



Modular Program Report

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

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

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

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

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Overview

<u>Request Description</u>	<p>FDA has requested execution of Modular Program #9 (MP9), version 1.0, to investigate prevalence and incidence of kidney stones among all members and among those with a pre-existing condition of anti-diabetic agent use. See the next tab for exact specifications used in this request. One run of MP9 was required. The query was run against the Mini-Sentinel Distributed Database (MSDD) for the time period of January 1, 2004 – December 31, 2012. The package was distributed to 18 Data Partners (DPs) on August 9, 2013; this report contains information from 18 DPs.</p> <p>Results provide counts of prevalent and incident kidney stone patients, total claims, eligible members, and member-years.</p>
<u>Request ID</u>	msy4_mpr54_v1
<u>Specifications</u>	Program parameter inputs and scenarios.
<u>Glossary</u>	List of terms found in this report and their definitions.
<u>Table 1</u>	Table displaying the number of prevalent and incident kidney stone patients, new starts, total claims, eligible members, member-years, number of patients per 1,000 eligible members, and number of patients per 1,000 member-years by pre-existing condition criteria - January 1, 2004 - December 31, 2012.
<u>Figure 1</u>	One figure displaying the information in the prior tab.
<u>Table 2</u>	Table displaying the number of prevalent and incident kidney stone patients, new starts, total claims, eligible members, member-years, number of patients per 1,000 eligible members, and number of patients per 1,000 member-years by pre-existing condition criteria and age group - January 1, 2004 - December 31, 2012.
<u>Table 3</u>	Table displaying the number of prevalent and incident kidney stone patients, new starts, total claims, eligible members, member-years, number of patients per 1,000 eligible members, and number of patients per 1,000 member-years by pre-existing condition criteria and sex - January 1, 2004 - December 31, 2012.
<u>Table 4</u>	Table displaying the number of prevalent and incident kidney stone patients, new starts, total claims, eligible members, member-years, number of patients per 1,000 eligible members, and number of patients per 1,000 member-years by pre-existing condition criteria and year - January 1, 2004 - December 31, 2012.
<u>Appendix A</u>	Description of kidney stone codes included in this request.
<u>Notes:</u>	Please contact the Mini-Sentinel Operations Center (MSOC_Requests@harvardpilgrim.org) for questions and to provide comments/suggestions for future enhancements to this document.

Modular Program Specifications MSY4_MPR54_v1

Modular Program #9, version 1.0, was used to investigate prevalence and incidence of kidney stones among all members and among those with a pre-existing condition of anti-diabetic agent use. The query period was from January 1, 2004 to December 31, 2012, and the enrollment gap was set at 45 days. Age groups were split as follows: 0-9, 10-16, 17-64, and 65+ years. In total, two different scenarios were examined in this report with differing pre-existing condition criteria. See below for a description of each of these scenarios.

Scenario	Exposure Criteria					Pre-existing Condition Criteria				
	Incident exposure	Care Setting	Incident w/ respect to (incidence criteria):	Incident Only Care Setting	Washout (days)	Incidence Type	Pre-existing Condition	Lookback Period Start	Lookback Period End	Care Setting
1	Kidney Stones	Any	Kidney Stones	Any	183	MULT	NA	NA	NA	NA
2	Kidney Stones	Any	Kidney Stones	Any	183	MULT	Anti-diabetic Agents	-183	-1	Any

Glossary of Terms in Modular Program 9*

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).

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

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

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

Incidence Type (drug/exposure)- *Minimum incidence type* will consider the first treatment episode in the query period as long as it is the first treatment episode in the user's entire available history. *Multiple incidence type* will use the washout period to establish incidence and will consider all qualifying incident treatment episodes.

Lookback Period (pre-existing condition) - number of days wherein a member is required to have evidence of pre-existing condition (diagnosis/procedure/drug dispensing).

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

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

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

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

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

Washout Period - Number of days a patient is required to have no evidence of prior diagnosis and continuous medical coverage.

*all terms may not be used in this report

Table 1. Summary of Kidney Stone Codes in the MSDD between January 1, 2004 and December 31, 2012, by Pre-Existing Condition Criteria

Group	Prevalent						Incident						
	Patients	Number of Claims	Eligible Members	Member-Years	Patients per 1K Eligible Members	Patients per 1K Member-Years	New Patients	New Claims	Number of Total Claims	Eligible Members	Member-Years	New Patients per 1K Eligible Members	New Patients per 1K Member-Years
No Pre-Existing Condition Requirement	2,031,642	9,700,196	104,030,894	255,935,814	19.53	7.94	1,623,105	2,110,108	7,474,764	87,130,439	205,115,496	18.63	7.91
Pre-Existing Condition of Anti-Diabetic Agent Use	220,999	1,169,467	5,319,273	11,051,344	41.55	20.00	183,356	235,528	916,007	4,969,884	9,661,341	36.89	18.98

Figure 1. Number of Prevalent and Incident Kidney Stone Patients per 1,000 Eligible Members in the MSDD between January 1, 2004 and December 31, 2012 by Pre-Existing Condition Criteria

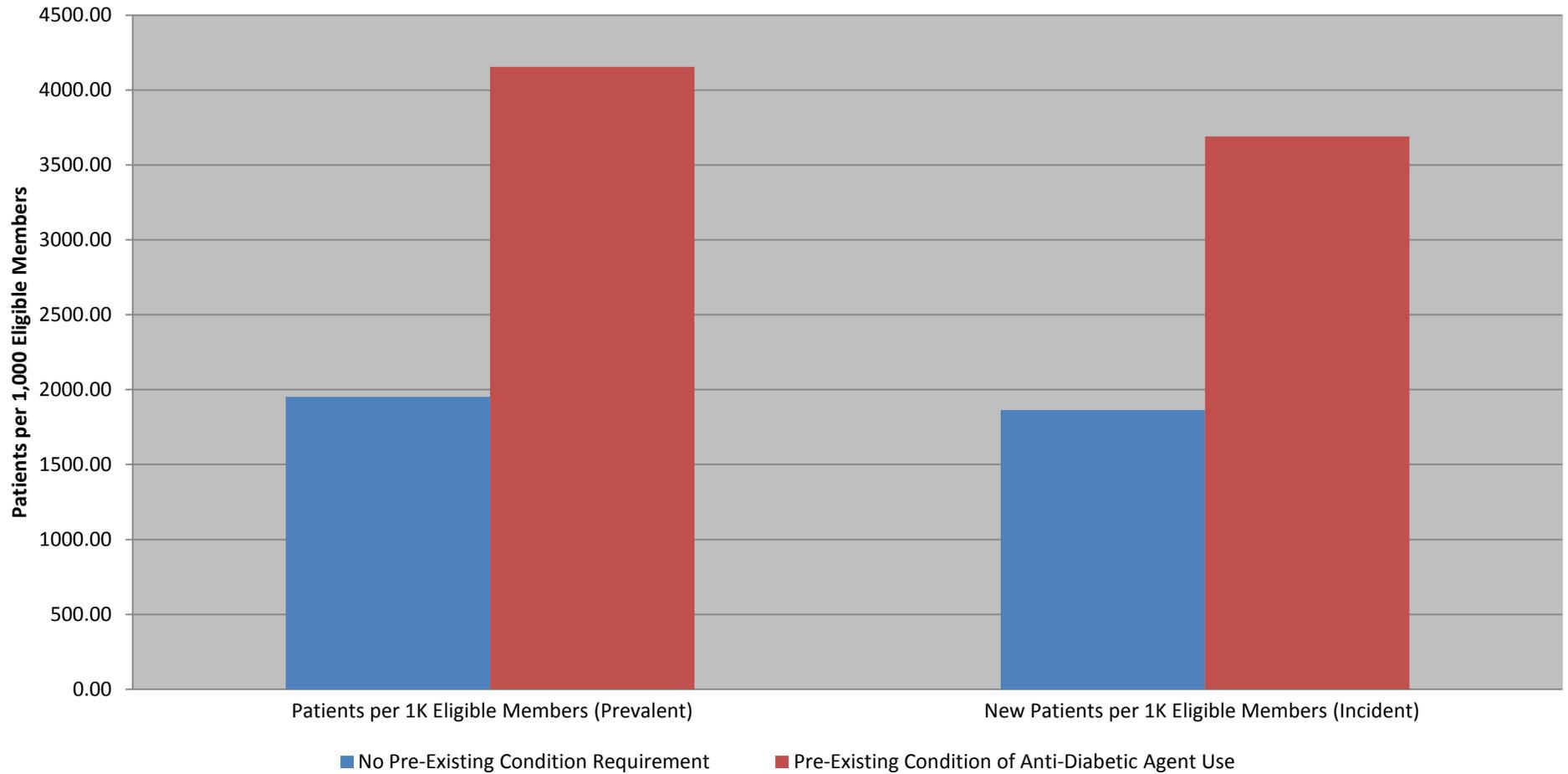


Table 2. Summary of Kidney Stone Codes in the MSDD between January 1, 2004 and December 31, 2012, by Pre-Existing Condition Criteria and Age Group

Group	Prevalent						Incident						
	Patients	Number of Claims	Eligible Members	Member-Years	Patients per 1K Eligible Members	Patients per 1K Member-Years	New Patients	New Claims	Number of Total Claims	Eligible Members	Member-Years	New Patients per 1K Eligible Members	New Patients per 1K Member-Years
<i>No Pre-Existing Condition</i>													
0 to 9 years	9,616	25,974	15,629,314	31,738,034	0.62	0.30	6,685	7,349	17,832	12,342,384	24,395,713	0.54	0.27
10 to 16 years	22,327	82,750	12,282,322	24,499,321	1.82	0.91	17,509	19,868	63,206	10,400,916	20,069,699	1.68	0.87
17 to 64 years	1,626,202	7,788,005	75,843,972	173,811,356	21.44	9.36	1,277,321	1,628,320	5,914,441	62,991,750	138,224,520	20.28	9.24
65+ years	394,812	1,803,467	8,716,231	25,887,104	45.30	15.25	334,868	454,571	1,464,659	8,116,035	22,425,564	41.26	14.93
<i>Pre-Existing Condition of Anti-Diabetic Agent Use</i>													
0 to 9 years	21	80	20,343	29,289	1.03	0.72	14	16	58	18,205	25,357	0.77	0.55
10 to 16 years	249	911	68,003	101,876	3.66	2.44	195	213	657	62,462	89,717	3.12	2.17
17 to 64 years	142,898	782,791	3,869,147	7,096,997	36.93	20.13	116,192	146,009	601,483	3,567,291	6,147,580	32.57	18.90
65+ years	81,387	385,685	1,641,181	3,823,182	49.59	21.29	68,911	89,290	309,502	1,560,820	3,398,687	44.15	20.28

Table 3. Summary of Kidney Stone Codes in the MSDD between January 1, 2004 and December 31, 2012, by Pre-Existing Condition Criteria and Sex

Group	Prevalent						Incident						
	Patients	Number of Claims	Eligible Members	Member-Years	Patients per 1K Eligible Members	Patients per 1K Member-Years	New Patients	New Claims	Number of Total Claims	Eligible Members	Member-Years	New Patients per 1K Eligible Members	New Patients per 1K Member-Years
<i>No Pre-Existing Condition</i>													
Female	900,833	4,095,334	52,712,423	131,683,176	17.09	6.84	714,658	906,990	3,127,377	44,389,629	106,031,104	16.10	6.74
Male	1,130,750	5,604,642	51,311,997	124,243,292	22.04	9.10	908,403	1,203,070	4,347,223	42,736,871	99,077,576	21.26	9.17
Unknown	59	220	6,474	9,346	9.11	6.31	44	48	164	3,939	6,816	11.17	6.46
<i>Pre-Existing Condition of Anti-Diabetic Agent Use</i>													
Female	88,830	464,352	2,706,401	5,456,266	32.82	16.28	73,415	91,860	361,039	2,536,530	4,794,925	28.94	15.31
Male	132,159	705,074	2,612,720	5,594,814	50.58	23.62	109,935	143,660	554,943	2,433,223	4,866,194	45.18	22.59
Unknown	10	41	152	263	65.79	38.02	6	8	25	131	222	45.80	27.03

Table 4. Summary of Kidney Stone Codes in the MSDD between January 1, 2004 and December 31, 2012, by Pre-Existing Condition Criteria and Year

Group	Prevalent						Incident						
	Patients	Number of Claims	Eligible Members	Member-Years	Patients per 1K Eligible Members	Patients per 1K Member-Years	New Patients	New Claims	Number of Total Claims	Eligible Members	Member-Years	New Patients per 1K Eligible Members	New Patients per 1K Member-Years
<i>No Pre-Existing Condition</i>													
2004	56,361	177,992	9,292,584	7,972,278	6.07	7.07	44,205	45,131	126,449	8,500,160	6,920,716	5.20	6.39
2005	60,894	188,867	9,614,091	8,209,325	6.33	7.42	49,252	50,369	142,420	8,763,003	7,296,583	5.62	6.75
2006	177,565	591,789	23,130,372	19,040,069	7.68	9.33	97,847	98,952	278,896	19,386,494	11,944,916	5.05	8.19
2007	214,061	708,827	26,459,889	20,827,386	8.09	10.28	151,472	155,057	466,872	23,118,672	16,900,914	6.55	8.96
2008	463,181	1,597,058	53,526,416	42,949,263	8.65	10.78	280,787	285,434	865,478	44,322,251	28,001,442	6.34	10.03
2009	474,684	1,653,640	51,853,790	42,278,953	9.15	11.23	370,079	378,927	1,211,136	46,242,790	36,045,750	8.00	10.27
2010	474,581	1,668,027	50,009,658	40,839,829	9.49	11.62	370,426	379,476	1,227,370	44,491,358	34,848,492	8.33	10.63
2011	479,818	1,677,326	48,712,336	40,062,561	9.85	11.98	374,829	384,255	1,234,122	43,355,226	34,302,985	8.65	10.93
2012	424,845	1,436,670	45,752,524	33,756,151	9.29	12.59	325,934	332,507	1,032,074	40,406,981	28,853,699	8.07	11.30
<i>Pre-Existing Condition of Anti-Diabetic Agent Use</i>													
2004	6,471	20,760	453,561	364,434	14.27	17.76	5,221	5,346	14,890	440,010	339,383	11.87	15.38
2005	7,336	23,459	486,620	388,291	15.08	18.89	5,972	6,110	17,277	473,240	369,286	12.62	16.17
2006	15,898	54,868	919,668	682,421	17.29	23.30	9,597	9,719	28,037	851,228	500,947	11.27	19.16
2007	22,386	76,982	1,239,688	870,463	18.06	25.72	14,794	15,142	46,934	1,170,921	721,094	12.63	20.52
2008	46,801	167,599	2,304,423	1,689,853	20.31	27.70	30,105	30,653	95,467	2,123,881	1,294,252	14.17	23.26
2009	52,481	191,584	2,423,851	1,800,019	21.65	29.16	39,553	40,519	132,690	2,320,419	1,643,784	17.05	24.06
2010	56,099	209,793	2,440,535	1,819,682	22.99	30.83	41,633	42,647	143,469	2,337,295	1,658,521	17.81	25.10
2011	59,335	223,109	2,451,133	1,838,134	24.21	32.28	43,888	44,976	152,263	2,344,035	1,681,126	18.72	26.11
2012	55,613	201,313	2,378,582	1,598,047	23.38	34.80	39,633	40,416	130,576	2,263,303	1,452,948	17.51	27.28

Appendix A. List of Kidney Stone Codes included in this Request

ICD-9-CM Diagnosis Codes

592.0	Calculus of kidney
592.1	Calculus of ureter
592.9	Urinary calculus, unspecified
274.11	Uric acid nephrolithiasis
594	Calculus of lower urinary tract

ICD-9-CM Procedure Codes

55.04	Percutaneous Nephrostomy With Fragmentation
55.92	Percutaneous aspiration of kidney (pelvis)
56.2	Ureterotomy
59.8	Ureteral Catheterization
59.95	Ultrasonic Fragmentation Of Urinary Stones
98.51	Extracorporeal shockwave lithotripsy of the kidney, ureter and/or bladder
55.04	Percutaneous Nephrostomy With Fragmentation
98.51	Extracorporeal shockwave lithotripsy of the kidney, ureter and/or bladder
59.95	Ultrasonic Fragmentation Of Urinary Stones

HCPCS

50060	Removal of Kidney Stone
50065	Incision of Kidney
50070	Incision of Kidney
50075	Removal of Kidney Stone
50080	Removal of Kidney Stone
50081	Removal of Kidney Stone
50130	Removal of Kidney Stone
50590	Fragmenting of Kidney Stone
50610	Removal of Ureter Stone
50620	Removal of Ureter Stone
50630	Removal of Ureter Stone
52320	Cystoscopy and Treatment
52325	Cystoscopy Stone Removal
52330	Cystoscopy and Treatment
52336	Cystourethroscopy with Ureteroscopy; with Remove Calculus
52337	Cystourethroscopy with Ureteroscopy; with Lith
50945	Laparoscopy Ureterolithotomy
50561	Kidney Endoscopy and Treatment
50580	Kidney Endoscopy and Treatment
51060	Removal of Ureter Stone
51065	Remove Ureter Calculus
50080	Removal of Kidney Stone
50081	Removal of Kidney Stone
50060	Removal of Kidney Stone
50070	Incision of Kidney
50075	Removal of Kidney Stone
50610	Removal of Ureter Stone
50620	Removal of Ureter Stone
50630	Removal of Ureter Stone
50590	Fragmenting of Kidney Stone
52320	Cystoscopy and Treatment
52325	Cystoscopy Stone Removal
52352	Cystouretero with Stone Remove
52353	Cystouretero with Lithotripsy