Late adverse event reporting from medical device manufacturers to the US Food and Drug Administration: cross sectional study

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ABSTRACT

OBJECTIVE

To describe the extent of late adverse event reporting by manufacturers to the US Food and Drug Administration's (FDA) Manufacturer And User Facility Device Experience (MAUDE) database as well as the distribution of late reporting among manufacturers and associations with device characteristics.

DESIGN

Cross sectional study.

SETTING

The FDA MAUDE database, a central postmarket safety surveillance tool for US medical devices, from 1 September 2019 to 31 December 2022.

PARTICIPANTS

Medical device manufacturers that submitted initial adverse event reports to the FDA between 1 September 2019 and 31 December 2022.

MAIN OUTCOME MEASURES

Time in days between date manufacturer was notified of event and date of FDA receipt of adverse event reports, proportion of reports reported late (after the required 30 day window as required by FDA regulation), and distribution of late reporting among manufacturers and medical devices.

RESULTS

13 587 reports were of deaths, 1 552 268 of injuries, and 2 866 693 of malfunctions received by the FDA from 3028 unique manufacturers and 88 448 unique medical devices in the three and a half year period. Of 4 432 548 included reports, 71.0% (n=3 146 957) of adverse events were reported within 30 days (on time), 4.5% (n=197 606) were reported between 31 and 180 days (late), and 9.1% (n=402 891) were after 180 days (late). 15.5% of reports (n=685 094) had missing or invalid date data provided by the manufacturer. Three manufactures and 13 medical devices were attributed to 54.8% of late reports.

CONCLUSIONS

Nearly a third of manufacturer reports of medical device adverse events were not demonstrably submitted to the FDA within the regulatory deadline, with most late reports being submitted more than six months after manufacturer notification. Most late reports were submitted by a small number of manufacturers. Late adverse event reporting may prevent early detection of patient safety concerns.

WHAT IS ALREADY KNOWN ON THIS TOPIC

Medical device adverse event reports in the US Food and Drug Administration's primary postmarket surveillance database have known concerns about their reliability

Multiple media reports suggest that adverse events reports from medical device manufacturers may not be submitted to the FDA within the required 30 day deadline set by federal regulations

WHAT THIS STUDY ADDS

Over 1.2 million medical device adverse event reports (nearly a third of the study sample) were not demonstrably submitted to the FDA within the deadline set by federal regulations

More than half of late medical device adverse event reports were submitted by three manufacturers

Patient safety concerns may not be identified in a timely manner due in part to late manufacturer reporting of medical device adverse events

Introduction

Most medical devices in the US and globally receive regulatory authorization based on non-clinical data or clinical trials with limitations in their design.[1-11] Given these limitations in premarket evidence, postmarket device safety surveillance is crucial. Postmarket surveillance is also increasingly important as the US Food and Drug Administration (FDA) explores and implements evaluations of existing postmarket data and future data collection plans during premarket authorization reviews. For example, through the Breakthrough Devices Program, the FDA may accept greater premarket uncertainty of the benefit-risk profile for highly novel ("breakthrough") devices, provided that the manufacturer commits to sufficient postmarket data collection.[12]

A central postmarket safety surveillance tool for US medical devices is the FDA's Manufacturer And User Facility Device Experience (MAUDE) database, where manufacturers and other stakeholders report device related adverse events and product problems (hereafter adverse events). MAUDE reports are the most common source of information used to initiate medical device safety communications, the FDA's primary mechanism for communicating postmarket device safety issues.[13]

While a key tool in detecting safety issues, MAUDE has known limitations. MAUDE relies on external individuals and organizations to report adverse events, rather than systematically and prospectively collecting safety and outcome data. Moreover, reporting is at times inaccurate and incomplete; key clinical details can be omitted from reports, and reports describing patients "expiring" or "dying" are often categorized as injuries or malfunctions rather than deaths.[14-16]

MAUDE reports may also not be timely. Over 95% of MAUDE reports are contributed by medical device

manufacturers.[17] Manufacturers are required by FDA regulation to submit adverse event reports to MAUDE within 30 days of becoming aware of them. However, recent media reports have described manufacturers withholding reports from MAUDE years beyond this deadline.[18-22] For example, the FDA determined that over the course of six years, a manufacturer of continuous positive airway pressure (CPAP) machines withheld hundreds of reports of injuries and deaths related to foam degradation in their machines, likely leading to otherwise preventable patient harm.[18] These reports have resulted in a Government Accountability Office inquiry into the FDA's oversight of manufacturer reporting and management of recalls.[23] Studies have also found that both pharmaceutical and device manufacturers sometimes withhold safety information from the public.[24-27] Delays in reporting may preclude regulators, clinicians, and patients from learning about emerging safety issues, resulting in avoidable patient harm.

This study quantified the timeliness of manufacturer reporting in the MAUDE database, including the distribution of late reporting among manufacturers and associations with device characteristics.

Methods

Medical device report data

This cross-sectional analysis was performed using the MAUDE database, a public database of adverse event reports involving medical devices.[14] Reports include device names; generic device functions; manufacturers; whether events were deaths, injuries, or product malfunctions; and dates that the FDA received the reports. Reports of death identify instances where medical device use may have caused or contributed to patient deaths, while reports of injury are instances where device use may have caused or contributed to an injury or illness that is life threatening, resulted "in permanent impairment of a body function or permanent damage to a body structure," or required a medical intervention to preclude permanent impairment or permanent damage.[28 29] Malfunctions are instances where devices did not meet performance specifications or otherwise perform as intended and did not cause or contribute to a death or injury but would likely contribute to a death or injury if the malfunction recurred.[28 29]

Manufacturers, importers, and device user facilities (certain health care facilities) must report adverse events. Others, including clinicians and patients, may voluntarily report. Over 95% of MAUDE reports are made by manufacturers,[17] who must submit reports within 30 days of becoming aware of events; manufacturers are required to report the dates that they were notified of events. Manufacturers are also required to submit reports within five working days for certain high risk events that require "requires remedial action to prevent an unreasonable risk of substantial harm to the public health," although MAUDE does not indicate which reports were subject to this requirement.[30 31]

For this study, manufacturer names as identified in MAUDE (or in device authorization databases if names were unavailable in MAUDE) were standardized by removing punctuation and division identifiers (eg, "Company X Neurology" and "COMPANY X, INC." were standardized to "COMPANY X").[32] Individual devices were identified based on unique combinations of branded device name, generic device function, and manufacturer name.

Study sample

Our study sample included manufacturer reports received by the FDA between 1 September 2019 and 31 December 2022. Before 1 September 2019, manufacturers could submit summary reports that aggregated multiple reports into a single submission outside of MAUDE (summary reports within MAUDE are still permitted).[29 33] We limited the sample to initial reports, meaning records wherein manufacturers first learned of events (versus follow up reports that describe previous events). We excluded reports listed as summary reports, missing manufacturer names, with "Other" as the event type, or missing device class.

Medical device characteristics

We identified characteristics wherein differences in reporting times may inform policy making and clinical practice. These included characteristics determined by the time of FDA authorization (hereafter preauthorization characteristics), including whether devices were lifesaving or life sustaining (hereafter lifesaving), whether devices were implantable, whether devices qualified for the Breakthrough Devices Program, clinical specialty of device, and device class. Devices are assigned to one of three classes based on patient risk, which informs the evidence needed to evaluate their safety and effectiveness.[34] Other characteristics included whether devices were the subject of an ongoing recall at the time that the FDA received the report or the subject of a terminated recall (ie, necessary corrective and preventive actions completed) when the FDA received the report.

Clinical specialty, class, lifesaving status, and implantable status were identified based on device product type codes and generic descriptions of device functions.[35] Breakthrough status and recall status were assessed using public FDA data.[36 37] We considered all classes of recalls. Recall status was only assessed for class II and III (intermediate and high risk) devices[38 39]; class I (low risk) devices do not have individual authorization records and cannot be reliably linked to FDA recall data.

Outcomes

The main outcome of interest was report time, the difference between the date a manufacturer reported that they were notified of an event and the date the FDA received the report. Report times were classified as filed in 0 to 30 days (required by regulation), 31 to 180 days, 181 days or greater, less than 0 days (reporting error caused by an invalid date), or missing manufacturer

Table 1 | Medical device report times by event type

Characteristic	Death (n=13 587)	Injury (n=1 552 268)	Product malfunction (n=2 866 693)	Total (n=4 432 548)
Unique manufacturers	397	1949	2032	3028
Unique devices	2584	48 003	49 372	88 448
Report time, mean (SD)*†	54.3 (171.1)	61.7 (151.1)	99.5 (270.2)	89.6 (245.2)
Report time, median (IQR)*†	23 (13)	22 (15)	17 (20)	19 (20)
Reported within 30 days, No. (%)	12 408 (91.3)	772 543 (49.8)	2 362 006 (82.4)	3 146 957 (71.0)
Reported from 31 to 180 days, No. (%)	377 (2.8)	126 431 (8.1)	70 798 (2.5)	197 606 (4.5)
Reported over 180 days, No. (%)	627 (4.6)	71 620 (4.6)	330 644 (11.5)	402 891 (9.1)
Missing or invalid date, No. (%)	175 (1.3)	581 674 (37.5)	103 245 (3.6)	685 094 (15.5)

SD=standard deviation; IQR=interquartile range.
*Report time defined based on difference between day Food and Drug Administration reported receiving device report and day manufacturer reported becoming aware of device event.
†Mean report time and percentiles only calculated for non-missing and non-negative report times.

notification date (missing report times). Report times greater than 30 days were considered late.

Statistical analysis

Means and percentiles for non-negative and non-missing report times were calculated. Proportions of reports that were reported late or had missing or invalid notification dates were calculated for each manufacturer and medical device. To characterize concentration in reporting patterns, manufacturers and devices were ranked on the basis of numbers of late reports, on time reports, and reports with missing or invalid dates. Distributions of late and on time reports across months were calculated to assess whether reports were released consistently throughout the sample period or concentrated in certain months; concentration in months was assessed via Gini coefficients.[40]

Z tests were performed to compare differences in Gini coefficients and in late reporting by device characteristics among reports with non-negative and non-missing report times. Cuzick tests were performed to assess whether month-by-month trends were present in late reporting.[41] Q values were calculated via the Simes procedure to adjust two sided P values for multiple testing. A significance threshold of Q<0.05 was used, implying a false discovery rate of 5%.[42-44] Statistical analyses were performed using Stata 15 SE.

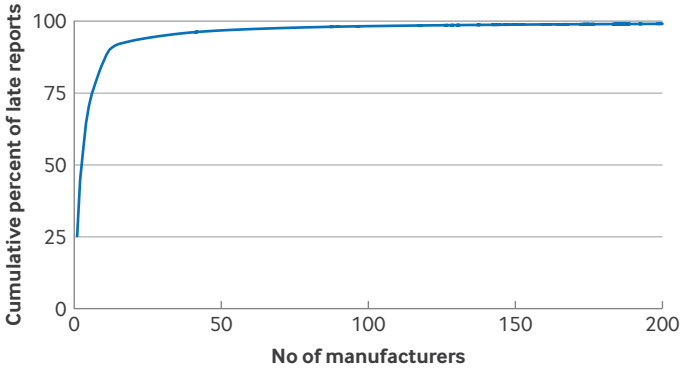

Fig 1 | Cumulative proportion of medical device reports among top 200 manufacturers with most late reports. Report time, defined as the difference between the day the FDA received a device report and the day the manufacturer became aware of the event, was considered late if it exceeds 30 days. Top 200 manufacturers ranked on late reports accounted for over 99% of all late device reports. Created using the analytical sample presented in appendix figure 6

Patient and public involvement

We did not directly involve patients or the public as part of the design or conduct of this study because we did not have funding to do so. However, this study was motivated in part by media reports of patient harm potentially caused by late reporting.[18-22] Additionally, as we prepared our findings for publication, we reviewed results with the leader of a patient and stakeholder advocacy group to ensure the importance of the work and revised the manuscript to improve its clarity, particularly results reporting and the implications of our findings.

Results

Study sample

Manufacturers reported 4 528 153 initial medical device reports in the MAUDE database to the FDA between 1 September 2019 and 31 December 2022. We excluded 57 779 (1.3%) for being a summary report and 37 826 (0.8%) for missing manufacturer name, device class, or event type. The resulting sample included 4 432 548 reports (98% of all initial manufacturer reports) (appendix table 1). These included 13 587 deaths, 1 552 268 injuries, and 2 866 693 malfunctions from 3028 unique manufacturers and 88 448 unique devices (table 1).

Extent of late reporting

Overall, 3 146 957 (71.0%) reports were made within 30 days (on time), 197 606 (4.5%) were between 31 and 180 days (late), 402 891 (9.1%) were after 180 days (late), and 685 094 (15.5%) had missing or invalid receipt dates (dates suggesting negative report times) (table 1). Among the 13.6% of reports made late, 66.9% were reported after 180 days. 1004 deaths (7.4%) were reported late, as were 198 051 (12.7%) injuries and 401 442 (14.0%) malfunctions. On time reporting significantly declined over time both overall (Q=0.02) and for deaths (Q=0.02) and injuries (Q<0.001) specifically, while on time reporting for malfunctions was stable over time (Q=0.81) (appendix figures 1-4). Approximately 99% of reports with missing or invalid receipt dates were categorized as such due to missing receipt dates (appendix table 2).

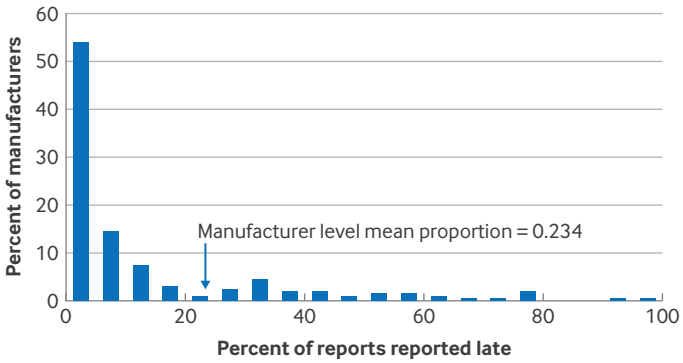

Fig 2 | Histogram distribution of proportion of medical device reports reported late among top 200 manufacturers with most total reports. Report time, defined as the difference between the day the FDA received a device report and the day the manufacturer became aware of the event, was considered late if it exceeds 30 days. Top 200 manufacturers ranked on total reports accounted for over 99% of all device reports. Created using the analytical sample presented in appendix figure 6

On time reporting rates ranged from 24.9% for dental devices to 99.7% for immunology devices (appendix table 3). Appendix figure 5 presents histograms of late report times.

Distribution of late reporting

Late reports were concentrated among a few manufacturers: three (0.1%) manufacturers contributed 54.8% of late reports (fig 1). The mean late reporting rate at the manufacturer level was 23.4% (fig 2). Among the top 200 manufacturers as ranked by total reports, 68.5% of manufacturers had fewer than 10% of their reports submitted late. The top 10 manufacturers ranked by the highest total number of late reports were: Becton Dickinson, Medtronic, Dentsply, Abbott, Boston Scientific, Nobel Biocare, Dexcom, Altatec, Biohorizons Implant Systems, and Institut Straumann (table 2). Reports with missing or invalid dates were more concentrated among manufacturers, while on time reports were less concentrated. (appendix table 4 and appendix figures 7-8).

Late reports were similarly concentrated among a few devices: 13 (<0.1%) devices accounted for 50.4% of late reports (fig 3). Overall, 71.5% of the top 200 devices had fewer than 10% of their reports submitted late (fig 4). The top 10 devices as ranked by total late reports included Becton Dickinson's infusion pumps, Abbott's glucose monitors, Medtronic's insulin pumps, Biohorizons Implant Systems' dental implants, and Dexcom's glucose monitors (table 3).

Late reports were more likely to be released in short time periods (Gini coefficient=0.554), while reports that were on time were more gradually released throughout the study period (Gini coefficient=0.278; Q<0.001) (appendix fig 9). Similar patterns were observed for death, injury, and malfunction reports (appendix fig 10-12). Distributions of reports over time for the top 10 devices as ranked by total late reports are presented in appendix figures 13-22.

Table 2 | Ranking based on the highest number of late medical device reports by top 10 manufacturers

Rank	Name	Total reports	Total late reports	Percent of all late reports, %
1	Becton Dickinson	1 087 292	151 617	25.2
2	Medtronic	415 809	116 958	19.5
3	Dentsply	117 481	60 727	10.1
4	Abbott	140 964	57 832	9.6
5	Boston Scientific	112 132	36 767	6.1
6	Nobel Biocare	366 448	25 362	4.2
7	Dexcom	542 333	18 567	3.1
8	Altatec	35 529	18 161	3.0
9	Biohorizons Implant Systems	42 569	17 097	2.8
10	Institut Straumann	316 851	14 168	2.4

Late reporting by preauthorization characteristics

Among reports with no missing or invalid report times, higher risk devices had higher percentages of late reports: 6.9% (95% confidence interval (CI) 6.7% to 7.1%) of the 70 160 reports for class I (low risk) devices were late compared with 13.8% (13.8% to 13.9%, Q<0.001) of the 2 667 628 reports for class II (intermediate risk) devices, and 22.4% (22.3% to 22.5%, Q<0.001) of the 1 009 666 reports for class III (high risk) devices (table 4). Late reporting by class varied by event type. Class III devices had the lowest percentage of injury reports reported late but the highest percentage of malfunction reports reported late. No significant differences were noted in late death reports by device class.

Reports related to lifesaving devices and implantable devices had higher percentages of late reports compared with non-lifesaving and non-implantable devices for injury reports but lower percentages of late reports for death and malfunction reports (table 4).

Breakthrough devices had less late reporting compared with non-breakthrough devices: 2.6% of the 3865 reports for breakthrough devices were reported late (2.1% to 3.1%), compared with 16.0% of the 3 743 589 reports for non-breakthrough devices (16.0% to 16.1%, Q<0.001). Results were similar for injury and malfunction reports. However, among death reports, 18.9% (11.1% to 26.8%) were late for breakthrough devices, compared with 7.4% (7.0% to 7.8%, Q<0.001) for non-breakthrough devices.

Differences in mean report times were qualitatively similar for device class and implantable status, but lifesaving devices had a lower mean report time for injuries compared with non-lifesaving devices and breakthrough devices had a lower mean report time for deaths compared with that of non-breakthrough devices (appendix table 5).

Late reporting by recall status

For reports related to class II and class III devices without missing or invalid report times, associations between recall status and report times varied by the adverse event type. Overall, class II and III devices with ongoing recalls and terminated recalls (recalls since resolved as manufacturers completed necessary corrective and preventive actions) had less late

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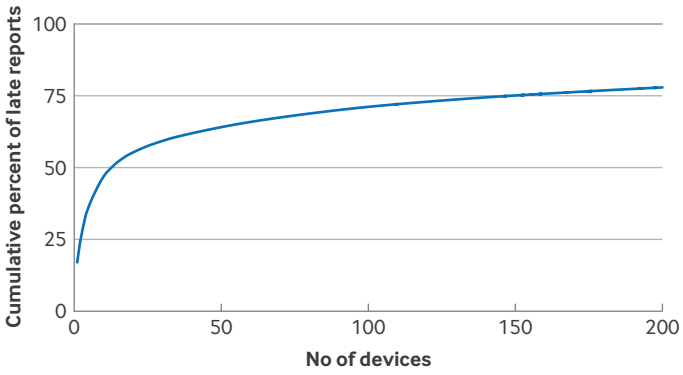

Fig 3 | Cumulative proportion of medical device reports among top 200 devices with most late reports. Report time, defined as the difference between the day the FDA received a device report and the day the manufacturer became aware of the event, was considered late if it exceeds 30 days. Top 200 devices ranked on late reports accounted for over 78% of all late device reports. Created using the analytical sample presented in appendix figure 6

reporting compared with non-recalled devices. Of the 1 277 990 reports for devices with at least one ongoing recall, 201 058 were late (15.7% (95% CI 15.7 to 15.8%)), compared with 394 573 of the 2 399 304 reports (16.4% (16.4% to 16.5%, Q<0.001)) for devices with no ongoing recalls (table 5). Similarly, 41 039 (13.9% (13.7% to 14.0%)) of the 296 061 reports for devices with at least one terminated recall were late, compared with 554 592 (16.4% (16.4% to 16.4%)) of the 3 381 233 reports for devices with no terminated recalls (Q<0.001).

In contrast to the overall results, death and injury reports for recalled devices were more likely to be reported late than devices with no ongoing recalls: 97 (18.7% (95% CI 15.4% to 22.1%)) of 518 death reports for devices with ongoing recalls were late compared with 865 (7.0% (6.6% to 7.4%)) of 12,790 death reports for devices with no ongoing recalls (Q<0.001; table 5). 22.9% (22.6% to 23.1%) of the 109 177 injury reports for devices with ongoing recalls were late, compared with 20.1% (20.0% to 20.2%) of the 855 057 injury reports for devices with no ongoing recalls (Q<0.001; table 5). Similar patterns in late death and injury reporting were present for terminated recalls.

When looking at mean report times rather than late reporting rates, devices with ongoing recalls had a higher mean report time compared with devices with no ongoing recalls, while devices with terminated recalls had a lower mean report time compared with devices with no terminated recalls (appendix table 6).

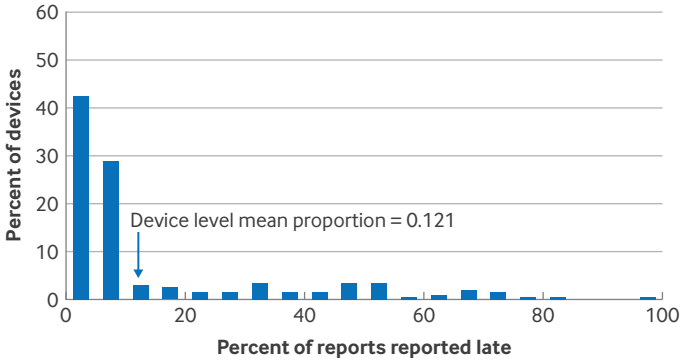

Fig 4 | Histogram distribution of proportion of medical device reports reported late among top 200 devices with most total reports. Report time, defined as the difference between the day the FDA received a device report and the day the manufacturer became aware of the event, was considered late if it exceeds 30 days. Top 200 medical devices ranked on total reports accounted for over 67% of all device reports. Created using the analytical sample presented in appendix figure 6

Discussion

Principal findings

In this cross sectional analysis of over 4 000 000 medical device adverse event reports submitted by manufacturers to the FDA's MAUDE database between 1 September 2019 and 31 December 2022, over 1 000 000 reports (nearly a third of all reports) were not demonstrably reported within the timeframe allowed by the FDA. Over 400 000 reports were reported more than six months (180 days) after manufacturer notification of the event, representing more than two thirds of all late reports. Many of the devices with large numbers of late reports were crucial to patient care, including devices like infusion pumps used in hospitals and continuous glucose monitors used by patients in ambulatory settings. Late reporting to the MAUDE database could preclude identification of patient safety concerns in a timely manner.

Policy implications

Late death reports are potentially the most serious omission from MAUDE and were concentrated in problematic areas. Breakthrough device deaths were reported late more often than non-breakthrough device deaths. This finding is concerning because breakthrough devices may have less developed premarket evidence supporting their safety and efficacy,[12 45 46] meaning any late reporting for breakthrough devices could have an outsized public health impact relative to late reporting for non-breakthrough devices. However, fewer than 100 death reports were made for breakthrough devices, and injuries and malfunctions were more often reported on time for breakthrough devices. Nonetheless, the program's rapid growth in combination with the potential public health impact of any late reporting for breakthrough devices suggests greater attention is warranted regarding their safety and reporting practices.[36]

Class II and III (intermediate and high risk) recalled devices had a lower overall late reporting rate but higher late reporting rates for deaths and injuries compared with devices with no recalls. Put differently, recall initiation was followed by the reporting of serious adverse events that should already have been reported to the FDA, according to regulations. Additionally, late reports were disproportionately released in large batches and in short time periods rather than consistently over time. For example, 7% of late reports in the study were attributable to one glucose monitor

Table 3 | Ranking based on number of late medical device reports by top 10 devices

Rank	Product name	Generic name	Manufacturer name	Total reports	Total late reports	Percent of all late reports, %
1	8100 Alaris pump module	Pump, infusion	Becton Dickinson	139 140	102 079	17.0
2	Libre sensor freestyle	Flash glucose monitoring system	Abbott	52 958	42 309	7.0
3	8015 Alaris system pc unit	Pump, infusion	Becton Dickinson	45 357	31 562	5.3
4	Pump mmt-1780kpk 670 g pathway black mg	Artificial pancreas device system, single hormonal control	Medtronic	60 324	26 857	4.5
5	Biohorizons dental implant	Dental implant	Biohorizons Implant Systems	42 493	17 040	2.8
6	640 g insulin pump mmt-1712k	Pump, infusion, insulin, to be used with invasive glucose sensor	Medtronic	26 662	15 123	2.5
7	Dexcom g6 continuous glucose monitoring system	Continuous glucose monitor	Dexcom	512 378	12 759	2.1
8	640 g insulin pump mmt-1711k	Pump, infusion, insulin, to be used with invasive glucose sensor	Medtronic	18 837	12 652	2.1
9	630 g insulin pump mmt-1715k 630 g black mg	Artificial pancreas device system, threshold suspend	Medtronic	21 627	11 403	1.9
10	8110 Alaris syringe pump	Pump, infusion	Becton Dickinson	19 515	9976	1.7

Manufacturers identified based on standardized version (removing extraneous punctuation, abbreviations, etc) of manufacturer name as reported in manufacturer and user facility device experience database or medical device approval or clearance databases if name was unavailable in the manufacturer and user facility device experience database. Medical devices are identified based on unique combinations of branded device name, generic device name, and manufacturer name. Report time defined based on difference between day Food and Drug Administration reported receiving device report and day manufacturer reported becoming aware of device event. Late reports are defined as those with report times greater than 30 days. "percent of all late reports" denotes what percent of all late medical device reports during the sample period were attributed to the given manufacturer or medical device.

(table 3). This device had a relatively constant flow of on-time reports during the sample period, but nearly 100% of its late reports were released in March 2021 (appendix fig 10), the same month the manufacturer issued a recall for the monitor.[47 48] This bunching pattern, observed both when looking at specific medical devices with large numbers of late reports and the entire sample (appendix fig 5-18), is consistent with media reports of manufacturers only reporting important safety information after recall initiation or other high profile events.[18 19] Releasing large batches of late reports may be especially concerning, as clinicians or patients may have been able to respond to the earliest reports of deaths and injuries within the batch and avoid later ones had the reports been released more consistently.

Reporting delays could stem from manufacturers knowingly withholding important safety information from the public, as has been previously reported.[18-22] At the same time, delays could also represent the time required for manufacturers to verify adverse events and gather additional information before reporting events to the FDA. Nonetheless, late reporting is not permitted under existing regulations, regardless of intent. Withholding safety information may cause avoidable patient harm given the role the MAUDE database currently has in identifying emerging safety issues.[13]

The findings from this study collectively show that while the MAUDE database often informs FDA safety actions,[13] this data source is incomplete for understanding medical device safety issues due to late adverse event reporting from manufacturers. Besides impacting how policy makers, clinicians, and patients make medical decisions, this may affect future device development. In a draft guidance for its largest device authorization pathway, the FDA has proposed that manufacturers use MAUDE reports to establish safety profiles for devices under review.[49] As these reports may be missing, manufacturers may incorrectly conclude that devices are safe by interpreting a lack of reports as a lack of adverse events rather than improper reporting.

Policy actions could address late reporting. Most reports were not late, and most late reports were submitted by just a few manufacturers, indicating that on time reporting is generally feasible under existing regulations. Accordingly, a limited number of FDA warning letters and follow-up enforcement actions related to consistently violative manufacturers may sufficiently deter late reporting. Mechanisms for enforcing manufacturer reporting requirements include "seizure, injunction, civil money penalties, and criminal prosecution."[50] However, the FDA instead typically "relies on the goodwill and cooperation" of manufacturers, rather than using the full set of sanctions available to the agency.[51] Insufficient enforcement may give manufacturers the impression that late reporting will be tolerated and result in ultimately harming patients by delaying access to important safety information.

Apart from stronger enforcement, the FDA and other organizations have intermediate steps they could pursue. The FDA could require manufacturer notification dates on electronic submissions of reports.[52] Given that almost all reports with invalid date information simply did not report the manufacturer notification date, this change would likely improve the quality of reports in MAUDE. Additionally, the FDA could consider regularly publishing a list of manufacturers or devices associated with large numbers of late reports. Such a list could help to inform patient and clinician decision making regarding medical device selection, as well as spur manufacturers to submit timely reports for the sake of avoiding negative media attention. The FDA has previously been reluctant to pursue strategies

Table 4 | Differences in percent reported late by event type and preauthorization device characteristics

Pre-authorization device characteristics	All				Death				Injury				Malfunction			
	Total No.	Reported late		Q	Total No.	Reported late		Q	Total No.	Reported late		Q	Total No.	Reported late		Q
		No.	% (95% CI)			No.	% (95% CI)			No.	% (95% CI)			No.	% (95% CI)	
Device class																
Class I	70 160	4866	6.9 (6.7 to 7.1)	Ref	104	12	11.5 (5.4 to 17.7)	Ref	6360	1085	17.1 (16.1 to 18.0)	Ref	63 696	3769	5.9 (5.7 to 6.1)	Ref
Class II	2 667 628	369 369	13.8 (13.8 to 13.9)	<0.001	2994	292	9.8 (8.7 to 10.8)	0.59	586 602	153 235	26.1 (26.0 to 26.2)	<0.001	2 078 032	215 842	10.4 (10.3 to 10.4)	<0.001
Class III	1 009 666	226 262	22.4 (22.3 to 22.5)	<0.001	10 314	700	6.8 (6.3 to 7.3)	0.06	377 632	43 731	11.6 (11.5 to 11.7)	<0.001	621 720	181 831	29.2 (29.1 to 29.4)	<0.001
Lifesaving device																
Non-life saving	3 476 956	557 059	16.0 (16.0 to 16.1)	Ref	8622	797	9.2 (8.6 to 9.9)	Ref	862 051	173 781	20.2 (20.1 to 20.2)	Ref	2 606 283	382 481	14.7 (14.6 to 14.7)	Ref
Life saving	270 498	43 438	16.1 (15.9 to 16.2)	0.64	4790	207	4.3 (3.7 to 4.9)	<0.001	108 543	24 270	22.4 (22.1 to 22.6)	<0.001	157 165	18 961	12.1 (11.9 to 12.2)	<0.001
Implantable device																
Non-implantable	2 778 561	394 013	14.2 (14.1 to 14.2)	Ref	4996	609	12.2 (11.3 to 13.1)	Ref	186 066	8 053	4.3 (4.2 to 4.4)	Ref	2 587 499	384 351	14.9 (14.8 to 14.9)	Ref
Implantable	968 893	206 484	21.3 (21.2 to 21.4)	<0.001	8416	395	4.7 (4.2 to 5.1)	<0.001	784 528	189 998	24.2 (24.1 to 24.3)	<0.001	175 949	16 091	9.1 (9.0 to 9.3)	<0.001
Breakthrough status																
Non-breakthrough	3 743 589	600 396	16.0 (16.0 to 16.1)	Ref	13 317	986	7.4 (7.0 to 7.8)	Ref	969 253	197 978	20.4 (20.3 to 20.5)	Ref	2 761 019	401 432	14.5 (14.5 to 14.6)	Ref
Breakthrough	3865	101	2.6 (2.1 to 3.1)	<0.001	95	18	18.9 (11.1 to 26.8)	<0.001	1341	73	5.4 (4.2 to 6.7)	<0.001	2429	10	0.4 (0.2 to 0.7)	<0.001

Report time defined based on difference between day Food and Drug Administration reported receiving device report and day manufacturer reported becoming aware of device event. Late reports were defined as those with report times greater than 30 days. Only reports with non-missing and non-negative report times included in statistical analyses. Statistical tests of differences in percentages compared percentages to reference group (denoted with Ref). Q values adjusted two sided P values for multiple testing and were estimated via the Simes procedure based on 64 total tests of statistical significance in analyses.
CI=Confidence interval

that involve singling out violative manufacturers.[53] However, other government and non-government organizations could publish a similar list, given that the MAUDE database is publicly accessible.

More generally, this study highlights the limitations of passive postmarket surveillance systems that rely on manufacturers and other non-government entities to report safety information to regulators, as well as the need to develop more active postmarket surveillance mechanisms. The US is not unique in this regard, as many countries primarily use passive surveillance mechanisms to detect emerging device safety issues.[54] Efforts to routinely collect standardized information on medical device usage and outcomes in national and global databases, such as integrating unique device identifiers into administrative claims and electronic health records, would likely provide a more comprehensive assessment of real-world safety outcomes compared with relying on manufacturers and others to passively report information.[55-57] Such efforts would also complement existing surveillance mechanisms such as device registries and postmarket studies ordered by the FDA, which are only available for a limited number of devices.[58 59]

Efforts to implement safety surveillance systems based on unique device identifiers would require few additional resources from medical device manufacturers, as most manufacturers already comply with the FDA's 2013 final rule to include unique device identifiers on all medical devices.[60] Instead, the costs of implementing such systems would likely fall on federal regulators and health care providers. The FDA estimates that establishing and maintaining an active medical device postmarket surveillance system would cost the agency US$8 million per year.[61] Health care providers also often face logistical difficulties in initially implementing safety surveillance system integration into medical records, but those that do report clinical and operational benefits as well as revenue potential.[60 62-68] In short, while establishing an active medical device surveillance system is not without its costs and challenges, doing so is feasible and would represent an important advance relative to the limitations of passive surveillance approaches as identified in this study.

Limitations

This study had several limitations. Firstly, measuring report times depended on dates reported by manufacturers, which may have been misreported. Secondly, MAUDE does not differentiate between reports with a five work day reporting requirement versus a 30 day requirement. This study only characterized report times greater than 30 days as late, meaning late reporting may be underestimated. However, an older analysis conducted by the FDA show that less than 0.1% of adverse event reports were subject to the five work day reporting requirement as of 2007, potentially indicating that the extent to which our study underestimates late reporting may be small.[69] Thirdly, MAUDE cannot identify unreported

Table 5 | Differences in percent reported late by event type and recall status

Recall status	All				Death				Injury				Malfunction			
	Total No.	Reported late		Q	Total No.	Reported late		Q	Total No.	Reported late		Q	Total No.	Reported late		Q
		No.	% (95% CI)			No.	% (95% CI)			No.	% (95% CI)			No.	% (95% CI)	
Ongoing recall																
No ongoing recall	2 399 304	394 573	16.4 (16.4 to 16.5)	Ref	12 790	895	7.0 (6.6 to 7.4)	Ref	855 057	172 008	20.1 (20.0 to 20.2)	Ref	1 531 457	221 670	14.5 (14.4 to 14.5)	Ref
At least one ongoing recall	1 277 990	201 058	15.7 (15.7 to 15.8)	<0.001	518	97	18.7 (15.4 to 22.1)	<0.001	109 177	24 958	22.9 (22.6 to 23.1)	<0.001	1 168 295	176 003	15.1 (15.0 to 15.1)	<0.001
Terminated recall																
No terminated recall	3 381 233	554 592	16.4 (16.4 to 16.4)	Ref	12 630	923	7.3 (6.9 to 7.8)	Ref	846 592	170 464	20.1 (20.0 to 20.2)	Ref	2 522 011	383 205	15.2 (15.2 to 15.2)	Ref
At least one terminated recall	296 061	41 039	13.9 (13.7 to 14.0)	<0.001	678	69	10.2 (7.9 to 12.5)	0.007	117 642	26 502	22.5 (22.3 to 22.8)	<0.001	177 741	14 468	8.1 (8.0 to 8.3)	<0.001

Report time defined based on difference between day Food and Drug Administration reported receiving device report and day manufacturer reported becoming aware of device event. Late reports were defined as those with report times greater than 30 days. Only reports for class II and class III medical devices with non-missing and non-negative report times included in statistical analyses. Statistical tests of differences in percentages compared percentages to reference group (denoted with Ref). Q values adjusted two sided P values for multiple testing and were estimated via the Simes procedure based on 64 total tests of statistical significance in analyses.
CI=confidence interval

adverse events, including events where manufacturers were not notified and events where manufacturers were notified but did not report.

Fourthly, this study did not directly identify harms caused by late reporting. Identifying such harms is difficult without a nationwide active surveillance infrastructure, as the relevant exposures (late reporting in MAUDE) and safety outcomes (for which MAUDE would be the likely data source) are necessarily linked. Fifthly, analyses examining associations between device characteristics and report times were exploratory and not causal. This study was unable to determine why manufacturers report late and their underlying motivations for doing so. However, late reporting is not permitted under existing regulations, meaning greater policy attention is warranted regardless of the cause.

Conclusions

This study found that during a recent three and a half year period, nearly a third of initial manufacturer reports of adverse events in the MAUDE database were not demonstrably reported on time, with over two thirds of late reports submitted more than six months after manufacturer notification of events. More than 50% of late reports were attributable to three manufacturers. MAUDE is an incomplete data source for understanding medical device safety issues, due partly to the timeliness of its reports.

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Data sharing: Statistical code and datasets are available on Mendeley Data at https://data.mendeley.com/datasets/mydr3vdzcr/1.

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: Results will be shared via the dissemination teams at Washington University in St Louis, University of Minnesota, University of California, San Francisco, and Yale University. Typical mediums include press releases, social media posts (X, Instagram, Facebook, and LinkedIn), and emails sent directly to journalists representing outlets such as the New York Times, STAT, ProPublica, Regulatory Focus, and Becker's Hospital Review, which summarize the study's main findings. The authors will publish a plain language summary of the study and its implications to a publicly available website. The authors will also provide public comments to government agencies when agencies solicit public input.

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Web appendix: Extra material supplied by authors