

## 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).

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### Overview for Request ID msy4\_mpr44\_v2 - Report 2 of 3

**Request ID:** msy4\_mpr44\_v2 - Report 2 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 2 presents results for use of robotic-assisted codes with specified primary procedures. Report 1 presents results for the robotic-assisted procedures codes only. Report 3 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) Cholecystectomy - open, (2) Cholecystectomy - laparoscopic, (3) Cholecystectomy - open or laparoscopic, (4) Nephrectomy - open, (5) Nephrectomy - laparoscopic, (6) Nephrectomy - open or laparoscopic, (7) Correction of ureteropelvic junction - open, (8) Correction of ureteropelvic junction - laparoscopic, (9) Correction of ureteropelvic junction - open or laparoscopic, (10) Prostatectomy - open, (11) Prostatectomy - laparoscopic, (12) Prostatectomy - open or laparoscopic, (13) Excision or destruction of lesion of uterus - open, (14) Excision or destruction of lesion of uterus - laparoscopic, and (15) Excision or destruction of lesion of uterus - 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](mailto:info@sentinelssystem.org)) for questions and to provide comments/suggestions for future enhancements to this document.

**Overview for Request ID msy4\_mpr44\_v2 - Report 2 of 3**

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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, by Associated Primary Procedure**

<b>Primary Procedure</b>	<b>Number of Unique Patients with Laparoscopic Robotic-Assisted Procedures</b>	<b>Number of Laparoscopic Robotic-Assisted Procedures</b>	<b>Number of Unique Patients with Primary Procedure</b>	<b>Laparoscopic Robotic-Assisted Patients per 1,000 Primary Procedure Patients</b>	<b>Procedures per Patient</b>
<b>Cholecystectomy</b>					
Open or Laparoscopic	534	564	570,944	0.9	1.1
Laparoscopic	524	554	541,107	1.0	1.1
Open	15	15	34,629	0.4	1.0
<b>Nephrectomy</b>					
Open or Laparoscopic	29,034	29,556	68,724	422.5	1.0
Laparoscopic	28,633	29,137	52,495	545.4	1.0
Open	4,117	4,236	31,345	131.3	1.0
<b>Correction of ureteropelvic junction</b>					
Open or Laparoscopic	1,309	1,365	70,302	18.6	1.0
Laparoscopic	1,056	1,103	2,311	456.9	1.0
Open	1,277	1,331	69,932	18.3	1.0
<b>Prostatectomy</b>					
Open or Laparoscopic	27,545	28,070	53,907	511.0	1.0
Laparoscopic	24,866	25,268	34,530	720.1	1.0
Open	25,279	25,771	47,388	533.4	1.0
<b>Excision or destruction of lesion of uterus</b>					
Open or Laparoscopic	1,222	1,355	97,531	12.5	1.1
Laparoscopic	941	1,039	16,506	57.0	1.1
Open	1,056	1,166	85,308	12.4	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**

<b>Primary Procedure</b>	<b>Number of Unique Patients with Laparoscopic Robotic-Assisted Procedures</b>	<b>Number of Laparoscopic Robotic-Assisted Procedures</b>	<b>Number of Unique Patients with Primary Procedure</b>	<b>Laparoscopic Robotic-Assisted Patients per 1000 Primary Procedure Patients</b>	<b>Procedures per Patient</b>
<b>Cholecystectomy</b>					
Open or Laparoscopic					
0 to 40 years	136	145	206,046	0.7	1.1
41 to 54 years	162	176	168,173	1.0	1.1
55 to 64 years	110	114	99,148	1.1	1.0
65 to 74 years	68	71	58,929	1.2	1.0
75 to 84 years	52	52	30,869	1.7	1.0
85+ years	6	6	8,021	0.7	1.0
Laparoscopic					
0 to 40 years	135	144	202,559	0.7	1.1
41 to 54 years	159	173	161,616	1.0	1.1
55 to 64 years	107	111	91,682	1.2	1.0
65 to 74 years	67	70	52,371	1.3	1.0
75 to 84 years	50	50	26,392	1.9	1.0
85+ years	6	6	6,706	0.9	1.0
Open					
0 to 40 years	2	2	4,751	0.4	1.0
41 to 54 years	5	5	7,811	0.6	1.0
55 to 64 years	3	3	8,440	0.4	1.0
65 to 74 years	2	2	7,274	0.3	1.0
75 to 84 years	3	3	4,915	0.6	1.0
85+ years	0	0	1,457	0.0	---
<b>Nephrectomy</b>					
Open or Laparoscopic					
0 to 40 years	505	514	4,898	103.1	1.0
41 to 54 years	6,387	6,511	16,311	391.6	1.0
55 to 64 years	13,927	14,171	27,338	509.4	1.0
65 to 74 years	7,397	7,520	15,662	472.3	1.0
75 to 84 years	778	793	4,041	192.5	1.0
85+ years	45	47	552	81.5	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**

<b>Primary Procedure</b>	<b>Number of Unique Patients with Laparoscopic Robotic-Assisted Procedures</b>	<b>Number of Laparoscopic Robotic-Assisted Procedures</b>	<b>Number of Unique Patients with Primary Procedure</b>	<b>Laparoscopic Robotic-Assisted Patients per 1000 Primary Procedure Patients</b>	<b>Procedures per Patient</b>
Laparoscopic					
0 to 40 years	465	469	2,755	168.8	1.0
41 to 54 years	6,292	6,414	12,401	507.4	1.0
55 to 64 years	13,806	14,047	22,678	608.8	1.0
65 to 74 years	7,297	7,415	12,099	603.1	1.0
75 to 84 years	739	752	2,322	318.3	1.0
85+ years	38	40	285	133.3	1.1
Open					
0 to 40 years	422	430	3,855	109.5	1.0
41 to 54 years	1,112	1,132	7,920	140.4	1.0
55 to 64 years	1,275	1,314	9,065	140.7	1.0
65 to 74 years	895	932	6,756	132.5	1.0
75 to 84 years	377	386	3,284	114.8	1.0
85+ years	40	42	502	79.7	1.1
<b>Correction of ureteropelvic junction</b>					
Open or Laparoscopic					
0 to 40 years	679	706	17,701	38.4	1.0
41 to 54 years	270	281	19,623	13.8	1.0
55 to 64 years	197	209	16,047	12.3	1.1
65 to 74 years	114	118	9,839	11.6	1.0
75 to 84 years	45	47	5,728	7.9	1.0
85+ years	4	4	1,840	2.2	1.0
Laparoscopic					
0 to 40 years	588	612	1,371	428.9	1.0
41 to 54 years	210	219	455	461.5	1.0
55 to 64 years	150	160	291	515.5	1.1
65 to 74 years	78	81	139	561.2	1.0
75 to 84 years	27	28	50	540.0	1.0
85+ years	3	3	6	500.0	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**

<b>Primary Procedure</b>	<b>Number of Unique Patients with Laparoscopic Robotic-Assisted Procedures</b>	<b>Number of Laparoscopic Robotic-Assisted Procedures</b>	<b>Number of Unique Patients with Primary Procedure</b>	<b>Laparoscopic Robotic-Assisted Patients per 1000 Primary Procedure Patients</b>	<b>Procedures per Patient</b>
0 to 40 years	661	687	17,482	37.8	1.0
41 to 54 years	266	277	19,549	13.6	1.0
55 to 64 years	193	204	16,002	12.1	1.1
65 to 74 years	110	114	9,817	11.2	1.0
75 to 84 years	43	45	5,719	7.5	1.0
85+ years	4	4	1,839	2.2	1.0
<b>Prostatectomy</b>					
Open or Laparoscopic					
0 to 40 years	87	89	691	125.9	1.0
41 to 54 years	5,696	5,830	10,749	529.9	1.0
55 to 64 years	13,989	14,255	25,857	541.0	1.0
65 to 74 years	7,324	7,440	14,447	507.0	1.0
75 to 84 years	446	452	2,024	220.4	1.0
85+ years	4	4	180	22.2	1.0
Laparoscopic					
0 to 40 years	69	70	300	230.0	1.0
41 to 54 years	5,252	5,355	7,493	700.9	1.0
55 to 64 years	12,644	12,849	17,684	715.0	1.0
65 to 74 years	6,500	6,586	8,502	764.5	1.0
75 to 84 years	398	404	560	710.7	1.0
85+ years	4	4	13	307.7	1.0
Open					
0 to 40 years	77	79	466	165.2	1.0
41 to 54 years	5,269	5,393	9,334	564.5	1.0
55 to 64 years	12,894	13,150	22,621	570.0	1.0
65 to 74 years	6,657	6,760	12,967	513.4	1.0
75 to 84 years	383	389	1,865	205.4	1.0
85+ years	0	0	169	0.0	---
<b>Excision or destruction of lesion of uterus</b>					
Open or Laparoscopic					

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

<b>Primary Procedure</b>	<b>Number of Unique Patients with Laparoscopic Robotic-Assisted Procedures</b>	<b>Number of Laparoscopic Robotic-Assisted Procedures</b>	<b>Number of Unique Patients with Primary Procedure</b>	<b>Laparoscopic Robotic-Assisted Patients per 1000 Primary Procedure Patients</b>	<b>Procedures per Patient</b>
0 to 40 years	755	841	47,324	16.0	1.1
41 to 54 years	400	441	42,888	9.3	1.1
55 to 64 years	39	42	5,278	7.4	1.1
65 to 74 years	21	23	1,591	13.2	1.1
75 to 84 years	8	8	518	15.4	1.0
85+ years	0	0	92	0.0	---
Laparoscopic					
0 to 40 years	613	675	11,091	55.3	1.1
41 to 54 years	295	326	4,701	62.8	1.1
55 to 64 years	22	25	520	42.3	1.1
65 to 74 years	9	10	147	61.2	1.1
75 to 84 years	3	3	49	61.2	1.0
85+ years	0	0	8	0.0	---
Open					
0 to 40 years	704	783	39,246	17.9	1.1
41 to 54 years	312	341	39,344	7.9	1.1
55 to 64 years	21	21	4,835	4.3	1.0
65 to 74 years	15	16	1,464	10.2	1.1
75 to 84 years	5	5	475	10.5	1.0
85+ years	0	0	85	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
<b>Cholecystectomy</b>					
Open or Laparoscopic					
Female	366	389	402,682	0.9	1.1
Male	168	175	168,238	1.0	1.0
Unknown	0	0	24	0.0	---
Laparoscopic					
Female	360	383	388,089	0.9	1.1
Male	164	171	152,997	1.1	1.0
Unknown	0	0	21	0.0	---
Open					
Female	9	9	17,491	0.5	1.0
Male	6	6	17,135	0.4	1.0
Unknown	0	0	3	0.0	---
<b>Nephrectomy</b>					
Open or Laparoscopic					
Female	1,699	1,752	14,495	117.2	1.0
Male	27,335	27,804	54,227	504.1	1.0
Unknown	0	0	2	0.0	---
Laparoscopic					
Female	1,536	1,579	7,868	195.2	1.0
Male	27,097	27,558	44,627	607.2	1.0
Unknown	0	0	0	---	---
Open					
Female	1,642	1,694	12,883	127.5	1.0
Male	2,475	2,542	18,460	134.1	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
<b>Correction of ureteropelvic junction</b>					
Open or Laparoscopic					
Female	715	743	32,358	22.1	1.0
Male	594	622	37,942	15.7	1.0
Unknown	0	0	2	0.0	---
Laparoscopic					
Female	580	603	1,221	475.0	1.0
Male	476	500	1,090	436.7	1.1
Unknown	0	0	0	---	---
Open					
Female	701	728	32,173	21.8	1.0
Male	576	603	37,757	15.3	1.0
Unknown	0	0	2	0.0	---
<b>Prostatectomy</b>					
Open or Laparoscopic					
Female	31	33	1,482	20.9	1.1
Male	27,514	28,037	52,425	524.8	1.0
Unknown	0	0	0	---	---
Laparoscopic					
Female	11	11	308	35.7	1.0
Male	24,855	25,257	34,222	726.3	1.0
Unknown	0	0	0	---	---
Open					
Female	28	30	1,185	23.6	1.1
Male	25,251	25,741	46,203	546.5	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
<b>Excision or destruction of lesion of uterus</b>					
Open or Laparoscopic					
Female	1,212	1,345	97,285	12.5	1.1
Male	10	10	243	41.2	1.0
Unknown	0	0	3	0.0	---
Laparoscopic					
Female	935	1,033	16,443	56.9	1.1
Male	6	6	62	96.8	1.0
Unknown	0	0	1	0.0	---
Open					
Female	1,048	1,158	85,117	12.3	1.1
Male	8	8	189	42.3	1.0
Unknown	0	0	2	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 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
<b>Cholecystectomy</b>					
Open or Laparoscopic					
2008	4	4	37,650	0.1	1.0
2009	42	44	146,396	0.3	1.0
2010	76	80	141,581	0.5	1.1
2011	109	117	135,785	0.8	1.1
2012	305	319	111,699	2.7	1.0
Laparoscopic					
2008	4	4	35,559	0.1	1.0
2009	42	44	138,217	0.3	1.0
2010	74	78	134,057	0.6	1.1
2011	106	114	129,025	0.8	1.1
2012	300	314	106,185	2.8	1.0
Open					
2008	0	0	2,485	0.0	---
2009	0	0	9,612	0.0	---
2010	2	2	8,755	0.2	1.0
2011	3	3	7,765	0.4	1.0
2012	10	10	6,216	1.6	1.0
<b>Nephrectomy</b>					
Open or Laparoscopic					
2008	1,410	1,446	4,300	327.9	1.0
2009	6,846	6,975	17,459	392.1	1.0
2010	6,857	6,955	16,560	414.1	1.0
2011	8,045	8,205	17,596	457.2	1.0
2012	5,913	5,975	13,236	446.7	1.0
Laparoscopic					
2008	1,405	1,441	3,188	440.7	1.0
2009	6,795	6,923	13,100	518.7	1.0
2010	6,796	6,894	12,556	541.3	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 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
2011	7,920	8,072	13,679	579.0	1.0
2012	5,752	5,807	10,146	566.9	1.0
Open					
2008	71	72	1,965	36.1	1.0
2009	622	634	7,960	78.1	1.0
2010	894	910	7,631	117.2	1.0
2011	1,233	1,271	7,680	160.5	1.0
2012	1,318	1,349	6,354	207.4	1.0
<b>Correction of ureteropelvic junction</b>					
Open or Laparoscopic					
2008	46	47	5,316	8.7	1.0
2009	292	305	19,143	15.3	1.0
2010	327	337	18,808	17.4	1.0
2011	340	354	18,164	18.7	1.0
2012	316	322	13,896	22.7	1.0
Laparoscopic					
2008	43	44	142	302.8	1.0
2009	248	259	522	475.1	1.0
2010	269	278	560	480.4	1.0
2011	273	285	585	466.7	1.0
2012	232	237	519	447.0	1.0
Open					
2008	45	46	5,293	8.5	1.0
2009	284	296	19,078	14.9	1.0
2010	317	327	18,723	16.9	1.0
2011	331	344	18,060	18.3	1.0
2012	312	318	13,786	22.6	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**

<b>Primary Procedure</b>	<b>Number of Unique Patients with Laparoscopic Robotic-Assisted Procedures</b>	<b>Number of Laparoscopic Robotic-Assisted Procedures</b>	<b>Number of Unique Patients with Primary Procedure</b>	<b>Laparoscopic Robotic-Assisted Patients per 1000 Primary Procedure Patients</b>	<b>Procedures per Patient</b>
<b>Prostatectomy</b>					
Open or Laparoscopic					
2008	1,438	1,481	3,622	397.0	1.0
2009	6,736	6,882	14,368	468.8	1.0
2010	6,549	6,652	13,148	498.1	1.0
2011	7,552	7,726	13,615	554.7	1.0
2012	5,290	5,329	9,249		
Laparoscopic					
2008	1,338	1,373	2,151	622.0	1.0
2009	6,213	6,330	8,714	713.0	1.0
2010	5,943	6,025	8,216	723.3	1.0
2011	6,806	6,928	9,210	739.0	1.0
2012	4,582	4,612	6,270	730.8	1.0
Open					
2008	1,377	1,419	3,279	419.9	1.0
2009	6,232	6,368	12,860	484.6	1.0
2010	6,005	6,105	11,569	519.1	1.0
2011	6,874	7,043	11,878	578.7	1.0
2012	4,810	4,836	7,878	610.6	1.0
<b>Excision or destruction of lesion of uterus</b>					
Open or Laparoscopic					
2008	38	45	8,022	4.7	1.2
2009	261	285	29,360	8.9	1.1
2010	332	372	25,961	12.8	1.1
2011	324	371	21,838	14.8	1.1
2012	271	282	13,809	19.6	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**

<b>Primary Procedure</b>	<b>Number of Unique Patients with Laparoscopic Robotic-Assisted Procedures</b>	<b>Number of Laparoscopic Robotic-Assisted Procedures</b>	<b>Number of Unique Patients with Primary Procedure</b>	<b>Laparoscopic Robotic-Assisted Patients per 1000 Primary Procedure Patients</b>	<b>Procedures per Patient</b>
Laparoscopic					
2008	30	36	981	30.6	1.2
2009	197	212	3,963	49.7	1.1
2010	258	286	4,038	63.9	1.1
2011	260	298	3,940	66.0	1.1
2012	199	207	3,696	53.8	1.0
Open					
2008	37	44	7,307	5.1	1.2
2009	219	242	26,465	8.3	1.1
2010	295	329	23,007	12.8	1.1
2011	280	315	18,946	14.8	1.1
2012	229	236	10,804	21.2	1.0

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

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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 (ICD-9) and Current Procedural Terminology (CPT) Primary Procedure Codes (Inclusion)**

**Cholecystectomy**

<u>Procedure Code</u>	<u>Code Type</u>	<u>Group</u>	<u>Description</u>
51.21	ICD-9	Cholecystectomy - open	Other partial cholecystectomy
51.22	ICD-9	Cholecystectomy - open	Cholecystectomy
47600	CPT	Cholecystectomy - open	Cholecystectomy
47605	CPT	Cholecystectomy - open	Cholecystectomy with cholangiography
47610	CPT	Cholecystectomy - open	Cholecystectomy with exploration of common duct
47612	CPT	Cholecystectomy - open	Cholecystectomy with choledochenterostomy
47620	CPT	Cholecystectomy - open	Cholecystectomy with exploration of common duct; with transduodenal sphincterotomy or sphincteroplasty, with or without cholangiography
51.23	ICD-9	Cholecystectomy - laparoscopic	Laparoscopic cholecystectomy
51.24	ICD-9	Cholecystectomy - laparoscopic	Laparoscopic partial cholecystectomy
47562	CPT	Cholecystectomy - laparoscopic	Laparoscopy, surgical; cholecystectomy
47563	CPT	Cholecystectomy - laparoscopic	Laparoscopy, surgical; cholecystectomy with cholangiography
47564	CPT	Cholecystectomy - laparoscopic	Laparoscopy, surgical; cholecystectomy with exploration of common duct

**Nephrectomy**

<u>Procedure Code</u>	<u>Code Type</u>	<u>Group</u>	<u>Description</u>
55.51	ICD-9	Nephrectomy - open	Nephroureterectomy
55.52	ICD-9	Nephrectomy - open	Nephrectomy of remaining kidney
55.4	ICD-9	Nephrectomy - open	Partial nephrectomy
55.5	ICD-9	Nephrectomy - open	Complete nephrectomy
55.54	ICD-9	Nephrectomy - open	Bilateral nephrectomy
50220	CPT	Nephrectomy - open	Nephrectomy, including partial ureterectomy, any open approach including rib resection
50225	CPT	Nephrectomy - open	Nephrectomy, including partial ureterectomy, any open approach including rib resection; complicated because of previous surgery on same kidney
50230	CPT	Nephrectomy - open	Nephrectomy, including partial ureterectomy, any open approach including rib resection; radical with regional lymphadenectomy and/or vena caval thrombectomy
50234	CPT	Nephrectomy - open	Nephrectomy with total ureterectomy and bladder cuff;
50236	CPT	Nephrectomy - open	Nephrectomy with total ureterectomy and bladder cuff; through separate incision
50240	CPT	Nephrectomy - open	Nephrectomy, partial
50300	CPT	Nephrectomy - open	Donor nephrectomy (including cold preservation); from cadaver donor, unilateral or bilateral Excluded from MFS

**Appendix B. Descriptions of International Classification of Diseases, Ninth Revision (ICD-9) and Current Procedural Terminology (CPT) Primary Procedure Codes (Inclusion)**

50320	CPT	Nephrectomy - open	Donor nephrectomy (including cold preservation); open, from
50340	CPT	Nephrectomy - open	Recipient nephrectomy (separate procedure)
50365	CPT	Nephrectomy - open	Renal allotransplantation, implantation of graft; with recipient
50543	CPT	Nephrectomy - laparoscopic	Laparoscopic, surgical; partial nephrectomy
50545	CPT	Nephrectomy - laparoscopic	Laparoscopy, radical nephrectomy (includes removal of Gerota's fascia and surrounding fatty tissue, removal of regional lymph nodes and adrenalectomy)
50546	CPT	Nephrectomy - laparoscopic	Laparoscopy, nephrectomy, including partial ureterectomy
50547	CPT	Nephrectomy - laparoscopic	Laparoscopy, donor nephrectomy from living donor (excluding preparation and maintenance of allograft)
50548	CPT	Nephrectomy - laparoscopic	Laparoscopy, nephrectomy with total ureterectomy
50549	CPT	Nephrectomy - laparoscopic	Unlisted laparoscopy procedure, renal
55866	CPT	Nephrectomy - laparoscopic	Laparoscopy, surgical prostatectomy, retropubic radical, including nerve sparing; includes robotic assistance, when performed

**Appendix B. Descriptions of International Classification of Diseases, Ninth Revision (ICD-9) and Current Procedural Terminology (CPT) Primary Procedure Codes (Inclusion)**

**Correction of ureteropelvic junction**

<u>Procedure Code</u>	<u>Code Type</u>	<u>Group</u>	<u>Description</u>
55.87	ICD-9	Correction of UPJ - open	Correction of ureteropelvic junction
55.1	ICD-9	Correction of UPJ - open	Pyelotomy and pyelostomy
55.11	ICD-9	Correction of UPJ - open	Pyelotomy
55.12	ICD-9	Correction of UPJ - open	Pyelostomy
56.0	ICD-9	Correction of UPJ - open	Transurethral removal of obstruction from ureter and renal pelvis
50400	CPT	Correction of UPJ - open	Pyeloplasty (Foley Y-pyeloplasty), plastic operation on renal
50405	CPT	Correction of UPJ - open	Pyeloplasty (Foley Y-pyeloplasty), plastic operation on renal
50392	CPT	Correction of UPJ - open	Introduction of intracatheter or catheter into renal pelvis for drainage and/or injection, percutaneous
50393	CPT	Correction of UPJ - open	Introduction of ureteral catheter or stent into ureter through renal pelvis for drainage and/or injection, percutaneous
50394	CPT	Correction of UPJ - open	Injection procedure for pyelography (as nephrostogram, pyelostogram, antegrade pyeloureterograms) through nephrostomy or pyelostomy tube, or indwelling ureteral catheter
50395	CPT	Correction of UPJ - open	Introduction of guide into renal pelvis and/or ureter with dilation to establish nephrostomy tract, percutaneous
50544	CPT	Correction of UPJ - laparoscopic	Laparoscopy surgical; pyeloplasty

**Prostatectomy**

<u>Procedure Code</u>	<u>Code Type</u>	<u>Group</u>	<u>Description</u>
60.3	ICD-9	Prostatectomy - open	Suprapubic prostatectomy; transvesical prostatectomy
60.4	ICD-9	Prostatectomy - open	Prostatectomy, radical; retropubic prostatectomy
60.5	ICD-9	Prostatectomy - open	Radical prostatectomy
60.6	ICD-9	Prostatectomy - open	Other prostatectomy
60.62	ICD-9	Prostatectomy - open	Perineal prostatectomy
55801	CPT	Prostatectomy - open	Prostatectomy, perineal, subtotal (including control of postoperative bleeding, vasectomy, meatotomy, urethral calibration and/or dilation, and internal urethrotomy)
55810	CPT	Prostatectomy - open	Perineal radical prostatectomy
55812	CPT	Prostatectomy - open	Prostatectomy, perineal radical; with lymph node biopsy(s) (limited pelvic lymphadenectomy)
55815	CPT	Prostatectomy - open	Perineal radical prostatectomy with bilateral pelvic lymph node
55821	CPT	Prostatectomy - open	Prostatectomy (including control of postoperative bleeding, vasectomy, meatotomy, urethral calibration and/or dilation, and internal urethrotomy); suprapubic, subtotal, 1 or 2 stages

**Appendix B. Descriptions of International Classification of Diseases, Ninth Revision (ICD-9) and Current Procedural Terminology (CPT) Primary Procedure Codes (Inclusion)**

55831	CPT	Prostatectomy - open	Prostatectomy (including control of postoperative bleeding, vasectomy, meatotomy, urethral calibration and/or dilation, and internal urethrotomy); retropubic, subtotal
55840	CPT	Prostatectomy - open	Retropubic radical
55842	CPT	Prostatectomy - open	Prostatectomy, retropubic radical, with or without nerve sparing; with lymph node biopsy(s) (limited pelvic lymphadenectomy)
55845	CPT	Prostatectomy - open	Prostatectomy, retropubic radical, with or without nerve sparing; with bilateral pelvic lymphadenectomy, including external iliac, hypogastric, and obturator nodes
55866	CPT	Prostatectomy - laparoscopic	Laparoscopy, surgical prostatectomy, retropubic radical, including nerve sparing; includes robotic assistance, when performed

**Appendix B. Descriptions of International Classification of Diseases, Ninth Revision (ICD-9) and Current Procedural Terminology (CPT) Primary Procedure Codes (Inclusion)**

**Excision or destruction of lesion or tissue of uterus**

<u>Procedure Code</u>	<u>Code Type</u>	<u>Group</u>	<u>Description</u>
68.2	ICD-9	Excision or destruction of lesion or tissue of uterus -	Excision or destruction of lesion or tissue of uterus
68.21	ICD-9	Excision or destruction of lesion or tissue of uterus -	Division of endometrial synechiae
68.22	ICD-9	Excision or destruction of lesion or tissue of uterus -	Incision or excision of congenital septum of uterus
68.23	ICD-9	Excision or destruction of lesion or tissue of uterus -	Endometrial ablation
68.29	ICD-9	Excision or destruction of lesion or tissue of uterus -	Other excision or destruction of lesion of uterus
37210	CPT	Excision or destruction of lesion or tissue of uterus - open	Uterine fibroid embolization (UFE, embolization of the uterine arteries to treat uterine fibroids, leiomyomata), percutaneous approach inclusive of vascular access, vessel selection, embolization, and all radiological supervision and interpretation, intraprocedural roadmapping, and imaging
58140	CPT	Excision or destruction of lesion or tissue of uterus - open	Myomectomy, excision of fibroid tumor(s) of uterus, 1 to 4 intramural myoma(s) with total weight of 250 g or less and/or removal of surface myomas; abdominal approach
58145	CPT	Excision or destruction of lesion or tissue of uterus - open	Myomectomy, excision of fibroid tumor(s) of uterus, 1 to 4 intramural myoma(s) with total weight of 250 g or less and/or removal of surface myomas; vaginal approach
58146	CPT	Excision or destruction of lesion or tissue of uterus - open	Myomectomy, excision of fibroid tumor(s) of uterus, 5 or more intramural myomas and/or intramural myomas with total weight greater than 250 g, abdominal approach
58579	CPT	Excision or destruction of lesion or tissue of uterus -	Unlisted hysteroscopy procedure, uterus
58957	CPT	Excision or destruction of lesion or tissue of uterus - open	Resection (tumor debulking) of recurrent ovarian, tubal, primary peritoneal, uterine malignancy (intra-abdominal, retroperitoneal tumors), with omentectomy, if performed;
58958	CPT	Excision or destruction of lesion or tissue of uterus - open	Resection (tumor debulking) of recurrent ovarian, tubal, primary peritoneal, uterine malignancy (intra-abdominal, retroperitoneal tumors), with omentectomy, if performed; with pelvic lymphadenectomy and limited para-aortic
58545	CPT	Excision or destruction of lesion or tissue of uterus - laparoscopic	Laparoscopy, surgical, myomectomy, excision; 1 to 4 intramural myomas with total weight of 250 g or less and/or removal of surface myomas
58546	CPT	Excision or destruction of lesion or tissue of uterus - laparoscopic	Laparoscopy, surgical, myomectomy, excision; 5 or more intramural myomas and/or intramural myomas with total weight greater than 250 g
58578	CPT	Excision or destruction of lesion or tissue of uterus - laparoscopic	Unlisted laparoscopy procedure, uterus

### 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. Please see Appendix C for a list of the inclusion codes used. This is report 2 of 3 from 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	Cholecystectomy - open	Include	-1	1	All	No
2	Laparoscopic robotic assisted procedure	All	No	Cholecystectomy - laparoscopic	Include	-1	1	All	No
3	Laparoscopic robotic assisted procedure	All	No	Cholecystectomy - open or laparoscopic	Include	-1	1	All	No
4	Laparoscopic robotic assisted procedure	All	No	Nephrectomy - open	Include	-1	1	All	No
5	Laparoscopic robotic assisted procedure	All	No	Nephrectomy - laparoscopic	Include	-1	1	All	No
6	Laparoscopic robotic assisted procedure	All	No	Nephrectomy - open or laparoscopic	Include	-1	1	All	No
7	Laparoscopic robotic assisted procedure	All	No	Correction of ureteropelvic junction - open	Include	-1	1	All	No
8	Laparoscopic robotic assisted procedure	All	No	Correction of ureteropelvic junction - laparoscopic	Include	-1	1	All	No
9	Laparoscopic robotic assisted procedure	All	No	Correction of ureteropelvic junction - open or laparoscopic	Include	-1	1	All	No
10	Laparoscopic robotic assisted procedure	All	No	Prostatectomy - open	Include	-1	1	All	No
11	Laparoscopic robotic assisted procedure	All	No	Prostatectomy - laparoscopic	Include	-1	1	All	No
12	Laparoscopic robotic assisted procedure	All	No	Prostatectomy - open or laparoscopic	Include	-1	1	All	No
13	Laparoscopic robotic assisted procedure	All	No	Excision or destruction of lesion of uterus - open	Include	-1	1	All	No
14	Laparoscopic robotic assisted procedure	All	No	Excision or destruction of lesion of uterus - laparoscopic	Include	-1	1	All	No
15	Laparoscopic robotic assisted procedure	All	No	Excision or destruction of lesion of uterus - open or laparoscopic	Include	-1	1	All	No