

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@mini-sentinel.org.

Overview

Request Description FDA requested use of Modular Program #6 to examine laparoscopic hysterectomy with and without robotic assistance and several outcomes (intraoperative complications, surgical site complications, and medical complications) in the Mini-Sentinel Distributed Database. Individuals with a gynecologic malignancy code in the 183 days prior to the hysterectomy were excluded from all scenarios in this analysis. In addition to the three broader categories of outcomes (intraoperative complications, surgical site complication, and medical complications), this request also examines specific intraoperative complications and surgical site complications. The intraoperative complications include bladder injury, ureteral injury, intestinal injury, vascular injury, and other operative injury. The surgical site complications include wound complications, abscess, hemorrhage, bowel obstruction, and reintervention. See the two orange specifications tabs for detailed information on each scenario in this request. See Appendix A for procedure codes used to define the exposure of interest (laparoscopic hysterectomy). See Appendix B for procedure and diagnosis codes used to define the inclusion/exclusion conditions of interest (gynecologic malignancy and robotic assistance). See Appendix C for a list of diagnosis and procedure codes used to define the outcomes of interest. The time window for the request was October 1, 2008 through May 31, 2013. This request was distributed to all 18 Mini-Sentinel Data Partners.

Results provide new hysterectomy patients, claims, lookup period duration (days), eligible members, member-years, new patients with incident post-exposure event, and number of event claims.

Request ID to09y05_mpr_wp32_v01 - Report 1 of 1

Specifications LapAlone Program parameter inputs for scenarios that examine laparoscopic hysterectomy without robotic assistance

Specifications Lap+Robot Program parameter inputs for scenarios that examine laparoscopic hysterectomy with robotic assistance

Glossary List of terms found in this report and their definitions

Table 1a Summary of Laparoscopic Hysterectomy (without Robotic Assistance) Use and Adverse Events in the MSDD between October 1, 2008 and May 31, 2013

Table 1b Summary of Laparoscopic Hysterectomy Use with Robotic Assistance and Adverse Events in the MSDD between October 1, 2008 and May 31, 2013

Table 2a Summary of Laparoscopic Hysterectomy (without Robotic Assistance) Use and Adverse Events in the MSDD between October 1, 2008 and May 31, 2013, by Age Group

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Table 4b Summary of Laparoscopic Hysterectomy Use with Robotic Assistance and Adverse Events in the MSDD between October 1, 2008 and May 31, 2013, by Year

Appendix A List of Exposure Procedure Codes included in this Request

Appendix B List of Inclusion/Exclusion Diagnosis and Procedure Codes included in this Request

Appendix C List of Outcome Diagnosis and Procedure Codes included in this Request

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

Specifications for Query ID to09y05_mpr_wp32_v01

Modular Program #6 was used to investigate the number of individuals with incident laparoscopic hysterectomies with and without robotic assistance and the number of those individuals who experience an adverse event in the following 30 days. In total, 52 scenarios are examined in this report. This tab describes the first 26 scenarios where members have a laparoscopic hysterectomy **without** robotic assistance. Members are excluded if they have a gynecologic malignancy in the 6 months before their hysterectomy, or if they have a robotic-assisted procedure on the day of their hysterectomy. See below for a description of each of these scenarios.

Coverage Requirement Medical Coverage
Query Period October 1, 2008 to May 31, 2013
Enrollment Gap 45 Days
Enrollment Days 183
Age Stratifications 0-39, 40-44, 45-49, 50-54, 55-59, 60+
Minimum Lookup Period Duration 30 Days

Scenario	Exposure Criteria (Defines Index Date)							Exclusion/Inclusion Criteria						Post-Exposure Event					
	Incident exposure	Incident w/ respect to:	Incidence Type	Washout Period (days)	Lookup Period Duration	Care Setting	Principal Dx	Condition	Exclude/Include	Lookback Period Start	Lookback Period End	Care Setting	Principal Dx	Post-Exposure Event	Incident w/ respect to:	Incidence Type	Washout Period (days)	Care Setting	Principal Dx
1	Laparoscopic Hysterectomy	Laparoscopic Hysterectomy	SING	0	30	Any	NO	Gynecologic malignancy	Exclude	-183	0	Any	NO	A. Intraoperative Complications	A. Intraoperative Complications	MULT	183	Any	NO
							Robotic Assistance Procedure	Exclude	0	0	Any	NO							
2	Laparoscopic Hysterectomy	Laparoscopic Hysterectomy	SING	0	30	Any	NO	Gynecologic malignancy	Exclude	-183	0	Any	NO	Bladder Injury	Bladder Injury	MULT	183	Any	NO
							Robotic Assistance Procedure	Exclude	0	0	Any	NO							
3	Laparoscopic Hysterectomy	Laparoscopic Hysterectomy	SING	0	30	Any	NO	Gynecologic malignancy	Exclude	-183	0	Any	NO	Ureteral Injury	Ureteral Injury	MULT	183	Any	NO
							Robotic Assistance Procedure	Exclude	0	0	Any	NO							
4	Laparoscopic Hysterectomy	Laparoscopic Hysterectomy	SING	0	30	Any	NO	Gynecologic malignancy	Exclude	-183	0	Any	NO	Intestinal Injury	Intestinal Injury	MULT	183	Any	NO
							Robotic Assistance Procedure	Exclude	0	0	Any	NO							
5	Laparoscopic Hysterectomy	Laparoscopic Hysterectomy	SING	0	30	Any	NO	Gynecologic malignancy	Exclude	-183	0	Any	NO	Vascular Injury	Vascular Injury	MULT	183	Any	NO
							Robotic Assistance Procedure	Exclude	0	0	Any	NO							
6	Laparoscopic Hysterectomy	Laparoscopic Hysterectomy	SING	0	30	Any	NO	Gynecologic malignancy	Exclude	-183	0	Any	NO	Other Operative Injury	Other Operative Injury	MULT	183	Any	NO
							Robotic Assistance Procedure	Exclude	0	0	Any	NO							
7	Laparoscopic Hysterectomy	Laparoscopic Hysterectomy	SING	0	30	Any	NO	Gynecologic malignancy	Exclude	-183	0	Any	NO	B. Surgical Site Complications	B. Surgical Site Complications	MULT	183	Any	NO
							Robotic Assistance Procedure	Exclude	0	0	Any	NO							

8	-	Laparoscopic Hysterectomy	Laparoscopic Hysterectomy	SING	0	30	Any	NO	Gynecologic malignancy	Exclude	-183	0	Any	NO	Wound Complications	Wound Complications	MULT	183	Any	NO
									Robotic Assistance Procedure	Exclude	0	0	Any	NO						
9	-	Laparoscopic Hysterectomy	Laparoscopic Hysterectomy	SING	0	30	Any	NO	Gynecologic malignancy	Exclude	-183	0	Any	NO	Abscess	Abscess	MULT	183	Any	NO
									Robotic Assistance Procedure	Exclude	0	0	Any	NO						
10	-	Laparoscopic Hysterectomy	Laparoscopic Hysterectomy	SING	0	30	Any	NO	Gynecologic malignancy	Exclude	-183	0	Any	NO	Hemorrhage	Hemorrhage	MULT	183	Any	NO
									Robotic Assistance Procedure	Exclude	0	0	Any	NO						
11	-	Laparoscopic Hysterectomy	Laparoscopic Hysterectomy	SING	0	30	Any	NO	Gynecologic malignancy	Exclude	-183	0	Any	NO	Bowel Obstruction	Bowel Obstruction	MULT	183	Any	NO
									Robotic Assistance Procedure	Exclude	0	0	Any	NO						
12	-	Laparoscopic Hysterectomy	Laparoscopic Hysterectomy	SING	0	30	Any	NO	Gynecologic malignancy	Exclude	-183	0	Any	NO	Reintervention	Reintervention	MULT	183	Any	NO
									Robotic Assistance Procedure	Exclude	0	0	Any	NO						
13	-	Laparoscopic Hysterectomy	Laparoscopic Hysterectomy	SING	0	30	Any	NO	Gynecologic malignancy	Exclude	-183	0	Any	NO	C. Medical Complications	C. Medical Complications	MULT	183	Any	NO
									Robotic Assistance Procedure	Exclude	0	0	Any	NO						
14	-	Laparoscopic Hysterectomy	Laparoscopic Hysterectomy	SING	0	30	IP or ED	NO	Gynecologic malignancy	Exclude	-183	0	Any	NO	A. Intraoperative Complications	A. Intraoperative Complications	MULT	183	Any	NO
									Robotic Assistance Procedure	Exclude	0	0	IP or ED	NO						
15	-	Laparoscopic Hysterectomy	Laparoscopic Hysterectomy	SING	0	30	IP or ED	NO	Gynecologic malignancy	Exclude	-183	0	Any	NO	Bladder Injury	Bladder Injury	MULT	183	Any	NO
									Robotic Assistance Procedure	Exclude	0	0	IP or ED	NO						
16	-	Laparoscopic Hysterectomy	Laparoscopic Hysterectomy	SING	0	30	IP or ED	NO	Gynecologic malignancy	Exclude	-183	0	Any	NO	Ureteral Injury	Ureteral Injury	MULT	183	Any	NO
									Robotic Assistance Procedure	Exclude	0	0	IP or ED	NO						
17	-	Laparoscopic Hysterectomy	Laparoscopic Hysterectomy	SING	0	30	IP or ED	NO	Gynecologic malignancy	Exclude	-183	0	Any	NO	Intestinal Injury	Intestinal Injury	MULT	183	Any	NO
									Robotic Assistance Procedure	Exclude	0	0	IP or ED	NO						

18	-	Laparoscopic Hysterectomy	Laparoscopic Hysterectomy	SING	0	30	IP or ED	NO	Gynecologic malignancy	Exclude	-183	0	Any	NO	Vascular Injury	Vascular Injury	MULT	183	Any	NO
									Robotic Assistance Procedure	Exclude	0	0	IP or ED	NO						
19	-	Laparoscopic Hysterectomy	Laparoscopic Hysterectomy	SING	0	30	IP or ED	NO	Gynecologic malignancy	Exclude	-183	0	Any	NO	Other Operative Injury	Other Operative Injury	MULT	183	Any	NO
									Robotic Assistance Procedure	Exclude	0	0	IP or ED	NO						
20	-	Laparoscopic Hysterectomy	Laparoscopic Hysterectomy	SING	0	30	IP or ED	NO	Gynecologic malignancy	Exclude	-183	0	Any	NO	B. Surgical Site Complications	B. Surgical Site Complications	MULT	183	Any	NO
									Robotic Assistance Procedure	Exclude	0	0	IP or ED	NO						
21	-	Laparoscopic Hysterectomy	Laparoscopic Hysterectomy	SING	0	30	IP or ED	NO	Gynecologic malignancy	Exclude	-183	0	Any	NO	Wound Complications	Wound Complications	MULT	183	Any	NO
									Robotic Assistance Procedure	Exclude	0	0	IP or ED	NO						
22	-	Laparoscopic Hysterectomy	Laparoscopic Hysterectomy	SING	0	30	IP or ED	NO	Gynecologic malignancy	Exclude	-183	0	Any	NO	Abscess	Abscess	MULT	183	Any	NO
									Robotic Assistance Procedure	Exclude	0	0	IP or ED	NO						
23	-	Laparoscopic Hysterectomy	Laparoscopic Hysterectomy	SING	0	30	IP or ED	NO	Gynecologic malignancy	Exclude	-183	0	Any	NO	Hemorrhage	Hemorrhage	MULT	183	Any	NO
									Robotic Assistance Procedure	Exclude	0	0	IP or ED	NO						
24	-	Laparoscopic Hysterectomy	Laparoscopic Hysterectomy	SING	0	30	IP or ED	NO	Gynecologic malignancy	Exclude	-183	0	Any	NO	Bowel Obstruction	Bowel Obstruction	MULT	183	Any	NO
									Robotic Assistance Procedure	Exclude	0	0	IP or ED	NO						
25	-	Laparoscopic Hysterectomy	Laparoscopic Hysterectomy	SING	0	30	IP or ED	NO	Gynecologic malignancy	Exclude	-183	0	Any	NO	Reintervention	Reintervention	MULT	183	Any	NO
									Robotic Assistance Procedure	Exclude	0	0	IP or ED	NO						
26	-	Laparoscopic Hysterectomy	Laparoscopic Hysterectomy	SING	0	30	IP or ED	NO	Gynecologic malignancy	Exclude	-183	0	Any	NO	C. Medical Complications	C. Medical Complications	MULT	183	Any	NO
									Robotic Assistance Procedure	Exclude	0	0	IP or ED	NO						

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Modular Program #6 was used to investigate the number of individuals with incident laparoscopic hysterectomies with and without robotic assistance and the number of those individuals who experience an adverse event in the following 30 days. In total, 52 scenarios are examined in this report. This tab describes the second 26 scenarios where members have a laparoscopic hysterectomy **with** robotic assistance. Members are excluded if they have a gynecologic malignancy in the 6 months before their hysterectomy, and they are included if they have a robotic-assisted procedure on the day of their hysterectomy. See below for a description of each of these scenarios.

Coverage Requirement Medical Coverage
Query Period October 1, 2008 to May 31, 2013
Enrollment Gap 45 Days
Enrollment Days 183
Age Stratifications 0-39, 40-44, 45-49, 50-54, 55-59, 60+
Minimum Lookup Period Duration 30 Days

Scenario	Exposure Criteria (Defines Index Date)							Exclusion/Inclusion Criteria					Post-Exposure Event						
	Incident exposure	Incident w/ respect to:	Incidence Type	Washout Period (days)	Lookup Period Duration	Care Setting	Principal Dx	Condition	Exclude/Include	Lookback Period Start	Lookback Period End	Care Setting	Principal Dx	Post-Exposure Event	Incident w/ respect to:	Incidence Type	Washout Period (days)	Care Setting	Principal Dx
1	Laparoscopic Hysterectomy	Laparoscopic Hysterectomy	SING	0	30	Any	NO	Gynecologic malignancy	Exclude	-183	0	Any	NO	A. Intraoperative Complications	A. Intraoperative Complications	MULT	183	Any	NO
								Robotic Assistance Procedure	Include	0	0	Any	NO						
2	Laparoscopic Hysterectomy	Laparoscopic Hysterectomy	SING	0	30	Any	NO	Gynecologic malignancy	Exclude	-183	0	Any	NO	Bladder Injury	Bladder Injury	MULT	183	Any	NO
								Robotic Assistance Procedure	Include	0	0	Any	NO						
3	Laparoscopic Hysterectomy	Laparoscopic Hysterectomy	SING	0	30	Any	NO	Gynecologic malignancy	Exclude	-183	0	Any	NO	Ureteral Injury	Ureteral Injury	MULT	183	Any	NO
								Robotic Assistance Procedure	Include	0	0	Any	NO						
4	Laparoscopic Hysterectomy	Laparoscopic Hysterectomy	SING	0	30	Any	NO	Gynecologic malignancy	Exclude	-183	0	Any	NO	Intestinal Injury	Intestinal Injury	MULT	183	Any	NO
								Robotic Assistance Procedure	Include	0	0	Any	NO						
5	Laparoscopic Hysterectomy	Laparoscopic Hysterectomy	SING	0	30	Any	NO	Gynecologic malignancy	Exclude	-183	0	Any	NO	Vascular Injury	Vascular Injury	MULT	183	Any	NO
								Robotic Assistance Procedure	Include	0	0	Any	NO						
6	Laparoscopic Hysterectomy	Laparoscopic Hysterectomy	SING	0	30	Any	NO	Gynecologic malignancy	Exclude	-183	0	Any	NO	Other Operative Injury	Other Operative Injury	MULT	183	Any	NO
								Robotic Assistance Procedure	Include	0	0	Any	NO						
7	Laparoscopic Hysterectomy	Laparoscopic Hysterectomy	SING	0	30	Any	NO	Gynecologic malignancy	Exclude	-183	0	Any	NO	B. Surgical Site Complications	B. Surgical Site Complications	MULT	183	Any	NO
								Robotic Assistance Procedure	Include	0	0	Any	NO						

8	-	Laparoscopic Hysterectomy	Laparoscopic Hysterectomy	SING	0	30	Any	NO	Gynecologic malignancy	Exclude	-183	0	Any	NO	Wound Complications	Wound Complications	MULT	183	Any	NO
									Robotic Assistance Procedure	Include	0	0	Any	NO						
9	-	Laparoscopic Hysterectomy	Laparoscopic Hysterectomy	SING	0	30	Any	NO	Gynecologic malignancy	Exclude	-183	0	Any	NO	Abscess	Abscess	MULT	183	Any	NO
									Robotic Assistance Procedure	Include	0	0	Any	NO						
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									Robotic Assistance Procedure	Include	0	0	Any	NO						
11	-	Laparoscopic Hysterectomy	Laparoscopic Hysterectomy	SING	0	30	Any	NO	Gynecologic malignancy	Exclude	-183	0	Any	NO	Bowel Obstruction	Bowel Obstruction	MULT	183	Any	NO
									Robotic Assistance Procedure	Include	0	0	Any	NO						
12	-	Laparoscopic Hysterectomy	Laparoscopic Hysterectomy	SING	0	30	Any	NO	Gynecologic malignancy	Exclude	-183	0	Any	NO	Reintervention	Reintervention	MULT	183	Any	NO
									Robotic Assistance Procedure	Include	0	0	Any	NO						
13	-	Laparoscopic Hysterectomy	Laparoscopic Hysterectomy	SING	0	30	Any	NO	Gynecologic malignancy	Exclude	-183	0	Any	NO	C. Medical Complications	C. Medical Complications	MULT	183	Any	NO
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									Robotic Assistance Procedure	Include	0	0	IP or ED	NO						
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17	-	Laparoscopic Hysterectomy	Laparoscopic Hysterectomy	SING	0	30	IP or ED	NO	Gynecologic malignancy	Exclude	-183	0	Any	NO	Intestinal Injury	Intestinal Injury	MULT	183	Any	NO
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18	-	Laparoscopic Hysterectomy	Laparoscopic Hysterectomy	SING	0	30	IP or ED	NO	Gynecologic malignancy	Exclude	-183	0	Any	NO	Vascular Injury	Vascular Injury	MULT	183	Any	NO
									Robotic Assistance Procedure	Include	0	0	IP or ED	NO						
19	-	Laparoscopic Hysterectomy	Laparoscopic Hysterectomy	SING	0	30	IP or ED	NO	Gynecologic malignancy	Exclude	-183	0	Any	NO	Other Operative Injury	Other Operative Injury	MULT	183	Any	NO
									Robotic Assistance Procedure	Include	0	0	IP or ED	NO						
20	-	Laparoscopic Hysterectomy	Laparoscopic Hysterectomy	SING	0	30	IP or ED	NO	Gynecologic malignancy	Exclude	-183	0	Any	NO	B. Surgical Site Complications	B. Surgical Site Complications	MULT	183	Any	NO
									Robotic Assistance Procedure	Include	0	0	IP or ED	NO						
21	-	Laparoscopic Hysterectomy	Laparoscopic Hysterectomy	SING	0	30	IP or ED	NO	Gynecologic malignancy	Exclude	-183	0	Any	NO	Wound Complications	Wound Complications	MULT	183	Any	NO
									Robotic Assistance Procedure	Include	0	0	IP or ED	NO						
22	-	Laparoscopic Hysterectomy	Laparoscopic Hysterectomy	SING	0	30	IP or ED	NO	Gynecologic malignancy	Exclude	-183	0	Any	NO	Abscess	Abscess	MULT	183	Any	NO
									Robotic Assistance Procedure	Include	0	0	IP or ED	NO						
23	-	Laparoscopic Hysterectomy	Laparoscopic Hysterectomy	SING	0	30	IP or ED	NO	Gynecologic malignancy	Exclude	-183	0	Any	NO	Hemorrhage	Hemorrhage	MULT	183	Any	NO
									Robotic Assistance Procedure	Include	0	0	IP or ED	NO						
24	-	Laparoscopic Hysterectomy	Laparoscopic Hysterectomy	SING	0	30	IP or ED	NO	Gynecologic malignancy	Exclude	-183	0	Any	NO	Bowel Obstruction	Bowel Obstruction	MULT	183	Any	NO
									Robotic Assistance Procedure	Include	0	0	IP or ED	NO						
25	-	Laparoscopic Hysterectomy	Laparoscopic Hysterectomy	SING	0	30	IP or ED	NO	Gynecologic malignancy	Exclude	-183	0	Any	NO	Reintervention	Reintervention	MULT	183	Any	NO
									Robotic Assistance Procedure	Include	0	0	IP or ED	NO						
26	-	Laparoscopic Hysterectomy	Laparoscopic Hysterectomy	SING	0	30	IP or ED	NO	Gynecologic malignancy	Exclude	-183	0	Any	NO	C. Medical Complications	C. Medical Complications	MULT	183	Any	NO
									Robotic Assistance Procedure	Include	0	0	IP or ED	NO						

Glossary of Terms in Modular Program 6*

Care Setting - type of medical encounter or facility where the exposure, event, or condition code was recorded. Possible care settings include: Inpatient Hospital Stay (IP), Non-Acute Institutional Stay (IS), Emergency Department (ED), Ambulatory Visit (AV), and Other Ambulatory Visit (OA).

Claims - number of exposure event claims experienced by new patients.

Eligible Members - Number of members eligible for an incident exposure/lookup period (defined by the exposure and event washout periods and any pre-existing inclusions or exclusions) with drug and medical coverage during the query period.

Member-Years - sum of all days a member is eligible for an incident exposure/lookup period (i.e., days that the member meets all inclusion criteria such as incidence, pre-existing condition, and enrollment requirements) divided by 365.23.

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

Inclusion/Exclusion Indicator - indicates whether condition(s) of interest are used for inclusion or exclusion criteria. A value of 1 instructs the program that members must have the condition of interest (inclusion criteria); a value of 0 instructs the program that members must not have the condition of interest (exclusion criteria).

Lookback Period Start and End - range of days relative to index that the program looks for inclusion/exclusion conditions of interest. For example, if the Inclusion/Exclusion Indicator =1, Lookback Period Start = -183 and Lookback Period End = 0, the cohort will only include members with the condition of interest present in the 183 days prior to and including the index date (the index date is day 0).

Lookup Period Duration - fixed period of time following an incident exposure that the MP6 program searches for events of interest.

Minimum Lookup Period Duration - minimum number of enrollment days required after an incident exposure/lookup period start. For example, if the minimum duration =10, a member must have 10 or more days of continuous enrollment in drug and medical benefit coverage following the exposure/lookup period start in order for the lookup period to be included in output metrics.

New Patients - number of members with incident exposure/lookup period during the query period. A user may only be counted once in a query period.

New Patients with Post-Exposure Event - number of patients who have an incident claim for the post-exposure event of interest.

Principal Diagnosis - diagnosis or condition established to be chiefly responsible for admission of the patient to the hospital. YES will only consider diagnoses flagged as Principal.

Query Period - period in which the modular program evaluates exposures of interest.

Washout Period (exposure)** - number of days a user is required to have no evidence of prior exposure (drug dispensing/procedure/diagnosis) and continuous drug and medical coverage prior to an incident exposure/lookup period.

Washout Period (event/outcome)** - number of days a user is required to have no evidence of a prior event and continuous drug and medical coverage prior to an incident claim.

Incidence Type (drug/exposure)- *Minimum Incidence type* will consider the first exposure/lookup period in the query period as long as it is the first exposure/lookup period in the user's entire available history. *Single* and *Multiple Incidence types* will use the washout period to establish incidence; however, *Single* will only consider the first exposure/lookup period whereas *Multiple* will consider all qualifying exposures/lookup periods.

Incidence Type (outcome)- *Minimum Incidence type* considers the first event in a valid episode as long as it is the first event in the user's entire available history. *Multiple Incidence type* uses the washout period to establish incidence and considers all qualifying incident exposures/lookup periods.

Time-to-Event (tte)/Time-to-Treatment - number of days between the start of an exposure lookup period (index date) and the first event claim.

*all terms may not be used in this report

Table 1a. Summary of Laparoscopic Hysterectomy (without Robotic Assistance) Use and Adverse Events in the MSDD between October 1, 2008 and May 31, 2013

	Incident Exposure (Laparoscopic Hysterectomy)					Post-Exposure Events			
	New Patients	Claims	Lookup Period Duration	Eligible Members*	Member-Years	New Patients with Incident Post-Exposure Event	Number of Post-Exposure Event Claims	New Patients/ 1000 Eligible Members*	% New Patients with Post-Exposure Event
Laparoscopic Hysterectomy without Robotic Assistance in Any Care Setting									
Intraoperative Complications	78,077	85,585	2,342,310	108,623,147	239,569,875	3,093	6,617	0.72	3.96%
Bladder Injury	78,624	86,181	2,358,720	108,639,890	239,913,904	1,170	2,103	0.72	1.49%
Ureteral Injury	78,500	86,050	2,355,000	108,634,716	239,814,930	1,031	1,541	0.72	1.31%
Intestinal Injury	78,581	86,122	2,357,430	108,635,650	239,836,247	393	600	0.72	0.50%
Vascular Injury	78,654	86,212	2,359,620	108,641,132	239,937,732	35	42	0.72	0.04%
Other Operative Injury	78,338	85,876	2,350,140	108,636,745	239,827,991	1,972	2,572	0.72	2.52%
Surgical Site Complications	77,111	84,521	2,313,330	108,543,844	237,449,655	4,762	8,222	0.71	6.18%
Reintervention	78,654	86,213	2,359,620	108,640,687	239,928,480	235	248	0.72	0.30%
Wound Complications	78,453	85,993	2,353,590	108,627,184	239,602,127	888	1,449	0.72	1.13%
Abscess	77,828	85,296	2,334,840	108,572,948	238,121,503	1,986	3,228	0.72	2.55%
Hemorrhage	78,206	85,721	2,346,180	108,631,586	239,662,869	2,273	3,029	0.72	2.91%
Bowel Obstruction	78,530	86,086	2,355,900	108,632,077	239,717,897	339	482	0.72	0.43%
Medical Complications	75,433	82,722	2,262,990	108,197,969	231,655,348	3,159	6,183	0.70	4.19%
Laparoscopic Hysterectomy without Robotic Assistance in the Inpatient or Emergency Department Care Setting									
Intraoperative Complications	60,231	60,694	1,806,930	108,623,913	239,619,226	2,686	5,666	0.55	4.46%
Bladder Injury	60,715	61,183	1,821,450	108,640,651	239,963,744	1,027	1,818	0.56	1.69%
Ureteral Injury	60,614	61,080	1,818,420	108,635,481	239,864,647	941	1,372	0.56	1.55%
Intestinal Injury	60,689	61,155	1,820,670	108,636,410	239,886,131	346	526	0.56	0.57%
Vascular Injury	60,749	61,216	1,822,470	108,641,894	239,987,697	34	40	0.56	0.06%
Other Operative Injury	60,455	60,923	1,813,650	108,637,506	239,877,708	1,710	2,143	0.56	2.83%
Surgical Site Complications	59,522	59,980	1,785,660	108,544,622	237,497,687	3,949	6,917	0.55	6.63%
Reintervention	60,748	61,216	1,822,440	108,641,448	239,978,427	209	220	0.56	0.34%
Wound Complications	60,587	61,055	1,817,610	108,627,945	239,651,730	750	1,268	0.56	1.24%
Abscess	60,133	60,595	1,803,990	108,573,721	238,170,287	1,589	2,611	0.55	2.64%
Hemorrhage	60,360	60,825	1,810,800	108,632,352	239,712,409	1,962	2,598	0.56	3.25%
Bowel Obstruction	60,643	61,109	1,819,290	108,632,837	239,767,742	296	424	0.56	0.49%
Medical Complications	58,096	58,541	1,742,880	108,198,758	231,702,568	2,811	5,480	0.54	4.84%

*To be included as an eligible member, an individual must meet the exclusion criteria (no evidence of a gynecologic malignancy or a robotic assistance procedure)

Table 1b. Summary of Laparoscopic Hysterectomy Use with Robotic Assistance and Adverse Events in the MSDD between October 1, 2008 and May 31, 2013

	Incident Exposure (Laparoscopic Hysterectomy)			Post-Exposure Events				
	New Patients	Claims	Lookup Period Duration	Eligible Members*	New Patients with Incident Post-Exposure Event	Number of Post-Exposure Event Claims	New Patients/ 1000 Eligible Members*	% New Patients with Post-Exposure Event
Laparoscopic Hysterectomy and Robotic Assistance in Any Care Setting								
Intraoperative Complications	23,796	26,407	713,880	92,989	976	1,870	255.90	4.10%
Bladder Injury	23,959	26,577	718,770	95,786	306	505	250.13	1.28%
Ureteral Injury	23,925	26,541	717,750	93,565	368	531	255.70	1.54%
Intestinal Injury	23,958	26,573	718,740	95,803	112	167	250.08	0.47%
Vascular Injury	23,979	26,597	719,370	95,986	8	10	249.82	0.03%
Other Operative Injury	23,889	26,505	716,670	95,695	539	706	249.64	2.26%
Surgical Site Complications	23,544	26,130	706,320	93,587	1,369	2,521	251.57	5.81%
Reintervention	23,978	26,596	719,340	95,984	51	57	249.81	0.21%
Wound Complications	23,913	26,526	717,390	95,734	298	440	249.79	1.25%
Abscess	23,769	26,371	713,070	94,655	619	1,098	251.11	2.60%
Hemorrhage	23,834	26,442	715,020	95,419	592	825	249.78	2.48%
Bowel Obstruction	23,945	26,562	718,350	95,632	112	166	250.39	0.47%
Medical Complications	22,835	25,358	685,050	88,501	1,184	2,367	258.02	5.19%
Laparoscopic Hysterectomy and Robotic Assistance in the Inpatient or Emergency Department Care Setting								
Intraoperative Complications	19,011	19,092	570,330	82,962	854	1,605	229.15	4.49%
Bladder Injury	19,153	19,234	574,590	85,666	267	436	223.58	1.39%
Ureteral Injury	19,126	19,207	573,780	83,519	324	462	229.00	1.69%
Intestinal Injury	19,154	19,235	574,620	85,687	101	147	223.53	0.53%
Vascular Injury	19,174	19,255	575,220	85,866	8	10	223.30	0.04%
Other Operative Injury	19,093	19,174	572,790	85,586	474	598	223.09	2.48%
Surgical Site Complications	18,816	18,897	564,480	83,636	1,161	2,142	224.97	6.17%
Reintervention	19,172	19,253	575,160	85,863	45	50	223.29	0.23%
Wound Complications	19,117	19,198	573,510	85,628	253	378	223.26	1.32%
Abscess	19,009	19,090	570,270	84,639	536	954	224.59	2.82%
Hemorrhage	19,054	19,135	571,620	85,343	492	678	223.26	2.58%
Bowel Obstruction	19,141	19,222	574,230	85,525	95	144	223.81	0.50%
Medical Complications	18,201	18,280	546,030	78,800	1,035	2,021	230.98	5.69%

*To be included as an eligible member, an individual must meet the inclusion and exclusion criteria (he or she must have evidence of a robotic assistance procedure code and no evidence of a gynecologic malignancy). Member-Years are not a relevant calculation for this table because each eligible member only meets eligibility criteria for approximately one day (a member is only eligible to be included in the study on the day that he or she has the pre-existing condition).

Table 2a. Summary of Laparoscopic Hysterectomy (without Robotic Assistance) Use and Adverse Events in the MSDD between October 1, 2008 and May 31, 2013, by Age Group

	Incident Exposure (Laparoscopic Hysterectomy)				Post-Exposure Events				
	New Patients	Claims	Lookup Period Duration	Eligible Members*	Member-Years	New Patients with Incident Post-Exposure Event	Number of Post-Exposure Event Claims	New Patients/ 1000 Eligible Members*	% New Patients with Post-Exposure Event
Laparoscopic Hysterectomy without Robotic Assistance in Any Care Setting									
Intraoperative Complications									
0-39 years	19,353	21,370	580,590	62,276,264	120,497,263	608	1,349	0.31	3.14%
40-44 years	18,699	20,571	560,970	11,740,281	18,254,262	755	1,602	1.59	4.04%
45-49 years	19,749	21,691	592,470	12,114,349	19,541,066	844	1,900	1.63	4.27%
50-54 years	10,376	11,318	311,280	11,879,878	19,619,368	466	960	0.87	4.49%
55-59 years	4,224	4,635	126,720	10,411,384	17,596,568	182	373	0.41	4.31%
60+ years	5,676	6,000	170,280	17,838,324	44,061,347	238	433	0.32	4.19%
Bladder Injury									
0-39 years	19,494	21,521	584,820	62,282,758	120,586,437	268	487	0.31	1.37%
40-44 years	18,817	20,702	564,510	11,742,893	18,280,176	282	494	1.60	1.50%
45-49 years	19,875	21,824	596,250	12,117,168	19,571,226	335	619	1.64	1.69%
50-54 years	10,445	11,389	313,350	11,882,842	19,652,130	156	297	0.88	1.49%
55-59 years	4,258	4,683	127,740	10,414,367	17,629,594	63	114	0.41	1.48%
60+ years	5,735	6,062	172,050	17,844,723	44,194,341	66	92	0.32	1.15%
Ureteral Injury									
0-39 years	19,466	21,491	583,980	62,280,884	120,562,042	189	303	0.31	0.97%
40-44 years	18,793	20,677	563,790	11,742,187	18,272,631	270	409	1.60	1.44%
45-49 years	19,845	21,793	595,350	12,116,379	19,562,260	281	434	1.64	1.42%
50-54 years	10,430	11,373	312,900	11,881,904	19,641,934	161	231	0.88	1.54%
55-59 years	4,252	4,676	127,560	10,413,379	17,619,118	54	68	0.41	1.27%
60+ years	5,714	6,040	171,420	17,842,585	44,156,946	76	96	0.32	1.33%
Intestinal Injury									
0-39 years	19,481	21,509	584,430	62,280,729	120,562,327	55	75	0.31	0.28%
40-44 years	18,809	20,689	564,270	11,741,944	18,271,408	88	146	1.60	0.47%
45-49 years	19,866	21,813	595,980	12,116,219	19,561,551	116	185	1.64	0.58%
50-54 years	10,442	11,385	313,260	11,881,895	19,642,672	55	77	0.88	0.53%
55-59 years	4,255	4,672	127,650	10,413,528	17,621,302	27	39	0.41	0.63%
60+ years	5,728	6,054	171,840	17,843,748	44,176,987	52	78	0.32	0.91%
Vascular Injury									
0-39 years	19,504	21,533	585,120	62,283,101	120,590,890	10	11	0.31	0.05%
40-44 years	18,828	20,712	564,840	11,743,077	18,281,628	7	11	1.60	0.04%
45-49 years	19,880	21,829	596,400	12,117,360	19,572,904	13	15	1.64	0.07%
50-54 years	10,447	11,391	313,410	11,883,015	19,653,759	4	4	0.88	0.04%
55-59 years	4,260	4,685	127,800	10,414,532	17,631,188	1	1	0.41	0.02%
60+ years	5,735	6,062	172,050	17,845,355	44,207,363	0	.	0.32	0.00%

	New Patients	Claims	Lookup Period Duration	Eligible Members*	Member-Years	New Patients with Incident Post-Exposure Event	Number of Post-Exposure Event Claims	New Patients/ 1000 Eligible Members*	% New Patients with Post-Exposure Event
Other Operative Injury									
0-39 years	19,419	21,443	582,570	62,281,397	120,560,860	407	519	0.31	2.10%
40-44 years	18,765	20,644	562,950	11,742,472	18,275,041	465	609	1.60	2.48%
45-49 years	19,807	21,752	594,210	12,116,714	19,565,048	530	709	1.63	2.68%
50-54 years	10,402	11,346	312,060	11,882,322	19,644,748	305	395	0.88	2.93%
55-59 years	4,238	4,658	127,140	10,413,764	17,621,361	120	161	0.41	2.83%
60+ years	5,707	6,033	171,210	17,843,555	44,160,932	145	179	0.32	2.54%
Surgical Site Complications									
0-39 years	19,073	21,064	572,190	62,236,951	119,741,287	1,396	2,352	0.31	7.32%
40-44 years	18,460	20,307	553,800	11,728,378	18,119,223	1,162	1,963	1.57	6.29%
45-49 years	19,551	21,471	586,530	12,101,437	19,382,215	1,133	1,899	1.62	5.80%
50-54 years	10,250	11,177	307,500	11,865,843	19,439,629	605	1,087	0.86	5.90%
55-59 years	4,179	4,587	125,370	10,397,763	17,416,896	200	425	0.40	4.79%
60+ years	5,598	5,915	167,940	17,814,949	43,350,405	266	496	0.31	4.75%
Reintervention									
0-39 years	19,502	21,531	585,060	62,282,932	120,588,337	64	66	0.31	0.33%
40-44 years	18,830	20,715	564,900	11,743,005	18,280,798	61	67	1.60	0.32%
45-49 years	19,880	21,829	596,400	12,117,264	19,571,891	47	48	1.64	0.24%
50-54 years	10,447	11,391	313,410	11,882,923	19,652,696	35	35	0.88	0.34%
55-59 years	4,259	4,684	127,770	10,414,440	17,630,094	13	15	0.41	0.31%
60+ years	5,736	6,063	172,080	17,845,210	44,204,664	15	17	0.32	0.26%
Wound Complications									
0-39 years	19,458	21,481	583,740	62,278,947	120,523,530	275	410	0.31	1.41%
40-44 years	18,777	20,655	563,310	11,740,980	18,260,695	226	342	1.60	1.20%
45-49 years	19,840	21,787	595,200	12,114,830	19,545,997	194	330	1.64	0.98%
50-54 years	10,419	11,363	312,570	11,880,055	19,621,078	108	208	0.88	1.04%
55-59 years	4,241	4,664	127,230	10,411,152	17,595,199	40	80	0.41	0.94%
60+ years	5,718	6,043	171,540	17,839,194	44,055,628	45	79	0.32	0.79%
Abscess									
0-39 years	19,253	21,253	577,590	62,245,765	119,873,810	560	860	0.31	2.91%
40-44 years	18,622	20,487	558,660	11,732,273	18,157,789	483	771	1.59	2.59%
45-49 years	19,713	21,641	591,390	12,106,090	19,430,173	483	778	1.63	2.45%
50-54 years	10,351	11,285	310,530	11,871,347	19,498,296	247	427	0.87	2.39%
55-59 years	4,222	4,644	126,660	10,403,705	17,480,605	89	187	0.41	2.11%
60+ years	5,667	5,986	170,010	17,828,554	43,680,831	124	205	0.32	2.19%
Hemorrhage									
0-39 years	19,379	21,404	581,370	62,279,559	120,530,403	732	1,013	0.31	3.78%
40-44 years	18,724	20,596	561,720	11,741,810	18,266,420	561	732	1.59	3.00%
45-49 years	19,776	21,720	593,280	12,115,988	19,554,985	514	666	1.63	2.60%
50-54 years	10,389	11,326	311,670	11,881,401	19,631,987	283	374	0.87	2.72%
55-59 years	4,235	4,647	127,050	10,412,900	17,607,659	85	119	0.41	2.01%
60+ years	5,703	6,028	171,090	17,841,201	44,071,415	98	125	0.32	1.72%

	New Patients	Claims	Lookup Period Duration	Eligible Members*	Member-Years	New Patients with Incident Post-Exposure Event	Number of Post-Exposure Event Claims	New Patients/ 1000 Eligible Members*	% New Patients with Post-Exposure Event
Bowel Obstruction									
0-39 years	19,477	21,506	584,310	62,281,114	120,562,962	46	55	0.31	0.24%
40-44 years	18,809	20,694	564,270	11,741,916	18,270,067	69	106	1.60	0.37%
45-49 years	19,854	21,802	595,620	12,115,903	19,557,484	102	131	1.64	0.51%
50-54 years	10,426	11,368	312,780	11,881,259	19,634,056	48	68	0.88	0.46%
55-59 years	4,254	4,679	127,620	10,412,590	17,609,309	22	37	0.41	0.52%
60+ years	5,710	6,037	171,300	17,840,392	44,084,020	52	85	0.32	0.91%
Medical Complications									
0-39 years	18,601	20,547	558,030	62,147,535	118,102,398	723	1,231	0.30	3.89%
40-44 years	18,080	19,901	542,400	11,699,231	17,917,831	708	1,426	1.55	3.92%
45-49 years	19,189	21,091	575,670	12,062,898	19,121,954	731	1,418	1.59	3.81%
50-54 years	10,084	11,005	302,520	11,816,438	19,098,754	460	899	0.85	4.56%
55-59 years	4,084	4,466	122,520	10,338,357	17,005,890	183	409	0.40	4.48%
60+ years	5,395	5,712	161,850	17,619,885	40,408,521	354	800	0.31	6.56%
Laparoscopic Hysterectomy without Robotic Assistance in the Inpatient or Emergency Department Care Setting									
Intraoperative Complications									
0-39 years	14,804	14,905	444,120	62,276,497	120,506,720	533	1,177	0.24	3.60%
40-44 years	14,147	14,254	424,410	11,742,099	18,264,232	646	1,353	1.20	4.57%
45-49 years	15,014	15,138	450,420	12,116,772	19,552,926	736	1,647	1.24	4.90%
50-54 years	8,026	8,092	240,780	11,882,183	19,627,548	403	810	0.68	5.02%
55-59 years	3,418	3,440	102,540	10,412,532	17,600,644	155	293	0.33	4.53%
60+ years	4,822	4,865	144,660	17,839,087	44,067,156	213	386	0.27	4.42%
Bladder Injury									
0-39 years	14,922	15,023	447,660	62,282,990	120,596,021	237	427	0.24	1.59%
40-44 years	14,249	14,357	427,470	11,744,721	18,290,245	239	412	1.21	1.68%
45-49 years	15,132	15,256	453,960	12,119,594	19,583,189	303	551	1.25	2.00%
50-54 years	8,091	8,159	242,730	11,885,156	19,660,374	140	264	0.68	1.73%
55-59 years	3,446	3,469	103,380	10,415,518	17,633,705	47	82	0.33	1.36%
60+ years	4,875	4,919	146,250	17,845,489	44,200,210	61	82	0.27	1.25%
Ureteral Injury									
0-39 years	14,905	15,006	447,150	62,281,117	120,571,575	171	271	0.24	1.15%
40-44 years	14,230	14,338	426,900	11,744,014	18,282,681	246	370	1.21	1.73%
45-49 years	15,103	15,227	453,090	12,118,802	19,574,199	257	385	1.25	1.70%
50-54 years	8,077	8,144	242,310	11,884,215	19,650,170	150	203	0.68	1.86%
55-59 years	3,441	3,463	103,230	10,414,532	17,623,224	50	58	0.33	1.45%
60+ years	4,858	4,902	145,740	17,843,350	44,162,797	67	85	0.27	1.38%
Intestinal Injury									
0-39 years	14,917	15,018	447,510	62,280,960	120,571,910	43	61	0.24	0.29%
40-44 years	14,243	14,351	427,290	11,743,773	18,281,495	77	122	1.21	0.54%
45-49 years	15,125	15,249	453,750	12,118,647	19,573,531	104	167	1.25	0.69%
50-54 years	8,089	8,156	242,670	11,884,208	19,650,929	49	69	0.68	0.61%
55-59 years	3,447	3,470	103,410	10,414,677	17,625,410	25	37	0.33	0.73%
60+ years	4,868	4,911	146,040	17,844,513	44,182,857	48	70	0.27	0.99%
Vascular Injury									
0-39 years	14,934	15,035	448,020	62,283,333	120,600,498	10	11	0.24	0.07%
40-44 years	14,261	14,368	427,830	11,744,907	18,291,728	6	9	1.21	0.04%
45-49 years	15,137	15,261	454,110	12,119,788	19,584,898	13	15	1.25	0.09%
50-54 years	8,093	8,161	242,790	11,885,330	19,662,024	4	4	0.68	0.05%
55-59 years	3,449	3,472	103,470	10,415,682	17,635,307	1	1	0.33	0.03%
60+ years	4,875	4,919	146,250	17,846,121	44,213,242	0	.	0.27	0.00%
Other Operative Injury									
0-39 years	14,855	14,956	445,650	62,281,629	120,570,422	365	454	0.24	2.46%
40-44 years	14,203	14,311	426,090	11,744,295	18,285,084	395	500	1.21	2.78%
45-49 years	15,069	15,193	452,070	12,119,140	19,576,983	459	589	1.24	3.05%
50-54 years	8,050	8,118	241,500	11,884,634	19,652,971	255	314	0.68	3.17%
55-59 years	3,429	3,452	102,870	10,414,913	17,625,464	102	125	0.33	2.97%
60+ years	4,849	4,893	145,470	17,844,320	44,166,783	134	161	0.27	2.76%
Surgical Site Complications									
0-39 years	14,584	14,683	437,520	62,237,186	119,750,445	1,148	1,954	0.23	7.87%
40-44 years	13,980	14,087	419,400	11,730,187	18,128,895	962	1,654	1.19	6.88%
45-49 years	14,880	14,999	446,400	12,103,824	19,393,762	929	1,581	1.23	6.24%
50-54 years	7,936	8,003	238,080	11,868,129	19,447,598	501	925	0.67	6.31%
55-59 years	3,387	3,410	101,610	10,398,908	17,420,885	171	353	0.33	5.05%
60+ years	4,755	4,798	142,650	17,815,708	43,356,102	238	450	0.27	5.01%

	New Patients	Claims	Lookup Period Duration	Eligible Members*	Member-Years	New Patients with Incident Post-Exposure Event	Number of Post-Exposure Event Claims	New Patients/ 1000 Eligible Members*	% New Patients with Post-Exposure Event
Reintervention									
0-39 years	14,932	15,033	447,960	62,283,164	120,597,943	59	61	0.24	0.40%
40-44 years	14,262	14,370	427,860	11,744,835	18,290,894	55	59	1.21	0.39%
45-49 years	15,137	15,261	454,110	12,119,691	19,583,878	38	39	1.25	0.25%
50-54 years	8,093	8,161	242,790	11,885,238	19,660,960	33	33	0.68	0.41%
55-59 years	3,448	3,471	103,440	10,415,591	17,634,211	10	12	0.33	0.29%
60+ years	4,876	4,920	146,280	17,845,976	44,210,541	14	16	0.27	0.29%
Wound Complications									
0-39 years	14,897	14,998	446,910	62,279,181	120,533,052	236	363	0.24	1.58%
40-44 years	14,221	14,329	426,630	11,742,809	18,270,708	184	281	1.21	1.29%
45-49 years	15,105	15,229	453,150	12,117,248	19,557,909	165	293	1.25	1.09%
50-54 years	8,070	8,138	242,100	11,882,368	19,629,297	89	185	0.68	1.10%
55-59 years	3,434	3,457	103,020	10,412,300	17,599,291	37	77	0.33	1.08%
60+ years	4,860	4,904	145,800	17,839,957	44,061,473	39	69	0.27	0.80%
Abscess									
0-39 years	14,741	14,841	442,230	62,245,999	119,883,152	447	680	0.24	3.03%
40-44 years	14,108	14,215	423,240	11,734,089	18,167,636	386	640	1.20	2.74%
45-49 years	15,023	15,145	450,690	12,108,496	19,441,890	383	622	1.24	2.55%
50-54 years	8,022	8,089	240,660	11,873,642	19,506,371	190	340	0.68	2.37%
55-59 years	3,423	3,446	102,690	10,404,852	17,484,647	77	153	0.33	2.25%
60+ years	4,816	4,859	144,480	17,829,316	43,686,591	106	176	0.27	2.20%
Hemorrhage									
0-39 years	14,824	14,924	444,720	62,279,791	120,539,892	619	854	0.24	4.18%
40-44 years	14,178	14,286	425,340	11,743,636	18,276,419	484	629	1.21	3.41%
45-49 years	15,041	15,163	451,230	12,118,404	19,566,891	445	576	1.24	2.96%
50-54 years	8,043	8,111	241,290	11,883,711	19,640,188	250	326	0.68	3.11%
55-59 years	3,428	3,451	102,840	10,414,051	17,611,747	72	95	0.33	2.10%
60+ years	4,846	4,890	145,380	17,841,968	44,077,271	92	118	0.27	1.90%
Bowel Obstruction									
0-39 years	14,909	15,010	447,270	62,281,346	120,572,547	39	47	0.24	0.26%
40-44 years	14,246	14,354	427,380	11,743,745	18,280,147	62	97	1.21	0.44%
45-49 years	15,115	15,238	453,450	12,118,328	19,569,455	83	105	1.25	0.55%
50-54 years	8,076	8,143	242,280	11,883,571	19,642,301	45	64	0.68	0.56%
55-59 years	3,443	3,466	103,290	10,413,741	17,613,419	17	28	0.33	0.49%
60+ years	4,854	4,898	145,620	17,841,157	44,089,872	50	83	0.27	1.03%
Medical Complications									
0-39 years	14,221	14,318	426,630	62,147,773	118,111,359	630	1,085	0.23	4.43%
40-44 years	13,648	13,749	409,440	11,701,003	17,927,396	625	1,253	1.17	4.58%
45-49 years	14,565	14,684	436,950	12,065,274	19,133,407	648	1,241	1.21	4.45%
50-54 years	7,786	7,851	233,580	11,818,699	19,106,608	417	824	0.66	5.36%
55-59 years	3,306	3,326	99,180	10,339,490	17,009,790	165	342	0.32	4.99%
60+ years	4,570	4,613	137,100	17,620,640	40,414,008	326	735	0.26	7.13%

*To be included as an eligible member, an individual must meet the exclusion criteria (no evidence of a gynecologic malignancy or a robotic assistance procedure)

Table 2b. Summary of Laparoscopic Hysterectomy Use with Robotic Assistance and Adverse Events in the MSDD between October 1, 2008 and May 31, 2013, by Age Group

	Incident Exposure (Laparoscopic Hysterectomy)			Post-Exposure Events				
	New Patients	Claims	Lookup Period Duration	Eligible Members*	New Patients with Incident Post-Exposure Event	Number of Post-Exposure Event Claims	New Patients/ 1000 Eligible Members*	% New Patients with Post-Exposure Event
Laparoscopic Hysterectomy and Robotic Assistance in Any Care Setting								
Intraoperative Complications								
0-39 years	4,973	5,572	149,190	9,784	175	320	508.28	3.52%
40-44 years	5,485	6,091	164,550	8,419	251	525	651.50	4.58%
45-49 years	6,063	6,759	181,890	11,018	249	460	550.28	4.11%
50-54 years	3,432	3,857	102,960	12,682	140	302	270.62	4.08%
55-59 years	1,578	1,727	47,340	15,113	65	108	104.41	4.12%
60+ years	2,265	2,401	67,950	35,992	96	155	62.93	4.24%
Bladder Injury								
0-39 years	5,004	5,604	150,120	10,669	67	100	469.02	1.34%
40-44 years	5,513	6,120	165,390	8,615	86	150	639.93	1.56%
45-49 years	6,109	6,809	183,270	11,300	67	105	540.62	1.10%
50-54 years	3,449	3,874	103,470	12,954	45	93	266.25	1.30%
55-59 years	1,591	1,741	47,730	15,401	20	29	103.30	1.26%
60+ years	2,293	2,429	68,790	36,867	21	28	62.20	0.92%
Ureteral Injury								
0-39 years	4,996	5,596	149,880	9,867	63	92	506.33	1.26%
40-44 years	5,503	6,109	165,090	8,470	87	145	649.70	1.58%
45-49 years	6,102	6,802	183,060	11,105	97	137	549.48	1.59%
50-54 years	3,449	3,874	103,470	12,755	62	93	270.40	1.80%
55-59 years	1,588	1,737	47,640	15,195	21	23	104.51	1.32%
60+ years	2,287	2,423	68,610	36,192	38	41	63.19	1.66%
Intestinal Injury								
0-39 years	5,006	5,606	150,180	10,679	21	30	468.77	0.42%
40-44 years	5,511	6,118	165,330	8,623	36	59	639.10	0.65%
45-49 years	6,105	6,802	183,150	11,308	21	32	539.88	0.34%
50-54 years	3,452	3,877	103,560	12,958	10	14	266.40	0.29%
55-59 years	1,591	1,741	47,730	15,391	4	7	103.37	0.25%
60+ years	2,293	2,429	68,790	36,864	20	25	62.20	0.87%
Vascular Injury								
0-39 years	5,008	5,608	150,240	10,705	1	1	467.82	0.02%
40-44 years	5,516	6,123	165,480	8,640	1	2	638.43	0.02%
45-49 years	6,114	6,814	183,420	11,335	4	5	539.39	0.07%
50-54 years	3,452	3,877	103,560	12,979	2	2	265.97	0.06%
55-59 years	1,594	1,744	47,820	15,427	0	.	103.33	0.00%
60+ years	2,295	2,431	68,850	36,920	0	.	62.16	0.00%
Other Operative Injury								
0-39 years	4,989	5,588	149,670	10,662	86	105	467.92	1.72%
40-44 years	5,504	6,111	165,120	8,612	135	174	639.11	2.45%
45-49 years	6,091	6,790	182,730	11,284	146	195	539.79	2.40%
50-54 years	3,440	3,865	103,200	12,944	78	115	265.76	2.27%
55-59 years	1,589	1,739	47,670	15,396	42	51	103.21	2.64%
60+ years	2,276	2,412	68,280	36,817	52	66	61.82	2.28%
Surgical Site Complications								
0-39 years	4,909	5,502	147,270	10,391	365	630	472.43	7.44%
40-44 years	5,423	6,023	162,690	8,436	345	652	642.84	6.36%
45-49 years	6,013	6,704	180,390	11,061	301	552	543.62	5.01%
50-54 years	3,393	3,812	101,790	12,677	187	331	267.65	5.51%
55-59 years	1,558	1,706	46,740	15,082	62	126	103.30	3.98%
60+ years	2,248	2,383	67,440	35,958	109	230	62.52	4.85%

	New Patients	Claims	Lookup Period Duration	Eligible Members*	New Patients with Incident Post-Exposure Event	Number of Post-Exposure Event Claims	New Patients/ 1000 Eligible Members*	% New Patients with Post-Exposure Event
Reintervention								
0-39 years	5,007	5,607	150,210	10,702	9	9	467.86	0.18%
40-44 years	5,515	6,122	165,450	8,639	17	22	638.38	0.31%
45-49 years	6,115	6,815	183,450	11,334	13	13	539.53	0.21%
50-54 years	3,453	3,878	103,590	12,980	6	6	266.02	0.17%
55-59 years	1,593	1,743	47,790	15,427	3	4	103.26	0.19%
60+ years	2,295	2,431	68,850	36,922	3	3	62.16	0.13%
Wound Complications								
0-39 years	4,992	5,592	149,760	10,666	82	106	468.03	1.64%
40-44 years	5,503	6,110	165,090	8,614	82	117	638.84	1.49%
45-49 years	6,094	6,792	182,820	11,292	64	102	539.67	1.05%
50-54 years	3,442	3,864	103,260	12,954	41	60	265.71	1.19%
55-59 years	1,592	1,742	47,760	15,394	7	17	103.42	0.44%
60+ years	2,290	2,426	68,700	36,834	22	38	62.17	0.96%
Abscess								
0-39 years	4,965	5,562	148,950	10,548	163	272	470.71	3.28%
40-44 years	5,469	6,071	164,070	8,532	160	288	641.00	2.93%
45-49 years	6,068	6,765	182,040	11,191	136	235	542.22	2.24%
50-54 years	3,425	3,847	102,750	12,801	92	158	267.56	2.69%
55-59 years	1,569	1,718	47,070	15,206	28	59	103.18	1.78%
60+ years	2,273	2,408	68,190	36,396	40	86	62.45	1.76%
Hemorrhage								
0-39 years	4,974	5,570	149,220	10,629	178	236	467.97	3.58%
40-44 years	5,486	6,091	164,580	8,581	146	205	639.32	2.66%
45-49 years	6,080	6,777	182,400	11,262	121	181	539.87	1.99%
50-54 years	3,431	3,856	102,930	12,910	67	82	265.76	1.95%
55-59 years	1,585	1,734	47,550	15,356	33	47	103.22	2.08%
60+ years	2,278	2,414	68,340	36,700	47	74	62.07	2.06%
Bowel Obstruction								
0-39 years	4,998	5,598	149,940	10,650	18	24	469.30	0.36%
40-44 years	5,508	6,115	165,240	8,617	23	32	639.20	0.42%
45-49 years	6,110	6,809	183,300	11,304	26	33	540.52	0.43%
50-54 years	3,449	3,874	103,470	12,939	24	33	266.56	0.70%
55-59 years	1,592	1,742	47,760	15,388	3	4	103.46	0.19%
60+ years	2,288	2,424	68,640	36,754	18	40	62.25	0.79%
Medical Complications								
0-39 years	4,767	5,345	143,010	10,068	234	401	473.48	4.91%
40-44 years	5,308	5,898	159,240	8,195	267	570	647.71	5.03%
45-49 years	5,851	6,530	175,530	10,667	239	465	548.51	4.08%
50-54 years	3,305	3,712	99,150	12,139	167	317	272.26	5.05%
55-59 years	1,502	1,643	45,060	14,305	84	168	105.00	5.59%
60+ years	2,102	2,230	63,060	33,145	193	446	63.42	9.18%
Laparoscopic Hysterectomy and Robotic Assistance in the Inpatient or Emergency Department Care Setting								
Intraoperative Complications								
0-39 years	3,794	3,808	113,820	7,640	154	280	496.60	4.06%
40-44 years	4,355	4,378	130,650	6,864	218	446	634.47	5.01%
45-49 years	4,813	4,833	144,390	9,298	213	390	517.64	4.43%
50-54 years	2,769	2,774	83,070	11,309	121	252	244.85	4.37%
55-59 years	1,293	1,302	38,790	13,900	59	98	93.02	4.56%
60+ years	1,987	1,997	59,610	33,966	89	139	58.50	4.48%
Bladder Injury								
0-39 years	3,821	3,835	114,630	8,490	60	89	450.06	1.57%
40-44 years	4,380	4,403	131,400	7,052	76	131	621.10	1.74%
45-49 years	4,853	4,873	145,590	9,564	60	93	507.42	1.24%
50-54 years	2,784	2,789	83,520	11,569	37	73	240.64	1.33%
55-59 years	1,304	1,313	39,120	14,180	18	27	91.96	1.38%
60+ years	2,011	2,021	60,330	34,827	16	23	57.74	0.80%

	New Patients	Claims	Lookup Period Duration	Eligible Members*	New Patients with Incident Post-Exposure Event	Number of Post-Exposure Event Claims	New Patients/ 1000 Eligible Members*	% New Patients with Post-Exposure Event
Ureteral Injury								
0-39 years	3,813	3,827	114,390	7,717	57	82	494.10	1.49%
40-44 years	4,372	4,395	131,160	6,915	75	129	632.25	1.72%
45-49 years	4,848	4,868	145,440	9,378	81	108	516.95	1.67%
50-54 years	2,784	2,789	83,520	11,380	56	83	244.64	2.01%
55-59 years	1,303	1,312	39,090	13,980	19	21	93.20	1.46%
60+ years	2,006	2,016	60,180	34,164	36	39	58.72	1.79%
Intestinal Injury								
0-39 years	3,823	3,837	114,690	8,501	18	25	449.71	0.47%
40-44 years	4,377	4,400	131,310	7,060	33	51	619.97	0.75%
45-49 years	4,851	4,871	145,530	9,574	18	27	506.68	0.37%
50-54 years	2,788	2,793	83,640	11,576	10	14	240.84	0.36%
55-59 years	1,304	1,313	39,120	14,168	3	6	92.04	0.23%
60+ years	2,011	2,021	60,330	34,824	19	24	57.75	0.94%
Vascular Injury								
0-39 years	3,825	3,839	114,750	8,526	1	1	448.63	0.03%
40-44 years	4,383	4,406	131,490	7,078	1	2	619.24	0.02%
45-49 years	4,859	4,879	145,770	9,599	4	5	506.20	0.08%
50-54 years	2,787	2,792	83,610	11,595	2	2	240.36	0.07%
55-59 years	1,307	1,316	39,210	14,204	0	.	92.02	0.00%
60+ years	2,013	2,023	60,390	34,880	0	.	57.71	0.00%
Other Operative Injury								
0-39 years	3,810	3,824	114,300	8,488	75	91	448.87	1.97%
40-44 years	4,372	4,395	131,160	7,052	117	139	619.97	2.68%
45-49 years	4,836	4,856	145,080	9,550	127	170	506.39	2.63%
50-54 years	2,776	2,781	83,280	11,560	67	95	240.14	2.41%
55-59 years	1,302	1,311	39,060	14,173	40	46	91.86	3.07%
60+ years	1,997	2,007	59,910	34,779	48	57	57.42	2.40%
Surgical Site Complications								
0-39 years	3,739	3,753	112,170	8,239	298	515	453.82	7.97%
40-44 years	4,306	4,329	129,180	6,898	295	561	624.24	6.85%
45-49 years	4,786	4,806	143,580	9,358	261	471	511.43	5.45%
50-54 years	2,737	2,742	82,110	11,317	154	270	241.85	5.63%
55-59 years	1,279	1,288	38,370	13,887	50	101	92.10	3.91%
60+ years	1,969	1,979	59,070	33,951	103	224	58.00	5.23%
Reintervention								
0-39 years	3,824	3,838	114,720	8,523	8	8	448.67	0.21%
40-44 years	4,382	4,405	131,460	7,077	15	20	619.19	0.34%
45-49 years	4,859	4,879	145,770	9,597	11	11	506.30	0.23%
50-54 years	2,788	2,793	83,640	11,596	6	6	240.43	0.22%
55-59 years	1,306	1,315	39,180	14,204	2	2	91.95	0.15%
60+ years	2,013	2,023	60,390	34,882	3	3	57.71	0.15%
Wound Complications								
0-39 years	3,811	3,825	114,330	8,492	72	95	448.78	1.89%
40-44 years	4,372	4,395	131,160	7,055	69	102	619.70	1.58%
45-49 years	4,842	4,862	145,260	9,560	50	77	506.49	1.03%
50-54 years	2,779	2,784	83,370	11,573	36	52	240.13	1.30%
55-59 years	1,305	1,314	39,150	14,170	7	17	92.10	0.54%
60+ years	2,008	2,018	60,240	34,794	19	35	57.71	0.95%
Abscess								
0-39 years	3,786	3,800	113,580	8,383	136	230	451.63	3.59%
40-44 years	4,344	4,367	130,320	6,982	143	254	622.17	3.29%
45-49 years	4,830	4,850	144,900	9,473	119	201	509.87	2.46%
50-54 years	2,767	2,772	83,010	11,434	73	128	242.00	2.64%
55-59 years	1,288	1,297	38,640	14,002	26	56	91.99	2.02%
60+ years	1,994	2,004	59,820	34,380	39	85	58.00	1.96%

	New Patients	Claims	Lookup Period Duration	Eligible Members*	New Patients with Incident Post-Exposure Event	Number of Post-Exposure Event Claims	New Patients/ 1000 Eligible Members*	% New Patients with Post-Exposure Event
Hemorrhage								
0-39 years	3,799	3,813	113,970	8,458	139	178	449.16	3.66%
40-44 years	4,359	4,382	130,770	7,028	122	168	620.23	2.80%
45-49 years	4,833	4,853	144,990	9,537	108	158	506.76	2.23%
50-54 years	2,767	2,772	83,010	11,531	54	67	239.96	1.95%
55-59 years	1,300	1,309	39,000	14,139	23	34	91.94	1.77%
60+ years	1,996	2,006	59,880	34,665	46	73	57.58	2.30%
Bowel Obstruction								
0-39 years	3,815	3,829	114,450	8,473	15	21	450.25	0.39%
40-44 years	4,375	4,398	131,250	7,057	20	29	619.95	0.46%
45-49 years	4,856	4,876	145,680	9,569	23	29	507.47	0.47%
50-54 years	2,784	2,789	83,520	11,556	18	24	240.91	0.65%
55-59 years	1,305	1,314	39,150	14,168	2	2	92.11	0.15%
60+ years	2,006	2,016	60,180	34,718	17	39	57.78	0.85%
Medical Complications								
0-39 years	3,624	3,637	108,720	7,957	199	341	455.45	5.49%
40-44 years	4,209	4,232	126,270	6,683	230	497	629.81	5.46%
45-49 years	4,636	4,655	139,080	8,994	201	357	515.45	4.34%
50-54 years	2,659	2,664	79,770	10,809	145	273	246.00	5.45%
55-59 years	1,231	1,240	36,930	13,137	79	158	93.70	6.42%
60+ years	1,842	1,852	55,260	31,234	181	395	58.97	9.83%

*To be included as an eligible member, an individual must meet the inclusion and exclusion criteria (he or she must have evidence of a robotic assistance procedure code and no evidence of a gynecologic malignancy). Member-Years are not a relevant calculation for this table because each eligible member only meets eligibility criteria for approximately one day (a member is only eligible to be included in the study on the day that he or she has the pre-existing condition).

Table 3a. Summary of Laparoscopic Hysterectomy (without Robotic Assistance) Use and Adverse Events in the MSDD between October 1, 2008 and May 31, 2013, by Sex

	Incident Exposure (Laparoscopic Hysterectomy)					Post-Exposure Events			
	New Patients	Claims	Lookup Period Duration	Eligible Members*	Member-Years	New Patients with Incident Post-Exposure Event	Number of Post-Exposure Event Claims	New Patients/ 1000 Eligible Members*	% New Patients with Post-Exposure Event
Laparoscopic Hysterectomy without Robotic Assistance in Any Care Setting									
Intraoperative Complications									
Female	77,796	85,268	2,333,880	55,498,076	123,480,766	3,083	6,597	1.40	3.96%
Male	260	296	7,800	53,092,513	116,042,142	6	10	0.00	2.31%
Unknown	21	21	630	32,558	46,967	4	10	0.65	19.05%
Bladder Injury									
Female	78,341	85,862	2,350,230	55,506,103	123,648,339	1,165	2,096	1.41	1.49%
Male	262	298	7,860	53,101,223	116,218,502	2	2	0.00	0.76%
Unknown	21	21	630	32,564	47,063	3	5	0.00	---
Ureteral Injury									
Female	78,217	85,731	2,346,510	55,503,736	123,602,439	1,030	1,540	1.41	1.32%
Male	262	298	7,860	53,098,419	116,165,471	0	.	0.00	0.00%
Unknown	21	21	630	32,561	47,020	1	1	0.64	4.76%
Intestinal Injury									
Female	78,300	85,805	2,349,000	55,504,310	123,613,570	391	598	1.41	0.50%
Male	260	296	7,800	53,098,775	116,175,632	1	1	0.00	0.38%
Unknown	21	21	630	32,565	47,046	1	1	0.64	4.76%
Vascular Injury									
Female	78,371	85,893	2,351,130	55,506,731	123,659,188	35	42	1.41	0.04%
Male	262	298	7,860	53,101,836	116,231,476	0	.	0.00	0.00%
Unknown	21	21	630	32,565	47,068	0	.	0.00	---
Other Operative Injury									
Female	78,055	85,557	2,341,650	55,504,245	123,596,282	1,965	2,562	1.41	2.52%
Male	262	298	7,860	53,099,937	116,184,667	5	7	0.00	1.91%
Unknown	21	21	630	32,563	47,042	2	3	0.64	9.52%
Surgical Site Complications									
Female	76,836	84,224	2,305,080	55,456,758	122,339,343	4,747	8,195	1.39	6.18%
Male	254	276	7,620	53,054,537	115,063,810	13	18	0.00	5.12%
Unknown	21	21	630	32,549	46,501	2	9	0.65	9.52%
Reintervention									
Female	78,371	85,894	2,351,130	55,506,491	123,653,926	235	248	1.41	0.30%
Male	262	298	7,860	53,101,631	116,227,488	0	.	0.00	0.00%
Unknown	21	21	630	32,565	47,066	0	.	0.64	0.00%
Wound Complications									
Female	78,170	85,674	2,345,100	55,498,956	123,464,828	887	1,448	1.41	1.13%
Male	262	298	7,860	53,095,664	116,090,317	0	.	0.00	0.00%
Unknown	21	21	630	32,564	46,981	1	1	0.64	4.76%
Abscess									
Female	77,550	84,982	2,326,500	55,472,705	122,719,110	1,979	3,215	1.40	2.55%
Male	257	293	7,710	53,067,692	115,355,733	5	9	0.00	1.95%
Unknown	21	21	630	32,551	46,660	2	4	0.65	9.52%
Hemorrhage									
Female	77,925	85,418	2,337,750	55,501,557	123,510,228	2,263	3,019	1.40	2.90%
Male	260	282	7,800	53,097,464	116,105,632	9	9	0.00	3.46%
Unknown	21	21	630	32,565	47,008	1	1	0.64	4.76%
Bowel Obstruction									
Female	78,248	85,768	2,347,440	55,501,898	123,536,046	337	478	1.41	0.43%
Male	261	297	7,830	53,097,615	116,134,838	1	1	0.00	0.38%
Unknown	21	21	630	32,564	47,013	1	3	0.64	4.76%
Medical Complications									
Female	75,174	82,440	2,255,220	55,283,647	119,353,515	3,141	6,138	1.36	4.18%
Male	239	262	7,170	52,881,858	112,256,374	15	32	0.00	6.28%
Unknown	20	20	600	32,464	45,459	3	13	0.62	15.00%
Laparoscopic Hysterectomy without Robotic Assistance in the Inpatient or Emergency Department Care Setting									
Intraoperative Complications									
Female	60,128	60,587	1,803,840	55,498,683	123,523,825	2,680	5,652	1.08	4.46%
Male	85	89	2550	53092672	116048433	2	4	0.00	2.35%
Unknown	18	18	540	32558	46968	4	10	0.55	22.22%
Bladder Injury									
Female	60612	61076	1818360	55506707	123691830	1,024	1,813	1.09	1.69%
Male	85	89	2550	53101380	116224851	0	.	0.00	0.00%
Unknown	18	18	540	32564	47064	3	5	0.55	16.67%

	New Patients	Claims	Lookup Period Duration	Eligible Members*	Member-Years	New Patients with Incident Post-Exposure Event	Number of Post-Exposure Event Claims	New Patients/ 1000 Eligible Members*	% New Patients with Post-Exposure Event
Ureteral Injury									
Female	60511	60973	1815330	55504342	123645838	940	1,371	1.09	1.55%
Male	85	89	2550	53098578	116171788	0	.	0.00	0.00%
Unknown	18	18	540	32561	47021	1	1	0.55	5.56%
Intestinal Injury									
Female	60586	61048	1817580	55504913	123657108	344	524	1.09	0.57%
Male	85	89	2550	53098932	116181976	1	1	0.00	1.18%
Unknown	18	18	540	32565	47047	1	1	0.55	5.56%
Vascular Injury									
Female	60646	61109	1819380	55507336	123702797	34	40	1.09	0.06%
Male	85	89	2550	53101993	116237831	0	.	0.00	0.00%
Unknown	18	18	540	32565	47069	0	.	0.55	0.00%
Other Operative Injury									
Female	60352	60816	1810560	55504849	123639656	1,706	2,137	1.09	2.83%
Male	85	89	2550	53100094	116191010	2	3	0.00	2.35%
Unknown	18	18	540	32563	47043	2	3	0.55	11.11%
Surgical Site Complications									
Female	59422	59876	1782660	55457372	122381192	3,943	6,899	1.07	6.64%
Male	82	86	2460	53054701	115069993	4	9	0.00	4.88%
Unknown	18	18	540	32549	46502	2	9	0.55	11.11%
Reintervention									
Female	60645	61109	1819350	55507095	123697517	209	220	1.09	0.34%
Male	85	89	2550	53101788	116233843	0	.	0.00	0.00%
Unknown	18	18	540	32565	47067	0	.	0.55	0.00%
Wound Complications									
Female	60484	60948	1814520	55499560	123508096	749	1,267	1.09	1.24%
Male	85	89	2550	53095821	116096652	0	.	0.00	0.00%
Unknown	18	18	540	32564	46982	1	1	0.55	5.56%
Abscess									
Female	60033	60491	1800990	55473317	122761649	1,586	2,602	1.08	2.64%
Male	82	86	2460	53067853	115361978	1	5	0.00	1.22%
Unknown	18	18	540	32551	46661	2	4	0.55	11.11%
Hemorrhage									
Female	60257	60718	1807710	55502163	123553445	1,957	2,593	1.09	3.25%
Male	85	89	2550	53097624	116111954	4	4	0.00	4.71%
Unknown	18	18	540	32565	47010	1	1	0.55	5.56%
Bowel Obstruction									
Female	60540	61002	1816200	55502501	123579556	295	421	1.09	0.49%
Male	85	89	2550	53097772	116141171	0	.	0.00	0.00%
Unknown	18	18	540	32564	47014	1	3	0.55	5.56%
Medical Complications									
Female	58000	58441	1740000	55284263	119394739	2,802	5,451	1.05	4.83%
Male	79	83	2370	52882031	112262369	6	16	0.00	7.59%
Unknown	17	17	510	32464	45460	3	13	0.52	17.65%

*To be included as an eligible member, an individual must meet the exclusion criteria (no evidence of a gynecologic malignancy or a robotic assistance procedure)

Table 3b. Summary of Laparoscopic Hysterectomy Use with Robotic Assistance and Adverse Events in the MSDD between October 1, 2008 and May 31, 2013, by Sex

	Incident Exposure (Laparoscopic Hysterectomy)			Post-Exposure Events				
	New Patients	Claims	Lookup Period Duration	Eligible Members*	New Patients with Incident Post-Exposure Event	Number of Post-Exposure Event Claims	New Patients/ 1000 Eligible Members*	% New Patients with Post-Exposure Event
Laparoscopic Hysterectomy and Robotic Assistance in Any Care Setting								
Intraoperative Complications								
Female	23,725	26,329	711,750	40,334	973	1,865	588.21	4.10%
Male	70	77	2,100	52,644	3	5	1.33	4.29%
Unknown	1	1	30	11	0	.	90.91	0.00%
Bladder Injury								
Female	23,888	26,499	716,640	41,896	306	505	570.17	1.28%
Male	70	77	2,100	53,879	0	.	1.30	0.00%
Unknown	1	1	30	11	0	.	0.00	---
Ureteral Injury								
Female	23,854	26,463	715,620	40,672	367	530	586.50	1.54%
Male	70	77	2,100	52,882	1	1	1.32	1.43%
Unknown	1	1	30	11	0	.	90.91	0.00%
Intestinal Injury								
Female	23,887	26,495	716,610	41,937	112	167	569.59	0.47%
Male	70	77	2,100	53,855	0	.	1.30	0.00%
Unknown	1	1	30	11	0	.	90.91	0.00%
Vascular Injury								
Female	23,908	26,519	717,240	42,034	8	10	568.78	0.03%
Male	70	77	2,100	53,941	0	.	1.30	0.00%
Unknown	1	1	30	11	0	.	0.00	---
Other Operative Injury								
Female	23,818	26,427	714,540	41,836	537	702	569.32	2.25%
Male	70	77	2,100	53,848	2	4	1.30	2.86%
Unknown	1	1	30	11	0	.	90.91	0.00%
Surgical Site Complications								
Female	23,473	26,052	704,190	40,927	1,366	2,516	573.53	5.82%
Male	70	77	2,100	52,649	3	5	1.33	4.29%
Unknown	1	1	30	11	0	.	90.91	0.00%
Reintervention								
Female	23,907	26,518	717,210	42,032	51	57	568.78	0.21%
Male	70	77	2,100	53,941	0	.	1.30	0.00%
Unknown	1	1	30	11	0	.	90.91	0.00%
Wound Complications								
Female	23,842	26,448	715,260	41,872	298	440	569.40	1.25%
Male	70	77	2,100	53,851	0	.	1.30	0.00%
Unknown	1	1	30	11	0	.	90.91	0.00%
Abscess								
Female	23,698	26,293	710,940	41,493	618	1,097	571.13	2.61%
Male	70	77	2,100	53,151	1	1	1.32	1.43%
Unknown	1	1	30	11	0	.	90.91	0.00%
Hemorrhage								
Female	23,763	26,364	712,890	41,760	589	821	569.04	2.48%
Male	70	77	2,100	53,648	3	4	1.30	4.29%
Unknown	1	1	30	11	0	.	90.91	0.00%
Bowel Obstruction								
Female	23,874	26,484	716,220	41,841	112	166	570.59	0.47%
Male	70	77	2,100	53,780	0	.	1.30	0.00%
Unknown	1	1	30	11	0	.	90.91	0.00%
Medical Complications								
Female	22,766	25,283	682,980	39,040	1,180	2,362	583.15	5.18%
Male	68	74	2,040	49,451	4	5	1.38	5.88%
Unknown	1	1	30	10	0	.	100.00	0.00%

	New Patients	Claims	Lookup Period Duration	Eligible Members*	New Patients with Incident Post-Exposure Event	Number of Post-Exposure Event Claims	New Patients/ 1000 Eligible Members*	% New Patients with Post-Exposure Event
Laparoscopic Hysterectomy and Robotic Assistance in the Inpatient or Emergency Department Care Setting								
Intraoperative Complications								
Female	18,990	19,071	569,700	33,330	852	1,601	569.76	4.49%
Male	21	21	630	49,622	2	4	0.42	9.52%
Unknown	.	.	.	10	.	.	0.00	---
Bladder Injury								
Female	19,132	19,213	573,960	34,827	267	436	549.34	1.40%
Male	21	21	630	50,829	0	.	0.41	0.00%
Unknown	.	.	.	10	.	.	0.00	---
Ureteral Injury								
Female	19,105	19,186	573,150	33,653	323	461	567.71	1.69%
Male	21	21	630	49,856	1	1	0.42	4.76%
Unknown	.	.	.	10	.	.	0.00	---
Intestinal Injury								
Female	19,133	19,214	573,990	34,873	101	147	548.65	0.53%
Male	21	21	630	50,804	0	.	0.41	0.00%
Unknown	.	.	.	10	.	.	0.00	---
Vascular Injury								
Female	19,153	19,234	574,590	34,967	8	10	547.75	0.04%
Male	21	21	630	50,889	0	.	0.41	0.00%
Unknown	.	.	.	10	.	.	0.00	---
Other Operative Injury								
Female	19,072	19,153	572,160	34,779	473	595	548.38	2.48%
Male	21	21	630	50,797	1	3	0.41	4.76%
Unknown	.	.	.	10	.	.	0.00	---
Surgical Site Complications								
Female	18,795	18,876	563,850	33,974	1,159	2,139	553.22	6.17%
Male	21	21	630	49,652	2	3	0.42	9.52%
Unknown	.	.	.	10	.	.	0.00	---
Reintervention								
Female	19,151	19,232	574,530	34,964	45	50	547.73	0.23%
Male	21	21	630	50,889	0	.	0.41	0.00%
Unknown	.	.	.	10	.	.	0.00	---
Wound Complications								
Female	19,096	19,177	572,880	34,817	253	378	548.47	1.32%
Male	21	21	630	50,801	0	.	0.41	0.00%
Unknown	.	.	.	10	.	.	0.00	---
Abscess								
Female	18,988	19,069	569,640	34,494	535	953	550.47	2.82%
Male	21	21	630	50,135	1	1	0.42	4.76%
Unknown	.	.	.	10	.	.	0.00	---
Hemorrhage								
Female	19,033	19,114	570,990	34,724	490	676	548.12	2.57%
Male	21	21	630	50,609	2	2	0.41	9.52%
Unknown	.	.	.	10	.	.	0.00	---
Bowel Obstruction								
Female	19,120	19,201	573,600	34,783	95	144	549.69	0.50%
Male	21	21	630	50,732	0	.	0.41	0.00%
Unknown	.	.	.	10	.	.	0.00	---
Medical Complications								
Female	18,180	18,259	545,400	32,250	1,034	2,020	563.72	5.69%
Male	21	21	630	46,541	1	1	0.45	4.76%
Unknown	.	.	.	9	.	.	0.00	---

*To be included as an eligible member, an individual must meet the inclusion and exclusion criteria (he or she must have evidence of a robotic assistance procedure code and no evidence of a gynecologic malignancy). Member-Years are not a relevant calculation for this table because each eligible member only meets eligibility criteria for approximately one day (a member is only eligible to be included in the study on the day that he or she has the pre-existing condition).

Table 4a. Summary of Laparoscopic Hysterectomy (without Robotic Assistance) Use and Adverse Events in the MSDD between October 1, 2008 and May 31, 2013, by Year

	Incident Exposure (Laparoscopic Hysterectomy)					Post-Exposure Events			
	New Patients	Claims	Lookup Period Duration	Eligible Members*	Member-Years	New Patients with Incident Post-Exposure Event	Number of Post-Exposure Event Claims	New Patients/ 1000 Eligible Members*	% New Patients with Post-Exposure Event
Laparoscopic Hysterectomy without Robotic Assistance in Any Care Setting									
Intraoperative Complications									
2008	5,610	6,071	168,300	55,556,689	13,238,232	191	394	0.10	3.40%
2009	20,907	22,633	627,210	64,598,841	51,731,775	686	1,430	0.32	3.28%
2010	19,178	21,201	575,340	63,630,876	51,276,510	741	1,580	0.30	3.86%
2011	17,213	19,351	516,390	63,895,091	51,864,088	701	1,559	0.27	4.07%
2012	11,616	12,570	348,480	63,774,504	51,534,688	565	1,207	0.18	4.86%
2013	3,553	3,759	106,590	51,341,428	19,924,580	209	447	0.07	5.88%
Bladder Injury									
2008	5,646	6,120	169,380	55,604,228	13,257,756	84	148	0.10	1.49%
2009	21,036	22,769	631,080	64,611,741	51,806,786	279	467	0.33	1.33%
2010	19,300	21,329	579,000	63,644,097	51,350,956	283	494	0.30	1.47%
2011	17,369	19,525	521,070	63,908,070	51,939,123	260	501	0.27	1.50%
2012	11,703	12,661	351,090	63,787,654	51,607,541	199	366	0.18	1.70%
2013	3,570	3,777	107,100	51,364,026	19,951,742	65	127	0.07	1.82%
Ureteral Injury									
2008	5,643	6,117	169,290	55,591,689	13,252,820	50	67	0.10	0.89%
2009	21,021	22,754	630,630	64,607,818	51,786,724	212	343	0.33	1.01%
2010	19,268	21,293	578,040	63,639,720	51,329,755	250	372	0.30	1.30%
2011	17,326	19,480	519,780	63,903,770	51,917,092	245	384	0.27	1.41%
2012	11,677	12,632	350,310	63,783,087	51,585,257	192	271	0.18	1.64%
2013	3,565	3,774	106,950	51,356,829	19,943,282	82	104	0.07	2.30%
Intestinal Injury									
2008	5,645	6,111	169,350	55,593,894	13,253,791	18	26	0.10	0.32%
2009	21,035	22,766	631,050	64,608,370	51,790,483	80	133	0.33	0.38%
2010	19,293	21,322	578,790	63,640,557	51,334,183	98	151	0.30	0.51%
2011	17,347	19,497	520,410	63,904,459	51,922,126	92	130	0.27	0.53%
2012	11,697	12,654	350,910	63,783,922	51,590,636	81	116	0.18	0.69%
2013	3,564	3,772	106,920	51,357,212	19,945,029	24	44	0.07	0.67%
Vascular Injury									
2008	5,650	6,124	169,500	55,607,944	13,259,305	2	3	0.10	0.04%
2009	21,047	22,779	631,410	64,612,770	51,812,263	13	16	0.33	0.06%
2010	19,305	21,334	579,150	63,645,003	51,355,947	7	9	0.30	0.04%
2011	17,373	19,529	521,190	63,908,990	51,944,281	8	9	0.27	0.05%
2012	11,708	12,666	351,240	63,788,575	51,612,438	5	5	0.18	0.04%
2013	3,571	3,780	107,130	51,365,535	19,953,498	0	.	0.07	0.00%
Other Operative Injury									
2008	5,624	6,093	168,720	55,591,246	13,251,965	134	163	0.10	2.38%
2009	20,962	22,691	628,860	64,609,516	51,786,488	438	530	0.32	2.09%
2010	19,236	21,263	577,080	63,641,950	51,331,845	478	610	0.30	2.48%
2011	17,290	19,436	518,700	63,906,194	51,920,666	436	597	0.27	2.52%
2012	11,661	12,619	349,830	63,785,954	51,590,940	359	492	0.18	3.08%
2013	3,565	3,774	106,950	51,360,859	19,946,087	127	180	0.07	3.56%
Surgical Site Complications									
2008	5,551	6,020	166,530	55,258,772	13,111,440	318	555	0.10	5.73%
2009	20,665	22,364	619,950	64,537,750	51,269,664	1,260	2,147	0.32	6.10%
2010	18,917	20,910	567,510	63,570,929	50,825,578	1,129	1,842	0.30	5.97%
2011	17,027	19,145	510,810	63,836,626	51,407,490	1,027	1,858	0.27	6.03%
2012	11,461	12,393	343,830	63,713,324	51,075,278	778	1,402	0.18	6.79%
2013	3,490	3,689	104,700	51,224,045	19,760,204	250	418	0.07	7.16%
Reintervention									
2008	5,650	6,124	169,500	55,606,565	13,258,666	14	16	0.10	0.25%
2009	21,048	22,781	631,440	64,612,431	51,810,139	68	73	0.33	0.32%
2010	19,305	21,334	579,150	63,644,678	51,353,958	52	55	0.30	0.27%
2011	17,374	19,530	521,220	63,908,695	51,942,192	58	60	0.27	0.33%
2012	11,706	12,664	351,180	63,788,348	51,610,669	38	39	0.18	0.32%
2013	3,571	3,780	107,130	51,365,130	19,952,856	5	5	0.07	0.14%

	New Patients	Claims	Lookup Period Duration	Eligible Members*	Member-Years	New Patients with Incident Post-Exposure Event	Number of Post-Exposure Event Claims	New Patients/ 1000 Eligible Members*	% New Patients with Post-Exposure Event
Wound Complications									
2008	5,630	6,101	168,900	55,564,783	13,238,131	66	108	0.10	1.17%
2009	21,004	22,735	630,120	64,601,612	51,739,967	229	370	0.33	1.09%
2010	19,253	21,274	577,590	63,633,701	51,287,007	212	339	0.30	1.10%
2011	17,322	19,474	519,660	63,897,535	51,872,454	189	303	0.27	1.09%
2012	11,680	12,636	350,400	63,776,544	51,538,523	141	258	0.18	1.21%
2013	3,564	3,773	106,920	51,342,158	19,926,044	51	71	0.07	1.43%
Abscess									
2008	5,598	6,069	167,940	55,348,353	13,151,514	129	198	0.10	2.30%
2009	20,841	22,548	625,230	64,560,971	51,415,968	528	854	0.32	2.53%
2010	19,104	21,113	573,120	63,594,349	50,966,399	459	713	0.30	2.40%
2011	17,183	19,312	515,490	63,859,906	51,551,750	428	734	0.27	2.49%
2012	11,576	12,525	347,280	63,737,531	51,221,008	340	567	0.18	2.94%
2013	3,526	3,729	105,780	51,270,956	19,814,863	102	162	0.07	2.89%
Hemorrhage									
2008	5,622	6,095	168,660	55,575,181	13,244,598	150	210	0.10	2.67%
2009	20,931	22,658	627,930	64,606,014	51,753,369	623	820	0.32	2.98%
2010	19,187	21,205	575,610	63,638,302	51,297,447	542	690	0.30	2.82%
2011	17,278	19,426	518,340	63,902,262	51,884,021	489	672	0.27	2.83%
2012	11,638	12,582	349,140	63,781,562	51,552,415	348	467	0.18	2.99%
2013	3,550	3,755	106,500	51,350,928	19,931,020	121	170	0.07	3.41%
Bowel Obstruction									
2008	5,643	6,117	169,290	55,580,253	13,247,567	21	42	0.10	0.37%
2009	21,027	22,760	630,810	64,605,773	51,765,335	83	123	0.33	0.39%
2010	19,270	21,298	578,100	63,637,743	51,308,737	71	97	0.30	0.37%
2011	17,354	19,509	520,620	63,902,145	51,896,585	90	113	0.27	0.52%
2012	11,676	12,633	350,280	63,781,374	51,564,373	58	90	0.18	0.50%
2013	3,560	3,769	106,800	51,351,065	19,935,300	16	17	0.07	0.45%
Medical Complications									
2008	5,442	5,889	163,260	54,712,578	12,900,210	190	371	0.10	3.49%
2009	20,214	21,895	606,420	64,222,772	49,932,763	824	1,501	0.31	4.08%
2010	18,466	20,426	553,980	63,246,024	49,560,774	719	1,423	0.29	3.89%
2011	16,655	18,748	499,650	63,543,665	50,168,929	732	1,416	0.26	4.40%
2012	11,253	12,169	337,590	63,409,088	49,984,098	522	1,089	0.18	4.64%
2013	3,403	3,595	102,090	50,490,238	19,108,574	172	383	0.07	5.05%
Laparoscopic Hysterectomy without Robotic Assistance in the Inpatient or Emergency Department Care Setting									
Intraoperative Complications									
2008	4,587	4,608	137,610	55,556,714	13,238,394	180	372	0.08	3.92%
2009	17,057	17,144	511,710	64,600,213	51,735,296	618	1,258	0.26	3.62%
2010	14,975	15,087	449,250	63,636,930	51,284,672	657	1,397	0.24	4.39%
2011	12,629	12,773	378,870	63,906,190	51,877,524	586	1,298	0.20	4.64%
2012	8,594	8,678	257,820	63,790,613	51,551,603	476	983	0.13	5.54%
2013	2,389	2,404	71,670	51,358,377	19,931,736	169	358	0.05	7.07%
Bladder Injury									
2008	4,614	4,635	138,420	55,604,254	13,257,922	82	146	0.08	1.78%
2009	17,174	17,262	515,220	64,613,121	51,810,354	241	398	0.27	1.40%
2010	15,086	15,199	452,580	63,650,166	51,359,202	247	434	0.24	1.64%
2011	12,759	12,904	382,770	63,919,195	51,952,701	226	431	0.20	1.77%
2012	8,677	8,762	260,310	63,803,806	51,624,609	176	301	0.14	2.03%
2013	2,405	2,421	72,150	51,381,047	19,958,956	55	108	0.05	2.29%
Ureteral Injury									
2008	4,612	4,633	138,360	55,591,715	13,252,985	47	62	0.08	1.02%
2009	17,161	17,249	514,830	64,609,196	51,790,287	192	299	0.27	1.12%
2010	15,060	15,172	451,800	63,645,783	51,337,988	229	334	0.24	1.52%
2011	12,726	12,871	381,780	63,914,886	51,930,628	218	328	0.20	1.71%
2012	8,653	8,737	259,590	63,799,226	51,602,279	177	250	0.14	2.05%
2013	2,402	2,418	72,060	51,373,825	19,950,479	78	99	0.05	3.25%
Intestinal Injury									
2008	4,615	4,636	138,450	55,593,919	13,253,956	15	20	0.08	0.33%
2009	17,175	17,263	515,250	64,609,747	51,794,060	73	124	0.27	0.43%
2010	15,079	15,192	452,370	63,646,626	51,342,445	92	137	0.24	0.61%
2011	12,747	12,891	382,410	63,915,582	51,935,720	77	110	0.20	0.60%
2012	8,672	8,757	260,160	63,800,067	51,607,707	71	101	0.14	0.82%
2013	2,401	2,416	72,030	51,374,225	19,952,243	18	34	0.05	0.75%

	New Patients	Claims	Lookup Period Duration	Eligible Members*	Member-Years	New Patients with Incident Post-Exposure Event	Number of Post-Exposure Event Claims	New Patients/ 1000 Eligible Members*	% New Patients with Post-Exposure Event
Vascular Injury									
2008	4,618	4,639	138,540	55,607,970	13,259,471	2	3	0.08	0.04%
2009	17,185	17,272	515,550	64,614,150	51,815,850	13	16	0.27	0.08%
2010	15,092	15,205	452,760	63,651,072	51,364,227	7	9	0.24	0.05%
2011	12,765	12,910	382,950	63,920,117	51,957,896	7	7	0.20	0.05%
2012	8,682	8,767	260,460	63,804,728	51,629,533	5	5	0.14	0.06%
2013	2,407	2,423	72,210	51,382,560	19,960,720	0	.	0.05	0.00%
Other Operative Injury									
2008	4,598	4,619	137,940	55,591,272	13,252,129	127	154	0.08	2.76%
2009	17,108	17,196	513,240	64,610,888	51,790,042	400	479	0.26	2.34%
2010	15,024	15,137	450,720	63,648,011	51,340,081	424	532	0.24	2.82%
2011	12,690	12,835	380,700	63,917,312	51,934,213	368	482	0.20	2.90%
2012	8,636	8,721	259,080	63,802,087	51,607,963	295	371	0.14	3.42%
2013	2,399	2,415	71,970	51,377,855	19,953,281	96	125	0.05	4.00%
Surgical Site Complications									
2008	4,540	4,561	136,200	55,258,805	13,111,597	286	499	0.08	6.30%
2009	16,868	16,955	506,040	64,539,113	51,273,050	1,097	1,851	0.26	6.50%
2010	14,785	14,896	443,550	63,576,911	50,833,498	958	1,592	0.23	6.48%
2011	12,497	12,637	374,910	63,847,600	51,420,590	830	1,539	0.20	6.64%
2012	8,480	8,563	254,400	63,729,275	51,091,766	596	1,126	0.13	7.03%
2013	2,352	2,368	70,560	51,240,785	19,767,186	182	310	0.05	7.74%
Reintervention									
2008	4,618	4,639	138,540	55,606,591	13,258,832	11	13	0.08	0.24%
2009	17,186	17,274	515,580	64,613,809	51,813,720	58	61	0.27	0.34%
2010	15,091	15,204	452,730	63,650,747	51,362,237	51	54	0.24	0.34%
2011	12,766	12,911	382,980	63,919,822	51,955,803	51	53	0.20	0.40%
2012	8,680	8,765	260,400	63,804,500	51,627,759	33	34	0.14	0.38%
2013	2,407	2,423	72,210	51,382,152	19,960,076	5	5	0.05	0.21%
Wound Complications									
2008	4,604	4,625	138,120	55,564,811	13,238,296	60	103	0.08	1.30%
2009	17,150	17,238	514,500	64,602,984	51,743,514	200	326	0.27	1.17%
2010	15,050	15,163	451,500	63,639,752	51,295,207	179	297	0.24	1.19%
2011	12,721	12,866	381,630	63,908,635	51,885,973	156	261	0.20	1.23%
2012	8,662	8,747	259,860	63,792,663	51,555,513	119	229	0.14	1.37%
2013	2,400	2,416	72,000	51,359,139	19,933,228	36	52	0.05	1.50%
Abscess									
2008	4,578	4,599	137,340	55,348,383	13,151,676	119	172	0.08	2.60%
2009	17,020	17,107	510,600	64,562,340	51,419,446	447	718	0.26	2.63%
2010	14,942	15,054	448,260	63,600,371	50,974,474	378	603	0.23	2.53%
2011	12,630	12,771	378,900	63,870,939	51,565,050	330	578	0.20	2.61%
2012	8,582	8,667	257,460	63,753,556	51,237,718	246	423	0.13	2.87%
2013	2,381	2,397	71,430	51,287,785	19,821,922	69	117	0.05	2.90%
Hemorrhage									
2008	4,595	4,616	137,850	55,575,211	13,244,761	135	192	0.08	2.94%
2009	17,085	17,173	512,550	64,607,391	51,756,894	556	727	0.26	3.25%
2010	14,988	15,100	449,640	63,644,350	51,305,638	472	598	0.24	3.15%
2011	12,686	12,830	380,580	63,913,353	51,897,526	424	577	0.20	3.34%
2012	8,617	8,701	258,510	63,797,675	51,569,392	282	379	0.14	3.27%
2013	2,389	2,405	71,670	51,367,909	19,938,198	93	125	0.05	3.89%
Bowel Obstruction									
2008	4,612	4,633	138,360	55,580,278	13,247,733	19	37	0.08	0.41%
2009	17,166	17,254	514,980	64,607,150	51,768,910	72	108	0.27	0.42%
2010	15,065	15,178	451,950	63,643,807	51,316,996	64	89	0.24	0.42%
2011	12,748	12,892	382,440	63,913,266	51,910,170	74	94	0.20	0.58%
2012	8,652	8,736	259,560	63,797,518	51,581,429	52	80	0.14	0.60%
2013	2,400	2,416	72,000	51,368,071	19,942,504	15	16	0.05	0.63%
Medical Complications									
2008	4,440	4,461	133,200	54,712,604	12,900,368	176	321	0.08	3.96%
2009	16,472	16,559	494,160	64,224,129	49,936,130	753	1,368	0.26	4.57%
2010	14,406	14,514	432,180	63,251,973	49,568,572	639	1,273	0.23	4.44%
2011	12,204	12,340	366,120	63,554,543	50,181,814	637	1,220	0.19	5.22%
2012	8,290	8,368	248,700	63,424,885	50,000,326	466	984	0.13	5.62%
2013	2,284	2,299	68,520	50,506,730	19,115,359	140	314	0.05	6.13%

*To be included as an eligible member, an individual must meet the exclusion criteria (no evidence of a gynecologic malignancy or a robotic assistance procedure)

Appendix A. Exposure Codes

Code	Description	Code Type
68.31	Laparoscopic Hysterectomy	ICD-9-CM Procedure
68.41	Laparoscopic Hysterectomy	ICD-9-CM Procedure
68.51	Laparoscopic Hysterectomy	ICD-9-CM Procedure

Appendix B. Inclusion/Exclusion Condition Codes

Code	Description	Code Type
17.42	Robotic-Assisted Procedure	ICD-9-CM Procedure
180*	Gynecologic Malignancy	ICD-9-CM Diagnosis
181*	Gynecologic Malignancy	ICD-9-CM Diagnosis
182*	Gynecologic Malignancy	ICD-9-CM Diagnosis
183*	Gynecologic Malignancy	ICD-9-CM Diagnosis
184*	Gynecologic Malignancy	ICD-9-CM Diagnosis

Appendix C. Event Codes

Code	Description 1	Description 2	Code Type
867.0	Bladder Injury	Intraoperative Complications	ICD-9-Diagnosis
867.1	Bladder Injury	Intraoperative Complications	ICD-9-Diagnosis
57.1	Bladder Injury	Intraoperative Complications	ICD-9-Procedure
57.19	Bladder Injury	Intraoperative Complications	ICD-9-Procedure
57.8	Bladder Injury	Intraoperative Complications	ICD-9-Procedure
57.81	Bladder Injury	Intraoperative Complications	ICD-9-Procedure
57.83	Bladder Injury	Intraoperative Complications	ICD-9-Procedure
75.61	Bladder Injury	Intraoperative Complications	ICD-9-Procedure
596.1	Bladder Injury	Intraoperative Complications	ICD-9-Diagnosis
596.2	Bladder Injury	Intraoperative Complications	ICD-9-Diagnosis
596.6	Bladder Injury	Intraoperative Complications	ICD-9-Diagnosis
619.0	Bladder Injury	Intraoperative Complications	ICD-9-Diagnosis
867.2	Ureteral Injury	Intraoperative Complications	ICD-9-Diagnosis
867.3	Ureteral Injury	Intraoperative Complications	ICD-9-Diagnosis
56.71	Ureteral Injury	Intraoperative Complications	ICD-9-Procedure
56.74	Ureteral Injury	Intraoperative Complications	ICD-9-Procedure
56.75	Ureteral Injury	Intraoperative Complications	ICD-9-Procedure
56.82	Ureteral Injury	Intraoperative Complications	ICD-9-Procedure
56.83	Ureteral Injury	Intraoperative Complications	ICD-9-Procedure
56.84	Ureteral Injury	Intraoperative Complications	ICD-9-Procedure
56.86	Ureteral Injury	Intraoperative Complications	ICD-9-Procedure
56.89	Ureteral Injury	Intraoperative Complications	ICD-9-Procedure
593.3	Ureteral Injury	Intraoperative Complications	ICD-9-Diagnosis
593.4	Ureteral Injury	Intraoperative Complications	ICD-9-Diagnosis
593.5	Ureteral Injury	Intraoperative Complications	ICD-9-Diagnosis
593.82	Ureteral Injury	Intraoperative Complications	ICD-9-Diagnosis
863.2	Intestinal Injury	Intraoperative Complications	ICD-9-Diagnosis
863.20	Intestinal Injury	Intraoperative Complications	ICD-9-Diagnosis
863.21	Intestinal Injury	Intraoperative Complications	ICD-9-Diagnosis
863.29	Intestinal Injury	Intraoperative Complications	ICD-9-Diagnosis
863.30	Intestinal Injury	Intraoperative Complications	ICD-9-Diagnosis
863.31	Intestinal Injury	Intraoperative Complications	ICD-9-Diagnosis
863.39	Intestinal Injury	Intraoperative Complications	ICD-9-Diagnosis
863.40	Intestinal Injury	Intraoperative Complications	ICD-9-Diagnosis
863.41	Intestinal Injury	Intraoperative Complications	ICD-9-Diagnosis
863.42	Intestinal Injury	Intraoperative Complications	ICD-9-Diagnosis
863.43	Intestinal Injury	Intraoperative Complications	ICD-9-Diagnosis
863.44	Intestinal Injury	Intraoperative Complications	ICD-9-Diagnosis
863.45	Intestinal Injury	Intraoperative Complications	ICD-9-Diagnosis
863.46	Intestinal Injury	Intraoperative Complications	ICD-9-Diagnosis
863.49	Intestinal Injury	Intraoperative Complications	ICD-9-Diagnosis
863.50	Intestinal Injury	Intraoperative Complications	ICD-9-Diagnosis
863.51	Intestinal Injury	Intraoperative Complications	ICD-9-Diagnosis

Code	Description 1	Description 2	Code Type
863.52	Intestinal Injury	Intraoperative Complications	ICD-9-Diagnosis
863.53	Intestinal Injury	Intraoperative Complications	ICD-9-Diagnosis
863.54	Intestinal Injury	Intraoperative Complications	ICD-9-Diagnosis
863.55	Intestinal Injury	Intraoperative Complications	ICD-9-Diagnosis
863.56	Intestinal Injury	Intraoperative Complications	ICD-9-Diagnosis
863.59	Intestinal Injury	Intraoperative Complications	ICD-9-Diagnosis
863.80	Intestinal Injury	Intraoperative Complications	ICD-9-Diagnosis
863.90	Intestinal Injury	Intraoperative Complications	ICD-9-Diagnosis
46.7	Intestinal Injury	Intraoperative Complications	ICD-9-Procedure
46.71	Intestinal Injury	Intraoperative Complications	ICD-9-Procedure
46.73	Intestinal Injury	Intraoperative Complications	ICD-9-Procedure
46.75	Intestinal Injury	Intraoperative Complications	ICD-9-Procedure
45.0	Intestinal Injury	Intraoperative Complications	ICD-9-Procedure
48.71	Intestinal Injury	Intraoperative Complications	ICD-9-Procedure
48.79	Intestinal Injury	Intraoperative Complications	ICD-9-Procedure
565.1	Intestinal Injury	Intraoperative Complications	ICD-9-Diagnosis
569.83	Intestinal Injury	Intraoperative Complications	ICD-9-Diagnosis
619.1	Intestinal Injury	Intraoperative Complications	ICD-9-Diagnosis
997.7	Vascular Injury	Intraoperative Complications	ICD-9-Diagnosis
997.79	Vascular Injury	Intraoperative Complications	ICD-9-Diagnosis
902.50	Vascular Injury	Intraoperative Complications	ICD-9-Diagnosis
902.51	Vascular Injury	Intraoperative Complications	ICD-9-Diagnosis
902.52	Vascular Injury	Intraoperative Complications	ICD-9-Diagnosis
902.53	Vascular Injury	Intraoperative Complications	ICD-9-Diagnosis
902.54	Vascular Injury	Intraoperative Complications	ICD-9-Diagnosis
902.55	Vascular Injury	Intraoperative Complications	ICD-9-Diagnosis
902.56	Vascular Injury	Intraoperative Complications	ICD-9-Diagnosis
902.59	Vascular Injury	Intraoperative Complications	ICD-9-Diagnosis
902.81	Vascular Injury	Intraoperative Complications	ICD-9-Diagnosis
902.82	Vascular Injury	Intraoperative Complications	ICD-9-Diagnosis
902.87	Vascular Injury	Intraoperative Complications	ICD-9-Diagnosis
902.89	Vascular Injury	Intraoperative Complications	ICD-9-Diagnosis
902.10	Vascular Injury	Intraoperative Complications	ICD-9-Diagnosis
902.19	Vascular Injury	Intraoperative Complications	ICD-9-Diagnosis
902.0	Vascular Injury	Intraoperative Complications	ICD-9-Diagnosis
902.2	Vascular Injury	Intraoperative Complications	ICD-9-Diagnosis
902.26	Vascular Injury	Intraoperative Complications	ICD-9-Diagnosis
902.27	Vascular Injury	Intraoperative Complications	ICD-9-Diagnosis
902.29	Vascular Injury	Intraoperative Complications	ICD-9-Diagnosis
902.9	Vascular Injury	Intraoperative Complications	ICD-9-Diagnosis
998.4	Other Operative Injury	Intraoperative Complications	ICD-9-Diagnosis
998.7	Other Operative Injury	Intraoperative Complications	ICD-9-Diagnosis
E871.0	Other Operative Injury	Intraoperative Complications	ICD-9-Diagnosis
E876.0	Other Operative Injury	Intraoperative Complications	ICD-9-Diagnosis
E876.2	Other Operative Injury	Intraoperative Complications	ICD-9-Diagnosis
E876.3	Other Operative Injury	Intraoperative Complications	ICD-9-Diagnosis

Code	Description 1	Description 2	Code Type
E876.5	Other Operative Injury	Intraoperative Complications	ICD-9-Diagnosis
512.1	Other Operative Injury	Intraoperative Complications	ICD-9-Diagnosis
620.6	Other Operative Injury	Intraoperative Complications	ICD-9-Diagnosis
998.2	Other Operative Injury	Intraoperative Complications	ICD-9-Diagnosis
665.5	Other Operative Injury	Intraoperative Complications	ICD-9-Diagnosis
665.51	Other Operative Injury	Intraoperative Complications	ICD-9-Diagnosis
E870.0	Other Operative Injury	Intraoperative Complications	ICD-9-Diagnosis
E870.4	Other Operative Injury	Intraoperative Complications	ICD-9-Diagnosis
956.1	Other Operative Injury	Intraoperative Complications	ICD-9-Diagnosis
956.2	Other Operative Injury	Intraoperative Complications	ICD-9-Diagnosis
956.3	Other Operative Injury	Intraoperative Complications	ICD-9-Diagnosis
956.4	Other Operative Injury	Intraoperative Complications	ICD-9-Diagnosis
956.5	Other Operative Injury	Intraoperative Complications	ICD-9-Diagnosis
956.8	Other Operative Injury	Intraoperative Complications	ICD-9-Diagnosis
956.9	Other Operative Injury	Intraoperative Complications	ICD-9-Diagnosis
54.12	Reintervention	Surgical Site Complications	ICD-9-Procedure
54.19	Reintervention	Surgical Site Complications	ICD-9-Procedure
54.92	Reintervention	Surgical Site Complications	ICD-9-Procedure
54.0	Reintervention	Surgical Site Complications	ICD-9-Procedure
54.61	Reintervention	Surgical Site Complications	ICD-9-Procedure
998.3	Wound Complication	Surgical Site Complications	ICD-9-Diagnosis
998.30	Wound Complication	Surgical Site Complications	ICD-9-Diagnosis
998.31	Wound Complication	Surgical Site Complications	ICD-9-Diagnosis
998.32	Wound Complication	Surgical Site Complications	ICD-9-Diagnosis
998.33	Wound Complication	Surgical Site Complications	ICD-9-Diagnosis
998.83	Wound Complication	Surgical Site Complications	ICD-9-Diagnosis
998.13	Wound Complication	Surgical Site Complications	ICD-9-Diagnosis
998.6	Wound Complication	Surgical Site Complications	ICD-9-Diagnosis
998.51	Wound Complication	Surgical Site Complications	ICD-9-Diagnosis
729.92	Wound Complication	Surgical Site Complications	ICD-9-Diagnosis
879.3	Wound Complication	Surgical Site Complications	ICD-9-Diagnosis
879.5	Wound Complication	Surgical Site Complications	ICD-9-Diagnosis
879.9	Wound Complication	Surgical Site Complications	ICD-9-Diagnosis
567.22	Abscess	Surgical Site Complications	ICD-9-Diagnosis
567.31	Abscess	Surgical Site Complications	ICD-9-Diagnosis
567.38	Abscess	Surgical Site Complications	ICD-9-Diagnosis
682.9	Abscess	Surgical Site Complications	ICD-9-Diagnosis
566	Abscess	Surgical Site Complications	ICD-9-Diagnosis
998.59	Abscess	Surgical Site Complications	ICD-9-Diagnosis
569.5	Abscess	Surgical Site Complications	ICD-9-Diagnosis
998.1	Hemorrhage	Surgical Site Complications	ICD-9-Diagnosis
998.11	Hemorrhage	Surgical Site Complications	ICD-9-Diagnosis
998.12	Hemorrhage	Surgical Site Complications	ICD-9-Diagnosis
459.0	Hemorrhage	Surgical Site Complications	ICD-9-Diagnosis
729.92	Hemorrhage	Surgical Site Complications	ICD-9-Diagnosis
623.6	Hemorrhage	Surgical Site Complications	ICD-9-Diagnosis

Code	Description 1	Description 2	Code Type
624.5	Hemorrhage	Surgical Site Complications	ICD-9-Diagnosis
560	Bowel Obstruction	Surgical Site Complications	ICD-9-Diagnosis
560.9	Bowel Obstruction	Surgical Site Complications	ICD-9-Diagnosis
560.81	Bowel Obstruction	Surgical Site Complications	ICD-9-Diagnosis
537.3	Bowel Obstruction	Surgical Site Complications	ICD-9-Diagnosis
560.1	Ileus	Medical Complications	ICD-9-Diagnosis
536.2	Ileus	Medical Complications	ICD-9-Diagnosis
415.1	VenousThromboembolism	Medical Complications	ICD-9-Diagnosis
415.11	VenousThromboembolism	Medical Complications	ICD-9-Diagnosis
415.12	VenousThromboembolism	Medical Complications	ICD-9-Diagnosis
415.19	VenousThromboembolism	Medical Complications	ICD-9-Diagnosis
v12.51	VenousThromboembolism	Medical Complications	ICD-9-Diagnosis
451.1	VenousThromboembolism	Medical Complications	ICD-9-Diagnosis
451.11	VenousThromboembolism	Medical Complications	ICD-9-Diagnosis
451.19	VenousThromboembolism	Medical Complications	ICD-9-Diagnosis
451.2	VenousThromboembolism	Medical Complications	ICD-9-Diagnosis
451.81	VenousThromboembolism	Medical Complications	ICD-9-Diagnosis
451.9	VenousThromboembolism	Medical Complications	ICD-9-Diagnosis
453.4	VenousThromboembolism	Medical Complications	ICD-9-Diagnosis
453.40	VenousThromboembolism	Medical Complications	ICD-9-Diagnosis
453.41	VenousThromboembolism	Medical Complications	ICD-9-Diagnosis
453.42	VenousThromboembolism	Medical Complications	ICD-9-Diagnosis
453.9	VenousThromboembolism	Medical Complications	ICD-9-Diagnosis
997.2	VenousThromboembolism	Medical Complications	ICD-9-Diagnosis
999.2	VenousThromboembolism	Medical Complications	ICD-9-Diagnosis
410	Myocardial Infarction	Medical Complications	ICD-9-Diagnosis
410.0	Myocardial Infarction	Medical Complications	ICD-9-Diagnosis
410.1	Myocardial Infarction	Medical Complications	ICD-9-Diagnosis
410.2	Myocardial Infarction	Medical Complications	ICD-9-Diagnosis
410.3	Myocardial Infarction	Medical Complications	ICD-9-Diagnosis
410.4	Myocardial Infarction	Medical Complications	ICD-9-Diagnosis
410.5	Myocardial Infarction	Medical Complications	ICD-9-Diagnosis
410.6	Myocardial Infarction	Medical Complications	ICD-9-Diagnosis
410.7	Myocardial Infarction	Medical Complications	ICD-9-Diagnosis
410.8	Myocardial Infarction	Medical Complications	ICD-9-Diagnosis
410.9	Myocardial Infarction	Medical Complications	ICD-9-Diagnosis
799.1	Cardiopulmonary Arrest	Medical Complications	ICD-9-Diagnosis
427.4	Cardiopulmonary Arrest	Medical Complications	ICD-9-Diagnosis
427.5	Cardiopulmonary Arrest	Medical Complications	ICD-9-Diagnosis
584	Renal Failure	Medical Complications	ICD-9-Diagnosis
584.5	Renal Failure	Medical Complications	ICD-9-Diagnosis
584.9	Renal Failure	Medical Complications	ICD-9-Diagnosis
586	Renal Failure	Medical Complications	ICD-9-Diagnosis
518.0	Respiratory Failure	Medical Complications	ICD-9-Diagnosis
518.4	Respiratory Failure	Medical Complications	ICD-9-Diagnosis
518.5	Respiratory Failure	Medical Complications	ICD-9-Diagnosis

Code	Description 1	Description 2	Code Type
518.81	Respiratory Failure	Medical Complications	ICD-9-Diagnosis
518.82	Respiratory Failure	Medical Complications	ICD-9-Diagnosis
997.02	Stroke	Medical Complications	ICD-9-Diagnosis
435	Stroke	Medical Complications	ICD-9-Diagnosis
435.0	Stroke	Medical Complications	ICD-9-Diagnosis
435.1	Stroke	Medical Complications	ICD-9-Diagnosis
435.8	Stroke	Medical Complications	ICD-9-Diagnosis
435.9	Stroke	Medical Complications	ICD-9-Diagnosis
434	Stroke	Medical Complications	ICD-9-Diagnosis
434.00	Stroke	Medical Complications	ICD-9-Diagnosis
434.01	Stroke	Medical Complications	ICD-9-Diagnosis
434.10	Stroke	Medical Complications	ICD-9-Diagnosis
434.11	Stroke	Medical Complications	ICD-9-Diagnosis
434.90	Stroke	Medical Complications	ICD-9-Diagnosis
434.91	Stroke	Medical Complications	ICD-9-Diagnosis
435	Stroke	Medical Complications	ICD-9-Diagnosis
437.1	Stroke	Medical Complications	ICD-9-Diagnosis
038	Bacteremia_Sepsis	Medical Complications	ICD-9-Diagnosis
038.0	Bacteremia_Sepsis	Medical Complications	ICD-9-Diagnosis
038.1	Bacteremia_Sepsis	Medical Complications	ICD-9-Diagnosis
038.10	Bacteremia_Sepsis	Medical Complications	ICD-9-Diagnosis
038.11	Bacteremia_Sepsis	Medical Complications	ICD-9-Diagnosis
038.12	Bacteremia_Sepsis	Medical Complications	ICD-9-Diagnosis
038.19	Bacteremia_Sepsis	Medical Complications	ICD-9-Diagnosis
038.2	Bacteremia_Sepsis	Medical Complications	ICD-9-Diagnosis
038.3	Bacteremia_Sepsis	Medical Complications	ICD-9-Diagnosis
038.4	Bacteremia_Sepsis	Medical Complications	ICD-9-Diagnosis
038.40	Bacteremia_Sepsis	Medical Complications	ICD-9-Diagnosis
038.41	Bacteremia_Sepsis	Medical Complications	ICD-9-Diagnosis
038.42	Bacteremia_Sepsis	Medical Complications	ICD-9-Diagnosis
038.43	Bacteremia_Sepsis	Medical Complications	ICD-9-Diagnosis
038.44	Bacteremia_Sepsis	Medical Complications	ICD-9-Diagnosis
038.49	Bacteremia_Sepsis	Medical Complications	ICD-9-Diagnosis
038.8	Bacteremia_Sepsis	Medical Complications	ICD-9-Diagnosis
038.9	Bacteremia_Sepsis	Medical Complications	ICD-9-Diagnosis
790.7	Bacteremia_Sepsis	Medical Complications	ICD-9-Diagnosis
480	Pneumonia	Medical Complications	ICD-9-Diagnosis
480.0	Pneumonia	Medical Complications	ICD-9-Diagnosis
480.1	Pneumonia	Medical Complications	ICD-9-Diagnosis
480.2	Pneumonia	Medical Complications	ICD-9-Diagnosis
480.8	Pneumonia	Medical Complications	ICD-9-Diagnosis
480.9	Pneumonia	Medical Complications	ICD-9-Diagnosis
481	Pneumonia	Medical Complications	ICD-9-Diagnosis
482.0	Pneumonia	Medical Complications	ICD-9-Diagnosis
482.1	Pneumonia	Medical Complications	ICD-9-Diagnosis
482.2	Pneumonia	Medical Complications	ICD-9-Diagnosis

Code	Description 1	Description 2	Code Type
482.3	Pneumonia	Medical Complications	ICD-9-Diagnosis
482.30	Pneumonia	Medical Complications	ICD-9-Diagnosis
482.31	Pneumonia	Medical Complications	ICD-9-Diagnosis
482.32	Pneumonia	Medical Complications	ICD-9-Diagnosis
482.39	Pneumonia	Medical Complications	ICD-9-Diagnosis
482.4	Pneumonia	Medical Complications	ICD-9-Diagnosis
482.40	Pneumonia	Medical Complications	ICD-9-Diagnosis
482.41	Pneumonia	Medical Complications	ICD-9-Diagnosis
482.42	Pneumonia	Medical Complications	ICD-9-Diagnosis
482.49	Pneumonia	Medical Complications	ICD-9-Diagnosis
482.5	Pneumonia	Medical Complications	ICD-9-Diagnosis
482.8	Pneumonia	Medical Complications	ICD-9-Diagnosis
482.81	Pneumonia	Medical Complications	ICD-9-Diagnosis
482.82	Pneumonia	Medical Complications	ICD-9-Diagnosis
482.83	Pneumonia	Medical Complications	ICD-9-Diagnosis
482.84	Pneumonia	Medical Complications	ICD-9-Diagnosis
482.89	Pneumonia	Medical Complications	ICD-9-Diagnosis
482.9	Pneumonia	Medical Complications	ICD-9-Diagnosis
483	Pneumonia	Medical Complications	ICD-9-Diagnosis
483.0	Pneumonia	Medical Complications	ICD-9-Diagnosis
483.1	Pneumonia	Medical Complications	ICD-9-Diagnosis
483.8	Pneumonia	Medical Complications	ICD-9-Diagnosis
485	Pneumonia	Medical Complications	ICD-9-Diagnosis
486	Pneumonia	Medical Complications	ICD-9-Diagnosis
487	Pneumonia	Medical Complications	ICD-9-Diagnosis
997.31	Pneumonia	Medical Complications	ICD-9-Diagnosis
998.0	Shock	Medical Complications	ICD-9-Diagnosis
785.50	Shock	Medical Complications	ICD-9-Diagnosis
785.51	Shock	Medical Complications	ICD-9-Diagnosis
785.59	Shock	Medical Complications	ICD-9-Diagnosis
458.0	Shock	Medical Complications	ICD-9-Diagnosis
458.9	Shock	Medical Complications	ICD-9-Diagnosis
958.4	Shock	Medical Complications	ICD-9-Diagnosis
639.5	Shock	Medical Complications	ICD-9-Diagnosis
669.1	Shock	Medical Complications	ICD-9-Diagnosis