

## **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 <u>not</u> 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	
Request	Mini-Sentinel's Clinical Data Elements Workgroup has requested execution of Modular Program # 6 (MP6), version
<u>Description</u>	4.0, to investigate the frequency of a Creatinine, Fasting Glucose, Random Glucose, and HgbA1c laboratory result that occur within 1 year of incident and prevalent diagnosis of diabetes (ICD-9 250) in both pediatric and adult members. The query was run against the Mini-Sentinel Distributed Database (MSDD) for the time period of January 1, 2006 - December 31, 2010. This request was distributed to 12 Data Partners on April 23, 2013. This report includes data from 11 Data Partners.
	Results in this report provide counts of eligible members with at least 1 diabetes diagnosis, stratified by number of results available in the MSDD for each laboratory test type. Diabetes diagnoses were considered new if the member did not have a diabetes diagnosis in the prior 183 or 365 days, depending on the specified washout period. Diabetes diagnoses did not require a principal diagnosis flag and could be found in any care setting. Laboratory results were prevalent and, thus, did not have incidence requirements.
Request ID	to04mp_clinvalidation2_v1
<b>Specifications</b>	Program parameter inputs and scenarios.
Glossary	List of terms found in this report and their definitions.
<u>Table 1a</u>	Table displaying the number of incident eligible members, member-days, and members with at least 1 diabetes diagnosis (183-day washout period) and subsequent laboratory results by laboratory test - January 1, 2006 to December 31, 2010.
Figure 1a	Two figures displaying the information in the prior tab.
<u>Table 1b</u>	Table displaying the number of incident eligible members, member-days, and members with at least 1 diabetes diagnosis (365-day washout period) and subsequent laboratory results by laboratory test - January 1, 2006 to December 31, 2010.
Figure 1b	Two figures displaying the information in the prior tab.
Table 1c	Table displaying the number of prevalent eligible members, member-days, and members with at least 1 diabetes diagnosis and subsequent laboratory results by laboratory test - January 1, 2006 to December 31, 2010.
Figure 1c	Two figures displaying the information in the prior tab.
<u>Table 2a</u>	Table displaying the number of incident eligible members, member-days, and members with at least 1 diabetes diagnosis (183-day washout period) and subsequent laboratory results by laboratory test and age group - January 1, 2006 to December 31, 2010.
<u>Table 2b</u>	Table displaying the number of incident eligible members, member-days, and members with at least 1 diabetes diagnosis (365-day washout period) and subsequent laboratory results by laboratory test and age group - January 1, 2006 to December 31, 2010.
<u>Table 2c</u>	Table displaying the number of prevalent eligible members, member-days, and members with at least 1 diabetes diagnosis and subsequent laboratory results by laboratory test and age group - January 1, 2006 to December 31, 2010.
<u>Table 3a</u>	Table displaying the number of incident eligible members, member-days, and members with at least 1 diabetes diagnosis (183-day washout period) and subsequent laboratory results by laboratory test and sex - January 1, 2006 to December 31, 2010.
<u>Table 3b</u>	Table displaying the number of incident eligible members, member-days, and members with at least 1 diabetes diagnosis (365-day washout period) and subsequent laboratory results by laboratory test and sex - January 1, 2006 to December 31, 2010.
<u>Table 3c</u>	Table displaying the number of prevalent eligible members, member-days, and members with at least 1 diabetes diagnosis and subsequent laboratory results by laboratory test and sex - January 1, 2006 to December 31, 2010.



Overview (continued)	
Table 4a	Table displaying the number of incident eligible members, member-days, and members with at least 1 diabetes diagnosis (183-day washout period) and subsequent laboratory results by laboratory test and year - January 1, 2006 to December 31, 2010.
<u>Table 4b</u>	Table displaying the number of incident eligible members, member-days, and members with at least 1 diabetes diagnosis (365-day washout period) and subsequent laboratory results by laboratory test and year - January 1, 2006 to December 31, 2010.
<u>Table 4c</u>	Table displaying the number of prevalent eligible members, member-days, and members with at least 1 diabetes diagnosis and subsequent laboratory results by laboratory test and year - January 1, 2006 to December 31, 2010.
<u>Table 5a</u>	Table displaying the number of incident eligible members, member-days, and members with at least 1 diabetes diagnosis (183-day washout period) and subsequent laboratory results by laboratory test and Data Partner type-January 1, 2006 to December 31, 2010.
<u>Table 5b</u>	Table displaying the number of incident eligible members, member-days, and members with at least 1 diabetes diagnosis (365-day washout period) and subsequent laboratory results by laboratory test and Data Partner type - January 1, 2006 to December 31, 2010.
<u>Table 5c</u>	Table displaying the number of prevalent eligible members, member-days, and members with at least 1 diabetes diagnosis and subsequent laboratory results by laboratory test and Data Partner type - January 1, 2006 to December 31, 2010.
<u>Figure 5</u>	Three figures displaying the information in the prior three tabs.
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.



## Modular Program Specifications: to04\_clinvalidation2\_v1

Modular Program #6, version 4.0, was used to investigate the presence of a HgbA1c, Glucose, or Creatinine laboratory result that occurs within 1 year of incident and prevalent diagnosis of diabetes (ICD-9 250). The query period was from January 1, 2006 to December 31, 2010, and the enrollment gap was set at 45 days. Age groups were split as follows: 0 - 24, 25 - 34, 35 - 44, 45 - 54, 55 - 64, 65 - 74, 75 - 84, and 85+. In total, 8 different scenarios were examined in this report.

	Index Event										Post-Event T	reatment		
Scenario	Event of Interest	Incident w/	Washout (days)	Incidence Type*	Lookup Period Duration	Min Lookup Duration	Principal Dx	Care Setting	Lab Test Name	Lab Test Subcategory	Washout (days)	Incidence Type**	Lab Frequency Categories	Episode Gap
1	Diabetes	Diabetes	183	Multiple	365	0	No	Any	Creatinine	N/A	0	Multiple	0, 1, 2-3, ≥4	0
2	Diabetes	Diabetes	365	Multiple	365	0	No	Any	Creatinine	N/A	0	Multiple	0, 1, 2-3, ≥4	0
3	Diabetes	Diabetes	183	Multiple	365	0	No	Any	Glucose	Fasting	0	Multiple	0, 1, 2-3, ≥4	0
4	Diabetes	Diabetes	365	Multiple	365	0	No	Any	Glucose	Fasting	0	Multiple	0, 1, 2-3, ≥4	0
5	Diabetes	Diabetes	183	Multiple	365	0	No	Any	Glucose	Random†	0	Multiple	0, 1, 2-3, ≥4	0
6	Diabetes	Diabetes	365	Multiple	365	0	No	Any	Glucose	Random†	0	Multiple	0, 1, 2-3, ≥4	0
7	Diabetes	Diabetes	183	Multiple	365	0	No	Any	HgbA1c	N/A	0	Multiple	0, 1, 2-3, ≥4	0
8	Diabetes	Diabetes	365	Multiple	365	0	No	Any	HgbA1c	N/A	0	Multiple	0, 1, 2-3, ≥4	0

NDC codes checked against First Data Bank's "National Drug Data File (NDDF®) Plus"

ICD-9-CM diagnosis and procedure codes checked against "Ingenix 2012 ICD-9-CM Data File" provided by OptumInsight

HCPCS codes checked against "Optum 2012 HCPCS Level II Data File" provided by OptumInsight

CPT codes checked against "Optum 2012 Current Procedure Codes & Relative Values Data File" provided by OptumInsight

<sup>\*</sup>A "multiple" incidence type for the index event will consider all lookup periods for a user during the query period that satisfies the washout period. A user may have more than one lookup period.

<sup>\*\*</sup>A "multiple" incidence type for the post-event treatment will consider all events for every lookup period that satisfies the Washout Period criteria.

<sup>†</sup>Random lab test subcategory includes all glucose test not labeled "fasting"



## **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).

**Eligible Members** - Number of members eligible for an incident exposure/lookup period (defined by the exposure and event washout periods) with drug and 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 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 (event/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.

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

**Member-Days** - 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 a incidence, pre-existing condition, and enrollment requirements).

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

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

<sup>\*</sup>all terms may not be used in this report



17,608,700,000

639,950 (47.2%)

267,846 (19.7%)

287,297 (21.2%)

161,100 (11.9%)

1,356,193 (100%)

Table 1a. Summary of incident diabetes diagnoses (183-day washout January 1, 2006 and December 31, 2010 by laboratory test	period) and subsequent lab results in the MSDD between
Creatinine	
Eligible members*	27,096,872
Member-days**	17,608,000,000
Members with at least 1 diabetes diagnosis:	1,356,193 (100%)
with no Creatinine results	556,362 (41.0%)
with 1 Creatinine result	269,356 (19.9%)
with 2-3 Creatinine results	289,721 (21.4%)
with ≥4 Creatinine results	240,754 (17.8%)
Fasting Glucose	
Eligible members*	27,121,676
Member-days**	17,611,300,000
Members with at least 1 diabetes diagnosis:	1,356,193 (100%)
with no Fasting Glucose results	1,021,010 (75.3%)
with 1 Fasting Glucose result	145,792 (10.8%)
with 2-3 Fasting Glucose results	131,326 (9.7%)
with ≥4 Fasting Glucose results	58,065 (4.3%)
Random Glucose	
Eligible members*	27,104,120
Member-days**	17,608,700,000
Members with at least 1 diabetes diagnosis:	1,356,193 (100%)
with no Random Glucose results	754,204 (55.6%)
with 1 Random Glucose result	267,687 (19.7%)
with 2-3 Random Glucose results	206,844 (15.3%)
with ≥4 Random Glucose results	127,458 (9.4%)
HgbA1c	
Eligible members*	27,104,120

Member-days\*\*

Members with at least 1 diabetes diagnosis:

with no HgbA1c results

with 2-3 HgbA1c results

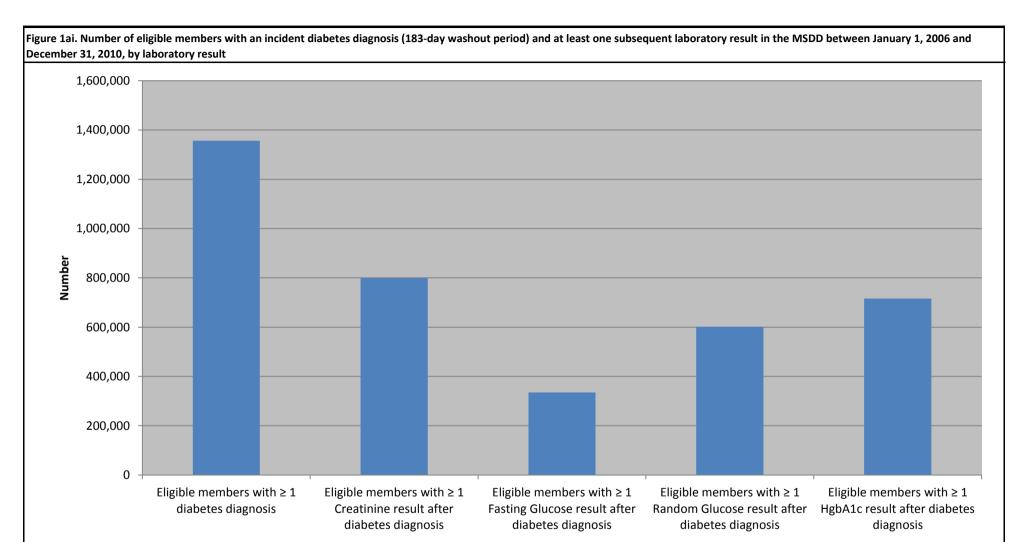
with ≥4 HgbA1c results

with 1 HgbA1c result

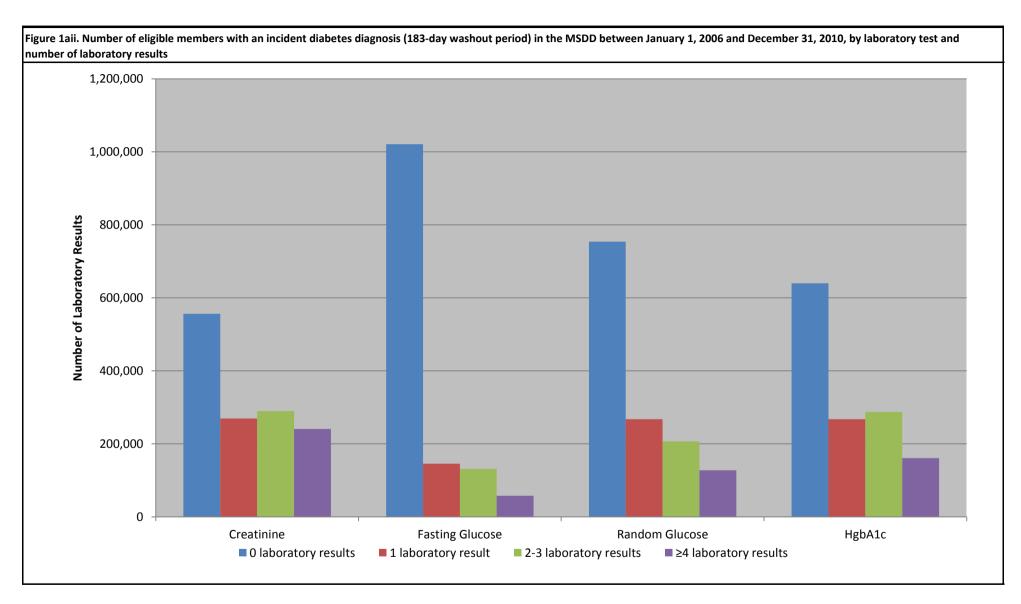
<sup>\*</sup>Number of members eligible for an incident treatment episode (defined by the drug/exposure and event washout periods) with drug and medical coverage during the query period.

<sup>\*\*</sup>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 a incidence, pre-existing condition, and enrollment requirements).











January 1, 2006 and December 31, 2010 by laboratory test	
Creatinine	
Eligible members*	20,862,569
Member-days**	13,821,800,000
Members with at least 1 diabetes diagnosis:	808,792 (100%)
with no Creatinine results	329,281 (40.7%)
with 1 Creatinine result	190,548 (23.6%)
with 2-3 Creatinine results	184,917 (22.9%)
with ≥4 Creatinine results	104,046 (12.9%)
Fasting Glucose	
Eligible members*	20,976,511
Member-days**	13,825,400,000
Members with at least 1 diabetes diagnosis:	808,792 (100%)
with no Fasting Glucose results	600,064 (74.2%)
with 1 Fasting Glucose result	109,774 (13.6%)
with 2-3 Fasting Glucose results	81,162 (10.0%)
with ≥4 Fasting Glucose results	17,792 (2.2%)
Random Glucose	
Eligible members*	20,871,338
Member-days**	13,822,500,000
Members with at least 1 diabetes diagnosis:	808,792 (100%)
with no Random Glucose results	474,369 (58.7%)
with 1 Random Glucose result	162,360 (20.1%)
with 2-3 Random Glucose results	110,032 (13.6%)
with ≥4 Random Glucose results	62,031 (7.7%)
HgbA1c	
Eligible members*	20,983,568
Member-days**	13,825,900,000
Members with at least 1 diabetes diagnosis:	808,792 (100%)
with no HgbA1c results	384,841 (47.6%)
with 1 HgbA1c result	191,501 (23.7%)
with 2-3 HgbA1c results	185,615 (22.9%)

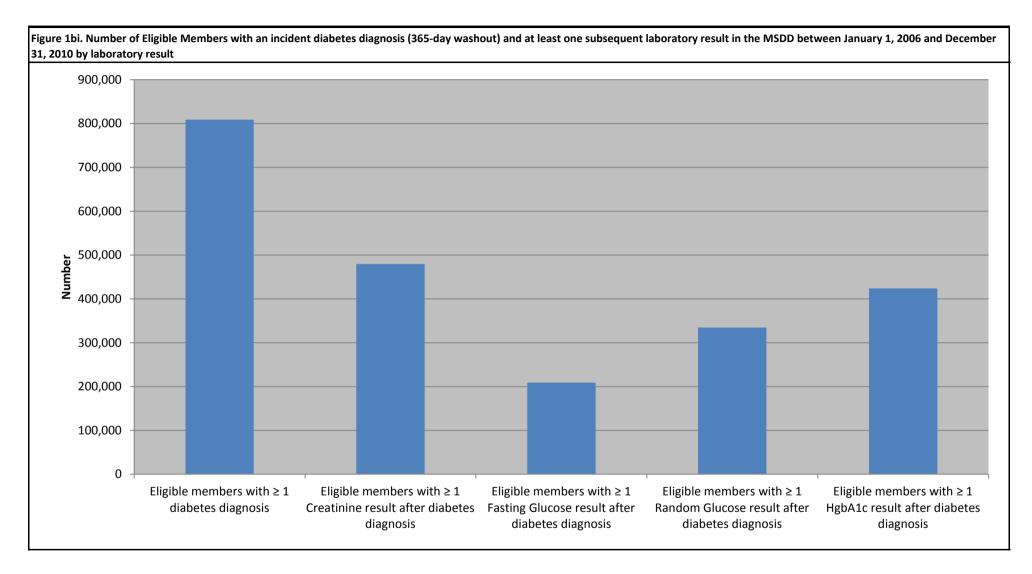
<sup>\*</sup>Number of members eligible for an incident treatment episode (defined by the drug/exposure and event washout periods) with drug and medical coverage during the query period.

46,835 (5.8%)

with ≥4 HgbA1c results

<sup>\*\*</sup>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 a incidence, pre-existing condition, and enrollment requirements).







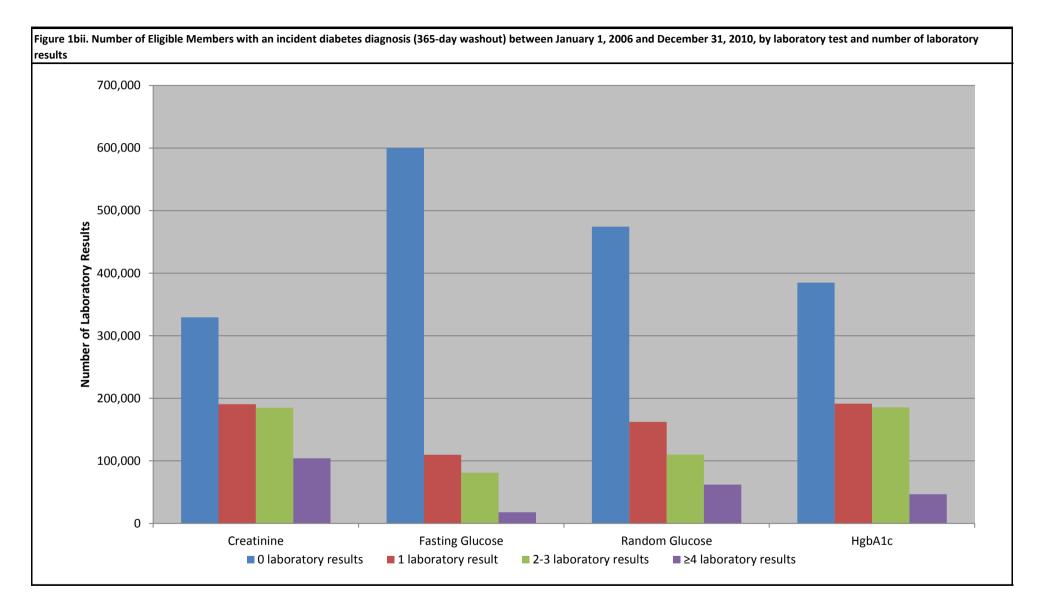


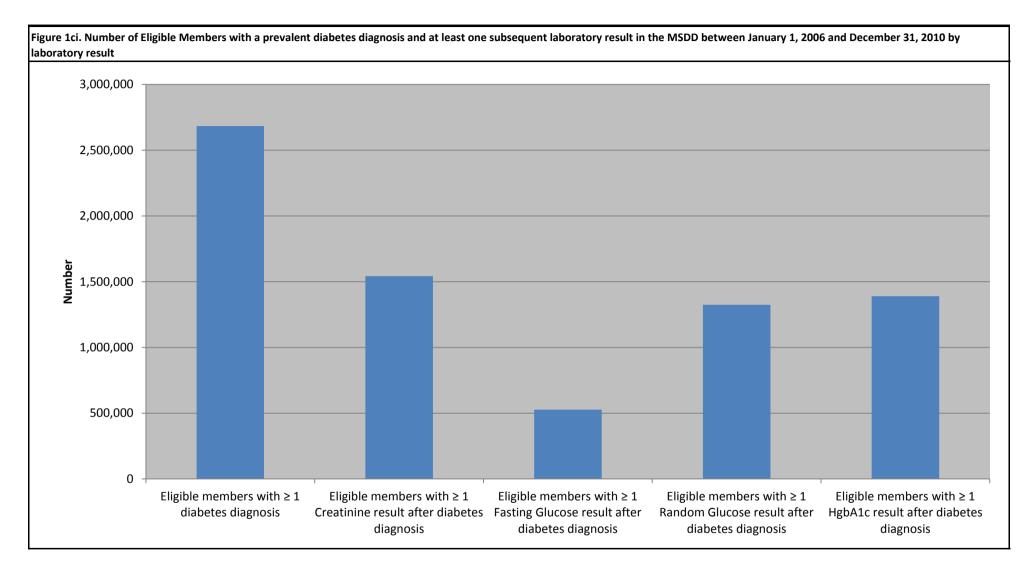


Table 1c. Summary of prevalent diabetes diagnoses and subsequent la December 31, 2010 by laboratory test	b results in the MSDD between January 1, 2006 and
Creatinine	
Eligible members*	33,640,579
Member-days**	24,158,200,000
Members with at least 1 diabetes diagnosis:	2,683,086 (100%)
with no Creatinine results	1,141,168 (42.5%)
with 1 Creatinine result	405,820 (15.1%)
with 2-3 Creatinine results	434,720 (16.2%)
with ≥4 Creatinine results	701,378 (26.1%)
Fasting Glucose	
Eligible members*	33,640,579
Member-days**	24,161,000,000
Members with at least 1 diabetes diagnosis:	2,683,086 (100%)
with no Fasting Glucose results	2,156,606 (80.4%)
with 1 Fasting Glucose result	184,918 (6.9%)
with 2-3 Fasting Glucose results	166,202 (6.2%)
with ≥4 Fasting Glucose results	175,360 (6.5%)
Random Glucose	
Eligible members*	33,640,579
Member-days**	24,158,700,000
Members with at least 1 diabetes diagnosis:	2,683,086 (100%)
with no Random Glucose results	1,359,166 (50.7%)
with 1 Random Glucose result	428,270 (16.0%)
with 2-3 Random Glucose results	404,547 (15.1%)
with ≥4 Random Glucose results	491,103 (18.3%)
HgbA1c	
Eligible members*	33,640,579
Member-days**	24,161,000,000
Members with at least 1 diabetes diagnosis:	2,683,086 (100%)
with no HgbA1c results	1,293,531 (48.2%)
with 1 HgbA1c result	398,860 (14.9%)
with 2-3 HgbA1c results	405,003 (15.1%)
with ≥4 HgbA1c results	585,692 (21.8%)

<sup>\*</sup>Number of members eligible for an incident treatment episode (defined by the drug/exposure and event washout periods) with drug and medical coverage during the query period.

<sup>\*\*</sup>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 a incidence, pre-existing condition, and enrollment requirements).







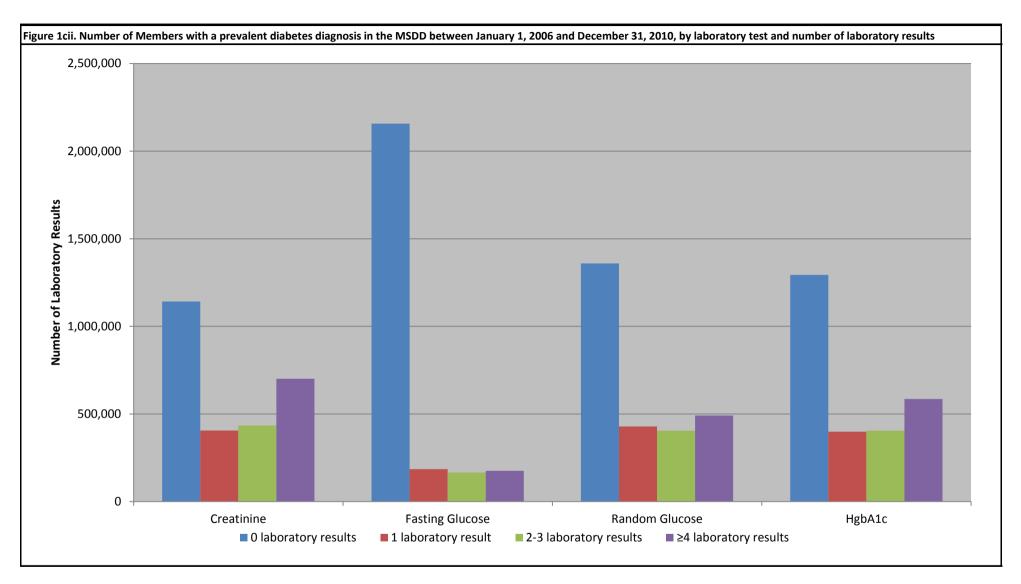




Table 2a. Summary of incident diabetes diagnoses (183-day washout period) and subsequent lab results in the MSDD between January 1, 2006 and December 31, 2010 by laboratory test and age group

and age group				Age (	Group			
	2-24 years	25-34 years	35-44 years	45-54 years	55-64 years	65-74 years	75-84 years	85+ years
	Number (%)	Number (%)	Number (%)	Number (%)	Number (%)	Number (%)	Number (%)	Number (%)
Creatinine								
Eligible members*	9,122,854	4,766,714	4,848,914	4,861,306	3,415,699	2,037,930	1,052,811	390,818
Member-days**	5,520,153,336	2,279,686,086	2,667,318,526	2,844,501,755	2,090,109,365	1,257,505,078	696,597,588	252,099,837
Members with ≥ 1 diabetes diagnosis:	25,803 (100%)	54,748 (100%)	145,645 (100%)	292,976 (100%)	360,704 (100%)	311,516 (100%)	179,028 (100%)	56,104 (100%)
with no Creatinine results	15,280 (59.2%)	27,054 (49.4%)	62,418 (42.9%)	116,013 (39.6%)	135,122 (37.5%)	127,933 (41.1%)	70,238 (39.2%)	24,847 (44.3%)
with 1 Creatinine result	6,444 (25.0%)	15,185 (27.7%)	38,408 (26.4%)	70,586 (24.1%)	78,508 (21.8%)	54,927 (17.6%)	27,608 (15.4%)	8,277 (14.8%)
with 2-3 Creatinine results	2,810 (10.9%)	8,964 (16.4%)	30,865 (21.2%)	68,394 (23.3%)	86,724 (24.0%)	69,709 (22.4%)	38,444 (21.5%)	10,310 (18.4%)
with ≥4 Creatinine results	1,269 (4.9%)	3,545 (6.5%)	13,954 (9.6%)	37,983 (13.0%)	60,350 (16.7%)	58,947 (18.9%)	42,738 (23.9%)	12,670 (22.6%)
Fasting Glucose								
Eligible members*	9,125,967	4,771,286	4,853,614	4,866,885	3,420,073	2,040,580	1,053,265	391,019
Member-days**	5,520,370,469	2,279,950,991	2,667,700,852	2,845,048,707	2,090,668,580	1,258,045,669	697,098,278	252,395,526
Members with ≥ 1 diabetes diagnosis:	25,803 (100%)	54,748 (100%)	145,645 (100%)	292,976 (100%)	360,704 (100%)	311,516 (100%)	179,028 (100%)	56,104 (100%)
with no Fasting Glucose results	22,179 (86.0%)	43,601 (79.6%)	110,216 (75.7%)	214,436 (73.2%)	256,431 (71.1%)	237,093 (76.1%)	137,569 (76.8%)	47,019 (83.8%)
with 1 Fasting Glucose result	2,690 (10.4%)	7,134 (13.0%)	19,251 (13.2%)	38,008 (13.0%)	46,679 (12.9%)	30,905 (9.9%)	17,591 (9.8%)	4,565 (8.1%)
with 2-3 Fasting Glucose results	809 (3.1%)	3,334 (6.1%)	12,652 (8.7%)	30,636 (10.5%)	41,785 (11.6%)	30,579 (9.8%)	16,821 (9.4%)	3,398 (6.1%)
with ≥4 Fasting Glucose results	125 (0.5%)	679 (1.2%)	3,526 (2.4%)	9,896 (3.4%)	15,809 (4.4%)	12,939 (4.2%)	7,047 (3.9%)	1,122 (2.0%)
Random Glucose								
Eligible members*	9,123,310	4,767,976	4,850,542	4,863,196	3,417,329	2,038,627	1,052,941	390,859
Member-days**	5,520,180,403	2,279,765,245	2,667,426,666	2,844,641,020	2,090,241,901	1,257,599,845	696,676,975	252,145,489
Members with ≥ 1 diabetes diagnosis:	25,803 (100%)	54,748 (100%)	145,645 (100%)	292,976 (100%)	360,704 (100%)	311,516 (100%)	179,028 (100%)	56,104 (100%)
with no Random Glucose results	16,567 (64.2%)	33,007 (60.3%)	84,458 (58.0%)	167,972 (57.3%)	205,983 (57.1%)	178,243 (57.2%)	93,906 (52.5%)	29,409 (52.4%)
with 1 Random Glucose result	6,014 (23.3%)	13,626 (24.9%)	34,590 (23.7%)	63,828 (21.8%)	72,672 (20.1%)	53,027 (17.0%)	28,189 (15.7%)	8,368 (14.9%)
with 2-3 Random Glucose results	2,173 (8.4%)	6,111 (11.2%)	19,385 (13.3%)	42,731 (14.6%)	53,598 (14.9%)	48,431 (15.5%)	29,621 (16.5%)	8,792 (15.7%)
with ≥4 Random Glucose results	1,049 (4.1%)	2,004 (3.7%)	7,212 (5.0%)	18,445 (6.3%)	28,451 (7.9%)	31,815 (10.2%)	27,312 (15.3%)	9,535 (17.0%)



Table 2a. Summary of incident diabetes diagnoses (183-day washout period) and subsequent lab results in the MSDD between January 1, 2006 and December 31, 2010 by laboratory test and age group

	Age Group									
	2-24 years	25-34 years	35-44 years	45-54 years	55-64 years	65-74 years	75-84 years	85+ years		
	Number (%)	Number (%)	Number (%)	Number (%)	Number (%)	Number (%)	Number (%)	Number (%)		
HgbA1c										
Eligible members*	9,126,425	4,772,660	4,855,011	4,868,086	3,420,986	2,040,720	1,053,304	391,018		
Member-days**	5,520,415,615	2,280,043,761	2,667,798,020	2,845,143,204	2,090,733,767	1,258,062,354	697,106,768	252,400,291		
Members with ≥ 1 diabetes diagnosis:	25,803 (100%)	54,748 (100%)	145,645 (100%)	292,976 (100%)	360,704 (100%)	311,516 (100%)	179,028 (100%)	56,104 (100%)		
with no HgbA1c results	16,879 (65.4%)	30,367 (55.5%)	68,944 (47.3%)	127,318 (43.5%)	150,056 (41.6%)	148,257 (47.6%)	88,318 (49.3%)	32,819 (58.5%)		
with 1 HgbA1c result	5,253 (20.4%)	13,523 (24.7%)	35,824 (24.6%)	67,857 (23.2%)	77,757 (21.6%)	56,979 (18.3%)	32,285 (18.0%)	10,145 (18.1%)		
with 2-3 HgbA1c results	2,630 (10.2%)	8,253 (15.1%)	29,980 (20.6%)	68,534 (23.4%)	89,372 (24.8%)	70,720 (22.7%)	39,969 (22.3%)	9,751 (17.4%)		
with ≥4 HgbA1c results	1,041 (4.0%)	2,605 (4.8%)	10,897 (7.5%)	29,267 (10.0%)	43,519 (12.1%)	35,560 (11.4%)	18,456 (10.3%)	3,389 (6.0%)		

<sup>\*</sup>Number of members eligible for an incident treatment episode (defined by the drug/exposure and event washout periods) with drug and medical coverage during the query period.

<sup>\*\*</sup>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 a incidence, pre-existing condition, and enrollment requirements).



Table 2b. Summary of incident diabetes diagnoses (365-day washout period) and subsequent lab results in the MSDD between January 1, 2006 and December 31, 2010 by laboratory test and age group

and age group				Age (	Group			
	2-24 years	25-34 years	35-44 years	45-54 years	55-64 years	65-74 years	75-84 years	85+ years
	Number (%)	Number (%)	Number (%)	Number (%)	Number (%)	Number (%)	Number (%)	Number (%)
Creatinine								
Eligible members*	6,850,775	3,460,734	3,743,633	3,856,989	2,765,697	1,614,950	881,301	339,461
Member-days**	4,225,019,103	1,669,040,464	2,077,076,684	2,281,921,080	1,731,835,390	1,026,269,771	592,971,078	217,678,152
Members with ≥ 1 diabetes diagnosis:	15,836 (100%)	32,743 (100%)	88,786 (100%)	175,483 (100%)	209,040 (100%)	170,006 (100%)	102,715 (100%)	34,189 (100%)
with no Creatinine results	9,274 (58.6%)	15,961 (48.7%)	37,643 (42.4%)	69,181 (39.4%)	78,228 (37.4%)	69,768 (41.0%)	41,079 (40.0%)	15,577 (45.6%)
with 1 Creatinine result	4,130 (26.1%)	9,697 (29.6%)	26,028 (29.3%)	48,042 (27.4%)	53,331 (25.5%)	35,602 (20.9%)	18,642 (18.1%)	5,623 (16.4%)
with 2-3 Creatinine results	1,698 (10.7%)	5,341 (16.3%)	18,769 (21.1%)	41,468 (23.6%)	51,900 (24.8%)	40,508 (23.8%)	23,534 (22.9%)	6,495 (19.0%)
with ≥4 Creatinine results	734 (4.6%)	1,744 (5.3%)	6,346 (7.1%)	16,792 (9.6%)	25,581 (12.2%)	24,128 (14.2%)	19,460 (18.9%)	6,494 (19.0%)
Fasting Glucose								
Eligible members*	6,861,752	3,475,609	3,768,501	3,887,476	2,788,029	1,622,324	883,766	340,288
Member-days**	4,225,267,702	1,669,338,100	2,077,518,758	2,282,546,783	1,732,447,926	1,026,816,758	593,476,011	217,975,696
Members with ≥ 1 diabetes diagnosis:	15,836 (100%)	32,743 (100%)	88,786 (100%)	175,483 (100%)	209,040 (100%)	170,006 (100%)	102,715 (100%)	34,189 (100%)
with no Fasting Glucose results	13,587 (85.8%)	25,573 (78.1%)	65,439 (73.7%)	125,054 (71.3%)	145,170 (69.4%)	129,131 (76.0%)	80,734 (78.6%)	29,382 (85.9%)
with 1 Fasting Glucose result	1,735 (11.0%)	4,842 (14.8%)	14,000 (15.8%)	27,664 (15.8%)	33,495 (16.0%)	20,636 (12.1%)	11,362 (11.1%)	2,731 (8.0%)
with 2-3 Fasting Glucose results	459 (2.9%)	2,050 (6.3%)	8,068 (9.1%)	19,228 (11.0%)	25,246 (12.1%)	16,636 (9.8%)	8,643 (8.4%)	1,687 (4.9%)
with ≥4 Fasting Glucose results	55 (0.3%)	278 (0.8%)	1,279 (1.4%)	3,537 (2.0%)	5,129 (2.5%)	3,603 (2.1%)	1,976 (1.9%)	389 (1.1%)
Random Glucose								
Eligible members*	6,851,172	3,461,752	3,745,642	3,859,670	2,767,728	1,615,540	881,482	339,496
Member-days**	4,225,044,134	1,669,121,566	2,077,187,866	2,282,063,377	1,731,968,169	1,026,363,177	593,050,597	217,723,646
Members with ≥ 1 diabetes diagnosis:	15,836 (100%)	32,743 (100%)	88,786 (100%)	175,483 (100%)	209,040 (100%)	170,006 (100%)	102,715 (100%)	34,189 (100%)
with no Random Glucose results	10,120 (63.9%)	20,125 (61.5%)	53,761 (60.6%)	106,182 (60.5%)	126,725 (60.6%)	100,613 (59.2%)	55,264 (53.8%)	18,300 (53.5%)
with 1 Random Glucose result	3,740 (23.6%)	8,269 (25.3%)	21,148 (23.8%)	38,184 (21.8%)	42,120 (20.1%)	29,651 (17.4%)	16,930 (16.5%)	5,395 (15.8%)
with 2-3 Random Glucose results	1,296 (8.2%)	3,286 (10.0%)	10,214 (11.5%)	22,153 (12.6%)	26,728 (12.8%)	24,788 (14.6%)	16,757 (16.3%)	5,318 (15.6%)
with ≥4 Random Glucose results	680 (4.3%)	1,063 (3.2%)	3,663 (4.1%)	8,964 (5.1%)	13,467 (6.4%)	14,954 (8.8%)	13,764 (13.4%)	5,176 (15.1%)



Table 2b. Summary of incident diabetes diagnoses (365-day washout period) and subsequent lab results in the MSDD between January 1, 2006 and December 31, 2010 by laboratory test and age group

		Age Group									
	2-24 years	25-34 years	35-44 years	45-54 years	55-64 years	65-74 years	75-84 years	85+ years			
	Number (%)										
HgbA1c											
Eligible members*	6,863,848	3,478,078	3,770,364	3,888,242	2,788,111	1,622,331	883,761	340,264			
Member-days**	4,225,323,527	1,669,450,480	2,077,637,329	2,282,660,037	1,732,523,749	1,026,836,238	593,485,155	217,980,317			
Members with ≥ 1 diabetes diagnosis:	15,836 (100%)	32,743 (100%)	88,786 (100%)	175,483 (100%)	209,040 (100%)	170,006 (100%)	102,715 (100%)	34,189 (100%)			
with no HgbA1c results	10,375 (65.5%)	18,018 (55.0%)	41,514 (46.8%)	75,723 (43.2%)	87,336 (41.8%)	83,531 (49.1%)	54,553 (53.1%)	21,634 (63.3%)			
with 1 HgbA1c result	3,455 (21.8%)	8,761 (26.8%)	24,369 (27.4%)	46,565 (26.5%)	53,299 (25.5%)	37,472 (22.0%)	21,940 (21.4%)	6,715 (19.6%)			
with 2-3 HgbA1c results	1,587 (10.0%)	4,988 (15.2%)	19,035 (21.4%)	43,210 (24.6%)	55,233 (26.4%)	39,934 (23.5%)	21,790 (21.2%)	5,033 (14.7%)			
with ≥4 HgbA1c results	419 (2.6%)	976 (3.0%)	3,868 (4.4%)	9,985 (5.7%)	13,172 (6.3%)	9,069 (5.3%)	4,432 (4.3%)	807 (2.4%)			

<sup>\*</sup>Number of members eligible for an incident treatment episode (defined by the drug/exposure and event washout periods) with drug and medical coverage during the query period.

<sup>\*\*</sup>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 a incidence, pre-existing condition, and enrollment requirements).



Table 2c. Summary of prevalent diabeter	s diagnoses and subs	equent lab results	in the MSDD betw			1, 2010 by laborate	ory test and age gro	oup		
	Age Group									
	2-24 years	25-34 years	35-44 years	45-54 years	55-64 years	65-74 years	75-84 years	85+ years		
	Number (%)	Number (%)	Number (%)	Number (%)	Number (%)	Number (%)	Number (%)	Number (%)		
Creatinine										
Eligible members*	11,570,147	6,122,350	5,955,432	5,899,765	4,387,516	2,668,931	1,374,771	487,388		
Member-days**	7,275,416,649	3,144,279,019	3,540,708,421	3,819,686,240	2,944,002,194	1,990,647,598	1,082,232,589	361,238,879		
Members with ≥ 1 diabetes diagnosis:	54,359 (100%)	105,956 (100%)	272,285 (100%)	556,908 (100%)	736,248 (100%)	726,853 (100%)	403,391 (100%)	117,106 (100%)		
with no Creatinine results	32,734 (60.2%)	52,309 (49.4%)	118,592 (43.6%)	226,008 (40.6%)	289,127 (39.3%)	316,316 (43.5%)	170,601 (42.3%)	53,542 (45.7%)		
with 1 Creatinine result	11,864 (21.8%)	26,084 (24.6%)	61,177 (22.5%)	108,282 (19.4%)	122,602 (16.7%)	91,963 (12.7%)	43,890 (10.9%)	13,203 (11.3%)		
with 2-3 Creatinine results	6,133 (11.3%)	16,979 (16.0%)	52,485 (19.3%)	111,918 (20.1%)	141,537 (19.2%)	117,865 (16.2%)	58,959 (14.6%)	16,139 (13.8%)		
with ≥4 Creatinine results	3,628 (6.7%)	10,584 (10.0%)	40,031 (14.7%)	110,700 (19.9%)	182,982 (24.9%)	200,709 (27.6%)	129,941 (32.2%)	34,222 (29.2%)		
Fasting Glucose										
Eligible members*	11,570,147	6,122,350	5,955,434	5,899,765	4,387,517	2,668,932	1,374,771	487,388		
Member-days**	7,275,496,182	3,144,355,908	3,540,846,731	3,819,984,061	2,944,511,215	1,991,273,344	1,082,935,879	361,611,079		
Members with ≥ 1 diabetes diagnosis:	54,359 (100%)	105,956 (100%)	272,285 (100%)	556,908 (100%)	736,248 (100%)	726,853 (100%)	403,391 (100%)	117,106 (100%)		
with no Fasting Glucose results	47,384 (87.2%)	86,622 (81.8%)	214,991 (79.0%)	431,630 (77.5%)	567,816 (77.1%)	601,092 (82.7%)	331,358 (82.1%)	100,427 (85.8%)		
with 1 Fasting Glucose result	4,719 (8.7%)	11,246 (10.6%)	27,551 (10.1%)	52,276 (9.4%)	61,830 (8.4%)	40,488 (5.6%)	23,277 (5.8%)	6,745 (5.8%)		
with 2-3 Fasting Glucose results	1,810 (3.3%)	5,842 (5.5%)	19,578 (7.2%)	43,570 (7.8%)	58,017 (7.9%)	41,183 (5.7%)	23,428 (5.8%)	5,641 (4.8%)		
with ≥4 Fasting Glucose results	446 (0.8%)	2,246 (2.1%)	10,165 (3.7%)	29,432 (5.3%)	48,585 (6.6%)	44,090 (6.1%)	25,328 (6.3%)	4,293 (3.7%)		
Random Glucose										
Eligible members*	11,570,147	6,122,350	5,955,433	5,899,765	4,387,516	2,668,931	1,374,771	487,388		
Member-days**	7,275,419,080	3,144,301,414	3,540,741,761	3,819,748,355	2,944,104,685	1,990,762,064	1,082,347,808	361,295,807		
Members with ≥ 1 diabetes diagnosis:	54,359 (100%)	105,956 (100%)	272,285 (100%)	556,908 (100%)	736,248 (100%)	726,853 (100%)	403,391 (100%)	117,106 (100%)		
with no Random Glucose results	34,980 (64.3%)	61,166 (57.7%)	147,966 (54.3%)	291,417 (52.3%)	375,306 (51.0%)	378,596 (52.1%)	199,571 (49.5%)	59,494 (50.8%)		
with 1 Random Glucose result	11,339 (20.9%)	24,566 (23.2%)	58,612 (21.5%)	106,660 (19.2%)	125,045 (17.0%)	96,756 (13.3%)	47,278 (11.7%)	13,664 (11.7%)		
with 2-3 Random Glucose results	5,142 (9.5%)	13,449 (12.7%)	40,922 (15.0%)	89,570 (16.1%)	118,764 (16.1%)	107,082 (14.7%)	56,348 (14.0%)	15,610 (13.3%)		
with ≥4 Random Glucose results	2,898 (5.3%)	6,775 (6.4%)	24,785 (9.1%)	69,261 (12.4%)	117,133 (15.9%)	144,419 (19.9%)	100,194 (24.8%)	28,338 (24.2%)		



	Age Group									
	2-24 years	25-34 years	35-44 years	45-54 years	55-64 years	65-74 years	75-84 years	85+ years		
	Number (%)	Number (%)	Number (%)	Number (%)	Number (%)	Number (%)	Number (%)	Number (%)		
HgbA1c										
Eligible members*	11,570,147	6,122,350	5,955,434	5,899,765	4,387,517	2,668,932	1,374,771	487,388		
Member-days**	7,275,495,720	3,144,355,036	3,540,842,528	3,819,973,120	2,944,495,015	1,991,263,213	1,082,937,880	361,615,552		
Members with ≥ 1 diabetes diagnosis:	54,359 (100%)	105,956 (100%)	272,285 (100%)	556,908 (100%)	736,248 (100%)	726,853 (100%)	403,391 (100%)	117,106 (100%)		
with no HgbA1c results	35,600 (65.5%)	58,228 (55.0%)	130,782 (48.0%)	247,967 (44.5%)	321,067 (43.6%)	357,634 (49.2%)	200,868 (49.8%)	65,630 (56.0%		
with 1 HgbA1c result	9,220 (17.0%)	23,312 (22.0%)	56,907 (20.9%)	104,079 (18.7%)	121,162 (16.5%)	93,916 (12.9%)	49,630 (12.3%)	15,623 (13.3%		
with 2-3 HgbA1c results	5,088 (9.4%)	15,088 (14.2%)	48,955 (18.0%)	107,073 (19.2%)	138,521 (18.8%)	114,165 (15.7%)	60,295 (14.9%)	16,461 (14.1%		
with ≥4 HgbA1c results	4,451 (8.2%)	9,328 (8.8%)	35,641 (13.1%)	97,789 (17.6%)	155,498 (21.1%)	161,138 (22.2%)	92,598 (23.0%)	19,392 (16.6%		

<sup>\*</sup>Number of members eligible for an incident treatment episode (defined by the drug/exposure and event washout periods) with drug and medical coverage during the query period.

<sup>\*\*</sup>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 a incidence, pre-existing condition, and enrollment requirements).



Table 3a. Summary of incident diabetes diagnoses (183-day washout period) and subsequent lab results in the MSDD between January 1, 2006 and December 31, 2010 by laboratory test and sex

	Sex				
	Female	Male	Unknown		
	Number (%)	Number (%)	Number (%)		
Creatinine					
Eligible members*	13,958,593	13,128,414	9,865		
Member-days**	9,191,330,966	8,411,290,276	5,350,329		
Members with ≥ 1 diabetes diagnosis:	657,951 (100%)	697,913 (100%)	329 (100%)		
with no Creatinine results	268,159 (40.8%)	288,046 (41.3%)	157 (47.7%)		
with 1 Creatinine result	132059 (20.1%)	137193 (19.7%)	104 (31.6%)		
with 2-3 Creatinine results	141,914 (21.6%)	147,754 (21.2%)	53 (16.1%)		
with ≥4 Creatinine results	115,819 (17.6%)	124,920 (17.9%)	15 (4.6%)		
Fasting Glucose					
Eligible members*	13,973,312	13,138,491	9,873		
Member-days**	9,193,187,126	8,412,740,757	5,351,189		
Members with ≥ 1 diabetes diagnosis:	657,951 (100%)	697,913 (100%)	329 (100%)		
with no Fasting Glucose results	499,228 (75.9%)	521,510 (74.7%)	272 (82.7%)		
with 1 Fasting Glucose result	70630 (10.7%)	75,123 (10.8%)	39 (11.9%)		
with 2-3 Fasting Glucose results	61,986 (9.4%)	69,326 (9.9%)	14 (4.3%)		
with ≥4 Fasting Glucose results	26,107 (4.0%)	31,954 (4.6%)	4 (1.2%)		
Random Glucose					
Eligible members*	13962606	13131646	9868		
Member-days**	9191716148	8411610961	5350435		
Members with ≥ 1 diabetes diagnosis:	657,951 (100%)	697,913 (100%)	329 (100%)		
with no Random Glucose results 359,660 (54.7%)		394,361 (56.5%)	183 (55.6%)		
with 1 Random Glucose result	132009 (20.1%)	135,596 (19.4%)	82 (24.9%)		
with 2-3 Random Glucose results	103,275 (15.7%)	103,516 (14.8%)	53 (16.1%)		
with ≥4 Random Glucose results	63,007 (9.6%)	64,440 (9.2%)	11 (3.3%)		



Table 3a. Summary of incident diabetes diagnoses (183-day washout period) and subsequent lab results in the MSDD between January 1, 2006 and December 31, 2010 by laboratory test and sex

industrial of the second of th		Sex				
	Female	Male	Unknown			
	Number (%)	Number (%)	Number (%)			
HgbA1c						
Eligible members*	13976406	13140502	9874			
Member-days**	9193438735	8412913762	5351283			
Members with ≥ 1 diabetes diagnosis:	657,951 (100%)	697,913 (100%)	329 (100%)			
with no HgbA1c results	315,003 (47.9%)	324,757 (46.5%)	190 (57.8%)			
with 1 HgbA1c result	130834 (19.9%)	136926 (19.6%)	86 (26.1%)			
with 2-3 HgbA1c results	137,664 (20.9%)	149,587 (21.4%)	46 (14.0%)			
with ≥4 HgbA1c results	74,450 (11.3%)	86,643 (12.4%)	7 (2.1%)			

<sup>\*</sup>Number of members eligible for an incident treatment episode (defined by the drug/exposure and event washout periods) with drug and medical coverage during the query period.

<sup>\*\*</sup>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 a incidence, pre-existing condition, and enrollment requirements).



Table 3b. Summary of incident diabetes diagnoses (365-day washout period) and subsequent lab results in the MSDD between January 1, 2006 and December 31, 2010 by laboratory test and sex

-		Sex	
	Female	Male	Unknown
	Number (%)	Number (%)	Number (%)
Creatinine			
Eligible members*	10,783,645	10,071,081	7,843
Member-days**	7,241,080,109	6,576,992,570	3,739,043
Members with ≥ 1 diabetes diagnosis:	393,448 (100%)	415,146 (100%)	198 (100%)
with no Creatinine results	160,731 (40.9%)	168,463 (40.6%)	87 (43.9%)
with 1 Creatinine result	92864 (23.6%)	97,608 (23.5%)	76 (38.4%)
with 2-3 Creatinine results	89,937 (22.9%)	94,951 (22.9%)	29 (14.6%)
with ≥4 Creatinine results	49,916 (12.7%)	54,124 (13.0%)	6 (3.0%)
Fasting Glucose			
Eligible members*	10,849,335	10,119,279	7,897
Member-days**	7,243,087,649	6,578,559,906	3,740,179
Members with ≥ 1 diabetes diagnosis:	393,448 (100%)	415,146 (100%)	198 (100%)
with no Fasting Glucose results	296,304 (75.3%)	303,596 (73.1%)	164 (82.8%)
with 1 Fasting Glucose result	52270 (13.3%)	57,473 (13.8%)	31 (15.7%)
with 2-3 Fasting Glucose results	37,176 (9.4%)	43,983 (10.6%)	3 (1.5%)
with ≥4 Fasting Glucose results	7,698 (2.0%)	10,094 (2.4%)	0 (0.0%)
Random Glucose			
Eligible members*	10,788,517	10,074,971	7,850
Member-days**	7,241,464,920	6,577,318,450	3,739,162
Members with ≥ 1 diabetes diagnosis:	393,448 (100%)	415,146 (100%)	198 (100%)
with no Random Glucose results	226,575 (57.6%)	247,687 (59.7%)	107 (54.0%)
with 1 Random Glucose result	80439 (20.4%)	81,864 (19.7%)	57 (28.8%)
with 2-3 Random Glucose results	55,752 (14.2%)	54,251 (13.1%)	29 (14.6%)
with ≥4 Random Glucose results	30,682 (7.8%)	31,344 (7.6%)	5 (2.5%)



Table 3b. Summary of incident diabetes diagnoses (365-day washout period) and subsequent lab results in the MSDD between January 1, 2006 and December 31, 2010 by laboratory test and sex

	Sex				
	Female	Male	Unknown		
	Number (%)	Number (%)	Number (%)		
HgbA1c					
Eligible members*	10,854,024	10,121,644	7,900		
Member-days**	7,243,390,108	6,578,766,392	3,740,332		
Members with ≥ 1 diabetes diagnosis:	393,448 (100%)	415,146 (100%)	198 (100%)		
with no HgbA1c results	192,461 (48.9%)	192,265 (46.3%)	115 (58.1%)		
with 1 HgbA1c result	93052 (23.7%)	98392 (23.7%)	57 (28.8%)		
with 2-3 HgbA1c results	87,169 (22.2%)	98,423 (23.7%)	23 (11.6%)		
with ≥4 HgbA1c results	20,766 (5.3%)	26,066 (6.3%)	3 (1.5%)		

<sup>\*</sup>Number of members eligible for an incident treatment episode (defined by the drug/exposure and event washout periods) with drug and medical coverage during the query period.

<sup>\*\*</sup>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 a incidence, pre-existing condition, and enrollment requirements).



		Sex		
	Female	Male	Unknown	
	Number (%)	Number (%)	Number (%)	
Creatinine				
Eligible members*	17,255,945	16,372,690	11,944	
Member-days**	12,515,400,000	11,635,200,000	7,667,142	
Members with ≥ 1 diabetes diagnosis:	1,314,994 (100%)	1,367,468 (100%)	624 (100%)	
with no Creatinine results	554,197 (42.1%)	586,674 (42.9%)	297 (47.6%)	
with 1 Creatinine result	199336 (15.2%)	206348 (15.1%)	136 (21.8%)	
with 2-3 Creatinine results	213,647 (16.2%)	220,957 (16.2%)	116 (18.6%)	
with ≥4 Creatinine results	347,814 (26.4%)	353,489 (25.8%)	75 (12.0%)	
Fasting Glucose				
Eligible members*	17,255,945	16,372,690	11,944	
Member-days**	12,516,800,000	11,636,500,000	7,667,361	
Members with ≥ 1 diabetes diagnosis:	1,314,994 (100%)	1,367,468 (100%)	624 (100%)	
with no Fasting Glucose results	1,062,326 (80.8%)	1,093,749 (80.0%)	531 (85.1%)	
with 1 Fasting Glucose result	89722 (6.8%)	95,143 (7.0%)	53 (8.5%)	
with 2-3 Fasting Glucose results	79,034 (6.0%)	87,148 (6.4%)	20 (3.2%)	
with ≥4 Fasting Glucose results	83,912 (6.4%)	91,428 (6.7%)	20 (3.2%)	
Random Glucose				
Eligible members*	17,255,945	16,372,690	11,944	
Member-days**	12,515,600,000	11,635,400,000	7,667,169	
Members with ≥ 1 diabetes diagnosis:	1,314,994 (100%)	1,367,468 (100%)	624 (100%)	
with no Random Glucose results	704,419 (53.6%)	654,418 (47.9%)	329 (52.7%)	
with 1 Random Glucose result	216,255 (16.4%)	211,900 (15.5%)	115 (18.4%)	
with 2-3 Random Glucose results	202,191 (15.4%)	202,241 (14.8%)	115 (18.4%)	
with ≥4 Random Glucose results	244,603 (18.6%)	246,435 (18.0%)	65 (10.4%)	



Table 3c. Summary of prevalent diabetes and sub	ubsequent lab results in the MSDD between January 1, 2006 and December 31, 2010 by laboratory test and sex  Sex				
	Female Male Unknown				
	Number (%)	Number (%)	Number (%)		
HgbA1c					
Eligible members*	17,255,945	16,372,690	11,944		
Member-days**	12,516,800,000	11,636,500,000	7,667,355		
Members with ≥ 1 diabetes diagnosis:	1,314,994 (100%)	1,367,468 (100%)	624 (100%)		
with no HgbA1c results	637,651 (48.5%)	655,532 (47.9%)	348 (55.8%)		
with 1 HgbA1c result	195093 (14.8%)	203652 (14.9%)	115 (18.4%)		
with 2-3 HgbA1c results	195,117 (14.8%)	209,788 (15.3%)	98 (15.7%)		
with ≥4 HgbA1c results	287,133 (21.8%)	298,496 (21.8%)	63 (10.1%)		

<sup>\*</sup>Number of members eligible for an incident treatment episode (defined by the drug/exposure and event washout periods) with drug and medical coverage during the query period.

<sup>\*\*</sup>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 a incidence, pre-existing condition, and enrollment requirements).



Table 4a. Summary of incident diabetes diagnoses (183-day washout period) and subsequent lab results in the MSDD between January 1, 2006 and December 31, 2010 by laboratory test and year

and year	Year					
	2006	2007	2008	2009	2010	
	Number (%)					
Creatinine						
Eligible members*	5,728,232	7,794,452	17,488,278	18,612,560	17,233,595	
Member-days**	1,710,336,076	1,824,643,911	3,894,185,151	5,253,367,101	4,925,439,332	
Members with ≥ 1 diabetes diagnosis:	186,213 (100%)	177,417 (100%)	396,504 (100%)	529,358 (100%)	516,868 (100%)	
with no Creatinine results	33,284 (17.9%)	37,186 (21.0%)	158,475 (40.0%)	222,862 (42.1%)	266,178 (51.5%)	
with 1 Creatinine result	52,259 (28.1%)	50,266 (28.3%)	95,261 (24.0%)	127,269 (24.0%)	155,074 (30.0%)	
with 2-3 Creatinine results	65,513 (35.2%)	59,315 (33.4%)	99,725 (25.2%)	129,779 (24.5%)	74,521 (14.4%)	
with ≥4 Creatinine results	35,157 (18.9%)	30,650 (17.3%)	43,043 (10.9%)	49,448 (9.3%)	21,095 (4.1%)	
Fasting Glucose						
Eligible members*	5,732,030	7,801,276	17,509,347	18,634,964	17,253,665	
Member-days**	1,710,669,449	1,825,223,377	3,895,293,104	5,254,011,745	4,926,081,397	
Members with ≥ 1 diabetes diagnosis:	186,213 (100%)	177,417 (100%)	396,504 (100%)	529,358 (100%)	516,868 (100%)	
with no Fasting Glucose results	85,282 (45.8%)	88,732 (50.0%)	298,369 (75.2%)	422,796 (79.9%)	445,182 (86.1%)	
with 1 Fasting Glucose result	53,882 (28.9%)	48,119 (27.1%)	55,392 (14.0%)	63,560 (12.0%)	55,481 (10.7%)	
with 2-3 Fasting Glucose results	41,183 (22.1%)	35,746 (20.1%)	38,313 (9.7%)	38,973 (7.4%)	15,343 (3.0%)	
with ≥4 Fasting Glucose results	5,866 (3.2%)	4,820 (2.7%)	4,430 (1.1%)	4,029 (0.8%)	862 (0.2%)	
Random Glucose						
Eligible members*	5,733,454	7,799,680	17,493,740	18,619,810	17,240,559	
Member-days**	1,710,481,035	1,824,783,631	3,894,364,178	5,253,487,029	4,925,561,671	
Members with ≥ 1 diabetes diagnosis:	186,213 (100%)	177,417 (100%)	396,504 (100%)	529,358 (100%)	516,868 (100%)	
with no Random Glucose results	117,165 (62.9%)	112,481 (63.4%)	234,222 (59.1%)	307,325 (58.1%)	339,713 (65.7%)	
with 1 Random Glucose result	30,644 (16.5%)	28,650 (16.1%)	73,360 (18.5%)	104,815 (19.8%)	112,021 (21.7%)	
with 2-3 Random Glucose results	20,380 (10.9%)	19,538 (11.0%)	58,866 (14.8%)	82,539 (15.6%)	49,789 (9.6%)	
with ≥4 Random Glucose results	18,024 (9.7%)	16,748 (9.4%)	30,056 (7.6%)	34,679 (6.6%)	15,345 (3.0%)	



Table 4a. Summary of incident diabetes diagnoses (183-day washout period) and subsequent lab results in the MSDD between January 1, 2006 and December 31, 2010 by laboratory test and year

-		Year				
	2006	2006 2007 2008 2009				
	Number (%)	Number (%)	Number (%)	Number (%)	Number (%)	
HgbA1c						
Eligible members*	5,738,623	7,806,845	17,515,517	18,640,789	17,258,702	
Member-days**	1,710,771,044	1,825,280,830	3,895,414,671	5,254,093,789	4,926,143,446	
Members with ≥ 1 diabetes diagnosis:	186,213 (100%)	177,417 (100%)	396,504 (100%)	529,358 (100%)	516,868 (100%)	
with no HgbA1c results	35,704 (19.2%)	40,816 (23.0%)	182,828 (46.1%)	255,893 (48.3%)	288,517 (55.8%)	
with 1 HgbA1c result	56,140 (30.1%)	53,005 (29.9%)	96,291 (24.3%)	124,698 (23.6%)	158,148 (30.6%)	
with 2-3 HgbA1c results	81,381 (43.7%)	72,641 (40.9%)	103,636 (26.1%)	131,377 (24.8%)	66,228 (12.8%)	
with ≥4 HgbA1c results	12,988 (7.0%)	10,955 (6.2%)	13,749 (3.5%)	17,390 (3.3%)	3,975 (0.8%)	

<sup>\*</sup>Number of members eligible for an incident treatment episode (defined by the drug/exposure and event washout periods) with drug and medical coverage during the query period.

<sup>\*\*</sup>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 a incidence, pre-existing condition, and enrollment requirements).



Table 4b. Summary of incident diabetes diagnoses (365-day washout period) and subsequent lab results in the MSDD between January 1, 2006 and December 31, 2010 by laboratory test and year

	Year						
	2006	2007	2008	2009	2010		
	Number (%)	Number (%)	Number (%)	Number (%)	Number (%)		
Creatinine							
Eligible members*	4,757,626	5,039,051	12,997,358	14,875,731	14,157,582		
Member-days**	1,506,234,124	1,607,902,546	1,960,133,700	4,463,771,183	4,283,770,169		
Members with ≥ 1 diabetes diagnosis:	88,099 (100%)	91,750 (100%)	132,735 (100%)	309,629 (100%)	300,053 (100%)		
with no Creatinine results	18,119 (20.6%)	19,436 (21.2%)	42,722 (32.2%)	135,311 (43.7%)	160,353 (53.4%)		
with 1 Creatinine result	25,015 (28.4%)	27,062 (29.5%)	34,671 (26.1%)	76,083 (24.6%)	86,953 (29.0%)		
with 2-3 Creatinine results	28,894 (32.8%)	29,672 (32.3%)	37,162 (28.0%)	70,450 (22.8%)	40,659 (13.6%)		
with ≥4 Creatinine results	16,071 (18.2%)	15,580 (17.0%)	18,180 (13.7%)	27,785 (9.0%)	12,088 (4.0%)		
Fasting Glucose							
Eligible members*	4,757,881	5,039,088	13,950,918	14,877,258	14,157,714		
Member-days**	1,506,553,007	1,608,220,498	1,961,770,554	4,464,363,167	4,284,480,508		
Members with ≥ 1 diabetes diagnosis:	88,099 (100%)	91,750 (100%)	132,735 (100%)	309,629 (100%)	300,053 (100%)		
with no Fasting Glucose results	41,752 (47.4%)	43,275 (47.2%)	86,389 (65.1%)	249,214 (80.5%)	261,945 (87.3%)		
with 1 Fasting Glucose result	25,289 (28.7%)	26,728 (29.1%)	26,505 (20.0%)	37,100 (12.0%)	29,705 (9.9%)		
with 2-3 Fasting Glucose results	18,353 (20.8%)	19,040 (20.8%)	17,880 (13.5%)	21,082 (6.8%)	7,896 (2.6%)		
with ≥4 Fasting Glucose results	2,705 (3.1%)	2,707 (3.0%)	1,961 (1.5%)	2,233 (0.7%)	507 (0.2%)		
Random Glucose							
Eligible members*	4,757,616	5,039,072	13,073,028	14,875,872	14,157,601		
Member-days**	1,506,332,683	1,608,067,584	1,960,342,013	4,463,879,308	4,283,900,944		
Members with ≥ 1 diabetes diagnosis:	88,099 (100%)	91,750 (100%)	132,735 (100%)	309,629 (100%)	300,053 (100%)		
with no Random Glucose results	55,221 (62.7%)	59,005 (64.3%)	81,222 (61.2%)	178,960 (57.8%)	194,714 (64.9%)		
with 1 Random Glucose result	14,247 (16.2%)	14,520 (15.8%)	22,124 (16.7%)	62,797 (20.3%)	66,608 (22.2%)		
with 2-3 Random Glucose results	9,640 (10.9%)	9,464 (10.3%)	17,239 (13.0%)	47,269 (15.3%)	29,430 (9.8%)		
with ≥4 Random Glucose results	8,991 (10.2%)	8,761 (9.5%)	12,150 (9.2%)	20,603 (6.7%)	9,301 (3.1%)		



Table 4b. Summary of incident diabetes diagnoses (365-day washout period) and subsequent lab results in the MSDD between January 1, 2006 and December 31, 2010 by laboratory test and year

		Year				
	2006	2007	2008	2009	2010	
	Number (%)	Number (%)	Number (%)	Number (%)	Number (%)	
HgbA1c						
Eligible members*	4,757,860	5,039,115	14,038,460	14,877,367	14,157,728	
Member-days**	1,506,596,840	1,608,376,702	1,961,921,054	4,464,435,800	4,284,566,436	
Members with ≥ 1 diabetes diagnosis:	88,099 (100%)	91,750 (100%)	132,735 (100%)	309,629 (100%)	300,053 (100%)	
with no HgbA1c results	20,974 (23.8%)	22,593 (24.6%)	51,938 (39.1%)	160,606 (51.9%)	177,714 (59.2%)	
with 1 HgbA1c result	27,222 (30.9%)	29,091 (31.7%)	36,349 (27.4%)	74,580 (24.1%)	87,164 (29.0%)	
with 2-3 HgbA1c results	34,515 (39.2%)	35,148 (38.3%)	39,402 (29.7%)	65,870 (21.3%)	33,100 (11.0%)	
with ≥4 HgbA1c results	5,388 (6.1%)	4,918 (5.4%)	5,046 (3.8%)	8,573 (2.8%)	2,075 (0.7%)	

<sup>\*</sup>Number of members eligible for an incident treatment episode (defined by the drug/exposure and event washout periods) with drug and medical coverage during the query period.

<sup>\*\*</sup>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 a incidence, pre-existing condition, and enrollment requirements).



			Year		
	2006	2007	2008	2009	2010
	Number (%)	Number (%)	Number (%)	Number (%)	Number (%)
Creatinine					
Eligible members*	6,441,967	9,606,697	22,360,438	22,021,905	20,562,688
Member-days**	2,051,198,960	2,649,543,082	6,617,050,967	6,652,646,891	6,187,771,689
Members with ≥ 1 diabetes diagnosis:	382,555 (100%)	717,175 (100%)	1,392,770 (100%)	1,393,822 (100%)	1,373,864 (100%)
with no Creatinine results	65,448 (17.1%)	268,829 (37.5%)	629,154 (45.2%)	602,395 (43.2%)	713,756 (52.0%)
with 1 Creatinine result	97,072 (25.4%)	137,567 (19.2%)	277,103 (19.9%)	278,202 (20.0%)	357,212 (26.0%)
with 2-3 Creatinine results	132,695 (34.7%)	187,647 (26.2%)	320,786 (23.0%)	335,779 (24.1%)	225,068 (16.4%)
with ≥4 Creatinine results	87,340 (22.8%)	123,132 (17.2%)	165,727 (11.9%)	177,446 (12.7%)	77,828 (5.7%)
Fasting Glucose					
Eligible members*	6,441,967	9,606,698	22,360,441	22,021,906	20,562,689
Member-days**	2,051,692,937	2,650,062,965	6,617,622,881	6,653,247,075	6,188,388,541
Members with ≥ 1 diabetes diagnosis:	382,555 (100%)	717,175 (100%)	1,392,770 (100%)	1,393,822 (100%)	1,373,864 (100%)
with no Fasting Glucose results	177,078 (46.3%)	534,269 (74.5%)	1,163,921 (83.6%)	1,164,511 (83.5%)	1,215,931 (88.5%)
with 1 Fasting Glucose result	103,440 (27.0%)	93,029 (13.0%)	118,584 (8.5%)	127,004 (9.1%)	115,365 (8.4%)
with 2-3 Fasting Glucose results	86,639 (22.6%)	76,670 (10.7%)	92,696 (6.7%)	88,691 (6.4%)	39,287 (2.9%)
with ≥4 Fasting Glucose results	15,398 (4.0%)	13,207 (1.8%)	17,569 (1.3%)	13,616 (1.0%)	3,281 (0.2%)
Random Glucose					
Eligible members*	6,441,967	9,606,697	22,360,439	22,021,905	20,562,688
Member-days**	2,051,339,782	2,649,672,038	6,617,149,839	6,652,719,148	6,187,840,167
Members with ≥ 1 diabetes diagnosis:	382,555 (100%)	717,175 (100%)	1,392,770 (100%)	1,393,822 (100%)	1,373,864 (100%)
with no Random Glucose results	226,652 (59.2%)	419,082 (58.4%)	788,824 (56.6%)	776,626 (55.7%)	874,416 (63.6%)
with 1 Random Glucose result	64,001 (16.7%)	102,774 (14.3%)	238,409 (17.1%)	243,806 (17.5%)	274,404 (20.0%)
with 2-3 Random Glucose results	45,778 (12.0%)	107,551 (15.0%)	234,963 (16.9%)	240,158 (17.2%)	165,817 (12.1%)
with ≥4 Random Glucose results	46,124 (12.1%)	87,768 (12.2%)	130,574 (9.4%)	133,232 (9.6%)	59,227 (4.3%)



Table 4c. Summary of prevalent diabetes	nd subsequent lab results in the MSDD between January 1, 2006 and December 31, 2010 by laboratory test and year  Year					
	2006	2007	2008	2009	2010	
	Number (%)	Number (%)	Number (%)	Number (%)	Number (%)	
HgbA1c						
Eligible members*	6,441,967	9,606,698	22,360,441	22,021,906	20,562,689	
Member-days**	2,051,701,101	2,650,066,456	6,617,614,532	6,653,230,480	6,188,365,495	
Members with ≥ 1 diabetes diagnosis:	382,555 (100%)	717,175 (100%)	1,392,770 (100%)	1,393,822 (100%)	1,373,864 (100%)	
with no HgbA1c results	67,690 (17.7%)	293,764 (41.0%)	690,121 (49.6%)	665,843 (47.8%)	761,719 (55.4%)	
with 1 HgbA1c result	104,348 (27.3%)	139,865 (19.5%)	275,127 (19.8%)	271,804 (19.5%)	373,302 (27.2%)	
with 2-3 HgbA1c results	175,319 (45.8%)	224,996 (31.4%)	350,919 (25.2%)	371,567 (26.7%)	218,595 (15.9%)	
with ≥4 HgbA1c results	35,198 (9.2%)	58,550 (8.2%)	76,603 (5.5%)	84,608 (6.1%)	20,248 (1.5%)	

<sup>\*</sup>Number of members eligible for an incident treatment episode (defined by the drug/exposure and event washout periods) with drug and medical coverage during the query period.

<sup>\*\*</sup>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 a incidence, pre-existing condition, and enrollment requirements).



Table 5a. Summary of incident diabetes diagnoses (183-day washout period) and subsequent lab results in the MSDD between January 1, 2006 and December 31, 2010 by laboratory test and Data Partner type

	Data Partner Type	
	Sites with Electronic Health Records	National Insurers Number (%)
	Number (%)	
Creatinine		
Eligible members*	8,526,566	18,570,306
Member-days**	8,774,187,480	8,833,784,091
Members with ≥ 1 diabetes diagnosis:	491,031 (100%)	865,162 (100%)
with no Creatinine results	80,382 (16.4%)	475,980 (55.0%)
with 1 Creatinine result	81,061 (16.5%)	188,295 (21.8%)
with 2-3 Creatinine results	142,451 (29.0%)	147,270 (17.0%)
with ≥4 Creatinine results	187,137 (38.1%)	53,617 (6.2%)
Fasting Glucose		
Eligible members*	8,529,496	18,592,180
Member-days**	8,775,908,184	8,835,370,888
Members with ≥ 1 diabetes diagnosis:	491,031 (100%)	865,162 (100%)
with no Fasting Glucose results	204,476 (41.6%)	816,534 (94.4%)
with 1 Fasting Glucose result	111,818 (22.8%)	33,974 (3.9%)
with 2-3 Fasting Glucose results	118,926 (24.2%)	12,400 (1.4%)
with ≥4 Fasting Glucose results	55,811 (11.4%)	2,254 (0.3%)
Random Glucose		
Eligible members*	8,532,608	18,571,512
Member-days**	8,774,778,879	8,833,898,665
Members with ≥ 1 diabetes diagnosis:	491,031 (100%)	865,162 (100%)
with no Random Glucose results	259,667 (52.9%)	494,537 (57.2%)
with 1 Random Glucose result	86,259 (17.6%)	181,428 (21.0%)
with 2-3 Random Glucose results	67,620 (13.8%)	139,224 (16.1%)
with ≥4 Random Glucose results	77,485 (15.8%)	49,973 (5.8%)
HgbA1c		
Eligible members*	8,535,958	18,590,824
Member-days**	8,776,333,459	8,835,370,321
Members with ≥ 1 diabetes diagnosis:	491,031 (100%)	865,162 (100%)
with no HgbA1c results	95,272 (19.4%)	544,678 (63.0%)
with 1 HgbA1c result	87,981 (17.9%)	179,865 (20.8%)
with 2-3 HgbA1c results	168,258 (34.3%)	119,039 (13.8%)
with ≥4 HgbA1c results	139,520 (28.4%)	21,580 (2.5%)

<sup>\*</sup>Number of members eligible for an incident treatment episode (defined by the drug/exposure and event washout periods) with drug and medical coverage during the query period.

<sup>\*\*</sup>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 a incidence, pre-existing condition, and enrollment requirements).



Table 5b. Summary of incident diabetes diagnoses (365-day washout period) and subsequent lab results in the MSDD between January 1, 2006 and December 31, 2010 by laboratory test and Data Partner type

	Data Partner Type	
	Sites with Electronic Health Records	National Insurers Number (%)
	Number (%)	
Creatinine		
Eligible members*	7,463,145	13,399,424
Member-days**	7,986,211,472	5,835,600,250
Members with ≥ 1 diabetes diagnosis:	337,285 (100%)	471,507 (100%)
with no Creatinine results	66,630 (19.8%)	262,651 (55.7%)
with 1 Creatinine result	80,738 (23.9%)	109,810 (23.3%)
with 2-3 Creatinine results	110,034 (32.6%)	74,883 (15.9%)
with ≥4 Creatinine results	79,883 (23.7%)	24,163 (5.1%)
Fasting Glucose		
Eligible members*	7,464,736	13,511,775
Member-days**	7,987,905,235	5,837,482,499
Members with ≥ 1 diabetes diagnosis:	337,285 (100%)	471,507 (100%)
with no Fasting Glucose results	154,249 (45.7%)	445,815 (94.6%)
with 1 Fasting Glucose result	90,344 (26.8%)	19,430 (4.1%)
with 2-3 Fasting Glucose results	75,546 (22.4%)	5,616 (1.2%)
with ≥4 Fasting Glucose results	17,146 (5.1%)	646 (0.1%)
Random Glucose		
Eligible members*	7,464,994	13,406,344
Member-days**	7,986,810,448	5,835,712,084
Members with ≥ 1 diabetes diagnosis:	337,285 (100%)	471,507 (100%)
with no Random Glucose results	200,626 (59.5%)	273,743 (58.1%)
with 1 Random Glucose result	57,558 (17.1%)	104,802 (22.2%)
with 2-3 Random Glucose results	39,493 (11.7%)	70,539 (15.0%)
with ≥4 Random Glucose results	39,608 (11.7%)	22,423 (4.8%)
HgbA1c		
Eligible members*	7,467,492	13,516,076
Member-days**	7,988,395,989	5,837,500,843
Members with ≥ 1 diabetes diagnosis:	337,285 (100%)	471,507 (100%)
with no HgbA1c results	78,690 (23.3%)	306,151 (64.9%)
with 1 HgbA1c result	87,028 (25.8%)	104,473 (22.2%)
with 2-3 HgbA1c results	131,020 (38.8%)	54,595 (11.6%)
with ≥4 HgbA1c results	40,547 (12.0%)	6,288 (1.3%)

<sup>\*</sup>Number of members eligible for an incident treatment episode (defined by the drug/exposure and event washout periods) with drug and medical coverage during the query period.

<sup>\*\*</sup>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 a incidence, pre-existing condition, and enrollment requirements).



Table 5c. Summary of prevalent diabetes and subsequent lab results in the MSDD between January 1, 2006 and December 31, 2010 by laboratory test and Data Partner type

	Data Partner Type	
	Sites with Electronic Health Records	National Insurers Number (%)
	Number (%)	
Creatinine		
Eligible members*	9,606,977	24,033,602
Member-days**	10,338,718,152	13,819,460,767
Members with ≥ 1 diabetes diagnosis:	656,697 (100%)	2,026,389 (100%)
with no Creatinine results	102,748 (15.6%)	1,038,420 (51.2%)
with 1 Creatinine result	72,169 (11.0%)	333,651 (16.5%)
with 2-3 Creatinine results	112,555 (17.1%)	322,165 (15.9%)
with ≥4 Creatinine results	369,225 (56.2%)	332,153 (16.4%)
Fasting Glucose		
Eligible members*	9,606,977	24,033,602
Member-days**	10,341,418,374	13,819,624,892
Members with ≥ 1 diabetes diagnosis:	656,697 (100%)	2,026,389 (100%)
with no Fasting Glucose results	247,137 (37.6%)	1,909,469 (94.2%)
with 1 Fasting Glucose result	119,454 (18.2%)	65,464 (3.2%)
with 2-3 Fasting Glucose results	133,087 (20.3%)	33,115 (1.6%)
with ≥4 Fasting Glucose results	157,019 (23.9%)	18,341 (0.9%)
Random Glucose		
Eligible members*	9,606,977	24,033,602
Member-days**	10,339,225,488	13,819,460,370
Members with ≥ 1 diabetes diagnosis:	656,697 (100%)	2,026,389 (100%)
with no Random Glucose results	280,299 (42.7%)	1,078,867 (53.2%)
with 1 Random Glucose result	103,443 (15.8%)	324,827 (16.0%)
with 2-3 Random Glucose results	94,007 (14.3%)	310,540 (15.3%)
with ≥4 Random Glucose results	178,948 (27.2%)	312,155 (15.4%)
HgbA1c		
Eligible members*	9,606,977	24,033,602
Member-days**	10,341,407,425	13,819,615,096
Members with ≥ 1 diabetes diagnosis:	656,697 (100%)	2,026,389 (100%)
with no HgbA1c results	121,985 (18.6%)	1,171,546 (57.8%)
with 1 HgbA1c result	80,755 (12.3%)	318,105 (15.7%)
with 2-3 HgbA1c results	124,820 (19.0%)	280,183 (13.8%)
with ≥4 HgbA1c results	329,137 (50.1%)	256,555 (12.7%)

<sup>\*</sup>Number of members eligible for an incident treatment episode (defined by the drug/exposure and event washout periods) with drug and medical coverage during the query period.

<sup>\*\*</sup>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 a incidence, pre-existing condition, and enrollment requirements).



