Medical Device Reporting Variance E2020002

for

Essure (P020014)

Final MDR Analysis Report

Medical Device Reports

Report Number: Final
Period: 01-JUN-2020 to 31-MAR-2021
Report Date: 29-JUN-2021
Version 1.0

Introduction

This final report contains information related to medical device reports (MDRs) derived from social media received in litigation. MDRs have many notable limitations, and they cannot be used alone to establish or compare rates of event occurrence. Based on the limited information in the event descriptions for the reports and the nature of the information, it is difficult to identify duplicate reports within this report, as well as duplicate reports previously submitted to the FDA. The limited information prevents the ability to draw any conclusions as to whether the device, or its removal, caused or contributed to any of the events described in this report.

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Background and Scope

On 24-APR-2020 the Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) approved Bayer's request for variance, E2020002, under 21 CFR 803.19(b) from certain medical device reporting requirements prescribed in 21 CFR Part 803 for the Essure System ("Essure"), approved under Premarket Approval (PMA) Application P020014, on November 4, 2002.

This variance is limited to MDR reports for Essure that Bayer becomes aware of from information received November 2016 through November 2020 in connection with litigation regarding Essure and that is derived from the following two sources:

a. publicly available social media information regarding certain Essure plaintiffs identified by Bayer's outside legal counsel; and
b. social media documents produced by plaintiffs' lawyers to Bayer's outside legal counsel.

The conditions of the variance include submission of a quarterly MDR analysis report after the close of each three-month period, as well as this final MDR analysis report. The scope of this final MDR analysis report is MDR reportable events submitted to the FDA as part of the variance for reports processed within the respective ten-month period. This analysis will capture all the requirements outlined in the FDA variance letter dated April 24, 2020.

Although MDRs are a valuable source of information, this passive surveillance system has limitations, including the potential submission of incomplete, inaccurate, untimely, unverified, or biased data. In addition, the incidence or prevalence of an event cannot be determined from this reporting system alone due to under-reporting of events, inaccuracies in reports, lack of verification that the device caused the reported event, and lack of information about frequency of device use. Because of this, MDRs comprise only one of the FDA's several important post-market surveillance data sources.

- MDR data alone cannot be used to establish rates of events, evaluate a change in event rates over time or compare event rates between devices. The number of reports cannot be interpreted or used in isolation to reach conclusions about the existence, severity, or frequency of problems associated with devices.
- Confirming whether a device actually caused a specific event can be difficult based solely on information provided in a given report. Establishing a cause-and-effect relationship is especially difficult if circumstances surrounding the event have not been verified or if the device in question has not been directly evaluated.
- MAUDE data does not represent all known safety information for a reported medical device and should be interpreted in the context of other available information when making device-related or treatment decisions.
- Submission of a medical device report and the FDA's release of that information is not necessarily an admission that a product, user facility, importer, distributor, manufacturer, or medical personnel caused or contributed to the event.[1]

[1] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm#fn1

Analysis

Data Source

Data sourced for the provision of this final MDR analysis report includes the reported line-item tabular data in ten spreadsheets[2] for the cumulative reporting period from 01-JUN-2020 to 31-MAR-2021 submitted as part of the Medical Device Reporting Variance Request for Essure (E2020002).

Reports processed and submitted by Bayer as part of this variance do not necessarily represent unique reports, but rather events identified in comment threads from social media posts, sometimes by the same individual. The time period in which the reports were processed also do not represent the time period in which the events occurred. Based on the limited information in the event descriptions for the reports and the nature of the information, it is difficult to identify duplicate reports within the spreadsheet of events, as well as duplicate reports previously submitted to the FDA. The limited information prevents the ability to draw any conclusions as to whether the device, or its removal, caused or contributed to any of the reported deaths or other events in the reports.[3]

In order to contextualize the received reports, a comparison of trends for all events reported under this variance to trends for all other initially reported MDRs related to Essure is provided. These reports, which are classified as 'non-variance other sources', include all Essure MDRs originating from different sources (e.g. spontaneous reports, medical literature) and submitted to the FDA as initial MDRs (outside of the variance) during the same time period (between 01-JUN-2020 and 31-MAR-2021).

[2] Spreadsheets: https://www.fda.gov/medical-devices/essure-permanent-birth-control/problems-reported-essure#reports
[3] https://www.fda.gov/medical-devices/essure-permanent-birth-control/problems-reported-essure

Comprehensive analysis

A comprehensive analysis of reports submitted to the FDA for the cumulative period has been performed and is provided below.

Total number of events by report type and patient or device problem code

Figure 1. Total number of variance MDRs by month submitted (Jun-2020 to Mar-2021)

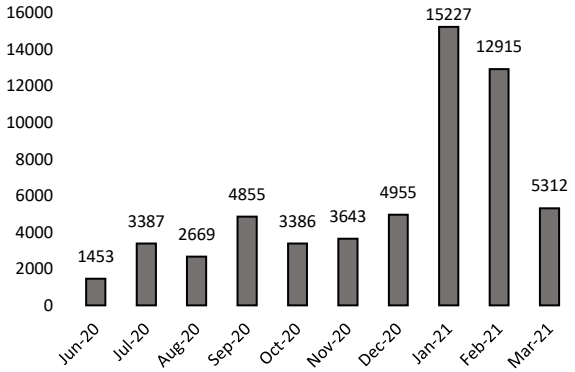


Figure 2. Total number of serious injury variance MDRs by month submitted (Jun-2020 to Mar-2021)

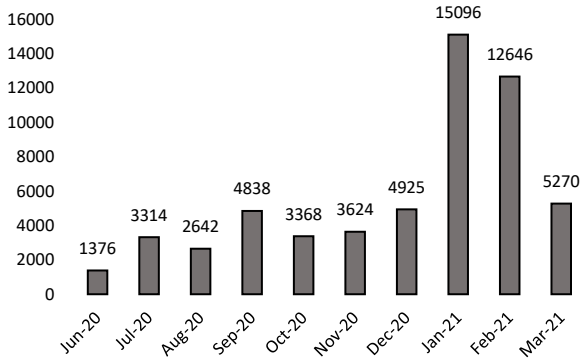


Figure 3. Total number of malfunction variance MDRs by month submitted (Jun-2020 to Mar-2021)

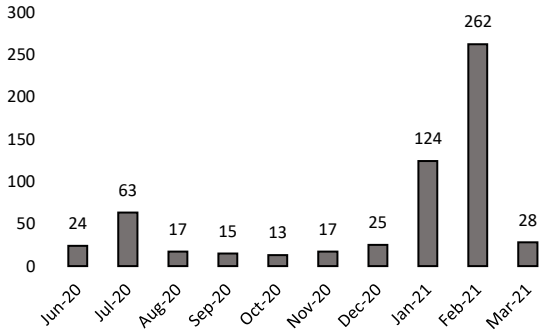
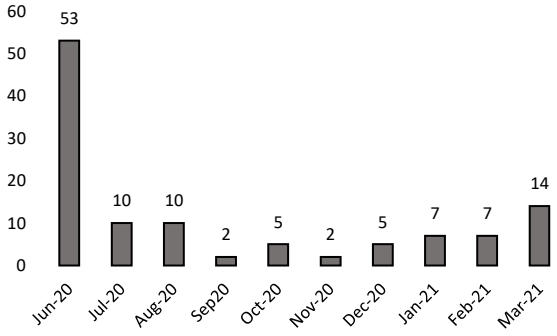


Figure 4. Total number of death variance MDRs by month submitted (Jun-2020 to Mar-2021)



Overall, there have been 57099 serious injuries, 588 malfunctions, and 115 deaths reported throughout the course of the variance for a total of 57802 MDRs.

For variance reports submitted, the time in which reports were processed does not necessarily represent the time in which the events reportedly occurred or when the patient made the information publicly available. Variance MDRs processed during the months of JAN-2021 and FEB-2021, on average, have fewer source documents per report compared to previous months. Therefore, the reduction in processing time per report contributed to an increase in MDR volume for the respective months.

Table 1. Variance MDRs by posting year and type of reportable event (Jun-2020 to Mar-2021)[4]

Year of Posting	Serious Injury	Malfunction	Death	Total
≤ 2010	3542	22	0	3564
2011	368	2	0	370
2012	574	18	0	592
2013	1823	33	17	1873
2014	5476	65	9	5550
2015	12287	84	24	12395
2016	5568	21	4	5593
2017	1898	11	1	1910
2018	1164	5	0	1169
≥ 2019	471	4	1	476
Total	**33171**	**265**	**56**	**33492**

Year of posting is intended to refer to the date in which the information appeared on social media. Due to the unreliable nature of social media information and the process by which the date of posting was determined, there may exist dates which are not precise. Table 1 reflects this known limitation. The majority, or approximately 70%, of the information from social media was posted between 01-JAN-2014 and 31-DEC-2016. Information about date of posting does not impact the known or labeled risks for the Essure device.

Table 2. Variance MDRs by event year and type of reportable event (Jun-2020 to Mar-2021)[4]

Year of Event	Serious Injury	Malfunction	Death	Total
≤ 2010	746	20	0	766
2011	266	11	0	277
2012	333	6	1	340
2013	486	12	2	500
2014	521	12	0	533
2015	569	7	0	576
2016	263	3	0	266
2017	97	2	0	99
2018	37	0	0	37
≥ 2019	9	0	0	9
Total	**3327**	**73**	**3**	**3403**

Year of event is intended to refer to the date in which the event described by the information happened according to the report. Given the unreliable nature of social media information and the challenges of determining the accuracy of any reported event date, there may exist dates which are not precise. Table 2 reflects this known limitation. The majority, or approximately 96%, of the reported event dates in the information from social media occurred during or before 2016. Information about date of event does not impact the known or labeled risks for the Essure device.

[4] The table reflects information for variance MDRs only when it was made available to Bayer.

Table 3. Patient problem codes for variance MDRs (Jun-2020 to Mar-2021)[5]

Patient Problem Code	Total
3191: No Code Available	19664
1994: Pain	18124
2121: Uterine Perforation	6314
2687: Foreign Body In Patient	5759
3165: Device Fragments In Patient	3766
3193: Pregnancy	3430
2666: Heavier Menses	2018
1685: Pain, Abdominal	1242
1888: Hemorrhage	1233
1907: Hypersensitivity	1046
All other Patient Problem Codes	4699

Table 4. Patient problem codes for serious injury variance MDRs (Jun-2020 to Mar-2021)

Patient Problem Code	Total
3191: No Code Available	19664
1994: Pain	18117
2121: Uterine Perforation	6267
2687: Foreign Body In Patient	5690
3193: Pregnancy	3403
3165: Device Fragments In Patient	3194
2666: Heavier Menses	2018
1685: Pain, Abdominal	1242
1888: Hemorrhage	1229
1907: Hypersensitivity	1045
All other Patient Problem Codes	4526

Table 5. Patient problem codes for malfunction variance MDRs (Jun-2020 to Mar-2021)

Patient Problem Codes	Total
3165: Device Fragments In Patient	572
2687: Foreign Body In Patient	68
2121: Uterine Perforation	45
3193: Pregnancy	23
2668: Bowel Perforation	3
2001: Perforation	2
1819: Pregnancy, Ectopic	2
2000: Pelvic Inflammatory Disease	1
1907: Hypersensitivity	1
1994: Pain	1
All other Patient Problem Codes	3

[5] It is possible for more than one Patient Problem Code to be selected per report. Therefore, the sum of the Patient Problem Codes is not expected to equal the total number of MDRs submitted during the period reviewed.

Table 6. Patient problem codes for death variance MDRs (Jun-2020 to Mar-2021)

Patient Problem Codes	Total
1802: Death	114
2465: Labor, Premature	19
1994: Pain	6
1498: Pulmonary Embolism	5
1971: Necrosis	5
3193: Pregnancy	4
1888: Hemorrhage	4
2108: Toxic Shock Syndrome	3
1930: Infection	3
2000: Pelvic Inflammatory Disease	3
All other Patient Problem Codes	13

Table 7. Device problem codes for variance MDRs (Jun-2020 to Mar-2021)

Device Problem Code	Total
2993: No Known Device Problem	54260
1069: Break	3541
4003: Migration	1

Review of the figures and tables above provides a synopsis of the information provided in the H10 section of all variance submissions.[6] Although limited, based on the information provided, reports are consistent with the known and labeled safety, quality and performance of the Essure device. No additional conclusions can be drawn as to whether the device, or its removal, caused or contributed to any of the reported deaths or other events in the reports.

Averages of patient demographics

Review of variance MDRs processed by Bayer over the variance time period of 01-JUN-2020 and 31-MAR-2021 indicates that the following measures related to patient age and weight.

Table 8. Table of patient demographics for age and weight (Jun-2020 to Mar-2021)

Measure	Age (years)	Weight (lbs)
Minimum	18	88
Median	35	161
Average	36	163
Maximum	60	238
Sample size (n)*	14098	41

* Excludes child / fetal reports (only ≥ 18y)

[6] The MAUDE link to each of the ten (10) variance submissions is provided in Appendix II.

Analysis of MDRs for Associated Mother Reports

As per standard practice, part of the evaluation process assesses whether the reported event is a fetus/neonate/infant report[7] associated with a mother report. All MDRs for fetus/neonate/infant reports identified throughout the variance were submitted within the monthly line-item tabular data spreadsheet for the month in which the report was processed.

Overall, there was a total of 38 MDRs for fetus/neonate/infant reports submitted in the monthly line-item tabular data spreadsheets which represents approximately 0.07% of all variance MDRs submitted. A complete table of fetus/neonate/infant report numbers and their associated mother report is available in Appendix I of this report.

Report Source

The report processed by Bayer as part of the variance periods 01-JUN-2020 to 31-MAR-2021 are from the two sources of social media information in connection with Essure litigation as described in the variance letter. As the variance letter outlines, the two sources are:

- Publicly available social media information regarding certain Essure plaintiffs identified by Bayer's outside legal counsel and;
- Social media documents produced by the plaintiffs' lawyers to Bayer's outside legal counsel.

Entities Submitting Reports

All variance MDRs for the period of 01-JUN-2020 to 31-MAR-2021 have been submitted to the FDA by Bayer Pharma AG.

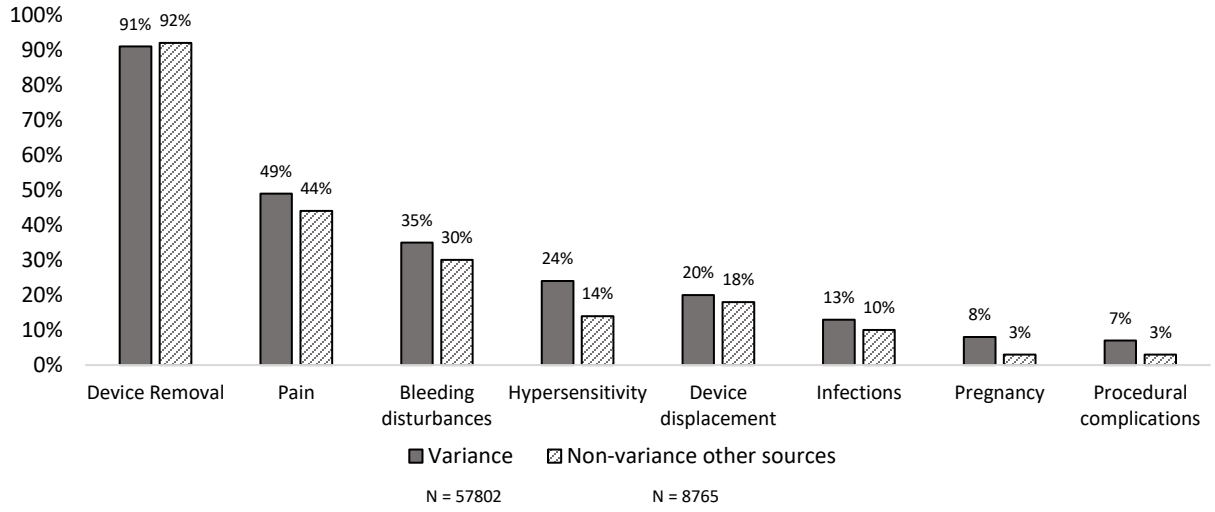
Devices Involved

All reports processed by Bayer in the cumulative variance period of 01-JUN-2020 and 31-MAR-2021 are related to the Essure System, model numbers ESS205 and ESS305.

[7] These reports were referred to by Bayer throughout the course of the variance as "child reports".

Synopsis of the nature of reports for the period

Figure 5. Distribution of initial MDR submissions by event grouping (Jun-2020 to Mar-2021)[8]



The representative event groupings for variance MDRs seem to be consistent with the non-variance other source MDRs processed during the same period. Information received as part of litigation accounts for 100% of variance MDRs and approximately 91% of non-variance other source MDRs. Device removal is the most frequently reported event for both variance and non-variance other source MDRs with 91% and 92%, respectively.
Pain is the second most frequent reported event in both variance and non-variance other source MDRs with 49% for variance MDRs and 44% for non-variance other source MDRs.

Bleeding disturbances comes in third for variance MDRs and non-variances source MDRs with 35% and 30% respectively.

Hypersensitivity and Device Displacement have different positions for variance MDRs when compared to non-variance other source MDRs.

[8] It is possible for more than one event grouping to be selected per report. Therefore, the sum of the event groupings is not expected to equal the total number (%) of MDRs submitted during the period reviewed.

Analysis of Additional Information

The following additional pieces of information were requested by FDA and prescribed within the variance letter.[9]

1. The variance MDRs processed by Bayer in the cumulative variance period between 01-JUN-2020 and 31-MAR-2021 have all been reported via the two sources of social media information in connection with Essure litigation as described in the variance letter.

2. The variance MDRs processed by Bayer in the cumulative variance period between 01-JUN-2020 and 31-MAR-2021 are consistent with expected outcomes.

3. Considering that variance MDRs processed by Bayer in the cumulative variance period between 01-JUN-2020 and 31-MAR-2021 are consistent with expected outcomes, there have been no investigations opened related to these reports.

4. No corrective actions have been opened, are in-process, or implemented as a result of Variance MDRs processed by Bayer in the cumulative variance period between 01-JUN-2020 and 31-MAR-2021 as there were no events reported which indicate a new technical failure mode for the device.

No additional actions were required to address the reports summarized in this analysis.

Number of returned devices

An evaluation on device returns was requested as part of the variance letter. An evaluation of device returns related to variance MDRs processed in the cumulative variance period between 01-JUN-2020 and 31-MAR-2021 indicates that there have been no devices returned to Bayer. Hence, as mentioned previously, no corrective actions have been opened or are in-process as a result of any variance MDRs processed in the same time period.

Presentation of report trends

An analysis of report trends in a comparative graphical display has been performed and is provided below. As stated previously, in order to contextualize the received reports, a comparison of trends for all events reported under this variance to trends for all other initially reported MDRs related to Essure is provided. These reports, which will be classified as ‘non-variance other sources’, include all Essure MDRs originating from different sources (e.g. spontaneous reports, medical literature) and submitted to the FDA as initial MDRs (outside of the variance) during the same time period (between 01-JUN-2020 and 31-MAR-2021).

As stated previously, for variance reports submitted, the time in which reports were processed does not necessarily represent the time in which the events reportedly occurred or when the patient made the information publicly available.

[9] Variance Letter: https://www.fda.gov/media/137316/download

Figure 6. Total number of variance MDRs vs. MDRs from non-variance other sources (Jun-2020 to Mar-2021)

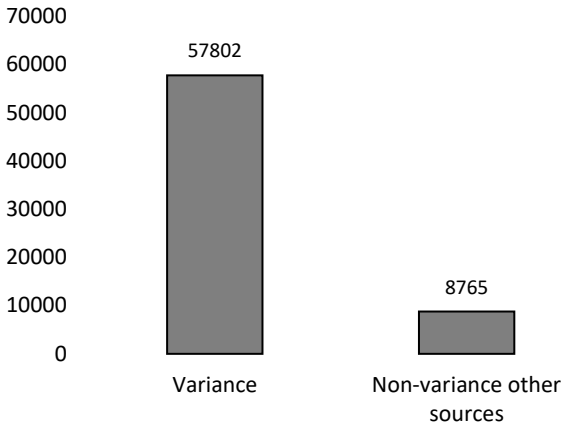


Figure 7. Variance MDRs vs. MDRs from non-variance other sources for serious injuries (Jun-2020 to Mar-2021)

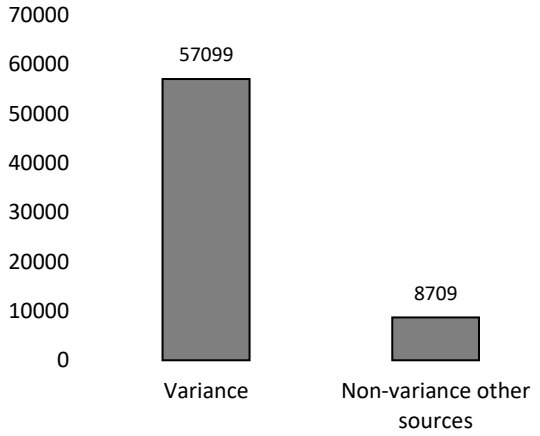


Figure 8. Variance MDRs vs. MDRs from non-variance other sources for malfunctions (Jun-2020 to Mar-2021)

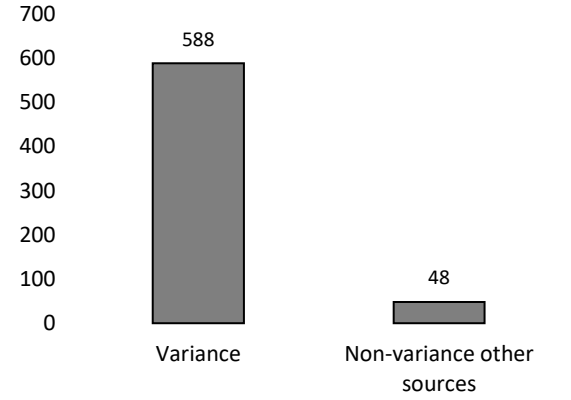


Figure 9. Variance MDRs vs. MDRs from non-variance other sources for deaths (Jun-2020 to Mar-2021)

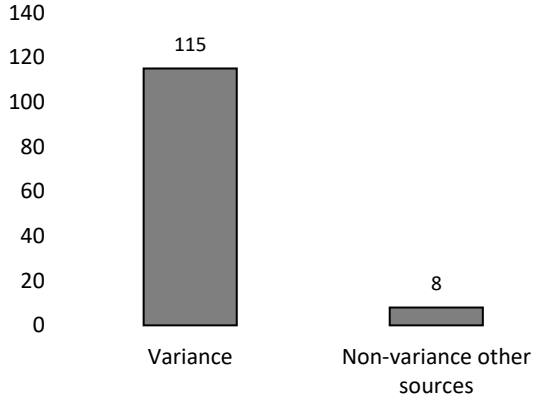
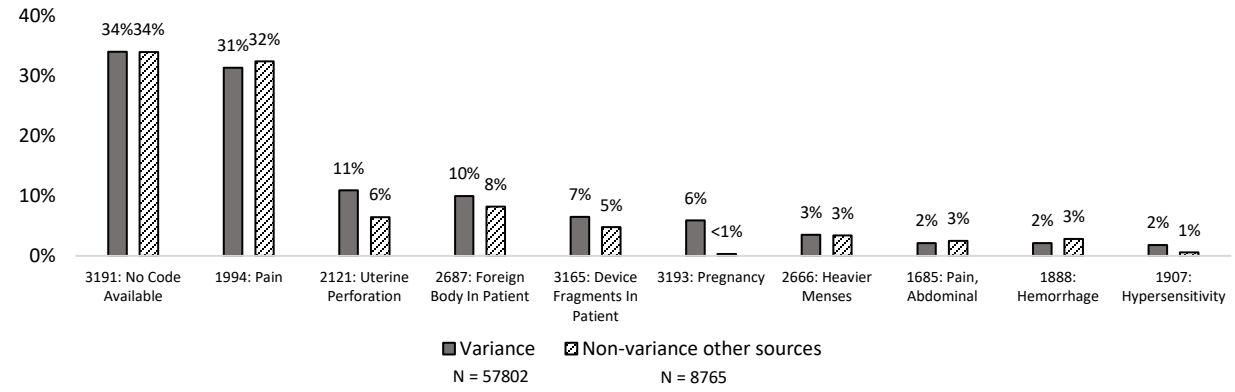


Figure 10. Top 10 patient problem codes for variance MDRs vs. MDRs from non-variance other sources (Jun-2020 to Mar-2021)[10]



[10] It is possible for more than one Patient Problem Code to be selected per report. Therefore, the sum of the Patient Problem Codes is not expected to equal the total number of MDRs submitted during the period reviewed.

Figure 11. Top 10 patient problem codes for serious injury variance MDRs vs. MDRs from non-variance other sources (Jun-2020 to Mar-2021)

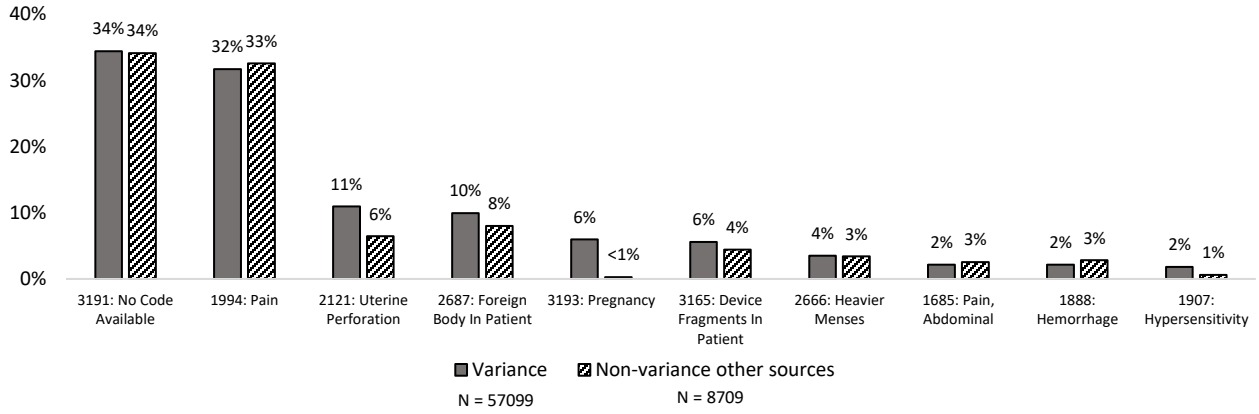


Figure 12. Top 10 patient problem codes for malfunction variance MDRs vs. MDRs from non-variance other sources (Jun-2020 to Mar-2021)[11]

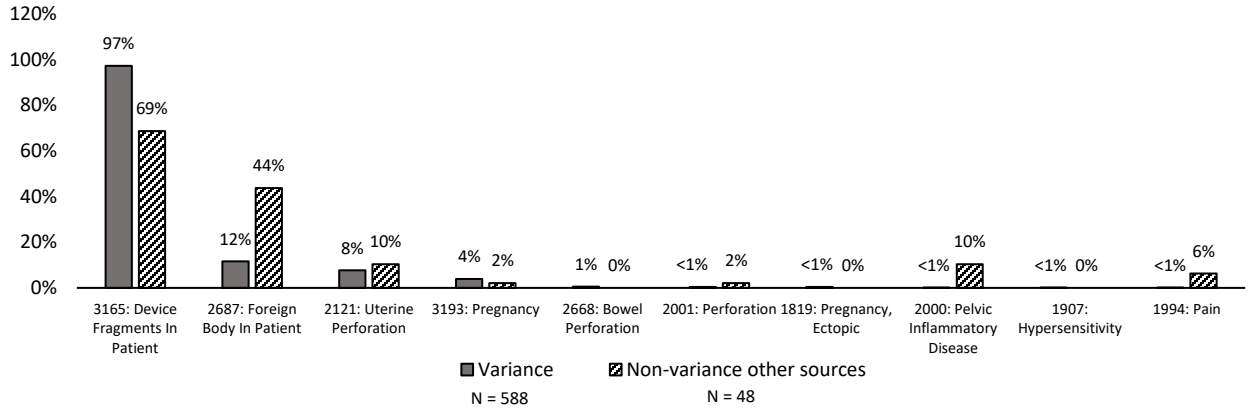
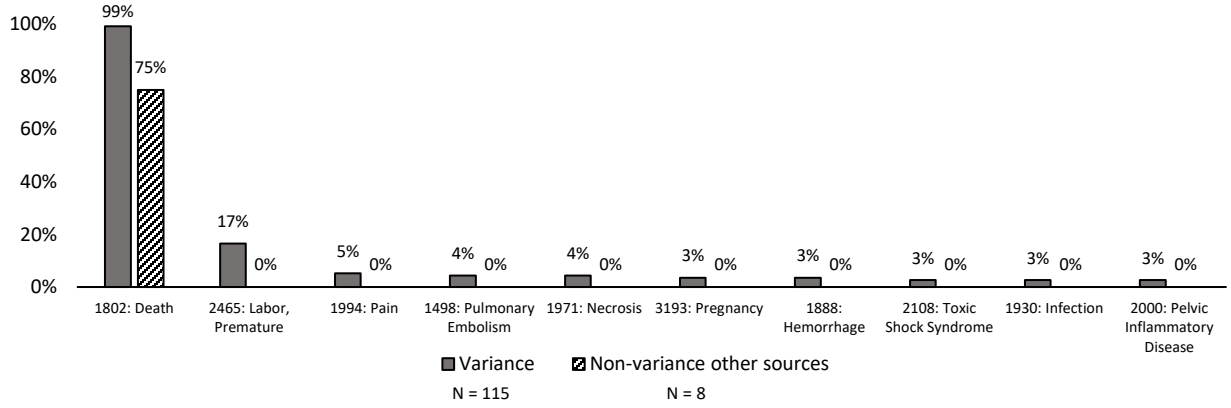
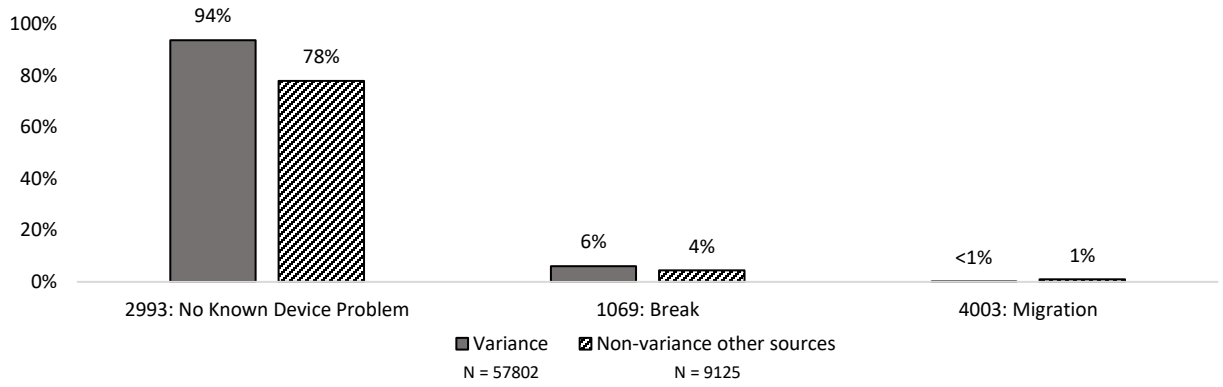


Figure 13. Top 10 patient problem codes for death variance MDRs vs. MDRs from non-variance other sources (Jun-2020 to Mar-2021)[12]



[11] The top 10 PPCs for malfunction non-variance other source MDRs is provided in Appendix III.
[12] For death non-variance other source MDRs, 75% of reports are for PPCs of 1802: Death while the remaining 25% (two (2) reports), have the PPCs of 4513: Unspecified Reproductive System or Breast Problem and 4581: Appropriate Clinical Signs, Symptoms, Conditions Term / Code Not Available, respectively.

Figure 14. All Device problem codes for variance MDRs vs. MDRs from non-variance other sources (Jun-2020 to Mar-2021)[13]



Based on the limited nature of social media information and the relatively small sample sizes for malfunction (Figure 12) and death variance MDRs (Figure 13) compared to all variance MDRs, no trends or conclusions related to safety, quality, or performance can be drawn. Review of the comparative graphical displays indicates that the overall distribution of Patient Problem Codes for variance information is consistent with non-variance other sources.

Comparative Analysis of Patient Demographics

Table 9. Table of patient demographics for age and weight for variance MDRs vs. MDRs from non-variance other sources (Jun-2020 to Mar-2021)

Measure	Age (years)		Weight (lbs.)	
	Variance	Non-variance other sources	Variance	Non-variance other sources
Minimum	18	18	88	90
Median	35	38	161	163
Average	36	38	163	177
Maximum	60	65	238	662
Sample Size (n)*	14098	1624	41	300

* Excludes child / fetal reports (only ≥ 18y)

The average age in the variance is slightly lower than reports from non-variance other sources. Considering the variance represents social media posting and the internet use decreases in older populations, this could justify the difference. Information about patient age was available in 24.4% of variance reports and 18.5% non-variance other source reports.

No statistically significant conclusions on weight differences can be drawn as the sample size is extremely small (0.1% in the variance and 3.4% in non-variance other source reports).

[13] For the purposes of comparison, only Device Problem Codes captured within variance reports are displayed.

Conclusions

Bayer has processed and submitted all MDR reports for the Essure variance cohort under the conditions of the variance letter.

The information analyzed within the variance cohort represents a source of passive surveillance information with limitations given the nature of the report data received from legally derived social media sources.[14] When comparing the variance to non-variance other source MDRs in the same time period, the observed trends assessed remain as expected and do not influence known or observed safety recommendations. In conclusion, there is no change in the understanding of the quality, safety and performance for the Essure product based on this information.

[14] https://www.fda.gov/medical-devices/essure-permanent-birth-control/problems-reported-essure

APPENDIX I

The table below represents the fetus/neonate/infant reports submitted as part of the variance between 01-JUN-2020 and 31-MAR-2021 via the line-item tabular data spreadsheets and their associated mother report.

Fetus/neonate/infant Report No.	Fetus/neonate/infant Report Month	Mother Report No.	Mother Report Month
2020-107940	JUN-2020	2020-107945	JUN-2020
2020-118960	JUN-2020	2020-118970	JUN-2020
2020-124755	JUN-2020	2020-124775	JUN-2020
2020-146029	JUL-2020	2020-145516	JUL-2020
2020-150995	JUL-2020	2020-144595	JUL-2020
2020-151017	JUL-2020	2020-151008	JUL-2020
2020-170774	AUG-2020	2020-195486	SEP-2020
2020-173510	AUG-2020	2020-158823	AUG-2020
2020-187991 [15]	SEP-2020	2020-204266	SEP-2020
2020-192279 [15]	SEP-2020	2020-192817	SEP-2020
2020-207289	SEP-2020	2020-205387	SEP-2020
2020-210523	SEP-2020	2020-191784	SEP-2020
2020-217695	OCT-2020	2020-226515	OCT-2020
2020-234635	OCT-2020	2020-234970	OCT-2020
2020-244236	NOV-2020	2020-234717	OCT-2020
2020-247313	NOV-2020	2020-275576	DEC-2020
2020-274851	DEC-2020	2020-274502	DEC-2020
2020-275451	DEC-2020	2020-275430	DEC-2020
2020-278381	DEC-2020	2021-008600	MAR-2021
2020-280045	DEC-2020	2020-280104	DEC-2020
2020-282169	DEC-2020	2021-001187	JAN-2021
2021-013091	JAN-2021	2020-278054	DEC-2020
2021-034451	JAN-2021	2021-051245	FEB-2021
2021-034489	JAN-2021	2021-046210	JAN-2021
2021-050001	FEB-2021	2021-084874	FEB-2021
2021-052001	FEB-2021	2021-064752	FEB-2021
2021-060845	FEB-2021	2021-084765	FEB-2021
2021-063191	FEB-2021	Non-MDR processed in JAN-2021	
2021-072107	FEB-2021	2021-073051	FEB-2021
2021-081295	FEB-2021	2021-099378	MAR-2021
2021-081647	FEB-2021	2021-070060	FEB-2021
2021-087438	FEB-2021	2021-096827	MAR-2021
2021-100197	MAR-2021	Non-MDR processed in FEB-21	
2021-102590	MAR-2021	2021-084793	FEB-2021
2021-102597	MAR-2021	2021-110797	MAR-2021
2021-102604	MAR-2021	2021-102592	MAR-2021
2021-103091	MAR-2021	2021-101091	MAR-2021
2021-107802	MAR-2021	Non-MDR processed in MAR-21	

[15] Bayer has submitted a supplemental report to MAUDE to amend the associated mother report provided in the "ESSURE Medical Device Reporting Variance Spreadsheet – September 2020" related to this fetus/neonate/infant report.

APPENDIX II

The table below provides the manufacturer report number, report period and MAUDE link for each of the ten (10) variance submissions.

Submission	Report period	Mfg Report No.	MAUDE link
Submission 1	01JUN2020 - 30JUN2020	2951250-2020-10578	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/detail.cfm?mdrfoi__id=10260064&pc=HHS
Submission 2	01JUL2020 - 31JUL2020	2951250-2020-12723	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/detail.cfm?mdrfoi__id=10464545&pc=HHS
Submission 3	01AUG2020 - 31AUG2020	2951250-2020-13991	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/detail.cfm?mdrfoi__id=10592806&pc=HHS
Submission 4	01SEP2020 - 30SEP2020	2951250-2020-14805	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/detail.cfm?mdrfoi__id=10819440&pc=HHS
Submission 5	01OCT2020 - 31OCT2020	2951250-2020-15608	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/detail.cfm?mdrfoi__id=10875268&pc=HHS
Submission 6	01NOV2020 - 30NOV2020	2951250-2020-15787	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/detail.cfm?mdrfoi__id=11036092&pc=HHS
Submission 7	01DEC2020 - 31DEC2020	2951250-2021-00073	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/detail.cfm?mdrfoi__id=11343533&pc=HHS
Submission 8	01JAN2021 - 31JAN2021	2951250-2021-00469	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/detail.cfm?mdrfoi__id=11574801&pc=HHS
Submission 9	01FEB2021 - 28FEB2021	2951250-2021-00716	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/detail.cfm?mdrfoi__id=11675301&pc=HHS
Submission 10	01MAR2021 - 31MAR2021	2951250-2021-01141	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/detail.cfm?mdrfoi__id=11876882&pc=HHS

APPENDIX III

The table below compliments Figure 12 as it provides the complete list of the PPCs associated with malfunction non-variance other source MDRs submitted between Jun-2020 and Mar-2021.

Patient Problem Codes	% of MDRs*
3165: Device Fragments In Patient	69%
2687: Foreign Body In Patient	44%
4581: Appropriate Clinical Signs, Symptoms, Conditions Term / Code Not Available	23%
2000: Pelvic Inflammatory Disease	10%
2121: Uterine Perforation	10%
1932: Inflammation	6%
1994: Pain	6%
4580: Insufficient Information	4%
4582: No Clinical Signs, Symptoms or Conditions	2%
2001: Perforation	2%
4507: Genital Bleeding	2%
3193: Pregnancy	2%

* Sample size (n) = 48