

Disclaimer

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.

Data obtained through Mini-Sentinel are intended to complement other types of evidence such as preclinical studies, clinical trials, postmarket studies, and adverse event reports, all of which are used by FDA to inform regulatory decisions regarding medical product safety. The information contained in this report is provided as part of FDA's commitment to place knowledge acquired from the Mini-Sentinel pilot in the public domain as soon as possible. Any public health actions taken by FDA regarding products involved in Mini-Sentinel queries will continue to be communicated through existing channels.

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).

If you are using a web page screen reader and are unable to access this document, please contact the Mini-Sentinel Operations Center for assistance at info@sentinelssystem.org.

Overview for Request ID msy4_mpr44_v2 - Report 3 of 3

Request ID: msy4_mpr44_v2 - Report 3 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 3 presents results for use of robotic-assisted codes with specified primary procedures. Report 1 presents results for the robotic-assisted procedures codes only. Report 2 also presents 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 of 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. Fifteen scenarios were examined in this report with differing exposures of interest and inclusion criteria: (1) Supracervical abdominal hysterectomy-open, (2) Supracervical abdominal hysterectomy-laparoscopic, (3) Supracervical abdominal hysterectomy-open or laparoscopic, (4) Total abdominal hysterectomy-open, (5) Total abdominal hysterectomy-laparoscopic, (6) Total abdominal hysterectomy-open or laparoscopic, (7) Radical abdominal hysterectomy - open, (8) Radical abdominal hysterectomy - laparoscopic, (9) Radical abdominal hysterectomy - open or laparoscopic, (10) Vaginal hysterectomy - open, (11) Vaginal hysterectomy - laparoscopic, (12) Vaginal hysterectomy-open or laparoscopic, (13) Repair of cystocele and rectocele-open, (14) Repair of cystocele and rectocele-laparoscopic, and (15) Repair of cystocele and rectocele-open or laparoscopic.

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.

Overview of Request ID MSY4_MPR44_V2, Report 3 of 3, Version 2, Report 3 of 3

<u>Glossary</u>	Glossary of Terms in Modular Program 9
<u>Table 1</u>	Summary of Prevalent Robotic-Assisted Procedure Codes between October 1, 2008 and December 31, 2012, by Associated Primary Procedure
<u>Table 2</u>	Summary of Prevalent Robotic-Assisted Procedure Codes between October 1, 2008 and December 31, 2012, by Associated Primary Procedure and Age Group
<u>Table 3</u>	Summary of Prevalent Robotic-Assisted Procedure Codes between October 1, 2008 and December 31, 2012, by Associated Primary Procedure and Sex
<u>Table 4</u>	Summary of Prevalent Robotic-Assisted Procedure Codes between October 1, 2008 and December 31, 2012, by Associated Primary Procedure and Year
<u>Appendix A</u>	Available Data in the Mini-Sentinel Distributed Database (MSDD) for Each Data Partner as of Request Distribution Date (July 29, 2013)
<u>Appendix B</u>	Descriptions of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), and Current Procedural Terminology, Fourth Edition (CPT-4) Primary Procedure Codes (Inclusion)
<u>Appendix C</u>	MSY4_MPR44_V1 Specifications

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, by Associated Primary Procedure

Primary Procedure	Number of Unique Patients with Laparoscopic Robotic-Assisted Procedures	Number of Laparoscopic Robotic-Assisted Procedures	Number of Unique Patients with Primary Procedure	Laparoscopic Robotic-Assisted Patients per 1000 Primary Procedure Patients	Procedures per Patient
Supracervical hysterectomy					
Open or Laparoscopic	2,123	2,270	62,476	34.0	1.1
Laparoscopic	2,089	2,235	44,068	47.4	1.1
Open	130	137	20,522	6.3	1.1
Total abdominal hysterectomy					
Open or Laparoscopic	15,756	17,112	207,509	75.9	1.1
Laparoscopic	15,527	16,881	88,291	175.9	1.1
Open	565	578	122,389	4.6	1.0
Radical abdominal hysterectomy					
Open or Laparoscopic	1,894	1,982	10,786	175.6	1.0
Laparoscopic	1,863	1,949	5,941	313.6	1.0
Open	42	44	4,928	8.5	1.0
Vaginal hysterectomy					
Open or Laparoscopic	9,455	10,379	166,689	56.7	1.1
Laparoscopic	9,363	10,286	106,154	88.2	1.1
Open	188	194	63,703	3.0	1.0
Repair of cystocele and rectocele					
Open or Laparoscopic	891	955	87,814	10.1	1.1
Laparoscopic	44	47	598	73.6	1.1
Open	877	939	87,623	10.0	1.1

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

Primary Procedure	Number of Unique Patients with Laparoscopic Robotic-Assisted Procedures	Number of Laparoscopic Robotic-Assisted Procedures	Number of Unique Patients with Primary Procedure	Laparoscopic Robotic-Assisted Patients per 1000 Primary Procedure Patients	Procedures per Patient
Supracervical hysterectomy					
Open or Laparoscopic					
0 to 40 years	368	393	16,601	22.2	1.1
41 to 54 years	1,286	1,377	39,704	32.4	1.1
55 to 64 years	298	322	4,392	67.9	1.1
65 to 74 years	138	143	1,358	101.6	1.0
75 to 84 years	26	27	394	66.0	1.0
85+ years	8	8	59	135.6	1.0
Laparoscopic					
0 to 40 years	359	384	12,209	29.4	1.1
41 to 54 years	1,265	1,355	27,974	45.2	1.1
55 to 64 years	297	321	2,973	99.9	1.1
65 to 74 years	135	140	766	176.2	1.0
75 to 84 years	26	27	154	168.8	1.0
85+ years	8	8	15	533.3	1.0
Open					
0 to 40 years	24	24	4,919	4.9	1.0
41 to 54 years	85	89	13,093	6.5	1.0
55 to 64 years	12	15	1,590	7.5	1.3
65 to 74 years	8	8	637	12.6	1.0
75 to 84 years	0	0	246	0.0	---
85+ years	1	1	46	21.7	1.0
Total abdominal hysterectomy					
Open or Laparoscopic					
0 to 40 years	3,427	3,788	54,156	63.3	1.1
41 to 54 years	8,011	8,758	113,040	70.9	1.1
55 to 64 years	2,426	2,615	25,321	95.8	1.1
65 to 74 years	1,324	1,364	10,506	126.0	1.0
75 to 84 years	494	502	3,876	127.5	1.0
85+ years	76	85	708	107.3	1.1

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

Primary Procedure	Number of Unique Patients with Laparoscopic Robotic-Assisted Procedures	Number of Laparoscopic Robotic-Assisted Procedures	Number of Unique Patients with Primary Procedure	Laparoscopic Robotic-Assisted Patients per 1000 Primary Procedure Patients	Procedures per Patient
Laparoscopic					
0 to 40 years	3,387	3,747	25,291	133.9	1.1
41 to 54 years	7,906	8,652	46,495	170.0	1.1
55 to 64 years	2,385	2,574	10,907	218.7	1.1
65 to 74 years	1,295	1,335	4,121	314.2	1.0
75 to 84 years	481	489	1,302	369.4	1.0
85+ years	75	84	223	336.3	1.1
Open					
0 to 40 years	114	116	29,545	3.9	1.0
41 to 54 years	269	278	68,274	3.9	1.0
55 to 64 years	99	101	14,911	6.6	1.0
65 to 74 years	62	62	6,569	9.4	1.0
75 to 84 years	19	19	2,645	7.2	1.0
85+ years	2	2	492	4.1	1.0
Radical abdominal hysterectomy					
Open or Laparoscopic					
0 to 40 years	271	284	1,470	184.4	1.0
41 to 54 years	618	656	3,522	175.5	1.1
55 to 64 years	466	494	3,278	142.2	1.1
65 to 74 years	356	360	1,704	208.9	1.0
75 to 84 years	159	164	693	229.4	1.0
85+ years	24	24	124	193.5	1.0
Laparoscopic					
0 to 40 years	269	282	833	322.9	1.0
41 to 54 years	613	651	2,000	306.5	1.1
55 to 64 years	456	482	1,838	248.1	1.1
65 to 74 years	346	350	875	395.4	1.0
75 to 84 years	156	161	345	452.2	1.0
85+ years	23	23	53	434.0	1.0
Open					

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

Primary Procedure	Number of Unique Patients with Laparoscopic Robotic-Assisted Procedures	Number of Laparoscopic Robotic-Assisted Procedures	Number of Unique Patients with Primary Procedure	Laparoscopic Robotic-Assisted Patients per 1000 Primary Procedure Patients	Procedures per Patient
0 to 40 years	6	6	653	9.2	1.0
41 to 54 years	8	8	1,561	5.1	1.0
55 to 64 years	12	14	1,459	8.2	1.2
65 to 74 years	10	10	833	12.0	1.0
75 to 84 years	4	4	353	11.3	1.0
85+ years	2	2	72	27.8	1.0
Vaginal hysterectomy					
Open or Laparoscopic					
0 to 40 years	2,546	2,846	53,881	47.3	1.1
41 to 54 years	4,523	5,018	79,944	56.6	1.1
55 to 64 years	1,329	1,425	20,099	66.1	1.1
65 to 74 years	736	759	9,466	77.8	1.0
75 to 84 years	279	285	3,018	92.4	1.0
85+ years	43	46	359	119.8	1.1
Laparoscopic					
0 to 40 years	2,525	2,825	37,324	67.7	1.1
41 to 54 years	4,479	4,974	52,721	85.0	1.1
55 to 64 years	1,316	1,412	11,121	118.3	1.1
65 to 74 years	723	745	3,842	188.2	1.0
75 to 84 years	278	284	1,051	264.5	1.0
85+ years	43	46	149	288.6	1.1
Open					
0 to 40 years	46	49	17,510	2.6	1.1
41 to 54 years	86	86	28,780	3.0	1.0
55 to 64 years	30	30	9,390	3.2	1.0
65 to 74 years	21	24	5,809	3.6	1.1
75 to 84 years	4	4	2,021	2.0	1.0
85+ years	1	1	217	4.6	1.0

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

Primary Procedure	Number of Unique Patients with Laparoscopic Robotic-Assisted Procedures	Number of Laparoscopic Robotic-Assisted Procedures	Number of Unique Patients with Primary Procedure	Laparoscopic Robotic-Assisted Patients per 1000 Primary Procedure Patients	Procedures per Patient
Repair of cystocele and rectocele					
Open or Laparoscopic					
0 to 40 years	100	114	10,754	9.3	1.1
41 to 54 years	321	346	30,368	10.6	1.1
55 to 64 years	238	257	23,393	10.2	1.1
65 to 74 years	182	186	16,369	11.1	1.0
75 to 84 years	48	50	6,369	7.5	1.0
85+ years	2	2	785	2.5	1.0
Laparoscopic					
0 to 40 years	2	2	92	21.7	1.0
41 to 54 years	10	10	213	46.9	1.0
55 to 64 years	16	18	191	83.8	1.1
65 to 74 years	11	12	80	137.5	1.1
75 to 84 years	5	5	19	263.2	1.0
85+ years	0	0	3	0.0	---
Open					
0 to 40 years	98	112	10,717	9.1	1.1
41 to 54 years	318	343	30,308	10.5	1.1
55 to 64 years	232	249	23,332	9.9	1.1
65 to 74 years	180	184	16,341	11.0	1.0
75 to 84 years	47	49	6,362	7.4	1.0
85+ years	2	2	783	2.6	1.0

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

Primary Procedure	Number of Unique Patients with Laparoscopic Robotic-Assisted Procedures	Number of Laparoscopic Robotic-Assisted Procedures	Number of Unique Patients with Primary Procedure	Laparoscopic Robotic-Assisted Patients per 1000 Primary Procedure Patients	Procedures per Patient
Supracervical hysterectomy					
Open or Laparoscopic					
Female	2,121	2,268	62,300	34.0	1.1
Male	2	2	174	11.5	1.0
Unknown	0	0	2	0.0	---
Laparoscopic					
Female	2,087	2,233	43,982	47.5	1.1
Male	2	2	85	23.5	1.0
Unknown	0	0	1	0.0	---
Open					
Female	130	137	20,428	6.4	1.1
Male	0	0	93	0.0	---
Unknown	0	0	1	0.0	---
Total abdominal hysterectomy					
Open or Laparoscopic					
Female	15,707	17,059	206,656	76.0	1.1
Male	46	50	845	54.4	1.1
Unknown	3	3	8	375.0	1.0
Laparoscopic					
Female	15,479	16,829	88,010	175.9	1.1
Male	45	49	275	163.6	1.1
Unknown	3	3	6	500.0	1.0
Open					
Female	563	576	121,811	4.6	1.0
Male	1	1	575	1.7	1.0
Unknown	1	1	3	333.3	1.0

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

Primary Procedure	Number of Unique Patients with Laparoscopic Robotic-Assisted Procedures	Number of Laparoscopic Robotic-Assisted Procedures	Number of Unique Patients with Primary Procedure	Laparoscopic Robotic-Assisted Patients per 1000 Primary Procedure Patients	Procedures per Patient
Radical abdominal hysterectomy					
Open or Laparoscopic					
Female	1,889	1,977	10,763	175.5	1.0
Male	5	5	23	217.4	1.0
Unknown	0	0	0	---	---
Laparoscopic					
Female	1,859	1,945	5,927	313.6	1.0
Male	4	4	14	285.7	1.0
Unknown	0	0	0	---	---
Open					
Female	41	43	4,919	8.3	1.0
Male	1	1	9	111.1	1.0
Unknown	0	0	0	---	---
Vaginal hysterectomy					
Open or Laparoscopic					
Female	9,423	10,345	166,163	56.7	1.1
Male	31	33	521	59.5	1.1
Unknown	1	1	5	200.0	1.0
Laparoscopic					
Female	9,331	10,252	105,873	88.1	1.1
Male	31	33	278	111.5	1.1
Unknown	1	1	3	333.3	1.0
Open					
Female	186	192	63,453	2.9	1.0
Male	2	2	248	8.1	1.0
Unknown	0	0	2	0.0	---

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

Primary Procedure	Number of Unique Patients with Laparoscopic Robotic-Assisted Procedures	Number of Laparoscopic Robotic-Assisted Procedures	Number of Unique Patients with Primary Procedure	Laparoscopic Robotic-Assisted Patients per 1000 Primary Procedure Patients	Procedures per Patient
Repair of cystocele and rectocele					
Open or Laparoscopic					
Female	884	948	87,316	10.1	1.1
Male	7	7	498	14.1	1.0
Unknown	0	0	0	---	---
Laparoscopic					
Female	44	47	598	73.6	1.1
Male	0	0	0	---	---
Unknown	0	0	0	---	---
Open					
Female	870	932	87,125	10.0	1.1
Male	7	7	498	14.1	1.0
Unknown	0	0	0	---	---

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

Primary Procedure	Number of Unique Patients with Laparoscopic Robotic-Assisted Px	Number of Laparoscopic Robotic-Assisted Procedures	Number of Unique Patients with Primary Procedure	Laparoscopic Robotic-Assisted Patients per 1000 Primary Procedure Patients	Procedures per Patient
Supracervical hysterectomy					
Open or Laparoscopic					
2008	81	85	4,614	17.6	1.0
2009	430	454	16,651	25.8	1.1
2010	556	599	15,565	35.7	1.1
2011	627	677	14,535	43.1	1.1
2012	431	455	11,235	38.4	1.1
Laparoscopic					
2008	81	85	3,072	26.4	1.0
2009	423	447	11,077	38.2	1.1
2010	548	591	10,883	50.4	1.1
2011	619	669	10,642	58.2	1.1
2012	420	443	8,478	49.5	1.1
Open					
2008	2	2	1,703	1.2	1.0
2009	29	32	6,161	4.7	1.1
2010	32	34	5,174	6.2	1.1
2011	34	35	4,387	7.8	1.0
2012	33	34	3,133	10.5	1.0
Total abdominal hysterectomy					
Open or Laparoscopic					
2008	484	515	13,877	34.9	1.1
2009	2,897	3,143	53,183	54.5	1.1
2010	4,164	4,563	50,538	82.4	1.1
2011	4,774	5,273	48,987	97.5	1.1
2012	3,462	3,618	41,488	83.4	1.0

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

Primary Procedure	Number of Unique Patients with Laparoscopic Robotic-Assisted Px	Number of Laparoscopic Robotic-Assisted Procedures	Number of Unique Patients with Primary Procedure	Laparoscopic Robotic-Assisted Patients per 1000 Primary Procedure Patients	Procedures per Patient
Laparoscopic					
2008	474	505	3,030	156.4	1.1
2009	2,848	3,093	15,278	186.4	1.1
2010	4,110	4,509	20,017	205.3	1.1
2011	4,718	5,216	24,963	189.0	1.1
2012	3,402	3,558	25,215	134.9	1.0
Open					
2008	30	30	10,991	2.7	1.0
2009	134	136	38,627	3.5	1.0
2010	140	143	31,284	4.5	1.0
2011	141	147	24,827	5.7	1.0
2012	120	122	16,962	7.1	1.0
Radical abdominal hysterectomy					
Open or Laparoscopic					
2008	60	60	689	87.1	1.0
2009	393	405	2,908	135.1	1.0
2010	484	504	2,698	179.4	1.0
2011	527	564	2,546	207.0	1.1
2012	434	449	1,963	221.1	1.0
Laparoscopic					
2008	58	58	251	231.1	1.0
2009	391	403	1,320	296.2	1.0
2010	473	491	1,457	324.6	1.0
2011	517	554	1,562	331.0	1.1
2012	428	443	1,358	315.2	1.0
Open					
2008	2	2	439	4.6	1.0
2009	8	8	1,609	5.0	1.0
2010	14	16	1,270	11.0	1.1
2011	10	10	1,001	10.0	1.0
2012	8	8	620	12.9	1.0

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

Primary Procedure	Number of Unique Patients with Laparoscopic Robotic-Assisted Px	Number of Laparoscopic Robotic-Assisted Procedures	Number of Unique Patients with Primary Procedure	Laparoscopic Robotic-Assisted Patients per 1000 Primary Procedure Patients	Procedures per Patient
Vaginal hysterectomy					
Open or Laparoscopic					
2008	365	409	11,552	31.6	1.1
2009	1,949	2,123	43,204	45.1	1.1
2010	2,567	2,836	42,427	60.5	1.1
2011	2,865	3,214	40,035	71.6	1.1
2012	1,727	1,797	29,972	57.6	1.0
Laparoscopic					
2008	362	406	6,700	54.0	1.1
2009	1,929	2,103	26,061	74.0	1.1
2010	2,543	2,811	26,673	95.3	1.1
2011	2,840	3,189	26,476	107.3	1.1
2012	1,707	1,777	20,581	82.9	1.0
Open					
2008	8	8	5,105	1.6	1.0
2009	46	46	18,143	2.5	1.0
2010	54	56	16,522	3.3	1.0
2011	49	51	14,222	3.4	1.0
2012	31	33	9,850	3.1	1.1
Repair of cystocele and rectocele					
Open or Laparoscopic					
2008	27	27	6,773	4.0	1.0
2009	146	154	24,588	5.9	1.1
2010	186	206	23,215	8.0	1.1
2011	279	295	20,621	13.5	1.1
2012	255	273	14,258	17.9	1.1

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

Primary Procedure	Number of Unique Patients with Laparoscopic Robotic-Assisted Px	Number of Laparoscopic Robotic-Assisted Procedures	Number of Unique Patients with Primary Procedure	Laparoscopic Robotic-Assisted Patients per 1000 Primary Procedure Patients	Procedures per Patient
Laparoscopic					
2008	2	2	36	55.6	1.0
2009	9	10	136	66.2	1.1
2010	10	10	120	83.3	1.0
2011	10	12	149	67.1	1.2
2012	13	13	159	81.8	1.0
Open					
2008	25	25	6,760	3.7	1.0
2009	142	149	24,541	5.8	1.0
2010	185	205	23,184	8.0	1.1
2011	276	291	20,569	13.4	1.1
2012	251	269	14,200	17.7	1.1

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. Descriptions of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), and Current Procedural Terminology, Fourth Edition (CPT-4) Primary Procedure Codes (Inclusion)

Supracervical hysterectomy

<u>Procedure (PX) Code</u>	<u>Code Type</u>	<u>Group</u>	<u>Description</u>
68.3	ICD-9	Supracervical hysterectomy - open	Subtotal abdominal hysterectomy
68.39	ICD-9	Supracervical hysterectomy - open	Other and unspecified subtotal abdominal hysterectomy
58180	CPT	Supracervical hysterectomy - open	Supracervical abdominal hysterectomy (subtotal hysterectomy), with or without removal of tube(s), with or without removal of ovary(s)
68.31	ICD-9	Supracervical hysterectomy - laparoscopic	Laparoscopic supracervical hysterectomy [LSH]
58541	CPT	Supracervical hysterectomy - laparoscopic	Laparoscopy, surgical, supracervical hysterectomy, for uterus 250 g or less;
58542	CPT	Supracervical hysterectomy - laparoscopic	Laparoscopy, surgical, supracervical hysterectomy, for uterus 250 g or less; with removal of tube(s) and/or ovary(s)
58543	CPT	Supracervical hysterectomy - laparoscopic	Laparoscopy, surgical, supracervical hysterectomy, for uterus greater than 250 g;
58544	CPT	Supracervical hysterectomy - laparoscopic	Laparoscopy, surgical, supracervical hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)

Total abdominal hysterectomy

<u>PX Code</u>	<u>Code Type</u>	<u>Group</u>	<u>Description</u>
68.4	ICD-9	Total abdominal hysterectomy - open	Total abdominal hysterectomy
68.49	ICD-9	Total abdominal hysterectomy - open	Other and unspecified total abdominal hysterectomy
58150	CPT	Total abdominal hysterectomy - open	Total abdominal hysterectomy (corpus and cervix), with or without removal of tube(s) and/or ovary(ies)
58152	CPT	Total abdominal hysterectomy - open	Total abdominal hysterectomy with colpo-urethrocystopexy
58200	CPT	Total abdominal hysterectomy - open	Total abdominal hysterectomy, including partial vaginectomy with para-aortic and pelvic lymph node sampling, with or without removal of tube(s), with or without removal of ovar(ies)
58240	CPT	Total abdominal hysterectomy - open	Pelvic exenteration for gynecologic malignancy, with total abdominal hysterectomy or cervicectomy, with or without removal of tube(s), with or without removal of ovary(ies), with removal of bladder and ureteral transplantations, and/or abdominoperineal resection of rectum and colon and colostomy, or any combination thereof

Appendix B. Descriptions of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), and Current Procedural Terminology, Fourth Edition (CPT-4) Primary Procedure Codes (Inclusion)

58951	CPT	Total abdominal hysterectomy - open	Resection of ovarian malignancy with bilateral salpingo-oophorectomy and omentectomy; with total abdominal hysterectomy, pelvic and limited para-aortic lymphadenectomy
58953	CPT	Total abdominal hysterectomy - open	Bilateral salpingo-oophorectomy with omentectomy, total abdominal hysterectomy and radical dissection for debulking
58954	CPT	Total abdominal hysterectomy - open	Bilateral salpingo-oophorectomy with omentectomy, total abdominal hysterectomy and radical dissection for Laparoscopic total abdominal hysterectomy
68.41	ICD-9	Total abdominal hysterectomy - laparoscopic	
58570	CPT	Total abdominal hysterectomy - laparoscopic	Laparoscopy, surgical, with total hysterectomy, for uterus 250g or less
58571	CPT	Total abdominal hysterectomy - laparoscopic	Laparoscopy, surgical, with total hysterectomy, for uterus 250g or less, with removal of tube(s) and/or ovary(ies)
58572	CPT	Total abdominal hysterectomy - laparoscopic	Laparoscopy, surgical, with total hysterectomy, for uterus greater than 250g
58573	CPT	Total abdominal hysterectomy - laparoscopic	Laparoscopy, surgical, with total hysterectomy, for uterus greater than 250g, with removal of tube(s) and/or ovary(ies)
58578	CPT	Total abdominal hysterectomy - laparoscopic	Unlisted laparoscopy procedure, uterus

Radical abdominal hysterectomy

<u>PX Code</u>	<u>Code Type</u>	<u>Group</u>	<u>Description</u>
68.6	ICD-9	Radical hysterectomy - open	Radical abdominal hysterectomy
58210	CPT	Radical hysterectomy - open	Radical abdominal hysterectomy, with bilateral total pelvic lymphadenectomy and para-aortic lymph node sampling
68.61	ICD-9	Radical hysterectomy - laparoscopic	Laparoscopic radical abdominal hysterectomy (TLAH)
58548	CPT	Radical hysterectomy - laparoscopic	Laparoscopy, surgical, with radical hysterectomy, with bilateral total pelvic lymphadenectomy and para-aortic

Vaginal hysterectomy

<u>PX Code</u>	<u>Code Type</u>	<u>Group</u>	<u>Description</u>
68.5	ICD-9	Vaginal hysterectomy - open	Vaginal hysterectomy
68.59	ICD-9	Vaginal hysterectomy - open	Other vaginal hysterectomy
68.7	ICD-9	Vaginal hysterectomy - open	Radical vaginal hysterectomy
68.79	ICD-9	Vaginal hysterectomy - open	Other and unspecified radical vaginal hysterectomy
58260	CPT	Vaginal hysterectomy - open	Vaginal hysterectomy, for uterus 250 grams or less
58262	CPT	Vaginal hysterectomy - open	Vaginal hysterectomy with removal of tube(s) and/or ovary(ies)
58263	CPT	Vaginal hysterectomy - open	Vaginal hysterectomy with removal of tube(s) and/or ovary(ies) with repair of enterocele

Appendix B. Descriptions of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), and Current Procedural Terminology, Fourth Edition (CPT-4) Primary Procedure Codes (Inclusion)

58267	CPT	Vaginal hysterectomy - open	Vaginal hysterectomy with colpo-urethrocystopexy (Marshall-Marchetti-Kranz type, Pereyra type, with or without endoscopic control)
58270	CPT	Vaginal hysterectomy - open	Vaginal hysterectomy with repair of enterocele
58275	CPT	Vaginal hysterectomy - open	Vaginal hysterectomy with total or partial vaginectomy
58280	CPT	Vaginal hysterectomy - open	Vaginal hysterectomy with total or partial vaginectomy with repair of enterocele
58285	CPT	Vaginal hysterectomy - open	Vaginal hysterectomy, radical (Schauta-type operation)
58290	CPT	Vaginal hysterectomy - open	Vaginal hysterectomy, for uterus greater than 250g
58291	CPT	Vaginal hysterectomy - open	Vaginal hysterectomy, for uterus greater than 250g; with
58292	CPT	Vaginal hysterectomy - open	Vaginal hysterectomy, for uterus greater than 250g; with removal of tube(s) and/or ovary(ies), with repair of enterocele
58293	CPT	Vaginal hysterectomy - open	Vaginal hysterectomy, for uterus greater than 250g; with colpo-urethrocystopexy (Marshall-Marchetti-Krantz type, Pereyra type) with or without endoscopic control
58294	CPT	Vaginal hysterectomy - open	Vaginal hysterectomy, for uterus greater than 250g; with repair of enterocele
68.51	ICD-9	Vaginal hysterectomy - laparoscopic	Laparoscopically assisted vaginal hysterectomy (LAVH)
68.71	ICD-9	Vaginal hysterectomy - laparoscopic	Laparoscopic radical vaginal hysterectomy [LRVH]
58545	CPT	Vaginal hysterectomy - laparoscopic	Vaginal hysterectomy with repair of enterocele
58546	CPT	Vaginal hysterectomy - laparoscopic	Vaginal hysterectomy with total or partial vaginectomy
58548	CPT	Vaginal hysterectomy - laparoscopic	Vaginal hysterectomy with total or partial vaginectomy with repair of enterocele
58550	CPT	Vaginal hysterectomy - laparoscopic	Laparoscopy surgical, with vaginal hysterectomy, for uterus 250 grams or less;
58552	CPT	Vaginal hysterectomy - laparoscopic	Laparoscopy surgical, with vaginal hysterectomy, for uterus 250 grams or less; with removal of tube(s) and/or ovary(s)
58553	CPT	Vaginal hysterectomy - laparoscopic	Laparoscopy, surgical, with vaginal hysterectomy, for uterus greater than 250 grams;
58554	CPT	Vaginal hysterectomy - laparoscopic	Laparoscopy, surgical, with vaginal hysterectomy, for uterus greater than 250 grams; with removal of tube(s) and/or ovary(s)

Repair of cystocele and rectocele

<u>PX Code</u>	<u>Code Type</u>	<u>Group</u>	<u>Description</u>
70.5	ICD-9	Cystocele and rectocele repair - open	Repair of cystocele and rectocele
70.50	ICD-9	Cystocele and rectocele repair - open	Repair of cystocele and rectocele
70.51	ICD-9	Cystocele and rectocele repair - open	Repair of cystocele
70.52	ICD-9	Cystocele and rectocele repair - open	Repair, rectocele

Appendix B. Descriptions of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), and Current Procedural Terminology, Fourth Edition (CPT-4) Primary Procedure Codes (Inclusion)

70.53	ICD-9	Cystocele and rectocele repair - open	Repair of cystocele and rectocele with graft or prosthesis
70.54	ICD-9	Cystocele and rectocele repair - open	Repair of cystocele with graft or prosthesis
70.55	ICD-9	Cystocele and rectocele repair - open	Repair of rectocele with graft or prosthesis
70.92	ICD-9	Cystocele and rectocele repair - open	Other operations, vaginal and cul-de-sac, other
70.93	PX09	Cystocele and rectocele repair - open	Other operations on cul-de-sac with graft or prosthesis
45560	CPT	Cystocele and rectocele repair - open	Repair of rectocele
57240	CPT	Cystocele and rectocele repair - open	Anterior colporrhaphy, repair of cystocele with or without repair of urethrocele.
57250	CPT	Cystocele and rectocele repair - open	Posterior colporrhaphy, repair of rectocele with or without perineorrhaphy
57268	CPT	Cystocele and rectocele repair - open	Repair of enterocele, vaginal approach
57270	CPT	Cystocele and rectocele repair - open	Repair of enterocele, abdominal approach
57284	CPT	Cystocele and rectocele repair - open	Paravaginal defect repair (including repair of cystocele, if performed); open abdominal approach
57285	CPT	Cystocele and rectocele repair - open	Paravaginal defect repair (including repair of cystocele, if performed); vaginal approach
57423	CPT	Cystocele and rectocele repair - laparoscopic	Paravaginal defect repair (including repair of cystocele, if performed), laparoscopic approach

Appendix C. MSY4_MPR44_V2 Specifications

Modular Program #9 was used to investigate prevalent use of robotic-assisted procedures. 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, 15 unique scenarios are examined in this report with differing exposures of interest and inclusion criteria. See below for a description of each of these scenarios. Since incident procedures are not requested, incidence criteria (Incidence Type, Washout Period) were not listed. Please see Appendix C for a list of the inclusion codes used. This is report 3 of 3 for request MSY4_MPR44_V2.

Scenario	Exposure Criteria			Inclusion/Exclusion Criteria					
	Prevalent Exposure	Care Setting	Principal Diagnosis	Condition	Inclusion/Exclusion	Lookback Start	Lookback End	Care Setting	Principal Dx
1	Laparoscopic robotic assisted procedure	All	No	Supracervical abdominal hysterectomy - open	Include	-1	1	All	No
2	Laparoscopic robotic assisted procedure	All	No	Supracervical abdominal hysterectomy - laparoscopic	Include	-1	1	All	No
3	Laparoscopic robotic assisted procedure	All	No	Supracervical abdominal hysterectomy - open or laparoscopic	Include	-1	1	All	No
4	Laparoscopic robotic assisted procedure	All	No	Total abdominal hysterectomy - open	Include	-1	1	All	No
5	Laparoscopic robotic assisted procedure	All	No	Total abdominal hysterectomy - laparoscopic	Include	-1	1	All	No
6	Laparoscopic robotic assisted procedure	All	No	Total abdominal hysterectomy - open or laparoscopic	Include	-1	1	All	No
7	Laparoscopic robotic assisted procedure	All	No	Radical abdominal hysterectomy - open	Include	-1	1	All	No
8	Laparoscopic robotic assisted procedure	All	No	Radical abdominal hysterectomy - laparoscopic	Include	-1	1	All	No
9	Laparoscopic robotic assisted procedure	All	No	Radical abdominal hysterectomy - open or laparoscopic	Include	-1	1	All	No
10	Laparoscopic robotic assisted procedure	All	No	Vaginal hysterectomy - open	Include	-1	1	All	No
11	Laparoscopic robotic assisted procedure	All	No	Vaginal hysterectomy - laparoscopic	Include	-1	1	All	No
12	Laparoscopic robotic assisted procedure	All	No	Vaginal hysterectomy - open or laparoscopic	Include	-1	1	All	No
13	Laparoscopic robotic assisted procedure	All	No	Repair of cystocele and rectocele - open	Include	-1	1	All	No
14	Laparoscopic robotic assisted procedure	All	No	Repair of cystocele and rectocele - laparoscopic	Include	-1	1	All	No
15	Laparoscopic robotic assisted procedure	All	No	Repair of cystocele and rectocele - open or laparoscopic	Include	-1	1	All	No