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The following report(s) provides findings from an FDA-initiated query using its Mini-Sentinel pilot. While Mini-Sentinel queries may be undertaken to assess potential medical product safety risks, they may also be initiated for various other reasons. Some examples include determining a rate or count of an identified health outcome of interest, examining medical product use, exploring the feasibility of future, more detailed analyses within Mini-Sentinel, and seeking to better understand the capabilities of the Mini-Sentinel pilot.

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FDA wants to emphasize that the fact that FDA has initiated a query involving a medical product and is reporting findings related to that query does not mean that FDA is suggesting health care practitioners should change their prescribing practices for the medical product or that patients taking the medical product should stop using it. Patients who have questions about the use of an identified medical product should contact their health care practitioners.

The following report contains a description of the request, request specifications, and results from the modular program run(s).

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Overview for Request ID msy4_mpr44_v2 - Report 1 of 3

Request ID: msy4_mpr44_v2 - Report 1 of 3

Request Description: This report investigates prevalent use of robotic-assisted procedures. In addition, this request analyzed use of laparoscopic robotic assistance for several specified primary procedures. Report 1 presents results for the robotic-assisted procedures codes only. Reports 2 and 3 present results for use of robotic-assisted codes with specified primary procedures.

Modular Program Tool Used: Modular Program #9 (MP9)

Data Source: Data from October 1, 2008 to December 31, 2012 from 18 Data Partners contributing to the Mini-Sentinel Distributed Database (MSDD) were included in this report. This request was distributed to Data Partners on July 29, 2013. See Appendix A for a list of dates available data for each Data Partner.

Study Design: This request was designed to provide counts of prevalent unique patients with robotic-assisted procedures, eligible members, and member-years. In addition, this request analyzed use of laparoscopic robotic assistance for several specified primary procedures. Seven scenarios were examined in this report with differing exposures of interest and inclusion criteria: (1) open robotic assisted procedure, (2) laparoscopic robotic assisted procedure, (3) percutaneous robotic assisted procedure, (4) endoscopic robotic assisted procedure, (5) thoracoscopic robotic assisted procedure, (6) other/unspecified robotic assisted procedure, and (7) all robotic assisted procedures.

Cohort Eligibility Criteria: Patients were allowed gaps in coverage of up to 45 days. The following age groups were included in the cohort: 0-40, 41-54, 55-64, 64-74, 75-84, and 85+ years. See Appendix C for the specifications for this request.

Limitation: Algorithms to define exposures are imperfect and, therefore, they may be misclassified.

Notes: Please contact the Sentinel Operations Center (info@sentinelssystem.org) for questions and to provide comments/suggestions for future enhancements to this document.

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Glossary of Terms in Modular Program 9*

Amount Supplied - Number of units (pills, tablets, vials) dispensed. Net amount per NDC per dispensing. This is equivalent to the "RxAmt" value in the Mini-Sentinel Common Data Model (MSCDM).

Care Setting - Contains the care settings considered for the individual diagnosis or procedure codes of interest. The following are valid entries:

- IP: inpatient hospital stays
- IS: non-acute institutional stays
- ED: emergency department visits
- AV: ambulatory visits
- OA: other ambulatory visits.

Days Supplied - Number of days supplied for all dispensings encountered by individuals in the prevalent or incident cohort. The number is reported by the pharmacist as the number of days that the medications supports, based on the number of doses. (To be included in the incident-based cohort, a member must have a dispensing that meets the criteria specified for incidence type and washout period. However, if a member has more than one dispensings claim on the index date, all claims identified on that date will be included in the number of dispensings. Claims identified any time after the index date are not included in dispensings.)

Dispensings - Total number of dispensings for members included in the prevalent- or incident-based cohort. To be included in the incident-based cohort, a member must have a dispensing that meets the criteria specified for incidence type and washout period. However, if a member has more than one dispensings claim on the index date, all claims identified on that date will be included in the number of dispensings. Claims identified any time after the index date are not included in dispensings.

Eligible Members (incidence-based cohort) - Number of members eligible for incident diagnosis (defined by the washout period) with drug and/or medical coverage during the query period.

Eligible Members (prevalence-based cohort) - Number of members with at least one day of drug and/or medical coverage during the query period.

Enrollment Gap - Number of days allowed between two consecutive enrollment periods without breaking a "continuously enrolled" sequence.

Exposure - NDC and/or procedure and/or diagnosis code values for the exposure(s) of interest.

Incidence Type (incidence-based cohort) - *Minimum incidence type* will only consider the first claim in the query period as long as it is the first claim in the user's entire available history. *Single incidence type* will consider the first claim in the query period that satisfies the washout period criteria. That is, incidence is defined as the first claim during the query period with no evidence of a prior claim during the previous washout period days. *Multiple incidence type* will use the washout period to establish incidence and consider all qualifying incident claims.

"Incident with Respect to" Codes - NDC and/or procedure and/or diagnosis codes to be used to refine the incident definition for the exposure(s) of interest. For example, if a requester is examining exposure to DRUG A but wants incidence of DRUG A to be defined with respect to DRUG A and DRUG B, the Incident with Respect to Code fields would include both DRUG A and DRUG B codes.

Incident Only Care Setting - Contains the care settings considered for the individual diagnosis or procedure codes included as "Incident with Respect to" codes.

Member-Years (incidence-based cohort) - Sum of all years of enrollment with drug and/or medical coverage in the query period preceded by a washout period.

Member-Years (prevalence-based cohort) - Sum of all years members are enrolled with drug and/or medical coverage during the query period.

New Starts - Number of incident dispensings during the query period. Patient must have no prior dispensings of interest in the washout period. For a single and minimum incidence type, an individual may have no more than one new start. For a multiple incidence type, an individual may have more than one new start.

New Users - Number of members with incident claims during the query period. Member must have no evidence of claims of interest (defined by incidence criteria) in the prior washout period. A patient may only be counted once in a query period.

Query Period - Period in which the modular program looks for diagnoses of interest.

Washout Period (incidence-based cohort) - Number of days a patient is required to have no evidence of prior claim of interest and continuous drug and/or medical coverage.

*all terms may not be used in this report

Table 1. Summary of Prevalent Robotic-Assisted Procedure Codes between October 1, 2008 and December 31, 2012

Procedure Name	Number of Patients	Number of Procedures	Eligible Members	Member-Years	Patients per 100,000 Eligible Members	Procedures per Patient
Open robotic assisted procedure	4,292	4,472	86,364,585	167,724,501	5.0	1.0
Laparoscopic robotic assisted procedure	61,653	64,674	86,364,585	167,724,501	71.4	1.0
Percutaneous robotic assisted procedure	87	91	86,364,585	167,724,501	0.1	1.0
Endoscopic robotic assisted procedure	484	502	86,364,585	167,724,501	0.6	1.0
Thoracoscopic robotic assisted procedure	1,372	1,403	86,364,585	167,724,501	1.6	1.0
Other/unspecified robotic assisted procedure	2,431	2,587	86,364,585	167,724,501	2.8	1.1
All robotic assisted procedures	70,223	73,729	86,364,585	167,724,501	81.3	1.0

Table 2. Summary of Prevalent Robotic-Assisted Procedure Codes between October 1, 2008 and December 31, 2012, by Age Group

Procedure Name and Group	Number of Patients	Number of Procedures	Eligible Members	Member-Years	Patients per 100,000 Eligible Members	Procedures per Patient
Open robotic assisted procedure						
0 to 40 years	450	484	52,679,376	91,633,066	0.9	1.1
41 to 54 years	1,272	1,316	20,928,689	37,704,984	6.1	1.0
55 to 64 years	1,341	1,400	11,589,829	21,125,073	11.6	1.0
65 to 74 years	883	915	5,259,407	10,161,737	16.8	1.0
75 to 84 years	307	316	2,442,257	5,202,469	12.6	1.0
85+ years	40	41	921,792	1,897,172	4.3	1.0
Laparoscopic robotic assisted procedure						
0 to 40 years	7,746	8,451	52,679,376	91,633,066	14.7	1.1
41 to 54 years	19,741	21,109	20,928,689	37,704,984	94.3	1.1
55 to 64 years	20,598	21,228	11,589,829	21,125,073	177.7	1.0
65 to 74 years	11,377	11,628	5,259,407	10,161,737	216.3	1.0
75 to 84 years	1,979	2,025	2,442,257	5,202,469	81.0	1.0
85+ years	222	233	921,792	1,897,172	24.1	1.0
Percutaneous robotic assisted procedure						
0 to 40 years	13	14	52,679,376	91,633,066	0.0	1.1
41 to 54 years	23	24	20,928,689	37,704,984	0.1	1.0
55 to 64 years	16	17	11,589,829	21,125,073	0.1	1.1
65 to 74 years	26	27	5,259,407	10,161,737	0.5	1.0
75 to 84 years	9	9	2,442,257	5,202,469	0.4	1.0
85+ years	0	0	921,792	1,897,172	0.0	---

Table 2. Summary of Prevalent Robotic-Assisted Procedure Codes between October 1, 2008 and December 31, 2012, by Age Group

Procedure Name and Group	Number of Patients	Number of Procedures	Eligible Members	Member-Years	Patients per 100,000 Eligible Members	Procedures per Patient
Endoscopic robotic assisted procedure						
0 to 40 years	54	58	52,679,376	91,633,066	0.1	1.1
41 to 54 years	143	145	20,928,689	37,704,984	0.7	1.0
55 to 64 years	158	163	11,589,829	21,125,073	1.4	1.0
65 to 74 years	97	99	5,259,407	10,161,737	1.8	1.0
75 to 84 years	24	28	2,442,257	5,202,469	1.0	1.2
85+ years	8	9	921,792	1,897,172	0.9	1.1
Thoracoscopic robotic assisted procedure						
0 to 40 years	137	141	52,679,376	91,633,066	0.3	1.0
41 to 54 years	293	302	20,928,689	37,704,984	1.4	1.0
55 to 64 years	372	381	11,589,829	21,125,073	3.2	1.0
65 to 74 years	372	379	5,259,407	10,161,737	7.1	1.0
75 to 84 years	179	181	2,442,257	5,202,469	7.3	1.0
85+ years	19	19	921,792	1,897,172	2.1	1.0
Other/unspecified robotic assisted procedure						
0 to 40 years	273	283	52,679,376	91,633,066	0.5	1.0
41 to 54 years	618	629	20,928,689	37,704,984	3.0	1.0
55 to 64 years	920	1,036	11,589,829	21,125,073	7.9	1.1
65 to 74 years	481	495	5,259,407	10,161,737	9.1	1.0
75 to 84 years	119	122	2,442,257	5,202,469	4.9	1.0
85+ years	21	22	921,792	1,897,172	2.3	1.0

Table 2. Summary of Prevalent Robotic-Assisted Procedure Codes between October 1, 2008 and December 31, 2012, by Age Group

Procedure Name and Group	Number of Patients	Number of Procedures	Eligible Members	Member-Years	Patients per 100,000 Eligible Members	Procedures per Patient
All robotic assisted procedures						
0 to 40 years	8,660	9,431	52,679,376	91,633,066	16.4	1.1
41 to 54 years	22,063	23,525	20,928,689	37,704,984	105.4	1.1
55 to 64 years	23,376	24,225	11,589,829	21,125,073	201.7	1.0
65 to 74 years	13,215	13,543	5,259,407	10,161,737	251.3	1.0
75 to 84 years	2,614	2,681	2,442,257	5,202,469	107.0	1.0
85+ years	310	324	921,792	1,897,172	33.6	1.0

Table 3. Summary of Prevalent Robotic-Assisted Procedure Codes between October 1, 2008 and December 31, 2012, by Sex

Procedure Name and Group	Number of Patients	Number of Procedures	Eligible Members	Member-Years	Patients per 100,000 Eligible Members	Procedures per Patient
Open robotic assisted procedure						
Female	2,310	2,419	43,799,283	86,021,808	5.3	1.0
Male	1,982	2,053	42,560,622	81,696,194	4.7	1.0
Unknown	0	0	4,680	6,499	0.0	---
Laparoscopic robotic assisted procedure						
Female	28,194	30,519	43,799,283	86,021,808	64.4	1.1
Male	33,455	34,151	42,560,622	81,696,194	78.6	1.0
Unknown	4	4	4,680	6,499	85.5	1.0
Percutaneous robotic assisted procedure						
Female	36	40	43,799,283	86,021,808	0.1	1.1
Male	51	51	42,560,622	81,696,194	0.1	1.0
Unknown	0	0	4,680	6,499	0.0	---
Endoscopic robotic assisted procedure						
Female	146	151	43,799,283	86,021,808	0.3	1.0
Male	338	351	42,560,622	81,696,194	0.8	1.0
Unknown	0	0	4,680	6,499	0.0	---
Thoracoscopic robotic assisted procedure						
Female	668	684	43,799,283	86,021,808	1.5	1.0
Male	703	718	42,560,622	81,696,194	1.7	1.0
Unknown	1	1	4,680	6,499	21.4	1.0
Other/unspecified robotic assisted procedure						
Female	856	984	43,799,283	86,021,808	2.0	1.1
Male	1,575	1,603	42,560,622	81,696,194	3.7	1.0
Unknown	0	0	4,680	6,499	0.0	---
All robotic assisted procedures						
Female	32,158	34,797	43,799,283	86,021,808	73.4	1.1
Male	38,060	38,927	42,560,622	81,696,194	89.4	1.0
Unknown	5	5	4,680	6,499	106.8	1.0

Table 4. Summary of Prevalent Robotic-Assisted Procedure Codes between October 1, 2008 and December 31, 2012, by Year

Procedure Name and Group	Number of Patients	Number of Procedures	Eligible Members	Member-Years	Patients per 100,000 Eligible Members	Procedures per Patient
Open robotic assisted procedure						
2008	85	86	44,593,269	10,787,007	0.2	1.0
2009	731	756	51,853,790	42,278,953	1.4	1.0
2010	1,065	1,123	50,009,658	40,839,829	2.1	1.1
2011	1,225	1,278	48,712,336	40,062,561	2.5	1.0
2012	1,204	1,229	45,752,524	33,756,151	2.6	1.0
Laparoscopic robotic assisted procedure						
2008	2,399	2,512	44,593,269	10,787,007	5.4	1.0
2009	12,762	13,341	51,853,790	42,278,953	24.6	1.0
2010	15,090	15,865	50,009,658	40,839,829	30.2	1.1
2011	17,530	18,596	48,712,336	40,062,561	36.0	1.1
2012	13,987	14,360	45,752,524	33,756,151	30.6	1.0
Percutaneous robotic assisted procedure						
2008	4	4	44,593,269	10,787,007	0.0	1.0
2009	16	17	51,853,790	42,278,953	0.0	1.1
2010	23	25	50,009,658	40,839,829	0.0	1.1
2011	19	20	48,712,336	40,062,561	0.0	1.1
2012	25	25	45,752,524	33,756,151	0.1	1.0
Endoscopic robotic assisted procedure						
2008	12	13	44,593,269	10,787,007	0.0	1.1
2009	133	135	51,853,790	42,278,953	0.3	1.0
2010	115	116	50,009,658	40,839,829	0.2	1.0
2011	120	127	48,712,336	40,062,561	0.2	1.1
2012	104	111	45,752,524	33,756,151	0.2	1.1

Table 4. Summary of Prevalent Robotic-Assisted Procedure Codes between October 1, 2008 and December 31, 2012, by Year

Procedure Name and Group	Number of Patients	Number of Procedures	Eligible Members	Member-Years	Patients per 100,000 Eligible Members	Procedures per Patient
Thoracoscopic robotic assisted procedure						
2008	27	27	44,593,269	10,787,007	0.1	1.0
2009	162	163	51,853,790	42,278,953	0.3	1.0
2010	258	264	50,009,658	40,839,829	0.5	1.0
2011	407	414	48,712,336	40,062,561	0.8	1.0
2012	521	535	45,752,524	33,756,151	1.1	1.0
Other/unspecified robotic assisted procedure						
2008	95	95	44,593,269	10,787,007	0.2	1.0
2009	447	457	51,853,790	42,278,953	0.9	1.0
2010	578	584	50,009,658	40,839,829	1.2	1.0
2011	673	705	48,712,336	40,062,561	1.4	1.0
2012	644	746	45,752,524	33,756,151	1.4	1.2
All robotic assisted procedures						
2008	2,622	2,737	44,593,269	10,787,007	5.9	1.0
2009	14,241	14,869	51,853,790	42,278,953	27.5	1.0
2010	17,112	17,977	50,009,658	40,839,829	34.2	1.1
2011	19,952	21,140	48,712,336	40,062,561	41.0	1.1
2012	16,469	17,006	45,752,524	33,756,151	36.0	1.0

Appendix A. Available Data in the Mini-Sentinel Distributed Database (MSDD) for Each Data Partner as of Request Distribution Date (July 29, 2013)

Data Partner ID	Start Date	End Date
DP001	10/1/2008	11/30/2012
DP002	10/1/2008	12/30/2012
DP003	10/1/2008	12/31/2012
DP004	10/1/2008	4/30/2012
DP005	10/1/2008	12/31/2011
DP006	10/1/2008	12/31/2011
DP007	10/1/2008	6/30/2012
DP008	10/1/2008	6/30/2012
DP009	10/1/2008	10/31/2012
DP010	10/1/2008	12/31/2012
DP011	10/1/2008	12/31/2012
DP012	10/1/2008	9/30/2012
DP013	10/1/2008	9/30/2012
DP014	10/1/2008	12/31/2012
DP015	10/1/2008	9/30/2012
DP016	10/1/2008	12/31/2012
DP017	10/1/2008	12/31/2012
DP018	10/1/2008	12/31/2012

**Appendix B. Robotic-Assisted International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM)
Procedure Codes**

Procedure Code	Code Type	Group
17.41	ICD-9-CM	Open robotic assisted procedure
17.42	ICD-9-CM	Laparoscopic robotic assisted procedure
17.43	ICD-9-CM	Percutaneous robotic assisted procedure
17.44	ICD-9-CM	Endoscopic robotic assisted procedure
17.45	ICD-9-CM	Thoracoscopic robotic assisted procedure
17.49	ICD-9-CM	Other/unspecified robotic assisted procedure
17.41-17.49	ICD-9-CM	All robotic assisted procedures

Appendix C. MSY4_MPR44_V2 Specifications

Modular Program #9 was used to investigate prevalent use of robotic-assisted procedures (see Appendix C). In addition, this request analyzed use of laparoscopic robotic assistance for several specified primary procedures. The query period is from October 1, 2008 to December 31, 2012, and the enrollment gap is set at 45 days. Age groups were split as follows: 0-40, 41-54, 55-64, 65-74, 75-84, and 85+ years. In total, seven unique scenarios were examined in this report with differing exposures of interest and inclusion criteria. See below for a description of each of these scenarios. This is report 1 of 3 for request MSY4_MPR44_V2.

Scenario	Exposure Criteria			Inclusion/Exclusion Criteria					
	Prevalent exposure	Care Setting	Principal Dx	Condition	Inclusion/Exclusion	Lookback Start	Lookback End	Care Setting	Principal Dx
1	Open robotic assisted procedure	All	No	None	---	---	---	---	---
2	Laparoscopic robotic assisted procedure	All	No	None	---	---	---	---	---
3	Percutaneous robotic assisted procedure	All	No	None	---	---	---	---	---
4	Endoscopic robotic assisted procedure	All	No	None	---	---	---	---	---
5	Thoracoscopic robotic assisted procedure	All	No	None	---	---	---	---	---
6	Other/unspecified robotic assisted procedure	All	No	None	---	---	---	---	---
7	All robotic assisted procedures	All	No	None	---	---	---	---	---