

Disclaimer

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

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

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

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Overview for Request to16_cap_mpl1r_wp017

Request ID: to16_cap_mpl1r_wp017

Request Description: This report examined the availability of International Normalized Ratio (INR) laboratory test values and INR test procedures among new warfarin users in the Mini-Sentinel Distributed Database (MSDD).

Mini-Sentinel Modular Program Tool Used: Modular Program #3 (MP3)

Data Source: Data from January 1, 2008 to December 31, 2014 from 11 Data Partners contributing to the MSDD were included in this report. This request was distributed to Data Partners on March 10, 2015. See Appendix A for a list of dates of available data for each Data Partner.

Study Design: This request examined the availability of INR laboratory test values and INR test procedures among incident warfarin users.

Events of Interest: The events of interest were INR laboratory test results and INR test procedures among incident warfarin users. Procedures were defined using Healthcare Common Procedure Coding System (HCPCS) procedure codes and Current Procedural Terminology, Fourth Edition (CPT-4) procedure codes. All qualifying events that occurred between January 1, 2008 and December 31, 2014 were included. Please see Appendix B for a list of HCPCS and CPT-4 procedure codes used to define INR in this request.

Cohort Eligibility Criteria: Patients were required to be continuously enrolled in health plans with medical and drug coverage for at least 183 days prior to their first qualifying warfarin dispensing date (index), during which gaps in coverage of up to 45 days were allowed. Individuals 40 years of age or older were included in the cohort. Please see Appendix C for a list of generic and brand drug names used to define warfarin in this request.

Please see Appendix D for the specifications of parameters used in this request.

Limitations: Algorithms used to define exposures and inclusion criteria are imperfect; thus, it is possible that there may be misclassification. Therefore, data should be interpreted with this limitation in mind.

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

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Glossary of Terms in Modular Program 3*

Blackout Period - number of days at the beginning of a treatment episode that events are to be ignored. If an event occurs during the blackout period, the episode is excluded.

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).

Days at Risk - number of days supplied plus any episode gaps and exposure extension periods.

Eligible Members - 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.

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

Episode Gap - number of days allowed between two (or more) consecutive exposures (dispensings/procedures) to be considered the same treatment episode.

Exposure Extension Period - number of days post treatment period in which the outcomes/events are counted for a treatment episode.

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. *Single* and *Multiple incidence types* will use the washout period to establish incidence, however *Single* will only consider the first treatment episode whereas *Multiple* will consider all qualifying incident treatment episodes.

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 treatment episodes. The program will only consider one event per episode, but the *Multiple incidence type* will consider more than one event per user if a user has more than one incident episode.

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-Days - sum of all days of enrollment with medical and drug coverage** in the query period preceded by an exposure washout period.

Minimum Days Supplied - specifies a minimum number of days in length of the days supplied for the episode to be considered.

Minimum Episode Duration - specifies a minimum number of days in length of the episode for it to be considered.

New Episodes - new treatment episodes; length of episode is determined by days supplied in one dispensing (or

New Users - number of members with incident exposure during the query period. Member must have no evidence of exposure (s) of interest (defined by incidence criteria) in the prior washout 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.

Query Period - period in which the modular program looks for exposures and outcomes of interest.

Total Days Supplied - number of days supplied for all dispensings in qualifying treatment episodes.

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 treatment episode.

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 treatment episode.

*all terms may not be used in this report

**incident treatment episodes must be incident to both the exposure and the event

Table 1a. Summary of Incident Warfarin Use and International Normalized Ratio (INR) Laboratory Results and Procedures in Any Care Setting in the Mini-Sentinel Distributed Database (MSDD), by Event Definition

New Users	Days Supplied	Amount Supplied	Years at Risk*	New Episodes with Events	Number of Events	Eligible Members	Member-Years	New Users per 1,000 Eligible Members	Days Supplied per User	New Episodes with Events per 1,000 Years at Risk	Percent of New Users with Events	Average Number of Events per New User with Event	Percent of Total Users with Lab Results who have Event	Percent of Total Users with Procedures who have Event	
INR lab result															
667,350	17,590,228	24,616,822	40,641.0	199,621	922,473	29,666,578	77,127,463.4	22.50	26.36	4,911.81	29.91%	4.62	100.00%	N/A	
INR procedure															
667,350	17,590,228	24,616,822	22,666.7	487,660	1,871,252	29,666,578	77,127,463.4	22.50	26.36	21,514.34	73.07%	3.84	N/A	100.00%	
INR lab result and procedure on the same day															
667,350	17,590,228	24,616,822	41,926.9	186,278	789,086	29,666,578	77,127,463.4	22.50	26.36	4,442.92	27.91%	4.24	93.32%	38.20%	
INR lab result with a procedure within 3 days (before or after)															
667,350	17,590,228	24,616,822	41,420.3	189,328	859,203	29,666,578	77,127,463.4	22.50	26.36	4,570.90	28.37%	4.54	94.84%	N/A	
INR lab result with a procedure in the prior 3 days															
667,350	17,590,228	24,616,822	41,563.0	188,433	839,241	29,666,578	77,127,463.4	22.50	26.36	4,533.67	28.24%	4.45	94.40%	N/A	
INR lab result with a procedure in the following 3 days															
667,350	17,590,228	24,616,822	41,671.3	187,556	831,156	29,666,578	77,127,463.4	22.50	26.36	4,500.85	28.10%	4.43	93.96%	N/A	
INR lab result without a procedure within 30 days (before or after)															
667,350	17,590,228	24,616,822	53,701.5	6,909	22,157	29,666,578	77,127,463.4	22.50	26.36	128.66	1.04%	3.21	3.46%	N/A	
INR procedure with a lab result within 3 days (before or after)															
667,350	17,590,228	24,616,822	41,740.4	188,407	815,980	29,666,578	77,127,463.4	22.50	26.36	4,513.78	28.23%	4.33	N/A	38.63%	
INR procedure with a lab result in the prior 3 days															
667,350	17,590,228	24,616,822	41,822.2	187,702	805,577	29,666,578	77,127,463.4	22.50	26.36	4,488.10	28.13%	4.29	N/A	38.49%	
INR procedure with a lab result in the following 3 days															
667,350	17,590,228	24,616,822	41,816.5	187,335	805,777	29,666,578	77,127,463.4	22.50	26.36	4,479.93	28.07%	4.30	N/A	38.42%	
INR procedure without a lab result within 30 days (before or after)															
667,350	17,590,228	24,616,822	35,690.3	294,037	989,470	29,666,578	77,127,463.4	22.50	26.36	8,238.57	44.06%	3.37	N/A	60.30%	

*Years at risk are truncated at a user's first event.

Table 1b. Summary of Incident Warfarin Use and International Normalized Ratio (INR) Laboratory Results and Procedures in the Outpatient* Care Setting in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2008 and December 31, 2014, by Event Definition

New Users	Days Supplied	Amount Supplied	Years at Risk**	New Episodes with Events	Number of Events	Eligible Members	Member-Years	New Users per 1,000 Eligible Members	Days Supplied per User	New Episodes with Events per 1,000 Years at Risk	Percent of New Users with Events	Average Number of Events per New User with Event	Percent of Total Users with Lab Results who have Event	Percent of Total Users with Procedures who have Event	
INR lab result															
667,350	17,590,228	24,616,822	41,319.8	195,826	830,153	29,666,578	77,127,463.4	22.50	26.36	4739.27	29.34%	4.24	100.00%	N/A	
INR procedure															
667,350	17,590,228	24,616,822	23,854.6	472,276	1,786,463	29,666,578	77,127,463.4	22.50	26.36	19798.11	70.77%	3.78	N/A	100.00%	
INR lab result and procedure on the same day															
667,350	17,590,228	24,616,822	42,173.9	183,980	761,593	29,666,578	77,127,463.4	22.50	26.36	4362.41	27.57%	4.14	93.95%	38.96%	
INR lab result with a procedure within 3 days (before or after)															
667,350	17,590,228	24,616,822	42,024.6	185,611	779,542	29,666,578	77,127,463.4	22.50	26.36	4416.72	27.81%	4.20	94.78%	N/A	
INR lab result with a procedure in the prior 3 days															
667,350	17,590,228	24,616,822	42,098.2	184,944	772,036	29,666,578	77,127,463.4	22.50	26.36	4393.16	27.71%	4.17	94.44%	N/A	
INR lab result with a procedure in the following 3 days															
667,350	17,590,228	24,616,822	42,074.7	184,935	772,909	29,666,578	77,127,463.4	22.50	26.36	4395.40	27.71%	4.18	94.44%	N/A	
INR lab result without a procedure within 30 days (before or after)															
667,350	17,590,228	24,616,822	53,654.5	7,695	23,745	29,666,578	77,127,463.4	22.50	26.36	143.42	1.15%	3.09	3.93%	N/A	
INR procedure with a lab result within 3 days (before or after)															
667,350	17,590,228	24,616,822	42,023.0	185,650	784,480	29,666,578	77,127,463.4	22.50	26.36	4417.82	27.82%	4.23	N/A	39.31%	
INR procedure with a lab result in the prior 3 days															
667,350	17,590,228	24,616,822	42,098.8	185,029	775,148	29,666,578	77,127,463.4	22.50	26.36	4395.12	27.73%	4.19	N/A	39.18%	
INR procedure with a lab result in the following 3 days															
667,350	17,590,228	24,616,822	42,075.1	184,888	776,019	29,666,578	77,127,463.4	22.50	26.36	4394.24	27.70%	4.20	N/A	39.15%	
INR procedure without a lab result within 30 days (before or after)															
667,350	17,590,228	24,616,822	36,525.6	282,049	943,070	29,666,578	77,127,463.4	22.50	26.36	7721.96	42.26%	3.34	N/A	59.72%	

*For this request, laboratory results with a patient location of "Unknown" were included in the outpatient care setting.

**Years at risk are truncated at a user's first event.

Table 1c. Summary of Incident Warfarin Use and International Normalized Ratio (INR) Laboratory Results and Procedures in the Inpatient Care Setting in the Mini-Sentinel Distributed (MSDD) between January 1, 2008 and December 31, 2014, by Event Definition

New Users	Days Supplied	Amount Supplied	Years at Risk*	New Episodes with Events	Number of Events	Eligible Members	Member-Years	New Users per 1,000 Eligible Members	Days Supplied per User	New Episodes with 1,000 Years at Risk	Percent of New Users with Events	Average Number of Events per New User with Event	Percent of Total Users with Lab Results who have Event	Percent of Total Users with Procedures who have Event	
INR lab result															
667,350	17,590,228	24,616,822	51,034.5	41,949	75,261	29,666,578	77,127,463.4	22.50	26.36	821.97	6.29%	1.79	100.00%	N/A	
INR procedure															
667,350	17,590,228	24,616,822	53,009.4	22,217	25,378	29,666,578	77,127,463.4	22.50	26.36	419.11	3.33%	1.14	N/A	100.00%	
INR lab result and procedure on the same day															
667,350	17,590,228	24,616,822	53,925.7	3,920	4,193	29,666,578	77,127,463.4	22.50	26.36	72.69	0.59%	1.07	9.34%	17.64%	
INR lab result with a procedure within 3 days (before or after)															
667,350	17,590,228	24,616,822	52,304.5	25,768	41,748	29,666,578	77,127,463.4	22.50	26.36	492.65	3.86%	1.62	61.43%	N/A	
INR lab result with a procedure in the prior 3 days															
667,350	17,590,228	24,616,822	52,311.3	25,712	40,865	29,666,578	77,127,463.4	22.50	26.36	491.52	3.85%	1.59	61.29%	N/A	
INR lab result with a procedure in the following 3 days															
667,350	17,590,228	24,616,822	53,887.4	4,448	5,748	29,666,578	77,127,463.4	22.50	26.36	82.54	0.67%	1.29	10.60%	N/A	
INR lab result without a procedure within 30 days (before or after)															
667,350	17,590,228	24,616,822	53,807.7	4,519	8,346	29,666,578	77,127,463.4	22.50	26.36	83.98	0.68%	1.85	10.77%	N/A	
INR procedure with a lab result within 3 days (before or after)															
667,350	17,590,228	24,616,822	53,701.9	8,345	9,383	29,666,578	77,127,463.4	22.50	26.36	155.39	1.25%	1.12	N/A	37.56%	
INR procedure with a lab result in the prior 3 days															
667,350	17,590,228	24,616,822	53,889.4	4,472	4,913	29,666,578	77,127,463.4	22.50	26.36	82.98	0.67%	1.10	N/A	20.13%	
INR procedure with a lab result in the following 3 days															
667,350	17,590,228	24,616,822	53,708.0	8,261	9,202	29,666,578	77,127,463.4	22.50	26.36	153.81	1.24%	1.11	N/A	37.18%	
INR procedure without a lab result within 30 days (before or after)															
667,350	17,590,228	24,616,822	53,434.3	13,608	15,341	29,666,578	77,127,463.4	22.50	26.36	254.67	2.04%	1.13	N/A	61.25%	

*Years at risk are truncated at a user's first event.

Table 2a. Summary of Incident Warfarin Use and International Normalized Ratio (INR) Laboratory Results and Procedures in Any Care Setting in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2008 and December 31, 2014, by Event Definition and Year

	New Users	Days Supplied	Amount Supplied	Years at Risk*	New Episodes with Events	Number of Events	Eligible Members	Member-Years	New Users per 1,000 Eligible Members	Days Supplied per User	New Episodes with Events per 1,000 Years at Risk	Percent of New Users with Events	Average Number of Events per New User with Event	Percent of total users with lab results who have event	Percent of total users with procedures who have event
INR lab result															
2008	107,429	2,841,317	3,991,109	6,696.5	30,385	138,511	15,185,409	11,001,858.4	7.07	26.45	4,537.43	28.28%	4.56	100.00%	N/A
2009	120,642	3,204,654	4,409,609	7,568.6	33,690	148,449	15,514,209	12,662,095.7	7.78	26.56	4,451.27	27.93%	4.41	100.00%	N/A
2010	116,802	3,095,486	4,315,452	7,244.2	33,815	150,502	15,117,242	12,332,993.3	7.73	26.50	4,667.88	28.95%	4.45	100.00%	N/A
2011	103,213	2,722,941	3,827,526	6,328.3	30,505	145,915	14,604,756	12,054,439.3	7.07	26.38	4,820.42	29.56%	4.78	100.00%	N/A
2012	98,956	2,614,254	3,658,200	6,002.4	30,151	142,220	14,375,330	11,864,209.5	6.88	26.42	5,023.20	30.47%	4.72	100.00%	N/A
2013	86,963	2,292,378	3,214,945	5,138.4	28,274	135,227	14,395,940	11,840,817.0	6.04	26.36	5,502.50	32.51%	4.78	100.00%	N/A
2014	33,345	819,198	1,199,982	1,662.6	12,801	61,649	12,106,936	5,371,050.2	2.75	24.57	7,699.20	38.39%	4.82	100.00%	N/A
INR procedure															
2008	107,429	2,841,317	3,991,109	3,795.6	76,589	288,463	15,185,409	11,001,858.4	7.07	26.45	20,178.42	71.29%	3.77	N/A	100.00%
2009	120,642	3,204,654	4,409,609	4,152.9	87,567	328,625	15,514,209	12,662,095.7	7.78	26.56	21,085.91	72.58%	3.75	N/A	100.00%
2010	116,802	3,095,486	4,315,452	3,999.2	85,261	325,051	15,117,242	12,332,993.3	7.73	26.50	21,319.47	73.00%	3.81	N/A	100.00%
2011	103,213	2,722,941	3,827,526	3,511.8	75,506	293,571	14,604,756	12,054,439.3	7.07	26.38	21,500.50	73.16%	3.89	N/A	100.00%
2012	98,956	2,614,254	3,658,200	3,297.2	73,676	286,059	14,375,330	11,864,209.5	6.88	26.42	22,345.27	74.45%	3.88	N/A	100.00%
2013	86,963	2,292,378	3,214,945	2,905.3	64,572	252,418	14,395,940	11,840,817.0	6.04	26.36	22,225.50	74.25%	3.91	N/A	100.00%
2014	33,345	819,198	1,199,982	1,004.8	24,489	97,065	12,106,936	5,371,050.2	2.75	24.57	24,372.69	73.44%	3.96	N/A	100.00%
INR lab result and procedure on the same day															
2008	107,429	2,841,317	3,991,109	6,909.2	28,000	118,403	15,185,409	11,001,858.4	7.07	26.45	4,052.54	26.06%	4.23	92.15%	36.56%
2009	120,642	3,204,654	4,409,609	7,783.2	31,278	127,432	15,514,209	12,662,095.7	7.78	26.56	4,018.67	25.93%	4.07	92.84%	35.72%
2010	116,802	3,095,486	4,315,452	7,449.8	31,575	129,391	15,117,242	12,332,993.3	7.73	26.50	4,238.39	27.03%	4.10	93.38%	37.03%
2011	103,213	2,722,941	3,827,526	6,518.5	28,718	123,613	14,604,756	12,054,439.3	7.07	26.38	4,405.65	27.82%	4.30	94.14%	38.03%
2012	98,956	2,614,254	3,658,200	6,205.9	28,170	120,918	14,375,330	11,864,209.5	6.88	26.42	4,539.22	28.47%	4.29	93.43%	38.23%
2013	86,963	2,292,378	3,214,945	5,320.0	26,476	116,406	14,395,940	11,840,817.0	6.04	26.36	4,976.66	30.45%	4.40	93.64%	41.00%
2014	33,345	819,198	1,199,982	1,740.3	12,061	52,923	12,106,936	5,371,050.2	2.75	24.57	6,930.30	36.17%	4.39	94.22%	49.25%
INR lab result with a procedure within 3 days (before or after)															
2008	107,429	2,841,317	3,991,109	6,838.5	28,476	127,520	15,185,409	11,001,858.4	7.07	26.45	4,164.05	26.51%	4.48	93.72%	N/A
2009	120,642	3,204,654	4,409,609	7,709.7	31,758	137,132	15,514,209	12,662,095.7	7.78	26.56	4,119.25	26.32%	4.32	94.27%	N/A
2010	116,802	3,095,486	4,315,452	7,382.8	31,976	139,336	15,117,242	12,332,993.3	7.73	26.50	4,331.14	27.38%	4.36	94.56%	N/A
2011	103,213	2,722,941	3,827,526	6,437.1	29,130	136,111	14,604,756	12,054,439.3	7.07	26.38	4,525.33	28.22%	4.67	95.49%	N/A
2012	98,956	2,614,254	3,658,200	6,113.1	28,739	133,282	14,375,330	11,864,209.5	6.88	26.42	4,701.25	29.04%	4.64	95.32%	N/A
2013	86,963	2,292,378	3,214,945	5,238.5	26,946	127,610	14,395,940	11,840,817.0	6.04	26.36	5,143.84	30.99%	4.74	95.30%	N/A
2014	33,345	819,198	1,199,982	1,700.6	12,303	58,212	12,106,936	5,371,050.2	2.75	24.57	7,234.44	36.90%	4.73	96.11%	N/A

Table 2a. Summary of Incident Warfarin Use and International Normalized Ratio (INR) Laboratory Results and Procedures in Any Care Setting in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2008 and December 31, 2014, by Event Definition and Year

	New Users	Days Supplied	Amount Supplied	Years at Risk*	New Episodes with Events	Number of Events	Eligible Members	Member-Years	New Users per 1,000 Eligible Members	Days Supplied per User	New Episodes with Events per 1,000 Years at Risk	Percent of New Users with Events	Average Number of Events per New User with Event	Percent of total users with lab results who have event	Percent of total users with procedures who have event
INR lab result with a procedure in the prior 3 days															
2008	107,429	2,841,317	3,991,109	6,854.4	28,383	124,992	15,185,409	11,001,858.4	7.07	26.45	4,140.85	26.42%	4.40	93.41%	N/A
2009	120,642	3,204,654	4,409,609	7,729.2	31,627	134,375	15,514,209	12,662,095.7	7.78	26.56	4,091.88	26.22%	4.25	93.88%	N/A
2010	116,802	3,095,486	4,315,452	7,404.0	31,839	136,307	15,117,242	12,332,993.3	7.73	26.50	4,300.23	27.26%	4.28	94.16%	N/A
2011	103,213	2,722,941	3,827,526	6,463.2	29,004	132,137	14,604,756	12,054,439.3	7.07	26.38	4,487.53	28.10%	4.56	95.08%	N/A
2012	98,956	2,614,254	3,658,200	6,141.9	28,528	129,808	14,375,330	11,864,209.5	6.88	26.42	4,644.84	28.83%	4.55	94.62%	N/A
2013	86,963	2,292,378	3,214,945	5,260.5	26,805	124,736	14,395,940	11,840,817.0	6.04	26.36	5,095.51	30.82%	4.65	94.80%	N/A
2014	33,345	819,198	1,199,982	1,709.7	12,247	56,886	12,106,936	5,371,050.2	2.75	24.57	7,163.18	36.73%	4.64	95.67%	N/A
INR lab result with a procedure in the following 3 days															
2008	107,429	2,841,317	3,991,109	6,882.2	28,135	123,346	15,185,409	11,001,858.4	7.07	26.45	4,088.06	26.19%	4.38	92.60%	N/A
2009	120,642	3,204,654	4,409,609	7,750.0	31,458	132,868	15,514,209	12,662,095.7	7.78	26.56	4,059.09	26.08%	4.22	93.37%	N/A
2010	116,802	3,095,486	4,315,452	7,414.2	31,758	135,264	15,117,242	12,332,993.3	7.73	26.50	4,283.41	27.19%	4.26	93.92%	N/A
2011	103,213	2,722,941	3,827,526	6,471.9	28,915	131,499	14,604,756	12,054,439.3	7.07	26.38	4,467.78	28.01%	4.55	94.79%	N/A
2012	98,956	2,614,254	3,658,200	6,155.1	28,455	128,623	14,375,330	11,864,209.5	6.88	26.42	4,622.99	28.76%	4.52	94.37%	N/A
2013	86,963	2,292,378	3,214,945	5,276.4	26,684	123,364	14,395,940	11,840,817.0	6.04	26.36	5,057.20	30.68%	4.62	94.38%	N/A
2014	33,345	819,198	1,199,982	1,721.4	12,151	56,192	12,106,936	5,371,050.2	2.75	24.57	7,058.82	36.44%	4.62	94.92%	N/A
INR lab result without a procedure within 30 days (before or after)															
2008	107,429	2,841,317	3,991,109	8,667.7	1,361	4,596	15,185,409	11,001,858.4	7.07	26.45	157.02	1.27%	3.38	4.48%	N/A
2009	120,642	3,204,654	4,409,609	9,735.6	1,361	4,458	15,514,209	12,662,095.7	7.78	26.56	139.80	1.13%	3.28	4.04%	N/A
2010	116,802	3,095,486	4,315,452	9,424.2	1,286	4,534	15,117,242	12,332,993.3	7.73	26.50	136.46	1.10%	3.53	3.80%	N/A
2011	103,213	2,722,941	3,827,526	8,348.4	919	3,138	14,604,756	12,054,439.3	7.07	26.38	110.08	0.89%	3.41	3.01%	N/A
2012	98,956	2,614,254	3,658,200	8,002.1	885	2,578	14,375,330	11,864,209.5	6.88	26.42	110.60	0.89%	2.91	2.94%	N/A
2013	86,963	2,292,378	3,214,945	7,026.6	817	2,118	14,395,940	11,840,817.0	6.04	26.36	116.27	0.94%	2.59	2.89%	N/A
2014	33,345	819,198	1,199,982	2,496.9	280	735	12,106,936	5,371,050.2	2.75	24.57	112.14	0.84%	2.63	2.19%	N/A
INR procedure with a lab result within 3 days (before or after)															
2008	107,429	2,841,317	3,991,109	6,887.8	28,245	121,831	15,185,409	11,001,858.4	7.07	26.45	4,100.74	26.29%	4.31	N/A	36.88%
2009	120,642	3,204,654	4,409,609	7,754.6	31,588	131,622	15,514,209	12,662,095.7	7.78	26.56	4,073.47	26.18%	4.17	N/A	36.07%
2010	116,802	3,095,486	4,315,452	7,421.4	31,894	133,879	15,117,242	12,332,993.3	7.73	26.50	4,297.56	27.31%	4.20	N/A	37.41%
2011	103,213	2,722,941	3,827,526	6,487.8	29,041	128,070	14,604,756	12,054,439.3	7.07	26.38	4,476.22	28.14%	4.41	N/A	38.46%
2012	98,956	2,614,254	3,658,200	6,168.9	28,615	125,562	14,375,330	11,864,209.5	6.88	26.42	4,638.61	28.92%	4.39	N/A	38.84%
2013	86,963	2,292,378	3,214,945	5,291.4	26,827	120,460	14,395,940	11,840,817.0	6.04	26.36	5,069.97	30.85%	4.49	N/A	41.55%
2014	33,345	819,198	1,199,982	1,728.5	12,197	54,556	12,106,936	5,371,050.2	2.75	24.57	7,056.28	36.58%	4.47	N/A	49.81%

Table 2a. Summary of Incident Warfarin Use and International Normalized Ratio (INR) Laboratory Results and Procedures in Any Care Setting in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2008 and December 31, 2014, by Event Definition and Year

	New Users	Days Supplied	Amount Supplied	Years at Risk*	New Episodes with Events	Number of Events	Eligible Members	Member-Years	New Users per 1,000 Eligible Members	Days Supplied per User	New Episodes with Events per 1,000 Years at Risk	Percent of New Users with Events	Average Number of Events per New User with Event	Percent of total users with lab results who have event	Percent of total users with procedures who have event
INR procedure with a lab result in the prior 3 days															
2008	107,429	2,841,317	3,991,109	6,899.2	28,151	120,317	15,185,409	11,001,858.4	7.07	26.45	4,080.31	26.20%	4.27	N/A	36.76%
2009	120,642	3,204,654	4,409,609	7,770.0	31,477	129,730	15,514,209	12,662,095.7	7.78	26.56	4,051.08	26.09%	4.12	N/A	35.95%
2010	116,802	3,095,486	4,315,452	7,435.8	31,777	131,941	15,117,242	12,332,993.3	7.73	26.50	4,273.49	27.21%	4.15	N/A	37.27%
2011	103,213	2,722,941	3,827,526	6,500.0	28,943	126,357	14,604,756	12,054,439.3	7.07	26.38	4,452.77	28.04%	4.37	N/A	38.33%
2012	98,956	2,614,254	3,658,200	6,181.2	28,488	124,115	14,375,330	11,864,209.5	6.88	26.42	4,608.80	28.79%	4.36	N/A	38.67%
2013	86,963	2,292,378	3,214,945	5,302.4	26,713	119,099	14,395,940	11,840,817.0	6.04	26.36	5,037.94	30.72%	4.46	N/A	41.37%
2014	33,345	819,198	1,199,982	1,733.5	12,153	54,018	12,106,936	5,371,050.2	2.75	24.57	7,010.71	36.45%	4.44	N/A	49.63%
INR procedure with a lab result in the following 3 days															
2008	107,429	2,841,317	3,991,109	6,894.6	28,139	120,638	15,185,409	11,001,858.4	7.07	26.45	4,081.28	26.19%	4.29	N/A	36.74%
2009	120,642	3,204,654	4,409,609	7,764.0	31,442	130,117	15,514,209	12,662,095.7	7.78	26.56	4,049.72	26.06%	4.14	N/A	35.91%
2010	116,802	3,095,486	4,315,452	7,431.9	31,736	132,152	15,117,242	12,332,993.3	7.73	26.50	4,270.24	27.17%	4.16	N/A	37.22%
2011	103,213	2,722,941	3,827,526	6,500.6	28,878	126,456	14,604,756	12,054,439.3	7.07	26.38	4,442.33	27.98%	4.38	N/A	38.25%
2012	98,956	2,614,254	3,658,200	6,187.3	28,363	123,722	14,375,330	11,864,209.5	6.88	26.42	4,584.08	28.66%	4.36	N/A	38.50%
2013	86,963	2,292,378	3,214,945	5,304.5	26,648	118,798	14,395,940	11,840,817.0	6.04	26.36	5,023.63	30.64%	4.46	N/A	41.27%
2014	33,345	819,198	1,199,982	1,733.6	12,129	53,894	12,106,936	5,371,050.2	2.75	24.57	6,996.62	36.37%	4.44	N/A	49.53%
INR procedure without a lab result within 30 days (before or after)															
2008	107,429	2,841,317	3,991,109	5,737.5	47,695	158,306	15,185,409	11,001,858.4	7.07	26.45	8,312.80	44.40%	3.32	N/A	62.27%
2009	120,642	3,204,654	4,409,609	6,333.9	55,084	185,096	15,514,209	12,662,095.7	7.78	26.56	8,696.69	45.66%	3.36	N/A	62.90%
2010	116,802	3,095,486	4,315,452	6,197.0	52,505	179,400	15,117,242	12,332,993.3	7.73	26.50	8,472.62	44.95%	3.42	N/A	61.58%
2011	103,213	2,722,941	3,827,526	5,528.2	45,673	155,386	14,604,756	12,054,439.3	7.07	26.38	8,261.85	44.25%	3.40	N/A	60.49%
2012	98,956	2,614,254	3,658,200	5,288.4	44,165	149,844	14,375,330	11,864,209.5	6.88	26.42	8,351.35	44.63%	3.39	N/A	59.94%
2013	86,963	2,292,378	3,214,945	4,779.7	36,971	122,736	14,395,940	11,840,817.0	6.04	26.36	7,734.94	42.51%	3.32	N/A	57.26%
2014	33,345	819,198	1,199,982	1,825.5	11,944	38,702	12,106,936	5,371,050.2	2.75	24.57	6,542.77	35.82%	3.24	N/A	48.77%

*Years at risk are truncated at a user's first event.

Table 2b. Summary of Incident Warfarin Use and International Normalized Ratio (INR) Laboratory Results and Procedures in the Outpatient* Care Setting in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2008 and December 31, 2014, by Event Definition and Year

	New Users	Days Supplied	Amount Supplied	Years at Risk**	New Episodes with Events	Number of Events	Eligible Members	Member-Years	New Users per 1,000 Eligible Members	Days Supplied per User	New Episodes with Events per 1,000 Years at Risk	Percent of New Users with Events	Average Number of Events per New User with Event	Percent of total users with lab results who have event	Percent of total users with procedures who have event
INR lab result															
2008	107,429	2,841,317	3,991,109	6,791.4	29,828	127,217	15,185,409	11,001,858.4	7.07	26.45	4,392.01	27.77%	4.27	100.00%	N/A
2009	120,642	3,204,654	4,409,609	7,656.2	33,237	136,247	15,514,209	12,662,095.7	7.78	26.56	4,341.18	27.55%	4.10	100.00%	N/A
2010	116,802	3,095,486	4,315,452	7,334.2	33,360	137,212	15,117,242	12,332,993.3	7.73	26.50	4,548.56	28.56%	4.11	100.00%	N/A
2011	103,213	2,722,941	3,827,526	6,437.1	29,950	130,150	14,604,756	12,054,439.3	7.07	26.38	4,652.73	29.02%	4.35	100.00%	N/A
2012	98,956	2,614,254	3,658,200	6,122.2	29,466	126,363	14,375,330	11,864,209.5	6.88	26.42	4,813.00	29.78%	4.29	100.00%	N/A
2013	86,963	2,292,378	3,214,945	5,260.4	27,520	118,966	14,395,940	11,840,817.0	6.04	26.36	5,231.49	31.65%	4.32	100.00%	N/A
2014	33,345	819,198	1,199,982	1,718.3	12,465	53,998	12,106,936	5,371,050.2	2.75	24.57	7,254.31	37.38%	4.33	100.00%	N/A
INR procedure															
2008	107,429	2,841,317	3,991,109	3,967.5	74,297	276,459	15,185,409	11,001,858.4	7.07	26.45	18,726.46	69.16%	3.72	N/A	100.00%
2009	120,642	3,204,654	4,409,609	4,352.1	85,025	314,933	15,514,209	12,662,095.7	7.78	26.56	19,536.52	70.48%	3.70	N/A	100.00%
2010	116,802	3,095,486	4,315,452	4,202.6	82,669	310,858	15,117,242	12,332,993.3	7.73	26.50	19,671.04	70.78%	3.76	N/A	100.00%
2011	103,213	2,722,941	3,827,526	3,695.2	73,150	280,314	14,604,756	12,054,439.3	7.07	26.38	19,796.15	70.87%	3.83	N/A	100.00%
2012	98,956	2,614,254	3,658,200	3,489.5	71,178	272,200	14,375,330	11,864,209.5	6.88	26.42	20,397.71	71.93%	3.82	N/A	100.00%
2013	86,963	2,292,378	3,214,945	3,087.7	62,222	239,407	14,395,940	11,840,817.0	6.04	26.36	20,151.42	71.55%	3.85	N/A	100.00%
2014	33,345	819,198	1,199,982	1,060.0	23,735	92,292	12,106,936	5,371,050.2	2.75	24.57	22,390.82	71.18%	3.89	N/A	100.00%
INR lab result and procedure on the same day															
2008	107,429	2,841,317	3,991,109	6,935.5	27,774	115,405	15,185,409	11,001,858.4	7.07	26.45	4,004.60	25.85%	4.16	93.11%	37.38%
2009	120,642	3,204,654	4,409,609	7,811.5	31,039	124,176	15,514,209	12,662,095.7	7.78	26.56	3,973.50	25.73%	4.00	93.39%	36.51%
2010	116,802	3,095,486	4,315,452	7,488.3	31,241	125,264	15,117,242	12,332,993.3	7.73	26.50	4,171.97	26.75%	4.01	93.65%	37.79%
2011	103,213	2,722,941	3,827,526	6,558.8	28,341	119,325	14,604,756	12,054,439.3	7.07	26.38	4,321.04	27.46%	4.21	94.63%	38.74%
2012	98,956	2,614,254	3,658,200	6,250.3	27,735	116,057	14,375,330	11,864,209.5	6.88	26.42	4,437.37	28.03%	4.18	94.13%	38.97%
2013	86,963	2,292,378	3,214,945	5,367.6	26,001	111,216	14,395,940	11,840,817.0	6.04	26.36	4,844.08	29.90%	4.28	94.48%	41.79%
2014	33,345	819,198	1,199,982	1,761.8	11,849	50,150	12,106,936	5,371,050.2	2.75	24.57	6,725.47	35.53%	4.23	95.06%	49.92%
INR lab result with a procedure within 3 days (before or after)															
2008	107,429	2,841,317	3,991,109	6,917.8	27,963	118,120	15,185,409	11,001,858.4	7.07	26.45	4,042.21	26.03%	4.22	93.75%	N/A
2009	120,642	3,204,654	4,409,609	7,790.6	31,276	126,606	15,514,209	12,662,095.7	7.78	26.56	4,014.60	25.92%	4.05	94.10%	N/A
2010	116,802	3,095,486	4,315,452	7,467.5	31,468	127,773	15,117,242	12,332,993.3	7.73	26.50	4,213.98	26.94%	4.06	94.33%	N/A
2011	103,213	2,722,941	3,827,526	6,532.8	28,598	122,646	14,604,756	12,054,439.3	7.07	26.38	4,377.60	27.71%	4.29	95.49%	N/A
2012	98,956	2,614,254	3,658,200	6,218.9	28,085	119,435	14,375,330	11,864,209.5	6.88	26.42	4,516.04	28.38%	4.25	95.31%	N/A
2013	86,963	2,292,378	3,214,945	5,345.7	26,251	113,544	14,395,940	11,840,817.0	6.04	26.36	4,910.67	30.19%	4.33	95.39%	N/A
2014	33,345	819,198	1,199,982	1,751.3	11,970	51,418	12,106,936	5,371,050.2	2.75	24.57	6,834.86	35.90%	4.30	96.03%	N/A

Table 2b. Summary of Incident Warfarin Use and International Normalized Ratio (INR) Laboratory Results and Procedures in the Outpatient* Care Setting in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2008 and December 31, 2014, by Event Definition and Year

	New Users	Days Supplied	Amount Supplied	Years at Risk**	New Episodes with Events	Number of Events	Eligible Members	Member-Years	New Users per 1,000 Eligible Members	Days Supplied per User	New Episodes with Events per 1,000 Years at Risk	Percent of New Users with Events	Average Number of Events per New User with Event	Percent of total users with lab results who have event	Percent of total users with procedures who have event
INR lab result with a procedure in the prior 3 days															
2008	107,429	2,841,317	3,991,109	6,926.1	27,898	116,923	15,185,409	11,001,858.4	7.07	26.45	4,027.94	25.97%	4.19	93.53%	N/A
2009	120,642	3,204,654	4,409,609	7,799.3	31,190	125,660	15,514,209	12,662,095.7	7.78	26.56	3,999.06	25.85%	4.03	93.84%	N/A
2010	116,802	3,095,486	4,315,452	7,478.2	31,370	126,650	15,117,242	12,332,993.3	7.73	26.50	4,194.89	26.86%	4.04	94.03%	N/A
2011	103,213	2,722,941	3,827,526	6,546.6	28,493	121,106	14,604,756	12,054,439.3	7.07	26.38	4,352.36	27.61%	4.25	95.14%	N/A
2012	98,956	2,614,254	3,658,200	6,236.3	27,913	117,966	14,375,330	11,864,209.5	6.88	26.42	4,475.86	28.21%	4.23	94.73%	N/A
2013	86,963	2,292,378	3,214,945	5,356.0	26,152	112,745	14,395,940	11,840,817.0	6.04	26.36	4,882.75	30.07%	4.31	95.03%	N/A
2014	33,345	819,198	1,199,982	1,755.7	11,928	50,986	12,106,936	5,371,050.2	2.75	24.57	6,793.87	35.77%	4.27	95.69%	N/A
INR lab result with a procedure in the following 3 days															
2008	107,429	2,841,317	3,991,109	6,924.6	27,870	117,054	15,185,409	11,001,858.4	7.07	26.45	4,024.81	25.94%	4.20	93.44%	N/A
2009	120,642	3,204,654	4,409,609	7,800.1	31,154	125,513	15,514,209	12,662,095.7	7.78	26.56	3,994.07	25.82%	4.03	93.73%	N/A
2010	116,802	3,095,486	4,315,452	7,474.4	31,376	126,819	15,117,242	12,332,993.3	7.73	26.50	4,197.79	26.86%	4.04	94.05%	N/A
2011	103,213	2,722,941	3,827,526	6,539.6	28,511	121,583	14,604,756	12,054,439.3	7.07	26.38	4,359.76	27.62%	4.26	95.20%	N/A
2012	98,956	2,614,254	3,658,200	6,227.5	27,965	118,400	14,375,330	11,864,209.5	6.88	26.42	4,490.53	28.26%	4.23	94.91%	N/A
2013	86,963	2,292,378	3,214,945	5,353.2	26,145	112,609	14,395,940	11,840,817.0	6.04	26.36	4,884.00	30.06%	4.31	95.00%	N/A
2014	33,345	819,198	1,199,982	1,755.3	11,914	50,931	12,106,936	5,371,050.2	2.75	24.57	6,787.38	35.73%	4.27	95.58%	N/A
INR lab result without a procedure within 30 days (before or after)															
2008	107,429	2,841,317	3,991,109	8,659.2	1,488	4,812	15,185,409	11,001,858.4	7.07	26.45	171.84	1.39%	3.23	4.99%	N/A
2009	120,642	3,204,654	4,409,609	9,724.9	1,520	4,816	15,514,209	12,662,095.7	7.78	26.56	156.30	1.26%	3.17	4.57%	N/A
2010	116,802	3,095,486	4,315,452	9,414.5	1,445	4,794	15,117,242	12,332,993.3	7.73	26.50	153.49	1.24%	3.32	4.33%	N/A
2011	103,213	2,722,941	3,827,526	8,341.6	1,032	3,356	14,604,756	12,054,439.3	7.07	26.38	123.72	1.00%	3.25	3.45%	N/A
2012	98,956	2,614,254	3,658,200	7,997.7	980	2,863	14,375,330	11,864,209.5	6.88	26.42	122.53	0.99%	2.92	3.33%	N/A
2013	86,963	2,292,378	3,214,945	7,022.5	893	2,313	14,395,940	11,840,817.0	6.04	26.36	127.16	1.03%	2.59	3.24%	N/A
2014	33,345	819,198	1,199,982	2,494.0	337	791	12,106,936	5,371,050.2	2.75	24.57	135.13	1.01%	2.35	2.70%	N/A
INR procedure with a lab result within 3 days (before or after)															
2008	107,429	2,841,317	3,991,109	6,919.5	27,961	117,826	15,185,409	11,001,858.4	7.07	26.45	4,040.88	26.03%	4.21	N/A	37.63%
2009	120,642	3,204,654	4,409,609	7,791.1	31,261	127,218	15,514,209	12,662,095.7	7.78	26.56	4,012.38	25.91%	4.07	N/A	36.77%
2010	116,802	3,095,486	4,315,452	7,466.0	31,489	128,791	15,117,242	12,332,993.3	7.73	26.50	4,217.63	26.96%	4.09	N/A	38.09%
2011	103,213	2,722,941	3,827,526	6,532.8	28,611	123,175	14,604,756	12,054,439.3	7.07	26.38	4,379.58	27.72%	4.31	N/A	39.11%
2012	98,956	2,614,254	3,658,200	6,218.7	28,098	120,408	14,375,330	11,864,209.5	6.88	26.42	4,518.29	28.39%	4.29	N/A	39.48%
2013	86,963	2,292,378	3,214,945	5,344.0	26,267	115,059	14,395,940	11,840,817.0	6.04	26.36	4,915.21	30.20%	4.38	N/A	42.21%
2014	33,345	819,198	1,199,982	1,750.7	11,963	52,003	12,106,936	5,371,050.2	2.75	24.57	6,833.08	35.88%	4.35	N/A	50.40%

Table 2b. Summary of Incident Warfarin Use and International Normalized Ratio (INR) Laboratory Results and Procedures in the Outpatient* Care Setting in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2008 and December 31, 2014, by Event Definition and Year

	New Users	Days Supplied	Amount Supplied	Years at Risk**	New Episodes with Events	Number of Events	Eligible Members	Member-Years	New Users per 1,000 Eligible Members	Days Supplied per User	New Episodes with Events per 1,000 Years at Risk	Percent of New Users with Events	Average Number of Events per New User with Event	Percent of total users with lab results who have event	Percent of total users with procedures who have event
INR procedure with a lab result in the prior 3 days															
2008	107,429	2,841,317	3,991,109	6,928.7	27,881	116,751	15,185,409	11,001,858.4	7.07	26.45	4,024.02	25.95%	4.19	N/A	37.53%
2009	120,642	3,204,654	4,409,609	7,803.6	31,165	125,782	15,514,209	12,662,095.7	7.78	26.56	3,993.68	25.83%	4.04	N/A	36.65%
2010	116,802	3,095,486	4,315,452	7,478.4	31,394	127,171	15,117,242	12,332,993.3	7.73	26.50	4,197.95	26.88%	4.05	N/A	37.98%
2011	103,213	2,722,941	3,827,526	6,543.9	28,527	121,682	14,604,756	12,054,439.3	7.07	26.38	4,359.32	27.64%	4.27	N/A	39.00%
2012	98,956	2,614,254	3,658,200	6,231.2	27,985	118,928	14,375,330	11,864,209.5	6.88	26.42	4,491.12	28.28%	4.25	N/A	39.32%
2013	86,963	2,292,378	3,214,945	5,356.0	26,157	113,596	14,395,940	11,840,817.0	6.04	26.36	4,883.66	30.08%	4.34	N/A	42.04%
2014	33,345	819,198	1,199,982	1,757.0	11,920	51,238	12,106,936	5,371,050.2	2.75	24.57	6,784.42	35.75%	4.30	N/A	50.22%
INR procedure with a lab result in the following 3 days															
2008	107,429	2,841,317	3,991,109	6,924.1	27,888	116,894	15,185,409	11,001,858.4	7.07	26.45	4,027.67	25.96%	4.19	N/A	37.54%
2009	120,642	3,204,654	4,409,609	7,796.7	31,168	126,058	15,514,209	12,662,095.7	7.78	26.56	3,997.59	25.84%	4.04	N/A	36.66%
2010	116,802	3,095,486	4,315,452	7,473.2	31,372	127,442	15,117,242	12,332,993.3	7.73	26.50	4,197.93	26.86%	4.06	N/A	37.95%
2011	103,213	2,722,941	3,827,526	6,542.4	28,487	121,768	14,604,756	12,054,439.3	7.07	26.38	4,354.20	27.60%	4.27	N/A	38.94%
2012	98,956	2,614,254	3,658,200	6,232.4	27,904	118,796	14,375,330	11,864,209.5	6.88	26.42	4,477.27	28.20%	4.26	N/A	39.20%
2013	86,963	2,292,378	3,214,945	5,352.2	26,156	113,663	14,395,940	11,840,817.0	6.04	26.36	4,886.94	30.08%	4.35	N/A	42.04%
2014	33,345	819,198	1,199,982	1,754.1	11,913	51,398	12,106,936	5,371,050.2	2.75	24.57	6,791.52	35.73%	4.31	N/A	50.19%
INR procedure without a lab result within 30 days (before or after)															
2008	107,429	2,841,317	3,991,109	5,871.0	45,753	151,081	15,185,409	11,001,858.4	7.07	26.45	7,793.05	42.59%	3.30	N/A	61.58%
2009	120,642	3,204,654	4,409,609	6,486.8	52,924	176,933	15,514,209	12,662,095.7	7.78	26.56	8,158.72	43.87%	3.34	N/A	62.25%
2010	116,802	3,095,486	4,315,452	6,343.5	50,412	171,387	15,117,242	12,332,993.3	7.73	26.50	7,947.00	43.16%	3.40	N/A	60.98%
2011	103,213	2,722,941	3,827,526	5,655.6	43,843	148,040	14,604,756	12,054,439.3	7.07	26.38	7,752.12	42.48%	3.38	N/A	59.94%
2012	98,956	2,614,254	3,658,200	5,417.3	42,317	142,444	14,375,330	11,864,209.5	6.88	26.42	7,811.44	42.76%	3.37	N/A	59.45%
2013	86,963	2,292,378	3,214,945	4,896.5	35,326	116,302	14,395,940	11,840,817.0	6.04	26.36	7,214.47	40.62%	3.29	N/A	56.77%
2014	33,345	819,198	1,199,982	1,854.8	11,474	36,883	12,106,936	5,371,050.2	2.75	24.57	6,186.16	34.41%	3.21	N/A	48.34%

*For this request, laboratory results with a patient location of "Unknown" were included in the outpatient care setting.

**Years at risk are truncated at a user's first event.

Table 2c. Summary of Incident Warfarin Use and International Normalized Ratio (INR) Laboratory Results and Procedures in the Inpatient Care Setting in the Mini-sentinel Distributed Database (MSDD) between January 1, 2008 and December 31, 2014, by Event Definition and Year

	New Users	Days Supplied	Amount Supplied	Years at Risk*	New Episodes with Events	Number of Events	Eligible Members	Member-Years	New Users per 1,000 Eligible Members	Days Supplied per User	New Episodes with Events per 1,000 Years at Risk	Percent of New Users with Events	Average Number of New User Events per with Event	Percent of total users with lab results who have event	Percent of total users with procedures who have event
INR lab result															
2008	107,429	2,841,317	3,991,109	8,382.9	5,000	9,441	15,185,409	11,001,858.4	7.07	26.45	596.45	4.65%	1.89	100.00%	N/A
2009	120,642	3,204,654	4,409,609	9,400.8	5,618	10,135	15,514,209	12,662,095.7	7.78	26.56	597.61	4.66%	1.80	100.00%	N/A
2010	116,802	3,095,486	4,315,452	9,059.0	6,032	11,126	15,117,242	12,332,993.3	7.73	26.50	665.86	5.16%	1.84	100.00%	N/A
2011	103,213	2,722,941	3,827,526	7,865.7	7,260	13,050	14,604,756	12,054,439.3	7.07	26.38	922.99	7.03%	1.80	100.00%	N/A
2012	98,956	2,614,254	3,658,200	7,526.9	7,184	12,603	14,375,330	11,864,209.5	6.88	26.42	954.44	7.26%	1.75	100.00%	N/A
2013	86,963	2,292,378	3,214,945	6,539.0	7,279	13,017	14,395,940	11,840,817.0	6.04	26.36	1,113.16	8.37%	1.79	100.00%	N/A
2014	33,345	819,198	1,199,982	2,260.2	3,576	5,889	12,106,936	5,371,050.2	2.75	24.57	1,582.16	10.72%	1.65	100.00%	N/A
INR procedure															
2008	107,429	2,841,317	3,991,109	8,578.8	3,489	3,955	15,185,409	11,001,858.4	7.07	26.45	406.70	3.25%	1.13	N/A	100.00%
2009	120,642	3,204,654	4,409,609	9,613.4	3,974	4,443	15,514,209	12,662,095.7	7.78	26.56	413.38	3.29%	1.12	N/A	100.00%
2010	116,802	3,095,486	4,315,452	9,304.5	3,840	4,728	15,117,242	12,332,993.3	7.73	26.50	412.70	3.29%	1.23	N/A	100.00%
2011	103,213	2,722,941	3,827,526	8,227.3	3,545	3,958	14,604,756	12,054,439.3	7.07	26.38	430.88	3.43%	1.12	N/A	100.00%
2012	98,956	2,614,254	3,658,200	7,903.8	3,174	3,551	14,375,330	11,864,209.5	6.88	26.42	401.58	3.21%	1.12	N/A	100.00%
2013	86,963	2,292,378	3,214,945	6,924.3	3,045	3,436	14,395,940	11,840,817.0	6.04	26.36	439.76	3.50%	1.13	N/A	100.00%
2014	33,345	819,198	1,199,982	2,457.4	1,150	1,307	12,106,936	5,371,050.2	2.75	24.57	467.98	3.45%	1.14	N/A	100.00%
INR lab result and procedure on the same day															
2008	107,429	2,841,317	3,991,109	8,726.6	456	490	15,185,409	11,001,858.4	7.07	26.45	52.25	0.42%	1.07	9.12%	13.07%
2009	120,642	3,204,654	4,409,609	9,792.3	476	501	15,514,209	12,662,095.7	7.78	26.56	48.61	0.39%	1.05	8.47%	11.98%
2010	116,802	3,095,486	4,315,452	9,476.7	503	537	15,117,242	12,332,993.3	7.73	26.50	53.08	0.43%	1.07	8.34%	13.10%
2011	103,213	2,722,941	3,827,526	8,375.4	562	609	14,604,756	12,054,439.3	7.07	26.38	67.10	0.54%	1.08	7.74%	15.85%
2012	98,956	2,614,254	3,658,200	8,026.7	672	701	14,375,330	11,864,209.5	6.88	26.42	83.72	0.68%	1.04	9.35%	21.17%
2013	86,963	2,292,378	3,214,945	7,034.5	842	901	14,395,940	11,840,817.0	6.04	26.36	119.70	0.97%	1.07	11.57%	27.65%
2014	33,345	819,198	1,199,982	2,493.4	409	454	12,106,936	5,371,050.2	2.75	24.57	164.03	1.23%	1.11	11.44%	35.57%
INR lab result with a procedure within 3 days (before or after)															
2008	107,429	2,841,317	3,991,109	8,540.6	3,054	5,249	15,185,409	11,001,858.4	7.07	26.45	357.59	2.84%	1.72	61.08%	N/A
2009	120,642	3,204,654	4,409,609	9,571.6	3,495	5,773	15,514,209	12,662,095.7	7.78	26.56	365.14	2.90%	1.65	62.21%	N/A
2010	116,802	3,095,486	4,315,452	9,254.2	3,525	5,903	15,117,242	12,332,993.3	7.73	26.50	380.91	3.02%	1.67	58.44%	N/A
2011	103,213	2,722,941	3,827,526	8,094.1	4,359	7,073	14,604,756	12,054,439.3	7.07	26.38	538.54	4.22%	1.62	60.04%	N/A
2012	98,956	2,614,254	3,658,200	7,732.6	4,554	7,185	14,375,330	11,864,209.5	6.88	26.42	588.94	4.60%	1.58	63.39%	N/A
2013	86,963	2,292,378	3,214,945	6,751.4	4,542	7,215	14,395,940	11,840,817.0	6.04	26.36	672.75	5.22%	1.59	62.40%	N/A
2014	33,345	819,198	1,199,982	2,359.9	2,239	3,350	12,106,936	5,371,050.2	2.75	24.57	948.76	6.71%	1.50	62.61%	N/A

Table 2c. Summary of Incident Warfarin Use and International Normalized Ratio (INR) Laboratory Results and Procedures in the Inpatient Care Setting in the Mini-sentinel Distributed Database (MSDD) between January 1, 2008 and December 31, 2014, by Event Definition and Year

	New Users	Days Supplied	Amount Supplied	Years at Risk*	New Episodes with Events	Number of Events	Eligible Members	Member-Years	New Users per 1,000 Eligible Members	Days Supplied per User	New Episodes with Events per 1,000 Years at Risk	Percent of New Users with Events	Average Number of Events per New User with Event	Percent of total users with lab results who have event	Percent of total users with procedures who have event
INR lab result with a procedure in the prior 3 days															
2008	107,429	2,841,317	3,991,109	8,541.3	3,047	5,136	15,185,409	11,001,858.4	7.07	26.45	356.74	2.84%	1.69	60.94%	N/A
2009	120,642	3,204,654	4,409,609	9,572.6	3,487	5,659	15,514,209	12,662,095.7	7.78	26.56	364.27	2.89%	1.62	62.07%	N/A
2010	116,802	3,095,486	4,315,452	9,256.4	3,504	5,754	15,117,242	12,332,993.3	7.73	26.50	378.55	3.00%	1.64	58.09%	N/A
2011	103,213	2,722,941	3,827,526	8,095.0	4,352	6,924	14,604,756	12,054,439.3	7.07	26.38	537.62	4.22%	1.59	59.94%	N/A
2012	98,956	2,614,254	3,658,200	7,733.4	4,547	7,042	14,375,330	11,864,209.5	6.88	26.42	587.97	4.59%	1.55	63.29%	N/A
2013	86,963	2,292,378	3,214,945	6,752.2	4,540	7,060	14,395,940	11,840,817.0	6.04	26.36	672.37	5.22%	1.56	62.37%	N/A
2014	33,345	819,198	1,199,982	2,360.4	2,235	3,290	12,106,936	5,371,050.2	2.75	24.57	946.89	6.70%	1.47	62.50%	N/A
INR lab result with a procedure in the following 3 days															
2008	107,429	2,841,317	3,991,109	8,722.1	524	699	15,185,409	11,001,858.4	7.07	26.45	60.08	0.49%	1.33	10.48%	N/A
2009	120,642	3,204,654	4,409,609	9,787.4	542	706	15,514,209	12,662,095.7	7.78	26.56	55.38	0.45%	1.30	9.65%	N/A
2010	116,802	3,095,486	4,315,452	9,469.3	603	794	15,117,242	12,332,993.3	7.73	26.50	63.68	0.52%	1.32	10.00%	N/A
2011	103,213	2,722,941	3,827,526	8,370.1	643	883	14,604,756	12,054,439.3	7.07	26.38	76.82	0.62%	1.37	8.86%	N/A
2012	98,956	2,614,254	3,658,200	8,020.3	761	940	14,375,330	11,864,209.5	6.88	26.42	94.88	0.77%	1.24	10.59%	N/A
2013	86,963	2,292,378	3,214,945	7,028.1	920	1,157	14,395,940	11,840,817.0	6.04	26.36	130.90	1.06%	1.26	12.64%	N/A
2014	33,345	819,198	1,199,982	2,490.1	455	569	12,106,936	5,371,050.2	2.75	24.57	182.72	1.36%	1.25	12.72%	N/A
INR lab result without a procedure within 30 days (before or after)															
2008	107,429	2,841,317	3,991,109	8,723.6	338	662	15,185,409	11,001,858.4	7.07	26.45	38.75	0.31%	1.96	6.76%	N/A
2009	120,642	3,204,654	4,409,609	9,786.3	435	775	15,514,209	12,662,095.7	7.78	26.56	44.45	0.36%	1.78	7.74%	N/A
2010	116,802	3,095,486	4,315,452	9,454.4	722	1,254	15,117,242	12,332,993.3	7.73	26.50	76.37	0.62%	1.74	11.97%	N/A
2011	103,213	2,722,941	3,827,526	8,354.4	746	1,443	14,604,756	12,054,439.3	7.07	26.38	89.29	0.72%	1.93	10.28%	N/A
2012	98,956	2,614,254	3,658,200	7,996.4	863	1,535	14,375,330	11,864,209.5	6.88	26.42	107.92	0.87%	1.78	12.01%	N/A
2013	86,963	2,292,378	3,214,945	7,010.2	952	1,881	14,395,940	11,840,817.0	6.04	26.36	135.80	1.09%	1.98	13.08%	N/A
2014	33,345	819,198	1,199,982	2,482.4	463	796	12,106,936	5,371,050.2	2.75	24.57	186.51	1.39%	1.72	12.95%	N/A
INR procedure with a lab result within 3 days (before or after)															
2008	107,429	2,841,317	3,991,109	8,691.1	1,185	1,349	15,185,409	11,001,858.4	7.07	26.45	136.35	1.10%	1.14	N/A	33.96%
2009	120,642	3,204,654	4,409,609	9,752.3	1,243	1,376	15,514,209	12,662,095.7	7.78	26.56	127.46	1.03%	1.11	N/A	31.28%
2010	116,802	3,095,486	4,315,452	9,434.6	1,286	1,480	15,117,242	12,332,993.3	7.73	26.50	136.31	1.10%	1.15	N/A	33.49%
2011	103,213	2,722,941	3,827,526	8,335.5	1,372	1,531	14,604,756	12,054,439.3	7.07	26.38	164.60	1.33%	1.12	N/A	38.70%
2012	98,956	2,614,254	3,658,200	7,998.7	1,254	1,388	14,375,330	11,864,209.5	6.88	26.42	156.78	1.27%	1.11	N/A	39.51%
2013	86,963	2,292,378	3,214,945	7,008.4	1,353	1,515	14,395,940	11,840,817.0	6.04	26.36	193.05	1.56%	1.12	N/A	44.43%
2014	33,345	819,198	1,199,982	2,481.3	652	744	12,106,936	5,371,050.2	2.75	24.57	262.76	1.96%	1.14	N/A	56.70%

Table 2c. Summary of Incident Warfarin Use and International Normalized Ration (INR) Laboratory Results and Procedures in the Inpatient Care Setting in the Mini-sentinel Distributed Database (MSDD) between January 1, 2008 and December 31, 2014, by Event Definition and Year

	New Users	Days Supplied	Amount Supplied	Years at Risk*	New Episodes with Events	Number of Events	Eligible Members	Member-Years	New Users per 1,000 Eligible Members	Days Supplied per User	New Episodes with Events per 1,000 Years at Risk	Percent of New Users with Events	Average Number of Events per New User with Event	Percent of total users with lab results who have event	Percent of total users with procedures who have event
INR procedure with a lab result in the prior 3 days															
2008	107,429	2,841,317	3,991,109	8,722.4	524	577	15,185,409	11,001,858.4	7.07	26.45	60.07	0.49%	1.10	N/A	15.02%
2009	120,642	3,204,654	4,409,609	9,787.5	548	591	15,514,209	12,662,095.7	7.78	26.56	55.99	0.45%	1.08	N/A	13.79%
2010	116,802	3,095,486	4,315,452	9,468.8	617	708	15,117,242	12,332,993.3	7.73	26.50	65.16	0.53%	1.15	N/A	16.07%
2011	103,213	2,722,941	3,827,526	8,370.6	644	709	14,604,756	12,054,439.3	7.07	26.38	76.94	0.62%	1.10	N/A	18.17%
2012	98,956	2,614,254	3,658,200	8,020.9	760	809	14,375,330	11,864,209.5	6.88	26.42	94.75	0.77%	1.06	N/A	23.94%
2013	86,963	2,292,378	3,214,945	7,028.6	925	1,010	14,395,940	11,840,817.0	6.04	26.36	131.60	1.06%	1.09	N/A	30.38%
2014	33,345	819,198	1,199,982	2,490.5	454	509	12,106,936	5,371,050.2	2.75	24.57	182.29	1.36%	1.12	N/A	39.48%
INR procedure with a lab result in the following 3 days															
2008	107,429	2,841,317	3,991,109	8,691.5	1,180	1,334	15,185,409	11,001,858.4	7.07	26.45	135.76	1.10%	1.13	N/A	33.82%
2009	120,642	3,204,654	4,409,609	9,753.5	1,227	1,351	15,514,209	12,662,095.7	7.78	26.56	125.80	1.02%	1.10	N/A	30.88%
2010	116,802	3,095,486	4,315,452	9,437.1	1,253	1,393	15,117,242	12,332,993.3	7.73	26.50	132.77	1.07%	1.11	N/A	32.63%
2011	103,213	2,722,941	3,827,526	8,336.1	1,362	1,519	14,604,756	12,054,439.3	7.07	26.38	163.39	1.32%	1.12	N/A	38.42%
2012	98,956	2,614,254	3,658,200	7,999.2	1,246	1,373	14,375,330	11,864,209.5	6.88	26.42	155.77	1.26%	1.10	N/A	39.26%
2013	86,963	2,292,378	3,214,945	7,008.8	1,347	1,497	14,395,940	11,840,817.0	6.04	26.36	192.19	1.55%	1.11	N/A	44.24%
2014	33,345	819,198	1,199,982	2,481.8	646	735	12,106,936	5,371,050.2	2.75	24.57	260.30	1.94%	1.14	N/A	56.17%
INR procedure without a lab result within 30 days (before or after)															
2008	107,429	2,841,317	3,991,109	8,637.3	2,257	2,510	15,185,409	11,001,858.4	7.07	26.45	261.31	2.10%	1.11	N/A	64.69%
2009	120,642	3,204,654	4,409,609	9,679.0	2,700	2,993	15,514,209	12,662,095.7	7.78	26.56	278.96	2.24%	1.11	N/A	67.94%
2010	116,802	3,095,486	4,315,452	9,375.5	2,497	2,966	15,117,242	12,332,993.3	7.73	26.50	266.33	2.14%	1.19	N/A	65.03%
2011	103,213	2,722,941	3,827,526	8,298.1	2,129	2,363	14,604,756	12,054,439.3	7.07	26.38	256.57	2.06%	1.11	N/A	60.06%
2012	98,956	2,614,254	3,658,200	7,962.3	1,883	2,107	14,375,330	11,864,209.5	6.88	26.42	236.49	1.90%	1.12	N/A	59.33%
2013	86,963	2,292,378	3,214,945	6,992.4	1,662	1,869	14,395,940	11,840,817.0	6.04	26.36	237.69	1.91%	1.12	N/A	54.58%
2014	33,345	819,198	1,199,982	2,489.8	480	533	12,106,936	5,371,050.2	2.75	24.57	192.79	1.44%	1.11	N/A	41.74%

*Years at risk are truncated at a user's first event.

Appendix A. Dates of Available Data for Each Data Partner (DP) in the Mini-Sentinel Distributed Database (MSDD) as of Request End Date (December 31, 2014)

DP ID	DP Start Date	DP End Date
DP01	1/1/2008	9/30/2014
DP02	1/1/2008	4/30/2014
DP03	1/1/2008	10/31/2014
DP04	1/1/2008	6/30/2012
DP05	1/1/2008	6/30/2012
DP06	1/1/2008	4/30/2014
DP07	1/1/2008	7/31/2014
DP08	1/1/2008	7/31/2014
DP09	1/1/2008	4/30/2014
DP10	1/1/2008	6/30/2014
DP11	1/1/2008	3/31/2014

Appendix B. List of Healthcare Common Procedure Coding System (HCPCS) and Current Procedural Terminology, Fourth Edition (CPT-4) Codes Used to Define International Normalized Ratio (INR) Procedures in this Request

Code	Description	Code Type
3555F	PT HAD INR MEASUREMENT PERFORMED	HCPCS
85610	PROTHROMBIN TIME	CPT-4

Appendix C. List of Generic and Brand Drug Names Used to Define Warfarin Exposure in this Request

Generic Name	Brand Name
WARFARIN SODIUM	JANTOVEN
WARFARIN SODIUM	COUMADIN

Appendix D. Specifications for Parameters in this Request

This request utilized Modular Program #3 to examine availability of International Normalized Ratio (INR) laboratory test values and INR test procedures among incident warfarin users.

Query Period: January 1, 2008 to December 31, 2014

Enrollment Gap: 45 days

Age Groups: 40+ years

Coverage Requirement: Medical and Drug Coverage

Enrollment Requirement: 183 days

Lab Date Algorithm: lab date, result date

Scenario	Drug/Exposure			Event/Outcome						
	Incident Exposure	Washout (days)	Exposed Time Duration (days)	Event/Outcome	Care Setting/Principal Diagnosis Indicator	Time Window	Event Date	Washout (days)	Event De-duplication	Blackout Period (days)
1	Warfarin	183	30	INR lab test result ≥ 0	Any	N/A	N/A	0	2	0
2	Warfarin	183	30	INR test procedure	Any	N/A	N/A	0	2	0
3	Warfarin	183	30	INR lab test result ≥ 0 and INR test procedure	Any	Same day	N/A	0	2	0
4	Warfarin	183	30	INR lab test result ≥ 0 and INR test procedure	Any	+ 3 days	Result date	0	2	0
5	Warfarin	183	30	INR lab test result ≥ 0 and INR test procedure	Any	- 3 days	Result date	0	2	0
6	Warfarin	183	30	INR lab test result ≥ 0 and INR test procedure	Any	+/- 3 days	Result date	0	2	0
7	Warfarin	183	30	INR lab test result ≥ 0 without an INR test procedure	Any	+/- 30 days	Result date	0	2	0
8	Warfarin	183	30	INR test procedure and INR lab test result ≥ 0	Any	+ 3 days	Procedure Date	0	2	0
9	Warfarin	183	30	INR test procedure and INR lab test result ≥ 0	Any	- 3 days	Procedure Date	0	2	0

Scenario	Drug/Exposure			Event/Outcome						
	Incident Exposure	Washout (days)	Exposed Time Duration (days)	Event/Outcome	Care Setting/Principal Diagnosis Indicator	Time Window	Event Date	Washout (days)	Event De-duplication	Blackout Period (days)
10	Warfarin	183	30	INR test procedure <i>and</i> INR lab test result ≥ 0	Any	+/- 3 days	Procedure Date	0	2	0
11	Warfarin	183	30	INR test procedure <i>without</i> an INR lab test result ≥ 0	Any	+/- 30 days	Procedure Date	0	2	0
12	Warfarin	183	30	INR lab test result ≥ 0	Outpatient or Unknown	N/A	N/A	0	2	0
13	Warfarin	183	30	INR test procedure	Outpatient or Unknown	N/A	N/A	0	2	0
14	Warfarin	183	30	INR lab test result ≥ 0 <i>and</i> INR test procedure	Outpatient or Unknown	Same day	N/A	0	2	0
15	Warfarin	183	30	INR lab test result ≥ 0 <i>and</i> INR test procedure	Outpatient or Unknown	+ 3 days	Result date	0	2	0
16	Warfarin	183	30	INR lab test result ≥ 0 <i>and</i> INR test procedure	Outpatient or Unknown	- 3 days	Result date	0	2	0
17	Warfarin	183	30	INR lab test result ≥ 0 <i>and</i> INR test procedure	Outpatient or Unknown	+/- 3 days	Result date	0	2	0
18	Warfarin	183	30	INR lab test result ≥ 0 <i>without</i> an INR test procedure	Outpatient or Unknown	+/- 30 days	Result date	0	2	0
19	Warfarin	183	30	INR test procedure <i>and</i> INR lab test result ≥ 0	Outpatient or Unknown	+ 3 days	Procedure Date	0	2	0
20	Warfarin	183	30	INR test procedure <i>and</i> INR lab test result ≥ 0	Outpatient or Unknown	- 3 days	Procedure Date	0	2	0
21	Warfarin	183	30	INR test procedure <i>and</i> INR lab test result ≥ 0	Outpatient or Unknown	+/- 3 days	Procedure Date	0	2	0
22	Warfarin	183	30	INR test procedure <i>without</i> an INR lab test result ≥ 0	Outpatient or Unknown	+/- 30 days	Procedure Date	0	2	0

Scenario	Drug/Exposure			Event/Outcome						
	Incident Exposure	Washout (days)	Exposed Time Duration (days)	Event/Outcome	Care Setting/Principal Diagnosis Indicator	Time Window	Event Date	Washout (days)	Event De-duplication	Blackout Period (days)
23	Warfarin	183	30	INR lab test result ≥ 0	Inpatient	N/A	N/A	0	2	0
24	Warfarin	183	30	INR test procedure	Inpatient	N/A	N/A	0	2	0
25	Warfarin	183	30	INR lab test result ≥ 0 and INR test procedure	Inpatient	Same day	N/A	0	2	0
26	Warfarin	183	30	INR lab test result ≥ 0 and INR test procedure	Inpatient	+ 3 days	Result date	0	2	0
27	Warfarin	183	30	INR lab test result ≥ 0 and INR test procedure	Inpatient	- 3 days	Result date	0	2	0
28	Warfarin	183	30	INR lab test result ≥ 0 and INR test procedure	Inpatient	+/- 3 days	Result date	0	2	0
29	Warfarin	183	30	INR lab test result ≥ 0 without an INR test procedure	Inpatient	+/- 30 days	Result date	0	2	0
30	Warfarin	183	30	INR test procedure and INR lab test result ≥ 0	Inpatient	+ 3 days	Procedure Date	0	2	0
31	Warfarin	183	30	INR test procedure and INR lab test result ≥ 0	Inpatient	- 3 days	Procedure Date	0	2	0
32	Warfarin	183	30	INR test procedure and INR lab test result ≥ 0	Inpatient	+/- 3 days	Procedure Date	0	2	0
33	Warfarin	183	30	INR test procedure without an INR lab test result ≥ 0	Inpatient	+/- 30 days	Procedure Date	0	2	0

National Drug Codes (NDCs) were checked against First Data Bank's "National Drug Data File (NDDF®) Plus"

Healthcare Common Procedure Coding System (HCPCS) codes were checked against "Optum 2012 HCPCS Level II Data File" provided by OptumInsight

Current Procedural Terminology, Fourth Edition (CPT-4) codes were checked against "Optum 2012 Current Procedure Codes & Relative Values Data File" provided by OptumInsight