report exemption” (fig 1). In total, 6308 medical device reports were submitted as summary reports, containing 159 503 aggregated adverse events (fig 1, fig 2). The majority (n=139 333, 87%) of these adverse events were classified as serious injuries, while 16 985 (11%) were classified as deaths and 3185 (2%) as malfunctions. The total number of summary reports submitted to the FDA increased significantly over the study period, from 808 in 2020 to 1757 in 2024, a factor of 1.21 per year ($P<0.001$) (fig 2). The total

number of adverse events contained within summary reports increased similarly, by a factor of 1.22 per year ($P<0.001$) (fig 2). By report type, serious injuries increased by a factor of 1.22 per year ($P<0.001$) and deaths by a factor of 1.07 per year ($P<0.001$). Malfunction reports also increased significantly (a factor of 2.97 per year, $P<0.01$), however, this finding should be interpreted with caution given a spike observed in 2023, which may not reflect a sustained trend.

We performed device level negative binomial regression analyses to evaluate whether observed trends were consistent across individual devices (fig 3, supplementary appendix, table 1). The cardiac transcatheter valve devices CoreValve and SAPIEN 3, which together accounted for the majority of summary reports and adverse events, demonstrated significant increasing trends in total adverse events, total reports, and serious injuries ($P\leq 0.03$) (supplementary appendix, table 1). WATCHMAN FLX, a left atrial appendage occlusion device, could not be modelled owing to an irregular reporting pattern reflecting interruption and resumption of its exemption, and several devices had insufficient data points for trend analysis (supplementary appendix, table 1).

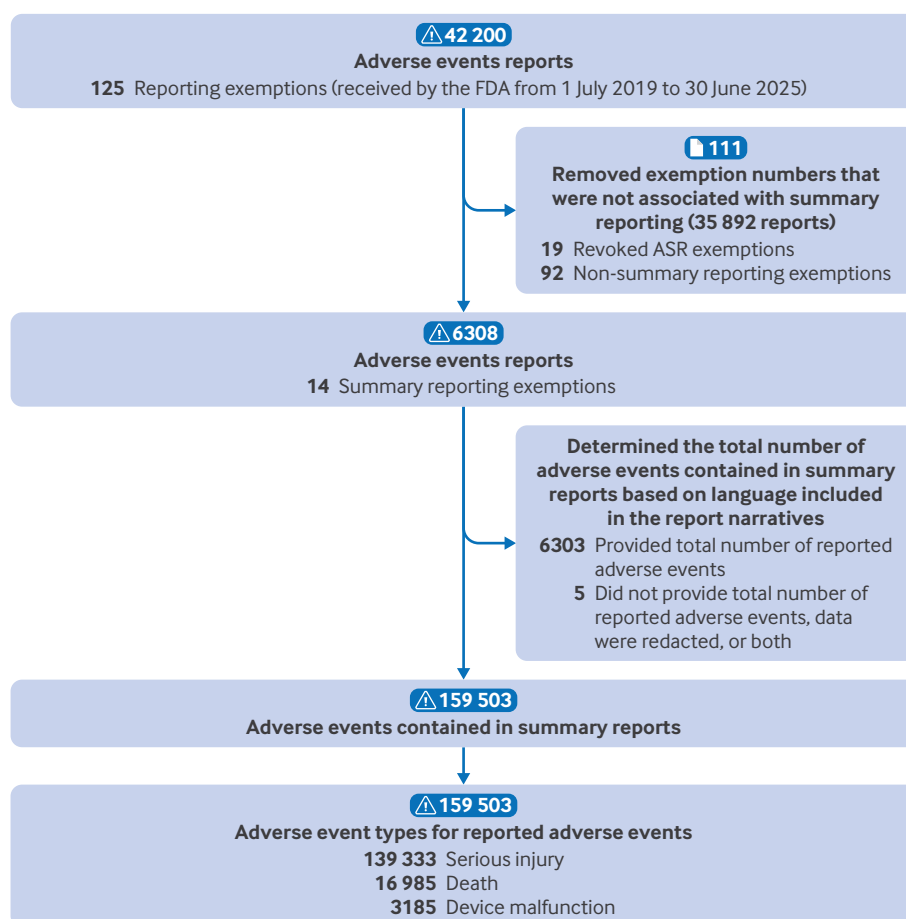
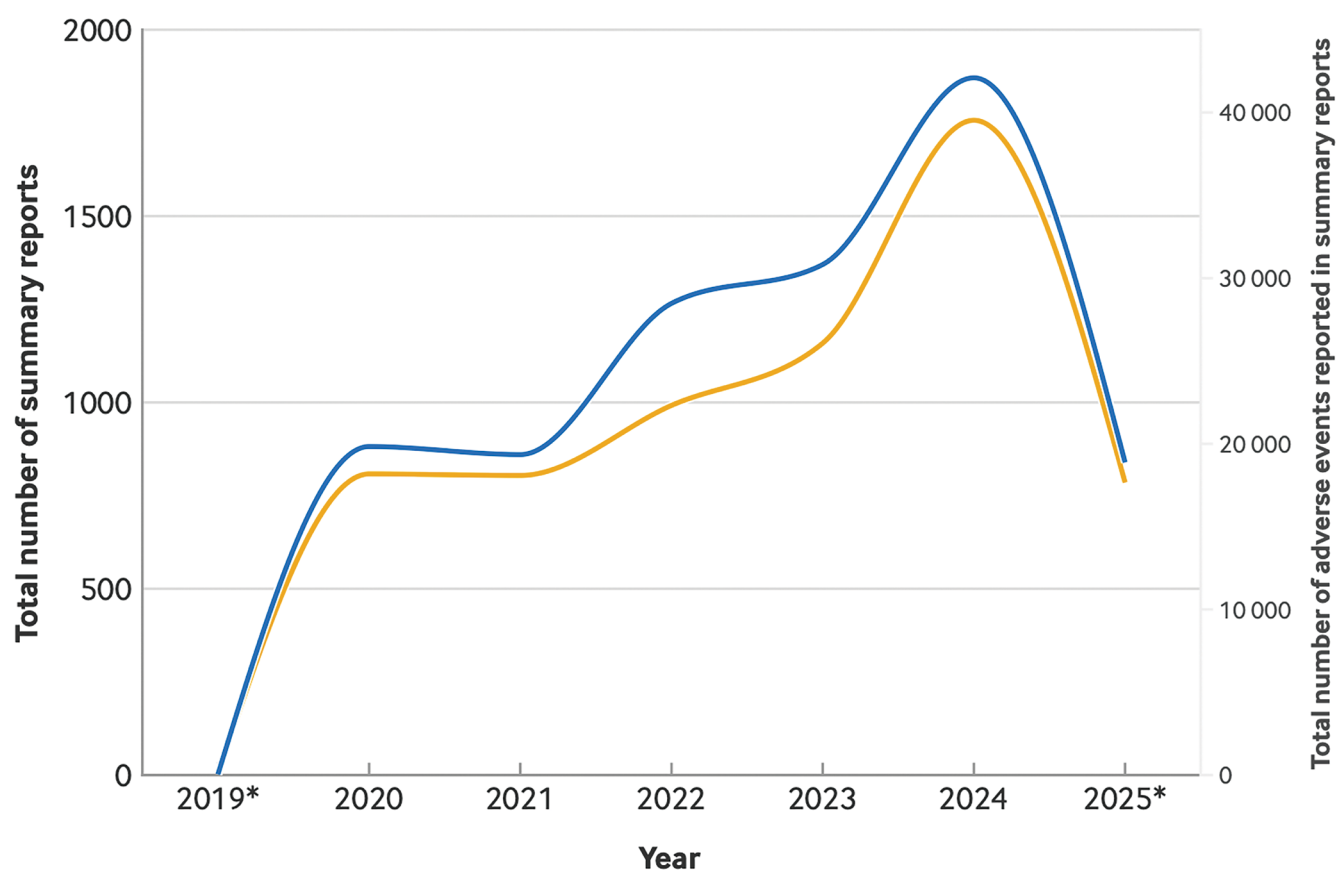


Fig 1 | Total number of summary reports and adverse events contained within summary reports, from July 2019 to June 2025. FDA=Food and Drug Administration; ASR=Alternative Summary Reporting

Total summary reports submitted to the Food and Drug Administration and the total number of adverse events contained in summary reports (2019-25)



■ Adverse events ■ Summary reports



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*Six months only

Fig 2 | Total number of summary reports submitted to the Food and Drug Administration and total number of adverse events contained in summary reports (2019-25). An interactive version of this graphic and downloadable data are available at <https://public.flourish.studio/visualisation/30320661/>

Summary reporting exemptions in this analysis were granted by the FDA so that reporting could rely on data from specified registries (table 1). Exemptions have been granted for 13 distinct devices. The Society of Thoracic Surgeons and American College of Cardiology Transcatheter Valve Therapy (STS/ACC TVT) Registry was the most common registry in summary reporting exemptions and was cited as the data source for 86% of adverse events in summary reports (table 1). The summary reporting exemption for SAPIEN 3 (Edwards Lifesciences) transcatheter aortic valve accounted for nearly half (2774) of all summary reports and contained 70 144 adverse events

(44% of adverse events contained in all summary reports). The second most used exemption number was for CoreValve (Medtronic) and the next generation Evolut transcatheter aortic valve (Medtronic) systems, representing about one third of all summary reports (30%) and all adverse events (35%). Both of these summary exemptions relied on data from the STS/ACC TVT Registry.

Ninety nine per cent of all adverse events submitted through summary reports were related to cardiac devices, and almost all adverse events (91%) were associated with class 3 high risk devices (table 2). The manufacturers submitting most adverse

Total number of Food and Drug Administration summary reports, and adverse events, serious injuries, deaths, and malfunctions reported therein by device



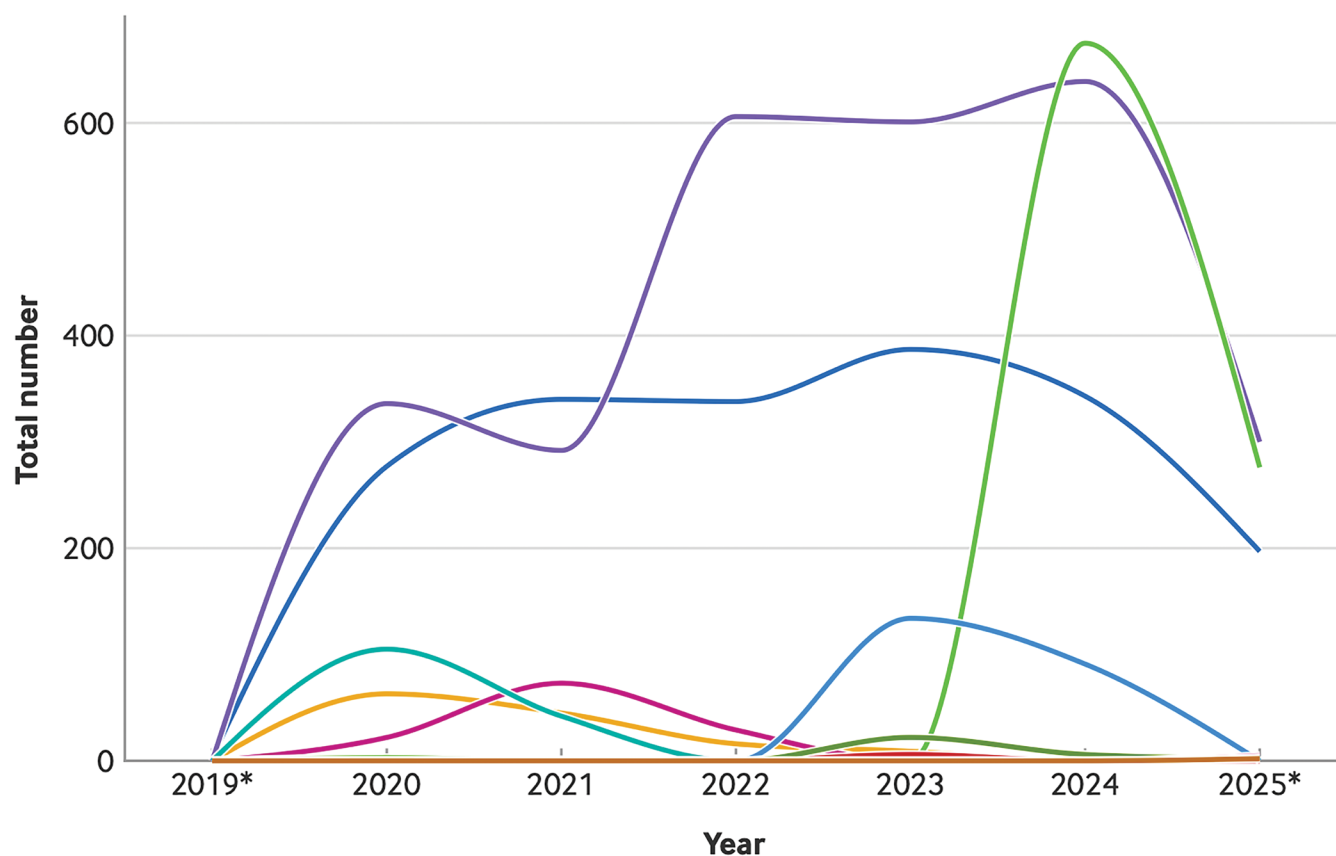
2019 and 2025 only include data for six months given the time scope of this study

Total number of summary reports submitted to the FDA between 1 July 2019 and 30 June 2025

Enter series to show

COREVALVE MITRACLIP VALIANT CAPTIVIA SAPIEN 3 IN.PACT ADMIRAL DCB
 WATCHMAN FLX LOTUS EDGE VALVE SHOCKWAVE IVL AMPLATZER AMULET
 PORTICO MOSES TRICLIP AGENT

Total number of summary reports submitted to the FDA between 1 July 2019 and 30 June 2025 by device



Article DOI: 10.1136/bmj-2026-100812 • Download data

*Six months only

Fig 3 | Total number of Food and Drug Administration summary reports, and adverse events, serious injuries, deaths, and malfunctions reported therein by device. An interactive version of this graphic and downloadable data are available at <https://public.flourish.studio/visualisation/30320903/>

Table 1 | Summary reporting exemptions in active use from July 2019 to June 2025

Exemption number	Device name	Data registry
E2014038	COREVALVE & EVOLUT	STS/ACC TVT Registry
E2015009	MITRACLIP	STS/ACC TVT Registry
E2015028	VALIANT CAPTIVIA	SVS VQI Registry
E2016006	SAPIEN 3	STS/ACC TVT Registry
E2017023	IN.PACT ADMIRAL	SVS VQI Registry
E2017028	WATCHMAN FLX	ACC Watchman SURPASS Registry
E2020001	LOTUS EDGE	STS/ACC TVT Registry
GEN2200325	SHOCKWAVE IVL	NCDR CathPCI Registry
GEN2201026	AMPLATZER AMULET	Amulet LAEO Registry
GEN2201027	PORTICO	STS/ACC TVT Registry
RWD2300134	PORTICO	STS/ACC TVT Registry
RWD2400413	MOSES	Truveta
RWD2400493	TRICLIP	STS/ACC TVT Registry
RWD2400570	AGENT	NCDR CathPCI Registry

Exemption numbers, device names, and data registries associated with adverse events submitted through summary reporting to the Food and Drug Administration.

STS/ACC TVT Registry=Society of Thoracic Surgeons and American College of Cardiology Transcatheter Valve Therapy Registry; SVS VQI Registry=Society for Vascular Surgery Vascular Quality Initiative Registry; ACC Watchman SURPASS Registry=American College of Cardiology WATCHMAN FLX Device Surveillance Post Approval Analysis Plan Registry; NCDR CathPCI Registry=National Cardiovascular Data Registry CathPCI Registry; Amulet LAEO Registry=Amulet Left Atrial Appendage Occlusion Registry.

events contained in summary reports were Edwards Lifesciences (44%), Medtronic (36%), Abbott Laboratories (10%), and Boston Scientific (9%) (table 2).

The summary reports often did not include information about possible device problems and failed to comply with FDA reporting requirements. For example, manufacturers reported an “adverse event without identified device or use problem” in the device problem field for 3589 summary reports (57%) and “insufficient information” for 2412 reports (38%), and did not provide additional information in the report narratives (table 3). Examples of statements commonly found in summary report narratives include “the type of serious injury information provided is limited in nature as it is provided via a third party database” and “specific clinical and procedural details are not available to determine potential contributing factors to the event, or if the event is related to [the medical device].” Figure 4 gives an illustrative example. In contrast, individual adverse event reports generally

contained clinical details of the specific adverse events as well as device problems and identification (fig 5). Manufacturers incorrectly checked “N” under the summary report (Y/N) field for 694 reports (11%). Additionally, 423 reports (7%) inaccurately listed “n=1” under the number of events field, resulting in an undercount of 11 902 adverse events (table 3). Most summary reports (55%) failed to comply with the FDA 30 day reporting deadline, with a total mean submission time of 50 days (median 35 days, SD 31 days, table 3).

Discussion

We found that a substantial number of adverse events, including deaths and serious injuries, for high risk medical devices are hidden from public view because of summary reporting exemptions. Furthermore, summary reports are pervasively inaccurate and do not meet standard FDA reporting requirements: (1) incomplete device problem identification, (2) undercounting of adverse events, evidenced by discrepancies between the number of events data field and the report narrative, which leads to undercounting of adverse events if researchers and FDA staff rely solely on structured data fields, (3) failure to correctly identify reports as summary reports, and (4) delays in serious adverse event reporting. The presence of a device problem code alone does not substitute for narrative clinical detail—such as patient factors, event chronology, and procedural details—that is typically available in individual adverse event reports and is important for comprehensive safety signal interpretation.

Our study characterises the extent of ongoing use of summary reporting; many of the harmful practices thought to have ended with the Alternative Summary Reporting programme in 2019 have continued. The use of summary reports has resulted in inaccurate adverse event counts and incomplete device problem identification. Moreover, summary reports were often

Table 2 | Device and manufacturer information for adverse events contained in summary reports from July 2019 to June 2025. Data are number (%) unless otherwise stated

Device information	No of adverse events (n=159 503)
Device type	
Cardiac	157 150 (99)
Vascular	1120 (<1)
Other	1233 (<1)
Device class	
Class 3	144 921 (91)
Class 2	14 568 (9)
Manufacturer	
Edwards Lifesciences	70 144 (44)
Medtronic	56 958 (36)
Abbott Laboratories	15 655 (10)
Boston Scientific	14 682 (9)
Lumenis	1233 (<1)
Shockwave Medical	831 (<1)

Device types, device classes, and manufacturers associated with adverse events submitted through summary reporting to the Food and Drug Administration between 1 July 2019 and 30 June 2025.

Table 3 | Report characteristics for all summary reports from July 2019 to June 2025. Data are number (%) unless otherwise stated

Characteristics	No of summary reports (n=6308)
Device problem code*	
Adverse event without identified device or use problem	3589 (57)
Insufficient information	2412 (38)
Other†	352 (6)
Summary report identification	
Correctly completed summary report field‡	5614 (89)
Incorrectly completed summary report field‡	694 (11)
Identification of number of events	
Correctly completed number of events field	5885 (93)
Incorrectly completed number of events field	423 (7)
Mandatory (≤30 days) reporting timeframes	
Report submitted ≤30 days after manufacturer made aware of adverse event	2811 (45)
Report submitted >30 days after manufacturer made aware of adverse event	3439 (55)
Date manufacturer received notification of adverse event not provided	58 (1)

Characteristics of summary reports received by the Food and Drug Administration (FDA) between 1 July 2019 and 30 June 2025, including the device problem code, summary report form field, number of events form field, and compliance with standard reporting requirements. The reported total number of adverse events in summary reports was 147 601 events; the true total number of adverse events contained in summary reports was 159 503 events. The average (mean) number of days between the date the device manufacturer received notification of an adverse event and date on which the manufacturer notified the FDA was 50 days (median 35 days, standard deviation (SD) 31 days). Serious injury, malfunctions, and death events must be reported to the FDA within 30 calendar days. Reports submitted >30 days after the manufacturer was made aware of the adverse event are considered to be late submissions.

*Manufacturers are allowed to select more than one device problem code per report.

†Device problem code category "Other" is defined as any device problem code that is not "adverse event without identified device or use problem" or "insufficient information" (eg, "device dislodged or dislocated," "positioning problem," "migration of device," and "incomplete coaptation").

‡Y/N (denoting yes/no).

submitted late, beyond the FDA 30 day reporting requirement. Such incompleteness and late reporting delays signal detection, complicates evaluation of medical devices, and does not permit accurate interpretation of publicly available safety information. These issues jeopardise the effectiveness of MAUDE and slow subsequent investigations using additional data sources. The downstream consequences are substantial: inaccurate adverse event counts mean adverse event incidence cannot be accurately determined, incomplete device problem identification limits the ability to detect emerging safety signals, and reporting delays may reduce the promptness of safety actions (eg, product recalls). These consequences all have direct implications for patient safety: nine of the 13 devices with summary reporting exemptions have been the subject of recalls,²⁴ which may have been delayed because of the difficulties of identifying individual adverse event counts and narratives from summary reports. For example, the devices that accounted for the majority of summary reports and adverse events received by the FDA, such as SAPIEN 3 device (Edwards Lifesciences) and CoreValve and Evolut systems (Medtronic), were subject to recalls in 2019 and 2021, respectively.^{25 26}

Policy and regulatory context

Identifying and correcting the existing flaws highlighted in this study are vital, particularly given the increasing number of summary reports submitted to the FDA. Between 2020 and 2024, the number of summary reports—and the number of adverse events contained within the summary reports—more than doubled. The FDA continues to grant summary reporting exemptions for new devices without established safety profiles. Several medical devices,

such as the WATCHMAN FLX, Amplatzer Amulet, Shockwave IVL, and PORTICO, received FDA approval or clearance during the study period and immediately received summary reporting exemptions from the FDA. Most recently, TriClip (Abbott Laboratories) was granted a summary reporting exemption. Our findings raise concerns that key postmarket safety information for these devices will be hidden from the public and clinicians because of summary reporting exemptions.²⁷ This process may exacerbate uncertainty soon after approval or clearance, when real world data on devices is first collected.

The FDA has a timely opportunity to resolve these shortcomings: the MAUDE database is transitioning to the new FDA adverse event monitoring system (AEMS) database.²⁸ The AEMS database is expected to consolidate legacy reporting systems, including MAUDE, into a unified platform in 2026 and will house all historical adverse event data from MAUDE.²⁸ The AEMS will publish reports in real time, rather than quarterly, in order to better serve agency scientists, researchers, and the public.²⁸ The FDA believes this represents a crucial opportunity to strengthen postmarket surveillance infrastructure, by assuring accurate, complete, and timely adverse event reports. The new system is intended to eliminate "blind spots in [the FDA] postmarket surveillance of products."²⁸

Improving transparency and surveillance

Improvements should focus on strengthening and optimising existing surveillance infrastructure. Passive, voluntary reporting systems such as MAUDE have limitations due to underreporting of adverse events, reporting bias, and inconsistent data quality. Device registries, while observational in design, can complement passive reporting by enabling active,

ABBOTT VASCULAR MITRACLIP CLIP DELIVERY SYSTEM; VALVE REPAIR		Back to Search Results
Catalog Number	UNK CDS	
Medical Device Problem Code	Adverse Event Without Identified Device or Use Problem (2993)	
Health Effect - Clinical Code	Death (1802)	
Date of Event	11/12/2020	
Type of Reportable Event	Death	
Additional Manufacturer Narrative	This will be filed as a death summary report per fda exemption approval number - e2015009. The devices were not returned for analysis. A review of the lot history record could not be performed due to unknown lot information. Based on the limited information reviewed, a cause for the reported death events could not be determined. The reported patient effect of death, as listed in the mitracclip instructions for use (ifu), is a known possible complication associated with mitracclip procedures. There is no indication of a product issue with respect to manufacture, design, or labeling. Na.	
Event or Problem Description	It was reported through transcatheter valve therapy (tvt) registry data that mitracclip devices may be related to 127 death events with the clarifier n/a. The relationship of the deaths to the mitracclip device could not be determined based on the limited data received from the registry. Patients, mean age 78 years, ranging from 28 - 98 years. 62% patients were male, 38% patients were female. Tvt registry data is reported as a summary per summary reporting exemption approval number - e2015009. No additional information was provided.	
Search Alerts/Recalls		
Brand Name	MITRACLIP CLIP DELIVERY SYSTEM	
Common Device Name	VALVE REPAIR	
Manufacturer (Section D)	ABBOTT VASCULAR 26531 Ynez Rd. Temecula CA 92591 4628	
MDR Report Key	10999280	
Report Number	2024168-2020-10421	
Device Sequence Number	2817298	
Product Code	NKM	
Combination Product (Y/N)	N	
PMA/510(K) Number	P100009	
Number of Events Summarized	1	
Summary Report (Y/N)	N	
Device Implanted Year	2019	
Reporter Type	Manufacturer	
Report Source	Study	
Type of Report	Initial	
Report Date (Section B)	12/13/2020	
1 Device was Involved in the Event		
1 Patient was Involved in the Event		
Is this an Adverse Event Report?	Yes	
Is this a Product Problem Report?	No	
Operator of Device	Health Professional	
Device Catalogue Number	UNK CDS	
Was Device Available for Evaluation?	No	
Type of Report (Section G)	Initial	
Initial Date Received by Manufacturer	11/13/2020	
Initial Report FDA Received Date	12/13/2020	
Is This a Single-Use Device that was Reprocessed and Reused on a Patient? (Y/N)	No	
Patient Sequence Number	1	
Outcome Attributed to Adverse Event	Death;	
Patient Age	76 YR	

Fig 4 | Summary report for MitraClip submitted to the Food and Drug Administration on 13 December 2020. A summary report (report No 2024168-2020-10421) submitted to MAUDE by the manufacturer of MitraClip on 13 December 2020. Details include the manufacturer narrative, event description, and manufacturer responses to fields included on the submission form. Red boxes have been added for emphasis

systematic, and longitudinal data collection in real world clinical settings. For example, the federal health insurance program Medicare requires that transcatheter aortic valve replacements be tracked in the STS/ACC TVT registry in order to secure reimbursement, and as a result, this registry can more accurately capture denominator data, although these data are not publicly available.

Using data from existing registries may therefore allow efficiencies for both manufacturers and the FDA, provided that registry data adheres to stringent reporting standards set by the FDA and is publicly available. However, the quality of registry data is highly variable and most United States registries are not independently audited. The effectiveness

of registry based postmarket surveillance remains heterogeneous and incompletely validated, varying substantially across systems in completeness, accuracy, audit quality, ascertainment practices, and the degree of manufacturer involvement in data collection and governance. The FDA should therefore establish clear qualification criteria ensuring that only registries meeting defined standards for data quality, independence, transparency, and completeness are eligible to contribute to postmarket safety reporting.

Standardising data elements across registries would further support this quality improvement goal and encourage the development of high quality clinical registries that complement standard adverse event reporting practices. Examples of required items that

ABBOTT MEDICAL MITRACLIP G4 CLIP DELIVERY SYSTEM; MITRAL VALVE REPAIR DEVICES [Back to Search Results](#)

Model Number CDS0701-KTW
Medical Device Problem Codes Incomplete Coaptation (2507); Expulsion (2933); Unintended Movement (3026)
Health Effect - Clinical Codes Foreign Body In Patient (2687); Embolism/Emboli (4438); Mitral Valve Insufficiency/Regurgitation (4451)
Date of Event 05/27/2022
Type of Reportable Event Serious Injury
Additional Manufacturer Narrative
 The clip remains in patient. The device will not be returned for evaluation. Investigation is not yet complete. A follow-up report will be submitted with all additional relevant information.

Event or Problem Description
 This is being filed to report the clip opened while locked and detached from one leaflet resulting in increased mr. It was reported that this was a mitralclip procedure to treat degenerative mitral regurgitation (mr) with a grade of 4. The clip delivery system (cda) was advanced and placed at a2p2. Post deployment it was noted the clip opened approximately 10 degrees. The procedure was completed with the mr reduced to 1. One day post procedure a follow up echocardiogram noted the clip had opened approximately 90 degrees and the clip detached from the posterior leaflet (single leaflet device attachment (slda)). Mr increased to 4. A second procedure was performed on (b)(6) 2022. It was noted the clip had embolized to the apex of the heart in the left ventricle (lv). The decision was made to leave the clip where it was in the lv as it was sitting on the bottom of the lv and not moving. Two additional clips were implanted, reducing mr to 1. No additional information was provided.

Additional Manufacturer Narrative
 The device was not returned for analysis. A review of the lot history record revealed no manufacturing nonconformities issued to the reported lot that would have contributed to this event. Additionally, a review of the complaint history did not indicate a lot-specific quality issue. A one was reviewed by a staff engineer clinical r&d, and the reviewer stated that the one noted the reported clip appears to be opened to ~60° and demonstrating significant movement throughout the cardiac cycle. While the clip arm angle cannot be confirmed and is based on visual assessment with the naked eye, it is evident that the clip arms have opened to a larger degree. Based on the rigid but repetitive movement of the clip, in addition to the observation of the single gripper arm, the video confirms the reported details that the clip experienced an slda. No video evidence of the reported complete clip detachment (cod) from the leaflets was provided. The reported recurrent mr appears to be related to the slda. Embolism and subsequent foreign body in patient were due to the clip expulsion. Mr and embolism are listed in the mitralclip instructions for use as known possible complications associated with mitralclip procedures. The reported hospitalization and unexpected medical intervention were results of case-specific circumstances. The investigation determined the reported clip expulsion appears to be a cascading effect of the reported slda. The slda appears to be related to the reported clip opened while locked. The investigation determined the reported clip open while locked appears to be related to a potential quality product issue. The issue is being addressed per internal operating procedures. Abbott vascular (av) will continue to trend the performance of these devices.

Search Alerts/Recalls

Brand Name MITRACLIP G4 CLIP DELIVERY SYSTEM
Common Device Name MITRAL VALVE REPAIR DEVICES
Manufacturer (Section D) ABBOTT MEDICAL
 5050 Nathan Lane N
 Plymouth, MN 55442-4628
Manufacturer (Section G) ABBOTT VASCULAR, REG # 3005070406
 3885 Bonannon Drive
 Menlo Park, CA 94025
Manufacturer Contact Karen Krouse
 5050 Nathan Lane N
 Plymouth, MN 55442-4628
 6517565400
MDR Report Key 14873907
Report Number 2024168-2022-06310
Device Sequence Number 10688295
Product Code NKM
UDI-Device Identifier 06717648231001
UDI-Public 06717648231001
Combination Product (Y/N) N
Initial Reporter State MD
Initial Reporter Country US
PMA/510(K) Number P100009
Number of Events Summarized 1
Summary Report (Y/N) N
Device Implanted Year 2022
Serviced by Third Party (Y/N) N
Reporter Type Manufacturer
Report Source Health Professional, Company Representative
Initial Reporter Occupation Physician
Type of Report Initial/Followup
Report Date (Section B) 08/01/2022
Device was Involved in the Event
Patient was Involved in the Event
Is this an Adverse Event Report? Yes
Is this a Product Problem Report? Yes
Operator of Device Health Professional
Device Expiration Date 01/23/2023
Device Model Number CDS0701-KTW
Device Catalogue Number CDS0701-KTW
Device Lot Number 20124R165
Was Device Available for Evaluation? No
Is the Reporter a Health Professional? Yes
Type of Report (Section G) Follow-Up
Initial Date Received by Manufacturer 05/27/2022
Supplement Date Received by Manufacturer 07/27/2022
Initial Report FDA Received Date 06/13/2022
Supplement Report FDA Received Date 08/01/2022
Was Device Evaluated by Manufacturer? (Y/N) Device Not Returned to Manufacturer
Date Device Manufactured 01/24/2022
Is the Device Labeled for Single Use? (Y/N) Yes
Is this a Single-Use Device that was Reprocessed and Reused on a Patient? (Y/N) No
Usage of Device Initial
Patient Sequence Number 1
Concomitant Medical Products and Therapy/Usage Dates STEERABLE GUIDE CATHETER
Outcome Attributed to Adverse Event Required Intervention; Hospitalization;
Patient Age 87 YR
Patient Sex Male

Fig 5 | Individual adverse event report for MitraClip submitted to the Food and Drug Administration on 13 June 2022. An individual adverse event report (report No 2024168-2022-06310) submitted to MAUDE by the manufacturer of MitraClip on 13 June 2022, including the manufacturer narrative, event description, and manufacturer responses to submission form fields. In contrast with summary reports, this individual adverse event report includes details related to the adverse event, follow-up investigations, patient demographic data, and device information. Red boxes have been added for emphasis

should be collected (and are not routinely collected) include device information (eg, the unique device identifier and the device lot numbers), analyses of

the cause of adverse events, investigations of device problems, and patient demographics. Additionally, enhancing data linkage between regulatory databases and clinical registries represents a pragmatic, incremental approach to improving surveillance. Lastly, strengthening the role of independent, academically governed registries in postmarket surveillance is essential to ensuring that registry data meaningfully complements existing passive reporting infrastructure. Academically sponsored registries are generally considered to be more objective than industry sponsored registries and better positioned to detect safety signals that may be unfavorable to manufacturers.

The lack of public access to patient level data for most registries in the United States, such as the STS/ACC TVT Registry, limits their use for independent safety monitoring by clinicians, researchers, and patients outside of participating institutions.²⁹ De-identified data from these registries must be accessible to the public in order to support transparency, safety, and equity. Furthermore, any use of registry data to inform adverse event reporting to the FDA should include public disclosure of de-identified registry data through a publicly accessible platform such as the AEMS database, to avoid perpetuating existing gaps in transparency. When registry findings are available only to participating institutions or specialty networks, clinicians and families outside these systems may lack access to critical information about device performance and safety.³⁰ This lack of access limits the ability of doctors and patients to make informed decisions or recognise emerging safety concerns.

Implementation of proposed reporting enhancements may be most feasible through a risk based approach to enhance data reliability without imposing unsustainable administrative or financial burdens on regulators or manufacturers. Prioritising higher risk devices (eg, class 3 devices, devices with limited premarket clinical evidence) for surveillance improvements would allow regulators to focus limited resources on devices with the greatest potential impact on patient safety, while minimising unnecessary burden for lower risk products. Additionally, a risk based reporting framework that prioritises investigating deaths and serious injuries may improve transparency and responsiveness within postmarket surveillance systems. Such an approach reflects established principles of risk proportionate regulation, adapting required data elements and reporting timelines to the clinical severity and uncertainty of adverse events.

Limitations of this study

Our research has limitations related to the nature of the MAUDE database. Passive reporting systems such as MAUDE have well documented limitations, including underreporting, reporter bias, and inconsistent data quality, driven in part by the predominance of manufacturer submitted reports.³¹ These limitations underscore the importance of complementary data sources, including device registries and studies after

device approval, for comprehensive postmarket surveillance. Reports may also be delayed, and long term adverse events may be omitted. Moreover, determining a causal relationship between a medical device and a reported adverse event solely based on reports available through MAUDE is impossible without additional investigation or clinical context from the reporter.

Another potential limitation of this study is the reliance on narrative text fields and structured data fields for the identification of summary reporting exemptions within MAUDE. Reports in which exemption language was absent, non-standard, or inconsistently recorded may not have been captured by our search strategy, potentially resulting in an underestimate of the total number of summary reports submitted during the study period. However, our multilayered approach, which combined structured field queries, free text keyword searches, and manual narrative review, was specifically designed to maximise capture of summary reports regardless of how exemption information was recorded. As such, any resulting selection bias would likely be minimal, and our findings may underestimate, rather than overestimate, the scope of the identified deficiencies. Future studies should consider formal sensitivity analyses using alternative search strategies to further validate these findings.

Lastly, our research is limited by the lack of information regarding the specific details outlined in the summary reporting exemptions. Incomplete reporting may arise at multiple levels of the reporting chain: in registry design, manufacturer summarization practices, and exemption structure itself. The FDA has not described the specific requirements for the FDA exemptions cited in the summary reports. We submitted a Freedom of Information Act request for a copy of the exemption requirements on 6 June 2024, which has remained unanswered. Therefore, we were unable to determine whether the inadequate details contained in summary reports reflect limited data fields in the associated registries, incomplete reporting by manufacturers when submitting summary reports, or ambiguity in the defined requirements of the FDA exemptions themselves. As this study exclusively analysed data publicly available in MAUDE, the evaluation of reporting completeness is inherently limited to publicly available information and does not reflect the quality or granularity of the underlying registry data.

Given the limited data provided in the summary reports for medical devices, no additional disaggregation of research data by sex, gender, or other patient characteristics was possible.

Box 1: Patient perspective on medical device safety data

Questions to ask your clinician

Evidence and experience

- How long has this device been in use, and how much data do we have on it?
- Was this device studied in clinical trials, registries, or through real world use?
- How was this medical device approved by the Food and Drug Administration (FDA)? Was it compared to an older device on the market or tested in new clinical trials?
- What are the most common complications and safety risks, and how often do they occur?
- How often have you used this device to treat patients? What has your experience been?
- Have you personally treated patients who have experienced complications related to this device?

Uncertainty and data availability

- Is this a new device, and if so, are there concerns about its long term safety that we do not yet know? How much long term safety data are available?
- Are safety complication rates still changing and/or increasing?

Interpreting safety data

- If I see reports of safety complications online, how should I interpret them? Are there any resources you suggest I use to better understand how safe this device is?
- Do reports published by the FDA reflect how common complications actually are for medical devices?
- Is this device subject to any reporting exemptions by the FDA that may compromise how representative the data published by the FDA may be?

Alternatives and follow-up

- Are there alternative treatment options with better long term safety and efficacy data?
- What are symptoms I should watch for after the procedure?
- How are problems with this device usually detected and handled? If something goes wrong, what should I do next?

Who can help?

- Your clinician or care team
- The hospital or clinic where the device was placed
- The device manufacturer
- The FDA MedWatch programme (Form 3500B for reporting device problems)
- Patient advocacy or support organisations

Implications for patients and caregivers

The increased transparency in adverse event data from the MAUDE database following the termination of the Alternative Summary Reporting programme is threatened by the ongoing use of summary reporting that we have identified. Summary reporting exemptions raise the same safety concerns that the terminated Alternative Summary Reporting programme presented. This poor reporting that has resulted from summary reporting exemptions may compromise informed consent quality, timely recalls, and device monitoring for patients. Additionally, because MAUDE is a passive surveillance system that is subject to reporting bias and underreporting and that lacks total device use data, these reports may be misinterpreted if used in isolation. Our findings underscore the need for careful contextualization from multiple data sources and more complete and transparent data. Patients may benefit from discussing device benefits, risks, and alternative treatments with doctors to better understand the safety concerns associated with medical devices (box 1). Patients and caretakers should also be encouraged to submit voluntary adverse event reports to the FDA themselves should device malfunctions or safety concerns arise, helping to strengthen public safety data (supplementary appendix).

Conclusion

Summary reports submitted by manufacturers do not accurately represent the total number of adverse events associated with medical devices, fail to adequately analyse potential device problems, and are often not compliant with standard FDA reporting requirements and timelines. This practice is a public health concern, because of the high risk nature of the devices associated with summary reports and the rapid rise in use of summary reporting exemptions for newly approved, high risk cardiac devices. Immediate improvements are needed to better protect patient safety and adhere to transparency principles outlined by the FDA. Making serious adverse event reports fully visible and accessible is critical to patient safety.

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Competing interests: All authors have completed the ICMJE uniform disclosure form at www.icmje.org/disclosure-of-interest/ and declare: AZ reports receiving a grant from the University of California, San Francisco School of Medicine as part of the Summer Explore programme for initial research on this topic; RFR reports receiving research funding from the Arnold Ventures Foundation and the National Institutes of Health, and MK and ST report receiving research funding from the Arnold Ventures Foundation; no other relationships or activities that could appear to have influenced the submitted work.

Ethical approval: This study used publicly available materials and did not involve human participants; ethics committee approval was not required.

Data sharing: The data used in this study are publicly available from the US Food and Drug Administration manufacturer and user facility device experience (MAUDE) database. Derived datasets and annotated analytical code used for data cleaning and analysis, including documentation and instructions sufficient to reproduce the analyses, will be made available upon reasonable request upon publication.

Transparency: The lead author (the manuscript's guarantor) affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

Dissemination to participants and related patient and public communities: This study did not involve human participants. Findings will be shared with the scientific community through publication, media interviews, press coverage, social media, and presentations.

Provenance and peer review: Not commissioned; externally peer reviewed.

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Web extra: Extra material supplied by authors

Supplementary information: Supplementary appendix